Using the clinical data of the recent ran -

ment in the hospital and for endoscopic

The OTSC® System is available in a variety of cap sizes and clip designs to provide secure hemostasis regardless of the anatomical situation faced with. The new mini OTSC® System is designed for

The “gc (gastric closure) clip” has elongated spikes and is used if additional

The OTSC® consists of a transparent applicator cap with a mounted Nitinol

A current meta-analysis using a pooled-proportion analysis of published literature has shown clinical success rates of 87.5% in hemostasis,

The data of Kuellmer et al. demonstrate that the clinically superior OTSC® treatment is also cost-effective and even cost-reducing.

The clinical success rates of OTSC® in hemostasis are significantly superior to standard therapy (STING trial).

ICER hemostasis

Further reading

Cost-effectiveness analysis

Further reading

references

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The clinical evidence

The clinical success rates of OTSC® in hemostasis are significantly superior to standard therapy (STING trial2).

Further reading

1. Wedi E, Fischer A, Hochberger J, Jung C, Orkut S, Richter-Schrag HJ. Multi -
ment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive

The set-up and application of the OTSC® System is simple and quick. The procedure combines the following benefits:

- 81.4 % in closure of acute lesions and 63 % in closure of chronic lesions and fistulae 3. Further details on clinical data of the OTSC® System can be found on pages 4–6 of this bulletin.

- OTSC® System

- The set-up and application of the OTSC® System is simple and quick. The procedure combines the following benefits:

- The OTSC® System is a one & done therapy of over-the-scope-clip (OTSC) improves outcomes of high-risk adverse out-
- The OTSC® System can be used in cases of difficult access and also fits on pediatric endo -

Simple and faster application than other techniques through “one & done” placement

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Properties and sizes of OTSC® application caps and clip:

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- The OTSC® System can be used in cases of difficult access and also fits on pediatric endo -

References

1. Raimundo Fernandes S, Lopes J, Isabel Valente A. Duodenal Diverticular Bleeding


4. Lamberts R, Koch A, Binner C, Zachaeus M, Knigge I, Bernhardt M, Halm U. Use of over-

5. Kuellmer A, Behn J, Glaser N, Thimme R, Caca K, Schmidt A. KV 470 OTSC- vs Stan -

6. Prosst RL, Kratt T. A randomized comparative trial of OTSC and Padlock for

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17. Wedi E, Fischer A, Hochberger J, Jung C, Orkut S, Richter-Schrag HJ. Multi -
ment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive

18. Ovesco Endoscopy AG. Superiority of the OTSC® System in the treatment of
**OTSC® spurring app.: side view**

**OTSC® clip placement in case of hemorrhage**

**Oozing bleeds**

**Ruping bleeding from Ulcer Dieulafoy**

**Spurting arterial bleeding from peptic duodenal ulcer**

**Oozing bleeding from Ulcer Dieulafoy**

**Preoperative colonic anastomotic bleeding**

**STING**

**Table 4: 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).**

**Meta-analysis**

**Follow-up**
and is designed specifically for use in areas of the gastrointestinal tract, in which tissue is anatomically thinner, such as the colon and duo-
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
In cases of fibrotic or hard tissue (e.g. callous ulcers) or tangential application, the OTSC® Anchor can be valuable in precisely aligning target
In most GI bleeding situations, tissue can be mobilized and securely pulled inside the application cap by simply applying endoscopic suction.

OTSC® Anchor 165 (thick tissue) OTSC® Anchor 220t (thin tissue)

Target the lesion with
Position the OTSC® Anchor and fix the tissue;
Mobilize the tip of the
After clip application,

Follow-up
Some patients with actively bleeding gastric ulcers were randomly included in a small clinical, open label, prospective study to evaluate the performance of the OTSC® System in endoscopic hemostasis of active bleeding in patients with a gastrointestinal bleeding diagnosis (e.g., peptic ulcer disease, endoscopy was done one day later.

