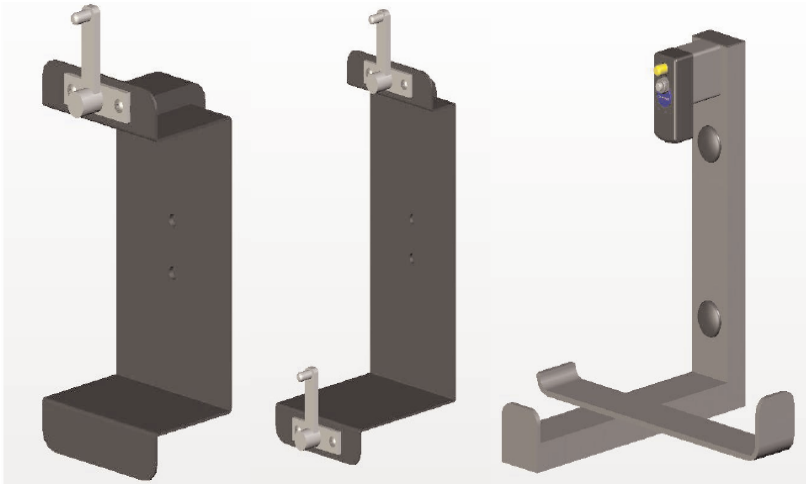


User's Manual

Fixing systems for suction devices



This appliance conforms with the Directive 93/42/CEE "Medical Devices" and UNI EN 1789 normative (not all models).

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 with the product, 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.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the serial number (SN) or lot number (LOT) on the label.

2 WARNINGS

2.1 GENERAL WARNINGS

- The product must be used by trained personnel only.
- 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. Regularly check the appliance.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and the safety, the appliance must be immediately removed from service.
- 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. In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself.
- 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.
- 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.
- Handle with care.
- 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 of any medical device.

2.2 SPECIFIC WARNINGS

- 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.
- 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 of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- When the device is being used, the assistance of qualified staff must be guaranteed.

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 suction device fixing systems have been developed for robust attachment to wall and / or support for the Spencer Suction devices. Models SC10012B, SC60006E and SC73031E are conform to the UNI EN 1789.

3.2 MAIN COMPONENTS

- Main frame in steel
- Lock and unlock mechanism in nylon/steel
- Strap for suction device in nylon (only for models certified UNI EN 1789 and excluding model SC60006E)

3.3 MODELS

SC10012B 10 G Fixation system for Blanco aspirator (certified EN 1789)
SC10013B Fixation system for Blanco aspirator
SC60006E 10 G Fixation system for Porta Vac aspirator (certified EN 1789)
SC73019E Fixation system for Vacu Aide aspirator
SC73031E 10 G Fixation system for Vacu Aide aspirator (certified EN 1789)

3.4 TECHNICAL DATA

Data	SC10012B/SC10013B	SC60006E	SC73019E/SC73031E
Length (mm)	234	134	80
Width (mm)	250	92	92
Height (mm)	254	246	194
Weight (kg)	1.2	1	0,5 / 0,8

3.5 ENVIRONMENTAL CONDITIONS

Functioning temperature: from -20 to +60 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 5 to 85%

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. 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 appliance must be stored in a dry place free from humidity.

4.2 PREPARATION

- On receipt of the product:
 - Remove the packaging and display the material so that all components are visible.
 - 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.

4.3 REQUIREMENTS OF EMERGENCY VEHICLE

The fixing systems for the suction devices have been designed for installation in the patient compartment of an ambulance. The vehicle must have the following features:

- level vertical surface
- vertical surface, large and wide enough to position the fixing without creating any obstacles
- the emergency vehicle should be conform to the UNI EN 1789 normative

4.4 FUNCTIONING

4.4.1 ASSEMBLING THE FIXING ON THE VEHICLE

1. Position the fixture on the vertical surface of the vehicle in its final position
2. Position the fixing fork with the base surface resting against the vehicle. Mark the position for the holes.
Make holes and match the following nuts and bolts:
 - TCEI M8 8.8 screws and washers Ø 8x24x2 (for models SC10012B/SC10013B)
 - TPSEI M6 10.9 screws and washers Ø 6x18x2 (for models SC60006E/SC73019E/SC73031E)From the opposite site, position a plate with the same dimensions as the surface to be attached.
3. When present (depending on model) take the strap and fix to suction device so the collection vase and the body of the suction device are firmly attached together.

For the device PORTAVAC make sure that the protection/transport bag is included.

4.4.2 BLOCKING THE SUCTION DEVICE TO THE FIXTURE

1. Load the suction device onto the fixture of the ambulance as required.
2. Using the purpose made mechanism, block the device.
Check that the suction device is properly and firmly attached to the structure.

4.4.3 RELEASING THE DEVICE FROM THE SUPPORT

1. Using the unblock mechanism release the device.
2. Remove the device and use as required.

4.5 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The fork hook does not move	The movement spring is broken or damaged	Remove the device immediately from service and contact the authorised service centre
Damage to the structure	Incorrect use	Remove the device immediately from service and contact the authorised service centre

5 MAINTENANCE AND CLEANING

5.1 CLEANING

The metal parts exposed to external agents are treated and / or coated to ensure a longer life span. Clean exposed parts with a delicate soapy sponge then dry using a soft cloth or a chammy leather. To increase the polished effect we advise use of creams normally used to polish car bodywork. High pressure water systems must not be used as it penetrates into joints and removes lubrication which increases the risk of corrosion. Failure to complete a correct cleansing routine will increase the risk of cross infection caused by the presence of residuals and/or secretions. We also advise use of the Spencer STX 99 (code ST50000E) polishing detergent on the metal components.

5.2 MAINTENANCE

5.2.1 Precautionary 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.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- 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.

Checks that must be done before each use:

- Device functioning
- Nuts and bolt tightening
- Wearing (for moving parts)
- Correct functioning of springs in fixing system.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device. Other than the controls previously mentioned, no programmed servicing routine is required.

5.2.2 Special servicing

Only the Manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device. The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the Manufacturer or by a centre authorised by the Manufacturer.

6 ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

No spare parts are available for these products.

6.2 SPARE PARTS

ST00419B Fixing straps for suction device vase.

Warning

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.