Eikon® LT Fixed Frame Retractor

REF A90FF / A90WFF
A135FF / A135WFF / A175FF

Instructions for Use

Invuity, Inc.
444 De Haro Street
San Francisco, CA 94107 USA
Tel: +1-866-711-7768
www.invuity.com

		NON STERILE	Rx Only		Consult Instructions for Use and Symbols Glossary on this website: www.invuity.com/documentlibrary

Eikon LT Fixed Frame Retractor - Instructions for Use

Description
The Eikon LT Fixed Frame Retractors are intended for use in a wide variety of surgical procedures. The retractors are non-sterile, reusable instruments comprised of stainless steel, non-conductive reinforced polymers, and silicone rubber. The Retractors are compatible with the PhotonGuide Illuminator, PhotonGuide Adapt Illuminator, and the Invuity Single and Bifurcated Fiber Optic Cables.

Indications for Use
The Eikon LT Fixed Frame Retractors are intended to provide tissue retraction and surgical site illumination from a high intensity light source.

Contraindications
There are no known contraindications.

For Use With

DESCRIPTION	REF
PhotonGuide Adapt Illuminator	PGA1
PhotonGuide, Wide/Flat	104015

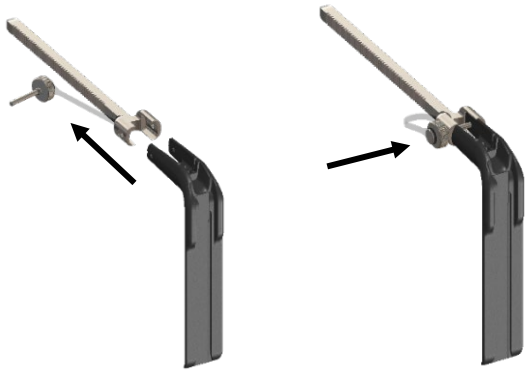
Warnings
- **Prior to each use, inspect the Retractor for damage and integrity**, to ensure that it is free from debris and defects such as cracks, chips, rough edges, or other general damage. Assess damaged instruments for potential hazard. Do not use damaged instruments.
- **Do not allow conductive instruments to be in close proximity to or contact active energy devices**, as unintentional patient burns may occur.
- **Only use Retractors with the PhotonGuide or PhotonGuide Adapt and Invuity Fiber Optic Cable products.** Using non-Invuity fiber optic cables may generate excessive heat at the connector and cause thermal injury to the patient or user.
- **Retractors may cause minor skin irritation in patients with sensitivity to nickel.**
- **If the Retractor is/was used in a patient with, or suspected of having *Creutzfeldt-Jakob Disease*** *(Mad Cow Disease)*, the instrument cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination. Consult WHO and local regulations for further information.

Precautions
- The Eikon LT Fixed Frame Retractors should be handled and operated by hospital personnel familiar with and trained with their use, assembly, and disassembly.
- Use of Retractors for any purpose or in any manner other than described in this Instructions for Use may cause instrument damage or failure, which could result in patient or user injury.
- The Retractors are provided non-sterile and must be thoroughly cleaned and sterilized prior to use.
- It is recommended to use an Invuity Sterilization Tray to help protect the Retractors from damage during transport, decontamination, sterilization, and storage. Space instruments far enough apart to avoid contact with other metal instruments or object which may dent, ding, scrape or otherwise damage the surface of the instrument.
- The Retractors are delicate medical devices and must be handled with care during cleaning and sterilization. If the instruments are not handled appropriately, surface abrasions may occur.
- The Eikon LT Fixed Frame Retractor must be disassembled prior to cleaning and sterilization.
- Avoid contact with sharp edges during assembly, disassembly, cleaning, and sterilization.
- If a PhotonGuide Illuminator or PhotonGuide Adapt Illuminator is inadvertently left in the retractor, remove the disposable before continuing the cleaning and sterilization process.
- Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) as these are known to cause discoloration of the surface.
- To prevent stains, use distilled or demineralized water and a neutral detergent when cleaning the Retractor.
- Refer to the Instructions for Use for the Invuity PhotonGuide(s) or PhotonGuide Adapt and Fiber Optic Cables for additional information.
- Ensure that the Instructions for Use provided with the Retractor are followed, including all user instructions, warnings, and precautions

Directions for Use

The following are general directions for the Eikon LT Fixed Frame Retractor products to be used with a fixed frame ratcheting system (e.g. Bookwalter):

1. Inspect the Retractor components for cleanliness and damage prior to use. Do not use if the product is damaged.
2. Prior to use, the Eikon LT Fixed Frame Retractor must be assembled. First, insert the Blade into the stem. Next, insert the Thumb Screw through the Stem and Blade and turn clockwise until secure.



