National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT457 Episcissors 60 for mediolateral episiotomy

Consultation comments table

Final guidance MTAC date: 15 November 2019

There were 40 consultation comments from 8 consultees:

- 7 NHS professionals
- 1 company representative

The comments are reproduced in full, arranged in the following groups – (Evidence, factual inaccuracies, version of technology, care bundle, cost analysis and general comments).

#	Consultee ID	Role	Section	Comments	Notes for chair/committee leads	NICE response DRAFT/FINAL
Theme 1: Evidence						
1	1	NHS Professional	Section 1	1a] Episcissors 60 show promise for mediolateral episiotomy. But there is currently not enough evidence to fully support the case for routine adoption in the NHS. REPLY- NICE is ignoring the evidence and the reason for the RCOG 60 degree episiotomy recommendation. If EPISCISSORS-60 is not recommended it will result in people interpreting it as		Thank you for your comment. The evidence base has been reviewed rigorously. There is no evidence using the disposable version of Episcissors, and as such the committee agreed that the current evidence base is not transferrable to the disposable version. We have not stated that there is no evidence, we

				the 60 degree cutting angle is not important. They will revert to old practices of eyeballing resulting in increased OASIS due to incorrect episiotomy angles. BSUG would be concerned if NICE guideline was interpreted as such. Although there is not enough high quality evidence re: the impact of an accurately cut 60 degree mediolateral episiotomy, this remains the Best Practice Recommendation from the Royal College for every episiotomy performed. In the absence of any evidence to show that eyeballing can consistently achieve 60 degree cutting angles, we do not believe a randomised trial would be ethical.		have stated that evidence is not high quality. Need to clarify OASI care bundles and the differences.
2	1	NHS Professional	Section 1	1b] Research is recommended to address uncertainties about the efficacy and safety of using Episcissors 60. REPLY- the EPISCISSORS-60 are just an error free way of achieving the 60 degree cutting episiotomy angle. The evidence for the 60 degree episiotomy cutting angle is firmly established. There is no evidence to show that eyeballing is accurate. In both their published studies Van Roon et al showed that the angles achieved by Episcissors-60 were consistently within the RCOG recommendation of cutting between 45 – 60 degrees. However this was not the case in a statistically significant group when cutting with straight Mayo scissor.		Thank you for your comment. Please see response to comment 1.
3	1	NHS Professional	Rationale	2] Why the committee made these recommendations Episcissors-60 are adapted surgical scissors. They are used to guide and make a cut between the vagina and		Thank you for your comment. Please see response to comment 1.

				anus (episiotomy) at an optimal angle (45 to 60 degrees to the midline, according to NICE's guideline on intrapartum care) during delivery. This is called a guided mediolateral episiotomy. REPLY- The RCOG Green Top Guideline 29 (2015) is NICE accredited evidence. It clearly recommends a 60 degree cutting episiotomy angle. The NICE intrapartum guidance does not specify cutting or sutured angles and there is no published evidence base for it. An episiotomy cut at 45 degrees will result in a sutured episiotomy angle of less than 30 degrees which has a 10-fold higher risk of OASIS; compared to an episiotomy cut at 60 degrees which results in an optimal sutured episiotomy angle of 45 degrees. It may interest the MTAC to know that a 60 degree angled episiotomy is recommended by various other international O&G societies: The SOGC (Canada), the French CNOG, the Saudi O&G Society, the WHA Australia, and alluded to in ACOG.		
4	1	NHS Professional	Rationale	3] There is not much good evidence that Episcissors-60 are better than standard scissors, when used with other best practice care measures to prevent OASI (such as the Royal College of Obstetricians and Gynaecologists OASI care bundle). REPLY- in fact the RCOG OASI Care Bundle study mandated the performance of an episiotomy at 60 degrees and showed a 21% OASI risk reduction (RCOG World Congress 2019, London, abstract 1826). To say that there is no evidence is misleading.		Thank you for your comment. Please see response to comment 1.

