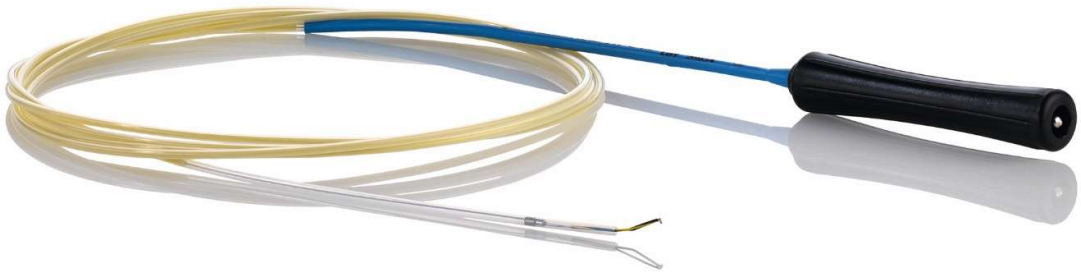
# Flat Adenoma Resection Instrument

## Description of function
## type U

Instrument for the incision, resp. circumcision
neoplastic lesions of the mucosa
prior to endoscopic submucosal resection (ESR)
or dissection (ESD)



| | | |
|---|---|---|
| Writer: | G. Farin | 01.12.2019 |
| Revised: | T. Schobert | 21.12.2021 |
| Translation: | T. Schobert | 08.02.2023 |

## Description of Flat Adenoma Resection Instrument type U

It is well known that prior to endoscopic submucosal resection (ESR) with a Flat Adenoma Resection Instrument type A, B, or C or prior to endoscopic submucosal dissection (ESD) with an ESD-Knife, the mucosa around the lesion must be incised in sano into the submucosa. For ESR with a flat adenoma resection instrument, the incision should be made as close to the muscularis propria as possible, and in such a way that the HF surgical resection loop can be applied into the incision gap thus formed as close to the muscularis propria as possible.

For this purpose, the type U instrument was developed for electrosurgical incision, or circumcision, with an effector optimized for this purpose at the distal end of a catheter (Fig. 1a and 1b).

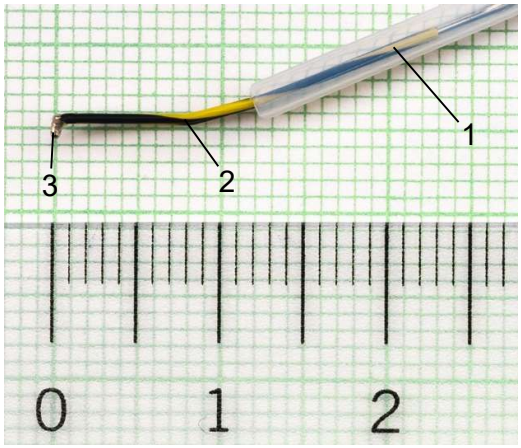



**Fig. 1a:** Effector type U side view.

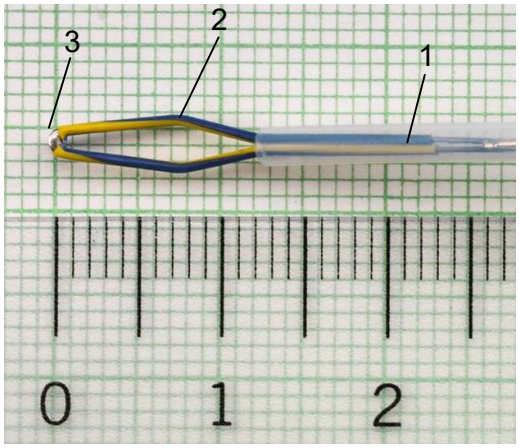



**Fig. 1b:** Effector type U top view.

The effector at the distal end of the catheter (1) consists of an electrically insulated and consequently electrosurgically inactive sliding skid (2) and a needle-shaped electrosurgical cutting electrode (3). The cutting electrode is available in three lengths 1.0 / 1.5 / 2.0 mm). The maximum depth of a cut is limited by the sliding skid, which rests or slides on the mucosa, and consequently corresponds to the length of the cutting electrode. Deeper cuts, e.g. 2, 3 or 4 mm, are possible by making several cuts in the same kerf.

