



Evaluating the Efficacy of a Combined Air and Fiber-Filled Heel Protector for the Prevention of Heel Pressure Injuries

Premarket Validation Trial Conducted in a Simulated Acute Care Setting

Premarket Product Validation Trial Project

Introduction

Prior to releasing new products to the market, EHOB rigorously evaluates and validates them to ensure they are clinically safe and effective for clinicians and patients when used as indicated. An evaluation plan is developed to address each user need that has been identified for a product.

Market research and existing customer feedback suggested a need for a heel protector that provides the trusted pressure reduction of static air yet has additional protection in the rare occasion that it deflates. The TruVue Air Heel Protector was created.

Objective

The goal was to validate the TruVue Air Heel Protector in a simulated acute care environment, prior to being released to the market. Components of the validation included verifying that the product met its predefined user needs and was clinically effective and safe when used as intended for assisting in the prevention and management of heel pressure injuries and skin protection of the feet while in bed.

Methods

EHOB clinicians performed the TruVue Air product validation with 28 total participants in **hospital simulation rooms** on three separate days. Participants were randomly placed on either a *Hillrom® NP100 Prevention Surface* or *Hillrom® P500 Therapy Surface*, based on the surface available in each room. Baseline bilateral knee goniometric testing was performed to rule out knee flexion contractures to accurately assess the product’s ability to maintain a knee position of the recommended 0-5 degrees. Additionally, baseline bilateral goniometric testing was performed with participants in the supine position to obtain resting hip rotation position to accurately assess the anti-rotation wedges’ effectiveness in holding the leg in a neutral position.

The clinicians applied bilateral TruVue Air Heel Protectors to each participant following the product's instructions for use. Each participant then remained in a supine position with the head of the bed elevated for 2 hours, followed by 2 hours in a side-lying position. **After each 2-hour period, clinicians verified offloading, assessed the skin of the lower extremities, conducted goniometric testing to evaluate hip rotation (supine position only), and asked participants a series of questions about their experience.**

Results

Product Efficacy

- ✓ 100% heels offloaded before and after use for 2 hours
- ✓ 100% of products stayed in place while in supine position
- ✓ 95% of products stayed in place while in side-lying position. 2 had slight turning of product
- ✓ 100% of heels could be offloaded by the fiberfill alone
- ✓ Product straps all remained intact during validation

Clinician Feedback

- ✓ Products were intuitive to apply by clinicians participating in clinical validation
- ✓ Participating clinicians confirmed the products allow for easy access to the foot and lower extremity for assessment purposes
- ✓ Of the subjects who were able to achieve a neutral knee position (n=10) during baseline testing prior to the trial, 100% experienced heel offloading with no knee hyperextension

‘Patient’ Participant Feedback

- ✓ Participants reported that the product is comfortable
- ✓ 100% subjects denied pressure in the malleoli area in the side-lying position
- ✓ 100% subjects denied pressure in the Achilles area in the supine position



Evaluation Summary

PARTICIPANTS
28



EVALUATIONS
38 Products



CALF
CIRCUMFERENCE
33 cm – 49 cm



Dual-Technology



Intuitive Design



Customizable Fit



Cost Effective



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Conclusion

Based on the premarket validation evaluation and lab testing results the TruVue Air Heel Protector meets the identified user needs and passed the required validation criteria. EHOB Clinical Affairs has determined it is clinically safe and effective for patients when used as indicated:

- For lifting the heel off of the bed for patients who are at risk of heel pressure injury
- For assisting in preventing and managing heel pressure injuries in patients who have existing or history of heel pressure injuries
- For assisting in preventing skin injury to the foot for patients at risk
- For assisting in preventing hip rotation with use of optional wedge

