# **PROADVANTAGE<sup>TM</sup>** IRS-200-AK, IRS-600-AK and IRS-600-AKT

## Important Notes

### GENERAL

1. Secure locking pin in suspension sleeve using LOCTITE® (not included). If a liquid thread-locker is not used, advise the patient the pin may become loose with use and provide instructions for tightening the pin using appropriate wrench.

2. Secure all prosthetic lock screws and release button using LOCTITE® (not included, reference item #LT-271).

3. The extended length release button (not included, reference item #IRS-200/600ELB) may be used.

### SPECIFIC TO IRS-200-AK AND IRS-600-AK

Not recommended for patients whose weight exceeds 275lbs.

1. For applications without a pyramid adapter, use 5/16" x 1-3/4" socket head screw supplied with tooling. For applications with a pyramid adapter, use 5/16" x 2-1/2" socket head screw supplied with tooling.

2. Delrin® construction requires the use of sheet metal screws (included Delrin® Laminating Sleeve with adapter).

3. Concave style button (included with IRS-200-AK) and dome style button (included with IRS-600-AK) are interchangeable. When using dome style button, advise the patient that accidental bumping of the protrusion may cause disengagement of the pin.

## SPECIFIC TO IRS-600-AK AND IRS-600-AKT

1. To reduce wear and lengthen the life expectancy of the prosthetic lock, orient the gear of the clutch toward the anterior aspect of the socket.

2. Instruct the patient to rotate the release button using the long end of the "T" wrench (supplied) and turn clockwise until suspension liner is drawn completely into the socket.

## **SPECIFIC TO IRS-600-AKT**

Not recommended for patients whose weight exceeds 350lbs.

1. Aluminum construction requires the use of socket head screws (supplied with adapter).

# **Plaster Model Preparation**

The plaster model from a cast taken over a suspension liner will have a center protrusion replicating the distal end of the liner. To ensure proper positioning of the tooling on the model, a 1/4" diameter centering hole may be drilled straight down through the protrusion prior to making the following modifications.

### LAMINATION APPLICATIONS

1. Remove enough plaster from the distal end of the model to equal the outer dimension of the Delrin® tooling. DO NOT exceed the outer dimension of the tooling as the resulting socket will be too short.

2. Center the tooling on the model and secure with the nails provided. Any discrepancy between the model and the tooling should be filled to create a smooth transition. It may be necessary to sand down nail heads.

3. Apply a PVA cap over the model and tooling OR seal the model using mold sealer made from Cellulose Acetate Crystals (not included, reference item #CAC-1LB) and Acetone (not included, reference item #DMK-G).

4. Draw a PVA bag over the model.

## THERMOPLASTIC APPLICATIONS Follow Steps 1 and 2 above.

3. Thoroughly powder model with Baby Powder (not included, reference item #BP-100).

# IRS-200-AK

Push Button Ratchet Mechanism Delrin<sup>®</sup> Body L 2-1/2"x W 1-5/8"x H 1-5/8"



KIT INCLUDES:	
IRS-200-B Body	
IRS-200-T Tooling	<b>Handrid and IIII</b>
IRS-200-API Pin, 10mm L 3"	
I <b>RS-200-W</b> Pin Wrench	<b>-</b>
IRS-200-LS Delrin® Laminating Sleeve	



KIT INCLUDES:	
IRS-600-B Body	
IRS-200-T Tooling	<b>B</b> ahananan <b>B</b> ahananan <u>1</u> 1111
IRS-600-API-RPC Pin, 10mm L 2-3/4"	
IRS-650-W "T" Wrench	
IRS-600-LS Delrin <sup>®</sup> Laminating Sleeve	
IRS-600-LW Hex Wrench	

IRS-600-AKT

Clutch Lock Mechanism with ClickLock™ Aluminum Body

with Titanium Liner L 2-3/4"x W 1-3/4"x H 1-5/8" Weight 144 grams

## **KIT INCLUDES:**

IRS-600-BT Body	
IRS-200-T Tooling	<b>B</b> ahananan <b>B</b> ahanan IIII 🥢
<b>IRS-600-API-RPC</b> Pin, 10mm L 2-3/4"	
IRS-650-W "T" Wrench	
IRS-600-LS Delrin <sup>®</sup> Laminating Sleeve	
IRS-600-LW Hex Wrench	

