National Institute for Health and Care Excellence

IP1056/3 Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids

Consultation Comments table

IPAC date: 10 June 2021

Due to the large number of comments received, the comments have been organised into the following themes:

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1 to 5	1 to 4	Comments on use of the term 'power morcellation' in the title and throughout the guidance – suggesting that use of the term 'power morcellation' is misleading and suggesting alternatives
6	4	Comment on specifying the location of uterine fibroids relevant to the procedure
7 to 11	4 to 13	Comments on the theoretical risk of dissemination of malignant tissue (section 3.6 and 1.1)
12 to 14	13 to 15	Comments disagreeing with the main recommendation in relation to other efficacy and safety issues (section 1.1)
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No.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company Medtronic	**General**	Hysteroscopic morcellators are not the same technology as the 'power morcellators' used in laparoscopy. For this reason, clinicians internationally now use the term Tissue Removal System or 'mechanical Hysteroscopic Tissue Removal Systems (mHTR)' to make a clear distinction between the hysteroscopic devices and laparoscopic power morcellators. We recommend that the committee remove the term 'power morcellators' and consider amending the description of the technology in the title of the guideline and throughout, to ensure that the difference between these technologies is clear to the reader.	Thank you for your comment. The title has been changed to: 'Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids'.
2	Consultee 2 Company Hologic Ltd	**General**	Title of the IPG – consider adjusting to 'Hysteroscopic Removal of uterine tissue with hysteroscopic tissue removal systems'. Misunderstanding of 'dissemination risk' for hysteroscopic vs. laparoscopic – should the term 'morcellation' be used to describe the hysteroscopic procedure as this is misleading – hysteroscopic tissue removal is more appropriate.	Thank you for your comment. The title has been changed to: 'Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids'.
3	Consultee 3 Manager on behalf of BSGE	**General**	The term hysteroscopic tissue removal system is now used in gynaecological practice and has replaced the term hysteroscopic morcellation. This change came about following the concerns over laparoscopic 'power' or 'electromechanical' morcellation and potential dissemination of malignant fibroid tissue. To keep consistent with this document we have used the term hysteroscopic morcellation in responses below but we do not believe this is the correct term.	Thank you for your comment. The title has been changed to: 'Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids'.

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4	Consultee 3 Manager on behalf of BSGE	**General**	Use of the term ‘’power morcellation’ has never been used to describe hysteroscopic morcellation. This term is synonymous with laparoscopic morcellation where a much more aggressive and larger technology is used to break up denser, larger uterine and fibroid tissue. The fact the mechanical hysteroscopic system needs a mains supply to the generator does not mandate the use of the term ‘power’, as we don’t use this qualification for most dynamic surgical mechanical equipment or energy modalities e.g. ultrasonic energy.	Thank you for your comment. The title has been changed to: ‘Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids’.
5	Consultee 3 Manager on behalf of BSGE	**General**	The committee recognises that hysteroscopic morcellators are not the same as laparoscopic morcellators, but despite this the term ‘power’ morcellation has still been used.	Thank you for your comment. The title has been changed to: ‘Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids’.
6	Consultee 3 Manager on behalf of BSGE	**General**	The document refers to ‘uterine fibroids’; treatment in the context of hysteroscopy is for a specific location of uterine fibroid i.e. and intracavity fibroid for which the term most commonly used to describe is submucous (or submucosal) fibroids	Thank you for your comment. Sections 2.3 and 2.4 have been changed to specify that the procedure is used with submucosal uterine fibroids.
7	Consultee 1 Company Medtronic	**3.5**	Committee comments (3.5). ‘The committee was informed that hysteroscopic morcellation has a potential risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes’. This statement is not aligned to the Overview document in which clinical experts stated that this is a theoretical risk only: ‘For this procedure, professional experts did not describe any anecdotal adverse events. They considered that the following was a theoretical adverse event: potential	Thank you for your comment. To align with the overview, section 3.6 has been changed to: *The committee was informed that hysteroscopic morcellation has a **theoretical** risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes. The committee noted that this is a **theoretical risk in contrast to** the*

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			theoretical risk of spread of malignant tissue via tubal ostia into peritoneum .' For accuracy and clarity for all stakeholders, we suggest that this section is reworded in line with the Overview statement to state that this is a theoretical risk. Further, it should be stated clearly that there are no published or reported incidences of this adverse event . This transparency is important because this statement underpins the draft NICE recommendation, and decisions may therefore be made based on this theoretical event.	***recognised*** *risk of dissemination in laparoscopic morcellation of fibroids, in which the morcellation takes place within the peritoneal cavity.*'
8	Consultee 2 Company Hologic Ltd	**3.5**	3.5 – 'The committee was informed that hysteroscopic morcellation has a potential risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes. The committee noted that this risk is lower than the risk of dissemination in laparoscopic morcellation of fibroids, in which the morcellation takes place within the peritoneal cavity. This potential risk underpins its recommendation that this procedure should only be used with special arrangements' This risk is theoretical based on the available data and the risk is confused with laparoscopic power morcellation. A suggestion to consider real world data through local hospital audits or a survey through the British Society of Gynaecological Endoscopy (BSGE) or BSGE Ambulatory Care Network would be able to quantify the percentage risk of dissemination	Thank you for your comment. To align with the overview, section 3.6 has been changed to: *The committee was informed that hysteroscopic morcellation has a* ***theoretical*** *risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes. The committee noted that this is a* ***theoretical this in contrast to*** *the* ***recognised*** *risk of dissemination in laparoscopic morcellation of fibroids, in which the morcellation takes place within the peritoneal cavity.*' Section 19.1 of the NICE intervention procedures programme manual states: 'Guidance on procedures with 'special' or 'research only' arrangements is proactively reviewed after 3 years, and the guidance is updated if important new evidence is available.

