RETRACTOR FOR SURGICAL OPERATIONS ON THE ARTERIA HAEMORRHOIDALIS

DESCRIPTION

In order to effect ambulatory operations on the haemorrhoids, without anaesthesia, it is known the use of the device described in the U.S. patent No. 5 570 692, which comprises a retractor tube closed on the end which is inserted in the anal cavity and opened on the external end, which is provided with a gripping handle. The retractor tube is provided on its lateral wall, at a short distance from its closed end, with an ultrasonic probe to detect the blood flow of the haemorrhoidalis artery and is provided near to the probe, with a lateral window through which may be detected and observed the portion of the anal mucosa upon which it must be operated for the ligature of said artery, for example by means of a curved needle or by means of cauterisation. The closed end of the retractor tube, may be illuminated by a luminous source housed in said end and connected to feeding means provided in the handle, together with the feeding means of said probe. This device, for the reason that incorporates the ultrasound probe and that houses the luminous source in its closed end, presents elevated production costs, so that it is not possible to propose the same as a disposable product, with all the drawbacks and the limitations deriving by this fact.

Object of the invention is to obviate to these and other limits of the known prior art, with a disposable device, for the realisation of which it has been necessary to resolve some technical problems connected with the removable housing in the same of the ultrasonic probe and other problems related to the means for the illumination of the lateral window for the exploration of the anal mucosa. The first of said problems has been solved providing in the retractor tube a longitudinal seat, closed toward the interior and opened with the end toward the outer end of the same tube, in which seat it is possible to removably house an ultrasonic probe which partially projects through a longitudinal opening of the retractor tube, to result in contact with the anal mucosa. The ultrasonic probe is preferably inserted and hygienically protected in a sterile, disposable and easily removable sheath, having a suitable conformation, in

such a manner that the same may be reutilized repeatedly in other disposable devices of the type which is referred to. Immediately downstream of the seat with the ultrasonic probe, there is provided the window for the exploration of the anal mucosa. To solve the problem of the illumination, it has been used the technique of the back illumination, known in the proctoscopies, which provides the movable insertion of a luminous source in the handle of the device. Instead of the use of curved light guide means, realised for example with optical fibre or with a bar of plastics, connected with one of their end to said luminous source and oriented with the other end in the field of view defined by the internal cavity of the retractor tube, as described for example in the Italian patent No. 1 234 169, in the device according to the invention are utilised curved means to reflect the light inside of the retractor tube, with the advantage of a better luminous yield and with the advantage that such devices result distant from the internal surface of the same retractor and can not be soiled and blinded by the physiological liquid which unavoidably is produced by the anal cavity during the operation which is referred to.

These and other features of the invention, and the advantages deriving therefrom, will appear better evident from the following description of a preferred embodiment of the same, made by way of non-limiting example, with reference to the figures of the attached sheets of drawings, in which:

- Figure 1 is a perspective view of the device without the ultrasonic probe and without the illumination source;

- Figure 2 shows the device in lateral elevation, decomposed in the pieces which compose it and with the illumination source placed between the two portion of the handle in which the same is inserted;

- Figures 3 and 4 show the device respectively in plan view from above and in plan view from the bottom;

- Figure 5 shows the device assembled and sectioned along the line V – V of Figure 2;

- Figure 6 shows further details of the device sectioned along the line VI – VI of Figure 5;

- Figures 5a and 6a show embodiments of the device respectively viewed as in the preceding Figures 5 and 6;

- Figure 7 shows the device of the Figure 5a according to a view of the front toward the operator.

