

Ottobock KISS System

4R160=1 / 4R160=2

Fabrication of a Transfemoral Prosthesis

Technical Information 2.6.5



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Explanation of Symbols

CAUTION	Warnings regarding possible risks of accident or injury.
INFORMATION	Note on processing.

2 Introduction

The KISS® System is a shuttle lanyard system for transfemoral amputees. The Ottobock KISS® System is to be used for prosthetic fitting of amputees in combination with the TF Adapt Liner 6Y80. It has a very low structural height and ensures high security to the patient thanks to its active rotational stability. This technical information describes the processing of the Ottobock KISS® System starting from the preparation of the plaster positive for vacuum form-

ing of the test socket up to the completion and delivery to the patient.

It only contains description of the specific processing steps as the Ottobock KISS® System is independent on the plaster technique.

The plaster cast can be made e.g. using the Ottobock SIT-Cast casting apparatus as described in Technical Information 646T2=3.1GB.

3 General Information

⚠ CAUTION

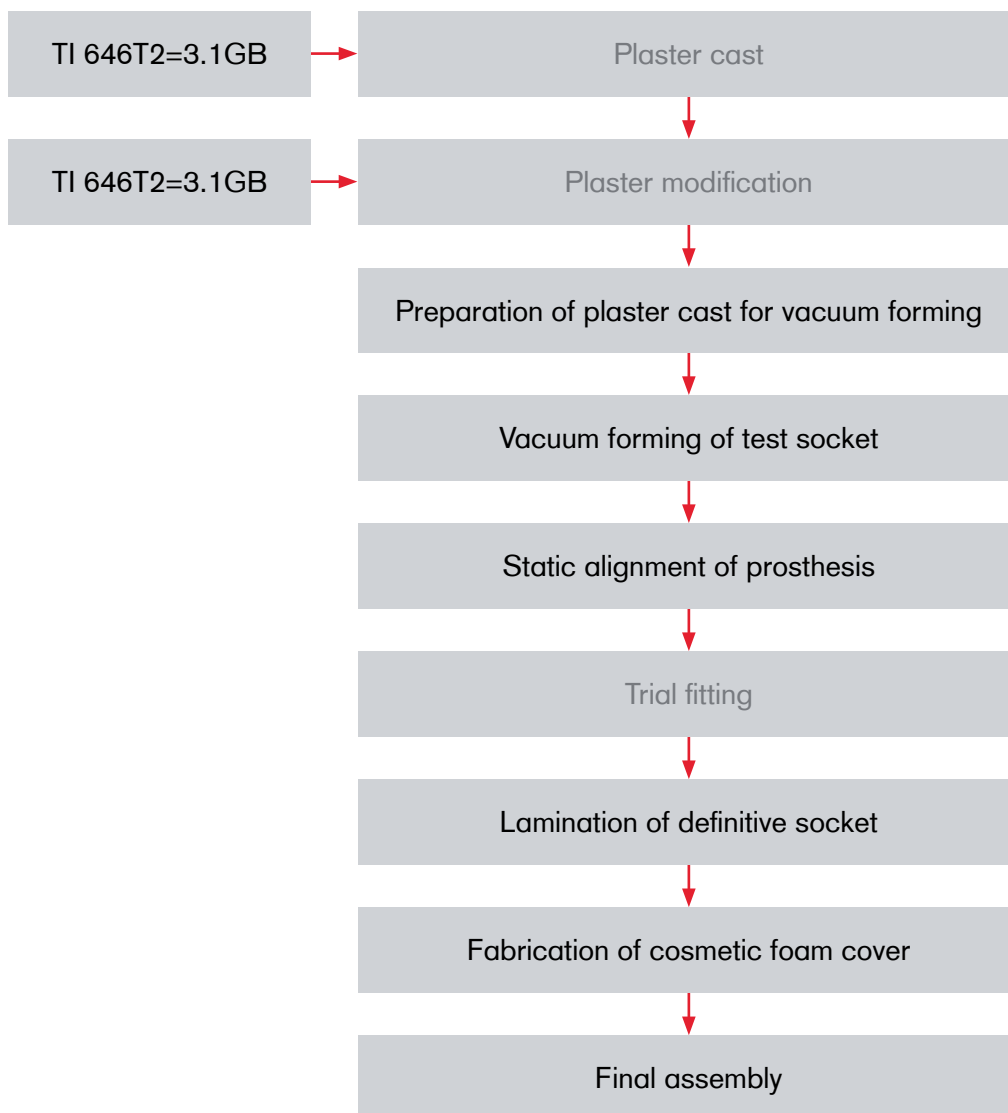
Risk of falling during trial gait with test socket. The test socket may only be used under supervision and responsibility of the prosthetist for the first walking tests at the workshop.