			reported cases within the 10 year+ of use of this technology in the UK (and globally). The benefits of this technology far outweigh any potential risks compared to alternative methods using other hysteroscopic techniques e.g. electro-surgical or major surgery. Recommended to evaluate surgical options with a risk/benefit analysis and stratification based on co-morbidities and treatment setting (outpatient / day surgery). Recommended ref: RCOG Hysteroscopy, Best practice in outpatients (green top guideline No.59) – due to be updated in summer 2021. https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg59/ A recent study published Feb 2021: Hysteroscopic Morcellation in Endometrial Cancer Diagnosis: Increased Risk? https://www.jmig.org/article/S1553-4650(21)00084-4/fulltext Evaluated the risks of hysteroscopic morcellation compared to alternative methods for diagnosis of endometrial cancer – showing that there is no evidence of increased risk of dissemination of malignant tissue into the peritoneal cavity. Conclusion: 'Our study demonstrates that hysteroscopy with morcellation is a safe diagnostic method for Low- and High-Grade endometrial	This may be done sooner if there is significant new evidence or emerging new safety concerns.' Ref 2 (Kelly, R, Contos, G, Walker, C.A, Ayoola-Adeola, M, & Winer, I. (2020). Hysteroscopic morcellation in endometrial cancer diagnosis: Increased risk? Gynecologic Oncology, 159, 237). The study selected people with endometrial cancer, a different indication to that under consideration for this procedure, and therefore does not meet the inclusion criteria for the overview.

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			pathologies and does not lead to increased dissemination of malignant cells, lymphovascular space invasion nor upstaging of patients.' The study also highlights additional benefits compared to alternative methods: Comments: 'In addition to being a safe method of biopsy for the diagnosis of endometrial cancer, modern hysteroscopy with morcellation allows for direct visualization and targeted biopsy of tissue or lesions, increasing precision of samples, decreasing the risk of uterine perforation and potentially increasing operating room efficiency and time in comparison to hysteroscopy dilation and curettage or blind dilation and curettage. Theoretically, in patients with a focus of neoplasia in the setting of endometrial hyperplasia, hysteroscopic morcellation can accurately aid in the resection of a foci of tissue suspicious for malignancy, allowing for decrease in operative time and indirect decrease in costs.'	
9	Consultee 3 Manager on behalf of BSGE	**3.5**	'The committee was informed that hysteroscopic morcellation has a potential risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes' This is a theoretical risk as stated in the overview document There is no compelling evidence to support the increased spread of malignant tissue using hysteroscopic morcellating of submucosal fibroids.	Thank you for your comment. To align with the overview, section 3.6 has been changed to: *The committee was informed that hysteroscopic morcellation has a **theoretical** risk of disseminating malignant tissue through uterine perforation or retrograde flow through the fallopian tubes. The committee noted that this is a **theoretical** risk **in contrast to** the **recognised** risk of dissemination in*

			Moreover, the risk of uterine perforation is low and at worst the same as with conventional electrical instrumentation and at best (and more likely) lower because the hysteroscopes are smaller and the simultaneous aspiration of removed tissue from the operating field facilitates a clearer view. Uterine sarcomas are generally found in postmenopausal women and in subserosal fibroids. Whilst prevalence data for sarcoma within fibroids by location are scarce, one small case controlled paper (mean age of patients 62 – I,e. postmenopausal) suggested that a minority - 19% of all sarcomas were in submucosally located fibroids despite submucosal fibroids being 28% prevalent overall (Chen I, Firth B, Hopkins L, Bougie O, Xie R, Singh S. Clinical Characteristics Differentiating Uterine Sarcoma and Fibroids. JSLS 2018;22:e2017.00066. doi: 10.4293/JSLS.2017.00066.). Also as pointed out in response 9, submucosal fibroids are rarely removed in women of post-menopausal age as there are few indications. Moreover, removal in such women (for recurrent PMB, or to facilitate the delivery of local progestogen therapy as part of an HRT regime) is also to provide histological tissue for diagnosis of potential malignant / pre-malignant changes. In addition, 'suspicious features' e.g. necrosis are rare and directed biopsies to make a diagnosis (as discussed in response to point 9) can be more easily achieved with hysteroscopic morcellators as multiple passes of conventional mechanical forceps or electrical instruments are avoided and larger histological samples to make a definitive diagnosis obtained.	*laparoscopic morcellation of fibroids, in which the morcellation takes place within the peritoneal cavity.*' The safety summary section of the overview includes evidence on uterine perforation as an outcome of the procedure. Ref 1 (Chen et al), 2 (Chang et al) and 4 (Soucie et al) do not specifically describe the relevant procedure and therefore do not meet the inclusion criteria for the overview. Ref 3 (Kelly et al) The study selected people with endometrial cancer, a different indication to that under consideration for this procedure, so therefore does not meet the inclusion criteria for the overview.

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			Data pertaining to the spread and stage and prognosis of endometrial cancer if diagnostic hysteroscopy with fluid distension is used or not (diagnosis being restricted to blind biopsy - 'D&C') does not support upstaging of disease or worse prognosis and data about peritoneal dissemination of malignant cells (as detected on cytology of washings from the peritoneal cavity) are conflicting and given the lack of worsening disease stage or prognosis observed, probably irrelevant. (Chang Y, Y, Wang Y, Wang L, Duan H. Effect of hysteroscopy on the peritoneal dissemination of endometrial cancer cells: a meta-analysis. Fertility and Sterility 2011; 96:957-961. https://doi.org/10.1016/j.fertnstert.2011.07.1146 Kelly RA, et al. Hysteroscopic Morcellation in Endometrial Cancer Diagnosis: Increased Risk? J Minim Invasive Gynecol. 2021 Feb 8: S1553-4650 (21) Soucie JE, Chu PA, Ross S, Snodgrass T, Wood SL. The risk of diagnostic hysteroscopy in women with endometrial cancer. Am J Obstet Gynecol 2012; 207: 71.e1-5. doi: 10.1016/j.ajog.2012.04.026.) Thousands of hysteroscopic electrical resection procedures for fibroids have been performed since 1985 and surely a any risk of malignant spread of sarcomatous tissue would have been elucidated if a significant issue?	
10	Consultee 1 Company Medtronic	**1.1**	Draft recommendations (1.1). We fully support the importance of documenting and highlighting all available safety data in the current review. However,	Thank you for your comment.

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			we believe the inclusion of theoretical events not supported by any published or documented safety data may be misleading. Specifically, the spread of malignant tissue is stated as a 'potential theoretical risk'; this has not been observed in either the available RCTs or real-world evidence including the MAUDE database, where very low event rates confirm an acceptable safety profile for this procedure. Further, available Medtronic post-market vigilance data on dense tissue shavers for this procedure does not contain any issues associated with this theoretic event (Medtronic post-market vigilance data report provided separately). As such, we contend that this specific potential event should not underpin the draft recommendation of 'special arrangements' as it is solely based on theoretical risk and therefore at odds with evidence-based decision making.	The committee has considered this comment but decided not to change the main recommendation – special arrangements.
11	Consultee 1 Company Medtronic	**1.1**	(Cont.) A recently published study by Kelly et al. (2021) investigated the question of whether there is an increased risk of extravasation of malignant cells into the peritoneal cavity, positive peritoneal cytology, lymphovascular space invasion or surgical upstaging associated with hysteroscopic morcellation in comparison to other intrauterine procedures (hysteroscopy without morcellation, endometrial biopsy and dilation and curettage). The authors identified no statistically significant differences between the techniques on any of the outcome measures and concluded that using modern hysteroscopic morcellation, gynaecologists should be reassured that increased intrauterine pressures are not associated with retrograde dissemination of occult malignant endometrial cells into the peritoneal	Thank you for your comment. The committee has considered this comment but decided not to change the main recommendation – special arrangements. Ref 1 (Kelly et al) and 4 (Vilos et al) The study populations were people with endometrial cancer, a different indication to that under consideration for this procedure, so do not meet the inclusion criteria for the overview.

			cavity in comparison with alternative methods of biopsy. The findings of Kelly et al (2021) are further supported by investigators who have also concluded that hysteroscopic procedures do not result in increased recurrence rates and/or reduced overall survival in comparison to endometrial biopsy and dilation and curettage (Ben-Arie A, et al 2008). Other authors also demonstrate that hysteroscopy has no effect on long term prognosis e.g. (Ettore C. et al. 2010), (Vilos GA, et al 2007). Taken together, these data challenge the validity of postulating that there is a theoretical risk of malignant spread by performing hysteroscopic morcellation in comparison to other uterine procedures. The United States is the largest market for hysteroscopic morcellation devices. In the period from 2015 – 2017 there were 171,226 hysteroscopic morcellation procedures conducted for uterine leiomyomas (source IBM MarketScan Research database). To date Medtronic has identified no record from safety reporting or in the literature of associated malignant spread. The draft recommendation also considers uterine perforation as presenting a potential risk of disseminating malignant tissue. The Haber et al. (2015) study of safety reporting to the MAUDE database identified 28 cases of uterine perforation. Although there are limitations in the estimate of the denominator in this study it is an indication of the rarity of uterine perforations associated with	Ref 2 (Ben-Arie et al) and 3 (Ettore Cicinelli et al) do not specifically describe the relevant procedure so did not meet the inclusion criteria for the overview. Ref 5 (Haber et al) was included in Table 2 of the overview.

			hysteroscopic morcellations 0.02% of procedures (28/180,000). There are 7,055 hysteroscopic myomectomies conducted in England per annum, although OPCS coding is insufficiently granular to enable exact figures for hysteroscopic morcellation to be reported (Hospital Episodes Statistics). It is evident that this procedure is being routinely and safely performed, supporting a recommendation of 'use with standard arrangements for clinical governance, consent and audit'. We urge the NICE Committee to consider the available UK real world data to inform their evidence-based decision and as a robust basis amending the draft recommendation to a 'standard' arrangement . Kelly RA, et al. Hysteroscopic Morcellation in Endometrial Cancer Diagnosis: Increased Risk? J Minim Invasive Gynecol. 2021 Feb 8: S1553-4650 (21) Ben-Arie A, et al. Does hysteroscopy affect prognosis in apparent early-stage endometrial cancer? International journal of gynecological cancer : official journal of the International Gynecological Cancer Society. 2008;18(4):813-819 Ettore C. et al. Risk of long-term pelvic recurrences after fluid minihysteroscopy in women with endometrial carcinoma, Menopause: May 2010 - Volume 17 - Issue 3 - p 511-515 George A. Vilos GA, et al, Hysteroscopic surgery does not adversely affect the long-term prognosis of women with endometrial adenocarcinoma, Journal of	

