

US008870962B2

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

(10) **Patent No.:** **US 8,870,962 B2**
(45) **Date of Patent:** **Oct. 28, 2014**

(54) **REVERSE SHOULDER PROSTHESIS**

(75) Inventors: **Christopher P. Roche**, Gainesville, FL (US); **Cary M. Mauldin**, Lake City, FL (US); **Pierre Flurin**, Bordeaux-Merignac (FR); **Thomas Wright**, Gainesville, FL (US); **Joseph Zuckerman**, New York, NY (US)

(73) Assignee: **Exactech, Inc.**, Gainesville, FL (US)
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 412 days.

(21) Appl. No.: **12/569,206**
(22) Filed: **Sep. 29, 2009**

(65) **Prior Publication Data**
US 2010/0087927 A1 Apr. 8, 2010
Related U.S. Application Data

(62) Division of application No. 11/690,516, filed on Mar. 23, 2007.
(60) Provisional application No. 60/785,664, filed on Mar. 23, 2006, provisional application No. 60/747,492, filed on May 17, 2006, provisional application No. 60/888,982, filed on Feb. 9, 2007.

(51) **Int. Cl.**
A61F 2/40 (2006.01)
A61B 17/80 (2006.01)
A61F 2/30 (2006.01)
A61B 17/86 (2006.01)
A61F 2/28 (2006.01)

(52) **U.S. Cl.**
CPC **A61F 2/40** (2013.01); **A61B 17/8047** (2013.01); **A61F 2002/30313** (2013.01); **A61F 2002/30902** (2013.01); **A61F 2230/0008** (2013.01); **A61F 2002/4085** (2013.01); **A61F 2310/00023** (2013.01); **A61F 2/4014** (2013.01); **A61F 2002/30125** (2013.01); **A61F 2230/0063** (2013.01); **A61B 17/86** (2013.01); **A61F 2310/00029** (2013.01); **A61F 2250/0006** (2013.01); **A61F 2002/30538** (2013.01); **A61F 2002/30616** (2013.01); **A61F 2002/30901**

(2013.01); **A61F 2002/30784** (2013.01); **A61F 2250/0074** (2013.01); **A61F 2002/3056** (2013.01); **A61F 2002/2835** (2013.01)

USPC **623/19.12**
(58) **Field of Classification Search**
USPC **623/19.12, 23.39, 23.4, 19.13**
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,869,730 A 3/1975 Skobel
3,916,451 A 11/1975 Buechel et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0345133 6/1989
EP 0538895 4/1993
(Continued)

OTHER PUBLICATIONS

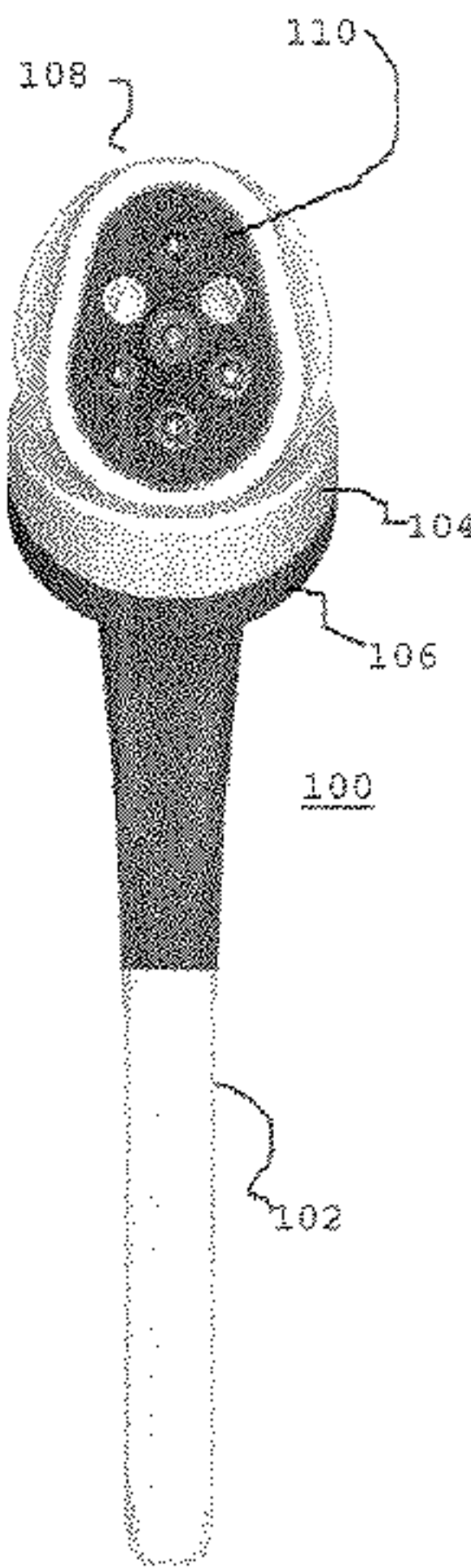
English language abstract of French Patent No. 2776506.
(Continued)

Primary Examiner — Bruce E Snow
Assistant Examiner — Melissa Hoban
(74) *Attorney, Agent, or Firm* — Greenberg Traurig, LLP; Danielle T. Abramson

(57) **ABSTRACT**

Various embodiments of the present invention relate to an apparatus and method for reverse shoulder arthroplasty (e.g., reverse total shoulder arthroplasty). In one specific example, a glenoid component used to resurface the scapula may be provided. Of note, unlike traditional total shoulder arthroplasty the glenoid component in a reverse shoulder is convex rather than concave; it acts as a physical stop to prevent the superior migration of the humeral head—a typical occurrence in patients suffering from rotator cuff tear arthropathy (CTA).

7 Claims, 62 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

3,978,528 A 9/1976 Crep
4,003,095 A 1/1977 Gristina
4,040,131 A 8/1977 Gristina
4,179,758 A 12/1979 Gristina
4,206,517 A 6/1980 Pappas
4,229,840 A 10/1980 Gristina
4,261,062 A 4/1981 Amstutz et al.
4,279,041 A * 7/1981 Buchholz 623/19.12
4,328,593 A 5/1982 Sutter et al.
4,550,450 A 11/1985 Kinnett
4,653,487 A 3/1987 Maale
4,693,723 A 9/1987 Gabard
4,964,865 A 10/1990 Burkhead et al.
4,986,833 A 1/1991 Worland
5,013,313 A 5/1991 Surer
5,032,132 A 7/1991 Matsen, III et al.
5,080,673 A 1/1992 Burkhead et al.
5,154,719 A 10/1992 Cotrel
5,255,838 A 10/1993 Gladdish, Jr. et al.
5,314,479 A * 5/1994 Rockwood et al. 623/19.14
5,437,677 A 8/1995 Shearer et al.
5,462,563 A 10/1995 Shearer et al.
5,489,310 A 2/1996 Mikhail
5,593,448 A 1/1997 Dong
5,611,800 A 3/1997 Davis et al.
5,702,447 A 12/1997 Welch et al.
5,702,453 A 12/1997 Rabbe et al.
5,800,551 A 9/1998 Williamson et al.
5,976,141 A 11/1999 Haag et al.
5,989,254 A 11/1999 Katz
6,045,582 A * 4/2000 Prybyla 623/19.11
6,156,069 A 12/2000 Amstutz
6,228,119 B1 5/2001 Ondrla et al.
6,228,120 B1 5/2001 Leonard
6,364,910 B1 4/2002 Shultz et al.
6,379,386 B1 4/2002 Resch et al.
6,406,495 B1 6/2002 Schoch
6,514,287 B2 2/2003 Ondrla et al.
6,673,115 B2 1/2004 Resch et al.
6,679,916 B1 1/2004 Frankle et al.
6,699,289 B2 3/2004 Iannotti et al.
6,736,851 B2 5/2004 Maroney
6,790,234 B1 9/2004 Frankle
6,911,047 B2 6/2005 Rockwood, Jr. et al.
7,241,314 B1 7/2007 Winslow
7,462,197 B2 12/2008 Tornier et al.
7,621,961 B2 11/2009 Stone
7,753,959 B2 7/2010 Berelsman et al.
2003/0158605 A1 8/2003 Tornier
2004/0006342 A1 1/2004 Altarac et al.
2004/0034433 A1 * 2/2004 Chan et al. 623/23.39
2004/0059424 A1 3/2004 Guederian et al.
2004/0064190 A1 4/2004 Ball et al.
2004/0122519 A1 6/2004 Wiley et al.
2004/0122520 A1 6/2004 Lipman et al.
2004/0138754 A1 7/2004 Lang et al.
2004/0220673 A1 * 11/2004 Pria 623/19.12
2004/0225360 A1 11/2004 Malone
2004/0225367 A1 11/2004 Glien et al.
2004/0236424 A1 11/2004 Berez et al.
2005/0015131 A1 1/2005 Fourcault et al.
2005/0049709 A1 3/2005 Tornier et al.
2005/0060039 A1 3/2005 Cyprien
2005/0209700 A1 9/2005 Rockwood, Jr. et al.
2005/0261775 A1 * 11/2005 Baum et al. 623/19.12
2005/0278032 A1 * 12/2005 Tornier et al. 623/19.12
2006/0020344 A1 1/2006 Shultz et al.
2006/0229726 A1 * 10/2006 Ek 623/17.11
2006/0235530 A1 * 10/2006 Shelokov 623/17.15
2006/0235537 A1 * 10/2006 Kuczynski et al. 623/20.3
2006/0259148 A1 * 11/2006 Bar-Ziv 623/19.14
2008/0058949 A1 * 3/2008 Dees et al. 623/20.35

FOREIGN PATENT DOCUMENTS

EP 0998885 5/2000
EP 1 064 890 A1 1/2001
EP 1486183 12/2004
EP 1520561 4/2005
FR 2652498 4/1991
FR 27765065 10/1999
FR 2790198 1/2000
FR 2 871 369 A1 12/2005
GB 2405346 3/2005
WO 2004/080331 9/2004

OTHER PUBLICATIONS

English language abstract of European Publication No. 1486183.
Official Action for U.S. Appl. No. 11/690,516 dated Jul. 27, 2009.
Boileau, P. et al. Grammont Reverse Prosthesis: Design, Rationale, and Biomechanics. JSES January/February: 147S-161S. 2005.
Checroun, A. J. et al. Fit of Current Glenoid Component Designs: an Anatomic Cadaver Study. JSES. vol. 11, #6: 614-617. 2002.
De Wilde, L. et al. Shoulder Prosthesis Treating Cuff Tear Arthropathy: a comparative biomechanical study. JOR 22: 1222-1230. 2004.
De Wilde, L. et al. Functional Recovery after a Reverse Prosthesis for Reconstruction of the Proximal Humerus in Tumor Surgery. CORR. #430: 156-162. 2005.
Grammont, P. M. et al. Etude et Realisation D'une Nouvelle Prothese D'Paule. Rhumatologie. #39: 17-22. 1987.
Iannotti, J. P. et al. The Normal Glenohumeral Relationships. JBJS. vol. 74-A, #4: 491-500 1992.
Katzner, A. Two-Year Results After Exchange Shoulder Arthroplasty Using Inverse Implants. Orthopedics. vol. 27, #11: 1165-1167. 2004.
Mell, A. G. et al. Effect of Rotator Cuff Tear Size on Shoulder Kinematics. Transactions of the 51st Annual Meeting of the Orthopaedic Research Society. Poster #0623. 2005.
Neer, C. S. et al. Cuff Tear Arthropathy. JBJS. #65: 1232-1244. 1983.
Nyffeler, R. W. et al. Biomechanical Relevance of Glenoid Component Positioning in the Reverse Delta III Total Shoulder Prosthesis. JSES. vol. 14 # 5: 524-528. Sep./Oct. 2005.
Rittmeister, M. et al. Grammont Reverse Total Shoulder Arthroplasty in Patients with Rheumatoid Arthritis and Nonreconstructable Rotator Cuff Lesions. JSES. January/February: 17-22. 2001.
Sirveaux, F. et al. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. JBJS 86-B: 388-395. 2004.
Vanhove, B. Grammont's Reverse Shoulder Prosthesis for Rotator Cuff Arthropathy. A Retrospective Study of 32 Cases. Acta Orthop Belg. #70 (3): 219-225. 2004.
Walch, G. The Reverse Ball and Socket: When is it Indicated? Orthopaedics Today. pp. 18-20.
Non-Final Office Action mailed from the USPTO on Oct. 21, 2009 for U.S. Appl. No. 11/690,516.
Final Office Action mailed from USPTO on Apr. 16, 2010 for U.S. Appl. No. 11/690,516.
Supplementary European Search Report issued in European Patent Appln. No. 07759285.5 dated Mar. 19, 2012.
Boileau et al., "Neer Award 2005: The Grammont reverse shoulder prosthesis: Results in cuff tear arthritis, fracture sequelae, and revision arthroplasty", J Shoulder Elbow Surg Sep./Oct. 2006; © 2006 Journal of Shoulder and Elbow Surgery Board of Trustees, pp. 527-240.
Boileau et al., "Grammont reverse prosthesis: Design, rationale, and biomechanics", J Shoulder Elbow Surg Jan./Feb. 2005; © 2005 Journal of Shoulder and Elbow Surgery Board of Trustees, pp. 147S-161S.
Boileau et al., "Normal and pathological Anatomy of the glenoid", in Shoulder Arthroplasty; Springer-Verlag Heidelberg, pp. 127-140, 1990 <<<http://www.maitrise-orthop.com/viewPage.do?id=575>>>.
Bufquin et al., "Reverse shoulder arthroplasty for the treatment of three- and four-part fractures of the proximal humerus in the eld

(56)

References Cited

OTHER PUBLICATIONS

erly—A Prospective Review of 43 Cases with a Short-Term Follow-up” The Journal of Bone & Joint Surgery (Br) 2007; pp. 516-520.

Farron et al., “Risks of loosening of a prosthetic glenoid implanted in retroversion”, J Shoulder Elbow Surg Jul./Aug. 2006, © 2006 Journal of Shoulder and Elbow Surgery Board of Trustees, pp. 521-526.

Gillespie et al., “Eccentric Reaming in Total Shoulder Arthroplasty: A Cadaveric Study”, Orthopedics 2009; pp. 1-7<<<http://www.orthosupersite.com/view.asp?rid=33723>>>.

Hopkins et al., “The effects of glenoid component alignment variations on cement mantle stresses in total shoulder arthroplasty”, J Shoulder Elbow Surg, vol. 13, No. 6, © 2004 Journal of Shoulder and Elbow Surgery Board of Trustees, pp. 668-675.

Nuttall et al., “A study of the micromovement of pegged and keeled glenoid components compared using radiostereometric analysis”, J Shoulder Elbow May/Jun. 2007, vol. 16, No. 3S; © 2007 Journal of Shoulder and Elbow Surgery Board of Trustees, pp. 65S-70S.

Shapiro et al. “Biomechanical effects of glenoid retroversion in total shoulder arthroplasty”, J Shoulder Elbow May/Jun. 2007, vol. 16, No. 3S; © 2007 Journal of Shoulder and Elbow Surgery Board of Trustees, pp. 90S-95S.

Simovitch et al., “Predictors of Scapular Notching in Patients Managed with the Delta III Reverse Total Shoulder Replacement”, The Journal of Bone & Joint Surgery 2007; 89, pp. 588-600.

Sirveaux et al., Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff—Results of a Multicentre Study of 80 Shoulders; The Journal of Bone & Joint Surgery (Br); 2004; 86-B, pp. 388-395.

Stechel et al., “Reversed shoulder arthroplasty in cuff tear arthritis, fracture sequelae, and revision arthroplasty”, Acta Orthopaedica 2010; 81 (3), pp. 367-372.

Vanhove et al., “Grammont’s reverse shoulder prosthesis for rotator cuff arthropathy. A retrospective study of 32 cases”, Acta Orthop. Belg., 2004, 70, pp. 219-225.

Werner et al., “Treatment of Painful Pseudoparesis Due to Irreparable Rotator Cuff Dysfunction with the Delta III Reverse-Ball-and-Socket Total Shoulder Prosthesis”, The Journal of Bone & Joint Surgery, vol. 87-A, No. 7, Jul. 2005, pp. 1476-1486.

Yian et al., “Radiographic and Computer Tomography Analysis of Cemented Pegged Polyethylene Glenoid Components in Total Shoulder Replacement”, The Journal of Bone & Joint Surgery, vol. 87-A, No. 9, Sep. 2005, pp. 1928-1936.

“Major BioJoint System: The New Frontier in Natural Biointegration”, Finceramica Biomedical Solutions (4 pgs).

* cited by examiner

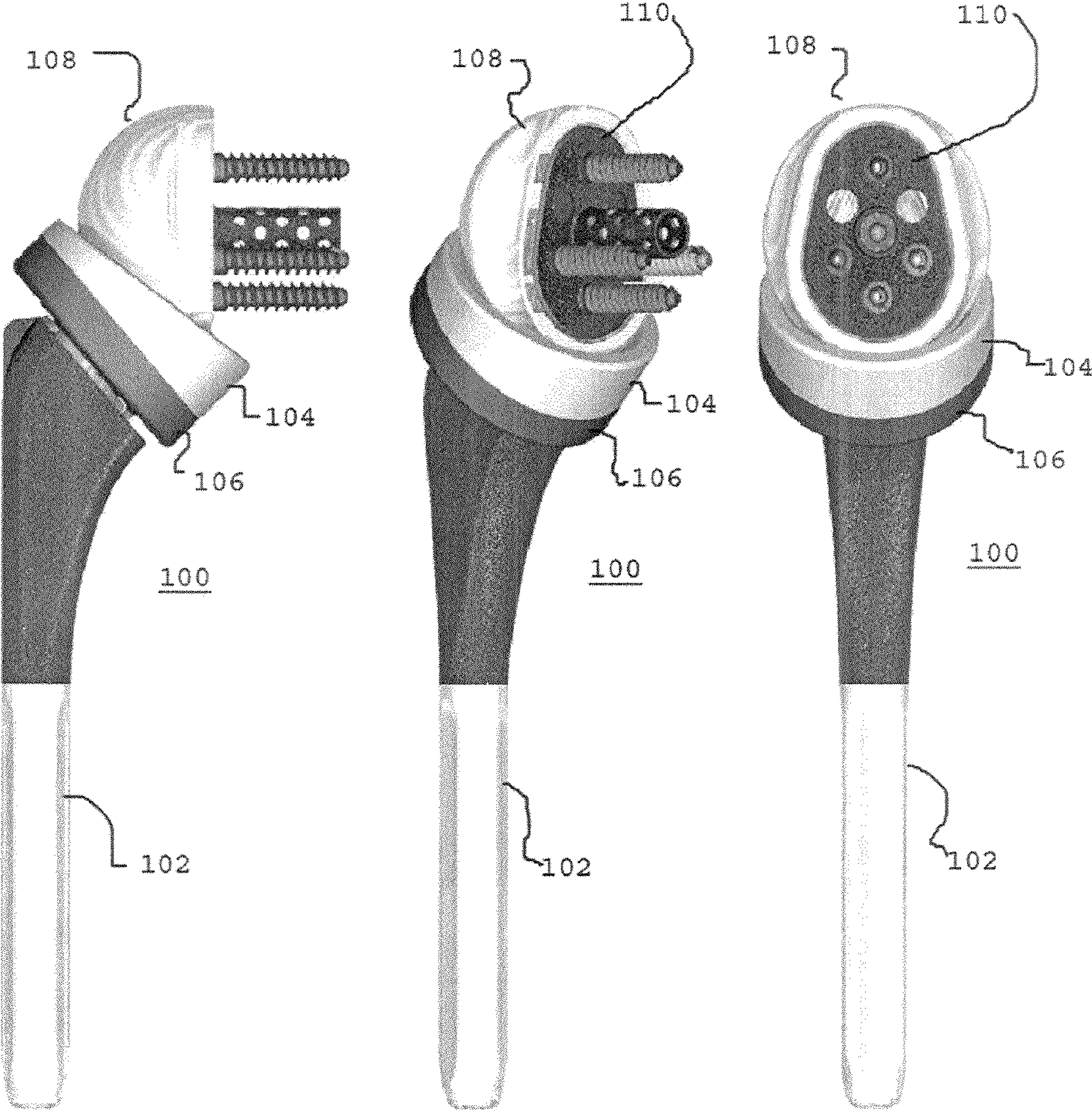


Fig. 1A

Fig. 1B

Fig. 1C

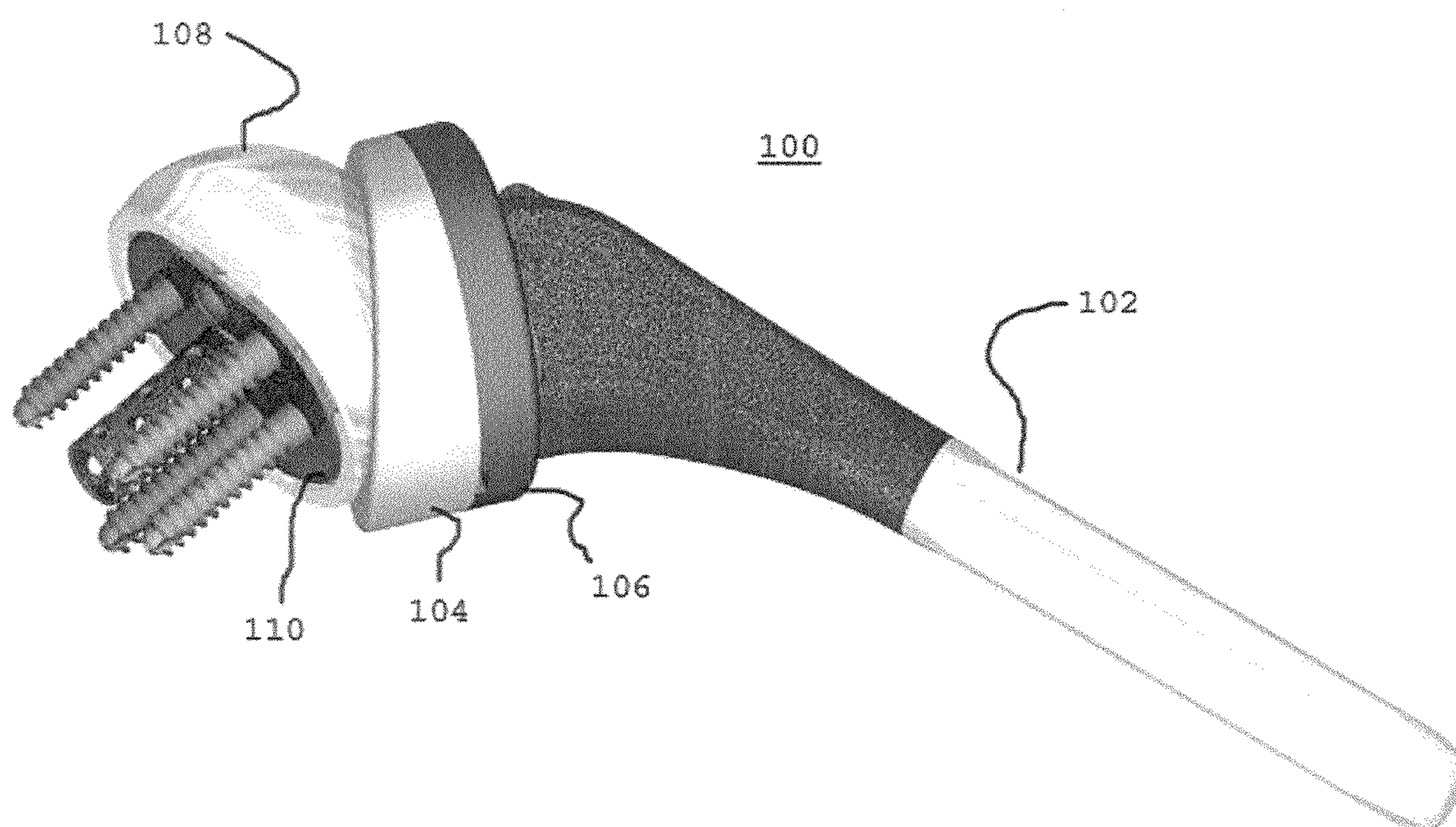
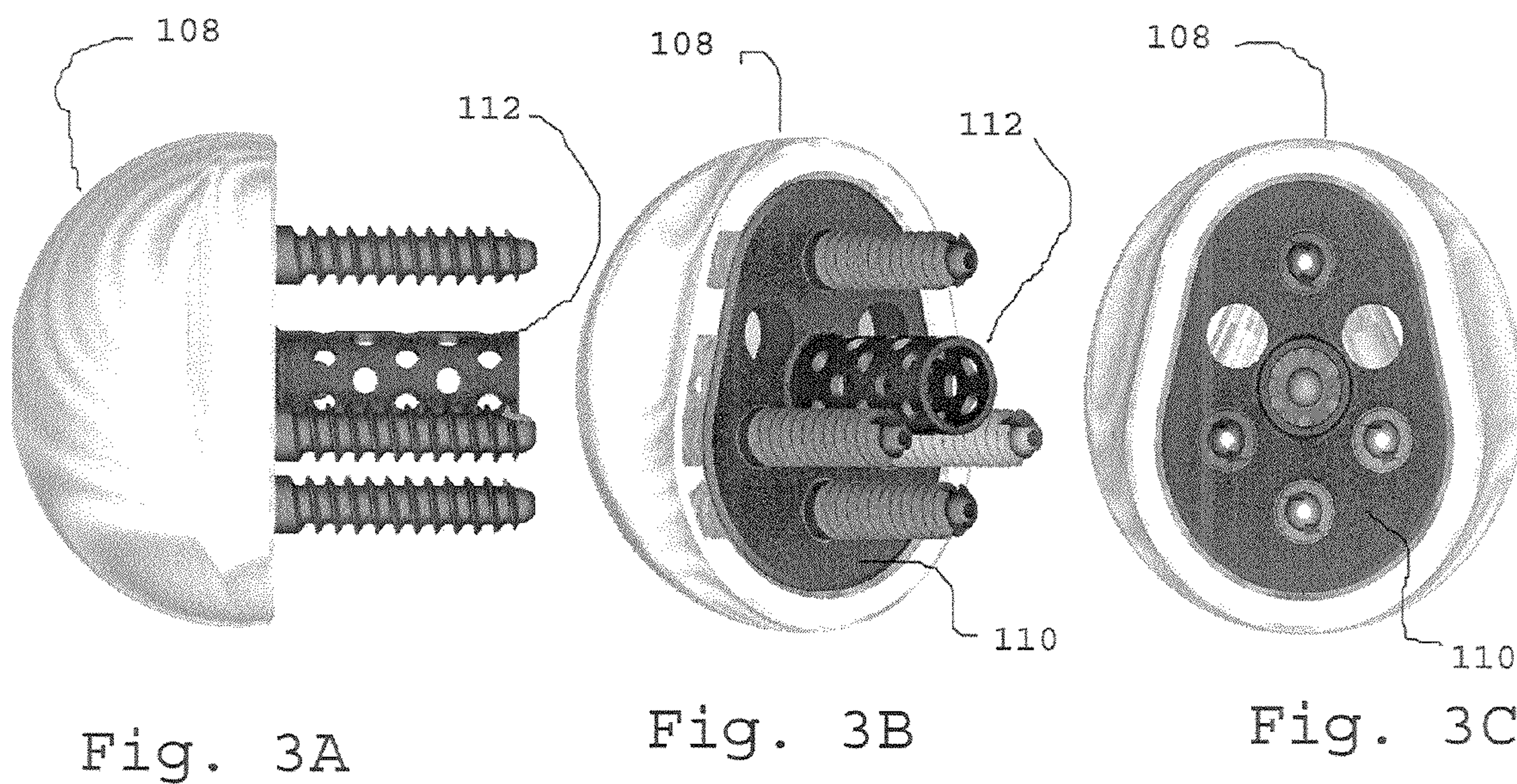


Fig. 2



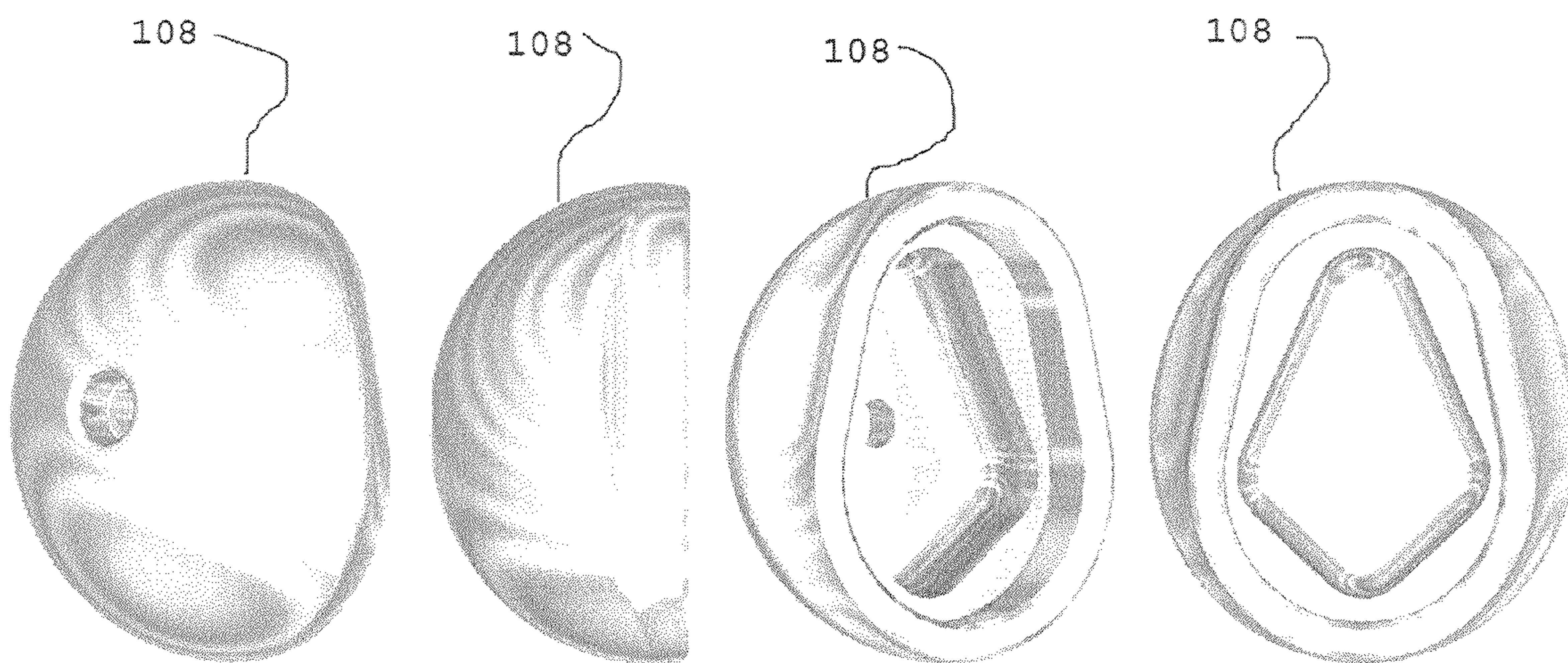
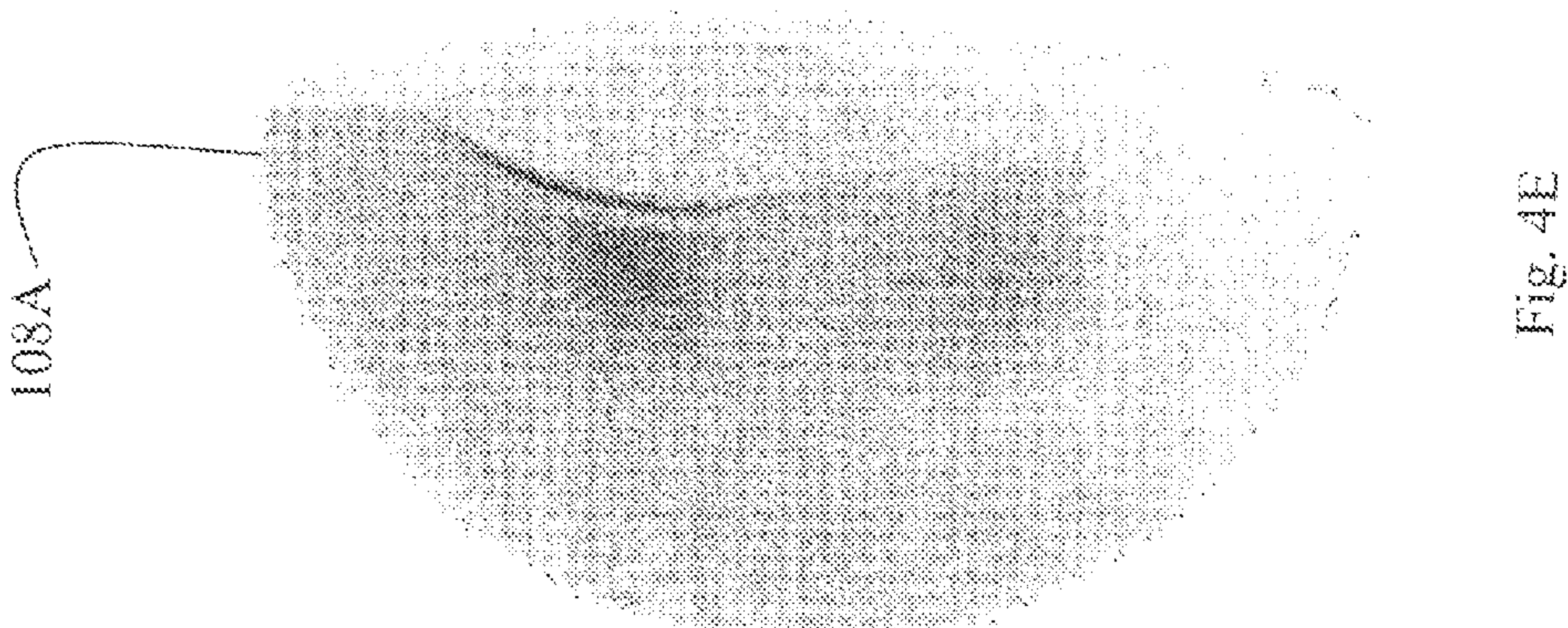
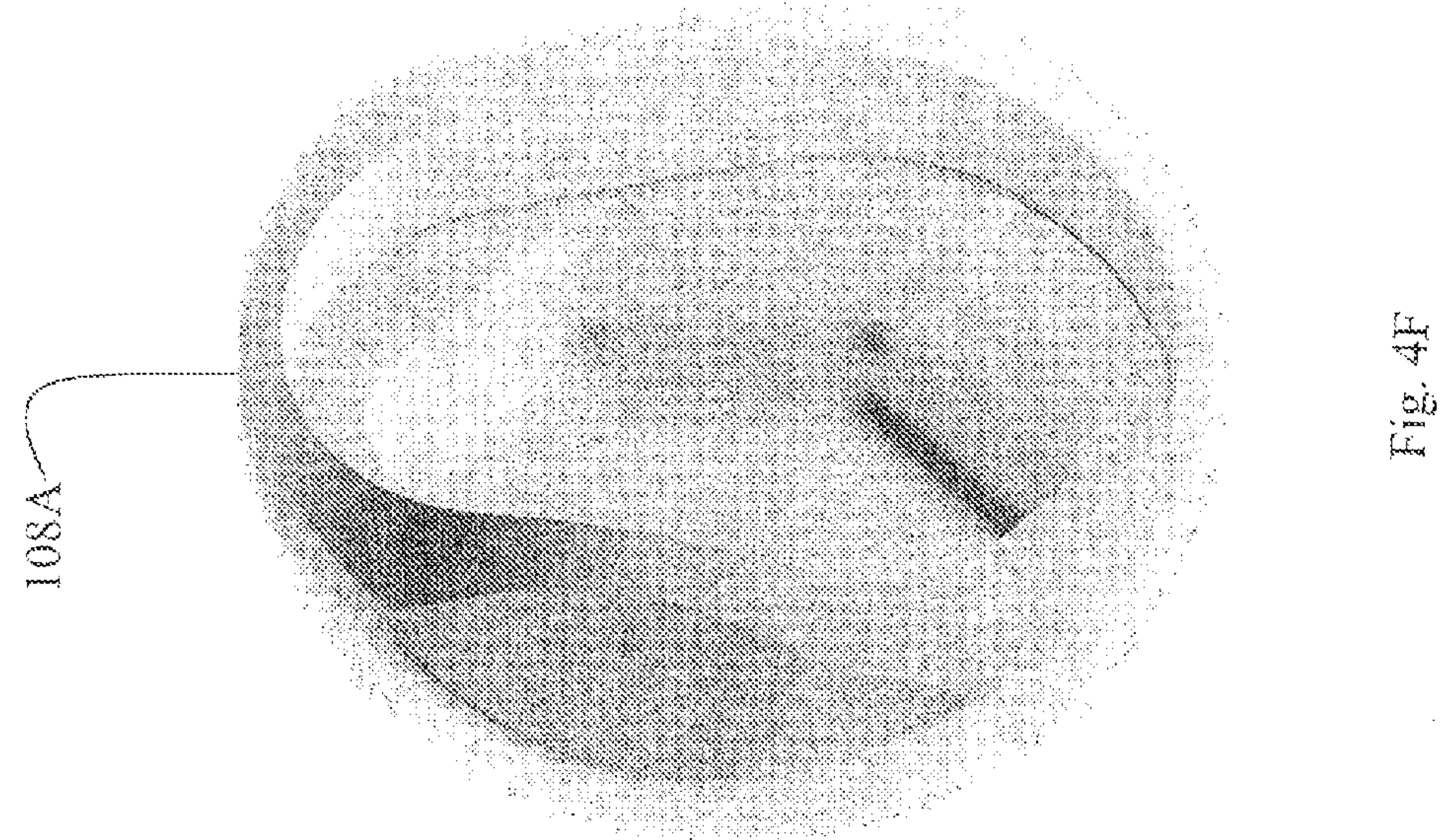
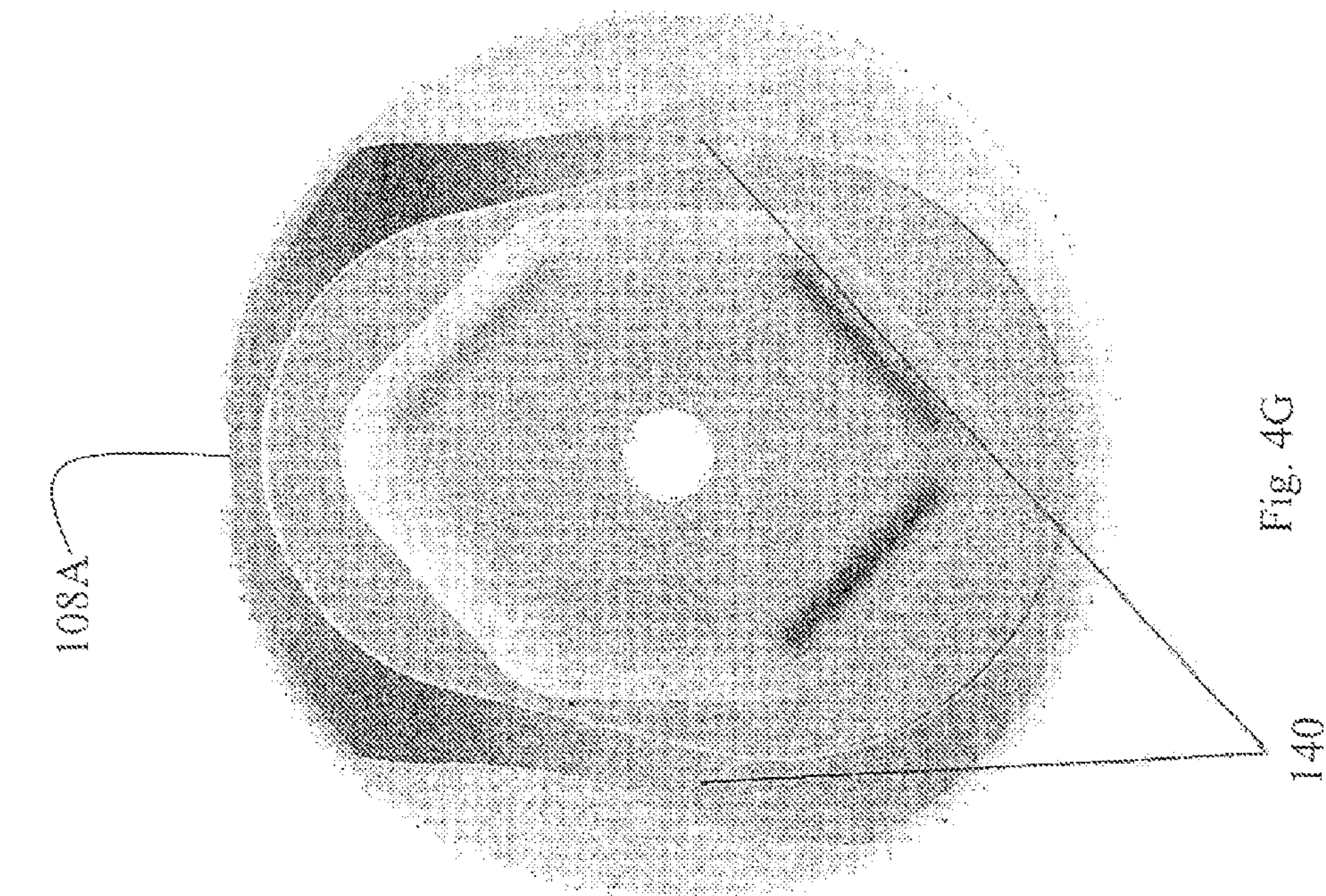


