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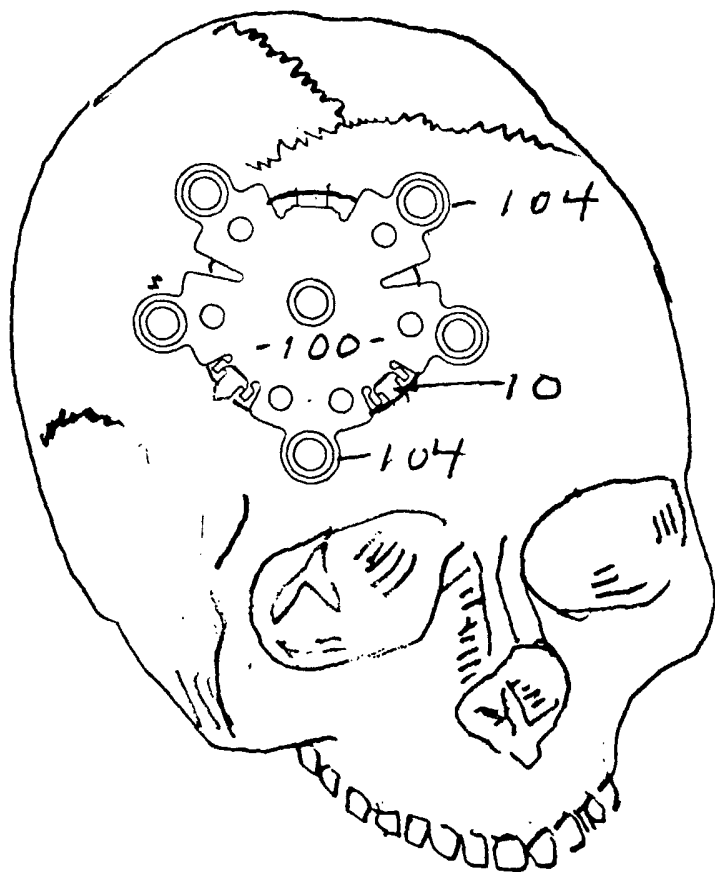
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[Continued on next page]

(54) Title: BONE ALIGNMENT AND FIXATION PLATE AND INSTALLATION METHOD



(57) Abstract: An attachment to connect two spaced apart zones (12, 15) having surface and edges (12a), one zone comprising a cranium bone zone (12), a plate (100), fastening openings (105) carried by the plate (100) at peripherally spaced locations, to receive fasteners that penetrate the bone zone at their surfaces, and at least one prong (25) to connect the plate (100) to at least one bone zone edge (12a).



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— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BONE ALIGNMENT AND FIXATION PLATE AND INSTALLATION METHOD

BACKGROUND OF THE INVENTION

This invention relates generally to the alignment and fixation of bone segments as required for appropriate bone healing, for example after fracture or surgical intervention, and specifically to a plate, and the tools needed to install the plate, for the alignment and fixation of cranial bone sections.

In cases of bone fragmentation where bone fixation is desired, the appropriate alignment of the bone is also a desired result. This is especially true in the cranium, where bone fragmentation can occur as a result of trauma, congenital deformity, or of surgical intervention. In the field of neurosurgery, cranial bone fragments are frequently cut and removed to create defects to allow for access into the cranial cavity and the brain.

The bony cranium is generally regarded to have two surfaces: the outer surface which is characterized by the outer cortex of the bone and is adjacent to the scalp and soft tissue; and the inner surface which is characterized by the inner cortex of the bone and which is adjacent to the cranial cavity and the brain. Between the inner cortex and the outer cortex, which are dense layers of bone, lies the diploe which generally consists of soft bone and bone marrow. When a bone fragment is created, a cut between the bone fragment (the primary bone zone) and the remainder of the cranium (the secondary bone zone) is present.

5 Several methods of alignment and fixation of primary and
secondary bone zones are known. Traditional techniques involve the use of
several pieces of filament, such as wire, that are tied after being threaded
through holes drilled obliquely through the outer cortex to the cut surface of
both bone zones. Precise alignment of the two zones can be difficult and the
10 technique can be cumbersome.

