

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SEASPINE HOLDINGS CORPORATION
Petitioner,

v.

ROGER P. JACKSON, M.D.
Patent Owner.

IPR2025-00773
U.S. Patent No. 11,399,873

**DECLARATION OF TROY D. DREWRY,
UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR
INTER PARTES REVIEW**

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I, Troy Drewry, do hereby declare as follows:

I. INTRODUCTION

1. I am making this declaration at the request of SeaSpine Holdings Corporation (“SeaSpine” or “Petitioner”) in the matter of the *Inter Partes* Review of U.S. Patent No. 11,399,873 (“the ’873 Patent”) to Jackson, which claims priority to January 10, 2012 at the earliest.

2. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this investigation. My compensation is not contingent on the outcome of this matter or the specifics of my testimony, and I have no other interest in this case or the parties thereto.

3. I have been asked to provide my opinions regarding whether claims 1-19 (“the Challenged Claims”) of the ’873 Patent are unpatentable as they would have been obvious to a person having ordinary skill in the art (“POSITA”) at the time of the alleged invention, in light of the prior art. It is my opinion that all of the limitations of the Challenged Claims would have been obvious to a POSITA.

4. In the preparation of this declaration, I have studied:

- a. the ’873 Patent, Ex.1001;
- b. the prosecution history of the ’873 Patent (“’873 File History”),

Ex.1002;

- c. the prosecution history of the '646 Patent ("'646 File History"),
Ex.1004;
- d. U.S. Patent Publication No. 2011/0152947 to Kirschman
("Kirschman"), Ex.1005;
- e. U.S. Patent No. 447,775 to Higbee ("Higbee"), Ex.1006;
- f. U.S. Patent Publication No. 2007/0088357 to Johnson *et al.*
("Johnson"), Ex.1007;
- g. U.S. Patent Publication No. 2005/0267477 to Jackson ("'477
Publication"), Ex.1008;
- h. U.S. Patent No. 7,857,834 to Boschert ("Boschert"), Ex.1009;
- i. ASME B1.7-2006 - Screw Threads- Nomenclature, Definitions, and
Letter Symbols, Ex.1010;
- j. Handbook H28 (1969) - Screw-Thread Standards for Federal
Services, Ex.1011;
- k. U.S. Patent Publication No. 2005/0286984 to Weise *et al.* ("Weise"),
Ex.1012;
- l. U.S. Patent Publication No. 2011/0106179 to Prevost *et al.*
("Prevost"), Ex.1013;
- m. U.S. Patent Publication No. 2010/0137918 to Wilcox *et al.*
("Wilcox"), Ex.1014;

- n. Machinery's Handbook, 3rd Edition (1914), Ex.1015;
- o. Machinery's Handbook, 28th Edition (2008), Ex.1016;
- p. U.S. Patent No. 4,707,001 to Johnson ("Johnson '001"), Ex.1017;
- q. U.S. Patent No. 6,010,502 to Bagby ("Bagby"), Ex.1018;
- r. American Heritage Dictionary, 5th Edition, Ex.1019;
- s. U.S. Provisional Application No. 61/631,746 ("First Provisional Application"), Ex.1029; and
- t. U.S. Provisional Application No. 61/634,361 ("Second Provisional Application"), Ex.1030.

5. In forming the opinions expressed below, I have considered:

the documents listed above;

the relevant legal standards, including the standard for obviousness,
and any additional authoritative documents as cited in the body of this
declaration; and

my own knowledge and experience based upon my work in the field
of bone screw assemblies for implantation into the spine as described below,
as well as the following materials.

6. Unless otherwise noted, all emphasis in any quoted material has been
added.

II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

7. My employment history, education, professional activities, patents, and other miscellaneous publications are set forth in my curriculum vitae, attached as Attachment A. Attachment A also includes a listing of publications including books and patents.

8. I am medical device product development engineer. I have a Bachelor of Science Degree in Mechanical Engineering from the University of Southwestern Louisiana in Lafayette, LA, a Masters of Science Degree in Biomedical Engineering from the University of Memphis in Memphis, TN, and a Masters of Engineering Management Degree from Christian Brothers University in Memphis, TN.

9. I am currently employed as a Professor of Practice in the Biomedical Engineering Department at the University of Mississippi in Oxford, MS. I teach a two-course senior design series (BME461 & BME 462) focused on medical device design. I am also the Operations Director of the Center for Diagnostics, Design, Device, and Biomechanics (D3B) at the University of Mississippi.

10. In addition to my faculty appointment, I am the Founder and Principal Engineer of Ragin Cajun Consulting LLC (“RCC”) in Memphis, TN, which I started in 2017. RCC is a medical device product development consulting firm that provides research, design, and development services for larger established

companies, surgeons, and inventors on a fee-for-service basis. RCC is focused on orthopedic medical devices and instruments in the spine, hip and knee, trauma, sports medicine, and extremities markets.

11. I have over 25 years of orthopedic product development experience. I have held several positions in medical device companies of increasing roles and responsibilities ranging from an entry level product development engineer all the way up to President and Chief Operating Officer (“COO”). These roles and responsibilities have been with a large Fortune 500 medical device company, mid-cap medical device companies, and venture capital backed startup medical device companies. The goal being designing and developing orthopedic medical devices (and, in particular, spinal fixation devices), driving them through the product development process, gaining FDA approval to manufacture, market, and sell these devices, and finally global commercialization of the final implant and surgical instruments – all while utilizing FDA defined design control processes.

12. After graduating from the University of Memphis with my Masters of Science in biomedical engineering, I joined Sofamor Danek as an Associate Produce Development Engineer in the Thoracolumbar Division in 1995. Over the next 13 years (from 1995-2008), I worked at Sofomar Danek and later Medtronic Sofamor Danek (which acquired Sofomar Danek) and Medtronic Spinal & Biologics as an engineer focusing on spinal technologies. I worked my way up

from an Associate Product Development Engineer up to the Group Director of Product Development for Medtronic Sofamor Danek and, then, Medtronic Spinal & Biologics. During this time period, I designed, developed, and launched several spinal implant products, including the CD Horizon Multi-Axial Screw System, which was Medtronic's first commercially-available modular, multi-axial bone anchor assembly for securing a rod to one or more vertebral levels for fixation thereof. After working as the Group Director of Product Development in the Intradiscal Division at Medtronic Spinal & Biologics, I worked at Active Implants Corporation ("Active Implants"), where I was the Vice President of Global Operations, then the COO. As Vice President of Global Operations, I was responsible for the global manufacturing and production planning for the European commercialization of one of Active Implant's hip replacement implants, the production and distribution of all products, and the development of global supply chains to support current and future products. As COO, I led multiple successful funding efforts, oversaw exceeded revenue projections for Active Implant's acetabular buffer system, finalized a major global manufacturing agreement for manufacturing of all of our implants in the United Kingdom and set up a Global Logistics Network for supplying European distributors.

13. From 2009-2011, I was the Vice President of US Operations for Paradigm Spine, LLC, where I oversaw US Manufacturing, R&D activities, and

regulatory affairs. I also liaised with Legal and IP on all patent activities, with Marketing and Field Operations on all marketing activities, and with Paradigm Spine GmbH on all quality activities. Additionally, I contributed to US Clinical & Regulatory Affairs, including clinical study enrollments and PMA filings.

14. From 2014-2017, I was the Chief Executive Officer (“CEO”) of View Medical. View Medical was a start-up company that designed and developed intraoperative lighting technology. From 2012-2017, I was the President and COO of MB Innovations, Inc. (“MBI”), which provided research, design, and development services for established firms in addition to creating and manufacturing its own technologies and intellectual property. MBI was focused on the medical device industry in Memphis, TN and, in particular, developed technologies for the musculoskeletal disease sector. In 2017, I founded Ragin Cajun Consulting, where I am currently the Principal Engineer, as discussed above.

15. In addition to working in the medical device industry, I have had experience working in academia as an Adjunct Professor and member of numerous Engineering Advisory Boards. In 2013, I joined Christian Brothers University as an Adjunct Professor in the Master of Business Administration (MBA) and Healthcare Masters of Business (HMBA) Programs. I taught a three-course series on Project Management and a course in Quality, Supply Chain, and Project Management. I have served on the Dean of Engineering’s Engineering Advisory

Board at the University of Mississippi in Oxford, Mississippi, the STEM Advisory Board at Christian Brothers High School in Memphis, Tennessee, the Engineering Biotech Advisory Board, Christian Brothers University in Memphis, Tennessee, the Industrial Advisory Board for University of Memphis's Department of Mechanical Engineering, and the Industrial Advisory Board for University of Southwestern Louisiana's Department of Mechanical Engineering.

16. As a medical device product development engineer, I have been inventor or co-inventor on over 60 issued US Patents, over 20 International Issued Patents, and numerous pending US and International Patent Applications. In particular, during my time as an engineer at Sofamor Danek, Medtronic Sofamor Danek, and Medtronic Spinal & Biologics, I was named as an inventor on dozens of patents directed to spinal fixation devices that use bone anchor assemblies to secure a rod to the spine. Some of these patents anticipate and/or render obvious one or more of the Asserted Patents, as described in more detail below. For example, the patents of which I am an inventor include:

- U.S. Patent No. 5,879,350 – Multi-Axial Bone Screw Assembly
- U.S. Patent No. 5,885,286 – Multi-Axial Bone Screw Assembly
- U.S. Patent No. 5,728,098 – Multi-Angle Bone Screw Assembly
Using Shape-Memory Technology
- U.S. Patent No. 5,797,911 – Multi Axial Bone Screw Assembly

- U.S. Patent No. 5,891,145 – Multi-Axial Screw
- U.S. Patent No. 7,867,258 – Multi-Axial Bone Attachment Member
- U.S. Patent No. 9,987,047 – Translating Polyaxial Screw

I have also authored several publications and presented at several conferences in the field of spinal implants, and, in particular, spinal fusion technologies, including:

- Lewis G, Drewry TD, Sherman MC, “*A Thoracic Spine Testbed for the Comparative Biomechanical Evaluation of Spinal Instrumentations*,” J. OF SPINAL DISORDERS, June 1995, 186-94.
- Drewry TD, Sherman MC, Lewis G, “*Biomechanical Comparison Between Single and Dual Rod Texas Scottish Rite Hospital (TSRH) Posterior Scoliosis Constructs: An Experimental Stress Analysis*,” Presented at The 30th Annual Meeting of the Scoliosis Research Society. Asheville, NC, September 13-16, 1995.
- Huntington CF, Betz RR, Maxy P, Clements III DH, Drewry TD, Sherman MC, Pafford JA, “*Biomechanical Finite Element Analysis of Spinopelvic Fixation in Long Segment Spinal Fixation Constructs*,” Presented at The 66th Annual Meeting of the American Academy of Orthopaedic Surgeons. Anaheim, CA, February 4-8, 1999.

- Drewry, TD, Braun, JT, Ogilvie, JW “*Fusionless Scoliosis Correction Using a Shape Memory Alloy Staple in the Anterior Thoracic Spine of the Immature Goat,*” Presented at the 19th Annual Science and Technology Conference at Medtronic Corporate Headquarters in Minneapolis, MN, September 20-22, 2000.
- Drewry, TD, Scifert, S, “*Resorbable Spinal Implants in a Sheep Model: Radiographic, Histologic, and Biomechanical Preliminary Results,*” Presented at the BioTechnologies for Spinal Surgery Meeting. Halle, Germany, April 11-13, 2002.
- Betz RR, Cunningham B, Selgrath C, Drewry TD, Sherman MC, “*Preclinical Testing of a Wedge-Rod System for Fusionless Correction of Scoliosis,*” SPINE, Vol. 28 No. 20, 15 OCT 2003, pp S275-278.

17. Therefore, based on my education, professional experience of 30 plus years, and the dozens of patents and publications of which I am named as an inventor and author (respectively), I am an expert in the relevant field of the Asserted Patents.

III. LEVEL OF ORDINARY SKILL IN THE ART

18. I understand that the level of ordinary skill may be reflected by the prior art of record, and that a POSITA to which the claimed subject matter pertains would have the capability of understanding the scientific and engineering

principles applicable to the pertinent art. I understand that a POSITA has ordinary creativity, and is not an automaton.

19. I understand there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including (1) the levels of education and experience of persons working in the field at the time of the invention; (2) the sophistication of the technology; (3) the types of problems encountered in the field; and (4) the prior art solutions to those problems.

20. In my opinion, the field of art of the '873 Patent involves bone screw assemblies for implantation into the spine (*e.g.* the pedicle of the spine). I have been informed by counsel that the earliest possible priority date for the '873 Patent is January 10, 2012.¹ I am also aware of the state of the art at the time the application resulting in the '873 Patent was filed.

21. Based on the technologies disclosed in the '873 Patent, I believe that a POSITA would include someone who had, as of the claimed priority date of the '873 Patent, at least a bachelor's degree in Mechanical Engineering, Biomedical Engineering, or an equivalent field, as well as at least 3-5 years of academic or industry experience related to the design of spinal fixation implants and/or spinal

¹ As explained in Section V.B. below, it is my opinion that the '873 Patent is entitled to a priority date no earlier than February 28, 2012.

deformity correction implants and, in particular, bone anchor assemblies. In addition, I recognize that someone with less formal education but more experience, or more formal education (e.g., MS, PhD, or MD) but less experience could have also met the relevant standard for a POSITA. I believe that I am at least a POSITA and, furthermore, I have provided consultation to engineers who were also POSITAs. Accordingly, I believe that I am qualified to opine from the perspective of a POSITA regarding the '873 Patent.

22. For purposes of this Declaration, unless otherwise noted, my statements and opinions, such as those regarding the understanding of a POSITA generally (and specifically related to the references I consulted herein), reflect the knowledge that existed in the art before the earliest claimed priority date of the '873 Patent.

IV. RELEVANT LEGAL STANDARDS

23. I am not an attorney. In preparing and expressing my opinions and considering the subject matter of the '873 Patent, I am relying on certain basic legal principles that counsel have explained to me. These principles are discussed below.

24. I understand that prior art to the '873 Patent includes patents and printed publications in the relevant art that predate the priority date of the alleged invention recited in the '873 Patent. For the purposes of this declaration, I am

applying January 10, 2012 as the priority date of the '873 Patent ("priority date"); however, as explained below in Section V.B., it is my opinion that the actual priority date of the '873 Patent is February 28, 2012.

25. I have been informed that a claimed invention is unpatentable under 35 U.S.C. § 103 if the differences between the invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. I have also been informed by counsel that the obviousness analysis takes into account factual inquiries including the level of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

26. I further understand that certain factors may support or rebut the obviousness of a claim. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus—a connection—between any such secondary considerations and the alleged invention

recited in the claims. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

27. I am not aware of any allegations by the named inventor of the '873 Patent or any assignee of the '873 Patent that any specific secondary considerations are particularly relevant to the obviousness analysis of any Challenged Claims of the '873 Patent.

28. I have been informed by counsel that the Supreme Court has recognized several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include the following: (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of a known technique to improve a similar device (method, or product) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (f) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

V. THE '873 PATENT

A. Overview of the '873 Patent

29. The '873 Patent “is directed to structures for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws.” Ex.1001, 1:27-31.

30. In certain spinal surgeries, a surgeon may “implant bone screws into certain bones which then in turn support a rod or are supported by the rod” to “stabiliz[e] and/or adjust[] spinal alignment.” Ex.1001, 1:32-38. In that regard, “[o]pen-ended anchors are particularly well suited for connections to longitudinal connecting members... because such rods or other connector members do not need to be passed through a closed bore, but rather can be laid or urged into an open channel within a receiver or head of such a bone anchor.” Ex.1001, 1:40-46. The '873 Patent acknowledged that “[t]ypical open-ended bone screws include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member.” Ex.1001, 1:54-58. The channel formed between the arms of the receiver are “closed by a closure member after the rod or other longitudinal connecting member is placed in the channel.” Ex.1001, 1:61-65. The '873 Patent lists several types of “[k]nown closures [that] include slide-on

types, twist-on varieties that are rotated ninety degrees to a locked in position, and a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread, reverse-angle buttress or square thread forms, to name a few, as well as other non-threadlike helically wound forms.” Ex.1001, 1:65-2:4.

31. The '873 Patent asserts that “extraordinary forces are placed on the implant and closure plug while the surgeon either pushes down on the rod or pulls up on the bone to get the rod in position between the implant arms and to initially push down upon the rod with the closure plug.” Ex.1001, 2:31-35; *see also* 2:7-19 (“As indicated above, the force required to press a closure structure down onto a rod or other connector located between arms of an open implant is considerable. Even though a head or receiver portion of an open polyaxial bone anchor may be pivoted in a direction to make it easier for the arms of the open implant to receive a rod or other connector, spinal misalignments, irregularities and the placement of other surgical tools make it difficult to place the rod or other connector between the arms of the implant while a closure structure is mated with the open implant as well as used to push the rod or other connector downwardly into the implant.”). Thus, these forces make it difficult to align the threads of the closure with the threads of the open implant. In a particular example, “when the closure is a cylindrical plug having a single start helically wound guide and advancement

structure,” a variety of which were well-known in the art, “such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.”

Ex.1001, 2:19-27.

32. Accordingly, the '873 Patent describes threaded closures with blunt start structures that are spaced above the bottom surface to make it easier for the start structures of the closure threads to align with the receiver threads. The '873 Patent discloses “a double-start closure...having two helically wound forms thereon, each form having a start structure for simultaneously engaging a mating helical form on a respective open implant arm.” Ex.1001, 2:47-51.

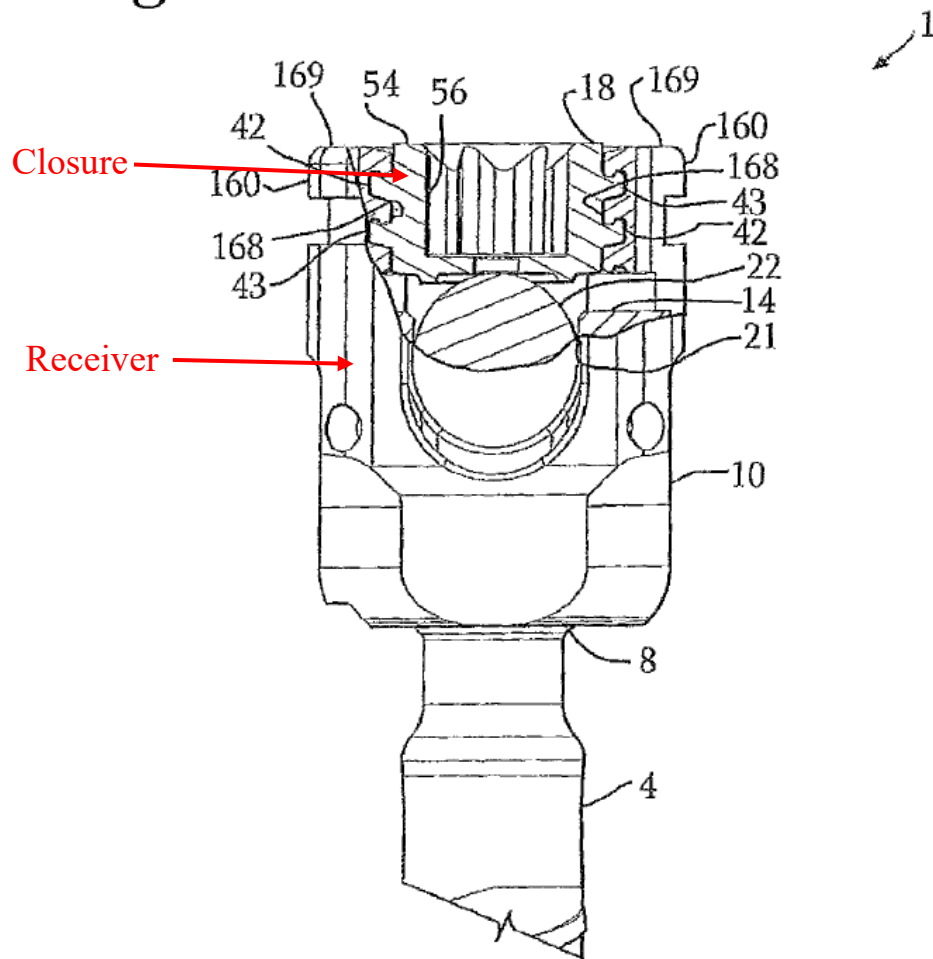
Advantageously, “[e]ach time the illustrated duel- or double-start closure plug is rotated one turn (three hundred sixty degrees) between the implant arms, the closure plug advances axially into the implant and toward the rod by a width of two helical forms.” Ex.1001, 2:51-59. These closures may include “non-threaded, interlocking flange forms” or “helically wound forms of other geometry, including, but not limited to helically wound threads such as reverse angle, buttress, square and v-threads,” as was well-known in the art. Ex.1001, 3:3-8; *see also* 2:19-27.

33. Figs. 1-8 of the '873 Patent illustrate “an open implant in the form of

a polyaxial bone screw apparatus or assembly that includes a shank 4, that further includes a body 6 integral with an upwardly extending upper portion or capture structure 8; a receiver 10; a retaining structure or retainer 12, a compression or pressure insert 14, and a multi-start closure structure or plug 18 of the invention in the form of a cylindrical plug having a double start helically wound flange-form.”

Ex.1001, 7:27-36, Figs. 1-8; *see also* 3:42-67. Fig. 1 illustrates the polyaxial bone screw assembly:

Fig. 8.



'873 Patent (Ex.1001), Fig. 8 (annotated)

34. The multi-start “closure structure 18 presses against and captures a longitudinal connecting member, for example, a rod 21 which in turn engages the compression insert 14 that presses against the shank upper portion 8 that is attached to the retaining structure that in turn presses against an inner surface of the receiver 10, so as to capture and fix the longitudinal connecting member 21 within the receiver 10 and thus fix the member 21 relative to a vertebra (not shown).” Ex.1001, 7:45-53. The '873 Patent explains that the multi-start closure structure 18 may have an axis of rotation and guide and advancement structures 168 that each include a start structure 46, 47 and variety of thread forms including those previously described in U.S. Patent No. 6,726,689 and well-known thread forms such as square threads, reverse angle threads, or v-threads:

With particular reference to FIGS. 1-7, the illustrated multi-start closure structure 18 is a double start closure having a substantially cylindrical plug body 40 having an axis of rotation that is the same as that of the receiver 10 and including a helically wound guide and advancement structure in the form of a pair of helically wound forms 42 and 43, each illustrated as an interlocking flange form that operably joins with mating flange form guide and advancement structures 168 disposed on the arms of the receiver 10. **The form 42 includes a start surface or structure 46 and the form 43 includes a start surface or structure 47. Each helically wound form 42 and 43 may take a variety of forms and geometries, including those described in**

Applicant's U.S. Pat. No. 6,726,689, which is incorporated by reference herein. It is noted (and also described in greater detail subsequently herein) that each of the closure structure guide and advancement structures or forms 42 and 43 could alternatively be in the form of a buttress thread, a square thread, a reverse angle thread, a v-thread or other thread like or non-thread like helically wound advancement structures, for operably guiding under rotation and advancing the closure structure downward between the arms of the receive [sic] 10 and preferably having such a nature as to resist splaying of the receiver arms when the closure structure 18 is advanced into the receiver channel. The specific flange forms 42 and 43 illustrated in FIGS. 1-7, as well as acceptable alternative locking forms, are described in detail in Applicant's U.S. Pat. No. 6,726,689, incorporated by reference herein, and thus shall not be discussed further herein. Such interlocking flange forms are preferred as the added strength provided thereby beneficially cooperate with and counter any reduction in strength caused by the any reduced profile of the receiver 10 that may more advantageously engage longitudinal connecting member components.

Ex.1001, 8:22-55.

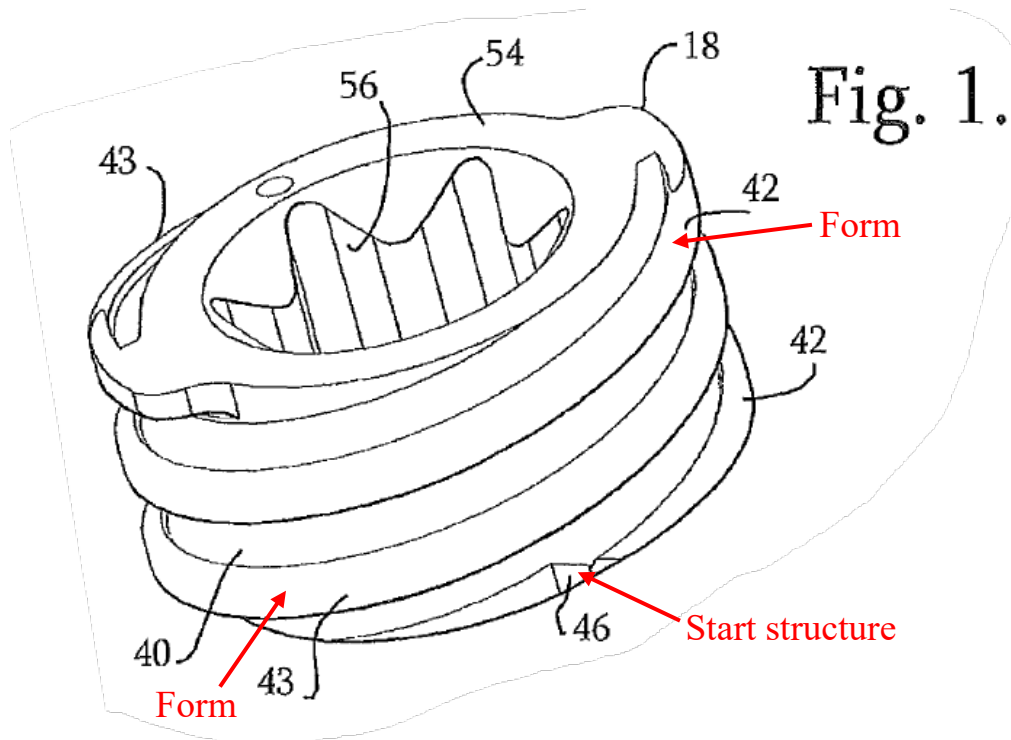
35. The start structures 46, 47 of the multi-start closure structure 18 may have a leading face with “at least one curvate surface”:

The closure structure 18 helically wound flange form start structures 46 and 47 of the respective forms 42 and 43 are located on opposite sides of the closure plug body 40 and are both located adjacent the bottom surface 58. As illustrated in FIG. 3, for example,

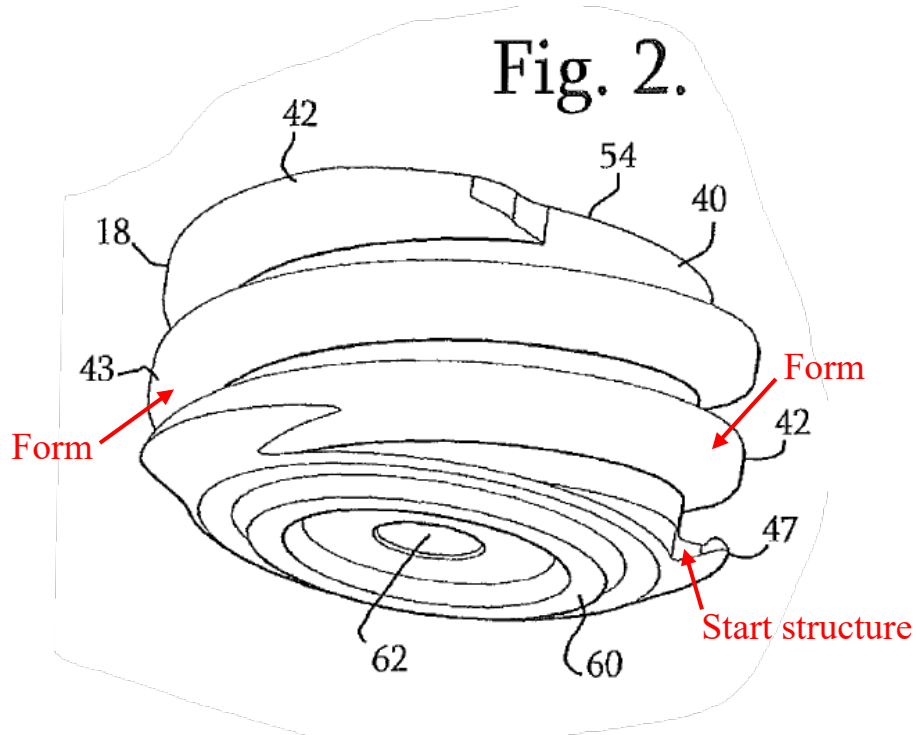
when the closure structure 18 is rotated into the receiver 10 between receiver arms 160, each having a guide and advancement structure 168, the start 46 engages mating guide and advancement structure 168 on one arm 160 and the start 47 simultaneously engages guide and advancement structure 168 on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160. As the structure 18 is rotated, the structure advances axially downwardly between the arms 160 and presses evenly down upon the captured rod 21. Each time the illustrated duel- or double-start closure plug 18 is rotated one complete turn or pass (three hundred sixty degrees) between the implant arms, the closure plug 18 advances axially into the implant and toward the rod by a width of two helical flange forms. The illustrated closure 18 is sized for at least one complete rotation (three hundred sixty degree) of the plug 18 with respect to the receiver 10 open arms 160 to substantially receive the plug between the implant arms. **Each of the start structures 46 and 47 includes a leading face having at least one curvate surface.** The at least one curvate surface includes at least one radius of curvature. In one embodiment, the at least one curvate surface is both concave and convex.

Ex.1001, 15-42.

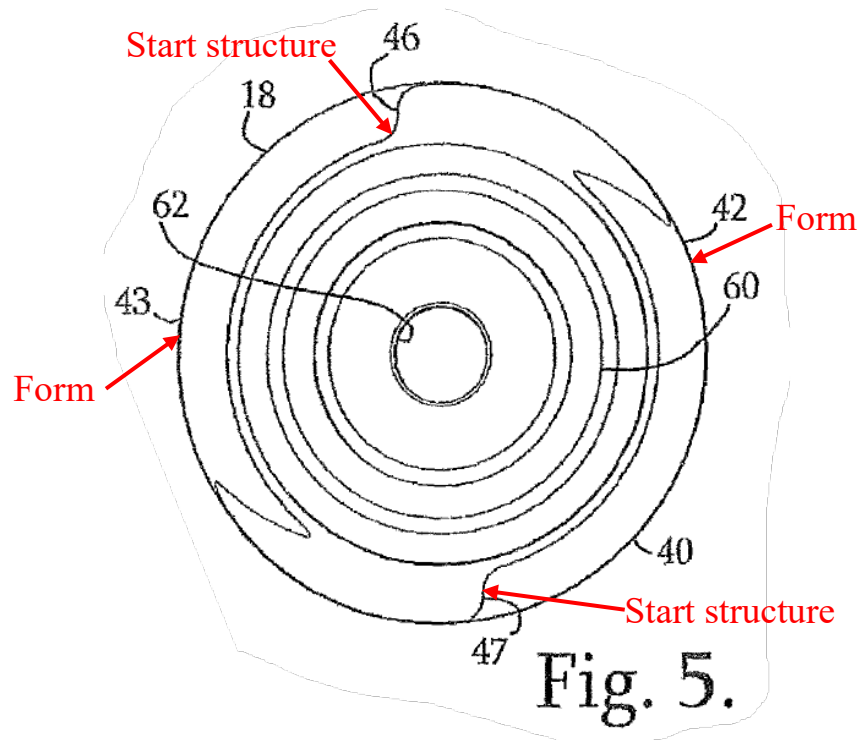
36. Thus, the start structures 46, 47 allow the closure 18 to better engage the guide and advancement structure 168 on the arms 160 of the receiver 10. The multi-start closure structure's 18 helically-wound flange forms 42, 43 and start structures 46, 47 are illustrated in Figs. 1, 2, and 5 below:



'873 Patent (Ex.1001), Fig. 1 (annotated)

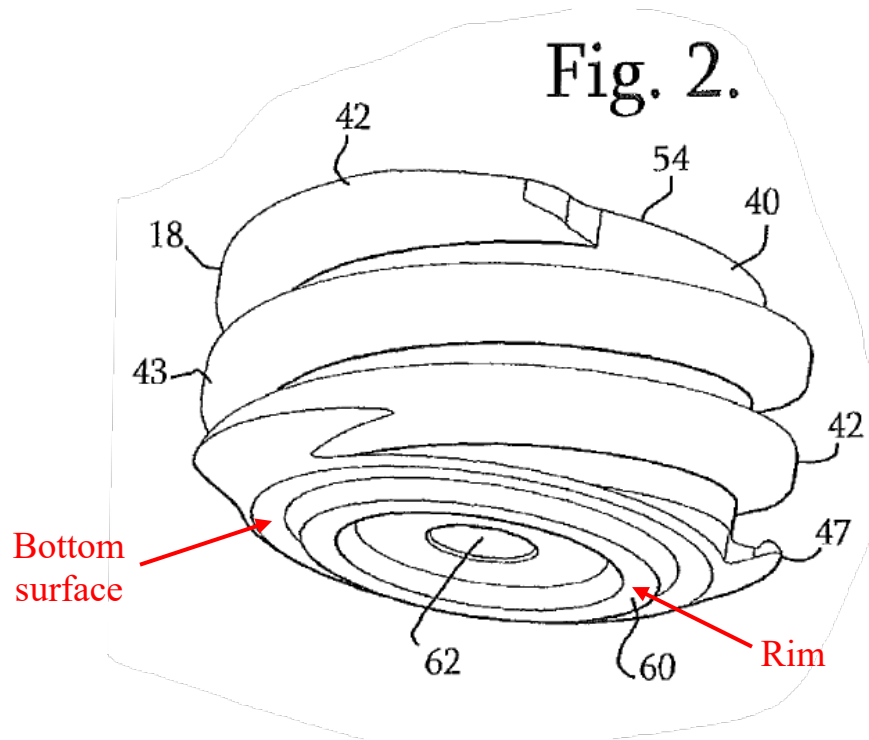


'873 Patent (Ex.1001), Fig. 2 (annotated)

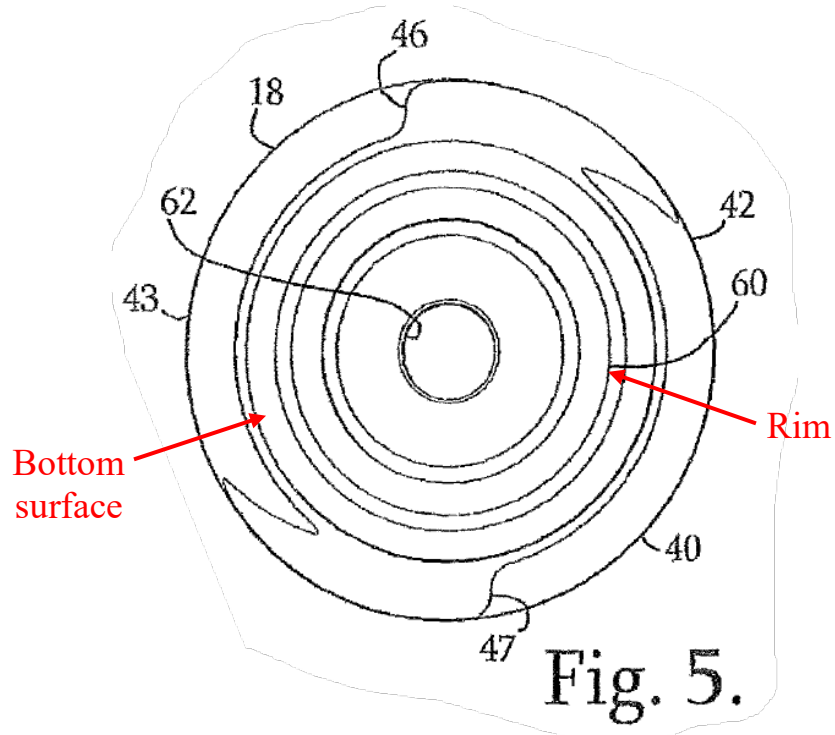


'873 Patent (Ex.1001), Fig. 5 (annotated)

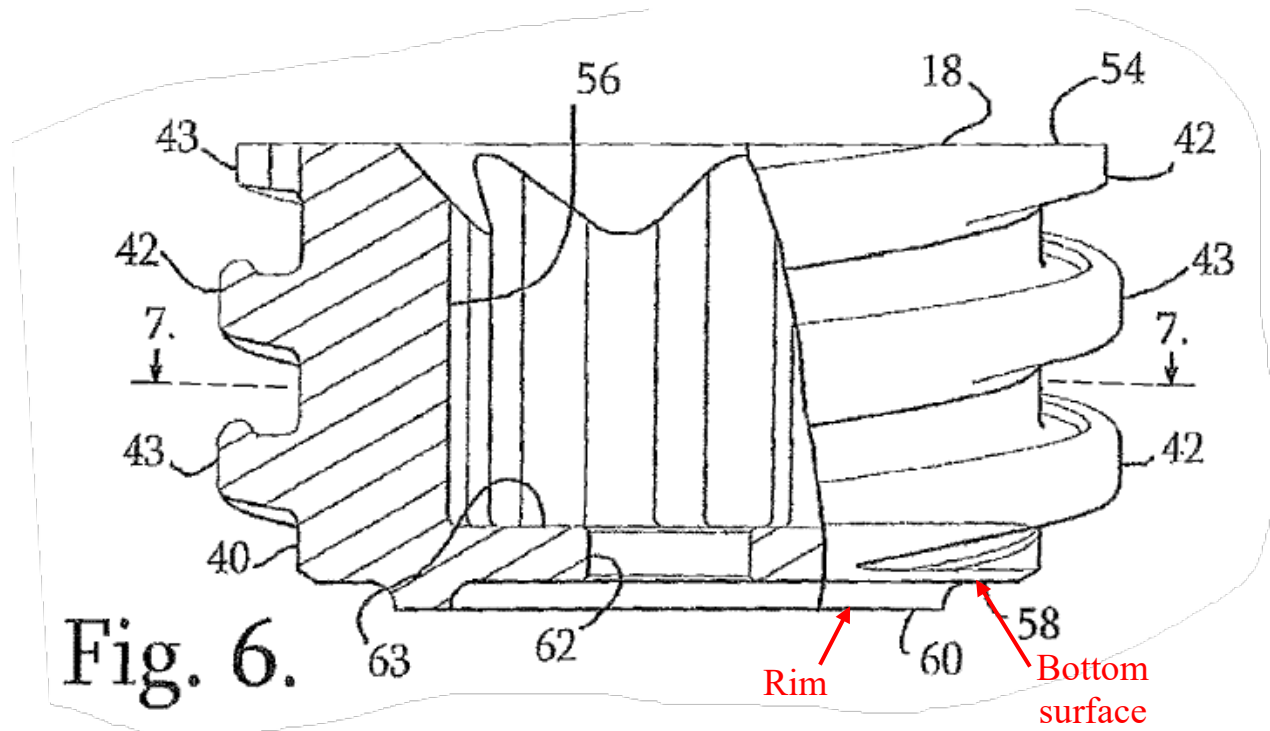
37. The multi-start closure structure 18 includes “[a] base or bottom surface 58 of the closure [that] is planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21 in certain embodiments of the invention.” Ex.1001, 9:4-7. Thus, the bottom surface includes both a planar base portion and a rim extending therefrom. One embodiment of the closure is shown in Figs. 2 and 5-6 below:



'873 Patent (Ex.1001), Fig. 2 (annotated)



'873 Patent (Ex.1001), Fig. 5 (annotated)

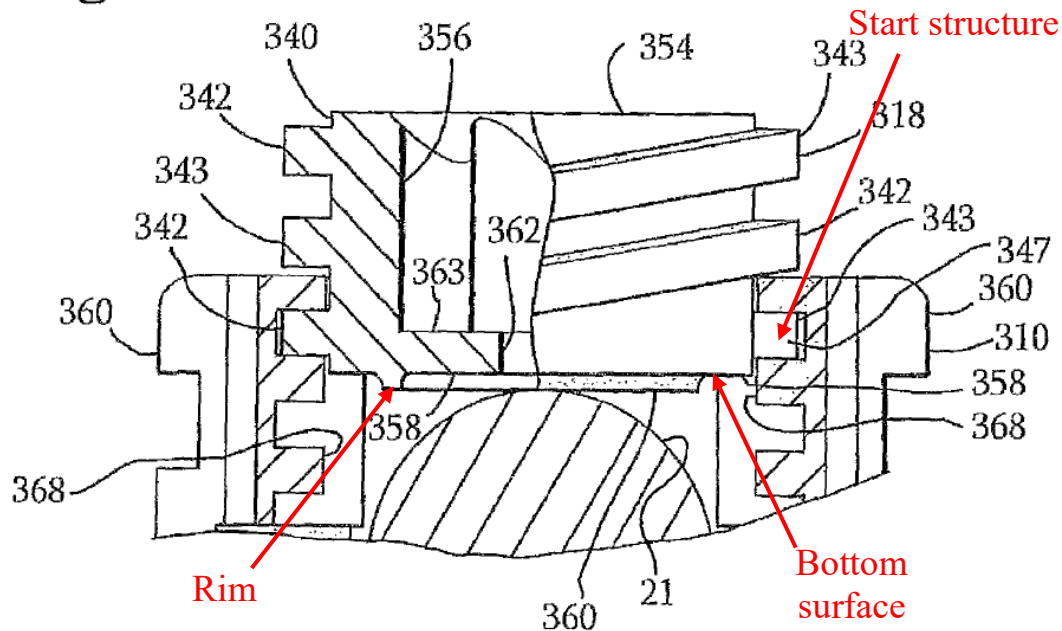


'873 Patent (Ex.1001), Fig. 6 (annotated)

38. The '873 Patent discloses several other embodiments of closures. For example, Fig. 11 illustrates "another alternative multi-start closure top 318...that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with square threads 342 and 343, with respective starts 346 (not shown) and 347." Ex.1001, 22:45-50. This embodiment includes "a base 358" and a "rim 360" that are "the same or substantially similar to the respective" "base 58" and "rim 60" in the embodiment shown in Figs. 1-8. Ex.1001, 22:50-57. As shown in Fig. 11 below, the start structure 347 of this closure 318 is spaced above both the base portion and the rim of the bottom surface to guide the closure 318 into the receiver 310 and align the

start structures 346, 347 with the guide and advancement structure 368 on the arms 360:

Fig. 11.

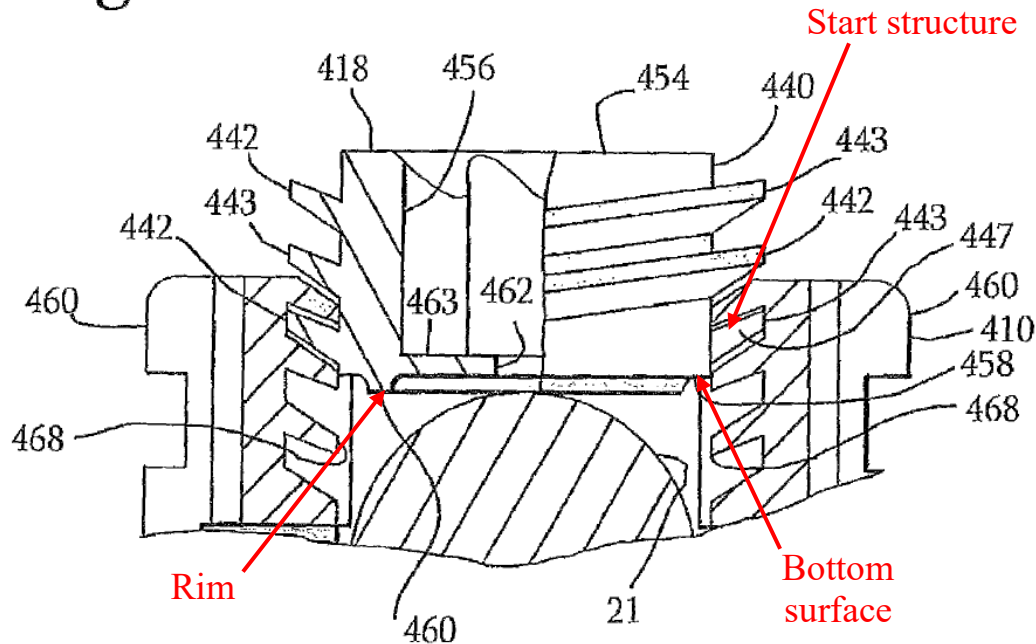


'873 Patent (Ex.1001), Fig. 11 (annotated)

39. Similarly, Fig. 12 illustrates “another alternative multi-start closure top 418...that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with reverse angle threads 442 and 443, with respective starts 446 (not shown) and 447.” Ex.1001, 22:66-23:4. This embodiment includes "a base 458" and a “rim 460” that are “the same or substantially similar to the respective” “base 58” and “rim 60” in the embodiment shown in Figs. 1-8. As shown in Fig. 12 below, the start structure 447 of this closure 418 is spaced above both the base portion and the

rim of the bottom surface to guide the closure 418 into the receiver 410 and align the start structures 446, 447 with the guide and advancement structure 468 on the arms 460:

Fig. 12.



'873 Patent (Ex.1001), Fig. 12 (annotated)

B. Summary of the Prosecution History of the '873 Patent

40. The '873 Patent was originally filed as U.S. Application No. 17/476,652 on September 16, 2021. The '873 Patent is a continuation of U.S. Application No. 17/123,499 ("the '499 Application"), issued as U.S. Patent No. 11,129,646 ("the '646 Patent").

41. I have been informed that '873 Patent is related to several earlier non-provisional applications, the earliest of which was U.S. Application No.

13/694,849, which was filed on January 10, 2013, and which is now U.S. Patent 8,911,479. I also understand that the '873 Patent claims priority to two provisional applications: U.S. Provisional Application No. 61/634,361 ("Second Provisional Application," Ex.1030), filed February 28, 2012, and U.S. Provisional Application No. 61/631,746, filed January 10, 2012 ("First Provisional Application," Ex.1029).

42. I have reviewed the patents and patent applications to which the '873 Patent claims priority, and, in my opinion, a variation of the polyaxial bone screw assembly having a plug with a continuously helical wound thread form having a start structure with a lower surface spaced from a bottom surface of the plug was not claimed or disclosed until the Second Provisional Application was filed on February 28, 2012. The First Provisional Application only includes an embodiment of a closure in which "the closure structure 18 helically wound flange form start structures 46 and 47...are both located adjacent the bottom surface 58" and, thus, are not spaced from and are connected to the annular outer edge of the bottom surface of the closure, which is shown in Figs. 1-8 of the '873 Patent. Ex.1029, 28, 69-82; Ex.1001, 9:15-19; Figs. 1-8. On the contrary, the Second Provisional Application discloses additional embodiments in which the lower surface of the start structure appears to be spaced apart and above the annular outer edge of the bottom surface of the closure, which are shown in Figs. 11-12 of the '873 Patent. Ex.1030, 38-43; Ex.1001, Figs. 11-12. Accordingly, it is my opinion that the claims

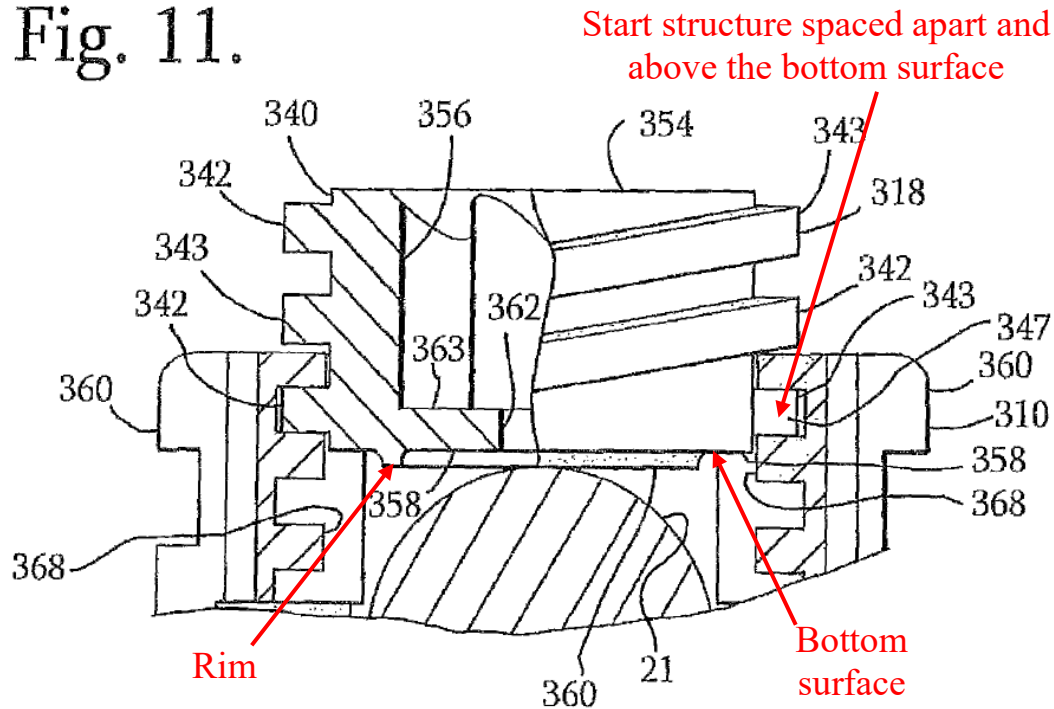
of the '873 Patent are entitled to a priority date no earlier than February 28, 2012.

43. During prosecution of the '873 Patent, the claims were only rejected on the ground of nonstatutory double patenting over the claims of the '646 Patent, which the applicant overcame by filing a terminal disclaimer. Ex.1002, 38-39 (terminal disclaimer), 59-61 (office action). Thus, the originally-filed claims were allowed on March 14, 2022. Ex.1002, 22 (notice of allowance); *compare* 213-216 (originally-filed claims) *to* 49-52 (no amendments in response to double patenting rejection).

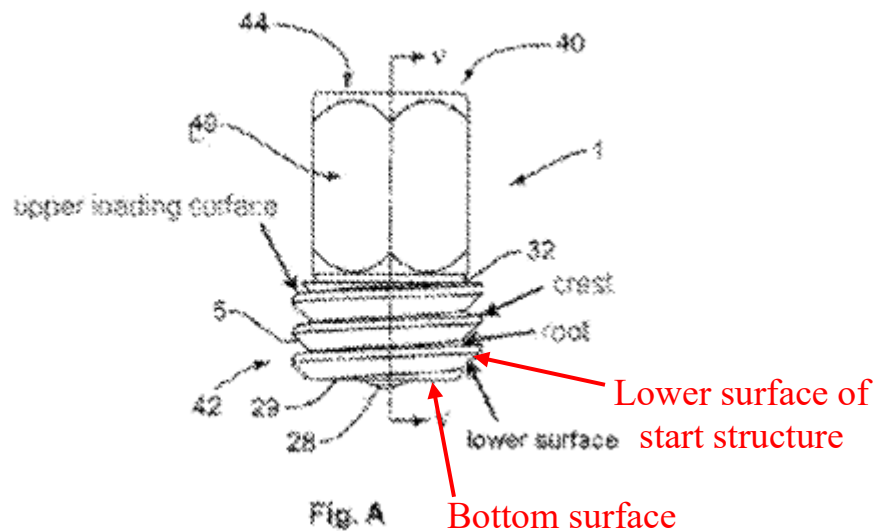
44. However, I have been informed that the prosecution history of the '499 Application (now the '646 Patent) may be relevant to the '873 Patent. Thus, I also reviewed the prosecution history of the '499 Application to inform my understanding of the '873 Patent.

45. During prosecution of the '499 Application, the examiner rejected the pending claims over U.S. Publication No. 2011/0106179 to Prevost ("Prevost," Ex.1013). Ex.1004, 88-90. In response, PO amended the claims to add the limitation: "the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof" (similar to limitation 1[h]). Ex.1004, 68-71. This limitation is shown in Fig. 11 of the '873 Patent below:

Fig. 11.

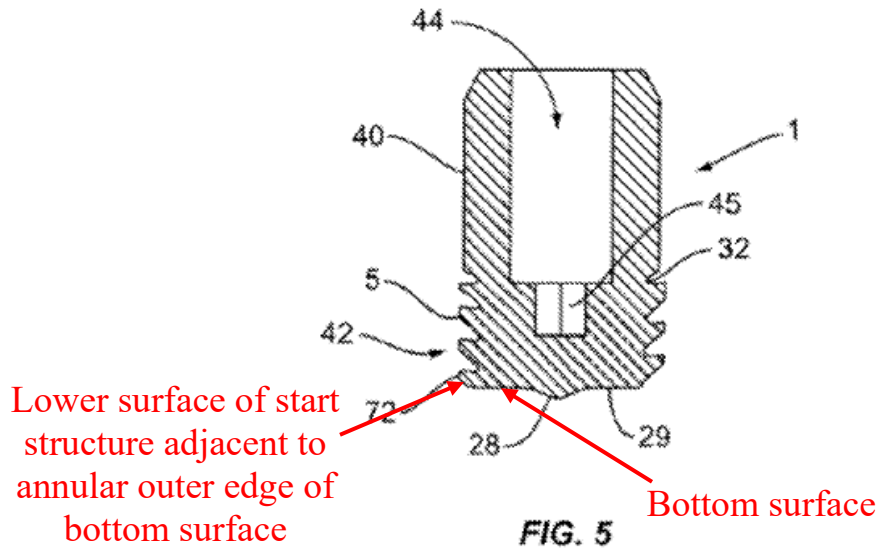
**'873 Patent (Ex.1001), Fig. 11 (annotated)**

46. PO argued that Prevost does not disclose this limitation because the surface that the examiner pointed to as the lower surface of the start structure “is contiguous with the bottom end 29 of the set screw 1.” Ex.1004, 73; *see also* 75-76. PO reproduced Fig. 3 of Prevost, which the examiner had annotated in the previous OA and I further annotated as shown below:



'646 Prosecution History (Ex.1004), 73 (annotated)

PO further asserted that “the lower surface, as identified by the Examiner, is connected to the outer edge of the bottom end 29” and, thus, is not spaced apart and above the annular outer edge so that it is not connected thereto. Ex.1004, 74; *see also* 76. PO reproduced Fig. 5 of Prevost in support of this assertion, as shown below, to which I added annotations:



'646 Prosecution History (Ex.1004), 74 (annotated)

47. Thus, Prevost's closure is different from Fig. 11 of the '873 Patent, which shows the start structure 347 spaced apart and above the bottom surface thereof.

48. Similarly, PO amended one of the independent claims to add "an outward facing surface encircling the substantially flat bottom surface" (similar to limitation 12[e]). Ex.1004, 5. PO argued that Prevost does not disclose this limitation because "the lower surface...is connected to the outer edge of the bottom end 29," again citing to Prevost's Fig. 5. Ex.1004, 76.

49. After these amendments and arguments, the claims of the '499 Application were allowed, issuing as the '646 Patent. Ex.1004, 39 (notice of allowance).

VI. TECHNOLOGY BACKGROUND

50. To provide background for my discussion of the prior art and the element-by-element analysis of the claims that follows, I present an overview of some of the relevant state of art at existing at the time of the alleged invention of the '873 Patent. In the background below, I discuss relevant technologies and techniques that would have been known to a POSITA.

A. Blunt Thread Starts

1. Manufacturing of Blunt Thread Starts

51. Before the priority date of the '873 Patent, it was well-known that thread starts could be truncated by removing the incomplete thread at the starting end to create a blunt thread start that is stronger and less-prone to cross-threading.

52. A POSITA would have understood that, when manufacturing a screw², the process starts with a metal cylinder. A tool would have then been used to cut or grind grooves into the cylinder to create the external thread. This could have been accomplished via several different processes including, lathing, cutting, milling, grinding, or rolling. A POSITA also would have understood that the

² Herein I refer to a male- or externally-threaded part generically as a “screw” (though it can also be referred to by other names, *e.g.*, a bolt). The screw is configured to threadedly mate with a female-threaded part (often referred to a nut.)

manufacturing process could have been performed using CNC techniques. *See* Ex.1016, 1250. During this process, the thread would have been cut into the cylinder along its length, terminating at an end of the cylinder.

53. However, a POSITA would have understood that when the thread ends approached and intersected the ends of the cylinder, the roots and/or crests of the thread would not have been fully formed, resulting in an incomplete thread at the end. *See* Ex.1010, 8 (“incomplete thread: a thread profile having either crests or roots, or both, whose profiles lie outside the size limits, resulting from the intersection with the cylinder or end surface of the work.... It may occur at either end of the thread.”) (emphasis removed); Ex.1011, 1.01 (“INCOMPLETE THREAD.—An incomplete thread is a threaded profile having either crests or roots, or both crests and roots, not fully formed, resulting from their intersection with the cylindrical or end surface of the work.... It might occur at either end of the thread.”). This incomplete thread would have been thinner and/or shorter than the complete thread formed between the ends. *See* Ex.1010, 3 (“complete thread: thread(s) whose profile lies within the size limits”) (emphasis removed); Ex.1011, 1.01 (“COMPLETE THREAD.—The complete or full form thread is that cross section of a threaded length having full form at crest and root.”). Thus, a POSITA would have understood that the incomplete thread would have been weaker and more prone to breaking than the complete thread. When broken or bent, the thread would

have been difficult to engage a corresponding thread or, in some cases, would have prevented it from engaging a corresponding thread at all. Because the incomplete thread would have been thin, it also would have been difficult for a user to properly engage the corresponding thread, which could have resulted in the screw thread being inserted out of alignment such that the screw thread becomes jammed in the nut thread. Moreover, a POSITA would have known that the incomplete thread could have been sharp, which, in the medical context, could have irritated the patient or cut a surgeon's glove or hand.

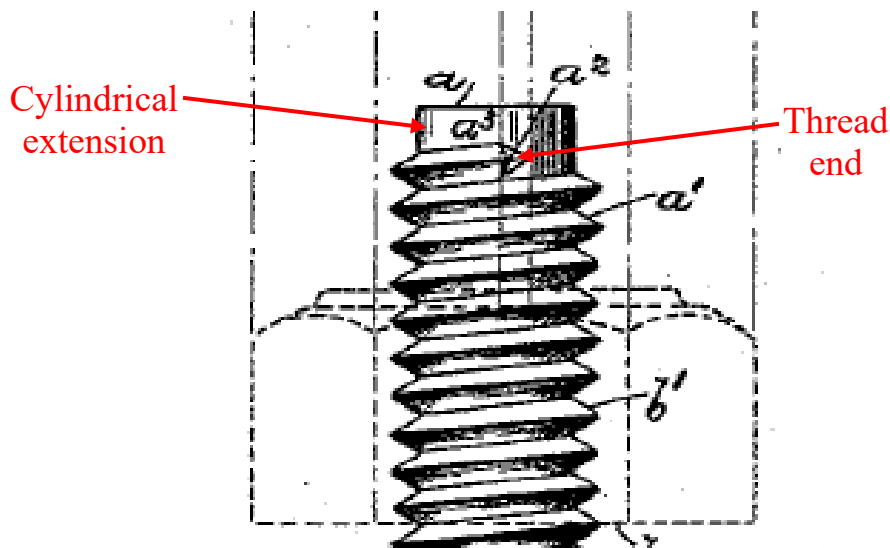
54. Thus, it was well-known that an additional manufacturing step could have been taken to remove the incomplete thread at the starting end of the thread. Ex.1010, 3 (“blunt thread start: a thread with removal of the incomplete thread at the starting end...Also known as Higbee cut”) (emphasis removed); Ex.1011, 1.04 (“BLUNT START OR BLUNT END THREAD.—‘Blunt start’ or ‘blunt end’ designates the removal of the incomplete thread at the end of the thread...which was formerly known as *Higbee cut*.”) (emphasis in original).³

55. The blunt thread start was first described in U.S. Patent No. 447,775

³ Herein I refer to the truncated start of a thread as a “blunt thread start,” but it can also be referred to a Higbee cut or a truncation cut. I refer to the thread form having a blunt thread start as a “blunt start thread.”

to Higbee (“Higbee,” Ex.1006). Higbee recognized that “the end of the thread is for some distance very thin” (*i.e.*, an incomplete thread), resulting in the two parts of the screw coupling often being “put together wrongly” and in the thread start being weak and “very apt to get bent or broken.” Ex.1006, 1:20-38. Thus, Higbee provided a solution to this problem by “terminating the thread below the face-level of the cylinder or annulus on which it is formed, and forming the extreme end so that it will have a broad blunt face.” Ex.1006, 1:40-44. In this way, the “ends of the threads are made strong, stout, and of substantially the same cross-section as the thread itself, and the two parts of the union are fitted together with automatic precision, so that there is the least possible risk of jamming or breaking the thread.” Ex.1006, 1:46-52.

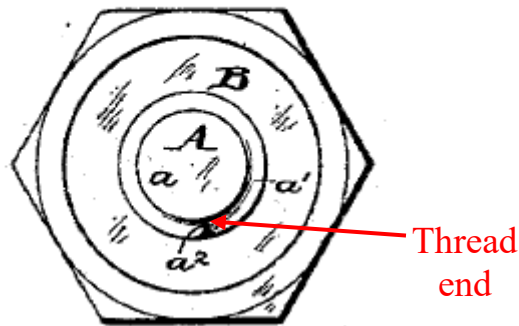
56. When the thin portion of the thread is terminated, “the thread end a^2 or b^2 lies below the face or end a or b of the part in or on which it is formed.” Ex.1006, 2:77-80. Thus, “[b]y leaving the smooth extensions a^3 or b^3 as shown the nut and bolt or their equivalents are brought together and properly aligned before the thread ends engage, and thus an additional safeguard against misadjustment is provided.” Ex.1006, 2:83-88. Fig. 1 below illustrates the resulting threaded screw:



Higbee (Ex.1006), Fig. 1 (cropped and annotated)

57. Higbee explains that “[t]he exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread.”⁴ Ex.1006, 2:88-92. Thus, the thread end “may be cut off on an oblique plane, as in Figs. 1, 2, 3, and 4, or cut off square, as in Fig. 5, or rounded, as shown in Fig. 6.” Ex.1006, 2:92-94. The rounded thread end is shown in Fig. 6 below:

⁴ Although Higbee only contemplated blunt start threads with blunt faces that were symmetrical about a center line, in the over 100 years between the issuance of Higbee and the priority date of the '873 Patent, it became well-known that this was not required for blunt start threads.

