

Dormia[®] Front

Nitinol hybrid grasper

Versatility gets smaller

Multifunctional Basket

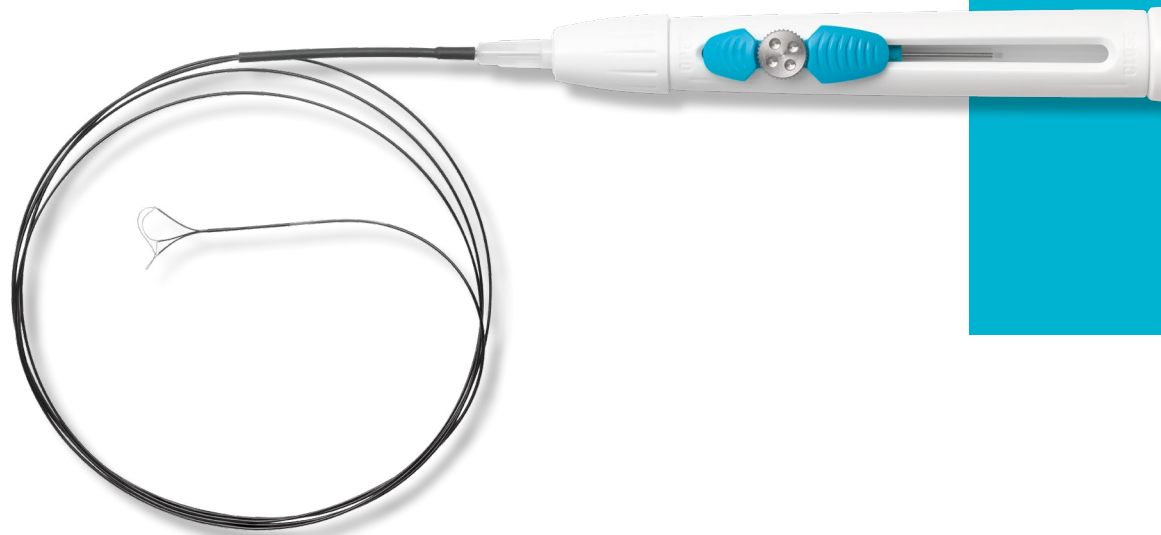
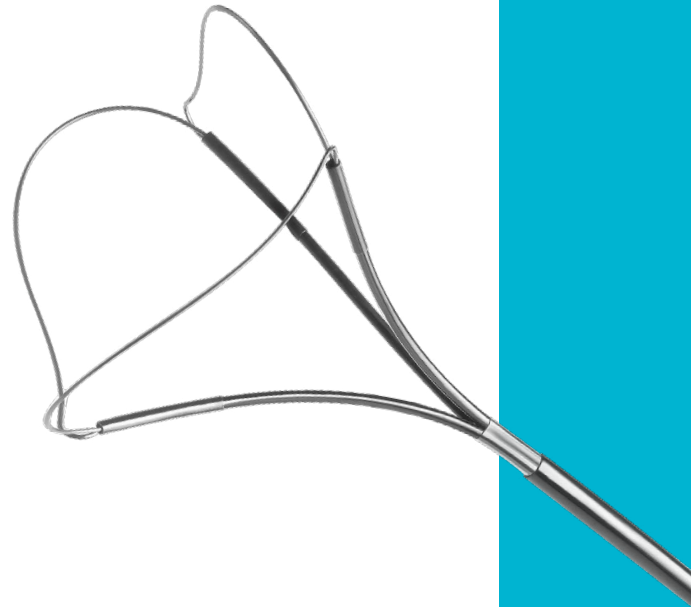
- Snare-like design permits capture, repositioning, and removal of stones as small as 1 mm
- Reinforced tip with shrink tubing made of polyester for durability
- Nitinol material has excellent kink-resistance and shape memory characteristics

Smooth Gliding Sheath with Small Diameter Option

- Polyamide sheath to facilitate glide and smoother movement. Two diameters: 1.5 and 2Ch/Fr
- 1.5 Fr diameter baskets are an effective option for use in the lower pole of the kidney because of their ability to increase irrigation, improve visualization, and extend scope deflection compared to larger diameter baskets
- 1.5 Fr Dormia[®] Front permits simultaneous placement of a 272 micron laser fiber within the working channel of the scope

Durable Construction Handle

- Allows the basket to be opened and closed multiple times during a procedure
- Engraved with open and close directions



Ordering Information

Coloplast Interventional Urology Service Support 800-258-3476

Dormia Front

Diameter	Length	Basket Size	Quantity	Product Code
1.5 Ch/Fr	120 cm	8 mm	1/box	DOF158
1.5 Ch/Fr	120 cm	11 mm	1/box	DOF151
2 Ch/Fr	120 cm	8 mm	1/box	DOF208
2 Ch/Fr	120 cm	11 mm	1/box	DOF201

DORMIA® FRONT STONE EXTRACTOR BRIEF STATEMENT

Indications: For stone removal during the course of rigid and flexible ureterorenoscopy, cystoscopy, endoscopic retrograde cholangioscopy (ERC), endoscopic retro- grade cholangiopancreatography (ERCP).

Intended Purpose: Stone retrieval devices serve for the endoscopic removal of stones and their fragments from the urogenital and gastroenterological tract during the course of retrograde interventions.

Contraindications: The contraindications of the above endoscopic interventions apply. The stone retrieval devices may not be used for Percutaneous Nephrolithotomy (PCNL). Stone retrieval devices may not be used for intravascular applications or other application areas, as sufficient clinical experience is lacking for this.

Warnings and Precautions: If used improperly, stone retrieval devices can cause the perforation of tissue, in particular if the stones are lodged on the vessel wall. The stone bed is then frequently very fragile. The use of contrast media can lead to adhesions that can limit the functionality of the stone retrieval device. Some stones may be too large to be removed with the stone retrieval device through the endoscope because the stone could get stuck in the working channel of the endoscope during removal. Therefore, always the complete system of endoscope and retrieval device shall be removed and the retrieval device shall be emptied outside the human body. Stone retrieval devices may not be used for mechanical stone crushing (lithotripsy). This type of device must be used only by trained and experienced professionals. Do not use the stone retrieval device if the stone is too large. If excessive force is used, there is a potential for vessel wall tear.

Potential Complications: The following complications are possible when using stone retrieval devices for stone removal:

- Entrapment of large stones
- Inability to disengage the dislodger from irretrievable stones requiring the application of other interventions
- Tissue perforation
- Breakage of the stone retrieval device
- Infection
- Non-retrievable stones

The risks and benefits of using Dormia® Front Stone Extractor should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings and precautions refer to the product's Instructions for Use.

Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

Complications from the use of this device should be brought to the attention of your Coloplast Representative and your physician.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.