

KENYA STANDARD

DKS 2613:2017

Orthoses – Neck and Spinal – Specification

PUBLIC REVIEW DRAFT

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Orthoses – Neck and Spinal – Specification

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FOREWORD

This Kenya Standard has been prepared by the TC 132, Assistive devices and Products for Persons with Disabilities Technical Committee, in accordance with the procedures of the Bureau.

The standard was found necessary to assist specialists within the medical field in ensuring the quality of orthoses either manufactured locally or imported to meet minimum requirements into the country. This is only a guide to the manufacturers, fabricators, service providers and users of spinal orthoses.

Spinal and Neck Orthoses are orthopaedic devices prescribed and designed to basically improve function, support, stabilize, immobilize, correct and accommodate an injured or weakened spinal column to prevent further deformity

The degree of restraint, ranges from the lesser amount provided by fabric corsets to the maximum immobilization and control of the spine afforded by a custom made spinal orthoses.

PUBLIC REVIEW DRAFT

1. Scope

This Kenya Standards specifies the requirements of Spinal Orthoses used by clients or patients with spinal problems or conditions.

Application

- 1.1 This standard covers requirements for prescription, assessment, fabrication and management of supportive, accommodative, maintenance, preventive, and corrective spinal Orthoses.
- 1.2 Spinal Orthoses are either mostly custom-made or prefabricated based on clinical assessment by the service provider. Ultimately they should meet client's needs.
- 1.3 Neck and Spinal Orthoses are applied to regions of the spinal based on the assessment and prescription by the service provider.

2. References

In the preparation of this standard, reference was made to the following documents, which we acknowledge:

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22. Vasiliadis E, Grivas TB, Savvidou O, Triantafyllopoulos G. The influence of brace on quality of life of adolescent with scoliosis. Attica, Greece.

3. Terminology

3.1 Spine – the region of the back between the head and the hip bones comprising of the vertebrae bones

3.2. Orthosis - an orthopaedic device/appliance designed to support, correct, compensate, accommodate, and prevent further deformity and aid movement to an injured or weakened limb or spine. Orthosis (es) are used for chronic conditions, acute injury and injury prevention. They are a non-surgical, removable and relatively cost effective treatment for many joint and muscular conditions.

3.3. Spinal Orthoses - basic Orthopaedic appliances or devices applied to the spine to protect and stabilize the spinal column, to prevent further deterioration, support, correct and aid in performance of body functions

Orthoses are applied to the spinal regions (cervical, thoracic, lumbar, or combination of two or more regions). The devices may be termed as Spinal Orthotic Devices, braces, corsets, or supports.

3.4. Orthopaedic technologist - medical professional who specializes in identification, assessment of clients, design, fabrication, fitting, maintenance and management of various orthopaedic devices

3.5. Prosthetist - medical professional who specializes in assessment of clients, design, fabrication, fitting, management and maintenance of Orthopaedic appliances that are artificial substitution of missing body parts

3.6. Orthotist - medical professional who specializes in assessment of clients, design, fabrication, fitting, management and maintenance of Orthopaedic appliances designed to support, correct, compensate, accommodate, and prevent further deformity.

3.7. Cervical Region - the region between the head and the shoulder made up of the first seven vertebrae of the spine usually called the neck region.

3.8. Thoracic Region - the region of the spine between the neck (cervical) and the lower back (Lumbar) comprising of 12 vertebrae.

3.9. Lumbar Region - the lower portion of the spine made up of 5 vertebrae; connects with the fused bones of the sacrum below.

3.10. Sacral Region - the five vertebrae at the base of the spine that provide attachment for the iliac (hip) bones.

3.11 Foam rubber also be known as cellular, sponge or expanded rubber.....

4. Shape and Dimensions

The typical shapes of the Spinal and Neck Orthoses shall conform to client's body size, contours and meeting the prescription criteria.

