INSTRUCTIONS FOR USE

UMBILICAL CATHETER (2L)

Intended use:
A Double-lumen umbilical catheter is a medical device used in neonatal care for umbilical vein access. It allows for the administration of medications, nutrition, and blood transfusions, as well as blood gas analysis.

Materials used:
LDPE, PU, ABS, Nylon

Indication :
The double-lumen umbilical catheter is indicated for intermittent or continuous access to the umbilical vein in newborns and premature infants. It allows pressure monitoring, facilitates blood withdrawal without the need for repeated needle sticks, and supports intravenous infusions and blood transfusions.

Contra Indication :
1.Active Infection: Risk of worsening infection.
2.Anatomical Abnormalities: Congenital issues affecting the cord or vessels.
3.Existing Thrombosis: Thrombosis in umbilical vessels.
4.Clinical Instability: Poor peripheral circulation or unstable conditions.
5.Prematurity Risks: Considerations in extremely preterm infants due to complications.
6.Hypersensitivity: Not to be used in patients with known hypersensitivity to any of the materials used.

Patient population :
Suitable for newborns and infants, especially those who are preterm, critically ill, or undergoing surgery.

Intended user -
Health care professionals involved in the care of newborns and infants, especially those who are premature, critically ill, or undergoing surgery, and require reliable intravenous access for treatment and monitoring should use this device.

Use environment :
Designed for use in controlled health care environments like neonatal and pediatric intensive care units (NICUs and PICUs), delivery rooms, operating rooms, and general hospital wards.

Clinical Benefits:
-Minimizes the need for repeated needle punctures, reducing discomfort to patients.
-Offers quick access to the bloodstream for urgent medical interventions.

Performance Characteristics:
-Made from bio-compatible materials.
-Smooth Taper Tip for easy insertion into the umbilical vein.
-Available in various sizes: 4.0 & 5.0 Fr.
-It allows visualization on X-ray to ensure correct placement.

Limitations of use regarding the device:
It is for single use only.

Sterlization:
Sterilized using ethylene oxide.

Storage and handling:
-Store in between 5°C to 35°C, avoid excessive heat, protect from direct sunlight and moisture.

Information on Medical Device Intended to be Used with Other Devices:
For connection with other devices, proximal & distal end of the umbilical catheter are provided with a 6% female conical fitting as per ISO 80369-7.

Risks Associated with Re-use:
Cross contamination/infection, device performance failure

Direction of use:
1. Check the packaging carefully, if the packaging is damaged, torn or punctured then discard the device.
2. Use aseptic techniques before opening the package.
3. Open the package and remove the device aseptically.
4. Connect the Luer connectors of the Umbilical Catheter to the male luer connector of the perfusion line.

6. Run infusion through the catheter in order to remove any air bubbles.
7. Gently insert the Umbilical Catheter inside the vessel following the standard protocol & perform the infusion.
8. In the case of intermittent applications, when the infusion line is not needed, the catheter remain in-situ.
9. Discard the catheter immediately after single use.

Cautions :

-Check the integrity of the sterile individual packaging before opening.
-Do not use if the sterile packing is opened or damaged.
-Use aseptic techniques before opening the package.
-Check the integrity of the device before performing the procedure.
-The product should be used only by qualified healthcare professionals.
-To prevent potential cracking of the device, it is recommended to avoid exposure to organic solvents, alcoholic disinfectants, infusion solutions, and substances with a high pH value. Always follow the instructions for use (IFU) provided with the medicine or disinfectant before application.
-Reuse and cleaning of product may alter their structural and mechanical properties. It may lead to infection or other illness/injury.
-The product should be replaced and disposed of as per facility approved protocol.
- Poly Medicure Limited will not be responsible for any direct incidental or consequential damages resulting from repeated use or repeated sterilization of product.
- Do not use after the expiry date.

Disposal of device:

Product should be disposed of as per facility approved protocol or CDC guideline, or Local ,state or country specific regulations.

Reporting of incident to manufacturer & regulatory authority:

For providing feedback on this product write to: customercare@polymedicure.com


Cautions


See Instructions for use

Product reference/Art. No.


For single use only

Do not Resterilize


Do not use if packaging or product has been damaged or contaminated

Batch Number


Date of Manufacturing


Use by / Expiry date

Sterilised by Ethylene Oxide


Single Sterile Barrier System


Manufactured by


Non Pyrogenic

Storage Condition


Keep Away from Sunlight


Keep Dry

Medical Device

POLYMED

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Not made with natural rubber latex
Not made with DEHP plasticizers