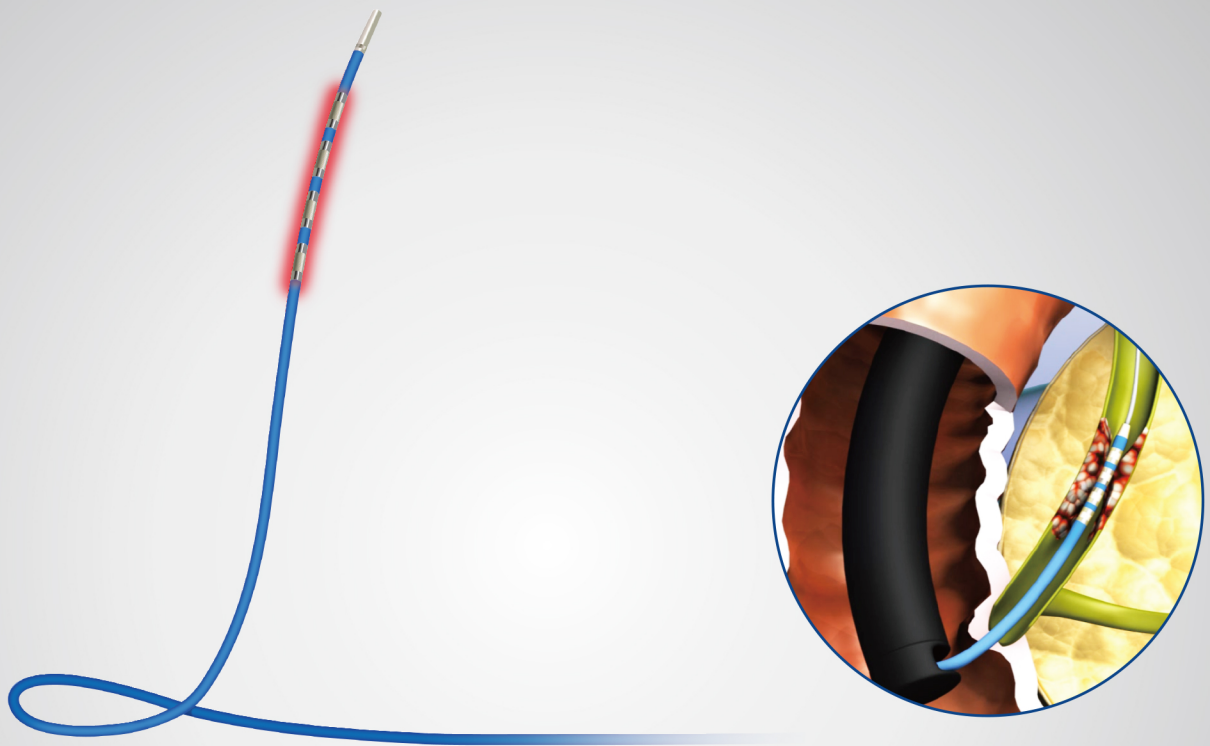


ELRA™

Endo Luminal Radiofrequency Ablation electrode



ELRA™ Endo Luminal Radiofrequency Ablation electrode

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

INTENDED USE: The ELRA Electrode is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.

CAUTIONS: Reuse is prohibited; Designed to be used by a qualified and trained Medical doctor; Do not touch the exposed tip of electrode while power supply is on; Do not touch hand piece/electrode cable with metallic materials; Do not use when cardiac pacemaker is placed within 4 meters; Do not use near conductive materials such as part of metallic bed or spring embedded mattress; Do not use in the presence of flammable anesthetics, oxidation-reduction gases or any other flammable substances. It might be a cause of fire in the electrosurgical unit.

POTENTIAL COMPLICATIONS: Burning by overheating of surgical unit; Side effects or cross infection from reuse; Weakness of liver functions; Delayed bleeding in the operated body parts; Recurrence of cancer; Symptoms after RFA treatment include: Perforation, Respiratory depression or arrest. See Instructions for use and User's guide for full product information.

