

Zhivon Whitepaper 3 · Low-Temperature Thermoplastic Splinting: Material, Working Window and Acceptance Criteria

Wuhan Zhiheng Technology Co., Ltd. · Technical Whitepaper · September 2026

Audience: procurement and technical evaluation teams, distributors, veterinarians and rehabilitation providers

Basis: enterprise standard Q/WHZH 001-2026 (publicly filed) and published literature. This document provides acceptance criteria; it contains no untested performance conclusions.

Summary

The value of a low-temperature thermoplastic sheet is not the sheet itself but the delivery capability it enables: moulding to an individual contour in-clinic, reheating the same sheet for fit adjustment within a course, and windowing the material to observe skin and wounds. This whitepaper covers the material definition, the working window, six key properties, a comparison with plaster and prefabricated braces, and an acceptance criteria list that buyers and quality teams can use directly.

1. Product definition (enterprise standard wording)

· Thermoplastic Memory Splint for Pets (Health Support Product): a healthcare support product made from a low-temperature thermoplastic material that becomes mouldable when heated and, once cooled, sets to a defined hardness and provides support for adjunct external stabilisation of limbs, spine, ribs and tail. (Q/WHZH 001-2026 §3.1)

Product classification: health support product, not a medical device.

2. Working window

2. Working window

Stage	Condition	Note
Softening	Hot water at about 70 °C, about 30 s	In-clinic, controlled conditions
Moulding	Formed to the individual contour; edges, padding and windows handled	Performed by a trained professional
Setting	Rigid after about 10 minutes at 25 ± 2 °C	Predictable in-clinic workflow
Service range	–10 °C to 40 °C, RH 10–90%	No visible deformation within the stated range (§4.3.3)

Key point: **formable does not mean automatically fitting.** Fit comes from measurement and technique, not from the material. Moulding temperature, target angle, edge finishing and padding placement all affect the outcome — which is why owners should not reheat or re-mould a sheet themselves.

3. Six key properties

3. Six key properties

Property	Description	Practical relevance
Low-temperature activation	Softens in water at about 70 °C	No high-temperature equipment required
Trimable	Can be cut to shape for the region	Accommodates different body sizes and regions
Lightweight	Lighter and can be made thinner than a cast	Reduces wear burden
Windowable	Openings can be designed in	Allows skin and wound observation
Re-adjustable	Same sheet can be reheated and adjusted within a course	Adapts to swelling change and recovery stage
Sets on cooling	Rigid after about 10 minutes	Predictable clinic timing

4. How it compares with other options

4. How it compares with other options

Dimension	Low-temperature thermoplastic splint	Plaster / fibreglass	Off-the-shelf brace	Custom orthosis
Fit	Moulded to contour on site	Fixed once set	Depends on sizing	Cast-based, highest
Adjustability	Reheat and adjust the same sheet within a course	Remove and redo	Structural adjustment	Often returned to maker
Weight & ventilation	Light, windowable	Heavier, fully occlusive	Design-dependent	Design-dependent
Fabrication time	In-clinic	In-clinic	Off the shelf	Days to weeks
Risk source	Moulding quality, edge finishing, recheck discipline	Hidden pressure, difficult observation	Sizing and migration	Lead time, adjustment cost

On stiffness comparison: a cadaveric model study (PMID 29660738) applied fibreglass or thermoplastic splints to the lateral or cranial aspect of the tibia in a mid-diaphyseal fracture model across eight cadaveric canine pelvic limbs, comparing construct stiffness and inter-fragmentary motion. The result direction: stiffness performance depends on placement and construct configuration — **there is no universal winner independent of configuration.** (Cadaveric model; not directly extrapolable to live clinical outcomes.)

5. Acceptance criteria list (for procurement and quality teams)

A. Material contact requirements (§4.1)

A. Material contact requirements (§4.1)

Item	Requirement	Test method
Sensory	No odour, non-toxic, suitable for skin or hair contact	Odour assessment and contact test

B. Appearance (§4.2)

Flat, even surface without visible bubbles, cracks, inclusions or colour variation; smooth, burr-free edges; uniform colour.

