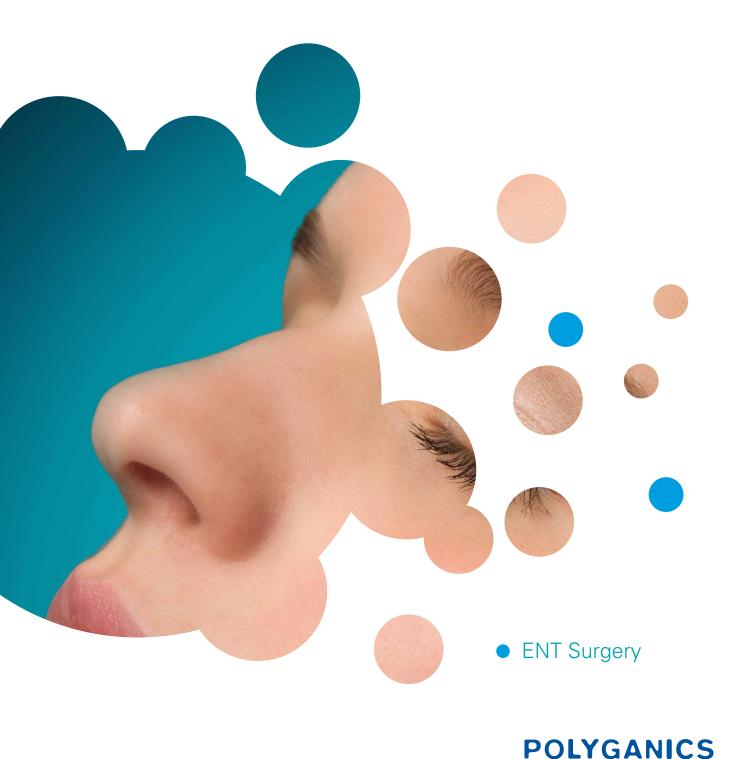


The Nasal Dressing for Improved Wound Healing



Bioresorbable Medical Devices

NASOPORE®

Topical Drug Application

Wound healing is a significant determinant of successful outcome in (functional) endoscopic sinus surgery, (F)ESS. Factors that can lead to poor surgical outcome include scarring/synechiae, infection, and persistent inflammation.

The use of resorbable nasal packing grows at the expense of removable nasal packing (Millenium Research Group, 2011). As resorbable dressings tend to improve wound healing (Wormald, 2006) they are more commonly used during ESS to potentially aid in local hemostasis, minimize synechiae and the prevention of lateralization.





Without nasal dressing granulation and formation of scar tissue is observed.

Use of NASOPORE[®] results in no adhesion

Improved Wound Healing

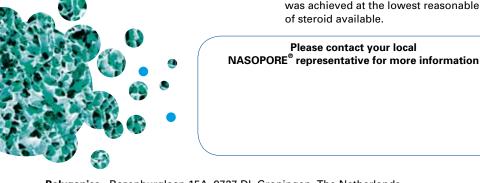
NASOPORE[®] bioresorbable nasal dressing is intended for use in patients undergoing nasal/sinus surgery as a temporary wound dressing. NASOPORE[®] is intended to support tissue healing, minimize edema and prevent adhesion formation.

NASOPORE[®] can also be used as a topical applicator^{*} for the steroid Triamcinolone and the antibiotics Ciprofloxcin, Gentamicin and Bacitracin.

NASOPORE® is a biologically inert and safe foam with a highly interconnected porous structure. This allows for a rapid and high fluid absorbent capacity (up to 25 times its weight).

By providing gentle mechanical support, NASOPORE® separates mucosal surfaces during the critical, early days of post sinus surgery when mucosal swelling is heightened. By keeping opposing mucosal tissues separated, NASOPORE® prevents formation of post-surgical adhesions in the nasal cavity.

