Eiberg® Illuminated Retractor System
REF E1S / E1SL
Instructions for Use

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

EC REP Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE 0086

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

Description

The Eiberg Illuminated Retractor System is comprised of non-sterile, metal, reusable retractors. Each Eiberg Retractor is compatible with the Invuity PhotonGuide® Illuminators and the Invuity Single and Bifurcated Fiber Optic Cables.

Indications for Use

The Eiberg Illuminated Retractor System is intended to provide soft tissue retraction and surgical illumination from a high intensity light source.

Contraindications

There are no known contraindications.

For Use With

DESCRIPTION	REF
Single Fiber Optic Cable, 10 ft [3.05 m], ACMI	FC1S
Single Fiber Optic Cable, Pink, 10 ft [3.05 m], ACMI	FC1SP
Bifurcated Fiber Optic Cable, 11.5 ft [3.50m], ACMI	FC1B
PhotonGuide, Narrow/Flat	104008
PhotonGuide, Wide/Flat	104015

Warnings and Precautions

Cleaning and Sterilization:

- See “Warnings and Precautions” in the Decontamination and Sterilization section of this Instructions for Use.

Product Use:

- Use this instrument only with the Invuity PhotonGuide and an Invuity Fiber Optic Cable. Using other fiber optic cables may generate excessive heat at the connector and cause thermal injury to the patient or user.
- Prior to each use, inspect the Eiberg Retractor for damage and mechanical integrity to ensure that it is free from debris and significant defects such as cracks, chips, rough edges, or other general damage. Assess damaged instruments for potential hazard. Do not use damaged instruments.
- If tapping to position the Eiberg Retractors is necessary during the procedure, use caution to prevent damage to the Eiberg Retractor and the PhotonGuide Illuminator.
- Refer to the Instructions for Use for the Invuity PhotonGuide and Invuity Fiber Optic Cables.
- **DO NOT USE** with a surgical light source greater than 300 watts. Using the Invuity PhotonGuide with a surgical light source with output greater than 300 watts or a surgical light source without an infrared (IR) filter may cause thermal injury to the patient or user or may cause damage to equipment.
- When using high-powered surgical light sources, reduce the power output to avoid thermal damage to the Invuity PhotonGuide.

Safety:

- Use of the Eiberg Retractors for any purpose or in any manner other than described in these Instructions for Use may cause instrument damage or failure, which could result in patient or user injury.

- The Eiberg Retractor may cause minor skin irritation in patients with sensitivity to nickel.

Directions for Use

1. Insert the PhotonGuide into the blade of the Eiberg Retractor ensuring that the L-clip on the PhotonGuide snaps into the L-connector slot on the Eiberg Retractor.
2. Insert the Invuity Fiber Optic Cable into the proximal end of the Eiberg Retractor handle and slide it towards the blade until it emerges at the distal opening.
3. Securely attach the Invuity Fiber Optic Cable to the PhotonGuide.
4. Connect the Invuity Fiber Optic Cable to the surgical light source.
5. Turn the surgical light source on.
6. Position the Eiberg Retractor as desired. Reposition as needed.

   Note: During the surgical procedure, debris may be removed from surgical instruments with a sponge, wipe, or gauze and sterile water.
7. After the procedure has been completed, turn the surgical light source off. Disconnect the Invuity Fiber Optic Cable from the surgical light source. Remove the PhotonGuide from the Eiberg Retractor. Carefully detach the Invuity Fiber Optic Cable form the PhotonGuide and gently slide the Invuity Fiber Optic Cable out of the handle.
8. Discard the PhotonGuide according to hospital protocol.

   Note: If further instructions are required for use of the PhotonGuide and Invuity Fiber Optic Cable, refer to the respective 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

Warnings/Precautions	**WARNING: If the Eiberg 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 Eiberg Retractors are provided non-sterile and must be thoroughly cleaned and sterilized prior to use. • The Eiberg 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. • When cleaning the Eiberg Retractor, use a neutral detergent to prevent stains. Do not use cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry sterilize as damage to the instrument finish may occur. • 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. • Do not process instruments of different metals during sterilization, as oxidation may occur. It is recommended to use the appropriate Invuity Sterilization Tray to help protect the Eiberg Retractor 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.
Cleaning: Manual	1. Soak surgically used Eiberg Retractor 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 object 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.

<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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</table>

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<tr><td>Packaging</td><td>Eiberg Retractor may be loaded into dedicated instrument trays or general-purpose sterilization trays.</td></tr>
<tr><td>Sterilization</td><td>
Eiberg Retractor 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></tr>
</table>

WARRANTY

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from 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 within the warranty period stated above, 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 the medical device is used for any purpose other than its intended purpose.

LIMITATION OF LIABILITY. IN NO EVENT SHALL INVUITY BE LIABLE FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, LOST PROFITS OR BUSINESS OPPORTUNITIES OR ANY OTHER INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR RELIANCE DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE WITH RESPECT TO THE INVUITY MEDICAL DEVICES AND INSTRUMENTS OR THIS WARRANTY. THESE LIMITATIONS SHALL APPLY REGARDLESS OF WHETHER INVUITY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY

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.

Revision History

Rev	CO #	Description	Approved Date	Effective Date	Originator
A	19-0168	Initial Release	06/24/2019	07/03/2019	J. Wentz

PRINTING INSTRUCTIONS

Print in-house or at an approved supplier.

Do not print Revision History or Printing Instructions page (page 8 & 9).

Print in black ink on white paper.

Fold in booklet (folded size is 8.5in x 5.5in) with stapled spine.