Original Shuttle Lock

Product Manual



Intended Use

The Original Shuttle Lock component is intended for use in lower extremity prostheses and is fabricated distally into the prosthetic socket. The shuttle lock serves to secure a suitable liner in the socket.

Indications

- · Transtibial or transfemoral amputees.
- Unilateral or bilateral patients

Contraindications

• Clearance: 1.25 in. (32 mm)

The device is intended for single patient use only.

Performance Characteristics

Patient Weight	N/A
Build Height	1.25 in. (32mm)
Weight	2.26 oz. (64.2g)
Durable	Meets ISO-22675 standard
Primary Materials	Delrin, Steel
Waterproof	No
Plunger	Sold separately See catalog for specific P/N and options. Compatible with Fillauer Plungers only.
Removeable Mechanism	Yes
Distal Attachment	None

Storage and Handling

It is recommended that shuttle locks are stored in a cool, clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

Warnings and Precautions



CAUTION: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the locks and is not covered under the warranty of the device. This prosthetic/orthotic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, activities which would damage the biological limb, or prolonged, extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and

its components during use. Rinse the Component with fresh water and dry immediately after exposure.



CAUTION: This device is not waterproof, if the lock is submerged, it should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.



CAUTION: The component should be inspected by the clinician every 6 months for signs of abnormal wear and to assure that every function is in working order.



NOTICE: If any serious incidents occur in relation to the usage of the device, contact your Fillauer Representative and the competent authority in your country.



CAUTION: For patient safety, be sure to install the button shield before final assembly.



WARNING: For patient safety, test for proper lock function after assembly into the socket and minimum of 3 serrations or rings must be engaged in the shuttle and clutch locks for safe operation. Failure to do so may result in serious injury.



CAUTION: Apply a small amount of medium strength threadlocker to the threads of the release pin/button before installation. Be sure that you do not get excess threadlocker on moving components.



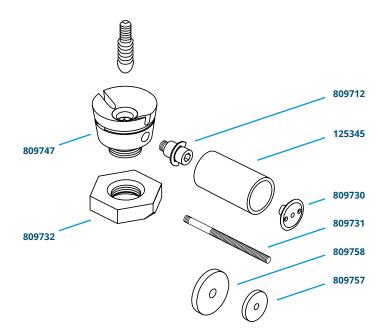
CAUTION: Be sure to keep the locking plunger free from foreign materials or fabrics when being inserted into the lock mechanism. Failure to do so may prevent the plunger from being sufficiently locked or may cause the lock to jam and prevent removal of the residual limb from the socket.



WARNING: For use with the recommended Fillauer lock plunger only. Failure to use the proper plunger may result in failure, damage to the device, and/or severe injury to the user.

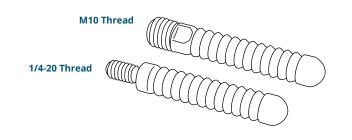
Original Shuttle Lock Assembly

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Description	Product Number
Shuttle Lock Kit	125229
Shuttle Lock Body	809747
Button Shield	125345
Guide Screw Assembly	809712
Latch Pin	809731
Latch Pin Button	809730
Mounting Nut	809732
Pe-Lite™ Washers ¾ in.	809757
Pe-Lite™ Washers 1 in.	809758



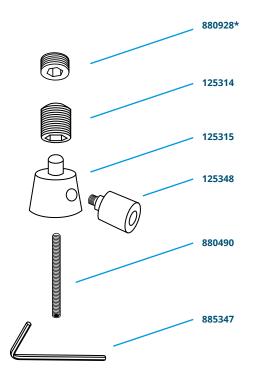
Plungers

Length	Thread	Product Number
1 in. (25 mm)	1/4-20	809722
1.5 in. (38 mm)	1/4-20	809725
2 in. (51 mm)	1/4-20	809727
1 in. (25 mm)	M10	809722MM
1.5 in. (38 mm)	M10	809725MM
2 in. (51 mm)	M10	809727MM
2.5 in. (64 mm)	M10	809720MM
3 in. (76 mm)	M10	809721MM



Fabrication Kit

Description	Product Number
Fabrication Kit	125239
Threaded Plug, ¾-16 × 1 in.	125314
Distal Socket Plug	125315
Plug Screw F/Shield	125348
Set Screw, 5⁄16-18 × 2 in.	880490
Hex Key, ¼ in.	885347
Socket Jam Screw, ¾-16 × ¾ in. *Used only with Unitized Housing Shuttle Lock	880928



Alignment (Specifications & Preparations Before Use)



NOTICE: Align the shuttle lock with the longitudinal axis of the residual limb to prevent unnecessary load and wear.

Fabrication Instructions

Procedure	Fabrication Instructions
Attach Assembly and Blend	Seat the set screw in the desired location on mold. Coat the distal surface of the distal socket plug, the threaded plug, and the Plug Screw for Shield with stick wax. Fill the hex cavity in the threaded plug, the lateral hole in the distal socket plug, and the socket of the plug screw with silicone gel or similar. Blend plaster from the mold to the distal socket plug. Assemble the mounting nut on the threaded plug screw and place the two on the distal socket plug with the flattened corner of distal end facing the buttonhole of the desired medial position for the release button. Press the
	mounting nut down firmly on the plug so it is seated squarely.
Plaster Model	Vacuum holes may be needed with plaster models especially near shuttle housing. If model is wet, use a casting balloon.
Foam Model	For foam models, apply a nylon hose and a PVA sleeve, tied off around protruding set screw.
Thermoforming	Any customary plastic may be used for definitive or check socket fitting. Standard drape or blister forming techniques may also be used with sufficient vacuum. Special care should be taken around the area of the button shield to prevent wrinkles especially when blister forming.
Lamination	Special care should be made to ensure no air bubbles remain over the fabrication dummies. Buildup for the attachment can then made with foam or a similar filler. Any attachment plate may be used; however, an allowance must be made for any part the plunger that may extend through the lock body. The second stage is then laminated with the desired reinforcement.
Assembly	Trim the lamination or plastic around the threaded plug even with Distal Socket Plug. Also, trim the lamination or plastic even with plug screw. Carefully remove the interface from the mold to reassemble shuttle lock. The Shuttle Lock Body is inserted into the distal cavity and is screwed into the Mounting Nut, drawing the Lock Body distally. The Guide Screw Assembly is placed inside the Button Shield pushed through a 1 in. Pelite Washer and is screwed into the Shuttle Lock Body. The Latch Pin is cut to desired length and the Latch Pin Button is screwed on and secured with blue Loctite. The Latch Pin is pushed through the ¾ in. Pelite Washer and threaded into the shuttle through the Screw Assembly. The Pelite washers are required to baffle air escape and prevent noise.

Compatibility

Compatible only with Fillauer plungers.

Disposal / Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

All metal components may be removed and recycled at the appropriate recycling facility.

Warranty

 12 months from date of patient fitting against manufacturer defects.

User Instructions

The providing health care professional must review the following information directly with the user.

Care and Maintenance



WARNING: Check the locking mechanism for proper operation before each use. Discontinue use of the prosthesis and contact your Prosthetist if the locking mechanism is not performing as expected.



CAUTION: Avoid bumping the button to prevent accidental unlocking. This risk increases if the prosthesis is fabricated without a button shield, which is not recommended.



CAUTION: Keep the lock clean and free of debris for the best performance and proper lock engagement.



CAUTION: 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.



CAUTION: Contact your Prosthetist should you have any questions or concerns.

Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.



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