DynaWell® L-Spine

Instructions for use

Contents

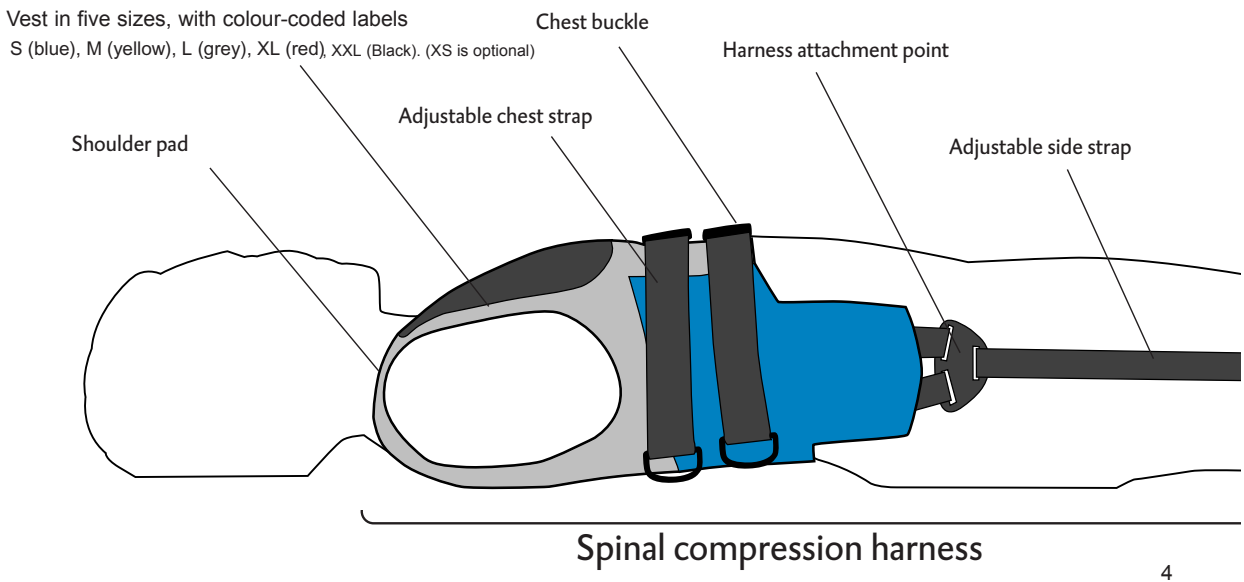
What is DynaWell® L-Spine?

DynaWell® L-Spine, is a medical compression device that facilitates the diagnosis of specific lumbar spine disorders. Compatible with most CT and MR scanners, DynaWell® L-Spine enables the examination of patients in a supine position, with straightened hips and knees, while simulating the axial compression the spinal canal is subjected to when a patient is standing.

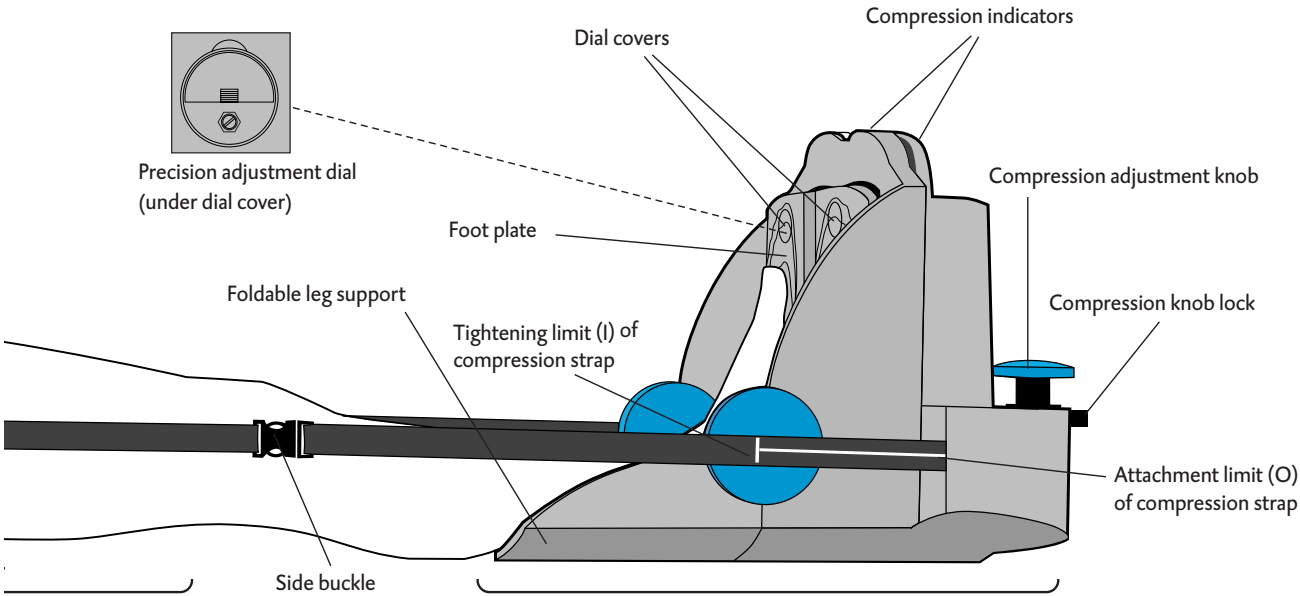
DynaWell® L-Spine consists of a compression device in hard plastic, and a neoprene-and-nylon compression harness. Worn by the patient, the harness is attached to the compression device using side straps. These are carefully tightened to axially load the lumbar spine. Compression indicators register the total weight exerted on the lumbar spine. Pressure should equal 40-50% of the patient's body weight – **never more than 50%** – and should be distributed equally on both legs. Pressure is regulated by tightening or loosening the compressionadjustment knobs.

