



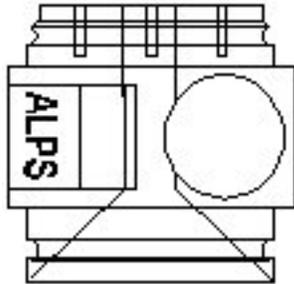
ALPS Lock S496-T

Product instruction

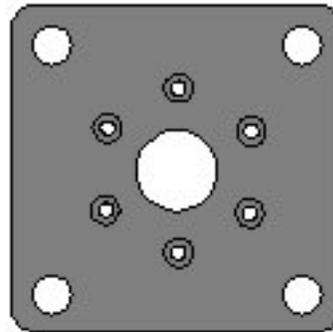


ALPS Lock S496-T

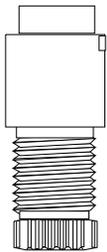
(Total product weight 163 grams)



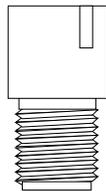
1 Body
35mmx33mm
With Flat
Bottom for
Universal
Mounting
Plate



1
Universal
Mounting
Plate
UMP-16



1
Housing
(Clutch)
Assembly
LDH-694A



1
Clutch
Housing
Dummy
Plug



1
Reducer
Hex Nut
LDA-694



1
Stainless
Steel
Serrated
Pin 3/8" X
2-5/8"
Long
1/4-20 US
Standard
Threads
LDP-695



6
#6
Stainless
Steel
Screws
UMS-16A



4
3/4" Stainless
Steel Socket
Head Cap
Screws
UMS-16

Intended purpose

The Alps Lock S496T is intended to be used as part of a lower limb external prosthetic leg.

The ALPS Lock S496-T is designed to be used in new socket fabrication in conjunction with ALPS liners which are equipped with distal attachments. The S496-T is a low profile, light-weight device containing a smooth and uniform gear system; it includes a universal 4 hole mounting plate for connection with a 4 hole socket adaptor.

Limitations and contraindications

The Alps Lock S496T is designed to be used in conjunction with liners equipped with distal attachments (locking liners) to create a pin and lock suspension system of the prosthetic leg.

The Alps Lock S496T is not suitable to be used in shower or swimming prosthetic legs.

Warnings

In case the pin is caught in the lock mechanism, and you are unable to remove the pin from the locking mechanism, immediately contact a certified prosthetist. Ask for someone's helps to release the residual leg.

Intended life

The ALPS Lock S496-T has been tested for 3,000,000 cycles, corresponding to approximatively 2 years of use under normal conditions; the device have then to be inspected by a certified prosthetist to verify the suspension system is working properly and looking for signs of deterioration. It is also recommended to perform a local risk assessment based upon activity and usage.

ALPS Lock S496-T Installation Instructions

Application Instructions

The ALPS Lock S496-T can be used in the following types of socket fabrication:

Type of Fabrication	Procedure
Transparent Diagnostic Sockets	Procedure 1
Vacuum Formed Thermoplastic Sockets	Procedure 2
Conventionally Laminated Sockets	Procedure 3

Note: The sockets above each require a different method of fabrication and setup. Please refer to the procedure, which applies to the type of socket you intend to use.

Note: The ALPS Lock S496-T is the mechanism of choice, when fabricating an ENDO-skeletal prosthesis. If you intend to fabricate an EXO-skeletal prosthesis, it is suggested you use the ALPS Lock S496-W.

Procedure 1:

Transparent Diagnostic Sockets

Note: It is important when fabricating a new socket with the ALPS Lock, the negative impression of the patient should be made over the liner that the patient will be using. When using an ALPS Thermoliner®, the negative impression is to be taken directly over the patient's limb.

Modifying the Positive Model

1. a. Prepare your positive model in the usual manner with the exception of the distal end. The liner will have left a protrusion during the casting stage.
- b. Rasp this protrusion to create a flat spot 1 $\frac{3}{4}$ " in diameter, again this flat area must be perpendicular to the floor reaction lines. Find the center of this area, and drill a $\frac{3}{8}$ " hole approximately 1" deep.

