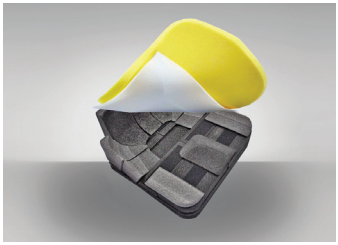
INSERTO SEAT TANTO

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 Tanto** of Inserto Seat Range comes in a form of a kit:

1) Structural kit composed by a flat base of construction, consisting of different densities of foam, and 17 closed cells polyethylene inserts, modular and configurable, useful to support or correct the posture of the pelvis during the life time use;
2) Kit of padding which presents a superior layer of memory foam with low spring back action, for the highest protection from decubitus sores, and an inferior layer of open cells polyurethane foam in the posterior part;
3) A cover, air-exchange and incontinent at the same time, made of three layers of different materials, latex free, not flammable and with low risk of skin irritation, commonly used in medical devices applications.



The pelvis positioning system Inserto Seat Tanto is recommended preferably, but not exhaustively, for users with mobility limits having mild deformities and high need of postural containment and trunk stabilisation, in particular:

- Those who have medium/severe leg length discrepancies, wind swept, pelvic obliquity, pelvic rotations, posterior and anterior pelvis tilt;
- Those who need to stabilise the ischium;
- Those who need ischium/trochateric/coxxygeal/sacral suspension;
- Those having high risk to develop decubitus sores;
- Those who need to balance and contain legs/pelvis/rachis/ relationship system;
- Those who need lateral control of the legs as well as that of the coccigeal/sacral/lumbar to improve the control of the trunk in order to maximise the coordinate function of the superior limbs (i.e. propelling).

The pelvis positioning system Inserto Seat Tanto 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 Seat Tanto**, in its design integrity 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 Seat Tanto**, 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**.

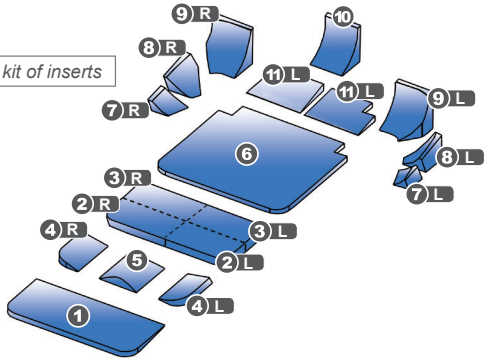
Pic.1 Pre-assembled Kit

Pic.3 Pre-assembled Kit + padding Kit

Inserto **Tanto**

17 MODULAR CONFIGURABLE INSERTS

Pic.2 kit of inserts



01) Leveling insert rigid
02) Anterior insert for thighs position rigid
03) Trapezoidal insert rigid
04) Adductor insert soft
05) Abductor insert rigid
06) Flat base of construction rigid
07) Medial thigh insert soft
08) Pelvis guide insert soft
09) Buttock guide insert rigid
10) Medial coccyx-sacral-lumbar guide insert rigid
11) Posterior leveling insert rigid

The structural kit of Inserto Seat Tanto is composed by a flat 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 flat 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 position thighs inserts (3,2) on the flat base of construction (6) 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 inserts (2,3) may be different for the right hand side and the left hand side.

It should be noted that the function of the flat base of construction (6) 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.

INDICATIONS FOR THE LENGTH OF THE SEAT

It is possible to reach the desired seat length by operating on the flat base of construction only (6) (see point a), or on the flat base of construction and consequently on the set of inserts supplied in the structural kit (see point b), or on the inserts of the structural kit only (see point c).
a) Flat base of construction: The flat base of construction (6) has its own sizes accordingly to the size of the positioning system chosen and have posterior notches of 5 cm. (1.96”) wide by 6 cm. (2.36”) deep.
Therefore it is possible to make it slide between the backrest tubes of the wheelchair /mobility device, once it has been positioned on the cloth of the seat, in order to reduce its depth up to 6 cm. (2.36”).
If the length achieved is not enough and it is preferable to maintain the entire length of the flat base or the user has an irregular morphology and anthropometric measurements (i.e. leg length discrepancy), it is possible to reduce the effective length of the flat base (6), as needed, 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.
b) Flat base of construction and consequently the set of inserts supplied:
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.

If it is necessary to reduce the depth of the buttock guide inserts (9) and of the coccyx-sacral-lumbar insert (10), remove only a small part of material, horizontally along the posterior surface, in order to avoid affecting the pelvic contour. It is suggested to keep the part of material removed, if not damaged, as occasionally, afterwards can be reused to adapt the device to user's changes.
Alternatively it can be suitable a placement of the inserts on the flat base of construction (6) by removing the exceeding inserts; alternatively both 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 position inserts (2,3) can be placed longitudinally along the flat base of construction (6) 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 flat base of construction can also be obtained. This can be achieved by positioning longitudinally one or both the anterior thigh positioning inserts (2) on the flat base of construction, 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 flat base by a hooked gripping tape.

c) 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. If it is necessary to reduce the depth of the buttock guide inserts (9) and of the coccyx-sacral-lumbar insert (10), remove only a small part of material, horizontally along the posterior surface, in order to avoid affecting the pelvic contour. 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 flat base of construction (6) 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 (2,3) can be placed longitudinally along the flat base of construction (6) 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 flat base of construction can also be obtained. What above can be achieved by placing the anterior thighs positioning inserts (2) longitudinally along the flat base with the anterior portion out of it for a max. of 2,5 cm. (0.98") and the posterior portion attached to the flat 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.

