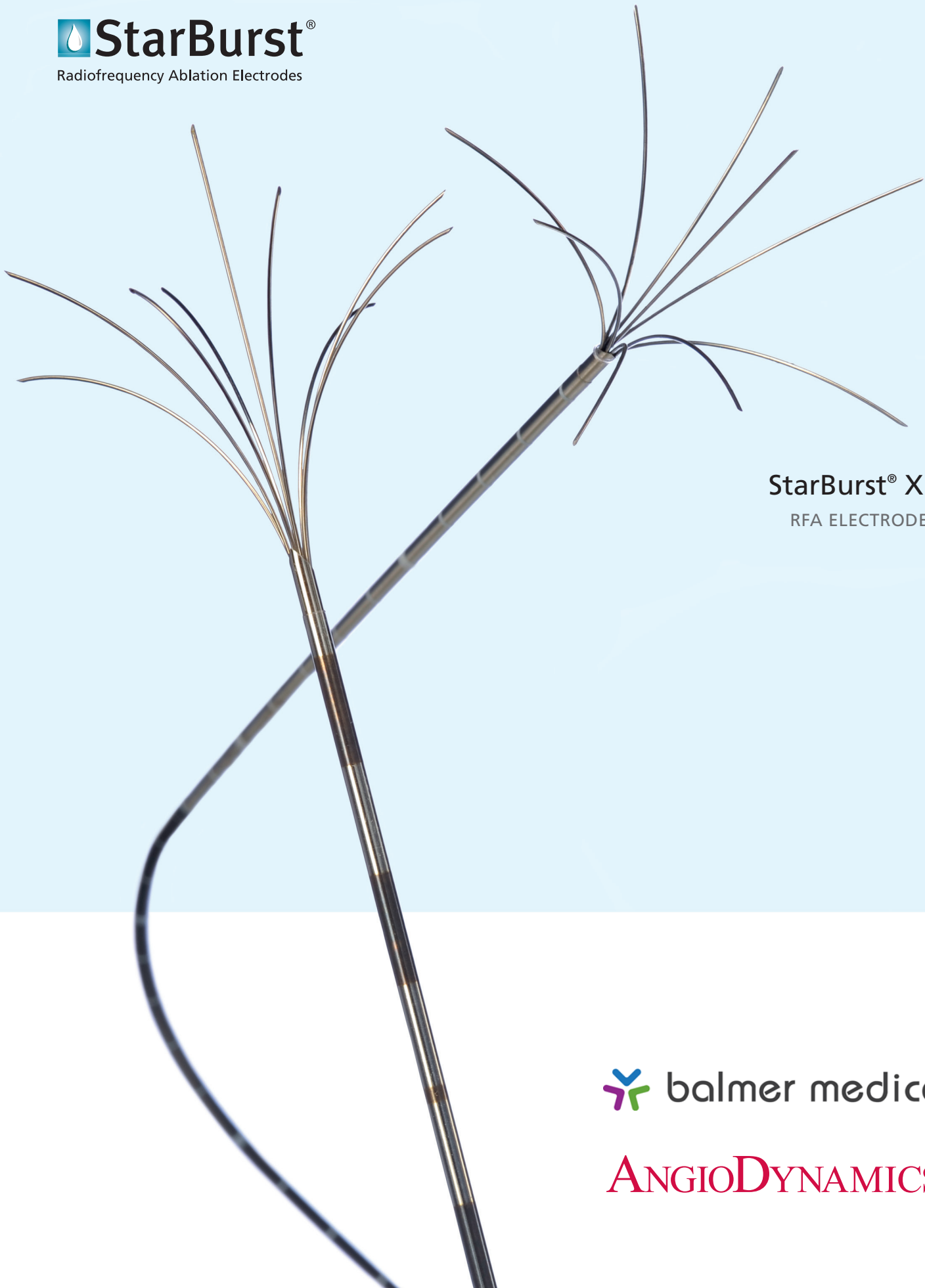


 **StarBurst**[®]
Radiofrequency Ablation Electrodes



StarBurst[®] XL
RFA ELECTRODES

 balmer medical

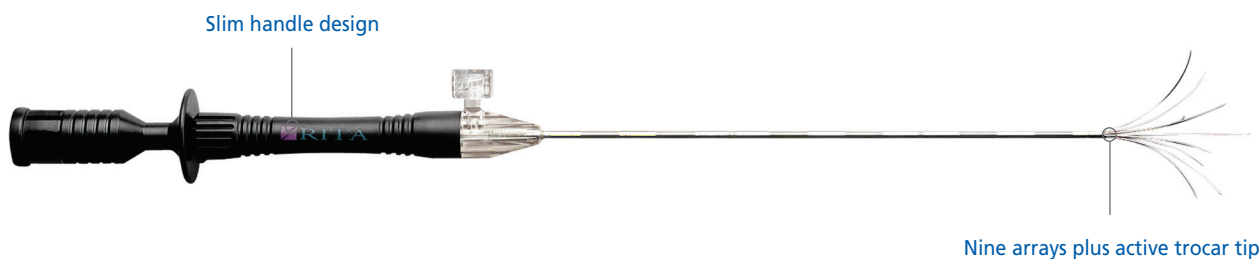
ANGIODYNAMICS[®]

