i-SEP
we believe in safer blood

INSTRUCTIONS FOR USE

D-PRO-026

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

Reference: BW1000

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UK CA
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TABLES

FIGURES

Instructions For Use

i-SEP Waste Bag
(EN - English)

I-SEP WASTE BAG REFERENCES: BW5000 AND BW1000

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 Waste Bag is a medical device associated 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, i-SEP Waste Bags can safely and adequately perform their function of collecting processed autologous blood waste, for the i-SEP Waste Bag.

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 Waste Bag.

SYMBOL	TITLE	SYMBOL	TITLE
Manufacturing			
	Manufacturer		Batch number
 YYYY-MM-DD	Production date		Catalogue number, reference
 YYYY-MM-DD	Expiry date	Bar code or 2D-Matrix with (01) … (17) … (10) …	Unique device identification: (01) Medical Device Identifier (17) Expiry date (YYMMDD) (10) Batch number
ea	Quantity		
Cleanliness / compatibility			
	Do not use if the packaging has been damaged or opened		
Transport, Storage			
	Can be broken or damaged if not handled with care		Protect from moisture
	Keep away from all sources of light		
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		
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 devices described

2. INTENDED USES / INDICATIONS FOR USE

The i-SEP Waste Bag is a non-sterile, single-use accessory for intraoperative collection of fluid and cell debris from blood processed in the i-SEP Autotransfusion System.
This device is intended for use by qualified personnel, namely anesthesiologists/ anesthetists or nurses.

3. CONTRAINDICATIONS

There are no known contraindications when the devices are used as intended.
Refer to the contraindications specified in the Instructions For Use of the devices associated with the use of the i-SEP Autotransfusion System (see D-PRO-021, Section 9).

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 Waste Bag 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 SAT user manual for detailed instructions on using the i-SEP Autotransfusion System.
- Only the i-SEP Waste Bag is approved for use with the i-SEP ATS. The use of 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 medical treatment.
- 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.

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.
- After use, dispose of the device in accordance with the applicable regulations of the country where the device is used.
- The i-SEP Waste Bag is a consumable designed for single use. Do not treat the device further. **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, 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.

5.3. ENVIRONMENTAL FACTORS

- The i-SEP Waste Bag 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 Waste Bag 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 Waste Bags must not be used.

5.4. RISKS OF SYSTEM FAILURE

Blood spillage or leakage or treatment failure

- Do not use if a device or consumables are cracked, have been dropped or physically damaged.
- Carefully observe the i-SEP Waste Bag for leaks before and during use. Leakage can lead to 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 pressure variation, which could lead to reduced blood quality or disruption to and failure of the treatment process.
- Ensure that the i-SEP Waste Bag is unrolled and open.
- Follow the i-SEP ATS Device alerts indicating when to change the i-SEP Waste Bag.
- Do not close the waste line clamp during a treatment cycle. This could lead to fluid dispersion and filtration failure. The i-SEP ATS device does not prohibit changing a Waste Bag during treatment. Replace a full Waste Bag with an empty one is possible when the system is in inactive mode or when the “Change Waste Bag” function is activated. For detailed instructions, follow the procedures described in the “Installation and Use” section.
- Carefully inspect all the tubing to ensure that it is not twisted or bent. If the waste bag tubing were to be kinked to the point of blocking the passage, it may stop the filtration.

Poor quality products

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

6. TECHNICAL DESCRIPTION

i-SEP offers a 10-litre waste bag compatible with the ST0301, ST0501, ST0600 Autotransfusion Sets.

The i-SEP Waste Bag (BW1000) consists of a transparent bag made of Polyvinyl Chloride or PVC (film), a tube and a male Luer also made of PVC, a clamp, and a drain valve (PVC/HDPE) with a capacity of approximately ten (10) litres.

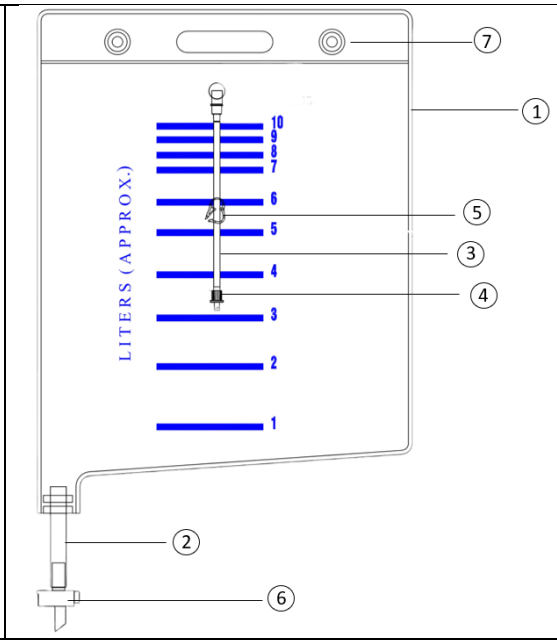
The BW1000 i-SEP Waste Bags is supplied individually wrapped.

