

Medical Technologies Evaluation Programme

MT 288 - The XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis Expert Adviser Questionnaire Responses

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Mr Andrew Swift	Consultant ENT Surgeon & Rhinologist	British Rhinological Society	NICE	Yes
Mr Paul Chatrath	Consultant ENT Surgeon	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)	Sponsor	Yes
Dr Hesham Saleh	Consultant Rhinologist and Facial Plastic Surgeon	British Society for Allergy & Clinical Immunology	Nominated	-
Professor Valerie Lund	Professor of Rhinology	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)	NICE	Yes
Mr Carl Philpott	Consultant ENT Surgeon & Rhinologist	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)	Nominated	-
Mr Rajiv Bhalla	Consultant ENT Surgeon & Rhinologist	British Rhinological Society	NICE	Yes
Mr Atef El-Kholy	Consultant ENT Surgeon	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)	NICE	Yes
Mr John de Carpentier	Consultant Otolaryngologist & Head & Neck Surgeon	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)	NICE	Yes

YOUR PERSONAL EXPERIENCE (IF ANY) WITH THIS TECHNOLOGY

Question 2: Please indicate your experience with this technology?

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Blank	Blank	Blank	Yes
Mr Paul Chatrath Consultant ENT Surgeon	Yes	Blank	Blank	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No	No	Yes	No
Professor Valerie Lund Professor of Rhinology	Yes	No	No	No
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Yes	No	No	No
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	No	No	No	No
Mr Atef El-Kholy Consultant ENT Surgeon	Yes	Blank	Blank	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Yes	No	No	No
<i>Any Comments?</i>				

<p>Mr Andrew Swift Consultant ENT Surgeon & Rhinologist</p>	<p>Worthy of investigating this technique further and introducing it for multicentre clinical trial</p>
<p>Mr Paul Chatrath Consultant ENT Surgeon</p>	<p>Blank</p>
<p>Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon</p>	<p>I have used similar technology previously and have not used this particular device</p>
<p>Professor Valerie Lund Professor of Rhinology</p>	<p>Blank</p>
<p>Mr Carl Philpott Consultant ENT Surgeon and Rhinologist</p>	<p>Blank</p>
<p>Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist</p>	<p>I use other balloon technologies in my practice, not this specific one</p>
<p>Mr Atef El-Kholy Consultant ENT Surgeon</p>	<p>Blank</p>
<p>Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon</p>	<p>Easy to perform under local anaesthetic. Useful to avoid ESS under GA</p>

Question 3: *Have you been involved in any kind of research on this technology? If Yes, please describe?*

Expert Advisers	Yes/No	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	No	Blank
Mr Paul Chatrath Consultant ENT Surgeon	No	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No	Blank
Professor Valerie Lund Professor of Rhinology	No	Blank
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	No	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	No	Blank
Mr Atef El-Kholy Consultant ENT Surgeon	No	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	No	Blank

THIS PRODUCT (TECHNOLOGY) AND ITS USE

Question 4: How would you best describe this technology?

Expert Advisers	It is a minor variation on existing technologies with little potential for different outcomes and impact	It is a significant modification of an existing technology with real potential for different outcomes and impact	It is thoroughly novel - different in concept and/ or design to any existing
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Blank	Yes	Blank
Mr Paul Chatrath Consultant ENT Surgeon	Yes	Blank	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Yes	Blank	Blank
Professor Valerie Lund Professor of Rhinology	No	Blank	Blank
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Yes	Blank	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	No	Yes	No
Mr Atef El-Kholy Consultant ENT Surgeon	Yes	Blank	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Blank	Yes	Blank
<i>Any Comments?</i>			

