Operating instructions
Stress device
GA III/E

acc. to Prof. Dr. G. Scheuba

telos

Designation of symbols

In this manual and/or on the device the following symbols are used:

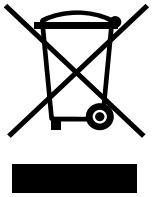
Attention – refer to the accompanying documents
Hints for the setup, maintenance and intended operation of the stress device, type GA **III**/E.
Must be observed to avoid bodily injuries, malfunctions or damage to your equipment.

Application part of type B
The device complies with the requirements of type B for protection against electrical shock.

Serial number of the device
The serial number is indicated to the right of the symbol.

Order number of the device
The order number is indicated to the right of the symbol.

The device complies with EC-Directive 93/42/EC (MDD)



Disposal (Recycling)

Manufacturer of the device
The name of the manufacturer is indicated to the right of the symbol.

Date of manufacture
The date of manufacture is indicated under the symbol.

Attention – refer to the accompanying documents
Hints for the setup, maintenance and intended operation of the stress device, type GA **III**/E.
Must be observed to avoid bodily injuries, malfunctions or damage to your equipment.

Table of contents

The accessories for the Stress Device depicted in various pictures are purely exemplary and may differ from what is actually delivered!

Safety Instructions

Please read the operating instructions carefully before operating the stress device.
This device is intended to be used in a professional healthcare environment by trained personnel only.

Prior to every use the device is to be checked for mechanical damage and proper function. If the damage is severe the device should not be used.

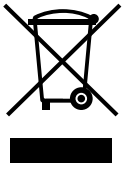
This device is manufactured and tested according to the current regulations for electrical and electromagnetical safety. In case you experience failures (e.g.: false reading or no display) caused by interference from other appliances, attempt to operate the stress device at a greater distance from the interfering appliance (see manufacturer's declaration regarding EMC on page 25).

After every use - especially where contact is made with injured skin - the device and all of its accessories should be cleaned and disinfected according to the locally applicable rules for proper hygiene.
For the purposes of cleaning and disinfection, any tested and local authority-approved wipe disinfectant available on the market can be used. Please adhere to the manufacturer's instructions for use.

Repair procedures may only be carried out by authorised personnel who are thoroughly familiar with the applicable safety regulations.
If necessary, it is recommended to have the device repaired by the manufacturer in order to maintain the warranty. For this device it is mandatory to perform frequent safety inspections (different regulations in other countries may apply).
For maintenance purposes it is recommended that the device be checked metrologically and if necessary recalibrated once a year by the manufacturer to maintain its accuracy.

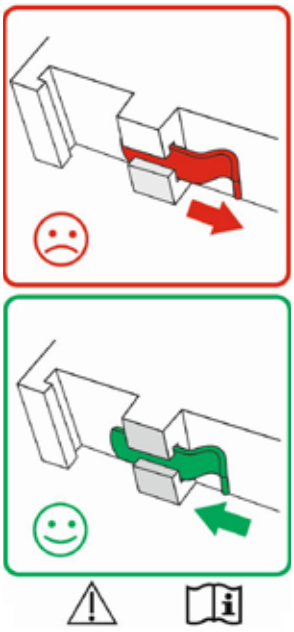
The minimum working life of the device is 5 years. After that period the device can be returned to the manufacturer for recycling purposes free of charge.

Please note that batteries and electronic parts in particular should not be disposed of in regular waste, and that they have to be disposed of according to local legal regulations.



Devices that are marked with the symbol on the left may not be disposed of with regular household waste, but must instead be disposed of at a recycling collection point for electrical and electronic waste.

All parts with the corresponding numbers of the stress device mentioned in the following text are further explained on page 8 and 9.



At the bottom of the pressure support **1** a safety latch **1.6** is mounted. This safety latch **1.6** secures the pressure support **1** from falling down off the guide rail **2.4** of the frame **2** unintentionally during operation of the stress device.
To mount the pressure support **1** onto the guide rail **2.4** slide the safety latch **1.6** until reaching the stop in the direction of the turning grip **1.8**.
If the position of the pressure support **1** on the guide rail **2.4** is correct, slide the safety latch **1.6** in the opposite direction (towards the display cover **1.4**) until reaching the stop. In this position of the safety latch **1.6** the risk of the pressure support **1** falling down during operation of the entire device is almost completely ruled out.

After using the pressure support **1**, the frame **2** and all other accessories should be carried separately to their place of storage.

It is not recommended to carry the pressure support 1 while it is attached to the guide rail 2.4 of the frame 2!

Do not immerse the stress device in water!

Do not spray cleaning agents onto the stress device!

Do not use any lubricants on the stress device!

Technical Data GA III/E

Manufacturer: telos Arzt- und
Krankenhausbedarf GmbH
Ottostraße 2
61200 Wölfersheim / Germany
Phone: +49 60 36 97 05 0
E-Mail: info@telos-gmbh.com
Internet:
www.telos-stress-device.com

Model:
telos-Stress-Device

Type:
GA **III**/E

Protection type:
B (= live parts feature only a single level of insulation against exposed metal parts)

The device complies with the requirements of type B for protection against electrical shock and is marked with the adjacent symbol.

Power Supply:
4.5 V DC through
3 x 1.5 V batteries (type AA/LR6)

Environmental conditions for
- storage: +10 to +40 °C, 85 % humidity. If the device is not used for more than 4 weeks it is recommended to remove the batteries (see „Changing the batteries“) and store them separately. Please observe the instructions from the batteries‘ manufacturer for storage of the batteries.
- **use**: +10 to +40 °C, 85 % humidity
- **transport**: -20 to +60 °C, 85 % humidity
All values apply for normal atmospheric pressure (transport by air is permissible).

Classification:
acc. Annex VIII MDR 2017/745/EC: I

Dimensions (Width x Depth x Height):
Min. space requirement for device:
500 x 650 x 220 mm
Dimensions of the transport and storage case:
557 x 410 x 175 mm

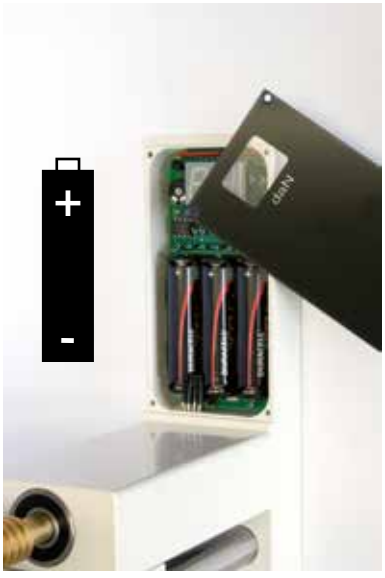
Weight:

Device w/o accessories in case:	10.1 kg
Accessories:	3.8 kg
Device complete in case:	13.9 kg

Changing the batteries

Remove the 4 screws of the front cover.

Remove the 3 batteries (type AA/LR6).



Insert the new batteries (please note the correct polarity). Replace the front cover and fasten the screws (tighten carefully).

Do not use rechargeable batteries (accumulators).

Stress device

The type of ligament rupture depends on the direction, speed and force impacting on the ligament or its attachments to the cartilage or bone.

X-rays can only reveal the injury when the ligament rupture is located at the bone and contains an avulsion. Normally, ligament rupture can be demonstrated by a stress X-ray. This procedure is designed to provoke an extreme positioning of the joint so that a dislocation (opening or subluxation) can be made visible. For each joint routine methods have been developed which have allowed the acquisition of standardised diagnostics.

For a proper functional diagnostic examination, all the biomechanically relevant joint stabilising factors must be considered, which include:

1. the specific anatomy of the joint
2. the muscles
3. the capsular ligament structures

For a proper assessment of the ligament, point 1 and 2 need consideration in particular, i.e. the patient must be positioned in such a way that the muscles are completely relaxed and when specific stress is applied to the joint anatomy the mobility is not restricted.

The Telos unit is designed so that with the correct positioning and regulation-compliant equipping of the device the anatomically determined joint stabilisation does not hinder mobility. Any muscular compensation becomes visible on the electronic display and can be checked simply by palpation.

Before considering taking a stress X-ray, native X-rays are taken in two different planes to rule out any fracture of the bone, if this is clinically suspected. In such cases, a stress X-ray is contraindicated.

The most common ligament injuries are those of the anterior ankle joint ligaments (fibular side), mostly caused by supination trauma. Injuries of the medial ligaments by pronation trauma occur rather rarely and are mostly accompanied by a fracture of the fibula.

The anterior ankle joint consists of the distal ends of the two bones of the lower leg (tibia and fibula), and one tarsal bone, the talus.

The anterior ankle joint is a hinge articulation that is equipped with collateral ligaments. These ligaments are characterised by their fanlike attachments which split up into several components that are fixed at different points on the tarsus. Therefore, one ligament is always tense to stabilise the ankle irrespective of the position in which the lower leg and the foot move.

The stress device allows for separate examination of each ligament

It is recommended to start with the examination of the ligamentum talofibulare anterius, since this ligament is usually ruptured first with a typical supination trauma. The examination is also less strenuous for the patient.

The ligamentum talofibulare anterius is examined in a lateral position through a subluxation of the talus into the ventral direction (The heel is fixed, the pressure is applied on the tibia.). Due to the proper positioning of the patient, the foot is flexed in the plantar direction (lig. talofibulare anterius is in function), characterised by the origin of the ventral tibia condyle being shifted to the vertex of the trochlea of the talus. Thus the stabilisation by the anatomy of the joint is reduced.

While applying pressure, the foot turns slightly inwards, the tibia outwards (only possible if the knee is flexed by at least 30°) around the pivot of the delta ligament suspension.

In order to obtain accurate findings, the X-ray needs to be taken after one minute in this case, because the talus slowly slides in the ventral direction.

The examination of the ligamentum calcaneofibulare is performed in anterior/posterior view by measuring the opening angle between the tibia and the talus.

Because of the previously described positioning, the foot is now oriented in a perpendicular position to the tibia (lig. calcaneofibulare is in function). The flexion of the knee entails a rectangular positioning of the tibia und calcaneus, so that the dorsally tapered talus is firmly fixed in the malleolar furca.
With a simple tilting motion the talus could get jammed in the furca. This problem is solved through the construction of the foot holding device. The heel is placed excentrically to the pivot of the foot holding device which in addition to tilting also pulls, thus pulling the talus out of the furca beyond the pivot of the ligamentum deltoideum.

Moreover, flexion of the knee prevents a pain-relieving hip turning motion of the patient. As to the examination of the medial ligaments of the anterior ankle joint (lig. deltoideum), the biomechanical problems are the same.

