i-SEP

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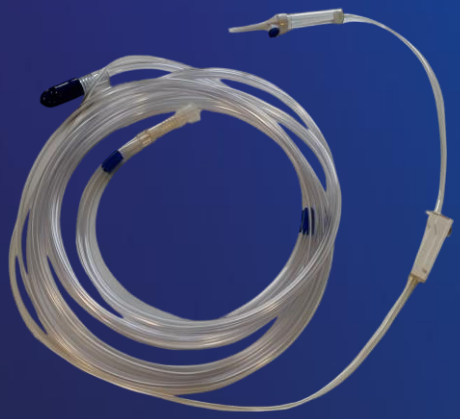
& efficiency for the patient

INSTRUCTIONS FOR USE

D-PRO-023

i-SEP Aspiration and Anticoagulation Line For use with the same™ Autotransfusion System by i-SEP

Reference: XJ-13-05



INSTRUCTIONS FOR USE

D-PRO-023

i-SEP Blood Collection Reservoir For use with the same™ Autotransfusion System by i-SEP

Reference: XJ-28-18

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TABLES

FIGURES

Instructions For Use

i-SEP Aspiration and Anticoagulation Line and i-SEP Blood Collection Reservoir

(EN – English)

REFERENCE FOR I-SEP ASPIRATION AND ANTICOAGULATION LINE: XJ-13-05

REFERENCE FOR I-SEP BLOOD COLLECTION RESERVOIR: XJ-28-18

For use with the same™ Autotransfusion System by i-SEP

1. IMPORTANT INFORMATION

1.1. INFORMATION FOR THE CUSTOMER

1.2. SAFETY INFORMATION

This Instructions For Use leaflet is intended to be used as a guide for the correct use of the medical devices presented. The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir are two separate medical devices, used in combination with the i-SEP Autotransfusion System (ATS). The instructions must be read carefully before using the devices for the first time. These Instructions For Use are part of the supporting documents and are therefore an integral part of the devices. They provide the user with all the information necessary to safely perform the procedures associated with the medical devices, and therefore to safely perform the procedures associated with the ATS as well.

i-SEP guarantees its products when they are used correctly by a properly informed user. Failure to follow the procedures described could result in impaired device function, as well as injury to the user and/or patient. When properly stored, transported, used, and disposed of, the i-SEP Aspiration and Anticoagulation Lines and i-SEP Blood Collection Reservoirs can safely and adequately perform their functions of blood aspiration and anticoagulation, in the case of the i-SEP Aspiration and Anticoagulation Line, and blood collection and filtration, in the case of the i-SEP Blood Collection Reservoir.

i-SEP accepts no responsibility for problems resulting from failure to follow the instructions and requirements described by the company. Any modifications deemed necessary by the customer must be evaluated by i-SEP's technical department.

The safe use of i-SEP equipment requires the user to correctly handle and dispose of blood-contaminated equipment. The user of any i-SEP device must fully understand and implement the local policies and procedures for blood-contaminated equipment and blood products in each facility where i-SEP products are used.

It is the sole responsibility of the customer to evaluate and ensure the safety of all products obtained from i-SEP's prescription procedures prior to any further application or use. i-SEP accepts no responsibility for the choices made by the user regarding the use of these products and by-products.

Please contact i-SEP for more information and/or complaints. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Table 1 describes and explains the symbols found on all labels associated with the i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir.

SYMBOL	TITLE	SYMBOL	TITLE
Manufacturing			
	Manufacturer		Batch number
	Production date		Catalogue number, reference
	Expiry date		Contains Phtalates (DEHP : Di(2-EthylHexyl))
ea	Quantity	Bar code or 2D-Matrix with (01) … (17) … (10) …	Unique Device Identification: (01) Medical Device Identifier (17) Expiry date (YYMMDD) (10) Batch number
Sterility			
	Sterilized with ethylene oxide		Do not use if the packaging has been damaged or opened
	Do NOT resterilise		Non pyrogenic
Transport, Storage			
	Can be broken or damaged if not handled with care		Protect from moisture
	Keep away from all sources of light		
Safe use			
	Single-use		Refer to the Instructions For Use for all important safety-related information such as warnings and precautions, which for various reasons cannot be included on the medical device itself
	Refer to the Instructions For Use		Medical Device
Disposable of cardboard packaging			
	General recovery / recycling symbol (only applicable for cardboard packaging, not applicable for the device itself)		

Table 1: Device labelling symbols

The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir are accessories used in combination with the i-SEP Autotransfusion System; they are single-use medical devices that are supplied sterile and packaged individually. Sterilisation by ethylene oxide.

2. INTENDED USES / INDICATIONS FOR USE

2.1. i-SEP Aspiration and Anticoagulation Line

The i-SEP Aspiration and Anticoagulation Line is a sterile, single-use, intraoperative accessory for the sterile intraoperative collection of salvaged blood.
This device is intended for use by qualified personnel, namely anesthesiologists/anesthetists or nurses.

2.2. i-SEP Blood Collection Reservoir

The i-SEP Blood Collection Reservoir is a sterile, single-use, intraoperative accessory for the sterile intraoperative collection and filtration of autologous blood.
This device is intended for use by qualified personnel, namely anesthesiologists/anesthetists or nurses.

