INSTRUCTIONS FOR USE

NASAL AND SINUS DRESSING

Sterile: The syringe contents are sterile unless the syringe has been opened or damaged.

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

Caution: Nasal and Sinus Dressing should be used by or on the order of a licensed physician, or properly licensed practitioner.

PRODUCT DESCRIPTION

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

Nasal and Sinus Dressing is benefit to prevent adhesions-related complications, and postoperative poor wound healing related risk.

INDICATIONS FOR USE

Nasal and Sinus Dressing is indicated for use in patients after nasal and sinus surgery as a space occupying dressing intended to prevent adhesions in the nasal cavity, separate mucosal surfaces, help control minimal bleeding following surgery, and act as an adjunct to facilitate 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. Nasal and Sinus Dressing 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. Nasal and Sinus Dressing 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 non-used product should be disposed as medical waste according to local laws.
13. For type II product where an Injection Cannula is provided, when the Gel is expired, the Injection Cannula will be invalid at the same time.
14. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

STERILITY

This product is provided sterile and is intended for single patient use only. Do not

resterilize this product. BioRegen Biomedical Co., Ltd. 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

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

SHELF-LIFE

Thirty-six (36) months from the date of manufacture.

INSTRUCTIONS FOR USE

1. Remove the Nasal and Sinus Dressing-filled syringe from the protective package and place on sterile field.
2. Use immediately after opening the package. Any unused portion of Nasal and Sinus Dressing should be discarded.
3. Confirm that the surgical site is free of excessive bleeding. Excessive bleeding should be controlled prior to Nasal and Sinus Dressing instillation.
4. After surgery, pull out the cap of syringe, connect the syringe to a large-bore sterile delivery cannula that is provided for type II product of Nasal and Sinus Dressing or a 14G or larger *i.v.* catheter that is usually available in operation room, and then slowly instill enough Nasal and Sinus Dressing to coat all exposed injury tissues and denuded mucosa. Typically, the gel is removed 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

Nasal and Sinus Dressing is supplied in a glass syringe containing 2ml, 5ml, 6ml, 8ml, 10ml or 20ml Nasal and Sinus Dressing. For type II product of Nasal and Sinus

Dressing, an Injection Cannula is provided in the same box.

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Symbols

Symbol	Meanings	Symbol	Meanings
	Do not re-use	STERILE	Sterilized using steam or dry heat
	Manufacturer		Date of manufacture
	Use-by date	LOT	Batch code
	Temperature limit		Do not use if package is damaged
CE	CE conformity marking		Consult instructions for use
	Keep dry		Keep away from sunlight
EC REP	Authorized representative in the European Community		Fragile, handle with care
REF	Catalogue number		Do not resterilize
STERILE EO	Sterilized using ethylene oxide	MD	Medical Device
UDI	Unique device identifier		Single sterile barrier system
	Single sterile barrier system with protective packaging outside	#	Model number