



3190T EZ Lock Fabrication Instructions

The low profile 3190T EZ lock uses either 1223T or 1221S socket adapter to provide a high 136Kg / 300Lb rated single lamination shuttle lock socket.

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. (Fig. 1, 2)

1. Prepare mold for lamination. Flatten distal end for lamination dummy for placement. (Fig.3)



Fig. 1

Fig. 2



Fig. 3



Fig. 4



Fig. 5

Make sure included bolt does not protrude past the lamination dummy, or it could puncture the PVA bag. Adjust length as needed. Apply PVC tape to the PVA bag under the lamination dummy (Fig.4) where the lamination dummy will be nailed into place (Fig. 5), and will keep the PVA from rupturing while being nailed into place.

Liner/Pin space compatibility: (Fig A-G for reference)

Liner construction varies so a given gap cannot be recommended, you will need to verify compatibility!. (Fig. A)

Be sure to check how much clearance you will need for the liner used by assembling 3190T with socket adapter and fully insert into the lock. (Fig. B/C)

1221S 3-Prong adapter has less depth versus 1223T 4-prong adapter, so verify clearance!

Mimic the adapter/lock spacing with the given dummy when

Check how much space is required with the given socket adapter used (ST&G Recommends 1223T or 1221S) for lock thread insertion engagement (Lock threaded area fully inserted into adapter). (Fig. F/G)

If Lock Body Threads are showing, weight limit/safety integrity will be jeopardized and is not recommended.

IMPORTANT:

Without full thread engagement of the 3190T lock body, ST&G cannot guarantee warranty of the lock!



Fig. A



Fig. B



Fig. C



Fig. D



Fig. E



Fig. F



Fig. G

It is recommended to utilize the 1223T rotating adapter:



NOTE: The 1223T 4 prong rotating adapter has a deeper seat. This in turn will ensure that there is adequate space for the liner pin insert and the lock when fully inserted into the socket. If the liner has a flush liner pin insert, then it may be possible to use the 3-prong 1221S adapter.

Use caution when screwing in the dummy, as it could possibly pull the cast dummy assembly off the mold when applying should there be excessive layup material!

Layup:

Layup as usual, but ensure that there are sufficient layers applied to prevent push through of the socket adapter. It is important that there be reinforcement braid under the socket adapter, and over it, as well as tying in strands into the holes to help improve socket integrity.

The reinforcement layers should always be separated by 1 nyglass to obtain the stiffness required for the distal end.

Tie off the braid and nyglass on the threaded dummy. Both of these layers are to be reflected back upon the cast. You want to end up with 2 layers of braid with 1 layer of nyglass in between. It is best to stagger the length of each layer of braid so that they do not end at the same level, but should be beyond the threaded adapter prongs.

Photo right:

Braid, nyglass, tied to threaded dummy and to be reflected back down in a staggered layer beyond the threaded adapter prongs.



Photo right:

After initial braid is reflected down, tie in separator layer of nyglass before installing threaded adapter and the final layup.



Prepare the 1223T 4-Prong adapter

The threaded areas of the adapter need to be prepared for lamination with application of petroleum jelly, and to stuff open areas with silicon putty. The purpose of the putty is to promote easier removal of any stray lamination, or to block resin infiltration into any cavity areas.

Component threaded area and clamp bolt threads should be generously coated with Petroleum Jelly (Fig. 7).



Fig. 7

Any pockets, slots, or chambers that are necessary should be packed with Silicon Putty (or similar) to avoid those areas to fill with resin. (Fig. 8)

Note that there are spacers on the bolt to ensure correct bolt length necessary to eliminate pulling off the lamination dummy while tightening the bolt to the dummy.

Ensure to tie in the ears of the adapter for good socket integrity.



Fig. 8

The 1221S 3 prong adapter can be utilized for 3190T EZ Lock, but the liner and pin will end up more within the 1223T 4 prong adapter with a deeper threaded base.

IMPORTANT: It is vital to confirm compatibility of the depth with the liner and lock with the socket adapter you are using PRIOR to fabrication to ensure that the lock body threads are fully engaged inside the adapter for safe socket integrity with the 3-prong you are using, or you should use the 1223T 4-prong adapter.

