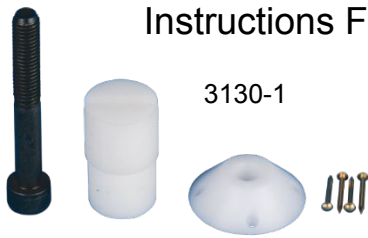


3130 Integra Clutch Lock

MD Medical Device

Instructions For Use



3130-1

P/N	Desc	Specification
3130	Integra Clutch Lock	125kg / 275lb
CLP	Pin for Clutch Lock	
3130-1	Fabrication Dummy Kit	60mm / 2 3/8"



3130

Application

3130 Integra Clutch Lock is designed to be used for locking liner with pin type new socket fabrication. This lock is to be exclusively used for lower extremity prosthetic fittings.

Description

The 3130 lock is a light weight, one-way clutch lock mechanism with corresponding gear for clutch lock pin engagement. There is a side mounted release button which allows for easy lock mechanism disengagement. The one-way clutch lock bearing mechanism promotes smooth operation, with fine pin lock engagement adjustment. The clutch lock also allows for the ability to draw the pin into the lock, unlike a shuttle lock. The standard threaded lock mechanism is removable.

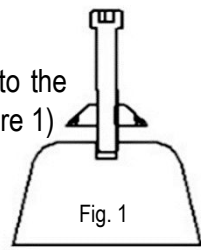
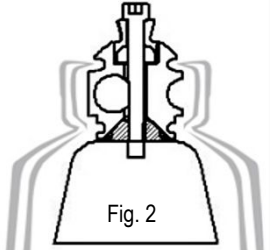
The 3130 is recommended to be used in laminated sockets, as the socket integrity will be more robust versus a plastic drape formed socket over the lock body.

LAMINATED SOCKETS

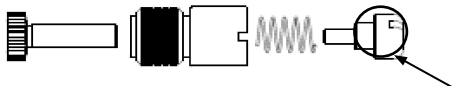
⚠ Note: Always cast your patient over the liner you intend to have them use with the lock. Either the pin or the liner threaded umbrella can be used to indicate the pin/lock location for the cast/mold.

- Prepare the positive model in the usual manner with the exception of the distal end where the umbrella protrusion is on the cast.
- Modify the protrusion to create a flat spot 44.4mm / 1 3/4" in diameter. Again, this flat area must be perpendicular to the line of progression of the socket. Find the center of this area and drill a 8mm / 5/16" hole approximately 25mm / 1" deep.

Fabrication

- Locate the Alignment Cone found in the fabrication kit.
 - Lightly coat the threads of the Anchor Bolt with silicone grease and screw it into the Alignment Cone until it protrudes approximately 1/4" beyond the flat surface. (figure 1)
 - Using the 4 nails, secure the Alignment Cone to the distal end of the model.
 - Once set, use plaster to blend the Cone into the Model.
 - Remove the Anchor Bolt and smooth the model for lamination
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- Fig. 1
- 
- Fig. 2
- Seal mold and apply a PVA bag. If the PVA can be drawn in over the Conical Dummy, so the 3130 seals end of the PVA, then a PVA cap is not necessary. If not, then cap PVA and make burnished reinforced hole with tape.
 - Coat the threads of the Dummy Plug with silicone grease and screw into lock body, and seal slot with tape or putty.
 - Apply a bead of silicone grease inside the receiving cone of the 3130 lock body.
 - Coat the threads of the M8 Anchor Bolt with silicone grease and anchor the 3130 lock body to the Alignment Cone.
 - Wipe away any excess grease and fill the head of the bolt with putty.
 - Care should be taken so that resin does not seep into the Anchor Bolt hole. PVA tape will provide moderate protection.
 - Select appropriate size of reinforcement braid (Carbon or other). Cut 2 pieces 2 X length of socket. Apply 1 of the longer braid to the cast so it is reflected down after being tied to the groove closest to the pyramid (figure 2). Make sure the braid is tied into the groove along the entire circumference.
 - Apply a double layer of Nyglass stockinette and tie off into the groove.
 - Apply the second piece of braid and tie it into the groove to be reflected down using a double knot so that it is tied around again. Reflect the tubular weave up and inspect to make sure that you have in fact tied it into the groove and not outside of the groove.
 - The suggested fabric lay-up includes 1" carbon fiber tape (P/N 4018) tied into the groove of the housing body and extending up several inches fanning out over the distal end of the socket in between the 2 reinforcement braid. Based on the patients

- weight (maximum of 275 lbs) and activity level, add appropriate stockinette and strengthening fabrics tied into the distal tie in groove.
- The selected resin should be prepared and poured into the outer PVA sleeve and thoroughly saturated around the Pyramid Housing body. After the resin has hardened, remove any excess from around the pyramid dome.
- ⚠ **Note:** Failure to follow these instructions properly may cause a failure of the interface between the socket and the lock.
- Once the lamination is complete, carefully remove any excess resin. Remove the Anchor Bolt and trim around the Clutch Housing Dummy Plug.
- Thoroughly clean the threads in the lock body and remove any resin which may have gotten into the lock body.



- ⚠ **Note :** It is recommended that thread-lock adhesive Loctite 242 be used on the push button threads. This will allow the parts to be firmly connected, but should the necessity arise, the parts can be taken apart.
- Full cure of resin and Loctite is 24 hours. (please note that factory setting already has Loctite 242 on the threads applied. The instruction below is only applied when you have to clean or maintain the push button assembly in case a correction is needed)**

- Check the function of the completely assembled housing in the locking device.
- Remove the housing from the body of the locking device. Lay out disassembled housing as shown above.
- With gear in housing, install spring from the opposite end of the housing.
- Place a drop of Loctite on the threads of the set screw.
- Screw push button into gear shaft tightly.
- Place ring of Loctite on the threads of the housing and screw in the locking device tightly.
- Locking device is now functional and useable but full cure of adhesive is obtained in 24 hours.

Fabrication Guidelines

- A trained technician must perform fabrication of the prosthesis.
- Do not modify the housing or the locking mechanism in any way.
- Use a thread locker to secure all threaded fasteners.
- A minimum of 3 serrations or rings must be engaged in the shuttle and clutch locks for safest operation.
- This device is intended for single patient use.

Daily Care and Maintenance



The Prosthetist should discuss the following inspection procedures and guidelines with the patient.

- Check the locking mechanism for proper operation before each use. Discontinue use of prosthesis and contact your Prosthetist if locking mechanism is not performing as expected.
 - Avoid bumping the button to prevent accidental unlocking. This risk increases if the prosthesis is fabricated without a button shield.
 - Keep the lock clean and free of debris for the best performance and proper lock engagement.
 - Avoid humid or wet environments and always dry the components should they get wet. Prolonged exposure to moisture can cause metal components to corrode and fail prematurely.
 - Should the lock malfunction in any way (e.g. accidentally disengage, fail to release, etc.), discontinue use of the lock immediately and contact your Prosthetist.
 - Contact your Prosthetist should you have any questions or concerns. Failure to follow these guidelines will void any warranty.
- Not to be submerged, and not for swimming purposes. Also, avoid contact with bodily fluids – if these fluids enter the lock, be sure to notify your prosthetist to clean out the lock and lock mechanism. Bi-annual inspection should be carried out.

Warranty

The product is warranted against defective materials and workmanship for a period of 1 year from the date of installation.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.

Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

**Unallowable environmental conditions**

Storage/transportation: high vibrations, impacts

Cleaning agents containing solvents

CE Conformity

This product meets the requirements Council EU 2017/745 (EU) 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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3130 IFU REV. G (5-14-26)