

# Evolution<sup>®</sup> colonic stent as a bridge to surgery



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## Indication for procedure

The laparoscopic resection of colorectal carcinomas is, more and more, replacing open surgery. This minimally invasive method shows equal oncological results with less perioperative pain, a better cosmetic result, and a shortened period of recovery.

A contraindication for the laparoscopic procedure is an ileus with dilated intestinal loops, because of an increased risk for perforation. Here, a preoperative stenting with colorectal metal stents offers the opportunity to relieve the ileus and to perform a minimally invasive resection later.

## About the author and facility

For the past 17 years, Dr. Michael Hünerbein has performed all current endoscopic examinations and interventions, including gastroscopy, colonoscopy, and ERCP. The Helios-Hospital Berlin has longstanding experience in stenting, including in placing colorectal stents. The hospital is certified as a reference center for surgical endoscopy by the German Society of Surgery.

## Device and accessories

A standard colonoscope and a fluoroscope are used in this procedure. For the x-ray image, a water-soluble contrast is used (Figures 3a–3c). The stenosis is probed using a wire guide with a hydrophilic tip. Over the wire guide, an uncovered Evolution Colonic Controlled-Release Stent (available in lengths of 6, 8, or 10 cm) is pushed through the stenosis. The distal end of the stent is deployed and the positioning rectified, as the situation requires. When positioned correctly, the stent can be fully deployed.

## Presentation and diagnosis

In the rescue center, a 43-year-old patient presented with significant abdominal pain and vomiting. The pain persisted for two days with increasing intensity. There had been no stool for the last four days. Clinically the patient showed a distended abdomen with meteorism and tenderness on palpation. Inflammation values were slightly raised (CRP 18 mg/L, leukocytes 12 Gpt/L). A computer tomography confirmed the suspected diagnosis of a colonic ileus with dilated small and large bowel loops (Figure 1). The cause for the ileus was a stenosing sigmoid carcinoma. Theoretically, there was an indication



Figure 1



Figure 2a

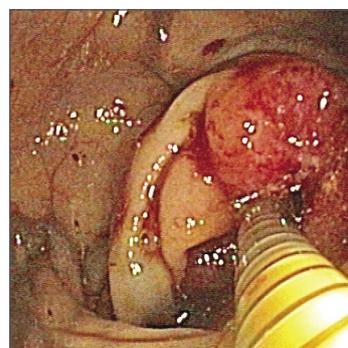


Figure 2b

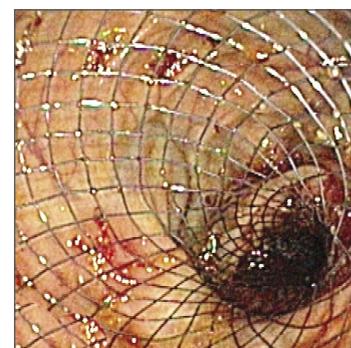


Figure 2c

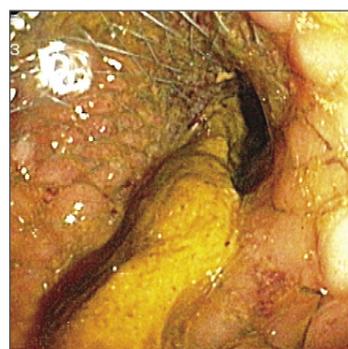


Figure 2d



Figure 3a

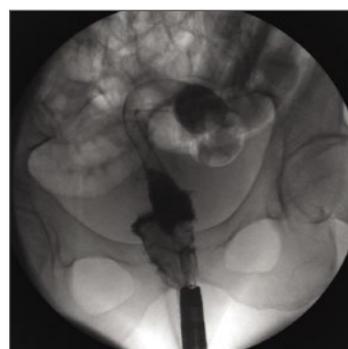


Figure 3b



Figure 3c

for a laparotomy with resection of the tumor and creation of a stoma or creation of a stoma alone. As an alternative, we preferred a stent implantation and afterwards an elective laparoscopic resection with an anastomosis.

## Procedure

On admission day, the patient underwent a colonoscopy. The examination was performed with additional ECG, oxygen saturation and blood pressure monitoring. The patient was sedated by

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Disoprivan (propofol, 100 mg, fractioned). Twenty centimeters from the anus, a stenosing tumor was found, leaving only a filiform rest of the lumen. Under contrast, a 4 cm long high-grade stenosis was visible (Figures 2a-2c). The stenosis was probed with a wire guide. Through the scope and over the wire guide, a 10 cm uncovered Evolution self-expanding metal stent (25 / 30 mm in diameter), so it was proximally and distally a few centimeters longer than the stenosis (Figure 3c).

## **Outcome**

Defecation happened immediately through the stent (Figure 2d) and the abdomen of the patient was relieved increasingly.

Three days after stent implantation, a laparoscopic sigma resection could be performed under routine circumstances. A continence-preserving resection without stoma creation could be achieved. Histologically, an adenocarcinoma with wall penetration (T3) was diagnosed. The lymph nodes were not infested, so chemotherapy was not necessary. The patient could leave the hospital seven days after the laparoscopic resection.

Because of the stenting, the complication risk of an emergency laparotomy in the ileus could be decreased, and a stoma could be avoided. ■

## **Evolution® Colonic Stent System – Uncovered**

**CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).**

**INTENDED USE:** This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

**CONTRAINDICATIONS:** Those specific to GI endoscopy and any procedure to be performed in conjunction with stent placement. • Additional contraindications include, but are not limited to: enteral ischemia, suspected or impending perforation, intra-abdominal abscess/perforation, inability to pass wire guide or stent through obstructed area, patients for whom endoscopic procedures are contraindicated, significant coagulopathy, benign disease.

**WARNINGS:** The stent is not intended to be removed or repositioned after stent placement and is intended to remain in the body permanently. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. Stent cannot be retrieved after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed. • This stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. • To minimize pain and tenesmus, the stent end nearest to the anal canal/anus should be placed 2 cm above the anal canal or 6 cm from the anus. • The device should be used with caution and only after careful consideration in patients with: - Patients with radiation colitis or proctitis. - Patients with elevated bleeding times, coagulopathies.

**PRECAUTIONS:** Refer to product package label for the minimum channel size required for this device. • A complete diagnostic evaluation must be performed prior to use to determine proper stent size. • If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. • Stent should be placed endoscopically with fluoroscopic monitoring. • The stent should only be placed with the Cook delivery system, which is provided with each stent. • This device is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. • After stent placement, alternative methods of treatment such as chemotherapy and radiation should not be administered as this may increase risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. • Long-term patency of this device has not been established. Periodic evaluation is advised.

**POTENTIAL COMPLICATIONS:** Those associated with GI endoscopy include, but are not limited to: perforation, hemorrhage, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest. • Additional complications include, but are not limited to: intestinal perforation, pain, inadequate Stent expansion, stent misplacement and/or migration, tumor ingrowth or overgrowth, stent occlusion, ulcerations, pressure necrosis, erosion of the luminal mucosa, septicemia, foreign body sensation, bowel impaction, diarrhea, constipation, peritonitis, symptoms of tenesmus or urgency/incontinence, death (other than due to normal disease progression).

**See Instructions for Use for full product information.**