

Guidant FLEXView™ System
Instructions for Use

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	Device Preparation
6.2	Patient Preparation
6.3	Inserting the Cannula
6.4	Introducing the Routing Snare
6.5	Retrieving the Routing Snare
6.6	Using the Routing Snare to Position the Guidant Microwave 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™ System is comprised of the Guidant FLEXView™ Cannula with Suction Assembly, Guidant FLEXView™ Routing Snare, and Guidant FLEXView™ Retrieval Tool.

The Guidant FLEXView™ Cannula (see Figure A) is used in conjunction with the Guidant 7mm Extended Length Endoscope. The Cannula consists of a lens, a metal shaft, and a handle. On top of the handle are two service ports that allow passage of surgical tools through the handle and out of the distal end of the device. One service port contains a Suction Tool (see Figure A) that has a female luer connector at the proximal end for engagement with standard operating room vacuum sources. A 5-foot long Extension Tubing (see Figure B) is provided to facilitate use of the Suction Tool. The other service port in the cannula is for use with the Guidant FLEXView™ Routing Snare or Retrieval Tool.

Figure A.
Guidant FLEXView™ Cannula

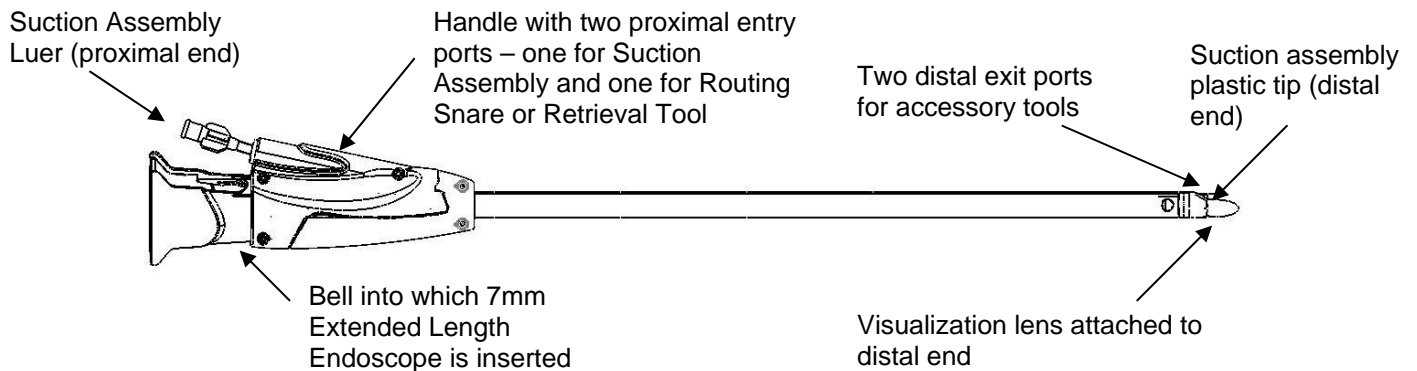
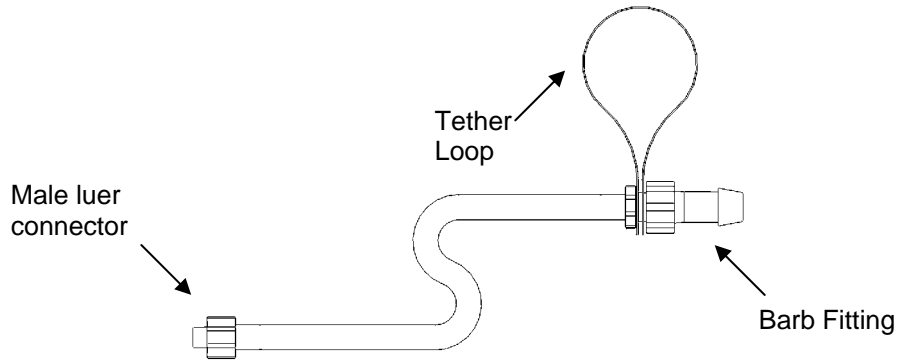


Figure B.
Guidant FLEXView™ Extension Tubing
(not to scale)



