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#26358

TITLE
INFLATABLE DEVICE FOR USE IN SURGICAL PROTOCOL RELATING TO FIXATION OF BONE

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By: Karen Talmadge

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: application of

MARK A. REILEY ET AL.

Serial No.: 08/188, 224

Filed: January 26, 1994

FOR: INFLATABLE DEVICE FOR USE IN SURGICAL PROTOCOL RELATING TO FIXATION OF BONE

Examiner: Scott B. Markow

Art Unit: 3309

AMENDMENT IN RESPONSE TO FIRST OFFICE ACTION

San Francisco, California 94105

Dated: November 27, 1995

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

In response to the office action of June 26, 1995, please amend the above application as follows:

CLAIMS

Claims 68 and 69, line 2 in each case, erase "44" and insert -- 60 --.

Rewrite claim 1 as follows:

1. [amended] A balloon for use in treating a bone predisposed to fracture or to collapse, or that is fractured or collapsed, comprising:

[an inflatable, non-expandable] a hollow balloon body having flexible, non-elastic, imperforate wall structure, said balloon body being deflatable to permit removable [for] insertion of the body into said bone and being inflatable to cause said wall structure to form a cavity in [the] cancellous bone, said body [and] providing a configuration with a predetermined shape and size for the body when said body is [substantially fully] inflated, said wall structure being capable of exerting equal pressure in all directions when said body is inserted in the bone and when said body is inflated, the outer surface of said wall structure being operable to engage and compress at least a portion of the [inner] cancellous bone to [create] form said cavity in said cancellous bone as the wall structure provides said shape and size, said wall structure having restraint means to limit said configuration of said body to said predetermined shape and size so that the [fully inflated] balloon body is prevented from applying [excessive] harmful pressure to the [inner surface of the outer cortical] bone [if said bone is unfractured or uncollapsed], said balloon body having a passage to allow an inflating fluid to pass into and out of the body.

Rewrite claim 5 as follows:

3 ~~5~~. [amended] A balloon as set forth in Claim ~~1~~ 55, wherein said body includes a pair of stacked body parts having means for coupling the body parts together, the coupling means of said body parts defining a restraint to restrain the balloon body, said wall structure being operable to apply equal pressure in all directions in all of said parts.

Claim 10, line 3 before "within" insert -- free of damage --.

Rewrite claim 16 as follows:

14 ~~16~~. [amended] A balloon set forth as in claim ~~15~~ 13, wherein said body has a length, a widest medial lateral dimension, a distal anterior portion dimension, and a proximal end whose dimensions range from 0.5 x 0.5 to 1.8 x

A3 1.8 cm, the length ranges from 1.0 to 12.0 cm, a widest medial lateral dimension ranges from 1.0 to 2.5 cm and the distal anterior-posterior dimension ranges from 0.5 to 3.0 cm.

Rewrite claim 18 as follows:

16 ~~18~~. [amended]....A balloon set forth as in claim ~~17~~ 15, wherein said A4 body has an anterior-posterior dimension, a medial-lateral dimension, and a height ranging from 0.5-5.0 cm, the anterior-posterior dimension ranging from 1.0-6.0 cm, and the medial[and]-lateral dimension ranging from 1.0-6.0 cm.

Claim 20, line 1, erase "12" and insert -- 1 --.

Claim 21, line 1, erase "11" and insert -- 1 --.

Claim 22, line 1, erase "11" and insert -- 1 --.

Claim 23, line 3, before the "." insert -- inflexible, non-expandable form --.

A5 Claim 23, line 3, erase "Kevlar" and insert -- KEVLAR --.

Claim 29, line 2, before "is" insert -- body --.

Claim 32, line 2, erase "balloon" and insert -- pair of --.

Rewrite claim 34 as follows:

25 ~~34~~. [amended] A balloon as set forth in claim ~~1~~ 85, wherein the wall A6 structure has end walls, the balloon [has] having a number of restraints interconnecting the end walls to limit expansion.

Claim 41, line 2, before "is" insert -- of the body --.

Claim 48, line 4, erase "without" and insert -- while --.

Rewrite claim 49 as follows:

49. [amended] [A non-expandable] An inelastic balloon device A7 suitable for compressing cancellous bone comprising:

a hollow, flexible, inflatable, non-elastic, imperforate balloon body having a shape approximating a configuration taken from the group including a square, a rectangle, an oblong member and a cylinder, said body having a

shape, when substantially fully expanded, to form a pair of sides, said body having restraints [operable] having a shape and size to cause the sides to be substantially parallel with each other when inflated.

Rewrite claim 60 as follows:

60. [amended] An inflatable device for insertion into a cortical bone to be treated for cavity formation and for compacting the bone marrow and trabecular bone thereof comprising:

[a] an inflatable balloon body having flexible, [non-expandable,] inelastic, imperforate wall means [for conforming to] approximating the shape of the inner cortical surface of the bone to be treated, said wall means including a generally continuous side wall and a pair of opposed [ends] end walls integral with the side wall, said balloon having a fluid duct for directing an inflating liquid into the balloon, whereby the balloon can be inflated, said wall means being capable of exerting equal pressure in all directions when said body is inserted into the bone and when said body is inflated, said walls extending outwardly and into engagement with the inner surface of the bone to be treated and into a compacting relationship to the cancellous bone.

Claim 63, line 2, before "is" insert -- body -- .

Claim 76, erase "non-expandable" and insert -- inelastic, imperforate --.

Claim 77, line 3, erase "space" and insert -- cavity former --.

REMARKS

Claims 1-3, 5, 10 -19, 21-24, 29-32, 34, 41-43, 48, 49, 52, 57-63, 66, 68, 69 and 76-83 remain in this application for consideration. Of these claims, claims 3, 10-19, 21-23, 41-43, 48, 49, 52, 57, 59, 76 and 78-83 are generic. Generic claims 68 and 69 have been included with the claims to be considered

because these two claims now depend from claim 60, one of the claims to be considered.

CLAIM REJECTIONS - 35 USC §112

Claim 1 has been amended to recite the wall means which provides a predetermined size and shape for the body when the body is in the bone and is inflated. Thus, the claim now recites sufficient structure to support the recitation that the body has a predetermined shape and size. The claim further recites "...restraint means to limit inflation of the body to the predetermined shape and size...". Thus, claim 1 additionally recites sufficient structure to support the second quoted phrase in the second full paragraph of main paragraph 2 of the last Patent Office Action.

Claim 10 has been amended to state that the material of the body can be free of damage within the cortical bone withstanding fluid pressures of 50-400 psi. Because the body is inflatable, there is sufficient structure to support the function of "capable of withstanding fluid pressures of..." as recited in claim 10.

Claim 16 has been rewritten to provide antecedent bases for the various characteristics and dimensional factors of the claim. Thus, the quoted phrases in the last Office Action as to claim 16 now provide antecedent basis for the elements of the claim. The same reasoning is applied to claim 18, as it now has antecedent basis for the elements recited therein.

Claim 19 needs no change because the claim stands on its own merits. The same reasoning is applied to claim 21. Claims 19, 20, 21 and 22 all depend from claim 1 and are supported by the parent claim 1.

Claim 23 has been amended to state that the terms PET and KEVLAR are in flexible, inelastic form. Thus, claims 23 and 57 do not contain an

improper Markush grouping of claims of materials. It is specifically requested that the requirement to recite the generic terminology of PET and KEVLAR be withheld or deferred until a later time or until any allowance of claims herein.

Claim 29 now has antecedent for "balloon body." Claim 32 now recites antecedent basis for balloon parts. Claim 34 now recites the "end walls." There is sufficient structure in claim 42 to "compress cancellous bone into the shaft of a long bone."

Claim 48 now has sufficient structure to support the function of the guard member inasmuch as claim 1 recites the means for inflating the balloon body.

Claim 49 now has sufficient structure to support the function of the restraints because claim 1 recites restraint means.

Claim 63 and claim 77 now have proper antecedent basis for recitation of their claim elements, and claim 66 relates the sides to the opposed end walls of claim 60 because these elements are different from each other and do not need further elaboration.

CLAIM REJECTIONS - 35 USC §102(e)

Bonutti

The present invention is adapted to be used within a bone to compact or compress the inner cancellous bone to form a cavity for receiving supporting materials which can harden to a solid and relatively rigid condition. The bone being compressed is diseased, and the balloon is designed to compact the unhealthy bone and make a cavity where the bone used to be so that it can be replaced. This provides the required structure to prevent the outer, cortical bone from breaking. If already broken, the outer cortical bone can be moved back into place by the balloon where it can heal and be supported, preventing further fractures. The balloon devices and the directions for their use provided by the

present invention allow a surgeon to accomplish this efficiently, yet without moving the outer cortical bone beyond its normal dimensions, preventing harm.