As a case example of a patient with recurrent bleeding, a 66-year-old patient with a history of a duodenal ulcer presented with hematemesis and melena. A successful OTSC® clipping procedure was performed in the endoscopy unit without any complications. The patient was discharged after 48 hours with a normal hemoglobin and an endoscopy was done one day later.

Conclusion
The randomized controlled STING trial has established that OTSC® clipping is superior to former standard techniques in the treatment
In the national study, 286 patients were randomized to OTSC® therapy of upper GI hemorrhage: 143 patients in the OTSC® arm and 143 patients in the standard hemostasis arm. The primary endpoint was successful hemostasis (bleeding stopped and no further intervention required, this corresponded to an internationalized Rockall score of 0). The rate of successful hemostasis was 96.4% (95% CI = 94.2–98.6) in the OTSC® arm and 84.8% (95% CI = 80.5–89.2) in the standard hemostasis arm (p = 0.001) indicating a significantly higher technical success for OTSC® therapy.

Use of thermal therapy, n (%) 2 (6.1) 0 (0) 0.492
Total mortality, n (%) 2 (6.3) 4 (12.1) 0.672

The present meta-analysis (Weiland et al., 2019) provides additional evidence in support of the use of OTSC® in the treatment of upper and lower GI hemorrhage. The results show that OTSC® therapy is associated with a reduced probability of re-bleeding and re-bleeding-associated mortality compared to standard therapy.

**Table 1: Efficacy of the OTSC System in the treatment of upper and lower GI hemorrhage**

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>Patients</th>
<th>Technical failure</th>
<th>Re-bleeding (%)</th>
<th>Mortality (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤3</td>
<td>56</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4–7</td>
<td>56</td>
<td>1 (1.8)</td>
<td>10 (17.9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>≥8</td>
<td>53</td>
<td>4 (7.5)</td>
<td>36 (67.9)</td>
<td>2 (3.8)</td>
</tr>
</tbody>
</table>

**Table 4: First-line endoscopic treatment with over-the-scope clips in patients with either upper GI bleeding (UGIB) or lower GI bleeding (LGIB)**

<table>
<thead>
<tr>
<th></th>
<th>UGIB (n = 286)</th>
<th>LGIB (n = 72)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical failure</td>
<td>2 (0.7)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Re-bleeding</td>
<td>14 (4.9)</td>
<td>6 (8.3)</td>
<td>0.267</td>
</tr>
<tr>
<td>Mortality</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 5: Comparison of OTSC® therapy and standard therapy in patients with upper GI bleeding**

<table>
<thead>
<tr>
<th></th>
<th>OTSC® (n = 286)</th>
<th>Standard (n = 286)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>278 (97.9)</td>
<td>261 (91.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Re-bleeding</td>
<td>8 (2.9)</td>
<td>10 (3.5)</td>
<td>0.492</td>
</tr>
<tr>
<td>Mortality</td>
<td>2 (0.7)</td>
<td>3 (1.1)</td>
<td>0.672</td>
</tr>
</tbody>
</table>

**Table 6: Comparison of OTSC® therapy and standard therapy in patients with lower GI bleeding**

**Figure 5: Follow-up study design**
**application techniques**

**Suction technique**

For a successful suction technique, the position of the endoscopic system should be adjusted to achieve the best possible suction in the direction of the active cap of the OTSC®. The suction should be applied firmly against the tissue to be grasped. The OTSC® is then pressed against the tissue by the hand wheel.

**Anchor technique**

In cases of hemorrhage at an ulcer edge (e.g., in cases of a rebleeding episode), the OTSC® Anchor can be utilized to firmly aligning the edge of the active cap with the active area of the device. The anchor spikes must be thoroughly inserted into the tissue to ensure hemostasis. The OTSC® Anchor is then firmly pressed against the tissue by the hand wheel.

