

FASTPro

Product Manual

Fillauer[®]

Table of contents

A. Introduction	
A1. Intended Use/Purpose	3
A2. Performance Characteristics	3
A3. Storage and Handling	4
A4. Warning and Precautions	4
B. Specifications and Preparations Before Use	
B1. FASTPro Lamination Adapter Fabrication Guide for kit	5
B2. FASTPro Sealed Lamination Adapter Fabrication Guide for kit	9
B3. FASTPro Open / Sealed kit with Female Adapter, AI	13
B4. How to prepare Sealed Lamination Adapter	14
B5. INSTRUCTIONS OF USE, FASTPro Female Pyramid Adapter, AI	17
B6. FASTPro 4-hole Adapter, AI Instruction Guide	18
C. General Information	
C1. Combination of Devices	19
C2. Disposal/Waste Handling	19
C3. User Information	20
C4. Consultation of Healthcare Professional	20
C5. Care and Maintenance	20
C6. Serious Incidents	20
C7. Warranty	20

A. Introduction

A1. Intended Use/Purpose

The FASTPro systems consist of a range of prosthetic alignment components for use in constructing custom lower extremity prosthetics. The FASTPro systems provide a way to connect a custom-made prosthetic socket to a prosthetic foot with the maximum amount of adjustment capabilities in all planes of movement.

The device is intended for single patient use only.

A2. Performance Characteristics

The FASTPro systems is available in two materials, Grade 5 Titanium, for the FASTPro, Ti line, and a custom developed aluminum alloy, in the FASTPro, Al line, to provide lightweight, versatile, proven and reliable function.

The systems durability is tested according with ISO 10328 P6-125kg

The FASTPro, Al four hole adapter components also provide an interface to connect and adjust the alignment of so called Direct Socket systems as well as traditional 4 hole socket connectors.

The FASTPro, Al tube clamp has a 0.45 in. (11.5 mm) horizontal slide and a 12° angle adjustment for unlimited rotation in all directions.

The FASTPro, Ti tube clamp is made of titanium for high activity level patients and has a 0.45 in. (11.5 mm) horizontal slide and a 10° angle adjustment for unlimited rotation in all directions.

The FASTPro, Ti Female pyramid adapter system is made of titanium for high activity level patients and has a 0.4 in. (10 mm) horizontal slide and a 6° angle adjustment for unlimited rotation in all directions

The FASTPro, Al Female pyramid adapter system has a 0.4 in. (10 mm) horizontal slide and a 8° angle adjustment for unlimited rotation in all directions

A3. Storage and Handling

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

A4. Warning and Precautions



WARNING: Do not exceed the specified weight limit



WARNING: This device has been designed and tested for activities of daily living and not for abnormal activities such as extreme sports. To avoid risk of injury, handle your prosthesis and its components with care. If your prosthetic components are subjected to abnormal stress (such as a fall) contact your prosthetist/orthotist to have the components inspected for any damage



NOTICE: Abnormal or improper environmental conditions will lead to malfunction and damage of the prosthesis and is not covered under the warranty of the device. This prosthetic component must not be subjected to dust/debris, harsh chemicals, abrasives, vibration, activities which would damage the biological limb, or prolonged exposure to extreme temperatures (<-15C or >50C). Do not allow debris or liquids to remain in the device and its components during use.



NOTICE: Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist/orthotist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.



NOTICE: Fillauer has tested (ISO 10328) and recommends the use of standard, adult, endoskeletal components from Fillauer together with FASTPro systems. Components from other manufacturers may or may not be compatible. Failure due to use of other manufacturers products is not covered under warranty.

