

**Guidant FLEX 10<sup>®</sup> XE Ablation Probe for the Microwave Ablation System**

*Information for Prescribers*

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

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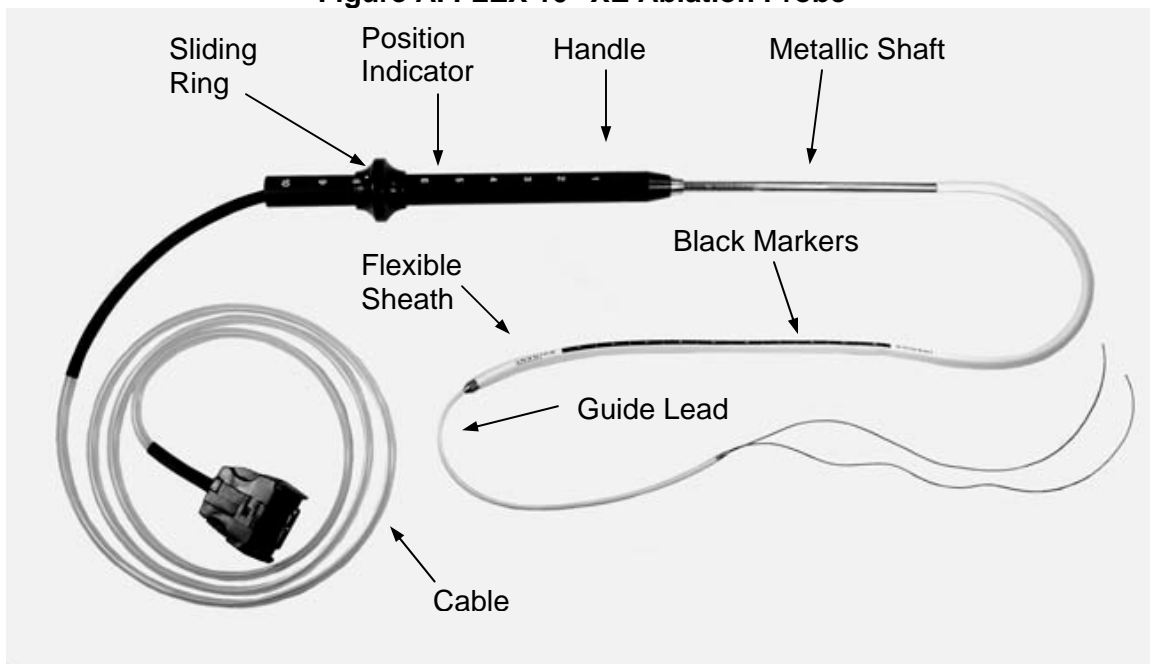
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Carefully read all instructions prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in complications.

## 1.0 DEVICE DESCRIPTION

The FLEX 10<sup>®</sup> XE Ablation Probe for the Guidant Microwave Ablation System is an intraoperative, sterile, single-use device designed to apply microwave energy to tissue. The microwave energy is generated by the Guidant 1000 Series Microwave Generator that is sold separately. The FLEX 10<sup>®</sup> XE Ablation Probe (see Figure A) includes a 24 cm long rigid handle, followed by a metallic shaft, a flexible sheath, and a guide lead. The FLEX 10<sup>®</sup> XE Ablation Probe further includes a 2 m long insulated coaxial cable which attaches to the generator output cable connector. The emitted microwave energy is directed toward the target tissue from the active surface opposite the corresponding numbered segment, and creates a continuous lesion approximately 26 mm long. The black markers indicate the shielded side of each numbered segment. The ablations are created by independently activating the microwave ablation element at one or more of the corresponding numbered segments (see Figure D), which are selected by moving the sliding ring on the handle.

**Figure A. FLEX 10<sup>®</sup> XE Ablation Probe**



## 2.0 HOW SUPPLIED

The Guidant FLEX 10<sup>®</sup> XE Ablation Probe is supplied STERILE in an unopened and undamaged package. The Ablation Probe has been sterilized using Ethylene Oxide and is for single patient use only. **DO NOT RESTERILIZE OR REUSE.**

### **3.0 INDICATIONS FOR USE**

The Guidant Microwave Ablation System is indicated for the surgical ablation of soft tissue and striated, cardiac, and smooth muscles. The system is a device indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures. The probes ablate the target tissue by creating an inflammatory response, or thermal necrosis.