Claim 1 now recites a balloon body which is deflatable to permit removal and insertion of the body into a bone and inflatable to form a cavity in the cancellous bone, the body having flexible, inelastic, imperforate wall structure providing a configuration with a predetermined shape and size for the body when the body is inflated. When inflated, the wall structure is capable of exerting equal pressure in all directions and thus provides an outer surface capable of engaging and compressing at least a portion of the cancellous bone to form a cavity in the cancellous bone when the wall structure provides said shape and size. The wall structure also has restraint means to limit the configuration of the body to the predetermined shape and size. Thus, harmful pressures cannot be exerted on the cortical bone so as to damage it when this is undesirable. Another element of the claim is the passage for directing an inflating fluid into and out of the balloon body.

Claim 5, which depends from claim 1, has been amended to additionally recite that the balloon body has wall structure capable of exerting equal pressure in all directions in all parts.

Independent claim 49 has been amended to recite a hollow, flexible, inelastic, imperforate balloon body which exerts equal pressure in all directions when inflated and in bone, making it capable of compressing cancellous bone, with restraints that have a shape and size to form a square, a rectangle, an oblong member and a cylinder with a pair of substantially parallel sides when inflated.

independent claim 60 has been amended to recite a device capable of insertion into bone for cavity formation and compacting bone comprising a flexible, inflatable, inelastic, imperforate balloon body with wall means

approximating the shape of the inner cortical bone where the wall means are a pair of opposed end walls integral with the side wall that are capable of exerting equal pressure on all of its outside walls when inserted into bone and inflated, and which extend outwardly during inflation to engage and compact the cancellous bone. Another element of the claim is a duct for directing fluid into the balloon body for inflation.

By virtue of these recitations, claims 1-3, 23, 24, 49, 57, and 59-63 are allowable over Bonutti under 35 USC §102(e).

Applicants respectfully submit that Bonutti does not teach or disclose balloon bodies for compressing cancellous bones. Specifically, Bonutti does not teach or disclose inelastic balloon bodies where pressure is exerted equally on all outside walls, restraint means to form parallel balloon body sides, inelastic balloon body walls that extend outwardly during inflation, or balloon body configurations with predetermined shapes and sizes.

Bonutti teaches a balloon retractor which selectively moves tissue out of the way of operating instruments, to enable a surgeon to see and work better at a surgical site within a body. The structure of Bonutti also moves body parts, such as whole bones, organs, joint parts or soft tissue planes, to create a space between them for visualization and for working.

The Examiner points to the Bonutti balloon body embodiments of Figs. 1, 2 and 6 as anticipating the present invention. Applicants respectfully disagree for the multiple reasons below.

The cited balloons are not inelastic. Indeed, Bonutti makes clear in Fig. 1 and in the specification that the balloon bodies of Fig. 1, 2 and 6, as well as related embodiments (which re called "bladders" in Bonutti), must stretch to achieve their shapes.

Describing Fig. 1, Bonutti recites in column 6, lines 65-66 and column 7, lines 1-2, "...The bladder is expandable under force of fluid pressure from an unexpanded condition as indicated in full lines at 14 to an expanded condition as shown in broken lines at 16." As can be seen in Fig. 1, the unexpanded bladder 14 (solid lines) is a small circle and the expanded bladder 16 is a "cigar" shape. Bonutti further recites in column 7, lines 2-8, "In the expanded condition, the transverse dimension 18 of the bladder 14 is significantly greater than its transverse dimension before expansion, the longitudinal dimension 20. Also, in the expanded condition, the transverse dimension 18 of the bladder 14 is significantly greater than its longitudinal dimension 20." Expanding from the circle bladder 14 into the cigar bladder 16 is a change in shape, and therefore requires stretching. This stretching must occur for the bladder to function, as stated in column 7, lines 9-10, referring to Fig. 1: "When the bladder of the retractor is expanded inside the body, it retracts tissue." With respect to Fig. 2, the specification recites, "...The bladder 22, when in its unexpanded condition is shown in broken line..." Like bladder 14 of Fig. 1, the unnumbered bladder with the broken line is much smaller and has a different shape than the expanded bladder 22 of Fig. 2. With respect to Fig. 6, the specification recites in column 8, lines 13-17, "...Fig. 6...shows a bladder 64 which in its expanded condition assumes a toroidal shape". Thus, the bladder in Fig. 6 is not a torus before its expansion.

The Bonutti specification recites expansion to allow the other balloon bodies to attain their effective shapes as well. Like Fig. 2, discussed above, Fig. 3 shows a small, curved dotted line inside the "cigar" which the specification describes as "...expandable bladder 46..." (column 7, line 32). Fig. 4 contains a variation where the small, circular dotted line is inside bladder 58, which the specification recites in column 8, line 57, "...expands into the

eccentric shape...". Figs. 5A-E contain, according to the specification, column 9, lines 1-4, "...retractor bladders which assuage in their expanded states in round, oval, eccentric, oblong and conical shapes." Fig. 8 illustrates retractor 10 with bladder 94 "...which can be expanded into a variety of shapes." All the other figures in Bonutti illustrate uses of the expanding retractors discussed above, except for Figs. 12, 12A, and Fig. 23, discussed later.

It is clear that there can be no non-expanding or inelastic capability for bladder 14 of Fig. 1, for the unnumbered, unexpanded bladder of Fig. 2, for bladder 64 of Fig. 6, or for the other bladders cited above, as is recited in claim 1 of the present invention. The Bonutti specification emphasizes the need for stretching to work. Expansion is not simply filling a balloon body configuration that has a predetermined shape and size with liquid or air to inflate it, but the stretching of material to change its shape. As cited above, this is stated for bladder 14, for the two unnumbered bladders in Figs. 2 and 3, which are drawn with different shapes after expansion, and for bladder 94, which we are told can become a variety of shapes. Stretching is implied for the others, as cited above.

The need for stretching by all the Bonutti balloon bodies of Figs. 1, 2 and 6, and related retractors, is underscored by the description of bladder 146 in Figs. 12 and 12A, where stretching is only optional, as cited in column 10, lines 5-10: "... The retractor 10 shown in Figs. 12 and 12A operates similarly [to the retractor in Figs. 11 and 11A] except that the bladder 146 is formed as a bellows-type device which expands in an accordion type manner. The material of which the bellows-type bladder 146 is made does not necessarily stretch although it may somewhat...". In column 4, lines 7-12, Bonutti makes it clear that non-elastic materials are recited for the bellows-type construction: "The bladder may be a bellows-type device...In this case, it would preferably be

made of a polymer of the class including Kevlar or Mylar for strength and structural integrity...".

According to the Bonutti specification, non-elastic materials, even though suggested as a possibility, are not actually workable for bladder 14 of Figs. 1 and 2 or for bladder 48 of Fig. 6, which Bonutti requires to expand and stretch to achieve their shapes, as cited above. Thus, all but one of the embodiment balloon bodies of Bonutti require elastic material, and require expansion and stretching to attain their shapes.

This is the opposite of the disclosure of the present invention, where the balloon bodies must be made of non-elastic material, as recited in claims 1, 49 and 60. The balloon bodies of the present invention have the same surface area and general configurations whether expanded or unexpanded. Therefore, none of the elastic balloon bodies of Bonutti, including all of the embodiments except Figs. 12, 12A and 23, fall within the scope of the present invention as recited in claims 1, 49 and 60 and their dependent claims, which require inelastic balloon bodies.

In the specification to the present invention, non-expandable is used to mean "non-stretchable," as when Applicants recite the preference for inelastic materials (page 10, lines 6-9). Except for the accordion-type balloon retractors, the Bonutti balloon bodies expand is used in the sense of stretching. However, the accordion-type balloon bodies only optionally stretch, and the word "expand" is probably used to describe its unfolding. Applicants have amended independent claims 1, 49, and 60 to ensure the meaning of their specification is clear: the requirement that the balloon bodies be constructed so that the wall structure cannot stretch.

As noted above, Bonutti discloses a bellows-type balloon body of Figs. 12, 12A and 23 which, as recited in column 10, lines 9-12, "...does not

necessarily stretch, although it may somewhat, but rather the expansion comes primarily when the various surfaces are repositioned relative to each other." The repositioning surfaces are the "...accordion-like ridges 148..." which may be "...made of differing degrees of resistance to straightening and flexing in order to vary the rate and/or sequence of inflation of various portions of the bladder 146. Alternatively, the material of which the bladder is made has areas of rigidity interleaved with areas of more elasticity, to provide the desired expansion effect..." (column 10, lines 12-19). The purpose of this construction for the bellows type bladder is recited in column 10, lines 22-25: "Such an accordion-like or bellows construction can provide greater stability in intermediate (partially expanded) positions..." As drawn in Figs. 12 and 12A, the accordion-like structure acts as a "...joint jack..." (see column 4, line 33), to push apart the knee bones and reveal the soft tissues for surgery. Fig. 23 shows a use for the bellows-type construction.

