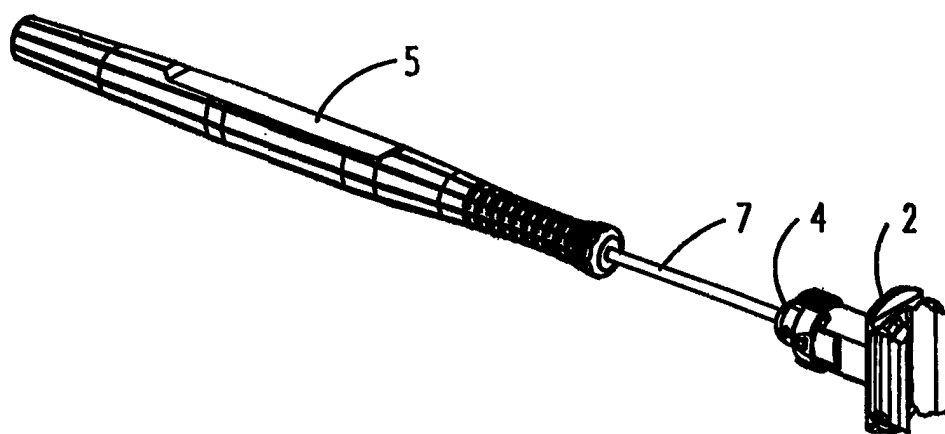




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(21) International Application Number: PCT/US98/09191 (22) International Filing Date: 5 May 1998 (05.05.98) (30) Priority Data: 08/851,572 5 May 1997 (05.05.97) US (71) Applicant: SULZER CARBOMEDICS INC. [US/US]; 1300 East Anderson Lane, Austin, TX 78752 (US). (72) Inventors: CAMPBELL, Louis, A.; 8122 Raintree Place, Austin, TX 78752 (US). MABREY, Jeffrey, M.; 10402 Grand Oak Drive, Austin, TX 78750 (US). HEINRICH, Christopher, A.; 4803 Transit Circle, Austin, TX 78727 (US). (74) Agent: BARROW, Kenneth, S.; Sulzer Medica USA Inc., 4000 Technology Drive, Angleton, TX 77515 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: LOW PROFILE INTRODUCER AND ROTATOR FOR A HEART VALVE PROSTHESIS

**(57) Abstract**

A device for positioning during surgery, a heart valve prosthesis (50) having a general annular configuration with an inside diameter that includes a handle and an introducer/rotator (2). The handle has a proximal end and a distal end. The introducer/rotator (2) is attached to the distal end of the handle and has a length (64) in operative relation to the inside diameter of the valve prosthesis. The introducer/rotator (2) has a width (62) that is less than the length (64), which facilitates intercostal insertion through a patient's ribs.

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Description

LOW PROFILE INTRODUCER AND ROTATOR FOR A HEART VALVE PROSTHESIS

5 Technical Field

The present invention relates to a low profile instrument for introducing and rotating a prosthetic heart valve during implantation.

Background Art

10 Holders for positioning heart valve prosthesis are used for positioning (*i.e.*, holding, supporting and rotating) prosthetic heart valves during surgery. Often heart valve replacement surgery includes a median sternotomy or a large left thoracotomy to gain unobstructed access into a patient's thoracic cavity. Such procedures allow the surgeon to see the patient's heart more directly, and to have more direct instrument access for: (1) excising the natural valve tissue; (2) introducing a heart valve prosthesis into the patient's natural valve annulus; (3) securing the
15 prosthetic valve into position; and (4) rotating the orifice and leaflet assembly of the prosthesis to minimize interference with the heart's subannular anatomy. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, extended hospital stay, and a painful recovery period for the patient.

20 Recently, less invasive cardiac surgery techniques have been developed where an open-heart surgery is performed through small incisions between two ribs. This small intercostal thoracotomy is performed instead of a median sternotomy or other form of gross thoracotomy, substantially reducing the above-mentioned trauma, risk of complication, recovery time, or pain for the patient. However, when performing this procedure, care must be taken not to spread the ribs too far. Some surgeons have recently indicated that a thoracotomy incision should not be
25 spread greater than 15 millimeters for an intercostal insertion since deflecting the ribs to a greater dimension can result in significant pain for the patient. The nerve under the rib can be crushed and damaged if the intercostal incision is spread beyond the 15 millimeters.

