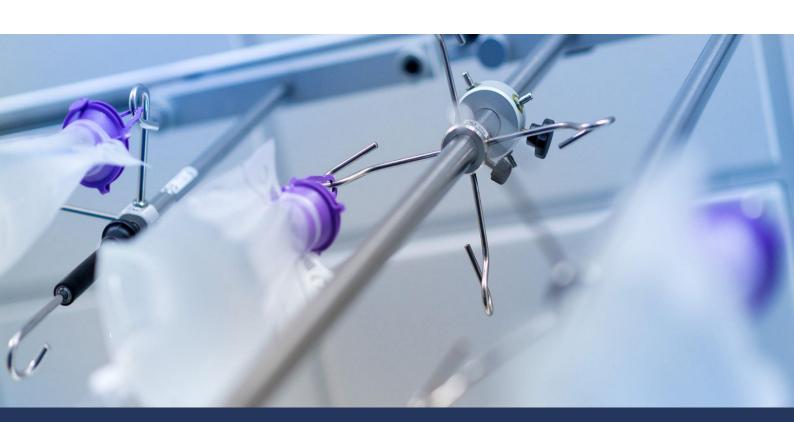


User Manual

Device carrier medical devices

42601239310J5_EN

V001





1	General information						
	1.1	Notes and their meaning	3				
	1.2	Information on the instructions for use	4				
	1.3	Intended use	4				
	1.4	Liability and warranty	4				
	1.5	Identification plate	5				
2		Safety information6					
3		Assembly					
4	Operation11						
	4.1	Screw hight-adjustment	11				
	4.2	Single-handed height adjustment	11				
5		Cleaning and maintenance	12				
6		Maintenance and care	13				
7	Environmental conditions13						
8	Maintenance history14						
9		Service life15					
10		Service	15				
11	1 Technical data						



1 General information

1.1 Notes and their meaning

A DANGER

This symbol in conjunction with the signal word "Danger" indicates an imminent danger. Failure to observe the safety instruction will result in death or serious injury.

A WARNING

The symbol in connection with the signal word "Warning" indicates a possibly dangerous situation. Failure to observe the safety instruction may result in death or serious injury.

A CAUTION

The symbol in connection with the signal word "Caution" indicates a possibly dangerous situation. Failure to observe the safety instruction may result in minor or slight injuries. It may also be used for property damage warnings.

NOTICE

The symbol indicates a possibly harmful situation.

Failure to observe the safety instruction may result in damage to or destruction of the product and/or other system parts.

NOTE

Here you can find information or references.



1.2 Information on the instructions for use

The product is a technical aid. They need to be explained, require regular care, and involve risks in the event of improper use.

It is therefore necessary to learn proper handling.

These instructions for use are intended to help you familiarise yourself with the handling of the product as well as avoid accidents.

Obligation to report serious incidents/incidents

All serious incidents that have occurred in connection with the product must be reported to the manufacturer and the relevant competent authority in accordance with the reporting deadlines of the MDR.

1.3 Intended use

Provita equipment carriers are used to hold equipment with suitable fixing material and to make it transportable by means of a chassis. Depending on the design of the carriers, it may also be possible to attach gravity infusion solutions in bag or bottle form. The infusion speed of the infusion is influenced according to medical aspects by the doctor's instructions by adjusting the relative suspension height to the patient.

Intended operator (user)

Professional users such as doctors, medical assistants, nurses, trainees in the hospital sector.

Age: from about 16 years.

(The operator must be able to read and understand the instructions).

The operator must be attentive.

Normal vision (also with glasses or contact lenses if necessary).

1.4 Liability and warranty

The statutory warranty applies for this product within the scope of our general terms and conditions.