B. Specifications and Preparations Before Use

B1. FASTPro Lamination Adapter Fabrication Guide for kit:

731162117 FASTPro-OPEN, Tube Clamp Adapter, Ti

731162119 FASTPro-OPEN, Tube Clamp Adapter (small), Ti

731163117 FASTPro-OPEN, Tube Clamp Adapter, Al

1. The plaster should have a surface fitting the silicone dummy for the alignment system used. **(A vs B)**.

See article *Small Internal Lamination Dummy for FASTPro instrument, silicone: 731162138* or *Internal Lamination Dummy for FASTPro instrument, silicone: 731162133 (C)*.

Apply a PVA bag over the positive mould and seal the joint with PVA tape and apply vacuum. If using a CSS valve, mount the CSS Lamination Housing (part of kit 721000089) **(D)**. Use some release agent between the lamination adapter and silicon dummy to prevent any acrylic from sticking to these areas. Reposition the lamination adapter and its dummy. **(D)**.



A



B



C



D

2. Apply 2 layers of polyester stockinette twisting of the top and turning it inside out to create the first two layers (E).

Apply 6 additional layers (or more depending on patient weight and activity level) of polyester stock-inette or other reinforcement stockinette.

Use a cord to tie off the layers above the grip surface of the Lamination Adapter (F).
Fold down the remaining layers. (G)



E



F



G

3. Apply the second PVA bag and attach a funnel or pipe at the top in order to help pouring in the resin. Seal the PVA bag against the exit valve of the vacuum system and temporarily seal off the funnel/ pipe and apply vacuum (H).

Mix the resin with the hardening powder and pigment, pour it into the funnel/ pipe and leave it to rest a few minutes in order for the excess air to surface. Open the temporary seal and let the resin absorb fully into the stockinette. Massage if needed and tie off excess resin into the funnel/ pipe (I). Pour off a major part of the excess resin but keep some in the funnel/pipe in order to have a fluid lock. Oversee the hardening process in order to reduce the risk of air bubbles in the lamination (J).



H



I



J

Removal of socket

When the lamination is fully hardened, remove excess material from the distal end of the Lamination Adapter by cutting or grinding so that protective paper on the distal side of the adapter is visible.

DO NOT grind onto the material of the adapter. Trim the proximal part of the socket and remove it from the positive mould

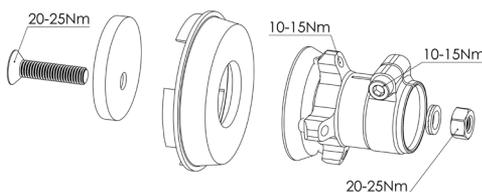
Before Patient Fitting

Grind the edges of the socket and smoothen all edges. Mount a CSS valve if it is being used.

Completion

To avoid damaging forces onto the center bolt that can result in breakage, it is **VERY IMPORTANT** that before delivering a prosthesis with an FASTPro adapter you need to;

1. Mark the position of the instrument with a marker onto the lamination adapter.
2. Open the angle adjustment screws one full turn (it is important to open all screws with the same amount in order not to change the alignment).
3. Tighten the center bolt.
4. Make sure that there is no contact between the flat surface and the angle adjustment screws. If that is the case, open the adjustment screws one additional turn. Repeat if necessary.
5. Tighten the center bolt with 20-25 Nm. The center bolt now has the right pretension.
6. Tighten the angle adjustment screws, all with the same number of turns, to ensure that the alignment is kept.
7. Loosen the angle adjustment screws one by one and add Loctite 243, or similar, over the whole threaded surface. Tighten with 10-15 Nm.



B2. FASTPro Sealed Lamination Adapter Fabrication Guide for kit: 731162102 and 731163102

1. Manufacture a protective cup of TFC, or similar, in order to protect the distal end from being deformed by the pressure from the Sealed Lamination Adapter. Roughen the surface of the protective cup with a sanding paper in order for the resin to bond properly (A).