 Commonly, the zones of bone can be aligned and fixated with
a system of plates and screws (U.S. Patents: 5,372,598; 5,413,577; and
5,578,036). A plate made of metal or other substance can be fixated to the
15 outer cortex of the primary bone zone with screws whose penetration of the
bone can be limited to the outer cortex. With three or more plates attached to
the primary bone in such a way that the plates protrude beyond the edges of the
primary bone zone, the primary bone zone can be introduced into a defect and
aligned to the outer cortex of the secondary bone zone without danger of the
20 primary bone zone falling too deeply into the defect in the secondary bone zone
and exerting pressure on the underlying tissue such as the brain. Fixation can
then be achieved by employing additional screws fixating the plates to the outer
cortex of the secondary bone zone. Plates and screws systems allow for the
alignment and fixation of the zones, while preventing the primary bone zone
25 from falling below the level of the secondary bone zone without actually
introducing a component of the device below the secondary bone zone. A plate
with a spring clip extension has been described (U.S. Patent 5,916,217).

 Devices that align the two bone zones by way of compressing
30 them between the two disks positioned along the inner and outer cortex have
been described. (Foreign Patents: DE 19603887C2, DE 19634699C1, DE
29812988U1, EP 0787466A1.) A pin connects the two disks aligning and
securing two bone zones. These devices introduce foreign material that is left

5 below the inner cortex, and they do not protect the underlying tissue from compression during the installation procedure.

10 Devices that fixate bone zones using friction forces created by a cam without a component that extends below the inner cortex are known and described (Patent DE 19634697C1). These devices also do not protect the brain from compression during the installation procedure.

15 Intramedullary pins are well known in the orthopedic fields for alignment of long bones. Such pins have also been described for cranial fixation (U.S. Patent 5,501,685); however, the bone zones can not be aligned in three dimensions with this technique.

20 There is a need for an alignment and fixation plate that is simple and rapid to use, versatile, and ultimately cost effective. There is also need for easily usable clip structure associated with such a plate.

OBJECTS OF THE INVENTION

25 One object of the invention is to provide a device and instruments for its use and installation that aligns one cortex of a primary zone with one cortex of a secondary bone zone without extending to the opposing cortex, and which accurately fixates the bone zones to each other. When used in the field of neurosurgery, the device is applied to the primary bone zone and it aligns the outer cortex of the primary bone zone with the outer cortex of the
30 secondary bone zone; it prevents the primary bone zone from entering the cranial cavity; and it provides fixation of the two bone zones.

One fixation feature of the invention relies on the principle that

5 the device is fixated to the primary bone zone and the fixation feature grips the
secondary bone zone by means of strut elements engaging the soft areas of the
medullary space, irregularities along the cut surface, or a slot cut into the cut
surface of the secondary bone zone. Another feature is the use on such a plate
of multiple struts or tab extensions to support a projection or projections to be
10 driven into the edge of a primary bone zone to retain the plate in anchored
position.

SUMMARY OF THE INVENTION

15 The invention provides an attachment to connect two or more
spaced apart bone zones, having surfaces and edges, and comprises:

- a) a plate,
- b) fastener openings carried by the plate at peripherally
spaced locations, to receive fasteners that penetrate the bone zone at their
20 surfaces,
- c) at least one prong to connect the plate to at least one bone
zone edge.

As will be seen there may be three or more of such fastener
openings, on and spaced about the plate; and the plate may have outer regions
25 carrying the fastener openings, such regions projecting away from a plate
central region, with gaps separating those projecting regions.

It is another object to configure the prong carried by the plate to
project in a direction extending away from the plate central region. The prong
30 may typically have a tip projecting at a lower level spaced below an upper level
defined by the plate main extent. Further, the plate may have an extension
through which the prong projects to fasten to bone tissue.

5 Yet another object is to provide at least one clip carried by the plate and projecting at the plate periphery, to connect with bone tissue. The clip typically includes at least one projection having a sharp terminal to engage an edge of a bone zone.

10 In another form of the invention, at least one barb is carried by the plate and projecting at the plate periphery. The barb has a sharp terminal to engage an edge of the bone zone.

15 In a preferred form of the invention, the plate is generally disc-shaped, with the clip or clips, barb or barbs, and projection or projections, spaced about the disc periphery, in alternating relation with retainer fastener openings, as will be seen.

