NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

The XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis

1 Technology

1.1 Description of the technology

The XprESS multi-sinus dilation system (MSDS) is a sterile, single-use device for treating chronic rhinosinusitis. The system comprises a balloon-tipped device with a re-shapeable end that is inserted through the nose into the maxillary, frontal or sphenoidal sinuses. The XprESS MSDS also includes an inflation syringe, bending tool and 2 extension lines to provide irrigation. The balloon is manipulated into the bony sinus outflow tracts (ostia) and inflated with saline to dilate and remodel them by displacing adjacent bone and paranasal sinus structures. This allows the sinuses to drain more effectively. The XprESS MSDS comes in 3 variants, the XprESS Ultra, LoProfile and Pro. These differ in the dimensions of the suction tip and the balloon diameter and length; selection is based on clinician preference. The XprESS device, inflation syringe and bending tool are included in all variants. The Ultra and LoProfile (the version sold in the UK) systems also include an integrated PathAssist LED light fibre, which is available as an add-on for the Pro. The XprESS procedure can be performed under local anaesthesia, once the surgeon has had sufficient experience of using the device.

1.2 Regulatory status

The XprESS Multi-Sinus Dilation System first received a CE mark in October 2010 for the treatment of chronic rhinosinusitis.

1.3 Claimed benefits

The benefits to patients claimed by the company are:

- A minimally invasive alternative to functional endoscopic sinus surgery (FESS) with equivalent efficacy but greater preservation of sinus tissue and mucosa with minimal acute inflammation
- Reduction in risks associated with general anaesthesia since the procedure can be undertaken under local anaesthesia
- Faster recovery time with less nasal bleeding and shorter duration of analgesic medication compared to FESS
- Improved patient comfort and tolerance compared with other balloon technologies, since XprESS allows more control of device placement, has a smaller profile, a malleable tip, and does not include a guidewire
- More accurate cannulation of the maxillary ostium compared to other balloon technologies.

The benefits to the healthcare system claimed by the company are:

- Reduction in theatre time compared to FESS
- Reduction in staff numbers since the XprESS procedure can be done in a day surgery setting under local anaesthesia rather than a main operating theatre under general anaesthesia
- Reduction in length of stay
- Reduction in duration of analgesic medication
- Reduction in post-operative nasal bleeding visits
- Reduction in hospital readmissions
- Ease of use versus other balloon technologies since no guidewire is needed.

The sustainability benefits claimed by the company are:

- Improved resource utilisation due to a quicker procedure time and fewer complications
- Reduction in components and packaging waste due to ability to treat all sinus types with a single device.

1.4 Relevant diseases and conditions

The XprESS Multi-Sinus Dilation System is intended for use in patients 2 years and older with chronic rhinosinusitis, including recurrent acute rhinosinusitis, for who all medical therapy options have failed. For children, the device is intended to access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach.

Rhinosinusitis occurs when the lining of the sinuses (mucosa) becomes infected or inflamed. Under these circumstances, there is mucosal swelling and an increase in mucus production. Mucosal swelling may interfere with sinus drainage, leading to mucus accumulation and a risk of secondary infection.

Chronic rhinosinusitis refers to a condition that lasts at least 12 weeks despite treatment and is associated with at least 2 of the following symptoms: nasal congestion; mucus discharge from the nose or mucus drip into the back of the throat; facial pain, pressure, or a feeling of 'fullness'; or a decreased sense of smell. It may be associated with the presence or absence of nasal polyps. Acute rhinosinusitis refers to a short-lived condition that resolves within 12 weeks, and which often occurs following upper respiratory tract infection[1,2]. Recurrent acute rhinosinusitis (RARS) is a type of chronic rhinosinusitis that is defined as 4 or more episodes of acute rhinosinusitis in a single year. Chronic rhinosinusitis is usually a local and uncomplicated condition. It may, however, in a minority of cases be complicated by local spread leading to orbital or intracranial infection (including abscess formation) or inflammation.

