

Instructions for use – RoboMarker Corneal Marking System: - Manufactured by Surgilüm LLC, 1717 Shipyard Blvd, Suite 140, Wilmington, 28403, 910-202-2202

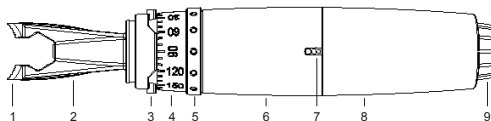
Congratulations! Thank you for purchasing your RoboMarker. Please read these instructions carefully, in order to achieve the best possible results.

Introduction RoboMarker by Surgilüm LLC, (Model: RMS101), is a corneal marking device

designed and intended to be used in ophthalmic surgery by trained health care personnel only. RoboMarker places highly accurate marks on the cornea for Toric Intraocular Lens, Limbal Relaxing Incisions, or Femtosecond Laser Alignment.

Part Identification The RoboMarker corneal marking system consists of a reusable handle and a single use RoboTip.

1. Inked Marking Edge
2. Single Use RoboTip
3. Indicator Arrow
4. Axis Degree Indicator
5. Dial
6. Upper Housing of Handle
7. Indicator Light
8. Lower Housing of Handle
9. Activation Button



Contraindications DO NOT USE ROBOMARKER, ROBOTIPS WITH ANY PATIENT THAT HAS SENSITIVITY OR ALLERGY TO GENTIAN VIOLET (CRYSTAL VIOLET) DYE.

Precautions

- Use of the RoboMarker is limited to health care professionals with appropriate training.
- The RoboMarker handle is sold NON STERILE. Do NOT attempt to sterilize.
- The RoboMarker and single use RoboTips are precision instruments and must be handled with care to prevent damage, which may adversely affect performance.
- Only use RoboMarker for its intended use and as directed within these instructions.
- Single Use RoboTips are exposed to Gamma Irradiation, and are intended for a single use ONLY. Do NOT attempt to re-sterilize.

Compatibility The RoboMarker handle is only compatible with single use RoboTips, that are produced by Surgilüm LLC. Do not attempt to use the RoboMarker with other systems or devices.

Marking Posture The RoboMarker handle should be held on the horizontal plane with the single use RoboTip directed towards the patient, who should be upright with a head position like it was when their K reading were obtained.

CAUTION Single use RoboTips should NOT be used if the outer packaging or product is open or damaged in any way.

CAUTION RoboMarker is NOT designed to be used with the patient in a lying down position. Any attempt to do so may result in inaccurate mark placement due to ocular cyclotorsion.

Using the Fixation Light RoboMarker contains an integrated fixation light, which mimics the fixation light of preoperative testing equipment.

The fixation light has 3 different settings: - White, Flashing Red, & Color Change

1. To turn on, push and hold the activation button twice for two (2) seconds, initiating the White light setting.
2. Push the activation button a third (3rd) time to change to Flashing Red.
3. Push the activation button a fourth (4th) time to change to Color Change.
4. The fixation light will automatically shut off after three (3) minutes of inactivity or on the fifth (5th) press of the activation button.

Inserting a single use RoboTip into the RoboMarker

1. Open and remove the single use RoboTip holding it by the cap so as to not contaminate the inked marking edge.
2. Insert the stem of the RoboTip into the aperture in the center of the dial.
3. Locate 1 of the 2 indicator arrows on the single use RoboTip, and rotate the RoboTip until the indicator arrow aligns with the desired axis degree mark on the dial.
4. Carefully remove the cap.

Corneal Marking Procedure

1. Check the handle indicator light to ensure the RoboMarker patient fixation light is active.
2. ENSURE YOUR PATIENT'S EYE IS NUMB! Even if the patient recently received numbing drops. IT IS HIGHLY ADVISABLE to place additional numbing drops just before using the RoboMarker.
3. After insertion and alignment of the RoboTip, hold the RoboMarker in your dominant hand leaving your index finger free and hovering above the axis dial. (See Figure 1 below)
4. Use your other hand to gently hold open the patients eyelids.
5. While the patient is sitting up, hold the RoboMarker at least 16 inches (40cm) from the eye to be marked and ask the patient to fixate on the fixation light.

