



sapi med

Products and systems
for coloproctology



LBet 88

A NEW APPROACH
TO HAEMORRHOIDS

SPTT - SINGLE PILE TAILORED TREATMENT

in partnership with Dr. Claudio Elbetti



INTRODUCTION: THE CLASSIFICATION OF HAEMORRHOIDS

A classification of haemorrhoids is useful in that it provides an adequate tool to both describe the disease and compare the results of various therapeutic procedures.

To date, despite the many attempts at proposing new systems, the most widely used classification is the one proposed by **Goligher**. However, haemorrhoids are extremely heterogeneous, and their variability is hard to reconcile with a classification that only takes into account the prolapse of internal piles, thus assigning the

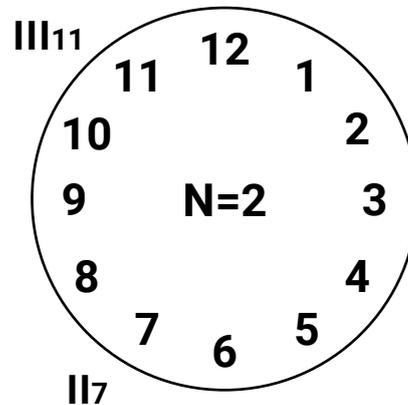
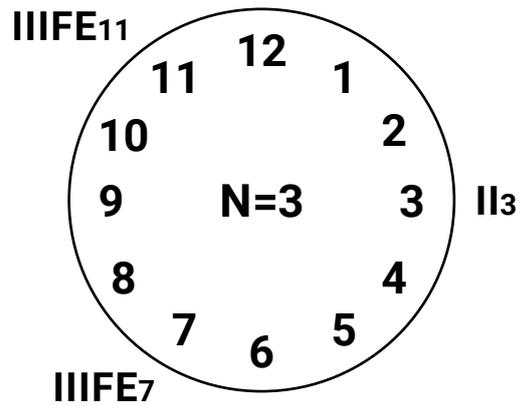
disease the severest grade of pathological piles. In fact, a patient with Goligher's 3rd grade haemorrhoids can present either one or more pathological piles, which can have a lower grade than the one with the greatest prolapse. Moreover, the fibrous, inelastic and redundant features of internal piles can be more or less enhanced, and there can also be an external pathological component, though such details might not be described in the classification.

Hence the need for a description of haemorrhoids that provides details of the characteristics of each pathological pile, both internal and external.

To achieve said goal, the **Single Pile Classification**:

- describes the number of piles (N) and the Goligher grade of each internal pathological pile;
- specifies the characteristics of the internal pathological pile (letter F, if it is fibrous, inelastic and redundant), and those of the external pile (letter E, if there is eversion of the pectinate line or congestion of the same; letter S, if there are any skin tags that are poorly tolerated by the patient);
- indicates the site of each pathological pile by using the watch dial with the patient in the lithotomy position.

NUMBER OF PATHOLOGICAL PILES 123456	LOCATION 	GOLIGHER'S GRADE OF EVERY SINGLE PILE I - II - III - IV	F if present	E if present	S if present



SINGLE PILE TAILORED TREATMENT

The use of the Single Pile Classification instantly underscores the remarkable variability of pathological haemorrhoids. The surgical method has been “customised” to appropriately approach the mentioned variability with surgical procedures tailored to meet the requirements of each haemorrhoidal condition.

Hence the Single Pile Tailored Treatment method, treatment that only envisages interventions on what is defined as pathological.

In detail, the surgical procedures proposed include:

- **1st-2nd grade without FES:** sutured anopexy with subsequent haemorrhoidopexy (4-5);
- **2nd-3rd grade with ES:** sutured anopexy and excision of the external component (6);
- **4th grade and 3rd grade with F:** haemorrhoidectomy according to Ferguson or Milligan-Morgan (7-8-9);
- **excision of the external component**, if it is the pathological component.

There are three tools available to solve all possible situations. The first three are known and have been included in Sapi Med’s catalogue for several years. They include:



A.4084 - The Beak Diagnostic

for 4th grade haemorrhoids, and for 2nd - 3rd grade haemorrhoids with FES



THE BEAK DIAGNOSTIC

- In outpatient or Day-Hospital.
.....
- **SURGICAL TECHNIQUE:** excision of external piles, haemorrhoidectomy according to Ferguson or Milligan-Morgan.
.....
- **ANAESTHESIA:** local according to Nivatvongs (10) on the pile to be removed, if single and the patient can tolerate the instrument diameter.



A.4086.1 - Gull

for 4th grade haemorrhoids and 2nd - 3rd grade with FES



• In outpatient or in Day Hospital; to check possible complications facilitating an easier access up to about 7 cm from anal edge

.....
 • **SURGICAL TECHNIQUE:** external piles excision, haemorrhoidectomy according to Ferguson or Milligan-Morgan.

.....
 • **ANAESTHESIA:** local according to Nivatvongs (10).



A.4083 - The Beak

for 2nd - 3rd - 4th grade haemorrhoids where piles are voluminous and a device with a bigger diameter is needed to perform the operation at best



THE BEAK

• In the operating room.