From the Figures it is noted that the device comprises a substantially cylindrical tube 1 having the function of retractor, closed at its terminal end 101 which is opportunely tapered and rounded, and on the contrary open on the initial end 201 which has a conical shape and which is outwardly divergent. Merely by way of example, the body 1 may have an external diameter which is comprised between 2,5 and 3,5 centimetres, for example of about 3 centimetres, an may have a general length comprised between 10 and 12 centimetres, comprehensive of the divergent end 201 which has alone the length of about 2 centimetres. However, it is to be understood that the device may be realised with dimensions which are different to the indicated dimensions, in order to comply with different use requirements. The conical end 201 is outwardly projecting with a portion having a substantially triangular plan 301, having a length of some centimetres, provided in its center line with a longitudinal and channel-shaped rib 401, outwardly convex, which has prevalently the function to increase the resistance to the bending and torsion stress of said appendices 301 and to partially define the duct along which will be effected the reflection of the light for the illumination of the working zone. The appendix 301, which has for example an inclination of about 30° with respect to the longitudinal axis of the body 1, integrally connects to said body an elongated shell 501 realised with a suitable ergonomic shape for the function of gripping handle, having for example a length of about 10 centimetres and which is forming with the axis of said body 1 an internal angle of about 105°. It is to be understood that also these last dimension data of the device are merely indicative and that the same may be widely modified. The connecting zone of the shell 501 to the appendices 301, is suitably curved. Upon the shell 501 there is placed and fixed with the male-female fixed coupling portions 2, 2', a complementary shell 501' which completes the formation of the gripping handle M and which is superimposed to the ribbed portion 401 of the appendix 301, with a

terminal portion 601 having the shape of a channel, which is connected to the same shell 501' with a suitable curvature, which ends in the connecting zone of the conical portion 201 to the cylindrical portion of the tube 1 and then in the internal portion of said tube which appears through the same conic mouth 201. The portion 601 realises with the portion 401 a tubular duct C which at least from the outside presents a flat shape also for the presence of lateral ribs, in such a manner to result with high features of resistance to the bending and to the torsion. In the conjunction zone of the shell 501 to the channel 601, there is provided a step 11 raised toward said shell, suitable for leaning the thumb of the hand which grasps the handle M, to ensure a steady grasp of the same handle and to facilitate in absolute the use of the device.

In the conjunction zone of the unit of the handle M to the appendix 301, inside of the two complementary shells which define the same handle, are obtained the two complementary portions of an annular seat 3 in which can be placed a small disk 4 made of transparent material, which realises a division barrier between the internal and absolutely sterile portion of the instrument, from the internal and hollow portion of the handle, in which is inserted and retained for example by means of friction, the end of the illumination optical waveguide F, of the known type, which may be not subjected to sterilisation treatments. The small disk 4 may have, if required, optical functions and may be made by means of a lens suitable to focalise the light on a reflection parabola 5 which covers the internal surface of the portion 601 of the duct C and which can be, for example, realised in a very economical and reliable manner, with an electrochemical metal spray coating of chrome. The advantages deriving from the backlight system described, with respect to the known systems which use light guides, are represented by a better luminous efficiency and especially by the fact that the same illumination means may be not blinded by the organic liquid which can come out from the hollow of the retractor tube, because the reflection parabola 5 remains raised from the path of said liquid, and because also in the most unfavourable condition shown in Figure 6, it is possible to foresee upstream of the small disk 3, on the ribbed zone 401, one or more drainage openings 6, suitably shaped, through which said organic liquid may freely come out. The device is

preferably realised with plastics of a changing white colour, to exalt the effects of the illumination inside the body 1. From the drawings, it appears that the retractor tube 1 is laterally provided with a longitudinal and rectilinear opening 7, for example with a rectangular shape, which begins in the zone in which the end conic portion 201 is connected to the cylindrical portion of the same retractor 1 and which has a length which is about equal to the half length of the same retractor. In the example which is referred to, the ideal plane in which lies the opening 7 is parallel to the center line plane of the device and the same opening is placed on the right side of the body 1 if the device is considered with the handle M downwardly oriented, but it is to be understood that said collocation may be diversified. It is not even excluded that the ideal plane on which the opening 7 lies, may be differently perpendicular to the vertical center line plane of the device, with the same window which results placed in the upper portion of the body 1 if the device is considered with the handle downwardly oriented, also to cause the terminal and internal portion of the body retractor, placed downstream of the zone interested by said opening, may be better illuminated by the beam which comes out from the reflection parabola 5. In fact, in said zone, the retractor body 1 presents a tapered and slightly flattened shape, as shown with numeral reference 701, in the initial portion of which is provided, transversally oriented with the greatest dimension, a window 8 for example with a rectangular shape, for example having the dimensions of centimetres 1 x 2, through which it will appears the anal mucosa which will be efficaciously illuminated by the above mentioned backlight means. The window 8 is distant from the outer end of the body 1, which is connected to the conical portion 201, of about 4-7 centimetres, for example of about 5-6 centimetres. In the zone which is comprised between the rear edge 208 of the window 8 and the rear side 107 of the openings 7, the body 1 presents internally and integral a flat division wall 9, which delimits inside the same body 1 a longitudinal chamber 10 open on the end toward the mouth 201 of the retractor and provided with the outer and lateral opening 7 above mentioned. In said chamber 10 is friction inserted a ultrasound probe, not illustrated, which will be realised with such shape to opportunely project from the opening 7, to result in