C. Physical performance (§4.3)

C. Physical performance (§4.3)

Item	Requirement	Test method
Thermoplastic behaviour	Fully soft and freely formable after 30 s immersion in hot water; regains hardness and holds the moulded shape after cooling	§5.3.1
Tensile strength	≥10 MPa	Per ASTM D638
Flexural strength	≥15 MPa	Per ASTM D790
Hardness (set)	Shore D ≥50	Shore D durometer
Dimensional stability	No visible deformation at -10 °C to 40 °C, RH 10–90%	§4.3.3

D. Safety (§4.4 / §5.4)

Non-toxic with no irritating odour, suitable for prolonged contact; no harmful release under normal use; saliva-resistant with no shedding under light chewing; surface integrity maintained after simulated saliva soak (pH 6.5–7.5, 37 °C, 24 h); third-party testing of harmful substances (heavy metals, soluble organics) commissioned where necessary.

E. Inspection rules (§6)

- Factory inspection: appearance, thermoplastic behaviour and dimensional stability on every batch
- Type test: on new production, on major changes to materials or process, and **every 12 months**
- Sampling: GB/T 2828.1-2012, AQL 1.5

· Safety reference: GB/T 43839-2024 (Safety technical requirements for companion animal (pet) products), effective 2024-10-01

6. Eight questions for buyers

1. Are you the manufacturer or a reseller? Who is responsible for material, forming, quality control and traceability?
2. Can you provide the enterprise standard number and the inspection rules (AQL, type-test interval)?
3. Can you provide material-class and skin-contact safety documentation?
4. Which mechanical test methods are used (ASTM D638 / D790)? Is third-party testing performed where applicable?
5. What are the size and thickness tolerances? Can you sample for a specific region and body size?
6. Are edge finishing, padding and strap arrangements standardised, with use and care instructions provided?
7. How are safety items (saliva soak, harmful substances) verified?
8. Are product descriptions and marketing material consistent with the "health support product, not a medical device" classification?

7. Boundaries and risks (to be communicated together)

- Not suitable for all fractures: whether external coaptation can be used depends on region, stability, soft-tissue condition, body weight and recheck capacity
- Skin and pressure risk exists: daily inspection of skin and distal limb, and scheduled rechecks, are required
- Does not replace diagnosis, imaging, surgery or post-operative rechecks
- Formability is a delivery capability, not a guarantee that a sheet "fits automatically"

8. Notes on data

1. **Enterprise standard values** are requirements stated in a publicly filed standard — verifiable, but not measured results
2. **Literature values** come from third-party studies, with design and subjects stated
3. **Product specifications** are manufacturer declarations: Universal 60 × 100 mm, Large 80 × 120 mm, Professional and Professional Large 60 × 100 / 80 × 120 mm; thickness 2.5 ± 0.5 mm; Professional models with a low-allergen medical backing

This whitepaper contains no untested performance conclusions. Any published test data must state the testing laboratory and report number, together with test conditions and applicable range.

References

1. Wuhan Zhiheng Technology Co., Ltd. — Enterprise Standard Q/WHZH 001-2026, Thermoplastic Memory Splint for Pets (Health Support Product)

2. GB/T 43839-2024 Safety technical requirements for products used for companion animals (pets), effective 2024-10-01
3. GB/T 2828.1-2012 Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL)
4. ASTM D638 / ASTM D790 standard test methods
5. Vet Times: Low temperature thermoplastics used for splinting small animals — vettimes.com
6. Evaluating stiffness of fibreglass and thermoplastic splint materials and inter-fragmentary motion in a canine tibial fracture model. PMID 29660738
7. Rosen S, et al. Prospective evaluation of complications associated with orthosis and prosthesis use in canine patients. *Front Vet Sci.* 2022;9:892662

This whitepaper is technical reference material and does not constitute veterinary advice. Clinical decisions must be made by a licensed veterinarian. The product is a health support product, not a medical device.

Zhivon™ · Wuhan Zhiheng Technology Co., Ltd. · www.zhivon.cn · service@zhivon.cn · WhatsApp +44 7743 764517



Specification sheet photo