SureTrans™
Autotransfusion System for Orthopaedics

Instructions for Use

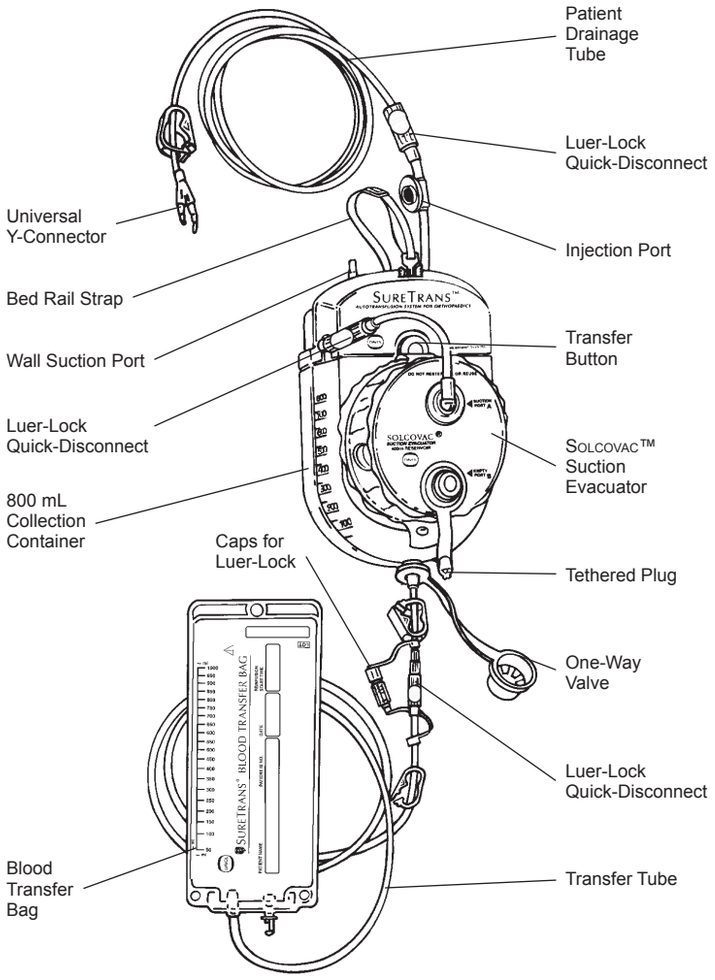

Figure 1, The SureTrans™ Autotransfusion System for Orthopaedics.

Single Use Only Rx Only PHT DEHP Contains phthalates

Non-pyrogenic Do not use if package is damaged

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, reprocessing, 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, the 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 Solcovac™ 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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7. For effective drainage, promptly recharge the SOLCOVAC™ suction evacuator when it is expanded.
8. Although the system will function without regulated suction, suction regulators (set at -80 to -100 mmHg) are always recommended.
9. The responsibility for the use of this device in all cases belongs solely to the physician ordering its use.
10. Actual performance results may very depending on the many in-use variables.

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.

TECHNICAL INFORMATION (Required per ANSI/AAMI AT6:2013. Data on file.)

- The amount of free hemoglobin present after collection (0.690 mg/mL), above the negative control (0.624 mg/mL), equals 0.066 mg/mL (0.690-0.624 = 0.066 mg/mL or 6.6 mg/dL).
- When used as described, the change in free hemoglobin (given as the average hemolytic index percentage) following system use is less than 1%.
- Average red blood cell loss is no greater than 5%.
- The SURETRANS™ reinfusion rate is dependent upon multiple factors including the infusion drip rate.
- The SURETRANS™ System aspiration rates are as follows:

Aspiration Rate (cc/min)*		
	Minimum	Maximum
1/8 inch Drain	25	82
3/16 inch Drain	107	258
1/4 inch Drain	172	374

* Flow rates were calculated with a 4 centipoise sucrose solution (blood viscosity equivalent) and are dependent on the suction source utilized.

THE SYSTEM (Figure 1)

NOTE: The SURETRANS™ System has no replaceable parts.

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.

The illustration (Figure 1) of the SURETRANS™ system identifies the above components.

Other required items not included with the system are:

- An anticoagulant solution (if desired)
- A standard blood administration set
- A 20-40 micron microaggregate blood transfusion filter
- A trocar and drain (if not supplied)

INSTRUCTIONS FOR USE

SETUP

1. Open the pouch containing the SURETRANS™ system and remove the double blue wrapped unit. Using aseptic technique, open the outer blue wrap then transfer the single blue wrapped unit to the sterile field. Remove the remaining single blue wrap.
2. If included, open the pouch containing the PVC drain and trocars. Place drains per surgeon preference.

