

remOVE System.

System for removal of OTSC® and FTRD® clips



The novel remOVE System for endoscopic OTSC® and FTRD® clip removal

- Effective endoscopic cutting and extraction of OTSC® and FTRD® clips
- Novel generator and probe technology based on direct current (DC)
- Safe and easy to use
- System designed for minimal and superficial thermal injury
- Safe retrieval of clip fragments

Applications for endoscopic removal of OTSC® and FTRD® clips:

- Misplacement of the clip at an unwanted place
- Accidental clipping of an instrument to the tissue
- Local complications due to the clip (e.g. luminal obstruction)
- Need for repeat biopsy or for successive lesion resection at the site
- Extraction of a stent fixed with a stentfix OTSC® clip

..... Application

Clip removal



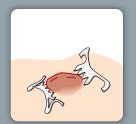


Establish contact with the clip When a continuous acoustic signal occurs, press the foot-activated switch once in order to cut the clip.





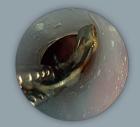
Repeat the procedure at a point of the clip opposite to the first cut.





lization that fragmentation of the clip has been successfully





Use the remOVE Grasper to pull the clip fragments into the remOVE SecureCap and remove them from the patient's body.



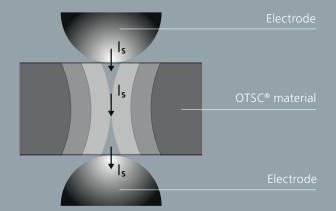
Clip removal with AWC®





Clip removal with the help of the remOVE Grasper introduced

Physical principle of functioning



The remOVE DC Impulse generates a bipolar current pulse. This DC pulse is applied onto the OTSC®/FTRD® clip via the remOVE DC Cutter resulting in localized melting and cutting of the clip. The clip is grasped with the remOVE DC Cutter preferably at the thinnest parts.

..... remOVE System

Details and Components



The remOVE DC Impulse (ref. no. 400.01) is a medical electrical device for fragmentation of OTSC® and FTRD® clips in the digestive tract.

The remOVE DC Impulse is designed to ensure that a direct current pulse can only be generated when sufficient contact with a segment of the clip is established. Sufficient contact is indicated through an acoustic signal.



Gefördert durch:

0 0 0



ovesco

aufgrund eines Beschlusses des Deutschen Bundestages

Components:

- A remOVE DC Impulse
- **B** Foot-activated switch with connector cable
- **C** DC cord in order to connect the remOVE DC Cutter
- **D** Power cord

The remOVE DC Cutter Set consist of (ref. no. 400.02.01 (12); ref. no. 400.02.02 (14)):



- Bipolar endoscopic direct current (DC) instrument for fragmentation of OTSC® and FTRD® clips in the digestive tract
- Designed to be used only with the remOVE DC Impulse and flexible endoscopes
- Flexible shaft, length 220 cm, compatible with working channel diameters of 2.8 mm or larger, single use product





rem0VE SECURECAP

• Elastic and transparent retrieval cap for safe extraction of clip fragments, single use product





rem0VE GRASPER

- Grasping forceps for retrieval of clip fragments into the remOVE SecureCap
- Flexible shaft, length 220 cm, compatible with working channel diameters of 2.8 mm or larger, single use product



rem0VE SHIELD

 Adhesive film which protects the optical lens of a flexible endoscope against flying sparks when using the remOVE System, single use product

Ovesco Endoscopy AG

Friedrich-Miescher-Straße 9 72076 Tuebingen Germany

Telefon +49(0)7071 96528-160 Fax +49(0)7071 96528-260 E-Mail service@ovesco.com

Ovesco Endoscopy USA Inc.

120 Quade Drive Cary, NC 27513 USA

Phone +1 919 651 9449 Fax +1 408 608 2077 customerservice@ovesco-usa.com



Ovesco Endoscopy AG is a medical device company specializing in the fields of fl exible endoscopy and endoluminal surgery. Ovesco develops, manufactures, and markets innovative products for the treatment of gastrointestinal disease. Ovesco products stand for therapeutic efficacy and efficient application.

