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INSTRUCTIONS FOR USE

D-PRO-022

i-SEP Autotransfusion Treatment Set
References: ST0501, and ST0301

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

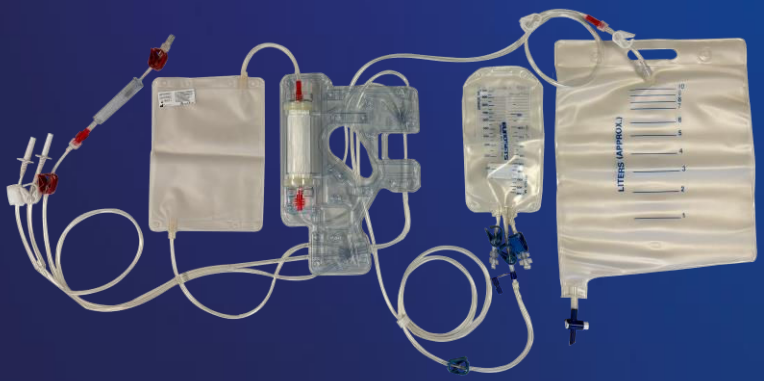

Illustration of the ST0501 reference, non-contractual image

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TABLES

FIGURES

Instructions For Use

i-SEP Autotransfusion Treatment Set
(EN – English)

REFERENCES: ST0501 AND ST0301

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

1. IMPORTANT INFORMATION

1.1. INFORMATION FOR THE CUSTOMER

The contents of this Instructions For Use leaflet are copyrighted and owned by i-SEP. Any information or description contained in this leaflet may not be reproduced and disseminated to the general public or stored in a database or used in conjunction with professional education without the written consent of i-SEP.

1.2. SAFETY INFORMATION

This Instructions For Use leaflet is intended to be used as a guide for the correct use of the medical device. The i-SEP Treatment Set is a medical device associated with the i-SEP Autotransfusion System (ATS). The instructions must be read carefully before using the device for the first time. These Instructions For Use are part of the supporting documents and are therefore an integral part of the device. They provide the user with all the information necessary to safely perform the procedures associated with the medical device, 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, i-SEP Autotransfusion Treatment Sets can safely and adequately perform their functions of blood concentration and washing.

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 the labels associated with the i-SEP Treatment Set.

SYMBOL	TITLE	SYMBOL	TITLE
Manufacturing			
	Manufacturer	 ABC123	Batch number
 YYYY-MM-DD	Production date	 ABC123	Catalogue number, reference
 YYYY-MM-DD	Expiry date		Contains Phthalates (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			
	Sterilised by irradiation		Do not use if the packaging has been damaged or opened
	Do not resterilise		Non-pyrogenic fluid path
Transport, Storage			
	Can be broken or damaged if not handled with care	max°C  min°C	Minimum and maximum temperatures to which the medical device can be safely exposed: Minimum = 15°C Maximum = 30°C
	Protect from moisture		
Safe use			
	Can only be used once		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		Patient identification
Disposal of cardboard packaging			
	General recovery/recycling symbol (only applicable to the cardboard packaging, not applicable to the device itself)		

Table 1: Labelling symbols on the device described

2. INTENDED USES / INDICATIONS FOR USE

The i-SEP Autotransfusion Treatment Set, a device associated with the i-SEP ATS, is a sterile, single-use, intraoperative medical device intended to treat salvaged blood. Concentrated and washed autologous blood product can be reinfused to the same patient.
This device is intended for use by qualified personnel, namely anesthesiologists/anesthetists or nurses.

3. CONTRAINDICATIONS

The i-SEP Treatment Set is 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.

The use of blood cell concentrate from the i-SEP ATS must be contraindicated in the event of sepsis or treatment of malignant tumours, for example.

Refer to the contraindications specified in the Instructions For Use of the devices associated with the use of the i-SEP ATS (see 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 the Instructions For Use for the i-SEP Treatment Set and use the device 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 the product.
- 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 ATS user manual (i-SEP document: D-PRO-021). Refer to the ATS user manual for detailed instructions on using the i-SEP ATS.
- Only single-use i-SEP accessories sterilised by i-SEP are approved for use with the i-SEP ATS. The use of single-use and disposable devices from other manufacturers instead of accessories 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 a 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 (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 elements incompatible with IOS (Intraoperative Blood Salvage) (listed above), debris that could clog the i-SEP ATS washing fluids, or fumes.
- Do not use the aspiration line dedicated to salvaging blood for autotransfusion to eliminate bone fragments, bone marrow, tissue fragments, etc. Use this line to salvage as much blood as possible.
- It is recommended to change the Treatment Set after 3 alarms indicating that the filtration rate has decreased. To do this, salvage the blood contained in the Set, if necessary, then change the Set by turning the machine off then on again (see D-PRO-021).

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 Treatment Set containing the final blood cell concentrate, as well as the other accessories for the i-SEP ATS in direct contact with blood, such as the i-SEP Blood Collection Reservoir and the i-SEP Aspiration and Anticoagulation Line, must be used within 6 hours of starting blood salvage. 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 in accordance with the applicable regulations of the country where the device is used.
- The Treatment Set is a consumable designed for single use. **Do not reuse, reprocess, or resterilise this product**. Reuse, reprocessing, or resterilisation may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in injury, illness, or death to the patient.
- If a single-use device contaminated with blood is to be returned to the company for examination, seek instructions from the medical device vigilance contact person, and at a minimum, carefully surround the device with absorbent material and wrap it in a sealed plastic bag.
- 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.
- Change the vacuum line and the antibacterial filter on the vacuum regulator each time the ATS is used.
- 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 intestinal fluid.
- 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 thoroughly rinsed, 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 may cause clots to form in the collection system and in the i-SEP Treatment Set. Clots in the salvaged 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 heparin in 1 litre of normal saline solution. 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 ATS 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, careful monitoring of the patient's coagulation status is crucial 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 blood from the operating fields and blood that may be subject to a high level of haemolysis (hyperventilated). Use an aspiration cannula of appropriate diameter to limit haemolysis during aspiration.
- The use of vacuum source connection and control systems by other manufacturers may increase haemolysis.
- Only use NaCl 0.9% as a washing solution. Do not use hyper- or hypotonic washing solutions as they may cause haemolysis.
- Carefully inspect all the tubing to ensure that it is not twisted or bent. Circulating blood in the presence of severe flow restriction is likely to result in high levels of haemolysis with high levels of free plasma haemoglobin. Severe flow restriction on the washing lines may reduce the effectiveness of the washing.
- 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 may result in haemolysis, do not use the i-SEP ATS at temperatures above those recommended (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

- Do not reinfuse the blood cell concentrate while the treated blood is being transferred into the Reinfusion Bag of the Treatment Set. The Reinfusion Bag must be disconnected from the Treatment Set prior to reinfusion. The i-SEP ATS Device is not equipped with any system for preventing dosing errors or air infusion. According to the applicable medical device classification, the Autotransfusion System is not intended to be used while directly connected to the patient.
- The Reinfusion Bag has two ports for punchers, allowing for the connection of a transfusion set composed of a filter (not provided by i-SEP).
- i-SEP recommends the use of a blood transfusion filter between the Reinfusion Bag and the patient in accordance with current standards ("Perioperative blood components intended for reinfusion shall be reinfused through a filter designed to retain particles that are potentially harmful to the patient - AABB").
- Prior to reinfusion, connect a transfusion set with an integrated filter (not supplied by i-SEP) to the Reinfusion Bag via one of the two ports for punchers. Always make sure that the transfusion set and its integrated filter are filled with blood and are free of air to limit the risk of gas embolism.
- Remove all air from the Reinfusion Bag before administering the contents.
- DO NOT USE A PRESSURE CUFF OR OTHER MECHANICAL DEVICE WITH THE i-SEP AUTOTRANSFUSION SYSTEM. PRESSURE REINFUSION MAY LEAD TO FATAL PERFUSION OF AIR INTO THE PATIENT and the creation of free haemoglobin.
- The blood product is reinfused by gravity.
- The Reinfusion Bag must not be completely emptied during reinfusion. If the tubing of the transfusion set contains air, it must be changed before continuing the reinfusion process.
- The blood cell concentrate product containing washed blood cells contains only a small amount of coagulation factors. The amount of blood cells reinjected must be monitored by the physician, and if necessary, the reinfusion procedure can be supplemented with a fresh plasma transfusion.
- Prior to reinfusion of concentrated blood products, the user must ensure that the concentrate is suitable for reinfusion. Diluted concentrates are the result of a system malfunction and may be accompanied by poor washing quality. If in doubt, check the quality of the concentrated blood products.