20 These and other objects and advantages of the invention, as well as the details of an illustrative embodiment, will be more fully understood from the following specification and drawings, in which:

DRAWING DESCRIPTION

25 Fig. 1 is a plan view of a clip blank in one plane, as may be used in conjunction with a plate to be attached to the skull;

Fig. 2 is a top plan view of the formed or bent clip of Fig. 1;

Fig. 3 is a frontal view of the clip taken on lines 3-3 of Fig. 2;

30 Fig. 4 is a right side elevation taken on lines 4-4 of Fig. 2;

Fig. 5 is a view like Fig. 4, but showing use of the clip;

Fig. 6 is a perspective view showing a bone flap fixated on a skull, employing fixation clips as in the form of a plate;

Fig. 7 is a plan view of a fixation plate, with integral clips, in blank form;

Fig. 8 is like Fig. 7 but shows the clips in bent condition; and

Fig. 9 is like Fig. 7, but shows a modification;

Fig. 10 shows a bent prong; and

Fig. 11 shows the bent prong inserted into bone tissue.

DETAILED DESCRIPTION

Referring first to Fig. 8, an attachment is shown, such as a plate 100, to connect two spaced apart zones, one zone comprising a cranium bone zone 12. Plate 100 has a top surface, and an edge 100a facing the edge 102a of the cranium 102. Edge 102a typically extends in a loop defining an opening into the interior of the cranium, as may be formed during surgery. Fastener openings are carried by the plate, as for example by peripheral projections or tabs 104 forming such openings 105 at spaced locations or intervals about the plate periphery. Four to six such openings may typically be provided, five being shown. Plate wings 106 typically integrally form such openings. Fasteners are passed through such openings, and into the skull for screw attaching the plate to the skull. See fastener 105a.

Also provided is at least one prong 110 to connect the plate to the skull 18, the prong extending generally in the plane of the bone zone 12, when formed into the position or positions as shown at 110, in Fig. 8, as by bending of leg 111 (see Fig. 7) carrying the prong. In the unbent position of Fig. 7, the prong extends away from the plate 100; and in Fig. 8, the bent prong also extends away from the plate central region and below it. See Fig. 10 showing a bent prong 110, and Fig. 11 showing the bent prong inserted into bone diploe 16. The prong is preferably barbed, as at 110a.

5 Extending the description to Figs. 1-5, at least one clip is carried by the plate, to project at its periphery. Multiple clips are preferably used. See for example preferred clip 10 configured to project between primary and secondary zones 12 and 15, the former having edge 12a. A gap 43 is formed between edge 12a and clip arms 32a and 32b, at zone 15. Diploe is shown at 10 16 between the top and bottom surfaces 12a and 12b of cranium zone 12. As also seen in Fig. 6, the primary bone zone may be defined by skull 18 and its looping zone extent at 12 opposing zones 15. In the adult, cranial bone or skull averages 7mm in thickness, but varies between 3 and 12 mm.

15 As seen in Figs. 1-5, the clip includes arms 32a-32d that form a generally rectangular shape in the blank form as seen in Fig. 1. Arms 32a and 32b extend in generally parallel relation, and are bowed as seen in Fig. 4, and providing a spring-like and stiffened support for each projection 25, having tip 25a, whereby the projections 25 are yieldably urged toward and into the 20 diploe 16 as the clips are installed into Fig. 5 position.

 The method of using the Fig. 7 device, includes orienting the prong 110 to align with an edge of the primary bone zone, and driving the prong 110 into the bone zone 12 at the edge thereof, by driving its bowed extension at anvil 111a, and attaching the tabs 104 to the skull. 25

 The method preferably also includes displacing the bent clips 10 in directions (typically relatively downwardly toward the skull to bring tip 25a of each clip into gap 43 as seen in Fig. 5) to effect scraping of the edge 12a of the bone zone 12 by the tip or tips 25a of the angled clip projection or projections 25. Projection or projections 25 is or are oriented, i.e. angled, to resist displacement of each clip in an upward or opposite direction, relative to bone zone 12. For example, attempted upward and outward displacement 30

5 would increase the "gouge-in" movement of the tips 25_a of the projections, into the diploe 16.

Projections 25 can resiliently deflect, as by spring bending of their bowed support struts, to accommodate the clips to the gap 43 between 15 and 12, as during plate downward installation. In Fig. 8, the peripheral spacing of elements 110 and 25 further enhances device installed stability.

