

StarBurst* MRI

RFA ELECTRODES

BENEFITS

- Compatible with MRI use
- A single device with the capability to produce scalable, spherical ablations (3-5 cm)
- Patented expandable, multi-array space filling configuration[†]
- Reliable, repeatable ablations^{††}
- Multi-point temperature feedback with dynamic, real-time readouts
- Beveled surgical tip for easier penetration of hard tissue

SPECIFICATIONS

- Nine arrays plus active trocar tip
- Five thermocouples



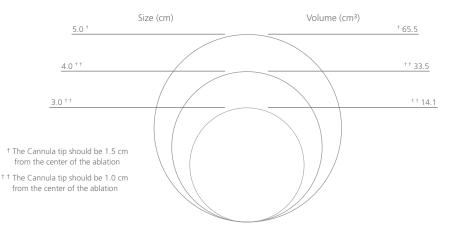
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MRI Scalable Spherical Ablations (3-5 cm)

Diagram drawn to scale



Product Name	Length	Part #	With Attached Cable	Outer Diameter (O.D.)
StarBurst MRI Electrode	10 cm	700-102441	700-103907	14 gauge/6.4 French
StarBurst MRI Electrode	15 cm	700-102421	700-103906	14 gauge/6.4 French
Main Cable (Green - 9 to 14 pin)	n/a	700-101892		n/a

Pre-attached Main Cable



Main cable is pre-attached for improved ease of use.

Model 1500X RF Generator

The Model 1500X RF Generator is designed specifically for use with RITA* electrosurgical devices. It is the latest radiofrequency generation system that features technological advances including software upgrade capabilities, potential for 250 watts of power, and three flexible serial ports.



IMPORTANT RISK INFORMATION

INDICATION FOR USE: The StarBurst MRI Electrosurgical Device is a tool to transmit monopolar radiofrequency energy (provided by the RITA 1500 or 1500X RF Generator) and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue including the partial or complete ablation of non-resectable liver lesions and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.

WARNINGS AND PRECAUTIONS: For single use only. Do not bend or kink the trocar or the needles; do not attach anything (i.e., clamps, etc.) to the Device, or use metal introducers that do not have insulation; inadvertent patient injury may result. To ensure safe

and effective use follow the manufacturer's directions and recommended practices for the preparation, placement, surveillance, removal and use of the dispersive electrode. To achieve the desired ablation follow the manufacturer's guidelines of ablation time and temperature. Ensure that the device is placed at least 1 cm away from structures not intended for ablation. In laparoscopic procedures, care must be taken to avoid a gas embolism, and activation of the device when not in contact with target tissue may cause capacitive coupling. In some cases, a liver lesion will only be partially destroyed; the final determination of the success of lesion destruction can only be made by imaging studies following the procedure and during regular long-term follow-up. For ablation of painful

bone metastases, do not perform RF ablation in weight-bearing bone with evidence of impending fracture. Pathologic fracture is more prevalent and serious in long bone. This product is MRI compatible to systems operating at 1.5 tesla or less (MRI conditional). Please see package insert for complete list of warnings and precautions.

Refer to individual product IFUs and/or User Manual to see full Warnings, Precautions, Possible Adverse Effects and Contraindications. Observe all instructions prior to use. Failure to do so may result in patient complications.

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



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- ¹ Covered by one or more of the following US patents: 5472441, 5486161, 5536267, 5672173, 5672174, 5683384, 5728143, 5782827, 5863290, 5913855, 5928229, 5935123, 5980517, 6071280, EP 0 777 445 B1, and Japanese patent 3009735. Other patents pending.
- ⁺⁺ SurgEndosc, E. Berber, NL Herceg, KJ Casto, & AE Siperstein, (2004) 18:390-396