

1238A 4-hole rotatable pyramid receiver aluminum

Instructions for use

- Please read this document carefully before using the product.
- Follow the safety instructions to avoid injuries and damage to the product.
- Please keep this document in a safe place.

Connector components:

- (1) Pyramid receiver with rotation slots offering 24 degrees total range
- (2) Mounting screws with notched washers
- (3) Threaded 4-Hole Mounting Plate

Indications for use

The structural parts shown are to be solely used for the prosthetic fitting of the lower limb.

The socket adapter is to be used for mounting onto the socket of a transfemoral or transtibial prostheses. Not rated for high activities.

Part application:

1238A Approved for a patient weight of up to 100 kg (220 lbs).

⚠ Attention!

Avoid exposing prosthetic components to corrosive elements such as water, salt water, bodily fluids, and acids.

Using this medical product under such conditions will render all claims against ST&G USA null and void.

Function

The 1238A is designed as socket adapter with pyramid receiver offering rotation adjustment:

Suitable for combination with male pyramid mounting.

Exception:

The 1238A cannot be used in situations where weight rated is too close to max weight rating, or in extremely high torque demand situations where a non-rotation 4-hole base should be utilized.

Technical data:

Part Weight: 82gm

Build Height: 15mm

Material: Aluminum

Max Weight: 100 kg / 220 lbs

Adjustments and final assembly

This attachment plate is intended to be utilized with the inner threaded mounting plate requiring a 6mm / 0.25in space (fig. 4) so that the socket floor can be sandwiched in between the plate, and the outer slotted pyramid receiver with mounting screws. An alternative is to utilize a threaded laminated attachment block. Static corrections are possible at any time during alignment and trial walking as well as after completion of the prosthesis using the four Pyramid Adjustment Screws for angulation (max of 10Nm of torque), or the four mounting screws by loosening and rotating as needed. There is a range of 24 degrees total.

The 4-hole mounting screws require that the notched washer be applied to the screw prior to assembling the pyramid receiver base to the socket and 4-hole base with the notch towards the round pyramid receiver structure. (fig. 3)



Fig. 1



Fig. 2



Fig. 3



Fig. 4

Torque the adjustment screws to 10Nm. Adjustments should be carried out utilizing a 4mm hex driver, and always loosen the adjacent set screw before doing any alignment adjustment to prevent galling of

the pyramid face or causing excessive force that could round out the adjustment screw.

- For trial fitting: **Tighten the Adjustment Screws clockwise to 10 Nm.**

- To finish the prosthesis: **Secure the set screws with Loctite and tighten to 10 Nm. Never use Red Loctite!**

- Base assembly screws should be secured with Loctite and torque to mounting plate specifications.**

Maintenance instructions

Depending on the amputee's activity there is a service life of three to five years. We recommend carrying out bi-annual inspection / safety checks. Do not reuse components on a different prosthesis after the life expectancy has passed.

Always rinse prostheses thoroughly when exposed to any liquids other than clean water to prevent corrosion of componentry.

Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly. **Storage / Environment**

Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)

Allowable relative humidity 0 % to 90 %, non-condensing

Do not submerge in water

Store away from UV exposure



Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.



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.

Warranty covers defects in workmanship for the given warranty period. Signs of abuse, lack of biannual inspection, improper installation are examples of areas not covered by warranty.

Useful Life

Service life of the product is covered by the warranty period. Not to be used on another wearer other than original intended wearer.



Disposal

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

Do not expose to sand, Salt Water, or high PH environments

Warranty can be void due to: Unusual usage or abuse (ex. excessive dusty/sand environmental, swimming, non-typical usage), Tampering with any fasteners, Modification to the module such as sanding or damaging the finish.

There is a 2 year warranty period against manufacturing or material defects. Does not include excessive wear and tear.

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