



acculis

Microwave Tissue Ablation System



A single device for fast,
predictable, large ablations.

 **angiodynamics**

Acculis MTA System

Accu2i pMTA Applicator

The Acculis[®] Microwave Tissue Ablation (MTA) System when configured for use with the Accu2i pMTA Applicators consists of the Sulis[®] V^{pMTA} Generator, optional MTA Temperature Probes, Acculis Local Control Station (LCS) and Accu2i pMTA Applicators. The Acculis MTA System is used to deliver energy to soft tissue for the purpose of thermal coagulation. The Acculis MTA System is designed to be used by physicians who are trained in the use and application of image-guided ablation procedures, intraoperative ultrasound and/or CT guided needle placement.

WHY ACCULIS?

Frequency

- 2.45 GHz vs. 915 MHz
- Larger ablation zone
- Faster procedure time
- Fewer probes required

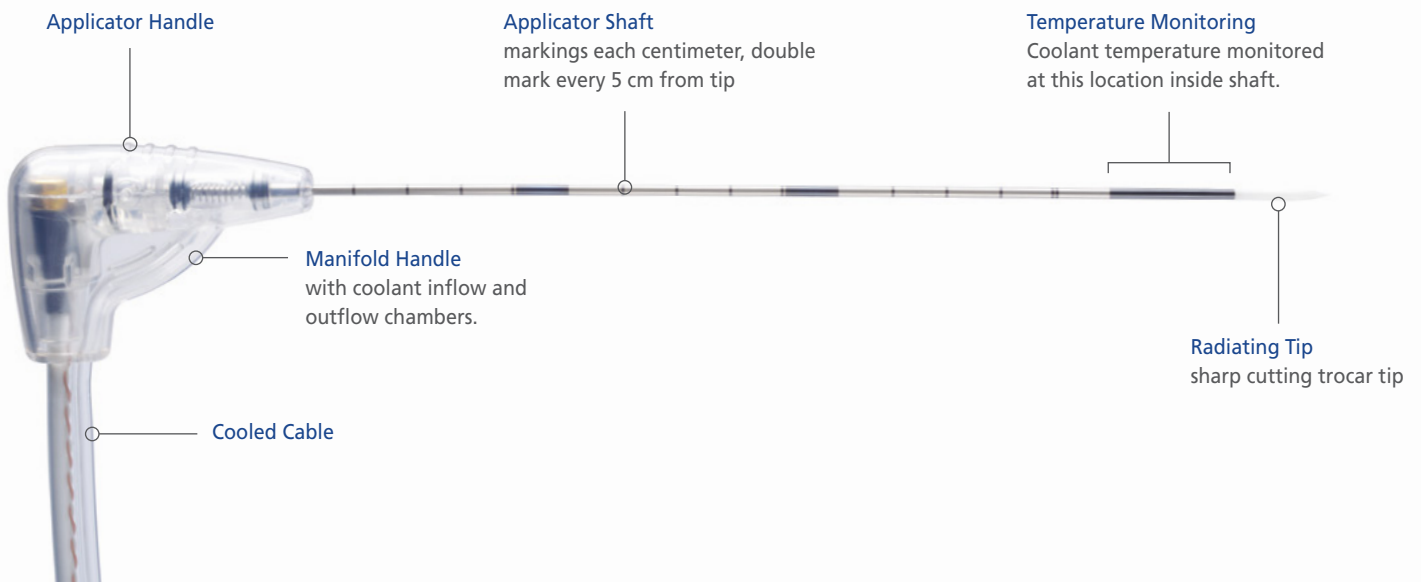


Ablation Zone

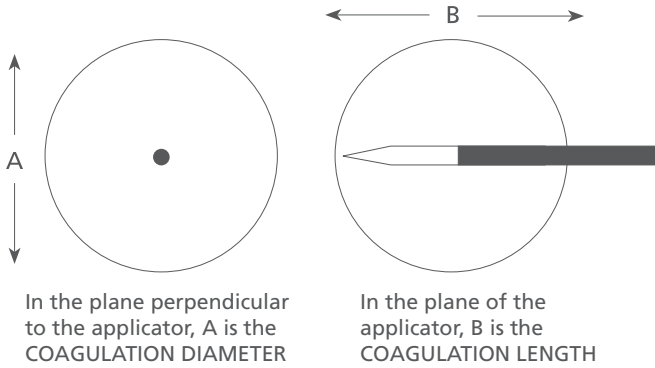
- Reliable diameter
- Predictable volume
- Maximum sphericity

Speed

- 4.5 x 5.5 cm ablation in 6 minutes[†]
- More Power = Faster Ablations



Planning



Placement

Under CT guidance



Post-ablation

Ex-vivo tissue, bovine



A single device for fast, predictable, large ablations.

