



# EndoRotor DEN™ System

## Powered Endoscopic Debridement (PED)

The only clinically validated solution for endoscopic debridement of walled-off pancreatic necrosis (WOPN)

### EndoRotor® Advantages

The EndoRotor PED™ Catheter is the first safe and effective, clinically validated, high-performance endoscopic instrument cleared by the FDA for simultaneous resection and removal of necrotic material from within WOPN.

EndoRotor® versus Conventional Instruments (forceps, snares, baskets, etc.)		
Data	EndoRotor®	Other Devices
FDA clearance	Yes*	Not Cleared, Not Indicated
Avg # of procedures for clearance	2.1 <sup>1</sup>	4.09 <sup>10</sup>
Avg patient length of stay	18 days <sup>1</sup>	32.85 days <sup>10</sup>
Procedural complication rate	5% <sup>1</sup>	21.33% <sup>10</sup>
Recurrence	0% <sup>1</sup>	10.88% <sup>10</sup>
Surgery required	0% <sup>1</sup>	12.98% <sup>10</sup>

\* DEN200016

EndoRotor® Powered Endoscopic Debridement catheter



### Safety

- A meta-analysis of conventional Direct Endoscopic Necrosectomy (DEN) demonstrated a 21% risk for serious adverse events (SAE), including bleeding and collection perforation.<sup>2,3</sup>
- In multiple clinical trials using EndoRotor® for DEN, there were no SAEs or adverse events (AE) related to the device and a 10% procedure AE rate related to the procedure, demonstrating an improvement in safety over conventional DEN.<sup>1,4,5,6,7,8</sup>

### Effectiveness

- Conventional instruments used for DEN require the user to resect necrotic debris followed by removal of the endoscope through the lumen apposing metal stent (LAMS) to deposit the debris in the stomach which is correlated to an increased number of procedures, increased procedure time, and stent dislodgement.<sup>2,3</sup>

- EndoRotor® enables the user to maintain the instrument within the collection which improves procedural efficiency resulting in fewer treatments with reduced risk of stent dislodgement.<sup>1,6,7,8</sup>

### Patient Hospital Length of Stay (LOS)

- Patients undergoing treatment for WOPN/WON using conventional, non-FDA cleared instruments averaged 32 days LOS.<sup>2</sup>
- Patients undergoing treatment WOPN/WON using EndoRotor® reported an average 18 days LOS.<sup>1</sup>



“EndoRotor® XT provides a necessary device in the management of pancreatic necrosectomies. A valuable feature is its ability to precisely remove necrotic material minimizing concerns of complications that may occur with traditional necrosectomy devices.”

– Ali Mir Ahmed, MD, Assistant Professor  
Interventional Endoscopy, University of Alabama at Birmingham,  
Alabama



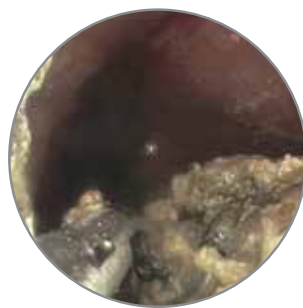
# Intended Use

The EndoRotor® device is intended for resection and removal of necrotic tissue in symptomatic WOPN/WON after patients have undergone endoscopic ultrasound (EUS) guided drainage.



## EndoRotor® Benefits

- **Direct Endoscopic Visualization** enables safe removal of necrosis
- **360° rotatable distal cutting window** optimizes instrument positioning relative to necrosis
- **Automated tissue extraction** eliminates the need for removal of debris into the stomach

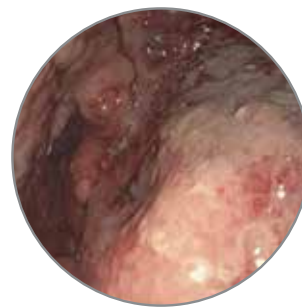


### Before treatment

8cm x 6cm cavity with 50% of collection volume filled with necrotic debris

### After one session

Successful clearance of the cavity



Images courtesy of Dr. Farhoud Khosravi

“We have seen staggering results since introducing EndoRotor® into our treatment algorithm for necrosectomy of WON/WOPN. This novel device has greatly improved our procedural efficiency, reduced inpatient length of stay and lowered our overall cost for the treatment of WOPN.”