3. CONTRAINDICATIONS

The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir are contraindicated for patients who are not eligible for autotransfusion, as determined by the physicians responsible for this decision.
The risk/benefit ratio of intraoperative blood salvage must be determined on an individual basis by the anaesthetists, surgeons, and transfusion medicine specialists involved in the patient's care.
Refer to the contraindications specified in the Instructions For Use of the devices associated with the use of the i-SEP Autotransfusion System (see i-SEP document D-PRO-021).

4. ADVERSE EFFECTS

Complications, i.e. morbidity and mortality in autotransfusion, as in allogeneic transfusions, are associated with the reinfusion of large volumes of blood, i.e. significant administration of anticoagulants and haemolysis. These complications include excessive free haemoglobin, haemoglobinuria, haematuria, gas embolism, sepsis, and pulmonary complications.

5. WARNINGS AND PRECAUTIONS

5.1. GENERAL WARNINGS AND PRECAUTIONS

- The user must read these Instructions For Use for the i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir and use the devices according to these instructions.
- These devices are intended to be used by a qualified and informed professional. A qualified and informed professional is someone who is able to use the devices according to the directions and methods of use given in this document.
- The user must carefully follow the labelling information on the packaging and products.
- i-SEP cannot be held responsible for problems arising from inexperienced or inappropriate use.
- For a complete description of the circuits, refer to the i-SEP Autotransfusion System user manual (i-SEP document: D-PRO-021). Refer to the ATS user manual for detailed instructions on using the i-SEP Autotransfusion System.
- Only the single-use i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir sterilised by i-SEP are approved for use with the i-SEP Autotransfusion System. The use of single-use and disposable devices from other manufacturers instead of devices recommended by i-SEP may put the patient at risk.
- The physician must consider the information provided by the i-SEP ATS device as indicative. This information must not be used as the sole basis for medical treatment.
- Due to the presence of phthalates (DEHP), use of this device on children and pregnant or breastfeeding women is restricted. In addition, due to the presence of heparin in the blood product for autotransfusion treatment, use of this device on children under three years old is restricted, though children are not part of the target population.
- The safe operation of all intraoperative blood salvage equipment requires the presence of a dedicated user. Never leave the machine unattended during operation as irreparable damage to the blood may occur. It is the responsibility of the hospital to ensure that the persons assigned to this task have received appropriate training in the operation of the i-SEP Autotransfusion System and its accessories and are alerted to potential problems.
- The collection of salvaged blood must not be carried out if the blood is contaminated by locally applied drugs or solutions (such as Betadine®, benzalkonium chloride, hydrogen peroxide, distilled water, water, alcohol, topical antibiotics) or by haemostatic agents (such as Avitene, Gelfoam, other collagen derivatives, other haemostatic products such as Horsley's wax), or when using biological (such as thrombin or fibrin-based) or chemical adhesives, thrombin for intravenous administration, or resin or cement (such as methyl methacrylate).
- A second aspiration line without blood collection must be used to remove any items incompatible with IOS (Intraoperative Blood Salvage) (listed above), debris that could clog the i-SEP ATS, washing fluids, or fumes.

5.2. INFECTION, RISK OF DISEASE TRANSMISSION

- Processed blood may be contaminated with transmissible infectious agents and must always be considered potentially contaminated. Treat all blood and liquids using universal precautions against blood-borne pathogens.
- The i-SEP Aspiration and Anticoagulation Line, the i-SEP Blood Collection Reservoir, and the Autotransfusion Treatment Set containing the *final* blood cell concentrate must be used within 6 hours of the start of blood collection. The blood, which was salvaged intraoperatively then processed, expires 4 hours after the end of the treatment when stored at room temperature (as recommended by the AABB, the American Association of Blood Banks). Bacterial contamination by germs in the air is always possible.
- After use, dispose of the device's accessories in accordance with the applicable regulations of the country where the device is used.
- The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir are consumables designed for single use. **Do not reuse, reprocess, or resterilise these products**. Reuse, reprocessing, or resterilisation may compromise the structural integrity of the devices and/or create a risk of contamination of the devices, which could result in injury, illness, or patient's death.
- If a single-use device contaminated with blood is to be returned to the company for examination, it is recommended that the medical device vigilance contact person be consulted and, *at a minimum,* that the device be carefully wrapped in a sealed plastic bag and protected with absorbent material.
- It is the responsibility of the healthcare facility to prepare and properly identify the product for return. Do not return products that have been exposed to blood-borne infectious diseases.
- Autotransfusion is contraindicated in cases of suspected sepsis and in cases of contamination with meconium, urine, prostatic fluid, faeces, and the contents of gastric, hepatic, biliary, or amniotic or intestinal fluids.
- The system must be carefully observed for leaks before and during use. Leakage can lead to a loss of sterility or blood loss. If a leak is observed before or during use, replace or tighten the connection at the leak if possible. If this is not possible, change the consumable.
- Install the consumable aseptically.
- Wear PPE for the handling of the treatment set and accessories.