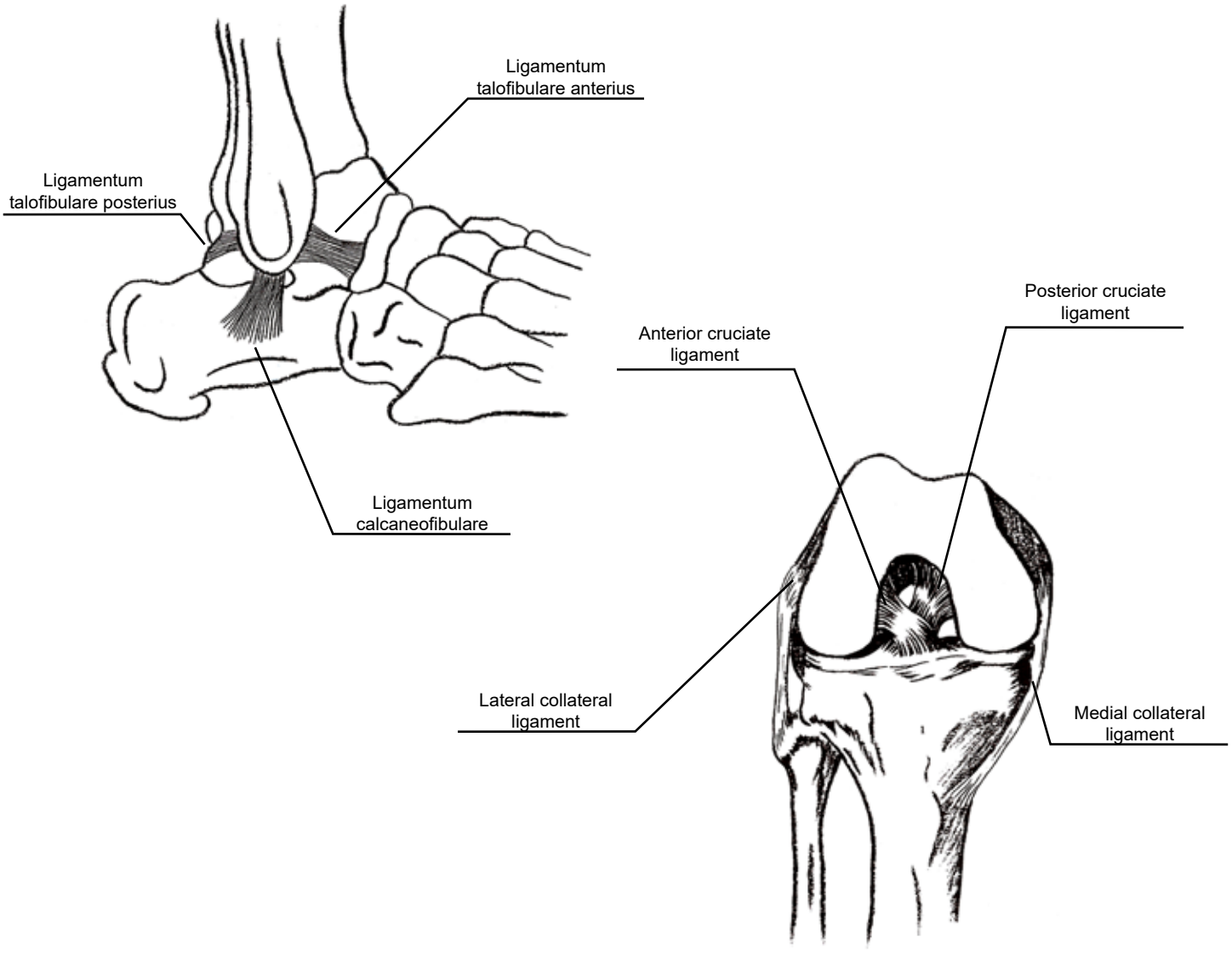
The stress applied in all the stress radiograph examinations should not exceed 15 daN. This is merely an empirical value which is internationally accepted. Studies performed under fluoroscopic control have shown that the joint opens at values between 6 daN and 7 daN when the ligament to be examined is ruptured. A higher stress than 15 daN is not advisable, because muscular tensing also then increases due to the pain.

If an X-ray is not taken with the recommended stress, the load actually used should be recorded on the image to prevent the examining physician from making a false diagnosis. Comparative X-rays of the contralateral side should always be taken under the same stress conditions.

When mounting the equipment, please follow the schematic drawings which depict the stress device from above. It is important that each accessory is mounted as depicted.

When examining the collateral ligaments of the knee the patient is in a sitting position, meaning that a desired flexion of 15° to 20° can easily be achieved due to the construction. An extension of flexion to 30° can also easily be achieved. If the knee needs to be examined while extended, supine positioning of the patient in combination with supporting the heel by a cushion is recommended.

The design of the stress device also allows for examining the cruciate ligaments of the knee while rotating the tibia inwards or outwards. A disadvantage with this procedure, however, is that the examiner may be exposed to indirect X-ray radiation since he has to manually maintain the inner or outer rotation of the tibia while the examination is taking place.



Instructions for use

The stress device consists of a frame **2**, with movable extension arms **2.2**, which can be adjusted to the length of the leg. The frame has four elastic footings **2.3**, so that the device stands firmly on the X-ray table. The extension arms **2.2** contain four guide bushes **2.1** into which a counter support **4**, the foot holding device **3** and other accessories may be mounted.

The pressure support **1** is equipped with electronic measuring equipment and is used to apply stress to the joint. The value of the stress is indicated by the digital display **1.3**. The values shown indicate the stress applied in decaNewton (daN) (e. g. read-out 15 = 15 daN). The electronic measuring equipment is powered by three commercially available batteries. It consumes very little power when the device is switched off, meaning that the display can work well for years.
If alkaline batteries are used, the lifetime will be approximately 150 - 200 hours of use. To avoid damage, the batteries should be removed if the device is not in use for a longer period of time. The light intensity of the display is controlled independently of the charging state of the batteries.

If the batteries need to be replaced, the display will start to blink, thus informing the user that the batteries need replacing. The display will still, however, show the correct values. If the charging state of the batteries decreases further, the display will show ’88’ and blink, so that false measurements can no longer be displayed. Although the electronics are quite shock-resistant it is advisable to handle the stress device as carefully as any other precision equipment, and it should not be sprayed with any solvents.

To apply stress the turning grip **1.8** is turned clockwise until the desired readout is reached. The pressure support has a built-in rapid repositioning function which can be operated by actuating the quick-release button **1.5**. This function allows long courses to be traversed quickly.

Do not use the rapid repositioning function if there is a pressure readout on the display!

Turn the turning grip counter-clockwise until the display shuts off (= no pressure) and then use the rapid repositioning function.

If the spatial proportion is appropriate it is recommended to turn the device 180° and leave the patient in his position when changing the sides to be examined.

1. Pressure support

1.1 Front cushion
1.2 Extension
1.3 Digital Display
1.4 Display cover
1.5 Quick release button
1.6 Safety latch
1.7 Guiding shaft
1.8 Turning grip
1.9 Threaded spindle

2. Frame

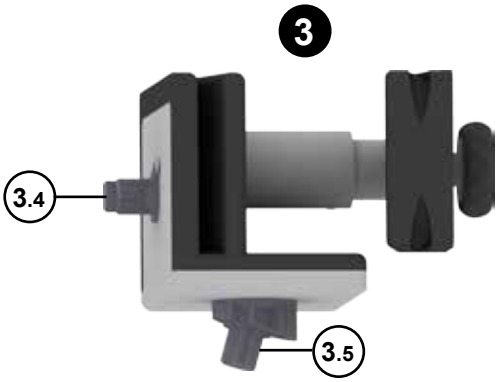
2.1 Guide bush
2.2 Extension arm
2.3 Elastic footings
2.4 Guide rail

3. Foot holding device

3.1 Fastening screw
3.2 Swivel clamp
3.3 Fastening cushion
3.4 Socket pin (for lateral X-ray)
3.5 Socket pin (for a.-p.-X-ray)
3.6 Reducer

4. Counter-support

4.1 Rounded cushion
4.2 Socket pin

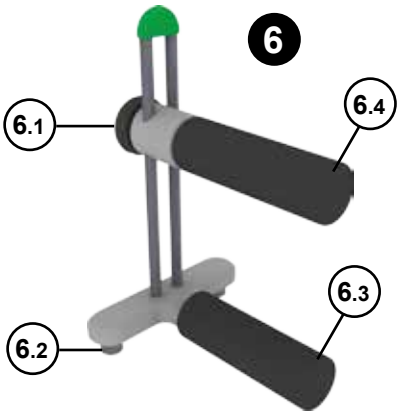


5. Extension bar

5.1 Socket pin
5.2 Guide bush

6. „Back drawer“

6.1 Fastening screw
6.2 Socket pin
6.3 Rounded cushion (fixed)
6.4 Rounded cushion (adjustable)



The working principle of the stress device is based on a lever action with two fixed points. For examination of the ankle joint the foot holding device **3** and one counter-support **4** are used.

The use of the reducer **3.6** is recommended for patients with very small feet (e.g. children). The foot holding device **3** has two socket pins **3.4** and **3.5**. The axial pin **3.4** is used for taking X-rays in lateral view, the slanted (15°) pin **3.5** is used for taking X-rays in a.-p.-view.

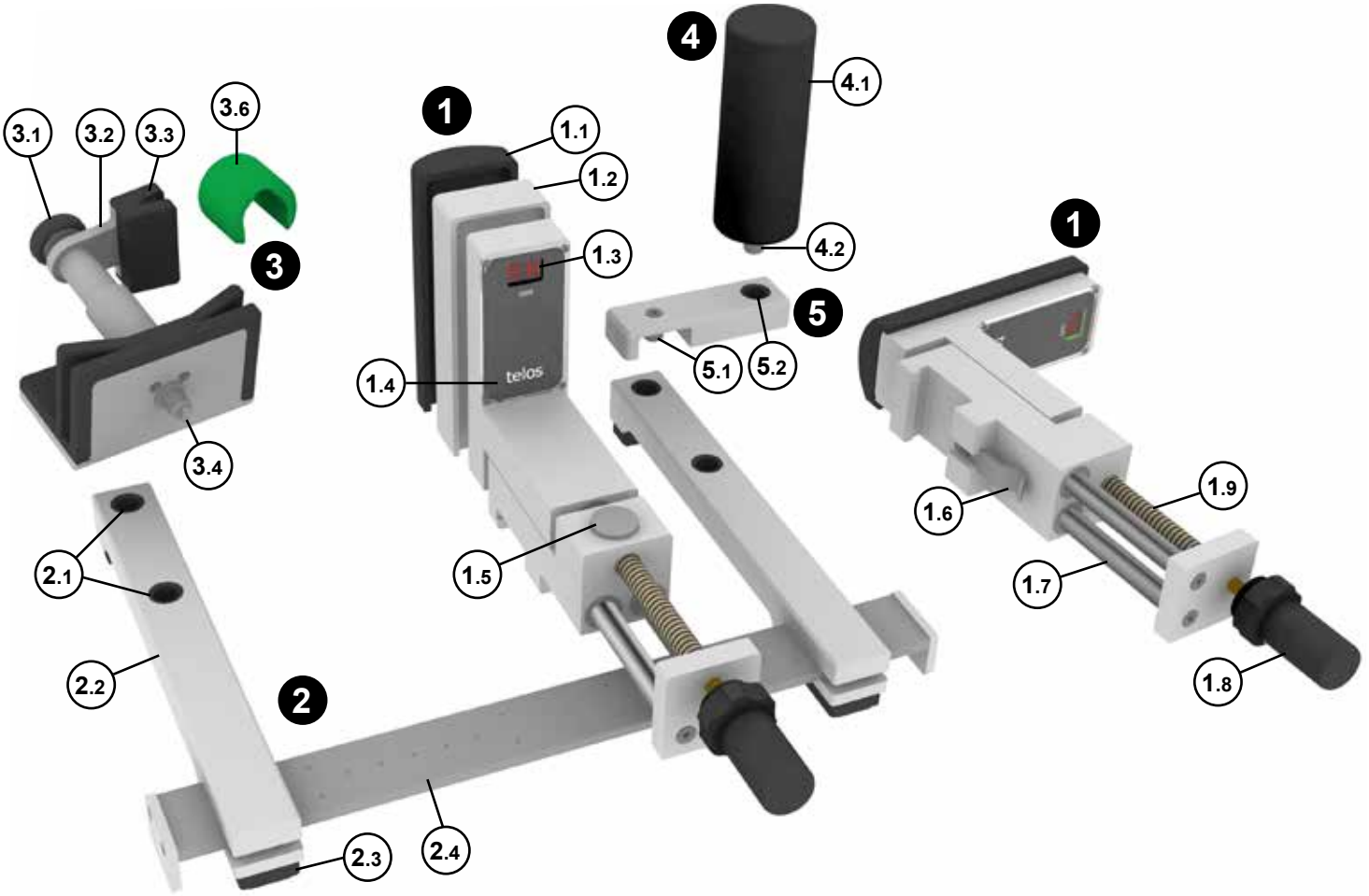
The fixation unit **3.2** is used to secure the heel into the foot holding device during examinations in a.-p. -view only.
Examination of the collateral ligaments and the cruciate ligaments is done using the extension **1.2** and two counter-supports **4**.

