

FIG. 1

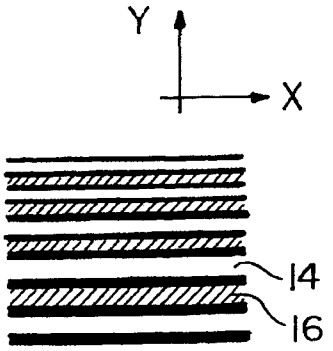


FIG. 2

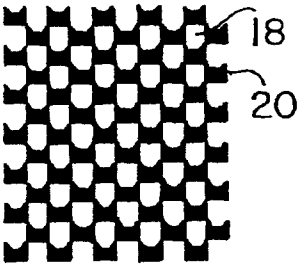


FIG. 3

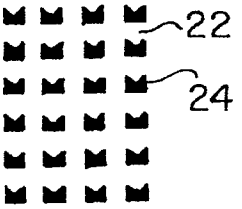


FIG. 4

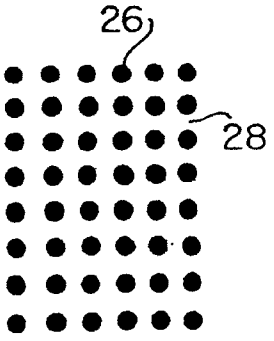


FIG. 5

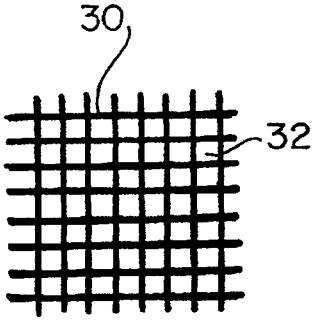


FIG. 6

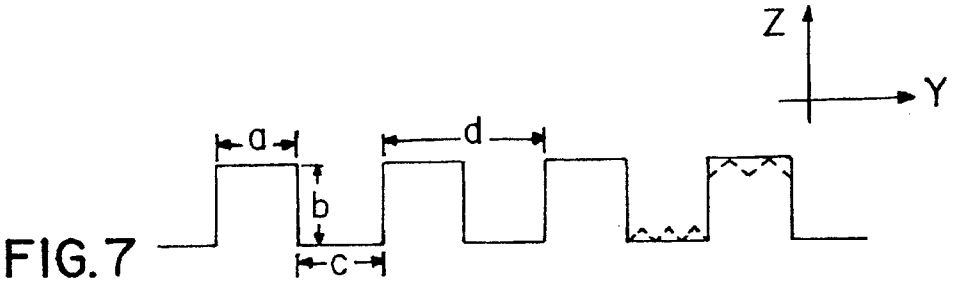


FIG. 7



FIG. 8



FIG. 9



FIG. 10

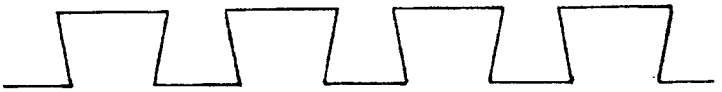


FIG. 11



FIG. 12



FIG. 13



FIG. 14

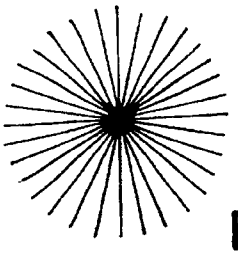


FIG. 15

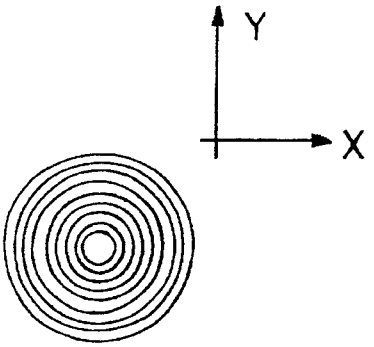


FIG. 16

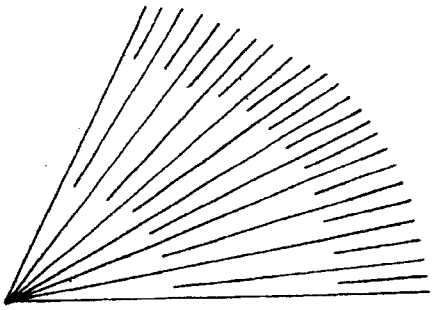


FIG. 17

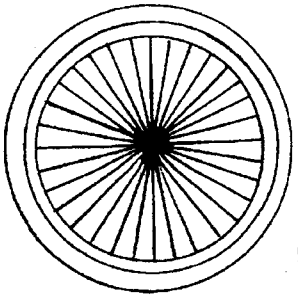


FIG. 18

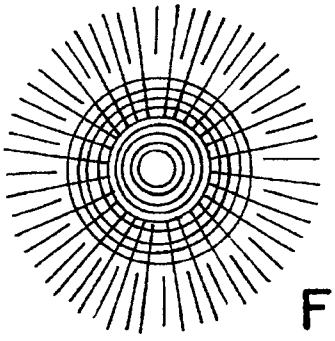


FIG. 19

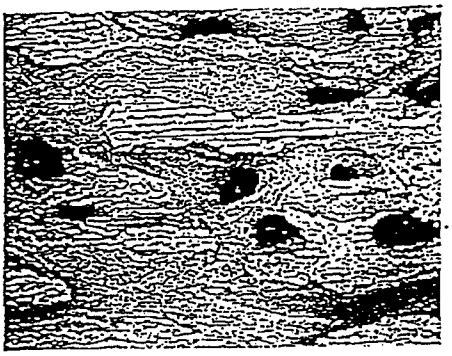


FIG. 20

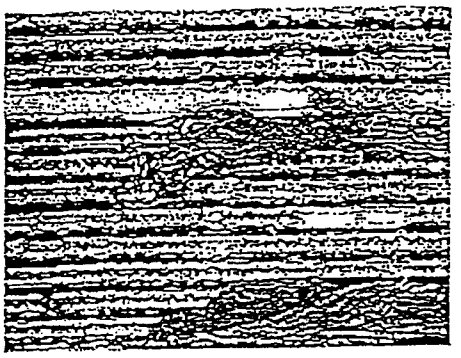


FIG. 21



FIG. 22

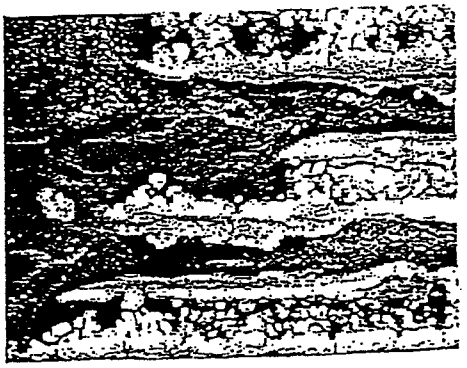


FIG. 23

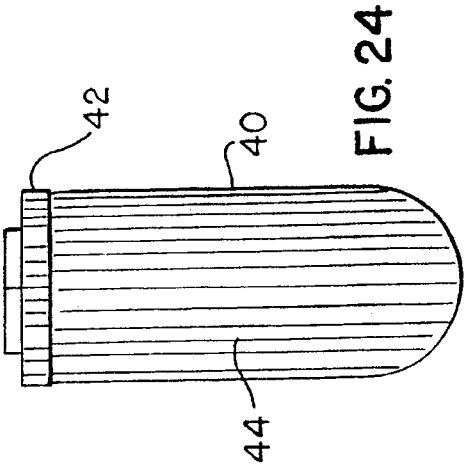


FIG. 24

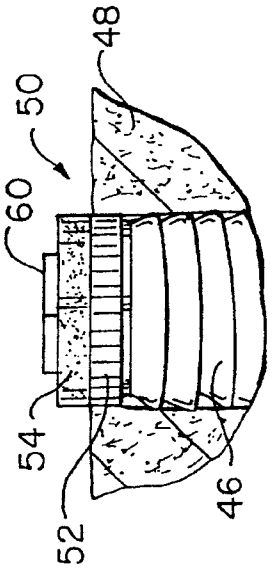


FIG. 25

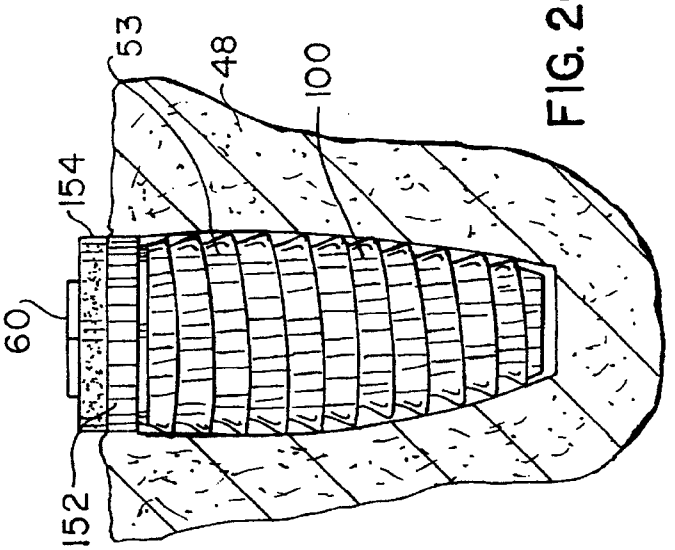


FIG. 26

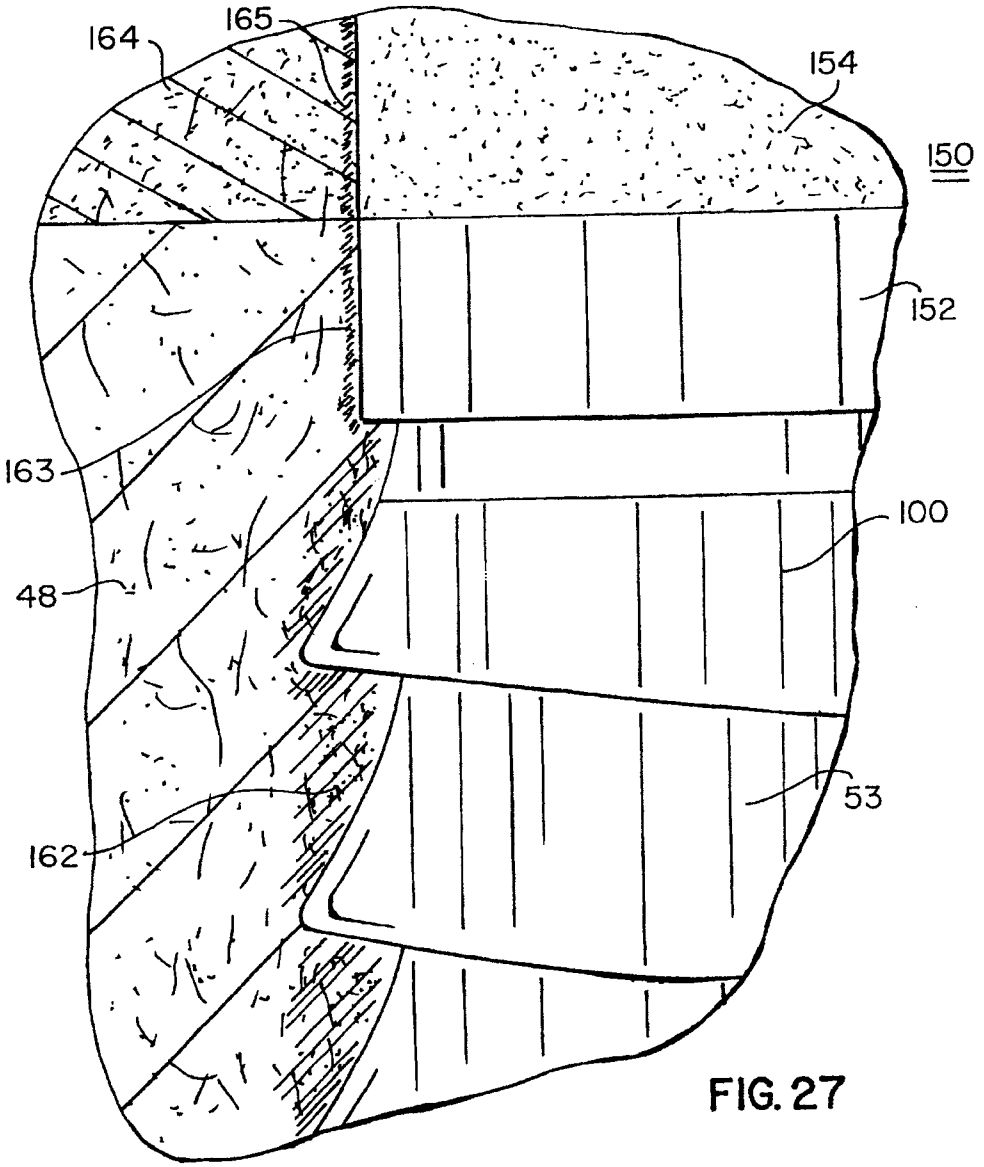


FIG. 27

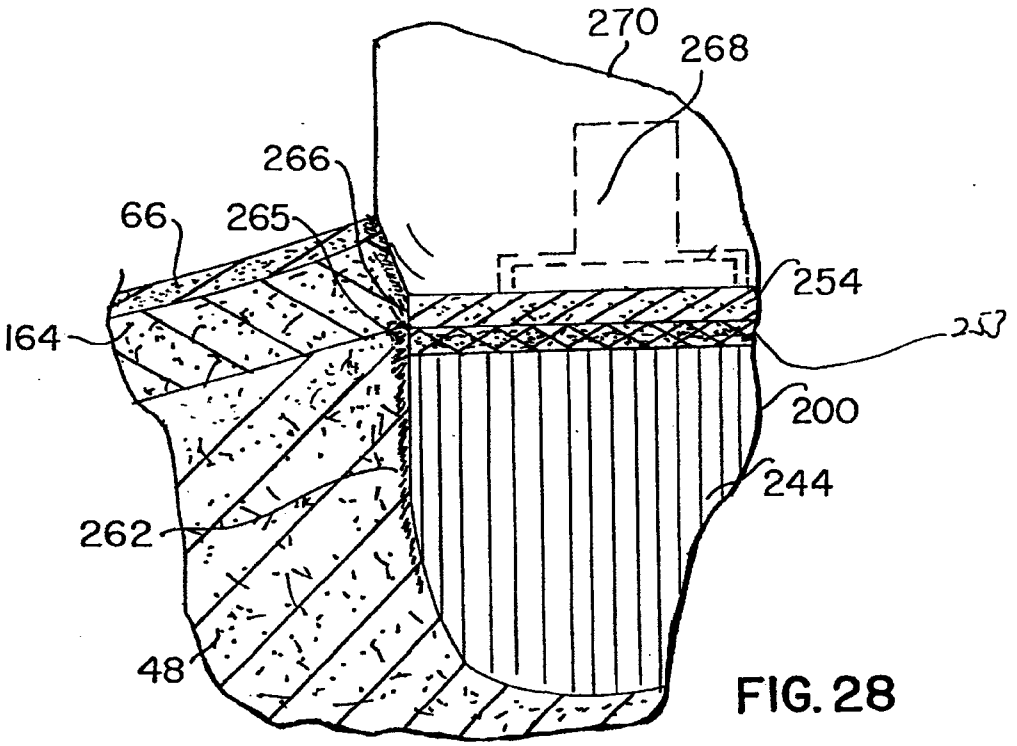


FIG. 28

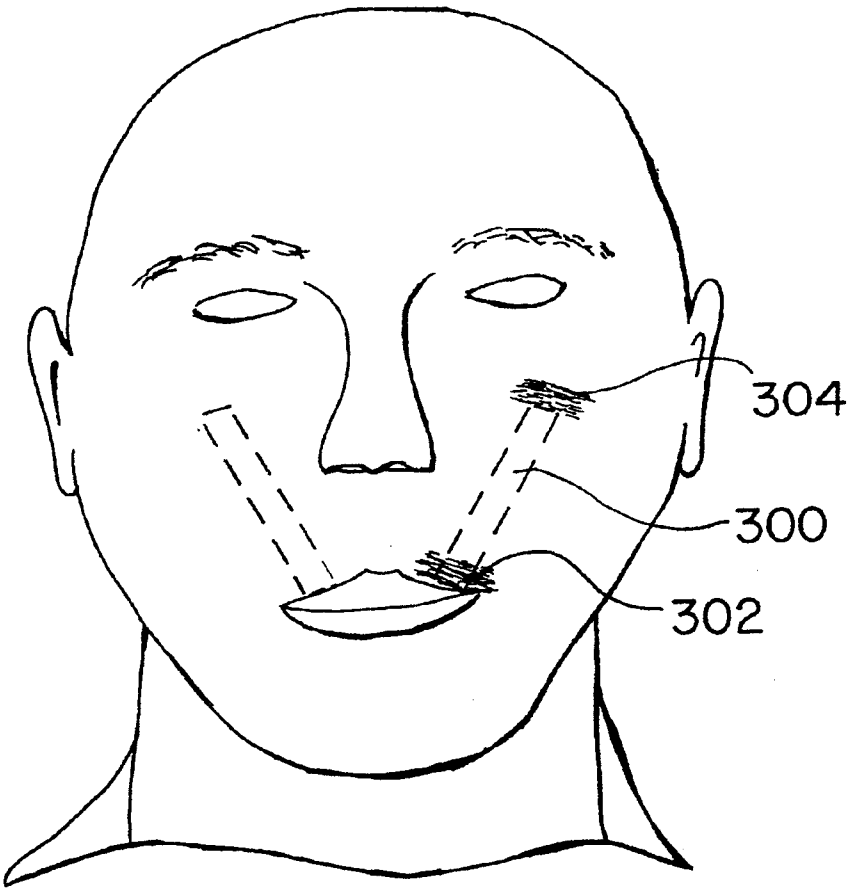


FIG. 29

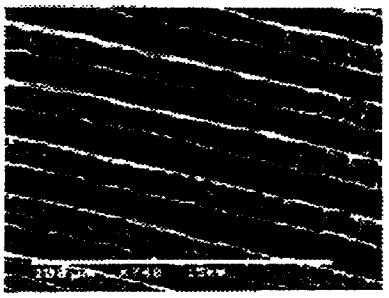


FIG. 30

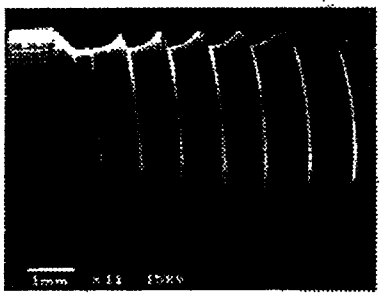


FIG. 31



FIG. 32

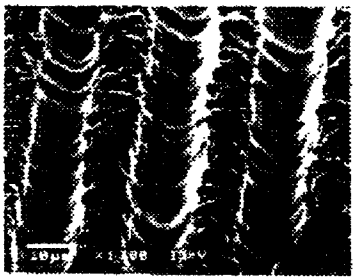


FIG. 33

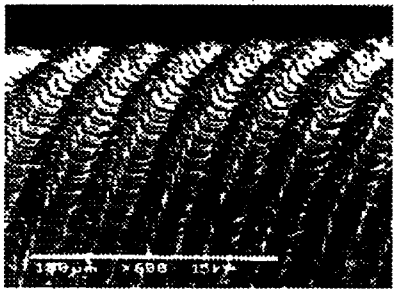


FIG. 34

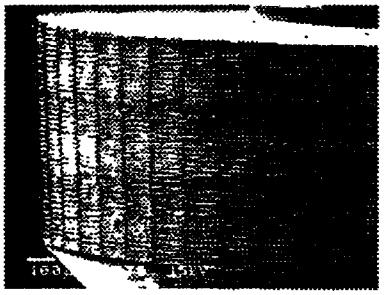


FIG. 35

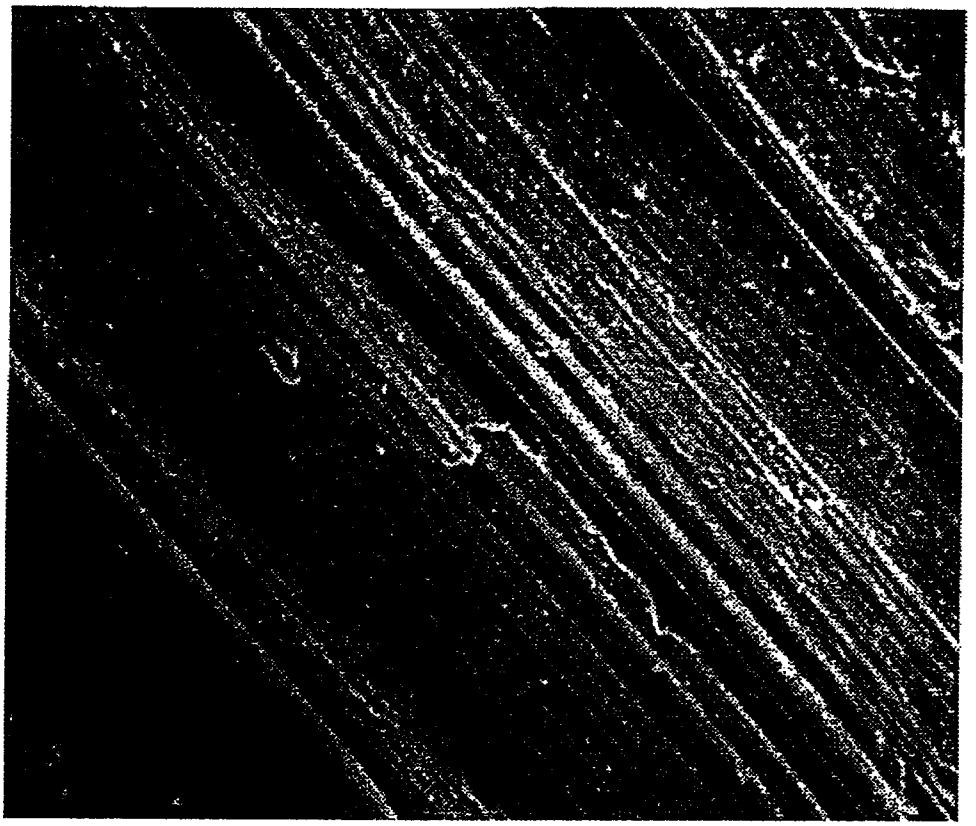


FIG. 36
PRIOR ART

DENTAL IMPLANT SYSTEM WITH REPEATING MICROGEOMETRIC SURFACE PATTERNS

REFERENCE TO RELATED APPLICATION

This case is a continuation-in-part of application Ser. No. 08/996,244, filed Dec. 22, 1997 now abandoned, which is a continuation of application Ser. No. 08/639,712, filed Apr. 26, 1996, now abandoned which is a continuation of Ser. No. 08/390,805 filed Feb. 15, 1995, now abandoned which is a continuation of Ser. No. 08/146,790 filed Nov. 2, 1993, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention relates to the provision of ordered repeating microgeometric patterns to bone and tissue interface zones of dental implants, to effect enhanced adhesion to soft tissue and osseointegration of an implant to bone.

2. Prior Art

Numerous publications establish that cell attachment growth, migration and orientation, as well as extracellular matrix synthesis and orientation thereof, are moderated by substrate surface shape (i.e., microgeometry) as well as by surface chemistry. However, the findings in such publications do not address what effect different substrate microgeometrics and dimension would have on various cell colonies' growth and migration parameters as opposed to the morphology of individual cells. Thus, while the prior art establishes that surface microgeometry of substrates influences cell orientation, it does not disclose or suggest what effect different surface microgeometry as implants would have on either the rate or direction of the cell colony growth of different cells of soft tissue or bone surrounding or abutting such a substrate.

Surface microgeometry interaction between soft tissue or bone and implant surfaces has been demonstrated on ceramic and metallic orthopedic implants. This interaction indicates that smooth implant surfaces promote the formation of thick fibrosis tissue encapsulation and that rough implant surfaces promote the formation of thinner, soft tissue encapsulation and more intimate bone integration. Smooth and porous titanium and titanium alloy implant surfaces have been shown to have different effects on the orientation of fibrous tissue or bone cells in vitro. In addition, surface roughness was demonstrated to be a factor in tissue or bone integration into implants having hydroxyapatite surfaces and to alter the dynamics of cell attachment and growth on polymer implants whose surfaces had been roughened by hydrolytic etching.

From the examination of in vitro growth characteristics of cells cultured on flat surfaces there have evolved the following cell "behavioral" characteristics:

1. attachment-dependent growth: the dependence of normal diploid cell or substrate attachment for normal growth;

2. density-dependent inhibition: the tendency of such cells to slow or stop growing once a confluent monolayer is formed;

3. substrate-exploring function: the ability of some types of cells to migrate on a surface in search of acceptable areas for attachment and growth; and

4. contact guidance: the ability of some types of cells to migrate and orient along physical structures. J. L. Ricci, et al Trans.Soc.Biomat. 17.253 (1991); J. L. Ricci, et al, *Tissue-Inducing Biomaterials*, Mat. Res. Soc. Symp. Proc. 252,221–229 (1992); J.Ricci, et al., *Bull.Hosp. Joint. Dis. Orthop. Inst. supra;* J. L. Ricci, et al, *J. Biomed Mater Res.* 25(5), supra.; D. M. Brunette, et al, J. Dent. Res., 11–26 (1986); P. Clark, et al. *Development,* 108, 635–644 (1990).

The behavioral characteristic of cellular contact guidance has been demonstrated in vitro on a variety of surfaces such as grooved titanium, grooved epoxy polymer, and collagen matrix materials of different textures and orientations. Grooved machined metal and polymer surfaces have also been shown to cause cellular and extracellular matrix orientation in vivo and to encourage or impede epithelial downgrowth in experimental dental implants. B. Cheroudi, et al. *J Biomat. Mater. Res.* 24. 1067–1085 (1990) and 22. 459–473 (1988); G. A. Dunn, et al supra; J. Overton, supra; S. L. Shor. supra; R. Sarber, et al, supra.

Substrates containing grooves of different configurations and sizes have been shown to have orientating effects on fibroblasts and substrates containing grooves of varying depth have been shown to have different degrees of effect on individual cell orientation establishing that grooved surfaces can modulate cell orientation in vitro and can cause oriented cell and tissue growth in vivo. For example, it has been shown that fibrous tissue forms strong interdigitations with relatively large grooves in the range of about 140 μm and can result in an effective barrier against soft tissue downgrowth perpendicular to the grooves. It has also been shown that smaller grooves on the order of about 3–22 μm were more effective in the contact guidance of individual cells. D. M. Brunette, et al. *Development,* supra; P. Clark et al, supra.

The findings in these publications do not address what effects different substrate microgeometries and sizes would have on various cell colonies growth and migration parameters as opposed to morphology of individual cells. That is, these publications do not disclose or suggest what effect different surface microgeometry of implants would have on either the rate or direction of the cell colony growth of different cells and different tissues surrounding an implant. In addition, these publications do not disclose or consider the most effective textured substrate or crude microgeometry for controlling cell colony growth.

The current methods used to texture the surfaces of dental implant elements typically employ sand, glass bead and alumina grit blasting techniques, and acid etching techniques, of the implant surface. In sand, glass bead or alumina grit blasting techniques, compressed air is generally used to drive a blasting medium onto the implant surface at a high velocity to deform and, in some instances, remove portions of the implant surface. The surface texture obtained depends upon the size, shape and hardness of the implant material and on the velocity at which the blasting medium is driven onto the implant surface. The most common surfaces produced by sand or glass bead blasting are matte or satin-finish, while alumina grit blasting produces a random roughened surface.

