

IMPORTANT CONSUMER INFORMATION

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

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

USER: Before using this product, read this entire manual and save for future reference.

MD Free Form Seating is a medical device

www.symmetric-designs.com
sales@symmetric-designs.com
tel:1.250.537.2177



Manufactured in Canada by Symmetric Designs Ltd., 125 Knott Place, Salt Spring Island, BC V8K 2M4

Introduction

The intended use of the medical device: To provide support and control for the body in a seated position within a wheelchair.

Free Form Seating is designed for the intended purpose of providing support to compensate for loss of mobility due to an injury or handicap. **The intended users** require seating support resulting from but not limited to, the following conditions: Cerebral Palsy, Paralysis, Arthritis, Multiple Sclerosis or Motor Neurone Disease.

Contraindications for Free Form Seating are limited to those individuals needing support and control of the body in a seated position. The device is only to be used when attached to another medical device i.e. a wheelchair. If a wheelchair is not present, the device should not be used.

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

We want to hear your questions or comments about this manual and the safety and reliability of your product. Please feel free to write, email or call us at the contact information below:

Symmetric Designs
125 Knott Pl
Salt Spring Island, BC V8K 2M4
Canada
sales@symmetric-designs.com
1 800 537 1724
1 250 537 2177

NOTICE:

This product manual for Symmetric Designs Free Form Seating is meant to be an informational and generic resource so that a basic understanding of the product and its finite adjustment can be available for the user and caregiver. This manual should always be referenced in conjunction with a licensed clinician for more advanced fitting and support techniques. Failure to consult a licensed clinician can result in muscular and skeletal issues and/or injury to the user. The Symmetric Designs Free Form Seating and Mounting Hardware user manual should be read and fully understood, prior to the installation, set-up, and use of this product.

NOTICE: Read Before Use

A. CHOOSE THE RIGHT FREE FORM CUSTOM BACK KIT

Symmetric Designs provides a choice of many Free Form Back Kit options, sizes and adjustments to meet the needs of the user; however, final selection of seating equipment rests solely with you and your health care professional. Choosing the best seating for you depends on such things as:

1. Your size, orientation, strength, balance and coordination.
2. Your intended use, and your level of activity.
3. The types of hazards you must overcome in daily use (in areas where you are likely to use your wheelchair).
4. The need for options for your safety and comfort.

B. ADJUST TO YOUR ABILITY

You need to work with your doctor, nurse or therapist, and your supplier, to fit this seating solution, and adjust the system for your level of function and ability.

C. REVIEW THIS MANUAL OFTEN

Before using this seating solution, you, and each person who may assist you, should read this entire Manual and make sure to follow all instructions. Review the warnings often, until they are second nature to you.

