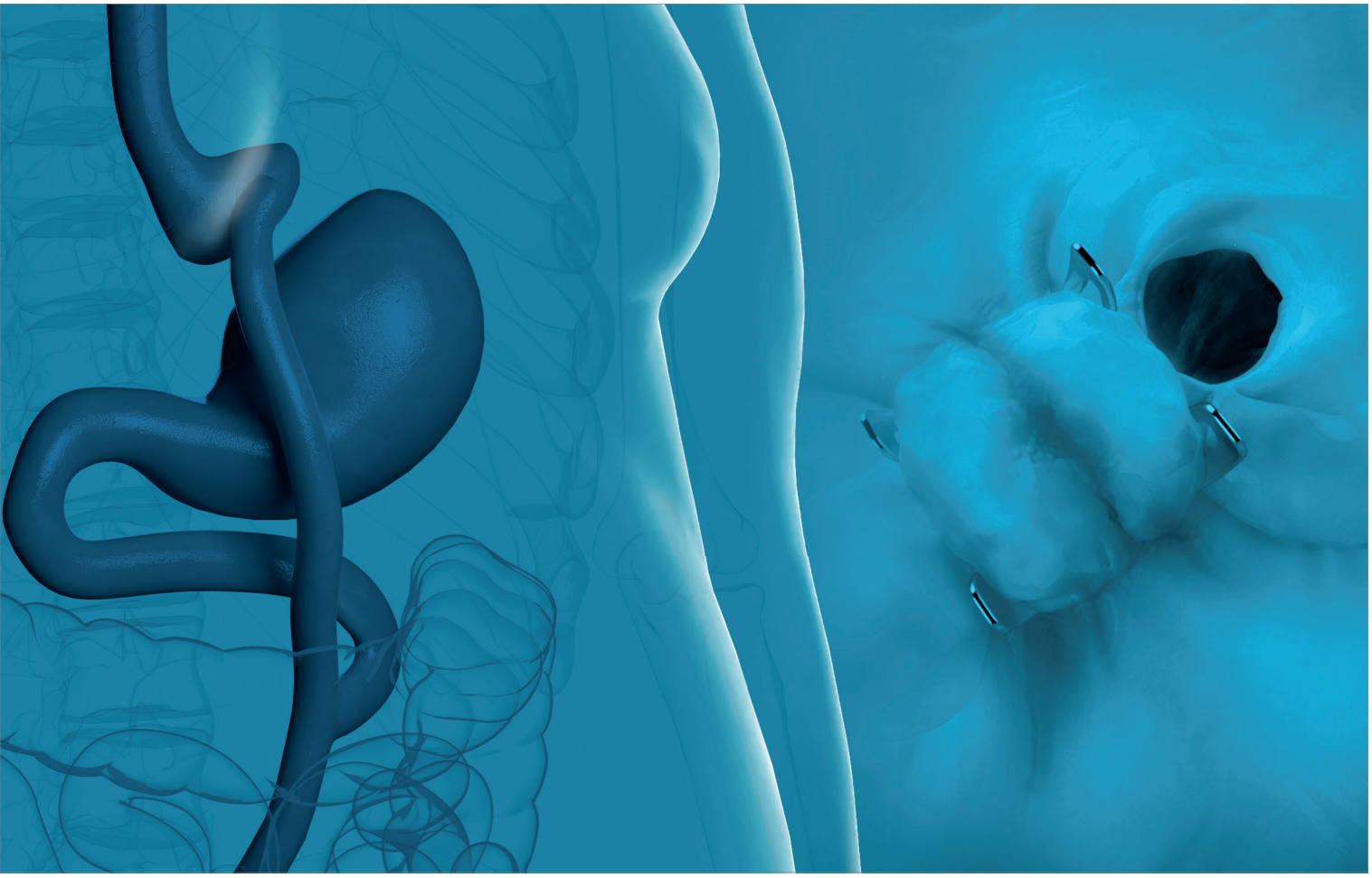


clinical bulletin

BARS®

for endoscopic anastomoses treatment and lumen reduction

OTSC® and stentfix OTSC®

for complication management in patients after previous bariatric interventions

BARS®, OTSC® and stentfix OTSC®

The systems described here constitute a **special class of endoscopic clips**. They consist of a transparent application cap with mounted clip, release thread and a hand wheel for clip application.

