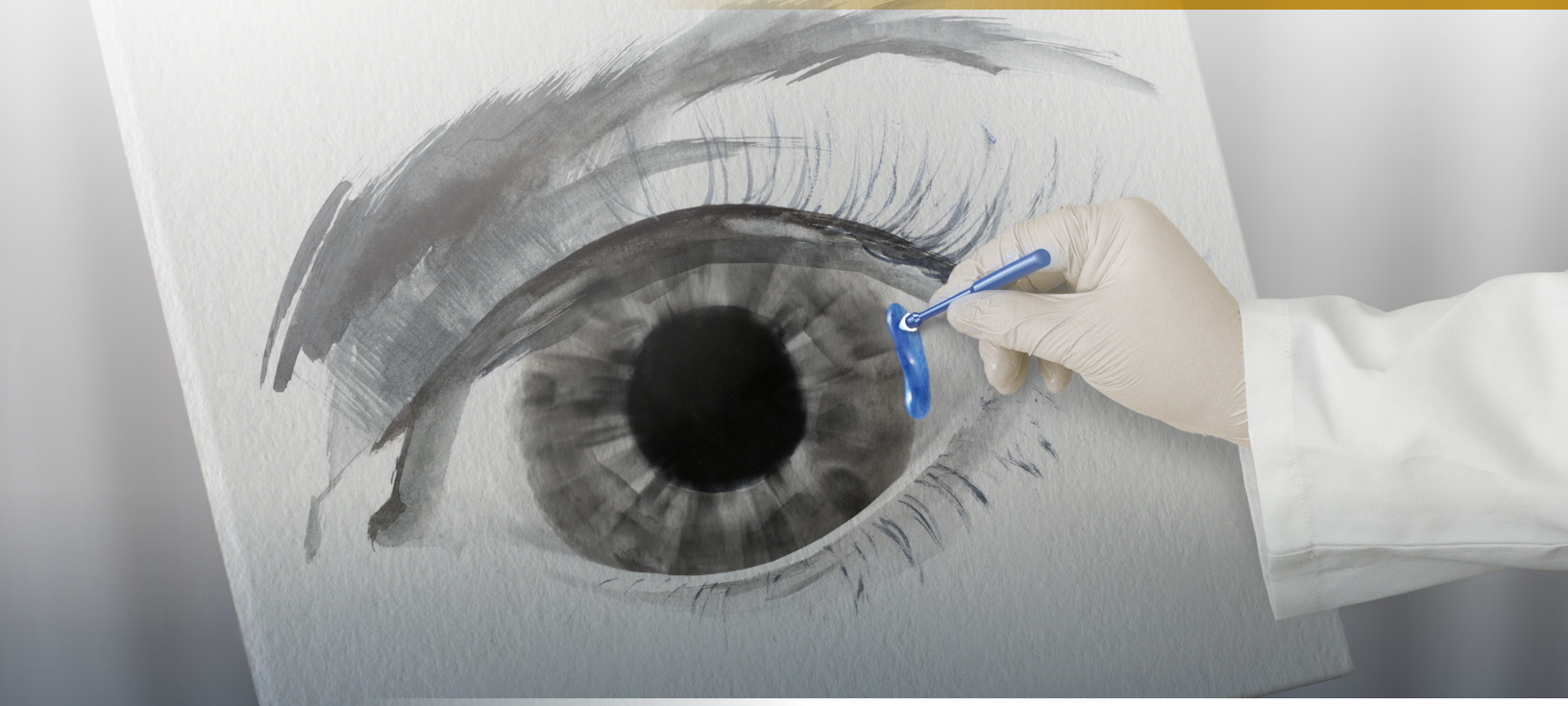
ReSure® SEALANT

WHEN A FINISHING TOUCH IS NEEDED

WOUND SEALANT FOR CATARACT CASES



ReSure Sealant was superior to a suture for preventing fluid egress in eyes with a demonstrated wound leak following cataract surgery.[1,2] *

INDICATION

ReSure Sealant is indicated for intraoperative management of clear corneal incisions (up to 3.5mm) with a demonstrated wound leak for which a temporary dry surface can be achieved, in order to prevent postoperative fluid egress from such incisions following cataract surgery with intraocular lens (IOL) placement in adults.

IMPORTANT SAFETY INFORMATION

WARNINGS

ReSure Sealant should not be used on actively leaking incisions in which a temporary dry ocular surface cannot be achieved.

Do not use in patients who are allergic to FD&C Blue #1.

PRECAUTIONS

ReSure Sealant is for single-use only; discard open and unused product. Use within 30 minutes of removing the mixing tray from foil pouch.

