



Artwork consists of:

- 8.25 X 9.50-inch Sheets

Artwork master disk contains the following file(s):

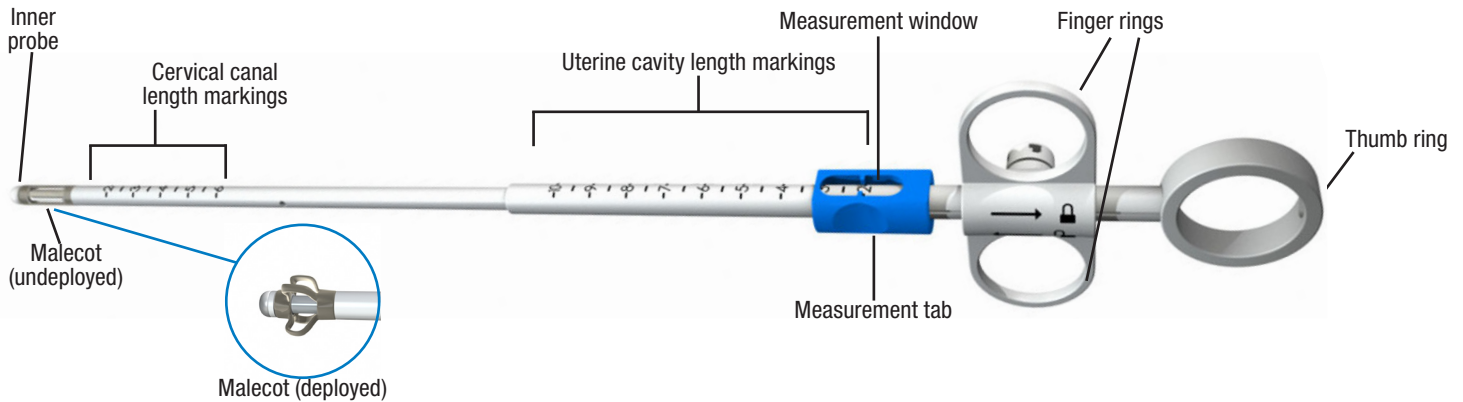
File Name	Description
AW-08411-001_003_01.zip	Source and supplier print file
AW-08411-001_003_02.pdf	View file

The Artwork prints CMYK

REV AUTHORED BY KBUJOLD	DATE 03/21/14	 HOLOGIC [®] A FAMILY OF COMPANIES		 SIGNATURES ON FILE
REV DRAFTED BY KBUJOLD	DATE 03/21/14			
PROPRIETARY: This document contains proprietary data of Hologic, Inc. No disclosure, reproduction or use of any part thereof may be made except by written permission from Hologic.		TITLE IFU, SURESOUND GEN 2, 6MM US	DOCUMENT NUMBER AW-08411-001	REV 003
REV. RELEASE DATE: 05/01/2014		ARTWORK	SIZE A	SHEET 1 OF 1

SureSound[®]

Uterine Sounding Device



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 uses two coaxial members to measure the uterine cavity. The outer sheath has a feature that is deployed using the handle to locate the internal cervical os and distal markings to measure the length of the cervical canal. The flexible inner probe has an atraumatic tip and telescopes within the outer sheath. The inner probe is extended until it contacts the fundus, and the uterine cavity length is read from the 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

The SureSound device is contraindicated for use in a patient who is pregnant and in a patient with an intrauterine device (IUD) currently in place.

WARNINGS AND PRECAUTIONS

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

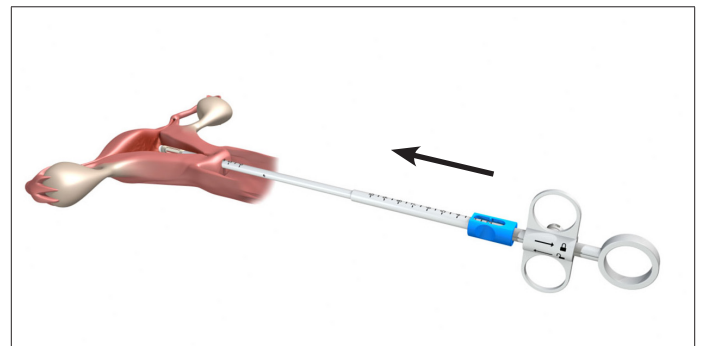
- The SureSound device is for single use only and is provided sterile. DO NOT re-sterilize the SureSound device.
- Store product at ambient conditions. Storage at high temperature and high humidity may damage the package.

