

MANUFACTURING GUIDELINES

Alignment jig for lower-limb prosthetics



Promoting
Independent
Lifestyle

rehabimpulse.org

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Foreword

The polypropylene (PP) technology

This technology was created by the International Committee of the Red Cross (ICRC) in 1979. Its use is appropriate to specific contexts i.e., countries affected by war and low-income or developing countries.

The technology has been tailored to meet the needs of the physically disabled in the countries concerned.

The features of this technology are:

- Freedom from the transport and storage restrictions of other materials and no shelf-life constraints;
- Durable, comfortable, easy for service users to use and maintain;
- Its hard cosmetic shell helps the device maintain a good appearance throughout its life;
- Easy for P&O technicians to learn, use and repair;
- Standardized but compatible with the environment in different regions of the world;
- Low-cost but modern and consistent with internationally accepted standards (ISO certification and CE marked);
- Does not require expensive machines, tools, and a large setup;
- Easily available.

The choice of technology is of great importance for promoting sustainable affordable quality physical rehabilitation services.

The Rehab'Impulse Brand – owned by ICRC, made by Alfaset!

The ICRC registered the Rehab'Impulse trademark in 2019 with the aim of developing a brand identity for its technology. The Rehab'Impulse brand remains under the ownership of ICRC, while the components are manufactured in Switzerland by the Alfaset Foundation, a social enterprise employing persons with disabilities.

Objectives of the manuals

The "Manufacturing Guidelines" are designed to provide the information necessary for production of high-quality assistive devices.

The main aims of these informative manuals are as follows:

- To promote good practice.
- To provide support for training in the use of this technology.
- To promote and enhance Rehab'Impulse technology.

This is another step forward in the effort to ensure that service users have access to high-quality services.

Introduction

Every manufacturing technique has its own specific requirements. The technique based on the use of polypropylene is also subject to this rule; it must combine quality, ease of use and low cost.

The polypropylene (PP) components for Trans-Tibial (TT) and Trans-Femoral (TF) prostheses produced by Rehab'Impulse allow for certain angular and translation adjustments, but these possibilities are limited:

- 20 mm in translation or sliding (2×10 mm in each direction from the neutral point)
- 20° in tilting ($2 \times 10^\circ$ in each direction from the median axis).

It is preferable to retain the maximum adjustment possibilities for dynamic alignment, and to take into account the fact that static alignment follows the weight-bearing reference lines to achieve a neutral position.

In most of the techniques used for socket manufacture with polypropylene, the socket connection component, referred to the cup, is included in the socket during the thermoforming phase. It is the link that holds the other parts of the prosthesis together. Using this technique requires that the cup alignment be correctly positioned BEFORE the socket thermoforming process.

Another technique allows the production of "full-contact" sockets. In this case, incorrect positioning of the connecting component (the conical cup) makes optimal alignment difficult or impossible to achieve.

Particular attention must, therefore, be paid to whether the connecting cup or socket cup is placed on the positive model before or after the thermoforming phase.

A special device has been designed to help Prosthetist-Orthotists and Prosthetic and Orthotic (P&O) technicians complete these alignment phases easily and with the required precision.

This device is the alignment jig (Rehab'Impulse reference: 74-02438).

Objective of this document

The purpose of this document is to demonstrate the relevance and usefulness of the alignment jig for obtaining high-quality results.

The alignment principles applied are based on international P&O standards.

Remark

This document is not a technical manual on the manufacture of TT and TF prostheses. Please refer to the manufacturing guidelines for the concerned device.

1. Use of the alignment jig

1.1 Description of the jig

The alignment jig consists of a stainless-steel frame about 2 metres high and 0.8 metres wide. It is sturdy and stable.

Positioning phase

The purpose of the alignment jig is to facilitate the positioning in space of the positive plaster model (Fig 1), and to hold the socket connection cup firmly and precisely during the operation to fix it to the rectified positive plaster model with plaster of Paris (Fig 2 and 3) or by welding in the case of a full contact socket (Fig 4).

Obviously, this fixation phase is independent of the type of socket used: the illustrations show TT prostheses with and without a soft socket.



Fig 1

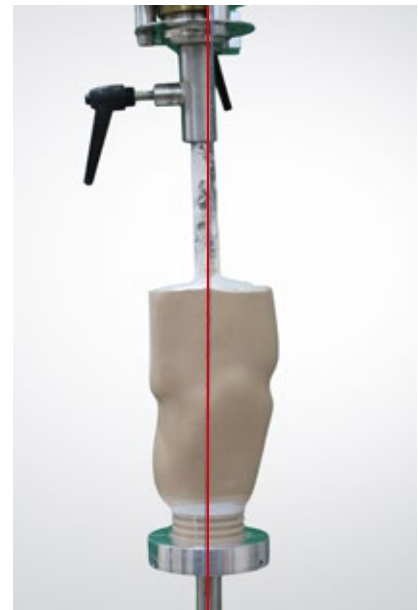


Fig 2

Fixation phase



Fig 3

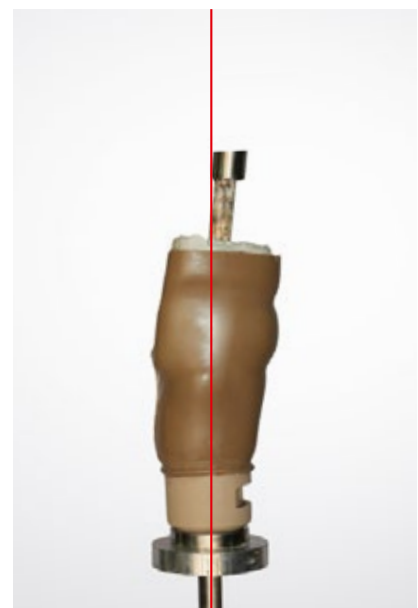


Fig 4

In the centre of the jig there are two components which allow the positioning in space and immobilization of the plaster positive model in relation to the position of the connection cup.

