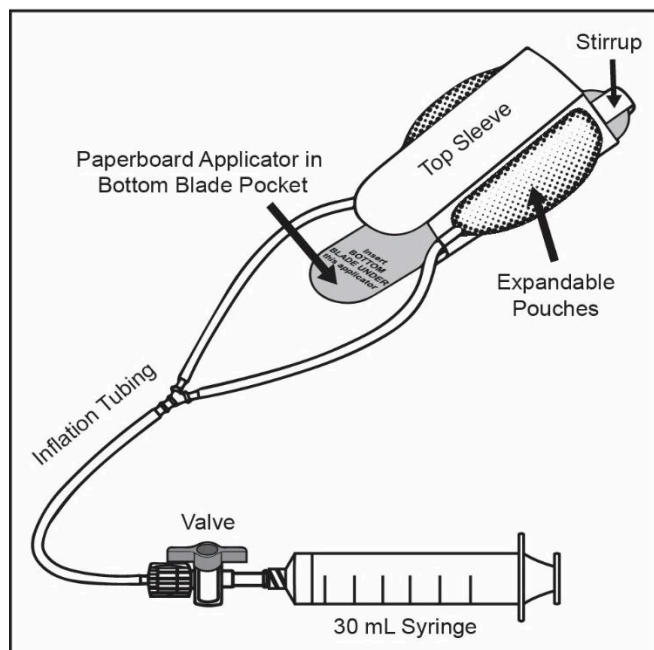


JFord Speculum Sleeve™

Single Use Inflatable Vaginal Wall Retraction Sleeve with Bottom Blade Pocket



DEVICE DESCRIPTION

The JFord Speculum Sleeve™ is a single use, non-sterile, inflatable vaginal wall retraction sleeve designed for use with single use or reusable vaginal specula (medium or large sizes). The speculum sleeve, while used with a vaginal speculum, provides lateral displacement of vaginal tissue during routine female pelvic examinations or other gynecological procedures. The speculum sleeve is intended to assist the clinician in examination when challenged by redundant vaginal walls.

The speculum sleeve has a bottom blade pocket and top sleeve for the speculum blades and bilateral expandable pouches. Using the supplied 30 mL syringe, the expandable pouches are filled as needed with potable water or saline during use to laterally displace redundant vaginal walls to enable optimal visualization.

INDICATIONS FOR USE

The JFord Speculum Sleeve™ is a single use, inflatable vaginal wall retraction sleeve intended for use with a vaginal speculum to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.

CONTRAINDICATIONS

There are no known contraindications.



WARNINGS

The warning statements in this document identify conditions or practices that could lead to illness, injury, or death.

WARNING: Inspect packaging and speculum sleeve for damage before use. Do not use if damaged.

WARNING: Do not sterilize. The single use speculum sleeve is provided clean and not intended for sterilization processes. Use clean protective gloves when handling the sleeve.

WARNING: Only use with medium and large size vaginal specula (29-37 mm speculum blade width). Do not use with any other specula sizes.

WARNING: Only use water-based vaginal lubricants with the speculum sleeve. The speculum sleeve has not been tested for compatibility with silicone-based or oil-based lubricants.

WARNING: Do not use the speculum sleeve with trichloroacetic acid as it can cause the device to deteriorate.

WARNING: Use the supplied 30 mL Luer lock syringe to fill the expandable pouches of the speculum sleeve with potable water or saline only. Do not inflate with air or any other gas.

WARNING: Only inflate the speculum sleeve as much as needed to provide adequate visualization and to minimize potential patient discomfort. The maximum fill volume is 30 mL (15 mL/pouch). Do not overfill.

WARNING: Do not use the speculum sleeve in patients with vaginal stenosis due to an increased risk of discomfort or pain.

WARNING: Do not use with laser or electrosurgical equipment. The speculum sleeve has not been tested for use with laser or electrosurgical equipment.

WARNING: Do not reuse. The speculum sleeve is for single use only. Treat the used speculum sleeve as biohazardous infectious material and discard it in a suitable disposal unit or in accordance with local, state, and federal regulations.

WARNING: Do not modify the device.



CAUTIONS

The caution statements in this document identify conditions or practices that could cause minor injury or damage to the equipment or other property.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CAUTION: For use by healthcare professionals qualified to perform a pelvic exam.

CAUTION: Do not add lubricant to the speculum blades before inserting into the speculum sleeve.

