<b>***</b>	Manufacturer
EC REP	Authorized representative in the European Community/ European Union
STERILEEO	Sterilized using ethylene oxide
$\otimes$	Do not re-use
STERIDE	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Date of manufacture
$\leq$	Use-by date
ī	Consult instructions for use or consult electronic instructions for use
$\overline{\mathbb{A}}$	Caution
MD	Medical Device
LOT	Batch Code
Ċ	On/off



# **INNOVATIVE** EXCIMER SOLUTIONS INC.

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EC REP

International Associates Auditing & Certification Limited The Black Church, St Mary's Place, Dublin 7, D07 P4AX, Ireland EUAR@ie.ia-net.com

If sterile seal is broken, DISCARD

CAUTION: Do not autoclave tip or handle

Manufactured in Canada

4201h-2 Revision Date: November 2024



PRODUCT : Amoils Epithelial Scrubber \*\*

Indications for use: Removal of the corneal epithelium prior to surgical procedures such as Advanced Surface Ablation/Photorefractive Keratectomy and Corneal Cross Linking

## Steps for use of the AMOILS Epithelial Scrubber

1. Place topical anaesthetic on the eye (0.5% Proparacaine).

**2.** Centre the TREATMENT EYE under the microscope and then turn on the fixation occluder asking the patient to look at the green occlude light. Move the occluder until the TREATMENT EYE is once again centred under the microscope while maintaining fixation on the light with the non-treatment eye. Tape the fixation occluder in place.

**3.** Using a gloved hand, unwrap the inner pack containing the Amoils Epithelial Scrubber and mount it on the neck of the Power Handle.

- 4. Set the microscope at low(10x) magnification.
- 5. Insert a lid Speculum.

**6.** Check that the patient is maintaining fixation on the occluder light, and that the treatment eye pupil is centred under the microscope.

7. Mark the area of epithelium to be removed with a corneal marker

8. Place a few drops of chilled B.S.S. (Balanced Salt Solution) on the inverted scrubber tip.

9. Place a few drops of chilled BSS on the patients Cornea.

**10.** Turn on the device and bring the Amoils Epithelial Scrubber gently in contact with the patients Corneal Epithelium using the microscope to keep it centred.

**11.** Within a few seconds the Epithelium will be removed in a specific zone centred around the pupil. Note that the edges of the zone are much smoother than with manual removal methods.

12. TURN OFF the Fixation Occluder before proceeding with Photorefractive Keratectomy or Advanced Surface Ablation.

\*\* Caution: To be used by qualified physicians in clinic or hospital settings only

#### The Amoils Starter Kits consists of:

- A reusable, rechargeable scrubber handle, neck and charger.
- A sterile single use tip for attachment to the handle

### Tips on using the AMOILS Epithelial Scrubber

1. Use a gently circular motion while applying the brush to the eye. This will prevent a central area of residual epithelial tissue and can be used to control or enlarge the zone of epithelial removal.

**2.** Always wet the Cornea and brush tip with B.S.S. solution prior to use. Invert the brush and place a few drops of B.S.S. on the concave tip.

**3.** Turn the brush on before placing it on the eye. It is often useful to tell the patient that this is the sound of the brush as it creates a smooth surface for the laser to work.

4. Turn the magnification in the microscope as low as possible while using this device.

5. Be sure to turn off the fixation occluder before proceeding with laser ablation.

**6.** Flood the Cornea with Chilled B.S.S.  $(5^{\circ}-7^{\circ}C)$  immediately after P.R.K. to equilibrate the corneal temperature (7-10 sec.).

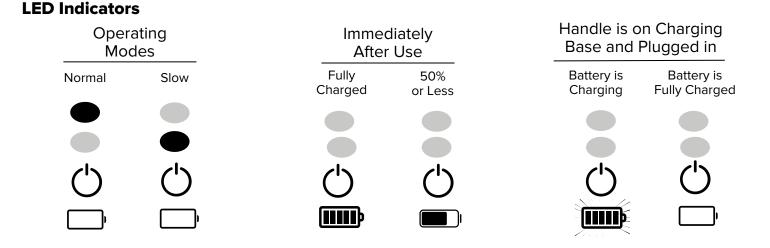
7. In Case of any incident while usage of this device Please call 1.800.461.1200

**8.** Amoils handle offers two different rotating modes, normal mode and slow mode. Physicians can choose which mode to use, based on their preference.

#### Care instructions for the power handle and charger

Amoils Epithelia Scrubber shall only be used with handle, neck and charger provided in the starter kits by the manufacturer. The power handle should be charged for 24 hours before its first use. Thereafter, recharge the unit overnight as required. Plug the charger into an electrical outlet and ensure the handle is in "off" position. After charging, remove the handle from the charger, as the instrument will not operate while the charger is connected. Never use a charger that has a damaged cord or wall plug. Never immerse the charger in water. Wipe the handle with Alcohol to sanitize. Do not heat the handle for sterilization.

## **Amoils Epithelial Scrubber Handle Charging Instructions**



Description	Handle Electrical Rating
Amoils Charger	120V, 50-60Hz, 150mA, AC only
Rechargeable Battery	1.5 DC

IMPORTANT: After pressing the on/off button to turn the unit off, the LED charge indicator will remain illuminated for a period of 30 seconds, indicating the level of charge remaining