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Remarks:
Claims 17 - 24 are deemed to be abandoned due to non-payment of the claims fees (Rule 31 (2) EPC).

(54) **Protecting means in particular for non-invasive procedures**

(57) A protecting means for non-invasive procedures, for example endoluminal or laparoscopic procedures, comprises a sheath (10) extending from a distal end (10a) to a proximal end, in which the sheath comprises at least one inflatable channel (12) having an opening and being suitable for receiving a fluid injected through said opening whereby said fluid injected into the inflatable channel through said opening inflates at least one portion of the sheath. The inflatable channel (12)

comprises a plurality of longitudinal inflatable segments (14) and a plurality of annular inflatable segments (16) connected to the longitudinal inflatable segments in shape of a frame or net of the sheath (10). The protecting means further comprises an outer sleeve (20) and an inner sleeve (22) forming a gap (24) that comprises the plurality of longitudinal inflatable segments (14) and the plurality of annular inflatable segments (16) connected to the longitudinal inflatable segments. The sleeves are made by a transparent material.

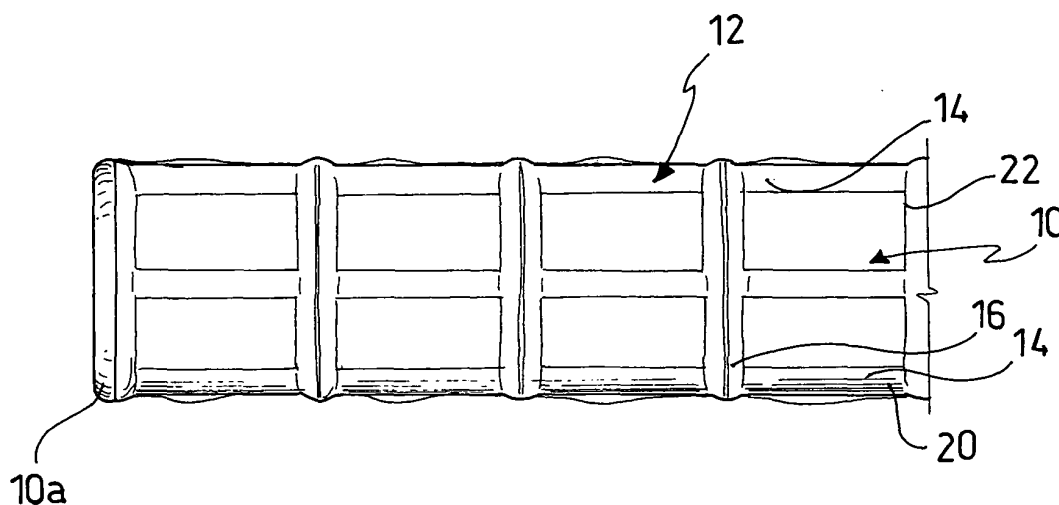


FIG.1

Description

[0001] FIELD OF THE INVENTION

[0002] The subject of the present invention is a protecting means suitable for being used during non-invasive procedures, for example in endoluminal or laparoscopic procedures. Moreover the present invention relates to a method for protecting tissues during non-invasive procedures, for example endoluminal or laparoscopic procedures. According to one specific example the present method may be applied for protecting a hollow body organ during endoluminal procedures.

[0003] BACKGROUND OF THE INVENTION

[0004] The advantages of endoluminal procedures in respect of traditional surgery are well known; they allow a less invasive approach with therefore a lower level of risk and a quicker and safer convalescence.

[0005] However always new needs arise while improving these advantageous procedures. In particular the development of always new therapeutic devices that allow treatment of different pathologies stresses new drawbacks.

[0006] Indeed whenever an endoluminal procedure is performed, the risk of perforation of the hollow organ is always a possibility. Perforation may occur during device introduction through the natural orifice, device navigation and during the therapeutic procedure itself. When a perforation occurs, the patient is immediately sent to surgery to obviate.

[0007] Currently there is no device available in the market to protect hollow organs while an endoscopic therapeutic instrument is introduced.

[0008] US 6,974,441 shows an inflatable intraluminal molding device for positioning, isolating and/or identifying relevant segments of a hollow viscous in which a sleeve comprises a plurality of independent balloon sections. Each balloon section is inflated by an individual air line. This structure has its better performance for isolating segments of a hollow viscous inflating selectively one or more balloon sections. However it has not been explicitly designed for protecting the tissues of the viscous and for forming a flexible structure suitable for absorbing the forces exerted by instruments introduced in the sheath.

[0009] The problem upon which the present invention is based is that of proposing a protecting means suitable for being used during non-invasive procedures, for example in endoluminal or laparoscopic procedures, which has structural and functional characteristics such as to satisfy the above-mentioned requirements and, at the same time, to overcome the disadvantages mentioned with reference to the prior art.

