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**First clinical evaluation of a new single-use flexible
cystoscope dedicated to double-J stent removal
(Isiris™): a European prospective multicenter study**

Steeve Doizi, Guido Kamphuis, Guido Giusti, JI Palmero, Jm Patterson,
Silvia Proietti, Michael Straub, Jean de La Rosette, Olivier Traxer

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1 **First clinical evaluation of a new single use flexible cystoscope dedicated to double-J stent**
2 **removal (Isiris™): a European prospective multicenter study.**

3 Steeve Doizi*, Guido Kamphuis*, Guido Giusti, JL Palmero, JM Patterson, Silvia Proietti,
4 Michael Straub, Jean de la Rosette, Olivier Traxer

5 *both authors contributed equally

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9
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11

12 **Steeve Doizi (MD, MSc)**

13 Department of Urology, Tenon Hospital, Assistance-Publique Hôpitaux de Paris, Paris France.
14 Pierre et Marie Curie University, Paris, France.

15 Groupe de Recherche Clinique sur la Lithiase Urinaire, Tenon Hospital, Assistance Publique –
16 Hôpitaux de Paris, Paris, France

17 Email: steeve.doizi@aphp.fr

18

19 **Guido Kamphuis (MD)**

20 Department of Urology, Academic Medical Center, Amsterdam, the Netherlands.

21 Email: g.m.kamphuis@amc.uva.nl

22

23 **Guido Giusti (MD)**

24 Department of Urology, IRCCS San Raffaele Scientific Institute, Ville Turro Division, Milan,
25 Italy.

26 Email: info@guidogiusti.it

27

28 **Jose Luis Palmero (MD)**

29 Department of Urology, Hospital Universitario La Ribera, Alzira, Valencia, Spain

30 Email: jlpalmero@hospital-ribera.com

31

32 **Jake Patterson (MD)**

33 Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield,
34 United Kingdom

35 Email : jake.patterson@nhs.net

36

37 **Silvia Proietti (MD)**

38 Department of Urology, IRCCS San Raffaele Scientific Institute, Ville Turro Division, Milan,
39 Italy.

40 Email: proiettisil@gmail.com

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Michael Straub (MD)

Department of Urology, Technische Universität München, Munich, Germany.

Email: michael.straub@tum.de

Jean de la Rosette (MD, PhD)

Department of Urology, Academic Medical Center, Amsterdam, the Netherlands.

Email: j.j.delarosette@amc.uva.nl

Olivier Traxer (MD)

Department of Urology, Tenon Hospital, Assistance-Publique Hôpitaux de Paris, Paris France.

Pierre et Marie Curie University, Paris, France.

Groupe de Recherche Clinique sur la Lithiase Urinaire, Tenon Hospital, Assistance Publique – Hôpitaux de Paris, Paris, France

Email : olivier.traxer@aphp.fr

CORRESPONDING AUTHOR:

Prof. Olivier Traxer

Department of Urology, Tenon Hospital, Assistance-Publique Hôpitaux de Paris, Paris France.

4 rue de la Chine, 75020, Paris, France

Phone: (+33) 1 56 01 61 53

Fax : (+33) 1 56 01 63 77

Email: steeve.doizi@aphp.fr

68 **ABSTRACT**

69 **Purpose:** We evaluated a new single use digital flexible cystoscope with an integrated
70 grasper designed for double-J stent removal, Isiris™ addressing success rate, image quality,
71 deflection, maneuverability and grasper functionality.

72 **Methods:** In September 2015 a prospective cohort study was conducted in six tertiary
73 European reference centers. All consecutive patients included underwent double-J stent
74 removal and were 18 years or older. Success rate was defined by complete stent removal.
75 Image quality, deflection, maneuverability and grasper functionality were rated with a Likert
76 scale.

