



Bariatric endoscopy

clinical bulletin

**BARS<sup>®</sup>**

for endoscopic reduction of  
anastomoses following RYGB

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**OTSC<sup>®</sup> and stentfix OTSC<sup>®</sup>**

for complication management in bariatric surgery

# BARS<sup>®</sup>, OTSC<sup>®</sup> and stentfix OTSC<sup>®</sup>

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<sup>®</sup>

The BARS<sup>®</sup> (ref. no. 100.60) is based on the well-established OTSC<sup>®</sup> System and facilitates **endoscopic lumen reduction** in contexts such as 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<sup>®</sup> Anchor) and balloons for safe insertion (Insertion balloon) and defining the diameter of the remaining lumen (Space keeper balloon)

BARS<sup>®</sup> Set auxiliary instruments



Insertion balloon with guide wire



Space keeper balloon with BARS<sup>®</sup> Anchors

### Applications:

- Treatment of weight regain or dumping syndrome after a gastric bypass

## OTSC<sup>®</sup> System

The OTSC<sup>®</sup> 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 acute and chronic complications after bariatric procedures, e.g. anastomosis leaks and fistulas
- Treatment of anastomotic bleeding

## stentfix OTSC<sup>®</sup> System

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

### Applications:

- Fixation of metal stents (SEMS) to treat complications after bariatric procedures, e.g. leaks

More information on the BARS<sup>®</sup>



More information on the OTSC<sup>®</sup>



More information on the stentfix OTSC<sup>®</sup>

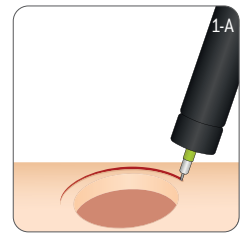


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# Application techniques

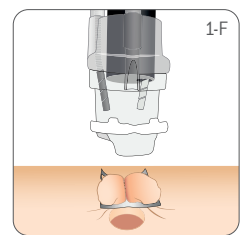
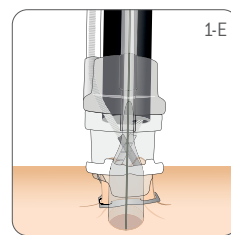
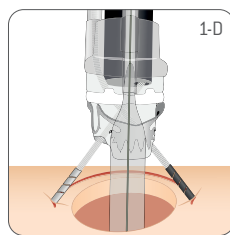
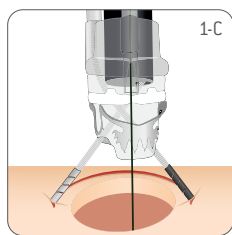
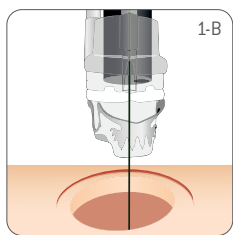
## Practical use of the BARS®

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 approx. 2.5 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).

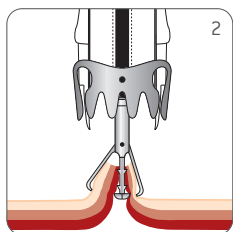


## Practical use of the OTSC® and stentfix OTSC®

### Perforation/leakage closure

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

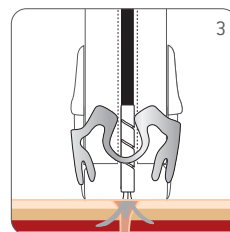
1. Grasp the perforation edges with the OTSC® Twin Grasper and retract into the OTSC® cap (fig. 2).
2. Secure the instrument and apply the clip.



### Fistula closure

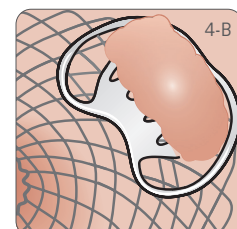
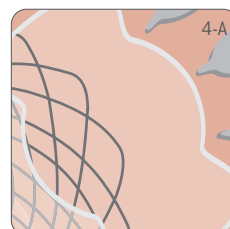
Fistula closure is carried out using the OTSC® Anchor:

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 or dumping syndrome with gastric bypass I

### Initial experience with the OTSC® System in bariatrics

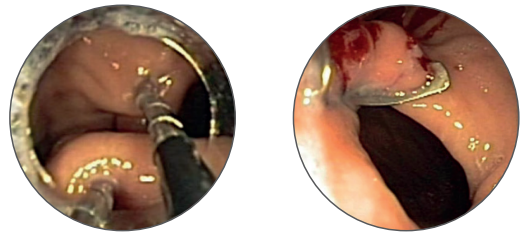
The OTSC®, which has proven itself across a range of indications, has also demonstrated a high degree of clinical efficacy and safety in treating weight regain following gastric bypass. Based on these promising results, the BARS® was developed as an optimised system for anastomosis reduction.

