

OmniBrace: A Fast Acting Expanding Foam Splint for Orthopedic Injuries

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Executive Summary

The OmniBrace is a stand-alone first-aid splint which utilizes expanding polyurethane foam technology to provide immediate temporary immobilization to orthopedic injuries.

The OmniBrace is 'one-size fits most,' and can be applied to any extremity in under 90 seconds.

Clinical Need

Each year in the United States:

- 4 million ER visits for fractures
- 6 million ER visits for sprains

Adequate immediate immobilization of such orthopedic injuries is necessary to prevent causing further harm to the surrounding soft tissue and to minimize pain

Market Analysis

Target market: Medical professionals

- Emergency responders
- Sports medics
- Military field medics

There are 225,000 registered EMS personnel in the US alone, as well as nearly 20,000 sports medics, all requiring immobilization equipment. These numbers alone suggest large market potential.

Novelty of Concept

- Uses quick-curing polyurethane foam
 - 25x increase in volume during deployment
 - Achieves a snug, supportive fit
 - Deploys in under 90 seconds
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- Single device can be used on any extremity on any individual

Original Concept Art for the OmniBrace



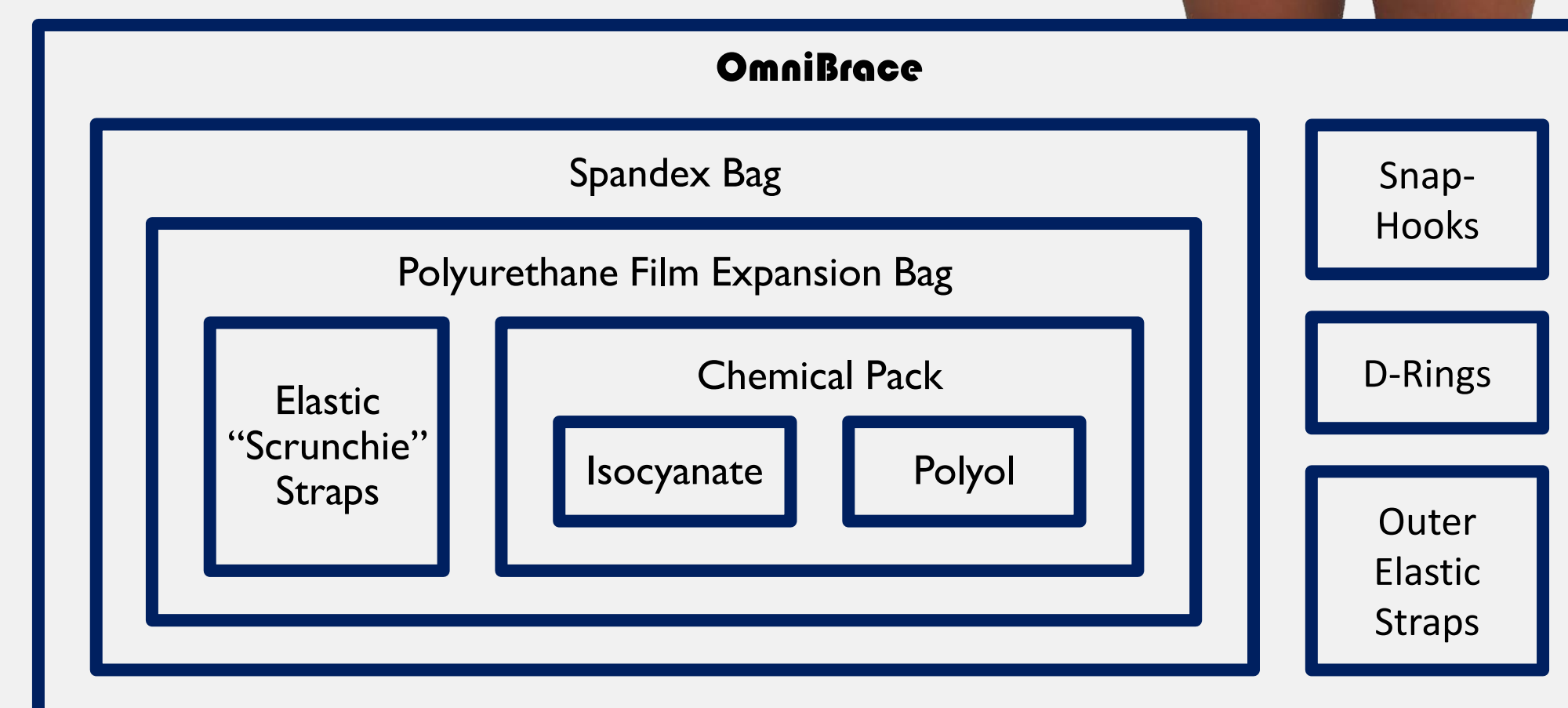
Device Overview

The OmniBrace is comprised of the following components:

- Spandex bag
- Chemical pack
- Polyurethane film bag
- Elastic straps
- Snap-hooks
- D-rings



The OmniBrace is constructed according to the following hierarchy:



Principle of Operation

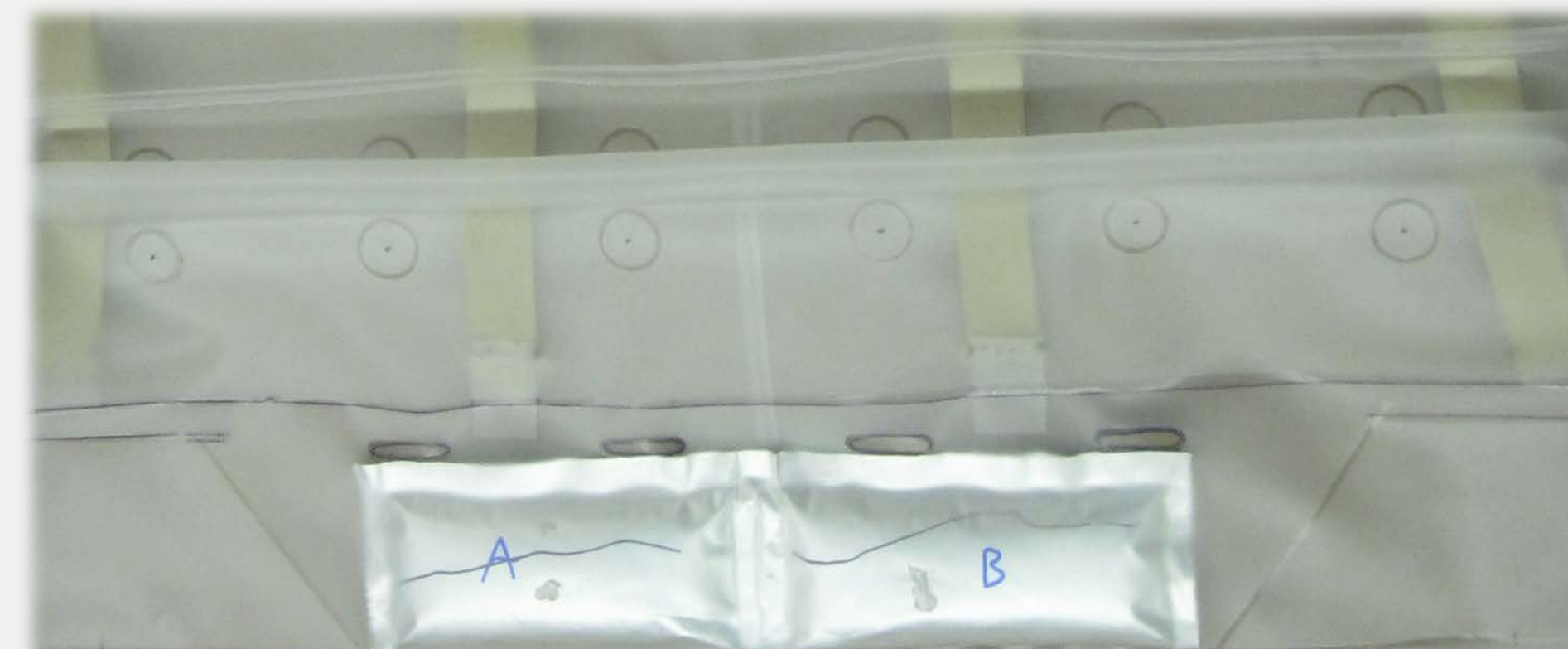
When the region labeled "1. Pop" is squeezed tightly, a seal between the two packets of Polyurethane foam precursor chemicals is broken, allowing them to be mixed by alternately squeezing each outlined area in rapid succession.

1. Pop

2. Mix

When the chemicals are fully mixed they react to form an expanding polyurethane foam which ruptures the chemical packet and flows into the expansion bag.

Internal elastic "scrunchie" straps (shown in beige, below) maintain open flow channels for the foam as it fills the bag, even if the bag is kinked.



In addition to maintaining flow channels, the "scrunchie" straps serve to gather excess material from the expansion bag which could otherwise impede using the OmniBrace on arms or legs of particularly small circumference (e.g., on children).



Principles of Operation, Cont'd

An array of "button" seals joining both faces of the expansion bag ensure that the foam distributes evenly during deployment and that the brace does not exceed the desired thickness.



Prior to expansion, the OmniBrace is secured around the injury site by snap-hooks clipping into D-rings. The snap-hooks provide a secure fit, and enable the OmniBrace to be both applied and removed very quickly.

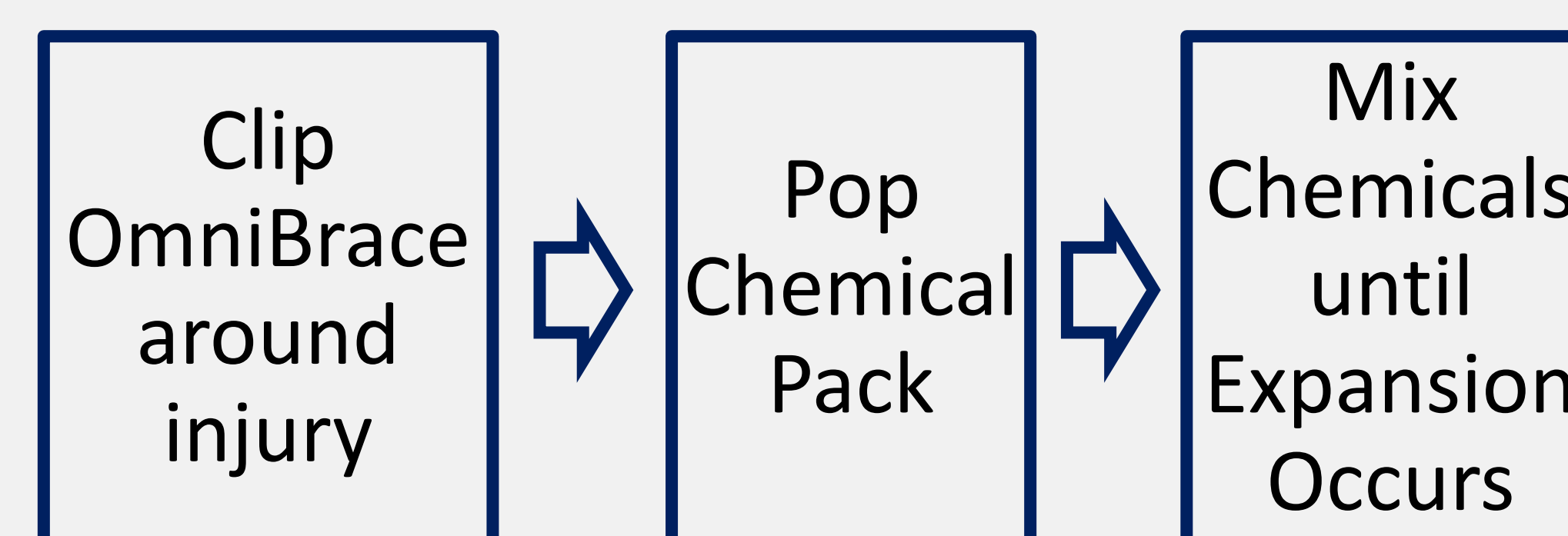


The snap-hooks are secured by the OmniBrace's outer elastic straps, which encompass the spandex bag. The snap-hooks are free to slide along the elastic, which enables them to pull away from the edge of the OmniBrace. This allows for the brace to be secured around limbs of greater circumference than would otherwise be possible.



Because the outer elastic bands hold the OmniBrace in place, it is the hoop-stress through these bands which causes pressure to be directed inwards, toward the limb. This effectively limits the force which expanding polyurethane foam can apply against the injured limb to safe levels, reducing the risk of ischemia and loss of circulation.

Deploying the OmniBrace in an emergency setting is as simple as:



Estimate of Production Cost

Market research has suggested that a sales price of \$30-40 per unit would be ideal. However, recent manufacturing quotes from several firms have placed the estimated production cost at nearly \$150 per part, indicating that there is room for additional work in materials selection and design for manufacture. Because the OmniBrace provides a superior solution for immobilization than existing options, a higher cost may be an acceptable trade-off in specific situations, including military operations and professional sports.