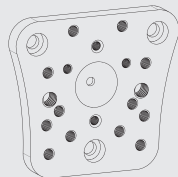
Free Form Mounting Hardware Components

Reinforcements



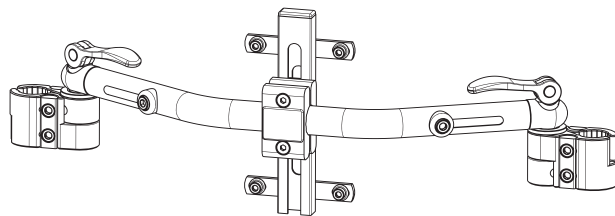
Alloy 2-Ball

Headrest Mounting Adapter



Universal Headrest Mounting Plate

Wheelchair Mounting

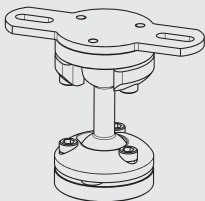


Centre Mount

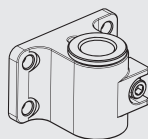


Independent Mount

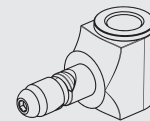
Seating Mounting Adapters



Surface Mount Adapter



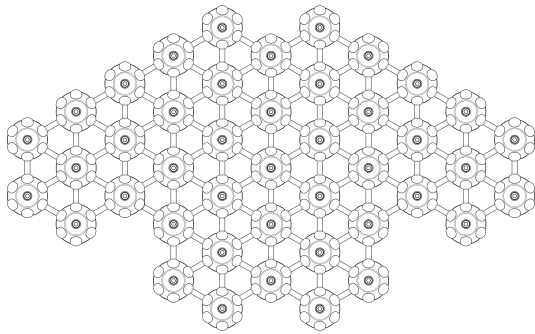
Flat Plate Mount Adapter



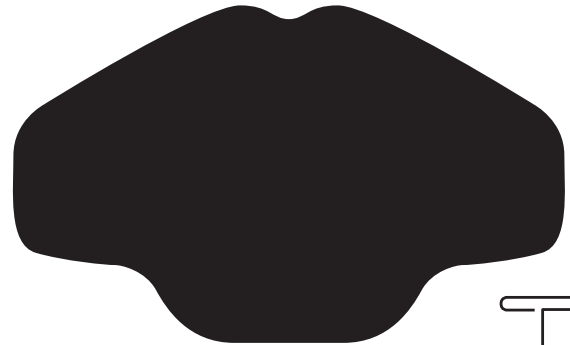
Vertical Adapter

Back Kits

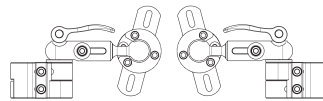
Lower Thoracic Kits



Shell



Stimulite
or
Foam Cover

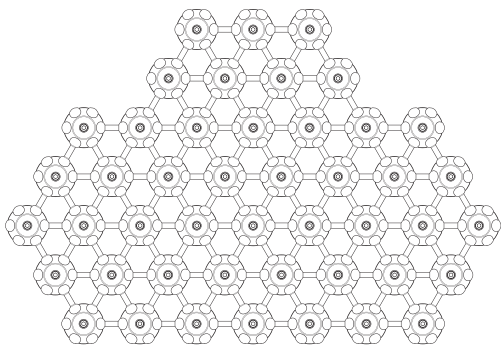


Independent Mounts



Hex Key

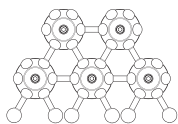
Upper Thoracic Kits



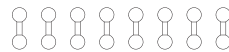
Shell



Stimulite or Foam Cover



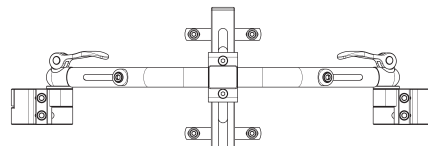
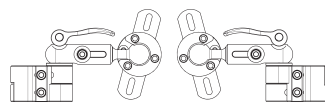
Array of 5 Clamps and 2-balls
(for expansion)



8 Alloy 2-balls for reinforcement
of high stress areas



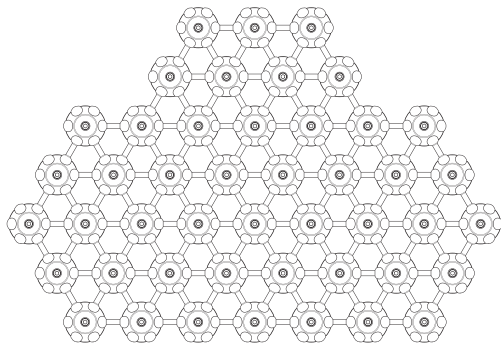
Hex Key



Independent Mount or Centre Mount

Back Kits

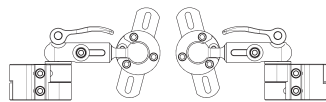
Upper Thoracic XL & XXL Kits



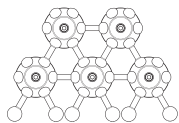
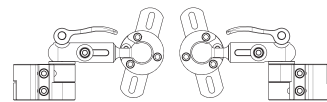
Shell



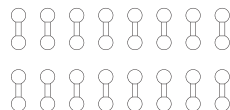
Stimulite or Foam Cover



2 Pair of Independent Mounts



Array of 5 Clamps and 2-balls
(for expansion)



16 Alloy 2-balls for reinforcement
of high stress areas




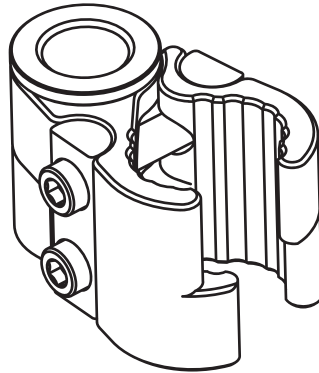
Hex Key

Mounting Clamp Installation

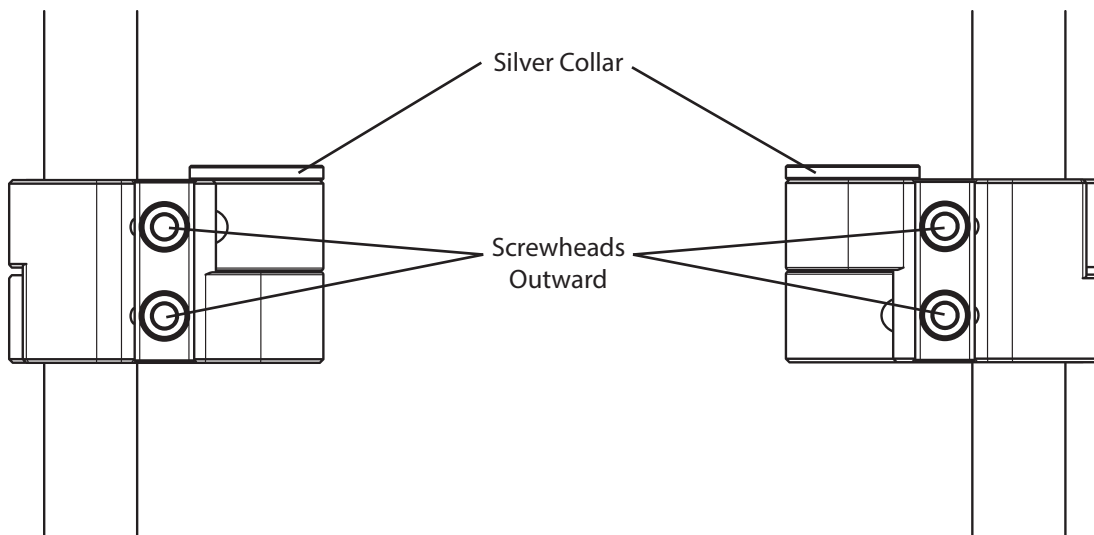
Mounting Clamp Installation on Wheelchair Posts

1.) Loosen clamp screws to expand arms.