Fig. 4A

Fig. 4B

Fig. 4C

Fig. 4D



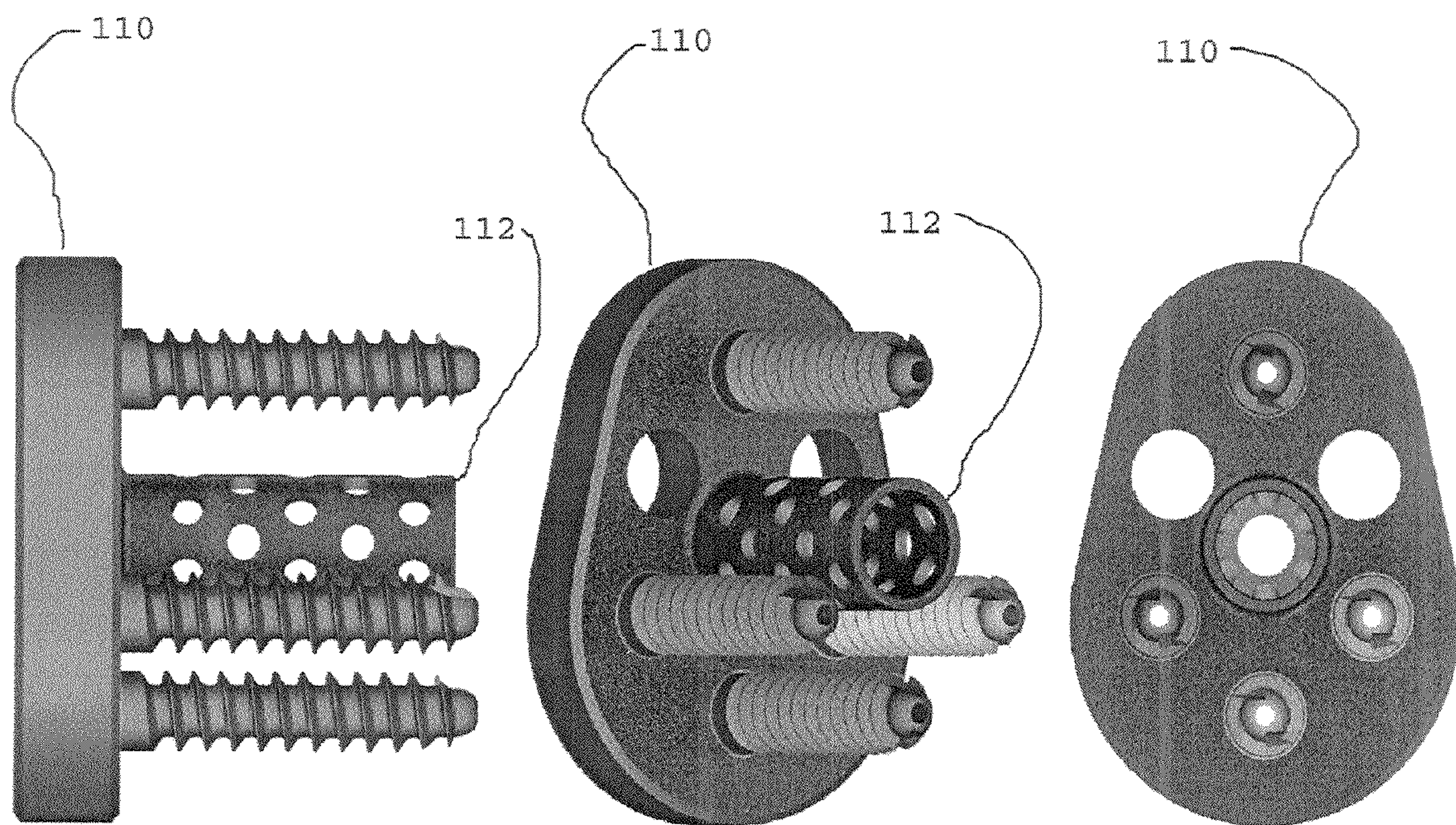
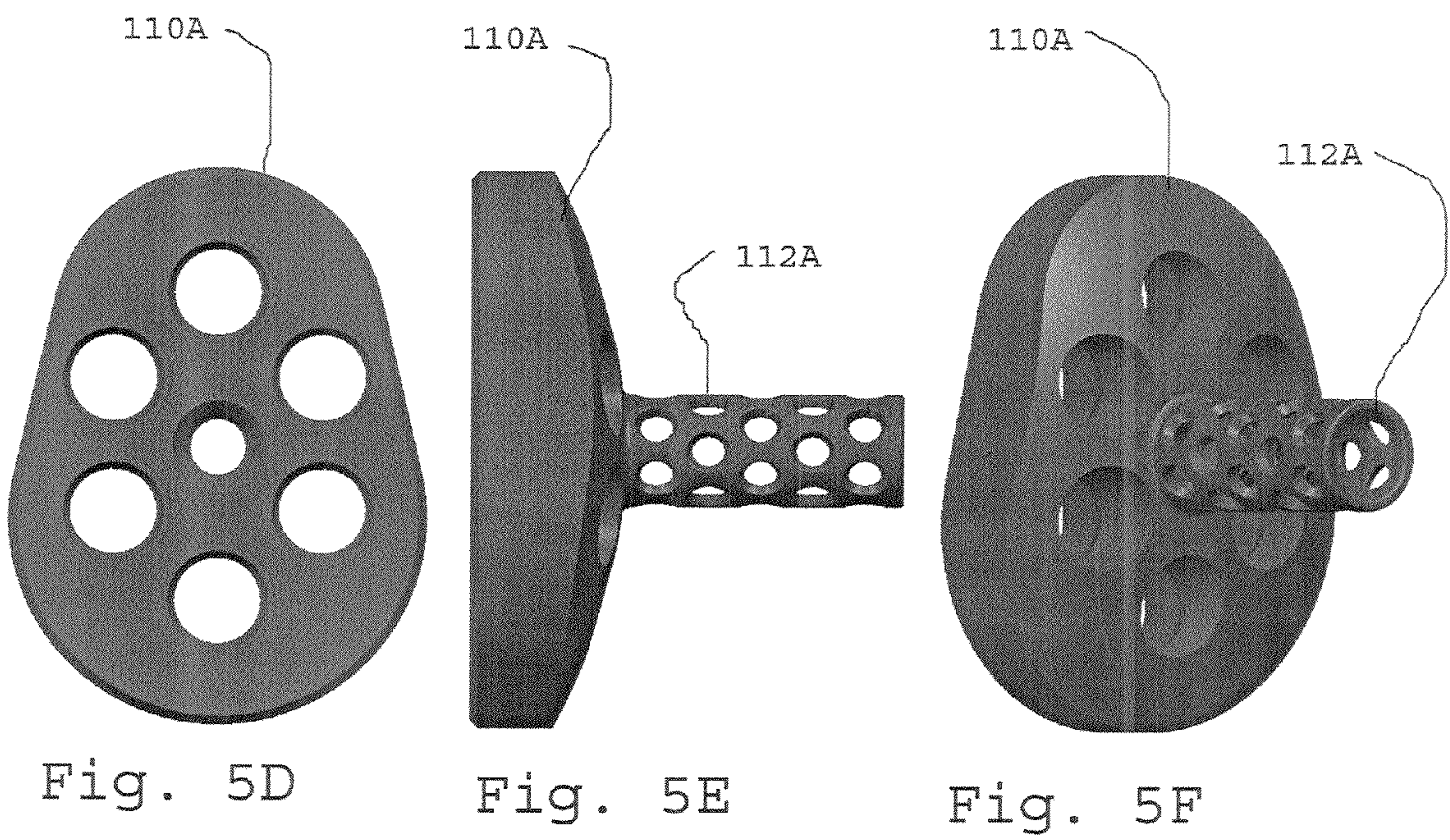


