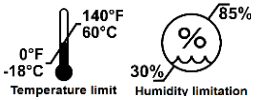
Smoke Evacuator Accessory Warnings, Cautions & Instructions

Manufacturer
I.C. Medical, Inc.
15002 North 25th Drive
Phoenix, Arizona 85023 USA
Phone: (623) 780-0700 (USA)
Fax: (623)780-0887 (USA)
www.icmedical.com

Made in the USA



ESU SHROUD:

Indications for Use
The ESU Shroud, slips over standard electrosurgery (ESU) hand switching pencil and is used to evacuate smoke and other airborne debris that is created when the ESU pencil is in use.

Technical Specification:
I.C. Medical, Inc. recommends the use of the ESU Shroud with the Crystal Vision® Smoke Evacuators-all models, and other I.C. Medical products.
The ESU Shroud product family, when used as a capture device positioned at a 45-degree angle and approximately 1 cm from the smoke source, with ø10 mm transfer tubing, and without interfering with the visibility of the surgical site, meets the ISO 16571:2024 standard for plume removal efficiency when paired with the Crystal Vision® Smoke Evacuator equipped with the SAFEGUARD BLUE® Hydrophobic ULPA Filter with a built-in fluid trap, operating at flow settings of ≥75 LPM.

Transport and Storage Conditions:
Temperature limits: -18°C to 60°C (0°F to 140°F);
Relative Humidity limitation: 30% to 85%.

GENERAL ESU WARNINGS:
1. Keep active accessories away from patient when not in use and away from flammable objects, gases, and vapors at all times.
2. Keep active accessories in the safety container (holster), when not in use.
3. After using the Cut or Coagulation function on an electrosurgical pencil, the tip/electrode is hot. Do not lay any active device on the patient, especially an electrosurgical pencil that has just been used on the patient. This is to prevent the patient, physician, and/or staff from accidental burns by the hot tip/electrode.
4. Keep the desired voltage/power as low as possible to achieve the desired end effect in order to minimize the potential for capacitive coupling and inadvertent burning at high voltages.
5. Check the product for damage before use, including all the insulation. If damaged, DO NOT use this product.
6. Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force! If there is a cable, and unless stated otherwise, DO NOT kink or wrap it around the product!
7. DO NOT use this device for the suction of liquids
8. Use only under the direction of a licensed physician.
9. The ESU Shroud may be used with an I.C. Medical Smoke Evacuator and any standard electrosurgery (ESU) hand switching pencil having an approximate length of 6in to 6.75in and outside diameter of 0.4in to 0.5in.

WARNINGS,
1. Check the product for damage before use. If damaged, DO NOT use this product.
2. Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force!
3. Use only under the direction of a licensed physician.

CAUTIONS:
1. Read instructions for Electrosurgery Unit (ESU) and Operating and Installation Manual for Smoke Evacuator.
2. **RX ONLY** Federal Law restricts this device to sale by or on the order of a licensed physician.

INSTRUCTIONS:
1. Place electrocautery pencil into shroud sleeve. Make sure it is all the way forward. Pencil should be snug in shroud and pencil blade tip should protrude approximately 1/3" to ¾" beyond the end of the shroud tip.
2. The shroud is supplied with a standard-length tip suitable for most uses.
3. For surgeon's comfort, fasten tubing (about 3 feet from pencil end) to a drape near the surgical site. Use towel clamp, or similar device. Do not occlude tubing.
4. Attach the hose to the input filter of the I.C. Medical smoke evacuator.
5. Connecting the electrocautery, pencil cord to the shroud hose will make it easier to move the shroud and pencil during surgery.
6. Air should flow through the shroud when pencil is active. If not, check for obstructions and see smoke evacuator operator manual.
7. Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol. **Do Not clean, re-sterilize or reuse.**

Expiration date:
The use-by-date is indicated on the packaging. DO NOT use this product if the use-by-date has been exceeded!