5	1	NHS Professional	Section 3.1	6] The evidence includes patients who had a mediolateral episiotomy with reusable Episcissors-60 or standard episiotomy scissors. Two studies introduced reusable Episcissors-60 with other care measures, such as antenatal perineal massage, manual perineal protection and training (the Royal College of Obstetricians and Gynaecologists obstetric anal sphincter injuries [OASI] care bundle) REPLY- The RCOG Green Top Guideline 29 (2015) recommendations are different from the RCOG OASI Care Bundle study (2017). For example, the RCOG GTG 29 described 3 OASIS prevention measures: a] 60 degree episiotomy b] manual perineal protection c] warm perineal compresses. In contrast, the RCOG OASI Care Bundle study does not include warm perineal compresses.		Thank you for your comment. Please see response to comment 1.
6	1	NHS Professional	Section 3.4	7] SECTION3.4 Pooled analysis suggests no significant reduction in OASI rates in women who had an episiotomy with reusable Episcissors-60 compared with standard episiotomy scissors. REPLY- this is because of inclusion of the Ayuk study. This study excluded the most high risk group for OASIS, the OVD group from their analysis. We request NICE to repeat the pooled analysis with this data and including only the data from first vaginal births as was done in the other two studies (van Roon 2015 and Mohiudin 2018). In fact, the highest OASIS reductions are seen in this OVD group.		Thank you for your comment. Please see response to comment 1.

				Ayuk study results- It is worth pointing out again that the average parity in the Ayuk study is 1. The parity in other published UK studies is Zero. Therefore the comparison is not valid. It would be helpful if Ayuk et al provide the EAC and MTAC with their figures in nulliparous women (zero parity) and women undergoing Operative Vaginal Deliveries (OVD). While the national overall OASIS rate is 2.85%, the nulliparous rate is 5.9% and OVD rate is 8-14%. The authors make no mention of the caesarean section rates in the two study periods. It is important to assess whether these changed, whether the percentage of vaginal deliveries in the two study periods remained the same.		
7	2	NHS Professional	Consultation questions	*Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* Yes, however it would be interesting to critique evidence regarding use of standard scissor compared to curved and critically appraise OASI trends and what evidence suggests makes the biggest impact on reducing them and reducing costs. This would enable a better cost analysis to be performed around OASI in general. E.g. is OASI more linked to confidence and timing of episiotomy rather than the tools used to perform this. Therefore would further research possibly be better placed looking at other issues that could have a bigger impact than on whether episcissors as a tool compared to standard scissors are more effective.		Thank you for your comment. The committee concluded that it is uncertain how much of an impact Episcissors has over other measures included in the OASI care bundle, which the experts inform us has become part of standard care, and hence the impact of other factors, in addition to episcissors, need to be investigated
8	3	NHS Professional	Consultation questions	*Has all of the relevant evidence been taken into account?*		Thank you for your comment.

				It would appear so. *Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* It appears so.		
9	4	NHS Professional	Consultation questions	*Has all of the relevant evidence been taken into account?* The BMFMS believe all the relevant evidence has been taken into account *Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* The BMFMS believe that they are.		Thank you for your comment.
10	4	NHS Professional	General	BMFMS have perused these documents and feel that all relevant data has been reviewed (inc the Ayuk paper from the Northeast) and that the recommendations are entirely appropriate		Thank you for your comment.
11	5	Company	Consultation questions	*Has all of the relevant evidence been taken into account?* "NO. Please refer to the ITP data provided by NHS England to NICE on 14th October. This is analysis of the entire Episiotomy HES data for year 1 (2017-18), circa 90,000 episiotomies. Part 1 report clearly shows a 6% risk reduction in OASIS in episiotomies with the EPISCISSORS-60 compared to trusts that did not use the EPISCISSORS-60. In part 2 of the report, page 4/7 chart 3; NHS England's analysis clearly shows a 25% risk reduction in OASIS in trusts using the EPISCISSORS-60 compared to other trusts. On page 6/7, chart 5, the 12 month and 18 month before and after EPISCISSORS-60 HES data shows an absolute OASIS decline of 1-1.5%.		Thank you for your comment. The HES data has been shared with NICE and reviewed by the EAC. This data does not provide anything new to the evidence base for Episcissors. It does that show that there is potential for Episcissors to offer a clinical benefit. It therefore supports the committee's decision to recommend further research, but it doesn't answer the draft research questions posed.