Using the Fabrication Kit

2. a. Locate the Alignment Cone (FKA-16) found in the ALPS Fabrication Kit, #FAB 946
- b. Scuff the flat bottom of the Alignment Cone with 80-100 grit sandpaper.
- c. Lightly coat the threads of the $\frac{5}{16}$ " x 3" Anchor Bolt (FKB-16) with silicone grease and screw it into the Alignment Cone until it protrudes approximately $\frac{1}{4}$ " beyond the flat surface (figure 1).
- d. Using an instant adhesive, i.e. Superglue, secure the Alignment Cone to the distal end of the model.
- e. Once set, use the plaster to blend the Cone into the model. Remove any excess which may have fallen on the Alignment Cone
- f. Remove Anchor Bolt, and smooth the model for vacuum forming.

Pre-Fabrication

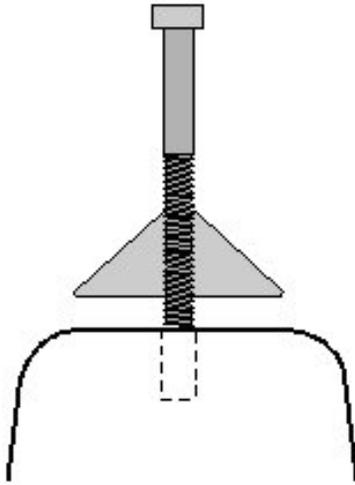


Figure 1

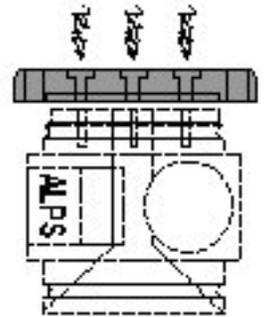
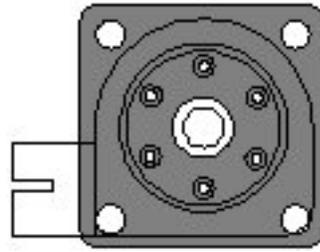


Figure 2

3. a. Secure the Universal Mounting plate (UMP-16) to the ALPS Lock body with the stainless steel screws provided. Be sure that the plate is aligned properly, with the four holes perpendicular and parallel to the clutch Housing Dummy Plug. (figure 2)
- b. Utilizing the 5/16" x 3" Anchor Bolt and the Fabrication Kit (FAB 946), attach the ALPS Lock body to the Alignment Cone. (figure 3)

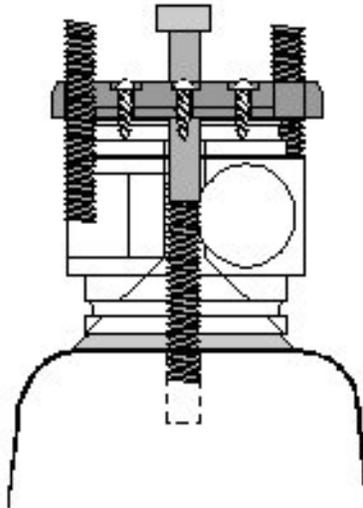


Figure 3

- c. Visually align the locking mechanism to be perpendicular to the line of progression.
- d. Screw the four 6mm x 35 mm studs found in the Fabrication Kit into the four outer holes of the universal Mounting Plate. They should protrude from the top of the plate approximately ¼". When the thermoplastic is formed over the plate, this will provide a bump which can be sanded off to expose the studs.

Note: Be sure the socket head end of the studs points distally.

Fabrication

4. a. Vacuum form the thermoplastic in your preferred manner, i.e. bubble forming or drape molding.
- b. When the plastic is cooled, sand or cut the plastic cover over the Anchor Bolt and studs and remove them.
- c. Remove the socket from the positive model and sand the thermoplastic flat over the Universal Mounting Plat. Be sure to leave a sufficient amount of plastic, for durability, over the Universal Mounting Plate.
- d. Remove the Clutch Housing Dummy Plug and replace with the mechanical clutch mechanism.
- e. The lock mechanism should be installed with **Red Loctite 262** thread locking adhesive prior to delivery.
- f. Attach the mounting hardware for the pylon system and the socket is complete.

