National Institute for Health and Care Excellence

IP398/2 – Single-incision short sling mesh insertion for stress urinary incontinence in women

Consultation Comments table

IPAC date: 7 July 2016

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

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Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
TITLE				
1	Consultee 2 Patient	**Title**	Title: 'Single-incision short sling (mesh) insertion for stress urinary incontinence in women': There can be no question about the addition of the word mesh in the title: Single-incision short mesh sling it is wholly necessary. The single- incision short mesh sling device is made from polypropylene mesh and women must know exactly what will be inserted in their body in order for consent to be informed and to protect surgeons from possible future litigation. We need transparency and uniformity throughout all UK Health Boards and Trusts.	Thank you for your comment. The committee considered your comment and decided to change the title to ‘’Single-incision short sling mesh insertion for stress urinary incontinence in women’’.
GENERAL COMMENT				
2	Consultee 1 Company June Medical	**General**	Previously distribution partner for former American Medical Systems (AMS)/Astora Health, who have seized operations and are no longer in this market. The product we used to sell is no longer being made. We currently are not under contract with any other sling manufacturers.	Thank you for your comment.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
3	Consultee 2 Patient	**General**	There is need to strengthen current mesh guidance regarding single-incision short mesh slings to take into account the conclusions of the Scottish Interim Report which identified safety concerns with transobturator procedures and recommended that they will no longer be routinely used in Scottish hospitals.	Thank you for your comment. The committee were aware of the Scottish report in their discussions and noted its findings. In its conclusions and recommendations, the Scottish Interim Report states about transobturator procedures: '' Conclusion 7 A review of the different sources of evidence available to and considered by the Independent Review (patient experience, clinical expert opinion, research evidence and epidemiological evidence from routine information) has led us to express concern in this Interim Report at the use of the transobturator rather than the retropubic approach for routine surgery for stress urinary incontinence using mesh. The clinical governance arrangements that we have recommended will allow an individual case to be considered in the context of a multi-disciplinary assessment, including patient views. We await the final publication of key research reports but wish to register these concerns and to recommend that the Expert Group in the following months before the publication of the final report explore further appropriate pathways to ensure the techniques chosen take the differential patient and clinical experience, as well as research evidence into account.''

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
				The committee considered your comment about transobturator procedures and decided to change the wording of Section 3.1 of the guidance to be clear about the anatomical placement of the sling in this procedure, as follows: *''These fixation systems do not enter the retropubic space (minimising the risk of major vessel or visceral injury) or the obturator fossa (potentially minimising the risk of groin pain) but they anchor in the obturator membrane or in the obturator muscles.''*

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
4	Consultee 24 Patient	**General**	Single-incision short mesh sling insertion for stress urinary incontinence in women Interventional procedure consultation Comments: The available evidence is insufficient and inadequate, cease Single-incision short mesh sling trials including all other polypropylene mesh procedures and commence long term follow up of existing patients by introducing an independent publicly accessible Mandatory national registry. The Scottish Parliament Petition PE1517 including associated relevant attached documents. The truth is we really know nothing about these devices. http://www.parliament.scot/GettingInvolved/Petitions/scottishmeshsurvivors	Thank you for your comment. NICE IPAC cannot mandate data submission to a registry. The committee had recommended registry data entry previously, and noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed. Report of serious adverse events to the Medicines and Healthcare Products Regulatory Agency (MHRA) from companies is compulsory.

SECTION 1				
5	Consultee 21 NHS Professional	**1**	I believe NICE should recommend that all single-incision short mesh slings be used only within research context, and not within any other special arrangement, for the following reasons: 1- The short term efficacy of the vast majority of short mesh slings is inferior to the standard. One short mesh slings (Johnson & Johnson TVT Secur®) was removed from the market in 2012 and another (AMS Miniarc®) will not be available from August 1st 2016 as the manufacturer stopped the production line. The long term efficacy for all short mesh slings is uncertain.	Thank you for your comment. The consultee disagrees with main recommendation. The committee has considered your comment but has decided not to change the main recommendations.

6	Consultee 21 NHS Professional	**1**	2- The safety is under question particularly with reports of serious complications including failure of the procedure, persisting pain and discomfort. In addition, the presence of two anchors could mean serious future problems if the short mesh sling requires removal. Currently, the incremental innovation of the recent two devices most commonly used in the UK (Bard Ajust® and Coloplast Altis®) relies on the robust anchoring mechanism to reduce the high failure rates. Therefore, these mesh slings are not tension-free and removal can be even more difficult than other transobturator slings. An adverse event that requires removal of the device, and the subsequent outcome, can be adequately captured only if the mesh sling procedure was performed within research context.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comment and has changed section 1.1 of the guidance to highlight the complexity of the device removal process as follows: '' *The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research*.'' The committee considered the option to recommend 'research only' but decided to retain the original recommendation of 'special arrangements'.

7	Consultee 21 NHS Professional	**1**	3- The special arrangements of clinical governance, consent and audit are variable among units. Unfortunately, the majority of surgeons (gynaecologists and urologists) appear not to regularly use the national registries (BSUG and BAUS) and not to regularly report adverse events to the MHRA. Only the research context provides the all-important governance structure necessary for careful postmarketing mesh device vigilance.	Thank you for your comment. The consultee disagrees with main recommendation. NICE IPAC does not mandate data submission to a registry. Report of serious adverse events to the Medicines and Healthcare Products Regulatory Agency (MHRA) from companies is compulsory. The committee has expressed its disappointment in regards to data collection for this procedure in section 6.3 of the guidance. Section 6.3 of the guidance states: ‘’ *The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed.”*

8	Consultee 2 Patient	**1.1**	1.1. Why are we even considering introducing a procedure that has so many potentially serious and life-limiting failings as listed: The evidence on the safety of single-incision short sling (mesh) insertion for stress urinary incontinence in women shows infrequent but serious complications including failure of the procedure, and persisting pain and discomfort. The evidence on efficacy in the long term is inadequate in quality and quantity. There must be long-term follow-up of existing studies as opposed to new trials.	Thank you for your comment. The consultee disagrees with main recommendation. This procedure is already done in the UK and this guidance is an update of an existing guidance. For the reasons reiterated by the consultee, the committee has decided to recommend that this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research. Section 1.5 of the guidance mentions the need for research with long-term follow-up as follows: ‘’ *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes*.’’

9	Consultee 3 Patient from organisation ‘Sling The Mesh’	**1.1**	Even animal trials cannot fix this a rabbit in a study cannot tell you if they are in pain from mesh. The truth is that all slings carry the risk of cause terrible problems, some immediately and some years down the line. It has nothing to do with pore size of the mesh, or how it is inserted. It is about plastic that leaches toxins inside a womans most delicate area. It is about inserting plastic through a clean contaminated field. It is about plastic causing allergic reaction or nerves growing into the plastic fibres and causing pain. It is about the plastic changing once implanted. Mesh is not inert. It can shrink and degrade inside the body. It should not be used if it causes serious complications.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.