Chronic rhinosinusitis is a common condition that is estimated to affect 10% of the UK adult population. It occurs in all age, gender and ethnic groups, and is reported to be increasing in prevalence. Acute sinusitis is more common in adults than in children whose sinuses are not yet fully developed. Individuals

[1] Patient information: Chronic rhinosinusitis (Beyond the Basics)
[2] ENTUK Commissioning guide: Rhinosinusitis (2013)

who suffer from allergy, diabetes or have a history of previous sinusitis have a greater risk of developing this condition.

1.5 Current management

Current treatment options for chronic rhinosinusitis include: nasal saline irrigation; intranasal corticosteroids; systemic antibiotics or topical drops; or FESS.

NICE has produced a clinical knowledge summary on the management of chronic sinusitis (2013) for people presenting in primary care. The summary describes measures to relieve symptoms, particularly for acute episodes, including the use of analgesics for pain or fever, the occasional use of intranasal decongestants and intranasal saline irrigation, and the application of warm face packs. Advice to patients about the management of associated disorders, such as allergic rhinitis, asthma, or dental infection should be offered along with advice on smoking cessation and dental hygiene, where appropriate. A short course of antibiotics may be prescribed for acute episodes, but longer-term courses are not recommended without seeking specialist advice. A course of intranasal corticosteroids may be considered, for up to 3 months, especially if there is a suspicion of an allergic cause (such as concomitant allergic rhinitis).

Hospital admission should be arranged if sinusitis is associated with a severe systemic infection, or a serious complication such as orbital or intracranial infection or inflammation.

Referral to an ear, nose, and throat (ENT) specialist should be considered for people with frequent recurrent episodes of troublesome acute sinusitis (for example more than 3 episodes requiring antibiotics in a year); unremitting or progressive facial pain (urgent referral for suspected malignancy); nasal polyps which are causing significant nasal obstruction, or if a person has received intranasal corticosteroids for 3 months without effect.

FESS is currently the conventional mode of surgery undertaken by ENT surgeons for persistent and severe cases of chronic rhinosinusitis[3]. In a FESS procedure, the surgeon uses a magnifying endoscope introduced through the nostrils to identify and remove affected sinus tissue and bone. The aim is to clear the obstructed ostia and flush out infected material, but retain sufficient healthy tissue for normal nose and sinus function. A FESS procedure is usually performed under general anaesthesia, but can also be done under local anaesthesia in selected cases[4]. However, scarring and adhesions can occur as a result of FESS, which may limit the patency of the sinus ostial opening and require post-operative removal of tissue, blood and bone (debridement). Other more serious risks occasionally associated with FESS, include intraorbital and intracranial complications

NICE interventional procedure guidance on balloon catheter dilation of paranasal sinus ostia for chronic sinusitis (2008) concluded that the current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raised no major safety concerns. This guidance stated the procedure could be done with normal arrangements in place for clinical governance, consent and audit, and by surgeons with appropriate experience of complex sinus surgery, and specific training in the procedure and the use of fluoroscopy.

2 Reasons for developing guidance on the XprESS multi-sinus dilation system for the treatment of chronic rhinosinusitis

The Committee considered that the XprESS multi-sinus dilation system may offer benefits to patients and the healthcare system when used in selected individuals with chronic rhinosinusitis who would otherwise require FESS.

The Committee was advised that the XprESS system is most suitable for use in patients with uncomplicated sinusitis (especially in the frontal sinuses), and

[3] Lawrence, K et al. (2012) Management of chronic rhinosinusitis. BMJ 345:e7054
[4] ENT UK (2015) – About Functional Endoscopic Sinus Surgery (FESS)

without nasal polyps. It considered that attention to patient subgroups such as these would be an important aspect of the evaluation.

The Committee was advised that adoption of this technology would require significant service redesign, because patients currently treated under general anaesthetic in operating theatres would instead be able to undergo treatment in an ambulatory care setting under local anaesthetic. These facilities would therefore need to be made available to ENT surgeons wishing to use the XprESS system, if adoption of this technology was supported.