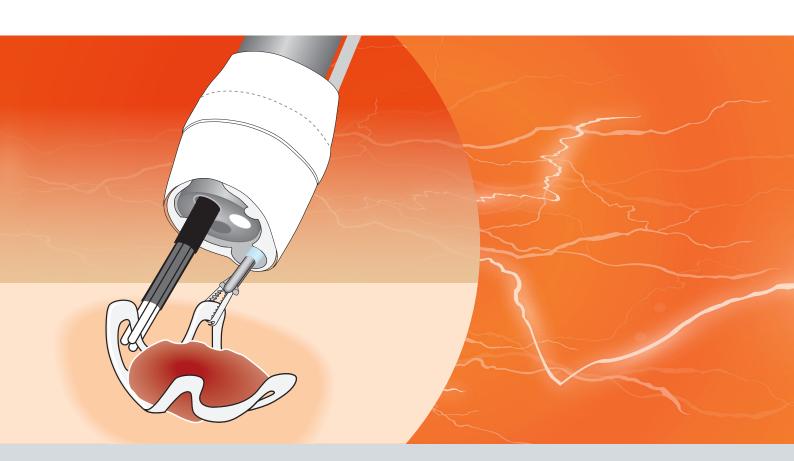
www.ovesco.com



Clip removal with the AWC®.

Optimized technique for the removal of OTSC® and FTRD® Clips

- Facilitates contacting the clip
- Stabilizes the clip during application
- Simplifies the procedure













. Optimized clip removal

Combined use of the remOVE System and the AWC® for facilitation of OTSC® or FTRD® clip removal in the gastrointestinal tract.

With the help of the additional working channel provided by the AWC® (additional working channel), it is possible to work bimanually with the remOVE DC Cutter and the remOVE Grasper.

The additional use of the remOVE Grasper can facilitate the following application situation in particular:

- Clip partially invisible or overgrown by tissue: the clip can be freed and fixed with the grasper.
- Clip loosely attached to the tissue: the clip can be fixed in the desired position.

This combination can also be used in other situations to save time and facilitate clip removal.

..... Application

Clip removal with the help of the remOVE Grasper introduced by the AWC®.





Source: Prof. Dr. Marc Schurr, Ovesco Endoscopy, Tuebingen, Germany (in-vivo model)

Ovesco Endoscopy AG

ovesco

Friedrich-Miescher-Straße 9 72076 Tuebingen Germany

Telefon +49(0)7071 96528-160 Fax +49(0)7071 96528-260 E-Mail service@ovesco.com

Ovesco Endoscopy USA Inc.

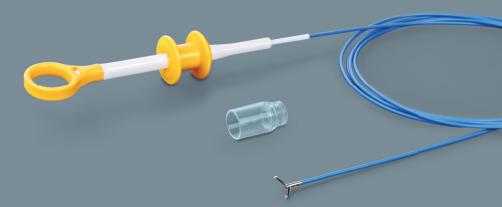
120 Quade Drive Cary, NC 27513 USA

Phone +1 919 651 9449 Fax +1 408 608 2077 customerservice@ovesco-usa.com



www.ovesco.com

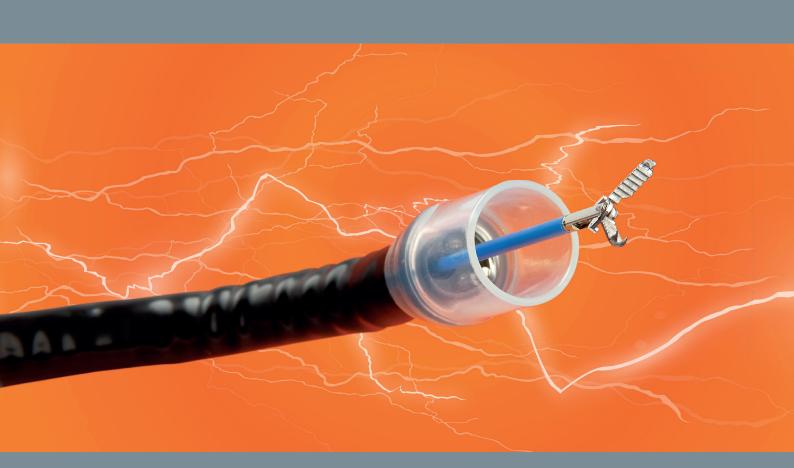
Ovesco Endoscopy AG is a medical device company specializing in the fields of flexible endoscopy and endoluminal surgery. Ovesco develops, manufactures, and markets innovative products for the treatment of gastrointestinal disease. Ovesco products stand for therapeutic efficacy and efficien application.

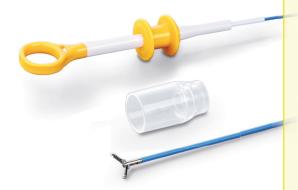


remOVE FBR Set

for safe foreign body retrieval

- Alligator and rat tooth in one grasping device
- Long and elastic retrieval cap
- Safe removal of sharp and foreign objects





remOVE FBR Set

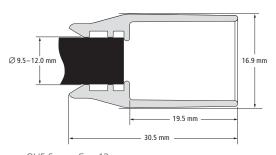
The remOVE FBR Set is a foreign body retrieval set for safe removal of various foreign body objects.