At the top: the ball and socket joint.
This allows:

- suspension and immobilization of the positive model;
- rotation around the pipe axis;
- anterior, posterior, and lateral and medial

Below: the tray. This immobilizes the socket connecting cup.

The height of the tray is adjustable. It is fixed on a vertical pylon, which represents the leg part of the future prosthesis.

To help the P&O technician visualize the component parts of the future prosthesis, a prosthetic foot is fixed to the lower end of this axis.

The alignment principles are independent of the length of the device.

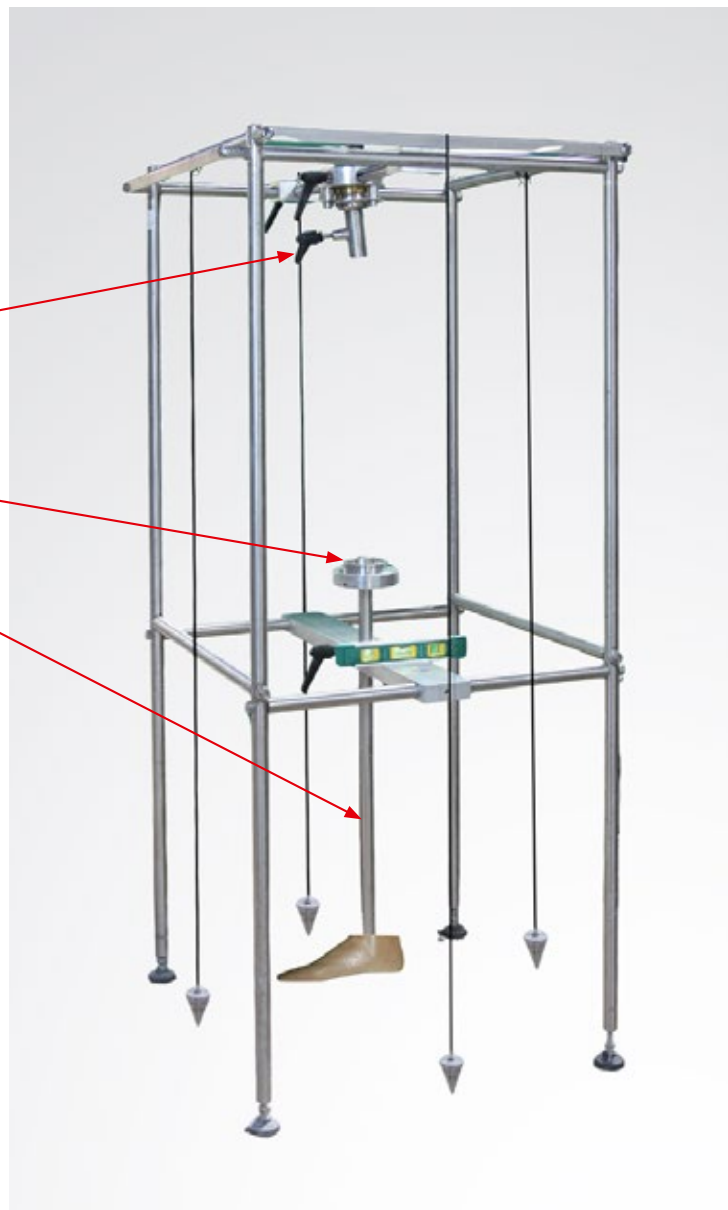


Fig 5

1.2 Possible movements for positioning the positive model in space (Fig 6)

Longitudinal movements

Lateral movements

Ball and socket for angular and rotation adjustments

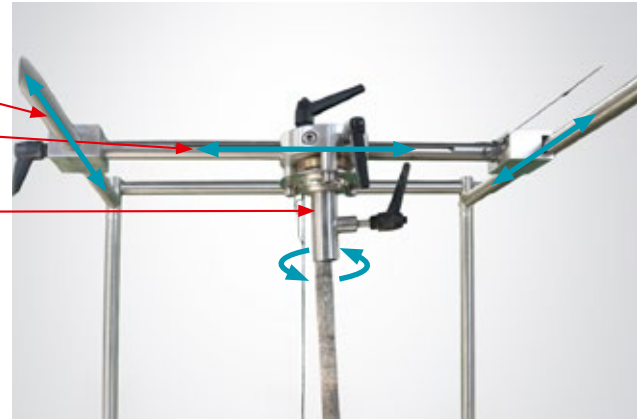


Fig 6

■ Locking handle for longitudinal movements.

■ Angulation of the pipe. The pipe can describe a cone of about 30° at the summit (about 15° from the vertical line).

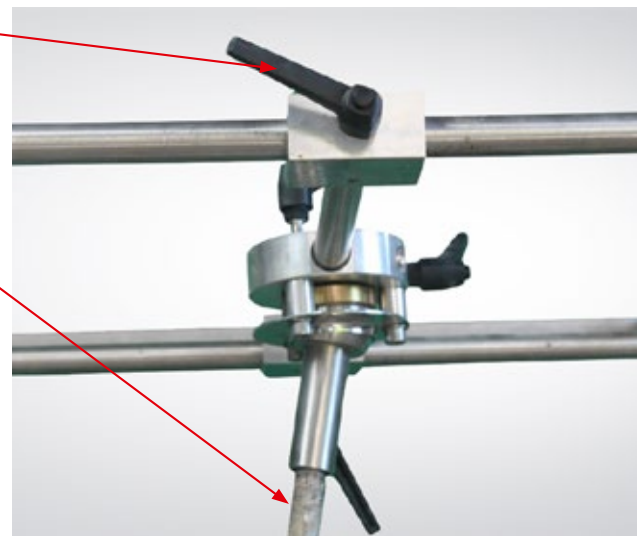


Fig 7

- The ball and socket allows correct positioning of the positive model even when the pipe is wrongly placed (Fig 8).