				On page 7/7, the averages are discussed. The 18 month before/after EPISCISSORS-60 HES data shows a decline from 4.72% to 3.9%, a relative risk reduction of 17%. The 12 month before and after EPISCISSORS-60 HES data shows a decline from 4.61% to 4.05%, a relative risk reduction of 12%. NHSE EPISCISSORS-60 adoption rates are mentioned as 25% (24,000 episiotomies) or 40% (36,000 episiotomies)"		
12	5	Company	Consultation questions	*Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* the summaries are significantly altered in respect of the ITP evidence which interprets the entire HES data for 2017-18, the first year of the ITT/ITP. Please consider the weightage of the HES data with 90,000 annual episiotomies, and NHSE EPISCISSORS-60 uptake of 25% and 40%		Thank you for your comment. Please see the response to comment 11.
13	5	Company	Consultation questions	*Are the recommendations sound and a suitable basis for guidance to the NHS?* No; because they ignore that the EPISCISSORS-60 are a patient safety device that ensures cutting a 60 degree episiotomy in an error- free manner. There is no published evidence to show that a 60 degree episiotomy can be achieved consistently by visual estimation. It would be even more dangerous to convey the message that the episiotomy cutting angle of 60 degrees is not important, when it is clear that acutely angled and widely angled episiotomies have much higher OASIS incidences, and the 60 degree standard is being adopted by more and more		Thank you for your comment. The committee concluded that further research is required to judge the efficacy of Episcissors-60, since there is no data available on the disposable, single-use version. It is also difficult to assess the effect Episcissors-60 has alone vs. the OASI care bundle.

				countries (USA, Canada, France, WHA-Australia) as the technical requirement for an episiotomy.		
14	5	Company	Section 1	"The RCOG Green Top Guideline 29 (2015) is NICE accredited evidence. It clearly recommends a 60 degree cutting episiotomy angle based on evidence. The NICE intrapartum guidance does not specify cutting or sutured angles and there is no published evidence base for it. An episiotomy cut at 45 degrees will result in a sutured episiotomy angle of less than 30 degrees which has a 10-fold higher risk of OASIS; compared to an episiotomy cut at 60 degrees which results in an optimal sutured episiotomy angle of 45 degrees (Eogan 2006). It may interest the MTAC to know that a 60 degree angled episiotomy is recommended by various other international O&G societies: The SOGC (Canada), the French CNOG, the Saudi O&G Society, the WHA Australia, and alluded to the in ACOG."		Thank you for your comment. There is no evidence on the single-use, disposable version of Episcissors-60, and the committee concluded that the current evidence based on Episcissors-60 is lack in quality and quantity.
15	5	Company	Section 1	The RCOG OASI Care Bundle study mandated the performance of an episiotomy at 60 degrees and showed a 21% OASI risk reduction (RCOG World Congress 2019, London, abstract 1826). Most English Hospitals in this study purchased the EPISCISSORS-60 according to NHS Supply Chain data. To say that there is no evidence is misleading.	Unclear if the comment refers to single use disposable or reusable Episcissors-60	Thank you for your comment.
16	5	Company	Section 1	"NICE are ignoring the evidence and the reason for the 60 degree episiotomy RCOG recommendation. A non-recommendation of the EPISCISSORS-60 will result in people interpreting it as the 60 degree cutting angle is not		Thank you for your comment. The draft guidance states that further research is required on single-use, disposable Episcissors-60. Please see the

