IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON, INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	Civil Action No. 04-0204-JJF **REDACTED – PUBLIC VERSION**

APPENDIX OF EXHIBITS TO DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S and DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S CLAIM CONSTRUCTION MEMORANDA AND MOTIONS FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY

VOLUME 3

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April 6, 2005

INDEX TO APPENDIX OF EXHIBITS TO DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S and DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S CLAIM CONSTRUCTION MEMORANDA AND MOTIONS FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY

Tab and Exhibit Number	*Title*
A	**REDACTED**
A-A	**REDACTED**
A-1	Curriculum Vitae of Michael David Mitchell, MD
A-2	U.S. Patent No. 4,969,888 (" '888 patent")
A-3	U.S. Patent No. 5,108,404 (" '404 patent")
A-4	U.S. Patent No. 6,235,043 (" '043 patent")
A-5	U.S. Patent No. 3,626,949 (" '949 patent")
A-6	U.S. Patent No. 4,878,495 (" '495 patent")
A-7	U.S. Patent No. 4,909,252 (" '252 patent")
A-8	U.S. Patent No. 5,049,132 (" '132 patent")
A-9	Aebi, M., "The internal skeletal fixation system. A new treatment of thoracolumbar fractures and other spinal disorders," Clin. Orthop., Vol. 227, pp. 30-43, 1988 ("Aebi")
A-10	Blauth, M., "Therapeutic Concept and Results of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: The Hannover Experience," J. of Orthop. Trauma, Vol. 1, No. 3, pp. 240–252, 1987 ("Blauth")
A-11	Campbell's Operative Orthopaedics, A.H. Crenshaw, Ed., 7th ed., Chapter 44, pp. 1653–1663, 1987 ("Campbell")
A-12	Carlson, "The Use of Methylmethacrylate in Repair of Neoplastic Lesions in Bone," Radiology, Vol. 112, pp. 43-46, July 1974 ("Carlson")
A-13	Daniaux, H., "Technik und Ergebnisse der transpedikulären Spongiosaplastik bei Kompressionsbrüchen im Lendenwirbelsäulenbereich," Acta Chir. Austr. (Suppl.), Vol. 43, pp. 79-80, 1982 ("Daniaux 1982")

Tab and Exhibit Number	*Title*
A-14	Daniaux, H., "Transpedikuläre Reposition und erste Spongiosaplastik bei Wirbelkörperbrüchen der unteren Brust und Lendenwirbelsäule," Unfallchirurg, Vol. 89, pp. 197-213, 1986 ("Daniaux 1986")
A-15	Dick, W., "Use of the Acetabular Reamer to Harvest Autogeneic Bone Graft Material: A Simple Method for Producing Bone Paste," Arch. Orthop. Trauma Surg., Vol. 105, pp. 235 – 238, 1986 ("Dick 1986")
A-16	Dick, W., "The 'Fixatuer Interne' as versatile implant for spine surgery," Spine, Vol. 12 (9), pp. 882-900, 1987 ("Dick 1987")
A-17	Edeland, H.G., "Open Reduction of Central Compression Fractures of the Tibial Plateau," Acta Orthop. Scand., Vol. 47, pp. 686-689, 1976 ("Edeland")
A-18	Kennedy, W., "Fractures of the Tibial Condyles: A Preliminary Report on Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol. 134, pp. 153-157, 1978 ("Kennedy")
A-19	Ma, Yuan-zhang, "Os Calsis Fracture Treated by Percutaneous Poking Reduction and Internal Fixation," Chinese Medical Journal, Vol. 97, No. 2, pp. 105-110, 1984 ("Ma")
A-20	Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures," Clin. Orthop., Vol. 227, pp. 44-51, 1988 ("Olerud")
A-21	Pentelenyi, T., "First Hungarian Neurosurgical Experiences with 'Fixateur Interne' in the Treatment of Thoraco-lumbar Spine Injuries," Acta Neurochir. (Wien), Vol. 93, pp. 104-109, 1988 ("Pentelenyi")
A-22	Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1st ed., Ch. 35, pp. 421 – 434, 1988 ("Schatzker")
A-23	Scoville, W., "The Use of Acrylic Plastic for Vertebral Replacement or Fixation in Metastatic Disease of the Spine," J. Neurosurg., Vol. 27: 274-279, Sept. 1967 ("Scoville")
A-24	Record Of Invention -- "Balloon Assisted Fixation of Osteoporotic Fractures" Invention Disclosure Statement, by Arie Scholten and Mark Reiley, dated September 26, 1988
A-25	**REDACTED**

Tab and Exhibit Number	*Title*
A-26	**REDACTED**
A-27	**REDACTED**
A-28	INTENTIONALLY LEFT BLANK
A-29	INTENTIONALLY LEFT BLANK
A-30	Memorandum Opinion, Kyphon Inc. v. Disc-O-Tech Medical Technologies Ltd. and Disc Orthopaedic Technologies, Inc., USDC-D-Del., Civil Action No. 04-204 JJF, dated December 10, 2004
B	**REDACTED**
B-A	Invalidity Charts for the '734 and '054 Patents
B-1	U.S. Patent No. 6,241,734 (" '734 patent")
B-2	U.S. Patent No. 6,613,054 (" '054 patent")
B-3	U.S. Patent No. 4,576,152 (" '152 patent")
B-4	U.S. Patent No. 4,801,263 (" '263 patent")
B-5	U.S. Patent No. 5,108,404 (" '404 patent")
B-6	U.S. Patent No. 5,312,333 (" '333 patent")
B-7	U.S. Patent No. 5,415,631 (" '631 patent")
B-8	U.S. Patent No. 5,741,261 (" '261 patent")
B-9	U.S. Patent No. 5,919,196 (" '196 patent")
B-10	U.S. Patent No. 6,017,348 (" '348 patent")
C	**REDACTED**
C-A	**REDACTED**
D	**REDACTED**
D-A	**REDACTED**
D-1	U.S. Patent No. 6,241,734 B1