Prior to application, ensure incision site is not actively leaking; remove any standing moisture from the surrounding ocular surface and incision and ensure the site is dry.

Prophylactic use of ReSure Sealant on corneal incisions without intraoperative leakage was not evaluated in the clinical study.

ReSure Sealant will not replace the need for sutures in certain circumstances, including the need for long-term mechanical support to the incision.

ADVERSE REACTIONS

The most commonly reported (≥1%) ocular adverse events that occurred in patients treated with ReSure Sealant in the pivotal trial included: worsening best corrected visual acuity (7%), increase in intraocular pressure (5%), corneal astigmatism (3%), eye pain (3%), posterior vitreous detachment (2%), and anterior chamber inflammation (1%).

Please see accompanying full Instructions for Use.

*As shown in a prospective, randomized, parallel-arm, controlled, multicenter (24 US clinical practices) subject-masked study with 488 (305 ReSure Sealant and 183 suture) eyes undergoing uncomplicated unilateral clear corneal cataract surgery with phacoemulsification and implantation of an IOL.

www.ReSureSealant.com

References: 1. Masket S, et al. *J Cataract Refract Surg*. 2014;40(12):2057-2066.
2. ReSure Sealant [Instructions For Use]. Bedford, MA: Ocular Therapeutix, Inc; LCN 80-1004-011 Rev C.

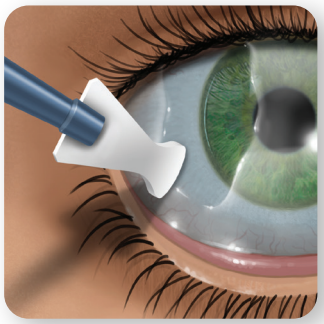
Ocular Therapeutix™

ReSure® SEALANT

PROCEDURAL REFERENCE GUIDE

This is not a substitute for the ReSure Sealant Instructions for Use. For complete instructions including indication for use, warnings, and precautions, please refer to the accompanying ReSure Sealant Instructions for Use.

PREPARATION[1]



Prior to application, ensure incision site is not actively leaking. Remove any standing moisture from the surrounding conjunctival surface and ensure that the site is dry.

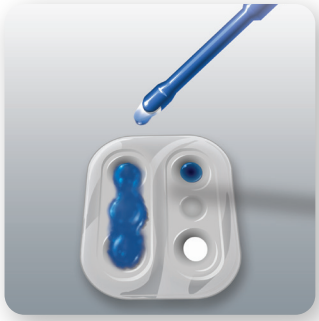
Select one channeled well for mixing and add two drops of Diluent to the blue deposit. Do not add any drops to the white deposit in the same channeled well.

NOTE: 1 package contains material for 2 applications.†

MIXING AND APPLYING[1]

Mixing and applying ReSure Sealant must be complete in less than 30 seconds. In vitro gel times suggest mixing and applying ReSure Sealant in less than 20 seconds.[2,3]

Use the applicator to thoroughly and rapidly mix the solutions using a back and forth motion (about 5 seconds).



Holding the applicator handle with the side edge of the foam tip facing down, gently dip the foam tip into the solution, picking up the material.

Apply over the entire length, width and edges of the incision, ensuring full coverage of the margins.

Delay introduction of any ophthalmic drops to the ocular surface for approximately 30 seconds after application of ReSure Sealant to ensure polymerization of the material and complete adherence and coverage of the target area.

The blue color serves as a visualization aid to ensure proper placement of ReSure Sealant, and diffuses from the hydrogel within hours of application.[1]

NOTES

- Stop manipulation of the applicator if liquid material stranding is observed. If application to the incision site was not completed prior to stranding, prepare the second channeled well and reapply.
- ReSure Sealant may be removed carefully with forceps if necessary.

CAUTIONS

- Each applicator is intended for single-use only. If a second application is required, use a new applicator.
- When full coverage of the incision cannot be achieved (including incisions with brisk/copious leaks, or incisions for which a temporary dry surface cannot be achieved), and for incisions at higher risk of postoperative wound leak, ReSure Sealant should not be used and suture placement should instead be considered.

† 40% of clinical trial subjects required >2 applications (ie, >1 package). It may be necessary to open additional packages to achieve full coverage.

References: 1. ReSure Sealant [Instructions For Use]. Bedford, MA: Ocular Therapeutix, Inc; LCN 80-1004-011 Rev C.
2. Mah FS. *J Ocul Pharmacol Ther*. 2016;32(6):396-399. **3.** Food and Drug Administration. FDA Summary of Safety and Effectiveness Data. https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130004b.pdf. Accessed March 24, 2021.

Ocular Therapeutix™

Bedford, MA | www.ocutx.com