CAUTION: The speculum sleeve has been tested and found **compatible with the following chemical solutions** used during gynecological exams or procedures:

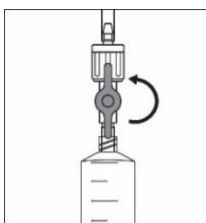
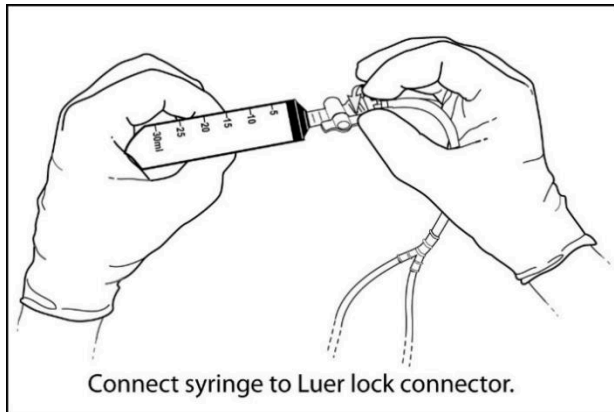
Acetic Acid 5%
Betadine Solution
Chlorhexidine 4%

Lugol's Iodine Solution 5%
 Monsel's Solution (Ferric Subsulfate)
 Saline Solution (0.9%)
 Silver Nitrate
 Water-based Lubricants

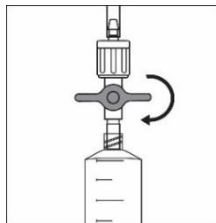
CAUTION: Should the speculum sleeve become detached from the speculum and remain within the vaginal cavity after speculum removal, gently pull the inflation tubing to remove the speculum sleeve. Ensure the speculum sleeve is intact.

DIRECTIONS FOR USE

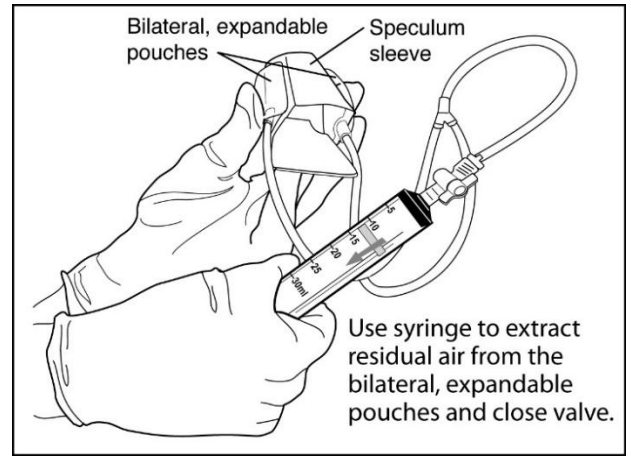
- 1) Use a new speculum sleeve for each gynecological exam or procedure.
- 2) Using gloved hands, remove the speculum sleeve from its packaging. Inspect the packaging and device for damage. Do not use if damaged.
- 3) **Before use, extract any residual air** in the bilateral expandable pouches of the speculum sleeve. Connect the syringe to the Luer lock connector of the inflation tubing and open the valve by turning it parallel with the tubing. Use the syringe to extract air. Close the valve by turning it perpendicular to the inflation tubing and disconnect the syringe.



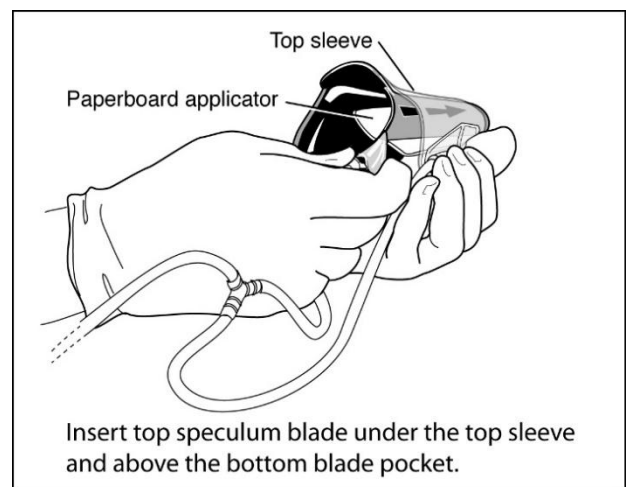
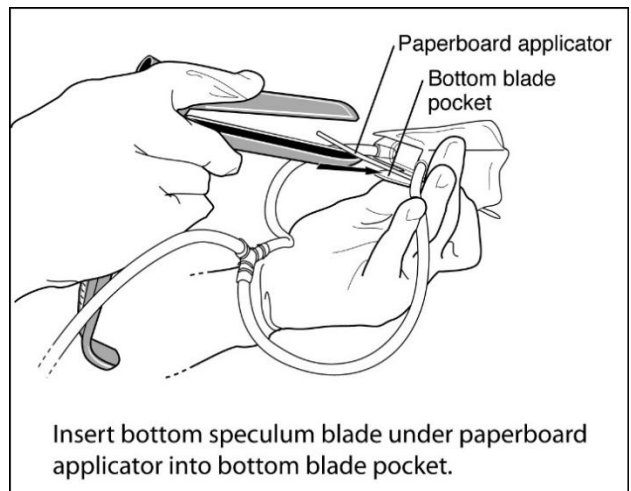
Valve Open

