

TRANSNASAL LACRIMAL STENT

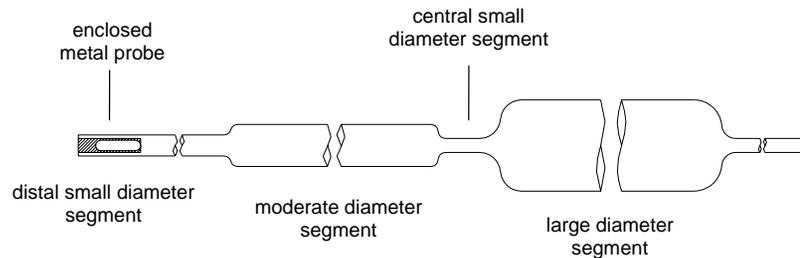
STERILE EO

DESCRIPTION - PRESENTATION

The TRANSNASAL LACRIMAL STENT is a lacrimal bicanalicular intubation stent. It consists of a silicone tube with different diameter segments : a large, a moderate and two small. The stent's distal small diameter segment ends with an enclosed malleable metal probe.

The TRANSNASAL LACRIMAL STENT is coated with polyvinylpyrrolidone (PVP) to improve its wettability.

Diagram of the TRANSNASAL LACRIMAL STENT



The TRANSNASAL LACRIMAL STENT is supplied with :

- a sheath : 170 mm polyetherimide tube to fit to the TRANSNASAL LACRIMAL STENT's rod in order to pull the sheath through the lacrimal system and nose.
- a 175 mm metal rod with rounded extremity that allows the sheath's introduction in the lacrimal ducts.

The TRANSNASAL LACRIMAL STENT is supplied sterile. It is sterilized by Ethylene Oxide. A green indicator shows that the product has completed the sterilization process. It is sterilized in its final packaging to make it easier to handle in aseptic conditions.

INDICATIONS

The TRANSNASAL LACRIMAL STENT is indicated in treatments of epiphora treated by dacryocystorhinostomy. Dacryocystorhinostomy (DCR) is the surgery used to correct nasolacrimal duct obstruction.

MODE OF ACTION

The silicone tube acts as a stent and enables drainage of tears by capillarity. In cases of canalicular lacerations, the silicone tube guides the wound healing and prevents the onset of synechia.

See diagrams

Brief description of stent placement



fig. 1

1. Rod is inserted into the lumen of the sheath
2. Inserted through the superior punctum, superior canaliculus, and DCR ostium
3. Sheath with contained rod is grasped in the nose and pulled down the nose and out the naris



fig. 2

4. Rod is removed from the top without moving the sheath
5. Empty sheath protrudes out the nose
6. Small diameter end of stent with enclosed probe is threaded into the distal end of the sheath



fig. 3

7. Sheath with enclosed stent is pulled back out of the superior canaliculus

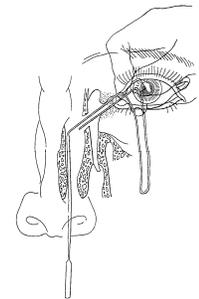


fig. 4

8. The distal small diameter segment of the stent with enclosed probe is pushed through the second canaliculus, lacrimal sac and into the nose



fig. 5

9. Stent with enclosed probe is pulled down the nose and out the naris with a hemostat



fig. 6

10. Final position of the stent with the moderate diameter segment cut to the appropriate length
 11. The stent is removed 4 to 5 months after surgery with appropriate pre- and post- removal medical therapy

WARNING AND CONTRA-INDICATIONS

- The use of the TRANSNASAL LACRIMAL STENT is contra-indicated in cases of epiphora that are not caused by lacrimal drainage system obstruction.
- At times tissue edema around the transnasal stent results in temporary functional lacrimal drainage obstruction and low grade dacryocystitis. This does not affect the final result as long as the stent is never removed when active infection is present.
- Never remove the stent if dacryocystitis or discharge is present.
- The stent should not be removed in patients with dacryocystitis which is usually manifest as low grade discharge when the stent is in place. Patients with dacryocystitis require a 2 week course of antibiotherapy before stent removal.
- The large diameter end of the stent may slip out of the lacrimal sac and DCR ostium over time. It is essential that the large diameter segment be brought into the lacrimal sac by pulling on the small diameter end at least once a month.

ADVERSE SIDE EFFECTS

As in any type of surgery, there are risks linked to the procedure used and/or to developments of the initial pathology. Potential complications associated with the implantation of the TRANSNASAL LACRIMAL STENT include, but are not limited to the following ones :

- Complications occurring during insertion :
 - false passages
 - separation of the stent lumen and the probe
- Post-operative complications :
 - conjunctival or nasal pruritus
 - nasal or caruncular irritation
 - reversible shrinkage of the palpebral fissure
 - synechia of the nasal mucosa
 - canaliculitis or dacryocystitis

Unexpected side effects and complications related to the TRANSNASAL LACRIMAL STENT must be reported to FCI.

RECOMMENDATIONS FOR USE

The silicone tube-metal probe junction is a fragile area. It is recommended that the metal probe be held with care while it is threaded into the distal end of the sheath. The sheath is a hollow and flexible part that should be handled with care to avoid twisting or flattening. It is recommended that the patient be shown the interpalpebral loop following the procedure.

PRECAUTIONS FOR USE

The TRANSNASAL LACRIMAL STENT, its sheath and the rod must be removed from their packaging and handled in aseptic conditions. Before use, the individual pack preserving the product's sterility should be checked to make sure it is intact. The TRANSNASAL LACRIMAL STENT, its sheath and the rod are single-use products and must not be re-sterilized. They should be stored at room temperature and must not be used after the expiration date shown on the package.

MANUFACTURED FOR

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