<p>Mr Andrew Swift Consultant ENT Surgeon & Rhinologist</p>	<p>This is a modification of the existing technique for balloon sinuplasty. The key factors are a finer balloon with a tip that can be re-shaped to aid entry into sinus ostia. A single balloon can be used for the frontal, sphenoid and maxillary sinus. This contrasts with existing balloon technology where a separate balloon is required for each sinus, thus increasing costs.</p>
<p>Mr Paul Chatrath Consultant ENT Surgeon</p>	<p>Blank</p>
<p>Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon</p>	<p>Blank</p>
<p>Professor Valerie Lund Professor of Rhinology</p>	<p>Blank</p>
<p>Mr Carl Philpott Consultant ENT Surgeon and Rhinologist</p>	<p>As Acclarent have now withdrawn from the non-US market, this device will be the main one available in the UK. Ergonomically and practically it is even easier to use than the Acclarent one but I felt it had some limitations for the maxillary sinus. So it is probably a significant modification, but the impact would only be felt by the surgical teams (easier for the nurse assistants).</p>
<p>Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist</p>	<p>Blank</p>
<p>Mr Atef El-Kholy Consultant ENT Surgeon</p>	<p>Blank</p>
<p>Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon</p>	<p>Is a variation on previous balloons. Is a major change to ESS under GA</p>

Question 5: What is the most appropriate use (e.g. clinical indication) for the technology?

Expert Advisers	Comment
<p>Mr Andrew Swift Consultant ENT Surgeon & Rhinologist</p>	<p>Management of rhinosinusitis, including recurrent acute and chronic rhinosinusitis. However, it is likely to be most useful in patients with mild to moderate disease.</p>
<p>Mr Paul Chatrath Consultant ENT Surgeon</p>	<p>In the treatment of patients with chronic rhinosinusitis where medical therapy alone is ineffective.</p>
<p>Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon</p>	<ul style="list-style-type: none"> • Chronic rhinosinusitis that failed maximal medical therapy • Acute rhinosinusitis • Recurrent acute sinusitis • Recurrent sinus barotrauma • Patients with high anaesthetic risk
<p>Professor Valerie Lund Professor of Rhinology</p>	<p>Acute frontal sinusitis, potentially in the outpatient setting, in theatre and in ICU. Although advertised for the sphenoid and maxillary sinuses as well, there is rarely a need for these indications</p>
<p>Mr Carl Philpott Consultant ENT Surgeon and Rhinologist</p>	<p>Patients with mild-moderate CRS or with recurrent ARS. Non-rhinologist ENT surgeons may also find it useful to provide treatment to the frontal sinus.</p>
<p>Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist</p>	<p>Recurrent acute sinusitis, intraorbital cells, completion frontal sinus surgery</p>
<p>Mr Atef El-Kholy Consultant ENT Surgeon</p>	<p>Chronic sinusitis not responding to medical treatment</p>
<p>Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon</p>	<p>For RARS or CRS For revision surgery For frontal disease in particular</p>

COMPARATORS (including both products in current routine use and also “competing products”)

Question 6: *Given what you stated is the appropriate indication (clinical scenario) for its use, what are the most appropriate "comparators" for this technology which are in routine current use in the NHS?*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	The current accepted treatment of rhinosinusitis in patients who have failed to respond to medication alone is endoscopic sinus surgery. This performed mostly under general anaesthesia as an in-patient.
Mr Paul Chatrath Consultant ENT Surgeon	1. Medical therapy alone. 2. Surgery in the form of FESS (Functional Endoscopic Sinus Surgery). 3. Surgery in the form of Balloon Sinuplasty Dilatation (by another system)
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Functional Endoscopic Sinus Surgery (FESS)
Professor Valerie Lund Professor of Rhinology	Standard endoscopic sinus surgery. Historically sinus washout procedures fulfilled the same function though are rarely if ever utilised these days as superceded by endoscopic techniques
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Standard endoscopic sinus surgery instrumentation
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Navigated balloon technology (Medtronic)
Mr Atef El-Kholy Consultant ENT Surgeon	Endoscopic sinus surgery
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Endoscopic sinus surgery

Question 7: "Competing products": Are you aware of any other products which have been introduced with the same purpose as this one?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Initially, Aclarent introduced their balloon sinuplasty device. Now, several companies are introducing their own variations on this procedure. These companies include Medtronic and Smith & Nephew.
Mr Paul Chatrath Consultant ENT Surgeon	Yes. Other balloon sinuplasty systems include by Acclarent, Medtronic and Smith & Nephew
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Acclarent balloons (have just gone out of market), Entrigue balloons, Fentex balloons and Sinusys osmotic dilation device.
Professor Valerie Lund Professor of Rhinology	Acclarent also have a very similar balloon dilation system
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Entrigue also have a balloon device - they are now owned by Smith & Nephew. Other companies have developed devices but as stated above Acclarent will no longer be in the UK market. Medtronic have a balloon for use with their navigation system.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	As (6)
Mr Atef El-Kholy Consultant ENT Surgeon	Similar balloon made by acclarent
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Acclarent system of balloons – no longer available