IRS-200-AK	IRS-200-AK	IRS-200-AK	IRS-200-AK	IRS-200-AK
IRS-600-AK	IRS-600-AK	IRS-600-AK	IRS-600-AK	IRS-600-AK
IRS-600-AKT	IRS-600-AKT	IRS-600-AKT	IRS-600-AKT	IRS-600-AKT
For use with a pyramid adapter* in amination applications	For use with modular adapter* in lamination applications	For use with modular adapter* in thermoplastic applications	For use with European 4-hole pattern wood block* in lamination applications	For use with conventional exoskeletal limbs in lamination applications
A single-lamination method offering a lightweight modular design, uitable for moderately active and geriatric patients.	A single-lamination method offering a heavy-duty modular design suitable for moderately active and heavier patients.	A single-pull thermoplastic method for test sockets as well as definitive limbs.	A double-lamination method offering the heaviest-duty modular design for patients with congenital deformities and flexion contractures.	A double-lamination method for heavier patients and for limbs exposed to extreme conditions.
NOTE: When using this fabrication method, Delrin® body kits (IRS-200- AK and IRS-600-AK) are not recommended for patients whose weight exceeds 175 lbs. or when using a dynamic response foot.	PLASTER MODEL PREPARATION Please refer to instructions in "IMPORTANT NOTES" section.	PLASTER MODEL PREPARATION Please refer to instructions in "IMPORTANT NOTES" section.	PLASTER MODEL PREPARATION Please refer to instructions in "IMPORTANT NOTES" section.	PLASTER MODEL PREPARATION Please refer to instructions in "IMPORTANT NOTES" section.
PLASTER MODEL PREPARATION Please refer to instructions in "IMPORTANT NOTES" section.	PREPARATION OF Prosthetic lock 1. IRS-200-AK only: Remove release button, sleeve nut, catch, and spring using the pin wrench provided.	PREPARATION OF Prosthetic lock 1. IRS-200-AK only: Remove release button, sleeve nut, catch, and spring using the pin wrench provided.	PREPARATION OF Prosthetic lock 1. IRS-200-AK only: Remove release button, sleeve nut, catch, and spring using the pin wrench provided.	PREPARATION OF Prosthetic lock 1. IRS-200-AK only: Remove release button, sleeve nut, catch, and spring using the pin wrench provided.
PREPARATION OF Prosthetic lock	2. Align the four bolt holes using standard European configuration.	2. Attach the modular adapter* to the body of the prosthetic lock using	2. Fill interior of the prosthetic lock body with DC-4 compound.	2. Fill interior of the prosthetic lock body with DC-4 compound.
. IRS-200-AK only: Remove release button, sleeve nut, catch, and spring	3. Attach the modular adapter* to the body of the prosthetic lock using	the six sheet metal screws (IRS-200-AK and IRS-600-AK) or socket head	3. Install the Delrin <sup>®</sup> laminating sleeve.	3. Install the Delrin <sup>®</sup> laminating sleeve.
ng the pin wrench provided. Attach the pyramid adapter* to the body of the prosthetic lock using s ix sheet metal screws (IRS-200-AK and IRS-600-AK) or socket head screws (IRS-600-AKT) provided with adapter, ensuring the adapter and kit are in total contact. Lubricate the four 6mm socket head screws with DC-4 compound and install securely.	screws (IRS-600-AKT) provided with adapter, ensuring the adapter and kit are in total contact. 3. Install the Delrin® laminating sleeve.	4. Position the prosthetic lock on the model so the concavity mates with the tooling and the Delrin <sup>®</sup> laminating sleeve is medially positioned. Secure the prosthetic lock using the 1-3/4" socket head screw provided with tooling. Fill the screw head and the slot in the Delrin <sup>®</sup> laminating	4. Position the prosthetic lock on the model so the concavity mates with the tooling and the Delrin <sup>®</sup> laminating sleeve is medially positioned. Secure the prosthetic lock using the 1-3/4" socket head screw provided with tooling. Fill the screw head and the slot in the Delrin <sup>®</sup> laminating	
