



PureRegen® gel Sinus for adhesion prevention and facilitation of mucociliary regeneration



Order information

Product name	REF Code	Description
PureRegen® gel Sinus	40-011-001	Sterile gel (2cc) in glass syringe, delivery cannula
PureRegen® gel Sinus	40-011-003	Sterile gel (5cc) in glass syringe, delivery cannula

Developed and manufactured by:



BioRegen Biomedical Co., Ltd.
167-5 East East Road, Changzhou,
Jiangsu 213025
China
Tel. +86 51988408555; Fax. +86 51988407911
Email. sm@bioregenmed.com
www.bioregenmed.com



Endotherapeutics

ABN 89 088 045 103
Level 1, 51 Rawson St
Epping NSW 2121 Australia
T: +61 (2) 9869 2868 F: +61 (2) 9869 7723
E: info@endotherapeutics.com.au
www.endotherapeutics.com.au

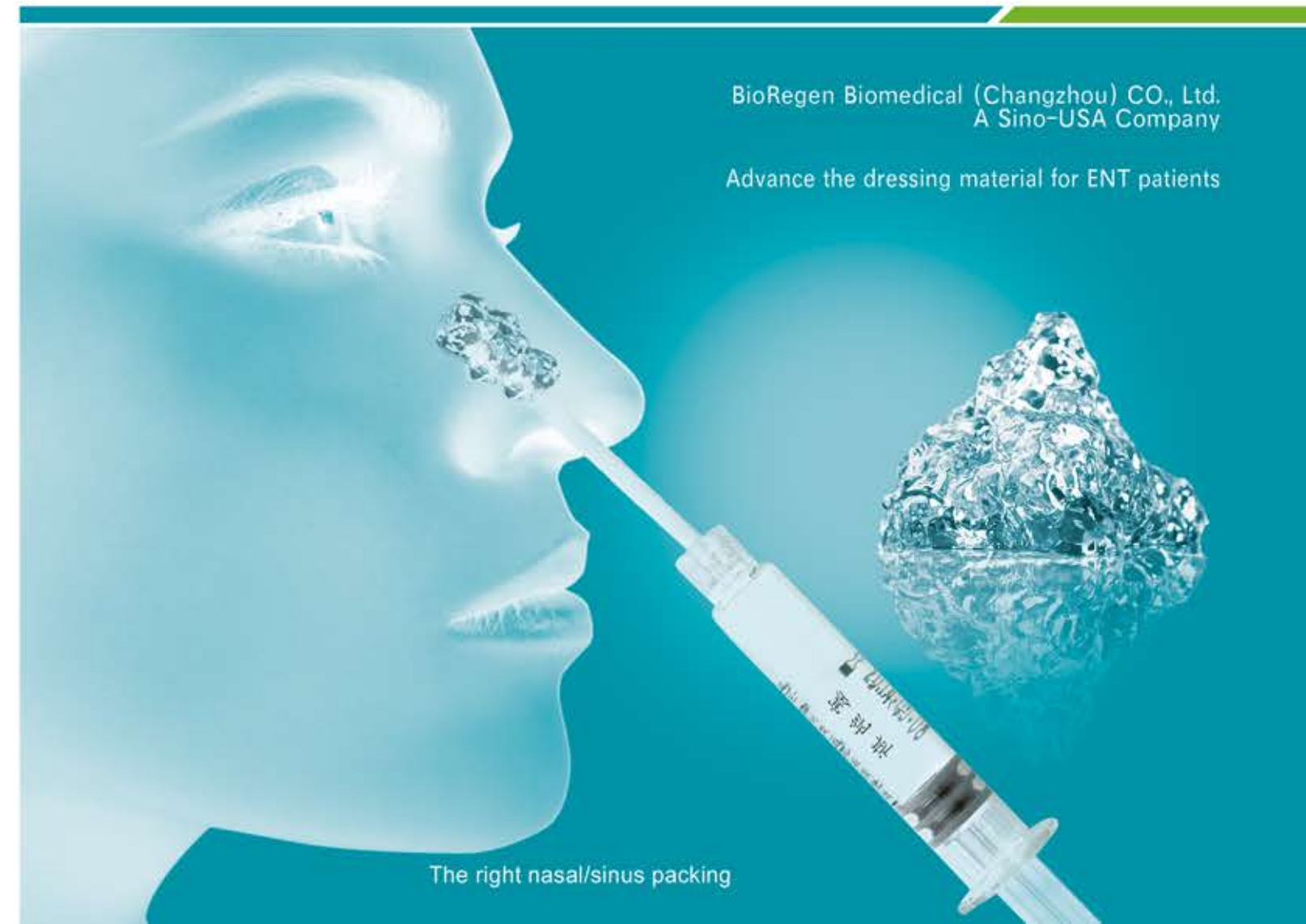
PureRegen® Gel SINUS

Self-crosslinked Hyaluronic Acid Gel Dressing
Viscous and Controlled Degradation: Balanced to match the tissue regeneration critical period

- Facilitates re-mucosalization acting as an adjunct
- Eliminates post painful removal
- Avoids secondary damage to the regenerated mucous
- Conforms to nasal cavity without dead space
- Prevents adhesion and scarring
- Minimize bleeding and edema

