Powered Endoscopic Debridement (PED)
The only clinically validated solution for endoscopic debridement of walled-off pancreatic necroses (WOPN).

EndoRotor® Power Rotating Endoscopic Debridement

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.

Safety
- A meta-analysis of conventional Direct Endoscopic Necrosectomy (DEN) demonstrated a 21% risk for serious adverse events (SAE), including bleeding and collection perforation.²,³
- 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.¹,⁴,⁵,⁶,⁷,⁸

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.²,³
- 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.¹,⁶,⁷,⁸

Patient Hospital Length of Stay (LOS)
- Patients undergoing treatment for WOPN/WON using conventional, non-FDA cleared instruments averaged 32 days LOS.²
- Patients undergoing treatment WOPN/WON using EndoRotor® reported an average 18 days LOS.¹

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.

<table>
<thead>
<tr>
<th>Data</th>
<th>EndoRotor®</th>
<th>Other Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA clearance</td>
<td>Yes*</td>
<td>Not Cleared, Not Indicated</td>
</tr>
<tr>
<td>Avg # of procedures for clearance</td>
<td>2.1¹</td>
<td>4.09¹⁰</td>
</tr>
<tr>
<td>Avg patient length of stay</td>
<td>18 days¹</td>
<td>32.85 days¹⁰</td>
</tr>
<tr>
<td>Procedural complication rate</td>
<td>5%¹</td>
<td>21.33%¹⁰</td>
</tr>
<tr>
<td>Recurrence</td>
<td>0%¹</td>
<td>10.88%¹⁰</td>
</tr>
<tr>
<td>Surgery required</td>
<td>0%¹</td>
<td>12.98%¹⁰</td>
</tr>
</tbody>
</table>

* DEN200016

**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

"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

**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.