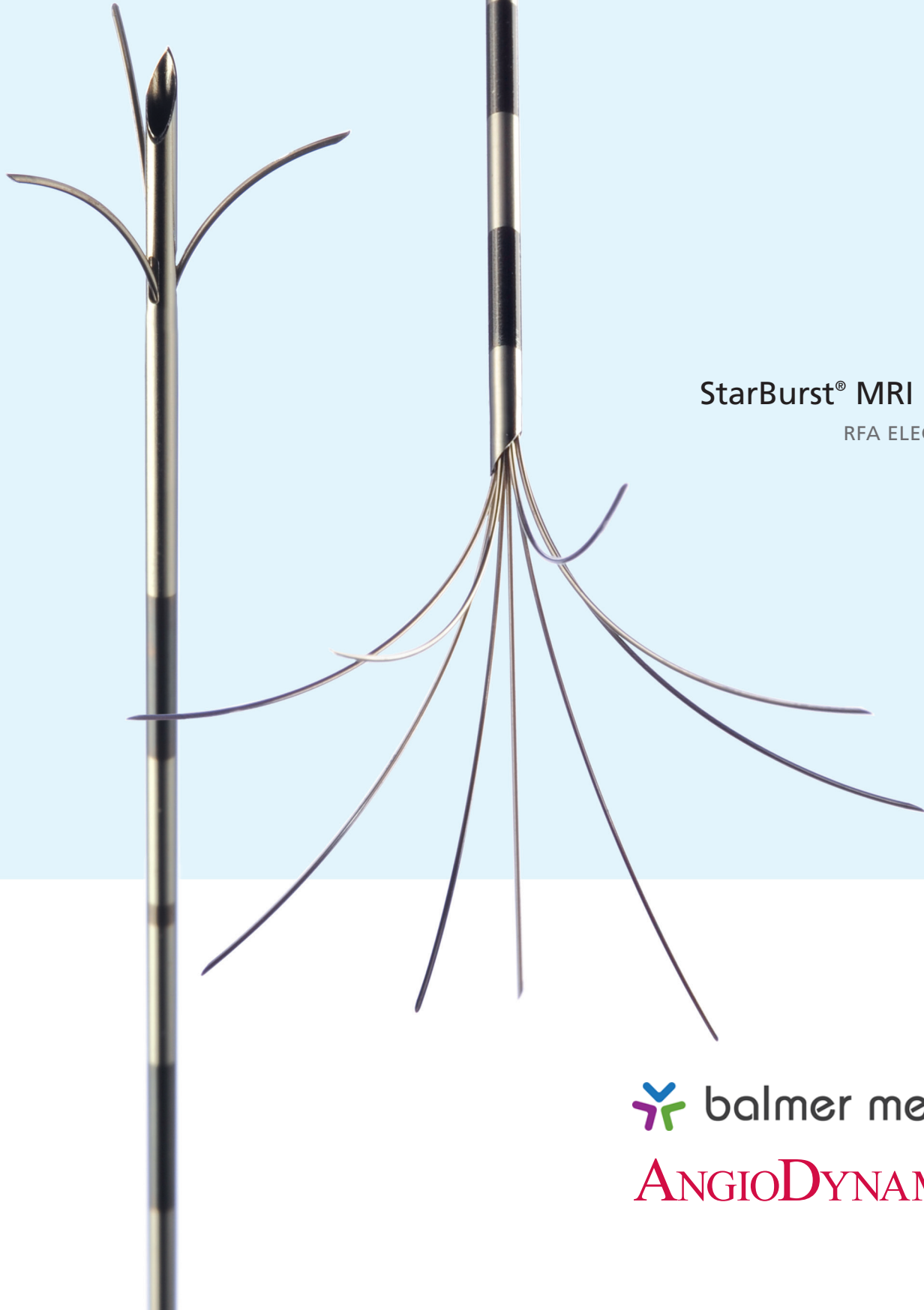


 **StarBurst**[®]
Radiofrequency Ablation Electrodes



StarBurst[®] MRI & SDE
RFA ELECTRODES

 balmer medical
ANGIODYNAMICS[®]

The Ultimate in Array Design

RADIOFREQUENCY ABLATION

StarBurst® MRI RFA Device

The StarBurst MRI RFA electrode is designed to enhance our family of disposable electro-surgical devices. This innovative adaptation of the StarBurst XL RFA electrode is compatible for use with magnetic resonance imaging (MRI) during device placement. This compatibility relates to magnetic field translational attraction, torque, RF heating, induced currents, and limited artifacts. Like the StarBurst XL RFA electrode, it is capable of creating spherical ablations in soft tissue from 3-5 cm in diameter. This member of the StarBurst XL RFA electrode family makes it possible to use RFA safely and effectively in an MRI environment.



