

EB Adaptive Skin Protection Platform

A modular, atraumatic skin-interface system for people with epidermolysis bullosa — from four standalone components toward a future EB Smart Suit.

RESEARCH CONCEPT — NOT A CERTIFIED PRODUCT

Maturity: CONCEPT

Evidence level: E0 (hypothesis)

Concept presentation · Phase 1 · October 2026 · Janez Jurančič



Illustrative concept render — not a prototype

In EB, the protection itself can become the injury

Epidermolysis bullosa is a group of inherited disorders in which skin — and in some forms mucosal tissue — is unusually vulnerable to mechanical stress. Minimal friction or shear can cause blistering and delamination.

The engineering problem is not wound coverage. It is a skin–device interface that introduces no friction, shear, focal pressure, edge loading or traumatic adhesion.

Five Phase 1 design principles

- 01 Minimise friction and shear at the skin–device interface
- 02 Distribute pressure without hard transitions or edge loads
- 03 Avoid aggressive adhesion and painful removal
- 04 Manage moisture without excessive drying or maceration
- 05 Keep every module compatible with later garment and sensor integration

Start with the physical interface — deliberately nothing more

In scope · Phase 1

- Passive, non-electronic skin protection
- Four modular technologies: Contact, Protect, Fix, Hydro
- Bench testing on surrogate skin and anatomical models
- Design controls, traceability and risk management from day one

Deliberately excluded

- Active electronics and sensing (later gates)
- Drug delivery and bioactive claims
- Gene, stem-cell or exosome therapies
- Any use on patients or open EB wounds

Following the Technology Commons hierarchy — **passive** → **mechanical** → **electronic** → **connected** — higher technology levels are added only when they provide measurable benefit.

Four modules — each a standalone product, all one system



01 · EB CONTACT

Atraumatic interface with skin or wound



02 · EB PROTECT

Absorption, cushioning, pressure distribution



03 · EB FIX

Low-trauma retention and positioning

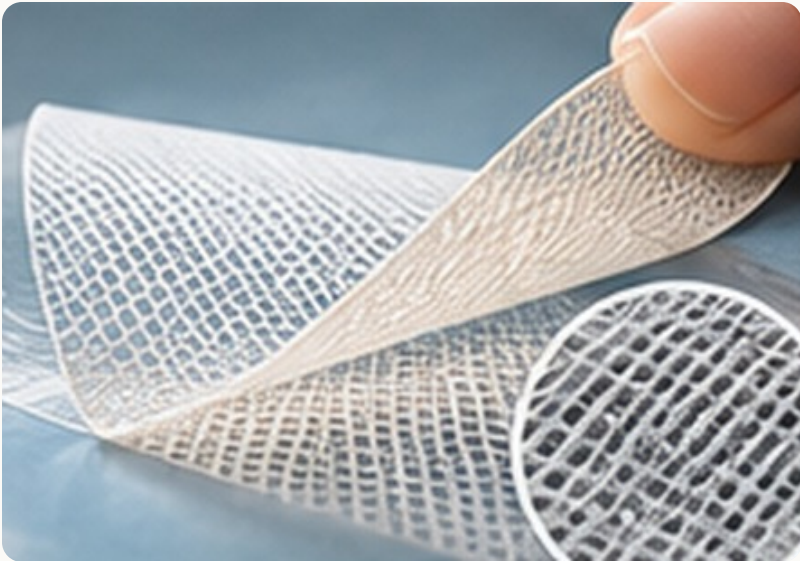


04 · EB HYDRO

Moisture and friction management

MODULE	STANDALONE PRODUCT	FUTURE SMART SUIT ROLE
EB Contact	Contact layer / mesh	Permanent skin-interface architecture
EB Protect	Protective dressing / pad	Localised protection panels
EB Fix	Soft fixation system	Garment-to-dressing retention interface
EB Hydro	Hydrogel / spray-gel	Skin-conditioning / delivery layer

EB Contact — the first thing the skin touches



A conformable, porous, non-traumatic layer that stays stable without bonding to the wound surface.

