INSERTO SPINE MODO

This Technical Sheet is to be intended as an integral section of the Inserto Seat Range Instruction Manual. Before use, it is essential for the professional operator to explain all procedures for a correct commissioning and a proper maintenance.

1. Commissioning

The pelvis positioning system Inserto **Spine Modo** of Inserto seat Range comes in a form of a kit:

1) Structural kit composed by a pre-shaped contenitive base and 8 polyethylene closed cells inserts, modifiable and configurable,useful to individually support or correct the posture of the pelvis during the lifetime use;
2) A Kit of padding which is composed by different layers of foam: a superior layer of memory foam for the highest protection from risk of decubitus issues and an inferior layer of visco-elastic foam with low spring back action, only in the posterior part, in order to enhance maximum comfort and adaptation to the body shapes; a central pad of polyurethane open celled foam with a pad of self-modeling polimeric foam and two pads of a self-modeling polymeric foam for increasing protection and/or levelling the ischium;
3) A cover, air-exchange and incontinent at the same time, made of three layers of different materials, latex free, not flammable and at a low risk of skin irritation, commonly used in medical devices applications.

The pelvis positioning system Inserto Spine Modo is recommended preferably, but not exhaustively, for users with spinal cord injuries, in particular:

- Those who need a low/mild positioning support;
- Those who lead an active life and need a cushion easy to transport and transfer from;
- Those who have low risk to develop pressure sores and need a coccygeal and trochanteric discharge;
- Those who have leg lenght discrepancies, pelvic rotation and obliquity, posterior and anterior pelvis;
- Those who have lack of gluteal mass.

The pelvis positioning system **Inserto Spine Modo** can be combined, by means of an adhesive gripping tape, to any supporting base and/or wheelchair, provided that the structure will host the positioning system is solid enough to safely support the user during the use.

Once the modifications have been completed, such as removals, for the preparation and configuration as per prescription of the seat individually customised to the perfect reconstruction of the anatomic shape, the seat itself cannot be used by other users.

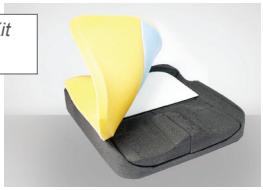
The Positioning System **Inserto Spine Modo**, in its design integrit and numerical and dimensional completeness of the supplied components (structural kit, padding kit, cover) can be easily adapted to sizes / morphology / deformities of the user. This kind of operations make the commissioning **referable to a serial manufacturing device**.

Alternatively

The commissioning of the Positioning System **Inserto Spine Modo**, deprived or modified, even partially, of its design integrity of numerical and dimensional completeness of the supplied components, built as per written prescription of a professional operator in function of the anatomy / morphology / deformities of the user, through the measurement detection and direct trials, can be **referable to a custom-made device**.

Pic.1 Pre-assembled structural kit

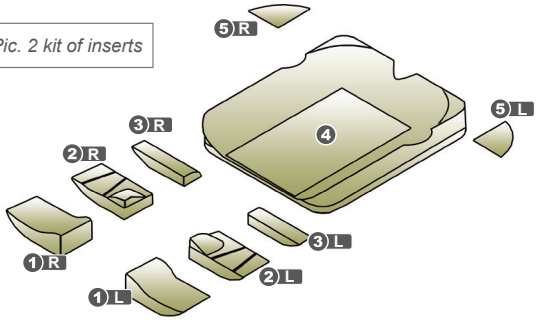
Pic.3 Pre-assembed Kit + padding Kit



Inserto **Modo**

8 MODULAR CONFIGURABLE INSERTS

Pic. 2 kit of inserts



1) Anterior insert for thigh accommodation
2) Medial insert for thigh accommodation
3) Posterior Trapezoidal Insert for leg accommodation
4) Pre-shaped base of construction
5) Lateral/pelvic filling insert

The structural kit of **Inserto Spine Modo** is composed by a pre-shaped base of construction and numerous inserts that can be customised, shaped, modified as needed (Pic.1) and (Pic.2);Each element of the structural kit is supplied with male/female hooks and loops tape that strongly fix the inserts to the pre-shaped base of construction. The preparation of the pelvis positioning system shape, based on the prescription and the user's anatomy and morphology, is done through the detection of measurement and direct trials, therefore it has to be carried out as follows in order to ensure a proper commissioning:

SUGGESTIONS RELATED TO SOME OPERATIONS

Positioning the gripping Tape

If it is necessary to replace or add the gripping hook and loops tape on one or more inserts of the structural kit, please use the extra tape supplied in the packaging. In order to do so: remove the adhesive film and stick the tape firmly on the insert to attach.

