National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT288 The XprESS multi-sinus dilation system for treating chronic sinusitis

Consultation Comments table

MTAC date: 23 September 2016

There were 25 consultation comments from 8 consultees (2 NHS professionals, 2 manufacturers and 4 others). The comments are reproduced in full.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	**3.** Manufacturer (Sponsor)	**General, including 1.2, 3.26**	We would like to provide the following comments and clarifications in response to the draft consultation document issued by NICE in June, 2016. We thank the committee for conducting a detailed review of the evidence submitted, the analysis performed by the external assessment center as well as listening to stakeholders feedback. We are largely in agreement that the committee has considered all of the relevant evidence, that the summaries of clinical effectiveness and resource savings are reasonable interpretations of the evidence, and that the provisional recommendations are sound. We would however like the committee to consider the suggested amendments below, which seek to either clarify the text or provide additional detail to substantiate the recommendations made by	Thank you for your comment.

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			NICE. Suggested amendments: clinical effectiveness Consistent terminology should be applied throughout the document when referring to the patient population indicated for XprESS to avoid any confusion. In section 1.2 and other places in the document, it states that XprESS should only be used in patients with non-complex chronic sinusitis who do not have nasal polyps. This is incorrect. XprESS can be used in patients with mild to moderate nasal polyps; XprESS is not recommended in patients with severe polyps. In section 3.26 the committee noted that the REMODEL study excluded patients with severe nasal polyposis and it was advised by clinical experts that balloon dilation is not suitable in these patients. We agree with this statement; therefore, we suggest that the term patients with non-severe polyps be used consistently throughout the document to describe the recommended patient population. The reference to maxillary and anterior ethmoid disease or maxillary or anterior ethmoid disease• throughout the consultation document is inaccurate and should be replaced with the term maxillary sinus disease with or without anterior ethmoid sinus disease to apply consistent and accurate terminology. Throughout the consultation document, many study populations are noted to have maxillary and anterior ethmoid disease or maxillary or anterior ethmoid disease. The correct statement describing these populations should be maxillary sinus disease	The committee decided to change section 1.2 to clarify the use of XprESS in patients with polyps Thank you for your comment. The committee decided to change section 3.5 to clarify the study population used in the REMODEL trial.

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			with or without anterior ethmoid sinus disease. All of the studies included patients with maxillary sinus disease. In addition, patients could have, but were not required to have anterior ethmoid disease. Although balloon sinus dilation does not directly treat ethmoid sinuses, subgroup analyses in several of the studies demonstrated resolution of the ethmoid disease when the maxillary sinuses are treated. Using the suggested terminology maintains consistency throughout the report while accurately describing the study populations.	
2	**3.** Manufacturer (Sponsor)	**General**	The REMODEL study time horizon should be clarified to avoid misinterpretation of the lost to follow-up rate. The time horizon of the REMODEL study was 12 months. This study was therefore closed, as planned, upon the completion of the 12-month visit for the last enrolled patient. The population followed up beyond 12-months was smaller than the initial study population because only a proportion of patients were eligible for follow-up at those time periods. Chandra et al (2016) reports long-term follow-up that included 66 patients followed at 18-months and 25 patients followed at 24-month; this includes 100% of the patients who were eligible for these follow-up visits No patients were lost to follow-up in the long-term follow-up period. It is important to clarify the planned approach to patient follow-up beyond 12-months to avoid any misinterpretation that the smaller numbers for follow-up beyond 12 months are due to high lost to follow-up rates. The description of long-term follow-up should note that 6 months is sufficient to demonstrate	Thank you for your comment. The committee decided to change 3.8 to make it clear that the smaller number of patients at 18 and 24 months was not due to loss to follow up. The EAC has stated that the reporting of the REMODEL study was confusing because, although the study by Bikhazi *et al.* (2014) reported 12 month outcomes, additional patients were recruited at a later time and reported in the later paper by Chandra *et al.* (2016). This created various reporting and technical issues which are fully addressed in the EAC's Assessment Report, see pages 51 to 60.

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			treatment efficacy. Soler et al. (2010) multi-institutional, longitudinal cohort study examined the durability in quality of life (QoL) and improvement after functional endoscopic sinus surgery (FESS). This study used 2 rhinosinusitis-specific survey instruments (Rhinosinusitis Disability Index (RSDI); Chronic Sinusitis Survey (CSS)) to record QoL in 127 patients at 6, 12, and 20 months post-surgery with FESS. This study found no significant differences in QoL scores between 6, 12, and 20 months and concluded Clinical trial designs incorporating QOL outcomes after [F]ESS should consider the six-month time frame as an appropriate primary endpoint.• As such, the assessment of follow-up beyond 12 months in the REMODEL study exceeds this standard and is sufficient to confirm that the durability of XprESS is similar to FESS. Therefore, based on the totality of the evidence for XprESS, no additional studies are warranted.	
3	**3.** Manufacturer (Sponsor)	**General**	The description of the REMODEL trial analysis should be reworded to clarify that the per-protocol analysis was part of the pre-specified statistical plan as the current wording suggests that this may have introduced bias. Section 3.2 of the consultation document states that the high initial attrition rates in the FESS arm [of the REMODEL trial] immediately following randomization, and the subsequent need for per-protocol rather than intention-to-treat analysis. This sentence is inaccurate and suggests that the approach to analyzing the data was changed post randomization. This sentence should be rephrased to emphasize that the pre-specified statistical plan was for a per-protocol analysis and	Thank you for your comment. The committee decided to change section 3.5 to clarify that the REMODEL trial used a modified intention to treat analysis

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			note that a post hoc intent-to-treat analysis was performed to address the concerns raised by the EAC team. The post hoc analysis confirmed that the differential attrition rates between the treatment arms did not impact the study outcomes or conclusions. This clarification is important to avoid any misinterpretation that the protocol was changed due to high attrition rates or that this approach had any impact on the study results. The description of the meta-analysis (Chandra et al, 2016) should be amended to describe the study aim and the primary outcomes as the current description is a little misleading. Chandra et al. (2016) report the results of a meta-analysis of patient-level data from the REMODEL randomized controlled trial and 5 prospective, multicenter, single-arm studies of standalone balloon sinus dilation. The aim of the meta-analysis was not to make a direct comparison to the REMODEL results to FESS, as implied by the consultation document. Rather, the aim was to combine a cohort of patients who had been treated with the Entellus Medical balloon dilation devices to evaluate overall outcomes in a larger study population. One of the primary outcomes of the analysis was the change in overall SNOT-20 scores. The results demonstrated statistically significance and clinically important improvements with Entellus Medical balloon dilation devices at all postsurgical time points through to 24-months. Although some selected outcomes were compared with the REMODEL FESS arm of the study, this was not the primary purpose of the meta-analysis; therefore, presenting the results in this way is misleading. We suggest that the	The committee decided to change section 3.17 to clarify the studies included in, and aim of the Chandra paper

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			description of the meta-analysis should instead focus on the study aim and primary outcome, rather than the comparison with FESS.	
4	**3.** Manufacturer (Sponsor)	**General, including section 3.11**	A more detailed description of the XprESS Registry should be provided to avoid any misinterpretation of the study population, treatments and timelines. This current description of the study population, technical success rate, and study time-horizon are inaccurate as reported in the consultation document. The text in section 3.11, should be edited to correct the following details. The XprESS Registry (Brodner et al, 2013) included treatment of maxillary sinuses in addition to frontal and sphenoid sinuses. In this study, surgery was attempted in 497 patients and 479 patients were successfully treated with the XprESS. Of the 479 successful cases, 448 sinuses were treated with hybrid procedures and 31 were treated with standalone balloon sinus dilation. The remaining 18 cases were not successfully dilated. The primary outcome was the change in SNOT-20 score which was measured at 1, 6, and 12 months. A SNOT-20 change from baseline of -1.1 was observed at both the 1-month and 12-month. This clarification will avoid any confusion. The committees considerations should include a recent UK study reporting the impact of delaying surgery to highlight the benefits associated with earlier intervention facilitated by using XprESS. In	Thank you for your comment. The EAC has stated that the XprESS registry was of limited applicability because the large majority of patients received hybrid surgery, and therefore the efficacy of standalone balloon dilation could not be determined. The Committee decided to change section 3.11 to clarify the registry population, and technical success rate, and the reporting of the SNOT and RSI scores The EAC assessed the study by Hopkins *et al.* (2015) and judged that it did not provide evidence relevant to the decision problem, because:

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			section 4.2 the committee acknowledges feedback from experts that outpatient XprESS is more easily deliverable than FESS. This potentially allows improvements in patients throughput and the treatment of more patients at an earlier stage in their disease. We recommend that this point is expanded upon to highlight the benefits associated with earlier surgical intervention as reported in a recently UK study by Hopkins et al (2015). This retrospective analysis included 1,493 UK patients enrolled within the National Comparative Audit of Surgery for Nasal Polyposis and Chronic Rhinosinusitis and compared patient outcomes in 3 groups stratified by the time to surgery. This study found that patients with delayed surgery reported less improvement in SNOT-22 scores than patients treated at earlier time points, regardless of comorbid status. The study concluded that delaying treatment may worsen long-term clinical outcomes. As the committee acknowledges that XprESS facilitates earlier intervention, it is important to outline the clinical benefits associated with this.	• Consideration of earlier surgical or balloon management of CRS is outside the scope of the guidance. The implications for clinical efficacy, safety, patient pathways, and resource use of early intervention have not been evaluated. • The study by Hopkins was restricted to surgical intervention (FESS), not balloon dilation. • This is also only one potential source of evidence and other evidence on the benefits of early intervention have not been considered. The Committee carefully considered this comment and the EAC's advice and decided to make no changes.
5	**3.** Manufacturer (Sponsor)	**General**	Suggested amendments: cost consideration Further justification should be provided for the rationale for assuming a 60-minute procedure time with FESS in the recommendation. We agree that the estimate of 60-minutes referred to in the recommendations is appropriate, albeit conservative but suggest that this should be justified with reference to the clinical studies below and the average estimates provided by experts. We strongly disagreed with the	Thank you for your comment. The EAC recognise that there is uncertainty regarding the procedure time with both FESS and XprESS given the paucity of data regarding the procedure time in the UK NHS for FESS and balloon therapy in matched patients. Whilst the sources quoted support a longer procedure time with FESS, other sources, notably the national audit data (41.6/39.6 minutes) and the UK HTA (46 minutes), report shorter durations as reported in the EAC's

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			procedure time of 42.2 minutes for FESS under general anaesthesia assumed in the first analysis produced by the EAC, referred to in the draft consultation. This estimate is at the very low end of the range of estimate provided and is not consistent with times reported in other clinical trials reference below, we therefore suggest that this time (42.2 minutes) is removed as is may cause confusion. We agree that 60 minutes is an appropriate assumption. This should be justified to provide greater context to the assumption applied in the recommendation, referring to the following: o 60 minutes falls within the lower bound of estimates reported in the literature obtained from 3 studies including the only randomized control trial (RCT) with a direct comparison of FESS and a balloon procedure that included over 300 patients. In these studies, the procedure times with FESS ranged between 60 and 82 minutes: o An Italian RCT study (Marzetti et al, 2014) of 40 patients randomized to undergo frontal sinus surgery with either FESS or balloon, reported mean procedure times with FESS of 65 (+/- 15) minutes compared to 32 (+/- 7) with balloon. o Cornet et al. (2012) conducted a prospective randomised double blind controlled trial, recruiting 60 patients in the Netherland and reported median procedure times with FESS of 71 minutes [41 minutes on one side and 30 minutes on the other] o A USA retrospective analysis of patients who	assessment report. The EAC contacted experts for advice on this specific question. Experts reporting the duration of FESS to the EAC in patients who would be eligible for treatment with XprESS reported procedure times of 40-45 minutes. The experts reporting longer procedure times were not considering patients eligible for balloon therapy, rather those undergoing more intensive surgery for more severe disease. The Committee considered the evidence from clinical experts and EAC. It heard advice that measurement may differ, depending on the time at which the procedure is assumed to begin and end, and noted this in its considerations, section 5.26. In the recommendations in 1.3, a FESS procedure time of 60 minutes is cited. The Committee carefully considered this comment and decided to make no changes.

