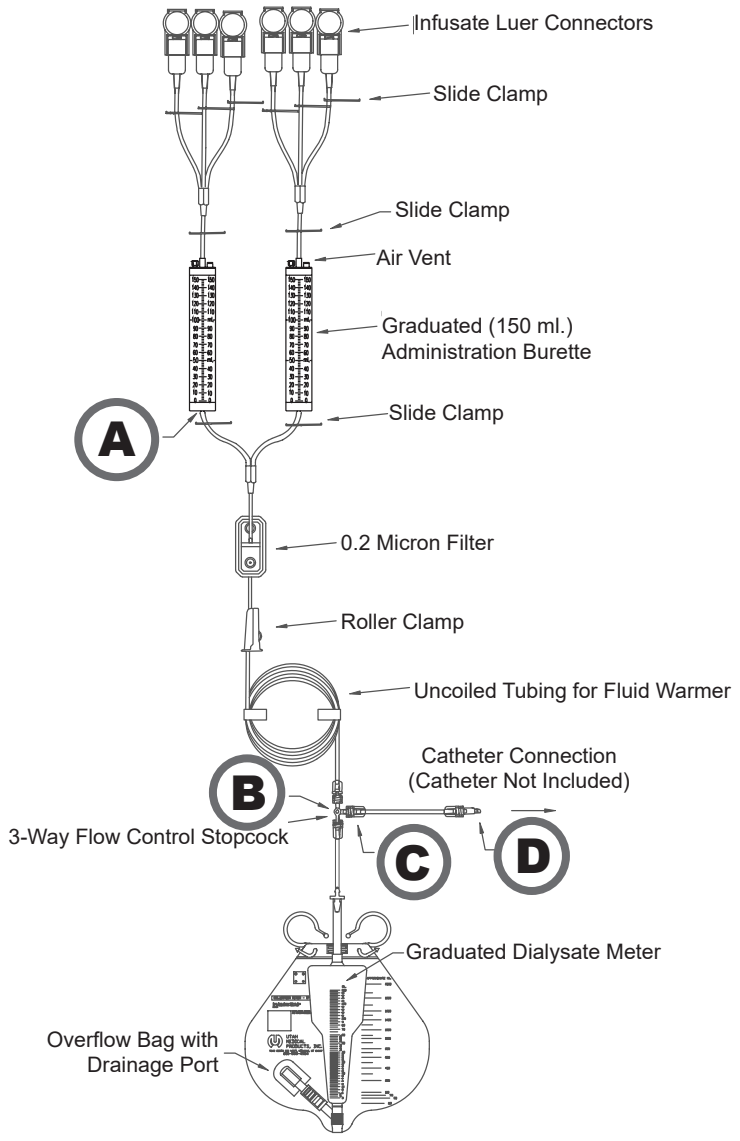
DIALY-NATE® WITH ADDITIONAL BURETTE ASSEMBLY

A Pediatric/Infant Disposable Peritoneal Dialysis Set



Priming Volumes	
A to B	22 ml
C to D	5 ml
Total	27 ml

REF **4000547**

Contents:

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

Outstanding Features

- Pre-assembled sterile system
- 2 Graduated 150 ml administration burettes with air vent
- 6 luer connectors for mixing infusate
- In-line bacterial retentive (0.2 micron) filter
- In-line 3-way flow control stopcock
- Finely graduated dialysate meter with over-flow bag

See Instructions on Back

UTAH MEDICAL PRODUCTS INC.

Manufacturer of:

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

A Company Sensitive to the Needs of the Neonatal Patient

Gesco®

Indications for Use

- The Dialy-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 preassembled administration set.
- **Do not attempt to disconnect connections.** Do not attempt to manually tighten stopcock luer connections.
- Do not overfill burettes, and keep burettes positioned to avoid wetting of the filters in the top of the burettes. Wetting of these filters 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.

Dialy-Nate® Instructions For Use

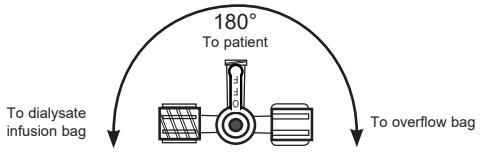
With patient properly catheterized, proceed as follows:

1. Always use aseptic technique when setting up, filling and connecting to indwelling catheter.
2. Hang the electrolyte bags above the patient so as to afford approximately a three foot head pressure.
3. Place / wrap the tubing between the 150ml burettes and three-way stopcock in blood / fluid warmer according to the warmer manufacturers' instructions**.**
4. Hang overflow / collection bag so that it is below the patient.
5. Clamp off lines as needed to prevent backflow.
6. Connect bags of selected electrolyte solution(s). Open clamp of bag(s) selected, as well as all other downstream clamps. Ensure that the 3-way stopcock is properly directed (handle toward the overflow bag) to permit the flushing and priming of the system to the patient.
7. Flush and prime the system.
8. 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.
9. Release pinch clamp(s) directly under the selected bag(s) and fill burette to the predetermined volume of fluid. Close off pinch clamp(s) to stop flow from bag(s) into the burette.
10. Turn stopcock handle toward collection bag. Open roller clamp and allow dialysate solution to infuse into the patient, carefully observing patient vital signs.
11. Once the predetermined volume has been infused, or earlier upon practitioner direction, close the roller clamp and turn the stopcock handle toward the patient.
12. After prescribed fluid dwell time, rotate stopcock handle toward dialysate source, allowing effluent from the patient to flow into the overflow bag.
13. Repeat steps 7 through 12, as directed by the attending physician.
14. Ensure that the administration set is changed every 24 hours to maximize infection control.

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
℞ 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

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.



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