

BRIEF USER MANUAL WITH BASIC SAFETY RULES



POSTURAL DYNAMIC SUPPORT PRODUCTS FlexPoint®

EN - ENGLISH



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The manufacturer holds the ISO 13485 international
Quality Management System certificate.

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ABOUT THE FlexPoint® SYSTEM

The FlexPoint® System consists of numerous elements which provide the correct and safe stabilization of the upper body, pelvis, upper and lower limbs while sitting. Due to the universal attachment methods, it is ideal for the vast majority of strollers and car seats offered on the market of medical devices. FlexPoint® is a system recommended especially for people with spasticity. The dynamic function of the FlexPoint® system is based on the proper resilience of the stabilizing elements, which provide the user with safety and comfort of use. This solution significantly reduces the risk of bodily injury which might be caused by, for example, the excessive pressure from inflexible belts.



TARGET GROUP

Products intended for people using medical devices in a sitting position (including rehabilitation chairs, wheelchairs), requiring body stabilization and with muscle tension disorders (including spasticity, flaccidity).



INDICATIONS FOR USE

- Neurological diseases that require stabilization of the user.
- Mental diseases (to protect the user in the used device).
- Muscle weakness, lack of control over correct posture.
- Hyperactivity.
- Epilepsy.
- Prevention and correction of faulty posture.



CONTRAINDICATIONS FOR USE

- Condition after cardiac surgery with unhealed wounds.
- People with medical certificate of contraindication to the use of safety belts.
- Respiratory system disorders.
- Pregnant women should consult their doctor about using FlexPoint® products.
- A person with mental disorders may use the products only under supervision of a caregiver.



BASIC SAFETY RULES

- These instructions for use contain important information for the safe use and maintenance of all the FlexPoint® products. Read them carefully before using the product. Keep them in order to be able to use them again if necessary.
- Using the FlexPoint® products against the instructions may be dangerous for the user.
- Before using the product, check if it has no signs of wear – no damage or tearing of straps, stitching, buckles or other elements of the system. In case of significant wear or damage, contact the manufacturer to have the product repaired or replaced. Only an undamaged product and proper use guarantee its right and safe working.
- Under no circumstances should an unqualified person repair or alter the product – health and safety of the user depend on it.
- For the FlexPoint® products installation, use only the mounting elements approved by the manufacturer. Failure to do so may pose a serious risk to the user. The product should be installed and adjusted by a person trained in its use.
- The FlexPoint® products should only be used for positioning a person in wheelchairs or other seats (in case of the BeltiCar® System also in a car seat). The FlexPoint® products are not intended to be used as transportation safety belts or in any other use where their failure could result in injury. Misuse of the FlexPoint® products is not authorized and not safe.
- The FlexPoint® products contain small elements that could be swallowed. Keep them away from children and animals.

ABOUT THE FlexPoint® SYSTEM

- Some of the FlexPoint® products are available with a 'PRESS' quick release system. Accidental release of these products may cause the user to slide forwards when sitting. If there is a possibility that the user's movements or cognitive abilities can lead to accidental release, a caregiver must be absolutely present at all times during their use.
- The manufacturer is responsible for the proper functioning of the FlexPoint® products only if the products are purchased from the manufacturer, an authorized distributor or in a specialized medical store.
- All the FlexPoint® products are equipped with the quick release system. Make sure that all caregivers know how to unfasten the products. Failure to do so may delay the user's release in case of emergency.
- It is absolutely necessary to periodically check the skin integrity, not only in places where the FlexPoint® products contact the user, but also in the sensitive body areas where there is a risk of developing bedsores. The contact with the sensitive body areas, which are particularly exposed to pressure, for example sacrum or buttocks, should be as limited as possible. In case of increased redness or irritation of the skin, discontinue use of the product and contact your physician or physiotherapist. Failure to do so may result in serious injury, such as bedsores. For users spending a lot of time in a sitting position, it is recommended to use antbedsores cushion, the BodyMap® cushions or the thermo-active foam VisMemo™ cushions, manufactured by Reh4Mat.
- In the event of e.g. fainting, please, stop using the product immediately and inform the attending physician.
- Serious incidents involving this device should be reported both to manufacturer and to the competent authority in your country.
- Due to the risk of strangulation, using the FlexPoint® products, especially vests and chest belts without the pelvis stabilization, is dangerous. always use a properly fitted pelvic belt.
- Using the BeltiCar® system in vehicles does not release the user from the obligation of using the regular seatbelts.



