

Hologic, Inc.

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

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION: The SureSound uterine sounding device is comprised of two coaxial members. The outer sheath has a step feature to locate the internal cervical os and distal markings to measure the length of the cervical canal. The flexible inner member has an atraumatic tip and is slidable within the outer sheath. The inner member is extended until it contacts the fundus and the uterine cavity length is read from markings on the proximal end of the device. It is intended for single use and is provided sterile.

INTENDED USE: The device is a uterine sound intended to measure the uterine cavity length and the cervical canal length.

CONTRAINDICATIONS:

This SureSound device is contraindicated for use in:

- A patient who is pregnant.
- A patient with an intrauterine device (IUD) currently in place.

WARNINGS AND PRECAUTIONS:



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



The SureSound device is for single use only and is provided sterile. DO NOT reuse or re-sterilize the SureSound device.



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

ADVERSE EVENTS:

Potential adverse events include, but are not limited to:

- Perforation of the uterine wall
- Infection or sepsis
- Complications leading to serious injury

INSTRUCTIONS FOR USE:

SureSound Device

1. Dilate the cervical canal up to 6 mm. Note: It may be necessary to dilate up to 8 mm with a Hagar dilator in patients with a tight cervical canal.
2. Unpack and inspect the SureSound device. Do not use if damaged or defective.
3. Ensure the deployment ring (blue) is in the locked position. If unlocked, rotate the deployment ring counterclockwise to lock.
4. Insert the SureSound device into the cervical canal until the step feature contacts the internal cervical os. If desired, read the cervical canal length from the distal markings. (Measurement in centimeters)
5. Rotate the deployment ring clockwise into the unlocked position.
6. Slide the deployment ring distally until the inner probe contacts the fundus. Read the uterine cavity length from the proximal markings. (Measurement in centimeters)
7. Slide the deployment ring proximally to retract the inner probe.
8. Rotate the deployment ring counterclockwise into the locked position.
9. Remove the SureSound device.
10. Properly dispose of the SureSound device after use.

Service Disclaimer

Should the products need to be returned for replacement, contact Hologic Technical Support Department for instructions and a Return Materials Authorization Number (RMA#). A biohazard kit will be provided upon request when returning used product.


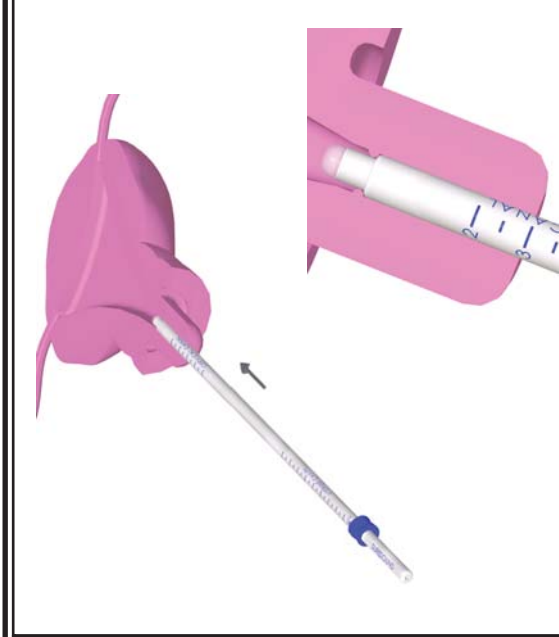
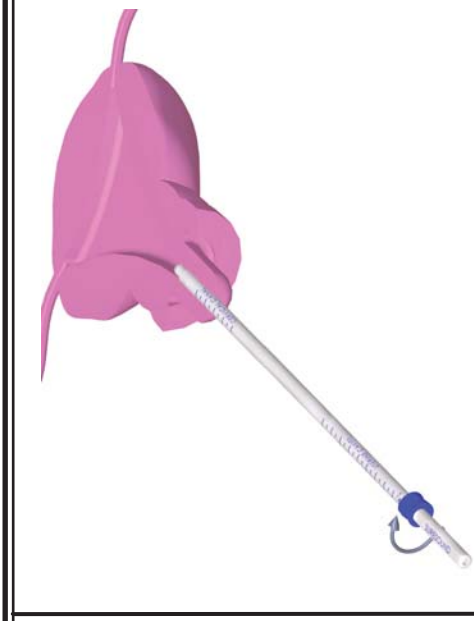



For service, technical support, or reorder information, contact, in the United States:

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 <p>Figure 1: Dilate the cervical canal up to 6 mm. Note: It may be necessary to dilate up to 8 mm with a Hagar dilator in patients with a tight cervical canal. Ensure the deployment ring (blue) is in the locked position. If unlocked, rotate the deployment ring counterclockwise to lock.</p>	 <p>Figure 2: Insert the SureSound into the cervical canal until you reach the resistance of the internal cervical os. If desired, read the cervical canal length from the distal markings. (Measurement in centimeters)</p>	 <p>Figure 3: Rotate the deployment ring clockwise into the unlocked position.</p>
 <p>Figure 4: Slowly slide the deployment ring distally until the inner probe meets resistance at the fundus. The inner probe will automatically flex to accommodate the position of the uterus. Read the uterine cavity length from the proximal markings. (Measurement in centimeters)</p>	 <p>Figure 5: Slide the deployment ring proximally to retract the inner probe.</p>	 <p>Figure 6: Rotate the deployment ring counterclockwise into the locked position and remove the SureSound.¹</p>

¹When finished with the procedure, properly dispose of the SureSound. **The SureSound is a disposable, single use device.**