National Institute for Health and Care Excellence

IP963 Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis Consultation Comments table

IPAC date: Friday 15 January

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1.1**	Agree Special Arrangements. The guidance does concede that there is evidence of improved sinus patency in the short term but seeks evidence of consequent patient benefit. This may well be challenged, as a patent (therefore functioning?) drainage hole is the whole basis of how Functional Endoscopic Sinus Surgery (FESS) has evolved. Latterly, there is much evidence that FESS is indeed associated with benefits to quality of life on validated symptom scores, but controlled studies are sparse. Increased benefit from this technique should logically follow if patency is enhanced, but that has not been shown in clinical studies.	Thank you for your comment.
2	Consultee 1 NHS Professional	**1.1**	There is a paper which, at first glance seems to offer everything that is being sought by you. (Han JK et al 2014 Int Forum Allergy Rhinology). It is an RCT, it does offer between patient comparison, it does look at patient benefit as well as observer scores. The Cochrane review rejected it and the team have not included it (wisely) as it is looking at office insertion...it is not part of FESS surgery. It involved sticking this or a sham device up the nose of polyp sufferers, with no other intervention (all had had earlier FESS it seems). I only mention this in case it emerges in consultation, as it did actually show benefit in a well designed controlled study. It might appear in the appendix with an explanation as to its irrelevancy at most?	Thank you for your comment. The cited paper was identified in the literature search. It was not included in the overview because it does not fit the remit – patients were not treated as part of endoscopic sinus surgery. Appendix A of the overview includes papers that meet the inclusion criteria but are less informative than those described in table 2. Excluded papers are not listed.

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3	Consultee 1 NHS Professional	**1.3**	This is of course what the Cochrane Review called for. It is ambitious in seeking a level of evidence not easily obtained. Within patient comparisons of patency are easily achieved. Randomising patients, ensuring matched disease states and co-morbidities, is far more challenging but perfectly feasible.	Thank you for your comment.
4	Consultee 1 NHS Professional	**2.2**	For clarity, final sentence. Such packing may be soaked or impregnated with any drug, but that is not the sustained slow release of â€œdrug elutionâ€• . Unless an issue at consultation, I do not feel this requires any rewording however.	Thank you for your comment.
5	Consultee 1 NHS Professional	**3.1**	â€œSeveralâ€• may be challenged. Two to three is correct but I fully appreciate the difficulties in such wording.	Thank you for your comment. Section 3.1 of the guidance has been changed.
6	Consultee 1 NHS Professional	**5.5**	Whilst appreciating the systemic risks of steroid therapy, only minute doses are employed in this pattern of stent. I do appreciate this is quoting what you were advised, however. Again, only if an issue raised at consultation, possibly 3.1 could read â€œaims to deliver a low dose of topical corticosteroid.....â€• ?	Thank you for your comment. Section 5.5 describes theoretical adverse events that were listed by Specialist Advisers.

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7	Consultee 1 NHS Professional	**General**	I note that there is no committee comment here. Steroid elution may convey added benefit to plain stenting and, if that is ever demonstrated, then the procedure is logically proved to be more effective than no stent (unless plain stenting is damaging to outcomes). The committee was advised (and literature search may have revealed) that there is actually no high level evidence for simple stenting, as conveying any advantage in FESS. 3.1 does call for research and, possibly, is wise in not being too specific. Dose this merit a cttee comment however? Stenting =/> no stenting Drug eluting stent>plain stent Ergo Drug eluting stent>no stent Unless the stent elicits a tissue reaction and worsens outcomes of course! No evidence for that however.	Thank you for your comment. Section 1.3 of the guidance states that NICE encourages further research on this procedure.

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8	Consultee 2 Company Healthcare Other	**Title**	We suggest that the title of the guidance would be more accurate and more comprehensive if the word â€˜implantâ€™ were added, thus (for example): â€˜Corticosteroid-eluting bioabsorbable implant, stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitisâ€™. Compatible wording should be applied throughout the document where the phrase â€˜bioabsorbable stent or spacerâ€™ appears in the draft. Some of the products used in this procedure are designed to remain in the body for more than 30 days, which defines them for regulatory purposes in the EU as â€˜implantable devicesâ€™ (defined as â€˜Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 daysâ€™ [Medical Devices: guidance document. Classification of medical devices. Guidelines relating to the application of the Council Directive 93/42/EEC on medical devices. EC DG Health and Consumer. MEDDEV 2.4/1 Rev. 9 June 2010].	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