The Ultimate in Array Design

RADIOFREQUENCY ABLATION

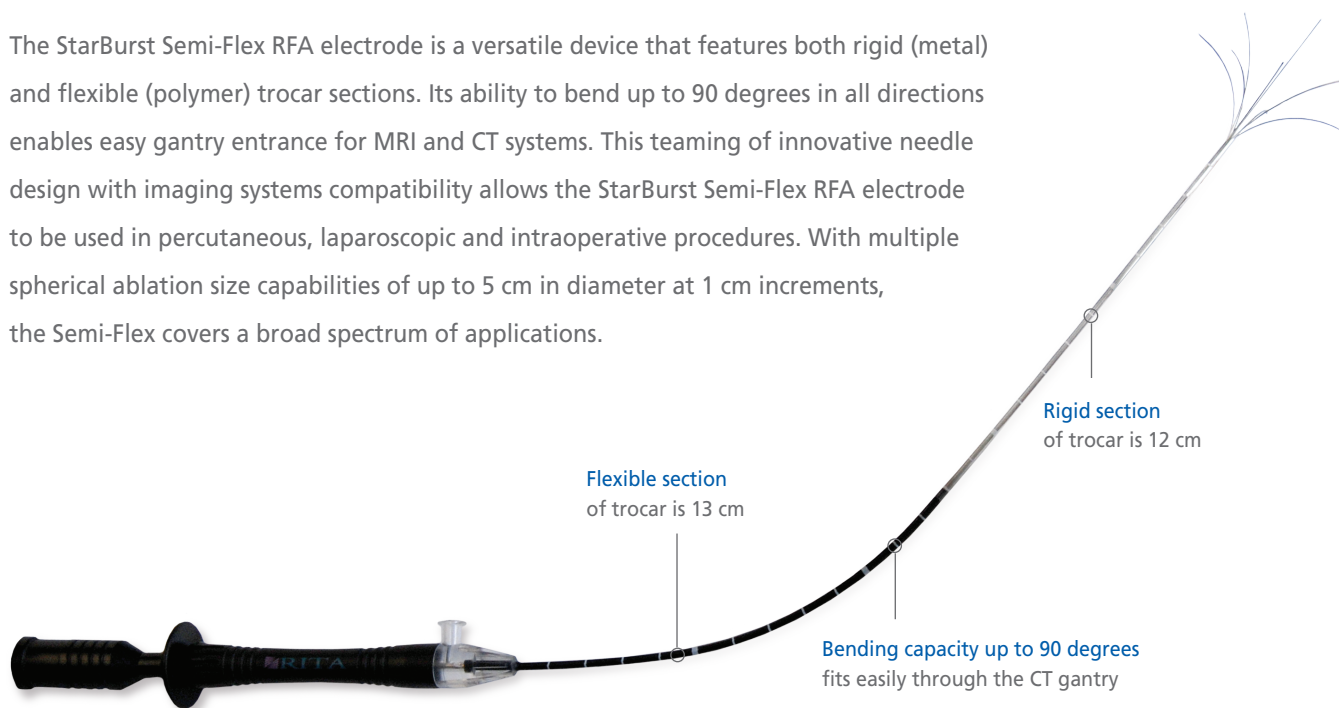
StarBurst® XL RFA Device

Its real-time, multi-point temperature feedback system ensures sustained target temperatures during the procedure. The patented temperature based end point provides predictable volumes of ablation with low local recurrence rates. Needle track ablation, adjustable array size, and temperature based technology of the revolutionary, first-generation StarBurst XL RFA electrode assures a high level of confidence that coagulative necrosis is taking place throughout the targeted radiofrequency interstitial tissue ablation.



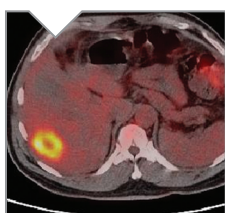
StarBurst® XL Semi-Flex RFA Device

The StarBurst Semi-Flex RFA electrode is a versatile device that features both rigid (metal) and flexible (polymer) trocar sections. Its ability to bend up to 90 degrees in all directions enables easy gantry entrance for MRI and CT systems. This teaming of innovative needle design with imaging systems compatibility allows the StarBurst Semi-Flex RFA electrode to be used in percutaneous, laparoscopic and intraoperative procedures. With multiple spherical ablation size capabilities of up to 5 cm in diameter at 1 cm increments, the Semi-Flex covers a broad spectrum of applications.

