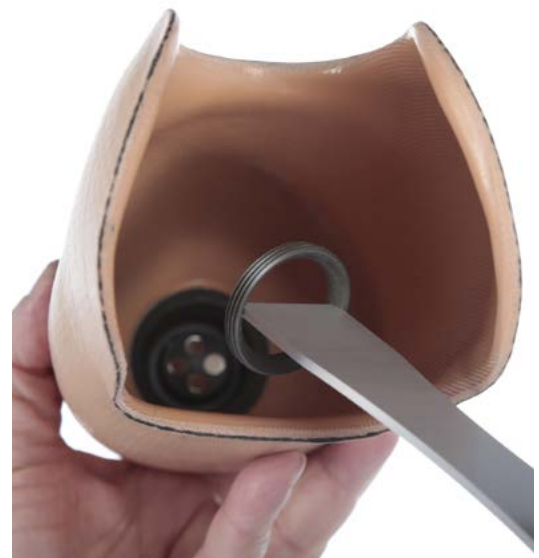


DVS - Dynamic Vacuum

Fabrication of a prosthesis



Technical information



1 Introduction

This technical information supports you in the fabrication of a prosthesis with the 4R220 Dynamic Vacuum System, a system used for the generation of an active vacuum. It consists of a structural component with an integrated piston pump, a liner and a sealing sleeve.

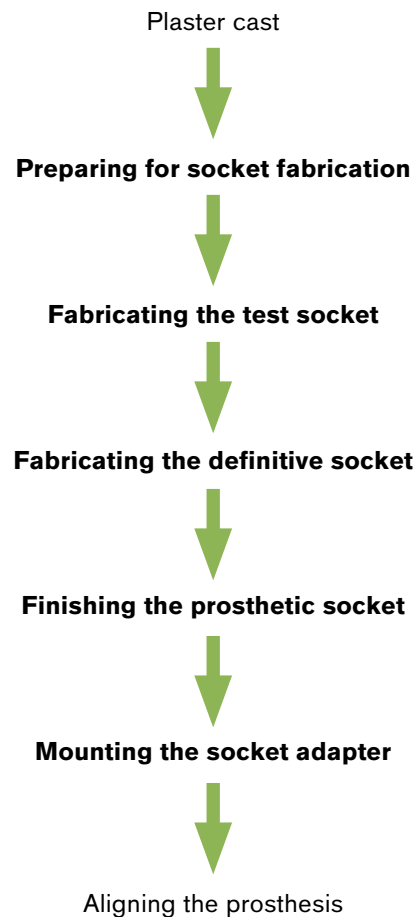
The Dynamic Vacuum System uses the pistoning movements between the residual limb and prosthetic socket to generate the vacuum. The piston of the pump is equipped with magnets. A metallic counter-piece is installed on the liner. Air is suctioned out of the space between the liner and prosthetic socket into the cylinder during the swing phase, and this air is pressed out during the stance phase. The result is a permanent vacuum, with a level that adapts to the user's activity level.

This document is directed to trained 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 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

Name	Reference number
Dynamic Vacuum pump	4R220

Materials

Name	Reference number
String	–
Plastaband	636K8*
Residual limb sock	99B25
BetaSil	616S5*
ThermoLyn	616T52=* , 616T53=*
Bonding agent	617H46
Wax	633W8
Polyethylene adhesive tape	627B4
Perlon stockinette	623T3=*
PVA bag	99B81=70X19X5, 99B81=100X19X5
Carbon fiber cloth strap	616B1=*
Carbon UD stockinette	616G2
Carbon fiber woven hose	616G15
Orthocryl lamination resin 80:20 PRO	617H119
Loctite® 241	636K13

Tools

Name	Reference number
Grease pen	–
Scissors	–
Flat file	715F1=*
Tensioning frame	755T4=360
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 Plaster cast

INFORMATION

The product can be used with a total surface weight-bearing socket or a specific weight-bearing socket.

Cast over the specific DVS liner and fabricate the plaster cast using the selected technique.

Fill the plaster cast with plaster and insert a reinforcement rod.

Modify the plaster model according to your socket design. Do not reduce more than 3% in any location.

3.2 Preparing for socket fabrication

Objective

The plaster model is prepared for the fabrication of a prosthetic socket. The piston dummy is placed on the plaster model in the longitudinal residual limb axis.

- The plaster model must be ground in such a way that the piston dummy is placed in the longitudinal residual limb axis and comes to rest in an even position.



- Position the piston dummy on the plaster model and loosely secure it with a plaster screw.



- Pull a nylon stockinette over the plaster model.
- Tie off the nylon stockinette below the piston dummy and trim off the excess nylon stockinette.



- Turn the plaster screw all the way in.





For definitive socket only

- Soak the shorter PVA bag and pull it over the plaster model.
- Use string to tie off the PVA bag in the undercut of the piston dummy.
- Cut off the excess PVA bag with a scalpel.



For definitive socket only

- Position the silicone dummy on the piston dummy. Verify that there is no excess of the PVA bag.



- Isolate the heads of the cap screws with wax.
- Fill the heads of the cap screws with Plastaband.

INFORMATION: Only screw in the valve dummy after positioning the cylinder body.

- Position the cylinder body on the piston dummy. Perform the mediolateral alignment of the exhaust opening depending on the alignment.



- Screw the valve dummy into the exhaust opening until the O-ring closes the opening.
- Close the slot in the valve dummy with Plastaband.



For test socket only

- Attach 2 strips of Plastaband each, anterior and posterior, over the cylinder in a lengthwise fashion. This makes it easier to remove the cylinder after the trial fitting.
- Place a strip of Plastaband circularly at the proximal edge of the cylinder. This provides distal sealing for the test socket.

3.3 Fabricating the test socket



- Fabrication of the prosthetic socket has been prepared.
- Complete the vacuum forming process.



- Finish prosthetic socket (see Page 11).



- Seal the transition from the cylinder body to the inside of the prosthetic socket with BetaSil or similar silicone sealant.

3.4 Fabricating the definitive socket

INFORMATION

The reinforcement described in this document was approved for the maximum product user body weight. The prosthetist assumes full responsibility for any change to the reinforcement

Objective

The following section describes the fabrication of the definitive prosthetic socket. The Dynamic Vacuum system is laminated into the prosthetic socket.



INFORMATION: The following steps are necessary to ensure the system's air tightness.

- Cut 3 pieces of perlon stockinette (each 2 times the length of the plaster model).
- Pull a perlon stockinette over the plaster model to the edge. Tie off the second half of the perlon stockinette with the string and fold it over the plaster model.
- Pull the 2 other pieces of perlon stockinette over the plaster model the same way.



- Expose the valve dummy using a scalpel.



- Wrap string around the valve dummy and tie the perlon stockinette off tight in the distal groove of the cylinder body

INFORMATION: Tie this off tight so the system is airtight after the lamination process.

- Tie off the 6 layers of perlon stockinette in the undercut of the cylinder body so they are up against the cylinder body.



- Position a layer of carbon fiber cloth strap from the medial condyle over the cylinder body to the lateral condyle.
- Expose the valve dummy.



- Position a layer of carbon fiber cloth strap from the MPT (mid-patella-tendon) point over the cylinder body to the opening for the back of the knee.



- Position a layer of carbon fiber cloth strap circularly around at the height of the MPT (mid-patella-tendon) point.





- Pull a nylon stockinette over the plaster model.
- Wrap string around the valve dummy and tie the nylon stockinette off tight in the distal groove of the cylinder body.



- With a perlon string, tie the nylon stockinette off tight in the undercut of the cylinder body.



- Cut off a piece of carbon fiber woven hose (1.3 times the length of the plaster model).
- Pull the carbon fiber woven hose over the plaster model to the edge.
- Tie off the carbon fiber woven hose at the distal end.



- Pull the excess carbon fiber woven hose over the plaster model.
- Expose the valve dummy.
- Tie off the carbon fiber woven hose tight in the distal groove of the cylinder body.
- Tie off the carbon fiber woven hose tight in the undercut of the cylinder body using a perlon string.
- Pull a nylon stockinette over the plaster model.

Prosthetic socket without carbon finish



- Cut a piece of carbon UD hose (1.5 times the length of the plaster model).
- Pull the carbon UD hose over the distal half of the plaster model.
- Tie off the carbon UD hose at the distal end.
- Fold the excess carbon UD hose over the plaster model.