5.3. COAGULATION DISORDERS

- Collagen-based haemostatic agents must not be used in combination with an autotransfusion system in general. If they are present, temporarily stop intraoperative blood salvage during the use of the agent. After allowing time for the agent to initiate haemostasis in the wound, irrigate the area thoroughly with saline solution and aspirate into non-autotransfusion collection containers before continuing to collect autologous blood for autotransfusion. If the area is not rinsed thoroughly, the haemostatic agent may be drawn into the salvaged blood. This could lead to clotting of the salvaged blood and possible complications of disseminated intravascular coagulopathy in the patient.
- The patient's blood must be anticoagulated, either systemically or regionally, before it is introduced into the i-SEP ATS. Non-anticoagulated or insufficiently anticoagulated blood can cause clots to form in the collection system and in the i-SEP Autotransfusion Treatment Set. Clots in the collected blood can block the system. Such coagulation makes the final blood

product unsuitable for reinfusion. Check the Blood Collection Reservoir (outside the filter) for clots and add a dose of anticoagulant, if necessary.
The recommended anticoagulant solution is 25,000 to 30,000 units of unfractionated heparin in 1 litre of sterile isotonic saline. The drip rate must be adjusted during the procedure at a rate of 2 drops per second depending on the blood flow being processed.

- Heparin is a prescription drug. The responsibility for the use of this medication when using the i-SEP Autotransfusion System lies solely with the responsible physician.
- Citrate (ACD-A or CPD 3% to 4% sodium citrate) can also be used as an anticoagulant solution, particularly in cases of known or suspected heparin-induced thrombocytopenia (HIT). The citrate solution to blood volume must be between 1: 5 and 1:10, or approximately 70 ml of citrate per 500 ml of salvaged blood. However, incompatible fluids for IV injection such as heparin or Ringer's solution must not be used in association with citrate, as they may cause coagulation in the system.
- The anticoagulant solution must be added to a saline solution suitable for intravenous use. Sterile water or another irrigation solution must not be used.
- It is possible that insufficient washing of the salvaged blood may result in insufficient removal of the anticoagulant and/or the development of coagulopathies on return of the blood to the patient. Therefore, in the context of intraoperative autotransfusion, careful monitoring of the patient's coagulation status is important to prevent complications.
- Washed and concentrated blood no longer contains coagulation factors. Patients must be monitored for coagulation abnormalities associated with reinfusion of large volumes of processed blood. Practitioners must be prepared to implement appropriate treatments.

5.4. CREATION OF HAEMOLYSIS ON COLLECTION AND DURING PROCESSING

- The quality of the washed blood concentrate is directly related to the quality of the blood salvaged from the patient. The quality of the patient's blood depends on the type of procedure and is mainly dependent on the aspiration technique and the vacuum used. The vacuum must be kept as low as possible and must not exceed typical values of -150 mbar (-112 mmHg). The user must be aware that a vacuum force greater than -200 mbar (-150 mmHg) can cause haemolysis.
- Avoid aspiration of highly ventilated blood that may be subject to high level of haemolysis. Use an aspiration cannula of appropriate diameter to limit haemolysis during aspiration.
- The use of vacuum source connection and control systems from other manufacturers may increase haemolysis.
- Carefully inspect the tubing to ensure that the i-SEP Aspiration and Anticoagulation Line tubes are not kinked or bent. Drawing blood into the line in the presence of severe flow restriction is likely to result in high levels of haemolysis with high levels of free plasma haemoglobin.
- If, during a procedure, it is discovered that any equipment in the vicinity of the blood has overheated, the processed blood cell concentrates must be considered unsuitable for reinfusion.
- Do not use a warm solution as high heat can destroy the blood cells.
- To avoid overheating the system, which could result in haemolysis, use the i-SEP Autotransfusion System at the recommended temperatures (see D-PRO-021).
- Avoid any situation that may cause the blood temperature to rise above 37°C.

5.5. REINFUSION: GAS EMBOLISM, POOR BLOOD QUALITY

- The risks associated with blood reinfusion, such as gas embolism or reinfusion of poor quality blood, are not directly associated with the i-SEP Aspiration and Anticoagulation Line or the i-SEP Blood Collection Reservoir. However, these risks may be associated with the use of the Line or Collection Reservoir in combination with the i-SEP Autotransfusion System and other accessories. The operator must refer to the Instructions For Use for the i-SEP ATS (i-SEP document: D-PRO-021) for descriptions of the risks associated with reinfusion of a blood concentrate originally collected by the i-SEP Blood Collection System.

5.6. ENVIRONMENTAL FACTORS

- The i-SEP Aspiration and Anticoagulation Line, the i-SEP Blood Collection Reservoir, and the i-SEP Autotransfusion System are intended to be used for autotransfusion in facilities providing patient care, such as operating rooms. This system is NOT intended for use in blood banks or apheresis centres or for use by the blood bank to handle, label, store, hold, or process blood for subsequent reinfusion into the same patient.
- The plastic materials used in the manufacture of the i-SEP Aspiration and Anticoagulation Line and i-SEP Blood Collection Reservoir may be sensitive to chemicals (solvents and some detergents) and to all halogenated hydrocarbon anaesthetic agents (Isoflurane (Forane), Enflurane (Efrane or Ethrane), Halothane (Fluothane or Rhodialothan)). Direct contact must be avoided as these agents attack plastics and can cause them to fail or malfunction. Many plastics are damaged by various solvents, cleaning solutions, or other chemicals. Damaged i-SEP Aspiration and Anticoagulation Lines and i-SEP Blood Collection Reservoirs must not be used with the i-SEP Autotransfusion System.