- The haematocrit monitoring function of the i-SEP ATS device is only used to monitor the treatment for programme implementation purposes and is not intended for diagnostic or quality control purposes. The haematocrit values given by the device are not a substitute for checking the haematocrit on the product before reinfusion into the patient. The sensors are not calibrated measuring instruments.
- Never reinfuse blood cell concentrate for which high haemolysis is suspected.

5.6. ENVIRONMENTAL FACTORS

- The Treatment Set and the i-SEP ATS are intended to be used for autotransfusion in facilities providing patient care, such as operating rooms. This device 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 Treatment Set 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. Damaged Treatment Sets must not be used.

5.7. RISKS OF SYSTEM FAILURE

Blood spillage or leakage or treatment failure

- In the unlikely event of a power failure, battery power is available and a cycle in progress can be finished, but a new cycle cannot be undertaken. The manual clamps of the i-SEP Treatment Set must be closed within five minutes of a power failure.
- Do not use if a device or consumables are cracked, have been dropped, or are physically damaged
- Carefully observe the consumable 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 Treatment Set tubes carrying fluid to or from the pump. Restricted flow would lead to increased pressure in this tube, which could result in significant blood spray, a leak, or a disruption to or failure of the treatment process.
- Do not close the waste line clamp during a treatment cycle. i-SEP ATS reusable devices may include a second Waste Bag canister to place a Bag in standby, which can be connected to the Set when the one being used is full. The i-SEP ATS does not prohibit changing a Waste Bag while the system is performing a treatment.
- 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 must not exceed 225 mmHg (300 mbar).
    - 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).
    - Make sure that the unused ports are properly closed and sealed with the caps fully pushed in.
    - To avoid the risk of it collapsing, do not block the open control valve on the Blood Collection Reservoir with foreign objects.
- 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.
- The Waste Bag must not be compressed during treatment and must have space to fill correctly. If the Bag is compressed or cannot fill correctly (if it is against a wall or other machine, for example), the treatment may be impaired.

Poor or inferior quality products with regard to the standard mode

- i-SEP advises that all autologous blood collected must be washed before reinfusion. The standard programme of the i-SEP ATS is designed to provide a safe and high-quality blood product.
- A correct process is not guaranteed if the whole process is not successfully completed.

Equipment sensitivity

- Before use and particularly after connecting the Treatment Set to the Collection Reservoir, make sure that the i-SEP Blood Collection Reservoir is fully inserted into its housing on the dedicated ATS holder. If it is not installed correctly, even the slightest accidental knock to the Collection Reservoir can cause it to detach from the holder.
- Handle the i-SEP Blood Collection Reservoir holder with care when handling the device, as the weight sensors are sensitive components.
- Always handle the treatment bag holder with care, particularly while positioning the Treatment Set, as the weight sensors are sensitive components.
- Follow the positioning of the bags to be hung from the two infusion poles. Do not hang the sterile isotonic saline solution bag containing anticoagulant from the washing solution holder. Only the washing saline solution must be on this holder. The weight of the washing saline solution is monitored using the washing solution holder.
- All manual clamps must be open and the tubes must not be kinked, bent, or flattened, in order to ensure accurate volume recording and monitoring functions.
- Make sure that the tubes are correctly positioned in the various optical sensors. Poor positioning may cause the system to be incorrectly calibrated and thus produce lower quality blood.

6. TECHNICAL DESCRIPTION

Every i-SEP Autotransfusion Treatment Set, no matter the model, consists of a set of lines joined by connectors and distributors linking the containers, bags, and filtration systems together.
Figure 1 shows the main functional components of an i-SEP Autotransfusion Treatment Set.

- A Set is composed of six lines primarily:
  - A collection line, colour coded red, to transfer the blood collected in the i-SEP Blood Collection Reservoir; it is fitted with red manual clamps.
  - A washing line, colour coded white, to introduce a washing solution (sterile isotonic saline solution) through two entrances in the i-SEP Autotransfusion Treatment Set circuit to wash the blood concentrate; each supply line is fitted with a white manual clamp.
  - A waste line, colour coded white to connect the circuit to a Waste Bag to eliminate the washing solution containing contaminants; it is fitted with a manual clamp.
  - A reinfusion line, colour coded blue, to transfer the washed blood concentrate to the Reinfusion Bag; it is fitted with a blue manual clamp.
  - An unclogging line for passing the washing solution to wash the filter and optimise cell salvage.
  - A circulation line, internal to the circuit, to direct the flows inside the different lines of the i-SEP Autotransfusion Treatment Set, using the peristaltic pump putting the fluids in motion and the electro-clamps of the i-SEP ATS.
- The lines are partially secured to a transparent plastic template to immobilise a portion of the lines and facilitate their installation on the i-SEP ATS. The lines are positioned in tubing guide insets to immobilise them, in the peristaltic pump head of the i-SEP ATS, or in insets to position them facing the sensors.
- A Set is composed of three bags:
  - A Reinfusion Bag, connected to the i-SEP Autotransfusion Treatment Set circuit by a Luer connector; the Reinfusion Bag contained in the Set must be replaced for each treatment cycle.
  - A Waste Bag connected to the i-SEP Autotransfusion Treatment Set circuit by a waste line; the Waste Bag contained in the Set must be replaced by a new empty i-SEP Waste Bag if the Set's original bag has been filled.
  - A treatment bag, an integral and non-removable part of the Set, which serves as an intermediary container for fluid from the i-SEP Blood Collection Reservoir and for the washing solution, during filtration treatment.
- A Set is composed of two "filters":
  - A Micro-aggregates Chamber at the entrance to the i-SEP Autotransfusion Treatment Set, to filter any potential aggregates that may have passed through the i-SEP Blood Collection Reservoir filter or that may have formed after it. The Micro-aggregates Chamber can be replaced by a new i-SEP Micro-aggregates Chamber if the original Set's chamber becomes clogged or the treatment time increases.
  - A filter composed of a cartridge of hollow fibres in order to perform the concentration and washing treatment of the fluid salvaged initially.
- A Set is attached to a *minimum* of two external containers:
  - A washing bag (sterile isotonic saline solution: NaCl 0.9% European Pharmacopoeia) to wash the blood concentrate: the connection is made by the uncapped spike located at the end of the washing line and the puncturable membrane of the twist-off of the washing bag. A second washing bag can be connected simultaneously via the second connection available.
  - An i-SEP Blood Collection Reservoir via its outlet tubing in order to salvage the blood to be treated: the connection is made by screwing Luers to the ends of the collection line of the i-SEP Autotransfusion Treatment Set and the Collection Reservoir outlet tubing.