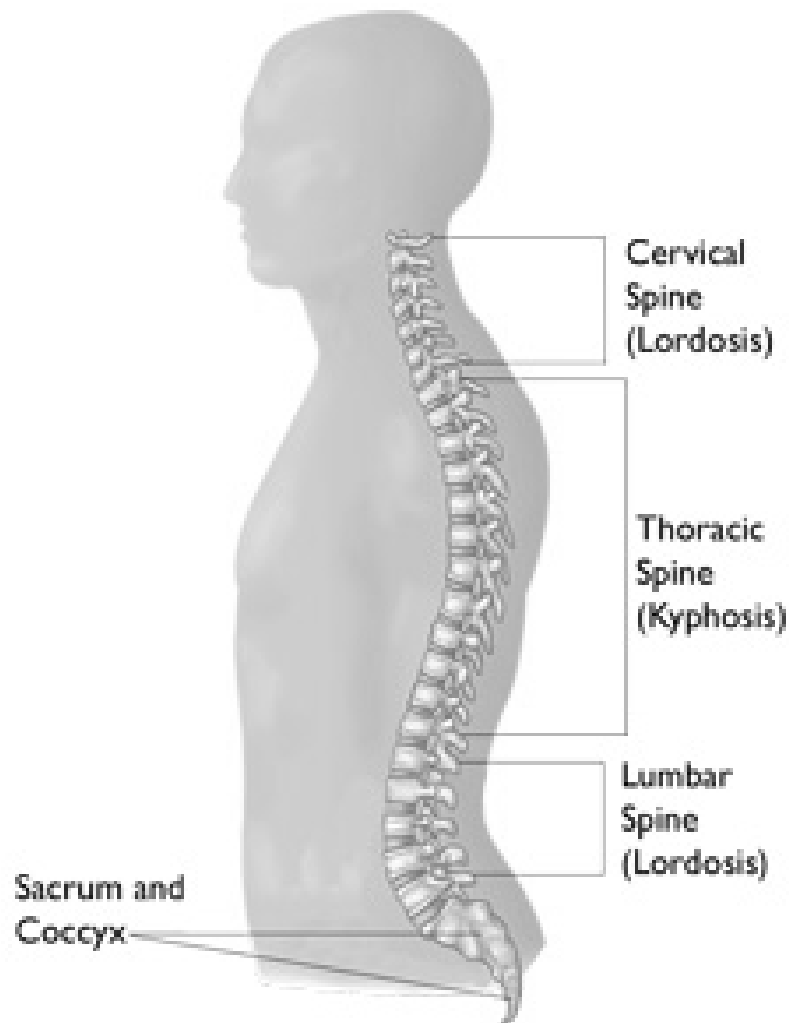
5. Classifications and Types

5.1. Classifications

Spinal and Neck Orthoses are classified as being active and passive. Active is corrective in nature. Passive is supportive in nature preventing the condition from worsening.

5.2. Types

Types are dependent on the affected part of the spine and function of the Orthosis. Braces can be worn on any section of the spine (cervical, thoracic, lumbar, and sacral) named according to the region of the spine to which they are applied. The types may be of different designs but shall meet the minimum requirements of this standard.



5.2.1 Neck (cervical) braces

This type of brace is applied on the neck region between the base of the skull and the shoulder. There are two types of neck braces: soft and rigid.

Rigid



Soft

5.2.2 Cervical-thoracic braces

This type of brace is applied from the neck up to the thoracic region to restrict neck and upper back movement after an injury or neck fusion surgery.



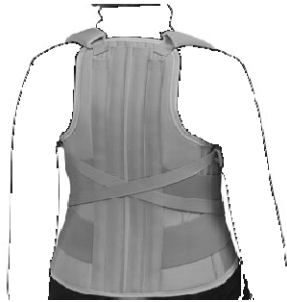
Figure 3: illustrations of cervical thoracic brace

5.3. Thoraco-lumbar braces

This type of appliance is applied from the thoracic region to the lumbar region. This brace shall be flexible or rigid.

