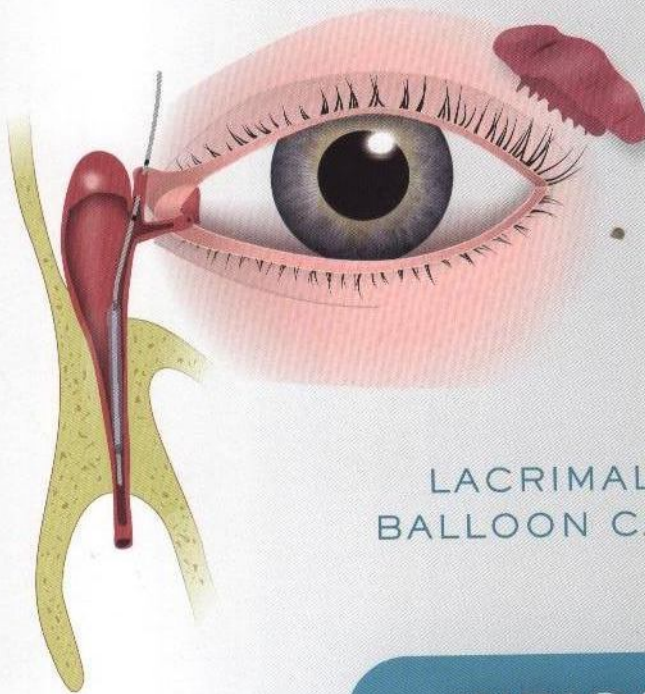




OPHTACATH®



LACRIMAL DUCT BALLOON CATHETER

INDICATIONS

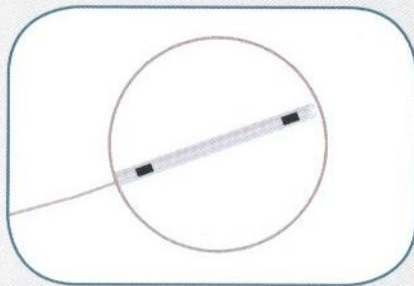
- Nasolacrimal duct obstruction
- Dacryocystoplasty (DCP)

OPHTACATH® FEATURES AND ACCESSORIES

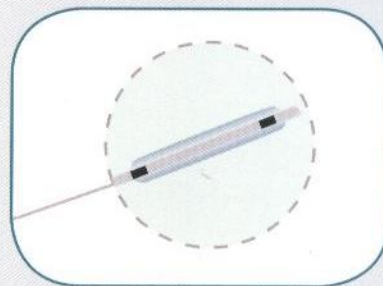
AVAILABLE IN 2 SIZES

2 mm balloon diameter / 13 mm length for patients under 30 months.

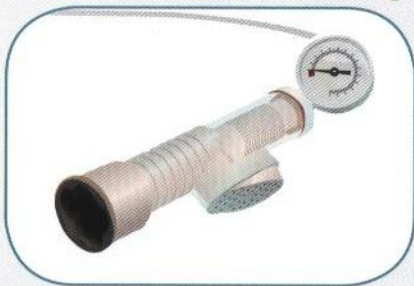
3 mm balloon diameter / 15 mm length for patients over 30 months.



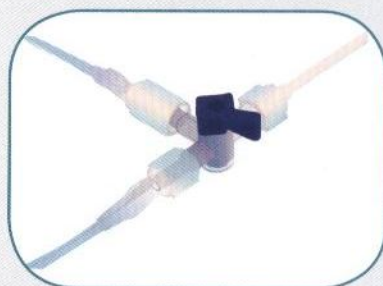
▲ OPHTACATH® before inflation



▲ OPHTACATH® inflated



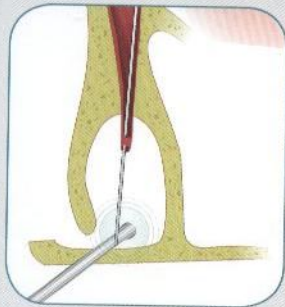
▲ Disposable inflation system



▲ 4-way stopcock

HOW TO USE THE OPHTACATH® ?

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.

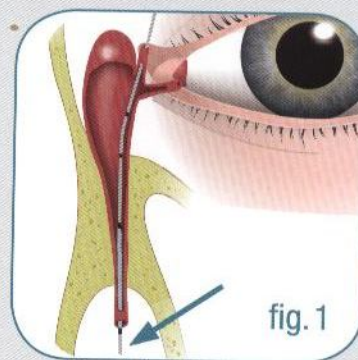
A second, wider lacrimal probe with a blunt tip is inserted and very gently steered through the inferior nasal meatus, until metal-to-metal contact is achieved.

