

Flat Adenoma Resection Instruments

Description of function Type C



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General

The aim of developing new procedures and instruments for endoscopic removal, especially of large polyps (>2 cm) and flat lesions of the mucosa of the gastrointestinal tract, is to meet the related requirements on the part of oncology, i.e., removal of pathological tissue in sano, and pathology, i.e., removal of pathological tissue as en-bloc as possible and below sm1, or close to the muscularis propria, optimally according to the incision A in Fig. 1.

The aforementioned oncology and pathology requirements cannot be safely met with the currently available endoscopic polypectomy (EPE) and mucosal resection (EMR) procedures, both of which are performed with conventional polypectomy and RF surgical resection loops, respectively.

One problem of conventional polypectomy snares is that they can cut in any direction, i.e. also towards and through the organ wall. To avoid this, the rule is to move polypectomy snares away from the organ wall during activation of the HF generator, i.e. in cutting direction B (Fig. 1). Accordingly, perforations of the organ wall due to unintentional cutting through the organ wall are rare. However, the risk that pathological tissue is not completely removed is accepted (Fig. 1).

Another known problem of en bloc removal of large lesions with conventional polypectomy snares is gating delay or even failure of the cutting effect. Conventional polypectomy snares require an RF current of at least $0.5 A_{eff}$ per cm of effective snare wire for a delay-free incision. RF surgical devices available in flexible endoscopy can deliver a maximum of 1.5 to $2 A_{eff}$ in cutting mode, so that lesions as small as 1.5 cm in diameter, which corresponds to a circumference of 4.5 cm, may experience long gating delays with the risk of thermal damage to the organ wall, especially if the snare is applied close to the organ wall. For more details on gating delay, see the document "Incision Delay in Endoscopic Polypectomy".

Endoscopic submucosal dissection (ESD) procedures can meet the above requirements of oncology and pathology, but these procedures require a great deal of skill, experience, and time, and the complication rate of EPE, EMR, and ESD increases with the size of the lesion, among other factors.

In order to overcome the problems and limitations of EPE, EMR and ESD, the so-called "Flat Adenoma Resection Instruments" and the "Endoscopic Submucosal Resection (ESR)" were developed. In suitable cases and when used as intended, the above-mentioned requirements of oncology and pathology can be fulfilled better than with the conventional methods of EPE, EMR and ESD, especially for lesions >2 cm.

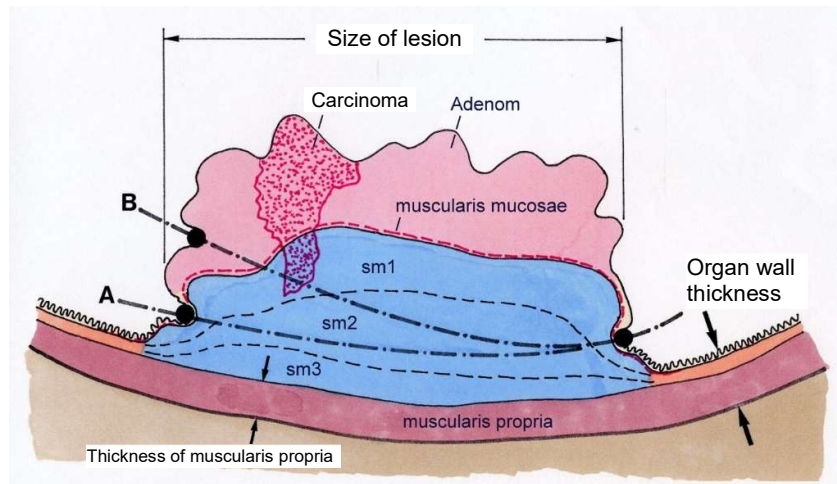


Fig. 1: Schematic representation of a 2 cm lesion on an organ wall only 2 mm thin and the incision guidance with HF surgical resection snares. Incision A with a FARIn, incision B with a conventional polypectomy snare.

Description of Flat Adenoma Resection Instruments

A Flat Adenoma Resection Instrument consists of a catheter with an effector (snare) at its distal end and a manipulator (handle) at its proximal end. An RF power cable can be connected to the handle.

The main focus of these instruments is the effector, which is available as a symmetrical opening and closing RF surgical resection snare.

