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**Classification and general technology requirements of spinal
orthoses**

脊柱矫形器的分类及通用技术条件

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3 Terms and definitions

3.1 Spinal orthoses: a device used outside the body to correct the structural and functional characteristics of the neuromuscular and skeletal system of the spine. Note: some such devices are custom-made to meet an individual functional need and some are prefabricated to meet a particular functional requirement; among the prefabricated ones, some can be adjusted to suit the individual fitting and some are finished products that cannot be adjusted or need no adjustment.

3.2 Fixed spinal orthoses: a spinal orthosis used to immobilize the spine or to limit its

movement.

3.3 Weight bearing spinal orthoses: a spinal orthosis used to reduce the pressure on the spine.

3.4 Orthotic spinal orthoses: a spinal orthosis used to correct or prevent a deformity of the spine.

3.5 Compensatory spinal orthoses: a spinal orthosis used to make up for or replace a lost function of the spine.

3.6 Cervical orthoses: an orthosis used on the whole or part of the cervical region, including the atlanto-occipital joint.

3.7 Cervico-thoracic orthoses: an orthosis used on the whole or part of the cervical and thoracic regions, including the atlanto-occipital joint.

3.8 Cervico-thoraco-lumbo-sacral orthoses: an orthosis used on the whole or part of the cervical, thoracic, lumbar and sacro-iliac regions, including the atlanto-occipital joint.

3.9 Thoraco orthoses: an orthosis used on the whole or part of the thoracic region of the trunk.

3.10 Thoraco-lumbar orthoses: an orthosis used on the whole or part of the thoracic and lumbar regions of the trunk.

3.11 Thoraco-lumbo-sacral orthoses: an orthosis used on the whole or part of the thoracic, lumbar and sacro-iliac regions of the trunk.

3.12 Lumbo-sacral orthoses: an orthosis used on the whole or part of the lumbar and sacro-iliac regions of the trunk.

3.13 Sacro-iliac orthoses: an orthosis used on the whole or part of the sacro-iliac region of the trunk.

4 Classification and model designation

4.1.1 By function, spinal orthoses are divided into fixed, weight bearing, orthotic and compensatory spinal orthoses. Note: one product may have two or more of these functions; in practice its main function or the function actually needed is settled and the other functions described.

4.1.2 By region, spinal orthoses are divided into cervical, cervico-thoracic, cervico-thoraco-lumbo-sacral, thoracic, thoraco-lumbar, thoraco-lumbo-sacral, lumbo-sacral and sacro-iliac orthoses.

4.2.1 The model designation of a spinal orthosis is made up of the region code, the function code, the abbreviated name of the company with the design serial number, and the improvement serial number. Example 1: CO-F-XX-01, the fixed cervical orthosis of original

design with design number 01 of the company abbreviated XX. Example 2:

LSO-O-XX-02-A, the orthotic lumbo-sacral orthosis with design number 02 of the company abbreviated XX, first improved design. Example 3: TLSO-U-XX-03-B, the weight bearing thoraco-lumbo-sacral orthosis with design number 03 of the company abbreviated XX, second improved design.

4.2.2 The region code follows Table 1 and uses the initial letters of the English name of the region together with the word orthosis. Table 1 has two rows, eight regions and eight codes: cervical CO, cervico-thoracic CTO, cervico-thoraco-lumbo-sacral CTLSO, thoracic TO, thoraco-lumbar TLO, thoraco-lumbo-sacral TLSO, lumbo-sacral LSO and sacro-iliac SO.

4.2.3 The function code follows Table 2 and uses the initial letter of the English name of the functional class. Table 2 gives four functions and four codes: fixed F, weight bearing W, orthotic O and compensatory C.

4.2.4 The design serial number of the product is written with two Arabic numerals.

4.2.5 The improvement serial number is written with one letter, A, B, C and so on in order; an original design carries no letter and the first improvement is marked A.

5.1 Appearance quality

5.1.1 Seams in soft materials shall be firmly sewn, with even stitching free of obvious defects.

5.1.2 Riveted joints shall be firm, with a smooth surface free of burrs and sharp faces.

5.1.3 The surface shall be even in colour and free of scratches and cracks, and free of sharp edges, sharp corners or burrs liable to injure the body.

5.2 Design and structure

5.2.1 General requirement. The design starts from the examination result and the prescription, which settle whether the main function of the orthosis is fixing, weight bearing, correction or compensation. A fixed spinal orthosis shall give the affected part stable fixation and protection: one acting as a complete fixation shall limit movement of the spinal segments concerned in the sagittal, coronal and transverse planes so as to avoid injury to nerves, bone and ligaments, and one acting as a partial fixation shall limit movement of the spine within a given angle or degree of freedom. A weight bearing spinal orthosis shall relieve the affected part, reducing the overall vertical pressure on the spine and the stress in parts of the structure such as the vertebral body or the vertebral arch. An orthotic spinal orthosis shall apply the correct corrective force to the deformed part, the magnitude, direction and point of application of the force being accurate, so as to correct in three dimensions a deformity or abnormal posture that departs from the physiological position of the spine. A compensatory spinal orthosis shall provide assisting force or stored energy to

help the spine move and so make up for the lost function.

5.2.2 Cervical orthoses. Table 3 gives, for each functional class, the design and structure requirements and examples of products. For the fixed and weight bearing class, the orthosis limits flexion, extension, lateral bending and rotation of the neck, reduces the pressure on the cervical spine and gives support and protection; the upper end reaches the mandible in front and the occiput behind, and the lower end is fixed with the shoulders as the stable base, reaching the manubrium in front and the spinous process of the second thoracic vertebra behind, leaving the scapulae free at both sides; the inner wall in contact with the body is of soft composite material and the outer wall of hard supporting material, and the flexion and extension angle and the supporting force are adjusted by changing the angle and height of the chin support and the occipital support; the structure is either two-piece front and back or one-piece, with the opening at both sides or at one side and closed by an adjustable soft strap so that the girth can be adjusted to the user. Products listed as examples are the cervical fixation device, the moulded fixed collar, the height-adjustable collar, the three-piece collar and the inflatable collar. For the orthotic and compensatory class, the compensatory function, the points of application of the corrective force and the release space are designed on biomechanical requirements and the three-point force principle, correction preferably being made in the over-corrected position with the balance of the body force line as the aim; the upper end reaches the mandible in front and the occiput behind, and the lower end reaches the manubrium in front and the spinous processes of the fourth to sixth thoracic vertebrae behind; the same material, structure and strap arrangement apply, and the magnitude and point of application of the corrective force are finely adjustable. The product listed as an example is the torticollis orthosis.

5.2.3 Cervico-thoracic orthoses. Table 4 gives the same three columns. For the fixed and weight bearing class, the orthosis limits flexion, extension, lateral bending and rotation of the cervical spine, reduces the pressure on it and gives support and protection; the upper end reaches the mandible in front and the occiput behind or extends forward to the temporal bone, leaving the ears free, and the lower end is fixed with the shoulders and chest as the stable base, reaching the thorax in front, leaving the breasts free for female users, and reaching below the scapulae behind, leaving the scapulae free at both sides without hindering shoulder movement; the inner wall in contact with the body is of soft composite material and the outer wall of hard supporting material; the whole is made of a front and a back piece, each of one-piece or component construction, adjustable in height, length and angle, the two pieces joined by an adjustable soft strap so that the girth can be adjusted without hindering breathing. Products listed as examples are the head-band cervico-thoracic orthosis, the halo cervico-thoracic orthosis, the post-reinforced cervical orthosis, the front and back shell cervico-thoracic orthosis and the frame cervico-thoracic orthosis. The orthotic and compensatory class adds the three-point force design and the fine adjustment of the corrective force, with the additive manufactured cervico-thoracic