30 Therefore, the devices and instruments for performing percutaneous penetrations within these intercostal spaces for less-invasive heart or great vessel surgery must be simple and have "low profile". Currently marketed rotators and valve holders are too bulky to fit through this intercostal space without spreading the patient's ribs too far, and are more complicated than necessary to simply and reliably percutaneously introduce and rotate a prosthetic valve during implantation.

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Disclosure of the Invention

The invention provides for a device for engaging a heart valve prosthesis during implantation and includes a handle and low profile introducer/rotator. An advantage of the introducer/rotator is that, when engaged with the valve prosthesis, the length of the rotator is in operative relation with the inside diameter of the valve annulus, and the width of the introducer is less than that diameter. The introducer/rotator is rigidly connected to, and easily engaged with, a reusable endoscopic instrument handle, avoiding cost associating with more complex (i.e., non-rigidly connected such as a holder that changes relational position with the handle) valve handles or introducers.

Another advantage is that the introducer/rotator passes through a small percutaneous intercostal incision avoiding the need to spread the ribs which would result in pain or injury to the patient. The valve introducer/rotator easily engages the heart valve prosthesis through self-aligning surfaces, and provides for positioning the valve axially via an axial contact surface that is parallel to the plane of valve annulus, and positioning the valve radially via a radial contact surface that is transverse to such plane. The introducer rotator has the advantage of providing these positioning forces to rotate the orifice and leaflets assembly of the valve with a protective groove, which protects the leaflets and other parts of the valve from structural damage. An understanding of these and other advantages and features of the invention is described below.

Brief Description of Drawings

FIG. 1 is a topside perspective view of a low profile introducer/rotator in accordance with the invention.

FIG.2 is a bottom side perspective view of the low profile introducer/rotator in FIG. 1.

FIG.3 is a width side view of the low profile introducer/rotator.

FIG.4 is the length side plan view of the low profile introducer/rotator.

FIG.5 is a cross-sectional view of the valve introducer/rotator taken a long line 40-40.

FIG.6 is a cross-sectional view of the valve holder introducer/rotator of FIG.3 connected to a heart valve prosthesis.

FIG. 7 is a perspective view of the handle in accordance with the invention.

Best Mode for Carrying Out the Invention

Referring to figures 1-6, prosthetic valve introducer/rotator 2 includes a handle 5 engaging end 4 which is designed to be releasably connected to the shaft 7 of the handle 5. Alignment indicator 6 marks the position for the user to introduce the handle into engaging end 4. A similar indicator exists on the distal of the handle (not shown), so that the user simply lines up the indicators in order to put the instrument together. In this particular embodiment, finger

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tabs 8 are provided to release the handle from engaging end 4. Engaging end 4 provides a snap fit with the distal end of the handle (not shown), with the distal tip of the handle resting in engagement recess 10 when the handle and introducer/rotator 10 are connected. Engagement recess 10 is shown as a smooth recess so that the distal end of the handle slip-fits into recess 10.

Also provided in the engaging end is self-guiding groove 12 which allows the distal end of the handle to be correctly positioned for coupling with rotator 2. For simplicity of operation and cost-efficient manufacture, the connection between the handle and introducer/rotator 2 is rigid; i.e., the rotator cannot pivot or reorient for introduction through the intercostal space of a patient's ribs. Radii 14 are provided so that the low profile rotator is more easily cleaned.

Referring to the Fig. 6, a heart valve prosthesis 50 is shown in cross-section, attached to introducer/rotator 2. The prostheses 50 generally includes annular valve body 66 with an interior surface 68. Surface 68 has a right circular cylindrical shape for a major portion of its length, but is interrupted by a pair of diametrically opposed flat sections 70 (as figure 6 is a cross-section, only one flat section 70 is shown). The distance between flat section 70 defines the smallest internal diameter of the annulus 56 of prosthesis 50. The annulus 56 is the central passageway through which blood flows, and contains leaflets 52 that swing or rotate about pivots 54. Pivots 54 reside in the flat section 70 of prosthesis 50. Surrounding annulus 56 is sewing ring 58 which provides means for the surgeon to attach prosthesis 50 to the patients natural valve annulus.

As shown in figure 1, introducer/rotator 2 has a length 64 designed to fit between flat section 70 of the heart valve prostheses when engaged with the valve. This operative relation between length 64 and the inside diameter of annulus 56 allows the introducer/rotator to position the valve while the leaflets are protected.