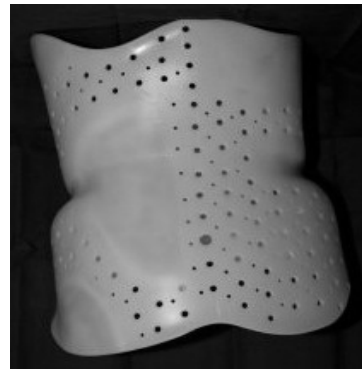
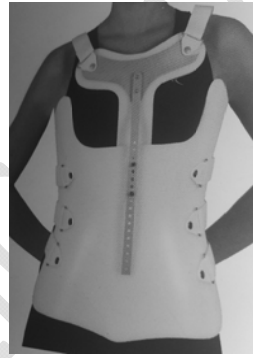
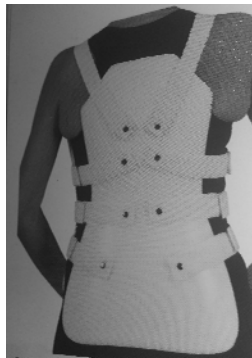
5.3.1. Flexible Thoraco-Lumbar Brace.

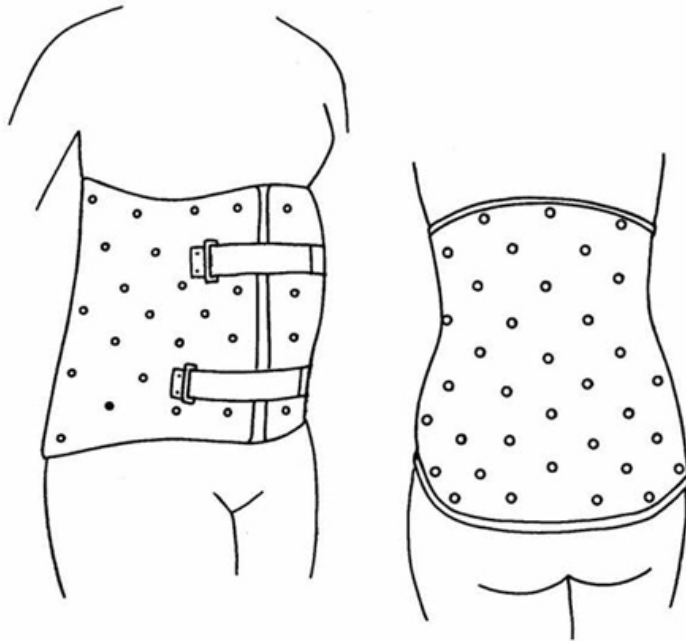
This type of device shall be made from an elastic cotton/nylon material to support the spine.



5.3.2. Rigid Thoraco –Lumbar Braces

This brace is applied on the Thoraco lumbar region to restrict motion of the spine during management and recovery.





5.4. Thoraco- Lumbar Sacral Orthosis (TLSO)

This brace is applied from the upper back (thoracic) to the sacral region to restrict movement and reduce stress on the spine and may be semi-rigid



5.5: Cervical Thoraco Lumbar Sacral Orthosis (CTLSO)

This device is applied on the whole spine from base of the skull to the sacral region to support weakened or damaged areas of the spine



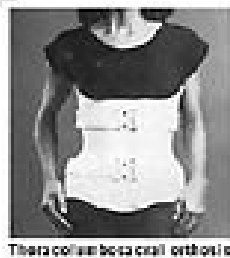
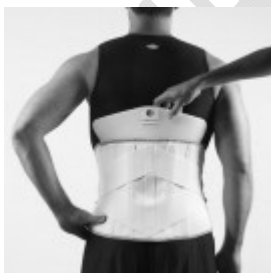
5.6. Lumbar Sacral Orthosis (LSO).

