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Suction Sump – Important Safety Information

SU-20601; SU-20602; SU.20802; SU-29602

INDICATIONS:

The Suction Sumps are intended to be used to remove fluids from the surgical field .
The Suction Sumps are intended to be used for 6 hours or less.

CONTRAINDICATIONS:

No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions. Do not use the device for any purpose other than indicated.

GENERAL WARNINGS:

- The device must only be used if sterile.
- Read directions carefully before using this device.
- This device is only intended to be used by professionally trained personnel. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. These instructions are furnished for informational purposes only. Each surgeon must evaluate the appropriate use of this device, case by case, based on medical training, experience, and the type of surgical procedure employed.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- Always apply and maintain a correct dose and accurate monitoring of the
- anticoagulant during the bypass.
- For single-use and for single patient use only. During use, the device is in contact with human blood, body fluids, liquids or gases and due to its specific design, it cannot be fully cleaned and disinfected at the end of use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).
- Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.
- The device must not undergo any further processing.
- Do not resterilise.
- Handle with care after use as the product may be contaminated with blood and/or body fluids. Dispose of in accordance with applicable regulations in the country of use.
- Do not use this device if package is damaged or opened as sterility of the device may have been compromised.
- Never use a device if it is beyond its expiration date.
- Dispose of unused device in accordance with applicable regulations in force in the country of use.
- This device contains stainless steel. Do not use this device in a MRI environment.
- If used on children, pregnant or nursing women, be aware that this device contains di(2-ethylhexyl) phthalate (DEHP) that is presently classified in the European Union as toxic to reproduction. The amount of phthalate which might be released from the device does not raise specific concerns about residual risks.
- This device is for short term use only (<6 hours).
- Do not intentionally place Sumps in contact with the heart.

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For professional use. Please visit www.sorinmanuals.com to find instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.

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