User's Manual

# WARMPAK HEATING BAG


CE This appliance conforms with the Directive 93/42/CEE "Medical Devices".

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH.

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# Thank you for choosing a Spencer product

## 1. GENERAL INFORMATION

### 1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

### 1.2 Conservation of the instruction manual

The instruction and maintenance manual must be kept together with the product, for the whole life of the device, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

### 1.3 Symbols used

| Symbol | Meaning |
|---|---|
|  | General or specific warning |
|  | See instructions for use |
|  | Lot number |
|  | Product code |
|  | The product is compliant with the specifications of the Directive 93/42/CEE |

### 1.4 Servicing requests

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

### 1.5 Demolition

Follow the current regulations.
When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

### 1.6 Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the Manufacturer, the product, CE mark, lot number (LOT). It must never be removed or covered.

## 2. WARNINGS

### 2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- Spencer Italia S.r.l. is always available for conducting training courses.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained personnel to help when using the device as they may cause injury to the patient or themselves.
- Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Use of the device in anyway other than described in this manual is forbidden.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.

- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Handle with care.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
  In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users o any medical device.

### 2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying an reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the Manufacturer in the user's manual.
- Never leave the patient on the device without supervision, he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Do not wash the device with a washing machine.
- Do not use a drying machine.
- Avoid contact with sharp objects.
- Do not use the device if it is punctured, torn, frayed or excessively worn.

### 2.3 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

## 3. DESCRIPTION OF PRODUCT

### 3.1 Intended use

The loss of heat in trauma patients can be reduced thanks to the use of the heating bag, Warmpak during the infusions.
It can be used with infusion bags of 500 and 1000 cc. At the front there is a window for the monitoring of the amount of solution remaining. Inside, a mesh bag allows for the positioning of an instant heat bag. It can also be used with the IV subministration bag Air WIV or WIV, thus obtaining an efficient control of both the temperature and the pressure of the infusion. The internal lining of Thinsulate guarantees a good thermal insulation from the external environment.

### 3.2 Techinical data

Materials:

- External cover in tear-proof nylon
- Internal lining in Alutex
- Padding in Thinsulate
- Velcro closure

Dimensions: 252 x 6 x h370 mm
Weight: 200 g

### 3.3 Environmental conditions

Functioning temperature: from -10 to +50 °C
Storage temperature: from 0 to +40 °C
Relative humidity: from 20 to 40%

## 4. OPERATING INSTRUCTIONS

### 4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

### 4.2 Functioning

On receipt of the product remove the packaging and display the material so that all components are visible and check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.
In particular, check:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure

## 5. MAINTENANCE AND CLEANING

### 5.1 Cleaning

Failure to carry out cleaning operations may involve the risk of cross infection due to the presence of secretions and/or residuals.

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

The heating bag should not be immersed in water. Wash exposed parts with warm water and mild soap, never use solvents or stain removers. In case of any disinfecting procedures do not use solvents wih corrosive action on the materials constituting the device.
Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which may deteriorate or compromise the integrity and durability of the device. Allow to dry thoroughly before storing.
Drying after washing or after use in wet environments must be natural and not forced, do not use flames or other sources of direct heat.

### 5.2 Maintenance

#### 5.2.1 Precautionary maintenance and periodic maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.
- During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.

Checks to be carried out before and after each use, and at least every 3 months, are indicated on paragraph 4.2.

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage. Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use.

Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance, warranty and will void the compliance to the Medical Device Directive 93/42/CEE.

The device does not require periodic review of the planned interventions by the Manufacturer or an authorized centre.

### 5.3 Special servicing and average life span

The device, when damaged, can not be repaired, but must be put out of service. The device, if used as indicated in the following instruction manual, has an average life span of 3 years. Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorised Service centres.

## 6. ACCESSORIES AND SPARE PARTS

There aren’t any accessories or spare parts for this item.