Clinical Article Summary

First clinical evaluation of a new innovative ureteral access sheath (Re-Trace®): a European study

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Abstract

The use of a ureteral access sheath (UAS) during flexible retrograde intrarenal surgery (RIRS) has become increasingly popular. Our aim was to evaluate the accessibility of a new UAS device, allowing the transformation of the working guidewire into a safety guidewire.

Methods: A prospective, multicenter study was conducted between January and February 2010 in six European tertiary reference centers. Patients needing flexible RIRS were eligible to participate in the study. In all cases, insertion of the Re-Trace (12/14Fr, Coloplast, Denmark) was attempted at the beginning of the procedure. Insertion success was defined as placement of the UAS in the lumbar ureter with successful disengagement of the working guidewire, which turned into a safety guidewire. Influence of gender and pre-stenting status was analyzed by univariate analysis.

Results: 137 UASs were used in 75 male and 62 female patients. 25.5 % of ureters were pre-stented: men were 2.17 more often pre-stented than women. The overall Re-Trace insertion rate was 82.5 %. Success rate was not significantly different between men and women (77.3 vs. 88.7 %, respectively, p = 0.11). Pre-stenting status did not significantly influence the success rate (p = 0.31). When analyzing the combined influence of pre-stenting status and gender, the worst success rates seemed to be obtained in men without pre-stenting, but no significant differences were found between groups.

Conclusions: Re-Trace UAS showed good overall insertion rates. This evaluation validated the new concept of guidewire disengagement: A single wire automatically switches from working to safety role.

World J Urol
(2014) 32:143–147

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Coloplast Key Takeaways

- The overall successful insertion rate of the Re-Trace® ureteral access sheath derived from this prospective multicenter study of 137 patients was 82.5%.
- 74.4% of the patients in this study (N=102 of 137) were not pre-stented. There was not a significant difference in the successful insertion rate of Re-Trace between pre-stented and not pre-stented patients.
- Internal piece removal to convert the working wire into a safety wire was possible in all successfully placed Re-Trace ureteral access sheaths.
- One can avoid the use of a dual lumen catheter and a second guidewire when using a Re-Trace ureteral access sheath because of the sheath's ability to convert a working wire into a safety wire.
- Its capability to inject contrast through its main channel.

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 ureteroscopic procedures. Any known allergies to the medical device materials. The evaluation of the allergic background of a patient is the health care professional's responsibility.

Warnings and Precautions

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

Advice to the Patient

The physician must inform the patient of the risks associated with the use of the device

The risks and benefits of using Retrace Ureteral Access Sheath should be considered in patients

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.

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476

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