

## Instructions for Use

### Trans-Epithelial Kit

#### Riboflavin Solutions for Accelerated Corneal Cross-Linking *For epithelium-on procedure*

#### Contents:

- ParaCel Part 1 syringe and ophthalmic cannula – syringe filled with 1.8ml ParaCel Part 1
- ParaCel Part 2 syringe and ophthalmic cannula – syringe filled with 2.0 ml ParaCel Part 2

#### *ParaCel™ Part 1*

##### Composition:

0.25% Riboflavin  
Benzalkonium Chloride  
EDTA  
Trometamol  
Hydroxypropylmethylcellulose  
with NaCl  
Phosphate buffered saline solution

#### *ParaCel™ Part 2*

##### Composition:

0.22 % Riboflavin  
with NaCl  
Phosphate buffered saline solution

#### FOR SINGLE USE ONLY

#### Characteristics:

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

### WARNING: USE ONLY ON INTACT EPITHELIUM

#### Usage:

##### **For surface applications:**

1. Do not remove corneal epithelium.
2. Place the patient in a supine position.
3. Apply topical anaesthetic to the cornea.
4. Apply a lid speculum using standard clinical techniques.
5. Measure corneal thickness to ensure that it is greater than 325 µm.
6. Apply sufficient **ParaCel Part 1** (with purple plunger) to completely cover the cornea and repeat this procedure every 90 seconds for a total of 4 minutes.
7. Rinse cornea completely with **ParaCel Part 2** (with white plunger).
8. Apply sufficient **ParaCel Part 2** to completely cover the cornea and repeat this procedure every 90 seconds for a total of 6 minutes.
9. Initiate UV treatment using the KXL System at the completion of Step 8, applying a drop of BSS every 90 to 120 seconds during irradiation.
10. Rinse cornea completely with BSS.
11. Remove speculum using standard clinical techniques.
12. Advise patient to refrain from eye rubbing.

#### Indications:

- Corneal strengthening

#### Contraindications:

- Corneal thickness, with epithelium, less than 325 µm
- Pregnancy, nursing women, children
- History of epithelial healing problems
- Refractive keratotomy
- Herpetic keratitis (UV can activate herpes)
- Rheumatic disorders
- Known sensitivity against one of the ingredients
- Corneal melting

#### Other information:

- ParaCel Part 1 & Part 2 are sterile medical devices (CE 0482).
- 1 syringe of each solution for use for one eye only.
- Any remaining solution should be discarded.

#### 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 Risk: (without specifying the frequency)

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

**Manufacturer:**  0482

 Medio-Haus Medizinprodukte GmbH  
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Distributed by:  
Avedro, Inc.  
201 Jones Road, 5<sup>th</sup> Floor West., Waltham, MA, 02451 USA

 LOT

Manufacturing LOT



Best before



See directions for use



Single use only



Steam-sterilized



Storage not over 28°C



End-packed product  
sterilized with Ethylene oxide



Store in the dark

ML-00024 Rev C