















MD	Medical Device		Keep Dry
LOT	Batch Number		Caution
	Date of Manufacture		Do not Resterilize
	Distributor	UDI	Unique Device Identifier
	Use by date	REF	Catalogue number
	Manufacturers Name and Address		Keep away from Sunlight
	Do not Reuse		Temperature Limits
	Consult Instructions for Use		
EC REP	Authorized Representative in the EU Community		
	Single Sterile Barrier System with protective packaging outside		
STERILE 	Sterilized using steam		
CE 0483	CE Certification Mark		
	Do not use if package damaged consult IFU		

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 8701002, Sderot, ISRAEL.
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 Otherwise known as CerviLube™

REF 1170

UKRP
 Emergo Consulting (UK) Limited
 Compass House, Vision Park Histon
 c/o Cr360 – UL International
 Cambridge
 England, United Kingdom
 CB24 9BZ

EC REP

Theo Manufacturing B.V.
 Slepeweg 44, 6222 NK Maastricht
 The Netherlands.
 Email: info@theomanufacturing.com
 Tel: +31 (0) 43 325 1773

Manufactured by Sion Biotext Medical Ltd.
 for Optimum Medical Solutions Ltd

1170-IFU-Dec23-V2.0



optimummedical®

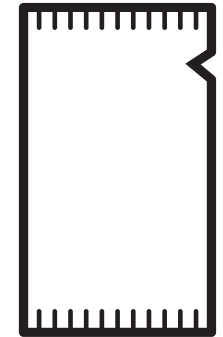


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optilube.™

zero

Sterile Lubricating Jelly
 Zero carbomers, Zero parabens, Zero CHG



Validated by Hologic for use with the
 ThinPrep® Pap test when used as instructed
 (see www.hologic.com/thinprep for more details)
For Hospital and Professional Use

INSTRUCTIONS FOR USE

OptiLube Zero

PRODUCT CODE:

1170 5g Sachet

DESCRIPTION:

OptiLube Zero Lubricant Jelly, containing zero Carbomers, zero Parabens and zero CHG is a sterile, clear, colorless, non-sticky, non-greasy, non-staining, non-irritating lubricant to the skin. It is a water soluble, high viscosity gel-like liquid for use as a lubricating media for insertion of medical instruments during medical procedures. It is easily rinsed off with water.

INGREDIENTS:

Purified water, Hydroxyethyl cellulose, Glycerin, Polyethylene Glycol (PEG), Polysorbate, Lactic Acid, Sodium Hydroxide, Sodium Benzoate, Sodium EDTA.

INTENDED PURPOSE:

OptiLube Zero is designed for medical purposes to lubricate body orifices, assisting in the insertion of devices for diagnostic and therapeutic purposes. Typical uses of the lubricating jelly include (but not limited to) insertion of catheters, endoscopes surgical instruments, gynecological, rectal, oral and rubber or plastic etc. Ensure that **OptiLube Zero** is suitable for the intended use and compatible with other medical devices to be used in conjunction with it.

INTENDED USERS:

The intended users of **OptiLube Zero** are patients, their Carers and/or Healthcare Professionals. Validated by Hologic for use with the ThinPrep® Pap test when used as instructed (see www.hologic.com/thinprep for more details).

WARNINGS AND PRECAUTIONS:

- Do not use the sachet if it is torn, damaged or cut.
- Keep out of eyes and ears.
- Keep out of reach of children.
- Re-use of this medical device may result in infection and/or cross-contamination.
- Resterilisation, reprocessing, cleaning and disinfection may also compromise the product characteristics, resulting in trauma or infection to the patient.
- Contents are sterile in unopened, undamaged packaging.

CONTRADICTIONS AND SIDE EFFECTS:

There are no known side effects associated with using **OptiLube Zero**, however, in rare cases local irritation or hypersensitivity may occur. Symptoms of irritation or hypersensitivity include redness, itchiness, or blistering. If this occurs, stop using **OptiLube Zero** and consult your Healthcare Professional. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority (of the Member state in which the user is established).

DIRECTIONS FOR USE:

Sterile and single use. Tear sachet at one end and squeeze to obtain desired amount. Apply as needed.

STERILE DEVICES:

OptiLube Zero products are supplied sterile. Sterilized by moist heat after packaging process.

STORAGE AND HANDLING:

- Keep dry and out of direct sunlight.
- Do not use after expiry date.
- Store at room temperature.
- Avoid excessive heat and humidity.
- Discard after single use.

DISPOSAL:

OptiLube Zero must be disposed of according to local policies and waste disposal procedures, including any accessories / consumables used with the device.