

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 polymeric 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 length 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.

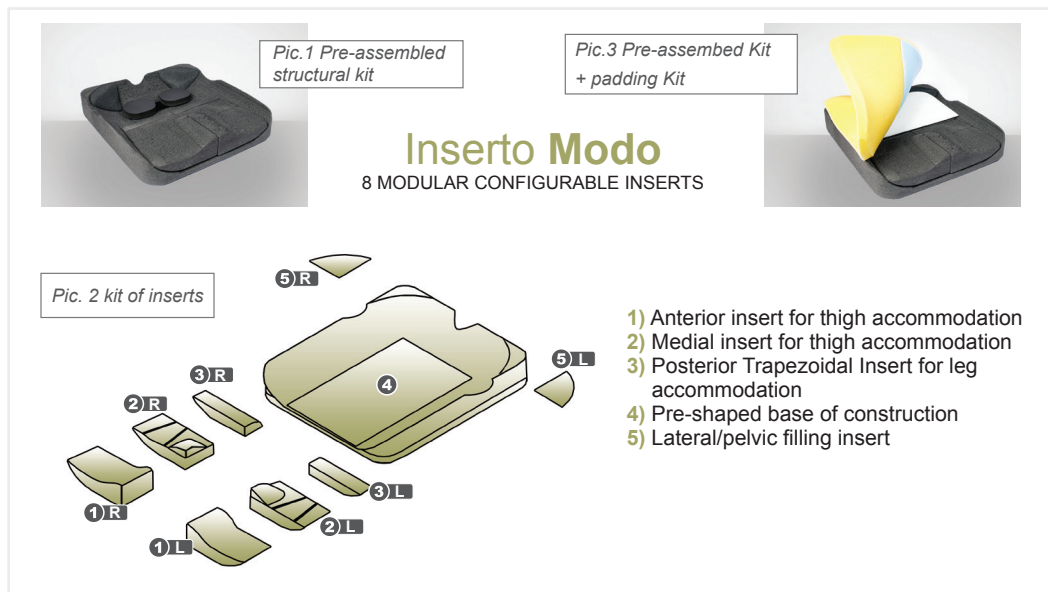


Once the modifications have been completed, such as removals, for the preparation and configuration as per prescription of the seat individually customised to the perfect reconstruction of the anatomic shape, the seat itself cannot be used by other users.

The Positioning System **Inserto Spine Modo**, in its design 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 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**.



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 consequently the 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. (0.78”), 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 it as 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 damp 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.

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