UDAPTION®

INSORS® GMBH

FrameClamps

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CE

General safety and warning instructions for the **"FrameClamps"**

1. General

Thank you for choosing a product from the UDAPTION® series.
Please read these safety and warning instructions before using the product.
Proper usage requires additional information from the "Assembly and Operation" manual and the cleaning instructions. You can find these on the website under the respective product (www.udaption.com). Please also consider the notices that may be placed directly on the products themselves. When passing on the product, all the documents mentioned here must be enclosed with the product so that the next user has all the necessary information.
The Udaption® series is an accessory for assistive communication (AC), information (IT) and environmental control (ECU) devices.

Symbolism

Safety and Warning Instructions


Warning of significant risk of damage to the user, the adapted auxiliary tool, or the Udaption® series product itself if these instructions are not followed.


Warning of significant injury risk to the user if these instructions are disregarded.


Warning of possible damage or malfunctions to the product if these instructions are ignored.


Notice of loss of warranty claim due to disregard of the prohibition.


Special attention to the user that is offered here!


Indication for correct handling or adjustment


Indication on handling or settings that fall within the scope of acceptance.


Notification of incorrect/improper setting or handling.


Close / Screw down


Open / Unscrew


Half-open / half-close


Note on accessories / attachments with a separate user manual.

Labels on manuals, packaging, products, and accessories


UKCA is the product labeling that confirms that the product may be marketed in England, Scotland and Wales because it meets their requirements.

The CE mark indicates that a product has been tested by the manufacturer and that it meets all EU-wide safety, health and environmental requirements.

Refer to the user manual!

REF Article number

SN Serial number

LOT Batch labeling

MD Medical device

UDI Unique Device Identification

Choking hazard (user exclusion / accessibility warnings)


Protect from moisture


Do not reuse


Manufacturer


Manufacture date

Purpose determination / Use purpose

The Udaption® "FrameClamps" models are clamping devices that can be removably fastened or clipped to mobility aids, nursing beds, nursing furniture in general, or other similar third-party products. They are designed to accommodate the "Mobile", "Headswitch" or "Bed" mounts of the Udaption® series. To ensure optimal support for each adaptation, there are different types of clamps available to meet the various requirements. These include: round tubes and square tubes in different sizes, oval tubes, plates with groove stones for rail mounting, plates for screw mounting M8/M6 for fixed mounting points, and more. The aforementioned Udaption medical products come into use when the usual operating routes are not available to users due to an existing disability (disability compensation). It is only through the use of the Udaption Frame Clamps that these medical products can be employed.
The Udaption® "FrameClamps" are an accessory for assistive devices and are neither life-sustaining nor supportive.
Places of use: Corresponding environmental conditions of connected mobility aids/third-party products. For indoor and outdoor use.
For further technical data and instructions, please refer to the manual "Assembly and Operation", as well as the manual for Cleaning and Disinfecting the Udaption® series.
Indications: Persons reliant on mobility aids and adaptive technologies to communicate (AC), to access information technologies (IT), or to control their environment (ECU).
Contraindications: None
Patient target group: individuals with significant motor impairments, also related to communication ability restrictions, due to diseases and disabilities (either acquired, hereditary, or degenerative in nature).
This includes, among other things:
Infantile cerebral palsy, neuromuscular diseases like ALS, muscular dystrophies, MS, spinal cord damage with tetraplegic development, multiple amputations, acquired brain injuries from strokes, traumatic brain injuries or inflammatory processes, Rett syndrome, Angelman syndrome or other severe multiple disabilities.
Intended user:

- Setup and commissioning: Qualified dealers or other suppliers with the appropriate expertise.

- Operation: Assistants, caregivers, family members, therapists, and other people working in the patient's environment who are knowledgeable about the handling of the Udaption® "Mobile series."
  In cases where there are indications of corresponding well-developed motor skills, operation by the user themselves cannot be ruled out, at least in part.

Scope of delivery

Check the delivery contents against the specifications in "Assembly and Operation" manual of the respective product. If necessary, additional complementary products may be required to fully utilize the product. Should these be absent or incomplete, please contact your supplier.

2. Safety

The products from the Udaption® series by Insors® GmbH meet all specifications and standards for medical devices. However, to ensure safe setup, operation, and reintegration of the Udaption® series, the following safety warnings and instructions must be observed:

General safety and warning instructions


The use of **unauthorized accessories or unacceptable modifications** to the product may lead to hazards and/or injuries to persons and damage to property. Therefore, **only use accessories approved by Insors® GmbH** for combination with the relevant product or that have standardized connection options. Make **modifications** to the product **only in accordance with the associated** assembly and operating instructions, or if the modifications have been **approved in writing by Insors® GmbH**.


Pay attention to **correct assembly** according to the assembly instructions. Incorrect assembly may impair the stability and functionality of the product and may continue to cause damage to the adapted aid or even lead to physical injuries.