BARS®

More information on the BARS®

The **BARS®** (ref. no. 100.60) is based on the well-established OTSC® System and facilitates **endoscopic lumen reduction** in contexts such as anastomosis treatment, e.g. after bariatric procedures.

Specifics:

- **Complete treatment unit** for endoscopic lumen reduction
- **Two additional working channels** enable the simultaneous use of three application aids with conventional single-channel endoscopes
- **Includes application aids** for bringing together the opposing sides of the anastomosis (2x BARS® Anchor) and balloons for safe insertion (Insertion balloon) and defining the diameter of the remaining lumen (Space keeper balloon)

BARS® Set auxiliary instruments

Insertion balloon with guide wire

Space keeper balloon with BARS® Anchors

Applications:

- Anastomoses treatment and lumen reduction, e.g. of enlarged anastomoses that can occur after previous bariatric interventions. Enlarged anastomoses following Roux-en-Y Bypass (RYGB) are often associated with dumping syndrome or weight regain

OTSC® System

More information on the OTSC®

The **OTSC® System** (ref. no. 100.01–100.14 and 100.27–100.31) is a clinically proven clip system used in a **variety of indications** in flexible endoscopy.

Applications:

- Treatment of mucosal and submucosal defects, e.g. anastomoses leaks and fistulas after previous bariatric intervention
- Treatment of anastomotic bleeding

stentfix OTSC® System

More information on the stentfix OTSC®

The **stentfix OTSC® System** (ref. no. 100.50) is an OTSC® System that has been designed especially for the fixation of endoscopic stents in the gastrointestinal tract.

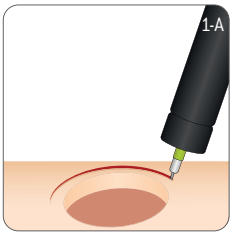
Applications:

- Fixation of metal stents (SEMS) that are used to treat complications following previous bariatric procedures, e.g. leaks

Application techniques

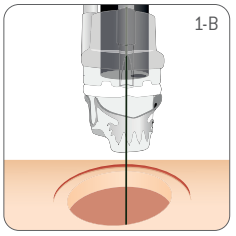
Practical use of the BARS®

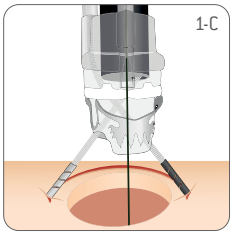
Before use, it is recommended that the target tissue is prepared for the clip, e.g. by means of a mucosal incision (fig. 1-A). This enables a more secure hold for the BARS® Anchors in the muscular (submucosal) layer of tissue. In addition, the fresh lesion encourages the gathered tissue to grow together, thus supporting the long-term result.

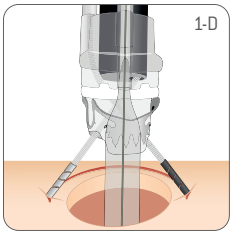


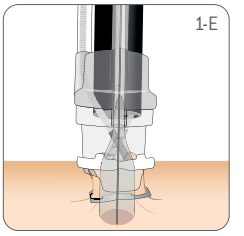
Anastomosis reduction

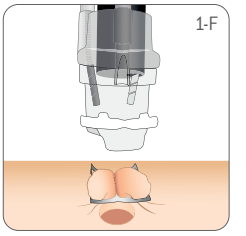
1. Guide the endoscope through the anastomosis. Insert the Space keeper balloon via the guide wire, position behind the anastomosis and inflate with max. 3 ml of fluid. Withdraw the endoscope and position it in front of the anastomosis (fig. 1-B).
2. Insert both of the BARS® Anchors into the respective working channel and place them so that they are crossed over each other on the target tissue (fig. 1-C).
3. Gradually pull tissue towards the application cap using alternating pulling motions. Withdraw the Space keeper balloon until it touches the working channel opening. Check whether the Space keeper balloon is correctly positioned in the lumen, has opened properly and is completely dilated (fig. 1-D).
4. Pull the tissue into the application cap using alternating pulling motions. Make sure that the tissue is positioned symmetrically in the cap. Secure the anchor to the endoscope handle and apply the BARS® clip by rotating the handwheel (fig. 1-E).
5. Withdraw instruments and inspect the clip application site (fig. 1-F).