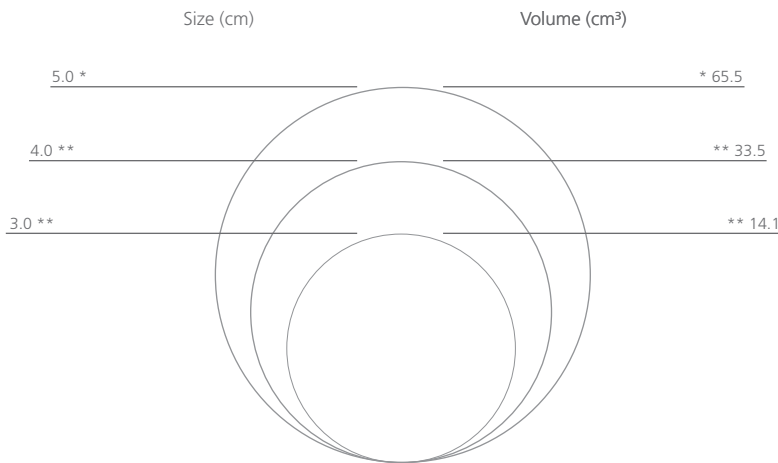
StarBurst® SDE RFA Device

The StarBurst SDE RFA electrode features a first in the industry: unique, side-deployed arrays that allow physicians to precisely position the trocar tip and see its location with greater ease. It is designed for small lesions, where a finer gauge may be of benefit. With the StarBurst SDE RFA electrode, stage deployment is not required. Instead, physicians deploy the device to the desired size and maintain the prescribed temperature and duration to complete the ablation. Like all StarBurst RFA devices, the SDE features controlled temperature monitoring, through multi-point temperature feedback.



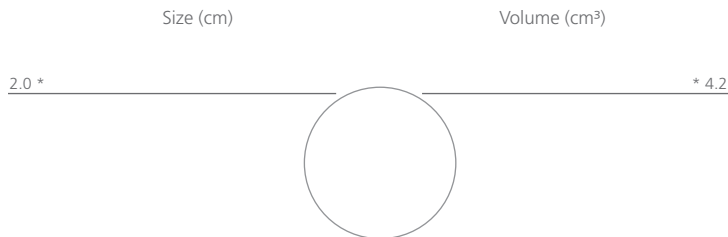
MRI Scalable Spherical Ablations (3-5 cm)

Diagram drawn to scale



SDE Scalable Spherical Ablations (2 cm)

Diagram drawn to scale



* The Cannula tip should be 1.5 cm from the center of the ablation

** The Cannula tip should be 1.0 cm from the center of the ablation

MRI 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[†]
- Predictable, repeatable ablations^{††}
- Multi-point temperature feedback with dynamic, real-time readouts
- Small minimally invasive incision with no soft tissue introducer required
- Beveled surgical tip for easier penetration of hard tumors

MRI SPECIFICATIONS

- Nine arrays plus active trocar tip
- Five thermocouples

SDE BENEFITS

- Straight needle with side-deployed arrays
- Small needle gauge and sharper trocar tip for easier access into the lesion site
- Smaller spherical ablations (2 cm)
- Dynamic, real-time temperature readouts
- Multi-point temperature feedback
- Patented side-deployment array design[†]

SDE SPECIFICATIONS

- Three arrays plus active trocar tip
- Three thermocouples

[†] 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

STARBURST® MRI ELECTRODES

Product Name	Length	Part #	Outer Diameter (O.D.)
StarBurst MRI Electrode	10 cm	700-102441	14 gauge/6.4 French
StarBurst MRI Electrode	15 cm	700-102421	14 gauge/6.4 French
StarBurst MRI Electrode w/ attached cable	10 cm	700-103907	14 gauge/6.4 French
StarBurst MRI Electrode w/ attached cable	15 cm	700-103906	14 gauge/6.4 French
Main Cable (Green - 9 to 14 pin)	n/a	700-101892	n/a
MRI Extension Cable (for 1500X, 14 to 14 pin)	n/a	700-102741	n/a
MRI Extension Cable (for 1500X, 9 to 9 pin)	n/a	700-102742	n/a

STARBURST® SDE ELECTRODES

Product Name	Length	Part #	Outer Diameter (O.D.)
StarBurst SDE Electrode	12 cm	700-102486	17 gauge/4.5 French
StarBurst SDE Electrode w/ attached cable	12 cm	700-103908	17 gauge/4.5 French

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 and SDE Electrosurgical Devices transmit monopolar radiofrequency energy (provided by the RITA® 1500 or 1500X RF Generator) and are 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.
CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.

CONTRAINDICATIONS: None known.

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. Please see package insert for complete list of warnings and precautions.

POTENTIAL COMPLICATIONS: Published reports on the use of the RFA system indicate low overall complication rates. These include bleeding, abscesses and, in cases involving the treatment of bone tumors, fractures and nerve damage.

Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

ANGIODYNAMICS®  **balmer medical**

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