5.7. RISKS OF SYSTEM FAILURE

Blood spillage or leakage or treatment failure

- Do not use if a device or consumables are cracked, have been dropped (i-SEP Blood Collection Reservoir), or are physically damaged.
- Carefully observe devices for leaks before and during use. Leakage can lead to a loss of sterility or a loss of blood and/or liquid. If leakage is observed before or during use, replace the leaking component or tighten the leaking connection, as the case may be.
- The user must avoid blocking any tubes carrying fluid to or from the pump. Restricted flow would result in increased vacuum in the i-SEP Blood Collection Reservoir, which could lead to reduced blood quality or disruption to and failure of the treatment process.
- A vacuum valve is provided to prevent the Blood Collection Reservoir from collapsing if it is exposed to a deep and sudden vacuum:
    - The negative pressure inside the Blood Collection Reservoir should not exceed -200 mbar (-150 mmHg).
    - The release pressure for the safety valve is 300 ± 13 mbar (-225 ± 10 mmHg) and the positive release pressure is 7 ± 3 mbar (5 ± 2 mmHg).
    - Check the watertight plugs of the unused ports by pushing them in completely.

- Do not block the open control valve on the Blood Collection Reservoir with foreign objects so as to avoid the risk of it collapsing.

- Given the possibility of exposure to blood (potentially contaminated with pathogens) for the user, handling precautions must be observed at all times to avoid such exposure and transmission of these pathogens.
- An adequate amount of processed and concentrated blood cannot always be provided and depends on the blood salvage procedure. Practitioners must be prepared to implement appropriate additional therapies, if necessary.

Equipment sensitivity

- Before use, check that the i-SEP Blood Collection Reservoir is fully inserted into its holder on the Autotransfusion System; the graduations on the Collection Reservoir must be legible in the window of the holder. If it is not installed correctly, even the slightest accidental knock to the Collection Reservoir can cause it to detach from the holder and the holder to be damaged.
- Handle the i-SEP Blood Collection Reservoir holder with care when handling the device, as the weight sensors are sensitive components. The accuracy of measuring the volume of blood in the Collection Reservoir is dependent on its correct positioning in the holder.
- All manual clamps must be open and the tubes must not be kinked, bent, or flattened, in order to avoid haemolysis and monitoring functions.

6. TECHNICAL DESCRIPTIONS

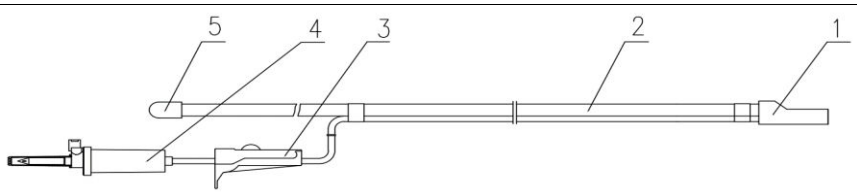
6.1. i-SEP ASPIRATION AND ANTICOAGULATION LINE

The i-SEP Aspiration and Anticoagulation Line consists of a double tube for the transfer and anticoagulation of blood salvaged intraoperatively. The large-diameter tubular component is the blood aspiration line; the small-diameter tubular component attached to the large-diameter tube is the anticoagulation line. The two tubes meet at a Y-type connector (with a removable transparent cap) which allows a surgical aspiration cannula (Yankauer type) to be connected, in order to make the anticoagulant immediately available to the aspirated blood. The aspiration line is designed to connect to the i-SEP Blood Collection Reservoir via a 1/4" female connector port, both closed with a blue protective cap. The anticoagulation line ends with a closure-piercing device (spike) for a saline injection container, protected by a transparent cap and fitted with a drip chamber. There is a roller flow regulator under the drip chamber to regulate the flow of anticoagulant.

Figure 1 shows the schematic drawing of the i-SEP Aspiration and Anticoagulation Line.

Figure 1: Drawing of the i-SEP Aspiration and Anticoagulation Line

1. Y-type connector with transparent protective cap
2. Dual-lumen tubular component
3. Roller flow regulator
4. Closure-piercing device with drip chamber
5. Blue protective cap



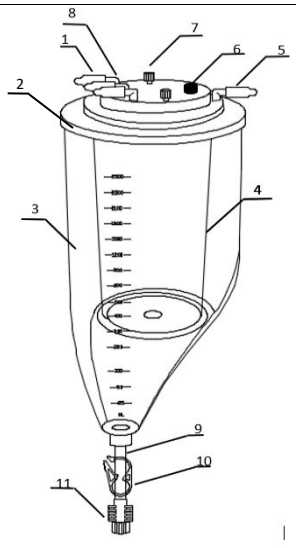
6.2. i-SEP BLOOD COLLECTION RESERVOIR

The i-SEP Blood Collection Reservoir is a container with an internal filtration system designed to filter and remove aggregates from salvaged blood.
During surgery, the device operates by the action of an external vacuum source to draw and filter blood intraoperatively, prior to subsequent processing by an i-SEP Autotransfusion System device. Entrained air is removed from the blood by the defoamer.
Figure 2 shows the schematic drawing of the i-SEP Blood Collection Reservoir.

