

Evaluation of the Capture Rate on the new BARD[®] DIMENSION[®] Articulating Stone Basket/Grasper and the Cook N-Circle[™] Stone Basket

INTRODUCTION AND OBJECTIVE:

To evaluate the capture rate of the new patented DIMENSION[®] Articulating Stone Basket/Grasper in comparison to Cook's N-Circle[™] basket.

METHOD:

Capture rate is defined as not only the ability to capture the stone but also, the ability to hold on to it while the basket is being closed for removal. Four (4) samples of the new DIMENSION[®] basket (Part Number 043310, Lot Number 4290) and four (4) samples of Cook's N-Circle[™] basket (Part Number NTSE-030115, Lot # 915775) were used to determine the capture rate for each type of basket. Multiple technicians performed the testing to reduce technician bias. Following is a synopsis of the protocol.

A steel bead was placed in a test fixture for retrieval. Testing was performed on 1mm, 1.5mm, 2.0mm, 2.5mm and 3.0mm steel beads. The technician positioned the basket on the test fixture, opened it and attempted to capture the bead. If unsuccessful, capture was attempted up to two additional times before it was considered a failure. Once captured, the next step was to determine whether the bead would remain captured during the normal closing process of the basket. To facilitate this function, after the bead was captured, the basket was closed using a 1 pound pull force standardizing the closing function to reduce technician to technician variation. If the test failed (the bead failed to remain captured), it was again repeated up to three times. The DIMENSION[®] and N-Circle[™] baskets were then tested in an alternating fashion to prevent experience gained from one type of basket from affecting the results of the other. Pass was defined as the ability to capture and retain the bead in three attempts or less; fail was defined as the inability to capture and retain the bead within three attempts. Good laboratory practices were used during the testing. Results were recorded on laboratory data sheets for future analysis.

RESULTS:

The following charts summarize the capture rate using multiple technicians and multiple baskets.

1mm Bead

	First Attempt Success Rate	Up to 3 Attempts Success Rate
DIMENSION [®] basket	100%	N/A
N-Circle [™] basket	23.1%	23.1%

1.5mm Bead

	First Attempt Success Rate	Up to 3 Attempts Success Rate
DIMENSION [®] basket	100%	N/A
N-Circle [™] basket	7.7%	25.1%

RESULTS (CON'T):

2.0mm Bead

	First Attempt Success Rate	Up to 3 Attempts Success Rate
DIMENSION® basket	100%	N/A
N-Circle™ basket	7.7%	7.7%

2.5mm Bead

	First Attempt Success Rate	Up to 3 Attempts Success Rate
DIMENSION® basket	92.3%	92.3%
N-Circle™ basket	7.7%	16.0%

3.0mm Bead

	First Attempt Success Rate	Up to 3 Attempts Success Rate
DIMENSION® basket	100%	N/A
N-Circle™ basket	30.8%	54.4%

Average Success Rate Across all Bead Sizes

	First Attempt Success Rate	Up to 3 Attempts Success Rate
DIMENSION® basket	98.5%	98.5%
N-Circle™ basket	15.4%	25.3%

CONCLUSION:

The testing shows that the DIMENSION® basket performs better than the N-Circle basket in capturing and retaining a range of simulated stone and fragment sizes.

The BARD® DIMENSION® Stone Basket is a teardrop-shaped basket with the ability to capture stones by: 1) simply opening and closing the basket and 2) articulating or moving the basket side to side. The device consists of 3 main parts: handle, shaft and basket.

Indications for Use:

This device is intended for use in the endoscopic removal of renal and ureteral stones.

Warnings:

- Some objects may be too large to be removed endoscopically using a retrieval device. The use of fluoroscopy and/or x-ray to determine the size of the object is recommended; do not use the BARD® DIMENSION® Stone Basket if the object is too large to be removed endoscopically.
- After use this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and applicable laws and regulations.

Caution:

Objects that are too large to be recovered through the sheath or through the scope channel will require the scope and basket to be removed simultaneously from the urinary tract. If resistance is encountered during advancement or withdrawal of the device, stop and determine the source of resistance, as continued resistance may damage the device and could result in patient injury. Take action to alleviate the resistance. Where necessary, use of a lithotripter may be required to reduce the stone burden within the basket, provided that no direct contact is made with the stone basket.

Precautions:

Do not allow the device to come in contact with any electrified instrument. Do not allow the device to be directly fired upon by any lithotripsy device. To do so may damage the device and could result in patient injury. Potential complications that may result from the use of a basket in an endoscopic urological procedure include, but are not limited to:

- Perforation • Evulsion • Edema • Entrapment
- Basket Inversion • Hemorrhage • Inability to disengage from irretrievable object

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