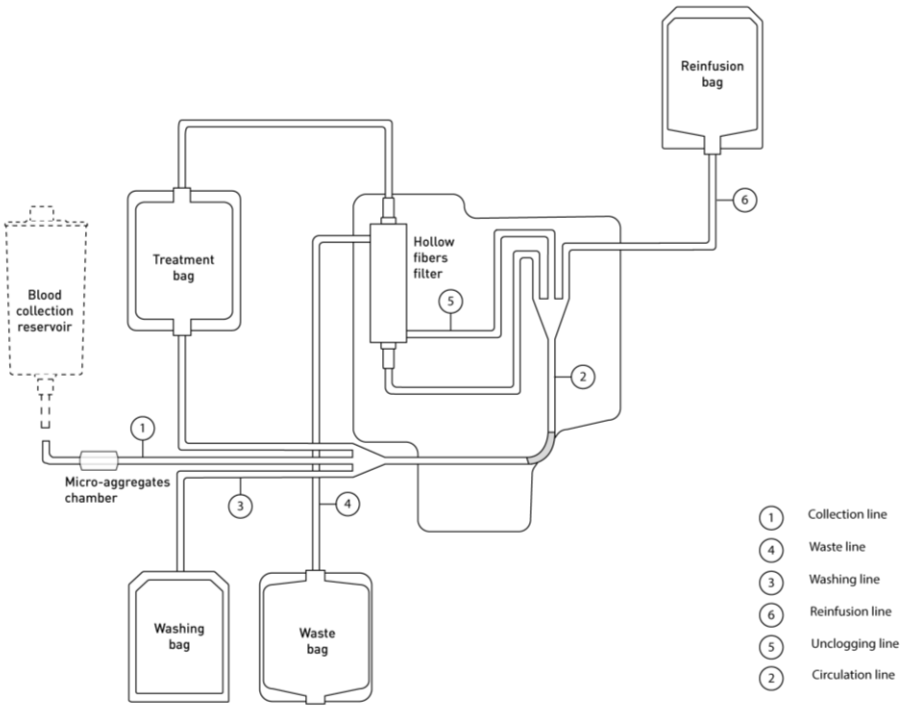

Figure 1: Drawing of the i-SEP Autotransfusion Treatment Set

- i-SEP Autotransfusion Treatment Set models vary mainly by the filtration capacities of the filtration cartridge with hollow fibres (ST0301 or ST0501) or by labelling (language).
- For the micro-aggregates chamber, the list of materials of the blood pathway, data related to cell damage as well as relevant tolerances for data presented are available upon request.

7. PERFORMANCE

According to the applicable standards, the Treatment Set is sterile, single-use, biocompatible, and non-pyrogenic.
Table 2 shows the main performances of the i-SEP Autotransfusion Treatment Sets.

	i-SEP Autotransfusion Treatment Set	
Specifications	**ST0301**	**ST0501**
Volume treated in the first cycle	500 ml	700 ml
Volume treated from the 2nd cycle	300 ml	500 ml
Maximum use features	15 cycles within 6 hours	15 cycles within 6 hours
Treatment capacity in blood volume	4.5 litres	7.5 litres
Waste Bag volume	5 litres	5 litres

Table 2: Main performances of i-SEP Autotransfusion Treatment Sets

8. INSTALLATION AND USE

The devices must be handled and used by qualified personnel, namely anesthesiologists/anesthetists or nurses, who are familiar with the Instructions For Use of the i-SEP ATS and its accessories.

A guide for installing the single-use devices associated with the i-SEP ATS is available (see i-SEP document: D-PRO-024).

8.1. INSTALLATION

8.1.1. Installing an i-SEP Blood Collection System

- Plug the i-SEP ATS into an electrical socket.
- Turn on the i-SEP ATS by pressing the ON/OFF button on the screen (also called HMI for Human-Machine Interface).
- Switch on the vacuum pump (pump ON/OFF button).
- Adjust the vacuum to a level of -150 mbar (-112 mmHg) or below using the external vacuum regulator.
- Read the Instructions for Use for the i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir (i-SEP document: D-PRO-023) and install an i-SEP Aspiration and Anticoagulation Line and an i-SEP Blood Collection Reservoir.
- Connect an i-SEP Aspiration and Anticoagulation Line and an i-SEP Blood Collection Reservoir per the Instructions for Use.
- Install an i-SEP vacuum line between the i-SEP ATS and the i-SEP Blood Collection Reservoir (see i-SEP document: D-PRO-021).

8.1.2. Installing the i-SEP Autotransfusion Treatment Set

The installation of the i-SEP Treatment Set is closely associated with the use of the i-SEP ATS. The main installation steps are outlined below. It is recommended to refer to the Instructions For Use for the i-SEP ATS (see i-SEP document: D-PRO-021) for a complete and detailed description of how to use the device.

The Set's installation screen displays a representation of the i-SEP Autotransfusion ATS where the different parts of the machine can be identified (see *Figure 2*). The HMI prompts the user to install the different elements of the Set. A red arrow on the left visual shows where the element is located on the machine. The right visual on the screen shows a magnified detail of the handling to be performed.

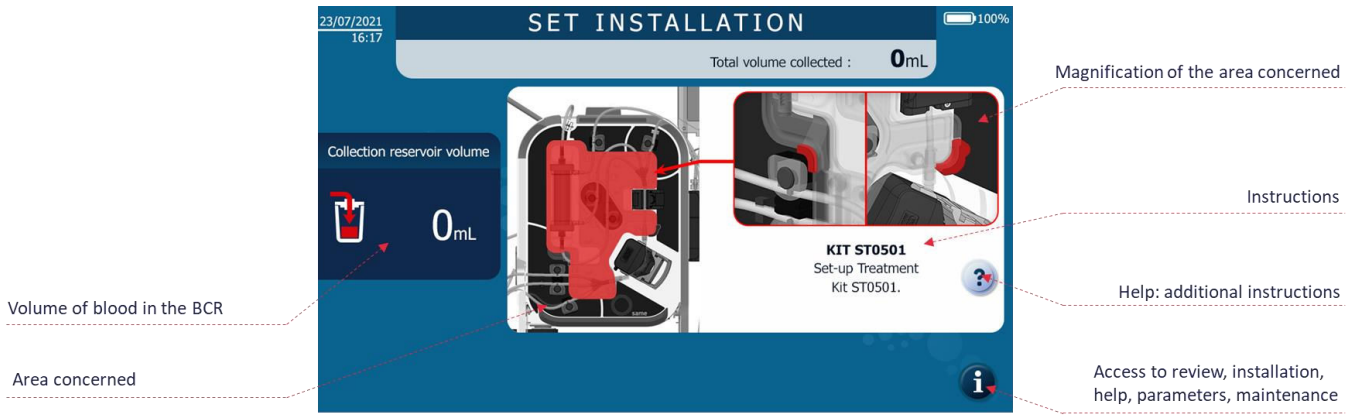

Figure 2: Installation screen

Once the element is installed, the screen disappears meaning that it has been positioned correctly. Then another screen appears to show the user the next operation. These screens will continue until the whole Set has been installed on the machine.

If the logical order is not followed, the machine automatically takes the completion of the steps into account and does now show the corresponding screens.
If an element is uninstalled after it was already installed, the screen will reappear to tell the user that the element is not installed correctly.

If needed, a help screen is available for each element by pressing the (?) symbol on the HMI. This screen details the operations to perform while providing a different visual.

At the end of installation, a message prompts the user to check the elements that could not be detected automatically and a calibration is performed.

In practice (see Figure 3),

- an i-SEP Autotransfusion Treatment Set is installed on an i-SEP ATS that is turned on. Make sure that the i-SEP ATS is connected to an electrical socket and that it is turned on.
- When the autotests haven been successfully passed, the HMI of the i-SEP ATS prompts the user to install the i-SEP Autotransfusion Treatment Set.
- Choose the desired Treatment Set model depending on the clinical context of use, particularly with regard to the volumes of blood loss expected.
- Open the protection lid on the i-SEP ATS and place the blister pack from the i-SEP Autotransfusion Treatment Set on top, with the lid upward and the opening tab towards the i-SEP ATS.
- Scan the QR code on the label on the lid of the i-SEP Autotransfusion Treatment Set using the Barcode Reader in order to identify the i-SEP Autotransfusion Treatment Set model by the device. To do this, slide the blister pack below the treatment area until the device detects it. In case of difficulty or a reading error, move the blister pack from left to right.