Information for Patients

INFORMATION

Function loss due to contamination. Soiling or clogging hook and loop closure with dust or textile particles can compromise safe fixation of the liner. Therefore, clean hook and loop closure from impurities on regular basis.

4 Fitting Procedure



5 Fabrication Procedure

There are two options for fabricating a test socket:

5.1 Test Socket Fabrication Using TF Design

For more information please refer to TF Design Test Sockets 646D329=GB or Ottobock Service Catalog 646K71=GB.

5.2 Test Socket According to Plaster Cast

Cut off the selected liner. Fabricate the plaster cast over the liner. Use your own preferred plaster cast technique. Modify the fabricated plaster positive.

5.3 Preparing Plaster Cast

5.3.1 Workplace

You will need the following tools and materials for preparing the plaster cast for vacuum forming:



- 754B1 Plaster Mixing Bowl
- 756G1=* Plaster Spatula
- 743E8=300 Flexible Ruler
- 716Y2 or 716Y3 Surform Blade, Fine
- 645C2=* Grease Pen
- 636K6 Plasticine
- 636K8=20 x 2 x 10 Plastaband
- 616F8 Coroplast PVC Adhesive Tape
- 719S4=235 Tailors Scissors
- Cordless Hand Drill with 724S9=6 Twist Drill
- Wet sanding paper, grit 400
- Delrin distal base for the KISS® System incl. metal dummy
- 4R162 Dummy for proximal socket opening

5.3.2 Distal base attachment



First, decide whether to place the KISS® System frontally or laterally.

Draw a line on the positive model frontally or laterally along the residual limb center line. The line should correspond to the run of the KISS® strap later on.



Fill the space along the rounded surface on the concave side of the distal base with 636K6 Plasticine.



Isolate the concave side with 616F8 Coroplast PVC Adhesive Tape.



Cut off excessive adhesive tape brims so they are flush with distal base.



Slide metal dummy into the recess on distal base.



Remove the screw from the metal dummy.



Fill the thread with 636K8 Plastaband.



Drill a 6 mm (1/4") dia. hole, depth approx. 2.5 cm (1") into the plaster model on distal end.



Slightly roughen the plaster model surface around the 6 mm (1/4") dia. hole.



Apply a bit of mixed plaster onto the distal base side provided with Coroplast.



Apply a bit of mixed plaster into the hole and around the hole onto the roughened area of the plaster positive.



Press the distal base onto the plaster positive. Make sure that the strap outlet position is centered in relation to the marked line. Remove the excessive plaster and have the bond hardened.

5.3.3 4R162 KISS® Dummy attachment



Determine the position of the proximal socket opening along the line marked according to section 5.3.2 which points in direction of the strap outlet. It should be located at a maximum of 2.5 cm (1") distally from ischial tuberosity. This opening may never be positioned higher than the lowest point of the liner brim. Screw the 4R162 Dummy on the model on the previously marked position. Make sure that the recessing in the dummy corresponds to the previously marked line.

5.3.4 Result check



Check the prepared plaster model with distal base and 4R162 Dummy in place.

5.4 Vacuum Forming the Test Socket



The following tools and materials are necessary for vacuum forming:

- Oscillating saw
- Vacuum pipe with disk and respective vacuum forming insert
- ThermoLyn rigid 616T52=* or clear 616T83=*
- 641H3 Thermal Gloves
- 99B25 Nylon Stockinette



Vacuum form the test socket with ThermoLyn rigid 616T52=* or clear 616T83=* in usual way.

TIP: Use the assistance of a second person for fixing the vacuum forming material in the area of the metal dummy to ensure sufficient strength of the material.



After cooling down cut open the socket on the proximal marked socket brim. Grind away the metal dummy inserted into the recess and the convexness caused by the 4R162 Dummy.



Screw the previously removed screw into the metal dummy again.



