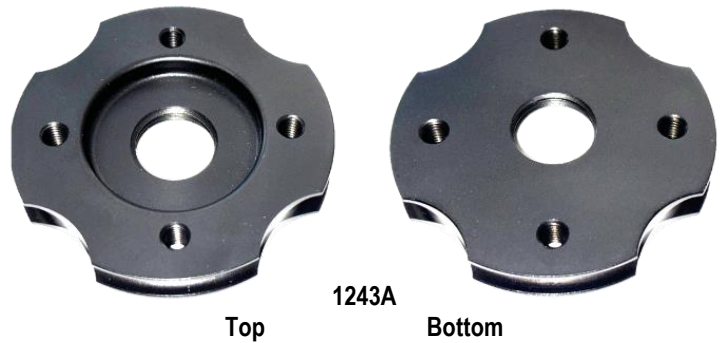


1243A

4-Hole Lamination Plate with threaded hole 10mm Instructions For Use



INTENDED USE

1243A Lamination Plate is intended to be used in the construction of laminated lower limb sockets with a 4-hole bolt pattern. The threaded central hole is intended for use with passive socket suspension systems.

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

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

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

For max rating of 136Kg/300lb, you must pair with the 310T kit! (You must assume a buffer factor to the weight limit for activities of daily living. I.E. stairs, stepping off curbs, any activity that will spike the loading of the prosthesis).

Indications For Use and Target Patient Population

- Lower limb loss, amputation, or deficiency
- No known contraindications



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

Recommended installation and use procedures must be followed for maximum safety and service life. Recommended Tools:

Additional Recommended Supplies:

- Synthetic Grease
- Plumber's Putty
- Fast curing adhesive
- High strength cord
- NSP, Parallex, or Carbon Braided Sleeve (You must isolate any Carbon from contact with the plate!)

Initial Preparation

1. Prepare and seal the positive model as necessary
2. After thoroughly cleaning all surfaces with rubbing alcohol, apply synthetic grease to the four threaded holes, and center threaded hole to allow for your block off screws and center dummy to be easily removed after lamination.
3. Apply your preferred lamination dummy to the threaded center hole and putty to the four M6 holes to prevent penetration of resin.

For 1243A, tape off socket side holes before bonding the socket to the plate.

4. Use the fast curing adhesive to attach the Plate at the appropriate location

LAMINATION

- Completely seal off the 4-hole mounting side of the plate prior to applying lamination materials
- Select materials to fabricate the socket appropriate to the weight/ activity of the patient, and avoid direct carbon material contact to the plate!

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.
- Use at least one shield layer of non-carbon containing material

P/N	Build Height	Part Weight	Weight Limit	Screw Torque
1243A	10mm / 0.38in	59g / 2oz	136Kg / 300lb	12Nm

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.
- When adjusting alignment or re-assembling components that had been previously assembled with thread locker, the threads of the fasteners and threaded holes should be cleaned and free of any retaining compound residue to ensure a smooth fit.
- 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.

The 1243A is anodized for corrosion control, but the anodizing could be damaged during fabrication, which can result to less anti-corrosion control.

It can tolerate occasional contact with: Clean water, perspiration, and mild soaps, but must be cleaned immediately or will void warranty if corrosion is present.

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: 24 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/repared by unauthorized persons. Damage from misuse, exposure to non-allowed conditions 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.

Specifications subject to change

