INSTRUCTIONS FOR USE

PureRegen® Gel Sinus

NASAL AND SINUS DRESSING

Sterile: Syringe and syringe contents are sterile unless the protective package has been opened or damaged.

Caution: Do not use the product if the protective package is opened or damaged.

Caution: Federal (USA) law restricts this device sale by or on the order of a licensed physician, or properly licensed practitioner.

PRODUCT DESCRIPTION

PureRegen® Gel Sinus dressing is a sterile, non-pyrogenic, transparent, viscoelastic, bioresorbable gel composed of cross-linked molecules of hyaluronan from non-animal sources, and used as nasal and sinus dressing or stent in patients undergoing nasal and sinus surgery. This dressing is prefilled in glass syringes with elastomeric cap, elastomeric plunger stopper and plastic plunger rod, and do not contain any medicinal, human or animal components. PureRegen® Gel Sinus is removed from the application site by natural elimination; it may be aspirated from the site earlier at the discretion of the physician.

INDICATIONS FOR USE

PureRegen® Gel Sinus is indicated for use in patients undergoing nasal and sinus surgery as a space occupying dressing and/or stent intended to prevent adhesions in the nasal cavity, separate mucosal surfaces, help control minimal bleeding following surgery, and act as an adjunct to aid in the natural healing processes. The device is indicated following nasal and sinus surgery to prevent lateralization of the middle turbinate during the post-operative period.

CONTRAINDICATIONS

Do not use in patients hypersensitive to hyaluronan or its derivatives.

WARNINGS AND PRECAUTIONS

1. In rare instances, the physiochemical condition associated with nasal and sinus surgery both with and without dressing, may present a risk of toxic shock syndrome (TSS). Warning signs of TSS include: sudden fever (usually 39°C/102°F or higher), vomiting, diarrhea, dizziness, fainting (or near fainting when standing up), and/or a rash that looks like sunburn.
2. PureRegen® Gel Sinus exhibits no antimicrobial properties; it is not bacteriostatic toward pre-existing infections, nor does it prevent the occurrence of new infections.
3. In the case of pre-existing infections, appropriate treatment should be instituted.
4. Do not use intravascularly.
5. Do not use if the product is expired.
6. Do not use if the packaging (the protective package, syringe, cap and stopper) is opened or damaged.
7. The device is transparent and colorless, do not use if the device has alternation in color or clarity.
8. Foreign body reaction may occur as with most surgical adjuncts.
9. PureRegen® Gel Sinus must be used according to the Instructions For Use. Read instructions prior to use.
10. This product should be used under the instruction of physicians.
11. This product should not be re-used; otherwise the product may be contaminated and cause infections.
12. The opened and not-used product should be disposed as medical waste according to local laws.

STERILITY

This product is provided sterile and is intended for single patient use only. Do not resterilize this product. BioRegen Biomedical Co. assumes no liability for products which have been resterilized by health care facilities. Inspect the packaging to be sure that it is intact and undamaged prior to use. Do not use the product if the protective package is opened or damaged.

STORAGE

PureRegen® Gel Sinus should be stored at 2° - 30°C (36° - 86°F) and protection from sunlight. **DO NOT FREEZE!**

SHELF-LIFE

Twenty four months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove the PureRegen® Gel Sinus-filled syringe from the protective packaging and place on sterile field.
2. Use immediately after opening the package. Any unused portion of PureRegen® Gel Sinus should be discarded.
3. Confirm that the surgical site is free of excessive bleeding. Excessive bleeding should be controlled prior to PureRegen® Gel Sinus instillation.
4. After surgery, pull out the cap of syringe, connect the syringe to a large-bore sterile delivery cannula with a standard luer lock that is provided or an 14G or lager *i.v.* catheter that is usually available in OR, and then slowly instill enough PureRegen® Gel Sinus to coat all exposed injury tissues and denuded mucosa. Typically, the gel is reabsorbed from the site of application in two weeks, although complete elimination may take longer (three weeks). Following sinus surgery, the gel may be removed through gentle irrigation and aspiration at the discretion of the physician.
5. Following sinus surgery patients should be instructed to avoid sneezing or blowing nose during the first few post-operative days.

HOW SUPPLIED

PureRegen® Gel Sinus dressing is supplied in a glass syringe containing 2.0 ml PureRegen® Gel Sinus dressing or 5.0 ml PureRegen® Gel Sinus dressing.

BioRegen Biomedical (Changzhou) Co., Ltd.
No. 167-5, East East Road, Changzhou, China 213025
Tel : (+86) 519-88408555 ; Fax: (+86) 519-88407911
E-mail : info@bioregenmed.com

EC REP Shanghai International Trading Corp. GmbH (Hamburg)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel : 0049-40-2513175 Fax: 0049-40-255726

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Symbol	Meaning	Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Keep away from sunlight		Keep dry		Temperature limitation		Do not use if package is damaged or open