10	Consultee 3 Patient from organisation ‘Sling The Mesh’	**1.1**	The report says that evidence on the safety of these slings shows infrequent but serious complications including failure of the procedure and persisting pain and discomfort. Serious complications are not acceptable for even one patient. This is not a long term study either and some women do not start suffering pain with mesh slings until years down the line. Therefore for this report to say infrequent• complications is not a true reflection of the scale of the problem. The NICE report quite rightly states that evidence in the long term is inadequate in quality and quantity. Therefore this procedure should not be trialled on women as the human guinea pigs. It is unfair to test something on them when there are already concerns expressed. Single Incision Short Mesh Slings (SISMS) should be stopped in the light of these serious complications.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.

11	Consultee 4 Public	**1.1**	If these sli gs cause serious complications and there ate no long time quality studies, then it should be STOPPED.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.
12	Consultee 10 Public	**1.1**	If these single incision short term mesh slings cause serious complications and these are on long term good quality studies then this procedure MUST stop. Other countries have already either banned or suspended, so England must look into the damage they are causing.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.
13	Consultee 12 Patient	**1.1**	If these slings causes serious complications and there are no long term good quality studies then it should be stopped. Please take a look at other countries who have banned the use of them and the increasing number of lawsuits being bought by women who have been injured by this procedure.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.

14	Consultee 14 Patient	**1.1**	If the complications are significant then why are long term studies not compulsary? Given the current mesh related claims arising all over the world...no mesh product should be approved that has potential to cause significant harm without long term studies.	Thank you for your comment. The consultee disagrees with main recommendation. Section 1.5 of the guidance states: ‘’ *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.’’*
15	Consultee 18 Patient	**1.1**	If these slings causes serious complications and there are no long term good quality studies then their use should be suspended. There are too many mesh injured women who's lives will never be the same again due to the use of vaginal slings used for SUI. It is appalling that they are still being implanted into women when the are very few competent surgeons in the UK who can remove them when there are catastrophic complications.	Thank you for your comment. The consultee disagrees with main recommendation. Section 1.4 of the guidance has been added to highlight the importance of clinician training for this procedure and for the removal of the implant, if needed: ‘’ *This procedure should only be done by clinicians with specific training in transobturator surgical techniques. If removal is attempted this should only be done by people with expertise in this specialised surgery.*’’

16	Consultee 19 Patient	**1.1**	If these slings causes serious complications and there are no long term good quality studies then it should be stopped. The fact there are trials,with so few patient in Scotland accepting to be part of such barbaric trials.The trials are now being done to unsuspecting woman ,in rest of uk,who have be ill informed,misled and have not been aware of the media attention.now face a lifetime of pain suffering,is shocking. With such things are adverse reactions ,alergic reactions to the sling, leading to inflammation urine infections ,chronic pain, multiple hospital visits or admissions.. To me the BENIFITS,MOST CERTAINLY DO NOT OUTWAY THE RISKS.....IN FACT FAR FROM IT. To enter into a surgical procedure that not one governing body can show conclusive benifits,is alarming.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.

17	Consultee 20 Patient	**1.1**	If these slings causes serious complecations and there are no long term good quality studies then it should be stopped! I'm one of those unfortunate women that is suffering and has been mamed for life.	Thank you for your comment. The consultee disagrees with main recommendation. Section 1.1 of the guidance has been changed to: ‘’ *The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.*’’

18	Consultee 21 NHS Professional	**1.1**	Therefore, to protect the patients and the public, particularly in the current situation where transvaginal mesh procedures are in the spotlight of the legal system, the media and policy-makers, short mesh slings must not be recommended for use outside the research context. Patient selection for participation in research should still be done, as already recommended, by the multidisciplinary team.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations. Sections 1.3 and 1.4 state: *‘’1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence* *1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. If removal is attempted this should only be done by people with expertise in this specialised surgery.’’*

19	Consultee 24 Patient	**1.1**	1. Draft recommendations 1.1. Single-incision short mesh sling: serious complications, including possible failure of the procedure. Reporting device complications to MHRA http://bsug.org.uk/MHRA.php Due to the recognised severe under reporting of adverse events, MHRA does not receive the information they require to make an accurate risk benefit analysis.	Thank you for your comment. Report of serious adverse events to the Medicines and Healthcare Products Regulatory Agency (MHRA) is compulsory for companies. The committee discussed the reporting of adverse events to the MHRA.
20	Consultee 25 Public	**1.1**	Draft recommendations 1.1 A National Register should have been put in place before any procedures were carried out to collect accurate data.	Thank you for your comment. NICE IPAC does not mandate data submission to a registry. The committee discussed recommending registry submission to a specific registry (as previously) but their disappointment at previous registry data collection (recorded in 6.3) led to a committee decision that they were unable to recommend a specific registry. The committee did recommend further research (which could include observational data) and audit. Section 6.3 of the guidance states: ‘’*The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed*.’’

21	Consultee 2 Patient	**1.2**	1.2. Why expose women to potentially serious and unnecessary risks (as highlighted above) when surgery for SUI is elective? There are other options available, both non-surgical and surgical, with evidence to support better long-term outcomes of the latter.	Thank you for your comment. The Interventional Procedures programme at NICE assesses the safety and efficacy of interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition. Section 2.2 of the guidance has been amended to emphasize that this procedure should be considered after other options have been tried first. It now reads: ‘’ *Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. Surgery is considered if these conservative measures do not help. Different types of surgery may be used, including intramural bulking procedures, insertion of a synthetic tension-free vaginal tape, insertion of a transobturator tape or other sling procedures, colposuspension or insertion of an artificial urinary sphincter*.’’

22	Consultee 2 Patient	**1.2**	1.2. Is it a mandatory requirement to enter details of all women having single-incision short mesh sling insertion for stress urinary incontinence into a national register (at the British Society of Urogynaecology or the Female and Reconstructive Urology Section of the British Association of Urological Surgeons). Is the data auditable and available for public scrutiny?	Thank you for your comment. NICE can only recommend that clinicians wishing to do single-incision short sling insertion for stress urinary incontinence in women should enter details of all women having single-incision short sling insertion for stress urinary incontinence into a national register. It cannot mandate this requirement. Most registers data submission is voluntary and down to individual clinicians and within the NHS other regulators have the responsibility for ensuring guidance has been followed when and where it has been appropriate to do so. NICE has contacted the register owners of the 2 national registers recommended for data collection in the existing guidance but has not received an analysis of any of the data that these registers have collected. The publication of the data is a matter for the registries concerned. The committee made a comment in section 6.3 of the guidance: '' *The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed.*'' Section 1.2 of the guidance has been changed as follows to recommend audit and review of clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence:

				‘’ *Clinicians wishing to do single-incision short sling mesh insertion for stress urinary incontinence in women should:* • *Inform the clinical governance leads in their NHS trusts.* • *Ensure that patients understand the uncertainty about the procedure’s safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, that the mesh implant is intended to be permanent and should removal be required this may be difficult or impossible, and provide them with clear written information. In addition, the use of NICE’s information for the public is recommended.* • *Audit and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.2).*’’ The committee also recommended further research (which could include observational data) in Section 1.5 of the guidance.