The DynaWell® L-Spine compression harness helps patients to remain in a motionless position, and ensures that pressure is distributed across the chest rather than the shoulders. Special shoulder pads also increase comfort during MR or CT examination. The compression device itself enables accurate axial compression, which may in turn result in more accurate cross-sectional images of the lumbar spine, often revealing disorders that are not otherwise visible.

Components of the DynaWell® L-Spine Device



US patent 5,779,733



Safety

The following pages include important safety information. They must be read in their entirety and followed at all times to ensure proper and safe usage of the DynaWell® L-Spine medical compression device.

In particular, failure to read warning and caution notices may jeopardise patient health.

WARNING: All steps in the ”How to use DynaWell® L-Spine” section on pages 10 – 16 must be followed exactly. Extra caution should always be taken to monitor that the patient does not experience any abnormal pain.

WARNING: If, at any stage during compression or examination, a patient complains of pain to which he or she is unfamiliar or unaccustomed, immediately release them from the medical compression device, in accordance with the instructions on page 15.

WARNING: Total axial compression must never exceed 50% of a patient’s body weight. For proper axial loading, equal pressure should be distributed on each leg, and the patient’s feet must always be placed within the designated areas on the foot plate.

Safety

CAUTION: The decision to examine a patient should be made in accordance with standard exclusion criteria for MRI/CT scanning (e.g. no pacemakers, metal implants, etc).

CAUTION: Before use, always check proper function of the compression indicators and compression adjustment knobs. Do not proceed with axial compression if there is any doubt as to compression indicator accuracy (see ”Fine-tuning the compression indicators” on page 17).

CAUTION: If the DynaWell® L-Spine device is dropped or sustains damage in any way, do not use until:

- it has been thoroughly inspected to ensure there are no broken parts with sharp edges.
- the compression indicators have been calibrated to confirm accuracy (see ”Calibration” on pages 18-19).

Criteria for use

Inclusion criteria*

• Clinical signs of neurogenic claudication
• Sciatica when:
-the DCSA (Dural Cross Sectional Area of the spinal canal) at any investigated level is below 130 mm^2 **and/or**
-there is suspected
Dural sac deformation
Disc herniation
Intraspinal synovial cyst
Foraminal stenosis
• Longstanding Low Back Pain

NOTE: As a basis for comparison, examination in the psoas-relaxed position should always be performed prior to examination with DynaWell® L-Spine

Exclusion criteria*

WARNING: Do not use DynaWell® L-Spine in cases of:
• Cerebral or acute vertebral trauma
• Tumors
• Known or suspected severe osteoporosis
• Severe cardiopulmonary disease
• Patients with a history of drug abuse
• Language barriers that prevent the patient from understanding the procedure
• Patients who do not meet standard inclusion criteria for MRI and CT scanning
• Patients who can not articulate pain or discomfort
• Patients with a body weight below 80 Lbs/40 Kgs

* Inclusion and exclusion criteria are based upon available clinical experience to date (see references on page 21).

