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Isiris™: A New Single Use Digital Cystoscope For Double-J Stent Removal

Isiris™: DJ Stent Çıkarılması için Tek Kullanımlık Dijital Sistoskop

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Abstract

Isiris™ (Porgès-Coloplast) is a single-use digital flexible cystoscope, with an integrated grasper approved for double-J stent removal with comparable characteristics with other digital cystoscopes in the market. Isiris has its own monitor that can be mounted anywhere; and also with an integrated camera and a grasper system, stent removal can be performed at any place without any time restriction and also without a delay between two procedures. Isiris provides the use of a brand-new device in each procedure without a risk of contamination. The digital image quality and easy maneuverability and the potential cost reduction with a single-use device are the advantages, which all urologists should appreciate.
Keywords: Cystoscopy, Disposable, Double J stent, Flexible cystoscope, Grasper, Isiris, New technology, Stent remova

Öz

Isiris™ (Porgès-Coloplast), piyasadaki diğer dijital fleksibl sistoskoplarla benzer özelliklere sahip çift J stentin çıkarılması için onaylanmış entegre bir tutuculu, tek kullanımlık bir dijital fleksibl sistoskopdur. Isiris'in her yere monte edilebilen kendi monitörü vardır; ve ayrıca entegre bir kamera ve bir tutma sistemi ile stent çıkarma, herhangi bir yerde herhangi bir zaman kısıtlaması olmadan ve ayrıca 2 prosedür arasındaki gecikme olmadan gerçekleştirilebilir. Isiris, her prosedürde steriliteden ödün vermeden yepyeni bir cihaz kullanılmasını sağlar. Dijital görüntü kalitesi ve kolay manevra kabiliyeti ve tek kullanımlık bir cihazla potansiyel maliyet azaltma imkanı, tüm ürologlar tarafından bilinmesi gereken avantajlardır.
Anahtar Kelimeler: Sistoskopi, Tek kullanım, Çift J stent, Fleksibl sistoskop, Forseps, Isiris, Yeni teknoloji, Stent çıkarılması

Introduction

The first double-J stent was placed by Finney, and since then, this procedure has become one of the most performed operations in urology (1). Stents are placed for various clinical situations and must be removed at an appropriate time after placement (2). There are two options for removal: either using an extraction string or via rigid/flexible cystoscopy with a grasper. In this latter case, Coloplast introduced Isiris™ in 2015; the first single-use digital flexible cystoscope, with an integrated grasper for double-J stent removal.

Isiris™

Isiris™ (Porgès-Coloplast) is a single-use digital flexible cystoscope with an integrated grasper approved for double-J stent removal (Figure 1). The handle is extremely ergonomic, permitting the user to easily perform the 6 principal movements in a natural way (deflection: up/down, supination/pronation, forward/backward), and includes an irrigation connector, a lever and a button that controls the grasper (Figure 2).

The deflection system moves the distal tip up and down by a thumb-controlled deflection lever and allows a maximum of 80°

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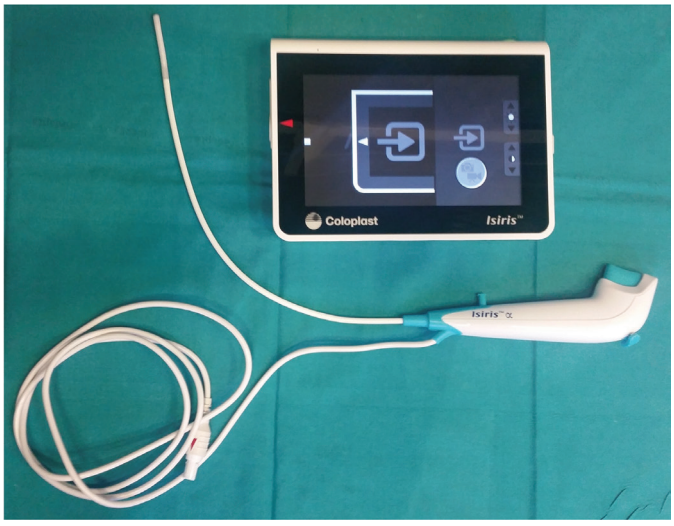

Figure 1. Isiris seen on the surgical table before plugging the device to its monitor

