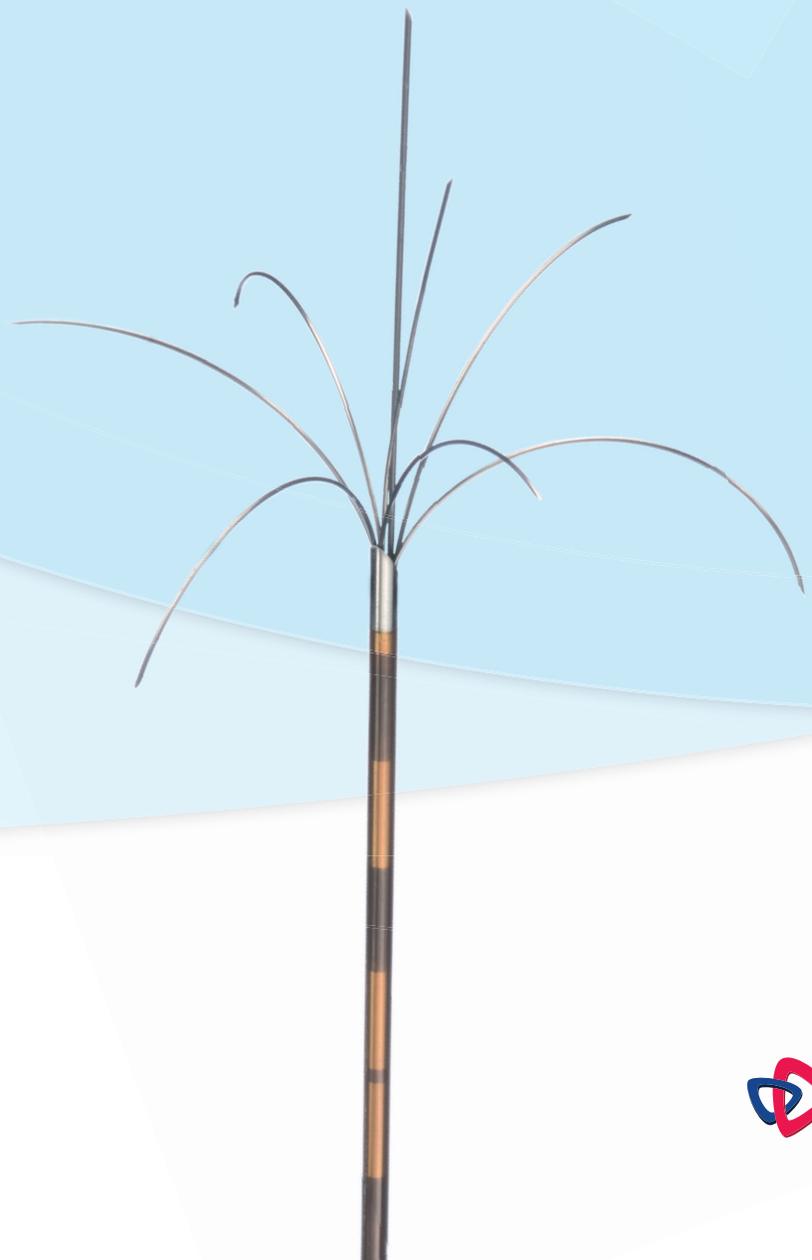




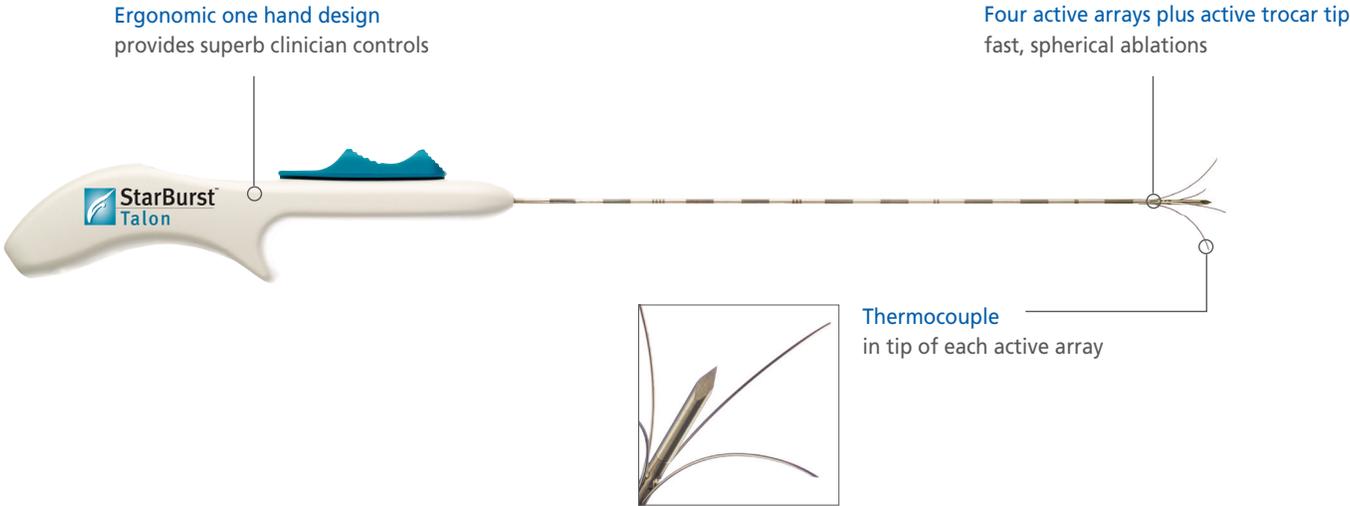
StarBurst

Radiofrequency Ablation Electrodes

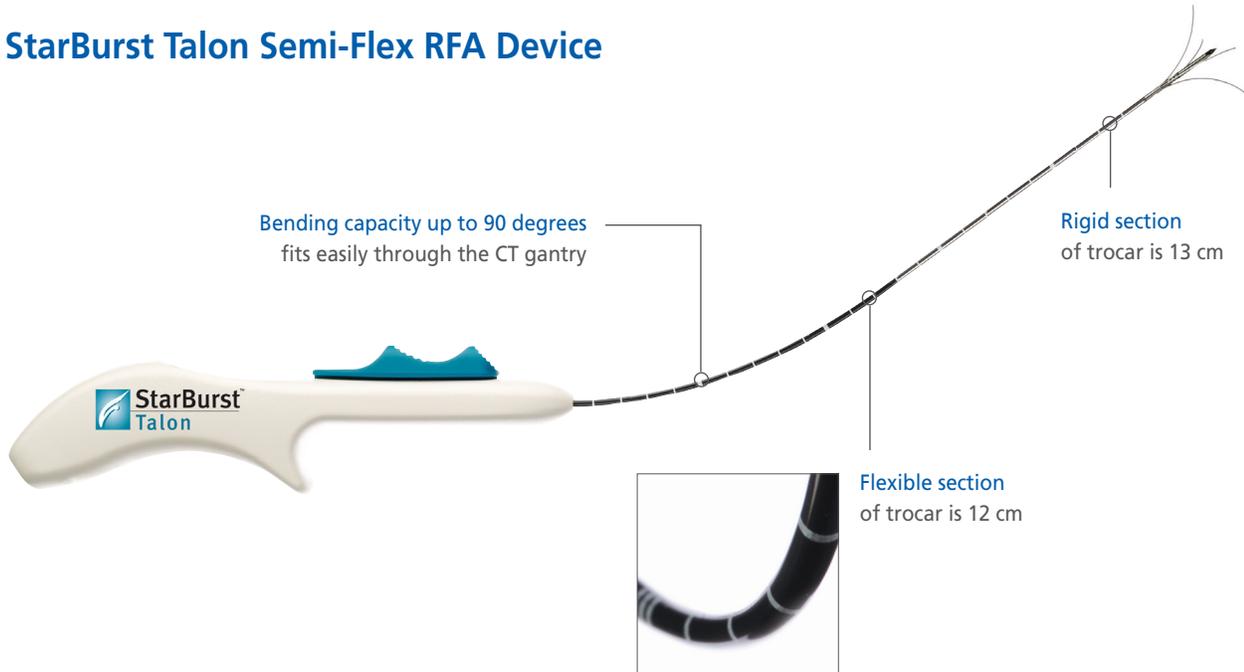


Fast—4 cm ablation in an average of 11 minutes

StarBurst[®] Talon RFA Device

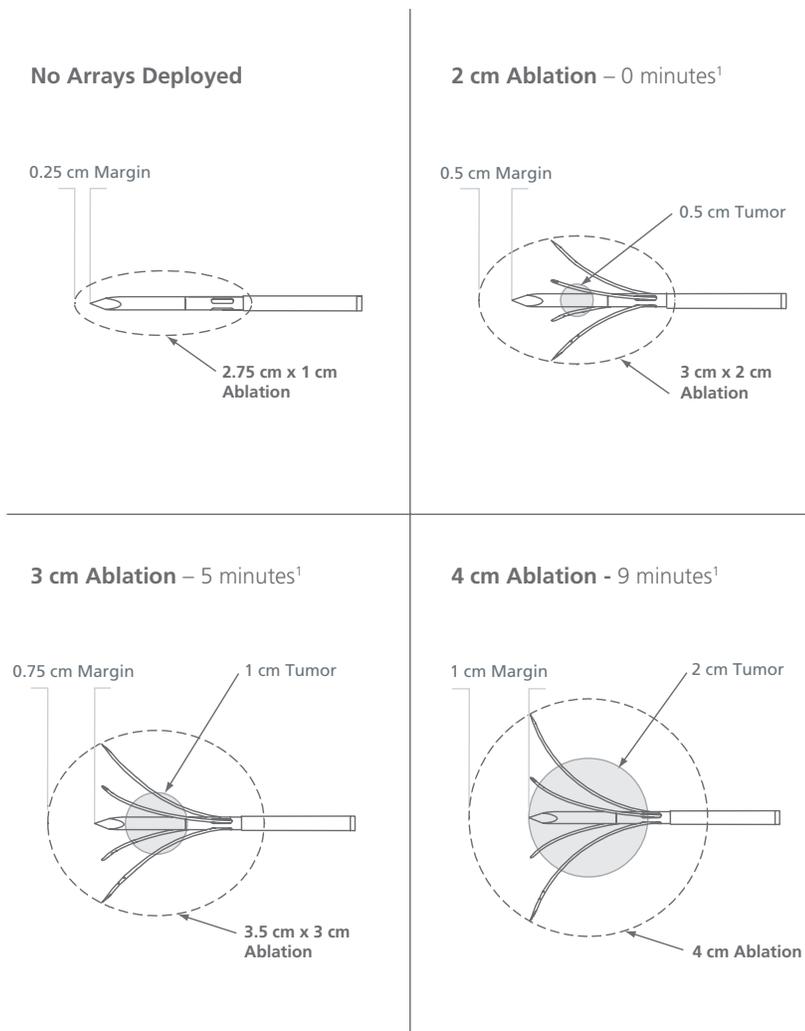


StarBurst Talon Semi-Flex RFA Device



Scalable Spherical Ablations (1-4 cm)

Diagram is not drawn to scale



