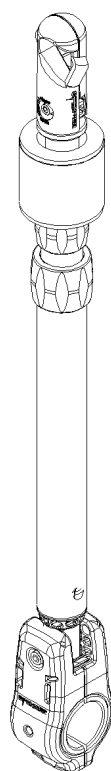


## User's Manual

# TRACK 4 Telescopic I.V. pole



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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## 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 [service@spencer.it](mailto:service@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 the lot number (LOT) shown on the label applied on the box or on the device.

### 1.5 Demolition

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 at your disposal to plan trainings on products.
- 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 persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the Manufacturer in this 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.
- 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. 24<sup>th</sup> 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.
- As a Distributor or End Users of products manufactured and/or marketed by Spencer Italia S.r.l., you are strictly required to have a basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the goods final destination Country (including laws and norms regarding technical specifications and / or safety requirements) and therefore you are also strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.
- Promptly notify Spencer Italia S.r.l. regarding any revisions to be made by Manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, as specified in the relevant User Manual.
- Actively contribute to product safety checks on products sold, by communicating any relevant risk analysis information both to the Manufacturer and to any competent authorities so that the necessary action can be promptly taken.
- You are aware that in the event of any failure to conform to the above mentioned requirements you will be deemed fully responsible for all damages that might occur. Therefore we expressly disclaim any responsibility and/or liability for your non-compliance with the present "Regulatory provisions".



## 2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying a 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.
- 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.

- Use only accessories/spare parts that are original or approved by Spencer Italia S.r.l., in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Always respect the maximum capacity of the device, as indicated in this user's manual.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Protect the device from strong bumps or vibrations.
- Avoid contact with sharp objects.
- Do not use the device if it excessively worn out.

### 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 telescopic I.V. pole Track 4 is a robust and practical I.V. pole made of aluminium, which can be fixed to the stretcher easily. When not in use, the I.V. pole is folded and fixed to the stretcher frame. Only two actions are required to take the device into vertical position and choose the correct height. At the top of the I.V. pole there are two robust hooks made of nylon, where to hang the intravenous bottles or bags (max. 2 pcs), with maximum load of 1 kg. A system made of a strap with Velcro® closure allows to fix the intravenous bottles or bags to the I.V. pole, avoiding roll movement.

### 3.2 Main components

n°	Description of component	Materials	Track 4-30	Track 4-E	Track 4-Rail	Track 4-28	Track 4 Ella Self
1	Main structure	Nylon	•	•	•	•	•
2	Folding tube	Aluminium	•	•	•	•	•
3	Regulation selectors	Aluminium	•	•	•	•	•
4	Strap for I.V. bottle support	Polypropylene	•	•	•	•	•
5	Hooks	Nylon	•	•	•	•	•
6	Manual fastener	Nylon				•	

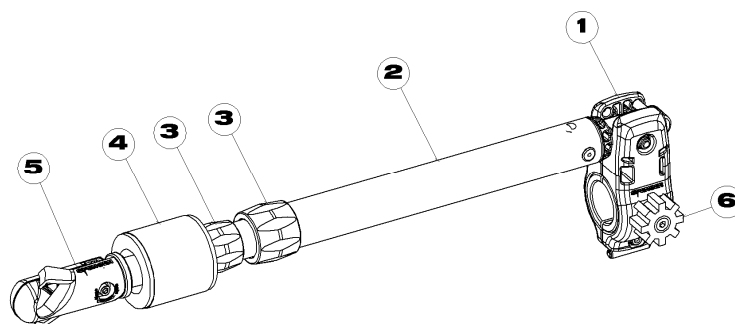


Fig. A

### 3.3 Models

**This model could be modified, with reference to codes and/or descriptions without any previous notification.**

IF01044B	Track 4 telescopic I.V. pole for Ella Self self-loading stretcher
IF01047C	Track 4-30 telescopic I.V. pole
IF01048C	Track 4-E telescopic I.V. pole
IF01064C	Track 4 for Rail-Sherpa
IF01046C	Track 4-28 for emergency stretcher

### 3.4 Technical data

Characteristics	Track 4-30	Track 4-E	Track 4-Rail	Track 4-28	Track 4 Ella Self
Width open (mm)	40	40	40	40	40
Width closed (mm)	490	490	490	490	490
Length (mm)	65	65	65	65	65
Maximum height (mm)	870	870	870	870	870
Minimum height (mm)	450	450	450	450	450
Weight (kg)	0.57	0.57	0.57	0.57	0.57
Load capacity (kg)	1	1	1	1	1
Material	Alluminium	Aluminium	Aluminium	Aluminium	Aluminium

### 3.5 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices
Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN ISO 15223-1	Medical devices - Symbols to be used in the medical device labels, labeling and information to be provided. Part 1: General requirements
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1 /Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans

### 3.6 Environmental conditions

Functioning temperature: from -15 to +50 °C

Storage temperature: from -20 to +60 °C

## 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 Preparation

On receipt of the product, remove the packaging, 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
- Correct fixation of all nuts, bolts and screws
- State of use
- Integrity of components
- No tube or metal sheet present bends or cracks

If the above conditions are met, the device may be considered ready for use; otherwise you must immediately remove the device from service and contact the Manufacturer.

