

ENGLISH**INTENDED USE**

The Sustain Medical Surgical Filter System provides suction of blood and other bodily fluids during surgical interventions, and is intended to filter debris, bone cement, and soft tissue procedures where the expected blood loss is greater than 100ml. The system consists of a surgical filter, suction tube w/ flexible tip, and exit tube.

STERILIZATION

This device is designed for single use only and is provided sterile using gamma irradiation. Do not use the package if it is damaged. Attempts to reprocess, and/or reuse may lead to device failure and/or disease transmission.

CONTRAINDICATIONS

Contraindications include connection directly to chest tubes and closed wound drainage systems. This system is also contraindicated in surgical procedures that limit the view of suction tip during surgery.

POTENTIAL ADVERSE EVENTS

- Bleeding
- Infection

WARNINGS

- The lid and tubing must firmly applied to the container to get the intended vacuum.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in surgical procedures.

INSTRUCTIONS FOR USE

1. Remove the device from the packaging.
2. Twist the lid clockwise to verify the container is sealed.
3. Connect the large suction tube to the inlet on the container
4. Connect the small exit tube to the exit of the container.
5. Connect the exit tube to the hospital suction source.

PRODUCT COMPLAINTS AND INQUIRIES

Customer complaints and product inquires should directed to complaints@sustainmedical.com. A paper copy of this IFU can be made available upon request at no charge.

REFERENCES

These instructions for use are based experience from physicians and (or) published literature.