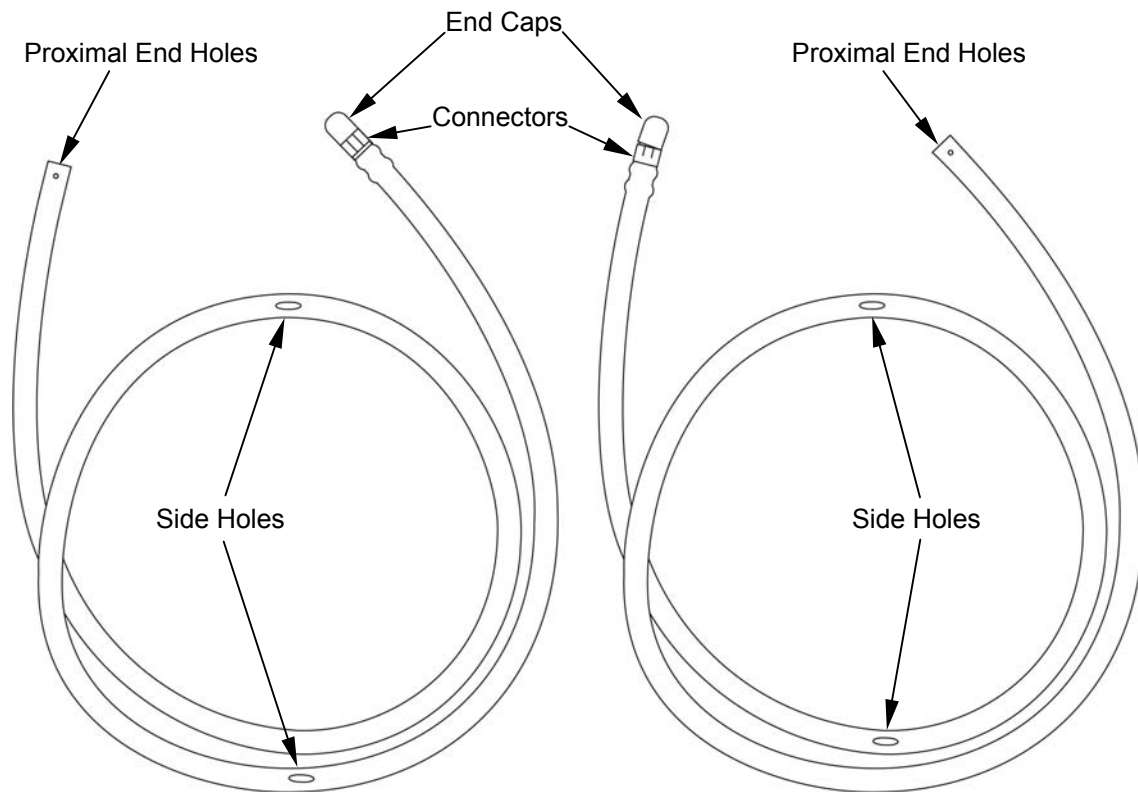


Guidant FLEXGuide™ Routing Tools

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

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Figure A: FLEXGuide™ Routing Tools

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

DEVICE DESCRIPTION

The FLEXGuide™ Routing Tools are an intra-operative single-use device designed to facilitate placement of the FLEX 10® Ablation Probe. The FLEXGuide™ Routing Tools include two 85 cm long elastic, flexible tubes. One is blue and the other is white. The tubes have mating male-female rigid plastic connectors (See figure B) on the distal end to enable the tubes to be easily snapped together. The connectors are provided with rounded end caps (See figure A) to facilitate advancing the tubes between tissues. The proximal end of each tube has holes (See figure A) for compatibility with the FLEX 10® Ablation Probe. The sutures at the distal end of the FLEX 10® Ablation Probe may be passed through these holes to connect the FLEX 10® Ablation Probe to the FLEXGuide™ Routing Tools. Each FLEXGuide™ Routing Tool has two additional holes along the tube length (See figure A) for compatibility with standard surgical instruments used in device placement.

HOW SUPPLIED

There are no latex components in the FLEXGuide™ Routing Tools.

Sterile. Sterilized by irradiation. Do not use if the package is open or damaged.

Contents. One (1) blue FLEXGuide™ Routing Tool, One (1) white FLEXGuide™ Routing Tool

Storage. Store in a dry, dark, cool place.

