

Dormia® 1.5Fr Nitinol Stone Retrieval Basket Deflection and Irrigation:

Evaluation of Coloplast, Boston Scientific, Olympus and Cook Stone Retrieval Baskets effect on Flexible Ureteroscopes.

ABSTRACT

The aim of this study was to evaluate the performance of stone retrieval basket interaction within the flexible ureteroscope. Testing was conducted on the interaction between the baskets' sheath and the irrigation flow within the working channel of the ureteroscope. Greater irrigation and flow allows for increased visibility during procedural use of the flexible ureteroscope and baskets. Testing was also conducted to determine the amount of deflection lost by placing the basket within the working channel of a ureteroscope.

The Dormia Front device is a hybrid design between a grasper and a stone basket; with this design, the user can capture, and release stones head on like a grasper and hold them like a basket. The device contains a three-arm hybrid basket head which is designed to capture stones in a frontal approach. The end-engaging basket design allows for head on stone capture. The handle is designed to be used with one hand.

The Dormia No Tip device is a tipless stone basket; The device is a four-wire basket with a flower design at the distal portion of the basket, designed for effective capture and retrieval of stones in the kidney. The tipless design allows for direct contact with tissue while providing minimal trauma and reduced bleeding. The handle is designed to be used with one hand.

The results of the deflection evaluation show that the 1.5 Fr Dormia Front and the 1.5 Fr Dormia No Tip device allowed a larger deflection angle, both with handle up and handle down than the Boston Scientific Zero Tip™* and Dakota™*, Olympus UltraCatch™* and Cook NGage™*.

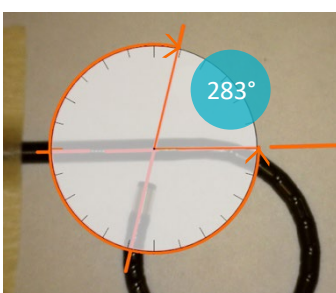
The results of the irrigation and flow evaluation show that the 1.5 Fr Dormia Front and the 1.5 Fr Dormia No Tip device allowed a substantially larger ($p < .05$) flow rate through the flexible ureteroscope than the Boston Scientific Zero Tip™* and Dakota™*, Olympus UltraCatch™* and Cook NGage™*.

DEFLECTION BENCH TEST

The purpose of this test was to show that the 1.5 Fr Dormia baskets provide a larger deflection angle through the working channel of a Flex Xc ureteroscope than larger diameter devices, which in turn allows better access into the lower pole.

Test Method Summary:

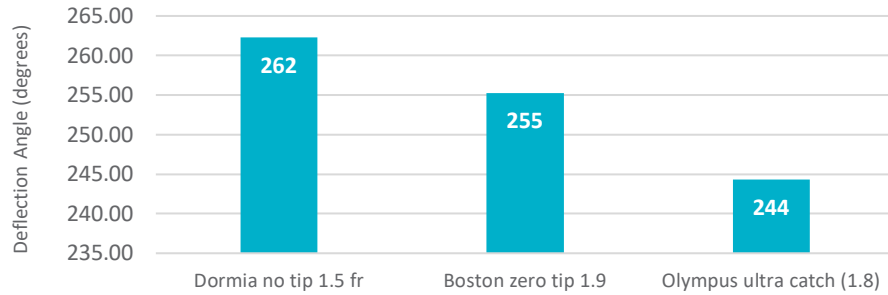
The basket was inserted into the working channel of a Flex Xc Ureteroscope until 1 cm extended out of the channel. The up and down deflection angles were recorded for 15 trials, and the process was repeated for each competing product. The angle was measured between the straight shaft and the deflected tip. The deflection angles for up and down of each basket were averaged.



No-Tip Basket Comparisons:

- The Dormia No Tip 1.5 Fr tipless basket permitted an average of 1-3% more ureteroscope deflection compared to the Boston Scientific Zero Tip™* 1.9 Fr tipless basket.
- The Dormia No Tip 1.5 Fr tipless basket permitted an average of 5-8% more ureteroscope deflection compared to the Olympus UltraCatch™* 1.8 Fr tipless basket.

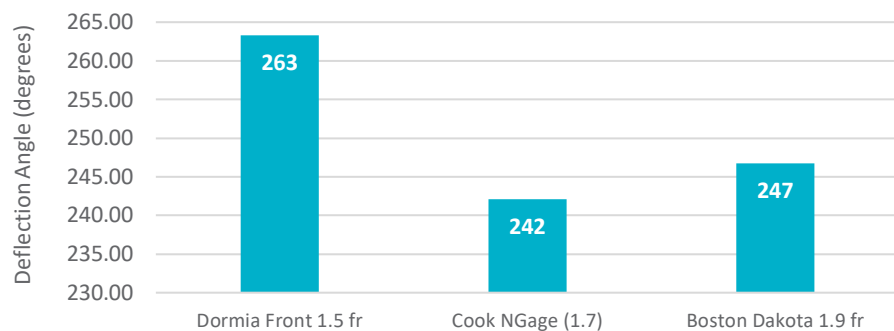
NO TIP BASKET DEFLECTION COMPARISON



Front Style Basket Comparisons:

- The Dormia Front 1.5 Fr frontal basket permitted an average of 6-9% more ureteroscope deflection compared to the Cook Ngage™* 1.7 Fr frontal basket.
- The Dormia Front 1.5 Fr frontal basket permitted an average of 5-7% more ureteroscope deflection compared to the Boston Scientific Dakota™* 1.9 Fr frontal basket.