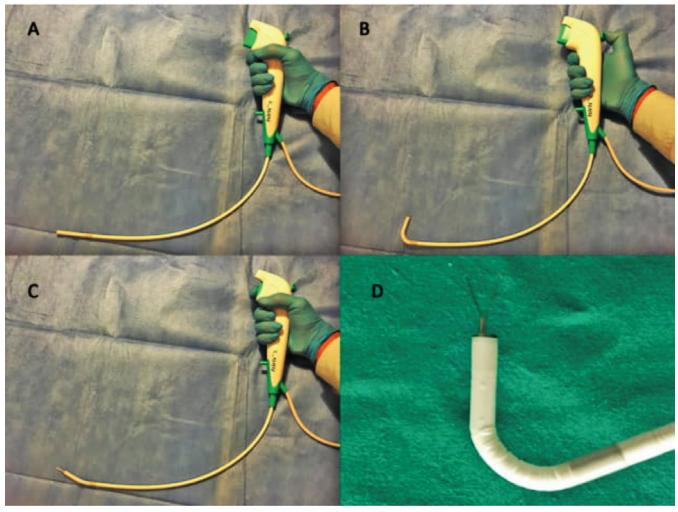

Figure 2. External view of Isiris. A) Isiris with the extended straight tip, B) Isiris with the tip flexed via the angulation control knob, C) Isiris with the tip straight and the grasper out via pushing the trigger, D) Close view of the tip of Isiris with the grasper outside

deflection in upward to and 90˚ in downward directions. The insertion cord diameter is 5 mm (0.20 inch), the distal diameter is 5.4 mm (0.21 inch) while the maximum diameter of insertion is 5.5 mm (0.22 inch) (Figure 2).

The length of the instrument is 39 cm. The grasper is integrated into the flexible system and cannot be removed or detached. Maximum length of protruded grasper is 18 mm. The distance between the 2 ends of the grasper arms is 4.5 mm when it is fully open. The camera is located at the tip and provides 0° direct view with 85° field of vision. The instrument is connected with a cable to a dedicated LCD monitor. The dimensions of the display on the monitor are 8.5 inches for a resolution of 800x600 pixels (Figure 3). There is a USB port that allows the recording of procedures (3).

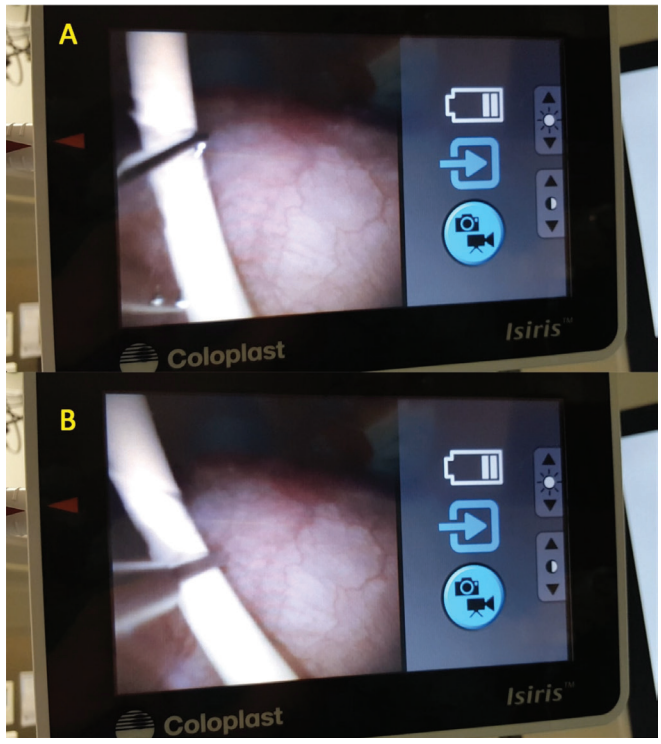

Figure 3. The view on the monitor. A) Double J stent is seen via Isisis while the grasper is outside the endoscope before grasping the stent, B) The double J stent is grasped by the grasper of Isiris before pulling it out

Discussion

Routine ureteral stenting before and after uneventful ureteroscopies is not recommended but still a subject of debate. However, stent placement is absolutely performed for drainage of urine from the collecting system in case of bilateral obstruction, unilateral obstruction with a non-functioning contralateral kidney, obstruction with hydronephrosis and urinary tract infection and for intractable renal colic unresponsive to analgesics (2). In the Clinical Research Office of the Endourological Society URS Global Study including 11.885 patients treated with ureteroscopy, it was reported that double-J stent placement was performed after the procedure in 82.6% (4). Stents must be removed at the earliest appropriate time, otherwise complications may arise due to encrustation. Thus, a flexible cystoscope is an important tool for urologists to provide easy and practical stent removal as well as various diagnostic and therapeutic maneuvers.