The Bonutti specification clearly states that materials with different degrees of rigidity and flexing, or differing degrees of rigidity and stretching, are required to provide the accordion-like structure during expansion. The design is described as a jack, as cited above. Such a construction maximizes upward thrust while minimizing sideways pressure (through increased rigidity at the sides), enhancing the height attainable. Sideways pressure would otherwise round out the sides and reduce upward thrust. Thus, the jack does not exert equal pressure in all directions when inflated, as now required in claims 1 and 60. Thus, this embodiment is outside the scope of these claims and the claims that depend from them.

The expanded bladder of Bonutti Fig. 2, and other similar bladders, while appearing to have parallel sides when drawn, are not described as such in the Bonutti specification. Besides the bellows type device, Bonutti names the

following shapes in column 5, lines 9-10: "...round, eccentric, oval, conical, wedge-shaped, U-shaped, curved, angled...". None of these have parallel sides. The appearance of parallel sides could simply be the result of drawing the longitudinal cross-section of a typical, sausage-shaped angioplasty balloon, well known in the art. This reading is supported by the apparent parallel sides of the balloon body 64 of Fig. 6, which is called a "torus" in the specification, a rounded shape.

However, assuming all expanded balloon bodies with parallel sides in the figures are intended as such, methods to create balloons with parallel sides are not taught or disclosed by Bonutti. Despite the assertions of Bonutti, a person skilled in the art knows that circular balloon bodies inflate to become a sphere. This is true whether the balloon body is made of expandable or inelastic material, even when it has continuous walls and even if manufactured by molding the balloon body into a shape with corners. This fact is demonstrated by the prior art reference, Campbell et al., U.S. Patent 5,183,989, which teaches a method to manufacture angioplasty balloons involving a prism-shaped injection mold. When such a prism-shaped balloon made of inelastic material is attached to a catheter at one end and inflated, the corners of the prism disappear, and the balloon becomes the typical, rounded angioplasty balloon body. (The advantage of such a balloon body is that less material is used, allowing insertion in the uninflated state through a smaller catheter than would otherwise be required.)

There is no support in Bonutti for parallel sides with any of the balloon bodies, including the bellows-type construction shown in Figs. 12 and 12A. While Bonutti recites strengthening materials to reinforce, prevent punctures and provide structural shape and support, no directions are provided for creating and maintaining parallel sides. Using strengthening materials as

described in the art involves coating the balloon body with mesh or fibers (see, for example, prior art reference, U.S. Patent 4,706,670, where continuous helical fibers cover balloon bodies to strengthen them). Such an application of strengthening material does not make a circle become a square or other shape with parallel sides. Bonutti suggests alternating materials with more and less rigidity to achieve the accordion-type folds of Figs. 12, 12A and 23, but providing for folds does not keep the two folded sides parallel when inflated. There are no directions in Bonutti for how to use inelastic materials to achieve parallel sides. Only the present invention teaches the restraints that would keep the balloons in shapes with parallel sides: tufts, inner strings and the other methods taught therein.

Thus, Bonutti is defective as a reference against claim 49, which requires parallel sides, and the present invention is allowable over Bonutti under 35 USC §102(e).

One key inventive insights of the present invention is that the supporting material replacing the disease cancellous bone should optimally comprise 70-90% of the cancellous bone in the area being treated (with a workable range of about 40-99%), although certain diseases, like avascular necrosis, affect only a small portion of the bone (see page 9, lines 17-22, of the present application). To provide that much supporting material means that there is a need to provide balloon body shapes which approximate the shape created by the inside of the cortical bone; other shapes and sizes either do not compress enough cancellous bone, or have aspects that are too large. The present invention identifies these shapes, provides novel balloon body designs to achieve them, and provides detailed directions on measurements of the patient's bone to determine the optimal size for the balloon body to be used at each treated site.

A balloon body used a particular site with the wrong shape, or with the right shape but in a size that is too small, will create a cavity which, when filled, will not adequately support the bone being treated. A balloon body used at a particular site that has the wrong shape, or with the right shape but in a size that is too large for the site, risks injury to the healthy, cortical bone, and to the patient.

Thus, the present invention provides balloon bodies that can only inflate to one size and one shape only. It provides detailed instructions to the surgeon for choosing the correct balloon body for each site and type of injury or disease at that site. This includes particular X-ray views, size measurements and guidelines for the amount of cancellous bone to be compacted. Once the surgeon has chosen a balloon body configuration based on the teachings of the present invention, its unique size and shape is manufactured into it and not under the control of the surgeon. The surgeon places the balloon body inside the bone to be treated and inflate the balloon body to its maximal dimensions, creating a cavity that can be filled to support the bone without risk of injury to the patient.

It is clear from the specification that Bonutti does not have, nor intend to provide, configurations of balloon bodies with predetermined sizes or shapes of balloons as defined within the scope of the present invention. As Bonutti recites in column 1, lines 66-69, "...The soft material of the fluid-filled portion, to an extent desired, conforms to the tissue confines...". Thus, the size and final shape of the stretchable balloon bodies of Figs. 1, 2, 6 and related bladders are dictated by the location of the retractor when the balloon body is expanded, the elasticity of the material used and by the needs of the surgeon. These balloon bodies conform to the surrounding tissue. That is to say, the shape

they assume is affected by the surrounding tissue. When deflated, they are meant to leave the tissue healthy or else damaged as little as possible.

Bellows-type retractors also do not have a predetermined size and shape; they are designed to be used and stable at "...intermediate (partially expanded) positions...".(column 10, line 24). Again, the structure into which bellow-type devices are inserted and the needs of the surgeon dictate the ultimate shape and size of the bellows-type device after inflation.

In sharp contrast, the balloon bodies of the present invention conform the surrounding tissue (cancellous bone) to them. After inflation of balloon body of the present invention, a cavity exists in the bone exactly in the shape of the balloon body being used. The cancellous bone is permanently changed because it is unhealthy and needs to be replaced. In this sense, the balloon bodies of the present invention "conform" to the inner cortical bone, as previously recited in claim 60, but only, as revealed by the specification, in their design, not in their operation. Claim 60 has been amended to change the words "...conform to the shape of the inner cortical bone..." to "...approximate the shape of the inner cortical bone...", to reflect more precisely the teachings of the present invention.

The fact that the size of the Bonutti balloon bodies are not inherent in their construction, unlike the balloon bodies of the present invention, is also shown by the need to monitor pressure. As Bonutti states in column 2, lines 28-31: "The pressure in the bladder is monitored and regulated to keep the force exerted by the retractor at a safe level for tissue to prevent tissue necrosis." This applies to all of the retractors, as Bonutti states in column 8, lines 26-27: "In all cases, the fluid pressure within the bladder of the retractor is monitored and controlled to keep the force...at a safe level...".

The present invention does not require pressure monitoring for safety, because the balloon is shaped and sized in advance. Using the directions of the present invention, the surgeon can chose a specific balloon body which is then safely, maximally inflated inside the bone being treated.

Thus, none of the Bonutti balloon bodies have configurations with a predetermined shape and size, as directly recited in independent claims 1 and 60 of the present invention, and suggested by the specified shapes in independent claim 49, and so the present invention is allowable over Bonutti under 35 USC 102(e).

In summary, Bonutti teaches away from the necessity of predetermining the shape and size of balloon body, and fails to teach or disclose any workable restraint means for doing this. Bonutti makes it clear that the bladder of Figs. 1, 2 and 6 and related bladders must stretch, and cannot be inelastic, to attain the shapes as drawn. The bladders of Figs. 12, 12A and 23 do not exert equal pressure in all directions when inflated. None of the balloon bodies have configurations with a predetermined shape and size, as defined in the specification of the present invention. Bonutti also does not teach or disclose the need for parallel sides, nor teach or disclose workable means to achieve them.

Claim 1 is allowable, therefore, under 35 USC §102(e) over Bonutti. Claims 2, 3, 23, 24, 57, and 59 depend from claim 1 and are allowable over Bonutti for the same reasons as claim 1.

With respect to claims 2 and 3, the Examiner states that the balloon body 14 of Fig. 1 of Bonutti has restraint means defined by its outer walls. This is not supported, because this balloon body must expand to achieve its shapes, as taught by Fig. 1 and the specification of Bonutti as cited above. It is therefore not inelastic, as required by claim 1. Accordingly, claims 2 and 3 are allowable

under 35 USC §102(e) over Bonutti. The other dependent claims contain structural features in combination with parent claim 1 to render these additional claims allowable over Bonutti under 35 USC §102(e).