FIG. 6.**Higbee (Ex.1006), Fig. 6 (annotated)**

58. Since Higbee issued in 1891, blunt start threads have become well-known in the art. For example, ASME B.17-2006, which outlines screw thread standards for engineers, provides an example of a blunt start thread. ASME B.17-2006 explains that a “blunt start thread” is “a thread with removal of the incomplete thread at the starting end (see Fig. 4). This is a feature of threaded parts that are repeatedly assembled by hand...to prevent cutting of hands and crossing of threads. Also known as Higbee cut.” Ex.1010, 3 (emphasis removed). Fig. 4 of ASME B.17-2006 below shows an example blunt start thread:

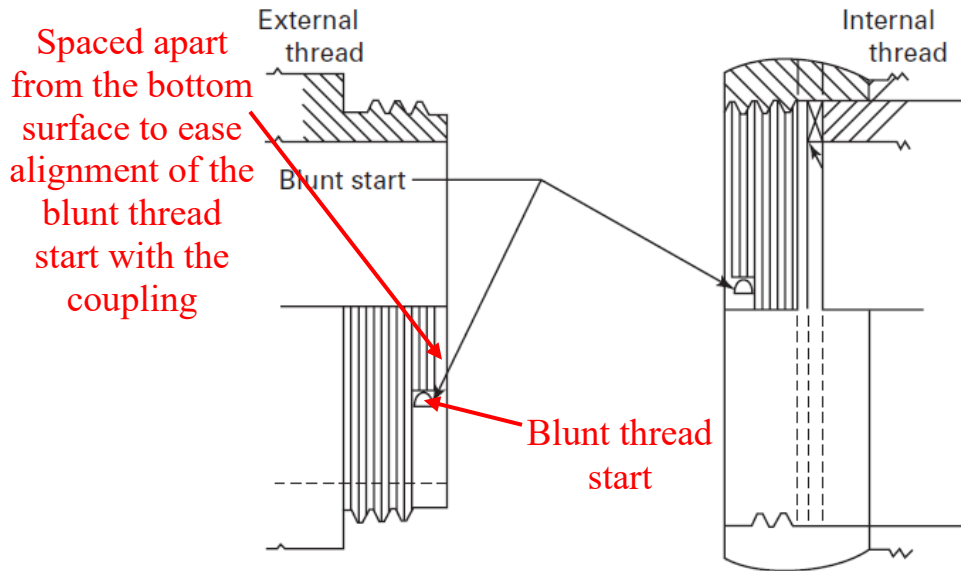
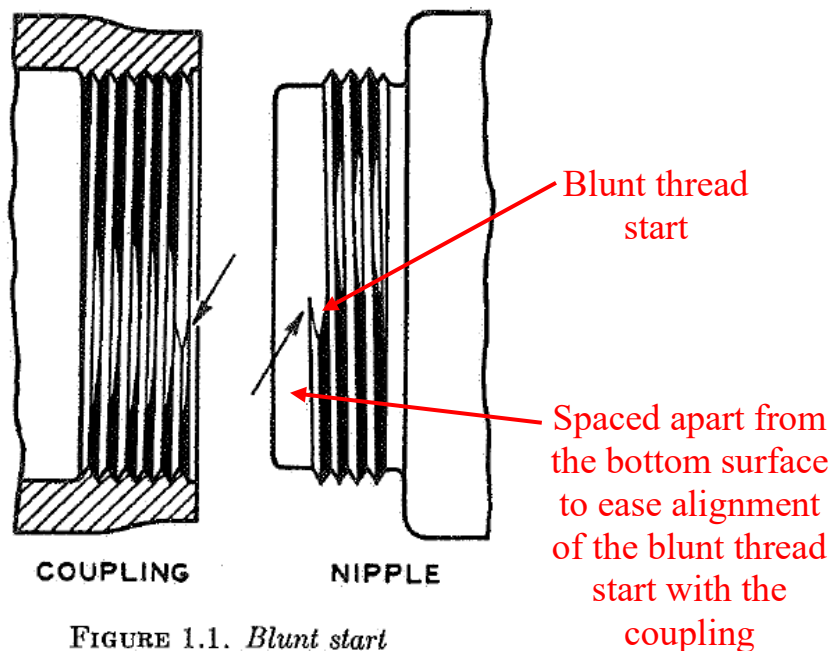


Fig. 4 Blunt Start Thread

ASME B1.7-2006 (Ex.1010), Fig. 4 (annotated)

As shown in Fig. 4 above, because the first thread form of the screw thread (*i.e.* the incomplete thread) has been removed, the blunt thread start is spaced from the blunt face of the screw.

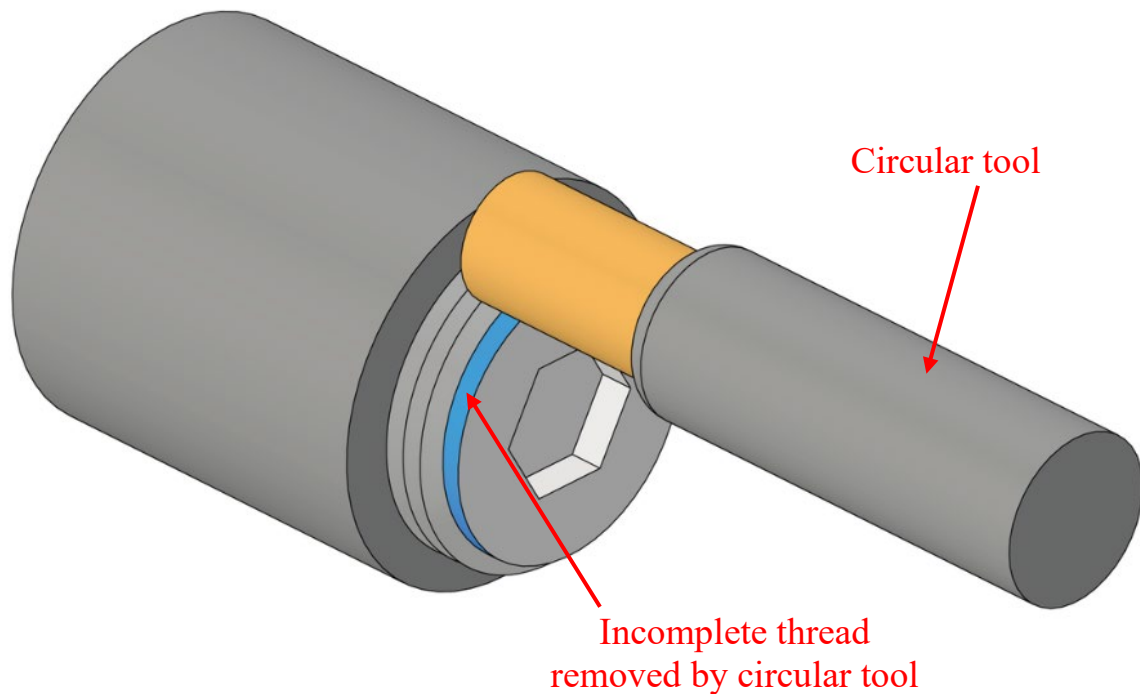
59. Similarly, the Handbook H28, outlining screw-thread standards for federal services, describes a blunt start thread as “the removal of the incomplete thread at the end of the thread,” which “prevent[s] cutting of hands and crossing of threads, which was formerly known as a Higbee cut.” Ex.1011, 1.04 (emphasis removed). Fig. 1.1 of Handbook H28 illustrates an exemplary blunt start thread:



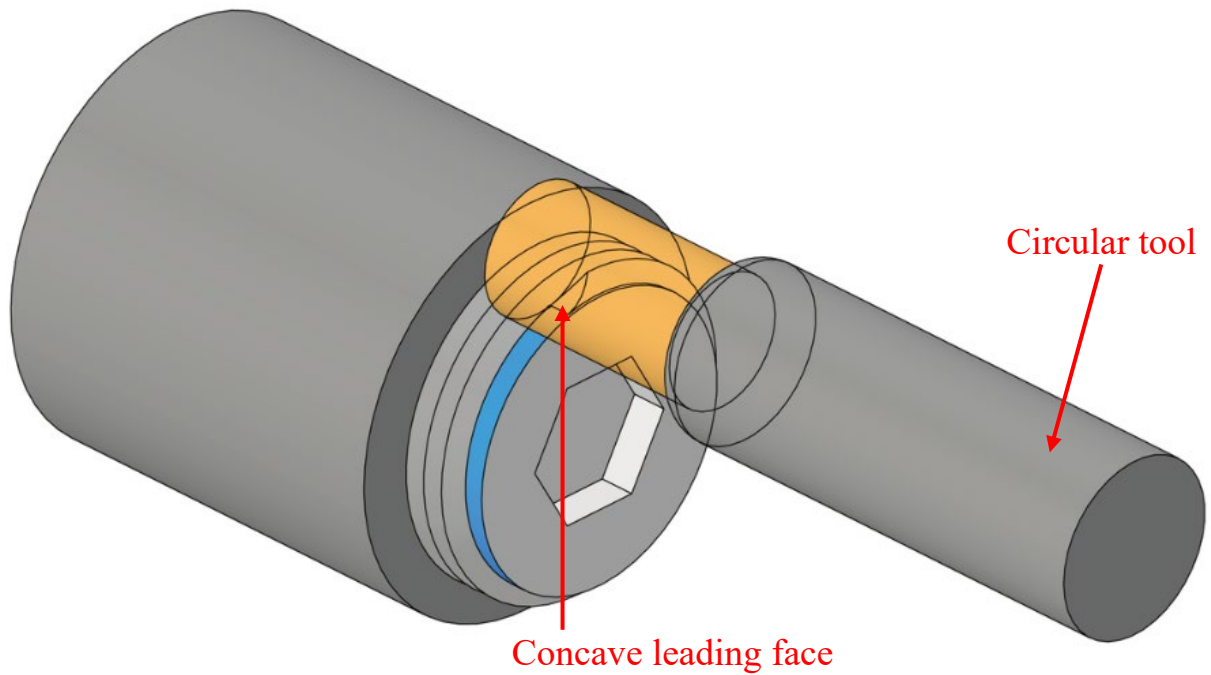
Handbook H28 (Ex.1011), Fig. 1.1

As shown in Fig. 1.1 of Handbook H28 above, because the first thread forms of the screw thread (*i.e.* the incomplete thread) have been removed, the blunt start is spaced from the blunt face of the screw.

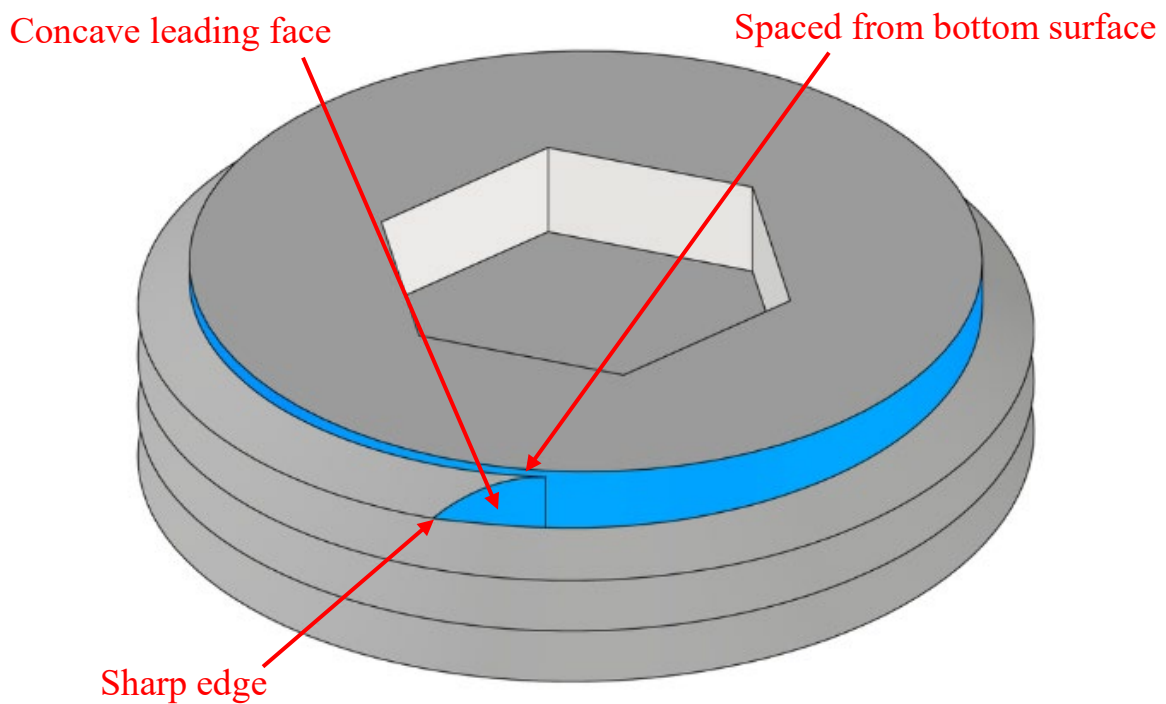
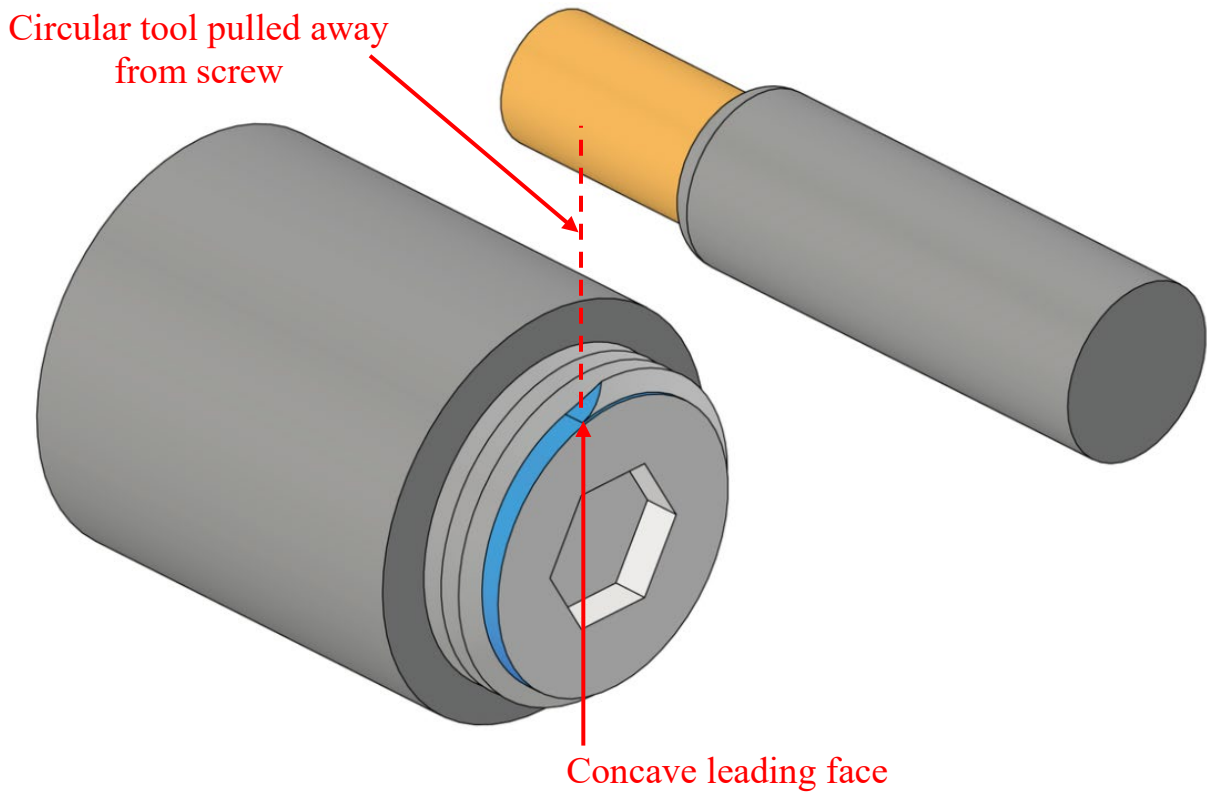
60. A POSITA would have understood that a blunt thread start would have been manufactured in a variety of ways. Generally, a circular tool would have been used to remove the incomplete thread. A POSITA would have been familiar with several types of circular tools, including a milling, grinding, or drilling bit. Specifically, the circular tool would have contacted the end of the incomplete thread, then would have been moved upward along the thread until a complete thread is reached. The below graphic illustrates this step:

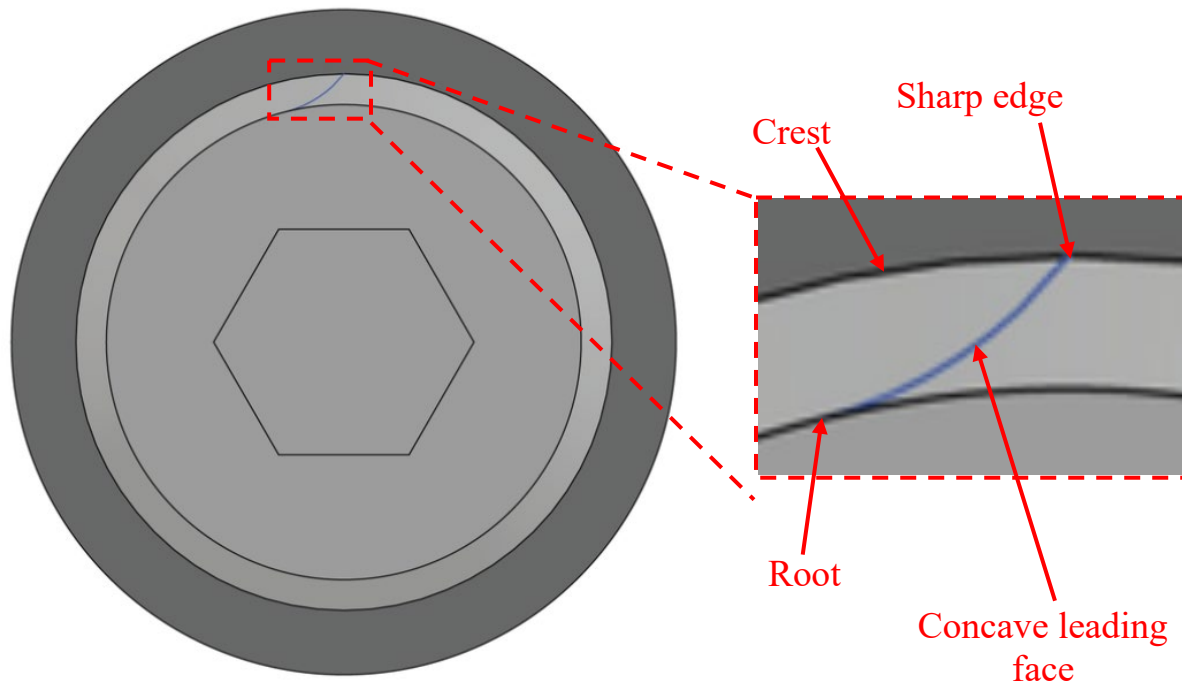


61. At this point, the leading face of the blunt thread start would have been formed. Because of the circular shape of the tool, it would have formed a curved surface at the leading face that would have been curved inward with respect to the thread. In other words, the curved surface would have been “concave.” For example, the below graphic illustrates the concave surface formed by the circular tool:



62. Once the circular tool reached the desired location of the blunt thread start, the circular tool would have been pulled away from the screw, generally perpendicularly from the longitudinal axis of the screw.

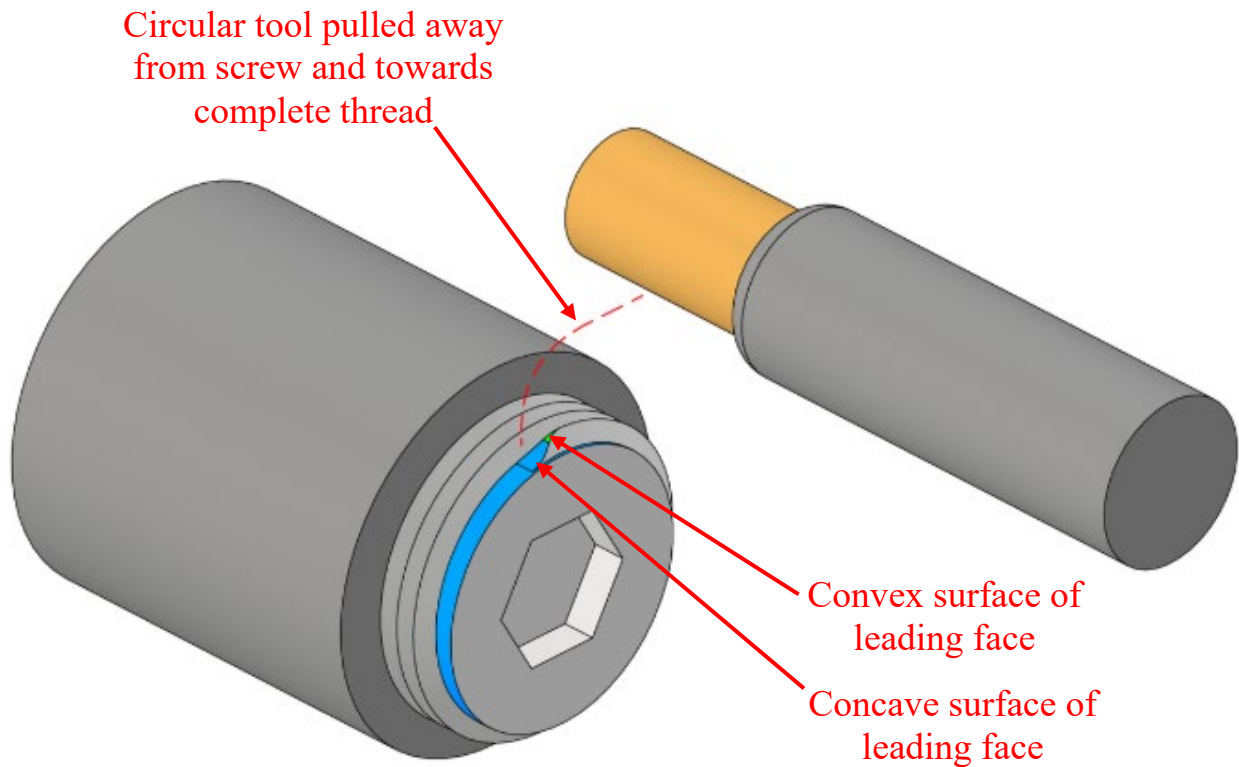


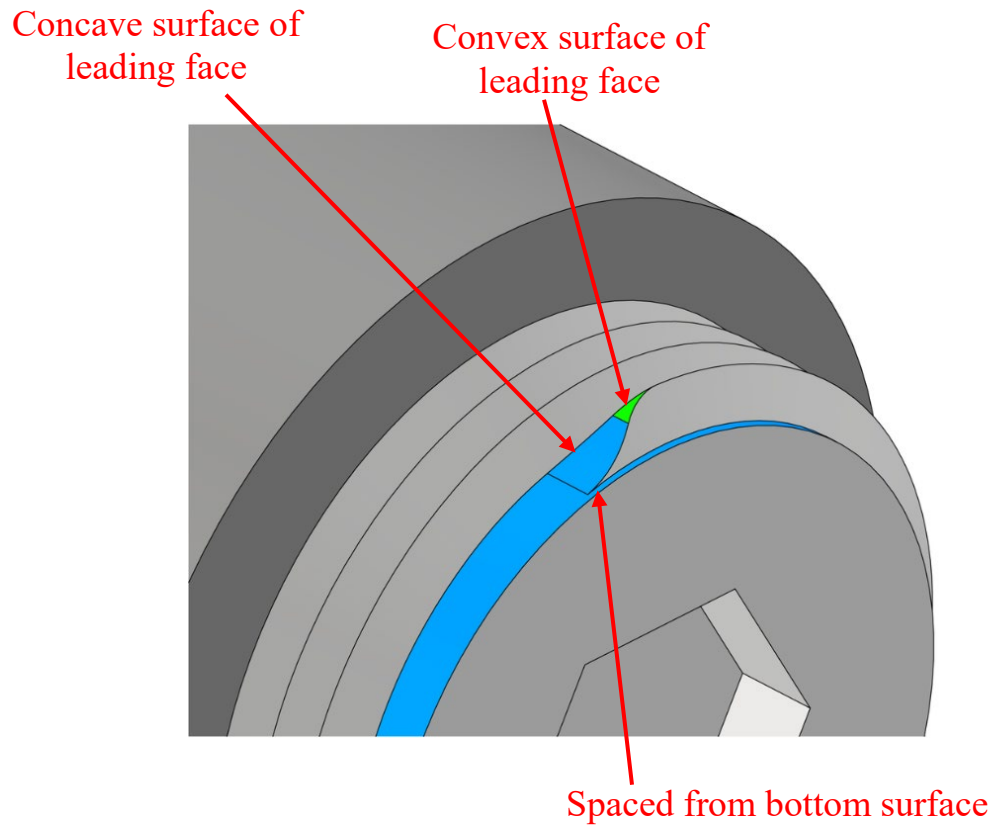


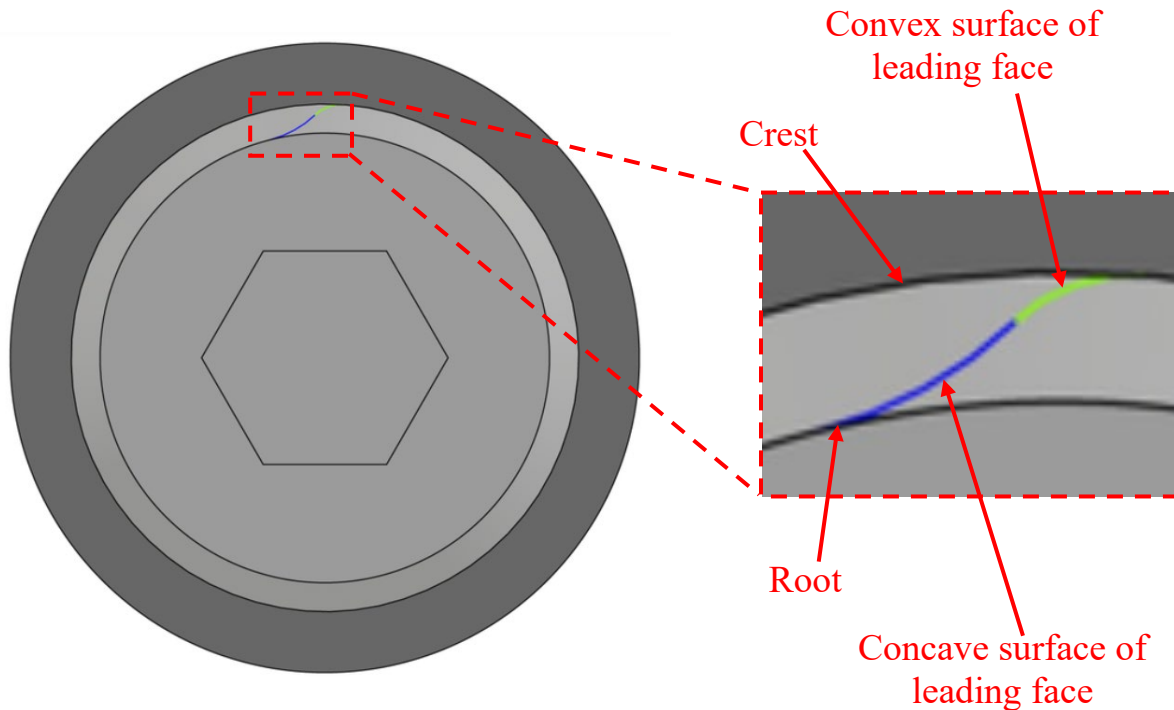
63. As shown in the above graphics, the intersection or edge between the concave blunt face and the crest would have been sharp. Particularly in medical applications, it would have been desirable to round-off or smooth the sharp edge so that the blunt thread start would not have irritated the patient or cut the glove or hand of the surgeon.

64. A POSITA would have understood that this sharp edge could have been removed when forming the blunt face. *See e.g.*, Ex.1015, 771 (describing rounding edges of a screw). In particular, when pulling the circular tool away from the screw after removing the incomplete thread, the circular tool would have been

curved back towards the complete thread at the crest, thereby forming a convex surface proximate the crest as shown in the below graphics:





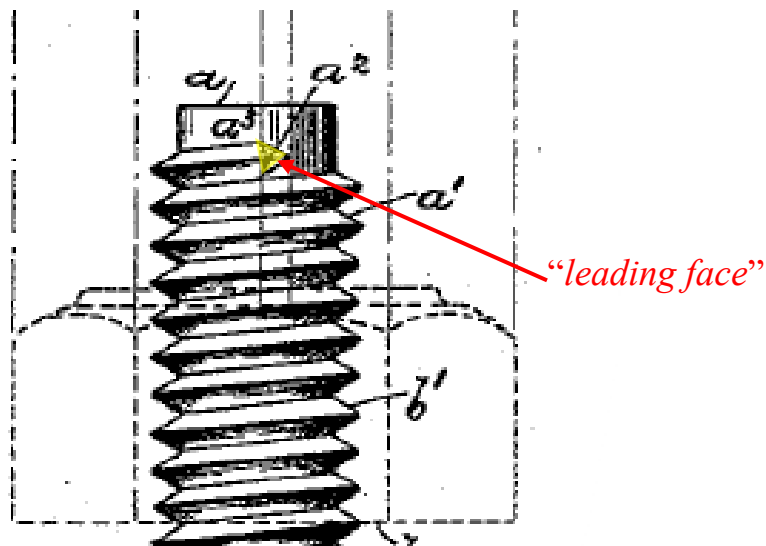


65. As shown in the above graphics, smoothing out the sharp edge at the crest would have resulted in a blunt thread start having a blunt face with a concave surface proximate the root and a convex surface proximate the crest. A POSITA would have known that an inflection point would be disposed at the transition between the concave and convex surfaces. Moreover, a POSITA would have understood that at the inflection point, the concave surface and the convex surface meet, forming a planar surface that is flat in all directions.

66. Additionally, it was common practice in medical device manufacturing to perform a tumbling process such as deburring or electropolishing

to each part to round off or smooth any sharp edges on the medical device. This would have created curved surfaces at any sharp edge marked in the design/engineering drawings. This process would have beneficially prevented the parts from cutting the surgeon's glove or hand or irritating the patient.

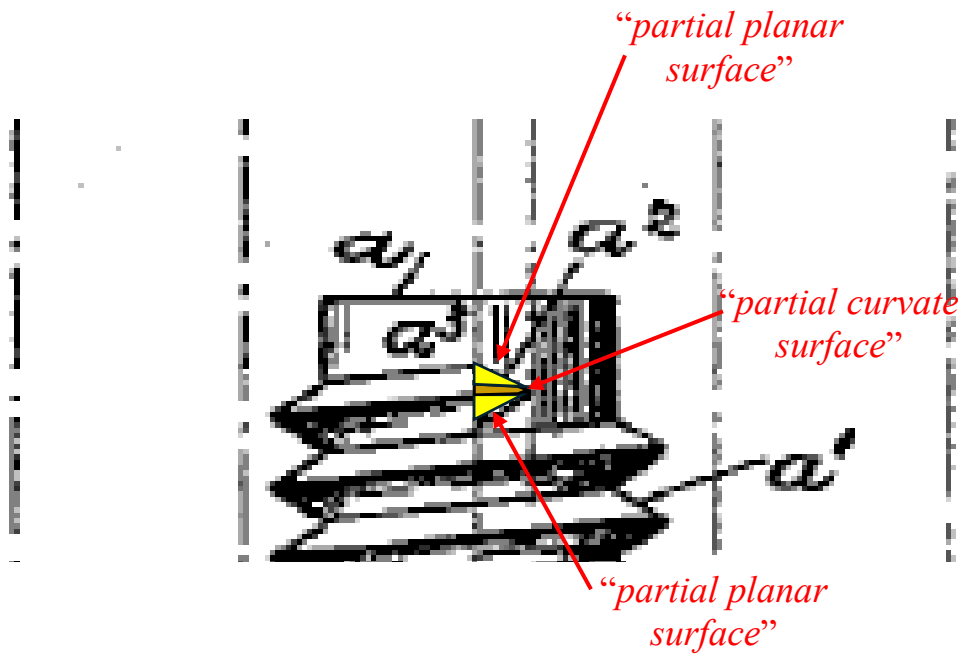
67. To illustrate this point, Higbee explains that “[t]he exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread.” Ex.1006, 1:89-92. One of these examples is a blunt face that is “cut off on an oblique plane, as in Figs. 1, 2, 3, and 4.” Ex.1006, 1:92-94. As shown in Fig. 1 below, there is a sharp edge between the oblique planes of the blunt face:



Higbee (Ex.1006), Fig. 1 (cropped and annotated)

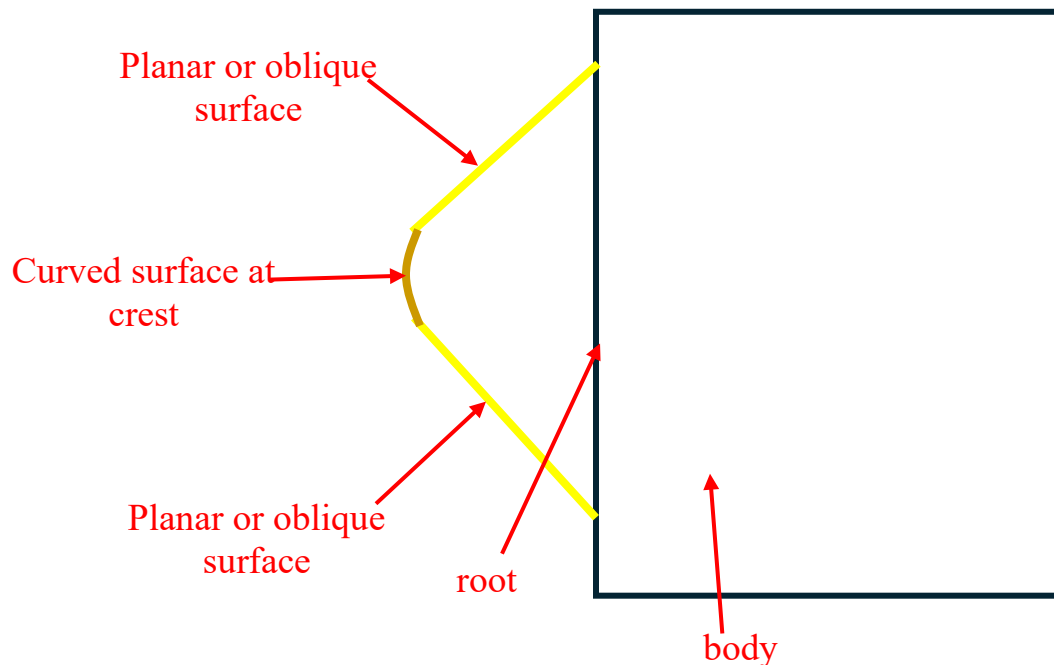
68. If a POSITA decided to use this blunt face in a medical device like a

closure for a polyaxial screw, it would have been obvious that during the tumbling process, this sharp edge would be rounded off, thereby forming a curved surface between the oblique planes. I modified Fig. 1 to illustrate this point:



Ex.1006, Fig. 1 (cropped, modified, and annotated)

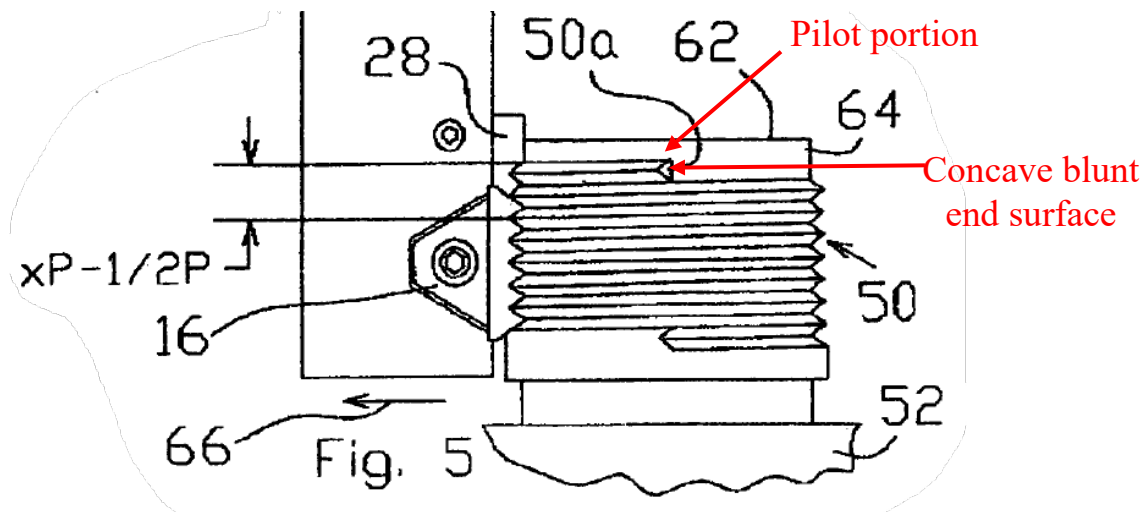
69. I also prepared the below graphic of a side view of the leading face:



70. In some cases, a POSITA may use a circular tool to specifically target and round off this edge before using the tumbling process to round off all sharp edges on the part. This would have allowed the POSITA to better control the desired curvature of the curved surface.

71. These Higbee cuts were incorporated into threaded parts in the prior art long before the priority date of the '873 Patent. For example, in U.S. Publication No. 2005/0286984 to Weise *et al.* ("Weise") (Ex.1012), a cutter is used to remove the "fine-edged partial thread" at the starting end so that the screw thread "start[s] with substantially a full thread form." Ex.1012, [0034]; *see also* [0033], [0035]-[0038]. Weise explains that "[b]ecause the tool 10 carries the

secondary cutter 28 in a radially outwardly disposed orientation, and at the completion of a thread cutting operation this tool is disengaged from the work piece 52 by the CNC milling machine effecting a quick radially outward relative motion (indicated by arrow 66) at the completion of the cutting of screw thread 50, **the starting end 50 a of screw thread 50 immediately adjacent to pilot portion 64 will inherently have a scalloped or concave blunt end surface which is of substantially full screw thread form.**" Ex.1012, [0034]. The concave blunt end surface is shown in Fig. 5 of Weise below:



Weise (Ex.1012), Fig. 5 (cropped and annotated)

As shown in Fig. 5 above, because the first thread form (*i.e.* partial or incomplete thread) has been removed, the pilot portion 64 has been formed between the concave blunt end surface and the end of the screw. Thus, the blunt thread start is

spaced from the starting end 62 of the screw.

72. Therefore, a POSITA would have understood that blunt thread starts would have been used before the priority date of the '873 Patent to create a stronger thread start that would have been less prone to cross-threading. A POSITA also would have understood how to manufacture blunt thread starts by removing the sharp, incomplete thread on the leading end and rounding out the sharp edges to prevent the screw from cutting a glove or hand of surgeon or irritating the patient. Moreover, a POSITA would have understood that it would have been beneficial for the blunt thread start to be spaced from the blunt face of the screw so that the screw can be more easily guided into the female-threaded part.

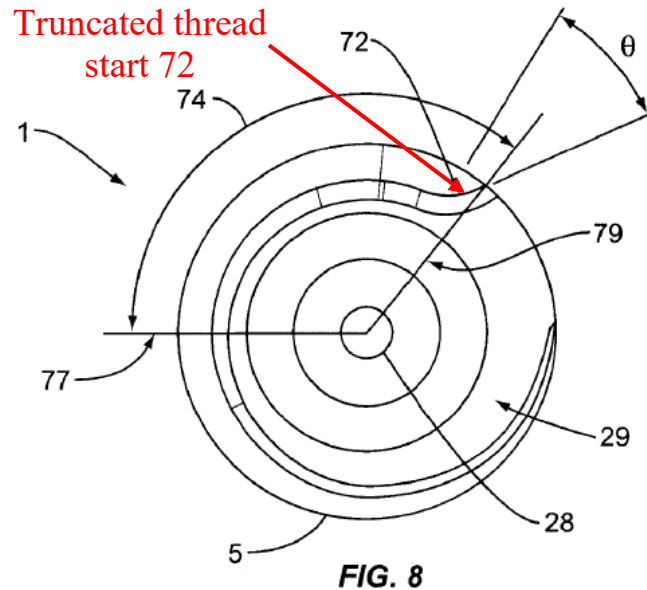
2. Blunt Thread Starts in Closures for Pedicle Screw Systems

73. As acknowledged by the '873 Patent, it was well-known in the art before the priority date of the '873 Patent that one type of system for spinal stabilization procedures included two or more bone anchors implanted into pedicles of the vertebrae and an elongate member connecting the bone anchors. Ex.1001, 1:32-38; *see also* Ex.1005, [0004]-[0005]; Ex.1007, [0001]-[0004]; Ex.1008, [0002]-[0004]; Ex.1009, 1:11-27; Ex.1013, [0001]-[0002]; Ex.1014, [0002]-[0007]. Often the bone anchors were open-ended allowing the elongate member to be seated through the top of the receiver and secured therein with a

closure. Ex.1001, 1:39-2:6; *see also* Ex.1005, [0004]; Ex.1007, [0031]; Ex.1008, [0003]-[0006]; Ex.1009, 1:45-2:27; Ex.1013, [0002]; Ex.1014, [0031]. Open-ended receivers generally included a U-shaped channel for seating an elongate member (*e.g.* rod) and threading for engaging corresponding threading on the closure. Ex.1001, 1:54-2:6; *see also* Ex.1005, [0034]-[0036]; Ex.1007, [0034]; Ex.1008, [0004]-[0005]; Ex.1009, 1:61-2:27; Ex.1013, [0002]; Ex.1014, [0031]. A wide variety of threaded closures were well-known in the art. *See* Ex.1005, [0004], [0036], [0038]-[0039]; Ex.1007, [0047]-[0048]; Ex.1008, [0030]-[0031], [0041]; Ex.1009, 6:32-28, 7:7-15; Ex.1013, [0029]-[0033]; Ex.1014, [0050]. For example, the '873 Patent explains that known closures include “a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread, [and] reverse-angle buttress or square thread forms.” Ex.1001, 1:65-2:3.

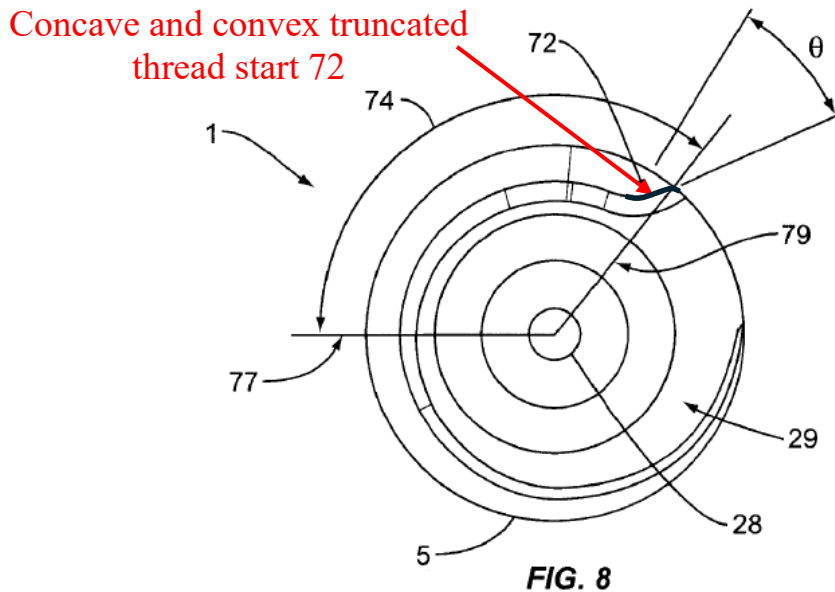
74. In particular, before the priority date of the '873 Patent, a POSITA would have known that blunt thread starts were used in closures for pedicle screw systems. For example, U.S. Publication No. 2011/0106179 to Prevost *et al.* (“Prevost,” Ex.1013) discloses a threaded set screw 1 (*i.e.* closure) in which the external thread 5 “includes a truncation cut 74 at the thread start 72.” Ex.1013, [0031]. The truncated thread start 72 allows “the threading [to] begin[] smoothly and consistently at the same location” and “the thread start 72 of the external

thread 5 [to] consistently enter[] the internal thread 7 of the threaded opening 11 at a particular circumferential location with respect to the U-shaped receptacle 21 of the receiver.” Ex.1013, [0031]. The truncated thread start 72 is illustrated in Fig. 8 of Prevost below:



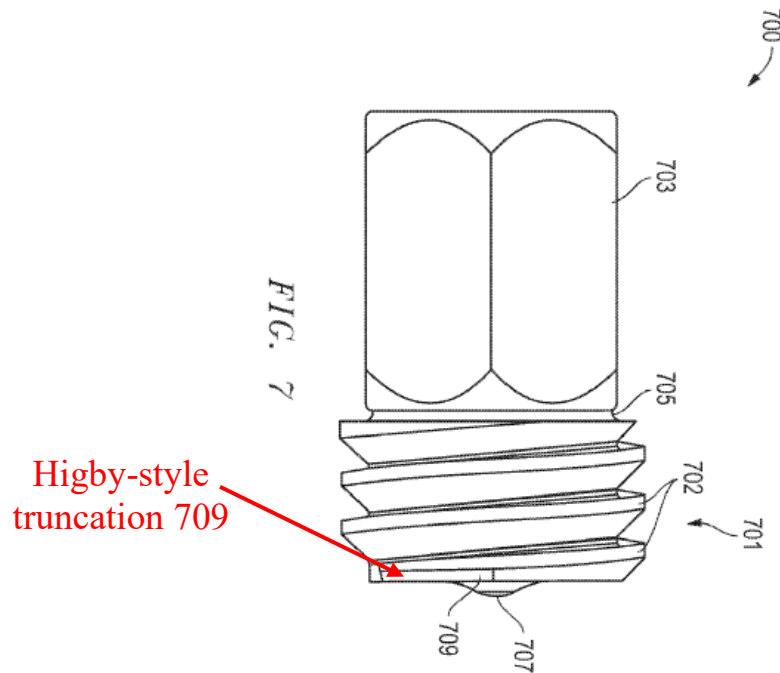
Prevost (Ex.1013), Fig. 8 (annotated)

As shown in Fig. 8 above, the blunt face of the truncated thread start 72 has a concave blunt face between the root and the crest thereof. In practice, the sharp edge between the leading face and the crest would have been rounded or deburred. Thus, a convex radius would have been formed at the leading face of the thread, as shown in a modified version of Fig. 8 below:



Prevost (Ex.1013), Fig. 8 (modified and annotated)

75. Moreover, U.S. Publication No. 2010/0137918 to Wilcox *et al.* (“Wilcox,” Ex.1014) explains that “the threaded portion 701 [of the set screw 700] includes a Higby-style truncation 709 of the initial thread 702 which facilitates easier threading of the set screw 700 within the head portion 307.” Ex.1014, [0050]. This “Higby-style truncation 709 is manufactured such that the leading razor edge of the thread is removed.” Ex.1014, [0050]. The set screw 700 with the Higby-style truncation 709 is illustrated in Fig. 7 of Wilcox below:



Wilcox (Ex.1014), Fig. 7 (annotated)

76. Therefore, it would have been obvious to a POSITA to design a closure for a pedicle screw system that incorporated a blunt thread start, the manufacturing and use of which were well-known in the art. A POSITA would have known that using a blunt start thread would have provided several benefits to the closure. For example, a POSITA would have known that creating a blunt start thread would have removed the sharp, weak incomplete thread at the leading end, thereby resulting in a stronger leading end that would not have cut the surgeon's glove or hand. A POSITA also would have understood that a blunt thread start would have prevented cross-threading of the closure and the receiver. Moreover, a POSITA would have known that the blunt thread start would have been spaced

from the bottom of the closure when removing the incomplete thread, and that this spacing would have beneficially made it easier to insert the closure into the receiver and align the blunt thread start with the corresponding thread on the receiver.

B. Multi-start Threads

1. Manufacturing of Multi-start Threads

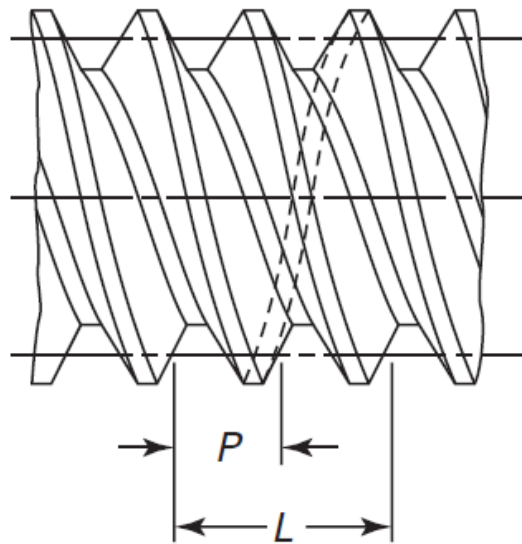
77. Before the priority date of the '873 Patent, it was well-known that screws would have been manufactured with multiple threads. Using multiple threads allows the screw to more easily engage corresponding threads, to balance forces during insertion, to strengthen the threaded coupling, and to increase the speed of insertion.

78. A POSITA would have understood that a “multiple start thread”⁵ is “a screw thread with two or more threads where the pitch is equal to the thread lead divided by the number of thread starts,” as described in ASME B1.7-2006.

⁵ Herein, I generally use the term “multi-threaded screw” to describe a male-threaded part having multiple threads. Specifically, I refer to a male-threaded part having two threads as being a “double-threaded screw.” However, there are a variety of terms that refer to this same constant including multi- or dual- lead thread and multiple or dual start thread.

Ex.1010, 13 (emphasis removed); *see also* Ex.1016, 1717 (“Multiple-Start Thread: A thread in which the lead is an integral multiple, other than one, of the pitch.”).

Fig. 42 of ASME B1.7-2006 below illustrates an exemplary screw having a two-start thread (*i.e.*, a double-threaded screw):



GENERAL NOTE: Two-start thread illustrated.

Fig. 42 Multiple Start Thread

ASME B1.7-2006 (Ex.1010), Fig. 42

79. A POSITA would have understood that a double-threaded screw would have moved forward twice as far per rotation compared to a single start thread, as explained below:

The lead of a screw thread is the distance the nut will move forward on the screw if it is turned around one full revolution. In a single-threaded screw, the pitch and lead are equal, because the nut would move forward the distance from one thread to the next, if turned around once.

In a double-threaded screw, the nut will move forward two threads, or twice the pitch, so that in this case the lead equals twice the pitch.

Ex.1015, 1028 (PDF p. 1109). Thus, a multi-threaded screw would have been fully inserted with fewer rotations than a single-threaded screw.

80. In one example, U.S. Patent No. 4,707,001 to Johnson, *et al.* (“Johnson ’001,” Ex.1017) discloses a joint structure that uses “multi-start helical thread paths which have entrant portions equidistantly spaced about the male pin and female box elements of the joint.” Ex.1017, 2:18-20; *see* Fig. 4. Johnson ’001 explains that “multiple starting helixes spaced equidistantly apart around the 360° circumference prevent differential strain rates caused by the sudden one-sided discontinuity of single start threads.” Ex.1017, 2:36-39. Moreover, “by introducing two separate thread helixes that start and finish 180° apart, the load the connection will carry has found to increase.” Ex.1017, 2:54-56; *see also* 2:60-65 (“With twin or multiple start threads, the effect of one-sided differential strain will not degrade or weaken the tensile load capacity of each joint, and the probability of failure will be much less, and non-existent if the rated loads are not exceeded.”). Thus, by forming the two threads such that they are 180° apart and, thus, diametrically opposite each other, the threaded joint is better able to withstand differential

forces.

81. In another example, U.S. Patent No. 6,010,502 to Bagby (“Bagby”) (Ex.1018) describes a spinal implant having “a pair of threads extending about the implant.” Ex.1019, 13:35-36. Bagby explains that “[w]ith such a dual thread construction, the threads start 180 degrees apart, such that cutting forces produced by self-tapping threads will substantially offset one another.” Ex.1019, 13:36-39. Accordingly, “a self-tapping implant will tend to rotate into a pilot hole in a balanced manner, tending to follow the pilot hole.” Ex.1019, 13:39-41.

82. A POSITA would have understood how to manufacture a screw with multi-thread screws and, in particular, how to manufacture multi-thread screws in which the threads are evenly spaced about the screw. A POSITA would have known that, when manufacturing a threaded screw, the process would have started with a metal cylinder. A tool would have then been used to cut or grind grooves into the cylinder to create the thread. This could have been accomplished via several different processes including, lathing, cutting, milling, grinding, or rolling. A POSITA would have known that each thread could have been cut individually or simultaneously into the metal cylinder. A POSITA also would have understood that the manufacturing process could have been performed using CNC techniques, as described in the Machinery Handbook, 28th Edition (Ex.1016):

Threads with more than one start can be programmed using either G32 or G76 threading commands. The lead (and feed rate) for multi-start threads is always the number of starts times the pitch. For example, a triple start thread with the pitch of 0.0625 (16 TPI) will be 0.1875 (F0.1875). **In order to achieve proper distribution of each start around the cylinder, each thread has to start at an equal angle, determined by the following calculation:**

$$\text{Thread cylindrical spacing angle} = 360 / \text{Number of starts}$$

To achieve this angular spacing, the Z-axis point for each start must be one pitch further than the previous start:

$$\text{Shift amount} = \text{Pitch}$$

$$\text{Number of shifts} - \text{Number of starts} - 1$$

Ex.1016, 1250. Thus, if a POSITA wanted to form dual-thread screw, the POSITA would have understood that the thread cylindrical spacing would have been 180° (*i.e.* $360 / 2$).

83. Moreover, it would have been obvious to a POSITA that each thread on the multi-threaded screw would have been identical, but spaced axially from the neighboring thread or threads. In fact, this would have been required. The manufacturing of multi-threaded screws with the same threads would have been much easier because the same tool would have been used to cut each thread. It would have been impractically complex to design and manufacture multi-threaded screws with different thread forms. Moreover, coupling the multi-threaded screw to a corresponding female threaded part would have been difficult, if not

impossible. If using different thread forms, each thread would have had to engage its corresponding thread during insertion. On the contrary, if all threads were identical, any thread on the screw would have been able to engage any thread on the female-threaded part.

84. If using a blunt thread start (*see* Section VI.A. above), each thread in the multi-threaded screw would have a blunt start thread. It would have been unnecessarily difficult to remove the incomplete portion of only one thread on the multi-threaded screw. Moreover, it would have been much easier to manufacture the blunt thread starts so that the blunt faces have the same profile. This also would have allowed each thread start on the multi-threaded screw to engage each corresponding thread on the female-threaded part.

85. Therefore, a POSITA would have understood that multi-threaded screws would have improved insertion and created a stronger connection. In particular, a multi-threaded screw in which the starts were evenly spaced so that they were symmetrical would have advantageously prevented differential strain on the threaded connection that may lead to failure. It was well-known that multi-threaded screws would have been easier to insert into a female-threaded part because they would have better engaged the corresponding starts on the female-threaded part. A POSITA also would have understood that during insertion a multi-threaded screw would have rotated in a more balanced manner as it was inserted

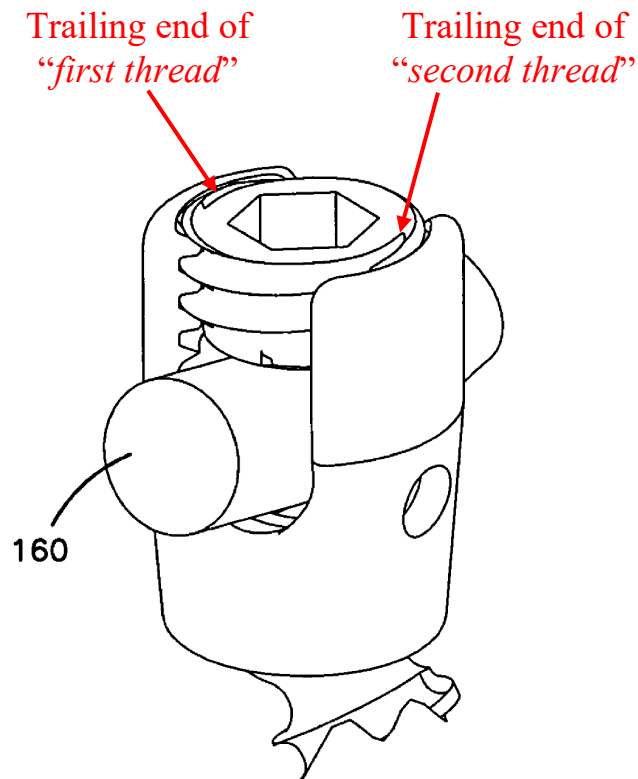
when compared to a single-thread screw. Moreover, multi-threaded screws were known to travel a longer vertical distance in fewer rotations compared to single-threaded screws, allowing them to be inserted faster and easier.

2. Multi-Threaded Closures for Pedicle Screw Systems

86. As explained above in Section VI.A.2., it was well-known in the art that closures for open-ended pedicle screw system could have a wide variety of thread forms. *See* Ex.1005, [0004], [0036], [0038]-[0039]; Ex.1007, [0047]-[0048]; Ex.1008, [0030]-[0031], [0041]; Ex.1009, 6:32-28, 7:7-15; Ex.1013, [0029]-[0033]; Ex.1014, [0050]. Even the '873 Patent acknowledges this. Ex.1001, 1:65-2:3. Thus, before the priority date of the '873 Patent, a POSITA would have understood that any known thread form could have been selected for use in a closure in a pedicle screw system based on the benefits desired for the particular system.

87. For example, U.S. Patent No. 7,857,834 to Boschert ("Boschert") (Ex.1009) discloses a setscrew 70 for use in an orthopedic fixation device (*e.g.* pedicle screw system) that "provides an axial locking force on the rod 60," thereby locking the device. Ex.1009, 7:7-15. Boschert explains that the "[t]he threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead." Ex.1009, 7:21-23. The term "double lead" simply means that the setscrew 70 has two threads. The setscrew 70 having

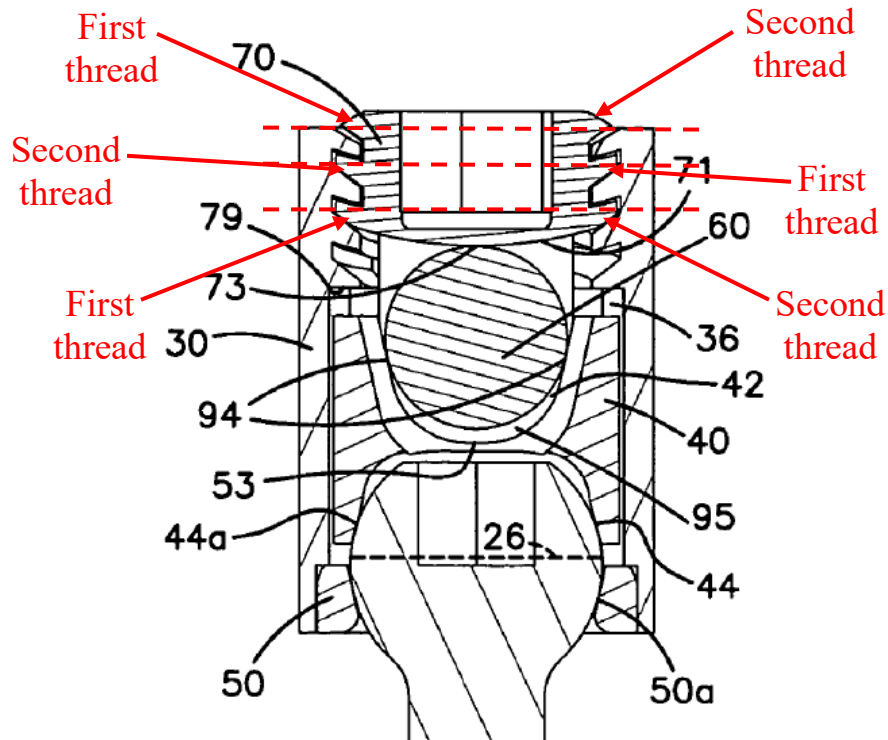
two threads is illustrated in Fig. 7 of Boschert below:



Boschert (Ex.1009), Fig. 7 (cropped and annotated)

The trailing ends on top of the setscrew 70 can be seen above in Fig. 7. These trailing ends are spaced at 180° from each other, indicating that the threads are symmetrically spaced and diametrically opposed from one another around the base of the setscrew 70.

88. This is further confirmed by Fig. 3 of Boschert, shown below:



Boschert (Ex.1009), Fig. 3 (cropped and annotated)

A POSITA would have understood that in a vertical cross-section of single-threaded screw (*i.e.* the same cross-section shown in Fig. 3 of Boschert above), the thread forms on either side of the body would not have been vertically aligned. Instead, because the single thread spirals upward from the single thread start, the thread forms on either side of the body would have been vertically misaligned. On the contrary, in a double-threaded screw (*e.g.*, Fig. 3 of Boschert above), when the threads were symmetrical and diametrically opposite each other, the thread form of the first thread on a first side of the body would have been aligned with the thread form of the second thread on a second side of the body. Thus, the thread form of

the first thread would have been vertically aligned with the thread form of the second thread on the opposite side of the body and vertically misaligned with other thread forms of the first thread on the opposite side of the body. This would have occurred because the first and second threads spiral upward from their respective thread start symmetrically about the body.