*The two anterior studs will need to be cut, as they come in contact with the ALPS Lock body.

* If the drape molding technique is used, it is recommended that the seam be down the side opposite the Clutch Housing Dummy Plug.

Procedure 2:

VACUUM FORMED THERMOPLASTIC SOCKETS

Note: It is important when fabricating a new socket with the Alps Lock, The negative impression of the patient should be made over the ALPS liner of the appropriate size.

Pre-Fabrication

1. a. Attach the Universal Mounting Plate to the ALPS Lock body (S496-W) with the #6 stainless steel screws provided.
- b. Screw the delrin Clutch Housing Dummy Plug into the side of the Lock body.
- c. Using the 5/16" x 3" Anchor Bolt and the 3/4" white spacer from the Fabrication Kit (#FAB 946), attach the ALPS Lock body to the distal end of the case.

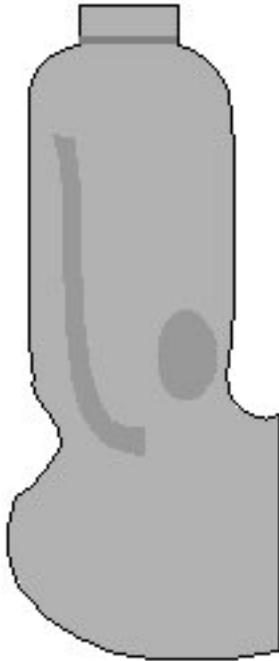


Figure 1

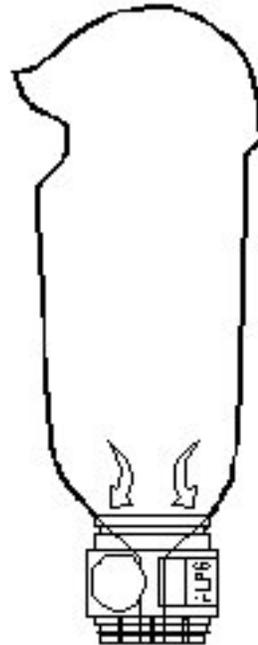


Figure 2

- d. Next screw the four 6mm x 35mm studs found in the Fabrication Kit into the 4 outer holes of the Universal Mounting Plate so that they stick up approximately $\frac{1}{4}$ ". When the thermoplastic is formed over the plate this will provide a bump which can be sanded off to expose the studs. Be sure the socket head end of the studs point distally. NOTE: It will be necessary to shorten 2 of the studs.

Fabrication

- a. Vacuum form the thermoplastic over the prepared model to form the socket.
- b. Trim the socket off the cast.
- c. Sand or cut the tips off of the bumps in the thermoplastic to expose the socket head of the Anchor Bolt and studs.
- d. Remove the Anchor Bolt, studs and spacer.
- e. Sand the thermoplastic flat over the Universal Mounting Plate.
- f. Remove the Clutch Housing Dummy Plug and replace it with the mechanical clutch mechanism.
- g. The lock mechanism should be installed with **Red Loctite 262** thread locking compound prior to delivery of prosthesis.
- h. Attach the mounting hardware for the pylon system and the socket is complete.

Procedure 3:

LAMINATED SOCKETS

Note: It is important when fabricating a new socket with the Alps Lock, the negative impression of the patient should be made over the liner the patient will be using.

Modifying the Positive Model

1. a. Prepare your positive model in the usual manner with the exception of the distal end. The Liner will have left a protrusion during the casting stage.
- b. Rasp this protrusion to create a flat spot 1 ¾" in diameter, **again this flat area must be perpendicular to the floor reaction lines.**
- c. Find the center of this area, and drill a 3/8" hole approximately 1" deep.

Using the Alps Fabrication Kit

1. a. Locate the Alignment Cone found in the ALPS Fabrication Kit, #FAB 946.