This device covers the whole of the lower back to serve as a postural support or a post-surgery brace.

5.6.1. Flexible LSO



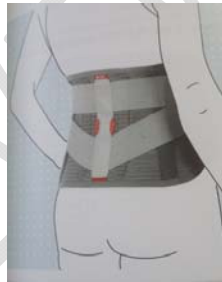
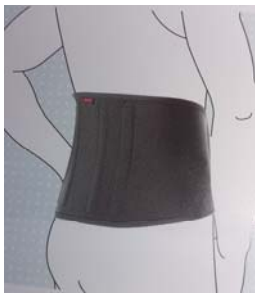
5.6.2. Rigid LSO



5.7. Sacro-iliac belt (brace)



The rigid pelvic belt is used to control instability of sacro-iliac joints after injury, and pubic symphysis instability after accident or childbirth. It assists in fixing the hip joint in case of joint laxity and shall be made from rigid or elastic webbing buckled or fastened in front using Velcro straps



luballo to

sketch

5.8. Hyperextension Braces



A hyperextension brace puts pressure and support on the thoracic spine, because it is primarily used to treat spinal compression fractures that occur where the upper back meets the low back. This pressure keeps the spine in an extended position.

6. Materials Requirements

The following materials shall be used in the manufacture of spinal orthoses or other materials which are equivalent or superior in performance.

6.1. Material used for the fabrication of spinal orthoses shall be plaster of paris, leather, metal, fabric, or lightweight thermoplastic. The thermoplastic sheets shall be moulded to fit body parts exactly, and some shall be reshaped repeatedly as the treated body part changes shape.

6.2. The material used in the manufacture of Spinal orthotic devices shall be low-temperature thermoplastics and thermosetting that can be custom-made, prefabricated or moulded to fit. The material used shall be durable, tough, cosmetic, light weight, non-corrosive and non-allergic to the skin.

6.3. Other materials shall include fasteners, fabric, adhesives and Velcro but shall meet the requirements of 6.2.

6.4 Custom-made Spinal and Neck Orthoses shall be fabricated by a qualified orthopaedic technologist or Orthotist and Prosthetist.

NOTE High-temperature thermoplastic materials shall be moulded over a plaster model of the body part at a temperature that is too high to come in contact with human skin, but they have the advantage of being stronger and more durable than low-temperature thermoplastics. They are used in situations where the Orthosis will under-go a lot of stress or will be used for a long time.

8.1 Plastics

Spinal orthoses shall be fabricated of low-temperature thermoplastics which becomes pliable below 180°F (80°C), and shall be moulded directly against the body. The material shall have excellent Ventilation, lightweight,

durable, Non-toxic, X-Ray translucent, Biodegradable, Self Bonding, Water resistant and easy to process. The material shall be in a variety of widths, thickness and colour and can be padded to cushion sensitive areas.

8.2 Plaster of Paris bandage

Plaster bandages consists of a cotton bandage that has been impregnated with plaster of Paris, which hardens after it has been made wet. Plaster of Paris is calcined gypsum and is used to get an impression. When water is added, the more soluble form of calcium sulphate returns to the relatively insoluble form and heat is produced.

Plaster of Paris shall be easy to mould with water and setting time shall be 3 - 10 minutes at 23 degrees centigrade. The mould should be hard and lightweight, durable, and readily adjustable. On setting it takes a shape impression and comfortable fit.

Must have a porous structure and yet still be fine-grained.

8.3. Plaster of Paris Powder

Plaster shall be easily worked and adaptable with other material and equipment.

Plaster of Paris has other several uses, in orthopedic casts are used for an immobilization of the spine in immediate care.

The setting and drying time should allow enough time for working.

8.4. Foam rubber Properties

Foam rubber lightweight to provide insulation, cushioning or impact dampening. The foam rubber can be flexible or rigid in applications.