The extension bar **5** holds a counter-support **4** and is needed to examine the cruciate ligaments in 10°-20° flexion (Lachman's test) as well as the anterior cruciate ligament in 90°-position (anterior drawer).

The accessory „Back Drawer" **6** is used for the examination of the posterior cruciate ligament in a 90°-position only. This clamp serves to fix the thigh distal to the femoral condyles. The antipole represents one counter-support **4**.

When mounting the pressure device 1 on the guide rail 2.4 of the frame, please secure the pressure device by sliding the safety latch 1.6 located at the bottom forward in order to avoid tilting of the pressure support off the guide rail 2.4!

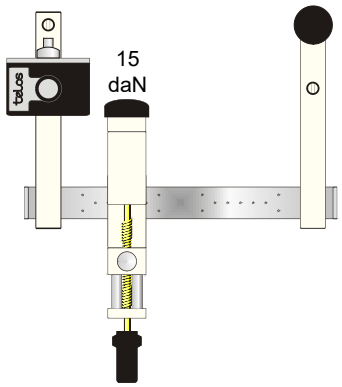
Transport and storage case



Examination of the ligamentum talofibulare anterius

Talocalcaneal joint in lateral view

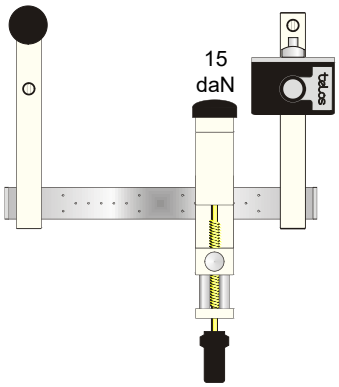
Device setup for the left leg



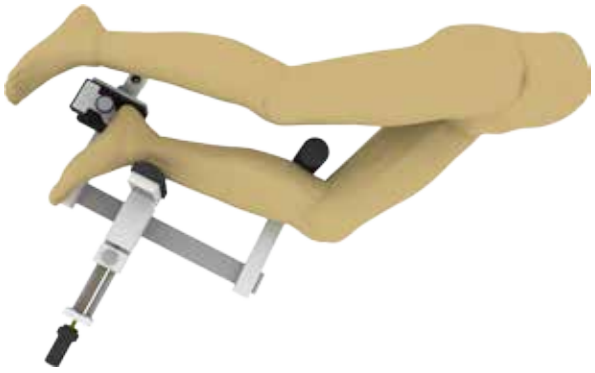
Please note

- Mount the foot holder to the extension arm by fitting the axial socket pin into the inner guide bush so that it cannot turn.
- Mount a counter-support in the outer guide bush of the opposite arm.
- Put the patient in a lateral position with the knee flexed at 30° (the leg is seen from medial).
- The heel must be placed firmly against the centre bar of the foot holder.
- Place the front cushion of the pressure support approx. 5 cm above the inner maleolus (see X-ray).
- Stress for routine examination: 15 daN.
- The X-ray should be taken after 1 minute of stress application.

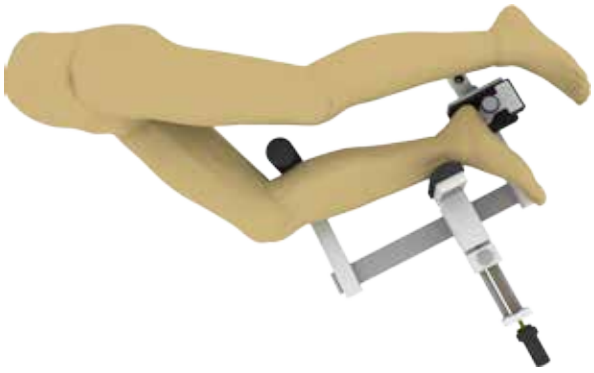
Device setup for the right leg



Positioning of the patient for the left leg



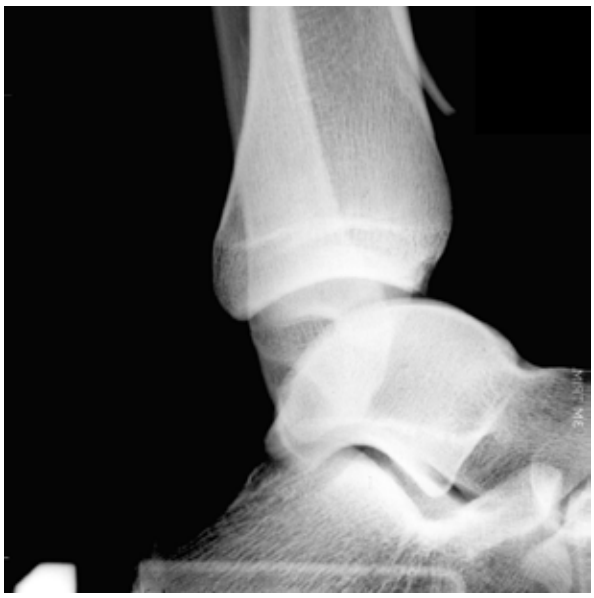
Positioning of the patient for the right leg



Information for diagnostics

The subluxation of the talus in the ventral direction is measured

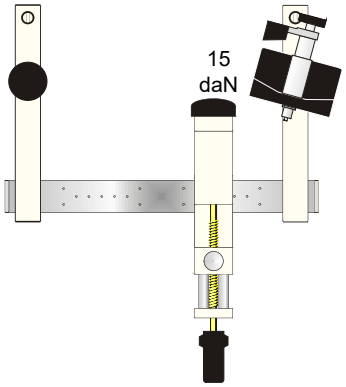
- The distance between the rearmost part of the tibia joint surface to the nearest point of the talus surface is measured.
- More than 10 mm = positive findings according to the actual state of medical scientific knowledge.
- With a clinically relevant measurement of 5 - 10 mm a comparative X-ray is recommended.



Examination of the ligamentum calcaneofibulare

Talocalcaneal joint in a.-p.-view

Device setup for the left leg

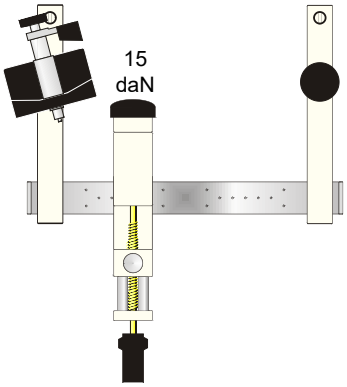


Positioning of the patient for the left leg

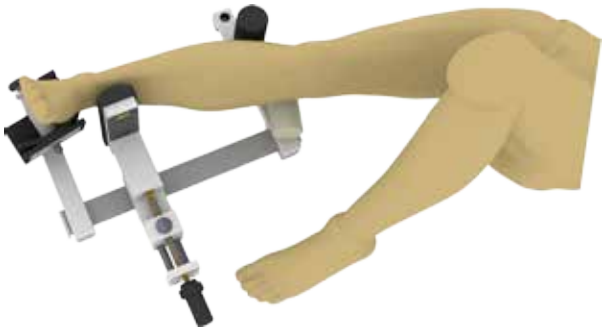
Please note

- Mount the 15° slanted pin of the foot holder into the inner guide bush.
- Mount the counter-support into the opposite guide bush.
- Sit the patient with his knee approx. 20° flexed (supported with a cushion under the hollow of the knee).
- The heel should be placed firmly against the centre bar of the foot holder.
- Fix the heel by using the swivel clamp and turning the fastening screw clockwise.
- Place the front cushion of the pressure support approx. 5 cm above the inner maleolus (see X-ray).
- Stress for routine examination: 15 daN.

Device setup for the right leg



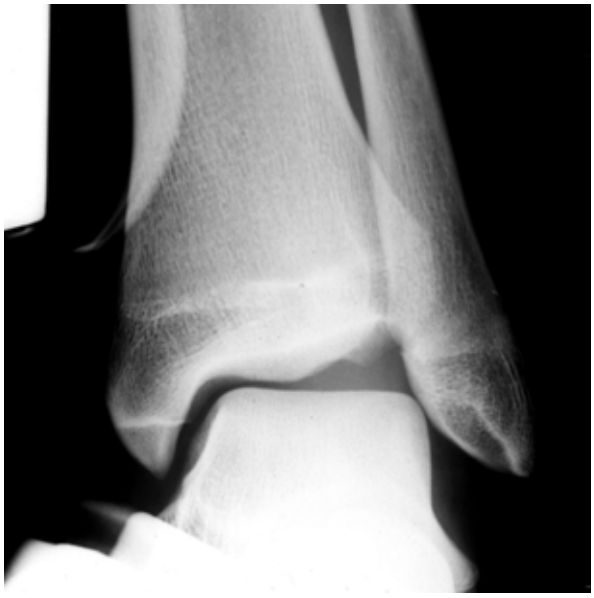
Positioning of the patient for the right leg



Information for diagnostics

The opening angle between the tibia and the talus is measured

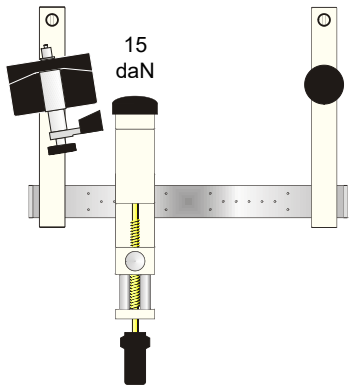
- A value above 10° is pathological according to the current state of medical scientific knowledge.
- A value between 5 - 10° makes a comparative X-ray necessary.
- In addition, a difference in the distances between the tip of the fibula and the talus (comparative X-ray) can also be evaluated as another sign for a rupture.