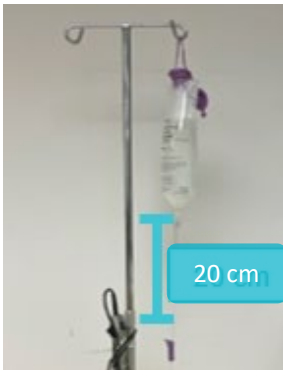
SMALLEST FRONTAL BASKET DEFLECTION COMPARISON



IRRIGATION/FLOW BENCH TEST

The purpose of this test was to show that the 1.5 Fr Dormia baskets provide for a larger flow rate through the working channel of a Flex Xc ureteroscope than larger diameter devices, which in turn allows for enhanced visibility.

[Size-does-matter-1.5-Fr-Stone-Baskets-Almost-Double-Irrigation-Flow-During-Flexible-Ureteroscopy.pdf \(iu.coloplast.us\)](#)



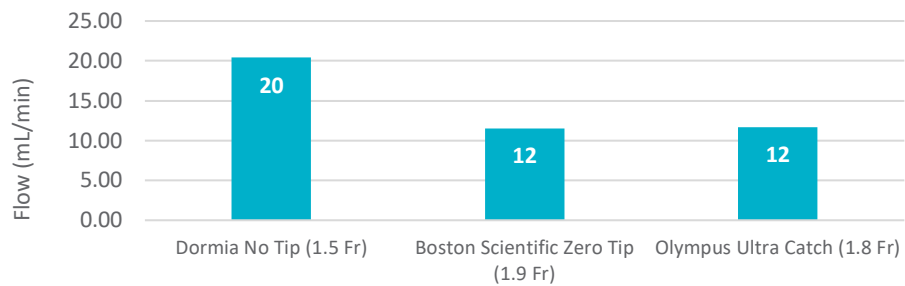
TEST METHOD SUMMARY:

The ureteroscope was held vertically in place and the basket was inserted through the working channel of a Flex Xc Ureteroscope until 1 cm was extended out of the channel. An IV bag filled with 1.2 litres of water was held 20 cm above the luer of the ureteroscope and connected to the irrigation channel of the scope via a luer. A container was placed below the working channel to catch the water that flowed through the scope channel. A 1-minute flow measurement was performed and repeated a total of 15 times for each basket.

NO-TIP BASKET COMPARISONS:

- The Dormia No Tip 1.5 Fr tipless basket permitted an average of 43% greater irrigation flow compared to the Boston Scientific Zero Tip™* 1.9 Fr tipless basket.
- The Dormia No Tip 1.5 Fr tipless basket permitted an average of 42% greater irrigation flow compared to the Olympus UltraCatch™* 1.8 Fr tipless basket.

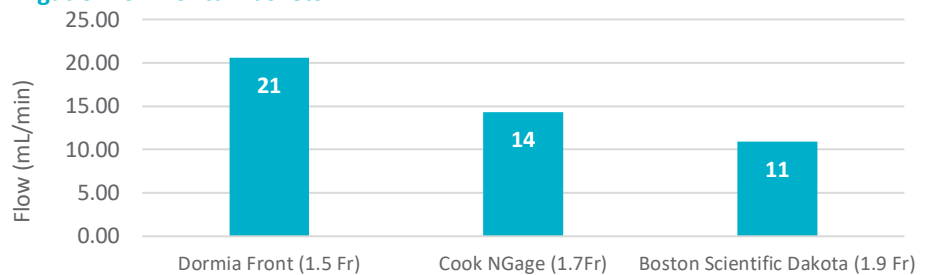
Irrigation for No Tip Baskets



FRONT STYLE BASKET COMPARISONS:

- The Dormia Front 1.5 Fr frontal basket permitted an average of 30% greater irrigation flow compared to the Cook Ngage™* 1.7 Fr frontal basket.
- The Dormia Front 1.5 Fr frontal basket permitted an average of 47% greater irrigation flow compared to the Boston Scientific Dakota™* 1.9 Fr frontal basket.

Irrigation for Frontal Baskets



DORMIA® NO-TIP BRIEF STATEMENT

Indications

Extraction of urinary tract calculi.

Contraindications

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

Warnings and Precautions

This type of instrument must only be used by trained and experienced professionals.

Adverse Events

Lesions of the urinary tract if the operating procedure and the warnings set out below are not observed. The risks and benefits of using Dormia® No-Tip 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.com.

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

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.com.

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

Based on bench test data. May not be indicative of clinical performance. Performance may vary.

TM* Third party brands are property of their respective owners.