In this particular embodiment, of fig. 1-6 the low profile introducer and rotator is composed of a series of coaxial cylinders which are truncated resulting in a width 62 small enough to pass through the intercostal spaces of the patient's ribcage, without significantly displacing any of the patient's ribs. In this embodiment, the width 62 of the cylinders are truncated to 14 millimeters. The restriction on width 62 always results in a low-profile rotator with a length to width ratio of greater than 1. Of course, the ratio is not significant, so long as the width 62 is less than length 64, and therefore is less than the inside diameter of the prosthetic heart valve.

Outside cylinder 16 acts as a stop for the introducer rotator when it contacts the inflow edge of the orifice of the prosthetic heart valve, therefore, preventing the leaflets from bearing any axial load. Engaging surface 18 of outside cylinder 16 is a surface that rests against the prosthetic heart valve and provides for axial engagement. Engagement flat 20 is a surface that

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engages the flat portion of the orifice of the prosthetic heart valve and provides rotational force for positioning the valve. Flat 20 is formed from an intermediate cylinder 17, and induces the rotation of the orifice and leaflets assembly. Flat 20 is formed by truncating cylinder 17 once more, the additional truncation occurring in 90 degrees from the truncation at intercostal release surface 28. This engagement flat 20 allows the introducer/rotator to match the opposing flat surfaces 70 of the valve internal diameter.

Proximal to this truncation (surface 28) is a notch 22 that aids in directing the introducer in the axial position. Notch 22 also helps guide the introducer/rotator into correct alignment for full engagement into the orifice and leaflets assembly when presented at an angle to the assembly's central axis. The cylinder formed at surface 24 is slightly less than the distance between the orifice flats 70 and will engage the valve for radial alignment. This cylinder is smaller than the orifice flats 70 so the introducer/rotator will be held in radial alignment with the valve while it is rotationally being aligned. Cylinder surface 24 allows the introducer/rotator to rotate freely on the leaflets inflow edge which helps guide the introducer/rotator 2 into the correct rotational alignment for full engagement into the orifice and leaflets assembly. Surface 26 is also a relieved surface to prevent excessive pressure from being applied to the leaflets. Relieved surfaces 32, 60, and 26 define leaflet groove 34 and protects the leaflets from rotational or axial pressure that may result in damage to the valve. Indeed, as shown in the embodiment in fig. 6, groove 34 surrounds leaflets 52 while the leaflets are in the open position, but does not exert pressure on, or necessarily touch the valve leaflets 52 during rotation of the valve. Intercostal relieved surface 28 provides the low profile character of this introducer rotator so that it can be easily inserted between the patient's ribs. Much of the construction of this embodiment contains rounded surfaces such as rounded surface 30 to limit possible damage to the heart valve and to provide for easier cleaning and molding. Relief angle 38 is designed to prevent surface 60 from having contact with leaflets 52. In the embodiment shown in figure 6, surfaces 60 are substantially parallel to leaflets 52 in the fully open position.

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WHAT IS CLAIMED IS:

1. A device for positioning during implantation a heart valve prosthesis (50) having a general annular configuration with an inside diameter comprising:

a handle having a proximal end and a distal end; and

5 a low profile introducer/rotator (2) coupled to the distal end of the handle, characterized by said introducer/rotator (2) having a low profile and having a length (64) and a width (62), the length (64) in operative relation to said diameter during engagement with the prosthesis (50), and a width (62) less than said diameter.

10 2. The device of claim 1, wherein the introducer/rotator (2) is rigidly connected to said handle and is configured to fit in an intercostal space between a patient's ribs.

3. The device of claim 1, wherein the valve prosthesis (50) has an annulus defining a plane, and said introducer/rotator (2) further comprises an axial contact surface parallel to said plane, and a radial contact surface transverse to said plane during engagement with the
15 prosthesis.

4. The device of claim 1, wherein the ratio of length to width is greater than 1.

5. The device of claim 1, wherein the prosthesis (50) further comprises leaflet occluders (52) rotatably attached to an annular valve body (66), said occluders (52) capable of rotatating from an open position to a closed position, and wherein the introducer/rotator (2)
20 further comprises a protective groove (34) for said occluders.

