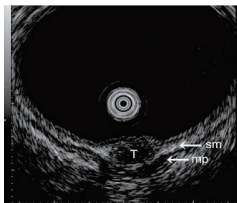


ESD procedure performed with the ClutchCutter (Case Presentation)

Diagnosis: 9 mm carcinoid tumor in the lower rectum
Diagnosis using EUS: sm3, NO
Device: ClutchCutter (Short type, 3.5 mm blade length)



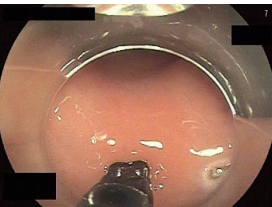
Endoscope image



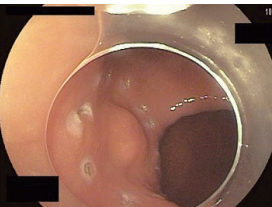
EUS image

Marking

Setting: FORCED COAG 30W, Effect3



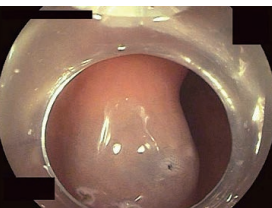
1 Marking is performed by lightly pressing on the mucosa with the jaws closed, and briefly applying FORCED COAG 30W with the ClutchCutter. Marking should be performed with the tip of the jaws perpendicular to the mucosa for the best results.



2 The circumference of the lesion has been marked.

Local injection into the submucosa

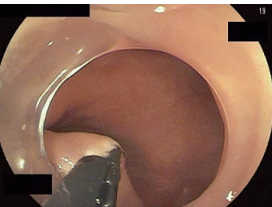
Local injection of sodium hyaluronate into the submucosa



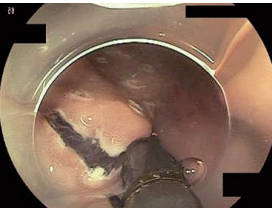
3 Sodium hyaluronate is locally injected into the submucosa below the lesion that will be dissected, in order to elevate it.

Mucosal incision

Setting: ENDO CUT Q, Effect2
SOFT COAG 100W, Effect5



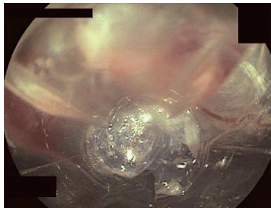
4 A large section of the area elevated by the local injection is grasped with the ClutchCutter to create a hole that reaches the middle layer of the submucosa.



5 One of the blades of the ClutchCutter is inserted into the hole and the submucosa and mucosa are grasped. Traction is applied toward the lumen, the area is coagulated using the SOFT COAG 100W setting, and then ENDO CUT Q is applied to dissect.

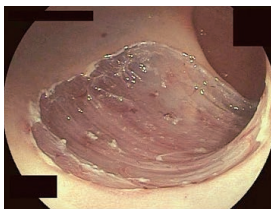
Submucosal dissection

Setting: ENDO CUT Q, Effect2
SOFT COAG 100W, Effect5



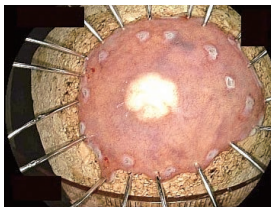
6 The hood is used to lift up the submucosa, and the lower layer of the submucosa is grasped. The jaws are gradually retracted into the hood while ENDO CUT Q is applied to dissect the lesion. If there are submucosal vessels, SOFT COAG 100W is applied first to coagulate the area before dissection. If bleeding occurs, the blood vessel is grasped and pressure is applied, before coagulating it using SOFT COAG 100W.

The tumor after dissection

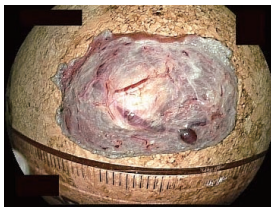


7 The tumor has been evenly dissected from the lower layer of the submucosa. There are no perforations.

Resected specimen



8 The en-bloc resection can be deemed a success as no carcinoid tumor cells can be found on the horizontal or vertical edges of the resected lesion (R0 resection).