3. Identify the compatible PhotonGuide or PhotonGuide Adapt and Fiber Optic Cable for the Retractor.
4. Securely attach the Fiber Optic Cable and PhotonGuide or PhotonGuide Adapt to the Retractor. Refer to the PhotonGuide or the PhotonGuide Adapt IFU for further details regarding installation in appropriate retractors.
5. Connect the Fiber Optic Cable to the ACMI port on the surgical light source. It is recommended to use an LED light source. The lower intensity light output from an LED light source reduces the risk of thermal injury to patient or user or to the PhotonGuide Illuminator. LED light sources are available from Invuity, Stryker, and Sunoptic.
6. Reduce the intensity setting of the light source to the minimum level before turning on the power. Then, turn the surgical light source on.
7. Increase the intensity setting of the light source to approximately 60% and assess the illumination transmitted by the PhotonGuide or PhotonGuide Adapt. Avoid increasing the intensity setting of the light source beyond the level of illumination required to perform the procedure. If using a xenon light source, keep the light intensity below 60%.
8. Do not use with a xenon light source greater than 300 watts.
9. Insert the Stem of the Retractor into the ratchet of the existing fixed frame retractor system and attach to the frame as per usual. For PhotonGuide Adapt, secure the Fiber Optic Cable to the stem using the Velcro strips included.
10. Position the Retractor as desired. Re-position as needed.

    Note: During the surgical procedure, debris should be removed from the surgical instruments with a sponge, wipe, or gauze and sterile water.

11. During the procedure, the PhotonGuide or PhotonGuide Adapt and Fiber Optic Cable may be transferred to another Retractor.
12. After the procedure has been completed, turn the surgical light source off and carefully disassemble the Fiber Optic Cable and PhotonGuide or PhotonGuide Adapt from the Retractor.
13. Disconnect the Fiber Optic Cable from the surgical light source. When removing the Fiber Optic Cable from the light source, grasp the widest area of the black strain relief closest to the ACMI connection on the light source.
14. Discard the PhotonGuide or PhotonGuide Adapt according to hospital procedures and in accordance with local, state and federal laws and regulations.

    Note: For further instructions, refer to the PhotonGuide or PhotonGuide Adapt and Fiber Optic Cable Instructions for Use.

Preparation for Cleaning

Equipment and Materials

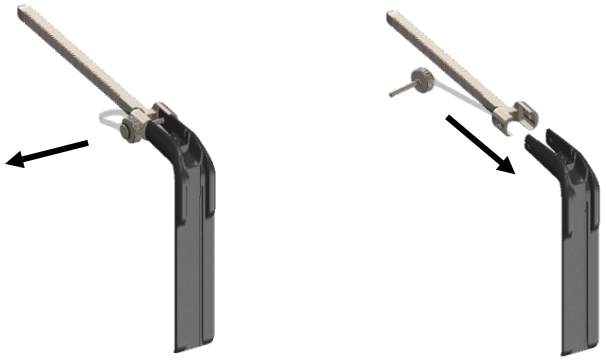
WARNING: Use only Invuity-approved equipment unless otherwise specified. DO NOT modify any system component or accessory.

The following equipment is required to process devices per the instructions in this manual:

- Warm water (See the Water Quality section)
- Prepared, specially formulated cleaning agents (See the Cleaning Agents section)
- Absorbent wipes
- Soft, nonlinting cloth
- Syringe
- Non-abrasive, soft, flexible, synthetic bristle brushes
- Washer-disinfector (complies with ISO 15883 series)
- Cleaning agents as required by the washer-disinfector manufacturer
- Instrument air[1] < 140 kPa [< 20 psi]
- Oven

[1]Instrument air is medical gas that falls under the general requirements for medical gases as defined by the National Fire Protection Association (NFPA) Health Care Facilities Code, is not respired, is compliant with the American National Standards Institute (ANSI) / International Society of Automation (ISA) Quality Standard for Instrument Air, and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °C [-40 °F].

