

Medtronic

HEALTHCARE PROFESSIONALS

EL Series

Blood Collection Reservoirs



INDICATIONS, SAFETY, AND WARNINGS

MODEL EL2 RESERVOIRS

INDICATIONS

The EL2 Autotransfusion Blood Collection Reservoir is indicated for use with patients undergoing autotransfusion procedures. The unit has a capacity of 4000 mL and contains either a 40 or 120 micron integral microfilter. The reservoir has been designed to collect, filter, and store blood aspirated during the perioperative period of surgery or trauma prior to subsequent cell washing.

CONTRAINDICATIONS

- The use of reinfused blood from the product may be contraindicated (eg, in the presence of sepsis or malignancy). This product used for any other purposes than for the indicated intended use is the responsibility of the user.
- The safe length of time that blood may remain in this reservoir is a medical decision and may vary with each case where intraoperative salvage is used.

(AABB Standards, 14th Edition 1991, Section L2.500 states: "If it is to be transfused, shed blood collected intraoperatively or under postoperative or posttraumatic conditions should be transfused within 6 hours of initiating the collection.")

WARNINGS

- Read all Warnings, Precautions, and Instructions for Use carefully prior to use. **Failure to read and follow all instructions, or failure to observe all stated warnings, could cause serious injury or death to the patient.**
 - Only persons thoroughly trained in cardiopulmonary bypass or autotransfusion procedures should use this product. Operation of each product requires constant supervision by qualified personnel for patient safety.
 - Each product has been carefully manufactured, tested, and packaged; however, the state of the art has not been developed to the point that Medtronic is able to ensure that the product will not leak, crack, or fail during use. Perfusion must be carefully and constantly monitored.
 - The product must be used immediately after the removal of the protective packaging.
 - The fluid pathway is sterile and nonpyrogenic. Inspect each package and product prior to use. Do not use if the package is opened or damaged or if the protective caps are not in place.
 - Disposable. Each product is intended for single use only. Do not reuse or resterilize. EO sterilized.
 - Use aseptic technique in all procedures.
 - Tubing should be attached in such a manner as to prevent kinks or restrictions that may alter blood or water flow.
 - Do not allow alcohol, alcohol-based fluids, anesthetic fluids (such as isoflurane), or corrosive solvents (such as acetone) to come into contact with the product as they may jeopardize the structural integrity.
 - Polycarbonate may react adversely upon direct contact with paregoric or halothane. Avoid contact between these agents and the reservoir.
 - If air bubbles and/or leaks are observed during priming and/or operation, these conditions may result in air embolism to the patient and/or fluid loss. The extracorporeal circuit must be continually monitored. Do not use the product if these conditions are observed.
 - All gas emboli must be cleared from the extracorporeal circuit before initiating bypass. Gas emboli are hazardous to the patient.
- The fluid level in the venous reservoir bag should be maintained above the oxygenator at all times.

- Monitor the blood level in the venous reservoir bag at all times during perfusion.
- Never agitate or invert the product once cardiopulmonary bypass is initiated.
- Should any evidence of damage to components be found during setup visual inspection, do not use the product.
- Never exceed 150 mm Hg negative pressure when aspirating blood, as excessive vacuum may create accelerated blood trauma.
- Failure to verify the security of the reservoir holder and reservoir position may result in inadvertent overturn of the system and/or improper operation.
- This product is not intended for use as a cardiotomy reservoir.

PRECAUTIONS

- Store in a dry place away from extremes of temperature. Refer to package labeling for storage temperature requirements.
- A strict anticoagulation protocol should be followed, and anticoagulation should be routinely monitored during all procedures. The benefits of extracorporeal support must be weighed against the risk of systemic anticoagulation and must be assessed by the prescribing physician.
- Medtronic strongly recommends the use of a blood transfusion filter between the reinfusion bag and the patient, in compliance with AAMI Standards for Autotransfusion Devices (A3.2.4): "The use of a filter is a medical decision, but because of the potential for extraneous debris, the incorporation of a filter is desirable."

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. For a complete listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product.

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MODEL EL4 RESERVOIRS

INDICATIONS FOR USE

EL400, EL402 and EL404 Cardiotomy Reservoirs are indicated for use with patients undergoing cardiopulmonary bypass or autotransfusion procedures. These units contain an integral microfilter with the following sizes that correspond with the catalog number: EL400 = 120 microns, EL402 = 20 microns and EL404 = 40 microns. The reservoir has been designed to collect, filter and store blood aspirated during surgery or trauma. This product has a maximum rated blood flow of 6 liters per minute.

CONTRAINDICATIONS

- The use of reinfused blood from the product may be contraindicated (eg, in the presence of sepsis or malignancy). This product used for any other purposes than for the indicated intended use is the responsibility of the user.
- The safe length of time that blood may remain in this reservoir is a medical decision and may vary with each case where intraoperative salvage is used.

WARNINGS

- Read all Warnings, Precautions, and Instructions for Use carefully prior to use. **Failure to read and follow all instructions, or failure to observe all stated warnings, could cause serious injury or death to the patient.**
- Only persons thoroughly trained in cardiopulmonary bypass or autotransfusion procedures should use this product. Operation of each product requires constant supervision by qualified personnel for patient safety.
- Each product has been carefully manufactured, tested, and packaged; however, the state of the art has not been developed to the point that Medtronic is able to ensure that the product will not leak, crack, or fail during use. Perfusion must be carefully and constantly monitored.
- The product must be used immediately after the removal of the protective packaging.
- The fluid pathway is sterile and nonpyrogenic. Inspect each package and product prior to use. Do not use if the package is opened or damaged or if the protective caps are not in place.
- Use aseptic technique in all procedures.
- Tubing should be attached in such a manner as to prevent kinks or restrictions that may alter blood or water flow.
- Do not allow alcohol, alcohol-based fluids, anesthetic fluids (such as isoflurane), or corrosive solvents (such as acetone) to come into contact with the product as they may jeopardize the structural integrity.
- If air bubbles and/or leaks are observed during priming and/or operation, these conditions may result in air embolism to the patient and/or fluid loss. The extracorporeal circuit must be continually monitored. Do not use the product if these conditions are observed.
- All gas emboli must be cleared from the extracorporeal circuit before initiating bypass. Gas emboli are hazardous to the patient.
- The fluid level in the venous reservoir bag should be maintained above the oxygenator at all times.

Monitor the blood level in the venous reservoir bag at all times during perfusion.

- Never agitate or invert the product once cardiopulmonary bypass is initiated

Never agitate or invert the product once extracorporeal bypass is initiated.

- Should any evidence of damage to components be found during setup visual inspection, do not use the product.
- **Never exceed 150 mm Hg negative pressure when aspirating blood, as excessive vacuum may create accelerated blood trauma.**
- Failure to verify the security of the reservoir holder and reservoir position may result in inadvertent overturn of the system and/or improper operation.

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PRECAUTIONS

- Store in a dry place away from extremes of temperature. Refer to package labeling for storage temperature requirements.
- A strict anticoagulation protocol should be followed and anticoagulation should be routinely monitored during all procedures. The benefits of extracorporeal support must be weighed against the risk of systemic anticoagulation and must be assessed by the prescribing physician.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. For a complete listing of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product.

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