StopLoss Jones Tube System Instructions for Use

Components

A range of individually packed, sterile Pyrex® glass Jones tubes with a rigid glass flange at the external end and a flexible silicone flange at the internal end

A set of introducer equipment comprising:

- Guide wire
- Button
- Double-ended dilator, with narrow and broad dilating elements and a central hub
- A set of 4 sizing devices with mm markings, lengths 15mm and 20mm each at external flange diameter 3.5mm and 4.0mm

A removal tool with additional guide wire

Intended use (indications)

The StopLoss Jones tube system is used to provide drainage of tears where the natural drainage mechanism has failed. Specific indications include:

- Canalicular agenesis
- Canalicular occlusion
- Damage to or loss of the normal lacrimal drainage mechanism
- Failure of dacryocystorhinostomy (DCR) surgery
- Permanent failure of the lacrimal pump mechanism

Contra-indications

Inability to cooperate in care of the tube, eg:

- Young children, especially pre-teenage
- Mental health problems
- Movement disorders
- Severe anxiety

Continuous Positive Airway Pressure (CPAP) ventilation is a partial contra-indication

⚠ Do not reuse this device

⚠ Do not use if expiry date on label is exceeded as shown by symbol yyyy-mm

⚠ Warnings

Do not use for any purpose outside the intended use of the device

Only for use by a qualified surgeon with prior knowledge of lacrimal surgery

Damage to or modification of the device may result in device failure

Under no circumstances should a device be re-used

Handle devices with care to avoid damage to staff or surgical gloves

Take great care with the sharp ends of the introducer equipment

Ensure an adequate bone opening is available prior to insertion. Do not attempt to pass introducer equipment or tube through bone

Glass is fragile. Excessive force must not be used

Technique of usage

Place the button on the blunt end of the guide wire

Use the sharp end of the guide wire to create the required track between the inner corner of the eye (caruncle) and the nose

Remove the button

Use the narrow end of the dilator to enlarge the track by passing it down the guide wire to the nose

Keep the guide wire in place, remove the dilator, reverse it and use the broad end of the dilator to widen the track

Keep the guide wire in place and remove the dilator

Pass a sizing device down the guide wire so that the flange is placed at the inner corner of the eye (caruncle) and the inner end enters the nose

If required use a sizing device with a different flange diameter to provide the correct fit in the inner corner of the eye (caruncle)

If required use a sizing device with a different length to ensure the inner end reaches the nose

Remove the guide wire

The flange of the StopLoss Jones tube is positioned 2mm from the tip of the tube. Use the sizing device to determine the length of tube required by reference to the mm markings at the tip and the known total lengths of the sizing devices (15 and 20mm). Aim for a 2mm separation of the flange from the lateral nasal wall

Replace the guide wire and remove the sizing device

Pass the StopLoss tube of appropriate length and flange diameter down the guide wire so that the silicone flange opens fully when in the nose

Remove the guide wire and check the placement of the tube

If necessary secure the tube for 1-3 weeks with a suture passed around the neck of the tube and tied to the skin

If required the tube can be removed using the extraction tool. Place the loop around the neck of the tube and rotate the shaft to grip the tube. Carefully apply sustained traction on the external flange to remove the tube

Post-operative care and patient information

Check patency and clean the inside of the tube and external flange approximately every 6-12 months

The patient should be encouraged to report any post-operative complications to the surgeon

Possible adverse effects

- Obstruction of the tube
- Infection
- Discomfort
- Double vision
Discharge from the nose
Dry eye
Watering from the eye
Mucus on glasses
Air and mucus regurgitation
Tube falls out
Cosmetic concerns

Sterility
The components of the StopLoss Jones tube system are supplied sterile
Prior to use check integrity of packaging to ensure that product sterility has not been compromised

DO NOT USE IF PACKAGE IS OPEN OR DAMAGED
Refer to package label for shelf-life
Products should not be re-sterilized

Storage
Store in a cool dry place between 0 and 30°C
Keep packaging dry
Keep out of direct sunlight

Disposal
Disposal should be in accordance with hospital or clinic policy for Disposal of Contaminated Waste

IP
EU patent no. EP 2073769
US patent no. US 7758534
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