ottobock.

Harmony system

Fabricating a transtibial prosthesis using example of Harmony P3

Technical information 2.1.8

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EN

1 Introduction

This technical information supports you in the fabrication of a prosthesis with the Harmony system, a system used for active generation of a vacuum. The system consists of a vacuum pump, a polyurethane liner, a gel-coated sealing sleeve and a total surface weight-bearing socket.

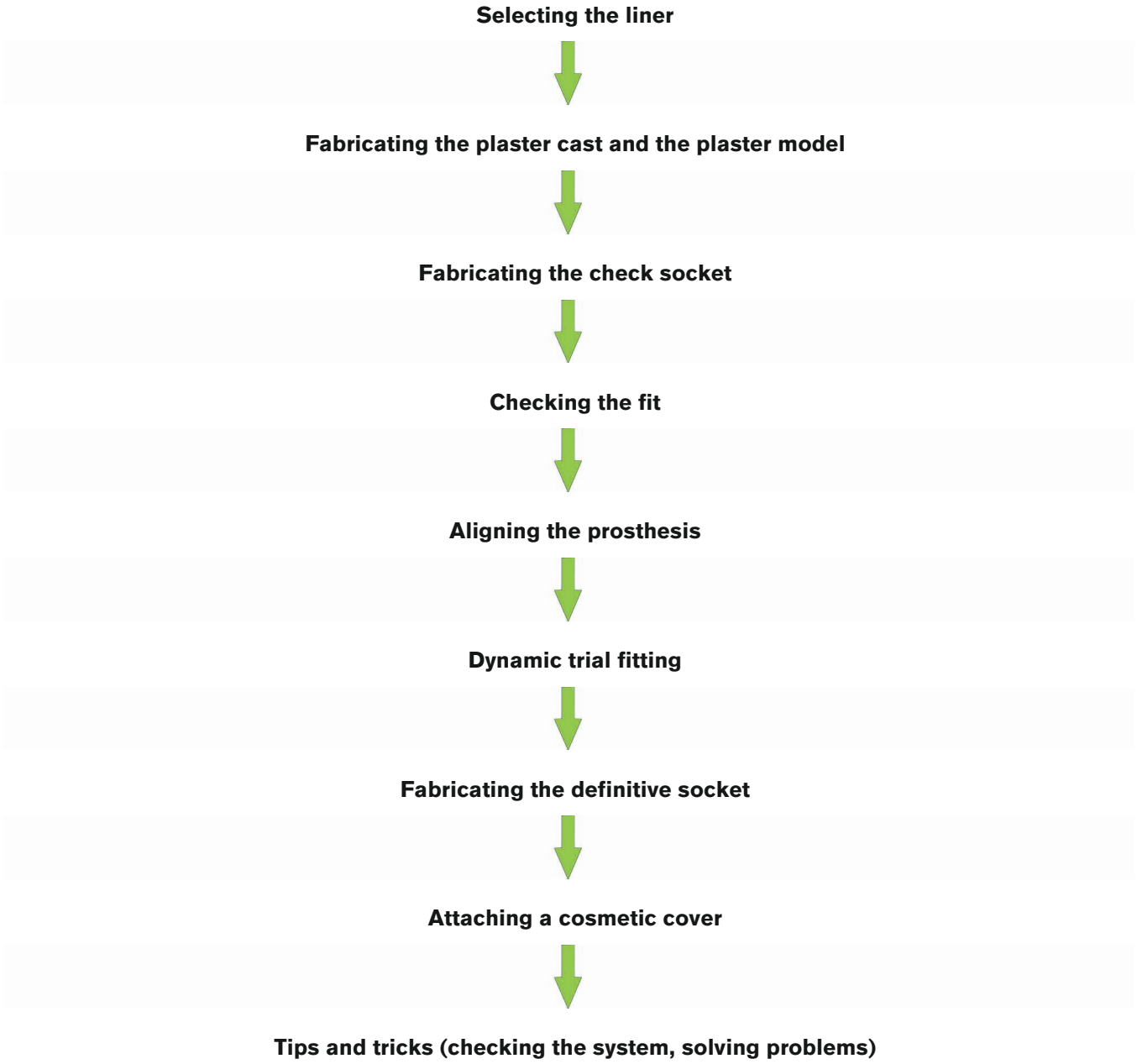
There are both mechanical and electronic Harmony vacuum pumps. In this document, the fitting procedure is explained on the example of a Harmony P3 vacuum pump. The central work steps can be applied to all Harmony vacuum pumps. For detailed information, please read the corresponding instructions for use.

This document is intended for certified Harmony experts. It is a prerequisite that the qualified personnel are trained in the handling of the various materials, machines and tools.

This technical information does not claim to be exhaustive. Reading this technical information does not replace reading the instructions for use for all required products.

1.1 Flowchart

The entire process is shown in the following flowchart. All work steps described in this document are highlighted in bold.



2 Preparation

The following preparations must be made in order to work effectively:

- Collecting the materials and tools
  - Components and auxiliary devices
  - Materials
  - Machines, equipment and accessories
  - Tools
- Preparatory work

2.1 Collecting the materials and tools

The materials and tools used in the photos within this technical information are listed in the tables below. The prosthetist assumes full responsibility for the use of any other materials.

Components and auxiliary devices

Designation	Reference number
Harmony P3	4R147*
Liner	–
Liner FitKit	451F20

Materials

Designation	Reference number
Plastic film	–
String	–
Nylon tube sock	99B25
Plaster bandages	e.g. 699G3=*
ThermoLyn soft	616T53=*
Bonding agent	617H46
Wax	633W8
Polyethylene adhesive tape	627B4
Perlon stockinette	623T3=*
Closed-cell foam	e.g.: 617S70=4
PVA bag	99B81=70X19X5, 99B81=100X19X5
Pastasil	85H11=*
Carbon fibre cloth strap	616B1=*
Carbon UD stockinette	616G2
Carbon fibre woven stockinette	616G15
Orthocryl lamination resin 80:20 PRO	617H119
Loctite® 241	636K13
Lubricating cream	453H1=1
SensiCare lotion	453H26

Tools

Designation	Reference number
Grease pen	–
Waterproof marker	–
Scissors	–
Measuring devices	–
Plaster cast scissors	–
Latex casting bag	683G1=*
Vacuum pump	755Z19=230
Copying pen	645C2=*
Half-round file	716Y3
Round file	716Y4
Grit cloth	649G22=180
Tensioning frame	755T4=360

Designation	Reference number
Vacuum tube (with vacuum sealing disc)	755X104=360
Vacuum pump	755E9
Torque wrench	710D4
Torque wrench (adjustable to 0.5 Nm)	–

3 Procedure

3.1 Selecting the liner

⚠ CAUTION

Use of an incorrect liner

Skin irritation due to vacuum on the skin

► Only use liners without a textile cover or with a partial textile cover for fittings with the Harmony system.

The selection of the liner is critical for the quality of the fitting. Ottobock recommends only using polyurethane liners for Harmony systems. There is a choice between standard liners (off the shelf) and custom liners.

Selecting a standard liner

There are various versions of the standard liners. Liners without pre-flexion are particularly appropriate for cylindrical residual limbs. Liners with pre-flexion have an anatomical shape and are appropriate for short to medium length, slightly conical residual limbs.