23	Consultee 3 Patient from organisation ‘Sling The Mesh’	**1.2**	1.2 Clinicians should ensure that patients understand the uncertainty about safety and efficacy including the potential for serious long term complications. On the face of it this seems like a good fix to ensure women know what they are letting themselves in for BUT the trouble with this recommendation is how do you police/oversee this? What one surgeon says to their patient may be very different to another. I certainly did not know of any serious risks with my TVT mesh sling for example before merrily skipping into the operating theatre. The new consent form for mesh is not mandatory to use in the UK. How are you going to make sure women REALLY know what they are letting themselves in for with SISS?	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. NICE issues guidance on Interventional procedures. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement, including the recommendations regarding consent. This guidance does not override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. Implementation of this guidance is the responsibility of local commissioners and/or providers.
24	Consultee 24 Patient	**1.2**	1.2. There are no exceptional circumstances that would merit risking a Single-incision short mesh sling procedure in even one patient as the possible severe complications are unacceptable. Current fragmented registries such as BSUG are insufficient and inadequate and only 30% of members currently use BSUG. To quote [redacted] Many different databases do exist, BSUG not exactly a registry• . Fragmented insufficient data collection is a real problem.	Thank you for your comment and for highlighting the fact that data submission to registries for this procedure is not satisfactory. Section 6.3 of the draft guidance states: ‘’ *The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed.”*

25	Consultee 25 Public	**1.2**	1.2 There is no existing National Register for monitoring any mesh devices. The BSUG data base is not mandatory for surgeons to comply with and therefore is not accurate. Furthermore this data base is funded by Boston Scientific, Bard and Ethicon and this represents a conflict of interest and is an unethical practice.	Thank you for your comment. NICE IPAC does not mandate data submission to a registry. Most registers data submission is down to individual clinicians and within the NHS, other regulators have the responsibility for ensuring guidance has been followed when and where it has been appropriate to do so. NICE has contacted the register owners of the 2 national registers recommended for data collection in the existing guidance but has not received an analysis of any of the data that these registers have collected. The publication of the data is a matter for the registries concerned. The committee made a comment in section 6.3 of the guidance: '' *The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed*.''
26	Consultee 2 Patient	**1.3**	1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence. Will this MDT be able to remove the single-incision short mesh sling in its entirety should complications occur?	Thank you for your comment. The committee considered your comment and section 1.4 has been added to the guidance to emphasize the complexity of the implant removal, should this be needed: '' *This procedure should only be done by clinicians with specific training in transobturator surgical techniques. If removal is attempted this should only be done by people with expertise in this specialised surgery.*''

27	Consultee 3 Patient from organisation 'Sling The Mesh'	**1.3**	1.3 MDT would still not fix the above	Thank you for your comment.
28	Consultee 24 Patient	**1.3**	1.3 Future patient selection should be done by a multidisciplinary team with experience/specific implant device knowledge in Single-incision short mesh slings in the assessment and management of women with stress urinary incontinence.	Thank you for your comment. Section 1.3 of the guidance states: '' *Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence*.'' The committee considered your comment and section 1.4 has been added to the guidance: '' *This procedure should only be done by clinicians with specific training in transobturator surgical techniques. If removal is attempted this should only be done by people with expertise in this specialised surgery.*''
29	Consultee 25 Public	**1.3**	1.3 Patient selection in the UK is a myth. When I asked [redacted] if he would insert a mesh medical device into a patient if they had any of the following conditions Diabetes, obesity or a heavy smoker he replied "yes probably" This begs the question what conditions would the patient have to have which would preclude them from this procedure?	Thank you for your comment. Section 1.3 of the guidance sates: '' *Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence*.''

30	Consultee 2 Patient	**1.4**	1.4 What long-term data is already available and does this include comprehensive patient QoL and the effect on active daily living? Until there is long-term follow-up of existing studies, which would be far more beneficial to the health, well-being and safety of women, there is absolutely no need for any further mesh trials. Existing data must be studied and evaluated by an independent source, this is the only way we can expand our knowledge and understanding of single-incision short mesh slings.	Thank you for your comment. The committee agreed that long term studies which measure quality of life and other patient reported outcomes are needed. Section 1.5 of the guidance has been changed as follows to include effects on quality of life and other patient-reported outcomes: '' *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes*.''

31	Consultee 3 Patient from organisation ‘Sling The Mesh’	**1.4**	QUESTIONNAIRE USED IN SCOTLAND I have seen the questionnaire given to women in Scotland who have had a SISS and it does not properly investigate the quality of life for women after having this procedure. The questionnaire focuses on if you are continent, how many pads do you need now compared to before, how does your continence/incontinence affect eg daily tasks. It very cleverly words questions in a confusing manner so that women have no real opportunity to write on the questionnaire if they are suffering eg leg pain, infections, unexplained pelvic pain, constant burning vaginal pain, difficulty walking, struggles to void, fibromyalgia, stomach inflammation, pain having sex. The study is not a proper quality of life study and for mesh injured women this is the issue. The issue is NOT about the procedure failing to cure incontinence; the procedure is about an operation that carries high risks which can greatly reduce a womans quality of life.	Thank you for your comment. Section 1.5 of the guidance has been changed as follows to include effects on quality of life and other patient-reported outcomes: ‘’ *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.*’’

32	Consultee 3 Patient from organisation ‘Sling The Mesh’	**1.4**	1.4 I attach 10 links of studies that will be useful in outlining that mesh is not inert and how nerve endings can grow into the plastic fibres causing lifelong, debilitating pain	Thank you for your comment and for sending us papers about mesh complications.

			http://www.europeanurology.com/article/S0302-2838(11)00492-1/fulltext/single-incision-mini-slings-versus-standard-midurethral-slings-in-surgical-management-of-female-stress-urinary-incontinence-a-meta-analysis-of-effectiveness-and-complications-img-src-manager-uploads-europeanurology-com-eur-articles-s0302- Linder B J, Trabuco E C, Carranza D A et al. (2016). Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. Int Urogynecol J. DOI: 10.1007/s00192-016-2961-4. Abbott S, Unger CA, Evans JM, et al. (2014) Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. Am J Obstet Gynecol;210:163.e1-8. Bendavid R, Lou W, Kocj A et al. (2014) Mesh-Related SIN Syndrome. A surreptitious irreversible neuralgia and its morphologic background in the etiology of post-herniorrhaphy pain. International Journal of Clinical Medicine, 799-810.	The Abdel-Fattah (2011) study is already included in Appendix A. The Linder (2016) paper is a retrospective case analysis which assessed the incidence of pelvic malignancy in 2474 women who underwent polypropylene midurethral sling placement for stress urinary incontinence over a median follow-up of 5 years. This paper has been included in Appendix A. The Abbott (2014) paper is a retrospective analysis of 347 women who attended 4 US centres for evaluation of mesh-related complications after surgery for SUI and/or POP between 2006 and 2010, with a median follow-up of 5.8 months. There is no specific data about the safety and efficacy of single-incision short sling (mesh) for stress urinary incontinence. This paper has been included in Appendix A. The Bendavid (2014) study is not a human study. Therefore it won't be included in the overview.

