

LACRIFLOW

Lacrimal Duct Tube

Federal law (USA) restricts this device to sale by or on order of a physician.
Single Use Only

【Indications for Use】

The LACRIFLOW is indicated in treatments of epiphora in patients 12 months and older, in cases of:

- Canalicular pathologies (stenosis, obstruction, lacerations),
- During Dacryocystorhinostomy (conventional or laser),
- Congenital nasolacrimal duct obstruction

【Description】

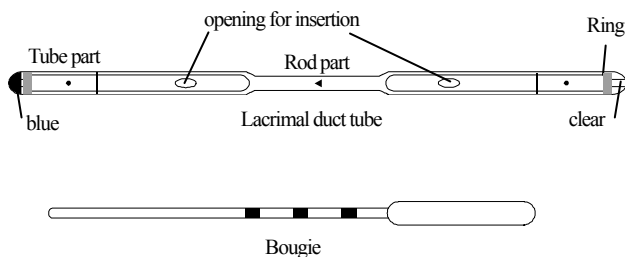
The LACRIFLOW is consisted of the Lacrimal duct tube intended to be inserted and placed inside the lacrimal canaliculus or other sites to dilate the lacrimal duct and the Bougie used for the insertion of the tube. The Lacrimal duct tube has hydrophilic coating.

Different models of the LACRIFLOW include:

- Different sizes of the Lacrimal duct tube (Length: 105, 90 and 50 mm)
- Different types of the Bougie (Tip type: Straight (Type I), Helicly grooved (Type II))

Two sterile Bougies are color-coded clear and blue. The two Bougies are inserted into each tube part of the Lacrimal duct tube in the package. (Clear Bougie to the tube part with clear tip, Blue Bougie to the tube part with blue tip).

Structure



Material

Lacrimal duct tube: Polyurethane resin mixture (Tube),
Stainless steel (Ring)
Bougie: Stainless steel

【Instruction for Use】

1. Before using the LACRIFLOW, dilate lacrimal puncta with an appropriate lacrimal dilator or by the snip incision of lacrimal punctum. Open an obstructed site of lacrimal duct (e.g. with an appropriate lacrimal duct probe; or by DCR(conventional or laser)). The opening should be confirmed by injecting fluid from the puncta and observing the fluid flow to the nasal cavity.
 2. While the Bougie is being inserted in the tip of the Lacrimal duct tube, drop saline onto the surface of the Lacrimal duct tube and check that it is adequately wetted.
 3. Insert the Lacrimal duct tube from lacrimal punctum into vertical canaliculus and then, tilt the Lacrimal duct tube downward until it is horizontal to an eyelid and advance the insertion.
 4. When the tip of the Lacrimal duct tube touches a nasal wall of the lacrimal sac, keep it touched to that position and using the position as a supporting point, turn the Lacrimal duct tube downward until it is horizontal to nasolacrimal duct. Continue insertion until one side of the Lacrimal duct tube is out of the view. Keep the position of central marking (arrowhead) outside the lacrimal punctum. Do not remove the Bougie since the Bougie is used for final adjustment.
 5. Repeat step 2-4 in order to insert another side of the Lacrimal duct tube to the other lacrimal punctum using another Bougie. Adjust the position of the central marking (arrowhead) between the two lacrimal puncta. After the adjustment, remove the both two Bougies.
 6. Check that both sides of the Lacrimal duct tube can be seen from nasal cavity.
- [Caution]** Remove the Lacrimal duct tube if you feel significant resistance when removing the Bougie because the Bougie may be in a false passage

[Caution] If it is difficult to change the direction of the Bougie, it is recommended to use type II Bougie (helically grooved) because the tip of the type II Bougie is more flexible than that of the type I straight Bougie.

[Caution] After the insertion procedure, inject fluid from the lacrimal punctum and check whether the fluid flows to the nasal cavity in order to ensure the LACRIFLOW is placed appropriately. When you do not see passing of water to the nasal cavity, remove the Lacrimal duct tube because a false passage may be formed. If the user re-inserts the LACRIFLOW, use a new device because the removed device could be broken.

[Caution] When the Lacrimal duct tube cannot be passed through a raised part between common canaliculus and lacrimal sac or a curved point in an inferior portion of nasolacrimal duct, bend the Bougie to 3~10 degree angle at 10mm from the tip and try insertion again.

[Caution] It is recommended to perform irrigation of lacrimal duct daily for the first 3 days post-treatment and once or twice a week afterwards in order to prevent adhesion between tissue and the Lacrimal duct tube. It is aimed to wash out clotted blood since clotted blood sticks to the Lacrimal duct tube and causes adhesion between tissue and the Lacrimal duct tube.

[Caution] Give instruction to patients not to pull or remove the tip of the Lacrimal duct tube protruding from the nostril. That portion protruding from the nostril may be cut if necessary.

[Caution] Do not perform MRI while the Lacrimal duct tube is implanted in the nasolacrimal drainage system because the ring included in the Lacrimal duct tube is made from stainless steel. There are risks that MRI may result in migration, heating of the device and/or degrading of MRI image quality due to strong magnetic fields.

