Fabrication of a Chopart Prosthesis

1E8* - 2C5/2E3 - SL=P078 - SL=P071

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1 Introduction
This technical information supports you as a prosthetist in the fabrication of a Chopart prosthesis. It explains how the individually fabricated prosthetic socket is glued to the Chopart footplate using the Chopart glue kit. All relevant steps are described in detail and illustrated with pictures.

The fabrication of the prosthetic socket is not explained within this technical information.

The fabrication of a Chopart prosthesis consists mainly of two steps:
1. Preliminary gluing of the prosthetic socket to the footplate for the dynamic trial fitting
2. Definitive gluing of the prosthetic socket, the footplate and the footshell to create a finished prosthesis

This document is directed to certified prosthetists. 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 substitute reading the instructions for use.

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

- Collecting the Materials and Tools
  - Components and Devices
  - Materials
  - Machines, equipment and accessories
  - Tools
- Preparatory Work

The following subsections include the required information for the above listed points.

2.1 Collecting the Materials and Tools

The required materials and tools are listed in the tables below. The tables contain the materials and tools shown in the photos within this technical information.

Only the materials listed in the technical information have been tested according to the ISO standard. The prosthetist assumes full responsibility for the use of any other materials.

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<thead>
<tr>
<th>Components and Devices</th>
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<td>Chopart Prosthetic Socket</td>
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<td>Residual Limb Sock</td>
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<td>Chopart Footplate</td>
<td>1E80/81/82/87</td>
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<tr>
<td>Footshell</td>
<td>2C5 (1E80/81/82)</td>
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<table>
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<td>Talcum Powder</td>
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<tr>
<td>Orthocryl Sealing Resin</td>
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2.2 Preparatory Work

The following preparatory work must be completed prior to the actual process:

- Fabrication of the prosthetic socket
  - The design is based on the needs of the patient.
  - The prosthetic socket must be very stiff in the distal area (1) for subsequent gluing with polyurethane. (In case of laminated sockets, at least 2 layers of carbon must be applied over the distal area in addition to the reinforcement.)

In the course of subsequent processing, the prosthetic socket lies above the footplate at a distance of 3 mm (0.12”). This gap is needed so that polyurethane can penetrate fully underneath the prosthetic socket.

In case of special physical features of the patient (e.g. growth deficits), the distal area (1) of the prosthetic socket must be fabricated so that the height difference is compensated.

<table>
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<tr>
<td>Hardening Powder (for Orthocryl Sealing Resin)</td>
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<td>Measuring Cup</td>
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<td>Disposable Fine Dust Mask</td>
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<td>“Combitox Nova” Respiratory Protection Half-Mask</td>
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<td>Chemical-Resistant Gloves</td>
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<td>Linen Adhesive Tape</td>
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<td>Monofilament Adhesive Tape</td>
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3 Process
The entire process is shown in the following flowchart. The steps and process sequences that are not described in this technical information are shown in a grey font.

**Fabrication of the prosthetic socket**

**Aligning the Prosthetic Socket**
- Preparing the Prosthetic Socket
- Preparing the Patient
- Marking the Frontal Plumb Line
- Marking the Sagittal Plumb Line

**Preparing the Prosthesis for the Trial Fitting**
- Preparing the Prosthetic Socket and Footplate
- Clamping in the Alignment Apparatus
- Gluing the Prosthetic Socket to the Footplate

**Trial Fitting of the Prosthesis**
- Putting on the Prosthesis
- Checking the Static Alignment
- Checking the Alignment in the Dynamic Trial Fitting

**Definitive Gluing of the Prosthesis Components**
- Creating the Mould
- Preparing the Prosthetic Socket and Footplate for Gluing
- Casting the Polyurethane
- Tempering the Polyurethane

**Finishing the Prosthesis**
- Preparing the Footshell
- Foaming the Footshell
3.1 Aligning the Prosthetic Socket

**Objective of the Process Sequence**

For the optimum fabrication of the prosthesis, the following physical characteristics of the patient are recorded:

- Valgus, varus and flexion position of the leg and residual limb
- Pelvic alignment

These physical characteristics determine the optimum position of the prosthetic socket relative to the footplate.

