

Navina Smart Product Information

Product description

Transanal Irrigation System with electronic control unit.

Shelf life and uses

All Navina Irrigation System components have a shelf life of 3.5 years, except the Navina Catheters and the Navina Cone, which have 2 years. When Navina components are packed in sets, the component with shortest shelf life determines the shelf life of the set.

Note that the Navina Smart Control Unit also has a "charge by date" set to 1.5 years from manufacturing date.

Navina catheters and cones are single use, the water container has 15 uses, the tube set has 100 uses, and the Navina Smart control unit 400 uses or two years from the date of the first use.

Material composition

Catheter Material: Styrene Ethylene Butylene Styrene (SEBS)/ Polypropylene (PP) with a hydrophilic Polyvinylpyrrolidone (PVP) coating.

Primary Package Material: PE/PET Pouch.

Secondary Package Material: Cardboard and corrugated cardboard.

Intended use

The Navina Systems is intended for Transanal Irrigation by instilling water up into the lower part of the colon through a rectal catheter.

Indications for use

The Navina Systems is indicated to help adults and children from 3 years who suffer from fecal incontinence, chronic constipation and/or time consuming bowel management. By instilling water up into the lower part of the colon, the peristaltic muscles in the bowel can be triggered and start to evacuate the content of the lower colon and rectum.

Contraindications

Do NOT use Navina Systems if you have one or more of the following:

- Known anal or colorectal stenosis.
- Active inflammatory bowel disease.
- Acute diverticulitis.
- Colorectal cancer.
- Ischemic colitis.
- You are within three months of anal or colorectal surgery.
- You are within 4 weeks of previous endoscopic polypectomy.

As the list may not be exhaustive, healthcare professionals will always consider individual user factors as well.



Navina Smart System

| Reference | Type | Specification |
|-----------|--------------------------------------|---|
| 69009 | Navina Smart System Regular | 1 Navina smart control unit |
| 69010 | Navina Smart System Small | 1 Power adapter |
| 69019 | Navina Smart System Cone | 1 Cable |
| | | 1 Water container |
| | | 1 Tube set |
| | | 2 Rectal catheters |
| | | 1 Navina case |
| | | 1 Accessory set |
| 69003 | Navina Consumable Set Regular | 1 Water container |
| 69004 | Navina Consumable Set Small | 15 Rectal catheters |
| 69016 | Navina Consumable Set Cone | |
| 68940 | Navina Catheter Set Regular | 10 Rectal catheters |
| 68943 | Navina Catheter Set Small | |
| 69011 | Navina Tube Set | 1 Catheter tube |
| | | 1 Water container tube |
| 6901200 | Navina Accessories | 2 Grip rings (1 vertical, 1 horizontal) |
| | | 1 Lanyard |
| | | 1 Positioning strap |
| | | 1 Navina Smart positioning clip |
| 69014 | Navina Smart Control Unit | 1 Navina smart control unit |
| | | 1 Power adapter |
| | | 1 Cable |
| 69015 | Navina Smart Power Adapter and Cable | 1 Power adapter |
| | | 1 Cable |

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