

applications

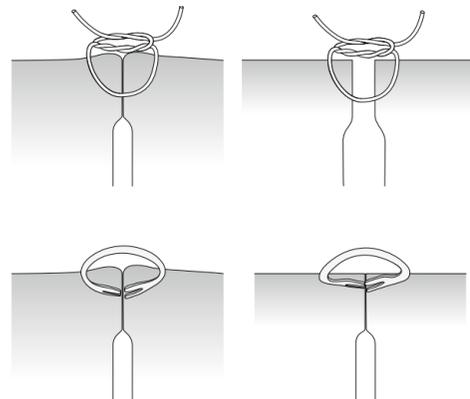
Background: Anorectal fistulas

Anorectal fistulas are abnormal tracts between the rectum or the anal canal and the perianal skin. Anal fistulas originate in most cases from an inflammation of anal glands, which are located between the two layers of the anal sphincter. The tract formed by this process is the anal fistula. Abscesses within the course of the fistulas can occur if they retain secretion, allowing the accumulation of pus. Pain and pus as result of anorectal fistulas can cause significant decrease in the patient's quality of life.

Surgical closure of anorectal fistulas often is a difficult challenge. Simple, superficial fistulas may be treated safely with fistulotomy. However, in high anorectal or complex fistulas fistulotomy is not an option because it will inevitably result in incontinence. The results of diverse fistula closure techniques, such as advancement flaps, fistulectomy and sphincter repair, fistula plugs, fibrin glue injection and other, vary widely with partly disappointing long-term outcomes. The use of the OTSC® clip overcomes the hypothesized insufficient closure of the internal opening of the fistula by sutures or by plugs: In contrast to knotted threads, the Nitinol® clip maintains a permanent compression on the internal fistula opening almost independently from the thickness of the captured tissue. Hence, the clip performs a dynamic and therefore more reliable closure of the fistula opening rather than a static and therefore potentially insufficient closure like sutures.

Principle of clip-tissue interaction in contrast to sutures

Closing of the internal fistula opening by sutures may result in re-opening of the fistula tract if the captured tissue shrinks and consolidates after surgery. In contrast to the static condition created by knotted threads, the OTSC® clip permanently adapts to the thickness of the tissue and maintains a consistent compression on the internal fistula opening. The superelastic Nitinol® characteristics and the design of the clip guarantee a permanent closure of the fistula opening during its healing process. Therefore, the clip performs a dynamic closure of the internal fistula opening rather than a static and therefore potentially inadequate closure like sutures.



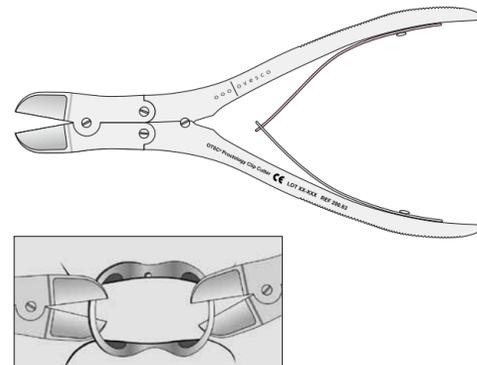
Clip removal

There are some circumstances when the OTSC® clip is advised to be removed:

- Intraoperative malplacement of the clip
- Unexpected discomfort or pain after surgery
- Dispensable clip after definitive fistula healing

In these cases the OTSC® Proctology Clip Cutter can be used for cutting the curved edges of the clip.

The resulting two halves of the clip can then be removed from the tissue and extracted transanally.



references

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3. Kirschniak A, Subotova N, Zieker D, Königsrainer A, Kratt T. The Over-The-Scope Clip (OTSC) for the treatment of gastrointestinal bleeding, perforations, and fistulas. *Surg Endosc*. 2011 Sep;25(9):2901-5.
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Educational scope:

In this booklet we offer information for health care professionals as an educational tool and in good faith. This information is offered without warranty of any kind although it has been thoroughly reviewed and is considered to be useful and precise at the time of publication. The authors and manufacturers shall not assume responsibility for any loss or damage arising from its use. We refer to the Instructions for Use coming with each device containing valid directives.