The following lines, which are important for clamping in the alignment apparatus, are marked on the prosthetic socket:

- Frontal plumb line
- Sagittal plumb line

**Required Tools and Materials**

- Prosthetic Socket
- Residual Limb Sock
- Parallel Bars
- Crosshair Laser with Universal Tripod
- Hip Levelling Guide
- Adhesive Tape
- Foot Blocks
- Permanent Marker

**Important Information**

⚠️ **WARNING**

Risk of falling when standing up or standing without parallel bars

Serious injuries caused by falling (patient)

- Only allow the patient to stand up / stand using parallel bars.

Should the prosthesis wearer wish to switch between several pairs of shoes, it is recommended to complete the prosthesis alignment process with the shoes that have the greatest heel height. For the other shoes, a compensating spacer should be secured in the heel area of the shoe on the prosthesis side (e.g. cork plate - height = difference between the heel heights). However, this method is not suitable to compensate for major heel height differences. The forefoot and hindfoot leverage will change.

A precise alignment recommendation, provided for other prosthetic feet, cannot be offered for the Chopart footplate due to the individual leverage, the respective material thicknesses difference of the Chopart footplates (of various sizes and stiffness) as well as the various cosmetic features and dimensions of the prosthetic sockets do not permit standardisation. The outward rotation of the foot and the heel height within the allowable limits of the Chopart footplate are adapted to the conditions accordingly. For the dynamic trial fitting, the most functional possible positioning of the Chopart footplate relative to the prosthetic socket should be found.

The frontal and sagittal plumb lines in combination with the the alignment apparatus laser facilitate the positioning of the prosthetic socket.
3.1.1 Preparing the Prosthetic Socket

Apply white adhesive tape to the sagittal side of the prosthetic socket.
Apply white adhesive tape to the frontal side of the prosthetic socket.

3.1.2 Preparing the Patient

Remove the shoe.
Put on the protective sock.
Apply the prosthetic socket.
Use adhesive tape or strap material to secure the prosthetic socket on the leg.

In order to prevent the prosthetic socket from sliding on smooth surfaces, apply adhesive tape to the distal side of the prosthetic socket.

To prevent falling and for load relief, ensure the patient stands between parallel bars.
Posture of the patient:
• Standing upright
• Looking straight ahead
Use foot blocks to compensate for any height difference.
Check the upright pelvis position.

Based on the needs and anatomy of the patient, use foot blocks to compensate for the length difference.

3.1.3 Marking the Frontal Plumb Line

Project the frontal plumb line onto the prosthetic socket with the laser and mark it.

3.1.4 Marking the Sagittal Plumb Line

Project the sagittal plumb line onto the prosthetic socket with the laser and mark it.
3.2 Preparing the Prosthesis for the Trial Fitting

**Objective of the Process Sequence**
The footplate and the prosthetic socket are temporarily glued together for the trial fitting with the help of putty. In the course of the subsequent trial fitting, the correct position of the footplate relative to the prosthetic socket is verified.
The putty is replaced 1:1 by the polyurethane in the glue kit during a later process sequence.

**Required Tools and Materials**

- Chopart Footplate
- Crepe Soles
- Chopart Glue Kit
- Mixing Cup
- Stir Sticks
- Double-Sided Adhesive Tape
- Fibreglass Adhesive Tape
- Scissors
- Alignment Apparatus
- Superglue
- Sealing Resin and Hardening Powder
- Talcum Powder
- Cardboard Underlay (approx. 50 x 50 cm)

**Important Information**
When gluing the footplate to the prosthetic socket, the values determined during the examination of the prosthetic socket must be taken into account for the positioning in the alignment apparatus.
The putty is a mixture of Orthocryl sealing resin and talcum. A solid mass is created by adding hardener.
The crepe sole represents the material thickness of the subsequent footshell.
3.2.1 Preparing the Prosthetic Socket and Footplate

Roughen the distal side of the prosthetic socket.

Roughen the footplate to the marked line.

Glue a rubber ring from the Chopart glue kit onto the centre of the prosthetic socket using superglue.

Draw crosshairs onto an underlay. Position the footshell with the inserted footplate so that the lines on the footplate line up with the crosshairs. Mark the outside contour of the footshell on the underlay.
Apply double-sided adhesive tape to the lower side of the footplate.

Lay the crepe sole onto the marked contour. Glue the footplate onto the crepe sole so that the lines of the footplate line up with the crosshairs. Put the footplate with crepe sole into the shoe.

Mark the spacer washer with chalk.

Ensuring it is plumb, press the prosthetic socket onto the footplate in order to transfer the marking. Make sure the plumb lines are positioned vertically.
The marking helps adjust an initial a – p position of the footplate to the prosthetic socket in the alignment apparatus.
Remove the footplate from the shoe.

3.2.2 Clamping in the Alignment Apparatus

Position the footplate in the foot adapter unit on the alignment table.
Set the effective heel height of the shoe.
Set the exterior rotation.
Transfer the lateral and medial markings onto the edges of the footplate at 90 degrees to the walking direction.
Clean the footplate and the roughened area of the prosthetic socket with isopropyl alcohol.
Clamp the prosthetic socket in the alignment apparatus and align it according to the frontal and sagittal plum lines.
Lower the prosthetic socket.
Adjust the footplate adapter with footplate in the a – p direction so that the lateral markings (2) line up with the spacer washer (1).

3.2.3 Gluing the Prosthetic Socket to the Footplate

Mix Orthocryl sealing resin and talcum powder to make a firm putty.
Add the hardener.
Apply a dot of putty onto the footplate.
Lower the prosthetic socket onto the footplate. Allow the putty to harden.
Remove the joined components from the alignment table.

Use a marker to transfer the outline of the footplate onto the crepe sole.
Before applying more putty, pull the crepe sole off the footplate.

Add putty to the joint between the prosthetic socket and the footplate so that the unit can withstand a dynamic trial fitting.
Allow the putty to cool.
If desired tear-resistant adhesive tape may be used to secure the glued joint between the footplate and prosthetic socket.
Glue the crepe sole back onto the footplate in the marked position.
3.3 Trial Fitting of the Prosthesis

Objective of the Process Sequence
The vertical load line is projected with the L.A.S.A.R. Posture and the static alignment is verified. The purpose of the dynamic trial fitting is to verify that the prosthetic socket and footplate are also positioned correctly relative to each other while walking.

Required Tools and Materials
- Provisional Prosthesis
- Parallel Bars
- L.A.S.A.R. Posture
- Adhesive Tape

Important Information

⚠️ WARNING
Risk of falling due to lack of stability of the provisional prosthesis
Serious injuries caused by falling (patient)
- Only allow the patient to stand up / stand using parallel bars.
- Only allow the patient to wear the prosthesis whilst supervised in the fitting room and for the purpose of verifying the static alignment and conducting the dynamic trial fitting.

3.3.1 Putting on the Prosthesis

Apply the prosthetic socket and secure it with adhesive tape or strap material.
Use filler (e.g. foam) to stabilise the footplate in the shoe.
Put on the shoe.
3.3.2 Checking the Static Alignment

Use the L.A.S.A.R Posture to optimise the static alignment based on the available technical information.

3.3.3 Checking the Alignment in the Dynamic Trial Fitting

Only test the prosthesis during normal walking since the glued joint is not designed for greater stress. Conduct the dynamic trial fitting.

If required, modify the alignment in regards to plantar flexion and dorsal flexion as well as pronation and supination by inserting small spacers into the shoe.

If the positioning of the prosthetic socket to the footplate has to be corrected, follow the instructions for separating the components in the section “Preparing the Prosthetic Socket and Footplate for Gluing” (see Page 19) and then continue with the instructions in the section “Clamping in the Alignment Apparatus” (see Page 12), taking into account the corrections.

Repeat the dynamic trial fitting and correct the footplate position until the prosthesis wearer exhibits a harmonious gait pattern and can walk physiologically and without stress.
3.4 Definitive Gluing of the Prosthesis Components

Objective of the Process Sequence
The prosthetic socket and the footplate are glued together into the definitive prosthesis using the Chopart glue kit. With the help of a polyethylene plate, the provisional glued joint on the distal part of the socket and the footplate is moulded. The resulting mould is used to secure the prosthetic socket and the footplate in the correct position to each other, and to accept and shape the polyurethane.

Required Tools and Materials
Chopart Glue Kit
Isopropyl Alcohol
Grinding and Milling Machine with Abrasive
Heating Oven
Protective Gloves
Scissors

Important Information
To achieve a stable joint between the prosthetic socket, polyurethane mixture and footplate it is necessary to follow all instructions within this technical information.
Care and cleanliness are required in order to ensure the polyurethane joint is sufficiently strong.

Information on the Workstation and Procedure
• The workstation must be kept clean.
• Work that raises dust must not be conducted at neighbouring workstations.
• Dirt, dust, oil, grease and materials such as talcum powder or silicone parting agents in spray form reduce the stability and therefore need to be avoided.
• Do not use compressed air for cleaning since it may contain oil residues.
• Surfaces must not be touched after cleaning them with isopropyl alcohol.
• After gluing the prosthetic socket to the footplate, the position can no longer be changed. This is why transferring the established position during the trial fitting requires great care during this step.

Processing the Polyurethane
The adhesion and stability of the Chopart glue kit is only assured if component A is decrystallised by heating it prior to processing. In order to prevent recrystallisation, the polyurethane must not be allowed to cool below 17 °C (< 62.6 °F) before processing.
Tempering of the finished glued joint in the heating oven is essential in order to achieve the required final strength and stability of the prosthesis.

Using the Primer
• In order to achieve a firm connection between the polyurethane and prosthetic sockets made of acrylic resin, the primer must be used as a bonding agent.
• Do not use the primer to join the polyurethane to the footplate or a prosthetic socket made of epoxy resin.
3.4.1 Creating the Mould

Open but do not remove the cover on component A in order to prevent the formation of overpressure during heating.
Warm component A in the heating oven in order to decrystallise it (min. 3 h at 65 °C / 149 °F).
The processing time for the polyurethane can be extended by cooling it (min. > 17 °C / > 62.6 °F).

Remove any pads that are positioned and/or secured on the prosthetic socket.
Pull the crepe sole off the footplate.
Remove glue residue from the footplate.
Remove the white adhesive tape from the prosthetic socket.

Grind the putty until it is straight to slightly concave.
The shape that is achieved by grinding will subsequently be the shape of the PU glued joint.
Grinding must result in a shape that permits the fitting of a footshell.

Clamp the prosthesis so it faces up at an angle of approximately 40°, with the toes pointing down.
Use a cloth to practice the application of the polyethylene plate to the heel area of the prosthesis.
Use isopropyl alcohol to clean both sides of the polyethylene plate.
Heat the polyethylene plate at 130 °C (266 °F) until it becomes transparent and can be moulded.
Remove it from the heating oven wearing temperature-resistant gloves.
Apply the polyethylene plate over the heel of the prosthesis (1/2 over the prosthetic socket, 1/2 over the footplate).

Mould the heated material. In doing so, avoid excessive undercutting and close the dorsal region by butting the edges up against each other rather than overlapping them.
Do not squeeze the polyethylene tight together in the dorsal area.

Apply the polyethylene plate carefully in the region with the putty.
Mould the polyethylene plate on the sides, in the anterior area of the footplate.
The mould has to firmly encompass the edges of the footplate and the edge in the heel area of the prosthesis, so that the footplate and the prosthesis are kept in their correct position to each other later during casting.
Allow the mould to cool.

Mark the trimming edge so that the edges of the mould hold the footplate and the prosthetic socket in place.
Expose the dorsal area of the prosthesis so the polyurethane can be poured in later.
Trim the mould so that the prosthesis can be removed.
Remove the prosthesis from the mould. Trim the mould so that the prosthetic socket and the footplate can be reinserted and are held firmly in place. Deburr and clean the mould.

### 3.4.2 Preparing the Prosthetic Socket and Footplate for Gluing

Use a band saw to cut the glued joint. Cut within the 3 mm gap between the prosthetic socket and footplate in order to avoid damage.

Completely remove the putty from the prosthetic socket. Avoid grinding the resin of the laminate as far as possible during this process, so that fibre exposure is minimised.

Remove the putty from the footplate by grinding. Avoid grinding or damaging the epoxy facing and the carbon.
If fibres are exposed during grinding or too much acryl­ic resin has been removed from the acrylic resin prosthetic socket, clean the affected area thoroughly and then apply a thin coating of sealing resin. Allow the material to dry fully for at least 24 h prior to further processing.