77 **Results:**

78 A total of 83 procedures were performed. 82% of procedures were performed in the
79 endoscopy room while the others were in the operating room since a consecutive
80 endourological intervention was planned. The median duration of stent implantation was 28
81 days [14; 60]. In five patients, stent removal was not possible. Four patients had an incrustated
82 double-J stent and in one patient the stent migrated into the ureter. After unsuccessful
83 attempts of stent removal with conventional flexible cystoscope and grasper, the five
84 patients had to be scheduled for an ureterorenoscopy procedure to remove the stent. In the
85 other 78 patients all double-J stents were removed successfully. Image quality, deflection,
86 maneuverability and grasper functionality were rated as “very good” in 72.3%, 78.3%, 72.3%
87 and 73.5% respectively.

88 **Conclusion:** This multicenter clinical evaluation of Isiris™ displayed good image quality,
89 active deflection, maneuverability and grasper functionality. Further evaluation of stent

90 removal outcomes, cost analysis and microbiology will help to delineate the possible place of
91 Isiris™ in the current practice.

92

93 INTRODUCTION

94 Since their introduction in 1978, double-J stents have become a fundamental tool in the
95 urological armamentarium and their placement is one of the most common procedures
96 performed in modern urology [1]. Although these stents are inserted for various indications,
97 the most common is probably after an ureterorenoscopic procedure to prevent the
98 incidence of postoperative ureteric obstruction and renal colic secondary to ureteral edema.
99 Ureteric stenting has also been advocated to facilitate the passage of stone fragments
100 secondary to the passive ureteric dilation [2-6]. Although this common practice is still
101 debated, it has been reported in large series that approximately 80% of urologists place a
102 ureteric stent after uncomplicated ureteroscopy for stone disease [7-15]. Once the double-J
103 stent has been placed, this has to be removed after a while. Currently, there are two options
104 common in practice to remove these stents: to use the extraction string suture with which
105 the current stents may be packaged, or a cystoscopic removal using a flexible or rigid
106 cystoscope with a grasper. For the latter procedure, this requires a dedicated place with
107 video equipment as well as cystoscopes and graspers. These instruments are fragile and
108 have to be disinfected after each procedure, which may limit the number of procedures due
109 to their availability [16-19].

110 For these reasons, a single use flexible cystoscope with integrated grasper dedicated to
111 double-J stent removal has been developed.

112 The objective of the current study was to evaluate the first clinical performance of the Isiris™
113 flexible cystoscope for double-J stent removal.

114 MATERIAL AND METHODS

115 *Study design and participants*

116 A prospective cohort study was conducted in six tertiary reference centers in Europe
117 (France, Germany, Italy, Spain, the Netherlands, and United-Kingdom) in September 2015.
118 All consecutive patients included were 18 years or older and had to undergo a double-J stent
119 removal. The following preoperative data were prospectively collected: gender, indication
120 for double-J stent placement, stent characteristics (length, diameter, type and
121 manufacturer), duration of stent implantation and type of anesthesia performed for stent
122 removal. All patients gave informed consent to undergo a cystoscopic removal of stent with
123 Isiris™, and the principles of the Declaration of Helsinki were followed.

124 *Isiris™*

125 Isiris™ (Porgès-Coloplast) is a single use digital flexible cystoscope, CE approved, with an
126 integrated grasper designed for double-J stent removal (Figures 1, 2 and 3). Isiris™ is
127 designed for ureteric stent removal only and not to perform regular diagnostic cystoscopy.
128 This flexible cystoscope has a 16-Fr outer diameter from the tip to the main part, no working
129 channel for insertion of instruments, minimum of 80° deflection in upward and 90° in
130 downward directions and a length of 39 centimeters (Figures 1 and 4). The handle includes
131 an irrigation connector, a deflection lever for upward and downward directions and a
132 grasper activation button (Figure 1). The digital camera is made of a complementary metal
133 oxide semiconductor (CMOS) sensor located at the tip of the endoscope and provides 0°
134 direct view with 85° field of vision. The scope is connected via a cable to a reusable
135 dedicated LCD portable monitor (Figure 3). The dimensions of display on monitor are 8.5

136 inches for a resolution of 800x600 pixels. A USB port is integrated in the monitor allowing
137 connecting a USB drive to record the case if needed. The Isiris™ cystoscope cannot be
138 sterilized.