Figure 3: Scanning the QR code on the i-SEP Autotransfusion Treatment Set

- Open the sterile packaging of the i-SEP Autotransfusion Treatment Set by pulling the opening tab on the lid towards you.
- Place the template in an upright position against the treatment area of the Device using the 2 centring supports (See Figure 4).

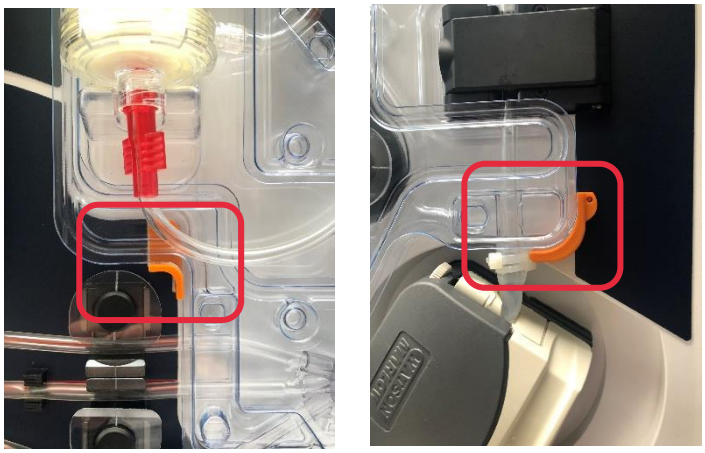

Figure 4: Placement of the template using the 2 centring supports

Warning:
Push strongly <u>on</u> the template at the centring supports (inside the red square in Figure 4) until the bottom. The template must pass through several grooves.
Make sure that each of the Luer connectors is tight throughout the installation in order to avoid losses of sterility.

Pay particular attention to the correct insertion of the tubes in the tubing guides, optical sensors, electro-clamps, haematocrit reader, overpressure sensor, and peristaltic pump (red circles) (See Figure 5).

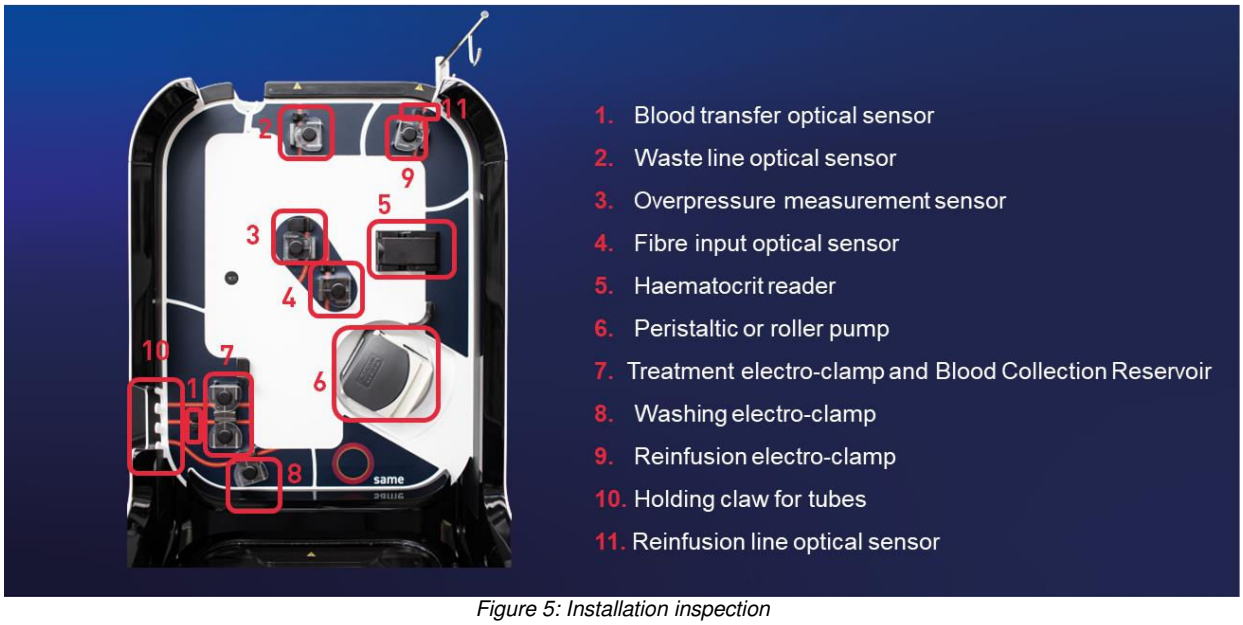

Figure 5: Installation inspection

→ Position the treatment bag in the dedicated holder on the left side of the ATS using the four holding pins (See Figure 6):

Figure 6: Positioning the treatment bag

Warning: it is crucial for the bag to be attached with the four pins in order to limit risks of disturbance as much as possible during blood circulation, as disturbances may cause haemolysis.

→ Make sure that the tube at the bottom of the treatment bag is properly positioned in the groove provided for this purpose (See Figure 7).

