

FTRD®

Endoscopic Full Thickness Resection

Closing the gap
between endoscopy and surgery

Decisive clinical difference in endoluminal surgery

FTRD® removes non-lifting and other complex GI lesions that were subject to surgery before.

The multicentric Wall Resect trial with a technical success rate of 89.5 %¹ demonstrates that a variety of difficult to resect lesions, such as adenomas with non-lifting sign or subepithelial tumors, can be resected effectively. FTRD® thus enhances the spectrum of resection techniques and helps to avoid surgery.

FTRD® achieves high rates of complete resection where superficial removal techniques have their limitations.

Full thickness samples collected with FTRD® improve histological diagnosis. An R0 resection rate in 1178 cases from 65 centers of the German colonic FTRD® registry of 80.0 %² substantiates the efficacy of FTRD® in clinical routine.

¹ Schmidt A, Beyna T, Schumacher B, Meining A, Richter-Schrag HJ, Messmann H, et al. Colonoscopic full-thickness resection using an over-the-scope device: a prospective multicentre study in various indications. Gut 2018 Jul;67(7):1280-1289.

² Meier B, Stritzke B, Kuellmer A, et al. Efficacy and safety of endoscopic full-thickness resection in the colorectum: Results from the German colonic FTRD registry. Am J Gastroenterol 2020; 115(12):1998-2006.



