

Guidant FLEXView™ Unilateral Routing System
Information for Prescribers

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

Table of Contents

1.0	DEVICE DESCRIPTION
2.0	HOW SUPPLIED
3.0	INDICATIONS
4.0	CONTRAINDICATIONS
5.0	WARNINGS AND PRECAUTIONS
6.0	INSTRUCTIONS FOR USE
6.1	Preparing the Routing Lens
6.2	Introducing the Routing Snare
6.3	Retrieving the Routing Snare
6.4	Using the Routing Snare to Position the Guidant FLEX 10® Ablation Probe
7.0	WARRANTY
8.0	GRAPHICAL SYMBOL DEFINITIONS

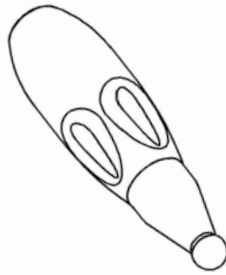
Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

1.0 DEVICE DESCRIPTION

The Guidant FLEXView™ Unilateral Routing System is comprised of the Guidant FLEXView™ Routing Lens and Guidant FLEXView™ Routing Snare.

The Guidant FLEXView™ Routing Lens (see Figure A) is used in conjunction with the Guidant 7mm Extended Length Endoscope. The lens can be attached to and removed from the distal end of the 7mm Endoscope by the user.

Figure A.
Guidant FLEXView™ Routing Lens



The Guidant FLEXView™ Routing Snare (see Figures B and C) is used in conjunction with the Guidant FLEXView™ Routing Lens. The Routing Snare is composed of a Snare Guide and a Snare Assembly, which has two Snare Loops (one at each end). The Routing Snare can be looped around and cinched onto the Routing Lens by the user.

Figure B.
Guidant FLEXView™ Routing Snare

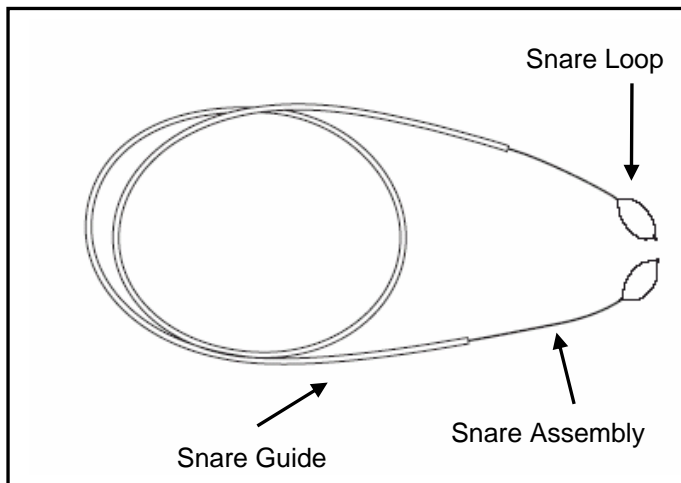
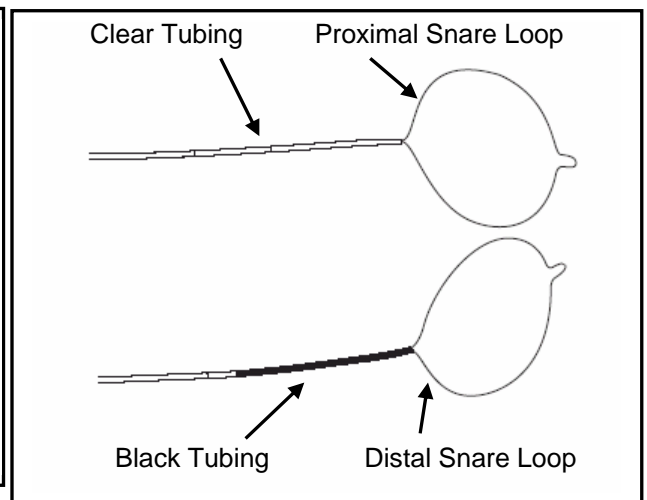


Figure C.
Close-Up of the Snare Loops



2.0 HOW SUPPLIED

STERILE- Sterilized by irradiation. Do not use if package is opened or damaged. DO NOT RESTERILIZE OR REUSE. **CONTENTS-** One (1) Routing Lens, one (1) Routing Snare. **STORAGE-** Store in a dry, dark, and cool place.

