



## SURGILUBE® Instructions for Use

MANUFACTURED BY: 

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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.

#### **STORAGE CONDITIONS**

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

**GLOSSARY OF SYMBOLS**

SYMBOL	MEANING
	<b>Catalog number</b>
	<b>Manufacturer</b>
	<b>Do Not Use if Opened or Damaged</b>
	<b>Sterile</b>
	<b>Do Not Re-Use/Single-Use Only</b>
	<b>Consult Instructions for Use</b>
	<b>Warning</b>
	<b>Lot Number</b>
	<b>Expiration Date</b>
	<b>Store between temperature limitations</b>
	<b>Not made with natural rubber latex</b>
	<b>Kosher Certified</b>
	<b>Halal Certified</b>
	<b>Made In USA</b>