

Instructions For Use

VibeX Xtra™

Riboflavin Solution for Accelerated Corneal Cross-Linking
For Lasik Xtraprocedure

Contents:

VibeX Xtra syringe (1) and ophthalmic cannula (1) – Syringe filled with 1.0 ml VibeX Xtra

FOR SINGLE USE ONLY

Composition:

- 0.22% Riboflavin
- Sodium Chloride
- Disodium hydrogenphosphate x 12 H₂O
- Sodium dihydrogenphosphate x 2 H₂O
- Water for injection

Usage:

For intrastromal applications in conjunction with Lasik:

1. After excimer ablation and before replacing the corneal flap, apply sufficient VibeX Xtra to the corneal bed to completely cover the exposed stroma.
2. Soak for **90 seconds**. Rinse corneal bed completely with balanced saline solution (BSS).
3. Replace the corneal flap using standard clinical techniques.
4. Irrigate cornea with BSS prior to UVA exposure.
5. Initiate UV treatment.
6. Irrigate cornea with BSS during UVA treatment.
7. Complete the Lasik procedure using standard clinical techniques.

Indications:

- Corneal strengthening

Contraindications:

- Pregnancy
- Epithelial healing problems
- Refractive keratotomy
- Herpetic keratitis (UV can activate herpes)
- Rheumatic disorders
- Known sensitivity to any of the ingredients
- Corneal melting

Characteristics:

- Riboflavin (vitamin B2) is a water-soluble yellow substance.

Storage:

- Store in dark place
- Storage temperature ≤ 28° C
- Discard solution 12 hours after opening outer package
- See expiry date
- Sterile if package is not broken, do not use if package is damaged
- Do not remove from dark bag prior to use

Side effects: (adverse effects without specifying the frequency)

- Hypersensitivity reactions (burning) may occur **temporarily**. These usually resolve after discontinuation.


Possible risks: (without specifying the frequency)

- Corneal edema
- Stromal scarring
- Inclusions
- Corneal haze
- Keratitis by bacteria
- Sterile infiltrates
- Corneal Calcification

Other information:

- VibeX Xtra is a sterile medical device (CE 0482).
- 1 syringe for use for one eye only.
- Any remaining solution should be discarded.
- Use as directed. Medio-Haus Medizinprodukte GmbH cannot guarantee the warranted characteristics such as function, material properties or sterility if product is used in manner that is not consistent with Usage described above, or if the product is reused.

Manufacturer:  0482

 Medio-Haus Medizinprodukte GmbH
Brunswiker Straße 50, 24105 Kiel, Germany

Distributed by:
Avedro, Inc.
201 Jones Road, 5th Floor West, Waltham, MA, 02451 USA

 LOT

Manufacturing LOT



Best before



See directions for use



Single use only

 STERILE

Steam-sterilized



Storage not over 28°C

 STERILE EO

Endpacked product sterilized with Ethylene oxide



Store in the dark

LBL--00082 Rev K