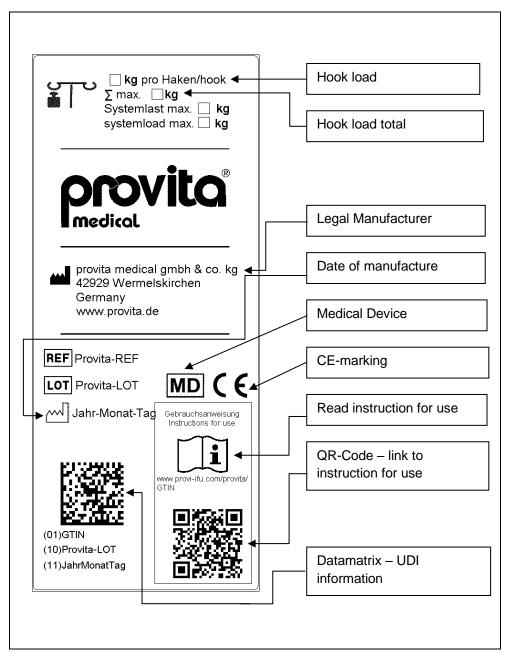
All data and information are supplied based on our previous experience and findings to the best of our knowledge. We reserve the right to make technical changes in line with further development.

NOTICE

We accept no liability for any damage caused by failure to observe this user manual.



1.5 Identification plate



NOTE

The operating instructions can be accessed in digital form by scanning the QR code on the type plate.

Blind and visually impaired users can download the operating instructions in digital form from the Provita homepage by scanning the QR code on the type plate and have them read aloud with their software.



2 Safety information

A DANGER

The product may only be assembled, handled and used by trained personnel. This requires careful observation of the information for safety. If the system is operated improperly, this may result in hazards to persons and objects!

A DANGER

To avoid dangerous situations, the use of the device carrier should first be practice.

- Before using the device carrier, please check that all attached parts are fixed correctly and are not damaged.
- The data for the possible maximum loads of the bottle crosses per hook; hook total and system load of the device carrier can be taken from the type plate which is attached to the device carrier.
- If necessary, it is possible to attach additional loads, e.g. devices, to the outer tube. The permitted system load can be taken from the type plate.
- The stability against tilting (stability) is guaranteed up to 5° inclined position. Never place the device carrier on inclined surfaces!
- Be careful with the device carrier when fully loaded, as it could tip over!
- To move the device carrier, the brake rollers must be released and the device carrier must be guided by hand! Special care must be taken when driving over obstacles, soft floor coverings and slopes. The extension tube of the IV-pole must be retracted completely.
- Only use accessories approved by the manufacturer.

NOTICE

The manufacturer accepts no liability for damage caused by insufficient maintenance or by failure to comply with the following instructions. Compliance with the user manual and the maintenance instructions is an essential part of the validity of the warranty.

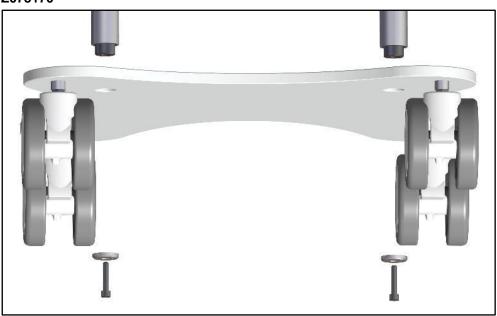
Obligation to report serious incidents/incidents

All serious incidents that have occurred in connection with the product must be reported to the manufacturer and the relevant competent authority in accordance with the reporting deadlines of the MDR.

