



StarBurst® Talon
INFUSION RFA ELECTRODES

 balmer medical

ANGIODYNAMICS®

The Ultimate in Deployment Design

RADIOFREQUENCY ABLATION

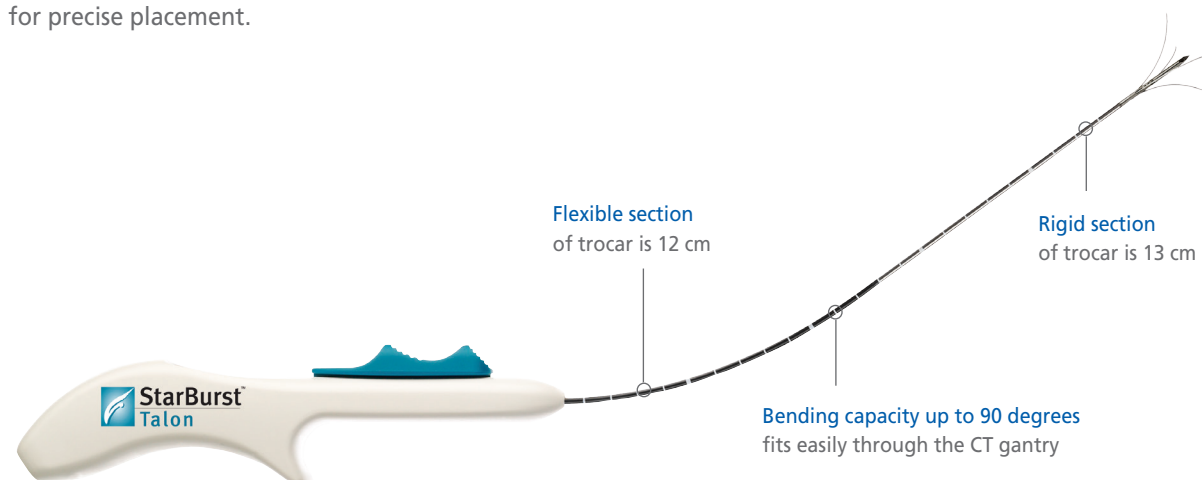
StarBurst® Talon RFA Device

The StarBurst Talon RFA electrode offers clinicians 4 cm ablations in a side-deployment device specifically designed for applications in lesions that may be mobile in soft tissue or adjacent to critical structures. The StarBurst Talon RFA electrode can be used in laparoscopic, percutaneous and intraoperative procedures. It is part of the RITA® infusion system family of products which uses the IntelliFlow Pump to deliver precise amounts of normal saline to the ablation zone. The saline infusion technology allows the Talon RFA electrode to quickly create 4 cm ablations in an average of 11 minutes.



StarBurst® Talon Semi-Flex RFA Device

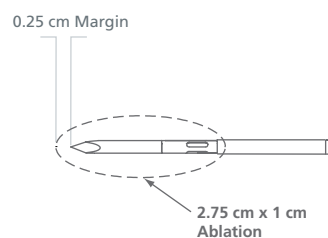
The StarBurst Talon Semi-Flex RFA electrode is a versatile device that features both rigid (metal) and flexible (polymer) trocar sections. The device offers all the benefits of the StarBurst Talon RFA electrode, but also has the ability to bend up to 90 degrees in all directions allowing for easy entry into the CT gantry. The active tip is also visible under CT imaging for precise placement.



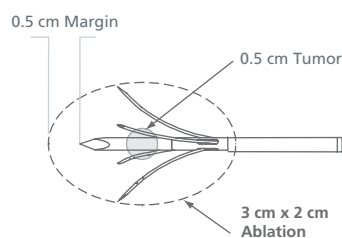
Scalable Spherical Ablations (1-4 cm)

Diagram is not drawn to scale

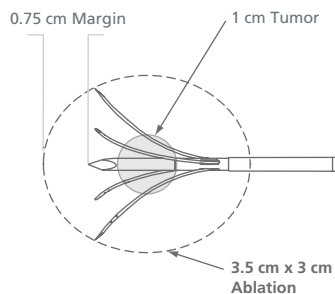
No Arrays Deployed



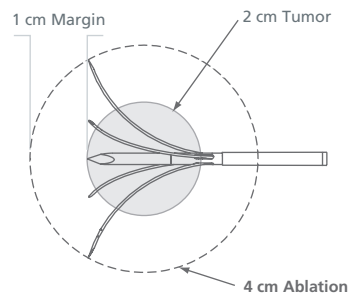
2 cm Ablation – 0 minutes*



3 cm Ablation – 5 minutes*



4 cm Ablation - 9 minutes*



* 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
- Creates fast, spherical 4 cm ablations
- Multi-point temperature feedback provides controlled ablation
- Infusion-based system increases conductivity of ablation zone
- Needle track ablation
- Used for percutaneous, laparoscopic and open cases
- Bending capacity of 90 degrees allows for easy entry into CT, without sacrificing penetration depth

SPECIFICATIONS

- Four active arrays plus active trocar tip
- Thermocouple in tip of each active array

"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.

STARBURST® TALON ELECTRODES

Product Name	Length	Part #	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	Part #	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	Part #	Talon 15 cm	Talon 25cm
Soft Introducer	10 cm	700-102636	to 14 cm mark	to 14 cm mark
Soft Introducer	13 cm	700-102637	not compatible	to 17 cm mark
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

Model 1500X RF Generator & IntelliFlow Pump

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. The IntelliFlow Pump is used in conjunction with the 1500X RF Generator for the ablation of soft tissue and offers the ultimate in ease of use, while delivering a precise amount of infused saline.



IMPORTANT RISK INFORMATION

The StarBurst® Talon Electrosurgical Device is a tool to transmit monopolar radiofrequency energy (provided by the RITA® RF Generator) in conjunction with the IntelliFlow Infusion pump. It 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 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.

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