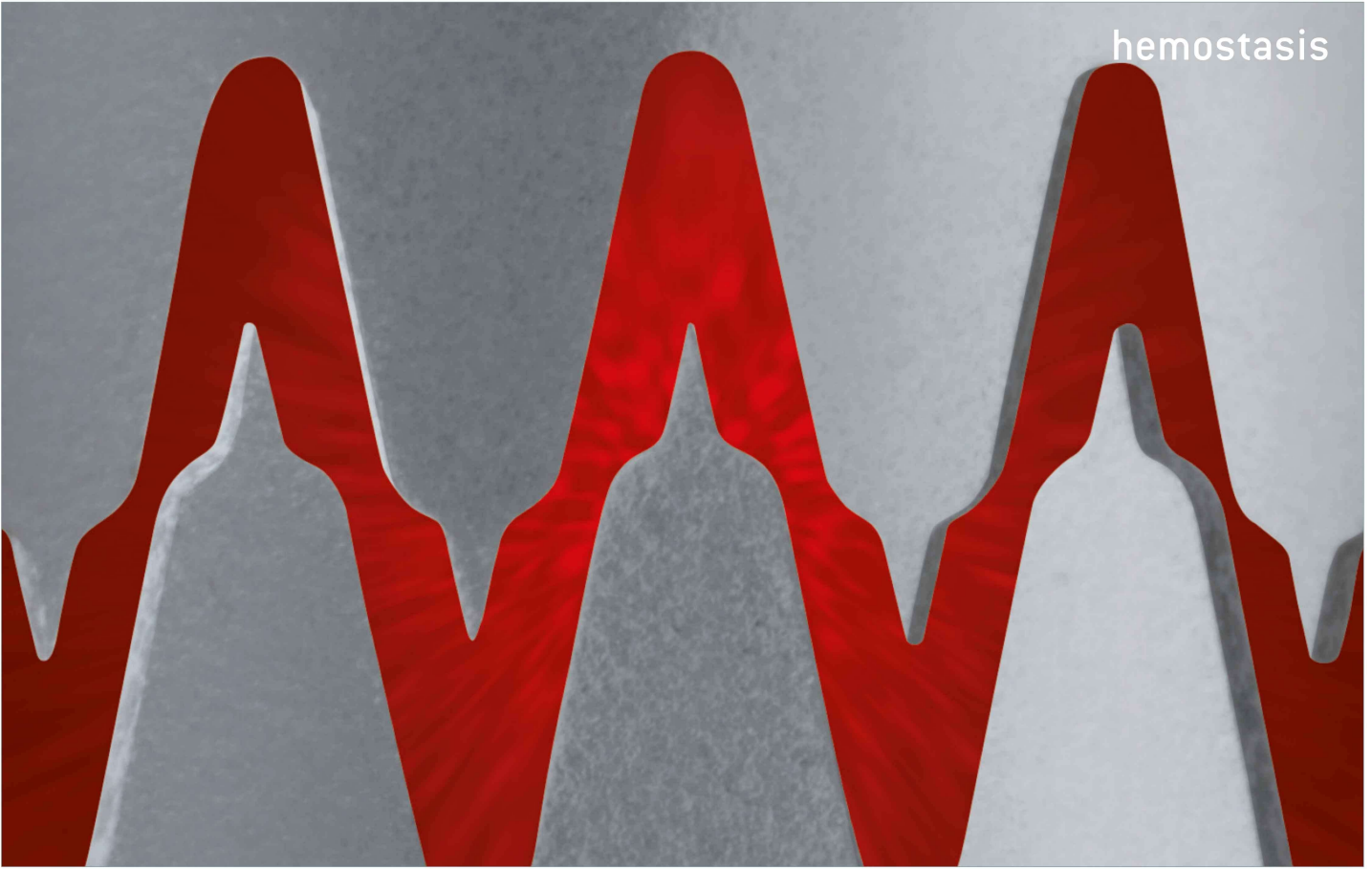


hemostasis



clinical bulletin

OTSC[®]neo for hemostasis

The OTSC®neo System

OTSC® – the ultimate hemostasis device (one & done)

The clinical benefit of the OTSC® technology and its products has been proven within multiple randomized controlled trials.

