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 Nidek® MK-2000 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).

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.

P/N: 900-0163-012

CLB®
CALIBRATED LASIK BLADE

ML7030

MED-LOGICS Blade for use with the Nidek® MK-2000 Keratome System

The MED-LOGICS ML7030 CLB® is a SINGLE USE blade designed to cut a precise corneal flap when used with the Nidek® MK-2000 Keratome system.

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Tel: +1-949-582-3891/ E-mail: info@mlogics.com

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Summit House, 4-5 Mitchell Street, Edinburgh, EH6 7BD, UK
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The MK-2000 Keratome System is a product of and Nidek® is a registered trademark of Nidek Co., LTD. MED-LOGICS is not affiliated with Nidek Co., LTD.
U.S. Patent No. 6,663,644. Additional foreign and U.S. patents pending.

CE 2797

℞ ONLY

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 Nidek® MK-2000 microkeratome head. HANDLE WITH CARE to avoid causing damage to the delicate cutting edge of the blade.
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WARNINGS

This product is not intended for purposes other than creating corneal flaps with the Nidek® MK-2000 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.

Symbols Used on Labeling

REF	Catalog Number
LOT	Lot Number
	Manufacturer
EC REP	Authorized Representative in the EU
UK REP	Authorized Representative in the UK
CE 2797	CE Marking and Authorized Rep No.
	Consult Instructions for Use
	Caution
	Do Not Reuse
	Do not use if package is damaged
STERILE EO	Sterilized using Ethylene Oxide
Rx ONLY	For Use by, or on the Order of, a Physician
	Date of Manufacture: (YYYY-MM)
	Use by: (YYYY-MM)
MD	Medical Device
UDI	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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