

3207 Valve 4-hole lamination plate Valve

Instructions For Use



INTENDED USE

The 3207 4-Hole Lamination Plate Valve is intended to be used in conjunction with the 1244A 4-hole Lamination Plate with threaded hole.

Suitability of the device for the prosthesis and the patient must be evaluated by a healthcare professional.

The device is designed to facilitate suspension of a prosthesis, specifically by:

- Creating differential air pressure in prosthetic socket

The valve device must be fitted and adjusted by a healthcare professional. Intended for single device use only, not to be reused on another device.

The valve device can be used for high impact use, e.g., walking, jogging, and running.

Note: The valves are positioned in a housing that seals securely against the inner surface of the hard socket near the distal end. The valve expels air under positive pressure when entering a socket.

Warning: Never use configurations with an expulsion valve or other valves without a functional release button when combined with solutions where liner is sealed against the inside wall of a socket. Some means of allowing air back in the socket must be in place.

Note: The device must be fitted and adjusted by a healthcare professional.

Note: Intended device installation to be by a Certified Prosthetist or Prosthetic Technician.

Indications For Use and Target Patient Population

- Lower limb loss, amputation, or deficiency

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.

Warning: If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional.

The device is for single patient use.

INSTALLATION AND USE

Laminated Socket Procedure

1. Drape a layer of PETG or equivalent over cast positive. Roughen distal area.

Note: Distal area must be clean of dirt, dust, and grease, otherwise the bonding agent may not hold.

2. Screw dummy into 1244A socket adapter. Using a designated 2-component PU adhesive, bond the adapter assembly to desired location directly onto the PETG socket taking care that the 4-hole side is not filled and is exposed. Take care to fill the center area for a bubble free bond between housing dummy and thermoplastic layer.

3. Tie reinforcement material in groove on socket adapter and do a second tie between socket and adapter. Apply the reinforcement material layup according to weight and activity level. Seal off the distal end of the 1244A to keep resin from infiltrating the entire area.

5. Apply PVA bag and laminate with conventional methods (Epoxy is recommended for superior strength).

6. Tie around lamination dummy, and apply tape to push out the resin between the PVA bag and dummy. This will produce optimum resin to fiber ratio, and minimize finishing work.

7. Once resin has set, drill through lamination dummy into cast using a sharp 3mm drill bit. Take care to align drill with centerline.

8. Remove excess resin, PVA bag and lamination dummy. Demold socket as usual taking care not to damage inner socket.

9. After removing dummy, clean out cavity, and apply 3207 housing with O-Ring.

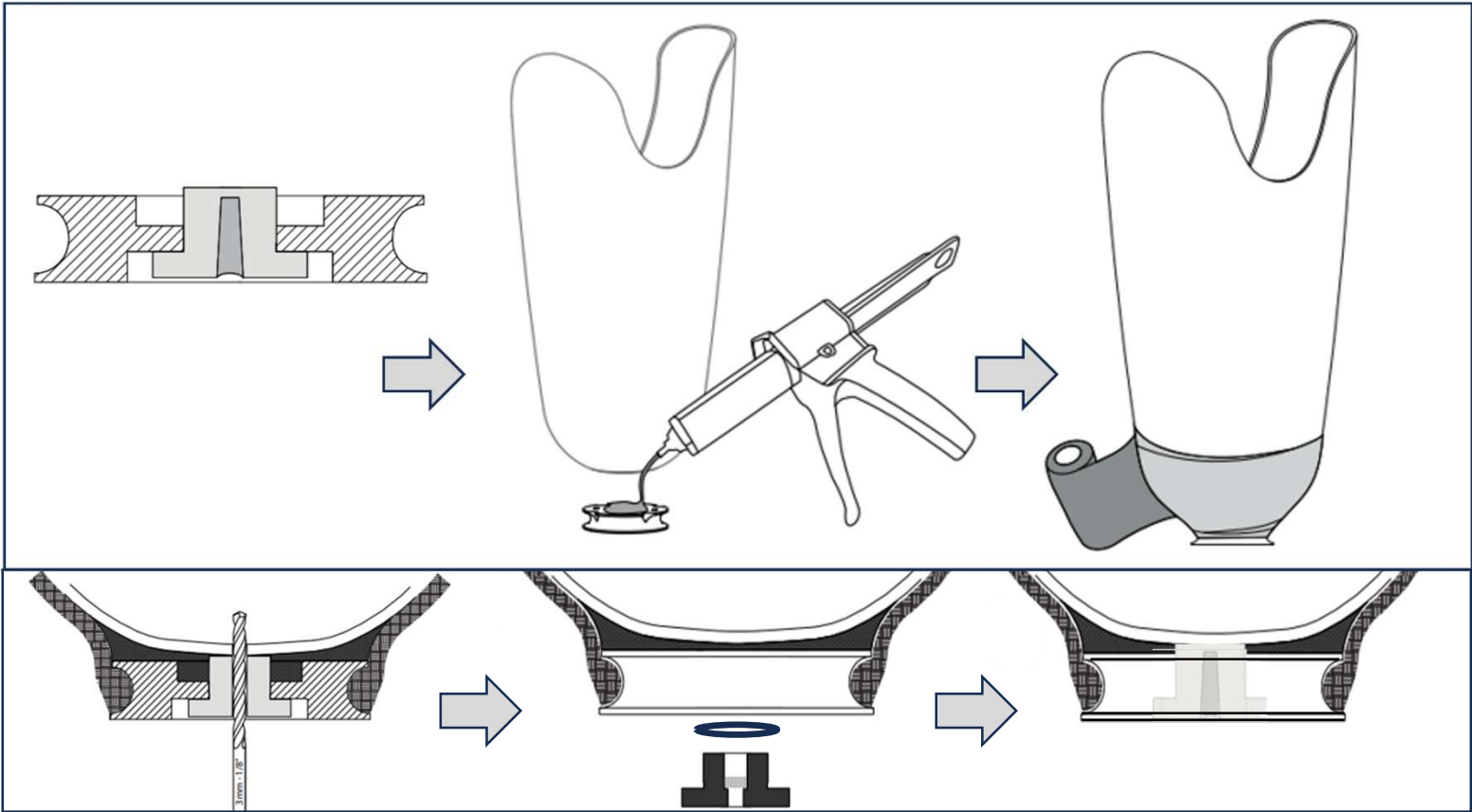
Note: When inserting the housing, make sure that it seats correctly, otherwise the housing may not hold vacuum properly.

