i-SEP

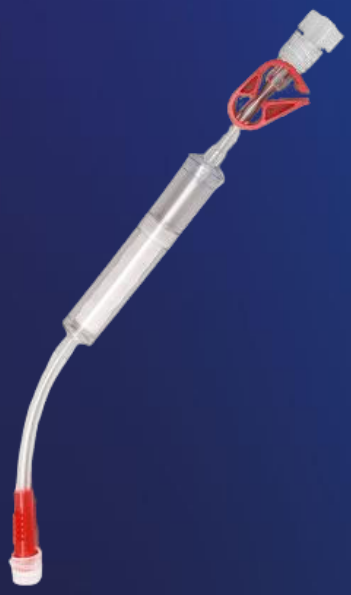
Innovative solutions
& efficiency for the patient

INSTRUCTIONS FOR USE

D-PRO-027

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

Reference: LF0000



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TABLES

FIGURES

Instructions For Use

i-SEP Micro-aggregates Chamber
(GB – English)

REFERENCE: LF0000
For use with the i-SEP same™ Autotransfusion System

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 device presented. The i-SEP Micro-aggregates Chamber 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 Micro-aggregates Chambers can safely and adequately perform their function of filtering autologous blood prior to subsequent treatment.

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 Micro-aggregates Chamber.

SYMBOL	TITLE	SYMBOL	TITLE
Manufacturing			
	Manufacturer	 ABC123	Batch number
 YYYY-MM-DD	Production date	 ABC123	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		
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 = 40°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 Micro-aggregates Chamber is a single-use sterile accessory intended to filter blood before it arrives in the i-SEP Autotransfusion System for treatment and subsequent intraoperative reinfusion to the patient. It is intended to replace the chamber already present in the treatment set.
This device is intended for use by qualified personnel, namely anesthesiologists/ anesthetists or nurses.

3. CONTRAINDICATIONS

There are no known contraindications when the device is 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 micro-aggregates chamber 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 i-SEP Micro-aggregates Chambers are 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.
- 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.

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 blood, which was salvaged intraoperatively then treated, expires 4 hours after the end of the treatment when stored at room temperature (recommendation of 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 i-SEP Micro-aggregates Chamber 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.
- 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.

5.3. COAGULATION DISORDERS

- 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 product 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 TREATMENT

- 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.
- If, during a procedure, it is discovered that any equipment in the vicinity of the blood has overheated, the processed blood product must be considered unsuitable for reinfusion.
- 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. ENVIRONMENTAL FACTORS

- The i-SEP Micro-aggregates Chamber and ATS 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 Micro-aggregates Chamber 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 Micro-aggregates Chambers must not be used.

5.6. 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 are physically damaged.
- Carefully observe the device 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 pressure variation, which could lead to reduced blood quality or disruption to and failure of the treatment process.
- 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.

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

The i-SEP Micro-aggregates Chamber consists of a transparent DEHP-free PVC filtration chamber with an approximate capacity of twenty (20) millilitres. The filter has a porosity of one hundred and fifty (150) micrometres.
It is joined to a PVC tube at the top and bottom:

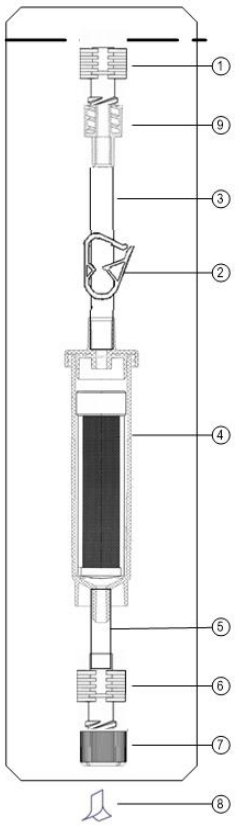
- The top tube is equipped with a clamp and a transparent male Luer closed with a transparent cap. This cap must be removed to connect it in place of the Micro-aggregates Chamber in the treatment set. The clamp secures the installation or removal of the i-SEP Micro-aggregates Chamber, and limits the risk of exposure to blood. This clamp must be open when the i-SEP Micro-aggregates Chamber is installed in its operating position.
- The bottom tube is equipped with a red dialysis Luer connector and its transparent cap. The cap must be unscrewed to connect the Luer to the salvage line of the i-SEP Autotransfusion Treatment Set used.