### **4.0 CONTRAINDICATIONS**

The FLEX 10<sup>®</sup> XE Ablation Probe is not intended for viable warming (thermotherapy) of tissues.

### **5.0 ADVERSE EVENTS**

Potential adverse events, apart from those typically associated with the procedure necessary for surgical manipulation of the target tissue, could include ablation or burns to non-targeted tissues, formation of unwanted scar tissue, and/or damage to adjacent nerves or blood vessels.

### **6.0 WARNINGS AND PRECAUTIONS**

#### **Warnings**

1. Do not use if device or package appears damaged.
2. Do not perform ablations at more than 65 watts/120 seconds per ablation.
3. Do not resterilize or reuse. Loss of function or injury to patient may occur.
4. Do not perform ablations directly on the atrial appendage. Clotting may occur.
5. Do not apply excessive force when advancing or withdrawing the device. This may cause device to become inoperable or create excessive force on tissue.
6. Ensure that the selected numbered segment of the flexible sheath is correctly oriented before starting the ablation procedure.
7. Do not lift or move device or attempt to select another numbered segment during the ablation cycle. This may lead to ablation of the wrong tissue, burns or other injuries to the patient or physician, and damage the device and/or generator.
8. Do not place anything in front of or behind the target tissue (tissue being ablated). Any tissue within the microwave energy field may experience heating and/or tissue damage. Ensure that non-target tissue such as the esophagus is adequately separated from the microwave field. One technique is to use wet gauze to separate the tissues. Ensure non-target tissue such as the coronary arteries is protected from the microwave field by carefully placing and orienting the sheath/ablation segment.
9. Do not hold the flexible sheath with metallic instruments on the active segment when it needs to be manipulated. Hold it at an adjacent segment.
10. Ensure that the numbered segments, adjacent to the one selected to perform tissue ablation, do not contact tissue unintended for ablation.

11. Device cable becomes warm during use and may cause burns with prolonged exposure. Do not lay the device cable directly on the patient's skin.

**Precautions**

1. Ensure that all connections between the Microwave Generator and the Ablation Probe are tight to avoid improper delivery of microwave energy.
2. Do not kink, pinch, cut or pull excessively on device cable. Damage to the cable may cause the device to become inoperable.
3. During placement, avoid damage to the device from other surgical tools.
4. Do not activate device if not in contact with tissue to be ablated. Do not activate the device in the air.
5. Do not over manipulate the flexible sheath. Over manipulation may cause the device to become inoperable.
6. Avoid sharp bends at the metallic shaft/flexible sheath junction. This may cause device to become inoperable (see Figure E).
7. Avoid bending the metallic shaft, it is not malleable.
8. Ensure that time and power settings are appropriate for the tissue to be ablated.
9. Do not pinch or grasp the flexible sheath with excessive force. This may cause device to become inoperable (see Figure F).
10. Do not place surgical instrument like forceps, graspers or hemostats in the area where microwave field is emitted.
11. Ensure that the entire length of the numbered segment selected to perform tissue ablation is in contact with the tissue to be ablated. Partial contact may lead to ineffective ablation and/or probe failure.
12. Store in dry, cool place. Do not expose to temperatures in excess of 110°F (43°C).
13. Do not perform more than 40 ablations per device.
14. The safety and effectiveness of the FLEX 10<sup>®</sup> XE Ablation Probe has not been evaluated in patients with cardiac pacemakers or metallic implants.

**7.0 INSTRUCTIONS FOR USE**

1. Inspect package and verify that it is unopened and undamaged. If breaks, bubbles or cracks are observed in the packaging or seal, do not use.
2. Open package. Keep device in the sterile field. Pass device cable off sterile field for generator connection. Do not overextend cable.
3. Connect the device to the generator output cable by aligning connector ends and pushing together until fully seated.
4. Prepare the patient for the surgical procedure.
5. Identify and expose sites to be ablated using standard surgical techniques.
6. Guide the FLEX 10<sup>®</sup> XE Ablation Probe into the desired location. Guiding catheters are often used as an aid.
7. Position and stabilize the active surface of the flexible sheath, opposite the corresponding numbered segment(s), upon the tissue to be ablated.

