

Symbols and definitions:

	Manufacturer: Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC, and 98/79/EC.
	Authorized representatives in the European Community. This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
	Use by date: Indicates the date after which the medical device is not to be used.
	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog Number: Indicates the manufacturer's catalog number so that the medical device can be identified.
	Sterilized using ethylene oxide: Indicates a medical device that has been sterilized using ethylene oxide.
	Do not re-sterilize: Indicates a medical device that is not to be re-sterilized.
	Do not use if package is damaged: Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use: Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use: Indicates the need for the user to consult instructions for use.
	Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

REV 112618



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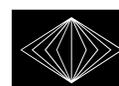
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## CLEARVIEW™ II

### INSTRUCTIONS FOR USE

Flexible Endoscope Sterile Cover System



**INVOTEC INTERNATIONAL, INC.®**

## CLEARVIEW™ II FLEXIBLE ENDOSCOPE COVER SYSTEM INSTRUCTIONS FOR USE

### INDICATIONS

The Clearview™ II Endoscope Sterile Cover is indicated as a one-time use sterile protective cover, placed over a flexible medical endoscope, during examination procedures performed by a trained medical professional. It is designed to fit onto specific manufacturers' flexible endoscope models.

Note: For full infection control documentation, please contact Invotec® International.

### OVERVIEW

The Clearview™ II Endoscope Sterile Cover is a DISPOSABLE SINGLE USE ONLY product, to encase a flexible endoscope's insertion tube and distal lens and to maintain a sterile barrier for patients undergoing endoscope procedures of the head & neck. It is also designed to provide a clear optical view via an optically clear lens cover. Its unique design supports aseptic and easy disposal of used endoscope covers.

To insure safe use of this endoscopic accessory, training is necessary. The clinician should be competent in the endoscopic procedure and the nursing staff knowledgeable in the proper care and handling of flexible endoscopes being used with Clearview™.

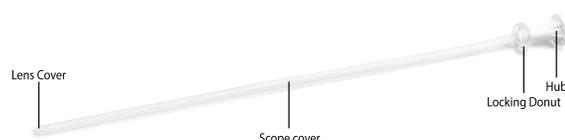
Medical product disposable procedure must be followed in order to maintain patient and staff safety. Flexible endoscopes are delicate glass instruments. Incorrect handling and reprocessing will cause damage.

**Read these instructions, carefully. Should you need additional training, please call your local Invotec Distributor.**

### SYSTEM DESCRIPTION

The Clearview™ II Endoscope Sterile Cover System consists of a soft elastomer tube with color coded endoscope insertion tube entry hub and distal optically clear lens cover. Clearview™ II contains no latex. The rigid protective tube is included to assist in loading the endoscope. Packaged 20 sterile covers per box.

### CLEARVIEW™ II COMPONENTS



## RECOMMENDED ENDOSCOPE CLEANING AND DISINFECTION PROTOCOLS

This Clearview™ II is FDA cleared as a Class II device used in conjunction with a nasopharyngoscope, a semi-critical device. If the scope cover was not torn during the endoscopy, please perform the below listed cleaning maneuvers and practice, at least, the minimum Intermediate Disinfection (ILD) Techniques.

Cleaning (after Clearview™ II cover has been removed)

- Gently and thoroughly clean the entire scope with an appropriate instrument detergent. (Always follow your scope manufacturer's recommendations.)
- Rinse all surfaces completely with clean lukewarm water.
- Dry the scope thoroughly prior to disinfection.

Disinfection

- Wipe the entire scope surface with a sponge soaked in 70% alcohol. Give close attention to super-gently wiping down the distal tip as hard wiping could create a rollover at the rubber articulating section.
- Leak test prior to storing or reusing
- Dry scope thoroughly prior to re-sheathing or storing.

**FOR SINGLE USE ONLY.**

## PRECAUTIONS & WARNINGS

**CAUTION: FAILURE TO FOLLOW INSTRUCTIONS CAREFULLY  
MAY CAUSE PATIENT INJURY.**

1. Prior to using the Clearview™ II Endoscope Cover System, read this Instruction Manual completely. If you wish further in-service training, call your local Invotec Distributor.
2. As with any sterile item, always inspect the integrity of the packaging for possible wetting or tearing and the enclosed product for damage prior to use.
3. Routinely inspect the insertion tube of the flexible endoscope for damage using the Cover Test Card. In particular, check for dented or rolled over vinyl scope skin.
4. NEVER USE FORCE to insert or withdraw Clearview™ II on-to or off-of your endoscope. This maneuver can damage the endoscope causing need for major repair.
5. DO NOT attempt to re-sterilize or re-use this ONE TIME ONLY disposable product.