NOTE: Foam rubber is also known as cellular, sponge or expanded rubber

8.5. Fabric

Fabrics are woven material that are soft, drapeable, strong and durable, resistant to shrinking and breathes well. Fabrics shall be washable, easy to clean and dries quickly, non-toxic, non reactive and cosmetically acceptable

8.6 Metal

The most commonly used metal is aluminium, stainless steel, duralumin, mild steel with the properties of being non corrosive, light weight, ductile, malleable and tough.

The material shall be cosmetically acceptable, ease of fabrication, high strength to weight ratio and high fracture toughness.

8.7 Paddings

The padding shall be made of foam, lining leather, eva foam, soft ban, and pelite. They shall be non-allergic, shall absorb and not retain moisture. The material shall be elastic in nature and not get permanent distortion. Most modern spinal Orthoses may be lined inside or may be without lining.

NOTE. Clients/users can use a separate interface that absorbs perspiration and protects the skin, and which can be washed or replaced as needed.

8.8. Attachments and accessories

The accessory parts shall be fasteners - buckles, rivets, Velcro straps, laces, hooks-and-loops, rigid and flexible webbings. They are used to secure the spinal orthoses on the body.

Head supports may be needed in some specific medical conditions. The orthoses may be reinforced by uprights in the back (which may be metallic or plastic).

7. Criteria of conformity and performance of materials

The orthoses shall meet the requirements specified in clauses 5, 6 and 8.

NOTE The manufacturer should state the specifications of the materials used for fabricating the orthoses.

8. Workmanship and Finish

Spinal orthoses shall be cosmetically acceptable, without rough sharp edges and easy to apply and remove. It shall conform to the body parts applied to and meet the prescription.

9. Test methods

When tested and subjected to tensile, comprehensive, shearing and twisting forces the orthoses shall not fail from fatigue.

11. Marking

Each pre-fabricated Orthosis shall be permanently and indelibly be marked with the manufacturer's name, initials or recognized trade-mark and the size.

12. Packaging

12.1. Each pre-fabricated Orthosis shall be supplied with a user manual and the country of origin.

12.2. Custom made Orthoses shall have clear instructions to the user / client regarding the use, assembling, maintenance and necessary follow-ups

ANNEX-A

USER MANUAL FOR NECK AND SPINAL ORTHOSIS

Neck and spinal Orthoses

1. Ask your service provider to evaluate the effectiveness and function of your neck and spinal orthosis.
2. If there is need for change of orthosis, have a written prescription from a service provider. Take your prescription to an orthopaedic technologist /orthotist (a person who makes orthosis).
3. Slip or fit the orthosis on affected part of the neck or the spine as directed by the service provider.
4. Use the Velcro strap or a buckle to position and fasten the orthosis as shown and trained by the service provider.
5. The service provider should train you on how to use and take care of the orthosis
6. Visit your orthopaedic technologist/orthotist for any adjustments until you have a proper fit. Expect to feel some discomfort at first.
7. Prevent skin problems from occurring with your new orthosis by following a “wearing” schedule. Wear your orthosis as recommended by the service provider.
8. Always check affected body part for any areas of redness or change of skin colour, blisters or swellings, when you remove your orthosis discontinue use and consult your service provider.
9. Notify your orthopaedic technologist/orthotist or doctor immediately if redness or change of skin colour occurs.
10. Adjust your orthosis by loosening the Velcro straps if you notice redness or feel uncomfortable but ensure that it is well secured.
11. Tips & Warnings

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- Orthosis are custom-made or off-the-shelf (prefabricated). The off-the-shelf (prefabricated) Orthosis will have to be adjusted to fit.
- Do not soak in water. Keep orthosis clean by wiping with clean damp piece of clothing.
- Always keep orthosis/ joints lubricated or well oiled
- Keep the orthosis away from fire.
- In case of wear and tear or damage, take the orthosis to the service provider for repair/ replacement.
- A cotton undershirt should always be worn under the Spinal Orthoses.