contact with the rectal mucosa. As said in the introduction of the present description, the probe may be contained in a thin sterilised, disposable and easily removable sheath, so that the same probe may be used several times in other disposable devices of the type which is referred to. The connection cable to the probe, will go out from the mouth 201 of the retractor and it may be temporarily fixed with an adhesive bandage on a side of the handle M. It is to be understood that the handle M and other portions of the device (see further) may be laterally provided with small loops having the shape of pincers, integral obtained upon the shells 501, 501' and suitable to temporarily support the cable of the ultrasound probe above mentioned. As appears from Figures 3-5, the window 8 lies on a terminal portion of the retractor tube which is slightly flattened and in recess and the rear side 208 of said window is connected with an inclined plane 801 with the lateral surface of the retractor. The forward edge 108 of the window 8 is then characterised by the fact that it is in relief and to have a slightly arcuate shape, with the convexity turned toward the outside. All these conditions allow to optimise the dilatation of the rectal tissues and contextually to avoid prolapse of the same inside the window 8, in such a manner that through said window the rectal mucosa presents itself in the better condition to operate on the same with the known and required means for the ligature of the arteria haemorrhoidalis, which can be identified with precision by means of the said ultrasonic probe.

The device shown in Figures 5a, 6a and 7 is different from the device previously described for the several features below considered. The window 8 is, for example, arcuate-shaped, is obtained on the retractor tube 1 substantially for half of its circumference, and has a length which is inferior to 1 centimetre, for example comprises between 8 and 5 millimetres. The inclined plane 801, placed immediately downstream of the window 8, is more wide and less inclined of that of the Figures from 1 to 5, and upon it there is localised the opening 7 which exposes the sensible portion of the ultrasonic probe S visible in Figure 7, in such a manner that this same portion results very close to the said window 8 and to the portion of the arteria haemorroidalis upon which the operation will be made.

The forward side 108 of the window 8 it is not in relief as in the previous solution, but it is lower with respect to the posterior side 208 of the same window and forms part of a flat portion 701' which is substantially aligned to the wall 9 for the delimitation of the chamber 10 housing the probe S, said portion being connected with a correct union to the remaining flat portion 701, in such a manner to form in the whole a flat portion with a sinuous profile and with a decreasing profile toward the rounded point 101.

Always from Figure 5a it appears that under the portions 701, 701' above mentioned, inside the body 1 is obtained a seat 12 having for example a rounded section and a conic shape, with a superior edge 112 slightly placed beyond the anterior edge 108 of the window 8, in such a manner to rest upon said edge and to insert in said seat, the terminal portion of a mandrel not shown, which holds the curved needle A with which will be made the ligature of the arteria haemorroidalis and that with the external end of the retractor tube 1 may be easily operated by the operator. The axis of the seat 12 is for example parallel and suitably displaced from the axis of the retractor tube 1.

From Figures 5a and 7 it is noted that the initial conic portion 201 of the retractor 1, is flattened on the side corresponding to the seat 10 for the housing of the probe S and on this side it carries a set of three appendices 13 upon which it is possible to firmly anchor the portion of the cable G which is near to the same probe.

From Figure 6 it is finally noted that the reflecting portion 5 is placed only in the terminal and rectilinear portion of the channel C, with an inclination of about 40-45° with respect to the longitudinal axis of the retractor 1, for example of about 43°. The terminal portion of the optical waveguide F for the illumination is now placed at a short distance from the reflecting surface 5, in such a manner to sensibly improve the illumination intensity of the internal cavity of the same retractor. The longitudinal axis of the terminal portion of the optical waveguide F inserted in the handle M, forms with the axis of the retractor 1 an internal angle of about 110°. Always from Figure 6a it is finally noted how the same terminal portion of the optical waveguide F results raised from the bottom of the channel C with the reflecting surface 5, for the presence of the

wide recessed portion 14 in the conjunction zone 401 of the handle M to the retractor tube 1, zone which may be provided with, if required, said drainage opening/s.