89. Therefore, it would have been obvious for a POSITA to design a closure for a pedicle screw system that incorporated two or more threads, the manufacturing and use of which were well-known in the art. A POSITA would have known that using two or more threads would have provided several benefits to the closure. For example, a multi-threaded closure would have resulted in a stronger pedicle screw system when coupled to the receiver because it would have better withstand one-sided differential strain or load. A multi-threaded closure also would have been easier to insert by making it easier to align the thread starts of the closure with the thread starts of the receiver. Moreover, when rotating the multi-threaded closure during insertion, the forces would have been balanced, making it easier to threadedly engage the corresponding threads on the receiver.

Additionally, insertion of the multi-threaded closure would have been faster because fewer turns would have been necessary to move the closure downward within the receiver.

VII. CLAIM CONSTRUCTION

90. It is my understanding that in order to properly evaluate the '873 Patent, the terms of the claims must first be interpreted. It is my understanding that for the purposes of this *inter partes* review, the claims are to be construed under the so-called *Phillips* standard, under which claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in light of the specification and prosecution history, unless the inventor has set forth a special meaning for a term.

91. For the purposes of this Declaration, I have reviewed the claim language, the specification, and the prosecution history. It is my opinion that the claim terms do not require a specific construction beyond the plain and ordinary meaning as would have been understood by a POSITA.

VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

92. I have been asked to provide my opinion as to whether the Challenged Claims of the '873 Patent would have been obvious in view of the prior art. The discussion below provides a detailed analysis of how the prior art references identified below teach the limitations of the Challenged Claims of the '873 Patent.

93. As part of my analysis, I have considered the scope and content of the prior art and any differences between the alleged invention and the prior art. I do so by describing in detail, on an element-by-element basis, for each Challenged

Claims of the '873 Patent.

94. As a consequence of the following analysis, the alleged invention of the Challenged Claims would have been obvious in view of the teachings of the identified prior art references as well as the knowledge of a POSITA.

A. Ground 1: Claims 1, 2, 4, and 7 are obvious under 35 U.S.C. § 103 over Kirschman.

1. Summary of Kirschman

95. Like the '873 Patent, Kirschman is directed to “[a]n implant having a receiver that is adapted to receive a polyaxial screw in the bore and either an internal or external cap.” Ex.1005, Abstract.

96. As with the '873 Patent, Kirschman recognizes that caps must withstand high torque loading to secure a rod to the receiver, thereby stabilizing the spine:

Spinal implant screws, such as those used in the pedicles of the thoracic and lumbar spines are commonly used today by spinal surgeons. In a typical prior art screw, there are three main components: a screw shaft, a polyaxial tulip head or receiver incorporating a female thread, and a locking cap incorporating a male thread. The purpose of the threaded locking cap is to affix a spinal stabilizing element, typically a cylindrical rod, to the screw assembly.

Ex.1005, [0004].

During the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap. Such seating affects

the desired correction of the spine. Therefore, **the threads of the locking cap and tulip must bear high torque loading which can result in cross-threading and/or thread failure upon initial thread engagement.**

Ex.1005, [0005].

Furthermore, **the cap may be difficult to engage in the tulip or receiver under such conditions because the thread start-point of both the male and female threads are difficult to identify in a surgical environment.** In standard threading, there is little, if any, tactile feedback that the thread is engaged. These problems are exacerbated by the necessity to make thread dimensions very small in order to limit the size of the implant due to anatomical constraints.

Ex.1005, [0006].

97. Thus, Kirschman recognizes that a stronger thread having a blunt-tip that prevents cross-threading, as was known in the art, was needed to improve previous spinal implant designs:

What is needed, therefore, is a spinal implant incorporating a thread design that prevents cross threading of the small-pitch threads of the locking cap/tulip pair, **achieves high connection strength immediately after initial thread engagement** and offers improved tactile feedback of thread engagement to the surgeon.

Ex.1005, [0008].

Utilizing blunt-tip threads for the prevention of cross threading was first invented by Higbee in 1891 (U.S. Pat. No. 447,775). Myriad spinal screw designs have been put forth, exemplified by U.S. Pat. No.

5,474,555, however none address the combined issues of threaded cap guidance, visual feedback, and tactile feedback. All of these patents are incorporated herein by reference and made a part hereof.

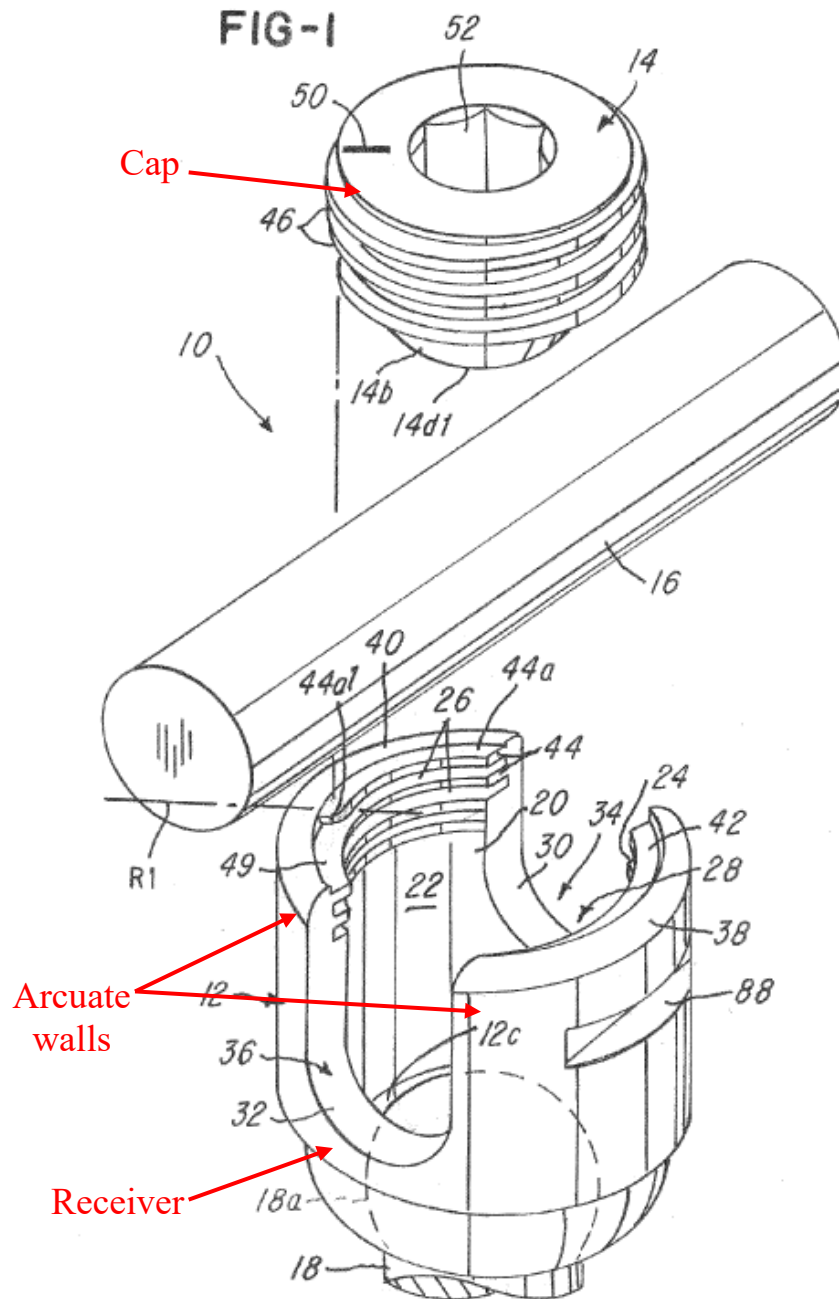
Ex.1005, [0009].

What is needed, therefore, is a system and method that improves the polyaxial screw by providing at least one improved locking aid in the form of at least one of a visual feedback, tactile feedback or enhanced fixations or locking of the cap on the tulip.

Ex.1005, [0010]. Therefore, Kirschman incorporates Higbee by reference.

98. In accordance with these goals, Kirschman discloses “an implant, polyaxial screw, system and method 10,” where “the system 10 comprises a receiver 12 and a cap 14 which is threadably mounted on the tulip or receiver 12.”

Ex.1005, [0034]. “The receiver 12 receives the cap 14 after a rod 16 and a polyaxial screw 18 are received in the receiver 12 in a manner conventionally known and as shown in FIG. 1.” Ex.1005, [0034]. Fig. 1 is reproduced and annotated below:



Kirschman (Ex.1005), Fig. 1 (annotated)

99. The receiver includes two arcuate walls 38, 40 defining a rod-receiving channel 28 and having threads 42, 44 on an internal side thereof for threadably receiving male cap threads 46 on a cap 14:

The receiver 12 comprises at least one internal wall 20 defining a bore 22. At least a portion of the receiver 12 comprises a plurality of female threads, such as threads 24 and 26. In this regard, note that the receiver 12 comprises a rod-receiving channel 28. The receiver 12 comprises a first generally U-shaped wall 30 that defines a first rod-receiving opening 34 and a generally opposed second generally U-shaped wall 32 that defines a second rod-receiving opening 36 as shown. The first and second rod-receiving openings 34 and 36 cooperate to define the rod-receiving channel 28 for receiving the rod 16. Note that **the receiver 12 further comprises a first arcuate wall 38 and a generally opposing second arcuate wall 40 that lie between the first and second rod-receiving openings 34 and 36 as shown.**

Ex.1005, [0035].

The first arcuate wall 38 comprises first arcuate wall threads 42 and the second arcuate wall 40 comprises second arcuate wall threads 44 as shown. The first and second arcuate wall threads 42 and 44 cooperate to define the receiver threads for threadably receiving male cap threads 46 on the cap 14 so that the cap 14 can be screwed onto the receiver 12 in order to lock the rod 16 in the rod-receiving channel 28 of the receiver 12.

Ex.1005, [0036].

100. Kirschman explains that the cap 14 includes a male cap thread 46 with a truncated leading edge portion 46a that provides tactile feedback to the surgeon when it aligns with a first truncated thread 44a of the second arcuate wall threads 44, thereby improving the surgeons ability to insert the cap 14:

In one illustrative embodiment, the lock aid comprises the tactile feedback system, method or means mentioned. In this regard, note in FIG. 1 that the first thread 44a of the second arcuate wall threads 44 defines a starting thread that is shorter than at least one other of the second arcuate wall threads 44 in order to define a cut-out area 49 for facilitating receiving a leading edge portion 46a (FIG. 3) of a male thread of the male cap thread 46. The surgeon or user can feel the cap 14 drop down into the receiver 12 when the leading edge portion 46a is aligned with the cut-out area 49. This design provides tactile feedback when the cap 14 is received on the receiver 12. This feature is particularly useful during surgery where sometimes it is difficult for the surgeon to see the cap 14 relative to the receiver 12. In the illustration being shown, the leading edge portion 46a of the male cap thread 46 may be identified with indicia 50 which provides the visual feedback of the location of the leading edge portion 46a of the cap 14. The cut-out area 49 and its cooperation and reception of the leading edge portion 46a are adapted to permit the drop down and define the lock aid.

Ex.1005, [0038].

Notice in FIG. 3 that **the leading edge portion 46a of the male cap thread 46 is truncated** as shown. Likewise, the leading edge portion 44a1 of the first thread 44a is also truncated. In one illustrative embodiment, **the leading edge portion 44a1 of the first thread 44a of the receiver 12 and the leading edge portion 46a of the male cap thread 46 of the cap 14 are truncated and adapted so that when these leading edge portions 44a1 and 46a are adjacent each other and initially pass each other when the cap 14 is mounted on the**

receiver 12, the leading edge portions 44a1 and 46a move relative to each other a drop down distance DD (FIG. 4)...

Ex.1005, [0039].

101. The cap 14 further includes a bottom 14b that facilitates guiding the cap 14 onto the receiver 12:

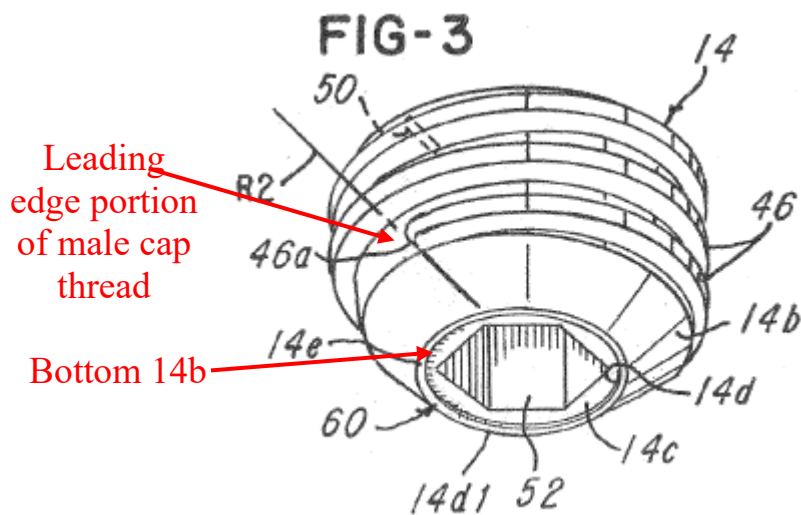
As illustrated in FIGS. 1, 3 and 4, note that **a bottom 14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a with the cut-out area 49 of the receiver 12 so that the cap 14 can be easily guided and screwed onto the receiver 12.** In the embodiment being described, notice that the bottom 14b is frusto-conical, but it should be understood that the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12. For example, the surface could have an arcuate, curved or semi-spherical shape such that **the bottom 14b is adapted to facilitate aligning and guiding the cap 14 onto the receiver 12 so that the cap 14 can be easily screwed onto the receiver 12.**

Ex.1005, [0043].

During use, the polyaxial screw 18 is received in the bore 22 and the head 18a is received in a seat 12c of the receiver 12. The polyaxial screw 18 is screwed into bone and the receiver 12 receives the rod 16 and the receiver 12 and rod 16 are positioned in a manner conventionally known. **The cap 14 is received on a tool and the user guides the cap 14 into the bore 22 using the tactile feedback that**

the bottom 14b provides as it engages and guides the cap 14 as it engages the second arcuate wall threads 44 in the receiver 12 and guides the cap 14 into alignment for threading in the receiver 12. After the positioning is achieved, the surgeon or user may use the at least one or a plurality of the tactile feedback in the form of the truncated leading edge portion 46a and which is aligned in the cut-out area 49. The user may use the indicia 50 to facilitate aligning the thread and the tactile feedback of the cap 14 dropping down in the receiver 12 the drop down distance DD (FIG. 4) as the cap 14 is positioned on the receiver 12.

Ex.1005, [0049]. The cap 14 is shown in Fig. 3 below:



Kirschman (Ex.1005), Fig. 3 (annotated)

102. Because Higbee is incorporated by reference in Kirschman, the disclosure of Kirschman includes the disclosure of Higbee.

103. Higbee “relates to screw-coupling devices, of which the screw bolt and nut are the most familiar examples, but which include as well all threaded

coupling devices made up of two parts having, respectively, male and female screw-threads” including “all fittings or parts adapted and formed to screw into each other by providing them with male and female threads, respectively.”

Ex.1006, 1:10-20.

104. Higbee recognized that, because the end of the thread was very thin for some distance, previous threaded couplings were often “put together wrongly” and the thin end of the thread had little strength and was likely to bend or break:

In threaded couplings of the kind described the thread is usually turned in or on a cylindrical or annular part prepared to receive it, and at the end of said part the thread merges gradually in its face, which is usually in a plane at right angles to the center of the thread. As a result of this mode of construction **the end of the thread is for some distance very thin** and by no means symmetrical to the center line of the thread. **As a result of this mode of construction the two parts of the screw-union can be and frequently are put together wrongly, not only cramping and binding the parts but breaking and injuring the threads. Besides this, the thin end of the thread is so situated as to be most exposed to injury, and having but little strength it is very apt to get bent or broken.**

Ex.1006, 1:20-38.

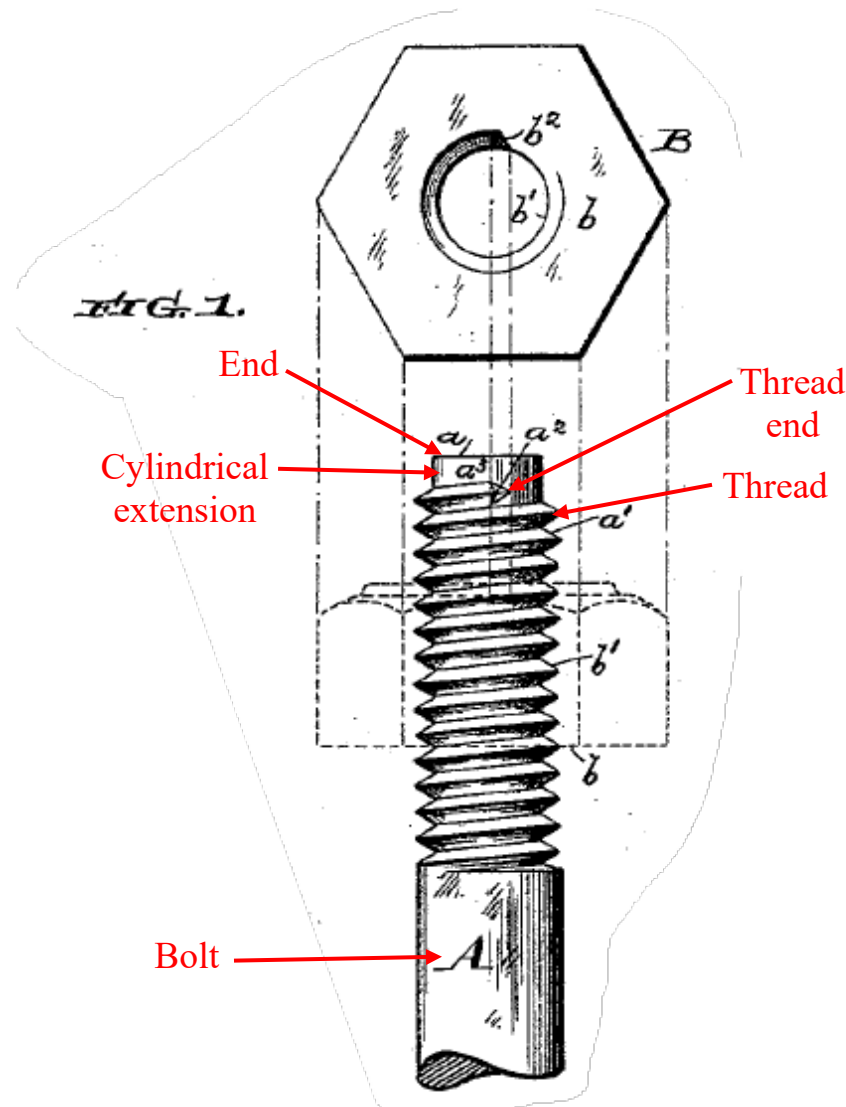
105. Higbee provided a solution to problems by terminating the thread below the face-level, thereby creating an extreme end with a blunt face that is stronger and can be fitted together with more precision:

My invention is intended to overcome the defects noted; and it consists in **terminating the thread below the face-level of the cylinder or annulus on or in which it is formed, and forming the extreme end so that it will have a broad blunt face** lying symmetrically on each side of the centerline of the thread. **By this construction the ends of the threads are made strong, stout,** and of substantially the same cross-section as the thread itself, **and the two parts of the union are fitted together with automatic precision,** so that there is the least possible risk of jamming or breaking the thread.

Ex.1006, 1:39-52.

106. For example, in Fig. 1 of Higbee, “A is the bolt, a its end, a' its thread, and a^2 the thread end” and “ a^3 , Fig. 1, is a cylindrical extension of the internal diameter of the nut-thread between the thread end a^2 and the bolt end a .”

Ex.1006, 2:57-58, 2:67-71. Fig. 1 of Higbee is shown below:

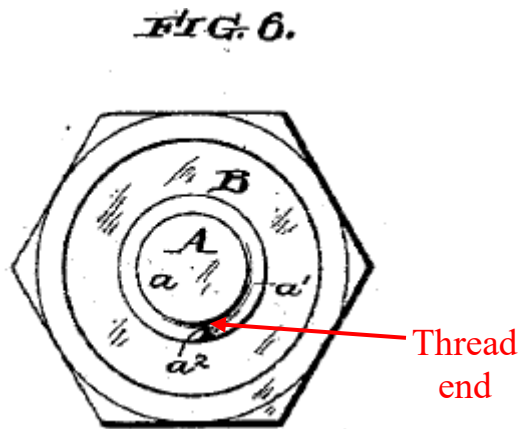


Higbee (Ex.1006), Fig. 1 (annotated)

As shown above, “the thread end a^2 or b^2 lies below the face or end a or b of the part in or on which it is formed.” Ex.1006, 2:77-80. Thus, “[b]y leaving the smooth extensions a^3 or b^3 as shown the nut and bolt or their equivalents are brought together and properly aligned before the thread ends engage, and thus an additional safeguard against misadjustment is provided.” Ex.1006, 2:83-88.

107. Higbee explains that “[t]he exact form of the thread end is not very

important so long as it is blunt and substantially symmetrical with respect to the center line of the thread.” Ex.1006, 2:88-92. Thus, the thread end “may be cut off on an oblique plane, as in Figs. 1, 2, 3, and 4, or cut off square, as in Fig. 5, or rounded, as shown in Fig. 6.” Ex.1006, 2:92-94. The rounded thread end is shown in Fig. 6 below:



Higbee (Ex.1006), Fig. 6 (annotated)

2. Claim 1

1[pre] A medical implant assembly comprising:

108. Kirshman renders obvious limitation 1[pre].

109. Kirschman’s “invention relates to a spinal implant system and method.” Ex.1005, [0002]. Kirschman explains that these spinal implants are implanted into the pedicles of the thoracic and lumbar spines:

Spinal implant screws, such as those used in the pedicles of the thoracic and lumbar spines are commonly used today by spinal surgeons. In a typical prior art screw, there are three main components:

a screw shaft, a polyaxial tulip head or receiver incorporating a female thread, and a locking cap incorporating a male thread. The purpose of the threaded locking cap is to affix a spinal stabilizing element, typically a cylindrical rod, to the screw assembly.

Ex.1005, [0004].

110. Kirschman specifically states that “one object of the embodiment is to provide an improved polyaxial screw.” Ex.1005, [0012]; *see also* [0011] (“What is needed, therefore, is a system and method that improves the polyaxial screw by providing at least one improved locking aid in the form of at least one of a visual feedback, tactile feedback or enhanced fixations or locking of the cap on the tulip.”). Thus, Kirschman’s polyaxial screw is a “*medical implant assembly*.”

111. Therefore, because Kirschman discloses a spinal implant system (*e.g.*, a polyaxial screw), Kirschman renders obvious “[*a*] *medical implant assembly*” as claimed.

1[a] *a receiver having an upper portion with an inner surface at least partially configured as a helically wound thread extending up to a top surface of the receiver, and*

112. Kirschman renders obvious limitation 1[a].

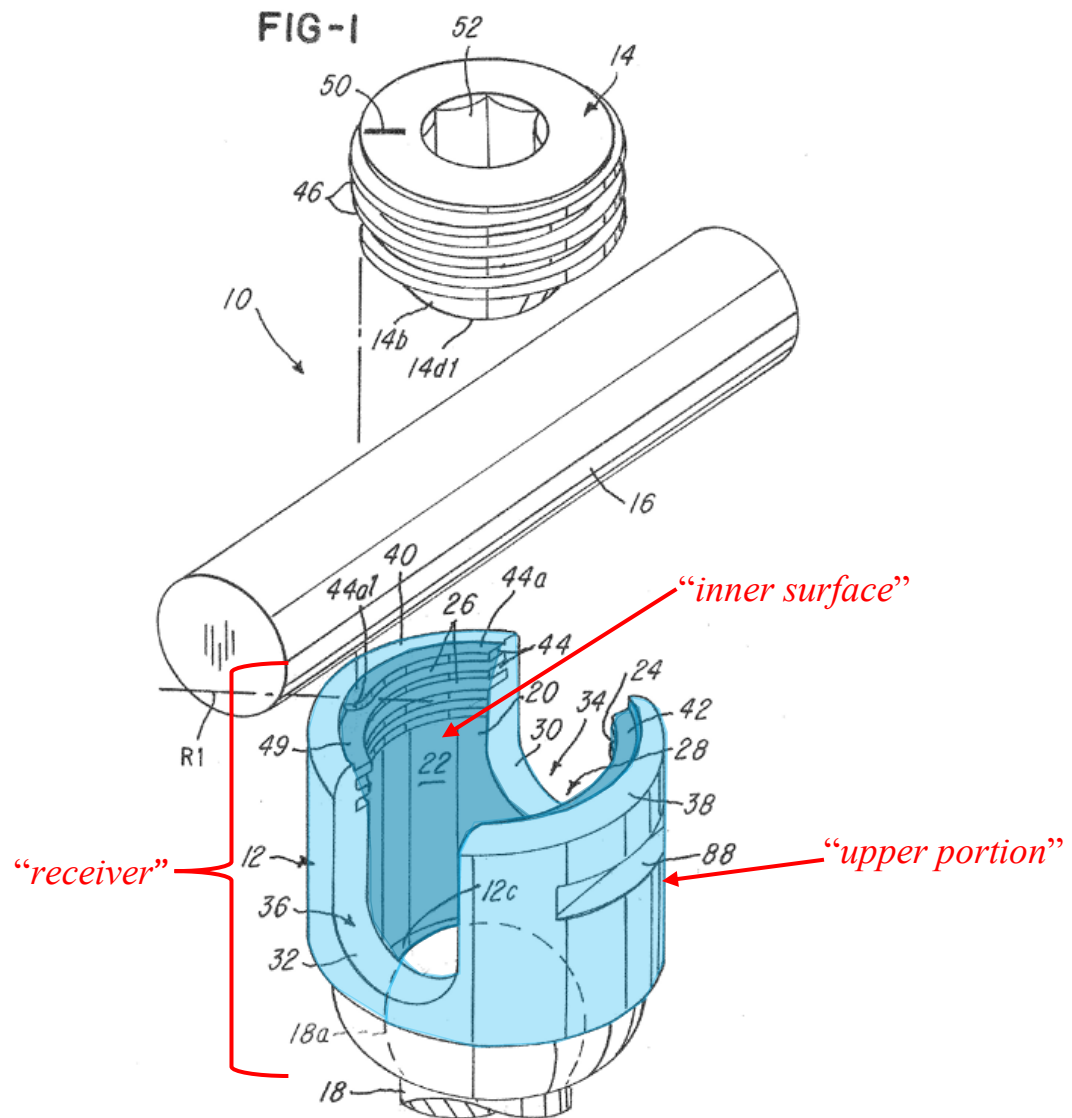
113. First, Kirschman discloses “*a receiver having an upper portion with an inner surface*.” Kirschman describes “an implant, polyaxial screw, system and method 10” that “comprises **a receiver 12** and a cap 14 which is threadably mounted on the tulip or receiver 12.” Ex.1005, [0034]. Kirschman’s receiver 12

(“receiver”) includes U-shaped walls 30, 32 and arcuate walls 38, 40 that define an “upper portion with an inner surface”:

The receiver 12 comprises at least one internal wall 20 defining a bore 22. At least a portion of the receiver 12 comprises a plurality of female threads, such as threads 24 and 26. In this regard, note that the receiver 12 comprises a rod-receiving channel 28. **The receiver 12 comprises a first generally U-shaped wall 30 that defines a first rod-receiving opening 34 and a generally opposed second generally U-shaped wall 32 that defines a second rod-receiving opening 36 as shown.** The first and second rod-receiving openings 34 and 36 cooperate to define the rod-receiving channel 28 for receiving the rod 16. Note that **the receiver 12 further comprises a first arcuate wall 38 and a generally opposing second arcuate wall 40 that lie between the first and second rod-receiving openings 34 and 36 as shown.**

Ex.1005, [0035]. Kirschman’s receiver 12 (“receiver”) is illustrated in Fig. 1

below:



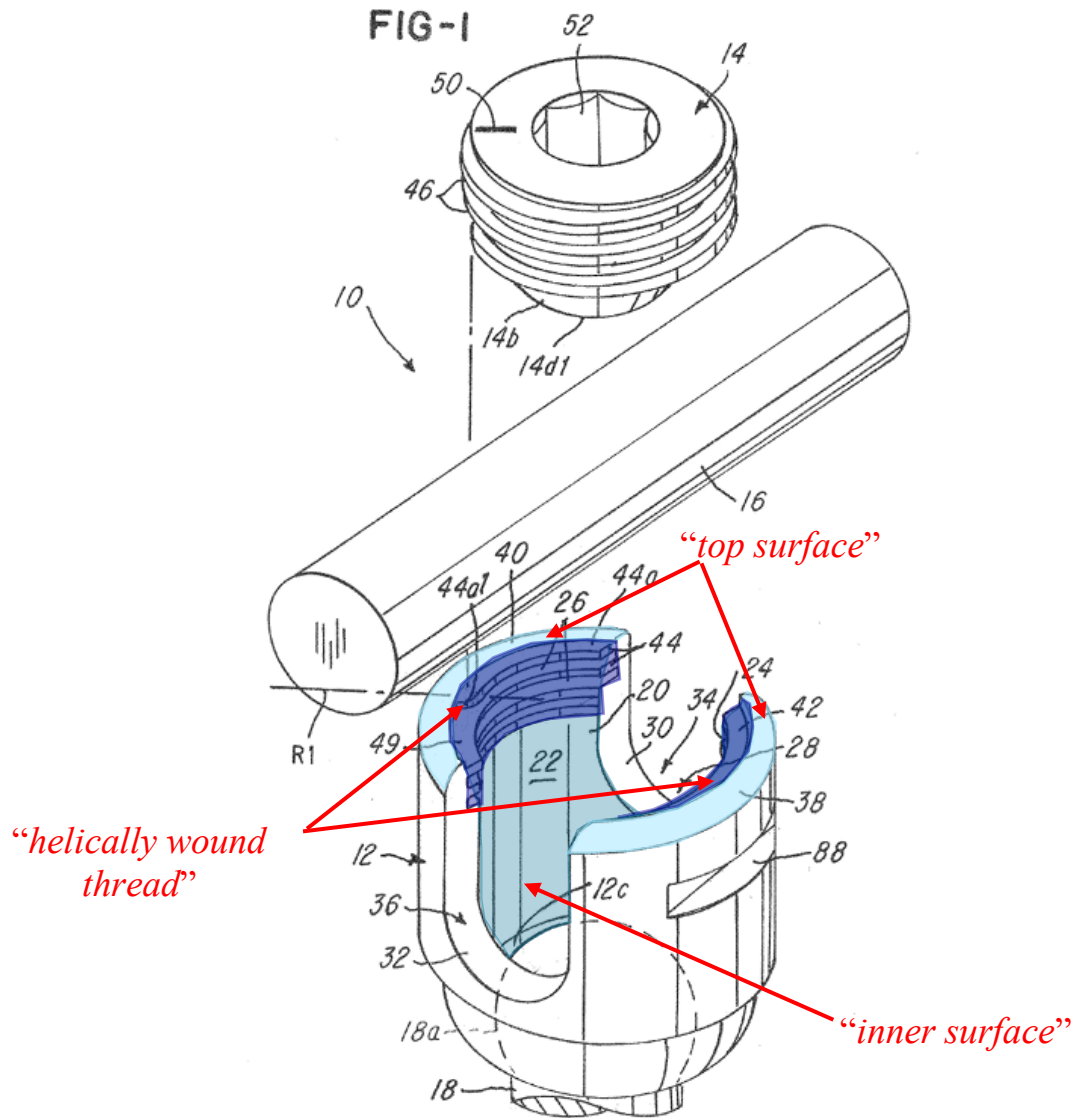
Kirschman (Ex.1005), Fig. 1 (annotated)

114. **Second**, Kirschman discloses that the “*inner surface*” of the arcuate walls 38, 40 are “*at least partially configured as a helically wound thread extending up to a top surface of the receiver.*” Kirschman explains that the “*inner surface*” of the arcuate walls 38, 40 includes arcuate wall threads 42, 44 (“*helically wound thread*”):

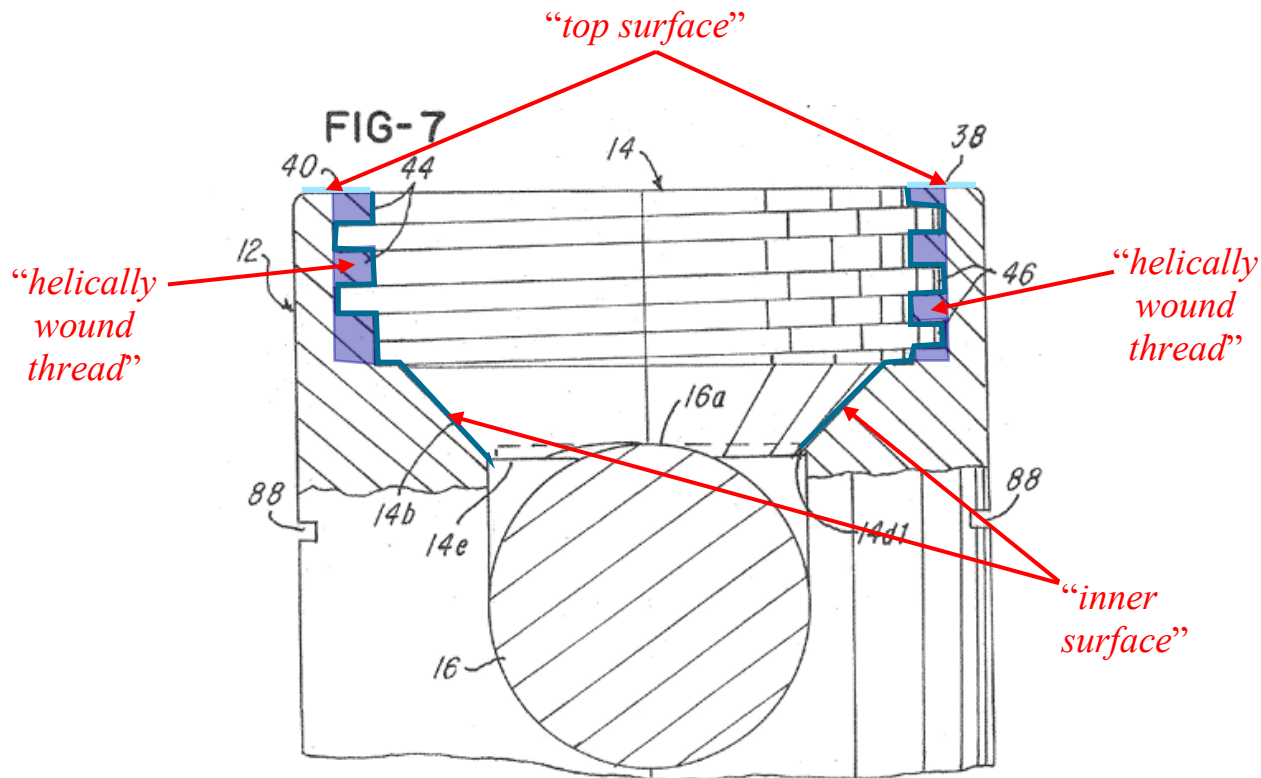
The first arcuate wall 38 comprises first arcuate wall threads 42 and the second arcuate wall 40 comprises second arcuate wall threads 44 as shown. The first and second arcuate wall threads 42 and 44 cooperate to define the receiver threads for threadably receiving male cap threads 46 on the cap 14 so that the cap 14 can be screwed onto the receiver 12 in order to lock the rod 16 in the rod-receiving channel 28 of the receiver 12.

Ex.1005, [0036]; *see also* [0035] (“At least a portion of the receiver 12 comprises a plurality of female threads, such as threads 24 and 26.”); [0040]. Thus, Kirschman’s arcuate walls 38, 40 are “*at least partially configured as a helically wound thread.*”

115. As shown in Figs. 1 and 7 of Kirschman below, the arcuate wall threads 42, 44 (“*helically wound thread*”) extend to a “*top surface*” of the receiver 12 (“*receiver*”):



Kirschman (Ex.1005), Fig. 1 (annotated)



Kirschman (Ex.1005), Fig. 7 (annotated)

116. Therefore, because Kirschman discloses a receiver 12 having arcuate walls 38, 40 with arcuate wall threads 42, 44 that extend to a top surface thereof, Kirschman renders obvious *“a receiver having an upper portion with an inner surface at least partially configured as a helically wound thread extending up to a top surface of the receiver”* as claimed.

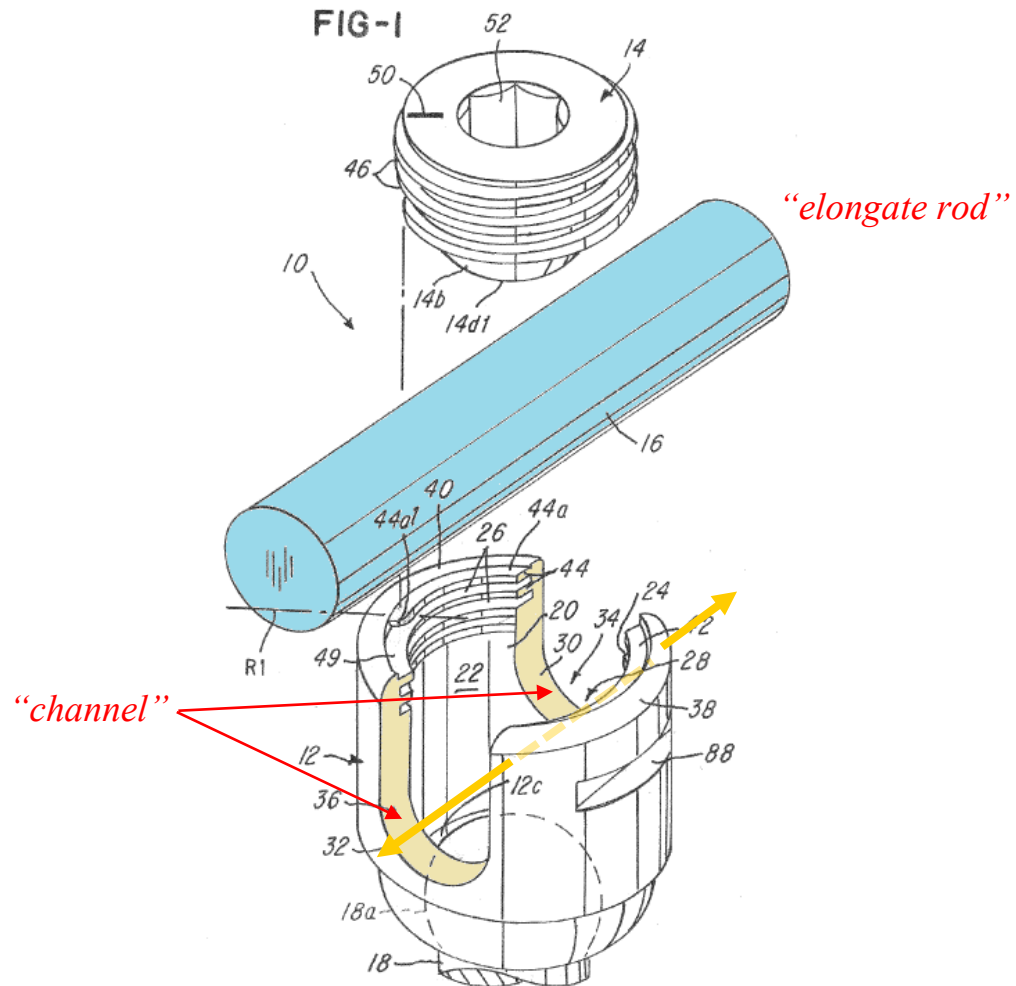
1[b] a channel configured to be attached to an elongate member; and

117. Kirschman renders obvious limitation 1[b].

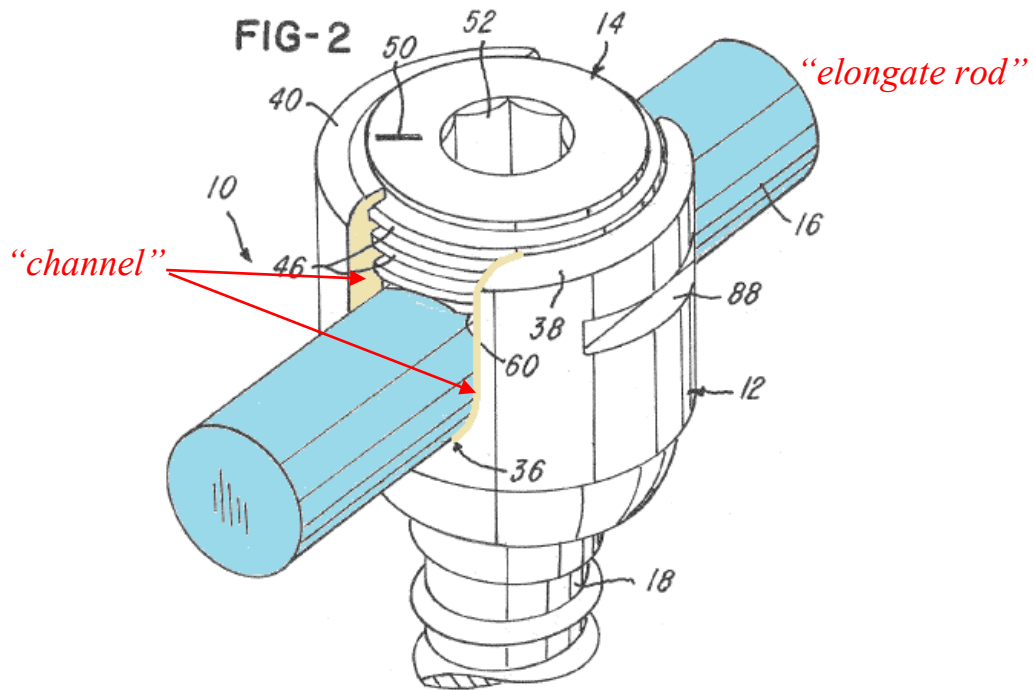
118. Kirschman explains that the receiver 12 (*“receiver”*) includes a rod-receiving channel 28 that is configured to receive (*“configured to attach[] to”*) the rod 16 (*“elongate member”*):

The receiver 12 comprises at least one internal wall 20 defining a bore 22. At least a portion of the receiver 12 comprises a plurality of female threads, such as threads 24 and 26. In this regard, note that the receiver 12 comprises a rod-receiving channel 28. **The receiver 12 comprises a first generally U-shaped wall 30 that defines a first rod-receiving opening 34 and a generally opposed second generally U-shaped wall 32 that defines a second rod-receiving opening 36 as shown. The first and second rod-receiving openings 34 and 36 cooperate to define the rod-receiving channel 28 for receiving the rod 16.** Note that the receiver 12 further comprises a first arcuate wall 38 and a generally opposing second arcuate wall 40 that lie between the first and second rod-receiving openings 34 and 36 as shown.

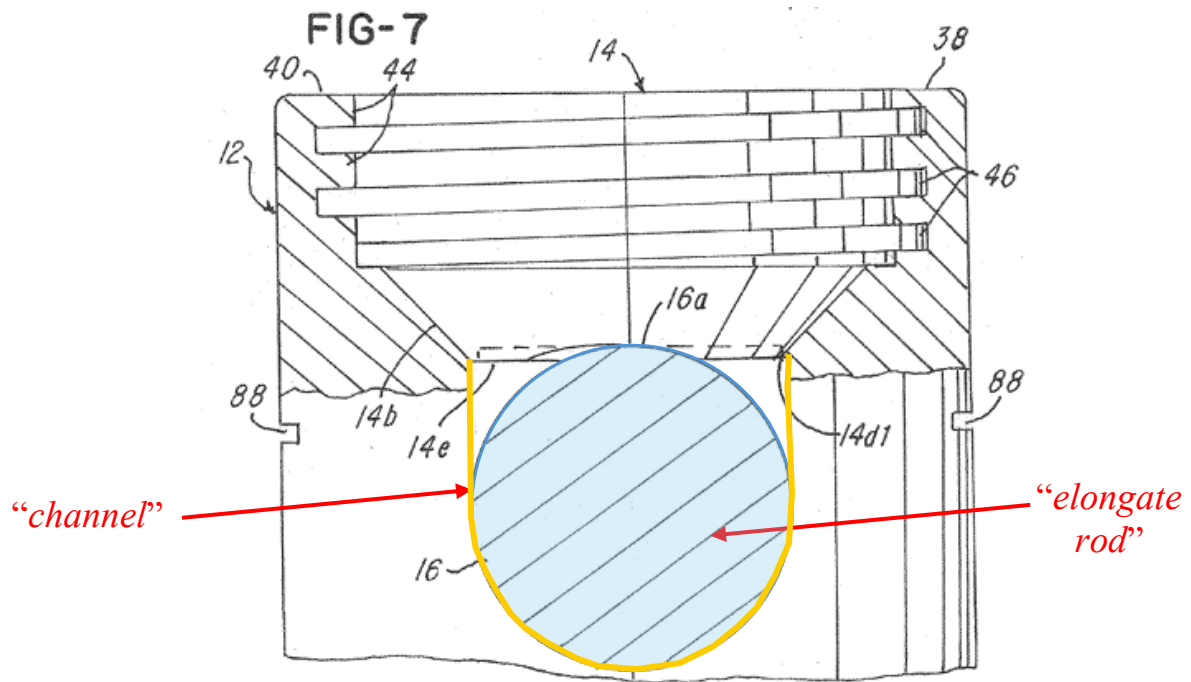
Ex.1005, [0035]. Figs. 1 and 7 illustrate the rod 16 (“*elongate rod*”) attached to the rod-receiving channel 28 (“*channel*”) of the receiver 12 (“*receiver*”):



Kirschman (Ex.1005), Fig. 1 (annotated)



Kirschman (Ex.1005), Fig. 2 (annotated)



Kirschman (Ex.1005), Fig. 7 (annotated)

119. Therefore, because Kirschman's receiver 12 includes a rod-receiving channel 28 for receiving a rod 16, Kirschman renders obvious *"a channel configured to be attached to an elongate member"* as claimed.

1[c] a plug being threaded and configured to be positioned within the upper portion of the receiver, the plug having an axis of rotation, a continuously helically wound thread form, and

120. Kirschman renders obvious limitation 1[c].

121. Kirschman discloses a cap 14 (*"plug"*) having male cap threads 46 (*"continuously helically wound threadform"*) that are threadably received by the threads 42, 44 on the arcuate walls 38, 40 (*"upper portion"*) of the receiver 12 (*"receiver"*):

Referring now to FIGS. 1-10, an implant, polyaxial screw, system and method 10 are shown. In a first illustrative embodiment, the system 10 comprises a receiver 12 and a **cap 14 which is threadably mounted on the tulip or receiver 12**. The receiver 12 receives the cap 14 after a rod 16 and a polyaxial screw 18 are received in the receiver 12 in a manner conventionally known and as shown in FIG. 1.”

Ex.1005, [0034].

The first arcuate wall 38 comprises first arcuate wall threads 42 and the second arcuate wall 40 comprises second arcuate wall threads 44 as shown. **The first and second arcuate wall threads 42 and 44 cooperate to define the receiver threads for threadably receiving male cap threads 46 on the cap 14** so that the cap 14 can be screwed onto the receiver 12 in order to lock the rod 16 in the rod-receiving channel 28 of the receiver 12.

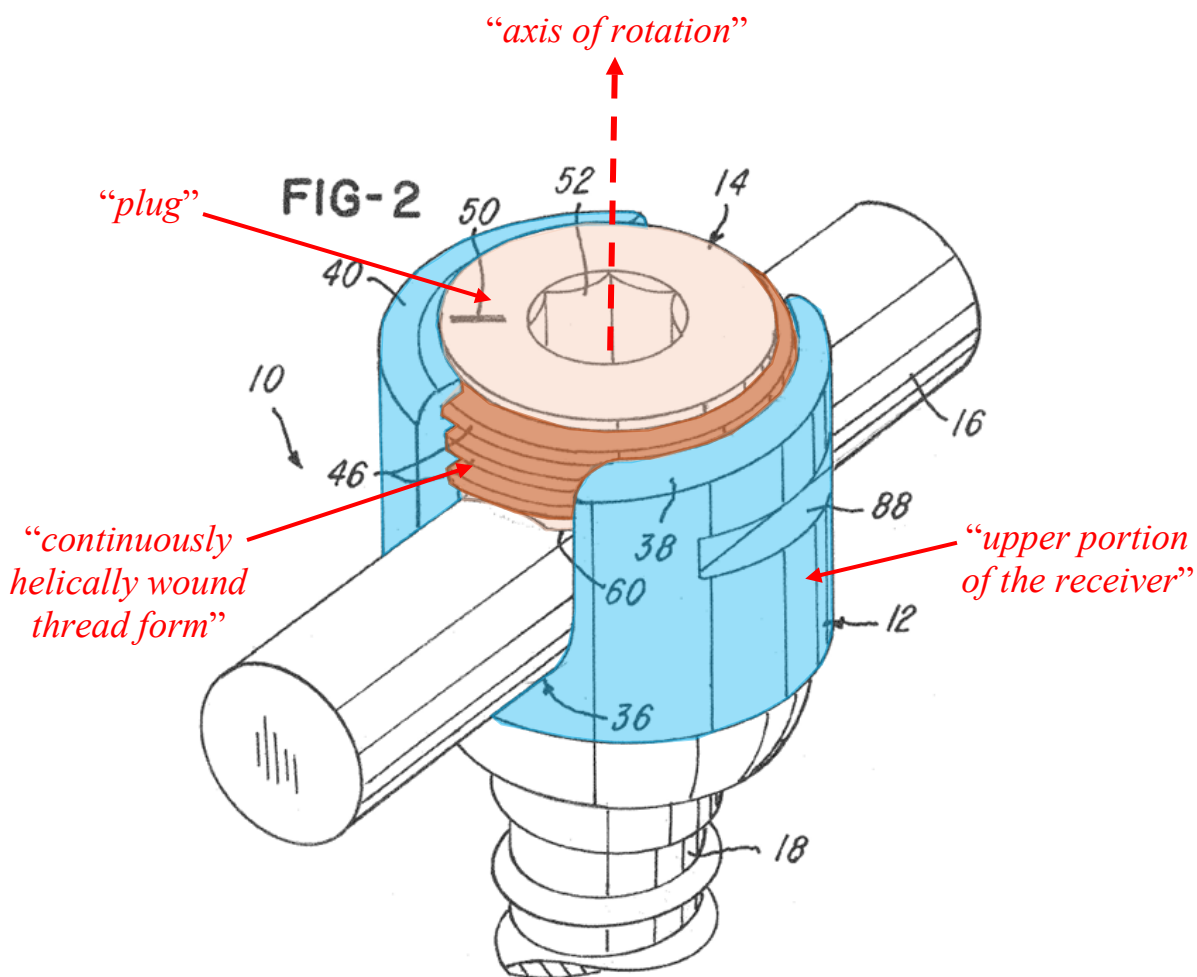
Ex.1005, [0036]; *see also* [0043] (“a bottom 14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a with the cut-out area 49 of the receiver 12 so that the cap 14 can be easily guided and screwed onto the receiver 12”). The male cap threads 46 are “*continuously helically wound*” about the body of the cap 14. *See* Ex.1005, Figs. 1-7.

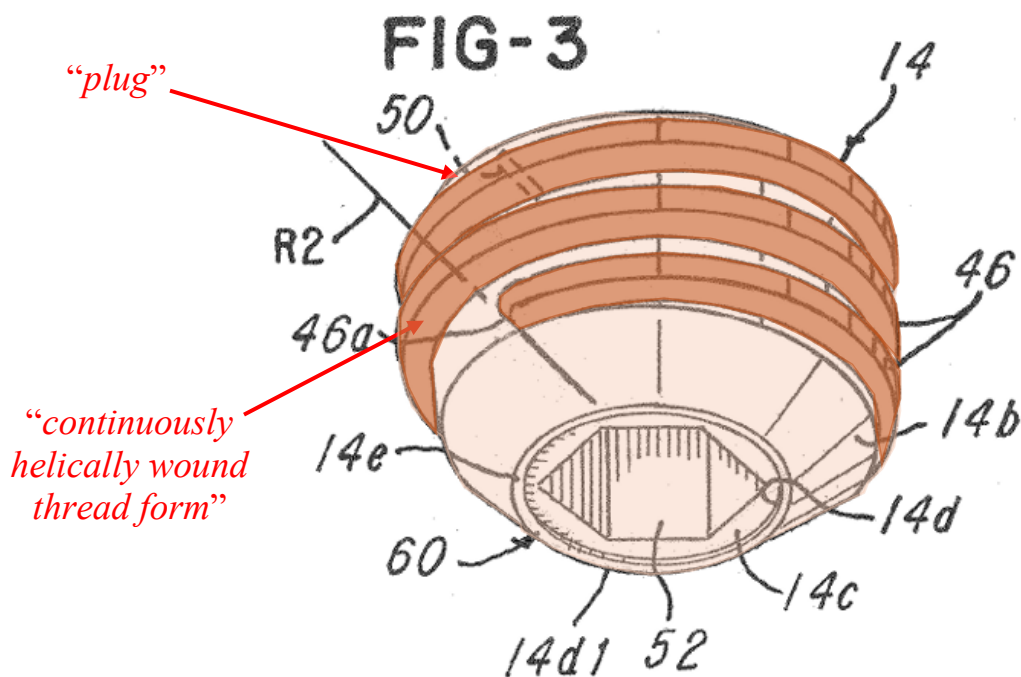
122. A tool is used to rotatably drive the cap 14 (“*plug*”) into the receiver 12 (“*receiver*”):

In the illustration being described, notice that the bottom 14b terminates at an end 14c (FIG. 6). In the illustration being described, **the cap 14 has a tool-receiving opening 52 (FIG. 2) for receiving a tool for rotatably driving the cap 14.** In the illustration being shown, the tool is a hex wrench (not shown), but it could be **any suitable tool adapted to rotatably drive the cap 14.**

Ex.1005, [0044]. The tool is configured to rotate the cap 14 (“*plug*”) about its “*axis of rotation*” to attach the cap 14 (“*plug*”) to the receiver 12 (“*receiver*”).

123. The cap 14 (“*plug*”) is shown in Figs. 2 and 3 below:



Kirschman (Ex.1005), Fig. 2 (annotated)**Kirschman (Ex.1005), Fig. 3 (annotated)**

124. Although I think Kirschman clearly discloses that the cap 14 has an “axis of rotation,” even if it does not explicitly disclose the “axis of rotation,” this would have been obvious to a POSITA. In order to thread the cap 14 into the receiver 12, the cap 14 is rotated about an axis extending through the center of the cap 14 from the bottom to the top. This would be the cap 14’s “axis of rotation.”

125. Therefore, because Kirschman discloses a cap 14 with male cap threads 46 that is configured to be rotatably attached to the receiver 12 between the arcuate walls 38, 40, Kirschman renders obvious “a plug being threaded and configured to be positioned within the upper portion of the receiver, the plug

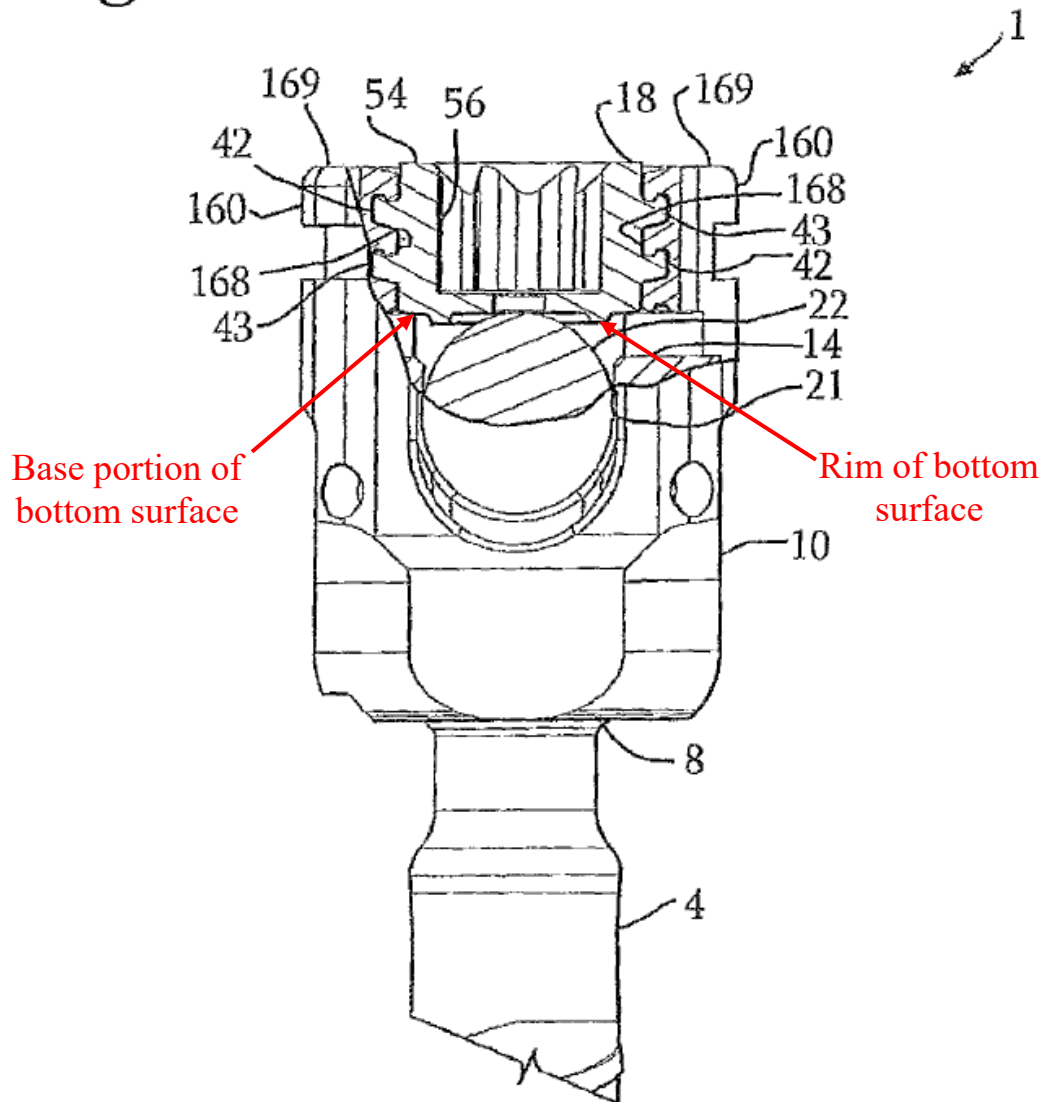
having an axis of rotation, a continuously helically wound thread form” as claimed.

1[d] a bottom surface with an annular outer edge,

126. Kirschman renders obvious limitation 1[d].

127. The '873 Patent does not describe an “*annular outer edge*” of a bottom surface. Based on the specification and figures, there are multiple ways to interpret the “*bottom surface*” and the “*annular outer edge*” thereof. With reference to the embodiment in Figs. 1-8, the '873 Patent states that the “base or bottom surface 58 of the closure [18] is planar and **further includes a rim 60** for engagement and penetration in the surface 22 of the rod 21.” (Ex.1001, 9:4-7). This is shown in Fig. 8 of the '873 Patent below:

Fig. 8.

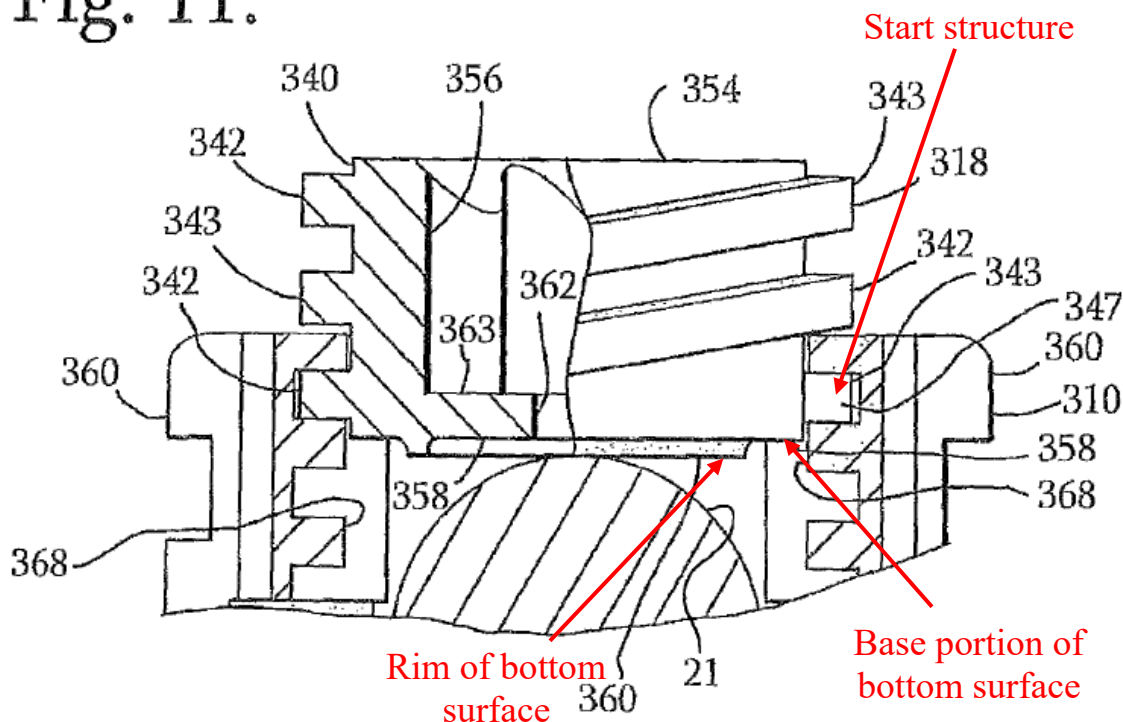


'873 Patent (Ex.1001), Fig. 8 (annotated)

128. Because the rim is a part of the bottom surface, the claimed “*bottom surface*” appears to refer to the base portion of the bottom surface or to the lower surface of the rim that contacts the rod and, thus, the “*annular outer edge*” appears to refer to an edge of the base portion or the rim.

