2. Insert the Composite Tube into the front end of the Composite Tube Cutting Guide until the mark made in Step 1 is visible through the slot in the guide. (The front end of the Guide is the end marked with an “F”.)

3. Tighten the Composite Tube Cutting Guide onto the Composite Tube using one of these methods:

   a. Clamp the guide into a vise.

      OR

   b. Tighten the capscrew on the side of the Guide (only when vise is not available).

   In either case, the Guide should only be tightened to the extent that the Tube no longer spins inside the Guide.

4. Cut the Tube by inserting a hacksaw through the slot in the Guide. To determine whether you have cut completely through the Tube, pull gently on the Tube at the front end of the Guide. Proceed to Step 6.

5. If the Composite Tube Cutting Guide is not available, wrap tape around the area to be cut to prevent the composite fibers from splintering. Do not pull splintered fibers, since pulling will cause the fiber to “run” the length of the tube. Lightly smooth the cut end using a sander after desired length is obtained.

6. Press a 30mm Composite Tube Insert into each end of the 30mm Composite Tube. The inserts should fit snugly and be flush with the ends of the tube.

Warning: Failure to install 30mm Composite Tube Inserts will lessen the structural integrity of the tube and could cause failure of the prosthesis and injury to the amputee.

7. Install a 30mm Titanium Adapter onto each end of the tube and tighten each adapter clamp bolt to 10-12 ft-lbs (14-16 Nm). For subsequent tightening, you may need to increase the torque to 12-14 ft-lbs (16-19 Nm).

8. To cut the 30mm Composite Tube after the 30mm Composite Tube Insert has been installed, press the insert slightly farther into the tube so that the 30mm Composite Tube Insert will not be cut. For definitive assembly, the insert must be pulled back out so that it is flush with the end of the tube. Install a 10mm bolt into the hole in the center of the insert to facilitate pulling the insert out.

9. Connect one of the 30mm Titanium Adapters to the Magnum Heavy Duty foot, and connect the other 30mm Titanium Adapter to the socket.

10. Once alignment has been achieved, apply Loc-Tite 242 (or equivalent) to all pyramid setscrews and tighten the setscrews to 12 ft-lbs (16 Nm).

11. Have the amputee don the prosthesis. If using System Part No. MHD-300:

    a. Air will be expelled as the limb enters the socket.

    b. Seal the top of the socket by using an Ohio Willow Wood Suction Seal or equivalent.

Increasing the Length of the Prosthesis

The only way to increase the length of a prosthesis made with Magnum components is to install a longer 30mm Composite Tube. Do not attempt to increase the length by inserting a spacer of any type into a 30mm Adapter.

Warning: Inserting a spacer between the pylon and the 30mm Titanium Adapter may cause failure of the prosthesis and injury to the amputee.

SPECIAL NOTE
Concerning the Magnum Heavy Duty Foot:

The Magnum Heavy Duty Foot is essentially water resistant, provided no open cracks have developed and no area of the foot has been sanded. Complete submersion in water is not recommended.

Warranty

The warranty against defects in materials and workmanship for the Magnum Heavy Duty System is two years for the endoskeletal components and one year for the foot (allowing three weeks from the date of purchase for installation), provided that the components are selected according to the following criteria:

Note: The weights listed below are <u>modified</u> body weights. Modified body weight is defined as the weight of the amputee plus any loads normally or routinely carried by the amputee.

Patient Weight Limit: 350 lbs./160 kg
(300 lbs./135 kg for CMS Level 4))
(refer to “Activity Level Definitions”)

Use of the Magnum Heavy Duty System for amputees who do not meet the above criteria or who engage in extremely high and abusive activities is against Ohio Willow Wood Company’s recommendations and will void the two year warranty for the endoskeletal components and the one year warranty for the foot. “Extremely high and abusive activities” are defined as activities such as skydiving, karate, and judo; activities that could result in injury to an individual’s natural limbs; and activities that expose the prosthesis to corrosives such as salt water.

Defective components will be repaired or replaced at Ohio Willow Wood’s discretion.