The HF setting examples and details regarding the surgery were provided by Dr. Kazuya Akahoshi of Aso Iizuka Hospital and are to be used as a guideline only. The operator of the product is responsible for using this product appropriately after fully understanding how to use it according to the part of the body where it will be used and the type of lesion.

<References>
1. Akahoshi K, Minoda Y, Komori K, et al. Endoscopic submucosal dissection using the "Clutch Cutter" for early esophageal squamous cell carcinoma. Endoscopy. 2013 Dec;45(12):1035-8(with video).
2. Akahoshi K, Honda K, Motomura Y, et al. Endoscopic submucosal dissection using a grasping-type scissors forceps for early gastric cancers and adenomas. Digestive Endoscopy (2011) 23, 24-29(with video).
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4. Akahoshi K, Akahane H, Motomura Y, et al. A New Approach: Endoscopic submucosal dissection using the ClutchCutter for early stage tract tumors. Digestion. 2012;85(2):80-84.
5. Akahoshi K, Honda K, Akahane H, et al. Endoscopic submucosal dissection by using a grasping-type scissors forceps: a preliminary clinical study Gastrointest Endosc. 2008 Jun;67(7):1128-33(with video).
6. Akahoshi K, Akahane H. A new breakthrough: ESD using a newly developed grasping type scissor forceps for early gastrointestinal tract neoplasms. WJG 2010 March 16;2(3):90-96.

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Clinical use of the ClutchCutter for ESD procedures

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The ClutchCutter is a new, innovative surgical tool that can safely grasp, apply pressure and traction to, and electrically dissect and coagulate the target area as in a biopsy. All stages of the ESD procedure can be performed with this one tool, from marking to making incisions and coagulating. In procedures that need to be performed perpendicular to the muscular layer, which can cause difficulties when using a needle knife, the ClutchCutter makes it possible to grasp, lift up and incrementally dissect the tissue. This makes the ESD procedure safer. As the tissue is grasped by the ClutchCutter before an incision is made, no accidental incisions are caused due to body movements. Furthermore, the tissue can be regrasped multiple times before an incision is made. This means that even those new to the procedure can perform ESD procedures on the esophagus, stomach, duodenum and colon under the supervision of a medical instructor.

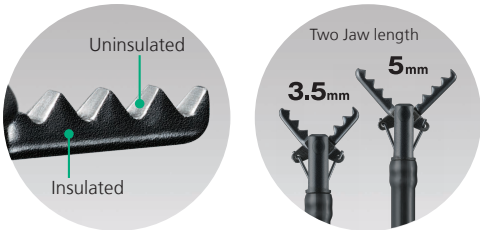


ClutchCutter

What is the ClutchCutter?



Features

- Serrated jaws**
Serrated jaws allow the mucosa to be grasped securely.
- Rotating jaws**
The jaws can be rotated to allow the lesion to be approached at precise angles.
- Insulated outer edge**
Insulation minimizes the risk of damage to local tissue.



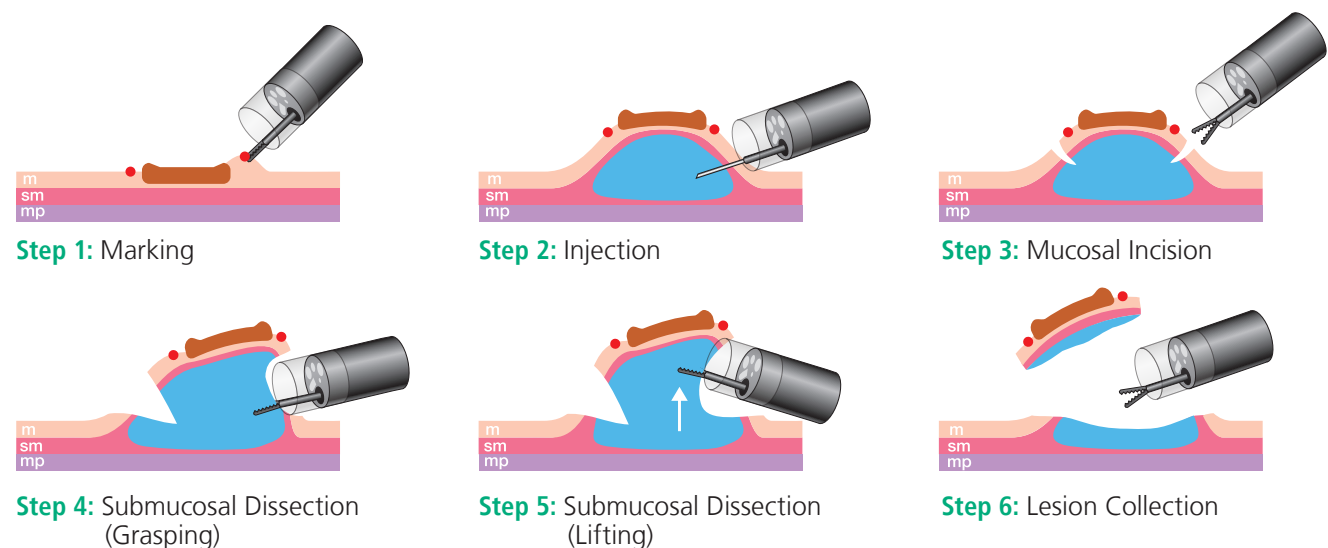
* Two jaw lengths are available, short (3.5 mm) and long (5 mm), to meet various situation. The appropriate one can be chosen based on the conditions and the hood that is to be used.

What is the difference between the ClutchCutter and needle knife ESD devices?

	ClutchCutter	Needle-type knives
Fixation effect	Yes	No
Lift-up effect	Yes	No*
Compression effect	Yes	No
Insulated coating	Yes (Whole Outer Blade) 	No** 
	The insulated coating allows only a small amount of electricity to pass to surrounding tissue	No insulation means that a large amount of electric current passes to surrounding tissue.

* Excluding Hook Knife
** Excluding Mucosectomy and IT Knife

Performing ESD with the ClutchCutter



Before using the ClutchCutter for the first time

There are two important things to keep in mind when using the ClutchCutter.

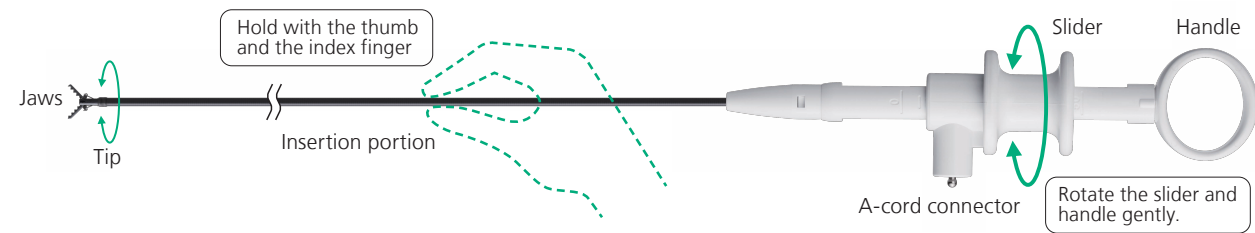
1 The basic incision process is the same as that of an EMR procedure

- Air feeding inside the tract should be minimized so as to lower the tension of the mucosa. Otherwise it would be difficult to obtain a firm grasp on the surface.
- When performing ESD using needle-type knives, incision is easier if the mucosa is extended by reasonable air supply, but this is not the case when with ClutchCutter.