Therefore, check for the correct placement. If it is correct remove the tape, taking care to heat the adhesive part for few seconds by using an industrial hot hair dryer at temperature of around 100° (212°F), then reposition the tape definitely.

Be careful not to damage the materials during this operation

Modifying the Structural kit Inserts

The modifications of reduction of the inserts by removal of material where necessary, will be implemented by cutter. If it is necessary to reconstruct the modified component (where the removed material makes it possible) use an industrial hot air dryer at a temperature of around 100 ° (212°F) to heat and weld together the two parts to be recomposed.

Be careful not to damage the materials during this operation

1) Accurately detect the measurements of the user and of his wheelchair/mobility device;
2) Remove the cover;
3) Remove the padding;
4) Dispose the thighs accommodation inserts (3,2,1) on the pre-shaped base (4) in order to match the distance ischium RH/LH – popliteal cave RH/LH (-2,5 cm. -0.98") with the length of the seat obtained by the their combination for both left and right hand sides. The combination of the distribution and direction of the thighs accommodation inserts may be different for the right hand side and the left hand side as far as it is permitted by the pre-shaped base of construction.
It should be noted that the function of the pre-shaped base of construction (4) is to provide a supporting base between the wheelchair / mobility device, as well as the primary structure of the construction kit on which to build or adapt the positioning system by using, removing or modifying, as necessary and as required by the prescription, all other inserts supplied with the construction kit.

5) Always take care to make the position of the profile on both sides of the pre-shaped base coincide with the position of the user's trochanter. In the same way, make sure to match the position of the profile on the back side of the pre-shaped base with the user's coccyx. Perform a slight removal of material by cutter if necessary to adapt the profile to the user's morphology.

INDICATIONS FOR THE LENGTH OF THE SEAT

It is possible to reach the desired seat length by operating both on the pre-shaped base of construction (4) and consequently on the set of inserts supplied with the structural kit (see point a), or on the set of inserts supplied with the structural kit (see point b).
a) Pre-shaped base of construction and consequentlythe set of inserts supplied:
The pre-shaped base of construction (4) has its own size accordingly to the size of positioning system chosen .
If the predefined size is not enough, or the user has an irregular morphology and anthropometric measurements (i.e.:leg length discrepancy), it is possible to reduce the actual measurement of the pre-shaped base (4) for a maximum of 2 cm. (078"), by removing the portion of exceeding material with a cutter horizontally along the entire front or a part of it so as to make it asymmetrical.
Having carried out the above operation as necessary, it may be advisable to make a dimensional adjustment of the depth measurement of the individual inserts supplied with the structural kit by removing the necessary

material using a cutter. It is suggested to keep the part of material removed, if not damaged by removal, occasionally, afterwards it may be reused in order to adapt the device to the modifications made to the user.
Alternatively it can be suitable a placement of the inserts (1,2,3) on the pre-shaped base (4) by removing the exceeding inserts, alternatively both previous operations can be adopted.
If it is necessary to increase the useful length of the seat depth for one or both legs, one or both rows of thighs accommodation inserts (1,2,3) can be placed longitudinally along the pre-shaped base of construction (4) and leave between them the necessary distance in order to reach the desired total length. For this purpose, a measurement up to 2.5 cm. (0.98")longer than the actual length measurement of the pre-shaped base of construction can also be obtained.
This can be achieved by positioning longitudinally one or both of the anterior thigh accommodation inserts (1) on the pre-shaped base with their front portion out of it for a maximum of 2.5 cm. (0.98") and the rear portion connected to the surface of the pre-shaped base by a hooked gripping tape. If necessary, in order to meet the bending angle of the user's knees, remove a portion of the lower corner of one or both of the anterior thighs accommodation inserts (1) with a cutter.
b) Set of inserts supplied:
It may be appropriate to make a dimensional adjustment of the measurement of depth of the individual inserts supplied with the structural kit by removing the necessary material using a cutter. It is suggested to keep the part of material removed if not damaged by removal, occasionally, afterwards it may be reuse in order to adapt the device to the modifications made to the user.
Alternatively it can be suitable a placement of the inserts on the pre-shaped base (4) by removing the exceeding inserts; alternatively both previous operation can be adopted.
If it is necessary to increase the useful length of the seat depth for one or both legs, one or both rows of thighs accommodation inserts (1,2,3) can be placed longitudinally along the pre-shaped base of construction (4) and leave between them the necessary distance in order to reach the desired total length. For this purpose, a measurement up to 2.5 cm (0.98") longer than the actual length measurement of the pre-shaped base of construction can also be obtained.What above can be achieved by placing the anterior thighs accommodation inserts (1) longitudinally along the pre-shaped base with the anterior portion out of it for a max. of 2,5 cm. (0.98") and the posterior portion attached to the pre-shaped base through a hooked gripping tape.

