

ADVERSE REACTION:

1. Patients should be carefully watched for evidence of unusual paleness, nausea, vertigo or weakness. Any cervical manipulation may cause a vasovagal reaction. These symptoms typically subside in about 15minutes of rest and/or a mild analgesic.
2. In some cases, there may be spot bleeding or mild cramps after this procedure has been performed. The patient should be instructed to notify the physician if spotting continues or if a persistent fever develops.

IMPORTANT INFORMATION: READ ALL INSTRUCTION, PRECAUTIONS, AND WARNING PRIOR TO USE. FAILURE TO FOLLOW THE ENCLOSED INSTRUCTIONS COULD RENDER THE DEVICE UNUSABLE AND VOID ANY EFFECTIVE WARRANTY.

The device is for single use only.

Do not re-use	Do not re-sterilize	Do not use if package is damaged	Keep dry	
Keep away from sunlight	Temperature limit 15°C 30°C	LOT	Use-by date	MD
Sterilized by Irradiation	Single Sterile barrier system	Authorized representative in the European Community / European Union	Conformity European	
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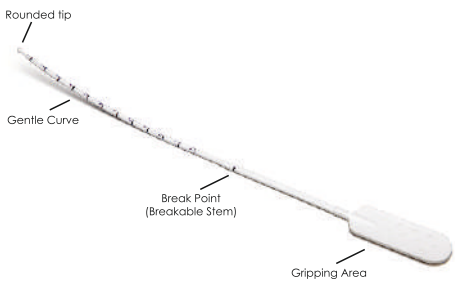
Disposable Uterine Sound

Esa – Disposable Uterine Sound

The Gamma Sterilized Esa – is used to sound the uterus for accurate fundal placement of Intrauterine Contraceptive devices. ESA is sterile unless the package is opened or damaged. The ESA – is designed for single use only.

INTENDED USE:

The device is a uterine sound intended to measure the uterine cavity depth.



INDICATIONS:

Esa – Disposable Uterine sound is used for sounding the uterus for accurate fundal placement of Intrauterine Contraceptive devices.

INSTRUCTION FOR USE:

1. Prepare the vagina and cervix as you would for any sterile intrauterine procedure.
2. Expose the cervix using a suitable speculum.
3. Dilate the cervical canal up to 6 mm. Note: It may be necessary to dilate up to 8 mm in patients with a tight cervical canal.
4. Gently insert the uterine sound to determine the depth and direction of the uterine cavity. It may be necessary to grasp the cervix with a tenaculum. If the uterus is retroverted, then the grasp should be on the posterior lip of the cervix. Apply gentle traction to straighten any cervical curvature.
5. After the depth of the cervix has been determined, insert the ESA paying close attention to the embossed scale. This will provide additional caution against perforation.
6. The ESA should be inserted and gently passed through the cervical canal and into the cavity of the uterus. Discontinue any traction applied with a tenaculum.
7. Measure the depth of Uterus once it has touched to Fundus by referring the embossed scale.
8. The ESA should be gently removed from the uterus.
9. Properly dispose of the ESA device after use. Break the Uterine sound by pushing the device sideways at the "Break Point". On applying pressure, ESA shall bend at the Break Point and can then be safely disposed off.



CONTRAINDICATIONS:

1. The procedure is contraindicated in suspected pregnancy or in women with acute pelvic inflammatory disease.
2. It is also contraindicated in women with chronic cervical infections or any conditions which contraindicate an outpatient surgical procedure.
3. A patient with an intrauterine device (IUD) currently in place.

PROCEDURE FOR TRAINED PHYSICIAN

While sounding the uterus and using this device, care should be taken to avoid perforation of the uterine wall.

CAUTION:

Federal law requires that this device be ordered by a physician.

PRECAUTION:

Product to be handled and used by applying aseptic techniques.

WARNING AND PRECAUTION:

Prior to use, inspect package for any visible damage or defect.

RISKS OF REUSE:

- Reuse to be avoided as user may get infected.
- Risk of cross-infection.
- Potential litigation issues.

Store product at ambient conditions. Storage at high temperature and high humidity may damage the package.

To be used by a physician / gynecologist or under the supervision of a registered healthcare practitioner.

