

## INSERTO SPINE NOVO

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 user to explain all procedures for a correct commissioning and a proper standard maintenance.

### 1. Commissioning

The **Inserto Spine Novo** pelvis positioning system of Inserto Seat Range comes as follows:

- 1) A structural kit, with different densities, composed by a flat base of construction and 24 closed cells polyethylene inserts, modular 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 a layer of memory foam in the superior part, for the highest protection from decubitus sores; an inferior layer, only in the posterior area, of open celled viscoelastic foam with low spring back action to enhance the maximum comfort and the best adaptation to body shapes; a central pad of flexible and elastic polyurethane foam with self-modeling polyethylene foam pad
- 3) "New 3D" air-exchange, incontinent, not flammable, antibacterial, latex free cover, which is commonly used in medical devices and reduces the risk of skin irritation.




### 2. Use

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

- those who need a higher positioning support
- those who have leg length discrepancies and/or fixed/flexible deformities
- those who need a very high lateral/anterior/posterior/medial support and containment of the pelvis
- those who need a block to prevent the sliding forward of the ischium or a ischial-trochanteric-coccygeal-sacral-perineal suspension
- those who have medium/high risk to develop pressure sores
- those who have leg length discrepancies, wind-swept, pelvic obliquity, pelvic rotation, severe posterior/anterior pelvic tilt
- those who have muscular and tissue atrophy, lack of gluteal mass, shapeless tissue and sensitive skin
- those who had both surgical and reconstructive operations.

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

Alternatively, the commissioning of the **Inserto Spine Novo** Positioning System, 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 user in function of the anatomy/morphologies/deformities of the end user, through the measurement detection and direct trials, **can be referable to a custom-made device**.



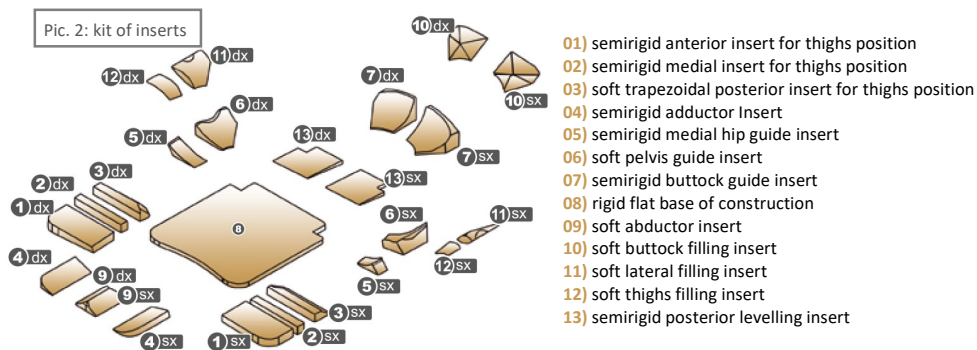
Pic. 1: Pre-assembled structural kit

Pic. 3: Pre-assembled Kit + padding Kit



## Inserto Novo

24 MODULAR CONFIGURABLE INSERTS



The structural kit of **Inserto Spine Novo** 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 end 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 the proper commissioning.

### 3. Suggestions related to some operations

#### 3.1 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.

To do this operate as follows: remove the adhesive film and stick the tape firmly on the insert to attach. Therefore, check for the correct placement. If it is correct, please 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*

#### 3.2 Modifying the Structural kit Inserts

Modifications to reduce inserts by removing material, where necessary, can be carried out using a cutter. If it is necessary to rebuild the modified component (where the material removed 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 assembled.



*Be careful not to damage the materials during this operation*

- 1) Accurately detect the measurements of the end user and of his wheelchair/mobility device
- 2) Remove the cover
- 3) Remove the padding

4) Dispose the thighs accommodation inserts (3, 2 and 1) on the flat base (8) 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 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.

It should be noted that the function of the flat base of construction (8) 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 (see point a), or on the flat base of construction (8) 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 (8) 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 end 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 (8) 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 (of the previous point a)), 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 (7) 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 (8) 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 (1, 2 and 3) can be placed longitudinally along the flat base of construction (8) 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 (1) 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 (7) 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 end user.

Alternatively it can be suitable a placement of the inserts on the flat base of construction (8) 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 position inserts (1, 2 and 3) can be placed longitudinally along the flat base of construction (8) 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 positioning longitudinally one or both the anterior thigh positioning inserts (1) 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.

 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 (6) 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 (6) directly with the end 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 (6) 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.

If it is necessary, please, combine the pelvis guide inserts (6) with the lateral filling inserts (11) the right, left or both, if the user has tissue atrophy and/or lack of gluteal mass and/or shapeless tissue or if the user had surgical operation. Care should be taken to match the position of the excavation on both the pelvis guide inserts (6) and the lateral filling inserts (11), if used, with the position of the user's greater trochanter.

### 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 (see point a), or on the flat base of construction (8) 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 (8) 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 flat 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 present (5, 12, 6 and 11); regarding the flat inserts (1, 2, 3 and 13) perform the operation along the inner longitudinal edges; regarding the buttock guide inserts (7) perform the operation along the inner longitudinal edges; Alternatively it can be suitable the placement of the inserts on the flat base of construction (8) 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 (7) remove only a small portion of material horizontally, along the posterior edge, in order to avoid affecting the concave or convex curve; it is necessary to increase the useful seat width with respect of all sizes defined for each model, it is possible to place each insert of the structural kit up to 1 cm (0,39") out of the flat base of construction, which is useful for the containment of the user positioning.

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 design where present (5, 12, 6 and 11), regarding the flat inserts (1, 2, 3 and 13) perform the operation along the inner longitudinal edges; regarding the buttock guide inserts (7) perform the operation along the inner longitudinal edges; If it is necessary to reduce the depth of the buttock guide inserts (7) remove only a small portion of material horizontally, along the posterior surface, in order to avoid affecting the concave or convex curve.

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 (8) by removing the exceeding inserts; alternatively both previous operation can be adopted. If it is necessary to increase the useful width of the seat with respect of all sizes defined for each model, it is possible to place each insert of the structural kit up to 1 cm (0,39") out of the flat base of construction, which is useful for the containment of the user positioning.

### 6) Place the other inserts 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 structural kit with the padding by adjusting it as shown in Pic. 3.

8) Place the cover. 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 user 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 the professional user has 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*

#### 4. 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 tepid water (max 30°C – 86°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. Drying machines are not recommended. The material does not require the use of disinfectants.



*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 further information, please contact our technical-Sales Department at the following number:

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INSERTO NOVO SIZE TABLE														
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
Max. width achieved with adaptation (cm)	38	38	40	40	42	42	44	44	44	47	47	50	50	52
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/or inserts (cm)*	32	36	34	39	34	39	36	39	44	39	44	42	44	44
Min. and max. range of anterior height of flat base of construction+ thighs position insert 1/2/3 (cm)	4.5 / 5.5 (heights referred to the models 3638 and 5050)													
Min. and max. range of posterior height of flat base of construction+pelvis guide inserts 6 (cm)	9.5 / 11.5 (heights referred to the models 3638 and 5050)													
Weight of positioning system: from 1.5 kg to 2.4 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.

**MANUFACTURED BY:**



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