Figure 1 shows the schematic drawing of the i-SEP Waste Bag.

Figure 1: Waste Bags

10-litre Waste Bag (BW1000)

1- Bag
2- Bag outlet tube
3- Bag inlet tube
4- Male Luer
5- Manual clamp
6- Drain valve
7- Eyelet



7. PERFORMANCE

According to the applicable standards, i-SEP Waste Bags are non-sterile, single-use, are supplied folded, can be expanded to a capacity of approximately 5 litres or 10 litres, and can withstand mechanical stress (dropping).

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 Autotransfusion System and its accessories.

8.1. FIGURE 2 AND FIGURE 3)

- Remove the additional Waste Bag from its packaging. Unfold the bag completely.
- Hang the Waste Bag on the i-SEP Autotransfusion System shelf using the 2 hooks on the bag.
- Connect the Waste Bag to the waste line of the ST0301 or ST0501 i-SEP Autotransfusion Set by screwing the Luer on the bag to the Luer on the waste line.
- Check that the manual clamp on the waste line of the i-SEP Autotransfusion Set is open.
- Check that the drain valve is closed.

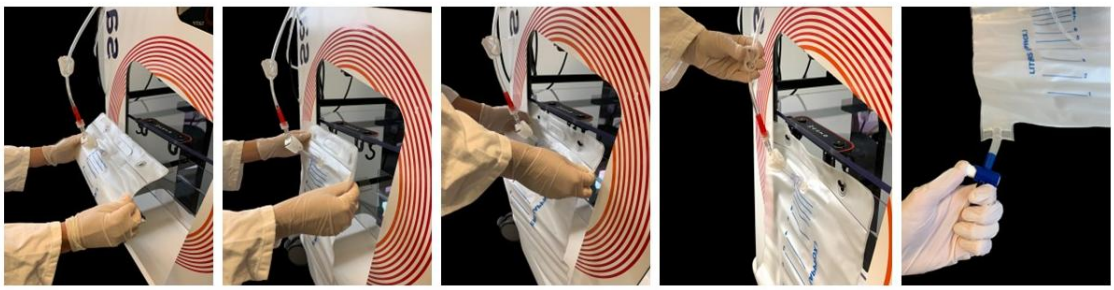


Figure 2: Installing the BW1000 i-SEP Waste Bag (1/2)

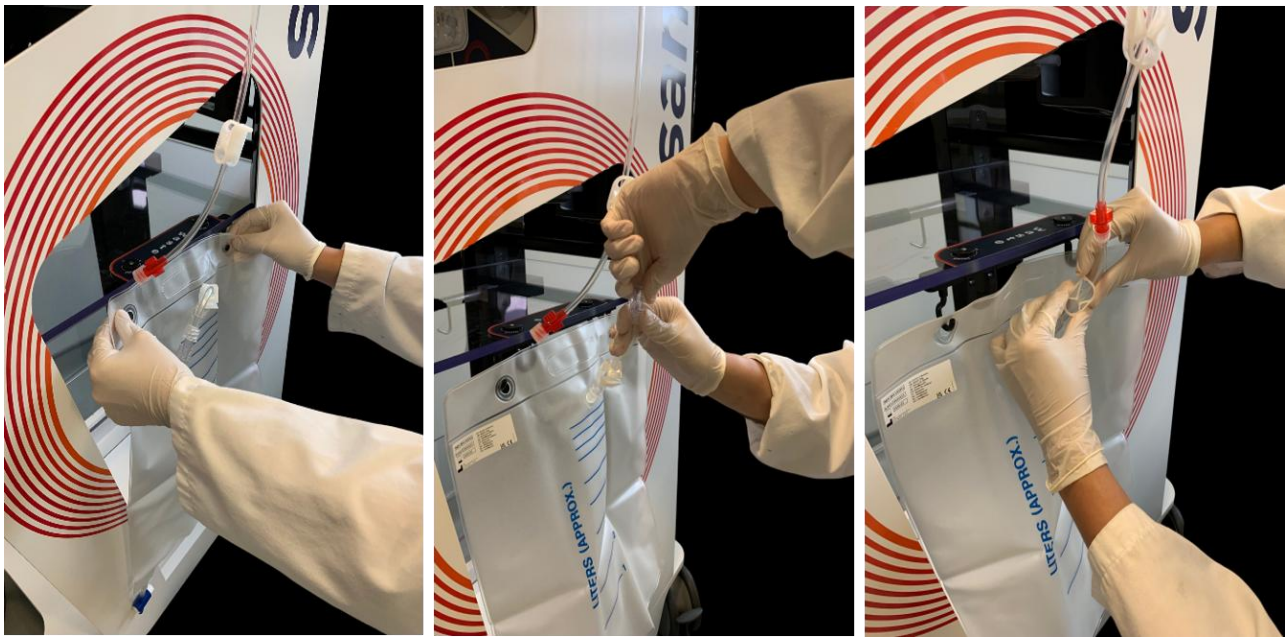


Figure 3: Installing the BW1000 i-SEP Waste Bag (2/2)