In acid etching techniques a pattern or mask is placed upon that surface of the implant desired not to be texturized. The exposed parts are then typically treated with an acid that corrodes the exposed surface of the implant whereupon the acid treated surface is washed or neutralized with an appropriate solvent and the pattern or mask is removed.

Illustrative of the sand or glass bead blasting technique is the method disclosed in U.S. Pat. No. 5,057,208 to H. R. Sherry, et al wherein the implant surface is shot blasted with metal shot followed by glass bead blasting and then electropolishing.

Illustrative of an acid etching technique is the method disclosed in U.S. Pat. No. 4,778,469 to R. Y. Lin, et al

wherein an acid soluble (e.g., aluminum or zinc) space occupier is used. The space occupier contains the pattern to be transferred to the implant surface and is placed on the desired portion of the implant surface that is to be texturized. The space occupier is pressed into the implant surface and is then removed by treating it with acid.

It has been found that these typical blasting techniques leave debris from the processing materials embedded in the implant surface as contaminants. This debris has also been found in soft tissue isolated from the areas adjacent to failed press-fit total hip replacements indicating that the debris was released from the surface of the implants. These problems of residual contaminants debris have been overcome by using the use of laser systems which produces texturized microgeometric substrates without introducing embedded, particulate contaminants. See, for example, U.S. Pat. Nos. 5,645,740 and 5,607,607 to Naiman and Lamson. This instant invention refines and extends the teaching thereof with particular reference to dental implants. The prior art is also characterized by implants intended for use in soft tissue, such as U.S. Pat. No. 5,011,494 to Von Recum, et al and its related patent family. Therein, texturized surfaces of implants are provided with a variety of geometric configurations which comprise a plurality of projection and recesses formed in a three-dimensional body. It is therein specified that the mean bridging, breadth and diametric distances and dimension play a role in optimizing cell anchorage to implant surfaces. However, the teaching of Von Recum is not applicable to hard bone-like organic tissue, as exists in a dental implant environment.

Another reference which employs randomized roughing of an implant is U.S. Pat. No. 5,571,017 (1996) to Niznick which, although addressing the area of dental implants, does not employ an ordered or pre-established repetitive microgeometric surface pattern. Similarly, U.S. Pat. No. 4,320,891 (1982) to Branemark employs a randomly micro-pitted surface to create pores in a range of 10 to 1000 nanometers (one micrometer). See FIG. **36**. Further, Branemark states that the optimal results in his system are obtained with pore diameters equal to or smaller than about 300 nanometers. Therein, although Branemark indicates that his implant surfaces may assume a pattern of grooves, corrugations or channels, such geometries are not ordered or repetitive, and it is apparent that the range of focus thereof is in the range of 0.3 to 1 micron in terms of diameters or width of such structures, whereas the lowest end of these invention relate to alternating ridges and grooves having a minimum width of six microns and extending in width to about 15 microns, the same based upon clinical studies as are more fully set forth below. Further, based upon the much smaller surface dimensions with which Brenemark is concerned, it is clear that the focus of Brenemark is that of individual cell growth, this as opposed to promotion of rate, orientation and direction of entire colonies of cells, i.e., the object of the present invention.

U.S. Pat. No. 4,752,294 (1988) to Lundgren refers to tissue ingrowth channels and openings having a dimension of about 30 microns. Accordingly, the dimension of interest to Lundgren is well in excess of the maximum dimension (25 microns) of concern in the present invention. Further, the teaching of Lundgrin is fundamentally that of a guide or element, of substantially three-dimensional character, for facilitating directed tissue regeneration. The present invention relates only to surface textures and does not address tissue regeneration.

U.S. Pat. No. 4,553,272 (1985) to Mears relates, as in Van Recum above, to the development of porous implants having pore sizes in a range of 25 to 400 microns, that is, a minimum range which is well in excess of the maximum range applicable to the ordered microgeometric repetitive surface patterns taught herein. Also, in view of the large dimension of the channels taught by Mears, no relationship exists or is suggested between cell size, structure size, and cellular control resultant thereof.

U.S. Pat. No. 5,004,475 (1991) to Vermeire relates to a hip prosthesis having channels or grooves which, similarly, to Mears, are intended to promote tissue ingrowth but which do not correlate between surface microgeometry, cell size, and cell growth. Further Vermeire does not teach any preferred structure or dimension for the channels or grooves thereof.

Patents such as U.S. Pat. No. 5,094,618 (1992) to Sullivan and 5,316,478 (1994) to Chalifoux teach the use of threaded dental post for endodontic use in association with dental restorations and improved securement between the restoration and a surviving tooth portion. Such references employ substantially random projections of a dimension much greater than that contemplated by the present invention, however, primarily differ from the in instant invention from the lack of teaching of ordered, repetitive, surface patterns within the applicable range in order to obtain advantageous characteristic of growth of colonies of cell at the interface between a maxillofacial bone and/or tissue and a dental implant and/or abutment element.

Thereby, all prior art of record addresses the issue of bone adhesion to an implant at either a level of tissue ingrowth entailing a dimension well above that set forth herein or relates to control of the growth or orientation of individual cells, as opposed to cell colonies, which resultingly require employment of surface characteristics of dimensions substantially smaller than that employed by the within inventors.

SUMMARY OF THE INVENTION

The invention relates to a dental implant system comprising implant element for surgical insertion into a maxillofacial bone or tissue of a patient, the implant element having a collar section and a distal, anchor-like section, said collar section having an ordered microgeometric repetitive surface pattern in the form or a multiplicity of alternating ridges and grooves, each having a fixed or established width in a range of about 2.0 to about 25 microns (micrometers) and a fixed or established depth in a range of about 2 to about 25 microns, in which said microgemoetric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of said maxillofacial bone or tissue which are in contact with said surface pattern.

It is accordingly an object of the invention to provide microgeometic surfaces which alter the growth behavior of colonies of cells attached thereto.

It is another object to provide microgeometric surfaces of the above type having cross-sectional configurations, which are preferential to particular cell or tissue types.

It is a further object to provide microgeometric implant substrate for controlling in vivo cell attachment, orientation growth, migration and tissue function and therein having dimensions preferential for the prevention of cell growth in a first-axis and for the inducement of growth along a second axis.

It is a further object to provide repetitive microgeometric texturized configurations to implants applicable in a variety of medical applications.

The above and yet other objects and advantages will become apparent from the hereinafter-set forth Brief

Description of the Drawings, Detailed Description of the Invention and Claims appended herewith.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan diagrammatic view in an xy axis and at about 750 magnifications, showing ordered microgemetric surface patterns having parallel ridges and grooves, each of approximately equal width, in accordance with the present invention.

FIG. **2** is a view, similar to that of FIG. **1**, however in which successive y-axis width of said ridges and grooves vary with y-axis direction of the surface pattern thereof.

FIG. **3** is a diagrammatic plan view of an ordered microgeometric surface pattern which defines a bi-axial x-y matrix formed of alternating recesses and projections along each axis.

FIG. **4** is a plan view, similar to that of FIG. **3**, however showing a pattern in which all recesses and projections thereof are co-linear with each other.

FIG. **5** is a plan view, similar to that of FIG. **4**, in which all ridges are circular in x-y cross-section.

FIG. **6** is a view, similar to that of FIGS. **3** thru **5**, in which the grooves of the pattern define an xy grid as the surface pattern thereof.

FIGS. **7** thru **14** are yz plane cross-sectional views of the patterns of FIGS. **1** thru **6** showing variations in yz plane geometry, that is, relationship of grooves to ridges that are applicable to one or more of the xy plane patterns shown in FIGS. **1** thru **6**.

FIGS. **15** thru **19** show further xy plane surface patterns which, respectively, comprise radiating, concentric, circular, radiating fan, radiating with concentric, and radiating with intersecting polar, patterns.

FIGS. **20** and **21** are scanning electron micrographs at about 750 magnifications of a deproteinated bone specimens from a bone to metal implant showing the surface of the implant after bone removal (FIG. **20**) and the surface of the bone after implant removal (FIG. **21**) both show bone ingrowth into microgrooves within the bone implant surface, the width of such grooves being about 12 microns.

FIGS. **22** and **23** are higher magnification micrographs of deproteinated bone/implant specimen showing bone growth into the grooves of the inventive microgeometric surface patterns.

FIG. **24** is an elevational view of a cylindrical dental implant in which all implantable surfaces thereof are provided with the same linear longitudinal microgeometric pattern.

FIG. **25** is an enlarged upper site view of a buttress thread implant in which the anchor portion thereof has not been provided with a surface pattern while the proximal or collar portion thereof has been provided with a first pattern for purpose of bone interface and a second pattern above the first pattern for purposes of soft tissue attachment.

FIG. **26** is a tissue breakaway view showing implantation of a buttress thread implant into bone in which the implant anchor and the lower portion of the collar thereof has been provided with a bone adhesion surface while an upper part of the proximal collar has been provided with a soft tissue adhesion surface.

FIG. **27** is an enlarged view showing bone and tissue adhesion interfaces using the structure of FIG. **16**.

FIG. **28** is a tissue breakaway view showing implantation of an implant into bone including an abutment, in which all implant and abutment surface have been provided with bone or tissue adhesion interfaces respectively.

FIG. **29** is a schematic view showing the use of an elongated maxillofacial implant to support the maxilla bone relative to the sinus complex.

FIG. **30** is an enlarged view of a buttress thread dental implant, of the type of FIG. **26**, which has been provided with the inventive ordered microgeometric surface on the collar.

FIG. **31** is an enlargement (at 170 magnifications) of the collar portion of FIG. **30**, showing a pattern of continuous grooves and ridges, as depicted in FIG. **1** above.

FIG. **32** is an electron micrograph showing use of ax-axis discontinuous ridges and grooves, in both x and y axes, therein corresponding to the pattern of FIG. **3** above.

FIG. **33** is an electron micrograph, however, at 1,700 magnifications, of the views of FIGS. **32** or **34** below.

FIG. **34** is an electron micrograph of the surface pattern upon the collar of an implant similar to that shown in FIG. **30** in which the grooves thereof are continuous, as opposed to the x-axis discontinuous ridge and groove segments of FIG. **32**, employed upon the collar of the implant of FIG. **35** below.

FIG. **35** is a 600-power electron micrograph enlargement of the collar of the implant shown in FIG. **32**. This was photographed on an angle to show ridge height and groove depth.

FIG. **36** is a micrograph of a prior art microgeometric surface pattern showing the randomness of such pattern.

DETAILED DESCRIPTION OF THE INVENTION

Bone Structure

Bone tissue is the rigid supporting tissue constituting the principal component of almost all adult vertebrate skeletal structures. It exists in either dense or spongy form, known respectively as compact and cancellous bone. The typical bone cell size is of the order of about 10,000 nm, that is 10 microns.

Bone tissue consists of a chemical mixture of inorganic salts (65 to 70 percent) and various organic substances (30 to 35 percent) and is both hard and elastic. Its hardness is derived from inorganic constituents, principally calcium phosphate and calcium carbonate, with small amounts of fluorides, sulfates, and chlorides; its elasticity is derived from such organic substances as collagen, elastic cellular material, and fats. Internal tubular structures called Haversian canals contain nerve tissues and blood vessels that provide bones with organic nourishment. Surrounding these canals is a somewhat porous tissue composed of thin plates, known as lamellae, and usually containing cavities filled with a network of connective tissue called marrow or myeloid tissue. Bone marrow accounts for from 2 to 5 percent of the body weight of a person and consists of tissue of two types. Yellow bone marrow is made up principally of fat, and red bone marrow is tissue in which red and white blood cells and blood platelets originate. The external portions of bones, enclosing all the components mentioned above, include the compact and hardest of all bone tissue, which is in turn generally sheathed by a vascular, fibrous membrane known as the periosteum.

Micro-Texturing of Surface

With respect to bone and soft tissue adhering thereto, it has been found that the rate and direction of cell colony growth and the growth of different cell types surrounding surgical or dental implant can be controlled and effected by

using the implants of this invention. In general, such implants comprise a plurality of separate zones of textured surface, each zone containing a different repetitive microgeometric design or pattern which is presented and exposed to the particular cell type for development of its unique colony growth. These different repetitive microgeometric textured design surfaces are intended to:

(a) promote the rate and orient the direction of bone growth, and discourage the growth of soft tissue to achieve secure fixation of the implant surface to bone tissue;

(b) promote the rate and orient the direction of the growth of soft tissue while discouraging the growth of bone tissue to achieve soft tissue integration with the implant surface; and/or

(c) create a barrier that discourages the growth of soft tissue, particularly soft fibrous tissue, and thereby prevent the migration of soft tissue growth in bone tissue attachment surfaces of the implant.

The implants of the invention can be provided from suitable and acceptable materials that are commercially available such as cast or wrought cobalt and chrome alloys, various grades of commercial titanium, titanium alloys, stainless steel alloys, thermoplastic resins such as polyethyletherketone, polyphenylene sulfide, ceramics, alumina, as well as combinations thereof.

Example of Enhanced Bone Growth Surface to Direct Conduction of Bone Tissue

A surface consisting of 12-μm groove and ridges has been shown to increase the RBM (rat bone marrow) to RTF (rat tendon fibroblast) cell colony growth ratio to encourage bone cell growth over fibrous tissue growth. In addition, this surface caused specific directional migration of bone cells at approximately twice the rate of cells on a flat surface. This surface can be used to enhance bone versus soft tissue growth as well as to direct bone growth into regions of an implant surface where bone fixation is needed.

Example Surfaces for Stimulation of Fibrous Tissue Growth

Since fibrous tissue and bone cells generally "compete" for surface areas, the ratio of bone to soft tissue colony area increase, on a given surface, is an important parameter in surface selection. The ratio indicates the relative stimulation or inhibition of cell growth on these surfaces (see FIG. **20**). Theoretically, this ratio would be significant to provide advantage for growth of one or another cell type on a surface, with high ratios favoring bone cell growth and low ratios favoring fibrous tissue growth. Based on these ratios, a 2-micron indentation or groove provided a 32.8% decrease in bone/soft tissue growth, providing a significant advantage in soft cell tissue growth. The surface could be used to increase fibrous tissue cell growth; it can also be used to significantly orient growth of these cells. A 4-micron indentation or groove surface provided a similar ratio, but it is based on lower overall growth rates. Therefore, if non-oriented fibrous cell growth is required, a flat control surface provides an inherent advantage to RTF tissue cells at a ratio of bone to soft tissue cell growth of approximately 0.6. This effect has been observed in vivo where smooth surfaces have been shown to favor formation of thick fibrous tissue capsule formation as compared to textured surfaces of the same composition, which show less fibrous capsule formation and more extensive osteointegration.

Example of Surfaces for Stimulation of Bone Tissue Growth

The surface having the highest ratio of bone to soft tissue cell growth is the 12-μm/micron indentation or groove substrate. The basis of the ratio is the fact that this surface inhibits soft tissue colony growth by 53.1% relative to controls (FIG. **21**). This is close to the maximal suppression of soft tissue cell growth seen on such microgeometrics. The same surface, however, does not maximally suppress bone cell growth (46.3% suppression relative to controls). See FIGS. **22** and **23**. The differential suppression results in a 14.4% increase in bone/soft tissue growth relative to the control ratio. Where both cell types are present and compete for growth, this provides a significant advantage to bone colony growth. Bone cells grown on this surface also exhibits greatly enhanced directional growth in the x-axis. Such an in vivo surface favors bone over soft tissue growth and can be used to conduct directional bone growth.

The textured substrates were further studied to determine the preferable substrates and their structure for control of cell growth. The study was conducted to determine the effect of a range of grooves on the control of cell growth.

Cell Orientation and Migration

The experimental surfaces were observed to cause oriented cell attachment and migration, resulting in elongated colony growth, which was accelerated in the x-direction (parallel to the axis of surface microgeometry) and inhibited in the y-direction (perpendicular to the axis of surface microgeometry) as shown in FIGS. **20–21**. On an individual cell level, the cells appeared to be "channelled" in the x-direction, as compared with control culture where outgrowing cells move randomly on flat surfaces. The most efficient "channelling" was observed on the 6-μm and 8 μm surfaces. On these surfaces, both hard and soft cell types were observed to attach and orient within the grooves. This resulted in enhanced x-axis growth and almost no y-axis growth by both cell types on these surfaces.

On smaller microgeometries, a different effect was observed. Both the RBM and RTF cells bridged the surfaces on the 2 μm grooves resulting in cells with different morphologies than those on the 6-, 8-, and 12-μm surfaces. These cells were wide and flattened and were not well oriented. On the 4-μm grooves, the rat bone marrow and RTF cells showed mixed morphologies, with most cells aligned and elongated but not fully attached within the grooves. This resulted in appreciable y-axis growth of the bone marrow cells on the 2-μm surfaces and by the RTF cells on the 2- and 4-μm surfaces. At the other end of the size range, limited y-axis growth was also observed when these cell types were grown on the 12-μm surfaces. This may be a result of the cell orientation and cell "wraparound" resulting in limited y-axis growth.

The results of the observed effects of these surfaces on overall bone marrow and RTF cell colony growth were pronounced. All the experimental substrates caused varying but significant increases in x-axis growth compared to the diameter increase of the controls and varying but pronounced inhibition of y-axis growth. (FIGS. **21**).

Importantly, suppression of cell growth differed between cell types. This offers the opportunity to differentially provide a growth advantage to one cell type over the other.

With reference to the means by which the above set forth principles and experimental data may be reduced to practice, it has been found that a dental implant system which includes at least an implant element and, in a given application, an abutment element, may be selectably surfaced in the fashion illustrated in FIGS. **1** thru **6** which show a variety of patterns which may comprise ordered microgeometric, repetitive surface patterns, and which may be applied to materials inclusive of titanium, stainless steel, plastics, ceramics, biocompatible glass and combinations thereof which materials may be coated with coatings inclusive hydroxyapatite, RBM roughening, titanium, plama

sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof. More particularly, with reference to FIG. 1, the subject ordered microgeometric repetitive patterns may take the form of a multiplicity of alternating grooves **10** and ridges **12** in which each respective ridge and groove displays a width between about 6.0 to about 25 microns and a depth in a range between about 2 to about 25 microns. In the embodiment of FIG. **1**, an infinite repeating pattern of co-parallel linear ridges and grooves having substantially equal width defines a micro textured surface of an implant or substrate as contemplated by the instant invention.

In the embodiment of FIG. **2** is shown a surface in which alternating ridges **14** and grooves **16** increase y-axis in width with reference to a transverse axis relative to the axis of said ridges and grooves. Accordingly, with reference to types of tissues with which a transition of tissue type or gradient of tissue density exists, a textured surface of the type of FIG. **2** may be employed.

In FIG. **3**, is shown a surface pattern in which ridges **18** take the form of projections while grooves **20** take the form of recesses to thereby define a checkerboard configuration. Therein such ridges and grooves alternate with reference to both a x and y axes of a given surface.

The embodiment of FIG. **4** differs from that of FIG. **3** in that ridges **22** thereof form a bi-axial linear pattern. Similarly, grooves **24** of the embodiment of FIG. **4** define a x-y matrix formed of recesses that may assume a number of geometries.

In FIG. **5** is shown embodiment of the invention in which circular depressions **26** define grooves or depressions while the areas therebetween, namely, spaces **28** define ridges or projections. It may, therefrom be appreciated that the terminology "alternating ridges and grooves," as used herein, encompasses a variety of microtexturized geometric patterns in which the ridges and grooves thereof while alternating relative to each other may themselves comprise any one of a variety of geometries inclusive of channels, rectangles, parallelograms, squares, circles and ovals.

With reference to FIG. **6**, there is shown a grid like arrangement in which grooves **30** define an xy matrix which is etched into a surface **32** such that surface **32**, when viewed relative to etched grooves **30**, comprises ridges.

From the embodiment of FIGS. **1** thru **6** it may be appreciated that the width (or diameter) of a given groove need not correspond to that of its respective ridge, providing such widths fall within the above-referenced range of about 2 to 25 microns with a depth in a range of about 2 to about 25 microns. It has, thereby, through extensive experimentation as set forth above, been determined that a microgeometric repetitive pattern within the scope of the present invention may define a guide for preferential promotion of the rate, orientation and directionality of growth of colonies of cells of maxillofacial bone or tissue without requirement that the width of a ridge be equal to that of a groove in that it is, essentially, the groove of the microtexturized surface that defines the guide for preferential promotion of growth of colonies of cells. In most applications, it is desirable to maximize the density of grooves upon a given surface to thereby attain the desired cell growth effect; however, differing clinical environments will dictate use of different surface patterns and density if distribution of grooves.

With reference to the views of FIGS. **7** thru **14**, there is shown diagrammatic cross-sections which may be employed in association with the microgeometric textured configurations above described with reference to FIGS. **1** thru **6**. In other words, the views of FIGS. **7** thru **14** illustrate the range of geometries which may be defined within the yz plane of the surface patterns. Resultingly, FIGS. **7** thru **9** show variations in ridge width a, ridge and groove height b, and groove width c. Typically, ridge height will equal groove depth. Parameter d is the sum of ridge and groove width.

The right side of FIG. **7** indicates that y-axis surfaces need not be linear.

FIGS. **10** and **11** show that the walls of the ridges and/or grooves may be yz sloped either inwardly or outwardly relative to the z-axis. FIGS. **12** and **13** show that the transition from a y-axis ridge surface to a groove surface need not be a sharp one but, rather, may be curved. In FIG. **14** is shown a cross-sectional view of a pattern in which all yz surfaces are sinusoidal. In such embodiment, the potential for "bridging" between lines of cell colony growth is maximized since an abrupt delineation between ridges and grooves is not present.

Shown in FIGS. **15** thru **19** are further xy surface patterns which are programmable through the use of processes selected from the process group consisting of laser etching, acid etching, mechanical etching and photolithography. More particularly, FIG. **15** comprises a radiating pattern. FIG. **16** a concentric circular pattern, FIG. **17** a radiating fan pattern, FIG. **18** a radiating/concentric pattern, and FIG. **19** a radiating pattern with an intersecting polar pattern. It is, therefrom, to be appreciated that an ordered microgeometric repetitive surface pattern may, within the scope of the invention, assume a wide variety of unidirectional linear, bi-axial linear, radial, radial and polar, non-linear, and differential linear or polar patterns.

With reference to FIG. **24**, there is shown a simple cylindrical implant element **40** of the present dental implant system in which both a platform section **42** and an anchor section **44** thereof are provided with a unidirectional linear repetitive surface pattern of the type of FIG. **1** above taken in combination with any of the cross sectional geometries of FIGS. **7** thru **14** above. Therein, a multiplicity of alternating ridges and grooves is applied to the entire lateral surface of implant **40** along an axis which is co-axial with the axis of surgical insertion of the implant into a maxo-facial bone or tissue.

In FIG. **25** is shown an upper portion of a buttress thread implant **46** which has been surgically inserted into bone **48**. However, in the embodiment of FIG. **25**, the anchor section has not been microtexturized while platform section **50** thereof has been provided with a first ordered microgeometric repetitive surface pattern as to a distal section **52** thereof while a proximal portion **54** has been provided with a second ordered geometric pattern more suitable for purpose of tissue (as opposed to bone) adhesion or interface. Such a second ordered pattern exhibits a width of about 2 to about 25 microns and a depth in a range of about 2 to about 25 microns in that it has been determined that tissue, such as gum tissue, is more amenable to preferential promotion of rate, orientation and directionality of growth of colonies of cells if the width of grooves is somewhat smaller than that above discussed with reference to bone adhesion and interface.

With reference to FIG. **26**, there is shown a further buttress thread implant **100** which has been surgically inserted within bone **48**. However, in the embodiment of FIG. **26**, the entire lateral surface of the anchor of the buttress thread implant has been furnished with the same first ordered repetitive surface **52** above described with reference to FIG. **25**. Further, proximal region **154** has been provided with a surface more suitable to tissue adhesion interface, namely, said second ordered pattern, while lower

region **152** has been provided with the same pattern as anchor surface **53**. At the top of each of the implants of FIGS. **24** to **26** is shown a gripping surface **60** used for purposes of surgical insertion and for complemental receipt of an abutment element of a dental implant system.

FIG. **27** comprises an enlarged view of a bone adhesion interface **162** which exists between bone **48** and the first ordered microgeometric repetitive of the anchor **53** of the implant of **100**. Also shown therein are lower and upper regions **152** and **154** of platform section **150** of the implant as well as an interface **165** of said upper region **154** with gum tissue **164**. Further shown is adhesion interfaces **163** between bone **48** and lower region **152** of platform **150**. Therefrom may be appreciated the effect of the inventive microgeometric repetitive surface patterns in the formation of bone and tissue adhesion interfaces, that is, the effect of which is to strengthen bone and tissue in the regions immediately surrounding a dental implant element.

Micro-geometric patterns of this type may be formed by various methods, including, without limitation, laser etching, acid etching, mechanical etching, and photolithography.

The above may be more fully appreciated with reference to the view of FIG. **28**, which is similar to the views of FIGS. **26** and **27**, but for the use of a textured cylindrical anchor **244**, as opposed to a buttress thread anchor section, of a dental implant **200**. However, additionally shown in the embodiment of FIG. **28** is gingival epithelium **66** above gum tissue **164** also referred to as the connective tissue, between the epithelium and the cortical bone **48**. Further shown in FIG. **28** is an abutment **270** (secured upon implant projection **268**) of a dental implant system, that has been provided with collars **254** having a microtexturized regions **266** to effect gum and epithelium tissue adhesion interfaces thereto. Also, a collar **253** of implant **200** has been provided with a microtexturized surface particularly adapted for bone adhesion interface **265**. It may, accordingly, from the view of FIG. **28**, be appreciated that in a given application as many as five different microtexturized surfaces may be employed to maximize bone and tissue adhesion to one or another portion of an implant element and/or of an abutment element of a dental implant system. As such, different patterns of tissue or bone interface and adhesion, that is, differing forms of promotion of rate, orientation and directionality of growth of contacting colonies of cells will be achieved with reference to differing micro-textured surfaces of the implant material. Such interfaces are indicated by numerals **262** (implant anchor to bone interface), **265** (implant collar to bone interface), **266** (collar to gum) **272**.

With reference to FIG. **29** there is shown the manner in which an implant **300** may be used as a means of surgical support of a maxillofacial bone **302** by securement thereof to a bone **304** of the sinus complex. Such implant is of value in the area of reconstructive surgery and in dental procedures in which the cortical bone lacks sufficient strength or stability to otherwise receive and hold an implant element. In the application of FIG. **29**, the upper and lower ends of the implant **300** will be provided with microtexturized surfaces as above described.

In FIGS. **30** thru **36** are shown micrographs of the inventive microgeometric surfaces at magnifications ranging from 600 to 1700.