[0010] SUMMARY OF THE INVENTION

[0011] This problem is solved by a protecting means according to Claim 1. In particular this problem is solved by a protecting means comprising a sheath extending from a distal end to a proximal end, in which the sheath comprises at least one inflatable channel having an opening and being suitable for receiving a fluid (liquid or gas)

injected through said opening whereby said fluid injected into the inflatable channel through said opening inflates at least one portion of the sheath. The inflatable channel comprises at least two annular inflatable segments along the length of the sheath and at least one longitudinal inflatable segment connecting said two annular inflatable segments. These advantageous features allow to introduce the protecting means in a deflated state in order to minimize transversal dimension and then to inflate it injecting a fluid in the at least one inflatable channel in order to protect the body tissues.

[0012] Moreover the present problem is solved by a method for protecting tissues during non-invasive procedures according to claim 17. In particular it is solved by a method comprising the steps of:

providing a sheath extending from a distal end to a proximal end, the sheath comprising at least one inflatable channel having an opening and being suitable for receiving a fluid injected through said opening, in which said inflatable channel comprises at least two annular inflatable segments along the length of the sheath and at least one longitudinal inflatable segment connecting said two annular inflatable segments,

[0013] introducing the sheath in a deflated state up to the desired location in the body,

[0014] injecting the fluid in the inflatable channel in order to inflate the sheath,

[0015] introducing at least an instrument through the inflated sheath.

[0016] BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Further characteristics and the advantages of the protecting means and the method according to the invention will become clear from the following description of a preferred embodiment thereof, provided by way of nonlimiting example with reference to the appended drawings, in which:

[0018] FIG. 1 shows a side view of the protecting means according to the present invention, in a inflated state;

[0019] FIG. 2 shows a perspective view of an enlarged detail of fig. 1;

[0020] FIG. 3 shows a perspective view of a step of the method according to the present invention in which the protecting means is shown in a deflated state and over an endoscope within a hollow body organ;

[0021] FIG. 4 shows a perspective view of an enlarged detail of fig. 3 in which the protecting means has been inflated;

[0022] FIG. 5 shows a perspective view of an enlarged detail of the protecting means.

[0023] DETAILED DESCRIPTION OF THE INVENTION

[0024] With reference to the drawings, a protecting means suitable for being used during non-invasive procedures, for example in endoluminal or laparoscopic pro-

cedures, has been shown. With reference to figures 3 and 4, an endoluminal procedure within a hollow body organ 1 has been shown.

[0025] The protecting means comprises a sheath 10 extending from a distal end 10a to a proximal end 10b (FIG. 5). Advantageously the sheath comprises at least one inflatable channel 12 having an opening 15 and being suitable for receiving a fluid (liquid or gas) injected through said opening whereby said fluid injected into the inflatable channel through said opening inflates at least one portion of the sheath.

[0026] More particularly, said inflatable channel may comprise at least one longitudinal inflatable segment 14 and/or at least one annular inflatable segment 16. In this last case, said at least one annular inflatable segment is located at the distal end of the sheath.

For example, said inflatable channel 12 may comprise at least one longitudinal inflatable segment 14 and at least one annular inflatable segment 16 connected to the at least one longitudinal inflatable segment for example by means of a cross 18. In case of at least one annular inflatable segment, this latter is located at the distal end of the sheath. Preferably said inflatable channel 12 comprises at least two annular inflatable segments 16 along the length of the sheath 10 and at least one longitudinal inflatable segment 14 connecting said two annular inflatable segments 16.

[0027] More preferably, as shown in figures, said inflatable channel 12 comprises a plurality of longitudinal inflatable segments 14 and a plurality of annular inflatable segments 16 connected to the longitudinal inflatable segments. The plurality of longitudinal inflatable segments 14 and the plurality of annular inflatable segments 16 are preferably disposed in shape of a frame, each annular inflatable segment 16 crossing one or more longitudinal inflatable segments 14.

[0028] In other words the plurality of longitudinal inflatable segments 14 and the plurality of annular inflatable segments 16 are a frame or net of the sheath.

[0029] In particular one annular inflatable segment of said plurality of annular inflatable segments is located at the distal end 10a of the sheath.

[0030] Figures 1 and 2 show the detailed structure of this latter embodiment of the sheath 10 and in particular of the longitudinal and annular inflatable segments 14, 16 that, in case of endoluminal procedure in a hollow organ 1, keep the hollow organ expanded and prevent kinking of the sheath itself.

[0031] Advantageously the inflatable segments 14, 16 of the sheath form a flexible structure suitable for absorbing the forces exerted by instruments introduced in the sheath.

[0032] According to a possible embodiment of the invention, the protecting means may further comprise an outer sleeve 20 that comprises the at least one inflatable channel 12. In this case the outer sleeve is preferably made by a transparent material.

[0033] According to a possible embodiment of the in-

vention, the protecting means may further comprise an inner sleeve 22 that comprises the at least one inflatable channel 12. In this case the inner sleeve is preferably made by a transparent material.