Please be aware that any depth customisation of the kit must be made by considering the harmony of the support and the compatibility with the wheelchair/mobility device with particular reference to the variables to the height and inclination of the footplates, depth of the seat cloth, inclination of the seating plan.

INDICATIONS FOR THE WIDTH OF THE SEAT
It is possible to reach the desired seat width in order to obtain the compatibility of the structural kit with the wheelchair and/or mobility system, by operating only on the pre-shaped base of construction (see point a).
a) Pre-shaped base of construction:
The pre-shaped base of construction (4) has its own size accordingly to the size of the positioning system chosen.
In order to insert the base on the cloth of the seat and reach the consequent compatibility with the width of the wheelchair/mobility system, it is possible to remove a portion of material from the sides of the base up to total 2 cm. (0.78") by using a cutter.

6) Place the other inserts and/or pad if and as necessary.

NOTE: The relation of the thrust, levelling and adhesion to the user's morphology exerted by the combined and harmonious use of each insert, enables the alignment and the postural compensation, as well as the distribution of the body loads along all the sitting surface. Use any useful insert among those supplied in order to achieve the compensation, support and posture correction and the individual seat most suitable to match the anatomic shapes of the user

7) Cover the inserts with the padding by adjusting itas shown in Pic.3;
8) Re-position the cover;
9) Once the pelvis positioning system has been assembled, have the user to be seated at least for one hour and verify if the new seat is causing pressure redness on the skin. If this happens it is recommended to adopt the most suitable interventions in accordance to the specifics defined for the user by the professional operator under his sole responsibility. On a contrary case, instead, proceed with the delivery of the product to the user.
10) It is advisable to keep documentary records of each operation carried out, as well as to provide the user with any deprived/removed parts which can be useful for after delivery interventions and/or adjustments.

It is strongly recommended to periodically check the skin of the user in order to verify any risk of redness appearance.

11) When all operations of preparation of the kit to the shape and measures of the user have been accomplished and the positioning system is ready to be delivered, it is possible to remove the excess of padding from the edges by using a cutter. Take care to follow the direction of the cut as in the original design.

In relation to the modification, processing and / or adaptation operations carried out on the structural kit and padding, the upper surface of the cover could result larger compared to the dimensions of the seating configuration obtained. Take care to spread the surface well when the user is sitting, in order to avoid wrinkles

2. Maintenance And Cleaning

In order to avoid the development of infections, it is recommended to perform a careful cleaning every 2 weeks and/or, if needed, check the pelvis positioning system in all its parts by avoiding malfunctions.
Regarding the cleaning of the padding, even if there is no direct contact with the skin, it is suggested to use a dump cloth or a brush with natural bristles and warm water (max 60°C – 140°F), with the addition of a light gentle detergent, by rubbing in a circular motion. Thenrinse with water. Wipe out the excess of water from the padding by using a dry cloth and dry away from heat sources. Do not expose the padding to the sun rays. Occasionally it can be also wash in the washing machine, at max 30°C (86°F), by using a light detergent and centrifuge at a low spin.

