DOCUMENT TYPE	DOCUMENT OWNER	PRODUCT NAME
ManuaL	**GJM Tuijthof**	**3D Footplate**
TITLE	RELEASED BY	DATE
2.02.3D Footplate User manual	**GJM Tuijthof**	**11-07-2025**

Document change history

BY	DATE	VERSION	SUMMARY OF CHANGES
E. Masih	02-10-2024	01	First draft
E. Masih	12-12-2024	02	Update after feedback orthopedic surgeon
GJM Tuijthof	11-07-2025	03	Added front page, optimized layout
GJM Tuijthof	10-09-2025	03	Added mandatory text and symbols according to ISO 20417; ISO 15223; ISO 7000

WARNING: 3D FOOTPLATE IS INTENDED TO BE USED SOLELY BY QUALIFIED AND TRAINED HEALTHCARE PROFESSIONALS

WARNING: 3D FOOTPLATE IS TO BE MAINTENANCED BY QUALIFIED AND TRAINED PROFESSIONALS

WARNING: BEFORE TRANSPORT, CLOSE ALL TELESCOPIC CLAMPS

WARNING: DURING TRANSPORT, DO NOT TILT 3D FOOTPLATE

WARNING: 3D FOOTPLATE HAS NOT BEEN TESTED FOR DURABILITY, EXPECTED LIFETIME IS UNCLEAR

3D Footplate User manual

This document contains instructions for use (IFU) and troubleshooting of the 3D Footplate.

Intended use, performance and contraindications

The intended use of the 3D Footplate is to move and fixate the foot in a certain extreme position relative to the lower leg for a short period of time. The 3D Footplate offers a single mode of action. The 3D Footplate is to be used in combination with a CT-scanner or fluoroscopy to acquire images of patients foot in extreme positions. The 3D Footplate can aid in diagnosis ligament damage or laxity when normal imaging is inconclusive, in preoperative surgical planning and in research of the ankle. The clinical benefit is that the imaging in various extreme positions and subsequent segmentation and registration of the bone can provide quantitative information on ligament problems, or to assess range of motion of patients with ankle implants or arthrodesis.

The 3D Footplate operates in a single mode of action. The user first fixates the lower leg with velcro straps to the base frame, subsequently the foot is fixated with the velcro straps to the footplate, and finally the footplate is positioned in the required orientation in space and fixated with the levers of six telescopic clamps. The fixation is critical to achieve proper performance of the 3D Footplate, as the fixation should be sturdy and foot kept in place during imaging.

Contraindication for use of the 3D Footplate is patients without open wounds of their lower extremity.

Precautions

Please follow instructions for proper use

Take care of proper cleaning

Use the levers of the telescopic clamp with care and do not to overload it. This can be seen by excessive bending of the lever material

Carefully instruct patient to hold still during image acquisition

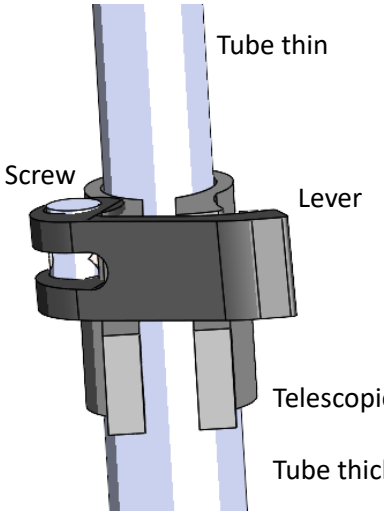
Take care of proper maintenance (see 2.02.3D Footplate Maintenance manual v1.0)

Do not use the 3D Footplate in the MRI

Check 3D Footplate

Before each use of the 3D Footplate, verify by visual inspection if all parts are present and if none of them is broken. Parts that are rather delicate are the levers of the telescopic clamps. In case parts are missing or broken, refrain from further use until all parts are replaced and visually verified for proper functionality.

Telescopic clamp calibration



If you are experiencing insufficient friction when the telescopic clamps are closed, it is important to calibrate the telescopic clamp.

CALIBRATION: Close the clamp with the lever as depicted left. Tighten the screw until it is not possible to move the inner rod anymore. Repeat for all six telescopic clamps.

Cleaning and disinfection

The 3D Footplate is reusable, and should be cleaned after each use.

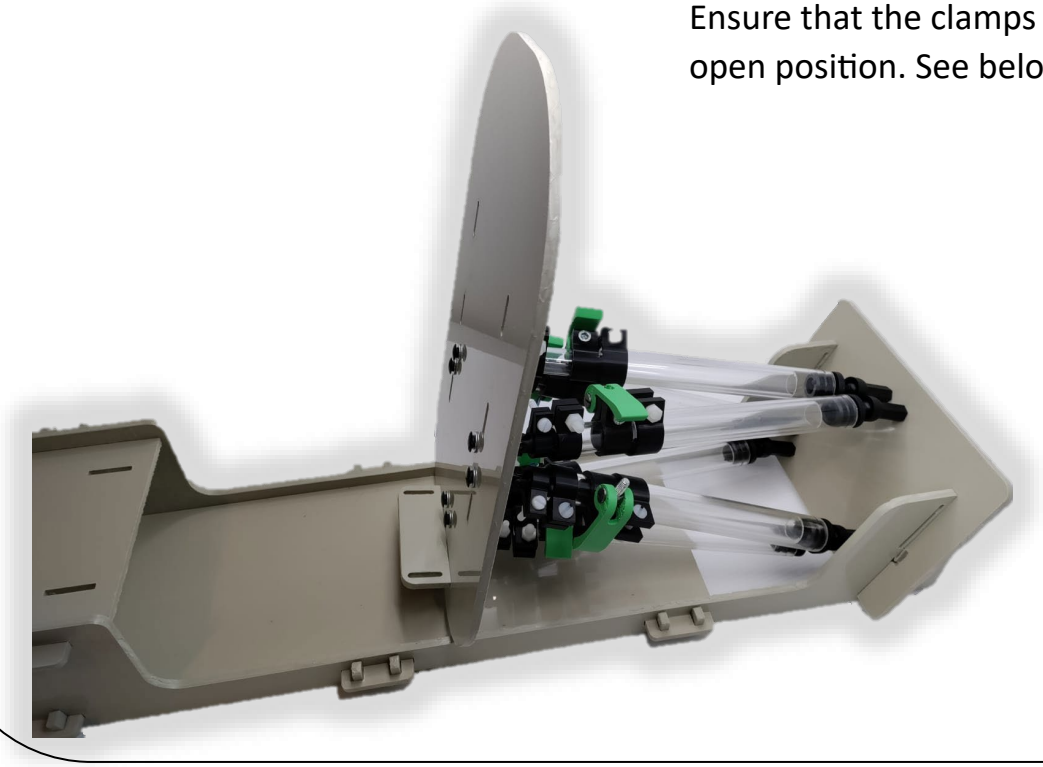
Perform cleaning and disinfection of the device before and after use.

1. Cover the PPMA tubes with a plastic tarp. Alcohol is not allowed on this part of the device.
2. Remove the screw caps and the Velcro straps from the foot plate. Use an alcohol-based disinfectant and a regular cloth to manually clean the front side of the actual footplate 3D Footplate. Do not forgot to disinfect the heel support.
3. Remove the Velcro straps from the leg rest. Use an alcohol-based disinfectant and a regular cloth to manually clean the top of leg rest.
4. When the alcohol has dried, place the screw caps and Velcro strap back on the device.

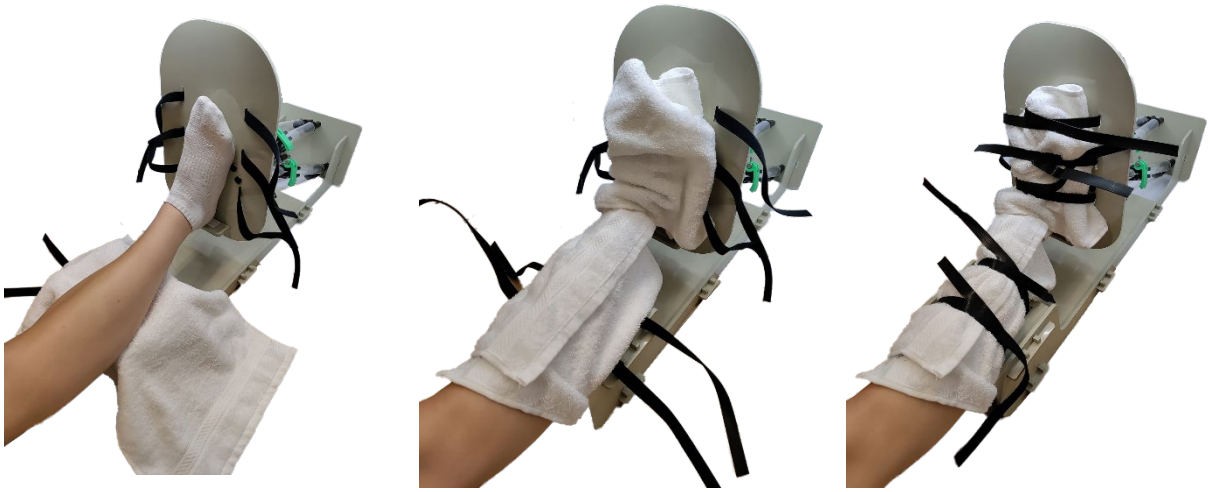
Instructions for use

Step 1: Neutral position

Put the device in neutral position. Ensure that the clamps are in the open position. See below:



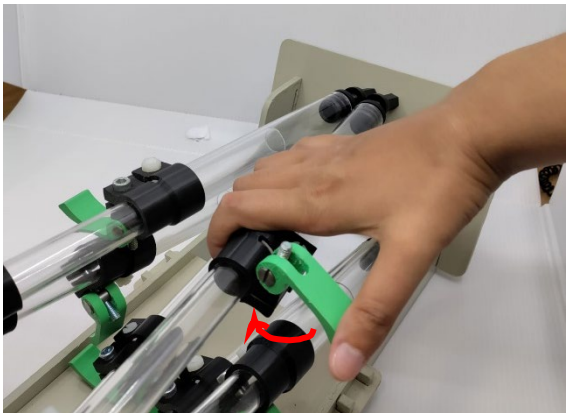
Step 2: Fixate the patient to the device

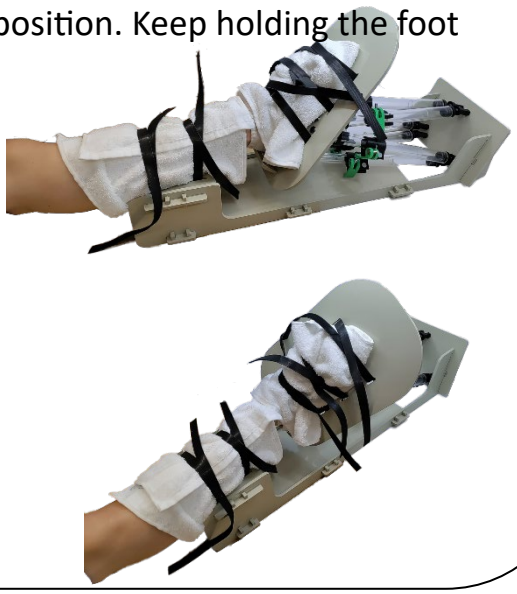


The patient puts lower leg and foot in position. Use towels as indicated above. Fixate the leg and foot to the device using the Velcro straps.

Step 3: Position and clamp fixation

Bring the foot with the footplate in the desired position. Keep holding the foot plate while closing all 6 clamps using the levers.





Step 4: Release foot

a) Hold the footplate
a) Open all 6 clamps one by one
b) Carefully bring the footplate back in the neutral position
c) Disconnect the foot and the lower leg from the device by releasing Velcro straps.

Instructions for transport

a) Slide the footplate towards its tilted base
b) Close all 6 clamps one by one
c) Pick up the 3D Footplate with two hands
d) Transport the 3D Footplate while taking care not to tilt it

Instructions for storage



5°C

25°C

Trouble shooting

- Thin tube is released from thick tube
  - Remove the foot of the patient. Assemble the tubes again in the following order: side tubes – upper tubes – lower tubes.
- Telescopic clamps are too tight/not tight enough to fixate
  - See calibration instruction
- Back plate breaks
  - Do **not** use the device, until broken part is replaced
- Other issues:
  - Do **not** use the device, until device is verified by a trained professional