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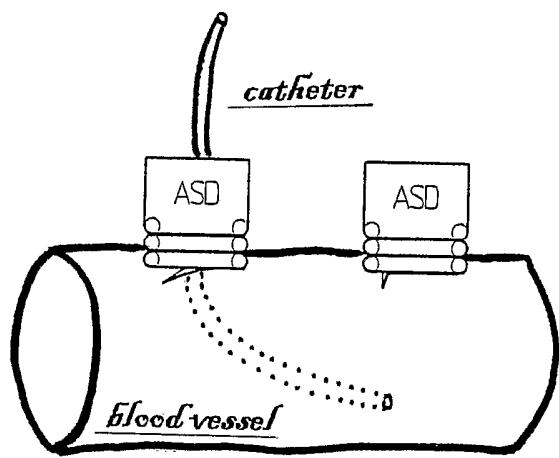
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ANCHORING SCREW DEVICE



(57) Abstract: The present invention, the ASD, is a mechanical device for anchoring hollow tube-like structures in the human body, such as blood vessels and ureters. It facilitates positioning needles or catheters in blood vessels and it prevents those from dropping out of the vessel or from "wandering off" in the vessel. The ASD can be used in every interventional medical situation for diagnostic or therapeutic purposes. The ASD is very easy to fix onto the vessel wall. Screwing is a fast technique saving operating time and requiring only basic microsurgical skills. The manufacturing is easy. It should be understood that the foregoing is illustrative and not limiting, and that modifications may be made by those skilled in the art, without departing from the scope of the invention.

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ANCHORING SCREW DEVICE

DESCRIPTION :

This invention relates to anchoring a SCREW-DEVICE onto a tube-like structure, for example a blood vessel, in such a way (1) that a needle or a catheter can be passed safely into the hollow structure and (2) that this needle or catheter can be positioned firmly in the vessel so that it cannot slip out or be displaced (i.e. be carried away by the fluid in the vessel).

BACKGROUND ART

In many interventional medical procedures we want to reach hollow structures like a blood vessel or a ureter. During these procedures we want to place a catheter or a needle into the hollow structure to have access to it, mostly for therapeutic reasons such as the administration of medication, the placing of a stent or a coil, dilatation and so one. Sometimes access to the aforementioned hollow structures is necessary for diagnostic purposes.

The firm and stable fixation of a catheter into the wall of a hollow structure is essential since the catheter should under no circumstances fall out of the vessel or 'wander off' into the vessel. In the human body some hollow structure are embedded in surrounding tissue which enables the catheter to stay in place. This is the case for example with the blood vessels in a limb. It is completely different in the thorax, skull, or abdomen, where hollow structure are surrounded by less connective tissue and a catheter can easily slip out or be displaced. To prevent this, the catheter has to be fixated by suturing it to the wall of the vessel, but this is difficult and time consuming.

The present invention, the ASD, can easily be screwed onto the vessel-wall, where it gives a maximum stability and support for the catheter, which can then safely be inserted into the vessel.

Interventional fields include diagnostic procedures that involve the implantation of a catheter or needle; and therapeutic procedures that involve interventions (such as placing a catheter for medication) or that involve surgical operations, laparascopy, possibly in combination with endoscopic procedures.

SUMMARY OF INVENTION

The invention makes it possible to anchor a hollow structure, like a blood vessel, easily and quickly. More specifically, the ASD allows the physician dealing with medical intervention to make a stable and safe connection with a hollow structure in such a way that a catheter can be firmly positioned without any need for time consuming suturing.

DETAILED DESCRIPTION OF THE ASD INVENTION

1 The ASD takes the form of a hollow screw, with an ending that is not – as in the regular screw – a point, but one full spiral winding (360 degrees). The end of the winding is sharp and round, i.e. it is non-cutting but it is capable of perforating the wall of the hollow tube-like structure in which it is screwed. The sharp, round point is bent inwardly and downwardly in an angle of 10 to 20 degrees (α) (see figure 1a). Alternatively, this sharp, round, non-cutting point may bend downwardly in an angle of 90 degrees (α) (see figure 1b). In this case, the end resembles a cork-screw, but the end is not situated in the middle of the final winding but on the periphery.