139 *Procedures*

140 According to local protocol, preoperative urine analysis and culture were performed and
141 appropriate prophylactic antibiotics were given. Procedures were performed as office-based
142 cystoscopy in the outpatient clinic if no other intervention was planned. Patients were
143 placed in dorsolithotomy position. The procedure was performed without anesthesia, local
144 anesthesia (intraurethral lidocaine gel instillation) or general anesthesia if patient had to
145 undergo an ureterorenoscopic procedure. All procedures were conducted by experienced
146 endourologists. Each procedure was performed as a regular flexible cystoscopy, starting with
147 disinfection of the genitalia with antiseptics according to local protocol followed by Isiris™
148 cystoscope insertion. Then, the stent was removed using the integrated grasper by activating
149 the button located on the handle.

150 *Evaluation criteria*

151 The main outcome was the evaluation of success for stent removal.

152 The secondary outcomes were the performance characteristics of the instrument as
153 experienced by the surgeon according to the following criteria evaluated during the
154 procedure:

- 155 - Image quality displayed on the monitor with native resolution: rated according to
156 a Likert scale of “bad” to “very good”.

- 157 - Active deflection: upward and downward deflections were rated according to a
158 Likert scale of “bad” to “very good” by the surgeon during the cystoscopy.
- 159 - Maneuverability: surgeons rated the maneuverability on a Likert scale of “bad” to
160 “very good”.
- 161 - Grasper activation: participants rated the ability to use the grasper by activating
162 the button using a Likert scale of “very difficult” to “very easy”.
- 163 - Grasper functionality: participants rated the ability of grasper to catch the stent
164 using a Likert scale of “bad” to “very good”.
- 165 - Estimation of procedure duration with Isiris™ compared to the usual double-J
166 stent removal with flexible cystoscope: participants rated the duration between
167 shorter, similar or longer than the usual one.
- 168 - Overall satisfaction: participants rated their overall satisfaction using a Likert
169 scale of “bad” to “very good”.

170 The following data were also collected: need of assistant and his role.

171 Per operative complications and technical failures were collected. No data were captured on
172 postoperative complications.

173 *Statistical analysis*

174 Qualitative variables were described as numbers and percentage. Quantitative variables
175 were described as median [interquartile range] values.

176

177 **RESULTS**

178 *Patient characteristics*

179 A total of 83 procedures were performed with Isiris™. The study included 45 men (54%) and
180 38 women (46%). 82% of procedures were performed in the endoscopy room while the
181 others were in the operating room as further urological intervention was planned. Double-J
182 stent diameters were 7-Fr, 6-Fr and 4.8-Fr in 60%, 36% and 4% respectively. Length of stent
183 was 24 cm, 26 cm, 28 cm in 31.3%, 14.5% and 30.1% respectively. The median duration of
184 stent implantation was 28 days [14; 60]. Indications for stent placement were drainage after
185 a ureterorenoscopy procedure for stone disease in 73.5% of cases, ureterorenoscopy
186 procedure for upper urinary tract tumor in 7.3%, ureteral stenosis, renal transplant and
187 other indications in 6% for each (Table 1).

188 *Primary outcome*

189 In five patients, stent removal was not possible. Four patients had an encrusted double-J
190 stent and in one patient the stent migrated into the ureter. In the four cases with encrusted
191 double-J stent, stent removal with conventional flexible cystoscope and grasper was
192 attempted and did not succeed. Finally, the five patients had to be scheduled for an
193 ureterorenoscopy procedure to remove the stent.

194 In the other 78 patients, all double-J stents were removed successfully (Table 2).

195 No complication occurred during the procedures and no technical failure has been
196 experienced.

197 *Secondary outcomes*

198 Image quality was rated as “very good” in 72.3%, “good” in 22.9% and “fair” in 4.8% of cases.

199 Deflection was rated as “very good” in 78.3%, “good” in 20.5% and “fair” in 1.2% of cases.

200 Maneuverability was rated as “very good” in 72.3%, “good” in 25.3% and “fair” in 2.4% of
201 cases.

202 Grasper activation button was rated as “very easy” to use in 69.9%, “easy” in 27.7% and
203 “fair” in 2.4%.

204 Grasper functionality was rated as “very good” in 73.5%, “good” in 22.9%, “fair” in 2.4% and
205 “poor” in 1.2% of cases.