INDICATIONS

The FLEXGuide™ Routing Tools are indicated for use in cardiovascular surgery to facilitate positioning of the Guidant FLEX 10® Ablation Probe.

CONTRAINDICATIONS

None known.

WARNINGS AND PRECAUTIONS

Warnings

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 Routing Tools are designed to be compatible with standard 6 French diameter, clinically approved stylets. Use of an incompatible stylet may cause the device to become inoperable or cause injury to the patient.
4. If a stylet is used with the Routing Tools, the stylet should be inserted through one of the Routing Tool side holes (See figure A) and advanced all the way to the tip of the Routing Tool prior to placement in the patient's body. Proper positioning of the stylet is necessary to prevent improper function or injury to patient. If the stylet is too short to reach the tip of the Routing Tool, the stylet should not be used.
5. Do not insert a stylet into the Routing Tool if the Routing Tool is already placed in the patient's body. Inserting a stylet into the Routing Tool while in the body may result in improper function or injury to patient.
6. Do not use excessive force to insert a stylet into the Routing Tool. Use of excessive insertion force may cause the device to become inoperable.
7. Do not apply excessive force when advancing or withdrawing the device. This may cause device to become inoperable. This may also create excessive force on tissue if the device is tangled or if its movement is obstructed by surgical tools, accessories, or ports.

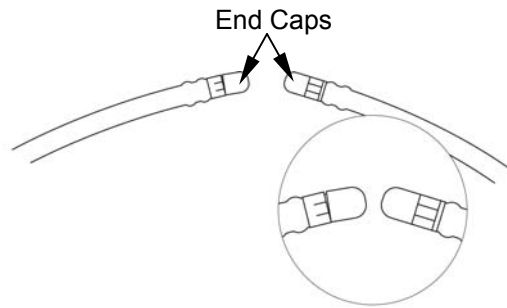
Precautions

1. Before introducing the Routing Tools to the surgical field, confirm that the connector end caps are secure in order to prevent caps from being unexpectedly dislodged in the surgical field.
2. Do not kink, pinch, cut, or pull excessively on the tubes. Damage to the tubes may cause the device to become inoperable.
3. During placement, avoid damage to the Routing Tools from other surgical tools.
4. Extra caution should be observed when inserting the Routing Tool with a stylet into tissue planes.
5. This product is designed for use with the Guidant FLEX 10® Ablation Probe. For proper use of the FLEX 10® Ablation Probe, see separate FLEX 10® Ablation Probe IFU (not available electronically).

