



International
Organization for
Standardization

ISO/TC 168

Prosthetics and orthotics

Presenter name

Glasgow October 2016

ISO/TC 168

ISO

International Standards Organisation

What ?

Why ?

How ?

ISO - What?

- **Established in 1947**
- **An NGO - a network of national Standards bodies,**
- **>160 countries (1 per country, all regions of the world)**
- **Central Secretariat in Geneva**
 - **> 19,500 standards in total**

ISO-Why?

- 1. Create uniform terminology
ease communication**
- 2. Encourage correct and accurate
language and terminology**
- 3. Ensures products and services are
safe, reliable and good quality**
- 4. Informs industry, helps marketing**

Health

**>1200 Standards focus on health e.g.
dentistry, health informatics,
traditional medicines and medical
devices**

Health (contd)

- **Promote global harmonisation of medical practices**
- **Protect health and safety of patients and providers**
- **Support efficient exchange of information and protection of data**



IMPROVE QUALITY OF CARE

Examples of Health TCs

- *TC 76, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*
- *TC 94, Personal safety - Protective clothing and equipment*
- *TC 106, Dentistry*
- *TC 121, Anaesthetic and respiratory equipment*
- *TC 150, Implants for surgery*
- *TC 157, Contraceptives/STI*
- **TC 168, Prosthetics and orthotics**
- *TC 173, Assistive products for persons with disability*
- *TC 194, Biological evaluation of medical devices*
- *TC 210, Quality management and corresponding general aspects for medical devices*
- *TC 215, Health informatics*
- *TC 249, Traditional Chinese medicine*

ISO – How?

Standards are developed by Technical Committees (TC), each concentrating on a particular subject

Standards in P and O

- **TC168 Prosthetics and Orthotics** (est. 1979)
- **3 Working Groups (WG)**
 - WG1 Nomenclature and Classification
 - WG2 Medical Aspects
 - WG3 Testing

WG1 and WG2 normally meet jointly

TC 168, WG 1 and 2

MEMBERSHIP:

Physicians and Surgeons

Engineers

Scientists

Prosthetists and Orthotists

Therapists

-2 meetings per year, hosted by members

-English language (standards always translated into French)

No funding from ISO!!

Development procedure

1. **NWIP** (new work item proposal)
 2. **WD** (working draft)
 3. **CD** (committee draft)
 4. **DIS** (draft international standard)
 5. **FDIS** (final draft international standard)
 6. **IS** (international standard)
- In rare cases, TS or TR** (technical specification or report)
- 2 years for development process**

Previous work

**WGs 1 and 2 have produced 18
Standards in 33 years,**

**e.g. Standards specifying terminology to
describe :**

- **Cause of amputation**
- **The person being treated with an orthosis**
- **Functions of components used in
manufacture of a prosthesis or orthosis**

Previous work (contd.)

WG 3 has produced 5 key Standards that industry uses for CE marking of products as combined work with CEN TC295 (joint WG)



e.g. Standards specifying terminology to describe:

- **Structural testing of lower limb prosthesis**
- **Testing of ankle-foot devices and foot units**

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Prosthetics and orthotics — Vocabulary — Part 2: Prosthetic gait

Warning

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Current work

Includes development of terminology to describe :

- the different phases of treatment of amputees**
- the abnormal gait patterns of persons with a physical disability requiring Prosthetic/Orthotic treatment**
- devices used in foot orthotics**

Q ?

“How can I purchase a Standard?”

Answer - ISO sells; approx. 50 Euros per Standard

WWW.ISO.ORG

Online Browsing Platform (OBP)

<https://www.iso.org/obp/ui/>

Contains brief description of each Standard

Thank you for listening

Questions please?