Isiris™

Single-use flexible cystoscope for stent removal

Consistent quality, availability and sterilization

ISIRIS™ Single-Use Flexible Scope

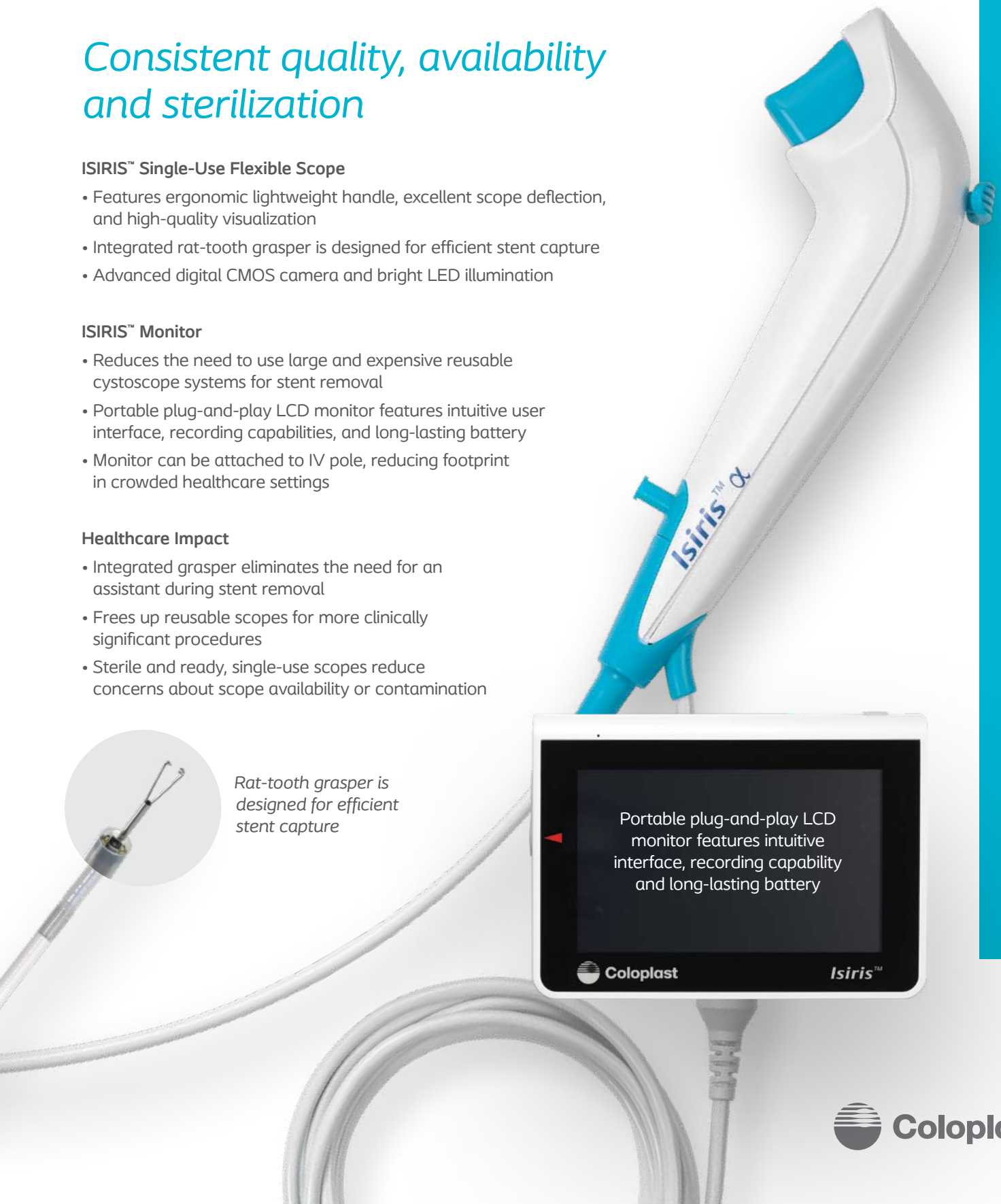
- Features ergonomic lightweight handle, excellent scope deflection, and high-quality visualization
- Integrated rat-tooth grasper is designed for efficient stent capture
- Advanced digital CMOS camera and bright LED illumination

ISIRIS™ Monitor

- Reduces the need to use large and expensive reusable cystoscope systems for stent removal
- Portable plug-and-play LCD monitor features intuitive user interface, recording capabilities, and long-lasting battery
- Monitor can be attached to IV pole, reducing footprint in crowded healthcare settings

Healthcare Impact

- Integrated grasper eliminates the need for an assistant during stent removal
- Frees up reusable scopes for more clinically significant procedures
- Sterile and ready, single-use scopes reduce concerns about scope availability or contamination



Rat-tooth grasper is designed for efficient stent capture

Coloplast

Ordering Information

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

Isiris

Component	Order #
Single use Isiris device (pack of 5)	**ALFA01**
Monitor	**MN0001**

BRIEF STATEMENT

Indications: Isiris™ is a sterile single use flexible cystoscope designed for removal of double loop ureteral stents accessible in the bladder via an urethral insertion in adults. Isiris™ has been designed to be used with the reusable Isiris™ monitor to visualize the observations obtained by Isiris™.

Contraindications: Do not use active endoscopic accessories such as laser probes and electrosurgical equipment in conjunction with the Isiris™ system, as this may result in patient injury or damage to the Isiris™ system. Alert the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the Isiris™ system. The Isiris™ system is neither MRI safe nor MRI compatible. Do not use the Isiris™ system during defibrillation. Only to be used by skilled physicians trained in clinical endoscopic techniques and procedures. Passive deflection and retrovision maneuvers may be hazardous as it may affect the device, especially the grasper functionality. The distal end of the endoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the tip of the device and the mucosal membrane as long, sustained contact with the mucosal membrane may cause mucosal injury. Do not enter any part of Isiris™ into the ureter. Do not activate the grasper when the distal end is inside the urethra. Do not activate the grasper during suctioning. Do not attempt to clean and reuse Isiris™ as it is a single-use device. Reuse of the product can cause contamination, leading to infections.

The risks and benefits of using Isiris™ stent removal should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings and precautions 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.us.

Complications from the use of this device should be brought to the attention of your Coloplast Representative and your physician.

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

Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology

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

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