Tab and Exhibit Number	*Title*
D-2	U.S. Patent No. 6,613,054 B2
E	**REDACTED**
E-1	**REDACTED**
E-2	Selected articles referring to ceramic calcium phosphate compounds
E-3	U.S. Patent No. 4,518,430
E-4	M. Malawer, M. Marks et al., " Effect of Cryosurgery and PMMA on Tumor Cavity: Evaluation of Bone Necrosis and Bone Graft Incorporation in a Dog Model"
E-5	Limb Salvage Article, bearing production numbers DOTINC 050479-050537
E-6	**REDACTED**
E-7	**REDACTED**
E-8	**REDACTED**
E-9	Mathis, J. M. et al., "Percutaneous Vertebroplasty: A Developing Standard of Care for Vertebral Compression Fractures,"
E-10	Tsai, T. T. et al., "Polymethylmethacrylate Cement Dislodgement Following Percutaneous Vertebroplasty: A case report"
E-11	Stricker, K. et al., "Severe Hypercapnia Due to Pulmonary Embolism of Polymethylmethacrylate During Vertebroplasty,"
E-12	Bernard Padovani et al., "Pulmonary Embolism Cause by Acrylic Cement: A Rare Complication of Percutaneous Vertebroplasty"
F	File History for U.S. Patent No. 5,108,404 bearing production numbers KY 228908- 229043
G	File History for U.S. Patent No. 4,969,888 bearing production numbers KY 228787-228907

Tab and Exhibit Number	*Title*
H	File History for U.S. Patent No. 6,235,043 (B1) bearing production numbers KY 229044-229364
I	Stedman's Medical Dictionary ("Stedmans"), (27th ed.)
J	Medline definitions
K	**REDACTED**
L	**REDACTED**
M	**REDACTED**
N	**REDACTED**
O	Letter from Thomas Halkowski to Judge Poppiti, dated February 9, 2005, and Letter from Jonathan Sobel to Thomas Halkowski, dated February 11, 2005 (re: Kyphon not asserting claims from the '110 Patent)
P	**REDACTED**
Q	**REDACTED**
R	**REDACTED**
S	**REDACTED**
S-A	**REDACTED**
T	**REDACTED**
U	**REDACTED**
V	**REDACTED**
W	Medrad, Inc. v. MRI Devices Corp., 2005 WL 605532 (Fed. Cir. Mar. 16, 2005)
X	**REDACTED**
Y	**REDACTED**
Z	**REDACTED**

Tab and Exhibit Number	*Title*
AA	**REDACTED**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	C.A. No. 04-204-JJF

DECLARATION OF DAVID MITCHELL, M.D.

I, Dr. David Mitchell, state under penalty of perjury that the attached **Expert Report of Dr. David Mitchell Regarding the Invalidity of U.S. Patent Nos. 6,241,734 (B1) and 6,613,054 (B2)**, dated March 11, 2005, is true and correct to the best of my knowledge, information and belief. If asked, I am prepared to testify as to the matters contained within my expert report.

Dated: April 6, 2005



Dr. David Mitchell

B

REDACTED

B-A

ANTICIPATION OF '734 PATENT BY '631 PATENT

The chart set forth below illustrates how U.S. Patent No. 5,415,631 teaches every single limitation of one or more of the asserted claims of the '734 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '734 Patent	'631 Patent
1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	'631 patent discloses an endoscopic device that delivers a quantity of material to a remote location within the body (such as into bone). (Abstract; Col. 1, ll. 10-14; Col. 5, ll. 52-57) The '631 discloses the insertion of the endoscopic shaft 26 through a subcutaneous cannula. (Col. 3, ll. 58-61) The '631 patent discloses a delivery device (parts 10 and 90) to convey the material at a delivery pressure, which may be less than about 360 psi. (Figs. 1-2, 5-6; Col. 1, ll. 64-68; Col. 3, ll. 61-Col. 4, l. 31; Col. 5, ll. 37-43, 52-57)
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure,	The '631 patent discloses endoscopic shaft 26 (i.e. a nozzle instrument) capable of advancement into the subcutaneous cannula. (Col. 3, ll. 58-61) The '631 patent discloses a proximal fitting (tapered end 28 into port 22; u-shaped key 126 to key 110) to couple the endoscopic shaft 26 or tube portion 114 to the delivery device 10 or 90. (Figs. 2 and 6; Col. 3, ll. 54-58; Col. 5, ll. 26-37) The '631 patent discloses a nozzle terminus (distal end of passageway 30 or 116) through which the material conveyed by the delivery device enters into the body (which includes bone) at the delivery pressure. (Figs. 2 and 7; Col. 3, ll. 61-68; Col. 5, ll. 39-43)
and a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.	The '631 patent discloses a plunger member 118 (i.e. tamping instrument) having a terminus portion 124 or 128 capable of advancement into the subcutaneous cannula, and which, during advancement, urges material residing in the subcutaneous cannula into the body (which includes bone); the portion 124 or 128 thereof follows the material out of the end of the endoscopic member and protrudes therefrom to maneuver the material. (Figs. 6 and 7; Col. 3, ll. 58-61; Col. 5, ll. 39-61)
3. Apparatus according to claim 1 wherein the nozzle instrument is made of a	*See* above at claim 1. The '631 patent discloses endoscopic shaft 26 (i.e. a