				important. They will revert to old practices of cutting at any angle. Although there is not enough high quality evidence re: the impact of an accurately cut 60 degree mediolateral episiotomy, this remains the Best Practice Recommendation from the Royal College for every episiotomy performed. In the absence of any evidence to show that eyeballing can consistently achieve 60 degree cutting angles, we do not believe a randomised trial would be ethical. Also, please refer to the ITP HES data analysis submitted by NHS England on 14th October 2019. This is analysis of Episiotomy HES data for year 1 (2017-18). Part 1 report clearly shows a 6% risk reduction in OASIS in episiotomies with the EPISCISSORS-60 compared to trusts that did not use the EPISCISSORS-60. In part 2 of the report, page 4/7 chart 3; NHS England's analysis clearly shows a 25% risk reduction in OASIS in trusts using the EPISCISSORS-60 compared to other trusts. On page 6/7, chart 5, the 12 month and 18 month before and after EPISCISSORS-60 HES data shows an absolute OASIS decline of 1-1.5%. On page 7/7, the averages are discussed. The 18 month before/after EPISCISSORS-60 HES data shows a decline from 4.72% to 3.9%, a relative risk reduction of 17%. The 12 month before and after EPISCISSORS-60 HES data shows a decline from 4.61% to 4.05%, a relative risk reduction of 12%.		response to comment 11 regarding the HES data.

				Please consider the scale of the HES data 90,000 episiotomies per year. EPISCISSORS-60 ITT adoption rates of 25% and total usage rates of 40%. This dwarfs the other evidence considered in the meta-analysis"		
17	5	Company	Section 1	In the absence of any evidence to show that eyeballing can consistently achieve 60 degree cutting angles, we do not believe a randomised trial would be ethical.		Thank you for comment. This question was posed at the committee meeting, and the experts agreed that an RCT comparing standard care (which includes standard measures to reduce the risk of an OASI as part of the OASI care bundle) with Episcissors-60 was not unethical.
18	5	Company	Section 1	The EPISCISSORS-60 are just a patient safety device to enable an error free way of achieving the 60 degree cutting episiotomy angle. The evidence for the 60 degree episiotomy cutting angle is firmly established. There is no evidence to show that eyeballing is accurate.		Thank you for your comment. There is no evidence on the single-use, disposable version of Episcissors-60, and the committee concluded that the current evidence based on Episcissors-60 is lacking in quality and quantity.
19	5	Company	Section 3	"This is because of inclusion of the Ayuk study. This study excluded the most high risk group for OASIS, the operative vaginal delivery (OVD) group from their analysis. We request NICE to repeat the pooled analysis with this data and including only the data from first vaginal births as was done in the other two studies (van Roon 2015 and Mohiudin 2018). In fact, the highest OASIS reductions are seen in this OVD group.		Thank you for your comment. The Ayuk study has been reviewed by the EAC and was critically appraised as an addendum to the assessment report. Ayuk et al. was excluded from the meta-analysis and so both versions of the EAC's meta-analysis (with Ayuk et al and without) were presented to the committee so that they were able to make an assessment on which was the most appropriate.

20	5	Company		Ayuk study results- It is worth pointing out again that the average parity in the Ayuk study is 1. The parity in other published UK studies is Zero. Therefore the comparison is not valid. It would be helpful if Ayuk et al provide the EAC and MTAC with their figures in nulliparous women (zero parity) and women undergoing Operative Vaginal Deliveries (OVD). While the national overall OASIS rate is 2.85%, the nulliparous rate is 5.9% and OVD rate is 8-14%. 3] Ayuk study methodology- I have separately forwarded an email from the Medical Director of Sunderland Hospitals to Lee Dobson of NICE, where he mentions that perineal protection was routinely practiced at their hospital as standard. Therefore it is not clear what measures practiced in the RCOG Care Bundle were not implemented. And whether this is just an under-powered study using all the protective measures recommended by the RCOG. The authors make no mention of the caesarean section rates in the two study periods. It is important to assess whether these changed, whether the percentage of vaginal deliveries in the two study periods remained the same."		Thank you for your comment. Please see the response to comment 19.
21	5	Company	Section 4.4	We have presented evidence at the MTAC on 13th September to NICE that the length of the episiotomy can be adjusted by not inserting the entire length of the blades into the perineum.		Thank you for your comment. This question was raised to the experts in the committee meeting, and it was concluded that experts (who have used Episcissors-60) were not confident that they were able to reduce the length of the cut using Episcissors-60.