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			had surgery with FESS (Gibbons et al. 2001) reported mean and median procedure times of 81.4 and 76.0 minutes respectively in 203 patient o The procedure time with FESS reported by clinical experts in the UK, collected by the EAC, ranged between 40 and 120 minutes [40, 45, 90 and 120 minutes]; 60 minutes is below the mid-point of 74 minutes within this range	
6	**3.** Manufacturer (Sponsor)	**General**	The description of the sensitivity analyses reported in the supporting documentation should replace prior analysis, as this captures more realistic scenarios for the procedure time with FESS. The univariate analysis reported in sections 5.21 -5.24 of the consultation document conducts one-way analysis of the model parameters in a base-case scenario that assumes the procedure times with FESS is 42.2 minutes. For the reasons outlined above we do not agree that this is a realistic scenario and therefore may be misleading. We suggest that sections 5.21-5.24 are either replaced or supplemented with a description of the two- or three-way sensitivity analysis which show the impact when the proportion of procedures conducted under local is varied between 0%-100% and the procedure time with FESS is varied between 40 and 90 minutes. This clearly depicts that costs savings are achieved where procedure times with FESS are greater than 60 minutes and more than half of all procedures with XprESS are conducted under local. This also shows that cost-savings are achieved in plausible scenarios and corresponds with the draft conclusions made by NICE.	Thank you for your comment The Committee decided to change section 5.15 to clarify that the revised costs apply to an operating theatre setting. The Committee decided not to make any changes to section 5.21-5.24, because it judged that the EAC analysis considered all scenarios relevant to a UK health care setting ***Length of hospital stay*** The use of HES data describing length of stay was reported in the company's submission and is therefore included in the results reported in Section 5.6/5.7 of the guidance. As noted in the EAC's assessment report the HES data have two serious limitations. First, the patients included within the HES data are a broader cohort than those included within the scope of the decision problem, i.e. patients with more severe disease or comorbidities will be included. Second, HES data do not report length of stay in the granularity required. Patients not requiring an overnight stay will have a length of stay of 0 and those requiring 1 night in hospital will have a length of stay of 1 etc. Therefore,

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			The approach to calculating the procedure costs under local anesthesia in an office setting with XprESS should be clarified to avoid any confusion regarding how greater cost-savings are achieved when a higher proportion of XprESS procedures are conducted in this way. The consultation document reports two approaches for calculating procedure cost under local anesthesia. The first approach detailed in section 5.15 assumes no difference in the unit cost of surgical resources for procedures conducted under general and local. The second approach detailed in section 5.22, calculates the cost in an office setting where the costs included staff time for one surgeon and one nurse and drapes and gowns. We agree that the second approach (in section 5.22) is appropriate as these assumptions are aligned with the feedback we obtained from clinicians now doing XprESS procedures under local anesthesia in the UK. We do not agree with the first approach as fewer staff and overheads are required to conduct procedures under local compared to general. Feedback from UK clinicians suggests that between six and eight staff are typically required to conduct a procedure under general, usually including a surgeon, an anesthetist, two nurses, one runner and one orderly. To avoid any confusion, we recommend removing section 5.15 and only describing the second approach to calculating resource use under local anesthesia in an office setting. The reference to length of hospital stay should note that real-world data suggests that the length of stay with FESS may be higher than the assumptions applied in the analysis and therefore	the data is very limited in determining how many hours patients remain in hospital for following what is largely day case surgery. Whilst the limitations with expert opinion are recognised, these limitations will apply to both arms of the model. The EAC considered both scenarios described in this comment (and both are reported). In a UK setting it is probable that not all XprESS procedures would be done in an office setting. The sensitivity analyses in the Assessment Report encompass all of the plausible proposed scenarios in a UK setting. The committee carefully considered this comment and decided not to make any changes.

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			the cost-savings with XprESS may be even higher. The original model applied data on the length of stay obtained from health episode statistics in 2014/15. The length of stay with FESS was assumed to be 0.97 days based on the average length of stay for frontal sinus procedures with FESS and 0.43 days with XprESS based average stay for frontal following hybrid balloon-FESS procedures. The EAC revised the length of stay assumptions to 0.208 and 0.174 days with FESS and XprESS respectively, based on expert opinion. The HES data is likely to be a more accurate as it records real-world UK data on time from admission to discharge compared to expert opinion which is likely to only consider immediate recovery time. However, given that there is no data on length of stay for standalone balloon procedures yet, we do not recommend revising the analysis. Instead we suggest that the conclusions acknowledge that real-world data suggests that the length of stay with FESS is longer than projected, in which case the cost-savings with XprESS may be evening higher.	
7	**3.** Manufacturer (Sponsor)	**General**	Finally, the draft recommendations should acknowledge that the additional analysis reported in the supporting documentation found XprESS to be cost-neutral or cost-saving at both price points of £820 and £900, when certain conditions were met. We therefore recommended adding the following point to section 1.3 of the draft recommendations: If more than 50% of treatments are performed under local anesthesia, in an office setting, XprESS is cost-saving compared to a 60-minute procedure time with	Thank you for your comment. The Committee carefully considered this comment and decided not to make changes to section 1.3. It considered the cost saving scenario already described to be the most relevant