CHARACTERISTIC	INITIAL DEVELOPMENT REQUIREMENT
Surface	Very smooth, soft, non-abrasive; no sharp perforation edges
Conformability	Follows joints and curved anatomy without wrinkling
Porosity	Transfers exudate toward EB Protect
Removal	Low peel / trauma; removal method must be validated
Candidates	Soft silicone contact mesh, non-adherent mesh, lipidocolloid-type interfaces

Verify: surface friction · peel force · conformability · pore geometry · fluid transfer · tensile · repeated movement · biocompatibility

EB Protect — buffer loads without becoming a new pressure point



Key R&D trade-off: thicker pads distribute load better, but add heat, bulk, edge pressure and movement shear. Thickness is selected experimentally, not fixed at concept stage.

CHARACTERISTIC	INITIAL DEVELOPMENT REQUIREMENT
Mechanical role	Cushioning and pressure distribution
Fluid role	Absorb / transport exudate appropriate to wound type
Geometry	Rounded, feathered, low-edge-load perimeter
Flexibility	Maintains protection during joint motion
Candidates	Soft absorbent nonwoven, foam, multilayer core, spacer textile
Integration	May later carry sensors — outside the wound-contact interface

EB Fix — retention treated as a force-management subsystem

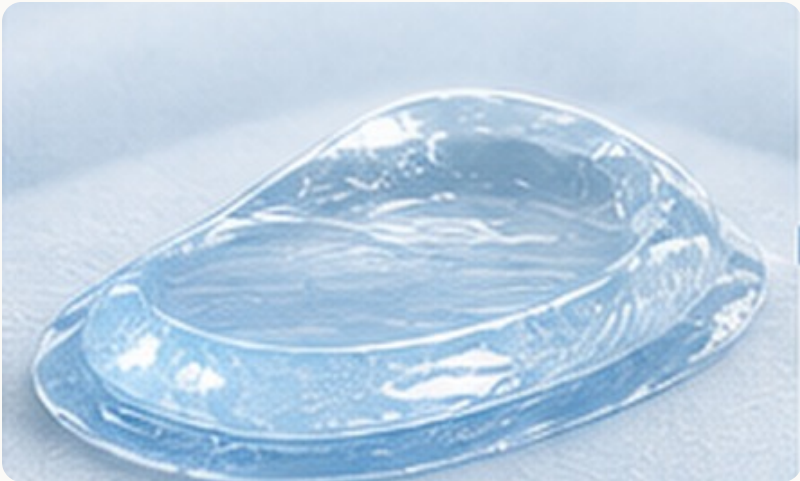
Holds the stack in place without aggressive adhesive on fragile skin — transferring retention forces to safer surrounding structures or to a garment, never concentrating them at the wound edge.

OPTION	ADVANTAGE	MAIN DEVELOPMENT RISK
Soft conformable wrap	Simple, low cost	Excess compression or slipping
Tubular retention textile	No local adhesive edge	Sizing and pressure control
Garment-integrated pocket	Direct path to Smart Suit	Requires anatomical product family
Selective silicone fixation	Precise positioning	Must prove atraumatic removal



Verify: retention force · circumferential pressure · migration during movement · edge loading · removal trauma

EB Hydro — a supportive, non-curative moisture and friction layer



First generation avoids drugs, cells, gene vectors and unvalidated bioactive claims — keeping the programme focused on the physical protection problem.

PARAMETER	CONCEPT DIRECTION
Form	Hydrogel, flowable gel, later controlled spray-gel
Primary role	Moisture balance and friction reduction
Removal	Gentle cleansing / removal by design
Compatibility	No degradation of Contact / Protect performance
R&D screening	HA-, alginate-, PVA- or PEG-based systems
Key risks	Maceration, drying, irritation, contamination, layer incompatibility

Formulation, preservatives, sterilisation and indication require specialist toxicological, microbiological and regulatory assessment.

EB Protective Patch — the smallest system that tests all four



Illustrative cross-section render. Layer order follows the concept document (below).

