

More freedom. More flexibility.



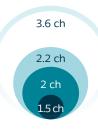


Dormia[®]

Coloplast's Dormia[®] **baskets are engineered for efficient stone retrieval, tailored to patient anatomy and scope longevity.** Dormia's smaller sizes offer superior irrigation and less scope strain compared to competitor's larger devices. Dormia represents innovation in materials, design, and support, providing the freedom to perform endourology your way.

A clear advantage

Larger instruments compromise space in the working channel resulting in less irrigation and lowered visibility. Dormia baskets start at sizes as small as 1.5 Fr, allowing for better visualization through improved irrigation.¹



Improved visibility with up to

Dormia 1.5 Fr

average degrees

····· Competitor 1.9 Fr | average 255°

····· Competitor 1.7 Fr | average 242°

of deflection²

more irrigation than competitors' larger baskets with Dormia 1.5 Fr²

The path of least resistance

Dormia baskets are made of flexible, no-kink nitinol, allowing for improved deflection,³ precision and efficient capture. Compared to competitors' larger baskets, the smaller size of Dormia[®] No-Tip 1.5 Fr makes it possible to deflect the ureteroscope further without forcing – accessing more places in the collecting system to remove stones with less ureteroscope stress.²

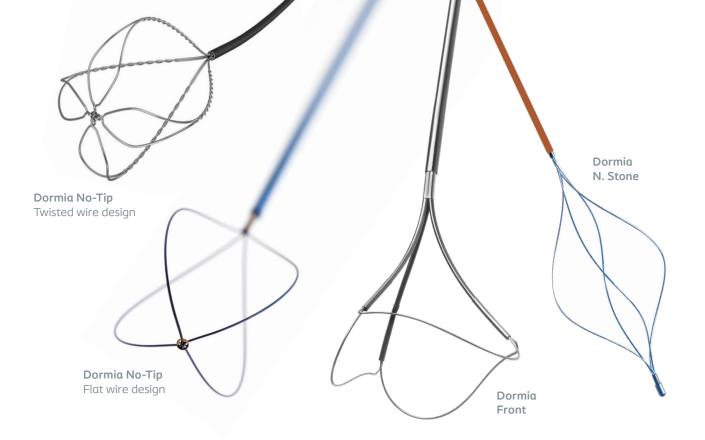
Easier on your scopes and your bottom line

In contrast to the estimated savings, the repair rate of scopes is 6.5%, and the average cost per repair is \$6,808. This could mean \$44,252 in scope repair costs every 100 cases.⁴



References:

- 1. Udo Nagele, Marcus Horstmann, Jörg Hennenlotter, Ute Walcher, Markus A. Kuczyk, Karl-Dietrich Sievert, Arnulf Stenzl, Aristotelis G. Anastasiadis (2006) Size does matter: 1.5 Fr. stone baskets almost double irrigation flow during flexible ureteroscopy compared to 1.9 Fr. stone. Urol Res (2006) 34:389–392 DOI 10.1007/s00240-006-0071-3 baskets.
- 2. Bench Test performed by Coloplast. Data on file with Coloplast.
- 3. Pasqui, Federico, Francis Dubosq, Kessile Tchala, Mohamed Tligui, Bernard Gattegno, Philippe Thibault, and Olivier Traxer. "Impact on active scope deflection and irrigation flow of all endoscopic working tools during flexible ureteroscopy." European urology 45, no. 1 (2004): 58-64.
- Rindorf, Dinah K., Thomas Tailly, Guido M. Kamphuis, Sara Larsen, Bhaskar K. Somani, Olivier Traxer, and Kevin Koo. "Repair rate and associated costs of reusable flexible ureteroscopes: A systematic review and meta-analysis." European Urology Open Science 37 (2022): 64-72.



Dormia® No Tip Stone Retrieval Devices

Quantity	Diameter (Ch/Fr)	Length (cm)	Basket Size (mm)	ltem
1 each	1.5	120	9	EXN934
	2.2	120	11	EXN734
	3	90	14	EXN434

Dormia[®] Front Nitinol Hybrid Grasper

Quantity	Diameter (Ch/Fr)	Length (cm)	Basket Size (mm)	ltem
1 each	1.5	120	8	DOF158
	1.5	120	11	DOF151
	2	120	8	DOF208
	2	120	11	DOF201

Dormia[®] N. Stone Retrieval Devices

Quantity	Diameter (Ch/Fr)	Length (cm)	Basket Size (mm)	ltem
1 each	2.5	90	12.5	EXT624
	3	90	15	EXT424
	4	90	15	EXT224

You know what's best for your patients, and how you deliver that care should be up to you.

