# Table of contents

- Indications ........................................... 3
- Console Features ................................... 3
- Catheter Features ................................... 3
- Complete Standard Colonoscopic Evaluation ...... 4
- Identify & Assess the Mucosal Lesion ............. 4
- Prepare the Instrument .............................. 4-8
- Techniques to Resect a Mucosal Lesion May Vary Based on the Size and Morphology .................... 9
- Colon Polyps ........................................ 9
- Resection ............................................. 9
- Simple Polyp Resection .............................. 9
- Endoscopic Mucosal Resection (EMR) of Larger Polyps ........................................ 10
- Establishing a Circumferential Margin ............ 10-11
- Planar Resection .................................... 11
- Resected Specimen ................................ 11
- Examples of Pathology .............................. 12
- Technical Contact Information ..................... 12
Indications:

The EndoRotor™ System is intended for the removal of alimentary tract mucosa during colonoscopy.

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.

Console Features
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

Catheter Features
1. Single Proximal Connection for Ease of Setup
2. Vacuum Tubing Load into Vacuum Control Valve
3. Irrigation Tubing Load into Irrigation Pump
4. Inner Cutting Cannula
5. Compatibility
   ≥3.2mm channel or greater
   ≥1680mm length scope
Complete Standard Colonoscopic Evaluation

Identify & Assess the Mucosal lesion:
Standard endoscopic assessment techniques should be used when evaluating a lesion for resection. The EndoRotor is designed for complete resection of mucosal lesions. Consider using submucosal injection for larger lesions similar to standard endoscopic mucosal resection technique.

Prepare the instrument:
Connecting the catheter to the console and inspecting the connections.

1. Ensure the console female connection is in the unlocked position.
2 Insert the proximal catheter hub into its female connection and ensure the hex connection aligns in the console receiving connection. This may require some slight rotation between 1 – 7.5 degrees of rotation, aligns in the console receiving connection. This may require some slight rotation between 1 – 7.5 degrees of rotation.

3 Once the connection is aligned and inserted, gently push the connector to its maximum allowable depth, which requires compressing a small internal spring. Next rotate the locking lever completely to the right, into the locked position.

4 The user must hold the catheter housing in place until the lock is engaged.
On the bottom surface of the proximal hub are 2 connected tubing sets. The shorter set closest to the console is the vacuum tubing connection. The vacuum control valve is directly.

To load the tubing, press the valve release button directly to the right of the power button. This will open the valve for 10 seconds to ease insertion of the tube. Use 2 hands to stretch a 2-4 inch segment of tubing and gently push the stretched segment into the valve until you hear a slight pop indicating the valve has engaged the tubing. One should also be able to visually see the tubing is completely within the valve not just one portion. If this takes more than 10 seconds the valve release button can be pressed again.
7 The lower portion of the specimen trap must be connected to available vacuum tubing of sufficient length to connect the trap to an overflow container.

8 The vacuum tubing must be connected to the top of the specimen trap by pressing it onto the connection.

9 The remaining standard vacuum tubing must be connected to an overflow canister for excess fluid, which is connected to procedure room or portable vacuum.

10 Ensure the irrigation pump at the lower right of the console face is open by using 2 hands and lifting the side (gray) bars of the pump until they are orientated 90 degrees to their closed position.
11 Take the irrigation tubing set and place on top of the rollers in the pump. Tubing should flow from left to right with the segment that exits the pump on the right going directly to the proximal connection as shown.

12 Close the side bars of the tubing to lock in place

13 Take the irrigation-tubing segment on the left of the peristaltic pump and use the bag spike and press into a standard irrigation bag of either water or saline.

14 Press the prime/irrigation button , which is directly to the right of the vacuum valve release button. If bubbles in the saline/water bag are visible then the irrigation tubing is loaded backwards.
Techniques to Resect a Mucosal Lesion May Vary Based on the Size and Morphology.

Colon Polyps:
The EndoRotor™ is a cold resection device. Mild bleeding can occur when using the device and while moderate bleeding may occur the device does not preclude the use of APC Coagulation or hemostasis using available instrumentation.

Resection:
Adjust the angle of approach to the desired trajectory. Using 2 fingers rotate the rotation hub to obtain the desired position of the outer cutter. The solid black line indicates that the cutter position is exactly 180° away. On either side of the black line are dotted lines. This indicates the cutter is positioned exactly 90° from the lines. A perpendicular solid black line indicates the center of the cutting orifice.

Simple Polyp Resection:
Activate the EndoRotor™ by first engaging cutter rotation by tapping on the left yellow pedal. Position the tip of the EndoRotor™ onto the polyp, then tap the right blue pedal, which adds suction, and shaves off the lesion. The EndoRotor™ resects approximately 3mm – 5mm lesions in a single tap once vacuum is engaged. Pulling away or scope thumb wheel down to complete the resection should follow each tap. Retract the tip of the EndoRotor™ to inspect the resection site for to ensure completeness of lesion removal. Adjust the position and repeat suctioning to remove additional polyp tissue if needed. The motor will stop automatically after 10 seconds, if no suction was actuated. To stop the motor, tap the left yellow pedal. This tap and inspect approach allows the physician to carefully resect a polyp while maintaining a safe profile.
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 higher risk of immediate bleeding with removal of larger lesions. Use physician’s discretion to determine whether to use Epinephrine 1:100,000 as part of the injectate.

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

Establishing a Circumferential Margin:
Use the EndoRotor™ to remove tissue immediately surrounding the lesion to create a marginal path within healthy tissue and eventually assure complete resection. Because of the rotational force of the EndoRotor™, general tip movement from left to right and from proximal to distal will help to follow the natural movement of the device and create this path.
The lesion can now be completely resected starting at the proximal margin of the lesion and by following a side to side movement, and removing the lesion in a horizontal (side to side) fashion. Because of the rotational pull, the resection should start on the left margin and continue to the right margin of the lesion. The vacuum (right pedal) can be engaged at all times as long as the tip continuously moves across the lesion. The physician will observe the rapid removal of mucosa and should not keep the cutting surface in one place while using suction to employ the safest technique. Once the right margin is reached the right pedal should be disengaged and the tip positioned back to the left margin to restart the next “row” of resection. The side-to-side movement should be repeated until the entire lesion is removed.

Planar Resection:
Medium size 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 of the rotating and vacuum engaged cutter until the lesion is completely resected. Variation in location and morphology of the polyp may require adjustment in the direction of the cutter.

Resected Specimen:
Once the operator resected the specimen the need may arrive to 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. 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.
Examples of Pathology:

EndoRotor™ specimen from in-vivo porcine experiments. Treatment (asterisk) extends well into colon submucosa but muscularis externa is unaffected and remains intact.

EndoRotor™ specimen from in-vivo porcine experiments. High magnification of EndoRotor™ colon specimen demonstrates excellent preservation of histologic features.

EndoRotor™ specimen from in-vivo porcine experiments. High magnification of additional EndoRotor™ colon specimen with excellent preservation of architecture and cellular detail.

Technical Contact Information:

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