Claim of the '734 Patent	'631 Patent
generally rigid material.	nozzle instrument), which includes an instrument made of generally rigid material. (Fig. 2; Col. 3, ll. 3-13)
4. Apparatus according to claim 1 wherein the delivery device comprises a syringe.	
5. Apparatus according to claim 1 wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	
7. Apparatus according to claim 1 wherein the tamping instrument is made of a generally rigid material.	*See* above at claim 1. The '631 patent discloses a plunger member 118 (i.e. tamping instrument), which includes an instrument made of generally rigid material. (Figs. 6 and 7; Col. 5, ll. 39-61)
8. Apparatus according to claim 1 wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle terminus through the subcutaneous cannula.	
10. Apparatus according to claim 1 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	
11. Apparatus according to claim 10 wherein the cavity forming instrument includes an expandable structure.	
12. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a	'631 patent discloses an endoscopic device that delivers a quantity of material to a remote location within the body (such as into bone). (Abstract; Col. 1, ll. 10-14; Col. 5, ll. 52-57) The '631 discloses the insertion of the endoscopic shaft 26 through a subcutaneous cannula. (Col. 3, ll. 58-

Claim of the '734 Patent	'631 Patent
subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	61) The '631 patent discloses a delivery device (parts 10 and 90) to convey the material at a delivery pressure, which may be less than about 360 psi. (Figs. 1-2, 5-6; Col. 1, ll. 64-68; Col. 3, ll. 61-Col. 4, l. 31; Col. 5, ll. 37-43, 52-57)
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure,	The '631 patent discloses endoscopic shaft 26 (i.e. a nozzle instrument) capable of advancement into the subcutaneous cannula. (Col. 3, ll. 58-61) The '631 patent discloses a proximal fitting (tapered end 28 into port 22; u-shaped key 126 to key 110) to couple the endoscopic shaft 26 or tube portion 114 to the delivery device 10 or 90. (Figs. 2 and 6; Col. 3, ll. 54-58; Col. 5, ll. 26-37) The '631 patent discloses a nozzle bore (passageway 30 or 116) through which the material conveyed by the delivery device enters into the body (which includes bone) at the delivery pressure. (Figs. 2 and 7; Col. 3, ll. 61-68; Col. 5, ll. 39-43)
and a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula.	The '631 patent discloses endoscopic shaft 26 (i.e. a nozzle instrument) capable of advancement into the subcutaneous cannula. (Col. 3, ll. 58-61) The '631 patent discloses a plunger member 118 having terminus portion 124 capable of advancement into the nozzle bore (passageway 116) to close the nozzle bore, and with the endoscopic shaft 112, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula. (Fig. 6; Col. 5, ll. 39-61)
13. Apparatus according to claim 12 wherein the nozzle instrument includes marking to visually gauge the advancement of the nozzle instrument through the cannula.	
14. Apparatus according to claim 12 wherein the delivery device comprises a syringe.	
15. Apparatus for introducing	'631 patent discloses an endoscopic device that delivers a quantity of material to a remote location within the body

Claim of the '734 Patent	'631 Patent
material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula, a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi,	(such as into bone). (Abstract; Col. 1, ll. 10-14; Col. 5, ll. 52-57) The '631 discloses the insertion of the endoscopic shaft 26 through a subcutaneous cannula. (Col. 3, ll. 58-61) The '631 patent discloses a delivery device (parts 10 and 90) to convey the material into the cannula at a delivery pressure which may be less than about 360 psi. (Figs. 1-2, 5-6; Col. 1, ll. 64- 68; Col. 3, l. 61-Col. 4, l. 31; Col. 5, ll. 37-43, 52-57)
and a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone.	The '631 patent discloses a plunger member 118 (i.e. tamping instrument) having a terminus portion 124 or 128 capable of advancement into the subcutaneous cannula and which, during advancement, urges material residing in the subcutaneous cannula into the body (which includes bone); the portion 124 or 128 at the proximal end thereof follows the material out of the end of the endoscopic member and protrudes therefrom to maneuver the material. (Figs. 6 and 7; Col. 3, ll. 58-61; Col. 5, ll. 39-61)
16. Apparatus according to claim 15 wherein the delivery device comprises a syringe.	
17. Apparatus according to claim 15 wherein the tamping instrument includes marking to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	
19. Apparatus according to claim 15 wherein the tamping instrument is made of a generally rigid material.	*See* above at claim 15. The '631 patent discloses a plunger member 118 (i.e. tamping instrument), which includes an instrument made of generally rigid material. (Figs. 6 and 7; Col. 5, ll. 39-61)
20. Apparatus according to claim 15 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous	

Claim of the '734 Patent	'631 Patent
bone.	
21. Apparatus according to claim 15 wherein the cavity forming instrument includes an expandable structure.	

ANTICIPATION OF '734 PATENT BY '333 PATENT

The chart set forth below illustrates how U.S. Patent No. 5,312,333 teaches every single limitation of one or more of the asserted claims of the '734 Patent. I reserve the right to supplement, modify or amend my opinions.

Claim of the '734 Patent	'333 Patent
1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	'333 patent discloses an endoscopic device that delivers a quantity of material to a remote location within the body (such as into bone). (Abstract; Col. 1, ll. 6-10; Col. 5, ll. 47-52) The '333 discloses the insertion of the endoscopic shaft 26 through a subcutaneous cannula. (Col. 3, ll. 55-58) The '333 patent discloses a delivery device (parts 10 and 90) to convey the material at a delivery pressure, which may be less than about 360 psi. (Figs. 1-2, 5-6; Col. 1, ll. 58-64; Col. 3, l. 58-Col. 4, l. 28; Col. 5, ll. 32-38, 47-52)
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure,	The '333 patent discloses endoscopic shaft 26 (i.e. a nozzle instrument) capable of. advancement into the subcutaneous cannula. (Col. 3, ll. 55-58) The '333 patent discloses a proximal fitting (tapered end 28 into port 22; u-shaped key 126 to key 110) to couple the endoscopic shaft 26 or tube portion 114 to the delivery device 10 or 90. (Figs. 2 and 6; Col. 3, ll. 51-55; Col. 5, ll. 21-32) The '333 patent discloses a nozzle terminus (distal end of passageway 30 or 116) through which the material conveyed by the delivery device enters into the body (which includes bone) at the delivery pressure. (Figs. 2 and 7; Col. 3, ll. 58-65; Col. 5, ll. 34-38)
and a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.	The '333 patent discloses a plunger member 118 (i.e. tamping instrument) having a terminus portion 124 or 128 capable of advancement into the subcutaneous cannula, and which, during advancement, urges material residing in the subcutaneous cannula into the body (which includes bone); the portion 124 or 128 thereof follows the material out of the end of the endoscopic member and protrudes therefrom to maneuver the material. (Figs. 6 and 7; Col. 3, ll. 55-58; Col. 5, ll. 34-56)
3. Apparatus according to claim 1 wherein the nozzle instrument is made of a	*See* above at claim 1. The '333 patent discloses endoscopic shaft 26 (i.e. a