The package contains two sets (ref. no. 400.05); each set includes a remOVE SecureCap 12 and a remOVE Grasper.

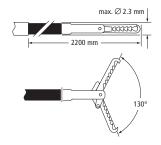
The remOVE SecureCap is an elastic and transparent retrieval cap. It allows safe extraction of ingested foreign objects in the digestive tract.

The remOVE Grasper is a grasping forceps used to grasp und retrieve foreign bodies in the digestive tract. It includes alligator and rat teeth to ensure a strong hold and easy retrieval of foreign bodies into the remOVE SecureCap.

Dimensions



remOVE SecureCap 12



remOVE Grasper

Application

Extraction of a clip fragment by using the remOVE FBR Set.





Source: Prof. Dr. K. Caca and Dr. A. Schmidt, Klinikum Ludwigsburg, Dept. of Internal Medicine, Gastroenterology, Hemato-Oncology, Diabetes, and Infectious Diseases, Germany

Ovesco Endoscopy AG

Friedrich-Miescher-Straße 9 72076 Tuebingen Germany

Telefon +49(0)7071 96528-160 Fax +49(0)7071 96528-260 E-Mail service@ovesco.com

Ovesco Endoscopy USA Inc.

120 Quade Drive Cary, NC 27513 USA

Phone +1 919 651 9449 Fax +1 408 608 2077 customerservice@ovesco-usa.com



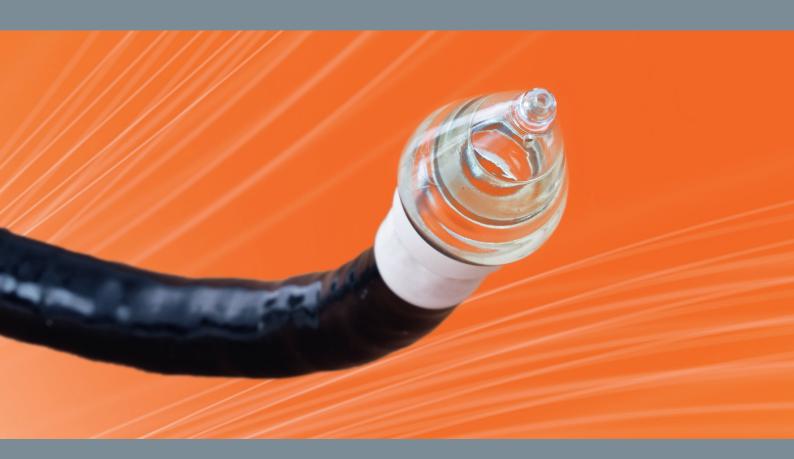
www.ovesco.com

Ovesco Endoscopy AG is a medical device company specializing in the fields of flexible endoscopy



for the dilation of stenoses in the upper gastrointestinal tract

- Direct visual control during passage
- Easy and fast bougienage with fewer instrument change
- Several BougieCap sizes, 7–16







ovesco

BougieCap

A new method for the bougienage/dilation of stenoses and strictures in the upper gastrointestinal tract.

The BougieCap allows direct visual control during the bougienage. The tension on the tissue is visible while passing the stenosis with the cap, thereby avoiding overstretching.

Moreover, the procedure time is reduced due to less instrument change. The evaluation can be done directly after the bougienage thanks to the attached transparent cap.

The distal end of the cap has three holes: two of them (lateral) for air insufflation and suction and one (center) for the insertion of a guide wire (max. 0.038").

Available versions

BougieCap size	7	8	10	12	14	16
Ref. no.	400.31.01	400.31.02	400.31.03	400.32.01	400.32.02	400.32.03
Endoscope diameter Ø [mm]		5.5-6.0			9.8-10.3	

Application

Esophageal stenosis



Guiding the endoscope with the attached BougieCap up to the stenosis.



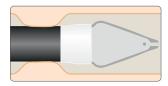




Carefully sliding the endoscope through the stenosis using gentle rotations under visual control. A guide wire can facilitate that step in case of high resistance.







Successful passage.