Criteria for use

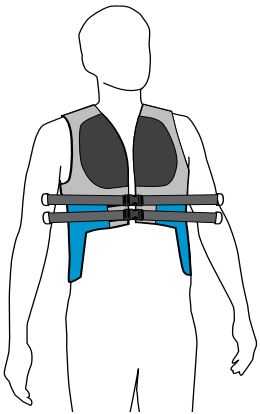
WARNING: Proper screening of patients with regard to examination using DynaWell® L-Spine is the responsibility of the referring and examining physicians, and not DynaWell Int. AB.

NOTE: Patients who weigh more than 175 kg may be included for DynaWell® L-Spine compression, although optimal compression (40-50% of body weight) may not be possible. Patients who have different leg lengths, or artifical limbs, may also use the DynaWell® L-Spine device, but should wear medically-approved, non-metallic support shoes or props.

NOTE: The DynaWell® L-Spine device is designed for use with patients who weigh 40 kg or more. For this reason compression is only recommended for patients above this weight.

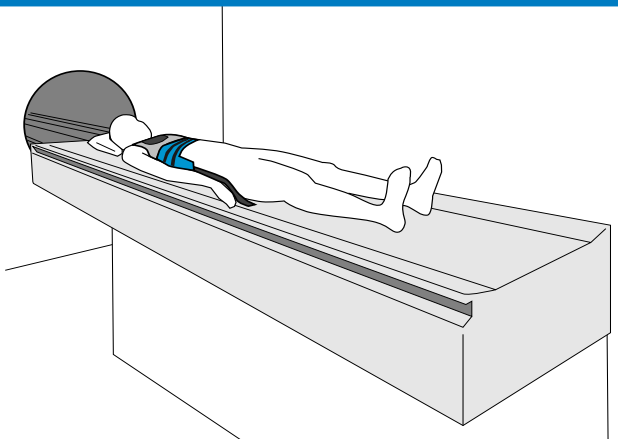
WARNING: For safety reasons, always refer to the following steps when carrying out an examination with the DynaWell® L-Spine medical compression device.

How to use DynaWell® L-Spine



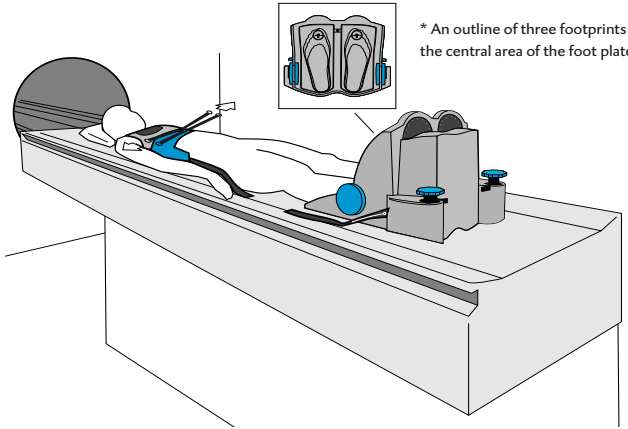
* Vests are colour-coded by label and hanger for faster identification of correct size:
S = blue
M = yellow
L = grey
XL = red
XXL = black

XS (white) is available on demand

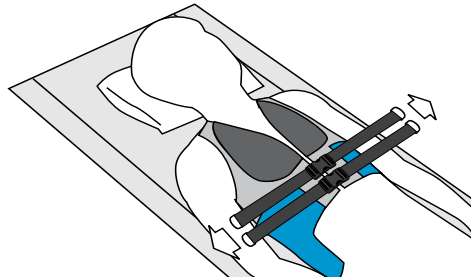


1. While the patient is standing, assist him or her in putting on the vest. Choose from 4 vests (S, M, L, XL)* according to the size of the patient's chest circumference (processus xiphoideus). In borderline cases, choose the smaller size. The front flaps of the vest **should never** overlap.

2. Have the patient lie on the examination table, on a low-friction mattress, in a supine position. Place one small pillow under the patient's head and another under the lumbar spine to maintain lordosis during subsequent compression.



* An outline of three footprints marks the central area of the foot plate.

