CAUTIONS

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

Gamma Sterilization is performed on the CleanTouch pouches. Never open the CleanTouch pouch until just before use. Do not use the CleanTouch product if the outer pouch has been broken. The sterilization effect may be weakened and the product may become non-sterile.

WARNINGS

This product is designed for single use. Do not re-use. Re-use will result in sub-optimal performance of the PVA material and may contaminate the surgical field.

If the expiration date has passed, do not use. Use past the expiration date may result in sub-optimal performance of the PVA material and the product may become non-sterile.

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P/N: 900-0795-011

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Description of Product

European Representative

The CleanTouch PVA Eye Spears are sterile, single-use devices designed to absorb excess fluids on the human eye.

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

EC REP

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

UK REP UK Representative

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

Instructions for Use

- 1. Remove foil pouches from the sterile pouch.
- 2. Remove spears from the foil pouch
- Introduce PVA material to any excess fluids. The PVA material will absorb fluid until it reaches its capacity.
- 4. Once a spear reaches its capacity, discard and use a new spear.

Storage Conditions

The CleanTouch PVA Eye Spears 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).

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REF Catalog Number LOT Lot Number Manufacturer EC REP Authorized Representative in the EU UK REP Authorized Representative in the UK 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 R For Use by, or on the Order of, a Physician

Symbols Used on Labeling

- Date of Manufacture: (YYYY-MM)
- Use by: (YYYY-MM)
- Medical Device

UDI

Unique Device Identifier

Description of Product

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European Representative

UK Representative

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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

Instructions for Use

- 5. Remove foil pouches from the sterile pouch.
- 6. Remove spears from the foil pouch.
- Introduce PVA material to any excess fluids. The PVA material will absorb fluid until it reaches its capacity.
- 8. Once a spear reaches its capacity, discard and use a new spear.

Storage Conditions

The CleanTouch PVA Eye Spears 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).

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.					
Ĩ	Consult Instructions for Use					
\triangle	Caution					
(Do Not Reuse					
\$	Do not use if package is damaged					
STERILE EO	Sterilized using Ethylene Oxide					
	For Use by, or on the Order of, a Physician					
\sim	Date of Manufacture: (YYYY-MM)					
><	Use by: (YYYY-MM)					
MD	Medical Device					
UDI	Unique Device Identifier					