

FLEXConnect™ Probe Fixation Device
Information for Prescribers

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

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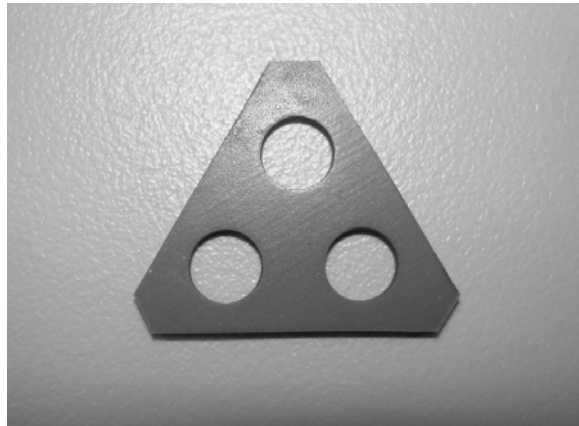
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Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

1.0 DEVICE DESCRIPTION

The FLEXConnect™ Probe Fixation Device is an inter-operative single-use device designed to hold the FLEX 10™ XE Microwave Surgical Ablation Probe in the desired position while the probe is ablating. The device is a symmetrical triangular shape and blue in color (See Figure A.) There are three holes on the device that are sized to allow the device to slide onto the flexible sheath portion of the FLEX 10™ XE Microwave Surgical Ablation Probe.

Figure A.
FLEXConnect™ Probe Fixation Device



2.0 HOW SUPPLIED

The FLEXConnect™ Probe Fixation Device is supplied STERILE in an unopened and undamaged package. The FLEXConnect™ Probe Fixation Device has been sterilized by gamma radiation and is for single use only. **DO NOT RESTERILIZE. DO NOT REUSE.**

The product package contains five (5) individually packaged FLEXConnect™ Probe Fixation Devices.

The product package should be stored in a dry, dark, and cool place before use. There is no latex in the FLEXConnect™ Probe Fixation Device.

3.0 INDICATIONS

The Guidant FLEXConnect™ Probe Fixation Device is indicated for use in open chest cardiovascular surgery to hold the FLEX 10™ XE Microwave Surgical Ablation Probe during the ablation process.

4.0 CONTRAINDICATIONS

None known.

5.0 WARNINGS AND PRECAUTIONS

1. Do not use if device or package appears damaged.
2. Do not sterilize or reuse. Loss of function or injury to patient may occur.
3. The FLEXConnect™ Probe Fixation Device is designed to be compatible with the Guidant FLEX 10™ XE Microwave Surgical Ablation Probe.
4. Do not use excessive force when advancing or withdrawing the FLEXConnect™ Probe Fixation Device along the sheath of the FLEX 10™ XE Microwave Surgical Ablation Probe.
5. Do not kink, pinch, cut, or pull excessively on the FLEXConnect™ Probe Fixation Device. Damage to the FLEXConnect™ Probe Fixation Device may cause it to become inoperable.
6. During placement, avoid damage to the FLEXConnect™ Probe Fixation Device from other surgical tools.
7. Extra caution should be observed when sliding the FLEXConnect™ Probe Fixation Device from the guide lead onto the flexible sheath.
8. Ensure that the FLEXConnect™ Probe Fixation Device is not positioned on an actively ablating segment.
9. Do not use artificial lubrication with the FLEXConnect™ Probe Fixation Device.
10. This product is designed for use with the FLEX 10™ XE Microwave Surgical Ablation Probe. For proper use of the FLEX 10™ XE Microwave Surgical Ablation Probe, refer to the FLEX 10™ XE Microwave Surgical Ablation Probe IFU.
11. Safety and Effectiveness of the Device has not been evaluated in thoracoscopic minimally invasive procedures.

6.0 INSTRUCTIONS FOR USE**6.1 Device Preparation**

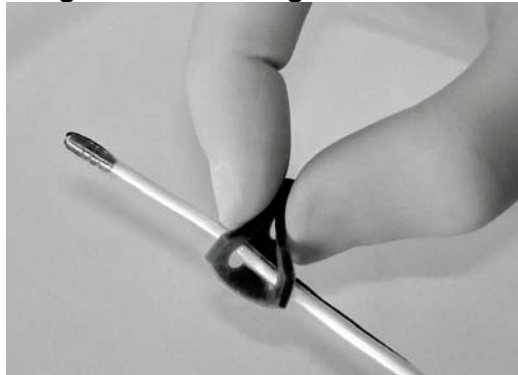
1. Inspect the package and verify that it is unopened and undamaged.
2. Open package. Keep device in the sterile field.
3. Fold the FLEXConnect™ Probe Fixation Device towards you in half to align 2 of the holes (See Figure B.)