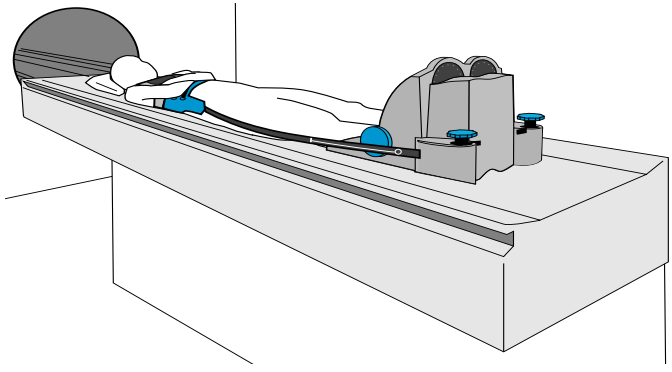


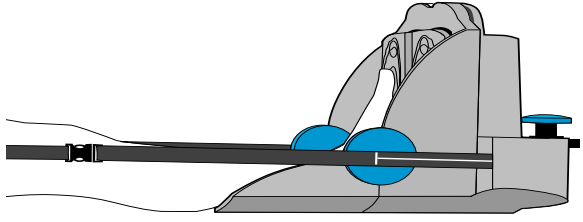
3. Check the compression indicators on the compression monitoring device to ensure that they register zero. Fine-tune if necessary, following the steps on page 17.

4. Place the monitoring device at the end of the examination table, on top of the mattress, and unfold the leg support. The patient's feet should be against the central part of the foot plates (within the designated outline of the footprints)*, with the lower calves resting on the leg support.

5. Ask the patient to take a deep breath and then exhale. At this time, tighten the 2 chest straps on the vest so it fits snugly. Be sure to check that the front flaps of the vest **are not** overlapping.

NOTE: This ensures that pressure from compression is not placed on the shoulders, but instead is distributed across the chest for greater accuracy and comfort in loading the lumbar spine.



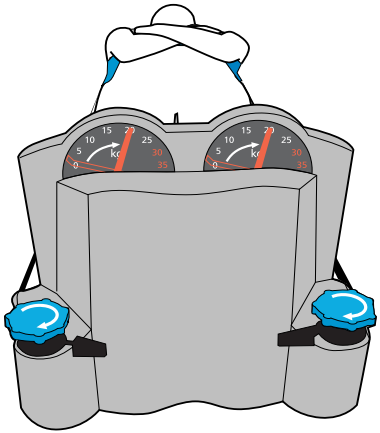


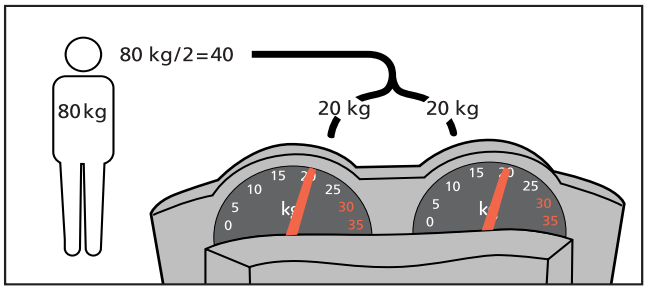
6. Ask the patient to lie with arms folded over the chest.

7. Attach the side straps (hanging from the bottom of the vest) to the compression device, using the side clips. Ensure that the straps are not twisted.

   CAUTION: For optimal results, the straps should always pass the **posterior part of the major femural trochanter**.

8. **NOTE:** The compression strap attachment limit (O) must always be visible before beginning the compression process. If the straps are very loose, adjust them at the side buckle, **not** by tightening the compression adjustment knobs.





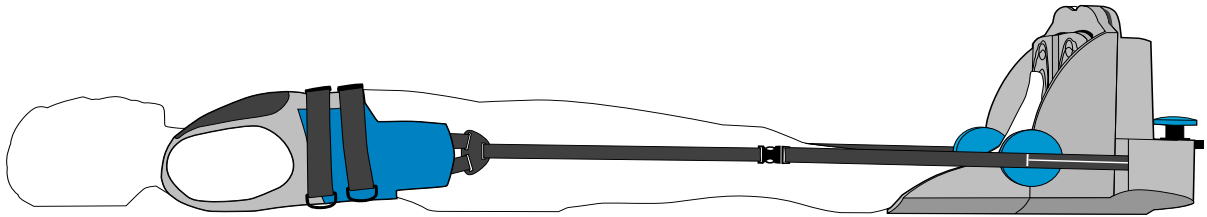
9 Apply pressure by simultaneously rotating the two compression adjustment knobs clockwise.

CAUTION: Check that the pointers on the compression indicators are moving.

