

## 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
69012	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

**Navina™** Smart