The small parts and packaging materials supplied should be kept out of the reach of children. **There is a risk of choking**.


Observe the **maximum permissible adaptation weight** of the product and the adaptation base (wheelchair, bed, wall, etc.) to prevent damage to the Insors® GmbH product or the adaptation base.


Do not use force or excessive pressure. This can damage the Insors®GmbH product or the adapted aid.


Caution, risk of crushing! Always ensure that when installing / using Insors®GmbH products, body parts do not come into contact with the moving parts of the mounts.


Products of the Udaption® series are delivered ready for use. **Do not use lubricants, solvents, or the like**. The use of such means should only occur during maintenance/repair by trained personnel. Refer to the chapter **"Maintenance and Repair".**


!Before transporting the mobility aid (e.g., wheelchair) or loosening the screws and levers, remove all adapted aids to prevent damage**!**


Do not permanently attach objects that are not part of the usage scope to the product of the Udaption® series, as this may negatively affect its function and stability.


All safety and warning labels on the product must always remain clearly visible.


Before assembling a "FrameClamp", the mounting surface should be thoroughly cleaned and kept grease-free. Only then should you apply any adhesive primer that might be used. Please pay attention to the instructions from the adhesive primer manufacturer.


Use only reduction sleeves from the Udaption® series.


Ensure that the "FrameClamp" is the correct size. Dimensions of the "FrameClamp" that are too large or too small reduce the stability of the connection or may damage the clamp base.


"Use the appropriate screws (length), as long as the product includes multiple selections. The threads should be completely penetrated by the screw. The thread protrusion should be kept to a minimum."


Ensure sufficient stability of the clamping points (pipes, plates, etc.) and do not use the clamps on curved pipe sections or carbon frames.

When selecting the mounting point on the mobility aid/third-party product, ensure that neither the mounting itself nor the operation of the holder with the adapted assistance adversely affects the critical functions of the mobility aid.
This includes, for example, brakes, adjustable levers, tilting, wheels, adjustable footrests, seat depth adjustment, seat height adjustment, swing-away armrests, and much more.
Align the adjustable handles of the clamping levers so they run parallel to the tubes.

When tightening the screws, ensure that the clamps are positioned symmetrically. Tighten the screws evenly and alternately. Observe the general maximum torques for 8.8 screws (e.g., M6 = 10 Nm, M8 = 25 Nm).

Udaption "FrameClamps" are not compatible with mounting systems from other manufacturers.

3. Responsibilities

Ensure **proper and stable assembly** of the product to use it as intended. Insors®GmbH disclaims any liability for improper assembly.
The responsibility for assembly, commissioning, and instruction lies with the specialized **personnel of the supplier**. **The responsibility for safety and functionality** during use lies with **the users**.

4. Lifespan

Using an Udaption® product beyond the intended usage period involves increased risks. Therefore, it is advisable to have a preliminary assessment by professional personnel (aid device supplier) to determine to what extent the product can be refurbished or maintained for continued use.

5. Safety for persons with impaired judgment

Insors®GmbH products are not toys! They should therefore not be used by children or individuals with impaired judgment for playing.
Otherwise, there is a risk of injury or damage to Insors®GmbH products or the adapted aids.

During the assembly or modification of products in the Udaption® Series, small parts can become separated (choking hazard) or other situations that could cause injury may arise. Young children or individuals with limited judgment should not be able to modify Udaption® products without the supervision of a responsible caregiver.

6. Report severe cases

Please report all incidents to the following email address (customercare@insors.de).
An "incident" refers to a malfunction or deterioration of the characteristics or performance of the Insors®GmbH product, including application errors due to ergonomic features, as well as a deficiency in the information provided by Insors®GmbH or the supply source, or an undesirable side effect (source MDR). All serious incidents related to the product must be reported to Insors®GmbH.

7. Installation

Installation of Insors®GmbH products must be carried out according to the instructions in the “Installation and Operation” manual and in compliance with the general safety and warning notices (this document).
The adaptation of aids to Insors®GmbH products must be carried out exclusively in accordance with the manufacturers' instructions for aids and/or according to the specifications of Insors®GmbH.
The safety and function of the adaptation base (wheelchair, bed, chair, etc.) must not be compromised by improper assembly of Insors® GmbH products (e.g., shift of center of gravity leading to a tendency to tip over, exceeding load limits, blocking of folding mechanisms, etc.).
Please contact the source of supply for the adaptation base if doubts arise regarding the maintenance of its safety and performance.

