The OTSC® System in flexible endoscopy
Practical use and clinical benefit – Information for hospitals

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1 The OTSC® System: Basics

2 Hemostasis

3 Closure of acute wall lesions / perforations

4 Closure of chronic wall lesions /fistulae

5 Stent fixation with stentfix OTSC®

6 Conclusion, sources and explanations

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The OTSC® System is intended for endoscopic treatment of gastrointestinal hemorrhage and closure of acute and chronic wall lesions.

The OTSC® System consists of an application cap with a pre-mounted clip, a release hand wheel and a thread retriever. The application cap is mounted on the tip of the endoscope. The clip is applied by turning the wheel.

OTSC® clip:

- shape memory alloy
- mounted to tip of endoscope
- tissue compression

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The OTSC® System is available in a variety of cap sizes and clip designs to provide a secure treatment regardless of the anatomical situation and endoscope type.

OTSC®
CLIP

OTSC® version		mini	11	12	14
Endoscope diameter Ø [mm]		8.5 – 10	8.5 – 11	10.5 – 12	11.5 – 14
Depth of cap	3 mm		11/3a 11/3t	12/3a 12/3t	14/3a 14/3t
	6 mm	mini/6a mini/6t	11/6a 11/6t	12/6a 12/6t 12/6gc	14/6a 14/6t
Max. outer diameter Ø [mm]		14.6	16.5	17.5	21

type a type t type gc

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OTSC® clip: Three different types – a, t, and gc

OTSC® a: blunt teeth, primarily compression effect

OTSC® t: teeth with small spikes, compression and anchoring effect

OTSC® gc: elongated teeth with spikes, application: closure of gastric wall
gc: gastric closure

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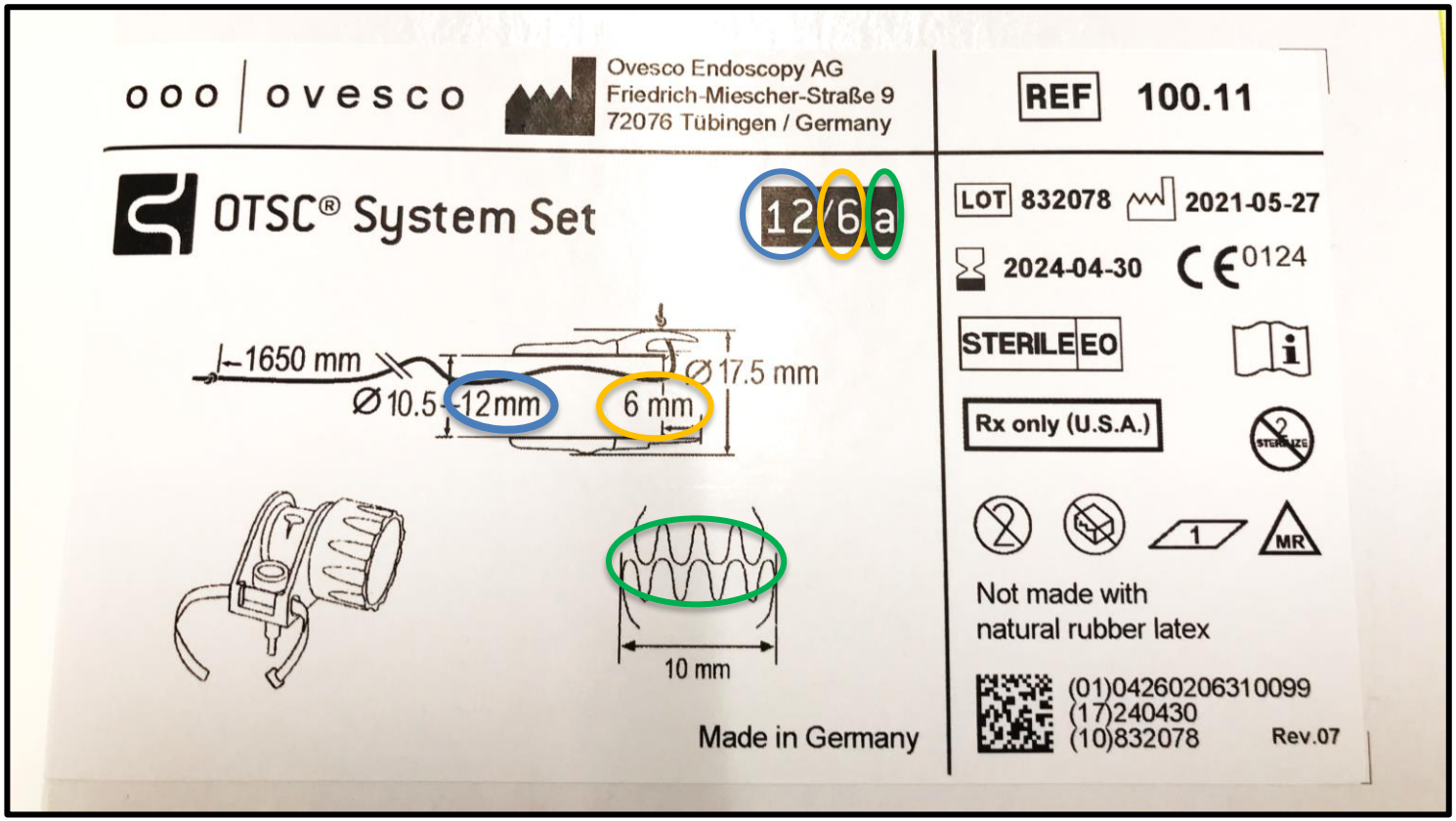
A distinction between the different variants can be made on the packaging by means of the below shown labeling.



Cap size

Depth of cap

Clip type

The mini OTSC® System enables big impact in a small device.

- The mini OTSC® System is ideal in the following situations:
- situations where endoscope tip maneuverability and controllability are particularly required
  - Bleeding
  - Hard-to-reach lesions e.g. post pyloric duodenal bleeding
- also fits to pediatric scopes
- access to small lumina
- Small introductory devices
  - bite blocks smaller in diameter, e.g. 16 mm
  - Overtubes
  - Endotracheal intubation, mini OTSC® System makes the pharyngeal passage easier in intubated patient
- Passage of esophageal strictures

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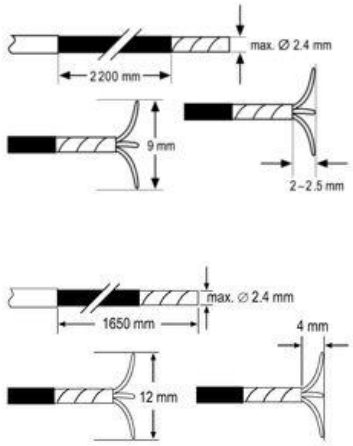
Application aids to support clip placement: OTSC® Twin Grasper® and OTSC® Anchor

OTSC® TWIN GRASPER®

OTSC® ANCHOR



OTSC® Twin Grasper®:

- supports wall closure
- 2 separate jaw parts
- approximates the wound edges before deployment of the clip

OTSC® Anchor:

- supports grasping of hard / fibrotic tissue (e.g. peptic ulcer, fistula orifice)
- NiTi Anchor
- holds tissue in place for application of the clip
- Available in two versions: normal (165 cm) and 220tt (220 cm) designed for thin tissue

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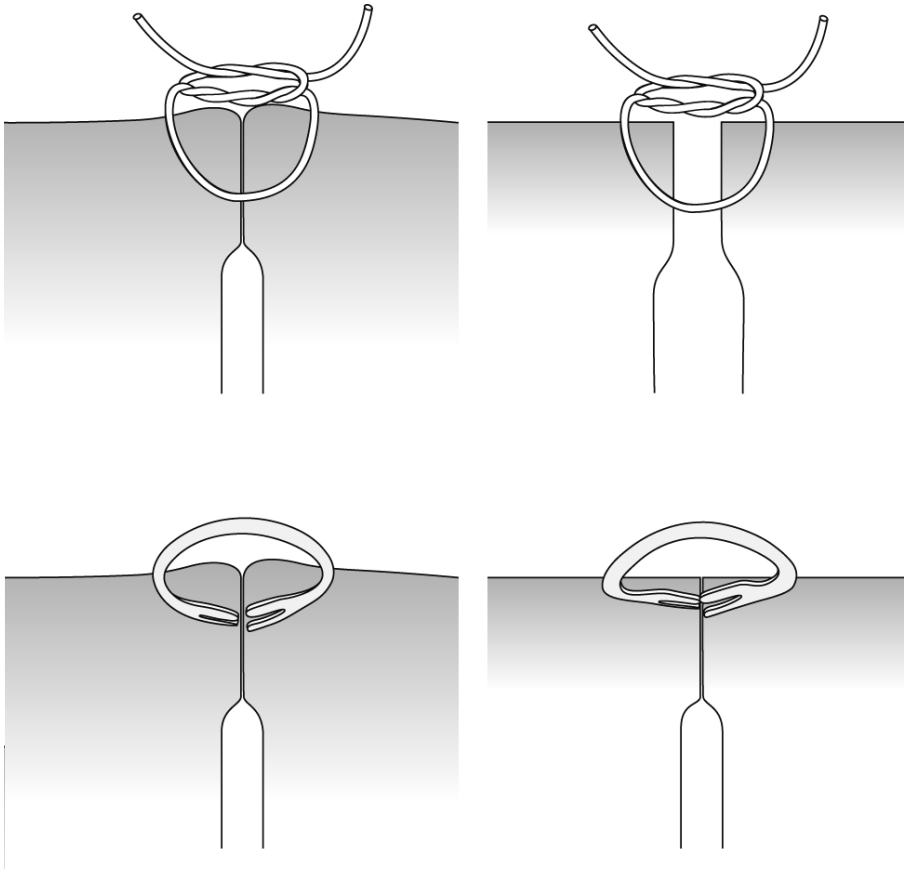
Functional principle of the OTSC® clip: dynamic compression