			Iakovlev VV, Guelcher SA, Bendavid R. (2015). Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. J Biomed Mater Res Part B 2015:00B:000–000. SIMS patient questionnaire. Lakovlev V, Mekel G and Blaivas. Pathological findings of transvaginal polypropylene slings explanted for late complications: Mesh is not inert. Poster. Blaivas J G, Purohit RS, Benedon MS et al. (2015) Safety considerations for synthetic sling surgery. Nature reviews urology. doi:10.1038/nrurol.2015.183 Coda A, Bendavid R, Botto-Micca et al. (2003) Structural alterations of prosthetic meshes in humans. Hernia 7:29-34. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0149971	The Lakovlev (2015) paper is not a human study. Therefore it won't be included in the overview. The SIMS trial is listed in the ongoing studies in the ''Issue for consideration by IPAC'' section in the overview. Thank you for submitting the patient questionnaire for this study. The Lakovlev poster does not report the results of a human study. Therefore, it won't be included in the overview. The Blaivas (2015) paper is a systematic review about the efficacy, effectiveness and complications of synthetic midurethral slings. It has been included in Appendix A. The Coda (2003) paper is not a human study. Therefore it won't be included in the overview. The Hillary (2016) paper is not a human study. Therefore it won't be included in the overview.

33	Consultee 24 Patient	**1.4**	1.4 Until studies can include details of patient selection and long-term outcomes on existing patients, NICE must seriously consider an immediate suspension of single incision short mesh sling procedures and similar polypropylene mesh medical implant devices. The single incision short mesh implant device should not be available in any capacity.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.

SECTION 2				
34	Consultee 2 Patient	**2**	2. Has the Scottish Interim Report and comprehensive ISD data seriously been taken into account here?	Thank you for your comment. The committee were aware of the Scottish interim report in their discussion. In the Scottish Interim Report, transobturator tapes are considered as a whole category and there is no specific data about Single-incision short sling mesh insertion. To clarify that the committee were aware of this report and other work, the following committee comment has been made in section 6.6 of the guidance: '' *The committee noted the work of the NHS England Mesh Working Group and the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women.*''

35	Consultee 21 NHS Professional	**2**	4- I believe it is important that NICE mentions in the document that the short mesh sling is a type of and builds on the technology of the transobturator sling. The incremental innovation includes more foreign material in the form of two anchors aiming to reduce the high failure rates. It is also important to note that the interpretation of the recent Cochrane Review on the subject (Ford et al 2015) by the Scottish Mesh Enquiry Panel has led to a recommendation to restrict the use of all transobturator tapes to circumstances where the retropubic approach is not suitable. There are concerns that the short mesh slings could be less efficacious and could lead to even more problems, particularly more difficult removals, due to anchorage, compared to transobturator tapes.	Thank you for your comment. In its conclusions and recommendations, the Scottish Interim Report states about transobturator procedures: '' Conclusion 7 A review of the different sources of evidence available to and considered by the Independent Review (patient experience, clinical expert opinion, research evidence and epidemiological evidence from routine information) has led us to express concern in this Interim Report at the use of the transobturator rather than the retropubic approach for routine surgery for stress urinary incontinence using mesh. The clinical governance arrangements that we have recommended will allow an individual case to be considered in the context of a multi-disciplinary assessment, including patient views. We await the final publication of key research reports but wish to register these concerns and to recommend that the Expert Group in the following months before the publication of the final report explore further appropriate pathways to ensure the techniques chosen take the differential patient and clinical experience, as well as research evidence into account.'' The sentence "*The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove*" has been added to section 1.1 of the guidance.

				Section 3.1 of the guidance has been changed as follows: *'' Single-incision short sling mesh insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. It is considered when conservative options (see Section 2.2) have been tried but incontinence persists. The procedure aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally invasive sling procedures. The single incision short slings have shorter tape lengths and different fixation systems to transobturator minimally-invasive slings. These fixation systems do not enter the retropubic space (minimising the risk of major vessel or visceral injury) or the obturator fossa (potentially minimising the risk of groin pain) but they anchor in the obturator membrane or in the obturator muscles.''*

36	Consultee 24 Patient	**2**	2. Indications and current treatments 2.2. All non-surgical interventions should be exhausted prior to any proposed non-mesh surgical procedure. If mesh implant surgery is still an option strict governance and monitoring is vital and Single incision short mesh slings and any considered mesh permanent implant procedure must be by a multidisciplinary team with experience/specific implant device knowledge in the assessment and management of women with stress urinary incontinence. A good source of Information: http://www.scottishmeshsurvivors.com/faq.html	Thank you for your comment. Sections 1.3 and 1.4 state: ‘’*1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence.* *1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. If removal is attempted this should only be done by people with expertise in this specialised surgery.*’’ Section 2.2 of the guidance has been edited to say: ‘’*Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. Surgery is considered if these conservative measures do not help. Different types of surgery may be used, including intramural bulking procedures, insertion of a synthetic tension-free vaginal tape, insertion of a transobturator tape or other sling procedures, colposuspension or insertion of an artificial urinary sphincter.*’’

37	Consultee 24 Patient	**2**	In regards to transobturator mesh permanent implant devices such as Single-incision short mesh sling please refer to conclusions of Scottish Government Interim Review on Transvaginal Mesh Medical Implants: http://www.gov.scot/Publications/2015/10/8485/0 Final review report is due in Summer of 2016.	Thank you for your comment. This review is listed in the overview in the ‘’ Existing assessments of this procedure’’ section. Please refer to comment 34.

38	Consultee 25 Public	**2.2**	Indications and current treatment 2.2 Why offer a transobturator mesh tape when they are notoriously impossible to remove when complications arise. Not one surgeon in the UK can remove obturator mesh tapes in their entirety. [redacted] [redacted] recently stated “" I am able to and have taken out TVT in their entirety but have not removed a TVTO type tape in its entirety as this would be extremely destructive.	Thank you for your comment. The committee considered your comment and has changed section 1.1 of the guidance to highlight the complexity of the device removal process as follows: ‘’ *The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research*.’’ The committee has also added a comment in section 6.2 of the guidance: ‘’ *The committee was advised that the mesh slings are intended to be permanent implants and that the presence of anchors make removal of an implant particularly difficult, should this be required.*’’

SECTION 3				
39	Consultee 2 Patient	**3**	3. Please confirm if the single incision short mesh sling is a transobturator procedure or a retropubic procedure?	Thank you for your comment. Single-incision short mesh slings are a subset of transobturator slings delivered via a single vaginal incision through the obturator muscles. Section 3.1 of the guidance has been changed to emphasize this as follows: '' *Single-incision short sling mesh insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. It is considered when conservative options (see Section 2.2) have been tried but incontinence persists. The procedure aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally invasive sling procedures. The single incision short slings have shorter tape lengths and different fixation systems to transobturator minimally-invasive slings. These fixation systems do not enter the retropubic space (minimising the risk of major vessel or visceral injury) or the obturator fossa (potentially minimising the risk of groin pain) but they anchor in the obturator membrane or in the obturator muscles*.''