– Sammy Ho, MD, Director of Pancreaticobiliary Services and Endoscopic Ultrasound, Montefiore Medical Center, New York

“Direct Endoscopic Necrosectomy with the EndoRotor® device is a game changer, greatly reducing the complexities, frustrations and logistical challenges associated with endoscopic necrosectomy. Coupled with ease of use and overall excellent safety profile, this device is the way to go for any endoscopist performing necrosectomy.”

– Eddie Villa, MD, Assistant Professor of Clinical Medicine, University of Illinois College of Medicine, Illinois

1. Stassen P, et al. Prospective trial evaluating the safety and effectiveness of the EndoRotor® for direct endoscopic necrosectomy of WON (EndoRotor® DEN Trial). Oral Presentation. Digestive Disease Week 2020. doi: 10.1016/j.gie.2020.03.622
2. Puli SR, et al. Endoscopic transmural necrosectomy for walled-off pancreatic necrosis: a systematic review and meta-analysis. Can j gastroenterol hepatol 2014; 28(1):50-53.
3. Yan L, Dargan A, Nieto J, Shariha RZ, Binmoeller KF, Adler DG, et al. Direct endoscopic necrosectomy at the time of transmural stent placement results in earlier resolution of complex walled-off pancreatic necrosis: Results from a large multicenter United States trial. Endosc Ultrasound 2019;8:172-9.
4. Rizzatti G, et al. Endorotor®-based endoscopic necrosectomy avoiding the superior mesenteric artery. Endoscopy. 2020 Apr 24. doi: 10.1055/a-1151-4694.
5. Mangas-Sanjuan C, et al. Endoscopic management of pancreatic necrosis using the EndoRotor®. Endoscopy. 2020;Apr;52(S01):S323. doi: 10.1055/s-0040-1705043.
6. van der Wiel SE, et al. Preliminary report on the safety and utility of a novel automated mechanical endoscopic tissue resection tool for endoscopic necrosectomy: a case series. Endosc Int Open. 2020;Mar;8(3):E274-E280. doi: 10.1055/a-1079-5015.
7. Morris L, et al. EndoRotor® use to manage walled-off pancreatic ne-crosis; first UK experience, Gut. 2019;Jun;68(Suppl 2):A160. doi: 10.1136/gutjnl-2019-BSGAbstracts.302.
8. Schlag C, et al. Endoscopic microdebrider-assisted necrosectomy for walled-off pancreatic necrosis. Endoscopy. 2020;52(S01):S29-S30. doi: 10.1055/s-0040-1704093.

**Warning:** The EndoRotor® device should not be used in patients with known or suspected pancreatic cancer as per the assessment of the treating physician. Refer to “Instructions for Use” for additional information.




### Distributed by:

Micro-Tech Endoscopy USA  
2855 Boardwalk Dr.  
Ann Arbor, MI 48104  
Tel: +1-877-552-4027

For more information visit [www.interscopemed.com](http://www.interscopemed.com)  
or contact Customer Service:

### USA

Tel: 800-461-4289 (toll-free in U.S.)  
Email: [info@interscopemed.com](mailto:info@interscopemed.com)

  
Interscope, Inc.  
200 Commerce Drive  
Northbridge, MA 01534  
USA  
TEL: +1-800-461-4289  
0031 (0) 73-3032541  
[www.interscopemed.com](http://www.interscopemed.com)

  
EMERGO EUROPE  
Prinsesgracht 20  
2514 AP The Hague  
The Netherlands  
EMERGObyJUL.com

  
2797