 4mm Hex Key

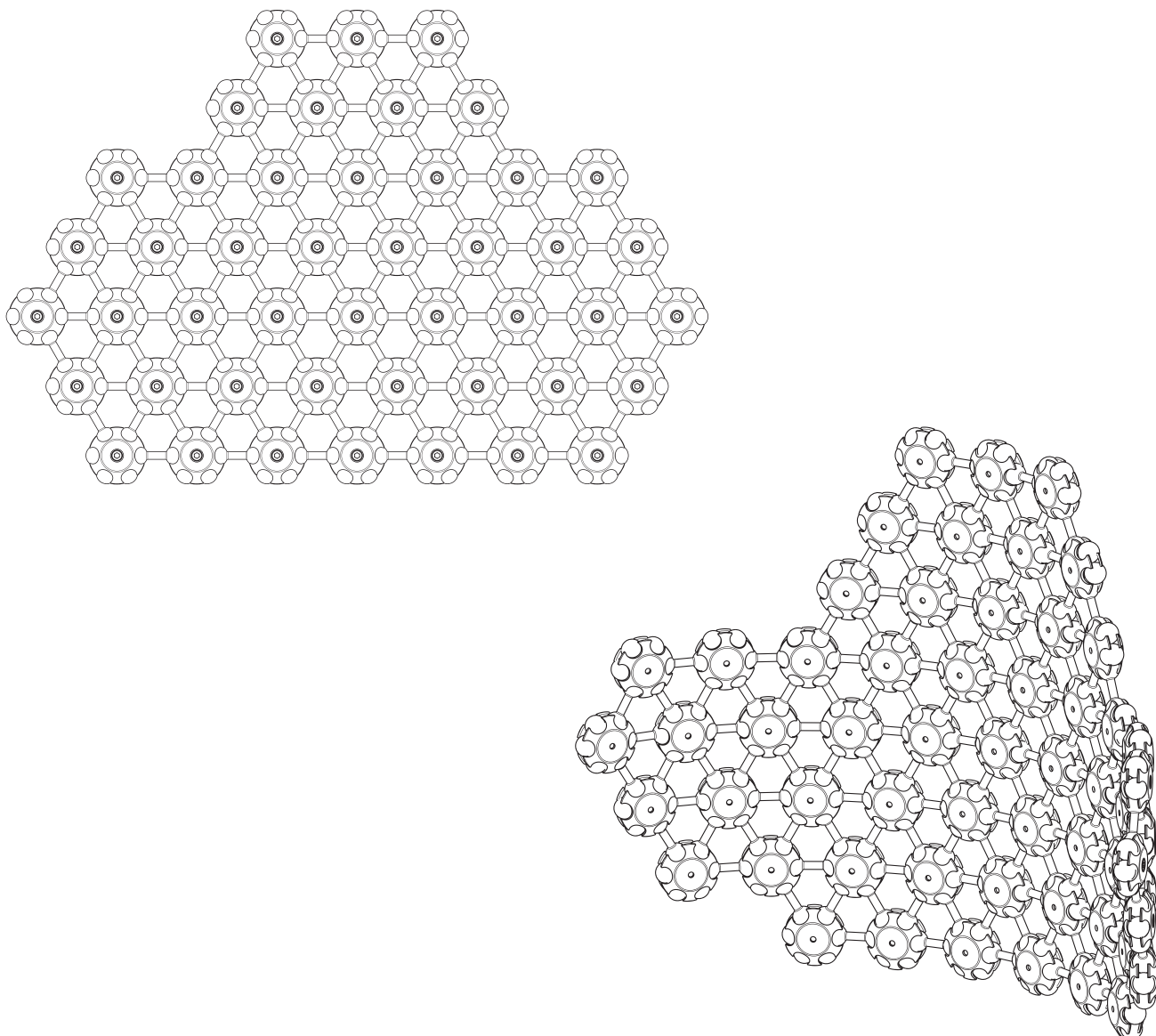


2.) Silver collar should be visible at the top and screws should be facing outwards on each side.
Position clamps at same height on posts.
Tighten clamp screws.



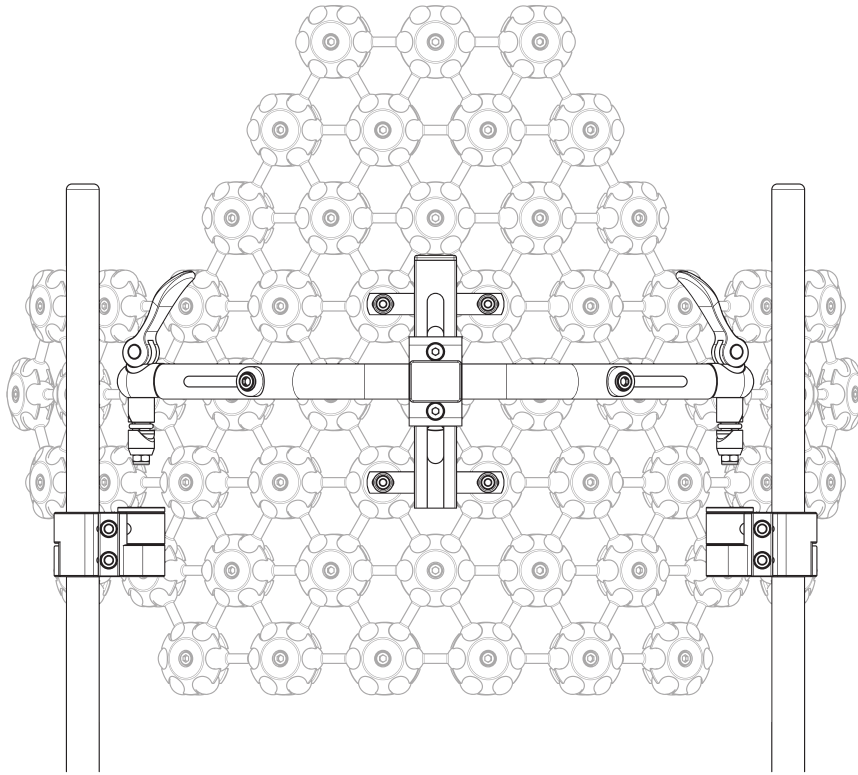
Free Form Shell Pre-shaping

Remove Free Form Shell from box and form to approximate shape. No tool is required to do this. Note that the Free Form shell is set to a specific torque level to allow shaping by hand without being too loose. Shaping can be done by forming around your own torso or the client's torso. Pre-shaping can also be done using measurements and the client's existing back support as a reference.

