EUSRA™ Endoscopic Ultra Sound guided Radiofrequency Ablation electrode

Caution: Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE: The EUSRA RF Electrode is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

CONTRAINDICATION: There is a risk that error may result due to the radiofrequency current when it comes to the patients who get transplanted with the pacemakers and cardioverter/defibrillators what are used to put into the body. Thus, do not use the radiofrequency lesion generator and electrode.

POTENTIAL COMPLICATIONS: Burning by overheating of surgical unit; Dangers from inexperienced operator's using; Side effects or cross infection from reuse; Weakness of liver functions; Delayed bleeding in the operated body parts; Recurrence of cancer; Syndromes after RFA treatment such as perforation, respiratory depression or arrest, abdominal pain, fever, nausea, vomit, right shoulder joint pain and chest discomfort and headache) might occur. The Potential complications are not limited to the above, and other complications may occur by using Endoscope.

See Instructions for use and User's guide for full product information.
Features

- Feasible and Safe ablative treatment for soft tissue with a focused application of controlled energy and minimal procedure time.
- Easy to use, all-in-one system, that reduces procedural steps and time of RFA treatment.
- Superb device visualization under EUS.
- Exclusive inner cooling system which eliminates charring of soft tissue.
- Controlled RFA environment with specialized VIVA Combo generator.

Ablation volume with EUSRA™ 19 Gauge

<table>
<thead>
<tr>
<th>Bovine ex-vivo test</th>
<th>Width x Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10W 10Sec</td>
<td>5.6x6.9(mm)</td>
</tr>
<tr>
<td>20W 15Sec</td>
<td>7.6x9.0(mm)</td>
</tr>
<tr>
<td>30W 20Sec</td>
<td>8.6x14.0(mm)</td>
</tr>
</tbody>
</table>

- Tip: 5mm
- Tip: 7mm
- Tip: 10mm

* Ablation volume is dependent upon status, temperature and humidity of tissue

Ordering Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Tip Length (mm)</th>
<th>Flexible Length (mm)</th>
<th>Tip Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-05E</td>
<td>5</td>
<td>1393 ± 20</td>
<td>19G (1.06mm)</td>
</tr>
<tr>
<td>19-07E</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19-10E</td>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference

- EUS-guided radiofrequency ablation for management of pancreatic insulinoma by using a novel needle electrode by Sundee Lakhtakia et al (Gastrointest Endosc. 2016 Jan;83(1):234-9)
- Initial experience of EUS-guided radiofrequency ablation of unresectable pancreatic cancer by Tae Jun Song et al (Gastrointest Endosc. 2016 Feb;83(2):440-3)
- Technique, safety, and feasibility of EUS-guided radiofrequency ablation in unresectable pancreatic cancer by Filippo Scopelliti et al (Surg Endosc. 2018 May 15)
- Endoscopic ultrasound-guided radiofrequency ablation for pancreatic neuroendocrine tumors and pancreatic cystic neoplasms: a prospective multicenter study by Marc Barhet et al (Endoscopy, 2019 Jan 22)