40	Consultee 2 Patient	**3**	3. One device used in the SIMS trial (Bard Ajust) states: The Ajust® Sling is uniquely designed to offer all the benefits of a Trans-Obturator sling procedure through just one incision. It also instructs: Step#2 œanchor through the obturator internus muscle/membrane complex. Question: Can all permanent single-incision short mesh slings that are inserted through the obturator route be removed safely, completely, (including the barbed anchors) in the longer-term if complications occur and what evidence is available to substantiate this?	Thank you for your comment. The IP programme issues guidance on procedures rather than individual devices. Please refer to response to comment 38.

41	Consultee 21 NHS Professional	**3.1**	TYPO: The fixation systems do enter the obturator fossa to anchor the mesh sling into a strong fixed structure. The trocar-mounted anchors pierce the perineal membrane, the obturator internus muscle, the obturator membrane and usually the obturator externus muscle too. This happens on both sides and there is no inherent mechanism in the delivery system to stop the anchor at the level of the obturator internus muscle. Please consider re-reviewing the manufacturers IFU (instructions for use). If used according to instructions, the anchors should avoid passing through the lateral thigh muscles and could reduce the incidence of chronic pain, particularly on walking, although this remains uncertain.	Thank you for your comment. Section 3.1 of the guidance has been changed as follows: '' *Single-incision short sling mesh insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. It is considered when conservative options (see Section 2.2) have been tried but incontinence persists. The procedure aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally invasive sling procedures. The single incision short slings have shorter tape lengths and different fixation systems to transobturator minimally-invasive slings. These fixation systems do not enter the retropubic space (minimising the risk of major vessel or visceral injury) or the obturator fossa (potentially minimising the risk of groin pain) but they anchor in the obturator membrane or in the obturator muscles*.''

42	Consultee 24 Patient	**3.1**	3.1 Single-incision short mesh slings have exactly the same possible serious complications associated with similar polypropylene mesh medical device implants. The Single-incision short mesh slings have a different fixation system. These fixation systems also go through the obturator. The Single-incision short mesh sling has one anchor fixation that I believe it can be confirmed it is nigh impossible to remove when complications arise.	Thank you for your comment. Please refer to responses to comment 38 and 41.

43	Consultee 25 Public	**3.1**	The procedure 3.1 You state “The procedure also aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally-invasive slings” This remains to be seen as there have been no long term studies carried out for this procedure to confirm this.	Thank you for your comment. Sections 1.1 and 1.5 of the guidance mention the lack and the need for long-term outcomes reporting as follows: ‘’1.1 *The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.’’* ‘’*1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.’’* Section 3.1. is stating what the procedure aims to do.

44	Consultee 2 Patient	**3.2**	3.2 What percentage of patients have been able to (a) tolerate local anaesthesia and (b) unable to tolerate local anaesthesia?	Thank you for your comment. This section of the guidance is intended to be a brief summary of the way the procedure is typically done.
45	Consultee 2 Patient	**3.2**	3.2 Can the single-incision short mesh sling be removed in its entirety i.e. including the barbed anchors, if complications occur in the longer-term?	Thank you for your comment. Please refer to response to comment 38.
46	Consultee 3 Patient from organisation ‘Sling The Mesh’	**3.2**	3.2 The SISMS is inserted through the obturator foramen. This is an area rich in nerves and even a skilled surgeon can cause nerve damage going in via this route. IF there are problems it is impossible to remove as it carries the risk of permanently disabling the patient. Therefore this procedure should be stopped	Thank you for your comment. The consultee disagrees with main recommendation. Please refer to response to comment 38.

47	Consultee 24 Patient	**3.2**	" "3.2 Patients usually have the Single-incision short mesh sling procedure in a Day Surgery setting with some form of general anaesthesia. The Single-incision short mesh sling length is incorrect in this NICE draft document paragraph. The draft document text in the last paragraph also contradicts the information in this one by saying the device does go through the obturator where in the last paragraph it stated it did not. The Single-incision short mesh sling has one anchor fixation that I believe it can be confirmed it is nigh impossible to remove when complications arise.	Thank you for your comment. Section 3.2 of the guidance states: *'' With the patient under local (with or without sedation), regional or general anaesthesia, a small incision is made in the vaginal wall, under the urethra. The sling, which is typically 8–14 cm long, is inserted using a delivery needle through the obturator foramen and retracted to deploy the sling into the obturator internus muscle. This is repeated with a second sling on the contralateral side. A special tip anchors the sling in place behind the mid urethra. Sling tension is then controlled using the delivery device until the appropriate tension is achieved. The delivery device is then removed and the incision is closed. The slings are permanent implants. Cystoscopy is used to check that bladder perforation has not occurred during the procedure.''* The single-incision short sling mesh length indicated in the draft guidance is the same as the one indicated in the Cochrane review on Single-incision sling operations for urinary incontinence in Women from Nambiar (2014).

				Section 3.1 of the guidance has been reworded as follows to better describe the anchoring mechanism: '' *Single-incision short sling mesh insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. It is considered when conservative options (see Section 2.2) have been tried but incontinence persists. The procedure aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally invasive sling procedures. The single incision short slings have shorter tape lengths and different fixation systems to transobturator minimally-invasive slings. These fixation systems do not enter the retropubic space (minimising the risk of major vessel or visceral injury) or the obturator fossa (potentially minimising the risk of groin pain) but they anchor in the obturator membrane or in the obturator muscles.''* Please also refer to response to comment 38 in regards to the removal of the implant.
48	Consultee 25 Public	**3.2**	3.2 You state "The slings are permanent implants" There is no data on how easily they can be removed. The worst scenario being is they cannot be removed at all.	Thank you for your comment. Please refer to response to comment 38.

SECTION 4				
49	Consultee 25 Public	**4**	EFFICACY It is reported in 4.1 through to 4.14 how the single-incision short mesh sling performed compared to other devices. Again there are no long term studies for single-incision short mesh sling so a comparison at the stage would not be comprehensive or useful. There are very few long term studies in the devices you were comparing the single-incision short mesh sling with so in effect this was a wasted and inaccurate project.	Thank you for your comment. Section 1.1 of the guidance states: *'' The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.''* It was decided to update this guidance because of the general concern in the NHS and elsewhere about the use of mesh procedures in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) and because there was a significant number of new studies published since original guidance.
50	Consultee 9 Patient	**4 and 5**	I think it's shocking that these devices are being used when there's evidence of serious complications being reported. There's also no adequate evidence on the efficacy of these also.	Thank you for your comment.

