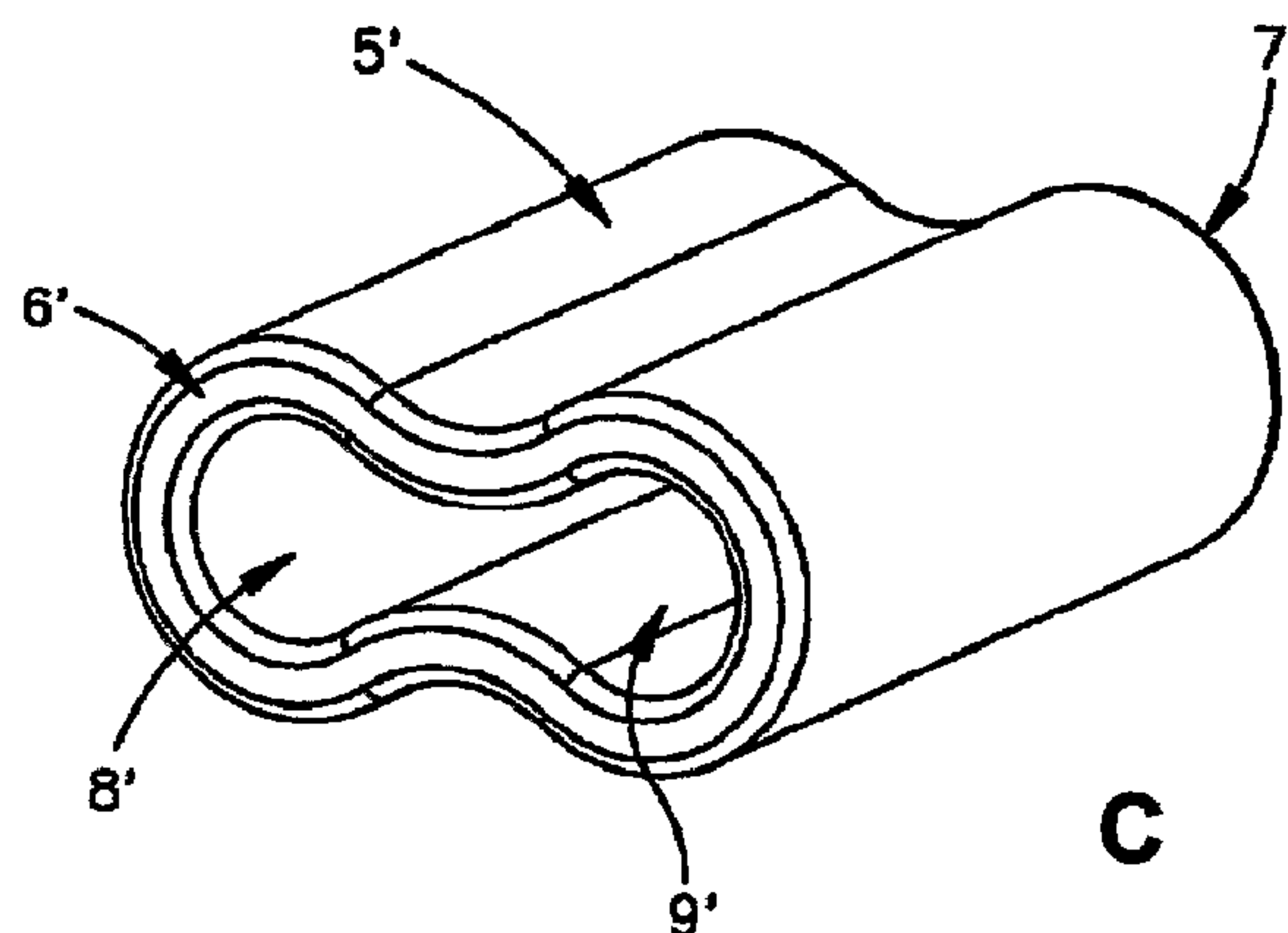
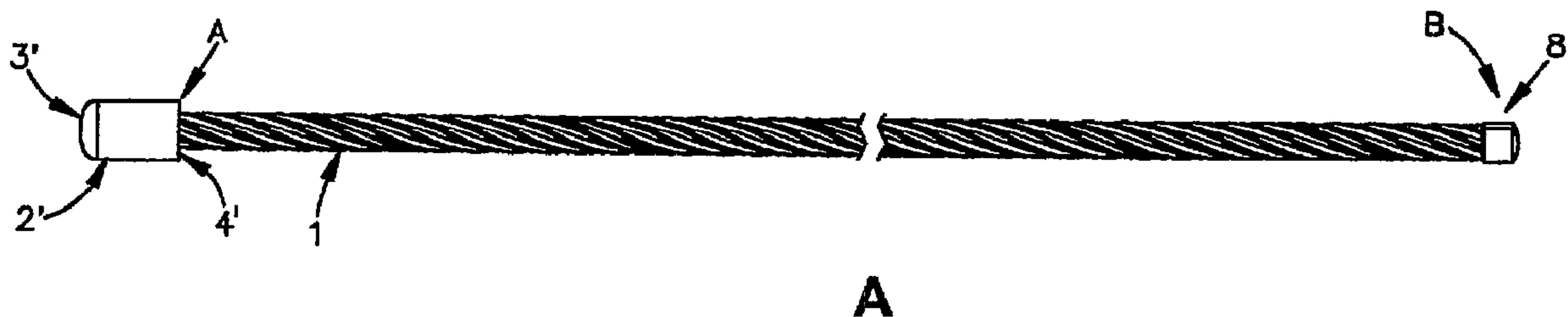




(86) Date de dépôt PCT/PCT Filing Date: 2006/06/13  
(87) Date publication PCT/PCT Publication Date: 2006/12/21  
(45) Date de délivrance/Issue Date: 2015/08/11  
(85) Entrée phase nationale/National Entry: 2007/12/07  
(86) N° demande PCT/PCT Application No.: US 2006/023229  
(87) N° publication PCT/PCT Publication No.: 2006/135935  
(30) Priorité/Priority: 2005/06/13 (US11/152,738)

(51) Cl.Int./Int.Cl. *A61B 17/82* (2006.01),  
*A61B 17/84* (2006.01)  
(72) Inventeurs/Inventors:  
ALBERTSON, THOMAS, US;  
GOHEEN, CHRISTOPHER, US;  
MICHELS, MARK, US  
(73) Propriétaire/Owner:  
DEPUY SYNTHES PRODUCTS, LLC, US  
(74) Agent: NORTON ROSE FULBRIGHT CANADA  
LLP/S.E.N.C.R.L., S.R.L.

(54) Titre : SYSTEME DE RECONSTRUCTION STERNALE  
(54) Title: STERNAL RECONSTRUCTION SYSTEM



(57) Abrégé/Abstract:

A sternal reconstruction system for securing parts of a sternum includes at least one flexible cable (1) with a fused end fitting (2') which may be crimped to one end of the cable, at least one parallel fitting piece (5') with two channels (8', 9') and at least one ferrule (9). Optionally, the system includes at least one cannulated screw. Circumferential or parasternal fixation may be brought about by use of the sternal reconstruction system. Also provided is a method for sternal reconstruction utilizing the sternal reconstruction system. Also provided is a kit for sternal reconstruction. The end of the cable without the end fitting may be passed through one of the channels, around the sternum, and then through the other channel, with the ferrule subsequently being crimped onto it.



## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
21 December 2006 (21.12.2006)

PCT

(10) International Publication Number  
**WO 2006/135935 A1**

(51) International Patent Classification:

A61B 17/82 (2006.01) A61B 17/84 (2006.01)

(21) International Application Number:

PCT/US2006/023229

(22) International Filing Date: 13 June 2006 (13.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

11/152,738 13 June 2005 (13.06.2005) US

(71) Applicant (for CA only): **SYNTHES (USA)** [US/US];  
1302 Wrights Lane East, West Chester, PA 19380 (US).

(71) Applicant (for all designated States except CA, US): **SYNTHES GMBH** [CH/CH]; Eimattstrasse 3, CH-4436 Oberdorf (CH).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ALBERTSON, Thomas** [US/US]; 159 Picket Post Lane, Phoenixville, PA 19460 (US). **GOHEEN, Christopher** [US/US]; 305 Sharon Drive, New Cumberland, PA 17070 (US). **MICHELS, Mark** [US/US]; 3 Tanguy Road, Glen Mills, PA 19342 (US).

(74) Agents: **ROTHERY, Brian, M.** et al.; JONES DAY, 222 East 41st Street, New York, NY 10017-6702 (US).

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

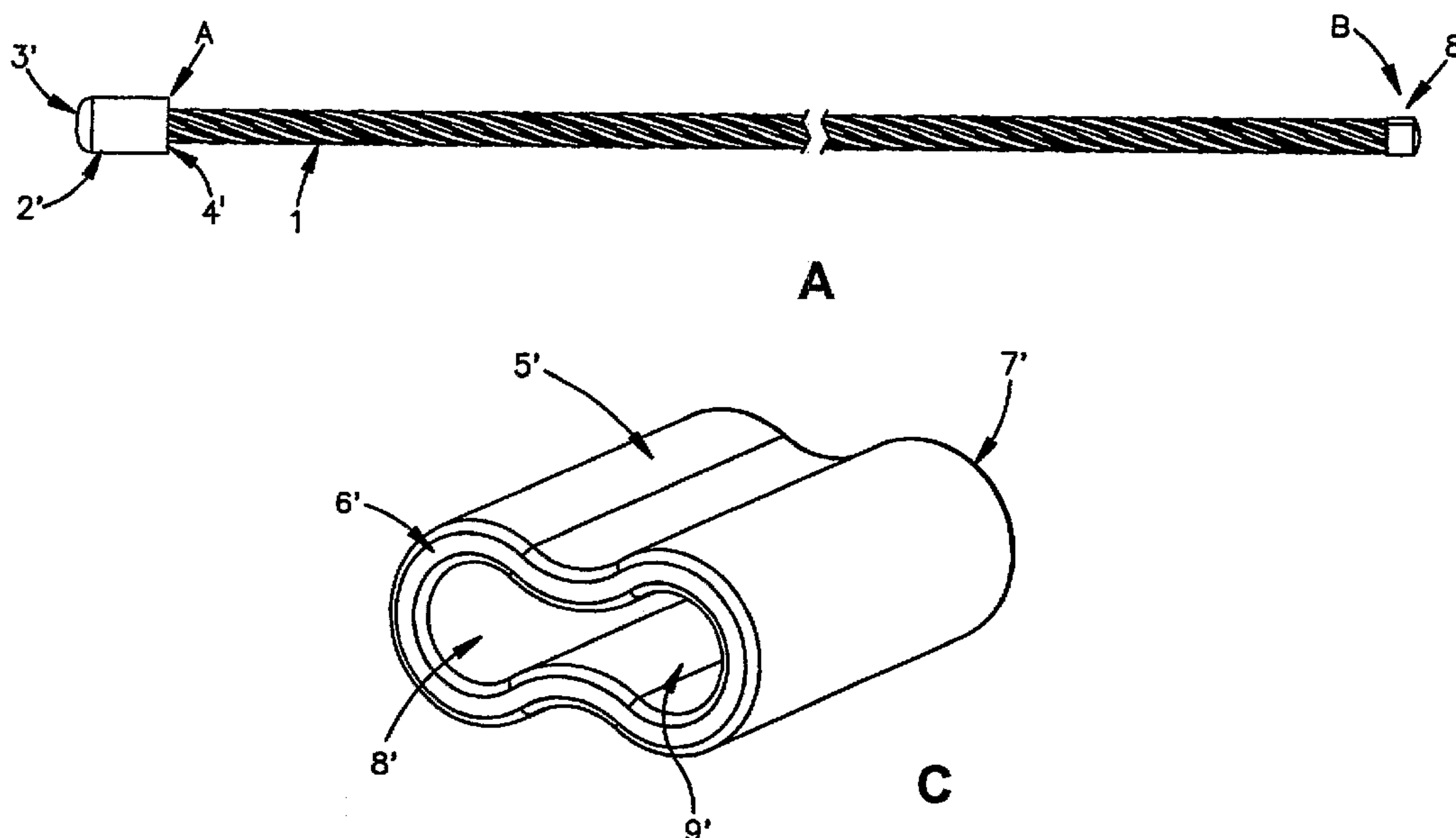
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

[Continued on next page]

(54) Title: STERNAL RECONSTRUCTION SYSTEM



(57) Abstract: A sternal reconstruction system for securing parts of a sternum includes at least one flexible cable (1) with a fused end fitting (2') which may be crimped to one end of the cable, at least one parallel fitting piece (5') with two channels (8', 9') and at least one ferrule (9). Optionally, the system includes at least one cannulated screw. Circumferential or parasternal fixation may be brought about by use of the sternal reconstruction system. Also provided is a method for sternal reconstruction utilizing the sternal reconstruction system. Also provided is a kit for sternal reconstruction. The end of the cable without the end fitting may be passed through one of the channels, around the sternum, and then through the other channel, with the ferrule subsequently being crimped onto it.

WO 2006/135935 A1

# WO 2006/135935 A1



- 
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*
- 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.*



## STERNAL RECONSTRUCTION SYSTEM

5

### **FIELD OF THE INVENTION**

The present invention relates generally to surgical reconstruction systems or devices, and more particularly, to devices for reapproximating two or more parts of a patient's sternum.

### **BACKGROUND OF THE INVENTION**

10

Many surgical procedures require two or more parts of a sternum to be reapproximated, or fixed together, such as sternal reconstruction and repair of sternal trauma. In addition, various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases involving tissues or organs located in a patient's thoracic cavity, such as the heart and lungs. These procedures typically require a partial or median sternotomy to gain access to the patient's thoracic cavity. A partial or median sternotomy is a procedure by which a saw or other appropriate cutting instrument is used to make a midline, longitudinal incision along a portion or the entire axial length of the patient's sternum, allowing two opposing sternal halves to be separated laterally. A large opening into the thoracic cavity is thus created, through which a surgeon may directly visualize and operate upon the heart and other thoracic organs, vessels, or tissues. Following the surgical procedure within the thoracic cavity, the two severed sternal halves must be reapproximated.

15

20

25

Various types of orthopedic devices are known for the reapproximation or fixation of bone fragments such as sternal halves. Such devices typically are used to stabilize bones by maintaining fractured bone portions in relatively fixed positions with respect to each other. The alignment and stability provided by the devices promotes the healing of fragments, allowing proper fusion to occur.

30

Internal fixation devices include bone screws, which are used in a variety of orthopedic applications for fixation of bone fragments. Bone fragments may be positioned in a desired configuration, and one or more holes may be drilled and tapped across the fracture. Compression and stabilization of the bone fragments may then be effected by

fracture. Compression and stabilization of the bone fragments may then be effected by screwing bone screws into the holes. One limitation associated with bone screws, however, is that repositioning or adjusting the bone screws following implantation is difficult. In order to accommodate a different alignment, it is often necessary to remove the original  
5 bone screws and drill new holes for subsequent bone screw implantation.

Metal pins also are often used to stabilize bones. Similar to bone screws, metal pins may be inserted in holes drilled across bone fragments to confer stability to the bone. However, as with bone screws, removal of the pins may be required if subsequent realignment of bone portions is necessary.

10 Bone plates are fastenable to the surface of a bone typically at both sides of a fracture to support and/or stabilize the fragments. Bone plates have typically been attached to the bone with bone screws that extend from the plate into the bone. In some examples, the head of the bone screw is locked to the plate (*e.g.*, by threaded engagement between the screw head and the bone plate) and in other plates the head of the screw is free to angulate  
15 with respect to the plate, such that the screw may be placed in the bone at a surgeon-selected angle. In yet other examples, the screw head may cooperate with the bone plate to provide compression or distraction of the fragments (*i.e.*, to push the bone fragments towards or away from one another).