The cutting electrode automatically aligns itself vertically to the respective tissue surface without manipulation at the proximal end of the catheter. For this purpose, the effector is mounted in the distal end of the catheter so that it can rotate freely and is angled between the catheter and the cutting electrode. The automatic vertical alignment of the needle electrode towards the tissue surface takes place thanks to this bending of the sliding skid when the effector is pressed against the tissue surface, whereby it does not matter how the tissue surface in question is shaped and spatially aligned.

The degrees of freedom of the cutting guide with this effector are limited only in the vertical direction by the sliding skid. Manipulation of the cutting guide can be performed with the endoscope and/or with the catheter. For cutting guides on convex and/or concave tissue surfaces, the cutting electrode always remains vertically aligned to the respective tissue surface when this instrument is used as intended.

## Special features

The Flat Adenoma Resection Instrument type U is characterized by the following features:

- The electrosurgical cutting needle automatically aligns itself vertically to the surface of the tissue to be cut even with slight pressure of the skid against the surface of the tissue to be cut.
- The maximum cutting depth is limited by the skid to the length of the cutting electrode. Deeper cuts are possible by repeated cutting guides in the same cutting gap.
- Cutting is possible horizontally in all directions.
- The incision is possible with the endoscope and/or with the catheter.
- Any length, straight and/or curved cuts can be realized per cutting guide.

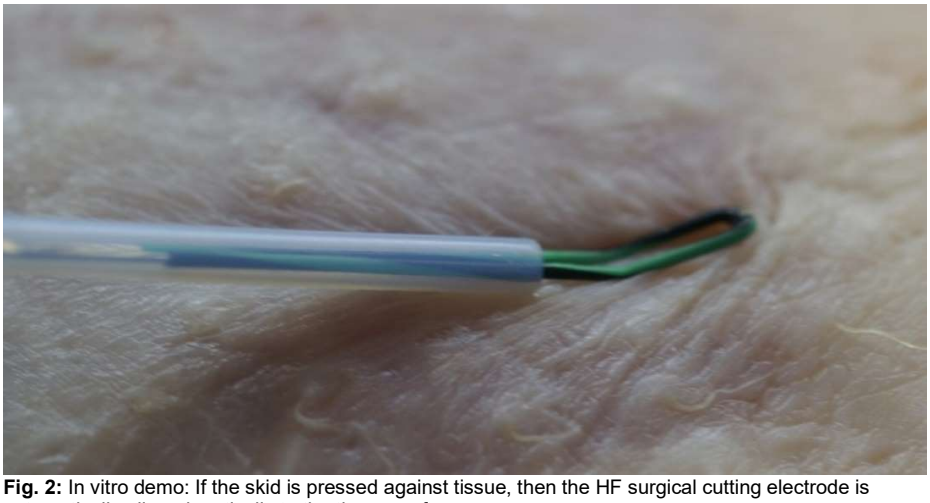


**Fig. 2:** In vitro demo: If the skid is pressed against tissue, then the HF surgical cutting electrode is automatically aligned vertically to the tissue surface.

**Automatically limited cutting depth even in case of indentation of the mucosa due to pressure of the skid on the mucosa**

If the skid is pressed so firmly onto the mucosa that the mucosa dents (see Fig. 2), then the depth of cut (measured from the surface of the mucosa) remains the same as the depth of cut without indentation because the tissues of all tissue layers are largely incompressible and consequently the indentation of the mucosa also results in a corresponding indentation in the submucosa and the tissue layers below.

However, if more injection fluid is injected into the submucosa in question than the submucosa can absorb, the excess fluid will be displaced laterally under the dent of the mucosa. However, this is negligible if the submucosa in question is already sufficiently swollen as a result of injection.

If the submucosa is heavily swollen as a result of injection of water-containing injectables, it may or may not be necessary to re-cut several times in the same incision gap with the same instrument until the muscularis propria is reached.

If the incision or incision around the mucosa/submucosa up to close to the muscularis propria is intended, then it can be advantageous if the underinjection agent contrasts in color against the tissue, in particular against the muscularis propria, and if the underinjection agent is also transparent in such a way that the muscularis propria can be recognized in good time in the incision trench through the respective remaining submucosa before cutting into the muscularis propria.