POSSIBLE BENEFITS FOR PATIENTS

Question 8: *What are the likely additional benefits for patients of using this technology, compared with current practice/comparators?*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Treatment can be done in the 'office' outpatient setting under local anaesthesia
Mr Paul Chatrath Consultant ENT Surgeon	Little difference compared with other balloon systems; less invasive than traditional surgical technique (FESS) with reduced surgical time, fewer surgical risks/complications and possibility of office based procedure under local anaesthetic (LA). No evidence available comparing balloon systems with medical therapy although previous studies comparing traditional surgery (FESS) with medical therapy showed similar outcomes. Also possibility of treating the frontal sinus more effectively than traditional surgical techniques
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Seems to be moderately easier to use when compared to other balloon devices.
Professor Valerie Lund Professor of Rhinology	May be undertaken under local as well and general anaesthesia. If used alone, it is theoretically a shorter procedure but often used in combination with standard ESS as a so-called 'hybrid' so advantage negligible
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Key advantages are - can be performed in clinic under LA and may enable a non-subspecialist ENT surgeon to treat the frontal sinus rather than not at all
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Perhaps an opportunity to downscale the extent of sinus surgery. Potential for outpatient surgery
Mr Atef El-Kholy Consultant ENT Surgeon	Safer less invasive, less trauma less bleeding, could be performed under local Anaesthesia. Less time in theatre and quick recovery as patient can return to work within 24hours compared to two week off sick with traditional surgery . the procedure could be done in outpatient setting which will be more cost effective

Expert Advisers	Comment
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Local anaesthetic sinus surgery No need to occupy hospital beds Faster surgery

Question 8.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
<p>Mr Andrew Swift Consultant ENT Surgeon & Rhinologist</p>	<p>Yes, the above benefit is attainable if the procedure is shown to be effective. Obstacles will include finding dedicated time to do the procedure in outpatient clinics and also convincing colleagues that this is as effective as the established technique of endoscopic sinus surgery. The outpatient setting will need to be appropriate and supported by nursing staff trained in the technique.</p>
<p>Mr Paul Chatrath Consultant ENT Surgeon</p>	<p>Additional benefits over traditional surgery with respect to reduced surgical time and reduced risks/complications are realistic and likely to be realised, as they have been with other available balloon systems eg. Acclarent. Benefits with respect to more procedures being undertaken under LA has not been fully realised even for existing balloon systems - suggested reasons for this include difficulties/costs in setting up an office based LA service in the UK NHS system compared with the US. Therefore this benefit with respect to the current system under evaluation cannot be accurately predicted.</p>
<p>Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon</p>	<p>Price</p>
<p>Professor Valerie Lund Professor of Rhinology</p>	<p>Potentially less bleeding is a benefit but main obstacle is cost</p>
<p>Mr Carl Philpott Consultant ENT Surgeon and Rhinologist</p>	<p>Tariffs and local units being set up and willing to embrace it in an ambulatory care setting.</p>
<p>Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist</p>	<p>Yes. Cost.</p>
<p>Mr Atef El-Kholy Consultant ENT Surgeon</p>	<p>Yes</p>
<p>Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon</p>	<p>Yes. Reluctance to change by surgeons with vested interests</p>