### 4.3 Functioning

#### 4.3.1 Assembly

The installation of Track 4 must be made as follows:

1. Insert the plastic pin n. 6 into the hole on the two plastic clamps n. 1 and couple them to the bearing tube of the device, as in fig. B.
2. Insert the aluminium tube n. 2 into the cavity which is obtained by the union of plastic parts, as in fig. C.
3. Secure the body obtained with the socket head screws n. 7 provided.
4. Tighten the TBEI screws n. 8 totally, which, according to the model of the device, will go to press against the walls of the supporting tube or will fit into the holes on the existing profile, fixing in each case the Track 4 I.V. pole.
5. For the emergency stretcher's version (IF01046C) tighten the fastener n° 6 fig. A, to solidarise to the emergency stretcher in the vertical position.

**Note:** In the model IF01044, the screw n° 8 is not present.

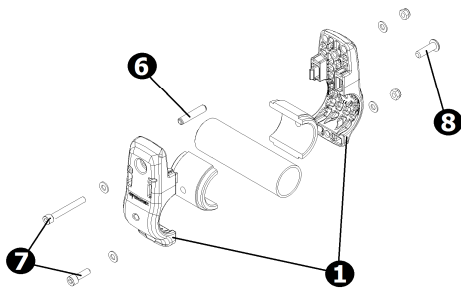


Fig. B

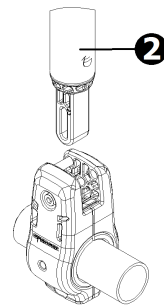


Fig. C

#### 4.3.2 Opening the device

6. Move to the right the aluminium tube n. 2.
7. Lift it until it is horizontal.
8. Slightly unscrew the nuts n. 3 to make possible to remove the inner tube.
9. Place the nuts to the desired height and then tighten.

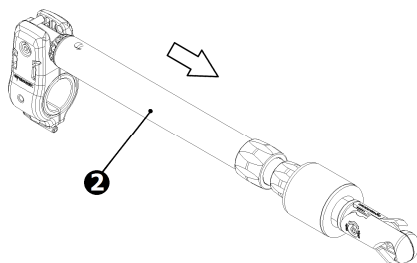


Fig. D

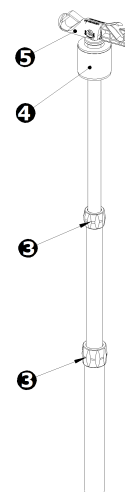


Fig. E

#### 4.3.3 Fixation of intravenous bottles and bags

1. Remove the support hooks n. 5 from their place.
2. Rotate them 90°, the first on one hand the second the other hand.
3. Unroll the band n. 4, surround the infusion bag or bottle and fix them by means of the Velcro® strap.

#### 4.3.4 Closing the device

1. Slightly unscrew the nuts n. 3 and close to the lowest position the various tubes.
2. Lower profile until it is horizontal.
3. Move to the left the aluminium tube n. 2.

#### 4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The I.V. pole is not perpendicular to the surface on which it has been applied	Wrong assembly	Disassemble and reassemble the device
Damages to the structure	Improper use or non adequately trained personal	Put the device out of service and contact the service centre

### 5. MAINTENANCE AND CLEANING

#### 5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals.



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

The exposed metal parts are usually treated and/or painted in order to increase their resistance. Clean the exposed parts with water and delicate soap, never use solvents or stain removers.

In the event of a possible disinfection use products that do not have solvent or corrosive action on the materials constituting the device. In order to obtain a shine effect, it is possible to use car waxes and creams. We recommend the use of the polishing detergent Spencer STX 99.

Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which could degrade or compromise the integrity and durability of the device. The use of high pressure water should be avoided. Water penetrates the joints and removes the oil, creating the risk of corrosion of components.

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

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.



**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 as follows:

- 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
- Correct fixation of all nuts, bolts and screws
- State of use
- Integrity of components
- No tube or metal sheet present bends or cracks

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 person responsible for routine maintenance must identify damaged/worn parts, but the replacement or restoration of them can only be carried out by the manufacturer or by an authorized service centre.

For other replacement/repair activities contact the Manufacturer or an authorized centre.



Use only accessories/original spare parts approved by Spencer Italia S.r.l., otherwise we 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. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

### 5.2.2 Periodic maintenance

The device does not require periodic review of the planned interventions by the Manufacturer or an authorized centre, but is prescribed to clean it and check it as described on the paragraphs "Cleaning" and "Maintenance".

### 5.2.3 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 3 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.

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, making void the guarantee and the conformity to the Medical Devices Directive 93/42/CEE.

## 6. ACCESSORIES AND SPARE PARTS

### 6.1 Accessories

There aren't any accessories for this product

### 6.2 Spare parts

IF00207A	Support strap
IF00204A	Upper part I.V. pole
IF00208A	Nylon hook



**ATTACHMENT A – TRAINING REGISTER**

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.



Keep this document at least 10 years from the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc.)	Trainer
	Basic training	Advanced training		

**ATTACHMENT B – MAINTENANCE REGISTER**

Keep this document at least 10 years from the end of life of the device.



Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

<b>Code and description of the device</b>	
<b>Purchase date</b>	
<b>Lot (LOT)</b>	
<b>Bought by</b>	

<b>SERVICE DATE</b>	<b>KIND OF SERVICE (Maintenance/ check/ extension of life span)</b>	<b>OPERATIONS MADE ON THE DEVICE</b>	<b>RESULT</b>	<b>PERSON IN CHARGE OF SERVICE (Operator/ Authorized centre/ Manufacturer)</b>

**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.

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