EN

Ambulatory Pressure Relief Boot (APRB)

Instructions for Use



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TalarMade Ltd is a UK-based manufacturer of Class I medical devices, committed to providing high-quality, safe, and effective products designed to support healthcare professionals and patients.

This Instruction for Use (IFU) document provides essential information for the correct and safe use of TalarMade products, in compliance with the requirements of the UK Medical Devices Regulations 2002 (as amended) and the EU Medical Device Regulation (EU) 2017/745 (MDR), as applicable.

All TalarMade medical devices are designed, manufactured, and distributed under a certified Quality Management System in accordance with ISO 13485:2016, ensuring that they consistently meet both regulatory and customer requirements for safety, performance, and reliability.

Prescribers and users are advised to read this document carefully before use. Proper

understanding and adherence to the instructions, warnings, and precautions outlined herein are essential to ensure optimal product performance and to minimise the risk of misuse or adverse events.

Product Details

Product Name: Ambulatory Pressure Relief Boot (APRB)

GMDN: 36206 – Ankle/foot orthosis

BASIC UDI-DI (if applicable): 50554023LLOAFODK

Packaging contents (list what is included in the package): 1 x Ambulatory Pressure Relief Boot

Manufacturer Details

Manufacturers Registered Address

TalarMade Ltd. Edinburgh House, Millennium Way, Chesterfield, Derbyshire, S41 8ND

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Device Description

The Ambulatory Pressure Relief Boot is a splint used to maintain functional alignment of the foot and ankle whilst suspending and protecting the heel from pressure or friction. It has the following features:

- Soft, breathable and washable liner
- Easy-to-remove sole plate
- Adjustable toe length support
- Anti-rotation bar
- Replacement soft liners available in case of soiling/regular washing

- Available in 2 sizes (Regular/Standard and Large)
- This device is intended for **single patient use only** and not designed for multi users

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Intended Use

The Ambulatory Pressure Relief Boot is a splint used to maintain functional alignment of the foot and ankle whilst suspending and protecting the heel from pressure or friction.

Target users are healthcare professionals and laypeople, both in hospital/healthcare environments and at home. The Ambulatory Pressure Relief Boot should be used as guided by a healthcare professional and as outlined in the instructions for use.

Indications

The Ambulatory Pressure Relief Boot is indicated for the following situations:

- Prevention of ankle contractures
- Heel ulcer prevention and treatment
- Lower level ambulation with heel pressure relief

Contraindications

- Gross fixed deformities
- Open wounds coming into contact with the device

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Excess local pressure or friction due to improper fit i.e. too loose	Skin irritation, blistering, callus, ulceration	Ensure correct application Discontinue use if redness, irritation, or skin breakdown re-occurs and seek professional advice
⚠ **Follow Instructions For Use**	User misapplication	Ineffective function, increased injury risk or skin breakdown	Read the IFU thoroughly before first use. Only use as directed by a healthcare professional.

⚠ **Consult a Healthcare Professional**	Device irritating foot, ankle or lower leg	Skin breakdown injury	Do not use if active ulcer or wound present
⚠ **Warning**	Worn when wet	Skin irritation, blistering or persistent and undue redness	Ensure device is dry after laundering before continuing use
⚠ **Warning**	Odour, contaminated with body fluids	Infection, cross contamination	Ensure device is laundered frequently to maintain its conformability, hygiene and comfort
⚠ **Warning**	Heating	Skin injury Damage to device	If heating thermoplastic shell, remove all soft goods before doing so and allow thermoplastic to cool fully before re-applying

Precautions

- This device is for **single patient use only**. Re-use by another individual may increase the risk of cross-contamination, improper fit, or compromised device performance
- The device should be worn as instructed by the prescriber
- Inspect the device integrity before use
- Remove brace and cease use if the brace causes pain, redness or skin breakdown

Instructions for Use

Preparation

- Remove packaging
- Inspect brace, making sure all parts are intact and without damage

Application

NOTE: Only use as directed by a Healthcare Professional.

1. Unfasten all touch-and-close straps
2. Pre-position the foot into a plantigrade position and apply the Ambulatory Pressure Relief Boot to the foot and ankle of the patient. Ensure that the sole of the foot is in contact with the boot and the heel is visibly suspended
3. Fasten the bottom touch-and-close strap over the dorsum of the foot and then fasten the calf touch-and-close strap. Strap tension should be firm and not be uncomfortable for patient
4. Leg rotation can be limited by folding out the anti-rotation bar of the Ambulatory Pressure Relief Boot when it is on the patient's limb and the patient is supine. The bar should be rotated back under the posterior cuff during ambulation.
5. The walking sole plate can be easily removed by undoing the touch-and-close tab extending up the posterior aspect of the ankle section
6. Begin wear schedule at 30 minutes before removing brace to check skin. Gradually increase wear time, as tolerance allows.

Removal

1. Release the touch-and-close straps
2. Remove Ambulatory Pressure Relied Boot from lower leg/foot/ankle
3. Inspect skin, checking for any signs of irritation, redness, or pressure marks.

During Use

- Wearing schedule - follow the duration and daily wear time recommended by your healthcare professional or medical care plan
- Monitoring:
    - Periodically check skin condition and comfort.

Cleaning & Maintenance

- Remove outer padding from thermoplastic section by undoing touch and close fastenings
- Thermoplastic base can be wiped clean as required
- Outer padding can be hand washed in cool water with mild detergent

- Do not use bleach or chlorine-based cleaning products
- Not for use in washing machine or tumble dryer

Storage Conditions

- Store in a **cool, dry place**, protected from direct sunlight and heat

Disposal Instructions

Dispose of the device and its packaging in accordance with applicable local, regional, or national regulations.

Regulatory Compliance

EU REP

EUROPEAN AUTHORIZED REPRESENTATIVE

MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

SRN number: DE-AR-000000002

CH REP

SWISS AUTHORIZED REPRESENTATIVE

MedNet SWISS GmbH, D4 Platz 4, 6039 Root D4, Switzerland

CHRN: CHRN-AR-20000730

Warranty Information

The device is supplied under the manufacturer's warranty as outlined in the current Terms and Conditions available on our website. Users are advised to review these terms prior to use.

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Contact Information

We are committed to continuously improving our products.
Please scan the QR code to share your feedback with us.

No camera? Click here or on the QR code to open the product feedback form.

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