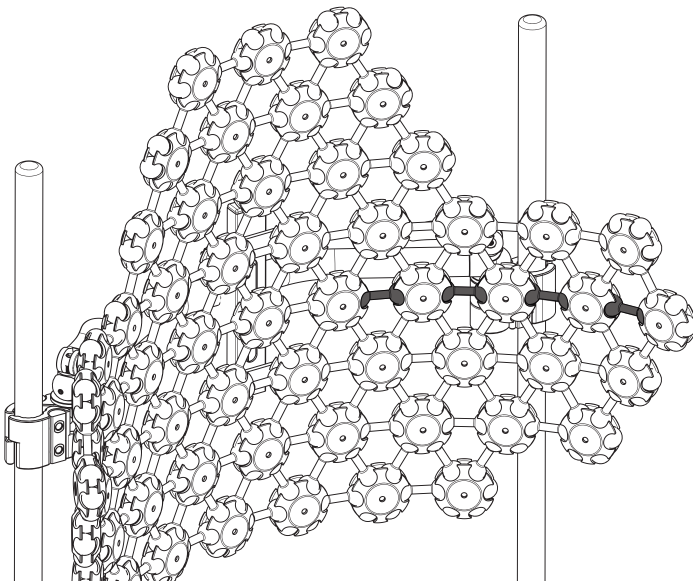


Securing the Free Form Shell to the Wheelchair

- 1.) Align the vertical mounting pins to the wheelchair clamps and fully insert the pins.



- 2.) Engage the lever to lock the pin into the wheelchair clamp.

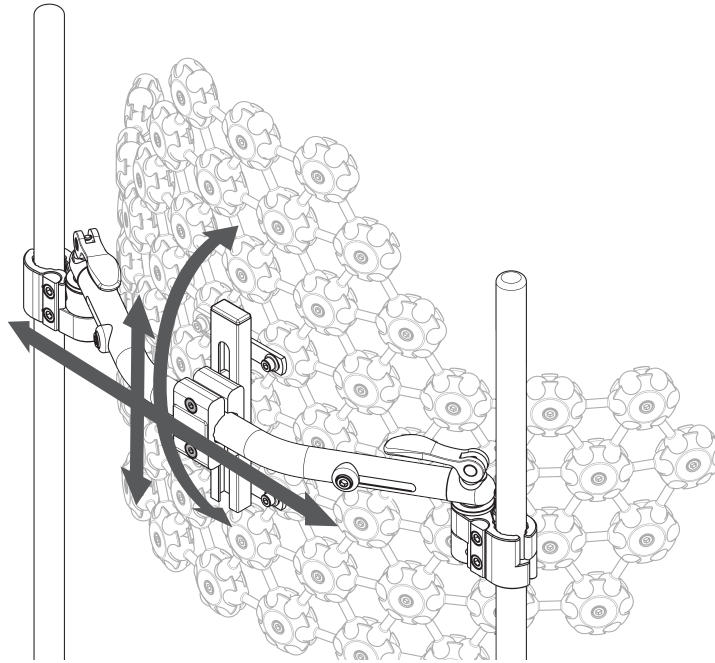


Free Form Shell Positioning

Adjust the height, depth and angle of the Free Form Shell to ensure appropriate positioning within the posts.

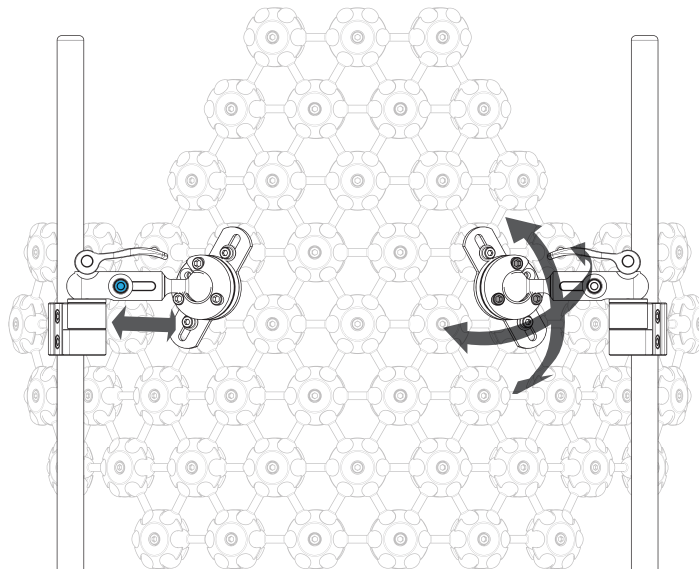
- 1.) The Centre Mount has two screws on the central track clamp with allow height, angle and offset positioning.

⦿ 4mm Hex Key



- 2.) The Independent Mounts have a blue screw on the slider bar to allow for depth and offset positioning. The angle and orientation adjustment is done through loosening the three screws on the mounting collar to allow the balls to rotate in the mounting plate cavities.