1. Hold Time at Target Temperature (Set Timer)

BENEFITS

- Side-deployment allows easier penetration of mobile tumors
- Easy to position for both surface and difficult to reach dome lesions
- Integrated disposable main cable and tubing allows for easy set-up
- Solid tip allows easier penetration of hard tumors
- Multi-point temperature feedback provides controlled ablation
- Needle track ablation
- Used for percutaneous, laparoscopic and open cases

“Saline infusion during RFA is associated with lower impedance, higher power delivery and larger lesion size.”

– **CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY**

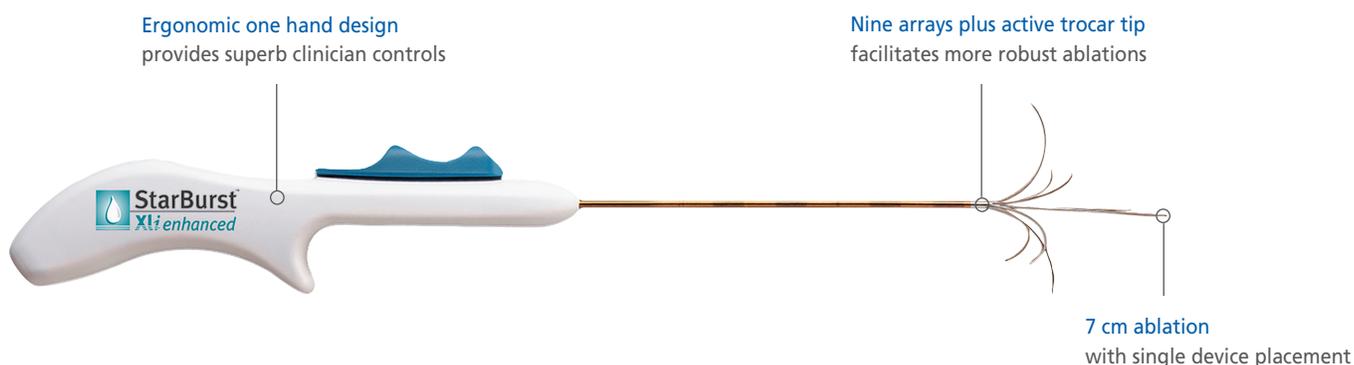
2004; 27(4):361-5 (ISSN: 0174-1551) Gananadha S; Morris DL UNSW Department of Surgery, St. George Hospital, Sydney, Australia.

