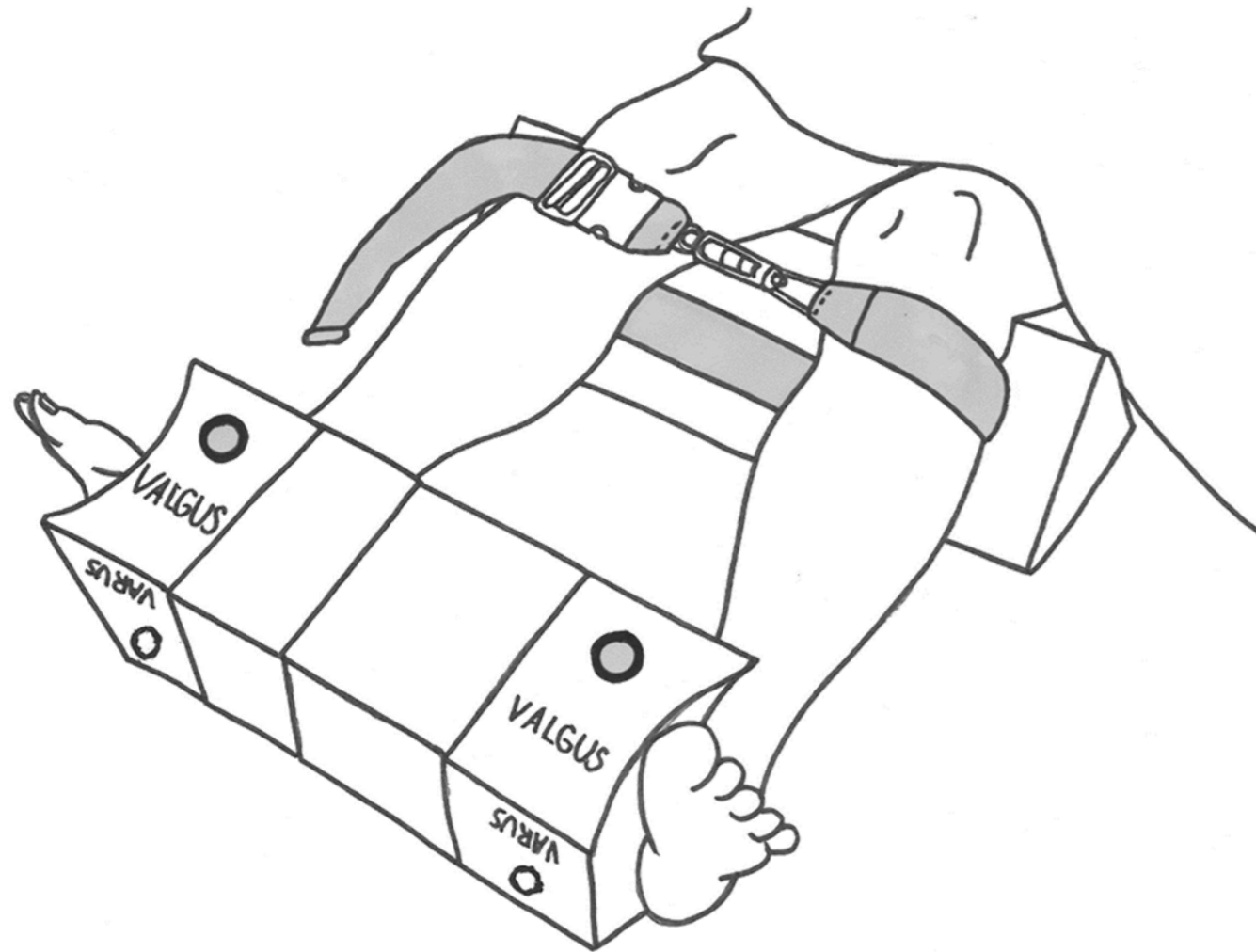


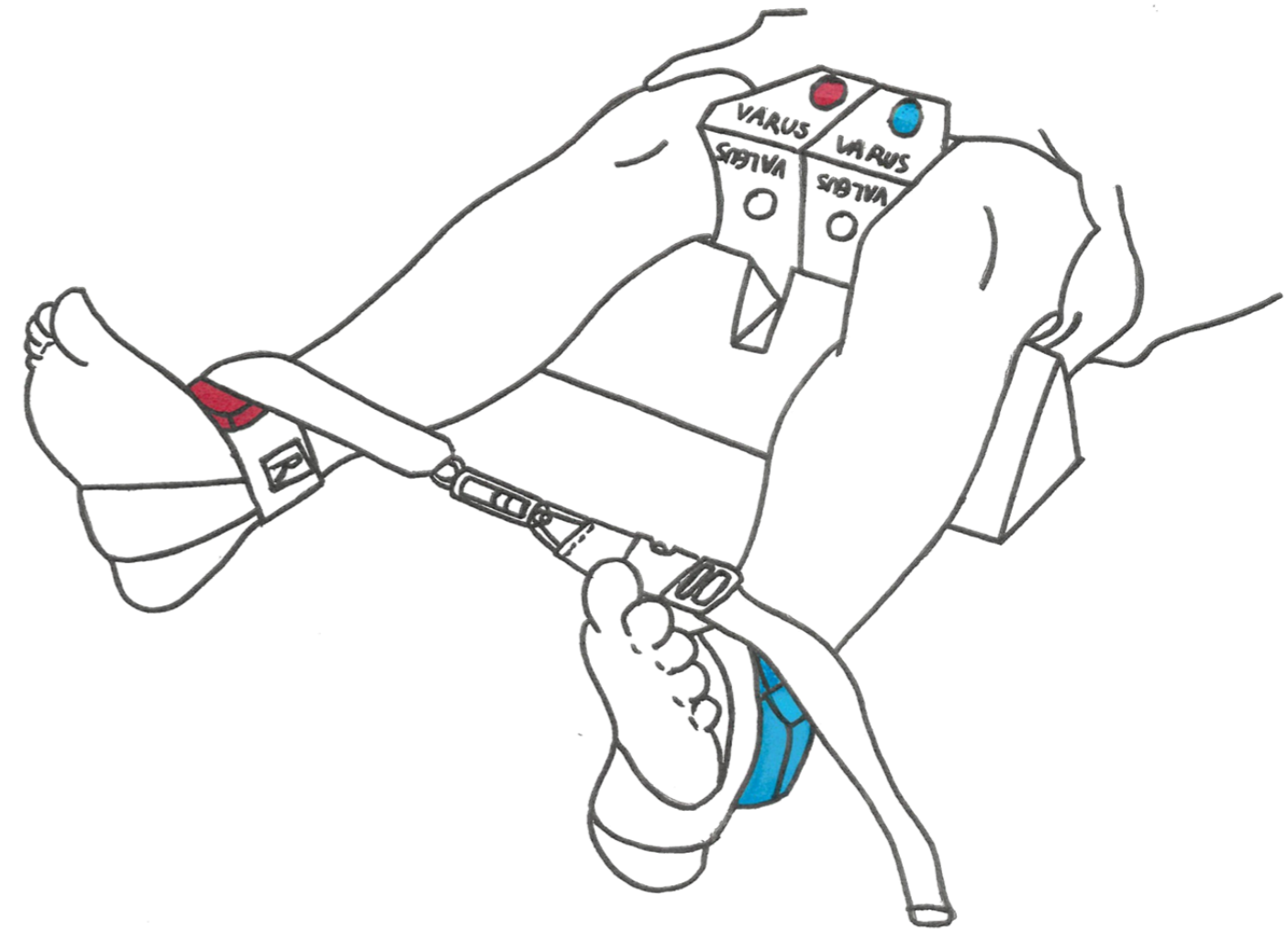
OSSkar

Oxford Stress System
for Knee Arthroplasty Radiographs

VALGUS VIEW



VARUS VIEW





ASKORN MEDICAL
44c rue de Bray
35510 Cesson-Sévigné – France
contact@askorn.bzh



INSTRUCTIONS FOR USE – REUSABLE MEDICAL DEVICE

Rev1 – Edited on November 15,2021

PRODUCT NAME

Oxford Stress System for Knee Arthroplasty Radiographs (OSSKAR)

INDICATIONS FOR USE

- Assessment of the pattern and severity of arthritis within the medial and lateral compartments of the adult knee.
- Assessment of the status of the ligamentous structures within the adult knee (collateral and cruciate ligaments).

CONTRA-INDICATIONS

- Acute ligamentous injury of the knee.
- Acute fracture of the lower limb, including pelvis.
- Non-union of femur or tibia.

