

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 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® Body

L 2-1/2"x W 1-5/8"x H 1-5/8"

Weight 91 grams

KIT INCLUDES:

IRS-200-B Body	
IRS-200-T Tooling	
IRS-200-API Pin, 10mm L 3"	
IRS-200-W Pin Wrench	
IRS-200-LS Delrin® Laminating Sleeve	

IRS-600-AK







Clutch Lock Mechanism
with ClickLock™

Delrin® Body

L 2-7/8"x W 1-3/4"x H 1-5/8"

Weight 105 grams

KIT INCLUDES:

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

IRS-200-AK

IRS-600-AK

IRS-600-AKT

For use with a pyramid adapter* in lamination applications

A single-lamination method offering a lightweight modular design, suitable for moderately active and geriatric patients.

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.

PREPARATION OF Prosthetic lock

1. IRS-200-AK only: Remove release button, sleeve nut, catch, and spring using the pin wrench provided.

2. Attach the pyramid adapter* to the body of the prosthetic lock using the six sheet metal screws (IRS-200-AK and IRS-600-AK) or socket head screws (IRS-600-AKT) provided with adapter, ensuring the adapter and body of the prosthetic lock are in total contact. Align flats of pyramid AP/ML.

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

4. Install the Delrin® laminating sleeve.

5. Position the prosthetic lock on the model so the concavity mates with the tooling and the Delrin® 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® laminating sleeve with Klean Klay (not included, reference item #KK-1LB).

LAY-UP AND LAMINATION

1. Tie-off the appropriate lay-up in the laminating groove on the pyramid adapter*.

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 the plaster model and trim the proximal edge of the 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 the Delrin® laminating sleeve. Remove 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. 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.

IRS-200-AK

IRS-600-AK

IRS-600-AKT

For use with modular adapter* in lamination applications

A single-lamination method offering a heavy-duty modular design, suitable for moderately active and heavier patients.

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.

2. Align the four bolt holes using standard European configuration.

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 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.

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

5. Install the Delrin® laminating sleeve.

6. Position the prosthetic lock on the model so the concavity mates with the tooling and the Delrin® 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® laminating sleeve with Klean Klay (not included, reference item #KK-1LB).

LAY-UP AND LAMINATION

1. Lay-up the selected materials over the model. Be sure to utilize the tie-off ring provided in the adapter. Ensure the materials cover the distal end of the adapter.

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.

TRIMMING

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

2. 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.

3. Sand away the material covering the end of the Delrin® laminating sleeve. Remove Delrin® 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. 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.

IRS-200-AK

IRS-600-AK

IRS-600-AKT

For use with modular adapter* in thermoplastic applications

A single-pull thermoplastic method for test sockets as well as definitive limbs.

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.

2. 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 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® 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® 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.

TRIMMING

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

2. 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.

3. Sand away the material covering the end of the Delrin® laminating sleeve. Remove the Delrin® laminating sleeve.

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

* Not included with prosthetic lock.

IRS-200-AK

IRS-600-AK

IRS-600-AKT

For use with European 4-hole pattern wood block* in lamination applications

A double-lamination method offering the heaviest-duty modular design for patients with congenital deformities and flexion contractures.

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.

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

3. Install the Delrin® laminating sleeve.

4. Position the prosthetic lock on the model so the concavity mates with the tooling and the Delrin® 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® laminating sleeve with Klean Klay (not included, reference item #KK-1LB).

LAY-UP AND LAMINATION

1. Lay-up the selected materials over the model. The lay-up must cover the distal end of the prosthetic lock.

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 distal to the socket head screw securing the prosthetic lock.

TRIMMING

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

2. Using a disc sander, sand away the material covering the head of the socket head screw securing the kit.

3. Remove the socket head screw securing the prosthetic lock. Protect the end of the prosthetic lock with tape.

BONDING AND LAMINATING THE SOCKET TO A 4-HOLE WOOD BLOCK

1. Bond the socket to the block with epoxy.

2. Trim the wood block to the desired size and shape.

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.

4. Lay-up and laminate the socket.

5. Break out the plaster model and trim the proximal edge of the socket as well as the distal end of the block.

6. Sand away the material covering the end of the Delrin® laminating sleeve. Remove Delrin® 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).

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.

IRS-200-AK

IRS-600-AK

IRS-600-AKT

For use with conventional exoskeletal limbs in lamination applications

A double-lamination method for heavier patients and for limbs exposed to extreme conditions.

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.

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

3. Install the Delrin® laminating sleeve.

4. Position the prosthetic lock on the model so the concavity mates with the tooling and the Delrin® 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® laminating sleeve with Klean Klay (not included, reference item #KK-1LB).

LAY-UP AND LAMINATION

1. Lay-up the selected materials over the model. The lay-up must cover the distal end of the prosthetic lock.

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 distal to the socket head screw securing the prosthetic lock.