body of the prosthetic lock are in total contact. Align flats of pyramid	4. Fill interior of the prosthetic lock body with DC-4 compound.	the tooling and the Delrin <sup>®</sup> laminating sleeve is medially positioned.	sleeve with Klean Klay (not included, reference item #KK-1LB).	sleeve with Klean Klay (not included, reference item #KK-1LB).
AF/ML.	5. Install the Delrin <sup>®</sup> laminating sleeve.	Secure the prosthetic lock using the 1-3/4" socket head screw provided		
I Install the Delrin® laminating closure	6. Position the prosthetic lock on the model so the concavity mates with	sleeve with Klean Klay (not included, reference item #KK-1LB).	LAY-UP AND LAMINATION	LAY-UP AND LAMINATION
A instant the Dennis faminating seeve.	the tooling and the Delrin <sup>®</sup> laminating sleeve is medially positioned.		the distal end of the prosthetic lock.	the distal end of the prosthetic lock.
he tooling and the Delrin <sup>®</sup> laminating sleeve is medially positioned. iecure the prosthetic lock using the 1-3/4" socket head screw provided server with tooling. Fill the screw head and the slot in the Delrin <sup>®</sup> laminating sleeve with Klean Klay (not included, reference item #KK-1LB).	THERMOPLASTIC MOLDING OF SOCKET Either a blister or drape mold method may be used.	<ol><li>Apply the outer PVA bag. Pull the bag down as far as possible to reduce any excess space around the exterior of the prosthetic lock.</li></ol>	<ol><li>Apply the outer PVA bag. Pull the bag down as far as possible to reduce any excess space around the exterior of the prosthetic lock.</li></ol>	
vith tooling. Fill the screw head and the slot in the Delrin® laminating		TDIMMING	3. Proceed with the lamination.	3. Proceed with the lamination.
leeve with Kiean Kiay (not included, reference item #KK-16b).	LAY-UP AND LAMINATION	1. Break out the plaster model and trim the proximal edge of the socket.	4. Before the resin gels, tie a string around the PVA bag distal to the	4. Before the resin gels, tie a string around the PVA bag distal to the
AY-UP AND LAMINATION	tie-off ring provided in the adapter. Ensure the materials cover the distal	2. Using a disc sander, sand away the material covering the distal end	socket head screw securing the prosthetic lock.	socket head screw securing the prosthetic lock.
.Tie-off the appropriate lay-up in the laminating groove on the pyramid	end of the adapter.	of the modular adapter until the four socket head screws are exposed.	TRIMMING	TRIMMING
idapter*.	2. Apply the outer PVA bag. Pull the bag down as far as possible to	Remove the screws.	<ol> <li>Break out plaster model and trim the proximal edge of socket.</li> </ol>	1. Break out plaster model and trim the proximal edge of socket.
Apply the outer PVA bag. Pull the bag down as far as possible to educe any excess space around the exterior of the prosthetic lock.	reduce any excess space around the exterior of the prosthetic lock. 3. Proceed with the lamination.	<ol> <li>Sand away the material covering the end of the Delrin<sup>®</sup> laminating sleeve. Remove the Delrin<sup>®</sup> laminating sleeve.</li> </ol>	<ol> <li>Using a disc sander, sand away the material covering the head of the socket head screw securing the kit.</li> </ol>	<ol> <li>Using a disc sander, sand away the material covering the end of the Delrin<sup>®</sup> laminating sleeve and the head of the socket head screw</li> </ol>
B. Proceed with the lamination.		4. Reinstall the sleeve nut, spring, catch, and release button using the pin wrench provided (IRS-200-AK) or install the cartridge (IRS-600-AK and	3. Remove the socket head screw securing the prosthetic lock. Protect	securing the kit.
