**Instructions for Use**

**Figure 1, The SureTrans™ Autotransfusion System for Orthopaedics.**

- **Single Use Only**
- **Non-pyrogenic**
- **Rx Only**
- **Contains phthalates**

**Sterile:** This device is supplied sterile. Inspect the package and do not use if package is damaged or open.

**Warning:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws (U.S.A.) and regulations.

**INDICATIONS**
Simultaneous collection and reinfusion of autologous shed blood following orthopaedic surgery.

**CONTRAINDICATIONS**
1. Systemic infections.
2. Suspected infection of wound or drain site(s).
3. Septic contamination of autologous blood.
4. Malignant neoplasms in the area of blood accumulation.
5. Collected blood containing topical hemostatic agents, topical antiseptics or antibiotics contraindicated for systemic use.

**WARNINGS**
1. **Due to the potential for air embolism, do not pressure reinfuse while using the SureTrans™ Autotransfusion Transfer Bag.**

2. This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.

3. To reduce the possibility of infection when reinfusing autologous shed blood, “The time from collection to expiration should be less than 6 hours for recovered blood that is not processed.” (AABB. (2010) Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma; pp. 10-11). For proper identification, record the patient’s name, ID number and time collection was initiated on the collection container label.

4. Autotransfusion of wound drainage blood has been associated with complications due to blood trauma. Coagulopathy and embolism from particulate, fat and air have been reported. Proper procedural techniques should be followed to avoid such complications.

5. Salvaged blood deficient in coagulation factors may, on reinfusion, dilute the patient’s clotting factors in vivo and promote postoperative bleeding. Therefore, monitoring of the patient’s coagulation status is necessary to avoid coagulopathy.

6. Anticoagulant (ACD-A) may be used at the discretion of the physician. Determination of the amount of anticoagulant to be used should be adjusted according to the patient’s condition and type of procedure. Careful attention should be paid to the amount of anticoagulant used and the amount of shed blood collected so as not to exceed 15 mL of ACD-A anticoagulant for every expected collection of 100 mL of blood. Per AABB Guidelines, the administration rate for citrate-bearing anticoagulants is 15 mL per 100 mL of collected blood. (AABB. (2010) Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma; pp. 3-4). The ratio should be followed to prevent reactions such as citrate toxicity or bleeding tendency. In the event of suspected citrate toxicity, calcium administration should be considered.

7. A 20-40 micron microaggregate blood filter is required for use during blood reinfusion.

8. Prior to reinfusion, fully prime the blood administration set to remove air. Also, monitor the infusion line for the presence of air during reinfusion.

9. The one-way valve must be replaced by the tethered plug on port (B) of the SUCOVAC™ suction reservoir when using it for drainage collection to prevent leakage.

10. When collection unit contains more than 500 mL of fluid, the SureTrans™ unit must be kept upright.

11. To avoid the possibility of drain damage or breakage:
- Additional perforations should not be made in the drain.
- Avoid suturing through drain.
- Drain should lie flat and in line with the skin exit areas.
- Particular care should be taken to avoid any obstacles to the drain exit path.
- Drain should be checked during closure for free motion to avoid possibility of breakage.
- Drain removal should be done gently by hand. It should not be handled with pointed, toothed or sharp instruments which could cause cuts or nicks and lead to subsequent structural failure of the drain.
- Surgical removal may be necessary if drain is difficult to remove or breaks.

**CAUTIONS**
1. Read all instructions prior to use.

2. To help prevent serious adverse events such as allergic reactions to autologous blood transfusions, all transfusion and medical society guidelines, as well as, hospital and institution specific rules, regulations and requirements must be strictly followed.

3. Aseptic technique should be used when exposing and making all connections.

4. Prior to use, ensure that the round white stickers on the 3 Quick-Disconnect Luer-Locks are not damaged or broken. All connections must be properly secured to provide an airtight system.

5. The closed wound drain(s) must be firmly inserted into the Y-connector. The eyes of the drain(s) should not be exposed.

6. To ensure proper blood flow during collection and reinfusion, routinely check the tubing for patency and make sure that the clamps are open.

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CALL 1-800-562-0027 OR CONTACT YOUR LOCAL SureTrans™ REPRESENTATIVE
The SURETRANS™ System aspiration rates are as follows: through the injection port if desired by the surgeon. The detachable SOLCOVAC™ wound drain(s). ACD-A anticoagulant may be added to the collection container following autotransfusion, either the SOLCOVAC™ suction evacuator or the collection container may be used for the continued collection of drainage fluids.

