National Institute for Health and Care Excellence

IP 1506 – Endoscopic full thickness removal of non-lifting colonic polyps
Consultation comments table

IPAC date: 9 March 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company SynMed	**General**	There is now a range of data available I have attached all the English language versions and you can download all FTRD relevant publications currently available here: https://we.tl/cGN2bO62TU Fähndrich M, Sandmann M (2015) Endoscopic full-thickness resection for gastrointestinal lesions using the over-the-scope clip system: a case series. Endoscopy 47: 76-79. Valli M, Vrugt B, Bauerfeind P (2014) Endoscopic Resection of a Diverticulum-Arisen Colonic Adenoma Using a Full-Thickness Resection Device. Gastroenterology 147:969-971. Schmidt A, Damm M, Caca K (2014) Endoscopic full thickness resection using a novel over-the-scope device. Gastroenterology 147: 740-742.	Thank you for your comment. This study is included in the main extraction table, paper 2 table 2. This study is included in the main extraction table, paper 4 table 2. This study is included in the main extraction table, paper 3 table 2.

			Klare P et al. (2015) Over-the-scope clip-assisted endoscopic full-thickness resection after incomplete resection of a rectal neuroendocrine tumor. Endoscopy 47:47-48.	This study reports outcomes of endoscopic full thickness resection used to treat lesions in a different anatomic location. Not covered under the current IP guidance.
			Probst A, Schaller T, Messmann H (2015) Gastrointestinal stromal tumor of the colon - endoscopic treatment by full-thickness resection. Endoscopy 47: 460-461.	This study is included in the main extraction table, paper 5 table 2.
			Schmidt A, Meier B, Cahyadi et al. (2015) Duodenal endoscopic full-thickness resection. Gastrointestinal endoscopy, 1-6.	This study reports outcomes of endoscopic full thickness resection used to treat lesions in a different anatomic location. Not covered under the current IP guidance.
			Schmidt A, Bauerfeind P, Gubler C et al. (2015) Endoscopic full-thickness resection in the colorectum with a novel over-the-scope device: first experience. Endoscopy 47:719-725.	This study is included in the main extraction table, paper 1 table 2.
			Lagoussis P, Soriani P, Tontin GE et al. (2016) Over-the-scope clip-assisted endoscopic full-thickness resection after incomplete resection of rectal adenocarcinoma. Endoscopy 48: 59-60.	This study reports outcomes of endoscopic full thickness resection used to treat lesions in a different anatomic location. Not covered under the current IP guidance.
			Grauer M, Gschwendtner A, Schäfer C et al. (2016) Resection of rectal carcinoids with the newly introduced endoscopic full-thickness resection device. Endoscopy 48: 123–124.	Same as above.

			Snauwaert C, Jouret-Mourin A, Piessevaux H (2015) Endoscopic full-thickness resection of a nonlifting adenoma in an ileal pouch using an over-the-scope full-thickness resection device. Endoscopy 47: 344-345.	Same as above.
			Probst A, Schaller T, Messmann H (2015) Gastrointestinal stromal tumor of the colon – endoscopic treatment by full-thickness resection. Endoscopy 47: 460–461.	This study reports outcomes of endoscopic full thickness resection used to treat malignant lesions. Not covered under the current IP guidance.
			Kratt T (2016) Endoscopic full-thickness resection of gastric metastasis from malignant melanoma by use of a novel over-the-scope device. Gastrointestinal endoscopy 84: 368.	This study reports outcomes of endoscopic full thickness resection used to treat lesions in a different anatomic location. Not covered under the current IP guidance.
			Kratt T, Kirschniak A, Schenk M et al. (2014) Die flexibel-endoskopische Vollwandresektion im GI-Trakt: Neuentwicklung und erste klinische Erfahrungen mit dem FTRD-System (full-thickness resection device). Meeting abstract.	Literature in German language.
			Kratt TP, Kirschniak A, Königsrainer A (2014) Neuentwicklung einer endoskopischen Vollwand-Resektionstechnik im GI-Trakt: erste klinische Erfahrungen mit dem FTRD-System.	Same as above.
			Kratt TP, Zerabruck E, Königsrainer A (2014) Full thickness resection device: Eine neue	Same as above.

			method zur endoskopischen vollwandresektio im kolorektum. Gastroenterologe. Online. Richter-Schrag HJ, Walker C, Thimme G et al. (2015) A. FischerFull-Thickness-Resection-Device (FTRD) Die endoskopische Vollwandresektion für das Rektum und Kolon. Chirurg. Online. Bulut M, Gogenur I, Hansen LB (2015) Endoskopisk fuldvaegsresektion af adenoma I colon. Ugeskr LAeger 177. Ohse GH, Hopk K, Krummenerl P et al. Endskopiche vollwandresektion (EFTR - endoscopic full-thickness resection) mit dem FTRD-system (Full-thickness resection device): Dolauer daten. Aepli P, Frei R, Borovicka J et al. (2016) Full thickness resection device (FTRD): A novel tool. Absctract	Same as above. Same as above. Same as above. Conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview, unless they contain important safety data.
2	Consultee 1 Company SynMed	**General**	Additionally we have attached a poster, in German.	Thank you for your comment. The consultee refers poster in German language. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally

				presented to the Committee, unless they contain important safety data.
3	Consultee 1 Company SynMed	**General**	It seems the available data has been used inconsistently – efficacy only from published papers; complications also from “unpublished” data (registry, wall resect presentation.	Thank you for your comment. The consultee disagrees with NICE IP process. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee, unless they contain important safety data.
4	Consultee 1 Company SynMed	**General**	One publication used where they only used 1x FTRD, other cases with OTSC clip first and resected with another snare in second step (Fähndrich et al.)	Thank you for your comment. The IP programme issues guidance on procedures rather than individual devices. The paper reports the use of an endoscopic full-thickness removal technique despite using a different snare device.
5	Consultee 2 Company Ovesco		I like to send you the current registry report for the FTRD System. I also attached a new publication.	Thank you for your comment. The registry analysis reports data on 250 patients, 69% (173) were treated for colonic lesions. Adverse event aren’t reported by subgroup so it is not possible to determine if they occurred as a result of colonic interventions. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the

				Committee, unless they contain important safety data.
			Marin-Gabriel J C, Diaz-Tasende J, Rodriguez-Munoz S, Del Pozo-Garcia , A , and Ibarrola-Andres C (2017) Colonic endoscopic full-thickness resection (EFTR) with the over-the-scope device (FTRD): a short case series. Rev Esp Enferm Dig 109.	This paper was selected from the update literature search. It was included in appendix A as it does not report any new safety data and larger case series were already included in table 2.
6	Consultee 2 Company Ovesco		Please see attached another publication. It is in German, however they present the interim results of the wall resect study on page 5. Meier B, Schmidt A, Caca K (2016) Die endoskopische Vollwandresektion. Internist 57:755-762.	Thank you for your comment. Literature in German language.
7	Consultee 3 British Society of Gastroenterology Endoscopy Committee		Sensible and considered guidance.	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."