Question 8.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for patients are being realised?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Benefits measured by reduced need for hospital admission and surgery, reduced waiting time to treatment, effect on symptoms as assessed by PROMS and VAS, reduced need for medication for sinusitis.
Mr Paul Chatrath Consultant ENT Surgeon	Risks: reported to Trust Clinical Governance Departments and onwards to NPSA. Reduced theatre time: by reference to theatre databases. Rhinological outcome measures and PROMs including SNOT-22 and/or NOSE scale; also Lund-Mackay scoring system for severity of CT scan findings (although with the latter, few postoperative CT scans are performed in the UK as benefit tends to be judged clinically)
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No direct benefits apart from ease of use in my opinion.
Professor Valerie Lund Professor of Rhinology	As there are few problems with standard FESS, the usual outcomes such as SNOT22 QoL questionnaires are unlikely to show any difference. Similarly as most FESS is done as a daycase, there is little advantage from any time saving
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Outcomes in CRS best measured with SNOT-22 and the need for further intervention. Also look at how many cases can be done in an outpatient setting which theoretically should be a cost-saving measure.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Symptom reporting. Further surgery unnecessary
Mr Atef El-Kholy Consultant ENT Surgeon	Balloon surgery is well established and many research has confirmed the benefits

Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Prospective audit
--------------------------------------------------------------------------------------	--------------------------

Question 8.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	I have not done a full literature review but I am not aware that the existing evidence is substantial at present. I would anticipate that most reports would be from surgeons treating mild to moderate chronic rhinosinusitis rather than the more complex patients that present to tertiary referral centres.
Mr Paul Chatrath Consultant ENT Surgeon	Evidence for reduced surgical complications and reduced surgical time exists for currently available balloon systems such as Acclarent balloon; I am unsure as to whether a similar level of evidence exists for the XPress system.
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	N/A
Professor Valerie Lund Professor of Rhinology	Poor
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Early papers claim outcomes from balloon sinuplasty are as good as ESS but the extent of the latter can be hugely variable.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Increasing body of evidence for benefit
Mr Atef El-Kholy Consultant ENT Surgeon	Level 1

Expert Advisers	Comment
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	No level 1 evidence

Question 8.4: Please add any further comment on the claimed benefits of the technology to patients, as you see applicable

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Blank
Mr Paul Chatrath Consultant ENT Surgeon	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	The device seems to have a better design than other similar devices which will possibly help to shorten the operating time and allow more use of local anaesthesia
Professor Valerie Lund Professor of Rhinology	These devices have a limited and rather specific indication for isolated sinus infection. However, the technology has been promoted to deal with all forms of sinus inflammation and it is my understanding that these claims are now the subject of litigation in the USA.
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Shorter (or no) anaesthetic. Shorter time in hospital. Smaller surgical intervention
Mr Atef El-Kholy Consultant ENT Surgeon	Blank

Mr John de Carpentier
Consultant Otolaryngologist & Head
& Neck Surgeon

Makes frontal sinus surgery much more safe, quick with minimal variability

POSSIBLE BENEFITS FOR THE HEALTHCARE SYSTEM

Question 9: *What are the likely additional benefits for the healthcare system of using this technology, compared with current practice/ comparators?*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Reduced need for hospital admission for surgical procedure for sinusitis
Mr Paul Chatrath Consultant ENT Surgeon	Reduced surgical time; reduced surgical complications and therefore need for secondary surgical procedures and/or readmissions; earlier more effective treatment of patients;
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	As 8.4
Professor Valerie Lund Professor of Rhinology	None
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	See comments above
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Shorter time in hospital. Less dependence on general anaesthesia as practitioner becomes more skilled
Mr Atef El-Kholy Consultant ENT Surgeon	Cost effective to the trusts will help to reduce the waiting list for surgery
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Cost saving

Question 9.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
<p>Mr Andrew Swift Consultant ENT Surgeon & Rhinologist</p>	<p>Yes, but only if sufficient numbers of patients undergo this procedure rather than endoscopic sinus surgery as an in-patient. Main obstacle will be setting up the service within an outpatient setting. The technique will also require time, so only a small number of patients would be expected to undergo treatment during a single clinic.</p>
<p>Mr Paul Chatrath Consultant ENT Surgeon</p>	<p>Additional benefits over traditional surgery with respect to reduced surgical time and reduced risks/complications are realistic and likely to be realised, as they have been with other available balloon systems eg. Acclarent. Earlier more effective treatment of patients is more difficult to prove as it relies upon engagement with primary care although given the minimally invasive nature of balloon systems it is likely that they will be used earlier in a patient's management pathway. This might entail, at least initially, an additional cost to CCGs</p>
<p>Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon</p>	<p>Price</p>
<p>Professor Valerie Lund Professor of Rhinology</p>	<p>No because the principle indications are limited and in most cases the device will be used in addition to conventional surgery, thus increasing costs.</p>
<p>Mr Carl Philpott Consultant ENT Surgeon and Rhinologist</p>	<p>Blank</p>
<p>Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist</p>	<p>Yes. Cost</p>
<p>Mr Atef El-Kholy Consultant ENT Surgeon</p>	<p>Yes</p>
<p>Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon</p>	<p>Yes</p>