Claim of the '734 Patent	'333 Patent
generally rigid material.	nozzle instrument), which includes an instrument made of generally rigid material. (Fig. 2; Col. 2, l. 68-Col. 3, l. 10)
4. Apparatus according to claim 1 wherein the delivery device comprises a syringe.	
5. Apparatus according to claim 1 wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	
7. Apparatus according to claim 1 wherein the tamping instrument is made of a generally rigid material.	*See* above at claim 1. The '333 patent discloses a plunger member 118 (i.e. tamping instrument), which includes an instrument made of generally rigid material. (Figs. 6 and 7; Col. 5, ll. 34-56)
8. Apparatus according to claim 1 wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle terminus through the subcutaneous cannula.	
10. Apparatus according to claim 1 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	
11. Apparatus according to claim 10 wherein the cavity forming instrument includes an expandable structure.	
12. Apparatus for introducing material into bone through a subcutaneous cannula, the	'333 patent discloses an endoscopic device that delivers a quantity of material to a remote location within the body (such as into bone). (Abstract; Col. 1, ll. 6-10; Col. 5, ll. 53-59) The '333 discloses the insertion of the endoscopic

Claim of the '734 Patent	'333 Patent
apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	shaft 26 through a subcutaneous cannula. (Col. 3, ll. 55-58) The '333 patent discloses a delivery device (parts 10 and 90) to convey the material at a delivery pressure, which may be less than about 360 psi. (Figs. 1-2, 5-6; Col. 1, ll. 58-64; Col. 3, l. 58-Col. 4, l. 28; Col. 5, ll. 32-38, 47-52)
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure,	The '333 patent discloses endoscopic shaft 26 (i.e. a nozzle instrument) capable of. advancement into the subcutaneous cannula. (Col. 3, ll. 55-58) The '333 patent discloses a proximal fitting (tapered end 28 into port 22; u-shaped key 126 to key 110) to couple the endoscopic shaft 26 or tube portion 114 to the delivery device 10 or 90. (Figs. 2 and 6; Col. 3, ll. 51-55; Col. 5, ll. 21-32) The '333 patent discloses a nozzle bore (passageway 30 or 116) through which the material conveyed by the delivery device enters into the body (which includes bone) at the delivery pressure. (Figs. 2 and 7; Col. 3, ll. 58-65; Col. 5, ll. 34-38)
and a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula.	The '333 patent discloses endoscopic shaft 26 (i.e. a nozzle instrument) capable of advancement into the subcutaneous cannula. (Col. 3, ll. 55-58) The '333 patent discloses a plunger member 118 having terminus portion 124 capable of advancement into the nozzle bore (passageway 116) to close the nozzle bore, and with the endoscopic shaft 112, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula. (Fig. 6; Col. 5, ll. 34-56)
13. Apparatus according to claim 12 wherein the nozzle instrument includes marking to visually gauge the advancement of the nozzle instrument through the cannula.	
14. Apparatus according to claim 12 wherein the delivery device comprises a syringe.	
15. Apparatus for introducing material into bone through a	'333 patent discloses an endoscopic device that delivers a quantity of material to a remote location within the

Claim of the '734 Patent	'333 Patent
subcutaneous cannula, the apparatus comprising a subcutaneous cannula, a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi,	body (such as into bone). (Abstract; Col. 1, ll. 6-10; Col. 5, ll. 53-59) The '333 discloses the insertion of the endoscopic shaft 26 through a subcutaneous cannula. (Col. 3, ll. 55-58) The '333 patent discloses a delivery device (parts 10 and 90) to convey the material at a delivery pressure, which may be less than about 360 psi. (Figs. 1-2, 5-6; Col. 1, ll. 58-64; Col. 3, l. 58-Col. 4, l. 28; Col. 5, ll. 32-38, 47-52)
and a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone.	The '333 patent discloses a plunger member 118 (i.e. tamping instrument) having a terminus portion 124 or 128 capable of advancement into the subcutaneous cannula, and which, during advancement, urges material residing in the subcutaneous cannula into the body (which includes bone); the portion 124 or 128 thereof follows the material out of the end of the endoscopic member and protrudes therefrom to maneuver the material. (Figs. 6 and 7; Col. 3, ll. 55-58; Col. 5, ll. 34-56)
16. Apparatus according to claim 15 wherein the delivery device comprises a syringe.	
17. Apparatus according to claim 15 wherein the tamping instrument includes marking to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	
19. Apparatus according to claim 15 wherein the tamping instrument is made of a generally rigid material.	*See* above at claim 15. The '333 patent discloses a plunger member 118 (i.e. tamping instrument), which includes an instrument made of generally rigid material. (Figs. 6 and 7; Col. 5, ll. 34-56)
20. Apparatus according to claim 15 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	

Claim of the '734 Patent	'333 Patent
21. Apparatus according to claim 15 wherein the cavity forming instrument includes an expandable structure.	