3 Statement of the decision problem

	Scope issued by NICE
Population	People with chronic rhinosinusitis, including recurrent acute rhinosinusitis, in whom all medical therapy has failed.
Intervention	The XprESS Multi-Sinus Dilation System
Comparator(s)	• Functional endoscopic sinus surgery (FESS) • Other balloon sinus dilation systems available in the NHS (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: *Patient outcomes:* • Change in rhinosinusitis symptoms (Sinus nasal outcome test [SNOT version 20 or 22] or rhinosinusitis symptom inventory [RSI]) • Number of post-procedure rhinosinusitis episodes requiring medication • Number of post-operative debridements • Change in ostial patency (assessment of sinus drainage pathway patency by endoscopy or CT scan) • Duration of analgesic medication • Patient-reported tolerance of the procedure and/or patient reported severity of pain scale • Number and types of sinus treated *Health care system outcomes:* • Length of hospital stay • Procedure time and theatre/outpatient treatment room time • Success rates of maxillary sinus ostial cannulation • Rate of revision surgery • Number of sinus-related follow-up appointments • Rate of readmission • Numbers and grade of staff required *Adverse effects* • Rate, and severity, of nasal bleeding • Device-related adverse events
Cost analysis	Comparator(s): Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different staff, treatment facilities (hospital theatre vs. day-case), and methods of anaesthesia are needed.
Subgroups to be considered	• Patients with uncomplicated chronic rhinosinusitis (or uncomplicated recurrent acute rhinosinusitis)

	• Patients with chronic rhinosinusitis (or recurrent acute rhinosinusitis), with orbital or intracranial involvement • Patients with chronic rhinosinusitis (or recurrent acute rhinosinusitis) with and without nasal polyps • Patients with chronic rhinosinusitis (or recurrent acute rhinosinusitis) affecting the anterior ethmoid sinus in addition to maxillary, frontal or sphenoid sinus disease • Patients with anatomic variants such as septal deviations and accessory ostia • Children and young people under 18 years of age	
Special considerations, including those related to equality	No equality issues have been identified. The XprESS MSDS may be a suitable alternative to FESS for patients who are unable or unwilling to tolerate general anaesthetic	
Special considerations, specifically related to equality issues		
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- Respiratory tract infections – antibiotic prescribing: Prescribing of antibiotics for self-limiting respiratory tract infections in adults and children in primary care. NICE guideline [CG69] (2008). Available from www.nice.org.uk/guidance/CG69
- Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. NICE interventional procedure guidance 273 (2008). Available from www.nice.org.uk/guidance/IPG273

- Powered microdebrider turbinoplasty for inferior turbinate hypertrophy. NICE interventional procedures guidance 498 (2014). Available from www.nice.org.uk/guidance/IPG498
- Radiofrequency tissue reduction for turbinate hypertrophy. NICE interventional procedures guidance 495 (2014). Available from www.nice.org.uk/guidance/IPG495
- Insertion of customised titanium implants, with soft tissue cover, for orofacial reconstruction. NICE interventional procedures guidance 449 (2013). Available from www.nice.org.uk/guidance/IPG449.
- Suction diathermy adenoidectomy. NICE interventional procedures guidance 328 (2009). Available from www.nice.org.uk/guidance/IPG328.

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- None identified.

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)
- British Rhinological Society
- British Society for Allergy & Clinical Immunology
- Royal College of Physicians
- Royal College of General Practitioners.

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)
- British Rhinological Society
- British Society for Allergy & Clinical Immunology
- Royal College of Physicians
- Royal College of General Practitioners.

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Action Against Allergy (AAA)
- Allergy Alliance
- Allergy UK
- Asthma Relief Charity
- Asthma UK
- Asthma, Allergy and Inflammation Research Trust
- British Lung Foundation
- Fungal Infection Trust.