ADVERSE EVENTS

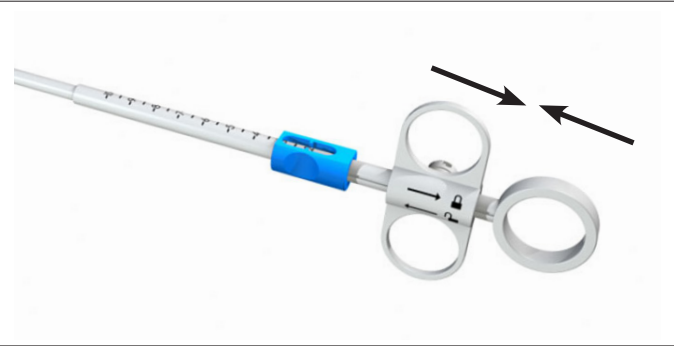
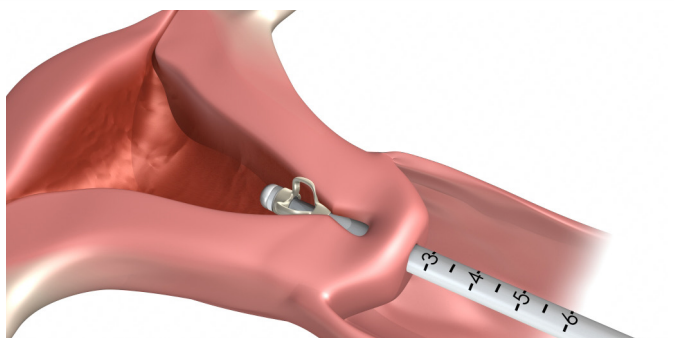
Potential adverse events include, but are not limited to: perforation of the uterine wall, infection or sepsis, and complications leading to serious injury.

INSTRUCTIONS FOR USE

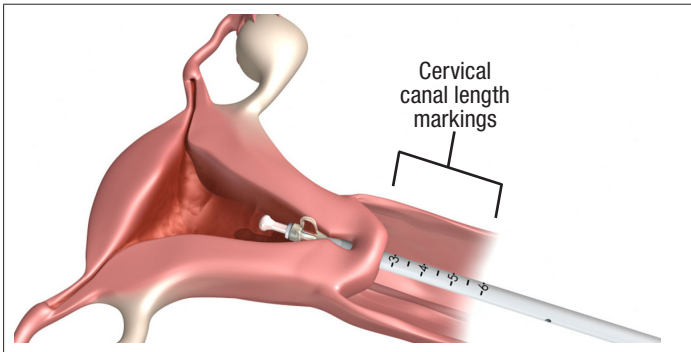
1. Dilate the cervical canal up to 6 mm.
2. Unpack and inspect the device. Do not use if damaged or defective.



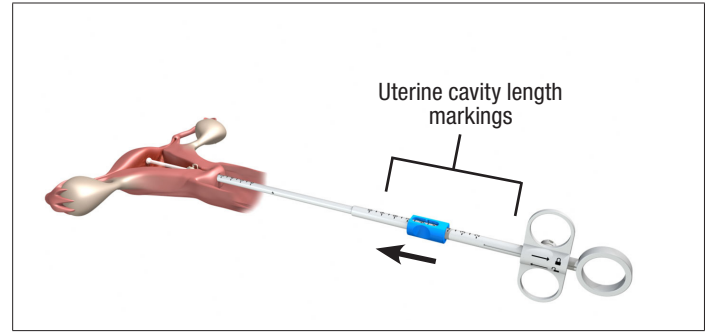
3. Insert the device transcervically until the distal end of the device has passed the internal os and the distal end is in the uterine cavity.