Having the power to choose the right products for each procedure and patient is crucial to your success. Together, we're reshaping and redefining endourology care, leveraging new technologies and innovative materials that enhance the patient experience, increase efficiencies, and are designed to improve outcomes.

For more information visit iu.coloplast.us Coloplast Interventional Urology Surgical Support 800-258-3476

DORMIA[®] FRONT STONE EXTRACTOR BRIEF STATEMENT

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.

Indications

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

Contraindications

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

Warnings

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).

Precautions

This type of device must be used only by trained and experienced professionals. If excessive force is used, there is a potential for vessel wall tear. Do not use the stone retrieval device if the stone is too large.

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, and 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, precautions, and adverse events 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.com.

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

DORMIA® NO-TIP BRIEF STATEMENT

Indications

The Dormia[®] No-Tip nitinol stone extractor is an interventional endourological device used to remove stones and stone debris following lithotripsy, located in urinary tract, through percutaneous access or through retrograde natural access.

Contraindications

Contraindications to the medical device

- The device is not intended for use other than for endourological procedure.
- Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.
- The device contains nitinol materials. Do not use in case of patient's known allergy to device materials.

Contraindications to the endourological procedure

Untreated urinary tract infection.

- Uncontrolled haemostasis disorder.
- Malignant kidney or urinary tract tumor
- PerCutaneous NephroLithotomy (PCNL) procedure is not indicated in:
- Pregnancy unless exceptional situationBleeding disorders

Warnings & Precautions

This device must only be used by trained and experienced physicians. Do not use REF. EXN434 with a flexible endoscope.

Potential Complications

Adverse events involving patients have been reported, which may be related to the procedures used or problems occurring with the device (such as detachment of a part of the device, breakage, or inability to withdraw the basket), especially if the operating procedure and the warnings above are not observed, although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: Tissue trauma (mucosal abrasion, perforation), infection (e.g. urinary tract infection, pyelonephritis, severe infection...), pain, bleeding, haematuria, foreign object in body, device embedded in tissue, prolonged procedure and stone impaction.

Advice to Patients

Patients should be educated on the interventional procedure and be advised to inform the physician immediately if any abnormality or adverse event occurs (e.g., hematuria, infection, pain).

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DORMIA® N.STONE BRIEF STATEMENT

Indications

The Dormia[®] N.Stone[®] nitinol stone extractor is an interventional endourological device used to remove stones and stone debris following lithotripsy, located in urinary tract, through percutaneous access or through retrograde natural access.

Contraindications

Contraindications to the medical device

- The device is not intended for use other than for endourological procedure.
- Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.
- The device contains nitinol materials. Do not use in case of patient's known allergy to device materials.

Contraindications to the endourological procedure

- Untreated urinary tract infection.
- Uncontrolled haemostasis disorder.
- Malignant kidney or urinary tract tumor
- PerCutaneous NephroLithotomy (PCNL) procedure is not indicated in:
- Pregnancy unless exceptional situationBleeding disorders

Warnings & Precautions

This device must only be used by trained and experienced physicians. Do not use with a flexible endoscope.

Potential Complications

Adverse events involving patients have been reported, which may be related to the procedures used or problems occurring with the device (such as detachment of a part of the device, breakage, or inability to withdraw the basket), especially if the operating procedure and the warnings above are not observed, although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: Tissue trauma (mucosal abrasion, perforation), infection (e.g. urinary tract infection, pyelonephritis, severe infection...), pain, bleeding, haematuria, foreign object in body, device embedded in tissue, prolonged procedure and stone impaction.

Advice to Patients

Patients should be educated on the interventional procedure and advised to inform the physician immediately if any side effect occurs (e.g., blood in the urine, signs of infection).

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Ostomy Care | Continence Care | Wound and Skin Care | Interventional Urology | Voice and Respiratory Care