[0034] In a preferred embodiment, shown in the annexed drawings, the protecting means further comprises an outer sleeve 20 and an inner sleeve 22 forming a gap 24 that comprise the plurality of longitudinal inflatable segments 14 and the plurality of annular inflatable segments 16 connected to the longitudinal inflatable segments.

[0035] According to a possible embodiment of the invention, the protecting means further comprises injecting means suitable for being connected to the inflatable channel through said opening. In particular said injecting means comprises means for injecting a saline solution or other bio-compatible fluid (gas or liquid). Fig. 5 shows an enlarged detail of the proximal end 10b in which a tube 25 is connected to the at least one inflatable channel. The tube 25 ends with the opening 15. An injecting means, for example a syringe, is connected to the tube 25 through said opening 15 in order to inject the fluid in the inflatable channel.

[0036] According to a possible embodiment of the invention, the protecting means further comprises a deploying device 26 suitable for retaining and inserting said sheath in a deflated state up the desired location of the body. In particular the deploying device comprises an elongate body and the sheath is suitable for being placed and fit over said elongate body in the deflated state (fig. 3). In this case the elongate body is transversally (radially) smaller than the sheath in an inflated state, whereby the elongate body runs within the sheath in the inflated state.

[0037] More particularly, as shown in the figures 3 and 4, the deploying device comprises an endoscope and the sheath is suitable for being placed and fit over said endoscope in the deflated state. In this case the endoscope is transversally (radially) smaller than the sheath in an inflated state, whereby the endoscope runs within the sheath in the inflated state.

[0038] Therefore, once at the desired location the inflated sheath separates from the elongate body (scope) and deploys in site, particularly in the hollow organ 1 in case of endoluminal procedures.

[0039] The present invention relates also to a method for protecting tissues during non-invasive procedures, for example endoluminal or laparoscopic procedures comprising the steps of:

[0040] providing a sheath 10 extending from a distal end 10a to a proximal end 10b, the sheath comprising at least one inflatable channel 12 having an opening 15 and being suitable for receiving a fluid (liquid or gas) injected through said opening,

[0041] introducing the sheath 10 in a deflated state up to the desired location of the body,

[0042] injecting the fluid in the inflatable channel 12 in order to inflate the sheath,

[0043] introducing at least an instrument through the inflated sheath.

[0044] More particularly said sheath is placed over an elongate body 24 before introducing it up to the desired location of the body. In this case the elongate body 24 runs within the sheath 10 in the inflated state as it is transversally smaller than an inner transversal dimension of the sheath in an inflated state.

[0045] According to a preferred embodiment, during endoluminal procedures in a hollow body organ 1, said sheath 10 is placed over an endoscope before introducing it up to the desired location of the hollow body organ. In this case the endoscope runs within the sheath in the inflated state it is transversally smaller than an inner transversal dimension of the sheath in an inflated state.

[0046] According to a possible embodiment of the present invention, said sheath is inflated via saline solution or other biocompatible fluid.

[0047] In case of an endoluminal procedure within a hollow body organ, the sheath 10 is introduced transanally or transorally up to desired location of the hollow body organ.

[0048] Finally said sheath 10 is deflated before removing from the body.

[0049] Summarising, the preferred way to deploy the sheath 10 in an endoluminal procedure would be through an endoscope and the step could be the followings:

[0050] placing the sheath over the endoscope in the deflated state,

[0051] introducing the endoscope and the sheath transanally or transorally up to desired site,

[0052] inflating the sheath, preferably via saline solution,

[0053] introducing endoscopic instruments to allow therapeutic procedure,

[0054] deflating and removing the sheath.

[0055] The present method is particularly suitable for being performed in the colon pathway. As a preferred solution, figures 3 and 4 show the sheath carried by a colonoscope through the colon pathway.

[0056] The present invention allows to protect tissues during endoluminal procedures. In particular the present invention allows to protect the inner walls of a hollow body organ in case of endoluminal procedures, such as introduction of an endoluminal stapler to treat suspicious lesion of the colon pathway. The protection is assured prior to introduction of therapeutic endoscopic instrument (i.e. staplers, anastomotic rings, suturing devices).

[0057] More particularly the flexible embodiment of the sheath allows to absorb the forces induced by instruments (in particular endoscopic instruments) which would otherwise be exerted on the hollow organ.

[0058] Moreover the protection is obtained by means of a simple structure such as an inflatable protective sheath to be deployed inside the body (in particular inside the hollow body organ).

[0059] The advantageous choice of an inflatable sheath allows to insert the sheath in a deflated state up

the desired location of the body and then to inflate the sheath to the desired shape in a simple and quick way, for example by means of saline solution. In this way it is possible to minimize the increase of diameter during insertion of endoscope and sheath.