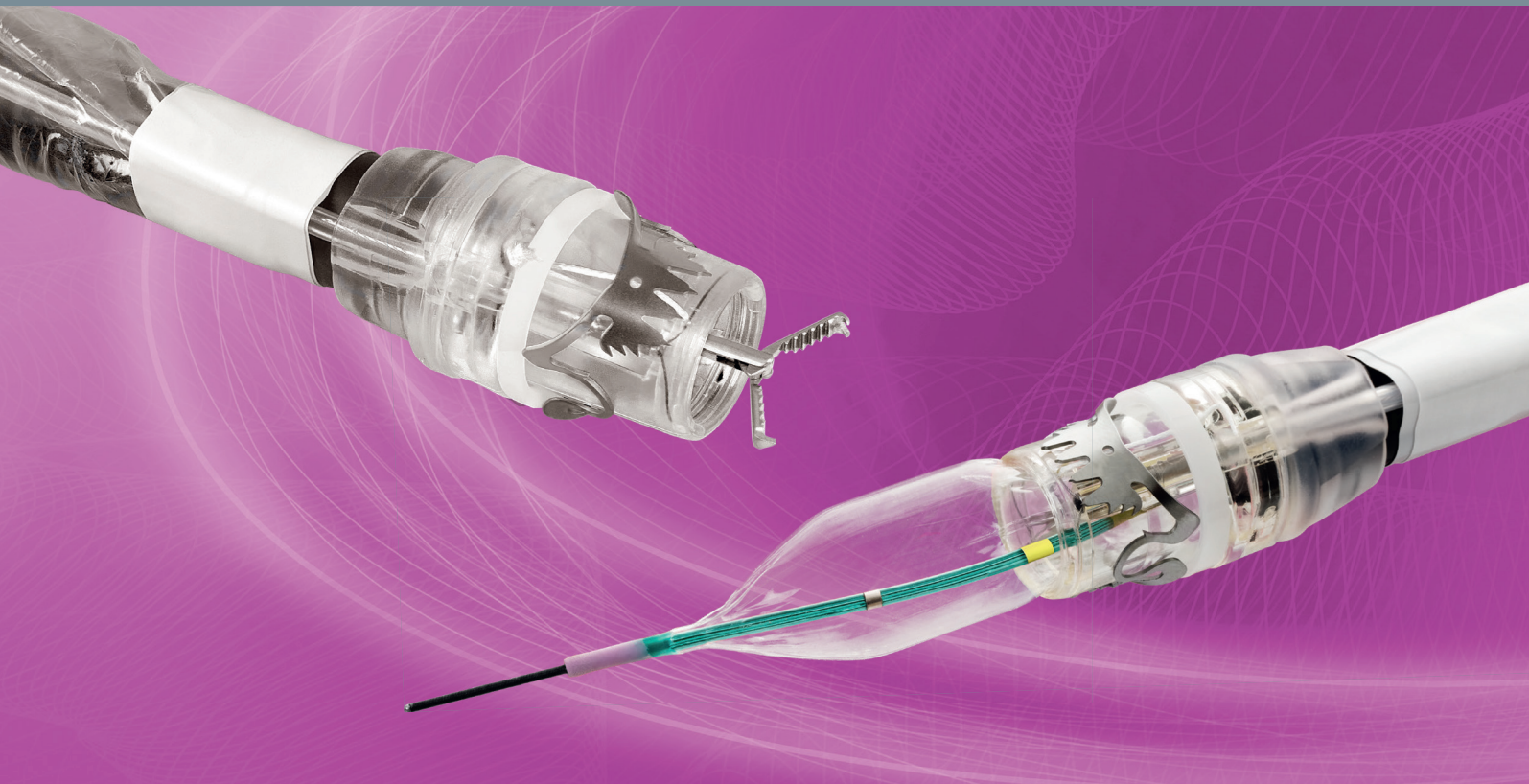
FTRD®
SYSTEM





FTRD[®] System.....

Full-Thickness Resection Device for flexible endoscopy



The FTRD® System enables endoscopic full-thickness resection (EFTR) of lesions and diagnostic tissue acquisition in the colon and rectum (colonic FTRD®/diagnostic FTRD®) respectively in the stomach and duodenum (gastroduodenal FTRD®).

- Transluminal and minimally invasive technique
- Proven OTSC® technology for safe closure
- Good histological evaluation of en bloc specimen with minimal thermal damage
- Complete set for endoscopic full-thickness resection procedure

..... FTRD® System

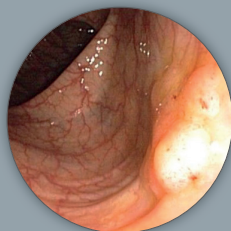
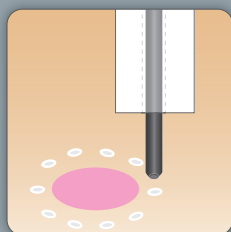
Full-Thickness Resection Device for flexible endoscopy

It is based on the well-established OTSC® System and enables the removal of suitable lesions with all layers of the wall including the serosa. The design of the FTRD® System ensures that the transection of the organ wall occurs only after the target site has been safely closed. The organ lumen is therefore never opened during the procedure.

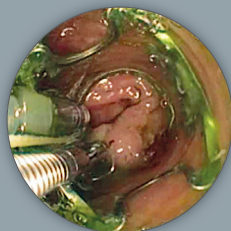
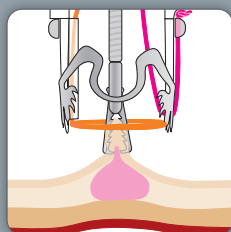
The FTRD® application cap is mounted on the tip of the endoscope with the snare running along the outside of the endoscope protected by the endoscope sleeve. By turning the hand wheel the thread is tensioned and the clip released. Subsequently, the tissue above the clip is resected with the integrated HF snare.

..... Application

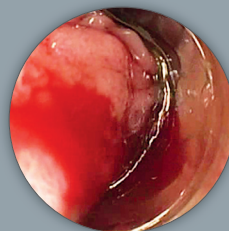
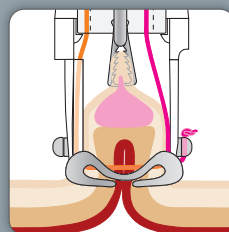
Endoscopic full-thickness resection



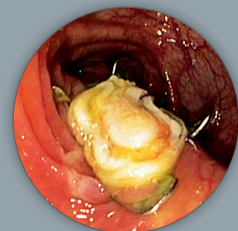
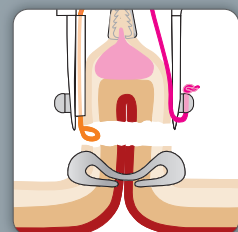
Marking the lesion with the FTRD® Marking Probe.