   You may keep the protective SURETRANS™ sleeve around the unit to keep it clean during set up. The following steps may be performed through the sleeve:
3. Close the pinch clamp located below the collection container on the 6 ft. transfer tube connected to the blood transfer bag to prevent blood from leaving the collection container prior to transfer for transfusion (Figure 2).
4. Remove universal Y-connector from SURETRANS™ sleeve. To facilitate removal, SOLCOVAC™ suction evacuator may need to be compressed slightly.
5. Using aseptic technique, cut the universal Y-connector located at the end of the patient drainage tube to the appropriate wound drain size (one leg of the Y-connector is pre-cut for 1/8 inch drain).
6. Connect the wound drain to the universal Y-connector.
7. If anticoagulant is to be used, it can be injected into the system via the injection port prior to blood collection. 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. See Warning #6).
8. On the patient drainage tube, close the clamp between the injection port and the patient. Aspirate the desired volume of ACD-A anticoagulant into a syringe. Holding the injection port located on the SURETRANS™ patient drainage tube vertical above the collection container, inject the ACD-A anticoagulant into the port. Open patient drainage tube clamp to begin collection.

   Periodically agitate the unit during collection to help ensure the proper mixture of anticoagulant and blood.
9. If gravity collection is desired, do not compress the SOLCOVAC™ suction evacuator attached to the unit.
10. 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 SURETRANS™ system.

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

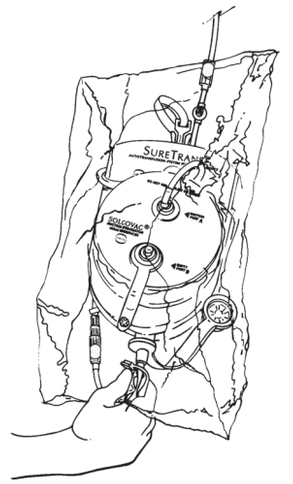

Figure 2, Closing the pinch clamp.

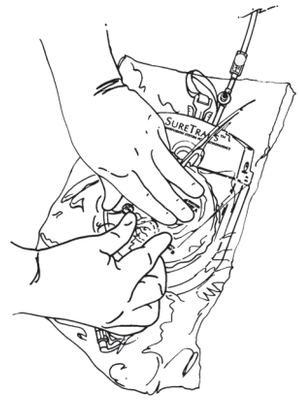

Figure 3, Attaching the tethered one-way valve.

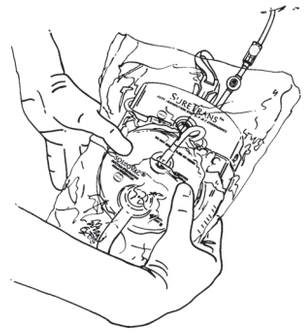

Figure 4, Compressing the SOLCOVAC™ suction evacuator.

TRANSPORTATION

1. If 500 mL of fluid or less is in collection container, unit may be placed on its back.

   Warning: When collection unit contains more than 500 mL of fluid, SURETRANS™ unit must be kept upright.
2. If more than 500 mL of fluid is in collection container, hang the unit via the bed rail strap from the end of the transport vehicle or keep it upright on the bed. Squeeze clip on bed rail strap to remove.

COLLECTION OF BLOOD (Figure 5)

1. Hang the SURETRANS™ system below the wound level in an upright position on the bed rail using the bed rail strap.

   Caution: For proper identification, record the patient name, patient number and time collection was begun in the spaces provided on the collection container.
2. If gravity collection is desired, do not compress the SOLCOVAC™ suction evacuator attached to the collection container. Gravity drainage will begin after the system is placed below the level of the patient.

   If suction drainage is desired, attach the tethered one-way valve by pushing it onto the open port (B) on the SOLCOVAC™ suction evacuator (Figure 3). Compress the SOLCOVAC™ suction evacuator attached to the collection container to create negative pressure in the container. Be sure not to obstruct the one-way valve when compressing the reservoir. Alternatively, wall suction may be used. It is automatically regulated to prevent suction from exceeding -90 mmHg.

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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 SOLCOVAC™ 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 SOLCOVAC™ suction evacuator to continue collection if suction is desired.