CLAIMS

1) Disposable device for surgical operations on the arteria haemorroidalis, of the type comprising a retractor tube (1) closed and rounded at the end with which is inserted into the anal orifice, which is provided upon its side surface with at least a window (8) through which there appears the rectal mucosa upon which the operation for the ligature of the artery will be made, which is provided with a gripping handle (M) integral with its external mouth and preferably diverging (201), through which it is possible to observe the tissue through said window and it is possible to insert in the tube the instruments required for the surgical operation, comprising means to illuminate said window and the mucosa which appears through this latter, characterised by the fact that said illumination means comprise a luminous source (F) fixed in removable manner inside said handle (M) and comprise at the level of the conjunction zone of the same handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (8).

2) Device according to claim 1, characterised by the fact that the means which provide to reflect the light supplied by the luminous source (F), comprise a specular parabola (5) longitudinally placed and in the portion raised from the bottom of a tubular channel (C) which connects the hollow portion of the handle (M) which houses said luminous source, to the external end of the retractor tube and which terminates at the interior of said tube.

3) Device according to claim 2, in which the tubular channel (C) which houses the reflection parabola (5) of the light, has at least externally a flat configuration which derives from a suitable reinforcement of the sides, in such a manner to result very resistant to bending and torsion.

4) Device according to claim 2, in which at least the high portion (601) of the channel (C) which houses the reflection parabola (5) is inserted and fixed upon the other portion of the same channel with the purpose to simplify the realisation and/or the installation of said reflecting parabola.

5) Device according to claim 4, in which the reflecting parabola (5) is realised with an electrochemical process of chromium plating of the internal surface of the high and inserted portion (601) of the channel (C).

6) Device according to claim 4, in which the high and inserted portion (601) of the channel (C) with the light reflecting parabola (5) is integrally obtained and with a connection opportunely jointed, with the upper shell-shaped portion (501') of the gripping handle (M), said portion being predisposed for example for the snap-coupling, by means of male-female appendices (2, 2') with the complementary inferior portion also shell-shaped (501) which completes the same handle (M) and which is integral with the longitudinally ribbed and outwardly convex portion (401) which forms the lower portion of the same channel (C) and which is obtained in an appendix (301) having a substantially triangular plan, with the sides which are tangent to the external edge of the conic mouth (201) of the retractor tube.

7) Device according to claim 6, in which the connecting zone of the upper portion (601) of the channel (C) with the internal light reflection parabola (5), to the upper shell (501') for the formation of the handle (M) presents a step (11) raised toward the said handle, upon which the operator can advantageously lean the thumb of the hand which grasps the same handle, to ensure a more steady grasp and a more easy use of the device.

8) Device according to claim 6, in which in the portion with which the two shells (501, 501') for the formation of the handle (M) are connected with the portions (601, 401) of the channel (C) which contains the light reflecting parabola (5) upstream of said channel, in said shells are obtained complementary portions for the formation of a seat (3) in which it is possible to house a small disk (4) of transparent material, which divides as much as possible in a tight manner said channel (C) from the seat of the handle in which is friction-fixed or in another removable manner the illumination source (F).

9) Device according to claim 8, in which the transparent small disk (4) may have optical functions, for example may be made by a lens which focalises on the reflection parabola (5) the light supplied by the luminous source F.

10) Device according to the preceding claims, in which the channel (C) with the light reflection parabola (5), presents an inclination comprised between 30° and 50°, for example 43°, with respect to the axis of the retractor tube (1), while the internal angle existing between the handle (M) and the axis of the retractor tube (1) is comprised between 100° and 120° and is for example of about 110°.

11) Device according to the preceding claims, characterised by the fact that it is formed with any suitable plastics of changing white colour, which facilitates the internal illumination of the retractor tube (1) and particularly of its lateral window (8).

12) Device according to one or more of the preceding claims, characterised by the fact that on the inferior portion (401) of the channel (C) which contains the light reflecting parabola (5) there may be provided at least one opening (6) to discharge outwardly the possible organic liquid which arrives by gravity to said opening and to avoid that such liquid arrives on the small disk (4) placed upwardly of the luminous source (F).