OTSC® in first-line therapy significantly increases hemostasis and reduces rebleeding risk in upper gastrointestinal bleeding (UGIB). Randomized controlled trials also show significantly higher clinical success, defined as no rebleeding between 7 and 30 days, of between 91.7%² and 96.8%⁴ compared to standard endoscopic treatment.

With OTSC®neo, we have further developed the OTSC® System based on the feedback of users worldwide. The proven strengths of the OTSC® System remain the same, while significantly improving areas such as clinical performance, application and handling.

Overview of the OTSC®neo System

The OTSC®neo System is an innovative product used in flexible endoscopy for hemostasis and for the closure of acute and chronic lesions.

The OTSC®neo consists of a transparent applicator cap with a mounted Nitinol® clip, thread, thread retriever and handwheel for clip release. The set-up and application of the OTSC®neo System is simple and quick. The procedure combines the following benefits:

- Securing of large tissue volume
- Stable tissue capture and durable effect at the site of intervention with dynamic compression
- Simple and faster application than other techniques through "one & done" placement



Properties and sizes of OTSC®neo application caps and clips

The OTSC®neo System is available in a variety of cap sizes and clip designs to **provide secure hemostasis regardless of the anatomical situation** and endoscope type. For hemostasis in the upper GI tract, the cap sizes (OTSC® and OTSC®neo versions) mini, 11 and 12 are used; the cap size 14 is usually used for colonoscopies.

The OTSC®neo application cap creates distance between the tip of the endoscope and the gastrointestinal wall. This distance provides **visibility** and allows the cap to **enfold sufficient tissue**, with the vessel in the center. With suction and flushing, the OTSC®neo cap can thereby support tissue cleansing and simplifies the visualization of the bleeding source.

The different cap sizes correspond to maximum diameters of the compatible endoscope and allow appropriate cap selection based on the anatomical situation you are faced with. There are two cap depths, shallow (3 mm) vs. deep (6 mm). The shallow cap provides unrestricted endoscopic visibility and maneuverability and is ideal for small lesions or thin tissue areas. The deeper cap enables the user to retract and clip a larger amount of tissue.

The size „mini“ is designed for cases of difficult access and also fits on pediatric endoscopes.

There are **three different shapes of clip teeth**: a, t, gc.

The space between the clip teeth enables microperfusion of the tissue in situ and therefore avoids necrosis and promotes healing.

All clips have the same tissue compression capabilities.



The "a clip" with round teeth is used if blunt compression of the tissue is intended.



The "t clip" has spikes at the end of the teeth and is used if additional anchoring of the clip is intended, e.g. in hard / fibrotic tissue.



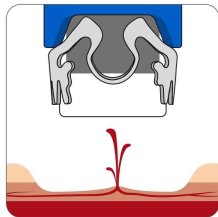
The "gc (gastric closure) clip" has elongated spikes and teeth and is only suitable for the treatment of perforations and lesions in the gastric wall.

Application techniques

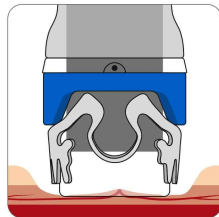
Practical application of the OTSC[®]neo System for hemostasis

Suction technique

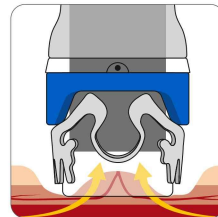
In most GI bleeding situations, tissue can be mobilized and securely pulled inside the application cap by simply applying endoscopic suction. Once the target tissue is captured inside the cap, hemostasis is achieved by turning the handwheel to release the OTSC[®]neo clip around the captured tissue.