The Blood Collection Reservoir is a closed cylindrical container with a bottom that allows for proper emptying. Graduations marking 100 mL volume intervals are printed on the outside of the Collection Reservoir in order to approximate the volume contained in it. The maximum capacity of the Collection Reservoir is approximately 2.5 litres.

Figure 2: Drawing of the i-SEP Blood Collection Reservoir

1. Removable blue protective caps (three in number)
2. i-SEP Blood Collection Reservoir cover
3. i-SEP Blood Collection Reservoir (shell)
4. Filter media, with defoamer
5. Connector for establishing vacuum (fitted with a yellow protective cap)
6. Safety valve
7. Luer connectors (two in number, each with a white protective cap)
8. i-SEP Blood Collection Reservoir input connectors (three in number) to connect the i-SEP Aspiration and Anticoagulation line.
9. i-SEP Blood Collection Reservoir outlet tubing
10. Manual tubing clamp
11. Luer connector, for connecting the i-SEP Autotransfusion Set (with transparent protective cap).



The top of the Collection Reservoir is sealed with a welded non-removable lid. The cover has a set of six (6) connectors/ports with removable coloured plugs:

- Three (3) input connectors with blue plugs:
  - Two 1/4" connectors can be used to connect an i-SEP Aspiration and Anticoagulation Line.
  - One 3/8" connector (middle one).
- One (1) connector with a yellow protective cap for connecting an i-SEP vacuum line for creating a vacuum.
- Two (2) Luer administration ports with white caps can be used to administer solution (stop the vacuum pump before use) thanks to a syringe (compliant to ISO80369-7). For this administration, the syringe is not intended to be connected to the reservoir during the complete surgery. The transferred solution is injected inside the head space (air) of the reservoir and not inside a liquid or under pressure. After administration, remove the syringe, close the connector with the cap and restore the vacuum.

The system is illustrated in Figure 3.

At the bottom of the i-SEP Blood Collection Reservoir, a Luer connector with a transparent cap allows the i-SEP Autotransfusion Treatment Set to be connected by screwing on 2 Luer connectors. A manual clamp is placed on the outlet tubing of the i-SEP Blood Collection Reservoir to hold the tubing in an open or closed position during procedures.
The system is illustrated in Figure 4.

Figure 3: Illustration of the i-SEP Blood Collection Reservoir cover and its connectors/input ports		*Figure 4: Illustration of the i-SEP Blood Collection Reservoir outlet tubing*	
YELLOW = vacuum BLUE small diameter = i-SEP Aspiration and Anticoagulation Line WHITE = Luer connector.		Outlet tubing at the bottom of the i-SEP Blood Collection Reservoir.	

The interior of the Collection Reservoir is composed of a filter media consisting of a foam wrapped in a filter fabric network, with an anti-foaming agent.

7. PERFORMANCE

7.1. i-SEP Aspiration and Anticoagulation Line

According to the applicable standards, the i-SEP Aspiration and Anticoagulation Line is sterile, single use, has a shelf life of 2 years, is non-pyrogenic, biocompatible, and complies with regulatory requirements in terms of particle release.

7.2. i-SEP Blood Collection Reservoir

According to the applicable standards, the i-SEP Blood Collection Reservoir is sterile single-use, has a 2-year shelf-life, is non-pyrogenic, and biocompatible.

- The release pressure for the safety valve is -225 ± 10 mmHg (-300 ± 13 mbar) and the positive release pressure is 5 ± 2 mmHg (7 ± 3 mbar).

8. INSTALLATION AND USE

The devices must be handled and used by qualified personnel, namely anesthesiologists/anesthetists or nurses after familiarising themselves with the Instructions For Use of the i-SEP Autotransfusion System and its associated devices.

8.1. Installation

8.1.1. Installing the i-SEP Blood Collection Reservoir

- Open the transparent outer packaging containing the i-SEP Blood Collection Reservoir using the easy-open systems on top of the seal (see Figure 5).
- Peel-off traceability labels are available on the overwrap label to complete the patient file.

Figure 5: Easy-open system for the i-SEP Blood Collection Reservoir and the i-SEP Aspiration and Anticoagulation Line

- Insert the i-SEP Blood Collection Reservoir into the Collection Reservoir holder on the i-SEP Autotransfusion System.
- Close the manual clamp on the Collection Reservoir outlet tubing.

8.1.2. Installing the i-SEP Aspiration and Anticoagulation Line

Read the installation instructions for the i-SEP Aspiration and Anticoagulation Line (i-SEP document: D-PRO-021). The main steps are described below.

- Extend the pole at the rear of the i-SEP ATS as far as the stop.
- Prepare a bag or bottle of anticoagulant solution containing heparin. Mix 25,000 IU of heparin per litre of sterile isotonic saline (injectable) to ensure sufficient anticoagulation of the blood to be aspirated.
- Hang the container of anticoagulant solution.
- Open the outer packaging of the i-SEP Aspiration and Anticoagulation Line using the easy-open systems above the seal (see Figure 5).
- Peel-off traceability labels are available on the overwrap label to complete the patient file.
- Open the first paper package using aseptic techniques, making sure never to touch the 2nd package. To do this, first pull on the label that says “TIRER DESSUS POUR OUVRIR / PULL TO OPEN ”, then unfold each piece using the ends (see Figure 6).