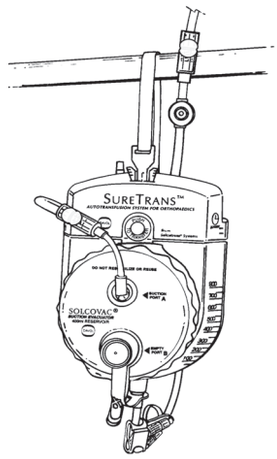

Figure 5, Hanging the system for collection.

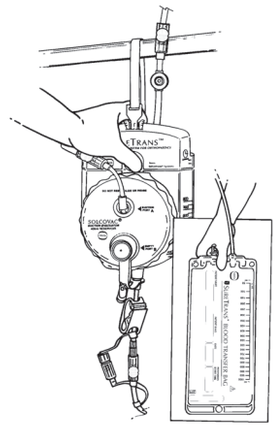

Figure 6, Venting the system to allow transfer of blood.

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".

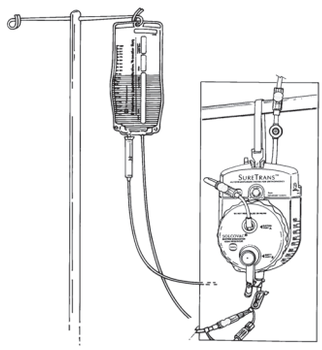

Figure 7, Reinfusion of Blood.

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 SOLCOVAC™ suction evacuator to initiate closed wound suction.

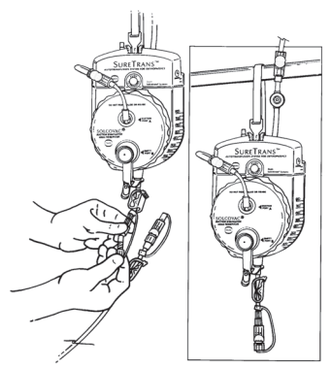

Figure 8, Using the collection container for closed wound suction.

Using the SOLCOVAC™ 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 SOLCOVAC™ 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 SOLCOVAC™ suction evacuator from the front of the collection container by detaching at hook and loop fasteners.
4. Disconnect the SOLCOVAC™ suction evacuator from the suction assembly at the luer-lock connector (breaking the round white sticker). Disconnect the collection container from the patient drainage tube at the luer-lock connector (breaking the round white sticker) and attach the SOLCOVAC™ 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 SOLCOVAC™ suction evacuator with tethered plug to initiate suction. Confirm that drainage flows from the patient drainage tube into the SOLCOVAC™ suction evacuator.

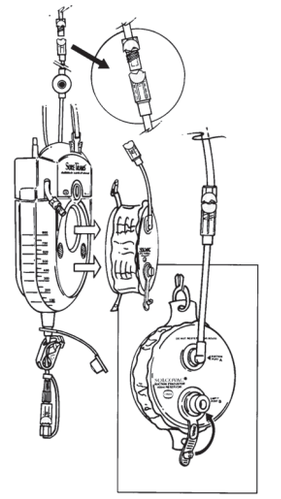

Figure 9, Separating the SOLCOVAC™ suction evacuator for closed wound suction.

Warning: The one-way valve must be replaced by the tethered evacuator plug on port (B) of the SOLCOVAC™ 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 SOLCOVAC™ 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 SOLCOVAC™ 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 SOLCOVAC™suction evacuator until the fluid is removed. Discard in accordance with hospital policy for contaminated waste.
3. For continued drainage, compress the SOLCOVAC™ suction evacuator fully and close the port (B) with tethered plug. Release the clamp on the patient drainage tube.

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	SureTrans™ PVC Round Drain, 1/8” (3.2 mm, 10 Fr.) O.D., 12.5” (31.7 cm) Hole Pattern, (2) Attached Trocars, X-Ray Opaque Stripe, 5 cm and 10 cm Depth Markings
	SureTrans™ PVC Round Drain, 3/16” (4.7 mm, 14 Fr.) O.D., 12.5” (31.7 cm) Hole Pattern, (2) Attached Trocars, X-Ray Opaque Stripe, 5 cm and 10 cm Depth Markings
	SureTrans™ PVC Round Drain, 1/4” (6.3 mm, 19 Fr.) O.D., 12.5” (31.7 cm) Hole Pattern, (2) Attached Trocars, X-Ray Opaque Stripe, 5 cm and 10 cm Depth Markings
	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
Rx Only	U.S. Federal law restricts this device to sales by or on the order of a physician.

DAV/STAT/0915/0004(5)

Manufacturer:
Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Crossings Boulevard
Warwick, RI 02886 USA
1-401-825-8300
1-800-556-6275
Assembled in Mexico

BARD
DAVOL INC.

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