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C A U T I O N !

THESE DEVICES ARE VERY FRAGILE.

GLASS TUBES WILL BREAK EASILY IF NOT HANDLED WITH CARE.

DO NOT RESTERILIZE

This document is an abridged IFU for the following Implantable Tubes:

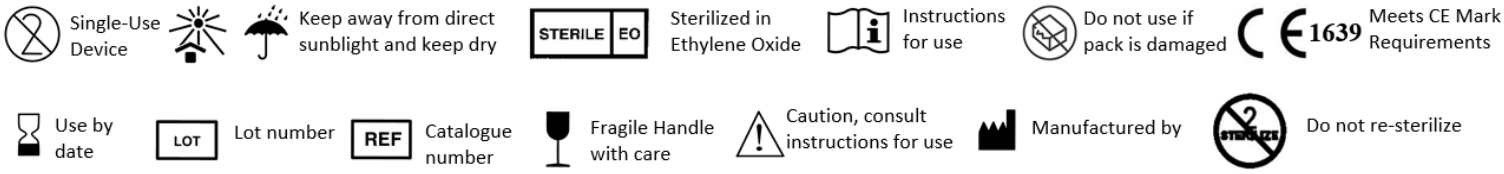
- **Lester Jones Tubes**
- **Gladstone Putterman Tubes**
- **Callahan Cox Tubes**
- **Double Collar Tubes**
- **MW Tubes**
- **Polyethylene Tubes**

For a copy of the unabridged Instruction Sheet ALT I004 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." 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.

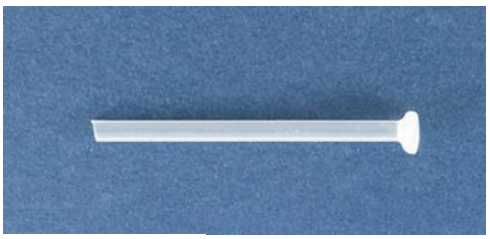
Symbols Used to BS EN ISO 15223-1 and ASTM F 2503 for Implantable tubes sold sterile:



Product Variants:

The type, size, angle of the Implantable tube depends on the anatomy of the patient and is determined prior to the surgery by the consultant surgeon after an evaluation of the patient's lacrimal sac. The following product variants can be available in different sizes, angles, frosted, as deemed suitable by the surgeon for the respective patient. (For full list of available sizes and variants please visit www.altomed.com).

Lester Jones Tube | Gladstone Putterman Tube | Callahan Cox Tube | Double Collar Tube | MW Tube (Lester Jones Tube angled)



Polyethylene Tube

Intended Use: The implantable tubes are used to provide a lumen in which tears can drain from the eye into the nose. Glass tubes are designed for long-term placement. Polyethylene tubes are designed for temporary placement until post-operative swelling subsides. The polyethylene tube can be removed and replaced with a glass tube at almost any time, deemed suitable by the trained surgeon.

Contraindications:

- 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.
- Patency of the lacrimal system
- Eye lid malposition
- Age less than 12 years

Complications:

Complications may include extrusion, malposition of tube, conjunctival overgrowth obstructing tube, granuloma overgrowth obstructing tube end, and discomfort. There might be a risk of dry eye following Lester Jones Tube placement. This can be due to subsequent and incidental development of dry eyes (exasperated by the presence of Lester Jones Tube), evaporation type (meibomian gland dysfunction) or aqueous deficiency (due to over-drainage) chances of which may be increased in case of prior intervention. This risk should be evaluated prior to surgery, especially for patients with underlying pre-disposing factors.

Warnings:

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. 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 patients are pleased with the results of Canalicular bypass surgery.

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.

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 hypertropic 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 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.