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			Minimally Invasive Gynecology, Volume 14, Issue 2, 2007, Pages 205-210, ISSN 1553 4650	
12	Consultee 2 Company Hologic Ltd	**1.1**	1.1 – 'but potentially serious side-effects', 'Evidence on it's efficacy is limited in quantity and quality' This minimally invasive technology has been on the market for over 10 years with more than 1 million women treated globally. There is strong evidence to support improvement in outcomes relating to complete removal of pathology, limited risk of perforation due to improved visualisation and limiting the number of insertions into the uterine cavity. Current evidence demonstrates improved outcomes vs. alternative methods such as hysteroscopic resection which has more frequent and serious risks of complications with electro-surgery such as thermal injury (mentioned in point 2.3) NICE Ng88 Heavy menstrual bleeding guidelines include recommendations to include surgical treatment for submucosal fibroids - point 1.5.6 'For women with submucosal fibroids, consider hysteroscopic removal' https://www.nice.org.uk/guidance/ng88/resources/heavy-menstrual-bleeding-assessment-and-management-pdf-1837701412549	Thank you for your comment. The committee has considered this comment but decided not to change the main recommendation – special arrangements. Evidence from studies comparing hysteroscopic morcellation with other methods of hysteroscopic resection of uterine fibroids are included in the overview.
13	Consultee 3 Manager on behalf of BSGE	**1.1**	Section 1.1 – the special arrangements for clinical governance ….audit. Published evidence (as produced in the NICE overview) shows that hysteroscopic morcellation of fibroids is safe and feasible for removing submucosal fibroids and points to better safety and ease of use	Thank you for your comment. The committee has considered this comment but decided not to change the main recommendation – special arrangements.

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			compared to conventional electrical resection, so it seems a little perverse that hysteroscopic morcellation of fibroids is being singled out for these 'special arrangements' and the need to inform 'clinical governance leads'. The British Society for Gynaecological Endoscopy (BSGE) has developed a surgical information collection system ('BSGESICS') to input data regarding the feasibility and peri-operative and post-operative complications of a range of endoscopic procedures including hysteroscopic myomectomy which records the type of procedure (hysteroscopic morcellation, electril resection etc). This is available via the internet for members and as an app through the app store and on line at http://bsgesics.com This would be an ideal tool to provide audit of feasibility and safety. If we could incentivise operators to use this too for consecutive cases in accordance with this NICE recommendation However, it should be noted that these 'special arrangements' are not in place for electrical resection where such data are also lacking; it would be useful to collect data on all types of hysteroscopic myomectomy. Within 6 to 12 months we should have accrued enough data to inform the NICE IPG process such that the requirement for ongoing 'special arrangements' could be reviewed	Section 19.1 of the NICE intervention procedures programme manual states: 'Guidance on procedures with 'special' or 'research only' arrangements is proactively reviewed after 3 years, and the guidance is updated if important new evidence is available. This may be done sooner if there is significant new evidence or emerging new safety concerns.'
14	Consultee 3 Manager on behalf of BSGE	**1.1**	It should be emphasised that the most serious risks associated with hysteroscopic myomectomy are uterine perforation and fluid overload and the prevalence of these complications are similar to the traditional electrical fibroid resection procedure, which has been in practice since approximately 1985.	Thank you for your comment. The committee has considered this comment but decided not to change the main recommendation – special arrangements.

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			The resection procedure has established its safety and efficacy as a simpler alternative to abdominal myomectomy or hysterectomy over the last 3,+ decades. The comparative trials show that hysteroscopic morcellation technologies are easier to learn and are faster, hence potentially improving the safety profile. For this reason, classifying this procedure into 'special arrangement's would be a disincentive, and this would be odd considering the established procedure (resection) may have a slightly worse safety profile given that larger diameter instruments are often needed requiring greater degrees of cervical dilatation (risking genital tract trauma – e.g. cervical tears / bleeding and uterine perforation) and electrical energy risks non-target thermal injury.	
15	Consultee 2 Company Hologic Ltd	**1.2 & 1.3**	1.2 / 1.3 'Healthcare organisations should: Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.' 'Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these' This technology should be compared to the alternatives and patients should be provided with information representing the potential risks of this minimally invasive treatment option to enable shared decision making, highlighting the advantages vs. outpatient/day case setting and alternative major surgical options. 1.2 - Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety	Thank you for your comment. The committee has considered this comment but decided not to change recommendations 1.2 and 1.3. NICE guideline NG88 'Heavy menstrual bleeding: assessment and management' (**https://www.nice.org.uk/guidance/ng88**) refers in general to hysteroscopic removal of submucosal fibroids but does not specifically recommend hysteroscopic morcellation.

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			outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion). To our knowledge all NHS hospitals in the UK conduct ongoing audits post implementation of this technology (and any new innovation), therefore would be a good source of data. The technology has been used in the UK (and Globally) for over 10 years and evidence supports the safety and efficacy of the procedure, adoption into an ambulatory gynaecology setting, high patient satisfaction and low complication rates. With the inclusion of an automated fluid management system and NICE Heavy Menstrual Bleeding Ng88 recommendations to offer this treatment, the statement appears to be unsubstantiated to caution patients and clinical governance regarding the risks.	
16	Consultee 2 Company Hologic Ltd	**1.4**	1.4 – 'The procedure should only be done by clinicians with specific training in this technique, including fluid management' It is recommended that trained gynaecologists to hysteroscopically resect and remove tissue should perform these procedures. However it should be noted that these techniques provide a much shorter learning curve than alternative more invasive methods. These techniques are also well adopted with Nurse Hysteroscopists trained to perform in an outpatient setting which provides considerable advantages to the healthcare system with effective use of resources, cost savings and staff development opportunities.	Thank you for your comment.

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			Ref: MyoSure instructions for use: https://gynsurgicalsolutions.co.uk/wp-content/uploads/2020/12/MAN-04370-9940_007_02-MyoSure-REACH-EN-DA-NLFI-FR-DE-IT-NO-PT-ES-SV.pdf	
17	Consultee 2 Company Hologic Ltd	**2.1**	2.1 – 'Uterine fibroids (also known as uterine leiomyomas or myomas) are benign tumours of the uterus. They can be asymptomatic or cause symptoms including heavy periods or bleeding between periods. They can be associated with fertility problems and miscarriage.' Fibroids are common, with around 1 in 3 women developing them at some point in their life. They most often occur in women aged 30 to 50. Fibroids are thought to develop more frequently in women of African-Caribbean origin. It's also thought they occur more often in overweight or obese women because being overweight increases the level of oestrogen in	Thank you for your comment. The overview summarises the indication for the procedure and is not intended to be comprehensive.

