VersaInserto®
SEATING SOLUTIONS

INSTRUCTION MANUAL

Inserto® SEAT

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ProMedicare®

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NOTE: The Illustrations in the following Instruction Manual may differ from reality; however, the methods of use and operation remain valid at all times. All technical data in this manual are approximate and do not constitute specifications.

INTRODUCTION

Dear User, thank you for choosing the Pelvis Positioning Solution of the *VERSA INSERTO SEAT* Range, which is the combination of technology and experience in the development of Positioning Systems for user with limited mobility. The Inserto Pelvis Positioning Solutions can be simply adapted to the user as needed. They can be customized, shaped and modified as written prescription, they can be fitted and adjusted to the anatomy and morphology of the user, by taking the body measurements and carrying out direct checks, in order to obtain a made-to-measure positioning for the perfect reconstruction of their anatomical shapes, for the support and compensations of the deformities and to provide the body pressure distribution.
The Pelvis Positioning Solutions of the *VERSA INSERTO SEAT* Range are adjustable to somatic growth and pathological changes. Their composition makes them very comfortable, achieving optional comfort with the maximum functionality by offering high postural solution. They can be placed on any support base and/or on any manual /electronic wheelchair by operating with male/female fastening systems, after checking that there is a support base or preferably a solid base.
As manufacturer, PRO MEDICARE declares that the medical device complies with Regulation (EU) 2017/745. PRO MEDICARE's Quality Management System is certified according to ISO 9001 and ISO 13485 standards. This manual, drawn up on the basis of the requirements of Regulation (EU) 2017/745 on Medical Devices, is an indispensable tool for learning how to use the Device safely. To this end, it is necessary to read the information about how to use it carefully, with the express invitation to follow the prescribed indications and the product technical sheet.
As a manufacturer, PRO MEDICARE refers to the *Professional User* as the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), and to the *End User* (or *lay person*) as the person who is intended to use the Device (caregivers, family members, etc.).

The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User.

After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, Monday to Friday from 9 a.m. to 1 p.m. and from 2.30 p.m. to 6.30 p.m.
In case of emergencies outside the working hours, please send an email to **sales@promedicare.it.**
We will call you back as soon as possible.
In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

The Pelvis Positioning Solutions of the *VERSA INSERTO SEAT* Range have been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
The wide variety of available sizes allows children and adults to use the Device.
It is recommended to make sure that the Device is compatible with the Positioning System or Wheelchair.
The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User. If a custom-made cushion is fitted and adjusted as prescribed, it may not be used for other users. Any removal and/or changes of the standard configuration, and configuration for the specific user based on the prescription, must exclusively be performed by the Professional User and make it a custom-made Device. The Professional User has the responsibility to guarantee the effectiveness and efficiency of the Device specially manufactured for the specific user. The CE Declaration of Conformity refers exclusively to the Medical Device prepared and provided by the manufacturer, "as-is", when the Device is unchanged with respect to the standard configuration.
Please also note that the commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User. PRO MEDICARE is constantly dedicated to innovate its own Devices; this can entail changes in form or technique on the devices and/or related accessories. Therefore, hypothetical complaints on values, images and schemes defined in the this manual, will not be accepted.
Furthermore, for the complete list of the optional parts and/or accessories, please refer to the latest order form in force. The Intended Use is shown in the relevant product Technical Sheet which is an integral part of this Instuction Manual.

1. INSTRUCTIONS OF USE

1.1 Packaging and Transport

The original packaging contains the following components:

- the *VERSA INSERTO SEAT* Pelvis Positioning System consisting of:
  - structural kit consisting of a flat and/or shaped base of construction + various types of inserts
  - padding kit or single padding
  - cover
- additional inserts (if any)
- labeling and Instruction Manual
- Hook-and-loop fasteners for use on the support base.

Upon delivery, please check for the integrity of the package and immediately note any damages or anomalies on the shipping document. Then open up the packaging and check that the various parts do not show dents, drippings, deformations or tears. Otherwise note the anomalies found on the shipping document.
After performing these checks and if the product has not to be put into immediate use, we recommend to repack and store it in a dry place.
The above operation will be carried out by the Professional User who has to perform the assembling procedures of the Base with the Positioning System.

