Ordering information:

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Indications:
The EndoRotor® System is intended for the removal of alimentary tract mucosa.

Guide Content: The purpose of the technique guide is to provide an additional resource for physicians supplementing the EndoRotor® System Instructions for Use (IFU). Please consult the IFU for complete details, precautions and troubleshooting.

Design Features:

Figure 1 EndoRotor Console

Figure 2 EndoRotor Catheter

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**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 EndoRotor® is a cold resection device. Mild to moderate bleeding can occur when using the device. The physician may consider the use of prophylactic injection or hemostasis instrumentation. Techniques to resect a mucosal lesion may vary based on the size and morphology.

**Colon polyps**

**Orientation:**

Adjust the angle of approach to the desired trajectory. Using 2 fingers rotate the rotation handle to obtain the desired position of the outer cutter (Figure 3). The solid black line indicates that the cutter position is exactly 180° away (Figure 4). On either side of the black line are hashed lines. This indicates the cutter is positioned exactly 90° from the lines (Figure 4). A perpendicular solid black line indicates the center of the cutting opening (Figure 5).

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 6 and 7 detail the same charts with and without anatomy to express examples.

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

Figure 6 Approach parameters in anatomy (swine example)
Endoscopic Mucosal Resection (EMR) of Larger Polyps:
Submucosal injection should follow the general approach of EMR technique. Because the EndoRotor® does not provide cautery, there is a risk of bleeding with removal of larger lesions. Use physician’s discretion to determine whether to use diluted Epinephrine as part of the injectate.

Following submucosal injection, two general technical approaches have shown to be safe to facilitate removal of larger lesions. Following submucosal injection, two general technical approaches appear useful to facilitate removal of larger lesions.

Establishing a Circumferential Margin:
Use the EndoRotor® as seen in Figures 9a – 9c to remove tissue surrounding the lesion to create a circumferential margin with healthy tissue. Tip movement from left to right and from proximal to distal follows the natural movement of the device to create a margin.

Simple Polyp Resection
Activate the EndoRotor® by first engaging cutter rotation by tapping once on the blue pedal. Position the tip of the EndoRotor® onto the polyp, then tap the orange pedal (suction) and completes a resection of the lesion. The EndoRotor® resects approximately 3mm – 5mm of tissue in a single tap once vacuum is engaged by suctioning tissue into the device and completing a cut with an inner rotating blade. Use the endoscope thumb wheel to lift the scope from the mucosa. Retract the tip of the EndoRotor to inspect the resection site for to ensure completeness of removal. Repeat suctioning to remove additional tissue if needed. If suction is not in use, the rotation will stop automatically after 10 seconds. To stop the rotation, tap the left blue pedal or merely wait for the 10-second time out feature. This tap and inspect approach allows the physician to carefully resect tissue while maintaining a safe profile.
Planar Resection (Colon and Esophagus):
Medium to large sized lesions may be removed without creating an initial margin. The method is identical to the last step of the circumferential margin technique whereby the physician starts the resection at the most proximal area of the lesion and makes left to right passes until the targeted tissue is completely resected. Variation in location and morphology of the polyp may require adjustment in the orientation of the cutter.

Resected starting at the proximal or distal margin of the lesion and by using a side-to-side sweeping motion taking care to maintain linear passes. Clockwise rotation allows the instrument to move easily to the right, so the resection should start on the left margin.

An opposite direction can be used as well and requires a counter pressure when using the endoscope wheels to account for torque. The vacuum (orange pedal) can be used at any time continuously across the surface of the lesion. Cutting requires continuous depressing of the orange pedal.

The physician will observe the removal of mucosa and should remain in one place while using suction and cutting to employ the safest technique. Once the right margin is reached the orange pedal should be disengaged going back to the left margin to restart the next row of the resection. The side-to-side movement should be repeated until the entire lesion is removed as seen in Figure 10a – 10c.

Frontal Face Resection (Colon):
In the illeo-cecal junction, rectal-sigmoid or other locations that require a frontal face approach using the EndoRotor® on a frontal is not a limitation of the device. In a frontal face the cutting surface does not have direct apposition to the mucosa and as a general rule will not cut tissue.

An opposite direction can be used as well and requires a counter pressure when using the endoscope wheels to account for torque. The vacuum (orange pedal) can be used at any time continuously across the surface of the lesion. Cutting requires continuous depressing of the orange pedal.

The physician will observe the removal of mucosa and should remain in one place while using suction and cutting to employ the safest technique. Once the right margin is reached the orange pedal should be disengaged going back to the left margin to restart the next row of the resection. The side-to-side movement should be repeated until the entire lesion is removed as seen in Figure 10a – 10c.
Examples of Pathology:

EndoRotor® Morphological findings in EndoRotor obtained Fundic Gland Giant Polyp with high-grade dysplasia (left) shows the characteristics and nuclear features (nuclear stratification, round nuclei, prominent nucleoli) needed for diagnosis and is comparable to standard biopsy forceps (right).

Stomach Resections:
The technique requires greater pressure than is normally used in the esophagus or the colon. The user enlarge the target just as is done in a planar resection.

Resected Specimen:
Once the operator resects the specimen the user may isolate the specimen or obtain a lateral margin resection or to remove a secondary site. Prior to doing so obtain a replacement filter from the EndoRotor Filter Set. Using two hands hold the lower half of EndoRotor Specimen Trap using a second hand rotate the upper half counter clockwise until an audible click is heard and separate the halves to remove the used filter. Replace with the new filter and reseal the Specimen Trap.

Esophagus, Day 14.
Dashed line indicates area of fibrosis suspected to represent healed treatment area. Overlying mucosa (arrow) is intact.

Stomach, Day 14.
Asterisk indicates center of large accumulation of tissue ink within the submucosa. No treatment site is visible.