51	Consultee 3 Patient from organisation ‘Sling The Mesh’	**4.1 to 4.14**	4.1 to 4.14 Efficacy all the statistics here talk about is incontinence after the procedure eg pad use. Do you leak, how is your incontinence in relation to sexual activities etc There are quality of life scores but it is measured with the Incontinence Impact Questionnaire so is still aimed at how is life now you dont wet yourself. It is not aimed at asking how is your quality of life overall eg if you have pain, infections, trouble voiding, leg pain, there is nowhere in the questionnaires to report it.	Thank you for your comment. The efficacy outcomes reported are those which are described in the available evidence. Section 1.5 of the guidance has been changed to include effects on quality of life and other patient-reported outcomes as follows: ‘’ *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.”*

52	Consultee 24 Patient	**4.1**	4. Efficacy 4.1. A multitude of studies and described as poor studies, the recognised under reporting and the recognised severe fragmented data available with the huge gaps that cant be filled will never change the efficacy of any procedure. The basics have not been put in place, more trials and putting patients at risk of severely debilitating daily quality of life challenges will not change the efficacy of this or similar mesh procedures. Introduce a precautionary principle and stop the line until the long term registry fills the evidence gaps.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered your comments but has decided not to change its main recommendations.
53	Consultee 2 Patient	**4.2**	4.2 Have single-incision short mesh slings proven to be more efficient than e.g. colposuspension?	Thank you for your comment. The IP programme does not assess the efficacy and safety of comparator interventions.
54	Consultee 24 Patient	**4.2**	4.2 Serious concerns over a Single-incision short mesh sling trial that is an obturator device polypropylene mesh implant, being randomised with another obturator mesh tape device procedure no longer recommended for use in Scotland by the Scottish Government. Then further randomised with a CR Bard obturator mesh tape device that has been withdrawn from the market in the U.S.A. but still being marketed in Europe.	Thank you for your comment. The efficacy outcomes reported are those which are described in the available evidence.

55	Consultee 3 Patient from organisation ‘Sling The Mesh’	**4.3**	4.3 TVTSecur has been withdrawn from use. Why? Does this in itself not raise serious concerns for mesh slings?	Thank you for your comment. The IP programme issues guidance on procedures rather than individual devices. Section 1.1 of the guidance states: ‘’ *The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.’’*

56	Consultee 24 Patient	**4.3**	4.3 Cochrane Evidence based medicine consists of Clinician-Research and Patient evidence, Cochrane is only Research evidence and a poor source of evidence at that from randomised trial studies. These are not the best studies for complication rates. Best is large analysis of a database and there is none. No analysis for quality of life in Cochrane. Longer term studies required.	Thank you for your comment. The efficacy outcomes reported are those which are described in the available evidence. Section 1.5 of the guidance says: '' *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.*''
57	Consultee 2 Patient	**4.14**	4.14 What about the effect on active daily living? There must be long-term follow-up of existing studies. Short-term studies are insufficient. As more information is coming to light regarding polypropylene mesh devices e.g. POP and transobturator approach, we cannot expose women to any further unnecessary risk, especially if a device is no more efficient than existing traditional surgery.	Thank you for your comment. Section 4.14 is the opinion of the Specialist Advisers and cannot be changed. Section 1.5 of the guidance has been changed to: '' *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes*.''

SECTION 5				
58	Consultee 24 Patient	**5**	5. Safety The available evidence is insufficient and inadequate, cease Single-incision short mesh sling trials including all other polypropylene mesh procedures and commence long term follow up of existing patients by introducing an independent publicly accessible Mandatory national registry. Current E.U. and U.K. Medical Device Regulations are not protecting patients from harm.	Thank you for your comment. The consultee disagrees with main recommendation. Please see response to Comment 4.

59	Consultee 25 Public	**5**	SAFETY The evidence reported in 5.1 through to 5.15 is short term evidence only and in the absence of any long term studies only gives the information available to date. Complications have anecdotally increased as time goes on with the other mesh devices for SUI. We have no reason to believe that this will not be the same for the single-incision short mesh sling. 5.16 The specialist advisors were asked about any anecdotal adverse events and theoretical adverse events they think may occur. They answered “that they may see reaction to mesh tape and poor anchoring of tape leading to failure in the short and long term. “ Their opinion on this is of no value whatsoever as it is conjecture and nobody knows what safety issues may arise in the future should these devices continue to be inserted into the human body.	Thank you for your comment. Section 5.15 is the opinion of the Specialist Advisers and cannot be changed. They provide advice about interventional procedures that complements findings from published research. This is very useful information particularly when evidence is inadequate in quantity and quality.

60	Consultee 3 Patient from organisation ‘Sling The Mesh’	**5.1 to 5.9**	5.1 Pain. Some pain does not cut in until eg 6, 12 months, 2,3, 5, 8 years down the line, so these stats mean nothing 5.3 As 5.1 5.4 As 5.1 5.5 as 5.1 5.7 as 5.1 5.8 As 5.1 5.9 As 5.1	Thank you for your comment. The data reported are those which are described in the available evidence.
61	Consultee 2 Patient	**5.8**	5.8 The lack of robust safety evidence, especially in the long-term for single-incision short mesh slings is seriously perturbing!	Thank you for your comment. The data reported are those which are described in the available evidence.
62	Consultee 3 Patient from organisation ‘Sling The Mesh’	**5.10**	5.10 As 5.1 Statistics for urinary tract infection in the first 30 days. Some women do not develop a UTI until later than this and then go on to suffer repeat chronic infections that do not respond well to anti-biotics.	Thank you for your comment. The data reported are those which are described in the available evidence.
63	Consultee 3 Patient from organisation ‘Sling The Mesh’	**5.12**	5.12 As 5.1 Also in the questionnaires dyspareunia is a word that is thrown in which the majority of women may will understand to report it	Thank you for your comment. The data reported are those which are described in the available evidence.

64	Consultee 3 Patient from organisation ‘Sling The Mesh’	**5.13 and 5.15**	5.13 as 5.1 5.15 as 5.1	Thank you for your comment. The data reported are those which are described in the available evidence.
65	Consultee 2 Patient	**5.15**	5.15 What evidence is available that the single incision short mesh sling and anchors can be safely and completely removed in the longer-term?	Thank you for your comment. Please refer to response to comment 38.
66	Consultee 2 Patient	**5.16**	5.16 Were ALL MHRA listed adverse events reported as such?	Thank you for your comment. The Medicines and Healthcare Products Regulatory Agency (MHRA) report published in 2014 was consulted. It is mentioned in the ‘’Existing assessments of this procedure’’ section of the overview. The safety outcomes reported in sections 5.1 to 5.14 are those which are described in the available evidence. Section 5.15 is the opinion of the Specialist Advisers and cannot be changed.