If you have any questions or concerns, contact the service provider or other health care professional before engaging in any activity related to health and diet. This information is not intended as a substitute for professional medical advice or treatment. Stick to appointment dates for reviews. For all spinal Orthoses, consult with your service provider before putting on.

ANNEX-B INFORMATIVE

1-Cervical Orthotics



Cervical orthoses are prescribed for patients requiring restraint of flexion, extension, lateral flexion and rotation of the neck.

Common types are:

- Soft Collar
- Rigid Collars
- Halos

S.O.M.I. Sterno Occipital Mandibular Immobilizer

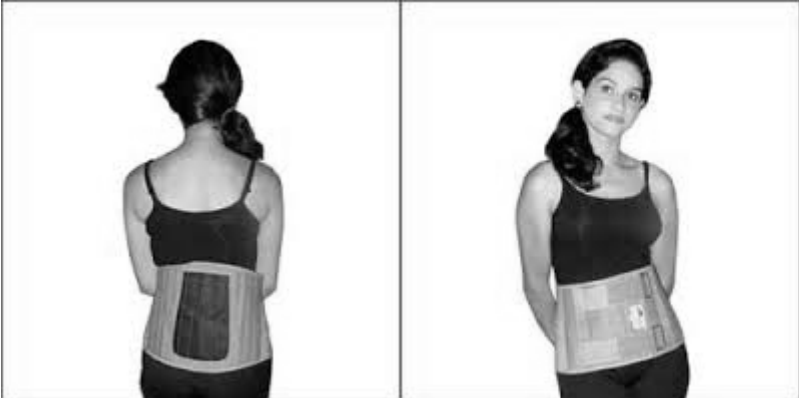
- **2-Spinal Orthotics**



. Types are:

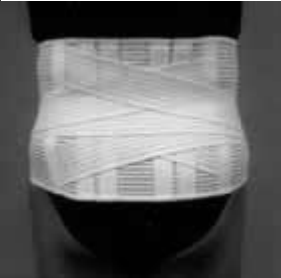
- Elastic Rib Binder
- Sacroiliac Belt
- Trochanter Belt
- Corset
- Soft lumbar-sacral support(LSO) and Thorac-lumbaro sacral support(TLSO)
- Rigid LSO and TLSO
- Scoliosis Brace

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Spinal Orthosis (SO)

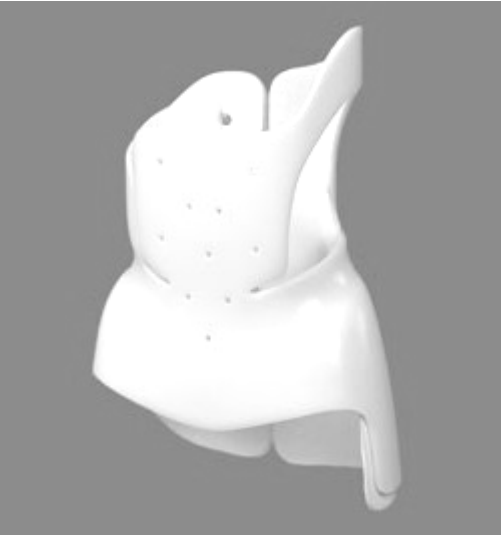
Clockwise starting top left: Charleston Bending Brace; 2 Thoraco-Lumbo-Sacral Orthoses (TLSO) for treating scoliosis; Plastic TLSO for a traumatic injury; Harris Brace for chronic low back pain.

Spinal orthoses can be made to support from the cervical spine to the lumbar spine.

Custom orthoses can be total contact plastic, fabric garments with rigid plastic inserts or a corset style to help control the back.

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Back and Spinal Bracing

Centre Spinal Orthoses includes cervical orthoses, cervical-thoracic orthoses, thoracic orthoses, thoracic-lumbar-sacral orthoses, lumbar-sacral orthoses and lumbar orthoses.