FIG. **31** is an enlarged view of a buttress thread dental implant, of the type of FIG. **26**, which has been provided with the inventive ordered microgeometric surface. FIG. **35** is an enlargement at **170** magnifications of the collar portion of FIG. **31**, showing a pattern of discontinuous grooves and ridges, as depicted in FIG. **1** above FIG. **32** is an electron micrograph comprising a further enlargement of the collar of FIG. **31**, showing use of alternating ridges and grooves in both x and y axes, therein corresponding to the pattern of FIG. **3** above. FIG. **32** is an electron micrograph, however, at 1,700 magnifications, of the view of FIG. **31**. FIG. **34** is an electron micrograph of the surface pattern upon the thread structure of the implant of FIG. **30** in which the grooves thereof are continuous, as opposed to the discontinuous ridge and groove segments of FIG. **32**, employed upon the collar of the implant of FIG. **30**. FIG. **35** is a 600-power electron micrograph enlargement of the collar of the implant shown in FIG. **34**. In all figures, the small longitudinal grooves therein reflect laser-related melting, rather than a part of the microgeometric surface of the implant.

While there has been shown and described the preferred embodiment of the instant invention it is to be appreciated that the invention may be embodied otherwise than is herein specifically shown and described and that, within said embodiment, certain changes may be made in the form and arrangement of the parts without departing from the underlying ideas or principles of this invention as set forth in the claims appended herewith.

We claim:

1. A dental implant system comprising an implant element for surgical insertion into a maxillofacial bone and tissue of a patient, said implant element having a collar section and a distal, anchor-like section, said collar section having a first ordered microgeometric, repetitive surface pattern in a form of a multiplicity of alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns, each groove having a base and a wall, each groove defining, in radial cross-section, a relationship of groove base to grove wall that is equal to, or less than, about ninety degrees;

whereby said micro-geometric repetitive pattern defines a guide for a preferential promotion of the rate, orientation and direction of growth of colonies of cells of said maxillofacial bone or tissue, which are in contact with said surface pattern.

2. The dental implant system as recited in claim **1**, in which said distal anchor-like section of said implant element also comprises said first repetitive micro-geometric pattern thereupon.

3. The dental implant system as recited in claim **1**, in which an uppermost region of said proximal section comprises a second ordered micro-geometric pattern of ridges and grooves in a range of width of between about 2 and about 25 microns, and a depth in a range of about 2 to 25 microns, said upper region of said proximal section defining a soft tissue adhesion interface, and in which a lower region of said proximal section comprises said first pattern of alternating ridges and grooves, lower region constituting a bone adhesion interface.

4. The dental implant system as recited in claim **1**, further comprising an abutment element proportioned for complemental engagement with said implant element, or as an extension of the implant platform, said abutment including a tissue adhesion zone defined by an ordered microgeometric repetitive pattern in the form of a multiplicity of alternating ridges and grooves having established widths in a range between about 2 and about 25 microns, and an established depth in a range of about 2 to 25 microns.

5. The system as recited in claim **4** in which base materials of said abutment elements are selected from the group

consisting of the materials of commercially pure titanium, titanium alloys, stainless steel, plastics, ceramics, biocompatible glass and combinations thereof.

6. The system as recited in claim **4** in which base materials of said implant elements are selected from the group consisting of the materials of titanium and alloys thereof, stainless steel, ceramics biocompatible glass and combinations thereof.

7. The dental implant system as recited in claim **6** in which said repetitive micro-geometric pattern comprises a product of the process selected from the process group consisting of laser etching, acid etching, mechanical etching, and photolithography.

8. The system as recited in claim **1** in which said repetitive micro-geometric pattern of ridges and grooves comprises application to surfaces of said implant element in orientations which, relative to a longitudinal axis of said implant system, are selected from the group consisting of vertical, horizontal, diagonal, radial, circumferential, and concentric orientations.

9. The dental implant system as recited in claim **8** in which a surface of said implant element comprises a coating selected from the group of surfaces consisting of hydroxyapatite, RBM roughening, titanium, plama sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof.

10. The dental implant system as recited in claim **1** in which said pattern of ridges and grooves define substantially parallel geometries thereof.

11. The dental implant system as recited in claim **10** in which said pattern is grid-like.

12. The dental implant system as recited in claim **1**, in which said pattern of ridges and grooves define a radial geometry.

13. The system as recited in claim **12** in which said pattern further includes polar geometries.

14. The dental implant system as recited in claim **1**, in which said pattern of ridges and grooves defines polar geometries.

15. The system as recited in claim **1** in which said maxillofacial bone includes mandible cortical or maxillofacial bone.

16. The system as recited in claim **15** in which said implant element exhibits a radial longitudinal cross-section selected from the group of geometries consisting of screw-like, tapered screw, cylindrical, tapered cylindrical, buttress thread, and reverse buttress thread.

17. The dental implant system as recited in claim **1**, in which a radial cross-section of said ridges and grooves comprises a sinusoidal cross-section.

18. A dental implant system comprising an implant element for surgical insertion into a maxillofacial bone and tissue of a patient, said implant element having a collar section and a distal, anchor-like section, said anchor section having a first ordered microgeometric, repetitive surface pattern in a form of a multiplicity of alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns, each groove having a base and a wall, each groove defining, in radial cross-section, a relationship of groove base to groove wall that is equal to, or less than, about ninety degrees,

whereby said micro-geometric repetitive pattern defines a guide for a preferential promotion of the rate, orientation and direction of growth of colonies of cells of said maxillofacial bone or tissue, which are in contact with said surface pattern.

19. The dental implant system as recited in claim **18**, in which said collar section of said implant element also comprises said first repetitive micro-geometric pattern thereupon.

20. The dental implant system as recited in claim **17**, in which an uppermost region of said proximal section comprises a second ordered micro-geometric pattern of ridges and grooves in a range of width of between about 2 and about 25 microns, and a depth in a range of about 2 to 25 microns, said upper region of said proximal section defining a soft tissue adhesion interface, and in which a lower region of said proximal section comprises said first pattern of alternating ridges and grooves, lower region constituting a bone adhesion interface.

21. The dental implant system as recited in claim **18**, in which a radial cross-section of said ridges and grooves comprises a sinusoidal cross-section.

22. A dental implant system comprising an implant abutment comprising a body for surgical insertion into a maxillofacial bone having a collar section having an ordered microgeometric, repetitive surface pattern in a form of a multiplicity of alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns, each groove having a base and a wall, each groove defining, in radial cross-section, a relationship of groove base to grove wall that is equal to, or less than, about ninety degrees,

whereby said micro-geometric repetitive pattern defines a guide for a preferential promotion of the rate, orientation and direction of growth of colonies of cells of said maxillofacial tissue, which are in contact with said surface pattern.

23. The dental implant system as recited in claim **22** in which a radial cross-section of said ridges and grooves comprises a sinusoidal cross-section.

* * * * *

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(12) **United States Patent**
Hollander et al.

(10) **Patent No.: US 6,454,569 B1**
(45) **Date of Patent: Sep. 24, 2002**

(54) **DENTAL IMPLANT HAVING A DUAL BIO-AFFINITY COLLAR**

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(73) Assignee: **BioLok International, Inc.**, Deerfield Beach, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/605,142**

(22) Filed: **Jun. 26, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/500,038, filed on Feb. 8, 2000, which is a continuation-in-part of application No. 08/996,244, filed on Dec. 22, 1997, now abandoned, which is a continuation-in-part of application No. 08/639,712, filed on Apr. 29, 1996, now abandoned, which is a continuation of application No. 08/390,805, filed on Feb. 15, 1995, now abandoned, which is a continuation of application No. 08/146,790, filed on Nov. 2, 1993, now abandoned.

(51) **Int. Cl.**[7] **A61C 8/00**

(52) **U.S. Cl.** **433/173**

(58) **Field of Search** 433/173, 174, 433/175, 201.1; 623/17.17, 17.18, 23.5, 23.76

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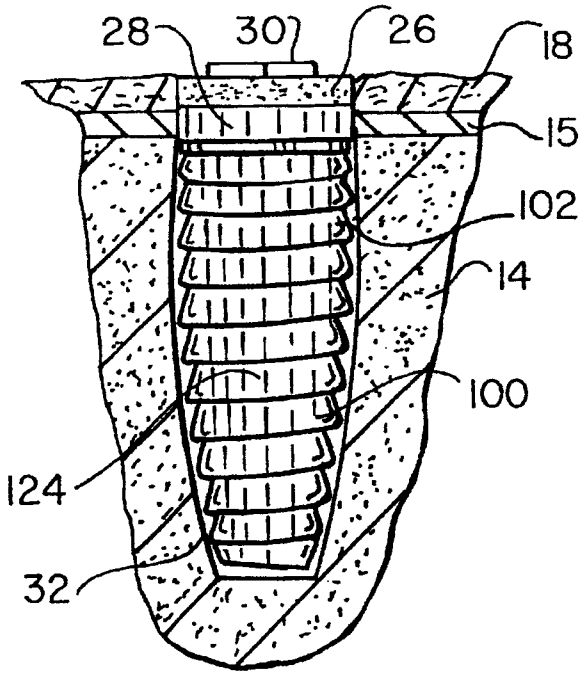
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(74) *Attorney, Agent, or Firm*—M. K. Silverman

(57) **ABSTRACT**

A dental implant comprises a solid elongated body including a longitudinal axis having distal and proximal ends in which the proximal end includes a collar having an axial length in a range of about 1 to about 3 millimeters. The collar exhibits a proximal and a distal segment in which the proximal segment includes a surface texture adapted for the promotion of tissue growth and in which the distal segment includes a surface texture adapted for the promotion of osseo-integration of surrounding preferably cortical bone. Either one or the other of the sub-segments is provided with an ordered microgeometric repetitive surface pattern in the form of alternating ridges and grooves, each having a fixed or established width in a range of about 2.0 to about 25 microns and a fixed or established depth in a range of about 2.0 to about 25 microns, in which the microgeometric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of the maxillofacial bone or tissue which is in contact with the surface pattern.

11 Claims, 2 Drawing Sheets



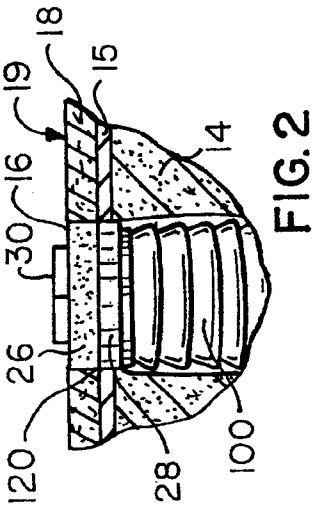


FIG. 2

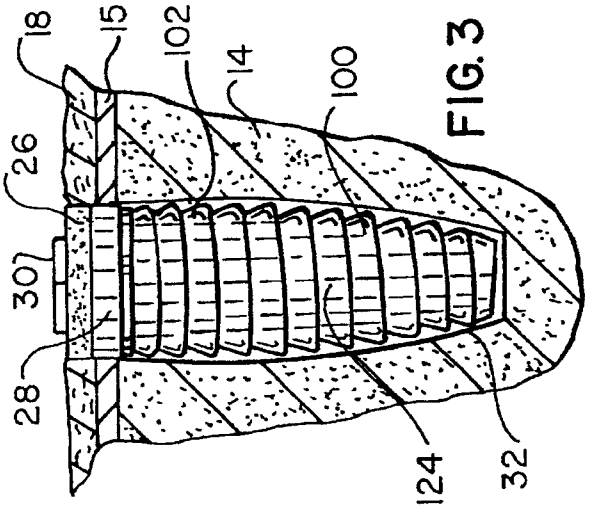


FIG. 3

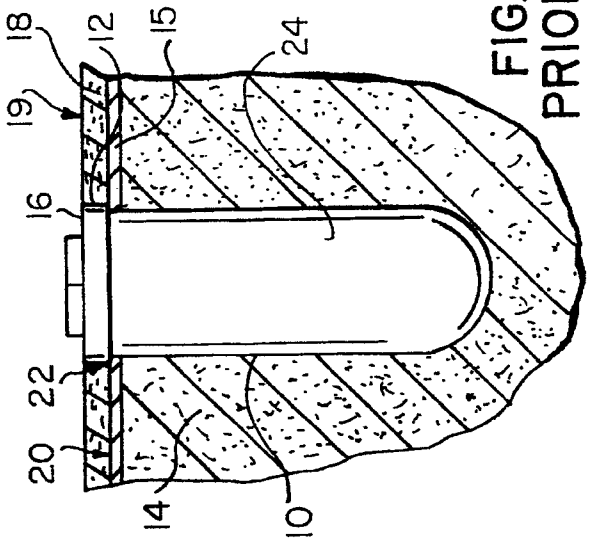


FIG. 1
PRIOR ART

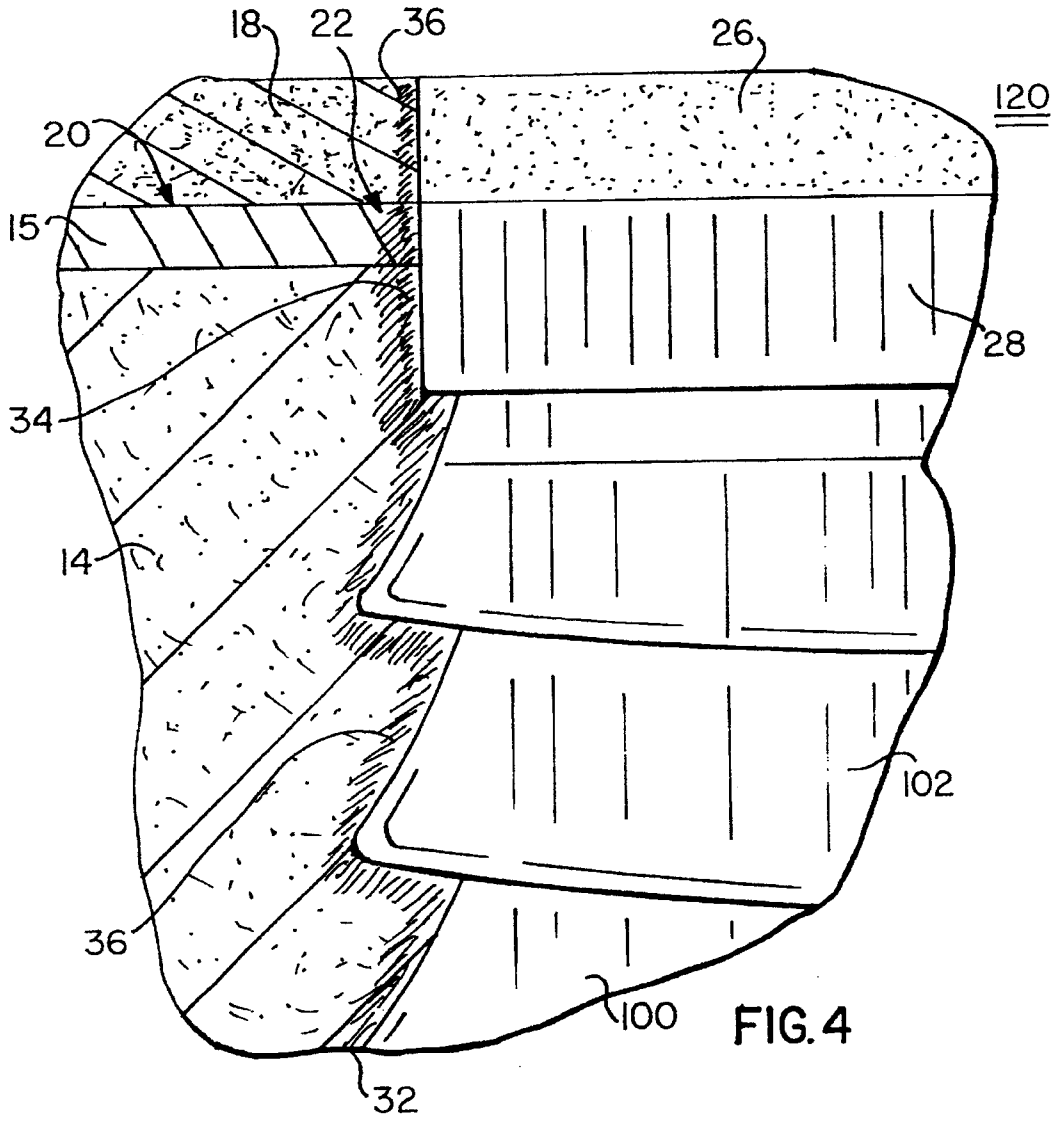


FIG. 4

DENTAL IMPLANT HAVING A DUAL BIO-AFFINITY COLLAR

REFERENCE TO RELATED APPLICATON

This case is a continuation-in-part of application Ser. No. 09/500,038, entitled Dental Implant System with Repeating Microgeometric Surface Pattern, filed Feb. 8, 2000, pending; which is a continuation in part of application Ser. No. 08/996,244 filed Dec. 22, 1997, now abandoned; which is a continuation in part of application Ser. No. 08/639,712, filed Apr. 29, 1996, now abandoned; which is a continuation of application Ser. No. 08/390,805, filed Feb. 15, 1995, now abandoned; which is continuation of application Ser. No. 08/146,790, filed Nov. 2, 1993, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to dental implants and, more particularly, to implants intended for insertion into the mandible, maxilla and facial bones. More particularly, the invention relates to a dental implant in which there is provided a collar having dual bio-affinity surfaces such that, in a healing process following insertion of the dental implant, the same is facilitated both with reference to bio-integration of bone and related dermal tissue which is next to the bone.

In the prior art, it is known to provide a variety of surface or texturing effects to enhance osseo-stability of the implant within bone, the same including the maxillofacial area, in the healing process. The collar or proximal portion of a dental implant plays a particularly significant role in that closure of the bone about the uppermost part of the implant is essential to assure proper sealing of the bone around the implant. An added aspect in the achievement of such sealing is also proper closure of the tissue, gum, or related dermal tissue above the bone at the point of entry. In general, if proper closure of the tissue about the plane of the upper radial surface of the implant is accomplished, proper closure of the cortical bone about the implant will follow as a matter of course. It is, accordingly, desirable to promote bio-integration of both soft tissue and hard tissue which is in interface with the dental implant after insertion into an osseotomy site. This, among other factors, will optimize the role of the implant as a base or foundation upon which the dental abutment and related prosthesis is secured.

While the prior art suggests a variety of different surface effects for various and sundry types of surgical implants, only a small subset of this art addresses the provision of any form of surface effect to dental implants for any purpose. This art, as best known to the within inventors, is represented by U.S. Pat. No. 5,011,494 to Von Recum; U.S. Pat. No. 5,057,208 to Sherry; U.S. Pat. No. 4,778,469 to Lia; U.S. Pat. No. 5,751,017 to Niznick; U.S. Pat. No. 4,320,891 to Branemark; U.S. Pat. No. 4,752,294 to Lundgren; U.S. Pat. No. 4,553,272 to Mears; and U.S. Pat. No. 5,004,475 to Vermeire.

In view of the above, no art known to the inventors, with the exception of the above-referenced parent of this application, teaches any use of multiple bio-affinity surfaces. However, said parent application does not attempt to generalize the principle of dual tissue bio-affinity surfaces as is taught herein.

SUMMARY OF THE INVENTION

The instant invention relates to a dental implant, which more particularly comprises a solid elongate body including

a longitudinal axis having distal and proximal ends, in which the proximal end defines a collar having an axial length in a range of about 1 to about 3 millimeters. The collar comprises both a proximal and a distal segment in which said proximal segment exhibits a surface texture adapted for the promotion of tissue growth thereinto and in which said distal segment exhibits a surface texture adapted for the promotion of osseo-integration thereinto preferably at a cortical surface of a bone. At least one of said subsegments is provided with an ordered microgeometric repetitive surface pattern in the form or a multiplicity of alternating ridges and grooves, each having a fixed or established width in a range of about 2.0 to about 25 microns and a fixed or established depth in a range of about 2.0 to about 25 microns, in which said microgemoetric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of maxillofacial bone or tissue which is in contact with said surface pattern.

It is accordingly an object of the invention to provide a dental implant having a collar portion consisting of proximal and distal cylindrical sub-segments, one having a surface effect adapted for the promotion of growth of soft tissue thereinto and the other adapted for the promotion of bone or hard tissue growth thereinto preferably at a cortical surface of the bone.

It is a further object to provide microgeometic surfaces which alter the growth behavior of colonies of cells attached thereto in order to preclude the cupping effect between an implant and an osseotomy site.

It is another object to provide microgeometric surfaces of the above type having cross-sectional configurations, which are preferential to particular cell or tissue types.

It is a further object to provide microgeometric implant substrate for controlling in vivo cell attachment, orientation growth, migration and tissue function and therein having dimensions preferential for the prevention of cell growth in a first-axis and for the inducement of growth along a second axis.

It is a further object to provide repetitive microgeometric texturized configurations to implants applicable in a variety of medical applications.

It is another object to provide a dental implant of the above type to facilitate a wide range of procedures in the area of dental implantology in which preclusion of the cupping effect of bone-to-bone interface is advantageous.

It is a further object of the invention to provide a dental implant of the above type to provide improved stability while reducing the possibility of complications due to infection at the implant site.

The above and yet other objects and advantages of the present invention will become apparent from the hereinafter set forth Brief Description of the Drawings, Detailed Description of the Invention, and Claims appended herewith.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of the prior art as it relates to the present invention.

FIG. 2 is an elevational view of the present invention shown relative to the bone and tissue area surrounding an implant site.

FIG. 3 is a view, similar to that of FIG. 2, however showing the entire length of an implant and also showing an alternate embodiment of the invention.

FIG. **4** is an enlarged view of the upper left hand corner of the view of FIG. **3**, the same showing the area of tissue to cortical bone to implant collar interface.

DETAILED DESCRIPTION OF THE INVENTION

With reference to FIG. **1**, there is shown an example of a prior art dental implant **10** inclusive of a collar **12**, and an anchor portion **24** which is positioned within bone **14** at a so-called ostectomy site. The outer or uppermost surface of bone **14** consists of a cortical bone **15** which comprises a hard shell-like layer. As noted in the Background of the Invention above, surface treatments for dental implants have been suggested only to bio-affinity of the implant relative to bone. Further, the prior art, as reflected in FIG. **1**, shows an upper radial surface **16** of the collar **12** reflects the general positioning of the gum line **19** of gum tissue **18** of a patient. However, the problem with such positioning of the implant within the osseotomy site is related to an interface **20** which exists between cortical bone **15** and gum line **18**, beneath said radial surface **16** of the implant collar **12**. Along this interface **20** and, particularly, where this interface meets collar **16**, i.e., at area **22**, occurs what is termed the cupping effect at the implant interface, that is, the tendency of bone tissue to die-back from the collar **12**.

The view of FIG. **2** indicates the manner in which the above problem is solved through the present invention. More particularly, shown in FIG. **2** is inventive implant **100** which has been provided with a collar **120** which includes a proximal cylindrical segment **26** and a distal cylindrical segment **28**. Shown above radial surface **16** is a hex-head connection **30** which, it is to be understood, is representative of but one of a variety of means that may be used to effect securement between the implant and a dental abutment with which the implant is to mate before securement of a dental restoration thereupon.

What is notable about the structure of FIG. **2** is that two different types of bio-affinity surface effects, or textures, have been provided to the collar **120** of the implant, namely, one surface for the purpose of promoting in-growth of soft dermal or gum tissue **18** denoted by the dotted or stippled effect on proximal segment **26** and the provision of a second bio-affinity texture (denoted by the vertical hatching) upon the distal segment **28** of collar **120**. Therein proximal segment **26** is axially aligned with gum tissue **18** and at least the top of distal segment is generally aligned with cortical layer **15** is of bone **14**. It has been found that for optimal result, at least one of the textured surfaces should define an ordered microgeometric repetitive surface pattern in the form or a multiplicity of alternating ridges and grooves, each having a fixed or established width in a range of about 2.0 to about 25 microns and a fixed or established depth in a range of about 2.0 to about 25 microns, in which said microgeometric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of maxillofacial bone or tissue which are in contact with said surface pattern. If both segments are furnished with such a surface pattern, the respective texture thereof will differ in that different widths and depths of texture are optimal for soft versus hard tissue interaction.

A further embodiment of the invention is shown in FIG. **3** in which an entire anchor portion **124** of the implant has been provided with the same osseo-integrative surface effect, the same indicated by reference numeral **102**, as has been the distal segment **28** of the implant collar.

Accordingly, in this embodiment, the entirety of an implant site below proximal segment **16** may be treated in the same fashion as the distal sub-segment **28**.

With reference to the view of FIG. **4**, which is an enlargement of a portion of FIG. **2**, there may be seen the above-referenced proximal collar segment **26** and distal collar segment **28**, as well as the optionally textured surface **102** of implant **100**, the same relative to the bone **14**, cortical bone **15**, and soft tissue **18**. However, further shown in FIG. **4** is a region **34** of osseo-integration between distal collar segment **28** and bone **14**, including cortical bone **15**, and a region **36** of osseo-integration between proximal segment **26** and gum tissue **18**. These regions comprise in-growth of tissue **22** relative to the implant collar segments. It is to be appreciated that regions **34** and **36** of in-growth or bio-affinity between tissue **18** and segment **26** and **28** accomplish an advantageous sealing of the tissue about area **22** of the interface **20** between tissue **18** and cortical bone **15**, and, particularly, at the point of entry of the collar into the cortical bone. As such, the dual affinity implant collar effectively promotes sealing of bone **22** both to implant collar **120** and, as well, sealing about the circumferential point of entry into the implant site. With such sealing the cupping effect is precluded.

If one of the collar segments **26** or **28** is not furnished with said ordered microgeometric repetitive surface matter, a variety of other surface textures may be effected for the other segments using such treatments including, without limitation, the following:

laser cutting, acid etching, photolithography, abrasion/roughening, plasma spraying, calcium sulfate, biocompatible glass, collagen, hydroxapatite, growth factor compounds, and combinations thereof.

With respect to the ratio of axial length of the proximal to the distal segments of the collar, it has been found that such axial lengths need not necessarily be equal, such that a range of axial length of the proximal to the distal segments may fall between about 1:4 to about 4:1, this within an aggregate axial length of between about 1 to about 3 millimeters.

While there has been shown and described the preferred embodiment of the instant invention it is to be appreciated that the invention may be embodied otherwise than is herein specifically shown and described and that, within said embodiment, certain changes may be made in the form and arrangement of the parts without departing from the underlying ideas or principles of this invention as set forth in the Claims appended herewith.

Having thus described our invention, what we claim as new, useful, and non-obvious and, accordingly, secure by Letters Patent of the Untied States is:

1. A dental implant for insertion into an ostectomy site, and reducing potential for related bone loss thereat, the implant comprising:

a solid elongate body having a longitudinal axis, said axis having a distal and a proximal end, said proximal end defining a collar having an axial length in a range of about 1 to about 3 millimeters, said collar further comprising a proximal segment and a distal segment in which said proximal segment comprises a surface texture for the promotion of tissue growth thereinto, and in which said distal segment comprises a surface texture for the promotion of bone growth thereinto, and further in which said distal segment defines an ordered microgeometric repetitive surface pattern in the form of a multiplicity of alternating ridges and grooves, each having a fixed or established width in a range of about

2.0 to about 25 microns and a fixed or established depth in a range of about 2.0 to about 25 microns, in which said microgemoetric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of soft tissue of said osseotomy site which are in contact with said surface pattern.

