



MagValve Installation Instructions for Use – Professional and Patient Document

For Professional Use Only

Technical Notes for MagValve Fabrication

Thank you for purchasing Energy Prosthetics' MagValve. We think you and your patients will agree that the MagValve represents a revolutionary step forward in prosthetic expulsion valve design. The following instructions are designed to make it easy for a prosthetist or technician to install the MagValve quickly and easily.

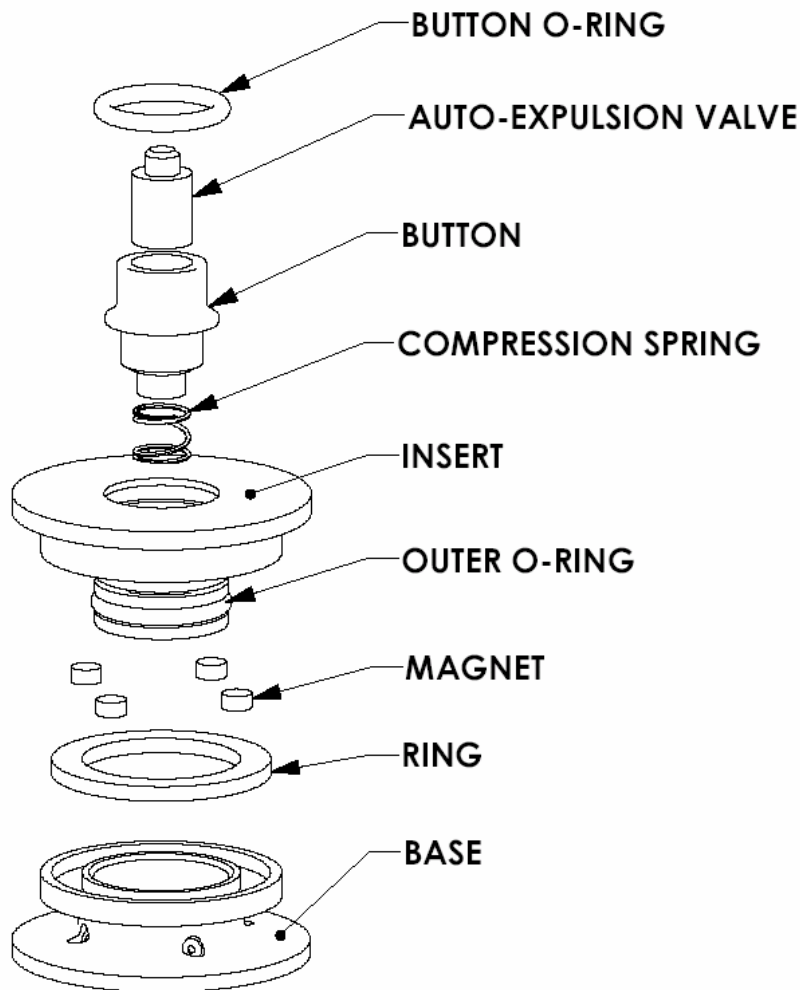


Figure 1 - Exploded View of MagValve

Set-up

1. Create level surface on positive mold upon which to mount **BASE**. Ensure that the level area extends just beyond the **BASE** boundary and that no portion of the **BASE** lies outside this region when placed on the model.
2. It is highly recommended to ensure optimal sealing of the **BASE** when thermoforming that you apply an appropriate adhesive that bonds plastic well to the **BASE** flange. Please feel free to email info@energyprosthetics.com or call 818.675.5083 for recommendations.
3. Place **BASE** on positive model, insert fabrication tool with countersink for screw head facing up into **BASE** and secure both to positive model by utilizing an appropriately sized screw or nail. For best results, a screw is recommended as it will allow for easier removal after fabrication.
4. Prior to thermoforming or laminating it is recommended to place a protective layer of material such as pelite, leather or other over the top of the tool to ensure its longer life. This will prevent excessive wear when grinding down to expose the tool's surface in preparation for removal.
5. For laminated sockets without a thermoformed insert, just laminate as usual.
6. For laminated sockets with a thermoplastic insert, it is highly recommended that during the thermoforming procedure the included zip tie is used to help ensure sufficient sealing of the thermoplastic to the **BASE** during vacuum. It should be applied during the thermoforming process, trimmed and left in place.



IT IS IMPERATIVE THAT THE THERMOPLASTIC MATERIAL AROUND THE BASE IS A UNIFORM THICKNESS TO ENSURE PROPER SEALING!

It is a good idea to trim the top layer of plastic off the fabrication tool after thermoforming to expose its face prior to laminating. This is best done by grinding with a drum sander or cone, or trimming with a sharp blade. This better defines the tool's profile after lamination, making it easier to determine where to trim or sand.


Prior to laminating, it is recommended that you create a build-up around the **BASE**, to allow the wearer's fingers ample room to grasp the **INSERT** of the valve for removal during daily use without damaging the inner liner. This build-up can be a material of your choice such as pelite, plaster or other. Laminate as usual.