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			the body. (Ref: NHS Fibroids Overview - https://www.nhs.uk/conditions/fibroids/) Women who do have symptoms (around 1 in 3) may experience: • heavy periods or painful periods • tummy (abdominal) pain • lower back pain • a frequent need to urinate • constipation • pain or discomfort during sex In rare cases, further complications caused by fibroids can affect pregnancy or cause infertility. Ref: https://www.nhs.uk/conditions/fibroids/	
18	Consultee 2 Company Hologic Ltd	**2.3**	2.3 – 'Hysteroscopic morcellation is intended to reduce the risks of traumatic injury to the uterus and the risk of inadvertent fluid overload associated with traditional procedures' Use of automated fluid management systems is recommended to monitor fluid absorption and	Thank you for your comment. The consultee refers to a guideline which is available as a peer-reviewed publication at the following link **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5133285/**

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			improve procedure outcomes such as optimise visualisation through maintaining fluid pressure and shorter procedure time. Recent systems introduced to the market in 2021 (Fluent Fluid Management by Hologic) use less fluid to reduce these risks further and limit intra-uterine pressure to further lessen fluid absorption and potential dissemination of fluid into the peritoneal cavity. Ref: UK BSGE Fluid Management guidelines: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5133285/	A hyperlink has been added to section 3.8 of the draft guidance.
19	Consultee 3 Manager on behalf of BSGE	**2.3**	"Hysteroscopic morcellation is intended to reduce ……..the risks of inadvertent fluid overload associated with traditional procedures". It is unlikely that this technology would reduce the risks of fluid overload compared to electrical resection for comparable types of submucous fibroid unless it conferred an advantage of much quicker surgery. To date there are no compelling data to support this.	Thank you for your comment. Section 2.3 has been changed to: 'Hysteroscopic morcellation is intended to reduce the **risk** of traumatic injury to the uterus associated with traditional procedures.' In addition committee comment 3.8 has been changed to: 'The committee was informed that automated fluid management systems are used with some devices to reduce the risk of causing excessively high uterine pressures and subsequent fluid overload. It noted there are published guidelines on management of fluid distension media in operative hysteroscopy.'
20	Consultee 3 Manager on behalf of BSGE	**2.4**	The whole point of hysteroscopic resection/morcellation is to get accurate histology as well as to cure symptoms without recourse to more invasive procedures like hysterectomy	Thank you for your comment.

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21	Consultee 1 Company Medtronic	**2.4**	Sections 2.4. states that hysteroscopic removal of uterine fibroids with power morcellation is usually done under general or spinal anaesthesia, typically as a day-case procedure. The statement should be amended to reflect that the procedure is also conducted as an outpatient procedure without general anaesthesia. “Hysteroscopic morcellation of uterine leiomyomas can be conducted with the patient under general or spinal anaesthesia, typically as a day-case or alternatively as an outpatient procedure without general anaesthesia ”.	Thank you for your comment. Section 2.5 has been changed to: ‘The procedure may be done under local, regional or general anaesthesia, typically as a day-case procedure.’
22	Consultee 2 Company Hologic Ltd	**2.4**	2.4 – ‘this procedure is usually performed under general anaesthesia’ – more hospitals in the UK are adopting this technique in an outpatient setting which further reduces risks of procedural complications and anaesthesia risks. A survey through the British Society of Gynaecological Endoscopy (BSGE) or BSGE Ambulatory Care Network would be able to quantify the percentage performed as outpatient vs. day case or through local hospital audits. No consideration of safety / outcome measures regarding outpatient use was included. Offering these minimally invasive treatment options to high risk patients with co-morbidities and avoiding a general anaesthesia provide considerably reduced risks and should be considered as part of the assessment vs. alternative surgical options.	Thank you for your comment. Section 2.5 has been changed to: ‘The procedure may be done under local, regional or general anaesthesia, typically as a day-case procedure.’

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23	Consultee 3 Manager on behalf of BSGE	**2.4**	'Hysteroscopic removal of uterine fibroids with power morcellation is usually done under general or spinal anaesthesia, typically as a day-case procedure.' Whilst this is true, the majority of procedures being done in the operating theatre under general / regional anaesthesia, in contrast to conventional electrical resection, In many centres, hysteroscopic morcellation procedures for submucous fibroids are performed in the outpatient setting facilitated by the smaller size,of endoscopes needed and ease of use. For references regarding the feasibility of outpatient hysteroscopic morcellation of submucosal fibroids see studies 5,6,7 and 9 of the NICE draft document.	Thank you for your comment. Section 2.5 has been changed to: 'The procedure may be done under local, regional or general anaesthesia, typically as a day-case procedure.'
24	Consultee 2 Company Hologic Ltd	**3.1**	3.1 – 'review of adverse events reported on the US Food and Drug Administration Manufacturer and User Facility Device Experience database' – this was the only publication considered to evidence 'safety' measures of the technology and taken from a US FDA database which stipulates: "Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources"	Thank you for your comment. All 12 references included in the overview were analysed for both efficacy and safety outcomes of the procedure. The MHRA's senior officer responsible for medical aspects of device regulation is a member of the Committee and the two organisations are in regular contact.