6. The device of claim 5 wherein said groove (34) maintains the occluders (52) in the open position.

7. The device of claim 1, wherein the introducer/rotator (2) further comprises self-aligning surfaces (22, 24) to aid in engaging the prosthesis (50).

25 8. A device for engaging during implantation a heart valve prosthesis (50) having a generally annular configuration around an axis and having an internal diameter and an inner surface defining a central passageway through which blood flows, said surface being generally cylindrical and including two opposing flat portions (70), and a pair of leaflet occluders (52) positioned in the flat portions of said surface, comprising:

30 a handle having a proximal and a distal end; and

a low profile introducer/rotator (2)

characterized by

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said introducer/rotator (2) having a length (64) and a width (62), the length (64) operatively related to said diameter between said flat portions (70), and said width (62) substantially parallel to said flat portions (70) when the introducer/rotator (2) is engaged with said prosthesis (50).

5 9. The device of claim 8, wherein the introducer/rotator (2) further comprises an engaging surface (20) along said width, said surface (20) capable of applying rotational force to the prosthesis (50).

 10. The device of claim 8, wherein the occluders (52) are capable of rotatating from an open position to a closed position, and wherein the introducer/rotator (2) further comprises a protective groove (34) in operative relation to the occluders.

10 11. The device of claim 8 wherein said groove (34) maintains the occluders (52) in the open position.

 12. The device of claim 8, wherein the introducer/rotator (2) further comprises self-aligning surfaces (22, 24) to aid in engaging the prosthesis (50).

15 13. The device of claim 8, said introducer/rotator (2) further comprising an axial contact surface substantially parallel to said axis, and a radial contact surface substantially transverse to said axis during engagement with the prosthesis.

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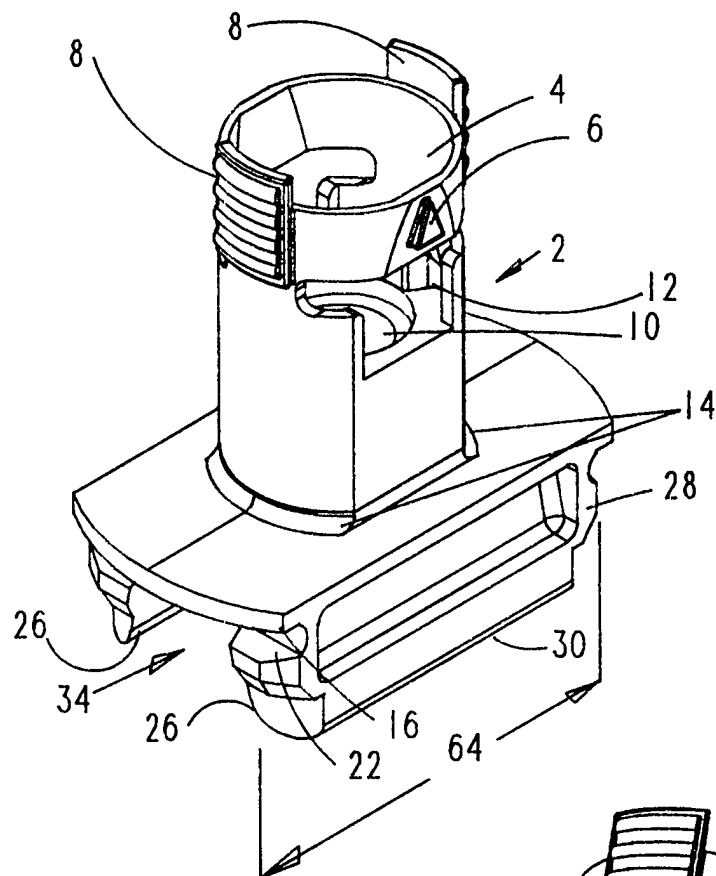


