



(51) International Patent Classification:
A61C 7/14 (2006.01)

(21) International Application Number:
PCT/US2010/027016

(22) International Filing Date:
11 March 2010 (11.03.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/159,859 13 March 2009 (13.03.2009) US

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD,
SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: METHODS OF MANUFACTURING ORTHODONTIC BRACKETS INCLUDING A RECTANGULAR ARCH
WIRE HOLE

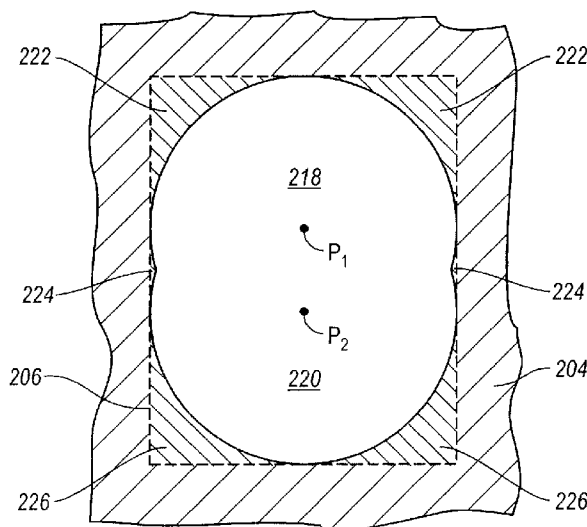


Fig. 2B

(57) Abstract: Methods of manufacturing orthodontic
tube brackets (100) including a hole (106) rather than an
open slot. A first pilot hole (218) is formed along a first
axis (P1) so as to extend mesially-distally through the
body (204) of the orthodontic bracket body. A second pi-
lot hole (220) is formed along a second axis (P2), in
which the second axis (P2) is offset relative to the axis
(P1) of the first hole (218). The result is that the first and
second holes (218, 220) are adjacent to, or may partially
overlap, one another depending on the diameter of each
hole (218, 220) and the dimensions of the finished rect-
angular arch wire hole (206). Once the pilot holes (218,
220) are formed, one or more shaping broaches are
pushed or pulled through the pilot holes so as to form a
desired rectangularly-shaped arch wire hole (206) within
the orthodontic bracket body (204).

5 **METHODS OF MANUFACTURING ORTHODONTIC BRACKETS**
 INCLUDING A RECTANGULAR ARCH WIRE HOLE

BACKGROUND OF THE INVENTION

1. **The Field of the Invention**

10 The present invention relates to orthodontic brackets and related methods of manufacture.

2. **The Relevant Technology**

 Orthodontics is a specialized field of dentistry that involves the application of mechanical forces to urge poorly positioned or crooked teeth into correct alignment and orientation. Orthodontic procedures can be used for cosmetic enhancement of teeth, as well as medically necessary movement of teeth to correct underbites or overbites. For example, orthodontic treatment can improve the patient's occlusion and/or enhanced spatial matching of corresponding teeth.

 The most common form of orthodontic treatment involves the use of orthodontic brackets and wires, which together are commonly referred to as "braces." Orthodontic brackets are small slotted bodies configured for direct attachment to the patient's teeth or, alternatively, for attachment to bands which are, in turn, cemented or otherwise secured around the teeth. Once the brackets are affixed to the patient's teeth, such as by means of glue or cement, a curved arch wire is inserted into the bracket slots. The arch wire acts as a template or track to guide movement of the teeth into proper alignment. End sections of the arch wire are typically captured within tiny appliances known as tube brackets or terminal brackets, which are affixed to the patient's bicuspid and/or molars. The remaining brackets typically include open arch wire slots and apply orthodontic forces by means of ligatures attached to the brackets and arch wire (*e.g.*, by means of tie wings on the brackets).

 Metallic orthodontic brackets are typically manufactured by a metal injection molding and sintering process, in which powdered metal is injected with a polymeric binder resin material to injection mold a green orthodontic body. The green body is thereafter sintered to drive off the binder, and cause the powdered metal particles to partially fuse and adhere together.

5

BRIEF SUMMARY OF THE INVENTION

The present invention is directed to methods of manufacturing orthodontic brackets that include a hole rather than an open slot. For example, the inventive method may be used in the manufacture of molar tube brackets or other brackets including a hole or tube open only on the mesial and distal ends. The arch wire hole is advantageously machined rather than formed by a metal injection molding and sintering process. A first pilot hole is formed along a first axis so as to extend mesially-distally through the body of the orthodontic bracket body. A second pilot hole is formed along a second axis, in which the second axis is offset relative to the axis of the first hole. The result is that the first and second holes are adjacent to one another or may partially overlap one another, depending on the diameter of each hole and the dimensions of the finished rectangular arch wire hole. Once the pilot holes are formed, one or more shaping broaches are pushed or pulled through the pilot holes so as to form a desired rectangularly-shaped arch wire hole within the orthodontic bracket body.

Such a method advantageously allows for the use of stronger, more dense metal materials (*e.g.*, 17-4 and/or 17-7 class stainless steels). In addition, because the bulk metal material is not a sintered powder, the overall strength of the bracket manufactured according to the inventive method exhibits for greater strength and durability. For example, during a molding and sintering process, tiny voids can form within the body, thereby reducing strength. In addition, the strength of a sintered body is limited by the adhesion of the powder particles to one another after sintering. Finally, machining the brackets allows for tighter manufacturing tolerances, as molded and sintered brackets are known to shrink or otherwise deform an unpredictable amount during sintering. Narrower tolerances provide for better fit for the patient, which results in reduced overall treatment times.