There are no latex components in the FLEXView™ Routing Lens and FLEXView™ Routing Snare.

3.0 INDICATIONS

The Guidant FLEXView™ Routing Lens, when used with the Guidant 7mm Extended Length Endoscope and Guidant FLEXView™ Routing Snare, is intended to aid in the visualization of anatomical structures and to facilitate placement of the Guidant FLEX 10® Ablation Probe during minimally invasive surgical procedures.

The Guidant FLEXView™ Routing Snare, when used with the Guidant FLEXView™ Routing Lens, is intended to facilitate placement of the Guidant FLEX 10® Ablation Probe during minimally invasive surgical procedures.

4.0 CONTRAINDICATIONS

The Routing Lens and Snare are contraindicated in situations where endoscopic techniques and minimally invasive surgery are contraindicated.

5.0 WARNINGS AND PRECAUTIONS

1. Read all instructions carefully. Failure to properly follow the instructions, warnings, and cautions may lead to serious surgical consequences or serious injury to the patient.
2. Endoscopic procedures should be performed only by physicians or surgical professionals having adequate training and familiarity with endoscopic techniques. Consult medical literature regarding techniques, complications, and hazards prior to performance of these procedures.
3. The Routing Lens and Snare are sterile unless the package is opened or damaged. The Routing Lens and Snare are designed for single use. Do not reuse or resterilize the Routing Lens or Snare.
4. Do not apply excessive force while navigating with the Routing Lens and Snare due to risk of hemodynamic compromise or laceration or perforation of vessels or other anatomical structures.
5. Do not apply excessive force when advancing or withdrawing the Routing Lens and Snare. Hemodynamic compromise or laceration or perforation of vessels or other anatomical structures may result.
6. Do not continue to use the Routing Lens and Snare if visualization is impaired.
7. Do not apply excessive force while cinching the Snare Loop onto the Routing Lens due to risk of procedural delay.
8. Do not clamp on the orange Snare Guide. Clamping on the Snare Guide may result in improper cinching of the Routing Snare onto the Routing Lens, causing procedural delay.

9. Do not use less than three suture knots to attach the Flex 10 Ablation Probe to the Routing Snare. This may cause the Ablation Probe to detach from the Routing Snare and result in procedural delay.
10. Do not cut the ends of the Flex 10 attachment sutures flush with the knot once the Flex 10 Ablation Probe is attached to the Routing Snare. This may increase risk of knot slippage or breakage, which may require retrieval of suture material.
11. Do not apply excessive force when advancing the Flex 10 Probe using the Routing Snare. This may create excessive force on tissue, which may require surgical treatment.
12. Application of excessive force may result in damage to the device.

6.0 INSTRUCTIONS FOR USE

This Instructions for Use document is not a reference for endoscopic techniques. Representative sources are listed in the bibliography of the Instructions for Use document provided with the Guidant 7mm Extended Length Endoscope. Do not use the FLEXView™ Routing Lens or FLEXView™ Routing Snare if the packaging is damaged or opened. Carefully remove devices from the shipping package. Inspect the devices to ensure no damage has occurred during transit. Prepare the patient in accordance with standard surgical techniques.

6.1 Preparing the Routing Lens

- 6.1.1 Follow the Guidant 7mm Extended Length Endoscope Instructions for Use in order to prepare the device for use endoscopically.
- 6.1.2 Attach the Routing Lens (see Figure A) to the distal end of the Guidant 7mm Endoscope. Screw the Routing Lens onto the Endoscope until the proximal edge of the Routing Lens lines up with the indicator band on the Endoscope shaft, and the Routing Lens is securely attached to the Endoscope.