Warning: Aluminum + Carbon + Moisture = Galvanic Corrosion! This can cause socket failure and void warranty!

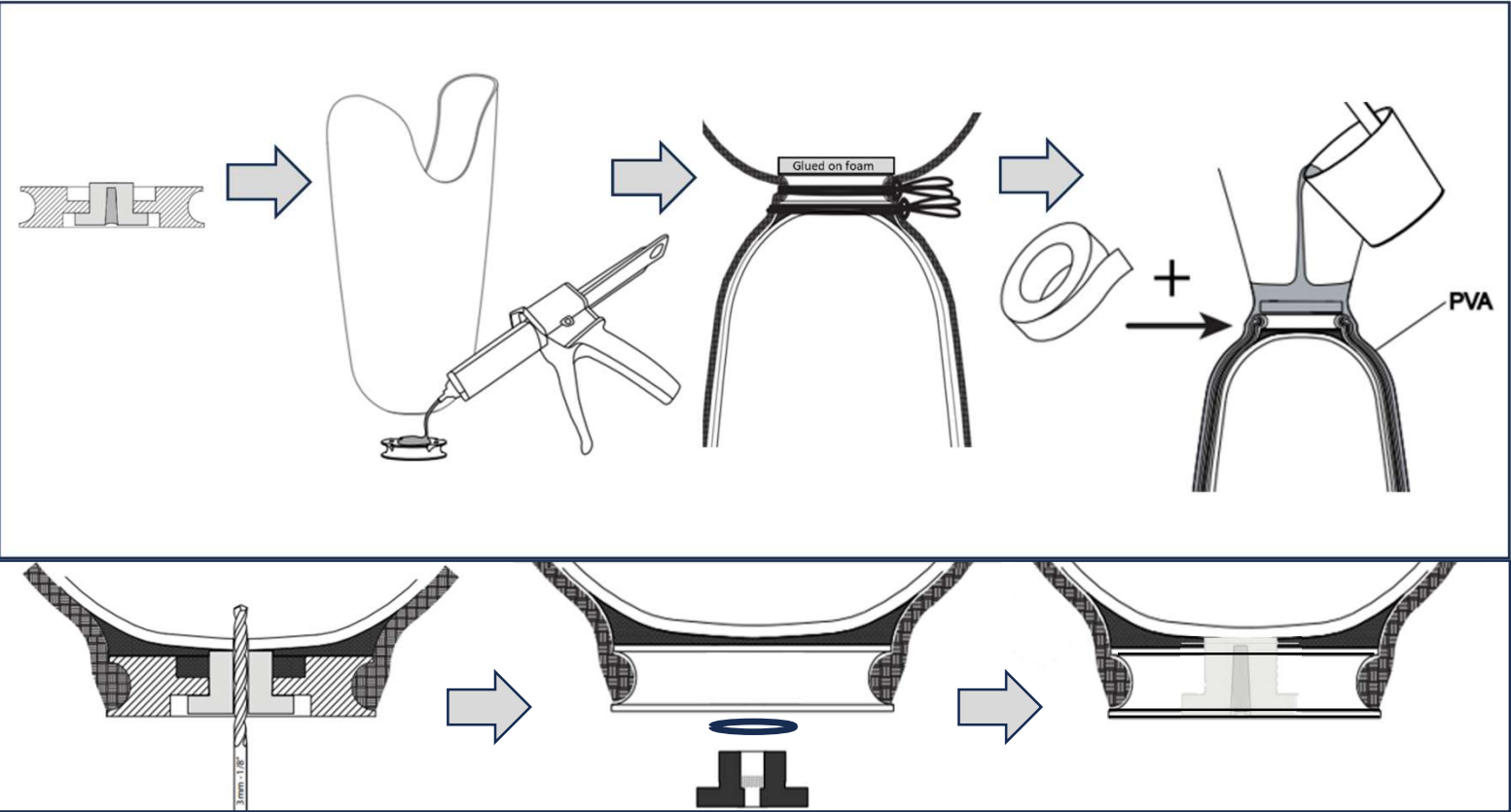
- Do not use carbon or materials containing carbon at the first layer which makes contact with the aluminum lamination plate, so NSP would be a good choice, or use Nyglass or equal.
- Use at least one shield layer of non-carbon containing material



