

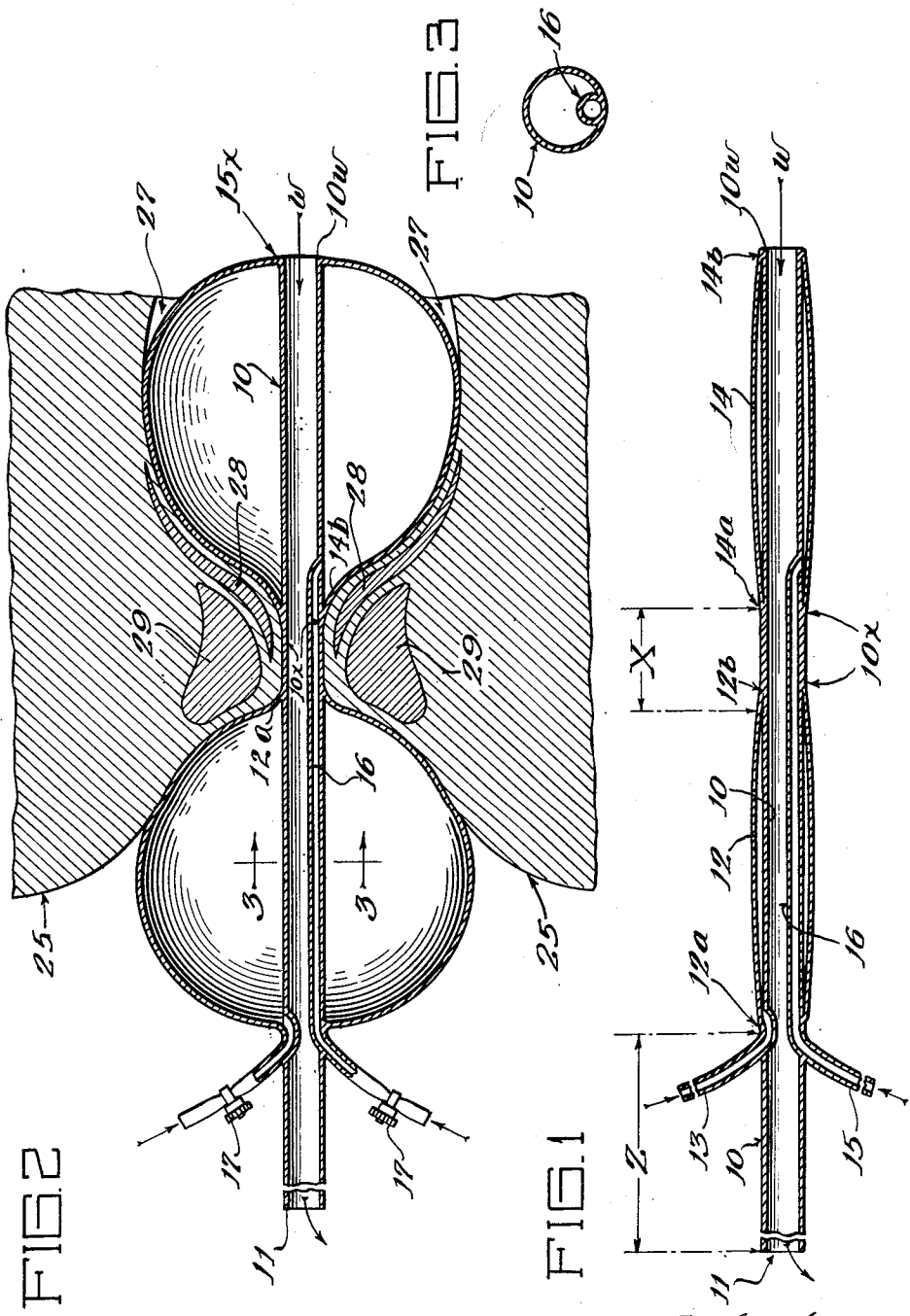
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HEMOSTATIC DEVICE FOR ANAL SURGERY

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HEMOSTATIC DEVICE FOR ANAL SURGERY
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This invention pertains to hemostatic devices, and more particularly to an improved form of hemostatic device for post-operative use in rectal surgery in the anal canal, as in cases of hemorrhoids, fissure in ano, fistula in ano, and related conditions.

