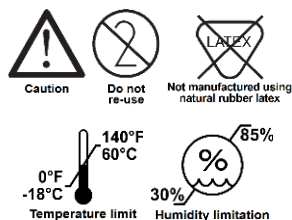


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Made in the USA



Rx Only

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:

- Keep active accessories away from patient when not in use and away from flammable objects, gases, and vapors at all times.
- Keep active accessories in the safety container (holster), when not in use.
- 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.
- 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.
- Check the product for damage before use, including all the insulation. If damaged, DO NOT use this product.
- 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!
- DO NOT use this device for the suction of liquids
- Use only under the direction of a licensed physician.
- 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:

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

CAUTIONS:

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

INSTRUCTIONS:

- Open package(s) containing the ESU Shroud.
- Place electrosurgical 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 3/4" beyond the end of the shroud tip.
- The shroud is supplied with a standard-length tip suitable for most uses.
- 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.
- Attach the hose to the input filter of the I.C. Medical smoke evacuator.
- Connecting the electrosurgical pencil cord to the shroud hose, will make it easier to use the shroud and pencil during surgery.
- Air should flow through the shroud when pencil is active. If not, check for obstructions & see smoke evacuator operator manual.

- Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol.

Non-Sterile product



The product "Non-Sterile" is indicated on the packaging by Non-Sterile symbol.

I.C. Medical intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging and/or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide only, as other sterilization methods have not been validated by I.C. Medical and may damage the product which could cause a device malfunction and/or injury to the patient.

This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.

Do Not clean, re-sterilize or reuse.

PACKAGING:

- Check the product for handling and shipping damage before packaging. If damaged, DO NOT pack this product.
- Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force.
- Follow your institutional protocol for packaging.

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%.

WARNINGS:

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

CAUTIONS:

- Read Smoke Evacuator Accessory Warnings, Cautions & Instructions; Electrosurgery Unit (ESU); and Operating and Installation Manual for Smoke Evacuator.

- RX ONLY** Federal Law restricts this device to sale by or on the order of a licensed physician

INSTRUCTIONS:

- 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.
- Replace and dispose all items labeled "Single Use" in accordance with your institutional protocol.

Non-Sterile product



The product "Non-Sterile" is indicated on the packaging by Non-Sterile symbol.

I.C. Medical intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging and/or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide only, as other sterilization methods have not been validated by I.C. Medical and may damage the product which could cause a device malfunction and/or injury to the patient.

This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.

Do Not clean, re-sterilize or reuse.

PACKAGING:

- Check the product for handling and shipping damage before packaging. If damaged, DO NOT pack this product.
- Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force.
- Follow your institutional protocol for packaging.

Smoke Evacuator Accessory Bulk Warnings, Cautions & Instructions

ULPA IN-LINE SUCTION FILTERS WITH or WITHOUT TUBING SETS



Indications for Use

The filter is used as an attachment to smoke accessories or smoke evacuator devices to filter surgical smoke, odors, organic solvent vapors, toxic vapors, noxious odors produced during surgical procedures.

Technical Specification:

I.C. Medical, Inc. recommends the use of the ULPA Inline Suction Filters With or Without Tubing Sets 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 it or wrap it around the product!
- 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 to smoke accessories, suction walls, smoke tubing or smoke evacuator devices.

- 2 Replace the filter assembly when discoloration shows on filter.
- 3 Dispose of filter according to your institution's policy for biologically contaminated waste disposal.
- 4 This is a NON-STERILE product. It may be used until there is an indication to replace the filter (listed above). After that time do not attempt to clean, sterilize, or re-use this filter.

PACKAGING:

- 1 Check the product for handling and shipping damage before packaging. If damaged, DO NOT pack this product.
- 2 Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force.
- 3 Follow your institutional protocol for packaging.

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.**

Non-Sterile product

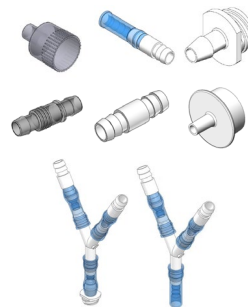


This is a Non-Sterile product.
I.C. Medical intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging and/or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide only, as other sterilization methods have not been validated by I.C. Medical and may damage the product which could cause a device malfunction and/or injury to the patient. This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.
Do Not clean, re-sterilize or reuse.

PACKAGING:

- 1 Check the product for handling and shipping damage before packaging. If damaged, DO NOT pack this product.
- 2 Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force.
- 3 Follow your institutional protocol for packaging.

CONNECTORS



Technical Specification:

I.C. Medical, Inc. recommends the use of connectors to ensure its products can be adapted and used with other smoke evacuators available on the market.

Transport and Storage Conditions:

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

INSTRUCTIONS:

- 1 Carefully remove the existing connector and replace for the one desired, making sure is inserted all the way into the tube;
- 2 Dispose in accordance with your institutional protocol.
- 3 This is a NON-STERILE product.

Do Not clean, re-sterilize or reuse.

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.

PACKAGING:

- 1 Check the product for handling and shipping damage before packaging. If damaged, DO NOT pack this product.
- 2 Protect this product from any form of mechanical damage! DO NOT throw! DO NOT use force.
- 3 Follow your institutional protocol for packaging.

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.