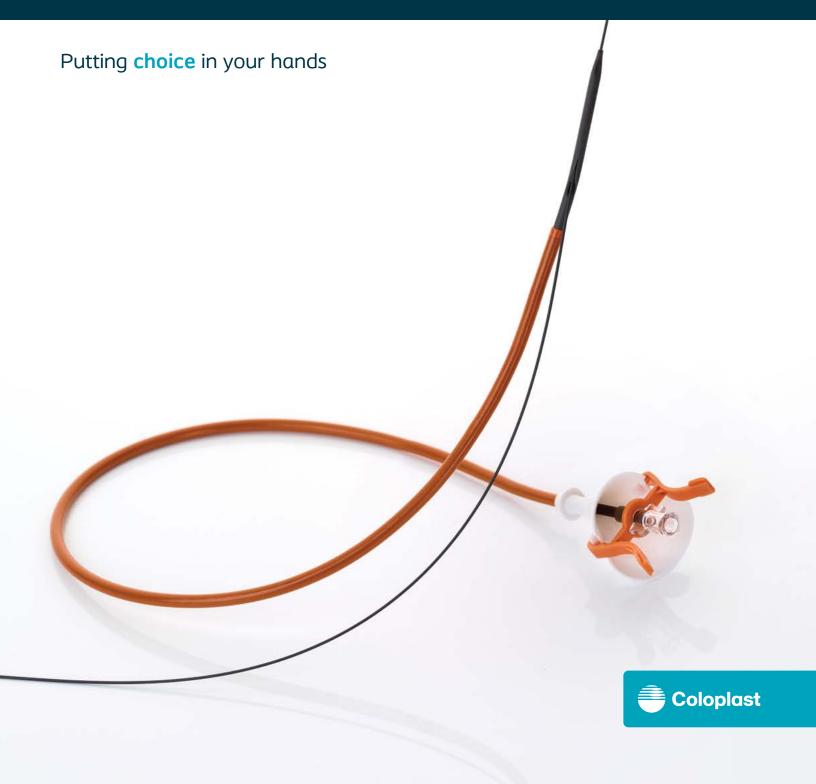
Ready, Set, ReTrace.



Putting choice in your hands

Unlimited access

ReTrace ensures usability in both traditional and single wire methods with ease

- ReTrace secures access in one simple, repeatable step
- · Positioning and placement are easy with radiopaque introducer and ring
- A white proximal funnel allows visualization of urine and irrigation colors
- Reinforced structure ensures high kink resistance
- Perform a retrograde pyelogram with or without a guidewire in place



While traditional UAS resulted in a time savings of 10.5 minutes and \$350 in OR costs,¹

using ReTrace can increase the savings by \$100 in OR time and additional product costs²⁻⁵



Unique design converts working guidewire into safety guidewire

Secure savings

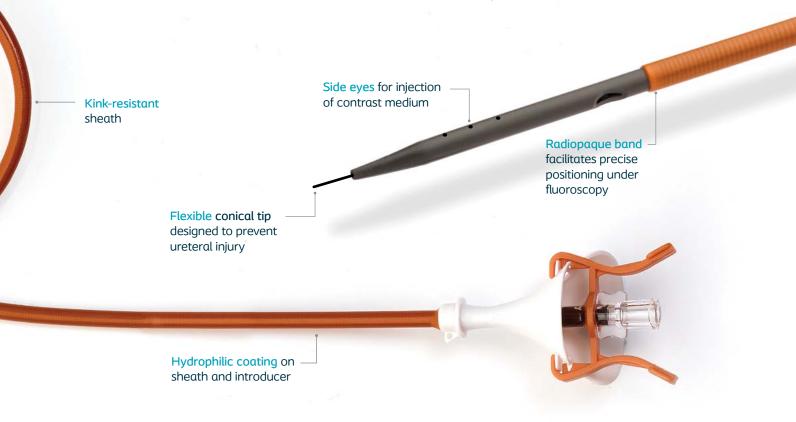
With ReTrace, your procedure requires less tools and less time

- The single wire insertion technique of ReTrace eliminates the need for a dual lumen catheter and a second wire
- ReTrace single wire placement minimizes the time and steps to perform the procedure compared to a standard access sheath

Complete comfort

ReTrace is designed to respect your patient's anatomy and prevent injury

- Innovated to be more flexible than other access sheaths
- A flexible tip design was created to negotiate difficult portions of the ureter
- Hydrophilic coating facilitates placement in the procedure



Endourology your way_

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

Ordering Information

Coloplast Interventional Urology Service Support: **800-258-3476**

This product may be ordered directly from Coloplast.

ReTrace®	Diameter (Fr)	Length (cm)
ASXL10	10-12	28
ACXL10	10-12	35
AXXL10	10-12	45
ALXL10	10-12	55
ASXL12	12-14	28
ACXL12	12-14	35
AXXL12	12-14	45
ALXL12	12-14	55

ReTrace® Ureteral Access Sheath Brief Statement

Indications

To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

Contraindications

All usual contraindications to retrograde or antegrade urological procedures, including but not limited to untreated urinary tract infection and uncorrected coagulation disorders (in case of antegrade access).

Possible limiting factors such as ureteral stricture, ureteral kinking, abnormality of the urinary tract anatomy or presence of large obstructing ureteral calculi must be considered before deciding to use a UAS.

The safety of some urologic procedures should be evaluated in pregnant women.

Do not use, when in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

Warnings & Precautions

This device must only be used by trained and experienced physicians.

Potential Complications

The following events have been reported although their occurrence greatly depends on patients' medical conditions. These events are either related to the use of UAS or to the urologic procedure. Adverse events include but

are not limited to: Bleeding (e.g., hematuria, hemorrhage), urinary tract injuries (e.g., mucosal injury/ tissue lesion, ureteral perforation...), infection (e.g., urinary tract infection, pyelonephritis, severe infection...), and foreign object in body.

Few cases of inadvertent disengagement of the guidewire during sheath insertion leading to prolonged procedure and urinary tract injury have also been reported. Other potential side effects that may be associated with the use of UAS are ureteral avulsion and ureteral stricture.

Advice to Patients

The physician should educate the patient on his/her urology procedure. The patient should be advised to immediately contact the attending physician if any side effect occurs.

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.

PM-15964, June 2024

References

- 1. Kourambas J, Byrne RR, Preminger GM. Does a ureteral access sheath facilitate ureteroscopy? J Urol. 2001 Mar;165(3):789-93. PMID: 11176469.
- 2. Childers, C., Maggard-Gibbons, M. Understanding costs of care in the operating room. JAMA surgery 2018; Vol. 153;4.
- 3. Tsianos, Georgios-Ioannis, Dahlerup, Benedicte, Golińska, Agnieszka, Vassiliadis, Efstathios. Efficiency and Safety in Operating Rooms: Current Limitations and Future Directions Journal of Advanced Research in Medical Science & Technology Volume 6, Issue 18.2 2019, Pg. No. 1-6 DOI: https://doi.org/10.24321/2394.6539.201901.
- 4. Data on File Competitive Pricing Data Compiled from ECRI.
- 5. Thomas A., Alqahtani S., Behr D., Traxer O. Ureteral Access Sheath New Insertion Concept. Eur Urol Suppl 2011;10(2)97.