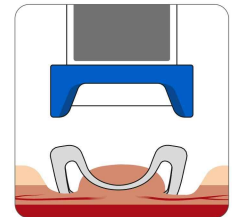
Target the lesion with the OTSC[®]neo System.



Bring the OTSC[®]neo cap in contact with the tissue.



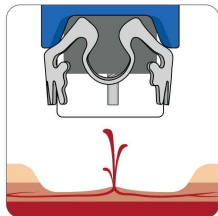
Suction the target tissue into the cap.



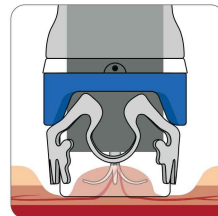
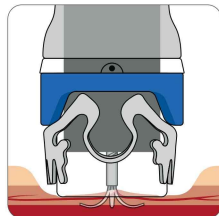
Apply the OTSC[®]neo clip by turning the hand wheel.

Anchor technique

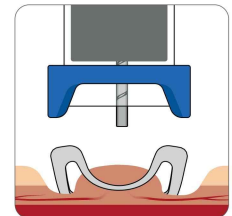
In cases of fibrotic or hard tissue or tangential application, the OTSC[®] Anchor can be valuable in precisely aligning target tissue with the cap opening and keeping it fixed during clip release. It may not always be possible to manipulate fibrotic tissue fully inside the cap. However, it is sufficient to pull the tissue firmly to the rim of the cap with the OTSC[®] Anchor, then apply the clip. The clip „jumps“ slightly forward upon release and grasps the tissue in front of the cap.



Position the OTSC[®] Anchor and fix the tissue; align the OTSC[®]neo cap to the lesion by pulling the anchor and advancing the endoscope.



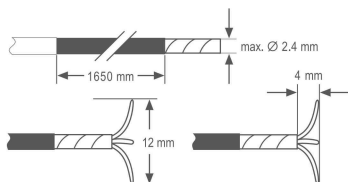
Mobilize the tip of the OTSC[®] Anchor shaft into the cap; anchor spikes may remain external; release the OTSC[®]neo clip.



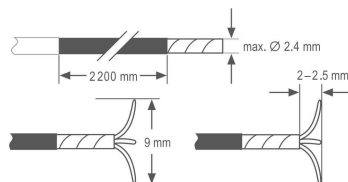
After clip application, detach the OTSC[®] Anchor from the tissue.

The OTSC[®] Anchor is available in two sizes. In contrast to the OTSC[®] Anchor 165, the OTSC[®] Anchor 220tt has shorter prongs and is designed specifically for use in areas of the gastrointestinal tract, in which tissue is anatomically thinner, such as the colon and duodenum.

OTSC[®] Anchor 165 (thick tissue)



OTSC[®] Anchor 220tt (thin tissue)

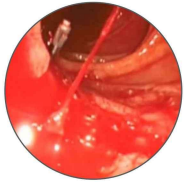


Case examples

OTSC® clip placement in case of hemorrhage

Bleeding

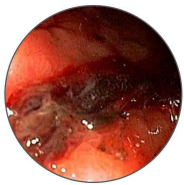
Treatment result



Spurting arterial bleeding from peptic duodenal ulcer

The images show the OTSC® treatment of a spurting arterial bleeding (Forrest Ia) from a duodenal ulcer.

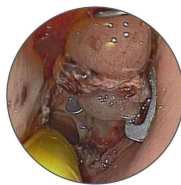
Source: Prof. Dr. P. Chiu, Department of Surgery, Prince of Wales Hospital, Hong Kong, China



Oozing bleeding from Ulcer Dieulafoy

A 70-year-old female patient was hospitalized for bronchopulmonary infection. The patient was under warfarin therapy (for recurrent deep vein thrombosis) and developed hematemesis (Hb 11.6 g/dl, INR 1.46). Upper GI endoscopy revealed an oozing bleeding from a Dieulafoy's lesion in the gastric antrum. Hemostasis was achieved successfully with OTSC®.