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<sup>1</sup>. 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®.

Heylen used type t OTSC® clips, which are particularly good at anchoring in fibrotic tissue. 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.

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 ( $\pm 3.6$ ), 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 ( $\pm 1.9$ ) (fig. 6). As a result of the treatment with the OTSC®, BMI decreased to an average of 29.7 ( $\pm 1.8$ ) within approx. three months (1st follow-up). The mean BMI was 27.4 ( $\pm 3.8$ ) around a year after treatment with the OTSC® (2nd follow-up). There were no major complications.

The authors concluded that the endoscopic treatment of weight regain due to a dilated pouch-outlet after gastric bypass using OTSC® is reliable and effective with favourable short- and midterm results. The procedure described by Heylen et al. forms the basis for the procedures carried out using the new BARS® instruments.



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<sup>1</sup>.

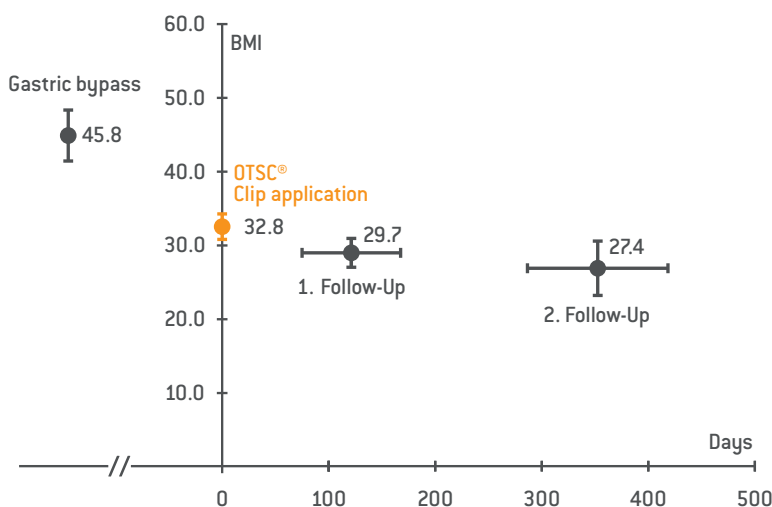


Figure 6: Progression of the BMI following gastric bypass, at the time the OTSC® clip was applied and at the two follow-up examinations approx. 3 months and 1 year after the endoscopic intervention<sup>1</sup>.

# Clinical evidence

## Treatment of weight regain or dumping syndrome with gastric bypass II

### The BARS® procedure – the minimally invasive treatment method for bariatric patients

In clinical use, BARS® demonstrates a high level of user-friendliness and safety, without introducing complications.

The first scientific description of the BARS® System [Di Lorenzo et al.<sup>2</sup>] included a case series of six patients who had regained at least 15% of their weight following a 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 BARS® treatment, the average BMI was 40.3 kg/m<sup>2</sup> (range: 36.4–42.6 kg/m<sup>2</sup>). The BARS® procedure's clinical application steps are described in figure 7.