Figure B.
Fold FLEXConnect™ Probe Fixation Device and align two holes.



4. Thread the FLEX 10™ XE Microwave Surgical Ablation Probe guide lead (thin, distal portion with attached suture) through the 2 aligned holes, leaving the 3rd hole open (See Figure C.)

Figure C.
Thread FLEX 10™ XE Microwave Surgical Ablation Probe guide lead through two holes.



5. Slide the FLEXConnect™ Probe Fixation Device up to the metal tip between the guide lead and the flexible sheath on the FLEX 10™ XE Microwave Surgical Ablation Probe (See Figure D.)

Figure D.
Slide FLEXConnect™ Probe Fixation Device to metal tip of Probe.



6. While holding the FLEX 10™ XE Microwave Surgical Ablation Probe flexible sheath, push the FLEXConnect™ Probe Fixation Device past the metal tip onto the flexible sheath past the #10 black marker (to logo area.) Rotate the third hole to the desired position (See Figure E.)

Figure E.
Positioning of FLEXConnect™ Probe Fixation Device on Probe.



7. With the FLEXConnect™ Probe Fixation Device in the proper position, the FLEX 10™ XE Microwave Surgical Ablation Probe can now be routed per the FLEX 10™ XE Microwave Surgical Ablation Probe IFU.

6.2 Securing the FLEX 10™ XE Microwave Surgical Ablation Probe with the Device

1. Once the FLEX 10™ XE Microwave Surgical Ablation Probe has been placed in its desired position, hold on to the FLEXConnect™ Probe Fixation Device and pull the distal end of the FLEX 10™ XE Microwave Surgical Ablation Probe through the 3rd hole until the FLEX 10™ XE Microwave Surgical Ablation Probe is looped into the desired position (See Figures F and G.) Verify that the FLEXConnect™ Probe Fixation Device is not on an actively ablating segment.

Figure F.
Thread FLEX 10™ XE Microwave Surgical Ablation Probe Guide Lead Through the 3rd Hole.

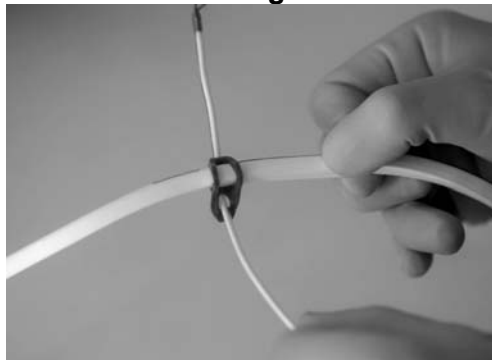


Figure G.
FLEXConnect™ properly affixed to
FLEX 10™ XE Microwave Surgical Ablation Probe



2. Verify alignment and placement of the FLEX 10™ XE Microwave Surgical Ablation Probe and proceed with the ablation process per the FLEX 10™ XE Microwave Surgical Ablation Probe IFU.





6.3 Removing the FLEX 10™ XE Microwave Surgical Ablation Probe from the FLEXConnect™ Probe Fixation Device

1. To remove the FLEX 10™ XE Microwave Surgical Ablation Probe pull the distal section of the FLEX 10™ XE Microwave Surgical Ablation Probe back out of the FLEXConnect™ Probe Fixation Device.
2. The FLEXConnect™ Probe Fixation Device can be left on the proximal portion of the FLEX 10™ XE Microwave Surgical Ablation Probe.

7.0 WARRANTY

GUIDANT CORPORATION (GUIDANT) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond GUIDANT's control directly affect the instrument and the results obtained from its use. GUIDANT's obligation under this warranty is limited to the repair or replacement of this instrument and GUIDANT shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. GUIDANT neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **GUIDANT assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

8.0 GRAPHICAL SYMBOL DEFINITIONS

REF Catalogue Number:	 Contents (Numeral represents quantity of units inside)
LOT Lot Number:	 Attention: See Instructions For Use
 Use By:	R_x ONLY Federal (USA) Law restricts this device to sale by, or on the order of, a physician.
STERILE R Sterilization by Irradiation	
 Do Not Reuse	

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EL2055798 Rev. A