13) Device according to one or more of the preceding claims, in which the channel (C) which contains the light reflection parabola, presents in contrast to the same parabola, a wide recess zone (14) which leaves uncovered a portion of the end of the optical illumination fiber (F) which is placed at a short distance from the said parabola.

14) Device according to claim 1, in which the window (8) for the exploration of the anal mucosa, lies on an ideal plane which is substantially parallel to the center line plane of the same device and may be placed on the right or on the left of the retractor probe, if the same device is considered with the handle (M) downwardly oriented.

15) Device according to claim 1, in which the window (8) for the exploration of the anal mucosa, lies on an ideal plane which is substantially perpendicular to the center line plane of the same device and is placed upwardly if the same device is considered with the handle (M) downwardly oriented.

16) Device according to claim 1, in which the window (8) for the exploration of the anal mucosa has a distance from the end of the retractor tube which is

connected to the conic end (201), which is comprised between 4 and 7 centimetres, for example of about 5-6 centimetres.

17) Device according to claim 1, in which the window (8) for the exploration of the anal mucosa, lies on a flattened and in slight recess portion (701) of the lateral wall of the retractor tube (1) which is near to the rounded and closed end (101) of said tube, the rear side (208) of said window being rounded and connected with an inclined plane (801) with the lateral surface of said tube, while the forward side (108) of the same window is also rounded and suitably raised and presents an arcuate shape, the whole for a better disposition of the anal tissue for the exploration and for the operation through said window.

18) Device according to claim 1, in which the window (8) for the exploration of the anal mucosa is transversally obtained on the retractor tube and interests the same for about the half of its circumference, the rear side (208) of said window being rounded and connected by means of a wide inclined plane (801) with the lateral surface of said tube, while the forward side (108) of the same window it is rounded too, is opportunely lowered with respect to the said rear side and it is connected to flat portions (701', 701) which extend with a sinuous shape and with a decreasing profile toward the rounded point (101) of the retractor tube.

19) Device according to claim 1 characterised by the fact that inside of the retractor tube (1) under the lateral window (8) for the exploration of the anal mucosa, at a short distance and preferably at the level of its center line there are provided means (12) suitable to receive and to rotatably center the end of a mandrel which carries the curved needle for the ligature of the arteria haemorroidalis.

20) Device according to claim 19, in which said receiving and centring means (12) are constituted by a rounded section seat, placed with its axis parallel and with a correct distance from the axis of the retractor tube (1).

21) Device according to claim 20 in which said seat (12) has a conical shape and gets narrower toward the point of the retractor tube (1).

22) Device according to anyone or more of the preceding claims, in which the retractor tube (1) is provided in alignment with the exploration window (8) and,

upstream of this, with a small longitudinal, rectilinear and internal chamber (10) delimited by a baffle (9) which is integral with the internal walls of the tube and with the posterior side (208) of the window (8), the whole in such a manner that the chamber results opened toward the mouth (201) of said tube, there being provided that in said chamber (10) is friction-housed an ultrasonic probe (S) which is partially projecting through an opening (7) longitudinally obtained on the lateral wall of the retractor tube, in such a manner that the same probe results to be in contact with the anal mucosa.

23) Device according to claim 22 in which the lateral opening (7) through which is projecting the sensible portion of the ultrasonic probe (S) interests the inclined portion (801) which is converging on the posterior wall (208) of the window (8) for the exploration of the anal mucosa.

24) Device according to claim 22 in which the ultrasonic probe (S) may be hygienically protected in a sterile, disposable and easily removable sheat, to allow hygienic re-utilisation of the same probe.

25) Device according to one or more of the preceding claims, in which the side of the conic mouth (201) of the retractor tube is flattened on the side of the seat (10) for the housing of the ultrasonic probe (S) and carries appendices (13) having the function of loops to which it is possible to removably anchor the cable (G) of the same probe.

26) Device according to claim 25, in which the handle (M) may be provided on the side near to the ultrasonic probe (S) with appendices which realise small loops to which may be removably anchored a further portion of the multipolar cable connected to the said ultrasonic probe (S).