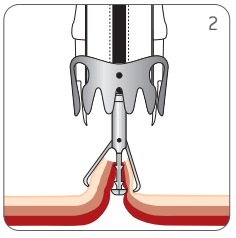


Practical use of the OTSC® and stentfix OTSC®

Perforation/leakage closure

The **OTSC® Twin Grasper** can be used for perforation closure:

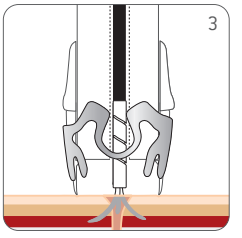
1. Grasp the perforation edges with the OTSC® Twin Grasper and retract into the OTSC® cap (fig. 2).
2. Secure the instrument and apply the clip.



Fistula closure

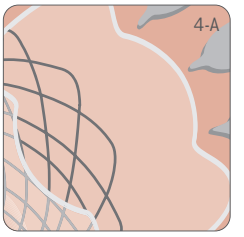
Fistula closure is carried out using the **OTSC® Anchor:**

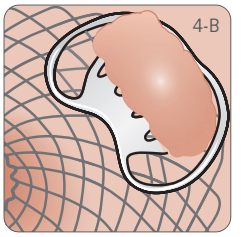
1. Fix the OTSC® Anchor to the fistula opening and retract it into the OTSC® cap (fig. 3).
2. Secure the instrument and apply the clip.



Stent fixation

1. Align the rows of teeth on the **stentfix OTSC®** clip parallel to the stent opening (fig. 4-A).
2. Place 1/3 of the cap on the stent mesh and 2/3 on the tissue.
3. Use suction to mobilise tissue into the stentfix OTSC® cap and apply the clip (fig. 4-B).





Clinical evidence

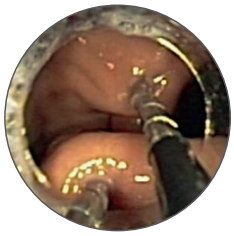
Treatment of weight regain after gastric bypass I

Initial experience with the OTSC® System in lumen reduction after gastric bypass

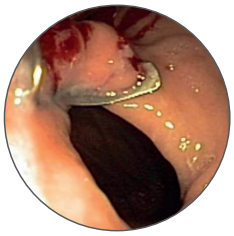
The OTSC®, which is a proven system for a range of indications, has also demonstrated a high degree of clinical efficacy and safety in the reduction of enlarged anastomoses after RYGB associated with weight regain. Based on these promising results, the BARS® was developed as an optimised system for anastomosis reduction.

As early as 2010, Heylen et al. reported on the use of the OTSC® System for **endoscopic lumen reduction** following bariatric procedures for the first time[1]. A total of 94 patients (19 men, 75 women) who had regained weight more than two years after a gastric pass received treatment with the OTSC®.

The edges of the anastomosis were mobilised using two OTSC® Anchors, which were inserted simultaneously via a double-channel gastroscope (fig. 5). The location of the clips and gastrointestinal patency were monitored using a contrast agent; gastroscopy was only performed where clinically necessary.



Endoscopic grasping of the edges of an anastomosis using two OTSC® Anchors



Successful anastomosis reduction using OTSC®

Figure 5: Use of the OTSC® System for endoscopic lumen reduction following bariatric procedures[1].

The application of the OTSC® clip enabled a successful reduction of the pouch-outlet in all patients. On average, the **gastric outlet** was **reduced by** more than **80%** (reduction of the mean anastomotic diameter from 35 mm (range: 21–48 mm) to 8 mm (range: 3–21 mm)). The **average procedure** time was **35 minutes** (range: 15–100 min). At the time of the gastric bypass operation, the average BMI was 45.8 (±3.6), which was significantly reduced by the operation. However, as a result of the progressive dilatation of the gastrojejunostomy, weight regain occurred. The patients regained at least 10% in weight. The **OTSC® treatment** was carried out at a mean BMI of 32.8 (±1.9) (fig. 6). As a result of the lumen reduction with the OTSC®, **BMI decreased** to an average of 29.7 (±1.8) within approx. three months (1st follow-up). The mean BMI was 27.4 (±3.8) around a year after lumen reduction with the OTSC® (2nd follow-up). There were no major complications.