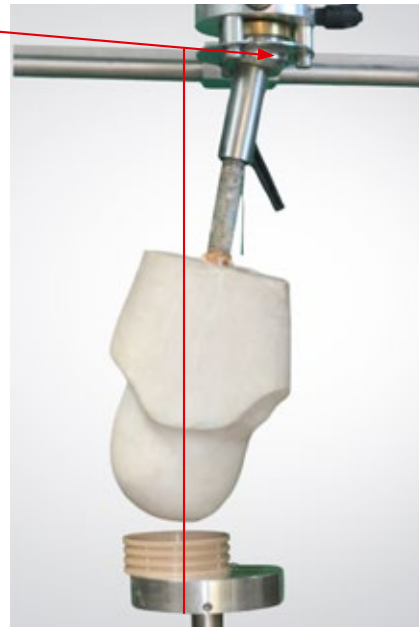


Fig 8

- Ball and socket details and locking screw.

Locking handle for rotation and angulation of the pipe carrier.

Locking handle for longitudinal movements

Handle for gripping of the pipe



Fig 9

2. Installation of the jig

Two precautions must be taken before starting to use the jig:

- Check with a spirit level that the central beam supporting the vertical axis (which in turn supports the tray) is perfectly horizontal, and make any necessary adjustments by means of the adjustable feet.
- Install plumb lines beyond the central beam.

By establishing frontal and sagittal planes, these plumb lines allow exact application of the principles of alignment.

■ Frontal and sagittal planes are established with plumb lines (x4) beyond the movements of the pipe carrier.

■ Check with a spirit level that the central beam is perfectly horizontal; adjust by means of adjustable feet.

■ Adjustable feet (x4)

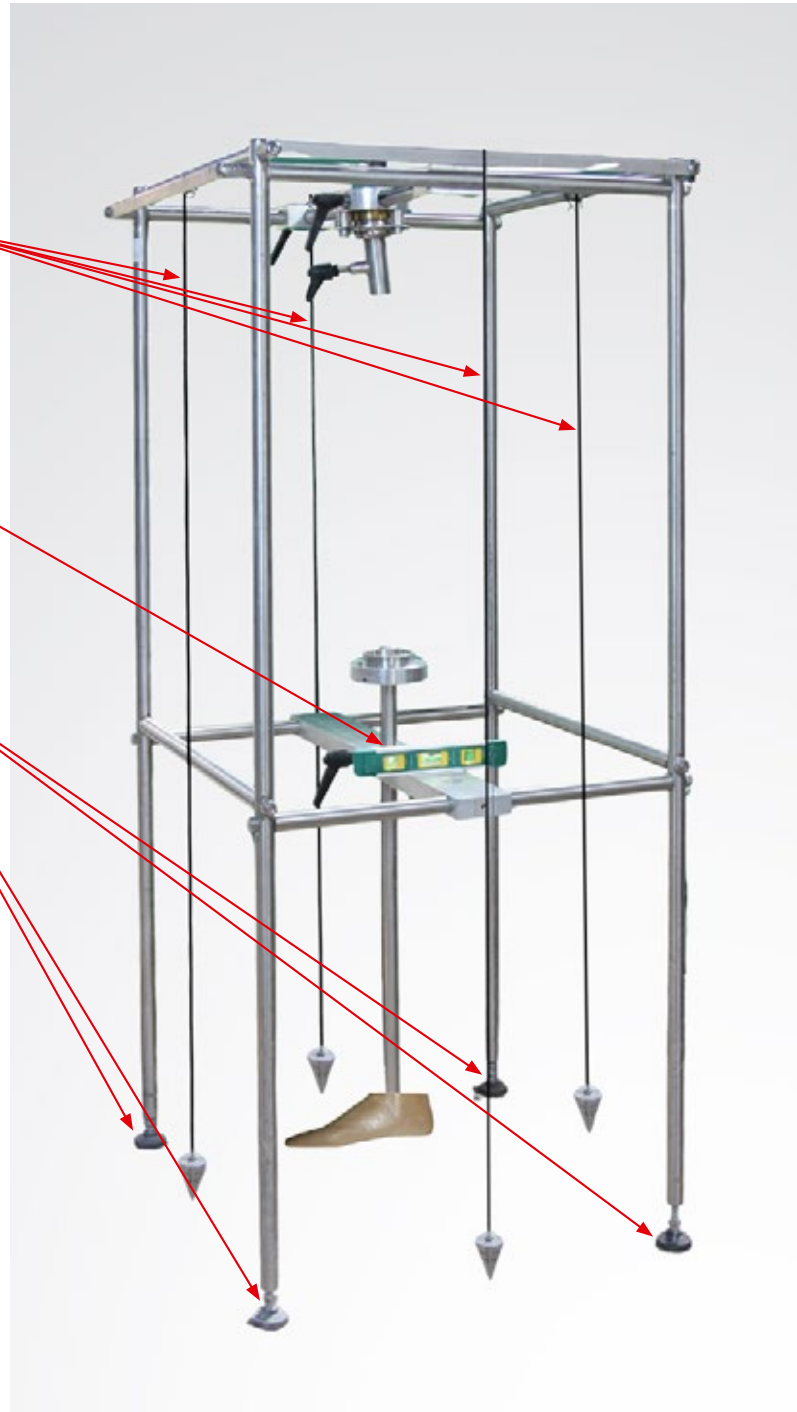


Fig 10

3. Choice and location of centring accessories

(A) The tray (Fig 11)

- The tray has 3 Ø M8 holes

The hole situated 2 cm from the centre is used for adult TF alignment.

The central hole is used for adult and child TT.

The hole situated 1 cm from the centre is used for child TF.

When used for adult TF, the positive model sagittal plane is perpendicular to the central beam, and when used for child TF, the positive model sagittal plane is parallel to the central beam.

