Instruction for Use

Elevate Drop Foot Brace 2.0

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1 Introduction

1.1 Intended use

To create stable dorsiflexion in foot and ankle in the absence of one's own wilful capacity. For use with a variety of shoe styles and to emphasize comfort and style over traditional AFO devices.

1.2 Identification of the target population

Medical product is for users concerned about muscle atrophy, for users wanting a customized lift angle as well as, potentially, a customized lateral or medial pull to the foot.

Elevate was designed for drop foot (also known as foot drop) patients anywhere along a full spectrum of severity. It is designed as an option to stiff, uncomfortable, in-the-shoe AFO braces on one hand, or relatively unsubstantial out-of-the-shoe market-options on the other.

1.3 Precautions / Warnings

- Always use under adult supervision.
- Keep out of the reach of children.
- If you have diabetes or you are affected by any circulatory issues seek medical advice before use.
- If any redness or irritation persists, consult a physician.
- Cease use if brace causes any discomfort.
- Consult your doctor if you have any concerns about your health.
- Check brace for any damages before use.
- Clean brace before use.
- Always read the instructions before use.
- If you experience any pain or discomfort STOP and contact a medical professional immediately.
- Brace cannot be used for other purposes than described in Instruction for Use

1.4 Limitations / Contra-Indications

- Not for diabetic neuropathy patients whose illness has progressed to lesions and neuronal insensitivity
- Not for patients who also have extremely compromised lateral medial muscle strength
- Users with severe neurological dysfunction sufficient to significantly impair fine motor skills will need help in putting on the brace
- Product Elevate Drop Foot Brace 2.0 is not intended for use when users can't follow instructions, due to excess movement, inability to read or hear instructions.
- Intense use of the device may result in chafing or irritation of the skin at the points of contact.
- Intensive use of the device could lead to muscle fatigue or even tendinitis and/ or muscle contractures

2 General safety Instructions

This Instruction for Use (IFU) deals with the specifications and way of use of Elevate Drop Foot Brace 2.0. FootScientific is by no means responsible for any malfunction or accident arising from a user ignoring the instructions described in this IFU.

This IFU contains description of all the functions available, so read this IFU carefully and familiarize yourself thoroughly with its contents before use of the product.

3 Product Pictures and Functions

Functions of medical product Elevate Drop Foot Brace 2.0. are listed below.

- The Elevate Drop Foot Brace 2.0 showcases ***ease of use*** and ***predictable function***. The brace wraps quickly around the ankle, attaching with Velcro. A buckle adds reinforcement and fit. The strong, durable spectra cord easily slips onto the included Eyelet Hook Kit, and lift angle is achieved and quickly released as desired with a simple to use dial created by BOA™ Fit System.
- The Elevate Drop Foot Brace 2.0 was designed to replace uncomfortable, stiff, or bulky braces that go inside the shoe, and the growing number of cheap and unpredictable braces for outside

of the shoe. Careful material selection created an ***amazingly lightweight (just 8 oz), yet sturdy and long-lasting brace***. Comfort is also enhanced by a customizable lift and quick release of the lift-angle as desired.

- The Elevate Drop Foot Brace 2.0 can be customized to the need and liking of the patient. The design allows diversity in shoe styles, including sandals. Shoes without eyelets can be accommodated with ease using additional accessories and tools.

Method of Operation

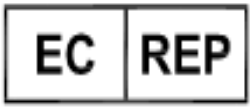
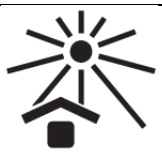
1. Orient the brace.
2. Place the Boa® center to your foot or shoe.
3. Wrap brace around ankle to test for fit.
4. Trim the brace if desired (not required).
5. Place the Boa® center to your foot or shoe.
6. Place the left side first against your leg, then follow with right to secure Velcro.
7. With Velcro secure, adjust the buckle and clip it in place.
8. Release Boa® by pulling the face of the Boa® away from you.
9. Attach hooks to the shoe using existing or created eyelets
10. With the Boa® outward, pull a medial and lateral portion of the Spectra® cord toward eyelet hooks.
11. Attach the Spectra directly to the eyelet hooks.
12. Push the Boa® inward until it clicks.
13. Wind the Boa® clockwise until the cord is tight and have the lift and angle desired.
14. Adjust as needed.
15. If you feel pressure anywhere, make adjustments in the fit and height of the brace around your ankle.

Note: For regular use please contact a medical professional to make sure that this product is suitable for your particular injury. This pack is not suitable for warm use. Do not expose to high temperatures, hot water, oven, microwave or other heating methods.

4 Symbols

Symbols explanation on product label is listed in table below.

Symbol	Name
	**Title/Meaning** : Manufacturer **Function/description** : To identify the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497
	**Title/Meaning** : Date of manufacture **Function/description** : To indicate the date on which a product was manufactured
	Company logo

	**Title/Meaning** : Catalogue number **Function/description** : To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
	**Title/Meaning** : Batch code **Function/description** : To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
	**Title/Meaning** : Medical device **Function/description** : To indicate that the product is classified as a medical device.
	**Title/Meaning** : Unique Device Identifier **Function/description** : To allow the identification and facilitate the traceability of devices according to Medical Device Regulation – Regulation (EU) 2017/745. The code shall be placed adjacent to the symbol.
	**Authorized representative in the European Community** Indicates the Authorized representative in the European Community.
	Mark of conformity according to the Medical Device Regulation – Regulation (EU) 2017/745.
	**Title/Meaning:** Operator's manual; operating instructions **Function/description:** To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	**Title/Meaning** : Keep away from sunlight **Function/description** : To indicate that transport package shall not be exposed to sunlight
	**Title/Meaning** : Keep away from rain **Function/description** : To indicate that the transport package shall be kept away from rain and in dry conditions.

	**Title/Meaning** : Importer **Function/description** : To indicate any natural or legal person established within the EU that places a device from a third country on the EU market, according to Regulation (EU) 2017/745 – MDR.

5 Regulations and standards

Medical product Elevate Drop Foot Brace 2.0 is classified according to Medical Device Regulation – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, Annex VIII: Class I, Rule 1. Products complies with the following standards and regulation:

- EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 1041:2008/A1:2013 – Information supplied by the manufacturer of medical devices
- EN ISO 14971:2019 Medical devices — Application of risk management to medical devices
- IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- Medical Device Regulation - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
- MEDDEV 2.7/1 Rev. 4 - CLINICAL EVALUATION: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
- MEDDEV 2.12/2 Rev. 2 - POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
- MEDDEV 2.12-1 Rev. 8 - GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM

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