

Umblicup™

Umbilical Cord Blood Collection Device

Rx Only
Do Not Reuse
Not made with natural rubber latex

IMPORTANT INFORMATION

Please read all instructions, warnings, and precautions before use. Correct application is essential for proper functioning of product.

INTENDED USE

The DeRoyal® Umblicup™ Umbilical Cord Blood Collection Device is intended to be used by a licensed practitioner for the collection and transport of umbilical cord blood for the purposes of routine laboratory testing.

INDICATIONS

Use of this device is indicated when it is necessary to collect umbilical cord blood for laboratory testing of newborns after either Vaginal or Cesarean Section Deliveries. The laboratory tests on the umbilical cord blood may be performed depending on local law or on the health and condition of the mother or baby as deemed and hereto ordered by the physician.

CONTRAINDICATIONS

Umblicup is not intended for the collection, transportation, or storage of umbilical cord blood intended for Stem Cell research or banking.

PRECAUTIONS

- Product should not be used if the cup is broken, cracked or chipped. Product should not be used if the cap or lid does not fit. If damage is found, remove the product from the sterile procedure area to prevent unintended use and return to the manufacturer.
- The package should be opened using sterile technique.
- Product should not be used if sterile packaging is damaged or opened or if shelf-life has expired. If damage is found or the product is expired, remove the product from the sterile procedure area to prevent unintended use and return to the manufacturer.
- This device is for single use only. It is not intended for disinfection and/or subsequent re-use, which can result in microbial contamination causing health deterioration of the patient or inaccurate laboratory results.
- This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.

WARNINGS

- Care should be exercised whenever handling blood to prevent splashes, sprays, and spills. Proper personal protective equipment should be worn according to local or facility policies.
- Care should be exercised whenever handling sharp needles to prevent accidental needle sticks.
- Product should not be used if the needle is detached, loose, or exposed.
- If needle becomes detached with the vacuum tube is inserted or removed, or if the needle sheath does not return to cover the needle, caution should be exercised when handling the device or separated needle.
- Product should be disposed of in a facility approved sharps container.

DIRECTIONS FOR GENERAL BLOOD COLLECTION

METHOD #1 - GRAVITY FLOW METHOD

- Double clamp and cut umbilical cord as usual.
- Place clamped free-end of the cord into Umblicup.
- Release cord clamp slowly to allow gravity flow to drain cord blood into Umblicup.
- Insert empty vacuum collection tube into sheath-protected needle at bottom of Umblicup.

- Once filled, remove collection tube from Umblicup, and send to the lab for designated studies.
- Place lid firmly on top of Umblicup and place red cap onto bottom of Umblicup by pressing down on a flat surface.
- Discard into sharps container.

DIRECTIONS FOR GENERAL BLOOD COLLECTION METHOD #2 - DOUBLE CLAMP METHOD

- Double clamp and cut umbilical cord as usual.
- Place clamped free-end of the cord into Umblicup.
- Release cord clamp slowly to allow gravity flow to drain cord blood into Umblicup.
- Insert empty vacuum collection tube into sheath-protected needle at bottom of Umblicup.
- Once filled, remove collection tube from Umblicup, and send to the lab for designated studies.
- Place lid firmly on top of Umblicup and place red cap onto bottom of Umblicup by pressing down on a flat surface.
- Discard into sharps container.

DIRECTIONS FOR CORD BLOOD GAS TRANSPORT

- Notify the laboratory that blood gas specimen is being collected.
- After delivery, double-clamp the cord; use a plastic clamp above the Pean or Kocher. Cut the cord.
- Place a second plastic clamp 2 to 3.7 inches beyond the first clamp and a stainless steel clamp just above the second clamp. Cut the cord between these clamps.
- The cord segment, secured by two plastic clamps, is placed into the top of the Umblicup.
- Pack sterile ice into the top of the Umblicup. Place the cap on the top of the Umblicup.
- Promptly transport the Umblicup containing the section of umbilical cord to the laboratory.

STERILIZATION INFORMATION

Non-Sterile product: DeRoyal intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging and/or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide only, as other sterilization methods have not been validated by DeRoyal and may damage the product which could cause a device malfunction and/or injury to the patient.

STORAGE CONDITIONS

Do not store product at extreme temperatures or in a moist/damp environment.

WARRANTY

DeRoyal products are warranted for one hundred and twenty (120) days from the date of shipment from DeRoyal as to product quality and workmanship. DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.