Beagle® ORTHOPAEDIC

Instructions for use: TheraCore Wrist Brace			
BWB/23L	BWB/25L	BWB/27L	BWB/28L
BWB/23R	BWB/25R	BWB/27R	BWB/28R

Device type: Non-invasive orthopaedic brace for wrist and hand
Supplied: Non-sterile
Use: Single patient multiple use.
Market: United Kingdom and Europe

Intended Purpose

The TheraCore Wrist Brace is intended to provide support, stabilisation and immobilisation of the wrist during the non-operative or post-operative management of wrist injuries and conditions, as directed by a suitably qualified healthcare professional.
The brace is designed to assist clinician-directed management of wrist injuries by helping to stabilise the wrist joint, limit unwanted movement, provide support during healing and improve comfort throughout treatment and rehabilitation.

Indications for use

The device may be used, where clinically appropriate, for:

- Management of stable wrist fractures during healing or post-cast removal.
- Treatment of acute wrist sprains and strains.
- Symptom relief from osteoarthritis and rheumatoid arthritis affecting the wrist joint.
- Conservative management of Carpal Tunnel Syndrome (CTS) and associated nerve impingement.
- Relief from wrist tendinopsynovitis, tendonitis, and Repetitive Strain Injuries (RSI).
- Post-operative wrist support and protection during rehabilitation.
- Clinician-directed wrist immobilisation, compression and stabilisation.

The decision to use this device, and the duration of use, must be determined by a suitably qualified healthcare professional.

Intended patient population

Adult and adolescent patients requiring wrist support, immobilisation and compression, as determined by a healthcare professional.

Contraindications

Do not use this device:

- Where compression is contraindicated.
- On open wounds or broken skin.
- Where the patient has a known allergy or hypersensitivity to any material listed in the product composition.
- On patients with severe circulatory impairment, unless specifically assessed and approved by a healthcare professional.
- On patients with advanced peripheral neuropathy or absent sensation, unless specifically assessed and approved by a healthcare professional.
- Where the brace cannot be fitted safely or comfortably.

Warnings and Precautions

Read all instructions and warnings before use.

- The brace should be fitted and adjusted in accordance with these instructions or as descriped by the clinician.
- Do not overtighten the brace or straps.
- Regular skin and circulation checks should be carried out, especially for patients with diabetes, vascular or neurological conditions.
- Seek clinical advice immediately if the patient experiences increased pain, numbness, tingling, colour change, coldness, swelling, pressure marks, skin irritation, skin breakdown or loss of sensation.
- Do not use if the device is damaged, incomplete or worn.
- Do not modify or repair the brace unless instructed.
- Do not apply creams, gels, ointments, liniments or similar products to the skin beneath the brace unless approved by a healthcare professional.
- Do not use if fasteners are not functioning correctly.
- Do not reuse between patients due to risk of cross-infection.

Product description

The TheraCore Wrist Brace is a non-invasive orthosis designed to provide wrist joint compression and support.
The brace features:

- TheraCore construction designed to conform comfortably to individual patient anatomy.
- An easily shapeable aluminium palmar bar to achieve an intimate fit, maintain a neutral wrist position, and promote optimal recovery.
- A durable medical-grade vinyl palmar bar pocket to securely hold the bar for stable immobilisation.
- Adjustable hook-and-loop fastenings to allow controlled, customisable adjustment and targeted support.

The brace is designed to assist with joint stability and compression, improve comfort, and support functional movement during clinician-directed treatment.

Product composition

Polyamide (Nylon), Polyester (PES), Cotton, Polyurethane (PU), Aluminium, Polyvinyl Chloride (PVC)
This product is latex-free.

Sizing

Measure:

- Wrist circumference

The healthcare professional is responsible for confirming correct size, fit and compression level.
Select the correct product code/size/quantity according to the sizing guide below:

Size	Wrist Cir. (mm)	Black Left Codes	Black Right Codes
Small	140 - 155	BWB/23L	BWB/23R
Medium	160 - 175	BWB/25L	BWB/25R
Large	180 - 200	BWB/27L	BWB/27R
X-Large	200 - 230	BWB/28L	BWB/28R

Before fitting

Before fitting the brace, the user or healthcare professional should:

- Confirm that the device is suitable for the patient and clinical indication.
- Check the device, fabric, and fasteners for any signs of damage or wear.
- Confirm correct size, colour and quantity selection.
- Assess skin condition, circulation and sensation.
- Confirm there are no contraindications to compression or immobilisation.
- Ensure the aluminium palmar bar is correctly inserted and pre-shaped, if required, to suit the patient's anatomy.
- Check that any open wounds, scratches, or broken skin are appropriately dressed before applying the brace.
- Explain the fitting process, proper use, and the review schedule to the patient.