The OTSC® clip is a superelastic Nitinol® clip which compresses the tissue in between its teeth.
The space between the teeth allows microperfusion of the clipped tissue. Therefore no necrosis of the tissue occurs.

Advantages of the clip over sutures

- Adapts continuously to the thickness of the tissue even when the volume of the tissue is shrinking while healing.
- Maintains consistent compression.

The OTSC® clip enables dynamic closure rather than static. This helps to avoid potentially inadequate closure over time, like it can happen in fixed suture loops.



Things to watch out when using the OTSC® System

Use of an instrument in combination with the OTSC® System

Inserting the instrument through the same channel as the thread of the OTSC® System, use of a 3.2 mm working channel is recommended.

To avoid clipping the instrument with the OTSC® clip, the following points have to be obeyed before applying the clip:

- The cap has to be mounted until reaching the stopper in the cap. If the endoscope is not pushed into the cap all the way, it could slide forward when turning the hand wheel.
- The instrument must be withdrawn completely into the cap (controlled by endoscopic view).
- The instrument must be fixed in the retracted position while clipping.
- Due to the shallowness, the caps with 3 mm depth cannot be used with the OTSC® Twin Grasper®. Otherwise there is the risk of clipping the instrument.

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Operating instructions for special cases

Using the OTSC® System under unusual conditions can lead to a problematic application of the OTSC® clip and the system can reach its performance limits.

- By applying too much pressure on indurated tissue (e.g. rectal area, fibrotic tissue) clip application can become more difficult or even be hindered.
  - ➢ Avoid applying too much pressure on the mentioned tissues.

- Many loops and twists of the endoscope (e.g. in the caecum) can reduce force transmission and make clip application more difficult as well.

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About 1 out of 1,000 persons/year suffer from a bleeding in the upper gastrointestinal tract. Peptic ulcers continue to be the main cause.

Epidemiology

- **UGIB incidence worldwide** 80-150/100,000; in Europe **about 100/100,000**
- **85 %** cause **emergency hospital admission**
- **Mortality 6-13 %**
- **50 % peptic ulcers**, 5-10 % esophageal varices, rest from various origins (e.g. Mallory-Weiss lesion or similar)

Among the risk factors for upper GI bleeding, the increasing age of the population plays a major role.

Incidence (n = 132)	Per 100,000
AUGIB incidence rate	87
Age standardized incidence rate	
18–24	30
25–39	15
40–59	48
60–79	213
80–105	570

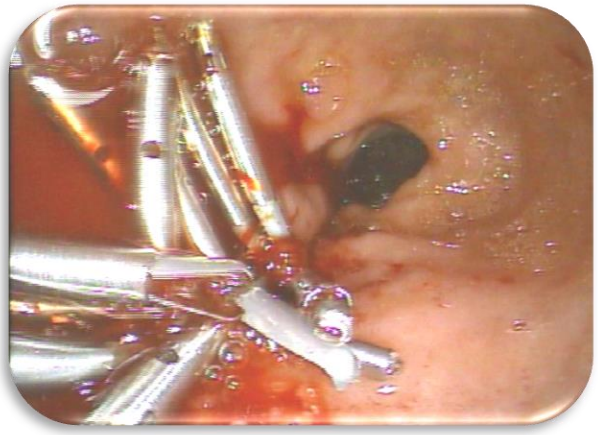
Source: Hreinsson JP, Kalaitzakis E, Gudmundsson S, Björnsson ES. Upper gastrointestinal bleeding: incidence, etiology and outcomes in a population-based setting. Scand J Gastroenterol. 2013 Apr;48(4):439-47

Conventional clips – local compression of the vessel is often only possible with exact localization and placement. Technical problems grow with severity of the lesion.

Conventional clip – treatment

Problems in practice:

- Rough/stiff tissue, fibrous ulcer
- Difficult localization or accessibility of the bleeding source
- Diffuse bleeding

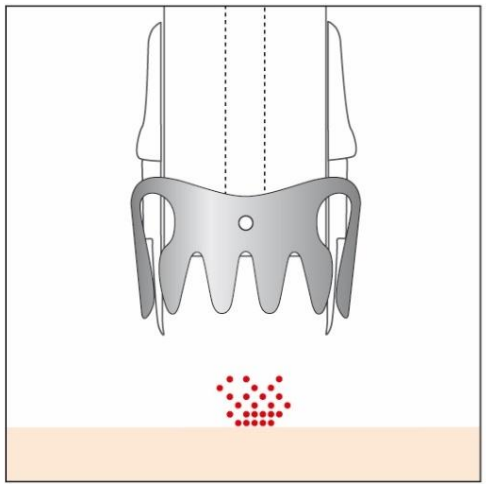


→ Continuing bleeding after several clips.

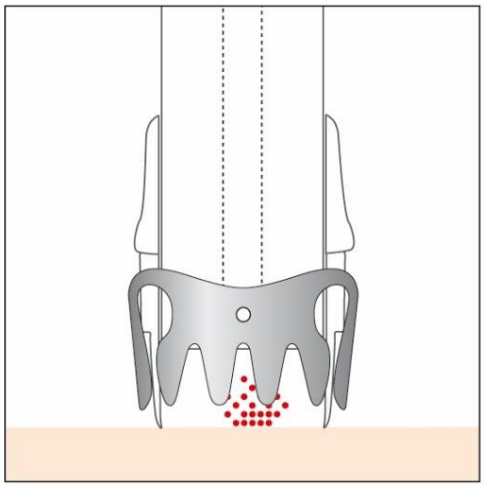
Source: Dr. Thomas Kratt, Interventional Endoscopy, Klinik für Allgemeine, Viszeral- und Transplantationschirurgie, University Hospital Tübingen, Germany

Application technique for endoscopic hemostasis

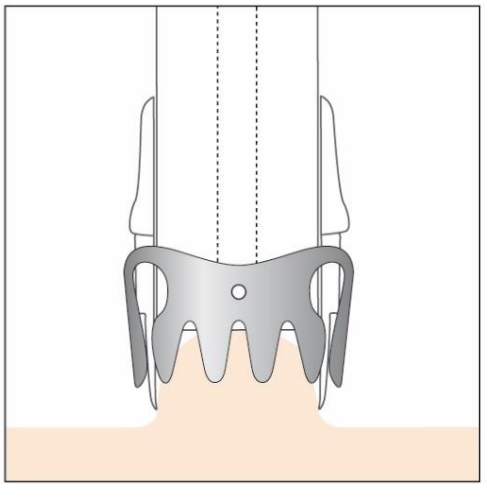
In cases of hemorrhage applying suction with the endoscope is often sufficient to mobilize the tissue into the application cap. The OTSC® clip is then applied.
In fibrotic or hard tissue, the OTSC® Anchor can be used to pull the tissue to the cap and keep it fixed during clip release.