The formation of two pilot holes that are axially offset has advantageously been found to greatly reduce tool wear on the drill bits, end mills, and shaping broaches used to form the finished rectangularly shaped hole. Not only is more material removed during formation of the pilot holes, which leaves less material to be removed during broaching, the inventors have found that the reduction in tool wear is even greater than would otherwise be expected as a result of simply removing as much material as possible during pilot hole formation.

5 The use of drill bits, end mills, and broaches including a carbide coating (*e.g.*, titanium carbide and/or tungsten carbide) is particularly preferred, as they have been found to surprisingly allow formation of tiny pilot holes (*e.g.*, typically less than 0.025 inch diameter) and rectangular finished arch wire holes (*e.g.*, typically having a width less than about 0.025 inch) with minimal wear and without breakage of the
10 tools. The ability to form such tiny holes is surprising, as those skilled in the art previously would have expected this manufacturing method to be unworkable as a result of severe tool wear and/or breakage.

 These and other advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be
15 learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

 To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is
20 appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

 Figure 1A is a perspective view of an exemplary molar orthodontic tube
25 bracket that may be manufactured according to the present inventive method;

 Figure 1B is a perspective view of an exemplary convertible bicuspid orthodontic bracket that may be manufactured according to the present inventive method;

 Figure 2A is a cross-sectional view through a portion of an orthodontic bracket
30 body in which a first pilot hole has been drilled mesially-distally through the body. The pilot hole is formed so as to be tangent to the longer side surfaces and the top surface;

 Figure 2B is a cross-sectional view through the body of Figure 2A, in which a second pilot hole offset from the first pilot hole has been drilled through the body.
35 The second pilot hole is formed so as to be tangent to the longer side surfaces and the remaining bottom surface;

5 Figure 3A is a cross-sectional view through the body of Figure 2B, in which a first shaping broach has been pushed or pulled through the first pilot hole so as to partially form the rectangular cross-section of the finished arch wire hole;

 Figure 3B is a cross-sectional view of the body of Figure 3A, in which a second shaping broach has been pushed or pulled through the second pilot hole so as
10 to complete formation of the rectangular cross-section of the finished arch wire hole;

 Figure 4A is a longitudinal cross-sectional view of an orthodontic body in which the first pilot hole is formed at an angle;

 Figure 4B is a transverse cross-sectional view of the body of Figure 4A;

 Figure 4C is a longitudinal cross-sectional view of the body of Figure 4A in
15 which the second pilot hole is also formed at an angle, such that the axes of the two pilot holes cross one another; and

 Figure 4D is a transverse cross-sectional view of the body of Figure 4C.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Introduction

20 According to one exemplary method of manufacture, a rectangular arch wire hole of an orthodontic bracket is made by forming a first pilot hole through the body of the bracket. The first pilot hole extends mesially-distally through the bracket body. A second pilot hole is then formed so as to also extend mesially-distally through the body. The axis of the second hole is offset relative to the axis of the first hole so that
25 the pilot holes do not completely overlap. Depending on the diameter and placement of each hole, the second hole may partially overlap the first hole. Once the pilot holes are formed, a broach is pushed or pulled through the pilot holes so as to form the desired arch wire hole having a rectangular cross-section.

 Forming the arch wire hole by such a machining process advantageously
30 results in a stronger more dense metal bracket body with tighter dimensional tolerances as compared to alternative manufacturing methods employing metal injection molding.

II. Exemplary Brackets and Manufacturing Methods

 Figures 1A-1B illustrate exemplary orthodontic “tube” brackets formed
35 according to the present inventive method. Figure 1A illustrates an exemplary molar tube bracket 100 including a bracket base 102 and a body 104. An arch wire hole 106 is formed so as to extend mesially-distally through body 104. As shown, one or both

5 ends of hole 106 may be flared, making insertion of an arch wire (not shown) into hole 106 easier. Body 104 further includes a plurality of tie wings 108, as well as a curved gingival hook 110.

Figure 1B illustrates an alternative convertible bracket 100' configured for placement on a bicuspid. Similar structures of bracket 100' bear identical reference
10 numerals as those of bracket 100 of Figure 1A. Besides being configured for placement upon a bicuspid rather than a molar, principal differences relative to bracket 100' include provision of a selectively removable labial web cover 112. In the illustrated embodiment, labial web cover 112 is bounded by two web regions 114, 116 of reduced cross-sectional thickness interconnecting cover 112 with portions of body
15 104 adjacent tie wings 108. By selectively removing the labial web cover 112 (*e.g.*, by peeling), the practitioner may convert arch wire hole 106 into an arch wire slot that is open along the labial side. In both illustrated embodiments, the arch wire hole 106 is closed on all four sides when manufactured. Such a configuration may advantageously be formed by the present inventive machining method.

20 Figures 2A-3B illustrate an exemplary method by which a rectangular arch wire hole (*e.g.*, hole 106) may be formed through the bracket body. Figure 2A shows a cross-sectional view through an intermediate bracket body 204. In Figure 2A, a first pilot hole 218 has been formed through body 204. Pilot hole 218 as illustrated has a diameter equal to the width of the finished arch wire hole 206. In other words, the sides of finished rectangular hole 206 are tangent to pilot hole 218. First pilot hole
25 218 is further advantageously formed so that either the shorter labial top side or lingual bottom side of finished hole 206 is tangent to pilot hole 218. Figure 2A illustrates the first pilot hole 218 tangent to both longer sides as well as the labial top side. Alternatively, pilot hole 218 could be placed tangent to lingual bottom side. First pilot hole 218 may advantageously be formed with a drill bit equal to the
30 diameter of the finished arch wire hole (*e.g.*, 0.018 inch or 0.022 inch).