TRIMMING

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

2. Using a disc sander, sand away the material covering the end of the Delrin® laminating sleeve and the head of the socket head screw securing the kit.

3. Remove the socket head screw securing the prosthetic lock. Protect the end of the prosthetic lock with tape.

IRS-650-AK-L

IRS-600-AKTP

IRS-600-AKT

IRS-600-AK

IRS-200-AK

Instructions for Use:

®

PROADVANTAGE®

IRS-200-AK	IRS-600-AKTP
IRS-600-AK	IRS-650-AK-L
IRS-600-AKT	

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.

CONTRAINDICATIONS The ProAdvantage Locks are contraindicated for patients whose weight exceeds the following:		
IRS-200-AK	= Delrin	275lbs
IRS-600-AK	= Delrin	275lbs
IRS-600-AKT	= Aluminum	350lbs
IRS-600-AKTP	= Aluminum w/ Pyramid	300lbs
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**
- Ensure the locks are assembled per the User Manual instructions to avoid patient risk and potential injury.
 - Avoid exposure to salt water. Salt water and potential rusting can lead to improper function of the device and potential discomfort to the patient.

INSTRUCTIONS FOR SAFE DISPOSAL
This product and its packaging should be disposed of in accordance with respective national and local environmental regulations. Please contact your local governmental office for information on how these items can be disposed of in an environmentally sound manner.

PROADVANTAGE®

DISTRIBUTED BY:

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CE

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PROADVANTAGE®

IRS-600-AKTP and IRS-650-AK-L

Important Notes

- GENERAL**
- 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.
 - Secure all prosthetic lock screws and release button using LOCTITE® (not included, please reference item number #LT-271).
 - The extended length release button (not included, please reference item #IRS-200/600ELB) may be used.
 - Instruct the patient to rotate the release button using the long end of “T” wrench (supplied) and turn clockwise until suspension liner is drawn *completely* into the socket.
 - 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.

SPECIFIC TO IRS-650-AK-L
When using alternate attachment screws, ensure OEM or equivalent quality and heed minimum (10mm) and maximum (18mm) screw depth 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**
- 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.
 - 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.
 - 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).
 - Draw a PVA bag over the model.

THERMOPLASTIC APPLICATIONS
Follow Steps 1 and 2 above.

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

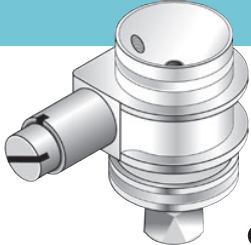
IRS-600-AKTP

Clutch Lock Mechanism with ClickLock™

Aluminum Body with Titanium Liner and factory-attached Titanium Pyramid







L 2-3/4”x W 1-3/4”x H 2-1/2”

Weight 192 grams



CE

KIT INCLUDES:

IRS-600-BTP Body	
IRS-200-T Tooling	
IRS-600-API-RPC Pin, 10mm L 2-3/4”	
IRS-650-W “T” Wrench	
IRS-600-LS Delrin® 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**
- Fill interior of the prosthetic lock body with DC-4 compound.
 - Install the Delrin® laminating sleeve.
 - 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, reference item #KK-1LB).

- LAY-UP AND LAMINATION**
- Tie-off the appropriate lay-up in the laminating grooves on the pyramid adapter and kit body.
 - 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.
 - Proceed with the lamination.
 - 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**
- Break out plaster model and trim the proximal edge of socket.
 - Clean off the excess resin on the pyramid and the dome of the adapter. DO NOT remove the resin from the screw holes.
 - Using a disc sander, sand away the material covering the end of the Delrin® laminating sleeve. Remove Delrin® 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).
 - Install the cartridge using cartridge wrench (not included, reference item #IRS-600-CW). Secure with set screw.

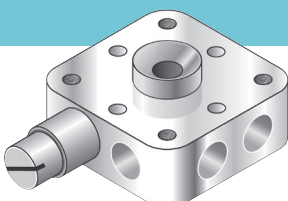
IRS-650-AK-L

Modular Clutch Lock Mechanism with ClickLock™

Aluminum Body with Stainless Liner for use with Laminated Sockets









L 2-7/8”x W 2”x H 3/4”

Weight 116 grams



CE

KIT INCLUDES:

IRS-650-AK-LR Laminating Ring	
IRS-650-B Body	
IRS-650-BMS M6 x 35mm Body Mounting Screws (4)	
IRS-650-MMS M6 x 20mm Modular Mounting Screws (4)	
IRS-650-SPACERS 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 “T” Wrench	

IRS-650-AK-L

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**
- 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.
 - Lubricate the Delrin® tooling screw and install. Fill the slot in the Delrin® tooling screw and the four socket head cap screws with Klean Klay (not included, reference item #KK-1LB).

- LAY-UP AND LAMINATION**
- 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.
 - Draw a PVA bag over the model and proceed with lamination.
 - Allow resin to gel.

- TRIMMING**
- 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® tooling screw.
 - 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).
 - 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).
 - 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.