## Application of 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 applied to one patient on other patients. The product is intended for single use and must not be resterilized!

### Intended use

The Flat Adenoma Resection Instrument type U is intended for HF surgical resection of polyps or flat lesions. The instrument is used for near-muscularis propria endoscopic resection of lesions of the mucosa prior to Endoscopic Submucosal Dissection (ESD) with an ESD instrument or prior to Endoscopic Submucosal Resection (ESR) with a Flat Adenoma Resection Instrument A, B or C.

### Procedure

- Marking the resection margins, e.g. with type U resection instrument.
- 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 gastric wall must be taken into account, especially in or below the folds.
- Secondary injection of the entire lesion, so that the lesion to be removed floats like the plateau of a mesa on the submucosa which, as a result of the injection, is swelling out of the level of the non-injected mucosa.
- When using a Flat Adenoma Resection Instrument type A, B or C, this can now be pressed into the incision gap near the muscularis propria and applied here around the submucosa.

**CAUTION:** When using a type U with a 2 mm needle electrode through a 2.8 mm instrument channel, care must be taken not to damage the instrument channel, i.e. move the instrument carefully through the instrument channel.

## Procedure to learn the characteristics and train the intended manipulations of the Flat Adenoma Resection Instrument type U

Before using a type U instrument in vivo for the first time, it is recommended to learn and master the properties of this instrument in vitro.

Thin slices of Lyon sausage are suitable for this purpose, for example, whereby the slice thickness should correspond to the respective needle length. On this material, the incision can also be made with a type U instrument without HF current, i.e., purely mechanically. In addition to purely mechanical sectioning, HF surgical sectioning should also be practiced. When using an electrosurgical unit, e.g. ERBOTOM ICC 200 or VIO 200, the cutting mode AUTO CUT / Effect 2 is suitable for this purpose. With AUTO CUT, power limitation below 200 watts is possible, but not mandatory. These settings are also recommended for clinical or in vivo use of this instrument.


**Fig. 3:** Sliced Lyon sausage, here 1,5 mm slices.

For and during cutting, the effector (as shown in Fig. 2) should be pressed lightly against the tissue surface to be cut so that the cutting electrode is automatically aligned in the direction of the tissue surface.

It is recommended to perform different cutting directions, as shown e.g. in Fig. 4, and with different cutting speeds in order to get to know the cutting possibilities as well as the limits of this instrument.

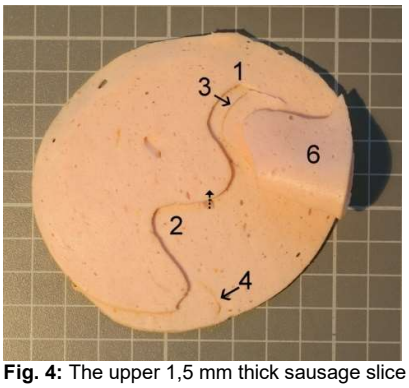



**Fig. 4:** The upper 1,5 mm thick sausage slice was completely cut through with a 1,5 mm needle electrode, whereby the sausage slice underneath was only minimally thermally injured at points 3 and 4, but not cut.

**Fig. 5:** This cut into the cutis of a chicken thigh was made with a single incision. The cut edges are smooth. The width of the coagulation zone at the cut edges can be adjusted to suit the purpose by making settings on the HF generator.

The type U instrument can also be used for incision/circumcision of lesions in ESD, as well as for marking before and for coagulative hemostasis during circumcision of lesions.

## Settings on high-frequency-generators

**ERBOTOM ICC 200**

| | | |
|---|---|---|
| Cutting: | Effect 2 | Power 200 watt |
| Coagulation or hemostasis: | Forced Koag | |

**ERBE VIO 200**

| | | |
|---|---|---|
| Cutting: | Effect 2 | Power 200 watt |
| Coagulation or hemostasis: | Forced Koag | |

## Technical Data

| | |
|---|---|
| Effective length of the needle electrode | 1,0 / 1,5 / 2,0 mm |
| Diameter of the needle electrode | 0,4 mm |
| Outer diameter of the catheter | 2,3 mm |
| Catheter length | 200 cm |
| Connector plug for RF power cable | 4 mm, male |
| Max. permissible amplitude of the HF voltage | 2000 $V_P$ |