If too much epoxy resin has been removed from the epoxy resin prosthetic socket or the footplate, or if fibres are exposed, clean the affected area thoroughly and then apply a thin coating of epoxy resin. Allow the material to dry fully for at least 24 h prior to further processing.

CAUTION! Only for acrylic resin prosthetic sockets, use the primer as a bonding agent.
NOTICE! Shake the container with the primer thoroughly so that all components that may have settled are dissolved and mixed.

Clean the prosthetic socket with isopropyl alcohol and allow it to dry.
CAUTION! Risk of falling – Do not apply the primer to the Chopart footplate and an epoxy resin prosthetic socket, as the polyurethane bond will not be durable enough and will break.
Apply a thin coat of primer to the prosthetic socket on the surfaces being glued.
The primer has to dry for 15 – 20 min before gluing.
Cut a piece (approx. 1/4) from the rubber ring.

Clean the mould with isopropyl alcohol.
Roughen the footplate with the sandpaper.
Clean the footplate and sides with isopropyl alcohol in the area being glued, and do not touch it again.
Insert the footplate in the mould.

Insert the prosthetic socket into the mould without touching the areas being glued.
Push the piece of the rubber ring under the centre of the prosthetic socket using a clean stir stick.
This ensures that the original 3 mm gap is maintained between the footplate and the prosthetic socket.

Secure the position of the prosthetic socket relative to the footplate in the mould using adhesive tape.
Clamp the assembled components facing down at an angle of approximately 45°, with the dorsal area (toes) pointing up.

3.4.3 Casting the Polyurethane

Add the entire contents of component B to the container with component A. Slowly and thoroughly stir the polyurethane to mix it (2 – 3 min). Trapped air bubbles must be avoided. In order to ensure that the polyurethane is thoroughly mixed, scrape the sides and bottom of the container while stirring.

Slowly pour the polyurethane into the mould to the side of the spacer ring. Trapped air bubbles must be avoided.

Do not pass the marked line on the footplate when pouring. The height of the joint to the prosthetic socket can be influenced by changing the angle of the prosthesis. If the polyurethane settles as it hardens, add more until the level of the marked line on the footplate is reached.

After casting, allow the glued joint to harden undisturbed (min. 3 h / min. 20 °C / 68 °F).
3.4.4 Tempering the Polyurethane

Place the prosthesis with the mould into the heating oven on its side and temper it to its final strength (16 h at 80 °C / 176 °F). Then remove the prosthesis from the heating oven and allow it to cool. Remove the mould.

Remove excess polyurethane from the bottom of the footplate. Trim excess polyurethane on the socket edge. Clean the prosthesis with isopropyl alcohol.
3.5 Finishing the Prosthesis

Objective of the Process Sequence
The following section describes the fitting process and gluing of the footshell.

Required Tools and Materials

- Chopart Prosthesis
- Footshell
- Fill Foam
- Isopropyl Alcohol
- Grinding and Milling Machine with Abrasive Steel
- Shoe Horn
- Underlay (e.g. 616T3=2 Thermolyn Trolene, household foil, glass plate)
- Plaster Parting Agent Cream
- Protective Gloves
- Scissors

Important Information

Using the Footshell
The footshell is not mandatory for the correct functioning of the Chopart prosthesis.

Using the footshell has the following advantages:

- The fit of the prosthesis within the shoe is improved.
- The appearance of the prosthesis is enhanced.
- The fill foam fills the spaces between the footplate and the footshell, and also glues the components together. The prosthesis does not generate noise while walking. The fill foam prevents deformation of the footshell when the shoe is tied.

Processing the Fill Foam
The fill foam consists of two components. After the components are combined, the mixture begins to react quickly and the processing time is very short. Preparation is therefore essential. All required products, materials and tools must be readily to hand. An underlay has to be positioned since fill foam will spill.

Inserting the footplate into the footshell should be practiced several times in advance so that the footplate is correctly positioned before fitting. A steel shoehorn can be used for this purpose. Changes are no longer possible after foaming. Prior to applying the fill foam, lifting the edge of the footshell from the prosthesis with the corresponding tool should also be practiced in order to work confidently before the fitting.