The authors concluded that the endoscopic treatment of a dilated pouch outlet with **OTSC®** is **reliable** and **effective** with favourable short- and midterm results. Symptoms associated with the enlarged anastomosis such as weight regain were ameliorated following the anastomosis treatment with OTSC®. Based on the results described by Heylen et al. BARS® was developed for the reduction of enlarged anastomoses.

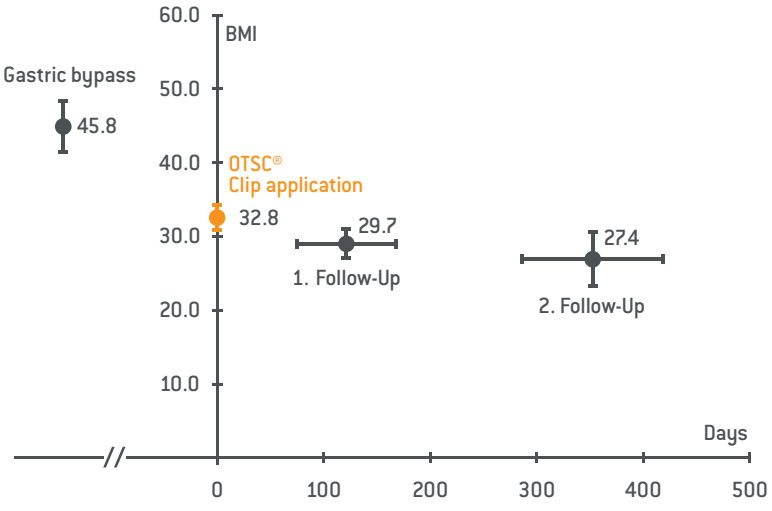


Figure 6: Progression of the BMI following gastric bypass, at the time the OTSC® clip was applied and at the two follow-up examinations approx. 3 months and 1 year after the endoscopic intervention[1].

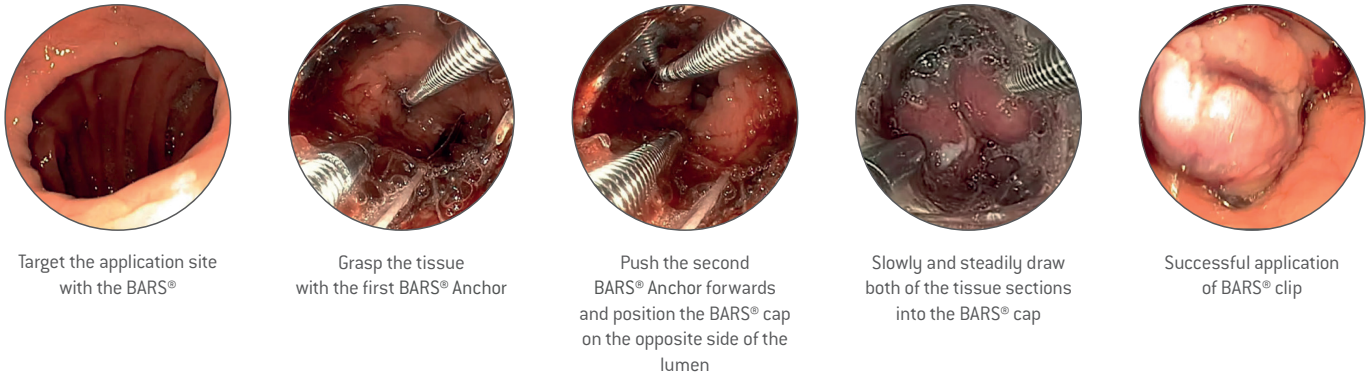
Clinical evidence

Treatment of weight regain after gastric bypass II

The BARS® procedure – the minimally invasive treatment method for lumen reduction and anastomosis treatment

In clinical use, BARS® demonstrates a high level of user-friendliness and safety.

The **first** scientific **description** of the **BARS® System** (Di Lorenzo et al.[2]) included a **case series** of six patients who had regained at least 15% of their weight following a previous gastric bypass operation. All patients had an enlarged gastrojejunostomy (>20 mm). Treatment with BARS® was performed approximately 8 years (range: 4–13 years) after gastric bypass surgery. The patients (average age: 49 years) regained an average of 18.7 kg (range: 15–40 kg) of their lowest weight after gastric bypass. At the time of anastomosis treatment with BARS®, the average BMI was 40.3 kg/m² (range: 36.4–42.6 kg/m²). The BARS® procedure's clinical application steps are described in figure 7.