2. The implant as recited in claim **1**, in which said surface texture of said proximal segment comprises a surface texture selected from the group of surface treatments consisting essentially of:

laser cutting, acid etching, photolithography, abrasion/roughening, plasma spraying, calcium sulfate, biocompatible glass, collagen, hydroxapatite, growth factor compounds, and combinations thereof.

3. The dental implant as recited in claim **2**, in which a ratio of axial length of said proximal to said distal segments comprises a range of about 1:4 to about 4:1.

4. The dental implant as recited in claim **3**, in which a proximal radial surface of said implant includes means for complemental securement with a dental abutment.

5. The dental implant as recited in claim **3**, in which a proximal radial surface of said implant includes means for complemental securement with a dental abutment.

6. The dental implant as recited in claim **2**, in which a ratio of axial length of said proximal to said distal segments comprises a range of about 1:4 to about 4:1.

7. The implant as recited in claim **1**, in which said surface texture of said distal segment comprises a surface texture selected from the group of surface treatments consisting essentially of:

laser cutting, acid etching, photolithography, abrasion/roughening, plasma spraying, calcium sulfate, bicompatible glass, collagen, hydroxyapatite, growth factor compounds, and combinations thereof.

8. A dental implant for insertion into an osseotomy site, and reducing potential for related bone loss threat, the implant comprising:

a solid elongate body having a longitudinal axis, said axis having a distal and a proximal end, said proximal end defining a collar having an axial length in a range of about 1 to about 3 millimeters, said collar further comprising a proximal segment and a distal segment in which said proximal segment comprises a surface texture for the promotion of tissue growth thereinto, and in which said distal segment comprises a surface texture for the promotion of bone growth thereinto, and further in which said proximal segment defines an ordered microgeometric repetitive surface pattern in the form of a multiplicity of alternating ridges and grooves, each having a fixed or established width in a range of about 2.0 to about 25 microns and a fixed or established depth in a range of about 2.0 to about 25 microns, in which said microgemoetric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of bone at said osseotomy site which are in contact with said surface pattern.

9. A dental implant for insertion into an osseotomy site, and reducing potential for related bone loss thereat, the implant comprising:

a solid elongate body having a longitudinal axis, said axis having a distal and a proximal end, said proximal end defining a collar having an axial length in a range of about 1 to about 3 millimeters, said collar further comprising a proximal segment and a distal segment in which said proximal segment comprises a surface texture for the promotion of tissue growth thereinto, and in which said distal segment comprises a surface texture for the promotion of bone growth thereinto, in which said proximal and distal segments define respective ordered microgeometric repetitive surface patterns in the form of a multiplicity of alternating ridges and grooves, each having a fixed or established width in a range of about 2.0 to about 25 microns and a fixed or established depth in a range of about 2.0 to about 25 microns, in which said microgemoetric repetitive patterns define a guide for preferential promotion of the rate, orientation and direction of growth colonies of cells of bone and soft tissue at said ossseotomy site which are in contact with said respective surface patterns.

10. The system as recited in claim **9**, in which a ratio of axial length of said proximal to said distal segments comprises a range of about 1:4 to about 4:1.

11. The system as recited in claim **10** in which a proximal radial surface of said implant includes means for complemental securement with a dental abutment.

* * * * *

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Hollander et al.

(10) **Patent No.: US 6,648,643 B2**
(45) **Date of Patent: Nov. 18, 2003**

(54) **DENTAL IMPLANT/ABUTMENT INTERFACE AND SYSTEM HAVING PRONG AND CHANNEL INTERCONNECTIONS**

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(73) Assignee: **BioLock International, Inc.**, Deerfield Beach, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 54 days.

(21) Appl. No.: **10/028,953**

(22) Filed: **Dec. 19, 2001**

(65) **Prior Publication Data**

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(51) **Int. Cl.**[7] **A61C 8/00**
(52) **U.S. Cl.** **433/173**
(58) **Field of Search** 433/172, 173, 433/174, 175, 176, 201.1

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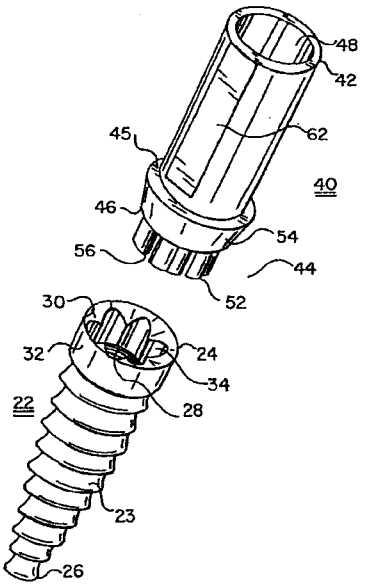
* cited by examiner

Primary Examiner—Cary E. O'Connor
(74) *Attorney, Agent, or Firm*—M. K. Silverman

(57) **ABSTRACT**

A dental implant-abutment interface and assembly comprising an implant, an abutment removably attachable to the implant, and a screw receivable within an axial threaded bore common to both the implant and abutment. The implant includes an elongate body having a proximal end and a distal end, the axial threaded bore open at the proximal end, a radial end surface of a collar comprising the proximal end, and a plurality of axially elongate recesses substantially arcuate in radial cross-section, disposed polarly at the proximal end, and extending distally away from the radial end surface. Each of the arcuate recesses exhibit a curved wall, each having a tangent lying on a common circle disposed inwardly of a circumference of the collar of the implant. The abutment includes the axial threaded bore, a proximal end, and a distal end itself including a collar and prongs projecting distally away from a radial plane at a distal-most axial extent of the collar in which the radial plane is complementally engagable with the radial end surface of the implant. The prongs are disposed equipolarly about the axial bore of the abutment, and each of the prongs are proportioned for engagement with a respective one of the axial recesses of the implant, the axial bore of the abutment communicating with the axial bore of the implant, and the radial surface of the collar having a like radius to that of the radial end surface of the implant. Each of the prongs has a radial cross-section of lesser area than that of its respective implant recess.

14 Claims, 8 Drawing Sheets



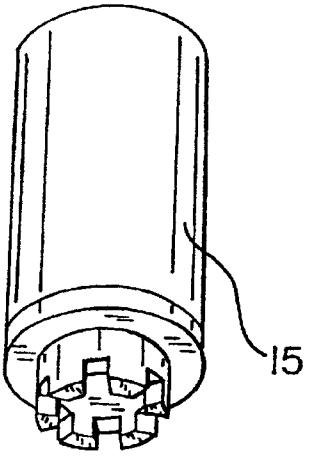


FIG. 1
PRIOR ART

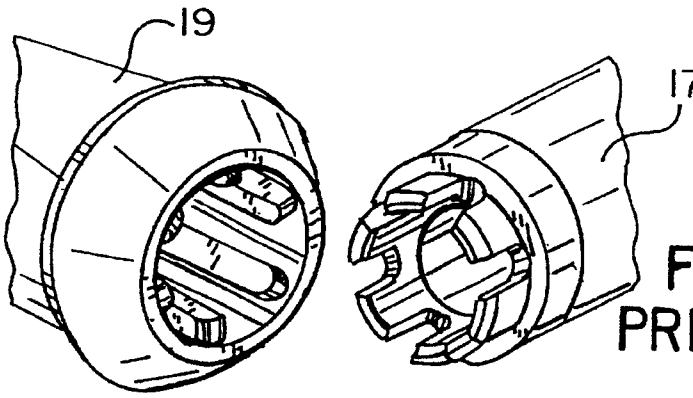


FIG. 1A
PRIOR ART

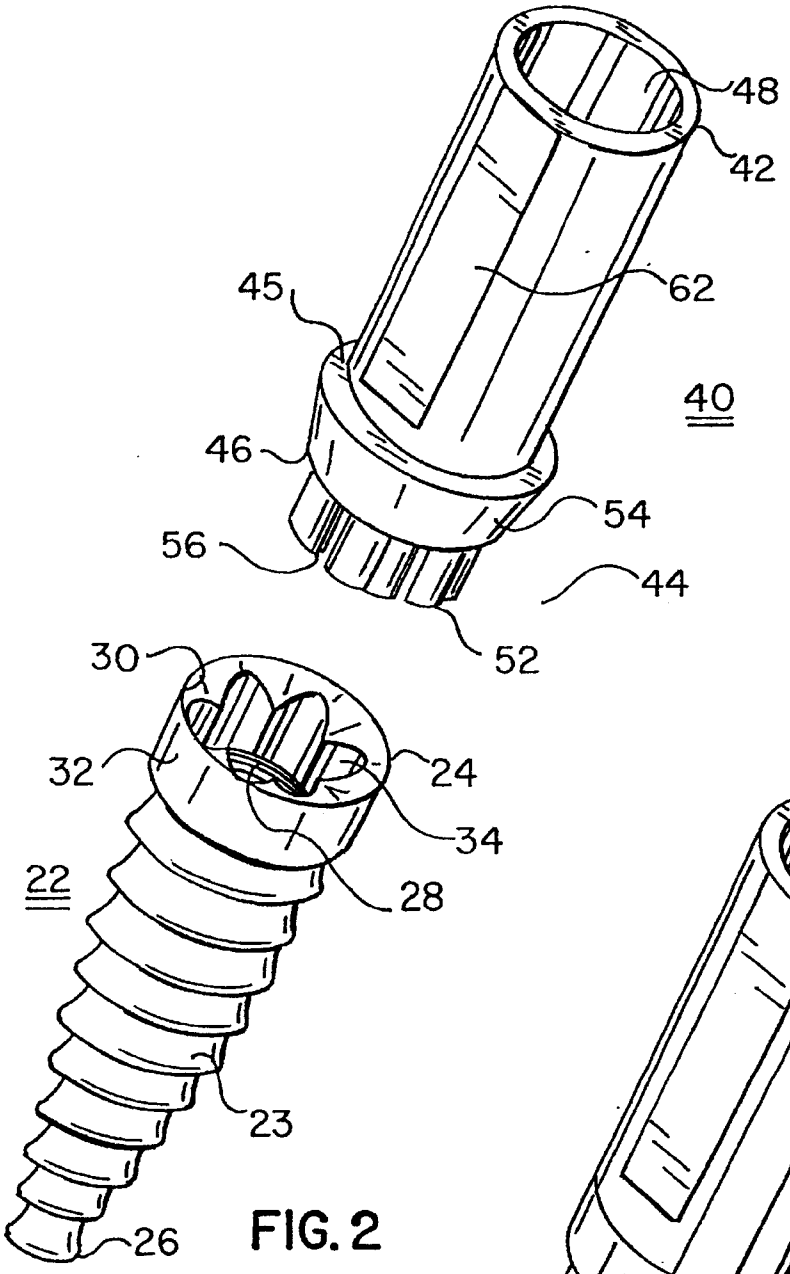


FIG. 2

FIG. 2A

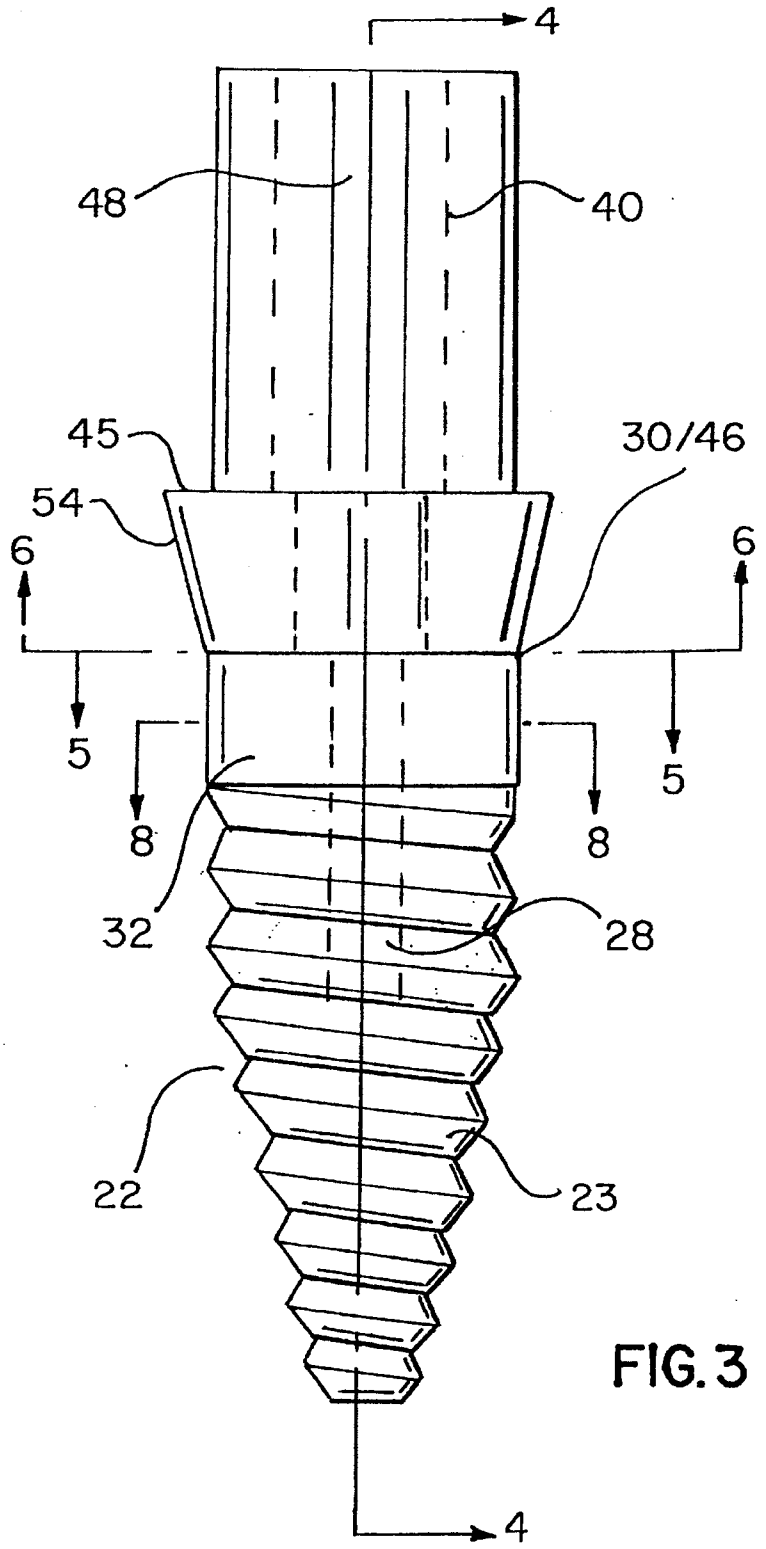


FIG. 3

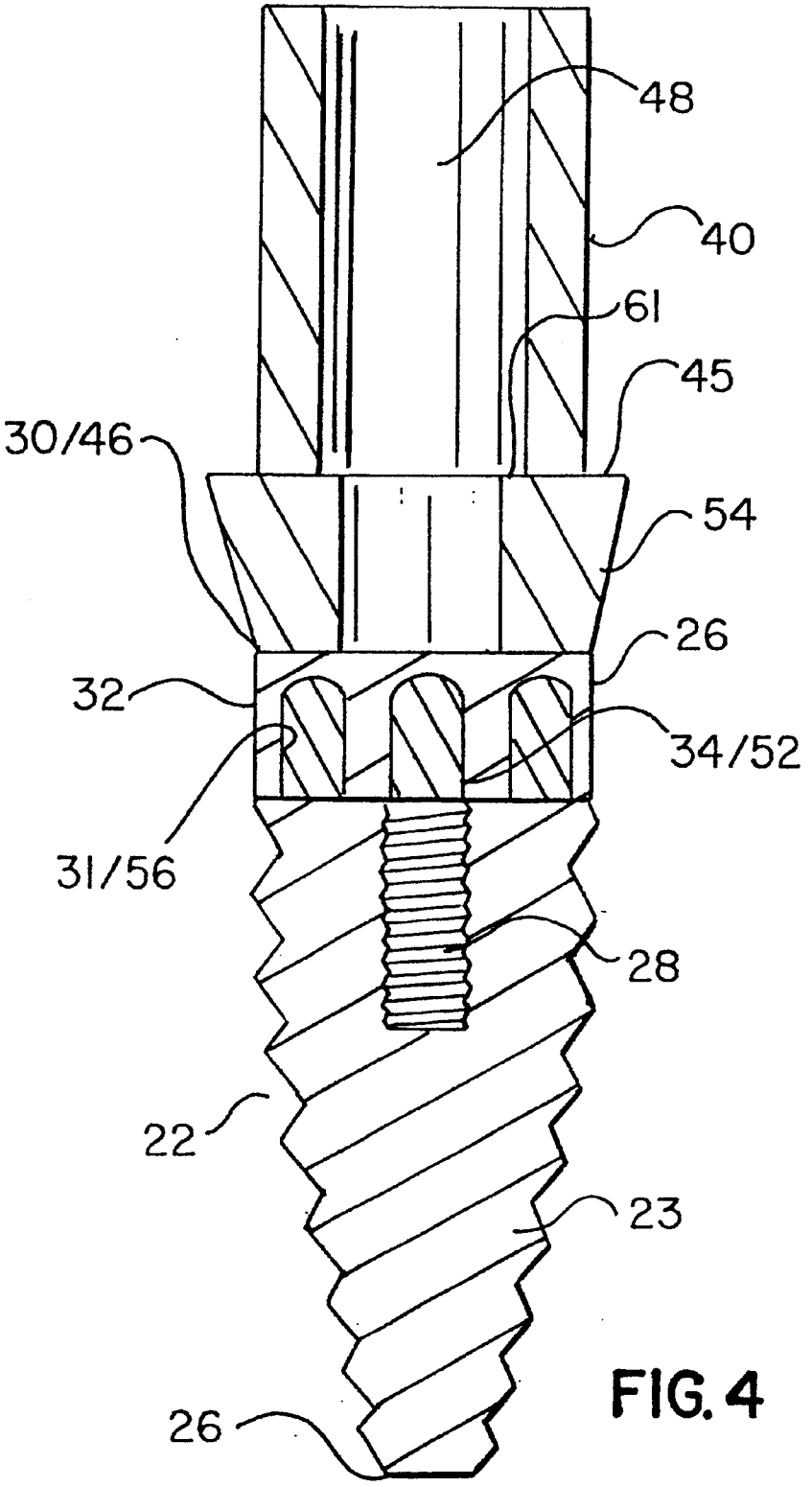


FIG. 4

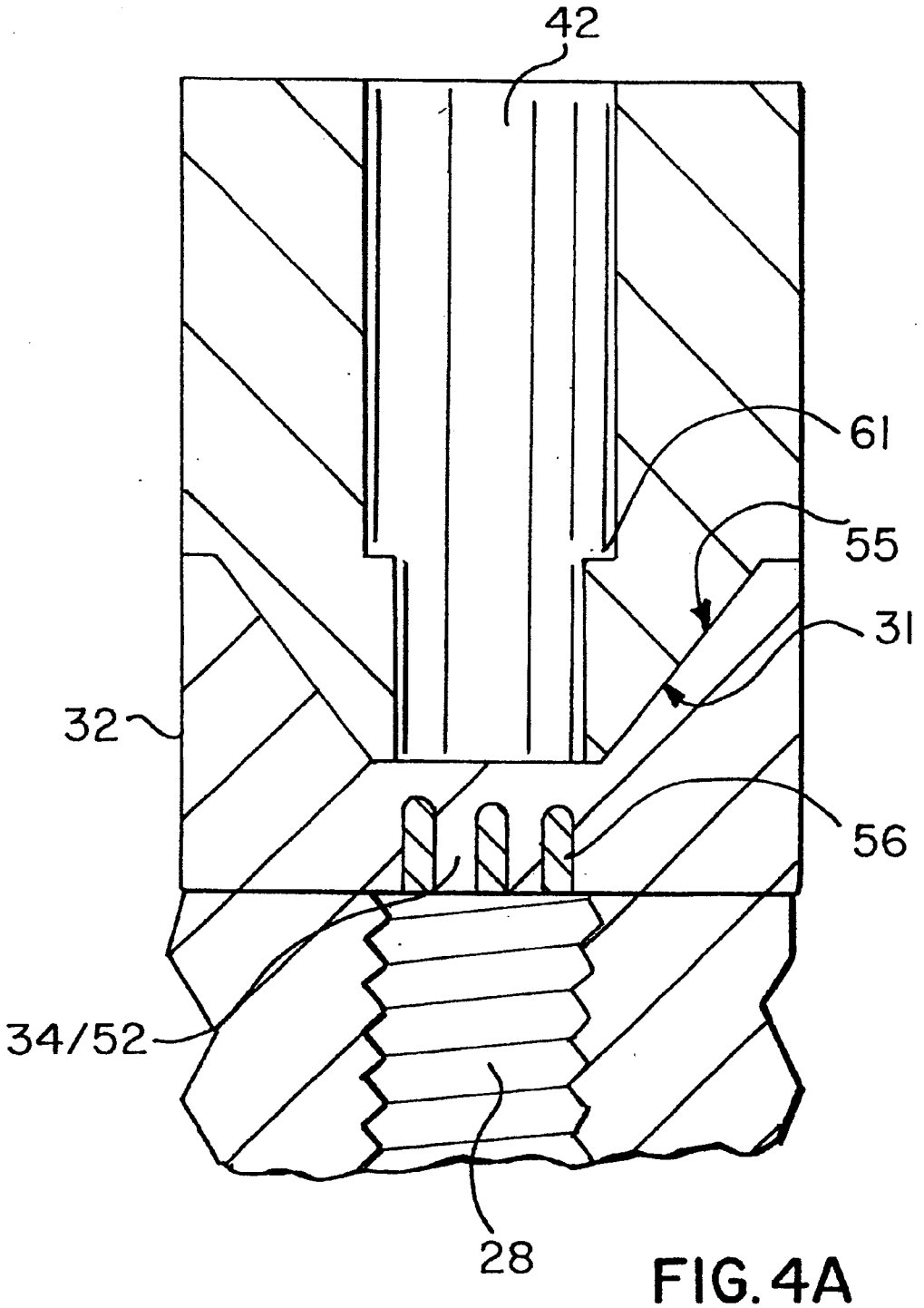


FIG. 4A

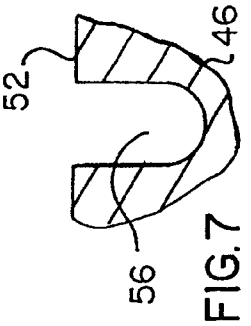


FIG. 7

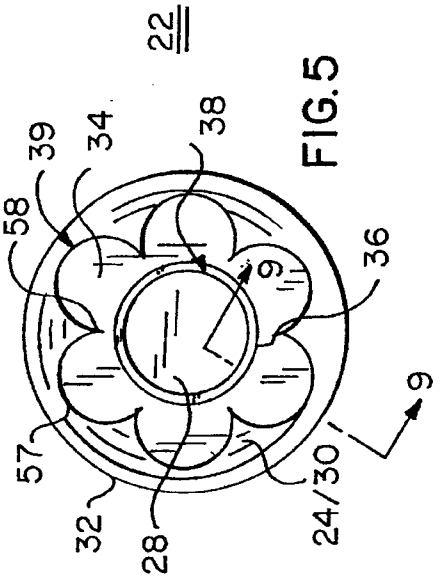


FIG. 5

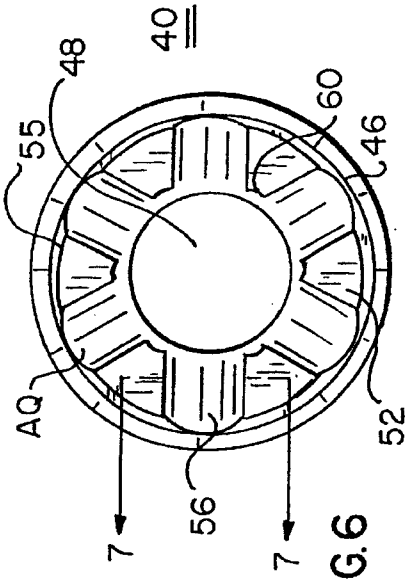


FIG. 6

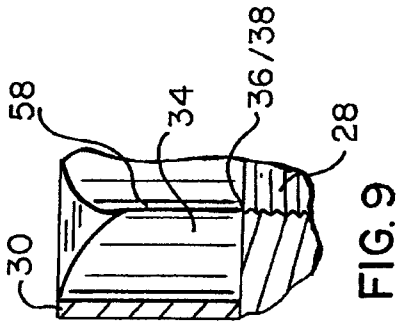


FIG. 9

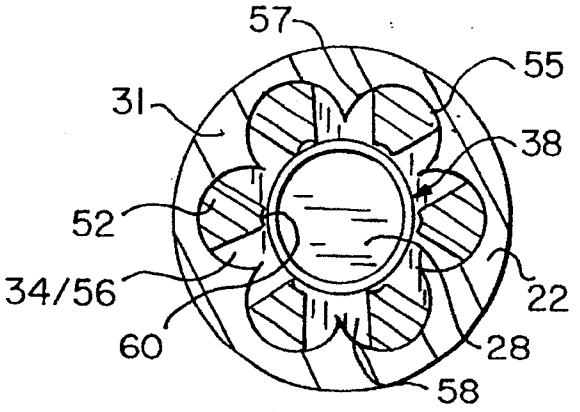


FIG. 8

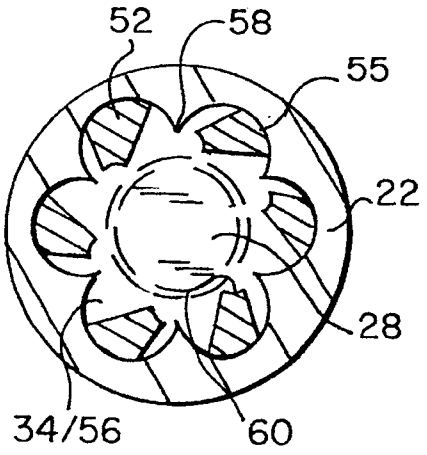


FIG. 8A

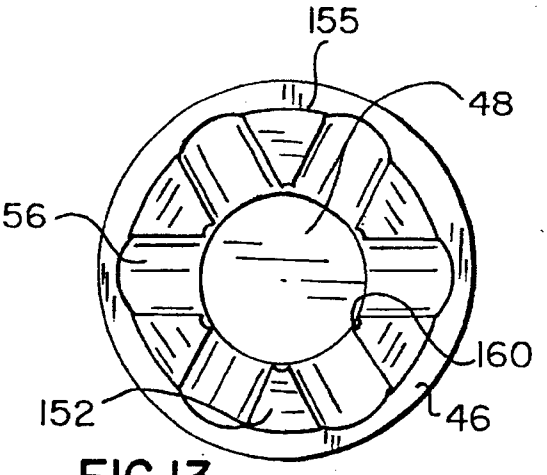


FIG. 13

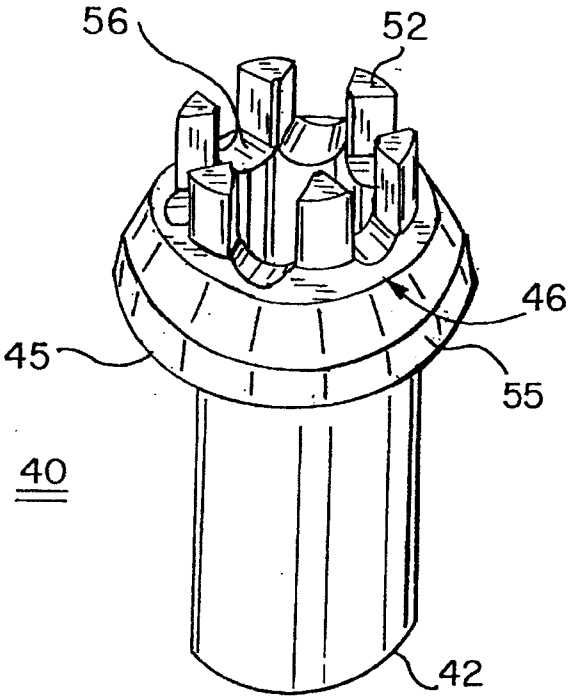


FIG. 10

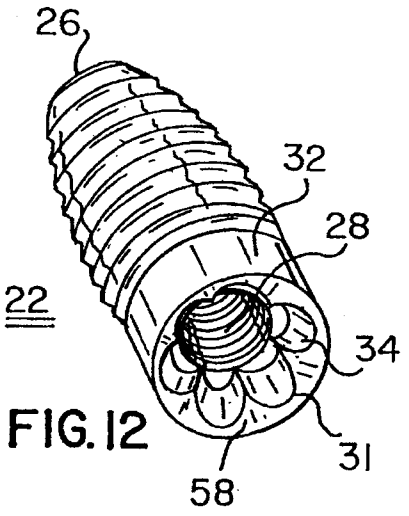


FIG. 12

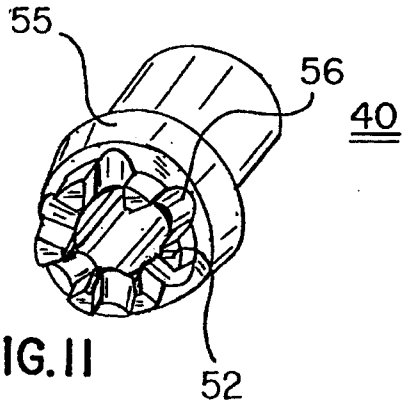


FIG. 11

DENTAL IMPLANT/ABUTMENT INTERFACE AND SYSTEM HAVING PRONG AND CHANNEL INTERCONNECTIONS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The instant invention relates generally to dental implants and, more particularly, to a dental implant interface and assembly having an implant portion for securement and osseointegration into an osseotomy site and an abutment portion, securable to the implant portion, for the support of a dental prosthesis.

