Instructions for Use

- 1. Remove blade carrier from the sterile pouch.
- 2. Place the CLB® shuttle on a flat surface and slide the shuttle drawer to the open position
- 3. Set the metal ML7[®] Head into the shuttle drawer and align the plastic pin inserting it into the side of the ML7® Head. Gently close the shuttle drawer.
- 4. Hold the CLB[®] shuttle with your thumb and forefinger at the opposing ends of the shuttle.
- 5. Slide the clear plastic tab towards the metal ML7[®] Head to insert the CLB® blade into the head at the proper position to mate the ML7® Handpiece.
- 6. Insert the ML7® Handpiece into the metal ML7® Head and silence for the handpiece to click into place.
- 7. Retracted the clear plastic tab back to the opposite side of the shuttle.
- 8. The shuttle drawer is then slightly opened and the assembled blade. head, and ML7[®] Handpiece emerges from the shuttle as one piece.
- 9. Before using, a test to confirm the blade is oscillating in the head is mandatory. Proceed according to the ML7® Operators Manual.

After Use

Carefully remove the blade from the ML7® Head and dispose of it into a medical waste sharps bin.

Storage Conditions

The MED-LOGICS CLB® products have no special storage conditions, but should be stored under normal warehouse conditions, which includes protection from moisture, extreme cold (less than 5°C), and excessive heat (greater than 40°C). lifetime of the product is 5 years from the manufactured date.

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CAUTIONS

U.S. Federal Law restricts sale and use to or on the order of a Physician.

EtO sterilization is performed on the blade pouches. Never open the blade pouch until just before use. Do not use the blade if its package is broken. The sterilization effect may be weakened, and the blade may become nonsterile.

This product is intended for use by experienced physicians or technicians who have received proper instruction on the use of the microkeratome being used.

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> > P/N: 900-3392-004

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ML7100

MED-LOGICS, Inc.® blade for use with the ML7[®] & NiTRO[™] Microkeratome



The MED-LOGICS, Inc.® ML7100 CLB® is a SINGLE USE blade designed to cut a precise corneal flap when used with the ML7[®] & NiTRO[™] microkeratome.



Tel: +353-89 225-1951/ E-mail: info@ecrep.ie

UK Representative UK REP Responsible Person Ltd,

CE

2797

Summit House, 4-5 Mitchell Street, Edinburgh, EH6 7BD, UK Tel: +44-7543-672-888/ E-mail: info@responsible-person.co.uk

U.S. Patent No. 6,663,644. Additional foreign and U.S. patents pending.





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UK REP Responsible Person Ltd,

Summit House, 4-5 Mitchell Street, Edinburgh, EH6 7BD, UK Tel: +44-7543-672-888/ E-mail: info@responsible-person.co.uk

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WARNINGS

This product is not intended for purposes other than creating corneal flaps with the $\mathsf{ML7}^{\circledast}$ microkeratome.

This product is designed for single-use and is therefore not intended to be re-used. In the event that the blade is re-used, it may cause infection and stromal bed or flap defects.

Do not resterilize. Additional sterilization can compromise the blade assembly, which may result in patient injury.

Verify the integrity of the blade prior to use. Inspect the cutting edge of the blade under a microscope to ensure it is free of damage. Test the blade in the microkeratome to ensure that it operates freely. If the blade is damaged or defective, DO NOT USE, it may damage the equipment or cause patient injury. If the blade is defective, please contact MED-LOGICS, Inc.® or an authorized representative.

If the expiration date has passed, do not use the product. The part may no longer be sterile and may have other deficiencies caused by age. These deficiencies may damage the equipment or cause patient injury.

WARNINGS

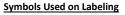
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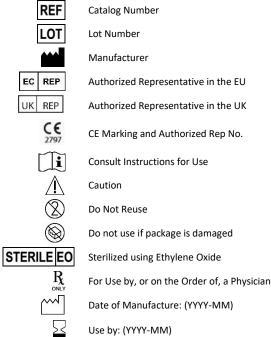
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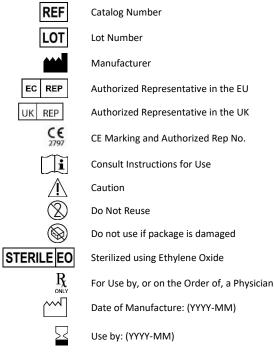
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Symbols Used on Labeling



 MD
 Medical Device

 UDI
 Unique Device Identifier

Product Warranty and Limitations of Liability

MED-LOGICS, Inc.[®] warrants that the Calibrated LASIK Blade (CLB[®]) will conform to MED-LOGICS, Inc.[®] then current version of the product specifications for such disposable blades in all material respects and shall be free from defects in material or workmanship for a period equal to the blade's expiration date. MED-LOGICS, Inc.[®] excludes all other warranties, whether expressed, implied or by operation of law, including, but not limited to any implied warranties of merchantability or fitness. MED-LOGICS, Inc.[®] shall not be liable for any incidental, consequential or exemplary loss, damage or expenses, directly or indirectly resulting from the use of the CLB[®] even if MED-LOGICS, Inc.[®] has been advised of the possibility of such loss, damage, or expense.



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