206 Duration of procedure compared to conventional cystoscopic double-J removal was
207 considered “shorter” in 37.4%, “similar” in 57.8% and “longer” in 4.8% of cases.

208 Overall satisfaction was “very good” in 68.7%, “good” in 22.9%, “acceptable” in 7.2% and
209 “poor” in 1.2% of cases (Table 2).

210 An assistant was present during the procedure in 51.8% of cases. His role consisted of
211 connecting the irrigation and scope to the monitor in 36.4%, preparing the endoscopic room
212 in 24.2% or because the hospital regulations required an assistant in 39.4%.

213

214 DISCUSSION

215 This study evaluated the first single use digital flexible cystoscope integrating a grasper
216 dedicated to double-J stent removal. We showed this device obtained a 94% success rate for
217 ureteric stent withdrawal and very good results in almost 70% of cases according to the
218 Likert scale rating for evaluation of image quality, deflection, maneuverability and grasper.
219 The five double-J stents that could not be successfully removed by the Isiris™ were also
220 unsuccessfully engaged by conventional cystoscopy.

221 As this is the first disposable device dedicated to double-J stent removal and no comparison
222 with similar instruments can be done, the release of Isiris™ addresses some questions. First
223 of all, the question arises if this instrument is functional for its purpose and safe to use. In
224 this first evaluation we confirmed that double-J stents can be removed safely with very good
225 results regarding of image quality, deflection, maneuverability and instrumentation of the
226 integrated grasper. The next question is related to costs. Since this endoscope is single use
227 and does not require a dedicated place with equipment to remove the stents, cleaning and
228 storage, the only direct costs are the one of the Isiris™ cystoscope. Besides this, the set up
229 with the Isiris™ might change the need for an assistant in the room. However, this has to be
230 balanced with the cost of a double-J stent removal using a flexible cystoscope and grasping
231 forceps. Many studies focused on the cost of ureteroscopy but no evaluation on the direct
232 and indirect costs of cystoscopic double-J stent removal is available. The only study partly
233 addressing this question is the one of Netto and colleagues where they assessed the cost-
234 effectiveness of routine ureteral stenting after ureteroscopic stone removal. They found that
235 the hospital charge per patient for stent use after uncomplicated ureteroscopy for stone
236 removal was \$2,445.31 with and \$3,727.82 without the string left in place. However, they

237 specified that stent removal was performed in the operating room, which may add an extra
238 charge compared to the office cystoscopic removal setting [11]. Another issue is the flexible
239 cystoscopes durability, implying repair costs. Although the durability of flexible
240 ureteroscopes has often been reported, only few studies assessed this issue on flexible
241 cystoscopes. In 2013, McGill et al prospectively evaluated the durability and repair costs of
242 six flexible cystoscopes over a study period of 14 months on an outpatient setting. They
243 excluded of their analysis the costs associated with cystoscope purchase. They found a total
244 of five failures occurring in four cystoscopes, with a mean of 412.8 procedures per
245 cystoscope. Damages occurred after 70, 194, and 236 uses for three cystoscopes and one
246 cystoscope had 2 failures after 168 and 255 uses. This meant a cost of cystoscope
247 maintenance of \$5.41 per procedure during the study period. They also underlined that
248 cystoscopes damages occurred earlier in cystoscopes with a higher percentage of uses
249 secondary to stent removals, biopsies, and fulgurations [16]. In 2011, Söylemez et al
250 reported a purchase cost of \$18.342 for a flexible cystoscope and \$2.057 for a 3-Fr flexible
251 grasper. The maintenance interval for each instrument was 10 times with a repair cost of
252 \$1.487 and \$491 for the flexible cystoscope and forceps respectively [17]. In a retrospective
253 study, Canales et al showed that flexible cystoscopes required repair every 2 to 3 years over
254 a four year study period. However, they did not report the number of uses before repair and
255 the mechanism of damage [18]. And finally, Fuselier and Mason found that 7 cystoscopes
256 were damaged over a two year study period including approximately 2,000 procedures.
257 Similarly, no details on number of procedures performed before repair and cause of failure
258 were reported and it was unclear whether the endoscopes were used or new before the

259 onset of the study [19]. None of the studies included costs related to cleaning instruments as
260 well as costs related to handling them.