Question 9.2: *How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for the healthcare system are being realised?*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Reduced waiting list for inpatient treatment, reduced need for medication for sinusitis
Mr Paul Chatrath Consultant ENT Surgeon	Risks: reported to Trust Clinical Governance Departments and onwards to NPSA. Reduced theatre time: by reference to theatre databases. Rhinological outcome measures and PROMs including SNOT-22 and/or NOSE scale; also Lund-Mackay scoring system for severity of CT scan findings (although with the latter, few postoperative CT scans are performed in the UK as benefit tends to be judged clinically)
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Clinical trials to compare to other devices and FESS using objective measures such as SNOT 22
Professor Valerie Lund Professor of Rhinology	N/A
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Patient reported outcome measure. Visual analogue score. Reduce dependence on operating room.
Mr Atef El-Kholy Consultant ENT Surgeon	There are proven business studies
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Time in hospital bed (costed) Time in theatre (costed)

Question 9.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Limited as far as I am aware
Mr Paul Chatrath Consultant ENT Surgeon	Evidence for reduced surgical complications and reduced surgical time exists for currently available balloon systems such as Acclarent balloon; I am unsure as to whether a similar level of evidence exists for the XPress system.
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No evidence yet
Professor Valerie Lund Professor of Rhinology	None
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Good
Mr Atef El-Kholy Consultant ENT Surgeon	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Will need to be collected

Question 9.4: Please add any further comment on the claimed benefits of the technology to the healthcare system, as you see applicable

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Colleagues treating rhinosinusitis by endoscopic sinus surgery would need to be convinced that the EXprESS device offered an effective alternative. This would also depend on the type of patients being seen in their clinics. The patients seen in tertiary rhinology clinics are likely to have difficult to treat advanced disease and complex associated medical problems, better treated by formal surgical procedures rather than balloon dilatation techniques.
Mr Paul Chatrath Consultant ENT Surgeon	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Blank
Professor Valerie Lund Professor of Rhinology	Blank
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Blank
Mr Atef El-Kholy Consultant ENT Surgeon	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Safer, faster, reduced time off work

FACILITIES, TRAINING AND FUNCTIONING

Question 10: *Are there any particular facilities or infrastructure which needs to be in place for the safe and effective use of this technology?*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Yes - a dedicated outpatient clinic with nursing assistance will be required
Mr Paul Chatrath Consultant ENT Surgeon	Training for surgeons unfamiliar with the use of balloon sinuplasty systems. Also onsite training for theatre nursing staff although current technology of Xpress system is very straightforward and is almost useable 'out of the box'
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No more than what is normally available in a standard NHS practice
Professor Valerie Lund Professor of Rhinology	Training of surgeons and nursing staff, usually offered by the commercial company
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Entellus have been running cadaveric training workshops and also provide local rep support.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Training day. Assigned mentor would be helpful
Mr Atef El-Kholy Consultant ENT Surgeon	The same facilities which are used for endoscopic sinus Surgery will be used
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Blank

Question 11: Is special training required to use this technology safely and effectively?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	yes - surgeon plus any nurses who will assist
Mr Paul Chatrath Consultant ENT Surgeon	Surgeons familiar with balloon sinuplasty systems in general are likely to require only minimal familiarisation with the new system. Surgeons unfamiliar with balloon systems at all ought to undertake a formal training course in balloon sinuplasty or a sinonasal training course at which balloon sinuplasty is taught as part of the course curriculum.
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	yes
Professor Valerie Lund Professor of Rhinology	Yes
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	It is a fairly simple device to use, so minimal training needed if familiar with endoscopic interventions.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	As (10)
Mr Atef El-Kholy Consultant ENT Surgeon	Training to use the balloon
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Yes