BioRegen Biomedical (Changzhou) CO., Ltd.
A Sino-USA Company

Advance the dressing material for ENT patients



The right nasal/sinus packing

PureRegen® Gel SINUS: unique features

- Proprietary self-crosslinking technique: no toxic residual and xenogenic proteins, excellent biocompatibility
- Gentle material modification method: preserved biological function of natural hyaluronan.
- Adequate viscosity and hydrophilic property: creation of moist environment facilitating re-mucosalization
- Controlled degradation profile: physical barrier during the mucous regeneration critical period to prevent adhesion and scar formation.
- Terminal sterilization of the gel: maximized safety after application
- Dissolvable hydrogel: reduced discomfort to the patients and no need to remove



Instruction for Use:

- ① Open the protection carton box and pull the product pack out.
- ② Following the indication peel-open the package, remove the PureRegen® Gel SINUS from the package and place on the sterile field.
- ③ Remove the tip cap from the syringe.
- ④ Attach the moldable delivery cannula with the syringe. The cannula is packed inside the same box as for the gel.
- ⑤ Upon completion of the FESS, inject the PureRegen® Gel SINUS to fill the cavity and cover all mucosa until small amount of gel leaking out from the ostiomeatal.

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Proven efficacy of PureRegen® Gel SINUS to prevent adhesion and facilitate mucociliary regeneration:

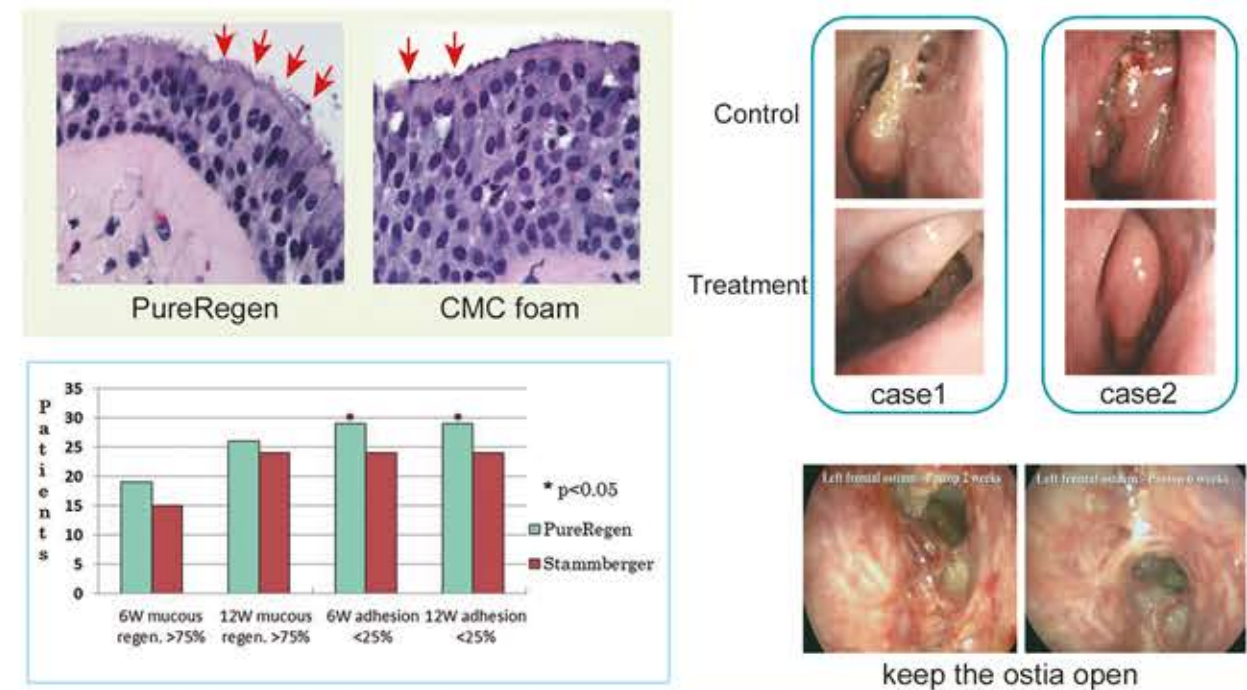
Controlled degradation profile:

PureRegen® Gel SINUS degradation profile matches the critical repair period, esp. the inflammatory processes after surgery, thereby providing effective barrier between the mucosal surfaces and prevent adhesion. The complete dissolution of PureRegen® Gel SINUS eliminates the need for painful packing removal and secondary damage to the fresh mucous.



PureRegen® Gel SINUS completely dissolves up to 14 days, which matches the critical inflammatory reaction time during the mucous healing (1,2).

Prospective, randomized, controlled multiple center clinical studies (Level I) in China and USA demonstrated that PureRegen® Gel SINUS resulted in fewer adhesion, better re-mucosalization, and reduced edema and crust than the control group (3,4,5).



References:

1. Watelet JB, et al: Wound healing of the nasal and paranasal mucosa: A review. Am. J. Rhinol. 16:77-84, 2002.
2. Pajic-Penavic I.: Endoscopic monitoring of postoperative sinonasal mucosa wounds healing. Advances in Endoscopic Surgery, Prof. Cornel Lancu (Ed.), ISBN: 978-953-307-717-8, InTech. Chapter 21: page 419-436, 2011.
3. Shi R. et al: The clinical outcomes of new hyaluronan nasal dressing: A prospective, randomized, controlled study. Am. J. Rhinol. Allergy. 27:71-76, 2013.
4. Matheny KM, et al.: Self-crosslinked hyaluronic acid hydrogel (PureRegen® Gel Sinus) in ethmoidectomy: A randomized, controlled trial. Am J Rhinol Allergy 28, 508-513, 2014
5. Preventing adhesion and keeping the ostia open after functional endoscopic frontal sinus surgery by a novel crosslinked hyaluronan gel: Internal data. Manuscript 2015.