4	EB Fix	Retention without damaging skin
3	EB Protect	Absorption + mechanical protection
2	EB Contact	Atraumatic physical contact
1	EB Hydro	Moisture / friction interface
0	Skin / wound	Protected biological surface

Developed first in **simple flat geometries** for bench testing. Anatomical variants follow only after the material stack is characterised.

From flat patch to the body's high-friction zones



Small wounds



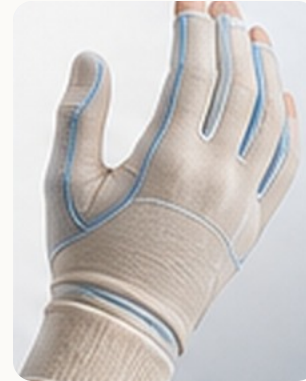
Elbows



Knees



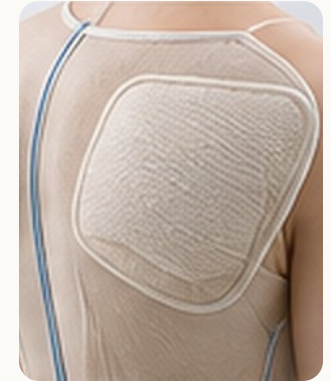
Ankles



Hands



Feet



Back / shoulders

Derived product family: **EB Patch**, **EB Glove**, **EB Sock**, **EB Joint**, an EB Spray for hydrogel application and an EB Bed Interface.

Each anatomical variant needs its own movement, pressure and retention testing — joints and hands are where shear and fixation migration are hardest to control.

Seven gates — each one produces its own evidence

G0 Need EB use scenario and unmet need	G1 Materials Screen candidate materials	G2 Components Validate each module separately	G3 Patch Integrate four modules	G4 Anatomy Joint / hand / foot variants	G5 Garment Passive protection in clothing	G6 Smart Sensing & microclimate modules
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GATE	TYPICAL EVIDENCE
G0 – G1	User needs, clinician input, intended-use draft · friction, absorption, softness and compatibility data
G2 – G3	Bench test reports per component · integrated system verification
G4 – G5	Movement and pressure testing · wearability and usability validation
G6	Electrical, software and system validation

Test the failure conditions, not only normal use

TEST FAMILY	WHAT IS MEASURED
Friction / shear	Friction vs. representative skin model, dry and moist
Pressure	Peak pressure and distribution on anatomical models
Fluid handling	Absorption, retention, transfer, leakage, rewet
Removal	Peel force and surface disturbance on surrogates

TEST FAMILY	WHAT IS MEASURED
Durability	Flexing, cyclic movement, abrasion, delamination
Microclimate	Temperature, humidity, water-vapour behaviour
Material safety	Biological evaluation for contact type and duration
Usability	Application / removal steps, error modes, caregiver burden

Test hierarchy: **simulation** → **component bench** → **subsystem** → **system rig** → **surrogate models**. Human testing is never the first validation method.

Every layer can fail in a way that harms fragile skin

HAZARD / FAILURE	POSSIBLE CONSEQUENCE	DESIGN CONTROL DIRECTION
Excess adhesion	Skin stripping, pain	Low-trauma interface + removal verification
High friction / shear	New blister or tissue damage	Material screening + movement testing
Excess pressure	Localised tissue injury	Pressure mapping + soft transitions
Moisture accumulation	Maceration	Fluid-management specification
Excess drying	Pain, adherence	Hydrogel and moisture-balance testing
Material irritation	Inflammation, dermatitis	Biological evaluation + formulation control
Contamination	Infection risk	Microbiological controls + packaging / sterility strategy
Fixation migration	Exposure, rubbing	Retention and movement validation

Concept-stage hazard map only — not a completed ISO 14971 risk analysis or DFMEA. Proposed internal classification: **TC-R3 (to be confirmed)**.

Built to be certifiable, before anything is claimed

EU MDR 2017/745

Medical device framework. Classification and conformity route depend on final intended use and claims.