For test socket use; Apply dummy to 1244A, Roughen bottom of PETG socket, Bond PETG socket and 1244A plate with 2-part Urethane Adhesive with 4-hole side down and not filled, Fill in and blend the area between the socket and 1244A plate, Over wrap with R-Form reinforcement, Drill through dummy, Replace dummy with 3207 Valve with O-Ring. If using a sealing type of liner system, be sure to install a release valve to doff socket.



For laminated socket use; Apply dummy to 1244A, Roughen bottom of PETG socket, Bond socket and 1244A plate with 2-part Urethane Adhesive with 4-hole side down and not filled, Fill in and blend the area between the socket and 1244A plate, Seal distal end of 1244A with foam to prevent resin infiltration, Layup adequately for activity level and weight tying in at the tie in ring and at the top part of 1244A, Laminate as usual, trim and demold cleaning off 1244A, Drill through dummy, Replace dummy with 3207 Valve with O-Ring. If using a sealing type of liner system, be sure to install a release valve to doff socket.



CLEANING

1. Unscrew the housing to access the duckbill valve, or mesh filter.
2. Clean under running water with mild detergent.
3. Dry thoroughly, but do not use compressed air which can damage the valve.

ENVIRONMENTAL CONDITIONS

The device is weatherproof and can be used in temperatures between -15 °C (5°F) and 50°C (122°F). It should be dried thoroughly after contact with fresh water.

LIABILITY

ST&G does not assume liability for the following:

- Device not maintained according to the instructions.
- Device assembled with components from other manufacturers.
- Device used outside of recommended conditions or applications.

WARNING:

- Avoid exposing any ST&G Aluminum Adapter to corrosives such as salt water, chlorinated water, ammonia, highly acidic, or highly alkaline agents. In case of exposure, rinse with fresh water and allow to thoroughly dry.
- Do not allow moisture to accumulate or dwell inside the adapter.
- Never modify any ST&G Aluminum Adapter.

Any modifications to an adapter will void the warranty and can lead to failure.

- Final application of fastener tightening torque must be done within 2 hours of initial application of blue Loctite 243 thread retaining compound.
- DO NOT use high-strength forms of thread retaining compound (example: Red or Green Loctite formulations).
- Insufficient fastener torque will lead to fatigue failure of any modular adapter.
- Excessive fastener torque can strip threads.
- Be sure to verify screw hole depth to screw length before assembly, and especially before applying torque to the screws.
- Torque settings should be checked periodically. A loose fastener may lead to component failure.
- Never reuse old bolts.
- Do not contaminate fasteners with any type of paint, glue, or cement, except for the recommended thread locker. For all fasteners, ensure a free-running thread fit prior to applying final tightening torque.
- Failure to follow the installation and use procedures set forth above may lead to structural failure of the components subjecting the user to a risk of serious personal injury.

Environmental Conditions and Maintenance

There are no identified restrictions on the temperature of storage and use.

Clean with fresh water after exposure to other liquids, chemicals, sand, dust, or dirt and dry with a cloth.



REPORT OF SERIOUS INCIDENT

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

WARRANTY

Warranty: 12 months against manufacturing defect only.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by unauthorized persons. Damage from misuse, exposure to non-allowed conditions (such as overly aggressive donning which could blow out the valve) will void the warranty.

LIABILITY

ST&G USA Corporation does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.



CE Conformity

This product meets the requirements Council EU 2017/1745 (MDR).

for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

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Specifications subject to change



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