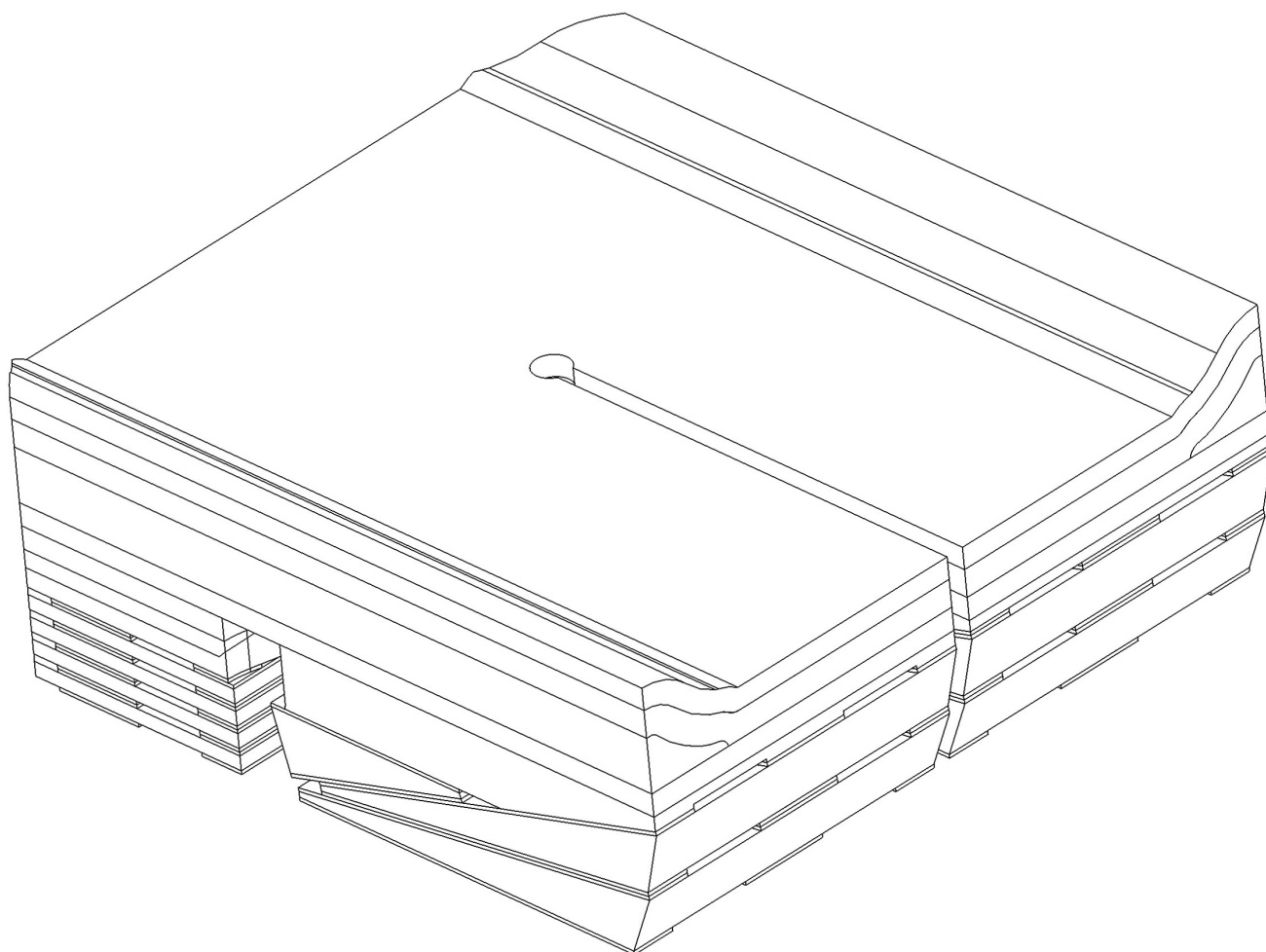


spex

Flex Cushion *Installation & User Manual*



User Name:

Serial Number:

IMPORTANT CONSUMER INFORMATION NOTICE:

This manual contains important instructions that must be passed on to the user of this product. Please do not remove this user manual before delivery to the end user.

SUPPLIER: This manual must be given to the user of this product.

USER/CAREGIVER: Before using this product, read entire manual and save for future reference. Transit Safety section **MUST** be read before product is used in a vehicle.

MD: This product is a Medical Device.

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Introduction

The Flex Cushion is a contoured, modular and adjustable cushion for users with symmetrical or asymmetrical limited hip flexions and extensions. It is designed for supporting the pelvis and legs correctly for users with pelvic obliquities, internal and external rotations, while offering skin protection. The strategic positioning system used underneath enables easy and on-the-spot adjustment.

Note: Check all parts are free from shipping damage. Contact Spex or your supplier for further instructions if needed. Spex recommends that a clinician such as an Occupational Therapist or Physiotherapist who is skilled in wheelchair seating and positioning be consulted to determine if the Flex Cushion is appropriate for the user.

