CLINICAL ARTICLE SUMMARY

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

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ABSTRACT

Purpose: 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.

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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 and its capability to inject contrast through its main chamber.

Indications for Use: 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: This type of device must be used only by trained and experienced professionals. Reuse of this single-use product may create a potential risk to the user. Reprocessing, cleaning, disinfection, and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

See Instructions for Use for detailed information regarding warnings/precautions, adverse events prior to using this product. For further information contact Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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