22	5	Company	Section 4.4	Please refer to the ITP data shared by NHSE on 14th October. This is HES data for the entire year 2017-18. No increase in episiotomy numbers noted in the ITT EPISCISSORS-60 adopting trusts. Please note the scale of the HES data evidence with the EPISCISSORS-60 maybe between 25% (24,000 episiotomies) to 40% (36,000 episiotomies) which dwarfs the previous evidence.		Thank you for your comment. The HES data has been reviewed (please see response to comment 11). We have acknowledged in the MTCD that Episcissors-60 may increase the rate of episiotomy, but that the evidence base is poor for this
23	5	Company	Section 4.14	Please refer to Orlovic 2018 quoted in our sponsor submission.	EAC comment to be added	Thank you for your comment.
24	6	NHS Professional	Consultation questions	"1] In our paper on the outcome of EPISCISSORS-60 adoption at two NHS Hospitals (Van Roon 2015), 84% of clinicians rated the EPISCISSORS-60 good or very good. There was an 84% OASIS reduction in nulliparous women given episiotomies (p=0.003). There was a 14% OASIS reduction in nulliparous OVD although this did not reach statistical significance as the numbers were small. 2] In our study comparing the angles of episiotomy cut with standard episiotomy scissors and the EPISCISSORS-60 (van Roon 2016): Mean angle was 45° with Mayo scissors [SD = 9, 95% confidence interval (CI) = 43.3–46.7, interquartile range (IQR) 38–50] and 60° with the EPISCISSORS-60 (SD = 3, 95% CI = 59.3–60.7, IQR = 58–60). Two-thirds of cuts with Mayo scissors were below 50°. The EPISCISSORS-60 cut an episiotomy a statistically significant 15°	EAC comment to be added	Thank you for your comment.

				wider than regular Mayo scissors and achieved the recommended 60° in the vast majority of cases. Variability in mediolateral episiotomies should be reduced by use of fixed-angle scissors or through validated health professional training programmes to improve visual accuracy. Currently there is no published evidence that visual accuracy can be improved by training. 3] Our manuscript ""Impact of the EPISCISSORS-60 mediolateral episiotomy scissors on obstetric anal sphincter injuries (OASIS): A 2-year data review in United Kingdom"" is under revisions by the International Urogynecology Journal (Koh 2019). This paper has also demonstrated a statistically significant reduction of OASIS in all nulliparous deliveries and a 50% reduction of OASIS in operative vaginal deliveries using Episcissors."		
25	7	NHS Professional	General	I would like to see a research paper on the comparison of the patient experience between Mayo and Episcissors- especially pain levels and healing		Thank you for your comment.
Theme 2: Factual inaccuracies						
26	5	Company	Section 1	This is incorrect. Both versions are currently available. Our intention was to phase out the reusable version in 2020. However, we will aim to ensure that both reusable and single-use EPISCISSORS-60 are available long-term.		Thank you for your comment. This statement differs from previous correspondence where it was stated that the reusable version was being discontinued and that the disposable, single-use version was being phased in, in June 2019