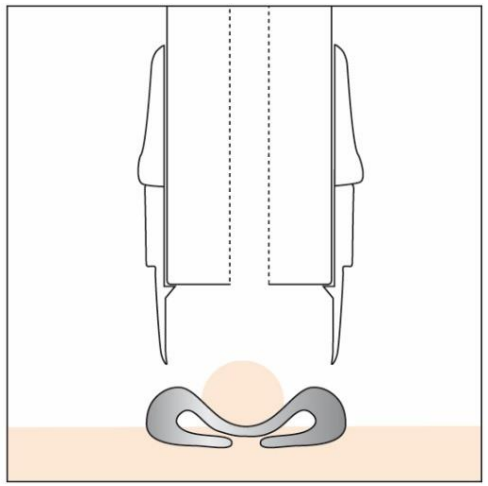
Targeting the lesion



Bring OTSC® cap in connection to tissue



Target tissue is sucked into the cap and OTSC® clip is released by turning the hand wheel



Clip is applied

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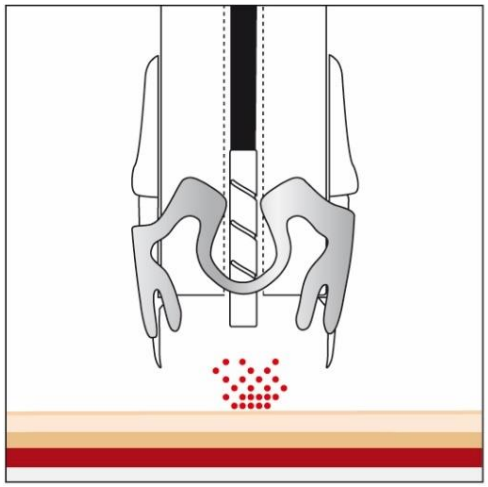
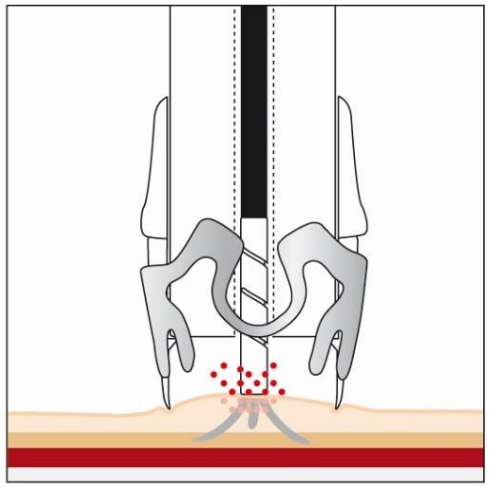
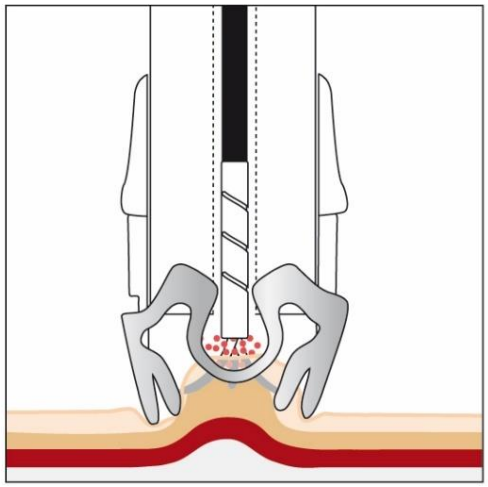
Application technique for fibrotic tissue or tangential application: Auxiliary instrument OTSC® Anchor

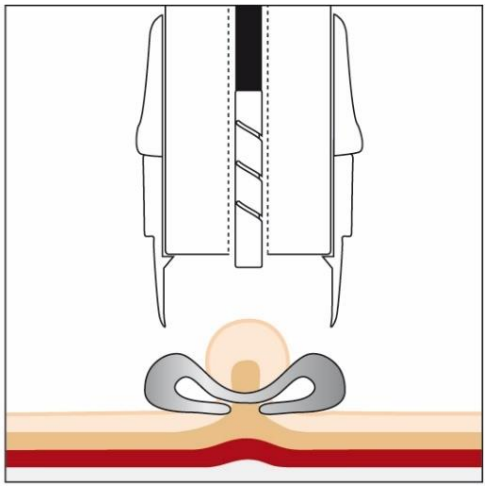


OTSC® Anchor positioning and tissue fixation; align the OTSC® cap to the lesion by pulling the Anchor and advancing the endoscope.





Mobilize the tip of the OTSC® Anchor shaft into cap. Anchor spikes may remain external. Clip release.



After clip application detach the OTSC® Anchor from the tissue.

In fibrotic tissue it may be impossible to manipulate the tissue into the cap. However, it is sufficient to pull the tissue firmly to the rim of the cap. The clip „jumps“ slightly forward upon release and grasps the tissue in front of the cap.

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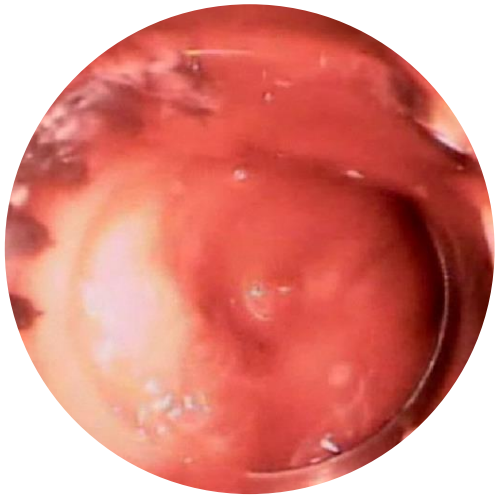
Clinical case example (I)

Bleeding peptic ulcer in the gastric antrum (anticoagulated patient)

Bleeding ulcer



Suction of bleeding site and clip application

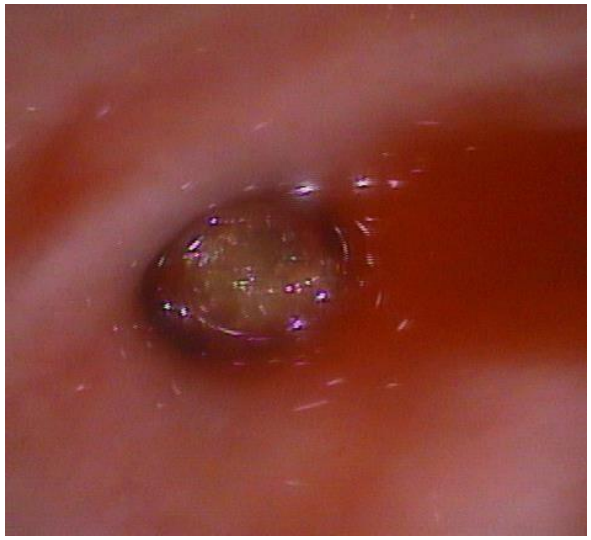
Control endoscopy shows result after 3 days

Source: Dr. Thomas Kratt, Interventional Endoscopy, Klinik für Allgemeine, Viszeral- und Transplantationschirurgie, University Hospital Tübingen, Germany

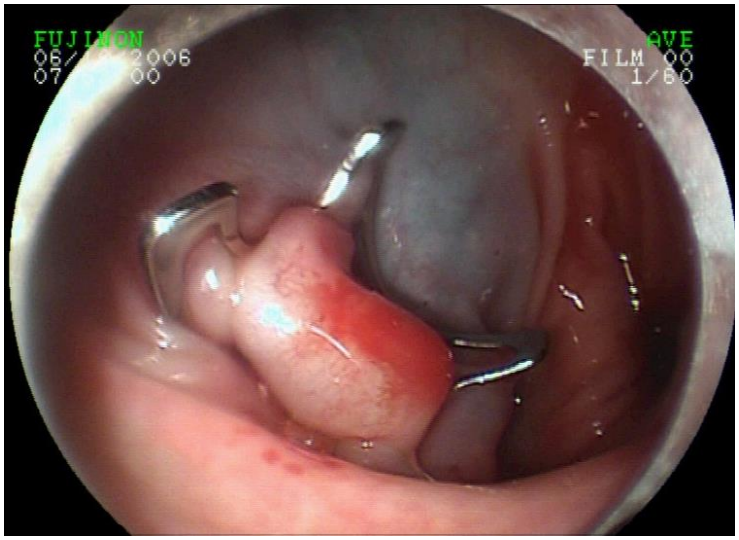
Clinical case example (II)

