DESCRIPTION
The Sorin SCCA Coronary Cardioplegia Adapter is a disposable quadrifurcated tubing set that can be attached to the male luer lock on the patient line of the Sorin Group USA, Inc. Blood Cardioplegia System (BCD Advanced or BCD Vanguard). It is comprised of four 3/32˝ (2.3mm) ID tubing segments with male luer connectors and vein graft cannulae on the distal ends, and the proximal ends joined with a four way wye connector. Each branch has a flow clamp to control the perfusion sites independently. A 2.0mm (14 Ga.) angiocath with introducer is included for aortic root perfusion. This angiocath is equipped with vent line, flow clamp and ¼ in. (6.4mm) tubing connector.

Contents have been sterilized by ethylene oxide gas and have nonpyrogenic fluid pathways unless unit package is opened or damaged.

INDICATIONS FOR USE
The Coronary Cardioplegia Adapter is intended for use in the delivery of cardioplegia solutions to the aortic root and vein grafts or directly to the coronary arteries and vein grafts. When used with the vent line, the adapter can be used for aspiration of the aortic root.

CONTRAINDICATIONS
The adapter is for use only as indicated. Not recommended for use in any abnormal or diseased physiological condition.

WARNINGS
ALL ADAPTERS SHOULD BE INSPECTED FOR STORAGE AND SHIPPING DAMAGE PRIOR TO USE. KINKED OR DISTORTED PARTS MAY LEAD TO OBSTRUCTION OR DISRUPTION OF BLOOD FLOW AND SHOULD NOT BE USED. SORIN GROUP USA, INC. DOES NOT RECOMMEND A PARTICULAR TECHNIQUE FOR THE USE OF THIS DEVICE. THE STEPS CONTAINED IN THE FOLLOWING SET-UP SECTIONS ARE FOR INFORMATION PURPOSES ONLY. EACH SURGEON SHOULD EVALUATE THEIR APPROPRIATENESS ACCORDING TO INDIVIDUAL PATIENT CONDITION AND HIS OR HER MEDICAL TRAINING AND EXPERIENCE.


PRECAUTIONS
1. Carefully read Instructions For Use prior to use.
2. This product is for single patient use only.
3. Do not resterilize this product.
4. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

ADDITIONAL SAFETY INFORMATION
1. Store in cool, dry place.

PROCEDURES FOR USE
SET-UP: AORTIC ROOT AND VEIN GRAFT PERFUSION
1. Using care not to contaminate the sterile product, remove adapter from its sterile pouch and place it into the sterile field.
2. Inspect the adapter for patency and any storage or shipping damage.
3. Attach the adapter to the male luer lock on the cardioplegia delivery set patient line.
4. Disconnect the vein graft cannula from the short aortic perfusion line and utilize for vein graft preparation.
5. Prime the adapter with cardioplegia solution, eliminating all air. Close flow clamps.
6. Using proper surgical technique, introduce and secure the aortic perfusion catheter. Remove the introducer needle and immediately attach the catheter to one branch of the adapter.
7. When all air has been removed, cardioplegia solution may be administered.

WARNING: LINE PRESSURE SHOULD BE MONITORED TO PREVENT OVER-PRESSURIZATION OF THE DELIVERY SITE.
8. After the distal anastomosis has been performed, the vein graft can be trimmed to an appropriate length and connected to another branch on the adapter for subsequent infusions.
9. When all air has been removed from this branch, cardioplegia solution may be administered.

WARNING: ADAPTER CANNULAE MUST BE PROPERLY AFFIXED TO THE VESSEL OR TISSUE TO PREVENT INADVERTENT REMOVAL DURING BYPASS PROCEDURE.
10. For additional vein grafts, repeat steps 8 and 9.
11. Appropriate surgical technique should be used for removal of the adapter and the repair of the infusion sites.

SET-UP: AORTIC ROOT ASPIRATION
1. Follow steps 1 through 4 of SET-UP: AORTIC ROOT AND VEIN GRAFT PERFUSION.
2. Attach the female luer of the vent line wye to the male luer on the short aortic perfusion line.
3. Connect the ¼” (6.4mm) vent line connector to a suction line (roller pump, siphon, etc.).
4. Prime the adapter with cardioplegia solution, eliminating all air. Suction may be used to aid in filling the vent line. Close flow clamps.
5. Using proper surgical technique, introduce and secure the aortic perfusion catheter. Remove the introducer needle and immediately attach the catheter to the male luer on the vent line wye.