The clips 10, prong 110, and plate 100, as referred to above are metallic,
15 and preferably consist essentially of one of the following:

- i) titanium
- ii) titanium alloy
- iii) an alloy consisting essentially of titanium, aluminum and vanadium
- 20 iv) an alloy consisting essentially of:
 - about 90% by weight of titanium
 - about 6% by weight of aluminum
 - about 4% by weight of vanadium.

25 Fig. 9 shows another form of the invention. It is like Fig. 9, but the plate 100 has an extension 125 to be bent down at about 90°, and which forms an opening or openings 126 through which the prong 134 is to be projected. The prong then functions in the manner of prong 110 described above. The edges of the opening 126 may form a succession of side receivers,
30 to selectively position the prong 134, lengthwise of the extension, i.e. vertically in gap 43. Prong 134 is in the form of a fastener having a shank 134_a, sharp forward tip 134_b, and a head 134_c to be driven.

5 Claims:

1. An attachment to connect two spaced apart zones having surface and edges, one zone comprising a cranium bone zone, comprising in combination:

- 10 a) a plate,
- b) fastener openings carried by the plate at peripherally spaced locations, to receive fasteners that penetrate the bone zone at their surfaces,
- 15 c) at least one prong to connect the plate to at least one bone zone edge.

2. The combination of claim 1 wherein there are at least four of said fastener openings.

20

3. The combination of claim 1, wherein the plate has outer regions carrying said fastener openings, said regions projecting away from a plate central region.

25

4. The combination of claim 4 wherein the plate has gaps separating said outer regions.

30

5. The combination of claim 3 wherein said prong projects in a direction away from said central region.

10

5 6. The combination of claim 1 wherein said prong having
a tip projecting at a lower level spaced from an upper level defined by the plate.

10 7. The combination of claim 1 wherein the plate has an
extension through which said prong projects.

15 8. The combination of claim 1 including at least one clip
carried by the plate and projecting at the plate periphery.

20 9. The combination of claim 8 wherein there are two of said
clips.

25 10. The combination of claim 8 wherein the clip includes at
least one projection having a harp terminal to engage an edge of a bone zone.

30 11. The combination of claim 8 wherein the clip includes two
projections, each having a sharp terminal to engage an edge of the bone zone.

35 12. The combination of claim 1 including at least one barb
carried by the plate and projecting at the plate periphery.

40 13. The combination of claim 12 wherein there are two of

11

5 said barbs.

10 14. The combination of claim 12 wherein the bard has a sharp
terminal to engage an edge of the bone zone.

15 15. The combination of claim 12 wherein there are at least
two of said barbs, each having a sharp terminal to engage an edge of the bone
zone.

20 16. The combination of claim 1 wherein the plate has a
substantially disc shaped configuration.