10 Continue to simultaneously rotate the two compression adjustment knobs clockwise until the compression indicators register 40-50% of the total body weight of the patient. Maximum 35 kg/leg, or a total of 70 kg. The load should be approximately equal on both legs, and should not exceed 50% of the patient's body weight, or 25% of total body weight on each foot.

CAUTION: Never tighten the side straps so that the tightening limit (white 'I' on the compression strap) disappears into the compression device. If further tension is needed, adjust the straps at the side buckle. Failure to comply may result in the strap jamming inside the device. For heavier patients (over 175 kg), a compression level of 40-50% may not be possible, though lower compression may still be beneficial.

5 minutes (minimum) of axial compression prior to scanning.

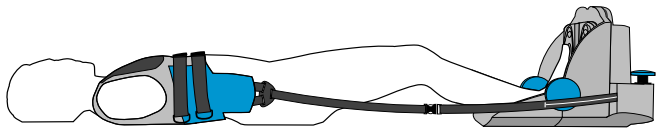


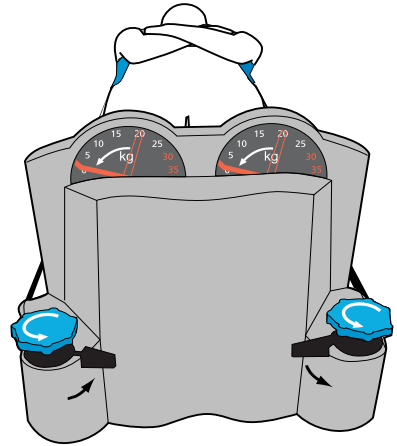
11 **WARNING:** Watch the patient carefully for any sign of pain that appears to be unfamiliar or exaggerated. Maintain a dialog with the patient to ensure that he or she does not feel pain of an unaccustomed nature.

12 **NOTE:** The patient should be in a state of compression for at least 5 minutes before beginning MR or CT scanning.

13 Adjust the level of compression, if necessary, before carrying out the MR or CT examination.

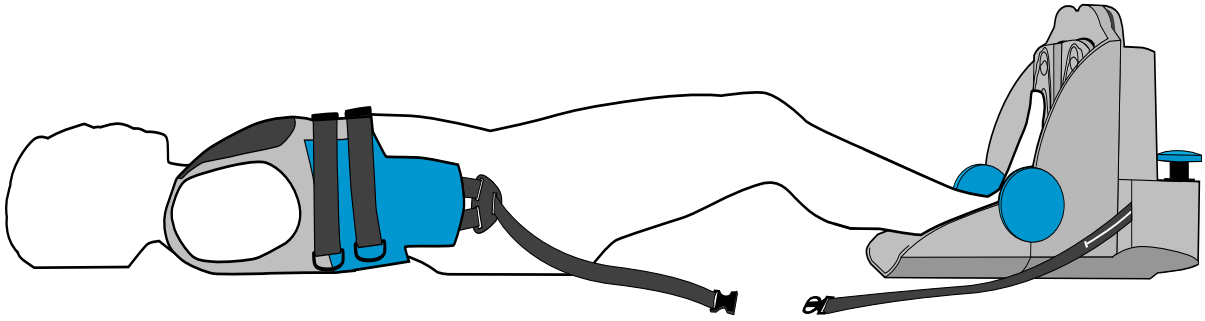
14 Carry out MR or CT examination.





15 **WARNING:** When the examination is completed, before removing the straps, ask the patient to bend his or her knees to unload the lumbar spine – this is important to prevent injury, since the straps are otherwise under pressure and may snap back dangerously when released.

16 In cases when patients are unable to bend their knees, first unlock the compression adjustment knobs. To do this, pull the black compression knob lock outward on the right side, and push the knob lock inward on the left side. Then decrease pressure by simultaneously rotating the compression adjustment knobs counter-clockwise until the compression indicators return to zero.



17 Release the side straps so that the patient can descend from the table, and then remove the vest, after first unclipping the chest straps.

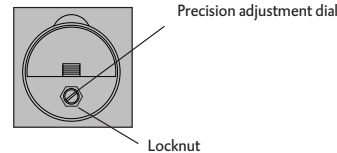
18 Ensure that the compression device is clean, and then store it by folding up the leg support and placing the compression harness and extra vests inside.

19 In the patient file, make a note that the examination was carried out in a loaded position, and record the actual weight of compression as registered on both respective compression indicators.