As shown in Figure 2B, a second pilot hole 220 is then formed through body 204. As illustrated, the diameter of second pilot hole 220 may be equal to that of first pilot hole 218, and also equal to the width of finished arch wire hole 206. The axes P₁
35 and P₂ of first and second pilot holes 218 and 220, respectively, are offset from one another, although in the illustrated configuration, pilot holes 218 and 220 also overlap

5 one another. Pilot hole 220 is advantageously formed so as to be tangent to the lingual bottom side of finished arch wire hole 206.

Second pilot hole 220 may advantageously be formed using an end mill tool. An end mill tool is capable of cutting along its side edges, while a drill bit only cuts at its axial end. Because the pilot holes overlap, the end mill used to form the second
10 pilot hole 220 may be used in conjunction with a high frequency spindle, which will allow formation of the desired hole, even with overlap of the first pilot hole 218. By way of example, the spindle may operate between about 15,000 and about 160,000 RPM, more preferably between about 25,000 and about 75,000 RPM, and most preferably between about 35,000 and about 45,000 RPM. Use of an end mill and a
15 high frequency spindle will advantageously allow formation of the second pilot hole 220 in an overlapping configuration, as illustrated. Once pilot holes 218 and 220 have been formed, only small portions of metal remain at each corner and along the center edges to be removed to form a finished arch wire hole 206.

As shown in Figure 3A, a shaping broach is then pushed or pulled through one
20 pilot hole (*e.g.*, first pilot hole 218), removing material 222 (Figure 2B) along the labial corners adjacent first pilot hole 218, as well as material 224 along the center of the longer side walls of arch wire hole 206. In the illustrated example (Figure 3B), a broach (either the same as the first broach or a different broach) is pushed or pulled through the remaining pilot hole 220, removing material 226 (Figure 3A) along the
25 lingual corners adjacent first pilot hole 218, as well as any remaining material 224 along the center of the longer side walls of arch wire hole 206. The result is the finished rectangular arch wire hole 206 (*e.g.*, having dimensions of 0.022 by 0.028 inch).

Pilot holes 218 and 220 may be formed parallel to one another or they may be
30 offset so as to have non-parallel axes. For example, in an alternative embodiment shown in Figures 4A and 4B, the pilot holes may be axially offset so that one pilot hole angles from the top labial corner at one end to the bottom lingual corner at the other end. The other pilot hole may be oppositely angled so that the pilot holes criss-cross (*i.e.*, the axes P_1 and P_2 cross one another) as they traverse through what will
35 become the arch wire hole 206.

Figure 4A shows a cross-sectional view taken along a plane defined by the longitudinal axis of the bracket body 204 (*i.e.*, perpendicular to the cross-sectional

5 views of Figures 2A-3B) after drilling first pilot hole 218'. As seen in Figures 4A-4B, first pilot hole 218' having axis P_1' is formed at an angle (*e.g.*, sloping lingually downward). As seen in Figures 4C-4D, second pilot hole 220' having axis P_2' is formed at an angle (*e.g.*, sloping labially upward) so that axes P_1' and P_2' cross one another. The remaining material 222', 224', and 226' may then be removed by
10 broaching, as described above in conjunction with Figures 3A-3B to produce the finished arch wire hole 206'.

The use of drill bits, end mills, and broaches including a carbide coating (*e.g.*, titanium carbide and/or tungsten carbide) is particularly preferred, as they have been found to surprisingly allow formation of tiny pilot holes (*e.g.*, typically less than
15 0.025 inch diameter) and rectangular finished arch wire holes (*e.g.*, typically having a width less than about 0.025 inch) without breakage of the tools. The ability to form such tiny holes is surprising, as those skilled in the art previously would have expected such manufacturing method to be unworkable as a result of severe tool wear and/or tool breakage. In particular, the formation of multiple pilot holes has been
20 found to surprisingly reduce overall tool wear as compared to the formation of a single pilot hole followed by broaching. This reduction in tool wear is surprisingly beyond what would normally be expected by simply employing multiple tools to form the pilot holes.

Machining the brackets rather than metal injection molding allows for use of
25 stronger, more dense metal materials, which materials are not suitable for metal injection molding. Use of stronger more dense metal materials (*e.g.*, 17-4 and/or 17-7 class stainless steels) provides for a stronger, more dense finished product. In addition, 17-4 and 17-7 class stainless steels may be heat treated after machining to further increase strength. Such heat treatments are not possible using classes of
30 stainless steels suitable for use in metal injection molding. By contrast, metal injection molded brackets are formed from stainless steel powder materials (*e.g.*, 303, 304, and/or 316L class stainless steels) which although they are better suited for powderization and sintering, exhibit less strength and lower density compared to 17-4 and 17-7 class stainless steel.

35 In addition, the strength and density of actual finished brackets formed by metal injection molding are less than the bulk strength and density of metal materials employed as micro air pockets can form during molding and sintering, and the

5 strength of the finished article may be reduced as the sintering process may result in weak bonding of the metal powder. No such issues occur when machining a bulk metal material.

