PRODUCT NAME: LAYERED NASAL AND LAYERED EPISTAXIS PACKS
PRODUCT INFORMATION AND INSTRUCTIONS FOR USE

Symbols Used

LOT GB- Lot Number	GB- Use Until Date	GB- Do Not Re-use	GB- Do not use if product is opened or damaged.	STERILE R GB- Sterilised by Irradiation	GB - Manufacturer	GB – Date of Manufacture	EC REP GB – EU Authorised Representative	Keep Dry
REF GB- Catalogue Number	GB- Caution	NEC_005 GB - Consult Electronic Instructions for Use	Rx only GB – Caution: United States Federal law restricts medical devices to sale by or on the order of a physician	GB- Do not resterilise	MD GB – Medical Device	UDI GB – Unique Device Identifier	GB - Sterile barrier system	GB – Keep away from sunlight

GB - INSTRUCTIONS FOR USE

Description

The products in the Network range of PVA sponge products have been designed to meet the requirements of the surgeon where there is a requirement to staunch blood loss after invasive surgery or traumatic injury. The products are quick and easy to use and reduce the time required to create haemostasis where blood loss is critical.

The products are available in a variety of designs, widths and lengths to best suit the surgeon's preference and needs. The range is further extended to accommodate for the requirements of children and adults of Asian origin.

Intended Use

PVA sponge ENT products are designed to staunch blood loss after invasive surgery or traumatic injury in ENT surgery. The PVA sponge reacts quickly to absorb blood and body fluids. PVA is biocompatible and in some instances can be used for post-operative tissue support and to carry medication to the operative site (where specified in the Instructions for Use).

Nasal Packs are intended for use after septal, Turbinate and Rhinoplastic surgery and provide gentle equal pressure within the nasal cavity when absorbing post-operative bleeding. Patient comfort can be enhanced by using an airway tube. The slimpack version nasal pack has been developed for use in conjunction with a nasal splint following septal surgery.

Epistaxis Packs are used to control nasal bleeding. Fluid absorption causes the packing to expand producing a tamponading effect. Long Epistaxis are used for the simple quick packing of the entire nasal cavity, the most efficient way to contain and restrict blood loss. Short Epistaxis pack for the quick convenient treatment of anterior Epistaxis.

Layered packs allow the packing to be adjusted to the individual patient.

CAUTIONS

- This device is supplied STERILE and ready to use.
- This device is for SINGLE USE ONLY. Do NOT re-sterilise or re-use.
- Do not use if the packaging has been opened or damaged.
- This device is intended for use by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device.
- The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination.
- CAUTION: US Federal Law restricts sales and use to or on the order of a Physician.
- String to be used as an indicator only.
- Securing the string to the patient's cheek will prevent the pack moving backwards, thus eliminating the possibility of the pack being imbibed further and causing an obstruction.
- Do not leave packing in place for more than 4 days or serious side effects may occur.

POSSIBLE ADVERSE EFFECTS

Tampons are associated with toxic shock syndrome (TSS). In case of symptoms such as sudden fever, vomiting, diarrhoea, dizziness, fainting or near fainting and for a rash appearing like a sunburn the treatment with NETCELL has to be interrupted immediately.

Incident Reporting

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

INSTRUCTIONS

1. Lubrication -Coat the leading edge of the Epistaxis Pack with an antibiotic ointment or lubrication for ease of insertion.
2. Insertion -Grasp the packing with forceps and insert along the nasal floor with a continuous motion until the entire pack is within the nose.
3. Expansion -After insertion, the Epistaxis pack will begin to expand. If the packing is not fully expanded after 30 seconds, hydrate the proximal end with saline or sterile water until it begins to expand.
4. Removal -Rehydrate the pack with saline or sterile water (approx.. 10cc-20 cc). Doctors recommend allowing pack to remain in place for 5-10mins. To facilitate ease of removal use forceps and grasp the pack and gently withdraw.

Sterilisation

This device is supplied sterile by Gamma Irradiation and are designated for SINGLE USE ONLY.

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES

1. Single use devices have not been validated for re-use. If you re-use a device you may be held Legally Liable for the safe performance.
2. Cross-contamination and infection risks to patients . Including transmission of:

- CJD & Variant CJD.
- Prion Diseases.
- Bacterial Endotoxins.
- Hepatitis B & Hepatitis C.
- Risks posed by HIV and AIDS

3. Device failure through material fatigue or degradation caused by initial use and design.
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials

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EC REP
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