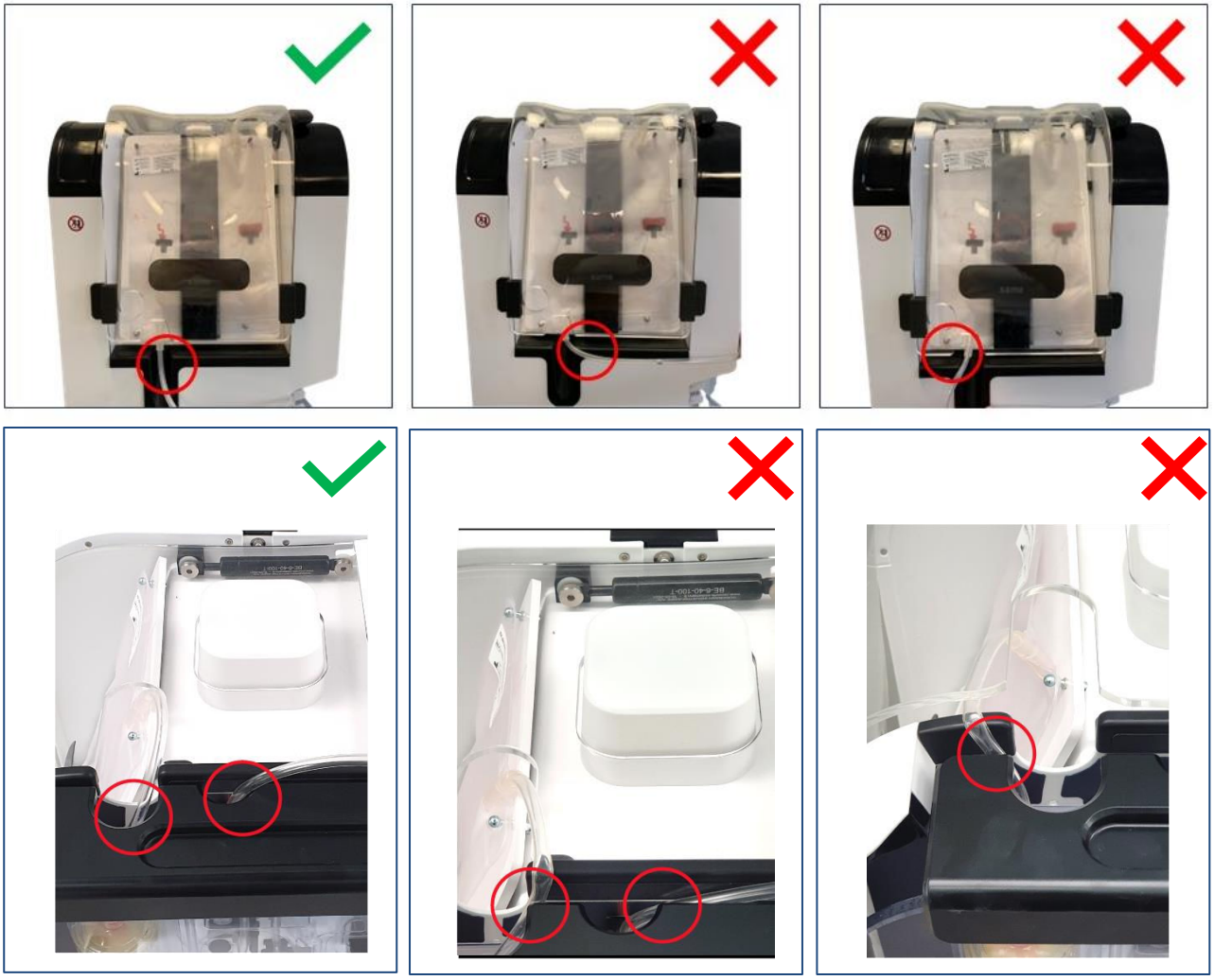

Figure 7: Correct or incorrect positioning of the treatment bag

→ Close the protection lid over the treatment bag.

Figure 8: Closing the protection lid

- Placement of the i-SEP Waste Bag (See Figure 9):
  - Take the i-SEP Waste Bag from the i-SEP Autotransfusion Treatment Set and unfold it completely,

Warning: If the Waste Bag stays stuck to itself, change the i-SEP Waste Bag.

- Hang the Waste Bag from the i-SEP Autotransfusion System shelf using the 2 hooks on the bag.
- Make sure that the Luer connector is properly tightened.
- Make sure that the drain valve is properly closed.

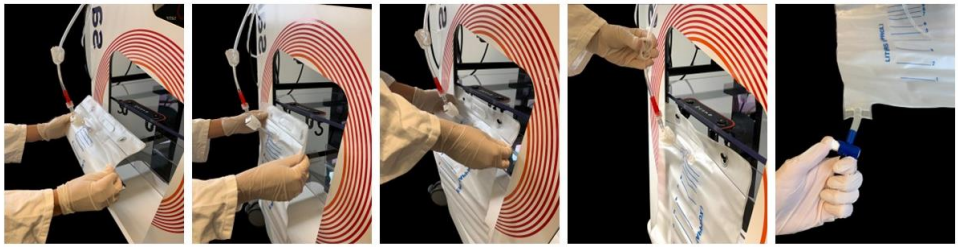

Figure 10: Installing the Waste Bag

- Put the circulation line in the peristaltic pump (See Figure 11):
  - With the pump head open, position the silicone tube in the roller pump while taking care to centre the tube on the rollers.
  - Make sure that the tubes feed into and come out of the pump without being kinked or pulled. If necessary, repeat the positioning by limiting the constraints on the tube in contact with pump.
  - Close the pump head and make sure that the silicone tube is not stuck in the flap as this may damage the tube and cause leaking. If this is the case, check the integrity of the tube and reposition the tube in the pump if it shows no deterioration. **In the event of integrity breach or doubt about integrity, replace the Set.**

Figure 11: Placement of the flow distribution tubing in the pump head

- Position the tubing in the Haematocrit Reader and use your finger to press on it so as to fully push it in place.
- Close the protection lid over the haematocrit reader (See Figure 12).

Figure 12: Placing the tube in the haematocrit reader

- Close the clamps on the collection line, and if necessary, on the line under the Collection Reservoir, then connect the collection line from the i-SEP Autotransfusion Treatment Set to the i-SEP Blood Collection Reservoir by screwing the two Luers (see Figure 13).

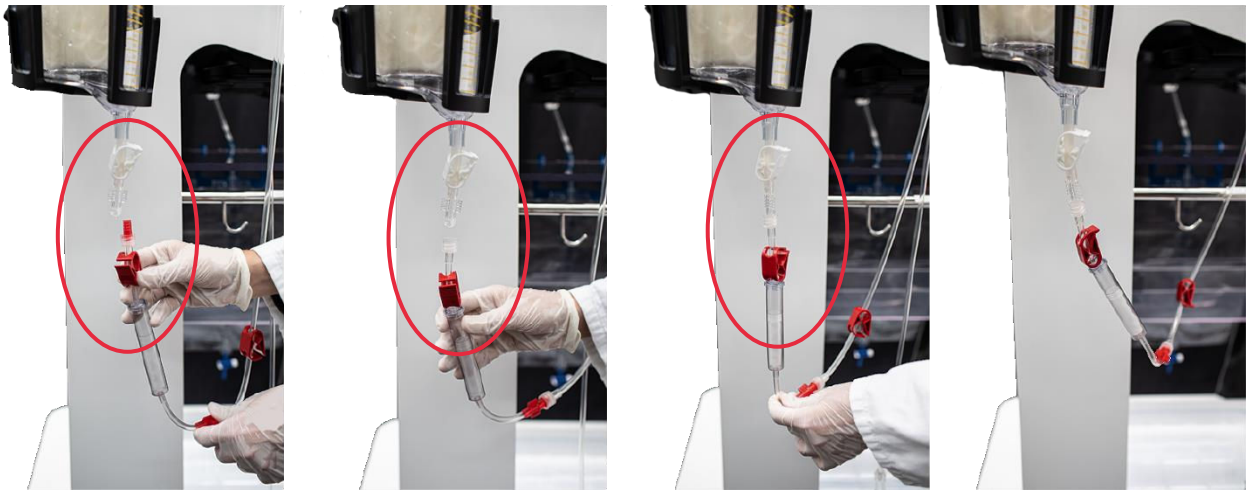

Figure 13: Installing the collection line

- Installing the washing bags (See Figure 14 and Figure 15):
  - Close the manual clamps on the washing line;
  - Connect one or two washing bags to the washing line with one or two washing line punchers.

- If the second bag of isotonic saline solution is not connected, leave the second manual clamp closed.
    i. Hang the washing solution bag(s) from the pole provided for this purpose on the ATS; if there are 2 bags suspended from the pole, it is then recommended to connect the 2 bags to the spikes. The remaining volume of washing solution is monitored by weight, and if the second bag is not connected, this will disrupt the alerts to change the bag.