67	Consultee 2 Patient	**5.16**	5.16 Due to **the increasing pullout force of** the whole complex, it seems necessary to pl**ace the anchors through fascia,** mus**cle and membrane to achieve the** highest possible retention force. The above statement from a single-incision short mesh sling manufacturer™s brochure is alarming! If it is necessary to achieve the highest possible retention force in this delicate area, how can single-incision short mesh sling devices be safely and completely removed without causing untold damage? The risks and difficulties increase especially when it is fact that mesh complications can take many years to manifest.	Thank you for your comment. Please refer to response to comment 38.
SECTION 6				
68	Consultee 2 Patient	**6.1**	.1 Why is BARD Ajust deemed suitable for use in UK but no longer marketed in US due to manufacturer non-compliance of 522 post-market surveillance studies? Question: What plans does the UK have for more stringent post-market surveillance studies (in line with US 522)? And what would the consequences be for manufacturers for non-compliance of more stringent post-market studies?	Thank you for your comment. This falls outside the scope of the guidance. Post-market surveillance is handled by the Medicines and Healthcare Products Regulatory Agency (MHRA).

69	Consultee 24 Patient	**6.1**	6. Committee comments 6.1. The committee noted there are a number of different devices in use. The committee should investigate the background of all such devices	Thank you for your comment. The IP programme issues guidance on procedures rather than individual devices.
70	Consultee 2 Patient	**6.2**	6.2 Can it be removed completely yes or no? What is the patient satisfaction rate after complete single-incision short mesh tape removal, including the anchors in the (a) short-term (b)* long-term? *5 year minimum but longer is preferable.	Thank you for your comment. Please refer to response to comment 38. Section 1.5 of the guidance has also been changed to ask for research on quality of life and other patient reported measures in the long term as follows: '' *NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes*.''

71	Consultee 3 Patient from organisation ‘Sling The Mesh’	**6.2**	6.2 Committee comments. I agree that removal of the device may be complex and should only be done by people with expertise in this specialised surgery BUT THERE ARE ONLY 6 IN THE UK THAT WOMEN ARE CONFIDENT TO GO TO With a growing number of women realising mesh slings are causing their pain the waiting lists for removal of TVT and TVTO are growing longer. Waiting lists for removal now stand at around 9 months. The report has already expressed concern for serious complications for SISS and not enough long term studies therefore this procedure should be stopped and not used not even under trial/research purposes. It is not fair to trial this on women at the potential cost to their health and well being.	Thank you for your comment. Provision of service is outside the scope of the guidance. Section 1.1 of the guidance has been reworded and section 1.4 has been added as follows: ‘’ *1.1 The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include persisting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but if removal is required due, to complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.*’’ ‘’ *1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. If removal is attempted this should only be done by people with expertise in this specialised surgery.*’’

72	Consultee 24 Patient	**6.2**	6.2. The committee was informed that removal of the device may be complex, may require multiple procedures and should only be done by people with expertise in this specialised surgery. Not an acceptable risk for even one patient. A device complex to remove should never be implanted.	Thank you for your comment. Please see response to Comment 71.
73	Consultee 25 Public	**6.2**	COMMITTE COMMENTS 6.2 The removal of this device may not only be complex and damaging to the woman. It is a permanent device and may not be able to be removed in its entirety leaving women with lifelong disabling pain.	Thank you for your comment. Sections 1.1 and 6.2 have been reworded. Please refer to responses to comment 38.

74	Consultee 2 Patient	**6.3**	6.3 Why is deemed acceptable to make yet another mesh device available when most surgeons fail to log data in the BSUG or BAUS database, which can track progress and potentially red flag problems? Current regulations are shambolic and means we cant track progress of devices or contact women who have mesh devices should a recall be necessary due to safety issues.	Thank you for your comment. The committee has expressed its disappointment in regards to data collection for this procedure in section 6.3 of the guidance. Section 6.3 of the guidance states: ‘’*The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed.’’* Section 1.2 of the guidance has been changed as follows to recommend audit and review of clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence: *‘’ Clinicians wishing to do single-incision short sling mesh insertion for stress urinary incontinence in women should:* • *Inform the clinical governance leads in their NHS trusts.* • *Ensure that patients understand the uncertainty about the procedure’s safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, that the mesh implant is intended to be permanent and should removal be required this may be difficult or impossible, and provide them with clear written information. In addition, the use of NICE’s information for the public is recommended.*

				• *Audit [and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.2).''* The further research recommended in Section 1.5 of the guidance could include observational data collection.
75	Consultee 3 Patient from organisation 'Sling The Mesh'	**6.3**	6.3 Data collection had been disappointing• Well said. More reason to stop SISMS There are other procedures which are effective like Burch colposuspension and autologous slings. If these fail, as some SISS slings do, the operation does not also carry the high risks of pain and chronic infections that can ruin a womans quality of life. Please hear the voices of mesh injured women, the ones who got unlucky in the Russian Roulette mesh operation, who have suffered from surgery that was supposed to improve their quality of life but in reality has changed it for the worse. For some women - those in wheelchairs and walking with zimmer frames it has changed life beyond recognition. On behalf of women in Sling The Mesh campaign	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.

76	Consultee 24 Patient	**6.3**	6.3. The committee noted that, despite the existence of 2 registries, data collection had been disappointing. Any registry must be mandatory to report to and be accessible to all including physiotherapists etc	Thank you for your comment. NICE IPAC does not mandate data submission to a registry. Report of serious adverse events to the Medicines and Healthcare Products Regulatory Agency (MHRA) from companies is compulsory.
77	Consultee 2 Patient	**6.4**	6.4 Encouragedâ€™ is unacceptable, only 30% of surgeons use the BSUG database. It is a sad reflection on the so called â€˜caring profession but nothing less than mandatory reporting is acceptable.	Thank you for your comment. NICE IPAC does not mandate data submission to a registry.
78	Consultee 24 Patient	**6.4**	6.4. The committee encouraged the reporting of all device-related adverse events to the Medicines and Healthcare Products Regulatory Agency. The committee must insist on mandatory reporting of adverse events, nothing less will be adhered to.	Thank you for your comment. NICE IPAC does not mandate data submission to a registry. Report of serious adverse events to the Medicines and Healthcare Products Regulatory Agency (MHRA) from companies is compulsory.

79	Consultee 2 Patient	**6.5**	6.5 Will this truthfully be used by every Health Board and Trust and how can we ensure this? Patient consent must be informed and we need auditable evidence to show that it is.	Thank you for your comment. NICE IP guidance is advisory and applies in England, Wales, Scotland and Northern Ireland. It is intended to address the practical steps that clinicians should take to carry out the procedure safely in relation to their hospital's clinical governance arrangements, the patient consent process and the collection of data. NHS clinicians are responsible for applying NICE guidance, in their local context.
80	Consultee 24 Patient	**6.5**	6.5. The committee was advised that a national standard consent form is being developed. Current patient advice leaflets for Single-incision short mesh slings trial is inadequate and out with the national standard being developed. " " Single-incision short mesh sling insertion for stress urinary incontinence in women Interventional procedure consultation	Thank you for your comment.

