3120 Link Clutch Lock

Link Clutch Lock **Part Number: 3120**
Part Weight **58g**
Build Height **approx. 23mm**
Includes:
Clutch Lock Body with mechanism
Clutch Lock Pin
Lamination Dummy kit

INTENDED USE

The device is intended as a component of a prosthetic system that replaces a missing lower limb.
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.

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.

DESCRIPTION

Components **(Fig. 1)**
1. Lock Body
2. Clutch Lock Mechanism
3. Assembly Bolt
4. Pin Cavity Dummy
5. Dummy Base for cast mounting (nails included)
6. Lock Cavity Dummy (a. Short and b. Long)
7. Screws

Before the second lamination, sand to expose and remove assembly bolt (3), and Pin Cavity Dummy (4), and ensure that Pin Cavity is sealed so no resin can enter during second lamination.
After completion of the second lamination, expose and remove Dummy assembly (6a or 6b), and be sure to thoroughly clean housing and threaded holes for the Clutch Lock Mechanism (2).
Insert and tighten Clutch Mechanism to 15 Nm.

Fig. 1

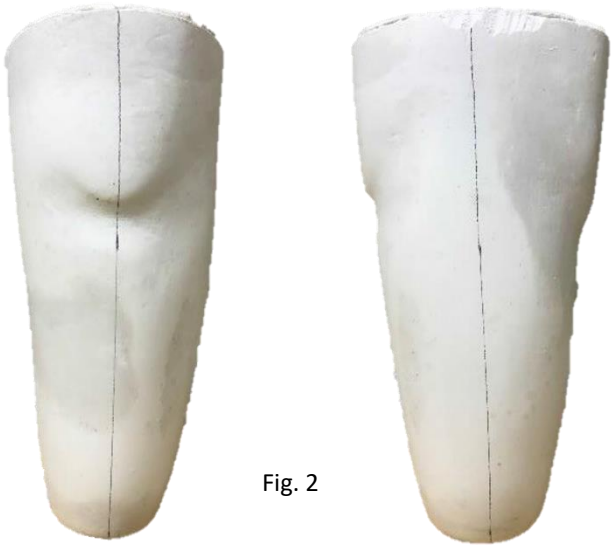
Fig. 2

Mold and Dummy Prep for Lamination

Important: Be sure to double check that the pin alignment is satisfactory so as not to introduce a binding alignment situation.

ASSEMBLY INSTRUCTIONS

Lamination Instructions

1. Flatten the distal end of Plaster Cast to center the Dummy Base (5) for cast mounting, being sure to maintain good pin alignment to reduce pin binding/friction. **(Fig. 2)**
Attach with screws provided (7) or double-sided tape maintaining original pin alignment.
2. Apply inner PVA bag and tie it around the neck on the Dummy Base.
3. Trim away excess PVA.
4. Place Lock Body onto Dummy Base, ensuring its rotation allows for correct positioning of Clutch Mechanism release button.
5. Secure Lock Body and Pin Cavity Dummy with Assembly Bolt (making sure to apply generous amount of petroleum jelly to the threads of the bolt and Pin Cavity Dummy as well as Cavity Dummy for Lock Body).
Note: Be sure to tighten so that resin will not leak in between components.
6. Place some putty, or glue Pelite into the hole on bolt and groove on Lock Cavity Dummies.
7. Tie half of the lamination material into the groove on Lock Body and remainder over the end of Lock Body leaving Pin Cavity Dummy head, and bolt head exposed. This will create the pin cavity space needed for a double lamination.
8. Apply outer PVA bag and fabricate first lamination.
9. When curing has finished, expose and remove Bolt, expose but do not remove Lock Cavity Dummy leaving Pin Cavity Dummy and bolt head (3) exposed.
10. Before the second lamination ensure that Pin Cavity Dummy is sealed.
11. After completion of the second lamination, expose and remove Lock Cavity Dummy.
12. Insert and tighten Clutch Mechanism to 15 Nm.

Thermoplastic Instructions

1. Flatten the distal end of Plaster Cast to center Dummy Base.
   Attach with nails provided or double-sided tape maintaining original pin alignment.
2. Place Lock Body onto Dummy Base, ensuring its rotation allows for correct positioning of Clutch Mechanism.
3. Secure Lock Body and Pin Cavity Dummy with Assembly Bolt.
4. Vacuum form thermoplastic, ensuring that plastic conforms well to the Lock Body and Pin Cavity Dummy.
5. Once the plastic has cooled, trim around Pin Cavity Dummy and Lock Cavity Dummy.
Note: Before making the outer socket, always ensure that Assembly Bolt has been removed and Pin Cavity Dummy resealed.
6. After manufacturing of outer socket, expose and remove Lock Cavity Dummy.
7. Insert and tighten the Clutch Mechanism to 15 Nm.

Attachment Pin

Apply Loctite 410/411 onto the threads on the Attachment Pin and screw it into the Locking Liner.
Torque the Attachment Pin to 4 Nm.

Caution:

Use ST&G CLP pins only.

Non-ST&G pins may lead to binding or damage to the lock mechanism and void warranty.

USAGE

Cleaning and care

Clean with a damp cloth and a mild soap. Dry with a cloth after cleaning. Unscrew the Release Unit, blow with compressed air alternately between the Pin hole and the hole for the Release Unit.
Caution: Do not use lubricant or any cleaning material. Only use air.
Regular cleaning is necessary to prevent compromise on function of
locking mechanism.

Environmental Conditions

The device is Weatherproof.

A Weatherproof device can be used in a wet or humid environment and can tolerate being splashed by fresh water (e. g., rain), no submersion is allowed.

No contact with salt water or chlorinated water is allowed.

Dry with a cloth after contact with fresh water or humidity.

Clean with fresh water in case of accidental exposure to other liquids, chemicals, sand, dust, or dirt and dry with a cloth.

Continuous exposure is not allowed.

The clutch lock bearing is susceptible to prolonged moisture or submersion exposure.

MAINTENANCE

The device and the overall prosthesis should be examined by a healthcare professional.

Interval should be determined based on patient activity, and at least annually.

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.

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

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