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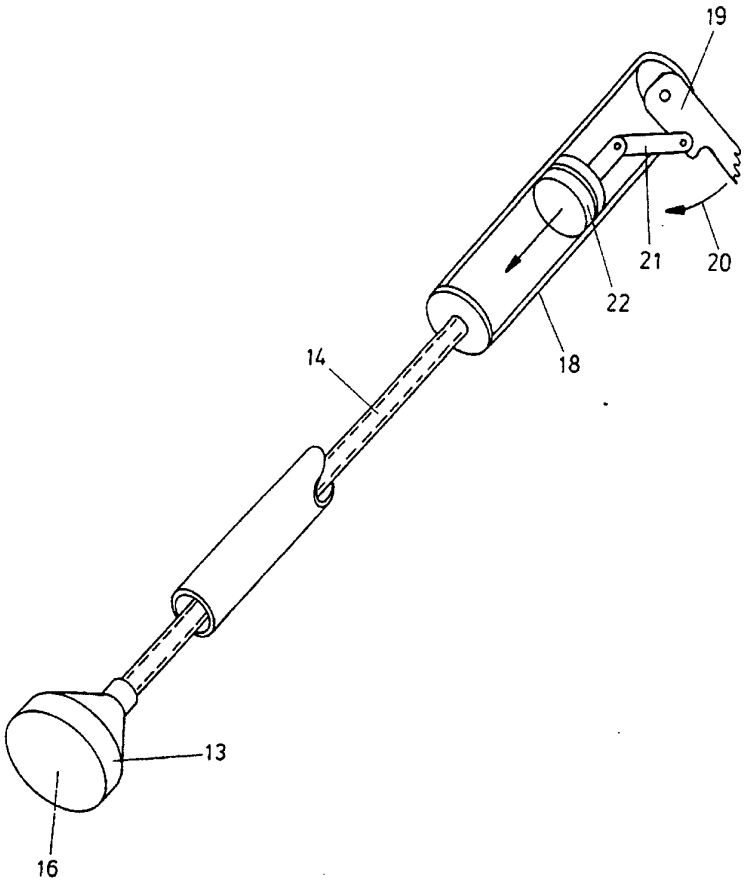
(57) Abstract

A tube (10) is inserted through a port in a body when bleeding occurs. The tube (12) is then slid back in order to expose a sack (13). The sack (13) is then inflated and pushed against the bleeding region in order to reduce the rate of bleeding.



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SURGICAL INSTRUMENT

The present invention relates to surgical instruments and in particular, although not exclusively, to instruments for use in endoscopic surgery.

Endoscopic surgery comprises the technique of making small holes in a persons body. Instruments are passed through those holes in order to operate on organs within the body. The operation is viewed on a screen which is supplied with an image of the cavity in the body from a camera which is manoeuvred within the cavity.

It occasionally happens that bleeding takes place within the cavity. The resultant blood restricts the vision and, although the blood can be sucked out, sometimes the rate at which it can be removed is less than the rate of the leak and accordingly the sight of the operation becomes obscured. If the bleeding is sufficient to jeopardise the successful carrying out of the operation, or if it is so severe that the patient risks being placed in danger because of blood loss then, up until now, a large emergency incision has had to be made through the cavity wall in order that the surgeon can reach the damaged area with his hands to stem the bleeding. However, considerable time can elapse between noticing the undue bleeding level and reaching the source of the leak with the hands, and that time can be critical.

It is an object of the present invention to attempt to alleviate at least some of the above described disadvantages by enabling the blood loss to be controlled, until it can be stopped without the need for emergency measures.

According to one aspect of the present invention, a surgical instrument includes a handle arranged, in use, to be located outside of a patient's body, and an elongate portion to which is connected a pressure applying portion, the pressure applying portion being movable between a first position in which the pressure applying portion can be inserted through a restricted cavity in the wall of a patient's body and a second position in which the pressure applying portion has an increased surface area in a direction transverse to the longitudinal extent of the elongate portion.

The pressure applying portion may comprise an inflatable portion.

According to another aspect of the present invention, a surgical instrument includes a handle arranged, in use, to be located outside of a patient's body, and an elongate portion connected to an inflatable pressure applying portion, the pressure applying portion being arranged, in use, to be inflated when within a patient's body in order to provide a surface which can be urged against a part of a body within a cavity by exerting a force with the handle.

The force may be arranged to extend in the general direction of the elongate portion.

When inflated, the surface area of the pressure applying portion may be increased in a direction transverse to the longitudinal extent of the elongate portion and may be so increased in two perpendicular directions transverse to the longitudinal extent of the elongate portion.