Intramedullary implants are another device used for fixation of bone  
20 fragments. Such a device may be placed in the central canal of a fractured bone and locked thereto at the longitudinal ends of the device using screws. The use of intramedullary implants is very invasive, though, and the implants are difficult to manipulate once installed within the canals of bone fragments.

External fixation devices also are commonly used to stabilize bone  
25 segments. These devices employ a plurality of pins which extend through a patient's skin into holes drilled in fractured bone. Clamps are used to secure the pins to a common apparatus, which may for example take the form of a rod that is disposed generally parallel to the anatomically correct longitudinal axis of the fractured bone. The clamps in combination with the common apparatus create a rigid frame for immobilizing the fracture  
30 to promote healing.

External skeletal fixation is a preferred method of treatment for various limb deformities, injuries, and other conditions including: severe open fractures, fractures



associated with severe burns, fractures requiring distraction, fractures requiring limb lengthening, arthrodesis, infected fractures, and nonunions. External fixation offers several advantages over the above-mentioned internal fixation approaches. For example, external fixation enables skeletal stabilization to be managed from a location that is generally remote from the deformity, injury, or disease, thereby permitting direct surveillance of the limb and wound during related or subsequent procedures. In addition, external fixation facilitates adjustment of fracture alignment, bone lengthening, bone compression, and fixed distraction following initial surgery. Furthermore, minimal interference with proximal and distal joints allows immediate mobilization of a wounded limb, and insertion of the fixator pins can be performed under local anesthesia.

Despite these developments, there remains a need for fixation devices with improved adjustability and selectivity.

### SUMMARY OF THE INVENTION

The present invention is directed to a sternal fixation device for securing parts of a sternum. The sternal reconstruction system for securing parts of a sternum comprises a flexible cable having first and second ends; a fused end fitting member; a parallel fitting piece; and a ferrule, wherein the first end of the cable comprises a fused end fitting member. In one embodiment the fused end fitting member is attached to the first end of the cable by crimping. Preferably the fused end fitting member comprises a preinstalled cylindrical end fitting having an upper surface and a lower surface, and having a diameter of from about 1mm to about 5mm and a length of from about 5mm to about 20mm, and is constructed from a material selected from the group consisting of titanium, alloys of titanium, stainless steel and resorbable materials.

In one embodiment the upper surface of the fused end fitting member has rounded edges and the lower surface of the fused end fitting member is flat. In another embodiment the lower surface of the fused end fitting member is designed to mate with an end surface of the parallel fitting piece.

In one embodiment the parallel fitting piece is a flattened cylindrical tube having a first end and a second end, a long cross-sectional axis and a short cross-sectional axis. Preferably the first and second ends of the parallel fitting piece are parallel to each other. In one embodiment at least one side having a long cross-sectional axis  $L$  is crimped along its length so as to provide two adjacent parallel channels through the parallel fitting piece.



Preferably the parallel fitting piece is from about 3mm to about 15mm in length, the long cross-sectional axis is from about 3mm to about 8mm, and the short cross-sectional axis is from about 1mm to about 5mm.

5 In another embodiment the both sides of the parallel fitting piece having a long cross-sectional axis L are crimped along their lengths so as to provide two adjacent parallel channels through the parallel fitting piece, and the channels have the same aperture and cross-section. Preferably each channel has a diameter of from about 0.7mm to about 2.5mm. Preferably the parallel fitting piece is constructed from a material selected from the group consisting of, titanium, alloys of titanium, stainless steel and resorbable materials.

10 In another embodiment, the sternal reconstruction system of the invention further comprises at least one cannulated screw. The at least one cannulated screw may be a locking or a non-locking screw, and may be at least partially threaded for attachment to bone. The at least one cannulated screw is constructed from a material selected from the group consisting of titanium, alloys of titanium, stainless steel and resorbable materials. In  
15 one embodiment, the head of the at least one cannulated screw comprises a head which comprises a hollow aperture which is sized and shaped so as to accommodate the fused end fitting member.

In another embodiment the present invention is directed to a method for sternal reconstruction, comprising the steps of passing a flexible cable having a first and a second  
20 end through one channel of a parallel fitting piece having two channels; wrapping the flexible cable around the sternum; passing the flexible cable through the second channel of the parallel fitting piece; tensioning the flexible cable to a desired tension; and securing the tensioned cable, wherein the first end of the flexible cable comprises a fused end fitting member, and is designed to mate with an end surface of the parallel fitting piece.

25 In another embodiment the present invention is directed to a method for sternal reconstruction, comprising the steps of attaching at least one cannulated screw into the sternum; feeding a flexible cable having a first and a second end through the lumen of the at least one cannulated screw; passing the flexible cable having a first and a second end  
30 through one channel of a parallel fitting piece having two channels; wrapping the flexible cable around the sternum; passing the flexible cable through the second channel of the parallel fitting piece; tensioning the flexible cable to a desired tension; and securing the tensioned cable, wherein the first end of the flexible cable comprises a fused end fitting member, and is designed to mate with an end surface of the parallel fitting piece.



In one embodiment the tensioned cable is secured by crimping a ferrule onto the flexible cable. In another embodiment the inner diameter of the ferrule comprises a sharp edge in order to facilitate the cutting of the flexible cable during crimping of the ferrule onto the flexible cable. The tensioned cable may be secured by crimping a ferrule onto the flexible cable, the ferrule being situated at one end of the parallel fitting piece and the fused end fitting member being situated at the other end of the parallel fitting piece.

In another embodiment the present invention is directed to a sternal reconstruction kit comprising at least one flexible cable; at least one parallel fitting piece; and at least one ferrule, wherein the first end of the flexible cable comprises a fused end fitting member, and is designed to mate with an end surface of the parallel fitting piece. In another embodiment, the sternal reconstruction kit further comprises at least one cannulated screw and/or at least one reconstruction plate.

In one embodiment the at least one flexible cable is attached to a suture. The inner diameter of the at least one ferrule comprises a sharp edge in order to facilitate the cutting of the flexible cable during crimping of the ferrule onto the flexible cable.

In one aspect there is provided a sternal reconstruction system for securing parts of a sternum comprising:

a flexible cable having first and second ends, the first end comprising an end fitting member;

the end fitting member having an upper surface and an opposing lower surface; and

a fitting piece having a first end, a second end, a length measured from the first end to the second end, and at least two channels each extending through the fitting piece along the length from the first end to the second end; and

a ferrule defining a hole that is sized to receive the flexible cable;

wherein the sternal reconstruction system defines an assembled configuration in which:  
1) the end fitting member abuts the first end of the fitting piece, and 2) the ferrule is crimped to the flexible cable to and abuts the second end of the fitting piece.



In another aspect there is provided use of a sternal reconstruction system comprising:  
a flexible cable having a first and a second end, for passing through one channel of a parallel fitting piece having first and second channels;  
the flexible cable also being for passing through the second channel of the parallel fitting piece;  
the flexible cable having being tensionable to a desired tension; and  
the tensioned cable being securable;  
wherein the first end of the flexible cable comprises a fused end fitting member, designed to mate with an end surface of the parallel fitting piece.

In another aspect there is provided use of a sternal reconstruction system comprising:  
at least one cannulated screw;  
a flexible cable having first and second ends, at least a portion of the flexible cable for feeding through a lumen of the at least one cannulated screw;  
the flexible cable for passing through one channel of a parallel fitting piece having two channels;  
the flexible cable for passing through the second channel of the parallel fitting piece;  
the flexible cable for tensioning and securing to a desired tension;  
wherein the first end of the flexible cable comprises a fused end fitting member, which mates with an end surface of the parallel fitting piece.

In another aspect there is provided a sternal reconstruction kit comprising:  
at least one flexible cable; and  
an end fitting member attached to the at least one flexible cable;  
at least one fitting piece having a first end, a second end, a length extending between the first end and the second end along a select direction, and at least two channels extending through the fitting piece along the length, such that each of the at least two channels are open to both the

first end and the second end, and the at least two channels are open to each other along a direction perpendicular to the select direction;

wherein the fitting piece is configured to abut the end fitting member, and the fitting piece is directly securable to the flexible cable when the second end of the flexible cable has been passed through the one of the at least two channels, looped around a sternum, and passed at least partially through another of the at least two channels of the fitting piece.

In another aspect there is provided a sternal reconstruction system configured to secure parts of a sternum, the system comprising:

a flexible cable having first and second ends, the first end comprising an end fitting member, the end fitting member having an upper surface and an opposing lower surface;

a fitting piece having a first end, a second end, a length extending between the first end and the second end, and at least two channels extending through the fitting piece along the length from the first end to the second end; and

a ferrule that is elongate along a longitudinal axis, the ferrule defining a hole extending along the longitudinal axis, such that the hole is configured to receive the flexible cable, the ferrule including a sharp edge extending into the hole to facilitate cutting of the flexible cable during crimping of the ferrule onto the flexible cable;

wherein the fitting piece is configured to abut the end fitting member when the fitting piece is positioned adjacent the sternum and the second end of the flexible cable is passed at least partially through the channels of the fitting piece.



### **BRIEF DESCRIPTION OF THE DRAWINGS**

Preferred features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

FIG. 1 is a perspective view of a first embodiment of a sternum reconstruction flexible cable with preinstalled flattened round crimp fitting;

FIG. 1A is a perspective view of a sternum reconstruction system with a preinstalled fused end fitting;

FIG. 1B is an end view of a parallel fitting piece;

FIG. 1C is a partial side-view of a parallel fitting piece;

FIG. 1D is an end view of a parallel fitting piece;

FIG. 2 is an end-view, partial cross-section of crimp fitting;

FIG. 3A is an end view of a cylindrical ferrule;

FIG. 3B is a side view of a cylindrical ferrule;

FIG. 4 is a side view of a flexible cable with crimp fitting at one end and a suture at the other end;

FIG. 5 is a perspective view of a safety cable tool;

5 FIG. 6 is a cross-sectional view of a safety cable tool;

FIG. 7 is a top view of a cannulated screw;

FIG. 8 is an end view of a cannulated screw;

FIG. 9 is an exploded side view of a cannulated screw;

FIG. 10 is an overhead view of a reconstruction plate;

10 FIG. 11 is a side view of a reconstruction plate;

FIG. 12 is a cross-sectional view of a reconstruction plate; and

FIG. 13 is a partial side view of a reconstruction plate.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The sternal reconstruction system of the present invention comprises a  
15 flexible cable with crimp, optionally one or more cannulated screws and optionally one or more reconstruction plates. In one embodiment of the present invention, simple circumferential or parasternal fixation may be provided by use of a sternal reconstruction system comprising a flexible cable and ferrule. In another embodiment, fixation may be achieved by use of a sternal reconstruction system comprising a flexible cable, crimp and  
20 cannulated screws. In yet another embodiment, fixation may be achieved by use of a sternal reconstruction system comprising a flexible cable, crimp, cannulated screws and one or more reconstruction plates.

While various descriptions of the present invention are described in the Figures, it should be understood that the various features described are for illustrative  
25 purposes, and are exemplary only. Therefore, this invention is not to be limited to only the specifically preferred Figures depicted herein.



A first illustrative embodiment of a sternal reconstruction system is shown in FIGS. 1 to 3. The sternal reconstruction system shown in FIG. 1 comprises a flexible cable 1 having two ends, a first end A having attached thereto a crimp fitting 2, and a second end B consisting of a thermally fused end 8. Thermally fused end 8 may assist in threading flexible cable 1 through the other elements of the sternal reconstruction system, and may also assist in preventing unraveling of flexible cable 1. Flexible cable 1 can be a single strand wire or a multi-wire stranded cable having from about 2 to about 1000 strands, preferably from about 50 to about 300 strands and most preferably from about 110 to about 145 strands, and has first and second ends A, B. Flexible cable 1 may have any suitable degree of flexibility from highly flexible like yarn to stiff like wire. The flexible cable 1, however, is sufficiently flexible to readily conform to the sternum, while sufficiently rigid to be manipulated as required. Flexible cable 1 is typically attached to crimp fitting 2 by crimping the fitting onto the cable. Crimp fitting 2 may be constructed from any suitable bio-compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel and resorbable materials, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used.

Crimp fitting 2 preferably comprises a preinstalled flattened disk-like crimp head 3 having an upper surface 4 and a lower surface 5. Upper surface 4 may be flat or curved and optionally has rounded edges. Lower surface 5 preferably is designed so as to mate with the top surface of a cannulated screw and/or a reconstruction plate, resulting in greater stability and/or a low profile. The flat lower surface 5 may assist in stabilizing the crimp fitting to a bone anchor, such as a screw, or to a bone plate, and results in greater stability of the system. In addition, the flat lower surface helps provide a low profile to the crimp fitting. Crimp head 3 has a diameter of from about 2mm to about 10mm, preferably about 6mm, and a thickness of from about 0.1mm to about 4mm, preferably about 2mm. While crimp head 3 is preferably a round disk, it may have other shapes such as square, rectangular or other polygon shape. Crimp head 3 has a diametrical hole or bore 6 through which the second or thermally fused end 8 of the flexible cable 1 is passed for attachment after the cable 1 is looped around the sternum. Diametric hole or bore 6 is sized so as to be able to accommodate the flexible cable 1, and preferably has a diameter of from about 0.7mm to about 2.5mm, and more preferably about 1mm.

Crimp fitting 2 further comprises a crimp shaft 7 that extends generally perpendicular to lower surface 4. Crimp shaft 7 may be cylindrically shaped, or have a non-circular cross-section. The crimp shaft 7 may be a cylindrical tube which has an opening



that receives the first end A of the flexible cable 1. The cylindrical tube may thereafter be crimped to attach the flexible cable 1 to the crimp fitting 2. The crimping process of the crimp shaft 7 may form a non-circular shape in the crimp shaft 7, or other desired shape.

The crimp shaft 7 is located on the lower surface 4 of the crimp head such that the perimeter  
5 of the lower surface 4 of the crimp head surrounds the crimp shaft 7 in order to provide an annular bearing surface C. Annular bearing surface C has a width of from about 0.5mm to about 3mm. Preferably the crimp shaft 7 projects perpendicularly from the lower surface 4 of the crimp head 3. Crimp shaft 7 preferably is sized and shaped so as to fit within a cannulated screw or a bone plate. The non-circular cross-section of the crimp shaft 7 may  
10 engage the non-circular recess formed in a cannulated screw to prevent rotation of crimp fitting 2 in the cannulated screw. Crimp shaft 7 preferably may range in size from about 0.7 mm to about 4mm in diameter, more preferably about 2.5mm, and from about 1.5mm to about 4mm in length, more preferably about 3mm. Preferably the diameter of crimp shaft 7 should not be less than the diameter of flexible cable 1. The length and shape of crimp shaft  
15 7 may assist in stabilizing the crimp fitting 2 to a bone anchor, such as a screw, or to a bone plate, and results in greater stability of the system.

