INSTRUCTIONS FOR USE
SpineSTAR Ablation Instrument
(English) (EN)

Important Information – Please Read Before Use

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

INDICATION
The SpineSTAR Ablation Instrument is indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

DESCRIPTION
The SpineSTAR Ablation Instrument is a sterile single use device for the ablation of tumor within the vertebral body. It is to be used with the StabiliT Introducer (Stylet and Working Cannula), the AE Cable, and the MetaSTAR RF Generator. The SpineSTAR Ablation Instrument Shaft is 3.0mm in outer diameter and 15.5cm in length (5|10 (Short)and 10|15 (Short)) or 17.5cm in length (5|10 (Long)and 10|15 (Long)).

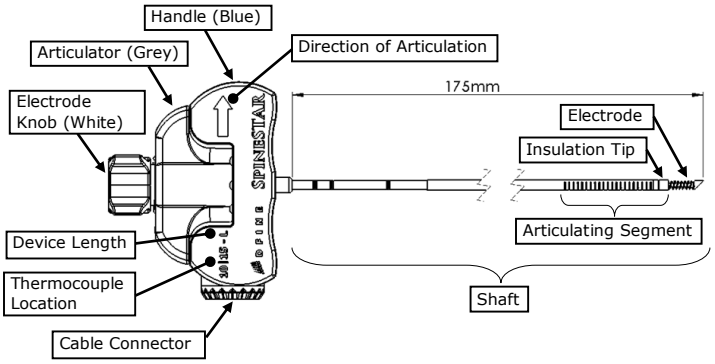

Figure 1: SpineSTAR Ablation Instrument

Figure 1: SpineSTAR (SS) Ablation Instrument has a handle that contains an Articulator (grey color) that curls the Articulating Segment in the direction of the Indicator (white arrow) and Electrode Knob (white color), which extends the Electrode from the distal end of the Articulating Segment.

The maximum length of the SpineSTAR Ablation Instrument that can extend beyond the Working Cannula (WC) is 35mm. There are two thermocouples (TC) on the articulating segment of the shaft (see Figure 5): For 10|15 (Long), the Distal TC is 10mm from the insulation tip while proximal TC is 15mm from the insulation tip; for 5|10 (Long), the Distal TC is 5mm from the insulation tip while proximal TC is 10mm from the insulation tip. Three black marker bands on the shaft represent the location of bevel tip and TCs in relation to the distal end of the Working Cannula.

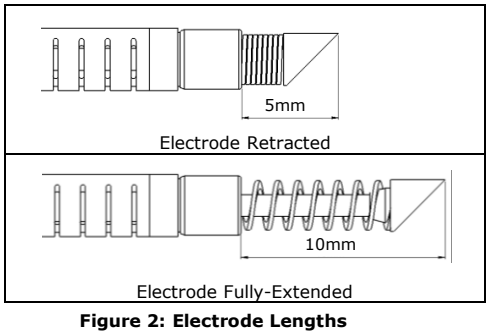

Figure 2: Electrode Lengths

Figure 2: The total maximum distance the Electrode extends beyond the end of the Articulating Segment is 10mm. When retracted, the Electrode extends 5mm beyond the end of the Articulating Segment.

Device	Working Length
SpineSTAR Ablation Instrument 5|10 (Long)	17.5 cm
SpineSTAR Ablation Instrument 10|15 (Long)	17.5 cm

HOW SUPPLIED
The SpineSTAR Ablation Instrument is supplied sterile in a peel-open package. The device is sterilized by gamma irradiation. The device is intended for single use only. Do not re-sterilize. Do not use if the package is open or damaged. In the event of damage to the sterile packaging, notify the manufacturer.

