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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.

Reprocessing / Reuse Guidance

DO NOT REUSE POLYETHYLENE TUBES. The polyethylene tubes are supplied sterile and are for single use only due to the risk of cross contamination and product deterioration resulting from reprocessing.

DO NOT REUSE A GLASS TUBE THAT HAS BEEN PLACED IN A PATIENT. The glass tubes are designed for single patient use only due to the risk of cross-contamination if reprocessed after implantation and/or use on a patient. These products have however been validated for sterilisation before use if sold non-sterile and may be decontaminated and resterilised if the sterile packaging has been opened in the operating theatre but not used on the patient.

DO NOT USE OR REPROCESS THE DEVICE IF THE STERILE PACKAGING IS DAMAGED.

The glass tubes are suitable for decontamination in an ultrasonic bath using a pH neutral enzymatic detergent. The glass tubes should be packaged in a suitable sterile barrier system confirming to EN ISO 11607-1 and then sterilised by moist heat at a minimum of 134˚C for a minimum of 3 minutes before use. These processes should be validated by the facility to the applicable national or international standards.

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 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.

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.

Contraindications:

Patency of the lacrimal system is a principal contraindication for the placement of a bypass tube. 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. There is a rare risk of diplopia following insertion of the tubes. Lid malposition is a relative contraindication. The proper eyelid closure is important drainage function and fixation of a tube. 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.) Because co-operation of the recipient is required for after-care of Tubes, their use is best avoided in children under twelve years or in the mentally retarded.

Warnings:

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 twelve years or in the mentally retarded.

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. Granulomas or tissue overgrowth may occur around the tube mouth and may need to be removed with a procedure. Despite the complications and necessity for further surgical intervention in many cases, majority of the patients are pleased with the results of Canalicular bypass surgery. To prevent cross contamination, a tube should only be used on one patient. For tubes sold as Sterile, if the pouch is damaged or a sealed pouch opened and the tube does not fit the patient/or is not used for other reasons, the tube should be immediately discarded to prevent risk of re-processing/re-use.

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 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.

Performance Claims:

Performance Claims include providing a safe and suitable channel with excellent capillary action to permit and encourage the free flow of tears from the eye; to be safe and easily used by the intended user population; to be supplied either sterile or non-sterile, clean, ready for sterilization; to act as a drain and be biocompatible.

Accessories:

The Cox accessories are used in the placement of the implantable tubes. For instructions for use for these accessories, please see ALT I020.