**PRINCIPLES OF OPERATION**

The SURETRANS™ autotransfusion unit is an easy-to-use system designed to allow the simultaneous collection and reinfusion of autologous shed blood following orthopaedic surgery. The surgeon connects the SURETRANS™ system to the closed wound drain(s). ACD-A anticoagulant may be added to the collection container through the injection port if desired by the surgeon. The detachable SOLCOVAC™ suction evacuator provides self-contained suction to the unit. Alternatively, wall suction may be used. An internal vacuum limiter prevents suction from exceeding -90 mmHg. Collected blood is transferred into the attached blood transfer bag for reinfusion. Reinfusion of the blood follows normal blood transfusion procedures utilizing a 20-40 micron microaggregate blood filter and a standard blood administration set by gravity drip. While the blood is reinfusing, collection can simultaneously continue into the collection container. For closed wound suction following autotransfusion, either the SOLCOVAC™ suction evacuator or the collection container may be used for the continued collection of drainage fluids.

**INSTRUCTIONS FOR USE**

1. If suction is desired, compress the SOLCOVAC™ suction evacuator attached to the collection container to create negative pressure in the container. While holding the SOLCOVAC™ unit in the compressed state, attach the tethered one-way valve by pushing it onto the open port (B) of the SOLCOVAC™ evacuator (Figure 3). It may be necessary to recompress the evacuator (until it remains compressed) to charge the unit (Figure 4). Alternatively, wall suction may be used by simply attaching suction tubing to the wall suction port on top of the unit. The vacuum will be limited to -90 mmHg automatically by the SOLCOVAC™ system.

2. If more than 500 mL of fluid is in collection container, unit may be placed on its back.

**DONE: The SURETRANS™ System has no replaceable parts.**

**THE SYSTEM (Figure 1)**

**NOTE:** The SURETRANS™ System consists of the following:

- An 800 mL transparent collection container with an internal 260 micron pre-filter and blood transfer button.
- A patient drainage tube incorporating an anticoagulant injection port and a universal Y-connector for connection to the closed wound drain.
- A VELCRO® brand hook and loop fastener attached suction assembly including a SOLCOVAC™ suction evacuator with one-way valve and a connecting suction line.
- A 1000 mL blood transfer bag connected to the blood container by a 6 ft. transfer tube with spaces for patient name, patient number, date, and reinfusion start time.

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Caution: Although the system will function without regulated suction, suction regulators (set at -80 to -100 mmHg) are always recommended.

NOTE: The S OLCOVAC™ suction evacuator will expand as blood or air enters the SureTrans™ collection container. Compress the evacuator to reestablish negative pressure in the container. If the drainage rate slows or stops under gravity or evacuator suction, wall suction may be used to enhance flow.

TRANSFER OF BLOOD (Figure 6)
NOTE: Prior to transferring blood from collection container to transfer bag, remove wall suction to facilitate flow.

NOTE: Blood bag volume markings are approximate. Markings on the rigid collection container should be used to estimate blood output/infusion volumes. For accuracy, volumes should be read without suction applied to the collection chamber.
1. When the collection container is full, or the user is ready to reinfuse the collected blood, remove and uncoil the transfer tube and transfer bag from the rear envelope and position the transfer bag below the collection container.
2. Close the clamp on the patient drainage tube.
3. Open the clamps on the transfer tube. Make sure both pinch clamps on the transfer tube are open when transferring blood.
4. Depress and hold the transfer button on the collection container until all the blood has drained into the transfer bag (approximately 30-60 seconds).
5. Close both clamps on the transfer tube.
6. Open the clamp on the patient drainage tube and compress the S OLCOVAC™ suction evacuator to continue collection if suction is desired.

REINFUSION OF BLOOD (Figure 7)
WARNING: DO NOT PRESSURE REINFUSE DUE TO THE POTENTIAL FOR AIR EMBOLISM.

Caution: To help prevent serious adverse events such as allergic reactions to autologous blood transfusions, all transfusion and medical society guidelines, as well as, hospital and institution specific rules, regulations and requirements must be strictly followed.

Reinfusing the first quantity of blood collected when using a straight or Y-type administration set:
1. Remove the protective cover of the spike port on the bag. Insert a 20 - 40 micron microaggregate blood filter into the spike port.
2. Insert the blood administration set into the microaggregate filter, if not already combined. Hang transfer bag on I.V. pole.
3. Using standard technique for priming blood filters and fluid administration sets, prime the filter and purge the administration set of air. Make sure all air has been cleared before attaching to patient I.V. access.
4. Attach the administration set to the patient I.V. access.
5. The blood is reinfused by gravity. Follow hospital policy (physician’s standing orders) regarding infusion rate, record keeping, use of blood warmers, etc. when transfusing blood.
6. Close the clamps on the administration set before the drip chamber empties.
7. If reinfusing additional quantities of blood, the transfer bag may be left hanging on the I.V. pole until blood is ready to transfer from the collection container.
8. If reinfusions are complete, see the directions entitled “When No Longer Collecting Blood for Autotransfusion”.