2. Background and Prior Art

The present invention relates to an improvement over existing spline implant to abutment interfaces as, for example, are reflected in U.S. Pat. No. 5,449,291 (1995) to Lueschen et al, entitled Dental Implant Assembly having Tactile Feedback as well as an improvement of implant/abutment assemblies which employ pin-type interfaces as is reflected in U.S. Pat. No. 5,302,126 (1994) to Wimmer et al, entitled Dental Implant with Adjustable Post. The prior art of Lueschen, and a variant thereof, are shown in FIGS. **1** and **1A**. Therein are shown implants **15** and **17** as well as an abutment **19**. As may be noted, the male or projecting elements are associated with the implant element, this in distinction to the invention as set forth below, i.e., in which the prongs occur from the abutment, not the implant.

A longstanding concern in the area of implant dentistry has been that of minimizing or eliminating rotation, or the potential therefore, of the abutment portion of the implant system relative to the implant or anchor portion which is embedded within the alveolar bone of the patient. As such, in all implant systems, it is imperative to provide resistance to rotation and, as well, provide for accurate radial, polar and axial indexing of the abutment portion relative to the implant portion. An additional requirement of attachment of the abutment to the implant is termed "tactile feedback," that is, the feeling provided to the hand of the clinician as the abutment is seated with the implant portion. That is, during assembly of the abutment to the implant, it is important for tactile feedback to clearly indicate that the abutment is fully seated in the implant before a securing screw is tightened. As such, implant systems in the prior art that address anti-rotation to the exclusion of tactile feedback will often result in a mis-seating of the abutment relative to the implant. Conversely, systems which are primarily concerned with tactile feedback often result in an implant-to-abutment interface which lacks long-term rotational stability. The instant invention therefore provides an optimization of these otherwise competing objectives in the prior art of abutment-implant interfaces.

SUMMARY OF THE INVENTION

The invention relates to a dental implant-abutment interface and assembly comprising an implant, an abutment removably attachable to the implant, and a screw receivable within an axial threaded bore common to both said implant and abutment. More particularly, said implant includes an elongate body having a proximal end and a distal end, said axial threaded bore open at said proximal end, a radial end surface of a collar comprising said proximal end, and a plurality of axially elongate recesses substantially arcuate in radial cross-section, disposed polarly at said proximal end, and extending distally away from said radial end surface. Each of said arcuate recesses exhibit a curved wall, each

having a tangent lying on a common circle disposed inwardly of a circumference of said collar of said implant. Said abutment includes said axial threaded bore, a proximal end, and a distal end itself comprising collar and prongs projecting distally away from a radial plane at a distal-most axial extent of said collar in which said radial plane is complementally engagable with said radial end surface of said implant. Said prongs are disposed equipolarly about said axial bore of the abutment, and each of said prongs are proportioned for engagement with a respective one of said axial circular recesses of said implant, said axial bore of the abutment communicating with the axial bore of said implant, and said radial surface of said collar having a like radius to that of said radial end surface of said implant. Each of said prongs has a radial cross-section of lesser area than that of its respective implant circular recess. The axial bore of said abutment is provided with a screw head-engaging internal shoulder upon which a head of the screw rests after the length thereof complementally engages said threaded bore of the implant.

It is an object of the instant invention to provide a dental implant assembly including an implant portion and an abutment wherein the abutment resists rotation relative to the implant and is radially indexable relative thereto.

It is another object to provide a dental implant/abutment interface having prong and circular channel interconnections to both provide accurate indexing and piloting of the abutment prior to full engagement with the implant.

It is a further object of the invention to provide an implant/abutment interface which provides tactile feedback to the clinician while also providing resistance to rotation after osseointegration of the implant into the alveolar bone of the patient.

It is a still further object to obtain an interface and assembly of the above type wherein interconnecting prongs thereof may fail as a result of over-torquing of the abutment without damage to the implant or failure of the implant-abutment interface, and in which indexing of the prongs can be reset within the implant to either continue to screw the implant into the bone or to remove the implant from such bone, thereby providing a fail-safe feature to the implant clinician not withstanding such prong failure

The above and yet other objects and advantages of the present invention will become apparent from the hereinafter set forth Brief Description of the Drawings and Detailed Description of the Invention as set forth herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **1A** are perspective views of prior art spline-type implant-abutment assemblies. Therein, prongs are on the implants, not the abutment, while the abutment has channeled grooves.

FIG. **2** is an exploded view showing the implant and abutment elements of the present invention. Therein, the prongs are on the abutment, which the implant has circular recesses.

FIG. **2A** is an enlarged view of an alternative collar structure for the abutment element.

FIG. **3** is an assembly view of the elements of FIG. **2**.

FIG. **4** is an axial cross-sectional view taken through Line **4**—**4** of FIG. **3**.

FIG. **4A** is a view similar to that of FIG. **4**, however showing a conical end surface interface between the implant and abutment elements.

FIG. **5** is a radial cross-sectional view taken through Line **5**—**5** of FIG. **3** showing the appearance of the proximal end of the implant.

FIG. **6** is a radial cross-sectional view taken through Line **6**—**6** of FIG. **3** showing the appearance of the distal-most end of the abutment, including the prongs thereof.

FIG. **7** is a cross-sectional view taken through Line **7**—**7** of FIG. **6**.

FIG. **8** is a radial cross-sectional view of the implant and abutment prongs taken through Line **8**—**8** of FIG. **3**

FIG. **8**A is a view similar to that of FIG. **8**, however showing the appearance of the prongs in the event of overtorquing of the abutment.

FIG. **9** is a partial radial cross-sectional view taken through Line **9**—**9** of FIG. **5**.

FIG. **10** is an inverted perspective view of the abutment element of the embodiment of FIG. **4**A.

FIG. **11** is a diagonal perspective view of the element of FIG. **10**.

FIG. **12** is a diagonal perspective view of the implant element of the embodiment of FIG. **4**A.

FIG. **13** is a view, similar to that of FIG. **8**, showing a further embodiment of the abutment elements.

DETAILED DESCRIPTION OF THE INVENTION

With reference to the exploded view of FIG. **2**, the inventive dental implant-abutment interface and assembly may be seen to include an implant **22** and an abutment **40**. The implant, which is adapted for insertion into an osseotomy site, includes an elongate body **23** having a proximal end **24**, a distal end **26**, and an axial threaded bore **28** which is open at said proximal end **24** of the implant. At said opening is defined a radial surface **30** as well as a collar **32**. As is shown in FIG. **3**, collar **32** typically comprise a cylindrical segment **31**. In another embodiment, collar **32** may taper outward in the direction of said implant body **23**.

Between the beginning of threads of threaded bore **28** and said radial surface **30** are a circumferential plurality of axially elongate recesses **34** (see also FIG. **5**), each of which are substantially arcuate in radial cross-section and, as well, are disposed equipolarly about a longitudinal axis of said threaded bore **28** of the implant **22**. As may be further noted, said recesses **34** extend axially away from said radial surface **30** and extend downwardly (distally) in the implant to the extent of said collar **32** (see also FIG. **4**).

As may be noted with reference to FIG. **5**, each of said recesses **34** exhibit a curved innermost wall **36** which lies upon a common circle **38** radially disposed slightly beyond a circumference which defines the opening of said bore **28**. Further, an outermost radius **39** of each recess **34** lies upon a common circle which is disposed slightly inwardly of the circumference of said radial surface **30** of the implant.

As may be noted in FIGS. **4**A and **12**, said radial surface may comprise a tapered radial surface **31**.

With further reference to the exploded view of FIG. **2**, the inventive system may be seen to further include said abutment **40** which, as in the case of all dental system abutments, is adapted for the support of a tooth prosthesis. Said abutment **40** includes a proximal end **42**, a distal end **44**, an annular shoulder **45** **54**, an axial bore **48**, a distally tapered collar **54** beginning at the axial location of said annular shoulder **45** and continuing to the axial position of a virtual radial plane **46**. Optionally, a cylindrical shoulder **154** (see FIG. **2**A) can be employed. Distally depending from said virtual plane **46** of said collar **54** or **154** are projecting prongs **52** which, together with said virtual radial plane **46**, are proportioned for engagement within said axial recesses

34 and said radial surface **30** or **31** which defines the proximal-most axial extent of said implant **22**.

As may be noted in the axial cross-sectional view of FIG. **6**, said prongs **52** are disposed equipolarly about an axis of abutment bore **48** and are proportioned for engagement of each of said axial circular recesses **34** of the implant, this as may be more fully appreciated with reference to the radial-cross sectional view of FIG. **8**. In FIGS. **6** and **8**, prongs **52** appear, in radial cross-section, as trapezoids with curved major and minor bases **55** and **60** respectively. Therein, each major base **55** thereof mates with a wall **57** of each elongate recess **34** of the implant **22**. However, interdigitaged between said prongs **52** are U-shaped regions **56** (see FIGS. **2**, **4** and **10**) which slip over intersections **58** (see FIGS. **2**, **5**, **8** and **9**) of curved surfaces **57** of said recesses **34**. As such, prongs **52**, when fully inserted within recesses **34** of the implant, appear in the manner shown in FIGS. **4** and **8**. That is, curved major base **55** of each prong **52** mates with curved wall **57** of each recess, and minor base **60** of each prong **52** contacts a wall of the circumference **38** of implant bore **28**. As may be further noted with reference to FIGS. **4** and **6**, the polar dimension of each U-shaped channel **56** will typically exceed that of the polar dimension (as defined by major base **55**) of each prong **52**. The invention therefore differs materially from the prior art (see FIG. **1**) and, as described in the Background of the Invention, with reference to both the polar and radial extent and geometry of the prongs of the abutment relative to recesses complemental thereto. The special-purpose radial geometry of the interlock between male and female elements is more particularly shown in the view of FIGS. **4** and **8**. It is to be appreciated that recesses **34** of the implant will not be entirely filled by the geometry of prongs **52** but, rather, are held in place through (a) the interdigitating interlock of channels **56** with curved surface intersections **58** of the implant and (b) the interlock between said prongs **52** and, particularly, major bases **55** with walls **57** of said axial recesses and of each prong minor base **60** with circumference **38** of the opening of the implant bore **28**.

With reference to FIG. **8**A, there is yet further noted that the difference in cross-sectional area between the prongs of the abutment and the recesses of the implant allows the prongs to fail when over-torqued, without fatally damaging the implant or the implant abutment interface, so that the prongs can be reset in the implant and will continue to engage, allowing the clinician to either continue to screw the implant into the bone or may remove the implant from the bone. This fail-safe feature is an important factor in implant dentistry.

After assembly of the elements in the manner shown in FIGS. **3**, **4** and **8**, a screw (not shown) is placed within both communicating abutment bore **48** and implant bore **28** to both secure the implant and abutment to each other and, as well, to provide a platform upon which the tooth prosthesis may be secured. Also shown is shoulder **61** of bore **48** upon which the screw head rests.

Further shown in the view of FIG. **2** is a flat lateral surface **62** of the abutment having utility in the rotation of the abutment relative to the implant after the complemental elements thereof have been inserted into each other, this to create a cam-lock action

A further distinguishing feature of the instant system is that of said collar **54** of the abutment tapers to a diameter equal to the diameter of implant collar **32** at the plane of contact with said radial surface **30** or **31** thereof. It has been found that such a collar provides enhanced strength and

stability to the resultant system. In FIG. 4A is shown the conical interface of implant-tapered surface **31** with abutment-tapered surface **55**.

It is to be further understood that a triangular cross-sectional geometry of prongs **152** may be utilized in lieu of the above trapezoidal geometry of prongs **52**. See FIG. **13**. In such triangular prongs, there would exist apex **160** and curved outer leg **155**.

While there has been shown and described the preferred embodiment of the instant invention it is to be appreciated that the invention may be embodied otherwise than is herein specifically shown and described and that, within said embodiment, certain changes may be made in the form and arrangement of the parts without departing from the underlying ideas or principles of this invention as set forth in the claims appended herewith.

We claim:

1. A dental implant-abutment interface and assembly, comprising:

(a) an implant for insertion into an osseotomy site, said implant including an elongate body having a proximal end and a distal end, an axial threaded bore open at said proximal end, a radial end surface of a collar comprising said proximal end, and a plurality of axially circular recesses substantially arcuate in radial cross-section and disposed equipolarly about said threaded bore at said proximal end and extending distally away from said flat radial surface, each of said recesses include a curved outer wall having a tangent with common circle disposed inwardly of a circumference of said implant;

(b) an abutment removably attachable to said implant for supporting a tooth prosthesis, said abutment including an axial bore, a proximal end, and a distal end comprising (i) a collar; and (ii) prongs projecting distally from a radial plane at a distal-most axial extent of said collar, said plane complementally engagable with said radial end surface of said implant, said prongs disposed equipolarly about said axial bore of said abutment, each of said prongs proportioned for engagement with a respective one of said axial recesses of said implant in which an area of radial cross-section defined by each of said prongs is less than an area of radial cross-section, at a like axial position, of said respective each one of said axial recesses with which said each prong is engaged, said axial bore of said abutment communicating with said axial bore of said implant, said radial plane of said collar having a like radius to that of said radial end surface of said implant; and

(c) a screw, receivable in said axial bore and upon a screw head-engaging internal shoulder of said abutment, and having screw threads complementally engagable with said threaded bore of said implant.

2. The assembly as recited in claim **1**, in which said prongs of said abutment each define a substantially trapezoidal radial cross-section having major and minor bases.

3. The assembly as recited in claim **2**, in which each minor base of said cross-section lies upon a common circle contiguous to a circumference of said bore of said abutment.

4. The assembly as recited in claim **3**, in which each major base of each prong cross-section lies upon a common circle contiguous to an outermost circumference of said radial plane of said abutment collar.

5. The assembly as recited in claim **4**, in which said prongs are separated by equipolar axially U-shaped interdigitating channels falling within the curvature of said common circle in which each polar dimension of said interdigitating channels exceeds each polar dimension defined by said curved outer base of each of said trapezoidal cross-section of said prongs.

6. The assembly as recited in claim **5**, which said major and minor bases are each curved.

7. The assembly as recited in claim **1**, in which an exterior surface of said implant comprises a tapered buttress thread geometry.

8. The assembly as recited in claim **1**, in which radial cross-sections of said prongs of said abutment each substantially define a triangle.

9. The assembly as recited in claim **8**, in which vertices of said substantially triangular radial cross-sections of said prongs comprise rounded surfaces.

10. The assembly as recited in claim **1**, in which said radial end surface of said implant and said radial plane of said abutment each define a section of a cone and are complemental to each other.

11. The assembly as recited in claim **10**, which said prongs of said abutment each define a substantially trapezoidal radial cross-section having curved major and minor bases.

12. The assembly as recited in claim **10**, in which said abutment collar comprises an annular collar tapering distally toward said radial plane of said abutment.

13. The assembly as recited in claim **10**, in which in which said prongs of said abutment each define a substantially trapezoidal radial cross-section having major and minor bases.

14. The assembly as recited in claim **13**, in which said major and minor bases are each curved.

* * * * *



SETTLEMENT AGREEMENT

This Settlement Agreement is entered into this 28th day of May, 1996, by and among MINIMATIC IMPLANT TECHNOLOGY, INC., a Florida corporation f/k/a MINIMATIC, INC., ("Minimatic"); AMERICAN BIODENTAL CORPORATION, a Delaware corporation f/k/a MINIMATIC IMPLANT TECHNOLOGY, INC., ("ABC"); (Minimatic and ABC are sometimes collectively referred to as "Minimatic/ABC"); JACK T. KRAUSER and IMPLANT CENTER OF THE PALM BEACHES, INC., a Florida corporation (collectively "Krauser"); and SHAWN MCDERMOTT ("McDermott").

WHEREAS, in 1988, Krauser, a practicing periodontist, has asserted that he conceived a new dental implant system, but did not have the facility to manufacture the system; and

WHEREAS, in 1988, Minimatic/ABC was then operating as a job/machine shop manufacturing dental implant parts for third party vendors; and

WHEREAS, in 1989-1990, Minimatic/ABC was desirous of manufacturing its own dental implant system but recognized the need for expert user input to create its own dental implant system; and

WHEREAS, in 1989-1990, Krauser has asserted that he associated himself with Minimatic/ABC for the purpose of imparting to Minimatic/ABC his invention for his new dental implant system so that said system could be manufactured by Minimatic/ABC in exchange for: (i) remuneration on the sale by Minimatic/ABC of the dental implant products produced; (ii) the ability to purchase stock in Minimatic/ABC at a discounted rate; (iii) the listing of Krauser as

"client" on all drawings comprising the dental implant system; (iv) an agreement by Minimatic/ABC to enter into a future arrangement with Krauser regarding his future use of such drawings; and (v) other considerations to be specifically set forth in a contract to be entered into between these parties; and

WHEREAS, Krauser has asserted that in reliance on certain representations made by officers and directors of Minimatic/ABC, Krauser allowed Minimatic/ABC to register his dental implant system with the Food and Drug Administration so as to enable Minimatic/ABC to obtain 510(k) approval from the Food and Drug Administration for the distribution and sale of the dental implant products referenced herein; and

WHEREAS, subsequent to Minimatic/ABC registering the dental implant system with the Food and Drug Administration and obtaining the necessary 510(k) approvals, Minimatic/ABC entered into a contract with Krauser dated March 14, 1991, as amended by an addendum thereto dated May 26, 1992, (the "Contract"); and

WHEREAS, as early as late 1991, Krauser and McDermott claimed to have created a video which eventually became entitled "New Designs-Stryker Dental Implant System", for which Krauser and McDermott thereafter obtained a registered copyright (the "copyright"); and

WHEREAS, subsequent to the parties entering into the Contract, ABC: (i) failed to pay Krauser various amounts called for therein based on their belief that certain defenses existed sufficient to excuse them from making some or all of such payments, those

defenses being limited to: (a) Krauser's failure to lecture on behalf of Minimatic/ABC pursuant to the Contract; (b) Krauser's failure to perform and document clinical studies on a timely basis for Minimatic/ABC; (c) Krauser's failure to exclusively represent Minimatic/ABC's products by lecturing on adjunct products at competitors' dental implant symposiums and conferences; and (d) Krauser's resignation from Minimatic/ABC (to each of which Krauser takes exception); (ii) failed to deliver to Krauser his stock in ABC; (iii) failed to list Krauser as "client" in some of the drawings comprising the dental implant system; and (iv) failed to enter into an agreement with Krauser regarding his future use of those drawings; and

WHEREAS, in or about July, 1993, Krauser instituted suit against ABC in the Fifteenth Judicial Circuit, in and for Palm Beach County, Florida, said suit being more specifically known as: JACK T. KRAUSER and IMPLANT CENTER OF THE PALM BEACHES, INC., a Florida corporation, vs. LEON SHAW and MINIMATIC IMPLANT TECHNOLOGY, INC., n/k/a AMERICAN BIO-DENTAL CORPORATION, a Delaware corporation, doing business in the State of Florida, CASE NO. CL 93-5862 AJ (hereinafter the "state court action") seeking substantial damages in excess of $1,000,000.00 for its failure to pay the sums referenced above and declaratory relief regarding the parties' future ownership of the dental implant system; and

WHEREAS, in response to the state court action, ABC filed numerous affirmative defenses to Krauser's claims, as well as a

counterclaim in connection therewith and a third party complaint against McDermott; and

WHEREAS, in May, 1994, Krauser obtained a patent from the United States Patent and Trademark Office on ~~the~~ dental implant ~~system~~ referenced herein, said patent being assigned U.S. Patent No. 5,316,476 (the "Patent"); and

WHEREAS, in or about October, 1994, Krauser instituted suit in the District Court for the Southern District of Florida against Minimatic and ABC for patent infringement, and Krauser and McDermott, in that same action, asserted a claim against Minimatic and ABC for copyright violation, said suit being more specifically known as: JACK T. KRAUSER, an individual and SHAWN MCDERMOTT, an individual vs. MINIMATIC IMPLANT TECHNOLOGY, INC., a Delaware corporation, MINIMATIC INC., a Florida corporation and LEON SHAW, an individual, CASE NO. CL-94-8521 CIV-HURLEY (the "federal court action"); and

WHEREAS, trial in the state court action is currently set to commence May 28, 1996; and

WHEREAS, in the federal court action, a hearing on Krauser's Motion for Preliminary Injunction for Patent Infringement against Minimatic and ABC (the "Preliminary Injunction Hearing") is currently set for July 15, 1996; and

WHEREAS, Minimatic, ABC, Krauser and McDermott are all desirous of amicably resolving both the state court action and the federal court action as it relates to those parties only; and

WHEREAS, in an effort to resolve all pending claims, disputes and litigation between these parties, Krauser is willing to accept certain monetary payments from Minimatic/ABC for all asserted past due royalties, and additional monetary sums from Minimatic/ABC for their future use of the Patent and other non-defined, non-measurable activities, for the liquidation of his general unsecured claim for asserted past due commissions and expenses owed to him by Minimatic/ABC, and for the liquidation of McDermott's asserted general unsecured claim relating to his claim maintained in the federal court action and Minimatic/ABC's current bankruptcy proceedings.

NOW THEREFORE, in light of the foregoing, and in consideration of the mutual promises and covenants set forth herein, as well as other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties to this Settlement Agreement hereby stipulate and agree as follows:

1. Each and every one of the foregoing recitals are true and correct and shall be admissible for all purposes against any party hereto in any existing or future legal or administrative proceeding(s) between any of them. Minimatic/ABC and Krauser hereby waive any evidentiary privilege they may have to object to the admissibility of any of the statements or representations contained in this Settlement Agreement on the basis that such statements constitute an offer of compromise or an offer to settle. For purposes of this Settlement Agreement, any reference herein to Minimatic or ABC or Krauser shall also include any successor

corporation thereto, including, but not limited to, merged or consolidated companies or name changes to Minimatic or ABC or Krauser.

2. As payment to Krauser for all past royalties due him from Minimatic/ABC for their prior use of the Patent and prior sale of Patented products, Minimatic and ABC hereby agree, jointly and severally, to pay to Krauser the total sum of $681,000.00 (or $706,000.00 if they so choose in accordance with ¶(d) below) in accordance with the following payment schedule: for the next sixty (60) months, with month one commencing thirty (30) days following the U.S. Bankruptcy Court's (the "Court") entry of an order approving this Settlement Agreement becoming final, and continuing on that same day of the month every month thereafter, Minimatic/ABC shall pay to Krauser, by delivering said sums to Krauser at 824 U.S. Highway One, North Palm Beach, FL 33408 -

(a) the sum of $3,000.00 per month during months one (1) through twelve (12);

(b) The sum of $5,000.00 per month during months thirteen (13) through twenty-four (24);

(c) The sum of $8,000.00 per month during months twenty-five (25) through thirty-six (36). Further, on or before thirty-six (36) months after Court approval of this Settlement Agreement becoming final, Minimatic/ABC shall pay to Krauser, in addition to all other sums set forth in ¶¶2(a) - (c) herein, the lump sum of $100,000.00;

(d) The sum of $10,000.00 per month during months thirty-seven (37) through forty-eight (48). No later than forty-eight (48) months after Court approval of this Settlement Agreement becoming final, Minimatic/ABC shall pay to Krauser, in addition to all other sums set forth in ¶¶2(a) - (d) herein, the lump sum of $125,000.00; however, in the event Minimatic/ABC shall elect not to make payment of this $125,000.00 lump sum payment due no later than forty-eight months after Court approval of this Settlement Agreement becoming final, Minimatic/ABC, at its sole option, shall notify Krauser of same, in writing, no later than thirty (30) days before said payment is due, and, instead, shall thereafter be obligated to pay Krauser the lump sum payment of $150,000.00 no later than sixty (60) months following the Court's order approving this Settlement Agreement becoming final; and

(e) The sum of $12,000.00 per month during months forty-nine (49) through sixty (60);

3. With regard to the lump sum payments of $100,000.00 due thirty-six months after Court approval of this Settlement Agreement becoming final, and the $125,000.00/$150,000.00 payment due forty-eight/sixty months after Court approval of this Settlement Agreement becoming final, interest will accrue on those amounts at 8% annual simple interest, to be paid to Krauser one time annually, with the first payment being due to Krauser twelve months from the date the Court order approving this Settlement Agreement becomes

final. The first three such interest payments shall be computed as if Minimatic/ABC will be electing to make payment to Krauser of the $125,000.00 lump sum payment due at the conclusion of forty-eight months from the date Court approval of this Settlement Agreement becomes final. Minimatic/ABC shall be entitled to pre-pay the lump sum amounts set forth in ¶¶(2)(c) and (d) above at any time prior to their maturation without penalty.

4. The parties hereto acknowledge that the total of all of the payments required to be paid by Minimatic/ABC to Krauser as set forth in ¶2 herein total $681,000.00, assuming Minimatic/ABC elects to pay Krauser the lump sum payment of $125,000.00 at the conclusion of the forty-eighth month following Court approval of this Settlement Agreement becoming final, and $706,000.00 should Minimatic/ABC elect to pay Krauser the lump sum payment of $150,000.00 at the conclusion of the sixtieth month following Court approval of this Settlement Agreement becoming final.