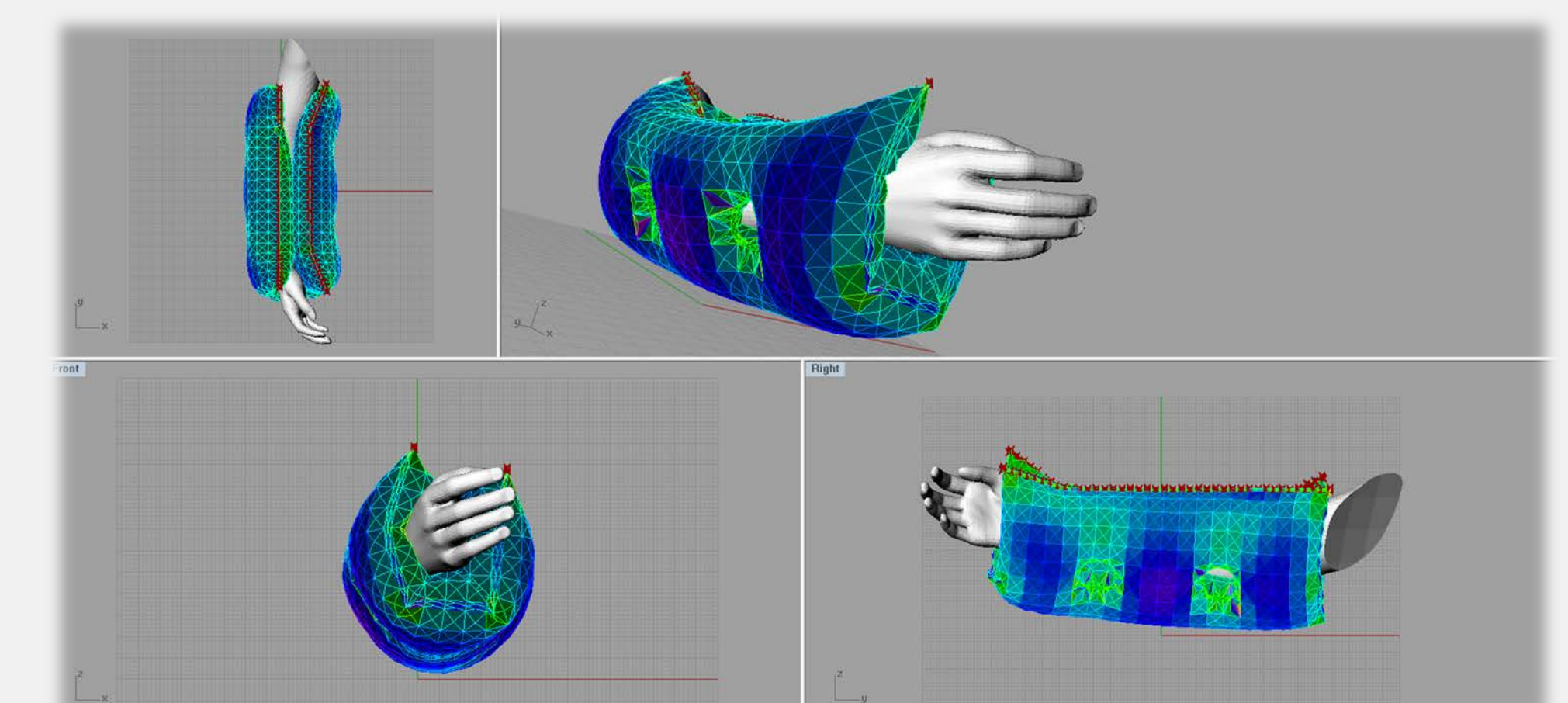
Anticipated Regulatory Pathway

The OmniBrace falls under the FDA regulatory category "Inflatable extremity splints," and is therefore a Class-I device, and exempt from the premarket notification (510(k) requirement.

A Note on Optimization

Since the process of manufacturing prototypes is very time consuming, a computational physics simulation was created to reduce the resource load of exploring various regions of the design parameter space.

Using the Kangaroo Live Physics Engine plugin for Grasshopper (a graphical algorithm editor for Rhinoceros 3D), and the Goat optimization solver, global non-linear gradient-free optimization was performed over the design space to determine what arrangement of "button" seals would maximize the brace stiffness without exceeding the desired thickness.



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