Warranty Disclaimer

Ohio Willow Wood warrants that each product manufactured will, at the time of delivery, be of workmanlike quality and substantially free of defects. **OHIO WILLOW WOOD MAKES NO OTHER WARRANTY, IMPLIED, OR EXPRESSED, AND MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** This warranty shall terminate immediately upon an action to combine our products with other materials or in any manner to change the nature of our products. The sole remedy is replacement of the products or credit for the products. Ohio Willow Wood's liability shall not exceed the purchase price of the product. **Ohio Willow Wood shall not be liable for any indirect, incidental, or consequential damage.**

Ohio Willow Wood Retention of Rights

Ohio Willow Wood retains all intellectual property rights reflected or incorporated in its physical products, regardless of the transfer of the physical products to another party or parties.

Activity Level Definitions

Level 1: Amputee has the ability or potential to use a prosthesis or transfers or ambulation on level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.

Level 2: Amputee has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or eneven surfaces. Typical of the limited community ambulator.

Level 3: Amputee has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetics utilization beyond simple locomotion.

Level 4: Amputee has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Patient Advisory Warning

The enclosed Patient Advisory Warning enables you, the prosthetist, to effectively notify your patients of the limitations of the components in their prosthesis, and of the need to monitor their weight and activity levels. Please review the Patient Advisory Warning with the patient upon delivery of a prosthesis with the Magnum Heavy Duty System. The patient and the prosthetist should then sign the Patient Advisory Warning to acknowledge that it has been reviewed and understood by both parties. Give one signed copy to the patient and place one copy in the patient’s file.

If a patient’s weight or activity level increases after receiving a prosthesis with the Magnum Heavy Duty System, the patient should immediately contact the prosthetist to determine whether the limits of the system have been exceeded. If a patient continues to use a prosthesis with the Magnum Heavy Duty System after experiencing an increase in weight and/or activity level, the system could fail with the possibility of serious injury to the patient.

To ensure that the patient is within the limits for the system, the prosthetist should weigh the patient on scales in the prosthetist’s office. Do not rely on the patient’s estimate of his/her own weight. Instruct the patient to monitor his/her weight weekly to ensure that it remains in a range appropriate for the prosthetic components being used.

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The Netherlands

PN-1219-G 13 AUG 2009

Assembly Instructions
for the
Magnum Heavy Duty System

Magnum Heavy Duty System Specifications

Patient Weight Limit (maximum actual body weight plus loads normally or routinely carried):
350 lbs./160 kg
(300 lbs./135 kg for CMS Level 4)

Heel Height: Women - 3/8" (10mm) or 1 1/8” (30mm)
Men - 3/4" (18mm) or 3/8" (10mm)

Available Sizes: Women - 22cm to 27cm
Men - 23cm to 31cm

Toe Resistance: Very Low, Low, Regular, High, Very High

Components included in system:

MHD-100:
Titanium Laminating Pyramid Adapter
Titanium 30mm Adapters (2)
30mm Composite Tube
30mm Composite Tube Inserts (2)
Foot

MHD-200:
Laminated Socket Attachment Block
Titanium 4-Hole Pyramid Adapter
Titanium 30mm Adapters (2)
30mm Composite Tube
30mm Composite Tube Inserts (2)
Foot

MHD-300:
Laminated Socket Attachment Block
Titanium 4-Hole Suction Pyramid Adapter
Titanium 30mm Adapters (2)
30mm Composite Tube
30mm Composite Tube Inserts (2)
Foot

Please read thoroughly before assembling a prosthesis using the Magnum Heavy Duty System. For System Part No. MHD-100, follow the “Fabricating a Socket Using the Titanium Laminating Pyramid Adapter” instructions. For System Part No. MHD-200 or MHD-300, follow the “Fabricating a Socket Using the Laminated Socket Attachment Block” instructions.

Fabricating a Socket Using the Titanium Laminating Pyramid Adapter (System Part No. MHD-100)

1. Apply a layup that is appropriate for the amputee's weight and activity level.
2. Before pulling the final layer of stockinette over the cast, apply the Titanium Laminating Pyramid Adapter to the layup so that the four pre-installed pieces of carbon tape extending from the adapter are in an A-P/M-L orientation.
3. Make sure that the laminating cap included with the adapter is still in place, covering the pyramid dome.
4. Pull the four pieces of carbon tape down tightly against the socket.
5. Secure the four pieces of carbon tape tautly to the socket with double-sided tape.

Warning: If the carbon tape is not pulled tautly and secured, the adapter may come loose from the socket and/or the structural integrity of the adapter may be affected.