FIG. 2 shows an end view, partial cross-section of the upper face 4 of the crimp fitting 2. Diametric hole 6 may have an included counter sink region D on both sides  
of the crimp head 3 where it opens to the exterior. FIG. 3A shows an end view of a  
20 cylindrical ferrule 9 which contains a hole 10 along its longitudinal axis. FIG. 3B shows a side view of the ferrule. The hole 10 along the longitudinal axis of the ferrule 9 is sized so as to accommodate the flexible cable 1. The inner diameter of the ferrule 9 may have a sharp edge in order to facilitate the cutting of the flexible cable 1 during crimping of the ferrule 9 onto the flexible cable 1. Ferrule 9 may be constructed from any suitable bio-  
25 compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel and resorbable materials, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used. In an illustrative embodiment, cylindrical ferrule 9 can be crimped onto the flexible cable 1 after flexible cable 1 is drawn through diametric hole 6 to a predetermined tension. The ferrule 9 preferably is sized so  
30 that it can not fit through the diametric hole 6, preferably at least after it is crimped onto the flexible cable 1. In another embodiment, ferrule 9 may be secured onto the flexible cable 1 by an adhesive. One of ordinary skill in the art will know and appreciate that any suitable biocompatible adhesive may be used. In another embodiment, flexible cable 1 and/or ferrule 9 are constructed from resorbable materials, and ferrule 9 may be secured onto the  
35 flexible cable 1 by thermal fusing.



Another illustrative embodiment of a sternal reconstruction system is shown in FIGS. 1A to 1D. In this embodiment, the sternal reconstruction system comprises a flexible cable 1 having two ends, a first end A having attached thereto a fused end fitting 2' and a second end B consisting of a thermally fused end 8. Fused end fitting 2' may be any  
5 suitable end fitting. Preferably fused end fitting member 2' is a tubular crimp fused end fitting. Flexible cable 1 is typically attached to fused end fitting 2' by crimping the fitting onto the cable. Fused end fitting 2' may be constructed from any suitable bio-compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel and resorbable materials, although one of ordinary skill in the art will know and appreciate that  
10 any biocompatible material may be used.

Fused end fitting 2' is preferably a preinstalled cylindrical end fitting having an upper surface 3' and a lower surface 4'. Upper surface 3' may be flat or curved and optionally has rounded edges. Lower surface 4' preferably is designed so as to mate with an end surface of a parallel fitting piece 5', resulting in greater stability and/or a low profile.  
15 Fused end fitting 2' has a diameter of from about 1mm to about 5mm, preferably about 2mm, and a length of from about 5mm to about 20mm, preferably about 10mm. While fused end fitting 2' is preferably either cylindrical or shaped so as to sit flush below the head of a cannulated screw 13, one of ordinary skill will know and appreciate that any suitable geometry may be used.

Parallel fitting piece 5', shown in FIGS. 1B to 1D, may be a cylindrical tube which is flattened along its length perpendicular to first end 6' and a second end 7'. Parallel fitting piece 5' has a long cross-sectional axis L and a short cross-sectional axis S. Preferably, parallel fitting piece 5' has parallel ends 6' and 7'. One or both sides of end fitting 2' having a long cross-sectional axis L may be flat, but preferably at least one side  
25 having a long cross-sectional axis L is crimped along its length so as to provide at least two adjacent parallel channels through the parallel fitting piece. Parallel fitting piece 5' may range in length from about 3mm to about 15mm, preferably about 5mm. Long cross-sectional axis L is from about 3mm to about 8mm, preferably about 4mm, and short cross-sectional axis S is from about 1mm to about 4mm, preferably about 2mm. One of ordinary  
30 skill in the art will know and appreciate that any suitable dimensions may be used for the parallel fitting piece 5'. Preferably, the at least one side having a long cross-sectional axis L is crimped at the midpoint along its length so as to provide two adjacent parallel channels 8' and 9' having the same dimensions of aperture and cross-section. Most preferably, both sides having a long cross-sectional axis L are crimped at the midpoint along their lengths.



The parallel channels 8' and 9' are sized so as to be able to accommodate the flexible cable 1, and preferably each has a diameter of from about 0.7mm to about 2.5mm, and more preferably about 1mm. Parallel fitting piece 5' may be constructed from any suitable bio-compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel and resorbable materials, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used.

As shown in FIG. 1D, in an alternative embodiment parallel fitting piece 5' may be may be a cylindrical bar which is planed along its length perpendicular to first end 6' and a second end 7', on two opposite sides to form a cylindrical bar which has a long cross-sectional axis L and a short cross-sectional axis S. The planing of the two opposite sides along the length of the cylindrical bar may be carried out by mechanical methods such as standard machining and milling, although one of skill in the art will know and appreciate that any suitable method may be used. Preferably the cylindrical bar has a round cross-section, and, following planing, the cylindrical bar in cross-section is rectangular, with the two opposite sides along long cross-sectional axis L being parallel to one another, and the two sided along short cross-sectional axis S having rounded sides. However, one of ordinary skill in the art will know and appreciate that a cylindrical bar having any suitable geometry may be used. Parallel fitting piece 5' has at least two parallel channels which extend along its length perpendicular to first end 6' and a second end 7'. The parallel channels are preferably introduced into parallel fitting piece 5' by drilling, however one of ordinary skill in the art will know and appreciate that any suitable method may be used. Preferably, the at least two parallel channels are countersunk toward both the first end 6' and a second end 7' of parallel fitting piece 5'. Countersunk channels better accommodate the fused end fitting 2', resulting in a highly stable system. Parallel fitting piece 5' may range in length from about 3mm to about 15mm, preferably about 5mm. Long cross-sectional axis L is from about 3mm to about 8mm, preferably about 4mm, and short cross-sectional axis S is from about 1mm to about 4mm, preferably about 2mm. One of ordinary skill in the art will know and appreciate that any suitable dimensions may be used for the parallel fitting piece 5'. Preferably, parallel fitting piece 5' has two adjacent parallel channels 8' and 9' having the same dimensions of aperture and cross-section. The parallel channels 8' and 9' are sized so as to be able to accommodate the flexible cable 1, and preferably each has a diameter of from about 0.7mm to about 2.5mm, and more preferably about 1mm.



In another embodiment, parallel fitting piece 5' comprises two or more cylindrical bars or tubes which are attached together along their lengths perpendicular to first ends 6' and second ends 7'. Preferably the two or more cylindrical bars or tubes are attached together by welding, although one of ordinary skill in the art will know and appreciate that any suitable method may be used. Preferably, first ends 6' of each cylindrical bar or tube are aligned so as to provide a flat first end of parallel fitting piece 5'. Similarly, preferably second ends 7' of each cylindrical bar or tube are aligned so as to provide a flat second end of parallel fitting piece 5'. A channel is introduced into each cylindrical bar. Preferably, the channels are introduced by drilling, however one of ordinary skill in the art will know and appreciate that any suitable method may be used. Preferably, the channels are countersunk toward both the first ends 6' and second ends 7' of parallel fitting piece 5'. Parallel fitting piece 5' may range in length from about 3mm to about 15mm, preferably about 5mm. Long cross-sectional axis L is from about 3mm to about 8mm, preferably about 4mm, and short cross-sectional axis S is from about 1mm to about 4mm, preferably about 2mm. One of ordinary skill in the art will know and appreciate that any suitable dimensions may be used for the parallel fitting piece 5'. Preferably, parallel fitting piece 5' has two adjacent parallel channels 8' and 9' having the same dimensions of aperture and cross-section. The parallel channels 8' and 9' are sized so as to be able to accommodate the flexible cable 1, and preferably each has a diameter of from about 0.7mm to about 2.5mm, and more preferably about 1mm.

Thermally fused end 8 may be passed through either channel 8' or 9', and after cable 1 is looped around the sternum, thermally fused end 8 is passed through the other channel 8' or 9' for attachment. After the flexible cable is drawn through the parallel fitting piece 5' to a predetermined tension, lower surface 4' of fused end fitting 2' preferably is situated flush to, or mates with an end surface of a parallel fitting piece 5', resulting in greater stability and/or a low profile. In one embodiment, fused end fitting 2' may be attached to parallel fitting piece 5' by crimping the parallel fitting piece 5' onto the fused end fitting 2'. As described below, once the flexible cable 1 is drawn through the parallel fitting piece 5' to a predetermined tension, cylindrical ferrule 9 can be crimped onto the flexible cable 1 to secure the system. Preferably cylindrical ferrule 9 is crimped onto flexible cable 1 on one end of the parallel fitting piece 5', while the fused end fitting 2' is situated at the other end of the parallel fitting piece 5'. Without being bound by theory, it is believed that the sternal reconstruction system described above, comprising a parallel fitting piece 5' and a flexible cable 1, wherein the flexible cable 1 is secured by a fused end fitting 2' situated at the one end of the parallel fitting piece 5' and a cylindrical ferrule 9 crimped



onto flexible cable 1 on the other end of the parallel fitting piece 5' after the flexible cable 1 is drawn to a predetermined tension, provides the benefits of an advantageous low profile, the system sitting flush to the sternum and improved tissue coverage.

Another illustrative embodiment of a sternal reconstruction system is shown in FIG. 4. In this embodiment, the second or thermally fused end 8 of the flexible cable 1 may be attached to a suture or needle 11. The suture 11 may typically be removed following its use, and is designed to be removed while preserving the fused end of the cable 1. The suture 11 may be constructed from any suitable bio-compatible material, including, but not limited to, titanium, alloys of titanium and stainless steel, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used.

The flexible cable 1 and crimp fitting 2 may be used to reapproximate, or secure together, two or more parts of a sternum by placing the crimp fitting 2 against a sternum to be mended and the flexible cable 1 wound around the separate portions of the sternum. The second or thermally fused end 8 of the flexible cable 1 to be attached to the crimp fitting 2 is pulled to bring the flexible cable 1 taut around the sternum, thus reapproximating the separated parts of the sternum. The second or thermally fused end 8 of the flexible cable 1 is passed through the diametrical hole 6, and the flexible cable 1 is pulled taut. The tensioning of the flexible cable 1 may be carried out, for example, by use of a safety cable tool. When the desired tension is achieved, the flexible cable 1 is secured in place by the ferrule 9. Attachment of the ferrule 9 to the flexible cable 1 may be carried out, for example, by crushing with pliers or any suitable crimping instrument. In an illustrative embodiment, a cylindrical ferrule 9 (FIG. 3) can be crimped onto the flexible cable 1 after the cable 1 is drawn through the hole 6 in crimp head 3 to a predetermined tension.

The flexible cable 1 has a diameter of from about 0.7mm to about 2.5mm. Typically, if the flexible cable 1 is constructed of non-resorbable materials, it has a diameter of from about 0.7mm to about 1.5mm. Preferably flexible cable 1 has a diameter of about 1mm. In one embodiment of the invention the flexible cable is Cerclage wire. The flexible cable 1 may be of any suitable length, and is preferably from about 10cm to about 1.5m in length. Flexible cable 1 may be constructed from any suitable bio-compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel and resorbable materials, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used.



FIGS. 5 and 6 show a safety cable tool. The safety cable tool can be used for tensioning the flexible cable or wire 1 used with the sternal reconstruction system. The tool can be used to grasp and pull a flexible cable 1 to a predetermined tension limit. At the predetermined tension, the tool can be used to crimp a ferrule 9 to secure the flexible cable

5 1. The tool may also be used to sever the unused portion of flexible cable 1. The crimping and severing processes may be carried out independently or simultaneously, and manually or automatically. FIG. 5 shows a ferrule 20 seated in aperture 21 of the safety cable tool. A cable 12 with free end 24 is passed through the ferrule and through a clamping assembly 26 connected to a reciprocal arm 34. The cable 12 is also connected to a second clamping

10 assembly 38. The clamping assemblies include pawls 28 and 40, which allow movement of the cable only in the direction of the cable's free end 24.

FIG. 6 shows an exploded perspective of the safety cable tool. Upon depression of handle 36 toward housing 54, handle 36 pivots about pin 80 and forces pin 70 to move upwards. As pin 70 goes up, arm 68 rotates clockwise about pin 110 and arm 72

15 rotates counterclockwise about pin 88, forcing pins 88 and 110 apart. Pin 110 is linked to reciprocal arm 34. As pin 110 moves away from pin 88, pressure is applied to move reciprocal arm 34 against the bias of spring 58, putting tension on cable 12. When the tension on cable 12 equals the bias of spring 58, pin 110 will move no farther and depressing handle 36 forces pin 88 to move toward the aperture 21. Pin 110 is also linked

20 to a plunger 94 such that when pin 88 is forced in the direction of the aperture 21, plunger end 94A is pushed into aperture 21, thereby crimping the ferrule 20 about the cable 12 and simultaneously cutting cable 12 on the free end side of the ferrule. Suitable safety cable tools are commercially available from Daniels Manufacturing Corporation and are described in United States Patents Nos. 5,320,663; 5,345,663; and 5,361,475, and United

25 States Patent Application Publication No. U.S. 2004/0199169.

In one embodiment of the sternal reconstruction system, one end of the cable 1 comprises a preinstalled flattened round crimp fitting 2 with a diametrical hole 6 through which the second or thermally fused end 8 of the flexible cable 1 may pass after the cable 1

30 is looped around the sternum or passes through the cannulated screw 13. In this embodiment, the separated parts of the sternum may be reapproximated by tensioning the flexible cable 1 to a desired tension, and securing the cable 1 by crimping. In one embodiment, a cylindrical ferrule 9 may be crimped onto flexible cable 1 after the cable 1 is drawn through a cannulated screw and the diametric hole 6 in crimp fitting 2 to the

preselected desired tension. The safety cable tool described above may be used to achieve such tensioning and crimping.

In another embodiment, the sternal reconstruction system comprises flexible cable 1 with fused end piece 2' and parallel fitting piece 5'. In this embodiment, the separated parts of the sternum may be reapproximated by passing the flexible cable through one channel of parallel fitting piece 5', looping flexible cable 1 around the sternum, passing it through the second channel of parallel fitting piece 5', tensioning the flexible cable 1 to a desired tension, and securing the cable 1 by crimping a cylindrical ferrule 9 onto the flexible cable 1. In another embodiment, the sternal reconstruction system comprises flexible cable 1 with fused end piece 2', parallel fitting piece 5' and one or more cannulated screws 13. A cylindrical ferrule 9 may be crimped onto flexible cable 1 after the cable 1 is drawn through one channel of parallel fitting piece 5', one or more cannulated screws and the second channel of parallel fitting piece 5' to the preselected desired tension. The safety cable tool described above may be used to achieve such tensioning and crimping.

In another illustrative embodiment, the sternal reconstruction system comprises flexible cable 1, crimp fitting 2 and at least one cannulated screw 13. FIG. 7 shows cannulated screw 13, having a shaft 14 that is at least partially threaded for attachment to bone. The length of shaft 14 and the shaft thread configuration is selected to be suitable for use in the sterna. As is well known in the art, the threads and a tip 15 can be made to be self-tapping and/or self-drilling to facilitate implantation. Shaft 14 has a diameter of from about 1mm to about 5mm, and is cannulated with a channel or throughbore 16 for receiving the flexible cable 1 to aid in fixation of the sternum. The diameter of throughbore 16 is preferably from about 0.7mm to about 2.5mm, and more preferably about 1mm. The head 29 of the cannulated screw 13 preferably has a flat or curved under surface 31 which will bear against a reconstruction plate (if used) or the anterior side of the sternum.