The Ultimate Micro-Infusion System

RADIOFREQUENCY ABLATION

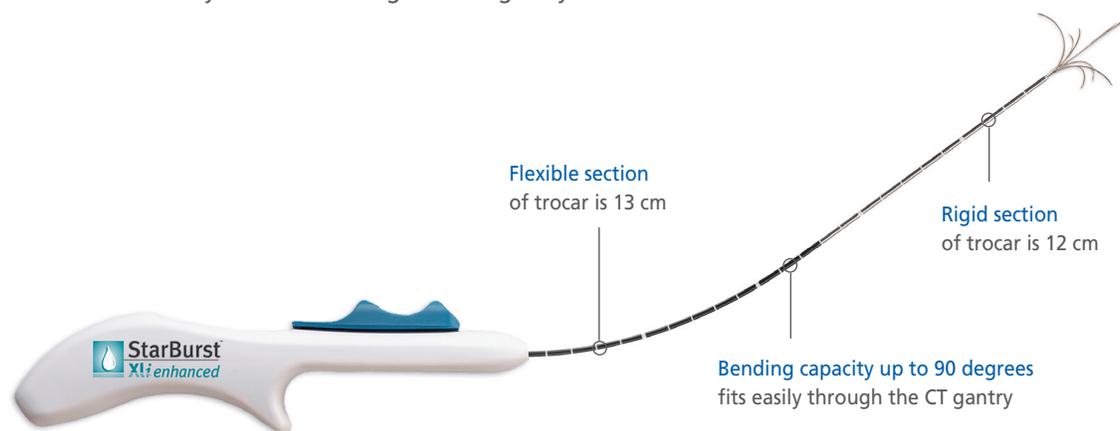
StarBurst Xli-enhanced RFA Device

The StarBurst Xli-enhanced RFA electrode offers clinicians the first single placement RFA device designed to create soft tissue ablation sizes of 4-7 cm. It can be used for percutaneous, laparoscopic and intraoperative procedures. This minimally invasive RFA device ensures consistent, sustained target temperatures and enables the precise ablation of predictable volumes of tissue. The StarBurst Xli-enhanced RFA electrode reduces the time required to perform procedures and in many cases, enables patients to resume normal activity within days.



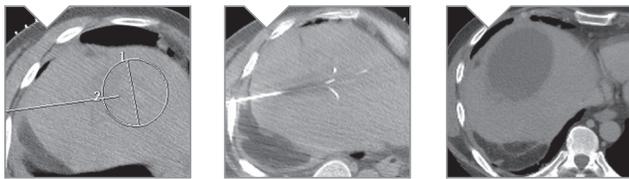
StarBurst Xli-enhanced Semi-Flex RFA Device

The StarBurst Xli-enhanced Semi-Flex RFA electrode is designed specifically for Interventional Radiologists. It is a versatile RFA device that features both rigid (metal) and flexible (polymer) trocar sections. The StarBurst Xli-enhanced Semi-Flex offers all the benefits of the Xli-enhanced rigid device, but with the ability to bend up to 90 degrees in all directions which enables easy entrance through the CT gantry.



Because Temperature Matters

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



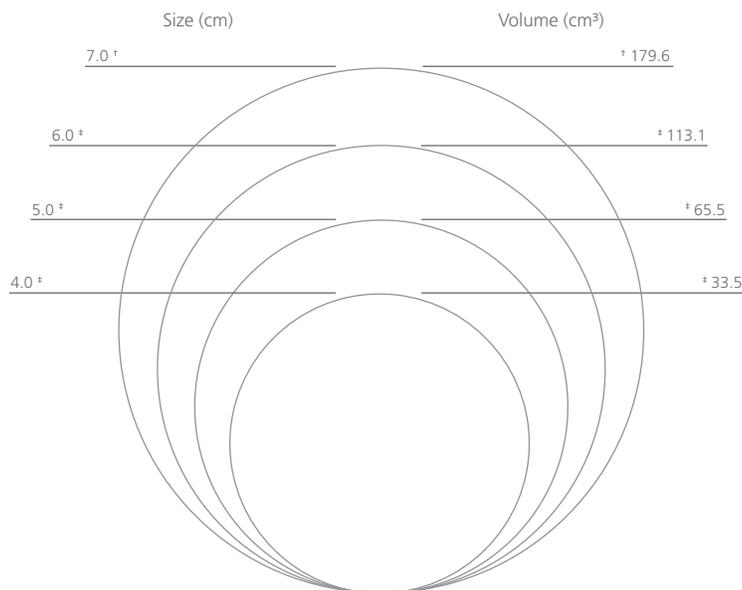
> Pre-Ablation

> During Ablation

> Post-Ablation

Scalable Spherical Ablations (4-7 cm)

Diagram drawn to scale



[†] The Cannula tip should be 1.5 cm from the center of the ablation

[†] The Cannula tip should be 2.0 cm from the center of the ablation

BENEFITS

- More robust ablations
- Faster ablation times
- Scalable, spherical ablations (4-7 cm)
- Dynamic, real-time temperature readouts
- Needle track ablation
- Superb ergonomics and clinician controls
- Expandable array configuration
- Infusion-based system increases conductivity of ablation zone
- Ergonomic one hand design
- Integrated tubing set allows for easy set up

SPECIFICATIONS

- Nine arrays plus active trocar tip
- Four thermocouples
- Pre-attached disposable main cable

“With proper electrode placement and technique, a single 15 Ga. multi-tined electrode insertion can be used to cover and destroy 5 cm tumors with appropriate ablative margins.”

