

## DiLumen C<sup>2</sup>™

DiLumen C<sup>2</sup>, like DiLumen, consists of a soft flexible sheath that fits over standard and small diameter endoscopes. The device employs two balloons, one behind the bending section of the endoscope and the second in front of the tip. When both balloons are deployed and inflated, the area in between is stabilized.

In addition, DiLumen C<sup>2</sup> employs two 6 mm working channels at the 3 and 9 o'clock position of the endoscope. These working channels accommodate the DiLumen I<sub>G</sub>™ grasper and the DiLumen I<sub>S</sub>™ scissor.

The DiLumen C<sup>2</sup> and instruments are designed to improve stability and manipulation of tissue in the rectum and colon during complex endolumenal procedures such as Endoscopic Submucosal Dissection or ESD.

ESD continues to be a challenging procedure to learn and adapt to a clinician's practice. However, many of the current limitations of ESD can be overcome with the DiLumen C<sup>2</sup> and instruments.

Inadequate Tissue Retraction and Tension	Improved Tissue Retraction and Tension
<p><b>Current techniques lack proper:</b></p> <ul style="list-style-type: none"> <li>- Visualization of dissection plane</li> <li>- Gross tissue retraction</li> <li>- 3D Orientation</li> <li>- Tension assisted dissection</li> </ul>	<p><b>DiLumen C<sup>2</sup> and instruments enables grasping and repositioning of tissue:</b></p> <ul style="list-style-type: none"> <li>- Proper retraction of tissue</li> <li>- Contiguous tissue tension</li> <li>- Visualization of submucosal tissue plane</li> <li>- Precise dissection 'up and away'</li> </ul>
<p><b>This results in:</b></p> <ul style="list-style-type: none"> <li>- Very steep learning curve</li> <li>- High risk of perforation</li> <li>- Difficulty in treating bleeding</li> <li>- Lengthy procedures</li> <li>- Failed cases</li> </ul>	<p><b>This may result in:</b></p> <ul style="list-style-type: none"> <li>- A shorter learning curve</li> <li>- Lower perforation risk</li> <li>- Improved control of bleeding</li> <li>- Shorter procedures</li> <li>- More complete resection</li> </ul>
Inadequate Tissue Dissection	Improved Tissue Dissection
<p><b>Current techniques and instruments:</b></p> <ul style="list-style-type: none"> <li>- Provide only slow and tedious dissection to reduce risk of perforation</li> <li>- Limited ability to manage bleeding</li> <li>- Constant exchange of instruments</li> </ul>	<p><b>DiLumen C<sup>2</sup> and instruments enables controlled tissue dissection:</b></p> <ul style="list-style-type: none"> <li>- Electrocautery and mechanical cutting</li> <li>- Improved visualization to manage bleeding</li> <li>- Fewer instrument exchanges</li> </ul>
<p><b>This results in:</b></p> <ul style="list-style-type: none"> <li>- a slow and tedious procedure lasting hours</li> </ul>	<p><b>This may result in:</b></p> <ul style="list-style-type: none"> <li>- Faster and more precise dissection</li> </ul>

### DiLumen C<sup>2</sup> and Instruments Intended Use/Indication for Use:

- The Lumendi DiLumen C<sup>2</sup> is an endoscope accessory intended to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, and endoscopic treatment. The DiLumen C<sup>2</sup> is intended for use with endoscopes having distal tip diameters between 11.5 mm and 14.3 mm in 501k.
- The DiLumen Endolumenal Interventional Grasper ("DiLumen I<sub>G</sub>") is a sterile, single use, disposable endoscope accessory intended to be used for grasping and manipulating tissue within the digestive tract under direct endoscopic visualization.
- The DiLumen Endolumenal Interventional Scissors ("DiLumen I<sub>S</sub>") is a disposable monopolar electrosurgical device intended to be used for cutting, dissecting, and cauterizing tissue within the digestive tract during endoscopic procedures.



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