Source: Prof. Dr. K. Caca & Dr. A. Schmidt, Department of Internal Medicine, Ludwigsburg Hospital, Germany



Postoperative colonic anastomotic bleeding

Endoscopy of a 50-year-old male patient revealed anastomotic bleeding from the area of the stapling line after laparoscopic sigmoid resection. The bleeding lesion was pulled into the OTSC® cap by gentle suction. The clip was released and immediate hemostasis was achieved.

Source: Dr. T. Kratt, Department of Surgery, University Hospital Tuebingen, Germany



Forrest Ib bleeding from peptic duodenal ulcer

The images show the OTSC® treatment of an oozing ulcer bleeding with large vessel in the duodenum.

Source: Dr. M. Manno & Dr. P. Soriani, UOS Endoscopia Digestiva Area Nord, Azienda USL di Modena, Italy

Follow-up and MR conditionality

Once an OTSC®neo clip is successfully deployed it will **stay in situ for several weeks to several months**. The exact duration depends on the amount and texture of the tissue secured. The OTSC®neo clip will **leave the GI tract naturally** in the majority of cases. Occasionally, it may be overgrown by mucosa and remain in the body as a **long-term implant**, which is no problem because of its design and **biocompatibility**.

MR Conditionality

The OTSC®neo clip is **MR conditional**. Patients can be scanned safely in an MRI system after OTSC®neo clip placement under the following conditions: a) **static magnetic field of 3 Tesla or less**, b) **maximum spatial gradient magnetic field of 4,000 gauss/cm (40T/m)**. For further details, please refer to the instructions for use. In rare cases, in which a clip removal is necessary, e.g. local complication or misplacement, the OTSC®neo clip can be easily removed with the **Ovesco remove System**. This gives you the option to reverse or repeat the procedure.

Clinical evidence

1. OTSC® for upper gastrointestinal bleeding

1.1 OTSC® is superior as first-line treatment for NVUGIB compared to standard therapy

Table 1: Comparison of the five randomized-controlled trials on the efficacy of OTSC®

	Jensen et al. ¹	Meier et al. ²	Chan et al. ³	Lau et al. ⁴	Soriani et al. ⁵
n (OTSC®/ Standard)	53 (25/28)	100 (48/52)	100 (50/50)	190 (93/97)	112 (61/51)
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	Clinical success defined as no rebleeding ≤ 30 days	Clinical success defined as no rebleeding ≤ 30 days
Main inclusion criteria	Ulcer bleeding & Dieulafoy	High risk lesions [cRS* ≥ 7]	Large peptic ulcers > 1.5cm	All NVUGIB**	Ulcer bleeding
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. 66 % thermocoag. / 30 % endoclips / 4 % other combination)	OTSC® arm vs. Standard arm (approx. 64.9 % thermocoag. / 26.8 % endoclips / 7.2 % other combination)	OTSC® arm vs. Standard arm (100 % endoclips)
Clinical success	96.0% / 71.4% p=0.017	91.7% / 73.1% p=0.019	90% / 82% p=0.23	96.8% / 85.4% p=0.006	96.7% / 74.5% p=0.001

*cRS = Complete Rockall Score

** NVUGIB = Non-Variceal Upper Gastrointestinal Bleeding

*** optional injection therapy allowed in both arms

Five randomized-controlled trials (RCTs) have analyzed the efficacy of OTSC® as first-line treatment for non variceal upper gastrointestinal bleeding (NVUGIB) compared to standard endoscopic therapy: Jensen et al. (2021), Meier et al. (2022), Chan et al. (2023), Lau et al. (2023) and Soriani et al. (2024). The main results of these studies are shown in table 1 and figure 1. The results highlight the efficacy of OTSC® as the first-line treatment option.

These five RCTs were evaluated in two comprehensive meta-analyses by Alali et al. and Mega et al. The meta-analyses underscore the potential of OTSC® as the effective primary hemostatic modality. The five RCTs included 555 patients (277 treated with OTSC® and 278 with standard endoscopic therapy).