Question 12: *Please comment on any issues relating to the functioning, reliability and maintenance of this technology which may be important to consider if it is introduced*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	I am not aware of any problems
Mr Paul Chatrath Consultant ENT Surgeon	Simple to use. Requires no maintenance as is single use. Few problems if any with reliability.
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	The device is disposable
Professor Valerie Lund Professor of Rhinology	No specific issues though some complications have been reported similar to those seen with conventional FESS eg CSF leak
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	As far as I'm aware this is a single use device
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Have not used myself
Mr Atef El-Kholy Consultant ENT Surgeon	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Have never had one fail

COSTS

Question 13: *Please provide any comments on the likely cost consequences of introducing this technology. In particular, please comment on the implications of this technology replacing the comparator/s you have described above*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Not known but it is likely that it would be much cheaper than admitting patients for sinus surgery
Mr Paul Chatrath Consultant ENT Surgeon	Additional cost required compared with medical therapy alone or traditional surgical techniques (FESS). However Xpress system appears to be cheaper than Acclarent system, although the latter are due to leave the UK market soon
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Price is equivalent to other balloons as far as I understand
Professor Valerie Lund Professor of Rhinology	See 9.1
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	The cost needs to be outweighed by setting the right tariff in the OPD.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Could reduce dependence on operating theatre if these straightforward applications could be performed under local anaesthetic
Mr Atef El-Kholy Consultant ENT Surgeon	The cost of the balloon kit will be outweighed by saving in theatre time and staff time and saving on general anaesthesia
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Device will pay for itself by reduced theatre time/ hospital bed etc.

GENERAL ADVICE BASED ON YOUR SPECIALIST KNOWLEDGE

Question 14: Is there controversy about any aspect of this technology or about the care pathway?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Effectiveness and place in the management of chronic rhinosinusitis is unknown. It is unlikely to replace the need for endoscopic sinus surgery in many patients with more advanced disease as seen in dedicated tertiary referral centres
Mr Paul Chatrath Consultant ENT Surgeon	None of which I am aware
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Some surgeons do not believe in using balloons and the evidence comparing them to FESS is weak. Additionally, balloons cannot be used in the thmoid sinuses
Professor Valerie Lund Professor of Rhinology	Yes
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Uptake of this technology in the UK has been lukewarm - in part due to the cost of the devices per case (£800 per patient with Acclarent system). Many patients with CRS are referred late by their GPs and so the scope for this intervention seems limited currently, however if patients were referred earlier according to ENT UK guidelines, perhaps there may be a greater role for this technology in the OPD.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	No
Mr Atef El-Kholy Consultant ENT Surgeon	No it is a tool to be used for treatment of sinus disease
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Yes, there is a reluctance by some surgeons to adopt this technology

Question 15: If NICE were to develop guidance on this technology, how useful would this be to you and your colleagues?

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	May be useful but this will depend on the patient cohort. If patients present with advanced disease then the use may be quite limited. Mild to moderate sinusitis may be more amenable to this form of therapy.
Mr Paul Chatrath Consultant ENT Surgeon	Very helpful indeed, not least in encouraging NHS Trusts to consider taking on the technology
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Useful
Professor Valerie Lund Professor of Rhinology	It would depend particularly as the UK ENT community were extremely surprised when NICE previously supported the use of similar technology (IPG273) in 2008 (which I presume is still in force) at a time when they were being subjected to an aggressive marketing campaign by the commercial company concerned.
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	I think it would be helpful to provide guidance to clinicians on this. Balloon sinuplasty kit should be seen as another sinus tool rather than a distinct separate procedure.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Very useful
Mr Atef El-Kholy Consultant ENT Surgeon	Very
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Very useful to ENT population as a whole

Question 16: *Do any subgroups of patients need special consideration in relation to the technology (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)? Please explain why*

