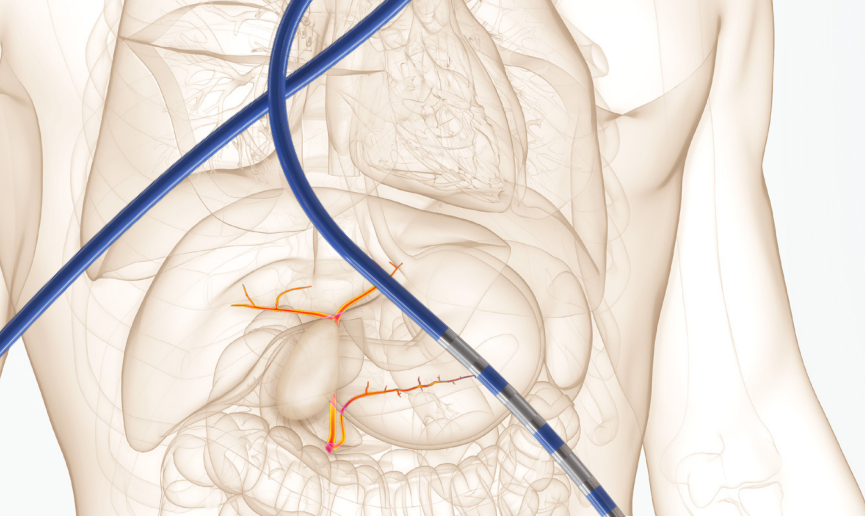


ELRA™

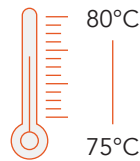
ENDOLUMINAL RADIOFREQUENCY ABLATION ELECTRODE



Dedicated Generator



VIVA combo RF Generator - Temperature Sensing System



Safe. Effective. Confirmative.

The ELRA Electrode is a radiofrequency (RF) catheter that provides bipolar energy to perform ablation of tissue in the biliary system. Combining with the VIVA combo Generator, it provides confirmation of a complete endobiliary ablation and offers a safe and effective solution.

The ELRA Electrodes come in a portfolio of sizes that enable physicians to target a variety of patient indications. Our 7FR catheter and conical tip promote uncompromised navigation through difficult anatomy.

Safely Perform Biliary Ablation²

- Working impedance monitoring with a dedicated generator
- Temperature and wattage control to ensure proper ablation
- Automatic shutoff when improper contact is made
- Real-time ablation monitoring from the generator to avoid false sense of ablation

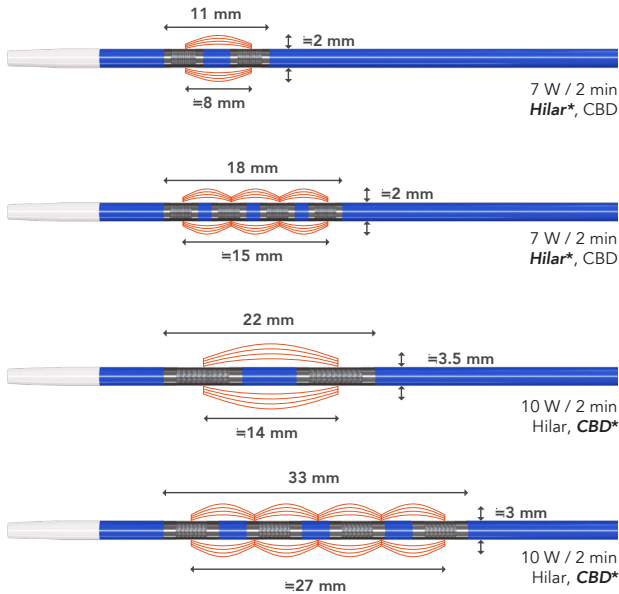
Article	A New Intraductal RF Ablation Device for Inoperable Biliopancreatic Tumors Complicated by Obstructive Jaundice¹	The Safety of Newly Developed Automatic Temperature-Controlled Endobiliary RF Ablation System for Malignant Biliary Strictures²
Study Design	Prospective, single-center, investigator-driven, open-label pilot study	Prospective, multicenter study
Patients Enrolled (n)	18	30
Conclusions	Intraductal RFA using the ELRA platform in patients with inoperable biliopancreatic cancer complicated by jaundice appeared feasible and safe with an acceptable biliary patency.	Temperature-controlled endoscopic RFA of the bile duct using a new RF catheter was safely performed in 30 patients. Temperature-controlled RFA avoids excessive heating and thus significant vessel or bile duct injury.
Complications	No complications within 3 months of the procedure	3 patients (10.0%; 2 mild pancreatitis and 1 cholangitis) without hemobilia and bile duct perforation.

Method of Action

ELRA offers a safe and effective method to perform endobiliary RFA.^{1,2}

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

ELRA Ablation Zone



*Recommended size for anatomy

DISCLAIMER: Bovine ex-vivo ablation results may vary from in-vivo test or clinical results due to different conditions. Animal Data is not necessarily indicative of human clinical outcomes.

REFERENCES

1. Laleman W, van der Merwe S, Verbeke L, Vanbeckevoort D, Aerts R, Prenen H, Van Cutsem E, Verslype C. A new intraductal radiofrequency ablation device for inoperable biliopancreatic tumors complicated by obstructive jaundice: the IGNITE-1 study. *Endoscopy*. 2017 Oct;49(10):977-982. doi: 10.1055/s-0043-113559. Epub 2017 Jul 21. PMID: 28732391.
2. Lee YN, Jeong S, Choi HJ, Cho JH, Cheon YK, Park SW, Kim YS, Lee DH, Moon JH. The safety of newly developed automatic temperature-controlled endobiliary radiofrequency ablation system for malignant biliary strictures: A prospective multicenter study. *J Gastroenterol Hepatol*. 2019 Aug;34(8):1454-1459. doi: 10.1111/jgh.14657. Epub 2019 Apr 14. PMID: 30861593.

IMPORTANT SAFETY INFORMATION

INDICATION

Treating malignant biliary obstruction caused by cholangiocarcinoma or pancreatic cancer.

CONTRAINDICATIONS

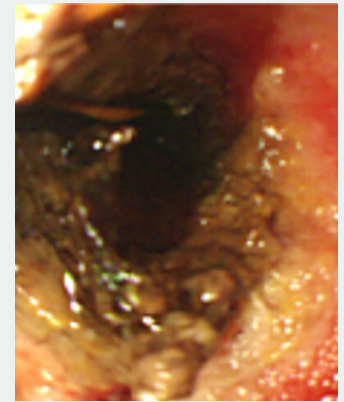
There is a risk that error may result due to the radiofrequency current on patients who have pacemakers and other active implants. Do not use the radiofrequency lesion generator and electrode on these patients.

Biliary Stricture

Before RFA



After RFA



Temperature-Controlled Intraductal Radiofrequency Ablation for Hilar Cholangiocarcinoma: Pilot Feasibility Study

Dong Uk Kim, Dong Hoon Baek, Chang Wong Kim, Geun Am Son

RFA in Right Duct



RFA in Left Duct



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POTENTIAL COMPLICATIONS

- Burning by overheating of surgical unit.
- Dangers from inexperienced operator's use.
- 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, (abdominal) pain, fever, nausea, headache, right shoulder joint pain and chest discomfort might occur.

The potential complications are not limited to the above, other complications may occur by using endoscope.