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

Figure C.
Guidant FLEXView™ Routing Snare

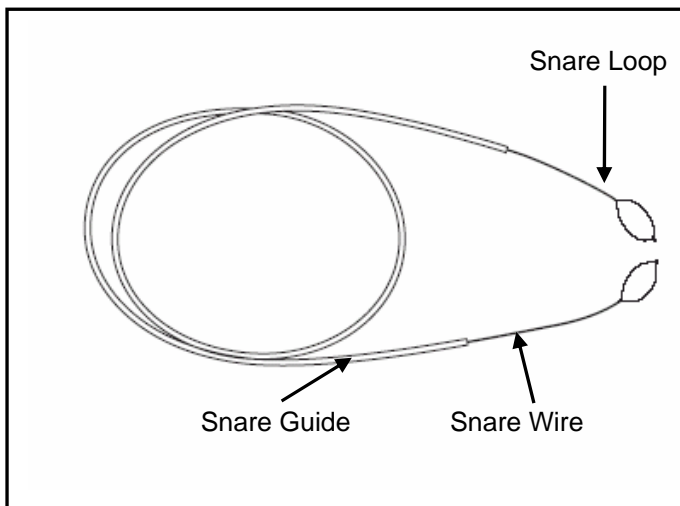
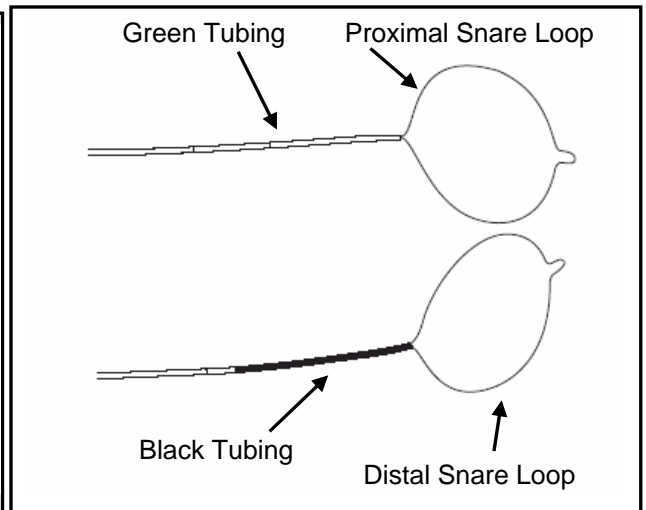
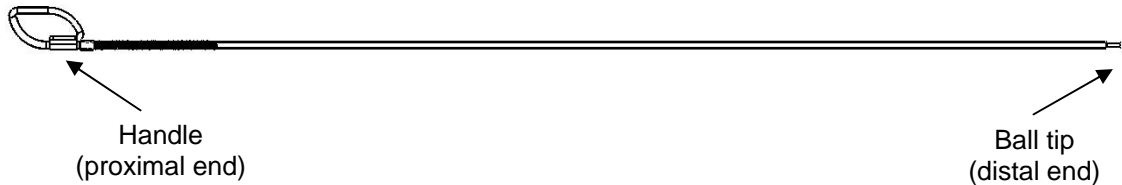


Figure D.
Close-Up of the Snare Loops



The Guidant FLEXView™ Retrieval Tool (see Figure E) is used in conjunction with the Guidant FLEXView™ Routing Snare. The Retrieval Tool is a metal guide that features a handle at its proximal end and a ball at its distal end onto which the Routing Snare is cinched. Both the Guidant FLEXView™ Retrieval Tool and Routing Snare are designed to fit individually through one of the service ports in the Cannula.

Figure E.
Guidant FLEXView™ Retrieval Tool



2.0 HOW SUPPLIED

The Guidant FLEXView™ System is supplied STERILE in an unopened and undamaged package. The Guidant FLEXView™ System has been sterilized by gamma irradiation and is for single use only. **DO NOT RESTERILIZE. DO NOT REUSE.**

The System contains one (1) Cannula with one (1) Suction Assembly inserted, one (1) Routing Snare, one (1) Retrieval Tool, one (1) 5-foot long Extension Tubing.

The System should be stored in a dry, dark, and cool place before use. There are no latex components in the FLEXView™ System.

3.0 INDICATIONS

The Guidant FLEXView™ System is indicated for use in minimally invasive surgery allowing access for delivery and placement of surgical instruments (e.g., Guidant Microwave Ablation Probe). It is indicated for patients requiring blunt dissection of tissue including structures in the thoracic space.