Diverticulum bleeding in the sigmoid colon

Lower GI bleeding



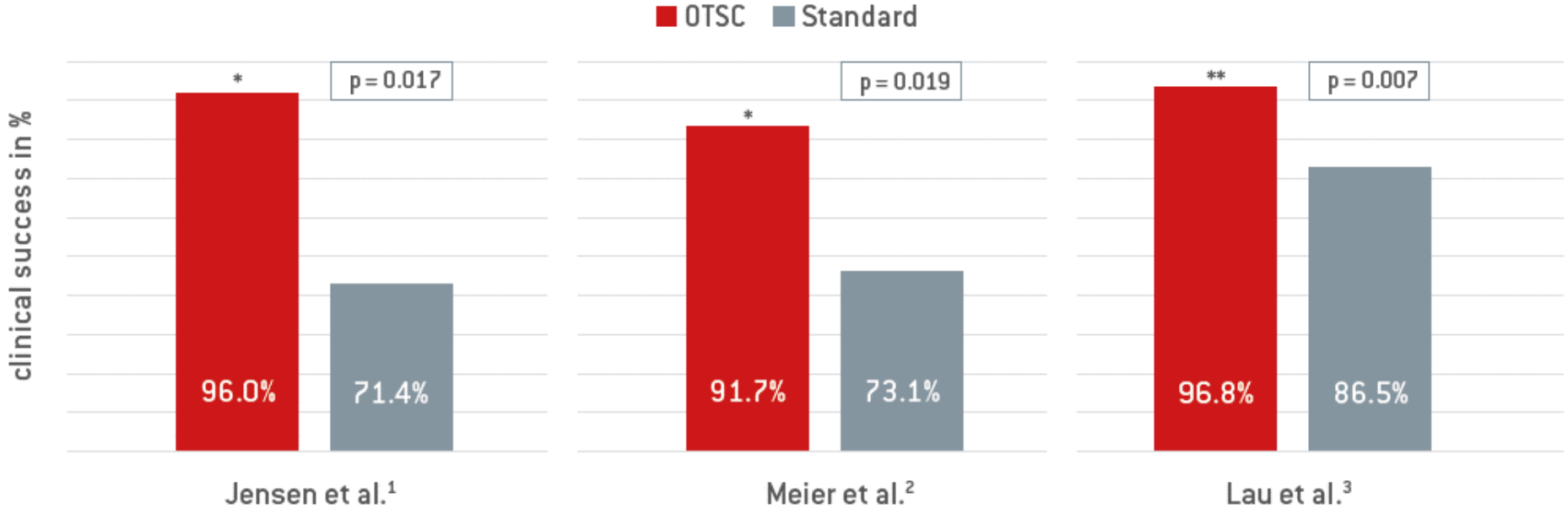
Bleeding sigma diverticulum detected



Hemostasis with OTSC®

Source: Dr. Thomas Kratt, Interventional Endoscopy, Klinik für Allgemeine, Viszeral- und Transplantationschirurgie, University Hospital Tübingen, Germany

Results of the 3 RCTs – OTSC® vs. former standard therapy in the first-line treatment of non-variceal UGI bleeding



n (OTSC/Standard)	53 (25/28)	100 (48/52)	190 (93/97)
Primary endpoint	Clinical success defined as no rebleeding ≤ 30 days	Clinical success defined as no rebleeding ≤ 7 days	Clinical success defined as no rebleeding ≤ 30 days
Main inclusion criteria	Ulcer bleeding & Dieulafoy	High risk lesions (cRS ≥ 7)	All NVUGIB
Intervention arm	OTSC arm‡ vs. Standard arm‡ (approx. 50 % endoclips / 50 % thermocoag.)	OTSC arm‡ vs. Standard arm‡ (approx. 98 % endoclips / 2 % thermocoag.)	OTSC arm‡ vs. Standard arm‡ (approx. 60 % thermocoag. / 30 % endoclips / 10 % other combination)

‡ optional injection therapy allowed

[1]Jensen DM, Kovacs T, Ghassemi KA, Kaneshiro M, Gornbein J. Clin Gastroenterol Hepatol. 2021 Nov;19(11):2315-2323
[2]Meier B, Wannhoff A, Denzer U, Stathopoulos P, Schumacher B, Albers D, Hoffmeister A, Feisthammel J, Walter B, Meining A, Wedi E, Zachäus M, Pickartz T, Küllmer A, Schmidt A, Caca K. Gut. 2022 Jul;71(7):1251-1258.
[3]Lau J, Tan CH, Sun X, Song H, Li L, Li R, Li P, Feng J, Wang B, Leung WK, Hartley I, Moss AC, Suen BY, Yu Y, Chan FK. Over-the-scope clips versus standard endoscopic treatment. UEG Week Virtual (October 3-5) 2021

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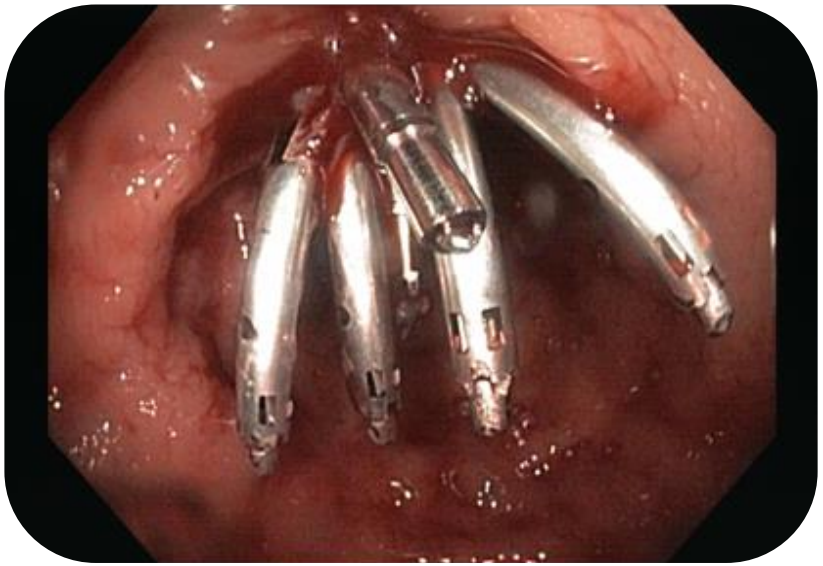
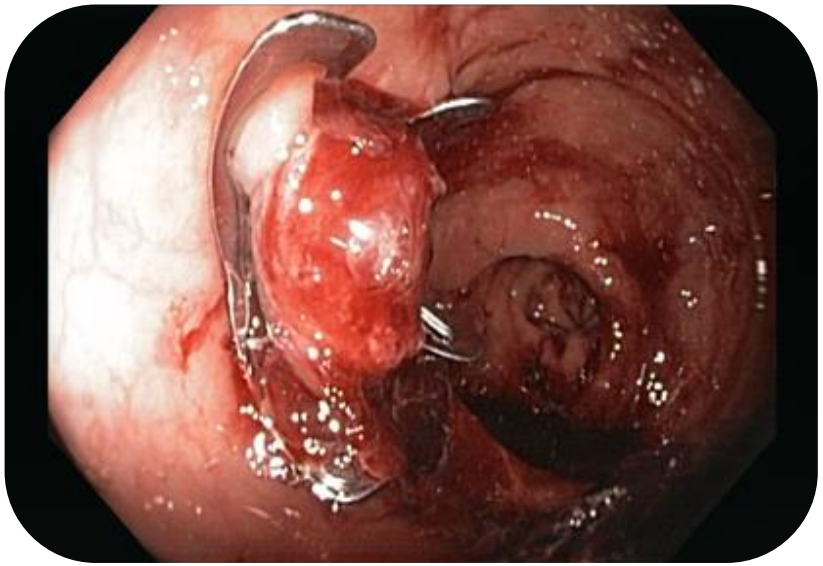
RCTs show global consensus that the OTSC® System is replacing conventional clips as the standard of care in first-line treatment.

‚Do it right the first time‘



TTS Clips



OTSC®: *one & done*

Source: Prof. Dr. K. Caca and Dr. A. Schmidt, Klinikum Ludwigsburg

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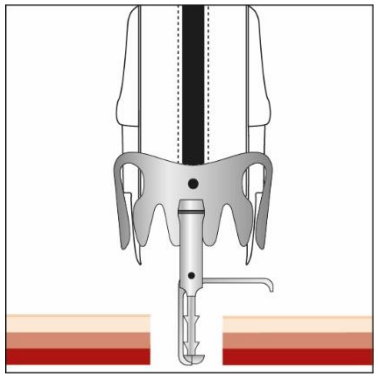
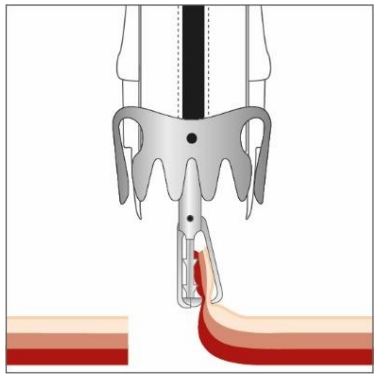
Application technique for closure of acute perforations

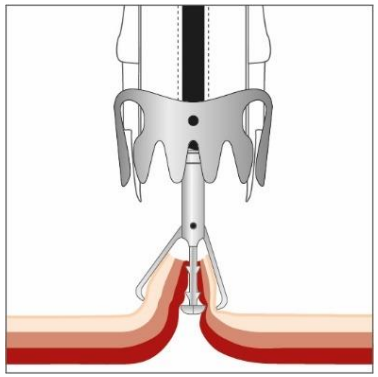
Perforation edges can be approximated using the OTSC® Twin Grasper® and the lesion can then be closed with an OTSC® clip.