The drying time is quite long; it is suggested to be equipped of an additional kit of padding

The removable cover can be washed as it follows:
- Hand wash and then air dry;
- Washing machine (max temperature 60°C – 140°F) with the addition of a gentle detergent, bleach free, then centrifuge at a low spin.

It is advisable to use a protective wrapping before inserting in the washing machine in order to avoid any tearing of the film present in the cover. It is suggested to be equipped of an additional cover.

For additional information, please contact our technical-Sales Department at the following number:

+39 0831 777840

INSERTO MODO SIZES TABLE	SIZES (cm.)													
MODEL	3638	3642	3840	3845	4040	4045	4242	4245	4250	4545	4550	4848	4850	5050
Effective Width (cm)	36	36	38	38	40	40	42	42	42	45	45	48	48	50
Min. width achieved with removal of material (cm)	34	34	36	36	38	38	40	40	40	43	43	46	46	48
Effective Length (cm)	38	42	40	45	40	45	42	45	50	45	50	48	50	50
Max length achieved with adaptation (cm)	40,5	44,5	42,5	47,5	42,5	47,5	44,5	47,5	52,5	47,5	52,5	50,5	52,5	52,5
Min. length achieved with removal of material and removal of inserts (cm)*	36	40	38	43	38	43	40	43	48	43	48	46	48	48
Min. and max. range of anterior height pre-shaped construction + leg housing inserts 1/2/3 (cm)**	4,5/5,5 ** height referred to models 3638 and 5050													
Min. and max. range of posterior height of pre-shaped base construction (cm)**	8/9 ** height referred to models 3638 and 5050													

Weight of positioning system (min./max): 1,0 Kg / 2,5 kg

Max. Load (referred to MODEL 5050): 135 Kg.

* possible and further reductions due to removal of material

Any operation of removal, preparation or adjustment for the specific user, on the basis of a prescription, have to be performed by a professional operator and those interventions get the device customised. The professional user has the charge and the responsibility to guarantee the efficacy and the performances of the device

Labeling

Below it is reported the description of the product as it is shown on the CE Label:
- The complete name of the device is: Seat VERSA INSERTO SPINE MODO size Xx
- The name of the product shown on the label is: VERSA INSERTO SPINE Mo. size Xx where Mo stays for Modo

MANUFACTURED BY:

COMPANY CERTIFIED WITH QUALITY MANAGEMENT SYSTEM ISO 9001 / EN ISO 13485 BY BUREAU VERITAS S.P.A.

Via Montagna Z.I. - Lotto 41 72023 Mesagne (BR) - ITALY
Tel. +(39) 0831 777840 - Fax. +(39) 0831 730739 - Email: sales@promedicare.it
www.versainserto.com - www.promedicare.eu

SCH.TEC.PRO.INS.SPI.MOD. EN Rev.2 - 04/2018

www.versainserto.com

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INSTRUCTION MANUAL

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ProMedicare®

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Index

The techinical sheet attached is to be intended as an integral part of the Instruction Manual

ANNEXES

- > Annex 1: Warranty replacements of components /Adaptations with structural changes and/or special maintenance
- > Annex 2: Monitor of any after-sale accident

Introduction

Thank you for choosing the VERSA pelvis positioning system INSERTO which is a combination of technology and experience in the development of positioning systems for disabled people.
“Inserto seats” pelvic positioning system, can simply be adapted to the user as needed.
“Inserto seats” pelvic positioning system can also be customised, molded, modified, in order to be set up and prepared as from prescription to anatomy and morphology of the user through the detection of its body mesurements, and direct trials so as to obtain a custom seat for the perfect replication of its anatomic shapes for supporting or compensing its deformities, as well as the body loads distribution.
The INSERTO range is adaptable to somatic growth and pathological changes. Their composition makes them very comfortable, achieving optimal comfort with the maximum functionality by offering high postural solution. The pelvis positioning system Inserto seat can be combined, by means of an adhesive gripping tape, to any supporting base and/or wheelchair whether manual or powered, provided that the structure will host the positioning system is solid enough to safely support the user during the use.
This manual is based upon the medical devices requirements of the 93/42/CEE directive. It is an indispensable instrument for the knowledge of the procedures for safe and correct use of the device.
All professionals and users are encouraged to carefully read the ‘placing in service instructions’ with the express invitation to strictly follow the indicated procedure.

