

INSTRUCTION FOR USE FOR UMBILICAL CORD CLAMP

- Product Name** : Umbilical Cord Clamp
- Brand Name** : Ultramed Umbilical Cord Clamp
- Manufacturer's Name** : Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E
- Manufacturer's Address** : Part no. (304 : 310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.

- Description of the Device:

- Umbilical Cord Clamp is a sterile small device used primarily in medical settings before cutting to temporarily clamp, compress and secure the umbilical cord after birth for new born. it is designed to prevent blood loss from the newborn by tightly sealing the blood vessels within the umbilical cord to provide asepsis, proper hemostasis and wound healing.
- The umbilical cord clamp is Made from non-toxic, Medical grade ABS (Acrylonitrile Butadiene Styrene) Compound which are widely used in hospitals and clinics.
- The ABS material provides excellent resistance to breakage, even under stress, ensuring that the clamp remains secure during its application and until it is removed.
- The umbilical cord clamp is designed with a dual security arms that makes a distinct 'Click' sound, indicating proper locking. The inner surface has serrated teeth that provide a firm grip on the umbilical cord, preventing slippage and ensuring the cord is clamped tightly. It is easy to use with gloved / wet hands safely, as clamp's thumb/ finger grip is appropriately designed for convenient & safe application. The umbilical cord clamp is Packaged in sterile conditions to ensure hygiene and avoid contamination during newborn delivery.
- Umbilical Cord Clamp is a Short-Term single use device and is being used as medical device for many years under different brands.
- The Umbilical Cord Clamp is individually packed in medical paper pouch or Plastic Pouch in a single box
- It can be used Until the cord dries, shrinks and turns black.
- Vaso Clamp has more grooves, its hinge has a collar (gated umbilical cord clamp), and the clamping surface more wider. The device is T-bar latch locking device.
- The Clamp should be taken off after the falling down of the cord, the baby's umbilical cord stump usually stays attached for around 5 to 21 days. Over this time, the cord dries, shrinks and turns black.
- Product is conventional and fully equivalent with many products in market.

- The product is CE marked.
- The product is approved by the Ministry of Health.
- The product is sterilized using EO (Ethylene Oxide)
- This product is for single use.

Material Used:

ABS (Acrylonitrile Butadiene Styrene)

Intended purpose:

- Umbilical Cord Clamp is intended to safely and securely close off the blood vessels in a newborn's umbilical cord after birth for short term use. This prevents blood loss and reduces the risk of infection in the newborn.
- It helps the remaining part of the umbilical cord dry up and fall off naturally after a few days, promoting natural healing.

Variants:

Ref Code	Item
9002 – 1	Umbilical Cord Clamp (Standard)
9002 – 2	Umbilical Cord Clamp [Vaso Clamp] (Premium)

Clinical Indications:

- Routine Clamping: After delivery of the baby (**Normal Vaginal or Caesarean Delivery**) to prevent bleeding from the blood vessels of the cord after it is cut.
- **Delayed clamping** may be indicated in **preterm** babies to allow the residual blood that remaining in the cord to flow back to the baby's body considering it a percentage of the actual fetal blood volume, reducing the risk of certain conditions like anaemia.
- WHO Recommendations: Delayed umbilical cord clamping (not earlier than 1 min after birth) is recommended for improved maternal and infant health and nutrition outcomes.
- 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.
- In some **full-term** infants, delayed cord clamping can increase **iron** levels and improve circulatory stability.

- In cases of **multiple births**, each baby's umbilical cord needs to be clamped immediately after delivery to prevent mixing of blood between the siblings and ensure proper separation from the placenta.
- In cases of placental complications, early clamping may be required to manage haemorrhage or ensure rapid separation of the baby from the placental circulation. Like **Placenta Previa or Abruptio**
- In cases of umbilical cord complications such as **true knots, cord prolapse, Nuchal Cord**, clamping may need to be done swiftly to prevent bleeding or compromise to the baby's circulation.
- In cases where the mother is experiencing severe **postpartum haemorrhage**, rapid clamping and cutting of the cord may be necessary to prioritize care for the mother.

Contraindications:

- ❖ Do not use in patients with known hypersensitivity to the material used.

Device Limitations:

Only used for newborn neonates

Only used for safely securing the umbilical cord after birth

Not used in any other medical procedures

Patient Target Group:

The target patient population of product includes most Neonates. When the baby is born, within a few minutes after birth, the cord is clamped and cut close to the navel. The product should be used by competent medical practitioner only.

Intended User:

- To be used by an expert qualified medical professional, Skilled or Trained Personnel (**In-Charge**)

Application site in the body:

Umbilical cord in the neonates

Clinical benefits:

- ❖ Umbilical Cord Clamp is designed to prevent blood loss from the newborn by tightly sealing the blood vessels within the umbilical cord to provide asepsis, proper hemostasis and wound healing.
- ❖ Delayed cord clamping allows for more blood from the placenta to flow into the newborn, which can increase blood volume and improve iron stores which reduce the risk of anemia in the first year of life.
- ❖ Delayed clamping may help with the transition from fetal to neonatal circulation, aiding in better oxygenation and stabilization of the newborn.