PATIENTS' EXPERIENCE				
81	Consultee 5 Patient	**General**	These slings cause long term complications, and there are no long term viability studies then these should be stopped. I have mesh, it has put my life on hold following erosion. I would not want anyone else to go through what I have.	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.
82	Consultee 6 Patient	**General**	I am a member of the public who has chronic pelvic and groin pain and am suffering from foreign body reaction to my polypropylene tvto mesh fitted . My life has changed so dramatically for the worse since the insertion of the plastic, that I believe no mesh should be fitted into any bodies as the side effects can be extremely debilitating and costly to deal with	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.

83	Consultee 7 Patient	**General**	Back in March 2014, I had an anterior wall repair alongside a TVT being fitted. The mesh was put in too tightly and I couldn't urinate so had a catheter. Two days later I had to have another op to "pull down" the tape. A few days later, I started experiencing razor blade type pain inside my vagina and a feeling like I was sitting on a hard stone. My pain got worse when sitting or walking. I then started to get an intense burning pain down below. I was told it could be a urine infection but that came back negative, then I was told it could be stitch irritation. There was no way this was stitch irritation, the burning pain was awful. My doctor was very concerned and sent me back to my consultant. He was very arrogant and refused to acknowledge my pain was anything to do with his op. He told me there were no nerves down there (as if!) as my dr thought he had damaged the nerve and this was what was causing my pain. He told me the TVT was in the right place because I was so thin that he could feel it - I was thin because I lost so much weight as I was In pain and fretting.	Thank you for your comment. The committee very much welcomes hearing from patients. It noted your experience of the TVT procedure. The consultee disagrees with main recommendation.

			Anyway, to cut a long story short it is now two years later. I am still in pain but Pregabalin is helping with the nerve pain a little. I now have pain in my buttock and sacroiliac joint pain too and struggle sitting. Sometimes I feel like I am being cut from the inside. I have finally managed to see a specialist after 2 yrs of fighting for it and am due to see her for the results of my scan shortly. Please put an end to this mesh being used and ruining the life's of do many women. I now face two more severe ops that terrify me as there is no guarantee I will get better and they could possibly make things worse. This mesh can be put in quickly and I was told it was a simple op with the only complication down as being erosion treatable by antibiotics. If I had known the true risks, I would never have gone ahead with this op. Please, please, please put an end to this.	

84	Consultee 8 Patient	**General**	Polypropylene Surgical Mesh Implants should never be placed within the human body. I am a Survivor of a Johnson & Johnson Ethicon Surgical Mesh Sling, implanted in 2002. After severe pain, migration, erosion, rejection and several major Mesh removal operations, I find that 14 years later I am still in severe pain and have problems with Mesh migration, erosion and rejection. I have to take regular pain relief, courses of antibiotics, laxatives and use Colonic irrigation daily. I am doubly incontinent and sexual intercourse is impossible. Surgeons describe Mesh removal as 'like trying to remove chewing gum from hair' - WE are talking about removing pieces of Mesh from LIVING tissue and nerves! - Many Mesh Survivors have been left bed-bound and wheel-chair bound because of nerve damage. I count my self as one of the lucky Survivors, although I am under constant daily threat of more major surgery, which would almost certainly lead to a Colostomy.	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.

			My latest problems include a sharp object embedded in the tissue at the base of my spine which can be felt on examination. I am just about to undergo further tests, MRIs and X-rays to try to establish what is happening. I am in severe pain all of the time. There are days when my life is HELL. I try really hard to hide it from my family, but there are increasingly more and more days when I am unable to participate in family life. Putting plastic into living, breathing Human Beings is barbaric. It should be completely banned. Washington and California Attorney Generals have just taken legal proceedings against certain Mesh Manufacturers. During the speeches Mesh failure rates were quoted at 30% - This was a Government Department! ..... In my opinion NICE need to be extremely careful that this does not backfire on the NHS. Legal proceedings could prove an end to our already overstretched Health Service. https://www.youtube.com/watch?v=kv1tXMlrNtk	

85	Consultee 11 Patient	**General**	I had TVT procedure. The consultant while blindly inserting the tape she cut my atery on my bladder, resulting in a hematoma needing a blood transfusion. All resulting in catheterisation for weeks and wheel chair bound. Also I have had prolapse operations with mesh slings and I am in agony and not been able to work since.	Thank you for your comment. The committee very much welcomes hearing from patients and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.
86	Consultee 11 Patient	**General**	Mesh should not be used in the human body, I know from experience how toxic it is and can cause so many health problems. Pleas ban this awful procedure.	Thank you for your comment. The committee very much welcomes hearing from patients and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.
87	Consultee 13 Patient	**General**	Surely if these slings cause serious complications and there are no long term good quality studies then they should be stopped to protect women! I have had a tvt-o erode into my bladder, urethra and vagina. My will never be the same again, there are not enough studies into any poly propylene mesh used in the pelvic area.	Thank you for your comment. The committee very much welcomes hearing from patients. The committee noted your experience of the TVT-O procedure. The consultee disagrees with main recommendation.

88	Consultee 15 Patient	**General**	If these slings cause serious complications and there are no long term good quality studies them the use of them should be stopped. I have mesh complications which didn't manifest themselves fully until 3 years ago. Not enough information is currently available due to lack of long term in depth studies for people to make an informed decision concerning mesh implants and subsequent complications. They are manifest and far reaching and are destroying the quality of many people's lives .	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.
89	Consultee 16 Patient	**General**	This operation destroys women's lives by causing pain, bleeding, nerve damage, painful sex and lots of other problems.	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.
90	Consultee 17 Patient	**General**	My life changed completely 5 months after mesh device implanted,for the last 7 1/2 years I have been in constant chronic pain,I can't walk,haven't worked for 7 years and lost my home due to this!!..I has to be stopped.	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.

91	Consultee 22 Public	**General**	Since these slings causes serious complications and there are no long term good quality studies then these slings should not be used. Women who are permanently injured by mesh worldwide are perplexed as to why our governments are not doing more to protect us. We feel abandoned and we are suffering alone, the only support we get is through each other in online groups. This is not acceptable. ALL transvaginal mesh kits need to be banned.	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.
92	Consultee 23 Patient	**General**	Mesh Is Dangerous Why Are You People Still Trying To Prove Its Safe When You Know Mesh Is Not Safe At All Have These women Who are signed up in this mesh trial warned of the dangers of mesh eroding shrinking moving piercing organs bladder bowels damaging nerves damaging there urethra i bet they have not been just like the thousands of us mesh survivors that were dragged into mesh trails with out knowing that they were guinepigs or crash test dummies shame on you you need to stop the use of mesh and stop creating more and more mesh injured women	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.
93	Consultee 26 Public	**General**	This sling can cause bleeding, painful sex, bleeding, pain, and destroys women's lives.	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.

94	Consultee 27 Patient	**General**	In my opinion all polypropylene mesh slings wether mini , tvt/o tvt etc should all be banned as they hurt women like myself. A victim of mesh	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation.