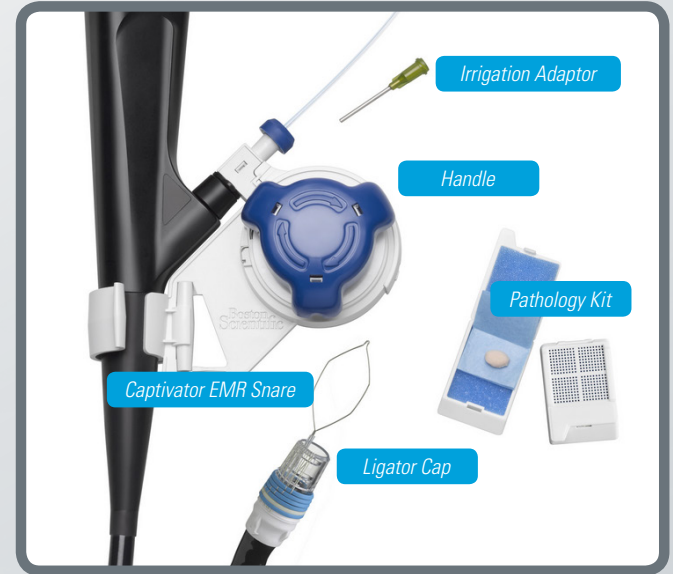


Captivator™ EMR Device Preparation for Use

The Captivator EMR Device is specifically designed for ligation-assisted Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) tract.



Device Set-Up

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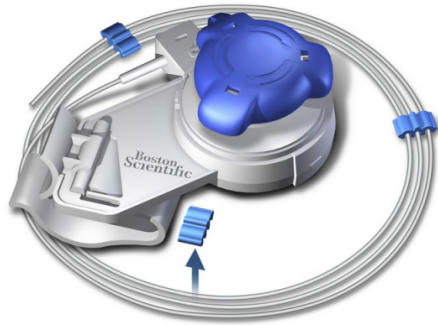


Illustration 1

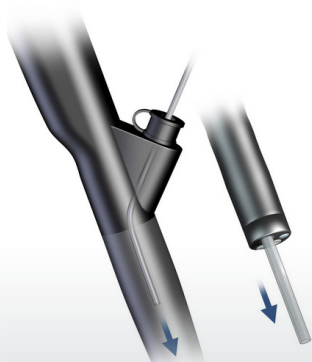


Illustration 2

Attach Handle Unit to Endoscope

- Step One** Straighten the endoscope
- Step Two** Remove clips from plastic sheath (illustration 1)
- Step Three** Feed sheath through biopsy cap, advance through the working channel of the endoscope until it exits through the distal end (illustration 2)

Attach Handle Unit to Endoscope

Step Four Firmly seat the handle into the biopsy cap (illustration 3) and snap scope fastener onto endoscope (illustration 4)

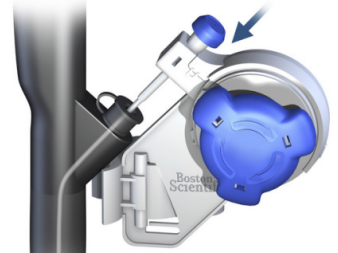


Illustration 3

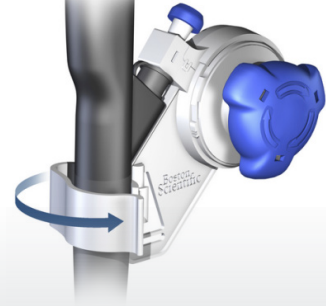


Illustration 4

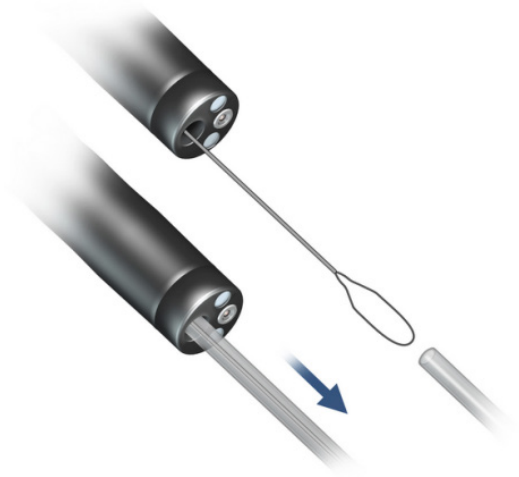


Illustration 5

Remove Sheath to Expose Trip Wire

Step Five Remove the plastic sheath from scope by pulling it from the distal end of the endoscope until it is fully detached and the metal trip wire is visible (illustration 5).

Discard the plastic sheath.

Attach Ligating Unit to Trip Wire

Step Six Attach suture loop of ligator cap to the loop on distal end of metal trip wire (illustration 6) by threading suture loop through trip wire loop (illustration 7), then threading ligator cap through suture loop (illustration 8)

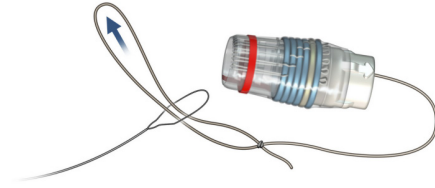


Illustration 6

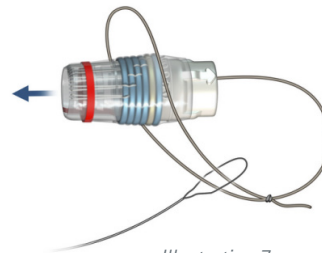


Illustration 7

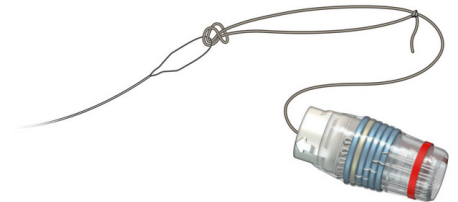


Illustration 8

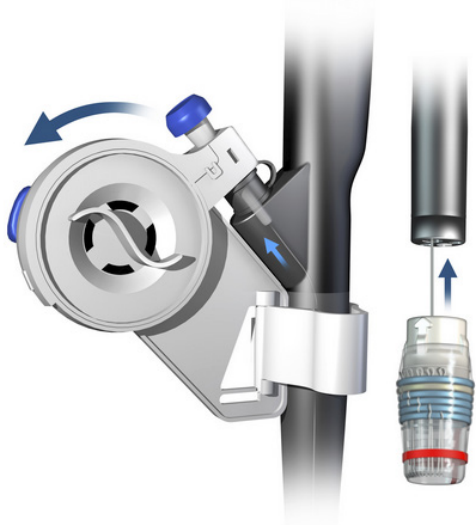


Illustration 9

Attach Ligating Unit to Scope

Step Seven Remove the slack in the line using the S-shaped knob by turning away from the scope (illustration 9). Stop turning when the soft proximal end of ligator cap is almost touching the distal end of endoscope. **DO NOT USE BLUE HANDLE TO TIGHTEN**

Step Eight If desired, apply lubricant to the distal end of the exterior of the endoscope sheath.

Attach Ligating Unit to Scope

Step Nine Line up the arrow on the soft proximal end of the ligator cap with the working channel of the endoscope (illustration 10).

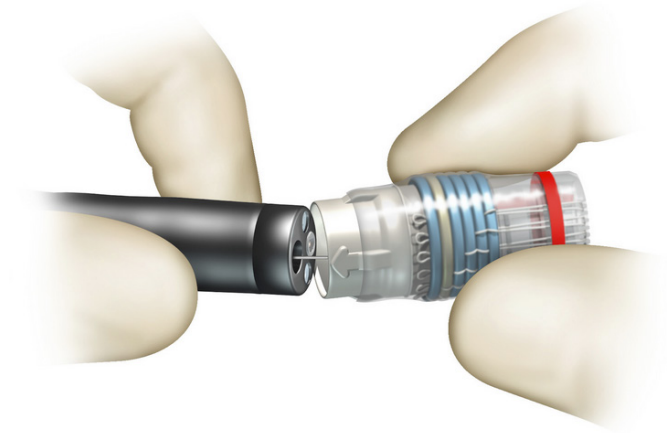


Illustration 10

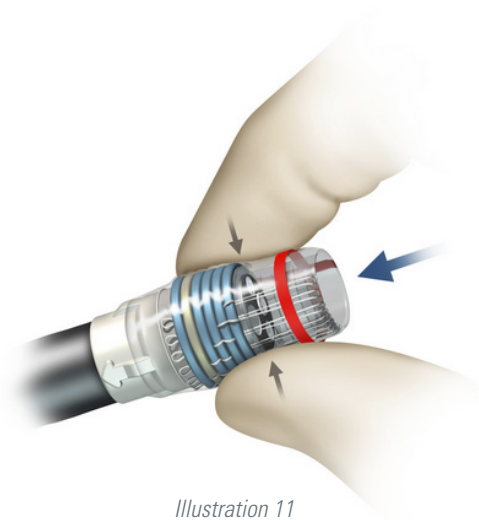


Illustration 11

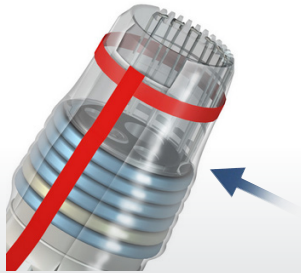


Illustration 12

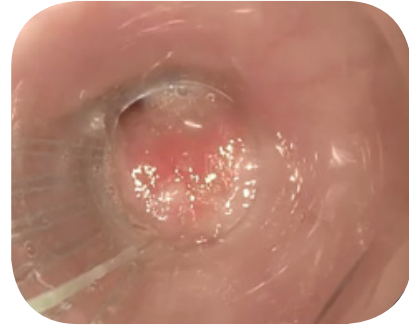
Ensure the Ligator Cap is Fully In Place

Step Ten Secure ligator cap to endoscope by twisting or rocking softer proximal end of ligator cap while pushing it onto distal tip of endoscope (illustration 11). The ligator cap should be pushed until tip of endoscope is up against the inner rim of ligator cap **with the endoscope visible over the first band** (illustration 12).