I. Before the resin gels, tie a string around the PVA bag at the base of he pyramid. Tie a second string distal to the pyramid.	TRIMMING 1. Break out the plaster model and trim the proximal edge of the socket.	IRS-600-AKT) using the cartridge wrench (not included, reference item #IRS-600-CW). Secure with set screw.	the end of the prosthetic lock with tape.	3. Remove the socket head screw securing the prosthetic lock. Protect the end of the prosthetic lock with tape.
RIMMING Break out the plaster model and trim the proximal edge of the socket.	<ol> <li>Using a disc sander, sand away the material covering the distal end of the modular adapter until the four socket head screws are exposed. Remove the screws</li> </ol>	* Not included with prosthetic lock.	BONDING AND LAMINATING THE SOCKET TO A 4-HOLE WOOD BLOCK	INCORPORATING THE SOCKET INTO AN EXOSKELETAL LIMB
Clean off the excess resin on the pyramid and the dome of the	3. Sand away the material covering the end of the Delrin® laminating		1. Bond the socket to the block with epoxy.	<ol> <li>Set the socket in balsa wood or rigid foam. Shape the limb in the conventional manner</li> </ol>
idapter. DO NOT remove the resin from the screw holes.	sleeve. Remove Delrin® laminating sleeve and any DC-4 compound		2. Trim the wood block to the desired size and shape.	2. Remove the Delrin <sup>®</sup> laminating sleeve and pack the opening with
B. Using a disc sander, sand away the material covering the end of he Delrin <sup>®</sup> laminating sleeve. Remove the Delrin <sup>®</sup> laminating sleeve.	f residue from the body of the prosthetic lock or any of the threaded holes. Clean with Acetone (not included, reference item #DMK-G).		3. Using a disc sander, smooth and sand the block and socket in the conventional manner. Apply tape to prevent resin from filling the four threaded holes	Klean Klay (not included, reference item #KK-1LB). 3. Laminate the socket.
Remove any DC-4 compound residue from the body of the prosthetic ock or any of the threaded holes. Clean with Acetone (not included, eference item #DMK-G). 4. Reinstall the sleeve nut, spring, catch, and release button using the pin wrench provided (IRS-200-AK), or install the cartridge (IRS-600-AK and IRS-600-AKT) using the cartridge wrench (not included, reference item		4. Lav-up and laminate the socket.	4. Trim the limb in the conventional manner.	
	IRS-600-AKT) using the cartridge wrench (not included, reference item		5. Break out the plaster model and trim the proximal edge of the socket	5. Remove any DC-4 compound and Klean Klay residue from the body
I. Reinstall the sleeve nut, spring, catch, and release button using the pin vrench provided (IRS-200-AK), or install the cartridge (IRS-600-AK and	#IRS-600-CW). Secure with set screw. * Not included with prosthetic lock.		as well as the distal end of the block. 6. Sand away the material covering the end of the Delrin® laminating	of the prosthetic lock or any of the threaded holes. Clean with Aceto (not included, reference item #DMK-G).
RS-600-AKT) using the cartridge wrench (not included, reference item IRS-600-CW). Secure with set screw.			sleeve. Remove Delrin <sup>®</sup> laminating sleeve and any DC-4 compound residue from the body of the prosthetic lock or any of the threaded holes. Clean with Acetone (not included, reference item #DMK-G).	6. Reinstall the sleeve nut, spring, catch, and release button using the pin wrench provided (IRS-200-AK), or install the cartridge (IRS-600-AK and IRS-600-AKT) using the cartridge wrench (not included, reference item #IRS-600-CW). Secure with set screw.
Not included with prosthetic lock.				
			7. Reinstall the sleeve nut, spring, catch, and release button using the pin wrench provided (IRS-200-AK), or install the cartridge (IRS-600-AK and	

