IFU

Shuttle Lock

- **PUSH BUTTONS NOT SOLD SEPARATELY, ONLY SOLD IN THE LOCK ASSEMBLY**
- **STAINLESS STEEL PUSH BUTTONS ALSO AVAILABLE, PER REQUEST.**
- **NO ADDITIONAL COST FOR DIFFERENT SIZE PUSH BUTTONS OR MATERIAL TYPE.**

1 Product description

► Please read this document carefully before using the product and observe the safety notices.

► Instruct the user in the safe use of the product.

► Please contact the manufacturer if you have questions about the product or in case of problems.

► Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.

► Please keep this document for your records.

1.1 Construction and Function The Lock is a shuttle lock with a flexible pin and integrated in the housing. It serves to secure a suitable liner in the prosthetic socket. The shuttle lock is installed in the check socket by vacuum forming and in the definitive socket by lamination. To connect to the distal prosthetic components, it is equipped with a four hole connector. The flexible pin is installed on the liner. When sliding into the prosthetic socket, the magnet in the Lock aligns the flexible pin with the opening. This makes it easier to don the pros thesis.

1.2 Combination possibilities This prosthetic component is compatible with TFI system of modular connectors. Functionality with components of other manufacturers that have compatible modular connectors has not been tested. Limited combination options for TFI components Designation Reference number Flat type -Pyramidal Socket Adapter, Flat type -Pyramidal Socket Adapter shuttle lock Socket adapter Slide plate

Intended use

2.1 Indications for use the product is intended exclusively for lower limb exoprosthetic fittings.
2.2 Area of application

• The maximum approved body weight.

2.3 Environmental conditions Allowable environmental conditions Temperature range for use: -10 °C to +60°C Allowable relative humidity 0 % to 90 %, non-condensing Unallowable environmental conditions Mechanical vibrations or impacts Perspiration, urine, fresh water, salt water, acids Dust, sand.

2.4 Depending on the user’s activity level, this corresponds to a lifetime of 2 years.

3 Safety

► Comply with the product's field of application and do not expose it to excessive strain.

► Note the combination possibilities/combination exclusions in the instructions for use of the products.

► To avoid the risk of injury and product damage, do not use the product beyond the tested lifetime.

► To avoid the risk of injury and product damage, only use the product for a single patient.

► Do not expose the product to prohibited environmental conditions.

► Check the product for damage if it has been exposed to prohibited environmental conditions.

► Do not use the product if it is damaged or in a questionable condition. Take suitable measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).

► To prevent mechanical damage, use caution when working with the product.

► If you suspect the product is damaged, check it for proper function and readiness for use.

► Do not use the product if its functionality is restricted. Take suit able measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).

►Observe the alignment and assembly instructions.

INFORMATION

►Not all of the materials may be available in your country. In this case, please contact the local branch of the manufacturer to obtain information on alternative materials.

5.1 Fabricating the prosthetic socket INFORMATION The layup described in this document was approved for the maximum product user body weight. The prosthetics assumes full responsibility for any change to the layup.

5.1.1 Preparing for socket fabrication > required tools and materials: Lamination Adapter, M6X8 Cap Screws, Vacuum forming dummy, Screw, Plastaband

1) Isolate the cap screws (thread and head from the outside).

2) Screw the cap screws into the lamination adapter.

3) Fill the heads of the cap screws with Plastaband.

4) Position the lamination adapter on the plaster positive along the longitudinal axis of the residual limb.

5) Place the vacuum forming dummy into the round opening of the lamination adapter and secure the two parts to the plaster positive with the flat head screw.

6) Isolate the head of the flat head screw with Plastaband.

7) If there is an undercut between the lamination adapters and plaster positive: Fill the undercut with wet plaster.