ASPREX Fact Sheet

Spinal orthosis

Assistive device attached to the body for supporting the neuro-muscular-skeletal systems or movement functions related to the functioning of the spine. Orthoses are designed to modify the structural and functional characteristics of the neuromuscular system of the spine; the device may be custom fabricated or prefabricated and adjustable to fit an individual user or may be ready to use so that adjustment is not possible or no adjustment is necessary for any user. The product may be custom manufactured or assembled from prefabricated components. It can be rigid or flexible (different types).

In case it is custom manufactured: Ideally, orthoses are custom fabricated to fit specific body landmarks so that the devices provide adequate motion control through the best possible leverage system biomechanics. The thoracic band is located so that the superior edge rests 24mm inferior to the inferior angle of the scapula. The band may be horizontal across the back or convex in a superior plane to provide the greatest height at the midline while allowing freedom of the scapula. Laterally to each scapula, the component dips inferiorly to allow space for the axilla. The component ends just anterior to the lateral midline of the body or the mid axillary trochanteric line, a line defined by the bisection of the body at the axilla and trochanter. The inferior edge of the pelvic band rests at the middle of the sacro-coccygeal junction, Lateral to the midline, the component usually dips inferiorly to contain the gluteal musculature. The rationale for the curve is to provide the greatest leverage for the orthosis. The paraspinal bars are contoured to follow the paraspinal musculature. All metal orthoses can be worn with either a corset or an anterior panel of corset material. The components used to construct the most common metal spinal orthoses are typically aluminum alloys that are radiolucent and malleable, yet of sufficient strength to hold their shape. Rigid immobilization is accomplished using a “body jacket” made of plastic with a soft foam interface (lining). Dynamic immobilization gives support with semi rigid materials like high density foam with plastic (permanent or removable). It allows some movement. A plastic frame can be incorporated into the foam for additional restriction of motion if desired. Tend to be better tolerated. The custom-made, soft, high-density Lumbosacral Orthosis (LSO) or off-the-shelf semi-rigid LSO with a compound closure system to optimize support are excellent alternative to rigid body jacket or corset, offering a balance between comfort and control.

Common materials used for spinal orthoses are plastic, thermoplastic, plastizote, aluminum bars, soft foams combined with plastic; the challenge in combining materials is to achieve a balance of comfort and control.

- Product Classification
  - APL (WHO Assistive Product Priority List): 24 (Orthoses, spinal)
  - ISO 9999:2016: 0603 (Spinal and cranial orthoses)
- Possible configuration variants
  - Sacrum-iliac orthosis (Iso 060303).
  - Lumbo-sacral orthosis (Iso 060306).
  - Thoracic orthosis (Iso 060307).
  - Thoraco-lumbar orthosis (Iso 060308).
  - Thoraco-lumbar-sacral orthosis (Iso 060309).
  - Cervical orthosis (Iso 060312), also including atlanto-occipital joint.
  - Cervico- thoracic orthosis (Iso 060315).
  - Cervico-thoraco-lumbo-sacral orthosis (Iso 060318).

- Articulating components for spinal orthosis (Iso 060327), which allow or control the motions of anatomical joints of spine.

- ## Possible accessories or optional components

  None specified.

- ## Product goals

  Activities or functions the product is mainly intended to support, according to WHO ICF Classification:

  - Caring for body parts [d520].
  - Maintaining body position [d415].
  - Transferring oneself [d420].
  - Walking [d450].

- ## Indicated impairments

  Difficulties the product is mainly intended to address, according to the WHO ICF Classification:

  - Mobility of joint functions [b710] (lack of mobility of spine joints).
  - Stability of joint functions [b715] (lack of stability of spine joints).
  - Muscle power functions [b730].
  - Muscle tone functions [b735].
  - Motor reflex functions [b750].
  - Involuntary movement reaction functions [b755].
  - Sensation of pain [b280].