[Caution] Do not perform therapy using electromagnetic induction including high frequency hyperthermia in an area close to the nasolacrimal drainage system while the Lacrimal duct tube is implanted. There is a risk that such therapy may result in migration or heating of the device.

7. Remove the Lacrimal duct tube from the puncta by pulling the Lacrimal duct tube. Do not cut the Lacrimal duct tube during the removal.

[Caution] Do not remove the Lacrimal duct tube rapidly. Grasp the tube not with tweezers but with operator's fingers and remove it as slowly as possible continuously applying tensile force for 5 to 10 minutes, when removing the Lacrimal duct tube which is inserted especially into a false

passage and passes through a raised part between common canaliculus and lacrimal sac.

[Caution] Do not pull the Lacrimal duct tube to a length more than 3 times long. [There is a risk that the stress of pulling on the tube may lead to breaking or snapping the tube into two separate pieces.]

[Caution] If any fractured piece of the Lacrimal duct tube is remained inside the body, remove it immediately.

【Contraindication】

Do not apply to patients with the following conditions:

- Epiphora that do not have a nasolacrimal origin.
(e.g. Lacrimal sac tumor, Lacrimal duct obstruction due to sarcoidosis, Nasolacrimal duct obstruction due to Nocardia dacryoliths, Nasolacrimal duct obstruction due to a progression of such as maxillary cancer, Lacrimal canalculitis due to actinomycete or other)

【Warning】

1. If a false passage passing through orbit was created during the insertion, it may cause serious adverse event including exophthalmos or orbital abscess by running pus in the lacrimal sac into the orbit. In such case, immediately take appropriate measure including dacryocystorhinostomy.
2. If the Lacrimal duct tube is inserted while the obstructed part of lacrimal duct is not adequately opened, there are risks that such insertion may damage to lacrimal duct which may cause bleeding or the Bougie may break the Lacrimal duct tube and its broken segments remain inside the body.

【Adverse events】

As in any type of surgery, there are risks linked to the material or to developments of the initial pathology. Potential complications associated with the implantation of the Lacrimal duct tube include, but are not limited to the following:

Complication occurring during the Bougie insertion:

- false passage
- bougie penetration
- loss of the Lacrimal duct tube

Post-operative complications

- conjunctival or nasal pruritus - nasal or caruncular irritation
- reversible shrinkage of the palpebral fissure
- exteriorization or loss of the Lacrimal duct tube
- stricturotomy - synechia of the nasal mucosa
- canaliculitis - induced mucocele
- cheese wiring -edema or inflammation of lacrimal punctum
- granuloma
- injury of lacrimal punctum and/or lacrimal canaliculus
- stenosis of lacrimal punctum and/or lacrimal canaliculus
- infection -arterial/venous perforation -nasal bleeding
- orbital encephalopathy -exophthalmos -orbital cellulitis
- temporal headache -diplopia -corneal damage

Report adverse events and complications related to the LACRIFLOW to Kaneka Pharma America LLC.

[Precautions]

1. Remove the package and handle The LACRIFLOW in aseptic condition.
2. Before use, check the individual pack preserving the LACRIFLOW 's sterility in order to make sure if it is intact.
3. Single Use Only. Do not re-sterilize the LACRIFLOW.
4. The LACRIFLOW shall only be used by physicians experienced in treatment of silicone tube intubation into lacrimal duct.
5. The physician shall choose the appropriate size of the Lacrimal duct tube by measuring the size of the patient's face and estimating the size of the lacrimal drainage system, or measuring the lacrimal drainage system.
6. Do not damage the Lacrimal duct tube with knives or scissors.
7. Do not use anything other than the Bougie when inserting the Lacrimal duct tube.
8. Do not perform insertion of the Lacrimal duct tube with the Bougie rapidly, and do not repeat insertion and removal.
9. If experiencing difficulty removing the Bougie after inserting the Lacrimal duct tube, remove it by holding the tube with tweezers and slightly twisting it to right and left while removing.
10. In order to avoid an insertion of the Lacrimal duct tube into a false passage, check an opening of the inferior nasolacrimal duct endoscopically as appropriate during the procedure.

11. Use immediately after opening the package. Properly discard the LACRIFLOW and the package after use according to the regulation of the hospital, government, and the local government.
12. Store the LACRIFLOW in the place avoiding direct sunlight at room temperature.
13. Do not use the LACRIFLOW after the expiration date shown on the packaging.

【Package】

2 sets/box

【Manufacturer】

Name : Kaneka Corporation

Address :2-3-18 Nakanoshima, Kita-ku, Osaka-city, Osaka, Japan,
530-8288

Tel : (+81)-(0)6-6226-5256

【Distributor】

Name : Kaneka Pharma America LLC

Address : 546 Fifth Avenue, 21st Floor, New York, NY, USA, 10036

Tel : 800-526-3522