Flex Cushion is an excellent choice for individuals who:

- Have symmetrical or asymmetrical limited hip flexion
- Have internal hip rotation with tight hamstrings on one side
- Require pelvic and thigh pressure distribution due to asymmetric sitting posture
- Have changing postural needs over time
- Require a high degree of pelvic stability and specific contouring

Intended Use

Spex Seating is intended for users (disabled and/or discomforted) that require specific postural and positioning support to provide comfort for body function in a sitting posture on wheelchairs for daily activities and for transportation in vehicles. It is designed with ergonomic adjustments to provide improved personal body-posture conditions and/or to help prevent/reduce physical problems associated with sedentary work or activities.

Contraindications

1. Use of Spex Wheelchair seating products may affect the center of gravity causing the Wheelchair to tip, potentially causing injury. Always judge the need for anti-tippers or amputee axle adapter brackets to be added to the Wheelchair to increase stability.
2. Check regularly for skin redness and that pressure spots are not developing. If your skin develops redness, stop using the product and consult your doctor or therapist.

Safety Instructions

To avoid injury, read, understand and follow all instructions and warnings in this manual before installing and using the Flex Cushion. There are hazards associated with the use of wheelchairs and adaptive equipment. If you misuse your wheelchair or your Cushion you can be seriously injured. If your Cushion ceases to function as intended, please consult your authorized Spex seating supplier immediately before continuing to use. Any serious incident that has occurred in relation to this product should be reported to Spex Ltd.

Flex Cushion meets the requirements of ISO 7176-16; wheelchairs - resistance to ignition of postural support devices. The cover and foam meet the flammability requirements of California Technical Bulletin 117. In rare cases the fabrics used in this product may cause a skin irritation for people with sensitive skin. If you experience any reddening or itching of the skin consult with your health care professional.

Disclaimer: Spex takes no responsibility as to the therapeutic effectiveness of our products. Our claims relate to the ability of the products to provide safe and reliable positioning and seating on the equipment onto which they are installed.

Weight Capacity

- 12-15" (25.4 -38 cm) width Cushion maximum user weight: **200 lbs. (90 kg)**
- 16-20" (41-51 cm) width Cushion maximum user weight: **350 lbs. (160 kg)**



WARNING

Never exceed the weight capacity of your cushion or the wheelchair as specified by the wheelchair manufacturer. Never perform exercise weight training that causes the user to exceed the weight capacity of the wheelchair. Ensure that the cushion is effectively secured in place, before carrying out a transfers. Only use foam wedges, inserts and covers provided by Spex.

Environment

Moisture: Keep your Cushion dry at all times, as contact with water or excess moisture could cause degradation to the functionality of your Cushion, or potential failure. If your Cushion becomes damp or wet, thoroughly wipe with a dry cloth as soon as possible. Do not use your Cushion in a showering or pool facility.

Temperature: Your Cushion may not function as intended when used at extreme temperatures. Keep the Cushion away from sources of extreme heat or extreme cold to avoid change in functionality of the foam.

Dirt: Small particles such as dust, dirt and sand may restrict optimum functionality. Regularly wash your Cushion cover to ensure no build-up occurs.

Compatibility

- The Flex Cushion has been designed to be compatible with most wheelchairs.
- The Flex Cushion must have a solid base to install to, such as a solid seat base pan or cushion rigidizer, which provides more stability to the user. Solid seat base must have hook velcro attached to it to ensure the cushion is held in place during use.



WARNING

RISK OF ACCIDENT, INJURY, PAIN OR DEATH IF WARNINGS ARE NOT HEEDED

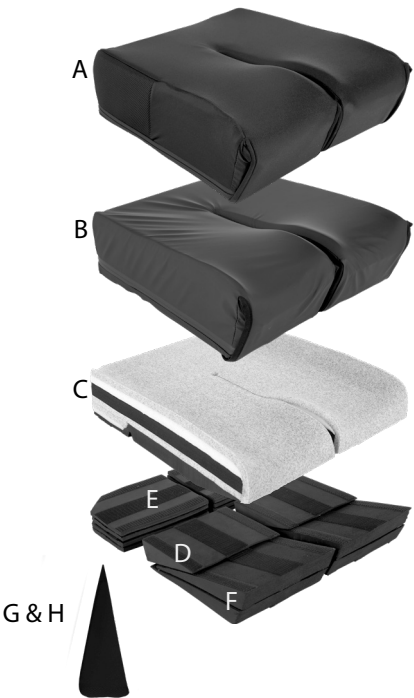
Seek assistance if you are uncertain about any of the following points