- ## Contraindicated impairments

  Difficulties for which the product may be inappropriate:

  - Lack of sensation or skin integrity (any skin damage in the area where the orthosis is in contact will worsen with the use of the device; extra caution with visual checking for areas of rubbing/ chafing).
  - Severe gastro-esophageal reflux (it may be exacerbated by abdominal pressure by an orthosis).
  - Severe asthma (in particular periods of exacerbation).

- ## Indicated environments

  Specific environments in which the product should be used:
  None specified.

- ## Contraindicated environments

  Environments in which the product may be inappropriate:

  - High temperature or humidity (persons who are less tolerant may experience discomfort and potential breathing restriction, and the skin may be less capable of withstanding the forces generated without its integrity being comprised; the decision to use a rigid rather than a more flexible system should therefore be based on the degree to which spinal motion restriction is required).

- ## Other indicated factors

  Other factors or situations the product is intended to address:

  - Correcting a distortion of any part of the spine.
  - Giving stability to the spine to provide postural control (for better arm and hand function and enable people to walk).

- ## Other contraindicated factors

  Other factors or situations in which the product may be inappropriate:
  None specified.

- ## Points to be considered in product selection

  - List the physical and environmental need of the user in relation to the lack of Lower Extremity stability, giving priority to determine which spinal motion control.
  - Find out if the product will be custom made or prefabricated: will it be rigid or dynamic? Will it be for providing stability for function? Will it be supportive for protecting and avoiding secondary complications?
  - Provide accurate measurements or mold (in case of custom made).

    - Deciding rigid or flexible: orthoses that are more rigid are often preferred in terms of protecting the involved spinal segment. The decision to use a more flexible system is based on the practical issue of orthotic tolerance and thus compliance with wearing the orthosis. The ideal orthosis serves no purpose at all if is not worn; it is sometimes necessary to make practical decisions that involve sacrifice orthotic control to gain person´s acceptance.
- Points to be considered in product fitting
    - Fitting to the need of the person, checking that the orthoses provides the appropriate stability and no part of the orthoses will injure the body of the person.
    - Appropriate training should be provided to caregivers: 1) maintain spinal precautions to facilitate optimal healing; 2) never use the orthosis as a handhold during transfers, 3) educate patient regarding any spinal precautions to promote carryover.
    - Identify how orthosis or spinal precautions will affect transfer.
- Points to be considered in product use
    - Training may be needed for the user to ensure that he or she is able to fit in the product with or without help (as expected). Usually help is needed to fit in this kind of orthosis so it is needed to train the caregivers how to do it.
    - Dosage use program. needs to adapt to the use increasing time and checking the possible skin injures.
    - Tolerance to wear the orthosis could be limited, especially when the need is to cover an extensive area.
    - What to do if there is discomfort or injury.
- Points to be considered in product maintenance / follow-up
    - Check the tolerance.
    - Carry out follow-up checks about every six months if there is no other sign of concern about the correct use of the orthoses.
- Examples of products available on the market
    - Live product search in the EASTIN website https://www.eastin.eu/en/searches/products/list?iso=0603

Source

This Fact Sheet was compiled in 2021 by an international team of experts, to provide the initial knowledge base for a project ("An online system to assist the selection of assistive product") supported by the World Health Organization in 2020-2021 within the GATE Initiative (Global collaboration on Assistive Product). Fact Sheets were compiled for each of the 50 types of products included in the WHO APL (Assistive Product Priority List).

The team was composed of Renzo Andrich (Italy, group leader), Natasha Layton (Australia), Stefan von Prondzinski (Italy), Jerry Weisman (USA), Silvana Contepomi (Argentina) and Hasan Minto (Pakistan).

The project led to a prototype online tool called ASPREX (ASsistive PRoduct EXplorer). At the end of the project, it was transferred to a WHO collaborating center (the Global Disability Hub in the UK), in view of possible future developments.