BEFORE USING THE FlexPoint® PRODUCTS, ALWAYS CHECK:

- ☑ If there are no signs of wear, damage or tearing of straps, stitching, buckles or other elements.
- ☑ If the product has been properly installed.
- ☑ If all the fastening elements have been properly and tightened firmly. If they do not uninstall or unfasten under pressure or when pulled.
- ☑ If all the buckles, adjustment straps and other fastening elements work correctly and do not unfasten under pressure or when pulled. In order to check that, pull the installed element firmly in different directions.
- ☑ If the product has been correctly fitted to the user. If it does not irritate skin or press too hard on any part of the user's body.
- ☑ If the user feels comfortable in the product. If the user can breathe freely. To check the fit of the FlexPoint® product, the user should lean forward and from side to side.
- ☑ If the straps are not twisted or too loose. The straps must be tight, they cannot twist or roll.
- ☑ If the product does not press the user's neck, causing the risk of strangulation. To check that, have the user lean forward.
- ☑ If the user has the pelvis stabilized, when using the vest.
- ☑ If the place of the FlexPoint® elements installation is appropriate and guarantees safe use of the product.
- ☑ If the installed product does not collide with the elements of the stroller / seat it has been fixed on.



POSSIBLE INCIDENTS TO THE USE OF THE VEST

If the lower vest straps are fastened too loosely. There is a risk that the vest will move upwards to the user's neck, making it difficult to breathe.

In a situation when the user slips off the seat. The upper edge of the vest cover's the user's neck and blocks the trachea, making it difficult to breathe.

There is a risk that the upper straps of the vest will press the user's neck, blocking the trachea and making it difficult to breathe. This might happen if the user's body is improperly secured in the seat or stroller.

The vest is fastened too tightly to the backrest and as a result the user cannot breathe easily.



SAFETY RULES REGARDING USE OF THE VESTS

Instructions for the proper use of the vest:

1. Make sure that the user is sitting in the best possible position - in the middle of the seat and deeply in the seat in such a way that the user's lumbar spine rests against the backrest.
2. Secure the user's pelvis with, for example, a pelvic belt, thigh abduction belts or an abduction block.
3. Make sure that the side supports of the device, if used, are set in the correct position. It is required that the users with the poor trunk control use the side supports. The side supports limit the lateral movements of the user's body, which could lead to the compression of the vest straps on the neck of the user.
4. Secure the vest. fasten and adjust the lower straps of the vest, so that the lower edge of the vest is located near the lower abdomen of the user. Straps must not remain too loose.
Fasten the horizontal strap of the vest (if present) and the shoulder straps of the vest. check if the buckles of the vest do not open under pressure.
5. Check the user's position. Make sure that the vest cannot move by itself towards the user's neck. Make sure that you can insert a straightened hand between the vest and the user's body.



To prevent injuries and to minimize the risks associated with the use of the vest, the following rules should be followed.


- ☑ The position of the vest must be checked each time after putting the user in the seat.
- ☑ Special attention should be paid to protecting the user from falling forward, slipping off the seat or lifting the pelvis. The vest must be used with the accessories which will secure the user's pelvis at all times. The use of the vest cannot be considered separately but as a part of a general posture support system including supports such as pelvic belts, foot support, torso stabilization, thigh abduction belts, tilt-in-space position and reclining backrest.
- ☑ Special attention should be paid to ensuring that the entire foot of the user has stable support.
- ☑ It should be remembered that any change of the inclination angle of the backrest, seat, foot support or tilt-in-space function might affect the effectiveness of the belts and supports!
- ☑ The mounting of the vest and adjusting it to the patient can only be carried out by a suitably trained person, who is familiar with the instructions for the use of the vest and the rules of its safe use.
- ☑ Do not make any repairs or modifications to the vest on your own. In order to repair or replace any part of the vest, please contact the manufacturer.
- ☑ Do not use a damaged or incomplete vest, as this poses a serious threat to the health and life of the user.
- ☑ Make sure that all people taking care of the user are familiar with the rules of the safe use of the vest.

- ⚠ HOW TO CARE FOR THE VEST**
- The vest works effectively only if kept clean and maintained in accordance with the manufacturer's instructions. Before each use of the vest, check whether:
- the vest straps are not frayed or worn, if so, have them exchanged for new ones,
 - the vest straps are not attached to the wheels of the device,
 - the buckles are not damaged, if so, have them exchanged for new ones,
 - there have been no changes in the user's height or weight from the moment the vest was adjusted to the user,
 - the vest should be cleaned regularly with the use of warm soapy water and dried out of the direct sunlight and other sources of heat. The vest must always be dry before usage.


⚠ MAINTENANCE


CLEANING:


  hand wash at or below 40°C

 dry flat

DO NOT:

 do not iron

 do not bleach

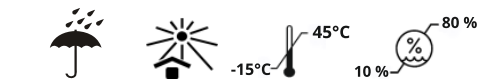
 do not machine wash, do not tumble dry

In order to keep the high quality and features of the FlexPoint® products, it is necessary to regularly check the condition of all the elements. The FlexPoint® products should not be used if any of their elements is worn or damaged.