Expert Advisers	Comment
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	The EXprESS system may have a place in the management of patients with difficult to treat chronic rhinosinusitis who are also a high anaesthetic risk
Mr Paul Chatrath Consultant ENT Surgeon	All of the above might necessitate a simpler shorter and less invasive procedure such as is possible with balloon systems in general. Also balloon systems allow for the possibility of office based procedure under LA
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	should not be used in patients with polyps, cystic fibrosis, fungal sinusitis and significant osteitis
Professor Valerie Lund Professor of Rhinology	Not as such but might be used in patients whose co-morbidities make a GA unsafe
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Patients with more advanced CRS, especially with CRSwNPs are probably less likely to benefit from these devices being used.
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Technology should not be applied to advanced or complex sinus disease, as revision rate and costs would both be high
Mr Atef El-Kholy Consultant ENT Surgeon	it much safer and easier to use as it can be done under local anaesthesia
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	N/A

CONFLICTS OF INTEREST

Question 18.1: Do you or a member of your family have a personal financial interest? The main examples are as follows:

Expert Advisers	Consultancies or directorships	Clinicians receiving payment for a procedure	Fee-paid work	Shareholdings	Financial interest in a company's product	Expenses and hospitality	Funds	Personal non-pecuniary interest
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	No	No	No	No	No	No	No	No
Mr Paul Chatrath Consultant ENT Surgeon	No	No	No	No	No	No	No	No
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Yes	No	No	No	No	No	No	Yes
Professor Valerie Lund Professor of Rhinology	No	No	Yes	No	No	No	No	Yes
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	Yes	No	No	No	No	No	No	Yes
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	Yes	Yes	Yes	No	Yes	No	No	No
Mr Atef El-Kholy Consultant ENT Surgeon	No	No	No	No	No	No	No	No

Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Yes	No	No	No	No	No	No	Yes
<i>If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.</i>								
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Blank							
Mr Paul Chatrath Consultant ENT Surgeon	Have received hospitality from another balloon manufacturer (NOT Xpress) over 12 months ago							
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	I have acted as a paid consultant for Sinusys that produces the vent-os osmotic sinus dilation system							
Professor Valerie Lund Professor of Rhinology	I have given lectures sponsored by the pharmaceutical sector I have undertaken trials on medical and surgical treatments for CRS I am a co-chairman of EPOS and Honorary Editor of 'Rhinology'							
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	See separate document							
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	I deliver training days (sinus and balloon) for Medtronic and receive honoraria for these							
Mr Atef El-Kholy Consultant ENT Surgeon	Blank							
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	One letter published in response to a very poor paper on balloons. I have in the past been an instructor in balloon course run by another company							

Question 18.2: Do you have a non-personal interest? The main examples are as follows:

Expert Advisers	Grant for the running of a unit	Grant or fellowship for a post or member of staff	Commissioning of research	Contracts with or grants from NICE
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	No	No	No	No
Mr Paul Chatrath Consultant ENT Surgeon	No	No	No	No
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No	No	No	No
Professor Valerie Lund Professor of Rhinology	No	No	No	No
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	No	Yes	Yes	No
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	No	No	No	No
Mr Atef El-Kholy Consultant ENT Surgeon	No	No	No	No
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	No	No	No	No
<i>If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.</i>				

Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	Blank
Mr Paul Chatrath Consultant ENT Surgeon	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	Blank
Professor Valerie Lund Professor of Rhinology	Blank
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	NIHR funded research in CRS and advisory role to Cochrane/NIHR review of CRS studies
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	n/a
Mr Atef El-Kholy Consultant ENT Surgeon	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	Blank

Question 18.3: Do you or your organisation or department have any links with, or funding from the tobacco industry?

Expert Advisers	Yes or No?	<i>If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.</i>
Mr Andrew Swift Consultant ENT Surgeon & Rhinologist	No	Blank
Mr Paul Chatrath Consultant ENT Surgeon	No	Blank
Dr Hesham Saleh Consultant Rhinologist and Facial Plastic Surgeon	No	Blank
Professor Valerie Lund Professor of Rhinology	No	Blank
Mr Carl Philpott Consultant ENT Surgeon and Rhinologist	No	Blank
Mr Rajiv Bhalla Consultant ENT Surgeon & Rhinologist	No	n/a
Mr Atef El-Kholy Consultant ENT Surgeon	No	Blank
Mr John de Carpentier Consultant Otolaryngologist & Head & Neck Surgeon	No	Blank