IRS-600-AKT) using the cartridge wrench (not included, reference item

#IRS-600-CW). Secure with set screw.

\* Not included with prosthetic lock.







RS-650-AK-L **3S-600-AKTP TXA-000-2KT** 3S-600-AK **RS-200-AK** 

Instructions for Use:



# **PROADVANTAGE**<sup>TM</sup>

IRS-200-AK RS-600-AK IRS-600-AKT

**RS-600-AKTP** IRS-650-AK-L

# Intended Use

THERAPEUTIC AND/OR DIAGNOSTIC INDICATIONS AND CLAIMS

The ProAdvantage Locks (IRS-200, IRS-600, IRS-650) are non-sterile prosthetic attachment kits intended to secure a residual limb to a prosthetic assembly.

### CONTRADICTIONS

The ProAdvantage Locks are contraindicated for patients whose weight exceeds the following:

IRS-200-AK	=	Delrin	275lb
IRS-600-AK	=	Delrin	275lb
IRS-600-AKT	=	Aluminum	350lb
IRS-600-AKTP	=	Aluminum w/ Pyramid	300lb
IRS-650-AK-L	=	4-hole Aluminum	275lbs

ProAdvantage Locks are contraindicated for patients who excessive redundant tissue or high-volume residual limbs

### WARNINGS

The ProAdvantage Locks are a low risk (non-sterile and non-invasive) medical device. Use of the ProAdvantage Locks will not lead to death and serious injury.

### PRECAUTIONS

- 1. Ensure the locks are assembled per the User Manual instructions to avoid patient risk and potential injury.
- 2. Avoid exposure to salt water. Salt water and potential rusting can lead to improper function of the device and potential discomfort to the patient.

# **PROADVANTAGE**<sup>TM</sup>

# DISTRIBUTED BY:

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# **PROADVANTAGE**<sup>TM</sup> **IRS-600-AKTP** and **IRS-650-AK-L**

## Important Notes

### **GENERAI**

1. Secure locking pin in suspension sleeve using LOCTITE® (not included, reference item #LT-271). If a liquid thread-locker is not used, advise the patient the pin may become loose with use and provide instructions for tightening the pin using the appropriate wrench.

2. Secure all prosthetic lock screws and release button using LOCTITE® (not included, please reference item number #LT-271)

3. The extended length release button (not included, please reference item #IRS-200/600ELB) may be used.

4. Instruct the patient to rotate the release button using the long end "T" wrench (supplied) and turn clockwise until suspension liner is draw completely into the socket.

5. To reduce wear and lengthen the life expectancy of the prosthet lock, orient the gear of the clutch toward the anterior aspect the socket.

### SPECIFIC TO IRS-650-AK-L

When using alternate attachment screws, ensure OEM or equivale quality and heed minimum (10mm) and maximum (18mm) screw dep penetration. Follow manufacturer's torque specifications.

### **ADVISING THE PATIENT**

Instruct the patient to rotate the release button using the long end of the "T" Wrench (supplied) and turn clockwise until suspension liner is drawn completely into the socket.

# **Plaster Model Preparation**

The plaster model from a cast taken over a suspension liner will have a center protrusion replicating the distal end of the liner. To ensure proper positioning of the tooling on the model, a 1/4" diameter centering hole may be drilled straight down through the protrusion prior to making the following modifications.

## LAMINATION APPLICATIONS

1. Remove enough plaster from the distal end of the model to equal the outer dimension of the Delrin<sup>®</sup> tooling. DO NOT exceed the outer dimension of the tooling as the resulting socket will be too short.

2. Center the tooling on the model and secure with the nails provided. Any discrepancy between the model and the tooling should be filled to create a smooth transition. It may be necessary to sand down nail heads.

3. Apply a PVA cap over the model and tooling OR seal the model using mold sealer made from Cellulose Acetate Crystals (not included. reference item #CAC-1LB) and Acetone (not included, reference item #DMK-G)

4. Draw a PVA bag over the model.

### THERMOPLASTIC APPLICATIONS

Follow Steps 1 and 2 above

3. Thoroughly powder the model with Baby Powder (not included, reference item #BP-100)

CE

# IRS-600-AKTP

Clutch Lock Mechanism with ClickLock™



## **KIT INCLUDES:**

IRS-600-BTP Body	
IRS-200-T Tooling	
IRS-600-API-RPC Pin, 10mm L 2-3/4"	000000000000000000000000000000000000000
IRS-650-W "T" Wrench	
IRS-600-LS Delrin <sup>®</sup> Laminating Sleeve	
IRS-600-LW Hex Wrench	

# IRS-600-AKTP

## For use in lamination applications

Not recommended for patients whose weight exceeds 300lbs

## PLASTER MODEL PREPARATION

Please refer to instructions in "IMPORTANT NOTES" section.