Sterile product
The sterilization method used is ETO. For details on sterilization process, contact I.C. Medical, Inc.

PACKAGING:
1. Use aseptic techniques when removing the product from the packaging.
2. Use this product only if the packaging has not been opened or damaged. In this case throw the product away.

INTRA-ABDOMINAL PLUME ELIMINATOR TUBING SETS

Indications for Use
It is used to eliminate smoke and any airborne debris that are generated during laparoscopic procedures.

Technical Specification:
I.C. Medical, Inc. recommends the use of the Intra-Abdominal Plume Eliminator Tubing Sets with the Crystal Vision® Smoke Evacuators-Model 450-D, and other I.C. Medical products.
The Intra-Abdominal Plume Eliminator Tubing Set capture device connects directly to the trocar with ø6.5 mm by 3m transfer tubing and meets the ISO 16571:2024 standard for plume removal efficiency when used with the Crystal Vision® Smoke Evacuator equipped with the SAFEGUARD BLUE® Hydrophobic ULPA Filter with a built-in fluid trap, operating at flow settings of ≤20 LPM in LAP mode.

Transport and Storage Conditions:
Temperature limits: -18°C to 60°C (0°F to 140°F);
Relative Humidity limitation: 30% to 85%.

WARNINGS:
1. Check the product for damage before use. If damaged, DO NOT use this product.
2. Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force! DO NOT kink or stretch the tube.
3. Use only under the direction of a licensed physician

CAUTIONS:
1. Read Operating and Installation Manual for Smoke Evacuator.
2. **RX ONLY** Federal Law restricts this device to sale by or on the order of a licensed physician.

INSTRUCTIONS:
1. The product connects to any model of an I.C. Medical Smoke Evacuator smoke evacuator at one end and to laparoscopic trocar at the other end.
2. Firmly attach adapters to desired connectors.
3. Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol. **Do Not clean, re-sterilize or reuse.**

Expiration date:
The use-by-date is indicated on the packaging. DO NOT use this product if the use-by-date has been exceeded!

Sterile product
The sterilization method used is ETO. For details on sterilization process, contact I.C. Medical, Inc.

PACKAGING:
1. Use aseptic techniques when removing the product from the packaging.
2. Use this product only if the packaging has not been opened or damaged. In this case throw the product away.

SPECULUM TUBING SET

Indications for Use
Smoke Accessories are intended to evacuate smoke plume produced during surgical procedures.

Technical Specification:
I.C. Medical, Inc. recommends the use of the Speculum Tubing Sets with the Crystal Vision® Smoke Evacuators-all models, and other I.C. Medical products.
The Speculum Tubing Set, when used as a capture device connects directly to the speculum with ø10 mm transfer tubing, and without interfering with the visibility of the surgical site, meets the ISO 16571:2024 standard for plume removal efficiency when paired with the Crystal Vision® Smoke Evacuator equipped with the SAFEGUARD BLUE® Hydrophobic ULPA Filter with a built-in fluid trap, operating at flow settings of ≥75 LPM in OPEN mode.

Transport and Storage Conditions:
Temperature limits: -18°C to 60°C (0°F to 140°F);
Relative Humidity limitation: 30% to 85%.

Smoke Evacuator Accessory Warnings, Cautions & Instructions

WARNINGS:
1. Check the product for damage before use. If damaged, DO NOT use this product.
2. Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force!

CAUTIONS:
1. Read Smoke Evacuator Accessory Warnings, Cautions & Instructions; Electrosurgery Unit (ESU); and Operating and Installation Manual for Smoke Evacuator.
2. **RX ONLY** Federal Law restricts this device to sale by or on the order of a licensed physician

INSTRUCTIONS:
1. Attach one end of speculum tubing to the speculum port, and opposite end of the tubing to the input filter on the I.C. Medical smoke evacuator or to any other smoke evacuator port that fits product output.
2. Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol.

Expiration date:
The use-by-date is indicated on the packaging. DO NOT use this product if the use-by-date has been exceeded!

