

Guidant FLEXView™ Visualization Lens
Information for Prescribers

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

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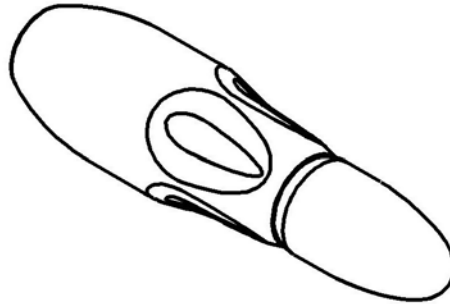


Figure 1.
Guidant FLEXView™ Visualization Lens

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

1.0 DEVICE DESCRIPTION

The Guidant FLEXView™ Visualization Lens is used in conjunction with the Guidant 7mm Extended Length Endoscope to provide visualization of anatomical structures and dissection in endoscopic and other minimally invasive surgical procedures. The Visualization Lens can be attached to and removed from the distal end of the 7mm Endoscope by the user.

2.0 HOW SUPPLIED

The Guidant FLEXView™ Visualization Lens, 5-pack is supplied STERILE in an unopened and undamaged package. The Visualization Lenses have been sterilized using irradiation and are for single patient use only. The carton includes five Visualization Lenses individually packaged. **DO NOT RESTERILIZE OR REUSE.** There are no latex components in the Visualization Lens.

3.0 INDICATIONS

The Guidant FLEXView™ Visualization Lens, when used with the Guidant 7mm Extended Length Endoscope, is intended to aid in the visualization of anatomical structures and dissection in endoscopic and other minimally invasive surgical procedures.

4.0 CONTRAINDICATIONS

The device 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 Guidant FLEXView™ Visualization Lens is sterile unless the package is opened or damaged. The Visualization Lens is designed for single use. **Do not reuse or resterilize the Visualization Lens.**
4. Do not apply force to any vessels or anatomical structures other than those being dissected while using the Visualization Lens due to risk of laceration or perforation of vessels.
5. Do not apply excessive force while dissecting with Visualization Lens due to risk of laceration or perforation of vessels or other anatomical structures.
6. Do not continue to use the Visualization Lens if visualization is impaired.

6.0 INSTRUCTIONS FOR USE






This is not a reference for endoscopic techniques. Representative sources are listed in the bibliography of the Instructions for Use for the Guidant 7mm Extended Length Endoscope.

1. Do not use if damaged or opened. Carefully remove device from its shipping package. Inspect to ensure no damage has occurred during transit.
2. Follow the instructions for use for the 7mm Extended Length Endoscope in order to ready the device for use in an endoscopic space.
3. Attach the removable Guidant FLEXView™ Visualization Lens to the distal end of the 7mm Extended Length Endoscope. Thread the Visualization Lens onto the Endoscope until the proximal edge of the Visualization Lens lines up with the indicator band on the Endoscope shaft, and the Visualization Lens is securely attached to the Endoscope.
4. Prepare the patient in accordance with standard surgical techniques.
5. Insert 7mm Extended Length Endoscope with Visualization Lens attached through standard surgical access. Use the Endoscope and Visualization Lens as indicated for visualization of anatomical structures and dissection in endoscopic and other minimally invasive surgical procedures.

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:	 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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