Ovesco Endoscopy AG Friedrich-Miescher-Straße 9 72076 Tuebingen Germany

Telefon +49(0)7071 96528-160 Fax +49(0)7071 96528-260 E-Mail service@ovesco.com

Ovesco Endoscopy USA Inc. 120 Quade Drive Cary, NC 27513 USA

Phone +1 919 651 9449 Fax +1 408 608 2077 customerservice@ovesco-usa.com



1 Source: Prof. Meining, University hospital Ulm, Endoskopie Live 2017 meets DGE-BV, Berlin, Germany.

2 Source: David L. Diehl, Geisinger Medical Center, Danville Pennsylvania, U.S.A.

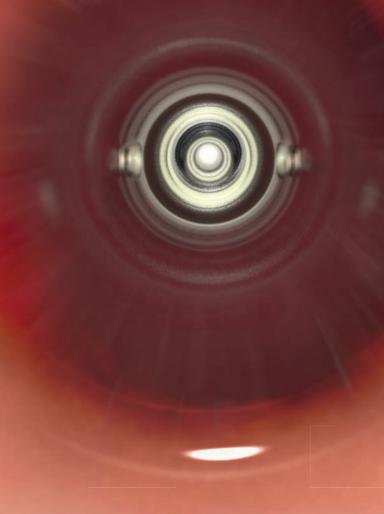
Ovesco Endoscopy AG is a medical device company specializing in the fields of flexible endoscopy and endoluminal surgery. Ovesco develops, manufactures, and markets innovative products for the treatment of gastrointestinal disease. Ovesco products stand for therapeutic efficacy and efficient application.

www.ovesco.com



BougieCap

Seeing is Knowing



The clear approach for dilation

Simply attach a BougieCap onto your endoscope for direct visualization and control during dilation of strictures in the upper gastrointestinal tract. Unlike conventional dilation methods, overstretching is easily avoided since the BougieCap provides a clear view of the tissue as the cap passes through the stricture.

Fewer instrument changes are needed with the BougieCap, ultimately reducing procedure time. Also, thanks to the transparent cap, endoscopic evaluation can be completed immediately after the bougienage.

BougieCaps are available in 6 sizes (Ø 7-8-10-12-14-16 mm) all with three distal holes; two of them (lateral) for air insufflation and suction and one (center) for the insertion of a guide wire (max. diameter .038 inch).







The BougieCap:

A new method for treatment of esophageal strictures



Introduction

The underlying pathophysiology of benign strictures of the esophagus is mainly caused by an increased production of fibrous tissue following an inflammatory process. Serial endoscopic dilation with bougies or balloons has been established as the standard treatment of esophageal strictures. The draw backs of these techniques are the lack of direct optical feedback of the bougienage and the need for fluoroscopic guidance during the procedure. The BougieCap allows direct visual control during the bougienage.

Methodology

The BougieCap is a single-use, clear, conical, endoscopic cap which can be used for endoscopic treatment of GI strictures. The endoscope with the mounted cap acts as mediator for the applied radial and longitudinal force vectors. Bougienage therapy with the BougieCap for treatment of stenosis was investigated within the framework of a prospective, interventional study conducted at three endoscopy units in Germany and UK between February and July 2018. 50 Patients (≥ 18 years) with benign stenosis of the esophagus were enrolled for study. Primary endpoint of the study was success of endoscopic dilatation, secondary endpoint was alteration of symptoms of dysphagia, as assessed by Dysphagia Handicap Index (DHI), before and 14 days after bougienage.

Table 1: Patients characteristics	
n	50
Sex (m/f)	25/25
Age (mean ± SD)	67.1 ± 16.8
Origin of stenosis, n (%)	
Peptic	23 (46)
Radiation	13 (26)
Anastomotic	6 (12)
Caustic ingestion	4 (8)
Post-ESD	2 (4)
EoE	1 (2)
Unknown	1 (2)

Results

Endoscopic bougienage was successful in 96% of all cases. In two cases bougienage failed because high resistance led to buckling of the endoscope in the pharynx. Symptoms of dysphagia (DHI) decreased after bougienage in short-time follow-up. Adverse events were loss of BougieCap in the stomach in two cases which evacuated spontaneously with the stool. No major complications occurred.

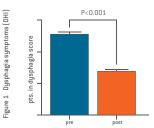


Table 2: Endoscopic results	
Successful bougienage (n)	48
BougieCap sizes used per session (mean ± SD)	2.3 ± 0.7
Applications with guide-wire (n)	
Pediatric gastroscope	8
Standard gastroscope	2

Summary and Conclusions

The endoscopic treatment of benign stenosis using the BougieCap enables direct visual control of the bougienage procedure. This might help to adapt endoscopic treatment even more precisely to the stricture. Symptoms of dysphagia are improved in short-term follow-up.

Usage of a guidewire is reasonable and necessary in special cases (i.e. very high-grade stenosis, usage of a pediatric gastroscope).







^{*}Walter B, Schmidbaur S, Rahman I, Schumacher B, Albers D, Meining A.

The BougieCap — a new method for endoscopic treatment of complex benign esophageal stenosis: results from a multicenter study. Endscopy 2019; 51: 866-870