1. **Installing a Cushion on a wheelchair may disturb the wheelchair's centre of gravity and cause the wheelchair to tip backwards potentially resulting in injury or death. Check if anti-tippers or other adaptations need to be added to the wheelchair to help increase stability.**
2. **Installation and adjustment of your Flex Cushion must only be performed by**
 - a) **An authorized Spex distributor or technician**
 - b) **A qualified healthcare professional who has undergone appropriate biomechanical training**
3. **The Flex Cushion must have a solid base to install to. A solid seat base pan will provide more stability to the user (the Cushion won't sag).**
4. **This Cushion must be trialled first to determine its effectiveness in meeting the needs of the user. The clinician must inspect the user's skin to ensure that red pressure spots are not developing.**
5. **The user and/or caregivers should regularly check for skin redness or tissue breakdown. If redness develops, discontinue the use of the Cushion immediately and consult your doctor or therapist. The Cushion can be reconfigured for better positioning.**
6. **With proper set-up and continued maintenance, the Flex Cushion is an excellent candidate for people who are at risk of skin breakdown, however no Cushion can completely eliminate sitting pressure or prevent pressure injuries.**
7. **Keep the Cushion dry. Moisture is a contributing factor in causing pressure injuries.**
8. **We recommend the user to have a good diet and have regular pressure relieving exercises/therapy to help prevent pressure injuries.**
9. **Do not leave the Flex Cushion outside overnight or at temperatures below 5° C/41° F. The Flex Cushion should be room temperature before sitting on it.**
10. **Avoid sharp objects or exposure to excessive heat or open flame.**
11. **The Flex Cushion has been specifically designed as a Cushion for users in mobility wheelchairs. Do not use the Cushion in any way not described and never modify the Cushion.**
12. **Never use the Cushion without its cover. Care should be exercised near open flame or burning cigarettes. Using the Cushion without its cover increases the risk of flammability and skin damage.**
13. **Never use the Cushion without the incontinence cover. Failure to do so will reduce the life of the Cushion.**

Cushion Contents

Your Cushion contains the following:

	Description	Quantity
A	Outer cover	1
B	Incontinence cover	1
C	Foam Unit	1
D	Front Facing Wedges	1L & 1R
E	Pelvic Obliquity Pads	
	Cushions up to 15" depth	5L & 5R
	Cushions 16" depth and larger	6L & 6R
F	Thigh Wedges	3L & 3R
G	Abduction Wedges	2
H	Abduction Wedge Cover	1



Re-issuing to Another User

Once the user has finished using the Flex Cushion, it must be refurbished and thoroughly cleaned if it is issued to another user. Below are the strict guidelines for refurbishing the Flex Cushion. Spex takes no responsibility for contamination, cross infection, or damage. Spex recommends using AHP (Accelerated Hydrogen Peroxide) disinfectant wipes. The disinfection product must be used as per the manufacturer instructions. Spex takes no responsibility for the effectiveness of the disinfecting process.

Part	Procedure
Safety check	All components to be checked for signs of stress or cracking.
Upholstery covers	Both the incontinence cover and outer cover must be replaced regardless of condition.
Strategic positioning Wedges & Pads	Ensure correct number of wedges and pads are supplied and all Velcro's are in good condition.
Foam	Foam should be checked for degradation and cleanliness.

Disposal & Recycling

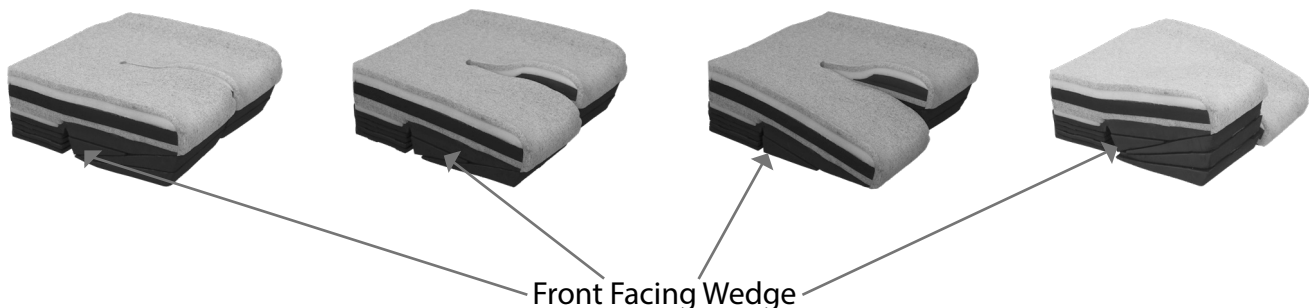
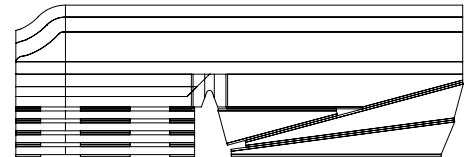
Your Spex Seating System is manufactured using a variety of materials, of which most can be recycled. Once it reaches the end of its life, if you are the legal owner, do not dispose of as ordinary household waste but take your Flex cushion to an approved recycling or collection point, to dispose of according to local laws and regulations. Separate collection and recycling of the Spex System when disposing ensures protection of the environment and assists with natural resource conservation.

Adjusting the Flex Cushion

The Flex Cushion can be configured to suit many different postures of persons with disabilities or sitting issues. By adjusting the strategic positioning base with wedges and pads, the Cushion surface can be contoured to improve overall posture, pelvic alignment, sitting ability, comfort and pressure reduction. Due to the adjustable nature of the Flex Cushion we recommend, initial assessment / configuration of the Cushion is carried out without the covers. Having a clear view and access to positioning base, wedges and pads will assist with the optimum setup of the Cushion. Once the optimal configuration is achieved both the outer and inner covers MUST be put back on the Cushion. The Flex Cushion must not be used without covers.

