

SINGLE USE / LOW VOLUME DIALY-NATE®

A Pediatric/Infant Disposable Peritoneal Dialysis Set

REF 4000557

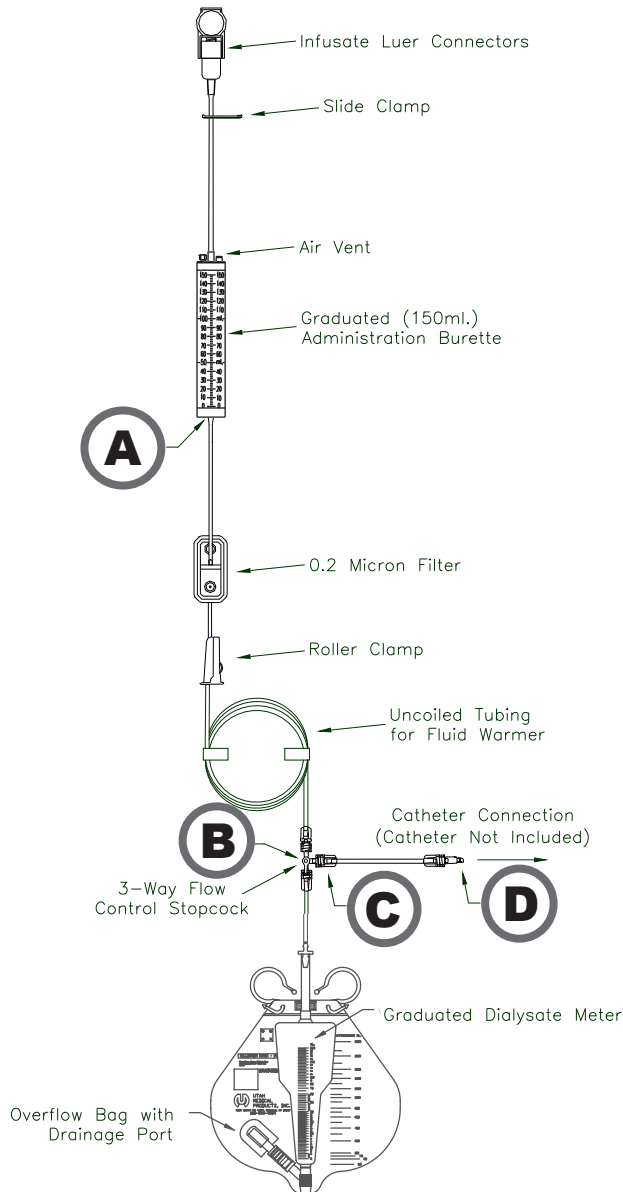
Contents:

One Neonatal Peritoneal Dialysis Administration Set (does not include invasive dialysis catheter)

Outstanding Features

- Pre-assembled sterile system
- Graduated 150 ml administration burette with air vent
- 1 luer connector for mixing infusate
- In-line bacterial retentive (0.2 micron) filter
- In-line 3-way flow control stopcock
- Finely graduated dialysate meter with overflow bag

See Instructions on Back



Priming Volumes

| | |
|--------------|---------------|
| (A) to (B) | 8.7 ml |
| (C) to (D) | 1.2 ml |
| Total | 9.9 ml |

Manufacturer of:

Umbili-Cath® Nutri-Cath®
 Myelo-Nate® Uri-Cath™
 Hemo-Nate® Thora-Cath®
 Pala-Nate® Picc-Nate®

A Company Sensitive to the Needs of the Neonatal Patient



Indications for Use

- The Dially-Nate set is indicated for use in a neonatal or pediatric critical care situation where manual peritoneal dialysis has been prescribed.

Cautions

- For Use within I.C.U. For Manual Exchanges Only.**

Precautions

- Only qualified healthcare practitioners should utilize this pre-assembled administration set.
- Do not attempt to disconnect connections. Do not attempt to manually tighten stopcock luer connections.**
- Do not overfill buretrol, and keep buretrol positioned to avoid wetting of the filter in the top of the buretrol. Wetting of this filter can compromise and/or stop flow. If vent on top of burette becomes wet, the system will no longer gravity feed.
- Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process. **This device is not structurally designed or validated for reuse.**
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations for products contaminated with bodily fluids and tissue.

Dially-Nate® Instructions For Use

With patient properly catheterized, proceed as follows:

- Always use aseptic technique when setting up, filling and connecting to the indwelling catheter.
- Hang the pre-heated electrolyte bag above the patient so as to afford approximately a three foot head pressure.
- Hang overflow / collection bag so that it is below the patient.
- Connect bag of pre-heated selected infusate. Open clamp of bag, as well as all other downstream clamps. Ensure that the 3-way stopcock is properly directed (handle turned toward the overflow bag), to permit the flushing and priming of the system to the patient.
- Flush and prime the system.
- Once primed, close the roller clamp and connect set to patient's indwelling peritoneal dialysis catheter. Then, determine the volume of dialysate to be infused into the patient.
- Release pinch clamp directly under the bag and fill burette to the predetermined volume of fluid. Close off pinch clamp to stop flow from bag into the burette.
- Turn stopcock handle toward collection bag. Open roller clamp and allow dialysate solution to infuse into the patient, carefully observing patient vital signs.
- Once the predetermined volume has been infused, or earlier upon practitioner direction, close the roller clamp and turn the stopcock handle toward the patient.
- After prescribed fluid dwell time, rotate stopcock handle toward dialysate source, allowing effluent from the patient to flow into the overflow bag.
- Ensure that the administration set is changed every pass.

Note: The 3-way stopcock has a 180° range of motion in accordance with three options for fluid delivery direction. Do not force the stopcock past these stops.

EU NOTICE: Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.

MD

Medical Device

Rx ONLY

Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner

REF

Catalog Number



Do not re-use



Do not resterilize



Do not use if package is damaged



Product is not manufactured with natural rubber latex

STERILE EO

Sterilized using ethylene oxide



Single sterile barrier system



Non-pyrogenic



Manufacturer

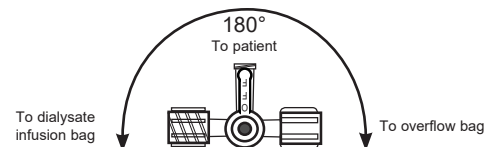


Date of Manufacture

EC REP

Authorized representative in the European Community

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