Align the wings of the Sealed Lamination Adapter along the positive mould in order to achieve a correct alignment and mark its position (B). Place the dummy (731162107) for the Sealed Lamination Adapter onto the adapter with a bit of grease added onto the surface (C). Apply a PVA bag over the positive mould and seal the joint with PVA tape and apply vacuum. Mount the protective cup and secure its position with a strip of double sided tape and place the Sealed Lamination Adapter according to your alignment. If using a CSS valve, mount the CSS Lamination Housing (part of kit 721000089) (D).



A



B



C



D

2. Apply 2 layers of polyester stockinette twisting of the top and turning it inside out to create the first two layers (E). Reposition the Sealed Lamination Adapter according to the marks and apply some stockinette around the wings to fill the gap between the Sealed Lamination Adapter and the positive mould (F).

Apply 6 additional layers (or more depending on patient weight and activity level) of polyester stockinette or other reinforcement stockinette. Use a cord to tie off the layers above the grip surface of the Sealed Lamination Adapter (G). Fold down the remaining layers (H)



E



F



G



H

3. Apply the second PVA bag and attach a funnel or pipe at the top in order to help pouring in the resin. Seal the PVA bag against the exit valve of the vacuum system and temporarily seal off the funnel/pipe and apply vacuum (I). Mix the resin with the hardening powder and pigment, pour it into the funnel/ pipe and leave it to rest a few minutes in order for the excess air to surface.

Open the temporary seal and let the resin absorb fully into the stockinette. Massage if needed and tie off excess resin into the funnel/ pipe (J). Pour off a major part of the excess resin but keep some in the funnel/pipe in order to have a fluid lock. Oversee the hardening process in order to reduce the risk of air bubbles in the lamination (K).



I



J



K

Removal of socket

When the lamination is fully hardened, remove excess material from the distal end of the Sealed Lamination Adapter by cutting or grinding so that protective paper on the distal side of the adapter is visible.

DO NOT grind onto the material of the adapter. Trim the proximal part of the socket and remove it from the positive mould.

Before Patient Fitting

Grind the edges of the socket and smoothen all edges. Mount a CSS valve if it is being used.

Completion

To avoid damaging forces onto the center bolt that can result in breakage, it is **VERY IMPORTANT** that before delivering a prosthesis with an FASTPro adapter you need to;

1. Mark the position of the instrument with a marker onto the lamination adapter.
2. Open the angle adjustment screws one full turn (it is important to open all screws with the same amount in order not to change the alignment).
3. Tighten the center bolt.
4. Make sure that there is no contact between the flat surface and the angle adjustment screws. If that is the case, open the adjustment screws one additional turn. Repeat if necessary.
5. Tighten the center bolt with 20 - 25 Nm. The center bolt now has the right pretension.
6. Tighten the angle adjustment screws, all with the same number of turns, to ensure that the alignment is kept.
7. Loosen the angle adjustment screws one by one and add Loctite 243, or similar, over the whole threaded surface. Tighten with 10 - 15 Nm.

B3. FASTPro Open / Sealed kit with Female Adapter, Al FASTPro-OPEN, Female Pyramid Adapter, Ti Manual for:

731 162 123 FASTPro-OPEN, Female Adapter, Ti Includes:

731162140 FASTPro-Lamination Adapter, Ti

731162167 FASTPro-Washer, Threaded M10 /Ti

731162120 FASTPro-Female Pyramid Adapter With Adjustment Screw, Ti

731162168 FASTPro-Center Bolt M10X16mm Lamination Adapter, Ti

Using the FASTPro-OPEN, Female Adapter, Ti

Once the static alignment is done the FASTPro-OPEN, Female Adapter, Ti needs to be secured.

1. Ensure that all mating surfaces are clean and not deformed in any way.
2. Mark the current setting with a permanent marker so that you ensure that the static alignment is maintained.
3. Tighten the M10 center bolt to 35-40Nm
4. The adjustment screws need to be tightened to 15Nm and secured with a suitable thread lock.

Loctite 243 is recommended.

Note to Practitioner

The units are tested and compatible with ISO 10328. P6 - 125 kg.