261 The other issue addressed is the risk of urinary tract infection after flexible cystoscopy.
262 Flexible cystoscopes mostly undergo high level disinfection (HLD) rather than sterilization
263 between patients [20]. Thus, the question of pathogenic cross contamination between
264 patients is addressed given that there is now an alternative with this single use cystoscope.
265 In the field of endourology, Chang et al first reported in 2013 15 patients developing
266 ertapenem-resistant *Enterobacter cloacae* urinary tract infections due to a contaminated
267 ureteroscope [21]. However, we have to emphasize that the risk of urinary tract infection
268 after flexible cystoscopy is low. In two large prospective studies, Herr et al reported that
269 1.9% of patients undergoing a diagnostic flexible cystoscopy developed a febrile urinary tract
270 infection within 30 days after the procedure [22, 23]. In another large study, the authors
271 found a 9% incidence of bacteriuria after cystoscopy and only 1.2% developed a
272 symptomatic urinary tract infection [24]. Other studies reported an incidence of bacteriuria
273 up to 7.8% and symptomatic urinary tract infection up to 3% [25-39].

274 And finally, what is the environmental impact of the single use devices? Further studies
275 should be conducted comparing this issue between single use endoscopes with reusable
276 scopes requiring disinfection with highly toxic detergents.

277 The present study has several limitations. First, we did not compare the clinical performance
278 of Isiris™ to a control group including current practice to remove ureteric stents i.e. flexible
279 cystoscope with grasping forceps. This may impact the strength of our results. However the
280 current study should be considered as a preliminary evaluation of this new device. All the

281 concerns discussed earlier highlight the need of further studies to define the place of Isiris™
282 in the current practice. A comparison with conventional flexible cystoscopic stent removal is
283 needed where the clinical performance, direct and indirect costs with cost-effectiveness
284 analysis are assessed. However, such studies comparing the costs of care display great
285 variation across countries due to differences in practices methods of calculating costs and
286 billing. Furthermore, studies comparing microbiological evaluation and the risk of urinary
287 tract infection between this new device and traditional stent removal with flexible
288 cystoscope are needed.

289 This new concept of double-J stent removal and single use endoscopes such as flexible
290 ureteroscopes may open a new era in the field of endourology [30]. However, further
291 evaluations are required to delineate the position of these instruments in the current
292 practice.

293

294 **CONCLUSIONS**

295 This preliminary study evaluated the Isiris™, the first single use digital flexible cystoscope
296 integrating a grasper dedicated to double-J stent removal. The evaluation of instrument
297 characteristics of image quality, active deflection, maneuverability and grasper functionality
298 by the surgeons on Likert scales was good. There were no complications or technical failures.

299 In five cases the double-J stent required additional ureteroscopic surgical removal due to
300 stent encrustation or stent migration into the ureter.

301 The position of single use endoscopes in day to day practice will depend on functional
302 outcome in larger series, local practice and local cost analysis and concerns about possible
303 infections.

304 **RESEARCH INVOLVING HUMAN PARTICIPANTS AND/OR ANIMALS**

305

306 Ethical approval: "All procedures performed in studies involving human participants were in
307 accordance with the ethical standards of the institutional and/or national research
308 committee and with the 1964 Helsinki declaration and its later amendments or comparable
309 ethical standards."