- b. Scuff the flat bottom of the Alignment Cone with 80-100 grit sandpaper.
- c. Lightly coat the threads of the 5/16" x 3" Anchor Bolt with silicone grease and screw it into the Alignment Cone until it protrudes approximately 1/4" beyond the flat surface. (Figure 1)
- d. Using an instant adhesive, i.e. Superglue, secure the Alignment Cone to the distal end of the model.
- e. Once set, use plaster to blend the Cone into the model. Remove any excess, which may have fallen on the Alignment Cone.
- f. Remove the anchor bolt, and smooth the model for lamination.

Pre-Fabrication

1. a. Seal the positive, and apply a PVA bag or casting balloon over the entire model. If the bag can be drawn in on the Alignment Cone so the lock body covers the end of the PVA, then a PVA cap is not necessary. If this is not the case, you may have to cap the bag and make a small hole for the Anchor Bolt.
- b. Locate the Clutch Housing Dummy Plug included with the ALPS Lock Kit.
- c. Coat the threads of the Dummy Plug with silicone grease and screw it firmly into the sides of the ALPS Lock body. Protect the slot either with masking tape or by forcing a scrap piece of 5mm Pelite into the slot to prevent it from filling up with laminate.
- d. Secure the Universal Mounting Plate to the ALPS Lock body with the 6 stainless steel screws provided. Apply a bead of silicone grease inside the receiving cone of the ALPS Lock body.
- e. Coat the threads of the Anchor Bolt with silicone grease, then with the 3/4" white spacer sleeve secure the ALPS Lock body to the alignment cone.
- f. Wipe away any excess silicone grease then fill the head of the Anchor Bolt with clay or putty to keep it from filling with resin.
- g. Coat the threads of the four 6mm x 35mm studs and screw them into the Universal Mounting Plate, again allow them to

- protrude approximately 1/4".
- h. Fill the studs and Anchor Bolt head with clay or putty to prevent resin from entering.
- i. Locate the 1/4" plastic spacer material from the Fab Kit and cut 4 equal length pieces.
- j. Slide the 4 spacers over the 4 studs in the mounting plate (figure 4).

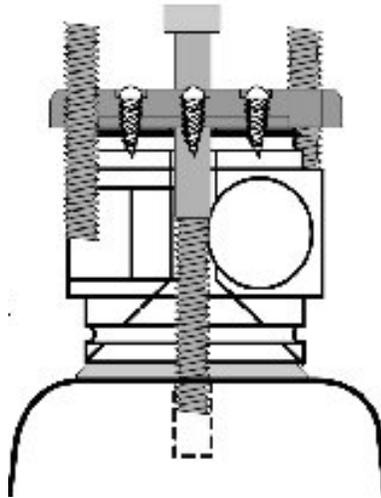
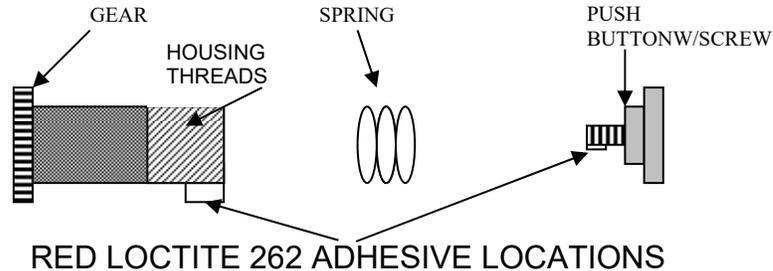


Figure 4

Fabrication

- a. The model is now ready for lay-up and lamination. The ALPS Lock S496-T will accommodate virtually any lay-up you choose; however, it is **essential** the lay-up go over the Universal Mounting Plate.
- b. Once the lamination is complete, carefully remove any excess resin, remove the anchor bolt and trim around the Clutch Housing Dummy Plug.
- c. Thoroughly clean the threads in the lock body, and remove any resin which may have gotten into the lock body.
- d. Trim the socket proximally and remove it from your positive model.
- e. Shape and finish the edges as you normally would. Sand over the four 6mm x 35mm studs and remove them from the Universal Mounting Plate. Sand the remaining resin to a flat surface ensuring a sufficient amount, for durability, is covering the plate.
- f. You may now proceed with bench alignment.