The initial commissioning operations, subsequent adjustments and special maintenance must be carried out exclusively by the professional operator.
If an individual custom seat has been prepared and set up as prescribed, it can not be used by other user.
Any operation of removal, preparation or adjustment for the specific user, on the basis of a prescription, have to be performed by a professional operator and those interventions get the device customised. The professional user has the charge and the responsibility to guarantee the efficacy and the performances of the device.

The EC declaration of conformity refers only and exclusively to the medical device “as it is” as prepared by the manufacturer, when it is not modified with respect to the standard configuration. The EC label is on the last pages of this manual and on the bottom of each medical device.

The features of the device are described in the Technical sheet here attached. After consulting this manual, for further details, please contact our Customer Service at the following number: +39 0831 777840 Monday to Friday from 9,00 to 13,00 and from 14,30 to 18,30.

In case of major emergencies out of working hours, please fax to the following number: +39 0831 730739 We will reply as soon as possible.

For an appropriate after-sale monitoring the device, or in the event of an accident during the use, please refer to the instructions stated in the relevant chapter.

1 CLINICAL INFORMATION/DESTINATION OF USE

The clinical information of medical device are written in the technical data sheet attached

2 OPERATING INSTRUCTIONS

2.1 Packaging and trasportation

The original package contains the following components :

1) The pelvic positioning system

- a structural kit composed by a flat base/preshaped base of construction and several inserts;
- a kit of padding or a single padding;
- cover.

2) Additional inserts (based upon model);

3) labeling and instruction manual;

4) hooks and loops (velcro) for use on seat bases.

Upon delivery, please check the integrity of the package. Any irregularity must be reported on the shipping document. Upon opening the package, please check for any damage, dents, cuts, or lacerations. The presence of one of these conditions must be reported on the shipping document.

After perfoming the above checks, if the product is not put into immediate use, we recommend that it is repackaged and stored in a dry place and protected from the bad weather.

The above procedure is the responsibility of the clinical professional or authorised dealer who will perform the adaptations.

 *handle with care*  *recycle*  *reading manual use*  *keep dry*

2.2 Placing into service

 *These operations must be performer by a clinical professional or authorised dealer*

For an appropriate assembling of the positioning system, please read the technical sheet of the product here attached.

2.3 User Instruction

"Inserto seat" positioning system, set up and configured by the professional operator under his responsibility, in accordance with the characteristics of design defined by the professional operator for the specific user, is ready for use, after the check of the color of the skin.
If an individual custom seat has been prepared and set up as prescribed, it can not be used by other user.
Any operation of removal, preparation or adjustment for the specific user, on the basis of a prescription, have to be performed by a professional operator and those interventions get the device customised.
The professional user has the charge and the responsibility to guarantee the efficacy and the performances of the device.

2.3.1 System Transfer

Before starting this operation we strongly reccomend that the user / caregiver is shown the correct method by a clinical professional / authorised dealer for reducing any possible danger.
when you want to proceed with any trasportation of the positioning system, it is necessary to:
• leave the positioning system in position as it is if the supporting frame is a rigid one, and then proceed with the transfer.
• remove the positioning system if the supporting frame is foldable. In this case, please proceed in the following way:
- operate the parking brakes and make sure the wheelchair is locked;
- unfasten any securing components on the positioning system wich could impede the removal;
- take out any kind of hip guides, if they could impede the removal of the positioning system;
- remove the positioning system from the supporting base taking care to preserve the hooks and loops stripes;
- proceed by folding the wheelchair.
• To replace the seat on the supporting base, please perform as follows:
- unfold the wheelchair;
- operate the parking brakes and make sure the wheelchair is locked;
- position the solid base (if present) on the wheelchair, taking care to verify it is locked;
- position the positioning system on the base, taking care to verify the complete adhesion of the hook and loops strip of the seat with respect to the support base (check the seat notches and the label REAR POSTERIOR are positioned in the rear part);
- proceed verifyng all adjustments.