– NAHUM GOLDBERG, MD

Algorithm Optimization for Multitined Radiofrequency Ablation:
A Comparative Study in ex vivo and in vivo bovine liver
L. Appelbaum, J. Sosna, R. Pearson, S. Perez, I. Nissenbaum,
P. Mertyna, E. Libson, and SN. Goldberg

The Ultimate in Array Design

RADIOFREQUENCY ABLATION

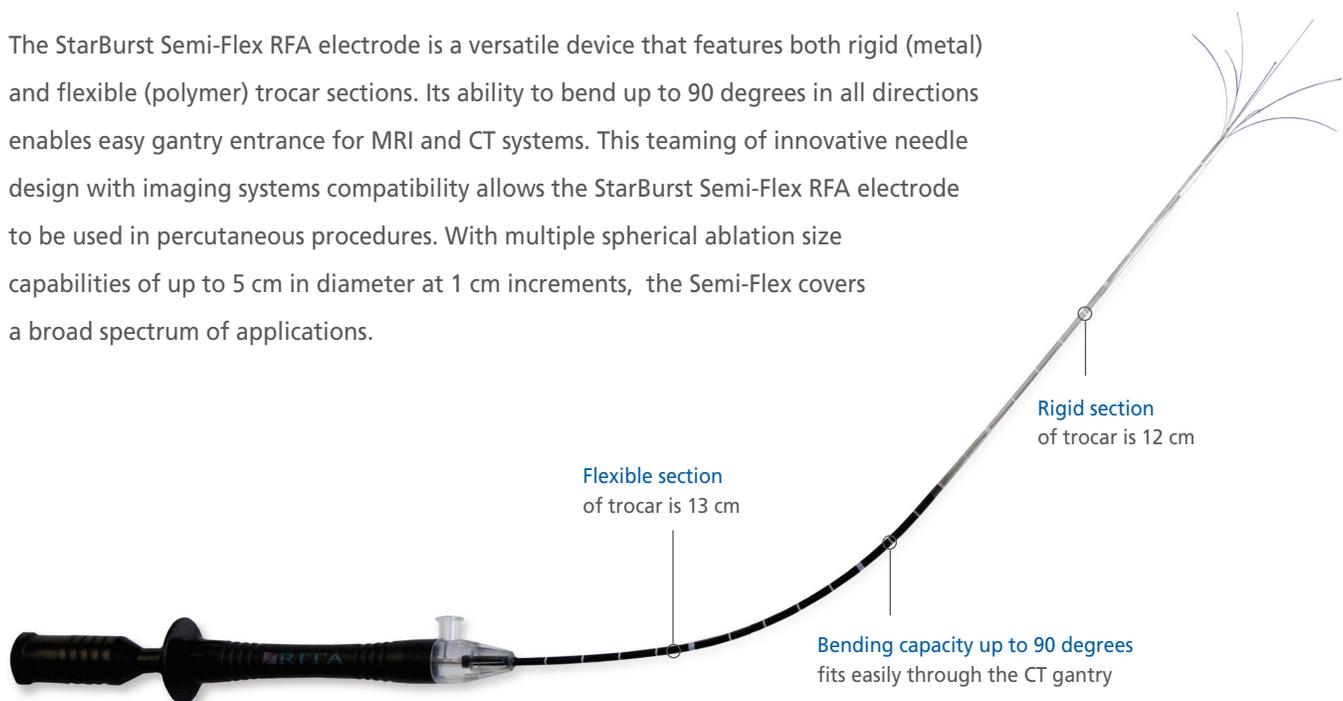
StarBurst XL RFA Device

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.



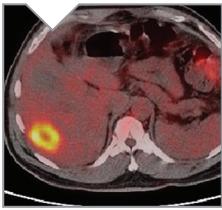
StarBurst XL Semi-Flex RFA Device

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 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.

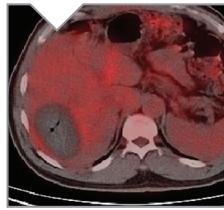


Because Temperature Matters

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



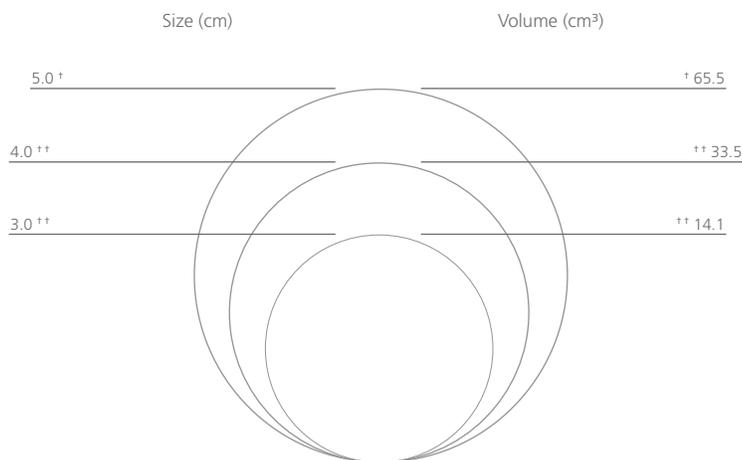
> Pre-Ablation



> 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 ablations²
- 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.