Further illustrative embodiment of a cannulated screw 13 are shown in FIGS. 8 and 9. As shown in FIG. 8, which shows an end view of cannulated screw 13, the head 29 of the cannulated screw 13 may comprise an internal hex 30 for receiving an installation tool. An installation tool for use in drilling a hole in bone and for driving any of a variety of cannulated fasteners into the drilled hole is further described in U.S. patent application Publication No. 2005/0222575 entitled "Adjustable Tool for Cannulated Fasteners," by Ciccone et al. The diameter of internal hex 30,



measured as the distance between opposite faces, is from about 1.5mm to about 4mm, and more preferably about 2.5mm. FIG. 9 shows a cross-sectional view of cannulated screw 13, and shows that the head 29 of the cannulated screw 13 comprises a hollow aperture 15, while the shaft of the cannulated screw 13 is cannulated with a throughbore 16 which may receive the flexible cable 1. The head 29 of the cannulated screw 13 has a top surface that may be curved, substantially flat or other complex geometry. In one embodiment, the lower surface 4 of the crimp fitting 2 has a geometry that compliments the top surface of the screw 13 or reconstruction plate 18 to assist in stabilizing the crimp fitting 2 in location on the screw 13 or reconstruction plate 18. The hollow aperture 15 is preferably sized and shaped so as to accommodate crimp shaft 7. The matching of the size and shape of crimp shaft 7 to the hollow aperture 15 may result in greater stability of the crimp fitting 2 in the screw 13, particularly if there is a close fit between the shaft 7 and aperture 15. In this manner the crimp shaft 7 may act as a journal inside the screw aperture 15. The flat lower surface 5 of the crimp fitting 2 preferably sits flush to the head of the cannulated screw 13, and also provides stability to the system. In another embodiment, fused end fitting 2' has a geometry that compliments the top surface of the screw 13 or reconstruction plate 18 to assist in stabilizing the fused end fitting 2' in location on the screw 13 or reconstruction plate 18. The hollow aperture 15 is preferably sized and shaped so as to accommodate fused end fitting 2'. The matching of the size and shape of fused end fitting 2' to the hollow aperture 15 may result in greater stability of the fused end fitting 2' in the screw 13. Fused end fitting 2' preferably sits flush below the head of the cannulated screw 13, and also provides stability to the system. In general, any surgical screw as described above, having a threaded or a non-threaded head 17 of an appropriate size and geometry for select plate holes of the bone plate can be used. The head 29 of cannulated screw 13 may be configured to lock with an optimally supplied bone plate or to be a non-locking screw. The head 29 of cannulated screw 13 has a diameter of from about 2mm to about 10mm, and preferably about 6mm.

The cannulated screws 13 may be constructed from any suitable bio-compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel and resorbable materials, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used. The cannulated screws 13 may be of any suitable length, and are typically from about 5mm to about 24mm in length. The skilled artisan will know that a screw 13 should be selected preferably so as to have a length such that, on use in sternal reconstruction, the tip of screw 13 will extend up to the posterior



surface of the sternum, but preferably will not protrude to an undesirable distance from the posterior of the sternum.

In one embodiment of the invention, the cannulated screws 13 are inserted into the sternum on opposite sides of the sternal fragments. Flexible cable or wire 1 is fed through the lumen 16 of the cannulated screws 13, and is tensioned to a desired tension, causing the portions of the sternum to be brought together. The tensioned flexible cable 1 is secured to secure the aligned sternum. The cannulated screws 13 prevent the flexible cable or wire 1 from bearing directly on the soft bone of the sternum, thus alleviating the clinical problems of "cut through" and sternal dehiscence, or separation of the bony sternum and manubrium following median sternotomy.

In another illustrative embodiment, the sternal reconstruction system comprises flexible cable 1, crimp fitting 2, cannulated screws 13 and at least one bone reconstruction plate 18. FIGS. 10 to 13 show illustrative embodiments of the reconstruction plate 12. FIG. 10 shows a top view of reconstruction plate 18, having a generally rectangular cross section. However, any suitable configuration for the reconstruction plate 18 could be used. The reconstruction plate 18 has a longitudinal axis 19, upper and lower surfaces 22, 23, at least one plate hole 25 disposed generally perpendicularly to the longitudinal axis 19 of the reconstruction plate 18, and at least one plate hole or bore 26 disposed transverse to the generally perpendicularly disposed plate hole 25. Generally perpendicular plate holes 25 are each independently angled at a solid angle of from 0° to about 30° from normal to the upper and lower surfaces of the plate 18. Preferably, perpendicular plate holes 25 are each independently angled at an angle of from 0° to about 30° from normal to the upper and lower surfaces of the plate 18 and along longitudinal axis 19. Most preferably, generally perpendicular holes 25 are normal to the upper and lower surfaces of the plate 18, *i.e.*, at 0°. Transverse plate holes or bores 26 are each independently angled at a solid angle of from 0° to about 30° from normal to the side surfaces of the plate 18. Preferably, transverse plate holes or bores 26 are each independently angled at an angle of from 0° to about 30° from normal to the side surfaces of the plate 18 and transverse to longitudinal axis 19. Most preferably, transverse holes or bores 26 are normal to the side surfaces of the plate 18, *i.e.*, at 0°. Reconstruction plate 18 has a length of from about 30mm to about 250mm, more preferably from about 80mm to about 200mm; a width of from about 5mm to about 20mm, more preferably from about 6mm to about 10mm; and a thickness of from about 0.5mm to about 10mm, more preferably from about 2mm to about 4mm. Plate holes 25 extend from the upper surface 22



through the lower surface 23 of the reconstruction plate, and can be optionally used for accommodating fasteners, e.g. cannulated screws 13, pins, and/or flexible cable 1, to secure the reconstruction plate 18 to the sternum.

5 Plate holes 26 extend transversely through the longitudinal axis 19 of the reconstruction plate 18, and can optionally also be used for accommodating fasteners, e.g. cannulated screws and/or flexible cable, to secure the reconstruction plate to the sternum. The transverse holes 26 are preferably located between generally perpendicular holes 25. Any suitable combination of fasteners, such as, for example, cannulated screws 13 or other screws, blades, nails, pins, etc. may be used to secure the reconstruction plate 18 to the  
10 sternum; for example, in one embodiment, bone anchors may be used solely with the generally perpendicular plate holes 25, while in another embodiment flexible cable such as cable 1 and crimp fitting 2 solely may be used with the transverse plate holes 25. In a preferred embodiment, a combination of generally perpendicular and transverse plate holes 25, 26 is selected so as to give optimum local securing of the reconstruction plates 18. In a  
15 preferred embodiment, the reconstruction plate 18 comprises a plurality of plate holes 25 disposed generally perpendicularly to the longitudinal axis 19 of the reconstruction plate 18, and a plurality of plate holes 26 disposed transverse to the generally perpendicularly disposed plate holes 25.

The reconstruction plates 18 may be constructed from any suitable bio-  
20 compatible material, including, but not limited to, titanium, alloys of titanium, stainless steel, resorbable materials, radio-translucent materials, allograft materials and resorbable materials, although one of ordinary skill in the art will know and appreciate that any biocompatible material may be used. The reconstruction plates 18 may comprise a plurality of generally perpendicular plate holes 25 which pass through the upper and lower surfaces  
25 of plate 18 and are generally perpendicular to the longitudinal axis for receiving bone anchors. The reconstruction plates 18 may further comprise a plurality of holes or bores 26 disposed generally transversely to the generally perpendicularly disposed plate holes 25. Typically, the reconstruction plates 18 comprise from about 2 to about 26 generally perpendicular plate holes 25 and from about 1 to about 25 transverse holes or bores 26. As  
30 shown in FIG. 10, an overhead view of the reconstruction plate 18, the generally perpendicular plate holes 25 are generally uniform in shape and size, and preferably are circular holes with a diameter of from about 2mm to about 9mm, more preferably from about 4mm to about 6mm. In another embodiment the holes may be oblong and may be ramped to provide compression. The generally perpendicular plate holes may be configured



to lock with an optionally supplied bone fastener. In FIG. 11, which shows a side view of reconstruction plate 18, the transverse plate holes 26 are disposed between adjacent generally perpendicular plate holes 25. FIG. 12 shows a cross-sectional view of reconstruction plate 18, wherein the location of the transverse plate holes 26 between adjacent generally perpendicular holes 25 can be seen. Transverse plate holes 26 typically have a diameter smaller than that of the generally perpendicular holes 25. Preferably, the transverse plate holes 26 have a diameter of from about 0.7mm to about 2.5mm, and more preferably about 1mm. The diameter of the transverse plate holes 26 preferably is selected so as to accommodate the flexible cable 1. Typically, the reconstruction plate 18 is counter-bored at the location of each transverse hole 26. FIG. 13 shows a side view of a reconstruction plate 18, with transverse hole 26 and counter-bore 27.

As shown in FIGS. 10 to 13, both the generally perpendicular plate holes 25 and transverse plate holes 26 may be round and cylindrical. This preferred geometry minimizes the change in material properties in the areas near the plate holes. In one embodiment, generally perpendicular plate holes 25 are countersunk toward either the upper or the lower surface 22, 23 of the reconstruction plate 18. In a preferred embodiment, the generally perpendicular plate holes 25 are countersunk toward both the upper and the lower surface 22, 23 of the reconstruction plate 18. Countersunk generally perpendicular plate holes 25 better accommodate the heads of the cannulated bone screws 13, resulting in a highly stable system. In a preferred embodiment, the countersinks are in the shape of a cone.

In one embodiment the upper and lower surfaces 22, 23 of the reconstruction plate 18 are planar. Because of the symmetry of the bone plate 18, the bone plate 18 can be attached with either upper or lower surface 22, 23 facing the bone with identical clinical results. In a preferred embodiment, at least one reconstruction plate 18 is attached to the sternum on opposite sides of the sternal fragments.

The use of flexible cable 1, reconstruction plates 18 and cannulated screws 13 may be necessary in more complicated sternal reconstruction procedures, such as procedures wherein both midline and transverse fractures must be addressed. The reconstruction plates 18 can be attached to each side of the split sternum by cannulated screws 13. Flexible cable or wire 1 may then be used to align and reduce the sternum. If transverse fractures are present, the reconstruction plates 18 function to reduce such fractures. Without being bound by theory, it is believed that the cannulations 16 in the



screw 13 and the transverse holes 26 in the reconstruction plates 18 provide improvements to the Chase technique, which is described in "Internal Fixation of the Sternum in Median Sternotomy Dehiscence," Chase et al., Plastic and Reconstructive Surgery, May 1999.

5                   In one embodiment, one end of the flexible cable 1 comprises a preinstalled flattened round crimp fitting 2 with a diametrical hole or bore 6 through which the second or thermally fused end 8 of the flexible cable 1 may pass after the flexible cable 1 is looped around the sternum or passes through the cannulated screws 13 and/or through the reconstruction plates 18 and throughbores 16 of the cannulated screws 13. In this  
10                   embodiment, the separated parts of the sternum may be reapproximated by tensioning the flexible cable 1 to a desired tension, and securing the flexible cable 1 by crimping. In one embodiment, a cylindrical ferrule 9 may be crimped onto flexible cable 1 after the cable 1 is drawn through the hole 6 in crimp fitting 2 to the preselected desired tension. The safety cable tool described above may be used to achieve such tensioning and crimping.

15                   The present invention also relates to a sternal reconstruction kit which comprises at least one flexible cable 1; at least one parallel fitting piece 5'; and at least one ferrule 9, wherein the first end of the flexible cable comprises a fused end fitting member, and is designed to mate with an end surface of the parallel fitting piece. Optionally the kit may contain at least one flexible cable 1, wherein the second or thermally fused end 8 of the  
20                   flexible cable 1 may be attached to a suture 11. Further, the kit may optionally comprise a plurality of sizes of cannulated screws 13 and/or a plurality of sizes of reconstruction plates 18. The inner diameter of the ferrule 9 may have a sharp edge in order to facilitate the cutting of the flexible cable 1 during crimping of the ferrule 9 onto the flexible cable 1.

25                   While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein. Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. For example, fixation of a sternum may be effected by  
30                   use of a flexible cable 1 with fused end piece 2' and parallel fitting piece 5', and/or in combination with cannulated screws 13 and/or further in combination with sternal reconstruction plates 18. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of

**WO 2006/135935**

**PCT/US2006/023229**

the present invention are to be included as further embodiments of the present invention.

The scope of the present invention is accordingly defined as set forth in the appended claims.



## CLAIMS

What is claimed is:

1. A sternal reconstruction system for securing parts of a sternum comprising:
  - a flexible cable having first and second ends, the first end comprising an end fitting member;
  - the end fitting member having an upper surface and an opposing lower surface;
  - and
  - a fitting piece having a first end, a second end, a length measured from the first end to the second end, and at least two channels each extending through the fitting piece along the length from the first end to the second end; and
  - a ferrule defining a hole that is sized to receive the flexible cable;
  - wherein the sternal reconstruction system defines an assembled configuration in which: 1) the end fitting member abuts the first end of the fitting piece, and 2) the ferrule is crimped to the flexible cable to and abuts the second end of the fitting piece.
2. The sternal reconstruction system of claim 1, wherein the end fitting member is fused and attached to the first end of the cable by crimping.
3. The sternal reconstruction system of claim 2, wherein the fused end fitting member comprises a preinstalled cylindrical end fitting having an upper surface and a lower surface, and having a diameter of from about 1mm to about 5mm and a length of from about 5mm to about 20mm.
4. The sternal reconstruction system of claim 3, wherein the fused end fitting member is constructed from a material comprising at least one of titanium, alloys of titanium, stainless steel and resorbable materials.
5. The sternal reconstruction system of claim 3, wherein the upper surface of the fused end fitting member has rounded edges.

6. The sternal reconstruction system of claim 3, wherein the lower surface of the fused end fitting member is flat.
7. The sternal reconstruction system of claim 1, wherein the fitting piece is a flattened cylindrical tube having a long cross-sectional axis and a short cross-sectional axis.
8. The sternal reconstruction system of claim 7, wherein the first and second ends of the fitting piece are parallel to each other.
9. The sternal reconstruction system of claim 7, wherein at least one side of the fitting piece has a long cross-sectional axis is crimped along the length so as to provide a necked region that partially defines the at least two channels.
10. The sternal reconstruction system of claim 7, wherein the fitting piece is from about 3mm to about 15mm in length, the long cross-sectional axis is from about 3mm to about 8mm, and the short cross-sectional axis is from about 1mm to about 5mm.
11. The sternal reconstruction system of claim 9, wherein both sides of the fitting piece having a long cross-sectional axis are crimped along their lengths so as to provide a necked region that partially defines the at least two channels, the channels having the same size aperture and cross-section.
12. The sternal reconstruction system of claim 9, wherein each channel has a diameter of from about 0.7mm to about 2.5mm.
13. The sternal reconstruction system of claim 7, wherein the fitting piece is constructed from a material comprising at least one of, titanium, alloys of titanium, stainless steel and resorbable materials.
14. The sternal reconstruction system of claim 1, further comprising at least one cannulated screw, the cannulated screw defining a cannulation configured to receive the flexible cable.



15. The sternal reconstruction system of claim 14, wherein the at least one cannulated screw comprises at least one of a locking and a non-locking screw.
16. The sternal reconstruction system of claim 14, wherein the at least one cannulated screw is at least partially threaded for attachment to bone.
17. The sternal reconstruction system of claim 14, wherein the at least one cannulated screw is constructed from a material comprising at least one of titanium, alloys of titanium, stainless steel and resorbable materials.
18. The sternal reconstruction system of claim 14, wherein the at least one cannulated screw comprises a head which comprises a hollow aperture, wherein the hollow aperture is sized and shaped so as to accommodate the end fitting member.
19. Use of a sternal reconstruction system comprising:
  - a flexible cable having a first and a second end, for passing through one channel of a parallel fitting piece having first and second channels;
  - the flexible cable also being for passing through the second channel of the parallel fitting piece;
  - the flexible cable having being tensionable to a desired tension; and
  - the tensioned cable being securable;
  - wherein the first end of the flexible cable comprises a fused end fitting member, designed to mate with an end surface of the parallel fitting piece.
20. The use of claim 19, wherein the tensioned cable is secured by a ferrule crimped onto the flexible cable.
21. The use of claim 20, wherein the ferrule inner diameter comprises a sharp for cutting the flexible cable when the ferrule is crimped onto the flexible cable.
22. The use of claim 19, wherein a ferrule crimped onto the tensioned flexible cable secures the flexible cable, and the ferrule is at one end of the parallel fitting piece and the fused end fitting member is at the other end of the parallel fitting piece.