Examination of the ligamentum deltoideum

Talocalcaneal joint in a.-p.-view

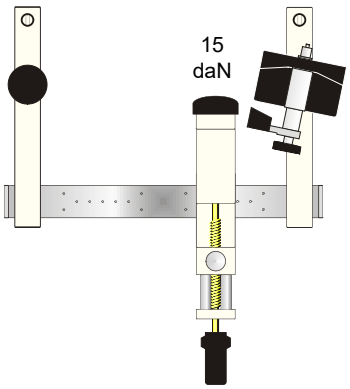
Device setup for the left leg



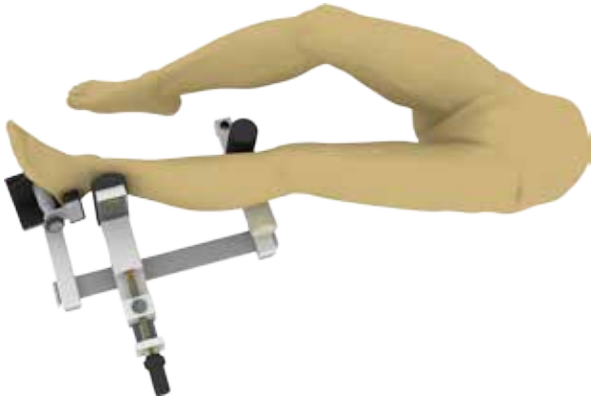
Please note

- Mount the 15° slanted pin of the foot holder into the inner guide bush.
- Mount the counter-support into the opposite guide bush.
- Sit the patient with his knee approx. 20° flexed (supported with a cushion under the hollow of the knee).
- The heel should be placed firmly against the centre bar of the foot holder.
- Fix the heel by using the swivel clamp and turning the fastening screw clockwise.
- Place the front cushion of the pressure support approx. 5 cm above the outer maleolus (see X-ray).
- Stress for routine examination: 15 daN.

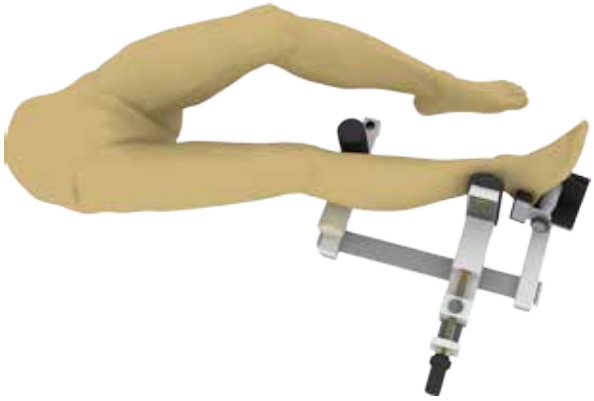
Device setup for the right leg



Positioning of the patient for the left leg



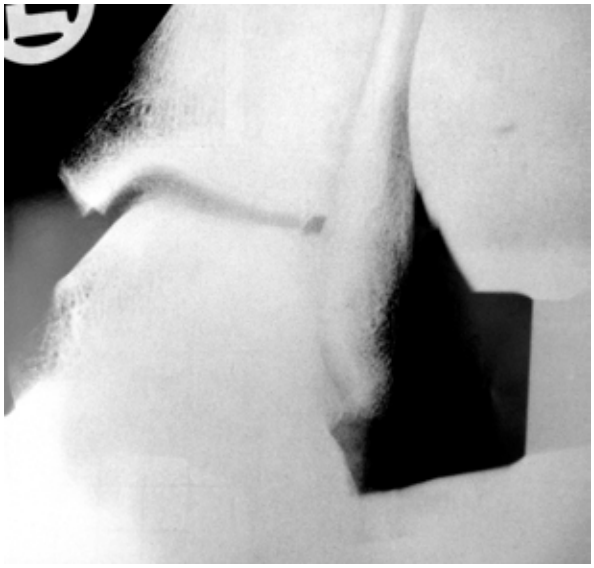
Positioning of the patient for the right leg



Information for diagnostics

Comparative X-rays are absolutely necessary

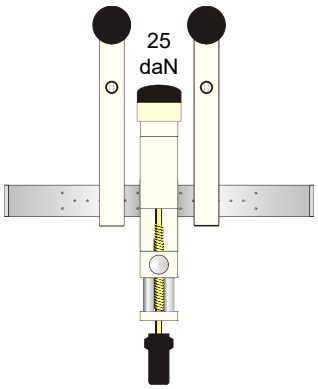
- A value above 10° is pathological according to the current state of medical scientific knowledge.
- A value between 5 - 10° makes a comparative X-ray necessary.
- This examination technique is rarely used in routine diagnostics since the typical eversion trauma is generally accompanied by a fibula fracture.



Examination of the ligamentum calcaneocuboideum dorsale

Lateral calcaneocuboidal joint in dorsoplantar view

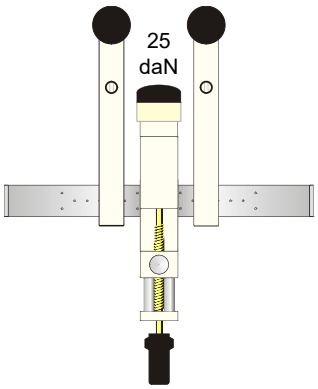
Device setup for the left leg



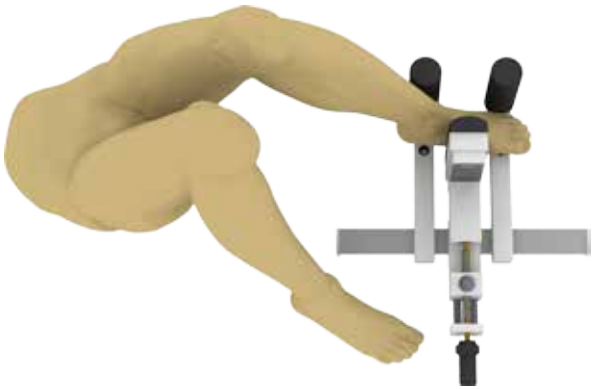
Please note

- Insert two counter-supports into the outer guide bushes.
- Place the extension arms approx. 2 cm adjacent to the pressure device.
- Mount the extension piece on the pressure support.
- Sit the patient with his knee flexed at 90° and the sole flat (see fig.).
- Place the pressure support a little proximal to the tuberositas ossis navicularis. (The lateral Chopart's joint lies more distal than the medial Chopart's joint).
- Stress for routine examination: 25 daN.

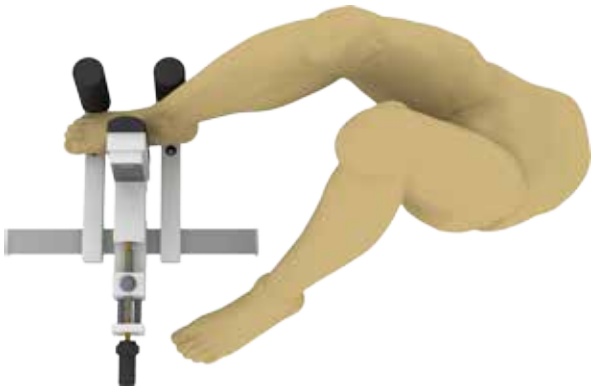
Device setup for the right leg



Positioning of the patient for the left leg



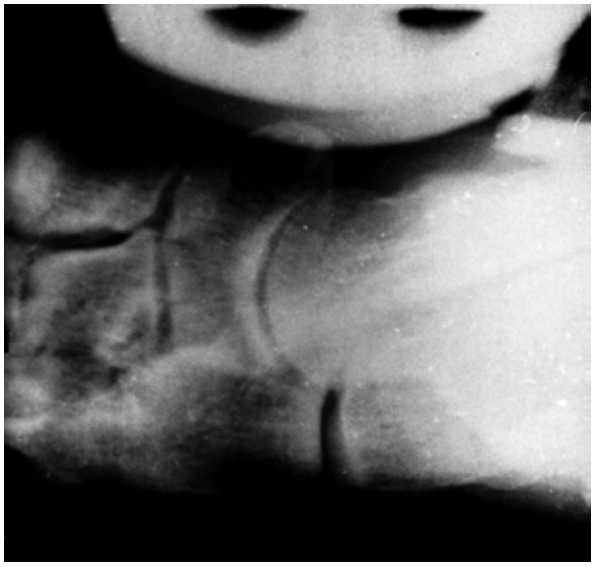
Positioning of the patient for the right leg



Information for diagnostics

Comparative X-rays are absolutely necessary

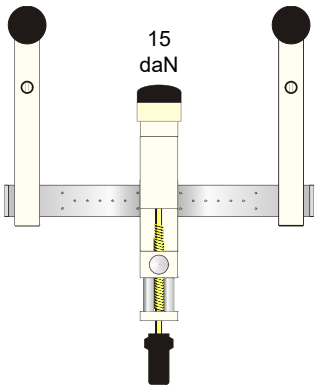
- An opening of more than 5 mm is pathological according to the current state of medical scientific knowledge.
- A difference of more than 2 mm between the comparative X-rays is pathological.



Examination of the ligamentum collaterale tibiale

Knee in a.-p.-view

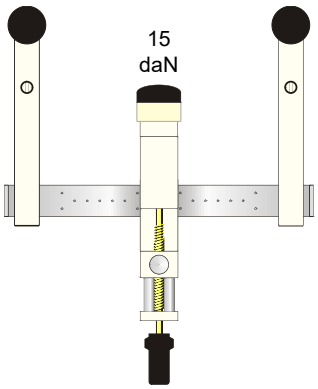
Device setup for the left leg



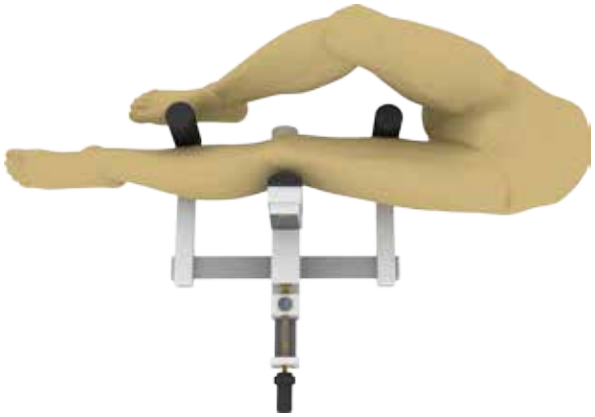
Please note

- Insert two counter-supports into the outer guide bushes.
- Mount the extension piece on the pressure support.
- Place the pressure support exactly in the middle between the counter-supports.
- Sit the patient with the knee flexed to a minimum of 15°.
- The flexion of the knee must not exceed 30°.
- The front cushion pad of the pressure support should lie on the lateral articular space.
- Stress for routine examination: 15 daN.