With respect to independent claim 49, the Examiner states that the expanded balloon body of Fig. 2 of Bonutti has a shape to form parallel sides with restraints provided by the continuous wall means. The existence of parallel sides is not supported by the specification, which calls only for balloon body shapes that are rounded. As described above, continuous wall means are inadequate to create the parallel sides suggested by the balloon bodies in Fig. 2 in Bonutti, and Bonutti fails to teach or suggest restraints capable of keeping the balloon body in the shapes shown in Fig. 2. The balloon body also falls outside the scope of claim 49 because it must expand to achieve its shapes, as taught by Fig. 1 and the specification of Bonutti as cited above, and is therefore not inelastic, as required by claim 49.

Accordingly, claim 49 is allowable over Bonutti under 35 USC §102(e). The other claims 52 and 57-59 depend from claim 49 and contain structural features in combination with parent claim 49 to render these additional claims allowable over Bonutti under 35 USC §102(e).

With respect to independent claim 60, the claim recites a balloon body having a flexible, inelastic wall means, with a configuration in a predetermined shape and size which exerts equal pressure in all directions when inflated and has wall structure approximating the shape of the inner cortical bone. Thus, the claim recites structure not shown or taught by Bonutti because Bonutti fails to teach or disclose an inelastic capable of approximating the shape of inner cortical bone that is also capable of exerting equal pressure in all directions when the balloon body is inserted into bone and inflated, as recited in claim 60.

Claims 61-63, 66, 68 and 69 depend on allowable claim 60 and are allowable for the same reasons as claim 60.

Moll et al.

Independent claims 1, 49 and 60 have now been amended to recite imperforate wall structure or means. Independent claims 1 and 60 have now been amended to recite wall structure or means that allow equal pressure to be exerted in all directions. Claim 5 has been additionally amended to recite wall structure that is operable to allow equal pressure to be exerted in all directions in all of its parts. Thus, these claims are now allowable under 35 USC §102(e) over Moll et al., explained below.

The Moll disclosure relates to a balloon retractor, the same type of instrument as in the Bonutti reference. Moll provides balloon retractors that aid working and visualization beyond those of Bonutti and others by providing the means for the surgeon to work around or through the retractor. In fulfilling this goal, none of the balloons of Moll are suitable for compressing cancellous bone, and their design teaches away from the concept of compressing bone with a balloon body as set forth in the present invention.

The Examiner relies upon Moll to point to the inelastic balloon body 1 of Fig. 1, the stacked body parts 45, 47 and 49 of Fig. 5, and the restraints 113 of Fig. 8b in Moll et al. as anticipating aspects of the present invention. Applicants respectfully disagrees with each of these, discussed below.

The balloon body 1 of Moll (which has a bladder they call an "envelope" enclosing a space they call a "chamber") forms the retractor of Fig. 1, and consists of an inflatable main envelope 3 enclosing main chamber 5 with a second inflatable envelope 11 enclosing a non-pressurized chamber 13. Envelope 3 and envelope 11 are contiguous, although envelope 11 turns up into chamber 5 to form non-pressurized chamber 13. The hole created by

turning envelope 11 inward is called face 4 and it is optionally covered by material.

Chamber 5 inflates and retracts tissue away from the site during an entire surgical procedure (see column 2, lines 44-46 and column 8, lines 17-23). Non-pressurized chamber 13 is positioned so that its face 4 surrounds the working area where the surgery needs to be performed. If material covers face 4, it is cut away before the start of surgery, so that the surgeon can insert a fiber optic assisted instrument through port 35 in envelope 11 to reach the surgical site. Non-pressurized chamber 13 may be briefly inflated during balloon inflation if it does not open at that time, but it must be non-pressurized during surgery to be effective in providing a working area for the surgeon. Non-pressurized chamber 13 is kept open by inflatable chamber 25. (See fig. 1 and column 8, lines 24-42.)

The fact that chamber 13 is non-pressurized prevents all the outer walls from being continuously under equal pressure; those of envelope 11 are under ambient pressure while main chamber 5 is inflated, putting envelope 3 under increased pressure compared to envelope 11. Thus, balloon body 1 of Moll does not have equal pressure applied to all outer walls, and now falls outside the scope of claims 1 and 60. This difference renders balloon body 1 of Moll unable to compress bone; it will not have the structural strength to do this. Pushing aside tissues and organs, which a retractor performs, does not require the strength that compressing cancellous bone does. Inelastic material is not sufficient to confer the ability to compress bone when one part of the outer wall is not pressurized.

In addition, balloon body 1 of Moll fig. 1 does not have a predetermined shape and size within the meaning of the present invention. There is no unique size and shape for each retractor. While general size ranges are given for

different retractor balloon bodies, the actual level of inflation (and therefore size) for any retractor is determined by the surgeon using it, not by the balloon itself. The surgeon will inflate the balloon body until it has moved unnecessary tissue out of the way.

Fig. 5 of Moll shows a modification of balloon body 1 where spherical balloons 45, 47 and 49 are stacked to replace the flat, inward-facing envelope 11 of fig. 1, now called envelope 51 (column 12, lines 7-14). This creates the equivalent of non-pressurized chamber 13, here called chamber 41 (column 11, lines 59-61). Balloons 45, 47 and 49 can be pressurized, either at the same time or optionally one at a time (column 11, lines 30-33), to raise or lower the height of envelope 51 comprising the side walls of the inward-facing chamber. This provides control over the height of non-pressurized working chamber 41, which is "...substantially cylindrical...".(column 11, line 60). Thus, these stacked balloons are circular and the top is covered by wall 65, which is the top of the non-pressurized chamber.

Since, as cited above, working chamber 41 of Moll Fig. 5 is cylindrical, the two stacks of balloon bodies 45, 47 and 49 do not form parallel sides. Instead, they form the rounded portion of the cylinder; they are circular and continuous. The appearance in Fig. 5 of parallel sides arises from drawing a cross-sectional view, as described in column 5, line 38 of the Moll specification. Thus, Fig. 5 does not have a pair of sides, as required in claim 49 of the present invention and its dependent claims.

As in Fig. 1 of Moll, the presence of the non-pressurized chamber in Fig. 5 prevents the balloon retractor from being able to compress bone. This is because Fig. 5's wall 65 is not pressurized and therefore its wall structure does not exert equal pressure in all directions, as required in claims 1 and 60 of the present invention.

In addition, the stacked balloons of Moll Fig. 5 do not have restraint means to hold the stacked balloons together, as recited in claim 5. Rather, they are kept apart or separated by wall 65 at the top, and by a hole at the bottom. They also do not exert equal pressure in all directions in all parts, as recited in claim 5. Again, this is because they are attached to wall 65 at the top and to nothing at the bottom of the stack, and the chamber they enclose is not pressurized.

An analogy can be made between the non-pressurized chamber 41 made with a wall of stacked balloons, 45, 47 and 49, and a child's wading pool with balloon tubes that form the sides. If the balloon sides (envelope 51 comprised of balloons 45, 47 and 49) are inflated and the pool is placed upside down, the bottom of the pool becomes the top (which is wall 65 in non-pressurized chamber 41). The pool "top" (by analogy, wall 65) can bear the weight of the air (by analogy, the soft tissues), but the side walls made of a single stack of balloons (the envelope 51 comprised of balloons 45, 47 and 49) will buckle if someone stands on the "top", applying too great a force (by analogy, the hard tissues of bone). The stacks can withstand this force only if they can exert equal forces in all directions, and in all parts. The balloon body of Fig. 5, and its stacked balloons of envelope 51, do not do this.

As recited in claim 1, 49 and 60 of the present invention, and revealed by the drawings and descriptions of the balloon bodies of the present invention, equal pressure must be applied to all outer walls for an inelastic balloon body to be capable of exerting sufficient outward force to compress cancellous bone. When the balloon bodies are stacked, the wall structure must also allow equal pressure to be exerted in all directions in all parts, as recited in claim 5 of the present invention. Wall 65 is not pressurized, so the balloon body of Fig. 5 in Moll does not exert equal pressure in all directions. Moreover, the stacked

balloons 45, 47 and 49 are not held together, as required in claim 5; they are kept apart by wall 65. For these reasons, Fig. 5 of Moll does not fall within the scope of independent claims 1, 49 and 60, and their dependent claims.

Fig. 8b of Moll describes a two part device, an inner inflatable retractor 105 and an outer maintainer 107A, both of which are collapsed when inserted into the body. As described in column 16, lines 64-69, an inner "...main inflatable chamber 105..." is enclosed by a "...main inflatable envelope 109, which is preferably a balloon of suitable elastomeric material, such as latex, rubber or silicone." In other words, envelope 109 is expandable.