27	5	Company	Section 2	This is incorrect. Both versions are currently available. Our intention was to phase out the reusable version in 2020. However, we will aim to ensure that both reusable and single-use EPISCISSORS-60 are available long-term.		Thank you for your comment. Please see response to comment 26.
28	5	Company	Section 3	NICE is confusing the RCOG Green Top Guideline 29 (2015) recommendations with the RCOG OASI Care Bundle study (2017). They are different. For example, the RCOG GTG 29 described 3 OASIS prevention measures: a] 60 degree episiotomy b] manual perineal protection c] warm perineal compresses. In contrast, the RCOG OASI Care Bundle study does not include warm perineal compresses.	This needs clarifying – to check with EAC	Thank you for your comment.
29	5	Company	Section 4	This is again factually incorrect. The RCOG GTG 29 (2015) recommended 3 OASIS prevention measures: a] 60 degree episiotomy b] manual perineal protection c] warm perineal compresses. These measures were included across the NHS as part of routine care by many hospitals. The RCOG OASI Care Bundle is a multicentre study which does not include warm perineal compresses which commenced 2 years later in 2017.	This needs clarifying – to check with EAC	Thank you for your comment.
Theme 3: Version of the technology						
30	5	Company	Section 4	The essential purpose of the EPISCISSORS-60 in both product versions is the ability to cut at a pre-determined 60 degrees from the anal midline. it is impossible to ascribe a scientifically plausible difference between the two versions . We request MTAC to review their conclusions.		Thank you for your comment. The committee did not think that the evidence on the reusable version was transferable to the single-use disposable version. Without any evidence on the disposable, single-use version, the committee recommend further

						research on the single-use disposable Episcissors-60
31	5	Company	Section 4.10	in response to NICE's concerns, we are happy to retain both the reusable and single use versions for the long term		Thank you for your comment. This differs from what was previously communicated.
32	7	NHS Professional	Section 1	All units in Greater Manchester have procured reusable Episcissors-this makes it difficult to compare to single use and they will no replacement potential for a considerable time		Thank you for your comment.
Theme 4: Care bundle						
33	5	Company	Section 4.6	Nobody has claimed that the episiotomy angle alone is a good marker for OASI. However, the importance of the episiotomy angle in OASI causation cannot be denied. It is the reason why midline (aimed at cutting in the perineal midline) episiotomies have 5 times higher OASI than mediolateral episiotomies (angled away from the midline). When a mediolateral episiotomy is visually estimated and accidentally given close to the midline, the risk of OASIS increases manifold. It is to prevent the OASI risk due to incorrectly angled episiotomies that a fixed angle device like the EPISCISSORS-60 is important. To prevent avoidable harm by eliminating human error. Perineal protection, antenatal perinatal massage will not change the angle of the episiotomy.		Thank you for your comment. The committee concluded that to be able to recommend disposable, single-use Episcissors-60, evidence using the device is required, and hence further research using the device is required.
34	8	NHS Professional	Consultation questions	*Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* In reference to the RCOG care bundle cited, please note that we do not have any data on Episcissors 60 and only		Thank you for your comment.

				advocate an episiotomy at 60 degrees with any scissors units.		
Theme 5: Cost analysis						
35	8	NHS Professional	Consultation questions	*Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* When the episitomy is being sutured there typically are pre-existing perineal repair backs with tissue grasping forceps, needle holder and scissors. These are sometimes bundled together with the 'spontaneous birth packs' and the 'forceps trolley'. There is usually a pair of suitable tissue scissors available to perform an episiotomy, sterilised and sharp already. I think the economic modelling is excessive and using the wrong comparators. The proposed cost of use of these scissors is much larger than current care plus a piece of paper with two lines at 60 degrees to each other to guide the position of the episiotomy. The economic costings do not take into account when the midwives & doctors are on the cusp of considering if an episiotomy be required, the 'special 60 degree scissors' are brought, opened and ultimately unused. I think there would be a significant amount of wastage from this scenario. When urgently required, delaying episiotomy because the special scissors cannot be located immediately would not be in the fetal interest.	EAC comment to be added.	Thank you for your comment.