129. Similarly, the embodiment of Fig. 11, shows that the “closure top 318...is almost identical to the closure top 18” shown in Figs. 1-8, including “a base 358 [and] a rim 360[] that is the same or substantially similar to the respective ... base 58 [and] rim 60 ... previously described herein with respect to the closure top 18.” Ex.1001, 22:45-57. As shown in Fig. 11 below, the start structure 347 of the closure thread is spaced above both parts of the bottom surface (*see* limitation 1[h] below):

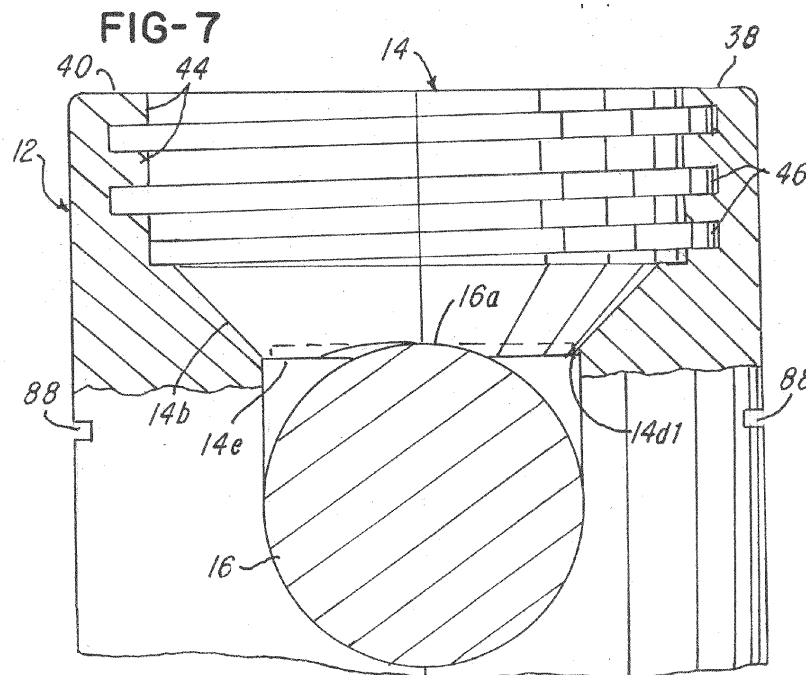
Fig. 11.



130. The embodiment in Fig. 12 similarly shows the same base 458 and rim 460 as the embodiment in Figs. 1-8, but with reverse angle threads and start structures 446, 447 that appear to be spaced above both the base portion and rim of

the bottom surface, like the embodiment in Fig. 11. *See* Ex.1001, 22:66-19; Fig. 12.

131. Although there are various interpretations of this limitation, Kirschman discloses a closure having a bottom surface with a flat base member and a protruding rim that is substantially similar to the closure embodiments in the '873 Patent. Ex.1005, [0047]. Thus, obviousness of limitation [d] can be resolved by comparing the structures in Kirschman to the embodiments of the '873 Patent.



Kirschman (Ex.1005), Fig. 7

132. Specifically, Kirschman discloses that the cap 14 (“*plug*”) includes a bottom 14b that makes it easier for the user to screw the cap 14 (“*plug*”) into the receiver 12 (“*receiver*”):

As illustrated in FIGS. 1, 3 and 4, note that **a bottom 14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a with the cut-out area 49 of the receiver 12 so that the cap 14 can be easily guided and screwed onto the receiver 12.** In the embodiment being described, notice that the bottom 14b is frusto-conical, but it should be understood that the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12. For example, the surface could have an arcuate, curved or semi-spherical shape such that **the bottom 14b is adapted to facilitate aligning and guiding the cap 14 onto the receiver 12 so that the cap 14 can be easily screwed onto the receiver 12.**

Ex.1005, [0049].

133. Thus, the bottom 14b of the cap 14 includes a frusto-conical guiding surface that facilitates guiding the cap onto the receiver 12.

134. Kirschman explains that “the **bottom 14b terminates at an end 14c.**”

Ex.1005, [0044]. The bottom end 14c is surrounded by a deformable ring 14d including bottom edge 14e that is configured to engage the rod 16:

Returning to FIGS. 3, 4 and 6, note that the cap 14 comprises a deformable area 60 that is adapted to provide the lock aid. In the illustration being described, **the deformable area 60 comprises a deformable ring 14d that is monolithically and integrally formed with the cap 14, as best illustrated in FIG. 6. As shown in FIG. 2, the cap 14 is received on the receiver 12 and screwed into the receiver**

12 until a bottom edge or surface 14e engages the rod 16. The deformable ring 14d and the deformable area 60 deforms about the rod 16 as the cap 14 is screwed into the receiver 12 and as it compresses against the rod 16 as illustrated in FIGS. 2 and 7.

Ex.1005, [0045].

135. The deformable ring 14d is configured to prevent the rod 16 from directly contacting the end 14c (*“bottom surface”*):

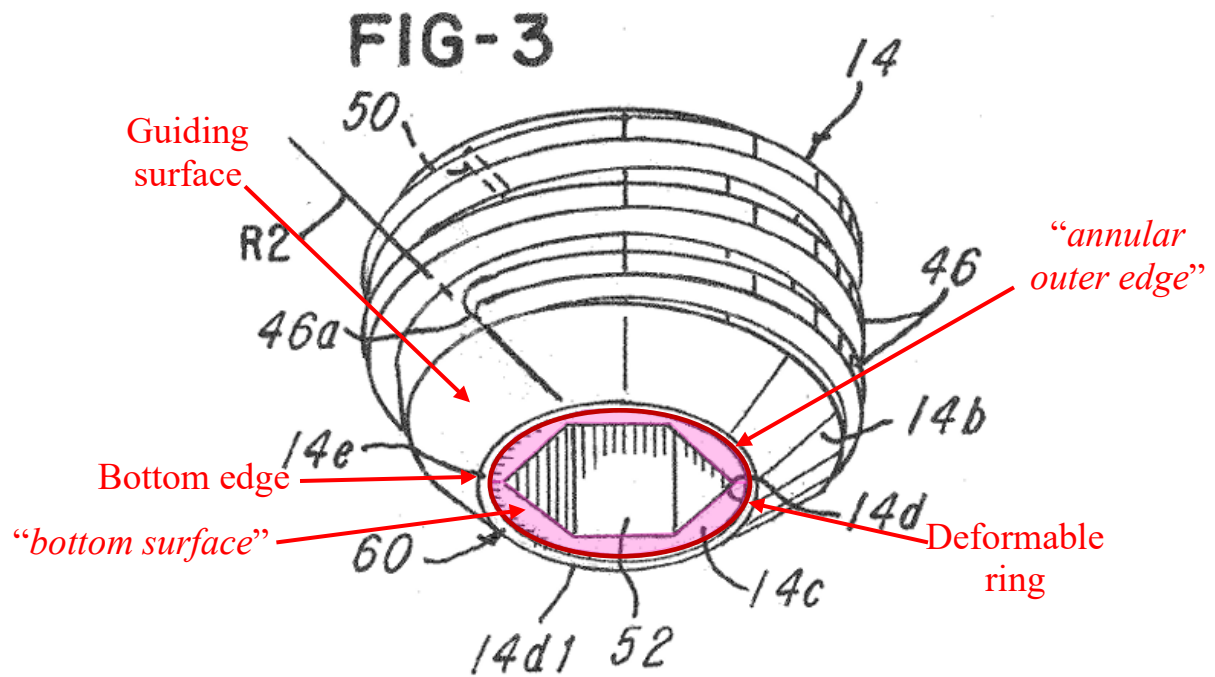
As best seen in FIGS. 3 and 6, note that the locking ring 14d comprises a locking ring wall or surface 14d1 (FIG. 6) that is generally parallel to an axis of the cap 14 and generally perpendicular to the end 14c as shown. Note also that the surface 14d1 comprises a thickness or dimension 62 which is generally smaller than a cross-sectional thickness 64 of the dimension defined by an inner surface 14a and the bottom 14b, as illustrated in FIG. 6. **This dimension 62 is adapted and selected to enable the deformable ring 14d or deformable area 60 to deform, while the end 14c remains undeformed as shown in FIG. 7.** In the illustration being described, the deformable ring 14d provides an enhanced fixation or even a cold-weld between the cap 14 and the rod 16 when the cap 14 is received on the receiver 12.

Ex.1005, [0047]; *see also* [0050] (*“After the cap 14 is mounted on the receiver 12 it is screwed using the tool (not shown) until the deformable ring 14d deforms on the rod 16, thereby providing the enhanced fixation by deforming on the rod 16, thereby locking the rod 16 against the head 18a of the polyaxial screw 18.”*).

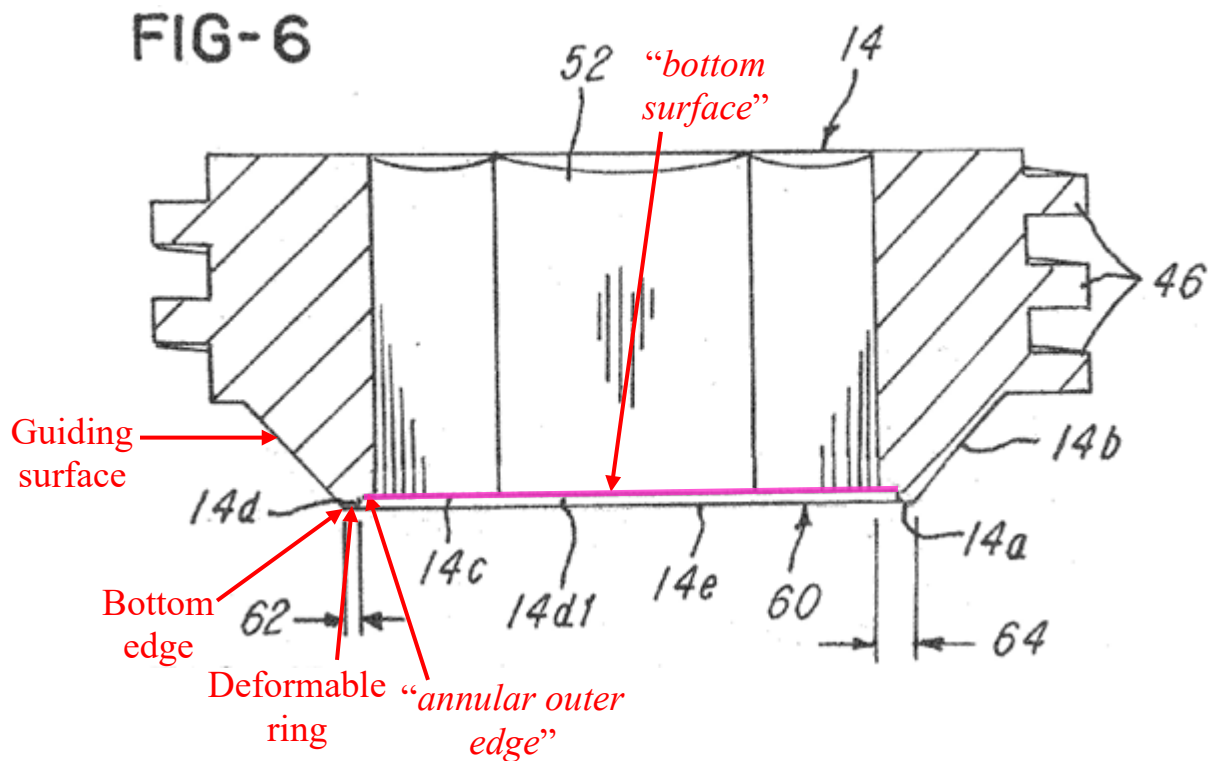
136. In one interpretation, the end surface 14c is the *“bottom surface”* of

the cap. Therefore, the outer edge of the end surface 14c adjacent to the deformable ring 14d defines the “*annular outer edge*” of the bottom surface, as shown in Figs.

3 and 6 below:

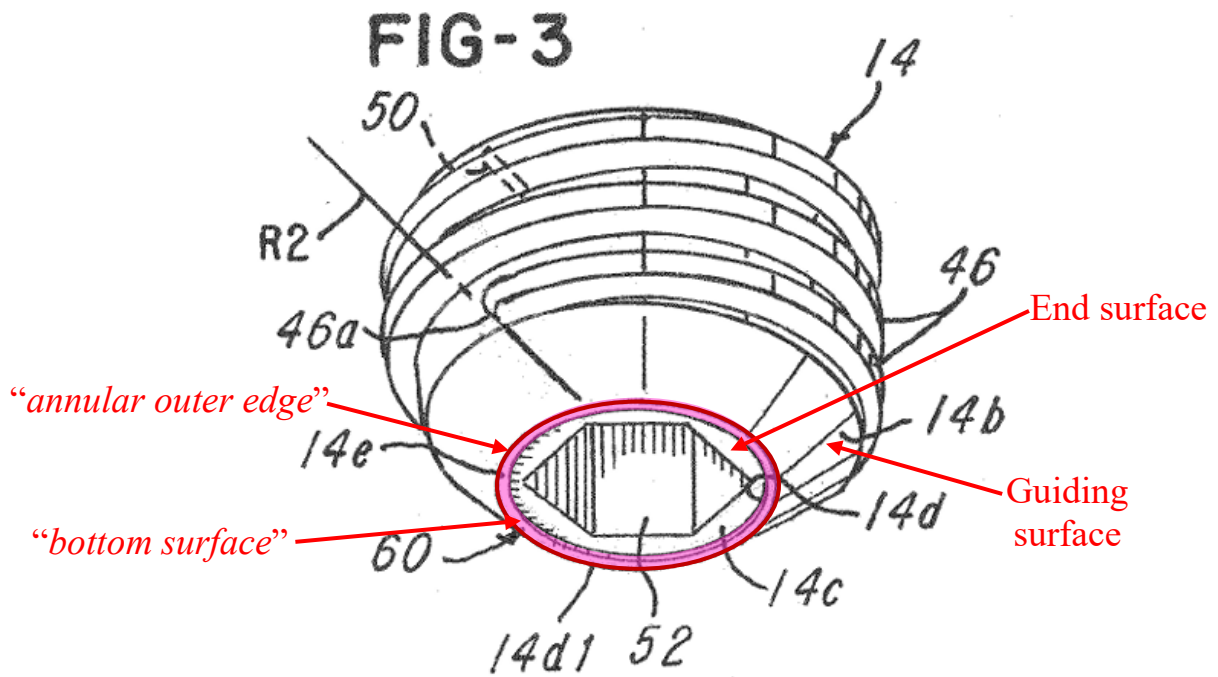


Ex.1005, Fig. 3 (annotated)

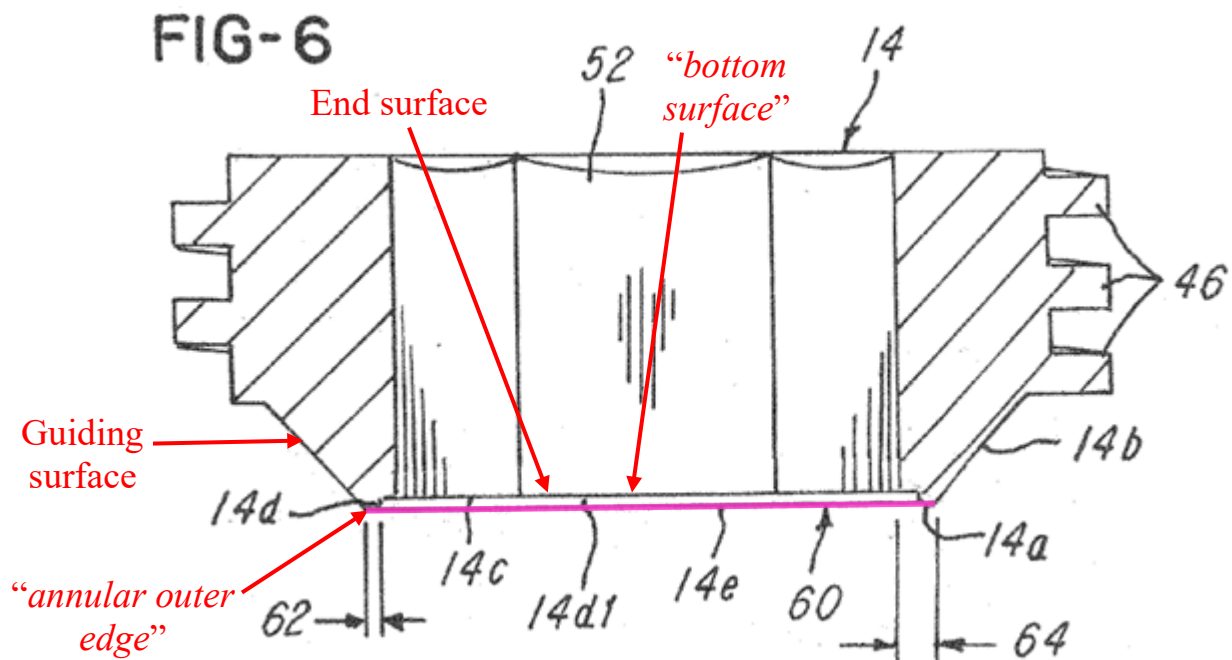


Ex.1005, Fig. 6 (annotated)

137. Alternatively, as the "bottom surface" includes a rim structure (e.g., the "rim 360" depicted in Fig. 12 of the '873 Patent (Ex.1001, 22:45-57, Fig. 12)), then the bottom surface of the deformable ring 14d is also the "bottom surface" and the outer edge 14e thereof, which is the outermost structure at the bottom of the cap, is the "annular outer edge," as shown in Figs. 3 and 6 below:

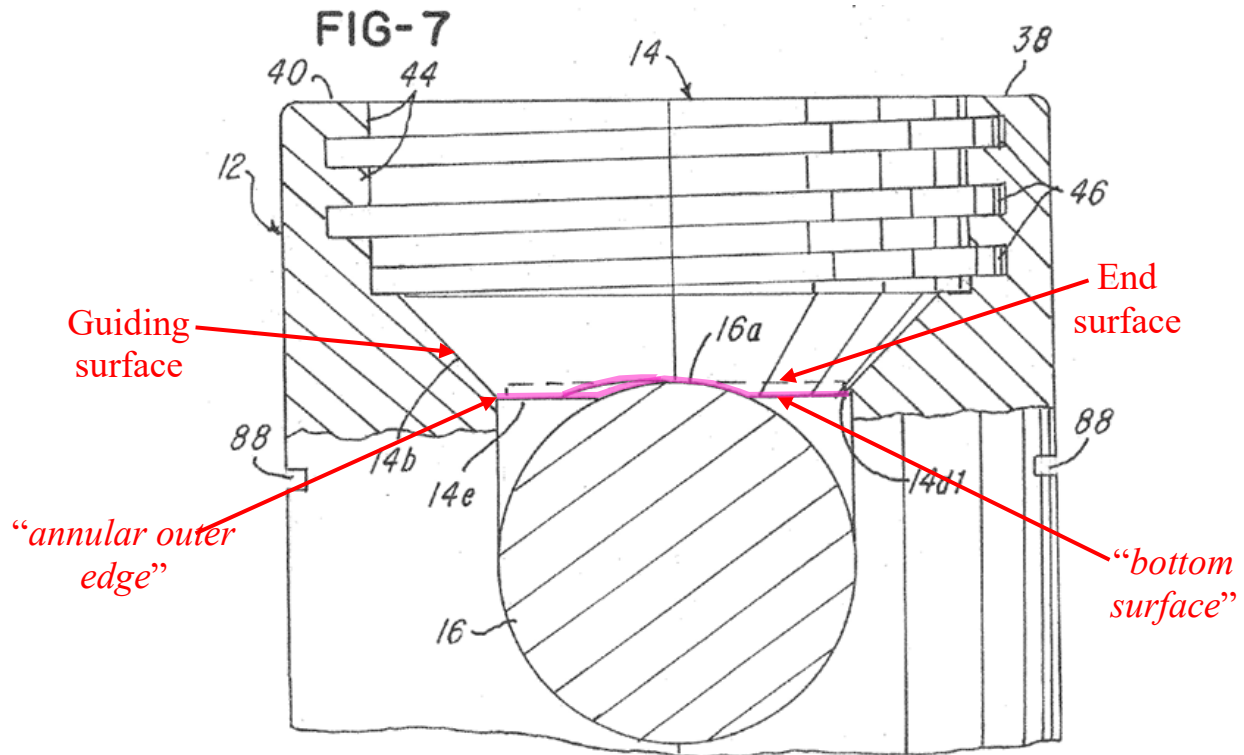


Ex.1005, Fig. 3 (annotated)



Ex.1005, Fig. 6 (annotated)

The cap 14 is “screwed into the receiver 12 until a bottom edge...14e engages the rod.” Ex.1005, [0045]. Fig. 7 below illustrates the cap 14 after deformation of the deformable ring 14d by the rod during rotation of the cap 14 (Ex.1005, [0047]):



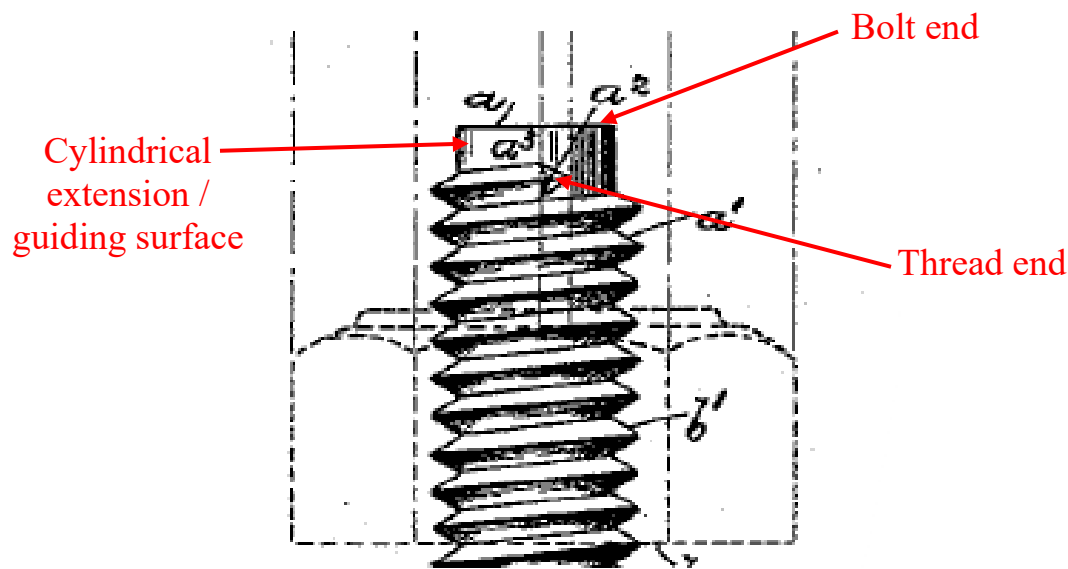
Ex.1005, Fig. 7 (annotated)

138. Thus, the embodiment shown in Figs. 1-7 of Kirschman discloses “a bottom surface” of a threaded closure having “an outer annular edge.”

139. To the extent the claimed “bottom surface” is understood to encompass a guiding surface, Kirschman also discloses use of a cylindrical guiding surface. Although the guiding surface in Figs. 1-7 is shown as “frustoconical,” Kirschman explains that “it should be understood that the surface shape could be any suitable shape adapted to guide the cap.” Ex.1005, [0043]. Thus, a POSITA

would have been motivated to consider alternative shapes for the guiding surface, including those disclosed in the patents incorporated by reference into Kirschman. Kirschman incorporates Higbee by reference, specifically pointing to Higbee as the “first inventor” of blunt start threads “for the prevention of cross threading.” Ex.1005, [0009]. Kirschman explains that a problem with previous polyaxial screws is that “the thread start-point of both the male and female threads are difficult to identify in a surgical environment” and “there is little, if any, tactile feedback that the thread is engaged.” Ex.1005, [0006]. Higbee solves these problems “[b]y leaving the smooth extension” between the thread start and the bottom surface thereby ensuring that the screw and nut “are brought together and properly aligned before the thread ends engage, and thus an additional safeguard against misadjustment is provided.” Ex.1006, 1:83-88.

140. In particular, Higbee describes a guiding surface in the form of a “cylindrical extension...between the thread end a^2 and the bolt end a ” (Ex.1006, 1:69-71):

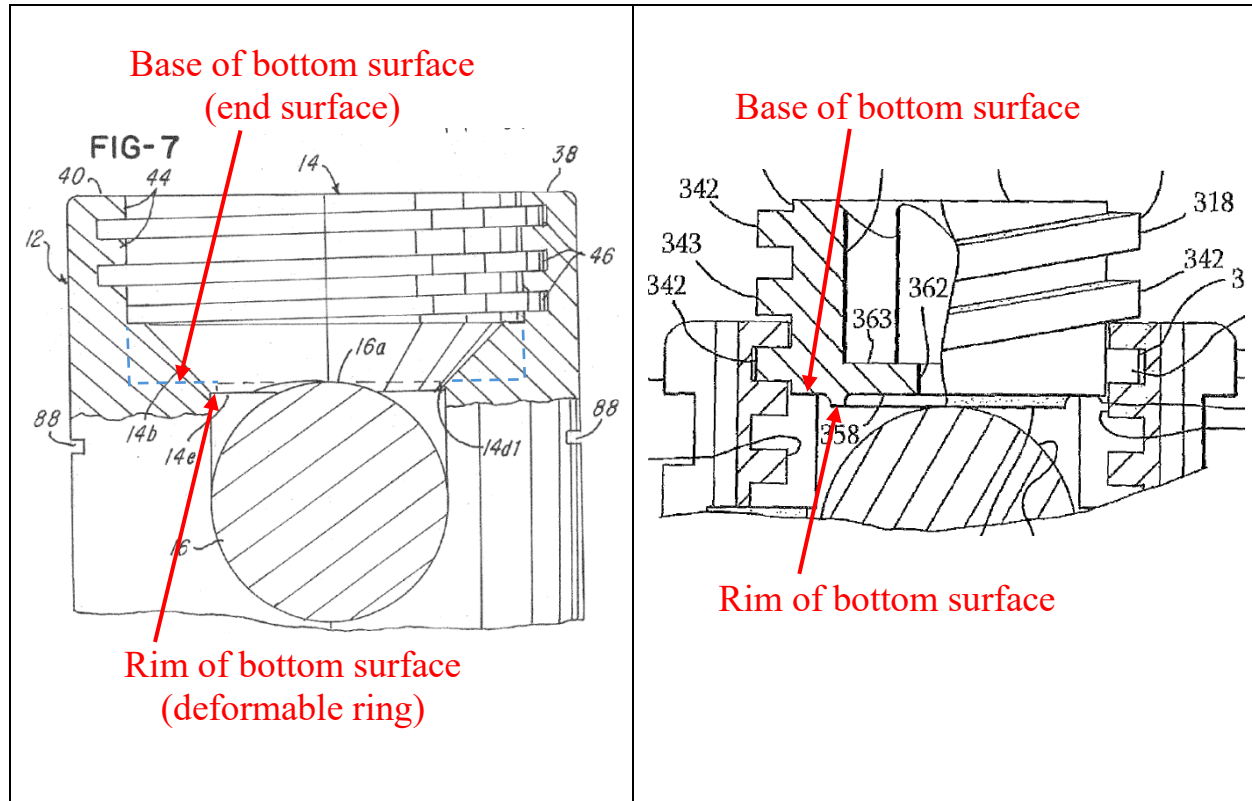


Higbee (Ex.1006), Fig. 1 (cropped and annotated)

141. Accordingly, a POSITA would have been motivated to modify the frustoconical guiding surface of Kirschman's cap to be a cylindrical guiding surface as disclosed in Higbee along with a corresponding cylindrical cavity in receiver to providing an alternative guiding feature for proper alignment.

142. Thus, with Kirschman's guiding surface modified to be cylindrical as shown by the dashed blue lines, Kirschman's cap includes the same structure as the '873 Patent's closure:

Kirschman (Ex.1005), Fig. 7 (annotated)	'873 Patent (Ex.1001), Fig. 11 (cropped and annotated)
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143. Therefore, because Kirschman discloses a circular bottom end surface 14c surrounded by a deformable ring 14d, Kirschman renders obvious “a bottom surface with an annular outer edge” as claimed.

1[e] *the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form,*

144. Kirschman renders obvious limitation 1[e].

145. **First**, Kirschman discloses “the continuously helically wound thread form having a start structure.” Kirschman describes a “lock aid” having a “tactile feedback system” that makes it easier to screw the cap 14 (“*plug*”) into the receiver 12:

In one illustrative embodiment, the lock aid comprises the tactile feedback system, method or means mentioned. In this regard, note in FIG. 1 that the first thread 44a of the second arcuate wall threads 44 defines a starting thread that is shorter than at least one other of the second arcuate wall threads 44 in order to define a cut-out area 49 for facilitating receiving a leading edge portion 46a (FIG. 3) of a male thread of the male cap thread 46. **The surgeon or user can feel the cap 14 drop down into the receiver 12 when the leading edge portion 46a is aligned with the cut-out area 49. This design provides tactile feedback when the cap 14 is received on the receiver 12.** This feature is particularly useful during surgery where sometimes it is difficult for the surgeon to see the cap 14 relative to the receiver 12. In the illustration being shown, the leading edge portion 46a of the male cap thread 46 may be identified with indicia 50 which provides the visual feedback of the location of the leading edge portion 46a of the cap 14. **The cut-out area 49 and its cooperation and reception of the leading edge portion 46a are adapted to permit the drop down and define the lock aid.**

Ex.1005, [0038].

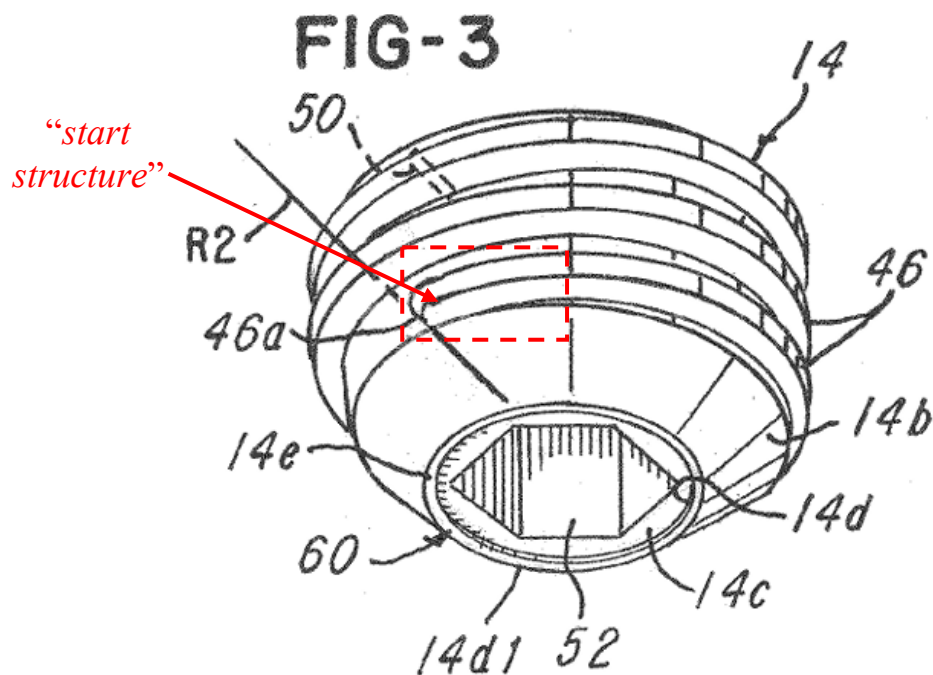
146. As a part of this lock aid, the leading edge portion 46a (“*start structure*”) of the male cap thread 46 (“*continuously helically wound thread form*”) is truncated to make it easier to align the male cap thread 46 (“*continuously helically wound thread form*”) with the arcuate wall threads 42, 44:

Notice in FIG. 3 that **the leading edge portion 46a of the male cap thread 46 is truncated** as shown. Likewise, the leading edge portion

44a1 of the first thread 44a is also truncated. In one illustrative embodiment, **the leading edge portion 44a1 of the first thread 44a of the receiver 12 and the leading edge portion 46a of the male cap thread 46 of the cap 14 are truncated and adapted so that when these leading edge portions 44a1 and 46a are adjacent each other and initially pass each other when the cap 14 is mounted on the receiver 12, the leading edge portions 44a1 and 46a move relative to each other a drop down distance DD (FIG. 4), which in the illustration being described is greater than at least one thread pitch associated with the second arcuate wall threads 44.**

Ex.1005, [0039].

147. Thus, the leading edge portion 46a defines a “*start structure*” of the male cap thread 46 (“*continuously helically wound thread*”). The leading edge portion 46a of the male cap thread 46 is shown in Fig. 3 below:



Kirschman (Ex.1005), Fig. 3 (annotated)

148. Second, Kirschman renders obvious “a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form.” A POSITA would have understood that Fig. 3 clearly shows the leading edge portion 46a having an upper surface that extends between a root and a crest. The terms “root” and “crest” are common, well-known terms in the art to describe the part of the thread disposed at the body of the screw (“root”) and the outermost surface of the thread (“crest”). Ex.1010, 3 (“crest: the surface of a thread that joins the flanks of the same thread, and is farthest from the cylinder...from which the thread projects.”), 15 (“root: that surface of the thread that joins the flanks of the adjacent thread forms and is immediately adjacent to the

cylinder...from which the thread projects.”); Ex.1011, 1.03 (“Crest.—The crest is that surface of the thread which joins the flanks of the thread and is farthest from the cylinder...from which the thread projects.”) (“Root.—The root is that surface of the thread which joins the flanks of adjacent thread forms and is identical with or immediately adjacent to the cylinder or cone from which the thread projects.”).

For example, the figure below illustrates the root and crest for cooperating internal and external threads:

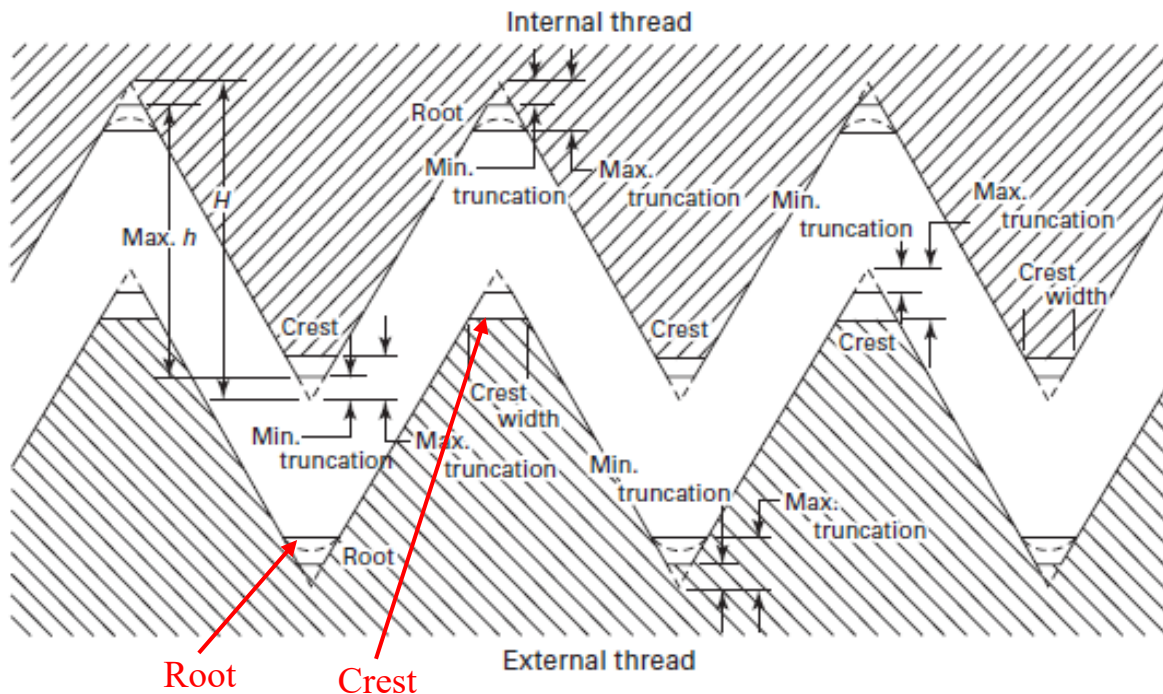


Fig. 9 Root and Crest Truncation

ASME B1.7-2006 (Ex.1010), Fig. 9 (annotated)

149. Moreover, it was well known that flanks of the threads extend between the root and crest. Ex.1010, 6 (“flank: the part of the helical thread surface that connects the crest and the root”); Ex.1011, 1.03 (“Flank.—The flank (or side)

of a thread is either surface connecting the crest with the root.”). The leading flank (or lower surface) of the thread is “the flank that, when the thread is about to be assembled with a mating thread, faces the mating thread” and the following flank (or upper surface) is the “flank of a thread is the one opposite to the leading flank.” Ex.1010, 6, 10; *see also* Ex.1011, 1.03 (“Leading Flank.—When a thread is about to be assembled with a mating thread, the leading flank of the thread faces the mating thread....Following Flank.—The following flank of a thread faces the leading flank.”). For example, the figures below illustrate the leading flank (lower surface) and the following flank (upper surface):

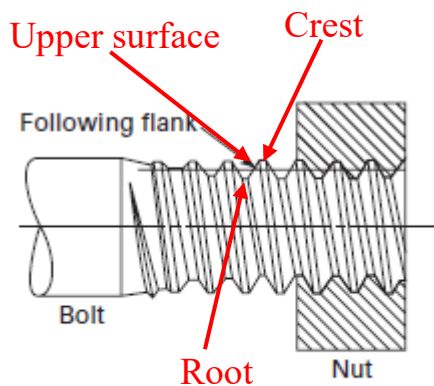


Fig. 16 Following Flank

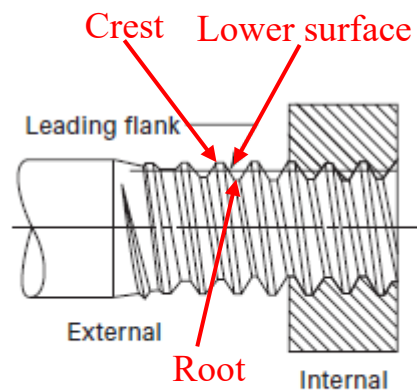


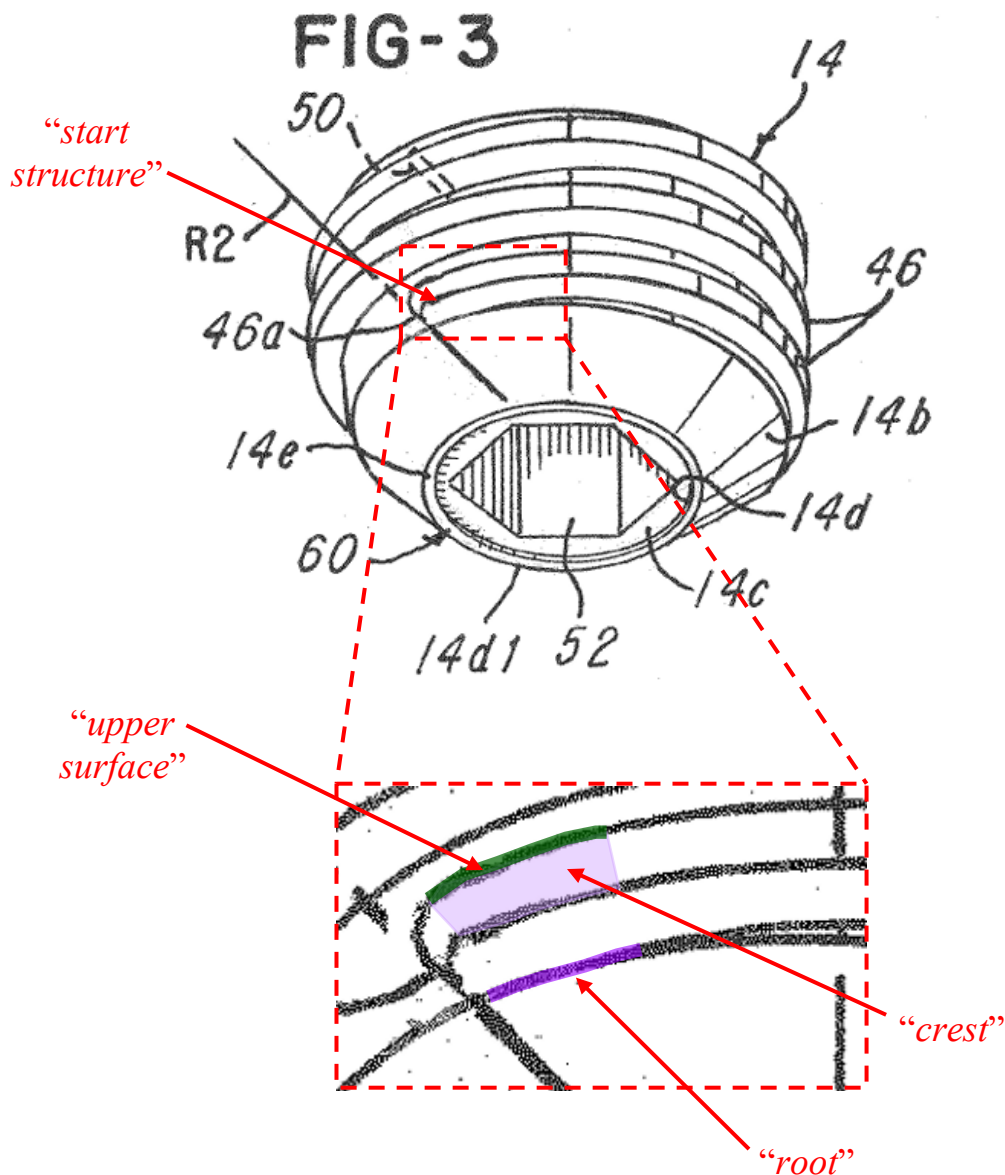
Fig. 27 Leading Flank

ASME B1.7-2006 (Ex.1010), Figs. 16 and 27 (annotated)

150. Accordingly, the following flank faces the trailing end of the screw and would be considered the “upper surface” of the thread.

151. Thus, as shown in Fig. 3 of Kirschman below, a POSITA would have

known that the leading edge portion 46a (“*start structure*”) has a “*root*” disposed adjacent the body of the cap 14, a “*crest*” disposed at the surface of the male cap thread 46 furthest from the body of the cap 14, and an “*upper surface*” extending between the “*root*” and “*crest*” on the trailing side of the thread:



Kirschman (Ex.1005), Fig. 3 (cropped and annotated)

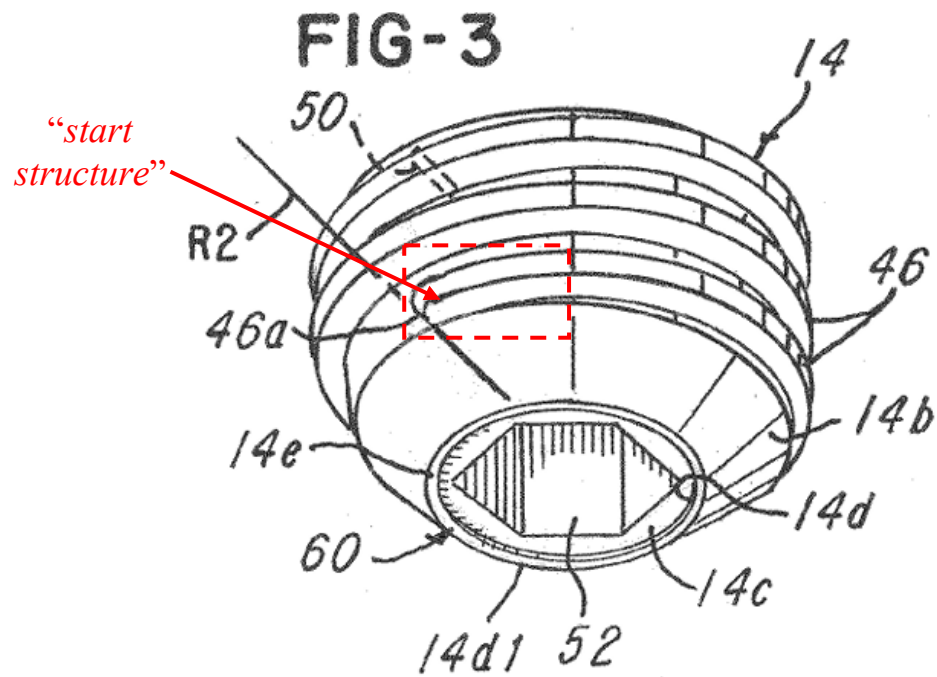
152. Because Fig. 3 above is bottom view of the thread, the “*upper surface*” (shown in green) extends into the page from the “*crest*” (in light purple) to the “*root*” (in dark purple).

153. Therefore, because Kirschman discloses a truncated leading edge portion 46a of the male cap threads 46 having an upper surface that extends from the root to the crest, Kirschman renders obvious “*the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form*” as claimed.

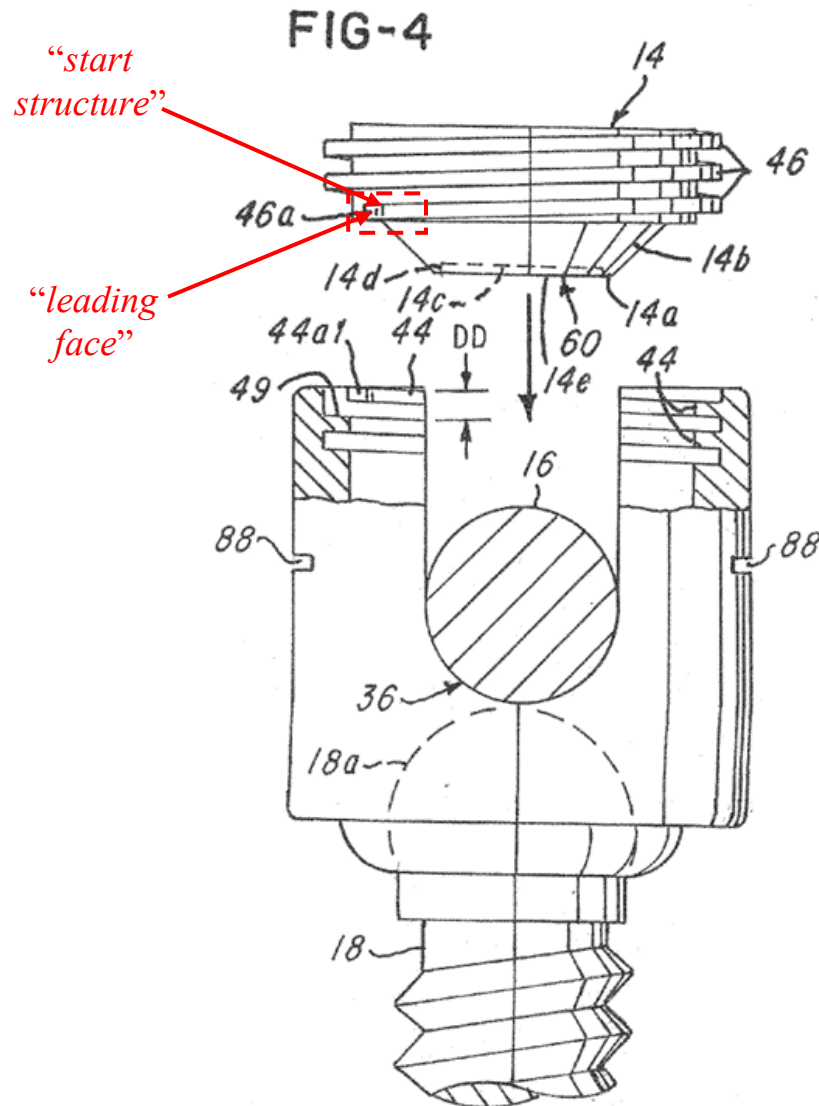
1[f] *the start structure having a leading face extending below the upper surface to a lower surface of the start structure,*

154. Kirschman renders obvious limitation 1[f].

155. As explained above in limitation 1[e], the male cap threads 46 (“*continuously helically wound thread*”) of the cap 14 (“*plug*”) include a leading edge portion 46a that defines the “*start structure*,” as shown in Figs. 3 and 4 below:



Kirschman (Ex.1005), Fig. 3 (annotated)

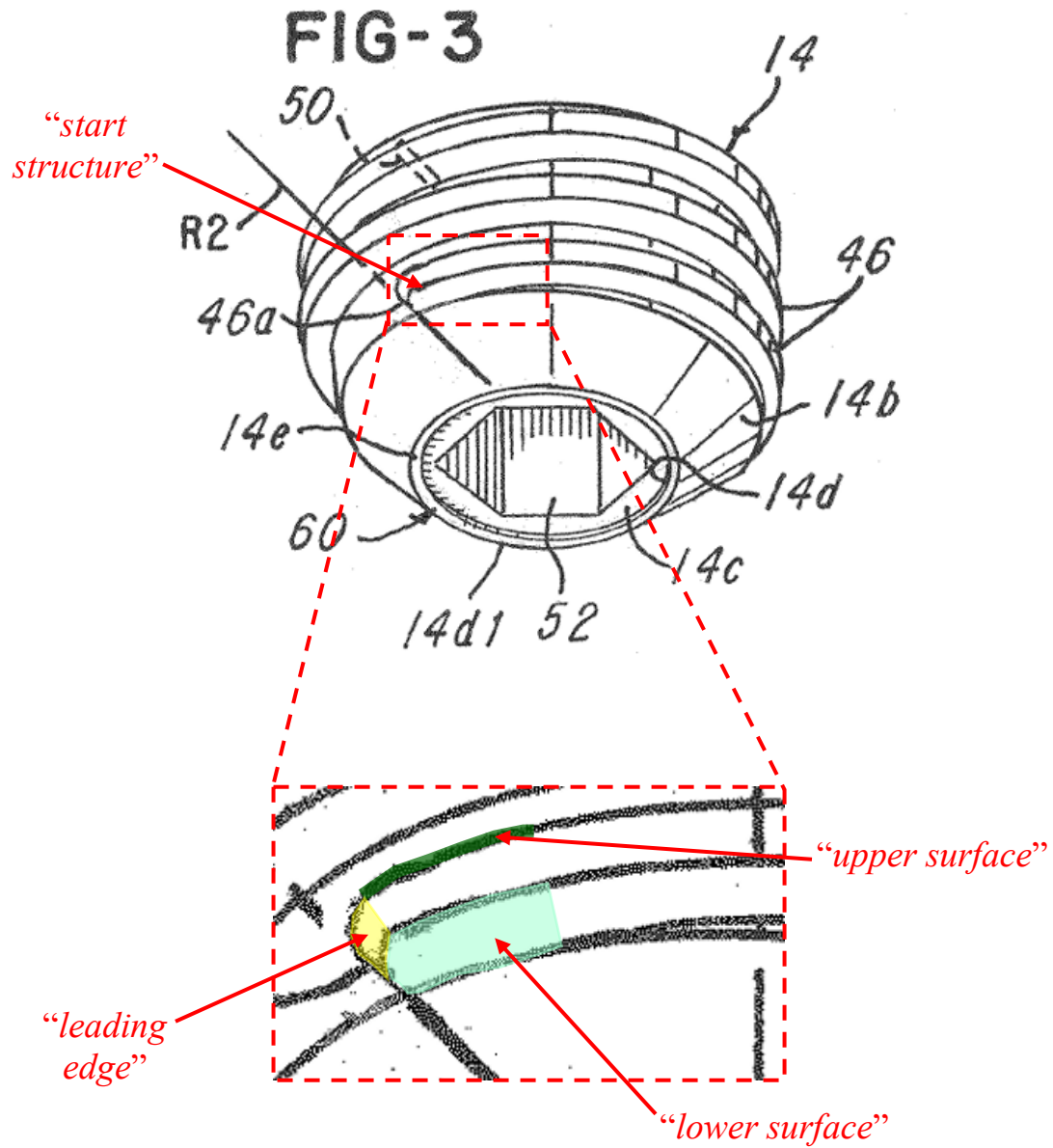


Kirschman (Ex.1005), Fig. 4 (annotated)

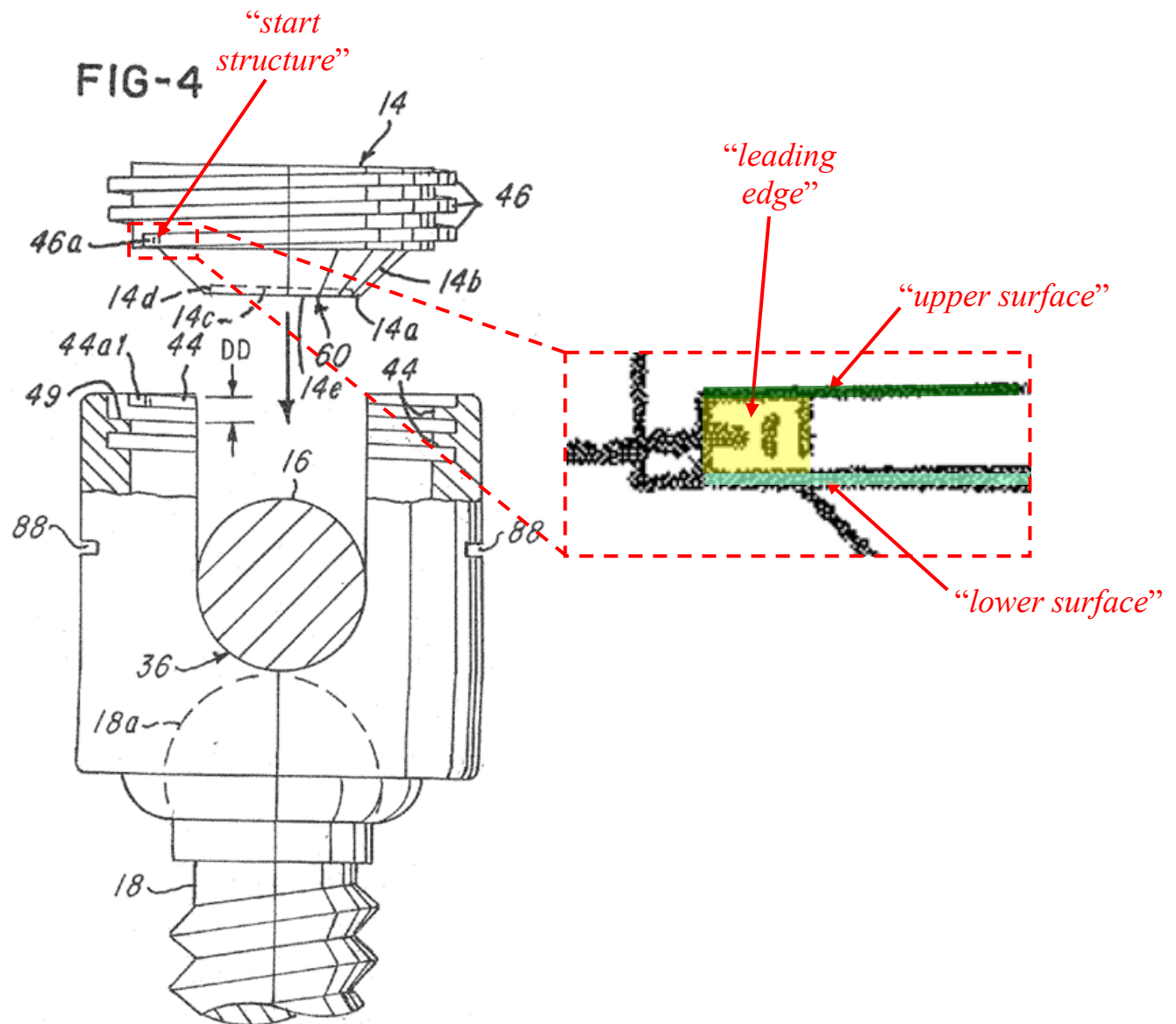
156. A POSITA would have understood that Figs. 3 and 4 show that the leading edge portion 46a (“*start structure*”) has a “*leading face*” that extends below the “*upper surface*” to a “*lower surface*.” It was well-known that a surface (*i.e.* flank) connects the crest and the root on the upper (*i.e.* following, trailing, or top) part of the thread form and another surface connects the crest and the root on

the lower (*i.e.* leading or bottom) part of the thread form. Ex.1010, 6 (“flank: the part of a helical thread surface that connects the crest and the root”) (“following flank: the following, or trailing, flank of a thread that is the one opposite to the leading flank”) (emphasis removed), 10 (“leading flank: the flank that, when the thread is about to be assembled with a mating thread, faces the mating thread”) (emphasis removed); (“FLANK.—The flank (or side) of a thread is either surface connecting the crest with the root”) (LEADING FLANK.—When a thread is about to be assembled with a mating thread, the leading flank of the thread faces the mating thread.”) (“FOLLOWING FLANK.—The following flank of a thread faces the leading flank.”).

157. As shown in Figs. 3 and 4 of Kirschman below, a POSITA would have understood that the surface at the leading end of the leading edge portion 46 a (“*start structure*”) corresponds to the “*leading face*” thereof because it “*extend[s] below*” the “*upper surface*” to the “*lower surface*” of the male cap thread 46:



Kirschman (Ex.1005), Fig. 3 (annotated)



Kirschman (Ex.1005), Fig. 4 (annotated)

158. Although I think Kirschman clearly discloses that leading edge portion 46a includes a “*leading face*,” even if it does not explicitly disclose a “*leading face*,” this would have been obvious to a POSITA because it was well-known that truncated thread starts (such as leading edge portion 46a) include a

leading face. For example, Higbee discloses a thread end (“*start structure*”) having a “broad blunt face” (“*leading face*”). Ex.1006, 1:39-52, 67-68, Figs. 1, 6; *see* limitation 1[g] below.

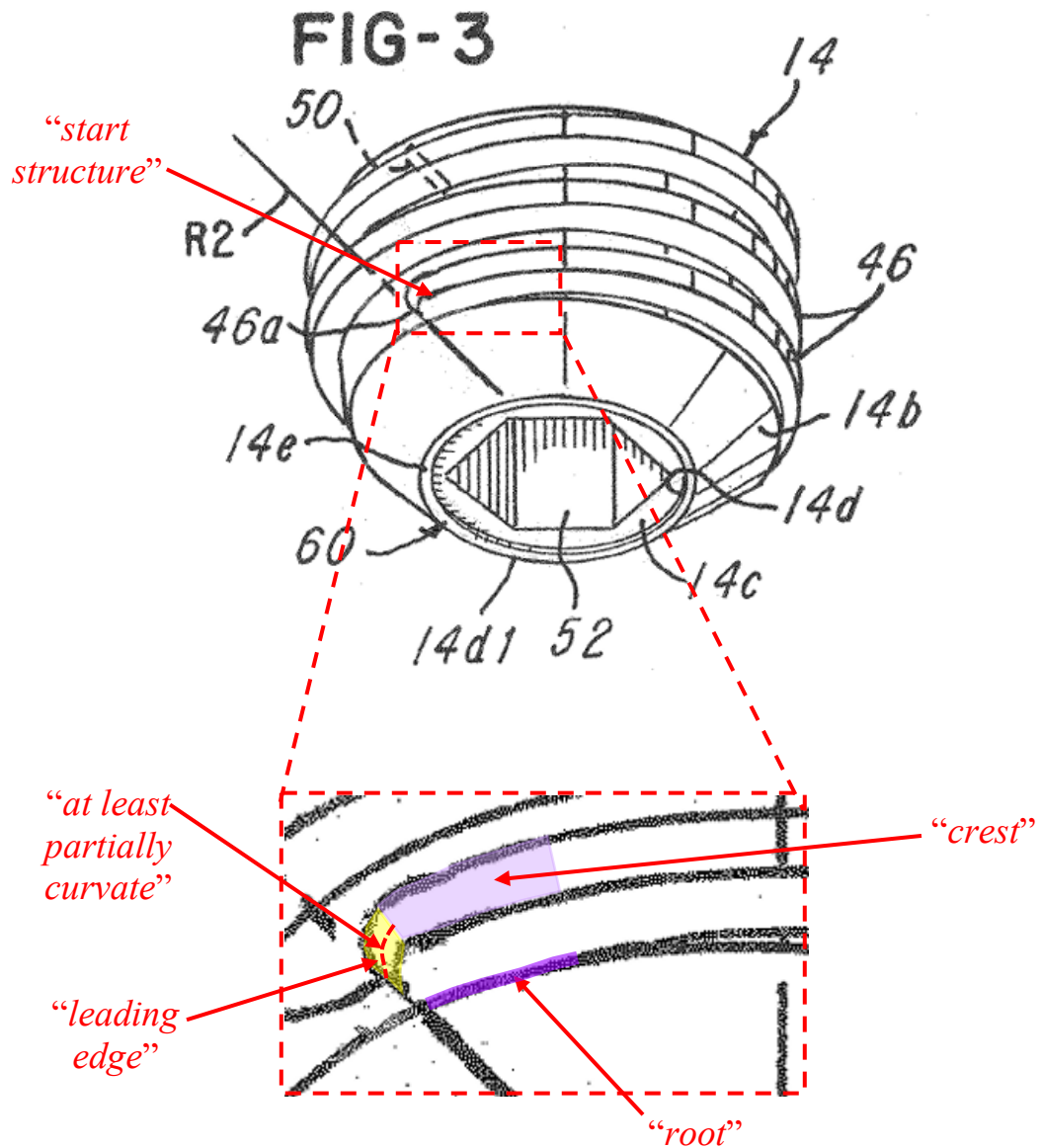
159. Therefore, because Kirschman discloses a truncated leading edge portion 46a of the male cap threads 46 having a lead surface/face at the end that extends from an upper surface to a lower surface thereof, Kirschman renders obvious “*the start structure having a leading face extending below the upper surface to a lower surface of the start structure*” as claimed.

1[g] *the leading face including at least one partial curvate surface between the root and the crest,*

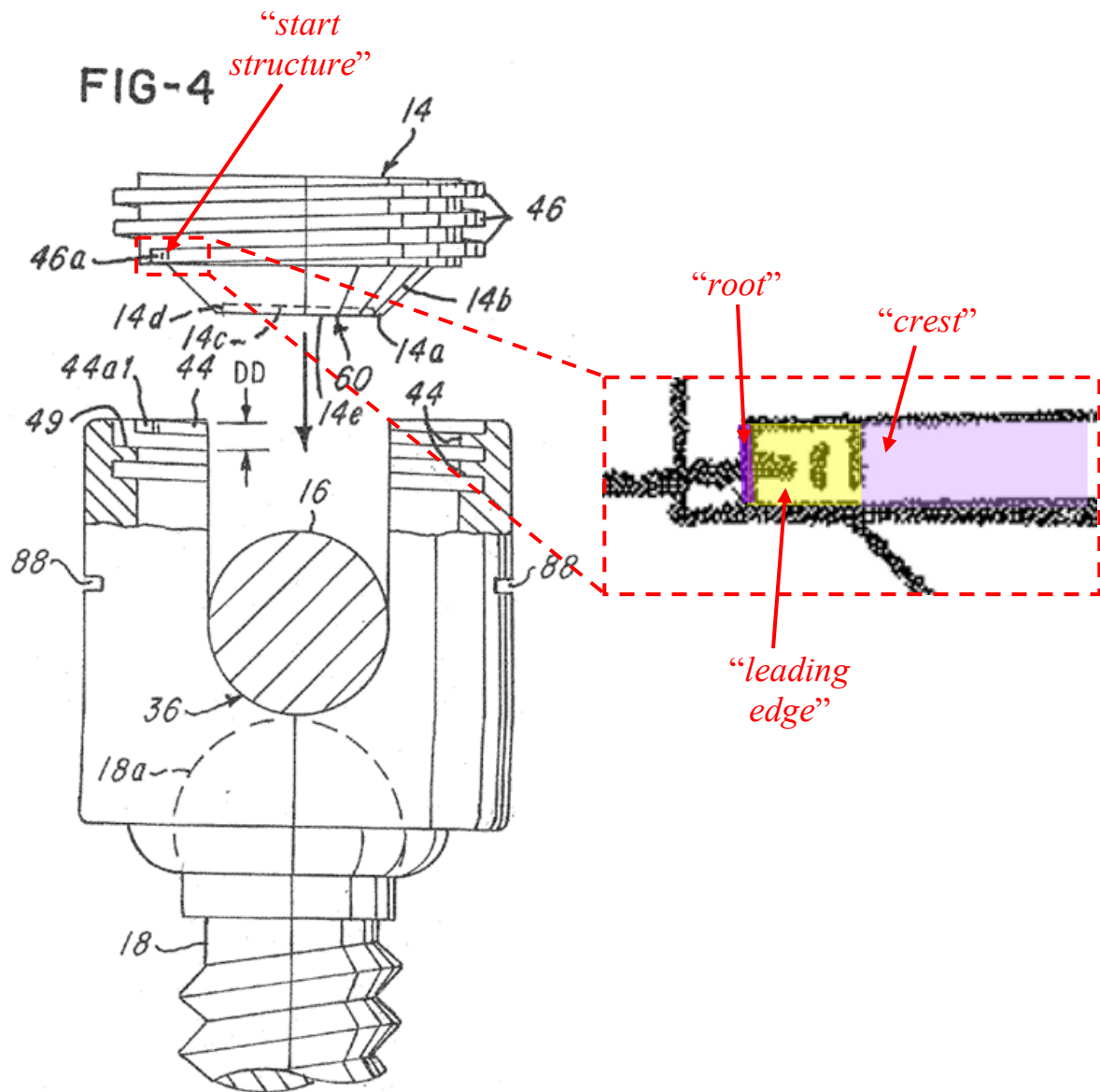
160. Kirschman renders obvious limitation 1[g].

161. As explained above in limitation 1[f], the leading edge portion 46a (“*start structure*”) of Kirschman has a lead surface at the end thereof that is a “*leading face*.” A POSITA would have understood that Figs. 3 and 4 clearly show that the lead surface (“*leading face*”) at the end of the leading edge portion 46a (“*start structure*”) includes “*at least one partial curvate surface between the root and the crest*.”

162. A POSITA would have understood that Figs. 3 and 4 of Kirschman below, show the leading edge portion 46a (“*leading face*”) is curved (“*at least partially curvate*”) between the “*root*” and the “*crest*” of the male cap thread 46 (“*continuously helically wound thread form*”):



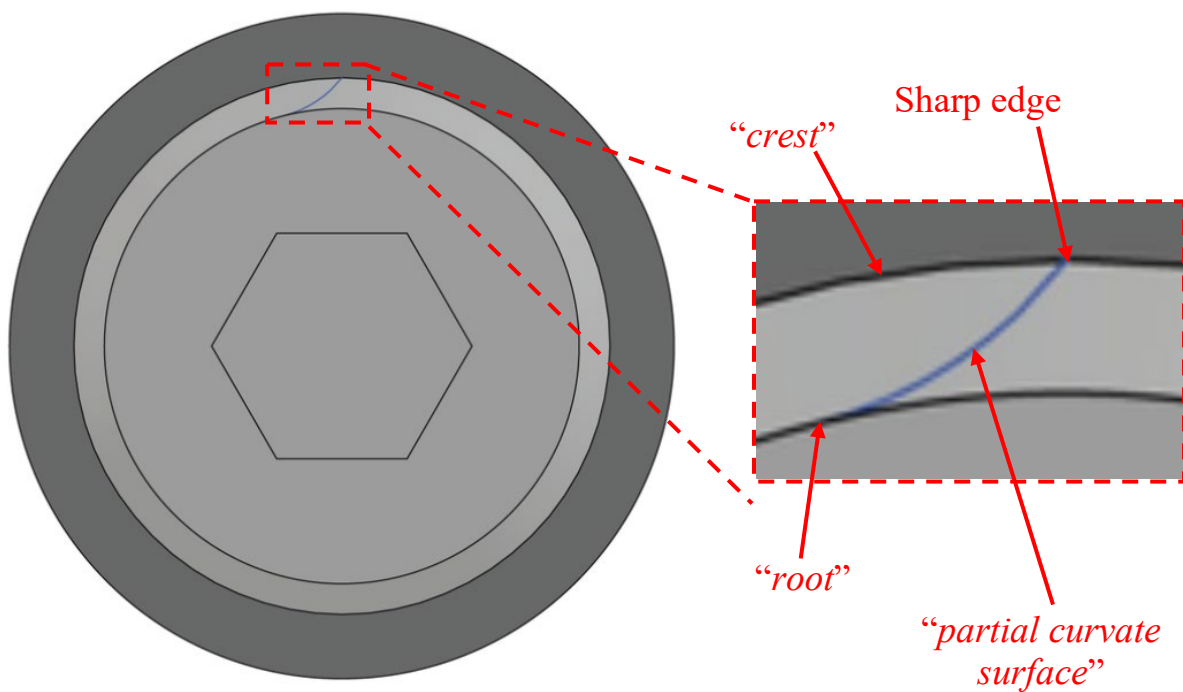
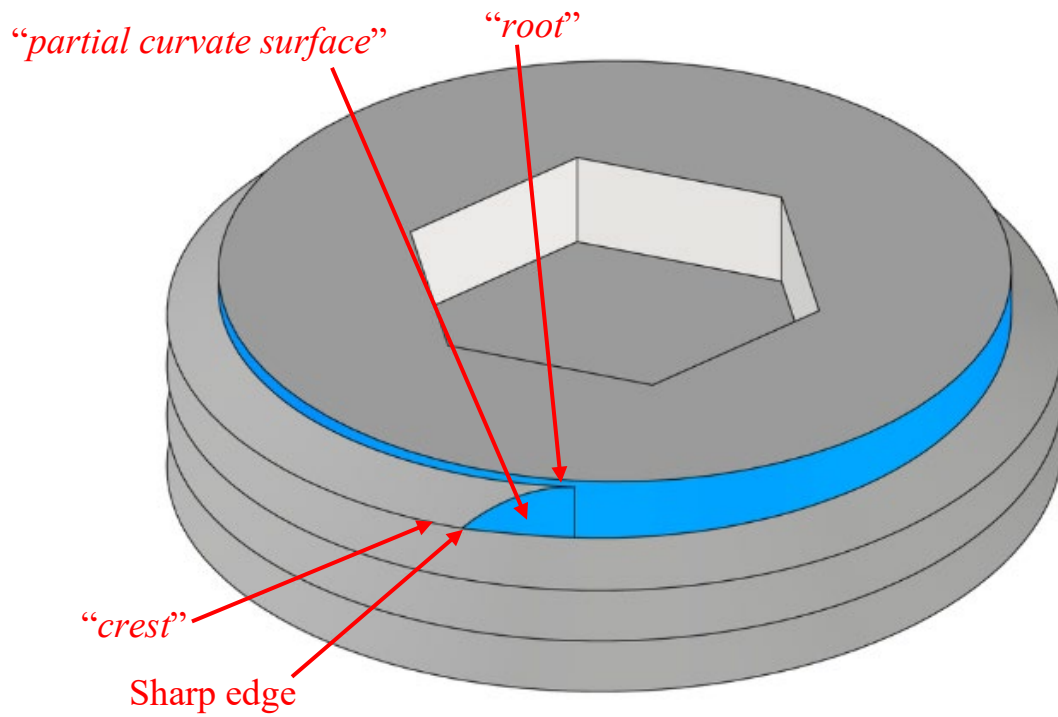
Kirschman (Ex.1005), Fig. 3 (annotated)



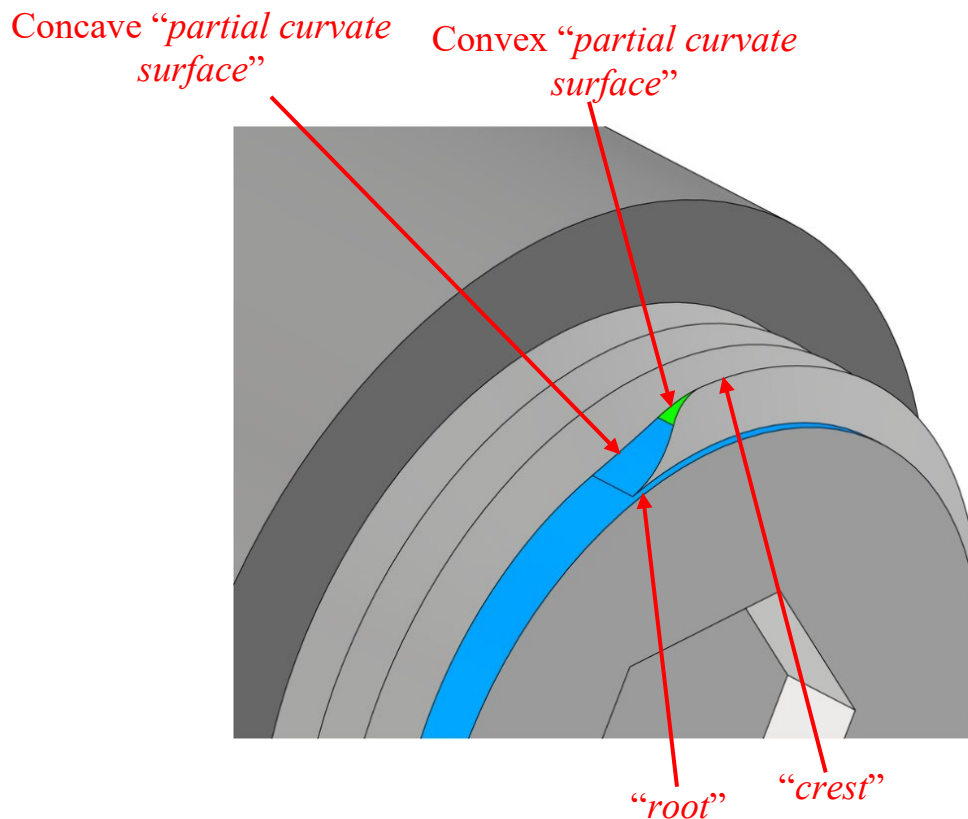
Kirschman (Ex.1005), Fig. 4 (annotated)

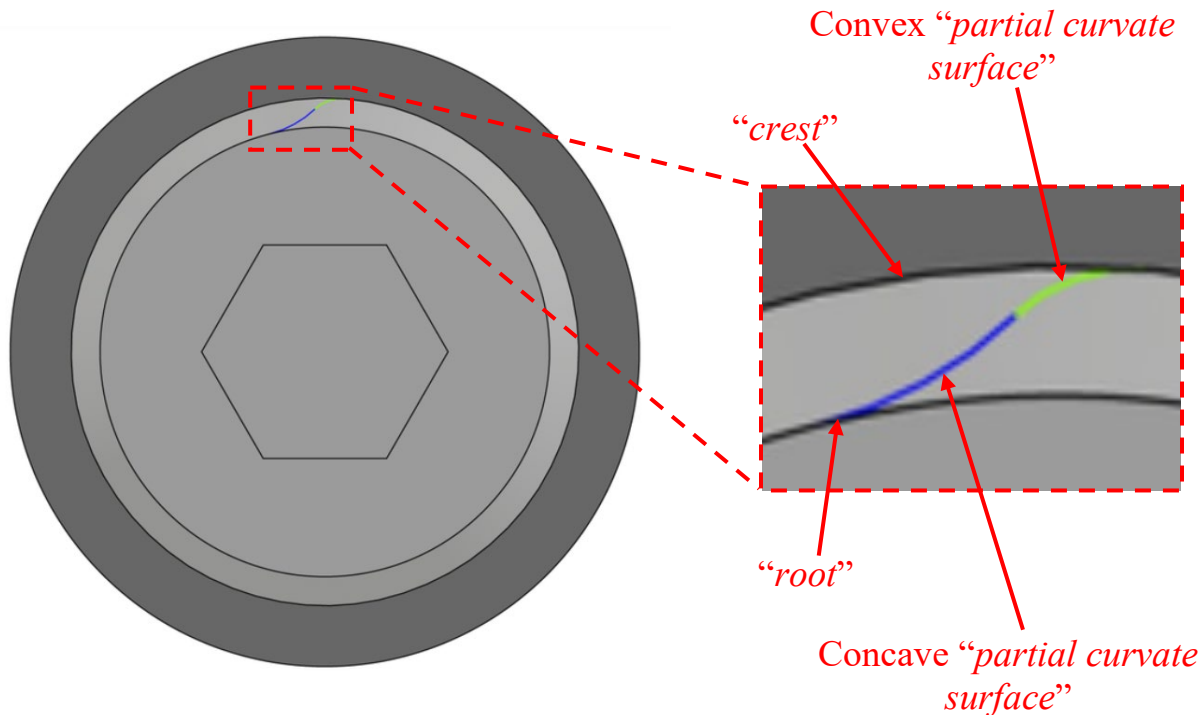
163. However, to the extent that Kirschman does not explicitly disclose that the leading face of the thread is “at least partially curvate,” this was well-known in the art. As explained above in Section VI.A., it was well-known in the art that a blunt thread start would have been formed such that “*at least one partial*

curvate surface” would have been formed between the root and the crest. In particular, a POSITA would have understood that blunt thread starts were generally formed by removing the thin, incomplete thread at the end of the thread with a circular tool. Because of the tool’s circular shape, the face of the blunt thread start would have been formed with a concave surface between the root and the crest such that it has a similar shape to the circular tool. *See* Ex.1012, [0034] (“Because the tool 10 carries the secondary cutter 28 in a radially outwardly disposed orientation, and at the completion of a thread cutting operation this tool is disengaged from the work piece 52 by the CNC milling machine effecting a quick radially outward relative motion (indicated by arrow 66) at the completion of the cutting of screw thread 50, **the starting end 50 a of screw thread 50 immediately adjacent to pilot portion 64 will inherently have a scalloped or concave blunt end surface which is of substantially full screw thread form.**”). The below graphics illustrate the leading face formed by the circular tool:



164. Moreover, it would have been obvious to a POSITA that, particularly in medical device applications, any sharp edges on the screw, including the sharp edge at the crest, would have been smoothed or rounded off with the circular tool to prevent the threads from cutting the glove or hand of the surgeon and to prevent irritation of the patient. This process of smoothing or rounding of the blunt thread start would have resulted in a convex curve proximate the crest of the thread, as shown in the below graphics:





165. The sharp edges would have been further smoothed using tumbling processes (*e.g.* electropolishing).

166. Moreover, a POSITA would have been motivated to combine the thread on Kirschman's cap member with the rounded blunt thread start disclosed in Higbee.

167. Kirschman incorporates the entirety of Higbee by reference:

Utilizing blunt-tip threads for the prevention of cross threading was first invented by Higbee in 1891 (U.S. Pat. No. 447,775). Myriad spinal screw designs have been put forth, exemplified by U.S. Pat. No. 5,474,555, however none address the combined issues of threaded cap

guidance, visual feedback, and tactile feedback. **All of these patents are incorporated herein by reference and made a part hereof.**

Ex.1005, [0009].

168. Because Kirschman specifically points to Higbee as being the first inventor of blunt-tip threads and describes using a “truncated” or blunt-tip thread (*see* Ex.1005, [0038]), a POSITA would have been motivated to look to Higbee for other ways of implementing the truncated thread described in Kirschman.

169. Moreover, Higbee aims to solve the same problem that Kirschman aims to solve. For polyaxial screws, Kirschman explains that “the threads of the locking cap and tulip must bear high torque loading which can result in cross-threading and/or thread failure upon initial thread engagement.” Ex.1005, [0005]. Kirschman explains that “[w]hat is needed, therefore, is a spinal implant incorporating a thread design that prevents cross threading of the small-pitch threads of the locking cap/tulip pair, achieves high connection strength immediately after initial thread engagement and offers improved tactile feedback of thread engagement to the surgeon.” Ex.1005, [0008].

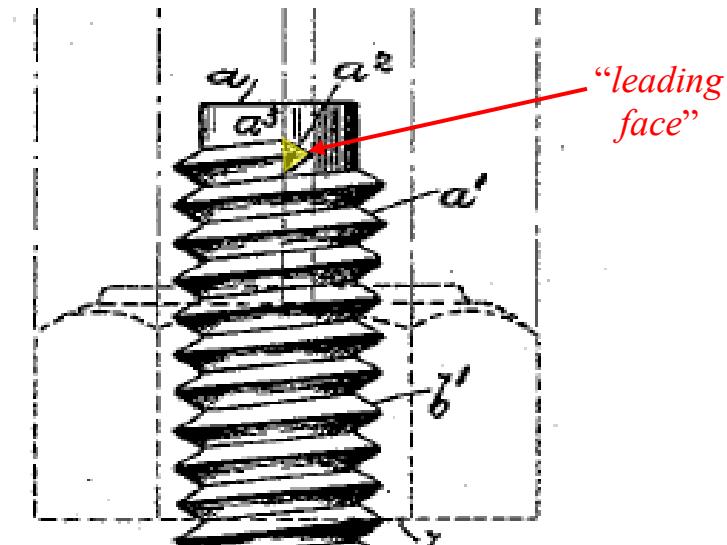
170. Similarly, Higbee “relates to screw-coupling devices, of which the screw bolt and nut are the most familiar examples, but which include as well all threaded coupling devices made up of two parts having, respectively, male and female screw-threads.” Ex.1006, 1:10-15. Higbee explains that, in previous designs, “the thread is usually turned in or on a cylindrical or annular part prepared

to receive it, and at the end of said part the thread merges gradually in its face,” which results in “the end of the thread [being] for some distance very thin.” Ex.1006, 1:21-30. “As a result of this mode of construction the two parts of the screw-union can be and frequently are put together wrongly” and “the thin end of the thread is so situated as to be most exposed to injury, and having but little strength it is very apt to get bent or broken.” Ex.1006, 1:26-38. Higbee’s invention overcomes these problems by “terminating the thread below the face-level of the cylinder or annulus on or in which it is formed, and forming the extreme end so that it will have a broad blunt face lying symmetrically on each side of the centerline of the thread.” Ex.1006, 1:40-45. This ensures that “the ends of the threads are made strong, stout, and of substantially the same cross-section as the thread itself, and the two parts of the union are fitted together with automatic precision, so that there is the least possible risk of jamming or breaking the thread.” Ex.1006, 1:46-52.

171. Thus, like Kirschman, Higbee also describes the problems of properly threading a screw into a coupling and having threads that are prone to failure. Higbee provides a solution to this problem: a screw with a blunt-tip thread that is stronger and less prone to breaking and cross-threading. Thus, a POSITA would have been motivated to look to Higbee for other blunt-tip thread designs that could have been used in Kirschman’s polyaxial bone screw design.

172. A POSITA would have understood that rounding the leading face of the thread start (as shown in Fig. 6 of Higbee) would have avoided sharp edges, which could have cut a surgeon's glove or hand or irritated the patient's skin, and would have improved insertion of Kirschman's cap 14. It would have been within the skill of a POSITA to manufacture a screw (e.g., Kirschman's cap 14) so that the leading edge of the thread (e.g., Kirschman's leading edge portion 46a) would have been rounded as described in Higbee.

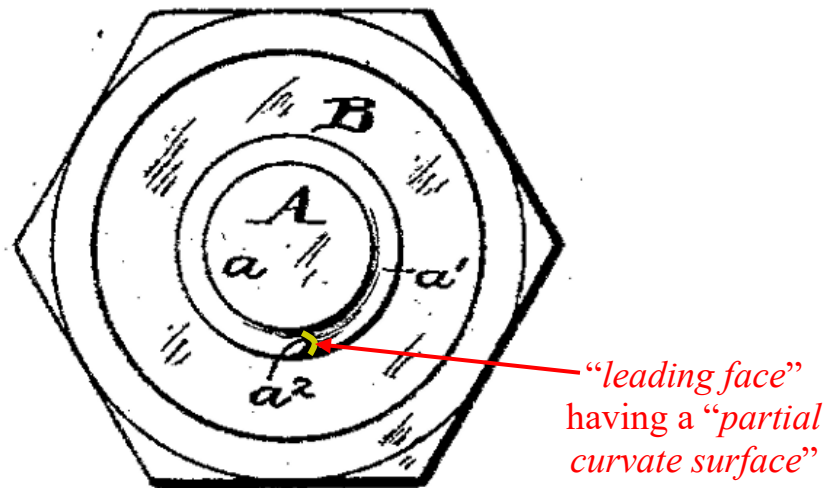
173. In particular, Higbee describes “**terminating the thread** below the face-level of the cylinder or annulus on or in which it is formed, and forming the extreme end **so that it will have a broad blunt face** lying symmetrically on each side of the centerline of the thread.” Ex.1006, 1:40-45; *see also* 1:67-68 (“A is the bolt, *a* its end, *a'* its thread, and ***a*² the thread end**”). Thus, the “broad blunt face” or “thread end *a*²” would be a “*leading face*” of the thread *a'*, as shown in Fig. 1 below:



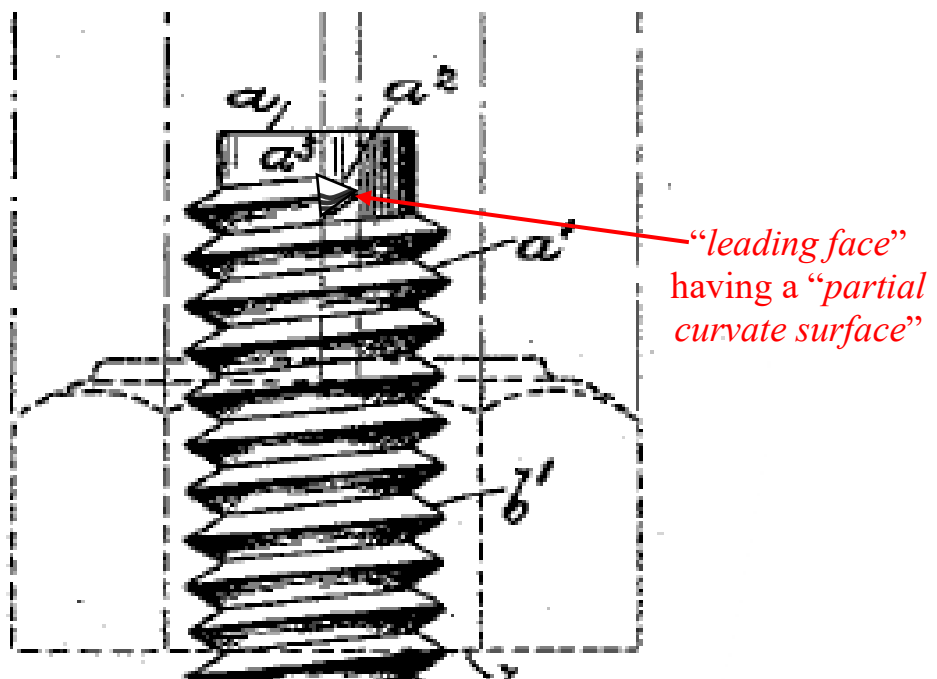
Higbee (Ex.1006), Fig. 1 (cropped and annotated)

174. The blunt thread start in Fig. 1 is “cut off on an oblique plane.”

Ex.1006, 1:92-93. However, Higbee explains that “[t]he exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread.” Ex.1006, 1:88-92. For example, the thread end “may be...rounded, as in Fig. 6.” Ex.1006, 1:92-94. Thus, the thread end a^2 (“leading face”) can be rounded (“at least partially curvate”), as shown in Fig. 6 below:

FIG. 6.**Higbee (Ex.1006), Fig. 6 (annotated)**

175. To further illustrate this rounded blunt thread start, I modified Fig. 1 below to show the thread with the rounded blunt thread start of Fig. 6:



Ex.1006, Fig. 1 (cropped, modified, and annotated)

176. Thus, to the extent Kirschman does not disclose a “*leading face including at least one partial curvate surface between the root and the crest,*” a POSITA would have been motivated to form Kirschman’s leading edge portion with a curved or rounded face as disclosed in Higbee according to his own knowledge. This would have simply included replacing the shape of Kirschman’s leading edge portion 46a with a curved or rounded face between the root and the crest, as was known in the art.

177. Therefore, because Kirschman discloses a truncated leading edge portion 46a of the male cap threads 46 having a lead surface at the end that is illustrated as being curved between the root and the crest and, alternatively, Higbee discloses a thread end a^2 that is rounded and a POSITA would have known that a blunt thread start could have been formed with a partial curvate surface, Kirschman renders obvious “*the leading face including at least one partial curvate surface between the root and the crest*” as claimed.

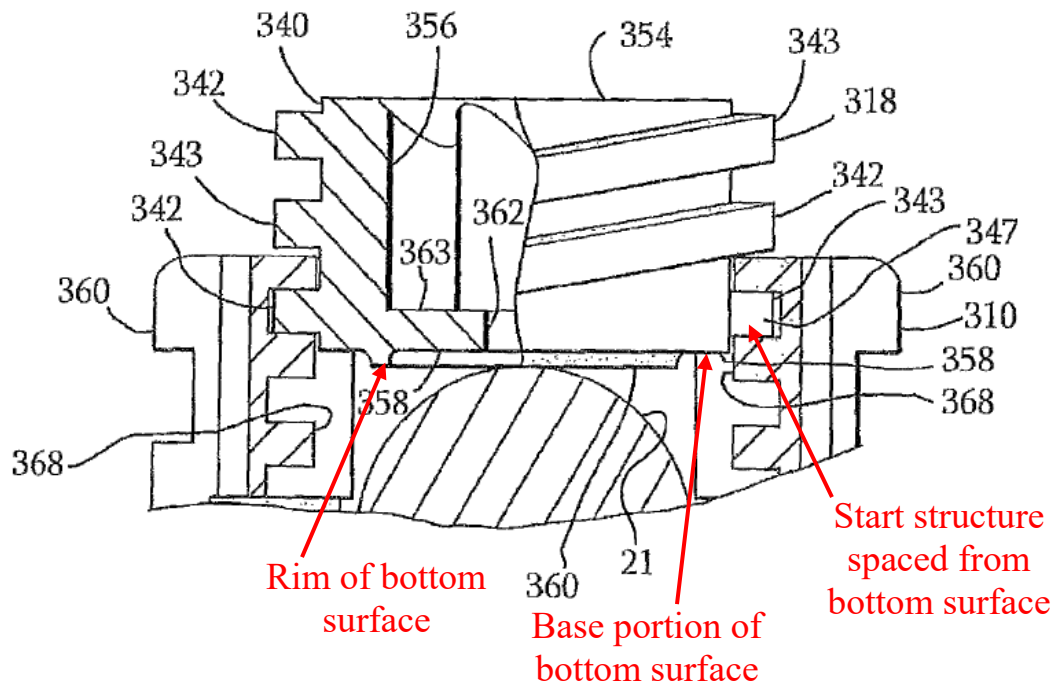
1[h] *the lower surface of the start structure being spaced apart and above the annular outer edge of the bottom surface of the plug so as to not be connected with the annular outer edge thereof.*

178. Kirschman renders obvious limitation 1[h].

179. As explained above in limitation 1[d], the ’873 Patent does not explain whether the “*annular outer edge*” refers to the edge of the base portion or

the rim of the bottom surface. The '873 Patent also does not explain what it means for *“the lower surface of the start structure”* to be *“spaced apart and above the annular outer edge....so as not to be connected therewith.”* Fig. 11 of the '873 Patent illustrates an embodiment in which both the exemplary bottom surfaces are spaced apart from the start structure 347:

Fig. 11.



Ex.1001, Fig. 11 (annotated)

180. As explained above in limitation 1[d], Kirschman discloses a closure with a bottom surface that is substantially similar to the closure embodiments in the '873 Patent.

181. As explained above in limitation 1[d], Kirschman discloses that a

bottom 14b of the cap 14 (“*plug*”) includes a guiding surface at the end 14c (“*bottom surface*”) that further includes a deformable ring 14d (“*annular outer edge*”).

182. Kirschman explains that the guiding surface is, for example, frustoconical and facilitates guiding of the cap 14 (“*plug*”) into the receiver 12 and alignment of the leading edge portion 46b (“*start structure*”) of the male cap threads 46 with the threads 42, 44 of the receiver 12:

As illustrated in FIGS. 1, 3 and 4, note that **a bottom 14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a with the cut-out area 49 of the receiver 12 so that the cap 14 can be easily guided and screwed onto the receiver 12.** In the embodiment being described, notice that **the bottom 14b is frustoconical**, but it should be understood that **the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12.** For example, the surface could have an arcuate, curved or semi-spherical shape such that the bottom 14b is adapted to facilitate aligning and guiding the cap 14 onto the receiver 12 so that the cap 14 can be easily screwed onto the receiver 12.

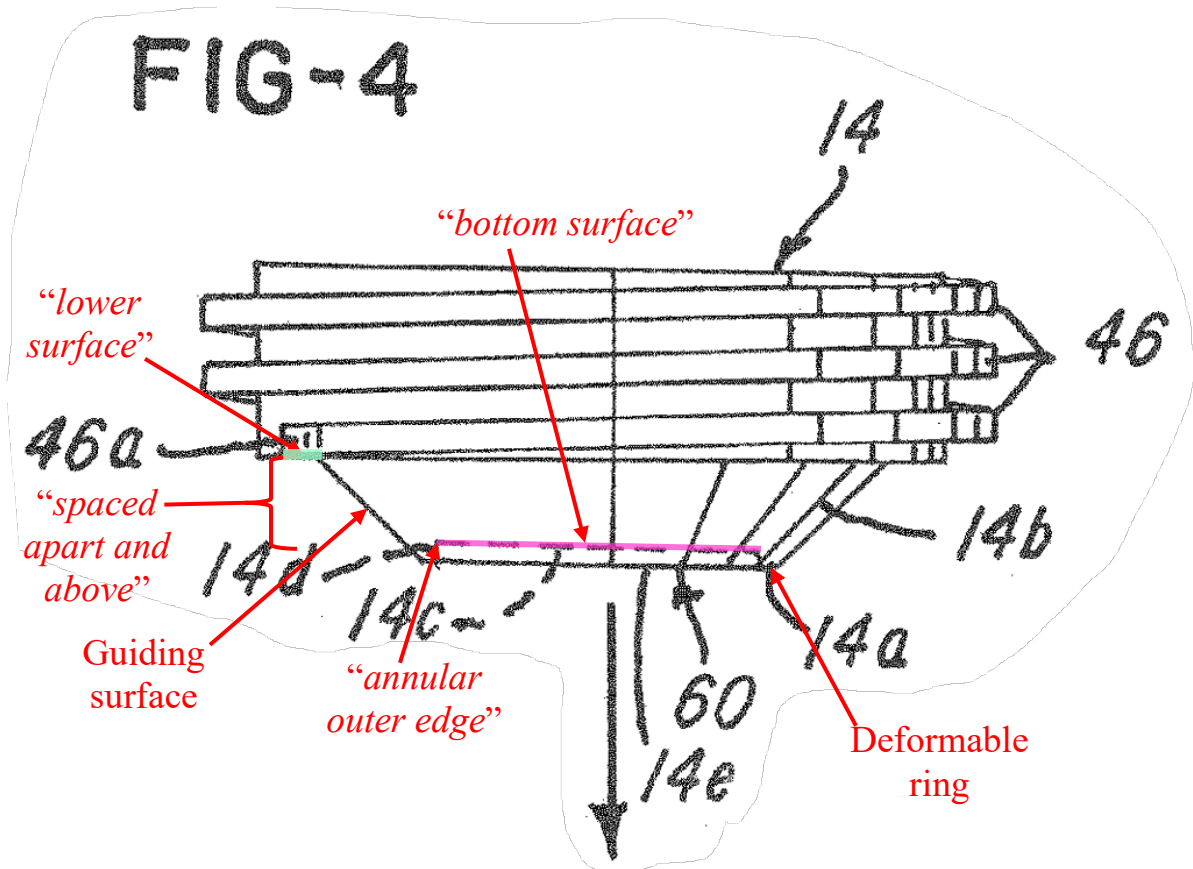
Ex.1005, [0043].

During use, the polyaxial screw 18 is received in the bore 22 and the head 18a is received in a seat 12c of the receiver 12. The polyaxial screw 18 is screwed into bone and the receiver 12 receives the rod 16

and the receiver 12 and rod 16 are positioned in a manner conventionally known. **The cap 14 is received on a tool and the user guides the cap 14 into the bore 22 using the tactile feedback that the bottom 14b provides as it engages and guides the cap 14 as it engages the second arcuate wall threads 44 in the receiver 12 and guides the cap 14 into alignment for threading in the receiver 12.** After the positioning is achieved, the surgeon or user may use the at least one or a plurality of the tactile feedback in the form of the truncated leading edge portion 46a and which is aligned in the cut-out area 49. The user may use the indicia 50 to facilitate aligning the thread and the tactile feedback of the cap 14 dropping down in the receiver 12 the drop down distance DD (FIG. 4) as the cap 14 is positioned on the receiver 12.

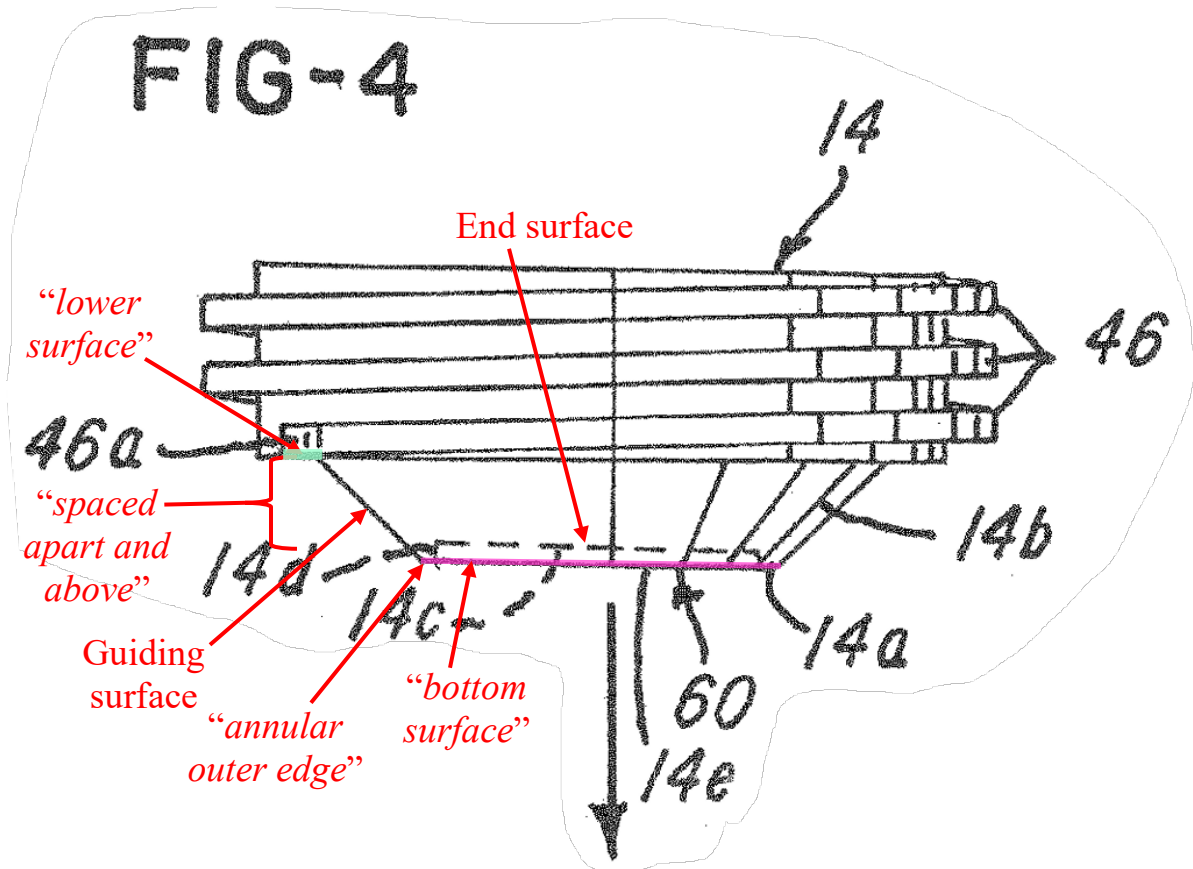
Ex.1005, [0049].

183. Because the frustoconical guiding surface of the bottom 14b provides this tactile feedback that guides the cap 14 (“*plug*”) into the receiver 12, the “*lower surface*” of the leading edge portion 46a (“*start structure*”) is “*spaced apart and above*” the bottom edge 14e of the deformable ring 14d (“*annular outer edge*”) and the end 14c (“*bottom surface*”) by the frustoconical guiding surface. Below shows this spacing under the first interpretation in which the end surface is the “*bottom surface*” and the edge thereof is the “*annular outer edge*”:



Ex.1005, Fig. 4 (cropped and annotated)

184. Below shows this spacing under the second interpretation in which the bottom surface of the deformable ring is the “*bottom surface*” and the bottom edge 14e thereof is the “*annular outer edge*”:

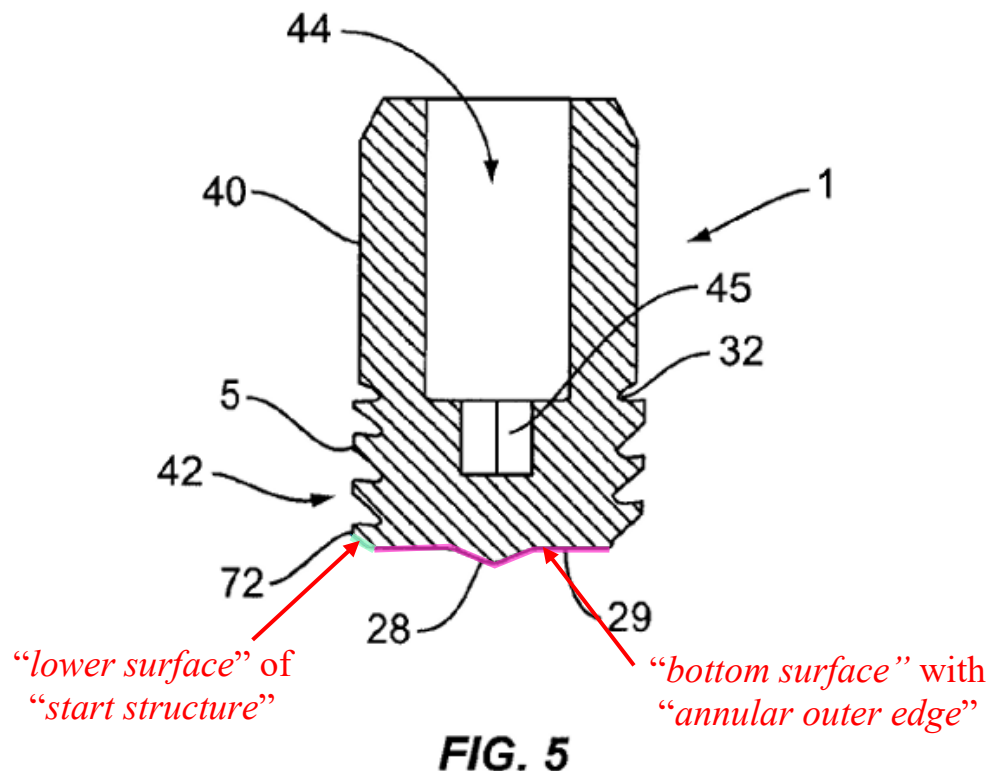


Ex.1005, Fig. 4 (cropped and annotated)

185. Thus, the “*lower surface*” of the leading edge portion 46a (“*start structure*”) is not “*connected with*” the end surface 14c or the deformable ring 14d surrounding it.

186. Additionally, Kirschman’s cap 14 is different from the closures that PO indicated did not have a start structure “*spaced apart and above*” the “*annular outer edge of the bottom surface so as not to be connected with the annular outer edge thereof*” during prosecution of the ’499 Application (parent to the ’873 Patent).

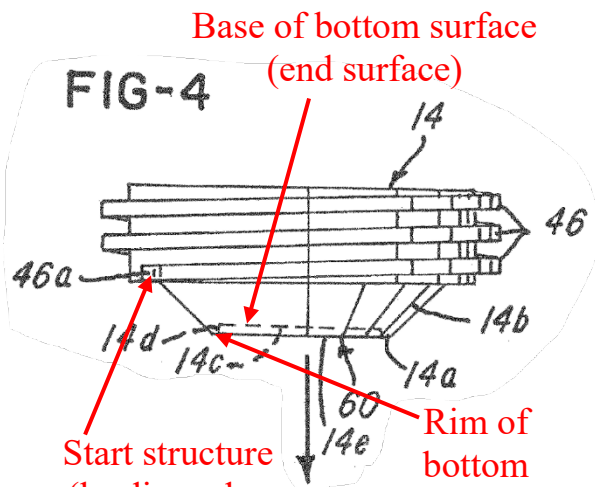
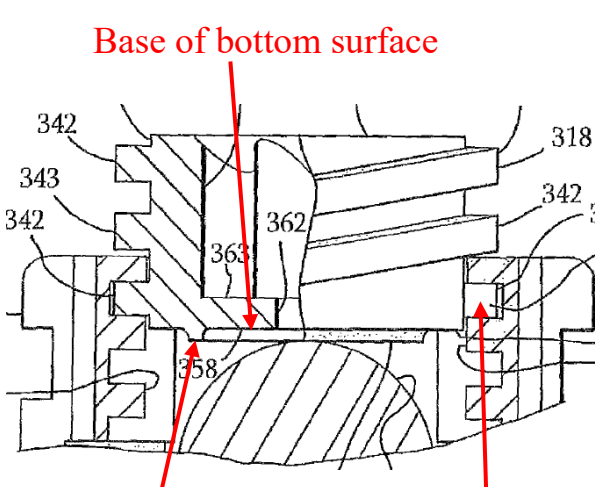
187. During prosecution of the '499 Application, PO distinguished this limitation from the cited references. *See* Section V.B. *supra*. PO asserted that the cited reference, Prevost, did not anticipate the claim limitation because “[t]he surface identified by the Examiner is contiguous with the bottom end 29 of the set screw 1” and, thus, “the surface of the external thread 5 and the bottom end 29 adjoin each other.” Ex.1004, 73; *see also* 76. PO specifically pointed to Fig. 5 of Prevost as showing a lower surface of a start structure that is not “*spaced apart and above*” the annular outer edge of the bottom surface. Ex.1004, 73-74; *see also* 76. As shown in Fig. 5 of Prevost below, the lower surface of the start structure extends to the annular outer edge of the bottom surface:



Prevost (Ex.1013), Fig. 5 (annotated)

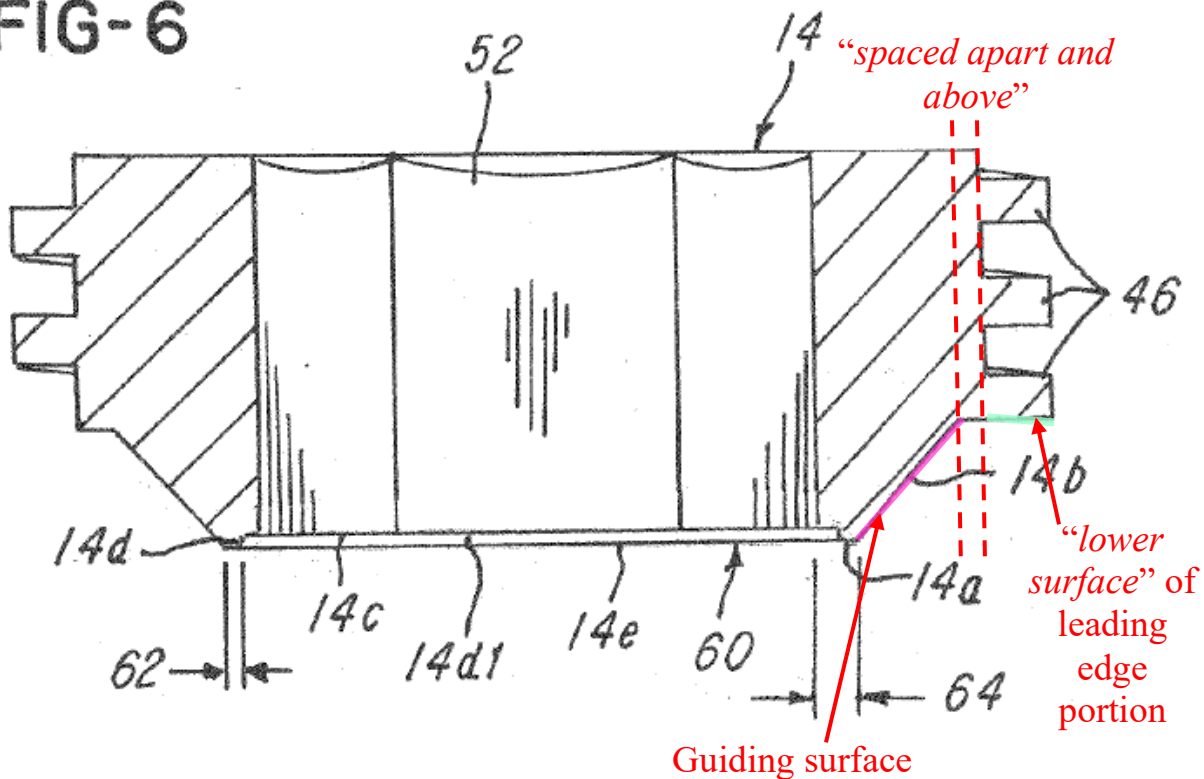
188. Unlike Prevost, the guiding surface in Kirschman spaces the leading edge portion 46a so that it is not connected to the end surface 14c or the deformable ring 14d. *See* Ex.1005, Fig. 4.

189. Thus, Kirschman's cap includes the same structure as the '873 Patent's closures:

Kirschman (Ex.1005), Fig. 4 (annotated)	'873 Patent (Ex.1001), Fig. 11 (cropped and annotated)
 FIG-4 Base of bottom surface (end surface) Start structure (leading edge portion) spaced above both parts of bottom surface Rim of bottom surface (deformable ring) Labels: 14, 46a, 14d, 14c, 14b, 14e, 60, 46	 Base of bottom surface Rim of bottom surface Start structure spaced above both parts of bottom surface Labels: 342, 343, 318, 362, 363, 358, 3

190. Moreover, to the extent PO asserts Kirschman's guiding surface is the only surface that can be the claimed "*bottom surface*," as set forth below, the start structure leading edge portion 46a is still "*spaced apart and above*" the top of the

guiding “so as to not be connected” thereto. As shown in Fig. 6 below, the diameter of the cap at the top of the guiding surface is smaller than the diameter of the cap at the root of the threads:

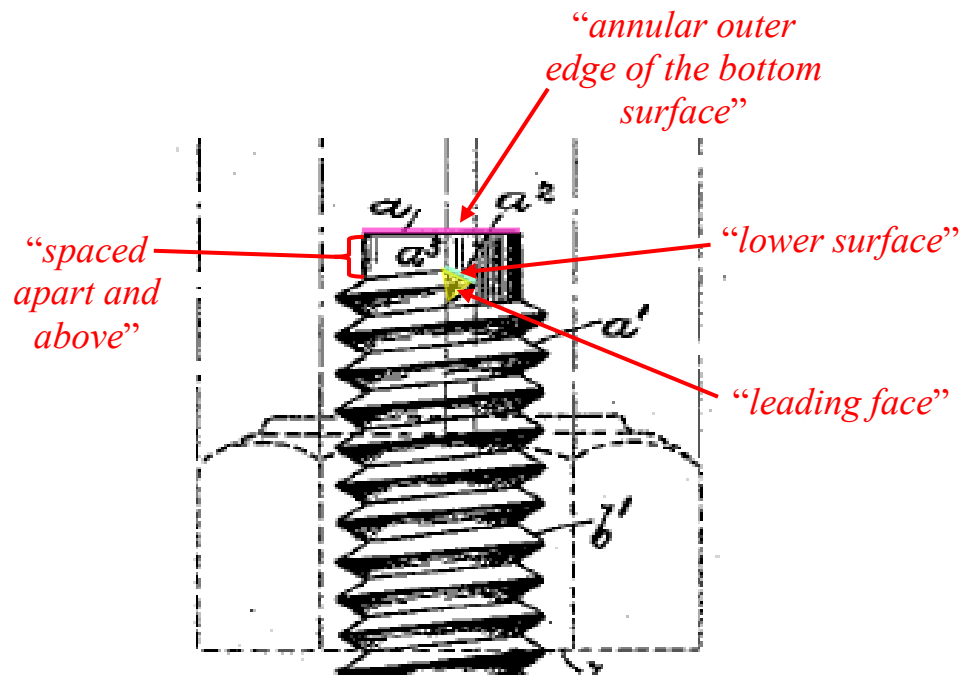
FIG-6**Kirschman (Ex.1005), Fig. 6 (annotated)**

191. Thus, the lower surface of the thread start leading edge portion 46a is “spaced apart and above” the guiding surface such that it is not “connected” thereto.

192. Moreover, to the extent PO argues that the Kirschman embodiment of Figs. 1-7 does not explicitly teach that “the lower surface of the start structure [is] spaced apart and above the annular outer edge of the bottom surface,” it was well-

known in the art that a cylindrical guiding surface would have been formed when removing the incomplete thread upward from the bottom surface during formation of the Higbee cut, as described above in Section VI.A.

193. As explained above in limitation 1[d], Higbee describes “terminating the thread below the face-level of the cylinder or annulus on which it is formed.” Ex.1006, 1:40-42. For example, “ a^3 , Fig. 1, is a cylindrical extension of the internal diameter of the nut-thread between the thread end a^2 and the bolt end a .” Ex.1006, 1:69-71. Accordingly, “in Fig. 1 **the thread end begins at some little distance below the face a .**” Ex.1006, 1:81-83. Higbee explains that “[b]y leaving the smooth extensions a^3 or b^3 as shown **the nut and bolt or their equivalents are brought together and properly aligned before the thread ends engage, and thus an additional safeguard against misadjustment is provided.**” Ex.1006, 1:83-88. Thus, the thread end a^2 (“*leading face*”) is “*spaced apart and above*” the bolt end a (“*bottom surface*”) by the cylindrical extension a^3 , as shown in Fig. 1 of Higbee below:



Higbee (Ex.1006), Fig. 1 (cropped and annotated)

194. Note, the blunt thread start in Fig. 1 includes oblique planes; however, this spacing would apply equally to the rounded blunt thread start shown in Fig. 6.

195. As explained above in limitation 1[d], a POSITA would have been motivated to modify Kirschman's guiding surface to be cylindrical as described in Higbee, thereby spacing Kirschman's leading edge portion 46a above the bottom surface. This would have included spacing the leading edge portion 46a above both the deformable ring 14d and the end surface 14c (as already described in Kirschman) or even spacing the leading edge portion 46a above the guiding surface, depending on the constraints of the particular polyaxial screw the POSITA would have been designing. For example, a POSITA may have wanted to include

an additional guiding surface to further improve the tactile feedback of Kirschman's polyaxial screw by including an additional guiding surface that is cylindrically shaped and extends between the frustoconical guiding surface and the leading portion of the thread.

196. Therefore, because Kirschman discloses a guiding surface, which can be modified to be cylindrical as disclosed in Higbee, that separates the deformable ring 14d and end surface 14c from the leading edge portion 46a of the male cap threads 46, Kirschman renders obvious "*the lower surface of the start structure being spaced apart and above the annular outer edge of the bottom surface of the plug so as to not be connected with the annular outer edge thereof*" as claimed.