The maintainer 107A is a "...geodesic structure formed from a plurality of interconnected inflatable plastic tubes 113...formed from a substantially inelastic plastic..." (column 17, lines 14-17). The main inflatable chamber 105 is used to unfold the maintainer 107A, which is then locked into placed by being inflated (column 18, lines 8-15). Finally, the main inflatable chamber is gradually deflated, leaving the cage-like maintainer in place, maintaining the tissue in a retracted state while providing improved access to the surgical site (column 18, lines 25-47).

As can be discerned from the preceding description, the plastic tubes 113 of maintainer 107A are not a restraining device for main inflatable balloon 105. Instead, once the main inflatable balloon has retracted the tissue or organs required, the maintainer is inflated into place to act as the retractor, allowing the surgeon to remove the main inflatable chamber and work through the cage, solving the problem of the large balloon retractors getting in the way of the surgical site. (See column 3, lines 61-69.)

The maintainer 107 of Fig. 8b falls outside the scope of independent claims 1, 49 and 60 because its walls are not imperforate, as required in independent claims 1, 49 and 60 as amended. Without imperforate walls,

maintainer 107 is not strong enough to compress bone. In fact, maintainer 107 is not even strong enough to retract soft tissue, which is why main inflatable chamber 103 is required.

The main inflatable chamber 103 of fig. 8b is not inelastic, as it is made of elastomeric materials, and so also falls outside the scope of claims 1, 49 and 60, which require inelastic balloon bodies.

Thus, Moll is defective as a reference against claim 1, 49 and 60, and the claims must be recognized as allowable under 35 USC §102(e) over Moll. Claims 5, 29-32, 34, 49, 58, 66, 68 and 69 are allowable under 35 USC §102(e) over Moll for the same reasons as claim 1, 49 and 60.

With respect to claim 1, 49 and 60, because one of the chambers is not pressurized in Figs. 1 and 5, the balloon bodies of these figures do not have a wall structure capable of exerting equal pressure in all directions when inflated, as recited in claims 1, 49 and 60. The main inflator of Fig. 8B is elastic, and is therefore not inelastic, as recited in claims 1, 49 and 60. The maintainer of fig. 8B is not imperforate, as recited in claims 1, 49 and 60. Thus, these claims are allowable under 35 USC §102(e) over Moll. Claims that depend on these are allowable for the same reasons.

In addition, with respect to claim 5, Fig. 5 does not have means to couple the stacked body parts together. Every part must be touching another part, as shown in the Figs. 1, 2, 3, 10 and 13 of the present invention. The two stacks of balloons do not touch each other, but are separated by a flat sheet of plastic.

CLAIM REJECTIONS - 35 USC §103

The Examiner suggests that the present invention is obvious when combining the teachings of Scholten and Bonutti. Applicants respectfully disagree.

Scholten teaches the method for compacting cancellous bone to create a cavity, but fails to teach or disclose non-elastic balloon bodies. While suggesting a checker-shaped and gourd-shaped balloon, no restraint means for achieving these shapes are taught or disclosed. In addition, while suggesting shapes and sizes for these balloon bodies, there is no recognition of the provide a configuration with a predetermined shape and size. This is shown in Scholten column 7, lines 20-23: "The balloon's inflation should be monitored on the lateral fluoroscopic view of the spine. Posterior displacement of the bone into the spinal canal or full inflation of the balloon 76 signals the termination of chamber preparation." Posterior displacement of bone into the spinal canal means the bone is being pushed beyond its normal size and shape. This is exactly one of the problems that the teachings of the present invention prevent.

Combining Scholten with Bonutti fails to overcome these defects. Bonutti does not teach inelastic balloons that exert pressure in all directions and does not teach or disclose configurations with predetermined shapes and sizes, as discussed above and further below. Bonutti also does not teach using balloons in bone.

Bonutti does not teach using a balloon inside bone, and in fact, teaches away from this. The devices are retractors and are designed to preserve tissue structure. They operate at low pressure ranges to prevent tissue damage. For example, the highest pressures in Bonutti, recited in column 2, lines 31-33 and 45-48, are 10-50 mm Hg, which is about 2-5 psi. The balloon retractors of Moll use even lower pressures, about 0.2-0.4 psi (Moll column 8, lines 67-68). The pressure range that the balloons of the present invention can withstand are as high as 250-400 psi (page 10, lines 13-15). These pressures are necessary to create a cavity inside bone, and the balloon bodies of Bonutti cannot withstand

them. For example, the Bonutti specification provides "stronger materials" like Kevlar (Bonutti column 2, line 41) to "...withstand the pressure of about several; pounds..." (column 2, line 46). The balloon bodies of the present invention have a construction and materials to withstand pressures about one hundred times as high.

A person skilled in the art of retractors would not think to use a retractor to retract cancellous bone; cancellous bone is never retracted, because it is never in the way of anything else. It is clear in every embodiment involving bone that Bonutti is not proposing balloons to deform and compact cancellous bone for therapeutic purposes, but is instead describing balloons that preserve bones intact by pushing on them from the outside to get them out of the way.

In column 1, lines 29-33, Bonutti notes, "While operating from within the body, i.e., fiber optic assisted surgery as opposed to open surgery, there is no known way to selectively move or retract tissue, either hard tissue such as bone or soft tissue, out of the way to improve visualization...". In other words, the bone is not the site of operation; it is between the surgeon and the site of operation, and it needs to be pushed aside while minimizing damage. In column 3, lines 51-55, the specification states, "An alternative preferred use for the retractor...is to operate in a joint of the spine, and specifically between two vertebrae. The retractor is used to spread the two vertebrae apart to enable removal of the spinal disc from between the vertebrae." This clearly describes bone being kept intact, but moved aside to facilitate removal of soft tissue nearby. Figs. 9-12 show the position of the balloon body in various joints, and the balloon bodies are never inside bone. This is supported in the specification. With respect to the knee joint, the specification recites in column 9, lines 13-17, "...Fig. 9 illustrates the use of the retractor 10 to retract soft tissue from bone, for example, within a joint. The retractor 10 is inserted

between the bone 110 and the soft tissue 112. The bladder 104 is then expanded The soft tissue is then forced away from the bone...". There is no soft tissue inside bone, so the retractor cannot have been placed inside bone. Similar recitations about separating soft tissue from bone occur with respect to fig. 10 covering the shoulder joint (see column 9, lines 37-51) and with respect to figs. 11, 11A, 12 and 12A covering the knee joint (see column 9, lines 52-62).

Bonutti never contemplates putting these retractors inside bone, teaches away from the concepts of deforming bone to create a cavity for therapeutic purposes, and does not reveal the required shapes and sizes of balloon bodies to compress cancellous bone sufficiently to confer a therapeutic benefit without breaking cortical bone which is intact.

There is nothing in Bonutti that tells the reader that balloons with inelastic materials should be used to compress bone, nor does Bonutti identify which bone or bones where such a balloon body should be used, nor does Bonutti specify the configuration with its predetermined shape and size for this balloon body to be effective at compressing and compacting cancellous but not cause unintended injury by breaking healthy cortical bone. Moreover, nothing in Bonutti teaches or enables restraining means for the purpose of limiting the balloon body to a predetermined shape and size for safely compacting bone.

The disclosure of Bonutti is instead inadequate to achieve some of its stated goals, and teaches away from the present invention as set forth in claim 1. Thus, according to the Bonutti specification, inelastic materials, even though suggested as a possibility, are not actually workable for bladder 14 of Figs. 1-3 or for bladder 48 of Fig. 6, which Bonutti require to expand to achieve their shapes, as cited above. This deficiency is the same as Scholten, cited in the specification of the present invention. Scholten discloses the concept of a checker-shaped balloon whose top and bottom are parallel, but does not

provide enabling methods for maintaining the parallel sides. Only the present invention teaches the restraints that would keep the balloons in shapes with parallel sides: tufts, inner strings, and the other methods taught therein.

In summary, Bonutti makes it clear that the bladder of Figs. 1, 2 and 6 must expand and cannot be inelastic to attain the shapes as drawn. Bonutti also fails to teach the necessity of inelastic wall means for bone, fails to teach compressing cancellous bone, fails to teach the necessity of defining the shape and size of balloon body for each bone, and fails to teach workable restraint means for holding the wall means against expansion beyond a predetermined size and shape for the bladders of Figs. 1, 2 and 6.

Thus, claim 1 is allowable under 35 USC §103 over Scholten in view of Bonutti because Scholten fails to teach or suggest an inelastic balloon body of claim 1, fails to show or suggest the restraint means of claim 1 and fails to support configurations with predetermined shapes and sizes of balloons bodies. By virtue of these recitations in claim 1, applicants are able to form a cavity without danger of causing injury by pushing bone beyond its normal size and shape. This is achieved by the inelasticity of the wall means and of the restraint means associated with the wall means, features not shown or suggested to a person skilled in the art by the Scholten and Bonutti references. The Scholten reference is defective because the cavity former is limited in inflation by viewing the inflation and stopping it if it proceeds too far and does not rely upon the inelastic nature of the wall former, nor does it rely upon restraints. Thus, claim 1 must be recognized as allowable under 35 USC § 103 over Scholten in view of Bonutti.