2.4 Processing Instructions

In order to guarantee safe use and a long lasting performance of the pelvis positioning system, please find below advice for the user and/or caregiver:

- carefully follow all instructions reported in this manual and in the technical sheet of the product;
- carefully follow all directions and advice provided by the clinical professional / authorised dealer;
- keep the positiong system away from heat;
- any unauthorised modifications performed by a non clinical professional or an unauthonsed dealer, or the use of components not supplied or approved by the producer, can affect the safety and proper use of the product and could he a cause of danger by the medical device;
- Clean carefully and pay particular attention to the standard maintenance.

In the case of the appeareance of the skin irritation or redness, please stop using the product and refer to the clinic professional/authorized dealer; should you ear noise, vibrations or encounter variations during the normal use, please refer to the clinical professional/authorized dealer in order to verify the safe and suitable conditions of use and good performances.

3 GENERAL WARNINGS

All warnings reported in this section describe the conditions and situations which may cause danger to end user. Please read carefully before putting the positioning system into the service. For an appropriate use of the device some operations, such as the starting and the making of adjustments, must be done exclusively by an authorised clinical professional or dealer - normal operations can be performed by the user or by his or her caregiver/attendant
The professional operator is, a person who by virtue of his professional qualification is authorised by the national law to issue a prescription containing specific characteristics and design for use addressed to a specific user. On the other hand, the end user is the person who uses the device or his companion /parent/care giver.

3.1 Warnings for the end user

Before use, have the clinical professional or authorised dealer explain all procedures for correct commissioning and maintenance. For further information or clarification, please contact a clinical professional or authorised dealer.

1) Environmental Conditions:

(A) some components can lose their properties when in direct contact with water or excess humidity:

- do not use the positioning system in a shower, swimming pool or in locations with the presence of water or high humidity. This will cause components to deteriorate and malfunction;
- do not take the positioning system in humid places (such as sauna or steamy bathroom after a shower);
- avoid the contact with sea water;
- if the seat is in contact with water and/or urine or becomes soiled, please clean thoroughly dry immediately all surfaces and/or covers.

(B) some environmental conditions may affect the positioning seat system and their functionality and performance, so, please:

- avoid exposure to extreme temperatures;
- avoid long exposure to direct sunlight.

2) Standard maintenance/cleaning

It is recommended to perform a careful cleaning and a standard maintenance every 2 weeks. It is also advisable to check all parts of the positioning system in order to avoid malfunctions.
For correct maintenance and cleaning operations, please read carefully the technical sheet of the product here attached.

4 ADVERSE EFFECTS

The use of the pelvis positioning system does not generate undesired collateral effects, such as allergies or skin irritations and redness. In a contrary case, it is necessary to refer to a doctor and to the clinical professional. Daily monitor the skin in contact with the positioning system in order to make a prompt diagnosis as to any occurrence of any pressure sore caused by an incorrect or outdated adjustment of the positioning system, in this case, please stop using it and refer to the clinical professional/authorized dealer.

5 RESTRICTION OF USE

The VERSA range of INSERTO seats has been designed and constructed to provide the end user the correct positioning support within the normal activities of daily working life, social relations, school and leisure time. Any other use may jeopardize the system.

6 ADAPTIONS WITH STRUCTURAL CHANGES AND/ OR EXTRAORDINARY MAINTENANCE

In case of breakage or tearing o fan INSERTO component, it is required to replace them with original parts only supplied by the producer. If the rupture or laceration is limited to the upholstery, only the material cover will be replaced. Only the strict observance of these requirements will guarantee the security required by Directive EEC 93/42 and subsequent amendments and additions. For any extraordinary o special maintenance procedures or repairs, the end user or the caregiver must refer to the authorized dealer or clinical professional, who will arrange the return the pertinent component form Annex 1 to the producer within 24 hours from the request of intervention.

7 PERFORMANCE AND DURABILITY

PRO MEDICARE S.r.l. ensures that its production line "VERSA", specifically "INSERTO SEAT" was designed and built in compliance with safety regulations as stated in the relevant directive 93/42/CEE.

The performances provided by the above-mentioned devices, used individually or in combination, are suitable and responsive to the design destination aimed to the positioning for users with mobility limits.