Furthermore, the dimensional tolerances of the machined arch wire hole are significantly tighter with the inventive machined brackets as compared to brackets
10 formed by metal injection molding. For example, when machining the arch wire hole as described, the dimensions of the arch wire hole are carefully controlled. Tighter dimensional tolerances with respect to the arch wire hole result in a better fit with the arch wire, which results in overall faster treatment times. Such control is simply not possible with metal injection molding, where the sintering process results in an
15 unpredictable amount of shrinkage.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the
20 foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

- 5 1. A method of manufacturing an orthodontic tube bracket, comprising:
 forming a first pilot hole having a first axis extending mesially-distally
 through the body of an orthodontic bracket;
 forming a second pilot hole having a second axis extending mesially-
 distally through the body of an orthodontic bracket, the second axis being offset
10 relative to the first axis so that the first and second holes are adjacent to and/or
 overlap one another; and
 pressing or pulling one or more shaping broaches through the first and
 second holes so as to form a rectangularly-shaped hole within the orthodontic
 bracket body.
- 15 2. A method as recited in claim 1, wherein the first pilot hole partially
 overlaps the second pilot hole.
3. A method as recited in claim 1, wherein the first pilot hole is separate
 from the second pilot hole so that they do not overlap.
4. A method as recited in claim 1, wherein the second pilot hole is formed
20 parallel relative to the first pilot hole through the body.
5. A method as recited in claim 1, wherein both pilot holes are formed at
 an angle relative to one another through the body such that the second axis of the
 second hole is not parallel to the first axis of the first hole.
6. A method as recited in claim 1, where the second axis of the second
25 hole crosses over the first axis of the first hole.
7. A method as recited in claim 1, wherein the first and second pilot holes
 have diameters less than about 0.05 inch.
8. A method as recited in claim 1, wherein the first and second pilot holes
 have diameters less than about 0.025 inch.
- 30 9. A method as recited in claim 1, wherein the first and second pilot holes
 have diameters between about 0.018 inch and about 0.022 inch.
10. A method as recited in claim 1, wherein the first and second pilot holes
 have approximately equal diameters.
11. A method as recited in claim 1, wherein the first and second pilot holes
35 have diameters approximately equal to the width of the finished rectangularly shaped
 hole.

5 12. A method as recited in claim 1, wherein the first and second pilot holes are formed with drill bits and/or end mills comprising at least one of titanium carbide or tungsten carbide.

 13. A method as recited in claim 1, wherein the one or more shaping broaches comprise at least one of titanium carbide or tungsten carbide.

10 14. A method as recited in claim 1, wherein the first pilot hole is formed with a drill bit and the second pilot hole is formed with an end mill.

 15. A method as recited in claim 14, wherein the end mill is used in conjunction with a high speed spindle that operates between about 35,000 and about 45,000 RPM.

15 16. A method as recited in claim 1, wherein the orthodontic bracket body comprises at least one of 17-4 or 17-7 class stainless steel.

 17. A method of manufacturing a molar orthodontic bracket, comprising:
 forming a first pilot hole having a first axis extending mesially-distally through the body of an orthodontic bracket;

20 forming a second pilot hole having a second axis extending mesially-distally through the body of an orthodontic bracket, the second axis being offset relative to the first axis so that the first and second holes are adjacent to or overlap each other, the first and second axes being angled relative to one another such that the first and second axes cross; and

25 pressing or pulling one or more shaping broaches through the first and second holes so as to form a rectangularly-shaped hole within the orthodontic bracket body, the diameters of the first and second pilot holes being approximately equal to the width of the finished rectangularly-shaped hole.

 18. A method as recited in claim 17, wherein the first pilot hole is formed
30 with a drill bit and the second pilot hole is formed with an end mill, each of which comprise at least one of titanium carbide or tungsten carbide.

 19. A method as recited in claim 18, wherein the end mill is used in conjunction with a high speed spindle that operates between about 35,000 and about 45,000 RPM.

35 20. A method as recited in claim 17, wherein the one or more shaping broaches comprise at least one of titanium carbide or tungsten carbide.

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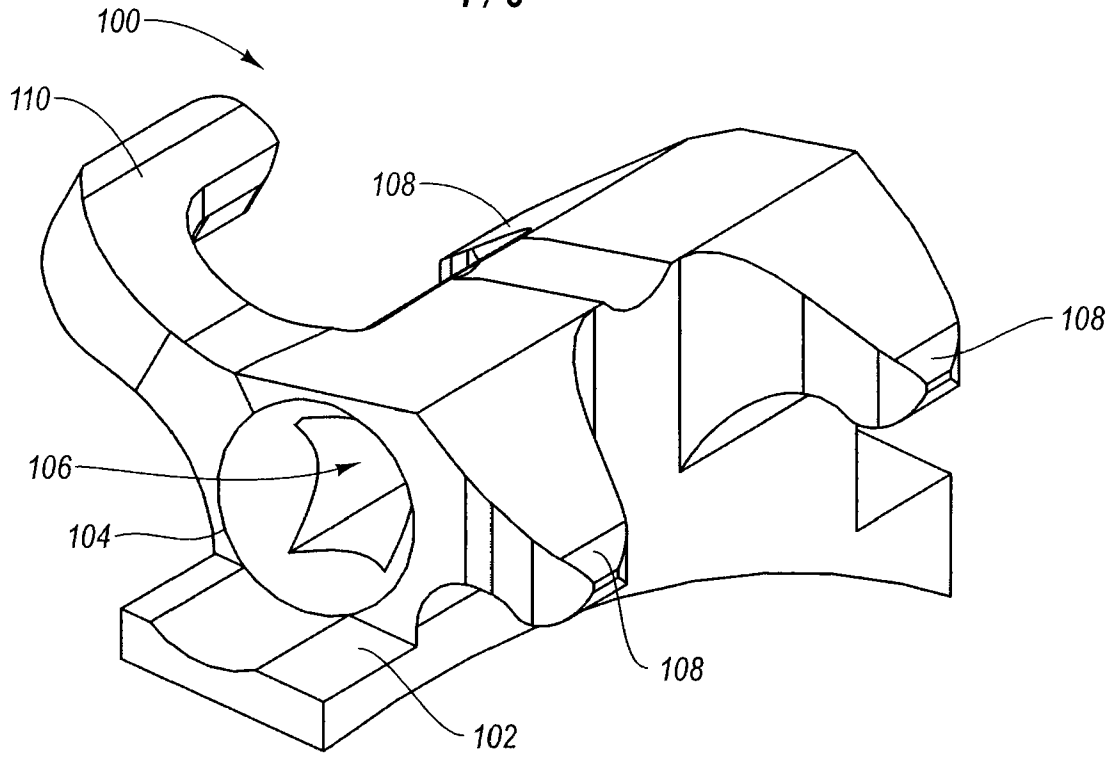