[0060] Moreover in particular in case of endoluminal procedure, besides providing protection of the hollow body organ, the membrane expands the lumen diameter in order to create more space for passage of endoscopic instruments. This is particularly important in the colon; where the sigmoid bend, the splenic and hepatic flexures can have tight bending radiuses and can compromise passage of endoluminal devices. In this particular case, it is preferable that the sheath expands to an inner diameter of approx 5 cm adhering to the colonic wall. In this way the sheath can act as a protective cushion for endoscopic instruments that need to reach the desired site.

[0061] The structure is completed by the inner and outer sleeves which are preferably made by a transparent material in order to allow to visualize the site, in particular the wall of the hollow organ with the endoscope if required.

[0062] Naturally variants and/or additions may be provided for the embodiment described and illustrated above.

[0063] In order to satisfy contingent and specific requirements, an expert in the art may apply to the above-described preferred embodiment of the protecting means many modifications, adaptations and replacements of elements with other functionally equivalent elements without, however, departing from the scope of the following claims.

Claims

1. Protecting means in particular for non-invasive procedures comprising a sheath (10) extending from a distal end (10a) to a proximal end (10b), in which the sheath comprises at least one inflatable channel (12) having an opening (15) and being suitable for receiving a fluid injected through said opening whereby said fluid injected into the inflatable channel through said opening inflates at least one portion of the sheath, in which said inflatable channel comprises at least two annular inflatable segments (16) along the length of the sheath (10) and at least one longitudinal inflatable segment (14) connecting said two annular inflatable segments (16).
2. Protecting means according to claim 1, in which one of said at least two annular inflatable segments (16) is located at the distal end (10a) of the sheath (10).
3. Protecting means according to one of preceding claims, in which said inflatable channel (12) comprises a plurality of longitudinal inflatable segments (14)

and a plurality of annular inflatable segments (16) connected to the longitudinal inflatable segments in shape of a frame or net of the sheath (10).

4. Protecting means according to claim 3, in which one annular inflatable segment of said plurality of annular inflatable segments (16) is located at the distal end (10a) of the sheath (10). 5
5. Protecting means according to one of preceding claims, further comprising an outer sleeve (20) that comprises the at least one inflatable channel (12). 10
6. Protecting means according to claim 5, in which the outer sleeve (20) is made by a transparent material. 15
7. Protecting means according to one of preceding claims, further comprising an inner sleeve (22) that comprises the at least one inflatable channel (12). 20
8. Protecting means according to claim 7, in which the inner sleeve (22) is made by a transparent material. 25
9. Protecting means according to one of preceding claims, further comprising an outer sleeve (20) and an inner sleeve (22) forming a gap (24) that comprise the at least one inflatable channel (12). 30
10. Protecting means according to claim 9, in which said inflatable channel (12) comprises a plurality of longitudinal inflatable segments (14) and a plurality of annular inflatable segments (16) connected to the longitudinal inflatable segments (14) in form of a frame or net of the sheath (10) within the gap (24) between the outer and inner sleeve (20, 22). 35
11. Protecting means according to one of preceding claims, further comprising injecting means suitable for being connected to the inflatable channel through said opening (15). 40
12. Protecting means according to claim 11, in which said injecting means comprising means for injecting a saline solution or other bio-compatible fluid. 45
13. Protecting means according to one of preceding claims, further comprising a deploying device (26) suitable for retaining and inserting said sheath (10) in a deflated state up the desired location of the body. 50
14. Protecting means according to claim 13, in which the deploying device (26) comprises an elongate body and the sheath (10) is suitable for being placed and fit over said elongate body in the deflated state. 55
15. Protecting means according to claim 14, in which the elongate body is transversally smaller than the sheath (10) in an inflated state, whereby the elongate

body runs within the sheath in the inflated state.

16. Protecting means according to claim 14 or 15, in which the elongate body is an endoscope.
17. Method for protecting tissues during non-invasive procedures comprising the steps of:
 - providing a sheath (10) extending from a distal end (10a) to a proximal end (10b), the sheath (10) comprising at least one inflatable channel (12) having an opening (15) and being suitable for receiving a fluid injected through said opening, in which said inflatable channel comprises at least two annular inflatable segments (16) along the length of the sheath (10) and at least one longitudinal inflatable segment (14) connecting said two annular inflatable segments (16),
 - introducing the sheath (10) in a deflated state up to the desired location in the body,
 - injecting the fluid in the inflatable channel (12) in order to inflate the sheath (10),
 - introducing at least an instrument through the inflated sheath.
18. Method for protecting tissues during non-invasive procedures according to claim 17, in which said sheath (10) is placed over an elongate body before introducing it up to the desired location of the body.
19. Method for protecting tissues during non-invasive procedures according to claim 18, in which the elongate body runs within the sheath (10) in the inflated state as the elongate body is transversally smaller than an inner transversal dimension of the sheath (10) in an inflated state.
20. Method for protecting tissues during non-invasive procedures according to claim 17, in which said sheath (10) is placed over an endoscope before introducing it up to the desired location of the body.
21. Method for protecting tissues during non-invasive procedures according to claim 20, in which the endoscope runs within the sheath (10) in the inflated state as the endoscope is transversally smaller than an inner transversal dimension of the sheath in an inflated state.
22. Method for protecting tissues during endoluminal or laparoscopic procedures according to claim 17, in which said sheath (10) is inflated via saline solution or other bio-compatible fluid.
23. Method for protecting tissues during non-invasive procedures according to claim 17, in which the sheath (10) is introduced transanally or transorally

up to desired location of a hollow body organ (1).

