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Prosthetics and orthotics — Foot orthotics — Uses, functions classification and description

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Foreword

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

This document was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Introduction

No internationally accepted method is available to describe devices applied to the foot to address neuromusculoskeletal impairments.

This situation has created problems for practitioners prescribing these devices, for manufacturers when describing their products and for those reporting on the devices used in the treatment of their patients and their effects.

This document proposes the adoption of the term “foot orthotics” for this field of orthotic practice. It also specifies the clinical objectives for the use of these devices and describes their functions and constituent components.

Manufacturers’ trade names and details of materials and manufacturing processes have been avoided.

Prosthetics and orthotics — Foot orthotics — Uses, functions classification and description

1 Scope

This document establishes a method of classifying and describing the devices that are used in the field of foot orthotics. It does not describe the materials or manufacturing methods used for their fabrication.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
foot orthoses
orthoses that encompass the whole or part of the foot intended to address the effect of a neuromusculoskeletal impairment(s)

Note 1 to entry: They can be custom fabricated or prefabricated.

Note 2 to entry: This definition supersedes the definition of “foot orthoses” in ISO 8549-3.

3.2
orthotic footwear
footwear intended to address the effect of a neuromusculoskeletal impairment(s)

Note 1 to entry: These can encompass the ankle joint. These devices are sometimes referred to as “orthopaedic footwear”. They can be custom fabricated or prefabricated.

3.2.1
custom fabricated orthotic footwear
orthotic footwear designed and manufactured to meet the clinical needs of the individual user based on information such as moulds, lasts and measurements

Note 1 to entry: They can include a custom fabricated foot orthosis.

3.2.2
prefabricated orthotic footwear
orthotic footwear designed and manufactured to meet the clinical needs of a particular group of users and which may be available in a range of sizes, styles and materials

Note 1 to entry: They can require adjustments and can include a foot orthosis in order to meet the clinical needs of the individual user.

3.3
adaptations (modifications) to footwear
adaptations (modifications) to either standard footwear or prefabricated orthotic footwear intended to meet the clinical needs of the individual user

4 Uses

Foot orthotic devices may be used to achieve the following clinical objectives:

a) to relieve pain;

b) to promote balanced standing and walking;

c) to manage deformities which are:

   1) reducible (flexible) (e.g. pes planus);

   2) irreducible (fixed) (e.g. fixed equinus);

d) to control joint instability (e.g. ankle ligament insufficiency);

e) to compensate for abnormal limb length and/or foot length or shape;

f) to protect tissues (e.g. diabetic neuropathy and inflammatory arthropathy);

g) to promote healing (e.g. foot ulcer);

h) to stimulate motor-sensory feedback.

5 Functions

The function of the device may be:

a) for deformities:

   1) to reduce or correct a deformity (i.e. to move a reducible (flexible) deformity into an improved alignment and hold the correction obtained);

   2) to hold a deformity (i.e. to prevent a fixed deformity from increasing);

b) to control the alignment of a joint;

c) to control the motion of a joint;

d) to compensate for abnormal limb length and/or foot shape and size;

e) to reduce or redistribute the load on the foot;

f) to apply increased pressure on a specific area(s) of the foot surface.

6 Classification and description of devices

6.1 Classification

Three classes of device are recognised:

a) foot orthoses;

b) orthotic footwear;

c) adaptations (modifications) to footwear.

6.2 Description of foot orthoses (used in conjunction with footwear)

Types of foot orthoses include:

a) heel raises;

b) heel cups/shells (which may be extended);

c) foot orthoses with:

   1) flares;

   2) supramalleolar extensions;

   3) medial/longitudinal arch supports;

   4) metatarsal supports;

   5) stiffening;

   6) cushioning;

   7) toe supports, spacers and protectors;

   8) medial and lateral wedges;

   9) local pressure relief;

   10) increased local pressure shaping;

   11) toe extension shaping.

6.3 Description of orthotic footwear

6.3.1 Type of fabrication

Orthotic footwear can be:

a) prefabricated orthotic footwear;

b) custom fabricated orthotic footwear.

6.3.2 Prefabricated orthotic footwear

Types include footwear with:

a) extra width and/or depth;

b) protective toe caps (excluding industrial footwear);

c) stiffened soles;

d) rocker soles;

e) extended openings;

f) easy closures;

and footwear to

g) partially unload the foot;

h) accommodate vulnerable (at risk) feet;