6. Cut two lengths of 3" (8cm) wide carbon tape long enough to extend from one side of the socket, across the Titanium Laminating Pyramid Adapter, to the other side of the socket. The tape should cover a minimum of 4" (10cm) on each side of the existing socket.
7. Cut a slit along the midline of each strip of carbon tape at the middle of its length. Each slit should be long enough to fit over the laminating cap.
8. Place the strips of carbon tape on the adapter so that the entire laminating cap protrudes through the slits. Orient one strip of tape A-P and the other M-L.
9. Pull one layer of nylon stockinette down over the socket.
10. Tie off the stockinette at the base of the pyramid dome beneath the laminating cap.
11. Pull the remainder of the stockinette down to create a double layer of stockinette over the socket. Make sure that all of the carbon tape stays underneath the stockinette.
12. Laminate using a layup that is appropriate to the amputee's weight and activity level. After the lamination has set, remove the laminating cap.
13. Proceed to "Assembling the Magnum Heavy Duty System."

Fabricating a Socket Using the Laminated Socket Attachment Block (System Part No. MHD-200 and MHD-300)

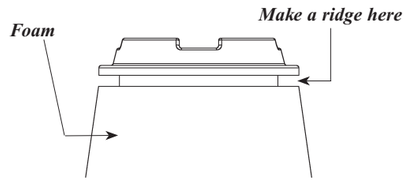
Materials included in the Laminated Socket Attachment Block kit:

1 Laminated Socket Attachment Block
1 metal laminating cap
4 6mm temporary attachment capscrews
4 gray plastic caps
4 6mm flat head attachment screws
2 Carbon Tape, 2" x 12"

Additional materials required:
Sealing resin or polyester resin, petroleum jelly, putty, or paste wax, standard lab supplies.

1. Attach the Laminated Socket Attachment Block to the socket with sealing resin or polyester resin. Make sure that the two 3/4" (2cm) channels on the block are in a true Anterior/Posterior-Medial/Lateral orientation.

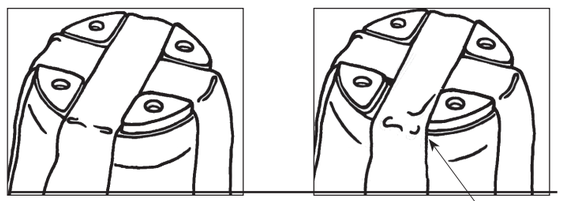
Note: When applying foam or a similar material between the Laminated Socket Attachment Block and the socket, be sure to form a ridge between the block and the foam as shown. The ridge will fill with laminate and provide a reinforcement to prevent the Laminated Socket Attachment Block from pushing up into the foam.



2. Fold the strips of carbon tape (included with the Laminated Socket Attachment Block) lengthwise into thirds so that they will fit completely within the 3/4" (2cm) channels.
3. Place one strip of carbon tape into each of the channels.

Note: Do not allow the carbon tape to come up above the sides of the channels and onto the four raised surfaces on the composite block. If carbon tape is pinched between the raised surfaces on the composite block and the metal laminating cap, two problems could develop: (1) gaps between the two surfaces may allow laminating resin to enter the threaded holes in the Attachment Block, and/or (2) the attachment surface may not be level. As an extra precaution against resin sticking to the threads, apply petroleum jelly, putty, or paste wax to the threads of the 6mm temporary attachment capscrews before installing.

Warning: Failure to use carbon tape (or similar) to reinforce the attachment could result in an attachment of inadequate strength and could lead to failure of the prosthesis.

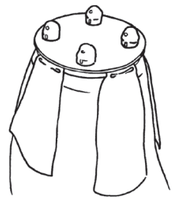


Correct: carbon tape fits entirely within the channels

Incorrect: carbon has come up above the side of the channel and is on top of one of the raised surfaces

4. Attach the metal lamination cap to the Laminated Socket Attachment Block with the 6mm temporary capscrews. (The cap will hold the carbon tape in place and provide an area to tie off the lamination.)
5. Place the gray plastic caps and/or putty onto the heads of the screws to prevent the resin from penetrating.
6. Fan out and pull tight the ends of the carbon tape onto the socket. Secure the carbon tape with spray adhesive.

Warning: If the carbon tape is not pulled tautly and secured, the attachment block may come loose from the socket and/or the structural integrity of the attachment block may be affected.