23. Use of a sternal reconstruction system comprising:  
 at least one cannulated screw;  
 a flexible cable having first and second ends, at least a portion of the flexible cable for feeding through a lumen of the at least one cannulated screw;  
 the flexible cable for passing through one channel of a parallel fitting piece having two channels;  
 the flexible cable for passing through the second channel of the parallel fitting piece;  
 the flexible cable for tensioning and securing to a desired tension;  
 wherein the first end of the flexible cable comprises a fused end fitting member, which mates with an end surface of the parallel fitting piece.
24. The use of claim 23, wherein the flexible cable is secured by a ferrule crimped onto the flexible cable.
25. The use of claim 24, wherein the inner diameter of the ferrule comprises a sharp edge to cut the flexible cable when the ferrule is crimped onto the flexible cable.
26. The use of claim 23, wherein the tensioned cable is securable by a ferrule crimped onto the flexible cable, the ferrule being at one end of the parallel fitting piece and the fused end fitting member being at the other end of the parallel fitting piece.
27. A sternal reconstruction kit comprising:  
 at least one flexible cable; and  
 an end fitting member attached to the at least one flexible cable;  
 at least one fitting piece having a first end, a second end, a length extending between the first end and the second end along a select direction, and at least two channels extending through the fitting piece along the length, such that each of the at least two channels are open to both the first end and the second end, and the at least two channels are open to each other along a direction perpendicular to the select direction;  
 wherein the fitting piece is configured to abut the end fitting member, and the fitting piece is directly securable to the flexible cable when the second end of the flexible cable has been passed through the one of the at least two channels, looped around a



sternum, and passed at least partially through another of the at least two channels of the fitting piece.

28. The sternal reconstruction kit of claim 27, wherein at least one of the at least one flexible cable is attached to a suture.

29. The sternal reconstruction kit of claim 27, further comprising a ferrule wherein an inner diameter of the ferrule comprises a sharp edge in order to facilitate the cutting of the flexible cable during crimping of the ferrule onto the flexible cable.

30. The sternal reconstruction kit of claim 27, further comprising at least one cannulated screw, the cannulated screw defining a cannulation configured to receive the flexible cable.

31. The sternal reconstruction kit of claim 30, wherein at least one flexible cable is attached to a suture.

32. The sternal reconstruction system of claim 9, wherein the fitting piece is crimped at a midpoint of the long cross-sectional axis along its length to form the at least two channels.

33. The sternal reconstruction system of claim 1, wherein the fitting piece has a beveled portion at the first end or the second end, the lower surface being configured to abut the beveled portion of the fitting piece such that the end fitting member sits at least partially within one of the at least two channels.

34. The sternal reconstruction system of claim 1, wherein the fitting piece has a countersunk portion at the first end or the second end, the lower surface being configured to abut the countersunk portion of the fitting piece such that the end fitting member sits at least partially within one of the two channels.

35. The sternal reconstruction kit of claim 27, wherein the fitting piece has a beveled portion at the first end or the second end, the lower surface being configured to abut the beveled portion of the fitting piece such that the end fitting member sits at least partially within one of the at least two channels.

36. The sternal reconstruction kit of claim 27, wherein the fitting piece has countersunk portion at the first end or the second end, the lower surface being configured to abut the countersunk portion of the fitting piece such that the end fitting member sits at least partially within one of the at least two channels.

37. The sternal reconstruction kit of claim 1, wherein the at least two channels extend through the fitting piece parallel to each other.

38. The sternal reconstruction kit of claim 27, wherein the at least two channels of the at least one fitting piece each extend through the fitting piece parallel to each other.

39. A sternal reconstruction system configured to secure parts of a sternum, the system comprising:

- a flexible cable having first and second ends, the first end comprising an end fitting member, the end fitting member having an upper surface and an opposing lower surface;

- a fitting piece having a first end, a second end, a length extending between the first end and the second end, and at least two channels extending through the fitting piece along the length from the first end to the second end; and

- a ferrule that is elongate along a longitudinal axis, the ferrule defining a hole extending along the longitudinal axis, such that the hole is configured to receive the flexible cable, the ferrule including a sharp edge extending into the hole to facilitate cutting of the flexible cable during crimping of the ferrule onto the flexible cable;

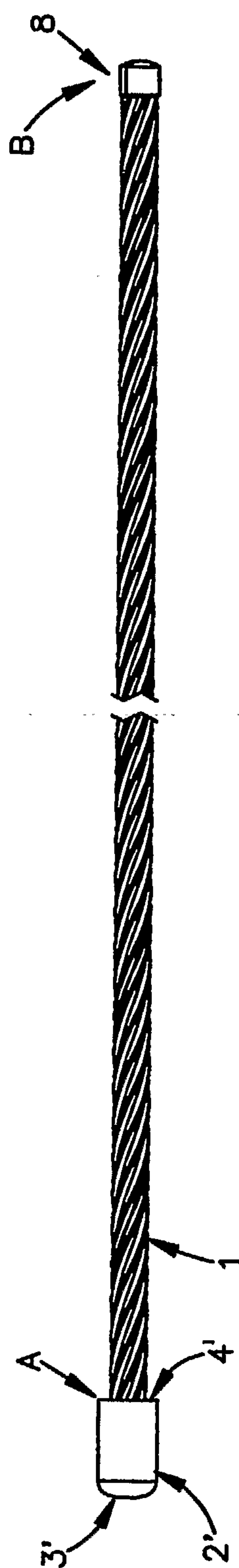
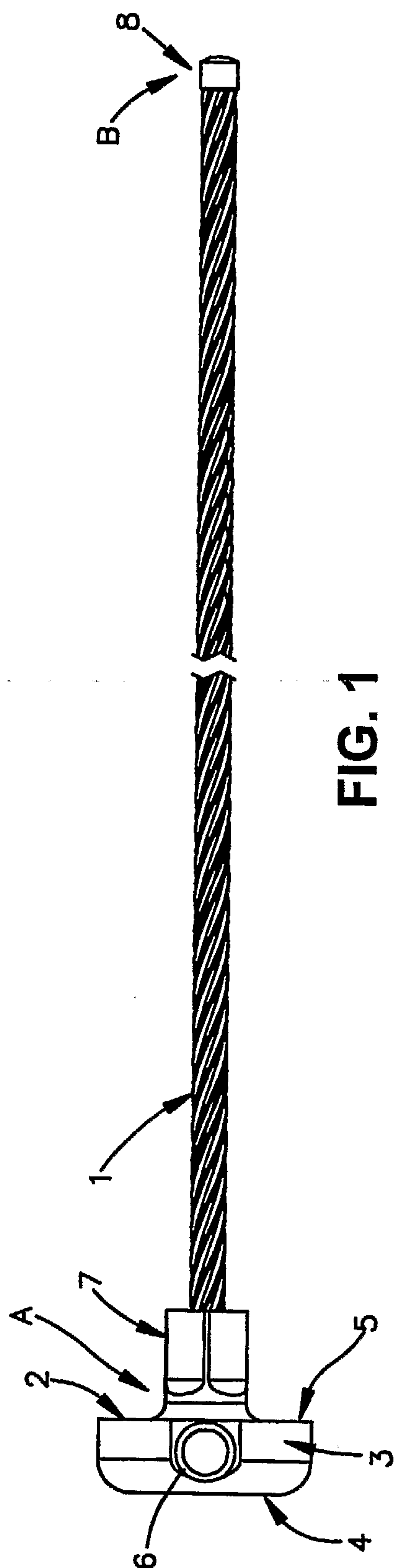
- wherein the fitting piece is configured to abut the end fitting member when the fitting piece is positioned adjacent the sternum and the second end of the flexible cable is passed at least partially through the channels of the fitting piece.

40. The sternal reconstruction system of claim 39, wherein the fitting piece is a flattened cylindrical tube having a long cross-sectional axis and a short cross-sectional axis.

41. The sternal reconstruction system of claim 40, wherein the first and second ends of the fitting piece are parallel to each other.

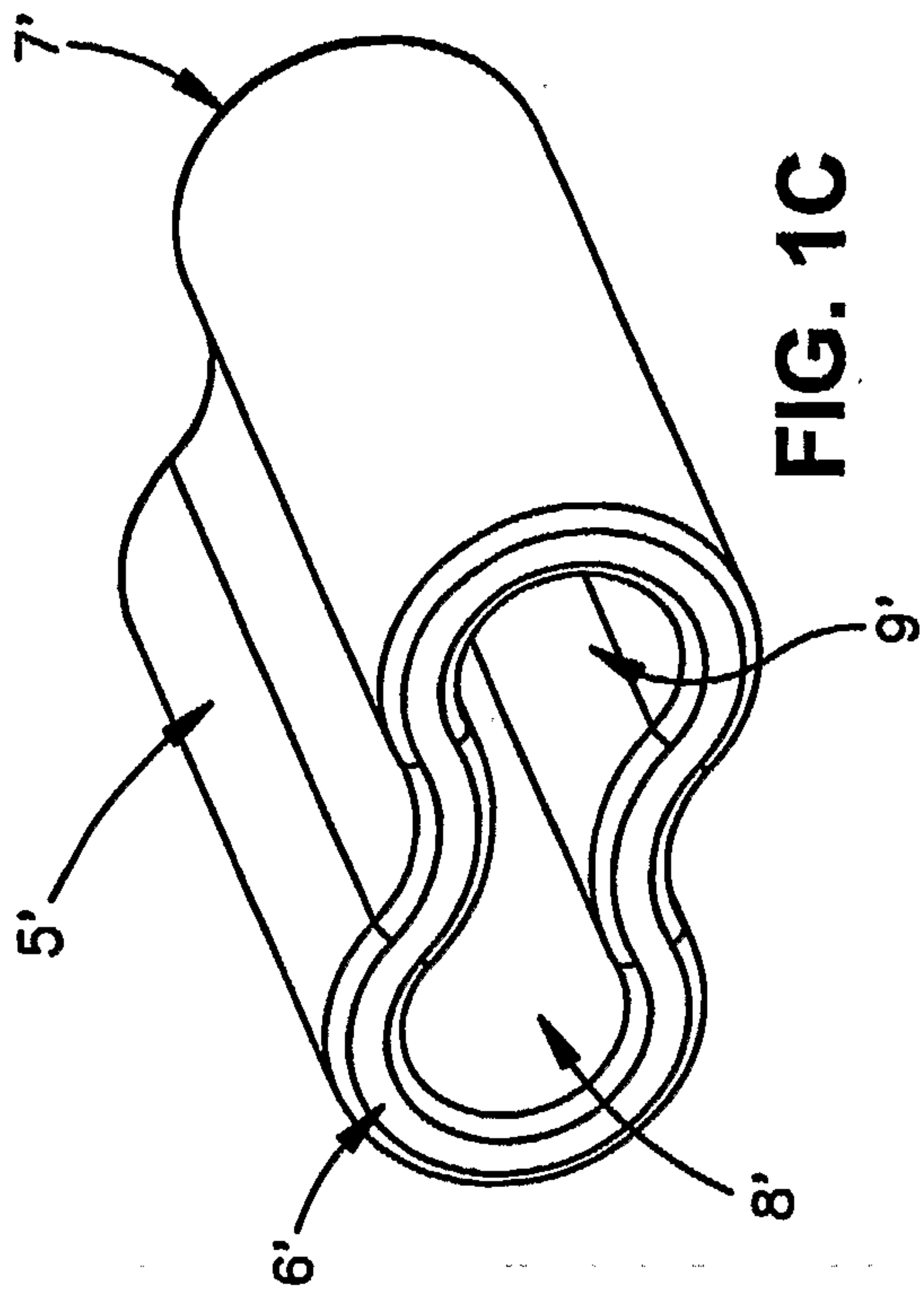
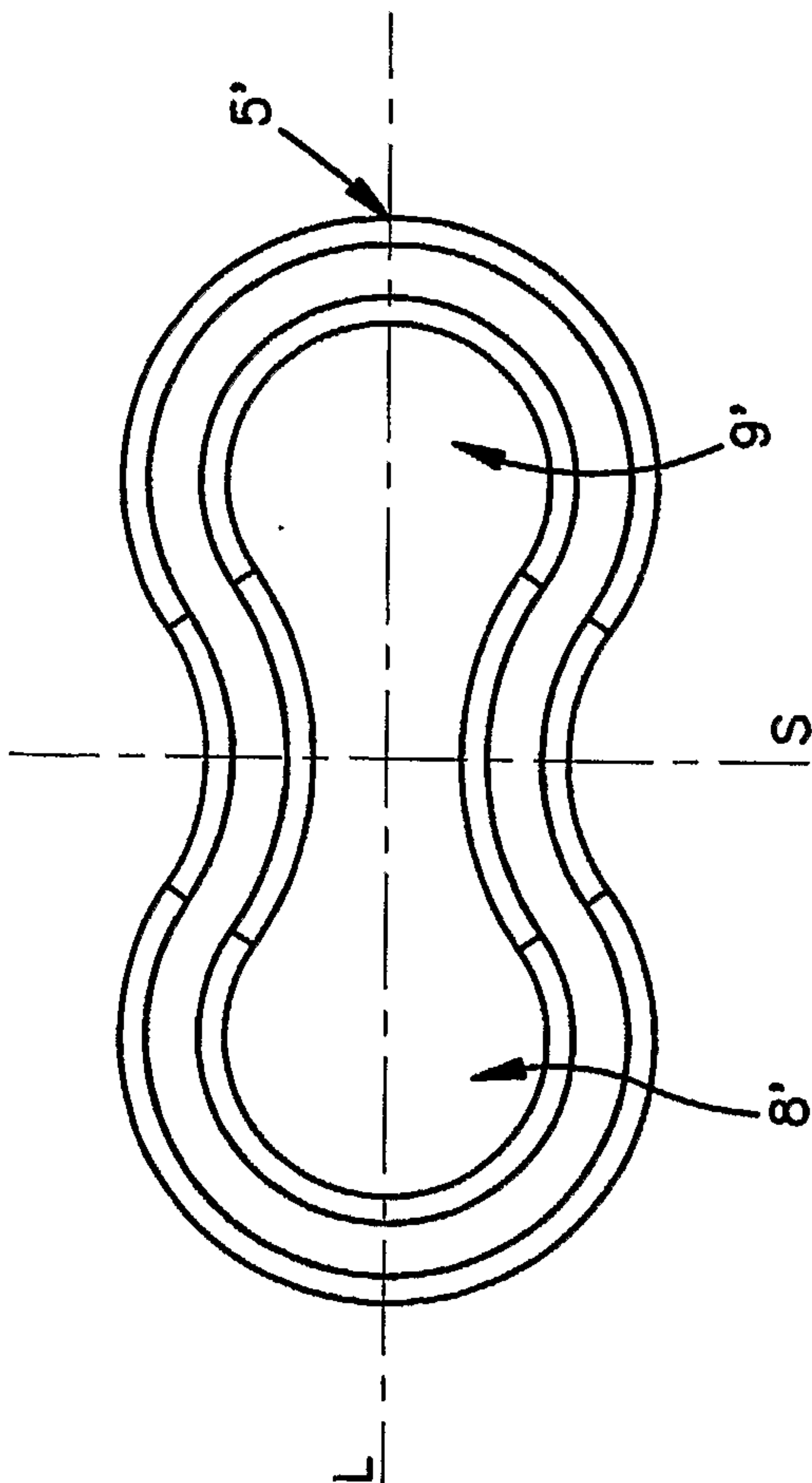
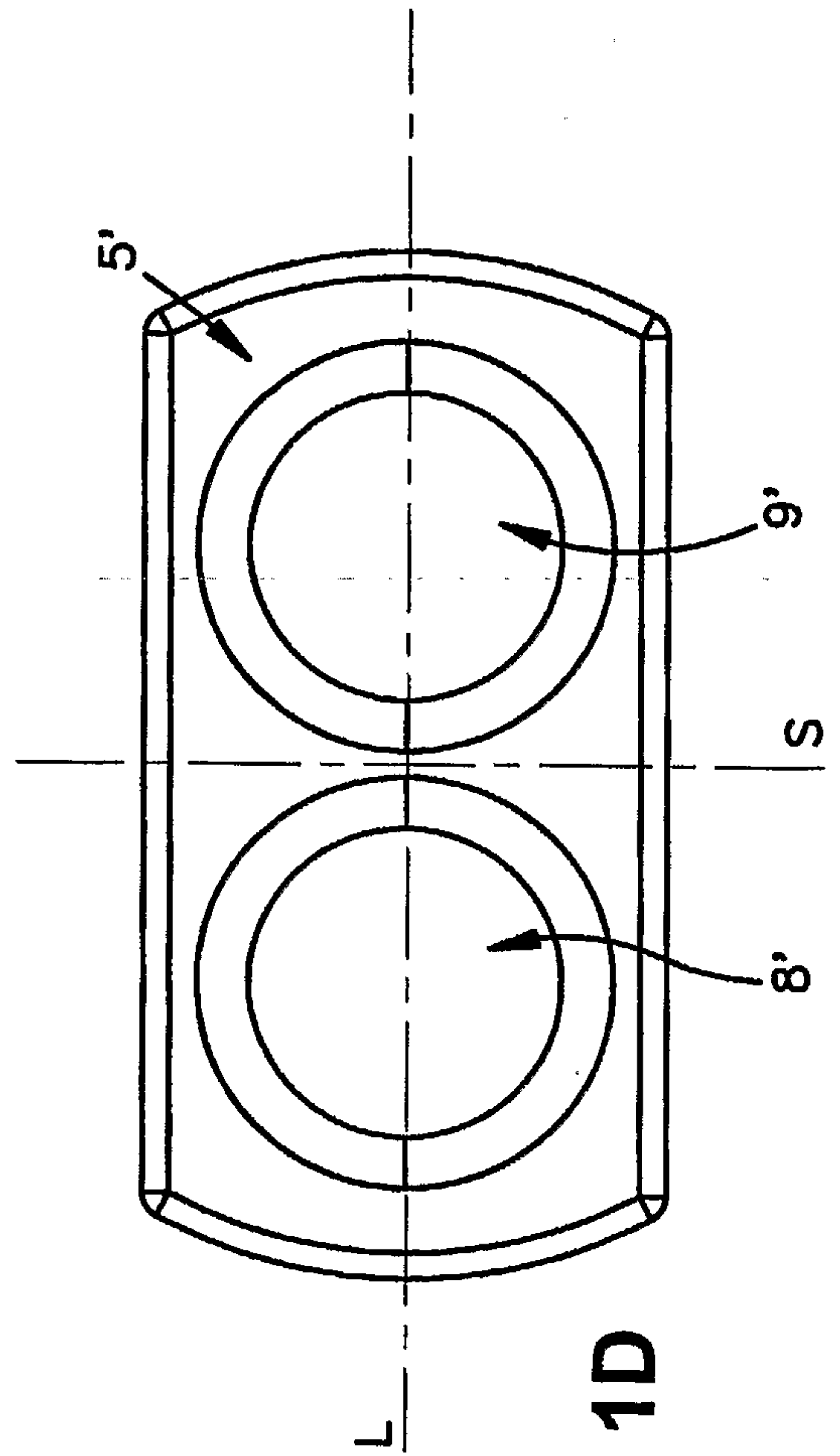


