

# Model 1196 • FUNDUS SOUND™ XM Intrauterine Sound

## Instructions for Use

### DEVICE DESCRIPTION / INDICATIONS FOR USE

The Fundus Sound™ XM Intrauterine Sound is used in place of a reusable silver malleable or stainless steel sound. The Fundus Sound is used to gauge the depth and position of the uterine cavity. It is also helpful with the placement of IUDs and the verification of the intrauterine position and length for HSG procedures. The proximal portion of the sound is 3.5 mm in diameter tapering to 2.5 mm at the distal portion with a tip of 2.9 mm. It is a sterile, disposable, single-use only device.

### WARNINGS

- Gently introduce and manipulate the tip of the sound through the cervical canal. Forced entry could create a false tunnel and bleeding.
- Contents supplied sterile. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

### CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

### PRECAUTIONS

- Do not use if pouch seal is damaged or broken.
- Minor bleeding, cervical inflammation, and abdominal cramps may occur.

### CONTRAINDICATIONS

This disposable Fundus Sound should not be used in the following cases:

- Possible pregnancy
- Infection, including but not limited to Acute Cervicitis and Endometriosis
- Unexplained Uterine Bleeding

### INSTRUCTIONS FOR USE

The Fundus Sound is a single-use sound. It is made of white, malleable, medical grade plastic. Prior to use, the sound can be curved between the thumb and finger in order to follow the curve of the cervical canal. The graduations are in centimeters and allow for the measurement of the uterine cavity. Dispose of the Fundus Sound in accordance with all applicable Federal, State and local Medical / Hazardous waste practices.

### EXPLANATION OF SYMBOLS

**REF** Reorder number

**LOT** Batch code

 Use-by date

**STERILE EO** Sterilized using ethylene oxide

**R<sub>x</sub> Only** **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Not made with natural rubber latex



Do not re-use



Do not re-sterilize



Do not use if package is damaged or opened.



Consult instructions for use




Caution



Manufacturer

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Made in the USA