Grasping and mobilizing the lesion with the FTRD® Grasper.



Ensuring that the tissue is completely within the FTRD® application cap – releasing clip with hand wheel.

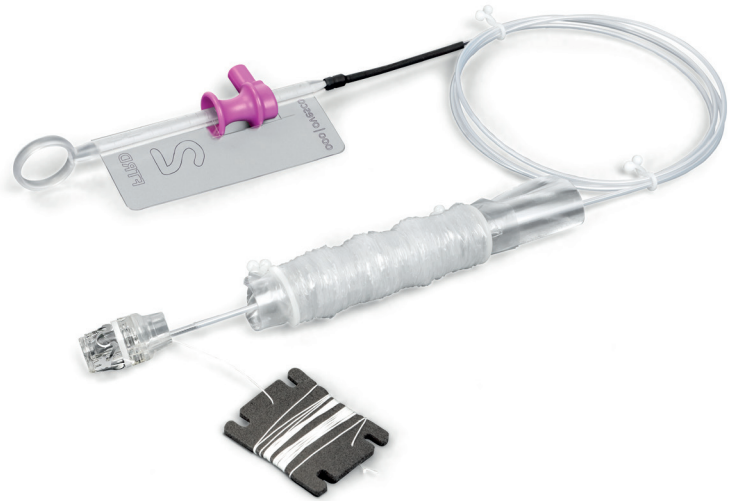


Closing snare and resecting tissue, retrieving specimen and inspecting resection site.

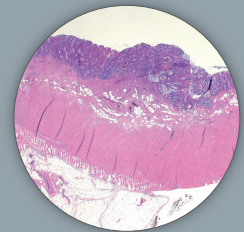
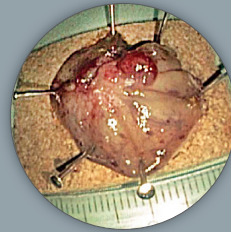
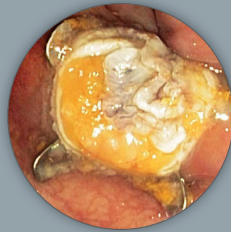
The colonic FTRD® is an instrument for flexible endoscopy for full-thickness resection and diagnostic tissue acquisition through resection of suitable lesions in the colon and rectum.

The colonic FTRD® can find application in:

- not pretreated non-lifting adenoma
- non-lifting recurrent adenoma
- adenoma at the base of the appendix
- adenoma at/in diverticula
- small subepithelial tumors
- early carcinoma



Endoscopic full-thickness resection in the colon



Upper row: De novo resection after incomplete polypectomy in the descending colon (early carcinoma).
Lower row: Resection of a recurrent adenoma (HG1EN) in the descending colon (non-lifting sign).

The diagnostic FTRD® is a smaller FTRD® System for full-thickness biopsy in the colon and rectum e.g. for diagnostic purposes.

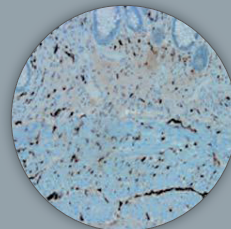
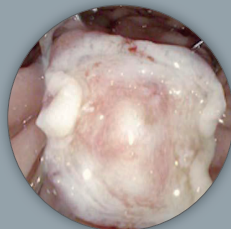
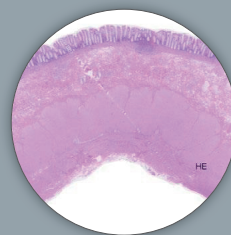
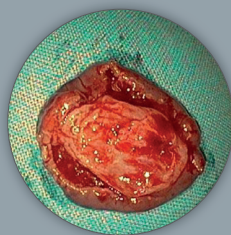
It enables histology in functional diseases in the colonic wall e.g. for neuro-gastroenterological examination. Full-thickness biopsies allow accurate histological presentation of enteric neurons and can provide important insights into the diagnosis of motility disorders.

