XeroGel™

nasal/epistaxis pack

Instructions for Use

entellus MEDICAL™

3769-002

Device Description

The XeroGel® nasal/epistaxis pack is a sterile, single use, copolymer of polyethylene glycol (PEG) and chitosan provided as a dry 4.0 cm x 2.4 cm x 0.3 cm pack. Upon placement, XeroGel® absorbs fluids in the field and swells and conforms to the mucosal tissue/treatment site surfaces to separate tissues and prevent adhesions, control minimal bleeding following surgery or trauma, to treat epistaxis and to act as an adjunct to aid in the natural healing process.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

Intended Use

XeroGel® is a sterile, single use device intended for use in patients undergoing nasal/sinus surgery as a space-occupying packing.

Indications for Use

XeroGel® is indicated for use in patients undergoing nasal/sinus surgery as a space-occupying packing to:

- Separate tissue or structures compromised by surgical trauma;
- Separate and prevent adhesions between mucosal surfaces; including during mesothelial cell regeneration in the nasal cavity;
- Help control minimal bleeding following surgery or trauma;
- Help control minimal bleeding following surgery or trauma by tamponde effect, blood absorption and platelet aggregation;
- Act as an adjunct to aid in the natural healing process.

XeroGel® is indicated for use as a nasal packing to treat epistaxis.

Contraindications

This product is contraindicated for use in patients with a known hypersensitivity/allergy to shellfish.

Precautions

- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- Use product immediately after opening sealed pouch. Discard any unused portion of product in accordance with the applicable facility procedures.
- Medical care practitioners/surgeons should base use of this product on clinical training, education, and current medical literature regarding the use of space-occupying packings for use in patients undergoing nasal/sinus surgery.
- In the case of pre-existing infections, appropriate treatment should be instituted.
- Common/expected complications of open, percutaneous, and endoscopic surgical procedures include infection and bleeding.

Possible Adverse Effects

Possible adverse effects associated with product use include:

- Infection
- Recurrent or persistent bleeding
- Scarring / synechia
- Dislodgement of the pack
- Toxic shock syndrome (rare)

Instructions for Use

1. Using sterile technique, remove XeroGel® from the sterile packaging and place on the sterile surgical field.
2. Using scissors, cut XeroGel® to appropriate size if necessary.
3. Fold, roll or keep flat as desired for application.
4. Using forceps, gently insert and position the XeroGel® in the nasal cavity.
5. In cases of epistaxis, the packing will begin to expand after placement. In the event the packing does not swell (expand), hydrate the pack with sterile saline or sterile water as desired.
6. For standard nasal packing, hydrate XeroGel® with sterile saline or sterile water.

Note: XeroGel® is dissolvable and any residual product material that has not dissolved or left the surgical site through natural mucus outflow may be removed by gentle aspiration and irrigation.

Limited Warranty

Entellus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical excludes all other warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical's control, directly affect the device and the results obtained from its use. Entellus Medical shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Entellus Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Refer to Entellus Medical, Inc. Standard Terms and Conditions.

SYMBOL KEY FOR PRODUCT LABELS

( )	Quantity contents of items provided in designated brackets
Rx Only	Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician
REF	Catalog Number
LOT	Lot Number
	Use By Date

Note: Maximum storage temperature 25ºC (77ºF)
Note: Not made with natural latex rubber

Manufactured By:
Entellus Medical, Inc.
3600 Holly Lane N., Suite 40
Plymouth, MN 55447
763.463.1595
www.entellusmedical.com

Reorder: Entellus Medical, Inc.
Customer Service: 866.620.7615 Fax: 866.620.7616
E-mail: customerservice@entellusmedical.com