Thigh Wedge:

The angle of the thigh section can be changed by adding or removing the wedges under each thigh. Each wedge represents approximately 7° of adjustment. Ensure the Velcro on the wedges securely interlock before use.



It is imperative that the Front facing wedge shown above must never be removed from the Cushion.



WARNING

- Adjustments to be done by a certified and experienced clinician such as a doctor, therapist or rehab engineer who is skilled in seating and positioning. Adjustments must be done following a proper assessment of the user's needs.
- Flex Cushion must not be used without covers.

Adjusting the Flex Cushion

Abduction Wedge:

Abduction wedges can be used to abduct the Flex Cushion. The wedges are 10°, but abduction angle of the thigh section can be changed by adding or removing the abduction wedges or by trimming the abduction wedges to required angle. Once the required angle is achieved ensure the abduction cover is placed over the wedges and the abduction wedge is securely attached to the Cushion covers.



Wind-sweeping and Asymmetrical Abduction/ Internal and External Rotations:

Pelvic rotation or abduction, internal and external rotation of one leg can also be allowed for by setting the position of one leg, using the velcro underneath, and then inserting the required abduction wedges.

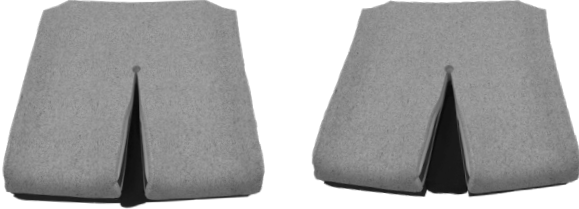
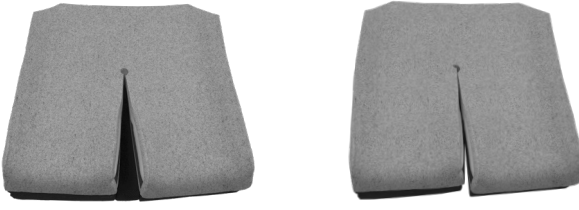
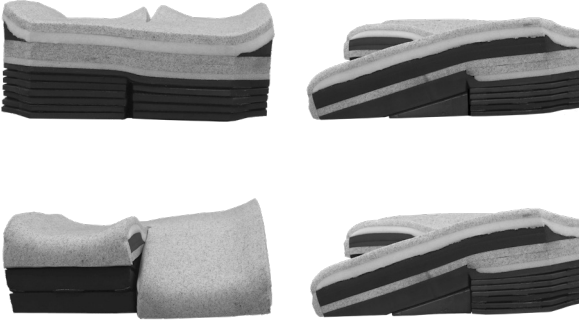


Pelvic Obliquity Adjustment:

The rear section of the Flex Cushion can be configured by adding or removing the Velcro pads or side wedges to correct or accommodate obliquity.



Configuring the Flex Cushion

Images are for illustrative purposes only	Disclaimer: The clinical evaluation assessment will determine which Cushion options are chosen to meet each client's needs.
	Thigh positioning and control The thigh section can be configured on both sides or either side independently for flexion or extension or can remain flat if required.
	Tight hamstrings/limited hip flexion/posterior pelvic tilt The front wedges can be added or removed to accommodate flexion or extension.
	Abduction Add, remove or trim the abduction wedges to accommodate thigh abduction.
	Wind-sweeping and Asymmetrical Abduction/ Internal and External Rotations: 'Secure the rear section with the Velcro section and flex the front leg sections laterally to accommodate rotations. To accommodate asymmetric abduction, set one leg (using the velcro) and then add or remove abduction wedges.'
	Pelvic obliquity Add or remove rear pads or side wedges to configure rear section of the Flex Cushion.

Other Configuring Tips

Configurations must depend on biomechanical evaluation and assessment.

- 1.** Anterior pelvic tilt: Leave Cushion flat or slightly raise front of Cushion for neutral alignment of the pelvis and/or promote weight bearing on ischial tuberosities.
- 2.** Extensor thrust: Increase hip and knee flexion by building more support under front of thighs.
- 3.** Pelvic obliquity: Build-up under low side to correct, under high side to accommodate.

NOTE: In all the above situations, adjust the back support and foot plates to fit.

Covering the Cushion

The Flex cushion is provided with two covers which must both be used; incontinence and outer. The abduction wedges are also provided with a cover which must be used if abduction is required from the cushion.

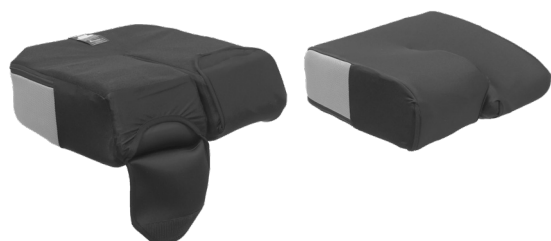
Once the adjustments are made to the cushion wedges, after assessing the user, the incontinence cover must be put on (ensure the velcro side is on the bottom). Insert each leg of the cushion and zip the cover up. The covers have two flaps at the front of the cushion, these are to be pulled tight, if wedges have been removed you may have to fold some of the cover under the cushion.