Target the application site with the BARS®

Grasp the tissue with the first BARS® Anchor

Push the second BARS® Anchor forwards and position the BARS® cap on the opposite side of the lumen

Slowly and steadily draw both of the tissue sections into the BARS® cap

Successful application of BARS® clip

Figure 7: BARS® sequence for endoscopic anastomosis treatment and lumen reduction[2].

In all six cases, the **clip** could be **placed correctly** and **no complications** arose (tab. 1). The mean procedure time was 52 minutes (range: 37–75 min). The follow-up examination (3 months after anastomosis treatment with BARS®) resulted in a **mean weight loss** of **6 kg** (range: 4–9 kg).

Table 1: Results of the BARS® case series by Di Lorenzo et al[2].

Result	Total (n=6)
Technical success*, n	6 (100%)
Complications, n	0 (0%)
Mean procedure time, min	52 (37–75)
Mean weight loss, kg	6 (4–9)

**Defined as correct clip placement.*

With regard to the technical modifications that were made to the original OTSC® System for the new BARS® procedure, the authors confirm a **high level** of **user-friendliness**, a **short procedure time** and **easy handling**. To date, the BARS® procedure has demonstrated a high success rate in effectively reducing the size of anastomoses. In contrast to OTSC®, BARS® povides additional working channels and instruments for **bimanual intervention** (for therapeutic single-channel gastroscopes) and the **cap** is **designed** to be customised to fit the requirements for anastomosis treatment and lumen reduction.

Di Lorenzo et al. state that the innovative endoscopic **BARS®** procedure is **safe** and **promising** for patients who have an enlarged anastomosis in cases where it is associated with weight regain after a previous gastric bypass.

Clinical evidence

Endoscopic management of complications that can arise after bariatric procedures

Despite their low incidence, **leaks** and **fistulas** are among the **most feared complications** after bariatric procedures. The probability of these complications arising is 0.4% to 5.6% following a Roux-en-Y gastric bypass (RYGB) and 1.9% to 5.3% following a **laparoscopic sleeve gastrectomy** (LSG)[3]. The type of **treatment** depends on the size of the defect, tissue condition, drainage required and how long the defect has been present. Various techniques are used for this, such as internal/external drainage, stents, endoscopic vacuum therapy (EVT), defect closure using OTSC®, fibrin glue and surgery. In most cases, a **multimodal approach** is used to carry out endoscopic treatment, which is reported to have good success rates.

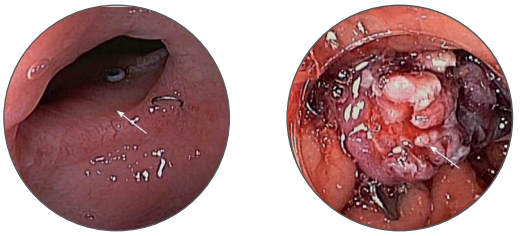
The OTSC® System as an essential element of the treating physician's tool box

Primary therapy using OTSC® can be carried out where:

- There is healthy tissue for the clip to grasp onto (fig. 8).
- Drainage is not required.
- The defect size is less than 20 mm.

Secondary therapy using OTSC® can be carried out following:

- EVT, resulting in the cleaning and reduction in size of the defect.
- Stent treatment for major defects and residual minor defects.



Fistula following RYGB

Successful fistula closure using OTSC®

Figure 8: Fistula closure using the OTSC® System[4].

Taking these framework conditions into account, the **OTSC®** contributes to a high rate of clinical success when used to **treat gastrointestinal defects and complications often also found after bariatric interventions.** A systemazic review (Shoar et al.[5]), which investigated 73 clinical cases of leakages/fistulas following previous laparoscopic sleeve gastrectomy, demonstrated a **successful closure rate** of 86.3% (63/73), where 40% (29/73) of the patients were treated solely with OTSC® and 60% (34/73) were treated with OTSC® in combination with other procedures.