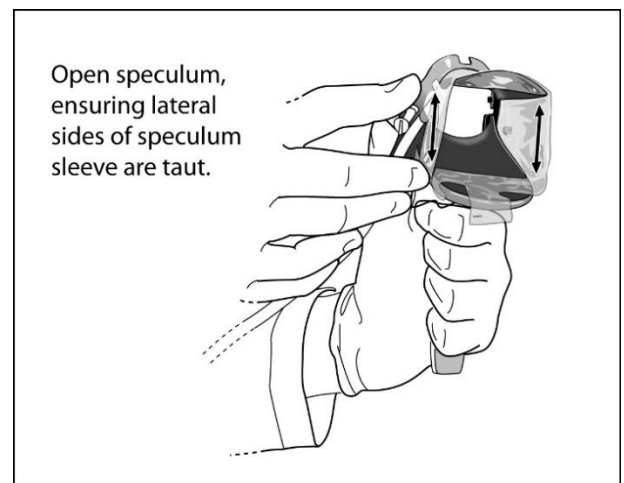
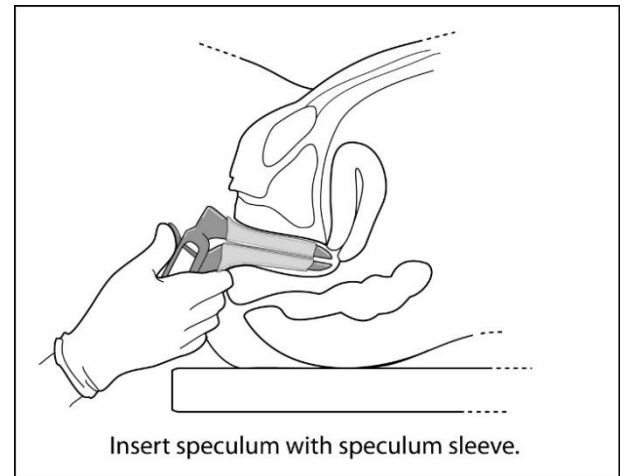
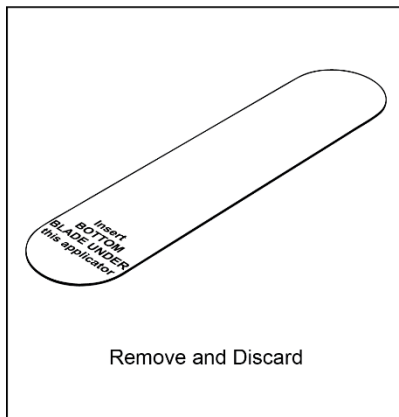
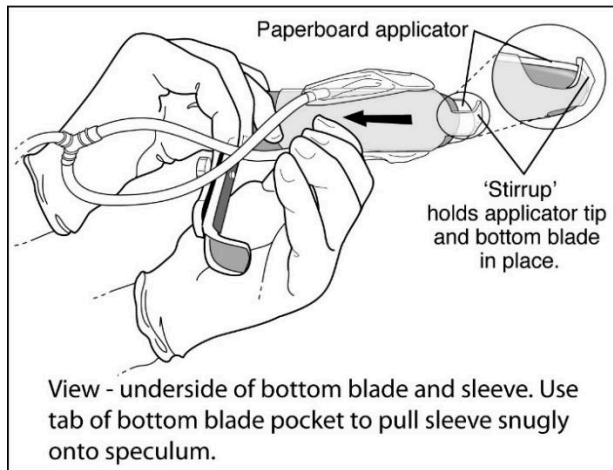