ADVERSE EVENTS
- As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury could occur
- Nerve injury including thermal injury, puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pulmonary embolism
- Hemorrhage
- Hemothorax or pneumothorax
- Hematoma
- Infection including deep or superficial wound infection
- Pain
- Unintended puncture wounds including vascular puncture and dural tear

PREPARATION AND USE

1. Check packaging for damage prior to placing contents in sterile field.
2. Remove product from package using standard sterile technique.
3. Check all components for damage.
4. Connect the Hand Switch Cable to the MetaSTAR RF Generator.
5. Connect the AE Cable to the MetaSTAR RF Generator and the SS.
6. Confirm the MetaSTAR RF Generator recognizes the SS – if it does not, the graphical display will illuminate a flashing warning "connect device".
7. To bend the Articulating Segment - turn the grey Articulato clockwise. It will only bend in one direction.
Caution: DO NOT turn the Articulator greater than 1/2 turn clockwise.
8. To straighten the Articulating Segment - turn the Articulator counterclockwise.
9. Insert the Introducer to desired location and remove the stylet from the WC.
WARNING: All device manipulations should be done/confirmed under imaging guidance (CT or fluoroscopy) that provides high quality images.
10. Ensure the Articulating Segment is in the straight position and the Electrode is fully retracted prior to inserting the SS into the WC.
11. In combination with image guidance, reference the marker bands on SS shaft to verify the position of SS and the TCs in relation to end of the WC:
a. Distal marker band on SS shaft is level with WC luer = SS bevel tip is at distal end of WC.
b. Middle marker band on SS shaft is level with WC luer = SS Distal TC is 2mm beyond distal end of WC.
c. Proximal marker band on SS shaft is level with WC luer = SS Proximal TC is 2mm beyond distal end of WC.
Note: Distance the SS extends beyond the end of the WC when fully inserted is:
- 30mm when Electrode is fully retracted.
- 35mm when Electrode is fully extended.

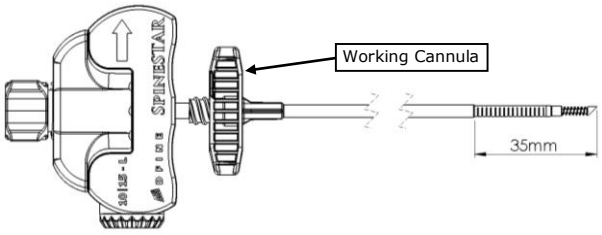

Figure 3: Working Cannula

12. After inserting the SS bevel tip to the distal end of the WC CONFIRM that the MetaSTAR RF Generator graphic display registers ≥ 35°C for both proximal and distal TCs before proceeding.
13. As the Articulating Segment of the SS is advanced beyond the WC into the vertebra, rotate the Articulator to bend the Articulating Segment, as necessary, to navigate to the desired location. The degree to which the Articulating Segment will actually bend will depend on bone density.
Caution: When the Articulating Segment is bent, the device handle should not be rotated
14. Extend the Electrode to the desired length by rotating the white Electrode Knob clockwise.
Caution: Do NOT rotate the SS Handle when the Electrode is extended.
Caution: Monitor the location of WC before advancing the SS through it.

White Knob Rotation		
Electrode Retracted	Electrode Half-Extended	Electrode Fully-Extended
		

Figure 4: Electrode Knob

15. Prior to initiating ablation confirm (with CT or fluoroscopic imaging) location of the distal end of WC, the radiolucent insulation tip and location of Electrode.
16. Confirm AE Cable is inserted into Cable Connector of SS.

CONTRAINDICATIONS

- Use of device is contraindicated in patients with heart pacemakers or other electronic device implants.
- Use of device is contraindicated in vertebral body levels C1-C7.

