

The EndoRotor[®] Mucosal Resection System Procedural Guide



EndoRotor[®]



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Indications:

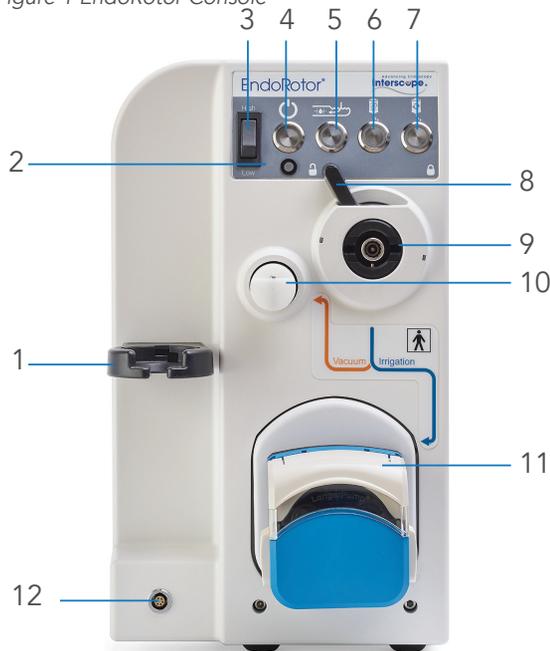
The EndoRotor is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove residual tissue of the gastrointestinal (GI) system including post-endoscopic mucosal resection (EMR) tissue persistence with a scarred base and residual tissue from peripheral margins following EMR.

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

Guide Content: This procedural 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.

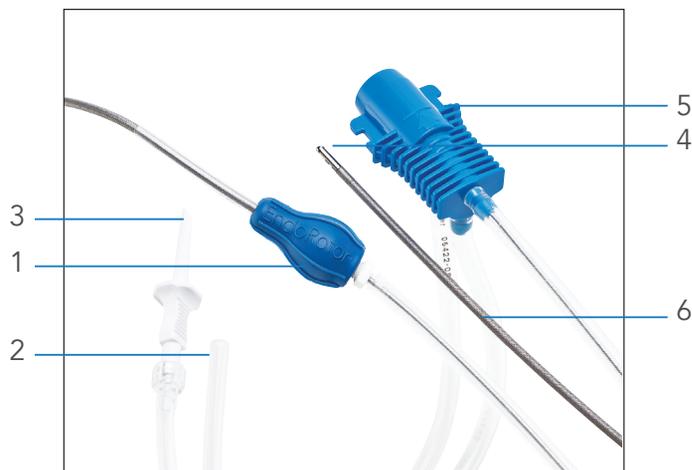
Design Features:

Figure 1 EndoRotor Console



1. Specimen trap holder
2. Indicator light
3. Speed control switch
4. Standby button
5. Vacuum control release button
6. Prime button
7. Irrigation on/off button
8. Catheter Interface locking level
9. Catheter interface
10. Vacuum control valve
11. Irrigation pump
12. Foot control interface

Figure 2 EndoRotor Catheter



1. Rotation handle
2. Aspiration tube
3. Saline bag connection
4. Cutting tip
5. Proximal housing/console interface
6. Flexible outer tubing

Identify & Assess the Mucosal lesion:

Standard endoscopic assessment techniques should be used when evaluating a lesion for resection. The EndoRotor is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove tissue, not intended for biopsy, of the gastrointestinal (GI) system including post-endoscopic mucosal resection (EMR) tissue persistence with a scarred base and residual tissue from the peripheral margins following EMR. The physician may consider the use of prophylactic injection or hemostasis instrumentation.

EndoRotor use during Endoscopic Mucosal Resection

Orientation:

Adjust the scope position 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), indicating the cutter is positioned exactly 90° from each set. A perpendicular solid black line indicates the center of the cutting opening (Figure 4b).

Resection

Activate the EndoRotor by engaging cutter rotation by depressing the blue pedal once. Position the tip of the EndoRotor onto the tissue, then continuously depress the orange pedal (suction) and resect the target tissue. The EndoRotor resects approximately 3mm – 5mm biopsy sized fragments every second the vacuum is engaged. This occurs by suctioning tissue into the device window and completing a cut with an inner rotating blade. Move the scope in a distal to proximal movement or torque the endoscope while cutting (Figure 5a, 5b).



Figure 3 Physician using rotation handle

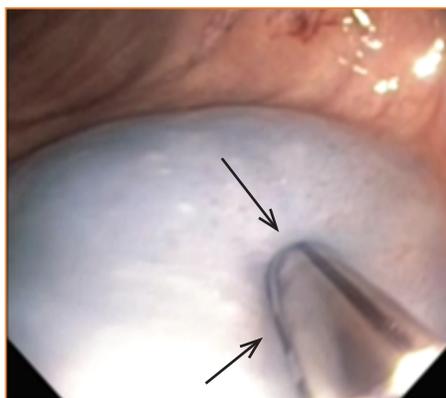


Figure 4a Solid and hashed lines indicating orientation

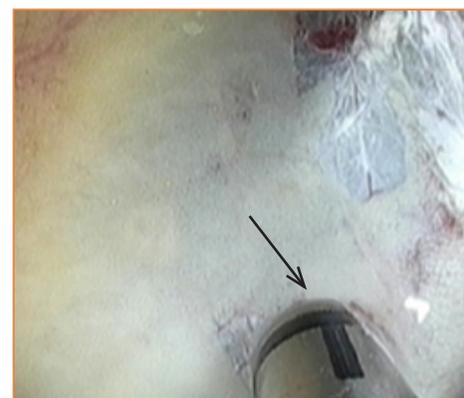


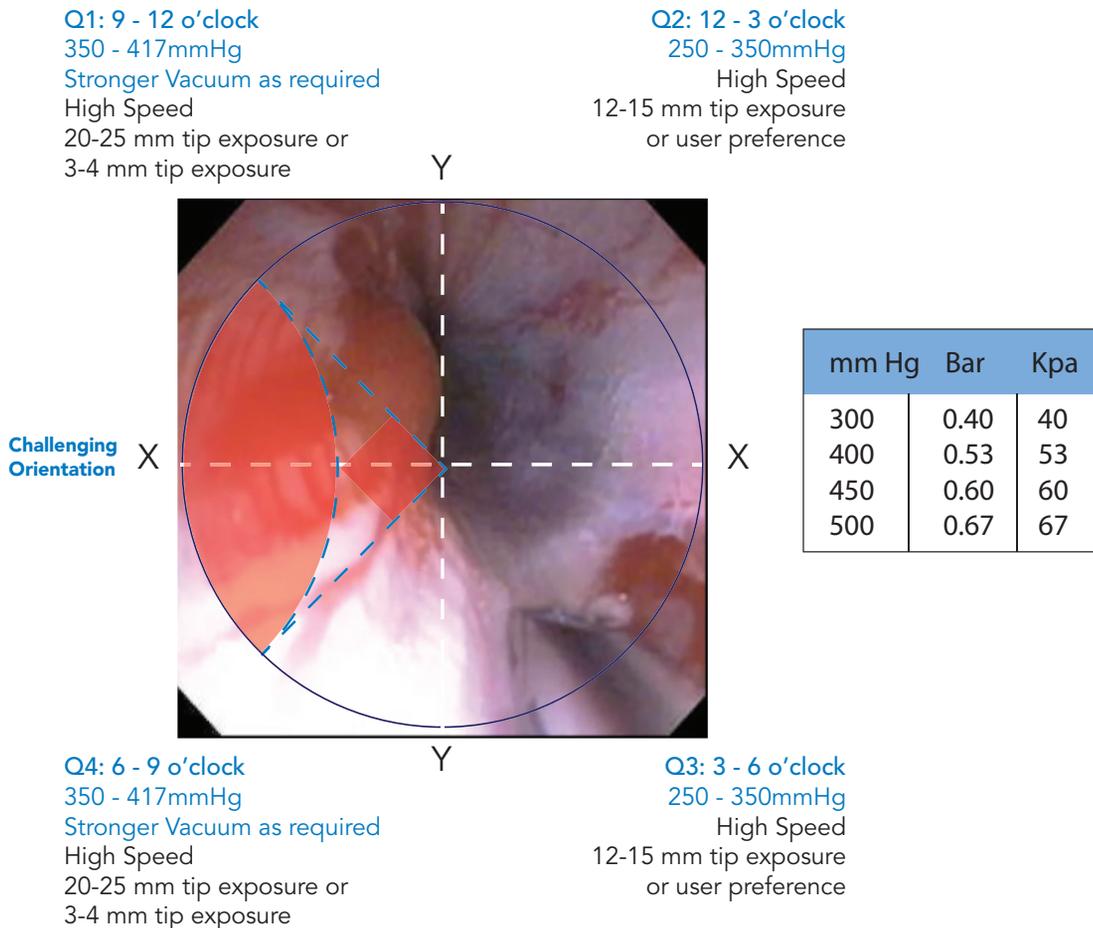
Figure 4b Line indicating center of cutter

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 approximately 15 seconds. To stop the rotation, depress the blue pedal or merely wait for the 15-second timeout. This tap and inspect approach allows the physician to carefully resect a target site in a safe manner.

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 in colonoscopes 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. Tip exposure should never exceed 30mm. however variable tip exposure can facilitate resection. If cutting in 3 or 9 o'clock positions then longer 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)



Approach parameters chart without anatomy

Figure 6 Approach parameters chart without anatomy

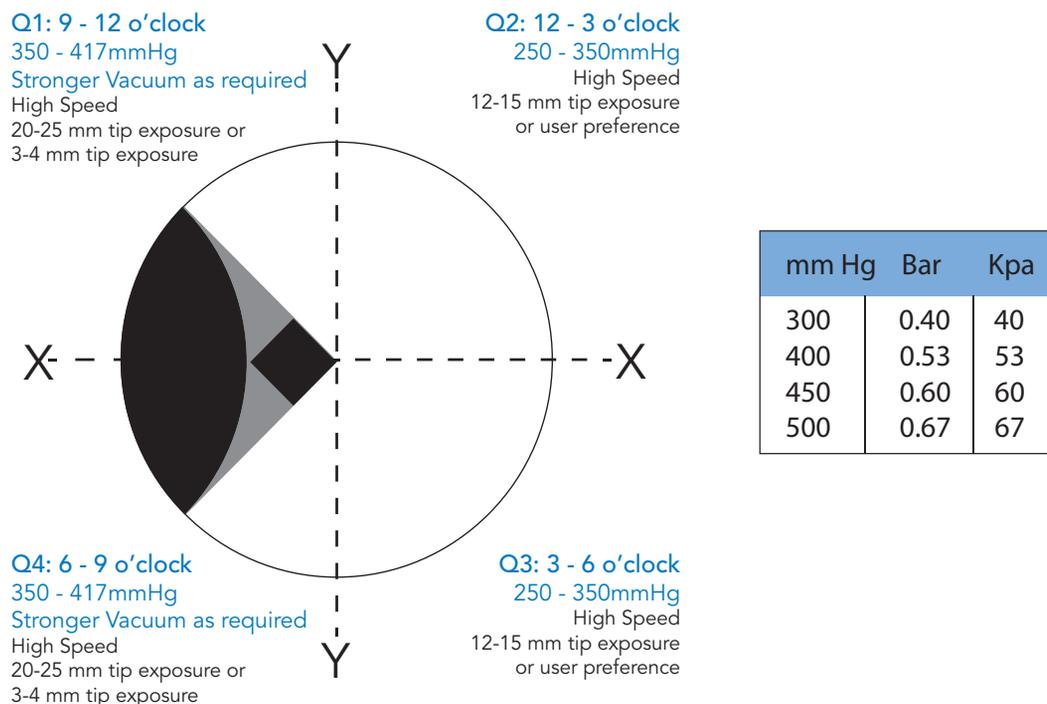


Figure 7a Cutting tip positioned in 6 o'clock orientation - touch and retract technique

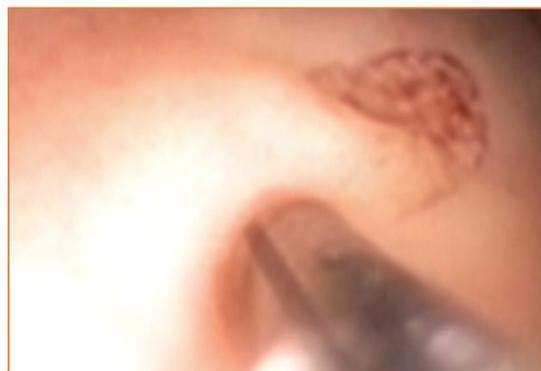


Figure 7b Resection after 1-second retraction

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 rotation of the EndoRotor tip is clockwise cutting which makes 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.



Figure 8a linear dissections creating circumferential margin start of left



Figure 8b linear dissections on right side moving down



Figure 8c linear dissections - completion of circumferential margin

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.



Figure 9 Frontal planar resection

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-OP	EndoRotor® Catheter 3.2mm x 1890mm
ER 10-01-OP-S	EndoRotor® Catheter 3.2mm x 1890mm
ER 10-02-O	EndoRotor® Catheter 3.2mm x 1540mm
ER 10-02-OP	EndoRotor® Catheter 3.2mm x 1450mm
ER 10-03-OP	EndoRotor® Catheter 3.2mm x 1240mm
ER 10-03-OP-S	EndoRotor® Catheter 3.2mm x 1240mm
ER 10-03-F-S	EndoRotor® Catheter 3.2mm x 1270mm
ER 10-03-F	EndoRotor® Catheter 3.2mm x 1270mm
ER 30-01	EndoRotor® Specimen Trap
ER 40-01	EndoRotor® Filter Set
ERC 20-01	EndoRotor® Console
ER-SYS-KIT	EndoRotor® System Kit: Console, Roll stand, Vacuum, and accessories
ERC 20-06-US	Vacuum Pump Dominant Flex

Technical Contact Information:

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