8. Maintenance and repair

A damaged product or worn components can injure users or third parties. Please only use the product if you can rule out any defects/wear. If you are unsure, please contact your supplier. Repairs/maintenance or safety checks may only be carried out by trained specialists. Depending on the intensity of use, annual maintenance is recommended (heavy use). In accordance with Sections 3 and 7 of the Ordinance on the Installation, Operation, and Use of Medical Devices (MPBetreibV), a safety inspection = **maintenance is recommended at least every 2 years**. In accordance with Section 7 (MPBetreibV), the responsibility lies with your medical device supplier. Therefore, please contact them in good time.

9. Verification of proper use:

To ensure proper use, all connections on Insors®GmbH products must be adjusted according to the "Assembly and Operation" instructions. Screwed connections should not be tightened with force. If unusual force is required to clamp a connection, have the product inspected by trained personnel. Regularly ensure that safe use is guaranteed. Detailed information and assistance with questions regarding maintenance and service can be obtained from your aid advisor / supplier or directly from Insors®GmbH.

10. General cleaning instructions:

Products from the Udaption® series should be cleaned regularly, depending on the intensity and the environment of use.
This ensures impeccable hygiene and functionality.
The user or their supportive environment is solely responsible for the cleaning of Udaption® products. Ignoring this directive may result in the loss of product warranty and may affect the clinical condition and safety of users and/or caregivers.
The necessary instruction "Cleaning and Disinfection Guidelines" can be found on our website (www.udaption.com) under each respective product.

Summary: Please wear protective gloves. Ensure that no water can penetrate pipes, bearings, or joints. Wipe all parts with warm water and a **non-abrasive detergent** using a wrung-out cloth. Then, wipe dry with a dry, lint-free cloth. Disinfect all surfaces that come into contact with users (70% alcohol wipes). Subsequently, the Udaption® product can be dried with a paper towel to prevent staining.

11. Lifespan

The expected lifespan, (considering typical usage intensity and number of reuses) is 5 years. Provided that the intended and proper use is followed, the service and maintenance intervals are adhered to, and the instructions from the manuals "Assembly and Operation", "General Safety and Warning Instructions" and the "Cleaning and Disinfection Guidelines" are observed.
The specified lifespan of 5 years is not guaranteed and is subject to a case-by-case assessment by qualified personnel, for example, in the event of reuse.
If the product is to be used beyond the 5-year period, an inspection of the condition/overhaul of the product by qualified personnel is necessary. The lifespan can also be shortened depending on the frequency of use, the operating environment, and maintenance. The lifespan does not apply to wear parts, such as wheels and plastic parts, which are subject to material-specific aging and/or wear. This specified lifespan has no relation to the warranty or guarantee.

12. Reutilization

Before reuse, please contact your assistive device supplier or Insors®GmbH. The Udaption® product may only be redistributed for reuse if it has been inspected and refurbished according to Insors®GmbH's safety and performance requirements.

13. Disposal

The Udaption® products of Insors® GmbH must be disposed of in accordance with the regulations applicable in the respective country.

14. Warranty terms

Insors®GmbH provides full warranty on all Udaption® brand products against any form of product defect, for a period of two years from the date of purchase, documented by a purchase receipt (referencing the serial number, if the article carries one).
This 2-year warranty covers all components supplied with the product and also includes the consequences of wear, improper handling, or faulty installation. During this 2-year warranty period, Insors®GmbH provides free replacement of defective parts or the complete product with new or like-new components. Shipping costs are covered by Insors®GmbH, but on-site assembly services are excluded from the warranty. Also excluded are damages resulting from deliberate use contrary to the intended usage or intentional damage.
Insors®GmbH assumes no liability for indirect damage to objects or persons caused by the use of Udaption® products. The company excludes any compensation for damages to adapted aids, adaptation bases (wheelchair, bed, chair, etc.), and furniture, as well as liability for personal injuries. Compensation for loss of use due to faulty Insors®GmbH products cannot be claimed.

Extended, yet limited, 5-year warranty on all Insors®GmbH products. Insors®GmbH warrants all products under the Udaption® brand for material and workmanship defects for a period of 5 years from the product's original purchase date, evidenced by a purchase receipt mentioning the serial number if applicable. During the 5-year warranty period, Insors®GmbH provides, at its discretion, free replacement of defective parts or the entire product with new or like-new components, or conducts repairs on the original product.
Shipping costs are the responsibility of the customer, on-site assembly services are excluded. This limited warranty applies to all components delivered with the product and only covers issues arising from material or workmanship defects of the product during intended use. Indications of non-compliance will void the warranty for the product. Excluded from the warranty are wear parts such as screws, levers, and all threads, as well as consequences of improper use.

15. Customer service

For technical questions, please contact your assistive devices consultant / supplier or email customercare@insors.de. To receive assistance as quickly as possible, have your Udaption® products nearby and know which product you have (article number / delivery note instructions or similar, where the exact designation / configuration of the product is specified).

16.Responsible Person

UK	REP

Patient Guard Ltd, Lancaster House, Amy Johnson Way, Blackpool, Lancashire, FY42RP. United Kingdom