Various forms of post-operative hemostatic devices have been in common use in anal surgery for many years, and have generally been considered as more or less satisfactory, the difficulties and annoyances associated with their use being considered as inherent in the nature of the surgery and accordingly to be necessarily tolerated. One common form of provision for post-operative hemostasis has been the use of a mere medicated gauze packing in the anus, of sufficient bulk so that the sphincteral construction holds the packing tightly against the wound. Such a packing required considerable care in application, both to assure its maintaining its position and proper hemostatic pressure for the required post-operative period and to minimize the pain and discomfort of the patient in the post-operative period during which hemostasis must be maintained. An even more serious problem with this simple type of hemostatic application is the lack of provision for passage of body wastes, with consequent severe patient discomfort and also the result that the removal of the packing, when this is ultimately done, releases the accumulated body function products. To alleviate these effects, there is sometimes used a Penrose drain, which is in essence merely a tube. This is sometimes used in conjunction with a packing and sometimes alone, but in either event such a tube must be of very small size in order that it will remain in proper position with its ends protruding from the anal canal, and is thus apt to become clogged, in addition to having severe limitations on its ability to remove waste.

The device of the present invention constitutes a substantial departure from such previous provisions for hemostasis in this type of surgery, simplifying the installation and removal and substantially reducing the pain and discomfort of the patient in the post-operative period; even more importantly, the device of the invention provides a new and improved type of hemostatic action, hemostasis being provided not only by the portion within the anus and bearing against the operative zone, but also by axial or lengthwise compression of the entire anal canal, thus clamping or constricting the blood vessels to produce a highly efficient hemostasis which can readily be controlled as regards pressure, the structure of the present device being such that this pressure is exerted by the inflation of balloons or cuffs which are inflated by means of a syringe, the "feel" of the syringe plunger thus giving an easily sensed indication of the pressure exerted by the hemostat which is virtually impossible with the prior devices described.

The invention may be described as a compressive anal catheter having hemostatic and isolative properties, superficially similar to catheters of the Foley tube type as used in prostate operations, particularly to those having two balloons or cuffs, or to the Whipple tube as used in the esophagus, but substantially differing in features of construction which are required for fully successful use in anal hemostasis, in which the mode of functioning is radically different. In the present construction the catheter lumen has a wide and fully-open axial inlet at its leading end merging in flush-integrated contiguity with the ballooned spheroidal surface of one of a pair of

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axially-juxtaposed inflatable cuffs which are both circumambient of the lumen, and which are spaced apart lengthwise thereof a distance approximating the length of the anal canal in such manner as to bear respectively against opposite ends of the anal canal when inflated. In this manner a compliant compressive force is exerted against the interior and posterior aspects of the anus to isolate the operative situs and dressings which may be used from rectal fluids and possible fecal matter, producing substantial hemostasis in addition to that of the portion within the anus, while at the same time affording a full-venting discharge passage to such fluids, particularly flatus.

More complete understanding of the foregoing and additional objects and advantages achieved and of the construction by which they are attained, will be obtained from study of the preferred form of the anal catheter now to be described, together with its manner of use, in connection with the annexed drawing in which:

FIGURE 1 is a longitudinal sectional view of a post-operative hemostatic device made in accordance with the invention in its deflated condition;

FIGURE 2 illustrates the method of use of the catheter in an emplacement showing the same and portions of the anal anatomy in lateral section, dressings and packings which may be employed being omitted for clarity;

FIGURE 3 is an enlarged lateral section through the catheter taken along the line 3—3 of FIGURE 2 illustrating the relationship of the principal lumen and the internal inflating duct for the endmost cuff.

As shown in section in FIGURE 1, the novel anal catheter comprises a principal tube or lumen 10 formed of suitably compliant surgical rubber or the like and having an outer discharge terminus 11 disposed at a distance of not more than two inches from the juncture 12a of a first or exterior cuff or balloon 12 which surrounds the tube and extends along the length thereof to an inner terminal juncture 12b at which there commences a medial bridging span 10x of the tube, the other end of said span terminating at the juncture 14a of a second cuff 14 identical to the first one and having its opposite juncture 14b with the tube substantially coincident with the inner terminus or mouth 10w of the tube, so that this latter cuff juncture is smoothly confluent with the peripheral margins of the mouth of the tube in order to present a substantially uninterrupted surface which will not be irritative of the mucosa of the rectum while at the same time presenting a maximum vent or opening of the lumen to ingress of matter from the rectal passage.