Other clinical bulletins

- OTSC® in GI hemostasis
- OTSC® in GI perforation closure
- OTSC® in GI fistula closure
- OTSC® in the treatment of bariatric surgery complications



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the OTSC® Proctology

OTSC® clip application is an established procedure for treating fistulas and anastomotic leaks in the digestive tract¹⁻⁶⁾. Now OTSC® is also available for proctology⁷⁾.

- Rapid, minimally invasive, surgical procedure
- Easy transanal clip application by ergonomic one-hand operated instrument
- Closure of anastomotic leaks
- No relaxation or rupture of sutures

These features and therapeutic functions of the system are based on material selection and design: the superelastic Nitinol® is biocompatible and, if needed, even suited and approved to be applied as a long-term implant. The dynamic tissue compression enabled by the superelastic material adapts to thickness and texture of the tissue grasped and readjusts depending on the actual requirements of the situation/tissue. This avoids overcompression and at the same time ensures constant pressure delivery to the tissue which makes it also most suitable for the treatment of anorectal fistulas and anastomotic leakages.

The use of the OTSC® Proctology system is based on a special handheld applicator device for transanal use. In addition, for support of the application two accessories are available: the OTSC® Fistula Brush for debridement of the fistula tract and the OTSC® Proctology Anchor for alignment of the internal fistula opening with the applicator cap.

OTSC® Proctology with clip and applicator and accessories



modes of application

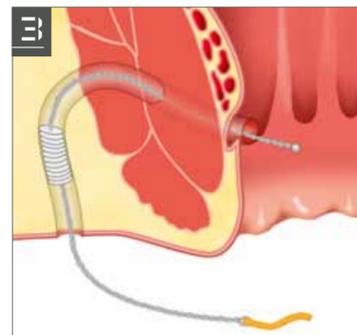
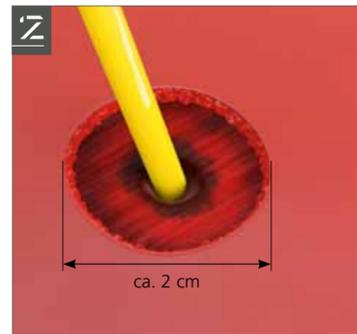
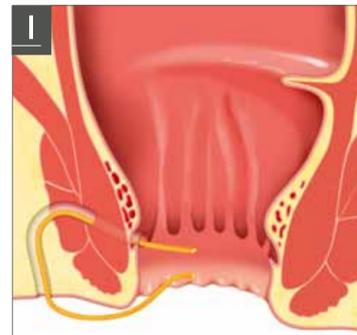
Clinical application

I Before application of the OTSC® Proctology it must be guaranteed that no abscess or major infection has developed in the course of the fistula. This can be achieved with the placement of a seton drainage at least three months before clip application.

The technique of clip application depends on the application site within the anorectum: unlike the anal canal, the rectum is not supplied with somatosensory nerves and therefore not subject to pain.

2 To avoid that the clip will be applied on the very sensitive anoderm rather than on the stable sphincter muscle, a circular area of anoderm about two centimeters in diameter around the internal opening of the fistula is excised. In the rectum, this preparation is not required.

3 For fistula preparation the special brush can be used to remove all of the granulation tissue lining the fistula tract. Therefore the seton for drainage is attached to the lug of the brush for simplified insertion of the brush. After debridement of the fistula tract by alternating movements of the brush, the tract is rinsed with saline. The shaft of the brush can be left in place to indicate the internal opening of the fistula.



4 Two resorbable U-shaped sutures of a minimal length of 90 centimeters are placed through the sphincter muscle centering the internal opening of the fistula in a cross-like fashion.

5 The sutures are knotted at their distal end to allow them to be pulled through the working channel of the clip applicator using the Thread Retriever (included in OTSC® Proctology delivery).

6/7 By holding the sutures under slight tension, the preloaded clip applicator is advanced towards the internal opening of the fistula. The applicator has to be parallelly aligned to the axis of the anal canal to achieve an anatomical orientation of the bent clip within the anorectum. The applicator cap is then brought in stable contact with the exposed sphincter muscle around the opening of the fistula. After deactivation of the safety-lock, the clip is released.

8 If performed correctly, the applied clip closes the internal opening of the fistula by digging its teeth into the sphincter muscle and compresses the proximal fistula tract. If the sutures have guided the clip applicator appropriately, the sutures must be seen in the center of the captured tissue within the clip after removal of the applicator. They can either be knotted for additional closure of the fistula or cut off.