Fig. 5A

Fig. 5B

Fig. 5C



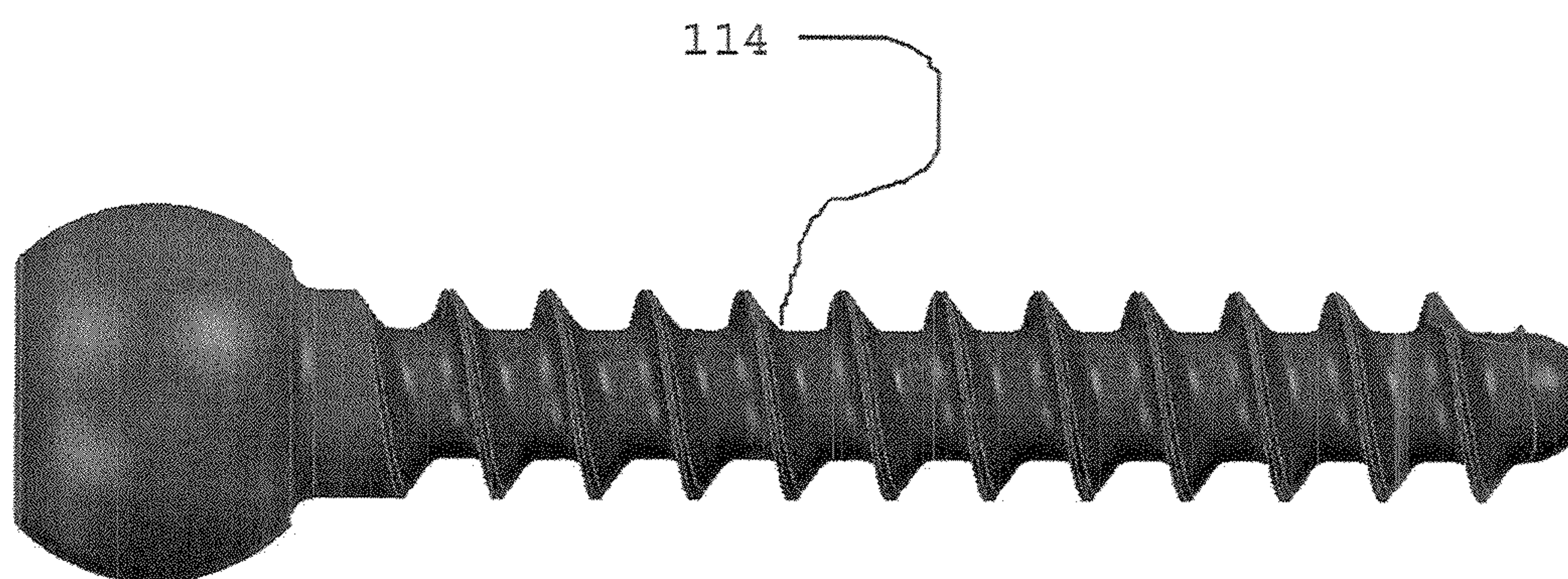


Fig. 6

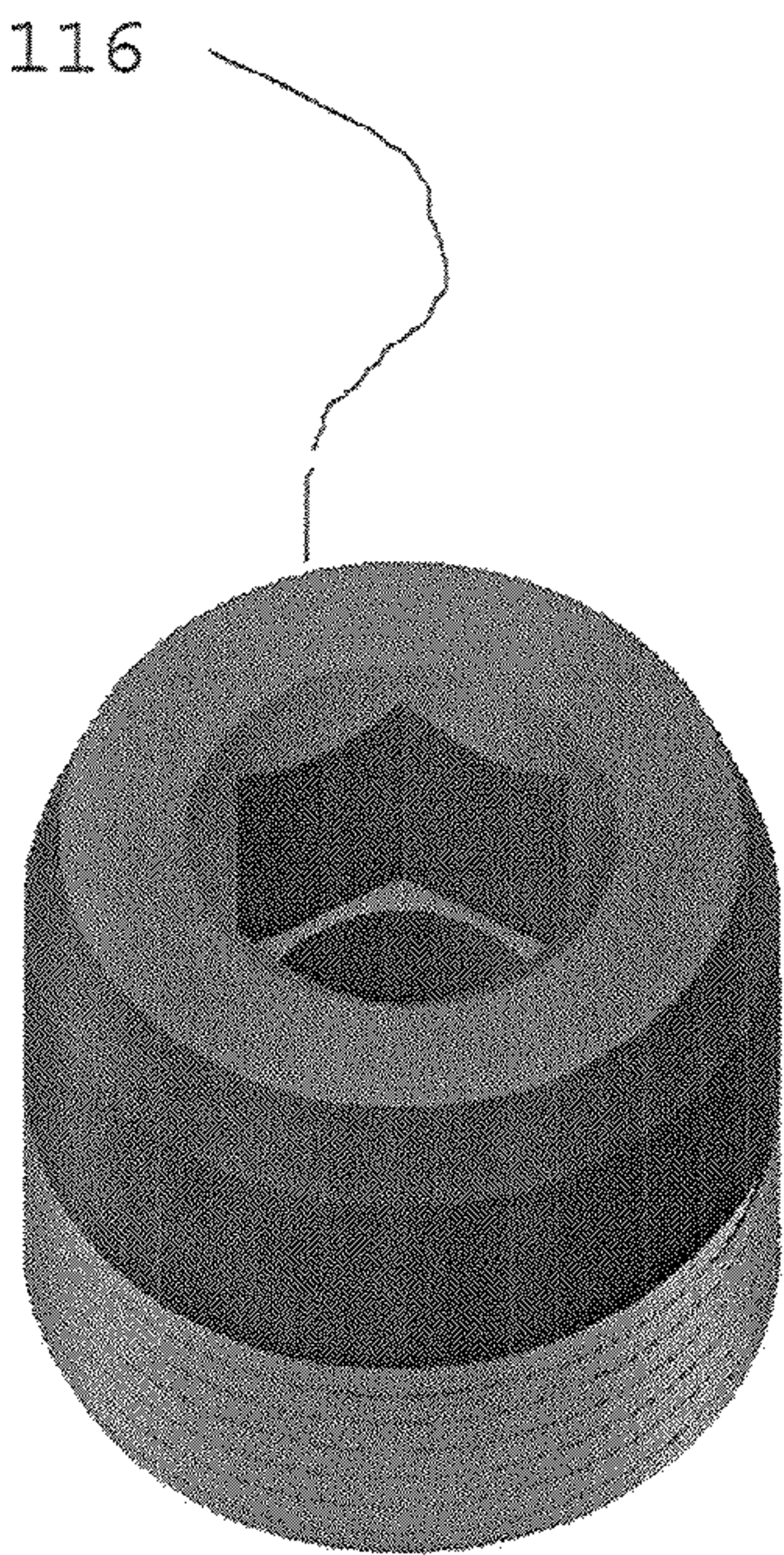


Fig. 7A

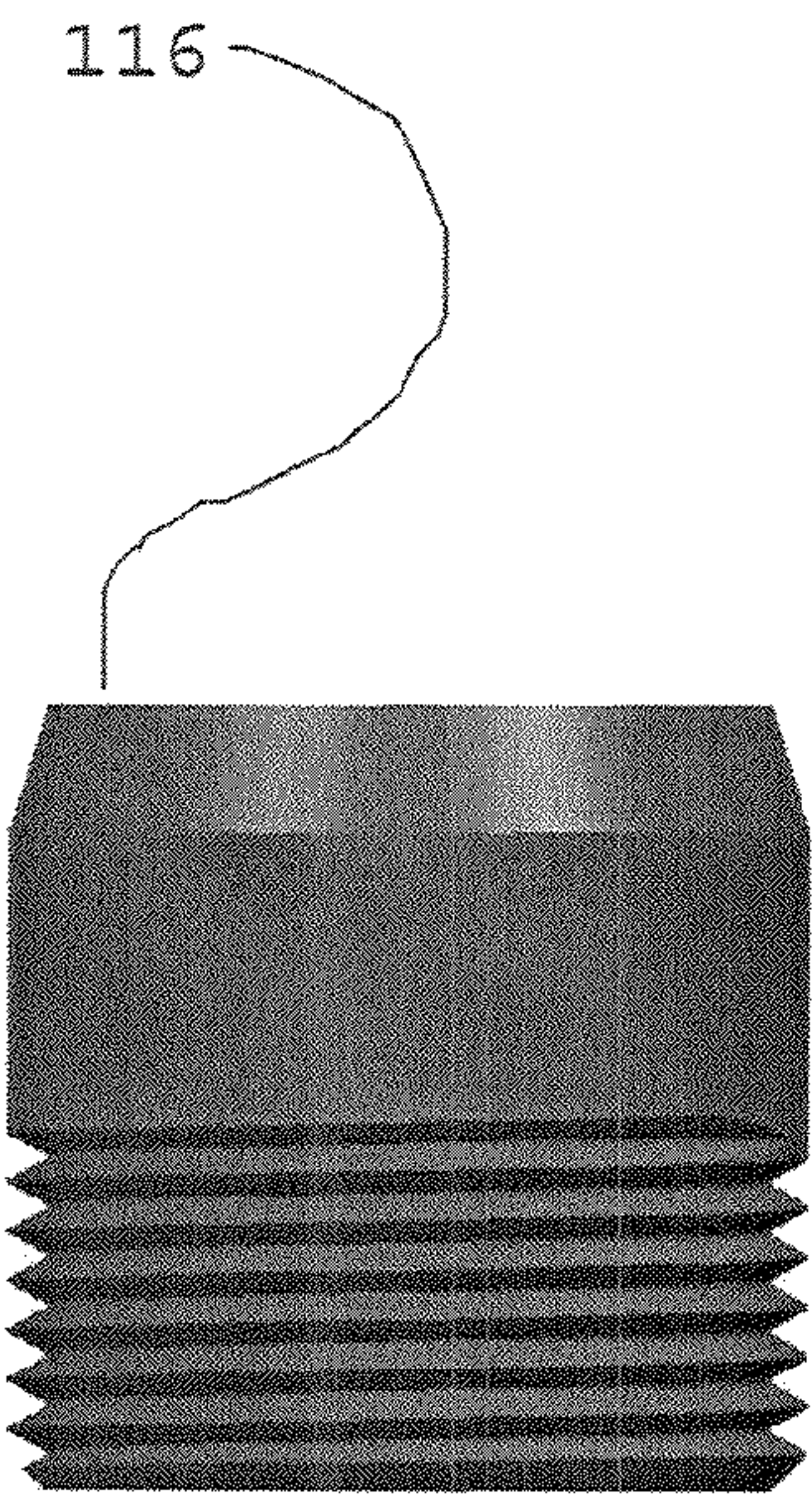


Fig. 7B

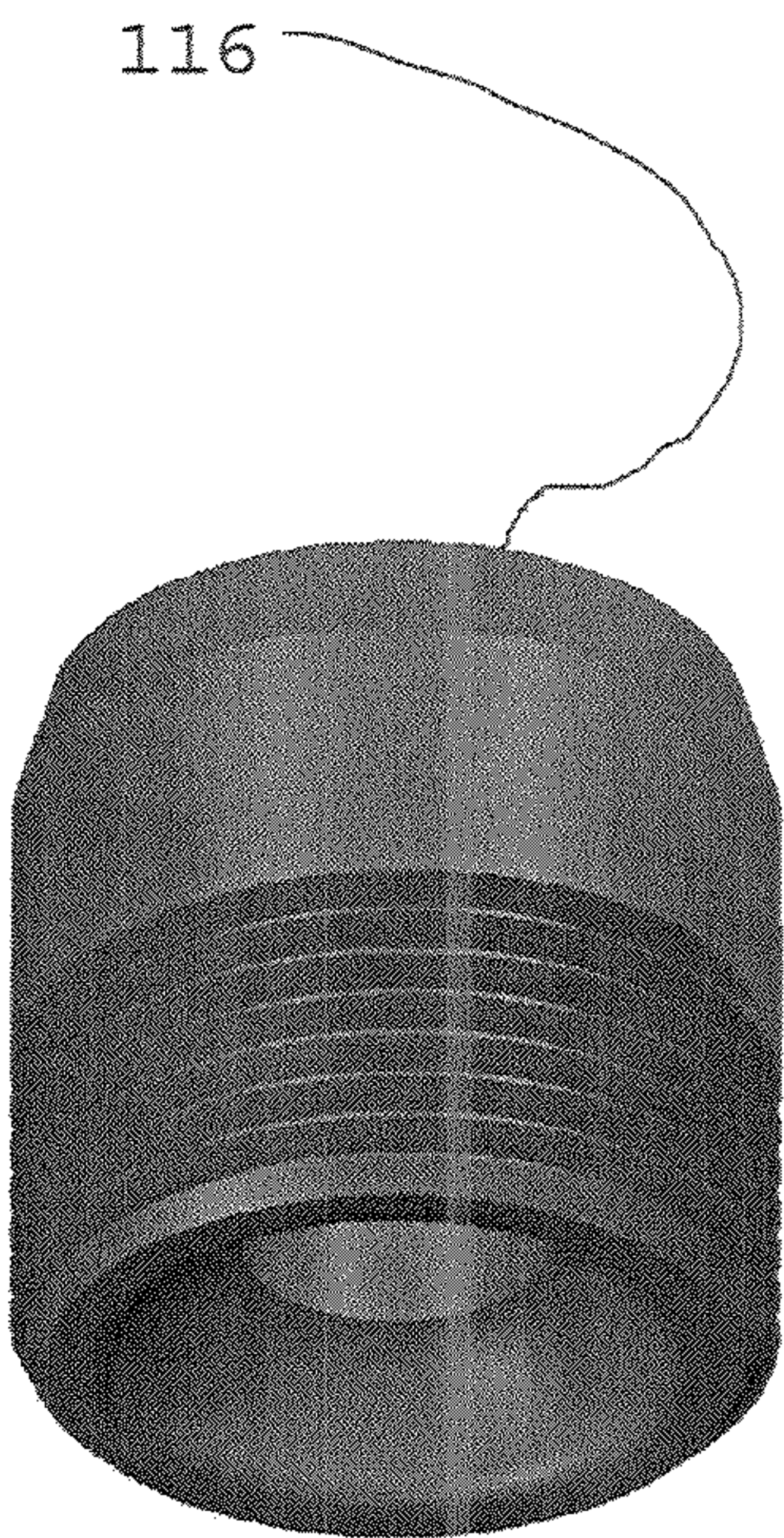


Fig. 7C

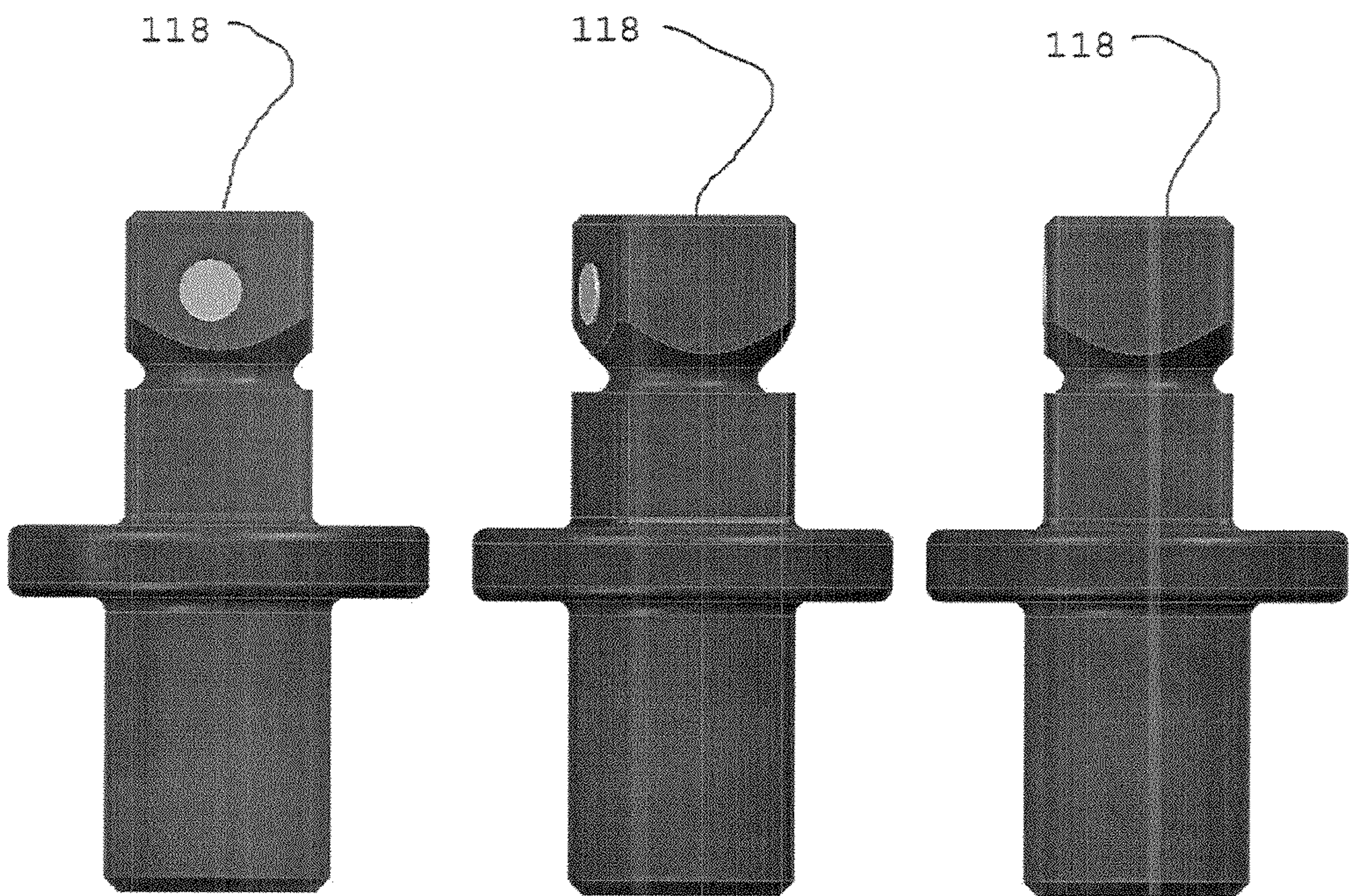


Fig. 7D

Fig. 7E

Fig. 7F

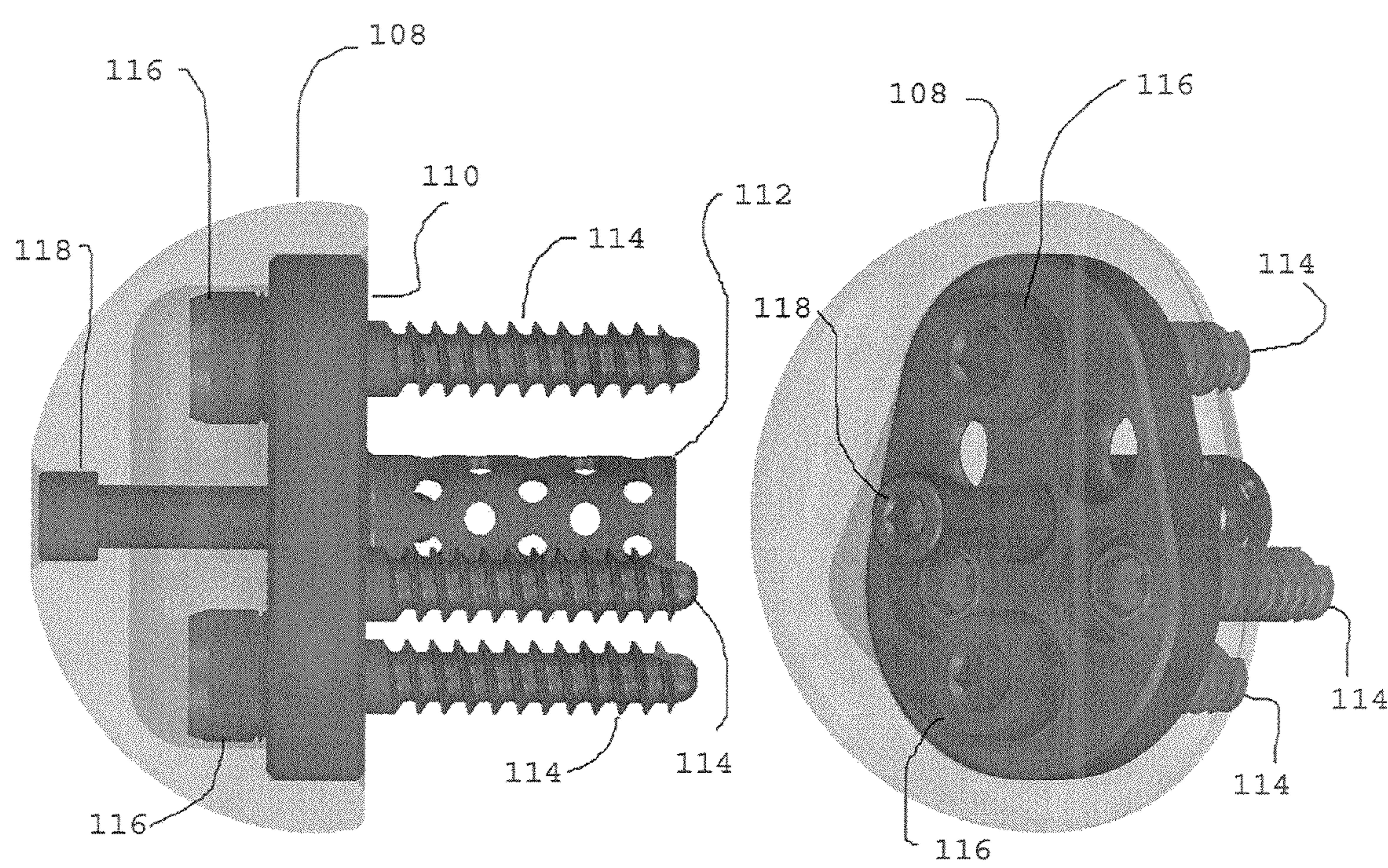


Fig. 8A

Fig. 8B

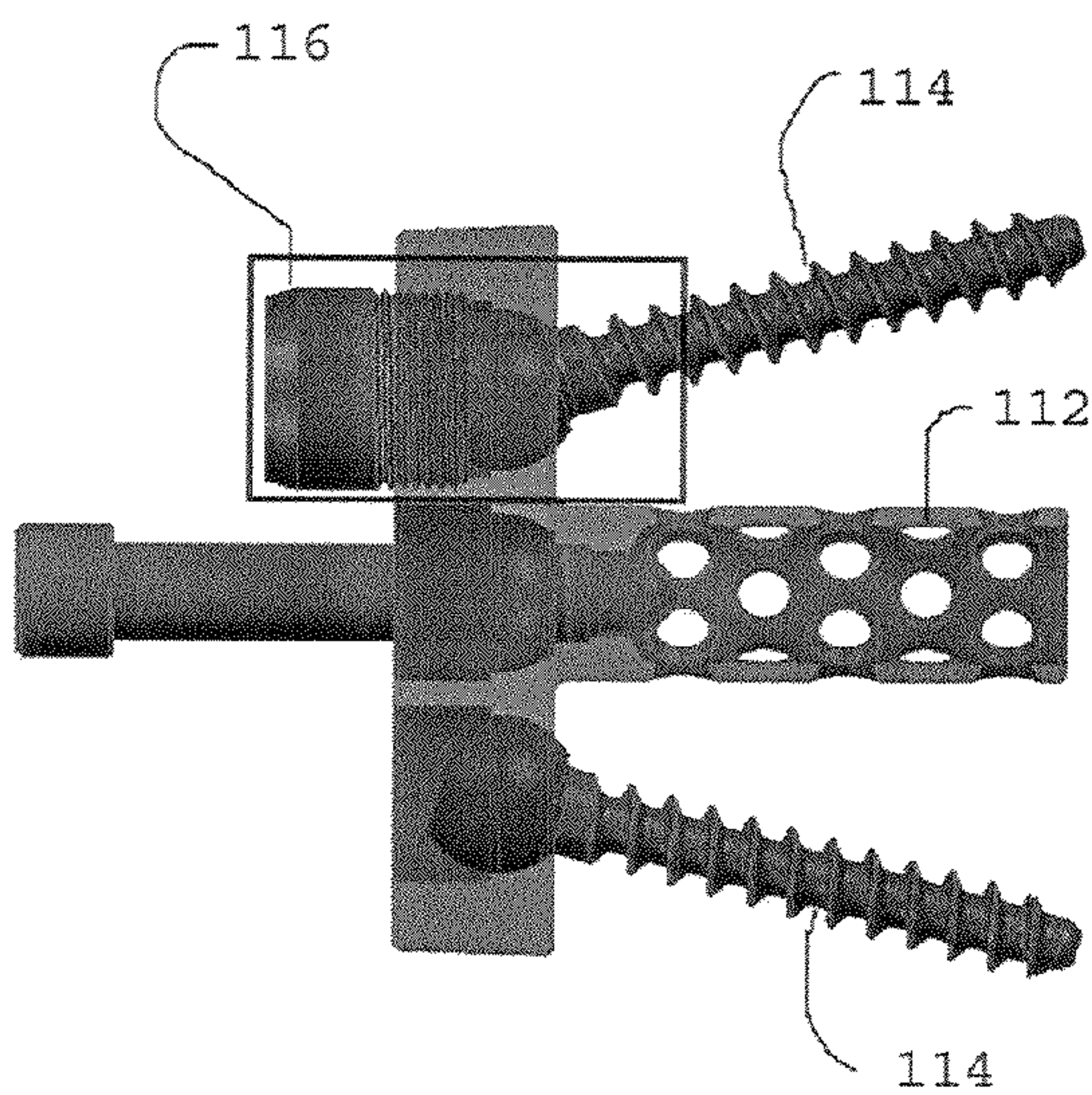


Fig. 9A

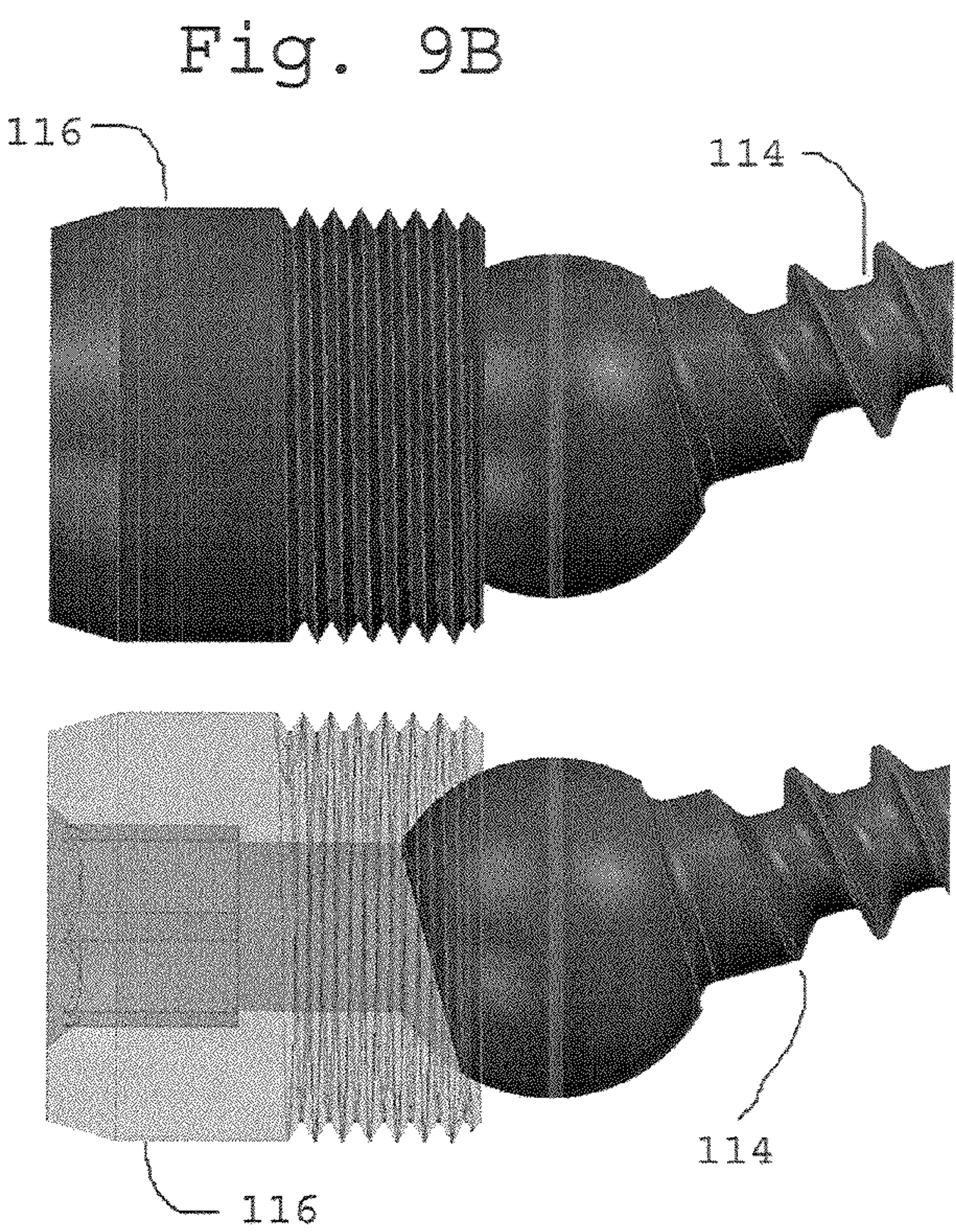


Fig. 9C

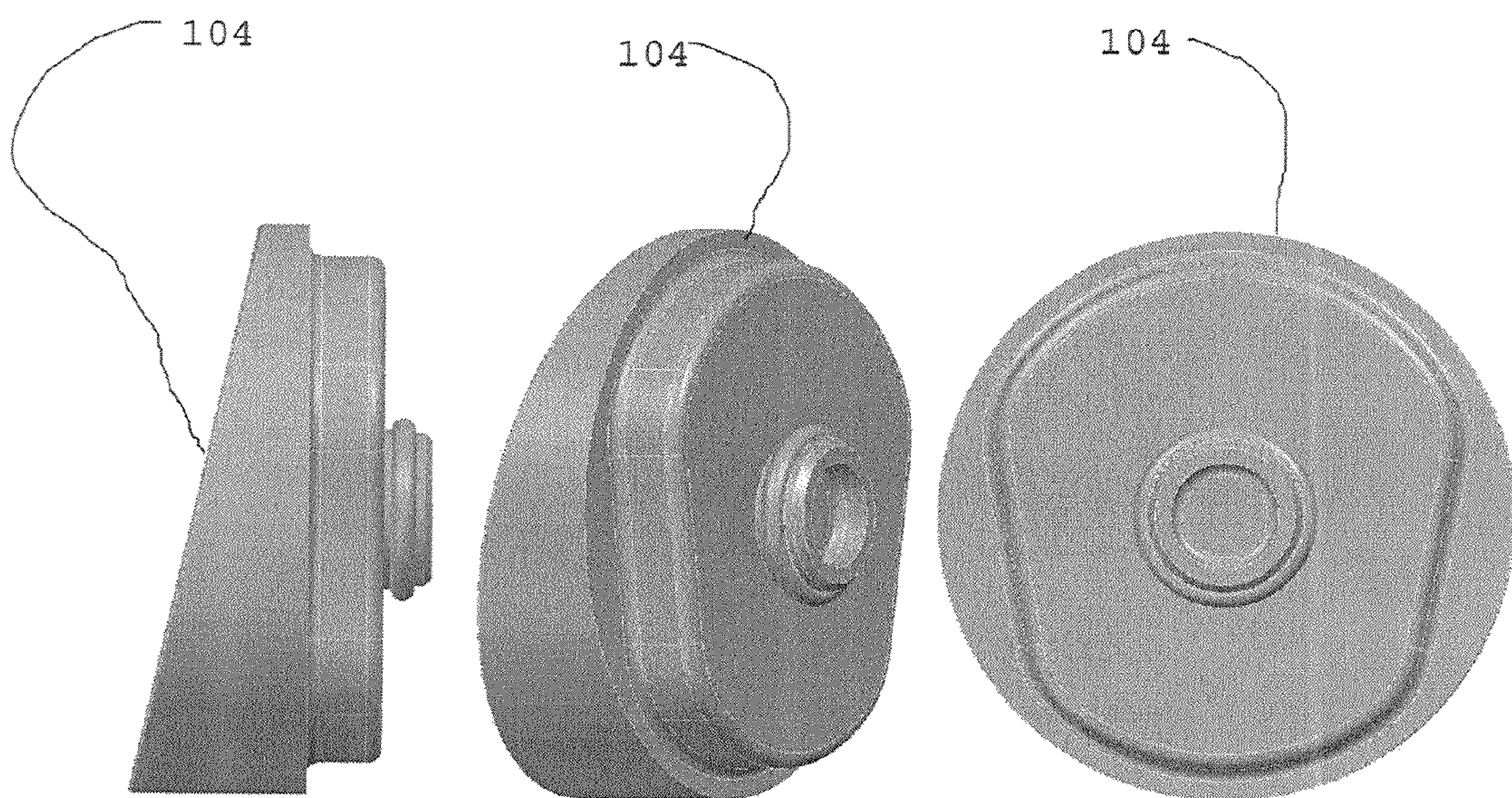


Fig. 10A

Fig. 10B

Fig. 10C

Fig. 11A

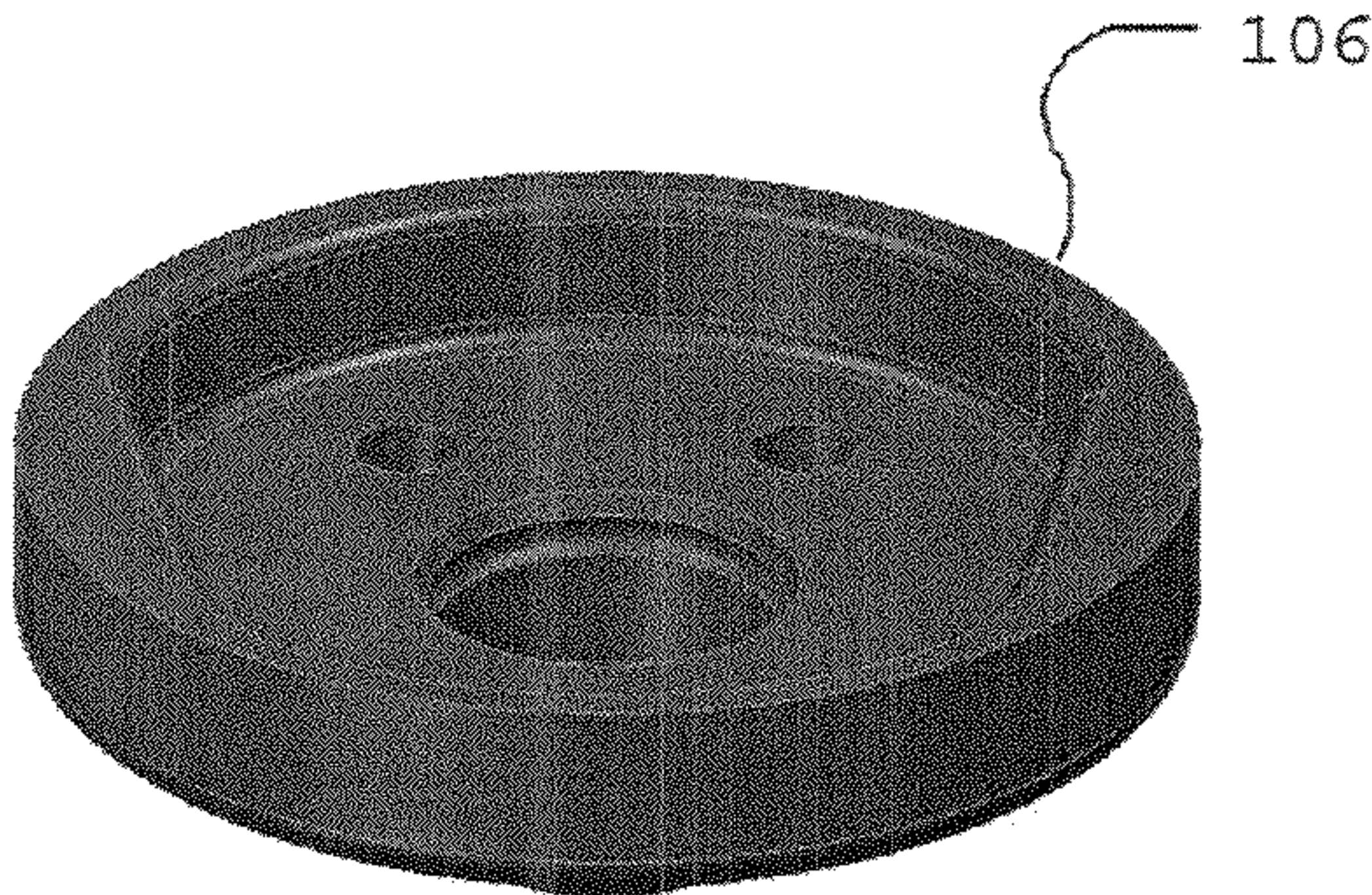


Fig. 11B

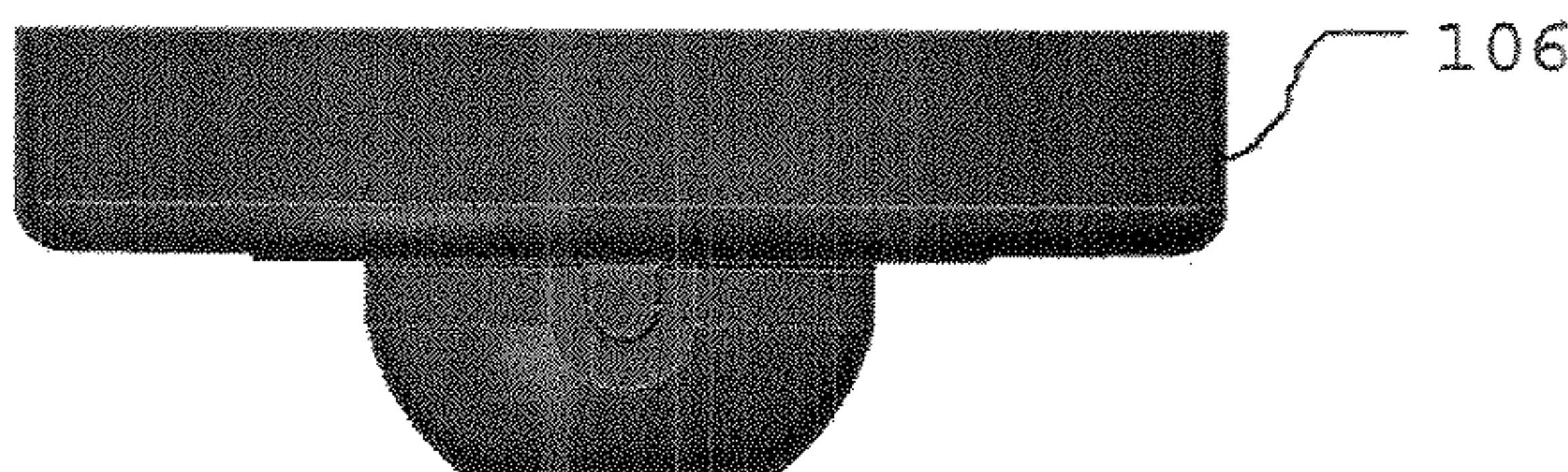
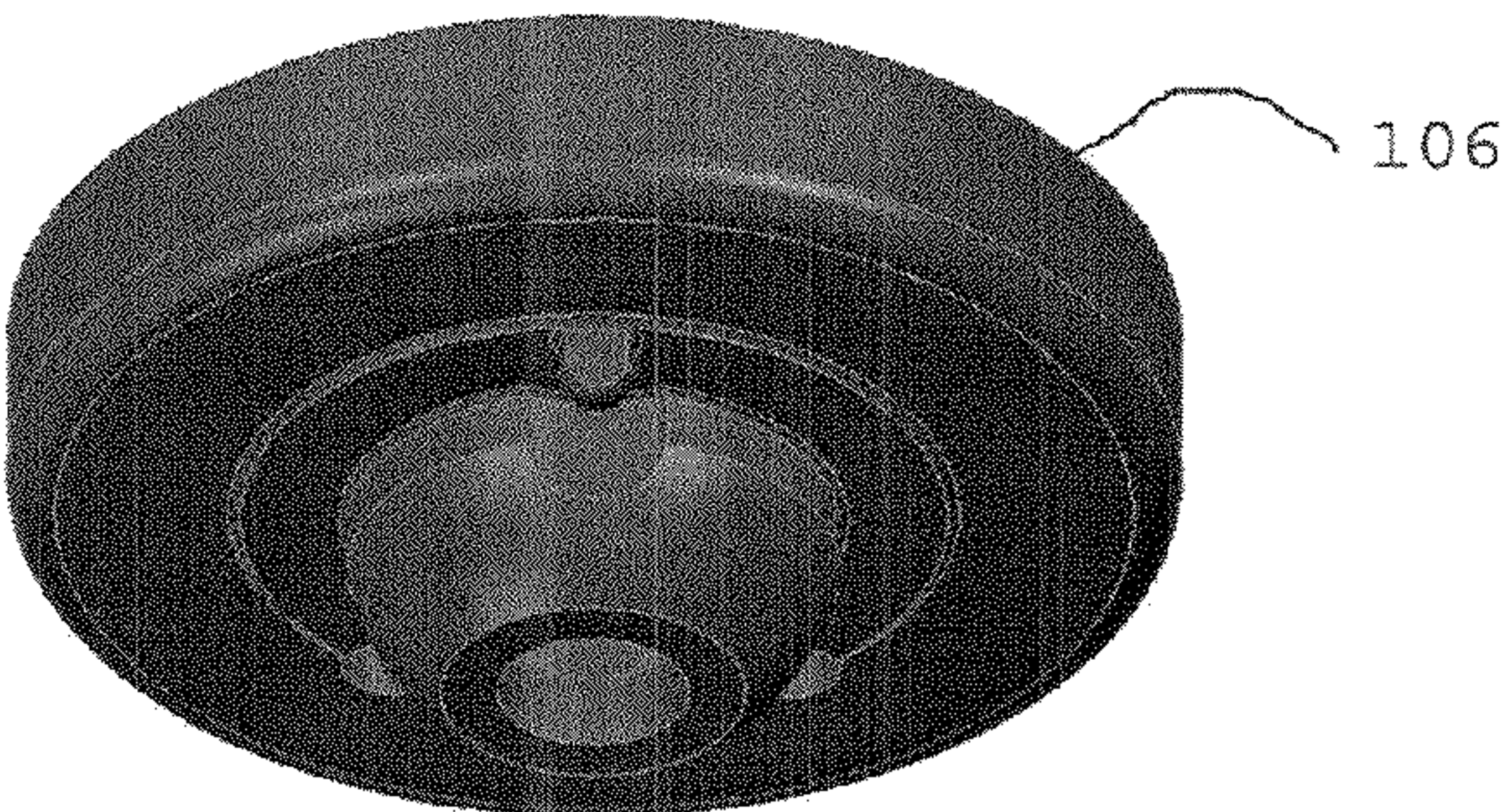


Fig. 11C



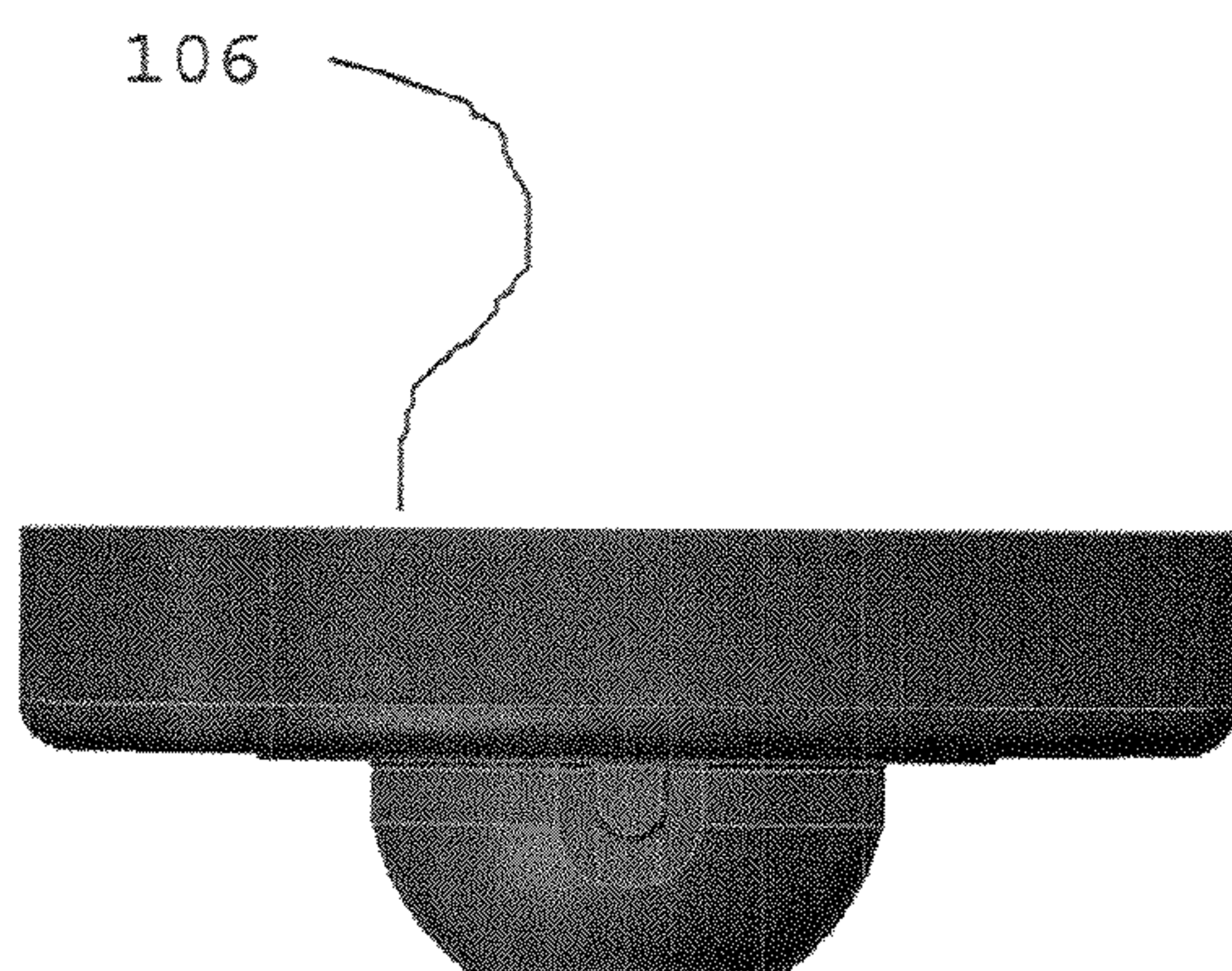


Fig. 11D

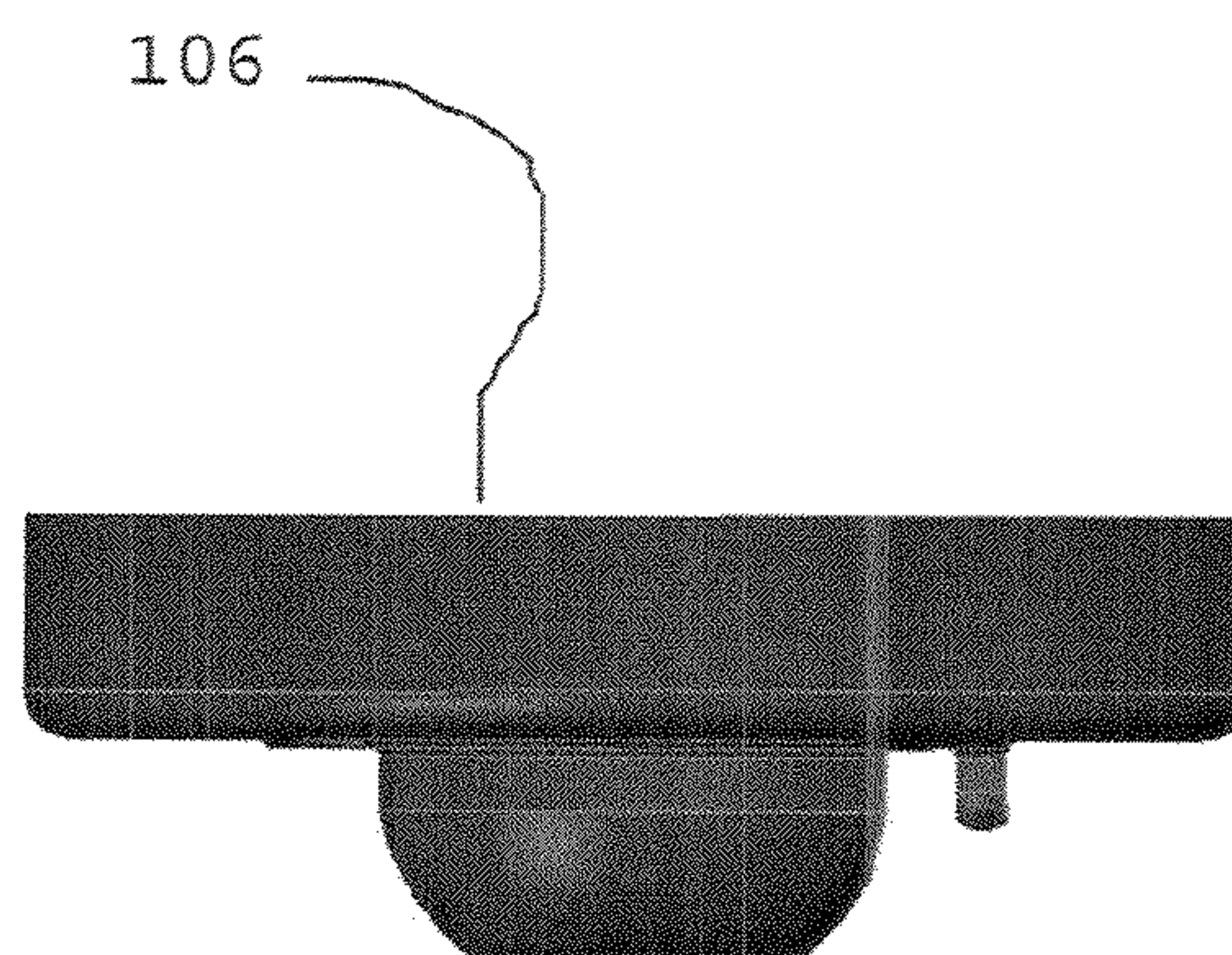
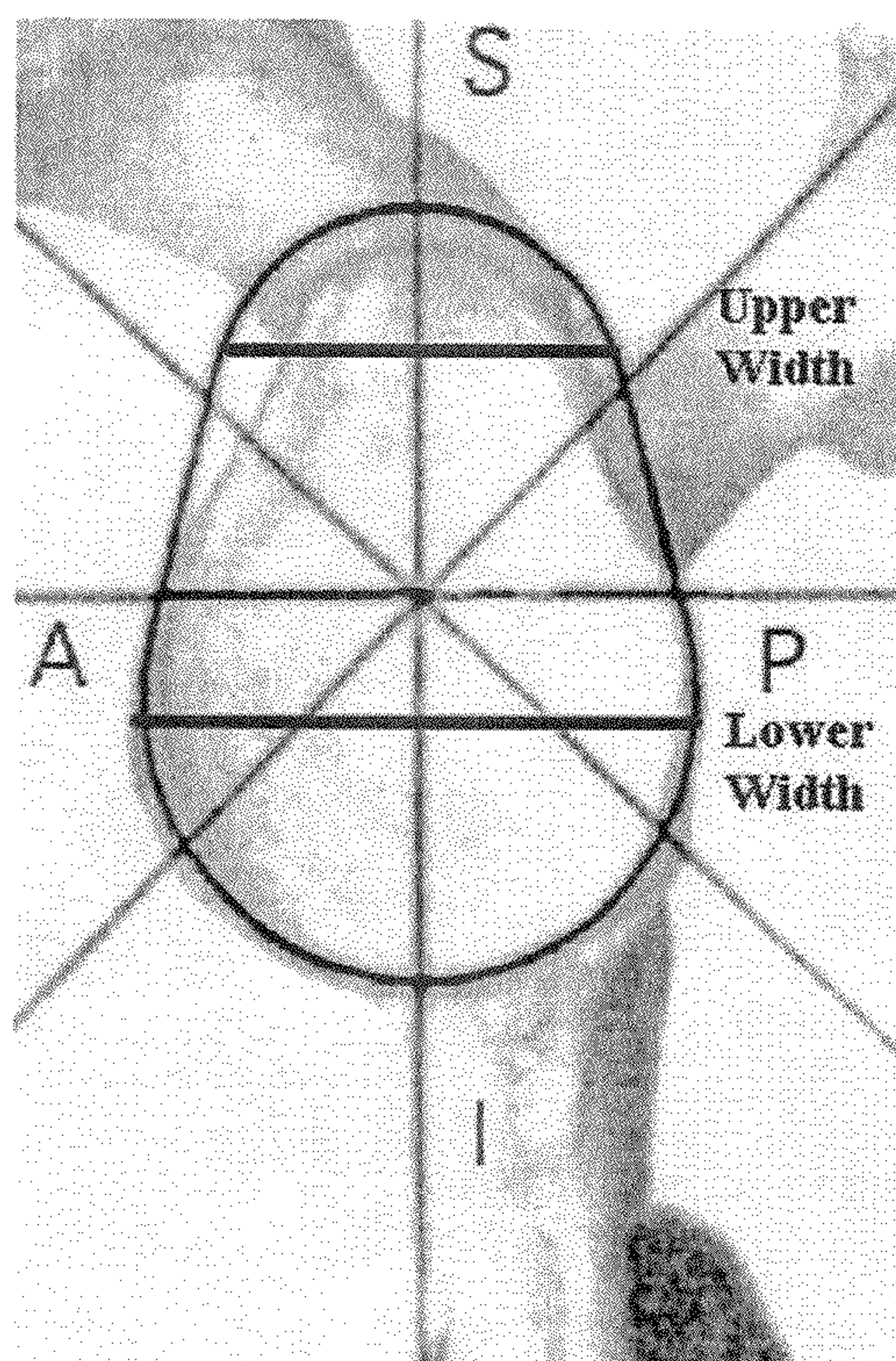


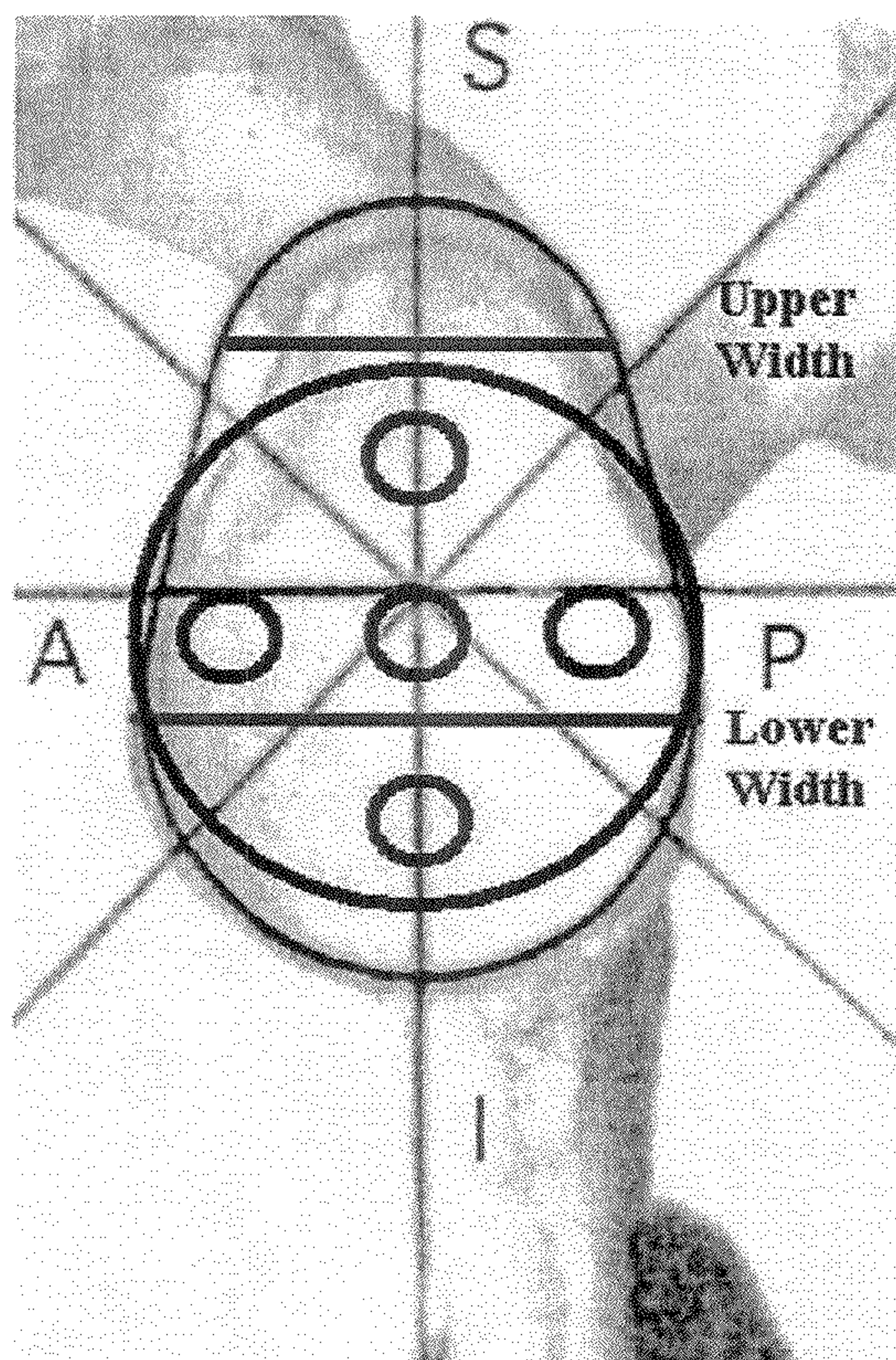
Fig. 11E



Upper Width: Study by Iannotti
measured the upper glenoid width to be
 $23 \pm 2.7\text{mm}$

Lower Width: Study by Checroun
measured the lower glenoid width to
be $29.3 \pm 2.4\text{mm}$. Study by Iannotti
measured it to be $29 \pm 3.1\text{mm}$

Fig. 12



**29mm Glenosphere Plate
(Approximate Diameter and Hole
Position of the Grammont and
Encore Design)**

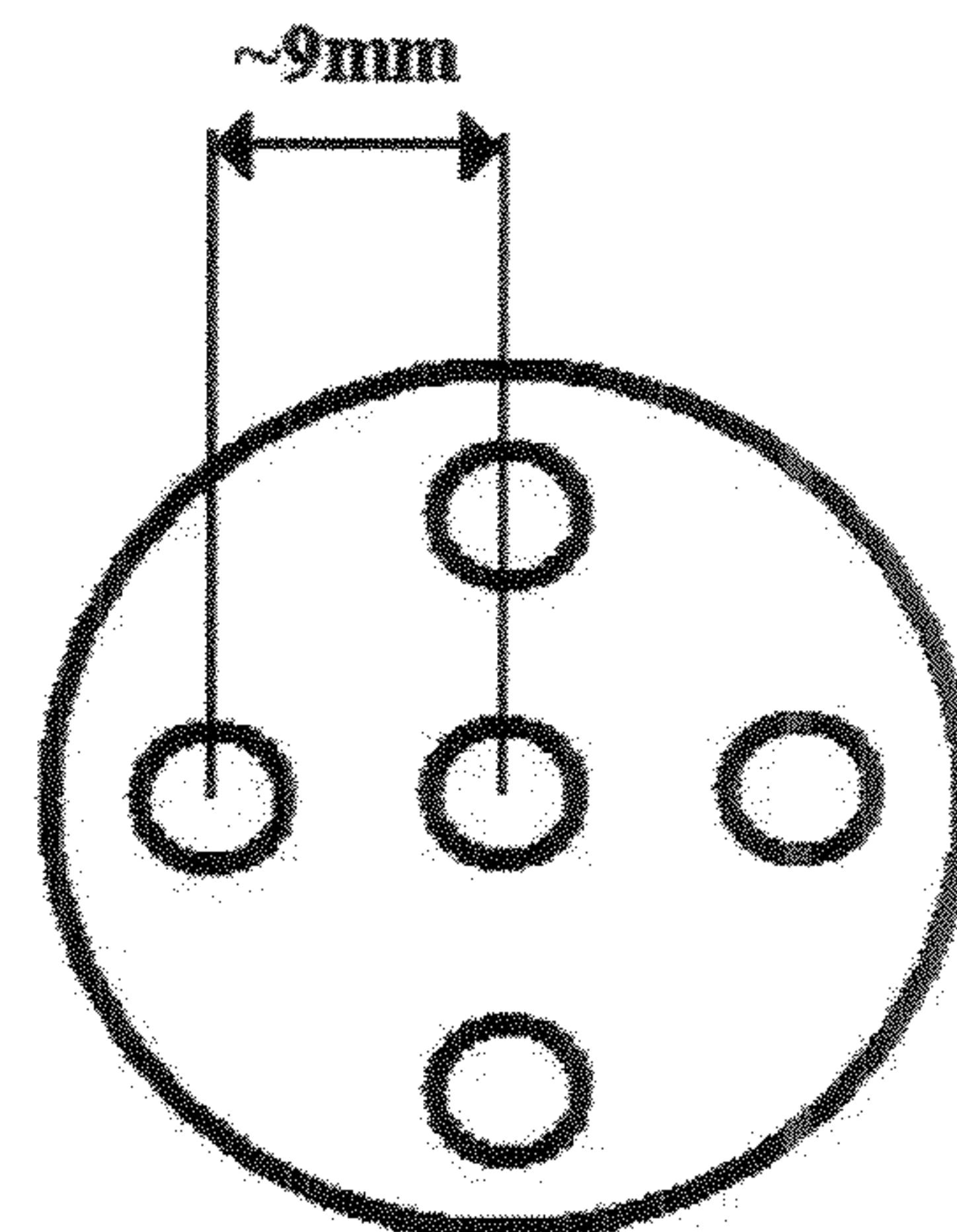


Fig. 13

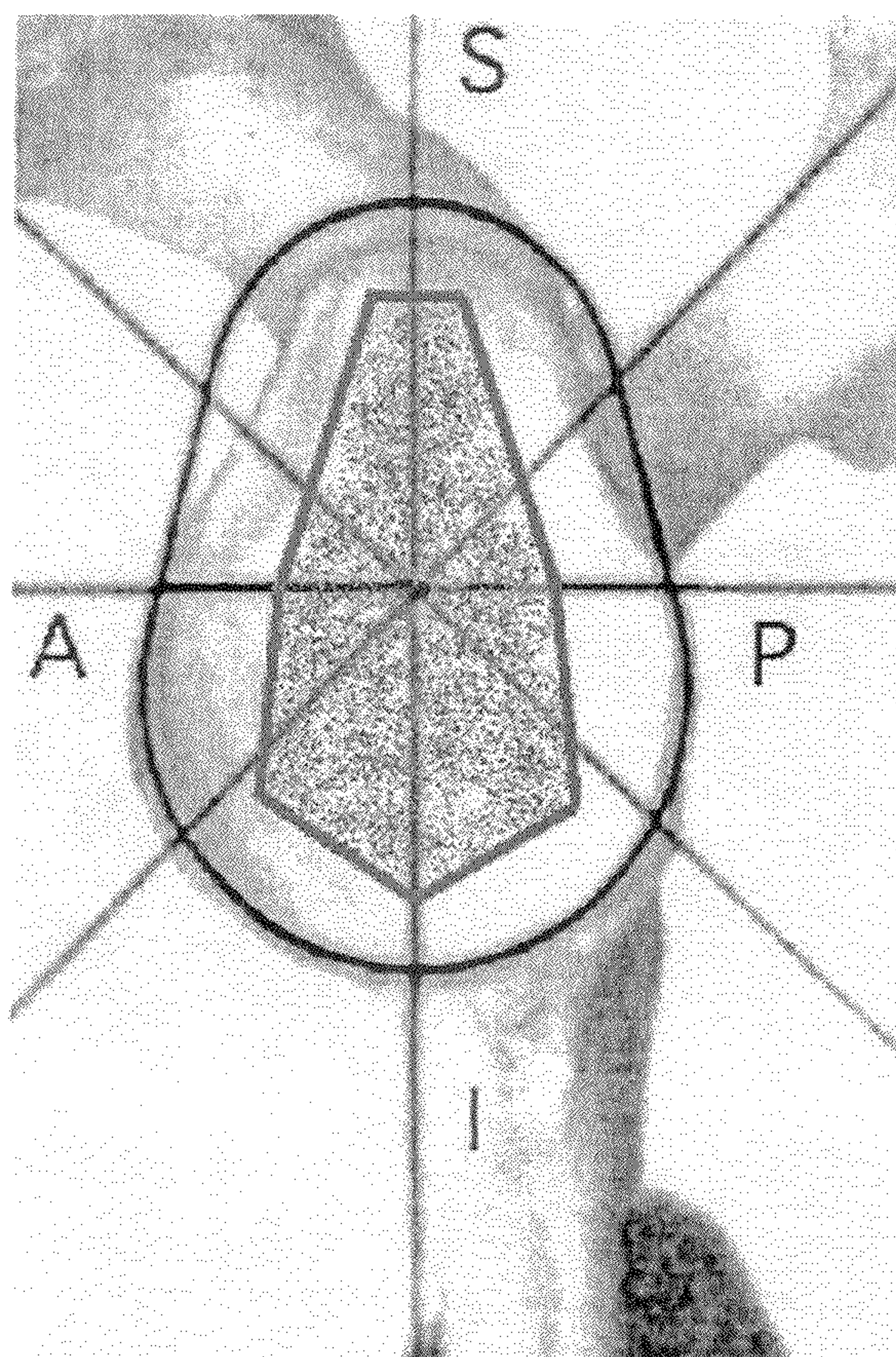


Fig. 14

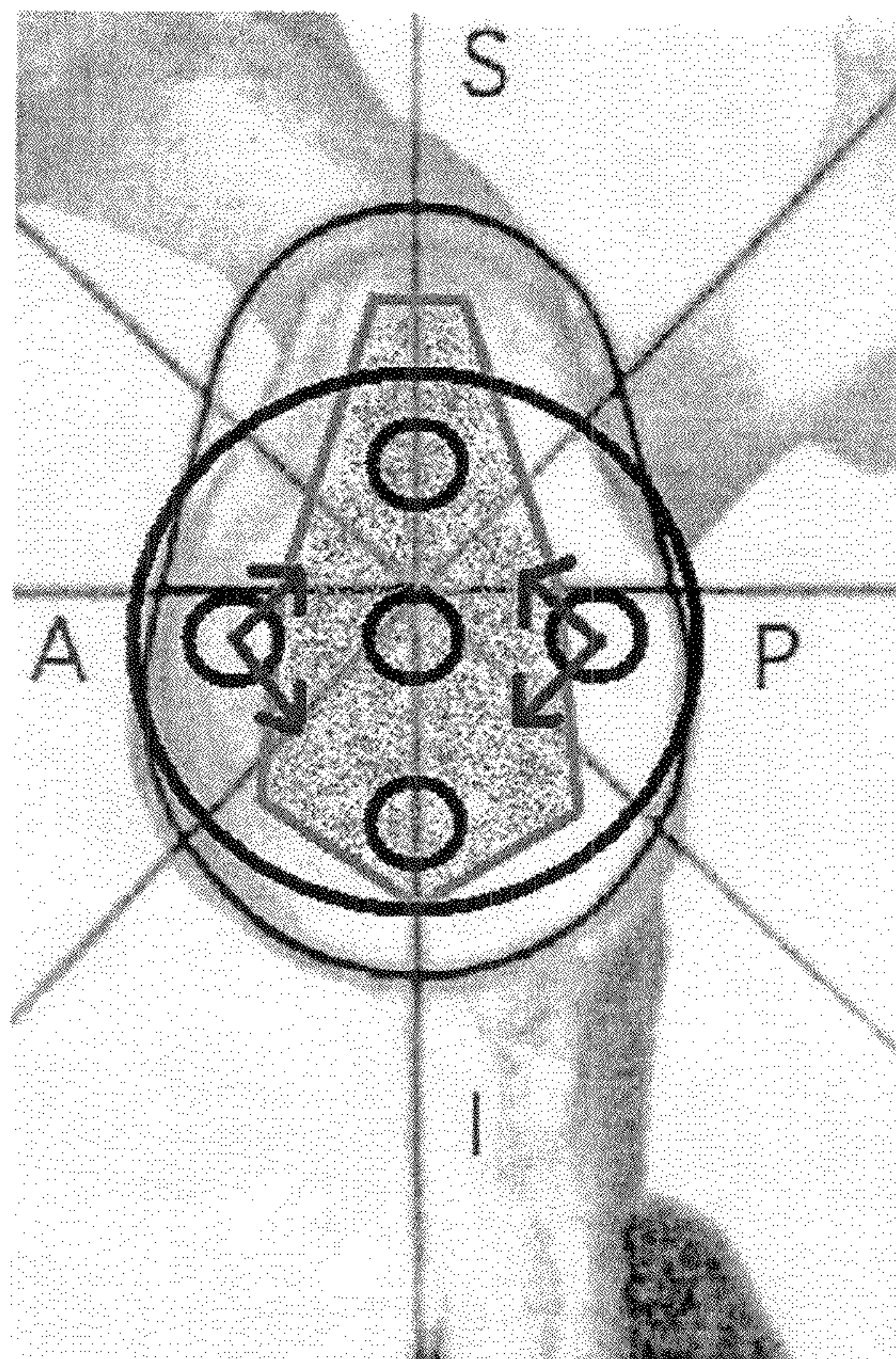
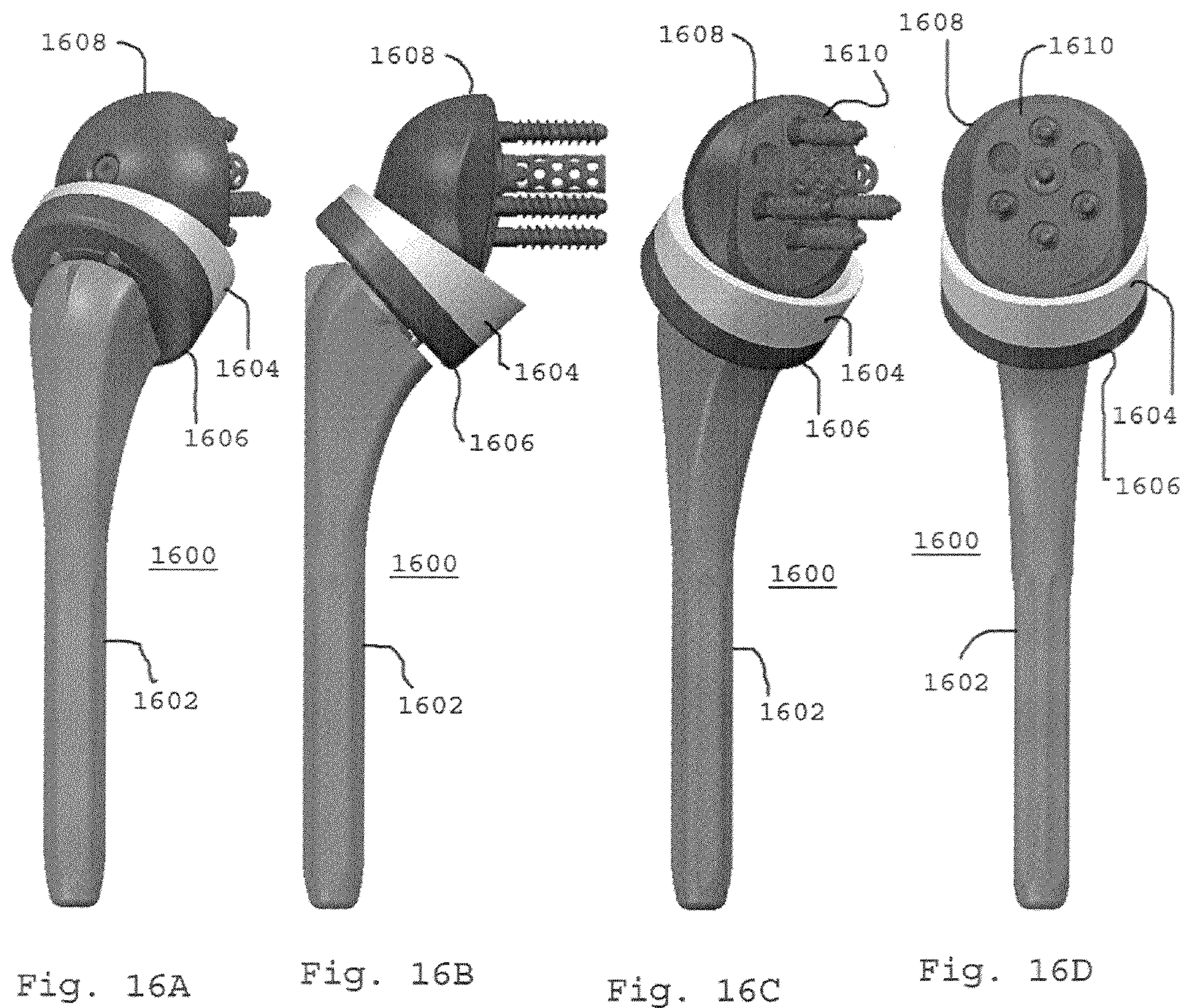
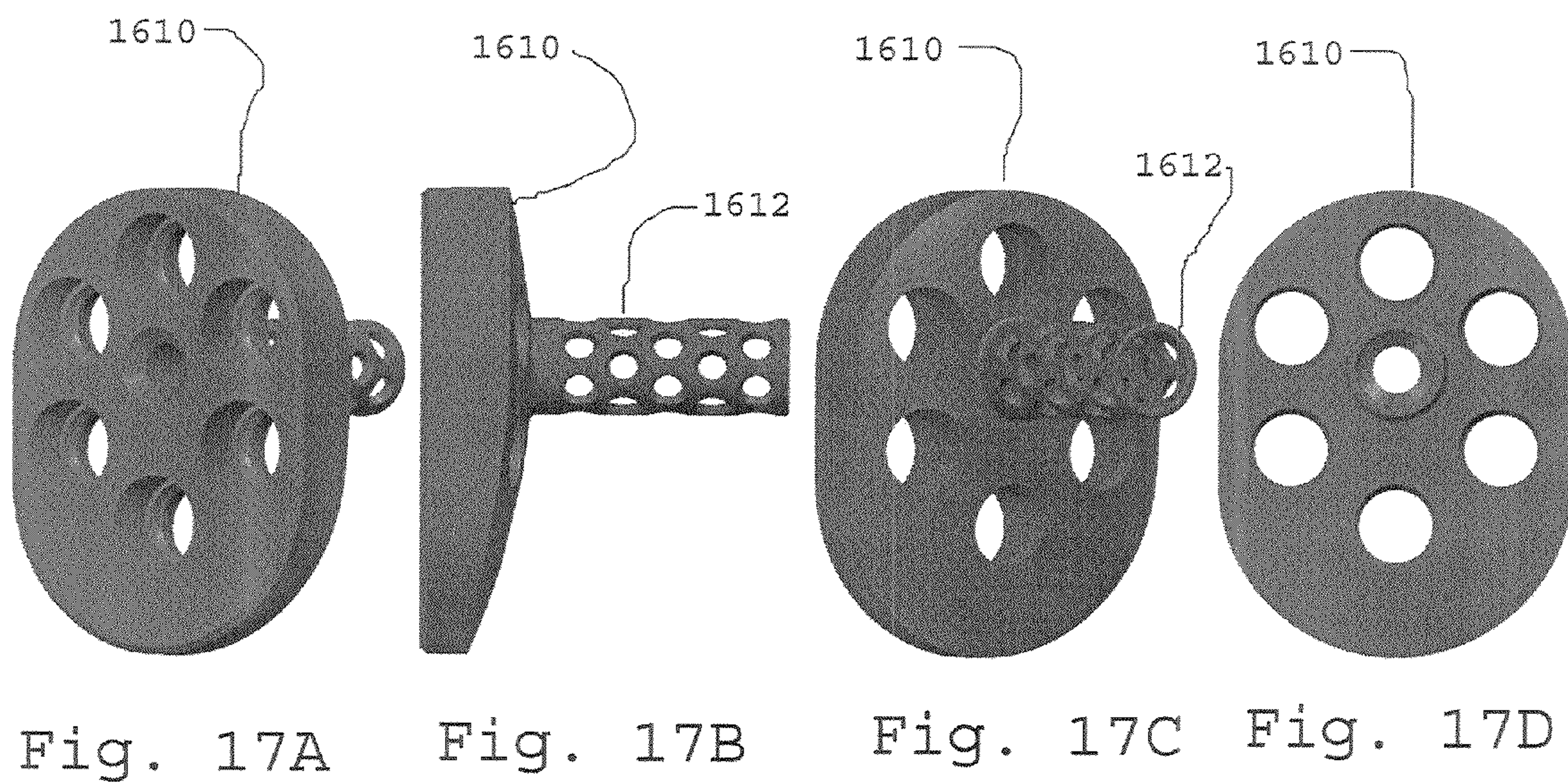
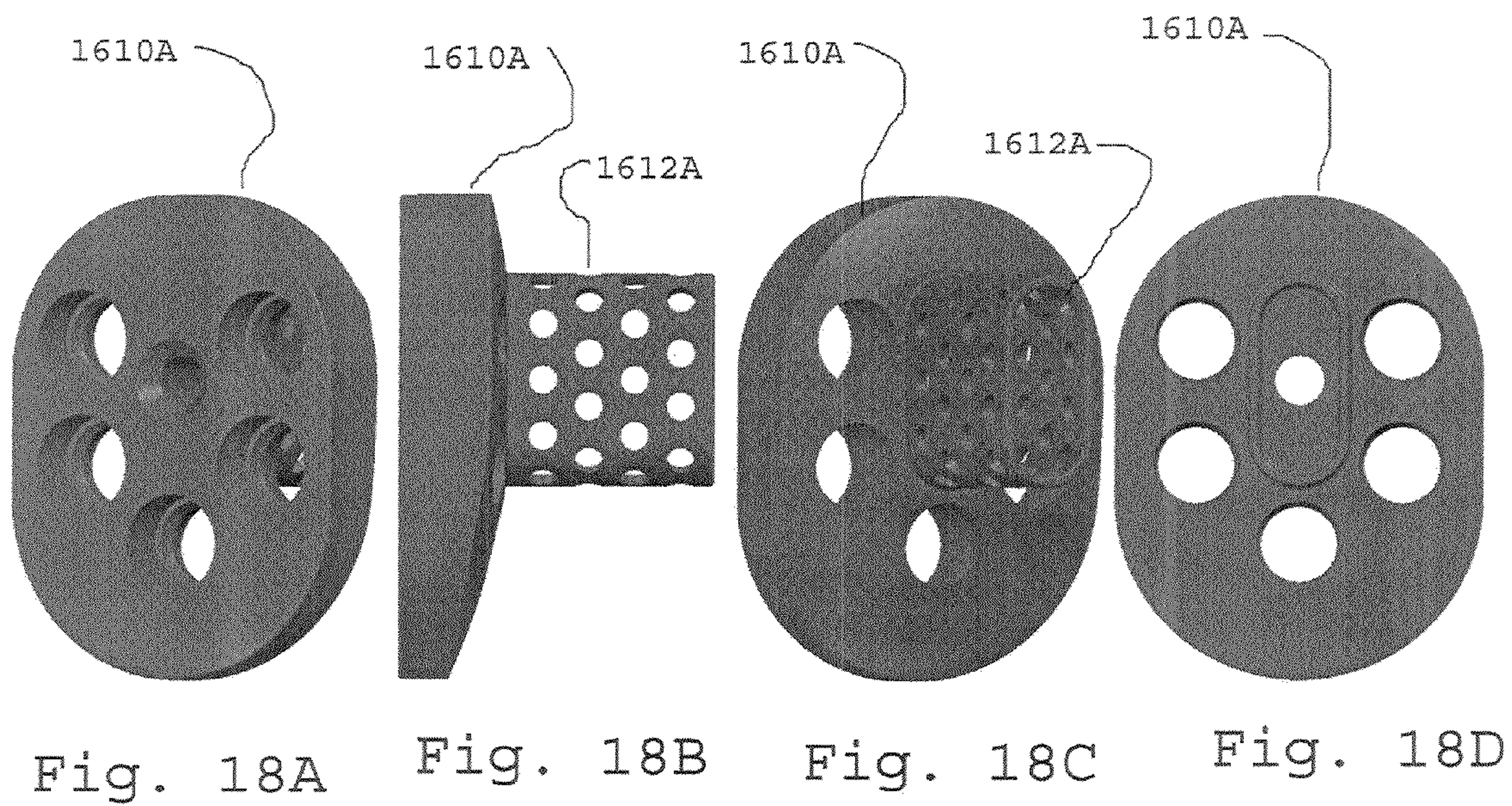
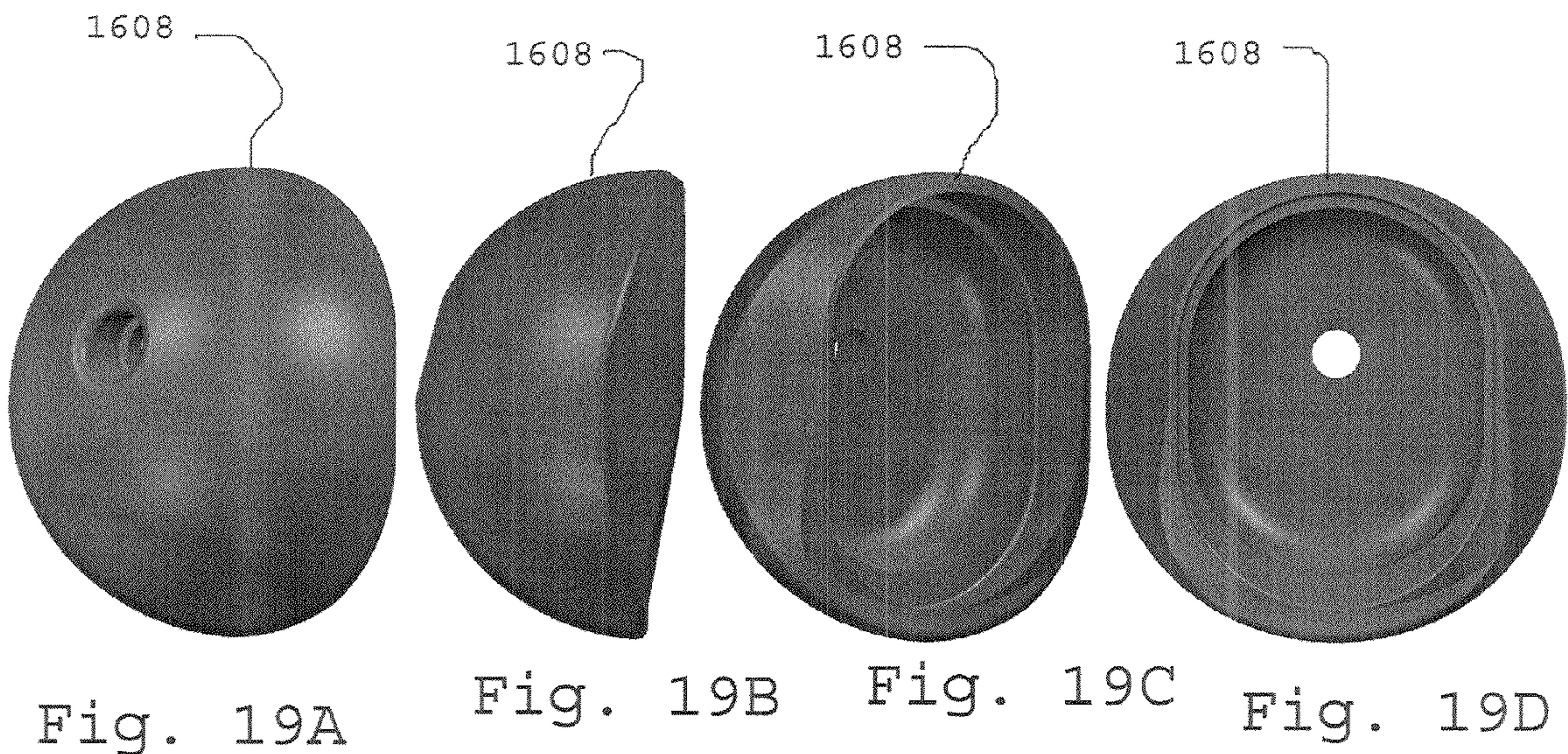


Fig. 15









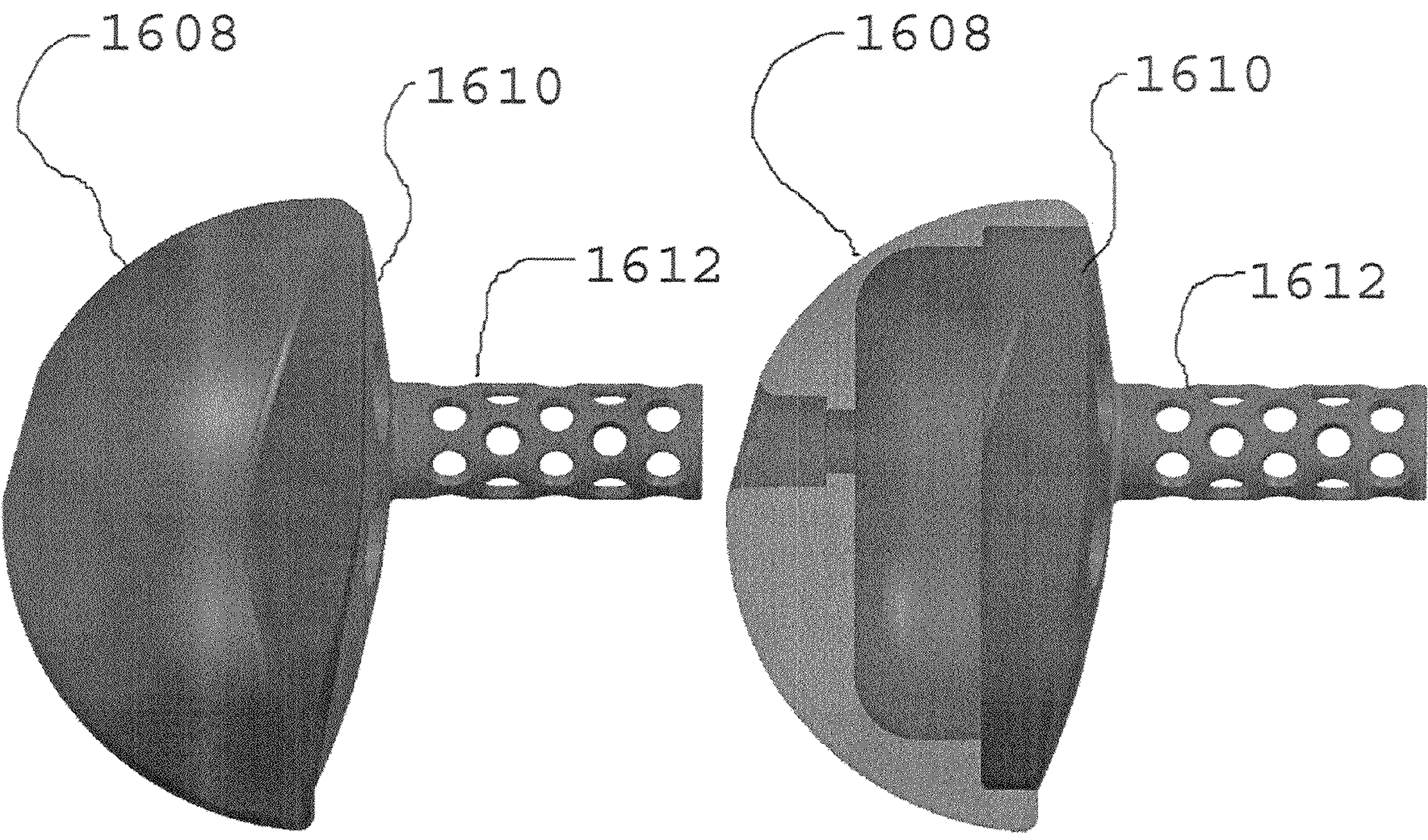
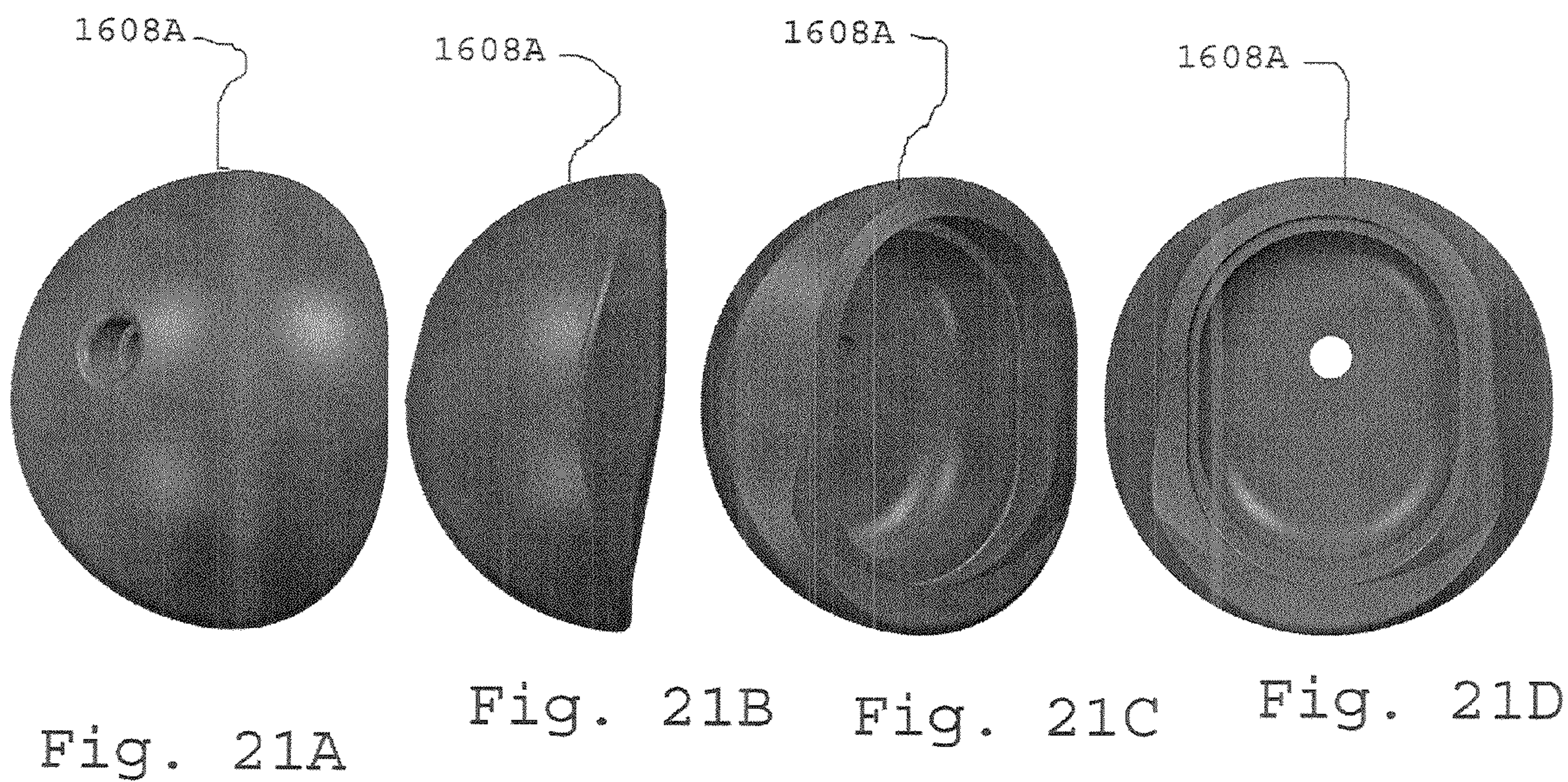


Fig. 20A

Fig. 20B



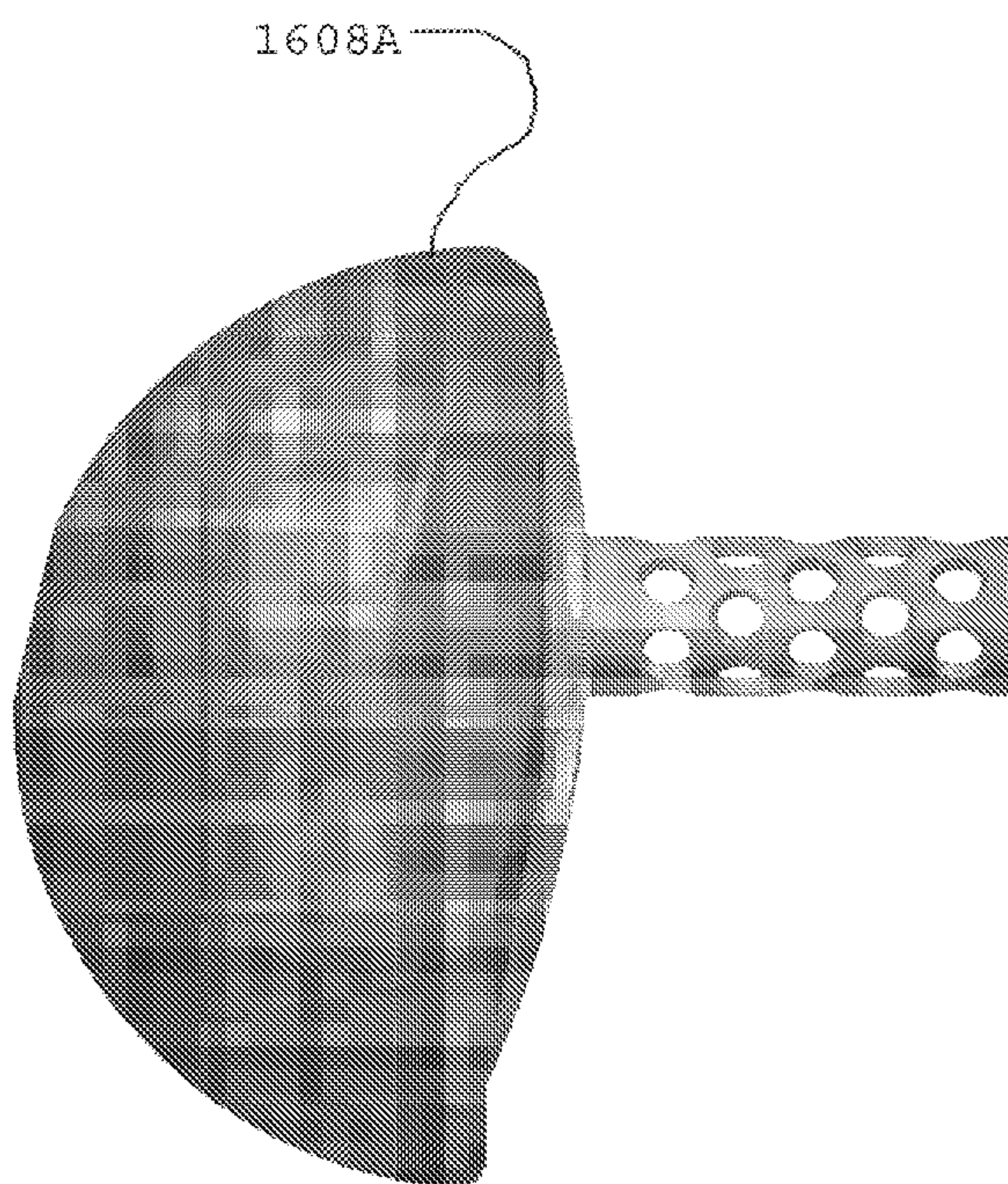


Fig. 22A

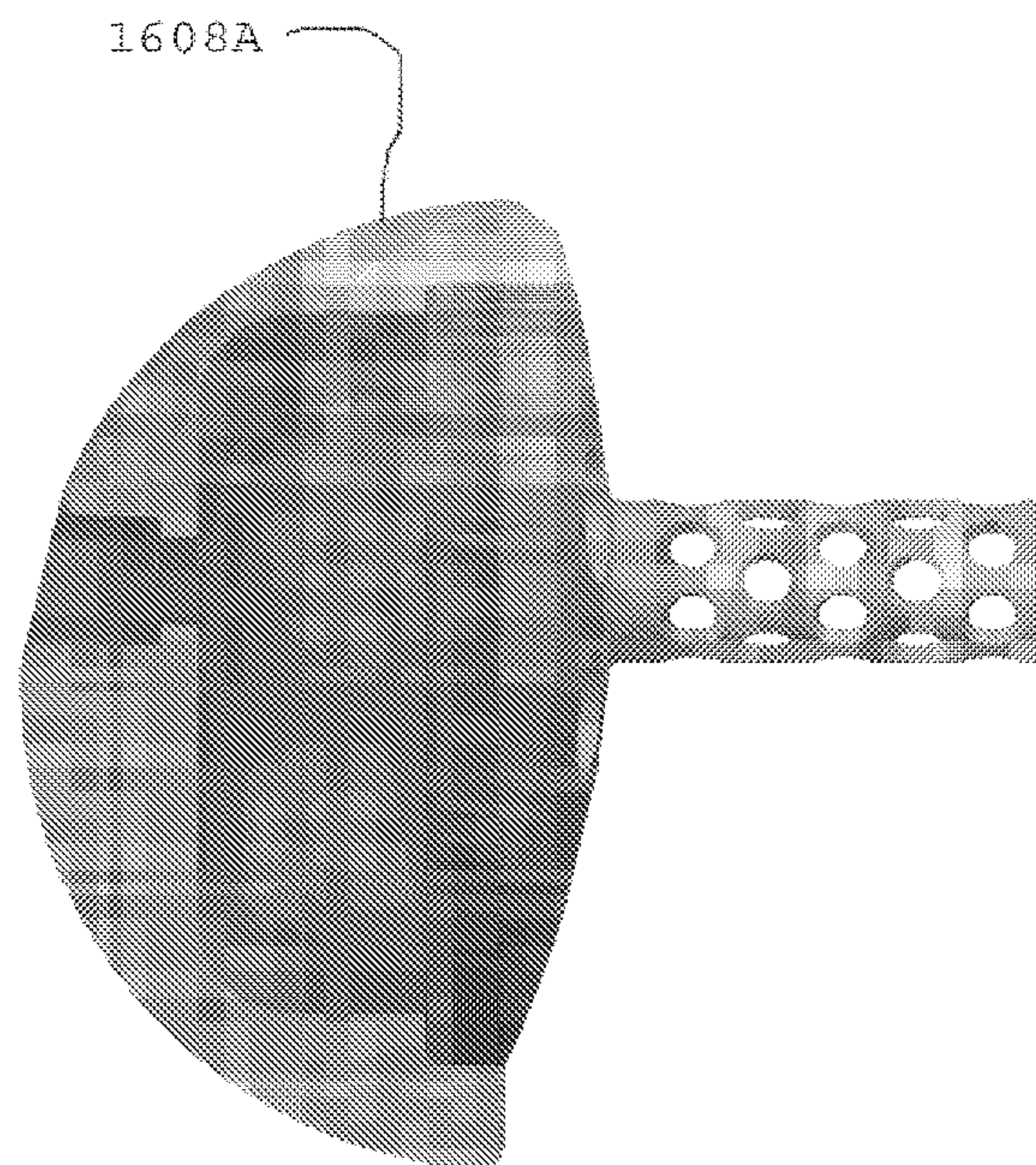
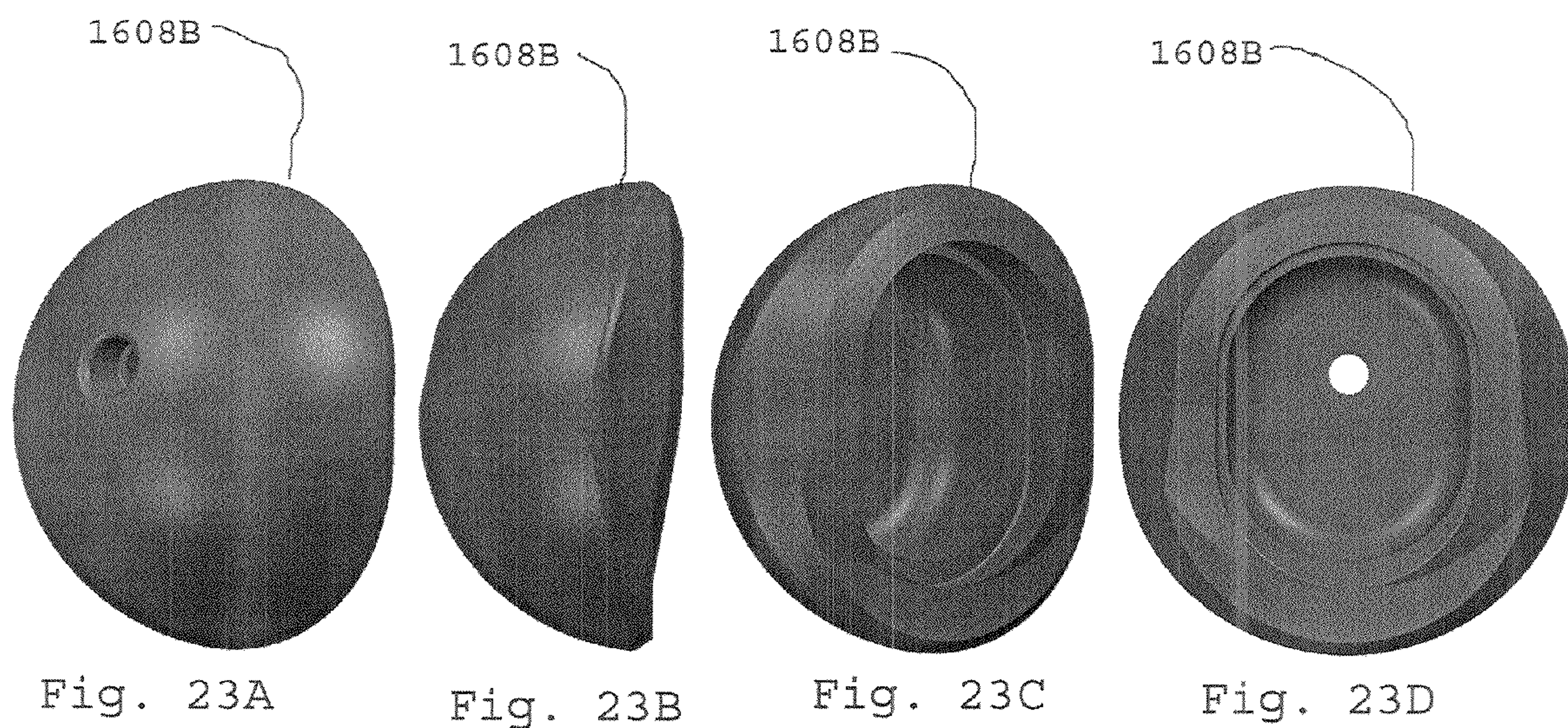


Fig. 22B



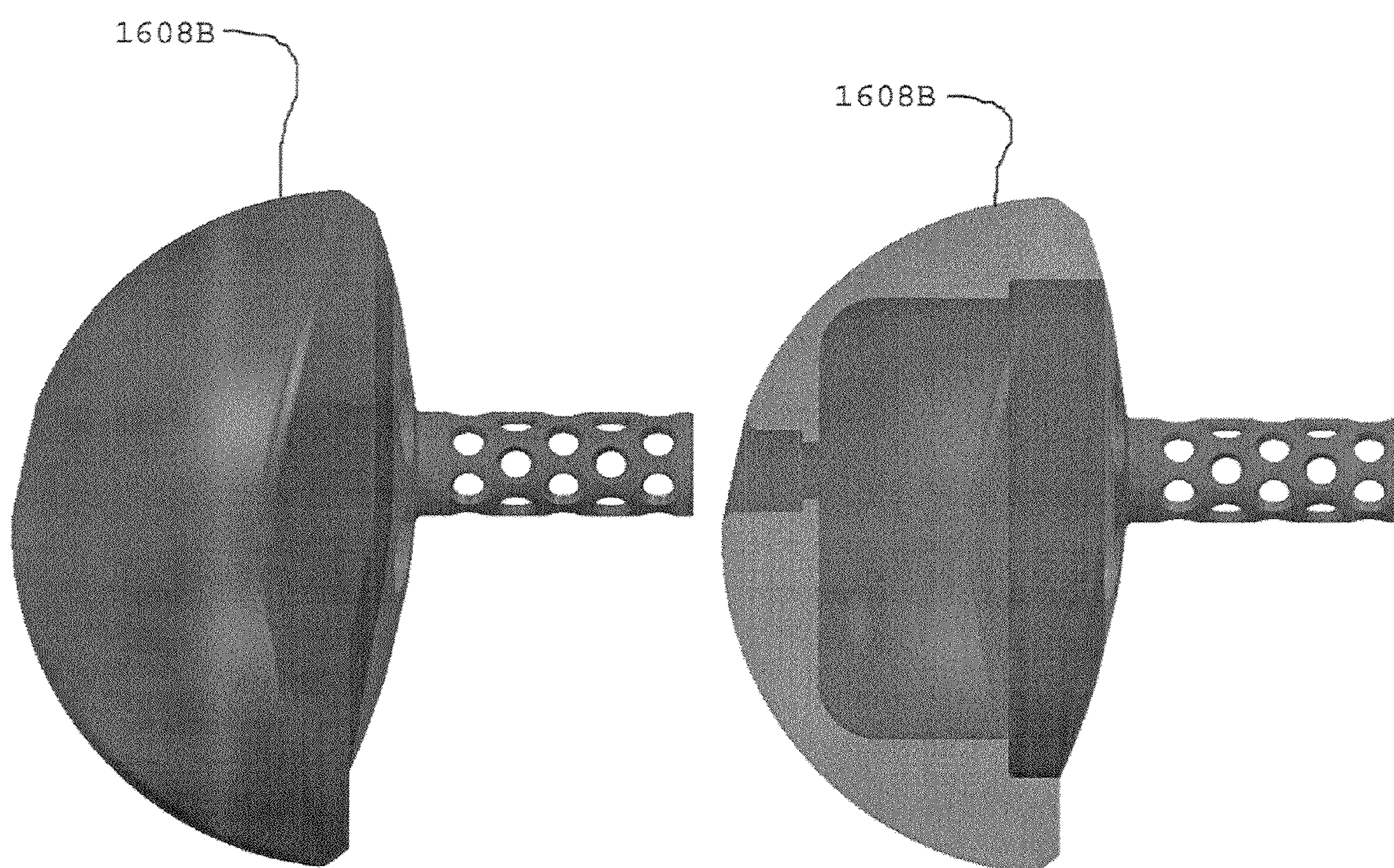


Fig. 24A

Fig. 24B

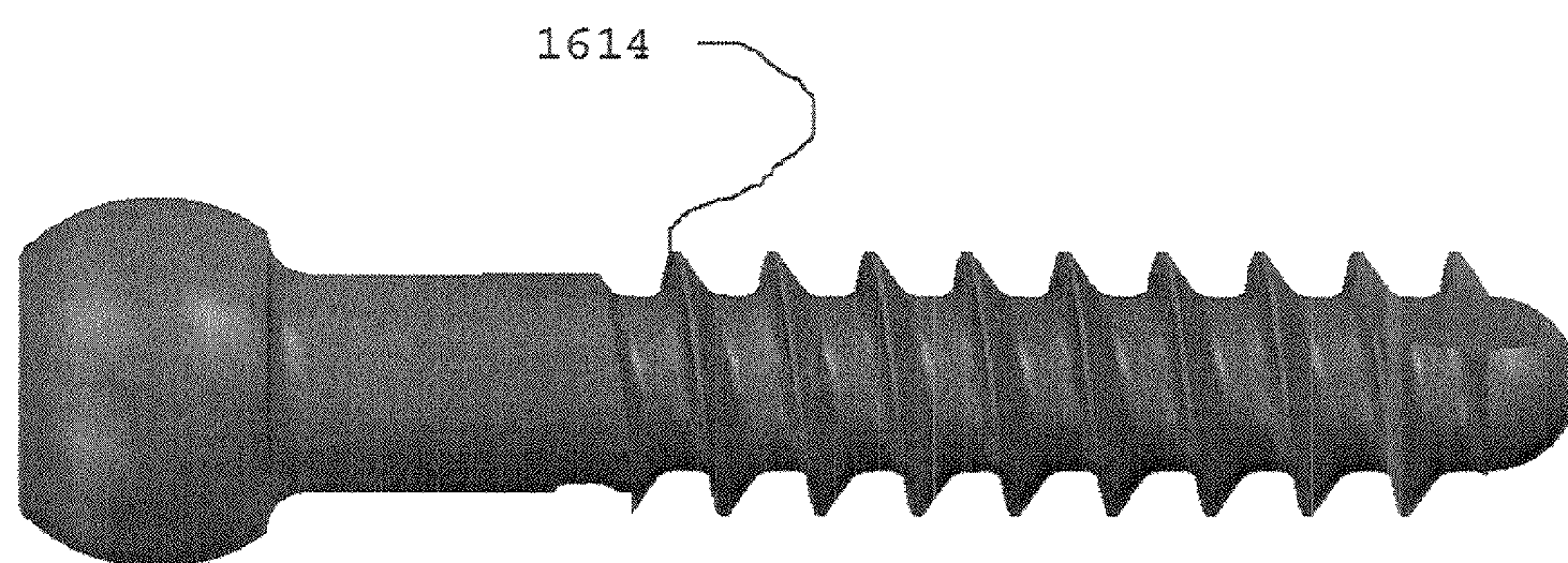


Fig. 25

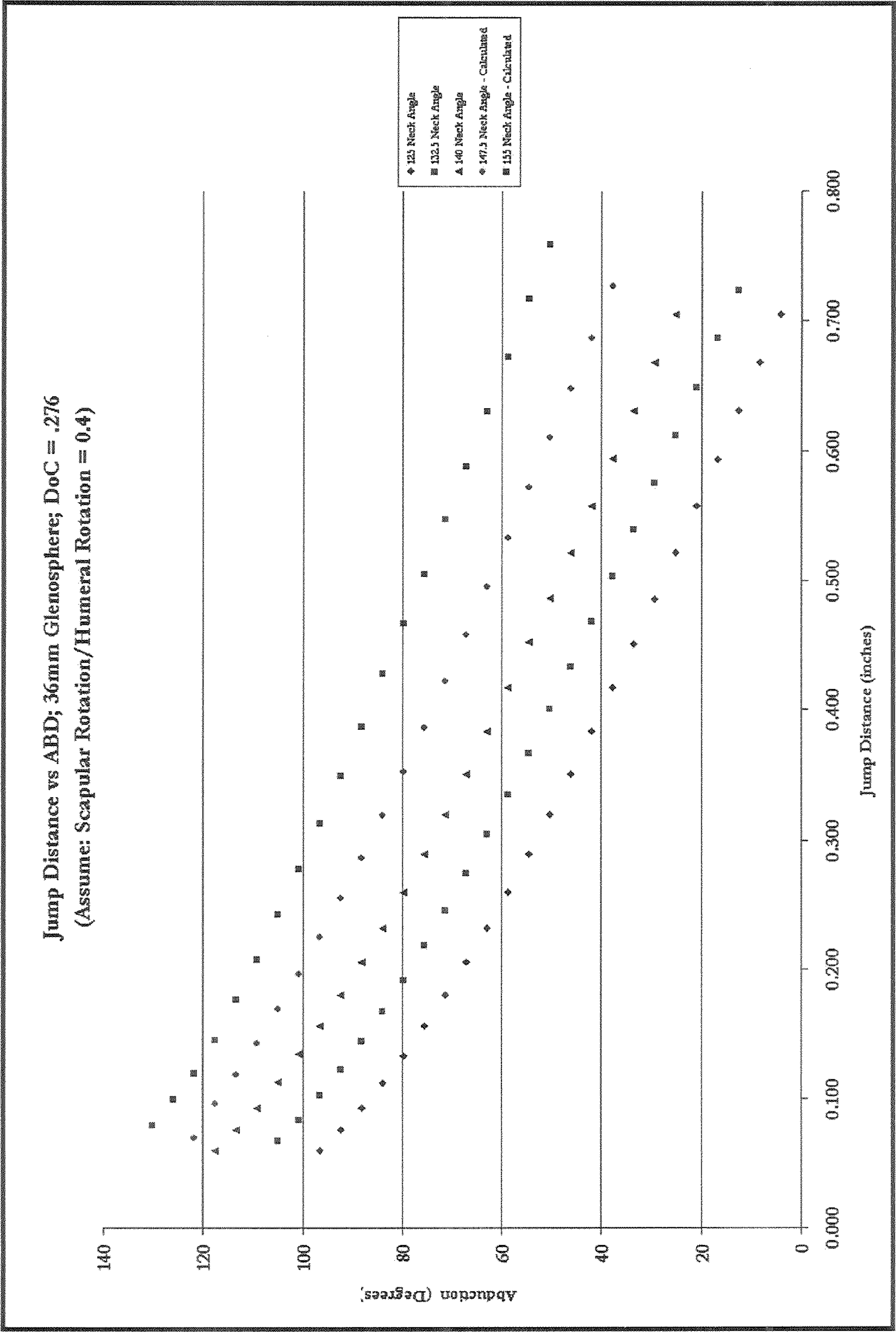


Fig. 26

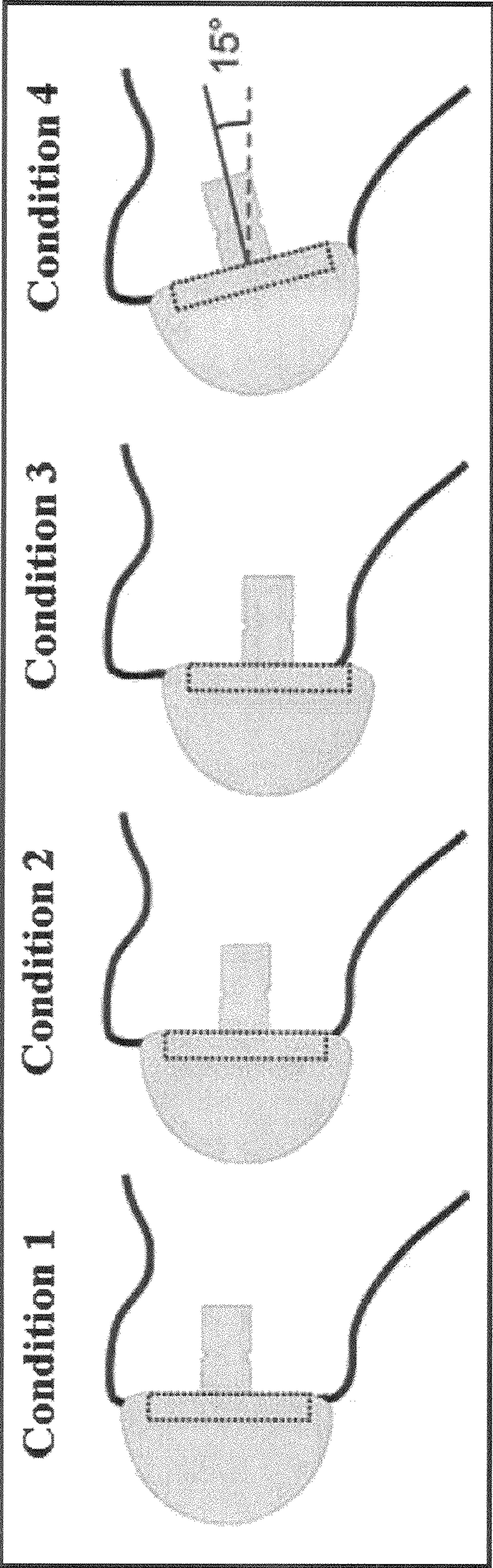


Fig. 27

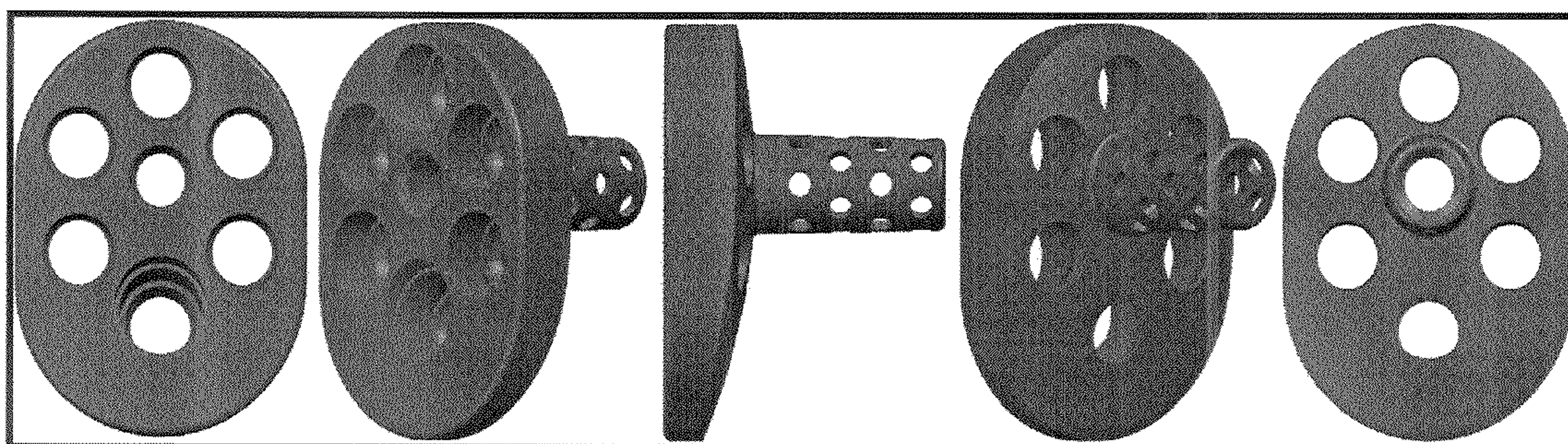


Fig. 28

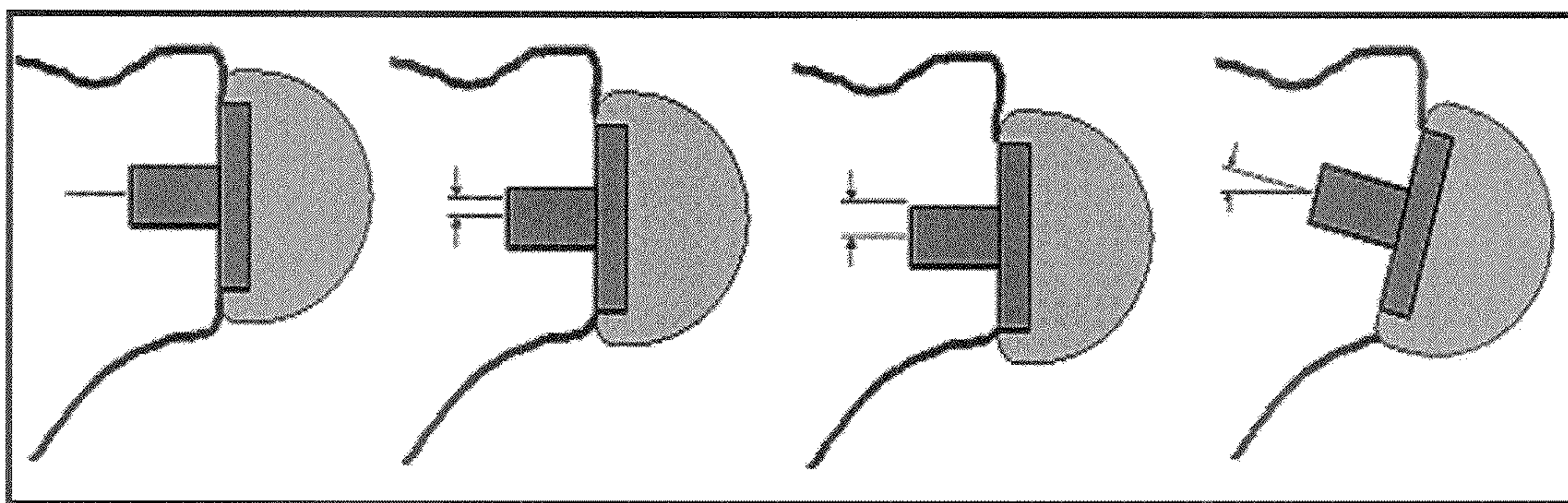


Fig. 29

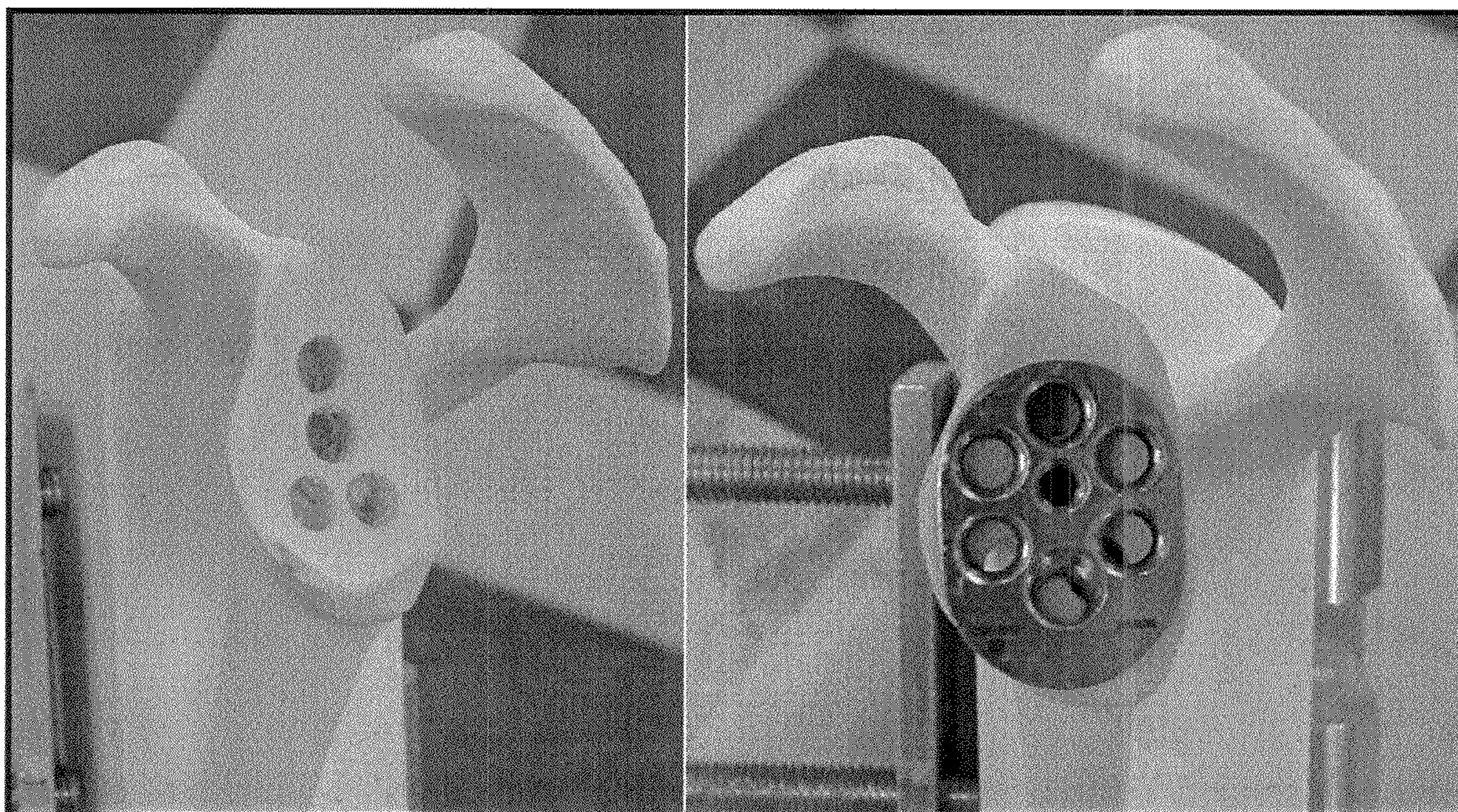


Fig. 30A

Fig. 30B

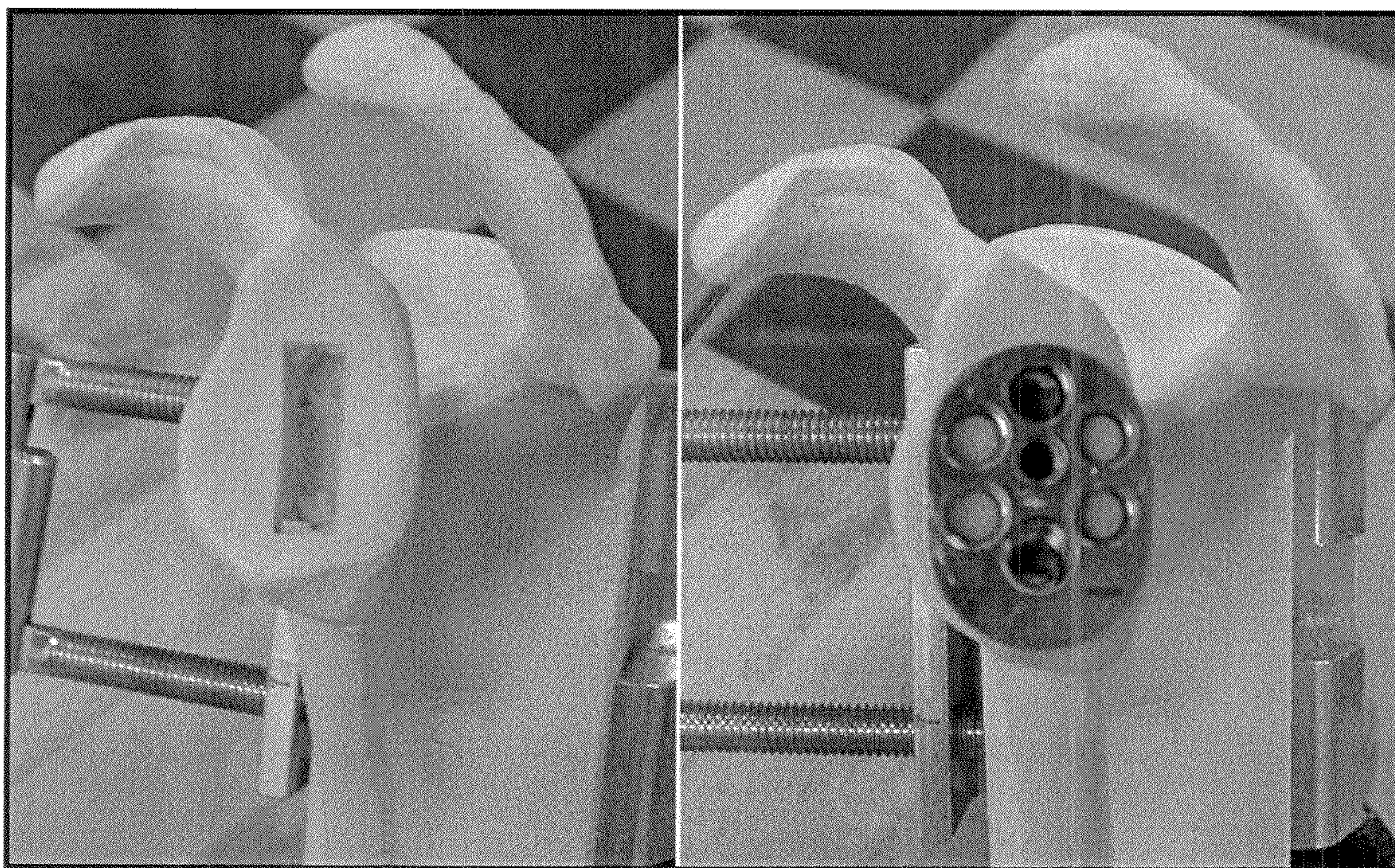


Fig. 31A

Fig. 31B

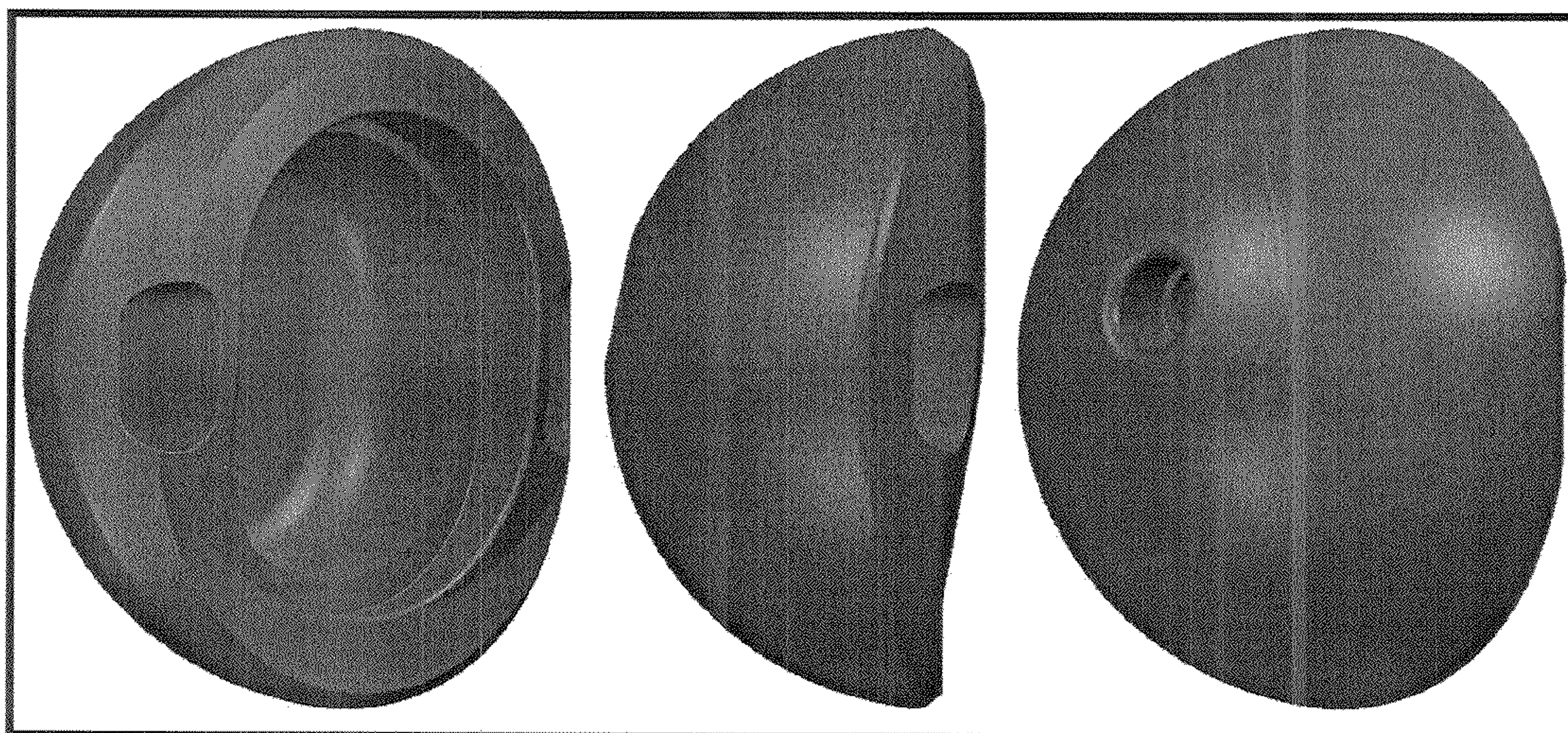


Fig. 32

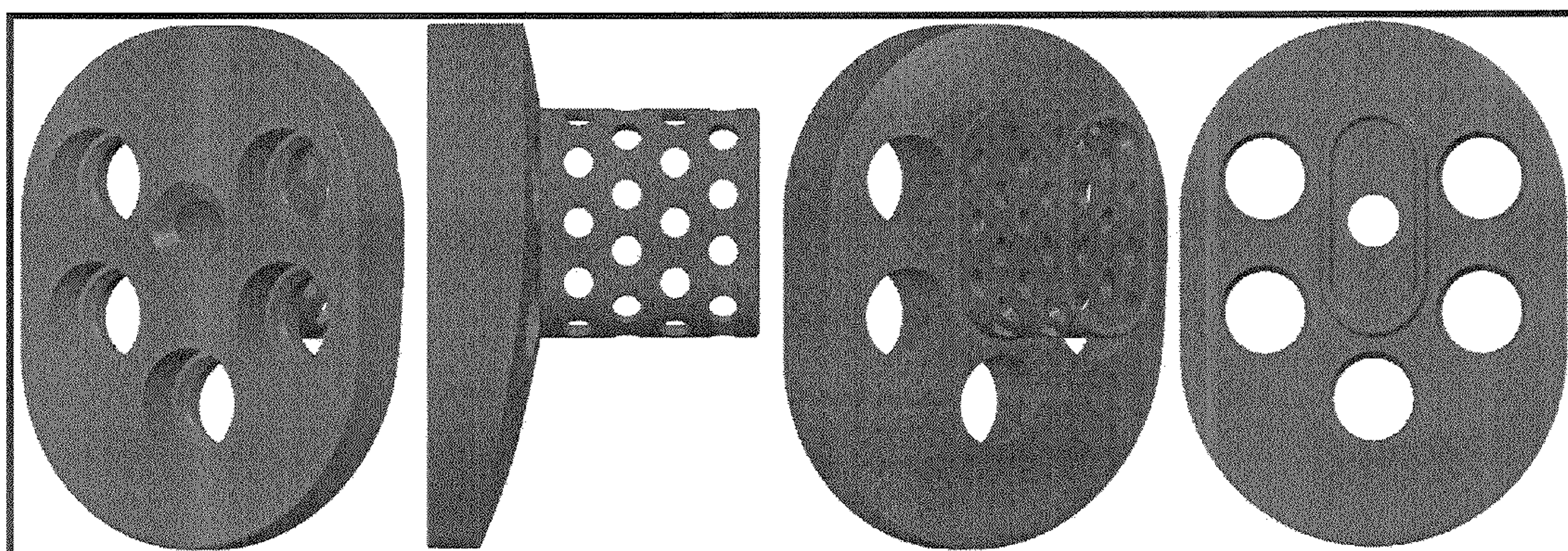


Fig. 33

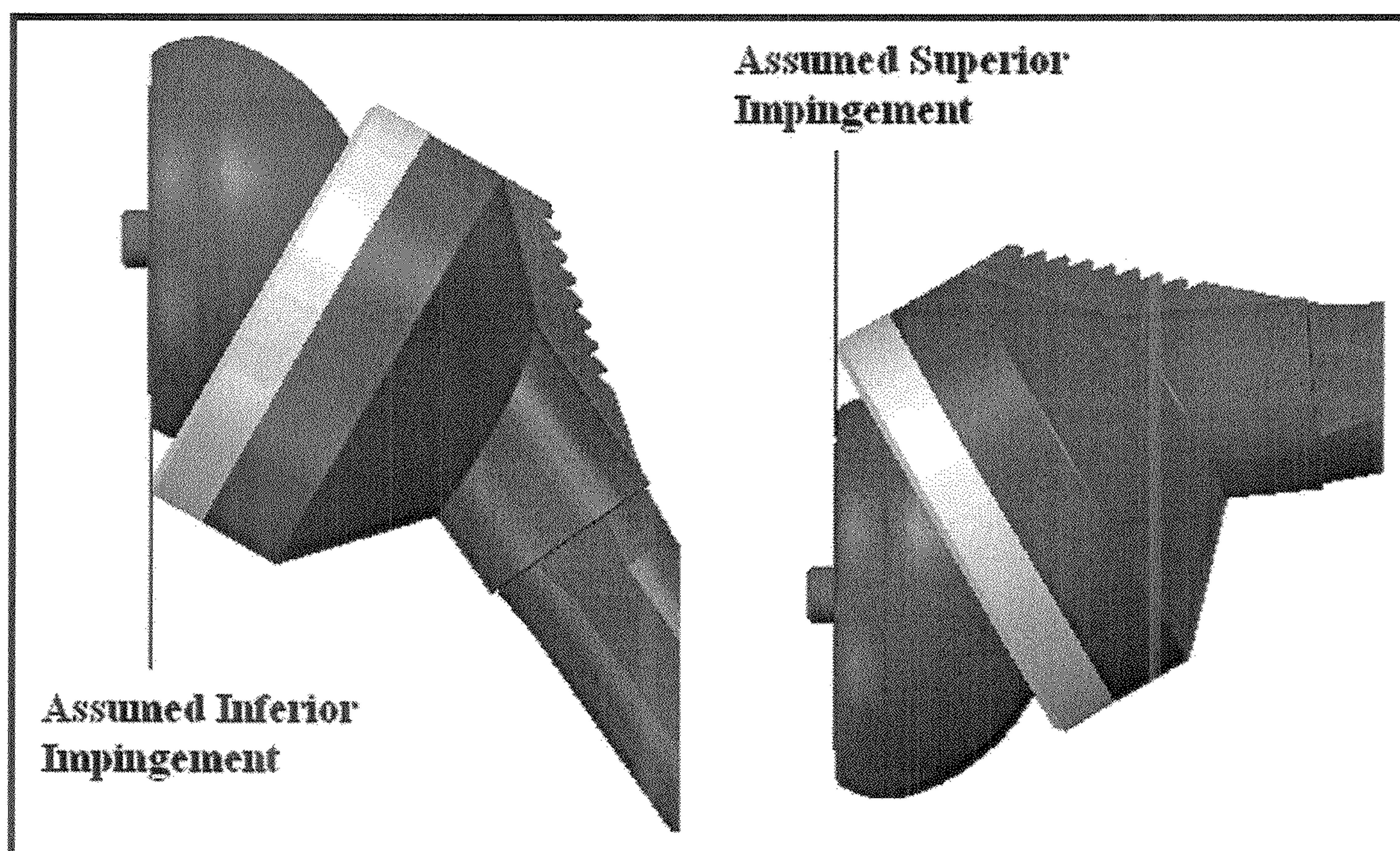


Fig. 34

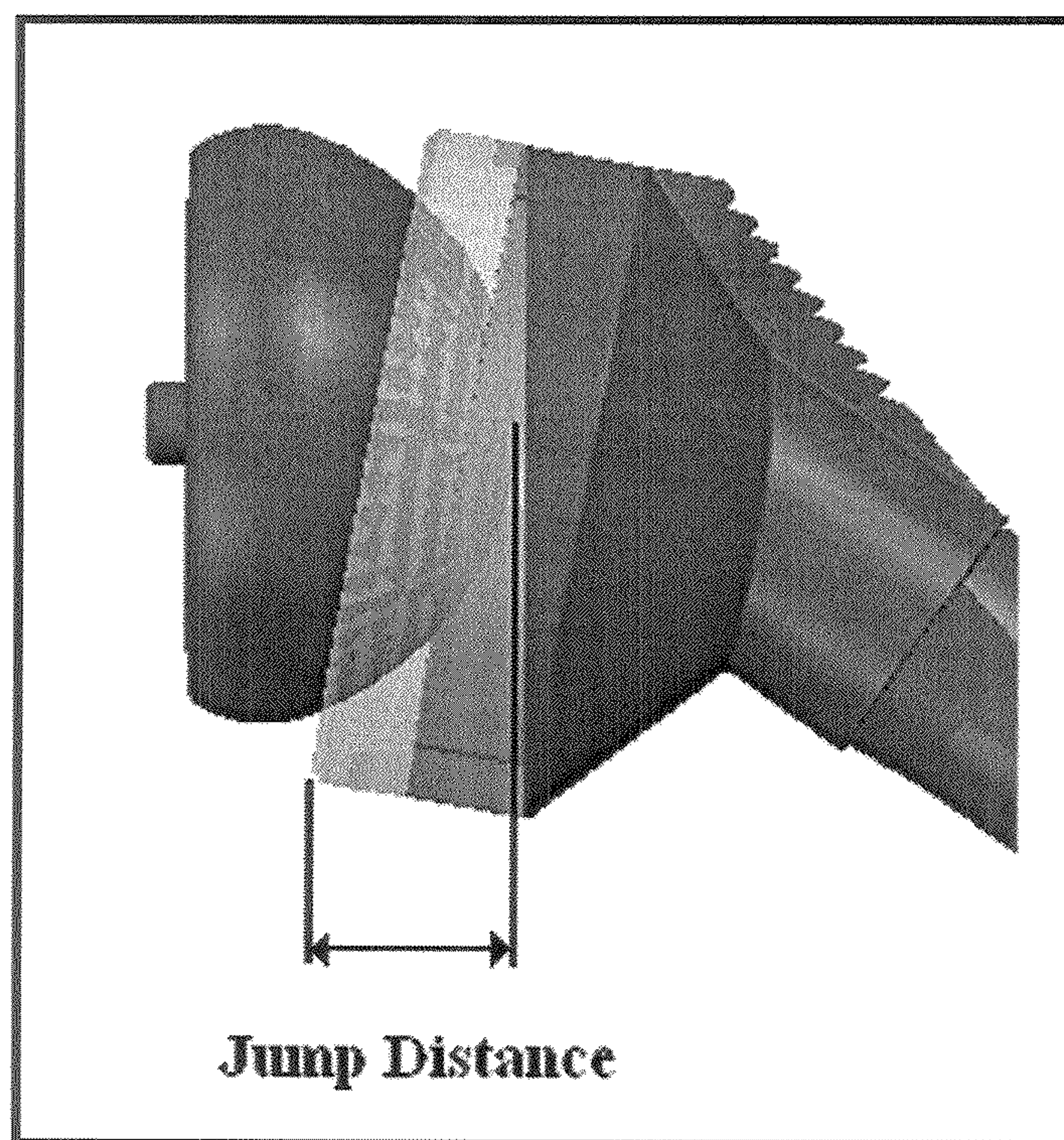


Fig. 35

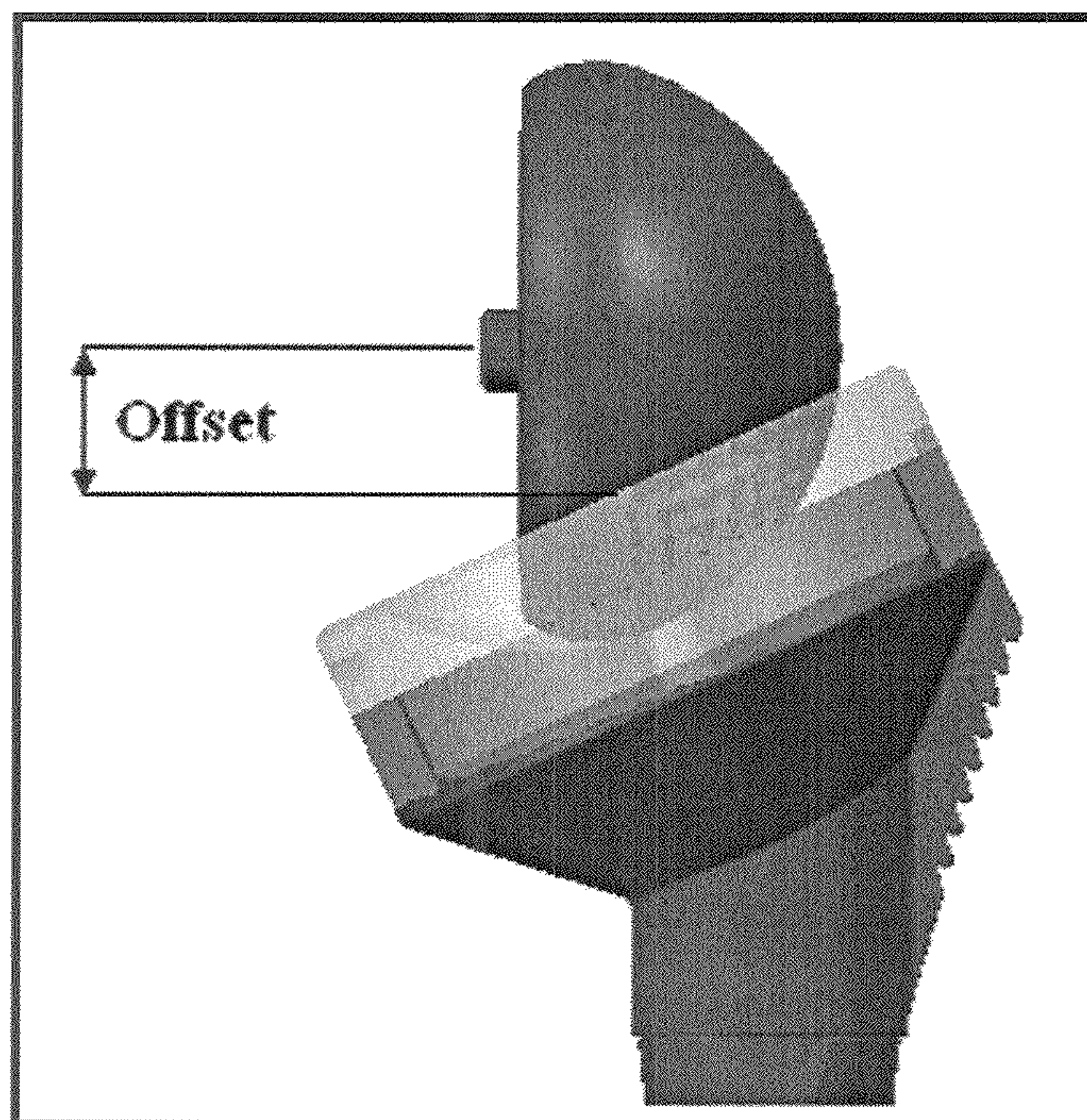


Fig. 36

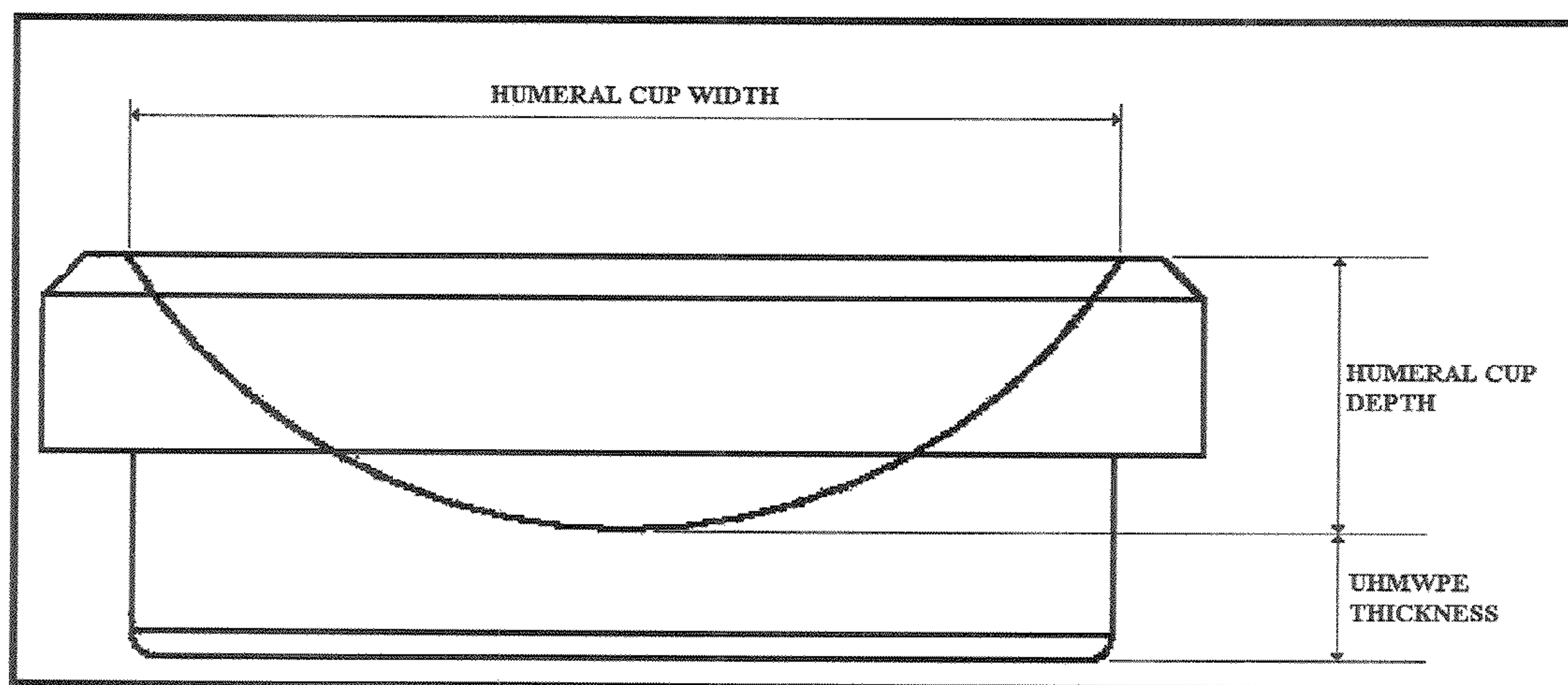


Fig. 37

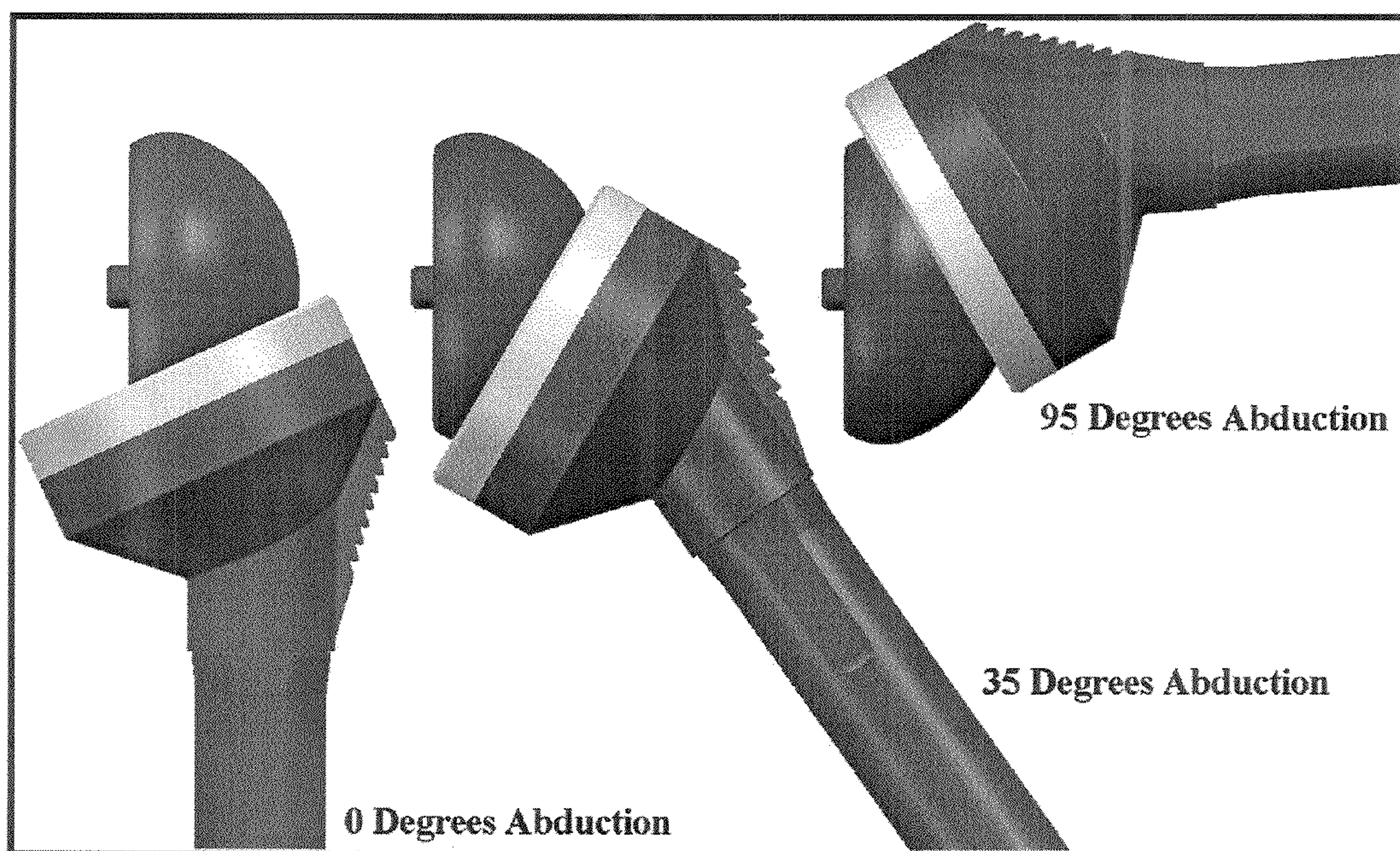


Fig. 38

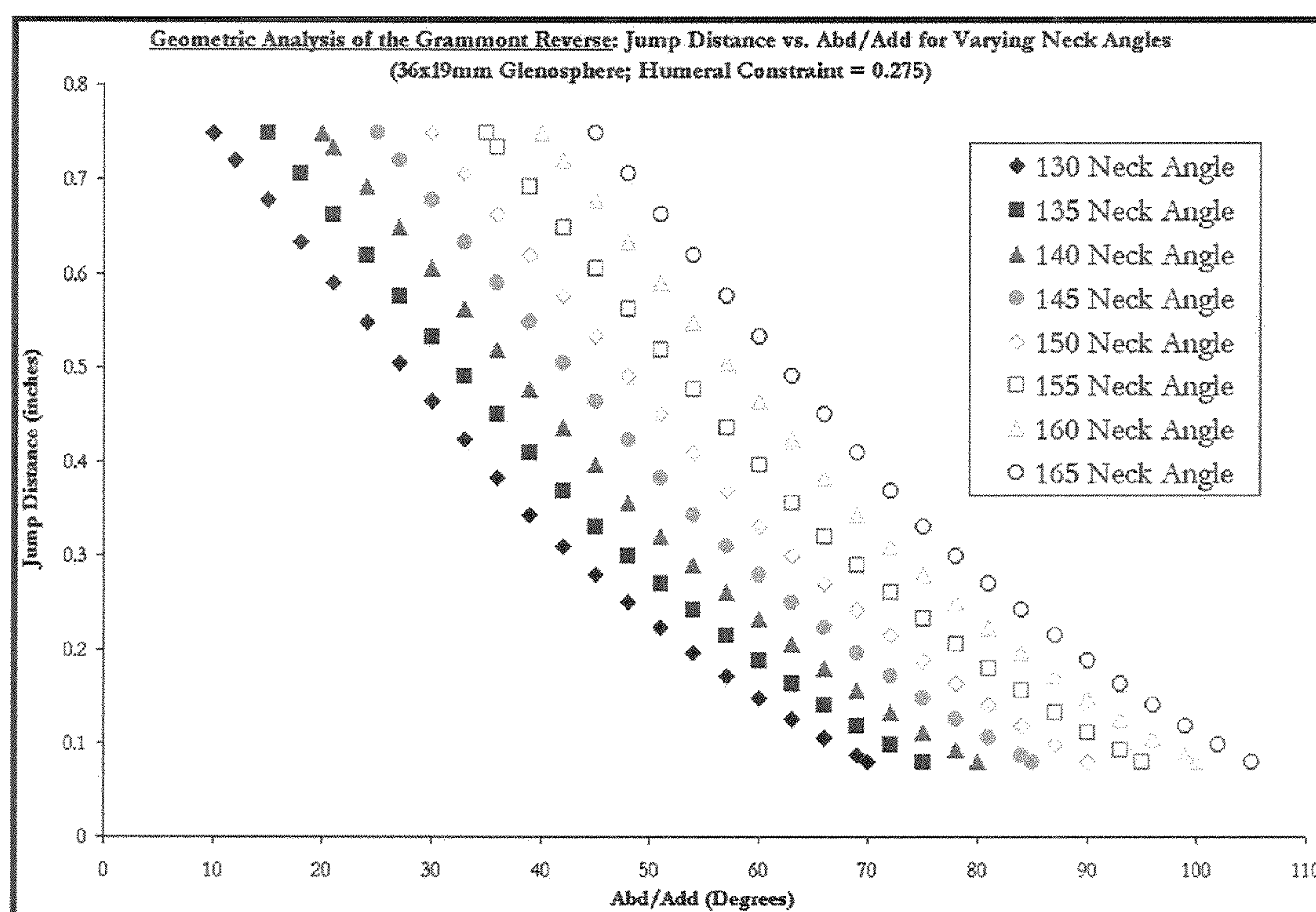


Fig. 39

Humeral Neck Angle	130°	135°	140°	145°	150°	155°	160°	165°
Inferior Impingement	10°	15°	20°	25°	30°	35°	40°	45°
Superior Impingement	70°	75°	80°	85°	90°	95°	100°	105°
ROM	60°	60°	60°	60°	60°	60°	60°	60°

Fig. 40

Humeral Constraint	0.2500	0.2625	0.2750	0.2875	0.3000	0.3125
Inferior Impingement	31.5°	33°	35°	37°	38.5°	40.5°
Superior Impingement	99°	97°	95°	93°	91.5°	89.5°
ROM	67.5°	64°	60°	56°	53°	49°

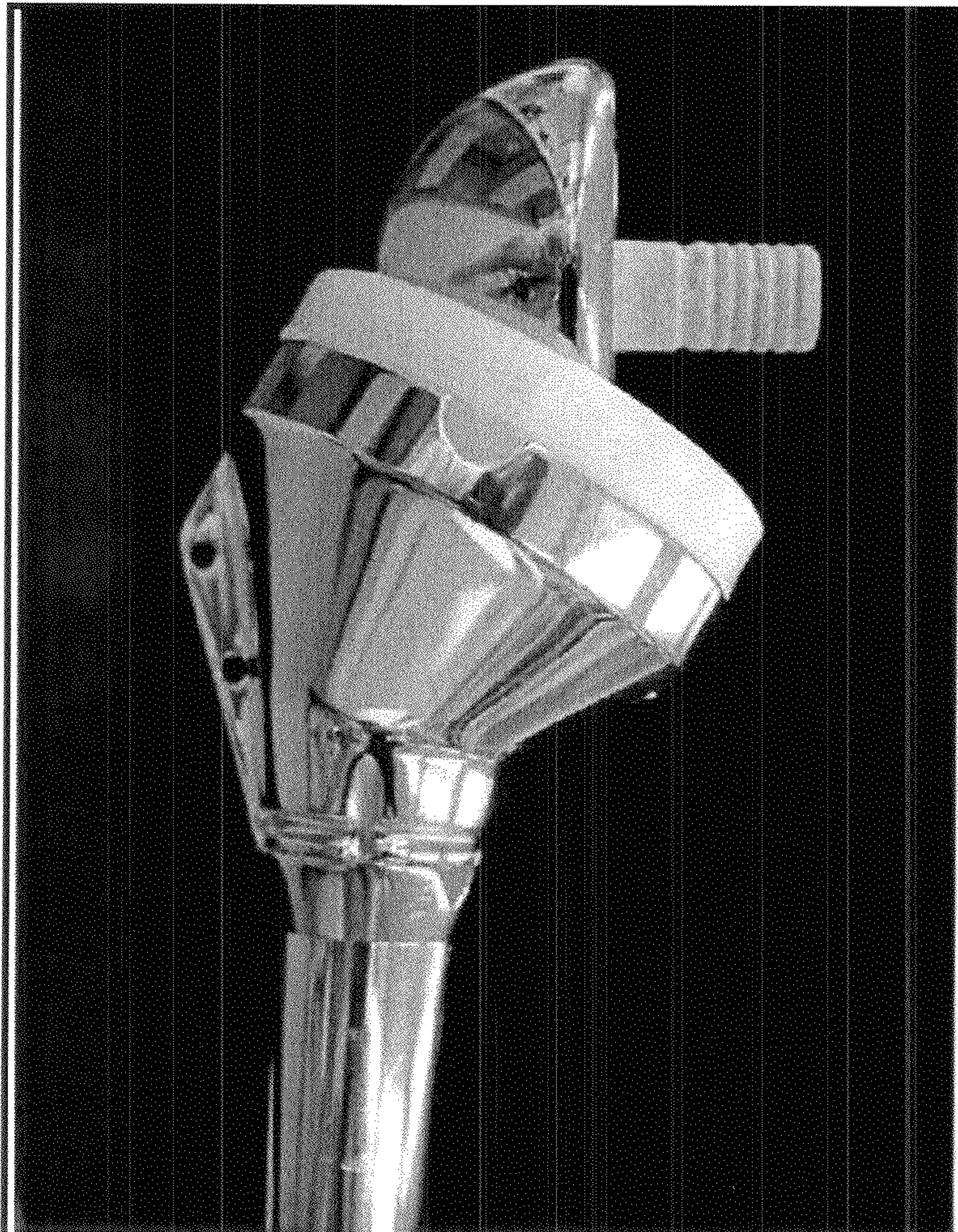
Fig. 41

Glenosphere Thickness*	17mm	18mm	19mm	20mm	21mm
Inferior Impingement	40.5°	38°	35°	32°	29.5°
Superior Impingement	89.5°	92°	95°	98°	100.5°
ROM	49°	54°	60°	66°	71°
*Assumes a constant humeral liner constraint between sizes					

Fig. 42

Glenosphere Diameter*	34mm	36mm	38mm	40mm	42mm	44mm
Impingement at 0° ABD	11.3mm	11.9mm	12.4mm	12.9mm	13.5mm	14.0mm
Jump Distance at 35° ABD	18.0mm	19.0mm	20.0mm	20.9mm	21.9mm	22.9mm
Jump Distance at 65° ABD	7.9mm	8.4mm	8.8mm	9.3mm	9.8mm	10.2mm
Jump Distance at 90° ABD	2.0mm	2.1mm	2.2mm	2.3mm	2.4mm	2.5mm
*Assumes a constant humeral liner constraint between sizes						

Fig. 43



Photograph of a reverse Delta III total shoulder prosthesis. In the neutral position, the stem of the humeral component is vertical and the polyethylene cup extends beyond the inferior border of the scapular component (glenosphere).

Fig. 44

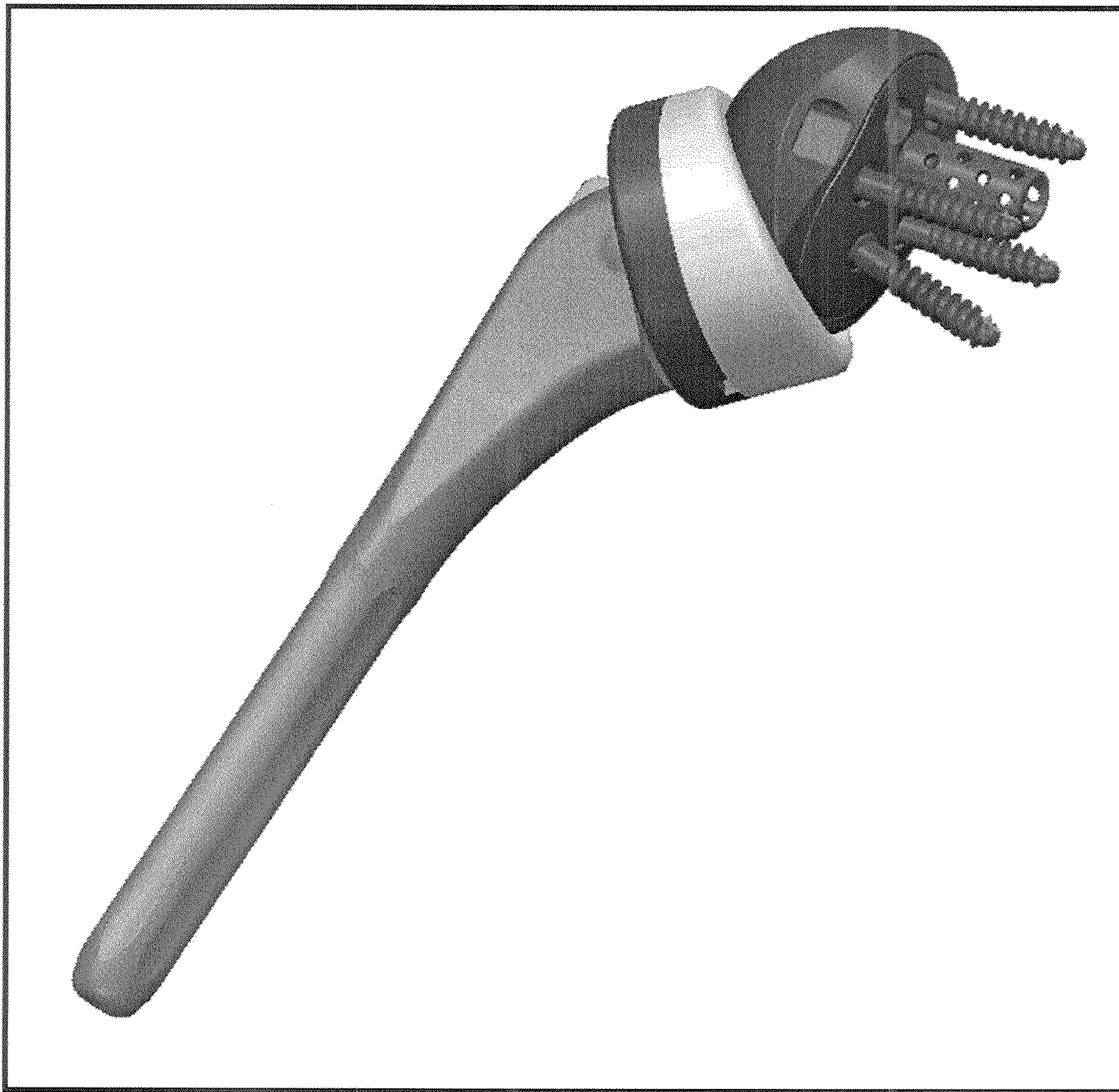


Fig. 45

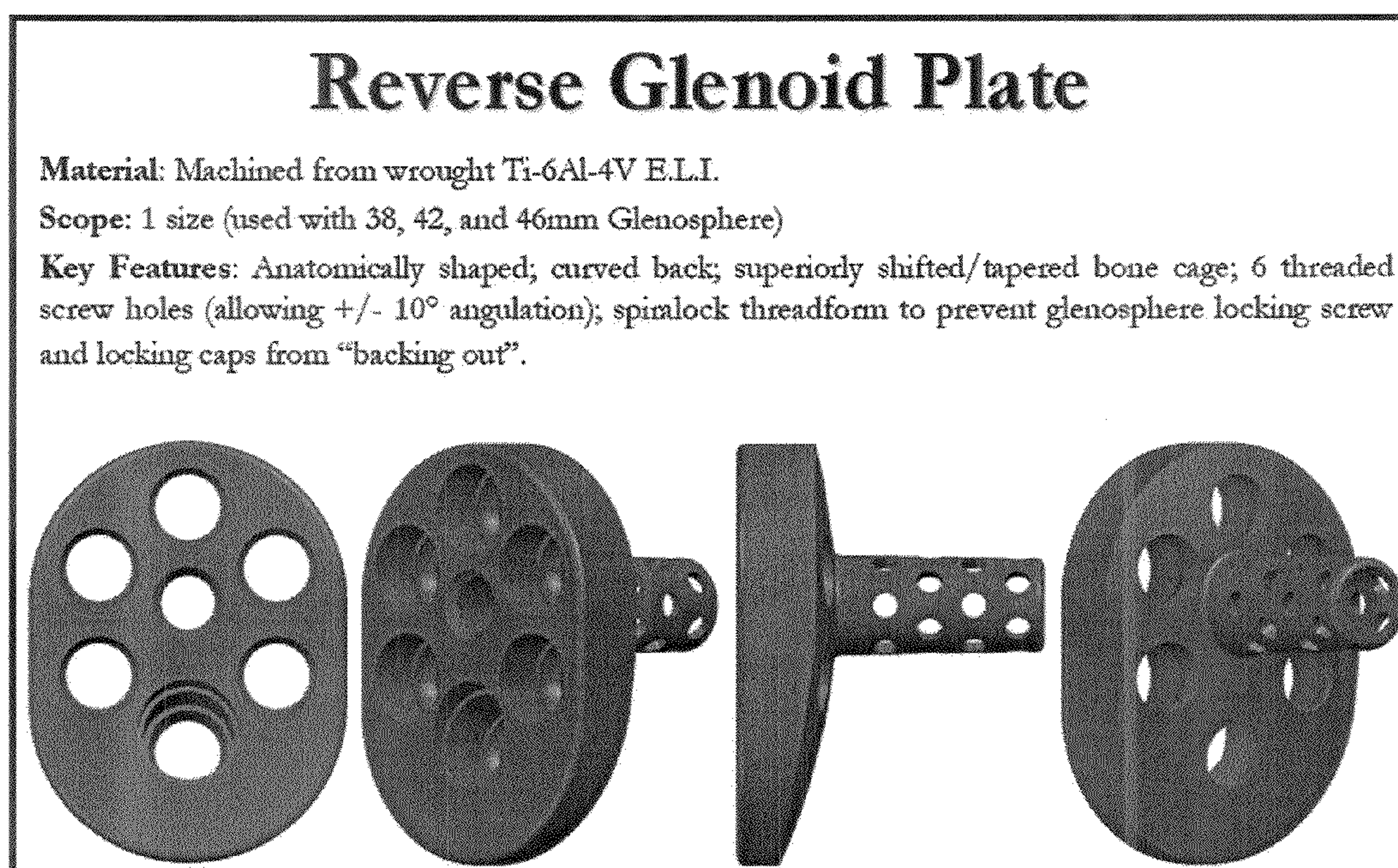


Fig. 46

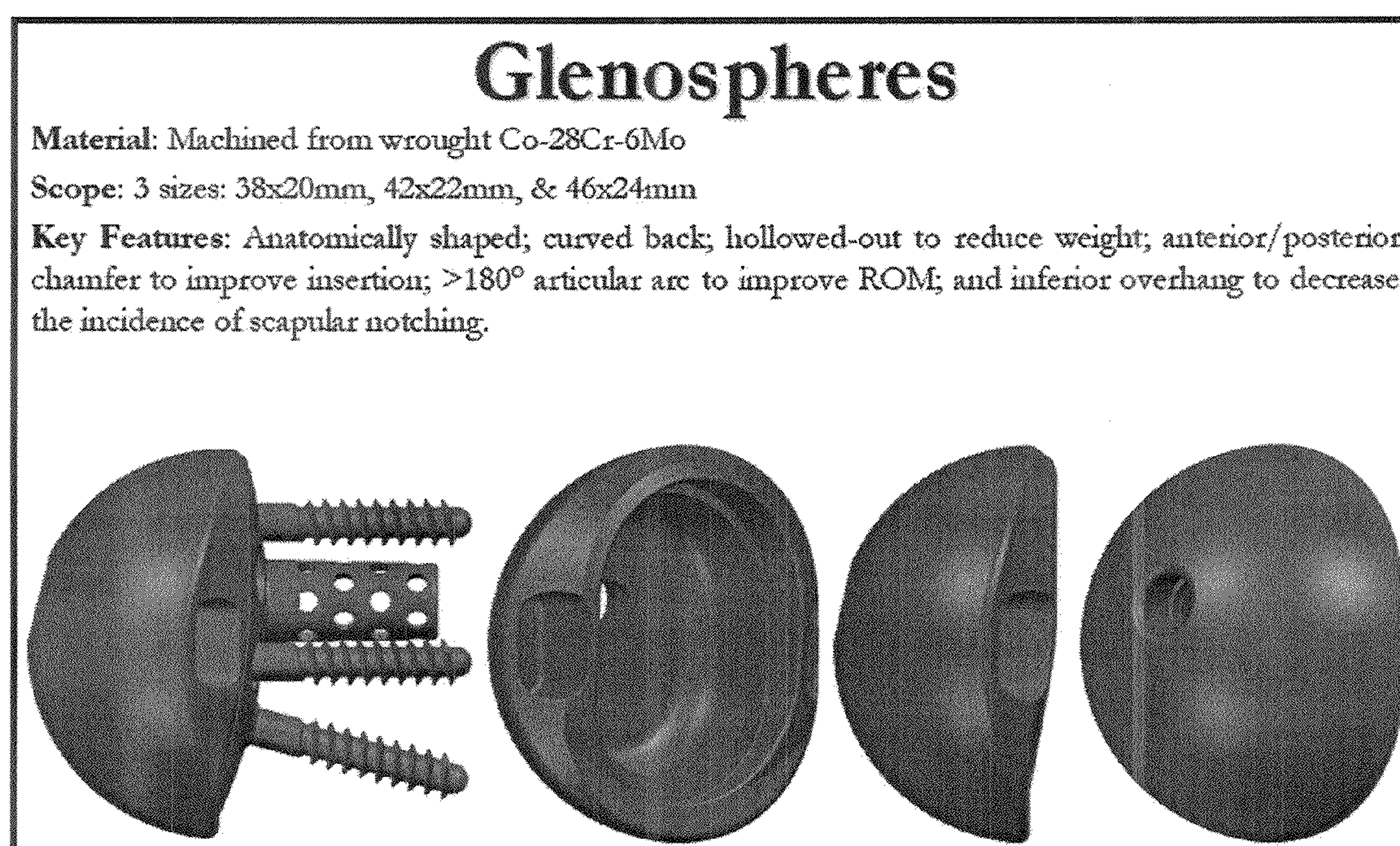


Fig. 47

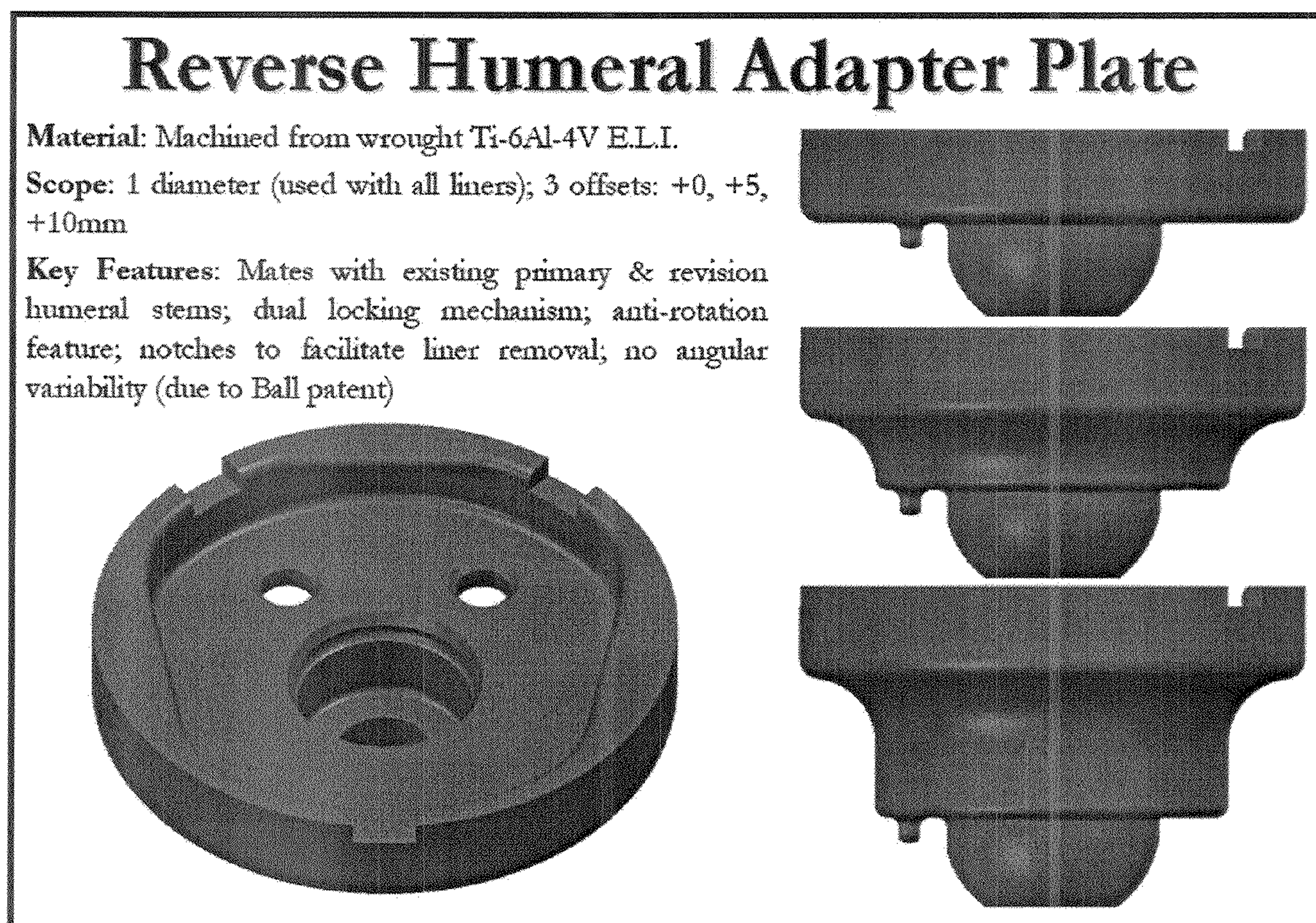


Fig. 48

Reverse Humeral Liners

Material: Machined from compression molded UHMWPE

Scope: 3 diameters: 38, 42, & 46mm; 2 offsets: +0, +2.5; standard & constrained

Key Features: Dual locking mechanism; 12.5° angled face; 4mm minimum apical thickness; anti-rotation base.

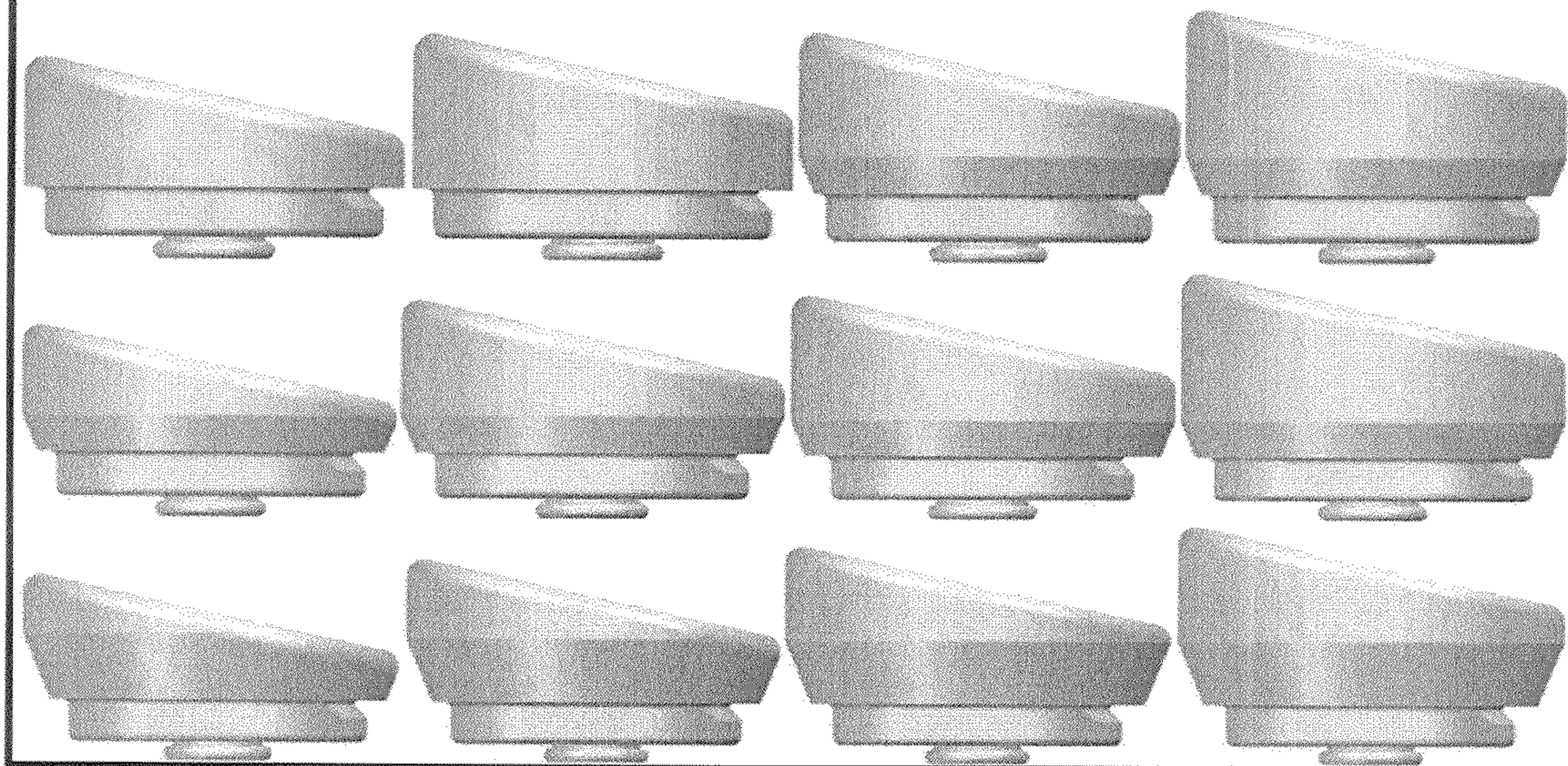


Fig. 49

Reverse Torque Defining Screw

Material: Machined from wrought Ti-6Al-4V

Scope: 1 size

Key Features: Superior portion of screw fractures after application of 11 N*m (100 in*lb) of torque; UHMWPE retention plug holds superior portion of screw at fracture; male square drive; mates with existing primary and revision humeral stems.

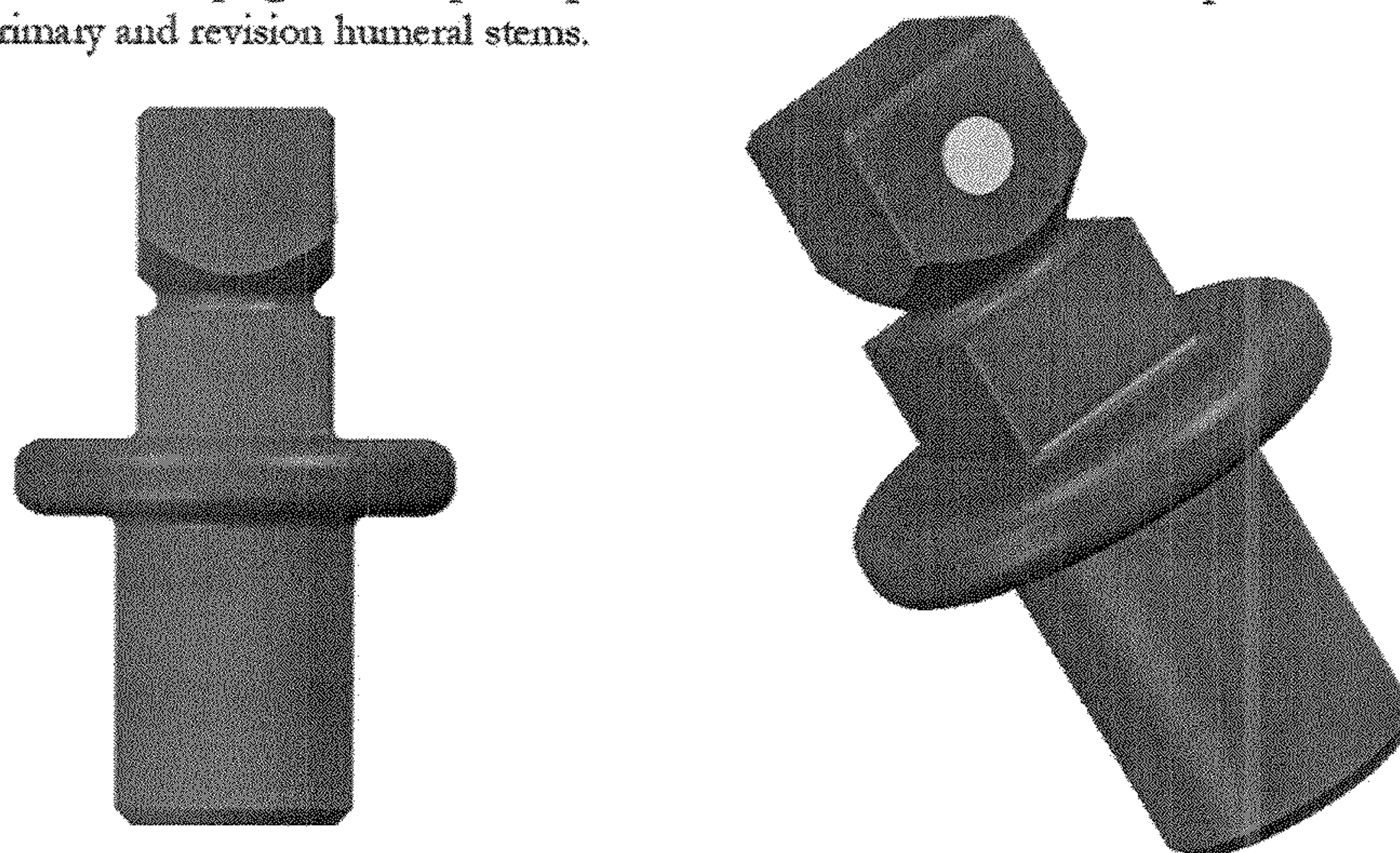


Fig. 50

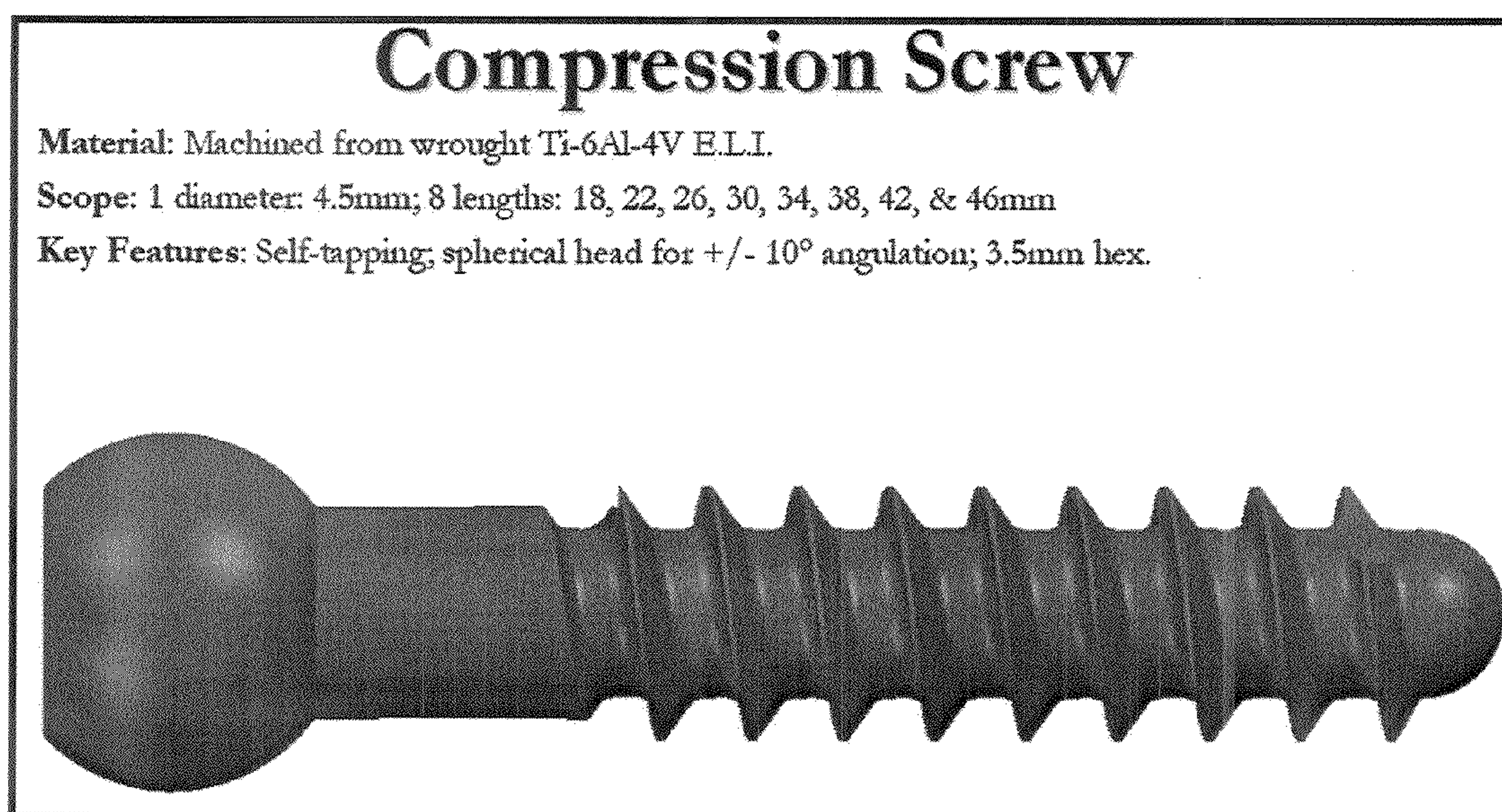


Fig. 51

Glenosphere Locking Screw

Material: Machined from wrought Ti-6Al-4V

Scope: 1 size; 5mm diameter

Key Features: Locks glenosphere to glenoid plate; 3.5mm hex.

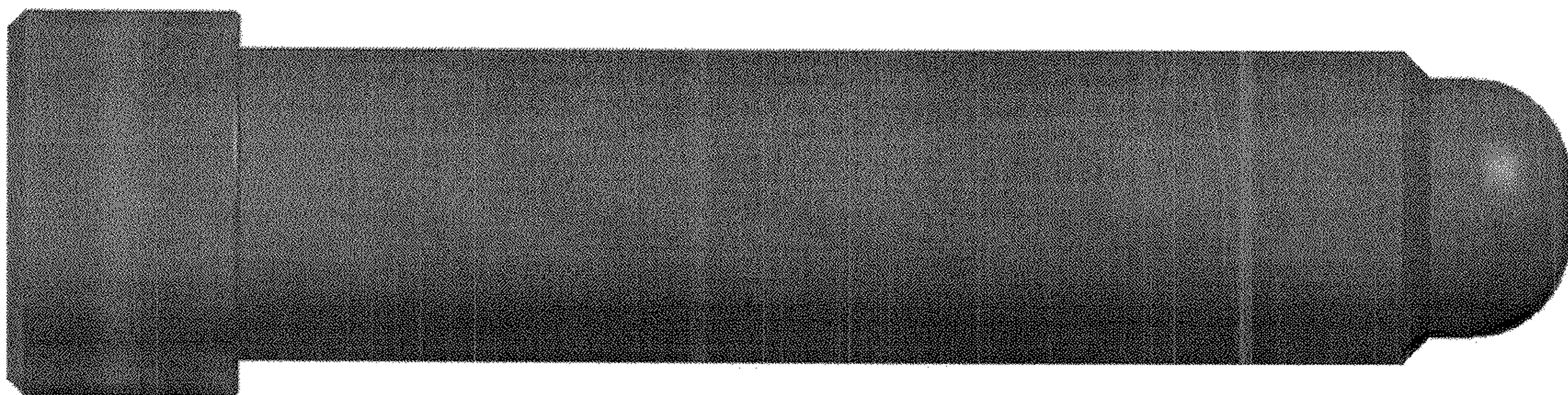


Fig. 52

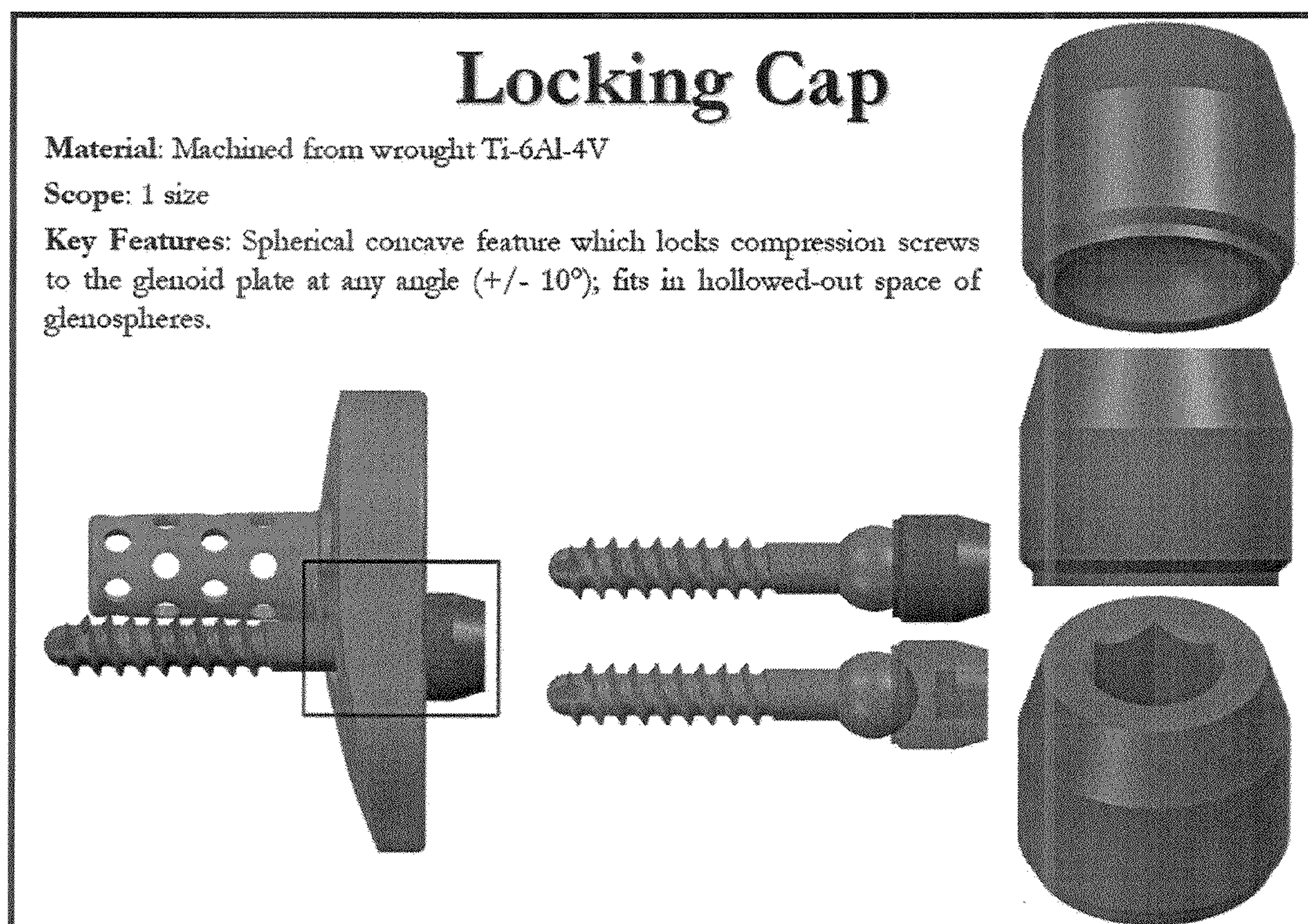


Fig. 53

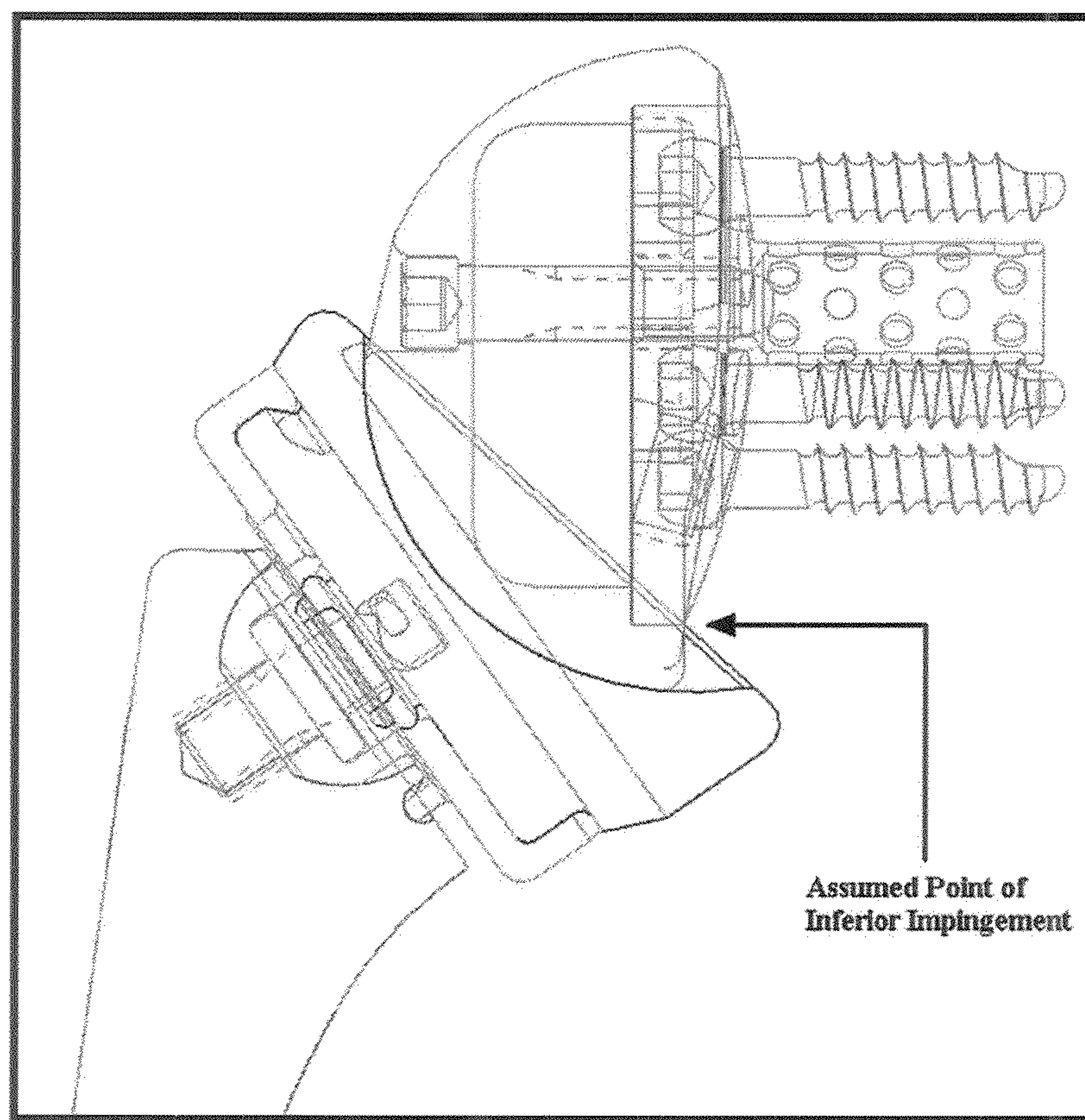


Fig. 54

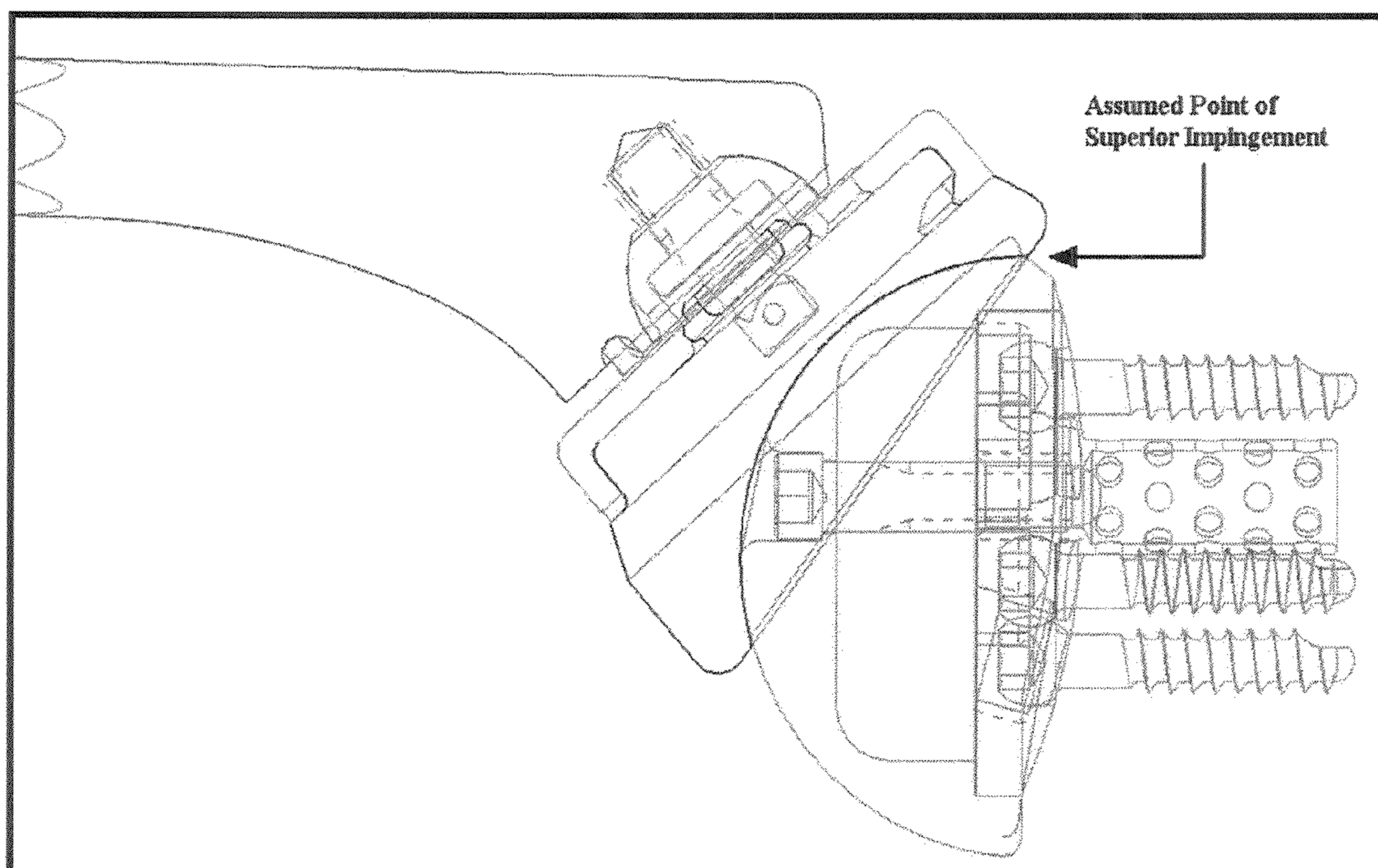


Fig. 55

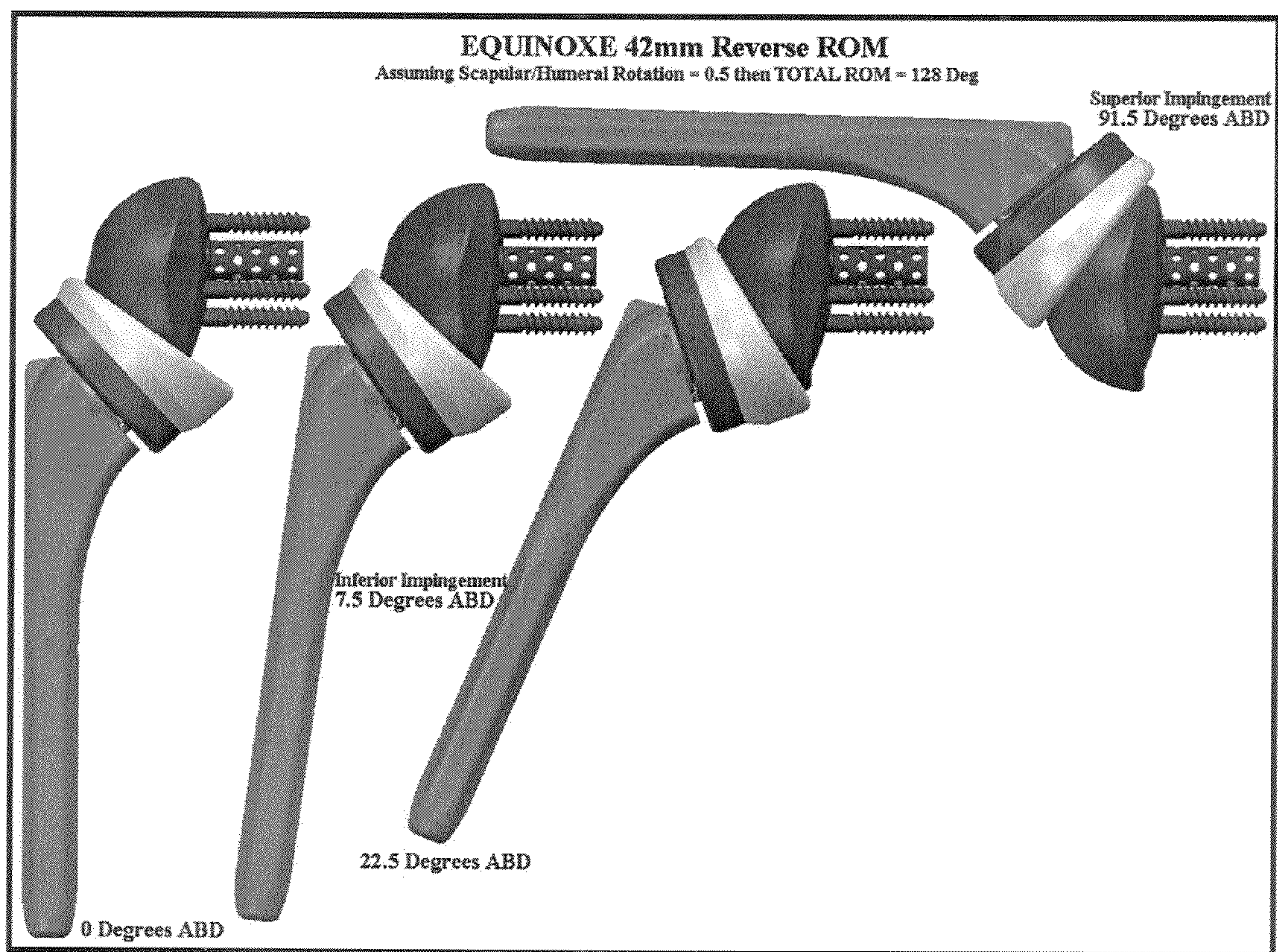


Fig. 56

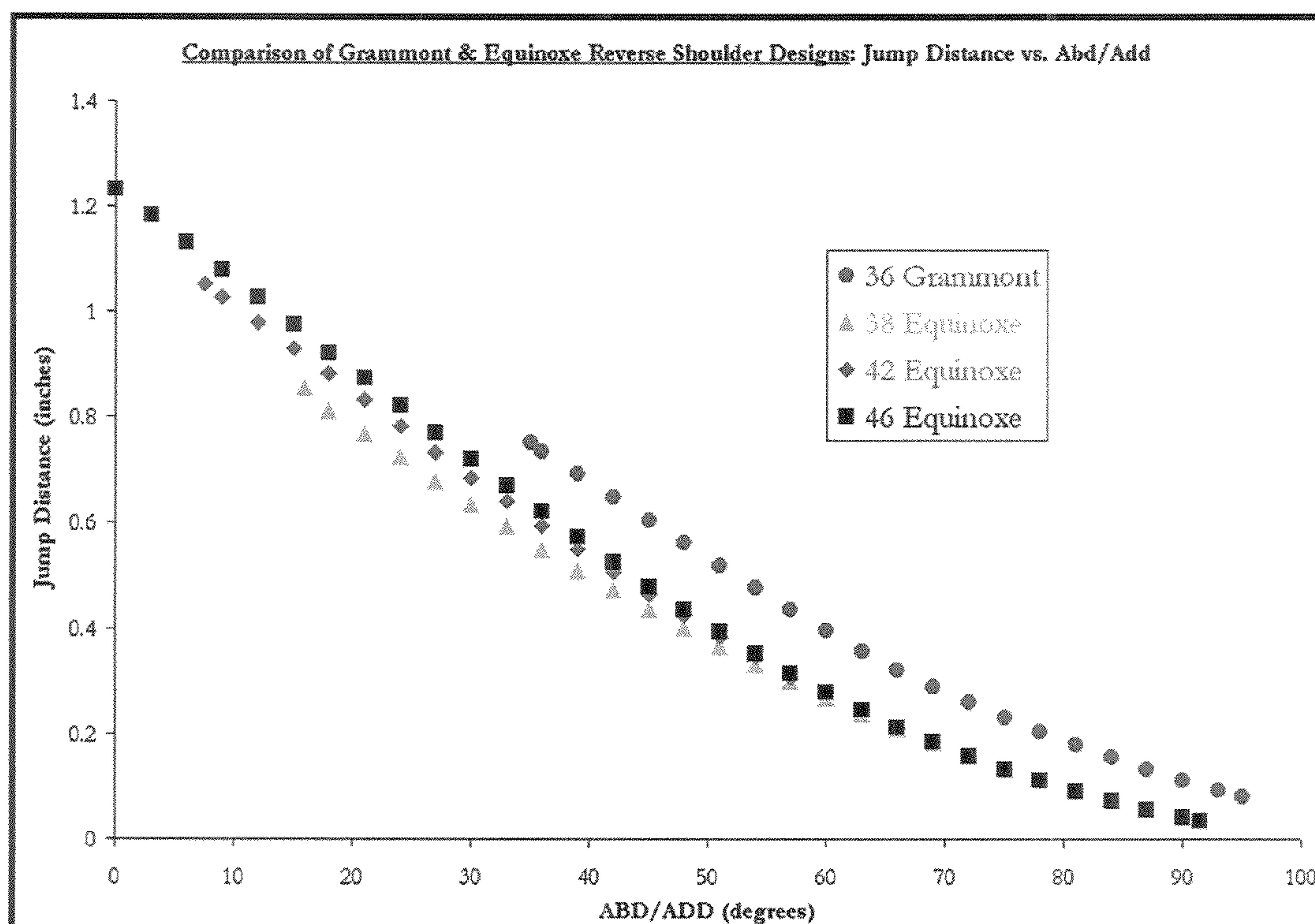


Fig. 57

	38mm Equinox	42mm Equinox	46mm Equinox	36mm Grammont	42mm Grammont*
Inferior Impingement	16°	7.5°	0°	35°	35°
Superior Impingement	91.5°	91.5°	91.5°	95°	95°
ROM	75.5°	84°	91.5°	60°	60°
*Assumes 42mm Grammont has the same humeral liner constraint as the 36mm Grammont					

Fig. 58

REVERSE SHOULDER PROSTHESIS**RELATED APPLICATIONS**

This application claims the benefit of U.S. Provisional Application Ser. No. 60/785,664, filed Mar. 23, 2006. This application also claims the benefit of U.S. Provisional Application Ser. No. 60/747,492, filed May 17, 2006. This application also claims the benefit of U.S. Provisional Application Ser. No. 60/888,982, filed Feb. 9, 2007. Each of the aforementioned applications is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

Various embodiments of the present invention relate to an apparatus and method for reverse shoulder arthroplasty (e.g., reverse total shoulder arthroplasty). In one specific example, a glenoid component used to resurface the scapula may be provided. Of note, unlike traditional total shoulder arthroplasty the glenoid component in a reverse shoulder is convex rather than concave; it acts as a physical stop to prevent the superior migration of the humeral head—a typical occurrence in patients suffering from rotator cuff tear arthropathy (CTA).

For the purposes of describing the present invention the term “Equinoxe” (such as, for example, Equinoxe reverse shoulder design or Equinoxe reverse shoulder prosthesis) is intended to refer to an embodiment of the present invention.

BACKGROUND OF THE INVENTION

Neer coined the term cuff tear arthropathy in 1972 to describe the arthritic, eroded/collapsed condition of the glenohumeral joint following prolonged/progressive subacromial impingement resulting from massive, full thickness rotator cuff tears. This pathology is associated with extreme pain and near complete loss of function. (see Neer, C. S. et al. Cuff Tear Arthropathy. JBJS. #65: 1232-1244. 1983).

Cuff tear arthropathy has been historically treated with acromioplasty, arthroscopic debridement, tendon transfers, humeral tuberosity, arthrodesis, total shoulder arthroplasty (constrained, semi-constrained, or unconstrained), bipolar shoulder arthroplasty, hemiarthroplasty (with and without acromial spacers), and most recently (and successfully) reverse shoulder arthroplasty.

The Reverse/Inverse shoulder was first conceived by Neer in the early 1970's to treat patients suffering from CTA; specifically, this device was intended to provide pain relief and prevent progressive acromial, coracoid, and glenoid erosion by resisting humeral head superior migration. This was theoretically accomplished by inverting the male and female ball and socket so that the glenoid component was now convex and the humerus now concave; doing so created a physical stop that prevents the humerus from migrating superiorly. Several reverse shoulder designs have since been conceived and developed: the Fenlin, Reeves, Gerard, Kessel, Kolbel, and the Neer-Averill to name but a few; of these, only the Kessel design has reported long-term outcomes (it is believed that each of the aforementioned designs have since been abandoned). Similar to constrained total shoulder arthroplasty, the fixed center of rotation resulted in an excessive torque on the glenoid that compromised fixation, ultimately leading to loosening.

In 1987, Paul Grammont introduced a new reverse shoulder design. It consisted of 2 components: the glenoid was a metallic or ceramic 42 mm ball (~ $\frac{2}{3}$ of a sphere) and the humeral component was a polyethylene “trumpet-shaped”

cup (whose concave surface was ~ $\frac{1}{3}$ of a sphere); the humeral component was fixed with PMMA. The preliminary results of this prosthesis were published in 1987 (see Grammont, P. M. et al. Etude et Realisation D'une Nouvelle Prothese D'Paule. Rhumatologie. #39: 17-22. 1987); after a mean follow-up of six months, all six patients (8 shoulders) were pain-free; however, mobility was variable: 3 patients had active anterior elevation between 100-130°, 3 patients had active anterior elevation less than 60°. These inconsistent results necessitated a redesign.

In 1991, the Grammont reverse shoulder was redesigned and renamed as the Delta III reverse shoulder prosthesis. The cemented glenoid failed; therefore, the glenosphere was redesigned to have a fixed central peg and divergent screws. The $\frac{2}{3}$ of a sphere in the glenoid was abandoned for $\frac{1}{3}$ of sphere to place center of rotation directly in contact with glenoid fossa; thereby, reducing the torque on the bone surface. The humeral component was designed for either cemented or uncemented applications (see Boileau, P. et al. Grammont Reverse Prosthesis: Design, Rationale, and Biomechanics. JSES January/February: 147S-161S. 2005).

This prosthesis was called the “Delta” because of its functional dependence on the Deltoid. The design rationale for the Delta III is described as follows:

the center of rotation is shifted medially (to increase the effective lever arm of the deltoid by recruiting more of the deltoid fibers for elevation and abduction).

the center of rotation is shifted distally by lowering the humerus (to tension the deltoid).

the center of the glenosphere is placed directly on the glenoid fossa to limit the torque on the fixation devices and resist loosening.

the inverted concavities of the glenohumeral joint create a physical stop to prevent humeral head superior migration; the status of the CA arch is irrelevant with this design.

Whether these theoretical biomechanical benefits of the Delta will actually become realized has yet to be determined as there has been limited long-term outcome studies (>5 yrs) which demonstrate its reliability; however, short-term and medium-term outcome studies suggest that the design provides pain relief and restores function (primarily in abduction/adduction and partially in flexion/extension; internal/external rotation is restored on a limited basis dependant upon the condition of the infraspinatus and the teres minor). In this regard, see the following: Boileau, P. et al. Grammont Reverse Prosthesis: Design, Rationale, and Biomechanics JSES January/February: 147S-161S. 2005; Rittmeister, M. et al. Grammont Reverse Total Shoulder Arthroplasty in Patients with Rheumatoid Arthritis and Nonreconstructable Rotator Cuff Lesions. JSES. January/February: 17-22. 2001; Vanhove, B. Grammont's Reverse Shoulder Prosthesis for Rotator Cuff Arthropathy. A Retrospective Study of 32 Cases. Acta Orthop Belg. #70 (3): 219-225. 2004; Sirveaux, F. et al. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. JBJS 86-B: 388-395. 2004; Katzer, A. Two-Year Results After Exchange Shoulder Arthroplasty Using Inverse Implants. Orthopedics. Vol. 27, #11: 1165-1167. 2004; Walch, G. The Reverse Ball and Socket: When is it Indicated? Orthopaedics Today. pp. 18-20.

Of note, the Delta reverse shoulder is associated with a number of different types of complications including glenoid loosening, scapular “notching” (more descriptively called inferior glenoid erosion), acromion fractures, dislocation (head from poly and poly insert from humeral stem), insta-

bility, humeral stem fracture, humeral stem loosening, and glenoid screw fracture. In this regard, see the immediately preceding cited references.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A-1C show three perspective views of a reverse shoulder prosthesis (including glenosphere/glenoid plate assembly and humeral mating components) according to one embodiment of the present invention;

FIG. 2 shows another perspective view of the embodiment of FIGS. 1A-1C;

FIGS. 3A-3C show three more detailed perspective views of the glenosphere/glenoid plate assembly of the embodiment of FIGS. 1A-1C;

FIGS. 4A-4D show four more detailed perspective views of the glenosphere of the embodiment of FIGS. 1A-1C (the glenosphere of this example is a 38 mm glenosphere);

FIGS. 4E-4G show three more detailed perspective views of an example pear-shaped glenosphere according to an embodiment of the present invention;

FIGS. 5A-5C show three more detailed perspective views of the pear-shaped glenoid plate of the embodiment of FIGS. 1A-1C (showing a stem provided with holes for bone “through growth”);

FIGS. 5D-5F show three more detailed perspective views of another example pear-shaped glenoid plate according to an embodiment of the present invention (showing a stem provided with holes for bone “through growth”);

FIG. 6 shows a perspective view of an example compression screw of the type which may be utilized with the present invention;

FIGS. 7A-7C show three perspective views of an example locking cap screw of the type which may be utilized with the present invention;

FIGS. 7D-7F show three views of an example torque defining screw driving element which may be utilized with the present invention;

FIGS. 8A and 8B show two views of the glenosphere/glenoid plate assembly of the embodiment of FIGS. 1A-1C (wherein the glenosphere is shown in phantom);

FIGS. 9A-9C show: (1) the glenoid plate/compression screw/locking cap screw assembly of the embodiment of FIGS. 1A-1C; (2) detail of the compression screw/locking cap screw; and (3) detail of the compression screw/locking cap screw (wherein the locking cap screw is shown in phantom);

FIGS. 10A-10C show three views of a reverse shoulder humeral liner according to an embodiment of the present invention;

FIGS. 11A-11E show five views of a reverse shoulder humeral plate according to an embodiment of the present invention;

FIG. 12 shows an outline of a pear-shaped glenoid and results from 2 anatomic studies: Iannotti, J. P. et al. The Normal Glenohumeral Relationships. JBJS. Vol. 74-A, #4: 491-500 1992 and Checroun, A. J. et al. Fit of Current Glenoid Component Designs: an Anatomic Cadaver Study. JSES. Vol. 11, #6: 614-617. 2002 (image modified from Checroun);

FIG. 13 shows the fit of a conventional reverse glenosphere plate on glenoid (image modified from Checroun, A. J. et al. Fit of Current Glenoid Component Designs: an Anatomic Cadaver Study. JSES. Vol. 11, #6: 614-617. 2002);

FIG. 14 shows an area of best quality/deepest glenoid bone (image modified from Checroun, A. J. et al. Fit of Current

Glenoid Component Designs: an Anatomic Cadaver Study. JSES. Vol. 11, #6: 614-617.2002);

FIG. 15 shows a theoretical improvement in probability of A/P bone-screw purchase if hole pattern is modified as shown according to an embodiment of the present invention (image modified from Checroun, A. J. et al. Fit of Current Glenoid Component Designs: an Anatomic Cadaver Study. JSES. Vol. 11, #6: 614-617. 2002);

FIGS. 16A-16D show four perspective views of a reverse shoulder prosthesis (including glenosphere/glenoid plate assembly and humeral mating components) according to an embodiment of the present invention;

FIGS. 17A-17D show four more detailed perspective views of the oval-shaped glenoid plate of the embodiment of FIGS. 16A-16D (showing a superiorly-shifted stem provided with holes for bone “through growth”);

FIGS. 18A-18D show four more detailed perspective views of another example of an oval-shaped glenoid plate of an embodiment of the present invention (showing a superiorly-shifted non-cylindrical stem provided with holes for bone “through growth”);

FIGS. 19A-19D show four more detailed perspective views of the glenosphere of the embodiment of FIGS. 16A-16D (the glenosphere of this example is a 38 mm glenosphere);

FIGS. 20A and 20B show two views of the glenosphere/glenoid plate assembly of the embodiment of FIGS. 16A-16D (wherein the glenosphere is shown in phantom in FIG. 20B and wherein the glenosphere of this example is a 38 mm glenosphere);

FIGS. 21A-21D show four more detailed perspective views of an example oval-shaped glenosphere of an embodiment of the present invention (the glenosphere of this example is a 42 mm glenosphere);

FIGS. 22A and 22B show two views of an oval-shaped glenosphere/glenoid plate assembly of an embodiment of the present invention (wherein the glenosphere is shown in phantom in FIG. 22B and wherein the glenosphere of this example is a 38 mm glenosphere);

FIGS. 23A-23D show four more detailed perspective views of an example glenosphere of an embodiment of the present invention (the glenosphere of this example is a 46 mm glenosphere);

FIGS. 24A and 24B show two views of an glenosphere/glenoid plate assembly of an embodiment of the present invention (wherein the glenosphere is shown in phantom in FIG. 24B and wherein the glenosphere of this example is a 42 mm glenosphere);

FIG. 25 shows a perspective view of an example compression screw of the type which may be utilized with the present invention;

FIG. 26 is a graph showing testing results demonstrating that a 10° reduction in neck angle results in a downward shift in range of motion (ROM);

FIG. 27 shows conditions discussed in a study by Nyffeler;

FIG. 28 shows a number of views of a glenoid plate according to another embodiment of the present invention;

FIG. 29 shows a modified image from Nyffeler study in which the clinical effectiveness of 4 different Glenosphere positions were examined;

FIGS. 30A and 30B show another embodiment of the present invention related to glenoid plate hole positions that are designed to allow conversion or revision of a traditional pegged glenoid;

5

FIGS. 31A and 31B show another embodiment of the present invention related to glenoid plate hole positions that are designed to allow conversion or revision of a traditional keeled glenoid;

FIG. 32 shows another embodiment of the present invention related to anterior/posterior glenosphere flats;

FIG. 33 shows another embodiment of the present invention related to a bone cage;

FIG. 34 shows a diagram associated with the definition of inferior and superior impingement;

FIG. 35 shows a diagram associated with the definition of jump distance;

FIG. 36 shows a diagram associated with the definition of offset;

FIG. 37 shows a diagram associated with the definition of humeral constraint;

FIG. 38 shows a diagram associated with a typical Grammont reverse shoulder ROM;

FIG. 39 shows a graph of effect of humeral neck angle on ROM and jump distance;

FIG. 40 shows a chart of effect of varying humeral neck angle on points of impingement (shaded data column third from right denotes typical Grammont design);

FIG. 41 shows a chart of effect of varying humeral constraint on ROM (middle shaded data column denotes typical Grammont design);

FIG. 42 shows a chart of effect of varying glenosphere thickness on ROM (middle shaded data column denotes typical Grammont design);

FIG. 43 shows a chart of effect of varying glenosphere diameter on jump distance (shaded data column second from left denotes typical Grammont design);

FIG. 44 shows an image from the Nyffeler study depicting the degree of inferior impingement when the humeral stem is placed in neutral position;

FIG. 45 shows another embodiment of a reverse shoulder prosthesis;

FIG. 46 shows another embodiment of a reverse glenoid plate design;

FIG. 47 shows another embodiment of a reverse glenosphere design;

FIG. 48 shows other embodiments of a reverse humeral plate design;

FIG. 49 shows other embodiments of a reverse humeral liner design;

FIG. 50 shows another embodiment of a reverse torque defining screw driver design;

FIG. 51 shows another embodiment of a compression screw design;

FIG. 52 shows another embodiment of a reverse glenosphere locking screw design (the threads are not shown in this view);

FIG. 53 shows another embodiment of a locking cap design;

FIG. 54 shows a diagram associated with a defined point of inferior impingement;

FIG. 55 shows a diagram associated with a defined point of superior impingement;

FIG. 56 shows ROM associated with another embodiments of a reverse shoulder prosthesis;

FIG. 57 shows a graph associated with a comparison of Jump Distance vs. Abduction/Adduction for an embodiment of the present invention and a typical Grammont Reverse Shoulder Prosthesis; and

FIG. 58 shows a chart of comparison of ROM for an embodiment of the present invention and a typical Grammont Reverse shoulder prostheses.

6

Among those benefits and improvements that have been disclosed, other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying figures. The figures constitute a part of this specification and include illustrative embodiments of the present invention and illustrate various objects and features thereof.

DETAILED DESCRIPTION OF THE INVENTION

Detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely illustrative of the invention that may be embodied in various forms. In addition, each of the examples given in connection with the various embodiments of the invention are intended to be illustrative, and not restrictive. Further, the figures are not necessarily to scale, some features may be exaggerated to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the present invention.

Of note, various embodiments of the present invention are directed to a reverse shoulder prosthesis incorporating some or all of the aforementioned benefits associated with the Delta reverse shoulder design (while also aiming to minimize the number and rate of observed complications). These benefits of various embodiments of the present invention may include (but are not limited to): 1) lengthen/tension deltoid to improve muscle efficiency; 2) maintain center of rotation on the glenoid fossa to minimize the effective moment arm; and/or 3) invert the concavities of the natural joint to create a physical stop to prevent humeral head superior migration. The complications that various embodiments of the present invention may minimize include (but are not limited to): 1) eliminate impingement to reduce the degree of scapular notching and the incidence of dislocation; 2) improve glenoid fixation by increasing the number of available fixation points, positioning the fixation points in such a manner that it maximizes the potential for fixation (e.g., position the fixation points in such a manner that their location corresponds to the region of best quality/deepest bone in the native glenoid), allowing for all screws to be oriented/angled in any direction (to improve possibility of screw purchase), and/or allowing for any compression screw (regardless of its angular orientation) to be converted into a locking screw (to prevent the screws from backing out); 3) reduce glenoid osteolysis by improving stress transfer through the use of an anatomic shaped glenoid plate (e.g., the anatomic plate limits overhang on the A/P sides of the glenoid); and/or 4) improve stability and ROM by allowing the use of a larger diameter glenosphere (certain embodiments of the present invention may not require reaming of the proximal humerus, as is typically required in the Grammont design . . . often the proximal humerus establishes the size of the glenosphere based upon the maximum size of liner that can be placed).

Referring now to FIGS. 1A-1C and 2, various views of an assembled construct **100** according to an embodiment of the present invention are shown. The components of this construct may include: a humeral stem **102** (which may be used in either pressfit or cemented applications and may be constructed, for example, from titanium); a humeral liner **104** (a concave component which mates with the convex glenosphere, this element may be constructed, for example, from UHMWPE); a humeral adapter plate **106** (which connects the humeral liner to the humeral stem, this element may be constructed, for example, from titanium); a glenosphere **108** (this

7

element may be constructed, for example, from cobalt chrome); a pear-shaped glenoid plate **110** (this element may be constructed, for example, from titanium); and a number of screws and fixation devices for assembly of the individual components to one another and for assembly of the construct to the native bone (these elements may be constructed, for example, from titanium). Of note, the glenoid plate of this example is pear-shaped.

Referring now to FIGS. **3A-3C**, more detailed views of the glenosphere/glenoid plate assembly of FIGS. **1A-1C** and **2** are shown (stem **112** is seen clearly in these Figs.).

Referring now to FIGS. **4A-4D**, more detailed views of the glenosphere of FIGS. **1A-1C** and **2** are shown (note that the glenosphere may be hollowed out to reduce weight).

Referring now to FIGS. **4E-4G**, detailed views of another example glenosphere **108A** are shown (note that the glenosphere **108A** may be hollowed out to reduce weight). In FIGS. **4E-4G**, the anterior and the posterior sides **140** are each chamfered, and the chamfered anterior and posterior sides **140** are designed so that a shape of the glenosphere **108A**: i) resembles that of the glenoid bone and ii) allows the glenosphere **108A** to sit flush on a resected surface of the glenoid bone when the glenosphere **108A** is disposed adjacent a glenoid plate **110** and the glenoid plate **110** is affixed to the glenoid bone.

Referring now to FIGS. **5A-5C**, more detailed views of the pear shaped glenoid plate of FIGS. **1A-1C** and **2** are shown. In this regard, several features should be noted: 1) the 6 screw holes on the backside of the plate; and 2) the bone “through-growth” cage stem which enables bone graft to be injected (e.g., via syringe) through the front of the plate and/or placed through the hole in the bottom surface of the cage stem).

Referring now to FIGS. **5D-5F**, detailed views of another example pear-shaped glenoid plate **110A** are shown.

Referring now to FIG. **6**, a compression screw **114** according to an embodiment of the present invention is shown (note the spherical head which enables the screw to be angularly oriented within glenoid plate **110** (e.g., up to 17.5 degrees) in any desired direction—in one specific example, the holes in glenoid plate **110** may have corresponding concavities).

Referring now to FIGS. **7A-7C**, a locking cap screw **116** according to an embodiment of the present invention is shown (a locking cap screw may be screwed into the glenoid plate on top of a compression screw to prevent the compression screw from backing out and/or to lock the compression screw in a desired angular orientation—see FIGS. **8A**, **8B**, and **9A-9C**). Further, FIGS. **7D-7F** show three views of a torque defining screw driving element **118** which may be utilized with the present invention (e.g., to drive a screw and/or locking cap with a predefined amount of torque (e.g., by breaking when the predefined amount of torque is applied)).

Referring now more particularly to FIGS. **8A** and **8B**, more detailed views demonstrating how the compression screw **114** and locking cap screw **116** mate with the glenoid plate **110** are shown. These FIGS. **8A** and **8B** also show how glenosphere **108** (depicted here in phantom form) may be assembled to glenoid plate **110** via use of assembly bolt **118**. FIGS. **9A-9C** further clarify the relationship of the compression screw **114** and locking cap screw **116** to the glenoid plate **110**. These FIGS. **9A-9C** also detail the spherical articulation between the compression screw **114** and locking cap screw **116**—a feature which enables the compression screw **114** to be locked regardless of its angular orientation.

Referring now to FIGS. **10A-10C**, three views of humeral liner **104** of FIGS. **1A-1C** and **2** are shown.

Referring now to FIGS. **11A-11E**, five views of humeral plate **106** of FIGS. **1A-1C** and **2** are shown.

8

Referring now to FIGS. **16A-16D**, various views of an assembled construct **1600** according to an embodiment of the present invention are shown. The components of this construct may include: a humeral stem **1602** (which may be used in either pressfit or cemented applications and may be constructed, for example, from titanium); a humeral liner **1604** (a concave component which mates with the convex glenosphere, this element may be constructed, for example, from UHMWPE); a humeral adapter plate **1606** (which connects the humeral liner to the humeral stem, this element may be constructed, for example, from titanium); a glenosphere **1608** (this element may be constructed, for example, from cobalt chrome); an oval-shaped glenoid plate **1610** (this element may be constructed, for example, from titanium); and a number of screws and fixation devices for assembly of the individual components to one another and for assembly of the construct to the native bone (these elements may be constructed, for example, from titanium). Of note, the glenoid plate **1610** of this example is oval-shaped.

Referring now to FIGS. **17A-17D**, more detailed views of the oval-shaped glenoid plate of FIGS. **16A-16D** are shown (stem **1612** is seen clearly in these Figs.).

Referring now to FIGS. **18A-18D**, more detailed views of another example oval-shaped glenoid plate **1610A** are shown (stem **1612A** is non-cylindrical in these Figs.).

Referring now to FIGS. **19A-19D**, more detailed views of the glenosphere of FIGS. **16A-16D** are shown (note that the glenosphere may be hollowed out to reduce weight).

Referring now to FIGS. **20A-20B**, more detailed views of the glenoid plate/glenosphere assembly of FIGS. **16A-16D** are shown (the glenosphere of FIG. **20B** is shown in phantom form).

Referring now to FIGS. **21A-21D**, more detailed views of another example glenosphere are shown.

Referring now to FIGS. **22A-22B**, more detailed views of an example glenoid plate/glenosphere assembly are shown (the glenosphere of FIG. **22B** is shown in phantom form).

Referring now to FIGS. **23A-23D**, more detailed views of another example glenosphere are shown.

Referring now to FIGS. **24A-24B**, more detailed views of an example glenoid plate/glenosphere assembly are shown (the glenosphere of FIG. **24B** is shown in phantom form).

Referring now to FIG. **25**, a compression screw **1614** according to an embodiment of the present invention is shown (note the spherical head which enables the screw to be angularly oriented within glenoid plate **1610** (e.g., up to 17.5 degrees) in any desired direction—in one specific example, the holes in glenoid plate **1610** may have corresponding concavities).

