

OphthaCath[®]

Lacrimal Duct Balloon Catheter

INDICATION

For Nasolacrimal Duct Obstructions
in the Treatment of Epiphora

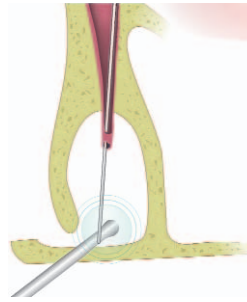


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INITIAL PROBING

- 1 Dilation of the punctum and insertion of a Bowman probe.
- 2 Search for bony contact.
- 3 90° rotation and vertical catheterization.
- 4 Once the nasal fossa floor is reached, the Bowman probe is gently removed.
- 5 A second, wider lacrimal probe with a blunt tip is inserted gently through the naris to confirm metal-to-metal contact.



OPHTACATH® PROCEDURE

- 1 Remove the protective sleeve on the catheter. For safety reasons, **never exceed a balloon inflation pressure of 15 bars**. Select the size of the balloon catheter suitable for the patient.
- 2 Insert the balloon into the superior punctum, then direct it through the lacrimal sac and push it down to the nasal floor. Insert a second probe into the nose to confirm contact with the balloon and eliminate the possibility of a false passage. (See Figure 1)
- 3 Pull back the balloon just until the most proximal mark on the catheter becomes visible at the punctum (15 mm distance from the balloon), and maintain the position. Fill the inflation device with 10 cc of sterile water. Gradually inflate the balloon to **8 atm** (bars). (See Figure 2). Maintain the balloon inflated for **90 seconds** in order to dilate the nasolacrimal duct, then deflate. If necessary, repeat the procedure for **60 seconds**.
- 4 Pull back the balloon until the second mark on the catheter becomes visible at the punctum (10 mm from the balloon), and maintain the position. Gradually inflate the balloon to **8 atm** (bars). (See Figure 3). Maintain the balloon inflated for **60 seconds** in order to dilate the nasolacrimal duct, then deflate. If necessary, repeat the procedure for **40 seconds**.
- 5 After the last inflation is performed, fully deflate the balloon by turning the handle counterclockwise until the inflator gauge of the manometer is in the red area (**0 atm**) and all fluid has been aspirated out of the balloon. Gently remove the catheter and confirm the success of the procedure with fluorescein.

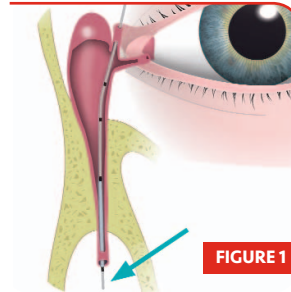


FIGURE 1

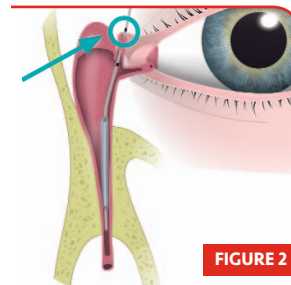


FIGURE 2

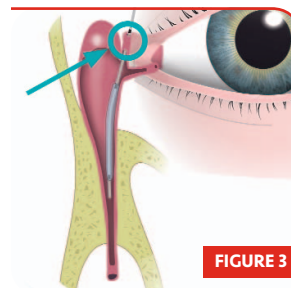


FIGURE 3

Please refer to OPHTACATH Instructions for Use for the full procedure.

FEATURES & BENEFITS

PROVEN RESULTS

- OPHTACATH achieves true dilation of the lacrimal duct and rapidly treats the symptoms of epiphora.

FAST AND EFFICIENT PROCEDURE

- Alternative to incisional procedures such as DCR.
- Reduced trauma.

FCI EXCLUSIVE DESIGN

- Easy to insert and remove thanks to the very low profile of the deflated balloon (0.9 mm for the 2 mm model/1.0 mm for the 3 mm model).
- Exclusive tapered tip.
- Exclusive balloon design features excellent shape memory before and after inflation.

FCI QUALITY STANDARDS

- Balloon made of nylon results in exceptional resistance to burst pressure.
- Semi-flexible balloon ensures a progressive inflation and exceptional precision of 1/10 mm.
- Highly precise and easy-to-use disposable inflation device supplied with each kit.
- Full traceability system: lot number, balloon diameter and length printed on each catheter.



UNILATERAL OPHTACATH KITS

S1-4121

2 mm Unilateral Kit
1x2 mm Balloon Catheter &
Disposable Inflation Device
Box of 1, sterile

S1-4131

3 mm Unilateral Kit
1x3 mm Balloon Catheter &
Disposable Inflation Device
Box of 1, sterile



Balloon Catheter

Disposable Inflation Device



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