The FASTPro-OPEN, Female Adapter, Ti is tested to withstand an axial torque of 50Nm for 30 seconds without the center bolt unscrewing or the alignment changing. If excess loads are suspected to occur a torsion adapter is recommended to ensure excess loads are not transferred to the patient's residual limb.

B4. How to prepare Sealed Lamination Adapter:

731 162 125 FASTPro-SEALED, Female Adapter, Ti

731162140 FASTPro-Lamination Adapter, Ti

731162167 FASTPro-Washer, Threaded M10 /Ti

731162120 FASTPro-Female Pyramid Adapter With Adjustment Screw, Ti

731162168 FASTPro-Center Bolt M10X16mm Lamination Adapter, Ti

731162108 FASTPro-Lamination Seal Washer

Manual: FASTPRO100103

How to prepare the Sealed Lamination Adapter

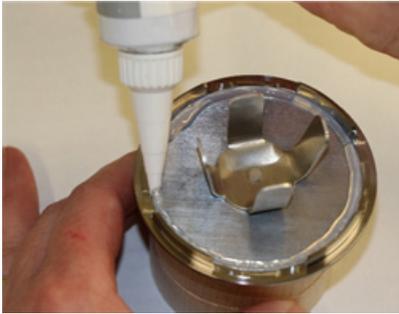
1. Clean all mating surfaces with a titanium compatible degreaser. Acetone will work.
2. Cut out a hole in the protective sticker that is mounted on the lamination adapter.



3. Flip the adapter and insert the washer with the protruding stud facing down into the hole, according to the picture.



4. Place the sealing washer in the lamination adapter and seal the edges with a narrow strip of silicone seal. Wacker Elastosil E43 is recommended, Part nr. 632040090.



5. Let the silicone cure and then fold down the arms of the sealing washer. Now the adapter is ready for use.



Using the FASTPro-OPEN Female Adapter, Ti

KIT: 731162123, 731162125 AND ART NR: 731162120

Once the static alignment is done the FASTPro-OPEN, Female Adapter, Ti needs to be secured.

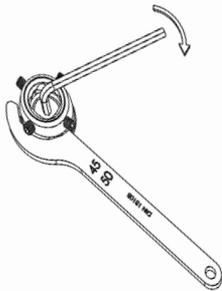
1. Ensure that all mating surfaces are clean and not deformed in any way.
2. Mark the current setting with a permanent marker so that you ensure that the static alignment is maintained.
3. Tighten the M10 center bolt to 35-40Nm , Please use, Pin Wrench - DIN1810B-45-50
Product number: **731000140 to hold the adapter still while torquing to the appropriate specs. (See figure)**
4. The adjustment screws need to be tightened to 15Nm and secured with a suitable thread lock. Loctite 243 is recommended.

Note to Practitioner

The units are tested and compatible with ISO 10328. P6 - 125 kg.

The FASTPro-OPEN, Female Adapter, Ti is tested to withstand an axial torque of 50Nm for 30 seconds without the center bolt unscrewing or the alignment changing.

If excess loads are suspected to occur a torsion adapter is recommended to ensure excess loads are not transferred to the patient's residual limb.



B5. INSTRUCTIONS OF USE, FASTPro-Female Pyramid Adapter, AI

KIT: 731163185 AND ART NR: 731163187

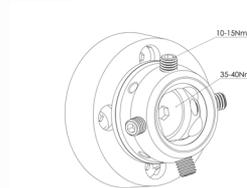
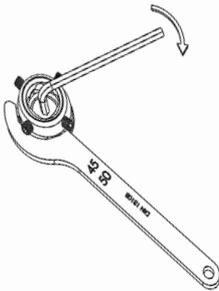
Once the static alignment is done the FASTPro-Female Adapter, AI needs to be secured. To avoid incorrect load on the center-bolt, which can lead to breakage or slippage of the rotation alignment, it is of outmost importance that the steps below are followed:

1. Ensure that all mating surfaces are clean and not deformed in any way.
2. Mark the current setting with a permanent marker so that you ensure that the static alignment is maintained.
3. Tighten the M10 center bolt to 35-40Nm, Please use, Pin Wrench - DIN1810B-45-50
Product number: **731000140** to hold the adapter still while torquing to the appropriate specs. (See figure)
4. The adjustment screws need to be tightened to 10-15Nm and secured with a suitable thread lock. Loctite 243 is recommended.