While sitting or standing, the upper body receives its support from the sacroiliac joint. But, over a period of time, the joint can wear out and cause lower back pain. Back pain is a common ailment that affects individuals of all ages and may result from conditions including, injury, obesity, age, disc disease, spinal stenosis, spinal sprains and strains.



Back pain treatments include back braces / spinal orthotics. It restricts spine movement after trauma.

Spinal orthoses include cervical orthoses, cervical-thoracic orthoses, thoracic orthoses, thoracic-lumbar-sacral orthoses, lumbar-sacral orthoses and lumbar orthoses.

Spinal orthoses have been recommended for the treatment of back pain and to stabilize the spine. Conditions for which spinal orthoses have been recommended for relieving pain, reducing progression of disease/injury, and improving function include spinal stenosis, vertebral fractures, scoliosis, spondylosis, spondylolisthesis, Scheuermann's disease and sprains.

Spinal orthoses have also been recommended for use following spinal surgery as a method of restricting excessive spinal motion, allowing for soft tissue healing, and to reduce postoperative pain. In addition, spinal bracing results in lower incidence of hardware failure, loss of surgical correction, and pseudoarthrosis. The indications for bracing are dependent on the degree of injury and spinal instability, the presence of neurological deficit, the type and quality of internal fixation, bone quality, and the patient's individual profile.

3-Types of Spinal Orthoses

Corset braces



Corsets are a type of spinal brace commonly used to treat low back pain.

Low back pain can be caused by a number of things and Corset braces are often prescribed to treat low back pain associated with:

- degenerative disc disease
- trauma, fracture, or injury

- spinal deformity (such as scoliosis)

A corset brace may also be used to immobilize your back after spine surgery.

Jewett Brace



A Jewett brace is a three points pressure system of orthosis, which is used for controlling the flexion of the spine. It is a hyperextension orthosis, which allows extension but prevents flexion of the spine.

The Jewett Hyperextension Spinal Orthosis helps control and support your spinal posture, helps reduce pain, prevents further injury and promotes healing. It will remind you to keep your back upright and straight. It is often prescribed for the treatment of compression fractures or fractures on the front side of the spine.

By activating the back muscles the support straightens the dorsal spine to decrease the osteoporotic kyphosis. Simulation of the body's own muscle power, when optimally fitted the support eases the patient's pain and improved mobility. The easily mend back brace makes it possible to adjust individually to each patient. The brace is light and barely visible under clothing, the "backpack" principle makes putting on the brace easy, no obstruction or thoracic or abdominal breathing, no restriction of shoulder or arm movements.

4-Molded Jackets



A molded jacket or a thoracolumbosacral orthosis (TLSO), provides rigid stabilization to treat a number of spinal conditions, including spinal fractures and scoliosis.

A molded jacket is a total-coverage brace that supports a large area - from the thoracic spine, lumbar spine and sacrum. This type of spinal brace provides a strong external support for your thoracic and lumbar regions. Molded jackets may help treat a variety of spinal conditions like:

- Spinal fractures (including burst fractures and spinal compression fractures)
 - Scoliosis
 - Scheuermann's kyphosis
 - Ankylosing spondylitis

5-Lumbosacral bel

Miami

®



The Miami Lumbar® is an easy-to-use lumbar orthosis for post-surgical immobilisation, pain relief and the protection of injured ligaments or muscles. The superior anatomical design follows the contours of the spine while simultaneously ensuring better immobilisation and patient comfort. The modular system enables step-down treatment options for every stage of the recovery process. A TLSO attachment can be used for maximum immobilisation, which stabilises the spine up to T7. Lumbosacral belts are designed to provide pressure on your abdominals, thereby reducing weight and stress on your low back. This type of brace provides lumbar spine stabilization, so it creates an optimal healing environment for a number of lumbar spine conditions, including low back muscle strain.