**[4.5 cm x 5.5 cm
ABLATION IN
6 MINUTES[†]]**

Spherical ablations

60 Watts

Time	Diameter	Length
2 min	2.3 cm	2.7 cm
4 min	3.3 cm	3.7 cm
6 min	3.5 cm	4.0 cm

100 Watts

2 min	2.7 cm	3.2 cm
4 min	3.6 cm	4.1 cm
6 min	4.0 cm	4.7 cm

140 Watts

2 min	2.9 cm	3.5 cm
4 min	4.1 cm	5.2 cm
6 min	4.5 cm	5.5 cm

[†]The liver coagulation results are from coagulations performed in ex-vivo animal tissue models.

Specifications

- Single Applicator
- 2.45 GHz operating frequency
- Generator powers from 60 W to 140 W
- Liquid cooled applicator and cable
- High reflected energy monitoring
- Available in 14 cm, 19 cm and 29 cm applicator lengths

Acculis LCS (Local Control Station)

- Coolant temperature monitoring system
- Integrated control interface for Acculis disposable microwave applicator systems
- Single-action multi-connector cartridge combining data signal, microwave, coolant and pump drive connections



Sulis V^{pMTA} Generator

- 2.45 GHz medical grade microwave generator
- Touch screen user interface
- 60 W to 140 W output
- High reflected energy feedback monitor

Acculis Cart

The cart supports the Sulis V^{pMTA} Generator. The articulating arm allows the Acculis LCS to be positioned on the edge of the sterile field.

Product Name	Diameter	Length	Part #
pMTA Accu2i Standard Applicator (cooled)	1.8 mm	14 cm	900-600-US
pMTA Accu2i Intermediate Applicator (cooled)	1.8 mm	19 cm	900-602-US
pMTA Accu2i Long Applicator (cooled)	1.8 mm	29 cm	900-601-US
MTA Temperature Probes (black and grey)	18G	20 cm	900-314

Product Name	Part #
Sulis V ^{pMTA} Generator	806-010-US
LCS Unit	806-011-US
Cart and Monitor Arm	700-006
Cord Set USA/Canada 10A/125v	800-017

IMPORTANT RISK INFORMATION

INDICATIONS FOR USE: The Accu2i pMTA Applicator with Sulis V^{pMTA} Generator Software release 2.1.0 is indicated for intraoperative coagulation of soft tissue.

CONTRAINDICATIONS: The Accu2i pMTA Applicators are contraindicated in patients with heart pacemakers and other electronic device implants.

WARNINGS & PRECAUTIONS: Do not place the applicator in the patient until the applicator has been connected, successfully primed and the LCS Ready Saline symbol is showing on the control unit. Use only Sterile Saline for the coolant reservoir. Patient injury may occur in the event of a coolant leak if non sterile saline, water, or other liquids are used. Use of a smaller coolant reservoir will increase the rate of coolant temperature rise. Do not energise the applicator unless coolant flow can be observed in the applicator handle. DO NOT bend

the Accu2i pMTA Applicator as this may impair the function of the cooling system and may damage the microwave feedline inside the applicator. DO NOT apply lateral forces on the ceramic tip of the applicator on insertion, during use or during removal as this may cause the ceramic to break and cause injury to the patient or user. Failure to locate the temperature probes and monitor the temperature levels of adjacent tissues, vital structures, ducts, vessels, or nerves could result in an unintended thermal injury. DO NOT energize the Accu2i pMTA Applicator unless the ACTIVE REGION of the applicator is fully inserted into target tissue. If the applicator is not properly located into the selected tissue, an unintended thermal injury to the user, or an unintended injury to tissues, vital structures, ducts, vessels, or nerve tissue may occur. Do not re-energise an applicator that has not been visually

inspected between uses. Re-energising the applicator without visually inspecting for damage may result in unnecessary patient injury as the Accu2i pMTA Applicator may not function. Failure to remove the applicator following a fault condition could result in thermal injury to user or patient due to thermal conduction from tissue in the heated coagulation zone. Attempting to re-use an Accu2i pMTA Applicator and coolant reservoir following a Fault condition may result in unnecessary patient injury as the Accu2i pMTA Applicator may not function.

Refer to individual product IFUs and/or User Manual to see full Warnings, Precautions and Contraindications.

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