By absorbing nasal fluids and blood, NASOPORE[®] slowly starts to fragment whilst still offering sufficient wound support



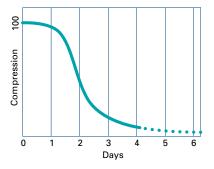
Polyganics - Rozenburglaan 15A, 9727 DL Groningen, The Netherlands T +31 (0)50 588 65 88 - F +31 (0)50 588 65 99 - sales@polyganics.com - www.polyganics.com

The information presented in this brochure is intended to inform and demonstrate the product. Always refer to the package insert, product label and/or user instructions before using this product. NASOPORE[®] is a registered trademark of and manufactured by Polyganics, The Netherlands.



during the critical healing period (36-48 hours after insertion). During this period NASOPORE® does not swell and so will not hinder natural drainage. After fragmentation NASOPORE® will be drained from the nasal cavity via natural pathways without any pain. Daily spraying with saline solution is recommended in the first week after surgery, this accelerates the fragmentation process.

NASOPORE[®] does not have to be removed is proven to minimize middle turbinate lateralization, significantly decreases synechiae and adhesions², and offers high patient tolerance.



The concept of impregnating NASOPORE[®] to further aid wound healing has been described in literature.^{1,3}

Shikani (1996) suggested that the use of nasal dressings to deliver topical antibiotics in the postoperative time period may be of value.

Côté et al. recently reported a significant improvement in early postoperative healing in sinonasal cavities receiving triamcinolone-impregnated NASOPORE® following ESS and is also associated with significantly improved healing up to 6 months postoperatively. More et al. demonstrated comparable efficacy of a Triamcinolone-

impregnated NASOPORE[®] in the management of early polypoidal changes of nasal mucosa after ESS. This clinical effect was achieved at the lowest reasonable dose of steroid available.

Application of the steroid Triamcinolone and the antibiotics, Gentamicin and Ciprofloxcin, onto NASOPORE[®], enables topical delivery directly to the sinus lining where it is needed most while NASOPORE[®] gradually dissolves.

The result is improved post-operative outcomes, reducing the need for additional surgical procedures and systemic steroids and antibiotics.

- Côté DW, et al. Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. Laryngoscope 2010;120:1269–1273.
- Thong M, et al. Clinical evaluation of a fully synthetic middle meatal stent for safety and tolerability. Otolaryngol Head Neck Surg. 2011 Mar;144(3):452-6
- More Y, et al. Management of early nasal polyposis using a steroid-impregnated nasal dressing. Int Forum Allergy Rhinol. 2011 Sep;1(5):401-4.

NASOPORE® Benefits

- Fully synthetic and inert foam, clinically proven to be safe.
- Unique structure enables rapid and high volume fluid absorption but does not swell and conforms to the anatomical shape.
- Topical application of steroids and antibiotics improves mucosal healing.
- Does not obstruct the airways and drainage, thereby offering high patient comfort
- Elastic properties allow gentle compression during the critical healing period (36-48 hours after insertion).
- Significantly decreases synechiae and adhesions and thus prevents scarring.
- Minimizes middle turbinate lateralization.
- Biodegradable property results in rapid and uniform clearance. No removal needed thereby preventing trauma and re-bleed.
- Flexibility in use.

NASOPORE[®] Product Description

Article number	Туре	Size
ND01/025-04B	Standard	4 cm
ND01/025-08B	Standard	8 cm
ND02/025-04B	Forte	4 cm
ND02/025-08B	Forte	8 cm
ND05/025-04B	Forte Plus	4 cm
ND05/025-08B	Forte Plus	8 cm

Each NASOPORE® is available in 8 units per box. NASOPORE® should be stored at or below 4°C (39,2°F). NASOPORE® Shelf life is 24 months.

NASOPORE® is CE-approved under CE 0344 and filed at the FDA under number K052099.

* The topical application of agents using NASOPORE[®] allows only for market clearance in the countries belonging to the EEA.

POLYGANICS

Bioresorbable Medical Devices PG/NP/250612