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			https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#disclaimer “MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.” The UK adverse event reporting is monitored through the Medicines & Healthcare products Regulatory Agency (MHRA) – is there an opportunity to also learn from the 10 years of safety reporting from the UK local audits, as well as global perspective?	
25	Consultee 2 Company Hologic Ltd	**3.2**	3.2 – ‘The professional experts ..’ The committee experts did not include a Gynaeocology Oncologist to provide advice regarding the risks of dissemination of malignant tissue. The experts present during the Committee meeting had limited experience using the technology and was not able to provide comprehensive assessment of oncology risks.	Thank you for your comment. The Interventional Procedures Advisory Committee is a standing committee of NICE. Before a procedure is considered by the Committee, NICE seeks the opinion of at least two Specialist Advisers who are nominated by relevant Specialist Societies. This specialist advice is normally provided in the format of a questionnaire response.
26	Consultee 2 Company Hologic Ltd	**3.3**	3.3 – ‘The professional experts and the committee considered the key safety outcomes to be: bleeding, uterine perforation, infection and need for a hysterectomy’ Also key safety measures would include vasovagal episode and fluid overload complications with hyponatraemia such as pulmonary oedema or heart failure.	Thank you for your comment. Although the committee considered bleeding, uterine perforation, infection and need for a hysterectomy to be the key safety outcomes, evidence on other safety outcomes from the included studies were presented in the overview and considered by the committee. These included fluid overload.

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			Ref: UK Fluid Management guidelines:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5133285/	
27	Consultee 2 Company Hologic Ltd	**3.6**	Point 3.6: indications for use are not limited to 'uterine fibroids' and include retained products of conception as well as polyps, myomas (uterine fibroids – FIGO classification; types 0,1 and 2) and endometrial biopsy. Ref: MyoSure instructions for use: https://gynsurgicalsolutions.co.uk/wp-content/uploads/2020/12/MAN-04370-9940_007_02-MyoSure-REACH-EN-DA-NLFI-FR-DE-IT-NO-PT-ES-SV.pdf	Thank you for your comment. Section 3.7 has been changed to: 'The committee was informed that the procedure can be used for other indications, but this guidance is only for treatment of uterine fibroids'
28	Consultee 2 Company Hologic Ltd	**3.6**	3.6 - The committee was informed that the procedure can be used for other indications including polyps, and for endometrial biopsy Indications for use are not limited to 'uterine fibroids' and include retained products of conception as well as polyps, myomas (uterine fibroids – FIGO classification; types 0,1 and 2) and endometrial biopsy. Ref: MyoSure instructions for use: https://gynsurgicalsolutions.co.uk/wp-content/uploads/2020/12/MAN-04370-9940_007_02-MyoSure-REACH-EN-DA-NLFI-FR-DE-IT-NO-PT-ES-SV.pdf	Thank you for your comment. Section 3.7 has been changed to: 'The committee was informed that the procedure can be used for other indications, but this guidance is only for treatment of uterine fibroids.'

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29	Consultee 3 Manager on behalf of BSGE	**3.6**	The document focusses on hysteroscopic morcellation of fibroids. Is there going to be another document on the more commonly encountered intrauterine structural pathology treated with hysteroscopic morcellators – endometrial polyps? The evidence is compelling for their feasibility, safety and efficacy over traditional electrical resection (Smith PP, Kolhe S, O'Connor S, Clark TJ. Vaginoscopy Against Standard Treatment: a randomised controlled trial. BJOG. 2019;126:891-899. doi: 10.1111/1471-0528.15665) and their utility for diagnosing endometrial cancer missed by conventional diagnostic work up based upon scan and blind endometrial biopsy (van Hanegem N, Breijer MC, Slockers SA, et al. Diagnostic workup for postmenopausal bleeding: a randomised controlled trial. BJOG. 2017; 124:231-240. doi: 10.1111/1471-0528.14126. Clark TJ.Hysteroscopy is needed in the diagnostic workup of postmenopausal bleeding. BJOG. 2017;124:241. doi: 10.1111/1471-0528.14128)	Thank you for your comment. NICE will assess any procedure notified and falling within the remit of the interventional procedures programme, as described in the interventional procedures programme manual. Ref 1 (Smith et al), 2 (van Hanegem et al) do not specifically examine the procedure of interest and therefore do not meet the inclusion criteria for the overview. Ref 3 (Clark TJ) is a commentary and therefore does not meet the inclusion criteria for the overview.
30	Consultee 3 Manager on behalf of BSGE	**3.6**	The use of hysteroscopic morcellators is now embedded in contemporary gynaecological practice. These technologies are most frequently used to remove endometrial polyps but are also well used to take directed biopsies and remove submucosal fibroids. There is also increasing interest in using hysteroscopic morcellators to remove retained products of conception following delivery or pregnancy loss.	Thank you for your comment. Section 3.7 has been changed to: 'The committee was informed that the procedure can be used for other indications, but this guidance is only for treatment of uterine fibroids.'
31	Consultee 2 Company Hologic Ltd	**3.8**	3.8 - The committee was informed that fluid management systems are used with some devices to	Thank you for your comment.

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			reduce the risk of causing excessively high uterine pressures and subsequent fluid overload Use of automated fluid management systems is recommended to monitor fluid absorption and improve procedure outcomes such as optimise visualisation through maintaining fluid pressure and shorter procedure time. Recent systems introduced to the market in 2021 (Fluent Fluid Management by Hologic) use less fluid to reduce these risks further and limit intra-uterine pressure to further lessen fluid absorption and potential dissemination of fluid into the peritoneal cavity. Ref: UK Fluid Management guidelines:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5133285/	The consultee refers to a guideline which is available as a peer-reviewed publication at the following link **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5133285/** A hyperlink has been added to section 3.8 of the draft guidance.
32	Consultee 2 Company Hologic Ltd	**3.9**	3.9 'It is possible to take a biopsy of the fibroid before or during the procedure' Hysteroscopy tissue removal systems enable targeted biopsies under visualisation which is recommended by NICE within the HMB guidelines. NICE Ng88 Heavy menstrual bleeding guidelines include recommendations to include surgical treatment for submucosal fibroids - point 1.3.11 'Obtain an endometrial sample only in the context of	Thank you for your comment. Ref 1 NICE guideline NG88 'Heavy menstrual bleeding: assessment and management' (**https://www.nice.org.uk/guidance/ng88**) refers to hysteroscopic removal of submucosal fibroids but does not specifically recommend hysteroscopic morcellation. Ref 2 (Loffer FD. The Time Has Come to Quit Relying on a Blind Endometrial Biopsy or Dilation and Curettage to Rule Out Malignant Endometrial Changes. J Minim Invasive Gynecol. 2019 Nov-Dec;26(7):1207-1208. doi:

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			diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB' https://www.nice.org.uk/guidance/ng88/resources/heavy-menstrual-bleeding-assessment-and-management-pdf-1837701412549 Additional supporting evidence: JMIG, April 2019. The time has come to quit relying on a blind endometrial biopsy or dilation and curettage to rule out malignant endometrial changes: https://www.jmig.org/article/S1553-4650(19)30189-X/fulltext	10.1016/j.jmig.2019.04.011) is an editorial and therefore does not meet the inclusion criteria for the overview.
33	Consultee 3 Manager on behalf of BSGE	**3.9**	"3.9 It is possible to take a biopsy of the fibroid before or during the procedure." The idea of hysteroscopic myomectomy whether using electrical resection or hysteroscopic morcellators is to remove the pathology in its entirety i.e. an excision biopsy. Operators should be reminded / mandated to send off all the removed specimen for histological assessment. The role of a (possibly unrepresentative) directed biopsy should be restricted to a suspicious looking submucosal fibroid e.g. with necrotic components. This is often done in the outpatient setting as part of diagnostic work up but if encountered in the operating room under general / regional anaesthesia then the decision whether to proceed to excising the entire lesion or restricting to a directed biopsy / biopsies should be left to the operator. However, encountering suspicious looking submucosal fibroids in women undergoing hysteroscopic myomectomy is rare; this	Thank you for your comment.

No.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			is because the current indications for hysteroscopic myomectomy are restricted to women of reproductive age due to reproductive problems (infertility and recurrent pregnancy loss) or heavy menstrual bleeding. Removing these fibroids in post-menopausal women is rarely indicated, and is usually only considered in the case of recurrent post-menopausal bleeding without any other clear explanation.	
34	Consultee 1 Company Medtronic	**Patient organisation submission**	The spread of malignant tissue as a potential theoretical risk has also been called to attention in the patient organisation submission. We are extremely sympathetic to the events recorded by Sarcoma UK, which have also been submitted for the NICE IPG on laparoscopic morcellation (gid-ipg10185): https://www.nice.org.uk/guidance/indevelopment/gid-ipg10185/consultation/html-content. However, the submission from Sarcoma UK describes a case of malignant spread associated with a hysterectomy procedure involving laparoscopic morcellation. As this example relates to hysterectomy where the morcellation takes place within the peritoneal cavity rather than hysteroscopic morcellation taking place within the uterus, we do not consider this to be an appropriate case to reference in the context of this consultation. We suggest that the case description should be removed as it misleadingly conflates the risk associated with the two very different procedures. To this point, we believe that the review of both hysteroscopic morcellation and laparoscopic morcellation procedures within the same NICE IPG Committee meeting section and across the same consultation period, has impacted upon the	Thank you for your comment. The committee has considered this comment but does not make changes to submissions from patient commentators. Please also note the changes made to section 3.6 in response to consultation comments received.

No.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			consideration of hysteroscopic morcellation as a safe and effective procedure.	
35	Consultee 1 Company Medtronic	**Patient organisation submission**	Regarding Patient Organisation Submission (pages 2-3). We are extremely sympathetic to the events recorded by Sarcoma UK, which have also been submitted for the NICE IPG on laparoscopic morcellation (gid-ipg10185): https://www.nice.org.uk/guidance/indevelopment/gid-ipg10185/consultation/html-content. However, the submission from Sarcoma UK describes a case of malignant spread associated with a hysterectomy procedure involving laparoscopic morcellation. As this example relates to hysterectomy where the morcellation takes place within the peritoneal cavity rather than hysteroscopic morcellation taking place within the uterus, we do not consider this to be an appropriate case to reference in the context of this consultation. We suggest that the case description should be removed as it misleadingly conflates the risk associated with the two very different procedures. To this point, we believe that the review of both hysteroscopic morcellation and laparoscopic morcellation procedures within the same NICE IPG Committee meeting section, and across the same consultation period, has impacted upon the consideration of hysteroscopic morcellation as a safe and effective procedure .	Thank you for your comment. The committee has considered this comment but does not make changes to submissions from patient commentators. Please also note the changes made to sections 3.6 in response to consultation comments received.
36	Consultee 1 Company Medtronic	**Patient organisation submission**	Regarding Patient Organisation Submission (p.3). The Patient Organisation Submission states that sometimes the uterine tissue or fibroid can unexpectedly contain a uterine cancer. If undetected, the morcellation process could cause the cancer to spread and worsen the chances of survival. However, it should also be noted that in hysteroscopic	Thank you for your comment. Section 2.5 of the draft guidance states: 'A morcellator is passed through the hysteroscope and used to cut and simultaneously aspirate the morcellated fibroid tissue. The aspirated tissue can be collected for histological analysis.'