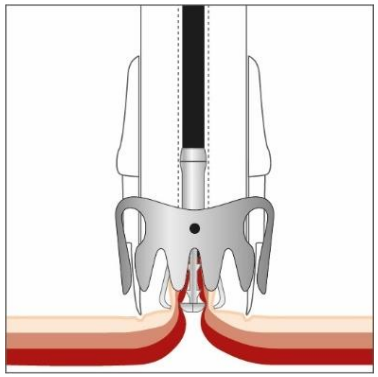
Grasping the first edge of the lesion with one of the two jaw parts of the OTSC® Twin Grasper®



Grasping the opposite edge with the second jaw part



Retraction of the perforation into the cap (OTSC® Twin Grasper® must be pulled back completely into the cap)



Clip release and removal of OTSC® Twin Grasper® from the tissue

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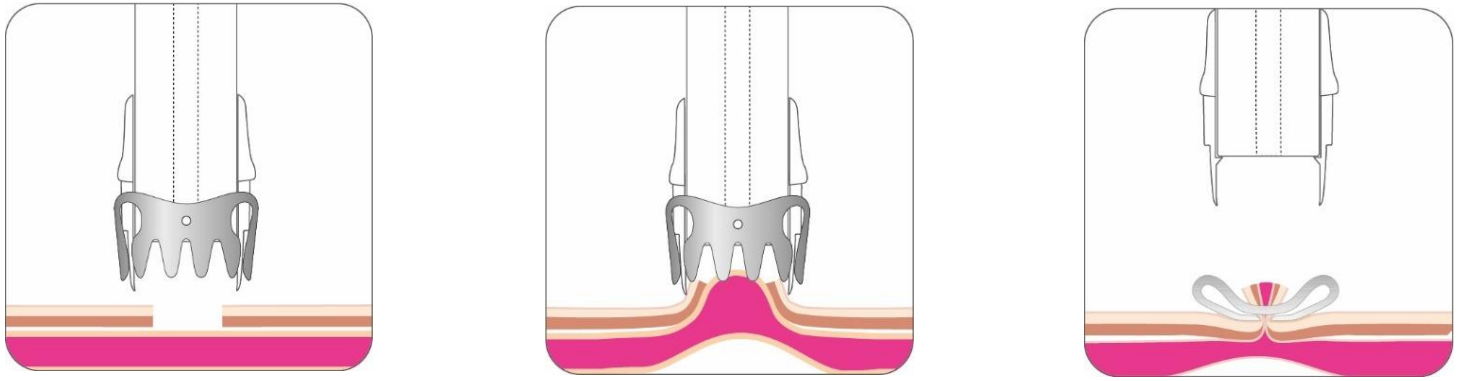
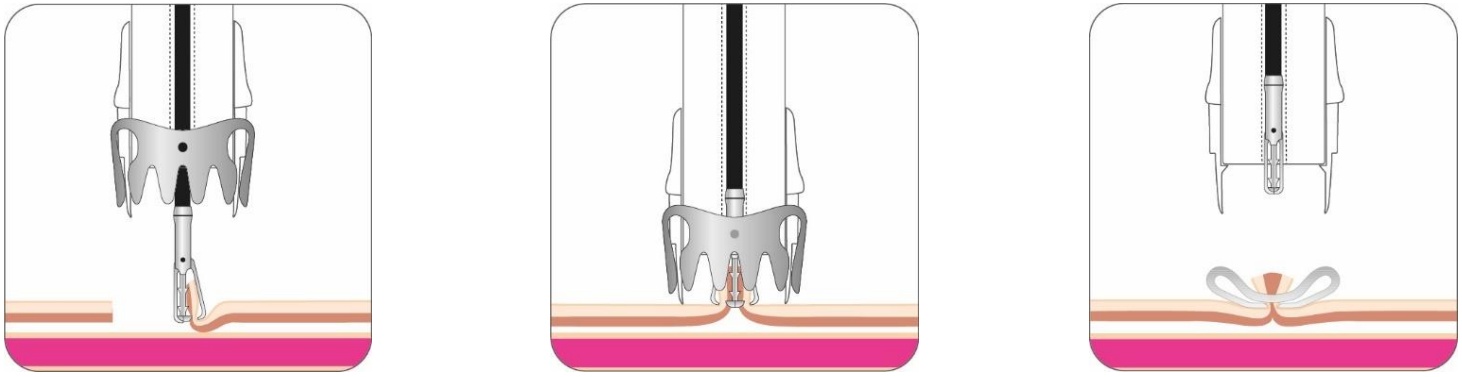
Suction vs. pulling tissue into the cap using OTSC® Twin Grasper®

Closing perforations by pulling the tissue into the cap using suction and subsequently applying the OTSC® clip can lead to unwanted fixation of nearby tissue. Surgical interventions might be necessary in case of complications.



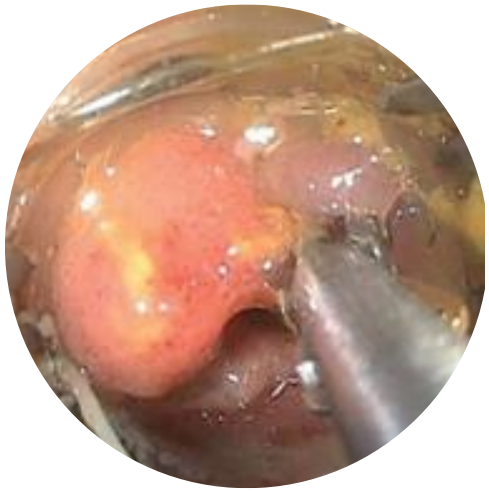
By using the OTSC® Twin Grasper® to mobilize the tissue the risk of clipping nearby tissue can be minimized.



Clinical case example (I)

Perforation closure in the colon with OTSC® Twin Grasper®

Locating the perforation



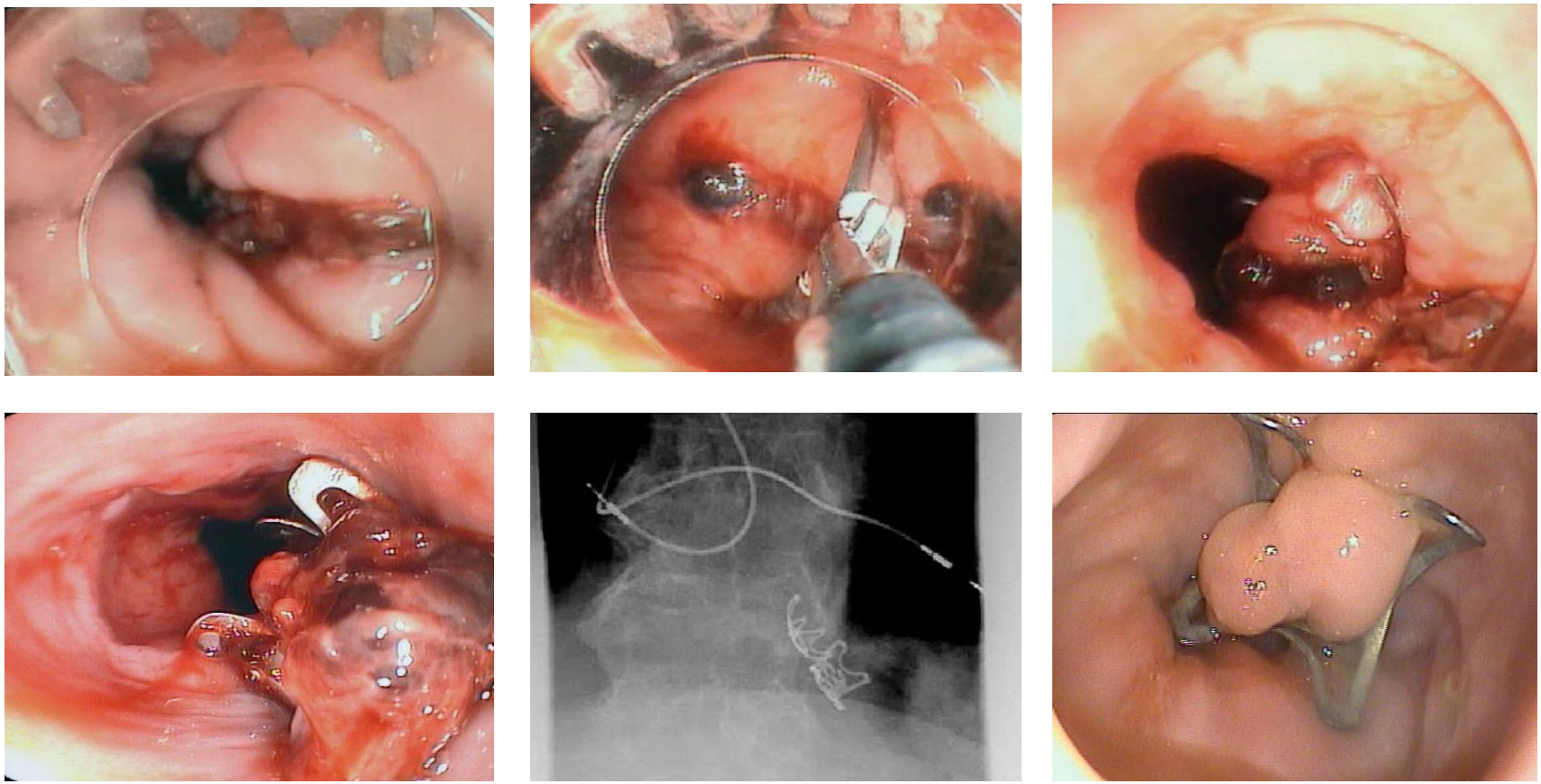
Grasping both edges of the perforation successively using the two jaws of the OTSC® Twin Grasper®