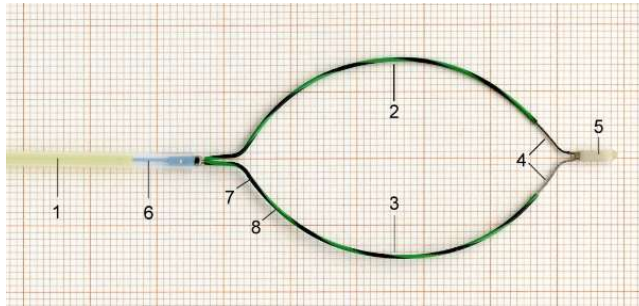


Fig. 2: Symmetrical effector type C.

ATTENTION: The Flat Adenoma Resection Instruments are delivered sterilized with ethylene oxide and sterile packed. The expiry date of sterility is indicated on the packaging and must be observed by the user!

Flat Adenoma Resection Instrument with symmetrical resection snare

The symmetrical resection snare (Fig. 2) is electrically insulated in its proximal sections (2) and (3). The cutting wire (4) at the distal end of the snare is only 1.5 cm long in total. Consequently, there are no incision problems even when resecting large polyps (> 2 cm), or lesions and used as intended.

An electrically non-conductive skid (5) is arranged at the distal end of this loop, which together with the insulated loop sections (2) and (3), as well as with the electrically non-conductive catheter (1), prevents a cut in the direction of the organ wall when used as intended.

Intended use of type C

The Flat Adenoma Resection Instrument type C is designed for endoscopic en-bloc resection of polypoid and flat lesions of the mucosa of the gastrointestinal tract close to the organ wall or muscularis propria with an average diameter of up to 4 cm. Larger lesions or polyps can be resected in several pieces with this instrument.

Manipulation handle

The **one-handed handle**, as shown in Fig. 3, is suitable for easy operation with one hand. It is a handle that is also used on a number of other instruments and therefore has the advantage of familiar handling. The printed scale has no meaning.

There is a finger slide on the plastic handle for mechanical displacement of the pull wire against the sheath. This allows the loop to be opened, closed and rotated



Fig. 3: Manipulation handle for one-handed use.

Application for Flat Adenoma Resection Instruments

Warnings

CAUTION: These instruments may only be used on the patient if:

- The user is familiar with the anatomy of the organs from which polyps or lesions are to be removed.
- The user is familiar with the basics of HF surgery required in flexible endoscopy.
- The user knows the properties of the Flat Adenoma Resection Instrument, in particular what can and cannot be done with it, and has tested and trained these properties in vitro..
- The operator knows and controls the possible complications (bleeding, perforation) of endoscopic removal, especially large polyps and lesions of the mucosa.
- The assistant is familiar with the handling of the Flat Adenoma Resection Instrument and is able to use it safely.
- The Flat Adenoma Resection Instrument is in perfect condition. This must be checked before inserting the effector into the working channel of an endoscope.

Although the instruments are designed for multiple resections on the same patient, neither the manufacturer nor the distributor of this instrument assumes any liability for damage resulting from the use of the instrument already used on one patient on other patients. The product is intended for single use and must not be resterilized!

Preparation

- Marking of the resection margins. The type U resection instrument is suitable for this purpose.
- Primary injection of the mucosa at the site where the incision is to be made.
- Incision of the mucosa including the submucosa outside the marking, i.e. in sano and close to the muscularis propria.
- Here, the architecture of the submucosa in the stomach wall must be taken into account, especially in or below the folds. For this purpose, the recutting instrument type U is suitable..
- Secondary injection of the entire lesion, so that the lesion to be removed floats like the plateau of a table mountain on the submucosa which, as a result of the injection, is swelling out of the level of the non-injected mucosa.
- The effector of the Flat Adenoma Resection Instrument can now be pressed into the incision gap near the muscularis propria and applied here around the submucosa.

Manipulation of the effector during application around a lesion

The effector of the Flat Adenoma Resection Instrument opens and closes symmetrically to the centerline of the catheter. This allows it to be pressed against the organ wall not only with the endoscope in the axial direction, but also with the catheter. The stiff design of the effector allows strong pressure and thus application close to the organ wall or the muscularis propria around the polyp, or around the lesion.

Application of the effector around polyps or flat lesions of the mucosa

The above-mentioned requirements on the part of oncology (removal of pathological tissue in toto and in sano) and on the part of pathology (removal of pathological tissue as en-bloc as possible) can only be met if the effector can and is applied accordingly close to the muscularis propria. Only in this way can the incision be made both outside the planar extension and below the *sm1*. For this purpose, large polyps or large-area lesions in particular must be prepared (see above).