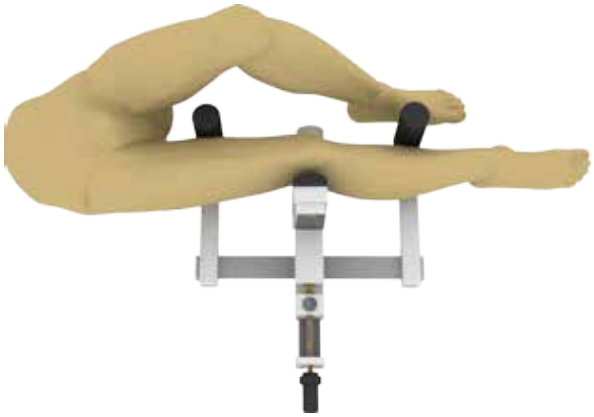
Device setup for the right leg



Positioning of the patient for the left leg



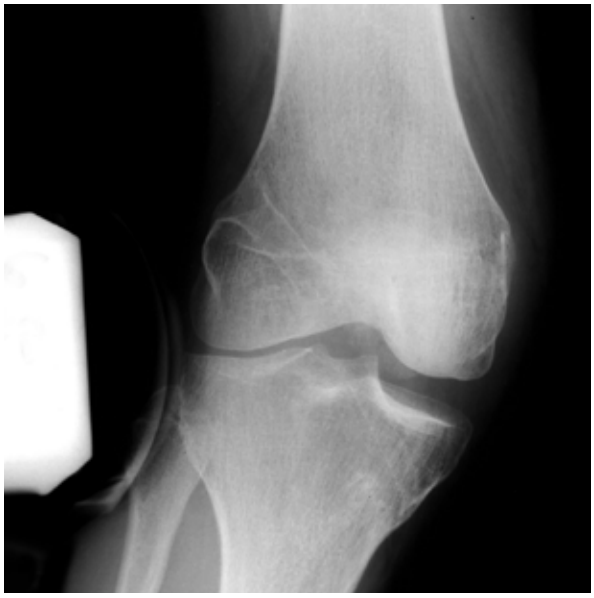
Positioning of the patient for the right leg



Information for diagnostics

The width of the medial articular space is measured

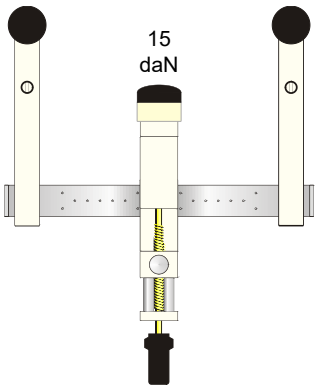
- An opening of more than 15 mm is pathological according to the current state of medical scientific knowledge.
- An opening of more than 10 mm: a comparative X-ray is strongly recommended.



Examination of the ligamentum collaterale fibulare

Knee in a.-p.-view

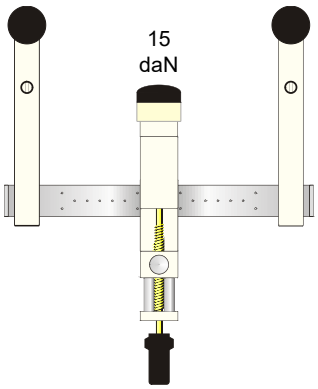
Device setup for the left leg



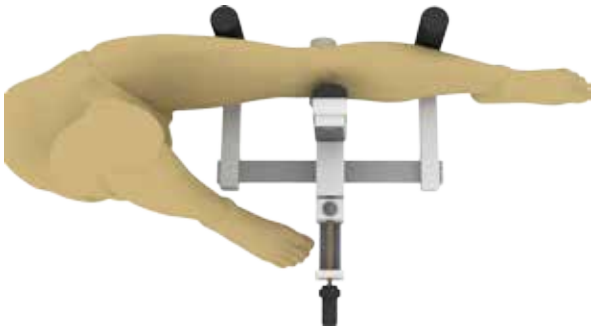
Please note

- Insert two counter-supports into the outer guide bushes.
- Mount the extension piece on the pressure support.
- Place the pressure support exactly in the middle between the counter-supports.
- Sit the patient with the knee flexed to a minimum of 15°.
- The flexion of the knee must not exceed 30°.
- The front cushion pad of the pressure support should lie on the medial articular space.
- Stress for routine examination: 15 daN.

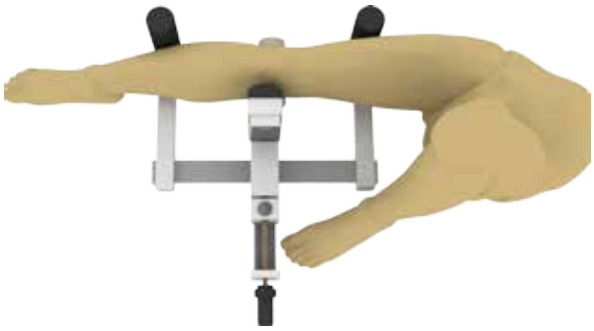
Device setup for the right leg



Positioning of the patient for the left leg



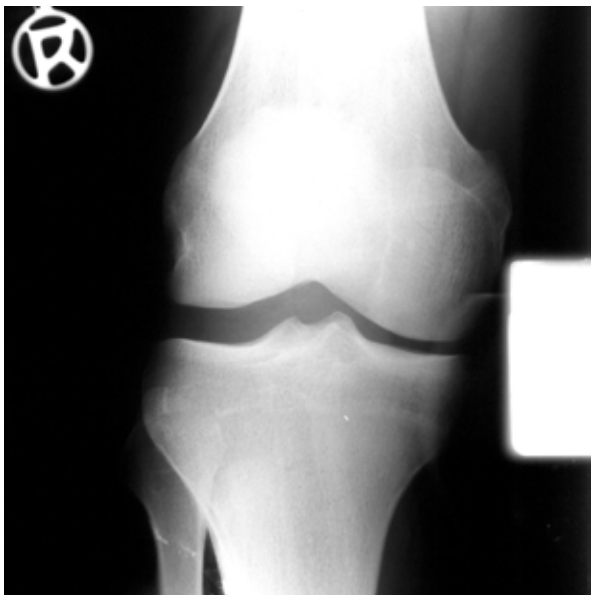
Positioning of the patient for the right leg



Information for diagnostics

The width of the lateral articular space is measured

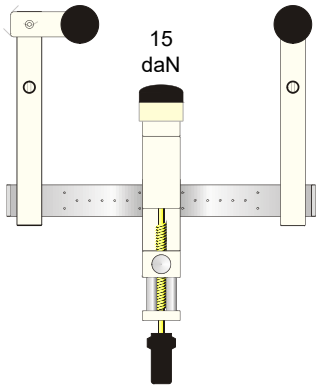
- An opening of more than 15 mm is pathological according to the current state of medical scientific knowledge.
- An opening of more than 10 mm: a comparative X-ray is strongly recommended.



Examination of the anterior cruciate ligament (Lachman's test)

Knee in lateral view

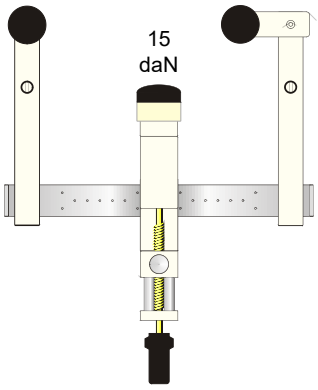
Device setup for the left leg



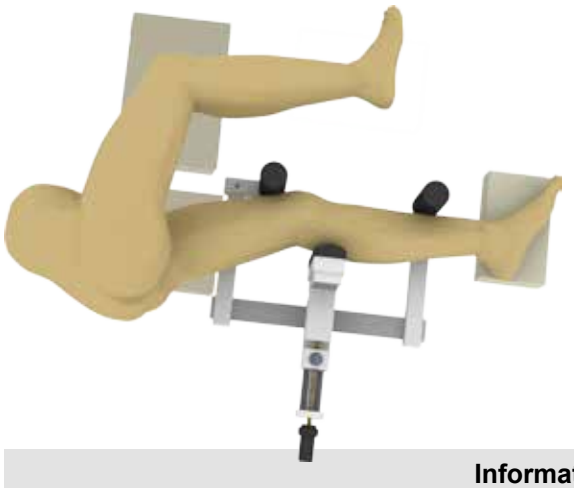
Please note

- Mount a counter support in the outer guide bush.
- Mount the extension bar as depicted and insert another counter-support in the guide bush of the extension bar.
- Position the patient in a "lateral recumbent position" (see fig.) with the knee flexed at 10-20°.
- The tibia should lie parallel to the X-ray table (place a cushion under the heel).
- The front cushion pad of the pressure device should lie approx. 6 cm distal to the hollow of the knee.
- Stress for routine examination: 15 daN.

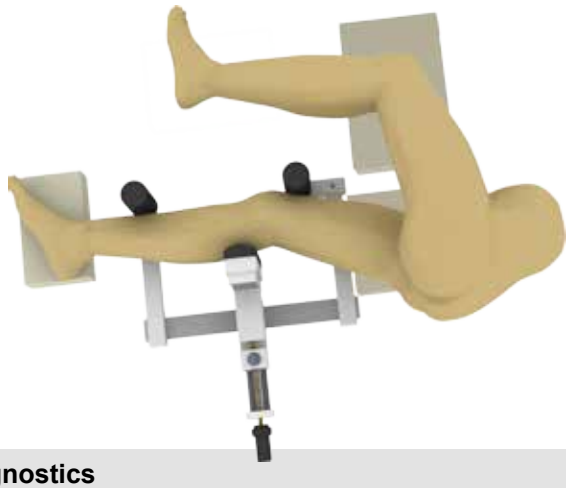
Device setup for the right leg



Positioning of the patient for the left leg



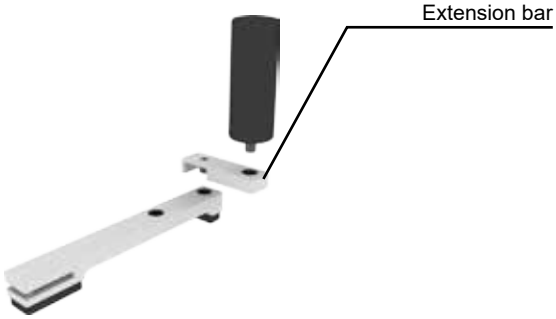
Positioning of the patient for the right leg

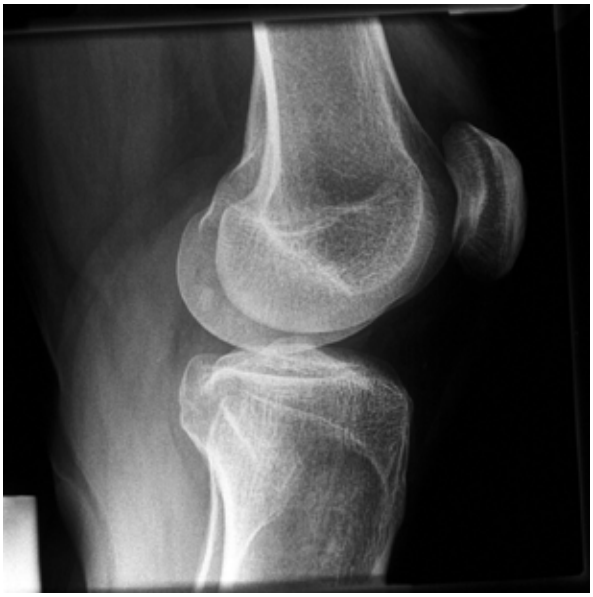


Information for diagnostics

Comparative X-rays are recommended

- The contours of the dorsal edge of the medial and lateral tibia plateau should lie as close as possible together, as well as the contours of the dorsal edge of the femoral condyles (= sufficient outer rotation).
- Anterior drawer values from 10 mm on are pathological for a lesion of the anterior cruciate ligament according to the current state of medical scientific knowledge.

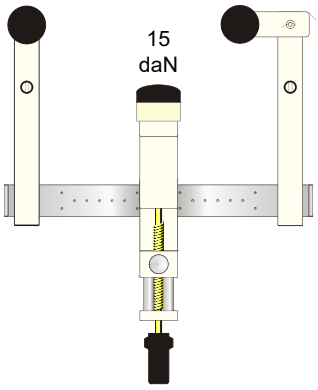




Examination of the posterior cruciate ligament (Lachman's test)

Knee in lateral view

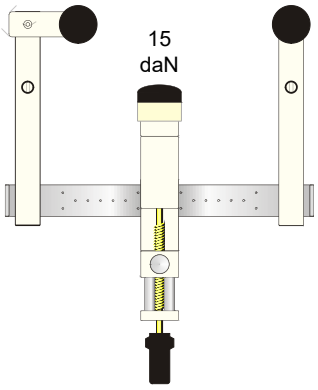
Device setup for the left leg



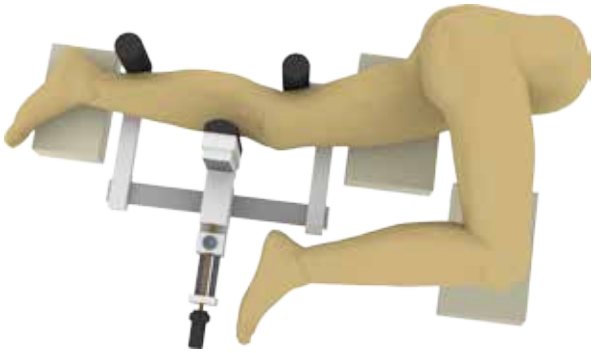
Please note

- Mount a counter support in the outer guide bush.
- Mount the extension bar as depicted and insert another counter-support in the guide bush of the extension bar.
- Position the patient in a "lateral recumbent position" (see fig.) with the knee flexed at 10-20°.
- The tibia should lie parallel to the X-ray table (place a cushion under the heel).
- The front cushion pad of the pressure support should lie on the tuberositas tibiae.
- Stress for routine examination: 15 daN.

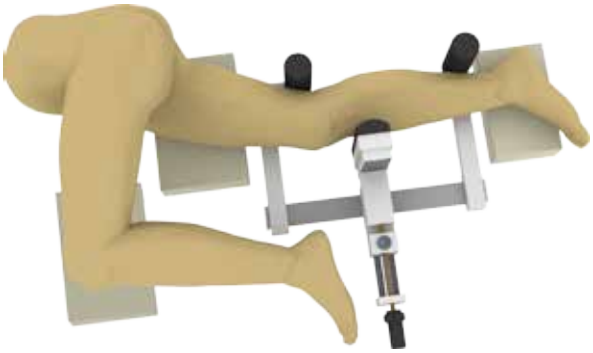
Device setup for the right leg



Positioning of the patient for the left leg



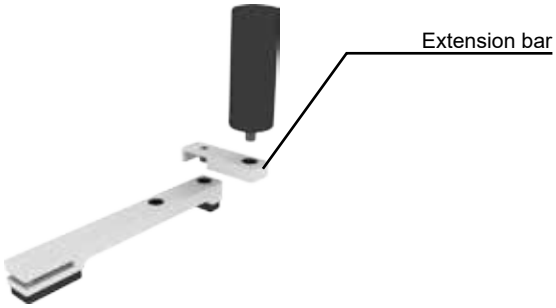
Positioning of the patient for the right leg

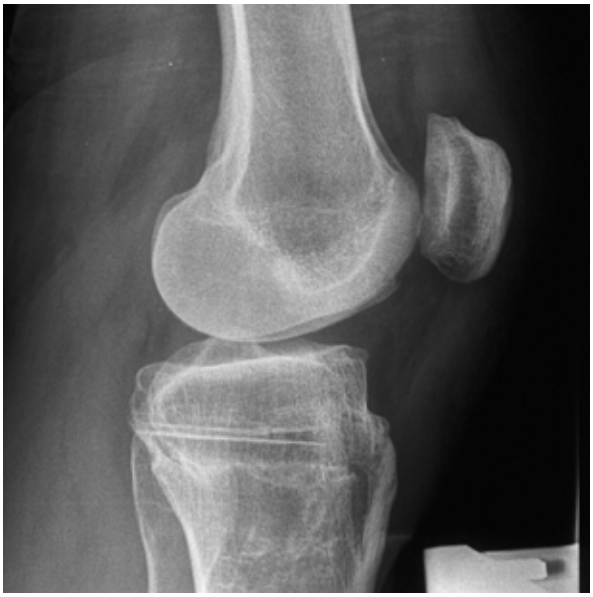


Information for diagnostics

Comparative X-rays are absolutely necessary

- The contours of the dorsal edge of the medial and lateral tibia plateau should lie as close as possible together, as well as the contours of the dorsal edge of the femoral condyles (= sufficient outer rotation).
- Posterior drawer values from 10 mm on are pathological for a lesion of the posterior cruciate ligament according to the current state of medical scientific knowledge.
- If necessary, superimpose the X-rays of both knee joints.

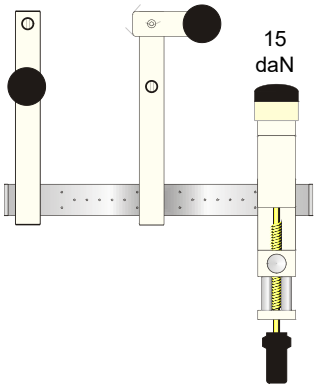




Examination of the anterior cruciate ligament (90°)

Knee in lateral view

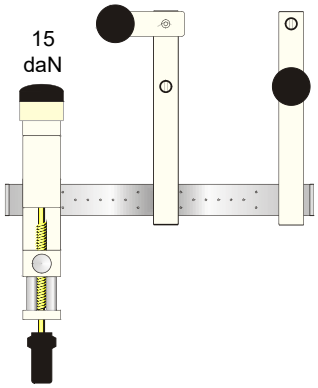
Device setup for the left leg



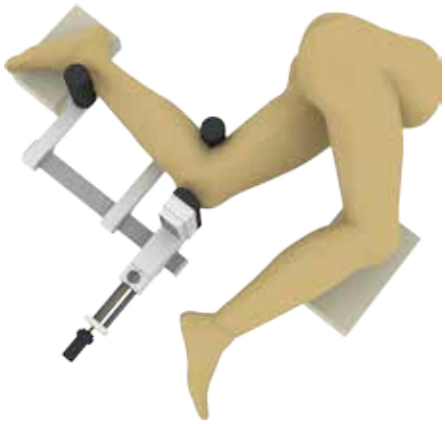
Please note

- Mount a counter-support in the inner guide bush.
- Mount the extension bar as depicted and insert another counter-support in the guide bush of the extension bar.
- Mount the pressure support outside of the extension arms.
- Position the patient in a “lateral recumbent position” (see fig.) with the knee flexed at 90°.
- The tibia should lie parallel to the X-ray table (Support under the ankle).
- The front cushion pad of the pressure device should lie exactly on the patella.
- Stress for routine examination: 15 daN.

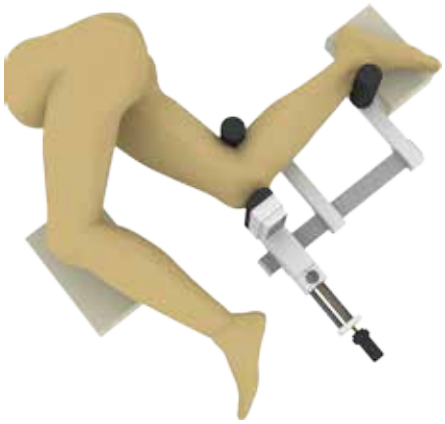
Device setup for the right leg



Positioning of the patient for the left leg



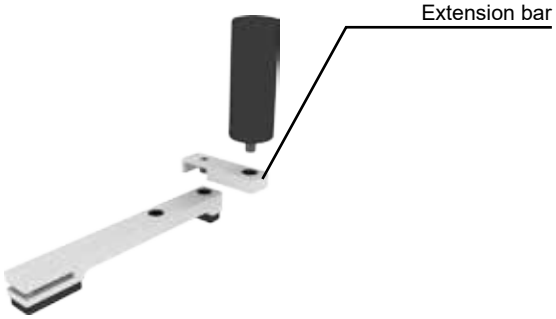
Positioning of the patient for the right leg

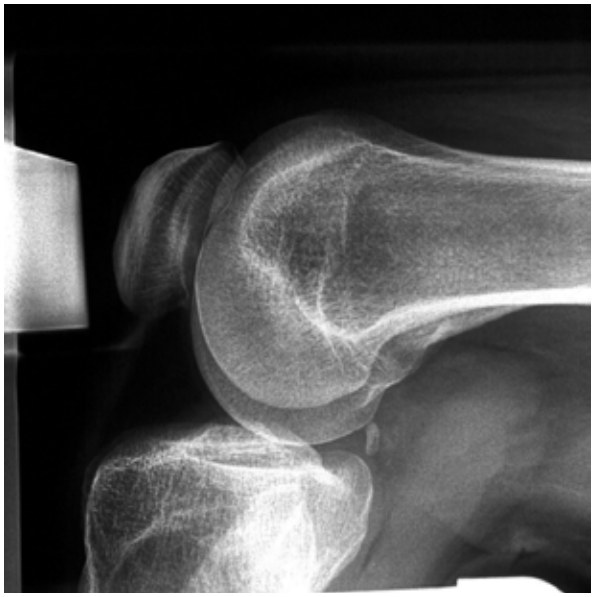


Information for diagnostics

Comparative X-rays are absolutely necessary

- Check ventral displacement of the tibia head (drawer phenomenon) by superimposing the X-rays.
- A difference of 3 mm is pathological according to the current state of medical scientific knowledge.
- A drawer of 2 mm could represent a rupture if clinically suspected.