Fig. 1A

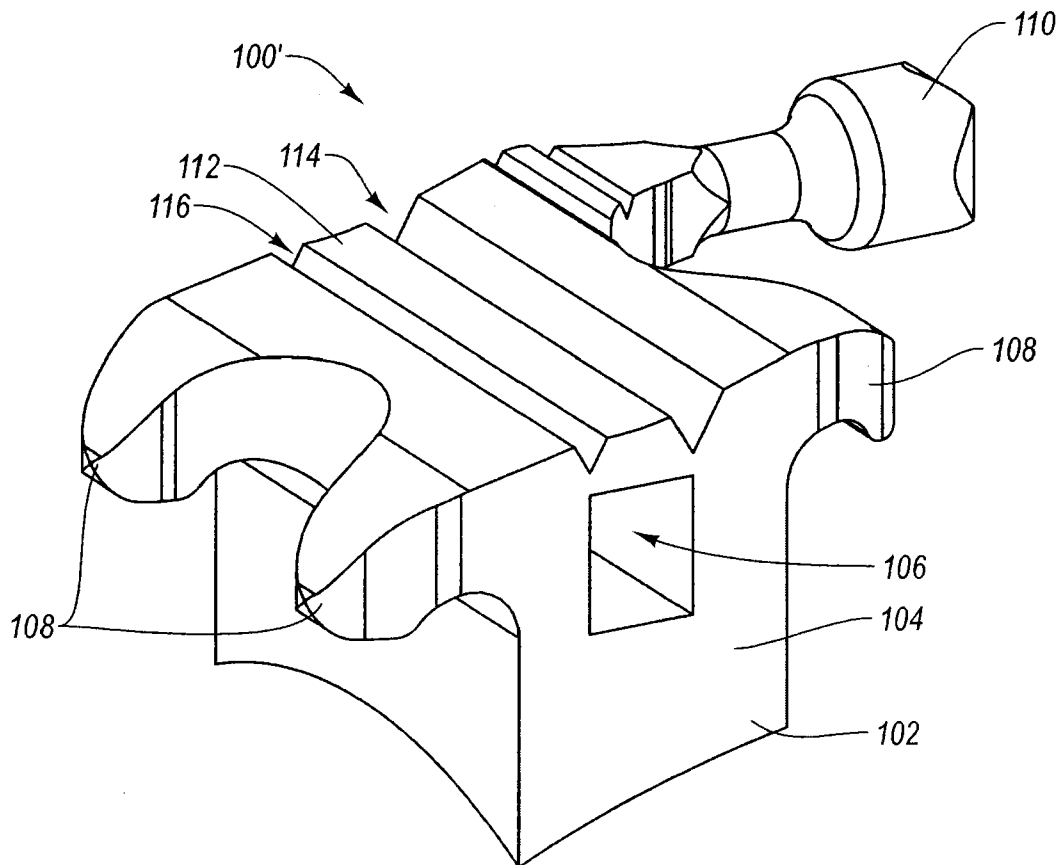


Fig. 1B

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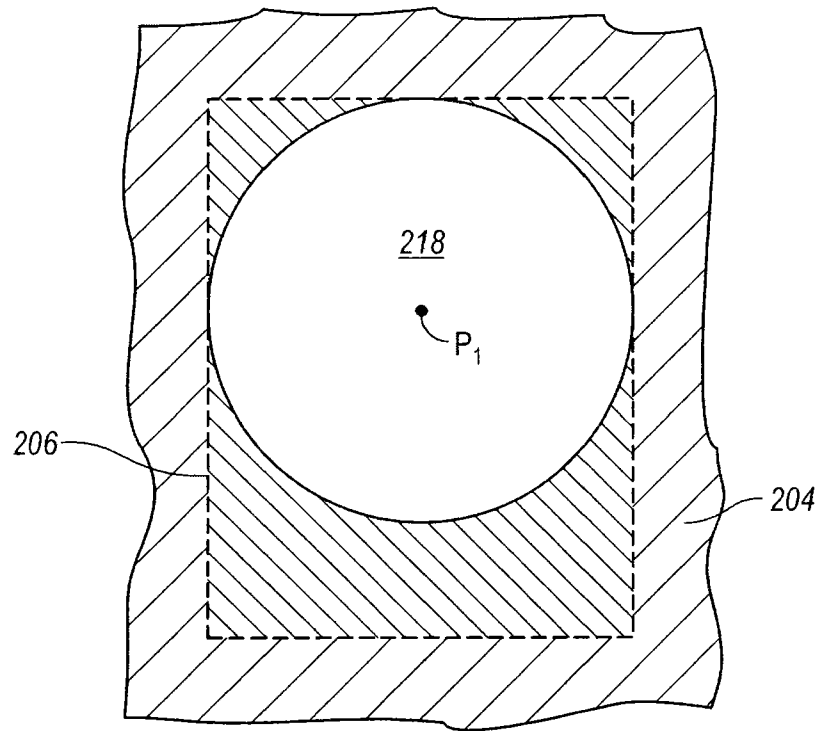