				Staff would become less familiar with the use of 'normal' scissors for RMLE over time.		
36	8	NHS Professional	Consultation questions	*Are the recommendations sound and a suitable basis for guidance to the NHS?* When considering whether to perform an episiotomy in current NHS practise, there are suitable instruments available to perform this. These will almost invariably include a pair of tissue scissors which are designed to cut the perineal skin in order to perform an episiotomy. Current NHS practise provides suitable instrumentation for the healthcare professionals to repair the episiotomy, or any vaginal tears incurred during birth. The emphasis of the comments provided in question 1 depends on whether NICE wish to be consulted on the content of these documents, or whether they are inviting consultation on whether the entire assessment is required. Both are addressed below. When considering the content of the document provided and looking at the economic modelling, it is comparing the cost of the disposable scissors to the reusable 60 degree scissors. This calculation does not take into account the fact that there are existing scissors designed to cut tissue in order to perform an episiotomy. This gives the implication or impression that the decision to switch to these 60 degree scissors has been made. It is not clear if this is intentional or inadvertent.		Thank you for your comment.

				The rationale for the introduction of these scissors is that it will result in fewer cases of anal sphincter injury related to childbirth. These show the 60 degree scissors reduced this type of injury compared to standard practice. This sounds good initially and appears to justify their introduction. A better comparator would be the use of standard straight scissors to perform episiotomy with additional training and education for the midwives and doctors. This could essentially be done for minimal cost with a change in guidelines / curriculum for obstetricians. A way of demonstrating the correct angle with a low cost teaching aid is a clock face with the hands pointing to 8 o clock. This gives the 60 degree angle. Just prior to the moment of birth of the baby's head, there can be a short time period when the need for an episiotomy is being considered by the birth attendant. It can take extra time to get equipment necessary to perform this. Often the sterilised instrument pack is opened in anticipation of this and in most cases the instruments are used subsequently. In order to perform an episiotomy the disposable episiotomy scissors would have to be readily available or opened ready for use each time. An episiotomy is not always needed, but >99% a pair of scissors is needed to cut the umbilical cord etc. In order to have the 60 degree scissors 'on hand' for when an episiotomy is being considered, a larger number would have to be opened (and hence paid for by the		

				NHS) than are eventually used to perform an episiotomy. This 'wastage' of opened but unused 60 degree scissors is not considered by the economic calculations in the NICE paperwork. Overall, taking a wider view of this the justification from the manufacturer to withdraw the re-usable scissors appears to be fairly weak and the potential for generating on-going income from single use instruments comes to mind. We think the cost benefit is over estimated. It is possible that the actual benefit is over estimated by comparing to current practise rather than against an improved current practice. This exercise to assess the re-usable vs single use instruments is unlikely to show any clinical difference because the design and materials are assumed to be comparable. The main assessment is an economic one; the current one over estimates the savings, and is being compared to the reusable version rather than the universal access to existing scissors.		
Theme 6: General comments						
37	2	NHS Professional	Consultation questions	*Has all of the relevant evidence been taken into account?* Yes *Are the recommendations sound and a suitable basis for guidance to the NHS?* Yes, very sensible *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?* No, I agree the most at risk populations for OASI need to be well represented within the new research whether this		Thank you for your comment.

				research is around episcissors or other impacting factors on OASI		
38	3	NHS Professional	Consultation questions	*Are the recommendations sound and a suitable basis for guidance to the NHS?* Yes *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?* No		Thank you for your comment.
39	4	NHS Professional	Consultation questions	*Are the recommendations sound and a suitable basis for guidance to the NHS?* The BMFMS believe that the recommendations are sound and a suitable basis for guidance for the NHS. *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?* The BMFMS do not believe there are there are equality issues.		Thank you for your comment.
40	7	NHS Professional	Consultation questions	*Has all of the relevant evidence been taken into account?* Yes all available at present *Are the summaries of clinical and resource savings reasonable interpretations of the evidence?* Yes *Are the recommendations sound and a suitable basis for guidance to the NHS?* Yes *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?* None known		Thank you for your comment.

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