



**RATED 220 LBS (100KG)
INSTRUCTIONS MUST BE FOLLOWED**

ALPS Lock S498-P

Product instruction



U.S. PATENT 5,507,837

Intended purpose

The Alps Lock S498P is intended to be used as part of a lower limb external prosthetic leg.

The ALPS Lock S498P is designed to be used in new socket fabrication in conjunction with ALPS liners which are equipped with distal attachments. The S498P is a low profile, light-weight device containing a smooth and uniform gear system; it includes an integrated alignment pyramid.

Limitations and contraindications

The Alps Lock S498P 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 S496W 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 help to release the residual leg.

*****ATTENTION*****

This device is rated for a maximum amputee weight of 220 LBS (100 KGS)

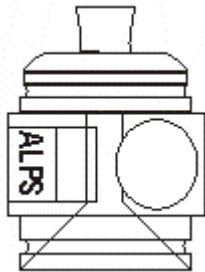
Please carefully follow the fabrication instruction.

FAILURE TO FOLLOW THE ENCLOSED INSTRUCTIONS WHEN FABRICATING THE SOCKET WILL RENDER THE WARRANTY NULL AND VOID

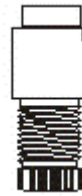
Intended life

The ALPS Lock S498P has been tested for 3,000,000 cycles, corresponding to approximately 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 S498-P



(1) BODY WITH INTEGRATED
PYRAMID
64mm X 43mm



(1) LOCKING MECHANISM
(CLUTCH)
LDH-694A



(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



(1) CLUTCH HOUSING DUMMY PLUG

(2) 3 FOOT LENGTHS OF KEVLAR THREAD

Application Instructions

The ALPS Lock S498-P can only be used in Conventionally Laminated Sockets.

NOTE: The ALPS Lock S498-P can be used when fabricating an ENDOskeletal prosthesis. If you intend to fabricate an EXOskeletal prosthesis, it is suggested you use the ALPS Lock S496-W. If you intend to fabricate a thermoplastic socket the ALPS Lock S496-T is recommended.

Do not use the S498-P with thermoplastic sockets.

LAMINATED SOCKETS

Note: It is important that when fabricating a new socket with an ALPS Lock that the negative impression of the patient be made over the liner which will be used by the patient.

Modifying the Positive Model

- a. Prepare the 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 the protrusion to create a flat spot 1 $\frac{3}{4}$ " 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 $\frac{3}{8}$ " hole approximately 1" deep.

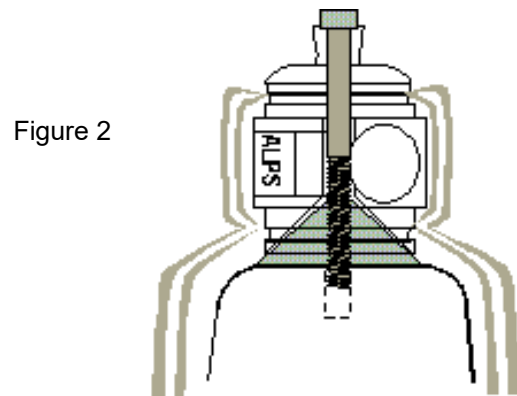
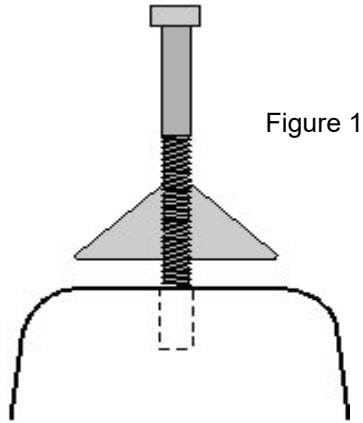
Using the ALPS Fabrication Kit

- 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 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

- 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 side of the ALPS Lock body.
- d. Protect the slot either with masking tape or by forcing a scrap piece of 5mm Pelite into the slot.
- e. Apply a bead of silicone grease inside the receiving cone of the ALPS Lock body.
- f. Coat the threads of the 5/16" Anchor Bolt with silicone grease and anchor the ALPS Lock body to the Alignment Cone.
- g. Wipe away any excess grease and fill the head of the bolt with clay or putty.
- h. Care should be taken so that resin does not seep through the Anchor Bolt hole. A silicone rubber lamination cap is useful in this situation. PVA tape will also provide moderate protection.