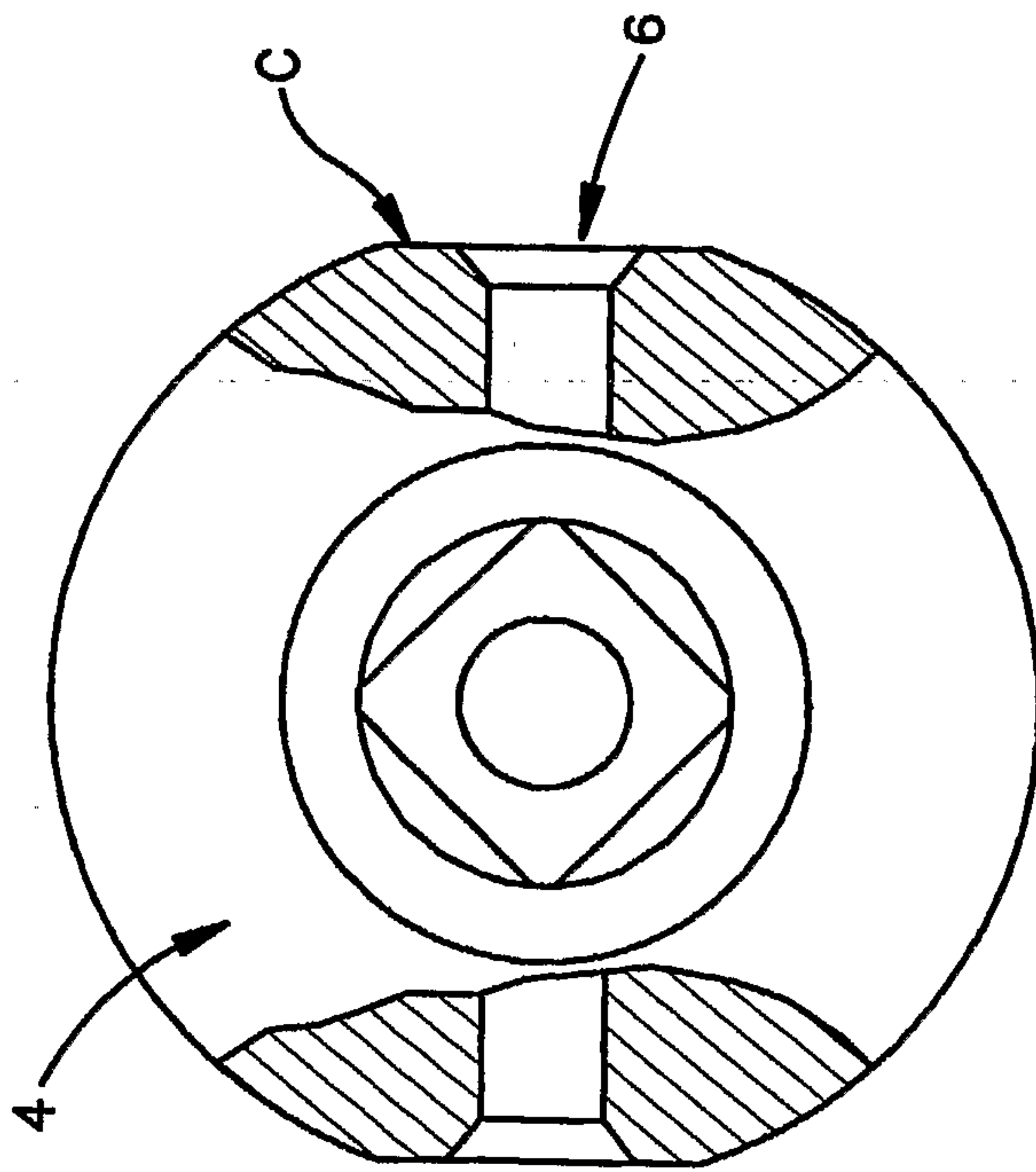
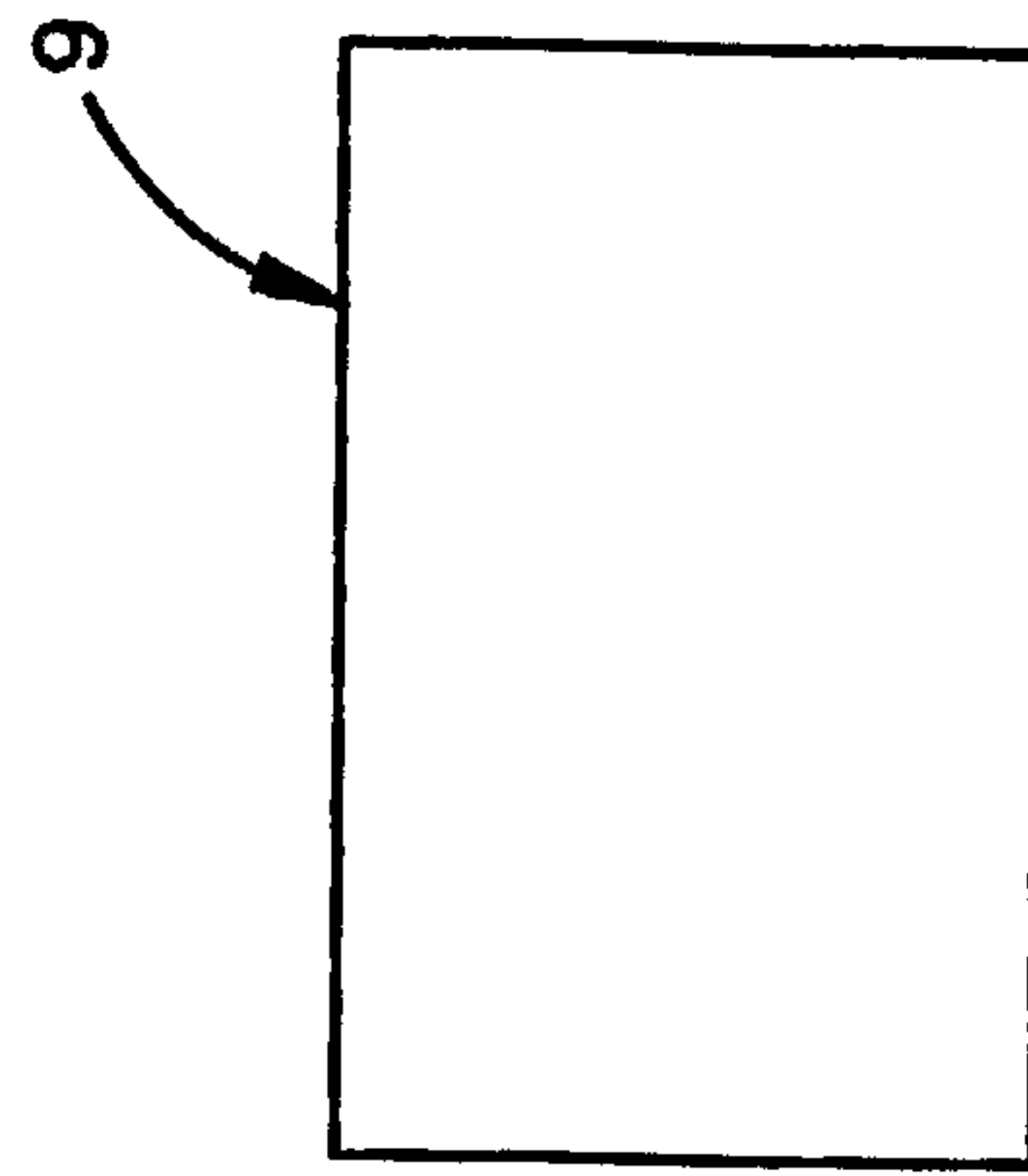
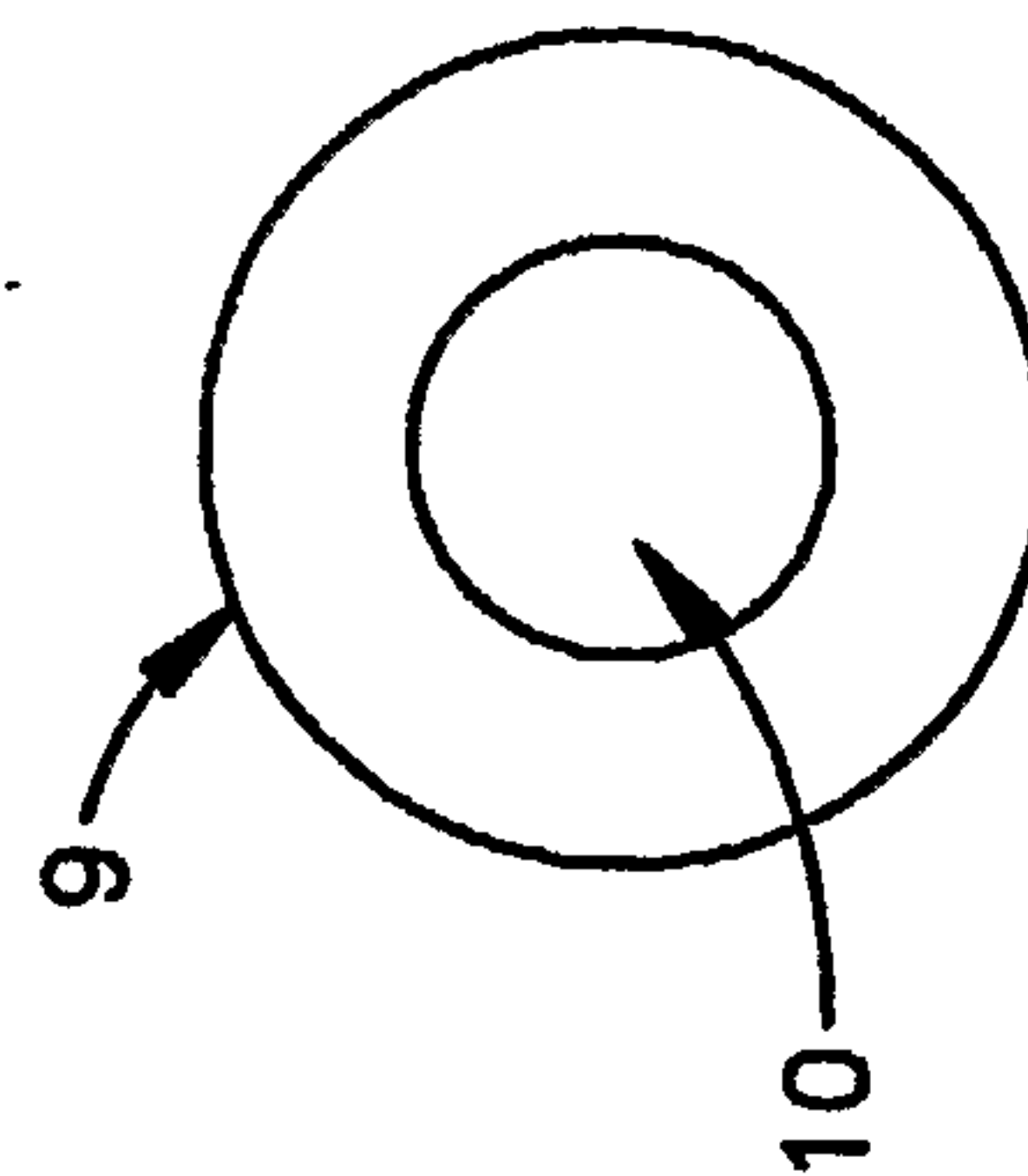
42. The sternal reconstruction system of claim 39, wherein the fitting piece is crimped along the length so as to provide the at least two channels.
43. The sternal reconstruction system of claim 39, wherein the at least two channels have the same aperture and cross-section.
44. The sternal reconstruction system of claim 39, wherein the at least two channels each extend through the fitting piece parallel to each other.
45. The sternal reconstruction system of claim 39, further comprising at least one cannulated screw.
46. The sternal reconstruction system of claim 45, wherein the at least one cannulated screw comprises at least one of a locking and a non-locking screw.
47. The sternal reconstruction system of claim 1, wherein the ferrule includes a sharp edge extending into the hole to facilitate cutting of the flexible cable during crimping of the ferrule onto the flexible cable.