OBVIOUSNESS OF '734 IN VIEW OF ONE OR MORE OF '631, '333, '152, '263, '404, '261, '196, AND/OR '348 PATENTS

It is my opinion that one or more of the asserted claims of the '734 patent is rendered obvious by one or more of the following prior art references: U.S. Patent Nos. 5,415,631, 5,312,333, 4,576,152, 4,801,263, 5,108,404, 5,741,261, 5,919,196 and/or 6,017,348. To one of ordinary skill in the art, there would have been a suggestion and motivation to combine any of the references above because all of the references pertain to the delivery of material into the bone. In addition, it is my opinion that many of the elements in the claims of the '734 patent are not novel at all. It is my opinion that at the time of the effective filing date of the '734 patent, the insertion of a tamping instrument into a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) in order to deliver material residing therein into bone would have been obvious to one of ordinary skill in the art. It is further my opinion that at the time of the effective filing date of the '734 patent, the inclusion of markings on a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) and/or markings on a tamping instrument inserted into the hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent), in order to measure the advancement of one instrument in relation to the other, would have been obvious to one of ordinary skill in the art. At the time of the filing date of the '734 patent, it was common for medical instruments, such as syringes, to include markings to measure the advancement of one instrument in

relation to another. The table below sets forth the elements that each of the references teaches. I reserve the right to supplement, modify or amend my opinions.

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses an osseous implant syringe for introducing substances into interdental bone. (Abstract) The '263 patent discloses an extension nozzle member 44 (i.e. cannula) or curved extension nozzle member 56 (i.e. cannula) through which material is introduced into bone (Figs. 4-7; Col. 2, l. 66- Col 3, l.7; Col. 4, l. 47-Col. 5, l.30; Col. 6, l. 51-Col. 7, l. 11) The '263 patent discloses a filling device member 68 for loading of the implant substances into the syringe barrel. (Abstract; Col. 3, ll.14-16; Figs. 8-9; Col. 5, l. 31 – Col. 6, l. 3; Col.6, ll. 22-40) The material can be delivered into bone at low pressure. The '152 patent discloses an injector for bone cement into bone cavity at low pressure (which would be less than about 360 psi). (Abstract; Col. 1, ll. 4-7, 57-61; Col. 3, ll. 41-45; Col. 3, l. 64-Col. 4, l. 4) The '152 patent discloses a nozzle tube 7 that establishes a path into the bone cavity. (Figs. 1 and 3; Col. 1, ll. 40-Col. 2, l. 2; Col. 3, ll. 46-51) The '152 patent discloses a cylinder tube 1 for receiving and delivering the bone cement with piston 12 (i.e. delivery device). (Figs. 1 and 5; Col. 1, ll. 40-49; Col. 2, ll. 52-55; Col. 3, ll. 34-45) The '261 patent discloses an endosurgical graft delivery assembly for introducing material into bone with delivery cannula 111; this material can be delivered at low pressure. (Figs. 20-21; Col. 10, ll. 41-49; Col. 13, ll. 41-59) The '348 patent discloses a bone emplacement tool that inserts a bone plug into the bone hole. (Col. 6, ll. 56- 58; Col. 10, ll. 57-64; Col. 13, ll. 30-57) The '348 patent discloses insertion of the harvester 270 including bone

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	plug 118 into a cannulated cylindrical endoscopic delivery guide (i.e. cannula) (Col. 10, l. 65 – Col. 11, l. 9; Col. 13, ll. 40-49) The '348 patent discloses a harvester 270 that is adapted to be slidably received in the cutting element bore 248, that includes a distal cavity 280 for receiving the bore plug cut by the cutting element 232 and through which the bone plug can enter bone at a low delivery pressure (Figs. 11-14; Col. 11, l.63-Col. 12, l. 13; Col. 12, ll. 55-61; Col.13, ll. 30-57) The '196 patent discloses graft and recipient harvesters with collared pins for transplantation of graft into the bone; delivery of this material can be at low pressure. (Abstract; Col. 2, ll. 16-27)
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure,	This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses a syringe barrel member 20 (i.e. nozzle instrument) capable of advancement into the extension nozzle member 44 or curved nozzle member 58 (i.e. cannula) (Figs. 2, 4-7; Col. 4, l. 47- 54, 62-66; Col. 6, ll. 51-54; Col. 6, ll. 66 - Col.7, l. 2) The '263 patent discloses a proximal fitting (neck 77 to outlet 28) to couple the nozzle instrument 20 to the delivery device 68 (Fig. 9; Col.5, ll. 50-58) The '263 patent discloses a nozzle outlet 28 through which the material conveyed enters bone at delivery pressure. (Fig. 2; Col. 3, l. 65-Col. 4, l. 11) The '152 patent discloses a nozzle element 6 with a proximal fitting such as a bayonet connection to couple the nozzle element to the delivery device. (Col. 2, ll. 5-7; Col. 2, l. 64 – Col. 3, l.12) The '152 patent discloses a nozzle terminus (distal end of nozzle tube 7) through which the material conveyed by the delivery device enters bone. (Figs. 3 and 5; Col. 1, ll. 50-56; Col. 1, l. 62-Col 2, l. 2; Col. 3, ll. 46-51; Col. 4, ll.4-8) The '261 patent discloses delivery cannula 111 (i.e. nozzle instrument) with opening 113 preferably surrounded by a funnel. (Figs. 20-21, Col. 13, ll. 41-59) The '261 patent discloses a nozzle terminus (distal end of