Full-thickness biopsy finds application in:

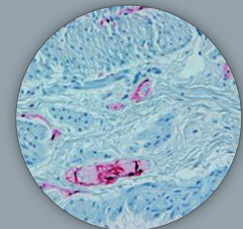
- Hypo- and aganglionosis (e.g. Hirschsprung's disease)
- Enteric ganglionitis
- Visceral neuro- and myopathy (e.g. in chronic constipation)
- Gastrointestinal amyloidosis
- Enteric manifestation or neurological diseases (e.g. Parkinson's disease)



Diagnostic full-thickness biopsy in the colon



Calretinin



S100

Upper row: Diagnostic EFTR to exclude a primary neurodegenerative motility disorder.¹
Lower row: EFTR for diagnosis of Hirschsprung's disease.²

¹ Source: Prof. Dr. P. Bauerfeind, Stadtspital Triemli, Zürich, Switzerland

² Source: MD A. Martínez-Alcalá, Centro de Innovaciones Digestivas Martínez-Alcalá, Sevilla, Spain

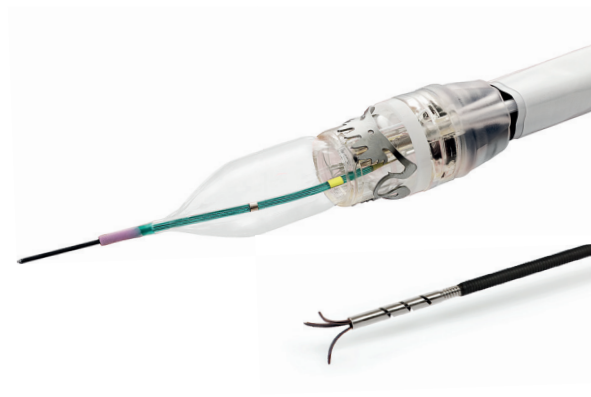
The gastroduodenal FTRD® is a smaller FTRD® System for endoscopic full-thickness respectively deep partial-wall resection (especially in the stomach) and diagnostic tissue acquisition in the stomach and duodenum.

For an easier and safer insertion of the system into the upper GI tract (esophageal/pyloric passage) the gastroduodenal FTRD® Set is delivered with an insertion balloon and guide wire. The clip of the gastroduodenal FTRD® has been modified especially for the application in the duodenum and stomach.

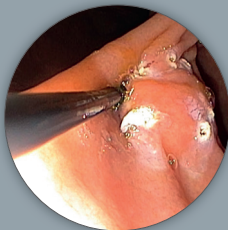
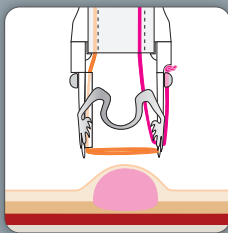
The gastroduodenal FTRD® can find application in:

- not pretreated non-lifting adenoma
- non-lifting recurrent adenoma
- small subepithelial tumors
- early carcinoma

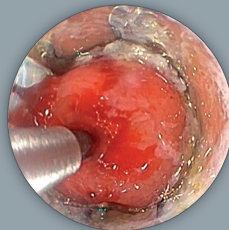
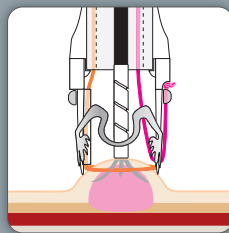
For submucosal lesions (especially for GIST indications) the utilization of the Anchor instead of the Grasper can represent a good alternative.



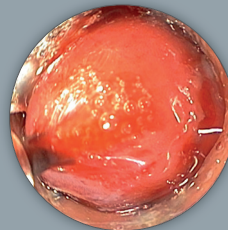
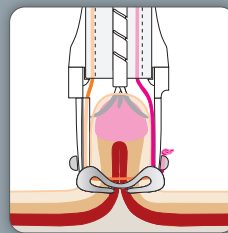
Endoscopic full-thickness resection in the stomach



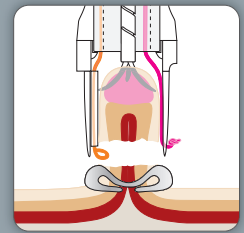
Marking and targeting the lesion with the FTRD®.