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Finishing

1. In frame-style sockets, remove the inner liner. In either laminated or frame style sockets, grind down to the fabrication tool face to expose it and remove any excess protective material still remaining.
2. Remove the screw or nail from the fabrication tool. Attempt to work fabrication tool free by partially inserting same nail, screw or similar type object into the center hole and leveraging it out using a pulling motion. Most likely you will have to trim away excess material surrounding **BASE** prior to removing fabrication tool.
3.  Removal of the vertical lip of material remaining after removal of the fabrication tool is essential in order to present a cleanly finished socket. This can be accomplished using either a Dremel® tool (or similar), or cast cutter for laminated sockets. For thermoplastic sockets, a sharp blade will also work fine. Take care not to cut too low or you might risk exposing the valve **BASE** excessively and compromising the seal.
4. Once you have completely removed this material, it may be necessary to polish the cut edge for a more finished appearance. For laminated sockets, it is also a good idea to seal this exposed edge with an approved sealant if carbon fiber is used (this is a good idea any time you have an exposed edge containing carbon fiber).
5. Once the edge has been properly finished, it is highly recommended that you apply a bead of cyanoacrylate (eg. Superglue®) around the edge where the valve **BASE** and the exposed surface of the trimmed thermoplastic meet.
6. If you are using a frame-type socket, reinstall the liner into the frame so it is fully seated and aligned. Install the **INSERT** by pressing it into the **BASE** until fully seated.
7. A slight clicking sound may be heard as the **MAGNETS** engage fully with the ring of the **BASE**. Remove the **INSERT** by simply pulling it out. You will feel a slight initial resistance due to the magnetic attraction. Ensure there is ample room between the trimmed frame and your patient's fingers for easy installation and removal of the valve. For laminated sockets without a flexible liner, simply ensure the **INSERT** properly seats into the **BASE** and is easily removed following the steps outlined above.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed medical practitioner

If you have any questions or wish to reorder, please don't hesitate to contact us by phone or email:

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Energy Prosthetics, Inc.






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Explanation of Symbols

Symbol	Explanation
	Manufacturer
	European Authorized Representative
	Lot number
	Catalogue Number
	Caution, Consult Accompanying Documents



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Patient Instructions

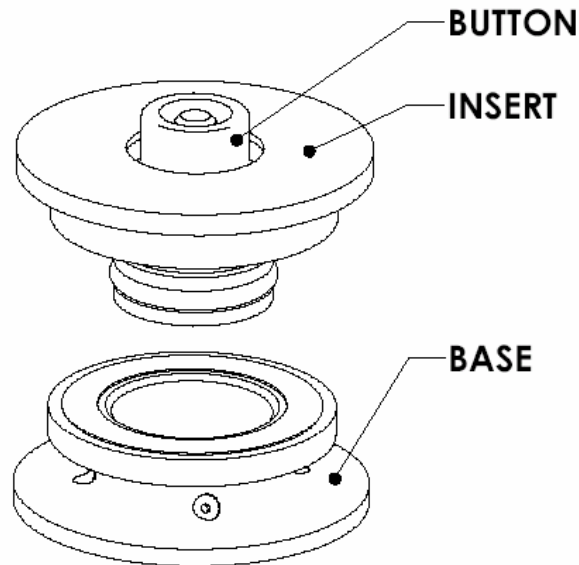


Figure 2 - MagValve Assembly

1. **Installation**-To ensure smooth operation of the **INSERT** when installing or removing, it is highly recommended that Vaseline® or similar lubricant be used to lubricate the O-ring and the inner walls of the **BASE** against which the O-ring will make contact. This should be applied to the O-ring prior to placing the **INSERT** into the **BASE** for the first couple of installations.



Do not attempt to use your prosthesis if the INSERT is not fully seated within the base.



2. **Removal**-Prior to removing the **INSERT**, it is recommended that the patient press the expulsion **BUTTON** located in the center of the **INSERT** while slightly lifting or pulling their limb back from the distal end of the interface. This will prevent a strong pulling sensation of the soft tissues that can occur with rapid removal of the valve **INSERT**.

- 3. Cleaning**-Soak valve in hot water for a few minutes. Take a toothbrush and scrub top of **INSERT** using a circular motion around **BUTTON**. If necessary, blow air through holes at bottom of **INSERT** to purge any remaining debris.

Annual inspection is recommended and careful attention should be paid to any excessive wear including the INSERT and its O-rings, as well as the exposed edge of the BASE in the socket.



If you are unsure about proper operation of the valve or are concerned about its function in any way, please do not hesitate to contact your clinician.

Explanation of Symbols

Symbol	Explanation
	Caution, Consult Accompanying Documents

If you have any questions or wish to reorder, please don't hesitate to contact us by phone or email:

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