ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Clubfoot braces

Objective:

The objective of this specification is to help organizations in procuring good quality clubfoot braces that are durable and which maintain feet position of children with idiopathic clubfoot.

World Health Organization

1. Product description

The purpose of this section is to provide specific key details relevant to the assistive product so that it is easily identifiable.	
Purpose of 1.1	Name of product as per WHO priority APL and/or commonly used names.
1.1 Name of product	Clubfoot braces
Purpose of 1.2	As per ISO 9999 classification and terminology document (refer https://www.iso.org/standard/60547.html).
1.2 ISO 9999 code	06 12 06 Ankle-foot orthoses* Orthoses that encompass the ankle joint and the whole or part of the foot ** this ISO code includes ALL ankle-foot orthoses;* *club foot braces doesn't have haven't a specific code*
Purpose of 1.3	Describes the product type in clear, simple, easily understood language and the intended use in addressing functional needs.
1.3 Description and intended use	Clubfoot braces are used to maintain correction of the foot position following the corrective phase of clubfoot treatment in infants (0-12 months) and children (1-5 years of age). The Ponseti method of treatment, which is the most widely accepted treatment for idiopathic clubfoot in children of pre-walking age, consists of: • Corrective phase: serial manipulation and casting of the feet to address cavus, adductus and varus deformities in the foot and ankle. This is followed by Achilles tendon tenotomy in the majority of cases, to address equinus in the ankle joint. • Maintenance phase: use of a foot abduction brace, which holds the feet in the corrected position in order to prevent recurrence of the deformity. Clubfoot braces are made up of specially made shoes attached to a bar which holds the feet apart, at shoulder width, in a position of abduction and dorsiflexion.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	There are several different types of clubfoot braces. Some braces are modular, and others come as a single, pre-fabricated unit. The bar may be extendable or not. Shoes may or may not be detachable from the bar. The shoes are usually made of leather or strong fabric. There are various types of shoe closure with hooks and loops (e.g. Velcro), straps and buckles or shoelaces. Heel cup, or well-rounded heel counter. An inspection hole on the medial side. A fastener to close the shoe and hold the foot firmly in position within the shoe. These could be straps and buckles, hook and loop closure (such as Velcro) or laces.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	• Clubfoot braces that hold both feet in a position of abduction and dorsiflexion in shoes attached to a bar.
Purpose of 1.6	Refers to product models that are excluded in the specific APS.
1.6 Exclusion	• Unilateral clubfoot braces.
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.

1.7 Keywords	Clubfoot, CTEV, Ponseti, Foot Abduction Brace, Clubfoot brace

2. Product requirements

The purpose of this section is to provide details of all applicable requirements relative to the specific assistive product. A requirement is mandatory and typically describes what a product should be able to do, how it should appear (product and packaging) etc. Only supply and service requirements considered applicable in procurement of clubfoot braces.

2.1 Functional requirements

Purpose of 2.1		A functional requirement refers to technical details and other specific functionality that define what a product variation is supposed to accomplish. Per product variation, the requirement should describe the typical user, specific characteristics of the product (in addition to the general features above) as well as the requirements for standard configuration of the product. It is important to focus on performance requirements rather than form factors. It is important to have a clear and specific description of the typical users including e.g. health condition, functional limitation or demographics (range of age, body weight, height, etc.). If applicable, specific context of use (e.g. indoor/outdoor, in noisy environment, etc.) should be specified in the product variations.		
Item	**Product variations**	**Typical user**	**Specific characteristics**	**Requirements for standard configuration**
1	Clubfoot braces made up of shoes attached to a bar which hold the feet at shoulder width apart in a position of abduction and dorsiflexion.	Child up to age 5 who has completed the corrective phase of clubfoot treatment.	Fixed bar (width adjustable optional). Bilateral shoes. Feet held in abduction and dorsiflexion (angles adjustable optional).	The length of the bar should be set so that the child's heels are shoulder width apart. The angle of abduction of the shoe on the bar is usually set to 60-70 degrees. The angle of dorsiflexion of the shoe on the bar is set to 10-15 degrees dorsiflexion. For unilateral cases, the angle of abduction is 60-70 degrees in the affected foot and in the unaffected foot is normally set to 30-40 degrees.