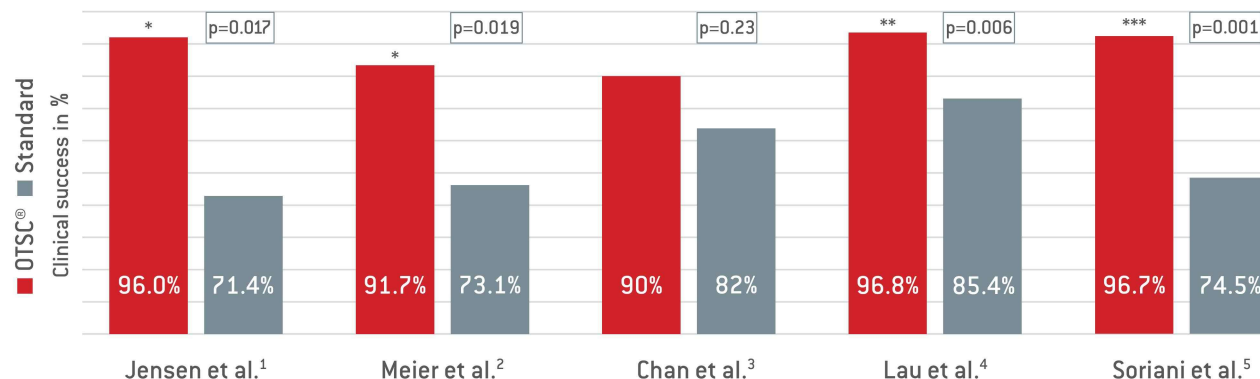
The findings revealed that OTSC® significantly reduces the 30-day rebleeding rate compared to standard endoscopic therapies. The primary endpoint in Alali et al., which focused on the composite outcome of further bleeding—either persistent or recurrent—at 30 days showed a

significant reduction with OTSC®, with a relative risk (RR) of 0.33 [95% CI 0.20-0.54]. This indicates that patients treated with OTSC® are substantially less likely to experience further bleeding episodes within 30 days post-treatment. The findings also revealed a significant reduction in 30-day rebleeding rates with OTSC®, with a relative risk of 0.38 [95% CI: 0.21-0.70]⁶ and 0.43 [95% CI: 0.24-0.77]⁷ respectively, compared to standard endoscopic therapies such as endoclips or thermal therapy in combination with injection therapy. **This reduction in rebleeding risk positions OTSC® as a superior option for initial intervention in NVUGIB cases.**^{6,7}

These findings support a shift in the standard of care for NVUGIB. By adopting OTSC® as a primary treatment, healthcare providers can potentially improve patient outcomes, reducing the need for repeat interventions and the associated healthcare costs.

Clinical evidence

Figure 1: Comparison of the clinical success rates of the OTSC® in the five RCTs



1.2 OTSC® as second-line treatment for NVUGIB

The prospective multicenter RCT, the STING trial (table 2) determined that OTSC® is more effective than standard therapy for patients with recurrent peptic ulcer bleeding following initially successful hemostasis. Conducted in 9 academic referral centers, 66 patients were randomly assigned to hemostasis with either OTSC® (n=33) or standard therapy (n=33). Standard therapy was defined as hemostasis with endoclips (n=31) or thermal therapy (n=2) plus injection with diluted adrenalin. The primary endpoint of the study was further bleeding within 7 days after successful hemostasis. In case of further bleeding, patients were allowed to cross over. OTSC® showed significantly higher technical success than standard therapy (93.9% vs 57.6%; p=0.001). In addition, OTSC® provided significantly higher clinical success (no persistent bleeding, no recurrent bleeding) compared to standard therapy (84.8% vs 42.4%; p=0.001).⁹