2 ESD using ClutchCutter is performed not only by the endoscopist but also by the ClutchCutter operator

- The ClutchCutter operator makes incisions, by rotating the ClutchCutter, opening the jaws and applying traction to the tissue, performs dissection and is responsible for coagulation.
- The endoscopist concentrates on the manipulation of the endoscope so that a clear view is obtained for the operator to perform the procedure efficiently.
- The operator and the endoscopist should work close together during the procedure. Both should have an understanding of each step of the procedure, relevant anatomy and the features of the ClutchCutter.

How to rotate the ClutchCutter



- Hold the catheter with one hand and rotate the handle slowly with the other hand.
- When rotating, do not close or open the Jaws fully so that the rotation is transmitted smoothly to the tip.
- Make sure that the rotation does not exceed 180 degrees.
- Do not allow the ClutchCutter to touch anything while it is being rotated. Keep the blades half open when rotating inside the hood.

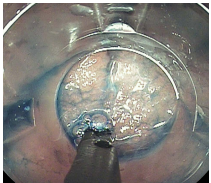
Advice on using the ClutchCutter proficiently

Usage of a hood

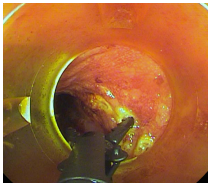
The procedure should be performed using a transparent hood. The hood will be helpful to ensure a clear field of vision when dissecting the submucosa and to apply traction to the incised part. It will also serve as a safe space for the tissue after being gripped and pulled into by the ClutchCutter for electrical dissection.

Marking techniques

Marking is normally performed by lightly touching the ClutchCutter to the surface of the mucosa, with the jaws closed and perpendicular to the surface using the hood. In the esophagus and other narrow areas where it is not possible to hold the tip of the jaws perpendicular to the surface, open the jaws and mark the surface using one of the blades.



Marking with the jaws closed and perpendicular to the surface

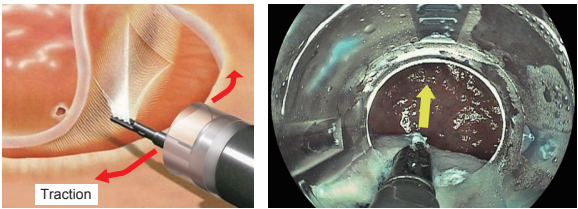


Marking with one blade at an angle to the surface

Dissection techniques

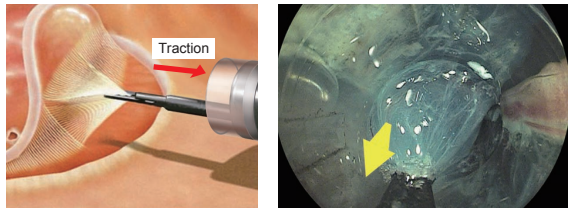
Lifting sideways or upwards

This technique allows for a large area to be dissected, making dissection more efficient.



Pulling backwards

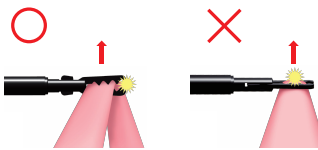
Use this technique when approaching at an angle or perpendicular to the muscular layer. The cutting area is relatively small.



Tips for safer dissection

Ensure that the tissue is grasped vertically, not horizontally.

Grasp the tissue vertically and lift upwards toward the inner lumen. When this is not possible, pull the tissue towards into the hood.

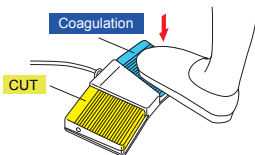


Recommended settings for electrosurgical generator

Setting examples	VIO300D	
	Mode	Setting
Procedure		
Marking	FORCED COAG	30W Effect3
Mucosal Incision	ENDO CUT Q	Effect2 Duration3 Interval1
Submucosal Dissection	ENDO CUT Q	Effect2 Duration3 Interval1
Coagulation	SOFT COAG	100W Effect5

Pre-cut coagulation technique

Press "SOFT COAG ⇒ SOFT COAG ⇒ ENDO CUT" when bleeding is likely.



The HF settings should be selected under supervision of a doctor.