Ensure that there are no wrinkles, folds and creases on top or front of the cushion



Repeat the process for the outer cover.



Fitting the Cushion

- 1.** Position the Cushion about 12mm (0.47") forward of the front edge of the seat base pan to protect the user's legs.
- 2.** Labels on the Cushion and covers show the BACK. The BACK label on the Cushion must face rearwards at all times.
- 3.** Check the size of the Cushion. The Cushion must fully support the base of the user. If a Cushion is too long it may force the user to sit with a posteriorly tilted pelvis. If hip flexion or extension is required, a long cushion may force the client to sit on the edge where the pivot point is located, which is not ideal from a pressure management and comfort perspective.
The Cushion must not overlap by more than 25mm (0.98") with the backrest cushion.
- 4.** Proper footrest and back support adjustment may enhance sitting comfort. Adjust the foot plates so the user's legs rest firmly but comfortably on the Cushion. Adjust back support to ensure the pelvis is posteriorly supported.

Maintenance & Cleaning

Monthly cleaning and regular maintenance will help extend the life of the Cushion. The expected lifetime of the Cushion is 5 years; however the Cushion needs to be checked regularly for performance.

Spex recommends using AHP (Accelerated Hydrogen Peroxide) disinfectant wipes. The disinfection product must be used as per the manufacturer instructions. Spex takes no responsibility for the effectiveness of the disinfecting process.



WARNING

- Replacing the cover after washing must be done correctly. Ensure the back of the cover matches up to the back of the foam base.
- If used in an institutional setting, write the resident's name with a permanent marker on the content label of the covers. This will help to ensure the return of the covers after washing.
- Use only Flex Covers on Flex Cushions. Changing the Cover, or using different materials, will alter the design and may cause harm or pressure/shear concerns to the user.

Foam

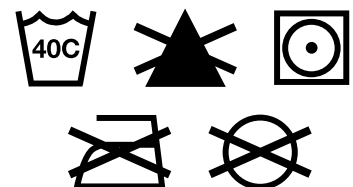
- Keep dry.
- Check the foam base regularly to ensure good foam consistency.
- If it accidentally becomes wet, dry thoroughly before replacing the covers.
- Ensure the all the Velcro strips on the cushion, wedges and pad are clean and not peeling away.
- Do not steam auto-clave.

Incontinence Cover

- Hand wash only.
- Do not use bleach or other strong cleaners.
- Do not tumble dry.
- Failure to use this cover may reduce the life of the cushion.

Outer Cover

- Remove the cover from the foam base and turn inside out.
- Machine wash in warm water (40° C / 104° F)
- Drip or tumble dry on low heat.
- Do not iron. Do not dry clean. Do not bleach.
- If chemical cleaners are used, covers must be rinsed thoroughly with water to remove all chemical residue and left to dry completely before reuse.
- Check the cover for tears and excessive wear and replace if ripped, torn or otherwise not fully functional.



If you have any additional questions regarding cleaning procedures, please contact your authorized Spex Seating dealer.

