PHYSICIAN INSTRUCTIONS

MONOSTENT™ MONOCANALICULAR STENT SYSTEM
PATENT PENDING

CAUTIONS:

U.S. Federal law restricts this device for sale by or on the order of a licensed medical practitioner.

If the patient experiences abnormal swelling, pain, irritation, or erythema after insertion, removal of the MonoStent™ should be considered. Frequent re-examinations should be made to detect any infection.

The MonoStent is not intended to remain in place for more than 29 days.

WARNINGS:

Single Use Only.

DO NOT RESTERILIZE.

Supplied Sterile. Sterility not guaranteed if package has been opened or damaged.

STORAGE CONDITIONS:

Store at Room Temperature.

Made in U.S.A.

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DESCRIPTION:

MonoStent™ Monocanalicular Stent system includes a length of silicone tubing with a modified silicone Eagle FlexPlug® punctum plug for immobilization at one end. MonoStent is packaged pre-loaded on a metal stylet which is designed to aid insertion.

MonoStent is L-shaped with approximately 50mm of medical grade silicone tubing. The distal end of the stent (the plug end) seats in the punctum. The stylet is 80mm in length including a 10mm diameter loop at one end.

MonoStent is supplied sterile pre-loaded on the stylet.

INDICATIONS FOR USE:

MonoStent is indicated for use in repair of lacerated canaliculi.

CONTRAINDICATIONS:

MonoStent is contraindicated for patients with known silicone sensitivity.

PREPARATIONS:

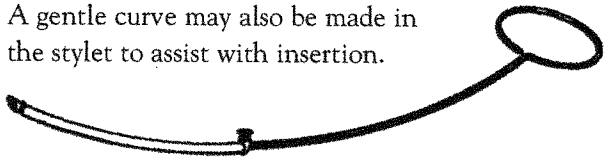
The desired length is determined. If a shorter

length is desired, the stylet is first withdrawn just enough so as not to interfere when the tubing is cut. It is suggested that the cut be made at an acute angle across the axis of the tubing to create a leading surface configuration. This should allow for more efficient insertion. The excess tubing is cut free and discarded.

IMPORTANT:
The leading end of the tubing is to be tied closed with an absorbable 6-0 suture.

This is to prevent the stylet from extending beyond the end of the tubing during insertion.

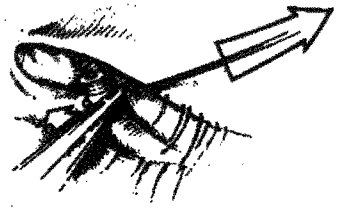
The stylet is now advanced to the closed portion of the tubing. The stylet loop may be rotated perpendicular to the plug to ease insertion.
A gentle curve may also be made in the stylet to assist with insertion.

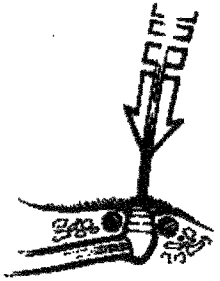


An ophthalmic ointment may be applied to the tubing immediately prior to insertion.

INSERTION:
The punctum is dilated, with a tapered probe, to a sufficient diameter to facilitate insertion of the MonoStent™ The stent should be ready for insertion since the punctum will rapidly constrict after dilation.
MonoStent is then threaded into the punctal opening and advanced through the distal portion of the severed canaliculus using the stylet. Continue insertion of the stent into the proximal portion of the lacerated canaliculus to the predetermined distance.

Once the tubing has been fully advanced through the canaliculus, the position of the plug should be immediately above the punctal opening. The stylet is removed by using forceps as a stop against the plug while gently withdrawing the stylet.





After the stylet is removed, either the end of the stylet or the tip of the forceps may be used to manipulate or nudge the remainder of the stent punctum plug into the punctal opening. The punctum plug is seated properly when the base of the rim is flush with the surface of the punctal opening.

MonoStent is designed so stitching to the eyelid is not required, however, the design allows for stitching if desired.

REMOVAL:
IMPORTANT:
DO NOT ATTEMPT TO REMOVE THE STENT BY GRASPING THE EDGES OF THE EXPOSED RIM.

Rather, MonoStent is removed by gently elevating the edge of the rim initally with one forceps so that the stent body may be visualized. Then, a platformed forceps is used to grasp the body UNDER the rim, as far down the shaft as possible. With a gentle upward motion, the stent can be slowly extracted from the punctal opening.