## PREPARATION OF Prosthetic lock

1. Fill interior of the prosthetic lock body with DC-4 compound.

## 2. Install the Delrin® laminating sleeve

3. Position the prosthetic lock on the model so the concavity mates with the tooling and the Derlin® laminating sleeve is medially positioned. Secure the prosthetic lock with the 1-3/4" socket head screw provided with tooling. Fill the screw head and the slot in the Delrin® laminating sleeve with Klean Klay (not included, head cap screws with Klean Klay (not included, reference item #KK-1LB). reference item #KK-1LB).

## LAY-UP AND LAMINATION

1. Tie-off the appropriate lay-up in the laminating grooves on the pyramid adapter and kit body.

2. Apply the outer PVA bag. Pull the bag down as far as possible to reduce any excess space around the exterior of the prosthetic lock

3. Proceed with the lamination.

4. Before the resin gels, tie a string around the PVA bag at the base of the pyramid. Tie a second string distal to the pyramid.

## TRIMMING

1. Break out plaster model and trim the proximal edge of socket.

2. Clean off the excess resin on the pyramid and the dome of the adapter. DO NOT remove the resin from the screw holes.

3. Using a disc sander, sand away the material covering the end of the Delrin® laminating sleeve. Remove Delrin<sup>®</sup> laminating sleeve and any DC-4 compound residue from the body of the prosthetic lock or any of the threaded holes. Clean with Acetone (not included, reference item #DMK-G).

4. Install the cartridge using cartridge wrench (not included, reference item #IRS-600-CW). Secure with set screw

### IRS-650-AK-L Modular Clutch Lock Mechanism with ClickLock<sup>™</sup> Aluminum Body with Stainless Liner for use with Laminated Sockets L 2-7/8"x W 2"x H 3/4" CE Weight 116 grams **KIT INCLUDES:** IRS-650-AK-LR O Laminating Ring IRS-650-B IRS-650-BMS M6 x 35mm Body Mounting Screws (4 IRS-650-MMS M6 x 20mm Modular Mounting Screws (4) **IRS-650-SPACERS** 9 Spacers (4) IRS-650-T Tooling (Includes: tooling screw, nails, and plate) IRS-600-API-RPC Pin, 10mm L 2-3/4 IRS-650-W

# IRS-650-AK-L

"T" Wrench

For use in lamination or thermoplastic\* applications

Not recommended for patients whose weight exceeds 275lbs.

For use in thermoplastic applications, please purchase with IRS-650-TPR\*

## PLASTER MODEL PREPARATION

Please refer to instructions in "IMPORTANT NOTES" section.

## **PREPARATION OF Prosthetic lock**

1. Place the laminating ring on the model so that the concavity mates with the tooling. Orient the laminating ring so that one of the socket head screws is anterior. DO NOT align in the European 4-hole orientation.

2. Lubricate the Delrin® tooling screw and install. Fill the slot in the Delrin® tooling screw and the four socket

### LAY-UP AND LAMINATION

1. Lay-up material over the model in the conventional manner, ensuring the entire laminating ring is covered distally and there is adequate material to cover the socket head cap screws and Delrin® tooling screw. Use the tie-off grooves in the laminating ring to ensure a complete bond.

2. Draw a PVA bag over the model and proceed with lamination.

3. Allow resin to gel.

1. Using a disc sander, sand off material at distal end of socket to create a flat surface. Remove enough material to expose the heads of the four socket head cap screws and the Delrin<sup>®</sup> tooling screw

2. Remove the four socket head cap screws and the Delrin® tooling screw. Remove any DC-4 compound residue from any of the threaded holes. Clean with Acetone (not included, reference item #DMK-G).

3. Install the prosthetic lock using the four body mounting screws and four cylindrical spacers provided with kit (spacers will ensure the socket ring and body of the prosthetic lock are parallel). Evenly torque the screws to 8.85 ft-lb (12 nm)

4. Install socket and prosthetic lock assembly to the remaining prosthetic components. When attaching conventional European 4-hole male or female pyramid components, use the 6mm x 20mm screws provided.

\* Not included with prosthetic lock.