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THE INVENDOSCOPY™ E40 SYSTEM WITH THE SINGLE-USE INVENDOSCOPE™ SC40 *For Gentle, Sedationless Colonoscopy*

Colonoscopy is the undisputed gold standard for colorectal cancer screening because it provides a very high sensitivity (>90%) with a false negative rate of 6% for adenomas 1 cm or more in diameter.¹ However, it is well known that colonoscopy is generally perceived as being a painful procedure² and the examination is often met with reluctance due to patient concerns about this associated pain. Based on initial clinical tests, the **invendoscopy™ E40 System** and single-use colonoscope, the **invendoscope™ SC40**, developed by **invendo medical GmbH** (Germany), has been shown to minimize discomfort for the patient during colonoscopy. This innovative colonoscope has a highly flexible sheath with a reduced bending diameter and a novel “inverted sleeve” technology, whereby the endoscope grows and shrinks only

at the distal end. The inner layer of the inverted sleeve is driven forward, also moving the inner endoscope sheath. As the inner layer unfolds at its tip, it becomes part of the outer layer, which stays in position. As a result, there is no relative movement of the outer layer of the endoscope to the colon wall (see figure below). These features allow the colonoscope to move gently and comfortably through the colon, making it possible to perform the procedure without sedating the patient, which should improve the acceptance of colonoscopy as a screening method.

Conventional endoscopes are flexible instruments with varying shaft stiffness, depending on the model, and have a fairly large bending diameter. Factors such as the degree of force applied to the colonoscope shaft or the stretching

Sedationless colonoscopy

Invendo's easy-to-navigate, single-use colonoscope, the invendoscope™ SC40, allows colonoscopy to be performed without sedation and with little or no discomfort to the patient. How it works:

Handheld device performs all endoscopic and software functions including push-button operation of the endoscope driving unit and joystick maneuvering of the endoscope tip.

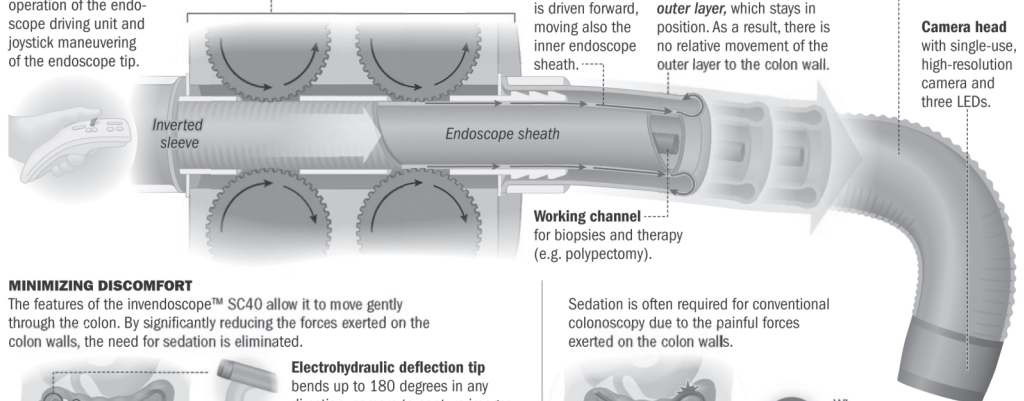
Driving unit moves the endoscope into and out of the colon. Eight wheels turn against the inner portion of the bi-layered inverted sleeve, driving it forward or backwards.

Inverted sleeve causes endoscope to grow and shrink only at its distal end.

Inner layer of inverted sleeve is driven forward, moving also the inner endoscope sheath. As the inner layer unfolds, it becomes part of the **outer layer**, which stays in position. As a result, there is no relative movement of the outer layer to the colon wall.

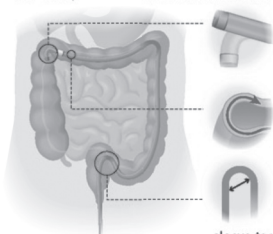
Electrohydraulic deflection

Camera head with single-use, high-resolution camera and three LEDs.



MINIMIZING DISCOMFORT

The features of the invendoscope™ SC40 allow it to move gently through the colon. By significantly reducing the forces exerted on the colon walls, the need for sedation is eliminated.

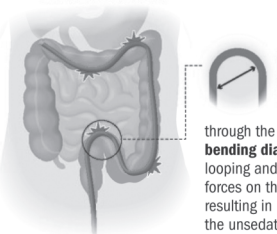


Electrohydraulic deflection tip bends up to 180 degrees in any direction, camera to capture images from any angle.