It will be recognized that the device as thus far described bears similarity to a type of catheter used in prostate surgery, except that such latter catheters usually have a closed, moderately blunt rounded nose at the leading end and the inlet venting is situated on the side-wall of the tube, whereas in accordance with the present invention the main lumen of the catheter tube is fully open at its leading end to present an axially-directed inlet of maximum cross-sectional area, and the tube at this end merges confluent into conjunction with the end of the appertaining cuff for the reasons previously stated.

Separate inflating ducts are preferably provided for each cuff, a first duct 13 communicating into cuff 12 at junction 12a, while a second duct 15 enters the main lumen or tube in the same region but on the opposite wall thereof from the first duct where it becomes an integrated internal lumen 16 extending into communication with the second cuff 14 in the region of juncture 14a of the latter.

The cuffs are of substantially identical dimensions and wall thickness so that they tend to assume roughly identical compliant more or less spherical configurations when

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properly inflated and unconfined, a volumetric capacity of about 30 cc. being suitable for each cuff to cause the same to balloon to a maximum diameter of approximately one and one-half inches responsive to injection of fluid, usually a liquid such as water or a normal saline solution. Inflation may be effected by any suitable means, preferably by manual operation of a syringe having a similar displacement so that each cuff can be filled, as required in each case, with around 25 or 30 cc. of liquid displaced by a single manipulation of the plunger.

In normally expanded condition, the cuffs 12 and 14 may be regarded for descriptive purposes as having a spheroidal contour and as being respectively penetrated by the main lumen 10 through their ends or juncture portions, it being noted that the juncture 14b for the internal cuff 14 coincides with the inlet end or mouth 10w of the tube, which has been especially contrived, as stated, to present a smoothly confluent surface for exposure in the rectum, and while the inflated cuffs have been illustrated as substantially spherical in shape, in practice they will normally assume contours which are in general far from this exact shape, the free shape of the balloons being of little importance because of the ready deformation which occurs in actual use.

While the majority of post-operative applications of the catheter will involve the use of some form of packing or dressing, the emplacement illustrated in FIGURE 2 omits the same for purposes of clarity, and shows the catheter with both cuffs inflated and the ducts 13 and 15 closed off by small screw clamps 17, the outer cuff 12 being ballooned between buttocks 25 with the inner junctional portion 12b thereof pressing firmly against the posterior aspect of the anus, while the inner cuff is ballooned within the rectum 27 with its junctural portions 14a bearing against the anterior aspect of the anus, the short anal bridging span 10x of the lumen, which is exteriorly free of any additional interconnection between the cuffs, lying in the anal canal and being sized circumambiently by muscular action of the internal and external sphincters 23 and 29, respectively, so that escape of matter from the rectum is substantially blocked by this action. Contact of such matter with the zone of the operation and dressings, where used, is likewise prevented, owing to the compliant pressures of the balloons against the adjoining areas, as a result of which the operative situs lying within the zone of opposite compressive force of the balloons is substantially isolated from the rectum without cutting off egress to gas, liquid, or other body wastes.

It will be seen that the compressive force exerted by the spaced balloons acts mainly in the direction of the axis of the catheter which produces a much more satisfactory degree of hemostasis than results from the mere radial pressures produced by the prior methods of building up packing around a cannula or drain tube, at the same time securely holding the catheter in proper position.

While inflatable catheter implements are known in the art in a variety of forms, such as the Penrose drain, Whipple tube, Foley tube, and multiple-bladder type catheters used for blockage draining and anesthesia in genito-urinary practice and proctology, such devices are not, as previously mentioned, suited to the particular purposes nor capable of the functions or results of the disclosed anal catheter, nor adapted to the practice of the post-operative ano-rectal technique described with particular regard to the degree of hemostasis produced. For present purposes it is required for best results, for instance, that the distance Z (FIGURE 1) from the trailing end or discharge terminus 11 to the juncture 12a of the first cuff should not be over two inches, and is accordingly substantially shorter than the portion bearing the cuffs. The distance along the bridging span X between the cuffs should be no longer than the length of a normal anal canal, i.e., not longer than $\frac{3}{4}$ inch, and

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the junction of the spheroidal surface of the inner cuff and the fully vented mouth 10w of the main lumen should be confluent and smoothly merging for the reasons set forth.