INSTRUCTIONS

Valgus Stress

1. The Knee Wedge (foam block with the OSSKAR logo) is placed on the X-ray table.
2. The patient lies on his back on the X-ray table, with the back of his knees resting on the Knee Wedge.
3. The Right and Left foam Blocks are positioned between the patient's feet. The VALGUS side of the Blocks must be facing up (side with the gray dots). Pictograms on the faces of the Blocks indicate the right/left position in relation to the patient's feet. Depending on the patient's anatomy, the blocks may need to be wider between the legs, to give enough space between the knees to allow a valgus stress to be applied at the level of the knee. In this case, a Cube Block and/or a Half Cube Block can be added between the Blocks
4. The gray valgus strap (Knee Strap) is positioned around the patient's legs, 100mm distal to the patella. The strap is tightened to apply tension. The applied stress level should be monitored and the load indicator should be within the green area of the dynamometer.
5. The user confirms the alignment of the leg by ensuring the tibial tubercles are facing anteriorly.

6. The X-ray beam is directed 10 degrees cephalic in the coronal plane, centered on the knee.
7. The X-ray is performed.
8. The X-ray source is positioned in order to be aligned parallel to the tibial plateau and the knee in neutral rotation prior to capture the image. If the image is satisfactory, remove the strap around the knee and Blocks. If the X-ray is misaligned, the positioning should be corrected and the capture of the image should be repeated.

Varus Stress

1. The patient remains lying on the X-ray table with the Knee Wedge positioned below the knees.
2. The Right and Left foam Blocks are positioned between the patient's knees. The VARUS side of the Blocks must be facing up (side with the red and blue dots). Pictograms on the faces of the Blocks indicate the right / left position in relation to the patient's knees. The block with the red dot should be placed against the patient's right knee and the block with the blue dot against the patient's left knee.
3. The black varus strap (Ankle Strap) is positioned around the patient's ankles. The loop with the red cushion is positioned around the patient's right ankle. The loop with the blue cushion is positioned around the patient's left knee. Both cushions should be facing the anterior-lateral areas of the ankles. The loops are passed behind the heel from the lateral side such as the heel sits within the loop. The strap is tightened to apply a varus tension. The applied stress level should be within the green area of the dynamometer.
4. The user confirms the alignment of the leg by ensuring the tibial tubercles are facing anteriorly.
5. The X-ray beam is directed 10 degrees cephalic in the coronal plane, centered on the knee.
6. The X-ray is performed.
7. The X-ray source is positioned in order to be aligned parallel to the tibial plateau and the knee in neutral rotation prior to capture the image. If the image is satisfactory, remove the strap around the knee and Blocks. If the X-ray is misaligned, the positioning should be corrected and the capture of the image should be repeated.

LATERAL X-RAY (OPTIONAL)

The recess in the knee wedge has been designed to accommodate an X-ray cassette to permit horizontal, cross table or X-ray views. To perform lateral X-ray views with OSSKAR an X-ray cassette should be placed in the recess within the knee wedge and the X-ray beam should be aligned to the knee using the standard technique.

Important: During the application of valgus or varus stress to the knee discomfort to the patient can occur. If this occurs gently reduce the force applied by loosening the strap until the patient is comfortable. Then, provided the patient remains comfortable, slowly re-apply the force to the knee. If, despite applying the force slowly the patient still experiences significant discomfort, pain visual analogue score > 4, the procedure should be abandoned and a manual stress X-ray should be performed.

STORAGE ADVICE:

The device should be stored at room temperature in a dry area, out of direct sunlight.

CLEANING INSTRUCTIONS:

The following instructions represent one method of cleaning OSSKAR. The following method should be checked and amended in line with local infection control policy.

1. Wash hands and put on gloves.
2. Find a suitable area to clean the device and display warning signs.
3. Prepare the cleaning solution accordance with the manufacturer's instructions and with your training.
4. Dampen or rinse a cloth in the cleaning solution. Change the cleaning solution and/or cloth should they become dirty.
5. Wipe the device using a systematic approach to wipe all surfaces. For greasy or stubborn soiling, use a non-abrasive pad.
6. Allow the device to dry.
7. On completion, dispose of the cloth, clean and dry all equipment and store appropriately.
8. Remove gloves and wash hands.