2. SurgEndosc, E. Berber, NL Herceg, KJ Casto, & AE Siperstein, (2004) 18:390-396

The Ultimate in Array Design

RADIOFREQUENCY ABLATION

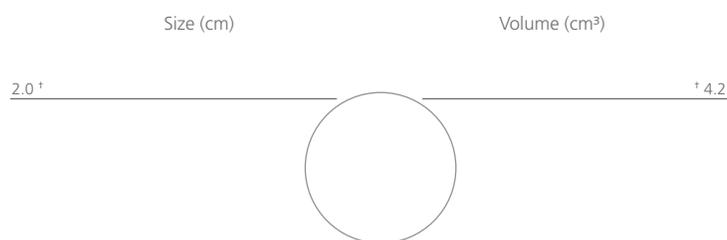
StarBurst SDE RFA Device

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.



SDE Scalable Spherical Ablations (2 cm)

Diagram drawn to scale



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

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

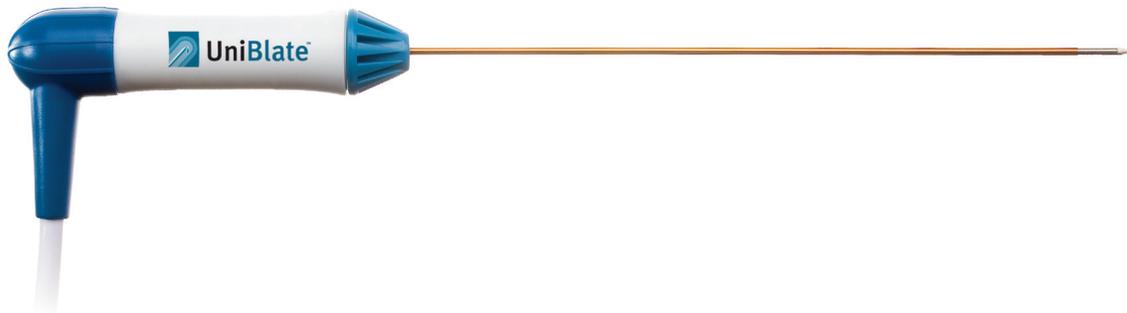
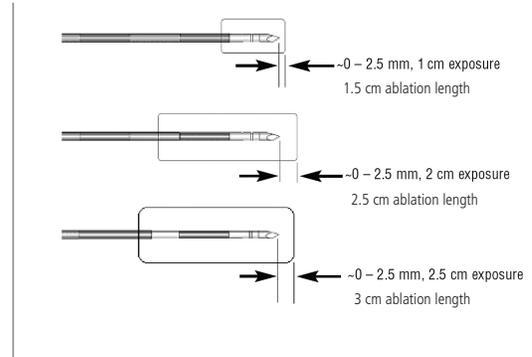
The Ultimate in Linear Deployment

RADIOFREQUENCY ABLATION

UniBlate RFA Device

The UniBlate[®] RFA electrode provides linear, scalable ablations from 1 to 3 cm in length and 1 to 2.5 cm in diameter.³ The benefits of ablation scalability with the same electrode are lower product stocking costs and the ability to spare the most normal tissue possible.

The UniBlate electrode provides a very low profile for CT gantry compatibility. A built-in thermocouple provides full temperature feedback and RF power control, as well as a cool down cycle and track ablation capabilities.



FEATURES & BENEFITS

- UniBlate exclusive linear deployment electrode feature allows user to "dial in" the desired length of active electrode
- The most CT-gantry compatible electrode available with right angle cable connection
- Built in cool down process after each ablation
- Provides full track ablation capabilities
- Eliminates the need to stock multiple electrodes for multiple ablation volumes
- Fully compatible with the AngioDynamics 1500X RF Generator
- Added safety near critical structures

SPECIFICATIONS

- Single 17 gauge cannula electrode with scalable active length from 1-2.5 cm
- One thermocouple

3. In Vivo Porcine Ablation Data per UniBlate IFU

The Ultimate in Power and Ease of Use

CAPITAL EQUIPMENT

Model 1500X RF Generator

The 1500X Electrosurgical Radiofrequency Generator supplies radiofrequency (RF) energy for the partial or complete coagulation and ablation of soft tissue. The 1500X is specifically designed to be compatible with the full family of AngioDynamics RFA based electrodes. The innovative electrosurgical devices can be utilized in percutaneous, open or laparoscopic surgical procedures.