A label identifies the device.

Figure 1 shows the schematic drawing of the i-SEP Micro-aggregates Chamber.

Figure 1: Drawing of the i-SEP Micro-aggregates Chamber

1. Red cap to be removed before connecting to the i-SEP Blood Collection Reservoir
2. Clamp
3. Top tube
4. Micro-aggregates Chamber containing the filter
5. Bottom tube
6. Female Luer connector
7. Transparent connector cap to be removed before connecting to the i-SEP Autotransfusion Treatment Set
8. Easy-open packaging
9. Transparent male Luer



7. PERFORMANCE

According to the applicable standards, the i-SEP Micro-aggregates Chamber is sterile, single-use, non-pyrogenic, biocompatible, and is compatible with i-SEP Blood Collection Reservoirs and 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 Autotransfusion System and its accessories.

8.1. INSTALLATION

WARNING: The Micro-aggregates Chamber **must not be changed** while the Blood Collection Reservoir is being emptied, or while blood is being transferred to i-SEP Autotransfusion Treatment Set. Before changing the Micro-aggregates Chamber, the i-SEP ATS must be paused (see D-PRO-021).

- Close the clamp on the outlet tubing of the i-SEP Blood Collection Reservoir and the clamp on the Micro-aggregates Chamber in place.
- Close the clamp on the transfer line of the i-SEP Autotransfusion Treatment Set in place.
- Open the outer packaging of the additional i-SEP Micro-aggregates Chamber using aseptic technique.
- Close the clamp on the new i-SEP Micro-aggregates Chamber.

- Unscrew the Luer connection of the Micro-aggregates Chamber in place just after the Collection Reservoir.
- Remove the cap from the red top luer of the new i-SEP Micro-aggregates Chamber.
- Connect the new i-SEP Micro-aggregates Chamber at the bottom of the outlet tubing of the i-SEP Blood Collection Reservoir. The connection is made with the dialysis Luer.
- Screw the previously removed red Luer cap onto the used Micro-aggregates Chamber to avoid any risk of blood spillage.
- Remove the transparent Luer cap from the bottom tube of the new i-SEP Micro-aggregates Chamber.
- Disconnect the Luer connector at the bottom of the Micro-aggregates Chamber in place, screw the previously transparent removed Luer cap and put the latter in the appropriate waste bin.
- Connect the salvage line from the i-SEP Autotransfusion Treatment Set to the bottom tube of the new i-SEP Micro-aggregates Chamber. The connection is made with the dialysis Luer.
- Open the clamp on the outlet tubing of the i-SEP Blood Collection Reservoir.
- Open the clamp on the i-SEP Micro-aggregates Chamber.
- Open the clamp on the salvage line of the i-SEP Autotransfusion Treatment Set.
- Remove as much air as possible from the i-SEP Micro-aggregates Chamber by pressing on it 3 or 4 times.
- Relaunch the i-SEP ATS (see D-PRO-021).

Warning:

- It is highly recommended to use PPE for this handling.