2 The ASD the same as mentioned in 1 but with the body of the screw filled with thrombostatic or haemostatic material that functions as a sponge against leakage of the vessel after the catheter has been removed (see figure 2).

3 The ASD with removable head. This device consists of two basic parts: first, the removable head with applicator (i.e. a long, thin shaft with a handle used to drill the head into the vessel wall) and second, a hollow ASD with a hollow screw of three windings, which remains in place (i.e. in the vessel wall).

The removable head consists of two windings, and ends in the form of a cork-screw (see figure 3a, 3b). This is, again, a round, sharp, non-cutting point. The head forms one whole with the applicator. Once the head is in place (i.e. in the middle of the vessel wall) (see figure 3c), it is removed, together with the applicator, from the rest of the ASD that stays within the vessel wall.

The second part is the body of the ASD. It consists of three hollow windings attached to the head by means of internal, anti-clockwise windings (see figure 3d). Every winding is wider than the previous one, thus expanding the vessel wall. The opening in the wall is made by the head in a non-occlusive way, i. e. the receptor vessel need not be temporarily occluded.

DIAMETER

Depending on the sort of hollow structure, like a blood-vessel, the diameter of ASD may vary from 1 millimetre to 2 centimetre, or even more.

SUBSTANCE

The ASD is made of inox material, or titanium, or super-elastic materials such as nitinol, or synthetic materials, or even resorbable materials.

THICKNESS OF MATERIAL

Depending on the diameter of the blood-vessel, the material may vary from 0,1 mm to any desirable thickness.

ELASTICITY

Depending on the material.

DESCRIPTION OF APPLICATION OF THE ASD.

The ASD is screwed one turn of 360 degrees into the receptor wall. This ensures a stable fixation on the wall. A needle or a catheter is then inserted through the ASD into the wall, and is fixed onto the ASD so that it cannot slip out of the vessel or 'wander off' into the vessel.

MANUFACTURING AND INDUSTRIAL APPLICABILITY

The SCREW-DEVICE can be manufactured commercially and be employed to anastomose two vessels of different or identical sizes. It can be used in all domains of vascular surgery, heart surgery, and neurosurgery.

BRIEF DESCRIPTION OF FIGURES

Figure 1a: ASD

Figure 1b: ASD onto the wall

Figure 2 : ASD filled with thrombostatic or haemostatic material

Figure 3a: ASD with removable head lateral view

Figure 3b: ASD with removable head top view

Figure 3c: ASD with removable head in situ view, position into the wall

Figure 3d: ASD with removable head, view of the way in which the removable head is attached to the boy of the ASD

CLAIMS

What is claimed is

1. A mechanical device, called Anchoring Screw Device (ASD), that takes the form of a hollow screw ending on a single spiral winding, and that has the function to anchor hollow structures. Anchoring means: enabling a stable fixation by means of screwing the ASD onto the wall of the hollow structure, thereby making it possible to fix a needle or a catheter onto the ASD.
2. The ASD according to claim 1 wherein said apparatus is characterized as follows: the hollow tube of the ASD is filled with haemostatic or thrombostatic materials so that after withdrawing the catheter or needle from of the blood vessel, there is no leakage of blood or other liquid.
3. The ASD according to claim 1 wherein said apparatus is characterized by two basic parts: first, the removable head with applicator (i.e. a long, thin shaft with a handle used to drill the head into the vessel wall) and second, a hollow ASD with a hollow screw of three windings, which remains in place (i.e. in the vessel wall).
4. The ASD according to claim 1 and characterized by the use of different materials: resorbable, non-resorbable, and super elastic materials such as nitinol.
5. Any ASD obviously based on the apparatus claimed in 1, 2, 3, 4.
6. The method of screwing the Anchoring Screw Device into the wall of the hollow tube-like structure and providing a stable support onto the wall so that a needle or catheter can be brought and fixed through the ASD into the vessel wall.