Claims 10-19, 21, 22, 41, 42, 43, 48 and 76-83 are allowable under 35 USC § 103 over Scholten in view of Bonutti for the same reasons as claim 1, from which they depend.

With respect to claim 76, the claim is allowable under 35 USC § 103 over Scholten in view of Bonutti because the claim recites relying upon the restraining step as being a step achieved by not overinflating the fluid pressure in the cavity former, thereby preventing the cavity former from applying excessive pressure and damaging bone.

In the present invention, as set forth in independent claim 76, the claim recites an inelastic cavity former and restraining the cavity former to create the predetermined size and shape for the cavity and preventing the cavity former from applying excessive pressure to the inner surface of the cortical bone is the bone is unfractured or uncollapsed. Neither Scholten nor Bonutti teach the step of forming an inelastic cavity former. Moreover, the step of restraining the cavity former to create a configuration with a predetermined size and shape is not taught in combination with the providing of the inelastic cavity former. A person skilled in the art with Scholten and Bonutti before him or her would have no teaching of the combination of steps in claim 76 without the benefit of Applicants' own disclosure. Thus, claim 76 and dependent claims 77-83 are allowable under 35 USC § 103 over Scholten in view of Bonutti.

INFORMATION DISCLOSURE STATEMENT

Applicant specifically requests that the requirement for an English translation of the French patent 439636 and the Dutch patent NL901858 be deferred until the time that claims are allowed, if any.

The term KEVLAR has been amended in the specification to capitalize all letters of the word.

Respectfully submitted,

Karen Talmadge
Co-inventor

I

STEDMAN'S Medical Dictionary

27th Edition

Illustrated in Color



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da tympani nerve issues from the skull. SYN Civinini canal, Huguier canal, iter chordae anterius.

auricular c., SYN mastoid c.

biliary c., one of the intercellular channels, about 1 μm or less in diameter, that occur between liver cells forming the first portion of the bile system. SYN bile capillary.

bone c., the c. interconnecting bone lacunae with one another or with a haversian canal; contains the interconnecting cytoplasmic processes of osteocytes.

caroticotympanic canaliculi [TA], small openings within the carotid canal that afford passage to the tympanic cavity of branches of the internal carotid artery and carotid sympathetic plexus. SYN canaliculi caroticotympanici [TA].

canaliculi caroticotympan'ici [TA], SYN caroticotympanic canaliculi.

c. chor'dae tym'pani [TA], SYN posterior c. of chorda tympani.

c. of chorda tympani, SYN posterior c. of chorda tympani.

c. coch'leae [TA], SYN cochlear c.

cochlear c. [TA], a minute canal in the temporal bone that passes from the cochlea inferiorly to open in front of the medial side of the jugular fossa. It contains the perilymphatic duct. SYN c. cochleae [TA].

canalic'uli denta'les, minute, wavy, branching tubes or canals in the dentin; they contain the long cytoplasmic processes of odontoblasts and extend radially from the pulp to the dentoenamel junction. SYN dental tubules, dentinal canals, dentinal tubules, tubuli dentales.

c. innomina'tus, SYN *foramen* petrosum.

intercellular c., one of the fine channels between adjoining secretory cells, such as those between serous cells in salivary glands.

intracellular c., a fine canal formed by invagination of the cell membrane into the cytoplasm of a cell, such as those of the parietal cells of the stomach.

lacrimal c. [TA], a curved canal beginning at the lacrimal punctum in the margin of each eyelid near the medial commissure and running transversely medially to empty with its fellow into the lacrimal sac. SYN c. lacrimalis [TA].

c. lacrima'lis [TA], SYN lacrimal c.

mastoid c. [TA], the canal that extends from the jugular fossa laterally through the mastoid process; it transmits the auricular branch of the vagus. SYN c. mastoideus [TA], auricular c.

c. mastoid'eus [TA], SYN mastoid c.

posterior c. of chorda tympani, a canal leading from the facial canal to the tympanic cavity through which the chorda tympani nerve enters this cavity. SYN c. chordae tympani [TA], c. of chorda tympani, iter chordae posterius, small canal of chorda tympani.

c. reu'niens, SYN *ductus* reuniens.

secretory c., SEE intercellular c., intracellular c.

Thiersch canaliculi, minute channels in newly formed reparative tissue, permitting the circulation of nutritive fluids, precursors of new vascularization.

tympanic c. [TA], a minute canal passing from the inferior surface of the petrous portion of the temporal bone between the jugular fossa and carotid canal to the floor of the tympanic cavity. Located in the wedge of bone separating the jugular canal and carotid canal, it transmits the tympanic branch of the glossopharyngeal nerve. SYN c. tympanicus [TA], Jacobson canal, tympanic canal.

c. tympan'icus [TA], SYN tympanic c.

ca·na'lis, pl. **ca·na'les** (ka-nā'lis, -lēz) [TA]. SYN canal. [L.]

c. adductor'ius [TA], SYN adductor *canal*.

cana'les alveola'res corpo'ris maxil'lae [TA], SYN alveolar *canals* of maxilla, under *canal*.

c. ana'lis [TA], SYN anal *canal*.

c. carot'icus [TA], SYN carotid *canal*.

c. car'pi [TA], SYN carpal *tunnel*.

c. centra'lis medul'lae spina'lis [TA], SYN central *canal*.

c. cervicis u'teri [TA], SYN cervical *canal*.

c. condyla'ris [TA], SYN condylar *canal*.

cana'les diplo'ici [TA], SYN diploic *canals*, under *canal*.

c. femora'lis [TA], SYN femoral *canal*.

c. gastricus [TA], SYN gastric *canal*.

c. hyaloid'eus [TA], SYN hyaloid *canal*.

c. hypoglossa'lis [TA], SYN hypoglossal *canal*.

canales incisi'vi [TA], SYN incisive *canals*, under *canal*.

c. infraorbita'lis [TA], SYN infraorbital *canal*.

c. inguina'lis [TA], SYN inguinal *canal*.

cana'les longitudina'les modi'oli [TA], SYN longitudinal *canals* of modiolus, under *canal*.

c. mandib'ulae [TA], SYN mandibular *canal*.

c. musculotuba'rius [TA], SYN musculotubal *canal*.

c. nasolacrima'lis [TA], SYN nasolacrimal *canal*.

c. ner'vi fa'cia'lis [TA], SYN facial *canal*.

c. ner'vi petro'si superfi'cia'lis mino'ris, SYN *hiatus* for lesser petrosal nerve.

c. nutri'cius [TA], SYN nutrient *canal*.

c. obturato'rius [TA], SYN obturator *canal*.

c. op'ticus [TA], SYN optic *canal*.

cana'les palati'ni mino'res [TA], SYN lesser palatine *canals*, under *canal*.

c. palati'nus ma'jor [TA], SYN greater palatine *canal*.

c. palatovagina'lis, SYN palatovaginal *canal*.

c. pterygoi'deus [TA], SYN pterygoid *canal*.

c. pudenda'lis [TA], SYN pudendal *canal*.

c. pylor'icus [TA], SYN pyloric *canal*.

c. radi'cis den'tis [TA], SYN root *canal* of tooth.

c. reu'niens, SYN *ductus* reuniens.

c. sacra'lis [TA], SYN sacral *canal*.

canales semicirculares anterior, anterior semicircular canal, SEE semicircular *canals* of bony labyrinth, under *canal*.

canales semicirculares lateralis, lateral semicircular canal, SEE semicircular *canals* of bony labyrinth, under *canal*.

cana'les semicircula'res os'sei, SYN semicircular *canals* of bony labyrinth, under *canal*.

canales semicirculares posterior, posterior semicircular canal, SEE semicircular *canals* of bony labyrinth, under *canal*.

c. spira'lis coch'leae [TA], SYN spiral *canal* of cochlea.

c. spira'lis modi'oli [TA], SYN spiral *canal* of modiolus.

c. umbilica'lis, SYN umbilical *ring*.

c. vertebra'lis [TA], SYN vertebral *canal*.

c. vomerorostra'lis [TA], SYN vomerorostral *canal*.

c. vomerovagina'lis [TA], SYN vomerovaginal *canal*.

can·a·li·za'tion (kan-al-i-zā'shŭn). The formation of canals or channels in a tissue.

