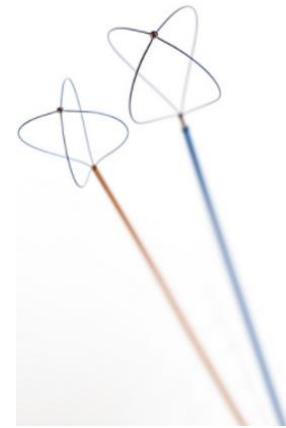


VAC INFORMATION FOR

Dormia[®] No-Tip 1.5 Stone Retrieval Device



PRODUCT OVERVIEW:

Essential devices for modern urinary stone treatments, the Dormia[®] No-Tip stone extractors are excellent for stone extraction during ureteroscopy within the upper urinary tract. The Dormia[®] No-Tip design allows for close contact with the stone for a direct capture with minimal trauma. The Nitinol material offers strong and flexible basket shape, maximizing shape retention and resisting basket assembling. All Dormia[®] No-Tip baskets feature an ergonomic and removable handle. Whether for use in the ureter or in the kidney, a Dormia[®] No-Tip stone extractor is designed for your stone retrieval needs.

Website:

<https://iu.coloplast.us>

[Dormia[®] No-Tip Stone Retrieval Devices - Coloplast](#)

Product Brochure

[Dormia Family Brochure](#)

KEY MESSAGES:

Flat Wire Basket

- Allows the basket to be positioned directly against the tissue with minimal trauma, reducing bleeding and maintaining a clear working channel
- Nitinol wire construction provides maximum shape retention
- Optimum control of the basket positioning with quality (1:1) torque

Sheath

- Flexible sheath allows continuous deflection of the scope during stone manipulation which can help improve access to the lower pole, where 37% of stones are located.¹
- Teflon coated sheath provides a smooth glide and easy passage through the scope
- Supplied with a Tuohy-borst to ensure waterproofness of endoscope, stone extractor and laser tool
- Teflon coated sheath reduces friction and provides smooth movements

Handle

- Removable, ergonomic, and single-handed use

Twisted Wire Basket

- Tipless basket for efficient capture and controlled release, with minimal risk of trauma
- Nitinol wire construction provides maximum shape retention
- Optimum control of the basket positioning with quality (1:1) torque

Size

- Dormia 1.5 is 12% smaller than a 1.7 basket. 28% of scope repairs are due to mechanical issues. Large instruments inside the scope can lead to more degradation.¹

1. Carey, R. et al. Frequency of Ureteroscope Damage seen at a tertiary care center. *Journal of Urology*. 2006; 176 (2). 607-610.

Is this product implantable? **No**
 Is this product disposable? **Yes**
 Does this product contain latex? **No**
 Does this product require sterilization? **No**

Model #'s/Catalog/ Vendor/Distributor Order #

Dormia No-Tip 1.5 Fr Ordering Information (To be used in the kidney and in the ureter, during flexible, semi-rigid, or rigid ureteroscopy)						
Item	Description	Diameter	Basket Size	Length	Sales UOM	EA/Sales UOM
EXN934	Dormia® No-Tip 1.5 Fr Retrieval Device	1.5 Fr	9 mm	120 cm	EA	1

COMPARABLE PRODUCT

Boston Scientific

Zero Tip™ Nitinol Retrieval Basket 1.9 Fr

The Coloplast 1.5 Dormia No-Tip Nitinol Basket has a smaller diameter than the Boston Scientific Zero Tip 1.9F Retrieval Basket. Smaller diameter baskets can increase the irrigation in the scope, thus increasing visibility during the procedure. Additionally, smaller diameter baskets can deflect with less resistance while in the scope, possibly reducing damage to the fragile inner lining of the flexible ureteroscope.

Boston Scientific Zero-Tip 1.9 Fr Ordering Information					
UPN/Order Code	Sheath Material	Fr	Length cm	Quantity	
M0063901040/390104	Polyimide/PTFE	1.9	90 (12mm OD)	Each	
M0063901050/390105	Polyimide/PTFE	1.9	120 (12mm OD)	Each	
M0063901000/390100	Polyimide/PTFE	2.4	90 (12mm OD)	Each	
M0063901010/390101	Polyimide/PTFE	2.4	120 (12mm OD)	Each	
M0063901020/390102	Polyimide/PTFE	3.0	90 (16mm OD)	Each	
M0063901030/390103	Polyimide/PTFE	3.0	120 (16mm OD)	Each	

