

CeuSafe®

Cesarian Safety Scalpel



"Safety with purpose"



www.ceumed.com



CeuSafe[®]

Cesarian Safety Scalpel

ECCENTRIC DESIGN TO
PROTECT THE CHILD'S SCALP
DURING C-SECTION
PROCEDURES

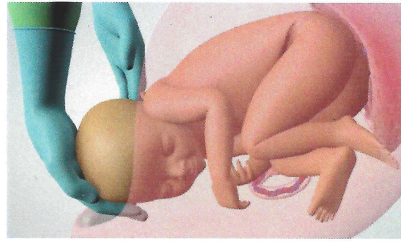
HIGH-QUALITY
STAINLESS-STEEL
BLADE

UNIQUELY DESIGNED
SURGEON GRIP

"Designed to safeguard the baby"



A Cesarean, known more popularly as a C-section, is a common and safe surgery where the baby from your womb is delivered through an incision in your lower abdomen and uterus. Accidental cuts and nicks on the baby's skin are one of the concerns during the procedure. CeuSafe is designed to safeguard the baby.



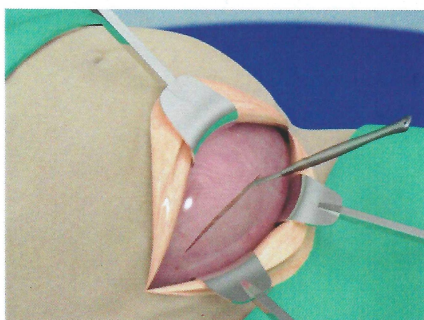
CEUSAFE HELPS TO BRING DOWN THE RISKS OF INCISIONS OR SCARS AND IMPROVE SAFETY FOR BABY, MOTHER, AND SURGICAL TEAM DURING THE ENTIRE PROCEDURE.

The CeuSafe Cesarean Safety Scalpel is designed to help reduce the risk of accidental cuts and nicks on the newborns during C section procedure. It has uniquely designed surgeon grip which allows a firm holding for the medical personnels to carry out the procedure with great control. The device has an eccentric design which provide added safety for child's scalp.

CeuSafe is a high quality stainless steel surgical blade encased in a medical grade plastic handle. CeuSafe is positioned in a triangular notch within the distal tip of the handle. The device tip is slightly pointed to achieve initial entry in to the uterus.

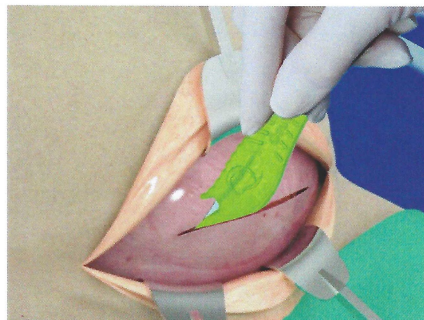
When used as per instructions, the CeuSafe Cesarean Safety Scalpel has the ability to enhance safety and prevent the possibility of fetal lacerations during C-Section procedures.

TRADITIONAL SCALPEL



A traditional scalpel exposes the fetus to the risk of laceration.

CEUSAFE SCALPEL

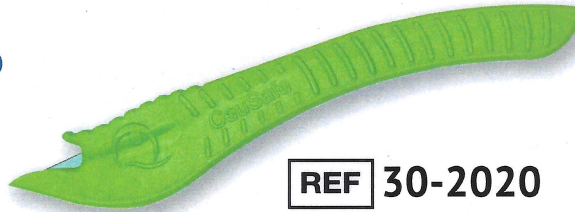


CeuSafe cuts up and away from the fetus to prevent accidental lacerations

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REF 30-2020

INDICATIONS FOR USE

CeuSafe is intended to be used by surgeons to make incisions into the uterine wall during cesarean section procedures.

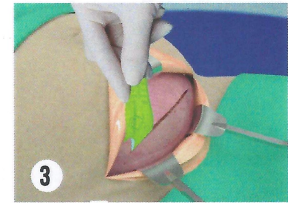
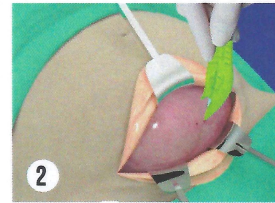
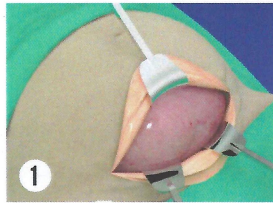
COMPLICATIONS

CeuSafe, if not used as instructed, may cause complications like scratches and inadvertent puncture of fetus. AS with any device incorporating a sharp blade, user error may cause unintended injuries.

- 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.

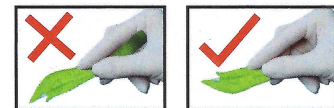
Step 2: Make the initial entry into the uterine wall using the distal tip of the CeuSafe cesarean safety scalpel. An oblique or slightly angled positioning of the hand should be utilized as seen in Figures. Adequate entrance into the uterine cavity may be achieved in either a single pass or multiple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

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

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

NOTE: Holding CeuSafe 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 CeuSafe in a reverse position!!



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.

CeuSafe® is a registered trademark of CEUMED Limited



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