OPHTACATH® PROCEDURE EXAMPLE - UNILATERAL DILATION (*)

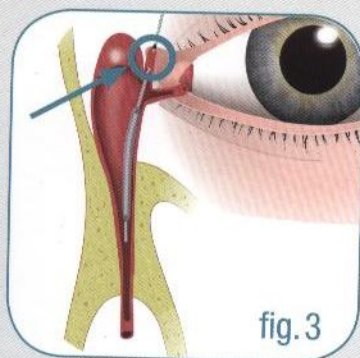
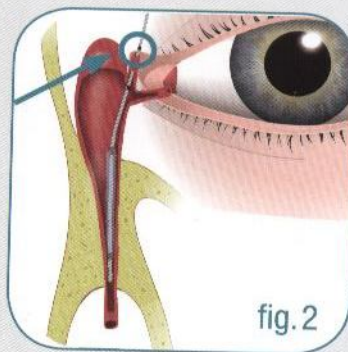
(*) Please refer to OPHTACATH® Instructions for Use for the full procedure.

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. The OPHTACATH® is first inserted into the superior punctum, then passed through the lacrimal sac and pushed down to the nasal floor. A second probe is inserted into the nose to get in contact with the OPHTACATH® and eliminate a false passage possibility. (fig. 1)



3. Pull back the OPHTACATH® so that the most proximal mark on the catheter is just 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 until **8 atm** (bars). (*fig. 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 OPHTACATH® so that the second mark on the catheter is visible at the punctum (10 mm from the balloon), and maintain the position. Gradually inflate the balloon until **8 atm** (bars). (*fig. 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. Unlock the inflation device and pull out the piston to remove all the sterile water. The gage should be in the red area. Once the OPHTACATH® is completely empty, lock the inflation device again. Gently remove the OPHTACATH®, and confirm the success of the procedure with fluorescein.

FEATURES AND BENEFITS OF OPHTACATH®

PROVEN RESULTS

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

FAST AND EFFICIENT PROCEDURE

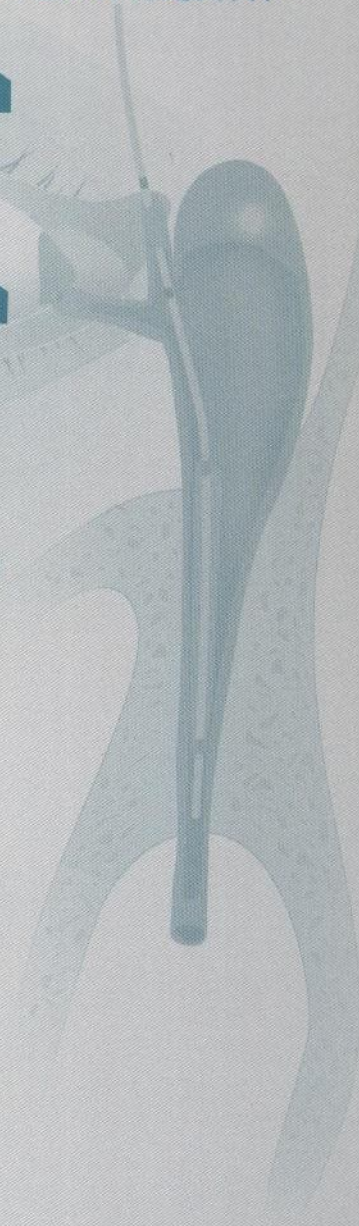
- Real alternative to incisional procedures such as DCR.
- Reduced trauma.
- Simultaneous bilateral inflation saves operating room and anesthesia time.

FCI EXCLUSIVE DESIGN

- **Easy to insert and remove** thanks to the very low profile of the balloon (0.7 mm for the 2 mm model / 0.75 mm for the 3 mm model).
- **Exclusive tapered tip.**
- **Exclusive balloon design retains folding memory** after inflation / deflation.

FCI QUALITY STANDARDS

- Balloon made of Nylon Polyn® results in **exceptional resistance to burst pressure.**
- Semi compliant 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.



INDIVIDUALLY PACKAGED, STERILE

S1.4121	OPHTACATH® 2 mm Unilateral Kit	1 x 2 mm balloon catheter & inflation device
S1.4122	OPHTACATH® 2 mm Bilateral Kit	2 x 2 mm balloon catheter, inflation device & 4-way stopcock
S1.4131	OPHTACATH® 3 mm Unilateral Kit	1 x 3 mm balloon catheter & inflation device
S1.4132	OPHTACATH® 3 mm Bilateral Kit	2 x 3 mm balloon catheter, inflation device & 4-way stopcock



FCI®

For more information please
contact your local distributor:



FCI12/046 Ind A - Nov. 2012 - Société par Actions Simplifiée au capital de 46 909 € - SIREN 351 670 385 - RCS PARIS