In the literature, there have been several studies evaluating safety and efficacy of Isiris™. In their multi-center prospective study, Doizi et al. (3) evaluated the image quality and grasper functionality of Isiris™ using a Likert scale in 83 procedures. They concluded that both parameters were rated as "good" and the procedures were performed with high success, without any complications, implicating the efficiency and safety of the device and the procedure (3).

Talso et al. (5) investigated the technical details of Isiris™ and compared image quality, loss of flow, and deflection loss with five different flexible cystoscopes. The highest image quality was obtained with Olympus CYF-VH and Isiris™ was rated 2nd. When the grasper was inside the cystoscopes, the deflection angle was highest with Storz 11272CL followed by Olympus CYF-5 and Isiris™. The authors also indicated that the deflection angle of Isiris™ increased when the grasper was outside the device. They concluded that Isiris™ was comparable to other cystoscopes in terms of quality of vision and water flow (5).

Another important consideration is sterilization. According to the Spaulding classification, all cystoscopes are considered semicritical devices, so they require high-level disinfection (6). Any damage to the cystoscope may impair the integrity and cause contamination leading to infectious complications. Therefore, handling of these devices requires specially trained personnel and standardized handling protocol. The steps of handling are pre-cleaning, leak testing, cleaning, disinfection, rinsing, drying and storage. Even with proper handling and despite a low proportion of post-cystoscopy infections, the contamination rate is still considerable and cystoscopes can be a source of infection when incorrect disinfection methods are used (7).

Fraser et al. (8) have demonstrated that there were no significant differences in contamination level of endoscopes between manual and automated sterilization (13% and 23%, respectively). Accordingly, use of single-use endoscopes is increasingly recommended with regard to sterilization standards that are still not high enough.

Another consideration is the costs. Currently, there are no studies in the literature calculating the removal costs of double-J stents. The only study that partially addresses this issue was done by Netto et al. (9) the authors reported that a ureteroscopic lithotripsy + DJ stent placement and subsequent DJ stent retrieval cost 2445 US Dollars if the DJ stent is left on a string and the procedure costs 3727 US Dollars when the DJ stent is left without a string and removed endoscopically and specified that all the procedures were performed in the operating room. Another brief analysis was made by Smith et al. (10) who used Isiris™ for the extraction of a foreign body in the bladder of a patient with a psychiatric disorder. They calculated that the total cost for foreign body removal from the genitourinary tract in the emergency department and emergency operating room was £390 and £1.530, respectively.

Another positive aspect of using Isiris™ is that when utilizing a reusable device, the operator may need an assistant to maneuver the grasper, whereas with Isiris™, an integrated system, the procedure can easily be performed by the urologist alone as the grasper is manipulated by the trigger on the device itself.

It should be noted as a limitation that although Isiris™ provides digital image quality, it is not designed for regular cystoscopy.

Conclusion

Isiris™ is a new single-use digital flexible cystoscope and is comparable with other digital cystoscopes that exist in the market in all basic characteristics. With integrated camera and grasper systems and its own monitor that can be mounted anywhere, stent removal can be performed everywhere without any time restriction, without any delay between two procedures. Use of a brand-new device in each operation without a risk of contamination, the digital image quality and easy maneuverability, and the potential cost reduction with a single-use device are the advantages, which all urologists should appreciate.

Ethics

Informed Consent: Not applicable for this article.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Concept: S.B., T.E.Ş., Design: S.B., T.E.Ş., L.D., Data Collection or Processing: S.B., M.T., E.E., Analysis or Interpretation: T.E.Ş., Y.T., L.D., Literature Search: L.D., T.E.Ş., S.B., Y.T., Writing: T.E.Ş., S.B., Y.T.

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