LivaNova

Health innovation that matters

Perfusion Adapters – Important Safety Information

CA-80010, CA-81010

INDICATIONS:

The Antegrade/Retrograde Perfusion Adapter is indicated for use to deliver cardioplegia solution to either the aortic root or coronary sinus. The Antegrade/Retrograde Perfusion Adapter with pressure line is indicated for use to deliver cardioplegia solution to either the aortic root or the coronary sinus while continually monitoring the pressure of the coronary sinus.

CONTRAINDICATIONS:

The Antegrade/Retrograde Perfusion Adapter is not designed, sold or intended for use other than indicated.

GENERAL WARNINGS:

- 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.
- 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).
- If used on children, pregnant or nursing women, be aware that this device contains di(2-ethylhexyl) phthalate (DEHP) and/or di-n-hexyl phthalate (DnHP) which are 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 the residual risks.
- 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.
- Do not use this device if it shows signs of damage, e.g., crimps, kinks, or crushed areas.
- This device is for short term use only (<6 hours).
- Removal should always be done under visualization.
- 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 REUSE. DO NOT RESTERILIZE.

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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