

Instructions for Use

1. Remove blade carrier from the sterile pouch.
2. Extract the blade from the blade carrier using forceps.
3. Insert the blade in the Zyoptix® Handpiece Head. HANDLE WITH CARE to avoid causing damage to the delicate cutting edge of the blade.
4. Proceed according to the instructions in the microkeratome operator's manual.

After Use

1. Carefully remove blade from 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). The shelf life of the product is 5 years from the date of manufacture.

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. This product is only intended for use on adults aged 18+ who have been deemed suitable candidates for LASIK surgery by a qualified physician.

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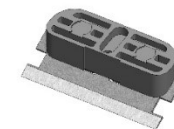
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CLB®

CALIBRATED LASIK BLADE

ML7071

MED-LOGICS Blade for use
with the Zyoptix® Handpiece



The MED-LOGICS ML7071 CLB® is a SINGLE USE blade designed to cut a precise corneal flap when used with the Zyoptix® Handpiece.



MED-LOGICS, Inc.®
1627 Enterprise Street, Athens, TX 75751 USA
Tel: +1-949-582-3891/ E-mail: info@mlogics.com



European Representative
E C Rep Ltd,
5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland
Tel: +353-89 225-1951/ E-mail: info@ecrep.ie



UK Representative
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

The Zyoptix® Handpiece is a product and registered trademark of Bausch & Lomb Inc. MED-LOGICS is not affiliated with Bausch & Lomb, Inc.

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

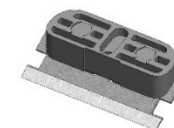


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European Representative
E C Rep Ltd,
5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland
Tel: +353-89 225-1951/ E-mail: info@ecrep.ie



UK Representative
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 Zyoptix® Handpiece.

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 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.

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Symbols Used on Labeling



Catalog Number



Lot Number



Manufacturer



Authorized Representative in the EU



Authorized Representative in the UK



CE Marking and Authorized Rep No.



Consult Instructions for Use



Caution



Do Not Reuse



Do not use if package is damaged



Sterilized using Ethylene Oxide



For Use by, or on the Order of, a Physician



Date of Manufacture: (YYYY-MM)



Use by: (YYYY-MM)

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Date of Manufacture: (YYYY-MM)



Use by: (YYYY-MM)



Medical Device



Unique Device Identifier

Product Warranty and Limitations of Liability

MED-LOGICS warrants that the Calibrated LASIK Blade (CLB®) will conform to MED-LOGICS 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 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 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 has been advised of the possibility of such loss, damage, or expense.



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