In two studies by Kuellmer et al. OTSC® was compared to transcatheter arterial embolization (TAE) and surgical interventions as a second-line treatment for refractory peptic ulcer bleeding. Both studies found OTSC® to have comparable clinical success rates, but significantly fewer adverse events. Compared to TAE, OTSC® resulted in lower adverse events (1.5% vs. 12.9%, p=0.042) and in-hospital mortality (9.1% with OTSC® vs 22.6%) as well as shorter ICU stays.⁹ When compared to surgical interventions, OTSC® led to shorter ICU stays (4.7±6.6 days vs. 16.2±18.0 days, p<0.001) and significantly fewer severe adverse events (4.5% with OTSC® and 70.3% with surgery, p<0.001) In-hospital mortality was

Table 2: Over the Scope Clips Are More Effective Than Standard Endoscopic Therapy for Patients With Recurrent Bleeding of Peptic Ulcers (Schmidt et al., 2018).

	Standard therapy (n=33)	OTSC® (n=33)	p value
Number of clips, median [range]	2 [1–8]	1 [1–2]	0.02
Use of thermal therapy, n [%]	2 [6.1]	0 [0]	0.492
Technical success*, n [%]	19 [57.6]	31 [93.9]	0.001
Technical failure, n [%]	14 [42.4]	2 [6.1]	0.001
Recurrent bleeding, n [%] (95% CI)	5 [16.1] [3.2–16.1]	3 [9.1] [0–18.2]	0.468
Clinical success**, n [%]	14 [42.4]	28 [84.8]	0.001
Hospital mortality, n [%]	1 [3.0]	3 [9.1]	0.613
Total mortality, n [%]	2 [6.3]	4 [12.1]	0.672

*Defined as successful hemostasis according to protocol
 **Defined as no persistent bleeding, no recurrent bleeding

also significantly lower with OTSC® (35.1% vs 9.1%, p=0.003).¹⁰ These findings suggest that OTSC® not only provides effective hemostasis but also offers a safer alternative with fewer complications, making it a preferable choice for managing refractory peptic ulcer bleeding when initial treatments fail.^{9,10}

Clinical evidence

2. OTSC® shows good results for endoscopic hemostasis in lower GI tract

OTSC® has also shown promising results in managing lower gastrointestinal bleeding (LGIB). In a multicenter study by Manta et al., data from patients with UGIB (n=214) and LGIB (n=72) treated with OTSC® as a first-line treatment were evaluated. Technical success was 97.9%, and primary hemostasis was 96.4%. The median hospital stay was four days.¹¹ Manta et al. also analyzed the use of OTSC® in patients with acute GI bleeding unresponsive to conventional endoscopic treatments. Primary hemostasis was achieved in 97% of cases (29/30). Rebleeding occurred in two patients within 24 hours, successfully treated with conventional endoscopic injection.¹² Kawano et al. in 2021 evaluated OTSC® for colonic diverticular bleeding in 36 patients. The procedure success rate was 100%, adverse events rate was 0%, and 30-day re-bleeding rate was 8.3%.

No additional transcatheter arterial embolization (TAE) or surgery was required.¹³ These studies show that OTSC® can be an excellent first-line treatment not just in the upper, but also in the lower GI-tract.

Table 3: First-line endoscopic treatment with over-the-scope clips in patients with either upper or lower gastrointestinal bleeding: a multicenter study [Manta et al., 2018].

	Total (n=286)	UGIB (n=214)	LGIB (n=72)
Technical success (%)	280 (97.9)	208 (97.2)	72 (100)
Primary hemostasis (%)*	270 (96.4)	202 (97.1)	68 (94.4)
Early rebleeding (%)**	12 (4.4)	9 (4.5)	3 (4.4)
Post treatment blood transfusion (%)	14 (4.9)	8 (3.7)	6 (8.3)
Hospital stay, median (range); days	4 (3–11)	4 (2–10)	4 (3–11)
Mortality (%)	5 (1.9)	4 (2)	1 (1.5)

UGIB, upper gastrointestinal bleeding; LGIB, lower gastrointestinal bleeding

*Calculated in 280 patients, in whom technical success was achieved.