Use Environment:

- Hospital, delivery Room, neonatal intensive care units and home until the fall of umbilical cord

Life time of device:

- The Clamp should be taken off after the falling down of the cord, the baby's umbilical cord stump usually stays attached for around 5 to 21 days. Over this time, the cord dries, shrinks and turns black.

Sterility status and Method of sterilization:

- Umbilical Cord Clamp supplied in sterile state and sterilized using ethylene oxide.

Information on medical device intended to be used with other devices:

- Umbilical Cord Clamp performs its function without connection with any other product and it is not intended to be connected with any other medical device.

Performance Characteristics:

- ❖ **Finger grip:** ensures safe & convenient handling.
- ❖ **Provided with grooves all along the length:** prevent slipping of umbilical cord.
- ❖ **the ring end of the clamp:** ensure a correct closure, If the baby has a thick umbilical cord
- ❖ The component has a Security lock to prevent accidental opening after clamping.
- ❖ **Appropriate angle:** for easy movement for clamping.
- ❖ **Very safe for clinicians and patients because** clipping surfaces are safely adjourned in notches to eliminate risk of injury.

Risks Associated with reuse

- Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

1. Gather Supplies: Umbilical cord clamp, Sterile scissors, Gloves (for hygiene), forceps.
2. Ensure you are in a clean, well-lit environment.
3. Check the packing carefully, if found damaged, torn or pierced discard the piece. Do not use if pack is damaged.
4. Wash up and scrub hands and preferably use sterile protective gloves to prevent the transmission of microorganisms
5. Peel open the pack & draw out the device with care.
6. Place the device on the sterile tray.
7. Locate the umbilical cord attached to the newborn.
8. Ensure the baby is stable and in a safe position.
9. Be sure the cord has stopped pulsing for most births. This is called delayed cord clamping and provides benefits for baby.

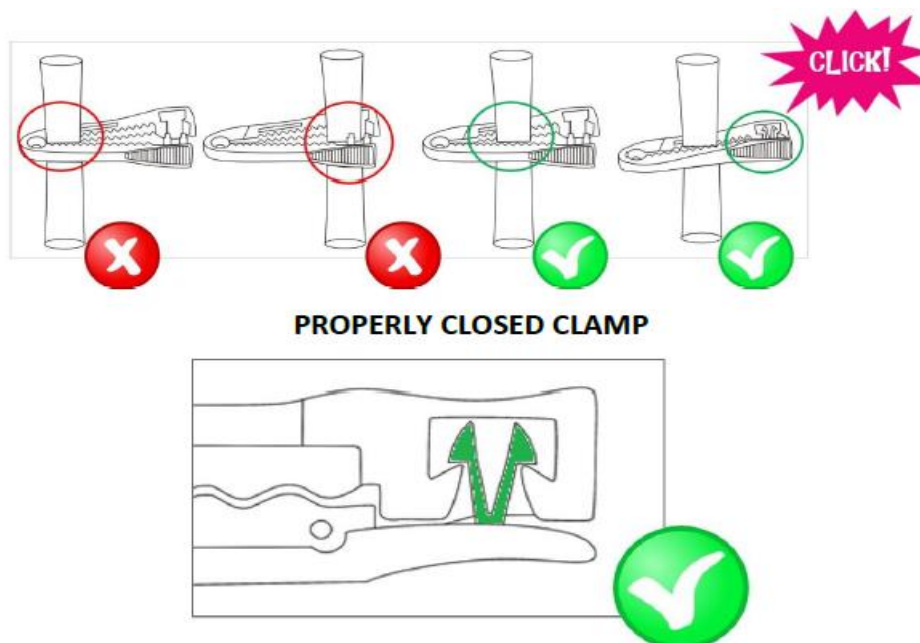
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Umbilical Cord Clamp