Note to Practitioner

The units are tested and compatible with ISO 10328. P6 - 125 kg.
The FASTPro-Female Pyramid Adapter, AI is tested to withstand an axial torque of 50Nm for 30 seconds without the center bolt unscrewing or the alignment changing.

If excess loads are suspected to occur a torsion adapter is recommended to ensure excess loads are not transferred to the patient's residual limb.



B6. FASTPro 4-hole Adapter, AI Instruction Guide

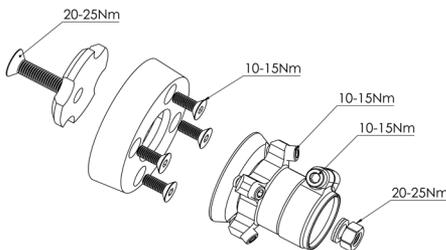
Assembly

1. Insert the M8x40mm screw through the FASTPro-4H washer, AI.
2. Set the washer and screw in the FASTPro-4H adapter, AI.
3. Use the 4 M6x16mm screws to secure the adapter against the sockets four-hole adapter using an appropriate thread lock, such as Loctite 243, and tighten them to 15Nm.
4. Secure the FASTPro-Tubeclamp with the M8x40 screw using the supplied washer and nut.

Delivery of Prosthesis

To avoid damaging forces onto the center bolt that can result in breakage, it is **VERY IMPORTANT** that before delivering a prosthesis with an FASTPro-4-Hole adapter, AI you need to:

1. Mark the position of the instrument with a marker onto the FASTPro-4H-adapter, AI.
2. Open the angle adjustment screws one full turn (it is important to open all screws with the same amount in order not to change the alignment).
3. Tighten the M8 nut within the tubeclamp portion of the instrument to 20-25 Nm. The center bolt now has the right pretension.
4. Make sure that there is no contact between the flat surface and the angle adjustment screws. If that is the case, open the adjustment screws one additional turn. Repeat if necessary.
5. Tighten the nut with 20-25Nm. The nut now has the right pretension.
6. Tighten the angle adjustment screws with applied threadlocker, all with the same number of turns to 10-15Nm of torque.



Note to Practitioner

Once the static alignment is done the FASTPro-4H Adapter, AI needs to be secured.

The units are tested and compatible with ISO 10328. P6 - 125 kg.

The FASTPro-4H, AI Adapter is tested to withstand an axial torque of 50Nm for 30 seconds without the center bolt unscrewing or the alignment changing.

If excess loads are suspected to occur a torsion adapter is recommended to ensure excess loads are not transferred to the patient's residual limb.

C. General Information

C1. Combination of Devices

Fillauer has tested (ISO 10328) and recommends the use of standard, adult, endoskeletal components from Fillauer to be used in combination with FASTPro Systems. Components from other manufacturers may or may not be compatible. Failure due to use of other manufacturers products is not covered under warranty.

C2. 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.

C3. User Information

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

Attachment, alignment, and delivery of this orthotic/prosthetic device must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be done by the clinician and not by the user.

C4. Consultation of Healthcare Professional

The user should monitor their prosthesis daily and contact their health care professional if they experience changes in performance of the device or noise.

C5. Care and Maintenance

Keep the FASTPro systems components clean, dry

C6. 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.

C7. Warranty

This product has a 12 month warranty against manufacturer defects.

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