National Institute for Health and Care Excellence

IP1837 Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach

IPAC date: 9 December 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Synectics Medical Ltd	**1.1 & 1.2**	"Ref pt 1- gastroduodenal FTRD is not only applicable for GISTs in the stomach, but the device can also be used for a greater range of indications and areas of application (including the duodenum) as indicated in the range of literature that was submitted. FTRD should not only be considered as final therapeutic approach to resect lesions but also as providing high diagnostic value. Whilst FTRD offers a minimally invasive technique especially for “low-threshold” submucosal tumours (SMTs) that can be diagnosed with FTRD, gastroduodenal FTRD can also be a diagnostic tool for incidental suspicious findings during ultrasound where an exact histological stratification and analysis is required (or desired) by collecting intact tissue samples, avoiding long-term follow-up of the patients (especially considered in younger patients). In this instance FTRD can provide diagnostic clarity and establish the way for further therapy. 2. Ref Draft recommendations-GISTs in the stomach are considered a relative rarity. It would require significant time to recruit the necessary patient cohort to conduct a study to derive substantial clinical data and deduce recommendations. A real world approach (registry studies) would therefore be a much more feasible approach, but ideally including a wider field of indications and fields of application (not only limited to GISTs in the stomach)."	Thank you for your comment. The committee has considered this comment but decided not to change the guidance. The indication of the procedure is GISTs in the stomach and other indications fall out of the scope. Sections 3.6 and 3.7 cover the comment relating to the indications and the purposes of the FTRD: *3.6 This procedure is used for curative resection of gastrointestinal stromal tumours and for diagnosis.* *3.7 This procedure is used for conditions other than gastrointestinal stromal tumours.* For further research, section 1.2 states: *“Further research should ideally be randomised controlled trials or registry studies. It should report patient selection, tumour type, size and anatomical position, and long-term outcomes (such as tumour recurrence).”*

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2	Consultee 1 Synectics Medical Ltd	**General**	With reference to the Interventional Procedures Programme (IPP) four-week public consultation period for Endoscopic full thickness removal of gastrointestinal stromal tumours of the stomach. On behalf of Ovesco, the manufacturer of the gastroduodenal FTRD, Synectics Medical Ltd as the UK distributer of the device has added some comments to the online document as indicated in your email below. I did encounter some issues with loading and response of the online document, but I hope the comments were added. Ovesco were keen to emphasise that gastroduodenal FTRD is not only applicable for GISTs in the stomach, but the device can also be used for a greater range of indications and areas of application (including the duodenum) as indicated in the range of literature that was submitted. Is it possible to expand the range of this guidance? FTRD should not only be considered as final therapeutic approach to resect lesions but also as providing high diagnostic value for incidental suspicious findings during ultrasound where an exact histological stratification and analysis is required (or desired) by collecting intact tissue samples, avoiding long-term follow-up of the patients. In these instances, FTRD can provide diagnostic clarity and establish the path for further therapy.	Thank you for your comment. The committee has considered this comment but decided not to change the guidance. Please see response to comment 1.

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