Compatible with the StarBurst and Habib[®] families of devices



BENEFITS

- Generator is equipped with computer driven protocols that automatically adjust wattage to maintain optimal temperatures during the ablation
- Temperature monitoring is in real time, which gives immediate visibility of the ablation zone and repeatable, reliable procedure endpoints
- 250 Watts of power combined with the IntelliFlow saline infusion pump allows faster and larger ablations
- Immediately recognizes the full family of AngioDynamics electrosurgical devices as they are plugged in and automatically sets the system to pre-loaded soft tissue protocols
- Remote foot pedal available for hands-free device activation
- “Smart Card” Technology means that upgrades can be accomplished with little or no additional capital expense

SPECIFICATIONS

- Dimensions: 14.75”w x 17.0”d x 5.25”h (37.5 cm x 43 cm x 13.5 cm)
- Weight: 23 lbs (10 kg)
- Power: 1–250 Watts
- Frequency: 460 kHz
- Power Delivery Accuracy: 20%
- Power Supply: 110–240 volts, 50–60 Hz, universal power supply
- Temperature Control Range: 15–125°C, $\pm 3^{\circ}\text{C}$, up to 8 independent channels
- Efficiency Range: 1–10

IntelliFlow Pump

The IntelliFlow peristaltic infusion pump is used in conjunction with the 1500X radiofrequency generator for the coagulation and ablation of soft tissue. The IntelliFlow offers the ultimate in ease of use, while delivering infused saline with automated precision. The IntelliFlow pump is specifically designed to be used with all infusion based StarBurst electro-surgical devices.



Occlusion Bed

Compatible with all StarBurst infusion-based devices



BENEFITS

- Automated communication with 1500X generator
- Integrated IV pole
- No battery to recharge
- No additional settings required
- Easy loading & securing of tubing sets
- Storage drawer for accessories
- Tubing sets are sterile and pre-attached to StarBurst family of infusion devices
- Occlusion bed offers easy device set up

SPECIFICATIONS

- Dimensions: 14.75" w x 8.8" d x 6.25" h (37.46 cm x 22.35 cm x 15.90 cm)
- Weight: 10 lbs (4.5 kg)
- Power: 100–240 VAC
- Frequency: 50 or 60 Hz
- Operating Temperature: 15°C–35°C
- Speed/Flow Rate: 1–40 rpm (.05–.7ml/min)

STARBURST TALON ELECTRODES

Product Name	Length	UPN	Outer Diameter (O.D.)
StarBurst Talon Electrode	15 cm	700-102847	14 gauge/6.4 French
StarBurst Talon Electrode	25 cm	700-102846	14 gauge/6.4 French

STARBURST TALON SEMI-FLEX ELECTRODE

Product Name	Length	UPN	Outer Diameter (O.D.)
StarBurst Talon Semi-Flex Electrode	25 cm	700-102845	14 gauge/6.4 French (rigid portion)

COAXIAL ACCESS SYSTEM INTRODUCERS

Introducer Type	Length	UPN	Talon 15 cm	Talon 25cm
Hard Introducer	6 cm	700-102330	to 12 cm mark	to 12 cm mark
Hard Introducer	11 cm	700-102331	not compatible	to 17 cm mark

STARBURST XLI-ENHANCED ELECTRODES

Product Name	Length	UPN	Outer Diameter (O.D.)
StarBurst Xli-enhanced Electrode	12 cm	700-103027	14 gauge/6.4 French
StarBurst Xli-enhanced Electrode	25 cm	700-103024	14 gauge/6.4 French

STARBURST XLI-ENHANCED SEMI-FLEX ELECTRODE

Product Name	Length	UPN	Outer Diameter (O.D.)
StarBurst Xli-enhanced Semi-Flex Electrode	25 cm	700-104077	14 gauge/6.4 French (rigid portion)

COAXIAL ACCESS SYSTEM INTRODUCERS

Introducer Type	Length	UPN	Xlie 12 cm	Xlie 25cm
Hard Introducer	6 cm	700-102330	to 10 cm mark	to 10 cm mark
Hard Introducer	11 cm	700-102331	not compatible	to 15 cm mark

STARBURST XL ELECTRODES

Product Name	Length	UPN	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	UPN	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	UPN	XL 10 cm	XL 15 cm	XL 25 cm	XL Semi-Flex 25 cm
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

STARBURST SDE ELECTRODES

Product Name	Length	UPN	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

UNIBLATE ELECTRODES

Product Name	Length	UPN	Outer Diameter (o.d.)
UniBlate	10 cm	700-103598	17 gauge / 5 French
UniBlate	15 cm	700-103597	17 gauge / 5 French
UniBlate	25 cm	700-103530	17 gauge / 5 French