ISO 13485

QMS framework — design controls and traceability structured from the start, certification later.

ISO 14971

Risk management — formal acceptability criteria, sequences of events, control verification.

ISO 10993 series

Biological evaluation by nature and duration of skin and wound contact.

IEC 62366-1

Usability engineering — application, removal and caregiver interaction affect safety.

Selected later

Textile, packaging, sterilisation and wound-dressing test standards, once intended use and materials are frozen.

The prototype is not described as a medical device until its legal status has been established.

The Smart Suit as integration of validated subsystems

Contact + Protect + Fix + Hydro

EB Protective Patch

Anatomical patches · glove · sock

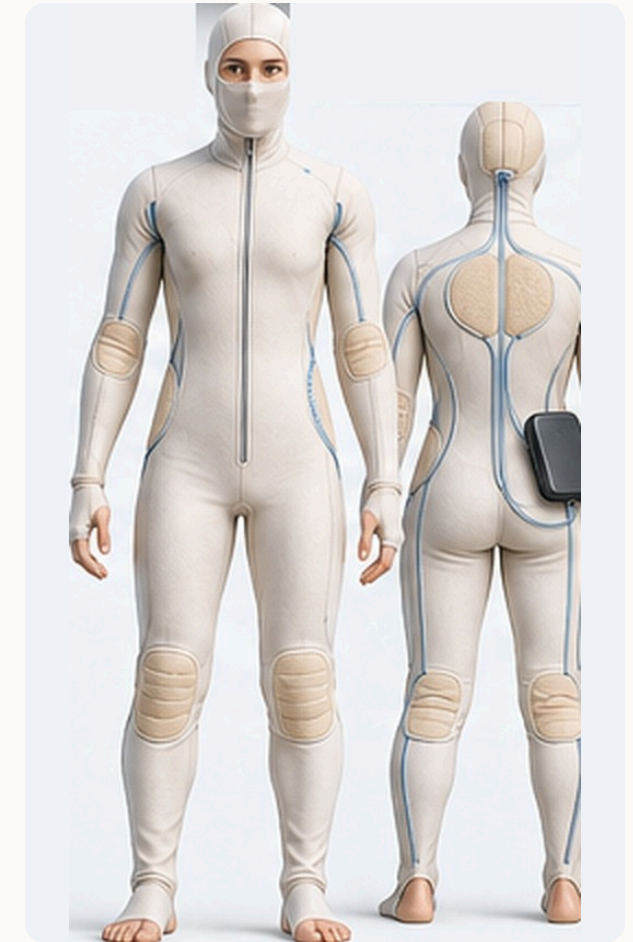
Passive EB protective garment

Sensor-integrated modules

Microclimate / active modules

EB Smart Suit

The suit does not depend on a single high-risk programme. Each earlier stage generates its own technical evidence and can stand as a useful product on its own.



Illustrative render of the long-term vision.

Development of an Atraumatic Modular Skin Protection System for EB

DEFINE

- User Needs Specification and intended-use hypothesis
- Material and supplier screening matrix
- Four component specifications

ANALYSE & BUILD

- Preliminary hazard analysis and design-risk register
- Bench methods: friction, pressure, fluid handling, removal
- First integrated patch prototypes

VERIFY & DECIDE

- Verification report comparing material stacks
- Design review and recommendation for anatomical prototypes
- Roadmap toward garment and Smart Suit

Partners sought: EB clinicians and nurses, wound-care and biomaterials specialists, textile engineers, test laboratories and EU MDR regulatory advisors — user needs must come from the people who live and work with EB.

This is an engineering concept, not a clinical protocol

No prototype described here should be applied to a child or to open EB wounds until intended use, materials, biological safety, microbiological controls, risk controls and the required regulatory and clinical validation have been established with EB clinicians and medical-device specialists.

STATUS	EVIDENCE	INTENT	CONTACT
Concept	E0 — hypothesis	Charitable, non-commercial	Janez Jurančič