Fast, precise work is required during gluing in order to avoid an incorrect glued joint.

3.5.1 Preparing the Footshell

The footshell is adapted step-by-step according to the instructions below, so that the prosthesis fits exactly in the footshell and the edge of the footshell fully contacts the prosthetic socket.
Grind the proximal edge of the footshell to 0 on the inside.
Remove the wedges in the heel area.

Insert the prosthesis into the footshell as far as possible.
Use a washable marker to make an initial trim line.

Trim the edge step-by-step.

Grind the edge from the inside.
Check the fit by inserting the prosthesis.
Repeat the process until the prosthesis fits exactly into the footshell and the edge of the footshell fully contacts the prosthetic socket.
3.5.2 Foaming the Footshell

Practice inserting the prosthesis into the footshell quickly and confidently.
Place the shoehorn within reach.

Apply plaster parting agent cream to the outside of the footshell in order to prevent the adhesion of fill foam.

Work quickly when processing the foam.
Add component A to the container with component B.
Mix the components by stirring quickly with a stir stick (stirring time approx. 10 s).

Pour most of the fill foam into the footshell.
Distribute the fill foam in the footshell by tilting it back and forth.

Insert the prosthesis into the footshell.

If required, raise the upper edge of the footshell and add more fill foam.

In order to avoid changing the heel height due to excessive fill foam between the footplate and footshell, push down on the prosthesis with moderate pressure until the foam has set.
Remove foam residue from the prosthesis so that the edge of the footshell fully contacts the prosthetic socket.

Add buckles or straps to the prosthesis. Position and secure pads if applicable.

Clean the prosthesis.
**4 Appendices**

**4.1 Order Forms**

**Chopart Plate**

Fax: +49-5527-848-1414

<table>
<thead>
<tr>
<th>Billing Address</th>
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<td>Orthopedic technician</td>
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**Patient Data**

Name _________________________________________________
Age ___________________________________________________
Sex  □ male  □ female
Weight ______________________________________________ kg
Size ________________________________________________ cm
Foot size ____________________________________________ cm
Heel height __________________________________________ cm
Amputation side  □ left  □ right
Bilateral amputation  □ yes  □ no
Previous foot (model) ____________________________________________

**Patient Mobility Grade**

- **Mobility Grade 3**
  - Moderate activity and low impact load.
  - Everyday activities such as walking and going up and down stairs.

- **Mobility Grade 4**
  - Moderate activity and moderate impact load.
  - Everyday activities, fast walking even on uneven ground.
  - Recreational activities such as hiking, golfing, etc.
  - Moderate activity and high impact load.
  - Diverse activities, above-average impact load and mechanical demands on the prosthesis.
  - High activity and high impact load.
  - Recreational activities such as skiing, sprinting, weight training etc.

**Amputation height (optional information)**

- □ Chopart
- (a) MPT to floor (sound side) ____________________ mm
- (b) MPT to socket end ________________________ mm

**Modular Foot System**

**Chopart Plate**

- Min. clearance: 17-24 mm
- Crepe soles are included in delivery.
- Please indicate the footshell and the glue set in the selection below (footshell, fill foam).

- □ 1E80 Chopart with 0 mm heel height
- □ 1E81 Chopart with 9 mm heel height
- □ 1E82 Chopart with 19 mm heel height

**Chopart Plate Pediatric**

- Minimal clearance: 17 mm. Crepe soles are included in delivery.

- □ 1E87 Chopart with 6 mm heel height

**Footshells**

**for Chopart (sizes 24 – 31 cm)**

<table>
<thead>
<tr>
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**for Chopart Plate Pediatric**

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**CHOPART PLATE WITH 0 mm HEEL HEIGHT**

- SL=P078 Chopart Bonding Kit
- SL=P071 Footshell Foam Kit

Date ______________  Place __________________________ Signature ________________________

Otto Bock HealthCare GmbH | Prosthetics – Lower Extremities | www.ottobock.com
# General Order Form

Fax order to: +49 5527 848-1414

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Appendices

- 1E8*
- 2C5/2E3
- SL=P078
- SL=P071
# General Order Form

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