Fine-tuning the compression indicators

If a compression indicator does not register zero when zero pressure is applied to the foot plate, the meter must be fine-tuned immediately for safe and accurate compression results. This should be done according to the following procedure, outside of any magnetic field:

1. Check that the compression indicators are functioning by pressing on each foot plate. If the pointers on the compression indicators move, follow steps 2-7.
   Otherwise, contact DynaWell Int. AB or your local distributor.
2. Remove the plastic adjustment dial cover from one of the two foot plates, using a screwdriver.
3. Loosen – but do **not** completely unscrew – the locknut, rotating it counter-clockwise.
4. Turn the precision adjustment dial until the compression indicator registers zero. (Turning clockwise increases the weight, counter-clockwise decreases it).
5. Check that you have not left any foreign materials – especially anything magnetic – inside the foot plate.
6. Tighten the locknut by rotating it clockwise. Be careful not to over-tighten the nut, as this may result in damage to the locking function.
7. Replace the plastic adjustment dial cover.
8. Follow steps 2-7 again, this time removing the plastic adjustment dial cover from the other foot plate.



Calibration

In addition to fine-tuning the compression indicators (see page 17), the DynaWell® L-Spine device must be calibrated annually, or whenever accuracy is in doubt. This must be done outside of any magnetic field, according to the following procedure:

CAUTION: Calibration is a 3-step procedure:

A. The zero point must be set (fine-tuned) while the DynaWell® L-Spine device is in the tilted position. (See illustration no. 1 below).

B. The 10-kg point (calibration) must be verified while the DynaWell® L-Spine device is in the tilted position. (See illustration no. 2 below).

C. The zero point must be set (fine-tuned) again with the DynaWell® L-Spine device in the upright position. (See illustration no. 3 below).

A. Setting the zero point in the tilted position (fine-tuning)

1. Place the compression monitoring device on a table with the foot plates facing upwards, as shown in illustration no. 1.

2. Balance the weight of the device on an appropriate support. Make sure that the plastic covers of the compression indicators are not bearing any weight.

3. Adjust the compression indicators to zero (fine-tune) by following the steps on page 17.

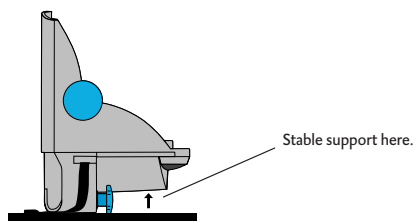


Illustration 1

Calibration

B. Calibrating the instrument (verifying the 10-kg point)

4. Place a calibrated weight that corresponds to 10 kg on one of the foot plates, in the central area of the largest footprint. (See illustration no. 2).

5. Check the compression indicator, which should read between 9.5 kg and 10.5 kg (10 kg +/- 0.5 kg).

6. Remove the weight from the foot plate and make sure the compression indicator returns to zero.

7. Repeat steps 4-6 for the other foot plate.

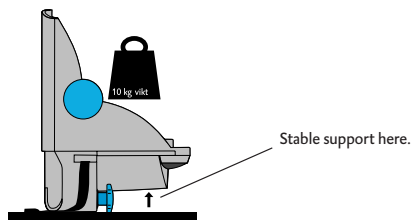


Illustration 2

CAUTION: If either of the compression indicators registers a margin greater than 0.5 kg (e.g. more than 10.5 kg or less than 9.5 kg), do not use the compression device. Contact DynaWell Int. AB immediately for service and/or repair.

C. Setting zero in the upright position (fine-tuning)

8. Place the device in an upright position, as shown in illustration no. 3 below.

9. Adjust the compression indicators to zero (fine-tuning) by following the steps on page 17.

WARNING: All 3 calibration steps must be completed before the DynaWell® L-Spine device is used for medical compression.

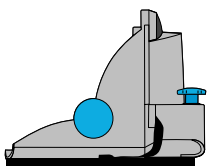


Illustration 3

Maintenance and cleaning

The DynaWell® L-Spine medical compression device requires regular visual inspection, in addition to regular cleaning. If inspection reveals any degree of component malfunction or damage, contact DynaWell® Int. AB for repair/service.

To clean:
1. Always check that the equipment is clean before use.
2. Clean the compression monitoring device and the spinal compression harness using a damp cloth which has been soaked in lukewarm water and mild detergent.

CAUTION: Never immerse the compression monitoring device in water.

Literature

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The diagnostic effect from axial loading of the lumbar spine during Computed Tomography and Magnetic Resonance Imaging in patients with degenerative disorders.
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