Grasping and mobilizing the lesion with the Anchor.



Clip application and subsequent resection of the tissue.



2 cm full-thickness specimen from the stomach.

FTRD® System

Details and components

The respective FTRD® Sets (colonic, diagnostic, gastroduodenal) are delivered as procedural set and consist of the following products:

- FTRD® cap with preloaded clip and thread
- snare integrated into the distal end of the cap
- FTRD® hand wheel
- thread retriever
- endoscope sleeve with fixation tapes
- FTRD® Marking Probe
- FTRD® Grasper
- insertion balloon (only gastroduodenal FTRD®)
- guide wire (only gastroduodenal FTRD®)



FTRD® MARKING PROBE



HF coagulation probe for marking the target lesion before using the FTRD® System. Marking will facilitate both finding the lesion and verify complete resection of the target tissue.

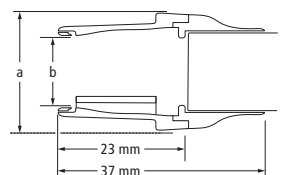
FTRD® GRASPER



Grasping forceps for proper grip on the target tissue and precise retrieval of the sample into the FTRD® application cap. The FTRD® Grasper is also available separately (5 items per package, ref. no. 200.73).

FTRD® versions

FTRD® versions	colonic	diagnostic	gastroduodenal
Ref. no.	200.70	200.76	200.72
Endoscope Ø (c) [mm]	11.5 – 13.2	10.5 – 12.0	10.5 – 12.0
Cap outer Ø (a) [mm]	21	19.5	19.5
Cap inner Ø (b) [mm]	13	12.1	12.1
Required working channel Ø [mm]	3.2	3.2	3.7



Application aid

FTRD® prOVE CAP

The FTRD® prOVE Cap is a cap with the same dimensions as the cap of the respective FTRD® Set in order to test the possible application of the FTRD® Set in advance. The FTRD® prOVE Cap is not included in the respective FTRD® Set. (2 items/package; colonic FTRD® prOVE Cap ref. no. 200.71; gastroduodenal FTRD® prOVE Cap ref. no. 200.77).



OTSC® ANCHOR

For a better mobilization of tissue in submucosal findings (especially in the stomach) a specially modified anchor is available (not included in the FTRD® Set).



Gefördert durch:



aufgrund eines Beschlusses des Deutschen Bundestages

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innovation in scope

FTRD[®]

Endoscopic Full Thickness Resection

Closing the gap

between endoscopy and surgery

- Enhancing the spectrum of resection techniques
- Improving histological diagnosis
- Avoiding unnecessary surgery
- Established procedure in clinical routine

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FTRD[®]

SYSTEM

Decisive clinical difference in endoluminal surgery

FTRD® removes non-lifting and other complex GI lesions that were subject to surgery before.

The multicentric Wall Resect trial with a technical success rate of 89.5 %¹ demonstrates that a variety of difficult to resect lesions, such as adenomas with non-lifting sign or subepithelial tumors, can be resected effectively. FTRD® thus enhances the spectrum of resection techniques and helps to avoid surgery.

FTRD® achieves high rates of complete resection where superficial removal techniques have their limitations.

Full-thickness samples collected with FTRD® improve histological diagnosis. An R0 resection rate in 1,178 cases from 65 centers of the German colonic FTRD® registry of 80.0 %² substantiates the efficacy of FTRD® in clinical routine. The major strength of the German colonic FTRD® registry is the high number of patients included.

Strong support by German endoscopists was provided reflected by the high number of participating centers (n=65) and rapid collection of data (n=1,178 cases in only 4 years).

Among the participants were expert centers as well as mid-sized and smaller hospitals throughout Germany. Nevertheless, similar data on efficacy and safety could be demonstrated compared with data from tertiary referral centers as illustrated in the Wall Resect study (see table below).

These results show that FTRD® has gained broad acceptance in the endoscopic community and become an integral part of clinical routine. The German colonic FTRD® registry is by far the largest study of colorectal EFTR using FTRD® and confirms efficacy and safety for difficult-to-resect lesions in a real-world setting.

	Wall Resect	FTRD® registry
Number of patients	181	1,178
Number of participating centers, type	9, referral	65, referral, mid-size, small
Max. diameter of lesion, mm [range]	15 [2-20]	15x15 [3x3-56x45¹]
Median procedure time, min [range]	50 [3-190]	35 [2-203]
Technical success (macroscopically complete)	89.5 % (162/181)	88.2 % (998/1,131 ²)
Full-thickness resection (histologically confirmed)	80.6 % (146/181)	89.9 % (970/1,079 ³)
R0 resection (histologically confirmed)	76.9 % (139/181)	80.0 % (823/1,029 ⁴)
Difficult adenomas	77.7 %	77.2 %
Adenocarcinomas	72.4 %	82.8 %
Subepithelial tumors	87.0 %	97.1 %
R0 resection lesions ≤ 20 mm	81.2 %	77.6 %
R0 resection lesions > 20 mm	58.1 %	81.0 %
Complications	9.9 % (18/181)	12.1 % (142/1,178)
Minor events*	5.5 %	9.0 %
Major events**	4.4 %	3.1 %
Surgery due to adverse events	2.2 %	2.0 %

¹Hybrid cases included ²EFTR not performed (n=47) because of technical difficulties or complications.

³ Histology available (n=1,086). Excluding: full-thickness-status not available (n=7).

⁴ Histology available (n=1,086). Excluding: diagnostic EFTR (n=14), R-status not determinable because of combined EFTR/EMR (n=36), R-status not available (n=7)

* complications that can be treated conservatively or endoscopically

** complications requiring surgical therapy or renewed endoscopic treatment

1 Schmidt A, Beyna T, Schumacher B, Meining A, Richter-Schrag HJ, Messmann H, et al. Colonoscopic full-thickness resection using an over-the-scope device: a prospective multicentre study in various indications. Gut 2018 Jul;67(7):1280-1289.

2 Meier B, Stritzke B, Kuellmer A, et al. Efficacy and safety of endoscopic full-thickness resection in the colorectum: Results from the German colonic FTRD® registry. Am J Gastroenterol 2020; 115(12):1998-2006.

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innovation in scope

FTRD[®]

Endoscopic Full Thickness Resection

Closing the gap
between endoscopy and surgery

Focus topic
Early colorectal cancer

- High quality tissue specimen for comprehensive histopathology
- Supporting exact risk stratification
- Reducing the need for surgery
- Curative endoscopic resection possible

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FTRD[®]

SYSTEM

Decisive clinical difference in endoluminal surgery

EFTR with FTRD® as a diagnostic and therapeutic intervention in colorectal T1 cancers

With an overall R0 resection rate of 88.2 %¹ of T1 colorectal cancer (CRC) (211 of 346 procedures), the Dutch colorectal EFTR registry underlines the efficacy of FTRD® in this group of lesions (R0 resection rate primary resections 77.9 %, secondary treatment 93.0 %). After resection of the scar for previously incompletely resected T1 CRCs (R1/Rx), only scar tissue was found at histology in 81.8 %, residual carcinoma in 7.7 %.

Finding only scar tissue and no residual cancer in 81.8 % at histopathology, it can be concluded that EFTR can confirm local radicality by enabling a transmural scar excision or serve as a potentially curative completion treatment where there is residual cancer.

EFTR allows exact risk stratification and represents a valuable option for local endoscopic treatment

Kuellmer et al investigated a total of 156 lesions and substantiate the findings above with an R0 resection rate of 87.5 %² in the subgroup of repeat resections of malignant polyps (56/64) (group 2: non-lifting lesions, n=92). Risk status was initially unclear in all patients and definitive discrimination between high-risk and low-risk lesions by histology examination of the EFTR specimen could be clarified in 99.4 % in both subgroups (final classification as low-risk after follow-up 84.1 %).