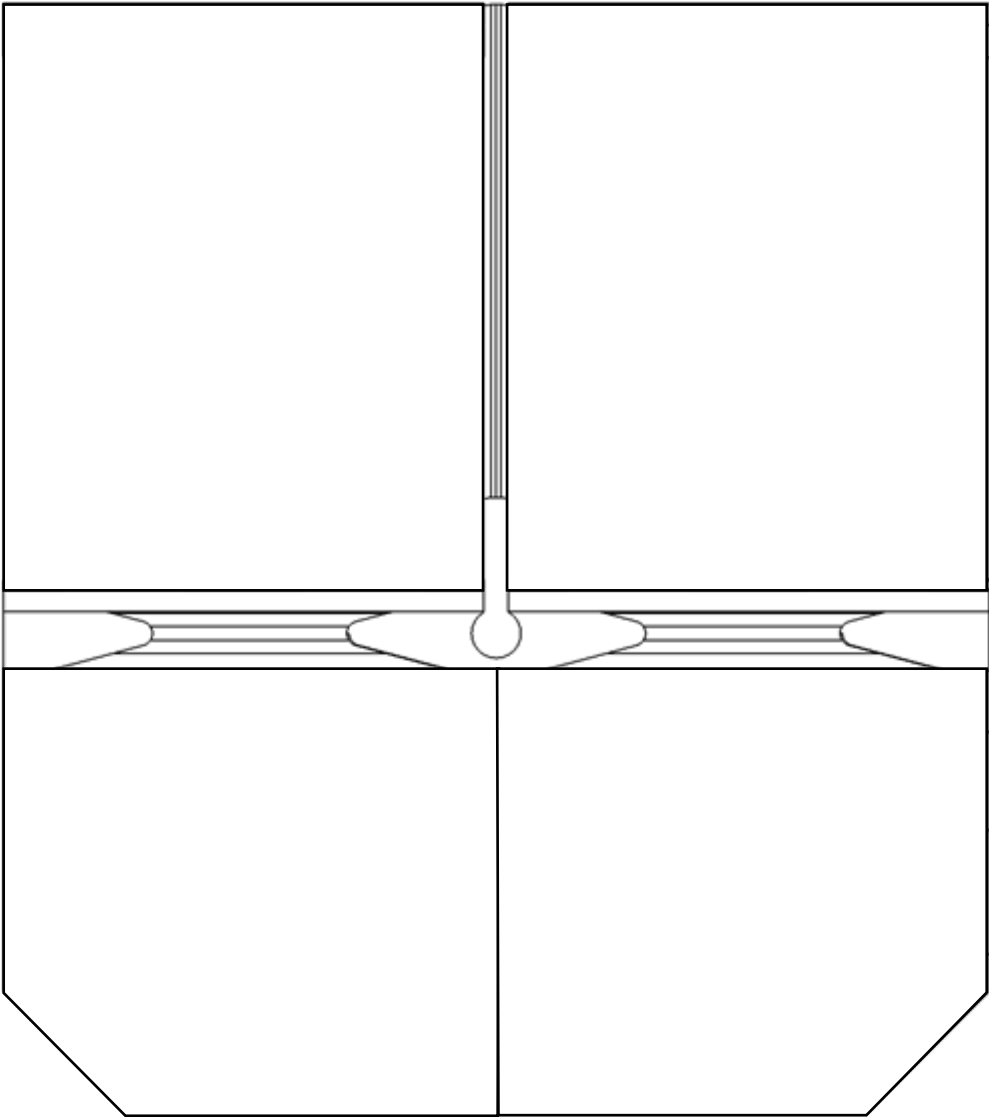
Cushion Strategic Base Chart

Once your Flex Cushion is set up in an optimal position, use the chart below to record the number of positioning pads and wedges in one of the 4 compartments. Mark unused/unavailable cells below with an 'X'.

Assessment Date	
Clinician Name	
Client Name	
Notes	

Front of Cushion - Underneath view

View of Cushion underneath



Bottom of Cushion - Underneath view

Transit Safety

The Spex Seating System has been successfully crash tested and complies with RESNA WC-4:2012, Section 20 (WC20). The Spex Seating System meets the requirements of ISO 16840-4:2009 and is suitable for use as a motor vehicle seat when used with an appropriate wheelchair base. Please follow all installation, use and maintenance instructions within this manual as well as the following transit instructions. If feasible, the wheelchair user should transfer to the vehicle seat and use the vehicle-installed occupant restraint systems.

Spex Seating System has been designed to accommodate the proper use of vehicle-anchored belt restraints. Spex achieved a rating of Excellent (16 out of 16), for ease of properly positioning a belt restraint, and the degree to which proper belt restraint can be achieved, based on the methods of Annex D. The following items of the Spex Seating System have been tested and are suitable for use in a motor vehicle:

- Full Height Back Support Models
- Seat Base
- Cushion Models
- Arm and Thigh Supports
- Trunk Lateral Supports
- Head Supports

Note: Back supports that are lower than the user's shoulder height are not certified and not recommended for transport in a vehicle. Eg. Vigour Lo and Vigour Mid back supports.

Assembly, Use, Maintenance & Limitations

- Adjustments to the set-up of the wheelchair must only be carried out by a qualified therapist, professional, or seating technician. Custom contoured/bespoke systems may require a qualified professional to configure and install the seating system.
- After carrying out any adjustments ensure all bolts, screws and nuts are securely fastened again to ensure safety when travelling in a vehicle.
- Ensure the top and bottom mounts of the backrest and the front and rear mounts of the seat pan are installed as far apart from each other as possible to give a stronger 4-point attachment to the wheelchair frame. Ensure the quick release latches are engaged.
- Do not use the Spex Seating System as a vehicle seat if seating components which have not been successfully crash tested are used anywhere on the seating system. Spex seating is designed and certified using only Spex components. Spex is not liable in the event where other manufactured seating systems are used in conjunction with Spex seating.
- At regular intervals check that all the fastenings on the Spex Seating System have not become loose during day to day use and re-tighten if necessary.
- Ensure the swing-away laterals are in their locked position before using the seat as a vehicle seat in a motor vehicle.

Transit Safety

Correct Positioning of Belt Restraints

When using the Spex Seating System as a vehicle seat, both a pelvic-belt restraint and shoulder-belt restraint must always be used. To correctly position the belt restraints on the wheelchair occupant, the following must be ensured:

- The pelvic-belt restraint should be worn low across the front of the pelvis near the junctions of the pelvis and thighs.
- The angle of the pelvic-belt restraint should be between 30° to 75° relative to the horizontal and, ideally, between 45° to 75° to the horizontal (as shown in Figure 2).
- The belt-restraint buckle of three-point belt restraints should be placed in contact with the occupant's body and away from wheelchair components.
- The junction of the shoulder-belt and pelvic-belt of three-point-belt restraints should be located near the hip opposite the shoulder over which the diagonal belt crosses and not near the midline of the occupant.
- Belt restraints should not be routed outside of the wheelchair wheels or over the wheelchair armrests, and should not be held away from the body by wheelchair components or parts.
- Upper torso belt restraints should fit directly over, and in contact with, the middle of the shoulder.
- Belt restraints should be adjusted to fit as snugly as possible, consistent with user comfort.
- Belt restraints should not be worn twisted in a manner that reduces the area of contact of the belt webbing with the occupant.