Cleaning and Sterilization

Disassembly	Prior to cleaning and sterilization, the retractor must be disassembled. First, unscrew the Thumb Screw from the Stem. Next, remove the Blade from the Stem. The Thumb Screw should remain attached to the Stem via the Tether during cleaning and sterilization. 
Cleaning: Manual	1. Soak surgically used retractors in an enzymatic solution or a neutral pH detergent according to hospital protocol. An alkaline cleaning agent (neat, up to pH 11) is allowable, but not preferred. Alkaline cleaning agents may cause cosmetic damage or reduce the life of the product. Pay close attention to instructions for correct detergent dilution, temperature, and soak time. Soak for a minimum of 1 minute. 2. Fully immerse the instrument in solution, and use a small, clean, soft, hand-held brush to remove debris from all instrument surfaces. Ensure debris is removed from tips, crevices, and channels. **Note: Do not use a stiff bristle brush or metal type brush to clean the instruments. Avoid contact with other metal instruments or objects which may dent, ding, scrape or otherwise damage the surface of the retractor.** 3. Rinse instruments to remove residual debris and cleaning agents. 4. Ensure sterilization trays are properly decontaminated according to hospital procedures. 5. If lumens are present, use an appropriately sized lumen brush to clean the lumen, then flush the lumen(s) with de-ionized water.

<table>
<tr>
<td>Cleaning: Automated</td>
<td>
1. Perform the following pre-cleaning steps:

Remove all visible soil from the equipment using the prepared cleaning agent, using brushes as necessary.
Rinse the equipment to remove all excess cleaning agent.

2. Load the equipment into the washer-disinfector in an appropriate insert tray, a wire basket or other washer-disinfector equipment holder.

Avoid contact between components.

3. Operate the washer-disinfector. Use the following phase parameters:
<table>
<tr><th>Phase</th><th>Time</th><th>Water Temperature</th><th>Cleaning Agent</th></tr>
<tr><td>Pre-Rinse</td><td>2 to 4 minutes</td><td>< 21 °C [< 70 °F]</td><td>Prepared cleaning agent (optional)</td></tr>
<tr><td>Wash[1]</td><td>2 to 4 minutes</td><td>60 to 82 °C [140 to 180 °F]</td><td>Prepared cleaning agent</td></tr>
<tr><td>Rinse</td><td>2 to 4 minutes</td><td>43 to 82 °C [110 to 180 °F]</td><td>-</td></tr>
<tr><td>Thermal Rinse[2]</td><td>1 minute</td><td>90 °C [194 °F]</td><td>-</td></tr>
<tr><td>Dry</td><td>15 minutes</td><td>-</td><td>-</td></tr>
</table>
[1]Wash may include enzymatic wash.

[2]Thermal rinse is optional. Thermal rinse does not replace sterilization. A thermal rinse phase may be used for up to 5 minutes at a water temperature of not more than 95 °C.

4. Unload the washer-disinfector and visually inspect the equipment for remaining soil or cleaning agent. If soil or cleaning agent remains, repeat the cleaning procedure using freshly prepared cleaning agent.
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<td>Water Quality</td>
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WARNINGS:

Use appropriate water quality for each stage of the cleaning process. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.
Use utility water for flushing, washing, and rinsing the equipment. Utility water is water that comes from the tap.
Use potable water for diluting cleaning agents. Potable water is water that is treated and delivered in a matter so that it meets United Sates (US) Environmental Protection Agency (EPA) or local guidelines as suitable for drinking.
Use critical water for final rinsing of the equipment prior to sterilization. Critical water is water that is extensively treated usually by a multistep treatment process that could include a carbon bed, softening, deionization, and reverse osmosis or distillation to ensure that the microorganisms and the inorganic and organic material are removed from the water. A final submicron filtration could also be part of the treatment process.

CAUTION:
Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per Association for the Advancement of Medical Instrumentation (AAMI) TIR 34.

Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F] is recommended for manual cleaning. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
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<tr>
<td>Disinfection (Optional)</td>
<td>Disinfection processes do not ensure the margin of safety associated with sterilization processes. Therefore, disinfection is optional. See the Automated Cleaning section and information related to the thermal rinse phase.</td>
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<tr>
<td>Packaging</td>
<td>Retractors may be loaded into dedicated instrument trays or general purpose sterilization trays.</td>
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<tr>
<td>Sterilization</td>
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Retractors (including Invuity Fiber Optic Cables) should be sterilized using steam sterilization by either gravity displacement or pre-vacuum. The following sterilization parameters have been validated for instruments in a tray, wrapped or unwrapped.
Note: Invuity endorses the following sterilization parameters per AAMI recommendations for wrapped instruments and container with combined weight of less than 25 lbs. [11.3 kg].
<table>
<tr><th colspan="3">Steam Sterilization Parameters</th></tr>
<tr><th>Description</th><th>Gravity Displacement</th><th>Pre-Vacuum</th></tr>
<tr><td>Temperature</td><td>132° C[2] (270° F)</td><td>132-138° C (270-280° F)</td></tr>
<tr><td>Cycle Time</td><td>15 minutes[1]</td><td>3-8 minutes[1]</td></tr>
<tr><td>Dry Time</td><td>45 minutes</td><td>30 minutes</td></tr>
</table>
[1] Maximum exposure time may be extended to 18 minutes.
[2] Maximum sterilization temperature may be extended to 137 °C.

