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Blood Collection Reservoir with 30 µm Filter – Important Safety Information

WARNINGS:

- Carry out a visual inspection and carefully check the device before use. Transportation and/or storage conditions other than those prescribed may have caused damage to the device.
- Do not use solvents such as alcohol, ether, acetone, etc.: as contact may cause damage to the device.
- Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This could cause damage which may compromise the integrity and proper function of the device.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- Do not attach access sites, drain lines, or luer port to arterial side of cardiopulmonary bypass system as this may allow introduction of air into the bypass circuit.
- Carefully observe for leaks before and during use. Leakage in the reservoir can result in loss of sterility or loss of blood. If leakage is observed before or during use, replace the reservoir or tighten the leaking connection as appropriate.
- To reduce the possibility of air or particulate embolism, Sorin Group Italia recommends the use of reinfusion protection devices, including microfilters, when infusing blood products. Failure to use an in-line filter may result in reinfusing particles potentially harmful to the patient.
- The American Association of Blood Banks recommends the following guidelines for expiration of salvaged Blood1:
    a. If not transfused immediately, units collected and processed under sterile conditions with a device for intraoperative blood collection that washes with 0.9% saline, USP, shall be stored under one of the following conditions prior to initiation of transfusion:
        - At room temperature for up to 4 hours after end of processing.
        - At 1° C to 6° C for up to 24 hours, provided that storage at 1° C to 6° C is begun within 4 hours of end of processing.

    b. The transfusion of shed blood collected under postoperative or posttraumatic conditions shall begin within 6 hours of initiating the collection.
- Failure to maintain adequate anticoagulation during blood collection can cause excessive clotting in and possible clogging of the collection reservoir or centrifuge bowl
- The user should check for tubing occlusions and kinks during set-up.

CAUTIONS:

- Carefully read these Instructions for Use before using this product.
- Due to the possibility of operator exposure to bloodborne pathogens (such as HIV, hepatitis viruses, bacteria, Cytomegalovirus, etc.) when handling extracorporeal blood circuits, adequate precautions should be taken at all times to prevent the exposure to and transmission of such agents.

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- Discard after single use. Do not resterilize this product or its package. 4. If the blood inlet pressure rises. Or if blood exits over the top of the filter element, the filtration capacity of the reservoir has been exceeded and the reservoir should be replaced immediately.
- Do not use this product if it is damaged, if the sterile package is damaged or opened, or if the protective caps are not in place.
- This reservoir is not vented. When pumping into the reservoir, the yellow vent cap must be removed from the 1/4" perimeter slip port to prevent inadvertent pressurization of the reservoir.
- When used with a vacuum system for suction, it is recommended that the vacuum level not exceed 150200 mmHg as a higher vacuum level may result in higher hemolysis. Users of the Blood Collection reservoir should verify the accuracy and functioning of the suction regulator2. A self-activating under-pressure relief valve is provided to prevent implosion of the device if exposed to a sudden, deep vacuum.
- In the event of decreased patient Anti-thrombin III levels, heparin anticoagulation may be ineffective. Consult the physician regarding an alternative anticoagulant solution.
- Avoid aspiration of any calcium containing IV solutions (e.g. Lactated Ringers) when citrate anticoagulation is used. Aspiration of calcium containing IV solutions may cause clotting in the Blood Collection Reservoir3.
- It is recommended that intraoperative and postoperative autologous blood be processed. Refer to a BRAT2 System Operator's Manual for complete instructions on the use of this device.
- If used with a non-Sorin Group device, the user is responsible for ensuring that a secure and appropriate connection exists between the Reservoir Outlet Port (D) and the blood processing system wash set.
- This product is intended for use by trained personnel only. Use proper aseptic technique while handling this reservoir.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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

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DAC Cardiotomy Reservoir – Important Safety Information

WARNINGS:

- The device must be used in accordance with the instructions for use provided in this manual.
- The device is intended to be used by professionally trained personnel.
- SORIN GROUP ITALIA is not responsible for problems arising from inexperience or improper use. - FRAGILE, handle with care.
- Keep dry.
- Do not expose to temperatures below 0°C (32°F) or above 60°C (140°F).
- For single use and for single-patient use only. During use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body, and due to its specific design it cannot be fully cleaned and disinfected after use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, the 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.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device must only be used if sterile.
- For further information and/or in case of complaint contact SORIN GROUP ITALIA or the authorised local representative.

CAUTIONS:

- The internal surface of the system is Ph.I.S.I.O. coated; currently, no contraindications relating to use of the systems equipped with Ph.I.S.I.O. treated components is known to SORIN GROUP ITALIA.
- Do not push on the over/under safety valve as it can be displaced or its ability to properly work might be impaired.
- Always check level inside the Inspire HCR cardiotomy reservoir. This prevents air from being sent to the venous reservoir.
- Do not use as chest drainage device.

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

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Inspire HCR and Inspire HCR DUAL – Important Safety Information

WARNINGS:

- The user should carefully check the device for leaks during set-up and priming. Do not use if any leak is detected.
- The device must be used in accordance with the instructions for use provided in this manual.
- For use by professionally trained personnel only.
- SORIN GROUP is not responsible for problems arising from inexperience or improper use.
- FRAGILE, handle with care.
- Keep dry. Store at room temperature.
- Do not use solvents such as alcohol, ether, acetone, etc.: as contact may cause damage to the device.
- Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This could cause damage which may compromise the integrity and proper function of the device.
- Always administer and maintain correct anticoagulant dosage before, during and after the bypass and provide its correct monitoring.
- For single use and for single patient use only: during use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body. Due to its specific design the device cannot be fully cleaned and disinfected at the end of use. Therefore, reuse on other patients might cause crosscontamination, 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 and its accessories must be handled applying sterile techniques.
- The device must not undergo any further processing.
- Do not resterilize.
- After use, dispose of the device in accordance with applicable regulations in force in the country of use.
- The device must only be used if STERILE.
- Inspire HCR should always be positioned with its blood outlet connector at least 5 cm above the upper point of the oxygenator used in conjuction with it.
- "Filtered" and "unfiltered" ports allow the administration of fluids and medicaments.
- Drugs which must be administered at low doses should be diluted with saline solution so that they can fully run into the extracorporeal circulation.
- It is recommended to administer all fluids through the filtered ports, even if this should result in a slight delay in the fluid reaching the circulation.
- The Inspire HCR used with vacuum must be carefully used following the instructions "USE OF VACUUM DRIVEN SUCTION" of this user's manual in paragraph J
- The special positive and negative overpressure valve built into the Inspire HCR ensures optimal intra- and post-operative performance of the system. The valve is activated and vents positive pressure higher than +5 mmHg (0.7 kPa/ 0.007 bar / 0.1 PSI) and negative pressure lower than -200 mmHg (26.7 kPa / -0.27 bar / -3.86 PSI). DO NOT OCCLUDE THE VALVE ORIFICE FOR ANY REASON WHATSOEVER.
- Inspire HCR cardiotomy reservoirs must be used with their dedicated holders.

- Use adequate technique to never exceed max recommended operating parameters described in the hereby Instructions for Use.
- For further information and/or in case of complaint contact SORIN GROUP or the authorised local representative.

CAUTIONS:

- The internal surface of the system is Ph.I.S.I.O. coated; currently, no contraindications relating to use of the systems equipped with Ph.I.S.I.O. treated components is known to SORIN GROUP ITALIA.
- Do not push on the over/under safety valve as it can be displaced or its ability to properly work might be impaired.
- Always check level inside the Inspire HCR cardiotomy reservoir. This prevents air from being sent to the venous reservoir.
- Do not use as chest drainage device.

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