Figure 1

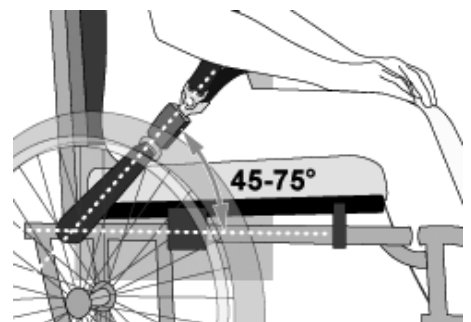


Figure 2



Figure 3a - Improper positioning of pelvic-belt restraints over wheelchair supports.

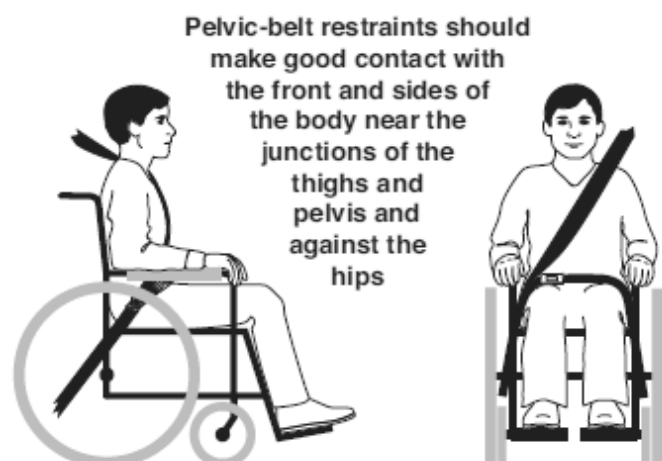


Figure 3b - Proper routing and positioning of belt restraints on the wheelchair occupant.

**WARNING**

- 1. The distance between the top of the user's shoulder and the top of the back should not exceed 6.5" (16.5 cm).**
- 2. The Spex Seating System must only be used with wheelchair bases that are tested as part of a wheelchair system that conforms to performance requirements of ISO 7176-19 and RESNA WC-4:2012, Section 19.**
- 3. The Spex Seating System should only be used on wheelchair frames that provide four securement points and pelvic-belt anchor points that conform to the requirements of RESNA WC-4: 2012, Section 19.**
- 4. The wheelchair must be labelled as appropriate for use as a seat in a motor vehicle, dynamically tested to the performance requirements of ISO 7176-19 and installed, used and maintained according to the manufacturer's instructions.**
- 5. The Spex Seating System must only be used as indicated in this user manual.**
- 6. Both pelvic and shoulder-belt restraints as a part of a complete Wheelchair Tie down and Occupant Restraint System (WTORS) which meets ISO 10542-1 shall be used to achieve effective occupant restraint and optimum protection in a vehicle impact; the belt restraints should be compatible with the specific wheelchair, and fitted to the user in accordance with WTORS manufacturer's instructions.**
- 7. Back supports with adjustable recline angles should not be tilted back more than 30° beyond the vertical during travel in vehicles unless necessary for the medical and postural needs of the occupant.**
- 8. If the back support must be adjusted to an angle that is greater than 30° beyond the vertical during travel, the upper shoulder-belt anchor point should be adjusted rearward to maintain belt**

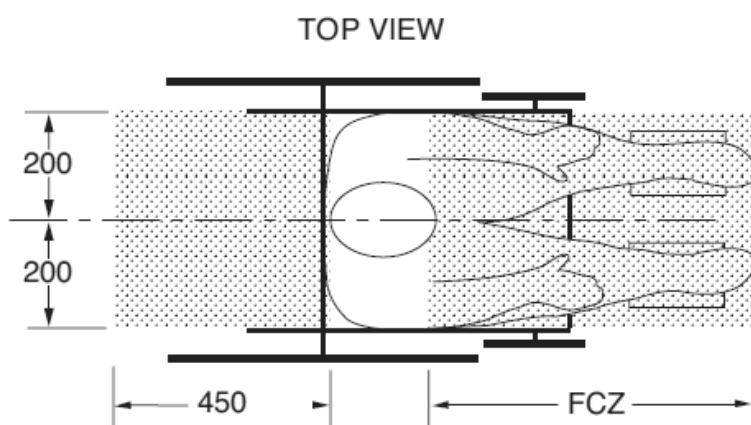
**WARNING**

8. cont... contact with the wheelchair occupant's shoulder and chest.
9. The Spex Seating System must only be used for forward-facing seating in motor vehicles.
10. In order to reduce the potential of injury to vehicle occupants, wheelchair-mounted rigid trays not specifically intended for use during travel in motor vehicles must be:
 - a. Removed and secured separately in the vehicle or
 - b. Secured to the wheelchair so they will not break free in a crash and
 - Be positioned with a gap of at least 3" (75 mm) between the back edge of the tray and the wheelchair occupant's abdomen and/or chest so as not to interfere with the proper belt-restraint use, and
 - Have energy absorbing padding placed between the back edge of the tray and the wheelchair occupant.
11. Alterations or substitutions must not be made to the seating system structure, parts or components, without first consulting Spex.
12. The use of a postural pelvic belt attached to the wheelchair base or seat frame is encouraged during travel, but these belts should be positioned so that they don't interfere with the proper positioning of crashworthy belt restraints, and they should not be relied on for occupant protection in crash situations unless the postural belt has been designed to comply with, and perform to the requirements of WC19.
13. Postural support devices that are not labelled as conforming to ISO 16840-4 may be used when in a vehicle, but should not be relied on for occupant restraint.

