SURGILUBE® Instructions for Use

MANUFACTURER:

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PRODUCTS

REF	Product Description	Sterile	Use	Package Size
281020502	Surgilube® 56.7g (2oz.) Screw Cap Metal Tube - Sterile	Yes	Multi-Use	56.7g
281020512	Surgilube® 56.7g (2oz.) Flip-Top Tube - Sterile	Yes	Multi-Use	56.7g
281020536	Surgilube® 120.49g (4.25oz.) Screw Cap Metal Tube - Sterile	Yes	Multi-Use	120.49g
281020537	Surgilube® 120.49g (4.25oz.) Flip-Top Tube - Sterile	Yes	Multi-Use	120.49g
281020543	Surgilube® 3g foilpac® - Sterile	Yes	Single-Use	3g
281020545	Surgilube® 5g foilpac® - Sterile	Yes	Single-Use	5g
281020555	Surgilube® 5g Snap-Off Tip Metal Tube - Sterile	Yes	Single-Use	5g
281020557	Surgilube® 31g (1.1 oz.) foilpac® - Sterile	Yes	Single-Use	31g

INDICATIONS FOR USE

Surgilube® is a sterile, water-soluble, latex-free jelly intended to facilitate entry of a diagnostic or therapeutic device into a body orifice by reducing friction between the device and the body orifice. Surgilube is mostly used for gynecological and urological procedures.

DESCRIPTION

Surgilube® sterile, surgical lubricant may be used where a sterile, water soluble, non-staining lubricating jelly is indicated. Will not affect surgical instruments, rubber or plastics.

DEFINITIONS

foilpac®--A single use packet in which the Surgilube® is packaged. *foilPac* is a registered trademark or licensed to HR Pharmaceuticals, Inc., its subsidiaries or divisions.

PRODUCT FEATURES

Water Soluble
Non-Staining
Latex Free
Sterile
Bacteriostatic
BPOC Compliant
Kosher

CONTRAINDICATIONS

Sensitivity to ingredients. Reference SDS.

WARNINGS AND PRECAUTIONS

Do not use if opened or damaged; do not use product beyond labeled expiration date as sterility cannot be guaranteed.

Re-use of the device could result in cross-contamination and risks of infection or adverse reaction for the patient.

Do not use if seal under cap is broken or missing (REF #'s 281020502, 281020512, 281020536, 281020537).

Consult your physician or institutional procedures on requirements for use of sterile or non-sterile products for the procedure being performed.

Do not use in eyes and ears.

Contains Chlorhexidine Gluconate. Severe allergic reaction may occur but is rare. If irritation occurs, discontinue use and consult a physician.

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Use of a lubricating jelly for a task other than that for which it is intended could result in risk to the patient or one which provides an unsatisfactory performance.

PRE-USE, HANDLING AND INSPECTION

The product must be thoroughly inspected upon receipt and prior to use to assure packaging is not damaged or defective. If any product damage or leakage is identified, the product should be discarded.

INSTRUCTIONS FOR USE

1. **Laminate Flip-Top Tubes (REF # 281020512 & 281020537)**
    a. Sanitize tube tip and cap prior to opening.
    b. Remove cap, remove foil seal and replace cap prior to use.
    c. Apply amount needed to complete procedure to provide adequate lubrication directly to the patient or instrument.
2. **Metal Tubes (REF # 281020502 & 281020536)**
    a. Sanitize tube tip and self-piercing cap prior to opening.
    b. Puncture metal seal with tube cap.
    c. Apply amount needed to complete procedure to provide adequate lubrication directly to the patient or instrument.
3. **Metal Single-Use Tube (REF # 281020555)**
    a. Sanitize tube tip prior to opening.
    b. Use force to break the tube tip.
    c. Apply amount needed to complete procedure to provide adequate lubrication directly to the patient or instrument.
4. **foilpac® (REF # 281020543, 281020545 & 281020557)**
    a. Open foilpac® at tear notch perforation.
    b. Apply amount needed to complete procedure to provide adequate lubrication directly to the patient or instrument.
    c. Discard package after use.

RECOMMENDED STORAGE CONDITIONS

Store at room temperature (15°-30°C or 59°-86°F).

GLOSSARY OF SYMBOLS

ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process
	5.1.5	Batch number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.4	Use-by date	Indicates the date after which the medical device is not be used.
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

Symbol	Reference	Title of Symbol	Description or Meaning
	5.4.5 and Annex B.2 and Guidance for Industry and US Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex; Issued on December 2, 2014	Not made with natural rubber latex	Indicates that neither the medical device nor the packaging of the medical device contains the presence of natural rubber latex.
Union of Orthodox Jewish Congregations of America (the "Orthodox Union") certification requirements for kosher products			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	Kosher Requirements per Union of Orthodox Jewish Congregations of America	Certified Kosher	Certified Kosher per the Union of Orthodox Jewish Congregations of America as Pareve (contains neither milk or meat ingredients)
Islamic Food and Nutrition Council of America certification requirements for Halal products			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	Halal Requirements per Islamic Food and Nutrition Council of America	Halal Certified	Certified Halal per the Islamic Food and Nutrition Council of America
Federal Trade Commission Guidance on Compliance with "Made in USA"			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	N/A	Made in USA	All or virtually all significant parts and processing of this product are of U.S. origin.