Keep the FlexPoint® products away from heat sources. Do not expose them to prolonged sunlight.

After washing, make sure the product is completely dry before use.

Check periodically for signs of wear in the stitching, webbing and pads. In case of significant wear or damage, contact your supplier or the manufacturer to have the product repaired or replaced. Under no circumstances should an unqualified person repair or alter the product, as the health and safety of the user depend on it.



FP-EM-1:



HOLDER CLAMP

The mounting set includes a holder clamp Ø25 mm, an M5x30 screw with a nut and two reducing holder clamps Ø22 mm and Ø19 mm.

FP-EM-2:



MOUNTING TRIANGLE

Included elements: mounting triangle of a selected size and a regulator.

FP-EM-3:



RETRACTABLE BELT WITH CINCH BUCKLE

Included elements: cinch buckle, retractable belt, countersunk screw with M6 thread, 10 mm long, with M6 cap nut, button-head screw with M6 thread, 12 mm long, with M6 cap nut.

FP-EM-4:



MOUNTING SCREW WITH WASHER

It is recommended to use it with the mounting triangle or retractable belt with cinch buckle. The mounting screw with washer is available in three variants.

FP-EM-5:



MOUNTING SCREW WITH CAP NUT

It is recommended to use it with the mounting triangle or retractable belt with cinch buckle. Included elements: screw with M6 thread with three lengths to choose from, and M6 cap nut.

FP-EM-6:



WOOD SCREW

It is recommended to use it with the mounting triangle or retractable belt with cinch buckle. Screw with M4 thread, 14 mm long.

FP-EM-7:



RETRACTABLE BELT WITH MOUNTING TRIANGLE AND CINCH BUCKLE

Included elements: cinch buckle, retractable belt with a riveted mounting triangle.

Mounting elements allow the configuration of various mounting sets. Details in the SYSTEM GUIDE (after scanning the QR code or at www.flex-point.pl/en).

To mount the FlexPoint® products, it is recommended to use a wheelchair / seat frame or already existing threaded fixing holes (in the case of the mounting screw with cap nut FP-EM-5, the fixing hole does not have to be threaded).

Do not drill the fixing holes in the wheelchair / seat yourself, as this may affect its construction and lower its durability.

Please note that the self-drilling holes in a wheelchair / seat may result in loss of warranty for this product.

The FlexPoint® products manufacturer is not liable for damage to the wheelchair / seat, which is a consequence of self-drilling to install the FlexPoint® products.

For the FlexPoint® products installation, use only the mounting elements approved by the manufacturer. Failure to do so may pose a serious risk to the user when using the FlexPoint® products. The use of not approved components will void the FlexPoint® product warranty.

Make sure that none of the mounting components come into direct contact with the user's body. There is a risk of injury.


⚠ WARRANTY


The FlexPoint® products are covered by a warranty for material defects as well as the defects caused in normal conditions of use. The warranty is specified in the warranty card included with the product. Contact your supplier or the manufacturer in order to make a warranty claim.


Warranty does not cover:


- damage caused by high temperature, caustic agents or fire,
- permanent discoloration caused by contact with clothing containing active, migrating dyes (e.g. leather, jeans etc.),
- stains caused by a pen, ink, marker, etc., containing active dyes,
- mechanical damage caused by pets or other users,
- defects caused by improper maintenance, improper installation or improper use of the products.


LABELLING


 Declaration that the product meets the essential requirements


 Catalog number

 Serial number


 Medical device


 Manufacturer


 Production date


 Please read the manual instructions before use

⚠ You need to take special precautions

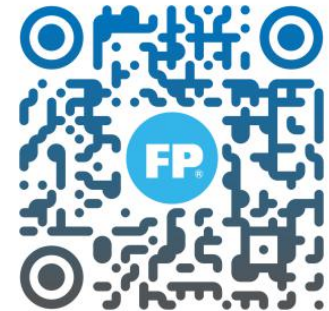
 Store in a dry place

 Protect from sunlight

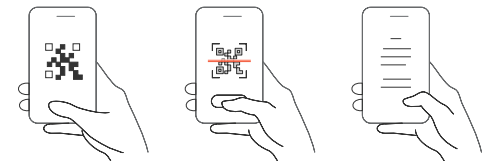
 45°C
-15°C Storage temperature limitation

 80 %
10 % Relative humidity storage

Description of the system and detailed information on the installation of the FlexPoint® system.



<https://flex-point.pl/en/download>



Other language versions of the user manual are available at www.flex-point.pl/en/