

ENGLISH
INSTRUCTIONS FOR USE
C SAFE™ Safety Scalpel



Manufactured For:

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DEVICE DESCRIPTION

The C SAFE™ Safety Scalpel is designed to help reduce the risk of fetal lacerations to newborns during Cesarean Section procedures. Its specially designed distal tip ensures blunt entry into the uterus while the shielded blade cuts up and away from the fetus.

C SAFE is comprised of a #23 stainless steel surgical blade encased in an ergonomically designed medical grade ABS resin handle. The surgical blade is positioned in a triangular notch within the distal tip of the handle. The device tip is slightly pointed in order to achieve initial entry into the uterus. When used in accordance with these instructions, the C SAFE Safety Scalpel has the potential to increase safety and prevent the possibility of a fetal laceration during Cesarean Section procedures.

INDICATIONS FOR USE

C SAFE is intended to be used by surgeons to make incisions into the uterine wall during Cesarean Section procedures.

COMPLICATIONS

Possible complications due to use of C SAFE include, but are not limited to, scratches and inadvertent puncture of fetus if not used as instructed. As with any device incorporating a sharp blade, user error may cause unintended injuries.

WARNINGS

- Do not reuse or resterilize. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or resterilization.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Device blade is sharp. Handle with care. Do not touch cutting edge.
- Use caution when using device to avoid inadvertent cutting of fetus, mother or physician fingers.
- Do not advance device against resistance without careful assessment of cause. If cause cannot be determined, withdraw device. Movement against resistance may result in patient injury or device damage.

PRECAUTIONS

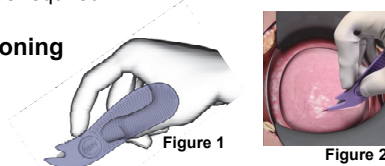
- Use by the "Use By" date.
- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Upon removal from package, inspect device to ensure it is not damaged.
- Dispose of used device in accordance with healthcare facility policy and local regulations associated with sharp objects.

INSTRUCTIONS FOR USE

STEP 1: Prepare the patient and expose uterine wall using standard abdominal incision techniques.

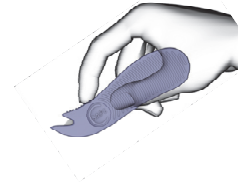
STEP 2: Make the initial entry into the uterine wall using the distal tip of the C SAFE Safety Scalpel. An oblique or slightly angled positioning of the hand should be utilized as seen in Figures 1 and 2. Adequate entrance into the uterine cavity may be achieved in either a single pass or multiple passes. For non-labored or thicker uterine walls, the use of a traditional scalpel prior to the use of C SAFE may be required.

Proper Hand Positioning

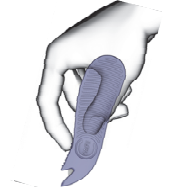


NOTE: Do not hold hand vertically to make initial entry into the uterine wall.

CORRECT HAND POSITIONING

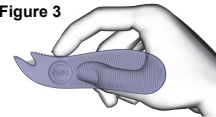


INCORRECT HAND POSITIONING



STEP 3: Once the distal tip passes through uterine wall, immediately rock the handle laterally so that the C SAFE distal tip points in direction of intended incision and slightly upwards toward the inner uterine wall as seen in Figure 3.

Figure 3



NOTE: Holding C SAFE at a slightly upward angle helps reduce the risk of the device tip catching on anything below, such as amniotic membrane or the umbilical cord.



DO NOT USE OR HOLD C SAFE IN A REVERSE POSITION

Symbols

	Attention, see instructions for use
	Catalog number
	Consult instructions for use
	Contents of package
	Do not resterilize
	Do not reuse
	Do not use if package is opened or damaged.
	Lot number
	Manufacturer
	Prescription only - device restricted to use by or on the order of a physician
	Sterilized using irradiation
	Use by date
	Not made with natural rubber latex

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