310

311 Informed consent: "Informed consent was obtained from all individual participants included
312 in the study."

313 **AUTHORS' CONTRIBUTION**314 **Doizi:** Protocol/project development, Data collection or management, Data analysis,

315 Manuscript writing/editing

316 **Kamphuis:** Protocol/project development, Data collection or management, Data analysis,

317 Manuscript writing/editing

318 **Giusti:** Protocol/project development, Data collection or management, Manuscript

319 writing/editing

320 **Palmero:** Protocol/project development, Data collection or management, Manuscript

321 writing/editing

322 **Patterson:** Protocol/project development, Data collection or management, Manuscript

323 writing/editing

324 **Proietti:** Protocol/project development, Data collection or management, Manuscript

325 writing/editing

326 **Straub:** Protocol/project development, Data collection or management, Manuscript

327 writing/editing

328 **de la Rosette:** Protocol/project development, Data collection or management, Manuscript

329 writing/editing

330 **Traxer:** Protocol/project development, Data collection or management, Manuscript

331 writing/editing

332

333 **CONFLICT OF INTEREST**

334 **Steeve Doizi:** None.

335 **Guido Kamphuis:** None.

336 **Guido Giusti:** Boston Scientific, Coloplast, Cook Medical, Olympus, Karl Storz, Rocamed.

337 **Jose Luis Palmero:** Boston Scientific, Coloplast, Cook Medical

338 **Jake Patterson:** Boston Scientific, Coloplast

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342 **Olivier Traxer:** Boston Scientific, Coloplast, Lumenis, Olympus, Rocamed.

343

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346

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427 **LEGENDS**

428 Table 1. Demographic data.

429 Table 2. Primary and secondary outcomes.

430 Figure 1. Isiris™ flexible cystoscope. Plain arrow: grasper activation button. Square
431 dotted arrow: irrigation connector. Round dotted arrow: deflection lever.

432 Figure 2. Activation of grasper. Maximum length of protruded grasper is 18 mm.
433 Minimum grasper opening distance is 4.5 mm.

434 Figure 3. Isiris™ connected via its cable to the reusable dedicated LCD portable monitor.
435 A: Activation of the grasper. B: Grasper catching a double-J stent.

436 Figure 4. Downward (left) and upward (right) deflections.

Characteristics		
Number of procedures		83
Gender, n (%)		
Male/Female	45/38	(54/46)
Double-J stent characteristics, n (%)		
Diameter (Fr)		
4.8	3	(4)
6	30	(36)
7	50	(60)
Length (cm)		
16	1	(1.2)
18	2	(2.4)
22	3	(3.6)
24	26	(31.3)
26	12	(14.5)
28	25	(30.1)
Other	14	(16.9)
Duration of stent implantation, median days	28	[14 ; 60]
Anesthesia, n (%)		
None	12	(14.5)
Local	59	(71)
General	12	(14.5)
Double-J stent removal indication, n (%)		
Stone	61	(73.5)
Upper Urinary Tract Tumor	6	(7.3)
Ureteral stenosis	5	(6)
Renal transplantation	5	(6)
Ureteral reimplantation	1	(1.2)
Unspecified	5	(6)

Data are presented as median with interquartile range

Table 1. Demographic data.

Category	78/83 (94)
Success, n (%)	
Deflection	
Very good	65/83 (78.3)
Good	17/83 (20.5)
Fair	1/83 (1.2)
Poor	0/83
Bad	0/83
Image quality, n (%)	
Very good	60/83 (72.3)
Good	19/83 (22.9)
Fair	4/83 (4.8)
Poor	0
Bad	0
Maneuverability, n (%)	
Very good	60/83 (72.3)
Good	21/83 (25.3)
Fair	2/83 (2.4)
Poor	0
Bad	0
Grasper activation button, n (%)	
Very easy	58/83 (69.9)
Easy	23/83 (27.7)
Fair	2/83 (2.4)
Difficult	0
Very difficult	0
Grasper functionality, n (%)	
Very good	61/83 (73.5)
Good	19/83 (22.9)
Fair	2/83 (2.4)
Poor	1/83 (1.2)
Bad	0
Procedure duration compared to usual stent removal, n (%)[*]	
Shorter	31/83 (37.4)
Similar	48/83 (57.8)
Longer	4/83 (4.8)
Overall performance satisfaction, n (%)	
Very good	57/83 (68.7)
Good	19/83 (22.9)
Acceptable	6/83 (7.2)
Poor	1/83 (1.2)
Bad	0

Table 2. Primary and secondary outcomes.