10. Before using, always check the locking system. Do not use the clamp if the system is incomplete or blocked.
11. Check the thickness of the umbilical cord. In case of thin umbilical cord, it may be necessary to fold it before applying the clamp to obtain a greater resistance when locking the clamp.
12. Place the cord in the most middle of the grooves area.
13. Make sure that no object blocks this place (e.g. gauze swab, surgical instruments, etc.).
14. Use two forceps for crashing the cord.
15. Or two clamps instead of two forceps are placed on the umbilical cord, and the cord is cut between the clamps.
16. The first clamp is placed closer to the infant, and the second is placed further away in appropriate distance from the mother to prevent injury.
17. Place the umbilical cord clamp appropriate distance according to applicable standards from the baby's abdomen about an inch (3 cm) from the baby's abdomen according to The Navy Bureau of Medicine and Surgery (BUMED) US Operational Obstetrics & Gynecology Clamp and Cut the Umbilical Cord brookside associates.
18. Press down on the clamp until it clicks into place, ensuring it is tight enough to prevent bleeding but not so tight that it pinches the cord excessively.
19. Note that in case of using two forceps the process of clamping the clamp will be after cutting the cord.
20. Hold the section of cord to be cut with a piece of gauze under it between the forceps or clamps.
21. Disinfect the site of cord that will be cut.
22. Use the sterile scissors for cut umbilical cord to prevent infection.
23. Dab excess blood if found.
24. Clean umbilical cord then raises it.
25. Ensure it is positioned securely over the cord.
26. After clamping and cutting, monitor the area for any signs of bleeding or infection.
27. Keep the clamp in place until it is time for it to be fallen down or to be removed by a healthcare professional.
28. Until the stump drops off and the belly button is completely healed, it's important to keep the area clean and dry, to prevent infection.
29. Remove gloves and wash hands thoroughly.
30. Dispose of any used materials according to local health regulations.
31. With passage of time the cord shall shrink & dry. Discard the Clamp, after the use.
32. The Clamp should be taken off after the falling down of the cord, the baby's umbilical cord stump usually stays attached for around 5 to 21 days. Over this time, the cord dries, shrinks and turns black.



PROPERLY CLOSED CLAMP

Warnings:

- For Single use.
- Discard after single use, Reusing can be associated with Cross infection,
- Do not use if the packaging is damaged or has been previously opened.
- DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use.
- The product should be used only by a qualified doctor or paramedic who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
- Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- Storage up to 32° C, avoid excessive heat, protect from direct sunlight and moisture.
- The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- Delayed cord clamping is contraindicated in situations where placental circulation is not intact, such as placental abruption, bleeding placenta Previa, bleeding vasa Previa or umbilical cord avulsion,
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.

- Precautions:

- Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.
- Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- The device is for Single Use Only.
- Use the product immediately after opening the packing.
- Do not Re-use the device, as this may lead to infection to the User & Patient, both, as once in lock position/ the clamp cannot be opened
- Check the integrity of the cord Clamp before use.
- Apply the clamp at the correct distance from the newborn's abdominal wall. Placing it too close to the skin can cause injury, while placing it too far can leave excess umbilical cord that may lead to infections.
- After applying the clamp, check that it has securely locked in place and that the serrated teeth have fully compressed the cord.
- During locking there is a distinct 'Click' sound signifying proper locking of the clamp over the cord.
- Once the clamp is applied, avoid touching or moving it to prevent contamination or injury to the cord stump.
- Delayed cord clamping is contraindicated in situations where placental circulation is not intact, such as placental abruption, bleeding placenta Previa, bleeding vasa Previa or umbilical cord avulsion.
- Avoid any undue tension or pulling on the umbilical cord during the application of the clamp, as this could cause tearing of the cord or bleeding.
- Exercise caution while applying umbilical cord clamp to exomphalos, omphalocele.
- If the baby has a thick umbilical cord, then the cord must be placed towards the ring end of the clamp to ensure a correct closure.
- Discard the set after single use.
- Determine patient's condition and vitals status During device application / Operation.
- Destroy the device after single use as bio-medical waste as per applicable laws.
- Do not Re-sterilize.
- Do not use the device after the Expiry Date.

Potential Complications / Risks:

- ❖ Inadequate cord clamping leading to bleeding.
- ❖ Infection
- ❖ Acute Intestinal Obstruction Due to misplaced clamping of the umbilical cord

- ❖ **Early clamping** may reduce the infant's blood volume, potentially leading to iron deficiency anemia, and Hypoxia.

General Instructions:

To be used by an expert qualified medical professional. Use maximal sterile barrier precautions during application. Dispose the device after use as bio-medical waste as per applicable laws.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartoons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Storage at room temperature up to $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
- Humidity: upto RH 65% (± 5)

Safe Disposal of single-use medical devices:

- Adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.
- Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner.
- Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility

Method of sterilization

- Sterilized Using Ethylene Oxide

Shelf life
















- 5 years (from the date of manufacturing)

Basic UDI: 622300425UCC9002TJ

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following [European Commission website:](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en)
https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
	EU REP
	CE Mark with notified body number 2803
	Sterilized by Ethylene Oxide
	For Single Use Only
	Lot No.
	Date of Manufacturing
	Use by / Expiry date
	Catalogue No.
	Non- Pyrogenic
	Medical Device
	Unique device Identifier
	Don't use if package is not intact
	Manufacturer's address
	Phthalate-Free
	Read Instructions for Use

Symbol	Meaning
	Not to be re-sterilized
	storage at room temperature up to 30 °C ± 2°C
	Cautions
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Recycle
	Don't put more than 5 cartons upon each other
	Latex Free

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