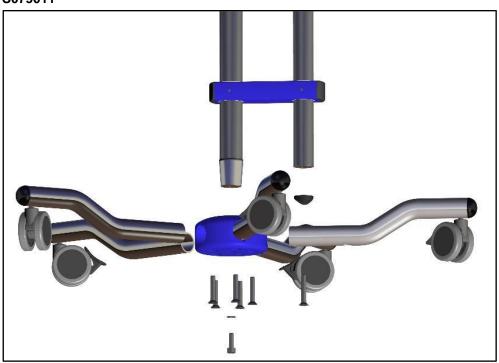


3 Assembly

Z073170

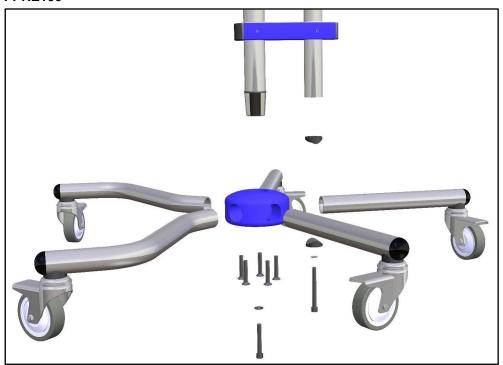


S079011

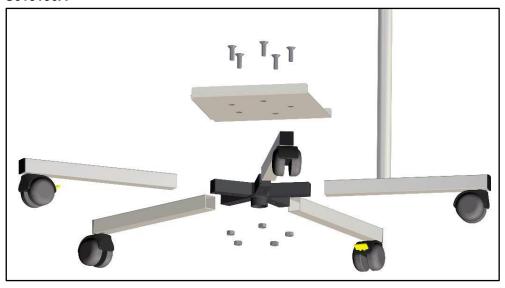




I-PRE100

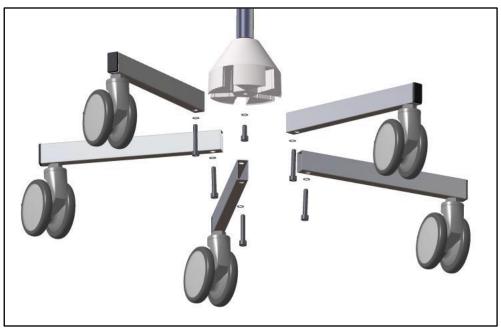


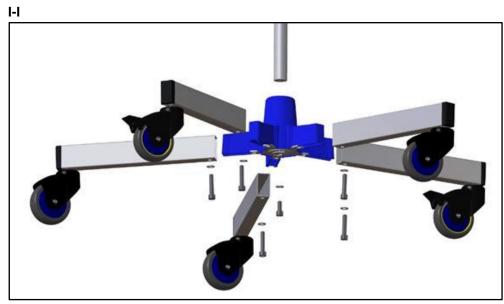
S013190A





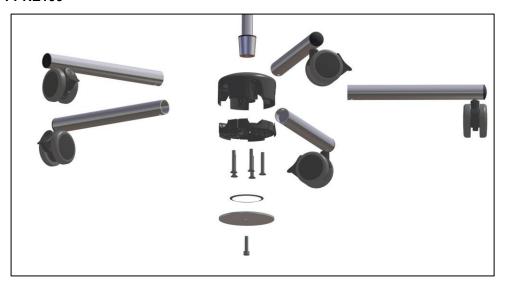
I-P



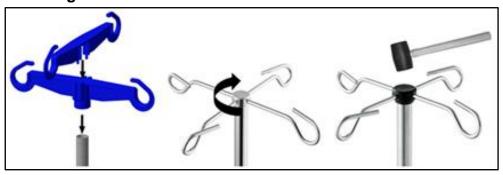




I-PRE100



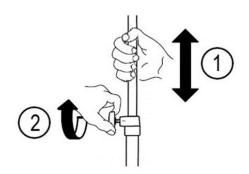
Mounting bottle cross





4 Operation

4.1 Screw hight-adjustment



Please do hold the upper tube ①, when releasing the adjustment screw ② for adjusting the tube. Position the tube into the required height and do tighten the adjustment screw ②. Do not release the upper tube ① until the clamping force is sufficient for the requested use. Please do not forget to include the additional weight of the infusion bottles.

A WARNING

Risk of eye injury. Keep a safe distance from the bottle hooks!