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	tube 111) through which the material conveyed by the delivery device enters bone by use of graft delivery piston 120. *Id.* The '348 patent discloses insertion of the harvester 270 including bone plug 118 into a cannulated cylindrical endoscopic delivery guide (i.e. cannula) (Col. 10, l. 65-Col. 11, l. 9; Col. 13, ll. 40-49) The '348 patent discloses a harvester 270 that is adapted to be slidably received and mated in the cutting element bore 248, and that includes a distal cavity 280 for receiving the bore plug cut by the cutting element 232 (Figs. 11-13; Col. 11, l. 63-Col. 12, l. 13; Col. 12, ll. 55-61) Harvester 270 has a terminus (distal end of shaft 194) through which the bone plug enters bone at the delivery pressure. (Fig. 14; Col.13, ll. 30-57) The '196 patent discloses a hollow tube harvester 2 with terminus through which the graft enters bone. (Fig. 19, Col. 2, ll. 16-23; Col. 3, ll. 19-30; Col. 5, ll. 33-38; Col.8, ll. 20-27)
and a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.	At the time of the effective filing date of the '734 patent, the insertion of a tamping instrument into a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) in order to deliver material residing therein into bone would have been obvious to one of ordinary skill in the art. This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses a syringe plunger member 10 capable of advancement into the syringe barrel member 20 and having a terminus 14 and plunger extension 54 which during advancement urges material residing in the syringe barrel member 20 into the extension nozzle member 44 or 56 into bone (Figs. 1-7; Col. 4, ll. 24-Col. 5, l.2; Col. 6, ll. 50-65) The '152 patent discloses a ram 10 having a terminus capable of advancing in the nozzle tube 7 to eject bone cement from the nozzle tube 7 into bone. (Figs. 3-5; Col. 1, ll. 54-56; Col. 1, l. 62-Col. 2, l. 2; Col. 3, ll. 25-33, 46-56)

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	The '261 patent discloses a graft delivery piston 120 capable of advancement in the delivery cannula 111 and having a terminus which, during the advancement, urges graft material from the cannula into the fusion site. (Figs. 20-21; Col. 13, ll. 41-59) The '348 patent discloses plunger 292 with terminus capable of advancement in the cannula to urge the bone plug into the bone hole, because the plunger has length sufficient to push bone plug 118 out of harvester cavity 280 and preferably 1-5 mm further. (Fig. 14; Col. 13, ll. 30-57) The '196 patent discloses a collared pin 26 with terminus capable of advancement in the hollow tube harvester 2 to urge the graft into the bone (Figs. 2, 5, 19; Col. 2, ll.16-23; Col. 3, ll. 19-30; Col. 5, ll. 24-38; Col. 8, ll. 20-27)
3. Apparatus according to claim 1 wherein the nozzle instrument is made of a generally rigid material.	*See* above at claim 1. This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses that all components, including the syringe barrel member 20, can be made of delrin, a generally rigid material. (Col. 2, ll. 39-42) The '152 patent discloses a nozzle element 6, which includes an instrument made of generally rigid material. (Fig. 3; Col. 1, ll. 50-53; Col. 3, ll. 3-18) The '261 patent discloses a delivery cannula 111, which includes an instrument made of generally rigid material. (Figs. 20-21; Col. 13, ll. 41-59) The '348 patent discloses a cannulated tube harvester that can be made of generally rigid material. (Col. 12, ll. 25-45) The '196 patent discloses a hollow tube harvester 2 that can be made of generally rigid material with sharp distal cutting edges to be driven into the bone (Col. 2, l. 44-60)
4. Apparatus according to claim 1 wherein the delivery device comprises a syringe.	*See* above at claim 1. The '263 patent discloses a filling device member 68 for loading of the implant substances into the syringe barrel.

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	(Abstract; Col. 3, ll. 14-16; Fig. 8-9; Col. 5, l 31–Col. 6, l. 3; Col.6, ll. 22- 40) The '152 patent discloses a cylinder tube 1 for receiving the bone cement with piston 12 (i.e. delivery device) which comprises a syringe. (Figs. 1 and 5; Col. 1, ll. 40-49; Col. 2, ll. 52-55; Col. 3, ll. 34-45)
5. Apparatus according to claim 1 wherein the tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula.	*See* above at claim 1. At the time of the effective filing date of the '734 patent, the inclusion of markings on a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) and/or markings on a tamping instrument inserted into the hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent), in order to measure the advancement of one instrument in relation to the other, would have been obvious to one of ordinary skill in the art. At the time of the filing date of the '734 patent, it was common for medical instruments, such as syringes, to include markings to measure the advancement of one instrument in relation to another. The '152 patent discloses a ram 10 with spaced circular discs 16 for guiding the ram in the nozzle tube 7. (Figs. 3-5; Col. 4, ll. 14-16). These spaced circular discs can serve as markings to visually gauge the advancement of the ram. The '196 patent discloses a harvester 2 with markings 12 for visual confirmation of depth during insertion (Fig. 1; col. 2, ll. 33-42; Col. 4, ll. 55-50; Col. 5, ll. 14-18)
7. Apparatus according to claim 1 wherein the tamping instrument is made of a generally rigid material.	*See* above at claim 1. This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses that all components, including the syringe plunger member 10, can be made of delrin, a generally rigid material. (Col. 2, ll. 39-42) The '152 patent discloses a ram 10, which includes an instrument made of generally rigid material. (Fig. 4, Col. 1, ll. 54-56; Col. 1, l. 66- Col. 2, l.2; Col. 3, ll. 19-33)