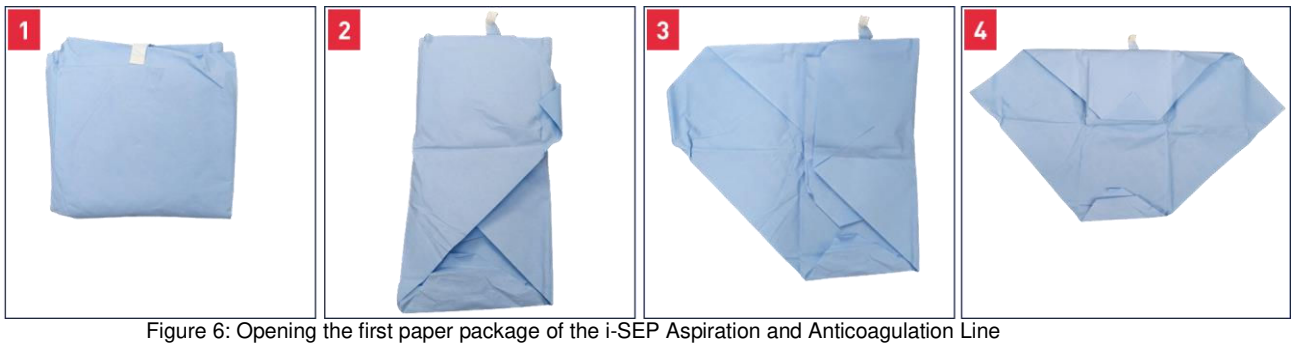


Figure 6: Opening the first paper package of the i-SEP Aspiration and Anticoagulation Line

- Use the tab on the 2nd piece (indicated by a red arrow in Figure 7) to access the 2nd package.

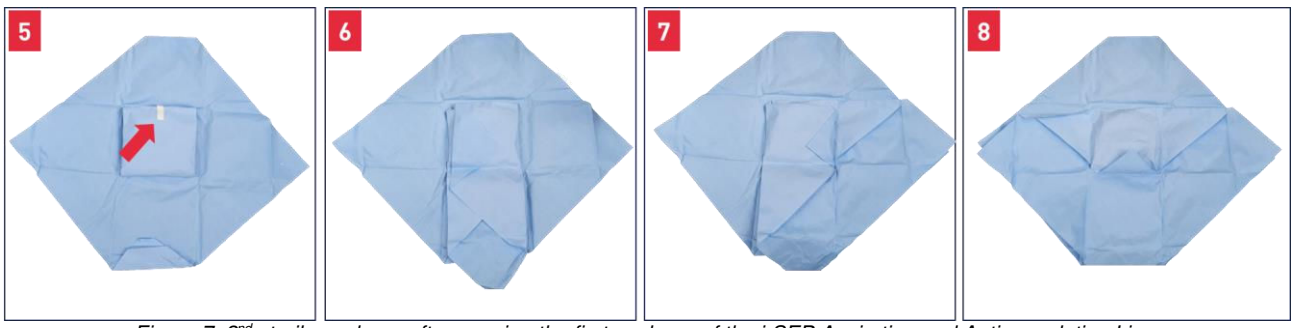


Figure 7: 2nd sterile package after opening the first package of the i-SEP Aspiration and Anticoagulation Line

- Give the line, still in its sterilised paper (see Figure 8), to the sterile operating room nurse.

Figure 8: i-SEP Aspiration and Anticoagulation Line in its sterile field

- Remove the transparent protective cap attached to the Y-type connector.
- Attach the Y-type connector to a surgical aspiration cannula.
- Transfer the other end (the split end with double tubing) of the Aspiration and Anticoagulation Line from the sterile field to the i-SEP Autotransfusion System user (non-sterile).
- Close the roller flow regulator below the dropper on the small-diameter tube for the anticoagulant supply.

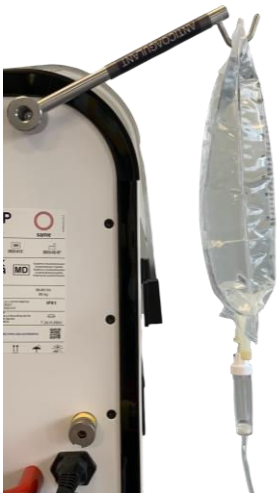


Figure 9: Anticoagulant bag hanging from the pole

8.1.3. Connecting the i-SEP Aspiration and Anticoagulation Line and Blood Collection Reservoir

- Remove the blue protective cap on the large-diameter tube connector from the aspiration line.
- Remove a blue plug attached to one of the two 1/4” inlet connectors (figure 2, #8) on the cover (figure 2, #2) of the i-SEP Blood Collection Reservoir.
- Connect the aspiration line to the uncapped 1/4” inlet connector (figure 2, #8) on the cover of the i-SEP Blood Collection Reservoir.

8.1.4. Connecting the i-SEP Aspiration and Anticoagulation Line to the anticoagulation solution

- Remove the protective cap from the spike positioned at the end of the anticoagulation line.
- Using aseptic technique, puncture non resealable closure port septum (twist-off) of the previously prepared anticoagulant solution container.

8.1.5. Installing the i-SEP vacuum line

- Refer to the i-SEP Autotransfusion System Instructions For Use leaflet (i-SEP document: D-PRO-021).
- Attach one end of the vacuum line to the antibacterial filter previously installed on the vacuum regulator supplied with the i-SEP Autotransfusion Device.