8.2. PROCEDURE FOR USE

- Resume the rest of the i-SEP ATS procedure.
- When fluid needs to be removed from the i-SEP Autotransfusion Treatment Set during blood processing, the effluent flows into the i-SEP Waste Bag.
- The i-SEP Waste Bag can be used until the i-SEP ATS alerts you of the need to change it.

8.3. UNINSTALLING AND DISPOSAL

There are two possible scenarios in terms of timing the change:

- If the i-SEP Waste Bag is too full according to the user and they decide to activate the bag change on the HMI:
  - Wait for the i-SEP Autotransfusion System to prompt you to change the i-SEP Waste Bag or wait for the i-SEP Autotransfusion System to finish a treatment cycle.
  - A message will appear to indicate that the i-SEP Waste Bag can be changed.

- If the i-SEP Waste Bag is too full and the machine detects too much waste, the ATS will prompt the user to change the i-SEP Waste Bag:
  - A message will appear to indicate that the i-SEP Waste Bag can be changed.

Both cases involve the following steps (according to Figure 4):

- Close the manual clamp on the waste line of the i-SEP Autotransfusion Treatment Set.
- Close the clamp on the Waste Bag on the i-SEP Autotransfusion Treatment Set.
- Unscrew the Luer connection from the waste line and Waste Bag of the i-SEP Autotransfusion Treatment Set.
- Dispose of the i-SEP Waste Bag according to the healthcare facility's standard procedures.
- Unpack an additional empty i-SEP Waste Bag.
- Connect the Waste Bag to the waste line of the ST0301 or ST05051 i-SEP Autotransfusion Set by screwing the Luer on the bag to the Luer on the waste line.
- Insert the new i-SEP Waste Bag as described in Chapter 8.1 (Installation).

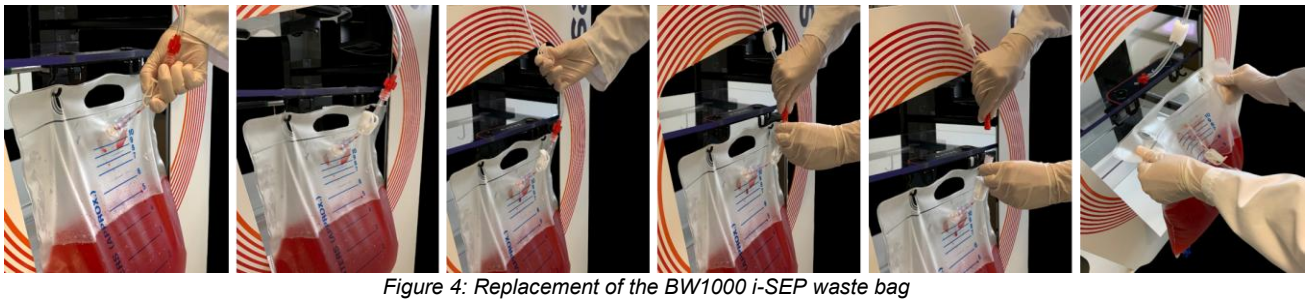


Figure 4: Replacement of the BW1000 i-SEP waste bag

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

The i-SEP Waste Bag must be used with the i-SEP Autotransfusion System. In particular, the Waste Bag must be connected to the i-SEP Autotransfusion Treatment Set.

Table 2 below shows the references directly 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 i-SEP Autotransfusion System Quick User Guide
ST0301 ST0501 ST0600	i-SEP Autotransfusion Treatment Set	D-PRO-022	i-SEP Autotransfusion Treatment Set Instructions For Use

Table 2: List of references directly 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 Waste Bag is manufactured in a clean factory. The products have not been sterilised.

12. STORAGE AND HANDLING

- Store all consumables in a dry place.
- Store at room temperature.
- Check the expiry date on the label. Do not use the device after the date indicated.
- Carry out a visual inspection and check the devices carefully 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 i-SEP Waste Bag consists of a medical device as described in figure 1 of this Instructions For Use leaflet.
i-SEP Waste Bags are bulk packaged in groups of twenty-four (24) in cardboard packaging.
Each cardboard box is properly labelled.
A cardboard box contains one (1) Instructions For Use leaflet such as this. i-SEP can provide additional 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).