Fig. 2A

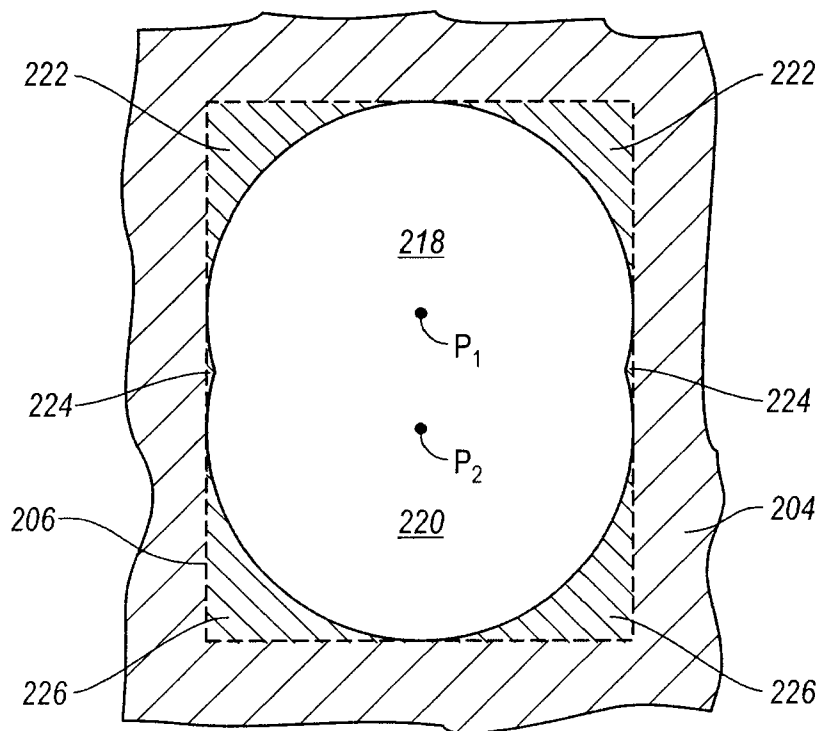


Fig. 2B

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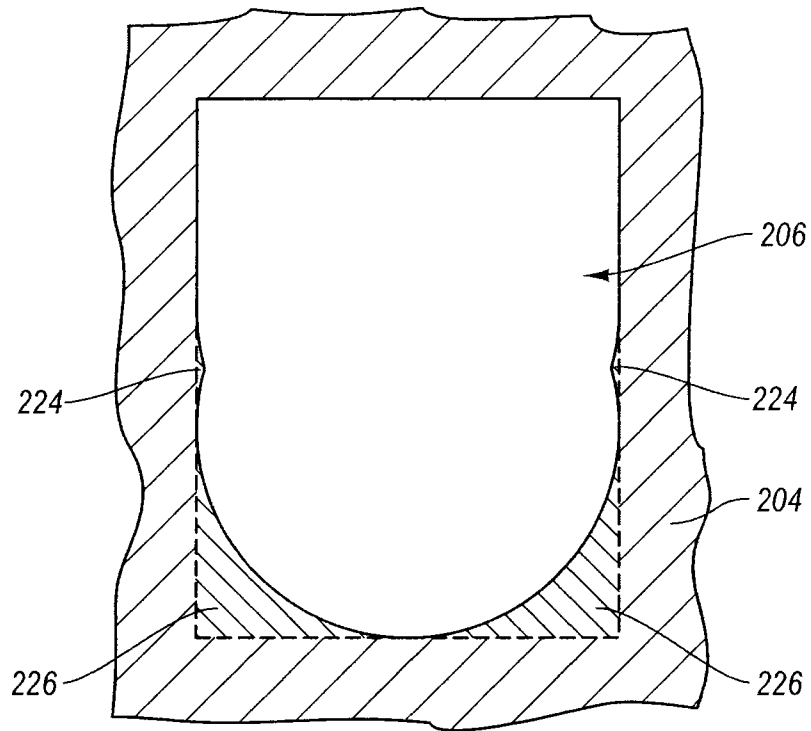