- 24.** Method for protecting tissues during non-invasive procedures according to claim 17, in which said sheath (10) is deflated before removing from the body. 5

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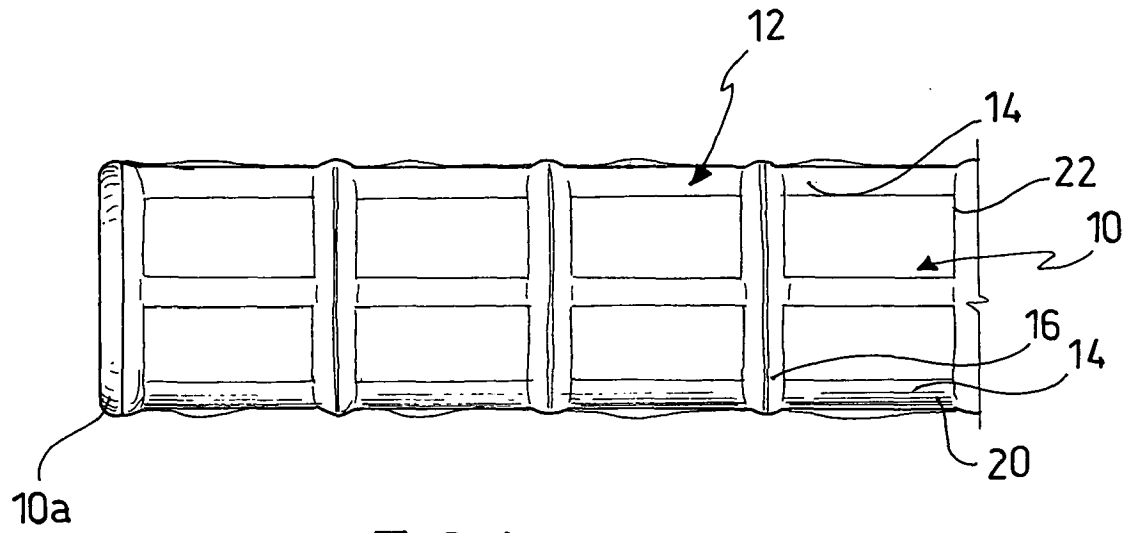


