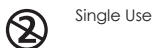


SYMBOL LEGEND



Single Use



Use by



Refer to Instructions for Use.



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



Do not use if pouch is damaged.

femCerv[®]

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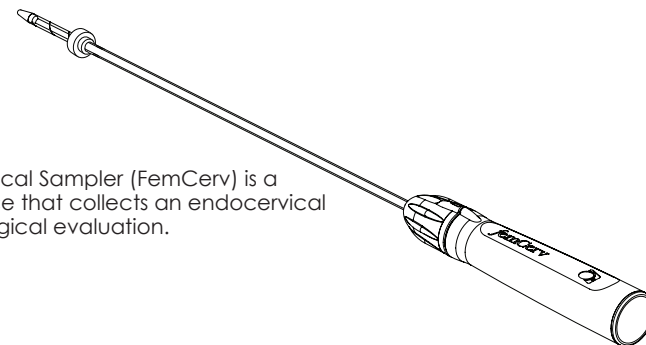
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femCerv[®]

Endocervical Sampler

Instructions for Use

Caution: Federal (USA) law restricts the device to sale by or on the order of a physician.



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:

- 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

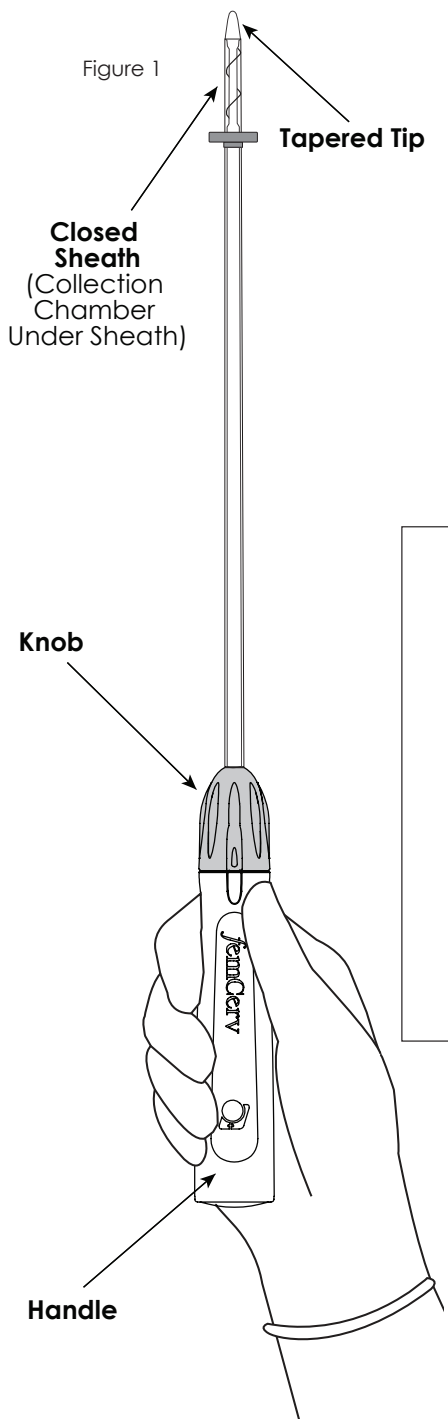
Sterile for single use only

RECOMMENDED ANCILLARY STERILE SUPPLIES:

- Vaginal speculum
- Large histological specimen container
- Gauze

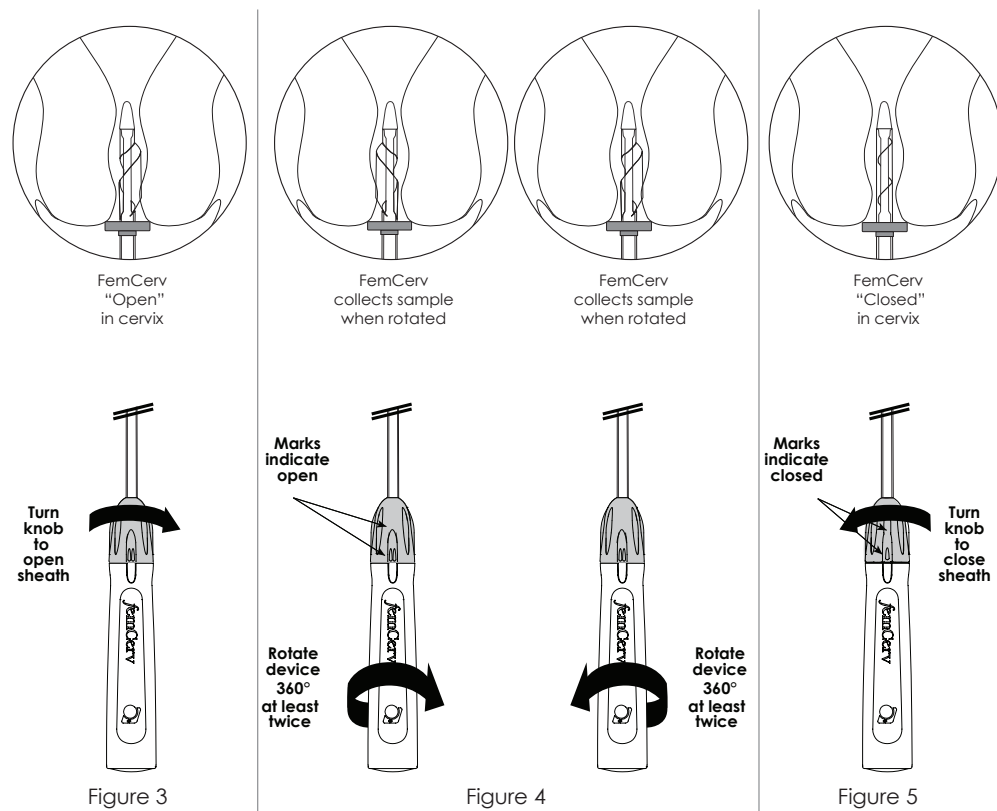
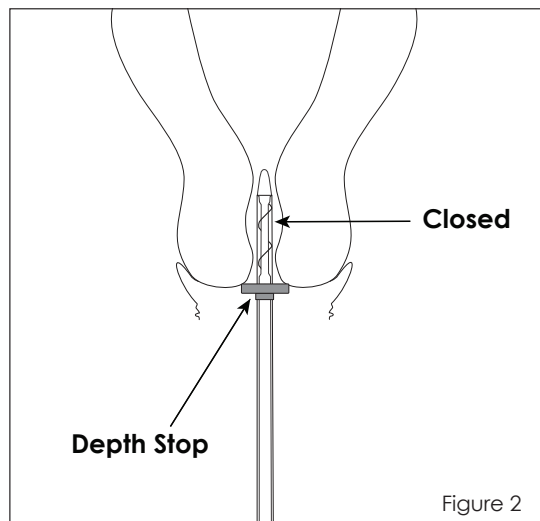
WARNINGS/PRECAUTIONS

- 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 gentle dilation 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.
- Do not insert the depth stop into the cervical canal. Maintain depth stop contact with the cervix while sampling. (Figure 2)
- At least two complete rotations of the device in each direction must be performed to optimize thorough sampling of the endocervical canal. Do not perform partial rotations or only a single rotation of FemCerv, because partial sampling could result in inadequate 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.



INSTRUCTIONS FOR USE:

1. Remove FemCerv from its sterile package.
2. Verify the sheath is in the "closed" position, as supplied. (Figure 1)
3. Use a speculum to visualize the cervical os.
4. Hold the device as pictured, with "FemCerv" imprint facing up. (Figure 1)
5. Gently insert the tapered tip of FemCerv into the endocervical canal until the depth stop contacts the cervix. FemCerv should now be in the desired position to collect an endocervical sample. Maintain depth stop contact with the cervix while sampling. (Figure 2)



6. Open the sheath to expose the collection chamber by turning the purple knob clockwise until it stops. (Figure 3) **NOTE:** Be sure to let go of the purple knob.
7. To collect tissue sample:
 - Rotate device clockwise 360° at least two complete rotations; then
 - Rotate device counter clockwise 360° at least two complete rotations (Figure 4).

Caution: At least two complete rotations in both directions must be performed to optimize thorough sampling of the endocervical canal. Do not perform partial rotations or only a single direction device rotation, because 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 5)
9. Remove FemCerv from the patient.
10. Wipe the outside of the sheath and the depth stop with clean gauze to minimize ectocervical contamination.
11. 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 additional sampling, and again wiped upon removal. Multiple insertions or rotations may be required to obtain an adequate sample.
12. To transfer the sample to a specimen container, open the sheath by turning the purple knob clockwise until it stops. Submerge the distal tip in the specimen container and swirl to dislodge sample.