If reinfusing additional quantities of blood:
1. Make certain the clamps on the blood administration set are closed.
2. Lower the empty transfer bag below the collection container and follow the instructions for the “Transfer of Blood” and “Reinfusion of Blood”.

WHEN NO LONGER COLLECTING BLOOD FOR AUTOTRANSFUSION

Using the collection container as the closed wound suction device: (Figure 8)
1. If no longer collecting blood for autotransfusion, close both pinch clamps on the transfer tube.
2. Disconnect transfer bag at luer-lock connector (breaking the round white sticker) and use tethered caps to close both free ends.
3. Discard the blood transfer bag and attached tubing in accordance with hospital policy for contaminated waste.
4. Compress the S OLCOVAC™ suction evacuator to initiate closed wound suction.

Using the S OLCOVAC™ suction evacuator as the closed wound suction device: (Figure 9)
1. If no longer collecting blood for autotransfusion, close the clamps on the blood transfer tube and patient drainage tube.
2. Convert to the S OLCOVAC™ suction evacuator for drainage collection by disconnecting the one-way valve from the port (B) of the evacuator using a twist/pull motion.
3. Remove S OLCOVAC™ suction evacuator from the front of the collection container by detaching at hook and loop fasteners.
4. Disconnect the S OLCOVAC™ suction evacuator from the suction assembly at the luer-lock connector (breaking the round white sticker) and attach the S OLCOVAC™ suction evacuator directly to the patient drainage tube luer lock connector.
5. Open clamp on patient drainage tube.
6. Compress and close the port (B) on the S OLCOVAC™ suction evacuator with tethered plug to initiate suction. Confirm that drainage flows from the patient drainage tube into the S OLCOVAC™ suction evacuator.

Warning: The one-way valve must be replaced by the tethered evacuator plug on port (B) of the S OLCOVAC™ suction evacuator when using it for drainage collection to prevent leakage.
7. Connect the 2 remaining luer-lock halves on top of the collection container.
8. Discard the collection container and blood bag in accordance with hospital policy for contaminated waste.
9. The table on the back of the S OLCOVAC™ suction evacuator can be used to monitor drainage. Columns have been provided to record the following:
   1. Time of emptying
   2. Date
   3. Volume Emptied
   4. Operator Initials

EMPTYING THE S OLCOVAC™ SUCTION EVACUATOR
1. Close the clamp on the patient drainage tube. Open the port (B) by removing tethered plug.
2. Turn the unit over, hold above proper receptacle, and compress the S OLCOVAC™ suction evacuator until the fluid is removed. Discard in accordance with hospital policy for contaminated waste.
3. For continued drainage, compress the S OLCOVAC™ suction evacuator fully and close the port (B) with tethered plug. Release the clamp on the patient drainage tube.

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<table>
<thead>
<tr>
<th>Drain Size</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1/8&quot; (3.2 mm, 10 Fr.) O.D.</td>
<td>12.5&quot; (31.7 cm) Hole Pattern, (2) Attached Trocars, X-Ray Opaque Stripe, 5 cm and 10 cm Depth Markings</td>
</tr>
<tr>
<td>3/16&quot; (4.7 mm, 14 Fr.) O.D.</td>
<td>12.5&quot; (31.7 cm) Hole Pattern, (2) Attached Trocars, X-Ray Opaque Stripe, 5 cm and 10 cm Depth Markings</td>
</tr>
<tr>
<td>1/4&quot; (6.3 mm, 19 Fr.) O.D.</td>
<td>12.5&quot; (31.7 cm) Hole Pattern, (2) Attached Trocars, X-Ray Opaque Stripe, 5 cm and 10 cm Depth Markings</td>
</tr>
</tbody>
</table>

**Do not use if package is damaged**

**Drain not included**

**Drain size**

**Includes PVC drain and two trocars**

**Y-Connector for patient drain**

**Contents**

**Non-pyrogenic**

**U.S. Federal law restricts this device to sales by or on the order of a physician.**

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**VELCRO is a registered trademark of the Velcro companies.**


DAV/STAT/0915/0004(5)

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