⦿ 4mm Hex Key

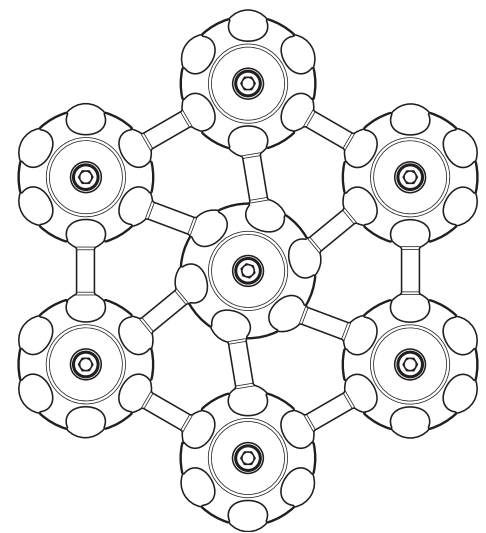


Free Form Shell Adjustments

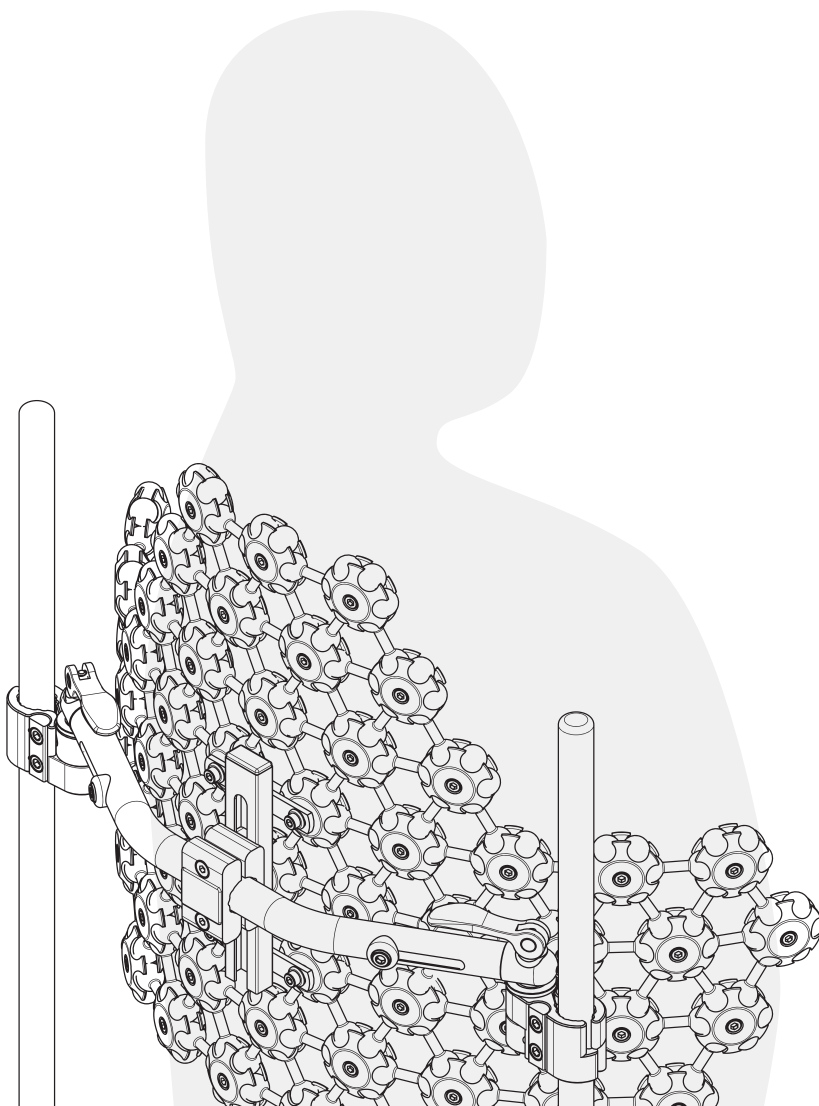
Now that the Free Form shell is mounted, fitting to the client can proceed. We typically recommend direct fitting to the client for a snug fit. To allow a slightly less snug fit, inlay the cover so that it sits between the client and the Free Form Shell.

When fitting directly to the client, have an assistant in front to help support their torso if necessary. Start contouring the Free Form shell by pushing and pulling the clamps to ensure even support, pressure distribution or off-loading, depending on the client's needs. You will be able to assess the support visually and through feel by through placing your fingers through the Free Form Shell. Use the Hex Key to loosen, adjust and then tighten the clamps.