The force being applied by the handle to the pressure applying portion may be arranged to be a pushing force.

The inflatable portion may be non-elastic.

The instrument may include inflation means arranged to be located outside of a body which means are arranged to cause the pressure applying portion to be inflated. The inflation means may comprise manual means such as a hand held pump. Alternatively or additionally, the inflation means may comprise automatic inflation means such as provided by a compressed gas source. The inflation means may include a pressure limiting valve and may also include a pressure release means such as to allow deflation of the pressure applying portion. The instrument may include a conduit extending through the elongate portion which the inflation media is arranged to communicate with the pressure applying portion.

The pressure applying portion may be arranged to be deflated or returned from the second to the first position when located within a body.

The inflatable pressure applying portion may be locatable within a sleeve and there may be means for causing relative sliding movement between the sleeve and the pressure applying portion when the pressure applying portion is located within the body to substantially expose the pressure applying portion. The instrument may include indication means arranged to indicate when sufficient relative sliding movement has occurred between the sleeve and the pressure applying portion.

The surface area of the pressure applying portion in a direction transverse to the longitudinal axis of the

elongate member, when in the second or the inflated position, may be arranged to be more than five times or more than ten times or more than twenty times the cross-sectional area of the longitudinal member.

Pressure should be such that the inflatable part can be pressed against the bleeding part with sufficient force that the bleeding is stopped. Inflation may be with gas or liquid.

The pressure applying portion when inflated or when in the second position may be arranged to provide a substantially flat surface.

The present invention includes any combination of the herein referred to features and limitations.

The invention may be carried into practice in various ways but several embodiments will now be described, by way of example and with reference to the accompanying drawings in which:-

Figure 1 is a schematic side view of the end of an endoscopic haemostat 10 being shown in a stored, non-operational configuration;

Figure 2 is a view similar to Figure 1 with the endoscopic haemostat being prepared for use;

Figure 3 is a view of the complete endoscopic haemostat ready for use; and

Figure 4 is a detailed view of an alternative way of operating the haemostat.

As shown in the drawings, the instrument 10 comprises a tube 12 which is approximately 11 mm thick. This tube 12 can be inserted through and removed from a port in a body. The tube 12 is provided with an integral gas seal 11 which cooperates with the port leading into the body. The tube 12 surrounds, as shown in Figure 1, an inflatable flexible sack 13. The sack is connected to an inner tube 14 at a sealed connection point 15.

When the end of the instrument shown in Figure 2 is inserted in the body then the sack 13 can be exposed, for instance by causing relative sliding movement between the tubes 12 and 14, with that sliding movement being controlled from outside of the body. With the seal 11 cooperating with the port, the tube 14 is pushed into the body to achieve this relative movement. An indication is given to the user of the instrument that sufficient relative sliding movement has occurred, for instance by causing a coloured portion on one of the tubes to be uncovered when the sliding movement is sufficient or by providing a mechanical "click", for instance by a notch in one of the tubes sliding over a recess in the other tube. The sack can then be inflated.

With the sack exposed with the patients' cavity, inflation can take place for instance by having a bladder with a one way valve provided on the outside of the instrument which is connected through the interior of the inner tube 14 to the sack. By repeatedly squeezing the bladder the sack can be inflated quickly. The bladder can be provided with a release tap to allow the sack to be collapsed after it has been used and to allow relative sliding movement of the tubes to occur again until the tube 14 and sack 13 are back within the outer tube 12. Alternatively, the inner tube 14 can be connected to a

carbon dioxide source which can fill the sack directly to the required pressure. Alternatively, a vent valve which limits the pressure may be provided on the supply line for the carbon dioxide. Alternatively, as shown in Figure 3, the handle 18 which is located outside of the body may also comprise a cylinder that contains a saline solution. If a lever 19 is then moved in the direction of arrow 20 a pivoted link 21 urges a piston 22 down within the cylinder to displace the liquid down the tube 14 thus causing the balloon or sack 13 to inflate. The haemostat can be arranged so that when the lever 19 is pushed fully home the balloon is at the required pressure. Alternatively, or additionally, the pressure within the balloon upon activation of the lever can be caused to be varied by adjusting the link 21.

The pressure within the sack is likely to be in the region of 1.5 to 2 lb sq. in. The pressure is sufficient to cause the sack to be rigid and retain its form even though the force being applied to the handle may be very significant.

The balloon is made out of non elastic material and accordingly it has a fixed volume and takes up a fixed shape, as shown in Figure 3.