Closure with the OTSC® clip

Source: Dr. Thomas Kratt, Interventional Endoscopy, Klinik für Allgemeine, Viszeral- und Transplantationschirurgie, University Hospital Tübingen, Germany

Clinical case example (II)

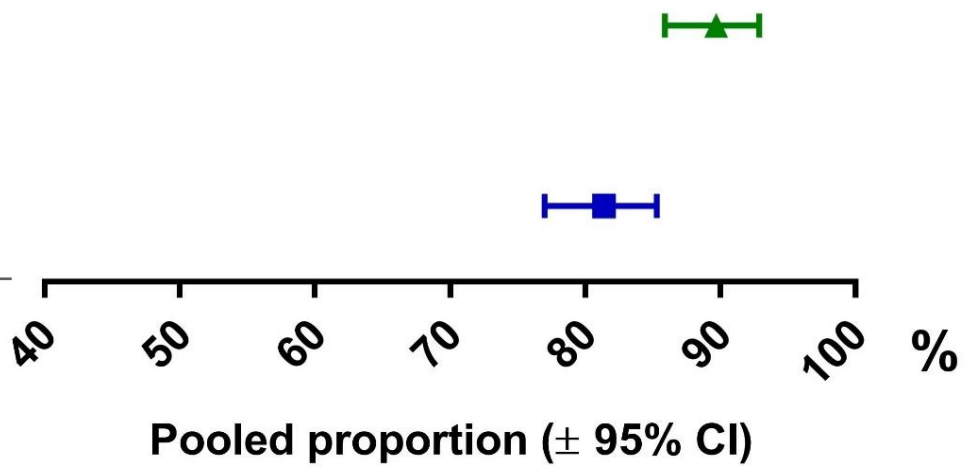
Several clips can be positioned next to each other in case of large lesions if required.
Closure of spontaneous esophageal rupture, 2 cm (Boerhaave Syndrom)



Source: Dr. Thomas Kratt, Interventional Endoscopy, Klinik für Allgemeine, Viszeral- und Transplantationschirurgie, University Hospital Tübingen, Germany

The treatment of acute lesions is facing a shift towards endoscopy. OTSC® shows high success rates.

	Pooled Proportion	95% CI
Technical success ▲	89.7%	85.9% - 92.9%
Clinical success ■	81.4%	77.0% - 85.3%



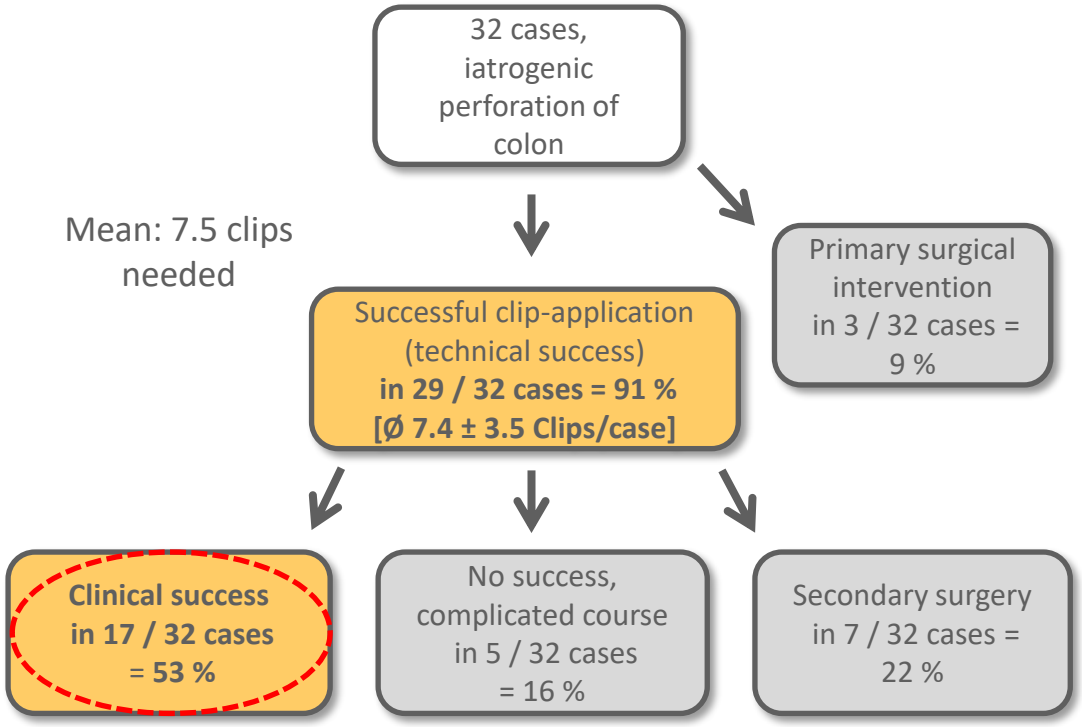
NB:
Given a sample size of 469 cases
Only clinical reports with n ≥ 4 patients were included.

Source: Weiland T, Rohrer S, Schmidt A, Wedi E, Bauerfeind P, Caca K, Khashab MA, Hochberger J, Baur F, Gottwald T, Schurr MO. Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive Ther Allied Technol. 2020 Jun;29(3):121-139.

OTSC® System vs. conventional endoclip study in the closure of iatrogenic perforations

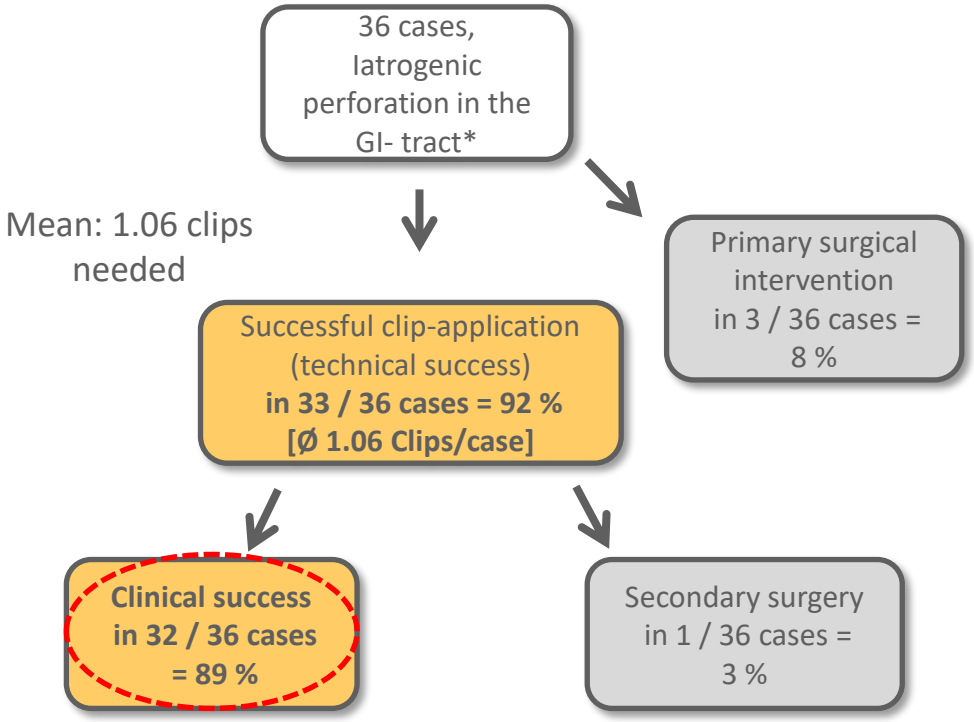
Conventional endoclips – Cho SB *et al.*, Surg Endosc 2012