## INSERTION OF ENDOSCOPES INTO CLEARVIEW™ II

Carefully read all instructions prior to sheathing the scope. The Clearview™ II System comes sterile as a ONE-TIME USE DISPOSABLE PRODUCT. Prior to opening the package, inspect the outer packaging for moisture damage or torn packaging. Please maintain sterile technique in loading these covers onto your endoscope.

**Important Note:** The sheath should glide onto the scope without resistance. If you experience any resistance, stop immediately and inspect your the surface of the scope insertion tube for rolls, tears or dents. Forcing the insertion tube into the sheath may cause significant damage to the scope.



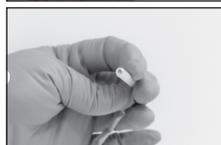
**STEP 1** Open the teardown seal on the outer packaging until you have aseptic access to the insertion hub.  
*Do not remove the sheath or its protective tube from the outer wrapper at this time.*



**STEP 2** Place the distal tip of the scope into in the hub.



**STEP 3** Grasping the hub gently forward the insertion tube into the cover. If you experience any counter pressure STOP and inspect the insertion tube.



**STEP 4** Remove the sheathed endoscope from the rigid protective tube.  
**Note:** The hub will NOT attach to the body of the endoscope.



**STEP 5** The scope tip should seat within the lens cover. If not seated, gently pull the cover up the insertion until the scope's distal lens fits within the lens cover.

**STEP 6** Roll down the locking ring onto the sheath to secure the cover into place.

**NOTE:** Keep the rigid cannula in the original Clearview™ II packaging for use in proper disposal after the procedure. See the following section for information on proper disposal instructions.

## TROUBLESHOOTING DURING INSERTION

Situation	Recommended Action
While inserting tip, the scope will not easily slide into the white insertion hub of the Clearview™ II Cover.	<b>STOP! Do not proceed!</b> 1. GENTLY withdraw the scope from the hub. If the scope will not easily withdraw, call your Invotec Distributor or 800-998-8580. 2. Closely inspect the endoscope's insertion tube specifically, the articulating tip section. 3. If, upon examination, the scope insertion tube is found to be oversized, due to bunching or rollover to denting, DO NOT USE Clearview™. The insertion tube section may have to be repaired.
Clearview™ II cover inserts with nominal difficulty over the scope insertion tube, and no apparent articulation section roll over or bunching is observed.	1. Check to see that the distal scope insertion tube is straight and not angled at the articulation section. 3. The vinyl skin of the endoscope may have become tacky, making drag. Clean the scope insertion tube with soap and water (using scope manufacturer's recommendation). You may also apply a dusting of cornstarch to the insertion tube only.  Do not add lubrication into the lumen of the Clearview™ II scope cover.
Clinician visualizes glare through the endoscope	The distal lens tip of the endoscope may not be seated against the inside surface of the Clearview™ II lens cover. Gently pull back the cover to seat the scope tip into the optically clear lens cover.

If you need further assistance, please call us at (800) 998-8580 or (904) 880-1229, Monday through Friday from 8 am - 5 pm EST.

## REMOVING AND ASEPTICALLY DISPOSAL OF CLEARVIEW™ II

**Important Note:** Carefully read all instructions prior to removing the sheath from the scope. If you experience any resistance, stop immediately.

**STEP 1** Roll up the locking ring onto the hub to release the sheath.



**STEP 2** Grasp the distal tip (lens cover) of the scope cover and slowly and gently remove the Clearview™ II cover from the scope.



**STEP 3** Place the used Clearview™ II cover into the protective tube and then into the original wrapper to dispose of per office, clinic or hospital protocol.

**STEP 4** The entire endoscope, including insertion tube, body and eyepiece must be washed and disinfected per manufacturer's instructions.

## TROUBLESHOOTING DURING REMOVAL

Situation	Recommended Action
While removing the cover, the Clearview encounters some resistance.	<b>STOP! Proceed with caution.</b>  Examine the sheath to make sure it has not rolled over and jammed itself onto the scope. To resolve this: 1. Grasp the sheath hub and distal tip and pull out the rolled over sheath. 2. GENTLY withdraw the scope from the hub. The Clearview™ II should now easily slide off.  If you cannot resolve this, call your Invotec Distributor or Invotec International at 800-998-8580.

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## WARRANTY

Invotec International, Inc. warrants that the product is free from defects in material and workmanship. Invotec will replace or provide a refund for any product found to be defective so long as the product is returned according to the Returned Goods instructions in Policy. Invotec shall not be liable for any consequential loss, damage or expense directly or indirectly arising from the use of, or inability to use, this product. THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, HOWEVER ARISING, INCLUDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST INFRINGEMENT OR OTHERWISE. Invotec International neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product.

If you have any questions or for further information, you can reach us at:

**(800) 998-8580 • (904) 880-1229**

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[www.invotec.net](http://www.invotec.net)