In use, when blood loss is noted, the instrument 10 can be inserted through a port in the body, the balloon can be exposed and inflated. Once inflated, then pressure can be applied to the leaking vessel by the substantially flat end face 16 of the balloon. The end of the instrument which is located outside of the body and which is provided with the handle 18 can be used to manoeuvre the pressure face 16 and to apply pressure over the area required. The force which can be applied to the handle

can be quite significant because of the large surface area of the face 16. Thus a significant pressure over a large area is applied, rather than applying a very high pressure to a very small area, which may in itself cause damage, as would be the case if it were attempted to push an item having a diameter of 11 mm against the bleeding area. Indeed, in endoscopic surgery, the actual source of the leak in the vessel 11 may not be readily apparent and accordingly, by affording the large area of the face 16, even though the surgeon may not be entirely certain that the centre of the cut in the vessel 11 is aligned with the centre of the instrument which is pushing against the cut, the surgeon can nevertheless be reasonably sure that the cut is located somewhere under the face 16. Furthermore, the damaged vessel is frequently surrounded by tissue which does not allow convenient access to the sight of the hole in the vessel. Accordingly it is important to be able to provide a large area to push against the damaged tissue.

The diameter of the face 16 may be in the region of 2 to 8 cm.

By being able to apply the pressure extremely quickly to the damaged area the blood flow may be stemmed either allowing the operation to be satisfactorily continued with the bleeding ceasing by itself, or the stemming of the flow may allow time for an emergency cut to be made in the cavity wall, at relative leisure, before more traditional methods are used to stem the blood loss.

CLAIMS

1. A surgical instrument including a handle, an elongate portion and an inflatable pressure applying portion, said handle being connected to said elongate portion and said handle being arranged, in use, to be located outside of a patients' body; said inflatable pressure applying portion being connected to said elongate portion and being arranged, in use, to be inflated when within a patients' body in order to provide a surface which can be urged against a part of a body within a cavity by exerting a force with the handle.

2. An instrument as claimed in Claim 1 in which, in use, said force which is exerted by the handle is arranged to extend in the general direction of the elongate portion.

3. An instrument as claimed in Claim 1 or 2 in which the inflatable pressure applying portion, when inflated, is arranged to have its surface area increased in a direction transverse to the longitudinal extent of said elongate portion.

4. An instrument as claimed in Claim 3 in which said surface area, on inflation, is arranged to be increased in two perpendicular directions each of which is transverse to the longitudinal extent of said elongate portion.

5. An instrument as claimed in any preceding claim in which said inflatable portion is non-elastic.

6. An instrument as claimed in any preceding claim including inflation means, said inflation means being arranged to be located outside of a body which means are arranged to cause the pressure applying portion to be inflated.

7. An instrument as claimed in Claim 6 in which said inflation means comprise a manual means.

8. An instrument as claimed in Claim 7 in which said inflation means comprise a hand held pump.

9. An instrument as claimed in any of Claims 6 to 8 including a pressure limiting valve, said pressure limiting valve being arranged to limit the inflation pressure of the pressure applying portion.

10. An instrument as claimed in any of Claims 6 to 9 including a conduit, said conduit extending through the elongate portion, through which conduit the inflation means is arranged to communicate with the pressure applying portion.

11. An instrument as claimed in any preceding claim including automatic inflation means, said automatic inflation means being arranged to cause said pressure applying portion to be inflated.

12. An instrument as claimed in any preceding claim in which said pressure applying portion is arranged to be deflated when located within a patients' body.

13. An instrument as claimed in any preceding claim including a sleeve, said inflatable pressure applying portion being locatable within said sleeve, and means for causing relative sliding movement between said sleeve and said pressure applying portion when said pressure applying portion is located within a body to substantially expose said pressure applying portion.

14. An instrument as claimed in Claim 13 including indication means, said indication means being arranged to indicate when sufficient relative sliding movement has occurred between the sleeve and the pressure applying portion.

15. An instrument as claimed in any preceding claim in which said pressure applying portion, when inflated, is arranged to provide a substantially flat surface.

16. A method of reducing bleeding within a patients' body during endoscopic surgery comprising inserting an inflatable portion into a patients' body, inflating said inflatable portion and urging said inflatable portion against a part of the body within the cavity by manipulating a handle from outside of the body in order to apply pressure in the region of the part of the body that is bleeding.