- Remove the yellow cap from the vacuum inlet connector on the lid of the i-SEP Blood Collection Reservoir and attach the other end of the vacuum line.

8.2. PROCEDURE FOR USE

The devices must be handled and used by qualified personnel who are familiar with the Instructions For Use of the i-SEP Autotransfusion System and its accessories.

Blood salvage and anticoagulation:

- Plug the i-SEP Autotransfusion System into an electrical socket.
- Switch on the i-SEP Autotransfusion System by pressing the ON/OFF button on the screen.
- Switch on the vacuum pump (pump ON/OFF button).
- Adjust the vacuum to a level of -150 mbar (-112 mmHg) or lower using the external vacuum regulator and clamping the vacuum line if necessary. If the Aspiration and Anticoagulation Line is not immediately connected to the Collection Reservoir, switch off the vacuum pump.
- Check that the protective cap on the end of the i-SEP Aspiration and Anticoagulation Line in the sterile field has been removed and that a surgical aspiration cannula has been properly connected.
- Check that the i-SEP Aspiration and Anticoagulation Line allows air to pass through (unblocked, unrestricted opening).
- With the vacuum system running, open the anticoagulant solution flow regulator on the small-diameter tube and allow 200 mL of anticoagulant solution to be drawn into the i-SEP Blood Collection Reservoir before beginning blood collection (priming). This volume should ensure adequate moistening of surfaces in contact with the blood. Turn off the flow regulator when waiting for bleeding.

NOTE: The i-SEP Blood Collection Reservoir has a graduated scale to allow the user to monitor the level of liquid inside it. The indication provided by the scale is only a rough estimate of the level of liquid contained in the device. In addition, the i-SEP Autotransfusion System incorporates a measurement and display system showing the volume of solution in the i-SEP Blood Collection Reservoir on the touchscreen. There may be a difference between the volume read on the scales and the volume displayed. The operator should rely on the volume displayed on the i-SEP ATS screen for an accurate reading.

- After transferring the anticoagulant solution into the i-SEP Blood Collection Reservoir (priming), adjust the flow rate of the anticoagulant solution to approximately 120 drops per minute. In the event of heavy bleeding, increase the flow rate according to the flow of salvaged blood collected.

NOTE: The flow rate of the anticoagulant into the i-SEP Blood Collection Reservoir is manually controlled by the drop flow regulator on the anticoagulation line. This flow rate must be matched to the rate of blood collected from the surgical field. If the collection rate varies without adjusting the anticoagulant rate, the anticoagulant to blood ratio may be too low or too high. The blood in the i-SEP Blood Collection Reservoir may clot if the amount of anticoagulant is insufficient.
In the event of excess heparin in the i-SEP Blood Collection Reservoir due to inappropriate proportions, the processed blood may contain residual heparin.
In the event of a decrease in antithrombin III levels in the patient using heparin anticoagulation, consult the physician to provide alternative anticoagulation.

- Continue the procedure for using the i-SEP Autotransfusion System according to the Instructions For Use of the i-SEP Autotransfusion System and its accessories.
- The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir, once in contact with blood, can be used for up to 6 hours.

8.3. UNINSTALLING AND DISPOSAL

- Once the i-SEP Autotransfusion System has been used to the satisfaction of the user responsible for its use, or once the 6 hours of use of the i-SEP Aspiration and Anticoagulation Line and/or the i-SEP Blood Collection Reservoir have elapsed, the devices are disposed of according to the standard procedures of the healthcare facility.
- All i-SEP consumables – Aspiration and Anticoagulation Line, Blood Collection Reservoir, Autotransfusion Treatment Set – connected at the end of use are disposed of in the appropriate operating theatre waste bin.
- Used or damaged products must be disposed of in accordance with national and international legal requirements.

9. OTHER MEDICAL DEVICES TO BE USED WITH THE DEVICE PRESENTED

- The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir must be connected to the i-SEP Autotransfusion Treatment Set for the removal of undesirable substances on reinfusion.
- Aspiration and collection of anticoagulated blood must be performed with the i-SEP Autotransfusion System's integrated surgical vacuum system or any other system with equivalent technical characteristics (under the responsibility of the physician ordering the use of the system).

Table 2 below shows the references associated with the use of the i-SEP Autotransfusion System and the associated documentation.

Reference	Description	Reference of the associated documentation	Description
DS1000	i-SEP Autotransfusion System	D-PRO-021 D-PRO-024	i-SEP Autotransfusion System Instructions For Use Quick Start i-SEP Autotransfusion System
ST0301 ST0501	i-SEP Autotransfusion Treatment Set	D-PRO-022	i-SEP Autotransfusion Treatment Set Instructions For Use

Table 2: List of references associated with the use of the i-SEP Autotransfusion System and associated documentation, if any

For a full description of the i-SEP Autotransfusion System and its accessories, please refer to its documentation (D-PRO-021).

10. RETURNING USED PRODUCTS

If the quality of the product does not meet the user's expectations, please inform the manufacturer, i-SEP, or its distributor.
All parameters considered critical by the user must be reported with particular attention and urgency. The minimum information required is as follows:

- Detailed description of the event, and if applicable, the conditions related to the patient;
- Identification of the product involved;
- Lot number of the product involved;
- Availability of the product involved;
- All indications that the user considers useful to determine the origin of the elements of dissatisfaction.

i-SEP reserves the right to authorise the return of the product involved in the notification for examination, if necessary. If the product to be returned is contaminated, it must be treated, packaged, and handled in accordance with the regulations in force in the country where the product was used.