1.2 Preliminary Operations for correct Commissioning

These operations must exclusively be performed by the Professional User, who is responsible for the safety performance of the combination and/or configuration.

The Commissioning must exclusively be performed by the Professional User.
For the correct assembly of the Pelvis Positioning System, please read the attached product Technical Sheet.

1.3 How to use it

After checking the User skin color, the Inserto Pelvis Positioning System is ready to be used when it is fitted and adjusted by or under the responsibility of the Professional User and when it is in accordance with the technical and design features defined by the Professional User for the specific User. If a custom-made cushion is fitted and adjusted as prescribed, it may not be used by other users. Any removal and/or changes of the standard configuration, and configuration for the specific user based on the prescription, must exclusively be performed by the Professional User and make it a custom-made Device. The Professional User has the responsibility to guarantee the effectiveness and efficiency of the Device specially manufactured for the specific user.

1.3.1 System Transfer

Before performing these operations, it is important to discuss with the end user and/or caregiver about the most natural and regular operations that needs to be done. This will help to make it easier for the user and it will reduce possible dangers. In case of transportation of the Positioning System, please perform as follows:

- *If the wheelchair is rigid*, plese leave the Positioning System in the same position and transport it
- *If the wheelchair is foldable*, please remove the Positioning System as follows:
  - apply the parking brakes and make sure the wheelchair is locked
  - unfasten any fixing components placed on the Positioning System which could impede the removal
  - disengage any Hip Guides which could impede the removal of the positioning system
  - remove the INSERTO SEAT Pelvis Positioning System from the wheelchair base taking care to preserve the male/female fastenig systems
  - close the wheelchair.
- To relocate the cushion on the wheelchair, please perform as follows:
  - open the wheelchair
  - apply the parking brakes and make sure the wheelchair is locked
  - place the solid base, where provided, on the wheelchair base, making sure that it is fully fixed to it
  - place the Positioning System on the wheelchair seat base (solid or canvas) taking care to check the complete adherence of the male/female fastening systems and how the Positioning system has been placed on the base (check that the REAR POSTERIOR label and postural unit cuts, if present, have been located to the rear)
  - check the adjustments.

1.4 Recommendations for Use

In order to guarantee safe use and a long lasting performance of the *VERSA INSERTO SEAT* Range Pelvis Positioning Solutions, please find below advices for the end user:

√ carefully follow the instructions reported in this manual
√ follow the recommendations provided by the Professional User
√ keep the Device away from heat sources
√ unauthorised modifications (if carried out by anyone other than the Professional User) or the use of parts not supplied or approved by the manufacturer, may affect the safety of the Device, may lead to dangerous situations and to the loss of the CE Mark
√ carry out thorough cleaning and pay close attention to the standard maintenance.

During daily use it may happen that components and/or accessories become loosen, affecting adjustments, this is why it is recommended to schedule a follow-up to monitor and check the posture. Never make any adjustments or changes without the intervention of the Professional User. In case of signs of redness, please stop using the Device and contact the Professional User. In addition, if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

2. GENERAL WARNINGS

All announcements reported in this section describe the conditions and situations that may cause danger to the user or to third parties. Please read carefully before using and putting the in service the *VERSA INSERTO SEAT* Range Pelvis Positioning Systems. To ensure the correct use of the Device, some operations, such as the first commissioning and adjustments, must only be performed by authorized people - *the Professional User* - Some daily operations can obviously be performed by the *End User* (or *lay person*). Therefore, there will be specific warnings for those concerned. In particular, the term *Professional User* describes the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), while, the term *End User* describes the person who is intended to use the Device (caregivers, family members, etc.).

2.1 Warnings for the Professional User

For further information, please contact the Technical Sales Department at the number **+39 0831 777840**
- Preliminary Operations for correct Commissioning: (*to be performed according to the instruction given in section 1.2*)
  * After these operations, make sure that the Device is firmly and that it is working properly
  * Always check that the tightness of the devices is suitable for the user to ensure safe use.