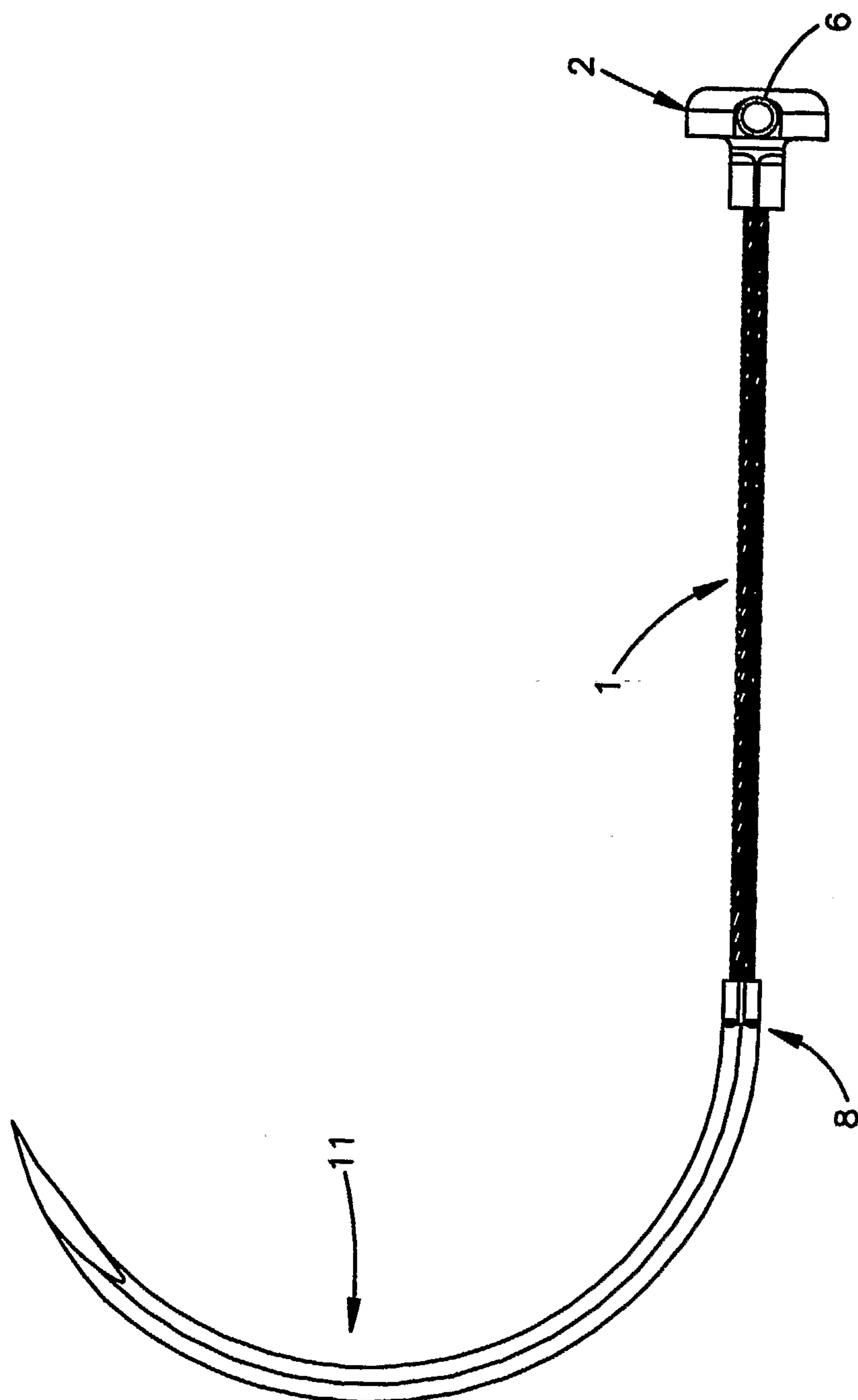
2/9

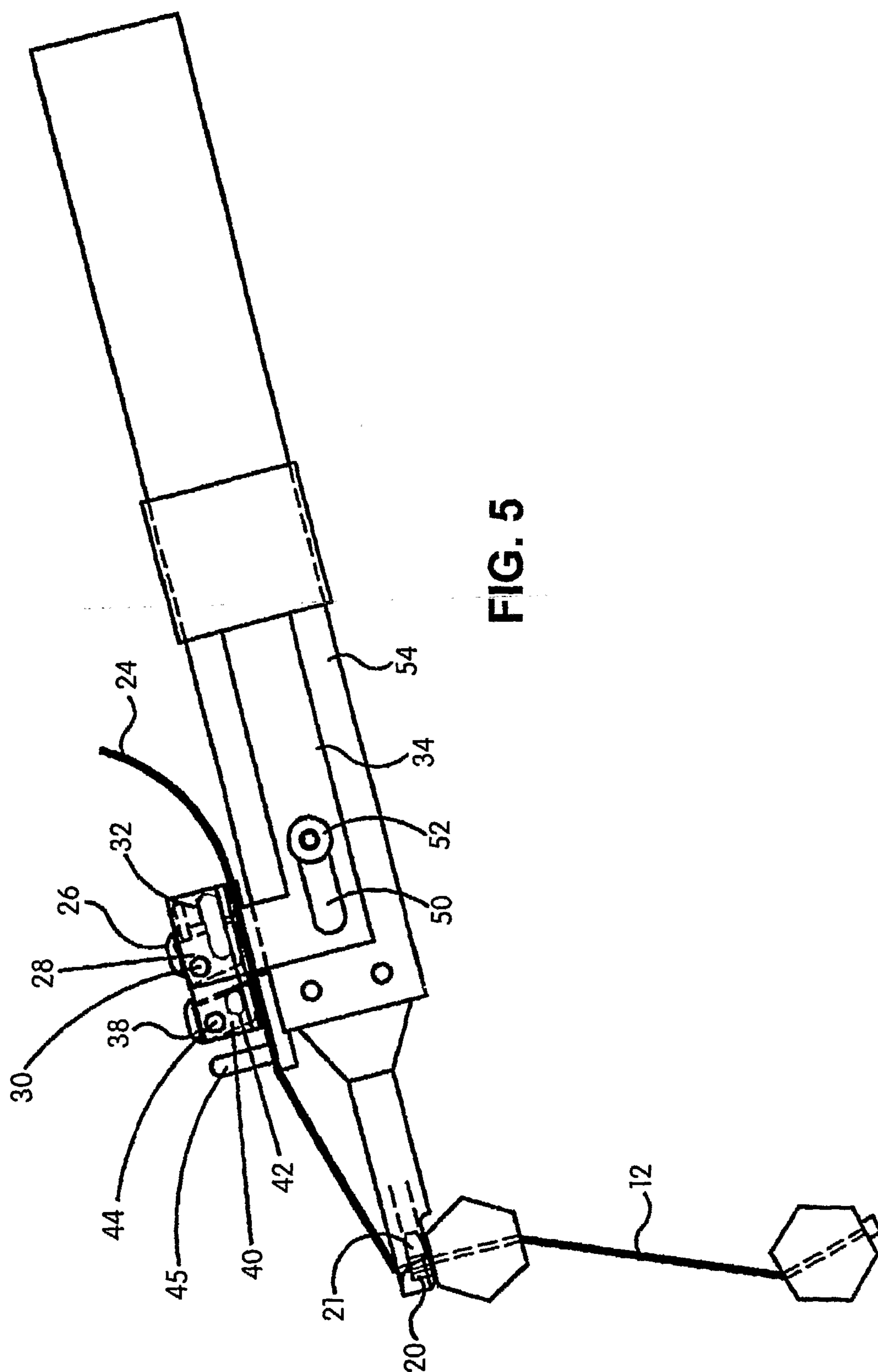
**FIG. 1C****FIG. 1B****FIG. 1D**

**FIG. 2****FIG. 3B****FIG. 3A**



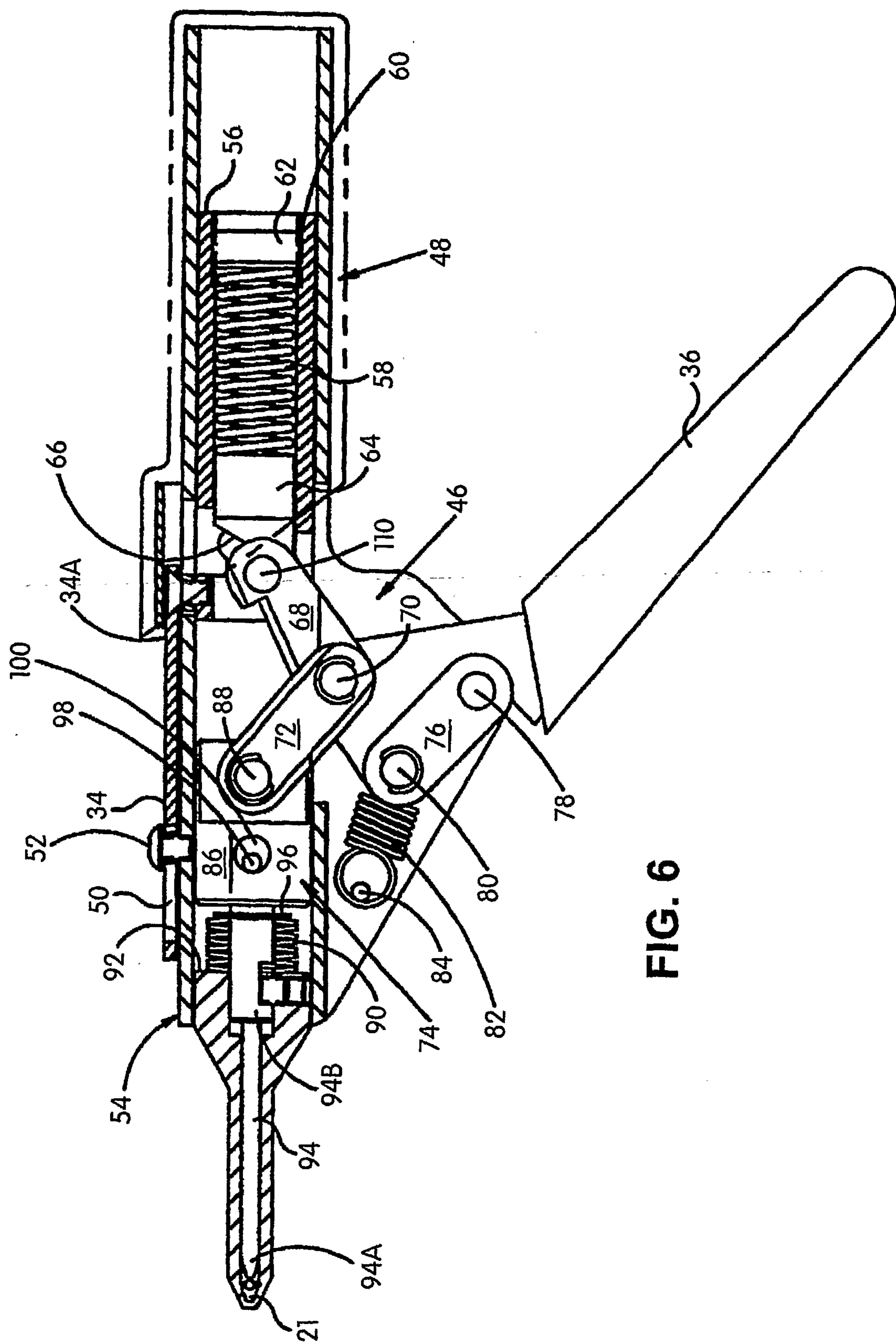
4/9



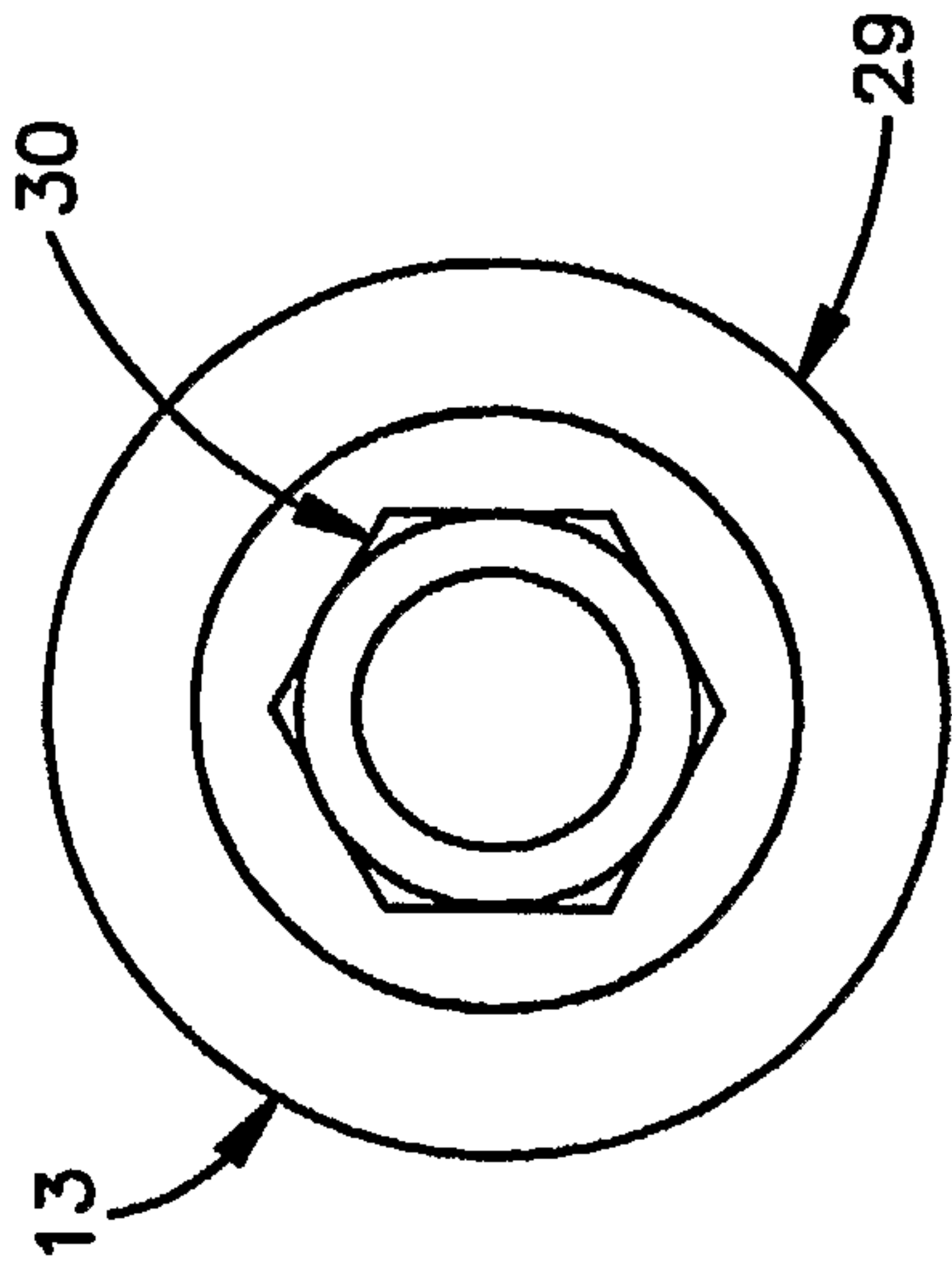
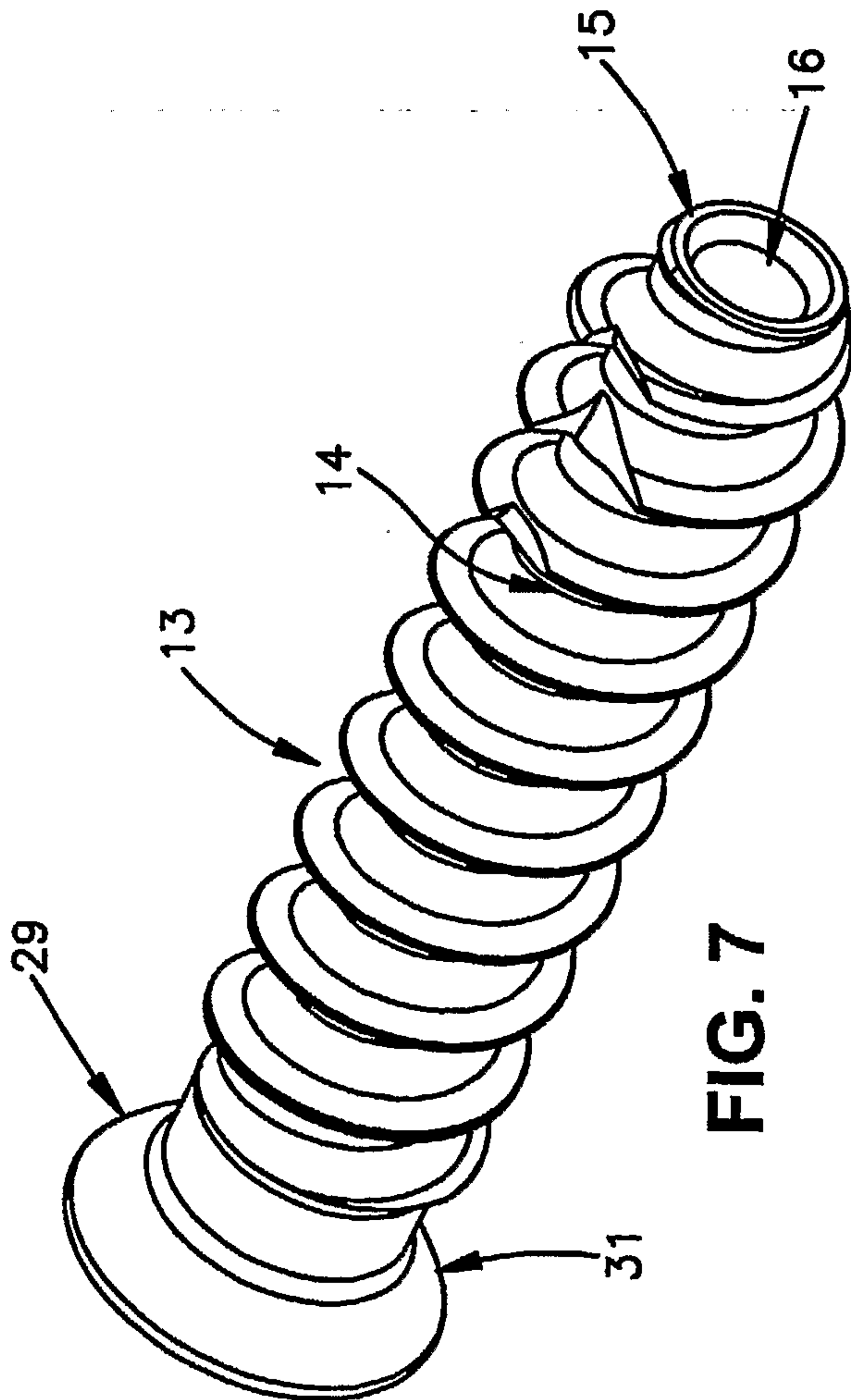