WARNINGS

- This device should only be used by qualified physicians with training in the clinical procedure in which it is being used. Physicians using the SpineSTAR Ablation Instrument should be familiar with the physiology and pathology of the selected anatomy.
- For safe use of the device, the physician should have specific training, experience, and thorough familiarity with the use and application of this product.
- Do NOT ablate in painful osteoporotic vertebra without tumor.
- Do NOT use the device in fractures due to osteoblastic metastases of the spine such as those which may occur due to prostatic cancer..
- Do NOT use this product in dense (sclerotic) bone including traumatic high energy fractures or purely blastic lesions, device damage resulting in patient injury may occur.
- Do NOT use this device in patients without metastatic malignant lesions in a vertebral body.
- Do NOT use this device in patients with multiple myeloma, solitary plasmacytoma, or primary malignant lesions in the index vertebra.
- Do NOT use a device in more than one vertebral body.
- Do NOT withdraw the device while power is still being applied.
- Do NOT touch the Electrode to metal objects while power is being applied, damage to the device may occur.
- Use standard electrosurgical precautions when using the device in the vicinity of nerves and nerve roots.
- It is essential to maintain strict sterile technique during all phases of handling and use of this product.
- Dispose of used product per Local, State and Federal blood borne pathogen controls including biohazard sharps container and disposal procedures.
- The product is sterilized by gamma radiation. Do NOT use if package is opened or damaged.
- Excessive ablation may create heat within the spine and adjacent neural tissue.
- Do NOT apply excessive force when operating the device; breakage of the device may require intervention or retrieval.
- Insertion and removal of the device, and straightening and actuation of the articulating segment, should be performed with the Electrode fully retracted, while carefully monitoring the position of the tip of the device under imaging guidance.
- Extension and retraction of the Electrode should be done slowly and under imaging guidance while carefully monitoring the position of the tip of the device.
- The ablation procedure must be performed under image guidance. Do NOT perform ablation without first imaging area as it may result in severe injury to patient.
- The device must be positioned such that when ablation is performed, nerves and nerve roots are beyond the ablation zone; failure to utilize the Ablation Zone Dimensions may result in severe injury to the patient. *See Figure 5*
- Do NOT use flammable anesthetics.
- Observe fire precautions at all times. Sparking and heating associated with electro surgery may be an ignition source.
- Do NOT rotate the Handle when the SpineSTAR Ablation Instrument is extended beyond the Working Cannula, breakage of the device may occur.

PRECAUTIONS

- It is important to read the Instructions For Use and these precautions prior to device operation.
- Use the device prior to Use By Date noted on the package.
- Do NOT use damaged product. Before use, inspect the device and packaging to verify that no damage has occurred.
- The device should be manipulated only while under fluoroscopic (and/or CT) observation with radiographic equipment that provides high quality images.
- As with other electrosurgical units, electrodes and cables can provide paths for high frequency current. Position cables and electrode to avoid contact with the patient or other leads.
- The location of the Working Cannula in the vertebra should be confirmed using image guidance before advancement as well as during removal of the SpineSTAR Ablation Instrument.
- Do NOT touch the Electrode at the tip of the device while power is being applied.
- Prior to device withdrawal, ensure that the Working Cannula is stabilized and that the power is no longer being actively applied.
- If the proximal thermocouple (TC) temperature suddenly drops below 30°C, stop the procedure and replace the SpineSTAR instrument.
- Do NOT re-sterilize and/or reuse. The device is for single use only. Reconditioning refurbishing, repair, modification, or re-sterilization of the device to enable further use is expressly prohibited as it will result in device malfunction and/or infection.
- Do NOT clean device with Isopropyl Alcohol or other solvents.
- Do NOT use device in more than one vertebral body.

17. Recommended starting power is 5W

18. Press the Blue Button on the Hand Switch to start ablation. A light on the MetaSTAR RF Generator will illuminate and an audible tone will emit from the MetaSTAR RF Generator.

19. During ablation the MetaSTAR RF Generator graphic display must be observed to monitor temperatures and impedance.

1. The MetaSTAR RF Generator software is designed to stop RF delivery when any one of following three conditions happen:
   - Proximal TC reaches 50°C.
   - Impedance is too high.
   - Cycle time counts down to zero.

Caution: If proximal TC temperature suddenly drops below 30°C; stop the procedure and replace the SS.

20. If larger ablation zone is desired, retract the Electrode and reposition the SS in desired location. Extend the Electrode and reinitiate ablation.