Retrospective multi-center study on feasibility/safety of conventional endoclips for the closure of iatrogenic perforations of the colon (Intention-to-treat basis)



OTSC® System – Voermans RP *et al.*, CGH 2012

Prospective multi-center study on safety and efficacy of OTSC® for the closure of iatrogenic perforations in the GI-tract (Intention-to-treat basis)



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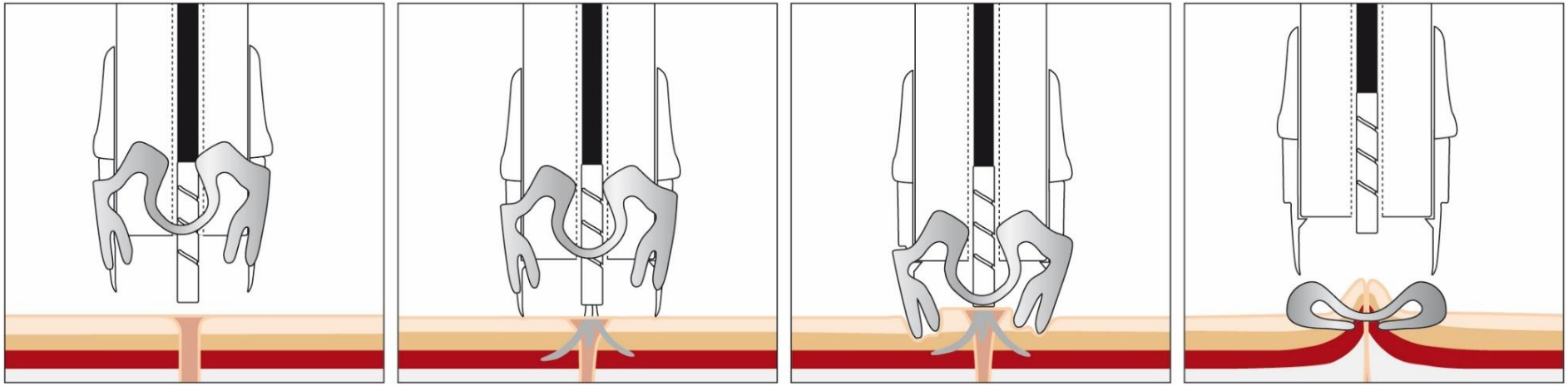
Application technique for closure of chronic lesions

In fibrotic tissue (e.g. fistula) the OTSC® Anchor can be used to pull and apply the tissue into the cap, even in tangential application. The OTSC® Anchor can also be used as a guide for the cap towards the lesion.



OTSC® Anchor positioning and tissue fixation; align the OTSC® cap to the lesion by pulling the Anchor and advancing the endoscope.

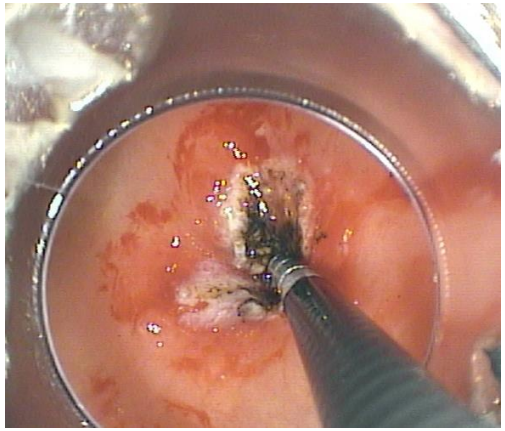
Mobilize the tip of the OTSC® Anchor shaft into cap. Anchor spikes may remain external. Clip release.

After clip application detach the OTSC® Anchor from the tissue.

In fibrotic tissue it may be impossible to manipulate the tissue into the cap. However, it is sufficient to pull the tissue firmly to the rim of the cap. The clip „jumps“ slightly forward upon release and grasps the tissue in front of the cap.

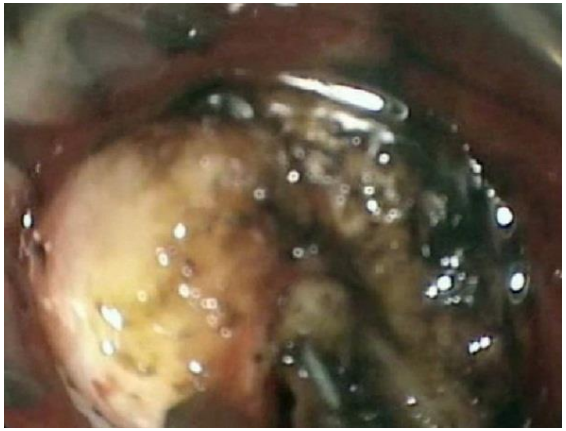
Clinical case example

Closure of persistent PEG-fistula using the OTSC® Anchor

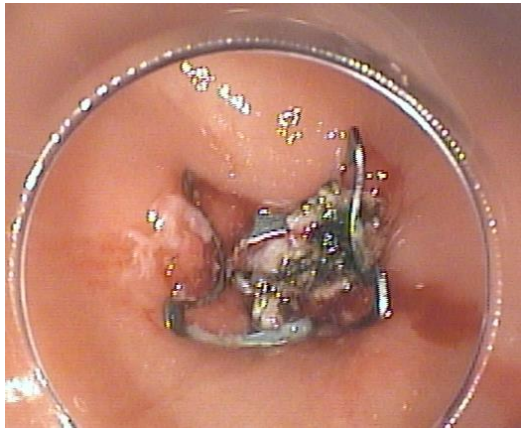


Grasping of fistula opening (here pre-treated with APC) with OTSC® Anchor

Cap is positioned on the lesion (Anchor is used as a guide)



Retracting the shaft of the OTSC® Anchor into cap; clip application

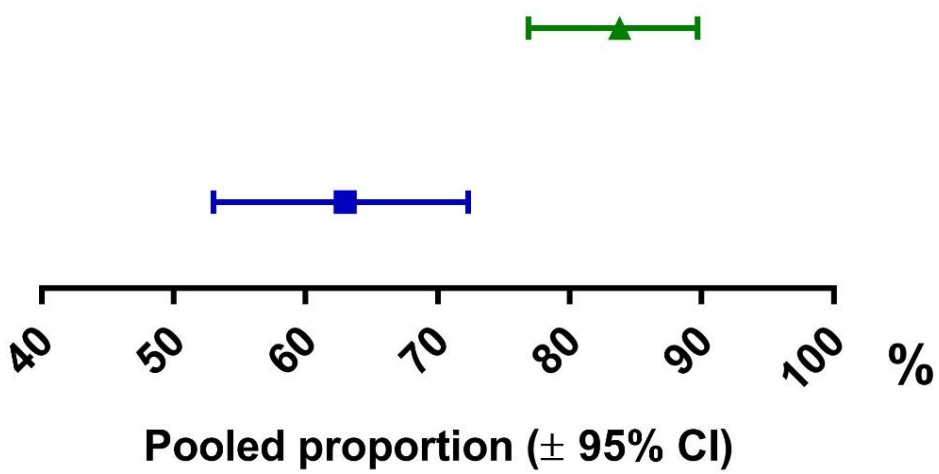


Closure of fistula opening

Source: Dr. Thomas Kratt, Interventional Endoscopy, Klinik für Allgemeine, Viszeral- und Transplantationschirurgie, University Hospital Tübingen, Germany

The mean statistical success rates underline OTSC® as a solid therapeutic option in this difficult patient population.

	Pooled proportion	95% CI
Technical success	83.8%	76.9% - 89.7%
Clinical success	63.0%	53.0% - 72.3%



NB:
Given a sample size of 546 cases
Only clinical reports with n ≥ 4 patients were included.

Source: Weiland T, Rohrer S, Schmidt A, Wedi E, Bauerfeind P, Caca K, Khashab MA, Hochberger J, Baur F, Gottwald T, Schurr MO. Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive Ther Allied Technol. 2020 Jun;29(3):121-139.

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The stentfix OTSC® System is a newly designed version of the OTSC® System especially for the fixation of metallic stents.

Advantages of the stentfix OTSC® System

- **Smaller cap**
  - improved maneuverability
  - Allows proximal and distal stent fixation
- **Dedicated cap shape** for easy positioning on both stent mesh and tissue
- **New clip design** adapts to the surface of both stent and tissue

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The compression force and the distance between the tooth remain unchanged compared to the OTSC® 11!

Product	OTSC® (11)	stentfix OTSC®
Outer diameter	16.5 mm	15.9 mm
Endoscope diameter	8.5 – 11 mm	8.5 – 11 mm
Depth of cap	3 mm 6 mm	7 mm

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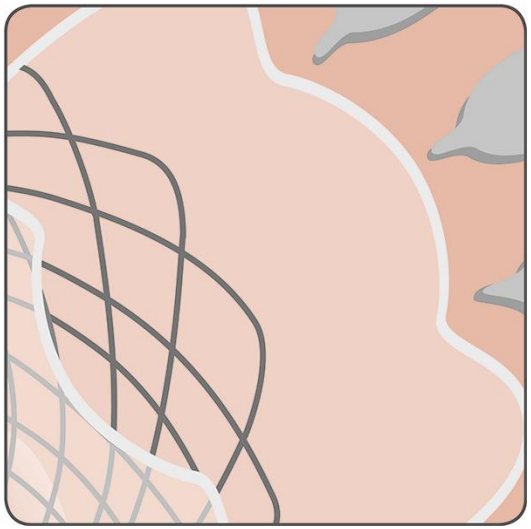
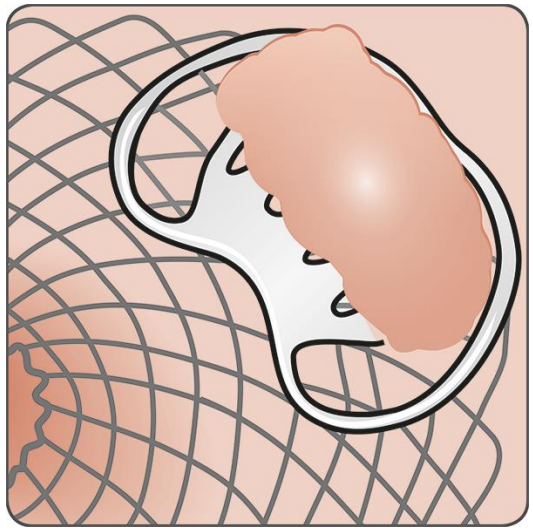
Depending on the clinical requirements, the stent can be fixed at its proximal or at its distal end.

Proximal fixation





1. The desired application site for the clip is targeted with the cap.
2. The cap is brought into proximity with the target location in the area of the stent opening. The application cap should be aligned with the clip so that the rows of teeth are parallel to the edge of the stent and grasp tissue and stent mesh simultaneously.
3. The user must ensure that the teeth of the stentfix OTSC® clip enclose both stent and tissue. To ensure a good fixation, positioning on 1 - 2 rows of meshes is enough, so that a suitable amount of tissue can be mobilized into the cap via suction.
4. The stentfix OTSC® is released by rotation of the hand wheel.

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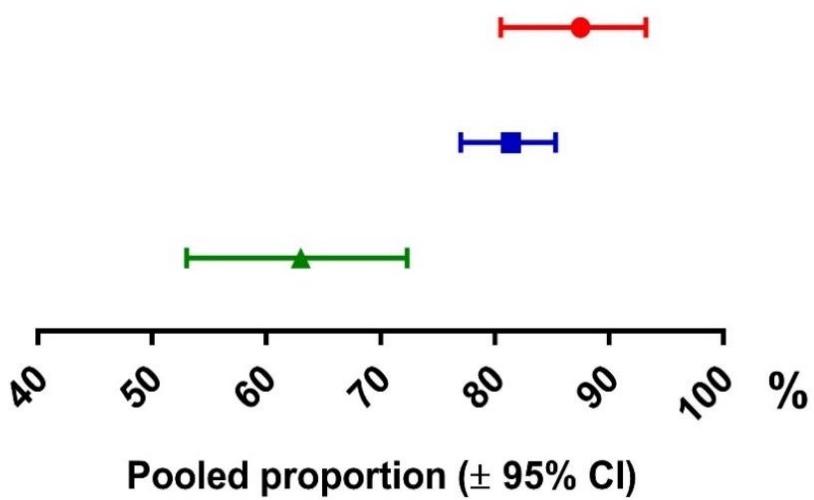
Use of OTSC® System leads consistently to high clinical success rates for hemostasis, perforation and fistulae closure.

- Over 400 peer reviewed clinical publications about OTSC®
- From case reports to retro- and prospective studies in all indications: Clinical success rates in

Hemostasis	88%
Closure of acute lesions / perforations	81%
Closure of chronic lesions / fistulae	63%

Clinical success across all indications



- The OTSC® System compares to the effectiveness of a surgical intervention and offers a new therapeutic option in situations where surgery is not feasible.

Source: Weiland T, Rohrer S, Schmidt A, Wedi E, Bauerfeind P, Caca K, Khashab MA, Hochberger J, Baur F, Gottwald T, Schurr MO. Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive Ther Allied Technol. 2020 Jun;29(3):121-139.

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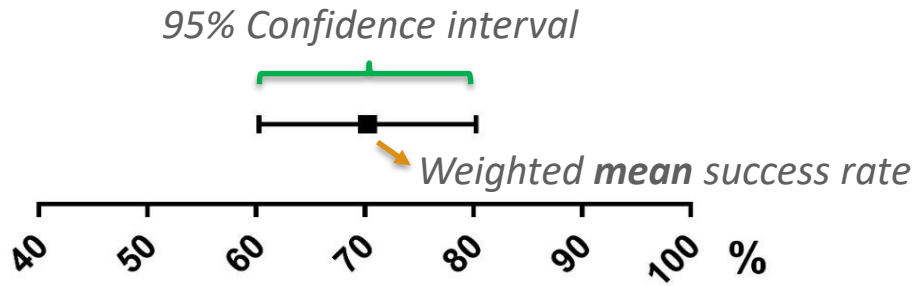
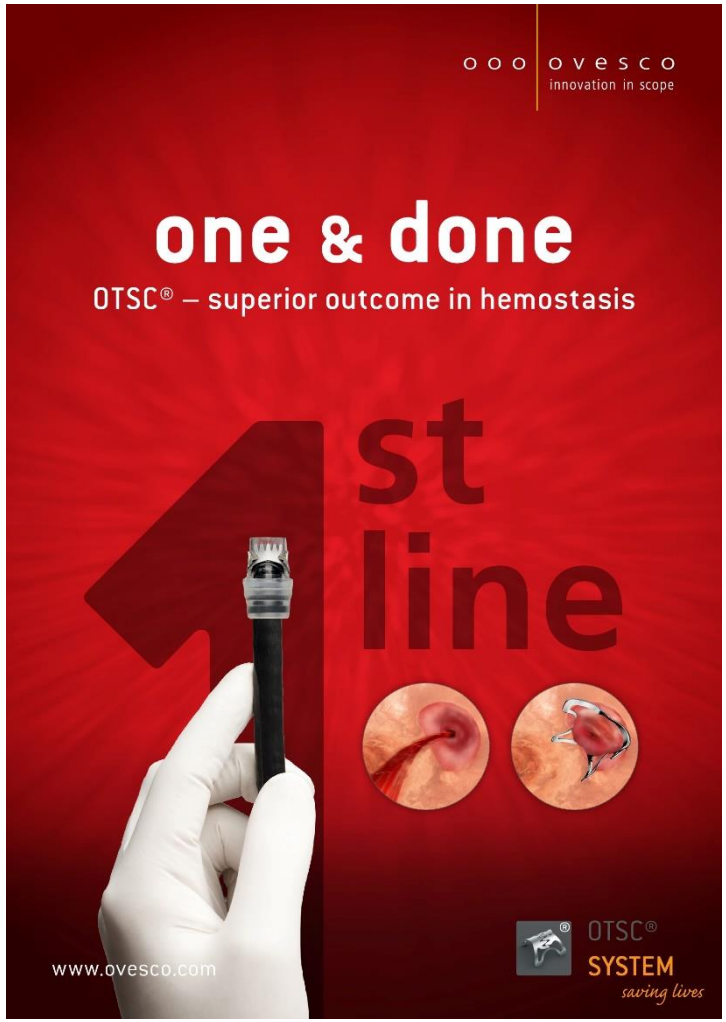
Systematic literature review: definitions / glossary

- **Technical success:**
  Successful application of clip at the desired location; not specified in all publications
- **Clinical success:**
  Permanent closure of defect/lesion as clinically intended
- **Success rate:**
  Percentage of successful treatment of lesion/all lesions (n/N).
- **Weighted mean success rate:**
  Average success rate of all studies: each study is being weighted according to reciprocal variance
  => the larger a study, the more precise the individual effect is to be assumed, the more weight it is attributed
- **Confidence interval:**
  The true value can be assumed to be within this area with a 95% propability



Source: Weiland T, Rohrer S, Schmidt A, Wedi E, Bauerfeind P, Caca K, Khashab MA, Hochberger J, Baur F, Gottwald T, Schurr MO. Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive Ther Allied Technol. 2020 Jun;29(3):121-139.

Please contact us in case of any questions.



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