○ 4mm Hex Key




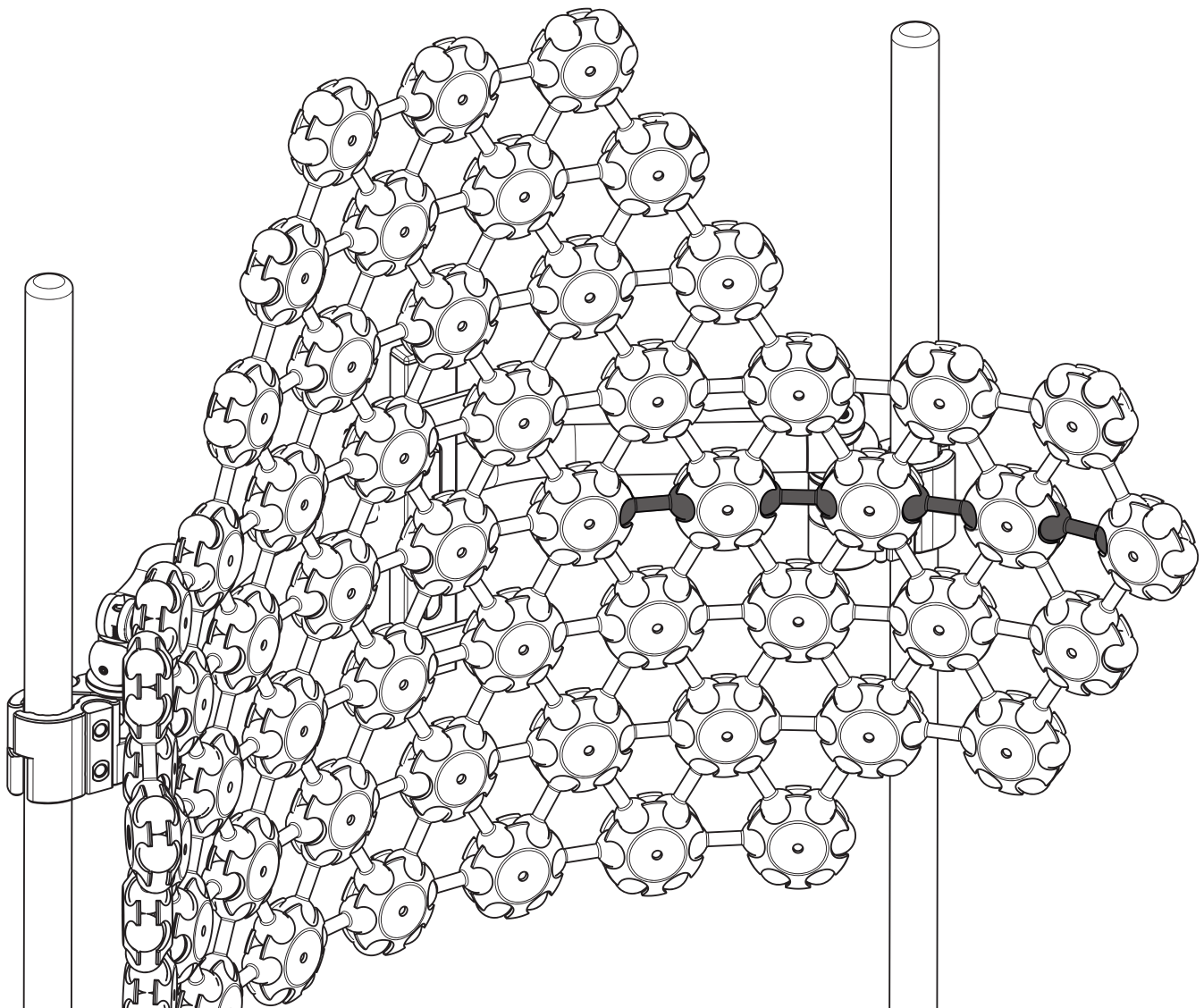
Note that the clamps can rotate which will reduce the space between them. This is useful for the end of the lateral supports to ensure a smooth contour.



Reinforcement and Mounting Positioning Accessories

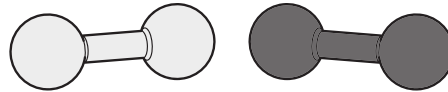
Free Form Upper Thoracic Kits include Alloy 2-Balls. These Alloy 2-Balls are meant to reinforce high stress areas of the Free Form shell such as lateral supports, the area around the headrest mounting plate, and the section around the mounting hardware. Do not use more than three alloy 2-balls per clamp. To reinforce a lateral support, simply replace the black 2-balls with the silver alloy 2-balls in a horizontal line from the tip of the lateral to the central part of the back. Positioning belt, buckle and straps can be mounted directly to the Free Form Shell using the included extended screws. Simply remove the existing screw in the centre of the clamp.

 4mm Hex Key



2-Ball Strength and Durability

2-Ball units are manufactured to be durable, resilient and have a small amount of flex. They are made from a formula containing glass fibre, rubber and nylon. They also contain UV protection and salt corrosion protection.



Occasionally 2-ball units on a Free Form shell can experience high stress due to a variety of factors including but not limited to:

- Increase of pressure
- Impact
- Angle of Free Form shell
- Size of Free Form shell

The breakage of a 2-ball unit is an indication of a high stress area on the Free Form shell. Symmetric Designs recommends re-enforcing the high stress area by replacing black 2-ball units with the alloy 2-ball units. Running a “line” of alloy 2-ball units is very effective when extra re-enforcement is required. It is recommended that no more than three alloy 2-ball units be mounted on a clamp as more 2-balls will reduce clamping power and could result in slippage.

Examples of where alloy 2-ball reinforcement might be needed include but is not limited to:

- A row on a lateral support that is leaned on heavily
- Around a headrest plate mount or accessory/positioning mount
- Mounting hardware area on the Free Form shell (e.g. Independent Mount plate or Centre Mount plate)

