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Health innovation that matters

Cardioplegia Adapters – Important Safety Information

CA-10010; CA-10020; CA-10030; CA-10040; CA-11030; CA-20010; CA-20020; CA-20030; CA-20070; CA-30010; CA-40010; CA-40020; CA-40030; CA-40040; CA-40060; CA-40068; CA-41020

INDICATIONS:

Model: CA-10010, CA-10020–Straight Adapter, CA-10030, CA-10040, CA-11030–Perfusion Adapter
The Adapter is indicated for use during cardiopulmonary bypass surgery for connecting a cannula or catheter to an administration and/or a vent line.
Model: CA-20030–Venting "Y" Adapter
The Venting "Y" Adapter is designed to be used in conjunction with cardiopulmonary bypass surgery to deliver cardioplegia solution, and venting the left atrium of the heart. It may also be used as an extension line by itself.
Model: CA-20020, CA-21040–Recirculation "Y" Adapter
The Recirculation "Y" Adapter is indicated for use for recirculating of cardioplegia solution during cardiopulmonary bypass surgery, to keep the cardioplegia solution at a constant temperature.
Model: CA-20010, CA-20070–Perfusion "Y" Adapter
The Perfusion "Y" Adapter is indicated for use in delivery of cardioplegia solution during cardiopulmonary bypass surgery.
Model: CA-40010, CA-30010, CA-31010, CA-40060–Multiple Perfusion Adapter
The Multiple Perfusion Adapter is designed to deliver cardioplegia solution through an aortic root cannula while also perfusing up to three vein grafts with appropriate cannula.
Model: CA-40020–Multiple Perfusion Adapter with Vent Line
The Multiple Perfusion Adapter with vent line models of the Cardioplegia Delivery Sets are designed to deliver cardioplegia solution through an aortic root cannula while also perfusing up to three vein grafts. This set also allows venting of (left atrium of the heart) an aortic root cannula if a non vented aortic root cannula is being used to perfuse the aorta.
Model: CA-41020–Multiple Perfusion Adapter with Vent Line with Vessel Cannula (Cat No: VC-11000)
The Multiple Perfusion Adapter with vent line with vessel cannula is designed to deliver cardioplegia solution through an aortic root cannula while also perfusing up to three vein grafts. This set also allows venting of (left atrium of the left heart) an aortic root cannula if a non vented aortic root cannula is being used to perfuse the aorta. This set is provided with three vessel cannulae pre-attached to the appropriate tubing lengths which are terminated with male luer connectors for perfusing vein grafts.
Model: CA-40030–Multiple Perfusion Adapter with Vessel Cannula (Cat No: VC-11000)
The Multiple Perfusion Adapter with vessel cannula is designed to deliver cardioplegia solution through an aortic root cannula while also perfusing up to three vein grafts. This set is provided with three vessel cannulae pre-attached to the appropriate tubing lengths terminated with male luer connector for perfusing vein grafts.
Model: CA-40040–Multiple Perfusion Adapter with Vessel Cannula with Valve (Cat No: VC-11010)
The Multiple Perfusion Adapter with vessel cannula with valve is designed to deliver cardioplegia solution through an aortic root cannula while also perfusing up to three vein grafts. This set is provided with three vessel cannulae with valve pre-attached to the appropriate tubing lengths terminated with male luer connector for perfusing vein grafts.

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CONTRAINDICATIONS:

The Cardioplegia Delivery Sets are 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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