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CAUTION!

THESE DEVICES ARE VERY FRAGILE.

**GLASS TUBES WILL BREAK EASILY IF NOT
HANDLED WITH CARE.**

**NON-STERILE DEVICES MUST BE CLEANED
AND STERILIZED BEFORE USE BY
FOLLOWING INSTRUCTIONS PROVIDED**

All tubes are **CE 0120** marked to 93/42/EEC.

This document is a Summary Sheet for Implantable Tubes!

For a copy of the unabridged Instruction Sheet containing the following, contact Customer Services on 0191 519 0111

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



Due to the fragile nature of the glass tubes 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."

The non-sterile devices should be washed and sterilized before use following hospital approved procedures for these devices or by following the steps outlined below. Dispose of used or failed devices by following hospital approved procedures for contaminated sharps. Only to be used by suitably trained and qualified healthcare professionals.

Processing Instructions – Glass Tubes

Follow hospital approved procedures for handling devices to be sterilized, maintain full product identification. Before sterilizing, 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. If using a Washer/Disinfector (W/D) a Basingstoke W/D Adaptor A11933 must be used. Ultrasonic Baths can be used if available following hospital approved procedures with a final rinse in purified water to remove any chemical residues, dry with filtered air. Ensure lumen is cleaned using a Ruhof Instrusponge or similar Endozyme impregnated sponge if a W/D is not used. Inspect device for handling or processing damage (see above) and make sure it is visually clean and dry prior to pouching. Steam sterilize the tubes using a standard 134°C - 137°C cycle with a 3 minute holding time, use a peel pouch to protect sterility. 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

Processing Instructions and Use - Polyethylene Tubes and Cleaning Rods.

Do not autoclave Polyethylene Tubes or Cleaning Rods as they will melt!

Non-sterile Polyethylene Tubes should be washed, inspected and packed as the glass tubes above, do not use isopropyl alcohol as this may affect the surface of the device. Non-sterile Cleaning Rods should be washed by hand in isopropyl alcohol or in the Ultrasonic Bath using a pH neutral detergent (see*). The Polyethylene Tubes and Cleaning Rods should be sterilized to EN 556 by Ethylene Oxide using a protocol verified by the sterilization plant to ISO 11135-1 with ISO 9001 and/or ISO 13485 procedures where applicable, autoclaving will melt these two products.

Polyethylene Tubes are to be cut to size by the surgeon and sutured into place. They are designed for temporary placement, no more than 29 days, until post-operative swelling subsides; however a glass tube can be inserted at almost any time when deemed suitable by the trained Surgeon.

Nylon Cleaning Rods. The cleaning rod is used to clear an obstructed Jones Tube of dried mucus by the physician whilst in situ. It does not contact the patient.

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. 0.5mm Suture should be used. Periodic irrigation with saline via an irrigating syringe or regular syringe attached to a piece of tubing can aid in preventing mucus accumulation, as can sniffing artificial tear drops down the tube.

If the prosthesis shifts laterally, the patient should seek medical attention. If a tube is expelled, 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.

Over time the inside surface of a Glass Tube will become covered with debris that the eye ejects through tearing. This coating of debris will allow mucus to collect better than the clean smooth surface of a new tube; we therefore recommend tube replacement or cleaning when a noticeable layer builds up. The frequency of replacement will be affected by environmental factors of the patient's surroundings. We recommend that only a physician use a cleaning rod made by Altomed Limited. Cleaning of the tube lumen should be carried out very carefully as the cleaning rod is sharp. The rod should not be given to a patient to use on their own accord. The cleaning rod is to be used while the tube is still in the patient. If the tube is taken out it is recommended that it is replaced with a new sterile one.

The Surgeon should determine how often a patient is to be seen depending upon their individual needs and the success of the operation and placement and retention of the tube, however annual inspection by a practitioner is recommended to ensure the device is clean and functional, or is cleaned or replaced as necessary otherwise recurrent ocular infections may occur or conjunctival scarring.

Patient Information:

The tube may be marginally visible to the patient, they should also be told not to fiddle with it initially as it may dislodge. 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; they should also be told not to blow the nose hard for at least 6 weeks after the operation as this may cause bleeding.

When a patient is experiencing a head cold or sinus blockage it may be necessary for the surgeon to use the "cleaning rod" to remove a mucus obstruction. Most patients clear their Tube throughout the day by creating a low pressure in the sinus and nose. The patient should also be shown how to clean the tube daily by sniffing artificial tear drops down the tube. Some patients may need to be reminded to do this on a regular basis to keep the tube clear. The patient should be told not to continually blow air from the nose up the tube, as this may cause pain, periorbital swelling and epiphora. The site around the tube should also be cleaned daily to remove any stickiness.

The patient should also 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 tube.

The procedure may also not work and may require further operations. There may also be scarring visible along the side of nose.

Possible Effects:

There are the well-known risks associated with anaesthesia which are common in all operations, these are very rare but may include loss of sight and life. The implant site may become sore. The suture may also cause general irritation and irritation when wearing glasses until it is removed. There may also be some discharge and bruising. The patient should be warned of the possibility that late haemorrhage may occur for 10 – 14 days. Keloid and Scar Formation: there is a possibility of hypertrophic scar formation or keloids and this should be discussed with the patients preoperatively. There is a rare risk of diplopia following insertion of the tubes. Granulomas or tissue overgrowth may occur around the tube mouth and may need to be removed with a procedure. Conjunctivitis 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. It may not be possible to clean a blocked tube and this may need to be replaced in a further operation. The tube may also become displaced and as such require a further operation. It may often be necessary to replace a tube 2 or 3 times however it is less likely to displace over time as it becomes more stable. Blowing air up the tube from the nose to the eye may cause pain, periorbital swelling and epiphora.

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 who scuba dive should also be advised they will no longer be able to do this as they will not be able to perform the Valsalva manoeuvre. Patients should be advised that they will probably need to retain their tubes for the rest of their lives. The procedure should be deferred if deemed necessary by the surgeon and patient. 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 Tubes, their use is best avoided in children under teenage years 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 an insertion rod) using either topical or 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.