FIG. 1

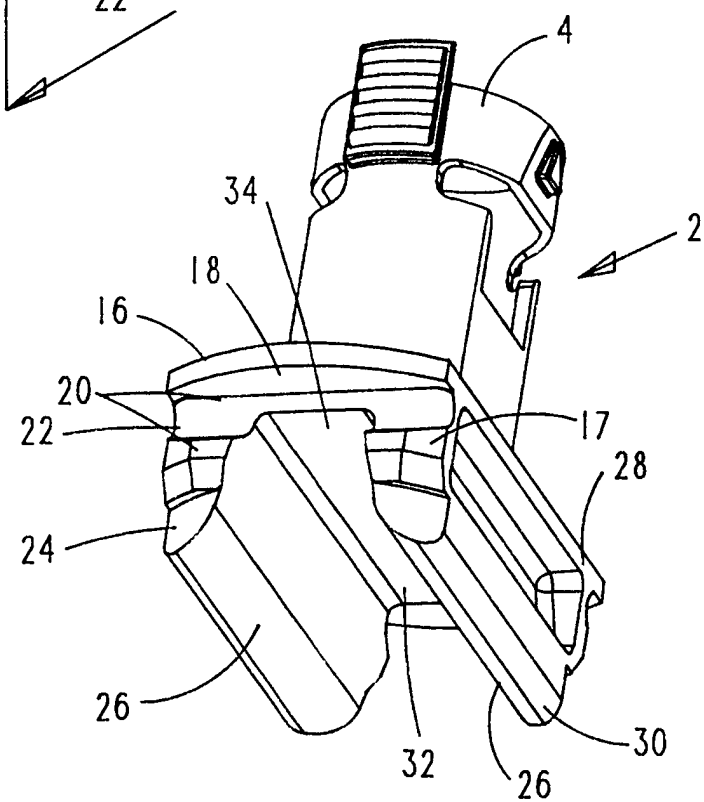


FIG. 2

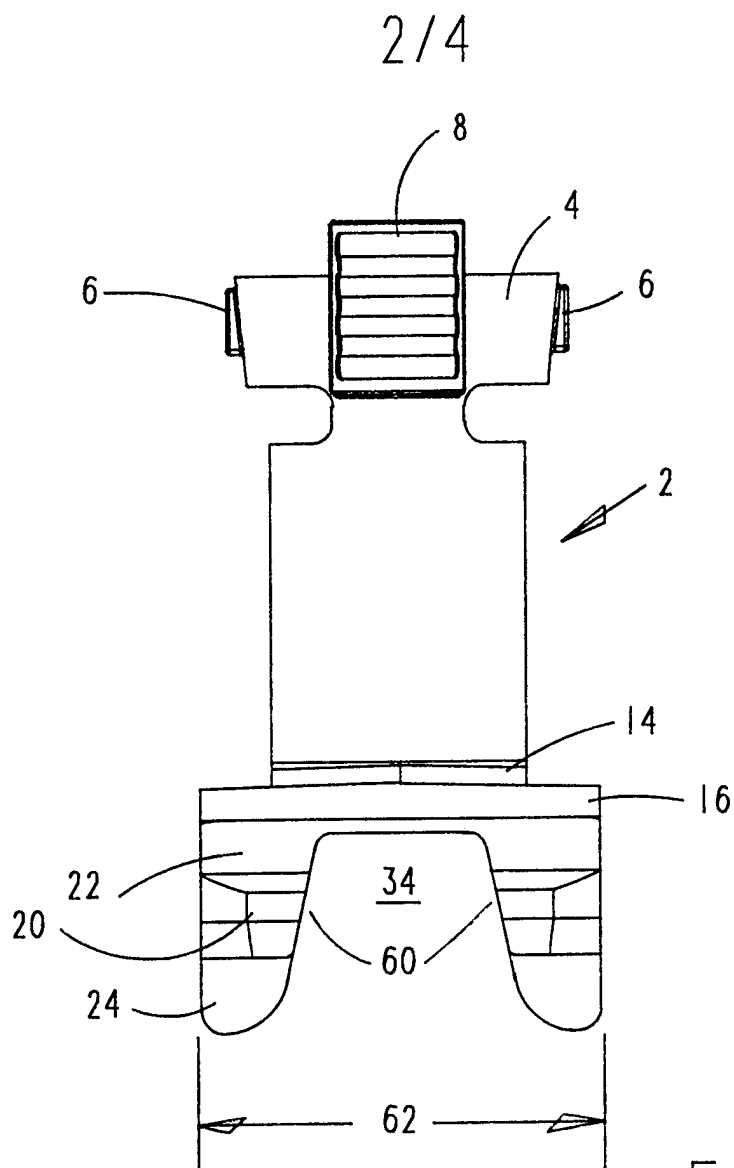


FIG. 3

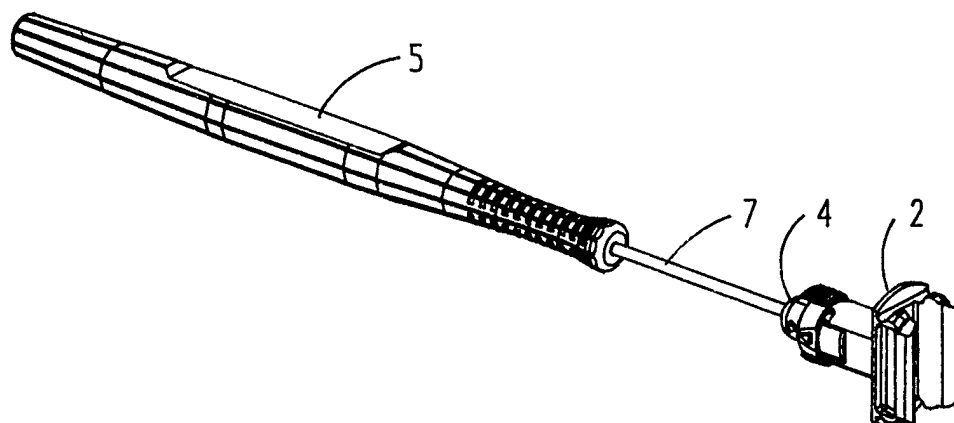


FIG. 7

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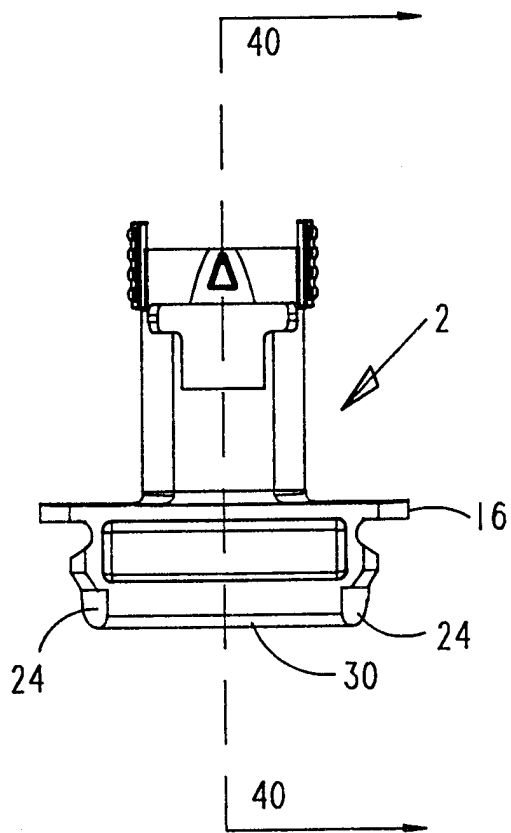


FIG. 4

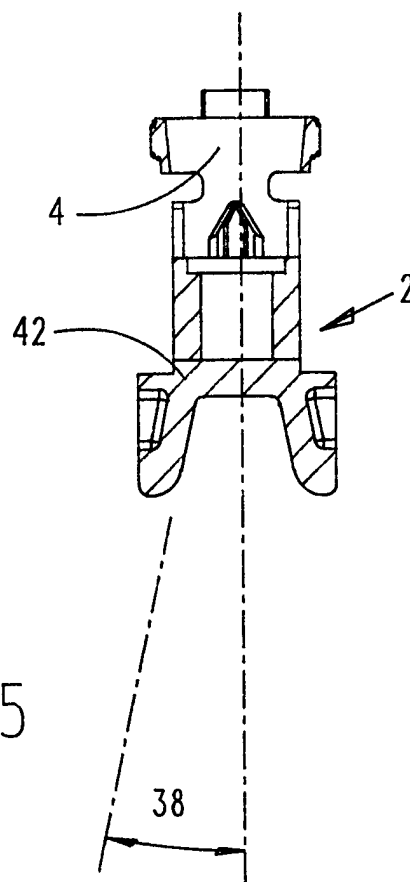


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/09191

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/24

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

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 practical, 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.
X	WO 92 12688 A (ZAVOD ELEKTROMASH) 6 August 1992	1
A	see figures 1,2 -----	8

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

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Papone, F

INTERNATIONAL SEARCH REPORT

Information on patent family members

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WO 9212688 A	06-08-1992	NONE	