- Expose the valve dummy.
- Tie off the carbon UD hose tight in the distal groove of the cylinder body.
- With a perlon string, tie the carbon UD hose off tight in the undercut of the cylinder body



- Cut a piece of perlon stockinette (2 times the length of the plaster model).
- Pull the perlon stockinette over the plaster model to the edge. Tie off the second half of the perlon stockinette with the string and fold it over the plaster model



- Soak the longer PVA bag and pull it over the plaster model.
- Perform the lamination process with Orthocryl.
- Because of the 6 layers of perlon stockinette, approx. 30 % more Orthocryl is needed.

Once the lamination resin is sufficiently distributed:

Displace excess lamination resin in the area of the cylinder body to the distal end by wrapping with polyethylene adhesive tape.

- Allow lamination resin to cure.
- Finish prosthetic socket (see Page 11).

Prosthetic socket with carbon finish



- Cut a piece of carbon UD hose (2 times the length of the plaster model).
- Pull the carbon UD hose over the plaster model up to the edge.
- Tie off the excess carbon UD hose at the distal end and fold it over the plaster model.



- Pull a nylon stockinette over the plaster model.



- Soak the longer PVA bag and pull it over the plaster model.
- Perform the lamination process with Orthocryl.
- Because of the 6 layers of perlon stockinette, approx. 30 % more Orthocryl is needed.

Once the lamination resin is sufficiently distributed:

Displace excess lamination resin in the area of the cylinder body to the distal end by wrapping with polyethylene adhesive tape.

- Allow lamination resin to cure.
- Finish prosthetic socket (see Page 11).

3.5 Finishing the prosthetic socket

Objective

The contours of the vacuum formed or laminated prosthetic socket are cut and ground. Then the valve bushing is mounted and the piston is placed in the cylinder.



- Mark and trim the contour of the prosthetic socket.
- Sand free the valve dummy and remove the Plastaband.
- Unscrew the valve dummy.
- Remove the prosthetic socket from the plaster model.



- Remove the piston dummy and silicone dummy from the plaster model and insert into the cylinder so it is closed.
- Close the opening in the piston dummy with Plastaband or polyethylene tape.
- Screw in the valve dummy.



- Sand the contour of the prosthetic socket.
- Sand the distal end of the socket down to the heads of the cap screws.
- On a level surface, check whether the sanded surface is flat. Rework as needed.



- Remove the cap screws.

INFORMATION: The proximal side of the snap bushings is marked with a notch.

- Apply silicone bonding agent to the snap bushings and insert them into the openings from which the cap screws were removed.



- Unscrew the valve dummy.
 - Remove the piston dummy and silicone dummy from the prosthetic socket.
- If necessary:** Wipe out the cylinder space with a lintfree cloth.
- Insert the duckbill valve into the valve bushing with the pointed end first.
 - Screw the valve bushing into the prosthetic socket (torque value: **3 Nm**).



- Insert the piston into the cylinder to the stop.



- Secure the stop ring with Loctite®, insert it into the thread of the cylinder and tighten it with the assembly wrench.

3.6 Mounting the socket adapter

Objective

A socket adapter is used as the distal connecting piece to the Dynamic Vacuum System. To ensure force transmission, a spacer plate is inserted between the socket adapter and prosthetic socket. The spacer plate makes it necessary to use longer countersunk head screws.



- Set the spacer plate onto the adapter.
- **If the pyramid adapter or the pyramid receiver of the adapter is rotatable:** Place the pressure plate on the adapter.



- Apply the adapter to the prosthetic socket.
- Optional:** Align the pyramid adapter or pyramid receiver.
NOTE: Only use the screws specified here.
- Select suitable countersunk head screws.
 - **Fixed pyramid adapter/pyramid receiver:**
501S28=M6x22
 - **Swivelling pyramid adapter/pyramid receiver:**
501S28=M6x25
 - Secure the screws with Loctite®.
 - Screw in the 2 posterior countersunk head screws and tighten them (torque value: **12 Nm**).
 - Screw in the 2 anterior countersunk head screws and tighten them (torque value: **12 Nm**).