WARNING: NOT INTENDED FOR REINFUSION.

3T MEDICAL SYSTEMS

R_x ONLY

STERILE R

CBCII ConstaVac™ Blood Collection Only System

REF 0225-029-000

IMPORTANT INFORMATION: File in your records. Read and understand these instructions. Familiarization with the 3T Medical CBCII prior to use is important.

SYMBOL DEFINITION

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

O	Off
I	Low Vacuum
II	Medium Vacuum
III	High Vacuum

KEEP UPRIGHT IN USE

INDICATIONS FOR USE

This system is used to collect post-operative surgical site drainage fluids. It is the responsibility of the attending physician to determine the appropriateness of this therapy for a particular surgical procedure.

RELATIVE CONTRAINDICATIONS

- Abnormal renal and/or hepatic function
- Malignant lesions
- Contamination/sepsis
- Amniotic fluid
- Bile
- Hemostatic agents
- Excessive hemolysis
- Coagulation disorders
- Potential for air embolism, microembolism, fat embolism

OPERATING ROOM

WARNINGS:

- Upon initial receipt and before use, inspect the package for damage and confirm the integrity of the sterile barrier. DO NOT use any equipment if damage is apparent or the sterile barrier has been compromised.
- DO NOT reuse, reprocess, or repackage a device that is intended for single use only.
  - A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
  - Design features may make cleaning difficult.
  - Reuse may create a contamination risk and compromise structural integrity resulting in operational failure.
  - Critical product information may be lost during repackaging.

  Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

1. Remove contents from package using aseptic technique.

NOTES:

- The blue cover should remain wrapped around the unit. Its intention is to reduce the chance of transfer of blood from the surgical field to the outer surface of the unit.
- DO NOT turn unit on until Y-connector is attached to the patient drain tube.

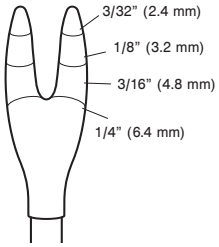
2. Slide evacuator tube (tube with Y-connector) from sterile cover.
3. Place wound drain(s) in wound and remove needle.

WARNINGS:

- Exercise care when removing protective cover from needle to avoid injury.
- ALWAYS follow the current local regulations governing the handling and disposal of sharps.

4. Trim Y-connector at proper level to accept wound drain outer diameter. Secure wound drain(s) to evacuator tube.

NOTE: Ensure all connections and disconnections are made using aseptic technique and that all connections are airtight.



5. The unit may remain in the sterile field or be passed back to the circulating nurse. The circulating nurse can remove and discard the blue cover.
6. The unit may be hung on bed rail and secured with the security strap for transport.

CAUTION: Exercise care when transporting the patient so that the unit is not damaged.

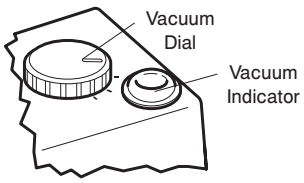
POST ANESTHESIA CARE UNIT

WARNING: Adherence to universal blood and body fluid precautions is highly recommended when handling any blood-related product.

1. Secure unit to foot board or side rail of bed. Depress the mounting clamp to adjust its fit. Secure unit with the security strap.
2. To initiate drainage, set the vacuum dial at the LOW setting for at least 10 minutes. After 10 minutes, set the vacuum level per physician's prescription.

APPROXIMATE VACUUM LEVELS:

LOW	0.5 psi	(25 mmHg)
MEDIUM	1.0 psi	(50 mmHg)
HIGH	<1.9 psi	(<100 mmHg)



ENGLISH (EN)

NOTES:

- To maintain accurate vacuum level setting, the unit should be at the level of the wound site. For every 12 inches that the pump unit is elevated above the wound site, the vacuum level is reduced by 0.5 psi (25.85 mmHg).
- If motor does not run, check if vacuum indicator is inverted. If so, release vacuum either by depressing and holding the blue lever fully or by disconnecting the male-female connection.

3. Note that the vacuum indicator has inverted. This indicates vacuum within the reservoir.
4. Record start time and volume output on reservoir label.

CAUTION: Exercise care when transporting the patient so that the unit is not damaged.

WOUND DRAINAGE

WARNING: Exercise care during removal of wound drain. Excessive force may cause drain to break and a broken drain portion to remain in wound, necessitating additional surgery to remove it.

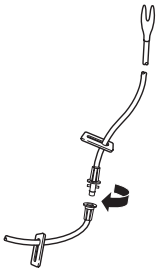
1. Wound drainage output is measured directly from the reservoir.

NOTE: Wound drainage output can be monitored by marking the fluid level and time of reading (as required) on the reservoir label.

2. The unit may be ambulated in an upright position along with the patient, if a wheelchair or transport stretcher is used.
3. The unit is discontinued for wound drainage per hospital protocol or physician's discretion.
4. The drains are removed from the patient and, along with the unit, disposed of properly.

UNIT REPLACEMENT

1. Using aseptic technique, clamp evacuator tube on each side of the quick-connect.
2. Twist quick-connect to separate evacuator tube.
3. Discard Y-connector portion of evacuator tube from new unit.
4. Attach quick-connect of new unit to quick-connect of evacuator tube attached to patient.
5. Set vacuum level at prescribed setting.
6. Unclamp evacuator tube.