The technique preferred in applying the catheter includes passing the leading end, properly lubricated, into the rectum with both cuffs deflated, inflating the inner cuff to the desired size in the manner explained, then retracting the catheter to seat the inner cuff firmly against the innermost aspect of the anus, and thereupon inflating the outer or remaining cuff to effect the described compressive seizure, the degree of pressure exerted being readily sensed in the operation of the syringe. Dressings or packing may be utilized as desired in each particular case, a dressing of gauze normally being applied over the outside end of the hemostatic device, with the outer end 11 terminating therein, so that non-gaseous wastes may be absorbed, such dressing being periodically replaceable, if desired, without substantial disturbance or interruption of the hemostatic action. It will be observed that the employment of the more or less balanced balloon structures acts to properly position the tube as the outer balloon is inflated, and also to accommodate or compensate for variations in length of the anal canal and configuration of its ends.

Although most embodiments of the invention will have general resemblance to that illustrated and described, modifications in appearance and details will readily be made without departure from the basic teachings of the invention. Accordingly, the scope of the protection to be afforded the invention should not be limited to the embodiment herein described, but should extend to all structures described in the appended claims, and equivalents thereof.

What is claimed is:

1. An anal compression catheter for post-operative use in ano-rectal surgery comprising an elongated lumen of compliant material of the class of rubber and having a leading inlet end and a trailing discharge end, and further having a pair of circumambient, independently inflatable cuffs joined thereto in axially-spaced juxtaposition separated by a short anal bridging span of the lumen which is substantially of the length of the anal canal and substantially free of further external connection of the cuffs, a first one of said cuffs terminating in smoothly-merging confluence with the peripheral margins of said leading end at the inlet to the lumen, said inlet end being fully vented to present a wide mouth opening having the cross-sectional area of the lumen itself, the second one of said cuffs being inward along the axis of the lumen from the opposite discharge end thereof, and separate duct means communicating with each cuff from locations internal of the lumen and respectively emerging from the lumen in the discharge end portion thereof, the trailing discharge end portion being of shorter length than the portion bearing the cuffs.

2. A device of the class described comprising an elongated tube of soft rubber or the like open at opposite axial ends respectively constituting the trailing and leading ends of a catheter, the opening at the leading end venting axially of the tube and being of the same cross-sectional area as the remaining bore thereof; a first inflatable cuff surrounding and joined to said tube with one of its margins substantially coinciding with the circumferential margins of said leading end and the opening thereof; said first cuff having a remaining margin joined to the tube and spaced a predetermined distance axially inward of said first margin thereof; a second inflatable cuff of similar dimensions to the first and likewise disposed circumambiently of the tube a short distance spaced along the tube from the proximate margin of the first cuff in a direction toward said trailing end thereof, that part of the tube intervening in the space between the two cuffs being an anal span of a short length adapted to lie in the anal canal between the anterior and posterior aspects of the anus

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and being substantially the sole exterior interconnection between the cuffs; the second cuff having a terminal margin disposed at a certain location on the tube which is at most two inches from said trailing end thereof, the trailing portion of the tube being shorter than the portion bearing the cuffs; and duct means communicating into said cuffs for admitting inflating fluid thereto, said cuffs when inflated to a predetermined volumetric displacement respectively forming enlarged deformable balloons each of which bears against the anus at one end of said canal whereby to exert a compliant compressive effort against the anus to produce hemostasis by pressure exerted in a generally axial, rather than a radial, sense.

3. In a device for post-operative hemostasis comprising a flexible tube having inner and outer ends, longitudinally inner and outer balloons surrounding the tube, and conduit means for inflating and deflating the balloons from the region of the outer end of the tube, the improved construction for use in anal surgery having the termination of the inner end of the tube substantially flush with the inner end of the inner balloon and having the termination of the outer end of the tube a maximum of two inches from the outer end of the outer balloon, said outer end being shorter than the portion bearing the balloons, the balloons being spaced by a maximum distance of three-quarters of an inch and the tube being exposed in this space, whereby the balloons may be inflated at opposite ends of the anal canal to aid in the production of hemo-

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stasis therein and at the same time position the tube for free egress of body-function products.

4. A device for post-operative anal hemostasis comprising a flexible tube having substantially full axial openings at the inner and outer ends, a balloon surrounding the inner end portion of the tube and having its inner end terminating at substantially the inner end of the tube, a second balloon surrounding a portion of the tube slightly spaced from the first balloon, the tube being substantially exposed in this space, the tube extending outwardly from the outer end of the second balloon a distance substantially less than the length of the portion of the tube bearing the balloons, and outwardly extending conduit means for inflating and deflating the balloons.

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