Valve Closed

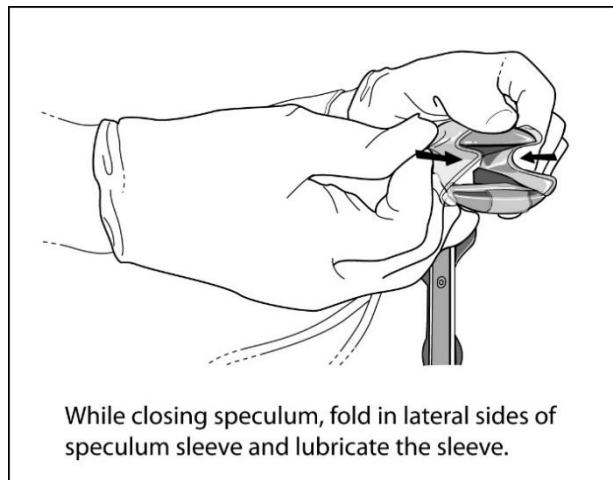


- 4) Insert the bottom speculum blade under the paperboard applicator into the bottom blade pocket and the top blade under the top sleeve. Holding the speculum handle, use the tab of the bottom blade pocket to pull it snugly onto the speculum. Ensure the bottom speculum blade is fully inserted into the bottom blade pocket to the stirrup (sleeve's tip). Remove the paperboard applicator and discard it.



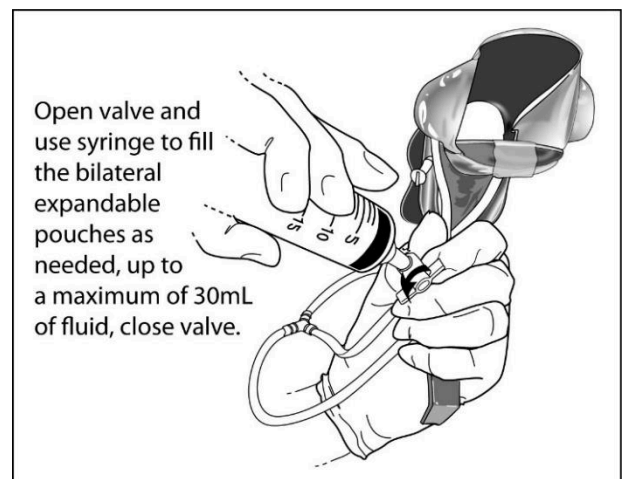


- 5) While closing the speculum, fold in the lateral sides of the speculum sleeve and lubricate the sleeve (while on the speculum) with a water-based vaginal lubricant.



- 6) Insert the speculum with speculum sleeve as you would normally insert a speculum. Open the speculum for optimal visualization ensuring that the lateral sides of the speculum sleeve are taut.

- 7) **Fill the supplied Luer lock syringe with 30 mL of potable water or saline.** Connect the fluid-filled syringe to the Luer lock connector of the inflation tubing and open the valve for filling by turning it parallel with the tubing.
- 8) Use the syringe to fill the bilateral expandable pouches of the speculum sleeve only as much as needed to provide adequate visualization and to minimize patient discomfort (up to a maximum of 30 mL). Do not overfill. Close the valve after filling by turning it perpendicular to the inflation tubing.



- 9) At the end of the exam or procedure, open the valve and use the syringe to extract the fluid from the expandable pouches. Close the valve.
- 10) When removing the speculum, ensure that the speculum sleeve is also removed and intact.
- 11) Discard the speculum sleeve as medical waste.

STORAGE

Store in a dark, dry, cool place (50-90°F / 10-32°C; 15-50% non-condensing room humidity). Avoid extended exposure to UV light.

TECHNICAL SUPPORT

For technical support, contact Ford Medtech at

Tel: +1 (516) 203-4316

Email: support@jfordspeculumsleeve.com



Manufacturer

Ford Medtech, LLC
251 Post Avenue, 2nd Floor
Westbury, NY 11590 USA

SYMBOL GLOSSARY

Symbol	Symbol Title/Explanatory Text	Symbol Ref No.
	CAUTION: Federal law restricts this device to sale by or on the order of a physician.	21 CFR §801.109 (b)(1)
	CAUTION or WARNING – In this document, indicates that a caution or warning is necessary when operating the device in order to avoid undesirable consequences	5.4.4*
	Do not reuse – Indicates a medical device that is intended for one single use only	5.4.2*
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process	5.2.7*
	Consult instructions for use – Indicates the need for the user to consult the instructions for use	5.4.2*
	Catalogue number – Indicates the manufacturer's catalogue number so that the medical device can be identified	5.1.6*
	Batch code – Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5*
	Use by – Indicates the date after which the medical device is not to be used	5.1.4*
	Do not use if package is damaged and consult instructions for use – Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	5.2.8*
	Temperature limit – Indicates the temperature limits to which the medical device can be safely exposed	5.3.7*
	Keep away from sunlight – Indicates a medical device that needs protection from heat and radioactive sources	5.3.2*
	Manufacturer – Indicates the medical device manufacturer	5.1.1*

* ISO 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements