Tear Duct Tube
Instructions for Use
& Patient Information Leaflet (all sizes)

Contents:
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x1 Tear Duct Tube
x1 Patient Implant Card
x3 Patient Labels

Tear Duct Tube
Instructions for Use
& Patient Information

List of countries and regulatory authorities

United Kingdom
Medicines and Healthcare Products Regulatory Agency MHRA
www.mhra.gov.uk

Australia
Department of Health Therapeutic Goods Administration
www.tga.gov.au

South Africa
South African Health Products Regulatory Authority SAHPRA
www.sahpra.org.za

Czech Rep
State Institute for Drug Control
www.sukl.eu

Germany
Federal Institute for Drugs & Medical Devices www.bfarm.de

Denmark
Danish Medicines Agency www.laegemiddelstyrelsen.dk/en/

Spain
Spanish Agency for Medicines and Health Products www.aemps.gob.es

Ireland
The Health Products Regulatory Authority www.hpra.ie/

Italy
Italian Medicines Agency www.aifa.gov.it

Patient identification card
Instructions for completion of implant card by healthcare provider:
- Patient name/ID
- Date of implantation
- Name and address of healthcare provider

Post-operative care
Tubes can become blocked during use. Patients are advised to keep free of mucus and debris by sniffing saline or artificial tears through the tube at least twice a day, or more often if required.
Caution when sneezing. Patient must place a finger over implant (inner corner of eye) when sneezing to prevent dislodgement.
If tip of implant is beginning to protrude the individual can apply gentle pressure to ease back to position. If implant comes out completely, contact healthcare provider.

General
Any serious incident in relation to this device must be reported to the manufacturer and the regulatory authority of the country where the event occurred.

Translations of this IFU are available on the manufacturer's website; https://jweiss.co/quality

Ce mode d'emploi est disponible dans les langues suivantes sur le site internet du fabricant; https://jweiss.co/quality

Překlady tohoto návodu jsou k dispozici na webových stránkách výrobce; https://jweiss.co/quality

Übersetzungen dieser Gebrauchsanweisung sind auf der Website des Herstellers verfügbar; https://jweiss.co/quality

Du kan finde oversættelser af denne IFU på fabrikantens website; https://jweiss.co/quality

Hay traducciones disponibles de estas instrucciones en el sitio web del fabricante; https://jweiss.co/quality

Le traduzioni di queste istruzioni per l’uso sono disponibili sul sito web del fabbricante; https://jweiss.co/quality

Translations of this IFU are available on the manufacturer’s website; https://jweiss.co/quality
Symbols

Caution: consult document for important safety related information

Consult instructions for use

Manufacturer

LOT

Batch code

2

Single patient use, do not re-use

Non-sterile

Medical Device

Intended purpose

Tear Duct Tubes are used to correct watering of the eye due to permanent blockage or loss of function in the tear drainage system.

Intended use

Use of the Tear Duct Tubes is indicated where the canalicular system has been lost through congenital absence or become obstructed through trauma or other diseases or patients that have had unsuccessful lacrimal surgery.

The Tear Duct Tube is a tubular glass implant that is surgically inserted to establish a conduit between the lacrimal lake and the nasal cavity.

The Tear Duct Tube implants are manufactured using 2.2mm orbital diameter borosilicate glass tubing, tooled flange on one end, bevelled and fire polished on the other. Typical flange diameters: 3, 3.5 or 4mm. Typical length specified in millimetre increments, longer than 9mm.

Tear Duct Tubes are intended for long-term implantation in an individual patient, they are not suitable for refitting. The implant must only be fitted in a clinical environment by a qualified Healthcare Professional, fully-trained in their use.

The lifetime of the device is dependent on the patient’s age and changes in facial shape.

Possible adverse reactions:

- Conjunctival overgrowth/conjunctival irritation
- Improper tube position
- Infection
- Tube obstruction
- Extrusion
- Persistent eye irritation
- Lost tubes

Inappropriate use of the device or incorrect size selected by the user during surgery could result in risk or serious medical risk to the patient.

- Product supplied NON STERILE
- DO NOT re-use. Risk of re-use includes but is not limited to; infection, rejection, exclusion and failure of the implant to properly vascularise and incorrect prognosis
- Use caution when cleaning to prevent damage to the device
- Devices must be carefully inspected prior to use. If device is damaged DO NOT USE
- Tear Duct Tubes are made of borosilastic glass and therefore must be treated with care at all times
- Do not use abrasive instruments or commounds on the surface of the tube
- Follow the cleaning and sterilisation procedure detailed below before use.

Clinical benefits

Correction of watering eyes. Variants of the device are available in the following; suture hole, frosted, angled, standard.

Contraindications

This device is not designed, sold or intended for use except as prescribed/indicated by a qualified healthcare professional.

Pre-operative cleaning instructions

1) Rinse excess soil from the device and ensure lumens are flushed through with running water.
2) Dilute cleaning solution at 2mls per litre with warm water (Do not exceed 55°C/130°F) and soak for a minimum of 5 minutes. Rinse thoroughly with distilled sterile water. Tubes to be submerged in 70% IPA for 5 minutes, then rinse thoroughly with distilled sterile water. Inspect for any residue. Repeat if required
3) Tubes to be submerged in 70% IPA for 5 minutes, then rinse thoroughly with distilled sterile water. Inspect for any residue.

Pre-operative inspection

Visual checks must be performed confirming suitability for use prior to operation.

The Healthcare Professional shall perform a visual examination of the implant prior to use, including:
- Confirm the finish of the Tear Duct Tube is smooth and free of contaminates
- Confirm it is free of cracks or deep scratches
- Confirm size suitability to patient.

Pre-operative cleaning instructions

Cleaning: Automated

Device not suitable for automated cleaning.

Cleaning: Manual

Equipment: Prolystica 2x Enzymatic pre-soak & Cleaner, 70% IPA, running water, distilled sterile water. Refer to alternative methods for alternative cleaning instructions.

Method:
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Storage

We recommend devices to be retained within their packaging until cleaning & sterilisation, to prevent damage to the device.

Ensure devices are dry before storage, and stored in a dry clean condition. It is recommended that devices are stored in the supplied packaging.

Care must be taken with surgical instruments when implanting this device, to prevent damage. In the event the device becomes dislodged, contact your healthcare professional.

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Possible adverse reactions:

- Pyogenic granuloma
- Damage to caruncle (inner corner of the eye).

Disposal

Upon removal of device, the healthcare professional should dispose of the device through sharps hazardous waste.

Drying

Dry with filtered air to remove residue/alcohol from all surfaces.

Pre-operative packing & sterilisation instructions

Tubes may be steam sterilised within an autoclave at 134°C to 137°C (273.2°F to 278.6°F) in a peel pack for a minimum of 3 minutes and then dried for a further 20 minutes.

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Limitations on reprocessing

Devices can be reprocessed, but should not be reimplanted.

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