Liners without pre-flexion

- Measure the residual limb circumference **4 cm** above the end of the residual limb.
- Select the next smaller liner size.

Example:

Measured circumference: **250 mm**, selection: **235 mm**

Liner with pre-flexion

- Determine the distance between the MPT (mid patella tendon) line and the end of the residual limb.
- Measure the residual limb circumference **4 cm** above the end of the residual limb.
- Select the corresponding length or the next shorter one.

Example:

Measured length: **125 mm**, selection: **125 mm**

Measured length: **135 mm**, selection: **125 mm**

- Circumference measured as for liners without pre-flexion

Ordering a custom liner

Custom liners are custom-produced for the user. This allows them to meet specific requirements and be appropriate for all residual limb shapes.

- Determine the necessary measurements on the patient and fill out the order form for the desired custom liner (see Page 31).
- Take a plaster cast according to the specifications in the order form.

3.2 Plaster cast

INFORMATION

► **Fabricating the plaster cast:** Total surface weight-bearing socket, "Harmony" principle
► **Shaping the plaster model:** Length reduction **5 mm** to **8 mm**; global circumference reduction: **4%**

3.2.1 Preparing the Plaster Cast

Objective

The liner fit is checked to prepare for the plaster cast. Residual limb dimensions can then be measured and critical structures on the residual limb marked to facilitate modelling.

Required tools and materials

- Grease pen, measuring devices, measurement sheet (see appendices), plastic film, 99B25 nylon stockinette

Roll the liner over the residual limb.
Check the fit.
Work out any air bubbles.
Position the residual limb such that the flexion angle is approx. **10°**.
Determine and document the necessary dimensions according to your own company's specifications.

Isolate the liner with plastic film up to 5 cm below the edge without changing the shape of the residual limb. The non-isolated part of the liner supports the connection between the liner and latex casting bag.

Pull a nylon stockinette over the residual limb.

Optional: Add markings to facilitate modelling, for example:

- MPT line
- Patella
- Prominent areas of residual limb
- Femoral condyles
- Distal end of the tibia

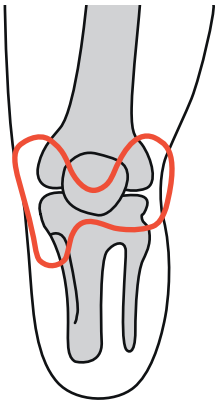
3.2.2 Moulding the femoral condyles and tibial plateau

Objective

In the first phase of plaster casting the femoral condyles and the tibial plateau are moulded with a plaster splint. The lower edge of the patella is also formed. The plaster splint is moulded by vacuum in a latex casting bag. Moulding is carried out at a flexion angle of approx. 85° to enable easy bending of the knee when the prosthesis is being worn.

Required tools and materials

- Plaster bandages, plaster cast scissors, 99B25 nylon stockinette, 683G1=* latex casting bag



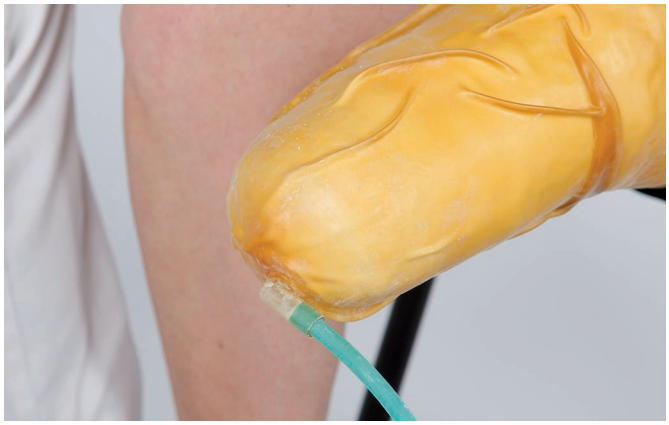
Cut a six-layer plaster splint.

INFORMATION: The plaster splint is part of the plaster cast and remains in the cast.

Place the plaster splint on the residual limb. Place the narrow part between the lower edge of the patella and the tibial tuberosity.

Cut the plaster splint according to the reference points.

Wet the plaster splint and place it on the residual limb.
Pull a nylon stockinette over the residual limb.



Pull a suitable latex casting bag over the plaster cast and seal proximally.
Connect the vacuum hose and position the distal connection of the casting bag on the nylon stockinette.

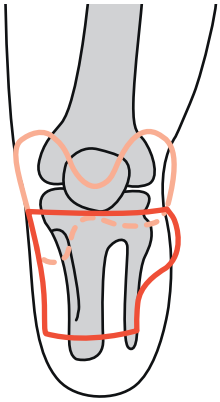
Position the residual limb such that the flexion angle is approx. **85°**.
Switch on the vacuum pump (vacuum: **min. 500 mbar**).
Mould the lower edge of the patella.
Let the plaster cure.
Hold the plaster splint in place and remove the casting bag and the nylon stockinette.

3.2.3 Moulding the tibia and the head of the fibula

Objective
In the second phase of plaster casting the front edge of the tibia and the fibular head are moulded with a plaster splint.

Required tools and materials

- Plaster bandages, plaster cast scissors, 99B25 nylon stockinette, 683G1=* latex casting bag, 755Z19=230 vacuum pump



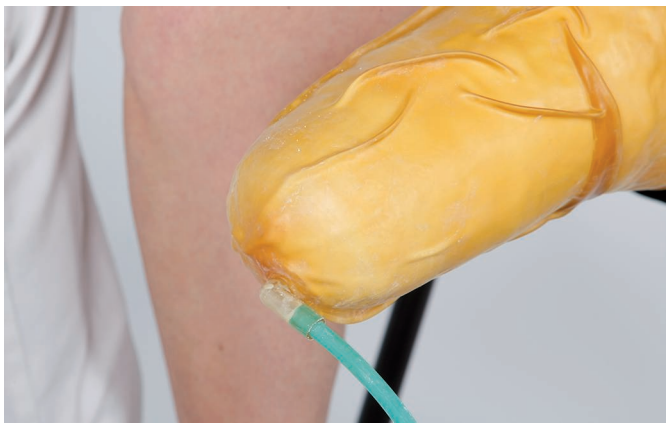
Cut a four-layer plaster splint.

INFORMATION: The plaster splint is part of the plaster cast and remains in the cast.

Place the plaster splint on the residual limb and ensure it is seated correctly. The clearance to the end of the tibia enables correct anterior positioning of the distal soft tissue.

Wet the plaster splint and place it on the residual limb.

Pull a nylon stockinette over the residual limb.



Pull the latex casting bag over the plaster cast and seal proximally.

Connect the vacuum hose and position the distal connection of the casting bag on the nylon stockinette.

Position the residual limb such that the flexion angle is approx. **10°**.

Switch on the vacuum pump (vacuum: **min. 500 mbar**).

Let the plaster cure.

Hold the plaster splint in place and remove the casting bag and the nylon stockinette.

3.2.4 Moulding the volume

Objective

In the third phase of plaster casting the residual limb volume is formed by wrapping with 2 to 3 plaster bandages.

Required tools and materials

- Plaster bandages, plastic film, 2x 99B25 nylon stockinette or 623T3=* Perlon stockinette, 683G1=* latex casting bag, 755Z19=230 vacuum pump

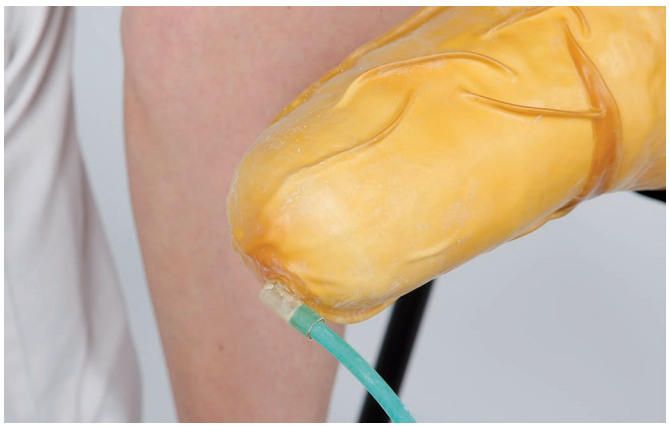
Instruct the patient to tense the residual limb muscles briefly. Check the change in shape of the residual limb.

Position the residual limb such that the flexion angle is approx. **10°**.

Wet the plaster bandages and wrap completely around the residual limb.

Isolate the plaster bandages with plastic film.

Pull two nylon stockinettes or two layers of Perlon stockinette over the plaster cast, allowing a small amount to protrude distally.



Pull a suitable latex casting bag over the plaster cast and seal proximally.

Connect the vacuum hose and position the distal connection of the casting bag on the nylon stockinette or the Perlon stockinette.

Switch on the vacuum pump (vacuum: **min. 500 mbar**).

If the shape of the residual limb changes significantly when the muscles are tensed: instruct the patient to tense and relax the residual limb muscles alternately while the plaster is curing.

Let the plaster cure.

3.3 Fabricating the plaster model

Objective

To fabricate the plaster model, the plaster cast is removed from the residual limb and filled with plaster. The plaster model is then reduced according to the requirements of the prosthetic socket.

INFORMATION

► Keep the shape of the plaster model unchanged during all reduction steps.

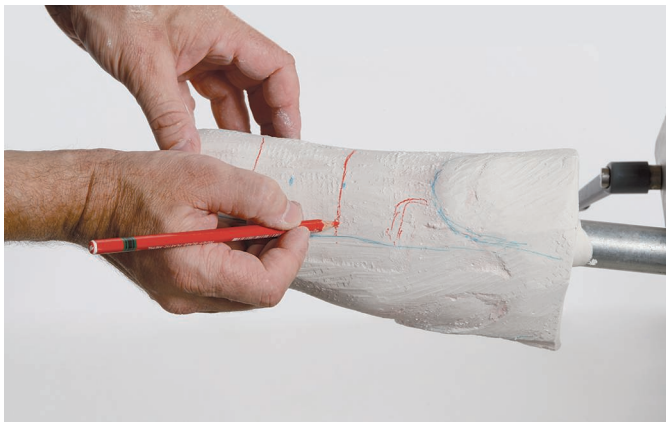
Required tools and materials

- 645C2=* copying pen, tape measure, measurement sheet and reduction table (see appendices), 716Y3 half-round file, 716Y4 round file, 649G22=180 grit cloth

Remove the plaster cast from the residual limb, fill with plaster, insert a reinforcing bar and allow the plaster model to cure.

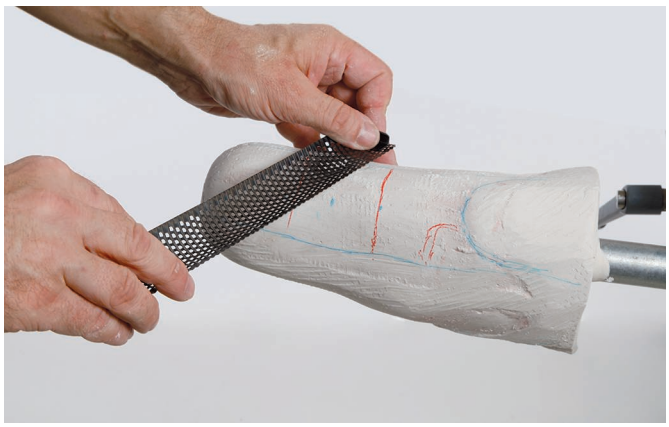
Identify and mark reference points for the circumferential and length measurements on the plaster model.

Determine the circumferential and length dimensions. Record the dimensions on the measurement sheet.



Divide the plaster model into four sections (anterior, posterior, medial and lateral) and mark.

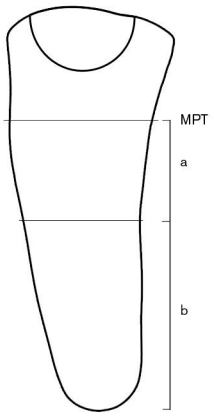
Mark the transitions between convex and concave shapes with horizontal lines.



Reduce the distal end of the model by **5 mm** to **8 mm** without changing the shape.

If there is overhang of soft tissue, more reduction may be necessary.

Reduce the circumference of the plaster model globally by **4%** or dependent on the residual limb shape and the tissue condition.



Reduce the circumference of the plaster model evenly, dependent on the residual limb shape and the tissue condition:

MPT: Reduce by **2%** to **2.5%**

Area a: Reduce by **3%** to **4%**

Area b:

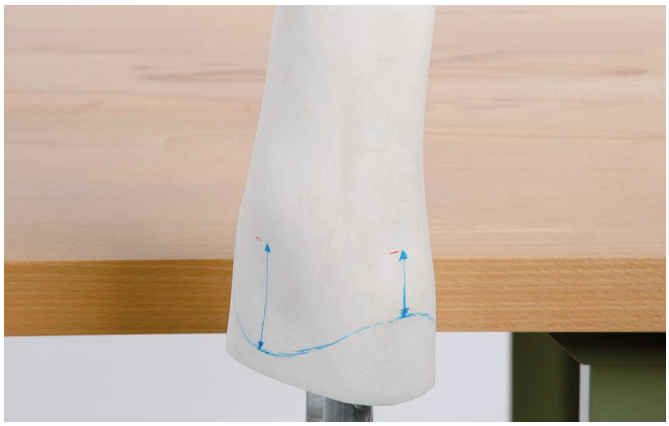
- Reduce globally by **3%** to **5%**

Muscular residual limb with firm soft tissue coverage

- Cylindrical residual limb: **4%**
- Conical residual limb: **5%**

Soft residual limb with easily movable soft tissues

- Cylindrical residual limb: **3%** to **4%**
- Conical residual limb: **4%**



Smooth the plaster model.

Mark the course of the socket brim on the plaster model. Use the MPT line as a reference.

- Anteriorly, the edge is located **2.5 cm (1")** proximal to the reference line
- Medially and laterally, the edge is located **6 cm (2.5")** proximal to the reference line

Create two recesses for the hamstrings in the posterior socket brim.

- Mark a point **5 mm (¼")** distal to the reference line for each hamstring.
- Between the points, the socket brim is located **5 mm (¼")** proximal to the reference line.

3.4 Fabricating the test socket

Objective

To ensure a good fit, a transparent ThermoLyn check socket is made. It allows the fit to be evaluated, since the colour of the skin and the flow properties of the liner are visible.

Required tools and materials

- 755T4=360 outer ring, 755X104=360 vacuum tube (with vacuum sealing ring), 755E9 vacuum pump, 99B25 nylon stockinette, ThermoLyn rigid 616T52=* or ThermoLyn clear 616T83=*

Pull a nylon stockinette over the model.

Complete the vacuum forming process with ThermoLyn rigid or ThermoLyn clear.

Transfer the course of the socket brim to the prosthetic socket.

Once the material has cooled, cut the prosthetic socket along the course of the socket brim.

Drill a **7.5 mm** hole in the position where the socket connector should be attached.

Remove the prosthetic socket from the plaster model.

Deburr the inside and outside of the hole.

Grind and smooth the socket brim of the prosthetic socket.

3.5 Checking the fit

3.5.1 Checking the volume

Objective

The fit of the prosthetic socket can be seen from the colour of the skin and the flow properties of the liner.

Required tools and materials

- 743A11 plaster device, 451F20 liner FitKit, 616S132 sticky spots, 453H1=1 lubricating cream or 453H26 SensiCare lotion, waterproof marker, check socket, liner

Mark at least three points on each side of the liner (anterior, posterior, medial, and lateral):

- **Vertical:** Align the points on an imaginary line and mark them at identical intervals.
- **Horizontal:** Mark the points at the same height on all sides of the liner.

Insert the liner into the prosthetic socket. The distal hole of the prosthetic socket allows air to escape.

Mark circles encompassing the points on the liner from outside.

Don the liner.

Apply the lubricating cream to the outside of the liner. This allows the liner to move in the prosthetic socket.

Don the prosthetic socket.

Ask the patient to stand on the plaster device and distribute the load equally between the prosthetic socket and the contralateral side.

Check the fit of the prosthetic socket as described in the following steps. Correct any deviations.

- If the compression is insufficient, the liner FitKit can be used to compensate for the deviations.
- If the compression is excessive, the thermoplastic check socket can be heated with a hot air blower and adapted.

The flow properties of the liner and thus the good fit of the prosthetic socket are verified by comparing the position of points on the liner with the circles on the prosthetic socket.

The points on the liner must move in a proximal direction.

- **Horizontal (from the point of view of the individual rows):** The flow properties of the points on the liner must be identical.
- **Vertical (looking at the points in the individual columns):** The distance between the points and the associated circles must increase from the distal to the proximal direction.

TIP: Insufficient compression can also be seen from extended skin redness.

The flow properties of the liner and the fit of the prosthetic socket are correct.

If all of the points of the liner are located within the circles, the liner is not compressed sufficiently.

Put on a residual limb sock from the liner FitKit to increase the compression.

TIP: If the residual limb sock hides the points on the liner, wear the residual limb sock under the liner. Only use this procedure while checking the volume. Then only wear the residual limb sock over the liner.

The liner flow properties are correct in the proximal area. The compression is insufficient in the distal and medial area.

Put on a half residual limb sock from the liner FitKit to increase the compression in the area.

The liner flow properties are correct in the proximal and medial areas. The compression is insufficient in the distal area.

Position a 616S134=* spot from the liner FitKit in the distal area of the prosthetic socket to increase the compression.

Insufficient compression in the lateral area of the prosthetic socket can be compensated with the 616S132=* sticky spots.

3.5.2 Checking the course of the socket brim

Objective

The course of the socket brim is critical for a comfortable seating of the prosthetic socket and sealing sleeve. The socket brim must not be seated to tightly; this can often be evaluated in the a – p direction.

Required tools and materials

- 743A11 plaster device, 743L20=230 L.A.S.A.R.-Line, waterproof marker, check socket, liner

Ask the patient to sit down. Position the residual limb in 90° flexion. The distal contact of the residual limb has to be ensured in the prosthetic socket.

Mark the course of the socket brim:

- There must be sufficient room for the femoral condyles during flexion. The medial and lateral socket brim must not extend over the flexed knee joint so as not to damage the sealing sleeve.
- Leave a distance of about the width of a finger between the thigh and the socket brim in the hollow of the knee.
- Allow the medial and lateral socket brim to fall steeply in the posterior direction in order not to limit the knee flexion and avoid the formation of bulges in the hollow of the knee.

Process the socket brim according to the markings.

Two lines each are marked medially and laterally on the liner. These lines make it possible to check the volume even if the prosthetic socket is opaque.

The prosthetic socket is not worn:

- Insert the liner into the socket. Mark one line on the liner both medially and laterally on the course of the socket brim.

The patient stands on the plaster device. Equal load is placed on the prosthetic socket and contralateral side:

- Mark one line on the liner both medially and laterally on the course of the socket brim.
- Mark the plumb line on the prosthetic socket from the frontal and lateral direction with the L.A.S.A.R.-Line.

3.6 Aligning the prosthesis

Objective

Carry out the alignment of the prosthesis according to the instructions for use of the prosthesis components used.

The alignment recommendation (TT modular leg prostheses: **646F336***) can be requested from Ottobock as needed.

Optional: Use the 4R1 sliding adapter to determine the alignment positions.

Use the L.A.S.A.R. Posture for static alignment of the prosthesis, if available.

3.6.1 Attaching the socket connector

Attach the 2R117=0 socket connector according to the instructions for use.

TIP: If no PUR adhesive is available, two-component epoxy adhesive can also be used.

3.6.2 Optional: Transferring the adapter position

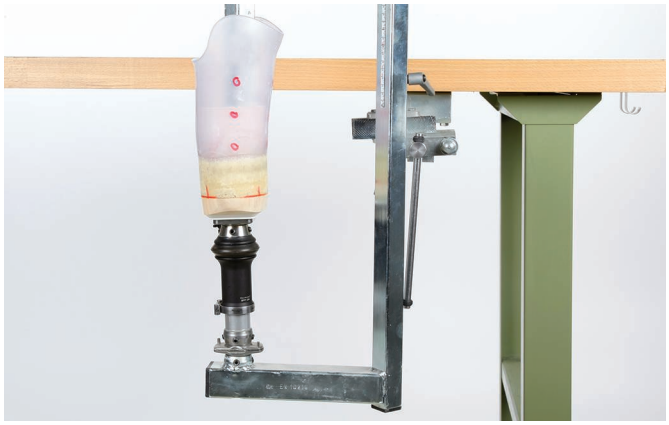
Objective

If the static alignment was performed without the Harmony P3 unit, the transfer device can be used to transfer the adapter position to the Harmony P3 unit.

Required tools and materials

- 743A160 transfer device

Determine the adapter position.



Transfer the adapter position to the Harmony P3 unit.

3.6.3 Selecting the functional ring

Objective

To adjust the Harmony P3 unit to the user, various functional rings can be selected. The hardness of the functional ring affects the vacuum generation and the heel strike with the prosthesis.

Required tools and materials

- Harmony P3 unit, functional rings, 4X247 pre-compression device

Ottobock recommends that vacuum of approx. **500 mbar** (**15 inHg**) should be reached after 50 steps with the prosthesis.

Select the appropriate functional ring from the following table.

If the recommended functional ring does not meet the requirements, select a different functional ring:

- If the user feels like he or she is sinking into the prosthesis, the functional ring is too soft.
- If the vacuum generated is insufficient, the functional ring is too hard.

Functional ring reference no.	Body weight	
	[kg]	[lbs]
4X147=0	40 to 47	88 to 103
4X147=1	48 to 55	104 to 121
4X147=2	56 to 65	122 to 143
4X147=3	66 to 75	144 to 165
4X147=4	76 to 87	166 to 192
4X147=5	88 to 100	193 to 220
4X147=6	101 to 112	221 to 247
4X147=7	113 to 125	248 to 276

New functional rings are very stiff. Ottobock recommends pre-compression to ensure that they work correctly.

No pre-compression is necessary with the pre-installed functional ring and with compressed units.

Open the pre-compression device and insert the functional ring.

Tighten the screw of the pre-compression device up to the stop in order to compress the functional ring completely.

Compress the functional ring from at least **3 minutes** to at most **15 minutes**.

Open the pre-compression device and remove the functional ring.

3.6.4 Replacing the functional ring

Objective

Loosen the tube clamp of the Harmony P3 unit. Remove the tube adapter with the prosthetic foot.

Unscrew the retaining screw (1) on the distal end of the Harmony P3 unit.

Pull the base (2) down distally.

Remove the current functional ring.

Put the new, pre-compressed functional ring on. The structure of the functional ring only allows attachment in the correct alignment.

Put the base on.

Secure the retaining screw with Loctite® 241 (636K13) and screw it in (tightening torque: **7 Nm)**.

Reattach the tube adapter with the prosthetic foot.

3.7 Dynamic trial fitting

INFORMATION

Using the check prosthesis

The user should only use the check prosthesis under the supervision of an orthopaedic technician.

On the basis of his or her professional experience, the orthopaedic technician can decide whether the user can take the check prosthesis home for an extended trial fitting.

3.7.1 Preparation

Secure the connection between the check socket and components of the modular system with a stiff bandage (e.g. Cellacast Xtra 699G30).

3.7.2 Testing the vacuum system

Required tools and materials

- 755Z37 manometer, air-tight adhesive tape,

Connect the manometer to a T-piece.

Seal the hole on the inside of the prosthetic socket with a piece of paper and air-tight adhesive tape.

Generate vacuum and verify that it is maintained.

If the vacuum is not maintained, check the system with the help of the troubleshooting table (see Page 24).

3.7.3 Trial fitting

Donning the prosthesis

1) Don the liner onto the residual limb.
2) **For liners without textile cover:** Pull a residual limb sock on.
3) Put on the prosthesis.
4) Pull the residual limb sock or the protruding textile material over the socket brim.
5) Pull the sealing sleeve over.

Dynamic trial fitting

► Perform the trial fitting, verifying the following:

- Seal between socket adapter and prosthetic socket.
- Screw lock and tightening torques.
- Prosthesis fitting with the L.A.S.A.R. Posture, if possible.

Instructing the user

► Instruct the user on the use of the prosthesis. The following are especially important:

- Check the fit of the prosthetic socket every morning on the basis of the mediolateral lines on the liner.
- Feel the vacuum.
- Use the 451F20 liner FitKit.

3.8 Fabricating the definitive socket

Objective

The following section describes the fabrication of the definitive prosthetic socket. The fitting of the check prosthesis is transferred for the definitive prosthesis. A sleeve protector can be laminated if necessary.

3.8.1 Transferring the adapter position

Objective

The transfer device is used to transfer the adapter position from the check prosthesis to the definitive prosthesis. The check socket is then filled with plaster and adapted to the plaster model.

Required tools and materials

- 743A160 transfer device, oscillating saw, tape measure, 716Y3 half-round file, 716Y4 round file, 649G22=180 grit cloth

Remove all parts used for the check socket of the liner FitKit.

INFORMATION: If more than three parts from the liner FitKit were used for the check socket, a new check socket should be made.

Transfer the adapter position of the check prosthesis to the transfer device.

Fill the check socket with plaster to secure the vacuum pipe.

Remove the plaster model from the check socket.

Prepare the plaster model for the lamination process.

Reduce the plaster model according to the parts of the liner FitKit used:

- **Thick residual limb sock:** Reduce the circumference by **5 mm**
- **Spot:** Reduce the plaster model locally by **2 mm**

3.8.2 Vacuum forming

Objective

A layer of ThermoLyn PETG is vacuum formed over the plaster model as the inner wall of the prosthetic socket. The ThermoLyn PETG reduces the risk of leaks in the prosthetic socket.

Required tools and materials

- 616T483=3 ThermoLyn PETG

Complete the vacuum forming process with ThermoLyn PETG.

Cut off material protruding over the model with a knife.

TIP: Further information on vacuum forming with PETG can be found in the 646T4=1.0 technical information.

Roughen the plastic with sandpaper and clean with isopropyl alcohol.

NOTE: Do not use acetone or thinners. These substances damage the plastic.

3.8.3 Laminating

Objective

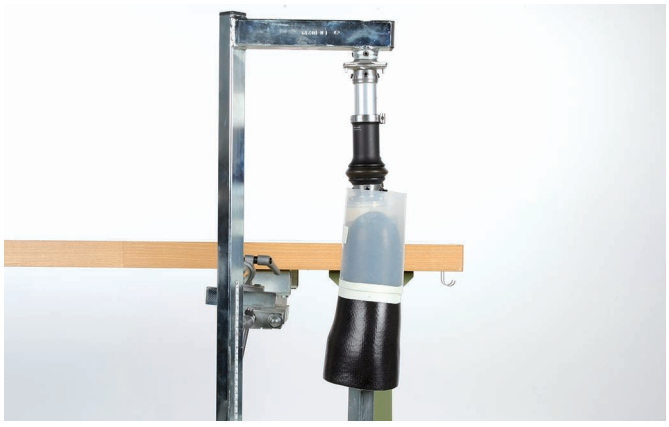
The ThermoLyn PETG layer is laminated with carbon.

Required tools and materials

- 616T483=3 ThermoLyn PETG

Carry out the first lamination process.

Clamp the plaster model with the laminate into the transfer device.



Establish the connection between the prosthetic socket and the prosthesis components (e.g. with a sealing resin/talcum mixture or hard foam)

Carry out the second lamination process.

If a sleeve protector is to be produced: Produce the sleeve protector before cutting the prosthetic socket (see Page 22).

Cut the course of the socket brim.

Attach the 2R117=0 socket connector according to the instructions for use.

TIP: If no PUR adhesive is available, two-component epoxy adhesive can also be used.

Check the system for leaks (see Page 19).

Instruct the user in the proper and safe use of the product.

3.8.3.1 Optional: Producing a sleeve protector

Ottobock recommends using a sleeve protector which protects the sealing sleeve from punctures and creates a cosmetically attractive closure. It does not protect against friction between the sealing sleeve and socket brim.

Required tools and materials:

- Laminated prosthetic socket, hook-and-loop pads, 623T1* cotton stockinette, 623T3* Perlon stockinette, 623T9* Nylglas stockinette, 616B17* carbon fibre cloth, 99B81* PVA bag, 627B40 polyethylene adhesive tape, 80:20 PRO 617H119 Orthocryl lamination resin

Pull a damaged or worn sealing sleeve over the prosthetic socket. The end of the sealing sleeve should extend **5 cm (2")** past the socket brim in the distal direction.

Place the hook-and-loop pads medially and laterally on the distal area of the prosthetic socket.

Pull four layers of cotton stockinette over the prosthetic socket.

Pull over one PVA bag.

Pull over one layer of Nylglas stockinette.

Position one layer of carbon fibre cloth

Pull on two layers of Perlon stockinette

Perform the lamination process with Orthocryl.

Cut the sleeve protector off flush with the prosthetic socket.

Take the sleeve protector off the prosthetic socket.

Cut the course of the edge of the sleeve protector:

- Medial, lateral: **0.5 cm** to **1 cm (¼" to ½")** above the socket brim
- Posterior: **0.5 cm (¼")** below the socket brim

Smooth the edges carefully.

3.9 Optional: Attaching a cosmetic cover

Objective

A foam cover can be used as a cosmetic cover. Correct attachment ensures the function of the Harmony P3 unit.

Required tools and materials:

- Foam cover with 34 mm opening, silicone spray, Superskin or 99B116* SoftTouch sock

Cut the foam cover so it is not crushed.

Grind the contour of the foam cover.

INFORMATION: Use silicone spray to eliminate noises. Talcum impairs the function of the vacuum pump. Pull the foam cover over the prosthesis and perform the fitting.

Do not bond the foam cover to the prosthetic foot.

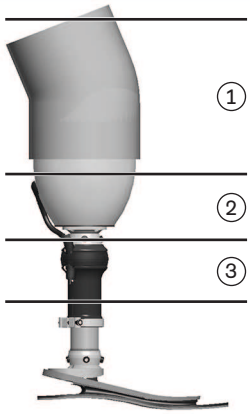
Position the discharge flange (Ottobock recommends a medial position at ankle height) and bond it to the foam cover.

Form the closure with Superskin or a SoftTouch sock.

4 Tips and tricks

4.1 Checking the system

This section gives a methodical troubleshooting procedure for when the vacuum system leaks.

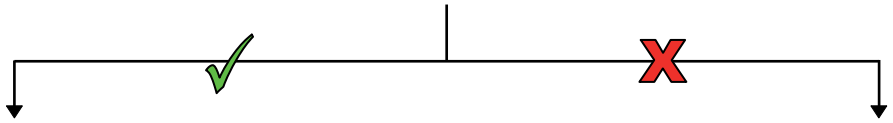


To check the system for leaks, the prosthesis is divided into areas.

- **Area 1:** Prosthetic socket and sealing sleeve
- **Area 2:** Socket connector and connection to the vacuum pump
- **Area 3:** Vacuum pump (valves or functional ring)

Seal the outlet opening on the inside of the prosthetic socket with a small piece of paper and air-tight adhesive tape (e.g. PVC tape).

- Activate the vacuum pump until vacuum of **500 hPa** to **850 hPa** is reached.
- Check whether the vacuum is maintained.

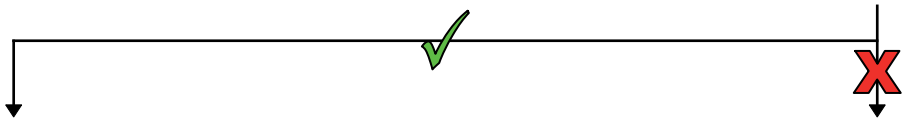


The fault is in area 1.

- Check the prosthetic socket and sealing sleeve for leaks and fix the fault.

The fault is in area 2 or 3.

- Connect the manometer directly to the suction connection of the vacuum pump.
- Activate the vacuum pump until vacuum of **500 hPa** to **850 hPa** is reached.
- Check whether the vacuum is maintained.

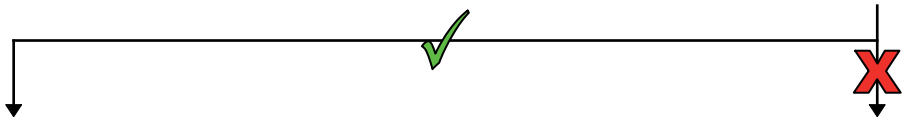


The fault is in area 2.

- Place the manometer with a T-piece between the socket connector and the vacuum pump.
- Seal the hole on the inside of the prosthetic socket with a piece of air-tight adhesive tape. This is how the hose connection and the socket connection are checked.
- Activate the vacuum pump until vacuum of **500 hPa** to **850 hPa** is reached.
- Check whether the vacuum is maintained.
- If the vacuum is maintained, reseal the socket connector with adhesive. Then recheck the system.

The fault is in area 3.

- Replace the valves of the vacuum pump.
- Check again whether the vacuum is maintained.



The fault has been fixed.

The functional ring is defective.

- Replace the functional ring.

4.2 Solutions to problems

Topic: Knee		
Problem	**Cause**	**Solution**
Knee flexion difficult or bulging in the hollow of the knee	**Medial and lateral socket brim runs too far in the posterior direction.** This squeezes the liner and the extremity.	• Cut socket brim so it no longer runs so far in the posterior direction.
	Prosthetic socket too tight in a–p direction.	• Extend a thermoplastic check socket accordingly. • Reduce the plaster model in the transition between the **MPT level** and **area a** less.
	Posterior socket brim too low. Bulging because the socket brim is too low. **Posterior socket brim too high.** The socket brim hits the hollow of the knee during flexion.	• Leave the posterior (w-shaped) socket brim as high as possible without impeding the knee flexion. Cut out the socket brim that one finger fits in between during 90° flexion with the flexor tendons tensed.
	User wears too many long residual limb socks.	• If the user must wear more than one long residual limb sock to compensate for the volume loss, a new prosthetic socket should be made.
	Relief areas are not aligned with the knee flexor tendons.	• Palpate the tensed knee flexor tendons and adapt the shape of the recesses in the socket brim. The tendons should be located in the lower area of the recesses.
	Sealing sleeve too small.	• Select a larger sealing sleeve. The sealing sleeve must enclose the proximal area of the prosthetic socket and the liner tightly without impeding knee flexion.
	Plaster cast was produced with 2-phase technique. The condyles do not have enough space during knee flexion.	• Make a new plaster cast according to the instructions of this document.
	Anterior socket edge too high. This limits the stretching of the sealing sleeve.	• Form the socket brim to a height where at most the distal third of the patella is covered.

Topic: Residual limb		
Problem	**Cause**	**Solution**
Red marks on skin	**Loss of vacuum.** Without vacuum, pistoning occurs in the prosthetic socket, causing skin irritation.	• Ensure that the vacuum is generated and maintained. Without vacuum, the user loses residual limb volume every day. • Instruct the user how to check whether there is vacuum. Instruct the user how to reestablish vacuum.
	Specific weight bearing socket. High area-specific compressive loads due to the socket shape.	• Make a new prosthetic socket according to the instructions of this document.
	Residual limb is pulled into an area of the prosthetic socket without load.	• The prosthetic socket must have contact across the entire surface. No relief should be incorporated. • If possible, compensate for a volume loss with a distal spot/half residual limb sock. Use of long sock can cause the limb to hang proximally and create a distal void.
	The limb shifts in the liner.	• See table section "Shifting in the liner".

Topic: Residual limb		
Problem	**Cause**	**Solution**
Red welt on the skin at top of the liner	**User wears liner with textile cover.** The textile cover prevents the seal between the liner and sealing sleeve. This causes the vacuum to extend up to the thigh, forming welts on the skin.	• Only use liners without textile or with partial textile cover.
	Residual limb sock reaches at least to the upper edge of the liner. This has the same effect as wearing a liner with a textile cover.	• Instruct the user to pull the residual limb sock up to only about **5 cm** below the edge of the liner. This allows the seal between the liner and sealing sleeve.
Blisters on the skin	**Liner not put on correctly.** The air between the liner and the residual limb was not removed when it was put on. This is the most frequent cause of blisters. **Liner or sealing sleeve is too loose on the thigh.** Air gets under the liner.	• Explain to the user how to properly remove all air from the liner when putting it on. • **When using a PU standard liner:** Ensure that the liner is seated correctly along the entire residual limb and the thigh. • Use a PU custom liner to ensure a correct fit.
Skin in distal region white and thickened	**Insufficient end contact of the residual limb in the prosthetic socket.** This generates pressure that is too low in the distal region.	• Compensate for the lack of residual limb contact with one or more distal spots or a half residual limb sock. • If the skin has thinned again after a few weeks and returned to a normal colour: Check whether a new prosthetic socket needs to be made.
Pressure in the distal region	**Volume loss in the distal region.** The volume loss creates an area without load. The vacuum pulls the liner and the residual limb into a gap and creates a feeling of pressure in the user. This feeling is frequently misinterpreted as contact in the prosthetic socket.	• If the medial and lateral markings on the liner have slipped into the prosthetic socket, the residual limb has lost volume. • Ensure that the vacuum is generated and maintained. Without vacuum, the user loses residual limb volume every day. • **If there is vacuum:** Compensate for the volume loss with a distal spot/half residual limb sock until the marks on the liner are located at the height of the socket brim again. • **If the distal fillers increase the feeling of pressure:** The residual limb has probably lost overall volume; see next table row.
	Volume loss on the entire residual limb. The volume loss has caused the residual limb to slip deeper into the socket, and the end of the residual limb now bears the majority of the body weight.	• Remove the distal fillers again. • Pull a long residual limb sock under the thin residual limb sock. • **If the markings on the liner become visible and the pressure abates:** Put on another distal spot/half residual limb sock to prevent the long residual limb sock from hanging and creating an area without load. • If more than three fillers are used, a new prosthetic socket should be made.
Pressure in the proximal area	**Volume loss in the distal region.** The volume loss creates an area without load. The residual limb hangs proximally in the prosthetic socket, which causes the	• Ensure that the vacuum is generated and maintained. Without vacuum, the user loses residual limb volume every day. • **If there is vacuum:** Compensate for the volume loss with a distal spot/half residual limb sock before putting on the thin residual limb sock.

Topic: Residual limb		
Problem	**Cause**	**Solution**
Pressure in the proximal area	pressure in the proximal area. The vacuum pulls the liner and the residual limb into a gap distally and also creates the feeling of pressure. The proximal pressure is usually the dominant sensation.	
	User wears too many long residual limb socks. The residual limb hangs proximally in the prosthetic socket due to the increased volume.	• Remove all fillers. • Compensate for the volume loss with distal spots and half residual limb socks until the markings on the liner become visible and the pressure abates. • **If the distal fillers do not produce a perfect, comfortable fit:** Pull a long residual limb sock over the liner and compensate again with distal spots and half residual limb socks. • If more than three fillers are used, a new prosthetic socket should be made.
	Prosthetic socket too tight.	• Make a new prosthetic socket according to the instructions of this document.
Pressure on the head of the fibula	**Area around the head of the fibula moulded incorrectly.** Either too much reduction or incorrect moulding occurred. This applies especially to the area of the head of the fibula, because the nerve behind it can be irritated.	• Modify the check socket in the area of the head of the fibula thermoplastically. • **Alternatively:** Make a new plaster cast.
	Volume loss on the residual limb. The residual limb has lost volume and slipped deeper into the prosthetic socket. This causes the head of the fibula to press against the lower edge of the recesses in the prosthetic socket.	• If the medial and lateral markings on the liner have slipped into the prosthetic socket, the residual limb has lost volume. • Ensure that the vacuum is generated and maintained. Without vacuum, the user loses residual limb volume every day. • **If there is vacuum:** Compensate for the volume loss with a distal spot/half residual limb sock until the marks on the liner are located at the height of the socket brim again. • Try pulling a long residual limb sock over the liner. It may be necessary to remove distal fillers.
Cramping/aching/throbbing while standing or sitting	**Prosthetic socket too tight overall.**	• Make a new prosthetic socket according to the instructions of this document.
	User wears too many long residual limb socks.	• Remove all long residual limb socks. • Compensate for the volume loss with distal spots/half residual limb socks until the markings on the liner become visible. • **If the distal fillers cause pressure in the distal area:** Try pulling a long residual limb sock over the liner. It may be necessary to remove distal fillers.
	User did not tense the calf musculature during moulding of the volume.	• Enclose the user's residual limb with both hands and ask him or her to tense his or her calf musculature. **If this significantly changes the residual limb shape:** Make a new prosthetic socket according to the instructions of this document.

Topic: Residual limb		
Problem	**Cause**	**Solution**
Cramping/aching/throbbing while standing or sitting	**Inadequate blood flow to the residual limb.**	• Go through the "Pressure in the proximal area" section of this table to rule out squeezing in the proximal area. • If the prosthetic socket has the correct fit: Consult the attending physician to rule out ischaemia, for example.

Topic: Liner		
Problem	**Cause**	**Solution**
Liner tears	**Incorrect prosthetic socket (specific weight bearing socket or prosthetic socket with relief structures)** Polyurethane causes irritation in the presence of large pressure differences. This can occur if the liner is exposed to selective strain.	• Make a new prosthetic socket according to the instructions of this document.
	Prosthesis is used without vacuum. The volume loss causes the residual limb to slip into the prosthetic socket, where it can damage the liner.	• Ensure that the vacuum is generated and maintained. Without vacuum, the user loses residual limb volume every day. • Instruct the user on how he or she can determine whether there is vacuum and how to restore the vacuum in the event of loss.
	User does not compensate for volume loss.	• Explain to the user how he or she can recognise volume losses from the markings on the liner and compensate for them using the liner FitKit.

Topic: Flow properties of the liner		
Problem	**Cause**	**Solution**
Flow properties of the liner not correct	**-** -	• Work through the "Checking the volume" section (see Page 13).

Topic: Noise		
Problem	**Cause**	**Solution**
Air rippling/burping between the skin and liner	**Air under the liner**	• Explain to the user how to properly remove all air from the liner when putting it on.
	No tailored spot for an entrance that does not close.	• Have a custom spot made for all entrances that do not close when you cup the limb with your hand.
	Liner or sealing sleeve too loose on the thigh.	• **When using a PU standard liner:** Ensure that the liner is seated correctly along the entire residual limb and the thigh. • Use a PU custom liner to ensure a correct fit.
Hissing noises on the vacuum pump	**Muffler on the expulsion valve of the pump removed.** In the delivery condition, a muffler is located in the outlet hose of the vacuum pump.	• Attach a 4Y360=5 muffler to the outlet opening of the vacuum pump.
	Set screws on the pyramid adapter are not tightened uniformly.	• Loosen all set screws and retighten them (torque according to the corresponding instructions for use).