8. If ablating on the endocardial surface, avoid ablating directly over blood by cleaning endocardial surface prior to ablation. After ablation, flush the resulting lesion to remove any debris from the endocardial surface.
9. Stabilization of the device can be achieved by wrapping the non-active surface of the sheath around adjacent structures. See Figure B.
10. Ensure contact between the active surface of the sheath and the target tissue is achieved and maintained throughout the ablation procedure.
11. When using a significant length of the ablating sheath, check for proper orientation and position of the sheath at three places. See Figure C.
12. Only one numbered segment can be activated at a time. The black marker of the selected numbered segment indicates the side shielded from microwave field emission (see Figure D). The numbers on the flexible sheath correspond to the numbers identified by the position indicator (a notch shaped window on the sliding ring indicates current position). Tissue directly beneath and approximately 3 mm on either side of the selected numbered segment will be ablated. Refer to Figure D for further details.
13. Set the TIME and POWER on the Guidant Microwave Generator to the settings indicated below. Complete TIME and POWER setting instructions are detailed in the Guidant Microwave Generator User's Manual Series 1000.

**NOTE:** Recommended Power and Time settings are given below for cardiac tissue. At the settings indicated below a 5 mm deep lesion can be expected in cardiac tissue. For lesion depth data collected in tissue studies, see Table of Ranges.

<b>ARRESTED HEART*</b>	
Power [W]	Time [sec]
65	45

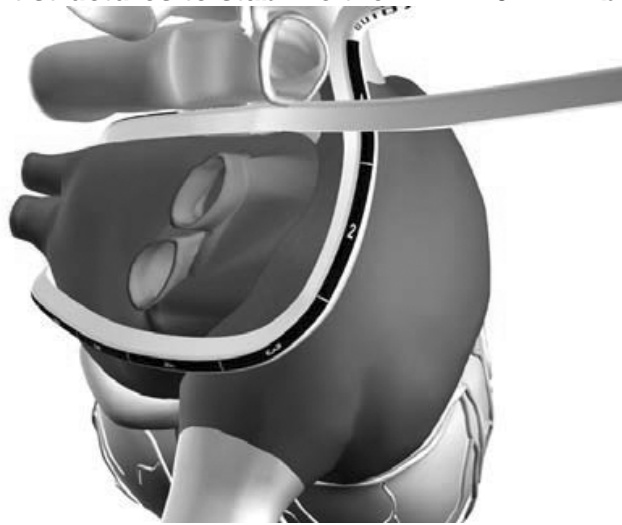
<b>NON-ARRESTED HEART**</b>	
Power [W]	Time [sec]
65	90

\*Arrested heart parameters should be used when ablating cardiac tissue with no blood flow. This includes full cardio-pulmonary bypass (CPB) when the heart is still beating but empty from circulating blood.

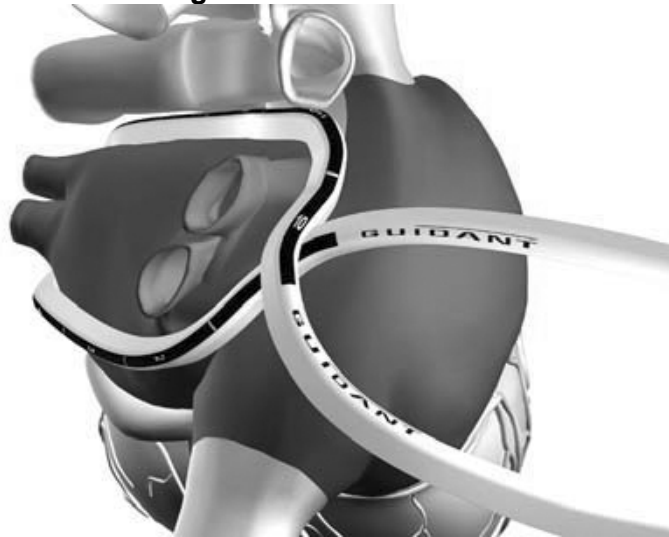
\*\* Non-Arrested heart parameters should be used when ablating cardiac tissue with blood flow. This includes partial CPB when the blood is partially circulating in the heart chambers.

14. Apply microwave energy to the targeted tissue by activating the Microwave Generator.
15. To create continuous lesions, activate the next numbered segment by moving the sliding ring to the next number. (See Figure D). If flexible sheath has to be repositioned to continue or close an ablation line, ensure the selected ablation segment overlaps the created lesion by 1 cm, which is approximately half of the numbered segment length.
16. Upon completion of all ablations, remove device from surgical site, and disconnect it from the generator by squeezing the latches on the connector of the device.
17. Discard the Probe after use. It is a single-use only product.