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Figure 1a :

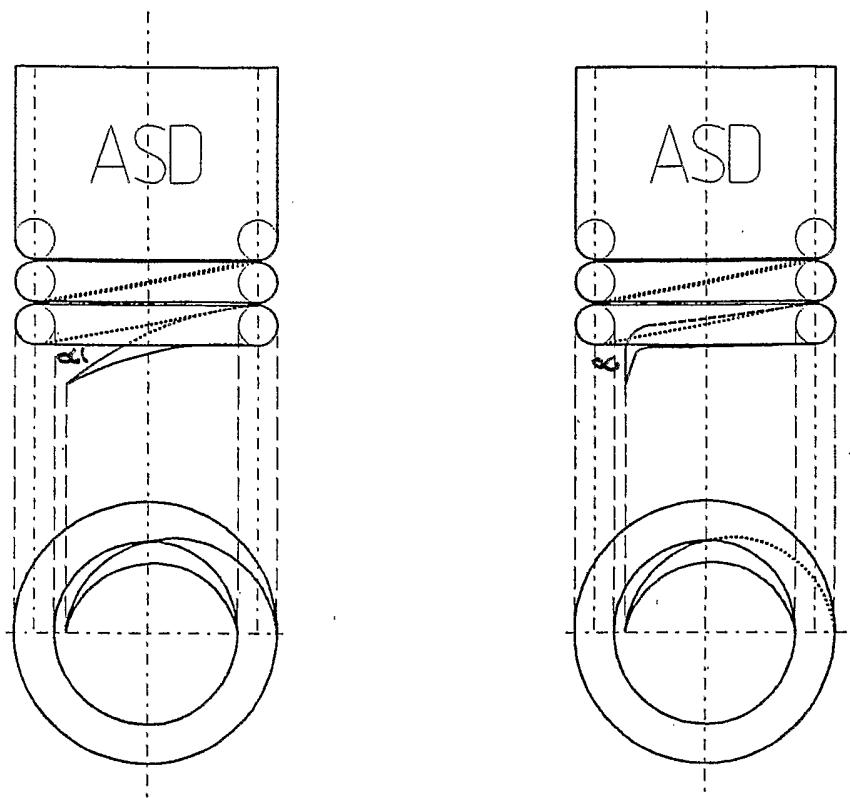


Figure 1b :

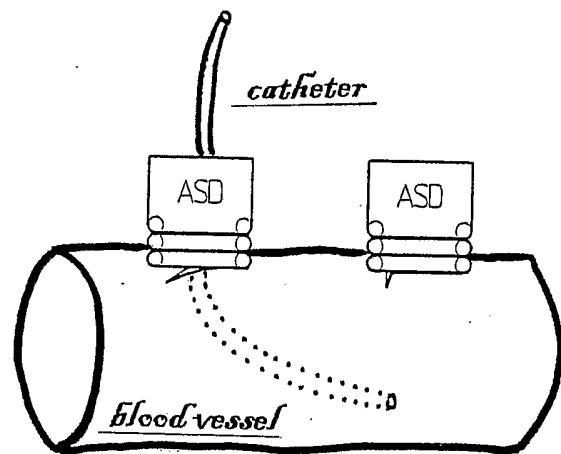
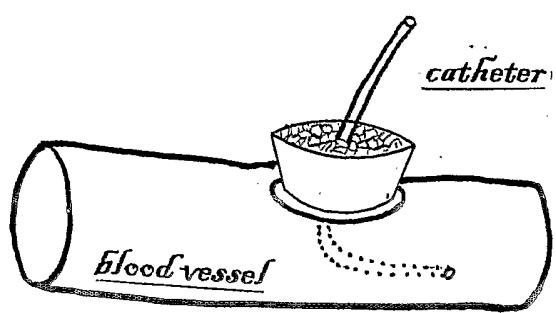