 17. The combination of claim 16 wherein said openings are
spaced about the disc configuration.

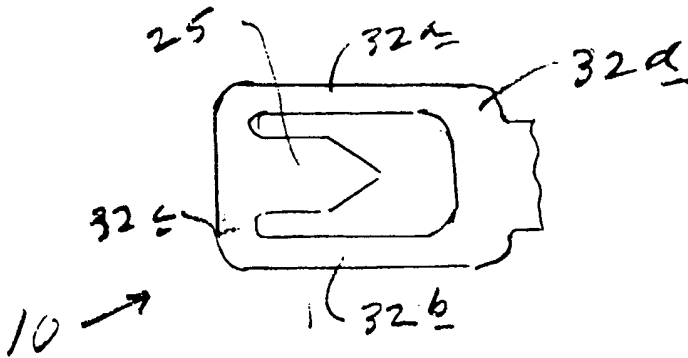


FIG 1

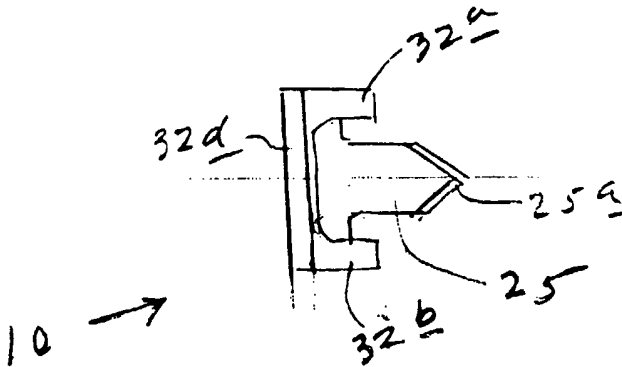