**Figure B. Stabilizing the FLEX 10<sup>®</sup> XE Ablation Probe.  
Use adjacent structures to stabilize the FLEX 10<sup>®</sup> XE Ablation Probe.**

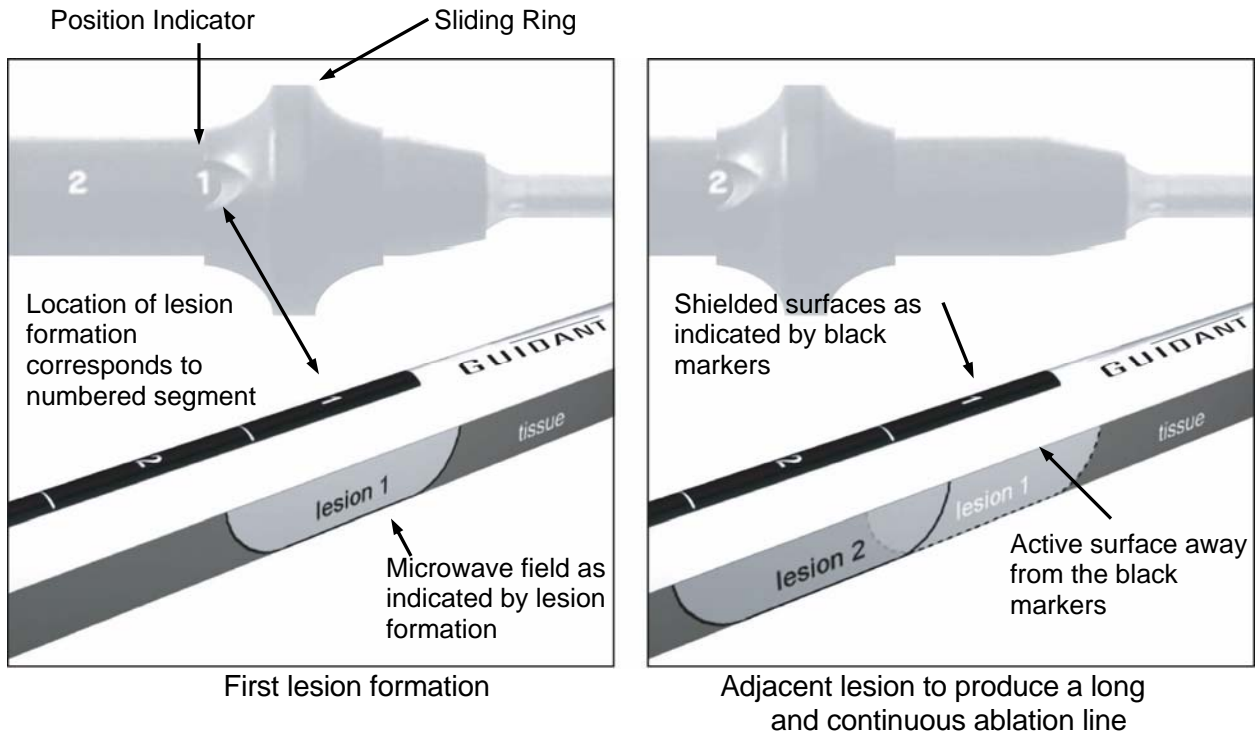


**Figure C. Positioning of the FLEX 10<sup>®</sup> XE Ablation Probe**



When using a long length of the FLEX 10<sup>®</sup> XE sheath, check orientation and positioning of sheath in three locations. FLEX 10<sup>®</sup> XE sheath should be posterior to the left atrial appendage (LAA).

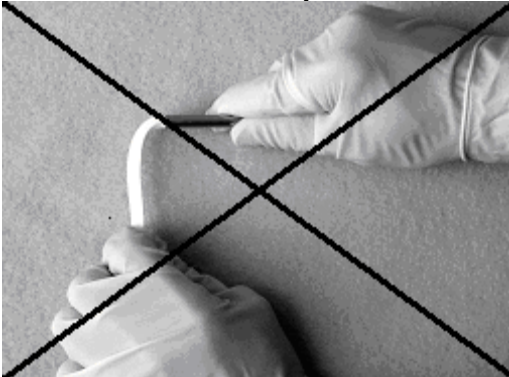
**Figure D. Lesion Overlap**



Ensure that non-target structures are not located within one marker length of the ablation site along the length of the probe

The numbered segments on the flexible sheath correspond to the numbers identified by the position indicator (a notch shaped window on the sliding ring that indicates current position). Tissue directly beneath and approximately 3 mm on either side of the selected numbered segment will be ablated. In curved configurations, distal end markers (1, 2, 3) can have a lesion offset of up to 1/2 marker length. For lesion placement in curved configurations use proximal end markers (8,9,10).