1. If impedance limit is reached, the MetaSTAR RF Generator will stop RF delivery. Retracting and extending the Electrode or slight manipulation of the Articulating Segment (with the Electrode retracted) may be required to continue ablation. In some cases removal of the SS from the WC and cleaning the Electrode of char may be required.
2. After the ablation is completed, remove the SS per the following steps:
   a. Fully retract the Electrode.
   b. If Articulating Segment has been deployed in the anterior third of the vertebra, pull the SS back to the middle third of the vertebra before fully straightening.
   c. Confirm the Electrode is still fully retracted before withdrawing the distal end of the SS into WC.

Caution: Before removing the device, stabilize the Working Cannula .

Caution: Do not withdraw the device while power is being applied.

Caution: Do not insert, withdraw or articulate or straighten the device while the Electrode is extended.

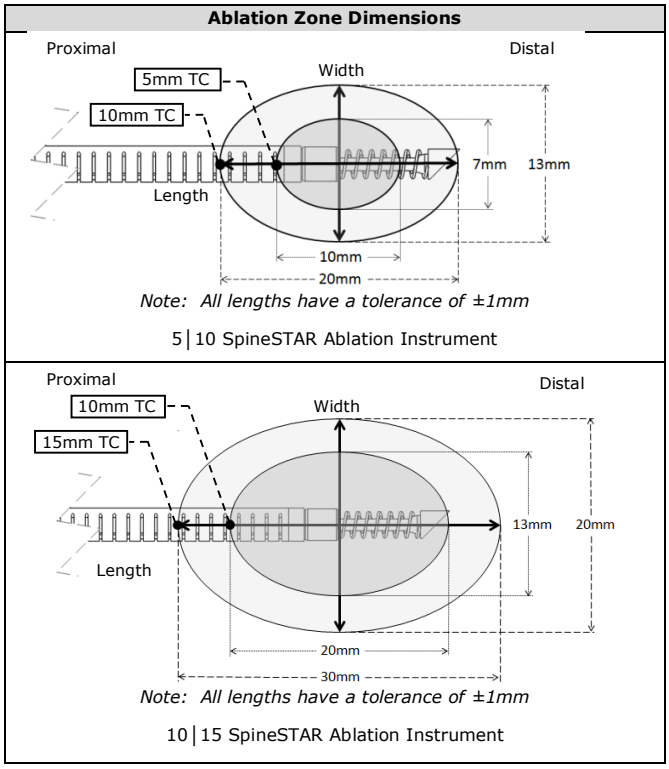

Figure 5: Ablation Zone

WARNING: If the patient complains of SUDDEN ONSET OF PAIN during ablation, STOP THE PROCEDURE and:

- Closely examine the position of the device using CT or fluoroscopic imaging.
- Confirm the path of and placement of device.
- Confirm insulation tip and Electrode is in the desired location within vertebra.
- DO NOT continue procedure until proper placement of device has been verified.

WARNING: Excessive ablation may create heat within the spine and adjacent neural tissue.

WARNING: See MetaSTAR RF Generator Operator's Manual for selection of power level and ablation time.

STORAGE & HANDLING

Handle with care. Store in original packaging in a clean, cool and dry location. Avoid exposure to temperature and humidity extremes.

SYMBOLS GLOSSARY

	Caution (see Instruction for Use)		Use By Date
	Consult instructions for use		Do not use if package is damaged
	Sterilized using Irradiation		Keep away from sunlight
	Batch Code		Keep dry
	Catalogue Number		Manufacturer
	11 gauge cannula outer diameter		Longer length instrument
	Shaft length 15.5cm		Shorter length instrument
	Shaft length 17.5cm		Do not re-use
	Thermocouple location 5 and 10mm from the device tip		Authorized Representative in the European Community
	Thermocouple location 10 and 15mm from the device tip		

CE 0086

Manufactured by:

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

EC REP

Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+31 43 358 82 22

403322001_001 2016-08-31