6. Guide the RoboMarker directly towards the patient's eye, until the RoboTip marking edges are approximately 1 inch (3 cm) away from the cornea. Gently rest your index finger onto the proximal rim of the rotary dial to prevent any further rotary motion. (See Figure 2 below)
7. If the marking edges do NOT touch the cornea at the same time, simply re-apply the marking edges to the cornea for correct marks. You MUST BE CAREFUL to use your finger as a gentle break to prevent rotation, while at the same time avoiding rotation of the dial with your index finger.
8. Press the RoboTip marking edges onto the cornea and maintain pressure for about 2 seconds. Light pressure yields thinner marks, heavier pressure yields thicker marks. CAUTION: Holding the marker on the eye too long will result in excess dye release.
9. After marking the cornea, keep the eyelids open for 5 – 10 seconds to allow the dye to set. Then ask the patient to keep both eyes CLOSED until surgery to avoid blinking off the marking dye
10. Remove single use RoboTip and turn off the fixation light.

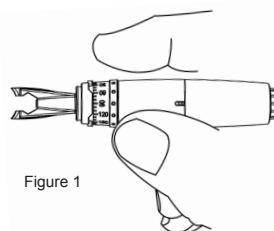


Figure 1

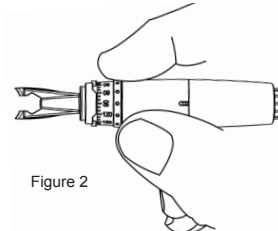


Figure 2

CAUTION Tell your patient they may feel momentary pressure but that they MUST continue to look at the fixation light.

CAUTION If the 2 marking edges do not touch the cornea at the same time the second marking edge to touch the cornea may torque out of alignment.

CAUTION The RoboTip uses a proprietary dried ink, which must remain in contact with a MOIST cornea long enough to rehydrate.

CAUTION Dispose the single use RoboTip and packaging appropriately.

Battery Replacement RoboMarker uses a ½ AA 3.6 volt battery.

To remove and replace the battery:

1. Ensure the fixation light is in the OFF position and a single use RoboTip is NOT inserted into the dial.
2. While holding the upper housing, gently twist the lower housing in a counterclockwise direction.
3. Once the two portions are completely separated, remove the battery from the lower portion.
4. Replace battery with a new ½ AA 3.6 volt battery.
5. Insert the replacement battery with the POSITIVE (+) terminal facing the rotary axis dial and handle fixation light.
6. Align the upper and lower housings and screw clockwise together, tighten until thumb tight.
7. Test the RoboMarker by cycling through the fixation light options to ensure the battery is installed correctly.

Please dispose of used batteries at a used battery-recycling center.

CAUTION Replacing or installing the battery incorrectly may cause harm or injury.

Storage and Cleaning Surgilüm LLC, recommends that the RoboMarker is stored within its case when not in use. Store in a dry area. The RoboMarker handle is NOT suitable for any form of sterilization. To clean the RoboMarker use either a soft cloth or alcohol wipe. Single use RoboTips should be stored in a dry area within their original individual packaging. Use immediately once opened. The RoboTip is approved as a single use disposable device and CANNOT be reused.

CAUTION Any attempt to sterilize the RoboMarker handle, may cause harm or injury. Any such actions will void any warranty associated with the device.

CAUTION Single use RoboTip CANNOT be reused. Any attempt to do so may cause harm or injury.

Recommendation Practice using the RoboMarker before surgery on a convenient round object of similar size to the cornea.

Limited Warranty RoboMarker, and the single use RoboTips are warranted to be free of defect in materials and workmanship. If any defects are discovered please return the device to Surgilüm LLC, for replacement. Surgilüm is pleased to maintain the RoboMarker handle under a limited 2-year repair/refurbish warranty.

RoboMarker and all associated imagery is a registered trademark of Surgilüm LLC, all rights reserved.