MODEL 1500X RF GENERATOR AND ACCESSORIES

Product Name	UPN
1500X RF Generator	700-101731
Main Cable (Green-9 to 14 pin)	700-101892

MODEL 1500X RF GENERATOR REPLACEMENT PARTS

Product Name	UPN
Foot Switch	400-100453
Power Cord	400-100702

INTELLIFLOW PUMP

Product Name	UPN
IntelliFlow Pump	700-102941

INTELLIFLOW PUMP REPLACEMENT PARTS

Product Name	UPN
Pump Communication Cable	700-102801
Power Cord	400-100702
Occlusion Bed	700-102938

IMPORTANT RISK INFORMATION

INDICATIONS FOR USE: The IntelliFlow Infusion Pump, Tubing Set and Reusable Occlusion Bed is designed for use in conjunction with the 1500X Radiofrequency (RF) Generator to provide local delivery of saline through the irrigation ports of the electrosurgical device during radiofrequency ablation procedures. The 1500X Generator (with software version 8.10 or higher) provides monopolar RF energy and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue.

CAUTION: Federal (USA) law restricts the sale of these devices by or on the order of a physician.

CONTRAINDICATIONS: Do not use the IntelliFlow Pump for drug delivery, for intravascular, intra-arterial or epidural delivery of fluids, or during MRI procedures. The use of the 1500X Generator is contraindicated in

the presence of flammable anesthetics, oxygen-enriched or explosive atmospheres.

WARNINGS AND PRECAUTIONS: Do not use the IntelliFlow Pump if four or more tubes become occluded, as improper or unpredictable lesion size may result. Do not use the IntelliFlow Pump if damage is suspected. Electric shock hazard: do not saturate the IntelliFlow Pump with liquids or allow liquids to run inside the unit, or immerse the IntelliFlow Pump in water; do not use the RF Generator if it has been dropped or damaged, and do not remove the cover of the RF Generator. There are no user-serviceable parts inside the RF Generator. Refer all service to AngioDynamics, Inc. Use of the 1500X Generator may interfere with the operation of other electronic medical equipment. In the case of a pacemaker, a theoretical hazard exists because interference with the action of

the pacemaker may occur, and the pacemaker may reset to its factory default; it is recommended that a patient see a cardiologist after the procedure to verify functionality of the pacemaker. It is important to read, understand and follow the instructions, warnings and precautions supplied with the equipment in order to enhance procedure safety and effectiveness.

POTENTIAL COMPLICATIONS: Possible complications include bleeding, infection, wound dehiscence, gas embolism, nerve damage, electric shock or thermal injury.

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.

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

INDICATIONS FOR USE: The UniBlate Electrosurgical Device is intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures, such as partial or complete ablation of non-resectable liver lesions, osteoid osteoma, and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

DESCRIPTION: The UniBlate device consists of an insulated primary trocar with two infusion holes and a temperature sensor positioned at the distal end. The UniBlate device is designed to fit in a CT gantry, is available in 10cm, 15cm & 25cm lengths and has an integrated main cable and tubing set. To be used in conjunction with the RITA 1500X RF Generator and IntelliFlow Infusion pump for the ablation of soft tissue.

WARNINGS: The distal 4 mm of the device is NOT Radio opaque and will not appear under CT imaging. If the Tubing Set becomes occluded, improper or unpredictable lesion size may result. Do not attach anything (i.e., clamps, etc.) to the device. This may damage the insulation, which could contribute to patient injury. Patients with peripheral vascular deficiency are at increased risk of thermal injury from Dispersive electrodes. Patients with frail skin are at increased risk of skin damage from the adhesive on the Dispersive pads. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure.

PRECAUTIONS: Do not bend or kink the trocar. This may cause damage and result in a nonfunctional device. If

the device is being used in a laparoscopic procedure, care must be taken to avoid a gas embolism. If the device is being used in a laparoscopic procedure, activation of the device when not in contact with target tissue may cause capacitive coupling. Having RF power on at the same time as infusion using a method different from these instructions may alter the path of the electrical energy away from target tissues.

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 the sale of the device by or on the order of a physician.

The StarBurst Talon, StarBurst Xli-enhanced, StarBurst XL, StarBurst MRI and StarBurst SDE Electrosurgical Devices are tools to transmit monopolar radiofrequency energy (provided by the 1500X RF Generator) in conjunction with the IntelliFlow Infusion pump. They 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 or exert forceful pressure on Device while it is deployed in the

tissue; 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. The Talon is not MRI safe. 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.

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

Consult your AngioDynamics representative for country specific product availability.



USA > 14 Plaza Drive, Latham, NY 12110 > tel: 800-772-6446 > fax: 518-798-1360 > Canada tel: 800-268-0184
International > Haaksbergweg 75 (Margrietoren), 1101 BR, Amsterdam Z-O > The Netherlands
tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

www.angiodynamics.com

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