US representative: Taewoong Medical USA

4801 Wilshire blvd. Suite 280, Los Angeles, CA90010

E: info@taewoongusa.com T: +1.323.692.0028 F: +1.323.692.0038

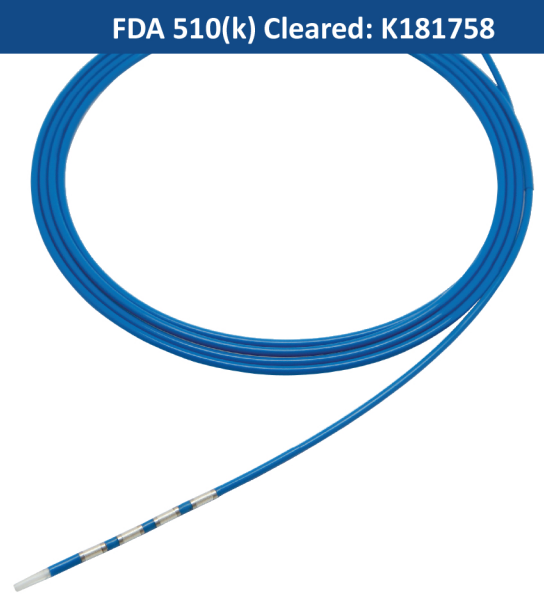
www.taewoongusa.com

Manufacturer:  STARmed

TaeWoong
MEDICAL 

Features

- Temperature Sensing System to manage consistent temperature of ablation zone
- Prevention of over-application of energy with specialized VIVA Combo™ generator's Impedance Monitoring System
- Various lengths (11mm, 18mm, 22mm, and 33mm) for the different anatomy and geometry of the stricture



Ablation volume with ELRA™

Bovine ex-vivo test

18mm

- Ablation Size: 6.3mm X 18.4mm (Diameter X Length)
- Setting: 80°C, 7W, 2min



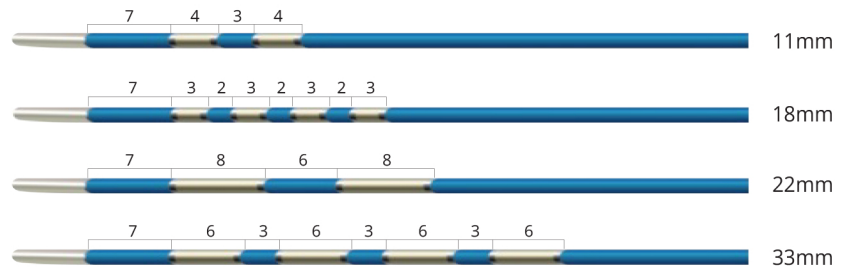
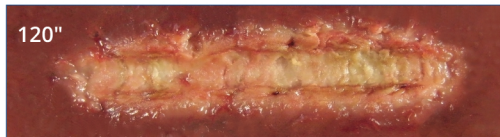
22mm

- Ablation Size: 7.7mm X 22.3mm (Diameter X Length)
- Setting: 80°C, 10W, 2min



Ablation Image (Bovine Liver)

Setting Condition: 75°C 10watt 2min



Ordering Information

Endoscopic Approach

Code	Total Length (cm)	Exposure Length (mm)	Diameter
7-2B11L	175	11	7Fr (2.31mm)
7-4B18L		18	
7-2B22L		22	
7-4B33L		33	

Reference

- A new intraductal radiofrequency ablation device for inoperable biliopancreatic tumors complicated by obstructive jaundice: the IGNITE-1 study by Wim Laleman et al [Endoscopy. 2017 Oct;49(10):977-982]
- Efficacy of endobiliary radiofrequency ablation for malignant distal biliary obstruction: multicenter experience of temperature controlled radiofrequency ablation by Eui Joo Kim et al
- Novel temperature-controlled RFA probe for treatment of blocked metal biliary stents in patients with pancreaticobiliary cancers: initial experience by Nayar ManuK et al [Endosc Int Open. 2018 May;6(5):E513-E517]
- Temperature controlled intraductal radiofrequency ablation for hilar cholangiocarcinoma by Dong Uk Kim [2015 DDW Abstract]
- Safety and effectiveness of endobiliary radiofrequency ablation according to the different power and target temperature in a swine model by Jae Hee Cho et al [J Gastroenterol Hepatol. 2017 Feb;32(2):521-526]