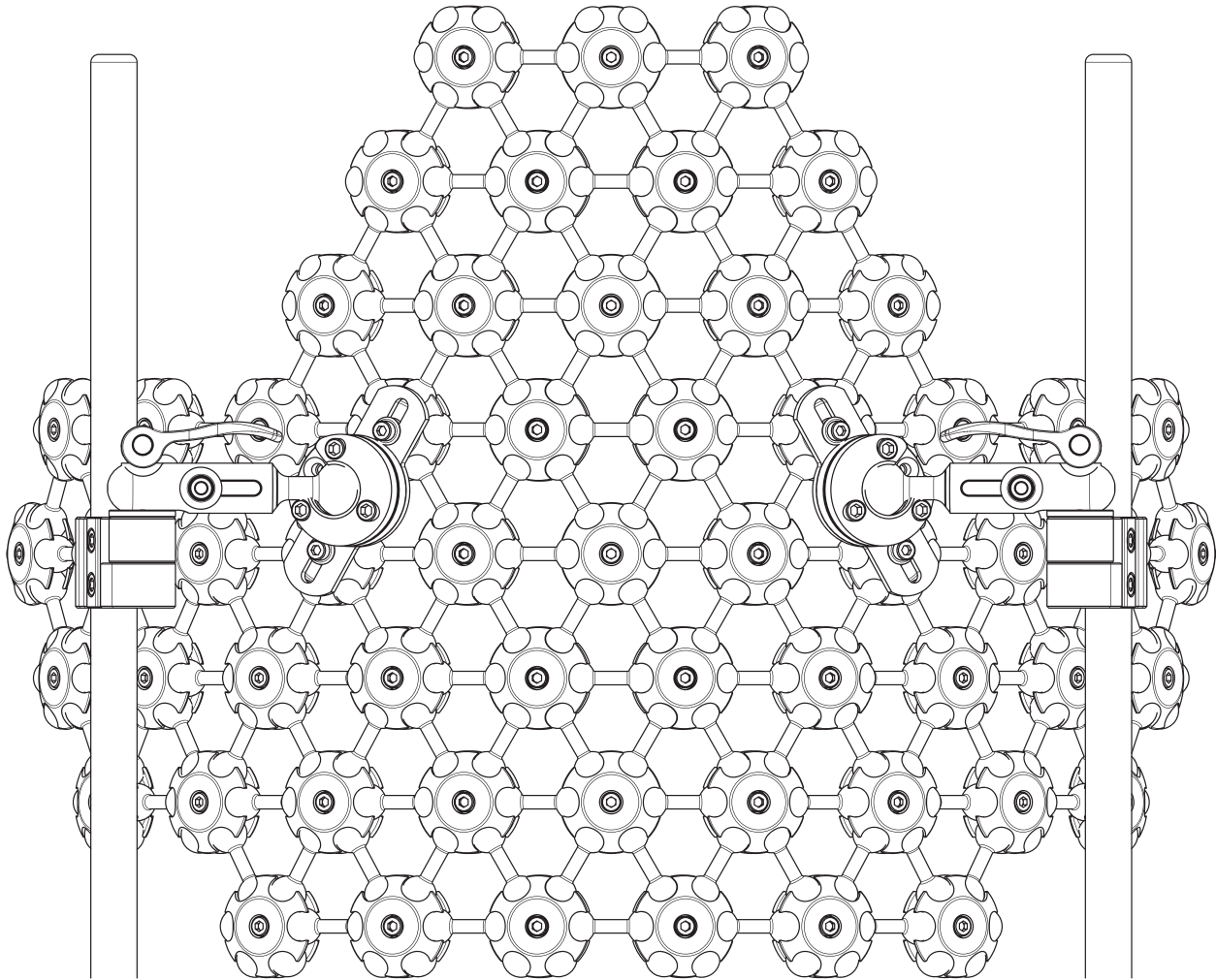
If you experience a 2-ball breakage, it is recommended the broken 2-ball be replaced with an alloy 2-ball for increased durability and rigidity.

Tightening tip:

Using the included 4mm Hex Key, ensure all clamps are tightened by hand as much as you can. If using a torque wrench, do not exceed 7 Nm. Clamps should be tightened to a minimum of 4.5 Nm. You may hearing the screw make a binding noise when tightening by hand. This is ok and to be expected. Note that you will still be able to loosen the screw for readjustments.