Risk of crushing fingers or hands by operating the height adjustment!

Risk of uncontrolled lowering of the load by actuating the height adjustment!

4.2 Single-handed height adjustment



For adjustment of the inner tube the re-lease ring needs to be lifted with the thumb.

When removing the thumb from the ring the inner tube is automatically fixed at the re-quested position.

A CAUTION

When the IV-pole is loaded, the inner tube lowers when the actuation ring is triggered.



5 Cleaning and maintenance

NOTICE

Chloride-containing fluids (e.g. physiological saline) and blood have to be removed to avoid formation of rust. After removal, rinse with water to fully remove any residues.

NOTICE

Follow the manufacturer's instructions and the current hygiene regulations for cleaning and disinfection.

NOTICE

Non-pH-neutral and chemically active disinfectants can lead to surface and material damage.

The following products/ingredients should not be used when cleaning and disinfecting:

- Hydrocarbon solvents (gasoline, paint thinner) can damage coatings and plastics
- Agents with more than 10% alcohol content for coated / plastic parts
- with strong acids or alkaline liquids
- Halide or Halogen releasing compounds (chlorine, bromine, iodine) can also cause corrosion.
- Surface-scratching products (e.g. abrasive, wire brush, steel wool)
- Water / cleaning sponges containing iron particles
- Hydrochloric acid-containing products

NOTICE

Do not use any mechanical cleaning and disinfection procedures (washer system, pressure washer)



6 Maintenance and care

The product must be checked annually by qualified staff regarding the correct function of the device:

Further information regarding Maintenance history can be found on page 14 In case that a component of the device is damaged, it must be replaced only with original parts by a trained specialist. Contact the manufacturer or your local distributor for more information.

Dispose the device according to the local and national regulations.

Apart from the transport and stock-keeping conditions below, no special measures are required for storing the product. Before returning to service after an extended period of non-use, the product should be inspected according to the maintenance plan/checklist.

7 Environmental conditions

For transport and stock-keeping the following stock-keeping conditions have to be heeded:

Temperature: -25 bis 70 °C Humidity: 30-75% Atmospheric pressure: 700-1060 hPa

-25 °C 700 hPa 700 hPa 30 % 75 %

At application you have to assure the ambient temperature from 10 °C to 75 °C.



8 Maintenance history

The user/operator is obliged to check/approve the system in regular times. In case of non-conformity to one of the below points the affected component has to be decommissioned immediately.

Please do confirm – by signing the below listed technical things- that the inspection was made and the result did not show any negative condition of the system:

Integrity		Function		Completeness	
The device carrier should be checked at least once a year on full functionality of all components.		The function of the bottle hooks. The function of the hight adjustment. Clean rolls of dirt so that the brakes work and the electrical conductivity is not reduced.		If an error is detected, only original spare parts may be used and only be replaced by a specialist or Customer Service.	
Date	Signature	Date	Signature	Date	Signature

A DANGER

If the products do not fit/fulfil all above mentioned items of the list, the safe use of the system cannot be guaranteed and suitable actions have to be taken – in order to solve the problems.

The system must NOT be used when proper operating is not guaranteed.



9 Service life

The product is expected to have a service life of 7 years, assuming that it is only used for its intended purpose and is subject to regular and correct maintenance.

The service life largely depends on the frequency of use, the operational environment, and upkeep.

The service life of the product can be extended by using original spare parts. For more information, contact the manufacturer or the distributor.

The service life indicated does not constitute an additional warranty.

10 Service

Please contact the manufacturer or the local distributor if you have any questions about the product, if a repair is due, or if you require information regarding service partners.

Address data is provided at the end of this manual.

11 Technical data

Type plate:	on the product
Service life	7 years





provita medical gmbh & co. kg

Auf der Huhfuhr 8 42929 Wermelskirchen Germany

Phone +49 2193 5105-0 Fax +49 2193 5105-269

www.provita.de info@provita.de