Remove the metal dummy.
Remove the screws from the 4R162 Dummy and the socket from the plaster model.
Trim the socket brim.

Checklist for the completed test socket:

- Removed socket with sanded out socket brim.
- Removed dummies
- KISS® System installed according to section 6.1 Final Assembly
- Remove Plasticine

5.5 Alignment



Bench alignment of the prosthesis in PROS.A.Assembly 743A200. The prosthesis is assembled for example with the 5R1=6 Attachment Block, 3R90 Knee Joint with Friction Brake and 1D35 Dynamic Motion.

For alignment recommendations please refer to the instructions for use of the knee joint.

5.6 Trial Fitting



Secure the socket attachment block for dynamic trial fitting as necessary. Carry out the trial fitting in usual way. For alignment recommendations for the L.A.S.A.R. Posture please refer to the instructions for use of the knee joint.

⚠ CAUTION Risk of falling during trial gait with test socket. The test socket may only be used under supervision and responsibility of the prosthetist for the first walking tests at the workshop.

5.7 Preparation for Lamination

5.7.1 Transferring the alignment result



Once the dynamic trial fitting has been completed, separate the prosthesis directly above the knee joint and clamp the prosthesis into the 743A160 Transfer Apparatus.

Extend the socket with a plaster pad and fill the socket with mixed plaster in usual way. Fix the vacuum pipe in the plaster properly and have the plaster hardened.

5.7.2 Vacuum forming the flexible inner socket for carbon frame socket

The vacuum forming of the flexible inner socket is explained in section 5.4. However, do not grind away the metal dummy for removal. In case you use the 4-hole distal base 4R160=2, cut it free completely.

Workplace description on the example of the 4-hole distal base.

You will need the following tools and materials for preparing the model for lamination (shown on the example of the 4-hole system 4R160=2):



- 636K8=20 × 2 × 10 Plastaband
- 616F8 Coroplast
- 719S4=235 Tailors Scissors
- 641H12 Latex Gloves
- 99B25 Nylon Stockinette
- 99B81 PVA Bags
- 627B40 Polyethylene Adhesive Tape
- 709S15=3 and =4 Allen Wrenches
- 4R161 Lamination Kit (with 4-hole system)
- 616F10=* Double-Sided Adhesive Tape
- 623T9=* Nylglas Stockinette
- 616G2=* Carbon UD Hose
- 616G12=* Carbon Fiber Cloth
- 5Z4 Lamination Kit
- Selected KISS® Kit incl. metal dummy
- Or 4R162 Dummy for proximal socket opening
- 633F11 Silicone Grease

5.8 Lamination

5.8.1 Laminating with the Delrin distal base



Isolate the vacuum formed socket in the area of the distal base with 627B40 PE Adhesive Tape. Fill all undercuts in the distal base and metal dummy areas with light putty. This serves for easy removal of the flexible inner socket from carbon frame.



Laminate the socket according to the patient's weight and functional requirements. Attach the socket adapter to the socket clamped in the transfer apparatus. Sand and laminate the socket adapter in usual way.

After removal of the inner socket, remove light putty from the inner socket.

5.8.2 Laminating with the 4-hole distal base



Attach the 4-hole distal base to the plaster model as described in 5.3.2. Attach the 4R162 Dummy to the model as described in 5.3.3. Pull over 99B25 Nylon Stockinette.



Cover the nylon stockinette on distal base with 627B40 PE Adhesive Tape up to the recess.



Cut the nylon stockinette circularly at the proximal edge of the recess.



Isolate all holes on distal base with 633F11 Silicone Grease.



Isolate the recess on distal base with 633F11 Silicone Grease.



Pull over PVA bag and turn on vacuum pump. Wrap 627B40 PE Adhesive Tape around the distal base so the latter can be easily replaced if need be later on. Cut away the excessive PVA bag and wrap around another layer of the PE adhesive tape.



Pierce the adhesive tape with a sharp point on the four screw holes of the distal base.



Dismantle the 4R161 KISS® Lamination Kit .
Use Allen wrench, size 3 mm for loosening the black screws and Allen wrench, size 4 mm for spacer screws.



Carefully isolate all screws with silicone grease.
Screw the spacer screws fully into the distal base.



Cut away the 627B40 PE Adhesive Tape in the recess area.



Carefully isolate metal dummy with silicone grease and slide the dummy into the recess. Remove the screw. Carefully isolate the thread with silicone grease and protect against resin penetration with 636K8=* Plastaband.



Apply reinforcement according to the patient's weight and functional requirement.



Cut the spacer screws and metal dummy open in every step.



Isolate the lamination disk included in the 4R161 Lamination Kit with silicone spray or silicone grease and fix the disk on spacer screws using screws already covered with silicone grease. Cover the hex socket with 638K8=* Plastaband to prevent from resin penetration. Pull over another PVA bag. Laminate in usual way.



Cut out as necessary after the lamination resin has hardened. Cut open the recess area on the distal base where the metal dummy is embedded, remove Plastaband, screw in the M4 screw and pull the metal dummy out of the distal base. You can facilitate pulling out the dummy by lightly heating the laminate. Grind away the 4R162 Dummy and remove the Philips screws. Dismantle the 4R161 Lamination Kit. Remove the socket from plaster model.

INFORMATION When the distal base must be replaced, slide M6 screws into the hole in the laminate and carefully remove the distal base with a hammer.

6 Final Assembly

6.1 Placing the Placard on the Liner



Attach long strap to the liner and secure with 636K13 Loctite®. For this purpose, an optional M10 screw with 7/32" hex socket and M10 screw with 6-mm hex socket are included. Make sure that the strap is oriented properly. The trimmed liner must be flush with socket brim.



Thread the short strap through proximal pull-in opening.



Cut the strap 1 cm proximally of the distal recessing. Melt together the cutting edge with a cigarette lighter and reinforce the edge with a seam if necessary.



Pull in liner completely. Take care that there is no contact between the hook and loop closure on the reverse side of the placard and the liner.



Pull the long strap through the plastic loop and attach with hook and loop closure.

INFORMATION Insert a double-sided loop strap between both layers of the hook strap if the velcroed surface is too small for enabling a safe attachment.



Press the liner with hand against the placard so that hook and loop closure clings to the liner fabric.



Cut off the strap distally. It is reasonable to make a V-shaped cut. This makes easier for the patient to pull the strap through the plastic loop. Melt together the cutting edge with a cigarette lighter and reinforce the edge with a seam if necessary. Secure the screw in the placard bushing with Loctite.



Checklist:

- Check knee joint adjustment
- Check torques and screw lock (Loctite®).
- Instruct the patient in the Ottobock KISS® System.

6.2 Anti-Fray-Iron-Ons 4X225



If the residual limb socks are worn on the liner for volume adjustments, they must be provided with one distal and one proximal opening. Residual limb socks with distal holes for the use on liners (451F4=* or 451F6=*) are available.

For marking the position of proximal opening, pull the residual limb sock on the liner and mark the placard screw position on the residual limb sock.



Slide a spacer e.g. a piece of wood into the residual limb sock. Place a small piece of foil with the glossy side onto the residual limb sock where the opening is to be stamped.



Place the large piece of foil on the small one with glossy side oriented outwards.



Iron the foil for about 20 seconds at medium to high temperature. Subsequently remove the large foil and store it for later re-use.

INFORMATION Avoid ironing on or near the printed labels to prevent from their damage..



Remove the small foil and stamp a hole into the ironed part.

7 Instructions on the Use

7.1 Donning the System



Turn the trimmed liner inside out and place it on the residual limb end.



Roll the liner on residual limb.



Thread the long strap into the distal base while sitting.



Pull the residual limb into the socket using the long strap. Take care that the proximal short strap comes out of the proximal opening.



Guide the long strap through the plastic loop.



Slightly retighten the strap and secure the hook and loop closure.



If the cosmetic cover is desired, select the cosmetic cover for the knee joint and proceed according to one of the following three options:

- The cosmesis is terminated distally at the opening for the long strap.
- The cosmesis is terminated at the distal third of the socket. Before donning the socket, slide the cosmesis in the direction towards the knee and, after donning the socket, pull the cosmesis upwards again. The KISS[®] system is placed under the cosmetic foam cover.
- The cosmesis is terminated proximally at the opening for the strap. Cut an opening for the long strap into the cosmesis. The KISS[®] system is located on the outside of the cosmetic foam cover.

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Ottobock has a certified Quality Management System in accordance with ISO 13485.