Dornier-Eclipse™

Eclipse™ Nitinol Zero Tip Retrieval Basket Tipless Ordering Information			
Item	French	Length (cm)	EA/Sale UOM
BEZ15120	1.5	120	1

Eclipse™ Nitinol Tipless Stone Extractor Ordering Information

Item	French	Length (cm)	EA/Sale UOM
G46206	1.5	115	1

REGULATORY:

Class II

FDA Product Code FFL - Dislodger, Stone, Basket, Ureteral, Metal

Regulation # 21CFR 876.4680

FDA Registration Number - Device is 510(k) Exempt. Earlier versions had original 510(k) Clearance under K900269. Clearance Letter and 510(k) Summary is no longer available on the FDA website.

EUA (Emergency Use Approval) N/A

What type of procedure will this product be used in? Stone retrieval procedures for use in the kidney and in the ureter, during flexible, semi rigid or rigid ureteroscopy.

FDA Indications for Use

Extraction of urinary tract calculi

FDA Contraindications

- Any conditions contraindicating the use of a stone extractor
- Any known allergies to the medical device materials
- Extraction of biliary duct calculi

IFU SUMMARY:

Dormia IFU's

CLINICAL SUMMARY

Size Does Matter. 1.5 Stone Double Irrigation:

- Vision is limited by the amount of irrigation flowing through the working channel of a ureteroscope. Irrigation flow improves with smaller diameter baskets.
- The studied 1.5 Fr. basket showed a significant improvement in flow rate in all degrees of deflection, even compared to one of the smallest available nitinol baskets in 1.9 Fr. In the 0° position there was a difference of up to 8.50 ml/min compared to baskets with 1.9 Fr and in the 180° a difference of 6.00 ml/min representing an improvement of irrigation flow of 68.0% and 42.9% respectively.
- The smaller the stone basket the higher the irrigation and therefore the greater the visibility. The authors recommend that a small basket be used to have optimal visibility and improve therapeutic efficiency of flexible ureteroscopy.

Scope Deflection and Irrigation Flow on Larger Diameter Instruments

- Larger caliber instruments result in more scope deflection degradation than smaller ones. Nitinol tools affect scope deflection less than instruments constructed of alternative materials.
- Irrigation flow is inversely proportional to the diameter of the tool inserted. The larger diameter of the instrument the less irrigation flow.
- Larger caliber instruments (usually over 3 Fr) results in almost zero irrigation flow in a ureteroscope working channel. This is true even when pressure of the irrigation flow is increased.
- Coloplast offers small, 1.5 Fr no-tip baskets which are among the smallest diameter urology baskets on the market.

Describe how this product will meet clinical needs.

Reduces Procedure time? **No**

Reduces infection rates? **No**

Reduces In-patient duration? **No**

Reduces patient mortality? **No**

How does this product improve patient outcomes?

Dormia No-Tip Nitinol Retrieval Basket 1.5 Fr reduces the potential for increased intrarenal pressure, due to small diameter of the device in the working channel of the endoscope. small diameter of the device in the working channel of the endoscope.

It improves irrigation compared to larger size baskets which may enable improved visibility for ureteroscopy and stone procedure.

Add clinical studies to consider (attachments to form)

Scope deflection and irrigation flow on larger diameter instrument

Size does matter 1.5 Fr stone double irrigation

Reimbursement—See 2023 Reimbursement guide saved in VAC folder for the following:

Click this link for CPT, DRG, APC, HCPCS

[2023 Coding and Payment Reference](#)

FINANCIAL ANALYSIS

Proposed VAC pricing can mirror what we would present in a trial agreement to the customer

- Attach Product Catalog and 2023 Interventional Urology Commercial List Price

[Pricing 2023](#)

[Product Catalog 2023](#)

Is the requested product available for consignment? If yes, provide details. —

Yes, consignment may be set up through mutually agreed upon terms

Additional Notes on Pricing-Per National Accounts team, it would be appropriate to include additional tier pricing or any additional incentives that may be included.

ADDITIONAL INFORMATION

[W9 2022](#)

Supply Chain Info:

Dormia® No-Tip Stone Retrieval Devices							
Item	Description	Diameter	Basket Size	Length	Sales UOM	EA/Sales UOM	GTIN
EXN934	Dormia® No-Tip	1.5 Fr	9 mm	120 cm	EA	1	03600040268599