ASPREX Fact Sheet

Lower limb prosthesis

Assistive device which consists of a selection of compatible components integrated together to replace wholly or in part an absent or deficient lower limb segment. Prostheses are designed to modify the structural and functional characteristics of the neuro-muscular systems of the lower limb; the devices may be custom fabricated or prefabricated devices that may be adjustable or ready to use.

The main configurations are TF (trans femoral i.e. above the knee), TT (transtibial i.e. below the knee) and PF (Partial foot).

The components of the device with the range of raw materials are: a) liner, sleeves and socks, which can be made of ethylene-vinyl acetate (EVA) foam, silicone, gel, urethane, thermoplastic elastomer (TPE), pelite, wool, cotton; socket, which can be made of polypropylene, thermoplastic elastomer (TPE), wood, aluminum, glass- reinforced plastic (GRP), resin, carbon fiber; c) knee joint, which can be made of titanium, aluminum, polypropylene, nylon, wood; d) pylon, which can be made of wood, titanium, aluminum, steel, carbon fiber, glass-reinforced plastic (GRP), polypropylene; e) foot, which can be made of polypropylene, For the cosmetics, common materials are silicone, local fabrics, ethylene-vinyl acetate (EVA) foam.

- Product Classification
  - APL (WHO Assistive Product Priority List): 31 (Prostheses, lower limb)
  - ISO 9999:2022: 0624 (Lower limb prostheses)
- Possible configuration variants
  - Partial foot prosthesis, including toe prostheses (Iso 062403).
  - Ankle foot unit (Iso 062427).
  - Ankle disarticulation prosthesis (Iso 062406).
  - Trans-tibial prosthesis (Iso 062409).
  - Knee disarticulation prosthesis (Iso 062412).
  - Trans-femoral prosthesis (Iso 062415).
  - Hip disarticulation prosthesis (Iso 062418).
  - Trans-pelvic prosthesis (Iso 062421).
  - Temporary prostheses for lower limb amputees (062448).
- Possible accessories or optional components
  - Axial rotators (Iso 062430).
  - Load attenuators (shock absorbers) (Iso 062431).
  - Prosthetic turntable (062432).
  - Knee units (062433).
  - Hip units (062436).
  - External (side) joints for lower limb prostheses (062437).
  - Liners for lower limb prostheses (062440).
  - Sockets for lower limb prostheses (062441).
  - Suspensory components for lower limb prostheses (062442).
  - Alignment components for lower limb prostheses (062445).
  - Structural components for lower limb prostheses (062446).
  - Cosmetic components for lower limb prostheses (062447).

- ## Product goals

  Activities or functions the product is mainly intended to support, according to WHO ICF Classification:
  - Walking [d450].
- ## Indicated impairments

  Difficulties the product is mainly intended to address, according to the WHO ICF Classification:
  - Walking [d450].
- ## Contraindicated impairments

  Difficulties for which the product may be inappropriate:
  - Stump with infected ulceration or lacking skin integrity.
- ## Indicated environments

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

  Environments in which the product may be inappropriate:
  None specified.
- ## Other indicated factors

  Other factors or situations the product is intended to address:
  - Avoid secondary complications related to the absence of segments of the lower limbs.
- ## Other contraindicated factors

  Other factors or situations in which the product may be inappropriate:
  None specified.
- ## Points to be considered in product selection
  - Better functioning with lower limbs enables better functioning in upright positions, standing, transferring oneself, walking and independence; improved lower extremity functioning can significantly improve many functional activities and participation including to the capacity to work, autonomy in daily living activities, recreation and leisure, use of transport, doing housework, undertaking single and multiple tasks).
  - User: level of amputation, clinical presentation of the residual limb, age, general health, weight, strength, desired mobility level, type of work, and lifestyle.
  - Context: environment (terrain, temperature, humidity), proximity to service providers for maintenance.
  - Find out availability of local or imported materials and components, types of fabrication equipment, and component supply available to the service provider.
  - A prosthetist takes measurements and casts impressions of residual limb. The cast of the stump is modified by the clinician to consider individual biomechanics attributes.
- ## Points to be considered in product fitting
  - The prosthetist fabricates the socket and assembles components; finally, the prosthesis is fitted and customized to the user´s needs.
  - As an important step to avoid secondary damage, ensure the prosthesis does not cause pain, or apply extra forces that will cause skin injury.
  - Check if the prosthesis provides appropriate stability.
- ## Points to be considered in product use
  - Functional training is needed for the user, to maximize benefits, ensure safety, and continued use.
  - Gait training and provide education on appropriate maintenance and care.
  - Education on appropriate maintenance and care after the device is provided.
  - Dosage use program.
  - Have a plan on what to do if there is discomfort or injury.
- ## Points to be considered in product maintenance / follow-up
  - For new users, regular socket fit assessment is needed as changes can occur as stump consolidation takes place.
  - Check the tolerance

    - Follow ups with the user tracks outcomes and troubleshoots issues that may arise after a period of use and are an important feedback loop.
- Examples of products available on the market
    - Live product search in the EASTIN website https://www.eastin.eu/en/searches/products/list?iso=0624

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.