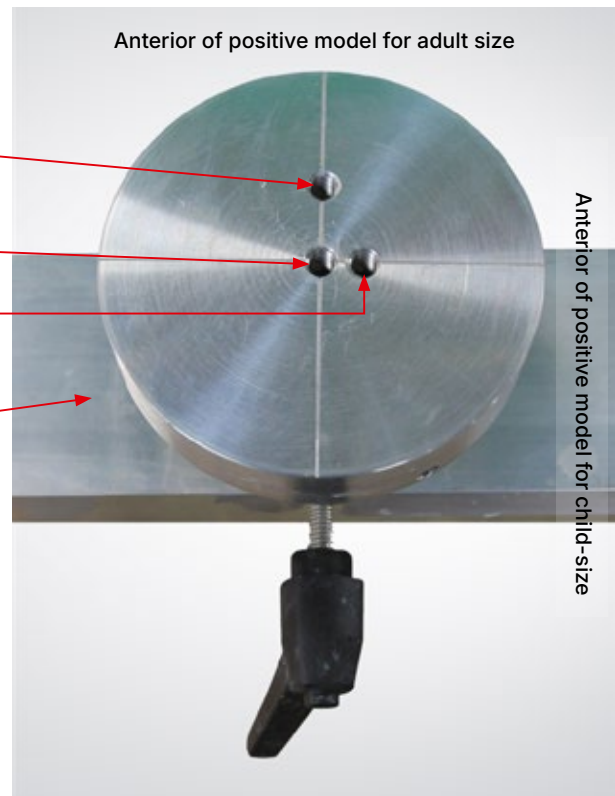


Fig 11

(B) Production by means of the "cup" (use of the centring cylinder)

Adult and child TT alignment
(Fig 12)

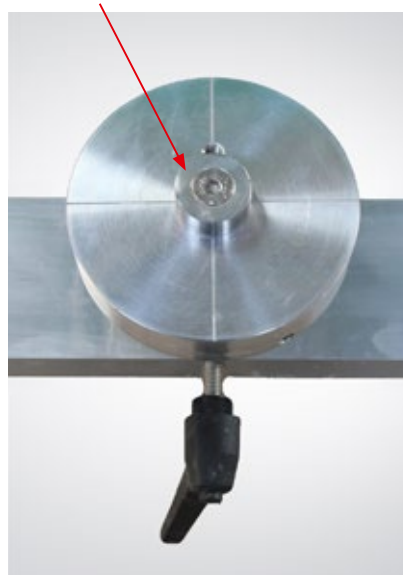


Fig 12

Adult TF alignment
(Fig 13)

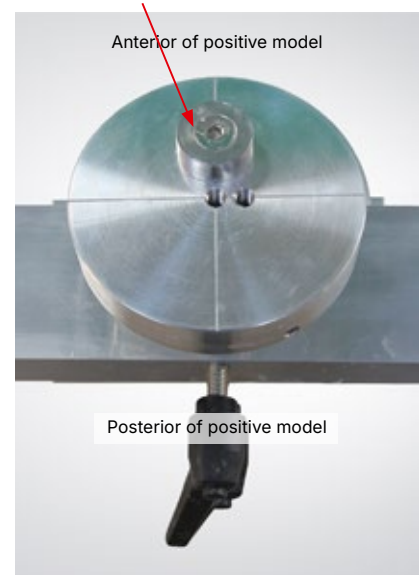


Fig 13

Child TF alignment
(Fig 14)

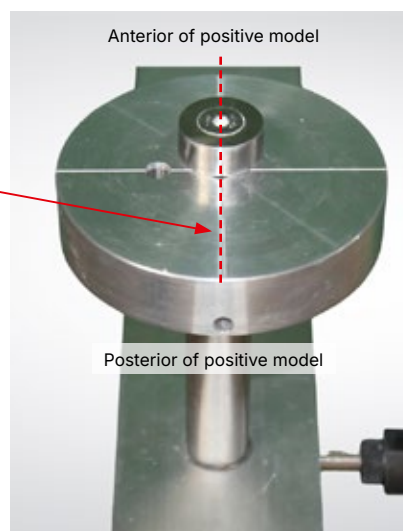


Fig 14

The connecting cup on the tray
(Fig 15)

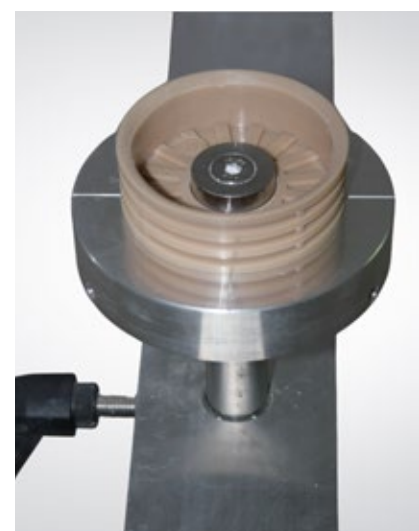


Fig 15

Central beam mid-line

(C) Production by means of the conical cup

The conical cup makes it possible to manufacture "full-contact sockets" (with contact on the entire surface of the stump, including the distal end).

The principles are the same; only the accessory is different.

The accessory for centring the conical cup is positioned for TT in the central hole (Fig 16).

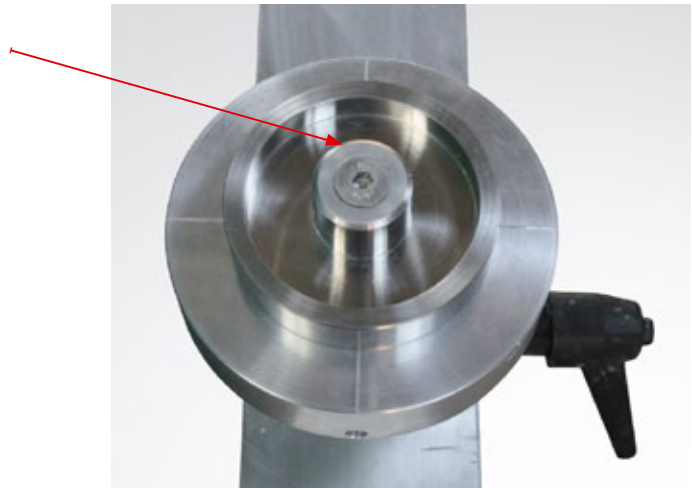


Fig 16

The conical cup positioned for adult TF (Fig 17).