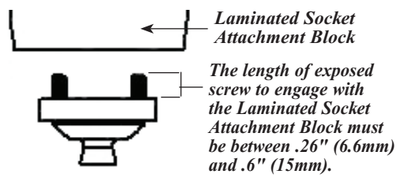
Carbon tape fanned out on socket

7. Cut a piece of tubular nylon stockinette twice as long as the socket.
8. Pull the stockinette onto the socket and tie it off just proximal to the metal lamination cap.
9. Pull the distal end of the stockinette down over the socket, so that there is a double layer of stockinette over the carbon tape and socket.
10. Proceed with the finish lamination. To ensure proper saturation of the carbon tape, use a full vacuum and work the resin into the 3/4" (2cm) channel areas.
11. After the lamination has completely cured, break the excess resin off of the lamination cap, remove the four screws from the cap, then remove the lamination cap.

Note: Before assembling the prosthesis, sand off the knob of resin left by the hole in the center of the laminating plate.

13. For System Part No. MHD-200, follow steps a and b below. For System Part No. MHD-300, proceed to "Attaching the Suction Pyramid."

a. Attach the Titanium 4-Hole Pyramid Adapter to the socket using the four 6mm flat head screws included with the socket block. Check to make sure that the length of the exposed screw to engage with the Laminated Socket Attacdment Block is between .26" (6.6mm) and .6" (15mm). Hand-tighten the screws to make sure that they turn freely over their entire usable length. Tighten the screws to 9 ft-lbs (12 Nm).



b. Proceed to "Assembling the Magnum Heavy Duty System."

Attaching the Titanium Suction Pyramid Adapter (System Part No. MHD-300)

Materials included with the Titanium Suction Pyramid Adapter:

1 Titanium Suction Pyramid Adapter
1 Porous Plastic Insert
1 Foam Muffler

Note: Make sure that the attachment block has a flat surface for the Suction Pyramid to seal against.

1. Drill a 7mm (9/32") diameter hole in the center of the socket (Figure 1). If the 4-hole attachment block is offset with respect to the socket, drill the hole at an angle from the center of the Attachment Block to the center of the distal end of the socket (Figure 2).

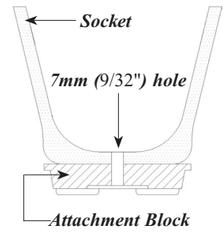


Figure 1

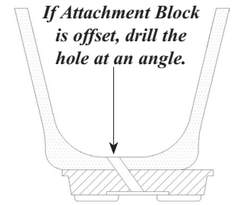


Figure 2

2. To prevent dirt and debris from clogging the airway, place the Porous Plastic Insert inside the 7mm (9/32") hole. Make sure the Porous Plastic Insert is flush with the inner surface of the socket (Figure 3). If the hole was drilled at an angle, cut or sand the Porous Plastic Insert at an angle as well (Figure 4).

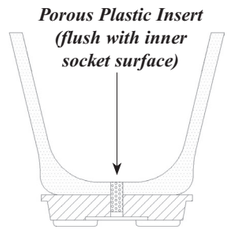


Figure 3

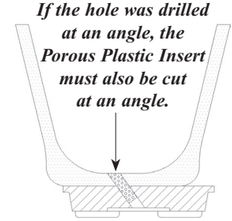


Figure 4

3. Attach the Titanium Suction Pyramid Adapter to the socket using the four 6mm flat head screws included with the socket block. Check to make sure that the length of the exposed screw to engage with the Laminated Socket Attacdment Block is between .26" (6.6mm) and .6" (15mm). Refer to the diagram in Step 13 (a) at left. Hand-tighten the screws to make sure that they turn freely over their entire usable length. Tighten the screws to 9 ft-lbs (12 Nm).
4. Insert the Foam Muffler down into the 30mm Composite Tube to reduce any air noise coming from the valve, and proceed to "Assembling the Magnum Heavy Duty System."

Assembling the Magnum Heavy Duty System

Note: The 30mm Composite Tube Inserts included with the system are required for each end of the 30mm Composite Tube. A Composite Tube Cutting Guide is also recommended and included free of charge with each facility's first Magnum purchase. If you do not have the Composite Tube Cutting Guide, follow the alternate instructions in Step 5.

1. Determine the length to which the Composite Tube should be cut. Make a mark on the Composite Tube at that point.