



Intended Use	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.
Indication(s)	Damaged tear ducts that cannot be repaired. Typically used in patients in whom previous lacrimal drainage operations Dacryocystorhinostomy haven't been successful; more likely in those patients with prior canalicular disease.
Sterility	Single use devices, supplied sterile (Ethylene Oxide). They should not be re-sterilized or re-processed or reused as the device may degrade or cause physical harm or infection.
Intended Patient Group(s)	Patients in whom previous lacrimal drainage operations (DCR) have not been successful (more likely in those with prior canalicular disease).
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel.
Clinical Benefits & Performance Characteristics	Provide a safe and suitable channel with excellent capillary action to permit and encourage the free flow of tears from the eye. Safe and easily used by the intended user population. Biocompatible.
Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water. 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. 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	The patient should be warned of the possibility that late haemorrhage may occur for 10 – 14 days.





	The possibility of hypertrophic scar formation or keloids should be discussed with the patients preoperatively. There is a rare risk of diplopia following insertion of the tubes. 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. Patency of the lacrimal system. Eye lid malposition. Age less than 12 years.
Warnings	It is possible to experience ocular irritation while smoking cigarettes. Patients have felt an air current before the eyes during inspiration and expiration. Some have also heard whistling noises during inspiration/ 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.
Precautions	These devices are very fragile and will break easily if not handled with care. 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.
Residual Risks & Undesirable Side-Effects	Complications may include extrusion, malposition of tube, conjunctival overgrowth obstructing tube, granuloma overgrowth obstructing tube end, and discomfort. Risk of dry eye following 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. There are 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. 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.





	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.
Additional Safety Information	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 a 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. <u>Replacing tubes:</u> 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. 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.





Disposal Considerations	Dispose of if the use by date has passed. Follow hospital approved procedures where provided. If there is no policy provided by your facility, dispose of as contaminated sharps.
In the event of an incident or defective device	If any serious incident has occurred in relation to the device, the user and/or patient should be report it to the manufacturer at the contact details below, and the competent authority of the Member State in which the user and/or patient is established (refer to https://ec.europa.eu/health/md_sector/contact_en)