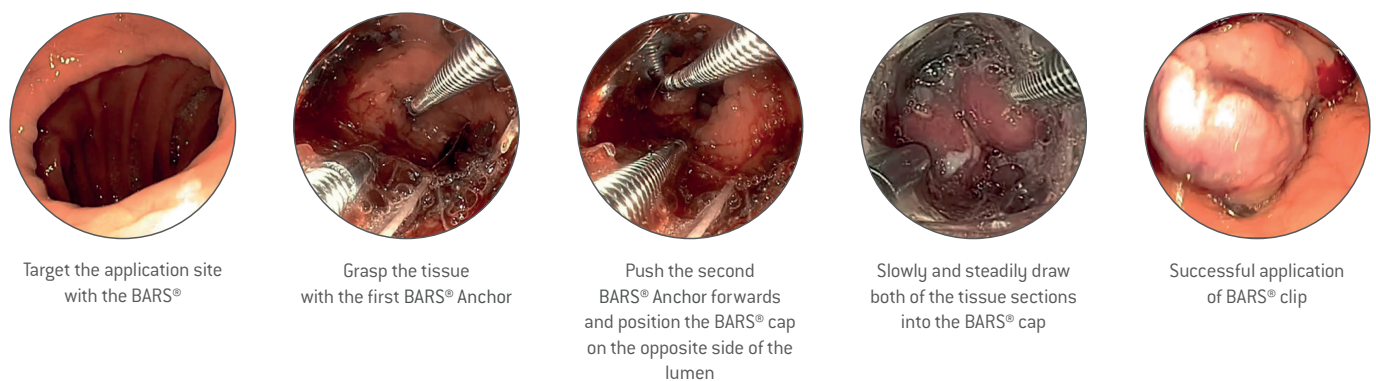


Figure 7: BARS® procedure for endoscopic treatment of weight regain<sup>2</sup>.

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 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.<sup>2</sup>.

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 a therapeutic way. In contrast to OTSC®, BARS® includes the **bimanual instruments** required (for standard single-channel gastroscopes) and the **cap** is **designed** to be customised to fit the requirements for reducing anastomoses after gastric bypass operations.

Di Lorenzo et al. state that the innovative endoscopic BARS® procedure is **safe** and **promising** for patients who have regained weight after gastric bypass due to enlargement of an anastomosis.

# Clinical evidence

## Managing complications following 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)**<sup>3</sup>. 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), closure using OTSC<sup>®</sup>, fibrin glue and surgery. In most cases, a **multimodal approach** is used to carry out endoscopic treatment, which is known to have good success rates.

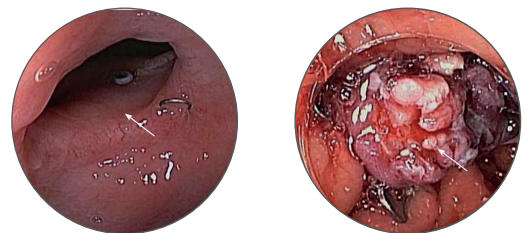
## The OTSC<sup>®</sup> System as an essential element of the treating physician's tool box

**Primary therapy** using OTSC<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>

Figure 8: Fistula closure using the OTSC<sup>®</sup> System<sup>4</sup>.

Taking these framework conditions into account, the OTSC<sup>®</sup> contributes to a high rate of clinical success when used to **treat bariatric complications**. A systematic review (Shoar et al.<sup>5</sup>), which investigated 73 clinical cases of leakages/fistulas following 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<sup>®</sup> and 60% (34/73) were treated with OTSC<sup>®</sup> in combination with other procedures.

## Stent therapy: stentfix OTSC<sup>®</sup> effectively prevents stent migration

In **stent therapy**, **stent migration** is one of the **most common complications** caused by defects after 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<sup>®</sup> 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.<sup>6</sup> and Schiemer et al.<sup>7</sup> as well as the special study conducted by Manta et al.<sup>8</sup> 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<sup>®</sup> vs. no fixation vs. suturing)

Stent migration	stentfix OTSC <sup>®</sup>	No fixation	Suturing	P value (stentfix OTSC <sup>®</sup> vs. no fixation)	P value (stentfix OTSC <sup>®</sup> vs. suturing)
Park et al. <sup>6</sup>	35% (19/54)	62% (148/239)	57% (79/140)	0.015	0.018
Schiemer et al. <sup>7</sup>	8.3% (2/26)	35.4% (17/51)	–	<0.001	–
Manta et al. <sup>8</sup>	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 treatment of weight regain or dumping syndrome

**BARS® has proven to be user friendly and safe in the treatment of bariatric patients experiencing weight regain or dumping syndrome following gastric bypass surgery.**

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

**OTSC® and stentfix OTSC® contribute to high clinical success in managing bariatric complications 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.<sup>5</sup>).
- 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.<sup>6</sup>).

» Based on the established OTSC® System, BARS® is an innovative procedure for anastomosis reduction following gastric bypass.

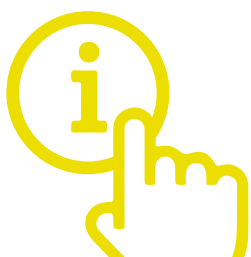
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## Further reading

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