Stent therapy: stentfix OTSC® effectively prevents stent migration

In **stent therapy, stent migration** is one of the **most common complications** caused by defects after previous bariatric procedures. In particular, this applies to fully covered SEMS (FCSEMS), which are primarily used in benign circumstances – like bariatric leaks, for example.

A promising method to prevent stent migration is the **fixation** of the **stent** with the **stentfix OTSC® System**. To date, there is no study that exclusively covers fixation in the case of bariatric complications. However, comparison studies conducted by Park et al.[6] and Schiemer et al.[7] as well as the special study conducted by Manta et al.[8] generally show an **effective reduction** in the **migration rate** (tab. 2). As is common for typical bariatric applications, the upper stent opening was primarily placed in the oesophagus in all three of the studies.

Table 2: Comparison of stent migration rates (stentfix OTSC® vs. no fixation vs. suturing)

Stent migration	stentfix OTSC®	No fixation	Suturing	P value (stentfix OTSC® vs. no fixation)	P value (stentfix OTSC® vs. suturing)
Park et al.[6]	35% (19/54)	62% (148/239)	57% (79/140)	0.015	0.018
Schiemer et al.[7]	8.3% (2/26)	35.4% (17/51)	–	<0.001	–
Manta et al.[8]	3.2% (1/31)	–	–	–	–

Follow-up

Following successful application, the **endoscopic clip** (BARS® clip, OTSC® clip or stentfix OTSC® clip) will remain in place for several weeks to several months. The exact duration depends on the quantity and condition of the tissue being gathered. In most cases, the clip leaves the gastrointestinal tract naturally. Occasionally, it may be covered by the mucous membrane and remain safely in the body as a **long-term implant**, thanks to its design and **biocompatibility**. The clips are made of **superelastic Nitinol®**, which ensures that the tissue gathered can be **dynamically compressed as needed.**

The endoscopic clips are **MR Conditional.** After the clip has been placed, patients can safely undergo examination in an MRI system under the following conditions: a) static magnetic field of 3 Tesla or lower, b) maximum spatial gradient of the magnetic field of 4,000 Gauss/cm (40 T/m). For further details, please refer to the instructions for use. In the rare cases where the clip needs to be removed, e.g. if there are any complications in the area it was applied or if the clip has been positioned incorrectly, it can be easily removed using the Ovesco remOVE System. This means that the procedure can be reversed or repeated.

Summary

Endoscopic anastomosis treatment and lumen reduction

BARS® has proven to be user friendly and safe in the treatment of anastomosis and for lumen reduction. Enlarged anastomoses are often found in patients who received previous bariatric interventions and can be associated with weight regain or dumping syndrome.

- Clinical experience with the OTSC® System for endoscopic clip application for anastomosis reduction demonstrated a **high level of clinical efficacy** and **safety** within a follow-up period of one year (Heylen et al.[1]).
- In a clinical setting, the minimally invasive treatment method with the new BARS®, which has been designed specifically for the treatment of anastomoses and lumen reduction, has shown itself to be a **technically successful** and **low-complication procedure** (Di Lorenzo et al.[2]).

OTSC® and stentfix OTSC® contribute to high clinical success in managing complications often found in patients after previous bariatric interventions using the multimodal approach.

- The OTSC® System has a **high closure rate**, when used to treat leakages and fistulas following laparoscopic sleeve gastrectomy, partly in combination with other endoscopic procedures (Shoar et al.[5]).
- In stent treatment, **stent migration** can be effectively **reduced** using the stentfix OTSC® and has proven itself to be beneficial compared to other procedures (Park et al.[6]).

» Based on the established OTSC® System, BARS® is an intuitive procedure for anastomosis treatment and lumen reduction.