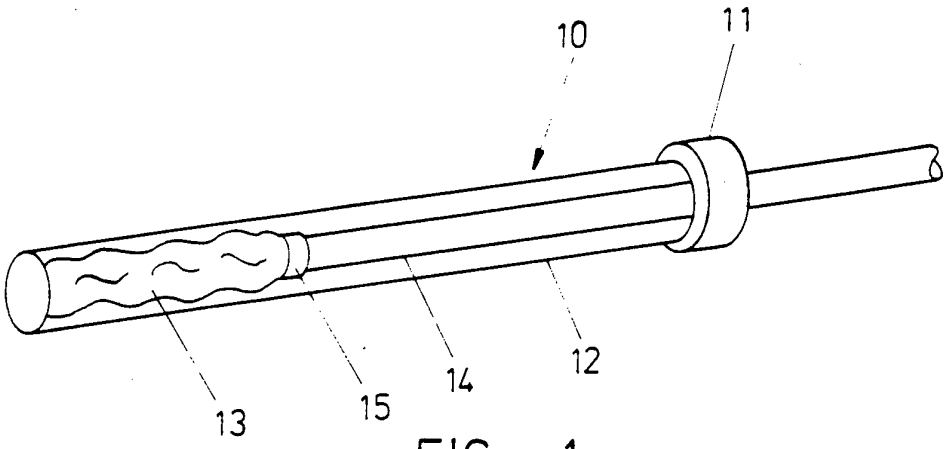


FIG. 1

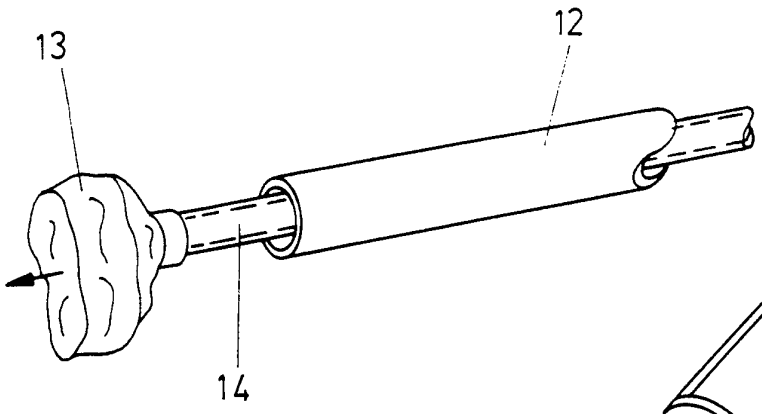
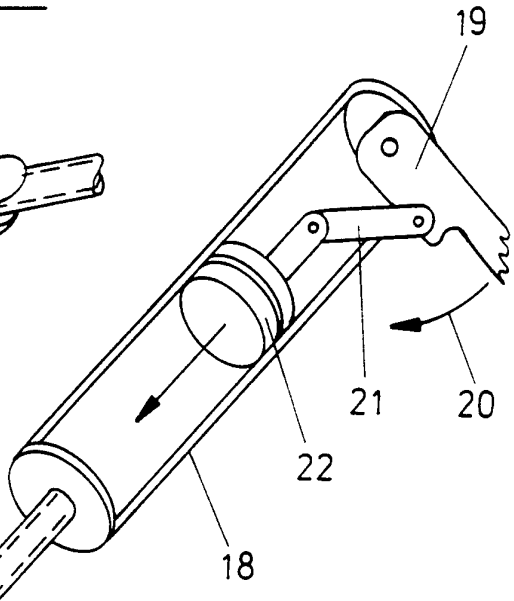