IMPORTANT INFORMATION

AIR LEAK:

- Check all tubing connections, including point where drain enters patient and where drain is attached to Y-connector. Bubbling in the reservoir or large amounts of air bubbles in evacuation tube are an obvious indication of an actual air leak and its origin.

In the event of an air leak, unit can be replaced. To replace the unit, refer to *UNIT REPLACEMENT.*

HIGH DRAINAGE:

- Observe total drainage into reservoir - high drainage may cause frequent cycling. No action required.
- Observe total drainage output and sanguineous fluid collection. A blood vessel may have lost its tie or sloughed a cauterized end and will require attention.

NO OR LOW DRAINAGE:

- Periodically check total drainage output and serous fluid condition in evacuator tube. This may be an indication that drainage has ceased. In this event, wound drainage is discontinued, the wound drains are removed and along with the reservoir, disposed of properly.
- Monitor total drainage output in relation to time post-op and procedure. Low volumes may be an indication of system occlusion.
- Check drain lines and evacuator tube for occlusion. Vacuum level may be increased and/or the evacuator tube can be "milked" to stimulate flow.

WARNINGS:

- Adherence to universal blood and body fluid precautions is highly recommended when handling any blood-related product.
- DO NOT RESTERILIZE OR REUSE ANY PART OF THIS SYSTEM OR ACCESSORIES. The CBCII system, as well as wound drains and needles, are intended for single patient use. Sterility guaranteed unless package is opened or damaged.
- ALWAYS follow the current local regulations governing the handling and disposal of sharps.
- ALWAYS follow the current local regulations governing biohazard waste to safely handle and dispose of surgical waste.

For additional information, especially safety information or inservice training, contact your 3T Medical sales representative or call 3T Medical customer service. Outside the US, contact your nearest 3T Medical subsidiary.

TROUBLESHOOTING

PROBLEM	CAUSE	ACTION
Vacuum indicator	Unit not turned on	Set vacuum at desired level.
	Air leak	Check all tubing connections. Decision to reinfuse is up to the physician's discretion. Refer to AIR LEAK.
	Reservoir air filter saturated	Replace unit. Refer to UNIT REPLACEMENT.
	Defective unit	Replace unit. Refer to UNIT REPLACEMENT.
Unit fails to run	Pre-existing vacuum pressure in system indicated by inverted vacuum indicator	To release vacuum pressure, clip Y-connector as required for connection to drain tube.
	Defective unit	Replace unit. Refer to UNIT REPLACEMENT.
Clotting in the reservoir	Rapid bleeding, preventing defibrination of the blood. Most likely with total knee where the tourniquet is released after the wound is closed.	Replace unit. Refer to UNIT REPLACEMENT. **NOTES:** ▪ To prevent this in the future, release the tourniquet and evacuate the 50 mL of the initial drainage with O.R. suction prior to attaching the Y-connector. ▪ To prevent this in the future, do not turn unit on until patient reaches the PACU. Then initiate vacuum at the LOW vacuum setting.
Insufficient drainage	Clotting in Y-connector	Manually "milk" clots through the Y-connector.
	Occluded prefilter	Replace unit. Refer to UNIT REPLACEMENT.
	Unit elevated above wound site	Lower unit or increase vacuum setting.
	Drain placement	Contact physician.

SPECIFICATIONS

Model:	CBCII ConstaVac Blood Collection Only System (REF 0225-029-000)
Dimensions:	9.0 inch [229 mm] height, 4.9 inch [125 mm] width, 6.5 inch [165 mm] depth
Volume:	Reservoir Capacity 800 mL +/- 10 mL
Evacuator Tube:	6 feet [183 cm] length
Filters:	0.45 micron Air Filter
Vacuum Level Settings:	LOW 0.5 psi [25 mmHg], MEDIUM 1.0 psi [50 mmHg], HIGH <1.9 psi [<100 mmHg]
Power Supply:	Internally powered 3.0 V ⎓ , two AA alkaline batteries factory installed
Duration:	>24 hours at high vacuum (level III on the vacuum control dial)
Ingress Protection:	IPX0
Mode of Operation:	Continuous Operation
Equipment Type:	Type BF Applied Part **NOTE:** The entire CBCII device is an applied part as defined by the manufacturer according to the standards listed under *Product Safety Certification*.
Product Safety Certification:	**Canadian Standards Association (CSA) International** **Canadian Standards Association (CSA)** CAN/CSA-C22.2 No. 601.1-M90, *Medical Electrical Equipment — Part 1: General Requirements for Safety* *CAN/CSA-C22.2 601.1S1-94 Supplement No 1-94 to CAN/CSA C22.2 601.1-M90* *CAN/CSA-C22.2 601.1B-98 Amendment 2 to CAN/CSA C22.2 601.1-M90* **Underwriters Laboratories (UL)** UL 60601-1, *Medical Electrical Equipment, Part 1: General Requirements for Safety — First Edition*; Revisions through and including April 26, 2006

Environmental Conditions:	**Operation**	**Storage and Transportation**
Temperature Limitation:	10 °C – 40 °C	-20 °C – 40 °C
Humidity Limitation:	30 % – 75 %	10 % – 75 %
Atmospheric Pressure Limitation:	70 *kPa* – 106 *kPa*	50 *kPa* – 106 *kPa*

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