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CAUTION!

THESE DVEICES ARE MADE OF BOROSILICATE GLASS AND ARE FRAGILE.

THEY MUST BE HANDLED WITH CARE

NON-STERILE!
THIS DEVICE MUST BE CLEANED AND STERILISED BEFORE USE BY FOLLOWING INSTRUCTIONS PROVIDED

This document is a Summary Sheet!

For a copy of the unabridged Instruction Sheet containing:

- **Surgery for insertion of Implantable Tubes**
- **Operative Care**
- **Post Operative Care of CDCR**

Contact Customer Services through the contact details shown or download from the Altomed web-site at: www.altomed.com

Due to the fragile nature of these products it is recommended that each device is inspected for signs of physical damage (scratches, cracks, devitrification, chips etc) under a microscope before use, especially if they have been held in stock for prolonged periods of time. Accidental damage may occur in handling, processing or storage. Any device showing signs of damage must not be used but disposed of following hospital approved procedures for "Sharps."
These devices are supplied non-sterile and should be washed and sterilised before use by following hospital approved procedures for these devices or by following the steps outlined below.

PROCESSING INSTRUCTIONS

Follow hospital approved procedures for handling devices to be sterilised.
Before sterilising, clean the tubes with a free rinsing, pH neutral endozymatic detergent such as Ruhof Endozyme Triple Plus or other Hospital approved detergent for implantable glass tubes. An Ultrasonic Bath can be used if available following hospital approved procedures. Rinse in purified water to remove any chemical residues and dry with filtered air. Ensure device is visually clean.
Steam sterilise the tubes using a standard 134°C -137°C cycle with a 3 minute holding time, use a peel pouch to protect sterility.
Ensure the tube is thoroughly dry before pouching and after sterilisation.
Repeated processing or mishandling may damage these products. To prevent devitrification do not process tubes more than 10 times.
These devices are single patient use. It is not recommended to re-use a device that has been placed during surgery.

Sterilisation of Polyethylene Tubes and Cleaning Rods:

Do not autoclave Polyethylene Tubes or Cleaning Rods!
Non-sterile Polyethylene Tubes and Non-sterile Cleaning Rods should be cleaned and packed as above but only sterilised using Ethylene Oxide to EN556 using a protocol verified by the sterilisation plant under EN550, ISO 9001 and ISO 13485

Maintenance:

To prevent infection, patients should be instructed to use antibiotic solution four times a day and irrigate with this same solution daily for 7 – 10 days, as well as an antibiotic ointment applied to the suture line for 7 – 10 days post operatively. Periodic irrigation with saline via an irrigating syringe or regular syringe attached to a piece of tubing can aid in preventing mucus accumulation.
If the prosthesis shifts laterally, the patient should seek medical attention.
If a tube is expulsed, the patient should see the Physician as soon as possible as complete closure of the tract can occur as soon as one week after the tube has been removed.

Patient Information:

The patient should be advised to inform any unknowing Physician of the need for special care when packing the nose, so that the Physician does not pack too high in the nose around the Lester Jones tube.
The patient should be taught to "sniff" and to "blow" the nose when possible, especially during the first few postoperative weeks. If patients anticipate coughing, sneezing or must blow their nose, they should close their eyelids tightly and place a finger over the tube at the medial canthus (over the end of the tube) to prevent dislodging it.
The patient should be warned to avoid straining or vigorous exercise for 10-14 days post operatively to decrease edema and the possibility of nasal bleeding.

Possible Effects:

Haemorrhage - The patient should be warned of the possibility that late haemorrhage may occur for 10 – 14 days.
Keloid And Scar Formation - The possibility of hypertropic scar formation or keloids should be discussed with the patients preoperatively.
Diplopia – there is a rare risk of diplopia following insertion of the tubes
Conjunctivitis – This may occur as a result of or independent of nasal infection. Frequent irrigation during periods of nasal congestion or infection to prevent retrograde accumulation of bacteria and mucus is helpful in preventing this problem. Irrigation of antibiotic solution and topical application of same appear to clear conjunctivitis fairly rapidly.
Other – It is possible to experience ocular irritation from cigarette smoke while smoking. It has also been reported that patients have felt an air current before the eyes during inspiration and expiration. Some users have also heard whistling noises during inspiration and expiration, and some have stated their glasses fogged with "heavy" breathing.
Patients should be advised that they will probably need to retain their tubes for the rest of their lives.
Despite the complications and necessity for further surgical intervention in many cases, the majority of patients are pleased with the results of Canalicular bypass surgery.

Implantation and restriction on implants:

A longer Jones tube will generally be required for children as they grow older and the distance from the medial canthus to the nasal cavity lengthens. Because co-operation of the recipient is required for after-care of Jones' Tubes, their use is best avoided in children under teenage or in the mentally retarded. Similarly, implantation is probably inappropriate where after-care is unavailable as most prostheses eventually require some form of active management. To prevent cross contamination, a tube should only be used on one patient.

Replacing tubes:

Local anaesthesia is usually sufficient except in children or extremely anxious adults. A dilator should be left in place while cleaning, and occasionally a larger dilator will be necessary to reinsert the tube. Whilst the tract remains patent for several days after removal of a tube, it is often possible to replace the bypass tube (placing it over a fine guide wire) using either topical of infiltrative local anaesthesia. Prolonged removal of the prosthesis leads to stenosis or closure of the fistula and recurrence of watering. Depending upon the amount of closure the Physician may have to use a Graefe knife, trocar, trephine or progressively larger dilators to re-enlarge the passageway. If the bony aperture of the previous operation was not of sufficient diameter, the surgeon may have to utilise a bone rasp to enlarge the diameter to allow proper positioning of the tube.