3. Claim 2

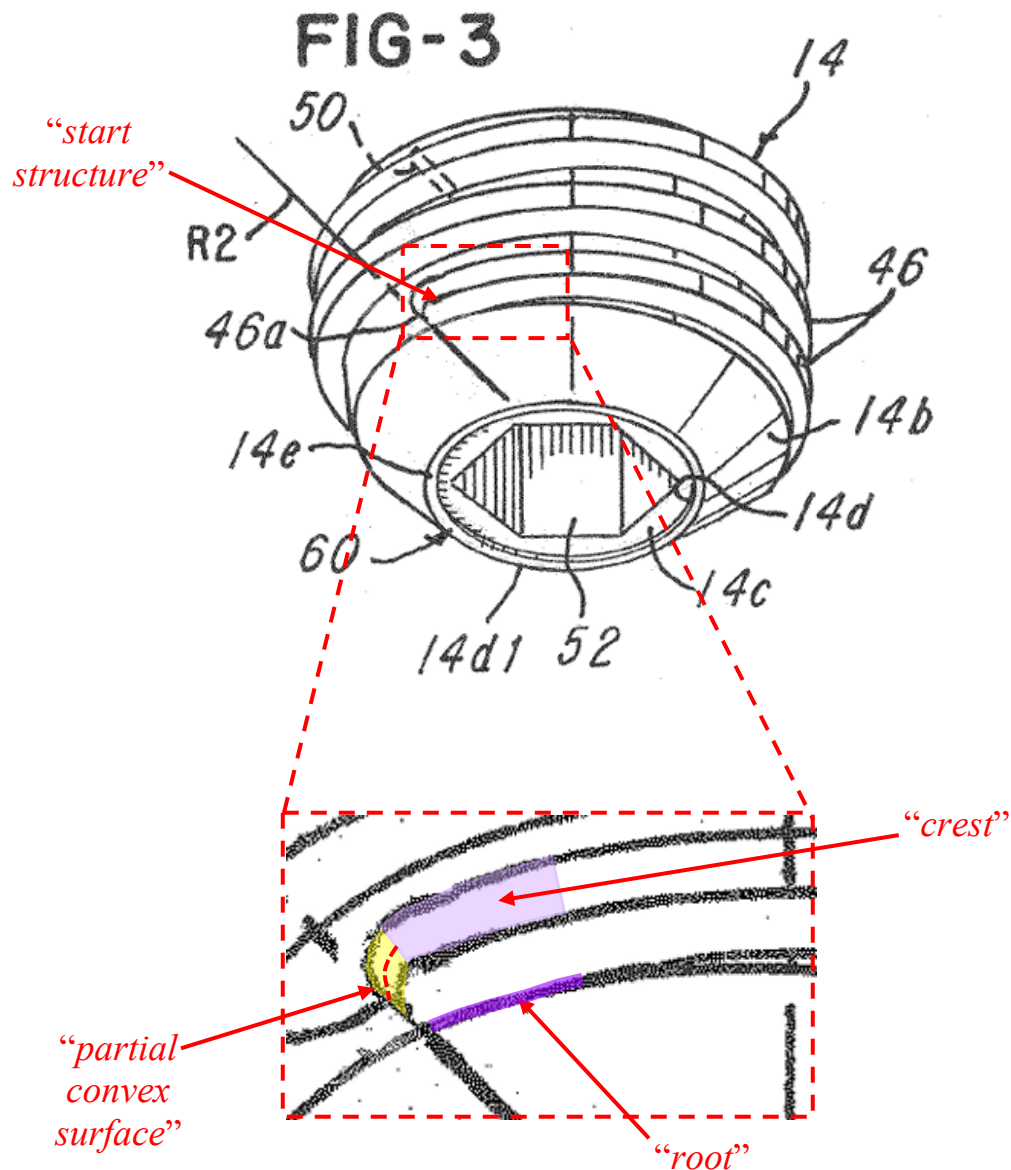
2[a] *The medical implant assembly of claim 1, wherein the at least one partial curvate surface is one of a partial concave surface or a partial convex surface.*

197. Kirschman renders obvious limitation 2[a].

198. As explained above in limitation 1[g], a POSITA would have understood that Figs. 3 and 4 of Kirschman show the lead surface at the end of the leading edge portion 46a ("*start structure*") has "*at least one partial curvate surface between the root and the crest.*"

199. Similarly, a POSITA also would have understood that Fig. 3 of Kirschman illustrates the face ("*leading face*") of the leading edge portion 46a ("*start structure*") as curving outward from the leading edge portion 46a ("*start*

structure”), i.e. having a “partial convex surface,” as shown below:

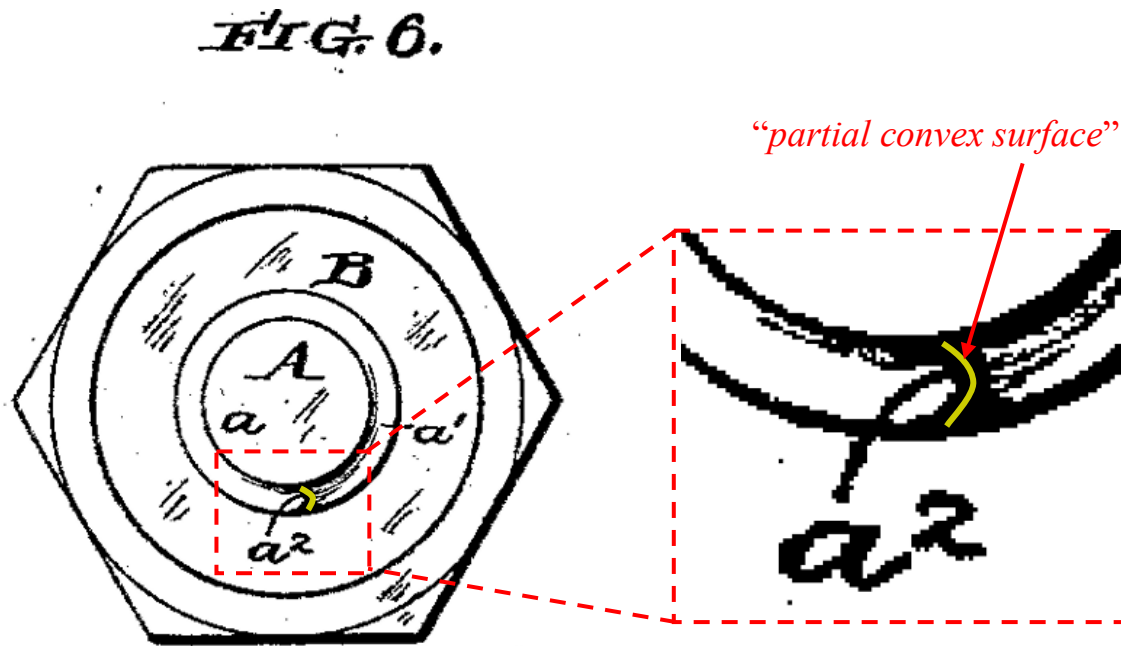


Kirschman (Ex.1005), Fig. 3 (annotated)

200. To the extent Kirschman does not explicitly disclose the face of the leading edge portion being “partial convex surface,” it was well-known to form blunt thread starts with “partial convex surface[s].” For example, as explained

above in limitation 1[g], Higbee discloses that the broad blunt face of the thread end a^2 is rounded and, thus, has an “*at least partial curvate surface.*”

201. A POSITA would have understood that Fig. 6 clearly illustrates the rounded thread end a^2 as curving outward from the thread a' , i.e. having a “*partial convex surface,*” as shown below:



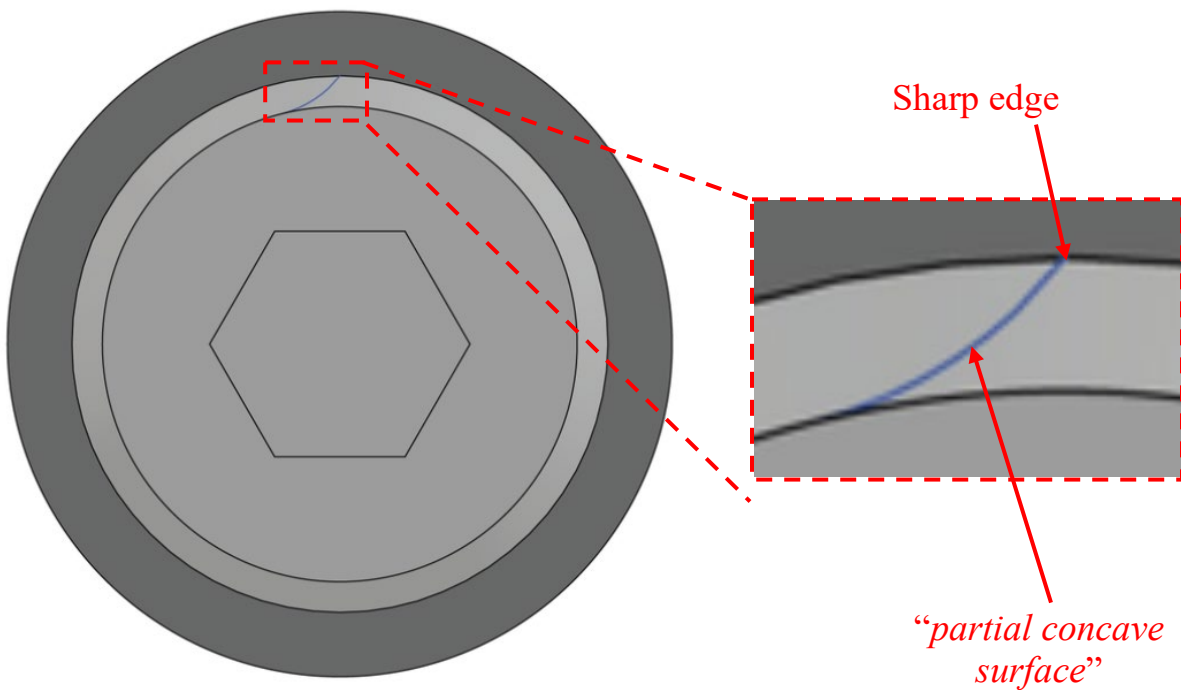
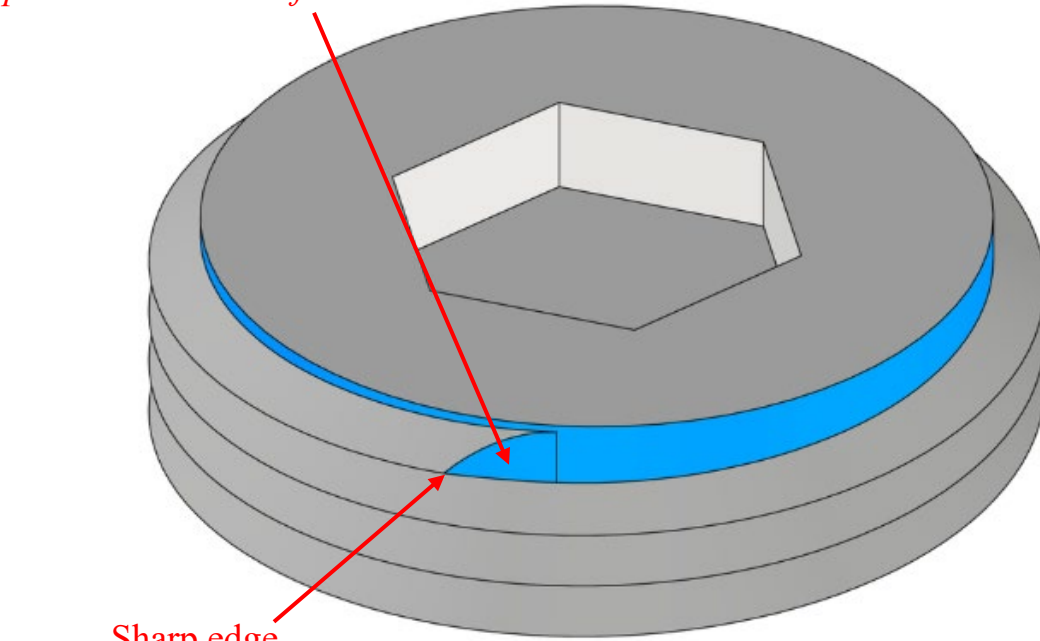
Higbee (Ex.1006), Fig. 6 (annotated)

202. Moreover, as explained above in Section VI.A., it was well-known in the art that a blunt thread start would have been formed such that the “*partial curvate surface is one of a partial concave surface or a partial convex surface.*”

For example, a POSITA would have understood that blunt thread starts are generally formed by removing the thin, incomplete portion of the thread with a circular tool such that a concave surface is formed, as shown in the graphics below:

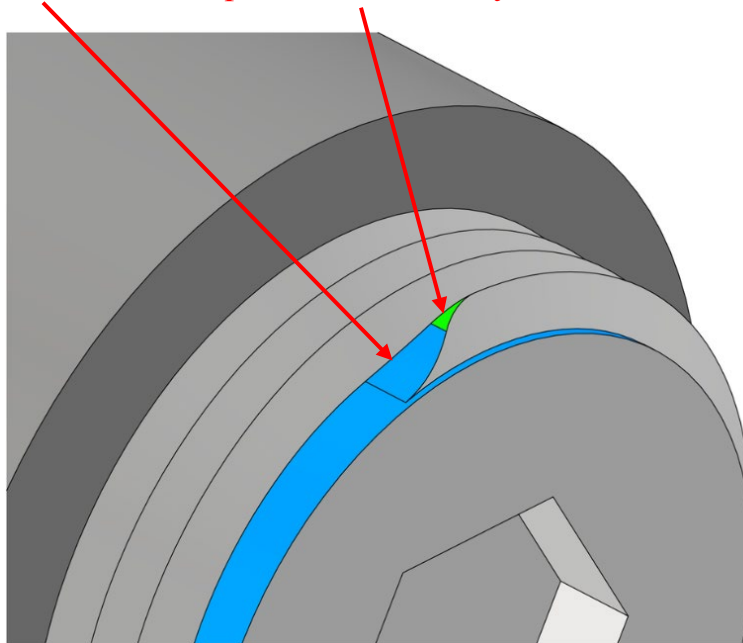
“partial concave surface”

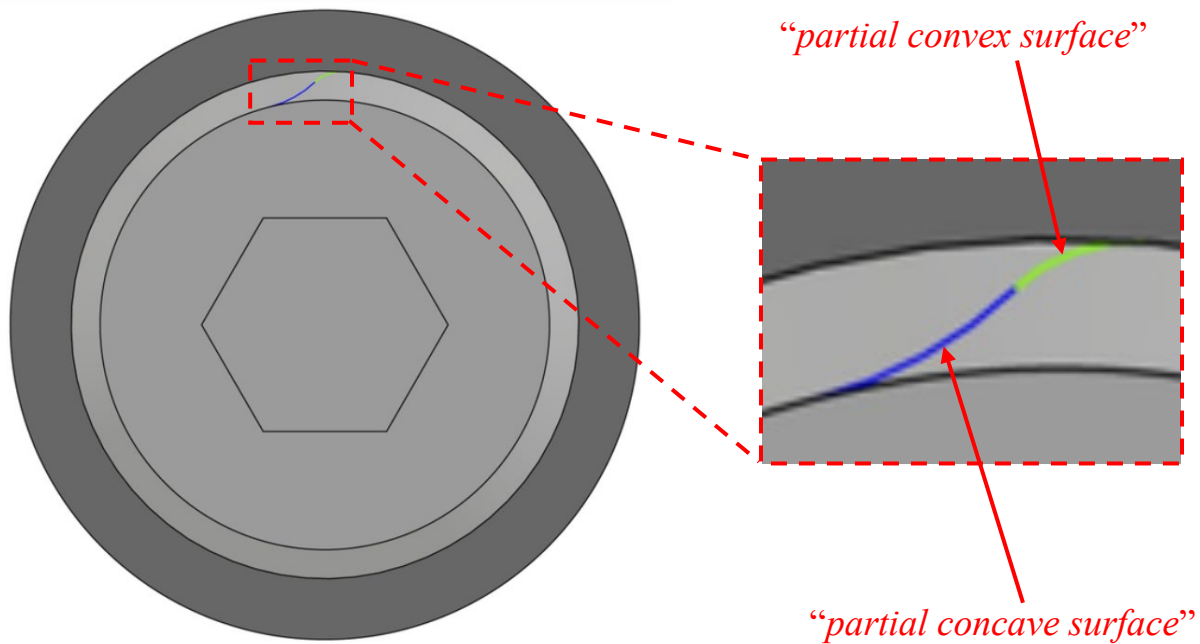
Sharp edge



203. A POSITA would have known that a fully-concave leading face would have formed a sharp edge proximate the crest. Thus, a POSITA would have smoothed or rounded off the sharp edge using the same circular tool to prevent the threads from cutting the glove or hand of the surgeon and to prevent irritation of the patient. Thus, a POSITA would have known that a convex surface would have been formed proximate the crest when removing the sharp portion and a concave surface would have been formed proximate the root, as shown in the graphics below:

“partial concave surface” *“partial convex surface”*





204. Therefore, because Kirschman discloses a truncated leading edge portion 46a of the male cap threads 46 having a lead surface at the end that is illustrated as being a convex curve, Higbee discloses a rounded thread end a^2 that is illustrated as being a convex curve and a POSITA would have known that that a blunt thread start would have been formed with a concave surface and/or a convex surface, Kirschman renders obvious *“wherein the at least one partial curvate surface is one of a partial concave surface or a partial convex surface”* as claimed.

4. Claim 4

4[a] *The medical implant assembly of claim 1, wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by*

the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.

205. Kirschman renders obvious limitation 4[a].

206. As explained above in limitation 1[a], Kirschman's receiver 12 ("receiver") includes arcuate walls 38, 40 and U-shaped walls 30, 32 that define an "upper portion" of the receiver 12 ("receiver"). As explained above in limitation 1[b], Kirschman's receiver 12 ("receiver") also includes a rod-receiving channel 28 ("channel") that is defined by the U-shaped walls 30, 32.

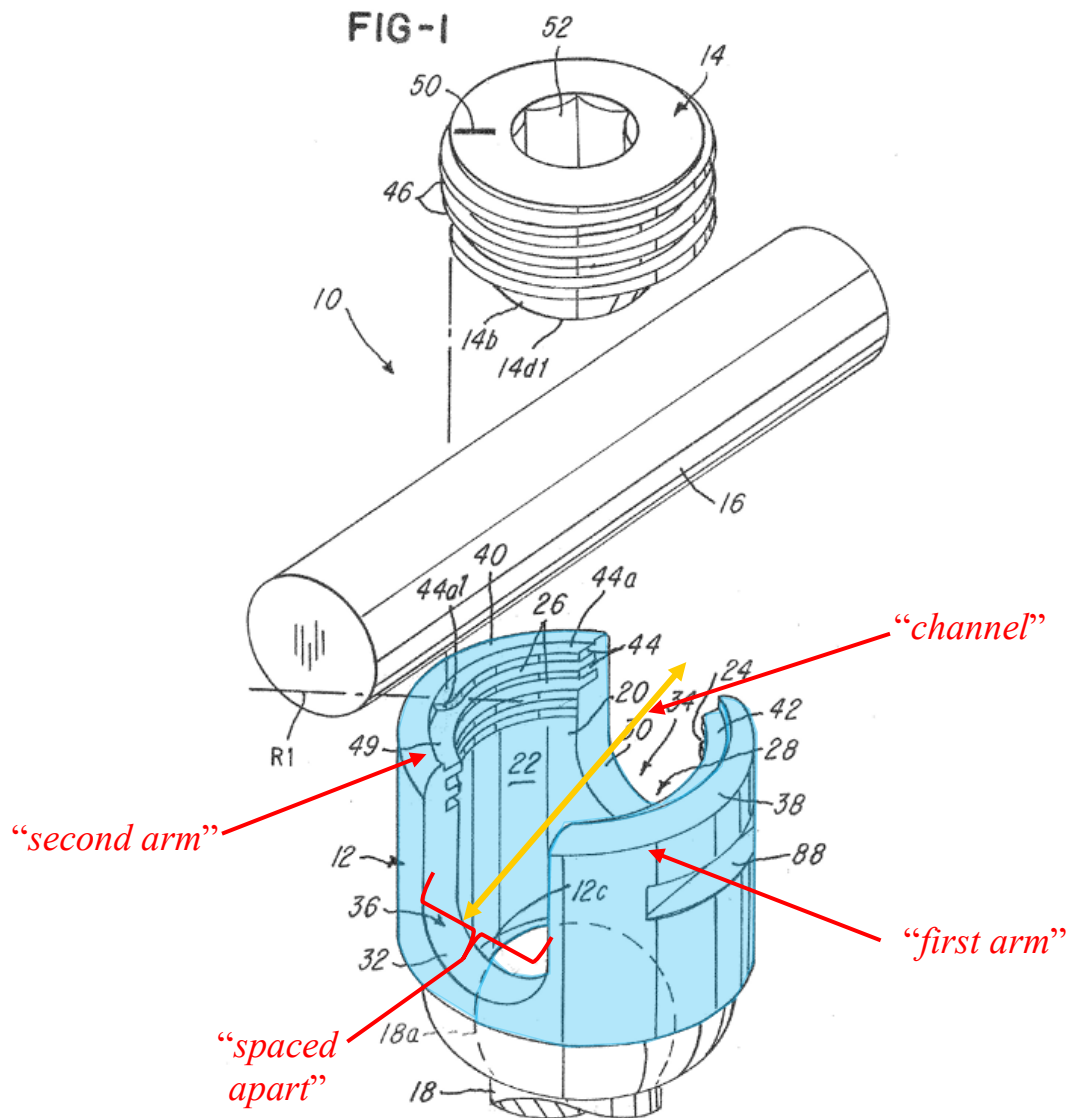
207. **First**, Kirschman discloses "*wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel.*" Kirschman explains that the receiver 12 ("receiver") includes a first arcuate wall 38 ("*first arm*") and a second arcuate wall 40 ("*second arm*") that are disposed between the U-shaped walls 30, 32 that define the rod-receiving channel 28 ("*channel*");

The receiver 12 comprises at least one internal wall 20 defining a bore 22. At least a portion of the receiver 12 comprises a plurality of female threads, such as threads 24 and 26. In this regard, note that the receiver 12 comprises a rod-receiving channel 28. The receiver 12 comprises a first generally U-shaped wall 30 that defines a first rod-receiving opening 34 and a generally opposed second generally U-shaped wall 32 that defines a second rod-receiving opening 36 as shown. **The first and second rod-receiving openings 34 and 36 cooperate to define the**

rod-receiving channel 28 for receiving the rod 16. Note that the receiver 12 further comprises a first arcuate wall 38 and a generally opposing second arcuate wall 40 that lie between the first and second rod-receiving openings 34 and 36 as shown.

Ex.1005, [0035].

208. As shown below in Fig. 1, the first arcuate wall 38 (“*first arm*”) and second arcuate wall 40 (“*second wall*”) are “*spaced apart from each other*” by the rod-receiving channel 28 (“*channel*”):



Kirschman (Ex.1005), Fig. 1 (annotated)

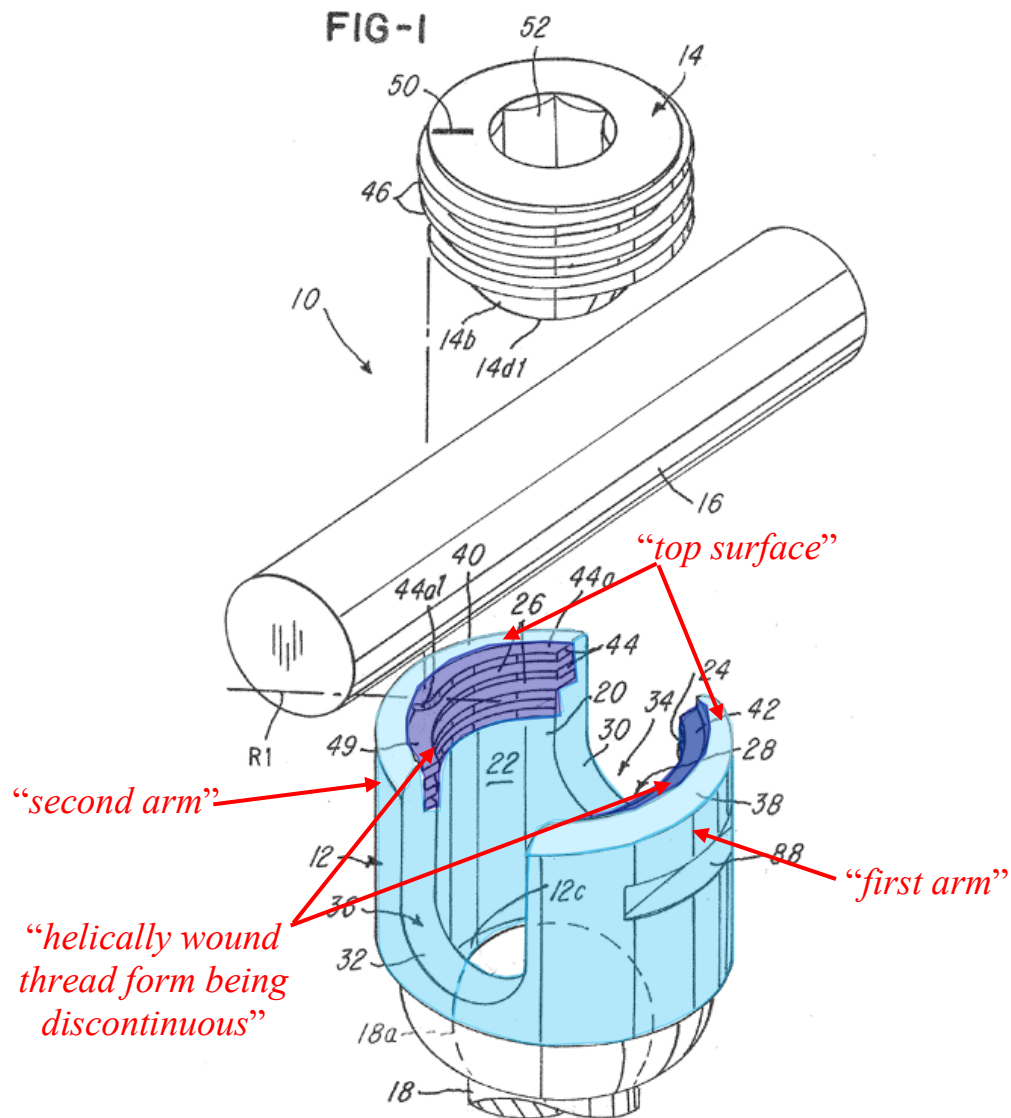
209. Second, Kirschman discloses “the helically wound thread being discontinuous and formed on the first and second arms.” Kirschman explains that the first arcuate wall 38 (“first arm”) includes first arcuate wall threads 42 and the second arcuate wall 40 (“second arm”) includes second arcuate wall threads 44 that cooperate to define receiver threads (“helically wound thread”) for receiving

the male cap threads 46 of the cap 14:

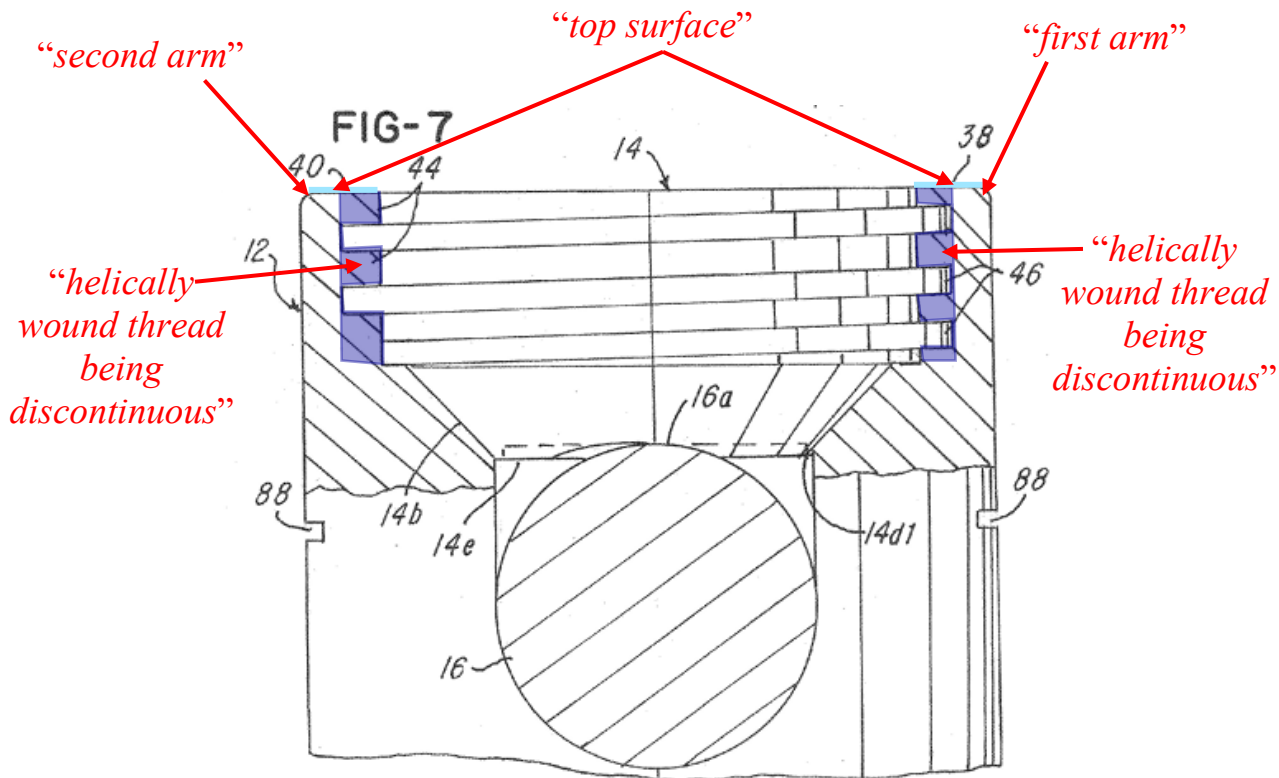
The first arcuate wall 38 comprises first arcuate wall threads 42 and the second arcuate wall 40 comprises second arcuate wall threads 44 as shown. The first and second arcuate wall threads 42 and 44 cooperate to define the receiver threads for threadably receiving male cap threads 46 on the cap 14 so that the cap 14 can be screwed onto the receiver 12 in order to lock the rod 16 in the rod-receiving channel 28 of the receiver 12.

Ex.1005, [0036]. Thus, the receiver threads (“*helically wound thread*”) are “*discontinuous*” because they are split between the first arcuate wall threads 42 and the second arcuate wall threads 44 “*formed on*” the first arcuate wall 38 (“*first arm*”) and the second arcuate wall 40 (“*second arm*”), respectively.

210. Third, Kirschman discloses “*the top surface of the receiver being formed on the first arm and the second arm.*” As explained above in limitation 1[a], the “*top surface*” is disposed on the tops of the first arcuate wall 38 (“*first arm*”) and the second arcuate wall 40 (“*second arm*”), as shown in Figs. 1 and 7 below:



Kirschman (Ex.1005), Fig. 1 (annotated)



Kirschman (Ex.1005), FIG. 7 (annotated)

211. Therefore, because Kirschman discloses a first arcuate wall 38 with first arcuate wall threads 42 and second arcuate wall 40 with second arcuate wall threads 44 spaced by a rod-receiving channel 28, Kirschman renders obvious *“wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helicallly wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm”* as claimed.

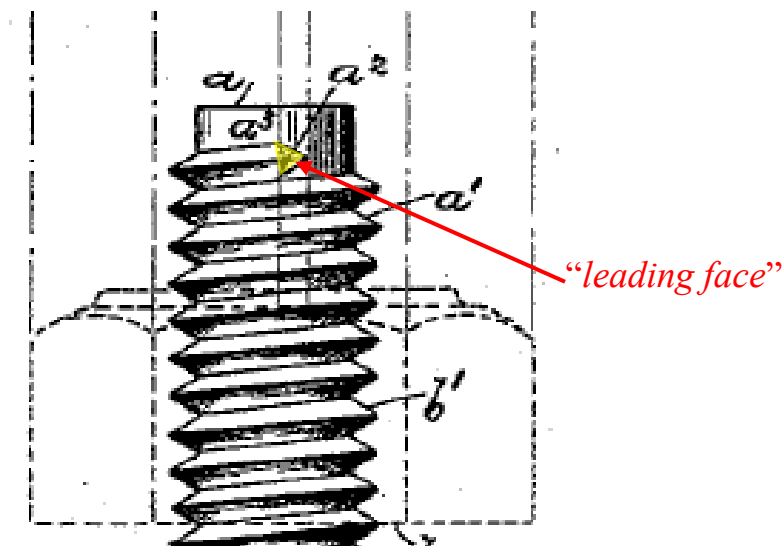
5. Claim 7

7[a] *The medical implant assembly of claim 1, wherein the leading face of the start structure includes at least a partial planar surface.*

212. Kirschman renders obvious limitation 7[a].

213. As explained above in limitation 1[g], Kirschman discloses a leading edge portion 46a that includes a leading face with a partial curvate surface and Higbee discloses a thread end a^2 that is rounded.

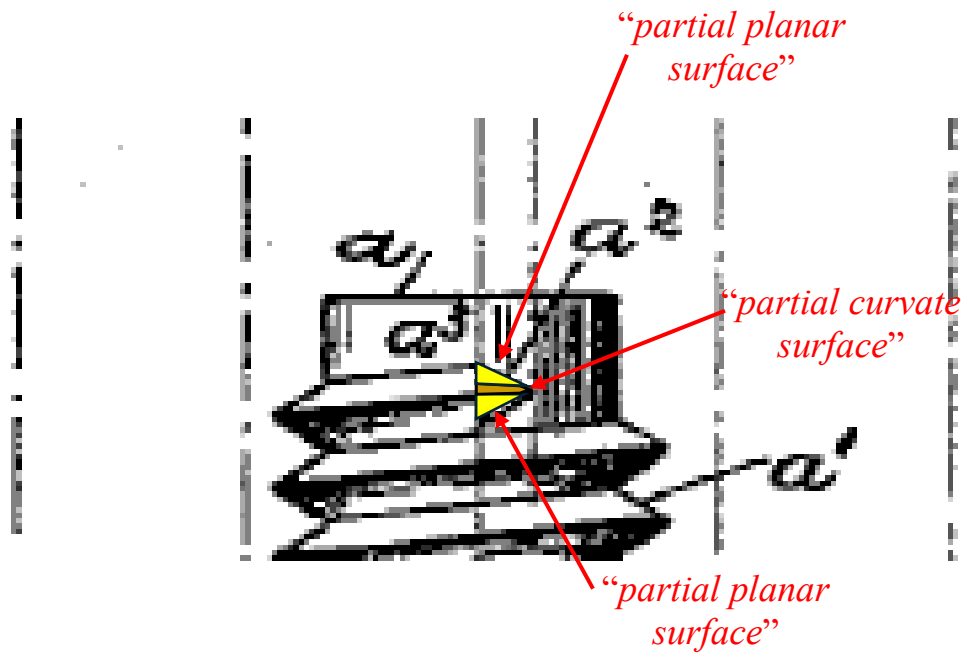
214. It would have been obvious to a POSITA that the leading face of the start structure would have included a partial planar surface. For example, Higbee explains that “[t]he exact form of the thread end is not very important so long as it is blunt.” Ex.1006, 2:89-92. Higbee explains that the thread end “may be cut off on an oblique plane, as in Figs. 1, 2, 3, and 4, or cut off square, as in Fig. 5, or rounded, as in Fig. 6.” Ex.1006, 2:92-94. Thus, Higbee contemplates that the thread end can have any suitable form, and discloses several thread ends that include planar surfaces (*e.g.*, oblique plane or square). For example, Fig. 1 shows a leading face with a oblique planes:



Higbee (Ex.1006), Fig. 1 (cropped and annotated)

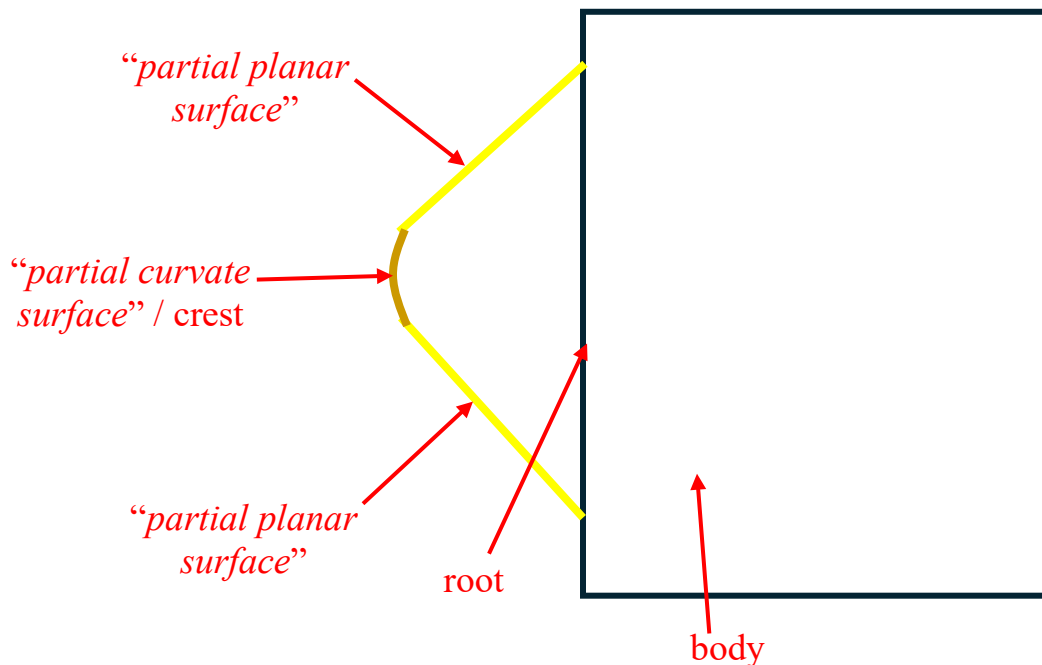
215. As explained above in Section VI.A., a POSITA would have known that sharp edges in medical devices could have cut the hand or glove of the surgeon or irritate the patient. Thus, a POSITA would have removed these sharp edges by either using a circular tool to round off or smooth the sharp edges of the thread or deburring the screw to remove the sharp edges of the thread.

216. Thus, a POSITA would have known that the sharp edge between the oblique planes in Higbee's blunt thread start shown in Fig. 1 would have been smoothed when used in a medical device, such as Kirschman's polyaxial screw. When smoothing this edge, a convex surface would have been formed between the two planar surfaces. I modified Fig. 1 of Higbee below to illustrate the leading face with a curved surface between the oblique planar surfaces:



Ex.1006, Fig. 1 (cropped, modified, and annotated)

I also prepared the below illustration of a side view of the leading face:



217. Thus, instead of using the rounded blunt thread start described in Higbee (as shown in Fig. 6) a POSITA would have also been motivated to use the blunt thread start with the oblique planes (as shown in Fig. 1) with the sharp edge rounded off because “[t]he exact form of the thread end is not very important so long as it is blunt.” Ex.1006, 2:89-92.

218. Therefore, because Higbee discloses a blunt thread start with oblique planes and a POSITA would have known that the sharp edges would have been rounded off, Kirschman renders obvious “*wherein the leading face of the start structure includes at least a partial planar surface*” as claimed.

B. Ground 2: Claims 5 and 6 are obvious over Kirschman and

Johnson.**1. Summary of the Johnson**

219. Johnson “relates to anchors and other implants for use in tissue, to be placed during orthopedic surgery.” Ex.1007, [0001]. Johnson explains that “techniques and systems have been developed for correcting and stabilizing damage or malformation of bones, such as the vertebrae of the spine.” Ex.1007, [0002]. Johnson explains that one of these systems includes coupling an elongate member to vertebrae via, for example, screws that are threaded into the vertebrae:

In one type of system, an elongated member such as a bendable rod is disposed longitudinally along vertebrae or one or more vertebral segments. The rod may be bent to correspond to or approximate the normal curvature of the spine in the particular region being instrumented. For example, the rod can be bent or otherwise formed into at least an approximation of a normal kyphotic curvature for the thoracic region of the spine, or a lordotic curvature for the lumbar region.

Ex.1007, [0002].

In such systems, **an elongated member can be engaged to vertebrae along a length of the spinal column by way of a number of fixation elements.** A variety of fixation elements can be provided which are configured to engage bones or bony tissue, such as specific portions of a vertebra or other bones. For instance, one such fixation element is a hook that is configured to engage a lamina of a vertebra. Another

fixation element is **a screw that can be threaded into various parts of the vertebra** or other bones.

Ex.1007, [0003].

Such procedures may be used to correct or treat a variety of deformities, injuries or other problems in bony structures such as vertebrae or other tissue. In one example of a spinal procedure utilizing a bendable rod, one or more rods are situated to one or both sides of the spine or spinous processes. Bone screws are threaded into several vertebral bodies, e.g. into the vertebral pedicles. The rods are affixed to the bone screws to apply corrective and/or stabilizing forces to the spine.

Ex.1007, [0004].

220. Johnson discloses a “[r]eceiver member 212 ha[ving] a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” Ex.1007, [0051]. Johnson explains that the receiver member 212 includes two branches, each forming a part of the lower portion 212a, the upper portion 212b, and the thinned section 212c therebetween, that define a U-shaped channel 254:

Receiver member 212 in the illustrated embodiment includes a pair of upright branches 250, 252 between which opening 222 extends. **Branches 250, 252 further define a substantially U-shaped channel 254** transverse to opening 222 that communicates with opening 222, and that is sized to accommodate an elongated member. **A portion of each branch 250, 252 forms at least a part of lower portion 212a of receiver member 212, and a portion of each branch 250, 252 forms at least a part of upper portion 212b of receiver member 212.**

Ex.1007, [0052]

221. Each branch 250, 252 also includes internal threads 250 that extend from the upper portion 212b to the lower portion 212a such that a set screw can be screwed first into the upper portion 212b, then down into the lower portion 212a:

In a specific embodiment, **internal threads 256 are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a.** Threads 256, if provided, end well above the floor of channel 254. If a cylindrical rod 220 of diameter equal to the width of channel 254 is placed in channel 254 as deep as possible, i.e. contacting the floor of channel 254, the upper limit of rod 220 will be below threads 256. A groove 257, which may be slightly larger than the major diameter of threads 256, separates threads 256 from that upper limit of rod 220. Branches 250, 252 may also be provided with indentations or holes 258, which allow the surgeon to grip receiver member 212 (or either or-both of portions 212a, 212b) with an appropriate forceps, wrench or other gripping or turning tool (not shown).

Ex.1007, [0052].

Upper portion 212b of receiver member 212 includes portions of branches 250, 252 having internal threads 256 and indentations 258 as discussed above, in the illustrated embodiment. **Threads 256 may be configured so that they are essentially continuous from upper portion 212b to lower portion 212a,** with the possible exception of the portion at or around section 212c. In that embodiment, a compression member (e.g. compression member 110 described above)

can be inserted into upper portion 212b and moved down to lower portion 212a. For example, **a set screw threaded into upper portion 212b can be threaded along opening 222 into lower portion 212a[.]**

In the illustrated embodiment, upper portion 212b is integrally formed with lower portion 212a, although in other embodiments portions 212a and 212b can be separately made and joined together, or otherwise formed.

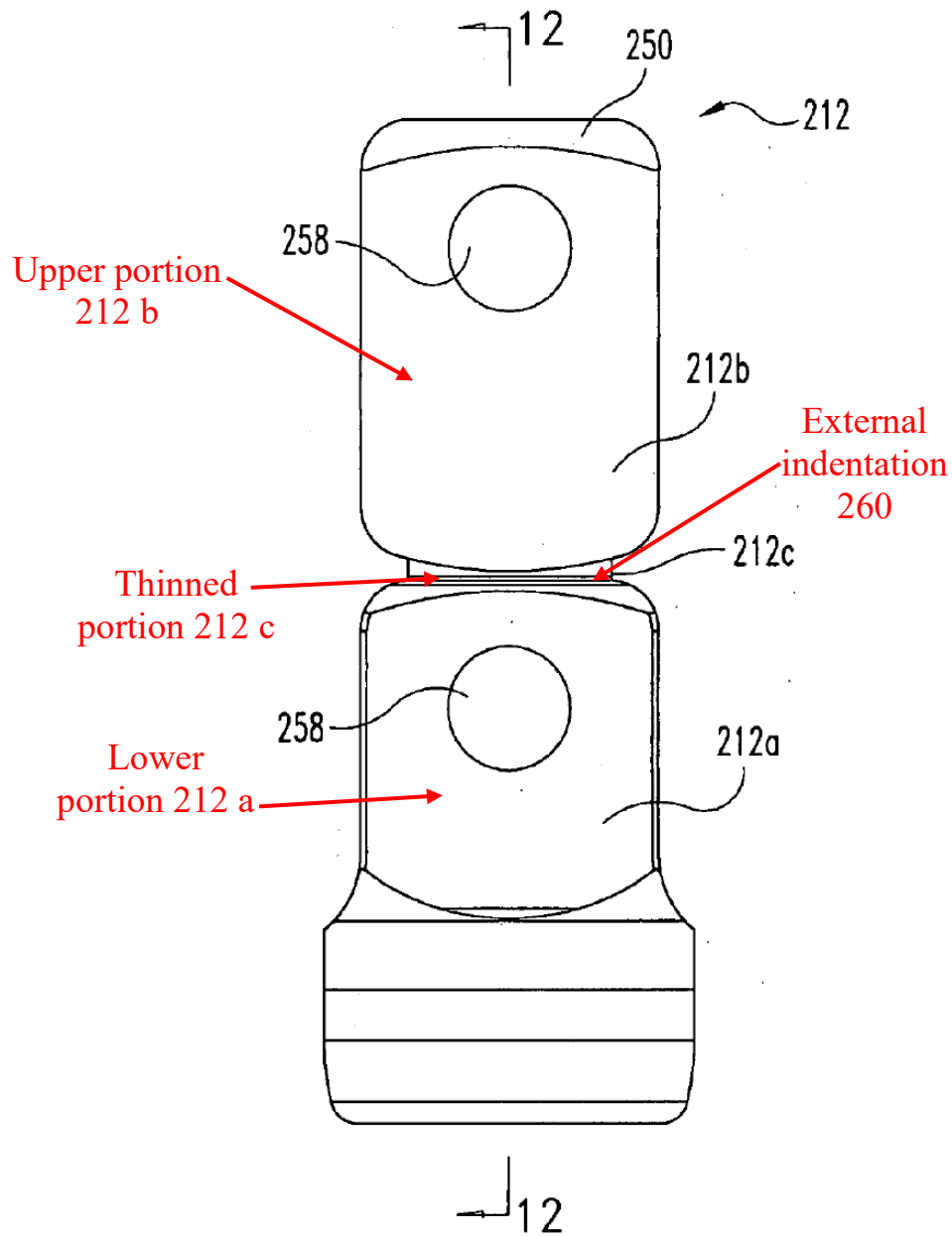
Ex.1007, [0053].

222. The thinned section 212c between the upper and lower sections 212b, 212a includes an external indentation or groove 260 and an interior indentation 261 that interrupts the threads 256 while still allowing passage of the set screw:

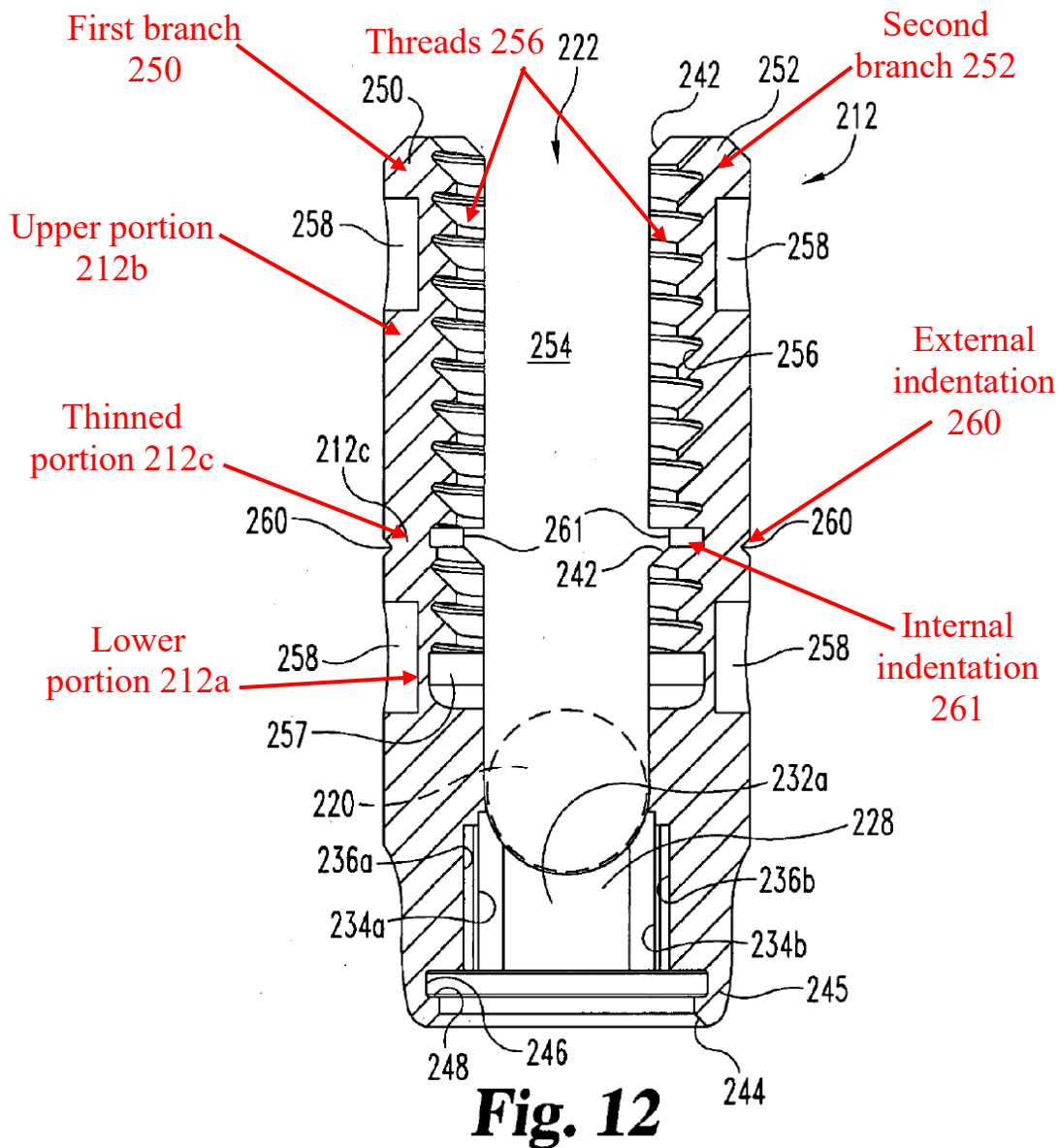
Thinned section 212c, as noted above, separates upper portion 212b and lower portion 212a in the illustrated embodiment. This embodiment of **section 212c includes an external indentation or groove 260, which may include scoring lines or other fracture-inducing or fracture-enabling features. An interior indentation 261 is also provided in the illustrated embodiment, which may interrupt threads 256 (if present) and may be somewhat deeper than the major diameter of threads 256.** Section 212c has a thickness which is at least slightly less than the overall thickness of branches 250, 252, and in a particular embodiment that thickness is at least slightly less than the thickness of branches 250, 252 measured from a thread trough in a branch to the exterior of that branch.

Ex.1007, [0054].

223. The receiver 212 is shown below in Figs. 11 and 12:

**Fig. 11**

Johnson (Ex.1007), Fig. 11 (annotated)



Johnson (Ex.1007), Fig. 12 (annotated)

224. Thus, the surgeon can insert an elongate member 220 into the receiver 212 without a special reducing tool by placing the elongate member 220 within the channel 254 and tightening the elongate member 220 within the receiver 212 by screwing the set screw down from the upper portion 212b to the lower portion

212a:

When the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she **places a portion of elongated member 220 into channel 254 in upper portion 212b of receiver member 212.** A set screw or other compression member (e.g. compression member 110 described above) is inserted into opening 222 above elongated member 220. In the embodiment in which the compression member is a set screw, **the set screw is threaded into threads 256, forcing elongated member 220 further down in channel 254. In this way, elongated member 220 is forced all the way through upper portion 212b, into lower portion 212a, and against a crown member and/or anchor member in chamber 228,** substantially as described above with respect to assembly 10.

Ex.1007, [0055].

225. After the elongate member 220 is tightened within the lower portion 212a of the receiver 212, the upper portion 212b is removed from the lower portion 212a at the thinned portion 212c:

Once the compression member is tightened against elongated member 220 to lock the assembly to the surgeon's satisfaction, **upper portion 212b may be cut or sheared off or otherwise removed from lower portion 212a** As one example, tool(s) for gripping or turning could be connected to one or both of upper portion 212b and lower portion 212a and torque could be applied to shear or twist the portions apart. As

another example, a tool with relatively sharp jaws could be applied to exterior groove 260 to cut off upper portion 212b. Other methods for physically separating upper portion 212a from lower portion 212b may be used. Once separated, upper portion 212b may be removed from the surgical site and discarded.

Ex.1007, [0056].

2. Reasons to Combine Kirschman and Johnson

226. As an initial matter, Kirschman and Johnson are analogous art to the '873 Patent because they are in the same field of endeavor as the '873 Patent. The '873 Patent "is directed to [a] structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws." Ex.1001, 1:27-31. Similarly, Kirschman "relates to a spinal implant system and method and, more particularly, to an implant having [] a lock aid that provides at least one of improved guidance, tactile or visual feedback or enhanced fixation and locking of a cap in a receiver of the implant." Ex.1005, [0002]. Moreover, Johnson "relates to anchors and other implants for use in tissue, to be placed during orthopedic surgery." Ex.1007, [0001]. For example, the implants may include "rods [that] are affixed to the bone screws to apply corrective and/or stabilizing forces to the spine." Ex.1007, [0004]. Thus, like the '873 Patent, Kirschman and Johnson are related to the field of bone anchors for use in spinal

surgery.

227. A POSITA would have found it obvious to combine Kirschman and Johnson because it would have simply required adding Johnson's well-known break-off extensions to the arcuate walls of Kirschman's receiver.

228. Kirschman explains that "[d]uring the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap," which "affects the desired correction of the spine." Ex.1005, [0005]. To this end, Kirschman proposes a variety of "locking aid[s]" that provide, for example, "enhanced locking," "facilitat[e] guiding and mounting the cap on the receiver," and "facilitat[e] locking the cap on the receiver and thereby locking a rod to a screw." Ex.1005, [0012]-[0017]. However, Kirschman states that "[a]lthough not shown, it should be appreciated that other conventional components may be used with the receiver." Ex.1005, [0051]. Therefore, a POSITA would have been motivated to look elsewhere in the art for other well-known components that would have further improved seating of the rod in the tulip/receiver.

229. Johnson describes one of these well-known components: receiver arms/branches with break-off extensions. Johnson's receiver member "includes a pair of upright branches" with a channel therebetween, "a portion of each branch form[ing] at least a part of upper portion 212b of receiver member." Ex.1007, [0052]. The "upper portion 212b may be cut or sheared off or otherwise removed

from lower portion” of the receiver member after locking the rod in the channel via a compression member. Ex.1007, [0056]. The upper portion (i.e. breakoff extensions) of the receiver branches allow the surgeon to insert the rod without “bend[ing] or us[ing] a special reducing tool to insert it into the lower end of a receiving channel,” thereby improving seating of the rod in the receiver member. Ex.1007, [0055].

230. It would have been obvious to a POSITA that Kirschman’s receiver 12 could have been combined with Johnson to further improve seating and locking of the rod within the receiver without requiring bending the rod or using a special reducing tool, as described in Johnson. Accordingly, a POSITA would have understood that Kirschman’s receiver 12 could have been modified by adding an upper portion 212b and thinned portion 212c (also known as break-off extensions) as described in Johnson to the receiver 12’s arcuate walls 38, 40, which would have improved seating of the rod 16 within the rod-receiving channel 26. It would have been obvious to a POSITA to form Johnson’s internal thread 256 on the upper portion 212b so that it would have been substantially continuous with Kirschman’s arcuate wall threads 42, 44 on the arcuate walls 38, 40. This continuous threading would have allowed the cap 14 to be threaded from Johnson’s upper portion 212b downward into the rod-receiving channel 26 between Kirschman’s arcuate walls 38, 40. A POSITA also would have understood

that the combination would have been formed such that Johnson's upper portion 212b would have been removed from Kirschman's arcuate walls 38, 40 by cutting or shearing the thinned portion 212c after the rod 16 is fully seated in Kirschman's receiver 12.

231. Johnson explains how these breakoff extensions may be formed on the branches. Johnson explains that the upper portion can be "integrally formed with lower portion 212a," "separately made and joined together, or otherwise formed" therewith. Ex.1007, [0053]. A POSITA would have reasonably expected that Kirschman's receiver would have been formed with breakoff extensions as described in Johnson. A POSITA would have formed Kirschman's receiver with two extended arcuate walls and removed material on the inner/outer part of the walls to form a groove, thereby defining an upper portion/breakoff extension on each wall. The groove would have been formed such that it would have been broken to remove the breakoff extensions from the walls. Alternatively, a POSITA would have formed Kirschman's receiver then attached breakoff extensions to the arcuate walls via a thinned portion such that the thinned portion would have been broken to remove the breakoff extensions. Either of these methods of forming breakoff extensions would have involved well-known techniques within the skill of a POSITA. A POSITA would have known that threads would have been formed on the inner surface of the walls according to well-known techniques before or after

forming the breakoff extensions so that the cap would have been continuously threaded from the breakoff extensions to the walls.

232. Therefore, a POSITA would have understood that the combination of Kirschman with Johnson would have been a combination of prior art elements (Kirschman's receiver 12 and Johnson's upper portion 212b and thinned portion 212c) according to known methods (integrally forming or joining together Johnson's upper portion 212b and thinned portion 212c with Kirschman's arcuate walls 38, 40) to yield predictable results (Kirschman's receiver 12 with a removable upper portion 212b as taught by Johnson).

3. Claim 5

5[a] *The medical implant assembly of claim 4, wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm,*

233. Kirschman in view of Johnson renders obvious limitation 5[a].

234. As explained above in limitation 4[a], Kirschman discloses a receiver 12 with a first arcuate wall 38 ("*first arm*") and a second arcuate wall 40 ("*second arm*").

235. To the extent Kirschman does not explicitly disclose the arcuate walls 38, 40 having "*breakoff extension[s]*," Johnson teaches this limitation.

236. Johnson discloses a "[r]eceiver member 212 ha[ving] a lower portion 212a and an upper portion 212b separated by a thinned section 212c." Ex.1007,

[0051]. The receiver member 212 includes a first branch 250 forming part of the upper portion 212b (“*first breakoff extension*”) and a part of the lower portion 212a and a second branch 252 forming another part of the upper portion 212b (“*second breakoff extension*”) and another part of the lower portion 212a:

Receiver member 212 in the illustrated embodiment includes a pair of upright branches 250, 252 between which opening 222 extends. Branches 250, 252 further define a substantially U-shaped channel 254 transverse to opening 222 that communicates with opening 222, and that is sized to accommodate an elongated member. A portion of each branch 250, 252 forms at least a part of lower portion 212a of receiver member 212, and a portion of each branch 250, 252 forms at least a part of upper portion 212b of receiver member 212.

Ex.1007, [0052].

237. The receiver member 212 is shown below in Figs. 11 and 12:

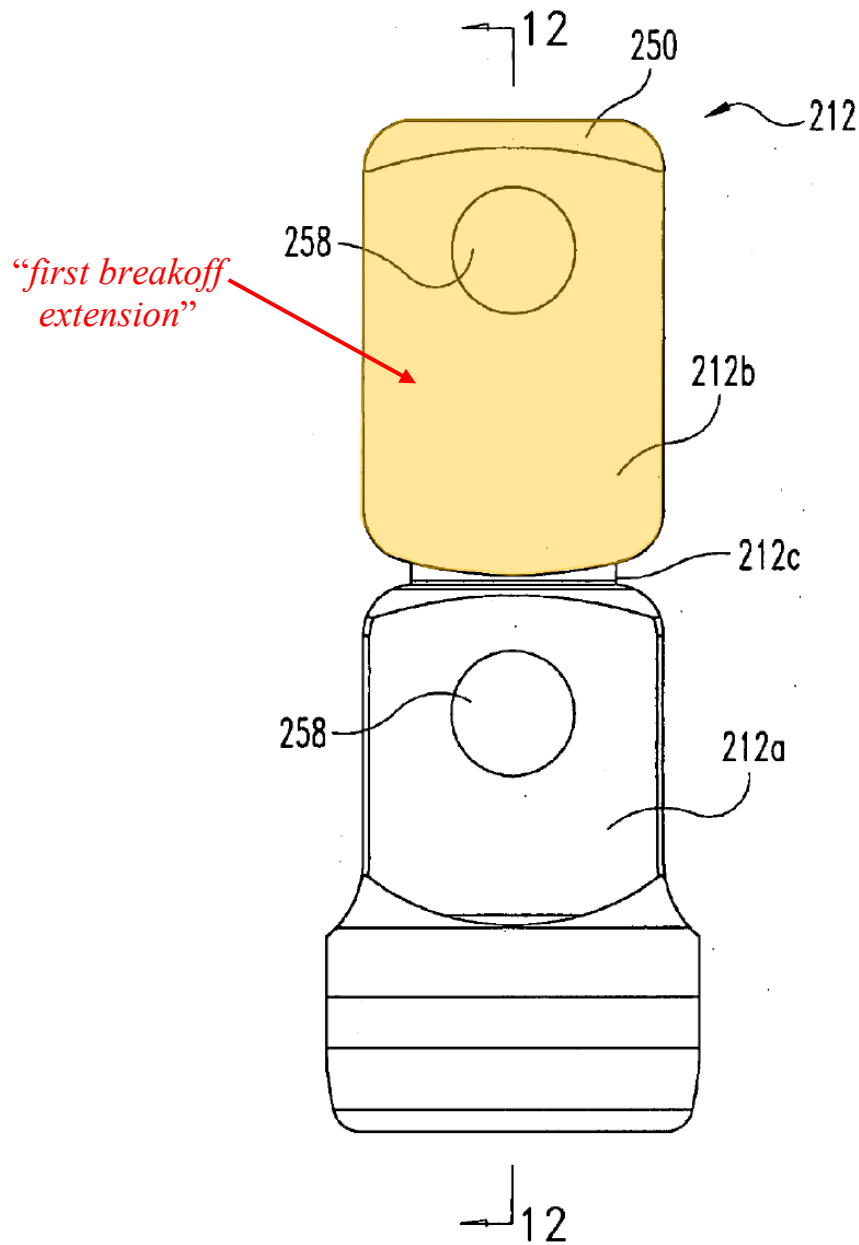
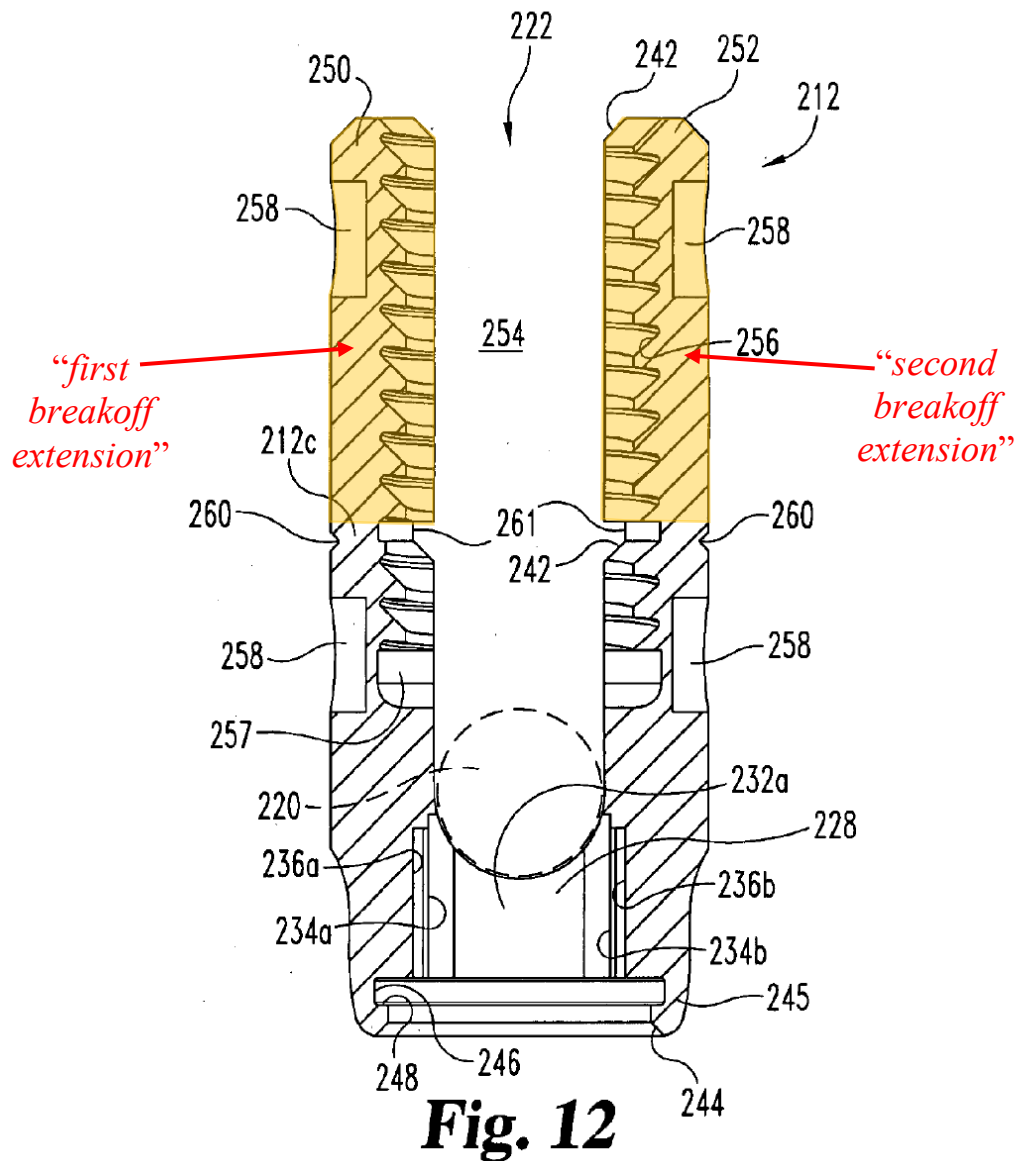


Fig. 11

Johnson (Ex.1007), Fig. 11 (annotated)



Johnson (Ex.1007), Fig. 12 (annotated)

238. Johnson explains that the upper portion can be removed by cutting or shearing the thinned section 212c disposed between the upper portion 212b (“*first breakoff extension*” and “*second breakoff extension*”) and the lower portion 212a:

Once the compression member is tightened against elongated member 220 to lock the assembly to the surgeon's satisfaction, **upper portion**

212b may be cut or sheared off or otherwise removed from lower portion 212a As one example, tool(s) for gripping or turning could be connected to one or both of upper portion 212b and lower portion 212a and torque could be applied to shear or twist the portions apart. As another example, **a tool with relatively sharp jaws could be applied to exterior groove 260 to cut off upper portion 212b.** Other methods for physically separating upper portion 212a from lower portion 212b may be used. Once separated, upper portion 212b may be removed from the surgical site and discarded.

Ex.1007, [0056].

239. For the reasons described above in Section VIII.B.2., a POSITA would have been motivated to combine Kirschman with Johnson such that Kirschman's arcuate walls 38, 40 are formed with Johnson's upper portion 212b to further improve seating of the rod 16 in the receiver 12.

240. Therefore, because Johnson teaches an upper portion 212b divided between two branches 250, 252 that can be removed via a thinned section 212c, Kirschman in view of Johnson renders obvious "*wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm*" as claimed.

5[b] *each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and*

the discontinuously helically wound thread form of the second breakoff extension configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and second breakoff extensions being separated from the first and second arms, respectively.