Purpose of 2.2	Brief and clear description of general product performance requirements and overall qualities (e.g. stability, strength, durability, waterproof, etc.).
2.2 General design requirements	The clubfoot brace should be easy for parents to fit on the child, able to fasten firmly enough to keep the child's heels down within the shoes, it should be light weight, strong, durable and easy to clean. The bar should be strong enough to maintain the shoes/feet in a position of abduction and dorsiflexion. The shoes should have: • A means of preventing forefoot adductus, e.g. a straight medial border on the shoe, and/or medial reinforcement of the shoe material • Features to prevent the heel slipping up inside the shoe, such as: • A low posterior cut (of the heel part) if the shoe is made of a strong/non-flexible material • There should be large shoelace holes or eyelets if laces are used. • The child's toes should not be covered in the brace (open toed shoes).
Purpose of 2.3	Details of existing or in-progress national or international standards should be provided here, whether freely or commercially available.

2.3 Standards	Clubfoot braces should comply with and be tested according to relevant and available national or international standards. Tests should be carried out by accredited test laboratories. If clubfoot braces do not comply with or are not tested according to relevant national or international standards, an explanation should be provided, (e.g. testing facilities may not exist). If a clubfoot brace does not comply with national or international standards, the supplier is liable for any damages and injuries caused by a product that is used according to its purpose by the typical user as stated above. At the time of writing there are no applicable ISO product standards for clubfoot braces, although manufacturers may comply with ISO 13485 and/or EN 12182. For the European market, CE marking of clubfoot braces according to Medical Device Directive/Regulation is required. All documentation should be in the official language or in English (other languages could be specified too).
Purpose of 2.4	A certificate of conformity confirms that a product conforms to applicable national and/or international regulations. If a certificate is required for the specific assistive product, this information should be requested, e.g., CE (Europe), COC (Japan), GCC (USA).
2.4 Certificate of conformity	A certificate that the product conforms with applicable national or international regulations and standards should be provided (for example, a declaration of conformity with the medical device directive or the medical device regulation of the European Union). If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product complies with the requirements in this call for tender and is safe and effective for use by the typical user. The certificate should specify the product, all applied standards, if any, and the name and contact information of the supplier and be provided with the tender. The certificate of conformity is a legal document and should be signed by an authorized person at the supplier. The certificate of conformity should be supplied in the official language or in English (other languages could be specified too).
Purpose of 2.5	Lists the relevant scope of information required to identify the appropriate size and weight of the assistive product in its standard configuration (specific dimensions may be given if appropriate).

2.5 Size and weight	Information about the overall width, height, length and weight of clubfoot braces should be provided. If adjustable, the minimum and maximum adjusted sizes for each product should be provided. There are two parts to clubfoot braces which have variable dimensions: the shoes and the bar. Shoes should be provided in a range of sizes to meet the needs of infants (0-12 months) and children (1-5 years of age). For example, clubfoot brace shoes that are currently available range in foot bed length from 6.4 cm to 20.4 cm. Bars should be provided in a range of sizes to meet the needs of infants (0-12 months) and children (1-5 years of age). For example, clubfoot brace bars that are currently available range in width from 12 cm to 38 cm. If the bar width is not adjustable, information should be provided about the increments in sizes (cm) between the available bar widths. The weight of the clubfoot brace when the shoes are attached to the bar should be provided. As an example, of the clubfoot braces that are currently available, the smallest assembled size ranges from 110-320 grams, and the largest assembled size ranges from 270-650 grams.
Purpose of 2.6	Lists the relevant scope of information that should be provided to service providers (e.g. how to select, assemble, fit, adapt, follow up, maintain, repair, refurbish the assistive product). The desired language(s) in which the technical information should be provided should be stated.
2.6 Technical information (for service providers)	Information on how to select, assemble, fit, and adapt the clubfoot brace should be provided. Instructions on how to maintain, service, repair, and refurbish the clubfoot brace should be provided. Instructions on how the brace should be worn, across ages 0-5 should be provided (e.g. for children of pre-walking age, the brace is usually used for 23/24 hours for 12 weeks immediately following the corrective phase of treatment, and then during sleep time until age 4-5). The technical information should be provided in the official language or in English (other languages could be specified too).
Purpose of 2.7	Lists the scope of information, and its format, that should be provided to end-users to show how to safely use the assistive product.
2.7 Instructions for use	A user manual with instructions for use of the clubfoot brace should be provided by the supplier. It should provide instructions on how to safely and effectively use the product, and how to service, maintain and clean it. It is intended for the user and/or care-giver. The user manual may be provided in print or electronic format. The user manual should be provided in the official language or in English (other languages could be specified too).
Purpose of 2.8	Refers to the various weather and other environmental conditions, e.g., temperatures, humidity, rain, snow, sunshine, that the assistive product should be able to withstand.
2.8 Environment of use	Clubfoot braces will generally be used indoors so do not need to withstand extreme weather conditions.
Purpose of 2.9	Refers to the duration of the warranty period and the details of the warranty the manufacturer/supplier should provide within the specified period.