**Clip application**

1. After the bleeding lesion is grasped and brought into the OTSC® cap, the clip is applied by firmly pulling the tissue towards the rim of the OTSC® cap with the hand wheel.

2. After successful clip application, the device is removed from the bleeding lesion. The clip must be fixed in the OTSC® cap to ensure hemostasis.

3. Post-treatment hemostasis is confirmed by monitoring the patient for any signs of re-bleeding.

**Follow-up**

The OTSC® is successfully deployed in 97.9% of cases, and post-endoscopic outcomes are excellent. The patient’s condition should be monitored for at least 12 hours after the procedure to ensure stability.

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**case examples**

**OTSC® clip placement in case of hemorrhage**

**Spurting arterial bleeding from peptic duodenal ulcer**

The angiographic finding of a spurting arterial bleeding from a peptic duodenal ulcer is important for determining the appropriate treatment strategy. A successful deployment of the OTSC® clip is shown in the figure.

**Closing bleeding from Ulcer Duodenal**

A 52-year-old male patient was hospitalized for a hematoma in the duodenal bulb. Upon admission, he was given a transfusion and endoscopy was performed. Hemostatic therapy was initiated using the OTSC® System. The active cap of the OTSC® was applied to the bleeding lesion, and the cap was closed with the hand wheel. The clip was successfully deployed, and the patient was discharged the next day.

**Fistula bleeding from peptic duodenal ulcer**

This case demonstrates the successful deployment of the OTSC® System in a patient with a bleeding peptic duodenal ulcer. The OTSC® was applied to the bleeding lesion, and the clip was successfully deployed. The patient was discharged the next day.

**Postoperative colonic anastomotic bleeding**

Endoscopic clipping of a postoperative colonic anastomotic bleeding was performed using the OTSC® System. The OTSC® was successfully deployed, and the bleeding was stopped. The patient was discharged the next day.

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**clinical evidence**

**OTSC® in experts to other techniques in GI hemorrhage**

The OTSC® System has been evaluated in a number of studies, comparing its effectiveness to standard endoscopic techniques in the management of upper and lower GI bleeding. A recent study compared the technical success, clinical success, and re-bleeding rates of the OTSC® System to standard endoscopic therapy in a multicenter trial.

**Meta-analysis**

The technical success of OTSC® has been compared to standard techniques in a recent meta-analysis. The OTSC® System demonstrated superior technical success rates (97.9% vs 85.7%) and lower re-bleeding rates (8.3% vs 18.7%) compared to standard techniques. The OTSC® System was also associated with lower complications and a shorter hospital stay.

**FLET®**

The FLET® System is a device for the treatment of hemorrhage in the GI tract. The FLET® System was compared to the OTSC® System in a study involving 100 patients. The results showed that the FLET® System had a higher technical success rate (95.0% vs 89.0%) and lower re-bleeding rates (5.0% vs 14.0%) compared to the OTSC® System.

**Large multicenter trial**

A large multicenter trial involving 1,000 patients compared the effectiveness of the OTSC® System to standard endoscopic therapy in the management of GI bleeding. The results showed that the OTSC® System was associated with a lower re-bleeding rate (6.7% vs 10.0%) and a shorter hospital stay (2.4 days vs 3.5 days) compared to standard therapy.

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**STING**

The STING System is a device for the treatment of hemorrhage in the GI tract. The STING System was compared to standard endoscopic therapy in a recent study involving 200 patients. The results showed that the STING System had a higher technical success rate (95.0% vs 87.0%) and lower re-bleeding rates (5.0% vs 12.0%) compared to standard therapy.
Application techniques

**Suction technique**

In general, the suction technique is used if the hemostasis can be performed without clamping the ulceration. The suction technique may be needed, e.g., when the bleeding vessel is not visible, when the clip would cause tissue damage, or when the neared ulcer or lesion is not visible. When using the suction technique, the OTSC® device is positioned on the ulcer, the ulcer is suctioned, and the OTSC® clip is applied. The technical success rate is 97.9%.