Patented inverted sleeve technology causes endoscope to grow and shrink at its distal end.

Highly-flexible materials **minimize the bending diameter** of the colonoscope. This small bending diameter combined with the inverted sleeve technology significantly reduces the forces on the colon walls, so that an unsedated patient feels no or only minimal discomfort.

Sedation is often required for conventional colonoscopy due to the painful forces exerted on the colon walls.



When a conventional endoscope is pushed through the colon, its **larger bending diameter** can cause looping and exert significant forces on the colon walls, resulting in pain for the unsedated patient.

of the colonic wall are what patients experience as pain. Consequently, sedation is used to reduce patient discomfort in more than 90% of the conventional colonoscopy examinations performed annually in the United States. In contrast, the reduced bending diameter of the invendoscope™ SC40, combined with the inverted sleeve technology, minimizes the forces exerted on the colon; therefore, the patient experiences little or no discomfort during a colonoscopy.

A pilot study of 28 asymptomatic paid volunteers conducted in Germany at Berlin (Charité) and Frankfurt University Hospitals revealed that 92% of the participants felt little or no discomfort during colonoscopy with the *invendoscopy*™ System, despite not being sedated at all. Prof. Thomas Rösch, MD, Head of Central Interdisciplinary Endoscopy Unit, Department of Gastroenterology, Hepatology and Metabolic Diseases, Charité University Hospitals, Campus Virchow Hospital, observes, “What impressed me was how comfortably the majority of the patients were during the procedure, despite having no sedation. Many patients were involved in conversations without really noticing the colonoscopy being performed, nor did they tend to focus on it. If there was any slight discomfort, such as some pressure due to insufflation, the patients let me know and I was usually able to make adjustments. This feedback was very helpful and I consider this interaction with the patient another benefit of performing the colonoscopy without sedation.” To date, more than 200 asymptomatic volunteers have been examined without sedation and the feedback has been excellent.

Patients were comfortable during the procedure and there were no complications during or after the examination.

What makes the *invendoscopy*™ System unique is the way the colonoscope is driven in and out of the colon with the support of a driving unit while the endoscopic tip is guided electrohydraulically by an easy-to-use joystick on a handheld device. Prof. Rösch explains that “with conventional colonoscopy, there is a fair amount of maneuvering that has to occur during the examination, such as straightening of the colon, but the *invendoscopy*™ System also does not require as many technical manipulations. The goal with the invendoscope™ SC40 is to find the colon lumen on the monitor and drive according to colon anatomy to reach the cecum.” Prof. Rösch further finds that with the handheld he can do the examination while sitting. “If you do many procedures per day, you can appreciate this comfort and convenience.” All endoscopic functions, including deflection of the tip, insufflation, rinsing, suction, and image documentation, are performed easily using this handheld device. The invendoscope™ also moves only if the physician presses the “forward” or “backward” button on the handheld device; therefore, the physician always controls the endoscope movement.

The invendoscope™ SC40 is for single use only (including camera head), which eliminates the risk of any cross-contamination. Although considered a rare event, the transmission of infection is a potential risk in conventional endoscopy. Despite well-established protocols for instrument

reprocessing, contamination of endoscopes can occur in routine work, sometimes with considerable frequency, as shown by quality control studies, and rigorous monitoring is necessary to achieve acceptably low levels of bacterial endoscope contamination. As a single-use endoscope, the invendoscope™ will put an end to these concerns.

Prof. Rösch further contends that “the invendo image quality is good and allows comprehensive diagnosis and therapy (thanks to a 3.2-mm working channel). Wider viewing angles and other planned modifications will even enhance the diagnostic capability.”

invendo medical GmbH aims to become a global leader in the development and distribution of novel disposable endoscopy products in the field of gastroenterology. It is the company’s goal to improve the convenience and tolerability of gastroenterological endoscopic procedures.

For more information concerning the *invendoscopy*™ E40 System and the invendoscope™ SC40, please e-mail to info@invendo-medical.com; or visit the company’s Web site at www.invendo-medical.com.

References:

1. Data on file with invendo™ medical GmbH
2. Shah, SG, *et al.*, Patient pain during colonoscopy: an analysis using real-time magnetic endoscope imaging. *Endoscopy*, 2002 June;34(6):435-40.