2.2 Warnings for the End User

Before using the Device ensure the Professional User explains the procedures for correct commissioning and standard maintenance For further information, please contact the Professional User.

- Environmental Conditions

Severe environmental conditions may affect the features of the materials used, the *VERSA INSERTO SEAT* Pelvis Positioning Systems, their functionality and performance, so:

- Avoid the exposure to extreme temperatures
- Avoid prolonged exposure to sunlight
- Avoid extreme humid places
- Do not use the device in the shower, pool or environment in contact with water. Some components may be damaged and cause malfunction
- Avoid contact with seawater
- If the device comes in contact with dirt, please carry out an immediate and thorough cleaning of the cover.

- Use

- If, after a few days of use, anomalies are found regarding the tightness of the device, please, contact the Professional User
- Always check the Device is properly fixed to the wheelchair base
- In the event that an accident causes a loss of performance, do not use the system and contact the Professional User
- Never perform any adjustment to the Device; adjustments may only be performed by the Professional User
- It is recommended to perform a thorough cleaning and standard maintenance of the Device every 15 days or if necessary checking all parts of the Device to avoid any inconvenience. For further information about the maintenance and cleaning, please read the attached product technical sheet.

3. NEGATIVE ADVERSE EFFECTS

Generally the use of the VERSA INSERTO SEAT Range Pelvis Positioning Solutions should not cause any adverse effects such as allergies, skin irritations or redness when in contact. Otherwise, please contact both the Doctor and the Professional User immediately. Daily monitor the skin area which is in contact with the Device for evidence of pressure sores caused by incorrect or outdated adjustments; in this case it is suggested to suspend the use and contact the Professional User.

4. RESTRICTIONS OF USE

The *VERSA INSERTO SEAT* Range Pelvis Positioning Solutions have been designed and manufactured to provide the end user the correct positioning support within the normal activities of daily working life, social relations, school or leisure time. Any other use may compromise the safety of the Device.

5. STANDARD MANTEINANCE

For information about the maintenance and cleaning, please read the attached product technical sheet.

6. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

Special maintenance should be performed when one or more structural components deteriorate in such way to compromise the performance and safety of users. In this case do not use the Device and immediately contact the Professional User who shall promptly inform the manufacturer about the nature of the malfunction and/or the failures found in order to proceed with the necessary interventions.
The instructions below must be followed at all times:

- Components failure: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
- Components Breakages or tears: they must be replaced with original items provided by the manufacturer
- For all structural components it is strictly forbidden to perform any repair
- We recommend a gradual adaptation of the system to any user's needs.

The non observance of the above clauses will automatically void the CE mark.
For special maintenance, the End User must refer to the Professional User who has to send the appropriate form *"Annex 1 – Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request for intervention.

7. PERFORMANCE AND DURABILITY

PRO MEDICARE S.r.l. ensures that its own *VERSA INSERTO SEAT Range Pelvis Positioning Solutions* production has been designed and produced in compliance with the safety regulations as required by the relevant Regulation (EU) 2017/745.
The benefits provided by the above mentioned medical devices, are therefore suitable and respond to the project's purpose, which is the mobility of users with severe disabilities, considering a more effective rehabilitation plan based on correct posture and stability.
The realistic life span of the *VERSA INSERTO SEAT* Range is approximately 3 years.
This value is purely indicative because, even if the duration expected in the design phase is much greater, it is significantly determined by the way the device is used (which may be how it has been used and if it has been used continuously compared to what was intended in the design phase), by the correct use and careful maintenance.
It is also reasonable to consider a slight reduction in performance over time due exclusively to:

- shocks and accidental events
- natural wear of the components.

Both performance and relative life span expectancy are however dependent by the periodic verification of the suitability, safety and device conditions and have to be exclusively performed by the Professional User; regular reassessment by the professional user should therefore be provided in order to check the suitability, safe and integrity of the system.
if the Professional User deems it necessary, he can make adjustments to provide the right support and maintenance.
The reconditioning of the device is prohibited if not expressly authorized by the manufacturer.