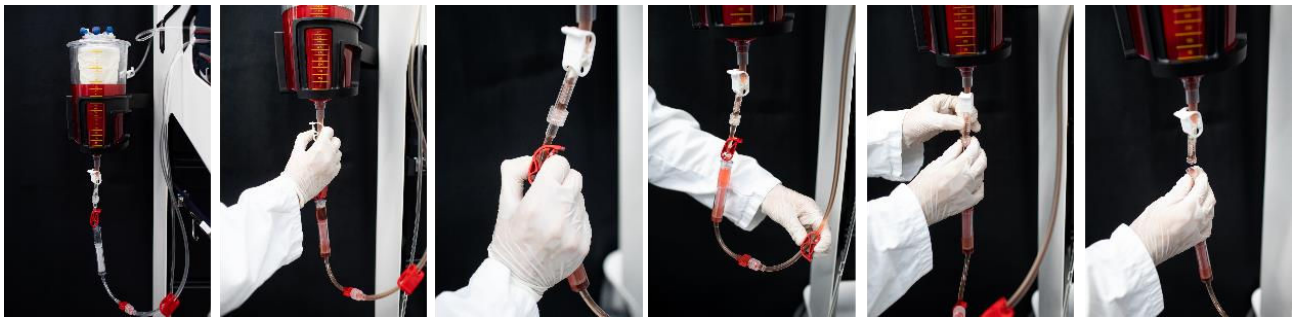


Figure 2 : Change of the Micro-aggregates Chamber 1/2

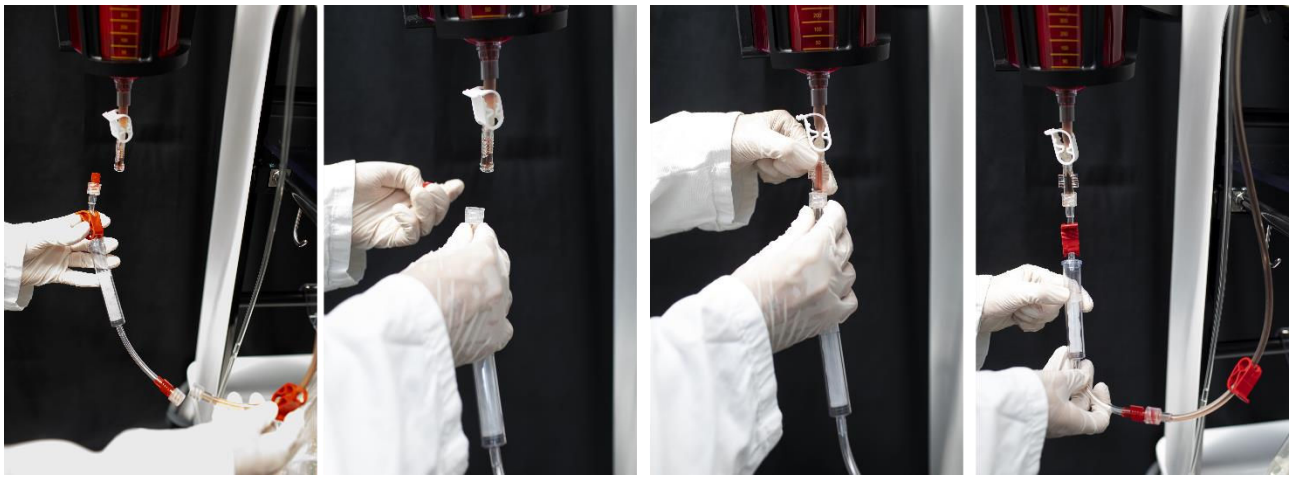


Figure 3 : Change of the Micro-aggregates Chamber 2/2

8.2. PROCEDURE FOR USE

The i-SEP Autotransfusion Treatment Set already contains a Micro-aggregates Chamber. The Micro-aggregates Chamber described in this leaflet is intended to replace a Micro-aggregates Chamber that is blocked or in which blood flow has slowed down.

8.3. DISPOSAL

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 Micro-aggregates Chamber must be used with the i-SEP Autotransfusion System, and in particular must be connected to the i-SEP Autotransfusion Treatment Set and to the i-SEP Blood Collection Reservoir to filter blood before its treatment.

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	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 associated devices, 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 Micro-aggregates Chamber has been sterilised by gamma sterilisation. See warnings and precautions for risks of infection.

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.
- 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 contaminating 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. Transport and/or storage conditions other than those prescribed may damage the device. 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 Micro-aggregates Chamber consists of a medical device as described in figure 1 of this Instructions For Use leaflet.
An i-SEP Micro-aggregates Chamber is individually packaged in a single package.
The packaging containing the i-SEP Micro-aggregates Chamber has been sterilised.
Twenty-five (25) i-SEP Micro-aggregates Chambers 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.
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.

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).