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			FESS and assuming a cost for XprESS of Â£900.• We would like to thank the committee for considering our suggestions. As noted above, we are largely agreement with the assessment and our recommendations aim to clarify the text or provide additional detail to substantiate the recommendations made by NICE. We therefore hope you find these suggestions helpful. Please feel free to contact me directly if any of the points raised are not clear or any additional information is required.	
8	**6.** Manufacturer	**General**	Consideration should be made to navigated balloon teechnology: The potential value navigated balloons as a solution that making the surgery safer, addressing patients with complex anatomy, increasing a comfort of surgeon, great teaching tool that shortening the learning path from the surgical theatre to the office. One should remember that in-office ESS is not for every patient and every doctor.	Thank you for your comment The decision problem set out in the scope did not include navigated balloons and no relevant evidence was presented. The committee carefully considered this comment and decided not to make any changes.
9	**7.** NHS Professional	**General**	It has not been made clear in any of the papers presented, or the economic evaluations that the main sinus group, the ethmoids, cannot be addressed by balloon dilatation. This makes almost all of the comparisons entirely meaningless. For example, the comparison on theatre time compares ballon treatment of the maxillary, frontal and occasionally sphenoid to FESS surgery treating the maxillary, frontal and occasionally	Thank you for your comment. The Committee decided to change section 3.5. See comment 1 The Committee changed section 1.2 and section 5.29 to clarify the patient group who may be suitable for

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			sphenoid and also the ethmoids, and it is ethmoid surgery that takes time - therefore the procedure is marginally longer. It is absolutely untrue that the majority of FESS procedures could be replaced with a balloon only procedure, as the majority of patients have ethmoid disease and need ethmoid surgery to address this. Two out of three patients having a FESS in the UK have polyps, and are unsuitable for a balloon only procedure. The company argues that a hybrid procedure could be performed, but if the patient is having a FESS under GA there can be virtually no justification whatsoever as the maxillary and sphenoid procedures taken minutes with the conventional instruments, and most patients do not need frontal surgery. The studies comparing outcomes between balloon and FESS procedures are undertaken in a highly selected group of patents who do not have ethmoid disease - in this group there appears to be equivalence. However, these results are not generalisable to the UK population, as only a very small number of our patients undergoing surgery have limited disease. I have only seen one patient since Christmas who I would consider suitable for a balloon only procedure, but have listed nearly a hundred for FESS at the same time. The company make the point that balloons would	XprESS

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			allow surgery to be performed in a ambulatory surgery unit - which is ridiculous as they know that FESS has been performed in this setting in the UK for over 10 years. To my knowledge, I am only one of at most a handful of surgeons undertaking sinuplasty under LA. I have never done so with the Entellus equipment, which I think is harder to use than the Acclarent products that are no longer available. I have only done one case in a year - mostly because there are very few suitable candidates. No-one at all is doing it in an office setting at the moment, and if the case is done in day theatres there is no cost setting at all. The reason that so many are done in the US us that the reimbursements mean that surgeons are paid $12,000 per patient and dont have to pay for theatre costs, In the UK there is no driver by way of reimbursement either privately or in the NHS and therefore no-one really does it - I cant see this changing at all. Us surgeons own the office, hence the drive for 'in office' - but most performing balloon procedures dont have admitting rights to hospitals and therefore cant perform conventional FESS. Faster recovery time is again only related to avoiding a GA, and if performed under anaesthesia this benefit is also lost I am really concerned that the company hoped to push that patients should have a balloon before they could be considered for a FESS, as this is a	