FIG. 1

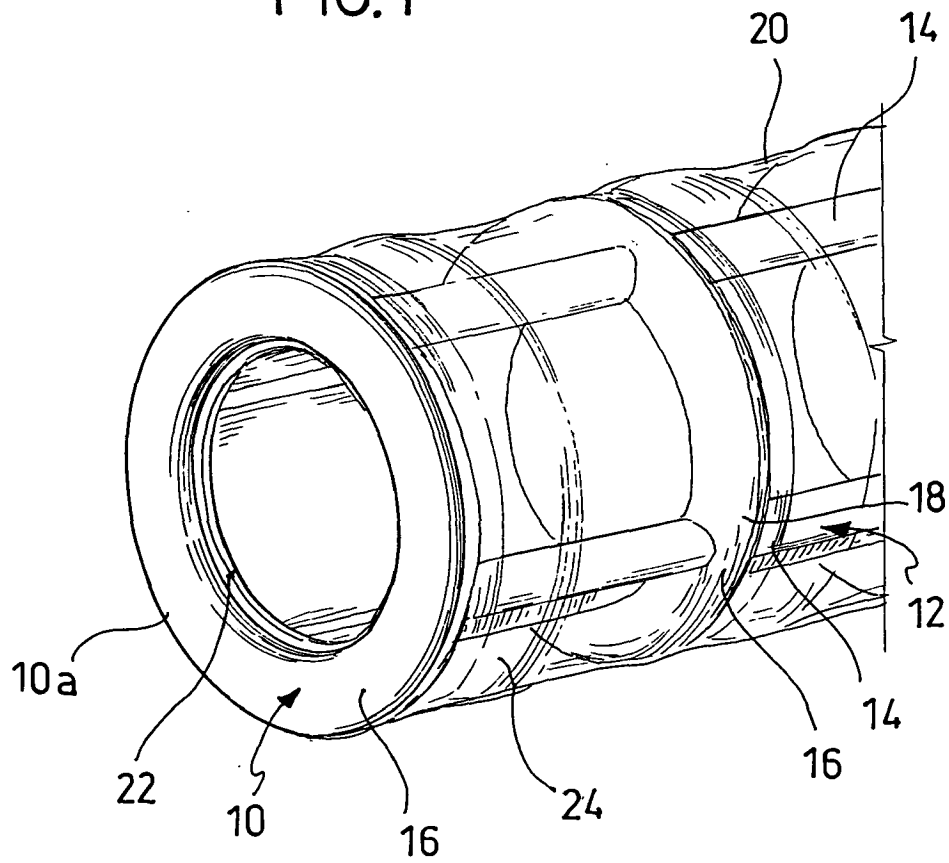