4.0 CONTRAINDICATIONS

The FLEXView™ System is 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 FLEXView™ System is sterile unless the package is opened or damaged. The FLEXView™ System is designed for single patient use. Do not reuse or resterilize the FLEXView™ System.
4. Do not apply excessive force while navigating with the Cannula, Retrieval Tool, and Routing Snare due to risk of laceration or perforation of vessels or other anatomical structures, and/or hemodynamic compromise.
5. Do not apply excessive force when advancing or withdrawing the Cannula, Suction Assembly, Routing Snare, or Retrieval Tool. Hemodynamic compromise or laceration or perforation of vessels or other anatomical structures may result.
6. Do not continue to use the FLEXView™ System if visualization is impaired.
7. Do not apply excessive force while cinching the Snare Loop onto the Retrieval Tool 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 Retrieval Tool, causing procedural delay.
9. Do not use less than three suture knots to attach the Guidant Microwave 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 Guidant Microwave Ablation Probe attachment sutures flush with the knot once the 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 Guidant Microwave Ablation Probe using the FLEXView™ System. This may create excessive force on tissue, resulting in tissue damage which may require surgical treatment.
12. Application of excessive force may result in damage to the device.
13. Once the endoscope is inserted into the device and the device is used in the patient, the endoscope must not be removed from the device until the procedure is completed. If removed, fluids will enter the lens chamber and compromise visualization capability.
14. Before connecting the Suction Tool to the hospital vacuum system, verify compatibility and ensure that the Cannula bell does not obstruct the movement of the Suction Assembly during the procedure.

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™ System 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 Device preparation

- 6.1.1 Insert the Guidant 7mm Extended Length Endoscope into the FLEXView™ Cannula until the devices snap together.
- 6.1.2 Connect the camera and light guide cable to the 7mm Endoscope.
- 6.1.3 Connect the male luer connector of the Extension Tubing to the female luer connector of the Suction Tool.
NOTE: Suction Tool is not intended to be removed from service port.
- 6.1.4 Connect the Tether Loop of the Extension Tubing to the Operating Table using a towel clamp or similar standard surgical tool.
- 6.1.5 Connect the Barb Fitting of the Extension Tubing to hospital vacuum.
NOTE: If clogging of the Suction Tool occurs during the procedure, gently purge the lumen with a saline injection per standard surgical technique.

6.2 Patient preparation

- 6.2.1 Access the chest cavity and the heart using standard surgical techniques.

6.3 Inserting the Cannula

- 6.3.1 A 12mm port is necessary for introduction of the FLEXView™ Cannula into the chest cavity if insufflation is required; compatibility with specific ports can be verified independently. If insufflation is not required, an incision may be used instead of a port.
- 6.3.2 Introduce the FLEXView™ Cannula through the chest wall.
- 6.3.3 Navigate into the thoracic space to the desired location for deployment of the Routing Snare.

6.4 Introducing the Routing Snare

- 6.4.1 When the FLEXView™ Cannula is in the proper position for deployment of the FLEXView™ Routing Snare, load the distal end of the Routing Snare into the proximal service port of the Cannula.
- 6.4.2 Advance the Routing Snare until the orange Snare Guide is visible in the lens field of view.
- 6.4.3 Continue advancing the Routing Snare, observing the direction that the Routing Snare turns as it exits the Cannula.
- 6.4.4 Ensure that the Routing Snare points in the desired direction before fully deploying it.
NOTE: If excessive resistance is encountered, retract the Routing Snare and re-deploy to reduce the risk of perforation.

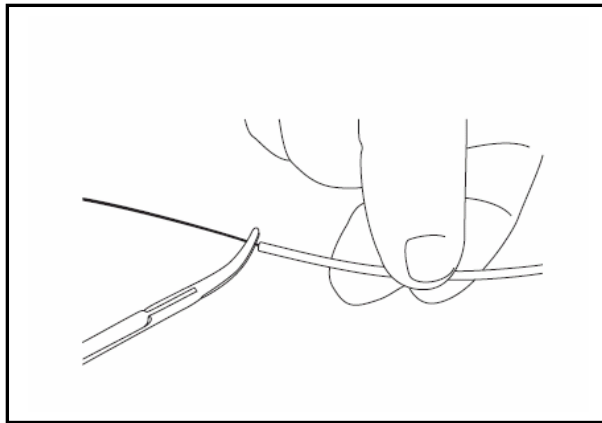
- 6.4.5 Advance the Snare Wire at its proximal end to deploy the distal Snare Loop.
NOTE: This will ensure that the Snare Wire remains within the Snare Guide during withdrawal of the FLEXView Cannula and prevent procedural delay.
- 6.4.6 To fully deploy the Routing Snare, advance it through the cannula service port by pushing the Snare Guide forward while simultaneously withdrawing the Cannula from the patient's chest.
NOTE: Take care not to tangle the proximal snare loop with the Suction Tool due to risk of procedural delay.
- 6.4.7 Once the Cannula is completely outside of the patient's chest, grasp the Snare Guide just as it emerges from the Cannula distal service port and pull the remaining length of the Routing Snare from the Cannula.