FIG. 2



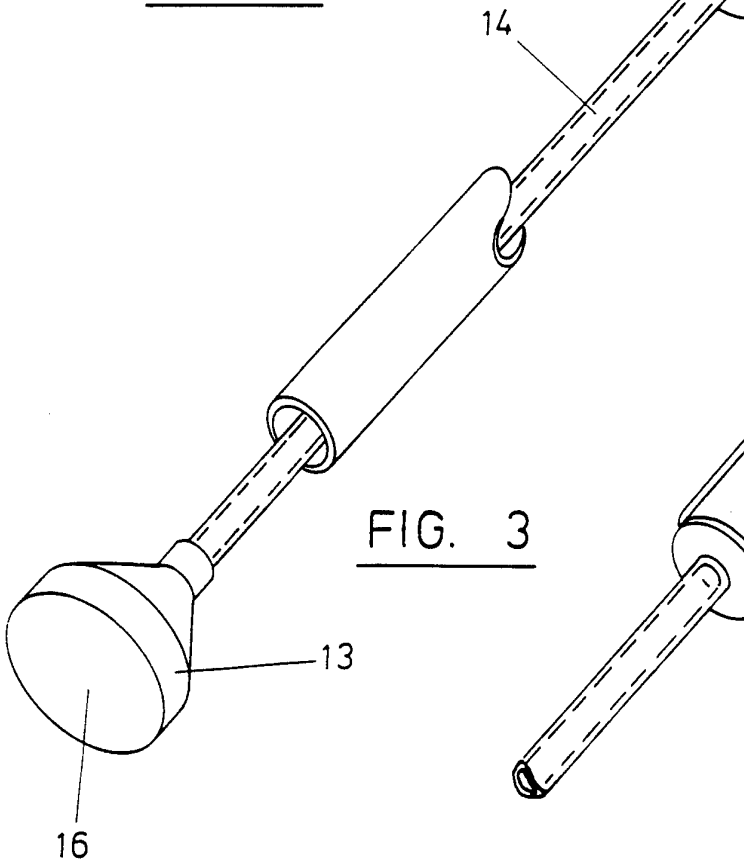


FIG. 3

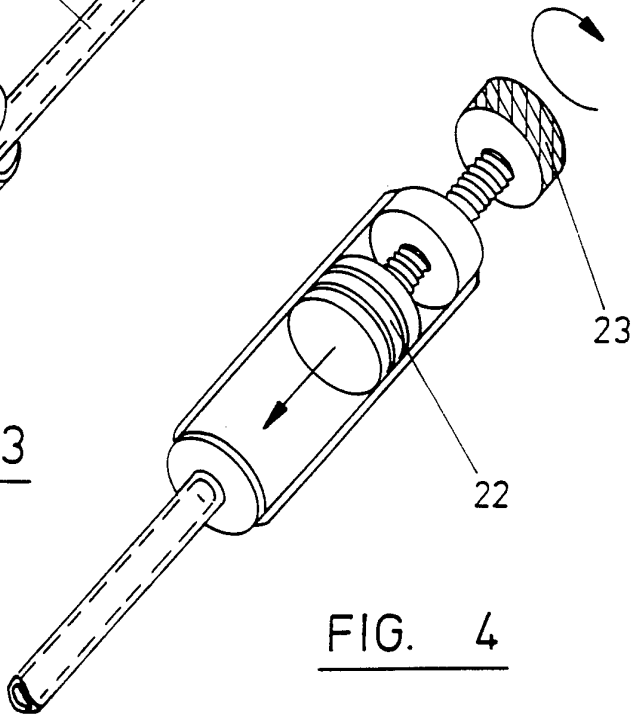


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 94/01969

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/12 A61B17/00

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 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	FR,A,2 668 695 (ETHNOR S.A.) 7 May 1992 see page 2, line 6 - page 4, line 27; figures	1,6-13 2-5
Y	US,A,5 163 949 (BONUTTI) 17 November 1992 see column 7, line 66 - column 8, line 13 see column 9, line 27 - line 32	2-5
X	WO,A,92 21295 (ORIGIN MEDSYSTEMS) 10 December 1992 see abstract	1
X	EP,A,0 141 589 (RANGASWAMY) 15 May 1985 see page 9, line 9 - page 10, line 20; figures	16

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Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
FR-A-2668695	07-05-92	AU-B-	639153	15-07-93
		AU-A-	8706291	14-05-92
		CA-A-	2055032	07-05-92
		EP-A-	0490714	17-06-92
		US-A-	5195507	23-03-93
US-A-5163949	17-11-92	US-A-	5331975	26-07-94
		US-A-	5345927	13-09-94
		US-A-	5197971	30-03-93
WO-A-9221295	10-12-92	US-A-	5309896	10-05-94
		AU-A-	1999292	08-01-93
		AU-A-	2145692	08-01-93
		AU-A-	2157492	08-01-93
		AU-A-	2158792	08-01-93
		AU-A-	2176892	08-01-93
		AU-A-	2185192	08-01-93
		CA-A-	2110152	10-12-92
		CA-A-	2110153	10-12-92
		EP-A-	0586516	16-03-94
		EP-A-	0586555	16-03-94
		EP-A-	0586561	16-03-94
		EP-A-	0586580	16-03-94
		JP-T-	6508049	14-09-94
		JP-T-	6507809	08-09-94
		JP-T-	6507810	08-09-94
		JP-T-	6508050	14-09-94
		WO-A-	9221298	10-12-92
		WO-A-	9221291	10-12-92
		WO-A-	9221292	10-12-92
		WO-A-	9221293	10-12-92
		WO-A-	9221294	10-12-92
		US-A-	5361752	08-11-94
		AU-A-	3136993	15-06-93
		CA-A-	2123317	27-05-93
		EP-A-	0613351	07-09-94
		WO-A-	9309722	27-05-93
EP-A-0141589	15-05-85	US-A-	4552557	12-11-85
		CA-A-	1213491	04-11-86

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0141589		JP-A- 60174142	07-09-85