Fitting Instructions

Initial fitting must be carried out by a healthcare professional, in accordance with these instructions.
Step 1: Undo all hook-and-loop fastening straps and open the brace.
Step 2: Remove the aluminium palmar bar from its pocket and carefully shape it to match the patient's anatomy.
Step 3: Reinsert the aluminium bar fully into the pocket, ensuring it is securely seated beneath the retaining tab.
Step 4: Position the brace on the hand and wrist, aligning the shaped palmar bar with the palm and forearm.
Step 5: Fasten the hook-and-loop straps in sequence, adjusting each to achieve a secure and comfortable fit.
Step 6: Check the final position to confirm that the wrist is supported, immobilised, and that circulation is not impaired.

Checks after fitting

After fitting, the healthcare professional should check:

- Confirm correct position and alignment of the brace and palmar bar.
- Verify strap security and ensure all fasteners are securely fastened.
- Assess the level of compression to ensure therapeutic support without constriction.
- Evaluate patient comfort.
- Inspect skin condition around the edges and the thumb web space.
- Monitor circulation and sensation in the fingers.
- Check for the absence of pressure points.

Wearing and review

The use schedule and duration of treatment must be determined by the healthcare professional.
The patient should attend scheduled clinical reviews as instructed. At review, the healthcare professional should check:

- Check brace fit and alignment.
- Inspect skin condition for signs of irritation or breakdown.
- Monitor swelling and adjust compression levels.
- Evaluate device condition and confirm continued suitability for use.

The patient, should not remove or adjust the brace unless instructed by their healthcare professional.

Washing and care instructions

Maintenance and cleaning should only be carried out by a healthcare professional during scheduled clinical reviews, unless the patient, has been specifically instructed otherwise.

Before cleaning:

- Cover all hook and loop straps.
- Remove aluminium palmar bar from pocket.
- Check the brace for signs of wear, damage or degradation.

Cleaning instructions:

Hand wash the brace in cool water using mild detergent. Do not use fabric conditioner. Rinse thoroughly.

Air dry flat and do not spin dry. Do not re-apply the brace until it is completely dry.

Do not tumble dry

Do not bleach

Do not dry clean

Do not iron

After cleaning:

- Uncover all hook and loop straps.
- Reinstall aluminium palmar bar into pocket.
- Check that all hook and loop straps, palmer bar and components are secure and functioning correctly.

Storage and transport conditions

Store in a cool, dry place, away from direct sunlight and in the original packaging until use.
Do not use the device if the packaging is damaged and device cleanliness or suitability may have been affected.

Recycling and disposal

Packaging and device components should be recycled or disposed of safely in accordance with local or national requirements.
If the device has been contaminated during use, dispose of it in accordance with local clinical waste procedures.

Serious incident

Any serious incident involving this device should be reported to the manufacturer and to the relevant competent authority.
In the United Kingdom, serious incidents should be reported to the MHRA.
In the European Union, serious incidents should be reported to the competent authority of the Member State in which the user and/or patient is established.
Patients should contact their healthcare professional or device provider if they experience any adverse reaction, discomfort, skin reaction, worsening symptoms or concerns during use.

Device identification and traceability

Product name: TheraCore Wrist Brace
Basic UDI-DI: 50563111HDWTB1AU
Catalogue number / REF: See product label
UDI: See product label
Batch / LOT: See product label
Date of manufacture: See product label
Use-by date: See product label

This device is CE marked in accordance with Regulation (EU) 2017/745.
For Great Britain, the device is placed on the market under applicable UK MDR 2002 transitional arrangements recognising CE marked medical devices.

Manufacturer

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Single patient multiple use.

This device is a medical device.

EU Authorised Representative

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