The realistic life spam of the product under normal and safe conditions is 3 years.
This period is purely indicative because the daily use demands are different for all users and will be significantly influenced by the adherence of regular and correct adjustments, installations and maintenance schedule. Improper use and poor maintenance will significantly reduce the life spam of the product.

It is strongly recommended to check periodically the patient in case of appearance of redness specially if the use of the positioning system is continuous during the day.

8 WARRANTY

PRO MEDICARE S.r.l. warrants functionality for a maximum period of 24 months, covering all manufacturing defects from the first use and 12 months on covers and components replaced under special maintenance from the first date of service installation.
The warranty is valid provided that the device is used as shown in this instruction manual.

The warranty is void in the following cases:
- for misuse and/or force major;
- for failure arising from unauthorised tampering or faulty maintenance caused by third persons that may affect the correct functionality and the safety of the product;
- modifications made without the producer's authorization;
- accidental damage of the essential components;
- structural changes of the user not being accounted for by seat modification;
- failure or damage during transportation. The clinical professional/authorised dealer, please see the general sale conditions in case of damage during the transport;
- robbery or loss.

Regarding any replacement of components under warranty, the user or the caregiver must refer to the clinical professional/authorised dealer who will arrange return to the producer with the relevant form Annex 1 within 24 hours after the intervention request.
It is essential for the producer to receive a completed warranty registration form from the authorized dealer.

9 MONITOR OF AFTER-SALE INCIDENTS

PRO MEDICARE S.r.l. ensures that their medical device products are produced within strict compliance with the criteria and requirements established by the relevant National EU rules and give adequate security of operation in the conditions required by Directive N° 93/42/EEC and subsequent amendments and additions for after-sale monitoring.
We consider it essential to monitor via after-sale and service, the reliability of our products and constantly search to improve the quality of our devices. The monitoring of any incident that may have caused serious physical harm to end users, their caregivers or to a clinical professional/ authorised dealer in connection with the use of any device, we will comply with the safety standards set by the Directive.
It follows that, in the case of any incident.

IT IS DULY REQUIRED

to send to the producer a copy of the Annex 2 completed in all its parts.
As soon as PRO MEDICARE S.r.l., receives the above form, we will immediately report to the appropriate authorised professional all information, as well as an authorisation to repair the damage device, or its complete replacement.

IN URGENT CASES IT IS DULY RECOMMENDED TO CALL THE PRODUCER
AT THE FOLLOWING NUMBER: +39 0831 777840

SENDING AS SOON AS POSSIBLE BY FAX THE ANNEX 2 CDULY COMPLETED.

Annex 1

Tecnical information

Clinical Professional / Authorised Dealer:_____

Address:_____City:_____

State:_____Post Code#:_____tel:_____fax:_____

Base:_____ Serial #:_____

Versa system:_____ Serial #:_____

Order Details: Invoice #_____Date: _____

Shipping Doc. #:_____ Date: _____

1. Replacement under warranty

Malfunction: _____

_____

_____

Component to replace : _____Quantity: _____

Note:_____

_____

2. Adaptation with structural changes and/or special maintenance

Cause of Intervention: _____

_____

Component to replace: _____

Related to: _____

Quantity:_____

Note (in case of maintenance please specify if the failure of the components is total or partial) :_____

_____

N.B. All unauthorized written interventions will void the CE mark

To be sent to the producer within 24 hours after the request of intervention to the fax +39 – 0831 - 730739

Annex 2 - Monitor of any after-sale incidents

Clinical Professional / Authorised Dealer:_____

Address:_____City:_____

State:_____Post Code#:_____tel:_____fax:_____

Base:_____ Serial #:_____

Versa system:_____ Serial #:_____

Order Details: Invoice #_____Date: _____

Shipping Doc. #:_____ Date: _____

Date of incident: _____

Description of incident: _____

_____

Causes (accidental, collision, not correct operation, structural failure, etc.)_____

_____

Component: _____

Related to the following part : _____ Quantity:_____

Severe injuries: _____

Rapair in safety conditions: **O** No

O Yes (continue to fill in the form)

Component to be replaced:_____

Related to the following part: _____Quantity:_____

Note:_____

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To be sent immediately to the producer at the following fax: +39 - 0831. 730739

N.B. All unauthorized written interventions will void the CE mark