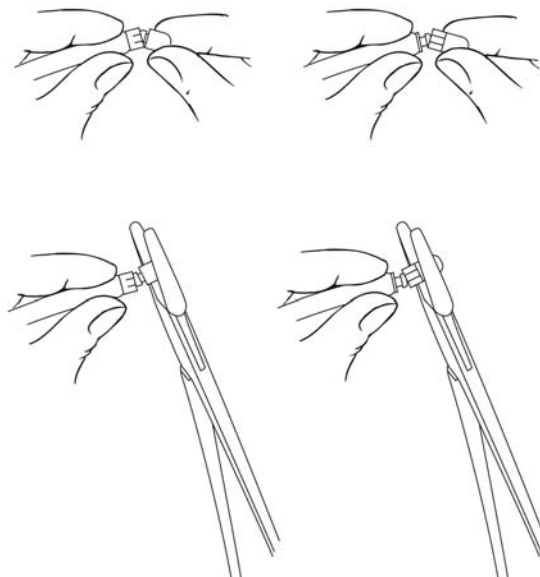
INSTRUCTIONS FOR USE

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.
3. Check to make sure that the rounded end caps are securely snapped onto the plastic connectors of the Routing Tools.
4. Examine the Routing Tools to make sure that all connectors and holes are free of debris. Each Routing Tool has two oval side holes for compatibility with a stylet, or other positioning device, and two small round holes in the proximal end for compatibility with the Guidant FLEX 10[®] Ablation Probe. (See figure A)
5. Prepare the patient for the surgical procedure.
6. There are various surgical methods to access cardiac tissue such as: sternotomy, mini-thoracotomy, thoracoscopy, and robot-assisted surgery.
7. Identify and expose the tissue planes through which the Routing Tools will be passed.
8. Insert the Routing Tools into the desired positions. For cardiac ablation procedures, one Routing Tool is commonly inserted through the transverse sinus and the other is inserted under the inferior vena cava through the oblique sinus. Note that the ends with the rounded plastic end caps are intended to be inserted first.
9. After the Routing Tools have been passed through the desired tissue plane, the end caps can be removed by bending the joint between the tube connector and the end cap. (See figure B) This will expose the connector.
10. The Routing Tools can be connected to each other by snapping the male plastic connector of one Routing Tool into the female plastic connector of the other Routing Tool. (See figure B)
11. The Guidant FLEX 10[®] Ablation Probe can then be connected to the proximal end of one of the Routing Tools using the sutures attached to the distal tip of the FLEX 10[®] Ablation Probe.
(See Figure C)
 - a. This is done by first passing one of the sutures at the distal tip of the FLEX 10[®] Ablation Probe into the open end (proximal end) of the Routing Tool and out through one of the holes located at the proximal end of the Routing Tool.
 - b. Likewise, the second FLEX 10[®] Ablation Probe suture should be passed into the open end of the Routing Tool and out through the other hole at the proximal end of the Routing Tool.
 - c. Next, the tip of the FLEX 10[®] Ablation Probe should be tucked into the Routing Tool as the sutures are pulled to position the FLEX 10[®] Ablation Probe tip inside the Routing Tool.
 - d. Finally, the sutures should be tied and knotted to secure the FLEX 10[®] Ablation Probe to the Routing Tool. (See Figure C) A French eye needle, or other needle passing device, may be used to assist in this step.
12. The Routing Tools may then be used to assist in positioning the Guidant FLEX 10[®] Ablation Probe. (See the FLEX 10[®] Ablation Probe IFU.)
13. Upon completion of use, remove Routing Tools from surgical site. Discard the Routing Tools after use. They are a single-use only product.

Figure B: FLEXGuide™ Distal End Caps and Connectors



Removing end caps by hand or with surgical instrument to expose connectors



Snapping male connector into female connector
Female Connector Male Connector

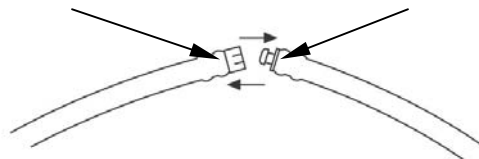
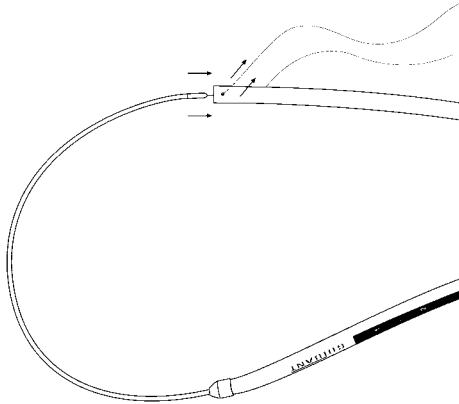
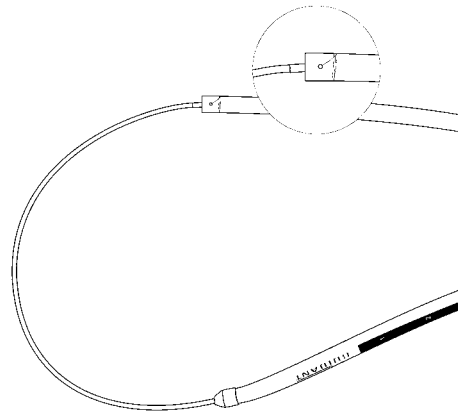


Figure C: Connecting the FLEX 10[®] Ablation Probe to the FLEXGuide[™] Routing Tool

Passing FLEX 10[®] Ablation Probe sutures through proximal end holes of Routing Tool



Tying and knotting FLEX 10[®] Ablation Probe tip into proximal end of the Routing Tool

**WARRANTY**






GUIDANT CORPORATION'S CARDIAC SURGERY GROUP (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 GUIDANT.** 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.

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**GRAPHICAL SYMBOLS
FOR MEDICAL DEVICE LABELING**

| | |
|---|---|
| REF Catalogue Number: |  Contents (Numeral represents quantity of units inside) |
| LOT Lot Number: |  Attention: See Instructions For Use |
|  Use By: |  Federal Law (USA) 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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