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Indications:

The EndoRotor is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove residual tissue from the peripheral margins following Endoscopic Mucosal Resection (EMR).

Contraindications: The EndoRotor should not be used for the primary resection of lesions or for tissue intended for biopsy.

Guide Content: This technique guide is intended as a physician supplement to the EndoRotor® System Instructions for Use (IFU). Please consult the IFU for complete details, precautions and troubleshooting.

Design Features:

Figure 1 EndoRotor® Console

1. Power
2. Indicator Light
3. Vacuum Control Release
4. Prime/Flush
5. Console/Catheter Interface
6. Irrigation Pump
7. Foot Pedal Connection
8. Specimen Trap Holder
9. Vacuum Control Valve
10. Speed Control

Figure 2 EndoRotor® Catheter

1. Proximal Housing
2. Vacuum Tubing
3. Irrigation Tubing
4. Flexible Outer Tubing
5. Cutting Cannula
**Identify & Assess the Mucosal lesion:**
Standard endoscopic assessment techniques should be used when evaluating a lesion for resection. The EndoRotor® is designed for resection of mucosal lesions. The physician may consider the use of prophylactic injection or hemostasis instrumentation.

**EndoRotor use during Endoscopic Mucosal Resection:**
Adjust the angle of approach to the desired trajectory. Using 2 fingers rotate the rotation handle (Figure 3) to obtain the desired position of the outer cutter. The solid black line indicates that the cutter position is exactly 180° opposite the user (Figure 4a). On either side of the black line are hashed lines (Figure 4a). This indicates the cutter is positioned exactly 90° from the lines. A perpendicular solid black line indicates the center of the cutting opening (Figure 4b).

**Resection**
Activate the EndoRotor® by first engaging cutter rotation and depressing the blue pedal once. Position the tip of the EndoRotor® onto the tissue, then tap the orange pedal (suction) and complete a resection of the targeted tissue. The EndoRotor® resects approximately 3mm – 5mm in a single tap once vacuum is engaged. This occurs by suctioning tissue into the device and completing a cut with an inner rotating blade. Retracting the scope or rotating the endoscope thumb wheel down to complete the resection should follow each tap (Figure 5a, 5b).
Retract the tip of the catheter into the working channel to inspect the resection site. Adjust the position and repeat to remove additional tissue if needed. If suction is not activated the motor will stop automatically after 10 seconds. To stop the rotation, depress the blue pedal or merely wait for the 10-second rotation timeout. This tap and inspect approach allows the physician to carefully resect a target site in a manner that makes safety the principal objective.

Orientation of endoscopic working channels varies by manufacturer. This should be considered when finding an optimal orientation of the cutting window. For example, orientations such as 6 o’clock are generally universally applicable however when positioning mandates adaptation such as a fold or frontal face it is important to understand correlation of vacuum level, orientation and tip exposure. Instrument or tip exposure should never exceed 30mm, however variable tip exposure less than 30mm can facilitate resection. If cutting is needed in 3 or 9 o’clock positions then greater tip exposure will provide improvement in visibility and optimal cutting position. Figure 5 and 6 detail the same charts with and without anatomy to express examples.

**Approach parameters in anatomy (swine example)**

*Figure 5 Approach parameters in anatomy (swine example)*

![Diagram of approach parameters in anatomy](image-url)
Endoscopic mucosal resection (EMR) and removal of lateral margin
Submucosal injection follows the approach of standard EMR technique. Therefore using physician’s discretion to determine whether to use adrenaline as part of the injectate can improve visualization loss normally caused by bleeding.
Establishing a circumferential margin before or after EMR
Use the EndoRotor® to remove tissue immediately surrounding the lesion to create a lateral margin with healthy tissue. Alternatively, once a standard EMR is complete, use the EndoRotor® to address the lateral margin and any residual adenomatous tissue present.

The rotational force of the EndoRotor® tip is clockwise making cutting a left to right movement. The resection should start on the left margin (Figure 8a – 8c) and continue to the right margin of the lesion. The vacuum (orange pedal) can be engaged at all times as long as the tip continuously moves across the target site.

The physician will observe the removal of mucosa and should take care to not keep the instrument in one place while using a fully operational catheter to employ the safest means to operate the instrument.

Once the margin is complete the orange pedal should be disengaged. This approach is analogous to using a dissecting knife to create a circumferential margin.

The lesion can now be resected using the preferred instruments for EMR. If the standard EMR was performed first and the EndoRotor® lateral margin second then the optically assess the resected site.
How to resect in different planes
In the illeo-cecal junction, rectal-sigmoid, etc. using the EndoRotor® on a frontal is not a limitation of the device but should be done when the physician has a working comfort with the device mechanics. During a frontal face (Figure 9) the cutting surface does not have direct apposition to the mucosa and will not cut tissue in this plane. To overcome this the user can first attempt to reorient the endoscope by rotating the endoscope until a more tangential plane is possible. Alternatively, patient repositioning can improve the plane of the approach. Lastly the catheter exposure and vacuum may be varied (Figure 5 & 6). In this technique the user can now use the endoscope to create leverage by adding some retroflex to the endoscope bringing the plane of interest into more of a tangential approach.

Resected Specimen:
Exchanging the specimen trap filter to separate sites is a consideration when using the EndoRotor®. Hold the lower half of EndoRotor® Specimen Trap using a second hand rotate the upper half counter clockwise until an audible click is heard. Separate the halves then remove the used filter. Replace with the new filter and reseal the Specimen Trap.

Ordering information:
- ER 10-01  EndoRotor® Catheter 3.2mm x 1900mm
- ER 10-02  EndoRotor® Catheter 3.2mm x 1550mm
- ER 10-03  EndoRotor® Catheter 3.2mm x 1250mm
- ER 30-01  EndoRotor® Specimen Trap
- ER 40-01  EndoRotor® Filter Set
- ERC 20-01 EndoRotor® Console

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