Medtronic News

# Medtronic Launches NovaShield(TM) Injectable Nasal Packing and Stent for Functional Endoscopic Sinus Surgery (FESS)

*NovaShield(TM) Offers Convenient Tool to Control Minimal Bleeding, Prevent Adhesions, and Provide Antibacterial Effectiveness after FESS**

MINNEAPOLIS - December 15, 2014 - Medtronic (NYSE: MDT) today announced the launch of the NovaShield(TM) Injectable Nasal Packing and Stent for functional endoscopic sinus surgery (FESS), manufactured by the company's Ear Nose and Throat (ENT) division of its Surgical Technologies business. Made from chitosan, NovaShield is a ready-to-use gel placed in the sinus or nasal cavities following FESS. It helps to control minimal bleeding, prevent adhesions, and has provided a level of antibacterial effectiveness in in vitro testing.* NovaShield is biofragmentable and eliminates the need for painful packing removal associated with traditional sponge or gauze nasal packing. NovaShield received clearance from the U.S. Food and Drug Administration on October 6, 2014.

Chronic sinusitis affects nearly 29 million American adults,1 and more than 525,000 FESS procedures are performed annually in the US.2 Common complications include bleeding and adhesions,3,4 which are scars that form at the surgical site as tissues heal. These scars can block the sinuses, potentially causing disease to recur that leads to additional surgery.3 NovaShield is used to separate tissue and prevent adhesions by promoting stenting of nasal structures, such as the turbinates.

"NovaShield is Medtronic's first chitosan-based nasal packing," said Lisa Sapp, Product Manager for ENT Biomaterials. "With the benefits of chitosan  and its unique design, NovaShield is helpful for both surgeons and patients."

Clinical Benefits of Chitosan

Chitosan is a polymer produced from chitin, a component of the external shell of shellfish with hemostatic (bleeding control) properties.5-14  Chitosan-based nasal packing has demonstrated fast hemostasis with fewer adhesions15,16 and a 95% success rate in the rapid control of nose-bleeding unresponsive to standard nasal packing, even in patients taking anti-platelet/anti-coagulant medications.5

"Nasal packing is an important factor in postoperative care and the ultimate outcome of sinus surgery," said Vince Racano, Vice President and General Manager of the ENT business at Medtronic. "We're excited to bring sinus surgeons this convenient new tool for FESS."

About the Medtronic Surgical Technologies Business

The Surgical Technologies business develops products and procedural solutions for surgical applications that include ear, nose, and throat; cranial and functional neurosurgery; spinal and orthopaedics; and general surgical oncology. The business designs, develops, manufactures, and supports healthcare providers with surgical navigation and imaging solutions, powered surgical tools and systems, intraoperative nerve monitoring devices, advanced energy-based devices for hemostatic sealing and tissue dissection, and implantable devices for hydrocephalus management.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

-end-

*In vitro *efficacy is not correlated to clinical effectiveness.*


1. Blackwell DL, Lucas JW, Clarke TC. Summary health statistics for US adults: National Health Interview Survey, 2012. National Center for Health Statistics. *Vital Health Stat.* 2014; 10(260).
2. Thomson Reuters Outpatient Procedure Database.
3. Musy P and Kountakis S. Anatomic findings in patients undergoing revision endoscopic sinus surgery.*Am J Otolaryngol*. 2004;25:418-422. doi:10.1016/j.amjoto.2004.06.002
4. Gross RD, Sheridan MF, and Burgess LP. Endoscopic sinus surgery complications in residency. *Laryngoscope.* 1997; 107:1080-1085.
5. Shikani AH, Chahine KA, Alqudah MA. Endoscopically guided chitosan nasal packing for intractable epistaxis.*Am J Rhinol Allergy.* 2011;25(1):61-63.
6. Kourelis K, Shikani AH. Effectiveness of chitosan-based packing in 35 patients with recalcitrant epistaxis in the context of coagulopathy. *Clin Otolaryngol.* 2012;37(4):309-313.
7. Rao SB, Sharma CP. Use of chitosan as a biomaterial: studies on its safety and hemostatic potential.*J Biomed Mater Res.* 1997; 34:21-28.
8. Malette WG, Quigley H, Gaines RD, Johnson ND, Rainer G. Chitosan: a new hemostatic.*Ann Thorac Surg.* 1983; 36:55-58.
9. Chou TC, Fu E, Wu CJ, Yeh JH. Chitosan enhances platelet adhesion and aggregation.*Biochem Biophys Res Commun.* 2003; 302:480-483.
10. Dutkiewicz JK. Superabsorbent materials from shellfish waste-a review. *J Biomed Mater Res.* 2002; 63:373-381.
11. Brandenberg G, Leibrock LG, Shuman R, Malette WG, Quigley H. Chitosan: a new topical hemostatic agent for diffuse capillary bleeding in brain tissue. *Neurosurgery.* 1984; 15:9-13.
12. Hirano S, Zhang M, Nakagawa M, Miyata T. Wet spun chitosan-collagen fibers, their chemical N-modifications, and blood compatibility. *Biomaterials.* 2000; 21:997-1003.
13. Belman A, Daya M, Steve M, Worley J. From the battlefield to the street-experience of a suburban fire/EMS agency with chitosan dressing. 2006; *Touch Briefings: Emergency Medicine & Critical Care Review.*
14. Wedmore I, McManus JG, Pusateri AE, Holcomb JB. A special report on the chitosan-based hemostatic dressing: experience in current combat operations. *J Trauma.* 2006; 60:655-658.
15. Li L, Wang N, Jin X, et al. Biodegradable and injectable*in situ* cross-linking chitosan-hyaluronic acid-based hydrogels for postoperative adhesion prevention. *Biomaterials.* 2014; 35:3903-3917.
16. Aziz MA, Cabral JD, Brooks HJL, et al. *In vitro* biocompatibility and cellular interactions of a chitosan/dextran-based hydrogel for postsurgical adhesion prevention. *J Biomed Mater Res.* Part B 2014; 00B:000-000.



Contacts:

Natalie St. Denis

Public Relations

+1-303-917-7772

Jeff Warren

Investor Relations

+1-763-505-2696


---


https://news.medtronic.com/2014-12-15-Medtronic-Launches-NovaShield-TM-Injectable-Nasal-Packing-and-Stent-for-Functional-Endoscopic-Sinus-Surgery-FESS