Fig. 3A

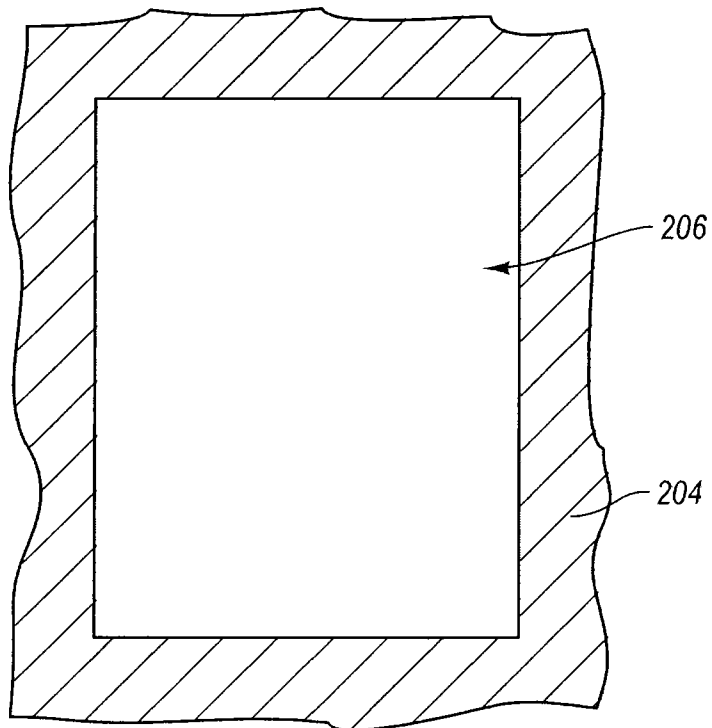


Fig. 3B

4 / 5

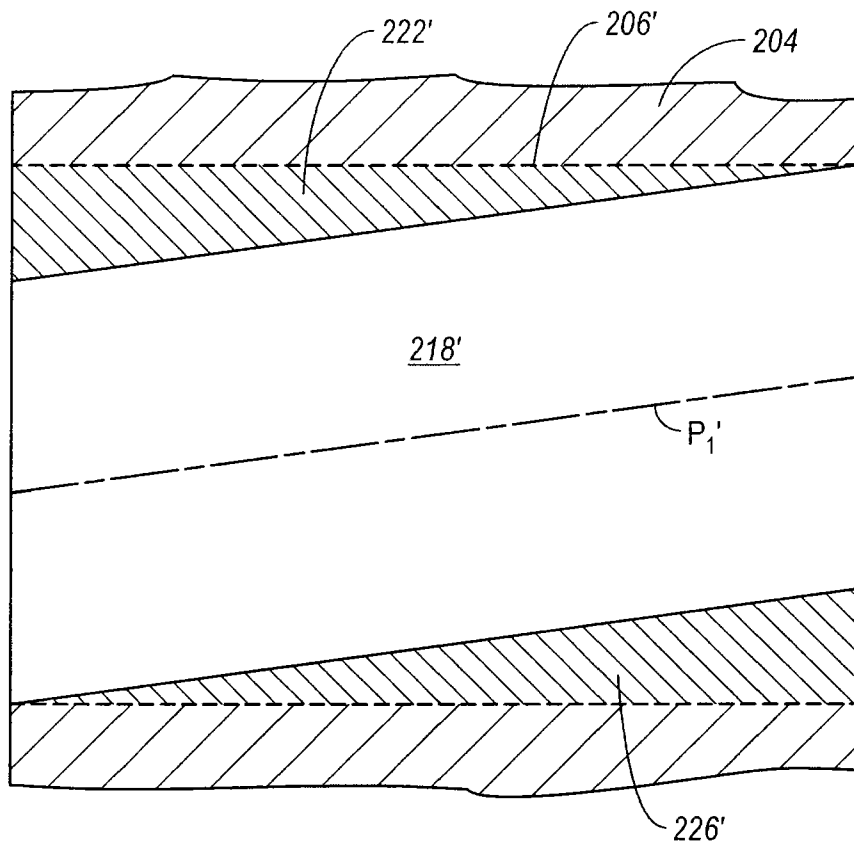


Fig. 4A

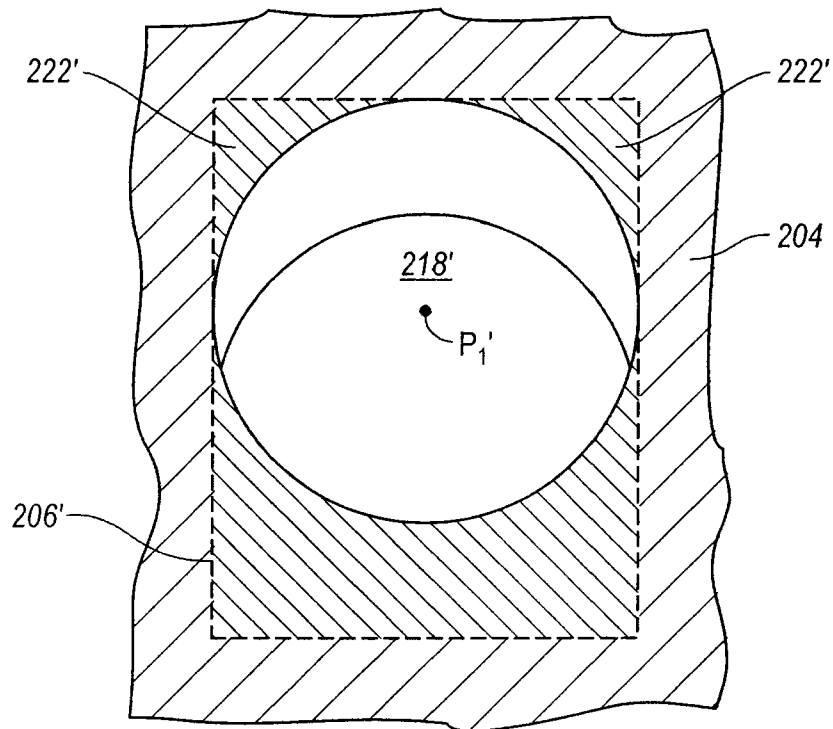


Fig. 4B

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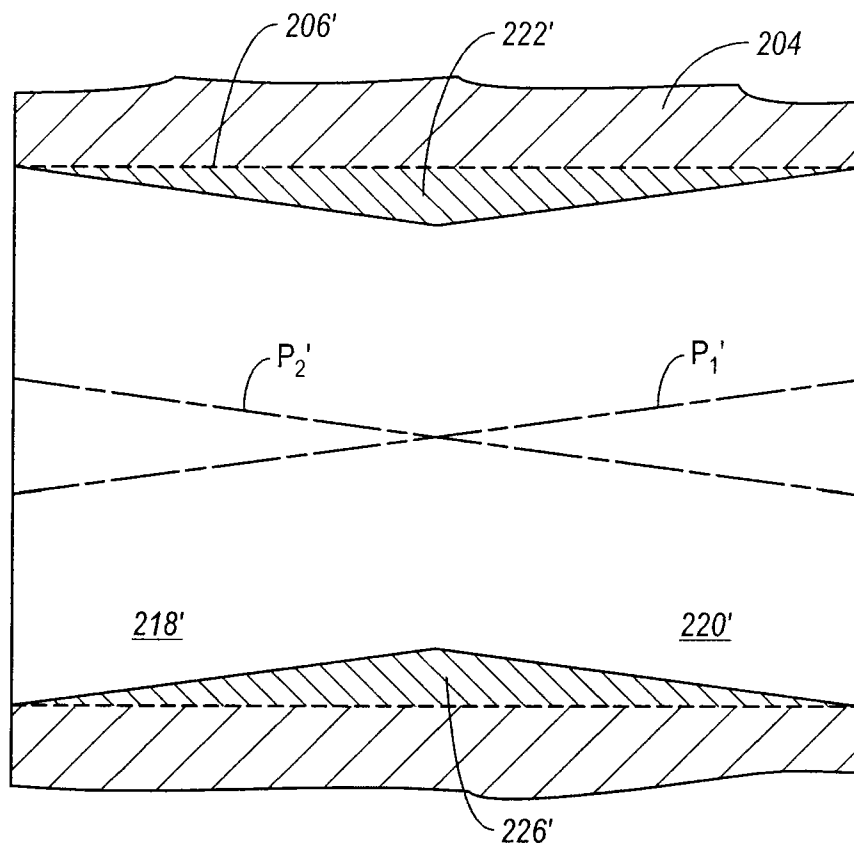


Fig. 4C

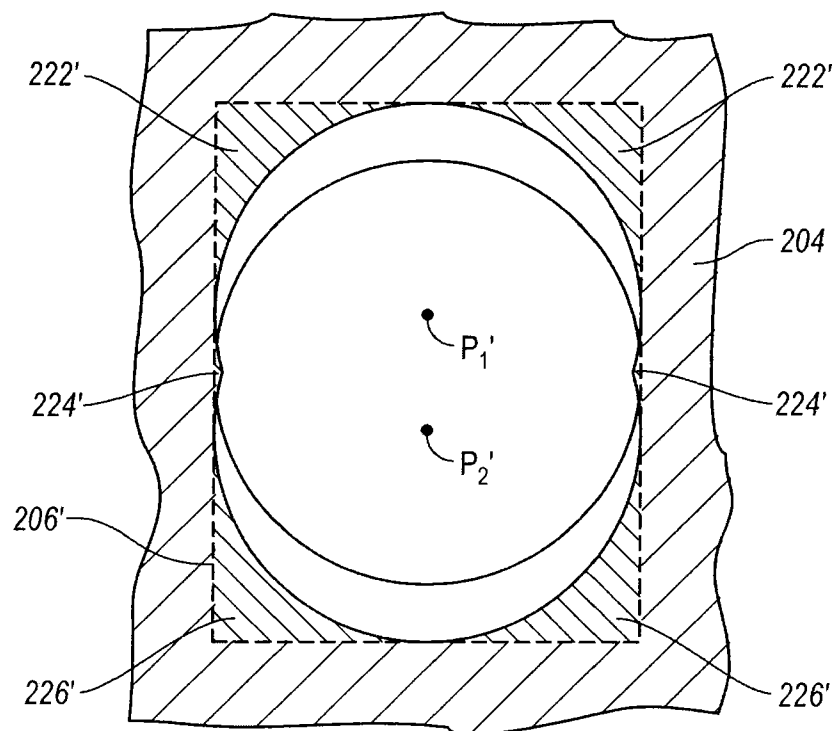


Fig. 4D

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/027016

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61C 7/14 (2010.01)

USPC - 433/8

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61C 7/14, 7/24, 7/28 (2010.01)

USPC - 433/2, 8, 10, 17, 22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,931,667 A (PAPANDREAS) 03 August 1999 (03.08.1999) entire document	1-11, 17
Y		12-16, 18-20
Y	US 2006/0172249 A1 (LAI et al) 03 August 2006 (03.08.2006) entire document	12-16, 18-20
A	US 2008/0254403 A1 (HILLIARD) 16 October 2008 (16.10.2008) entire document	12, 14-15, 18
A	US 4,655,708 A (FUJITA) 07 April 1987 (07.04.1987) entire document	1-5, 10-12, 17-18

☐ Further documents are listed in the continuation of Box C.


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Date of the actual completion of the international search

27 April 2010

Date of mailing of the international search report

12 MAY 2010

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