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9	Consultee 2 Company Healthcare Other	**3.1**	Some functional endoscopic sinus surgery can be performed under local anaesthesia. [Sikand A. Introduction to an office-based sinus surgery technique. Ashley Sikand, MD, FACS September 2011 Volume 22, Issue 3, Pages 246â€“252; Sillers MJ, Melroy CT. In-office functional endoscopic sinus surgery for chronic rhinosinusitis utilizing balloon catheter dilation technology. Curr Opin Otolaryngol Head Neck Surg. 2013 Feb;21(1):17-22. Slack R, Bates G. Functional Endoscopic Sinus Surgery. Am Fam Physician. 1998 Sep 1;58(3):707-718.] We therefore propose the statement â€˜It is done with the patient under general anaesthesia during functionalâ€¦â€™ be reworded to â€˜It is usually done with the patient under local or general anaesthesia during functionalâ€¦â€™	Thank you for your comment. Section 3.1 of the guidance has been changed.
10	Consultee 2 Company Healthcare Other	**3.1**	We suggest that the words â€˜The stent dissolves over several weeksâ€™, which only applies to one of the products included in the overview, is amended to â€˜Implants deliver drugs and dissolve over 30 days or longer, whereas stents and spacers dissolve over a much shorter period of time, generally less than seven days The implanted material releases steroid over this period post-operatively and is either removed or dissolves over a varying period of time.â€™ This more accurately describes the procedure.	Thank you for your comment. Section 3.1 of the guidance has been changed.
11	Consultee 2 Company Healthcare Other	**3.1**	We suggest that the words â€˜inserted into the ostium under endoscopic guidanceâ€™ are amended to â€˜inserted into the sinus under endoscopic guidanceâ€™. This more accurately describes the procedure.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

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12	Consultee 2 Company Healthcare Other	**5.5**	We understand the intent of involving input from Specialist Advisers in the development of IP guidance. However, we suggest that while this may be useful in alerting the Committee to adverse events and other factors which may assist an evidence review, it is not useful to include exhaustive lists of theoretically possible adverse events in the guidance document itself. The Committee is aware that â€œadverse eventâ€• has a very specific meaning in EU medicinal product and medical device legislation and includes any event that is a result of user error or intentional misuse, and does not imply causality. Finally, only one specialist adviser (not â€œspecialist adviserâ€•) reported the stent falling out as an anecdotal adverse event. If included, these observations should be put in context. For example, systemic absorption of corticosteroids has been shown not to occur [Murr AH, Smith TL, Hwang PH, et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. Int Forum Allergy Rhinol, 2011;1(1):23-32.00; Li PM, Downie D, Hwang PH. Controlled steroid delivery via bioabsorbable stent: safety and performance in a rabbit model. Am J Rhinol Allergy 2009;23(6):591-6; Ow R, Groppo E, Clutter D, Gawlicka AK. Steroid-eluting sinus implant for in-office treatment of recurrent polyposis: a pharmacokinetic study. Int Forum Allergy Rhinol 2014;4(10):816-22].	Thank you for your comment. It is part of the standard process of producing Interventional Procedure guidance to ask specialist advisers about theoretical adverse events. Murr et al, 2011 is included in table 2 of the overview. Li et al, 2009 is not included in the overview because it is an animal study and therefore does not meet the criteria for inclusion. Ow et al, 2014 is not included in the overview because the sinus implant was inserted in-office after polyposis recurred following ethmoidectomy.

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13	Consultee 2 Company Healthcare Other	**Overview**	The Interventional Procedure Overview includes a study by Dautremont (2014) in Table 2. This is a study of postoperative systemic oral corticosteroids vs placebo. The inclusion criteria for identification of relevant studies (Table 1) include that the intervention under investigation is â€˜Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery.â€™ We suggest either removal of this study from Table 2 since this publication does not qualify or modification of the wording of Table 1.	Thank you for your comment. The Dautremont study does meet the criteria for inclusion in the overview. All patients were treated by endoscopic sinus surgery and a dissolvable spacer soaked with corticosteroid. They were then randomised to receive either postoperative systemic oral corticosteroids or placebo.

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