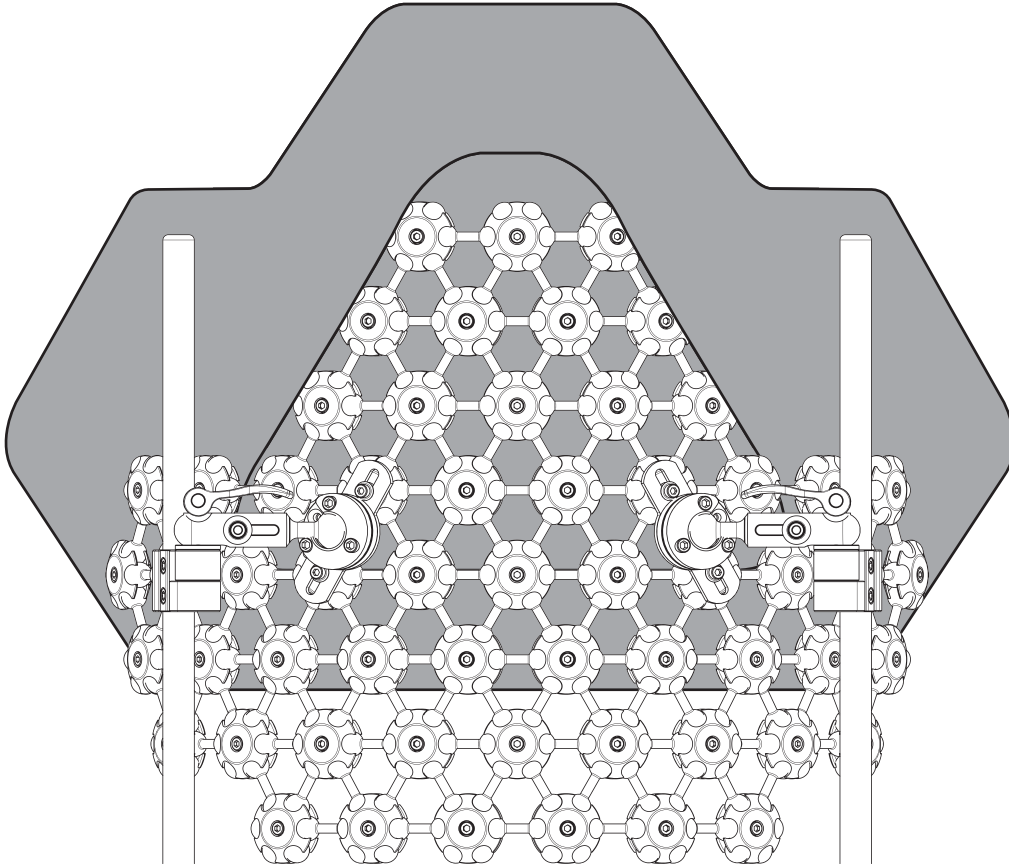
Final Tightening

To complete the fitting, tighten each clamp screw by hand using the hex key. Tighten as much as possible. It is usually best to go row by row to ensure no clamp is missed.



Install the Cover

The cover's outer lycra perimeter will stretch over the Free Form shell.



Final Checks

After a period of approximately 30 minutes of use, check the client's skin to ensure there are no areas of redness. Also check to ensure the sitting posture is functional and the client is comfortable. Make any final adjustments to the orientation and contour of the shell as needed.

Warnings

A. NOTICE TO USER

Before using the seating equipment, you should be trained in its safe use by a health care provider. Failure to consult a professional can lead to extreme discomfort or serious injury for the user of this equipment.

B. NOTICE TO CAREGIVER

1. Be sure to work with the user's health care professional to learn proper adjustment, safety, and support methods that are best suited to the specific needs of the person using the seating equipment.
2. Always move the user to another seated area before installing, or adjusting the seating system.
3. To prevent injury to your back, always use good posture and proper body mechanics when adjusting seating hardware.

C. SAFETY CHECKLIST

Before each use of the seating system:

1. Check the equipment for any loose components, and/or fasteners. Adjust the equipment to the original specifications and tighten to a sufficient torque. Failure to do so, may result in a risk of equipment failure, damage to components and/or user injury.
2. Repair any problem that you encounter. Seek help -your authorized supplier can help you find and correct any issues.
3. Never allow the seating equipment to be used unless it is fully functional and is free from significant wear to metal components and pads.
4. Before use, ensure that no component applies direct pressure to pressure sensitive areas such as bony prominences or vulnerable soft tissue areas.
5. Make sure that the seating system is attached securely to the wheelchair.

D. CHANGES AND ADJUSTMENTS

1. See your health care professional, and have them adjust seating components and accessories as growth or change occurs in the user.
2. When a support component is added to the original system, be sure to consult your health care professional and have them adjust and fit the new component.

E. ACCESSORIES

Unauthorized modifications or use of parts not supplied or approved by Symmetric Designs may change the product's structure and effectiveness. Unauthorized modifications will void any warranty and may cause a safety hazard for the user.

F. SEATING EQUIPMENT SUPPORT MISUSE

Never use the seating equipment to maneuver, lift or change direction of the wheelchair that it is attached to. It should not be used as a handle to push the chair. Misuse in this way can cause damage and excessive wear to the equipment, which could put the user at risk.

G. FASTENERS

Many of the screws and nuts on this product are special high-strength fasteners. They require periodic checks and maintenance to ensure the safety of both the user and attendant.

1. Only use fasteners provided by an authorized supplier (or ones of the same type and strength, as indicated by the markings on the hardware).
2. Do not over- or under- tighten fasteners. If screws or nuts become loose, tighten them as soon as possible.
3. ALWAYS tighten fasteners to a sufficient torque to ensure the strength and longevity of your products.

H. MOTOR VEHICLE SAFETY

If possible and feasible, never use the seating system in a motor vehicle.

1. Symmetric Designs seating equipment is not transit tested for use in a motor vehicle. When seating a user in a motor vehicle, it is always suggested to transfer the user to the original equipment manufactured vehicle seat and use the vehicle restraints.
2. In an accident or sudden stop, the rider's body may be thrust forward, backward, or to the side, and dislodge or change adjustment to the seating equipment.
3. Do not use this product if it has been involved in a motor vehicle accident.

Warnings

The following suggestions will help ensure safe and successful product use.

MECHANICAL COMPONENTS

We recommend checking all system components on a regular basis. The frequency of these checks will depend on how rigorously the product is used.

Checking the following items will ensure safe and functional product use:

1. Check tightness of all fasteners and hardware attachment points.
2. Review metal parts for signs of wear, cracks, bent parts or excessive flexing.
3. Replace or repair any parts showing wear.

THREADED HOLES

Do not force any fasteners. Being gentle, and tightening fasteners evenly will usually correct any fastener problems.


Warranty



Each Symmetric Designs product is carefully inspected to provide peak performance and is guaranteed to be free from defects in materials and workmanship for a period of 12 months from the date of purchase, provided normal use. Should a defect in materials or workmanship occur within 12 months from the original date of purchase, Symmetric Designs will, at its option, repair or replace it without charge. This warranty does not apply to general wear and use, including the application of excessive loads. Claims and repairs should be processed through the nearest authorized Symmetric Designs 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.

Glossary
of
Symbols

 EU Representative
 Swiss Authorized Representative

 Manufacturer
 Medical Device

 MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug Switzerland

 MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague, The Netherlands
 Designed and Manufactured In Canada

Date of issue: 2021-02