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			statement that cannot be supported by the current evidence.	
10	**6.** Manufacturer	**Pg. 2; Sec 1.2**	There is no clear definition of non-complex chronic sinusitis. It does not exist in literature, but it seems to be important when we claim that 80% of patients could be treated with balloon technology. It is accepted that CRS is a multifactorial condition and this has an impact on clinical course, including healing process after FESS.	Thank you for your comment. The Committee decided to change 1.2 and section 2.5 to clarify the study population and terminology used
11	**8.** NHS Professional (Expert Adviser)	**Pg. 3; Sec 1.3**	xPress should be considered another tool to use for ESS rather than a minimally invasive alternative to functional endoscopic sinus surgery (FESS); however using this tool makes the procedure more amenable to a local anaesthetic approach. Rather than some of the technical claims in this section, I would simply say that it's easier to use than any of its predecessors.	Thank you for your comment. The Committee carefully considered this comment and decided to make no changes. Medical Technology Guidance is based on the claims made by the company and the assessment of submitted evidence.
12	**8.** NHS Professional (Expert Adviser)	**Pg. 3; Sec 1.4**	Recurrent acute rhinosinusitis (RARS) is NOT a type of chronic rhinosinusitis because CRS by definition has to be continuous for 12 weeks or more and acute rhinosinusitis resolves within 10 weeks. Suggest checking the European Position Paper on Sinusitis for definitions. Would also suggest checking this document for risk factors as this is also inaccurate.	Thank you for your comment. The Committee decided to change section 2.5 to clarify the clinical definition for severity of sinusitis.
13	**8.** NHS Professional (Expert Adviser)	**Pg. 3; Sec 1.5**	This section remains confused as it starts with the term chronic sinusitis and then refers to details of acute rhinosinusitis. These two need separating due to above differences in diagnosis.	Thank you for your comment. There is no section 1.5, please see the response to comment 12 for details of how sinusitis is defined in the guidance.
14	**6.** Manufacturer	**Pg. 3-4; Sec 2.4**	“Improved patient comfort and tolerance compared with other balloon technologies because XpreESS allows more control of device	Thank you for your comment The Committee carefully considered this comment

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			placement“ What is the rationale for this statement? The tip of this balloon has two markers of measure, there is no confirmation of proper position of the instrument, except the depth and light shining through the skin. It does not confirm that the tip of the balloon enters the e.g. frontal ostium following the drainage pathway (it can potentially go through the supraorbital cell). Easier to use than other balloon technologies, because XprESS is based on a sinus seeker and no guidewire is needed“ every balloon device looks similar to ostium seeker (it can't be a curette or Blakesley forceps), but it does not guarantee proper placement of the instrument in the sinus ostium. Navigated balloon is the only solution that allows CT confirmation of entering sinus through the natural ostium, particularly in the frontal sinus. XprESS does not have any visualization or landmarks except markers and light. It is not proven superior to NuVent for example in term of feasibility, comfort and lowering the risk of complications. The shape of the seeker is mandatory, but it does not protect from the complications as a value per se. One can penetrate the skull base or orbit by the seeker. Having the navigation makes the seeker useful. More accurate cannulation of the maxillary ostium“ in which way XprESS can make is easier? No rationale or proof delivered.	and decided to make no changes. Section 2.4 simply states the company's claimed benefits for their technology, and is not endorsing them. In the subsequent sections these are evaluated.
15	**8.** NHS Professional (Expert Adviser)	**Pg. 5; Sec 2.4**	same comment about xPress being a tool for fess, not an alternative	Thank you for your comment The Committee carefully considered this comment and decided to make no changes. See response to

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				comment 14.This section simply states the company's claimed benefits for their technology, and is not endorsing them. In the subsequent sections these are evaluated
16	**8.** NHS Professional (Expert Adviser)	**Pg. 7; Sec 3**	Use SNOT-22 not SNOT-20 (SNOT = Sinonasal outcome test)	Thank you for your comment. The Committee carefully considered this comment and decided to make no changes. The use of SNOT-22 and SNOT-20 are as described in the studies presented.
17	**6.** Manufacturer	**Pg. 25; Sec 5.2.7**	Considerations to societal perspective on costs: Analysis of this economic model to consider the productivity losses with delayed time to return to work	Thank you for your comment. The Committee carefully considered this comment and decided to make no changes. The principle economic method used in developing medical technologies guidance is cost consequences analysis, as described in the published methods guide, in which costs are considered from a NHS and personal social service perspective.
18	**6.** Manufacturer	**Pg. 25; Sec 5.2.9**	It is true when considering specific groups of CRS patients (such as no asthma, uncontrolled allergy, cystic fibrosis etc.)	Thank you for your comment. The Committee decided to change section 5.29 to clarify the potential population suitable for XprESS
19	**1.** Private sector professional	**General**	I am a board certified otolaryngologist practicing in the United States. I have been performing in-office balloon sinus dilation with Entellus instruments for almost 4 years. During that time, I have cared for many patients with chronic sinusitis. In my experience balloon sinus dilation is a very effective treatment. Patients tolerate the procedure under local anesthesia and return to work in 1 to 2 days as opposed to 1 to 2 weeks for FESS performed in the operating room. I have had no complications from balloon sinus dilation. There are numerous studies proving the efficacy	Thank you for your comment

