



INSTRUCTIONS FOR USE UMBILICAL CORD CLAMP

***Please Read All Instructions Carefully before Use (Sterile, for single use only)**

SMDPL/IFU/UCC/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Umbilical Cord Clamp (Non-Openable) (SMD 801):

A PP device that is designed to compress (clamp) the umbilical cord after birth. It is used before cutting or ligating the cord and is intended to provide asepsis, proper haemostasis and wound healing.

Umbilical Cord Clamp (Openable) (SMD 810):

A PP device that is designed to compress (clamp) the umbilical cord after birth. It is used before cutting or ligating the cord and is intended to provide asepsis, proper haemostasis and wound healing.

INTENDED PURPOSE:

Umbilical cord clamp design to pinch the umbilical cord and locked after pinching for short term use.

INDICATIONS:

Umbilical Cord Clamp used to clamping the umbilical cord of newly born babies.

CONTRAINDICATIONS:

- Cases with interruption of the placental blood flow/oxygenation:
 - Abruptio
 - Vasa previa
 - Cord avulsion
- Hypersensitivity to device material
- Cord rupture / Torn cord
- Fetomaternal hemorrhage

LIMITATION

Delayed umbilical cord clamping (not earlier than 1 min after birth) is recommended for improved maternal and infant health and nutrition outcomes.

INTENDED USER

Trained and registered healthcare professional.

INTENDED PATIENT POPULATIONS

New-born babies.

DIRECTIONS FOR USE:

- Open the package from the peel-open area and remove the device.
- Wash hands with warm soapy water. Dry thoroughly. Put on gloves and aprons.
 - Steps to Cut the Umbilical Cord
- Be sure the cord has stopped pulsing for most births. This is called delayed cord clamping and provides benefits for baby.
- Ensure that there are two clamps on the cord. (The practitioner will be responsible for this part.)
- Hold the section of cord to be cut with a piece of gauze under it.
- Use the sterile scissors for cut umbilical cord.
- Dab excess blood. (The amount of blood depends on how long you wait to cut the cord, the longer you wait, the less blood.)

WARNING:

Delayed cord clamping is contraindicated in situations where placental circulation is not intact, such as placental abruptio, bleeding placenta Previa, bleeding vasa Previa or umbilical cord avulsion.

The cord should not be clamped earlier than 1 minute after birth. It's recommended that the cord is clamped before 5 minutes (so the placenta can come out after it has separated from the uterus).

Recommendation (By WHO)

- In newly born term or preterm babies who do not require positive-pressure ventilation, the cord should not be clamped earlier than 1 min after birth (strong recommendation).
- When newly born term or preterm babies require positive-pressure ventilation, the cord should be clamped and cut to allow effective ventilation to be performed (conditional recommendation).

- Newly born babies who do not breathe spontaneously after thorough drying should be stimulated by rubbing the back 2 – 3 times before clamping the cord and initiating positive-pressure ventilation (Conditional recommendation).
- Late cord clamping (performed approximately 1–3 min after birth) is recommended for all births, while initiating simultaneous essential neonatal care (strong recommendation).
- Early umbilical cord clamping (less than 1 min after birth) is not recommended unless the neonate is asphyxiated and needs to be moved immediately for resuscitation (strong recommendation).

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.**
- Do not clean or Re-use the device, for single use only.
- Discard after use.
- Store in a Cool and dry place.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packing.
- Do not use if the package is opened and damaged.
- Do not Re-sterile the Device.
- Do not use the device after expiry Date mentioned on the Label.

ADVERSE EFFECTS:

- Inadequate cord clamping leading to bleeding.

CLINICAL BENEFIT:

- Safe, feasible, and effective
- Decreases iron deficiency anemia
- Minimizing blood loss for women
- Low Cost
- Improves neonatal oxygen transport and red blood cell flow
- Preterm infants decrease the need for blood transfusion
- Prevent neonatal resuscitation

RESIDUAL RISKS:

- Infection, Bleeding

SUPPLY:

Umbilical Cord Clamp (Non-Openable) (SMD 801)



Umbilical Cord Clamp (Openable) (SMD 810)



MATERIAL USED:

Component	Material	Specification/Grade
Cord Clamp	PVC (Poly Vinyl Chloride) Compound	Medical Grade

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused Device.

STORAGE:



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These products should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.


DEVICE DISPOSAL:

Used devices may be contaminated with infectious and/or other hazardous materials. Discard used devices in the container meant for infectious waste.

Unused expired devices should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

SYMBOLS:

	Catalogue No.		See instructions for Use
	Cautions		Keep Dry
	Do not use it if the packaging is damaged.		Sterile Barrier System
	Single-Use		Do not Re-sterilize
	Batch / Lot No.		Ethylene Oxide Sterilized
	Date of Mfg.		Latex Free
	Date of Exp.		Medical Device
	Avoid Direct Sunlight		Keep in a dry place between 5°C to 45°C
	Phthalate Free		Pyrogen Free
	Unique Device Identifier		



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