No.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			morcellation the resected tissue is continually removed from the uterine cavity via vacuum pressure and is transported via the tissue removal device and handpiece through tube sets to a collection canister. The tissue is therefore available for histological examination thus enabling an opportunity for diagnosis that may not be applicable to other therapies such as Uterine Artery Embolization (UAE).	
37	Consultee 1 Company Medtronic	**Overview**	Overview document: General Efficacy section. Various UK case studies/retrospective audits have been conducted since the last review, listed below. Although observational only, these data provide UK real world data and a potential source for considering additional safety data. Krishnamurthy R. et al., 2015. Outcome of outpatient use of myosure technique - an audit. Gynecol Surg. 12(1): S133-S133 Veal L, Pathak M, Arya P. The feasibility of outpatient MyoSure for removal of endometrial plyps and submucous fibroids. BJOG An Int J Obstet Gynaecol. 2018;125:27. (Abstract presentations RCOG congress 2018) Pappala S, Das S, Baghat N. Evaluation of efficacy and safety of outpatient hysteroscopic morcellation of large uterine fibroid and endometrial polyps. Is high complexity hysteroscopy myomectomy achievable as an outpatient procedure? BJOG An Int J Obstet Gynaecol. 2019;126:105 (congress abstract)	Thank you for your comment. Ref 1 (Krishnamurthy et al), 2 (Veal et al) and 3 (Pappala et al) are conference abstracts addressing outpatient delivery of the procedure. 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.

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38	Consultee 1 Company Medtronic	**Overview**	Overview document: Quality of Life section. Additional QOL data are also available from a recent RCT (Tam et al, 2018) with n=69, where the authors reported an overall increase in QOL following both hysteroscopic morcellation and medical intervention for uterine fibroids. Although the comparative increases were not statistically different, there was a trend towards a greater increase in QOL following hysteroscopic morcellation compared with medical intervention. Tam, M. et al. 2018. Randomized Prospective Study of the Effectiveness of the TruClearTM Device for Hysteroscopic Myomectomy on Patient's Quality of Life. Journal of Minimally Invasive Gynecology, Volume 25, Issue 7, S44	Thank you for your comment. Ref 1 (Tam et al) is a conference abstract. 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.
39	Consultee 1 Company Medtronic	**Overview**	Overview document: Device Failure section. This section states that device failure was reported in 25 patients in the MAUDE database (Haber et al., 2015), however it does not state what the denominator or percentage was to put this into context. Further, no timeframe is given for this reporting period. We are aware that these data are reported later in the overview document, however we urge that this information is provided in the 'Device Failure' summary section as it is critical in order to make sense of the data provided. Medtronic collect ongoing post-market vigilance data that demonstrate an acceptable safety profile for the TruClear technology. We have provided the most recent post-market vigilance data on TruClear™ Dense Tissue Shavers to NICE (provided separately as commercial in confidence).	Thank you for your comment. The device failure paragraph in the safety summary of the overview has been changed to reflect that the review of the MAUDE database estimated that approximately 180,000 hysteroscopic morcellation procedures had taken place during the study period.

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40	Consultee 1 Company Medtronic	**Overview**	Overview document: Issues for Consideration by IPAC. Issues for Consideration by IPAC. The FDA Safety communication (2014) on laparoscopic power morcellation is included as an 'Issue for consideration', however, no distinction between laparoscopic morcellation and hysteroscopic morcellation procedures has been made in this section. As these are two separate procedures, with different principles and modes of operation, we strongly urge that this distinction is made within the text for accuracy and clarity to the reader . Specifically, we recommend that the reference to hysteroscopic morcellation within the 2014 FDA report is included for full transparency i.e the FDA report states that their guidance "…does not apply to hysteroscopic morcellators, which have a different principle of operation....when used in accordance with current indications and instructions for use, hysteroscopic morcellators do not pose the same risk as the devices addressed in this guidance because any sarcomatous tissue present does not enter the peritoneal cavity." U.S FDA Guidance 2014. "Immediately in Effect Guidance Document : Product Labeling for Laparoscopic Power Morcellators." https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf. Further, a statement should be included in this section to acknowledge that the two procedures each have a different evidence base and are being considered separately within the IPG process .	Thank you for your comment. The reference to the 2014 FDA statement has been removed from the overview because it is no longer referred to in the draft guidance. Section 3.5 of the guidance states that this is a different procedure to laparoscopic morcellation, for which there is separate guidance.

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41	Consultee 1 Company Medtronic	**Overview**	The concern of theoretical risk of malignant spread is historical, as a consequence of the FDA's inquiry and actions on laparoscopic power morcellators in 2014 based on case reports and studies on peritoneal dissemination of occult leiomyosarcoma following laparoscopic morcellation procedures. The same risk has not been observed for hysteroscopic morcellation, and this is evident in the FDA report which states that the guidance "…does not apply to hysteroscopic morcellators, which have a different principle of operation....when used in accordance with current indications and instructions for use, hysteroscopic morcellators do not pose the same risk as the devices addressed in this guidance because any sarcomatous tissue present does not enter the peritoneal cavity." U.S FDA Guidance 2014. "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators." https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf The theoretical risk of malignant spread would not be limited to hysteroscopic morcellation but could be considered in respect of any intrauterine procedure to resect intrauterine fibroids, for example resectoscopy where the fibroid is removed using cold loop, scalpel, or radiofrequency energy. 7,055 hysteroscopic myomectomies are conducted in England per annum across these techniques and no instances of subsequent malignant spread have been reported in the literature. (7,055 procedures were identified in NHS Hospital Episode Statistics April 2019 – March	Thank you for your comment. The reference to the 2014 FDA statement has been removed from the overview because it is no longer referred to in the draft guidance. Section 3.5 of the guidance states that this is a different procedure to laparoscopic morcellation, for which there is separate guidance.

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			2021. OPCS Q171 Endoscopic resection of lesion of uterus, ICD10s D250 Submucous leiomyoma of uterus, D251, D259). Continued below.	

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