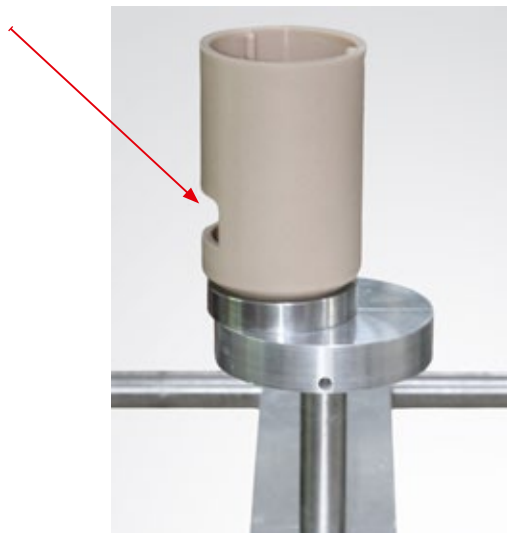


Fig 17

4. Some examples of use

Sockets without total contact

The connection cup is assembled with the positive model before the socket thermoforming operation (method most frequently used).

4.1 TT sockets

(A) Alignment of a short TT positive model (from Fig 18 to Fig 21)

View before joining

View after joining

Posterior view:

The picture is taken of the positive model without soft socket to make the shapes and marks of the positive model more clearly visible. The presence or absence of a soft socket has no effect on the alignment principles.

As a general rule, the mid-line at the level of the posterior shelf of the socket should be in line with the centre of the cup.

Socket abduction

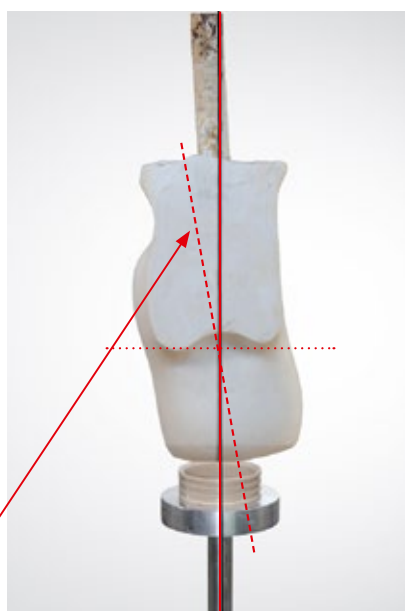


Fig 18

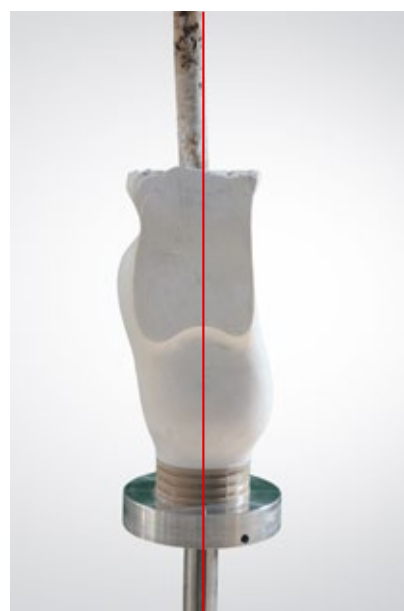


Fig 19

Lateral view:

As a general rule, the mid-line of the cast should be in line with the posterior 1/3 of the prosthetic foot.

Socket flexion

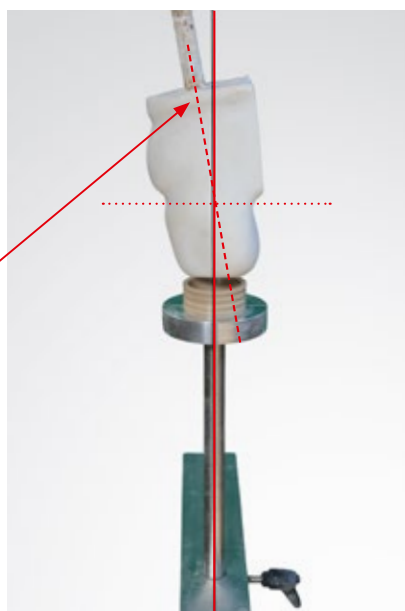


Fig 20

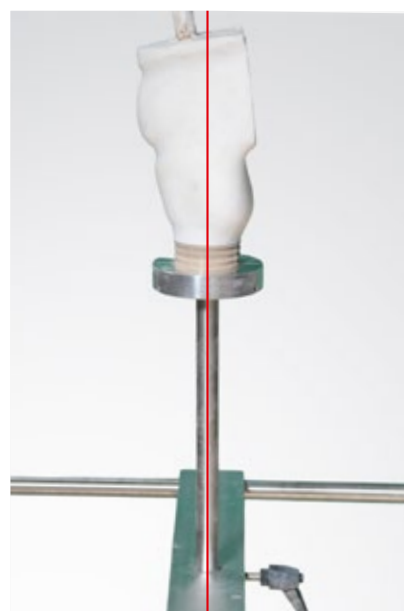


Fig 21

(B) Alignment of a long TT positive model (Fig 22 and Fig 23)

Lateral view before joining

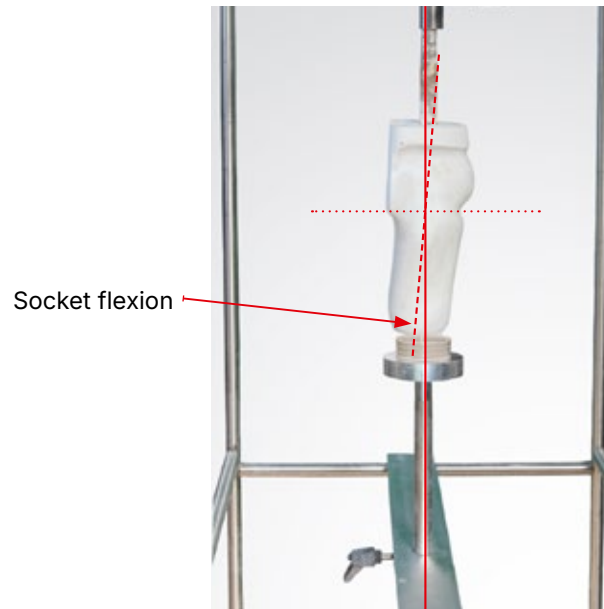


Fig 22

Posterior view after joining



Fig 23

4.2 TF sockets

(A) Parameters to be observed between the monocentric knee-joint and the alignment jig

- There is a 20 mm offset between the socket fixation screw and the knee axis to take the socket flexion into account.
- The knee axis is on the same vertical line as the stainless-steel pylon tube: (Fig 25).

The same positioning features are found on the alignment jig.

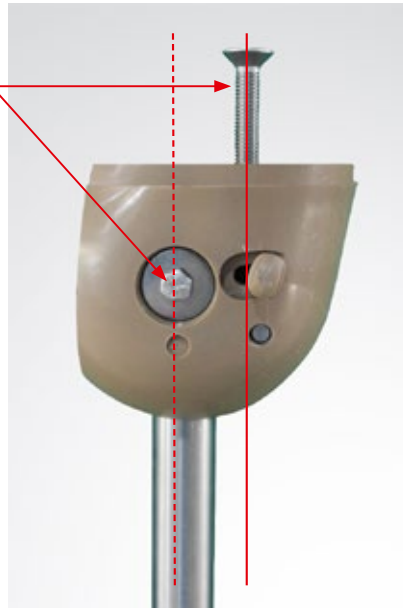


Fig 24

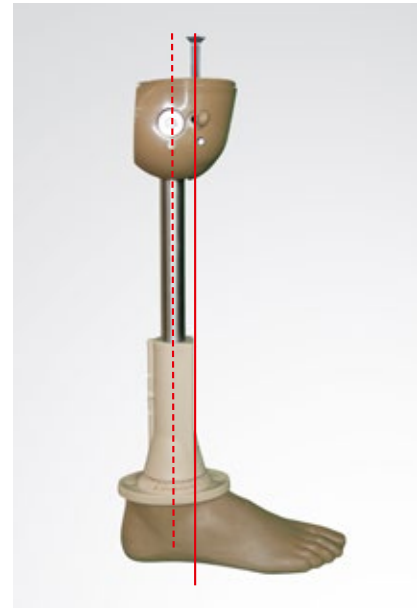


Fig 25

Dimensions to be determined (Fig 26):

- A** Device for adjusting alignment
22 mm (minimum)
- B** Distance between upper part of the knee
and knee axis
40 mm

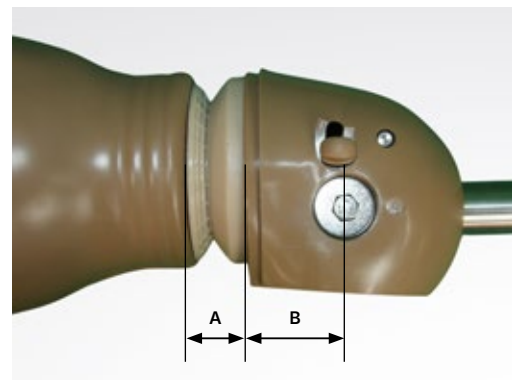


Fig 26

(B) Parameters to be observed between the polycentric knee-joint and the alignment jig

- There is a 15 mm offset between the socket fixation screw and the axis of the proximal anterior linkage joint to take the socket flexion into account (Fig 27).
- The proximal anterior linkage joint is on the same vertical line as the front edge of the pylon tube when it is vertical (Fig 28).

The same positioning features are found on the alignment jig.

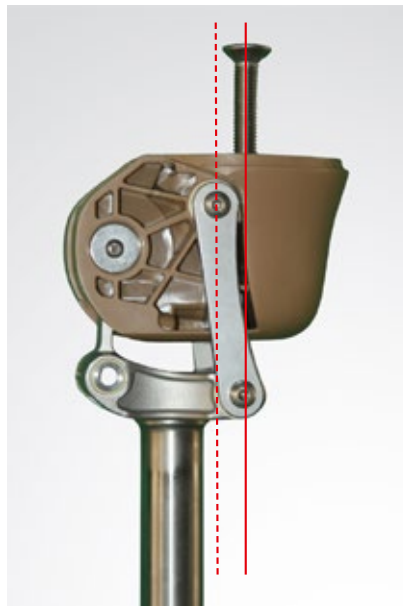


Fig 27



Fig 28

Dimensions to be determined (Fig 29):

- A** Device for adjusting alignment
22 mm (minimum)
- B** Distance between upper part of the knee-joint and knee anterior-proximal axis
20 mm

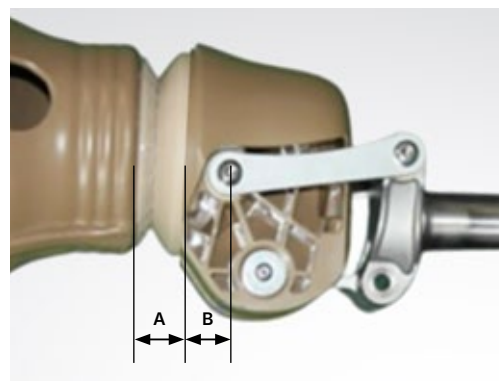


Fig 29

(C) Long stumps (Fig 30 and 31)

It is possible to adjust the distance from ischium to knee when the connection cup is being fixed by calculating height A in advance according to the details given above.

Posterior view before joining

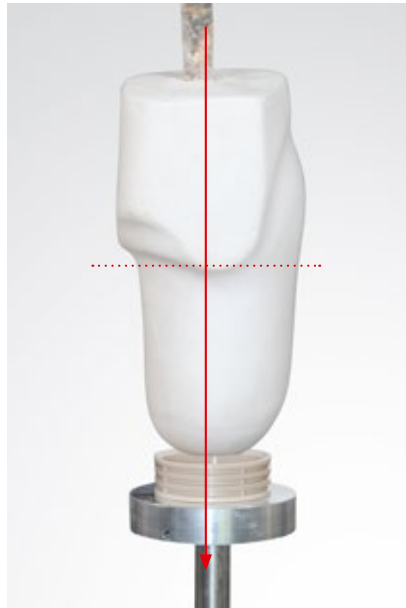


Fig 30

Medial view after joining

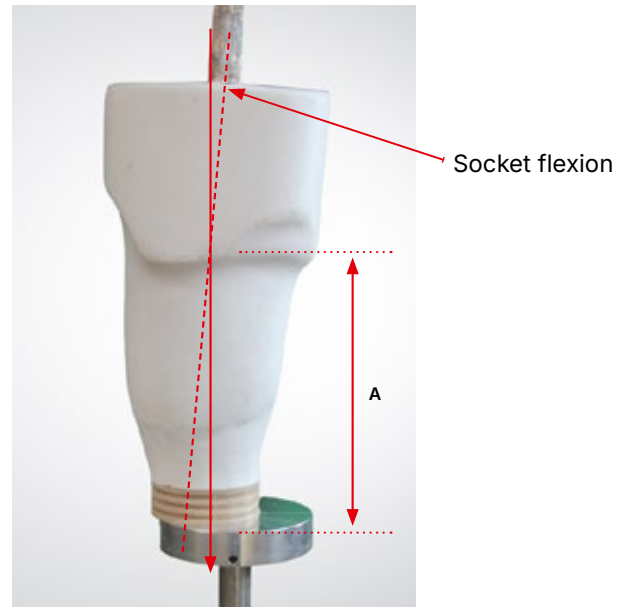


Fig 31

(D) Short stumps (Fig 32 and 33)

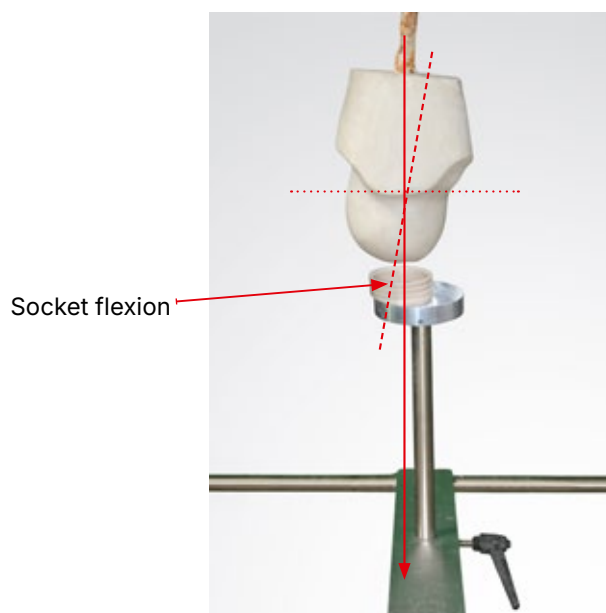


Fig 32

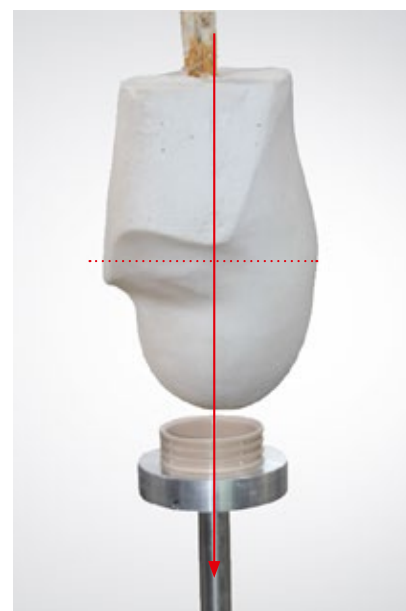


Fig 33

4.3 "Full-contact" sockets

The connecting element (the conical cup in this case) is assembled with the socket after the thermoforming operation.

Caution:

When using the conical cup as a connecting component with the "full-contact-socket", it is essential to exercise special care **to ensure the safety of the service user**. Reinforce the weld between the socket and the conical cup after thermoforming – the socket must be precisely adjusted according to the instructions and illustrations provided below.

Then, to further ensure the service user's safety:

- The welding should be performed with particular care;
- The service user should not be left alone during the fitting and alignment phases;
- Only polypropylene must be used for finishing so as to form an "exoskeleton" to guarantee the strength of the prosthesis.

The conical cup is easy to use:

- Align the socket according to the possibilities offered by the jig.
- Install in the tray the centring accessory designed for conical cups.
- Cut the conical cup at the desired length and give it the appropriate shape.
- Weld the conical cup to the socket lightly with a welding iron to hold the cup in position.
- Remove the assembly thus obtained.
- End with careful welding.

(A) TT socket (Fig 34 and 35)

Short TT socket (lateral view)

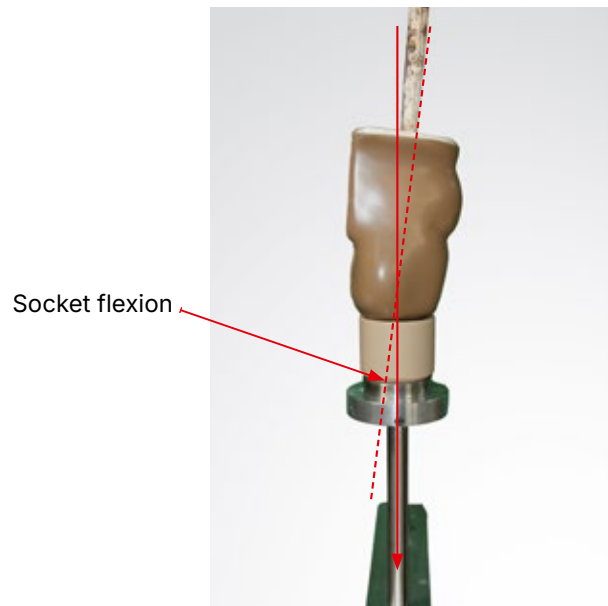


Fig 34

Long TT socket (posterior view)

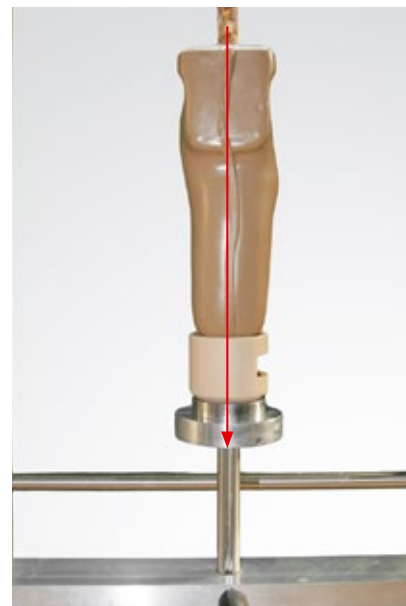


Fig 35

(B) TF socket (Fig 36 and 37)

Short TF socket (posterior view)



Fig 36

Long TF socket (medial view)

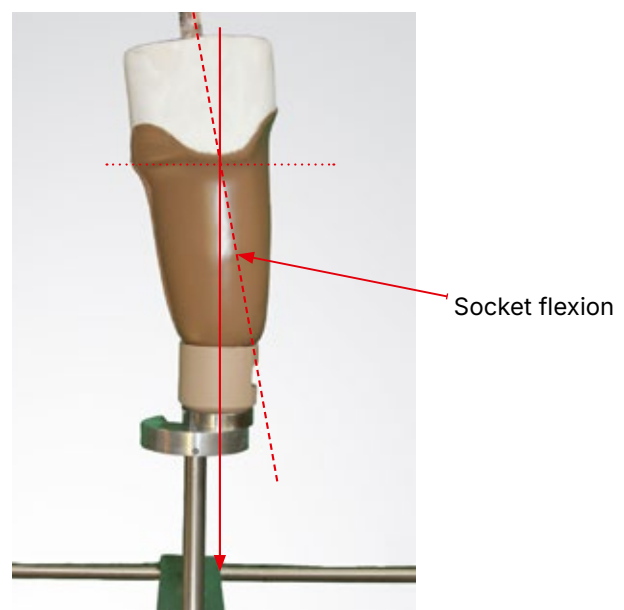


Fig 37

5. Constituent parts of the alignment jig

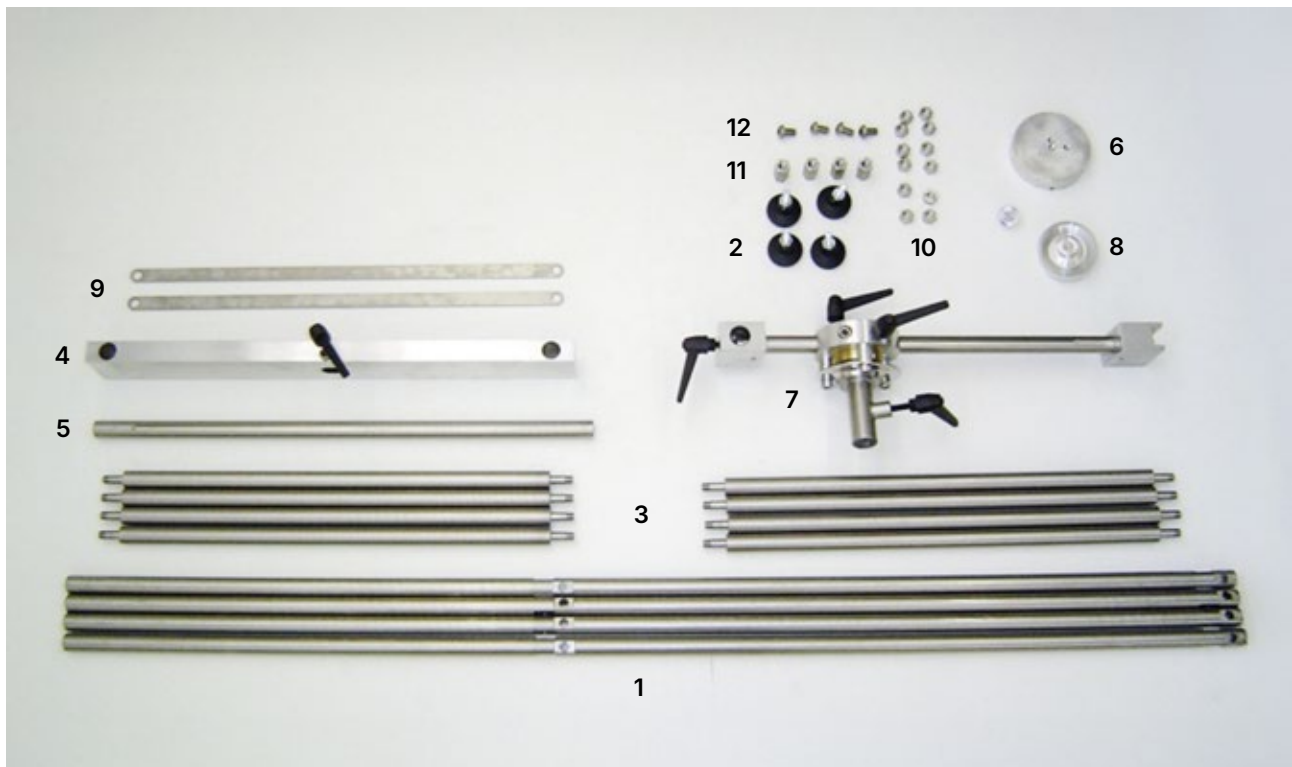


Fig 38

- | | |
|---|--|
| 1. Vertical uprights | 7. Ball and socket/upper displacement device |
| 2. Height adjustable feet | 8. Conical cup accessory/centering cup |
| 3. Horizontal bars | 9. Plumb line's support |
| 4. Central beam/bottom cross piece | 10. M12 nuts |
| 5. Vertical pylon/device for rise-descent | 11. Lengthened M12 nuts |
| 6. Tray/alignment plate | 12. M12 screws |

To assemble the alignment jig, you can see the ATP supply manual through this link: atpsupply.org

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