These results underline the benefit of FTRD® to support the decision for the optimal individual treatment strategy. As a primarily diagnostic procedure for tissue acquisition, it allows for exact histologic risk stratification in patients with untreated lesions suspicious of T1 carcinoma and avoid surgery for low-risk lesions. For patients with high-risk lesions unfit for surgery, it can even be a valuable option for local endoscopic treatment.

FTRD® can change traditional treatment paradigms and reduce the need for surgery^{1,2}

FTRD® demands less procedural skill and time than ESD and provides high quality pathological specimens optimizing histological assessment. It enables safe and radical endoscopic resection of deep submucosal invasive cancer and offers an alternative to radical surgery in lesions considered incurable with current resection techniques¹.

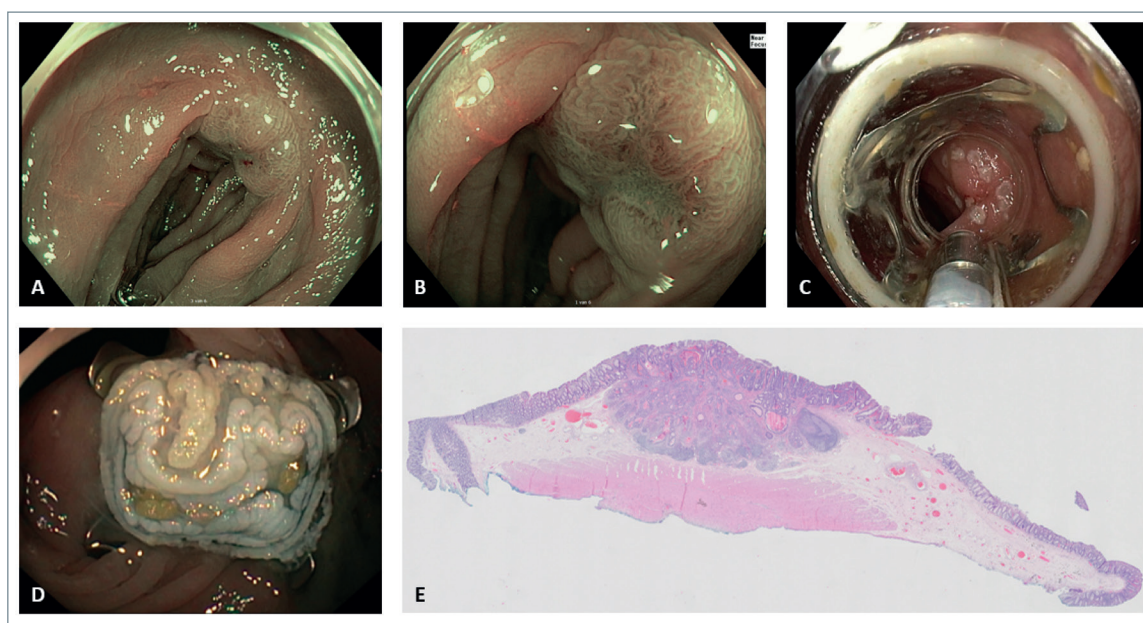


Fig. Completion endoscopic full-thickness resection after a previous incomplete resection of a low risk T1 colorectal cancer. a – d Endoscopic images showing: a, b narrow-band imaging of the target lesion; c the mounted full-thickness resection device on the marked lesion; d the full-thickness resection site with the over-the-scope clip. e Histopathological appearance showing a R0 resection of a moderately differentiated adenocarcinoma with deep submucosal invasion (SM3), without lymphovascular invasion or tumor budding. Source for Fig. e: Lianne Koens.

Source: Zwager et al [2020], Endoscopy

¹ Zwager LW, Bastiaansen BAJ, Bronzwaer MES, van der Spek BW, Heine GDN et al. Endoscopic full-thickness resection (eFTR) of colorectal lesions: results from the Dutch colorectal eFTR registry. Endoscopy. 2020 Nov;52(11):1014-1023.

² Kuellmer A, Mueller J, Caca K, Aepli P, Albers D et al. Endoscopic full-thickness resection for early colorectal cancer. Gastrointest Endosc. 2019 Jan 14. pii: S0016-5107(19)30013-6.