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	The '261 patent discloses a graft delivery piston 120, which includes an instrument made of generally rigid material. (Fig. 3; Col. 1, ll. 50-53; Col. 3, ll. 3-18) The '348 patent discloses a plunger 292 that can be made of a generally rigid material. (Fig. 14; Col. 13, ll. 52-57) The '196 patent discloses a collared pin 26 that can be made of a generally rigid material. (Fig. 5; Col. 2, ll. 20-23; Col.3, ll. 19-27; Col. 5, ll. 19-38)
8. Apparatus according to claim 1 wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle terminus through the subcutaneous cannula.	*See* above at claim 1. At the time of the effective filing date of the '734 patent, the inclusion of markings on a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) and/or markings on a tamping instrument inserted into the hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent), in order to measure the advancement of one instrument in relation to the other, would have been obvious to one of ordinary skill in the art. At the time of the filing date of the '734 patent, it was common for medical instruments, such as syringes, to include markings to measure the advancement of one instrument in relation to another. The '152 patent discloses a ram 10 with spaced circular discs 16 for guiding the ram in the nozzle tube 7. (Figs. 3-5; Col. 4, ll. 14-16) These spaced circular discs can serve as markings to visually gauge the advancement of the ram. The '196 patent discloses a harvester 2 with markings 12 for visual confirmation of depth during insertion (Fig. 1; col. 2, ll. 33-42; Col. 4, ll. 55-50; Col. 5, ll. 14-18)
10. Apparatus according to claim 1 and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.	*See* above at claim 1. The '404 patent discloses an inflatable cavity forming instrument capable of advancement through the subcutaneous cannula (part 30) to compress cancellous bone. (Figs. 21-24; Col. 6, l. 65 – Col. 7 l. 36)
11. Apparatus according to claim 10 wherein the cavity	*See* above at claim 1. The '404 patent discloses an inflatable cavity forming

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
forming instrument includes an expandable structure.	instrument with an expandable structure. (*passim*)
12. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including a subcutaneous cannula, a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses an osseous implant syringe for introducing substances into interdental bone. (Abstract) The '263 patent discloses an extension nozzle member 44 (i.e. cannula) or curved extension nozzle member 56 (i.e. cannula) through which material is introduced into bone (Figs. 4-7; Col. 2, l. 66- Col 3, l.7; Col. 4, l. 47-Col. 5, l.30; Col. 6, l. 51-Col. 7, l. 11) The '263 patent discloses a filling device member 68 for loading of the implant substances into the syringe barrel. (Abstract; Col. 3, ll.14-16; Figs. 8-9; Col. 5, l. 31 – Col. 6, l. 3; Col.6, ll. 22-40) The material can be delivered into bone at low pressure. The '152 patent discloses an injector for bone cement into bone cavity at low pressure (which would be less than about 360 psi). (Abstract; Col. 1, ll. 4-7, 57-61; Col. 3, ll. 41-45; Col. 3, l. 64-Col. 4, l. 4) The '152 patent discloses a nozzle tube 7 that establishes a path into the bone cavity. (Figs. 1 and 3; Col. 1, ll. 40-Col. 2, l. 2; Col. 3, ll. 46-51) The '152 patent discloses a cylinder tube 1 for receiving and delivering the bone cement with piston 12 (i.e. delivery device). (Figs. 1 and 5; Col. 1, ll. 40-49; Col. 2, ll. 52-55; Col. 3, ll. 34-45) The '261 patent discloses an endosurgical graft delivery assembly for introducing material into bone with delivery cannula 111; this material can be delivered at low pressure. (Figs. 20-21; Col. 10, ll. 41-49; Col. 13, ll. 41-59) The '348 patent discloses a bone emplacement tool that inserts a bone plug into the bone hole. (Col. 6, ll. 56- 58; Col. 10, ll. 57-64; Col. 13, ll. 30-57) The '348 patent discloses insertion of the harvester 270 including bone plug 118 into a cannulated cylindrical endoscopic delivery guide (i.e. cannula) (Col. 10, l. 65 – Col. 11, l. 9;

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	Col. 13, ll. 40-49) The '348 patent discloses a harvester 270 that is adapted to be slidably received in the cutting element bore 248, that includes a distal cavity 280 for receiving the bore plug cut by the cutting element 232 and through which the bone plug can enter bone at a low delivery pressure (Figs. 11-14; Col. 11, l.63-Col. 12, l. 13; Col. 12, ll. 55-61; Col.13, ll. 30-57) The '196 patent discloses graft and recipient harvesters with collared pins for transplantation of graft into the bone; delivery of this material can be at low pressure. (Abstract; Col. 2, ll. 16-27)
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure,	This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses a syringe barrel member 20 (i.e. nozzle instrument) capable of advancement into the extension nozzle member 44 or curved nozzle member 58 (i.e. cannula) (Figs. 2, 4-7; Col. 4, l. 47- 54, 62-66; Col. 6, l. 51-54; Col. 6, l. 66-Col.7, l. 2) The '263 patent discloses a proximal fitting (neck 77 to outlet 28) to couple the nozzle instrument 20 to the delivery device 68 (Fig. 9, Col.5, ll. 50-58) The '263 patent discloses an axial lumen 24 (i.e. nozzle bore) through which the material conveyed enters bone at delivery pressure. (Fig. 2; Col. 3, l. 65-Col. 4, l. 11) The '152 patent discloses a nozzle element 6 with a proximal fitting such as a bayonet connection to couple the nozzle element to the delivery device. (Col. 2, ll. 5-7; Col. 2, l. 64 –Col. 3, l. 12) The '152 patent discloses a nozzle bore (passageway of nozzle tube 7) through which the material conveyed by the delivery device enters bone. (Figs. 3 and 5; Col. 1, ll. 50-56; Col. 1, l. 62-Col 2, l.2; Col. 3, ll. 46-51; Col. 4, ll. 4-8) The '261 patent discloses delivery cannula 111 (i.e. nozzle instrument) with opening 113 preferably surrounded by a funnel. (Figs. 20-21; Col. 13, ll. 41-59) The '261 patent discloses a nozzle bore (passageway in tube 111) through which the material conveyed by the delivery device enters bone. *Id.*