Canavan, Myrtelle M., U.S. pathologist, 1879–1953. SEE C. *disease, sclerosis;* C.-van Bogaert-Bertrand *disease*.

can·a·van'ase (kan-a'vă-nās). SYN arginase.

can·a·van'ine (kan-ă-van'in). 2-Amino-4-guanidinohydroxybutyric acid, an analog of arginine found in certain legumes; used in studies of arginine-dependent systems; it is also a potent growth inhibitor. [*Canavalia* + -ine]

can·cel·lat·ed (kan'sĕ-lā-ted). SYN cancellous. [L. *cancello*, to make a lattice work]

can·cel·lous (kan'sĕ-lŭs). Denoting bone that has a latticelike or spongy structure. SYN cancellated.

can·cel·lus, pl. **can·cel'li** (kan-sel'ŭs, -ī). A latticelike structure as in spongy bone. [L. a grating, lattice]

can·cer (CA) (kan'ser). General term frequently used to indicate any of various types of malignant neoplasms, most of which invade surrounding tissues, may metastasize to several sites, and are likely to recur after attempted removal and to cause death of the patient unless adequately treated; especially, any such carcinoma or sarcoma, but, in ordinary usage, especially the former. [L. crab, a cancer]

betel c., carcinoma of the mucous membrane of the cheek, observed in certain East Indian natives, probably as a result of irritation from chewing a preparation of betel nut and lime rolled within a betel leaf. SYN buyo cheek c.

buyo cheek c., SYN betel c. [Philippine *buyo*, betel]

chimney sweep's c., a squamous cell carcinoma of the skin of

tin·gi·bil·i·ty (tin'ji-bil'i-te). The property of being tingible.

tin·gi·ble (tin'ji-bl). Capable of being stained. [L. *tingo*, to dye]

tin·gle (ting'gl). To feel a peculiar pricking sensation.

tin·gling (ting'ling). A pricking type of paresthesia.

distal t. on percussion (DTP), SYN Tinel *sign*.

ti·nid·a·zole (ti-nid'ă-zōl). An antiprotozoal agent.

tin·ni·tus (ti-ni'tŭs). Noises (ringing, whistling, hissing, roaring, booming, etc.) in the ears. [L. a jingling, fr. *tinnio*, pp. *tinnitus*, to jingle, clink]

t. au·ri·um, sensation of sound in one or both ears usually associated with disease in the middle ear, the inner ear, or the central auditory pathways. SYN syringism.

t. cere·bri, subjective sensation of noise in head rather than ears.

clicking t., an objective clicking sound in the ear in cases of chronic catarrhal otitis media; it may be audible to the bystander as well as to the patient and is supposed to be due to an opening and closing of the mouth of the eustachian tube, or to a rhythmical spasm of the velum palati.

Leudet t., a dry spasmodic click, audible also through the otoscope, heard in catarrhal inflammation of the eustachian tube, caused by reflex spasm of the tensor palati muscle.

tint. A shade of color varying according to the amount of white admixed with the pigment. [L. *tingo*, pp. *tinctus*, to dye]

ti·o·con·a·zole (ti-ō-kon'ă-zōl). An antifungal agent.

tip. 1. A point or more or less sharp extremity. 2. A separate but attached piece of the same or another structure, forming the extremity of a part.

t. of auricle, SYN *apex* of auricle.

t. of ear, * official alternate term for *apex* of auricle.

t. of elbow, SYN olecranon.

t. of nose, * official alternate term for *apex* of nose.

t. of posterior horn, SYN *apex* of posterior horn.

root t., SYN root *apex*.

t. of tongue, * official alternate term for *apex* of tongue.

t. of tooth root, SYN root *apex*.

Woolner t., SYN *apex* of auricle.

tip·ping. A tooth movement in which the angulation of the long axis of the tooth is altered.

ti·pren·o·lol hy·dro·chlo·ride (tip-ren'ō-lol). A β-receptor blocking agent.

TIPS Acronym for transjugular intrahepatic portosystemic *shunt*.

Tiselius, Arne W.K., Swedish biochemist and Nobel laureate, 1902–1971: SEE T. *apparatus*, electrophoresis *cell*.

Tis·si·er·el·la prae·acu·ta, SYN *Bacteroides praeacutus*.

Tissot, Jules, early 20th century French physiologist: SEE T. *spirometer*.

tis·sue (tish'ū). A collection of similar cells and the intercellular substances surrounding them. There are four basic tissues in the body: 1) epithelium; 2) connective tissues, including blood, bone, and cartilage; 3) muscle tissue; and 4) nerve tissue. [Fr. *tissu*, woven, fr. L. *texo*, to weave]

adenoid t., SYN lymphatic t.

adipose t., a connective t. consisting chiefly of fat cells surrounded by reticular fibers and arranged in lobular groups or along the course of one of the smaller blood vessels. SYN fat (1), fatty t. (1), white fat (1).

areolar t., loose, irregularly arranged connective t. that consists of collagenous and elastic fibers, a protein polysaccharide ground substance, and connective t. cells (fibroblasts, macrophages, mast cells, and sometimes fat cells, plasma cells, leukocytes, and pigment cells).

bone t., SYN osseous t.

bronchus-associated lymphoid t. (BALT), patches of lymphoid t.'s composed mainly of B and T lymphocytes and extending throughout the bronchial airways of the lung.

brown adipose t., SYN brown *fat*.

cancellous t., latticelike or spongy osseous t.

cardiac muscle t., SEE cardiac *muscle*.

cartilaginous t., SEE cartilage.

cavernous t., SYN erectile t.

chondroid t., (1) in an adult, t. resembling cartilage. SYN fibro- aline t., pseudocartilage. (2) in an embryo, an early stage cartilage formation.

chromaffin t., a cellular t., vascular and well supplied nerves, made up chiefly of chromaffin cells; it is found in medulla of the suprarenal glands and, in smaller collections, in paraganglia.

connective t., the supporting or framework t. of the animal bod formed of fibrous and ground substance with more or less numer ous cells of various kinds; it is derived from the mesenchyme and this in turn from the mesoderm; the varieties of connective t. are areolar or loose; adipose; dense, regular or irregular, white fi brous, elastic; mucous; and lymphoid t.; cartilage; and bone. B blood and lymph may be regarded as connective t.'s the ground substance of which is a liquid. SYN interstitial t., tela conjunctiva.

dartoic t., t. resembling tunica dartos.

elastic t., a form of connective t. in which the elastic fibers predominate; it constitutes the ligamenta flava of the vertebra and the ligamentum nuchae, especially of quadrupeds; it occurs also in the walls of the arteries and of the bronchial tree, and connects the cartilages of the larynx. SYN elastica (2), tela elastica.

epithelial t., SEE epithelium.

erectile t., a t. with numerous vascular spaces that may become engorged with blood. SYN cavernous t.

fatty t., (1) SYN adipose t. (2) in some animals, brown *fat*.

fibrohyaline t., SYN chondroid t. (1).

fibrous t., a t. composed of bundles of collagenous white fibers between which are rows of connective t. cells; the tendons, liga ments, aponeuroses, and some of the membranes, such as the dura mater.

Gamgee t., a thick layer of absorbent cotton between two layers of absorbent gauze, used in surgical dressings.

gelatinous t., SYN mucous connective t.

gingival t.'s, SEE gingiva.

granulation t., vascular connective t. forming granular projections on the surface of a healing wound, ulcer, or inflamed t. surface. SEE ALSO granulation.

gut-associated lymphoid t. (GALT), lymphoid t. of the gastrointestinal mucosa that contains both B and T cells. This t. is responsible for localized immunity to pathogens such as bacteria, viruses, and parasites.

Haller vascular t., SYN vascular *lamina* of choroid.

hard t., (1) t. that has become mineralized; (2) t. having a firm intercellular substance, e.g., cartilage and bone.

hemopoietic t., t. in which there is a development of blood cells or other formed elements.

indifferent t., undifferentiated, nonspecialized, embryonic t.

interstitial t., SYN *connective t.*

investing t.'s, the t.'s covering or enclosing a structure.

islet t., SYN *islets* of Langerhans, under *islet*.

lymphatic t., lymphoid t., a three-dimensional network of reticular fibers and cells the meshes of which are occupied in varying degrees of density with lymphocytes; there is nodular, diffuse, and loose lymphatic t. SYN adenoid t.

mesenchymal t., embryonic connective tissue. SEE mesenchyme.

mesonephric t., intermediate mesoderm situated in the thoracic and lumbar regions of the embryo or fetus; it develops into the mesonephros and associated structures.

metanephrogenic t., t. derived from the intermediate mesoderm caudal to mesonephric levels and concerned with the formation of the nephrons of the metanephros.

mucosa-associated lymphoid t. (MALT), a class of lymphoid t. comprising nodular aggregates found in association with the mucosal surfaces of the body such as those of the respiratory, digestive, and urinary systems.

mucous connective t., a type of connective t. little differentiated beyond the mesenchymal stage; its ground substance of glycoproteins is abundant and contains fine collagenous fibers and fibroblasts; in its most characteristic form, it appears in the umbilical cord as Wharton jelly. SYN gelatinous t.