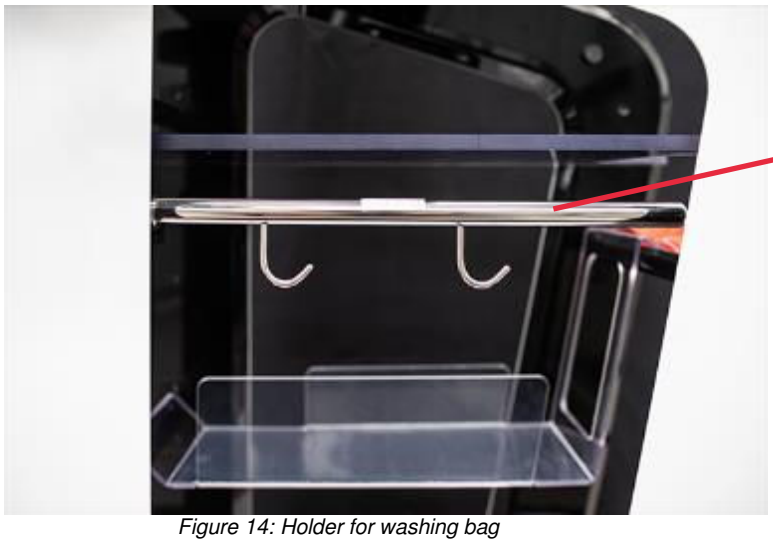

Figure 14: Holder for washing bag

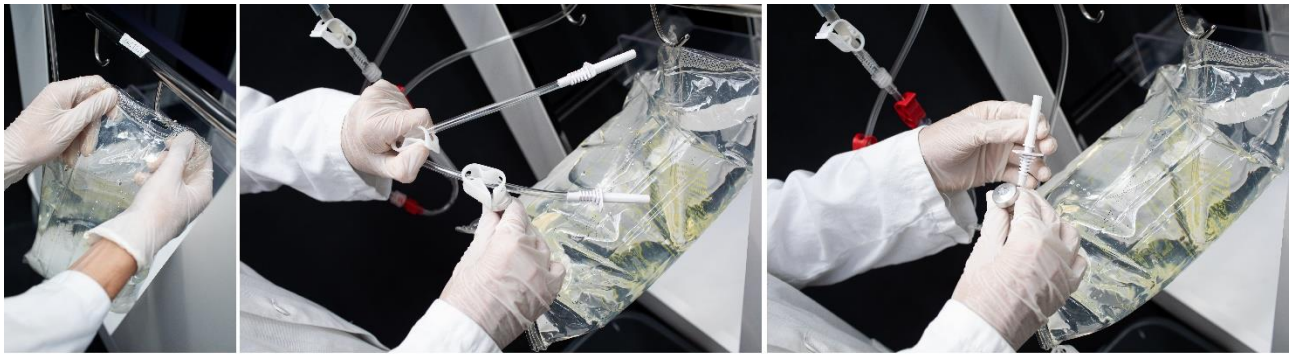

Figure 15: Installing the washing bag

- Placement of the reinfusion bag
- Open out the reinfusion pole by lifting the button as shown in Figure 16.
- Hang the reinfusion bag from one of the hooks on the top reinfusion bag bracket of the ATS using the central eyelet on the bag;

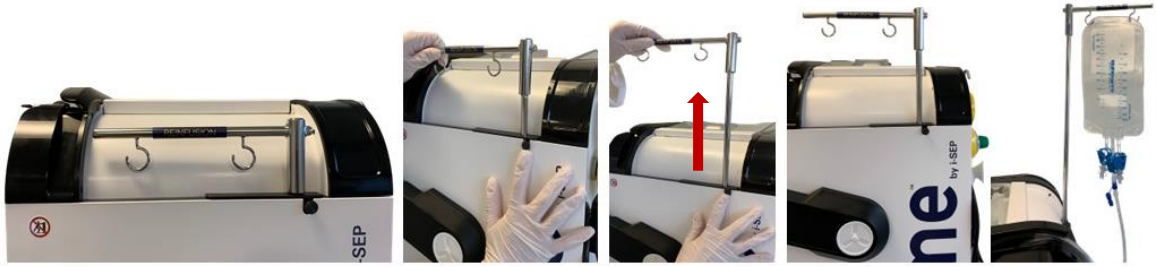

Figure 16: Installing the reinfusion bag

→ Put the reinfusion line in the line presence sensor (See Figure 17).

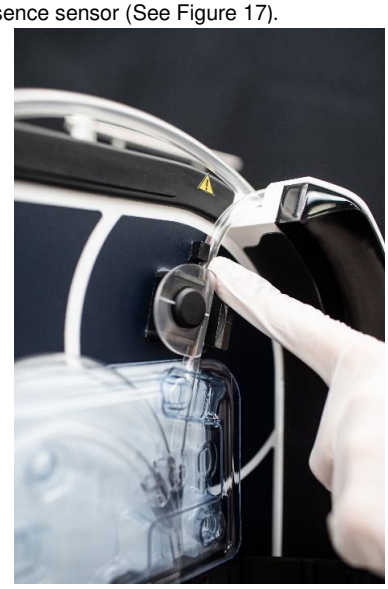

Figure 17: Reinfusion line presence sensor

- Once finished installing the i-SEP Autotransfusion Treatment Set, there will be a summary screen in the form of a checklist of the last steps to carry out; these cannot be automatically detected by the machine and must be performed to finish the installation.

8.2. PROCEDURE FOR USE

8.2.1. Blood salvage and anticoagulation

- Introduce approximately 200 ml of sterile isotonic saline solution containing 25,000 UI of unfractionated heparin per litre of saline solution into the i-SEP Blood Collection Reservoir through the i-SEP Aspiration and Anticoagulation Line.
- Proceed with blood salvage with simultaneous anticoagulation, with an anticoagulant solution flow of 120 drops per minute. In the event of heavy bleeding, increase the flow rate according to the inflow of salvaged blood.
- The blood salvaged in the i-SEP Blood Collection Reservoir can be used for treatment for a duration of 6 hours.

8.2.2. Using an i-SEP Autotransfusion Treatment Set

Using the i-SEP Autotransfusion Treatment Set to obtain a blood concentrate can only be done by using the i-SEP ATS. It is recommended to refer to the Instructions For Use for the i-SEP ATS (i-SEP document: D-PRO-021) for a complete and detailed description of how to use the device.

After installing the Set and starting the procedure, check all of the existing Luer connectors.

In practice,

- The system operates in standard mode by default. Depending on the medical context, the user can choose a specific operating mode suited to the context of use.
- The user follows the instructions displayed on the i-SEP ATS screen.
- Before completing the initial launch of the i-SEP Autotransfusion Treatment Set, open all the clamps, prioritising those:
  - On the reinfusion line (under the reinfusion bag and on the infusion line, either side of the Luer connector), two (2) in number.
  - On the salvage line (under the Blood Collection Reservoir), three (3) in number.
  - On the washing line, one or two (1 or 2) in number.
  - On the waste line, two (2) in number.
- As a first step, the i-SEP ATS primes the i-SEP Autotransfusion Treatment Set with washing solution in order to establish the physiological saline conditions in the circuit of the i-SEP Autotransfusion Treatment Set.
- Once the volume of blood salvaged matches the volume of blood necessary to launch a cycle, check one last time to ensure all the clamps are open before completing the launch of the treatment cycle.
- The treatment continues automatically.

8.2.3. Alarms, errors, and alerts

If the i-SEP ATS is paused because of an alert or alarm, the visual and audio interface of the i-SEP ATS will emit signals. Refer to the i-SEP ATS Instructions For Use leaflet (i-SEP document: D-PRO-021) and the i-SEP ATS messages to solve the problems encountered.

8.2.4. Changing a washing solution bag

- To change a bag of washing solution, wait for a notification from the i-SEP ATS that the bag can be changed or for the end of a treatment cycle.
- Close the manual clamp of the washing line on which the washing bag is empty.
- Disconnect the spike of the empty washing bag.
- Pierce the Twist-off of the new washing bag with the now feed spike.
- Reopen the clamp of the washing line that is now being fed again.
- Resume the rest of the procedure.

8.2.5. Changing the i-SEP Micro-aggregates Chamber (Ref. LF0000, refer to D-PRO-027 for more details)

- To change an i-SEP Micro-aggregates Chamber (See Figure 18), **pause** the machine. The change can also be done when the machine is waiting for blood at the beginning of salvage (Volume in the Blood Collection Reservoir < 150 ml approximately) or during treatment when blood transfer to the i-SEP Autotransfusion Treatment Set is finished. The i-SEP Micro-aggregates Chamber **must not be changed** while the Blood Collection Reservoir is being emptied, or while blood is being transferred to the i-SEP Autotransfusion Treatment Set.