5) Dispose the pelvis guide inserts (8) so as to match the width of the pelvis with the width of the seat obtained by their combination. It is suggested to accomplish this operation by preparing the inserts (8) directly with the user seated on the structural kit in order to better align the above inserts. During this operation make sure that the distance between the pelvis guide inserts (8) is increased of 1,5 cm (0,59") per side with respect to the width of the user's pelvis, in order to allow the perfect fit when the padding is applied.

It should be noted that the function of the flat base of construction (6) 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.

INDICATIONS FOR THE WIDTH OF THE SEAT

It is possible to reach the desired seat width by operating only on the flat base of construction (6) (see point a), or on the flat base of construction and consequently on the inserts of the structural kit (see point b), or on the inserts of the structural kit only (see point c).

a) Flat base of construction: The flat base of construction (6) has its own sizes 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.

b) Flat base of construction and consequently the set of inserts supplied:
After having carried out the operation of point a) it may be necessary to make dimensional adjustment of the width of the individual insert supplied with the structural kit, by removing the necessary material using a cutter. It is suggested to remove a small portion of material from the outer edges (max. 1 cm. – 0.39") in order to avoid affecting the concave or convex design where available (4.7.8). Regarding the flat inserts (2.3.11) perform this operation along the inner longitudinal edges; for the buttock guide inserts (9) perform this operation along the inner longitudinal edges; for the coccyx-sacral-lumbar insert (10) along one or both the outer longitudinal edges. Alternatively it can be suitable the placement of the inserts on the flat base of construction (6) by removing the exceeding inserts; alternatively both previous operation can be adopted. 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. If it is necessary to reduce the depth of the buttock guide inserts (9), and of the coccyx-sacral-lumbar insert (10), remove horizontally along the posterior surface, only a small portion of material in order to avoid affecting the pelvis contour. If it is necessary to increase the useful length with respect of all sizes defined for each model, it is possible to protrude each insert of the structural kit up to 1 cm (0,39") out of the flat base of construction.

c) Set of inserts of the structural kit:
It also may be appropriate to operate a dimensional adjustment of the width of each insert of the structural kit by removing the necessary material using a cutter. It is suggested to remove a small portion of material along the outer edges (max. 1 cm. – 0.39") in order to avoid affecting the concave or convex curves where present (4.7.8 Regarding the flat inserts (2.3.11) perform this operation along the inner longitudinal edges; for the buttock guide inserts (9) perform this operation along the inner longitudinal edges; for the coccyx-sacral-lumbar insert (10) along one or both the outer longitudinal edges. If it is necessary to reduce the depth of the buttock guide inserts (9), and of the coccyx-sacral-lumbar insert (10), remove horizontally along the posterior surface, only a small portion of material in order to avoid affecting the pelvis contour. 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 the placement of the inserts on the flat base of construction (6) by removing the exceeding inserts; alternatively both previous operation can be adopted. If it is necessary to increase the useful length with respect of all sizes defined for each model, it is possible to protrude each insert of the structural kit up to 1 cm (0,39") out of the flat base of construction.

6) Place the other inserts as needed.

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 structural kit with the padding by adjusting it as shown in Pic. 3.
8) Place the cover back onto the structure. There are elastic sides that can be securely positioned by pulling the drawstring provided
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.
Before to use the product have the professional user to show the procedures for a correct commissioning and maintenance.

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. Then rinse 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 provided 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 TANTO SIZES TABLE	PAEDIATRIC		ADULT							SIZES (cm.)	
MODEL	US	XXS	XS	XS1S	XS1	S	M	M1S	M1	L	XL
Effective width (cm)	30	36	36	40	40	42	42	45	45	48	48
Max width achieved with adaptation (cm)	32	38	38	42	42	44	44	47	47	50	50
Min. width achieved with removal of material (cm)	28	34	34	38	38	40	40	43	43	46	46
Effective length (cm)	38	38	42	40	45	45	50	45	50	45	50
Max. length achieved with adaptation (cm)	40,5	40,5	44,5	42,5	47,5	47,5	52,5	47,5	52,5	47,5	52,5
Min. length achieved with adjustment through seat notches and removal inserts (cm)*	32	32	36	34	39	39	44	39	44	39	44
Min. and max. range of anterior height of flat base of construction+ insert 2/3 (cm)**	3,5/4,5 ** height referred to models US and XL										
Min. and max. range of posterior height of flat base of construction+ insert 9 and 11 (cm)**	15/19,5 ** height referred to models US and XL										

Weight of positioning system (min/max): 0,8 kg/2,9 kg

Max load (referred to model XL 48cm x 50cm): 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 TANTO size Xx
- The name of the product shown on the label is: VERSA INSERTO T. size Xx where T stays for Tanto

MANUFACTURED BY: ProMedicare

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

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Inserto® SEAT

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MAN. VER. INS. SEA. EN REV. 5 04/2018

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:_____

_____

_____

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