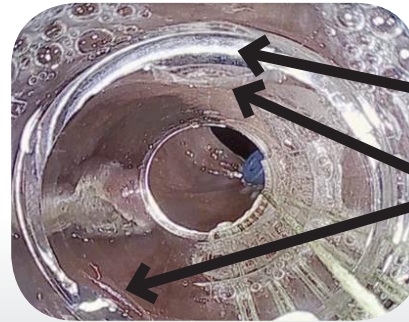
Ensure the Ligator Cap is Fully In Place (Continued)

To ensure correct set-up:

- Ensure view is not obstructed
- NO blue bands in view
- NO stops in view
- NO cap seam in view



Correct Set Up



Incorrect Set Up

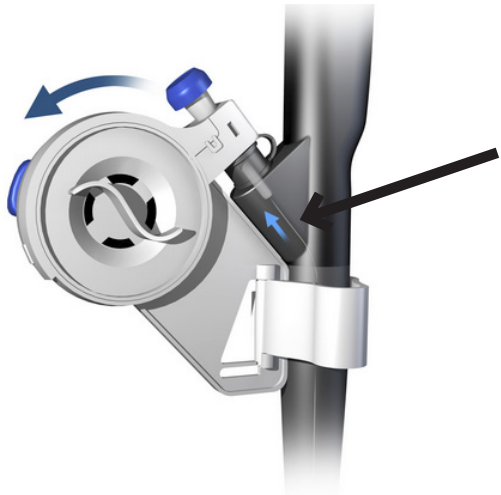
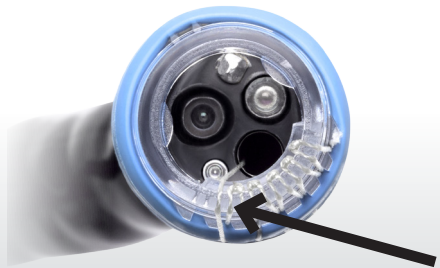


Illustration 13

Remove Slack from Trip Wire

Step Eleven Turn the S-shaped knob to take up remaining slack until the white suture is visibly taut.

**DO NOT USE BLUE HANDLE TO TIGHTEN.
DO NOT OVERTIGHTEN.**



Complete Preparation for Use

Step Twelve Carefully remove the shrink wrap from the ligator cap by pulling marked tab from the soft end of the cap, without disturbing the ligator bands and threads.

Clinical image showing 360 degree peripheral view of tissue in ligator cap, when cap is properly placed.

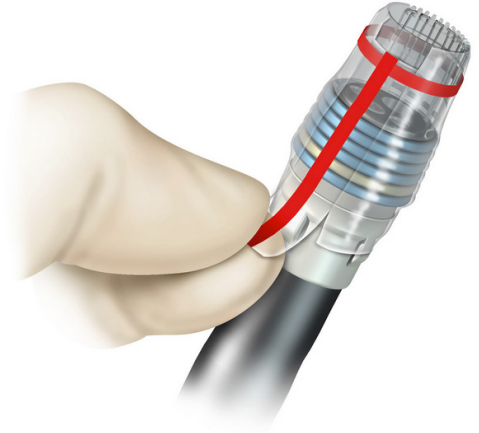
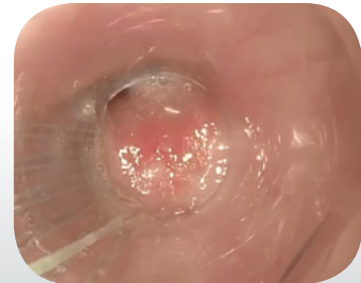


Illustration 14



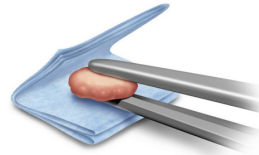
Pathology Kit Steps

If pathology is desired following pseudopolyp resection and retrieval, follow standard institutional guidelines.

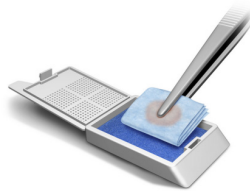
Retrieved tissue samples may be placed in Captivator EMR Pathology Kit per standard hospital procedures.



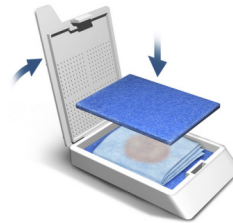
Step 1



Step 2



Step 3



Step 4



Step 5*

* This item is not included with the Captivator EMR Device

This overview is provided for illustrative purposes only and is intended only as a brief summary of how the operational steps during a procedure are generally performed. Please refer to the Directions For Use for complete instructions.

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All trademarks are the property of their respective owners.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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