Fabrication

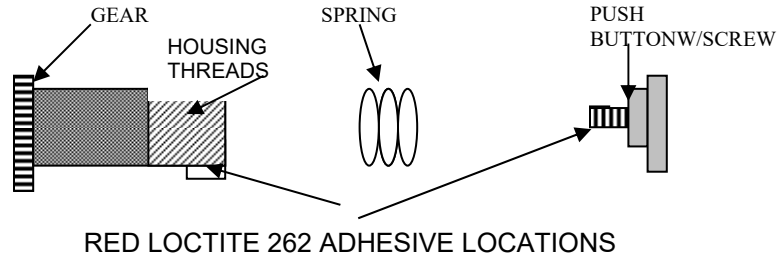
- a. The model is now ready for lay-up and lamination. Select the appropriate size of carbon tubular weave. Cut a piece 30" to 40" long (twice the socket length) and a piece 8" to 10" long. Apply the longer carbon weave to the cast. **Using the enclosed kevlar thread, tie the carbon into the steel groove of the pyramid (figure 2). Make sure that the carbon weave is pulled into the groove along the entire circumference. The kevlar thread is supplied in 3 foot lengths to allow you to wrap the ends around two handles, (Example: Two pieces of aluminum tube), in order to be able to apply enough force to pull the carbon into the groove. Wrap the kevlar around the pyramid again and make a double knot.**

- b. **Apply the second piece of carbon and pull the carbon into the groove. Make a double knot and tie around again. Reflect the carbon up and inspect to make sure that you have in fact tied the carbon into the steel groove and not outside of the groove. Place a 16" wide strip of 1 ounce felt between the two layers of carbon and around the body of the lock. Tack the felt in place by melting the felt in 2 or 3 spots with the tip of a soldering iron. This will increase the strength of the socket around the body of the lock. Reflect the carbon and continue lamination procedure.**

NOTE: Failure to follow these instructions properly may cause a failure of the interface between the socket and the lock.

- c. Once the lamination is complete, carefully remove any excess resin. Remove the Anchor Bolt and trim around the Clutch Housing Dummy Plug.
- d. Thoroughly clean the threads in the lock body and remove any resin which may have gotten into the lock body.
- e. Trim the socket proximally and remove it from your positive mold.
- f. Shape and finish the edges as you normally would and proceed with bench alignment.
- g. The lock mechanism should be installed with **Red Loctite 262** thread locking compound prior to delivery.

LOCKING DEVICE HOUSING ASSEMBLY ADHESIVE PROCEDURE



Adhesive Procedure

Note
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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 Lock S498-P, call ALPS Customer Service for a Return Authorization Number and return the purchase.

Warranty

ALPS locks are warranted against manufacturing 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 Ask Questions

What parts of the Fabrication Kit are needed for the fabrication of the S498-P?

The Fabrication Kit must be used if fabricating a lock into a laminated socket. The parts to use for the S498-P are the Mounting Alignment Cone, Anchor Bolt and Flat washer. All other parts are to be used with the S496-T.

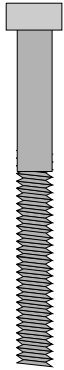
How to create a smooth transition from the side of the socket into the lock?

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 into 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 distal umbrella will be subjected to unusual side loads. The ALPS Locking Devices 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.

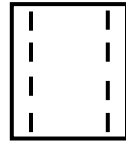
FABRICATION KIT (FAB 946) PARTS LIST



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



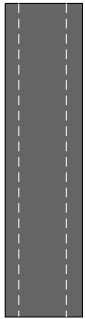
4
6mm X
35mm
Studs
FKS-16



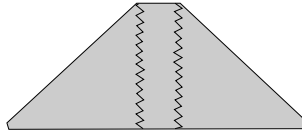
1
1 3/4" White
Sleeve
FKB-16A



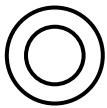
4
6mm Hex Nuts
FKN-16



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



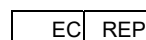
Symbol legend	
Medical device	
Single patient multiple use	
Manufacturer	

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



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