Figure 18: i-SEP Micro-aggregates Chamber

- Close the manual clamp on the outlet tube of the i-SEP Blood Collection Reservoir.
- Close the manual clamp on the collection line of the i-SEP Autotransfusion Treatment Set.
- Unpack a new i-SEP Micro-aggregates Chamber using the usual aseptic technique.
- Unscrew one of the Luer connectors of the i-SEP Micro-aggregates Chamber on the Treatment Set.
- Remove the cap on the Luer of the new Micro-aggregates Chamber, and screw the Luer onto the previously disconnected connector on the Treatment Set.
- Unscrew the second Luer connector of the i-SEP Micro-aggregates Chamber on the Treatment Set.
- Remove the cap on the second Luer connection of the new Micro-aggregates Chamber, and screw the Luer onto the previously disconnected connector on the Treatment Set.
- Dispose of the i-SEP Micro-aggregates Chamber according to the healthcare facility's standard procedures.
- Open the manual clamp on the outlet tube of the i-SEP Blood Collection Reservoir, on the collection line of the i-SEP Autotransfusion Treatment Set, and on the i-SEP Micro-aggregates Chamber.
- Resume the rest of the procedure.

8.2.6. Changing the i-SEP Waste Bag (Ref. BW5000 and BW1000, refer to D-PRO-026 for more details)

The Waste Bag (See Figure 19) can be changed at 2 different times:

Figure 19: Waste Bag (BW5000: left and BW1000: right)

If the Waste Bag is too full according to the user and they decide to activate the bag change on the HMI 

- Wait for the Autotransfusion System to prompt you to change the Waste Bag or wait for the Autotransfusion System to finish a treatment cycle
- A message will appear to indicate that the Waste Bag can be changed.

If the Waste Bag is too full and the machine detects too much waste, the ATS will prompt the user to change the Waste Bag:

- A message will appear to indicate that the Waste Bag can be changed.

In both situations, carry out the following steps (See Figure 20).

1. Close the manual clamp on the waste line of the i-SEP Treatment Set.
2. Unpack a new empty i-SEP Waste Bag.
3. Unscrew the Luer connection on the waste line.

4. Screw the empty bag onto the Luer connector connection on the waste line.
5. Close the full Waste Bag with the cap provided for this purpose on the Waste Bag.
6. Dispose of the Waste Bag according to the healthcare facility's standard procedures.
7. Insert the Waste Bag.

Figure 20: Replacement of the waste bag (BW1000)

Warning:

- **Reopen the clamp on the waste line so that the following concentrations run correctly.**
- **Remember to wear PPE for this handling.**

8.2.7. Changing the Reinfusion Bag (Ref. BE1000, refer to D-PRO-025 for more details)

- To change the Reinfusion Bag (See Figure 21 and Figure 22), wait until the i-SEP ATS has finished a treatment cycle.
- Close the manual clamp on the reinfusion line of the i-SEP Autotransfusion Treatment Set.
- Close the manual clamp on the i-SEP Reinfusion Bag (on the connection fitted with a female Luer lock system).
- Unpack a new empty i-SEP Reinfusion Bag.
- Disconnect the i-SEP Reinfusion Bag containing the concentrate by unscrewing the Luer connectors.
- Close the cap on the Luer of the i-SEP Reinfusion Bag containing the concentrate.
- Connect the empty i-SEP Reinfusion Bag (after removing the cap) by screwing the Luer connectors together.
- Make sure that the manual clamp on the empty i-SEP Reinfusion Bag (on the connection fitted with a female Luer lock system) is open.
- Open the manual clamp on the reinfusion line of the i-SEP Autotransfusion Treatment Set. Resume the rest of the procedure.

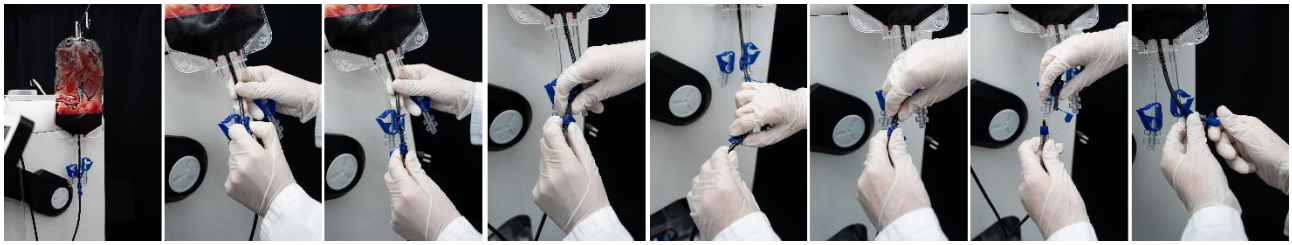

Figure 21: Changing the i-SEP Reinfusion Bag (1/ 2)

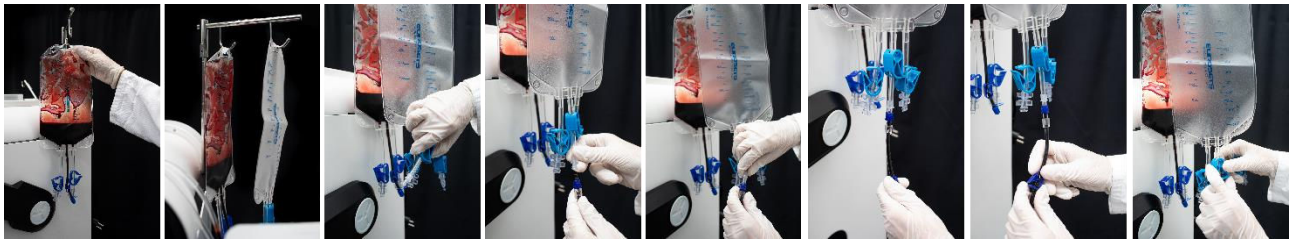

Figure 22: Changing the i-SEP Reinfusion Bag (2/ 2)

Warning:

- **Properly connect a new Reinfusion Bag in order to avoid blood loss or accidental exposure to blood.**
- **Remember to wear PPE for this handling.**

8.3. UNINSTALLING AND DISPOSAL

Refer to the i-SEP ATS Instructions For Use (i-SEP document: D-PRO-021). A guide for uninstalling the single-use devices associated with the i-SEP ATS is available (see i-SEP document: D-PRO-024).

- Once the procedure for using the i-SEP ATS is deemed finished by the user responsible for its use, or once the 6 hours of use of one of the ATS accessories in contact with blood have elapsed, the accessory in question must be disposed of according to the standard procedures of the healthcare facility.
- The "End of surgery" function stops the machine.

→ Press the 

button to activate the machine stop function (See Figure 23)

- The following message appears on the screen:

"Device shutdown requested. WARNING, in case of validation, the Set can no longer be used. Validate shutdown"

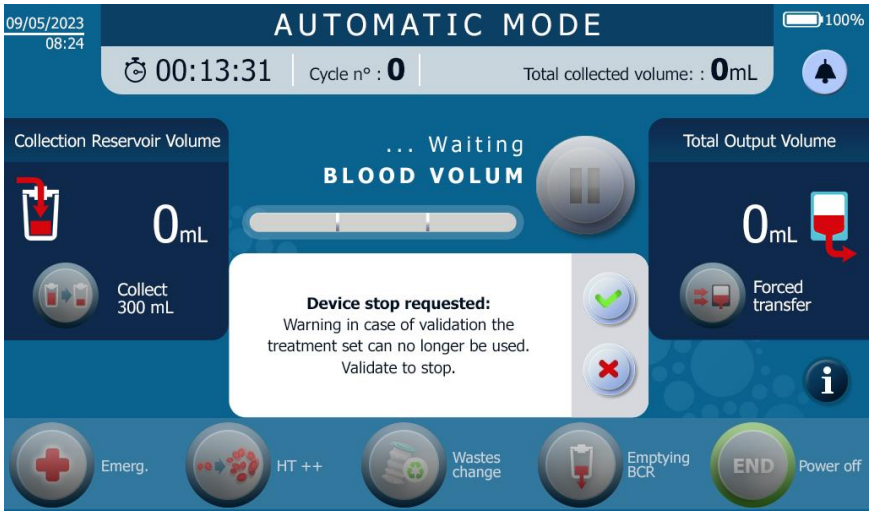

Figure 23: Screen after having pressed the END button

- Validate by pressing the  button or cancel by pressing the  button.
- If validated, a new screen appears with the summary of the surgery (See Figure 24).