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SEE muscle. SYN fle
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STEDMAN'S Medical Dictionary

27th Edition

Illustrated in Color

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mar·i·no·bu·fo·tox·in (mar'i-nō-boo'fō-toks-in). A poison produced by the parotid gland of *Bufo marinus* (family Bufonidae), a large toad native to Central and South America; used in tropical countries for insect control.

Marion, Georges, French urologist, 1869–1932. SEE M. *disease*.

Mariotte, Edmé, French physicist, 1620–1684. SEE M. *bottle, experiment, law*, blind *spot*.

mar·i·po·sia (mar-i-pō'zē-ă). Thallasoposia; rarely used term for abnormal consumption of sea water as a result of psychogenic factors. SYN thalassoposia. [L. *mare*, the sea, + G. *posis*, drinking]

Marjolin, Jean N., French physician, 1780–1850. SEE M. *ulcer*.

mar·jo·ram (mar'jō-ram). Sweet, leaf, or garden m. whose leaves, with and without a small portion of the flowering tops of *Majorana hortensis* (*Origanum majorana*) (family Labiatae), are used as seasoning and medicinally as a stimulant, carminative, and emmenagogue.

mark. 1. Any spot, line, or other figure on the cutaneous or mucocutaneous surface, visible through difference in color, elevation, or other peculiarity. [A.S. *mearc*]

alignment m., m.'s made in tracings while the kymograph or other recording apparatus is at rest in order to indicate the time relations between two tracings inscribed one above the other, e.g., jugular and radial pulses.

stretch m.'s, SYN *striae* cutis distensae, under *stria*.

mark·er. 1. A device used to make a mark or to indicate measurement. 2. A characteristic or factor by which a cell or molecule can be recognized or identified. 3. A locus containing two or more alleles that, being harmless, are common and therefore yield high frequencies of heterozygotes which facilitate linkage *analysis*.

allotypic m., SYN allotype.

cell m., an identifying characteristic of a cell; e.g., formation of rosettes with sheep erythrocytes as a m. of T lymphocytes, or the presence of surface immunoglobulin as a m. of B lymphocytes.

cell surface m., a surface protein, glycoprotein, or group of proteins that distinguish a cell or subset of cells from another defined subset of cells.

genetic m., SYN genetic *determinant*.

linkage m., a locus at which there is a high probability of heterozygotes (indispensible state for linkage analysis), but in itself perhaps of no clinical interest. SEE ALSO marker *locus*.

oncofetal m., a tumor m. produced by tumor tissue and by fetal tissue of the same type as the tumor, but not by normal adult tissue from which the tumor arises.

polymorphic genetic m., inherited characteristic that occurs within a given population as two or more traits.

time m., an instrument that marks the time, usually in seconds or fractions of seconds, on a kymograph record in physiologic experiments.

tumor m., a substance, released into the circulation by tumor tissue, whose detection in the serum indicates the presence of tumor.

tumor markers used in primary diagnoses

testicular carcinoma, choriocarcinoma	β-subunit of human chorionadotropin (β-HCG) and α-1-fetoprotein (AFP)
[illegible] myeloma	immunoglobulins, Bence Jones protein
neuroblastoma, pheochromocytoma	catecholamines, vanillylmandelic acid, metanephrines
[illegible]	5-hydroxyindoleacetic acid
[illegible] liver cell [illegible]	α-1-fetoprotein
[illegible]	
[illegible] thyroid gland carcinoma	calcitonin
[illegible] lymphoma, [illegible]	surface antigens

Markov, Andrei, Russian mathematician, 1865–1922. SEE Markov *process*.

Marme re·a·gent. See under reagent.

mar·mo·rat·ed (mar'mō-rā-ted). Denoting a condition in which the appearance of the skin is streaked like marble. SEE ALSO *cutis marmorata*. [L. *marmoratus*, marbled]

mar·mot (mar'mot). A woodchuck or groundhog; a hibernating rodent that may serve as reservoir host of plague bacillus in North America. [Fr. *marmotte*]

Maroteaux, Pierre, French medical geneticist, *1926. SEE M.-Lamy *syndrome*.

Marquis re·a·gent. See under reagent.

mar·row (mar'ō) [TA]. 1. A highly cellular hematopoietic connective tissue filling the medullary cavities and spongy epiphyses of bones; it becomes predominantly fatty with age, particularly in the long bones of the limbs. 2. Any soft gelatinous or fatty material resembling the m. of bone. SEE ALSO medulla. [A.S. *mearh*]

bone m. [TA], the soft, pulpy tissue filling the medullary cavities of bones, having a stroma of reticular fibers and cells; it differs in consistency by age and location. SEE ALSO gelatinous bone m., red bone m., yellow bone m. SYN medulla ossium [TA].

gelatinous bone m. [TA], degenerated marrow of cranial bones in old age.

red bone m. [TA], bone marrow in which the stroma primarily contain the developmental stages of erythrocytes, leukocytes, and megakaryocytes; it is present throughout the skeleton during fetal life and at birth. After the fifth postnatal year, it is gradually replaced in the long bones by yellow marrow. SYN medulla ossium rubra [TA].

spinal m., SYN spinal *cord*.

yellow bone m. [TA], bone m. in which the stroma of the reticular network are largely filled primarily with fat; it replaces red marrow in the long bones after the fifth year of life. SYN medulla ossium flava [TA].

Marshall, Don, U.S. ophthalmologist, *1905. SEE M. *syndrome*.

Marshall, Eli K., U.S. pharmacologist, 1889–1966. SEE M. *method*.

Marshall, John, English anatomist, 1818–1891. SEE M. vestigial *fold*, oblique *vein*.

Marshall, Victor F., U.S. urologist, *1913. SEE M. *test*; M.-Marchetti *test*; M.-Marchetti-Krantz *operation*.

Mar·shal·la·gia mar·shalli (mar-sha-lā'jē-ă mar-shal'ī). One of the medium stomach worms of the nematode family Trichostrongylidae, found in the abomasum of sheep, goats, camels, and various wild ruminants.

marsh·mal·low root (marsh'mal-ō). SYN althea.

mar·su·pi·al (mar-soo'pē-ăl). 1. A member of the order Marsupalia, which includes such mammals as kangaroos, wombats, bandicoots, and opossums, the female of which has an abdominal pouch for carrying the young. 2. Of or pertaining to marsupials. [L. *marsupium*, a pouch]

mar·su·pi·al·i·za·tion (mar-soo'pē-ăl-i-zā'shŭn). Exteriorization of a cyst or other such enclosed cavity by resecting the anterior wall and suturing the cut edges of the remaining wall to adjacent edges of the skin, thereby creating a pouch. [L. *marsupium*, pouch]

mar·su·pi·um (mar-soo'pē-ŭm). 1. SYN scrotum. 2. A pouch or sac; e.g., in marsupials. [L. pouch]

Martegiani, L., 19th century Italian anatomist. SEE M. *area, funnel*.

Martin, August E., German gynecologist, 1847–1933. SEE M. *tube*; M.-Gruber *anastomosis*.

Martin, Henry A., U.S. surgeon, 1824–1884. SEE M. *bandage, disease*.

Martin, J.E. SEE Thayer-M. *medium*.

Martinotti, Giovanni, Italian physician, 1857–1928. SEE M. *cell*.

mar·ti·us yel·low (mahr'shē-ŭs) [C.I. 10315]. An acid dye used as a stain in plant and animal histology, and as a light filter for photomicrography. [Karl A. *Martius*, Ger. chemist, *1920]



Medical Dictionary

One entry found for **bone marrow**.

Main Entry: **bone marrow**
Function: *noun*
: a soft highly vascular modified connective tissue that occupies the cavities and cancellous part of most bones and occurs in two forms: **a** : a whitish or yellowish bone marrow consisting chiefly of fat cells and predominating in the cavities of the long bones -- called also *yellow marrow* **b** : a reddish bone marrow containing little fat, being the chief seat of red blood cell and blood granulocyte formation, and occurring in the normal adult only in cancellous tissue especially in certain flat bones -- called also *red marrow*

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Pronunciation Key

\&\ as a and u in abut	\ch\ as ch in chin	\o\ as aw in law
\ᵊ\ as e in kitten	\e\ as e in bet	\oi\ as oy in boy
\&r\ as ur and er in further	\E\ as ea in easy	\th\ as th in thin
\a\ as a in ash	\g\ as g in go	\th\ as th in the
\A\ as a in ace	\i\ as i in hit	\ü\ as oo in loot
\ä\ as o in mop	\I\ as i in ice	\u\ as oo in foot
\au\ as ou in out	\j\ as j in job	\y\ as y in yet
	\ng\ as ng in sing	\zh\ as si in vision
	\O\ as o in go	

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