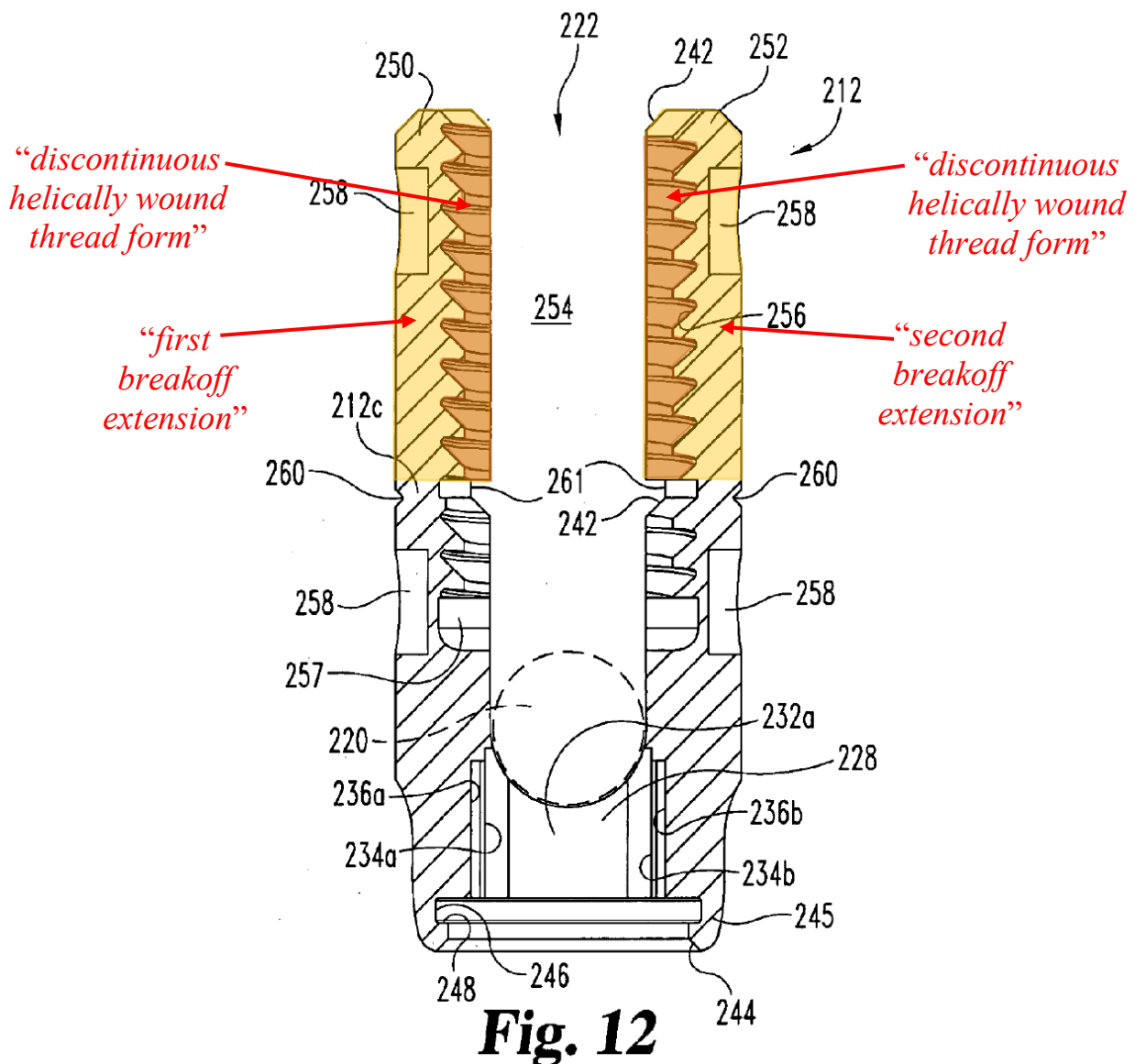
241. Kirschman in view of Johnson renders obvious limitation 5[b].

242. Johnson explains that internal threads 256 (“*discontinuously helically wound thread form*”) are formed on the branches 250, 252 “through substantially the entire length of upper portion 212b and into lower portion 212a.” Ex.1007, [0052]. The internal threads 256 (“*discontinuously helically wound thread of the first breakoff extension*” and “*the second breakoff extension*”) are substantially continuous along the length of the branches 250, 252 so that the set screw can be threaded (“*rotatably transfer[ed]*”) from the upper portion 212b (“*[first]/[second] breakoff extension*”) to the lower portion 212a of the receiver 212:

Upper portion 212b of receiver member 212 includes portions of branches 250, 252 having internal threads 256 and indentations 258 as discussed above, in the illustrated embodiment. **Threads 256 may be configured so that they are essentially continuous from upper portion 212b to lower portion 212a**, with the possible exception of the portion at or around section 212c. In that embodiment, **a compression member (e.g. compression member 110 described above) can be inserted into upper portion 212b and moved down to lower portion 212a. For example, a set screw threaded into upper portion 212b can be threaded along opening 222 into lower portion 212a[.]**

Ex.1007, [0053].

243. Thus, as shown in Fig. 12 below, the internal threads 256 (“discontinuous helically wound thread form”) extend from the upper portion 212b (“[first]/[second] breakoff extension”) to the lower portion 212a:



Johnson (Ex.1007), Fig. 12 (annotated)

244. As explained above in limitation 4[a], Kirschman discloses first arcuate wall threads 42 (“*discontinuously helically wound thread form*”) being formed on a first arcuate wall 38 (“*first arm*”) and second arcuate wall threads 44 (“*discontinuously helically wound thread form*”) being formed on the second arcuate wall 40 (“*second arm*”). For the reasons described above in Section VIII.B.2., a POSITA would have been motivated to combine Kirschman with Johnson to form the internal threads 256 on Johnson’s upper portion 212b so that they are substantially continuous with Kirschman’s arcuate wall threads 42, 44 to allow the set screw to be threaded therebetween.

245. Therefore, because Johnson discloses internal threads 256 formed in the upper portion 212b that extend substantially continuously downward into the lower portion 212a such that a set screw can be threaded downward from the upper portion 212b to the lower portion 212a, Kirschman in view of Johnson renders obvious “*each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and the discontinuously helically wound thread form of the second breakoff extension configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and*

second breakoff extensions being separated from the first and second arms, respectively” as claimed.

4. Claim 6

6[a] *The medical implant assembly of claim 5, wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.*

246. Kirschman in view of Johnson renders obvious limitation 6[a].

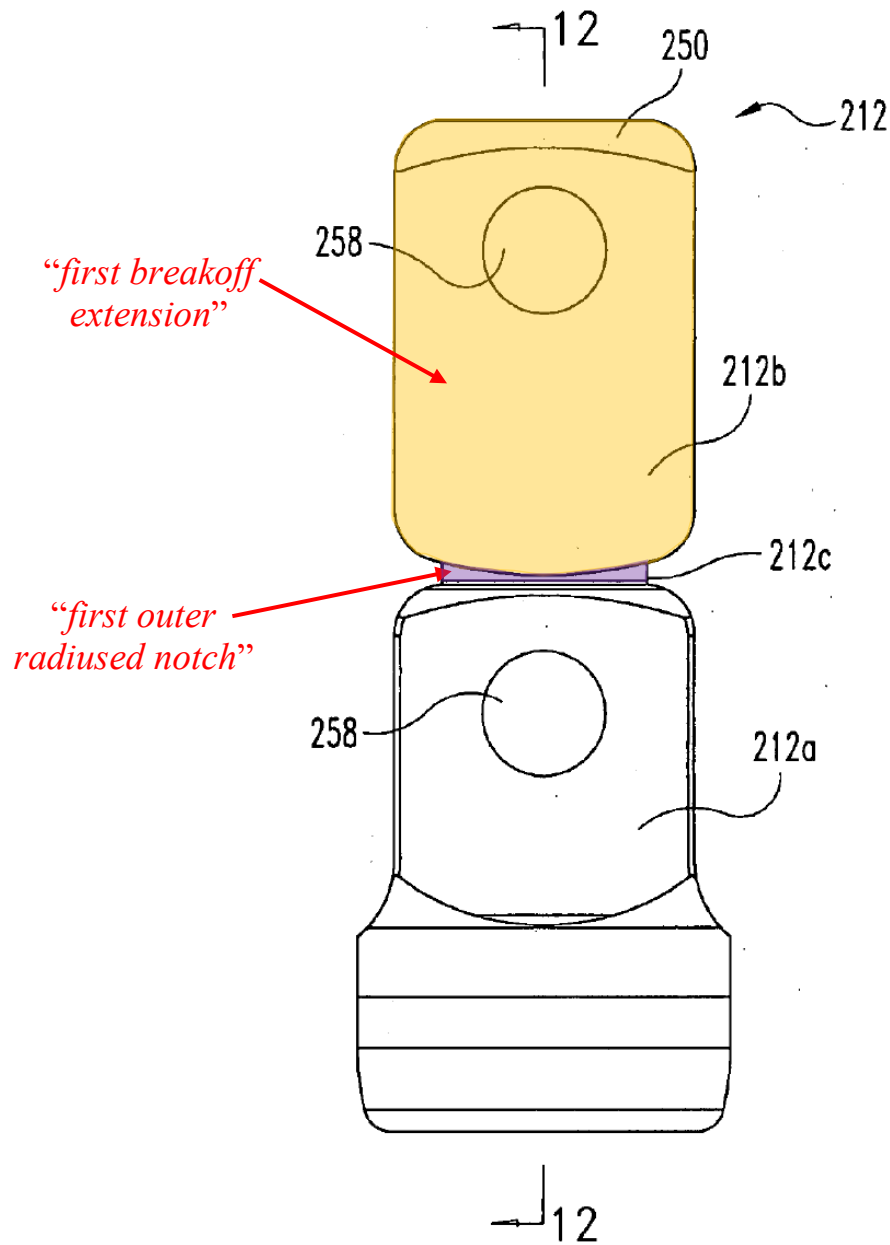
247. As explained above in limitations 5[a] and 5[b], Johnson discloses a thinned portion 212c disposed between the upper portion 212b (“*[first]/[second] breakoff extension*”) and the lower portion 212a. Johnson explains that the thinned portion 212c includes an external indentation 260 (“*outer radiused notch*”) and an internal indentation 261 (“*inner radiused recess*”) on each branch 250, 252:

Thinned section 212c, as noted above, separates upper portion 212b and lower portion 212a in the illustrated embodiment. **This embodiment of section 212c includes an external indentation or groove 260, which may include scoring lines or other fracture-inducing or fracture-enabling features. An interior indentation 261 is also provided in the illustrated embodiment, which may interrupt threads 256 (if present) and may be somewhat deeper than the major diameter of threads 256. Section 212c has a thickness which is at least slightly less than the overall thickness of branches 250, 252, and in a particular**

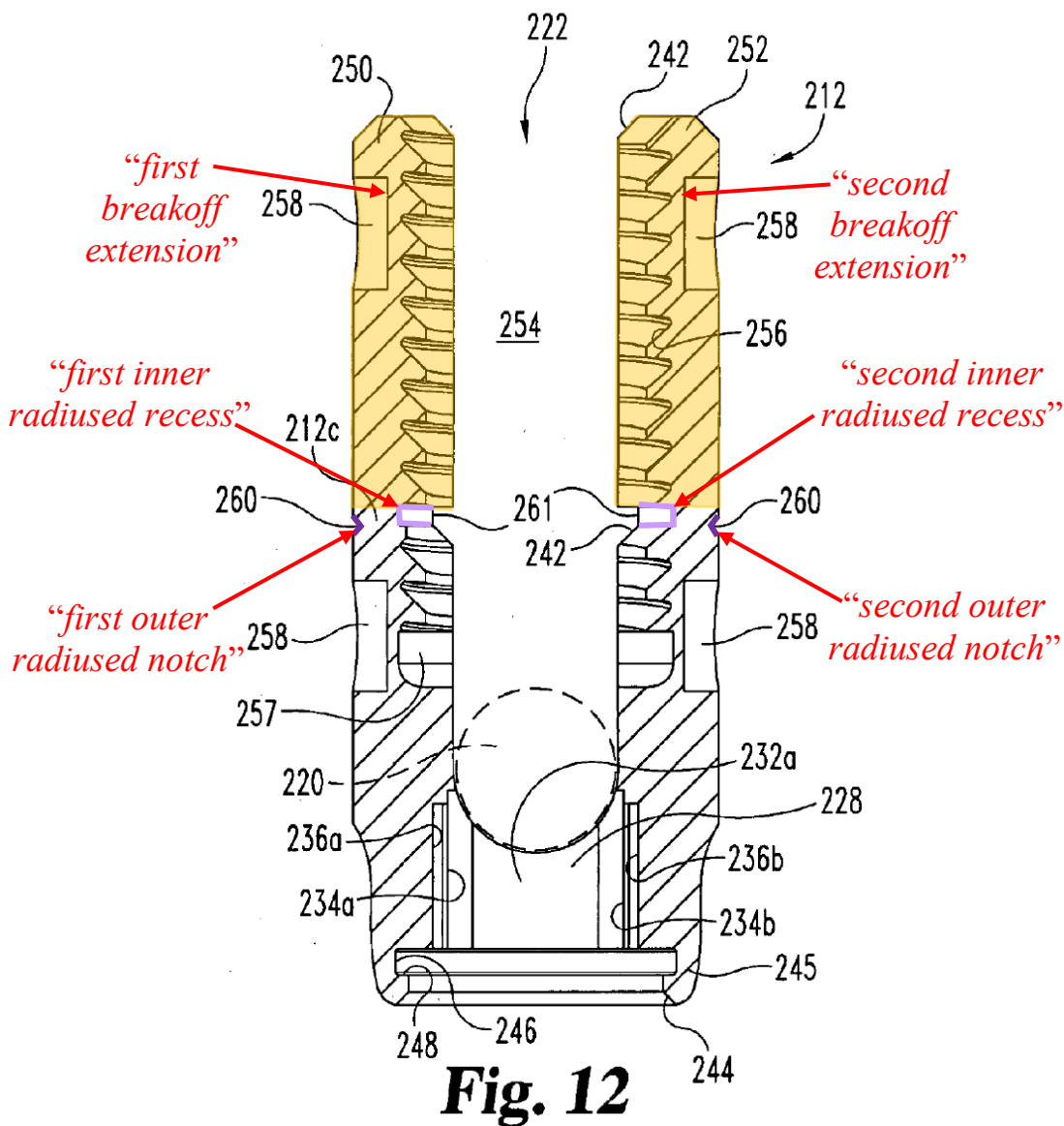
embodiment that thickness is at least slightly less than the thickness of branches 250, 252 measured from a thread trough in a branch to the exterior of that branch.

Ex.1007, [0054]; *see also* [0053] (“Threads 256 may configured so that they are essentially continuous from upper portion 212b to lower portion 212a, **with the possible exception of the portion at or around section 212c.**”).

248. As shown in Figs. 11 and 12, the external indentations 260 (“*[first]/[second] outer radiused notch*”) are “*located opposite*” the internal indentations 261 (“*[first]/[second] inner radiused recess*”):

**Fig. 11**

Johnson (Ex.1007), Fig. 11 (annotated)



Johnson (Ex.1007), Fig. 12 (annotated)

249. Johnson explains that the upper portion 212b may be cut or sheared off at the thinned portion 212c so that it can be removed after the elongate member 220 is secured within the receiver 212 by the compression member:

Once the compression member is tightened against elongated member 220 to lock the assembly to the surgeon's satisfaction, **upper portion**

212b may be cut or sheared off or otherwise removed from lower portion 212a As one example, tool(s) for gripping or turning could be connected to one or both of upper portion 212b and lower portion 212a and torque could be applied to shear or twist the portions apart. As another example, **a tool with relatively sharp jaws could be applied to exterior groove 260 to cut off upper portion 212b.** Other methods for physically separating upper portion 212a from lower portion 212b may be used. Once separated, upper portion 212b may be removed from the surgical site and discarded.

Ex.1007, [0056].

250. For the reasons described above in Section VIII.B.2., a POSITA would have been motivated to combine Kirschman with Johnson to form Johnson's thinned portion 212c including the external indentations 260 and internal indentations 261 between Johnson's upper portion 212b and Kirschman's arcuate walls 38, 40 so that the upper portions 212b would have been removed after the rod 16 is secured within Kirschman's receiver 12.

251. Therefore, because Johnson discloses a thinned section 212c between the upper portion 212b and lower portion 212a with an outer indentation 260 opposite an inner indentation 261 that allows for the upper portion 212b to be removed after securing an elongate member within the receiver 212, Kirschman in view of Johnson renders obvious "*wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface*

thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess” as claimed.

C. Ground 3: Claims 8-11 are obvious over Kirschman and the '477 Publication.

1. Summary of the '477 Publication

252. The '477 Publication “is directed to a closure and/or locking member for use in conjunction with medical implants that have open or closed receivers or heads for receiving rods and the like and, in particular, to such a closure that includes a break-off installation head and a second removal head.” Ex.1008, [0002]; *see also* Abstract (“A closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant includes a radially outward threaded cylindrical body sized and shaped to be threadably received between two arms of a head of the implant.”).

253. The '477 Publication explains that “[o]pen headed implants or receivers normally have a pair of spaced arms that are positioned on opposite sides of a channel that receives a rod, dynamic stabilizer or the like for securing the implant to the rod.” Ex.1008, [0004]. These “open headed implants have to be effectively closed to capture the rod or rod-like member and locked in order to

secure the rod member in a fixed position relative to the implant.” Ex.1008, [0004].

254. The ’477 Publication explains that previous closures had a large profile and could not be sufficiently tightened against the rod:

Plug-like closures have been provided for open headed implants in the prior art. Such prior art closures are externally threaded and are screwed into mating threads on the interior surfaces of the implant arms. **Most of the prior art plug like closures have had a fairly large profile in that they extend substantially above the implant in order to have sufficient structure to both install and remove the plug or, alternatively, the implant is made taller.** Both of these alternatives are undesirable, since **it is preferred to have as low a profile as possible with respect to the overall system in order to have a minimal impact on the patient's body subsequent to installation.** Furthermore, **many of the prior art devices cannot be sufficiently tightened or torqued against the rod member so as to lock the rod from both axial and rotational movement relative to the implant.** The various elements of the overall implant system are relatively small and the body can exert substantial forces on these elements, especially in situations where greater than normal forces are applied, such as accidents or the like. Slippage between the various elements can result in failure of the overall system and serious injury to a patient.

Ex.1008, [0005].

255. Thus, the ’477 Publication states that “it is desirable to be able to both lock the rod member relative to the implant with the closure by use of high torquing forces during installation with a relatively low profile subsequent to

installation.” Ex.1008, [0006]. The ’477 Publication discloses two embodiments of closures that aim to solve these problems.

256. First, the ’477 Publication discloses “[w]ith reference to FIGS. 1-4, the closure 1 includes a body 24 that has a generally cylindrical or plug shape with a substantially circular horizontal cross section and a central axis of rotation B.”

Ex.1008, [0029]. The cylindrical closure body 24 includes a guide and advancement structure 34 that is a reverse angle thread form 36 that prevents splaying of the bone screw receiver 13:

Located on the cylindrical closure body 24 is a guide and advancement structure 34 mateable with the guide and advancement structure on the inner surfaces 20 of the arms 15 of the bone screw receiver 13. In the illustrated embodiment, **the guide and advancement structure 34 is a helically wound reverse angle thread form 36.** The guide and advancement structure 34 acts cooperatively, as described below with the bone screw receiver 13 to allow the closure 1 to be inserted into and rotated relative to the bone screw receiver 13 and to guide and advance the closure 1 along the axis B as the closure 1 is rotated clockwise or to the reverse direction when rotated counterclockwise. **The guide and advancement structure 34 resists splaying in the bone screw receiver 13 as forces applied to the closure 1 are conveyed by the reverse angle thread form 36 during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.** It is foreseen that other types of guide and advancement structure could be utilized. For

example, a buttress thread form, a square thread form or some other type of structure such as a flange form may be effectively used which theoretically has little or no radially outward directed forces, especially if the arms are thickened to resist splaying.

Ex.1008, [0030].

With reference to FIG. 2, the illustrated thread form 36 has a root 38 and a crest 40. Further, the thread form 36 has a lead surface 42 and a trailing surface 44 (described relative to the position thereof during insertion of the closure 1 into the bone screw receiver 13). **In a reverse angle thread, the trailing surface 44 from the root 38 to the crest 40 extends at an angle rearwardly from a perpendicular line relative to the axis B. Typically, the trailing surface 44 is at an angle between 1 and 20 degrees relative to such a perpendicular.**

Ex.1008, [0031].

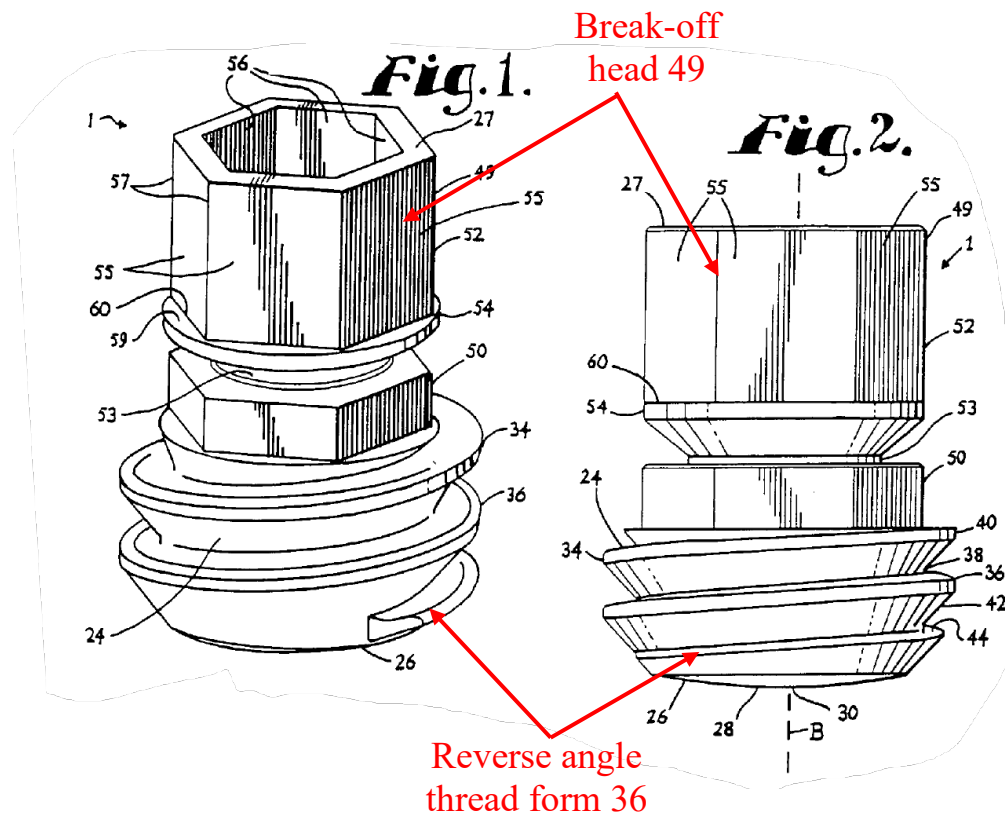
257. Additionally, the closure 1 includes a break-off head 49 that breaks away from the remainder of the closure 1 when a predetermined torque is applied thereto:

The closure 1 also includes a driving or installation break-off head 49 and a removal head 50 that are coaxially attached to the body 24. The removal head 50 is located between the body 24 and the driving head 49 and disposed near the guide and advancement structure 34. **The driving head 49 is disposed on a break-off portion 52 that is secured to the body 24 at a breakaway region 53 adjacent the removal head 50 and is designed to break away from the remainder of the closure 1 subsequent to a predetermined torque being applied to the**

driving head 49, such as 100 inch pounds, during installation of the closure 1 into the bone screw 5. A barrier in the form of a cylindrical rim stop 54 is disposed on the break-off portion 52 between the breakaway region 53 and the driving head 49. The illustrated rim stop 54 is adjacent to the driving head 49.

Ex.1008, [0032]; *see also* [0033]-[0034].

258. The first embodiment of the closure 1 is shown in Figs. 1 and 2 below:



The '477 Publication (Ex.1008), Figs. 1-2 (annotated)

259. Second, the '477 Publication discloses “[w]ith reference to FIGS. 7-10, the reference numeral 101 generally represents a second or alternative

embodiment of a closure according to the present invention,” which “includes a body 124 that has a generally cylindrical or plug shape with a substantially circular horizontal cross section and a central axis of rotation C.” Ex.1008, [0039], [0040]. The closure 101 includes “guide and advancement structure 134 is a helical interlocking form, such as that described in U.S. Pat. No. 6,726,689, incorporated by reference herein” with a bevel at the thread start. Ex.1008, [0041]; *see* Figs. 7-8.

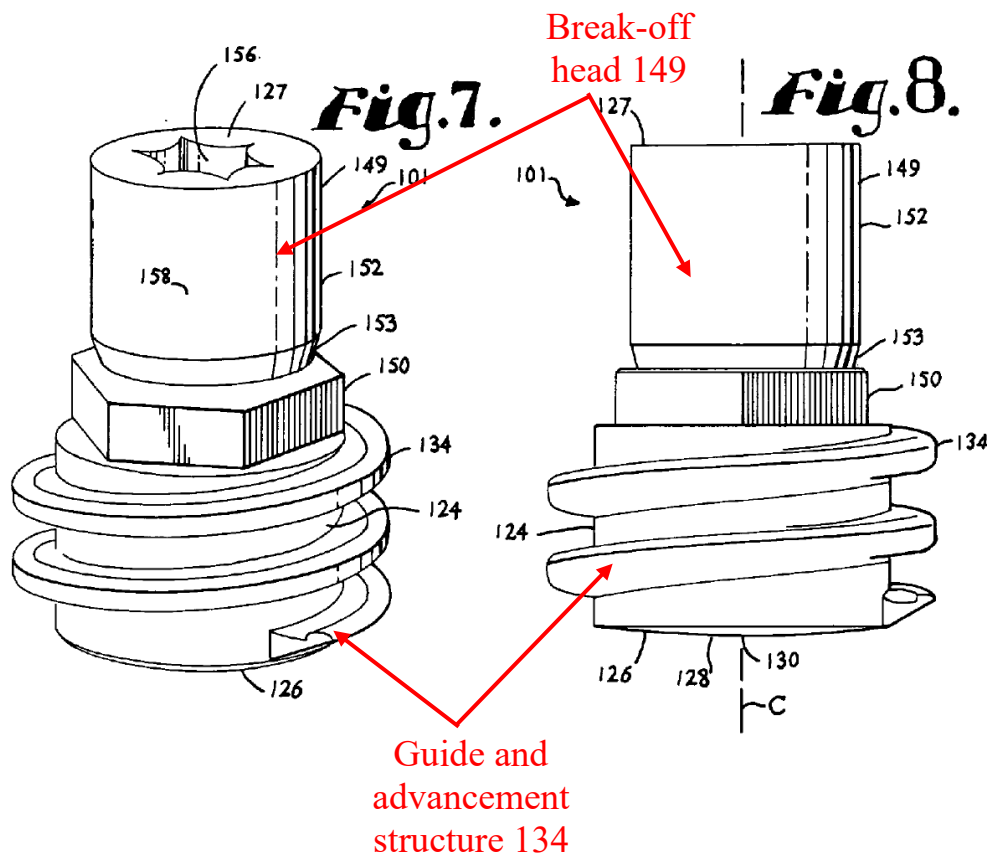
260. As with the first embodiment shown in Figs. 1-4, the second embodiment shown in Figs. 7-8 includes a break-off head 149 that breaks away from the remainder of the closure 1 when a predetermined torque is applied thereto:

The closure 101 also includes a driving or installation break-off head 149 and a removal head 150 that are coaxially attached to the body 124. The removal head 150 is located between the body 124 and the driving head 149 and disposed near the guide and advancement structure 134. **The driving head 149 is disposed on a break-off portion 152 that is secured to the body 124 at a breakaway region 153 adjacent the removal head 150 and is designed to break away from the remainder of the closure 101 subsequent to a predetermined torque being applied to the driving head 149,** such as 100 inch pounds, during installation of the closure 101 into a bone screw receiver or other medical implant.

Ex.1008, [0042]; *see also* [0043]-[0044].

261. The second embodiment of the closure 101 is shown in Figs. 7 and 8

below:



The '477 Publication (Ex.1008), Figs. 7-8 (annotated)

2. Reasons to Combine Kirschman and the '477 Publication

262. As an initial matter, the '477 Publication is analogous art to the '873 Patent because both are in the same field of endeavor. The '873 Patent "is directed to [a] structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws." Ex.1001, 1:27-31. Similarly, the '477 Publication "is directed to a closure and/or

locking member for use in conjunction with medical implants that have open or closed receivers or heads for receiving rods and the like,” specifically for “medical implants that are used in conjunction with spinal surgery.” Ex.1008, [0002]-[0003]; *see also* Abstract (“A closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant includes a radially outward threaded cylindrical body sized and shaped to be threadably received between two arms of a head of the implant.”). Thus, like the ’873 Patent, the ’477 Publication is related to the field of bone anchors for use in spinal surgery.

263. A POSITA would have found it obvious to combine the ’477 Publication with Kirschman because it would have simply added the ’477 Publication’s well-known closure features (beveled thread start, reverse angle thread, and/or break-off extension) to Kirschman’s cap 14.

264. Kirschman explains that “[d]uring the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap,” which “affects the desired correction of the spine.” Ex.1005, [0005]. To this end, Kirschman proposes a variety of “locking aid[s]” that provide, for example, “enhanced locking,” “facilitat[e] guiding and mounting the cap on the receiver,” and “facilitat[e] locking the cap on the receiver and thereby locking a rod to a screw.” Ex.1005, [0012]-[0017]. However, Kirschman states that “[a]lthough not shown, it should be appreciated that other conventional components may be used

with the receiver.” Ex.1005, [0051]. Therefore, a POSITA would have been motivated to look elsewhere in the art for other well-known components that would have further improved locking of the cap on the receiver.

265. The '477 Publication describes some of these well-known components of closures: beveled thread starts, reverse angle threads, and break-off heads. First, a POSITA would have recognized that the '477 Publication's beveled thread start would have improved engagement of the closure's threads with the threads of the receiver. By removing excess material from the thread start, a smooth angled surface on the bottom of the thread would have been provided that would have improved contact with the uppermost thread of the receiver, alignment with the receiver axis, and would have allowed rotation of the closure to begin more smoothly. Moreover, the '477 Publication's reverse angle thread form “resists splaying in the bone screw receiver 13 as forces applied to the closure 1 are conveyed by the reverse angle thread form 36 during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.” Ex.1008, [0030]. Thus, these threads would have improved locking of the closure on the receiver. *See* Ex.1008, [0005] (“[M]any of the prior art devices cannot be sufficiently tightened or torqued against the rod member so as to lock the rod from both axial and rotational movement relative to the implant.”). Additionally, “[t]he breaking away” of the '477 Publication's break-off head “provides for a low

profile” of the closure, thereby preventing the closure from extending substantially above the receiver. Ex.1008, [0008], [0005].

266. Thus, it would have been obvious to a POSITA to modify Kirschman’s cap to include one or more of the ’477 Publication’s improved components to further improve locking of the cap on the receiver.

267. A POSITA would have had a reasonable expectation of success in forming a bevel on the leading edge portion 46a of Kirschman’s cap threads 46 because this was well-known in the art. Ex.1015, 864 (“In making a thread roll, the ends are beveled at an angle of 45 degrees.”). Thus, forming a beveled start structure would have involved well-known techniques within the skill of a POSITA.

268. A POSITA would have had a reasonable expectation of success in forming the threads of Kirschman’s cap as the ’477 Publication’s reverse angle thread because forming closures with reverse angle threads had successfully been accomplished in the art (as recognized by the ’873 Patent itself). Ex.1001, 1:65-2:6 (“Known closures include...a variety of single start helically wound guide and advancement structures including, for example, thread forms having...reverse-angle buttress or square thread forms....”); Ex.1007, [0047] (“thread 112 [of the set screw] is a reverse angle thread as disclosed in U.S. Pat. No. 6.296,642 to Morrison et al., incorporated herein by reference in its entirety...”); Ex.1013,

[0030] (“[T]he external thread 5 [of the set screw] illustrated preferably has about 45° reverse angle buttress thread form.”). Thus, forming a reverse angle thread would have involved well-known techniques within the skill of a POSITA.

269. Moreover, a POSITA would have had a reasonable expectation of success in adding the '477 Publication's break-off head to Kirschman's cap because forming caps with break-off heads had been successfully accomplished in the art. Ex.1013, [0026]-[0027] (“A frangible portion 32 connects the upper portion 40 and the lower portion 42 of the set screw1. The frangible portion 32 is easily or readily ruptured, separated or broken when a pre-selected torque or force is applied.”); Ex.1014, [0051] (“The set screw 700 can further include a break off region 705 located between the cap 703 and threaded portion 701. As will be appreciated, the break off region 705 facilitates separation of the cap 703 from the threaded portion 701 upon engaging the set screw 700 at a specified torque within the head portion 307.”). A POSITA would have known that a break-off head could have been formed integrally with the cap by removing material between the head and the cap such that a thinned breakaway region would have been formed. This would have allowed the break-off head to be removed from the cap at a known torque. Alternatively, a POSITA also would have known that a separate break-off head could have been attached to the cap via a breakaway region. Either of these methods of forming the cap with a break-off head would have involved well-

known techniques within the skill of a POSITA.

270. Therefore, a POSITA would have understood that the combination of Kirschman with the '477 Publication would have been a combination of prior art elements (Kirschman's cap 14 and the '477 Publication's beveled thread start, reverse angle thread form 36, and/or break-off head 49/149) according to known methods (forming Kirschman's male cap threads 46 with a beveled start, as a reverse angle thread form and/or forming a break-off head 49/149 and a breakaway region 53/153 on top of Kirschman's cap 14 as taught by the '477 Publication) to yield predictable results (Kirschman's cap 14 with a beveled thread start, a reverse angle thread form 36, and/or a break-off head 49/149 as taught by the '477 Publication).

3. Claim 8

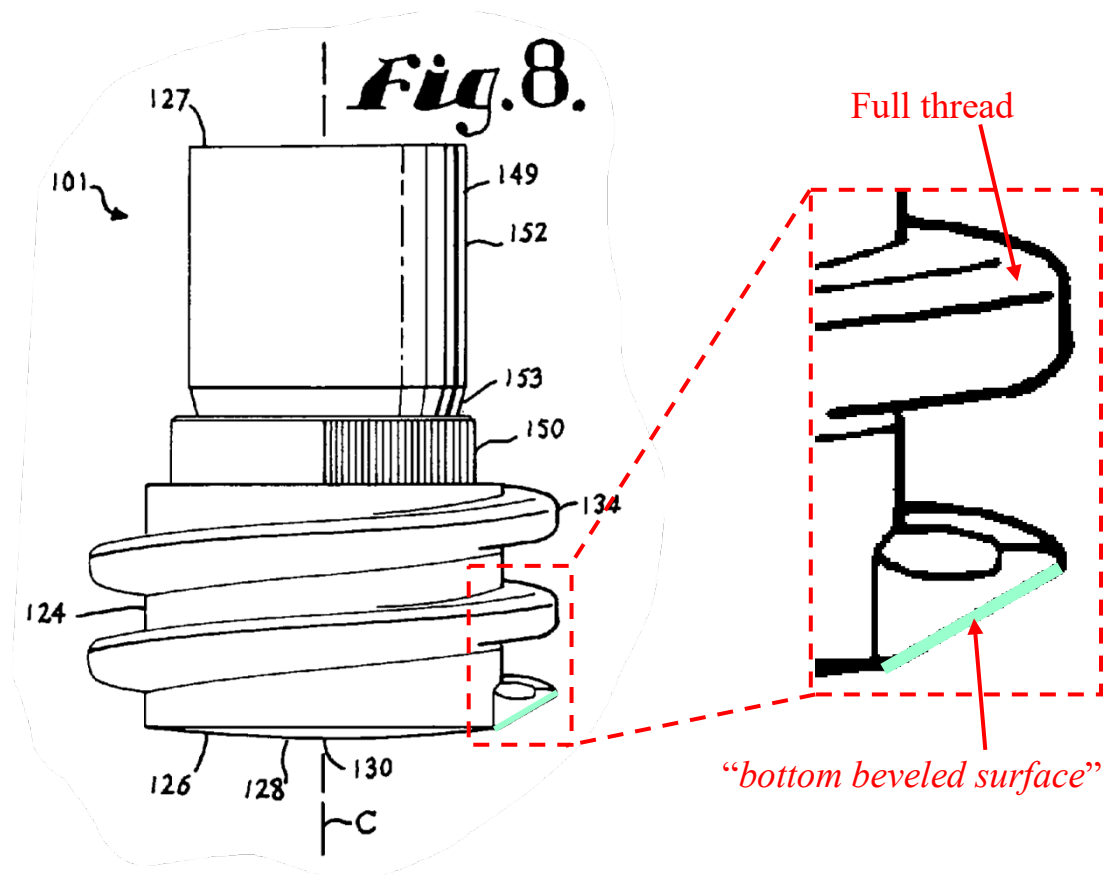
8[a] *The medical implant assembly of claim 1, wherein the lower surface of the start structure includes a bottom beveled surface.*

271. Kirschman in view of the '477 Publication renders obvious limitation 8[a].

272. As explained above in limitation 1[f], Kirschman discloses a leading edge portion 46a ("start structure") having a "lower surface." To the extent Kirschman does not explicitly disclose that the "lower surface" of the leading edge portion 46a includes "a bottom beveled surface," the '477 Publication teaches this limitation.

273. A POSITA would have understood that a “*beveled surface*” is a surface that meets another surface at an angle other than 90°. See Ex.1019, 174 (“bevel” “The angle or inclination of a line or surface that meets another at any angle but 90°....To cut an inclination that forms an angle other than a right angle.”).

274. As shown in Fig. 8 of the '477 Publication below, a POSITA would have understood that the lower surface of the start structure of the guide and advancement structure 134 is cut at an angle other than 90° relative to the other portions of the thread, *i.e.*, “*beveled*” (as compared to the full thread):



The '477 Publication (Ex.1008), Fig. 8 (annotated)

275. For the reasons described above in Section VIII.C.2., a POSITA would have been motivated to combine Kirschman with the '477 Publication's guide and advancement structure 134 to form the lower surface of Kirschman's leading edge portion 46a as a "*bottom beveled surface*."

276. Therefore, because the '477 Publication teaches that the bottom surface of the guide and advancement structure 134 is beveled, Kirschman in view of the '477 Publication renders obvious "*wherein the lower surface of the start structure includes a bottom beveled surface*" as claimed.

4. Claim 9

9[a] *The medical implant assembly of claim 1, wherein the upper surface of the continuously helically wound thread form of the plug slopes rearward from the root towards the crest.*

277. Kirschman in view of the '477 Publication renders obvious limitation 9[a].

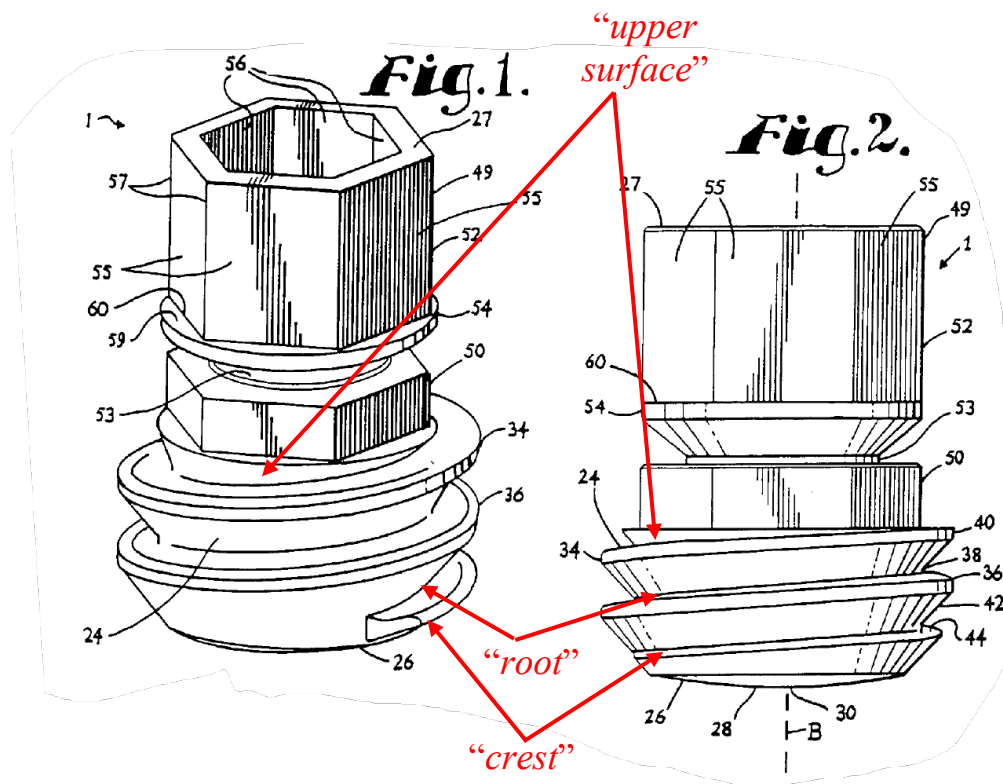
278. The '477 Publication explains that the guide and advancement structure 34 "is a helically wound reverse angle thread form 36." Ex.1008, [0030]. Specifically, "the closure 1 includes a body 24 that has a generally cylindrical or plug shape with a substantially circular horizontal cross section and a central axis of rotation B." Ex.1008, [0029]. The '477 Publication describes the reverse angle thread form 36 as having a trailing surface 44 ("*upper surface*") that extends at an

angle rearwardly from a perpendicular relative to the axis B:

With reference to FIG. 2, the illustrated thread form 36 has a root 38 and a crest 40. Further, the thread form 36 has a lead surface 42 and a trailing surface 44 (described relative to the position thereof during insertion of the closure 1 into the bone screw receiver 13). **In a reverse angle thread, the trailing surface 44 from the root 38 to the crest 40 extends at an angle rearwardly from a perpendicular line relative to the axis B.** Typically, the trailing surface 44 is at an angle between 1 and 20 degrees relative to such a perpendicular.

Ex.1008, [0031].

279. Thus, as shown in Figs. 1 and 2 below, the trailing surface 44 (“*upper surface*”) “*slopes rearward from*” the root 38 (“*root*”) to the crest 40 (“*crest*”):



The '477 Publication (Ex.1008), Figs. 1-2 (annotated)

280. For the reasons described above in Section VIII.C.2., a POSITA would have been motivated to combine Kirschman with the '477 Publication to form Kirschman's male cap threads 46 as the '477 Publication's reverse angle thread from 36 to prevent splaying of Kirschman's receiver 12.

281. Therefore, because the '477 Publication discloses a reverse angle thread form 36 with a trailing surface 44 that angles rearwardly from a perpendicular relative to the axis B, Kirschman in view of the '477 Publication renders obvious "*wherein the upper surface of the continuously helically wound thread form of the plug slopes rearward from the root towards the crest*" as claimed.

5. Claim 10

10[a] *The medical implant assembly of claim 9, wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn along the upper surface.*

282. Kirschman in view of the '477 Publication renders obvious limitation 10[a].

283. As explained above in limitation 9[a], the '477 Publication discloses a closure 1 with a reverse angle thread form 36 having a trailing surface 44 that angles rearwardly from a perpendicular relative to the axis B. The '477 Publication further discloses that "the trailing surface 44 is at an angle **between 1 and 20**

degrees relative to such a perpendicular.” Ex.1008, [0031]. Thus, the ’477 Publication explains that the trailing surface 44 (“*upper surface*”) is “*at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation.*”

284. For the reasons described above in Section VIII.C.2., a POSITA would have been motivated to combine Kirschman with the ’477 Publication to form Kirschman’s male cap threads 46 as the ’477 Publication’s reverse angle thread from 36 to prevent splaying of Kirschman’s receiver 12.

285. Therefore, because the ’477 Publication discloses a reverse angle thread form 36 with a trailing surface 44 that is angled at 1-20 degrees, Kirschman in view of the ’477 Publication renders obvious “*wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn along the upper surface*” as claimed.

6. Claim 11

11[a] *The medical implant assembly of claim 1, wherein the plug is a breakoff plug.*

286. Kirschman in view of the ’477 Publication renders obvious limitation 10[a].

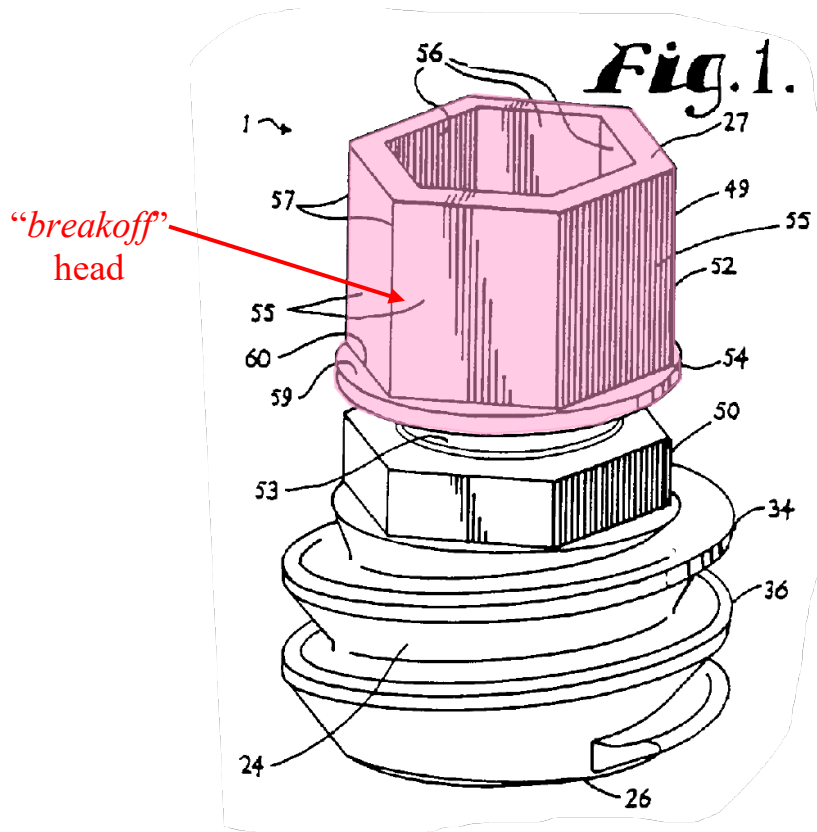
287. The ’477 Publication discloses a closure 1 that includes a break-off head 49 that breaks away from the remainder of the closure 1 when a

predetermined torque is applied thereto:

The closure 1 also includes a driving or installation break-off head 49 and a removal head 50 that are coaxially attached to the body 24. The removal head 50 is located between the body 24 and the driving head 49 and disposed near the guide and advancement structure 34. **The driving head 49 is disposed on a break-off portion 52 that is secured to the body 24 at a breakaway region 53 adjacent the removal head 50 and is designed to break away from the remainder of the closure 1 subsequent to a predetermined torque being applied to the driving head 49,** such as 100 inch pounds, during installation of the closure 1 into the bone screw 5. A barrier in the form of a cylindrical rim stop 54 is disposed on the break-off portion 52 between the breakaway region 53 and the driving head 49. The illustrated rim stop 54 is adjacent to the driving head 49.

Ex.1008, [0032]; *see also* [0042] (second embodiment).

288. The break-off head 49 of the closure 1 is illustrated in Fig. 1 below (*see also* Ex.1008, Fig. 7 (break-off head 149)):



The '477 Publication (Ex.1008), Fig. 1 (annotated)

289. For the reasons described above in Section VIII.C.2., a POSITA would have been motivated to combine Kirschman with the '477 Publication so that Kirschman's cap 14 includes the '477 Publication's break-off head 49/149 so that the cap 14 has a lower profile.

290. Therefore, because the '477 Publication discloses a closure 1/101 having a break-off head 49/149, Kirschman in view of the '477 Publication renders obvious “*wherein the plug is a breakoff plug*” as claimed.

D. Ground 4: Claims 3, 12, 13, 14, 15, and 16 are obvious over

Kirschman and Boschert.**1. Summary of Boschert**

291. Boschert “provides intervertebral connection systems suited for stabilization of the spine.” Ex.1009, 1:5-7. Specifically, Boschert describes spinal fixation using pedicle screws coupled to rods:

One spinal fixation technique involves immobilizing the spine by using orthopedic rods, commonly referred to as spine rods, that run generally parallel to the spine. This may be accomplished by exposing the spine posteriorly and fastening bone screws to the pedicles of the appropriate vertebrae. **Clamping elements adapted for receiving a spine rod therethrough are then used to join the spine rods to the screws.** The aligning influence of the rods forces the spine to conform to a more desirable shape. In certain instances, the spine rods may be bent to achieve the desired curvature of the spinal column.

Ex.1009, 1:45-55.

292. Boschert explains that “[s]urgeons have encountered considerable difficulty when attempting to insert spinal fixation devices...because the U-shaped heads of adjacent screws are often out of alignment with one another due to curvature in spines and the different orientations of the pedicles receiving the screws.” Ex.1009, 2:6-11. Thus, “spine rods must often be bent in multiple planes in order to pass the rods through adjacent U-shaped channels,” thereby “weaken[ing] the strength of the assembly and result[ing] in significantly longer

operations.” Ex.1009, 2:12-15.

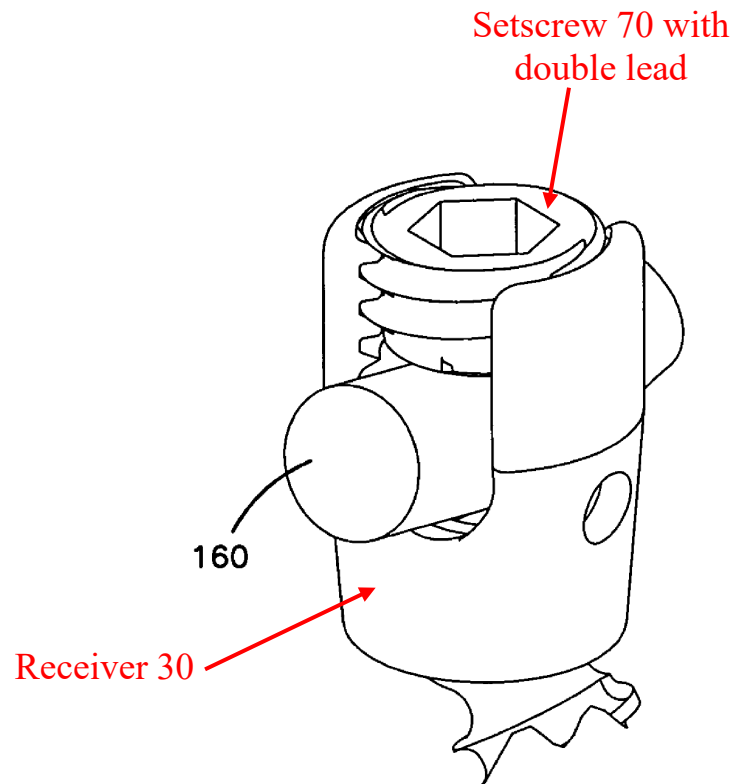
293. Accordingly, Boschert describes “a need for a screw head securing mechanism or device that provides a strong, effective, and secure lock of the screw head in its desired position” and “a screw head securing mechanism or device that is minimal in size and has a reduced amount of components to provide for a simpler, more effective, and less cumbersome device for fixing screws.” Ex.1009, 2:28-34.

294. To this end, Boschert discloses that “[t]he fixation device 10 includes a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60, and a bottom portion 31 adapted for receiving a head 23 of a bone fastener such as a bone screw 20.” Ex.1009, 4:16-19. The fixation device 10 “includes a fastener such as a setscrew 70 for clamping the rod 60 within the saddle 39 of the receiver 30” (Ex.1009, 4:26-28):

In use, **the setscrew 70 provides an axial locking force on the rod 60.** When contacted by the setscrew 70, the rod 60 is caused to axially apply a force on the seat structure 40. The seat structure 40, in turn, moves to create a clamping effect on the spherical head 23 of the bone screw 20 against the ring 50 coupled to the bottom end 31 of the receiver 30. **When the setscrew 70 is fully tightened, the rod 60 is locked between the setscrew 70 and the seat structure 40,** and the screw head 23 is locked between the seat structure 40 and the retainer 50.
Ex.1009, 7:7-15.

295. Boschert explains that “[t]he threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” Ex.1009, 7:21-23. The fixation device 10 is shown in Fig. 7 below:

FIG.7



Boschert (Ex.1009), Fig. 7 (annotated)

2. Reasons to Combine Kirschman and Boschert

296. As an initial matter, Boschert is analogous art to the '873 Patent because both are in the same field of endeavor. The '873 Patent “is directed to [a] structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some

embodiments thereof, for use with spinal bone anchors such as polyaxial screws.” Ex.1001, 1:27-31. Similarly, Boschert “provides intervertebral connection systems suited for stabilization of the spine.” Ex.1009, 1:5-7. Specifically, Boschert discloses a “fixation device 10 includ[ing] a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60” and “a fastener such as a setscrew 70 for clamping the rod 60 within the saddle 39 of the receiver 30.” Ex.1009, 4:16-18, 4:26-28. Thus, like the ’873 Patent, Boschert is also related to the field of bone anchors for use in spinal surgery.

297. A POSITA would have found it obvious to combine Boschert with Kirschman because it would have simply involved forming Kirschman’s cap 14 with Boschert’s two threads, which was well-known in the art.

298. Kirschman explains that “[d]uring the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap,” which “affects the desired correction of the spine.” Ex.1005, [0005]. To improve seating of the rod in the channel, Kirschman discloses a polyaxial screw that “incorporat[es] a thread design that prevents cross threading of the small-pitch threads of the locking cap/tulip pair, achieves high connection strength immediately after initial thread engagement and offers improved tactile feedback of thread engagement to the surgeon.” Ex.1005, [0008]. Kirschman states that “[a]lthough not shown, it should be appreciated that other conventional

components may be used with the receiver.” Ex.1005, [0051]. Therefore, a POSITA would have been motivated to look elsewhere in the art for other well-known components that would have further improved locking of the cap on the receiver.

299. Boschert also describes problems with attaching rods to pedicle screws. Boschert explains that “[s]urgeons have encountered considerable difficulty when attempting to insert spinal fixation devices...because the U-shaped heads of adjacent screws are often out of alignment with one another due to curvature in spines and the different orientations of the pedicles receiving the screws.” Ex.1009, 2:6-12. Although polyaxial spinal fixation devices had been developed, Boschert states that “[t]here is a need for a screw head securing mechanism or device that provides a strong, effective, and secure lock of the screw head in its desired position” and “a screw head securing mechanism or device that is minimal in size and has a reduced amount of components to provide for a simpler, more effective, and less cumbersome device for fixing screws.” Ex.1009, 2:17-35.

300. In that regard, Boschert discloses a “fixation device 10 includ[ing] a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60” and “a fastener such as a setscrew 70 for clamping the rod 60 within the saddle 39 of the receiver 30.” Ex.1009, 4:16-18, 4:26-28. Thus, “the

setscrew 70 provides an axial locking force on the rod 60” such that “[w]hen the setscrew 70 is fully tightened, the rod 60 is locked between the setscrew 70 and the seat structure 40.” Ex.1009, 7:7-8, 7:12-14. In particular, “[t]he threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” Ex.1009, 7:21-23. A POSITA would have understood that “double lead” means that the setscrew 70 includes two leads or, in other words, two threads.

301. It would have been obvious to a POSITA that Kirschman’s cap 14 could have been combined with Boschert to further improve the cap 14, as described in Boschert. Accordingly, a POSITA would have understood that the male cap threads 46 of Kirschman’s cap 14 would have been modified by forming the male cap threads 46 with two threads as taught by Boschert, thereby allowing the cap 14 to start more easily. A POSITA would have understood that this would have improved the cap 14’s ability to secure the rod 16 within the rod-receiving channel 26 by making it easier for the cap 14 to be inserted into the receiver 12.

302. A POSITA would have had a reasonable expectation of success in forming Kirschman’s cap 14 with two threads because, as explained in Section VI.B., multi-threaded screws and the manufacturing thereof were well-known in the art. *See* Ex.1010, 20 (“multiple start thread: a screw thread with two or more threads where the pitch is equal to the thread lead divided by the number of thread

starts (see Fig. 42). Also called multiple lead thread.”) (emphasis removed); Ex.1011, 1.01 (“MULTIPLE-START THREAD.—A multiple-start thread is one having the lead equal to the pitch”); Ex.1015, 1028 (describing design of multi-start threads); Ex.1017, 2:36-65 (“[B]y introducing two separate thread helixes that start and finish 180° apart, the load the connection will carry has found to increase....This increase in strength is made possible by balancing the two areas of greatest train, that is at the thread discontinuities at opposing sides.”); Ex.1018, 13:35-41 (“With such a dual thread construction, the threads start 180 degrees apart, such that cutting forces produced by self-tapping will substantially offset one another. Hence a self-tapping implant will tend to rotate into a pilot hole in a balanced manner.”). Thus, forming a double-threaded closure would have involved well-known techniques within the skill of a POSITA.

303. Therefore, a POSITA would have understood that the combination of Kirschman with Boschert would have been a combination of prior art elements (Kirschman’s cap 14 and Boschert’s double lead threads 72) according to known methods (well-known manufacturing techniques for forming multi-threaded closures) to yield predictable results (Kirschman’s cap 14 with two threads as taught by Boschert).

3. Claim 3

3[a] *The medical implant assembly of claim 1, wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from*

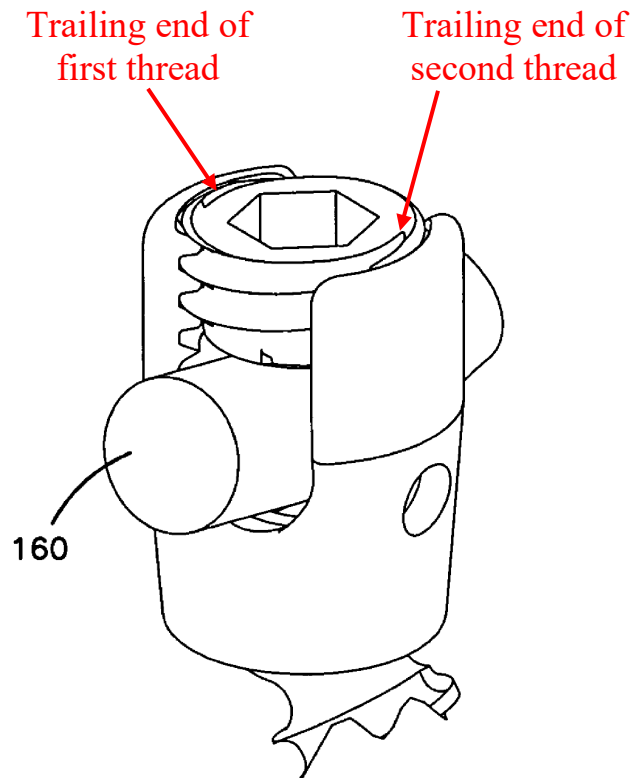
a second start structure.

304. Kirschman in view of Boschert renders obvious limitation 3[a].

305. As explained above in limitation 1[e], Kirschman discloses a male cap thread 46 having a leading edge portion 46a (“*start structure*”). To the extent Kirschman does not explicitly disclose “*a second start structure*” that is “*disposed at a diametrically opposite location*” from the “*first start structure*,” Boschert teaches this limitation.

306. First, Boschert discloses a setscrew 70 with threads 72 that “can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” Ex.1009, 7:21-23. A “double lead” means that the setscrew 70 has two threads, each having a lead or start structure. Thus, Boschert discloses a “*first start structure*” and a “*second start structure*.”

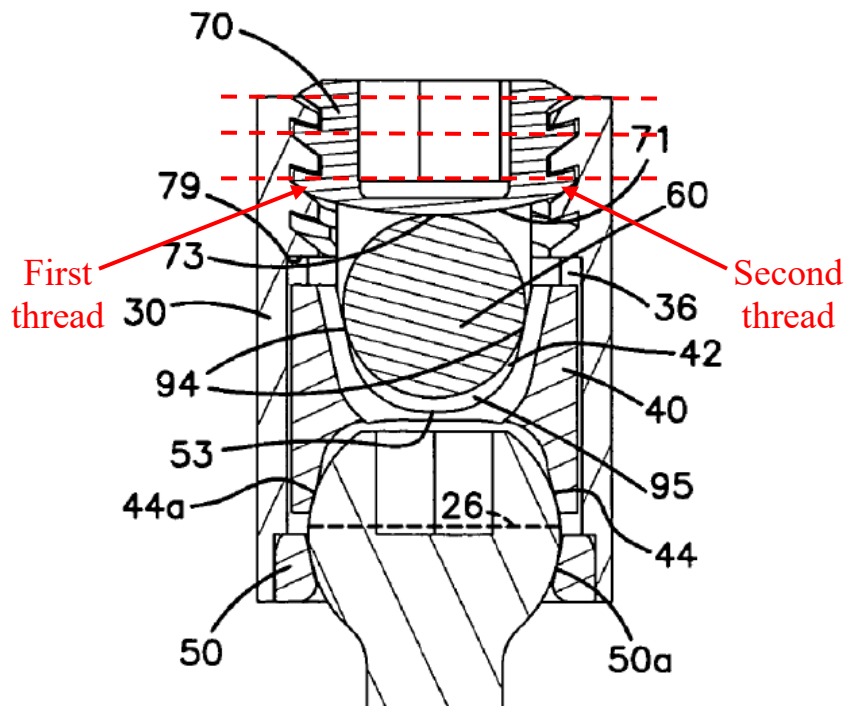
307. Second, Boschert teaches that the threads 72 are “*diametrically*” opposed. As shown in Fig. 7 below, the trailing ends of the threads 72 are located opposite each other (approximately 180° from each other) on the top of the setscrew 70, *i.e.* are at “*diametrically opposite location*” from each other:



Boschert (Ex.1009), Fig. 7 (cropped and annotated)

As explained above in Section VI.B., this indicates that the “*first start structure*” and “*second start structure*” also are disposed at a similarly “*diametrically opposite location*” from each other.