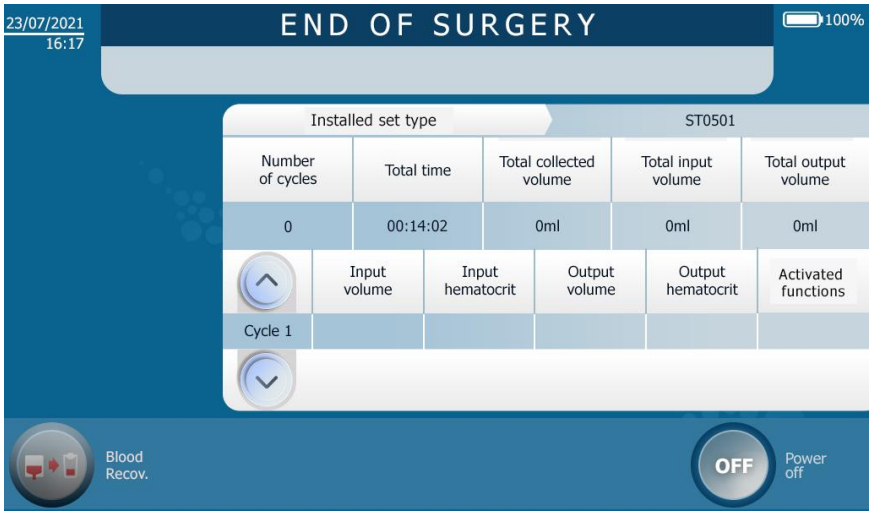

Figure 24: End of surgery screen

- The user is prompted to turn off the machine in order to uninstall the i-SEP Autotransfusion Treatment Set by pressing "OFF" 

- As shown in Figure 25:

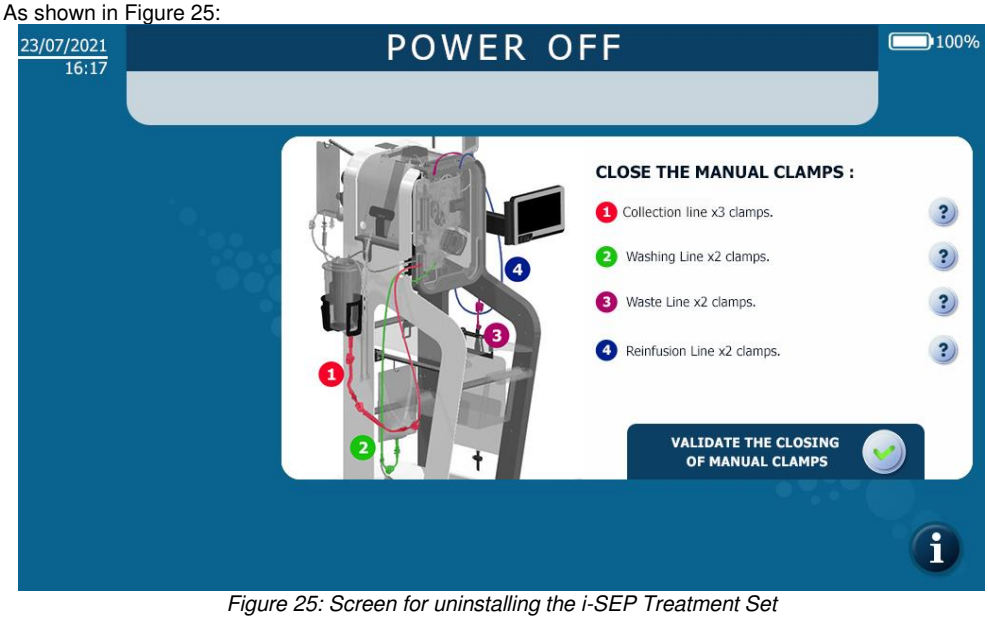

Figure 25: Screen for uninstalling the i-SEP Treatment Set

Close all the manual clamps:

- On the reinfusion line (under the reinfusion bag and on the infusion line, either side of the Luer connector), two (2) in number.
- On the salvage line (under the Blood Collection Reservoir), three (3) in number.
- On the washing line, one or two (1 or 2) in number.
- On the waste line, two (2) in number.

- The machine's electro-clamps open and the screen turns off.
- End of procedure.
- Definitive uninstallation of the accessories happens while the i-SEP ATS is off.
- Remove the used consumable accessories from the treatment area, poles, and specific holders on the device one by one.

Note:

The accessories can only be uninstalled if the i-SEP Autotransfusion System is off.

- All consumables still connected at the end of use — Aspiration and Anticoagulation Line, Blood Collection Reservoir, and Treatment Set — are disposed of in the appropriate operating theatre waste bin.

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

- The i-SEP Aspiration and Anticoagulation Line must be connected to the i-SEP Blood Collection Reservoir, itself connected to the Treatment Set to eliminate undesirable substances on reinfusion.
- Aspiration and collection of anticoagulated blood before its transfer to the i-SEP Treatment Set must be performed with the integrated surgical vacuum system of the i-SEP ATS or any other system with equivalent technical characteristics (under the responsibility of the physician ordering the use of the system).

Table 3 below shows the references associated with the use of the i-SEP ATS 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 i-SEP Autotransfusion System Quick User Guide
XJ-13-05	i-SEP Aspiration and Anticoagulation Line	D-PRO-023	Instructions for Use for the i-SEP Aspiration and Anticoagulation Line and i-SEP Blood Collection Reservoir
XJ-28-18	i-SEP Blood Collection Reservoir	D-PRO-023	Instructions for Use for the i-SEP Aspiration and Anticoagulation Line and i-SEP Blood Collection Reservoir
BE1000	Additional i-SEP Reinfusion Bag	D-PRO-025	Instructions for Use for the i-SEP Reinfusion Bag
BW5000	Additional i-SEP Waste Bag	D-PRO-026	Instructions for Use for the i-SEP Waste Bag
BW1000	Additional i-SEP Waste Bag	D-PRO-026	Instructions for Use for the i-SEP Waste Bag
LF0000	Additional i-SEP Micro-aggregates Chamber	D-PRO-027	Instructions for Use for the i-SEP Micro-aggregates Chamber
LE0000	Vacuum line	D-PRO-023	Plastic, non-sterile, single-use accessory
11813	Antibacterial filter for vacuum line	N/A	Sterile, single-use filtration accessory
18837	Vacuum regulator	N/A	Reusable, non-sterile, repeated use accessory

Table 3: 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 ATS and its accessories, please refer to its documentation (see i-SEP document: 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 Autotransfusion Treatment Set has been sterilised by gamma sterilisation. See warnings and precautions for risks of infection.

12. STORAGE AND HANDLING

- Keep the packaging from i-SEP Autotransfusion Treatment Sets by facing either the two blister sides towards each other or the two lid sides towards each other.
- Store all devices in a dry place.
- Store at room temperature.
- 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.
- 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

The Treatment Set is described in Figure 1 of this Instructions for Use leaflet.
The Treatment Set is packaged in a transparent blister pack sealed with an opaque lid.
The blister packaging and its lid have been sterilised.
Five (5) i-SEP Autotransfusion Treatment Sets 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.

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).