Sterile product
The sterilization method used is ETO. For details on sterilization process, contact I.C. Medical, Inc.

PACKAGING:
1. Use aseptic techniques when removing the product from the packaging.
2. Use this product only if the packaging has not been opened or damaged. In this case throw the product away.

SMOKE EVACUATOR WANDS

Indications for Use
Smoke Accessories are intended to evacuate smoke plume produced during surgical procedures.

Technical Specification:
I.C. Medical, Inc. recommends the use of the Smoke Evacuator Wands with the Crystal Vision® Smoke Evacuators-all models, and other I.C. Medical products.
The Smoke Evacuator Wands product family, when used as a capture device positioned at a 45-degree angle and approximately 1 cm from the smoke source, with ø15 mm transfer tubing, and without interfering with the visibility of the surgical site, meets the ISO 16571:2024 standard for plume removal efficiency when paired with the Crystal Vision® Smoke Evacuator equipped with the SAFEGUARD BLUE® Hydrophobic ULPA Filter with a built-in fluid trap, operating at flow settings of ≥75 LPM.

Transport and Storage Conditions:
Temperature limits: -18°C to 60°C (0°F to 140°F);
Relative Humidity limitation: 30% to 85%.

WARNINGS:
1. Check the product for damage before use. If damaged, DO NOT use this product.
2. Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force. DO NOT kink or stretch the tube.
3. Use only under the direction of a licensed physician.

CAUTIONS:
1. Read Operating and Installation Manual for Smoke Evacuator.
2. **RX ONLY** Federal Law restricts this device to sale by or on the order of a licensed physician.

INSTRUCTIONS:
1. Attach wand hose to the input filter of the smoke evacuator.
2. Place wand close to source of smoke.
3. Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol. **Do Not clean, re-sterilize or reuse.**

Expiration date:
The use-by-date is indicated on the packaging. DO NOT use this product if the use-by-date has been exceeded!

Sterile product
The sterilization method used is ETO. For details on sterilization process, contact I.C. Medical, Inc.

PACKAGING:
1. Use aseptic techniques when removing the product from the packaging.
2. Use this product only if the packaging has not been opened or damaged. In this case throw the product away.

SMOKE TUBES

Indications for Use
Smoke Accessories are intended to evacuate smoke plume produced during surgical procedures.

Technical Specification:
I.C. Medical, Inc. recommends the use of the Smoke Tubes with the Crystal Vision® Smoke Evacuators-all models, and other I.C. Medical products.

Transport and Storage Conditions:
Temperature limits: -18°C to 60°C (0°F to 140°F);
Relative Humidity limitation: 30% to 85%.

WARNINGS:
1. Check the product for damage before use. If damaged, DO NOT use this product.
2. Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force! DO NOT kink or stretch the tube.
3. Use only under the direction of a licensed physician.

CAUTIONS:
1. Read Operating and Installation Manual for Smoke Evacuator.
2. **RX ONLY** Federal Law restricts this device to sale by or on the order of a licensed physician.

INSTRUCTIONS:
1. Connect tubing to smoke evacuator's filter and to the handpiece connector.
2. If using 7/8" Smoke Tubing, connect to smoke evacuator filter. Connect other end to smoke evacuator accessory, using any required adapters.
3. Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol. **Do Not clean, re-sterilize or reuse.**

Expiration date:
The use-by-date is indicated on the packaging. DO NOT use this product if the use-by-date has been exceeded!

Sterile product
The sterilization method used is ETO. For details on sterilization process, contact I.C. Medical, Inc.

PACKAGING:
1. Use aseptic techniques when removing the product from the packaging.
2. Use this product only if the packaging has not been opened or damaged. In this case throw the product away.

SERIOUS ADVERSE EVENTS:
Any serious adverse event or incident that occurs in relation to the device or accessory should be reported to the manufacturer, I.C. Medical, Inc., at complaints@icmedical.com and to the FDA.