**Figure E.**  
**Manipulation of metallic shaft and flexible sheath**



**Incorrect:** Sharp bend at the transition between metallic shaft and flexible sheath



**Correct:** Smooth transition between metallic shaft and flexible sheath

**Figure F. Manipulation of the flexible sheath**



**Incorrect:** Manipulation of flexible sheath with excessive pinching force



**Correct:** Manipulation of flexible sheath with gentle force

**8.0 TABLE OF RANGES**

The tables below provide an example of appropriate time and power setting ranges for cardiac tissue.

**CARDIAC TISSUE- ARRESTED HEART\***

	<b>Lesion Depth- Average (Min. - Max.)</b>		
<b>Power/Time</b>	<b>30 Seconds</b>	<b>45 Seconds</b>	<b>60 seconds</b>
55 Watts	-	3.7 mm (2.4 – 6.3)	-
65 Watts	2.5 mm (0.9 – 5.8)	4.7 mm (3.3 - 6.6)	6.2 mm (5.3 – 9.6)
75 Watts	-	5.4 mm (4.1 – 9.1)	-

\*Data was obtained in a study where ablations were performed on excised porcine heart at room temperature.

**CARDIAC TISSUE- NON-ARRESTED HEART\*\***






	<b>Lesion Depth- Average (Min. – Max.)</b>	
<b>Power/Time</b>	<b>90 seconds</b>	<b>120 seconds</b>
65 Watts	7.4 mm (5.0 - 10.9)	7.8 mm (6.5 - 9.6)

\*\*Data was obtained during an in vivo canine study where ablations were performed on the epicardial surface of ventricular tissue to fully evaluate the depth of the lesions. Tissue thicknesses varied significantly, ranging from 8.3 mm - 19.3 mm; deeper lesions were created in thicker tissues. Since some ventricular lesions were limited by the thickness of the tissue, those lesions were excluded from the data. In addition to the ventricular lesions, ablations were performed on the epicardial surface of atrial tissue. Transmural lesions were obtained without damage to the atrial endocardial surface as evidenced by the lack of coagulation (thrombus), carbonization, or tissue rupture.

## 9.0 WARRANTY

GUIDANT CORPORATION (GUIDANT) warrants that this product has been manufactured, packaged and tested with reasonable care and will be free from defects in workmanship and materials. GUIDANT further warrants that this product will remain sterile for a period described on the product's label, provided the original packing remains intact. This product is designed for single-use only and is not intended or designed for re-use. This warranty shall not apply to products that have been re-sterilized, repaired, altered, or modified in any way, or to products that have been improperly stored or improperly installed, operated or maintained. GUIDANT will not be liable for any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from the use of this product. The sole obligation of GUIDANT shall be to repair or replace, as its option, any device that GUIDANT determines was defective at time of shipment if notice thereof is received within the "use before" or expiration date described on such products label. Buyer assumes all liability, whether based upon warranty, contract, negligence, or otherwise, for damage resulting from the handling, possession, use or misuse (including re-use) of this product. Because GUIDANT has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over the selection of patients, **THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.** The remedies set forth in the Warranty and limitations shall be the exclusive remedy available to any person. No agent, employee, or representative of GUIDANT has any authority to change any of the foregoing or assume or bind GUIDANT to any additional liability or responsibility in connection with this product. Buyer's use of this product shall be deemed acceptance of the terms and conditions of this Warranty and limitations.

## 10.0 GRAPHICAL SYMBOL DEFINITIONS

<b>REF</b> Catalogue Number:	 Contents (Numeral represents quantity of units inside)
<b>LOT</b> Lot Number:	
 Use By:	 Attention: See Instructions For Use
<b>STERILE</b>   <b>EO</b> Sterilization by Ethylene Oxide	 Federal (USA) Law restricts this device to sale by, or on the order of, a physician.
 Do Not Reuse	

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