6.2 Introducing the Routing Snare

- 6.2.1 While outside of the patient's chest cavity, place the ball end of the Routing Lens through the distal Snare Loop. The distal end can be identified by the black tubing adjacent to the loop (see Figure C).
- 6.2.2 To engage the distal Snare Loop onto the Routing Lens:
 - a. Pull the proximal end of the Snare Assembly to cinch the distal snare loop onto the Routing Lens (see Figures D and E)
 - b. While applying traction to the proximal end of the Snare Assembly, use a standard surgical instrument (e.g., hemostat) to clamp the Snare Assembly adjacent to the proximal end of the Snare Guide (see Figure F) in order to keep the distal Snare Loop cinched tightly onto the Routing Lens. The proximal end can be identified by the clear tubing adjacent to the Snare Loop (see Figure C).

- 6.2.3 Insert the Guidant 7mm Extended Length Endoscope with the attached Routing Lens and Snare through standard surgical access.
- 6.2.4 Use the Routing Lens and Endoscope to visualize anatomical structures and position the distal end of the Routing Snare as desired.
- 6.2.5 After reaching the desired location, release the distal Snare Loop from the Routing Lens and Endoscope by detaching the surgical clamping instrument from the Snare Assembly.
Note: Advancement and re-engagement (Step 6.3.1) of the Routing Snare can be facilitated by withdrawing the distal Snare Loop into the Snare Guide.

Figure D.
Pulling the Proximal End of the Snare Assembly

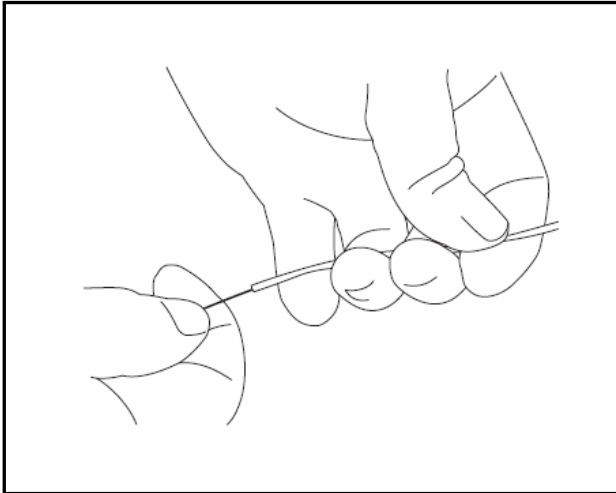


Figure E.
Snare Assembly Cinching the Routing Snare onto the Routing Lens

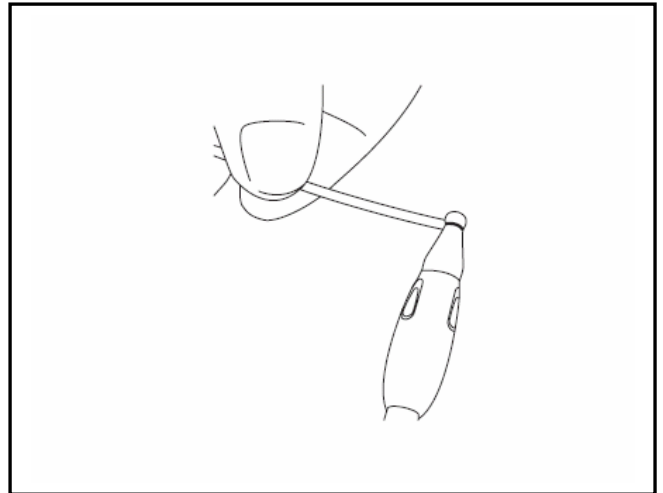
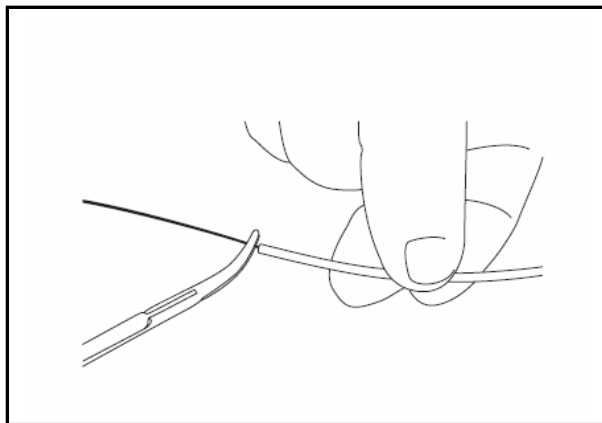