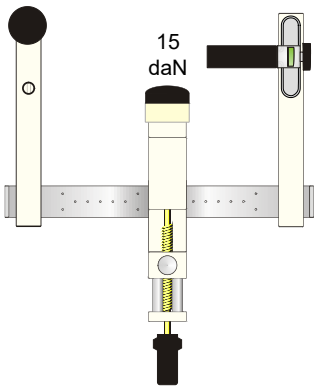




Examination of the posterior cruciate ligament (90°)

Knee in lateral view

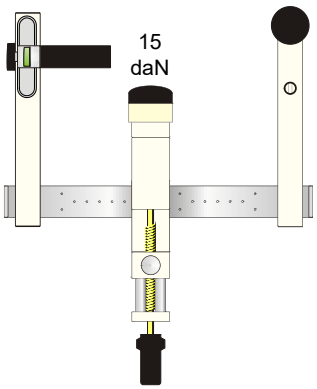
Device setup for the left leg



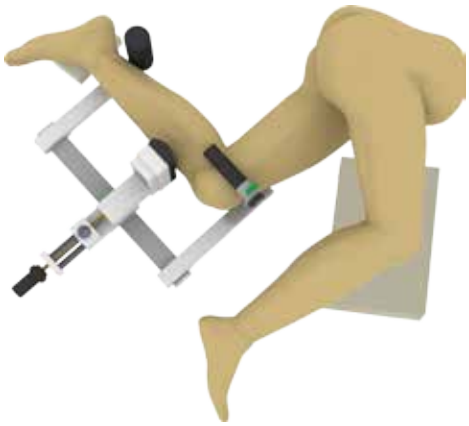
Please note

- Mount a counter support in the outer guide bush.
- Mount the accessory „Back Drawer“ as depicted.
- Position the patient in a “lateral recumbent position” (see fig.) with the knee flexed at 90°.
- The tibia should lie parallel to the X-ray table (Support under the ankle).
- The accessory “Back Drawer” should fix the thigh closely above the femoral condyles.
- The front cushion pad of the pressure device should lie approx. 2 cm below the tibia head.
- Stress for routine examination: 15 daN.

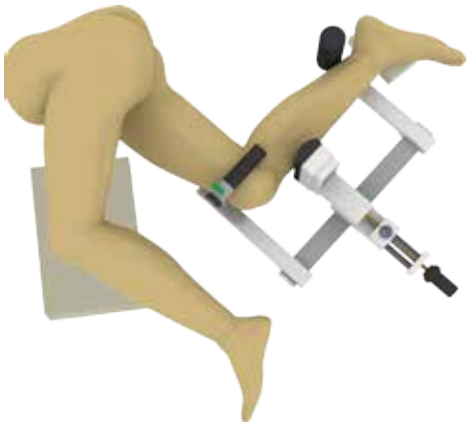
Device setup for the right leg



Positioning of the patient for the left leg



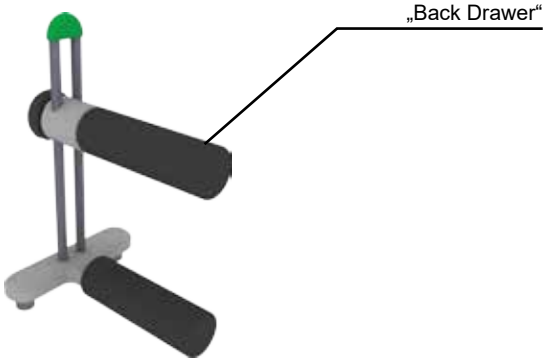
Positioning of the patient for the right leg

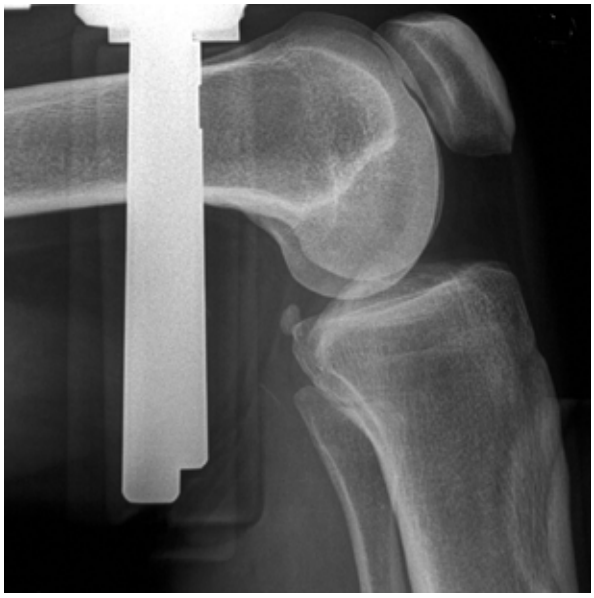


Information for diagnostics

Comparative X-rays are absolutely necessary

- Check dorsal displacement of the tibia head (drawer phenomenon) by superimposing the X-rays.

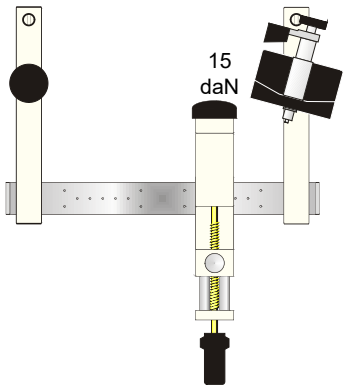




Examination of the ligamentum talocalcaneare interosseum

Subtalar joint

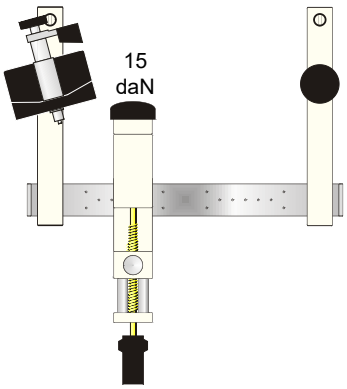
Device setup for the left leg



Please note

- Mount the 30° - adaptor into the inner guide bush.
- Mount the 15° slanted pin of the foot holder into the adaptor.
- Mount the counter-support into the opposite guide bush.
- Sit the patient with his knee approx. 20° flexed.
- The heel should be placed firmly against the centre bar of the foot holder.
- Fix the heel with the swivel clamp by turning the fastening screw clockwise.
- Place the front cushion of the pressure support approx. 5 cm above the inner maleolus.
- Stress for routine examination: 15 daN.

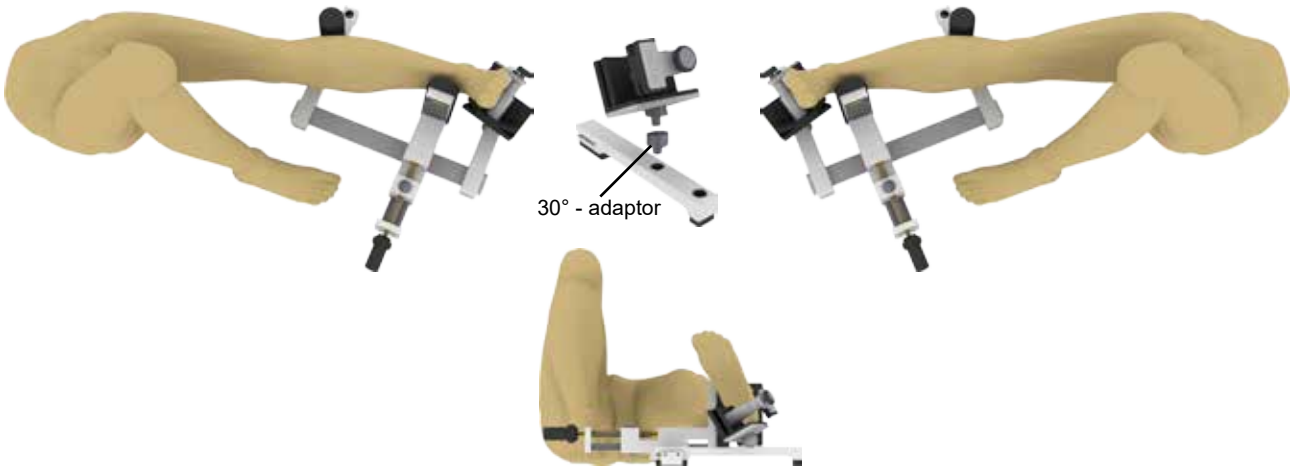
Device setup for the right leg



IMPORTANT: The tube has to be tilted 30° caudally-cranially!

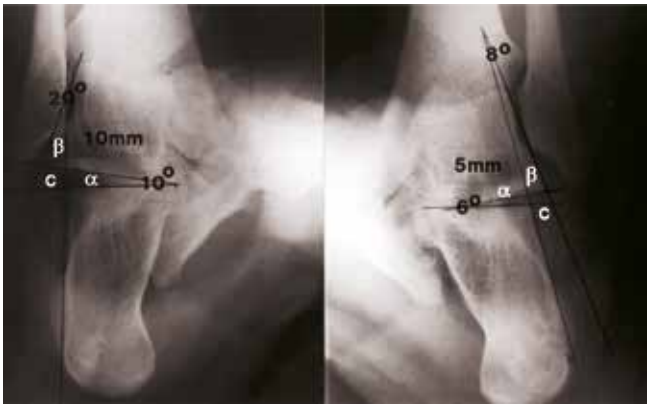
Positioning of the patient for the left leg

Positioning of the patient for the right leg



Information for diagnostics

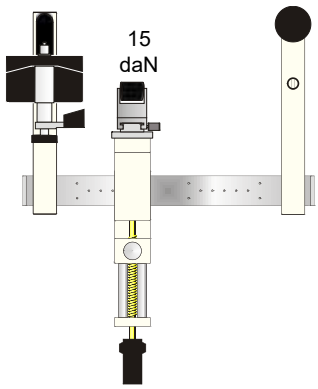
- The horizontal opening between the talus and the calcaneus is measured (∠ α) - more than 5° is pathological according to the current state of medical scientific knowledge.
- The translation inwards from the calcaneus towards the talus is measured (c) - more than 5 mm is pathological according to the current state of medical scientific knowledge.
- The vertical talo-calcaneare angle, determined by outer tangents at the talus and the calcaneus, is measured (∠ β) - more than 10° is pathological according to the current state of medical scientific knowledge.



Examination of the syndesmosis

Shank in a.-p.-view

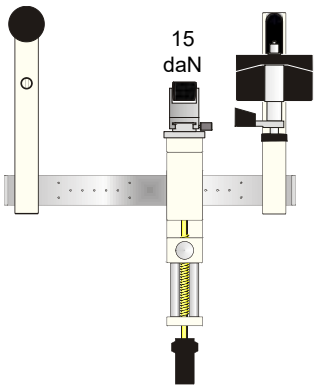
Device setup for the left leg



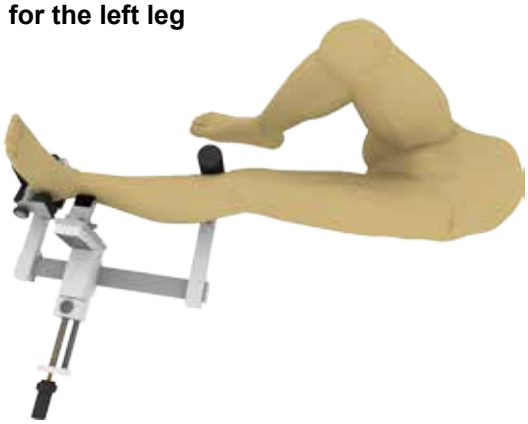
Please note

- Mount a counter-support into the outer guide bush.
- First mount the anti-rotation lock and then the foot holder on the opposite extension arm (see fig.).
- In place of the front cushion, install the adaptor with the pressure roll on the pressure support.
- The height of the pressure roll can be fixed with the fastening screw.
- Sit the patient with his knee approx. 20° flexed.
- Fix the heel with the swivel clamp by turning the fastening screw clockwise.
- Place the pressure roll approx. 5 cm above the lateral maleolus and anterior to the tibia.
- Stress for routine examination: 15 daN.

