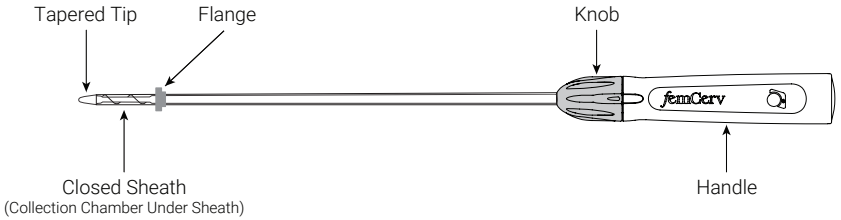
femCerv®
Endocervical Sampler

FCV-011
FCV-013

CAUTION – Federal (USA) law restricts this device to sale by or on the order of a physician.

Instructions for Use



DEVICE DESCRIPTION

The FemCerv® Endocervical Sampler (FemCerv) is a sterile, disposable device that collects an endocervical tissue sample for histological evaluation.

INDICATIONS FOR USE

The Femasys FemCerv is a sterile, disposable endocervical sampler indicated for single patient use in obtaining tissue samples from the endocervical canal for histological analysis. Clinical indications include, but are not limited to:

- further evaluation of an abnormal Pap smear
- cervical lesions extending into the endocervical canal
- undiagnosed uterine bleeding

CONTRAINDICATIONS

FemCerv should not be used when the patient has contraindications to endocervical sampling procedures, including the following conditions:

- Pregnancy or suspected pregnancy
- Caesarian section within the past 14 days
- Presence of vaginal, cervical, and/or pelvic infection(s)
- Blood clotting disorders

STORAGE

Store in a cool, dry place.

HOW SUPPLIED

Sterile for single use only.

RECOMMENDED ANCILLARY STERILE SUPPLIES

- Vaginal speculum
- Histological specimen container
- Gauze

WARNINGS/PRECAUTIONS

- For use only by or under the directions of a qualified person. Use by unqualified personnel may result in serious injury or disease possibly leading to infertility or death.
- Practitioners should exercise vigilance when using FemCerv in patients with a history of uterine perforation.
- Do not use force to overcome resistance during insertion of FemCerv, particularly with nulliparous or stenotic os patients. Attempt smaller diameter FemCerv device or gently dilate up to the size of the device to overcome resistance. Also consider using a tenaculum to assist in accessing the endocervical canal. If unable to overcome resistance, withdraw the device and re-evaluate patient situation before continuing.
- Insert the device until the flange touches the external cervical os. Maintain visualization of the flange while sampling (Figure 2).
- Both complete rotations of FemCerv must be performed to optimize thorough sampling of the endocervical canal. Do not perform partial rotations or only a single rotation of FemCerv, because such partial sampling could result in insufficient histological samples and/or decreased diagnostic acuity.
- Intended for single patient use only. FemCerv cannot be cleaned or re-sterilized for reuse. Reuse creates a potential risk of patient or user infections.
- Do not use if pouch is damaged.
- Dispose of in accordance with all local, state, and national Medical/Hazardous Waste practices.

FCV-011, FCV-013 • FemCerv®

Endocervical Sampler

INSTRUCTIONS FOR USE

1. Remove FemCerv from its sterile package.
2. Verify the sheath is in the "closed" position, as supplied.
3. Use a speculum to visualize the cervical os.
4. Hold the device as pictured, with "FemCerv" imprint facing up.
5. Gently insert the distal portion of FemCerv into the endocervical canal until the flange touches the external cervical os. Maintain visualization of the flange while sampling.(Figure 1)
6. Open the sheath to expose the collection chamber by turning the purple knob clockwise until it stops. (Figure 2)
7. To collect tissue samples:
   - Turn FemCerv clockwise one complete rotation (360°); then
   - Turn FemCerv counter clockwise one complete rotation (360°). (Figure 3)

   Caution: *Both complete rotations of FemCerv must be performed to optimize thorough sampling of the endocervical canal. Do not perform partial rotations or only a single rotation of FemCerv, because such partial sampling could result in inadequate histological samples and/or decreased diagnostic acuity.*
8. Close the sheath by turning the purple knob counterclockwise until it stops to protect and contain the sample in the collection chamber. (Figure 4)
9. Remove FemCerv from the patient.
10. Wipe the outside of the sheath with clean gauze to minimize contamination.
11. Repeat steps 5–10.
12. Visually confirm that a tissue sample is present in the collection chamber. If a sample is not visually present, the device can be re-inserted for sampling, and again wiped upon removal. Multiple passes may be required to obtain adequate sample.
13. Open the sheath to expose the collected sample within the collection chamber by turning the purple knob clockwise until it stops. Submerge the distal tip in the specimen container and swirl to dislodge sample.

    Tip: Swirling in a container with formalin 1¼" high (min.) improves removal of sample from FemCerv.

DISPOSAL

Dispose of all products in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

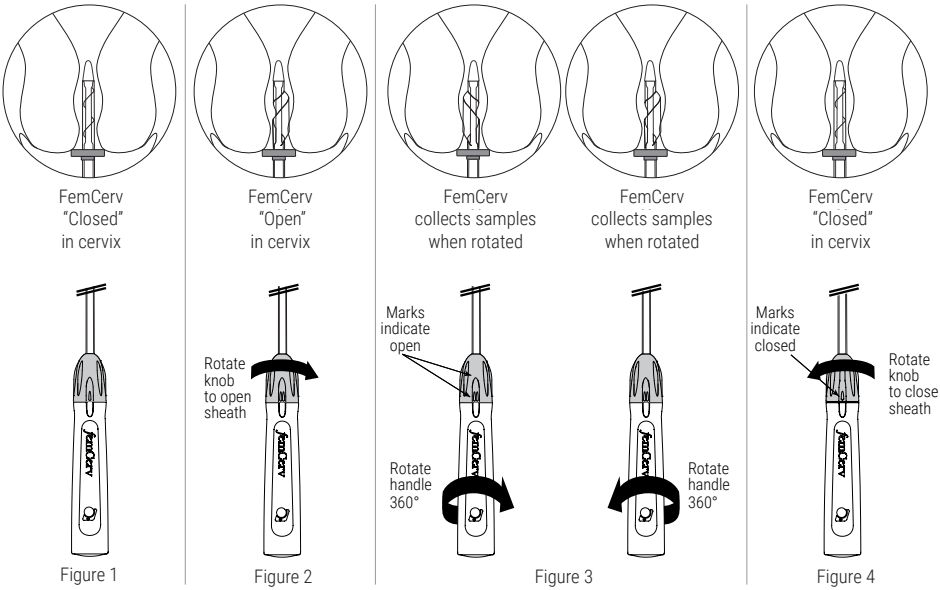


Figure 1 Figure 2 Figure 3 Figure 4

CE 0123

EC REP Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
Tel: (31) (0) 70 345-8570

Manufacturer
Femasys Inc.
3950 Johns Creek Court, Suite 100
Suwanee, GA 30024 USA
Toll Free: (877) 336-2562
International: +1 (770) 500-3910
www.femasys.com
Patent Listing: www.femasys.com/patents

www.femcerv.com

A symbol glossary can be found at:
https://femasys.com/resources/downloads

VIGILANCE REPORTING

Serious incidents occurring in the European Union in relation to FemaSeed should be reported to the Authorized Representative and/or the Manufacturer as indicated below:
Authorized Representative: Emergo – EmergoVigilance@ul.com
Manufacturer: Femasys Inc. – Vigilance@femasys.com

femasys®

02625 R03 02.August.2024