Of course, it should be noted that there are other embodiments of the invention and/or of the individual components comprising the invention, including (but not limited to) various shapes, sizes, and materials. For example (which example is intended to be illustrative and not restrictive), the materials of the humeral liner and glenosphere could be inverted (reverse designs typically have a metal glenosphere/glenoid plate and a plastic humeral liner—an alternative embodiment is a metal humeral liner and a plastic glenosphere)—doing so could theoretically reduce the weight cyclically imposed on the native glenoid bone (by eliminating many of the much heavier metal components). This may also reduce the cost of the device by eliminating the need for multiple metal screws and fixation components. In another example (which example is intended to be illustrative and not restrictive), if both the glenosphere and glenoid plate were manufactured of plastic then the device could be used exclusively in cemented applications—an application that has been shown to be the stan-

dard of care in traditional shoulder arthroplasty. Conversely, both the humeral liner and the glenosphere/plate could be manufactured from the same material then a metal-on-metal (or ceramic-on-ceramic) articulation could be achieved (which have been shown to produce less wear in hip arthroplasty applications and as a result have a lower incident of osteolysis). In yet another example (which example is intended to be illustrative and not restrictive), the glenoid plate design may have a central screw rather than a central cage stem (the central screw hole could be advantageous in cases in which a central bone defect exists; the screw could be oriented in various directions to ensure that screw purchase is obtained).

Of note, various embodiments of the present invention may offer a number of advantages over the prior art—some of these advantages are described above. FIGS. 12-15 further elaborate on some of these advantages.

More particularly, FIG. 12 summarizes the results of two different anatomic studies (see Iannotti, J. P. et al. The Normal Glenohumeral Relationships. JBJS. Vol. 74-A, #4: 491-500. 1992 and Checroun, A. J. et al. Fit of Current Glenoid Component Designs: an Anatomic Cadaver Study. JSES. Vol. 11, #6: 614-617. 2002)—each of these studies demonstrate that the glenoid is wider inferiorly than superiorly and that it has a characteristic pear or “inverted-comma” shape.

Further, FIG. 13 graphically illustrates the fit of a traditional Grammont-style glenoid plate on a representative glenoid fossa; it is believed that the typical 4-quadrant location of the screw holes is not ideal due to the anterior and posterior slope of the scapula—this slope results in a thin base of bone in these locations.

Further still, FIG. 14 graphically illustrates the region of best quality/deepest bone in the native glenoid.

Finally, FIG. 15 graphically illustrates the rationale for screw hole position utilized in an embodiment of the present invention.

In other examples (which examples are intended to be illustrative and not restrictive), the present invention may be constructed as follows:

Reverse Shoulder Glenoid Plate

Material: Machined from Wrought Ti-6Al-4V

Scope: 1 Size (used with 38, 42, and 46 mm Glenosphere);

Dimensions/Features: 29 mm diameter, 5 mm taper, 20 mm length bone “through growth” cage, each screw hole has a spherical base allowing the compression screws to be angled 15°, each hole also has a threaded portion for attachment of a locking cap screw.

Reverse Shoulder Glenosphere

Material: Machined from Cast Co—Cr

Scope: 3 Sizes (38/22 mm, 42/24 mm, and 46/26 mm Diameter and Thickness)

Dimensions/Features: Glenosphere hollowed out to reduce weight

Reverse Shoulder Humeral Liner

Material: Machined from Compression Molded UHMWPE Bar (Enhanced Poly: Connection GXL)

Scope: 3 Diameters (38, 42, and 46 mm Liners); Multiple offsets

Dimensions/Features: Connection to humeral plate configured for rotational stability (e.g., “mushroom” or other non-circular shape).

Reverse Shoulder Humeral Plate

Material: Machined from Wrought Ti-6Al-4V

Scope: 3 Sizes (38, 42, and 46 mm)

Dimensions/Features: Connection to liner configured for rotational stability (e.g., “mushroom” shaped or other non-circular shape); male pin(s) may connect to humeral stem for rotational stability

Reverse Shoulder Compression Screw

Material: Machined from Ti-6Al-4V or SS Alloy

Scope: 1 diameter (4.0 mm) at multiple lengths

Dimensions/Features: Spherical head for insertion at a variable angle (e.g., up to 15°); cannulated

Reverse Shoulder Locking Cap Screw

Material: Machined from Ti-6Al-4V or SS Alloy

Scope: 1 size (~9 mm long, 8 mm wide)

Dimensions/Features: Locks compression screws to glenoid plate at any angle; cannulated; fits in hollowed out space of glenosphere.

Glenosphere Locking Screw

Material: Machined from Ti-6Al-4V or SS Alloy

Scope: 1 size (~25 mm long, 4 mm wide)

Dimensions/Features: Locks glenosphere to glenoid plate.

Reverse Shoulder Torque Defining Screw Driving Element

Material: Machined from wrought Ti-6Al-4V; UHMWPE plug

Scope: 1 Size; minimum cross section as required

Dimensions/Features: Design Utilizes poly plug to retain square head after fracture

According to another example (which example is intended to be illustrative and not restrictive), the present invention may provide for:

The reverse prosthesis may be integrated with the primary system—may retain the primary stem for revision (which is beneficial because ~30% of reverse shoulders are implanted as revisions). Additionally, the prosthesis may use existing humeral implant inventory, existing humeral instrumentation, and/or a similar surgical technique (e.g., may maintain a 132.5° humeral osteotomy).

As described by the ROM study (see Table 1, below), the reverse prosthesis may be associated with a 16.7% to 18.9% increase in ROM (as compared to the traditional Grammont prosthesis).

As described by the ROM study (see Table 1, below), the reverse prosthesis may be associated with a reduction in the incidence of scapular notching (i.e. medial/inferior impingement of humerus on scapula) as a result of the reduction in neck angle from 155° to 145° (as compared to the traditional Grammont design) and the increase in humeral liner size (since the liner may be brought out of the proximal humerus).

The reverse prosthesis may maintain the low incidence of glenosphere loosening by utilizing the proven traditional Grammont-style glenosphere/screw/baseplate designs (note: the glenosphere design may be hollowed out to reduce weight).

The glenoid plate may utilize a bone “through-growth” cage design to enhance fixation.

The glenoid plate may allow for the insertion of a compression screw (e.g., at up to 15 degrees of angular variability) in any of the 4 holes to maximize bone purchase.

The glenoid plate may allow the use of a locking cap screw which can be attached to any compression screw thereby making each screw a locking/compression screw.

The humeral liner may be manufactured from Connection GXL (i.e. enhanced poly) and may utilize a “mushroom” apical-locking mechanism to attach the humeral liner to the humeral plate (see FIGS. 10A-10C showing three views of such an example humeral liner and FIGS. 11A-11E showing five views of such an example humeral plate)—therefore, a low incidence of humeral liner wear and disassociation may be expected.

TABLE 1

Reverse Shoulder ROM Comparison									
Glenosphere Diameter/ Thickness	Neck Angle	Degree of Constraint	Lateral Offset (inches)	Jump Distance (inches)	ROM Range (w/o scapular motion)	Total ROM (w/ scapular motion of 1.5)	Total ROM (w/ scapular rotation, 15° Correction)	Percent Increase in ROM over Grammont	Glenosphere Weight (grams)
38/22 mm	145°	0.312	0.893	0.323 inches at 55° Abd	17 to 83°	112.9°	135°	16.7%	65
42/24 mm	145°	0.300	0.944	0.334 inches at 55° Abd	13 to 87°	116.6°	136.9°	17.8%	98
46/26 mm	145°	0.288	0.969	0.341 inches at 55° Abd	11 to 90°	120.8°	138.8°	18.9%	140
Grammont 36/18 mm	155°	0.276	0.584	0.330 inches at 65° Abd	35 to 95°	90°	112.5°	NA	47

Another embodiment of the present invention relates to a reverse shoulder prosthesis and method for implantation that incorporates many or all of the aforementioned benefits associated with the traditional Grammont reverse shoulder design while at the same time minimizing the number and rate of observed complications and to address other areas of concern related to the method of implantation. The historic benefits which may be incorporated include (but are not limited to): 1) lengthen/tension deltoid to improve muscle efficiency; 2) maintain center of rotation on (or close to) the glenoid fossa to minimize the effective moment arm; and/or 3) invert the concavities of the natural joint to create a physical stop to prevent humeral head superior migration. The complications/concerns that are minimized include (but are not limited to): 1) reduce the incidence of impingement; 2) reduce the incidence of scapular notching; 3) improve stability; 4) decrease the incidence of dislocation; 5) improve glenoid fixation; 6) conserve bone; and/or 7) better facilitate a conversion of a hemi- or total shoulder to a reverse shoulder. A detailed description of each design feature which may address the aforementioned complications/concerns concerns is disclosed below.

To reduce the incidence of impingement and scapular notching, the neck angle of the reverse shoulder component may be reduced from 155° (the neck angle of the traditional Grammont reverse prosthesis and essentially every subsequent reverse shoulder prosthesis on the market) to 145°. Testing has demonstrated (see FIG. 26) that a 10° reduction in neck angle results in a downward shift in range of motion (ROM) . . . this downward shift acts to provide a ROM that is more in alignment with a patient's activities of daily living (ADL). Evidence of the need for a downward shift in ROM was objectively demonstrated in a study by De Wilde (see De Wilde, L. et al. Shoulder Prosthesis Treating Cuff Tear Arthropathy: a comparative biomechanical study. JOR 22: 1222-1230. 2004) who used radiographic templates to demonstrate that the traditional Grammont design was associated with inferior impingement at 16° abduction. Additional evidence of this design flaw is documented in a study by Nyffeler (see Nyffeler, R. et al. Biomechanical Relevance of Glenoid Component Positioning in the Reverse Delta III Total Shoulder Prosthesis. JSES. Vol. 14, #5: 524-528. 2005) who compared the incidence of scapular notching at 4 different conditions: 1) when the glenosphere is centered on the glenoid; 2) when the glenoid is positioned at the inferior glenoid rim; 3) when the glenosphere inferiorly overhangs by 2-4 mm; and 4) when the glenosphere is tilted inferiorly at 15 degrees and flush with the scapular neck; as depicted in FIG. 27. Nyffeler concluded that a glenosphere with an inferior overhang of 2-4 mm was asso-

ciated with significantly improved abduction/adduction ROM (as a result of the reduced inferior impingement).

It should be noted that glenosphere conditions 2-4 in the Nyffeler study are believed to be surgical modifications to the manufacturer-endorsed technique [condition 1]—these modifications are believed to be necessary to specifically address the aforementioned design flaw. There may be some benefit to positioning the glenosphere so that it overhangs inferiorly; however, it is believed that locating the glenosphere inferiorly may present a number of new concerns—most notably in the presence of a central bone defect, as would be common in the conversion of a total shoulder to a reverse shoulder (to obtain inferior glenosphere overhang with typical reverse designs a hole would need to be drilled in the inferior portion of the glenoid, causing the removal of additional glenoid bone). In order to conserve this much needed glenoid bone, one embodiment of the present invention utilizes a glenoid plate so that its central stem is shifted superiorly by 4 mm—enabling the surgeon to maintain the traditional surgical technique with the reverse as would be performed for total shoulder arthroplasty (i.e. drilling a hole in the center of the glenoid where the defect would occur; thereby, conserving bone). From a technique standpoint, a hole is drilled in the center of the glenoid, the glenoid bone is reamed, and the glenoid plate is inserted and secured with screws so that the inferior edge of the plate would sit flush on the inferior edge of the native glenoid bone. An added advantage of the superiorly shifted stem is that the locking screw hole in the glenosphere will no longer be positioned at the apex of the glenosphere (a region which is commonly loaded)—instead it will be superiorly shifted to a region that is not as commonly loaded (which corresponds to the location of the superiorly shifted stem on the glenoid plate).

To improve stability and decrease the incidence of dislocation, the humeral liner may in one embodiment be brought out of the proximal humerus so that the proximal humerus is no longer used to establish the size of glenosphere. This feature may be advantageous for a number of reasons (including, but not limited to): 1) proximal humeral bone is conserved since proximal reaming is not required and 2) the glenosphere size can be established by the size of the native glenoid bone (rather than being established by the size of liner placed in the proximal humerus)—testing has demonstrated improved ROM and stability with an increasing glenosphere diameter. This feature also facilitates the conversion from a hemi- or total shoulder to a reverse (or vice-versa: the conversion of a reverse to a hemi- or total shoulder) since this reverses design may utilize the same humeral stem as that used for hemi- and total shoulder arthroplasty (i.e. the surgeon does not have to remove a well fixed humeral stem to convert to a reverse

13

shoulder). It should be noted that this embodiment maintains the same humeral neck cut that is utilized for a hemi- and/or total shoulder (i.e. the humeral head is resected at or about the anatomic neck). Other systems typically require a resection at a different location as that utilized for hemi- and/or total shoulder arthroplasty.

An additional embodiment to reduce the incidence of dislocation involves the use of a tension band that may connect the glenosphere and humeral components and may be sized according the length of the patient's deltoid. The band may break during trial reduction at a tension that corresponds to an appropriate lengthening of the deltoid to achieve adequate stability and function. Two studies by De Wilde (see De Wilde, L. et al. Shoulder Prosthesis Treating Cuff Tear Arthropathy: a comparative biomechanical study. JOR 22: 1222-1230. 2004; De Wilde, L. et al. Functional Recovery after a Reverse Prosthesis for Reconstruction of the Proximal Humerus in Tumor Surgery. CORR. #430: 156-162. 2005) suggest that a 10-20% increase in deltoid length is appropriate.

In one example, the glenosphere and humeral size range is therefore increased to 38-46 mm (relative to the size range provided by competitive designs: 34-42 mm, which do not utilize this technique). To achieve these large size glenospheres the anterior and posterior sides of the glenospheres may be chamfered; thereby, allowing them to be inserted into the wound site and sit flush on the resected surface without having to remove any excess glenoid bone (see FIGS. 4E-4G). The internal geometry of each glenosphere may be hollowed out to reduce its weight, doing so may minimize the incidence of fatigue-induced bone fractures. To increase ROM and improve stability, each glenosphere may have an extended articular surface (i.e. an arc larger than 180°—see FIG. 32).

To improve glenoid fixation, the invention may utilize a bone “through-growth” glenoid plate stem which accepts the use of bone graft. Bone graft can be placed into the stem prior to securing the plate with screws and/or after (e.g., by injecting the graft through a syringe in the top of the plate). The bone through-growth fixation stem can be either cylindrical (e.g., to revise a peg glenoid) or non-cylindrical (e.g., to revise a keel glenoid). Modifying the shape and profile of the glenoid plate may also improve glenoid fixation; in one example the inventors modified the plate from the traditional Grammont-style circular design (utilized by other conventional designs on the market) to a pear/oval design (which more accurately reflects the anatomy of the scapula). Doing so may improve glenoid fixation by allowing for an increase in the number of glenoid screw holes available for fixation (e.g., an increase from 4 to 6) and an improvement in the position of the screw holes so that it maximizes the potential for fixation (i.e. each screw hole is located according the region of best quality/deepest bone). FIGS. 12-15 further elaborate on these advantages. More particularly: FIG. 12 summarizes the results of two different anatomic studies (Iannotti, J. P. et al. The Normal Glenohumeral Relationships. JBJS. Vol. 74-A, #4: 491-500. 1992; Checroun, A. J. et al. Fit of Current Glenoid Component Designs: an Anatomic Cadaver Study. JSES. Vol. 11, #6: 614-617. 2002); each of these studies demonstrate that the glenoid is wider inferiorly than superiorly and that it has a characteristic pear or “inverted-comma” shape. FIG. 13 graphically illustrates the fit of a typical Grammont-style glenoid plate on a representative glenoid fossa; it is believed that the typical 4-quadrant location of the screw holes is not ideal due to the anterior and posterior slope of the scapula—this slope results in a thin base of bone in these locations. FIG. 14 graphically illustrates the region of best

14

quality/deepest bone in the native glenoid. Finally, FIG. 15 graphically illustrates the rationale for screw hole position utilized in an embodiment of the present invention.

The glenoid plate may also incorporate several other features which should work to conserve glenoid bone and/or improve fixation. The glenoid plate may have a curved-back to minimize the amount of bone removed for implantation, (compared to the flat-back glenoid plate designs, as the native glenoid bone is also curved). Additionally, one or more screw holes in the glenoid plate may have a female spherical feature which mates with the male spherical head of the compression screw. Doing so may allow for each compression screw to be angled/oriented in any desired direction—thereby improving the possibility of screw purchase. Additionally, one or more of the screw holes in the glenoid plate may have a threaded feature for attachment of a locking cap—this cap screw may have a female spherical feature which compresses the spherical head of the compression screw; thereby locking it to the plate at whatever angle/orientation the screw was inserted into the bone (preventing it from backing out).

Various details of a reverse shoulder design according to an embodiment of the present invention are shown herein. FIGS. 16A-16D depict the assembled construct of an example reverse shoulder prosthesis. The components of this construct include a humeral stem (which may be used in pressfit and/or cemented applications and may be constructed from titanium), a humeral liner (a concave component which mates with the convex glenosphere; may be constructed from UHMWPE), a humeral adapter plate (which connects the humeral liner to the humeral stem; may be constructed from titanium), a glenosphere (may be constructed from cobalt chrome), a glenoid plate (may be constructed from titanium), and a number of screws and fixations devices for assembly of the individual components to one another and for assembly of the construct to the native bone (all may be constructed from titanium). FIGS. 17A-17D depict an example glenoid plate design (several features should be noted: 1) the 6 screw holes on the backside of the plate, and 2) the bone “through-growth” cage stem which enables bone graft to be injected via syringe through the front of the plate and/or placed through the hole in the bottom surface of the cage stem). FIGS. 18A-18D and 5D-5F depict two other embodiments of the glenoid plate design (incorporating curved back glenoid plates). FIG. 25 depicts an example compression screw (note the spherical head which enables the screw to be angularly oriented in any desired direction).

As discussed above, various embodiments of the reverse shoulder design may include (but not be limited to): Superiorly shifted Glenoid Plate Stem; Non Cylindrical Glenoid Plate Stem; Oval/Pear Shaped Glenoid Plate to Improve Fixation; Non 155 Degree Humeral Neck Angle; Extended Articular Surface Glenosphere; and/or Tension Band to gage deltoid tension; a bone “through growth” cage may be applied for use in the reverse shoulder prosthesis.

As described herein, one embodiment of the present invention relates to a superiorly shifted glenoid plate stem (see, e.g., FIG. 28 as well as other Figs. herein). In this regard, an inferiorly overhanging glenosphere is associated with less scapular notching and a better clinical result (based upon the clinical observations by Nyffeler—third image from left in FIG. 29 (modified image from Nyffeler study in which the clinical effectiveness of 4 different Glenosphere positions were examined)). However, the positioning the glenosphere inferiorly may present a number of new concerns, mainly, in the presence of a central bone defect as would be common in the conversion of a total shoulder to a reverse shoulder (as a result of the glenoid being removed). To obtain inferior gle-

15

nosphere overhang with other reverse designs, a hole would typically need to be drilled in the inferior portion of the glenoid, causing the removal of additional glenoid bone. In order to conserve this much needed glenoid bone, a glenoid plate according to one embodiment is designed so that its central stem is shifted superiorly (e.g., by 4 mm)—enabling the surgeon to maintain the traditional surgical technique with the reverse as would be performed for total shoulder arthroplasty (i.e. drilling a hole in the center of the glenoid where the defect would occur; thereby, conserving bone). Additionally, with other glenoid plate designs the inferior hole (which is typically angled inferiorly to allow for insertion of a screw along the inferior scapular neck) is typically no longer in the correct position to allow the screw to be inserted along the inferior scapular neck.

As further described herein, another embodiment of the present invention relates to glenoid plate hole positions that are designed to allow conversion of a traditional peg and keel glenoid. In the case of the revised peg glenoid, the central peg of the glenoid plate of this embodiment is designed to fill the central bone defect left by the removed glenoid's central peg. As depicted in FIGS. 30A and 30B, the superior anterior/posterior set of screw holes are positioned at a location where no bone was removed in the revision of a pegged glenoid; using these features, adequate fixation was achieved. The tilted inferior hole and superior hole also successfully contributed to fixation, particularly when the $\pm 10^\circ$ angulation of the compression screws were utilized. In the case of the revised keeled glenoid, the central stem of the glenoid plate of this embodiment is designed to partial fill the central bone defect left by the removed keeled glenoid; graft may be used to completely fill the defect—which could be, for example, injected in the front (see below for additional discussion). As depicted in FIGS. 31A and 31B, the two sets of anterior/posterior holes are positioned at a location where no bone was removed in the revision of the keeled glenoid; using these features, adequate fixation was achieved. As in the revision of a pegged glenoid, the tilted inferior hole and superior hole also successfully contributed to fixation, particularly when the $\pm 10^\circ$ angulation of the compression screws were utilized.

As further described herein, another embodiment of the present invention relates to anterior/posterior glenosphere flats (see, e.g., FIG. 32 as well as other Figs. herein).

As further described herein, another embodiment of the present invention relates to an extended articular surface to improve ROM (i.e. greater than 180 degrees articular surface—see, e.g., FIG. 32 as well as other Figs. herein).

To improve stability and decrease the incidence of dislocation, the humeral liner of this embodiment was brought out of the proximal humerus (as is the case in the traditional Grammont design) so that the proximal humerus is no longer used to establish the size of glenosphere. This feature is advantageous for a number of reasons: 1) proximal humeral bone is conserved, since proximal reaming is not required and 2) glenosphere size can be established based upon the size of the native glenoid bone (rather than being established by the size of liner placed in the proximal humerus). Testing has demonstrated that improved ROM and stability can be achieved with a larger glenosphere diameter of this embodiment. This feature also better facilitates the conversion from a hemi- or total shoulder to a reverse (or vice-versa: the conversion of a reverse to a hemi- or total shoulder), because the reverse design of this embodiment utilizes the same humeral stem as that used for hemi- and total shoulder arthroplasty (i.e. the surgeon does not have to remove a well fixed humeral stem to convert to a reverse shoulder). It should be noted that this embodiment also maintains the same humeral

16

neck cut that is utilized for a hemi- and/or total shoulder (i.e. the humeral head is resected at or about the anatomic neck). Other systems typically require a resection at a different location as that utilized for hemi- and/or total shoulder arthroplasty. Therefore, the glenosphere and humeral liner size range in this embodiment is increased to 38-46 mm (relative to the size range provided by the other designs on the market of 34-42 mm, which do not utilize this technique). To achieve these large glenosphere sizes, the anterior and posterior sides of the glenospheres may be chamfered (see FIGS. 4E-4G). This allows the glenosphere to be inserted into the wound site and sit flush on the resected surface without having to remove any excess glenoid bone. In certain conventional systems the glenosphere is spherical, by chamfering the anterior and posterior sides of the glenosphere the inventors are able to make the shape of the glenosphere better resemble that of the native glenoid which is thinner in the anterior and posterior directions. Additionally, adding an anterior and posterior chamfer to the glenosphere under this embodiment has the added benefit of making it easier to insert since it allows it to more easily get by the humerus during insertion of the device.

Regarding other features of the glenosphere under various embodiments of the present invention, the internal geometry of each glenosphere may be hollowed out to reduce its weight (and provide space for a locking cap). This may minimize the incidence of fatigue-induced bone fractures. Additionally, to increase ROM and improve stability, each glenosphere may have an extended articular surface (i.e. an arc larger than 180 degrees—see FIG. 32).

In another embodiment of the present invention an optimized combination of humeral neck angle, humeral liner constraint, glenosphere diameter, and glenosphere thickness may be used to maximize ROM and jump distance and limit scapular notching.

In another embodiment of the present invention a bone cage (cylindrical and/or noncylindrical—for example, to fill a bone defect in the revision of a pegged and/or keeled glenoid—see, e.g., FIGS. 28 and 33, respectively) with a frontal opening to allow bone through growth and insertion of a therapeutic agent before and/or after implantation in situ and/or through the front in a revision case may be provided.

In another embodiment, a method of reconstructing a diseased shoulder is provided, comprising: providing a glenosphere, a glenoid plate and a humeral liner which interact to achieve a range of motion of a desired number of degrees (e.g., in at least a generally superior-inferior direction).

As discussed herein, various embodiments of the present invention provide an anatomic design of a glenoid plate which enhances stress transfer to the glenoid fossa and limits prosthesis A/P overhang. Additionally, the anatomic shaped glenoid plate may optimize the number of screw holes that can be used for fixation while at the same time maximizing their location relative to the best quality/deepest bone available in the native glenoid. Moreover, one or more compression screws may be utilized as locking screws by using a locking cap screw.

Reference will now be made to a study to evaluate the relationships between the design parameters associated with the typical Grammont reverse shoulder design and the commonly reported clinical complications. The results of this study may be used to identify and establish design inputs used for a reverse shoulder prosthesis according to various embodiments of the present invention.

For the purposes of this discussion, the following definitions may apply: Range of Motion (ROM) is defined as the humeral rotation occurring between inferior and superior impingement, wherein inferior and superior impingement are

17

defined as the point where the liner extends past the glenosphere (see FIG. 34). It should be noted that rotation of the scapula was not considered in this measurement; only humeral motion was considered to enable a one-to-one comparison between designs. Therefore, the presented ROM values are not intended to correspond with clinically reported values. Jump Distance is defined as the lateral distance necessary for the glenosphere to escape from the humeral liner; it is a measure of the resistance to dislocation (assuming no impingement) (see FIG. 35). Offset is defined as the vertical distance between the center of the humeral liner and glenosphere; it is related to deltoid tensioning (see FIG. 36). Humeral Constraint is defined as the ratio between humeral liner depth and width (at its face). For clarification, a constraint >0.5 is a constrained joint (see FIG. 37).

Under the study, a typical 36 mm Grammont reverse shoulder prosthesis (Depuy, Inc./Tornier Inc.) was obtained and reverse engineered using an optical comparator and calipers. The prosthesis was then geometrically modeled (in a parametric fashion—thereby allowing the design parameters to be varied) using Unigraphics (UGS, Inc.) based upon the elucidated design parameters. A ROM simulation was constructed (also using Unigraphics) to simulate humeral abduction/adduction and quantify the aforementioned study parameters.

The subject typical Grammont reverse shoulder was geometrically modeled using three dimensional (3-D) computer-aided design software (Unigraphics; UGS, Inc.). An assembly analysis was conducted to quantify the effect of several prosthetic design parameters (humeral neck angle, humeral liner constraint, glenosphere thickness, and glenosphere diameter) on several functionally relevant measurements (ROM, jump distance, and offset) during simulated humeral abduction/adduction. By implication, the relationship between the aforementioned design parameters and functional measurements will elucidate the failure mechanisms associated with the commonly reported clinical complications for reverse shoulder arthroplasty (scapular notching, dislocation, improper deltoid tensioning, etc. . . .). Specifically, ROM, jump distance, and offset were quantified and compared for each of the following design conditions: as humeral neck angle varied from 130 to 165° (in 5° increments); as humeral constraint varied from 0.250 to 0.3125 (in 0.0125 increments); as glenosphere thickness varied from 17 to 21 mm (in 1 mm increments); and as glenosphere diameter

varied from 34 to 44 mm (in 2 mm increments). Under this study the typical Grammont reverse shoulder (i.e. 155° neck angle, humeral constraint of 0.275, 36×19 mm Glenosphere) was observed to impinge inferiorly and superiorly at 35° and 95° abduction, respectively. (see FIG. 38).

Increasing the humeral neck angle by 5° positively shifts the ROM by 5° by changing the points of impingement. Additionally, increasing the humeral neck angle by 5° also increases the offset from 0.25 to 0.5 mm, depending upon the angle of abduction. For clarification, the Nyffeler study reported that implanting a glenosphere with a 15° inferior tilt was associated with a decrease in scapular notching. FIGS. 39 and 40 illustrate why—removing 15° from the glenosphere is functionally the same thing as removing 15° from the humeral neck angle. Both minimize inferior impingement; the only difference being in the later, glenoid bone is conserved.

Increasing the humeral constraint by 0.0125 decreases the ROM by 4°; more constraint, less motion (see FIG. 41). Similarly, increasing the humeral constraint by the same amount also increases the jump distance by 0.5 mm; more constraint, greater resistance to dislocation.

18

Increasing glenosphere thickness by 1 mm (when humeral constraint is constant) increases the ROM by 5°. Offset and Jump Distance are not affected (see FIG. 42).

Increasing glenosphere diameter by 2 mm (when humeral constraint is constant) increases the jump distance by 0.5 mm. ROM is not affected (see FIG. 43).

The results of this study demonstrate the relationship between each design parameter and functional measurement. Furthermore, the results demonstrate the typical Grammont design inferiorly impinges on the scapula prior to the patient being able to adduct his/her arm to their side, which is required for many activities of daily living. These results are validated by those presented in the literature from both radiographic and clinical studies (see FIG. 44; see also, Nyffeler, R. W. et al. Biomechanical Relevance of Glenoid Component Positioning in the Reverse Delta III Total Shoulder Prosthesis. JSES. Vol. 14. #5: 524-528. 2005; De Wilde, L. F. et al. Shoulder Prostheses Treating Cuff Tear Arthropathy: a comparative biomechanical study. JOR. #22: 1222-1230. 2004).

Based upon these observations, the conclusion is that the specific combination of humeral neck angle, glenosphere geometry, and humeral liner geometry are interrelated but not necessarily optimized in the traditional Grammont design—and thus make it susceptible to scapular notching and dislocation via inferior impingement. The knowledge of these relationships can serve as the basis for optimizing a traditional Grammont-style reverse shoulder prosthesis according to various embodiment of the present invention.

In this regard, various embodiments of the present invention may provide a reverse shoulder design shifting the inferior impingement point to a location that permits a ROM better accommodating a patient's activities of daily living. The application of these relationships is useful in the design of a reverse shoulder prosthesis that maximizes ROM and jump distance, minimizes impingement, and provides sufficient offset to tension the deltoid and maintain certain biomechanical benefits associated with the traditional Grammont reverse shoulder design.

Reference will now be made to another study to: 1) quantify the range of motion and jump distance associated with an Equinox reverse shoulder design during simulated humeral abduction/adduction as determined using a three-dimensional computer aided assembly analysis; and 2) compare these parameters to those associated with the typical Grammont reverse shoulder design during the same simulated motion, quantified using the same methodology. The results of the comparison verify that the Equinox reverse shoulder achieves an increase in the amount of motion and a decrease in the amount of inferior impingement (a measure of motion and stability, indicative of scapular notching) while maintaining a similar amount of jump distance (a measure of stability, indicative of the probability of dislocation), relative to the typical Grammont design.

The Equinox reverse shoulder that is the subject of this study was designed based upon the principles elucidated and described in connection with the study described above. Some design goals of this prosthesis are described below (some the design specifics of each component are shown in FIGS. 45-53):

- 1) Maintain the Biomechanical Benefits of the typical Grammont Reverse Design: Prevent Superior Humeral Migration, Minimize Lever Arm by Placing Center of Rotation on Glenoid Fossa (by moving it medially and distally), Elongate Deltoid by ~15%.
- 2) Minimize Scapular Notching/Inferior Bone Impingement

- 3) Improve Range of Motion
- 4) Maximize Jump Distance
- 5) Seamlessly Integrate Equinox Primary System with a Reverse Option (i.e. utilize the same humeral stem)

As described below, this study demonstrates that the Equinox reverse shoulder achieves an increase in the amount of motion and a decrease in the amount of inferior impingement (a measure of motion and stability, indicative of scapular notching) while maintaining a similar amount of jump distance (a measure of stability, indicative of the probability of dislocation), relative to the typical 36 mm Grammont design.

For the purposes of this study, the aforementioned prostheses were designed and geometrically modeled by using Unigraphics (UGS, Inc.), based upon the elucidated design parameters described in the study discussed above. A ROM simulation was constructed (also using Unigraphics) to simulate humeral abduction/adduction and quantify the aforementioned study parameters.

The same methodology described in the study discussed above was applied to quantify the points of inferior and superior impingement, the total ROM, and the jump distance at 3° increments during simulated humeral abduction/adduction of the Equinox reverse shoulder prosthesis. It should be noted that the definitions used in this study for inferior and superior impingement are slightly different than those used in the study discussed above due to the differences in design. As shown in FIGS. 45 and 46, the Equinox reverse shoulder glenoid plate has a central stem that is superiorly shifted by 4 mm; doing so, results in a 4 mm distal shift to the glenosphere assuming that the central stem of the glenoid plate is implanted so that the distal rim of the glenoid plate aligns with the distal edge of the glenoid articular surface. A 4 mm distal shift of the glenosphere creates an inferior overhang that has been demonstrated by Nyffeler to be associated with superior clinical results, compared to alternative glenosphere implantation techniques. For this reason the defined points of inferior and superior impingement are modified as depicted in FIGS. 54 and 55, respectively.

During simulated humeral abduction/adduction, inferior and superior impingement was measured to occur for the 38 mm, 42 mm, and 46 mm Equinox reverse shoulder at 16° and 91.5°; 7.5° and 91.5°; and 0° and 91.5°, respectively. Therefore, the total ROM during simulated humeral abduction/adduction for the 38 mm, 42 mm, and 46 mm Equinox reverse shoulder was measured to be 75.5°, 84°, 91.5°, respectively. For clarification, FIG. 56 depicts several defined angles during this simulated motion for the 42 mm Equinox reverse shoulder of this example.

Over this ROM, the minimum and maximum jump distance associated with the 38 mm, 42 mm, and 46 mm Equinox reverse shoulder was measured to be 0.035 in-0.855 in; 0.035 in-1.052 in; and 0.035 in-1.234 in, respectively. The average jump distance (in 3° increments over the aforementioned ROM) associated with the 38 mm, 42 mm, and 46 mm Equinox reverse shoulder was measured to be 0.371 in, 0.458 in, and 0.522 in, respectively.

By comparison, the typical 36 mm Grammont reverse shoulder inferiorly and superiorly impinged at 35° and 95°, providing a total ROM of 60°. The minimum and maximum jump distance for this ROM was measured to be 0.081-0.749 inches; having an average jump distance of 0.374 in over this ROM (in 3° increments). As depicted in FIGS. 57 and 58, the Equinox reverse shoulder of this example is associated with a 20.5%, 28.6%, and 34.4% greater ROM and a -0.8%, a 18.3%, 28.3% greater average jump distance than the typical Grammont reverse shoulder prosthesis.

The results of this design verification demonstrate that the Equinox reverse shoulder prosthesis of this example is associated with more motion, less impingement, and a similar amount of stability as the typical 36 mm Grammont design.

Regarding this conclusion, three points should be considered. First, the ROM values obtained in this study are less than those reported clinically. The reason for this discrepancy is due at least in part to scapular motion not being considered in the analysis, only humeral motion was considered. The ratio of scapular motion to humeral motion has been reported between 0.4-0.7; depending upon the condition of the rotator cuff: the larger the cuff tear the greater the amount of scapular motion relative to humeral motion (see, De Wilde, L. F. et al. Functional Recovery after a Reverse Prosthesis for Reconstruction of the Proximal Humerus in Tumor Surgery. CORR. #430: 156-162. 2005; Mell, A. G. et al. Effect of Rotator Cuff Tear Size on Shoulder Kinematics. Transactions of the 51st Annual Meeting of the Orthopaedic Research Society. Poster #0623. 2005). Therefore, for cuff tear arthropathy, the most common indication for reverse shoulder arthroplasty, it is reasonable to assume that the amount of scapular motion relative to humeral motion is on the high end of this ratio—when this is considered, the results of this study comply with the clinical ROM data published in the literature.

Second, the average jump distance for the 38 mm Equinox reverse shoulder design of this example was 0.371 inches; this value is 0.003 inches (i.e. 0.075 mm) less than that of the typical 36 mm Grammont (0.374 inches). However, it is believed that this minute difference falls within the allowable manufacturing tolerances of either part and is also probably negligible when the accuracy and precision of the test methodology is considered. For this reason, it was concluded that these two designs have similar jump distances and therefore similar levels of stability.

Third, only the typical 36 mm Grammont design was considered, both Depuy and Tornier provide a 42 mm glenosphere. However, it is believed that the 42 mm prosthesis is rarely used clinically because the Grammont surgical technique typically requires reaming of the proximal humerus and 90%-95% of the time the proximal humerus is too small to accept a 42 mm humeral liner. Dr. Walch presented that the 42 mm glenosphere is used in <5% of his reverse arthroplasty cases at the 2005 American and Shoulder Elbow Society meeting in Orlando. Depuy in its Delta III marketing literature reported that the 42 mm glenosphere was used in only 11% of cases in 2004. Because the Equinox reverse shoulder of this example does not require reaming of the proximal humerus, (e.g. it is implanted using a traditional humeral head osteotomy along the anatomic neck of the humerus) it is possible to implant a larger diameter glenosphere. In this way, the size of the glenosphere used is determined based upon the size of glenoid, rather than the size of the proximal humerus. That being said, FIG. 58 approximated the ROM that would be associated with the 42 mm glenosphere design assuming the 42 mm humeral liner constraint was the same as that of the 36 mm humeral liner constraint. If this assumption is valid, then the same percentage increases in ROM of the Equinox reverse shoulder of this example over the typical 36 mm Grammont design would also apply for the typical 42 mm Grammont design.

For all these reasons, the results of this study have demonstrated that the Equinox reverse shoulder prosthesis of this example is associated with more motion, less impingement, and a similar amount of stability as the typical 36 mm Grammont design.

While a number of embodiments of the present invention have been described, it is understood that these embodiments

21

are illustrative only, and not restrictive, and that many modifications may become apparent to those of ordinary skill in the art. For example, any element described herein may be provided in any desired size (e.g., any element described herein may be provided in any desired custom size or any element described herein may be provided in any desired size selected from a “family” of sizes, such as small, medium, large). Further, one or more of the components may be made from any of the following materials: (a) any biocompatible material (which biocompatible material may be treated to permit surface bone ingrowth or prohibit surface bone ingrowth—depending upon the desire of the surgeon); (b) a plastic; (c) a fiber; (d) a polymer; (e) a metal (a pure metal such as titanium and/or an alloy such as Ti—Al—Nb, Ti-6Al-4V, stainless steel); (f) any combination thereof. Further still, the metal construct may be a machined metal construct. Further still, various cage designs (e.g. square/elliptical/angled cages) may be utilized. Further still, various keel designs (e.g. anterior/posterior keel, medial/lateral keel, dorsal fin keel, angled keel) may be utilized. Further still, the prosthesis may utilize one or more modular elements. Further still, any desired number of cages(s) and/or keel(s) may be utilized with a given prosthesis. Further still, any number of protrusions (e.g., such as for initial fixation by forming a bond with cement and/or such as for supplemental fixation by forming a bond with cement) may be utilized with a given prosthesis. Further still, any number of female features that increase the cement mantle may be utilized with a given prosthesis. Further still, any number of male features that could dig into the bone so that initial/supplemental fixation can be improved may be utilized with a given prosthesis. Further still, any number of bone screws (e.g., such as for initial fixation and/or such as for supplemental fixation) may be utilized with a given prosthesis. Further still, any steps described herein may be carried out in any desired order (and any additional steps may be added as desired and/or any steps may be deleted as desired).

What is claimed is:

1. A glenosphere for a reverse shoulder prosthesis comprising:
 - a glenosphere body having an articular surface configured to interface with a humeral liner, an anterior side configured to interface with a glenoid bone, a posterior side configured to interface with the glenoid bone, a superior

22

side configured to interface with the glenoid bone, and an inferior side configured to interface with the glenoid bone,

wherein the articular surface is generally spherical where the articular surface interfaces with the humeral liner, wherein the anterior side and the posterior side are each chamfered, wherein the chamfered anterior side and the chamfered posterior side results in a non-spherical face to interface with the glenoid bone, wherein the non-spherical face has an anterior-posterior axis length that is smaller than a superior-inferior axis length, and wherein the chamfered anterior side and the chamfered posterior side are designed so that the non-spherical face of the glenosphere that interfaces with the glenoid bone:

i) resembles that of the glenoid bone and ii) allows the glenosphere to sit flush on a resected surface of the glenoid bone when the glenosphere is disposed adjacent a glenoid plate and the glenoid plate is affixed to the glenoid bone.

2. The glenosphere of claim 1, wherein the glenosphere body is at least partially hollow.

3. The glenosphere of claim 2, wherein the glenosphere body affixes to a glenoid plate such that at least a portion of the glenoid plate is disposed within the hollow part of the glenosphere body.

4. The glenosphere of claim 3, wherein the hollow part of the glenosphere body in which at least part of the glenoid plate is disposed has a perimeter shape that is generally elongated along the superior-inferior axis.

5. The glenosphere of claim 4, wherein the hollow part of the glenosphere body in which at least part of the glenoid plate is disposed has a perimeter shape that is generally elongated along the superior-inferior axis to substantially match a perimeter shape of the glenoid plate.

6. The glenosphere of claim 3, wherein the hollow part of the glenosphere body in which at least part of the glenoid plate is disposed has a perimeter shape that is generally circular.

7. The glenosphere of claim 6, wherein the hollow part of the glenosphere body in which at least part of the glenoid plate is disposed has a perimeter shape that is generally circular to substantially match a perimeter shape of the glenoid plate.

* * * * *