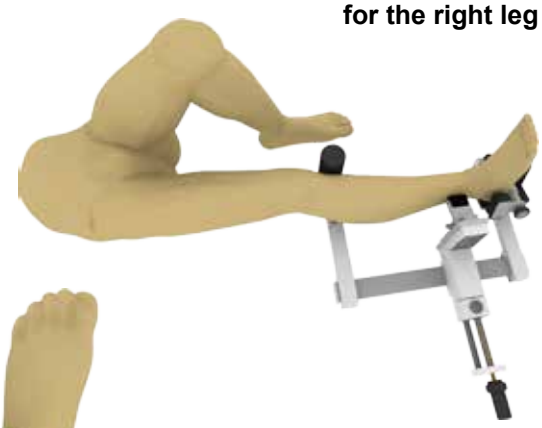
Device setup for the right leg

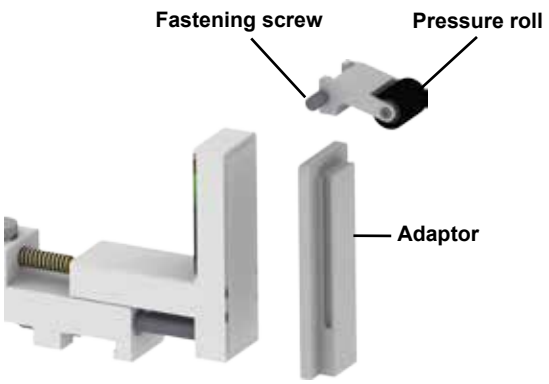


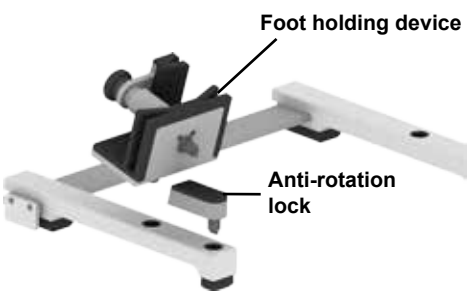
Positioning of the patient for the left leg



Positioning of the patient for the right leg



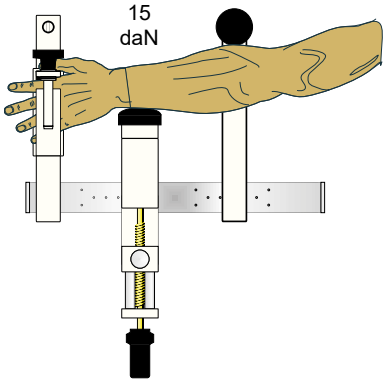




Examination of the ligament structure of the proximal row of the wrist bones

Wrist joint in a.-p.-view

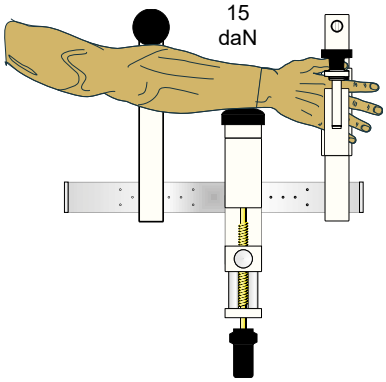
Device setup
for the left arm - ulnar



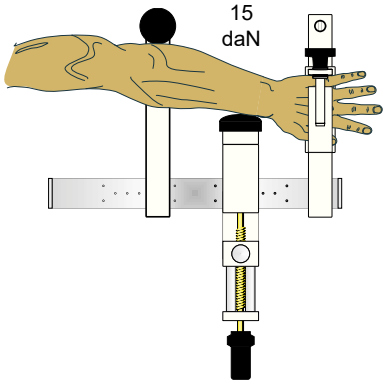
Please note

- Position the patient sitting at the X-ray table with shoulder, elbow and hand forming a horizontally even line (s. fig.).
- The hand and the lower arm should lie flat on the device.
- To prevent rotation, fix the hand with the upper bar against the back of the hand.
- For a radial stress X-ray place the pressure support proximal to the proc. styloideus radii.
- For an ulnar stress-X-Ray place the pressure support proximal to the proc. styloideus ulnae.
- Stress for routine examination: 15 daN.
- The X-ray should be taken after 1 minute of stress application.

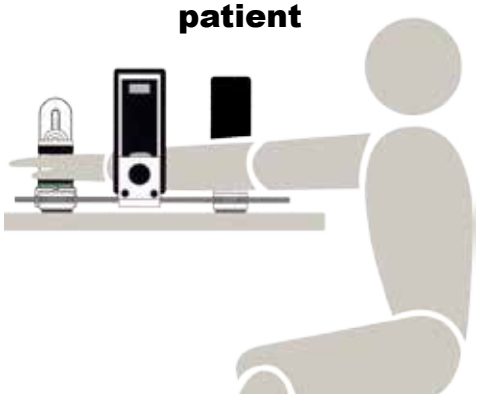
Device setup
for the right arm - ulnar



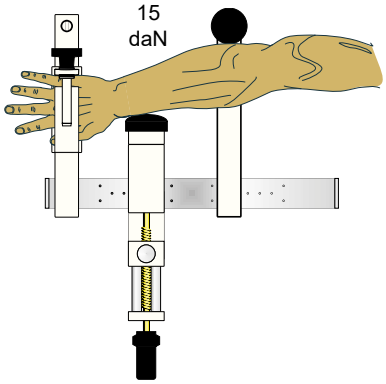
Device setup
for the left arm - radial



Positioning of the patient



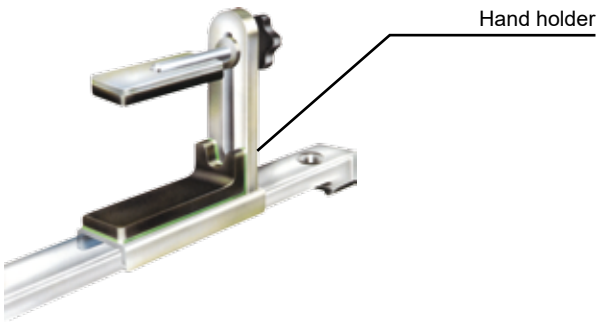
Device setup
for the right arm - radial

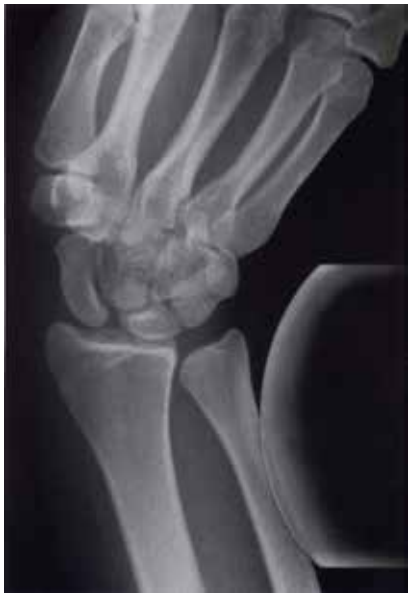


Information for diagnostics

Examination of the ligament carpal stability

- In order to confirm scapho-lunal dislocation it is sufficient to carry out an X-ray with ulnar stress.
- A scapho-lunal distance of more than 3 mm is pathological according to the current state of medical scientific knowledge.
- The radial stress X-ray serves to diagnostically confirm a less common dislocation between the os lunatum and the os triquetrum.





Guidelines and manufacturer's declaration
Electromagnetic compatibility (EMC acc. EN 60601-1-2)

Medical electrical devices are subject to special precautions concerning EMC and must be installed und operated according to the following information. Portable and mobile RF-communication devices may influence medical electrical devices.

Electromagnetic emissions

The stress device, type GA III/E is intended for use in a professional healthcare facility environment. The customer or the user of the stress device (type GA III/E) should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The stress device (type GA III/E) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Not applicable	Battery powered device
Harmonic emissions EN 61000-3-2		
Voltage fluctuations/flicker emissions EN 61000-3-3		

The device should not be arranged beside or stacked with other devices when used. If operation besides or stacked to other devices is necessary, the device must be observed to verify its operation in accordance with the intended use in this arrangement.

Guidelines and manufacturer's declaration
Electromagnetic compatibility (EMC acc. EN 60601-1-2)

Electromagnetic immunity			
The stress device, type GA III/E is intended for use in a professional healthcare facility environment. The customer or the user of the stress device (type GA III/E) should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) acc. IEC 61000-4-2	+/- 8 kV Contact discharge +/- 15 kV Air discharge	+/- 8 kV Contact discharge +/- 15 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM Fields IEC 61000-4-3	80-2700 MHz: 3V/m	3V/m	Field strengths of stationary RF transmitters, as determined by locally surveying, should be less than the compliance level in each frequency range.
Radiated RF EM Fields and Proximity Wireless fields	380 MHz - 5.8 GHz D1, E, Bluetooth	passed	
Magnetic field at the mains frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should be that of a typical commercial or hospital environment.

Comments regarding local electromagnetic field strengths:

These guidelines may not apply in all situations. The spreading of electromagnetic radiation is affected by absorption and reflection from buildings, objects and people.

Field strengths of stationary transmitters, such as base stations for radio and mobile telephones, CB radios, AM and FM radio broadcasters and TV broadcasters cannot be
predicted theoretically with accuracy. To assess the electromagnetic environment due to stationary RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the location in which the stress device (type GA III/E) is used exceeds the applicable RF compliance level quoted above, the stress device (type GA III/E) should be monitored to confirm it is working properly. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the stress device (type GA III/E).

Guidelines and manufacturer's declaration
Electromagnetic compatibility (EMC acc. EN 60601-1-2)

Recommended separation distances between portable and mobile RF communications equipment and the Stress device (type GA III/E)

The stress device, type GA III/E is intended for use in a professional healthcare facility environment. The customer or the user of the stress device (type GA III/E) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the stress device (type GA III/E) as recommended below, according to the rated output power of the communications equipment.

	Separation distance according to frequency of transmitter in m	
Rated output of transmitter ($P_{transmitter}$) in W	**80 MHz - 800 MHz** $d = 0.22\sqrt{P_{transmitter}}$	**800 MHz - 5.8 GHz** $d = 0.73\sqrt{P_{transmitter}}$
0.01	0.02	0.07
0.1	0.07	0.24
1	0.22	0.75
2	0.32	1.05
10	0.71	2.36
100	2.24	7.45

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

An additional factor of 10/3 is used when calculating the recommended separation distance for transmitters in the ISM frequency bands between 800 MHz and 5.8 GHz over the frequency range to decrease the likelihood that mobile/portable communications equipment might cause interference if it is inadvertently brought into the patient area.

Portable and mobile RF communications equipment should be used no closer to any part of the stress device (type GA III/E) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.

Notes

Notes

telos Arzt- und Krankenhausbedarf GmbH
Ottostraße 2
61200 Wölfersheim
Germany
Phone: +49 60 36 97 05 0
E-Mail: info@telos-gmbh.com
www.telos-stress-device.com

Rev 3.5 / 2021-12-01