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			of balloon sinus dilation. Studies have shown that balloon sinus dilation is as effective as FESS with a quicker recovery and quicker return to work. No further studies are needed to prove this fact. In addition, in-office balloon sinus dilation saves the healthcare system dollars by not paying for a facility fee or anesthesia fee. In summary, balloon sinus dilation is a very effective treatment for patients with chronic sinusitis. Patients appreciate not having to have general anesthesia and the convenience of having an office procedure performed. Patients appreciate improvement in their symptoms with a quicker return to normal activities. And, saving the healthcare system dollars and resources is important as well. Thank you for your time.	
20	**4.** Private Sector Professional	**General**	I am a Board certified otolaryngologist who has performed balloon sinuplasty for over 10 years. I have employed balloon sinuplasty as it has tremendous cost-savings benefit to my patients while maintaining excellent clinical efficacy. The time saved from going under general ensthesia is significant. In the REMODEL paper which I co-authored, the average time off of work was 1.6 days for the balloon treated group and 4.8 days for traditional sinus surgery. It also saves the patient on higher deductible costs as there are marked reductions in facility fees as the patient is having the balloon procedure in the office. There was a significant reduction in the number of future sinusitis episodes from an average of 5 per year to 1 per year. This leads to much less time off of work and reduces antibiotic exposure (resistance). It is for these reasons I have successfully introduced Balloon Sinus Dilation	Thank you for your comment

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			into my practice.	
21	**5.** Private Sector Professional	**General**	I am a board-certified Otolaryngologist that has been performing sinus surgery for 20 years in the US. I recently attended the ERS meeting in Stockholm where I was training UK surgeons and other European ENTs on balloon sinus dilation (BSD). At the meeting, I heard about the draft guidance. Additionally, I presented at the ERS my groups experiences doing standalone balloon dilations in the US under local anesthesia in the office setting. I believe there is solid clinical evidence to support the use of BSD to treat patients with chronic rhino sinusitis and recurrent acute rhino sinusitis, and I agree with the draft recommendation. The clinical studies support the use of the Entellus Medical balloon device to effectively treat sinusitis patients who have failed medical management. Given the weight of the clinical evidence, no further studies should be necessary. Studies have shown that uncomplicated mild to moderately severe CRS can be treated with the balloon only approach. Those with more extensive or complex sinus disease would still require FESS (primarily ethmoidectomy) which would include severe polyps, severe septal deviation, severe pan sinus opacification and aspirin sensitive patients. I have treated over 300 patients with BSD. These patients have had very similar outcomes as the patients in the BSD clinical studies. The mean	Thank you for your comment

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			SNOT-20 scores have had significant improvement (0.7-1.5 reduction) and relapses less than 2%. The Entellus XprESS system is a single, malleable device designed to treat all sinuses with a reshapable tip. It is uniquely suited for the demands of the day case and an awake patient under local for patient comfort and tolerance. Compared to FESS, balloon sinus dilation can be performed under local anesthesia with the avoidance of the possible risks associated with general anesthesia. This approach is much safer than FESS b/c there is less bleeding (therefore better visualization of landmarks) and the patient can give feedback if there is impingement on important structures. BSD under local also provides cost savings compared to FESS in the OR. BSD takes approx 30min or less, whereas FESS is usually over an hour. BSD requires less personnel (usually just one assistant), and is significantly cheaper to perform in an ambulatory setting since no general anesthesia is required and no OR time. In addition, patients return to work or school in less than half the time after BSD compared to FESS. I treat 80% of my sinus patients with BSD under local in the office. Even patients with mild-moderate septal deviation and /or polyps can be managed in this setting with excellent results.	

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
			Patients are observed 30-45min after their procedure and then are released with a family member or friend. They are awake and alert with minimal to no discomfort. I wholeheartedly support the use of BSD to treat sinus patients. I believe it will revolutionize sinus treatment by treating patients soon in their disease pathway. Dr. Claire Hopkins' research has clearly shown that patients treated earlier in the course of their disease process (12mo or less) have a much higher cure rate, with less expenditure of healthcare resources than patients whose treatments are delayed. I believe BSD under local is the perfect approach to reaching patients sooner, for less cost, and better results. Thank you!	