**Calculated in 270 patients, in whom primary hemostasis was achieved.

3. Cost-effectiveness analysis: OTSC® can be more cost-effective for hemostasis compared to standard therapy

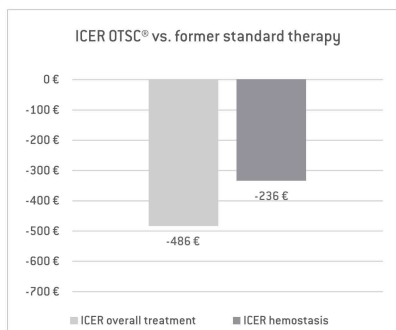
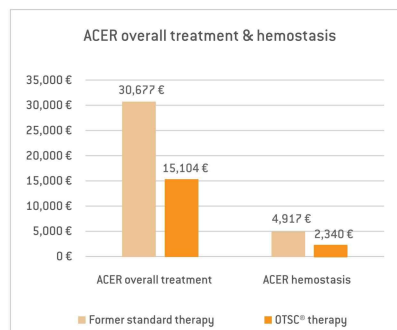
Using the clinical data of the randomized controlled STING trial, Kuellmer et al. analyzed the cost-effectiveness of the OTSC® System for hemostasis and compared it with the former standard therapy (conventional endoclips or thermal coagulation plus injection). For analysis, the cost-effectiveness parameters ACER* and ICER** were calculated from the perspective of the health care provider. The results of the analysis (Table 4) show that the ACER of OTSC® therapy is 50% less than the ACER* of former standard therapy, for overall treatment in the hospital 15,104.48 € vs. 30,677.05 € and for endoscopic intervention alone (hemostasis) 2,340.46 € vs. 4,917.41 €. The ICER (OTSC® therapy vs. former standard therapy) is -468 € for overall treatment and -236 € for hemostasis alone; i.e. use of the OTSC® does not incur additional costs

but actually reduces the costs compared to the former standard therapy. This cost benefit results from the avoidance of follow-up costs for treatment of secondary bleeding.¹⁴ These findings are further supported by Yu et al. who demonstrated that OTSC® is particularly cost-effective as a first-line treatment for patients with medium Rockall 4-7 or high-risk Rockall ≥ 8 peptic ulcer bleeding.¹⁵

This data demonstrates that the clinically superior OTSC® treatment is also cost-effective and even cost-reducing.

Table 4: OTSC vs standard therapy of recurrent ulcer bleeding: a cost-effectiveness analysis [Kuellmer et al., 2019].

	ACER* overall treatment	ACER* hemostasis	ICER** overall treatment	ICER** hemostasis
Former standard therapy	30,677.05 €	4,917.41 €	-468 €	-236 €
OTSC® therapy	15,104.48 €	2,340.46 €		



*Average Cost-Effectiveness Ratio (ACER): average costs (in Euro) per successful hemostasis (without rebleeding)

**Incremental Cost-Effectiveness Ratio (ICER): average incremental costs (in Euro) associated with the additional therapeutic effect of the OTSC® (successful hemostasis without rebleeding)

Summary

OTSC® consistently shows a clinical benefit and is superior to standard techniques in GI hemostasis

Treatment with OTSC® shows higher success rates than former standard therapy. As first-line procedure for UGIB, OTSC® improves hemostasis and prevents rebleeding

- The clinical success rates of OTSC® in hemostasis are significantly superior to standard therapy, both for first- and second-line therapy
- As second-line therapy, OTSC® significantly reduces ICU stay and in-hospital mortality
- OTSC® has also shown promising results in hemostasis for lower GI bleeding
- OTSC® clipping is a cost-saving procedure (cost-effectiveness analysis)
- » **OTSC® provides a clinically relevant, scientifically proven benefit for patients with bleeding.**

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Educational scope:

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