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	The '348 patent discloses insertion of the harvester 270 including bone plug 118 into a cannulated cylindrical endoscopic delivery guide (i.e. cannula) (Col. 10, l. 65-Col. 11, l. 9; Col. 13, ll. 40-49) The '348 patent discloses a harvester 270 that is adapted to be slidably received and mated in the cutting element bore 248, and that includes a distal cavity 280 for receiving the bore plug cut by the cutting element 232 (Figs. 11-13; Col. 11, l. 63-Col. 12, l. 13; Col. 12, ll. 55-61) Harvester 270 has a bore 276 through which the bone plug enters bone at the delivery pressure. (Fig. 14; Col.13, ll. 30-57) The '196 patent discloses a hollow tube harvester 2 with bore through which the graft enters bone. (Fig. 19, Col. 2, ll.16-23; Col. 3, ll. 19-30; Col. 5, ll. 33-38; Col. 8, ll. 20-27)
and a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula.	At the time of the effective filing date of the '734 patent, the insertion of a tamping instrument into a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) in order to deliver material residing therein into bone would have been obvious to one of ordinary skill in the art. This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses a syringe plunger member 10 capable of advancement into the axial lumen 24 of the syringe barrel member 20 (i.e. nozzle bore) through the inlet 30 to close the nozzle bore. (Figs. 1-3, Col. 3, l. 65-Col. 4, l. 46) The '152 patent discloses a ram 10 capable of advancement into the nozzle bore (passageway of nozzle tube 7) through the proximal fitting to close the nozzle bore. (Figs. 3-5; Col. 1, ll. 54-56, Col. 1, l. 62 - Col. 2, l.2; Col. 3, ll. 25-33, 46-56) The '261 patent discloses graft delivery piston 120 (i.e. stylet) capable of advancement into the passageway of delivery cannula 111 (i.e. nozzle bore) through the opening 113 preferably surrounded by a funnel to close the nozzle bore. (Figs. 20-21, Col. 13, ll.41-59) The '261

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	patent discloses that in one embodiment where the cannula 111 is 15 cm, the piston 120 is 30 cm in length. (Col. 13, ll. 58-59) The '348 patent discloses plunger 292 capable of advancement into the harvester 270 through the proximal fitting 286 to close the bore 276 of the harvester 270. (Fig. 14; Col. 11, l. 63-Col. 12, l. 13; Col. 13, ll. 30-57) The '196 patent discloses a collared pin 26 capable of advancement in the hollow tube harvester 2 to close the bore of harvester 2 (Figs. 2, 5, 19; Col. 2, ll. 16-23; Col. 3, ll. 19-30; Col. 5, ll. 24-38; Col.8, ll. 20-27)
13. Apparatus according to claim 12 wherein the nozzle instrument includes marking to visually gauge the advancement of the nozzle instrument through the cannula.	*See* above at claim 12. At the time of the effective filing date of the '734 patent, the inclusion of markings on a hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent) and/or markings on a tamping instrument inserted into the hollow tube (such as the cannula or nozzle instrument disclosed in the '734 patent), in order to measure the advancement of one instrument in relation to the other, would have been obvious to one of ordinary skill in the art. At the time of the filing date of the '734 patent, it was common for medical instruments, such as syringes, to include markings to measure the advancement of one instrument in relation to another. The '152 patent discloses a ram 10 with spaced circular discs 16 for guiding the ram in the nozzle tube 7. (Figs. 3-5; Col. 4, ll. 14-16). These spaced circular discs can serve as markings to visually gauge the advancement of the ram. The '196 patent discloses a harvester 2 with markings 12 for visual confirmation of depth during insertion (Fig. 1; col. 2, ll. 33-42; Col. 4, ll. 55-50; Col. 5, ll. 14-18)
14. Apparatus according to claim 12 wherein the delivery device comprises a syringe.	*See* above at claim 12. The '263 patent discloses a filling device member 68 for loading of the implant substances into the syringe barrel. (Abstract; Col. 3, ll. 14-16; Fig. 8-9; Col. 5, l. 31–Col. 6, l. 3; Col. 6 , ll. 22- 40)

Claim of the '734 Patent	Combination of '631, '333, '152, '263, '404, '261, '196, and/or '348 Patents
	The '152 patent discloses a cylinder tube 1 for receiving the bone cement with piston 12 (i.e. delivery device) which comprises a syringe. (Figs. 1 and 5; Col. 1, ll. 40-49; Col. 2, ll. 52-55; Col. 3, ll. 34-45)
15. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising a subcutaneous cannula, a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi,	This element is anticipated and rendered obvious by each of the '631 and '333 patents, as set forth in the anticipation charts with respect to the '734 patent. The '263 patent discloses an osseous implant syringe for introducing substances into interdental bone. (Abstract) The '263 patent discloses an extension nozzle member 44 (i.e. cannula) or curved extension nozzle member 56 (i.e. cannula) through which material is introduced into bone (Figs. 4-7; Col. 2, l. 66- Col 3, l.7; Col. 4, l. 47-Col. 5, l.30; Col. 6, l. 51-Col. 7, l. 11) The '263 patent discloses a filling device member 68 for loading of the implant substances into the syringe barrel. (Abstract; Col. 3, ll.14-16; Figs. 8-9; Col. 5, l. 31 – Col. 6, l. 3; Col.6, ll. 22-40) The material can be delivered into bone at low pressure. The '152 patent discloses an injector for bone cement into bone cavity at low pressure (which would be less than about 360 psi). (Abstract; Col. 1, ll. 4-7, 57-61; Col. 3, ll. 41-45; Col. 3, l. 64-Col. 4, l. 4) The '152 patent discloses a nozzle tube 7 that establishes a path into the bone cavity. (Figs. 1 and 3; Col. 1, ll. 40-Col. 2, l. 2; Col. 3, ll. 46-51) The '152 patent discloses a cylinder tube 1 for receiving and delivering the bone cement with piston 12 (i.e. delivery device). (Figs. 1 and 5; Col. 1, ll. 40-49; Col. 2, ll. 52-55; Col. 3, ll. 34-45) The '261 patent discloses an endosurgical graft delivery assembly for introducing material into bone with delivery cannula 111; this material can be delivered at low pressure. (Figs. 20-21; Col. 10, ll. 41-49; Col. 13, ll. 41-59) The '348 patent discloses a bone emplacement tool that inserts a bone plug into the bone hole. (Col. 6, ll. 56- 58;