

Instructions for Use

1. Remove blade carrier from the sterile pouch.
2. Extract the blade from the blade carrier using forceps.
3. Install the blade in the Hansatome® microkeratome 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). Lifetime of the product is 5 years from manufactured date.

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 non-sterile.

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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CLB[®]
CALIBRATED LASIK BLADE

ML7070

**MED-LOGICS Blade for use
with the Hansatome™
Microkeratome**



The MED-LOGICS ML7070 CLB® is a SINGLE USE blade designed to cut a precise corneal flap when used with the Hansatome® microkeratome.



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The Hansatome® microkeratome is a product and registered trademark of Bausch & Lomb, Inc. MED-LOGICS, Inc.® 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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WARNINGS

This product is not intended for purposes other than creating corneal flaps with the Hansatome® 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 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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

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

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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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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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