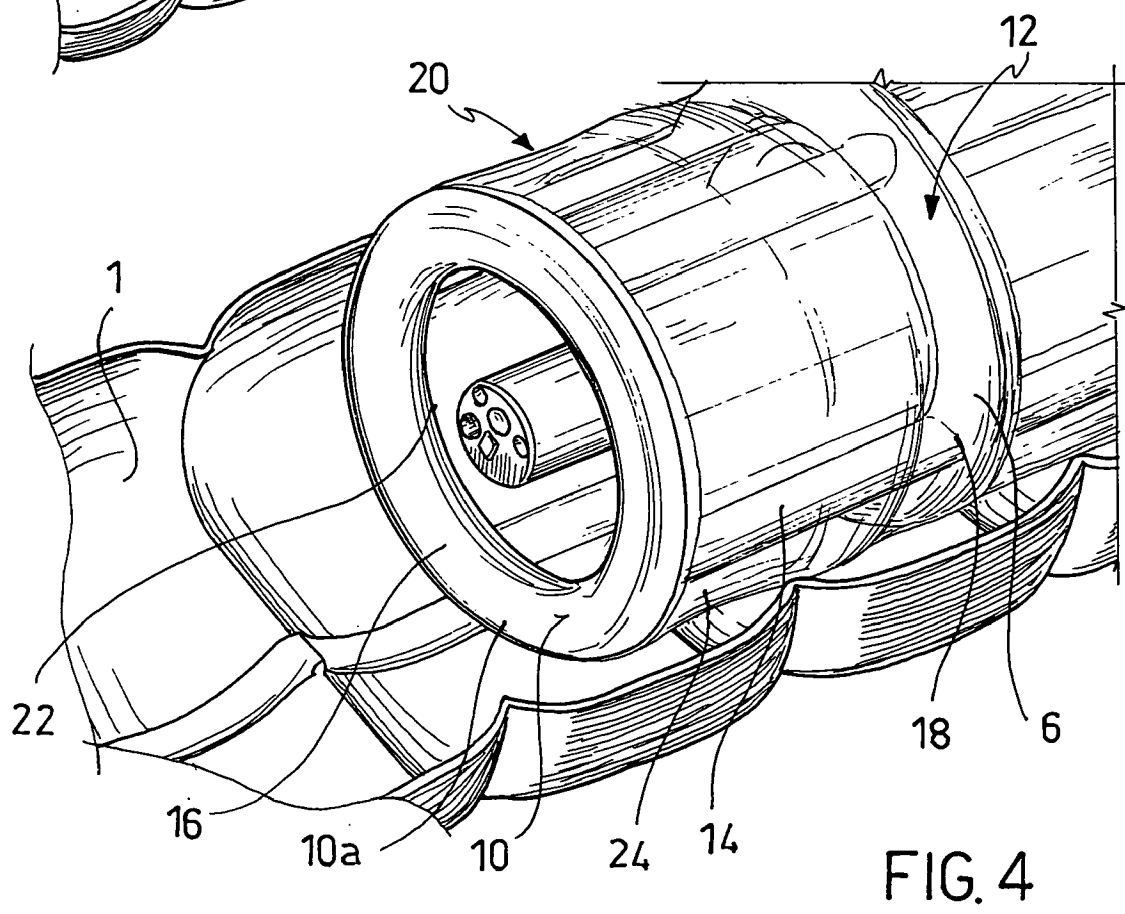
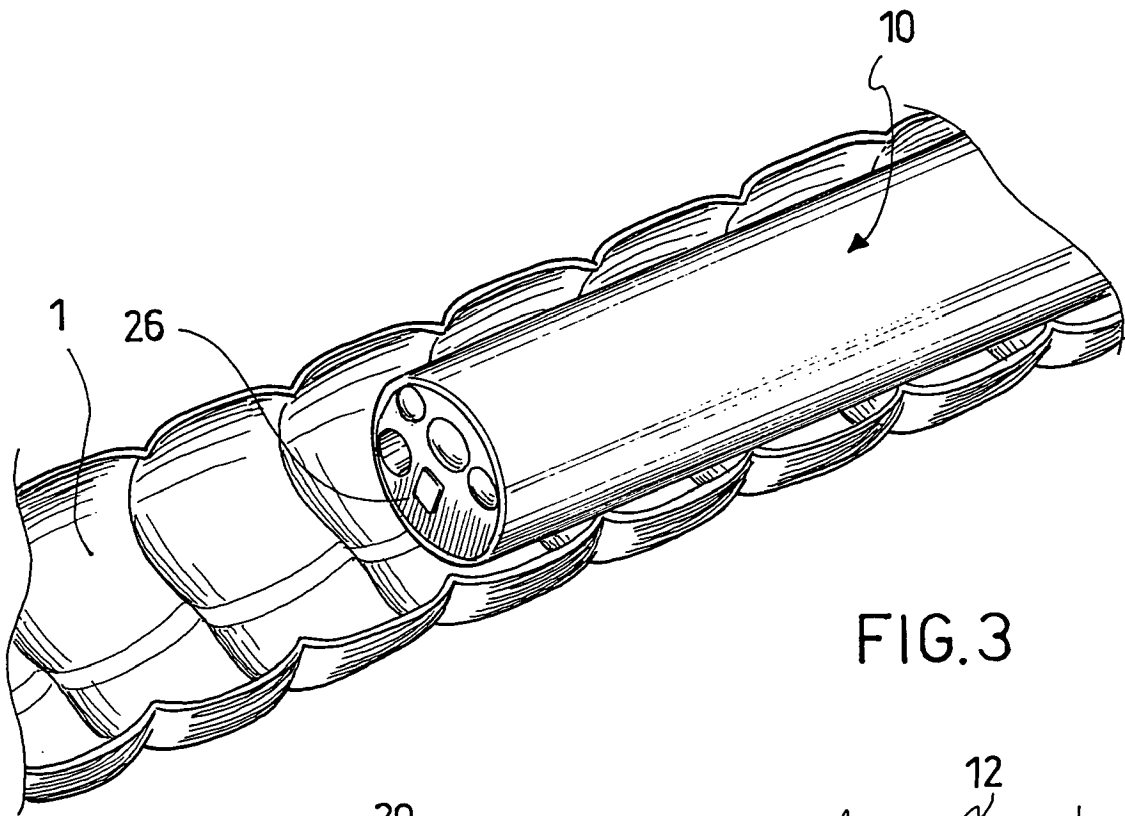