Tape off clamp bolt and clamp area with tape, then carefully snug down lamination anchor bolt (Fig. A).

Apply lamination material and tie off into adapter tie off groove (Fig. B/C)

Apply PVA bag and laminate as usual – be sure the allow the vacuum and gravity to introduce the resin. If you squeeze resin into the material, you could trap air and compromise socket integrity (Fig. D).



Fig. A



Fig. B



Fig. C



Fig. D



After full saturation, the distal end can be taped off to reduce excessive resin to accumulate. Note how the photo shows how taping off the distal end reveals the shape and controls excessive resin for easier demolding and disassembly.

Disassembly of Lamination Dummy from Assembly:

- 1) Cut the brim area of the socket and remove excess left over.
Expose Lamination Anchor Bolt and Clamp Bolt.
- 2) Remove left over resin of the threaded lamination dummy, and the Lamination Anchor Bolt head.
- 3) The Clamp bolt head and clamp slot can now be cleaned up and exposed.
- 4) After the Clamp bolt is removed and slot is cleaned of putty, the Lamination Anchor Bolt can be loosened but do not remove.
- 5) Remove the socket from the cast
- 6) The Cast Lamination Bolt can now be used to loosen the Cast Lamination Dummy from the socket, and the Threaded Lamination dummy can then be removed with either an adjustable wrench or vise.



Check fit and function of the EZ lock within the laminated socket, and the ability to cycle the lock/push button/pin.

Ensure that there is sufficient room for the liner fully inserted into the socket and adjust the 3190T accordingly. All the threads should be engaged on the lock, or there is possibility of failure of socket integrity with the lock body to perform safely.

The lock push button shaft can be shortened up to 12.5mm / 0.5 inch. Be sure to apply thread locker so the push button does not back out during use.

Check Socket

It is recommended to utilize a 3-prong adapter for Check Socket

1. Mold Prep

Important:

Check that the pin alignment is satisfactory so as not to introduce a binding alignment situation.



Flatten area for Cast Dummy



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Fig. A



Fig. B



Fig. C



Fig. D



Fig. E



Fig. F



Fig. G

2. Dummy Preparation:

Fig. 4 Mock up the cast dummy with the threaded dummy.

Fig. 5 & 6 Drill a hole centered on the quadrant marks so bolt will easily fit inside and not interfere with centering the dummy and verify depth so dummy is flat on the cast.

Fig. 7 Nail dummy onto cast centered on the quadrant marks with included brads.

(NOTE: Cast Dummy and Threaded Dummy subject to change)



Fig. 4



Fig. 5



Fig. 6



Fig. 7

3. Pulling plastic:

Pull Check Socket as usual, and bond a 1221S to the distal end.

We recommend the use of a rotatable 3 prong socket adapter as there is more surface area to bond to the check socket.

Ensure that there is adequate space for the liner with pin fully inserted into the socket and fully engaged into the lock prior to fabrication, or adjust spacing with plastic thickness accordingly to allow for room!

Assemble the socket adapter with lamination dummy and bolt to the check socket – checking for clearance (fig. 10) and where the adapter will need to be contoured (fig. 11). Tape up the pinch bolt area so it can move (fig. 12).

Roughen the surface thoroughly, and bond the adapter to the socket filling in the voids, covering the adapter (fig. 13).



Fig. 10



Fig. 11

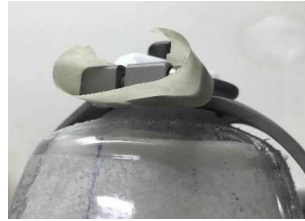


Fig. 12



Fig. 13

When the adhesive has hardened, remove the bolt from the assembly, and proceed to remove the socket from the mold (fig. 14). After the dummy is removed, ensure that there is no adhesive in the gap or the adapter (Fig. 15). Thread the 3190T lock assembly into the socket adapter, and ensure that there is no binding as this will gall the threads. Ensure that there is adequate clearance for the liner/pin and lock with full inserting of the liner into socket! (fig. 16).

IMPORTANT!

Verify that there is sufficient room for the liner and pin with the lock at full insertion to prevent patient limb from bottoming inside the liner!

Over wrap the adapter to the socket prior to walking the patient!



Fig. 14



Fig. 15



Fig. 16

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 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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