Histopathology of a resected specimen resected with a Flat Adenoma Resection Instrument

One of the first results of an ESR with a flat adenoma resection instrument (resector: OA Dr. med. S. Gölder, III. Med. Klinik of Zentralklinikum Augsburg, CA Prof. Dr. H. Messmann) confirms the fulfillment of the above mentioned requirements of oncology and pathology.

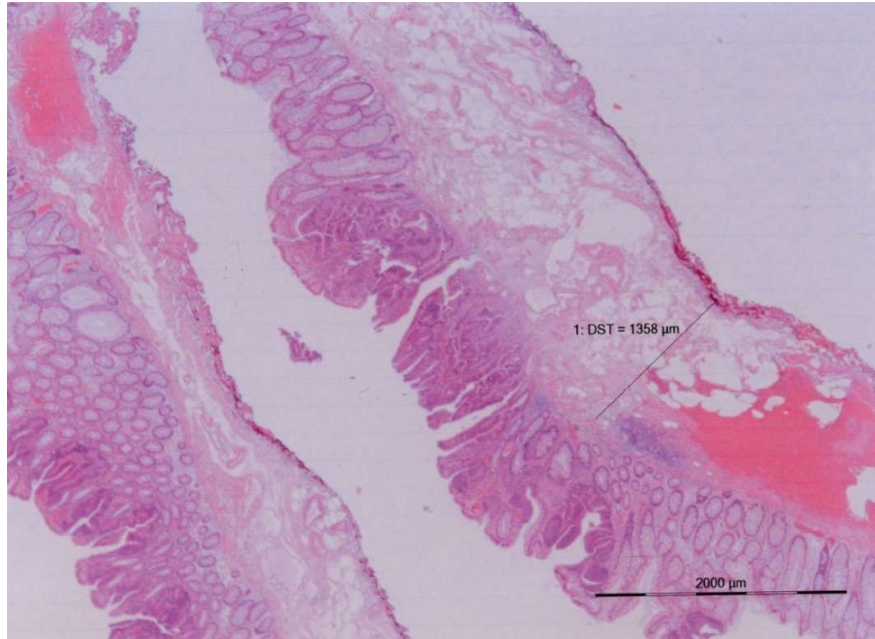


Fig. 4: Resectate after resection with a Flat Adenoma Resection Instrument (S. Gölder, H. Messmann, Augsburg).

Settings on high-frequency generators

All Flat Adenoma Resection Instruments have identical HF surgical cutting wires (0.38 mm diameter and 15 mm long). In addition, the length of the cutting wires remains constant during the cutting procedure until shortly before the end of the cut.

ERBE ICC 200

Cutting: Auto Cut Effect 2 200 Watt
Coagulation: Forced Coag 50 Watt

ERBE VIO 200

Cutting: Auto Cut Effect 3 200 Watt
Coagulation: Forced Coag 50 Watt

Cutting speed: slow

The slower the incision, the more effective the incision synchronous vessel occlusion.

Technical Data

symmetrical resection snare type C

Opening and closing of effector	Symmetrical
Rotating of effector	around the catheter axis
Shape of effector	see Fig. 2
max. opening-width of effector	2-4 cm (depending on size)
Effective length of cutting wire	15 mm
Diameter of cutting wire	0,39 mm
Length of catheter	200 cm
Outer diameter of catheter	2,3 mm
required HF current for incision phase	max. 1,5 A _{eff}
required HF current during cutting phase	<1,0 A _{eff} , depending on cutting speed
required amplitude of the HF voltage for cutting	
* with low risk of bleeding	250 to 300 V _p
* with moderate risk of bleeding	300 to 400 V _p
* with high risk of bleeding	400 to 500 V _p
max. permissible HF operating voltage U _a	1600 V _p
When using HF generators with automatic regulation of the amplitude of the HF output voltage, power limitation below 200 watts is neither necessary nor recommended.	
Connector provided on the instrument for cable connection to an HF surgical unit	4 mm, male
Test voltage	
between connection plug and surface clamping bend	2000 V _p / 350 kHz
between connector plug and surface handle	2000 V _p / 350 kHz
between connector plug and surface catheter	2000 V _p / 350 kHz