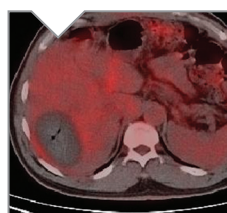


Because Temperature Matters

This minimally invasive RFA device ensures consistent, sustained target temperatures and enables the precise ablation of predictable volumes of tissue.



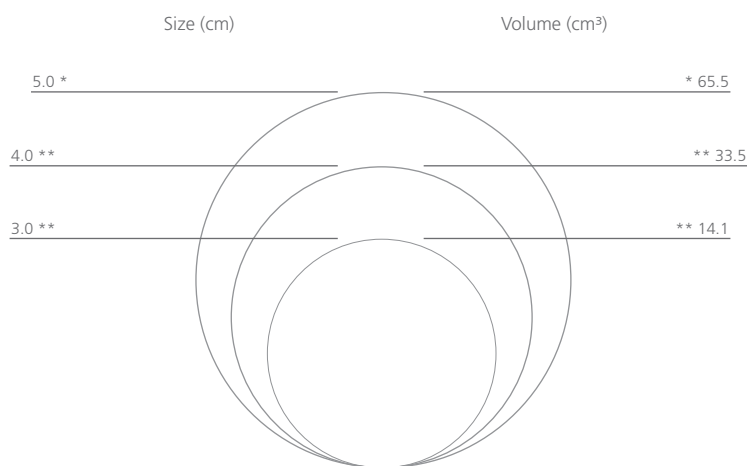
> Pre-Ablation



> Post-Ablation

Scalable Spherical Ablations (3-5 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

BENEFITS

- 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
- 5 mm active tip allows for needle track ablation
- Slim handle design
- Small minimally invasive incision with no soft tissue introducer required
- Fits both CT and MRI gantries
- Beveled surgical tip for easier penetration of hard tumors

SPECIFICATIONS

- Nine arrays plus active trocar tip
- Five thermocouples

531 ablated lesions in 154 patients confirmed the optimal algorithms for creating dependable, reproducible zones of ablation up to 5 cm with the StarBurst XL RFA device.

Laparoscopic radiofrequency ablation of hepatic tumors: Prospective clinical evaluation of ablation size comparing two treatment algorithms E. Berber, N. L. Herceg, K. J. Casto, A. E. Siperstein; *Surgical Endoscopy* (2004) 18: 390-396.

[†] 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® XL ELECTRODES

Product Name	Length	Part #	Outer Diameter (O.D.)
StarBurst XL Electrode	10 cm	700-101930	14 gauge/6.4 French
StarBurst XL Electrode	15 cm	700-101320	14 gauge/6.4 French
StarBurst XL Electrode	25 cm	700-101317	14 gauge/6.4 French
StarBurst XL Electrode w/ attached cable	10 cm	700-103903	14 gauge/6.4 French
StarBurst XL Electrode w/ attached cable	15 cm	700-103902	14 gauge/6.4 French
StarBurst XL Electrode w/ attached cable	25 cm	700-103901	14 gauge/6.4 French
Main Cable (Green - 9 to 14 pin)	n/a	700-101892	n/a

STARBURST® XL SEMI-FLEX ELECTRODES

Product Name	Length	Part #	Outer Diameter (O.D.)
StarBurst XL Semi-Flex Electrode	25 cm	700-102615	14 gauge/6.4 French
StarBurst XL Semi-Flex Electrode w/attached cable	25 cm	700-103909	14 gauge/6.4 French

COAXIAL ACCESS SYSTEM INTRODUCERS

Introducer Type	Length	Part #	XL 10 cm	XL 15 cm	XL 25 cm	XL Semi-Flex 25 cm
Soft Introducer	10 cm	700-102636	not compatible	to 12 cm mark	to 12 cm mark	to 12 cm mark
Soft Introducer	13 cm	700-102637	not compatible	to hub	to 15 cm mark	to 15 cm mark
Soft Introducer	23 cm	700-102638	not compatible	not compatible	to hub	to hub
Hard Introducer	6 cm	700-102330	to hub	to 10 cm mark	to 10 cm mark	to 10 cm mark
Hard Introducer	11 cm	700-102331	not compatible	to hub	to 15 cm mark	to 15 cm mark

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® XL 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. **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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