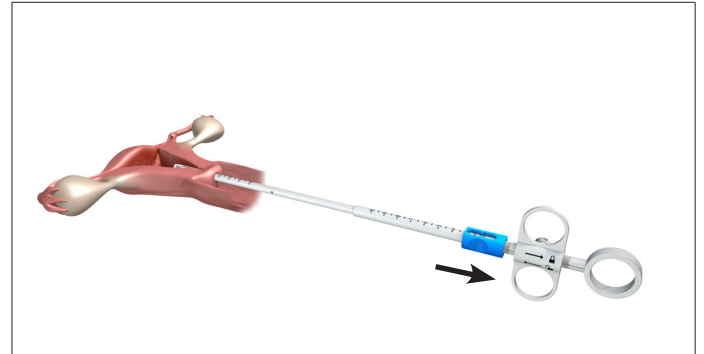
4. Once inside the cavity, squeeze the finger rings and the thumb ring to deploy and lock the malecot.



5. Pull the device toward the internal os until the malecot meets resistance at the internal os.
If desired, determine the cervical canal length from the distal markings (measurement in centimeters).



6. Slide the measurement tab distally until the inner probe reaches the fundus. Determine the uterine cavity length using the indicating markers in the window of the measurement tab.



7. Slide the measurement tab proximally to fully retract the inner probe.

TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the SureSound device fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable. Return the SureSound device according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it and include all accessories in the box with the returned unit.



Return used or opened product according to the instructions provided with the Hologic-supplied biohazard kit.

Hologic Technical Support

United States

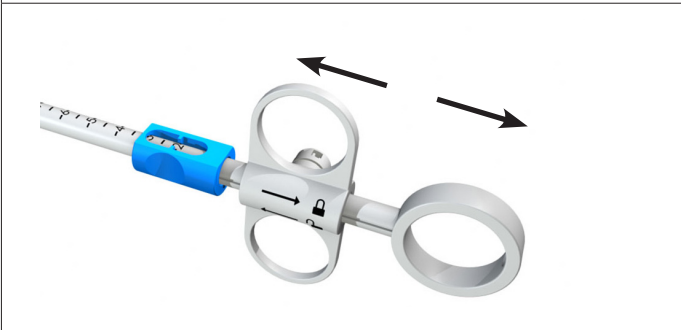
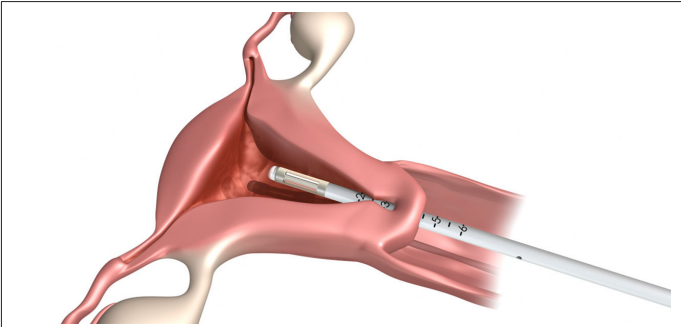
Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA
 Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900
 Fax: 1.508.229.2795

Symbol Definitions

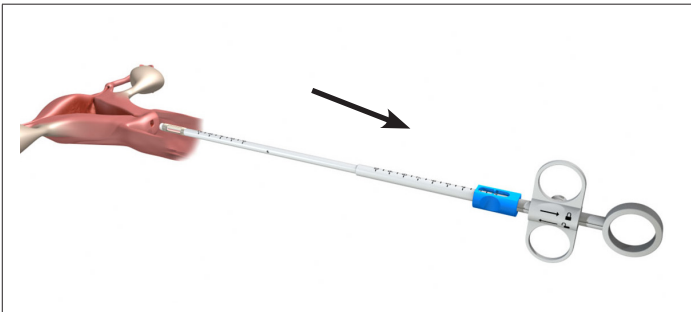
	Locked
	Unlocked

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- 8. Separate the thumb ring from the finger rings to unlock the malecot.



- 9. Remove the SureSound device.
- 10. Properly dispose of the SureSound device after use.