5. Krauser has filed a Proof of Claim in the respective bankruptcies filed by Minimatic and ABC asserting an entitlement to an unspecified amount, as well as ownership rights in and to the drawings comprising the dental implant system referenced above. In consideration of the amounts asserted by Krauser to be due and owing to Krauser by Minimatic and ABC pursuant to the Contract, Minimatic and ABC agree that Krauser is entitled to file an Amended Proof of Claim in each of their respective bankruptcy proceedings for the collective amount of $400,000.00 and further agree and stipulate not to file objections thereto. In the event this

Settlement Agreement is not approved by the Court, Krauser shall not be limited to this sum as his total unsecured claim, but instead, shall be entitled to file an Amended Proof of Claim for any amount he deems appropriate subject always to any appropriate objections being raised by Minimatic and ABC other than to the timeliness of the filing of the Amended Proof of Claim, so long as said Amended Proof of Claim is filed within fifteen (15) days of the Court's order denying the approval of this Settlement Agreement becoming final, or the time permitted by law, whichever is later. In the event the Court approves this Settlement Agreement, Krauser's claims of $400,000.00 shall be liquidated and undisputed general unsecured claims to be paid consistent with all other payments made to the general unsecured creditors in the Minimatic and ABC bankruptcy proceedings. Notwithstanding anything to the contrary set forth in this Settlement Agreement, any payments made by Minimatic or ABC, or their respective bankruptcy estates, to Krauser in accordance with any plan of reorganization wherein such payments are specifically made to Krauser as a general unsecured creditor shall immediately be credited against any sums then due and owing to Krauser pursuant to ¶2 herein so that the net effect to Minimatic/ABC is that pursuant to ¶2 herein, they shall never be obligated to pay Krauser more than the $681,000.00/$706,000.00 provided for in ¶2 herein. By way of example only, if Krauser is to receive a monthly payment of $3,000.00 from Minimatic/ABC in accordance with ¶2(a) above, and at the same time Krauser, as a general unsecured creditor of Minimatic or ABC, receives payment of

the sum of $1,000.00 as his distribution on his general unsecured claim in accordance with an approved plan of reorganization, then Minimatic/ABC's obligation to pay Krauser the sum of $3,000.00 during that particular month in accordance with ¶2 herein shall be reduced by the $1,000.00 payment actually received by him as payment on his general unsecured claim.

6. As future royalties to Krauser for Minimatic/ABC's continued future use of his Patent, Minimatic/ABC will pay to Krauser the following sums in the following manner:

(a) During the first twelve months after Court approval of this Settlement Agreement:

(i) 0% of the total net sales between zero and $1,750,000.00 of all products set forth and described in the catalog attached hereto as Exhibit "A" (with exceptions being marked for purchase re-sale items (page 49 therein)), as well as any other dental implant products listed for sale in any future Minimatic or ABC catalog, which products are line extensions, line expansions, modifications to existing products or derivative items produced from any and all currently designed and/or produced products (with exceptions in Exhibit "A" being marked for items not associated with the subject dental implant system (page 40/part #8051 and page 49/part #s 8200 and 8170)). These products also include any dental implant products hereafter manufactured and sold by Minimatic/ABC for which Krauser

participated in the creation and/or development of, so long as Minimatic/ABC agree to conspicuously identify Krauser as the inventor or collaborator thereof, whichever is appropriate. All of the foregoing are hereinafter collectively referred to as the "Products";

(ii) 4% of the total net sales between $1,750,000.00 and $3,500,000.00 of the Products;

(iii) 5% of the total net sales between $3,500,000.00 to $5,000,000.00 of the Products; and

(iv) 6% of the total net sales in excess of $5,000,000.00 of the Products.

(b) During the second twelve months after Court approval of this Settlement Agreement:

(i) 0% of the total net sales between zero and $1,750,000.00 of the Products;

(ii) 4% the total net sales between $1,750,000.00 and $3,500,000.00 of the Products;

(iii) 5% of the total net sales between $3,500,000.00 to $5,000,000.00 of the Products; and

(iv) 6% of the total net sales in excess of $5,000,000.00 of the Products.

(c) After the expiration of the second twelve months following Court approval of this Settlement Agreement becoming final, and continuing for so long as Krauser shall own the Patent, plus an additional ten (10) years thereafter, (approximately twenty three (23) years in total):

(i) 4% of the total net sales between zero and $3,500,000.00 of the Products;

(ii) 5% of the total net sales between $3,500,000.00 to $5,000,000.00 of the Products; and

(iii) 6% of the total net sales in excess of $5,000,000.00 of the Products.

For purposes of this ¶6, the term "net sales" shall mean all gross sales of the Products less only returns, discounts, credits given in lieu of returns and freight and handling charges, if applicable, and nothing else.

7. Notwithstanding anything to the contrary set forth in ¶6 above, commencing with the third year following the Court's approval of the Settlement Agreement becoming final, and for all years thereafter, in any two consecutive years where sales by Minimatic/ABC of the Products, each year, comprise less than fifty percent (50%) of Minimatic/ABC's annual net sales of dental implant products and the royalty amount to be paid to Krauser in accordance with ¶6(c) above is greater than 20% less than Krauser's royalty payment was for the immediately preceding year wherein sales of the Products did exceed 50% of Minimatic/ABC's annual net sales of dental implant products, Krauser shall be entitled to receive a guaranteed minimum royalty payment or request and receive the complete return to him of the dental implant system comprised of the 510(k)s, the 510(k) files, drawings and related documents (as those terms are defined below). The guaranteed minimum royalty payment shall be the greater of the following: (i) the amount

called for in ¶6(c) above; or (ii) the amount paid by Minimatic/ABC to Krauser under ¶6(c) above for the immediately preceding year wherein sales of the Products did exceed fifty percent (50%) of Minimatic/ABC's annual net sales of dental implant products. In the event Minimatic/ABC is obligated to pay Krauser under this ¶7 (to wit: sales of the Products for two consecutive years are, each year, less than 50% of total dental implant sales and Krauser's royalty has decreased by the requisite amount), then Minimatic/ABC shall first have the option of paying Krauser the amount called for in this ¶7. Should Minimatic/ABC elect not to pay Krauser the amount called for in this ¶7, then Krauser shall have the option to either accept from Minimatic/ABC 100% ownership in and to the 510(k)s, 510(k) files, drawings and related documents (as those terms are defined below), or to accept payment of the actual royalty amount due Krauser in accordance with the formula set forth in ¶6(c) above. In the event Krauser elects to accept 100% ownership in and to the 510(k)s, 510(k) files, drawings and related documents (as those terms are defined below), same shall be effectuated in the exact manner as if Krauser was receiving such ownership under an event of default and therefore in accordance with ¶¶12, 15 and 16 of this Settlement Agreement, except that Minimatic/ABC shall not be deemed to be in "default" of this Settlement Agreement. In the event Krauser elects to accept 100% ownership in and to the 510(k)s, 510(k) files, drawings and related documents (as those terms are defined below), and same is completely effectuated in accordance with ¶¶ 12, 15 and 16 herein,

and Minimatic/ABC have completely ceased and desisted from selling any of the Products, and Krauser has been offered the opportunity by Minimatic/ABC to purchase from them all of the remaining Products in Minimatic/ABC's inventory at the manufacturer's cost for same, Minimatic/ABC shall have no further obligation to pay Krauser any royalties whatsoever under ¶6 herein. All payments which are to be made by Minimatic/ABC to Krauser as provided for herein shall be paid to Krauser on a monthly basis, in arrears, as is described in ¶8 below.

8. All of the foregoing payments identified in ¶¶6 and 7 above shall be paid to Krauser at the address set forth in ¶2 herein on the first day of each month in arrears commencing on the first month immediately after Minimatic/ABC's net sales reach the specified net sales level and shall continue to be paid on the first day of each month in arrears for the remainder of the twelve month period at the amount provided for herein. In order to ensure that Krauser will be paid, on a timely basis, all amounts called for in ¶6 above, Minimatic/ABC shall furnish to Krauser, on a monthly basis, a complete and accurate sales report evidencing the total gross and net sales of the Products for that preceding month. Upon Minimatic/ABC's net sales of the Products reaching any of the specified levels set forth in ¶6 above, said monthly gross and net sales report shall be delivered to Krauser accompanied by the royalty payment due in connection therewith.

9. Minimatic/ABC will keep adequate records and books of accounts in accordance with generally accepted accounting

principles evidencing all sales and deliveries of the Products and all income or other consideration received as a result of the sale or delivery of the Products. Following the giving of reasonable notice, Krauser and his agents, accountants and attorneys will be entitled to visit and inspect the business premises of Minimatic/ABC (or any other place where Minimatic/ABC's financial records may be kept in the ordinary course of business) and examine Minimatic/ABC's records and books of accounts as they relate to gross and/or net sales of the Products at such reasonable times as Krauser shall request not to exceed one time per each quarter in any given year. Krauser shall bear the initial expense of conducting such audit. However, in the event Krauser's audit demonstrates a discrepancy between reported and actual net sales of 5% or more, Minimatic/ABC shall pay the whole cost of the audit.

10. "Events of default" as referenced herein shall include, but shall not be limited to, the following: (1) The failure of Minimatic or ABC to pay to Krauser, at the time said payments are due, or in the amount called for herein, any of the sums required by this Settlement Agreement to be paid to him, but only after receipt by Minimatic/ABC of ten (10) days' written notice thereof by telecopier at (407) 997-8232 and/or regular mail to Minimatic/ABC's business premises; however, Minimatic/ABC's failure to have paid Krauser timely (to wit: on or before the date payment is specifically due in accordance with the terms of this Settlement Agreement without regard to any ten (10) day written notice period) three (3) or more times in any given twelve (12) month period shall

be deemed an event of default herein notwithstanding anything to the contrary; (2) The failure of Minimatic or ABC to comply with any of the provisions of this Settlement Agreement, and in the case of their failure to comply with a non-monetary provision of this Settlement Agreement, their failure to cure such non-compliance following ten (10) days after their receipt of written notification from Krauser specifying the non-compliance; (3) The conversion to, or a voluntary filing of, Chapter 7 proceedings in bankruptcy (at any time) by either Minimatic or ABC; (4) The failure of Minimatic or ABC (or a merger of the two, if applicable) to have filed a plan of reorganization with the Court by August 1, 1996. For purposes of this subparagraph, the filing of any plan must specifically include the incorporation of all of the terms and conditions of this Settlement Agreement or any modification thereof which has been approved by the parties hereto; (5) A judicial or other dissolution of either Minimatic or ABC other than the merger and/or consolidation of one of them into the other; (6) both Minimatic and ABC ceasing business operations at any time for more than fifteen (15) consecutive days (excluding destruction by fire or other act of God); and (7) The granting of any lien or other encumbrance from the date of this Settlement Agreement forward by Minimatic or ABC to any third party on any of the 510(k)s, the 510(k) files, drawings or related documents (as defined later in this Settlement Agreement) without the express, written consent of Krauser.

11. If Minimatic/ABC default under any of their payment obligations hereunder, all sums due to Krauser pursuant to ¶2

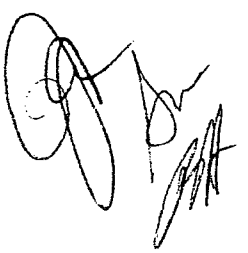
herein, less any amounts previously paid, shall become immediately due and payable without notice to Minimatic/ABC at the option of Krauser. For the purpose of determining the total amount due and owing pursuant to ¶2 herein, Krauser shall be entitled to utilize the $706,000.00 amount.

12. Immediately upon the order entered by the Court approving this Settlement Agreement becoming final, Krauser shall be deemed a co-owner of each and every premarket notification (510(k) submission) currently cleared for marketing by the Food and Drug Administration as submitted by and in the name of Minimatic/ABC and as are more specifically identified in the Amended List and Description of Proprietary Information attached hereto as Exhibit "B" and as codified into 510(k) #K952905 (hereinafter the "510(k)s"). Attached hereto as Exhibit "C" is a true and accurate copy of Minimatic/ABC's letter granting them marketing rights for 510(k) #K952905 from the Food and Drug Administration. Upon the Court's order approving this Settlement Agreement becoming final, Minimatic/ABC shall be deemed to have conveyed and transferred to Krauser a fifty percent (50%) equal co-ownership interest with Minimatic/ABC in the 510(k)s, with the full knowledge and consent of its board of directors. Following the Court's order approving this Settlement Agreement becoming final, Minimatic/ABC agree to execute any and all additional documentation, including, but not limited to, a notification letter to the Food and Drug Administration, in sufficient form as may be necessary and/or as may be required by the Food and Drug Administration, to

acknowledge, in an official manner, that Krauser is, in fact, the 50% equal co-owner with Minimatic/ABC of all of the 510(k)s, with rights in and to the 510(k)s equivalent to Minimatic/ABC. Notwithstanding Krauser's co-ownership of the 510(k)s, Krauser acknowledges and agrees that for so long as Minimatic/ABC are not in default under any of the terms and/or conditions of this Settlement Agreement, the 510(k)s shall be for the exclusive use of Minimatic/ABC and that Krauser will not utilize same for any purpose. Additionally, in exchange for Krauser's agreement that the 510(k)s shall be for the exclusive use of Minimatic/ABC, Minimatic/ABC agree to pay Krauser the sum of $750.00 annually, said sum being due on the first day following the Court's order approving this Settlement Agreement becoming final, and each year thereafter on that same date. Minimatic/ABC agree that they will comply with any and all requirements of the Federal Food, Drug and Cosmetic Act and implement all Food and Drug Administration requirements necessary to maintain the 510(k) clearances obtained from the Food and Drug Administration and to otherwise maintain the legal marketing status of the Products sold in connection therewith, e.g., obtaining premarket approvals (PMAs) in the future, if necessary. Additionally, Minimatic/ABC agree that for any 510(k) clearances they obtain for any product modifications to the Products (as defined in ¶6(a)(i)) requiring such clearances, Krauser will automatically be granted a 50% co-ownership interest in and to those product(s) modifications immediately upon their issuance to Minimatic/ABC. In the event either Minimatic or ABC

fails to comply with any of the terms and conditions of this Settlement Agreement or otherwise "defaults" as defined in this Settlement Agreement, Krauser's agreement that the 510(k)s are for the exclusive use of Minimatic/ABC shall immediately be of no further effect. Additionally, in the event of a default by Minimatic/ABC under this Settlement Agreement, Minimatic/ABC's 50% co-ownership interest in and to the 510(k)s shall automatically transfer to Krauser without execution of any further documentation and thereafter Krauser shall automatically be vested with 100% ownership rights in and to the 510(k)s free of any claims or defenses by Minimatic/ABC. At that time, Krauser shall be entitled to exercise any and all rights in and to the 510(k)s which would otherwise be available to him as the sole and complete owner of those 510(k)s as recognized by the Food and Drug Administration, including, but not limited to, his use of the customer lists and the 510(k) files, drawings and related documents (those terms being later defined herein) to be delivered to him by Ackerman, Bakst.

13. Minimatic/ABC covenant that they have title to the 510(k)s and have not assigned or conveyed any title or interest in or to the 510(k)s to any third party and further represent that there are no liens or encumbrances held against the 510(k)s except for those held by Austria International Fund, Ltd. (the "Liens") for which Minimatic/ABC agree to obtain releases or terminations thereof and to deliver evidence of the releases or terminations of the Liens to Krauser prior to or simultaneously with the execution of this Settlement Agreement. The releases or terminations of the



Liens must be in a form satisfactory to Krauser's attorneys and also must be recorded of record wherever prior liens encumbering the 510(k)s have been recorded. Thereafter, neither party shall, in the future, encumber the 510(k)s without the express, written consent of the other. Notwithstanding the foregoing, Krauser recognizes and acknowledges the lien asserted by the Internal Revenue Service against Minimatic which is of record as of the date of this Settlement Agreement; however, neither party hereto expresses an opinion as to whether such lien encumbers the 510(k)s, the 510(k) files, the drawings or related documents (as those terms are defined below).

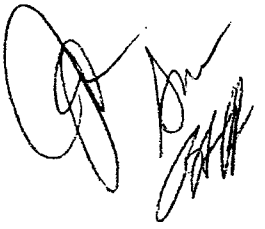
14. Minimatic/ABC hereby agree to hold harmless and indemnify Krauser and its respective officers and directors from and against any and all claims, liabilities, costs, expenses or damages whatsoever, including reasonable attorneys fees incurred by Krauser and/or its officers and directors at the trial and appellate levels, arising out of or in any way related to Krauser's co-ownership interest in the 510(k)s for so long as Minimatic/ABC exercise exclusive use of such ownership rights and such co-ownership is not being used by Krauser for any purpose as provided for in this Settlement Agreement, and further agree to hold harmless and indemnify Krauser and its respective officers and directors from and against any and all claims, liabilities, costs, expenses or damages whatsoever, including reasonable attorneys fees incurred by Krauser and/or its officers and directors at the trial

and appellate levels, arising out of or in any way related to Minimatic/ABC's use of the 510(k)s.

15. As security for Minimatic/ABC's performance of their covenants and obligations hereunder, immediately upon the order entered by the Court approving this Settlement Agreement becoming final, Minimatic/ABC shall deliver to their bankruptcy attorneys, the law firm of Ackerman, Bakst and Cloyd, P.A. ("Ackerman, Bakst"), a complete and accurate current domestic and international customer list containing the names, addresses and purchasing information of each and every customer of Minimatic/ABC. Minimatic/ABC shall update this customer list no less than quarterly each year by delivering to Ackerman, Bakst a new and updated customer list every three months. In order to ensure that Minimatic/ABC's customer list is being updated quarterly in accordance with this provision, a copy of the transmittal letter sent by Minimatic/ABC to Ackerman, Bakst enclosing the customer list shall be sent to Krauser at the address set forth in ¶2 above. In the event of a default (as defined in this Settlement Agreement) by Minimatic/ABC under this Settlement Agreement, Ackerman, Bakst shall immediately deliver to Krauser the entire customer list, as updated, without regard to any defenses for such default which may be raised by Minimatic/ABC.

16. In connection with Krauser's co-ownership of the 510(k)s as provided for in ¶12 of this Settlement Agreement, and as further security for Minimatic/ABC's performance of their covenants and obligations hereunder, immediately upon the Court's order approving

this Settlement Agreement becoming final, Minimatic/ABC agree to provide Ackerman, Bakst, at Minimatic/ABC's expense, complete and accurate copies of each and every document listed in the Amended List and Description of Proprietary Information attached hereto as Exhibit "B", as well as complete copies of all other documents not listed in Exhibit "B" but which are in Minimatic/ABC's possession which have been submitted to the Food and Drug Administration by Minimatic/ABC for its Food and Drug Administration 510(k) files. Minimatic/ABC will also immediately provide to Ackerman, Bakst, at Minimatic/ABC's expense, copies of all letters, memoranda and other records or documents from and to the Food and Drug Administration which relate in any way to the 510(k)s, including, but not limited to, all labeling and promotional information, product specifications, clinical or other test data and all other documentation in the Device Master Record, complete and accurate copies of all engineering drawings, and any updates or revisions to those drawings, for each and every finished device (and any component thereof) and accessory currently sold by Minimatic/ABC in their current catalog for which 510(k) clearance has been granted, to wit: the Products as defined in ¶6(a)(i). All of the foregoing items shall hereinafter be collectively referred to as the "510(k) files, drawings and related documents." Minimatic/ABC must provide Krauser with a copy of the transmittal letter sent by it to Ackerman, Bakst transmitting the 510(k) files, drawings and related documents as provided for herein immediately upon the Court's order approving this Settlement Agreement becoming final. As with the



customer list referenced in ¶15 above, in the event of a default by Minimatic/ABC under this Settlement Agreement, Ackerman, Bakst shall immediately deliver to Krauser the 510(k) files, drawings and related documents without regard to any defenses for such default which may be raised by Minimatic/ABC.

17. The board of directors of Minimatic/ABC does not contest Krauser's ownership of the Patent for ~~the~~ a cylindrical implant design which is sold and described in Minimatic/ABC's current catalog and recognizes same as valid, being subject only to the claimed defense of shop-rights and associated shop-right defenses under applicable law. The parties hereto acknowledge that Krauser maintains that no such shop-rights exist and that the Patent is free of all defenses whatsoever. Moreover, Minimatic/ABC hereby waive any and all other defenses they may have to Krauser's enforcement of the Patent, including, but not limited to, Krauser's alleged fraudulent procurement of the Patent. As a result, Minimatic/ABC hereby agree to pay Krauser the sum of $1.00 per year, said payment being due on the first day following the Court's entry of an order approving this Settlement Agreement becoming final, and annually thereafter, as a license fee for the conditional exclusive right to market his dental implant design which is the subject of the Patent. Notwithstanding the foregoing, following Court approval of this Settlement Agreement becoming final, and thereafter, in the event of a default by Minimatic/ABC under this Settlement Agreement, Krauser shall be entitled to revoke the license granted herein to Minimatic/ABC for their use of

his patented design. Upon revocation by Krauser of the license to use the Patent, Minimatic/ABC shall immediately cease and desist all activity which infringes the Patent. If Minimatic/ABC fails to do so, Krauser shall immediately be entitled to commence legal proceedings to enjoin any further production or use by Minimatic/ABC of any and all dental implant products which infringe the Patent, and agree at that time that all defenses to Krauser's enforcement of the Patent, including the defense of shop-rights, shall not be raised in any such proceeding and therefore deemed waived.

18. The board of directors of Minimatic/ABC does hereby recognize Krauser's significant individual contribution to the invention and creation of what is today known as the "Minimatic Implant System" in concept, design, design application, ease of installation and overall system requirements. The Board of Directors of Minimatic/ABC also hereby recognize that without Krauser's contribution, it is unlikely that the current product line would have ever been developed or would have ever reached the market place.

19. With regard to each and every one of the payments referenced in ¶¶2, 3, 5, 6 and 7 above, Krauser is hereby given the option, but not the obligation, to accept, in lieu of monetary payment, shares of stock in ABC for all amounts due him under this Settlement Agreement. In the event Krauser elects to receive payment in stock, Krauser shall notify Minimatic/ABC of its/his election to do so in writing at least ten (10) days before any

payment becomes due. Thereafter, ABC shall issue the appropriate number of shares or fractional number of shares of stock to Krauser and deliver such shares or fractional shares to Krauser on the date a monetary payment would otherwise be due. All shares delivered to Krauser pursuant to this paragraph shall be restricted Rule 144 stock. For purposes of this paragraph, the value attributed to the stock delivered to Krauser shall equal the average sale price for the stock for the three months immediately preceding the date Krauser exercises this option, less forty percent (40%). For purposes of calculating the three month average price, Minimatic/ABC shall total the average weekly highs and average weekly lows for the preceding twelve weeks and divide that amount by twelve. Notwithstanding the foregoing, Minimatic/ABC shall always have the option of declining Krauser's request to be paid with ABC stock in accordance with this ¶19 at anytime ABC's stock is trading below $1.00 per share.

20. Commencing upon the Court's order approving this Settlement Agreement becoming final, Krauser shall at all times be entitled to purchase all products then being manufactured by Minimatic/ABC at a discount of 60% of Minimatic/ABC's catalog price, so long as the purchase of such products are for Krauser's own use in his own dental practice and/or any other dental practice of a dentist treating Krauser's patients. For purposes of this paragraph, any partnership or corporation practicing implant dentistry in which Krauser owns any interest shall be entitled to the 60% discount provided for herein, as long as such partnership

or corporation applies the products for its own use. Further, any and all implant systems manufactured by Minimatic/ABC which Krauser uses in studies which are specifically conducted for Minimatic/ABC (which studies must have been pre-approved by Minimatic/ABC but which Krauser has no obligation to perform) will be sold to Krauser at no cost or expense to him/it. For purposes of this paragraph, any partnership or corporation practicing implant dentistry in which Krauser owns an interest will also be entitled to acquire Minimatic/ABC products at no cost so long as such entity is using those products in a pre-approved study being conducted for Minimatic/ABC.

21. In lieu of receiving any particular monetary payment due to Krauser under ¶¶2, 3, 5, 6 or 7 of this Settlement Agreement, Krauser shall have the option, but not the obligation, to accept any products manufactured by Minimatic/ABC. In the event Krauser agrees to accept any such products manufactured by Minimatic/ABC in lieu of a particular monetary payment due him under this Settlement Agreement, such products shall be valued at the catalog price, less 60%. Minimatic/ABC will not have the right to make payments due to Krauser under this Settlement Agreement by delivering products at a 60% discount unless Krauser requests, in writing, that a particular payment be satisfied by the delivery of such products hereunder at least ten (10) days before the due date of any such payment.

22. In further consideration of the execution of this Settlement Agreement, upon the Court's order approving this

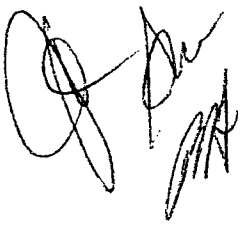
Settlement Agreement becoming final, Minimatic/ABC and each of its current officers and directors, hereby release Krauser from any and all claims, demands, judgments, etc., they may have against Krauser and waive their rights to demand as being due and owing from Krauser any sums whatsoever. In return, and at the same time, Krauser agrees to release Minimatic/ABC's current officers and directors (but not Minimatic/ABC) from any and all claims, demands, judgments, etc., it/he may have against them and waives its/his rights to demand as being due and owing from them any sums whatsoever.

23. Any and all accounts receivable which Minimatic/ABC has, in the past, claimed as being due and owing from Krauser to it/them for any sums whatsoever be and the same are hereby cancelled in light of the amounts of money which have been owed to Krauser since 1991.

24. Minimatic/ABC specifically acknowledge and recognize that Krauser is currently involved in litigation with Minimatic/ABC's former president and chief executive officer, Leon Shaw ("Shaw"). Minimatic/ABC understand and agree that Krauser is seeking monetary damages from Shaw for past commissions and expenses due to Krauser, as well as compensation for the 7.5 million shares of ABC stock which was authorized by its board of directors to be delivered to Krauser and which was actually issued in his name, but which was never delivered to him. The board of directors of Minimatic/ABC hereby specifically acknowledge that after careful consideration and a review of their internal records, the 7.5 million shares were

considered by Minimatic/ABC, per correspondence from Minimatic/ABC to Interwest Transfer Co., Inc., dated June 29, 1992, to have been paid for by Krauser and were to have been issued in his name. Notwithstanding this fact, these shares were never delivered to Krauser because Shaw, using his position as president and chief executive officer of Minimatic/ABC, unilaterally withheld the delivery of such shares of stock to Krauser in contradiction to the board's authorization that such shares be delivered to him. Minimatic/ABC acknowledge and represent that these 7.5 million shares of common stock were approved by their board of directors and were requested by them to be issued to Krauser in June, 1992, in accordance with the Interwest correspondence referenced above, but were never delivered to Krauser by Shaw, despite Minimatic/ABC's 10K for the fiscal year ending October 31, 1992, affirmatively stating that Krauser owned such shares.