FIG. 2



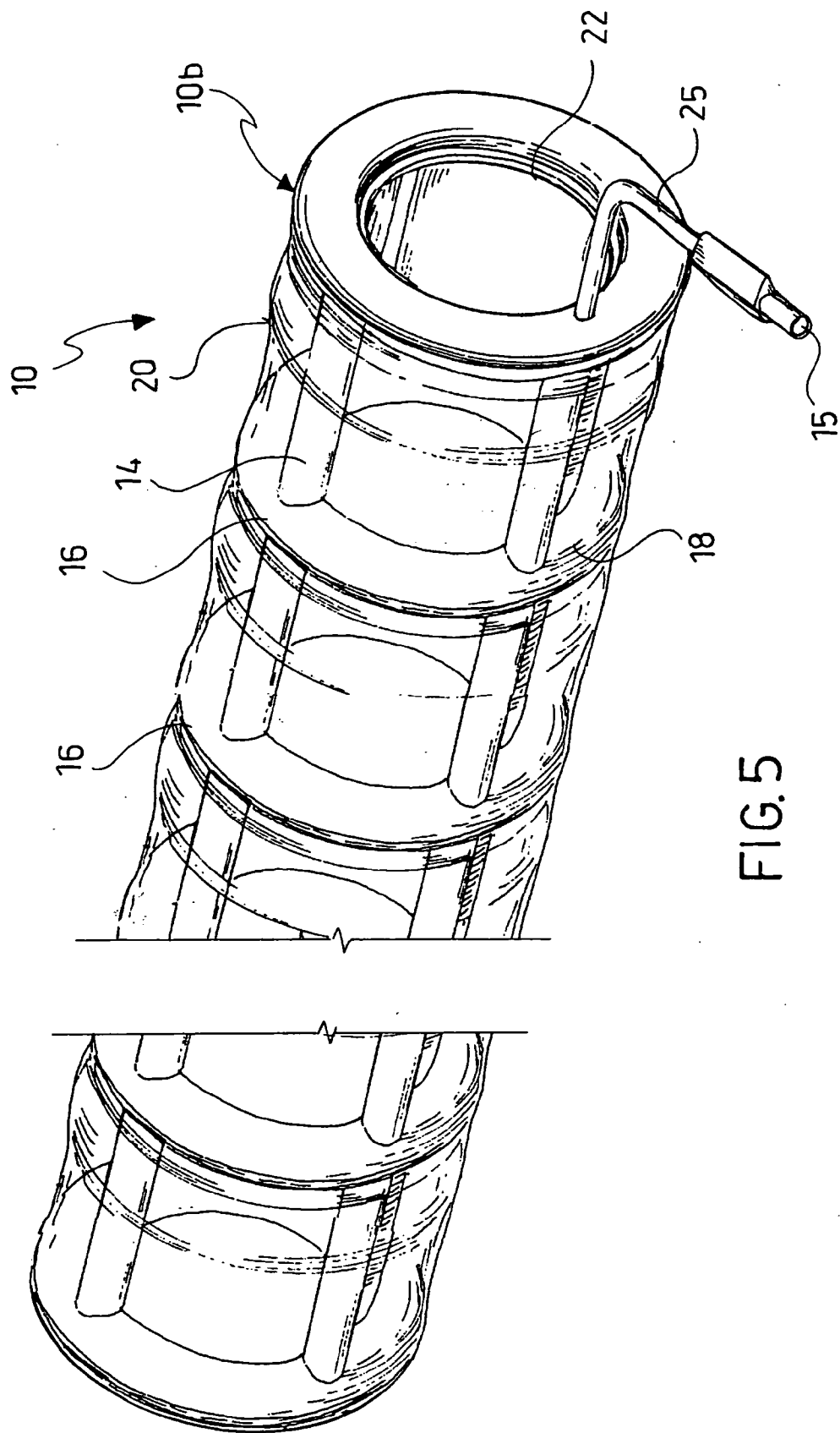


FIG. 5



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 06 02 4998

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	GB 2 071 502 A (NAT RES DEV) 23 September 1981 (1981-09-23) * page 1, line 67 - line 98; figure 2 *	1-5,7, 9-12	INV. A61B5/00
X	JP 07 079909 A (TERUMO CORP) 28 March 1995 (1995-03-28) * paragraph [0009] - paragraph [0022] * * paragraph [0036] * * figure 1 *	1-12	
X	WO 2006/094243 A (BARD INC C R [US]; WOLFE JUSTIN B [US]) 8 September 2006 (2006-09-08) * page 3, line 4 - page 6, line 12; figures 1-3 *	1-4,7, 11-16	
A	US 5 716 321 A (KERIN JOHN [AU] ET AL) 10 February 1998 (1998-02-10) * column 5, line 61 - column 6, line 14; figure 5 *	1	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61B A61M
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
Berlin		18 September 2007	Trachterna, Morten
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EPO FORM 1503 03.82 (P04C01)



European Patent
Office

Application Number

EP 06 02 4998

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☒ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

11-16

- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

- ☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 06 02 4998

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-09-2007

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REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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专利名称(译)	保护意味着特别是对于非侵入性手术		
公开(公告)号	EP1929936A1	公开(公告)日	2008-06-11
申请号	EP2006024998	申请日	2006-12-04
[标]申请(专利权)人(译)	伊西康内外科公司		
申请(专利权)人(译)	爱惜康内镜手术, INC.		
当前申请(专利权)人(译)	爱惜康内镜手术, INC.		
[标]发明人	DARCANGELO MICHELE PASTORELLI ALESSANDRO BILOTTI FEDERICO POPOVIC DRAGO		
发明人	D'ARCANGELO, MICHELE PASTORELLI, ALESSANDRO BILOTTI, FEDERICO POPOVIC, DRAGO		
IPC分类号	A61B5/00		
CPC分类号	A61B1/00135 A61B1/00142 A61B1/00154 A61B17/0218 A61B2017/00557		
其他公开文献	EP1929936B1		
外部链接	Espacenet		

摘要(译)

用于非侵入性手术的保护装置, 例如腔内或腹腔镜手术, 包括从远端 (10a) 延伸到近端的护套 (10), 其中护套包括至少一个可充气通道 (12), 其具有打开并适于接收通过所述开口注入的流体, 由此通过所述开口注入可充气通道的所述流体使护套的至少一部分膨胀。可充气通道 (12) 包括多个纵向可充气段 (14) 和多个环形可充气段 (16), 其连接到纵向可充气段, 其形状为护套 (10) 的框架或网状。保护装置还包括外套管 (20) 和形成间隙 (24) 的内套管 (22), 该间隙包括多个纵向可充气段 (14) 和连接到纵向可充气段的多个环形可充气段 (16) 段。袖子由透明材料制成。

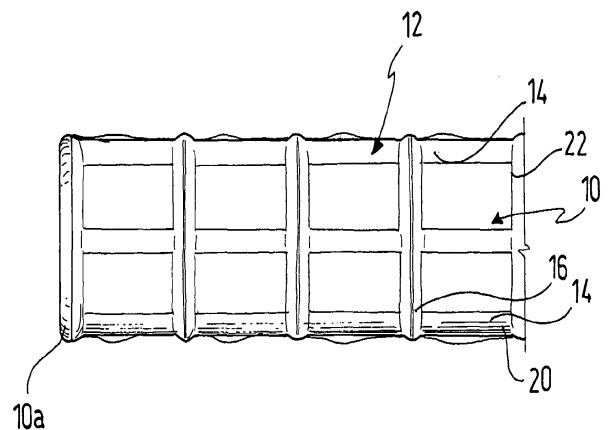


FIG.1