References

Literature cited in this bulletin

1. Heylen AM, Jacobs A, Lybeer M, Prosst RL. **The OTSC®-clip in revisional endoscopy against weight gain after bariatric gastric bypass surgery.** Obes Surg. 2011 Oct;21(10):1629-33.
2. Di Lorenzo N, Camperchioli I, Scozzarro A, Grossi C, Altorio F, Caputo A, Gottwald T, Schurr MO. **Bariatric reduction system – BARS®: device, technique and first clinical experience.** Minim Invasive Ther Allied Technol. 2021 Aug;30(4):187-194.
3. de Oliveira VL, Bestetti AM, Trasolini RP, de Moura EGH, de Moura DTH. **Choosing the best endoscopic approach for post-bariatric surgical leaks and fistulas: Basic principles and recommendations.** World J Gastroenterol. 2023 Feb 21;29(7):1173-1193.
4. Bartell N, Bittner K, Kaul V, Kothari TH, Kothari S. **Clinical efficacy of the over-the-scope clip device: A systematic review.** World J Gastroenterol. 2020 Jun 28;26(24):3495-3516.
5. Shoar S, Poliakin L, Khorgami Z, Rubenstein R, El-Matbouly M, Levin JL, Saber AA. **Efficacy and Safety of the Over-the-Scope Clip (OTSC®) System in the Management of Leak and Fistula After Laparoscopic Sleeve Gastrectomy: a Systematic Review.** Obes Surg. 2017 Sep;27(9):2410-2418.
6. Park KH, Lew D, Samaan J, Patel S, Liu Q, Gaddam S, Gupta K, Jamil LH, Lo SK. **Comparison of no stent fixation, endoscopic suturing, and a novel over-the-scope clip for stent fixation in preventing migration of fully covered self-expanding metal stents: a retrospective comparative study (with video).** Gastrointest Endosc. 2022 Nov;96(5):771-779.
7. Schiemer M, Bettinger D, Mueller J, Schultheiss M, Schwacha H, Hasselblatt P, Thimme R, Schmidt A, Kuellmer A. **Reduction of esophageal stent migration rate with a novel over-the-scope fixation device (with video).** Gastrointest Endosc. 2022 Jul;96(1):1-8.
8. Manta R, Del Nero L, Todd B, Parodi A, De Ceglie A, Zito F, Pasquale L, Zullo A, Conio M. **Newly designed OTS Clip for preventing fully-covered self-expandable metal stent migration in the gastrointestinal tract.** Endosc Int Open. 2023 Mar 24;11(3):E284-E287.

Further reading

9. Rogalski P, Swidnicka-Siergiejko A, Wasielica-Berger J, Zienkiewicz D, Wieckowska B, Wroblewski E, Baniukiewicz A, Rogalska-Plonska M, Siergiejko G, Dabrowski A, Daniluk J. **Endoscopic management of leaks and fistulas after bariatric surgery: a systematic review and meta-analysis.** Surg Endosc. 2021 Mar;35(3):1067-1087.
10. Shehab H, Abdallah E, Gawdat K, Elattar I. **Large Bariatric-Specific Stents and Over-the-Scope Clips in the Management of Post-Bariatric Surgery Leaks.** Obes Surg. 2018 Jan;28(1):15-24.
11. Rodrigues-Pinto E, Pereira P, Sousa-Pinto B, Shehab H, Pinho R, Larsen MC, Irani S, Kozarek RA, Capogreco A, Repici A, Shemmeri E, Louie BE, Rogalski P, Baniukiewicz A, Dabrowski A, Correia de Sousa J, Barrias S, Ichkhanian Y, Kumbhari V, Khashab MA, Bowers N, Schulman AR, Macedo G. **Retrospective multicenter study on endoscopic treatment of upper GI postsurgical leaks.** Gastrointest Endosc. 2021 Jun;93(6):1283-1299.e2.
12. Jena A, Chandnani S, Jain S, Sharma V, Rathi P. **Efficacy of endoscopic over-the-scope clip fixation for preventing migration of self-expandable metal stents: a systematic review and meta-analysis.** Surg Endosc. 2023 May;37(5):3410-3418.

Further **clinical bulletins** can be found on our website.
You can access the latest clinical literature via our scientific information service.
Sign up to receive our **scientific newsletter** and stay up-to-date.

Sign up here

Who is this brochure aimed at?

In this brochure, we provide information that can be used, to our best knowledge and judgement, as a teaching tool for healthcare professionals. This information is provided without any guarantee. It has been carefully reviewed and was considered accurate and useful at the time of publication. The authors and manufacturers are not liable for any losses or damages resulting from its use. Please refer to the instructions for use, which are supplied with every product and contain references to the applicable guidelines.

ovesco
innovation in scope

Ovesco Endoscopy AG
Friedrich-Miescher-Strasse 9
72076 Tuebingen, Germany
www.ovesco.com

Contact us here

BARS_CB_eng_Rev03_2025-01-21_800143