LOCKING DEVICE HOUSING ASSEMBLY ADHESIVE PROCEDURE



Adhesive Procedure

Note:

It is required that thread-lock adhesive Red Loctite 262 be used on the housing because it is the only one that adheres to nylon adequately. This will allow the parts to be firmly glued, but should the necessity arise, the parts can be taken apart.

Full cure of adhesive is 24 hours.

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

ALPS Satisfaction Guarantee

ALPS offers a no hassle return policy within **30 days** from the date of purchase. If you are not 100% satisfied with the ALPS S496-T Lock, call ALPS Customer Service for a Return Authorization Number and return the purchase (excluding freight charges).

Warranty

ALPS locks are warranted against manufacturer's defects for 6 months from the date of purchase. ALPS South warrants only that its products will meet its specifications. **THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR USE, NOR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.** The user's exclusive remedy and ALPS South's sole liability is limited to the replacement of any product shown to be otherwise than as warranted. ALPS South will not be liable for incidental or consequential damages of any kind.

To obtain an Alps Return Authorization Number (RA#) call ALPS Customer service between the hours of 8 am and 5 pm EST and provide an ALPS representative with the following information:

- 1. Customer ID Number**
- 2. Invoice Number**
- 3. Date of Invoice**
- 4. Nature of return**

*The RA# must be displayed on the exterior of the returned item box or it will be refused at the dock.

Frequently Asked Questions

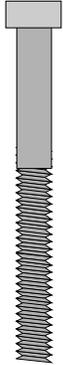
How to create a smooth transition from the side of the socket to the lock?

It is very important to blend the Alignment Cone to the mold so that you create a smooth transition from the side of the socket to the lock.

How to properly seat the liner to the locking device?

You must be sure that the bottom side of the liner is touching (seated on) the edge of the locking device for maximum strength. If the two are not seated properly the pin and the distal umbrella will be subjected to unusual side loads. The ALPS Locking Device are recessed enough to allow proper seating of the liner and other silicone suction sockets. If you are using a locking device other than ALPS that exhibits a geometry that prevents proper seating of the socket, please install a spacer between the liner and the locking device.

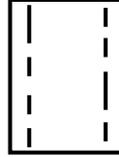
FABRICATION KIT (FAB 946) PARTS LIST



1
1 5/16" X
3"
Anchor
Bolt
FKB-16



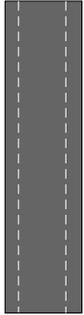
4
6mm X
35mm
Studs
FKS-16



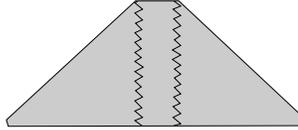
1
1 3/4" White
Sleeve
FKB-16A



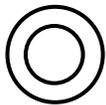
4
6mm Hex Nuts
FKN-16



1
1/4" ID x
2"
Plastic
Spacer
Material
FKS-16A

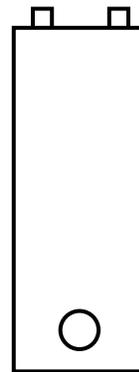


1
Alignment
Cone
FKA-16



4
1/4" Flat
Washers
FKW-16

1
Gear Extraction
Wrench
LDN694A



Symbol legend	
Medical device	
Single patient multiple use	
Manufacturer	

CE Conformity

This product meets the requirements of the European Regulation EU2017/745 for medical devices. This product has been classified as a class I device accordingly to the classification rules outlined in Annex VIII of the regulation.

Reporting of serious incidents

In the unlikely event of a serious incident occurring in relation to this device, it should be reported to the manufacturer and your national competent authority



CE

EC	REP
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CEpartner4U
Esdoornlaan 13, 3951DB Maarn, The Netherlands
www.cepartner4u.com

900005 Rev N, CAN# 9463
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ALPS South LLC
2895 42nd Ave. N.
St. Petersburg, FL. 33714
USA

Tel: 1-727-528-8566

Fax: 1-727-528-8862

Info@easyliner.com

www.easyliner.com