6.5 Retrieving the Routing Snare

- 6.5.1 Introduce the FLEXView™ Cannula through the chest wall taking care to avoid accidentally withdrawing the Routing Snare.
- 6.5.2 Navigate to position the FLEXView™ Cannula so that the Snare Guide is visible.
- 6.5.3 Slowly withdraw the Routing Snare until its tip appears in the field of view. Once the Snare Loop appears in the field of view, introduce the FLEXView™ Retrieval Tool into the FLEXView™ Cannula service port.
- 6.5.4 Extend the Retrieval Tool until it appears in the field of view. Continue to advance the Retrieval Tool into the Snare Loop.
- 6.5.5 To engage the distal Snare Loop onto the Retrieval Tool:
- Pull the proximal end of the Snare Assembly to cinch the distal snare loop onto the Retrieval Tool (see Figures D and E)
 - 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 Retrieval Tool. The proximal end can be identified by the green tubing adjacent to the Snare Loop (see Figure D).
 - Release the Retrieval Tool to allow it to retract fully, while engaged to the Routing Snare.
- 6.5.6 If moving the distal end of the Routing Snare to another location within the thoracic cavity, go to step 6.5.7. If the Routing Snare has been positioned at the target location within the thoracic cavity, go to step 6.5.9.
- 6.5.7 Navigate the FLEXView™ Cannula with the Routing Snare attached to the desired site. To release the Routing Snare, extend the Retrieval Tool and release the clamp at the proximal end of the Routing Snare.
- 6.5.8 To reposition and retrieve the snare, repeat steps 6.5.2 to 6.5.6 until the desired position is achieved.

- 6.5.9 Once the Routing Snare is captured, retract the Retrieval Tool and withdraw the FLEXView™ Cannula from the chest cavity while simultaneously advancing the proximal end of the Routing Snare into the chest cavity. Once outside the patient, release the Routing Snare by extending the Retrieval Tool and releasing the clamp at the proximal end of the Routing Snare.
- 6.5.10 After the Routing Snare is placed, the Cannula can be used to verify the proper orientation of the Routing Snare in the thoracic cavity.

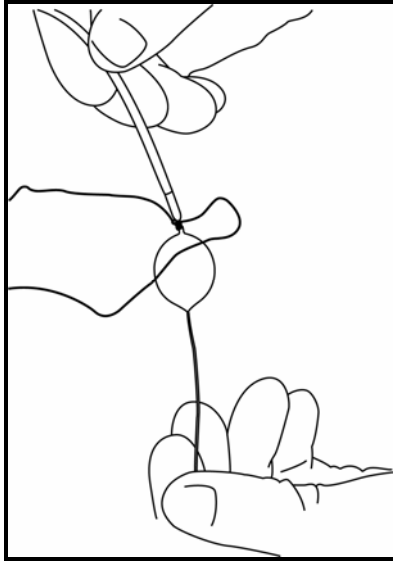
Figure F.
Clamping the Snare Assembly



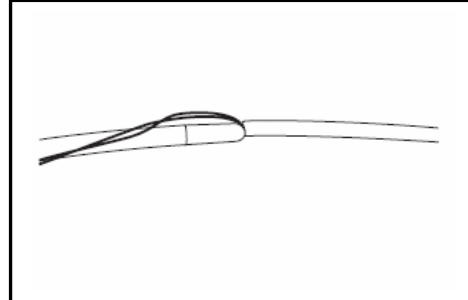
6.6 Using the Routing Snare to Position the Guidant Microwave Ablation Probe

- 6.6.1 Attach the Ablation Probe to the Routing Snare by tying the Ablation Probe sutures to the proximal Snare Loop (see Figure G).
- 6.6.2 Ready the Routing Snare and Ablation Probe for positioning:
 - a. Apply tension to the distal end of the Snare Wire 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 Wire adjacent to the distal end of the Snare Guide (see Figure F).
 - c. Advance the Ablation Probe into the desired position by feeding the Ablation Probe into the thoracic cavity while simultaneously pulling the Routing Snare out of the thoracic cavity.
- 6.6.3 To detach the Ablation Probe from the proximal Snare Loop, cut the attachment sutures.
- 6.6.4 After the Ablation Probe is placed, the Cannula can be used to verify the proper orientation of the Ablation Probe in the thoracic cavity.

**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	

©2006 Guidant Corporation or its affiliates. All Rights Reserved. Made in U.S.A.

**Guidant Corporation
Cardiac Surgery**

3200 Lakeside Drive
Santa Clara, CA 95054 USA
Toll-free tel: (888) 880-2874 Tel: (408) 845-3400
Toll-free fax: (888) 899-2874 Fax: (408) 845-3568
Email: CVSurgery@guidant.com
www.guidant.com

EL2053858 Rev. A