2.9 Warranty	Provided normal heedful use, the supplier should, during the warranty period and without extra expenses, repair parts which break on the products delivered. This comprises of all spare parts and labour, except for normal wear and tear of the product. The warranty period should be at least 6 months after delivery of the clubfoot brace. The same should apply for spare parts and accessories. Documents describing how this is ensured should be provided.
Purpose of 2.10	Refers to the expected duration, in years, of the assistive product. Documents describing how this is ensured must be provided.
2.10 Lifespan	Given the purpose of use by typical users, the clubfoot brace should be designed for a lifetime of at least 6 months.
Purpose of 2.11	Lists the scope of information required in packaging and labeling the assistive product. Explains the state of assembly the assistive product should be in when received by the end-user.
2.11 Packaging, labelling, and state of assembly	Each clubfoot brace should be delivered with a label clearly stating details of the product. All necessary parts should be included in the package. The package should withstand handling during transport. The clubfoot brace should be delivered fully assembled or assembled to such an extent that the remaining assembly can be carried out with the use of commonly available screwdrivers or wrenches. If any special tool is required, it should be included with the delivery.
Purpose of 2.12	Refers to additional product requirements, depending on the specific assistive product, e.g., material, corrosion-resistance, adjustability, foldability, etc.
2.12 Other product requirements	Not applicable in this call for tender.

3. Supply and service requirements

From the information provided below, only those supply and service requirements considered applicable may be used in a procurement bid.

The purpose of this section is to describe key supply and service requirements that are needed in order to ensure that the assistive product is received in due time, operational, being maintained/repaired and refurbished.	
Purpose of 3.1	Lists the scope of information to be requested on how the assistive product will be transported to the place of delivery.
3.1 Transportation	Information on how the clubfoot brace will be transported should be provided and who should pay for the transportation
Purpose of 3.2	Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 calendar days).
3.2 Delivery time	The time between placing an order of clubfoot braces and receiving delivery of them should not exceed 30 working days.
Purpose of 3.3	Refers to the specific details of the various accessories and spare parts available for the assistive product, including pricing and availability.

3.3 Accessories and spare parts	For modular clubfoot braces, the supplier should offer the following accessories and spares: • Spare bars, shoes, bar and shoe connectors, screws and other assembly parts The following may also be offered: • Padding for the bar • Strap saddles to prevent pressure sores on the skin • Shoelaces All parts that the clubfoot brace consists of, and which may be replaced at some stage, should be offered as spare parts. The supplier should state which variations of the clubfoot brace the accessories and spare parts are meant for. When an accessory consists of one part, the same part should not be offered both as an accessory and a spare part, but only as an accessory. When an accessory consists of several parts that can be replaced, all replaceable parts should be offered as spare parts.
Purpose of 3.4	Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency.
3.4 Maintenance	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.5	Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.
3.5 Repair	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.6	Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.
3.6 Refurbishing	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.7	Specifies if training service providers is required by suppliers, and the key elements included in the training (e.g. selection, assembly, fit, maintenance and repair of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.7 Training of service providers	Information on how to assemble, fitting, maintain, clean, repair, and instruct caregivers/parents in the use of clubfoot braces should be provided to service providers. (e.g. for training resources, please see Africa Clubfoot Training http://www.globalclubfoot.org/training and other sources , such as http://www.ponseti.info/bracing-tips.html and https://global-help.org/?s=clubfoot)
Purpose of 3.8	Specifies if training users is required by suppliers, and the key elements included in the training (e.g. training to users should include fit, use, maintenance and cleaning of the assistive product). Refers to detailed training contents or materials, if available and applicable.

3.8 Training of users	Information on how to safely and effectively use clubfoot braces, and how to service, maintain and clean should be provided to the end-user.
Purpose of 3.9	Provides information regarding other supply and service requirements.
3.9 Other supply and service requirements	Not applicable in this call for tender.