Topic: Vacuum		
Problem	**Cause**	**Solution**
Vacuum is only generated distal to the prosthetic socket. (The sealing sleeve is **not** pulled over the edge of the prosthetic socket.)	**Outlet opening of the prosthetic socket covered with adhesive tape.**	• Remove the adhesive tape.
	Outlet opening of the prosthetic socket blocked with spot.	• Instruct the user to always wear spots or residual limb socks under the thin residual limb sock.
	Socket connector or filter clogged.	• Disconnect the hose from the intake valve of the vacuum pump. Blow air through the hose to dislodge the clog. • **If the clog remains:** Replace the socket attachment piece.
Vacuum is generated in the prosthetic socket but decreases again.	**User wears liner with textile cover.** The textile cover prevents the seal between the liner and sealing sleeve. This causes air to penetrate into the prosthetic socket.	• Only use liners that do **not** have a textile cover in the proximal area.
	Residual limb sock reaches at least to the upper edge of the liner. This has the same effect as wearing a liner with a textile cover.	• Instruct the user to pull the residual limb sock up to only about **5 cm** below the edge of the liner. This allows the seal between the liner and sealing sleeve.
	No lubricant in the proximal area of the liner. This allows air to leak along the thigh and the non-stick surface of the liner.	• Apply a thin layer of lubricant to seal the area.
	Sealing sleeve does not form a tight seal with the prosthetic socket. This allows air to penetrate at the transition between the prosthetic socket and the sealing sleeve.	• Roll the lower end of the sealing sleeve upwards from the prosthetic socket. Ensure that at least **5 cm** of the prosthetic socket is designed so that the sealing sleeve can form a tight seal. • Apply a thin layer of lubricant to seal the area. • Roll the sealing sleeve onto the prosthetic socket and use a hook-and-loop strip or electrical tape to ensure that it is seated tightly against the prosthetic socket.
	Laminate not completely saturated with resin. Air can get through the layers of the laminate and into the prosthetic socket. This generally occurs on the outlet opening of the prosthetic socket.	• Remove the socket connector. • Drill a larger hole. • Seal the hole with epoxy resin. • Drill a hole for the socket connector in the middle of the epoxy resin. • Attach the socket connector. • **If the system still leaks:** Make a new prosthetic socket according to the instructions of this document.

5 Appendix

5.1 Reduction tables

3% reduction

	205	210	215	220	225	230	235	240	245	250	255	260	265	270	275	280	285	290	295	300
	199	204	209	213	218	223	228	233	238	243	247	252	257	262	267	272	276	281	286	291
	305	310	315	320	325	330	335	340	345	350	355	360	365	370	375	380	385	390	395	400
	296	301	306	310	315	320	325	330	335	340	344	349	354	359	364	369	373	378	383	388
	405	410	415	420	425	430	435	440	445	450	455	460	465	470	475	480	485	490	495	500
	393	398	403	407	412	417	422	427	432	437	441	446	451	456	461	466	470	475	480	485

4% reduction

	205	210	215	220	225	230	235	240	245	250	255	260	265	270	275	280	285	290	295	300
	197	202	206	211	216	221	226	230	235	240	245	250	254	259	264	269	274	278	283	288
	305	310	315	320	325	330	335	340	345	350	355	360	365	370	375	380	385	390	395	400
	293	298	302	307	312	317	322	326	331	336	341	346	350	355	360	365	370	374	379	384
	405	410	415	420	425	430	435	440	445	450	455	460	465	470	475	480	485	490	495	500
	389	394	398	403	408	413	418	422	427	432	437	442	446	451	456	461	466	470	475	480

5% reduction

	205	210	215	220	225	230	235	240	245	250	255	260	265	270	275	280	285	290	295	300
	195	200	204	209	214	219	223	228	233	238	242	247	252	257	261	266	271	276	280	285
	305	310	315	320	325	330	335	340	345	350	355	360	365	370	375	380	385	390	395	400
	290	295	299	304	309	314	318	323	328	333	337	342	347	352	356	361	366	371	375	380
	405	410	415	420	425	430	435	440	445	450	455	460	465	470	475	480	485	490	495	500
	385	390	394	399	404	409	413	418	423	428	432	437	442	447	451	456	461	466	470	475

5.2 Measurement form

Measurement Form for Polyurethane (PUR) Liner

Transtibial and Syme amputations

Contact		Customer number		Date	

Customer		Shipping address (if different from customer address)	
Company		Company	
Street		Street	
Postal code/city		Postal code/city	
Email		Phone	
Patient ID			

Affected side: ☐ Left ☐ Right

☐ **6Y400** PUR custom liner from plaster cast and measurement form

☐ **6Y400=M** PUR custom liner from measurement form

☐ **6Y416** Shape Plus PUR custom liner from plaster cast and measurement form

- If the plaster cast has complex features such as knee flexion >15°, a bulging, eccentric or concave residual limb end, pronounced invaginated scar tissue or excess size (length >50 cm, circumference >50.5 cm), a 6Y416 Shape Plus Liner is required.

☐ **Replacement custom liner: please contact customer service.**

- Wall thickness tolerances of ±10% are possible on subsequent orders.
- Ottobock stores the plaster cast data as a file for two years after the most recent order.

Wall thickness

☐ **Uniform** (with 13 mm distal cushion)
(Wall thickness: ☐ 4 mm ☐ 5 mm ☐ 6 mm)

☐ **Tapered** (6 mm wall thickness at knee centre tapering to 3 mm [± 1 mm] with 13 mm distal cushion)

☐ Width of the distal residual limb end ..... mm (if deviating from 13 mm)

Distal connector

☐ **Without**

☐ **With** (requires the selection of a textile coating)

Exterior coating

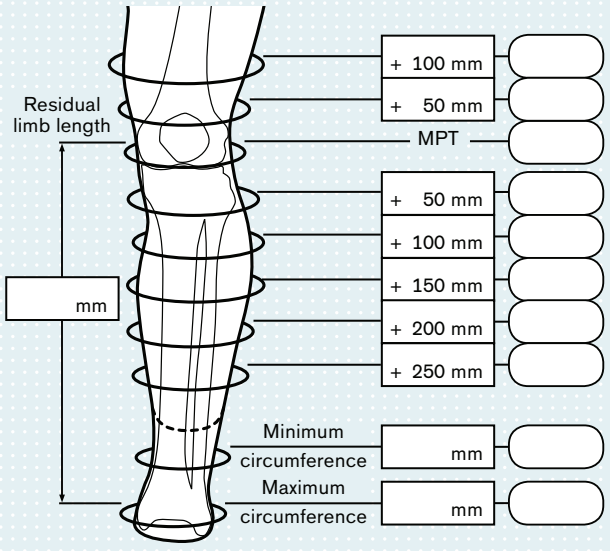
☐ **With textile coating**
- ☐ 1.6 mm, colour: ☐ Skin colour or ☐ Black
- ☐ 0.6 mm, colour: ☐ Skin colour or ☐ Black
- ☐ 1.0 mm, colour: Silver

☐ **Without textile coating** (requires a non-adhesive coating)

☐ **SKINGUARD TECHNOLOGY**

Lower leg measurements

- Extend the measurement sections if necessary.



Comments: .....

.....

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Kundenservice/Customer Service

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