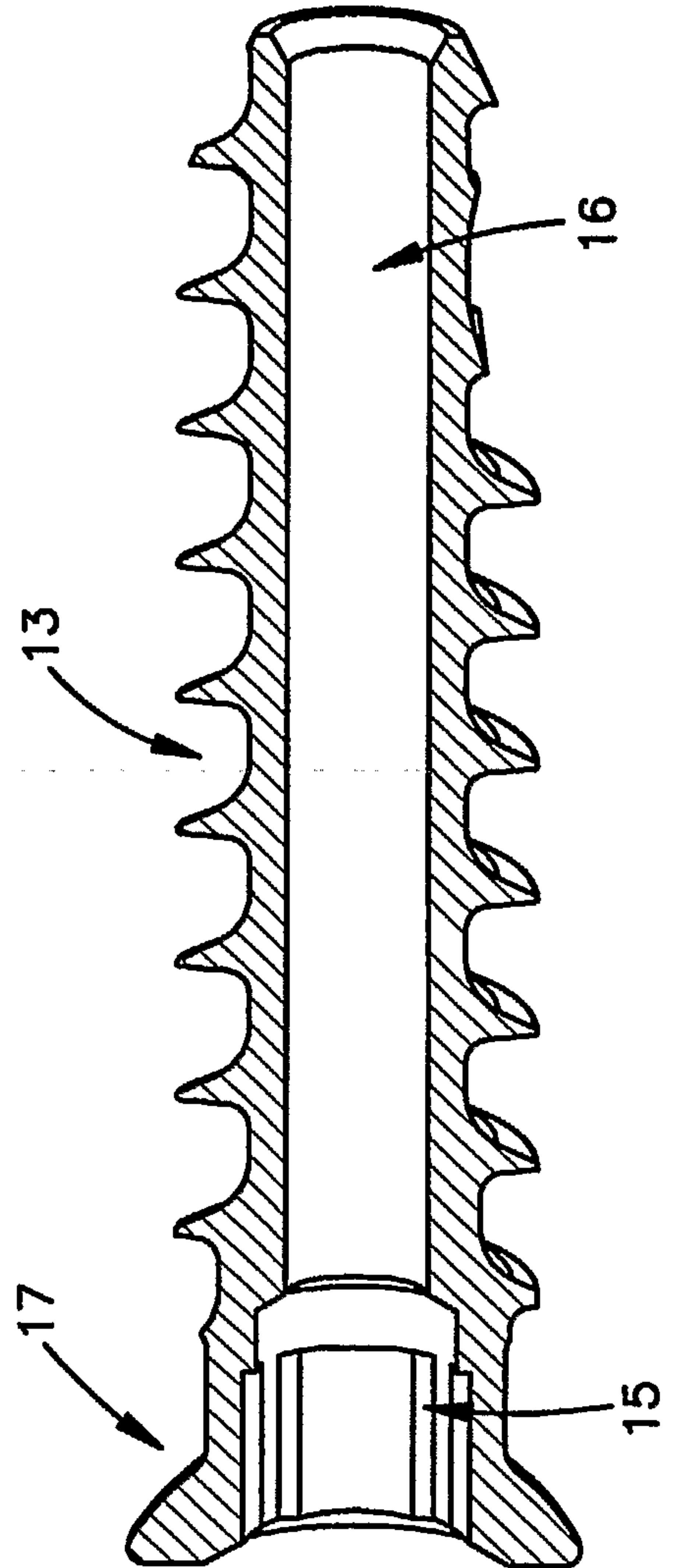
**FIG. 5**



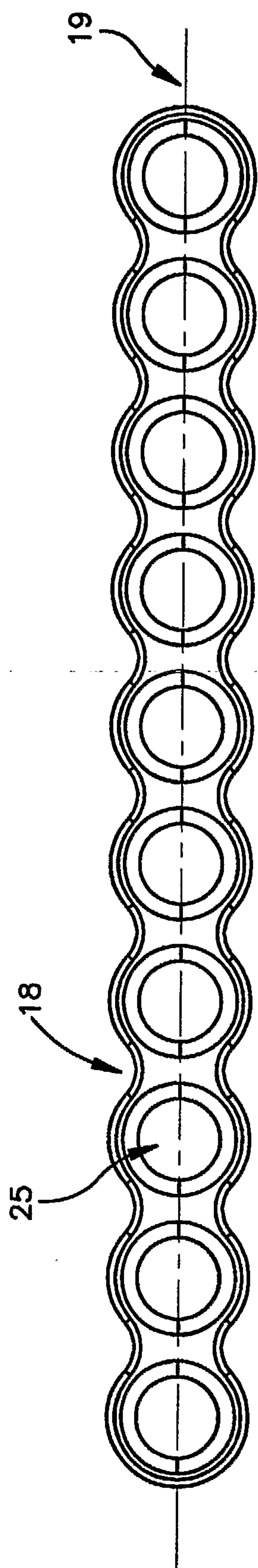
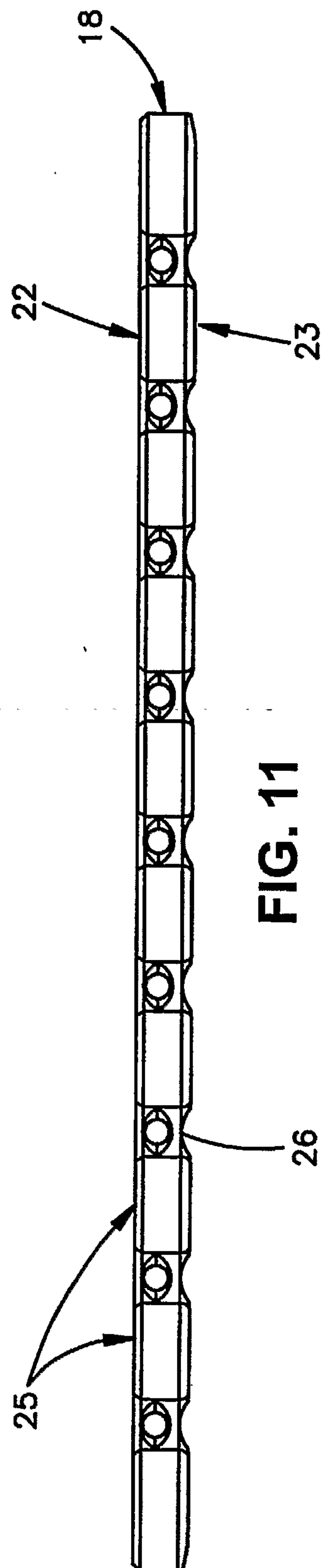
6/9

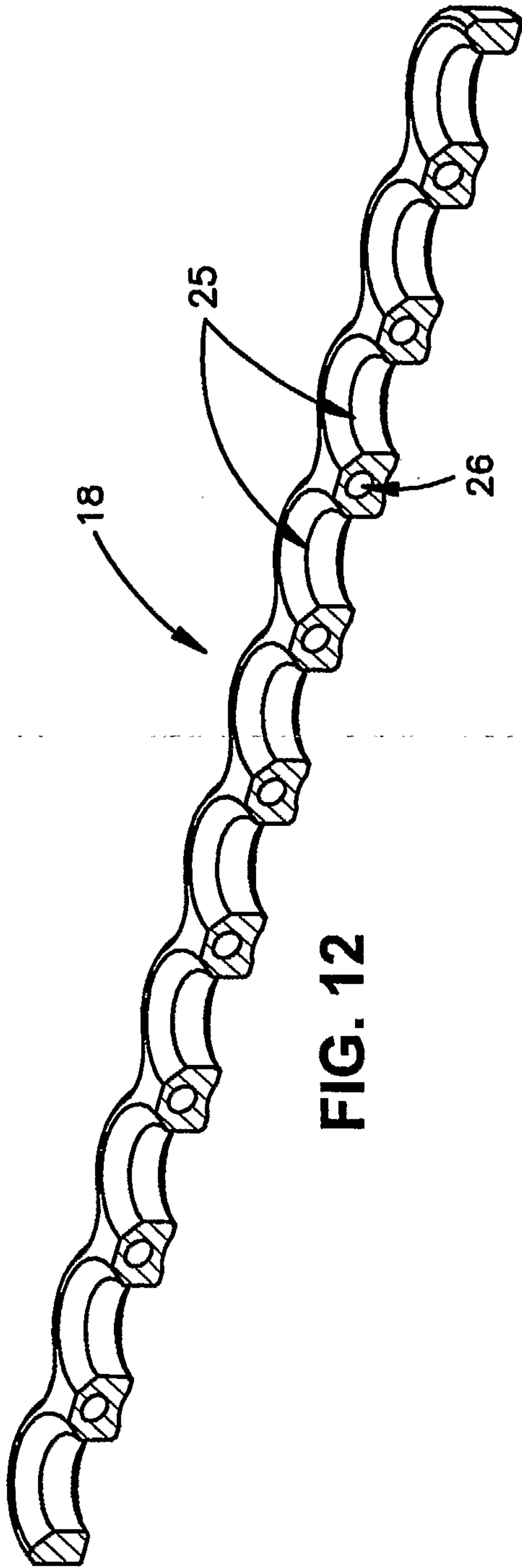
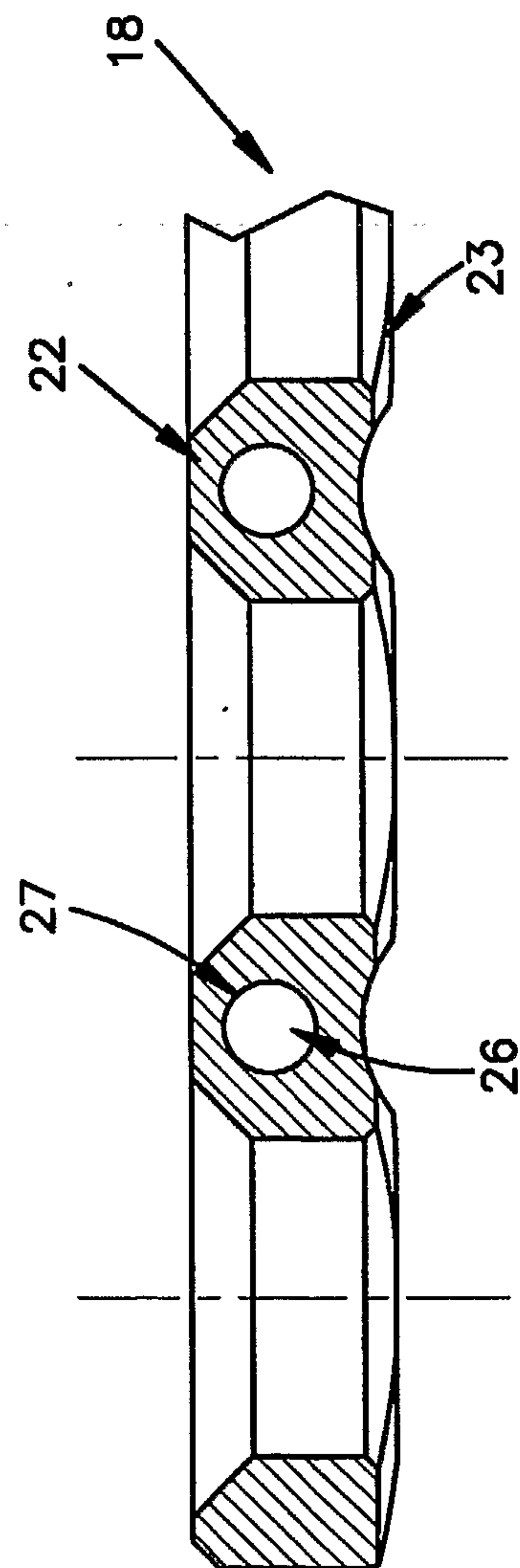
**FIG. 6**

7/9

**FIG. 8****FIG. 7****FIG. 9**



**FIG. 10****FIG. 11**

**FIG. 12****FIG. 13**