WARNING: THE ADAPTER SET, VENT LINE (UP TO CLOSED FLOW CLAMP) AND CATHETERS MUST BE PRIMED AND FREE OF ALL AIR PRIOR TO INFUSION OF CARDIOPLEGIA.
6. Continue following steps 7 through 11 of SET-UP: AORTIC ROOT AND VEIN GRAFT PERFUSION.

SET-UP: AORTIC VALVE-REPLACE AND VEIN GRAFT PERFUSION
1. Using care not to contaminate the sterile product, remove adapter from its sterile pouch and place it into the sterile field.
2. Inspect the adapter for patency and any storage or shipping damage.
3. Attach the adapter to the male luer lock on the cardioplegia delivery set patient line.
4. Disconnect vein graft cannula from the short aortic perfusion line and utilize for vein graft preparation.
5. Prime the adapter with cardioplegia solution, eliminating all air. Close flow clamps.
6. If direct coronary perfusion is desired during aortic valve replacement, two branches of the adapter can be connected to standard coronary perfusion cannulae (not included).
7. When all air has been removed, cardioplegia solution may be administered.

WARNING: LINE PRESSURE SHOULD BE MONITORED TO PREVENT OVER-PRESSURIZATION OF THE DELIVERY SITE.
8. After the distal anastomosis has been performed, the vein graft can be trimmed to an appropriate length and connected to another branch on the adapter for subsequent infusions.
9. When all air has been removed from this branch, cardioplegia solution may be administered.

WARNING: ADAPTER CANNULAE MUST BE PROPERLY AFFIXED TO THE VESSEL OR TISSUE TO PREVENT INADVERTENT REMOVAL DURING BYPASS PROCEDURE.
10. For additional vein grafts, repeat steps 8 and 9.
11. Appropriate surgical technique should be used for removal of the adapter and the repair of the infusion sites.

Sorin Group USA, Inc.
DISCLAIMER STATEMENT

SORIN GROUP USA, INC. WARRANTS THAT REASONABLE CARE HAS BEEN USED IN THE MANUFACTURE OF THIS DEVICE. THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED, IMPLIED, WRITTEN OR ORAL, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS. AS A RESULT OF BIOLOGICAL DIFFERENCES IN INDIVIDUALS, NO PRODUCT IS 100% EFFECTIVE UNDER ALL CIRCUMSTANCES. BECAUSE OF THIS FACT AND SINCE WE HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THE DEVICE IS USED, DIAGNOSIS OF THE PATIENT, METHODS OF ADMINISTRATION OR ITS HANDLING AFTER THE DEVICE LEAVES OUR POSSESSION, SORIN GROUP USA, INC. DOES NOT WARRANT EITHER A GOOD EFFECT OR AGAINST AN ILL EFFECT FOLLOWING ITS USE. SORIN GROUP USA, INC. SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF THE DEVICE. SORIN GROUP USA, INC. WILL REPLACE ANY DEVICE THAT WE FEEL WAS DEFECTIVE AT THE TIME OF SHIPMENT. NO REPRESENTATIVE OF SORIN GROUP USA, INC. MAY CHANGE ANY OF THE FOREGOING OR ASSUME ANY ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS DEVICE.

RETURN OF USED PRODUCT

For Customers within the United States

If for any reason this product must be returned to Sorin Group USA, Inc., a returned goods authorization (RGA) number is required from Sorin Group USA, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton, or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of the shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from the Sorin Group USA, Inc., Returned Goods Coordinator, Quality Assurance Department (800-650-2623).

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

The shipping address for returned goods is:

Sorin Group USA, Inc.
Returned CV Products
14401 West 65th Way
Arvada, CO 80004-3599 USA

For Customers Outside the United States

If for any reason this product must be returned please contact your sales representative for specific instructions.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton, or an equivalent carton, to prevent damage during shipment.

CAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

ADDRESS:

Manufacturer:
Sorin Group USA, Inc.
14401 W. 65th Way
Arvada, CO 80004 USA
Telephone: 800-221-7943
Telephone: 303-425-5508
Fax: 303-467-6584

Distributor in Canada:
Sorin Group Canada, Inc.
280 Hillmount Road Unit 8
Markham Ontario L6C 3A1
Telephone: 416-751-8767
Fax: 416-751-9849

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