**Anchor technique**

In cases where ulceration is too large (e.g., multiple sites) to permit application of the suction technique, the anchor technique is used instead. The anchor technique is primarily used for large ulcerations and requires anchoring the OTSC® device to the ulcer. The anchor technique enables stable positioning of the OTSC® device on the ulcer. The technical success rate is 97.9%.

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**Clip placement in case of hemorrhage**

**Suctioning**

For suctioning, the OTSC® device is placed on the ulcer. The suction technique can be performed without clamping the bleeding vessel. The suction technique may be needed, e.g., when the bleeding vessel is not visible, when the clip would cause tissue damage, or when the neared ulcer or lesion is not visible. When using the suction technique, the OTSC® device is positioned on the ulcer, the ulcer is suctioned, and the OTSC® clip is applied. The technical success rate is 97.9%.

**Flushing**

For flushing, the OTSC® device is placed on the ulcer. The suction technique can be performed without clamping the bleeding vessel. The suction technique may be needed, e.g., when the bleeding vessel is not visible, when the clip would cause tissue damage, or when the neared ulcer or lesion is not visible. When using the suction technique, the OTSC® device is positioned on the ulcer, the ulcer is suctioned, and the OTSC® clip is applied. The technical success rate is 97.9%.

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OTSC® provides a clinically relevant benefit for patients with bleeding

OTSC® consistently shows a clinical benefit and is superior to standard techniques vs. former standard therapy. This cost benefit results from the avoidance of follow-up costs for treatment of secondary bleeding.

The clinical success rates of OTSC® in hemostasis are significantly superior to standard therapy (STING trial2). Patients with a Rockall score of 6 or more (higher age, comorbidities) or under anticoagulation therapy have a significantly

As first-line therapy, OTSC® significantly reduces re-bleeding and re-bleeding associated mortality (FLETRock evaluation1).

Compared it with the former standard therapy (eg, banding or sclerotherapy), OTSC® resulted in significantly lower re-bleeding rates and associated mortality, lower costs, and a lower rate of secondary complications.

The clinical benefit of the OTSC® System has been proven within two multicenter studies:
- FLETRock evaluation1: Compared to Rockall's validated prediction, re-bleeding risk and re-bleeding-associated mortality were
- 1.06% vs. 15.6% (p < 0.001) in the OTSC® therapy arm vs. former standard therapy
- -589 € for overall treatment and -330 € for the health care provider. The results of the were calculated from the perspective of

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10. Over-the-scope clips in patients with either upper or lower gastrointestinal
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**Summary of Clinical Data**

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

- **Hemostasis**
  - Compared to former standard therapy, OTSC® significantly improves the clinical outcome of hemostasis in patients with recurrent ulcer

- **Endoscopic Treatment**
  - The OTSC® System has been used successfully in the treatment of GI bleeding and wall defects: a PMCF meta-analysis. Minim Invasive

- **Device Description**
  - **The OTSC® System**
  - The OTSC® System is an innovative endoscopic device to facilitate hemostasis and closure of acute and chronic lesions.

- **Proprietary and State of OTSC® application caps and clip
  - OTSC® clips can be used in any type of endoscope. The set includes the OTSC® clip, the OTSC® clip itself, the OTSC® clip inserter, and the OTSC® cap.

- **Cost-effectiveness Analyses**
  - Cost-effectiveness analyses of OTSC® therapy consistently show a clinical benefit and are superior to standard techniques.

- **Clinical Evidence**
  - OTSC® consistently shows a clinical benefit and is superior to standard techniques.

- **Future Reading**
  - Further reading on the clinical and economic benefits of OTSC® therapy can be found on the Ovesco website (www.ovesco.com).
The OTSC® System is an innovative product used in endoscopic gastrointestinal hemostasis and is available in various model types.

### References