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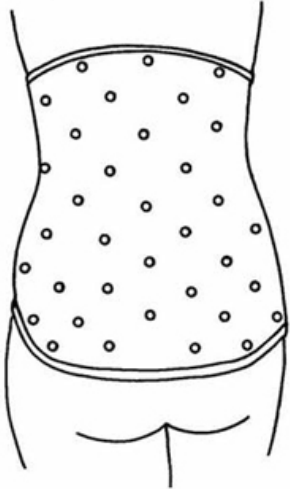
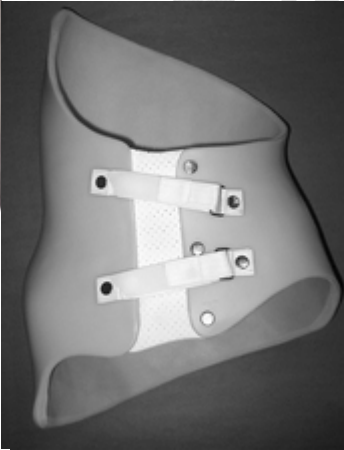


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Thoracic (Upper Torso) Orthoses

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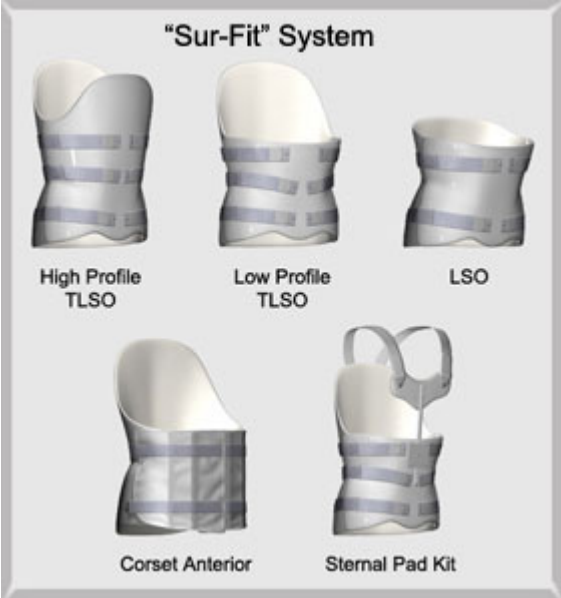
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NOTE

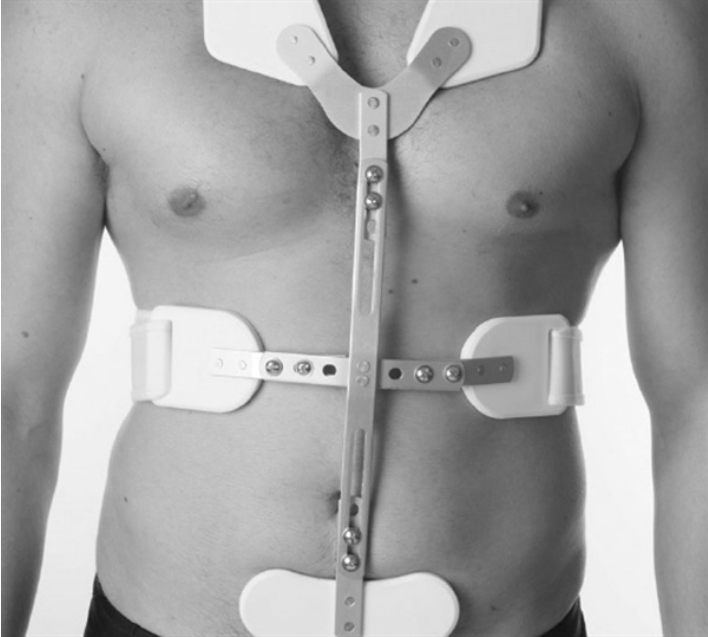


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Chairback Spinal Brace



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