Figure 2 :



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Figure 3a :

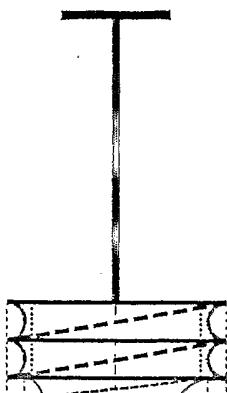


Figure 3b :

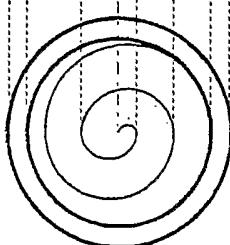


Figure 3c :

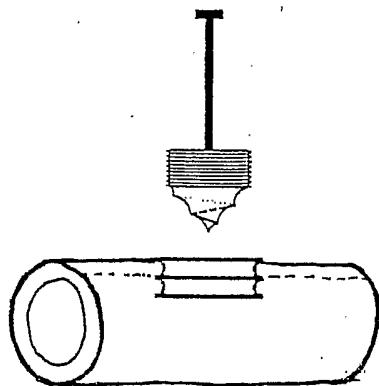
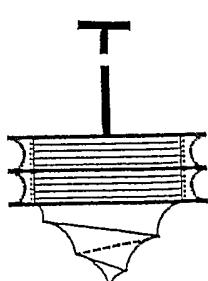


Figure 3d :



INTERNATIONAL SEARCH REPORT

International Application No

PCT/BE 03/00120

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/02

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 7 A61M

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 210 397 B1 (ABOUL-HOSN WALID NAJIB ET AL) 3 April 2001 (2001-04-03) column 4, line 57 -column 5, line 27; figures 1,4,7 ---	1,2,4,5
X	US 5 755 697 A (JESCOVITCH JR ANTHONY J ET AL) 26 May 1998 (1998-05-26) column 5, line 2 -column 6, line 35; figures 1,2 ---	1,3-5
X	US 5 671 773 A (PARK JAE-GYEONG) 30 September 1997 (1997-09-30) column 2, line 43 -column 4, line 59; figures 1,3A-3C ---	1,3-5
X	DE 198 26 078 C (GMS) 19 August 1999 (1999-08-19) column 2, line 23 - line 47; figure 1 ---	1,3,5
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

26 September 2003

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/BE 03/00120

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 100 A (FLECKENSTEIN WOLFGANG) 6 April 1999 (1999-04-06) column 2, line 66 -column 3, line 60; figure 1 ---	1,3,5
A	US 6 132 438 A (FLEISCHMAN SIDNEY D ET AL) 17 October 2000 (2000-10-17) figures 7-9 -----	1-5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/BE 03/00120

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

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

1. Claims Nos.: 6 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/BE 03/00120

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 6210397	B1	03-04-2001	AU WO	2848900 A 0041759 A1	01-08-2000 20-07-2000	
US 5755697	A	26-05-1998		NONE		
US 5671773	A	30-09-1997		NONE		
DE 19826078	C	19-08-1999	DE	19826078 C1		19-08-1999
US 5891100	A	06-04-1999	DE DE WO EP ES JP	19502183 C1 59603859 D1 9622798 A1 0805693 A1 2143177 T3 10512775 T	14-08-1996 13-01-2000 01-08-1996 12-11-1997 01-05-2000 08-12-1998	
US 6132438	A	17-10-2000	CA EP JP WO US US	2223152 A1 0836507 A1 11507262 T 9640356 A1 2002111636 A1 6379366 B1	19-12-1996 22-04-1998 29-06-1999 19-12-1996 15-08-2002 30-04-2002	