It is recommended to periodically check the patient, especially if the device is used continuously during the day.

8. WARRANTY

PRO MEDICARE s.r.l. warrants the devices functionality for a maximum period of 24 months, covering all manufacturing defects from the first commissioning and 12 months on covers, paddings and components replaced under special maintenance starting from the date of commissioning after refurbishment.
The warranty is valid if the device is used as indicated within this instruction manual.
The warranty is voided in the following cases:

- improper use and/or in case of force majeure
- a failure arising from an unauthorized tampering or faulty maintenance by third party that compromises the correct functionality and safety of the products
- any modification made without the manufacturer's authorization
- accidental damages and wear of the essential components
- structural changes of the end user
- failure or damages during the transportation: the Professional User is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the End User or caregiver must refer to the Professional User who has to send the appropriate form "*Annex 1 – Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request for intervention.
It is also essential for the manufacturer to receive a completed *Warranty Registration Form.*

9. POST-MARKET SURVEILLANCE AND POSSIBLE INCIDENTS

Pro Medicare S.r.l. ensures that their medical devices have been manufactured within the strict compliance, criteria and requirements established by the relevant applicable standards, guarantee functioning under the safety conditions prescribed by Regulation (EU) 2017/745.
The post-market surveillance system is set up and implemented in accordance with the quality management system adopted by Pro Medicare S.r.l. and is aimed to actively and systematically collect, record and analyse relevant data on the quality, performance and safety of its devices during their whole life, to establish the necessary conclusions and to determine, implement and monitor any preventive and corrective actions (art. 83 MDR).
These activities are also ensured through accurate market surveillance of the medical devices already present on the market, as also included in Art. 84 of the same Regulation (EU)2017/745.
To ensure Post-Market Surveillance, Pro Medicare S.r.l. shall implement all activities together with Professionals and Stakeholders to establish and keep updated a systematic procedure which is useful to collect and promptly analyze the experience gained on devices that have been placed on market, in order to identify any need for improvement or modification.
This surveillance activity also includes any incidents or serious incidents defined by the MDR as:

- "*incident*": means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (art. 2(64) MDR)
- "*serious incident*": means any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person; b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; c) a serious public health threat (art. 2(65) MDR).

Serious incidents must be reported to the manufacturer and, through EUDAMED, to the competent authority.
Non-serious incidents, on the other hand, do not have to be reported to the competent authority; they must, however, be documented and taken into account in the manufacturer's quality management system and reported in accordance with the requirements of Art. 88 MDR.
It follows, therefore, that upon the occurrence of both serious incidents and possible non-serious incidents to end users and their companions or to professional users in connection with the use of the device **it is mandatory to send** to **Pro Medicare** a copy of a fully completed "*Annex 2 - Reporting of after-sale incidents*".
Pro Medicare S.r.l., as soon as it receives the aforementioned form, will provide the appropriate communications to the professional/end user, including the possible authorization to repair the damaged device or its replacement, also providing for the adoption of measures within its competence, appropriate to the nature and gravity of the incident detected.
In cases of particular urgency **it is mandatory to** contact the manufacturer at the following number **+39 0831 777840** sending to ***sales@promedicare.it*** the fully completed *Annex 2* as soon as possible.

10. DISPOSAL/RECYCLING

Please follow the local law and regulation in matter of disposal and recycling.
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of the positioning system accessories):

- Synthetic fabric covers (polyester, elastane, etc.), padding belonging to the polyethylene or polyurethane foam family, structural kits belonging to polyethylene foams
- Paper: cartoon or wrapping paper.

11. LABELING

The label is placed under the flat base of construction of the pelvis positioning system and it is also sticked on the second page of this Manual. Product data are indicated on the label. In case of replacing parts orders and/or reports, the serial number of the product is duly requested. A facsimile of the label is shown below:

MD Medical Device
SN Serial Number
REF Catalog Number
CE CE Mark
Manufacturer
Manufacturing date
Recovery/Recyclable
Handle with care
UDI Unique Device Identifier
Consult Instruction for Use
Keep dry