FIG 2

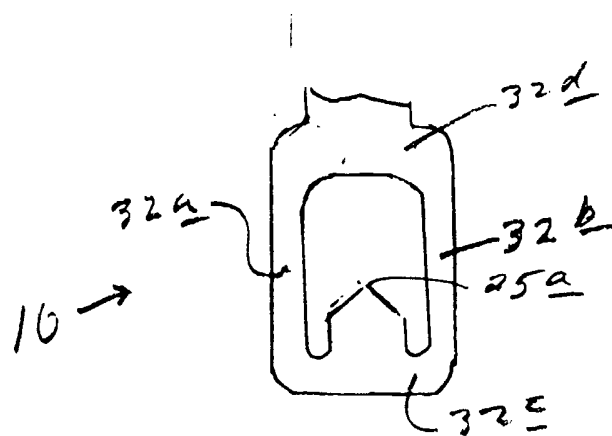


Fig 3

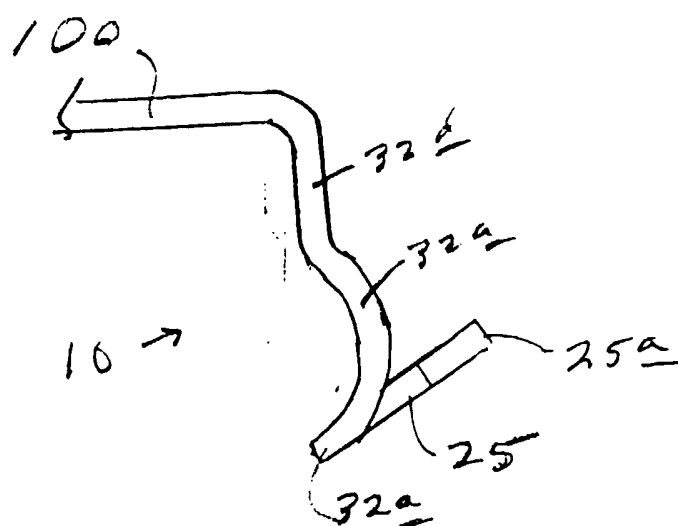


Fig 4

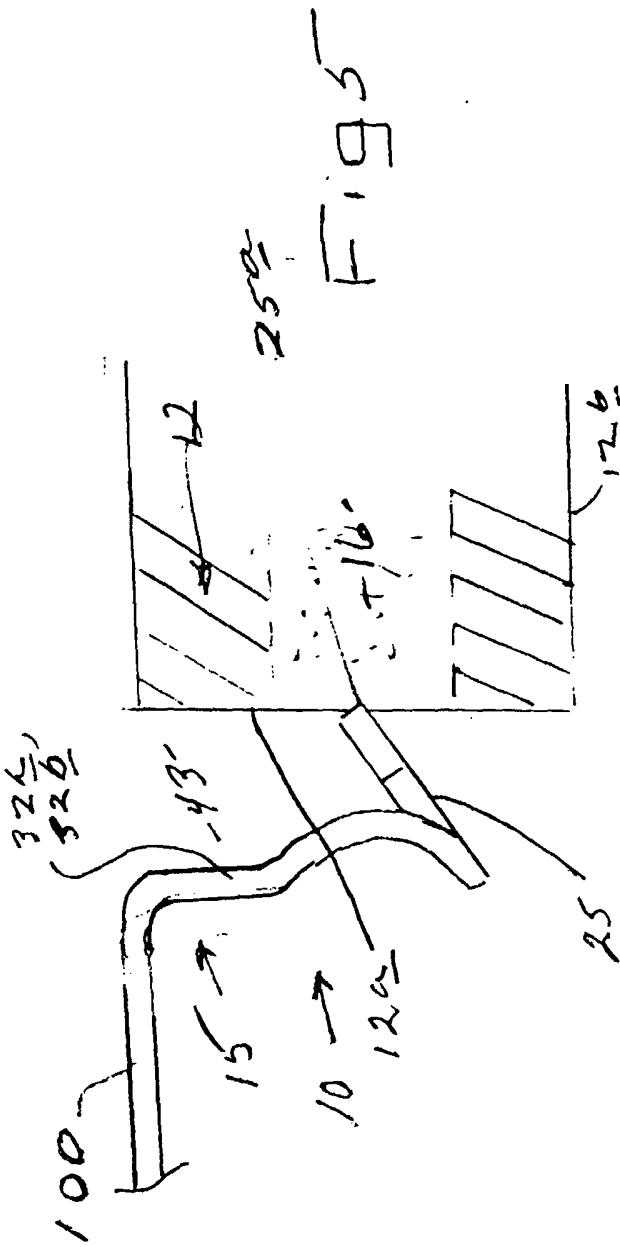
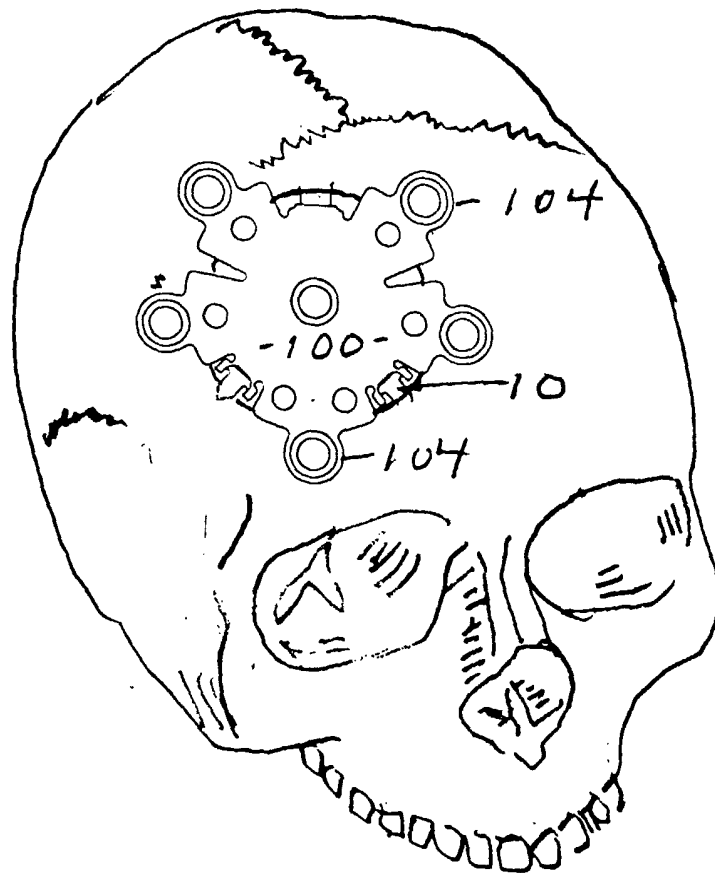