Figure F.
Clamping the Snare Assembly



6.3 Retrieving the Routing Snare

- 6.3.1 To reposition the distal end of the Routing Snare within the anatomy, locate and re-engage the distal Snare Loop as stated in Steps 6.2.1 and 6.2.2 under direct visualization with the Routing Lens and Endoscope.
- 6.3.2 Once the distal Snare Loop is again engaged around the Routing Lens, use the Endoscope with attached Routing Snare to withdraw the distal end of the Routing Snare from the chest cavity.

6.4 Using the Routing Snare to Position the Guidant FLEX 10[®] Ablation Probe

- 6.4.1 Attach the Ablation Probe to the Routing Snare by tying the Ablation Probe sutures to the proximal Snare Loop (see Figure G).
- 6.4.2 Ready the Routing Snare and Ablation Probe for positioning:
 - a. Apply traction to the distal end of the Snare Assembly to draw the proximal Snare Loop and attachment knots into the lumen of the Snare Guide (see Figure H).
 - b. After the Snare Loop and attachment knots are drawn into the Snare Guide, use a standard surgical instrument (e.g., hemostat) to clamp the Snare Assembly adjacent to the distal end of the Snare Guide (see Figure F).
 - c. Advance the Ablation Probe using the Routing Snare to the desired location.
- 6.4.3 To detach the Ablation Probe from the proximal Snare Loop, cut the attachment sutures.

Figure G.
Attaching the Ablation Probe Sutures to the Proximal Snare Loop

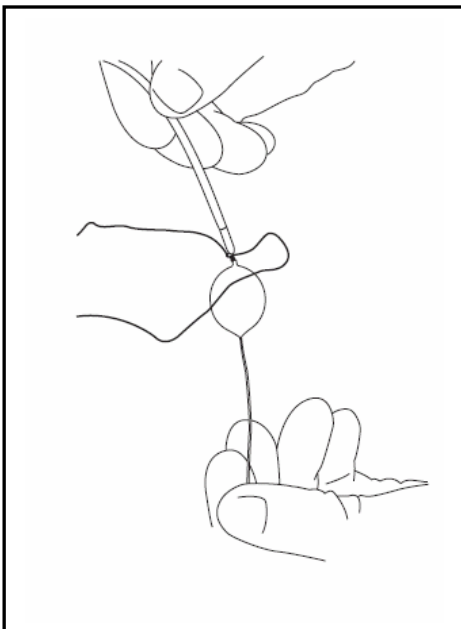
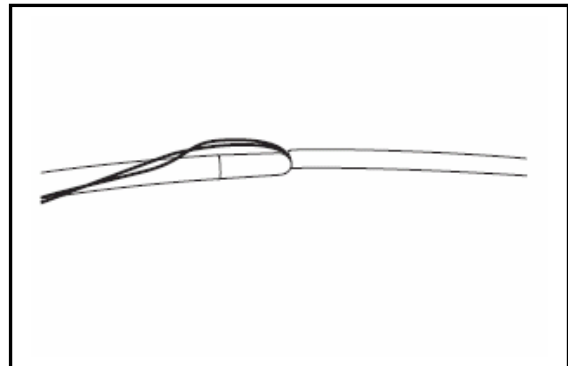






Figure H.
Attachment Knots Drawn Into The Snare Guide



7.0 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.

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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