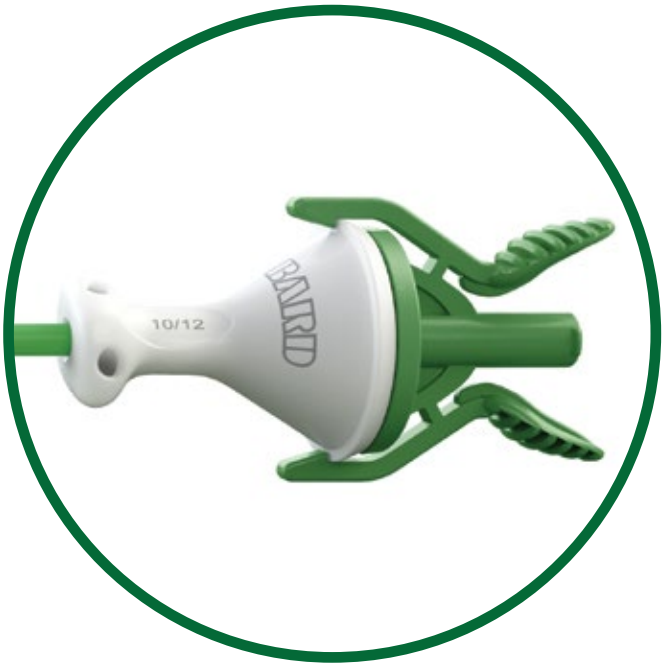
BARD | ENDOUROLOGY

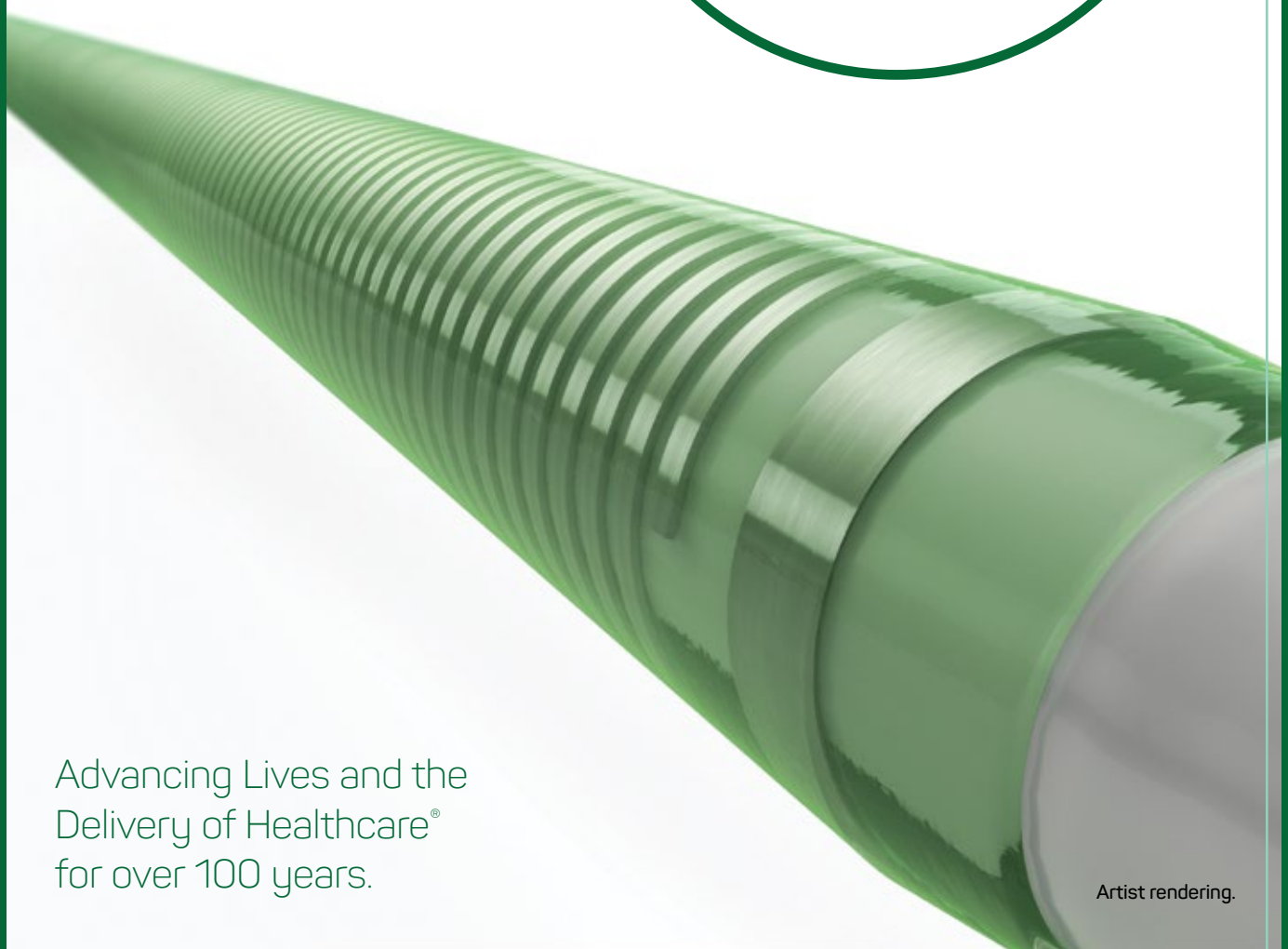
Proxis™

URETERAL ACCESS SHEATH

ACCESS SHEATH



Get closer.



Advancing Lives and the Delivery of Healthcare® for over 100 years.

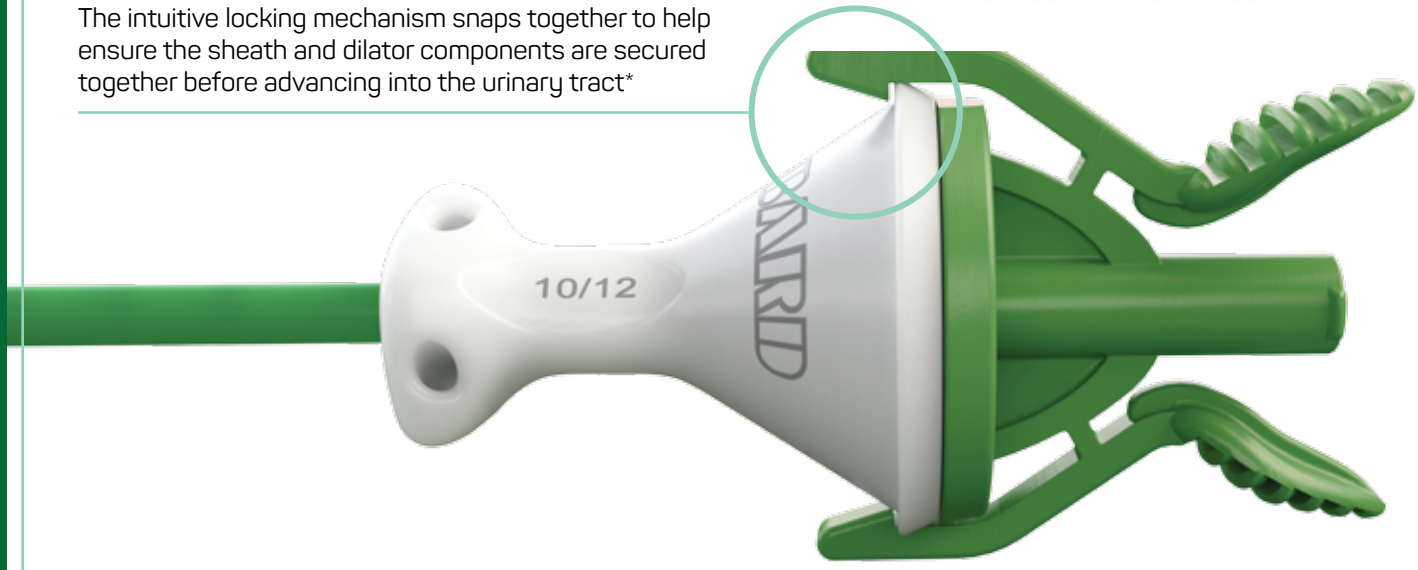
Artist rendering.

ACCESS SHEATH

Hydrophilic coating designed to help ease insertion*

A smooth dilator-sheath transition is achieved by increasing the diameter of the dilator near the end of the sheath to help minimize the space between components*

The intuitive locking mechanism snaps together to help ensure the sheath and dilator components are secured together before advancing into the urinary tract*



Item Number	Outer Dilator/Sheath Diameter (Fr)	Length (cm)
231025	**10/12**	**25**
231035	10/12	35
231045	10/12	45
231225	12/14	25
231235	12/14	35
231245	12/14	45

*Data on file: preclinical testing may not correlate to outcomes in humans.

PLEASE CONSULT PRODUCT LABELS AND PACKAGE INSERTS FOR INDICATIONS, CONTRAINDICATIONS, HAZARDS, WARNINGS, CAUTIONS AND INSTRUCTIONS FOR USE.

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Indications for Use:
The Proxis™ ureteral access sheath is indicated for use in endoscopic urology procedures where ureteral dilation and ureteral access is desired for injection of fluids and insertion and removal of endoscopes and related instruments.

Contraindications:
Patients who are contraindicated for retrograde urological procedures

- Patients who are contraindicated for antegrade urologic procedures, including but not limited to patients with blood clotting anomalies due to coagulopathies or pharmacological anticoagulations
- Patients who have the presence of tight strictures which would limit the use of the device
- Patients who have the presence of large obstructing distal ureteral calculi

Warning:
For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transition of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Do not use if barrier is damaged. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and with applicable laws and regulations.

CAUTION: Federal (U.S.A.) Law restricts this device sales by or on the order of a physician.

Precautions:
The recommendations given are meant to serve only as a basic guide to the utilization of this access sheath. The ureteral access sheath should not be used without comprehensive knowledge of the indications, techniques, and risks of the procedure.

To minimize resistance during advancement, ensure the hydrophilic coating on the dilator and sheath is activated with saline or sterile water prior to placement. Do not advance sheath without the dilator in place as this could lead to trauma or injury to patient. Do not bend the device prior to placement as this could damage the integrity of the device and result in patient injury. Do not advance or withdraw device if any resistance is encountered during placement or removal without determining cause and taking action.

Adverse Events
Potential adverse events associated with the use of the transurethral access device include, but are not limited to:

- Mucosal irritation, inflammation and edema
- Urethral strictures
- Acute bleeding or hemorrhage
- Urethral, bladder, or ureteral perforation
- Other injury to the urinary tract

AUSTRIA Bard Medica SA, MGC-Top Nr. D36, 3.OG Ebene, Modecenterstraße 22, A-1030 Wien, Austria. Tel: +43 14 949130. Fax: +43 14 94913030.
BENELUX Bard Benelux n.v., Hagelberg 2, 2250 Olen, Belgium. Tel: +32 14 286950. Fax: +32 14 286955.
CZECH REPUBLIC Bard Czech Republic s.r.o., Taborska 619, 140 00 Prague, Czech Republic. Tel: +420 242 408630. Fax: +420 242 410 185.
FRANCE Bard France SAS, Av. Joseph Kessel 164-166, Parkile P14, 78960 Voisins-le-Bretonneux, France. Tel: +33 1 39305858. Fax: +33 1 39305859.
GERMANY C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Germany. Tel: +49 721 94450. Fax: +49 721 9445111.
GREECE Bard Hellas SA, 1 Filellinon Str. & Megalou Alexandrou, 16452, Argyroupoli, Greece. Tel: +30 210 9690770. Fax: +30 210 9628810.
ITALY Bard srl., Via Cina 444, 00144 Roma, Italy. Tel: +39 06 524931. Fax: +39 06 5295852.
NETHERLANDS C. R. Bard Netherlands Sales B.V., Lorentzlaan 4, 3401 MX IJsselstein, The Netherlands. Tel: +31 (0)88 01 22 500. Fax: +31 (0)88 01 22 501.
NORDIC Bard Norden AB, Rönnowsgatan 10, 252 25 Helsingborg, Sweden. Tel: +46 42 386000. Fax: +46 42 386010.
POLAND Bard Poland sp. z o.o., ul. Cybernetyki 9, 02-677 Warszawa, Poland, Tel: +48 22 3210930. Fax: +48 22 3210938.
RUSSIA Bard Russia LLC, Gorbunova st, bl 2/204, Business Center Grand Setun Plaza, 5th floor, office A 511, Russia, Tel: +7 499 372 50 02. Fax: +7 499 372 50 03.
SAUDI ARABIA CR BARD Gmbh, Bahrain Tower, 2nd Flr. King Fahad Road, P.O Box 8953, Riyadh 12214-2393, T: +971 4 314 0900. F: +971 4 359 8980.
SOUTH AFRICA Bard Medical SA (Pty) Ltd. Building 13 Emerald Boulevard Greenstone Hill 1645 South Africa Office: +27 (0) 86 102 BARD (2273). Fax: +27 (0) 86 537 7250.
SPAIN Bard de Espana S.A.U., Plaza Europa 41-43, 5a Planta, (Torre Realia), 08908 L'Hospitalet de Llobregat, Barcelona, Spain. Tel: +34 93 2537800. Fax: +34 93 205 82 00.
SWITZERLAND Bard Medica SA, Seestrasse 64, 8942 Oberrieden/Zürich, Switzerland. Tel: +41 44 7225360. Fax: +41 44 7225370.
UAE C. R. Bard GmbH (Dubai Branch), 12th Flr. Unit 1204 Conrad Offices Bldg, Sheikh Zayed, PO Box 413043 Dubai, UAE. Tel: +971 4 314 0900. Fax: +971 4 359 8980.
UK Bard Limited, Forest House, Tilgate Forest Business Park, Brighton Road, Crawley, West Sussex RH11 9BP, UK. Tel: +44 1293 52955. Fax: +44 1293 552428.