Note: Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions as these are known to cause discoloration of the surface.

The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods, and/or various loading configurations.
International sterilization parameters are per the following standards:

Australia/New Zealand per AS/NZS 4187
Netherlands per Field Standard for Loaner Instruments, Rev 03.02, April 2008
Europe and the United Kingdom per EN ISO 17664
Canada per CSA ISO 17664

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<tr>
<td>Storage</td>
<td>Store instruments in a clean, dry area.</td>
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Warranty

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from the date of purchase, that this medical device is free from defects in both material and workmanship when used normally for its intended purposes. Suitability of the medical device for any surgical procedure shall be determined by the user alone (in light of relevant instructions for use) and not by INVUITY, and such user shall be responsible for understanding how to use the device for its intended purpose. In the event that purchaser believes that any INVUITY medical device is defective, purchaser will promptly notify INVUITY. Any INVUITY brand named instrument delivered from INVUITY proving to be defective will, as purchaser's sole and exclusive remedy, be replaced at no charge or the amount paid refunded, at INVUITY's discretion, so long as the defect is discovered and reported to INVUITY within the earlier of thirty (30) days of discovery or one (1) year of purchase, and INVUITY determines that the product is defective and is covered by the warranty. Notwithstanding, INVUITY shall not be responsible for normal wear and tear, including minor cosmetic damage compromise or defect caused by re-sterilization. INVUITY does not repair, sharpen, recoat or otherwise refurbish any used product. The foregoing limited warranty and limited obligation of replacement is void and of no effect in the event that there is any modification made to the medical device or the medical device is used for any purpose other than its intended purpose.

LIMITATION OF LIABILITY. INVUITY DOES NOT ACCEPT LIABILITY TO CUSTOMER OR ANY THIRD PARTY BEYOND THE REMEDIES EXPRESSLY SET FORTH HEREIN, INCLUDING ANY LIABILITY FOR PRODUCTS NOT BEING AVAILABLE FOR USE. IN NO EVENT SHALL INVUITY BE LIABLE FOR LOST PROFITS, LOSS OF BUSINESS, LOSS OF USE, COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, OR ANY OTHER CONSEQUENTIAL, EXEMPLARY, INCIDENTAL, SPECIAL, INDIRECT OR PUNITIVE DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR FOR ANY CLAIM BY ANY THIRD PARTY, EXCEPT AS EXPRESSLY PROVIDED HEREIN.

Customer must obtain a Return Material Authorization to return product to Invuity. Returned product must be thoroughly cleaned and sterilized.

CUSTOMER ACKNOWLEDGES UNDERSTANDING THAT NO OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT AS TO ITS MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER, EVEN WHEN APPLIED OR UTILIZED IN ACCORDANCE WITH ITS INSTRUCTIONS, ARE MADE OR GIVEN BY INVUITY. AND INVUITY EXPRESSLY DISCLAIMS ALL SUCH REPRESENTATIONS AND WARRANTIES.

REVISION HISTORY

Rev	CO #	Description	Approved Date	Effective Date	Originator
A	17-0799	Initial release	10/23/17	10/23/17	V. Douglas
B	18-0330	-Updated diagrams -Updated Warnings and Precautions -Revised language regarding LED usage and intensity levels for Xenon -Added diagrams for assembly and disassembly	6/11/18	06/11/18	P. Bieniek
C	18-0590	-Added CE mark and notified body address. -Added precaution to avoid contact with sharp edges. -Updated sterilization table for OUS parameters.	10/05/18	02/18/19	P. Bieniek
D	19-0379	-Removed CE Mark (not a CE marked Product) -Added additional instructions and warnings to Decontamination and Sterilization Instructions	10/16/2019	11/04/2019	J. Clark

PRINTING INSTRUCTIONS

Print In-House, or at an approved supplier and route to receiving.

Do not print Revision History and Printing Instructions Page (page 8 & 9)

Print in black ink on white paper.

Print subsequent pages double sided, booklet style.

Fold in booklet and staple fold along spine (folded size is 8.5in x 5.5in).