.....
 • **SURGICAL TECHNIQUE:** sutured anopexy, excision of external piles, haemorrhoidectomy according to Ferguson or Milligan-Morgan.

.....
 • **ANAESTHESIA:** local according to Nivatvongs, spinal or general perineal block.



A.4088 - LBet88

The fourth, the last-born into the Sapi Med family and identified by code A.4088, is the smallest of the four, and is called **LBet88**.

Studied and created in partnership with Dr. Claudio Elbetti, LBet88 allows to perform sutured anapexies even in the out-patient clinic, under topical anaesthesia or local according to Selvasekar (11).

This device offers the choice of selecting patients for outpatient or Day Hospital treatments.



LBet88

OUTPATIENT TREATMENT OR DAY SURGERY

Outpatient treatment is indicated for patients having up to 4 pathological piles in which at least two cutaneous wounds are present. This is to avoid the treatment of voluminous haemorrhoids with small diameter instruments and to reduce the post-operative pain, leading patients to go back home after 2 hours from surgery.

Candidate patients must not present important comorbidities (ASA I-II), must tolerate the proctological examination well, and must not report panic episodes.

Day Hospital treatment is, instead, indicated for:

- Patients with haemorrhoids that could be treated on an outpatient basis but who present contraindications for said type of treatment; in this case, outpatient devices or The Beak can be used.
- Perform anopexies when there are more than 4 pathological piles, or when more than two cutaneous wounds are present, using The Beak.

The usage of smaller diameter instruments leads to a minor traumatism and reduces the risks post-operative urinary retention.

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LBet88

CLOSED ANOSCOPE WITH WINDOW FOR SUTURED ANOPEXY OF HAEMORRHOIDS

DISPOSABLE AND STERILE



The surgical anoscope **LBet88** is designed to offer the proctologist a device that allows to perform sutured anopecty of haemorrhoids both in the outpatient clinic and in the operating room.

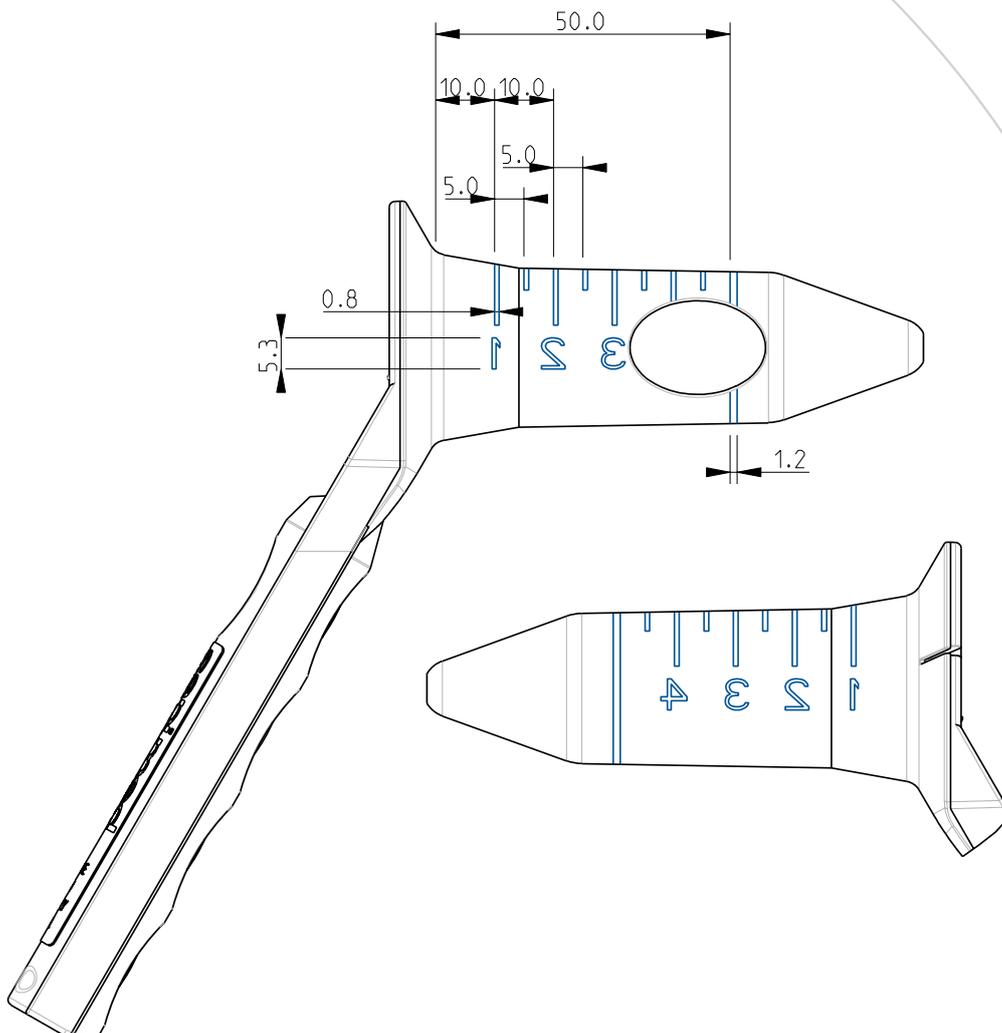
LBet88 is a closed tip surgical anoscope with approx. length 80 mm. As all Sapi Med anoscopes and retractors, it has a hollow handle that contains a fibre optic bar for lighting.

