INSTRUCTIONS FOR USE
Lacrimal Intubation Set

Description:
Lacrimal Intubation Sets are used for intubating of the lacrimal ducts. The silicone tube acts as a conformer and enables drainage of tears by capillary action. In cases of canalicular lacerations, the silicone tube guides wound healing and combats the onset of synechia.

The Anodyne Surgical Lacrimal Intubation Set is composed of two flexible 23g stainless steel probes with an outer diameter of 0.22" attached to each end of a 12" length medical grade silicone elastomer tubing having an outer diameter of 0.025". Lacrimal Intubation Set may also come with a retriever hook.

Each Lacrimal Intubation Set is packaged in a Tyvek pouch and supplied sterile. Pouches are sterilized by gamma irradiation using a validated sterilization cycle in compliance with EN ISO 11137-1. Ten pouches are packaged in an enclosable carton.

Indications:
The Lacrimal Intubation Set is intended for use for nasolacrimal intubation in patients 12 months of age or older. Indication for nasolacrimal intubation are:

- Canalicular pathologies (congenital or acquired stenosis, lacerations)
- During dacryocystorhinostomy (DCR) procedures
- Congenital lacrimal duct obstruction

Contraindications:
Lacrimal Intubation Sets should not be used in cases involving lacrimal sac tumors or the presence of dacryoliths.

Insertion:
Each punctum should be dilated and the lacrimal system should be probed to open any blockages by using a standard lacrimal probe.

The first probe of the Lacrimal Intubation Set is passed through the upper punctum and across the upper canaliculus and then oriented down through the lacrimal system into the nose approximately 4cm.

For Lacrimal Intubation Set that come with retriever proper positioning of the probe can be confirmed by achieving metal-to-metal contact with the retrieval instrument inserted through the nostril. The probe end should be located lateral to the inferior turbinate in the inferior meatus of the nose. The retrieval instrument can be used to engage the probe at its olive tip and pull the probe out of the nose.

The second probe is passed down the inferior canaliculus and out of the nose in a similar fashion.

The two exposed probes are cut from the silicone tube and removed. The ends of the silicone tube are tied to each other and securely knotted. The silicone tubes may be further secured by a tiny suture. Tuck the knotted silicone tubes up into the nose.

Removal:
Removal of the silicone tubes is accomplished by locating the silicone tube in the eye between the upper and lower puncta and pulling the tube upward. The silicone tube is then cut and pulled out completely from the ducts.

The knot used to tie the silicone tubes together is too big to pass through the canaliculus and the silicone tubes must be removed through the nose. In older patients it may be possible to expel the knot by having the patient blow their nose. In small children, location of the knot and silicone tube removal may need to be performed under general anesthesia.

Warnings:
All precautions for a surgical operation are to be followed.

Ease of passage of the stainless probe through the lacrimal system will bary widely from patient to patient. Placement of the silicone tubing in some patients may be quite difficult due to narrow openings in lacrimal system, especially at the lower end of the bony canal.

Occasionally, a patient may pull the tubing out from between the upper and lower puncta. In this case the tubing should be removed. If desired, a replacement Lacrimal Intubation Set may be inserted int eh normal manner.

It is important to note that tearing may persist while the tubing is in place since they do not act as passages for the tears.

In the case of complications or unusual symptoms, it is recommended to quickly contact an ophthalmologist.

Adverse Side Effects:
As in any type of surgery, there are risks linked to the material or to the development of the initial pathology. Potential complications associated with the implantation of the lacrimal tube include, but are not limited to, the following:

1. Complications occurring during the procedure:
    a. False passages
    b. Bleeding
    c. Canalicular trauma
    d. Separation of the silicone tubing from the probe. Refer to “Precautions for Use”.
2. Post-operative complications:
    a. Conjunctival or nasal prurius
    b. Stricturotomy
    c. Canaliculitis
    d. Bleeding
    e. Reversible shrinkage of the palpebral tissue
    f. Nasal or canalicular irritation
    g. Exteriorization or loss of tubing
    h. Synechia of the nasal mucosa
    i. Induced muclocele

Side effects and complications related to the Lacrimal Intubation Sets must be reported to Anodyne Surgical.

Precautions For Use:
Always handle the Lacrimal Intubation Sets in an aseptic manner. Before use, examine the packaging and product for signs of damage which could compromise the sterility or function of the product.

Separation of the silicone tubing from the stainless probe or breakage of the silicone tube may occur when intubation patients with sever blockage or narrowing of the lower nasolacrimal duct or patients with a pronounced bony prominence. Often a push/pull technique and some working of the stainless probe will be required to complete the intubation. Although the tubing is highly elastic and strong for its size, it is still possible the tubing can broken as result of undue stress.

Store at room temperature. Do not use after expiration date.

Symbols and Explanations:

	Symbol	Explanation		Symbol	Explanation
1		Manufacturer	7		Prescription use only
2		Non Latex	8		Catalog number
3		Sterilized using irradiation	9		Batch code
4		Do not re-use	10		Exp date
5		Do not use if the package is damaged	11		Quantity
6		Manufactured in the USA and/or applies to medical devices sold in the USA	12		Carrier contains unique device identifier information