11. STERILISATION

The i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir have been sterilised by ethylene oxide. See warnings and precautions for risks of infection.
The level of ethylene oxide residues in the devices is within the limits established by the national regulations in force in the country where the devices are used.

12. STORAGE AND HANDLING

- Store all devices in a dry place.
- Store at room temperature (5°C to 40°C).
- Check the expiry date on the label. Do not use the device after the date indicated.
- The single-use device must be used immediately after opening the sterile packaging.
- Single-use products are sterile and non-pyrogenic as long as the integrity of the packaging has not been breached. Do not use if the packaging is damaged or open.
- Change the vacuum line and antibacterial filter on the vacuum regulator each time you use the i-SEP Autotransfusion System.
- Handle devices aseptically. It is important to use aseptic technique to minimise the possibility of contamination of the devices and/or the patient. Make the connections using appropriate aseptic technique.
- Carry out a visual inspection and check the devices carefully before use. In particular, tighten all Luer connections before use. Transport and/or storage conditions other than those prescribed may damage the devices. Do not use the device if damage to components is found during inspection or installation.
- FRAGILE! Handle with care.
- The devices must always be stored in a dry, clean, and well-ventilated area, free from exposure to chemical vapours and out of direct sunlight.
- As a matter of priority, devices must be stored in their cardboard packaging. Alternatively, they can be stored in light-tight containers.

13. PRESENTATION

13.1. i-SEP ASPIRATION AND ANTICOAGULATION LINE

The i-SEP Aspiration and Anticoagulation Line consists of a medical device as described in Figure 1 of this Instructions For Use leaflet.
An i-SEP Aspiration and Anticoagulation Line is individually packaged in an inner package (double layer of blue paper) and then in an outer flexible transparent overwrap. Both packages were sterilized simultaneously
Six (6) i-SEP Aspiration and Anticoagulation Lines are packaged in one cardboard box.
Each cardboard box is properly labelled.
A cardboard box contains one (1) document which allows the access to the electronic Instructions For Use. i-SEP can provide paper form instructions upon written request from the healthcare facility.

13.2. i-SEP BLOOD COLLECTION RESERVOIR

The i-SEP Blood Collection Reservoir consists of a medical device as described in Figure 2 of this Instructions For Use leaflet.
An i-SEP Blood Collection Reservoir is packaged in a flexible transparent package.
The overall packaging containing the i-SEP Blood Collection Reservoir has been sterilised.
Each blood Blood Collection Reservoir is packaged in a single cardboard box.
Six (6) i-SEP Blood Collection Reservoirs are packaged in a cardboard transport box.
Each cardboard box is properly labelled.
A cardboard box contains one (1) document which allows the access to the electronic Instructions For Use. i-SEP can provide paper form instructions upon written request from the healthcare facility.
List of materials of the blood pathway, data related to cell damage as well as relevant tolerances for data presented are available upon request.

14. LIMITED WARRANTY

This Limited Warranty is in addition to the purchaser's statutory rights under the applicable regulations.
i-SEP guarantees that all necessary care has been taken in the manufacture of this medical device as required by the nature and intended use of the device. i-SEP guarantees that the medical device can function as described in the Instructions For Use provided it is used in accordance with the Instructions For Use by a qualified user and before the expiry date indicated on the packaging. However, i-SEP cannot guarantee that the user will use the device correctly, nor can it guarantee that incorrect treatment or diagnosis and/or the particular physical and biological characteristics of a patient will not affect the performance and effectiveness of the device with detrimental consequences for the patient, even if the specified Instructions For Use have been followed. i-SEP, while stressing the need to strictly comply with the Instructions For Use and to adopt all necessary precautions for the proper use of the device, shall not be liable for any loss, damage, costs, incidents, or consequences arising directly or indirectly from the misuse of this device. i-SEP undertakes to replace a defective medical device at the time of its release or during its shipment by i-SEP until the time of delivery to the end user, unless such defect is due to improper handling by the purchaser. The above Warranty is in lieu of all other warranties, express or implied, written or

oral, including, but not limited to, warranties of merchantability and fitness for a particular purpose. No person, including a representative, agent, reseller, distributor, or intermediary of i-SEP or any other industry or trade organisation is authorised to make any representation or warranty with respect to this medical device, except as expressly set forth herein. i-SEP disclaims any warranty of merchantability and any warranty of fitness for a particular purpose with respect to this product other than as expressly set forth herein. The purchaser agrees to abide by the terms of this Limited Warranty and agrees in particular, in the event of any dispute or litigation with i-SEP, not to bring any claims based on alleged or proven modifications or alterations to this Limited Warranty by any representative, agent, reseller, distributor, or other intermediary. The existing relationship between the contracting parties (also in the event that this is not in writing) to which this Warranty is given, as well as all disputes connected with it or in connection with it, as well as anything connected with it or any dispute concerning this Warranty, its interpretation and its execution, without exception or reservation, shall be governed exclusively by French law and jurisdiction. The court selected is the court in Nantes (France).