25. McDermott has filed a Proof of Claim in the respective bankruptcies filed by Minimatic and ABC asserting an entitlement to an unspecified amount. As payment to McDermott for his claims (which are more particularly set forth in the federal court action), and without admitting any liability therefore, upon the Court's order approving this Settlement Agreement becoming final, McDermott shall be entitled to file an Amended Proof of Claim in the Minimatic/ABC bankruptcy proceedings in the collective sum of $20,000.00 as a general unsecured claim. Minimatic/ABC agree that any plan of reorganization submitted for approval by Minimatic/ABC will provide for payment to McDermott of no less than 20% of said



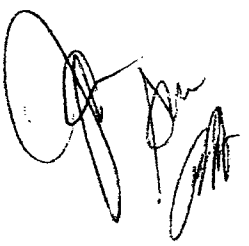
claim over a period not to exceed six (6) years without interest thereon. Minimatic/ABC further agree that said sum shall be liquidated and undisputed and that Minimatic/ABC shall not file any objections thereto. If the foregoing conditions are met, McDermott agrees to support any such plan of reorganization offered for approval by Minimatic/ABC. In the event this Settlement Agreement is not approved by the Court, McDermott shall not be limited to this sum as his total unsecured claim, but instead, shall be entitled to file an Amended Proof of Claim for any amount he deems appropriate subject always to any appropriate objections being raised by Minimatic/ABC other than as to the timeliness of the filing of the Amended Proof of Claim, so long as said Amended Proof of Claim is filed within fifteen (15) days of the Court's order denying the approval of this Settlement Agreement becoming final, or as allowed by law, whichever is later.

26. Minimatic/ABC agree that in the event Krauser is able to recover any monetary amounts whatsoever from Shaw in either the state court action or the federal court action, that Minimatic/ABC are not entitled to any credit against amounts due under this Settlement Agreement or otherwise based on any payments made by Shaw to Krauser, whether said payments be by settlement or by judgment and execution, and that the amounts agreed to be paid by Minimatic/ABC herein are separate and independent from any sums which Krauser may be seeking against Shaw or recover, by settlement or by judgment and execution, from Shaw.

27. The Board of Directors of Minimatic/ABC has reviewed this Settlement Agreement and has determined that in light of the trial in the state court action set to commence on May 28, 1996, and the Temporary Injunction Hearing set for July 15, 1996, it is in the best interest of Minimatic and ABC to enter into this Settlement Agreement. Any adverse ruling in either proceeding would possibly cause severe financial repercussions for Minimatic and ABC. Accordingly, Minimatic/ABC agree to use their best efforts to have this Settlement Agreement approved by the bankruptcy court administering its current Chapter 11 proceedings as expeditiously as possible after execution of same. Moreover, Minimatic/ABC and Krauser each agree not to take any action which in any way would impede the Court's approval of this Settlement Agreement. Minimatic/ABC also agree to include this Settlement Agreement in any plan of reorganization for both of them and Krauser agrees to support such a plan. In that regard, and as an inducement to Krauser, immediately upon the execution by Minimatic/ABC of this Settlement Agreement, said execution to include the signatures of a majority of the board of directors of Minimatic/ABC, Krauser agrees to drop as a party, without prejudice, ABC from the state court action. At that same time, ABC agrees to voluntarily dismiss, with prejudice, its counterclaim and third party claim currently pending against Krauser and McDermott, respectively, in the state court action; however, such a dismissal will not prejudice Minimatic/ABC's ability to maintain any of the defenses set forth in the eighth (8th) "WHEREAS" paragraph of this

Settlement Agreement in defense of any claim brought by Krauser against Minimatic/ABC in the future. Minimatic/ABC's voluntary dismissal, with prejudice, of its Third Party Complaint against McDermott shall not prejudice Minimatic/ABC from raising any defenses and/or counterclaims already set forth against McDermott in the federal court action. In connection with Krauser's dropping ABC as a party to the state court action and ABC's filing a notice of voluntary dismissal, with prejudice, of each of its claims in the state court action, each party hereto agrees to bear its own costs and attorneys fees and ABC hereby waives its right under Florida Rule of Civil Procedure 1.420(c) to stay any subsequent proceedings instituted by Krauser based on the claims now pending in the state court action conditioned upon Krauser's payment of costs incurred by ABC in the state court action and hereby waives its right to collect, recover, demand or receive any costs incident to it being dropped as a party to the state court action.

28. With regard to the federal court action, Minimatic/ABC will not be dropped from that matter, with or without prejudice, nor shall the Temporary Injunction Hearing be cancelled, unless the Court approves this Settlement Agreement. Immediately upon the Court's approval of this Settlement Agreement, Krauser and McDermott will drop Minimatic and ABC as parties to the federal court action, with prejudice. At that same time, Minimatic and ABC agree to voluntarily dismiss, with prejudice, their counterclaim pending in the federal court action. In connection with the voluntary dismissals referenced in this ¶28, each party agrees to



bear its own costs and attorneys' fees. Krauser reserves the right to continue prosecuting both the state court action and the federal court action (and McDermott reserves his right as to the federal court action, alone) against Shaw even after dropping, with or without prejudice, Minimatic and ABC from those respective proceedings.

29. In the event the Court denies the parties' joint request to approve this Settlement Agreement, the Temporary Injunction Hearing shall proceed against Minimatic/ABC, as scheduled, on July 15, 1996.

30. Minimatic/ABC specifically acknowledge and agree that in the event the Court denies the approval of this Settlement Agreement for any reason whatsoever, that each of the representations made by each of the parties in ¶13 (only with regard to the status of existing liens on the 510(k)s and not the release or termination of those liens); ¶17 (the first three sentences only); ¶18 (in its entirety); ¶24 (in its entirety); ¶26 (in its entirety); ¶27 (in its entirety); and ¶29 (in its entirety) of this Settlement Agreement may be used in any proceeding between these parties, including, but not limited to, the Temporary Injunction Hearing in the federal court action and any other proceeding before the Court on objections raised by Minimatic/ABC to Krauser and/or McDermott's claims made against the estates of Minimatic and ABC in their current Chapter 11 proceedings.

31. Each party to this Settlement Agreement agrees that in the event it becomes necessary for either or any of them to execute

further documentation, including, but not limited to, more formal agreements regarding licensing of the Patent, collateralization of Krauser's claim by virtue of the customer lists, 510(k) files, drawings and related documents (to wit: the execution by Ackerman, Bakst of an appropriate escrow agreement), UCC-3 and UCC-1 documentation regarding the 510(k)s, etc., each party agrees to execute, in good faith, any and all such documentation as may be required by the other. In the event Court approval is required for the execution by Minimatic/ABC of such additional documentation, Minimatic/ABC agree to present same to the Court and to utilize their best efforts to have the Court approve the form and substance of such documentation as expeditiously as possible once said documentation is requested by any party.

32. The waiver by Krauser of any default by Minimatic or ABC of any term, condition or covenant set forth in this Settlement Agreement shall not be deemed a waiver of any subsequent default of the same or any other term, condition or covenant set forth in this Settlement Agreement. No delay on Krauser's part to enforce any of his rights hereunder shall be deemed a waiver of any preceding default by Minimatic or ABC of any term, covenant or condition of this Settlement Agreement, or a waiver of Krauser's right to later declare Minimatic or ABC in default of this Settlement Agreement.

33. The parties to this Settlement Agreement agree and acknowledge that although the initial draft of this Settlement Agreement may have been prepared by the attorneys for Krauser, it is the result of extensive negotiations between all of the parties

hereto. Accordingly, each party agrees that neither is the "drafting party", and therefore, this Settlement Agreement shall not be construed against any party hereto.

34. Once this Settlement Agreement has been finally approved by the Court, then in the event of any litigation brought by any of the parties hereto to enforce any of the terms or conditions of this Settlement Agreement or to seek a declaration of his/its rights hereunder, the prevailing party to such litigation shall be entitled to recover its/his attorneys' fees and costs, including all fees and costs at the appellate level, incurred by it/him/them from the non-prevailing party. Venue for any such proceeding shall be in Palm Beach County, Florida and the laws of the state of Florida shall govern any such litigation. Each party to this Settlement Agreement also agrees to waive trial by jury in any litigation involving any aspect of this Settlement Agreement.

35. This Settlement Agreement shall be binding on all of the parties hereto, including each of their successors and assigns, specifically including any successor corporation to either Minimatic and/or ABC and Krauser.

36. This Settlement Agreement may be executed in two or more counterparts, including facsimile counterparts, none of which need contain the signatures of all the parties hereto, each of which shall constitute an original, and all of which, taken together, shall constitute one and the same agreement.

37. This Settlement Agreement is subject to the approval of the U.S. Bankruptcy Court having jurisdiction over Minimatic and

ABC's bankruptcies. Immediately upon the Court's approval of this Settlement Agreement becoming final, each of the parties hereto agree to comply with all of the terms and conditions set forth herein.

IN WITNESS WHEREOF, the parties hereto have set our hands and seals to this Settlement Agreement on the date first written above.

WITNESSES:

JACK T. KRAUSER, individually

IMPLANT CENTER OF THE PALM BEACHES, a Florida corporation

By: _____
JACK T. KRAUSER
As Its: President

SHAWN McDERMOTT

[SIGNATURES CONTINUED ON NEXT PAGE]

MINIMATIC IMPLANT TECHNOLOGY, INC., a Florida corporation, f/k/a MINIMATIC, INC.

By: _____
BRUCE HOLLANDER
As Its: President

AMERICAN BIODENTAL CORPORATION a Delaware corporation, f/k/a MINIMATIC IMPLANT TECHNOLOGY, INC.

By: _____
BRUCE HOLLANDER
As Its: President

BROAD AND CASSEL
Ronald M. Gache', Esquire
Attorneys for Krauser and McDermott

ACKERMAN, BAKST AND CLOYD, P.A.
Leslie Gern Cloyd, Esquire
Attorneys for Minimatic and ABC

[BOARD OF DIRECTORS' SIGNATURES ON NEXT PAGE]

Each of the undersigned hereby acknowledges that: (i) the undersigned constitute all members of the Board of Directors of American Biodental Corporation and Minimatic Implant Technology, Inc.; and (ii) the foregoing Settlement Agreement is unanimously approved by the Board of Directors of American Biodental Corporation and Minimatic Implant Technology, Inc.; and (iii) Bruce Hollander, President and CEO of American Biodental Corporation and Minimatic Implant Technology, Inc., is authorized and directed to execute and deliver this Settlement Agreement on behalf of Minimatic/ABC. Each of the undersigned further acknowledges that the foregoing shall constitute a written action taken as a member of the Board of Directors of American Biodental Corporation and Minimatic Implant Technology, Inc., pursuant to Section 607.0821 of the Florida Business Corporation Act.

WILLIAM SIMMONS

INGO KOZAK

BRUCE HOLLANDER

LEONARD MARTIN

Each of the undersigned hereby acknowledges that: (i) the undersigned constitute all members of the Board of Directors of American Biodental Corporation and Minimatic Implant Technology, Inc.; and (ii) the foregoing Settlement Agreement is unanimously approved by the Board of Directors of American Biodental Corporation and Minimatic Implant Technology, Inc.; and (iii) Bruce Hollander, President and CEO of American Biodental Corporation and Minimatic Implant Technology, Inc., is authorized and directed to execute and deliver this Settlement Agreement on behalf of Minimatic/ABC. Each of the undersigned further acknowledges that the foregoing shall constitute a written action taken as a member of the Board of Directors of American Biodental Corporation and Minimatic Implant Technology, Inc., pursuant to Section 607.0821 of the Florida Business Corporation Act.

WILLIAM SIMMONS

INGO KOZAK

BRUCE HOLLANDER

LEONARD MARTIN

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 96-30109-BKC-SHF
CHAPTER 11 PROCEEDING



In The Matter Of:

MINIMATIC IMPLANT TECHNOLOGY, INC.

Debtor.
_____/

JOINTLY ADMINISTERED

AMERICAN BIO-DENTAL CORPORATION,

CASE NO. 96-31318-BKC-SHF

Debtor.
_____/

SETTLEMENT AGREEMENT WITH KRAUSER ET AL

This Settlement Agreement is entered into this 16 day of October, 1996, by and between MINIMATIC IMPLANT TECHNOLOGY, INC., a Florida corporation f/k/a MINIMATIC, INC., ("Minimatic"); AMERICAN BIODENTAL CORPORATION, a Delaware corporation f/k/a MINIMATIC IMPLANT TECHNOLOGY, INC., today known as Biolok International, Inc. ("ABC") (Minimatic and ABC are sometimes collectively referred to as Debtors); JACK T. KRAUSER and IMPLANT CENTER OF THE PALM BEACHES, INC., a Florida corporation (collectively "Krauser"); and SHAWN MCDERMOTT ("McDermott").

WHEREAS, in or about July 1993, Krauser instituted suit against ABC in the Fifteenth Judicial Circuit, in and for Palm Beach County, Florida, said suit being more specifically known as: *JACK T. KRAUSER and IMPLANT CENTER OF THE PALM*

BEACHES, INC., a Florida corporation vs. LEON SHAW and MINIMATIC IMPLANT TECHNOLOGY, INC., n/k/a AMERICAN BIO-DENTAL CORPORATION, a Delaware Corp., doing business in the State of Florida, Case No. CL 93-5862 AJ (the "state Court action") seeking monetary damages against ABC, to which ABC filed several affirmative defenses; and

WHEREAS, in May 1994, Krauser obtained a patent from the United States Patent and Trademark Office on a dental implant (the "Patented device"), said patent being assigned U.S. Patent No. 5,316,476 (the "Patent"); and

WHEREAS, in or about October 1994, Krauser instituted suit in the U.S. District Court for the Southern District of Florida against Minimatic and ABC for patent infringement, and Krauser and McDermott, in that same action, asserted a claim against Minimatic and ABC for copyright violation, said suit being more specifically known as: *JACK T. KRAUSER, an individual and SHAWN MCDERMOTT, an individual vs. MINIMATIC IMPLANT TECHNOLOGY, INC., a Delaware corporation, MINIMATIC INC., a Florida corporation and LEON SHAW, an individual, Case No. CL 94-8521 CIV-HURLEY* (the "federal Court action"); and

WHEREAS, Krauser filed a voluntary dismissal in the state Court action against ABC without prejudice, which state Court action has not yet been refiled, but went forward to trial against co-defendant Leon Shaw ("Shaw"); and

WHEREAS, in the federal Court action, a hearing on Krauser's Motion For Preliminary Injunction for Patent Infringement against Minimatic and ABC (the "Preliminary Injunction Hearing") is currently set for December 13, 1996; and

WHEREAS, in the federal Court action, Shaw claims to be the inventor or co-inventor of the Patented device; and

WHEREAS, McDermott has filed claims in the Debtors' bankruptcy proceedings for prepetition damages in connection with his copyright claim and Krauser has filed claims in the Debtors' bankruptcy proceedings for prepetition damages in connection with his state and federal Court claims as well as a motion to determine administrative claim; and

WHEREAS, the Debtors have filed a Joint Amended Plan of Reorganization ("Plan"), which they anticipate amending ("Amended Plan"); and

WHEREAS, Minimatic, ABC, Krauser and McDermott are all desirous of amicably resolving the matters raised in the state Court action, the federal Court action and the claims in the Debtors' bankruptcy proceedings; and

WHEREAS, in an effort to resolve all pending claims, disputes and litigation between these parties, Krauser is willing to accept certain stock and future monetary payments as detailed herein from Minimatic/ABC for their future use of the Patent, for the liquidation of his general unsecured claim for asserted past due royalties, commissions and expenses owed to him by Minimatic/ABC, and for the liquidation of McDermott's asserted general

unsecured claim relating to his claim maintained in the federal Court action and Minimatic/ABC's current bankruptcy proceedings.

NOW THEREFORE, in light of the foregoing, and in consideration of the mutual promises and covenants set forth herein, as well as other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties to this Settlement Agreement hereby stipulate and agree as follows:

1. Krauser has filed proofs of claim and amendments thereto in the respective bankruptcies filed by Minimatic and ABC asserting unliquidated pre-petition damage claims as well as ownership rights in the dental implant system currently being manufactured by the Debtors. In order to resolve all prepetition claims of Krauser against the Debtors, as well as Krauser's claim for injunctive relief in the federal Court action, Krauser's existing claims shall be liquidated, undisputed and allowed as general unsecured claims against the Debtors' bankruptcy estates in the collective sum of $720,000.00. Upon Court approval of this Settlement Agreement, these general unsecured claims in the collective sum of $720,000.00 shall then be paid consistent with all other payments made to the general unsecured creditors in the Minimatic and ABC bankruptcy proceedings, however, the monetary distribution to Krauser of his collective general unsecured claims shall not be less than 25% of the amount of these claims paid over a period of six (6) years commencing at the time of the effective date of the Debtors' Amended Plan in equal consecutive monthly installments without interest. Confirmation of the Debtors' Amended Plan must occur on or before one year from

the date of this Settlement Agreement. Any variation of the terms of payment to Krauser as set forth herein of his general unsecured claims or the Debtors' failure to have their Amended Plan confirmed within one year from the date of this Settlement Agreement, shall automatically entitle Krauser, but not the Debtors, to void this Settlement Agreement.

2. As consideration for their performance under this Settlement Agreement, Krauser will conditionally grant to the Debtors an exclusive license by separate document, a copy of which is attached hereto as ***Exhibit "A"***, any and all rights he may have in the Patent and the dental implant system currently being manufactured by the Debtors. The license shall be for a term of no less than 10 years from the date of confirmation of Debtors' Amended Plan. At the end of the 10 year term, and assuming full compliance by the Debtors with the terms of this Settlement Agreement, the Patent and any claimed rights to the dental implant system shall be unconditionally assigned to the Debtors. In the event of a default by the Debtors in any of the terms of this Settlement Agreement, Krauser's conditional grant of an exclusive license will automatically terminate and he shall thereafter be entitled to enforce all of his rights available to him in connection with his ownership of the Patent, including, but not limited to seeking injunctive relief.

3. As payment to Krauser for the Debtors' continued sale of the dental implant products which comprise their dental implant system, which Krauser maintains he has rights in and to but which Krauser is willing to forego for so long as said payments are fully and timely made, the Debtors will pay to Krauser the following sums in the following manner:

a. During the first two years after confirmation of the Debtors' Amended Plan:

(i) 0% of the total net sales of the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquition, between zero and $1,750,000.00 of all dental implant products set forth and described in the Debtors' current product catalog, a copy of which is attached hereto as ***Exhibit "B"***, as well as any other dental implant products of any kind or nature whatsoever which are designed and/or used for dental implantology which are sold by the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquition, now or in the future, whether they be listed for sale or not in any current or future Minimatic, ABC, any subsidiary's thereof or any successor owner of the Debtors by merger or acquition, catalog. All such dental implant items defined above are hereinafter collectively referred to as the "Products". Notwithstanding the foregoing, Products shall specifically exclude non-dental implant purchase/resale items, i.e. products purchased from other manufacturers, suppliers and distributors which are not part of a dental implant system such as, but not limited to, motors, ratchets, and marking pens. This exclusion does not include any dental implant products that will in any way dilute or adversely affect sales by the Debtors of their current dental implant system which

includes dental implants, prosthetic, abutments, drills, tools or dental laboratory components or derivations or line extensions thereof, whether those items are purchased in a finished or semi-finished state and thereafter re-sold by the Debtors (as more specifically explained in the letter attached hereto as ***Exhibit "BB"***); and

(ii) 2% of the total net sales of the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquisition of the Products above $1,750,000.00;

b. During years 3 through 10, inclusive, following confirmation of Debtors' Amended Plan: 2% of all total net sales by the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquition, of the Products, irrespective of the net sales amount.

For purposes of this paragraph, the term "net sales" shall mean all gross sales from the Products less only returns, discounts (including discounts to customers, distributors and agents), credits given in lieu of returns and freight and handling charges, if applicable, and nothing else. Notwithstanding the foregoing, Krauser shall not be entitled to payment for all Products given by the Debtors to legitimate third parties for educational or promotional use, (so long as the Debtors are not receiving any remuneration or payment for services rendered for such Products and so long as such products are not being given for debt reduction) or on interest charged to customers of the Debtors on delinquent accounts. Further, the Debtors

shall make a semiannual adjustment to net sales to charge off delinquent accounts in determining annual net sales, so long as such charge offs are consistent with generally accepted accounting principles. In the event such charge offs are later paid by those customers, such charge offs will be reversed and included as net sales for purposes of payment to Krauser. The Debtors' obligation to pay Krauser in connection with their sale of the Products will not be diminished nor eliminated in any manner by the Debtors' merger into, or acquisition by, any other entity, and any such successor entity will remain liable to Krauser for all obligations set forth in this Settlement Agreement, unless otherwise agreed to by Krauser, whose agreement to same may be unreasonably withheld.

4. All of the foregoing payments identified in paragraph 3 above shall be paid to Krauser on the 15th day of each month in arrears commencing with the first month immediately after Minimatic/ABC's net sales reach the specified net sales level for years 1 and 2, and thereafter every month irrespective of the sales amount for years 3 thru 10, and shall continue to be paid on the 15th day of each month in arrears for the remainder of the twelve month period at the amount provided for in Paragraph 3. The first year's payments under this Settlement Agreement shall be based on sales of the Debtors' Products beginning November 1, 1996, which is the beginning of the Debtors' fiscal year, irrespective of when the Debtors' Amended Plan is confirmed. For example, in the event Debtors' Amended Plan is confirmed on January 1, 1997, and by that date, Debtors' sale of the Products (since November 1, 1996) have reached $1,000,000.00, then as soon as those sales reach

$1,750,000.00, Krauser's payments in accordance with Paragraph 3 above will commence. All subsequent years shall also be based on the November first fiscal year. In order to ensure that Krauser will be timely paid all amounts called for in paragraph 3 above, Minimatic/ABC shall furnish to Krauser, on a monthly basis, a complete and accurate sales report evidencing the total net sales of the Products for that preceding month, however, customers shall be identified by account number only and the Debtors shall not be required to provide customer's names and addresses, unless same becomes necessary to conduct the audit referenced in paragraph 5 below, or if the Debtors are ordered to produce same by a Court of competent jurisdiction. Said monthly net sales reports shall be delivered to Krauser each and every month, and upon Minimatic/ABC's net sales of the Products reaching any of the specified levels set forth in paragraph 3 above for years 1 and 2, and thereafter every month irrespective of the sales amount for years 3 through 10, said monthly net sales report shall be accompanied by the royalty payment due in connection therewith.

5. Minimatic/ABC will keep adequate records and books of accounts in accordance with generally accepted accounting principles evidencing all sales and deliveries of the Products and all income or other consideration received as a result of the sale or delivery of the Products. Following the giving of reasonable notice, Krauser and his accountants will be entitled to visit and inspect the business premises of Minimatic/ABC (or any other place where Minimatic/ABC's financial records may be kept in the ordinary course of business) and examine Minimatic/ABC's records and books of accounts as they relate to gross and/or

net sales of the Products at such reasonable times as Krauser and the Debtors shall agree not to exceed one time per each quarter in any given fiscal year. Krauser and his accountants shall maintain the confidentiality of all information pertaining to the Debtors' customers, products, techniques and operations observed during such examinations. Krauser shall bear the expense of conducting such audit. However, in the event Krauser's audit demonstrates a discrepancy between reported and actual net sales of 5% or more, Minimatic/ABC shall pay the whole cost of that particular audit.

6. ABC shall issue one million shares of it's common stock to Jack T. Krauser within thirty (30) days of confirmation of the Debtors' Amended Plan, in addition to any other stock Krauser may be entitled to in connection with his general unsecured claim, which stock shall be issued on the effective date of the Debtors' Amended Plan. All shares delivered to Jack T. Krauser pursuant to this paragraph shall be restricted Rule 144 stock.

7. "Events of default" as referenced herein shall include, but shall not be limited to, the following: (1) The failure of Minimatic or ABC to pay to Krauser, at the time said payments are due, or in the amount called for herein, any of the sums required by this Settlement Agreement to be paid to him, however, Minimatic/ABC shall be entitled to five (5) business days' written notice thereof by telecopier at (954) 698-9925 and/or regular mail to Minimatic/ABC's business premises to cure any such default; (2) The failure of Minimatic or ABC to comply with any of the provisions of this Settlement Agreement or the terms of the Debtors' Amended Plan as it pertains to Krauser, and in the case of their failure to

comply with a non-monetary provision of this Settlement Agreement, their failure to cure such non-compliance following ten (10) business days after their receipt of written notification by telecopier at (954) 698-9925 and or regular mail to Minimatic/ABC's business premises from Krauser specifying the non-compliance; (3) The conversion to, or a voluntary filing of, a Chapter 7 or Chapter 11 proceeding in bankruptcy by either Minimatic or ABC, or any parent corporation thereof, or successor to either of them by merger or acquisition, at any time while any monies are then owed or will be owed in the future to Krauser; or (4) A judicial or other dissolution of either Minimatic or ABC other than the merger and/or consolidation of one of them into the other.

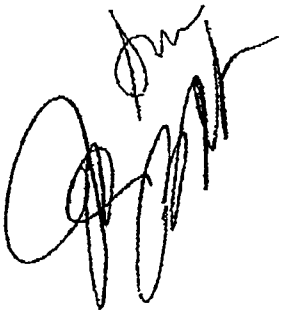
8. In the event of a default (as defined above) by either or both of the Debtors, Krauser's conditional license of his Patent shall terminate. In addition, Krauser shall have the option, but not the obligation, to institute suit against the Debtors for money damages and/or a declaration of his rights in and to the dental implant system currently being manufactured by the Debtors, as well as any and all 510(k) filings, related documents and drawings of the Debtors.

9. McDermott has filed a proof of claim in the respective bankruptcies filed by Minimatic and ABC for unliquidated pre-petition damages which are more particularly set forth in the federal Court action. Without admitting any liability therefore, upon the Court's order approving this Settlement Agreement becoming final, McDermott's existing claim shall be liquidated, undisputed and allowed against the Debtors' bankruptcy estates in the

collective sum of $20,000.00 as a general unsecured claim. Minimatic/ABC agree that any Amended Plan submitted for approval by Minimatic/ABC will provide for monetary payment to McDermott of no less than 25% of said claim over a period of not to exceed six (6) years without interest thereon. Minimatic /ABC further agree that said sum shall be liquidated and undisputed and that Minimatic/ABC shall not file any objections thereto. If the foregoing conditions are met, McDermott agrees to support any such Amended Plan. In the event this Settlement Agreement is not approved by the Court, or the Debtors' Amended Plan is not confirmed within one year of the date of this Settlement Agreement, McDermott shall not be limited to the foregoing sum as his total unsecured claim, nor shall he be required to perform any of the other acts called for herein.

10. The Debtors' existing Plan shall be amended to include the incorporation of all of the terms and conditions of this Settlement Agreement or any modification thereof which has been approved by the parties hereto, and Krauser and McDermott shall support that Amended Plan, including, but not limited to, filing a ballot accepting the terms of that Amended Plan.

11. The Debtors and Krauser are presently involved in litigation with Shaw both in the state Court case and the federal Court case. The intention of the parties to this Settlement Agreement is to also reach a full and complete settlement with Shaw. Krauser agrees not to object to the separate settlement agreement between the Debtors and Shaw, a copy of which is attached hereto as ***Exhibit "C"***.



12. Upon this Settlement Agreement being approved, the parties to this Settlement Agreement will exchange releases as to any and all claims or causes of action between them, subject only to the terms, obligations and reservations of rights imposed under this Settlement Agreement, in the forms attached as ***Exhibits "D", "E", "F" and "G"*** respectively. These releases will become effective immediately upon the Debtors' Amended Plan being confirmed.

13. Until such time as the Debtors' Amended Plan incorporating this Settlement Agreement is confirmed, the federal Court action between the Debtors, Krauser and McDermott (but not between Krauser, McDermott and Shaw) shall be stayed in all respects. Upon such time as the Debtors' Amended Plan incorporating this Settlement Agreement is confirmed, the Debtors, Krauser and McDermott, at that time, agree to dismiss their respective claims in the federal Court action, each party to bear their own costs and attorneys fees. Notwithstanding the foregoing, the stay of the federal Court action shall not be in effect longer than one year from the date that this Settlement Agreement is approved by the Court.

14. If this Settlement Agreement is approved by the Court, and the Debtors, for any reason, fail to incorporate the material terms of this Settlement Agreement into the Debtors' final Amended Plan, then Krauser shall have the right to seek, and the Debtors agree to pay, his attorney fees for his representation in the Debtors' Chapter 11 proceeding, to be paid by the Debtors in an amount not to exceed $25,000.00.

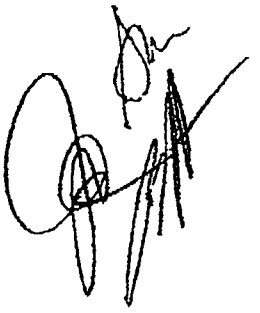
15. In the event Krauser retains the services of any attorney and is successful in enforcing any of the terms or conditions of this Settlement Agreement (whether suit be brought or not) he shall be entitled to recover his attorneys fees and costs through trial and appeal from the Debtors. In the event the Debtors are successful in defending Krauser's actions in enforcing any of the terms and conditions of this Settlement Agreement (whether suit be brought or not) they shall be entitled to recover their attorneys fees and costs through trial and appeal from Krauser.

16. This Settlement Agreement shall be binding on all of the parties hereto, including each of their successors and assigns, specifically including any successor corporation to either Minimatic and/or ABC, or any subsidiary thereof, and Krauser.

17. This Settlement Agreement may be executed in two or more counterparts, including facsimile counterparts, none of which need contain the signatures of all the parties hereto, each of which shall constitute an original, and all of which, taken together, shall constitute one and the same agreement.

18. This Settlement Agreement is subject to the approval of the U.S. Bankruptcy Court having jurisdiction over Minimatic and ABC's bankruptcies. Immediately upon the Court's approval of this Settlement Agreement becoming final, each of the parties hereto agrees to comply with all of the terms and conditions set forth herein.

IN WITNESS WHEREOF, the parties hereto have set our hands and seals to this Settlement Agreement on the date first written above.



WITNESSES:

JACK T. KRAUSER, INDIVIDUALLY

IMPLANT CENTER OF THE PALM BEACHES, a Florida Corporation

JACK T. KRAUSER, PRESIDENT

SHAW McDERMOTT

BROAD AND CASSEL, Ronald Gache, Esq., Attorneys for Krauser & McDermott

MINIMATIC IMPLANT TECHNOLOGY, INC., a Florida corporation, f/k/a MINIMATIC, INC.

BY: _____
BRUCE L. HOLLANDER, PRESIDENT

(SIGNATURES CONTINUED ON NEXT PAGE)

AMERICAN BIO-DENTAL CORPORATION., a Delaware corporation, f/k/a MINIMATIC IMPLANT TECHNOLOGY, INC., today known as BIOLOK INTERNATIONAL, INC.

BY: _____
BRUCE L. HOLLANDER, PRESIDENT

ACKERMAN, BAKST & CLOYD, P.A.
Leslie Gern Cloyd, Esq.
Attorneys for Minimatic and ABC



—Original Message—
From: Steve Boggan <SBoggan@biohorizons.com>
To: Jtkrauser@aol.com
Sent: Thu, Aug 6, 2009 10:53 pm
Subject: RE: Hi Steve: Whats up with the BioLok monies....?

Dear Jack,

We completed an extensive review of the amounts owed to you per your previous agreement with BioLok. We included all sales of BioLok implants including MicroLok and Silhouette. In addition, this agreement was selected for audit by Ernst and Young so the numbers should be exact. The analysis shows that we owe you $103,226.75 which will complete all obligations of BioLok and BioHorizons as indicated in the agreement. I assume that this will resolve all open matters that we have with you. Please let me know if you prefer a check or wire transfer for the amount owed.

Best regards,

Steve Boggan

—Original Message—
From: Jtkrauser@aol.com [mailto:Jtkrauser@aol.com]
Sent: Thu 8/6/2009 3:38 PM
To: Steve Boggan
Cc: Jtkrauser@aol.com; plaesq@yahoo.com
Subject: Hi Steve: Whats up with the BioLok monies....?



—Original Message—
From: Kendyl Lowe <klowe@biohorizons.com>
To: Steve Boggan <SBoggan@biohorizons.com>; Jtkrauser@aol.com
Sent: Tue, Sep 1, 2009 6:10 pm
Subject: RE: KRAUSER BIOLOK DATA

Dr. Krauser,

We have collected the publically-filed audited sales of BioLok International Inc. for the ten-year time period covered by the royalty agreement. I will have it all summarized and compiled to send to you tomorrow. I apologize for not getting back to you sooner. I just didn't want you to think we weren't working on your request for data.

Thanks,

Kendyl

Kendyl D. Lowe

Executive Vice President and CFO

BioHorizons, Inc.

klowe@biohorizons.com

Direct 205.986.1216

Law Offices
GONZALEZ & HENLEY, P.L.
Attorneys at Law

324 DATURA STREET, SUITE 200 * WEST PALM BEACH, FLORIDA, 33401

TELEPHONE (561) 820-8100
FAX (561) 655-5660

EDMUND GONZALEZ, P.A.
RANDALL W. HENLEY, P.A.
MICHAEL NUGENT, P.A.
GUILLERMO FARINAS, P.A.
JONATHAN FLOM*
*OF COUNSEL

8519 SOUTH U.S. HIGHWAY ONE
PORT ST. LUCIE, FLORIDA 34952

TELEPHONE (772) 343-9292
FAX (772) 343-9773

EMAIL: Edatlaw2000@aol.com

PLAINTIFF'S EXHIBIT "K" Composite

TRANSMITTED BY: Hand, with Service of Process.

DATE : 15.OCTOBER.2009.

TO : **MINIMATIC Implant Technology, Inc.,**
succeeded through merger into BioLok International Inc.,
itself owned or considered an affiliate of Biohorizons Implants Systems, Inc.
["Minimatic"]
C/o
MINIMATIC, now known as BIOHORIZONS Implant Systems Inc.
C/o REGISTERED AGENT:
NRAI SERVICES, INC.
2731 EXECUTIVE PARK DRIVE, SUITE 4
WESTON, FL 33331

FROM: Jonathan Flom

RE : MINIMATIC SETTLEMENT AGREEMENT by and between Dr. Jack T. Krauser, D.M.D and Minimatic.
: Declaration of Regaining Ownership Rights in Dental Implant System and License Termination.

Dear Minimatic:
This Letter is to advise that Dr. Krauser has retained this Office to represent his interests and rights in defaults under the Minimatic Settlement Agreement.

This Letter is additional notice - as you aware - that under the Minimatic Settlement Agreement, entered into by and between Minimatic and Dr. Krauser, there are defaults that remain uncured. As a result of those uncured defaults, Minimatic's rights automatically terminate and Dr. Krauser regains his ownership rights in and to the dental implant system. You are no longer authorized to use the dental implant system.

In addition, the conditional grant of license, also provided for under the Minimatic Settlement Agreement, is hereby terminated.

In the event you are interested in continuing use, sale and marketing of the dental implant system, we will be pleased to coordinate the discussion with you and Dr. Krauser on terms to be agreed under a new arrangement.

In the interim, as a result, you are further hereby notified:

[1] that Dr. Krauser regains his ownership rights to the dental implant system, without limitation, owned, developed, licensed or sold by Minimatic.

[2] that Minimatic is no longer authorized to use the dental implant system, also referred to as the BioHorizon Implant system;

[3] that Dr. Krauser is scheduling a forensic audit, as part of and provided under the Minimatic Settlement Agreement; and

[4] that the conditional grant of license as provided for under the Minimatic Settlement Agreement is terminated..

Please advise:

[a] with whom at Minimatic the full and proper transfer of ownership rights in the dental implant system back to Dr. Krauser by Minimatic will be coordinated and scheduled;

In advance of your reply with the name of the responsible or designated Minimatic coordinating person, and, your cooperation, we remain,

Sincerely,
GONZALEZ & HENLEY, P.L.

JONATHAN FLOM.
JF/fj.

Law Offices
GONZALEZ & HENLEY, P.L.
Attorneys at Law

324 DATURA STREET, SUITE 200 * WEST PALM BEACH, FLORIDA, 33401

TELEPHONE (561) 820-8100
FAX (561) 655-5660

EDMUND GONZALEZ, P.A.
RANDALL W. HENLEY, P.A.
MICHAEL NUGENT, P.A.
GUILLERMO FARINAS, P.A.
JONATHAN FLOM*
*OF COUNSEL

8519 SOUTH U.S. HIGHWAY ONE
PORT ST. LUCIE, FLORIDA 34952

TELEPHONE (772) 343-9292
FAX (772) 343-9773

EMAIL: Edatlaw2000@aol.com

TRANSMITTED BY: Hand, with Service of Process.

DATE : 15.OCTOBER.2009.

TO : **MINIMATIC Implant Technology, Inc.,**
succeeded through merger into BioLok International Inc.,
itself owned or considered an affiliate of Biohorizons Implants Systems, Inc.
["Minimatic"]
C/o
MINIMATIC, now known as BIOHORIZONS Implant Systems Inc.
C/o REGISTERED AGENT:
NRAI SERVICES, INC.
2731 EXECUTIVE PARK DRIVE, SUITE 4
WESTON, FL 33331

FROM: Jonathan Flom

RE : MINIMATIC SETTLEMENT AGREEMENT by and between Dr. Jack T. Krauser, D.M.D and Minimatic.
: Demand for Audit

Dear Minimatic:
This Letter is to advise that Dr. Krauser has retained this Office to represent his interests and rights in defaults under the Minimatic Settlement Agreement.

This Letter is additional notice - as you aware - that under the Minimatic Settlement Agreement, entered into by and between Minimatic and Dr. Krauser, there are defaults that remain uncured.

As a result, you are further hereby notified:

[1] that Dr. Krauser regains his ownership rights to the dental implant system sold by Minimatic.

[2] that Minimatic is no longer authorized to use the dental implant system, also referred to

as the BioHorizon Implant system; and,

[3] that Dr. Krauser is scheduling a forensic audit, as part of and provided under the Minimatic Settlement Agreement.

Please advise:

[a] with whom the Audit can be coordinated and scheduled;

In advance of your reply with the name of the responsible or designated Minimatic coordinating person, and, your cooperation, we remain,

Sincerely,
GONZALEZ & HENLEY, P.L.

JONATHAN FLOM.
JF/fj.



Law Offices

GONZALEZ & HENLEY, P.L.

Attorneys at Law

324 DATURA STREET, SUITE 200 * WEST PALM BEACH, FLORIDA, 33401

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FAX (772) 343-9773

EMAIL: Edatlaw2000@aol.com

TRANSMITTED BY: [i.a] Minimatic/Biolok/Biohorizon: USPC RRR#7009.1680.0000.2069.7935.
And [i.b] Fax to: 954.698.9925.
[i.c.] [Minimatic/Biolok/Biohorizon Corp.Reg.Agent, FL].
USPC.RRR# 7009.1680.0000.2069.7904.
AND, [i.d.] By Hand / Courier.

: [ii.a] USPC RRR#7009.1680.0000.2069.7911.[Biohorizon/Mintz].
[ii.b.] And Biohorizon, Ms. Lowe, EVP & CFO & Mr. Boggan, CEO.
USPC.RRR.#7009.1680.0000.2069.7928.[Biohorizon].
[ii.c] Fax To: 205.870.0304.
: [iii.a.] USPC RRR#7009.1680.0000.2069.7942.
[Healthpoint Capital Partners II, L.P.

DATE : M14.DECEMBER.2009.

TO : **MINIMATIC Implant Technology, Inc., succeeded through merger into BioLok International Inc., And Biohorizons Implants Systems, Inc. ["Minimatic"]** **: [i.d] By Courier.**
c/o 368 S. Military Trail
Deerfield Beach, FL 33442-3007
T: 954.698.9998. [i.a.]
F: 954.698.9925. [i.b.].
c/o Registered Agent: NRAI Services Inc.
2731 Executive Park Drive, suite 4
Weston, FL. 33331
[i.c.]

TO : **MINIMATIC Implant Technology, Inc., succeeded through merger into BioLok International Inc., And Biohorizons Implants Systems, Inc. ["Minimatic"]** **[ii.a.]**
ATTN : Seth Goldman, Esq., counsel.
Mintz Levin et al
Chrysler Center
666 Third Avenue
New York, NY 10017
T: 212.692.6845.
T: 212.935.3000.
F: 212.983.3115.

cont'd:

TO : **MINIMATIC Implant Technology, Inc., [ii.b.]**
succeeded through merger into BioLok International Inc.,
And Biohorizons Implants Systems, Inc. ["Minimatic"]
c/o : Biohorizons T: 205.986.1216 [Ms. Lowe]
2300 Riverchase Center O: 866.872.9785.
Birmingham, AL 35244. F: 205.870.0304. [ii.c].

C/o Healthpoint Capital Partners II, L.P. [iii.a].
505 Park Avenue, 12th Floor
New York, NY 1002.

FROM: Jonathan Flom
RE : MINIMATIC SETTLEMENT AGREEMENT by and between Dr. Jack T. Krauser, D.M.D and Minimatic.
: NOTICE Under Settlement Agreement

Dear Minimatic/Biolok/Biohorizons-Healthpoint:
As you may know, this Office serves as counsel for Dr. Jack T. Krauser who has instructed us to provide and serve this Notice, concerning events of default, as provided for under the language of the Settlement Agreement between you and Dr. Krauser, as dated16 October 1996 and effective in March 1997 for a period of no less than 10-years.

Events of default have occurred. Despite previous efforts to resolve those events, there has been no resolution, including as by and between the executive management of Minimatic/Biohorizons [including without limitation, Mr. Boggan and Ms. Lowe with Dr. Krauser].

As you also know, Events of Default remain uncured.

Without limitation:
[] Failure to complete or honor in full compliance of your obligations as set forth in the Settlement Agreement;

[] Failure to complete payments due on the collective sum of $720,000;
and,
[] as to products of any kind or nature for dental implantology sold,
Failure to make payments fully;
Failure to make payments timely, to wit by the 15th of each month;
Failure to provide reports,

all and each of which items or provisions including as based on 2% of all total net sales, shall be cured with the cure period provided herein below:

cont'd:

Cure Period:
You shall have Ten [10]- business days to correct and cure the Events of Default, and that is a date no later than Dec.31st.2009.

The Ten[10]-business days to cure covers each of :
i. Monetary provisions under the Settlement Agreement [5-business days], and,
ii. Non-monetary provisions, under the Settlement Agreement [10-business days];

You were obligated, by example and without limitation, to be in full compliance with the provisions or terms of the Settlement Agreement, for a period of no less than 10-years; among other things, and by example, payments and reports, even when inconsistent prior to October 2006, did not continue past October 2006 and into 2007, per the language of the Settlement Agreement. These events of default have been known to executive management fo your Company and remain uncured. As such, other rights of Dr. Krauser are triggered.

Dr. Krauser exercises and reserves all his respective rights and remedies under the Settlement Agreement.

In advance of your continued cooperation, we remain,

Sincerely,
GONZALEZ & HENLEY, P.L.

JONATHAN FLOM.
JF/ff.
Cc. Client.

BIOHORIZONS IMPLANTS SYSTEMS

Payment Number	Check Date	Check Number
0065627	12/18/2009	006611

DR. KRAUSER Dr. Jack Krauser

Voucher Number	Invoice Number	Invoice Date	Outstanding Amt	Net Paid Amt	Discount Taken	Write Off	Net Check Amt
23522	ROYALITY & INTEREST	12/18/2009	$71,780.83	$71,780.83	$.00	$.00	$71,780.83

PLAINTIFF'S EXHIBIT "M"

TOTALS:	$71,780.83	$71,780.83	$.00	$.00	$71,780.83

BIOHORIZONS

2300 Riverchase Ctr
Birmingham, AL 35244-2808
205-967-7880

Regions Bank
61-373-622

006611

Pay Seventy One Thousand Seven Hundred Eighty Dollars and 83 Cents

DATE Dec 18, 2009

AMOUNT $71,780.83

to the Order of:

Dr. Jack Krauser

1499 W. Palmetto Park Rd.
Suite 302
Boca Raton, FL 33486

Security features. Details on back.

⑈006611⑈ ⑆062203735⑆ 5990012070⑈

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TELEPHONE (772) 343-9292
FAX (772) 343-9773

EMAIL: Edatlaw2000@aol.com



TRANSMITTED BY: Fedex Track#8709.7239.5310.

DATE : 29.DECEMBER.2009.

TO : **MINIMATIC Implant Technology, Inc.,**
succeeded through merger into BioLok International Inc.,
itself owned or considered an affiliate of Healthpoint Capital and of Biohorizons Implants Systems, Inc. ["Minimatic"]
ATTN : MINIMATIC, now known as BIOHORIZONS Implant Systems Inc.
Mr. Seth Goldman, Esq. em: srgoldman @ mintz.com
Mintz Levin et al. T: 212.692.6845.
Chrysler Center F: 212.983.3115.
666 Third Avenue
New York, NY 10017
FROM: Jonathan Flom
RE : REPLY TO Biolok / Biohorizons Letter.

Dear Minimatic/Biohorizon and Seth:
Your Letter dated Dec.22nd delivered by Fedex around mid-day Dec.23rd was shared with our client.

Previous notices received by Biolok/Biohorizons identified non-monetary and monetary issues deemed defaults under the Settlement Agreement. Each category remains uncured. Dr. Krauser provided Biolok/Biohorizons ample opportunity to comply and comply in full.

As you know, your Biolok/Biohorizon client and its various interests have long known of the uncured defaults, among them, the failure to provide or fully satisfy its obligations under the Settlement Agreement.

Uncured default has existed during the period of the Settlement Agreement, including from the period of successor interest of Biolok and Biohorizons as now represented by Mr. Boggan and Mrs. Lowe ['Successor' or 'Obligor']. The incomplete satisfaction of the Settlement Agreement has been known and acknowledged by Successor, even by Mr. Boggan CEO and Mrs. Lowe CFO [See, Aug.2009 and Sept.2009 emails, copies again attached].

Various examples have existed, known to all parties. BY example, the obligations of Successor under the Settlement Agreement were recognized during the due diligence of Healthpoint and Biohorizons when assuming successor interests in October 2006; despite this event, there existed continued on-going efforts to seek resolution, including through Dr. Krauser's direct dealings with Mr. Boggan, use of counsel and a filing of a lawsuit. Obligor's own due diligence and information demonstrated that the initial period of " no less than 10-years" ran at a minimum up to March 2007, and Successor failed to comply. As has been discussed, upon reasonable belief and information, Successor, including through various operations or activities of Biohorizons, did not fulfill its reporting and payment obligations of monthly sales detail reports, calculations, nor payments during the period of October 2006 into current period.

In the totality of circumstances which apply in this Matter, there has existed and continues to exist sufficient knowledge by Successor/Obligor of the instances of default. Those uncured defaults, even when added to the more current notices, triggered rights to Dr. Krauser. He had the right to assert his interests and has asserted his rights.

The facts remain uncontroverted. By another example, the Settlement Agreement language clearly states a 2% royalty due calculated against as to the dental implant system being manufactured and sold by Successor/Obligor; the Settlement Agreement language plainly places the obligation of reporting, calculation, and payment squarely in the hands of the Successor / Obligor, and its various interests claiming use, sale and ownership of the dental implant system [again, Successor / Obligor]. The series of obligations as described in the Settlement Agreement rests with and is a burden of the Successor / Obligor; it is not for Obligor, when it fails to provide full detailed reporting, calculation or payment, to punt its burden and to force Dr. Krauser to determine specificity based on records that Obligor controls and has not provided. The Settlement Agreement provides an option for Dr. Krauser to assert his rights.

In a hypothetical example, if Obligor provided reports, reports with a calculation, and reports with a calculation and the required corresponding check, and if Dr. Krauser did not agree with a calculation provided by Obligor, he would have the opportunity [not the obligation] to challenge; in this Matter, facts exist that Successor / Obligor has failed to pay, failed to fully provide information or has failed to satisfy its simplest obligations.

Suggestion: Even if you believe that you have provided information before, and we contend it was not in full or timely, then simply provide: i. copies again of information previously

requested; copies of specific information requested through the prior lawsuit in the request to produce [itself its own notice] and to which we extended to you substantial professional courtesies, and despite the extensions, no information was delivered by obligor; and iii. Copies and information as noted below.

The uncured default of obligations triggered rights under the Settlement Agreement [also known to Obligor and plainly described by the Settlement Agreement]. Successor / Obligor was aware of Dr. Krauser's various challenges to Obligor's reporting practices, a fact noted on occasion by each of Mr. Boggan, CEO and, Mrs. Lowe, CFO. Obligor, when it did reply, was not in full, even when Dr Krauser was represented by counsel; such different and on-going uncured events provided on-going life to the Settlement Agreement; Dr. Krauser is within his rights to cancel the conditional license, and, separately, claim his ownership interests in the dental implant system being manufactured and sold.

Ownership interests lie in the dental implant system and products of any kind and nature of dental implantology sold or marketed by Obligor. Without limitation, the following are noted even though we identified these to you previously:
[ ] US FDA numbers:
K 073268
K 081818
K 071638
K 952905
K 911776
K 032454
K 041136

[ ] USPTO , including Biohorizon dental implant marketed products, with reference numbers such as, without limitation:
[] Pat.No.#6,149,432 Biolok buttress thread dental implant;
[] Pat.No.#6,454,569, Biolok dental implant;
[] Pat.No.#6,419,491, Biolok dental implant system;
[] Pat.No.#5,964,766, Biolok buttress thread implant;

[ ] And, as provided under the Settlement Agreement, all 510K's and related documentation to the interest and benefit of Dr. Krauser.
In the event your IP-department needs another example of a 510(k), we enclose a copy of 510(k) "K081818", as a sample of dental implant system rights and interests that Obligor must provide and deliver to Dr. Krauser [K081818, Nov.13.2008]. [4-pgs].

Obligor did not and has not provided details when previously requested. The previous events of uncured default were not waived by Dr. Krauser, and as has been described previously, Successor / Obligor provided assurances of resolution, which did not occur. Details were even requested by Dr. Krauser's counsel during the previous filing of lawsuit, demanding records or explanation. Those most recent requests from late October 2009 were not complied with over a period of 6-weeks; I am pleased to provide a short list, including of the longer request Obligor received in late October 2009:

[] detail sales reports for products of any kind or nature for dental implantology sold, the dental implant system manufactured and sold, without limitation, where distributed and sold, in the amount sold, for each month and period of January 2003 to current:

[] calculation of royalty due for each month of the period January 2003 to current;

[] history, calculations, detail report, and summary of the payment obligation under the $720K obligation;

[] copies of checks paid and processed for the $720K obligation, from January 2001 to current; our understanding is that no less than $108,000 was due and owing and not paid;

[] copies of checks paid and processed for the royalty obligation paid from January 2003 to current;

[] 510[k] for each product of the dental implant system, from 1997 to current;

[] copies of the dental implantology products sales list and marketing catalogue, from January 1, 2007;

[] copies of the distributor, license, and marketing lists, globally, starting from January 1, 2006 through to current, including Japan [Shofu], Pan-Asia, India, and Europe;

[] monthly product sales reports, with product codes, for Biohorizons, Biohorizon Implant Systems, the dental implant system performance as discussed or disclosed to Merrill Lynch [Y2007 and Y2008] which includes the Biolok dental implant system, Biolok, Biolok Europe, and Biolok International, and reports provided to Healthpoint of the same, for the periods January 1, 2003 through to current; even a modest calculation using Merrill Lynch reports and sales under the 2% royalty obligation would derive a sum owing of no less than $3 MM per year for Y2007, Y2008 and Y2009.

[] transmittal letters or memos evidencing the payment of checks to Dr. Krauser, with a sales report matched to the check, for each month Obligor claims it paid;

[] reports or other accounting entries detailing cancelled checks as processed pertaining to the royalties, and, to the $720K obligation;

[] due diligence reports from January 1, 2006 disclosing the settlement agreement; and,

[] Given the clear obligation language of the Settlement Agreement, Obligor including Biohorizon and Biolok, to demonstrate its full compliance from August 2006 through to current.

Obligor had and continues to have the burden of obligation to demonstrate its compliance. Failing that, the Settlement Agreement is expressly deemed for a period of "no less than 10-years" and Dr. Krauser is within his rights to assert all rights and remedies available to him under the Settlement Agreement.

Krauser – Biolok.Biohorizons/29.dec.2009/pg.5.of.5/ .

SUMMARY.
In summary, without limitation, as has been described in telephone conferences, emails, and, during the process of the earlier suit brought, our client's position remains:
Uncured default, as provided under the Settlement Agreement, triggers, among other things:
[] The conditional license could automatically transfer to Obligor ONLY where there had been full compliance; there was not and still is not full compliance, and this fact is uncontroverted. Therefore, Dr. Krauser has asserted the language of the Settlement Agreement which provides very clearly that the License is conditional and when there is not full compliance by Obligor, the conditional license can be terminated, and is terminated.
[] Similarly, when there is not full compliance, and there has not been full compliance, the Settlement Agreement triggers the return to Dr Krauser of and rights to the dental implant system being used, manufactured and sold; Dr. Krauser asserts that right and interest.

As a reminder, - and as you aware - under the Minimatic Settlement Agreement, entered into by and between Minimatic [and a burden of Successor / Obligor], and Dr. Krauser, there are defaults that remain uncured. As a result of those uncured defaults, Minimatic's rights automatically terminate and Dr. Krauser regains his ownership rights in and to the dental implant system. We re-assert that Minimatic has been and is no longer authorized to use the dental implant system; In addition, the conditional grant of license, also provided for under the Minimatic Settlement Agreement, remains terminated.

This informative reply should not be construed to nor inferred and does not change the time for cure provided under the Settlement Agreement, previous course of dealings, nor the time for cure as may be used under the most recent Notices that Dr. Krauser through his counsel sent, both under the previous lawsuit and the recent Notice dated December 14th 2009.

Dr. Krauser reserves all his rights and interests, and, remedies, including recourse through the courts.

Sincerely,
GONZALEZ & HENLEY, P.L.
JONATHAN FLOM.
JF/fj.
cc. Client.

ATT./
1. USPTO [cover page of sample of 4-patents of dental implant system][4-pgs];
2. Biohorizon emails to Dr. Krauser of Aug.6 2009 and Sept.1,2009 [2-pgs];
3. Sample FDA: FDA. 510(k), K081818. [4-pgs].