The handle and body of the anoscope are connected by a circular flange that, besides acting as an end stop, has a small slot on the left side to pass the tip of the suture thread to prevent it from falling on the surgical field.

The device has a cylindrical body with an elliptical window (approx. 20 mm) on the right side, through which surgery can be performed on the internally protruding mucous tissue. The window is approx.

35 mm apart from the flange to protect the pectinate line from the anoscope wall. Instead, on the left side there is a graded centimetre scale that is legible from inside the device.

The body of the anoscope ends with a closed conical tip that replaces the mandrel during insertion, and allows to maintain the surgical field free of any faecal residue that might be present in the rectal ampoule.



DIRECTIONS FOR USE AND SURGICAL TECHNIQUE

ANESTHESIA:

- **Topical** with instillation of about 10 cc of Lidocaine 2%, in the distal rectum. This can be performed if patient can well stand the instrument and has to be operated for 1 or 2 pexies.
- **Local** according to Selvasekar. The technique is made by performing 4 wheals of about 2 cc of anesthetic in the sub-mucosa right above the pectinate line using a normal diagnostic anoscope (A.4018 and A.4023) and a 22 Gauge spinal needle. These wheals are then squeezed with index finger to spread the anesthetic. The usage of Bupivacaine 3,75-5%. If a more anal relaxation is needed inject other 5 cc above flexor muscles at the back of the anal canal.

This technique showed up to be better than the topical anesthesia guaranteeing a better post-operative control and better home comeback for the patient. The anal relaxation and the analgesia obtained allow to use, when needed, bigger diameter instruments. The device is then connected to the light source, adequately lubricated and inserted into the anus-rectum with the surgical window facing the side where the pathological haemorrhoid to be treated is located. The presence of the conical tip makes the presence of a mandrel for insertion pointless. During said manoeuvre, the surgeon must insert the index finger into the anoscope to close the window and prevent mucous tissue from entering before the device is correctly positioned. After the device has been fully inserted, the surgeon ensures that the pectinate line is protected from the



device walls and cannot be touched in any way. Outward traction of perianal skin is required at times to restore the pectinate line to its correct position. At this point, exuberant mucous and submucous tissue, which will be the focus of sutured anopexy surgery, protrudes through the lateral window.

Anopexy is performed with Vicryl 2/0 absorbable sutures and 26 mm needle 5/8 (Ethicon). The needle is first passed near the marker that is on the device, 50 mm from the external anal edge. The stitch is tied after the second pass of the needle upstream of the previous one. Traction of the two ends of the suture thread allows another 1-2 passes towards the distal apex of the window, and the thread is tied once again. At this point the tip of the thread is placed in the slot present on the flange to prevent it from falling on the surgical field, and additional passes are performed with the needle, moving outwards until the external edge of the window is reached (3-4

passes). The suture is tied once again, anopexy is completed and the thread is cut.

To change operating position, never rotate the device but remove it and reposition it for the window to correspond to the new area to be treated, following the same method in order to avoid the risk of dragging mucous tissue. Hence, mucous tissue protrusion must be reduced with the index finger, the suture must be positioned outside the device and the window must be closed until the device has been completely removed from the anus.

The device can be cleaned without removing it during surgery by using a small piece of gauze, washing with physiological solution or using a suction device.

To remove the device, use the index finger to reduce protruding mucous tissue or the suture that is performed outside the device. The index finger must then keep the window closed until the device has been completely removed from the anus.

With an internal diameter that is wide enough to use the necessary instruments without being too invasive, LBet88 allows to perform sutured anopexy of haemorrhoids under local anaesthesia both in the outpatient clinic and in the operating room. The package contains: a silk-screened LBet88 anoscope with window, one knot pusher and 4 suture threads (Vicryl 2/0, 26 mm needle 5/8).



Available in the following versions:

- > **A.4088:** LBet88 closed anoscope with window and a knot-pusher.
- > **A.4088.4:** L-Bet88 closed anoscope with window, a knot-pusher, 4 Vicryl 2/0 suture threads and 5/8 needle of 26mm.

SPTT

SINGLE PILE TAILORED TREATMENT

Sapi Med devices are available for customised treatment for pathological haemorrhoids:

REF A.4083 – The Beak

Surgical anal retractor, self-illuminated.
Diameter: 32 mm.



REF A.4084 – The Beak Diagnostic

Diagnostic anal retractor, self-illuminated.
Diameter: 22 mm.



REF A.4086.1 – Gull

Opened retractor.
Diameter: 31 mm.



REF A.4088 – LBet88

Closed anoscope with window for sutured anopexy of haemorrhoids.
Diameter: 23 mm.





...every anus has its own story...

Betti Panduri Nurse

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