Fig 1



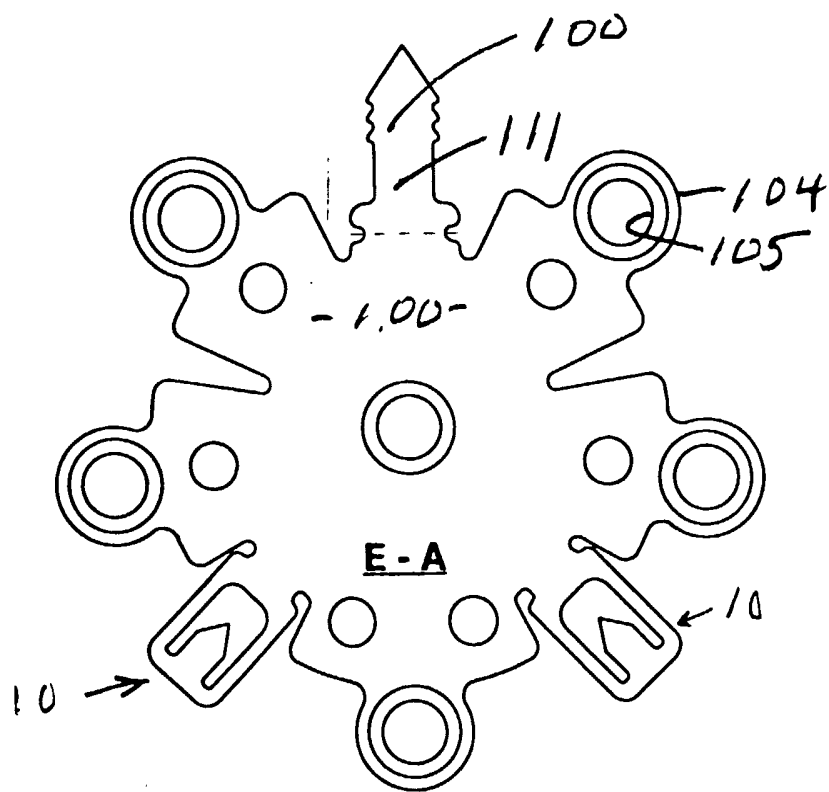


Fig 7

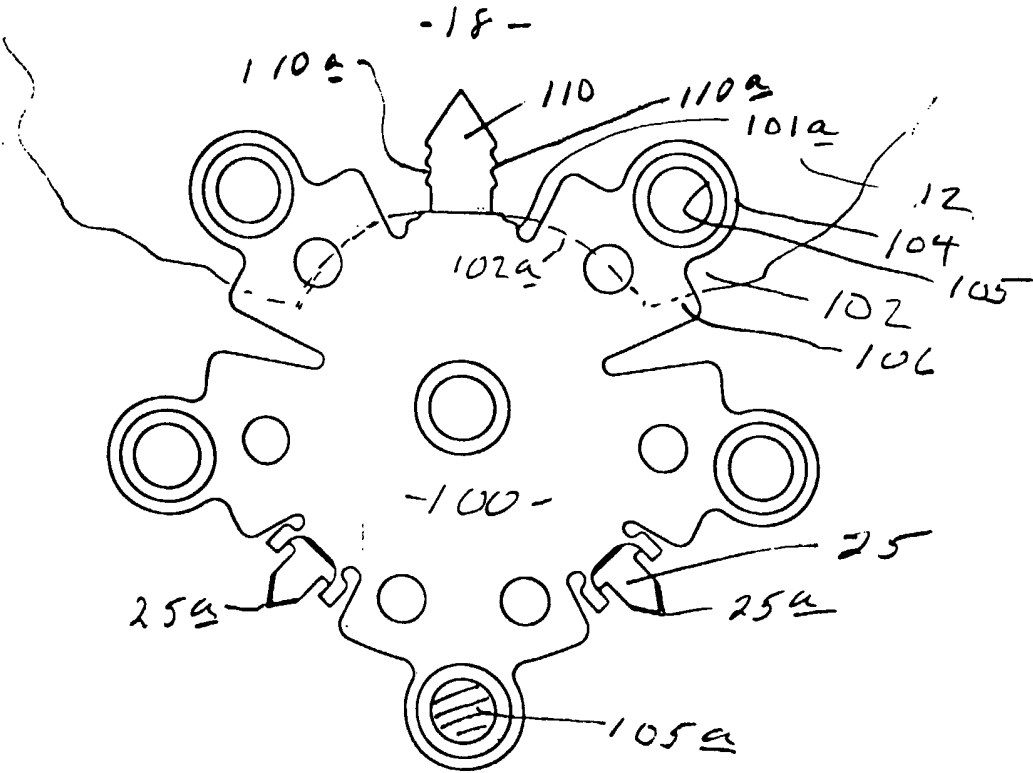
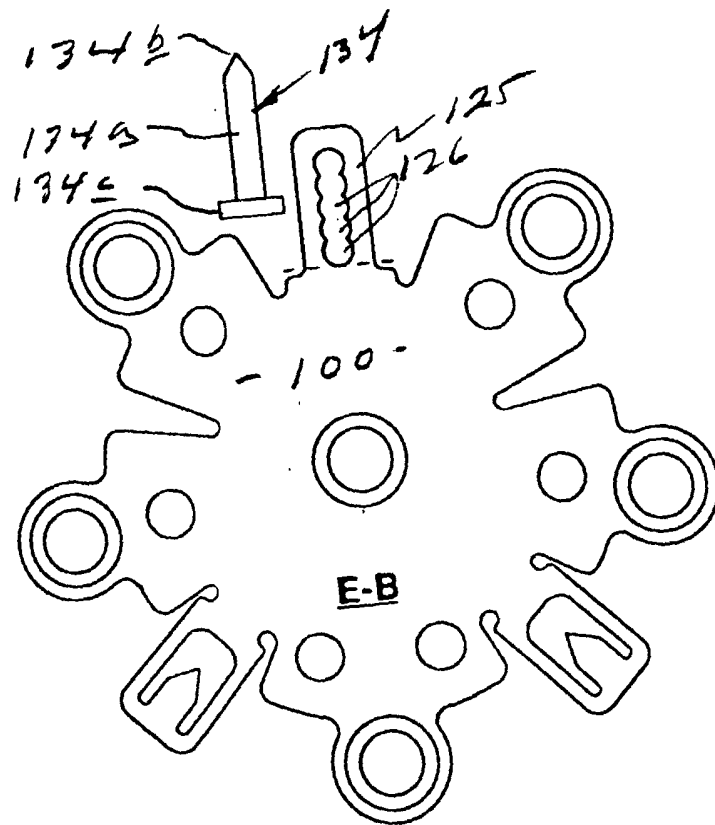
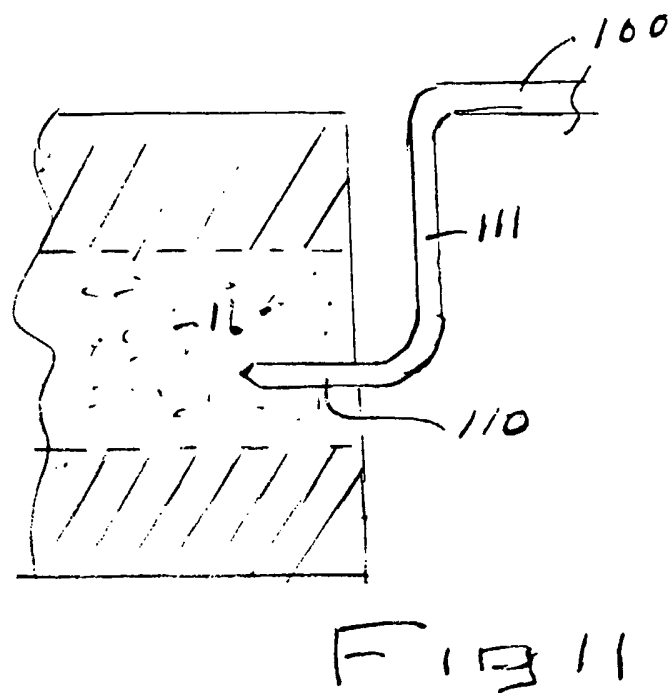
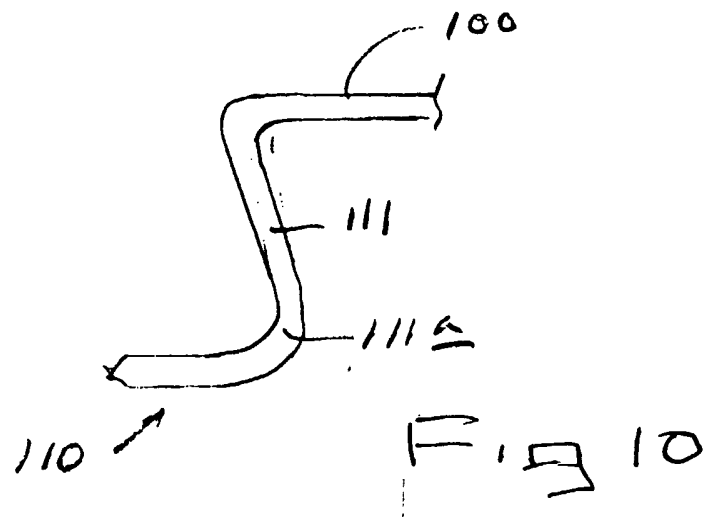


Fig 8



F. 199



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/37787

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/56

US CL : 606/69

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)

U.S. : 606/69,70,72,73,75,77,86,104,151; 411/61,508

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,961,519 A (Bruce et al) 5 October 1999, see entire document	1-17
Y	US 5,941,878 A (Medoff) 24 August 1999, see entire document	1-17
A	US 5,201,737 A (Leibinger et al) 13 April 1993	1-17
A	US 6,126,663 A (Hair) 3 October 2000, see entire document	1-17
A	US 6,197,037 B1 (Hair) 6 March 2001, see entire document	1-17
A	US 5,578,036 A (Stone et al.) 26 November 1996, see entire document	1-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 23 JANUARY 2003	Date of mailing of the international search report 19 MAR 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PEDRO PHILOGENE Telephone No. (703) 308-2252

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/57787

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.