308. Moreover, as shown below in Fig. 3, the threads are symmetrical and diametrically opposed about the length of the setscrew 70:



Boschert (Ex.1009), Fig. 3 (cropped and annotated)

As explained above in Section VI.B., because the first thread and second thread on opposite sides of the setscrew 70 are vertically aligned, a POSITA would have understood that the first and second start structures are symmetric and diametrically opposed.

309. Because both the trailing ends of the first and second threads are located “*diametrically opposite*” each other and the threads are symmetrical and diametrically opposed along the length of the setscrew 70, it would have been obvious to a POSITA in view of Boschert that the “*first start structure*” would be “*disposed at a diametrically opposite location*” from the “*second start structure*” as well.

310. Additionally, as explained above in Section VI.B. above, it was well-known in the art that, “to achieve proper distribution of each start around the cylinder, each thread has to start at an equal angle, determined by the following calculation: Thread cylindrical spacing angle = $360 / \text{Number of starts}$.” Ex.1016, 1250; *see also* Ex.1015, 1028; Ex.1017, 2:18-65; Ex.1018, 13:35-41. Accordingly, a POSITA would have understood that a double-threaded setscrew 70, as disclosed in Boschert, would have had a thread cylindrical spacing angle of 180° (*i.e.*, $360^\circ / 2$). Thus, the “*first start structure*” would be disposed 180° from the “*second start structure*” at a “*diametrically opposite location*.”

311. For the reasons described above in Section VIII.D.2., a POSITA would have been motivated to combine Kirschman with Boschert so that Kirschman’s cap 14 would have included a second thread with a start structure at a diametrically opposed location from Kirschman’s leading edge portion 46a of the male cap threads 46 as taught by Boschert.

312. Therefore, because Boschert discloses a setscrew 70 with dual lead threads that are symmetric and diametrically opposed to each other, Kirschman in view of Boschert renders obvious “*wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure*” as claimed.

4. Claim 12

12[pre] *A medical implant assembly comprising:*

313. This limitation is substantially similar to limitation 1[pre], and for the same reasons as discussed above, the prior art renders this limitation obvious.

12[a] *a receiver having an upper portion with an inner surface, a top surface, and a channel, the inner surface having a helically wound thread extending up to the top surface, the channel configured to receive a rod; and*

314. This limitation is substantially similar to limitations 1[a] and 1[b], and for the same reasons as discussed above, the prior art renders this limitation obvious.

12[b] *a plug configured for positioning within the upper portion of the receiver, the plug having an axis of rotation,*

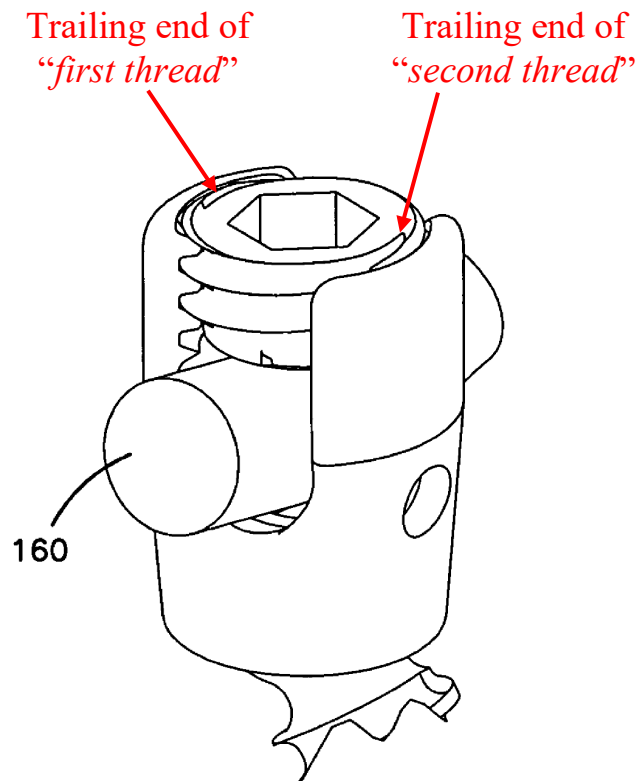
315. This limitation is substantially similar to limitation 1[c], and for the same reasons as discussed above, the prior art renders this limitation obvious.

12[c] *a continuously helically wound thread form comprising a first thread and a second thread,*

316. Kirschman in view of Boschert renders obvious limitation 12[c].

317. Boschert discloses a setscrew 70 with threads 72 that “can also be designed with a **double lead** to allow the setscrew 70 to start more easily than with a single lead.” Ex.1009, 7:21-23. A “double lead” means that the setscrew 70 has two threads, each having a lead or start structure (*see* limitation 3[a]). Thus, Boschert discloses a “*first thread*” and a “*second thread*.” Fig. 7 below shows the

trailing ends of the “*first thread*” and “*second thread*”:



Boschert (Ex.1009), Fig. 7 (cropped and annotated)

318. For the reasons described above in Section VIII.D.2., a POSITA would have been motivated to combine Kirschman with Boschert so that Kirschman’s cap 14 would have included a second thread the male cap threads 46 as taught by Boschert.

319. Therefore, because Boschert discloses a dual lead setscrew 70, Kirschman, alone or in combination with Higbee, and Boschert renders obvious “*a continuously helically wound thread form comprising a first thread and a second thread*” as claimed.

12[d] a bottom surface with an annular outer edge,

320. This limitation is substantially similar to limitation 1[d], and for the same reasons as discussed above, the prior art renders this limitation obvious.

12[e] and an outward facing surface encircling the bottom surface,

321. Kirschman renders obvious limitation 12[e].

322. As explained above in limitation 1[d], Kirschman discloses a bottom end surface 14c (“*bottom surface*”) with a deformable ring 14d (“*annular outer edge*”) disposed around the end surface 14c.

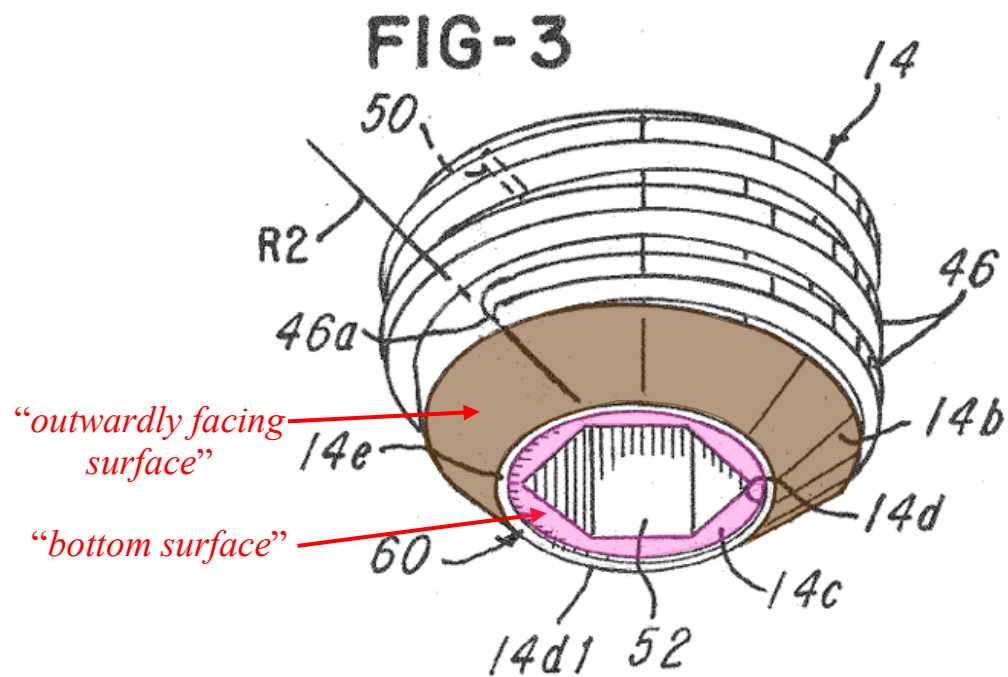
323. Moreover, as described in limitation 1[d], Kirschman’s bottom 14b also has a frusto-conical guiding surface (“*outwardly facing surface*”) to facilitate guiding the cap 14 onto the receiver 12:

As illustrated in FIGS. 1, 3 and 4, note that **a bottom 14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12** to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a with the cut-out area 49 of the receiver 12 so that the cap 14 can be easily guided and screwed onto the receiver 12. In the embodiment being described, **notice that the bottom 14b is frusto-conical, but it should be understood that the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12.** For example, the surface could have an arcuate, curved or semi-spherical shape such that the bottom 14b is adapted to facilitate

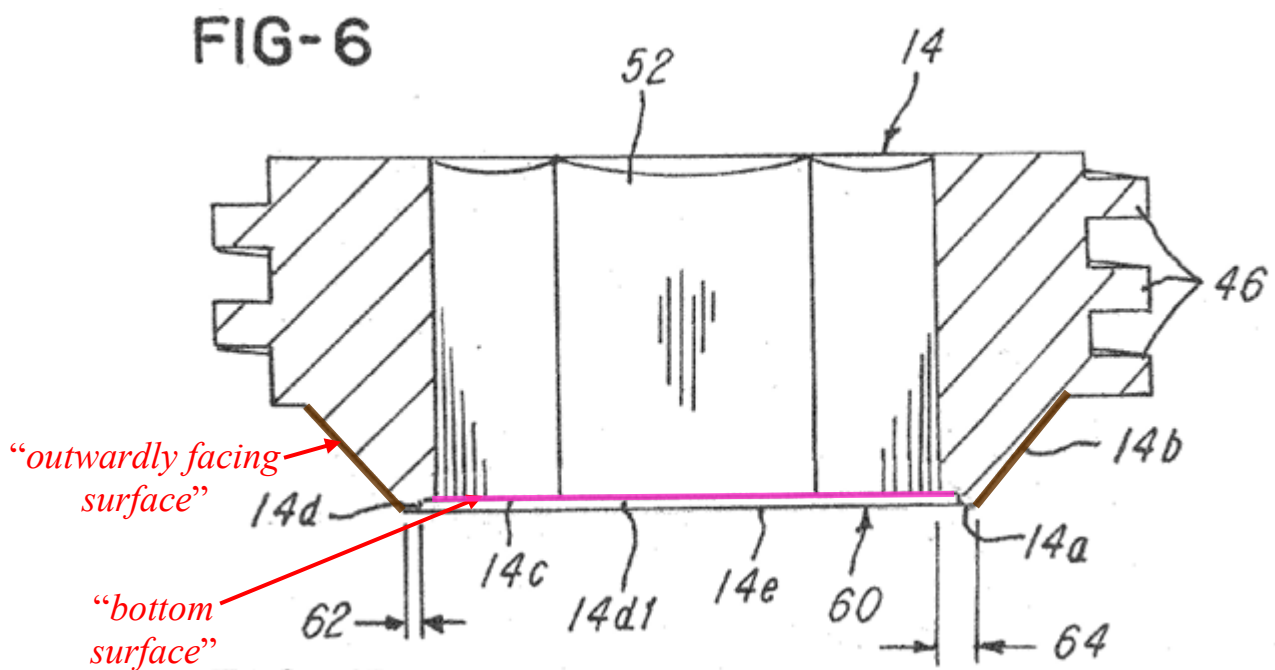
aligning and guiding the cap 14 onto the receiver 12 so that the cap 14 can be easily screwed onto the receiver 12.

Ex.1005, [0043].

324. Kirschman explains that the guiding surface of “the bottom 14b terminates at an end 14c” (“*bottom surface*”). Ex.1005, [0044]. The frusto-conical guiding surface (“*outwardly facing surface*”) of the bottom 14b faces outward from the body of the cap (“*outwardly facing*”) and surrounds (“*encircles*”) both the end surface 14c (“*bottom surface*”) and the deformable ring 14d. Thus, both interpretations of the “*bottom surface*,” the guiding surface (“*outwardly facing surface*”) surrounds the “*bottom surface*.” Below in Figs. 3 and 6, the guiding surface (“*outwardly facing surface*”) is illustrated under the first interpretation in which the “*bottom surface*” is the end surface 14c:

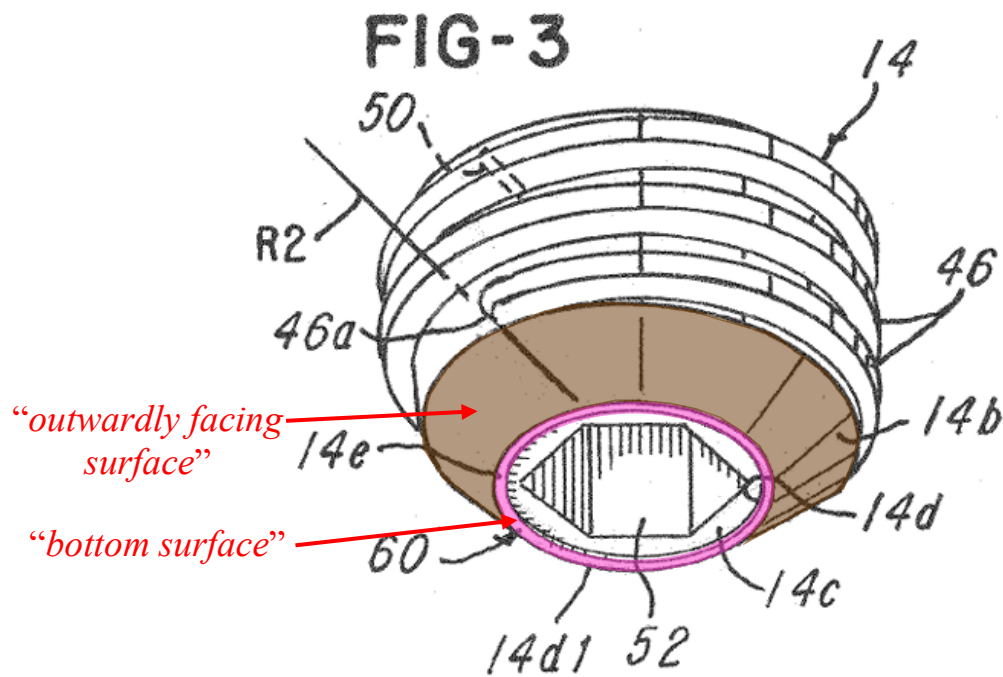


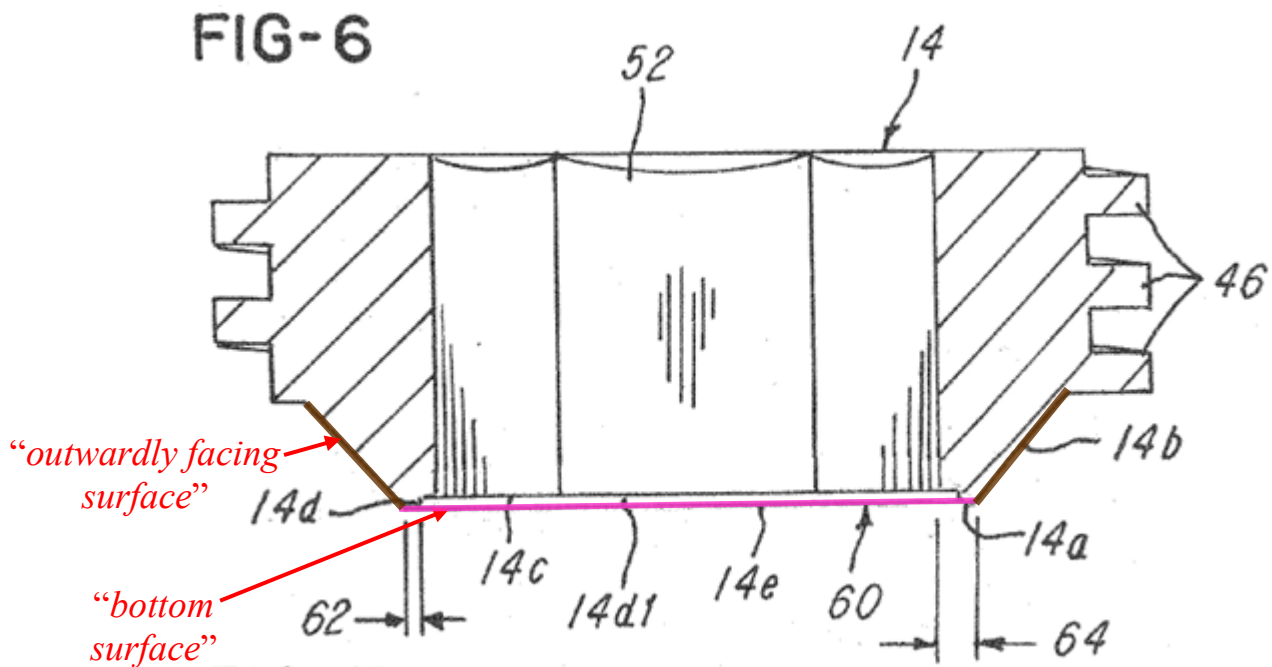
Kirschman (Ex.1005), Fig. 3 (annotated)



Kirschman (Ex.1005), Fig. 6 (annotated)

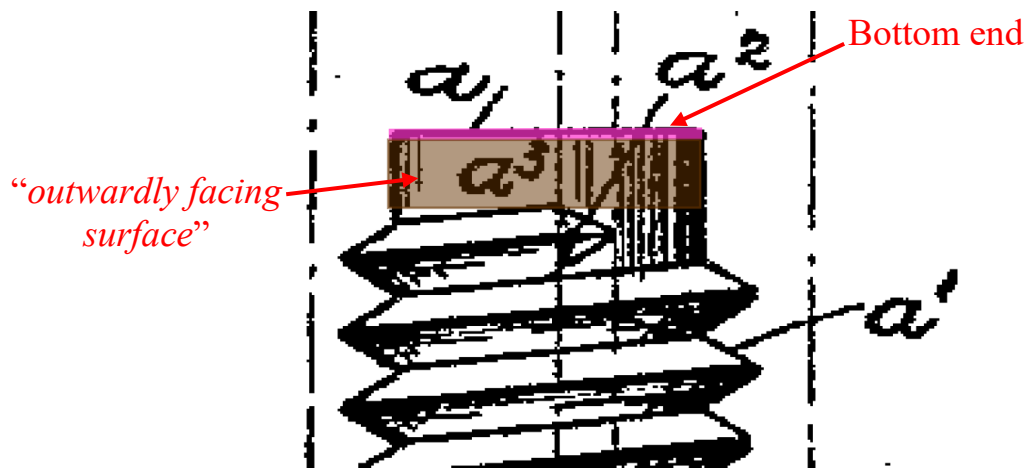
Below in Figs. 3 and 6, the guiding surface (“*outwardly facing surface*”) is illustrated under the second interpretation in which the “*bottom surface*” is the bottom surface of the deformable ring 14d:

**Kirschman (Ex.1005), Fig. 3 (annotated)**



Kirschman (Ex.1005), Fig. 6 (annotated)

325. To the extent Kirschman does not explicitly disclose an “*outwardly facing surface*,” this was well-known in the art. For example, Higbee’s bolt/screw includes “a cylindrical extension...between the thread end a^2 and the bolt end a ” (Ex.1006, 1:69-71):



Higbee (Ex.1006), Fig. 1 (rotated, cropped, and annotated)

326. For the same reasons described above in limitations 1[d] and 1[h], a POSITA would have been motivated to form Kirschman’s guiding surface as the smooth, cylindrical extension described in Higbee. Thus, to the extent that Kirschman’s guiding surface is not considered an “*outwardly facing surface*” of the cap, a POSITA would have modified Kirschman in view of Higbee’s embodiment to formed as a cylindrical surface (“*outwardly facing surface*”) that surrounds the end surface 14c and the deformable ring 14d (“*encircl[e] the bottom surface*”).

327. Therefore, because Kirschman discloses a frusto-conical guiding surface that extends to and surrounds the end surface 14c and the deformable ring 14d and Higbee discloses a cylindrical extension a^3 between the thread end a^2 and the bolt end a , Kirschman renders obvious “*an outward facing surface encircling*

the bottom surface” as claimed.

12[f] *the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread,*

328. This limitation is substantially similar to limitations 1[e], and for the same reasons as discussed above, the prior art renders this limitation obvious.

12[g] *the first start structure including a first leading face extending below the first upper surface to a first lower surface,*

329. This limitation is substantially similar to limitation 1[f], and for the same reasons as discussed above, the prior art renders this limitation obvious.

12[h] *the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread,*

330. Kirschman in view of Boschert renders obvious limitation 12[h].

331. As explained above in limitation 12[c], Boschert discloses a “double lead” setscrew 70 that has a “*first thread*” and a “*second thread*.”

332. Further, as explained above in Section VI.B., a POSITA would have known that the “*second thread*” would be the identical to the “*first thread*” and simply axially spaced from the “*first thread*.” This would have been the simplest way to manufacture the threads and would have ensured easy insertion of the closure into the receiver.

333. Thus, for the same reasons as explained above for limitation 12[f], Kirschman in view of Boschert renders obvious “*the second thread comprising a second start structure and a second upper surface extending between a second root*

and a second crest of the second thread” as claimed.

12[i] *the second start structure including a second leading face extending below the second upper surface to a second lower surface,*

334. Kirschman in view of Boschert renders obvious limitation 12[i].

335. As explained above in limitation 12[h], a POSITA would have understood that the “*second thread*” would have been the same as the “*first thread*,” but axially spaced therefrom.

336. Thus, for the same reasons as explained above for limitation 12[g], Kirschman in view of Boschert renders obvious “*the second start structure including a second leading face extending below the second upper surface to a second lower surface*” as claimed.

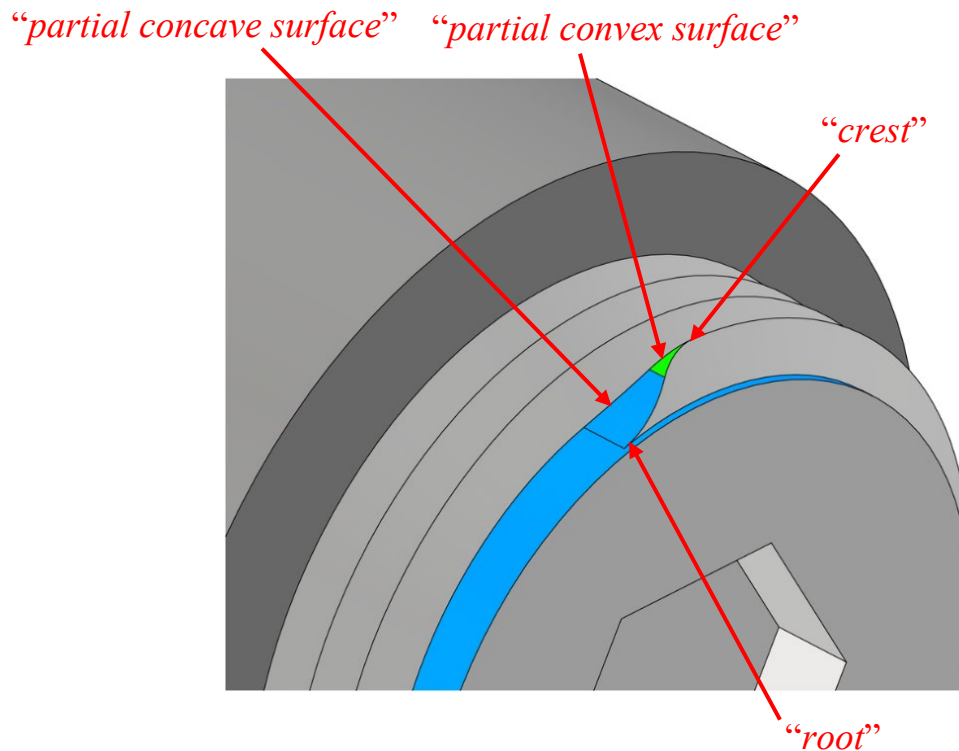
12[j] *the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively,*

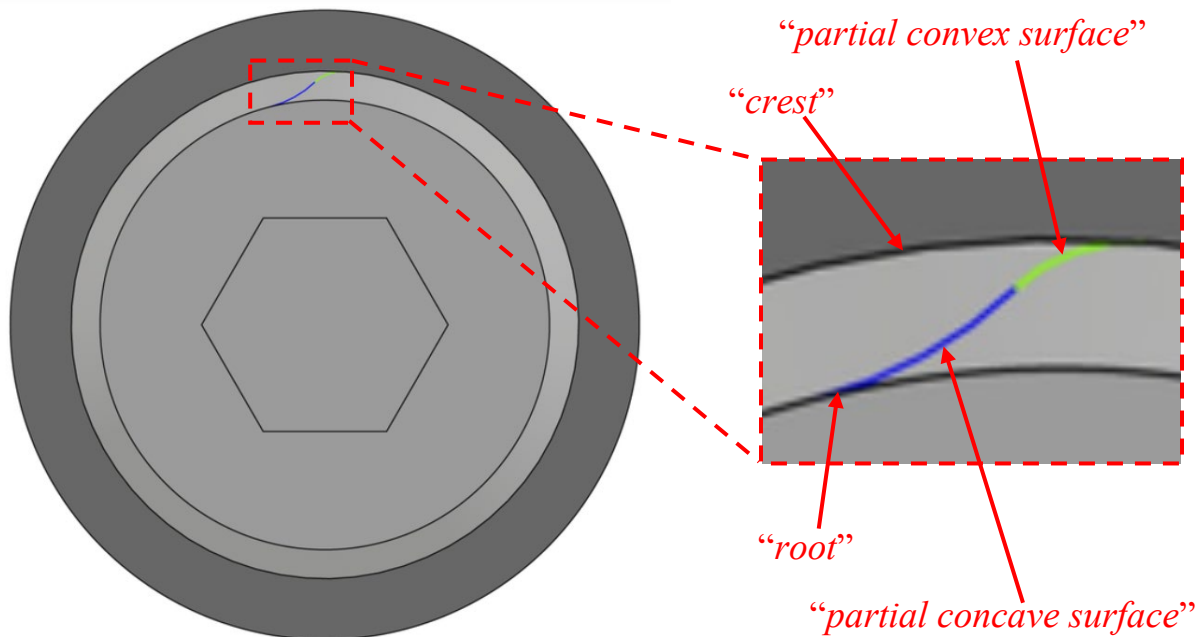
337. Kirschman in view of Boschert renders obvious limitation 12[j].

338. As explained in limitation 2[a] above, Kirschman discloses that the leading edge portion 46a has a convex surface (*see* Ex.1005, Fig. 3) and Higbee discloses that the thread end a^2 is a rounded,convex surface (*see* Ex.1006, Fig. 6). To the extent Kirschman and Higbee do not explicitly disclose that the “*partial convex surface*” is “*adjacent the...crest*” or that the blunt face also includes “*a partial concave surface adjacent the...root*,” this was well-known in the art.

339. As explained in Section VI.A above, a POSITA would have

understood how to form a blunt thread start with a convex surface proximate the crest and a concave surface proximate the root. *See* limitation 2[a]. A POSITA would have known that blunt thread starts are generally formed by removing the thin, incomplete portion of the thread with a circular tool such that a concave surface is formed. Because a fully-concave leading face would have formed a sharp edge at the crest, it was also well-known to round off the edge along the crest using the same circular tool such that a convex surface would have been formed at the crest, as shown in the below graphics:





340. This would have smoothed out the leading face, thereby preventing the threads from cutting the surgeon’s glove or irritating the patient. Accordingly, a POSITA would have understood that the blunt face would have had both a *“partial concave surface adjacent...the root”* and a *“partial convex surface adjacent the...crest.”*

341. As explained above in limitation 12[h], a POSITA would have understood that the *“second thread”* would have been the same as the *“first thread,”* but axially spaced therefrom. Thus, a POSITA would have understood that both the *“first thread”* and *“second thread”* would have been formed with a

“partial concave surface adjacent...the root” and a “partial convex surface adjacent the...crest.”

342. Therefore, because forming a thread having a blunt face with a concave surface proximate the root and a convex surface proximate the crest was well-known to POSITAs, Kirschman in view of Boschert renders obvious *“the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively”* as claimed.

12[k] *the first lower surface of the first thread and the second lower surface of the second thread are spaced above and apart from the annular outer edge of the bottom surface of the plug.*

343. Kirschman in view of Boschert renders obvious limitation 12[i].

344. As explained above in limitation 12[h], a POSITA would have understood that the *“second thread”* would have been the same as the *“first thread,”* but axially spaced therefrom.

345. Limitation 12[k] is substantially similar to limitation 1[f]. Therefore, for the same reasons as discussed above, Kirschman in view of Boschert renders obvious *“the first lower surface of the first thread and the second lower surface of the second thread are spaced above and apart from the annular outer edge of the bottom surface of the plug”* as claimed.

5. Claim 13

13[a] *The medical implant assembly of claim 12, wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug.*

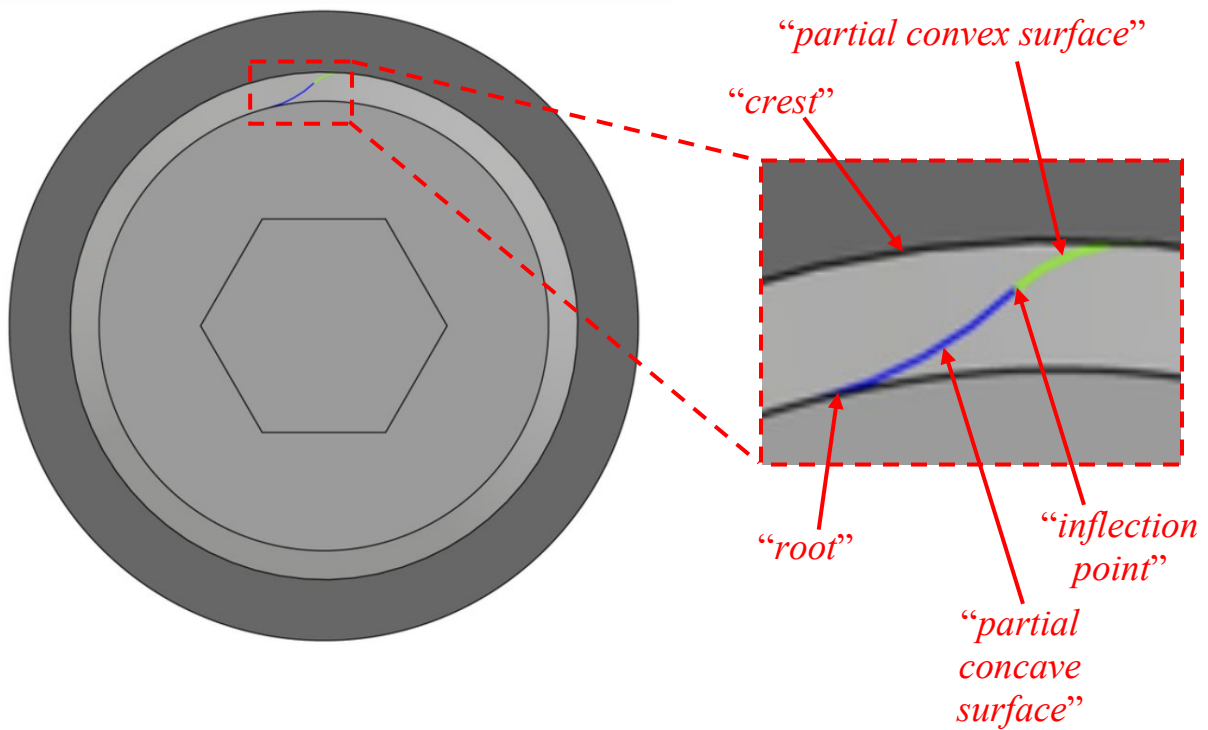
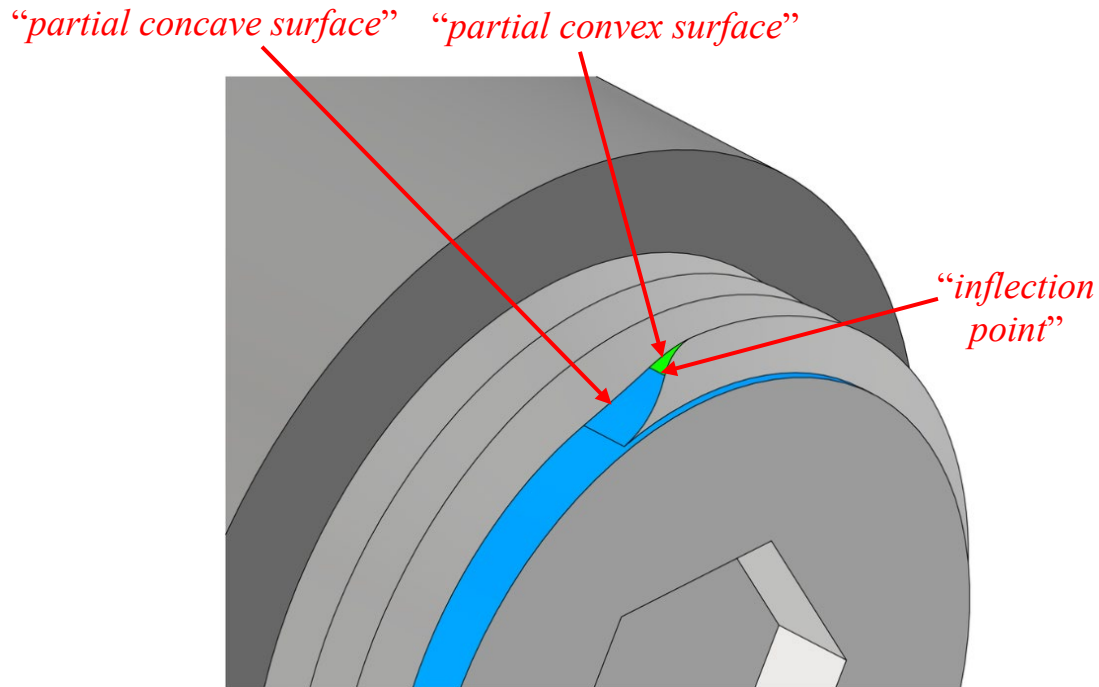
346. This limitation is substantially similar to limitation 3[a], and for the same reasons as discussed above, the prior art renders this limitation obvious.

6. Claim 14

14[a] *The medical implant assembly of claim 12, wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face.*

347. Kirschman in view of Boschert renders obvious limitation 14[a].

348. As explained above in limitation 12[j], a POSITA would have known that a blunt face of a blunt start thread would have been formed with a concave surface proximate the root and a convex surface proximate the crest to remove sharp portions of the blunt face after cutting. As explained above in Section VI.A., a POSITA also would have known that an “*inflection point*” would have been formed where the concave surface transitions to the convex surface, as shown in the below graphics:



349. As explained above in limitation 12[h], a POSITA would have understood that the “*first thread*” and the “*second thread*” would have been the same, but axially spaced from each other.

350. Therefore, because a POSITA would have known that an inflection point would have been formed where the concave surface transitions to the convex surface, Kirschman in view of Boschert renders obvious “*wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face*” as claimed.

7. Claim 15

15[a] *The medical implant assembly of claim 12, wherein the first and second leading faces each includes at least a partial planar surface.*

351. Kirschman in view of Boschert renders obvious limitation 15[a].

352. As explained above in limitation 12[h], a POSITA would have understood that the “*first thread*” and the “*second thread*” would have been the same, but axially spaced from each other.

353. Limitation 15[a] is substantially similar to limitation 7[a]. Therefore, for the same reasons as discussed above, Kirschman in view of Boschert renders obvious “*wherein the first and second leading faces each includes at least a partial planar surface*” as claimed.

8. Claim 16

16[a] *The medical implant assembly of claim 12, wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.*

354. This limitation is substantially similar to limitation 4[a], and for the same reasons as discussed above, the prior art renders this limitation obvious.

E. Ground 5: Claim 17 is obvious over Kirschman, Boschert, and Johnson.

1. Reasons to Combine Kirschman, Boschert, and Johnson

355. A POSITA would have been motivated to combine Kirschman and Boschert with Johnson for at least the same reasons described above in Section VIII.B.2.

2. Claim 17

17[a] *The medical implant assembly of claim 16, wherein the top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.*

356. This limitation is substantially similar to limitation 5[a], and for the same reasons as discussed above, the prior art renders this limitation obvious.

F. Ground 6: Claims 18 and 19 are obvious over Kirschman, Boschert, and the '477 Publication.

1. Reasons to Combine Kirschman, Boschert, and the '477

Publication

357. A POSITA would have been motivated to combine Kirschman and Boschert with Johnson for at least the same reasons described above in Section VIII.C.2.

2. Claim 18

18[a] *The medical implant assembly of claim 12, wherein the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface.*

358. This limitation is substantially similar to limitation 8[a], and for the same reasons as discussed above, the prior art renders this limitation obvious.

3. Claim 19

19[a] *The medical implant assembly of claim 12, wherein the plug is a breakoff plug.*

359. This limitation is substantially similar to limitation 11[a], and for the same reasons as discussed above, the prior art renders this limitation obvious.

IX. CONCLUSION

360. This declaration and my opinions herein are made to the best of my knowledge and understanding, and based on the material available to me, at the time of signing this declaration. I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code.

Date: 25MAR25

Troy D. Drewry
Troy D. Drewry

T R O Y D . D R E W R Y

EDUCATION

Masters of Engineering Management, Christian Brothers University, Memphis, TN

Masters of Biomedical Engineering, University of Memphis, Memphis, TN

Bachelor of Science in Mechanical Engineering, CAD/CAM Option, University of Southwestern Louisiana, Lafayette, LA

PROFESSIONAL EXPERIENCE

2019 – Present University of Mississippi, Oxford, MS

Professor of Practice – Biomedical Engineering

Currently teaching a two-course Senior Design Capstone program within the Department of Biomedical Engineering – BS in Biomedical Engineering program focused on the design and development of medical devices.

- ◆ **BME 200 – Introduction to Biomedical Engineering**
- ◆ **BME 461 – Biomedical Engineering Senior Design I**
- ◆ **BME 462 – Biomedical Engineering Senior Design II**

2019 – Present University of Mississippi, Oxford, MS

Operations Manager – Center for Diagnostics, Design, Devices, & Biomechanics

Currently managing this four-discipline center focused on the design, development, and verification and validation of new medical devices and diagnostics with the goal to ultimately incubate new business entities around this technology for commercialization.

2017 – Present Ragin Cajun Consulting LLC, Memphis, TN

Founder & Principal Engineer

RCC is a product development consulting firm helping innovators and inventors take their ideas from concept to commercialization. Services provided include but are not limited to:

- ◆ Project Management
- ◆ Engineering Design and Development
- ◆ Design Control and DHF Management
- ◆ Intellectual Property Landscape and Analysis
- ◆ Forensic Engineering & Expert Witness Services including Medical Devices

2013 – 2019 Christian Brothers University, Memphis, TN

Adjunct Professor – MBA Program

Taught a three-course Project Management Certification program within the Masters of Business Administration Degree Program and a course in the Healthcare MBA Program.

- ◆ **CMBA 601 – Business Ethics**
- ◆ **PMGT 681 – Project Management**
- ◆ **PMGT 682 – Project Management, Organization, Planning, and Leadership**
- ◆ **PMGT 683 – Project Analysis and Control**
- ◆ **HMBA 613 – Supply Chain Management and Project Management in Healthcare Systems**

- 2012 – 2017** **MB Innovations, Inc., Memphis, TN**
President & COO
 MB Innovations, Inc. ("MBI") is a medical technology development and manufacturing company, providing research, design and development services for established firms on a fee-for-service basis. MBI also creates and manufactures its own technologies and intellectual property to be the basis for new venture formation and job creation. MBI's presence in Memphis utilizes the region's workplace and logistics advantages in the medical device field, especially the musculoskeletal disease sector. The proximity to Memphis-based research and development capabilities is an important strategic advantage. MBI's team of accomplished engineers and surgeon advisors accelerates the time to market through a focused approach to product development.
- 2014 – 2017** **View Medical, Memphis, TN**
CEO
 View Medical is an intraoperative lighting technology company and a recent graduate of the ZeroTo510 Medical Device Accelerator in Memphis, TN funded by MB Venture Partners and Innova.
- 2009 – 2011** **Paradigm Spine, LLC, Memphis, TN**
VP, US Operations
- ◆ Oversight of US Manufacturing Activities and Memphis Inventory Facilities (Millstone)
 - ◆ Oversight of US R&D activities
 - ◆ Oversight of US Regulatory affairs
 - ◆ Liaison with Legal and IP on all patent activities
 - ◆ Liaison with Marketing and Field Operations on all publication activities
 - ◆ Liaison with Paradigm Spine GmbH on all quality activities
 - ◆ Contributed to all US Clinical & Regulatory Affairs, including clinical study enrollments & PMA filings
- 2008 – 2009** **Active Implants Corporation, Memphis, TN**
Chief Operating Officer
- ◆ Successfully closed \$10M C-Round of funding in April 2009
 - ◆ Exceeded 2008 revenue projection for TriboFit® Acetabular Buffer system - \$1M in sales
 - ◆ Worked alongside CEO and CFO with FORTIS Bank in the Netherlands to prepare Private Placement Memorandum (PPM) and conducted Fundraising road shows in Netherlands, France, and England
 - ◆ Finalized Global Manufacturing Agreement with Joint Replacement Instrumentation Ltd in the UK for all implants
 - ◆ Set up Global Logistics Network with Fed/Ex in Eindhoven to supply our EU distributors in Italy, United Kingdom, Spain, and Germany
- 2008** **Active Implants Corporation, Memphis, TN**
Vice President of Global Operations
- ◆ Responsible for the global manufacturing and production planning for the European commercialization of the TriboFit™ Modular Hip System
 - ◆ Established, advanced, and maintained all internal and external processes and operations necessary to produce and distribute all company products
 - ◆ Developed global supply chain to support current and future product introductions

1995 – 2008 Medtronic Spinal & Biologics/Medtronic Sofamor Danek/Sofamor Danek

2007 – 2008 Medtronic Spinal & Biologics, Memphis, TN

Group Director of Product Development, Intradiscal Division

- ◆ In May 2007 assumed responsibility for all Interbody implants (Cervical and Thoracolumbar) and an 11-member product development team
- ◆ Oversight of \$4.2M R&D budget
- ◆ Intradiscal products represented approximately 30% or \$550M of MS&B revenues
- ◆ Served as General Manager for Millennium Biologics Acquisition
- ◆ 2007 Circle of Excellence Winner for the Best Product Launch by a team – **VERTEX MAX™ Posterior Cervical Spinal System Japanese Product Introduction**
- ◆ Responsible for driving new material platforms for intradiscal applications that included Calcium Phosphate bone substitutes, HA coatings, and porous PEEK
- ◆ Led the integration of the Cervical and Thoracolumbar teams into one cohesive Product Development team
- ◆ Worked with Marketing to develop 5 to 10 year Product Pipeline to integrate new materials and biologics into the Intradiscal Product Portfolio

2006 – 2007 Medtronic Sofamor Danek, Memphis, TN

Group Director of Product Development, Cervical /Trauma Division

- ◆ Assumed responsibility for the Interdiscal as well as the Posterior Cervical Engineering Team
- ◆ Managed \$2.5M R&D budget
- ◆ Products under management represented \$250M in US revenues
- ◆ Directed the product development efforts for the next generation **VERTEX SELECT™ Posterior Cervical Spinal System**
- ◆ Led the development efforts for three new Cervical Interbody Implant systems

2004 – 2006 Medtronic Sofamor Danek, Memphis, TN

Director of Product Development, Cervical /Trauma Division

- ◆ Directed Posterior Cervical Engineering Team
- ◆ Launched **VERTEX MAX™ Posterior Cervical Spinal System** – the number one posterior cervical spinal system in the US
- ◆ Worked with Key Opinion Leaders to layout next generation system to accommodate **degenerative, deformity, and trauma indications**
- ◆ Led effort to design and protect intellectual property in the field of Minimally Invasive Posterior Cervical Surgery and Dynamic Stabilization of the Cervical Spine
- ◆ Worked with Medtronic Surgical Navigation to design and develop a system of instruments and implants to utilize image guided technologies to treat posterior cervical pathologies
- ◆ Managed KOL consulting agreements and worked with Legal to acquire necessary license agreements and IP acquisitions as needed by the business unit

2003 – 2004 Medtronic Sofamor Danek, Memphis, TN

Director of Product Development, Interbody/Ortho/Motion Technologies Division

- ◆ Managed engineering team of five (5) engineers and annual product development budget of **\$2.4M**
- ◆ Launched **first PEEK spinal implant – PEEK LT Cage™** with FDA approval via PMA supplement
- ◆ Launched the **PEEK Verte-Stack™ Vertebral Body Spacer, PEEK Telamon™ Vertebral Body Spacer, CATALYST™ Instrument set, Modular Spreader System, HOURGLASS™ Vertebral Body Spacer, and the HYDROSORB™ family of resorbable implants**

- ◆ Initiated a European Clinical Study comparing the **PEEK Telamon™** to the **HYDROSORB™ Telamon™** in a Posterior Lumbar Interbody Fusion (PLIF) model
 - ◆ Corporate member of the Trauma Spine Study Group that worked with spine surgeons to design and develop instruments and implants to treat spinal trauma
- 2001 – 2003 Medtronic Sofamor Danek, Memphis, TN**
Senior Manager, Product Development, Interbody/Ortho/Motion Technologies Division
- ◆ Managed engineering team of five (5) engineers and annual product development budget of **\$2.4M**
 - ◆ Responsible for New Biomaterials Development Initiative to get Resorbable and PEEK polymer implants to market
 - ◆ Conducted preclinical animal studies to determine radiographic, histologic, and biomechanical performance of these new materials
 - ◆ Corporate member of the Lumbar Spine Study Group that worked with spine surgeons to promote the use of new materials in the lumbar spine
- 2000 – 2001 Medtronic Sofamor Danek, Memphis, TN**
Manager, Product Development, Technology Development Division
- ◆ Managed Global Product Development Team of engineers and surgeons for the **COLORADO 2™ Spinal System**
 - ◆ Responsible for working with US and International KOLs to evaluate, test, and launch the system in the US with FDA approval
 - ◆ Corporate member of the Spinal Deformity Study Group that worked with deformity surgeons to refine and promote the concept of Fusionless Scoliosis treatment
- 1998 – 2000 Sofamor Danek, Memphis, TN**
Senior Product Development Engineer, Technology Development Division
- ◆ Selected to be part of new division entitled Technology Development with the mission to “develop, design, or acquire technologies and products with a targeted launch 3 to 5 years out”
 - ◆ Worked with KOL Surgeons to design, develop, and patent three concepts for **Fusionless Correction of Scoliosis**
 - ◆ Conducted necessary biomechanical testing and preclinical animal studies for FDA submission of Fusionless Scoliosis Systems
 - ◆ Received FDA approval for the **first shape memory alloy implant** – the **SMA Staple**
- 1997 – 1998 Sofamor Danek, Memphis, TN**
Product Development Engineer, Thoracolumbar Division
- ◆ Designed, developed, and launched the **CD Horizon™ Multi-Axial Screw System**, **PYRAMESH™ Surgical Titanium Mesh System**, **PLIF Instrument Set**, and the **Low-Profile MULTI-SPAN™ Crosslink System**
 - ◆ Maintained Design History Files per Quality System requirements and conducted pre-launch product evaluations with KOL surgeons
 - ◆ Worked with Regulatory department to obtain necessary FDA approvals for launch
- 1995 – 1997 Sofamor Danek, Memphis, TN**
Associate Product Development Engineer, Thoracolumbar Division
- ◆ Provided engineering support for the Texas Scottish Rite Hospital (TSRH™) Spinal System
 - ◆ Designed and developed auxiliary instruments and implants as dictated by the surgeon customer
 - ◆ Conducted implant and instrument optimization via ProEngineer CAD, ProMechanica FEA, and biomechanical testing and cadaveric evaluations

PATENTS

Ranked 17th out of the Top 100 Spinal Device Inventors (1971-2003)

Source: Spinal Implant Orthopedic Intellectual Property Report
MedicineLodge, Inc. 2003

1. **5,728,098 – Multi-Angle Bone Screw Assembly Using Shape-Memory Technology**
Inventors: Michael C. Sherman and Troy D. Drewry
2. **5,782,831 – Method and Device for Spinal Deformity Reduction Using A Cable and a Cable Tensioning System**
Inventors: Michael C. Sherman and Troy D. Drewry
3. **5,797,911 – Multi Axial Bone Screw Assembly**
Inventors: Michael C. Sherman and Troy D. Drewry
4. **Des. 403,069 – Orthopedic Bone Support**
Inventors: Troy Drewry and Michael C. Sherman
5. **5,879,350 – Multi-Axial Bone Screw Assembly**
Inventors: Michael C. Sherman and Troy D. Drewry
6. **5,885,286 – Multi-Axial Bone Screw Assembly**
Inventors: Michael C. Sherman and Troy D. Drewry
7. **5,891,145 – Multi-Axial Screw**
Inventors: Matthew Morrison, Michael C. Sherman, and Troy D. Drewry
8. **5,897,556 – Device for Supporting Weak Bony Structures**
Inventors: Michael C. Sherman and Troy D. Drewry
9. **5,947,966 – Device for Linking Adjacent Rods in Spinal Instrumentation**
Inventors: Troy Drewry, Michael C. Sherman, James E. Van Hoeck, Denis S. Drummond, David L. Brumfield, and M. Neil Anderson
10. **5,951,553 – Methods and Apparatus for Fusionless Scoliosis Treatment of Spinal Deformities**
Inventors: Randall Betz, Michael C. Sherman, and Troy D. Drewry
11. **5,954,725 – Multi-Angle Bone Screw Assembly Using Shape-Memory Technology**
Inventors: Michael C. Sherman and Troy D. Drewry
12. **5,976,135 – Lateral Connector Assembly**
Inventors: Michael C. Sherman, Eddie Ray III, Troy D. Drewry, and David Shapiro
13. **6,053,917 – Multi-Axial Bone Screw Assembly**
Inventors: Michael C. Sherman and Troy D. Drewry
14. **6,132,434 – Multi-Angle Bone Screw Assembly Using Shape-Memory Technology**
Inventors: Michael C. Sherman and Troy D. Drewry
15. **6,149,651 – Device for Supporting Weak Bony Structures**
Inventors: Troy D. Drewry and Michael C. Sherman
16. **6,235,028 – Surgical Guide Rod**
Inventors: David L. Brumfield, Paige A. Myrick, B. Thomas Barker, and Troy D. Drewry

17. **6,287,308 – Methods and Apparatus for Fusionless Treatment of Spinal Deformities**
Inventors: Randall Betz, Michael C. Sherman, Troy Drewry
18. **6,287,311 – Multi-angle Bone Screw Assembly Using Shape-Memory Alloy Technology**
Inventors: Michael C. Sherman, Troy Drewry
19. **6,296,643 – Device for the Correction of Spinal Deformities Through Vertebral Body Tethering Without Fusion**
Inventors: Christoph Hopf, Troy Drewry, Michael C. Sherman
20. **6,299,613 – Device for the Correction of Spinal Deformities Through Vertebral Body Tethering Without Fusion**
Inventors: James Ogilvie, Christoph Hopf, Michael C. Sherman, Troy Drewry, Jean Saurat
21. **6,325,805 – Shape Memory Alloy Staple**
Inventors: James Ogilvie, Troy D. Drewry, Michael C. Sherman
22. **6,436,099 – Adjustable Spinal Tether**
Inventors: Troy D. Drewry, Michael C. Sherman, David Brumfield
23. **6,454,773 – Multi-angle Bone Screw Assembly Using Shape-Memory Alloy Technology**
Inventors: Michael C. Sherman, Troy Drewry
24. **6,605,090 – Non-metallic Implant Devices and Intra-Operative Methods for Assembly and Fixation**
Inventors: Michael C. Sherman, Troy Drewry
25. **6,616,669 – Method for the Correction of Spinal Deformities Through Vertebral Body Tethering Without Fusion**
Inventors: James Ogilvie, Michael C. Sherman, Troy Drewry, Jean Saurat
26. **6,623,484 – Method and Apparatus for Fusionless Treatment of Spinal Deformities**
Inventors: Randall Betz, Michael C. Sherman, Troy Drewry
27. **6,773,437 – Shape Memory Alloy Staple**
Inventors: James Ogilvie, Michael C. Sherman, Troy Drewry, Jean Saurat
28. **6,783,527 – Flexible Spinal Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz
29. **6,991,653 – Vertebral Body and Disc Space replacement device**
Inventors: White, John L., DeRidder, Steven D., Berry, Bret M., Frey, George, Moore, Jeffrey D., Scifert, Jeffrey L., Drewry, Troy D., Smithey, Jeffrey S., and Lange, Eric C.
30. **7,018,379 – Flexible Spinal Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz
31. **7,094,240 – Flexible Member Tensioning Instrument and Methods**
Inventors: Fred J. Molz, Michael C. Sherman, and Troy D. Drewry
32. **7,172,593 – Non-metallic Implant Devices and Intra-operative Methods for Assembly**
Inventors: Hai H. Trieu, Jeff R. Justis, Troy D. Drewry, Michael C. Sherman, Bradley J. Coates, and Bradley T. Estes
33. **7,285,121 – Devices and Methods for the Correction and Treatment of Spinal Deformities**
Inventors: John T. Braun, Fred J. Molz, Troy D. Drewry, and Michael C. Sherman

34. **7,367,978 – Adjustable Spine Tether**
Inventors: Troy D. Drewry, Michael C. Sherman, and David L. Brumfield
35. **7,517,359 – Vertebral Rod Assemblies and Methods**
Inventors: Troy D. Drewry and Barry Null
36. **7,556,630 – Flexible Member Tensioning Instrument and Methods**
Inventors: Fred J. Molz, Michael C. Sherman, and Troy D. Drewry
37. **7,615,078 – Vertebral Body and Disc Space Replacement Device**
Inventors: John L. White, Steven D. DeRidder, Bret M. Berry, George Frey, Jeffrey D. Moore, Jeffrey L. Scifert, Troy D. Drewry, Jeffrey S. Smithey, and Eric C. Lange
38. **7,625,380 – Dual Distractor Insertor**
Inventors: Troy D. Drewry and Bret M. Berry
39. **7,722,648 – Crosslink Interconnection of Bone Attachment Devices**
Inventors: Troy D. Drewry, William Barry Null, and Marc T. Paul
40. **7,828,826 – Flexible Spine Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz
41. **7,837,714 – Methods and Devices Interconnection of Bone Attachment Devices**
Inventors: Troy D. Drewry, William Barry Null, and Marc T. Paul
42. **7,867,258 – Multi-Axial Bone Attachment Member**
Inventors: Troy D. Drewry, William Barry Null, and Marc T. Paul
43. **7,901,434 – Vertebral Rod Assemblies and Methods**
Inventors: Troy D. Drewry and William Barry Null, and Marc T. Paul
44. **7,909,855 – Orthopedic Implant Assembly**
Inventors: Troy D. Drewry, William Barry Null, and Marc T. Paul
45. **7,951,177 – Non-metallic Implant Devices and Intra-operative Methods for Assembly and Fixation**
Inventors: Hai H. Trieu, Jeff R. Justis, Troy D. Drewry, Michael C. Sherman, Bradley J. Coates, and Bradley T. Estes
46. **7,988,711 – Low Profile Vertebral Stabilization Systems and Methods**
Inventors: David R. Erickson, Troy D. Drewry, Robert A. Farris, and Jason Michael May
47. **8,142,483 – Flexible Spine Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz
48. **8,353,934 – Crosslink Interconnection of Bone Attachment Devices**
Inventors: Troy D. Drewry, William Barry Null, and Marc T. Paul
49. **8,512,406 – Vertebral Body and Disc Space Replacement Devices**
Inventors: John L. White, Steven D. DeRidder, Bret M. Berry, George Frey, Jeffrey D. Moore, Jeffrey L. Scifert, Troy D. Drewry, Jeffrey S. Smithey, Eric C. Lange
50. **8,672,972 – Low Profile Vertebral Stabilization Systems and Methods**
Inventors: David R. Erickson, Troy D. Drewry, Robert A. Farris, and Jason Michael May

51. **8,911,480 – Non-metallic Implant Devices and Intra-operative Methods for Assembly and Fixation.**
Inventors: Hai H. Trieu, Jeff R. Justis, Troy D. Drewry, Michael C. Sherman, Bradley J. Coates, and Bradley T. Estes
52. **9,101,489 – Expandable Anterior Lumbar Interbody Fusion Device.**
Inventors: Dimitri Protopsaltis, Troy D. Drewry, Joshua Morin, and Hugues Malandain
53. **9,358,045 – Flexible Spine Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz
54. **9,370,382 – Translaminar Interspinous Stabilization System**
Inventors: John S. Thalgott, David T. Stinson, and Troy D. Drewry
55. **9,387,089 – Expandable Anterior Lumbar Interbody Fusion Device**
Inventors: Dimitri Protopsaltis, Troy D. Drewry, Joshua Morin, and Hugues Malandain
56. **9,707,094 – Expandable Anterior Lumbar Interbody Fusion Device**
Inventors: Dimitri Protopsaltis, Troy D. Drewry, Joshua Morin, and Hugues Malandain
57. **9,949,842 – Expandable Anterior Lumbar Interbody Fusion Device**
Inventors: Dimitri Protopsaltis, Troy D. Drewry, Joshua Morin, and Hugues Malandain
58. **9,387,089 – Expandable Anterior Lumbar Interbody Fusion Device**
Inventors: Dimitri Protopsaltis, Troy D. Drewry, Joshua Morin, and Hugues Malandain
59. **9,968,381 – Translaminar Interspinous Stabilization System**
Inventors: John S. Thalgott, David T. Stinson, and Troy D. Drewry
60. **9,987,047 – Translating Polyaxial Screw**
Inventors: Dimitri Protopsaltis and Troy D. Drewry
61. **10,206,715 – Flexible Spine Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz
62. **10,278,741 – Translating Polyaxial Screw**
Inventors: Dimitri Protopsaltis and Troy D. Drewry
63. **10,898,230 – Flexible Spine Stabilization System and Method**
Inventors: Troy D. Drewry and Fred J. Molz

PUBLICATIONS / PRESENTATIONS

1. Lewis G, Drewry TD, Sherman MC: **A Thoracic Spine Testbed for the Comparative Biomechanical Evaluation of Spinal Instrumentations.** *Journal of Spinal Disorders*, June 1995, 186-94.
2. Drewry TD, Sherman MC, Lewis G: **Biomechanical Comparison Between Single and Dual Rod Texas Scottish Rite Hospital (TSRH™) Posterior Scoliosis Constructs: An Experimental Stress Analysis.** Presented at The 30th Annual Meeting of the Scoliosis Research Society. Asheville, NC, September 13-16, 1995.
3. Huntington CF, Betz RR, Maxy P, Clements III DH, Drewry TD, Sherman MC, Pafford JA: **Biomechanical Finite Element Analysis of Spinopelvic Fixation in Long Segment Spinal Fixation Constructs.** Presented at The 66th Annual Meeting of the American Academy of Orthopaedic Surgeons. Anaheim, CA, February 4-8, 1999.

4. Drewry, TD, Braun, JT, Ogilvie, JW: **Fusionless Scoliosis Correction Using a Shape Memory Alloy Staple in the Anterior Thoracic Spine of the Immature Goat.** Presented at the 19th Annual Science and Technology Conference at Medtronic Corporate Headquarters in Minneapolis, MN, September 20-22, 2000.
5. Drewry, TD, Scifert, S: **Resorbable Spinal Implants in a Sheep Model: Radiographic, Histologic, and Biomechanical Preliminary Results.** Presented at the BioTechnologies for Spinal Surgery Meeting. Halle, Germany, April 11-13, 2002.
6. Betz RR, Cunningham B, Selgrath C, Drewry TD, Sherman MC: **Preclinical Testing of a Wedge-Rod System for Fusionless Correction of Scoliosis.** *SPINE*, Vol. 28 No. 20, 15 OCT 2003, pp S275-278.
7. Drewry, TD: Represented AIC at **MB Venture's 5th Annual Musculoskeletal New Ventures Conference.** Memphis, TN, October 9-10, 2007.
8. Drewry, TD: Represented AIC at **Canaccord Adams Musculoskeletal Conference.** Las Vegas, NV, February 24, 2009.
9. Drewry, TD: Represented MB Innovations at **Musculoskeletal New Ventures Conference.** Memphis, TN, October 29, 2015.

PROFESSIONAL AFFILIATIONS (PAST AND PRESENT)

- ◆ Member, Engineering Advisory Board, University of Mississippi
- ◆ Member, Engineering Biotech Advisory Board, Christian Brothers University
- ◆ Member, Industrial Advisory Board for University of Memphis's Department of Mechanical Engineering
- ◆ Member, Industrial Advisory Board for University of Louisiana at Lafayette's Department of Mechanical Engineering
- ◆ Orthopedic Research Society
- ◆ Society of Biomaterials
- ◆ American Society of Mechanical Engineers
- ◆ American Society of Testing and Materials
- ◆ Society of Biomedical Engineers
- ◆ Engineer in Training

INTERESTS AND ACTIVITIES

- ◆ Parishioner, St. Louis Catholic Church
- ◆ Fly Fishing & Fly Tying
- ◆ Duck, Turkey, & Deer Hunting
- ◆ Cycling (Road and Mountain Bike)
- ◆ Swimming
- ◆ Reading
- ◆ Cooking

JAN – 2024