**WARNING**

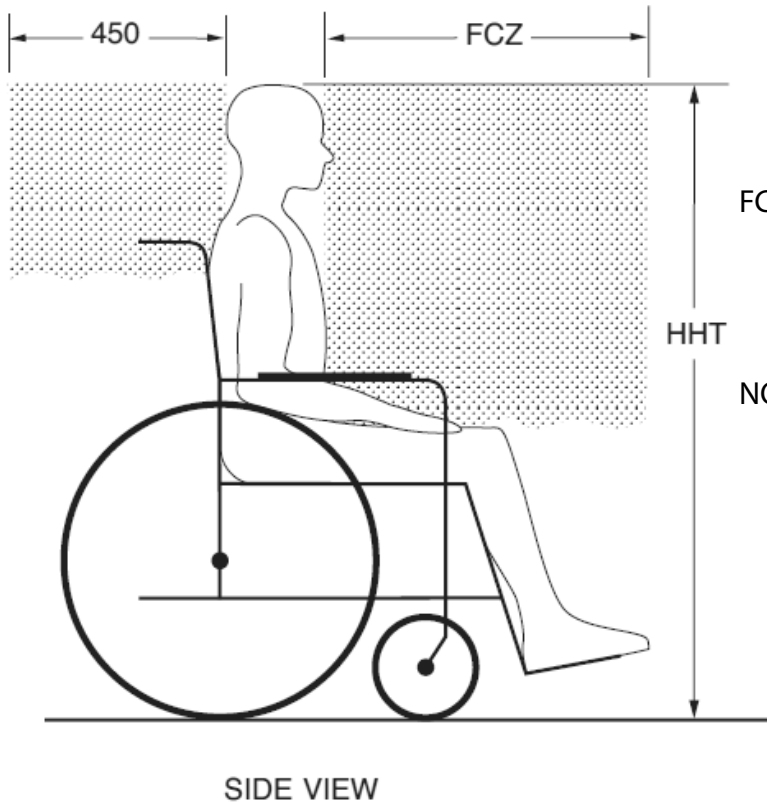
14. Both pelvic-belt and shoulder-belt restraints that comply with WC18 and/or WC19 should be used to limit occupant movement in a crash and reduce the likelihood of occupant ejection from the vehicle and/or injurious contact of the occupant with the vehicle interior.
15. Belt restraints should be positioned on the wheelchair occupant in accordance with WTORS manufacturer's instructions.
16. Backrest mounting hardware must be installed correctly. Refer to the appropriate section for correct backrest hardware mounting instructions.
17. If the wheelchair is being transported while occupied, the wheelchair must still be secured to the WTORS.
18. Children whose mass is less than 48.5 lbs. (22 kg) should be transferred from their seating system into appropriate child restraint systems intended for use in motor vehicles.
19. Sufficient forward and rearward clear space should be provided around the wheelchair occupant. Forward clear-space zone (FCZ) needs to be larger when a shoulder-belt restraint is not used.

FAILURE TO HEED THESE WARNINGS COULD CAUSE SEVERE INJURY TO THE WHEELCHAIR USER OR OTHERS.



NOTES: The rear clear zone is measured from the rearmost point on an occupant's head. The front clear zone is measured from the frontmost point on an occupant's head.

Seated head height (HHT) ranges from about 47" (1200 mm) for a small adult female to about 61" (1550 mm) for a tall adult male.

**WARNING**

FCZ = 25.5" (650 mm) with upper torso restraint
 = 37" (950 mm) with only pelvic restraint

NOTE: It is strongly recommended that both pelvic and upper torso belts be used.

Recommended forward and rearward clear zones for wheelchair seated occupants. (Note: the FCZ may not be achievable for wheelchair seated drivers).

Warranty

Each Flex Cushion is carefully inspected to provide peak performance and is guaranteed to be free from defects in materials and workmanship for a period of 24 months from the date of purchase, provided normal use. Should a defect in materials or workmanship occur within 24 months from the original date of purchase, Spex will, at its option, repair or replace it without charge. This warranty applies to the cushion components including the outer cover, incontinence cover, foam unit and strategic positioning base. This Warranty does not apply to the general wear and use, including punctures, tears or burns or customer abuse of any of the cushion components.

Claims and repairs should be processed through the nearest authorized Spex supplier. Except for express warranties made herein, all other warranties, including implied warranties of merchantability and warranties of fitness for a particular purpose are excluded. There are no warranties which extend beyond the description on the face hereof. Remedies for breach of express warranties herein are limited to repair or replacement of the goods. In no event shall damages for breach of any warranty include any consequential damages or exceed the cost of non-conforming goods sold.

The serial number of your Cushion can be located at the rear of the Cushion cover.



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