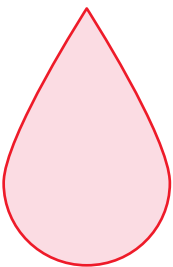


Medtronic

Balance™

Biosurface

Heparin-free biocompatible coating for
Medtronic perfusion technologies



Balance biosurface is a heparin-free, biocompatible coating for cardiopulmonary bypass circuit and ECLS devices that reduces platelet activation and preserves platelet function.^{†,1}

† Compared to uncoated in vitro bench test devices.

1 Prime coat

A priming layer is strongly bonded to the device surface.

2 Functional layer

The hydrophilic (“water loving”) functional layer is strongly bonded to the prime coat and provides the key endothelial-like benefits for the blood-contacting surfaces of cardiopulmonary bypass circuits^{2,4}:

• **Negative charge**

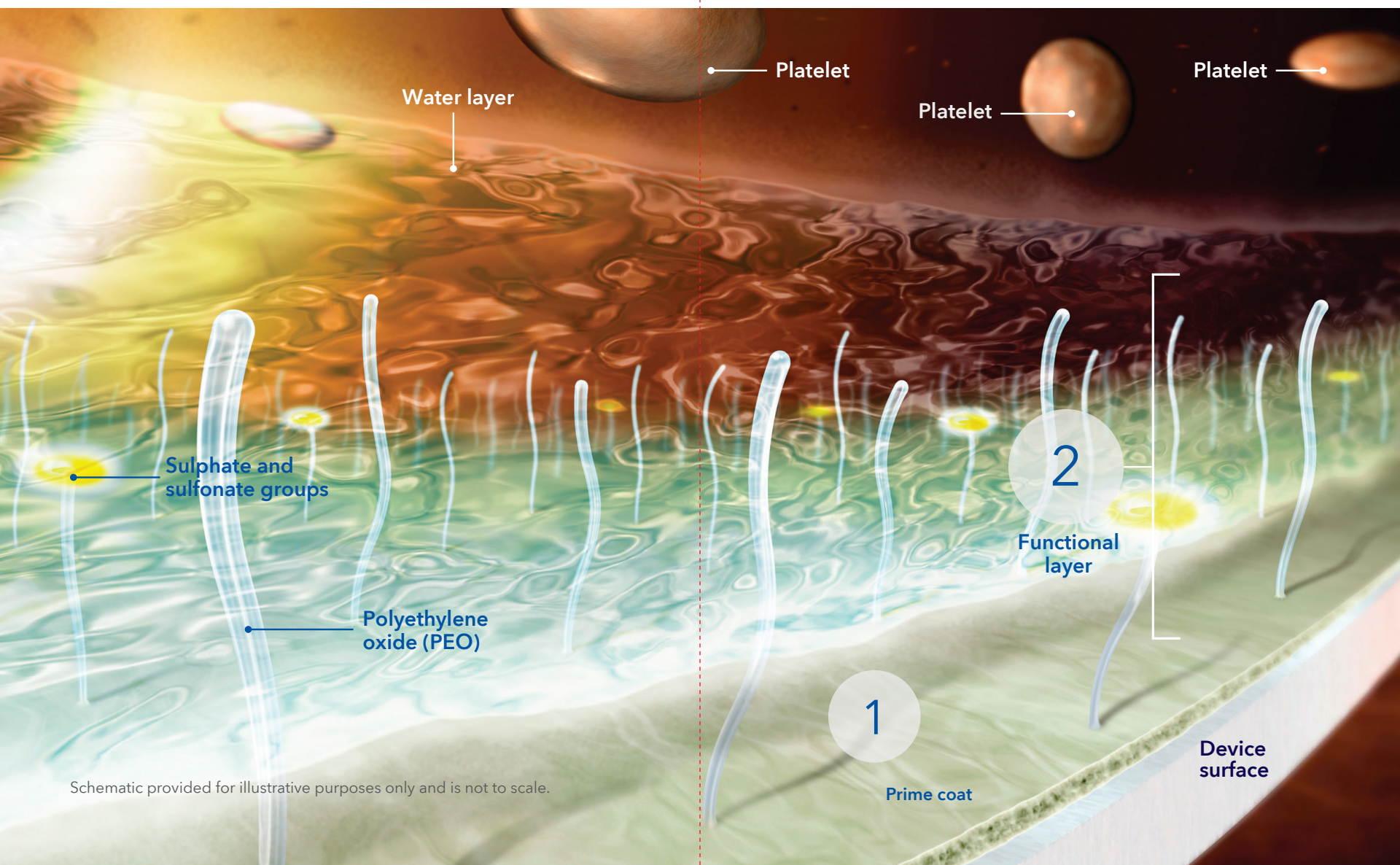
Sulphate and sulfonate groups are incorporated into the Balance biosurface functional layer to mimic the negative charge of the vascular endothelium.

Negatively charged sulphonated polymers:

- Inhibit thrombin by binding to antithrombin in a heparin-like manner⁵⁻⁷

• **Hydrophilicity**

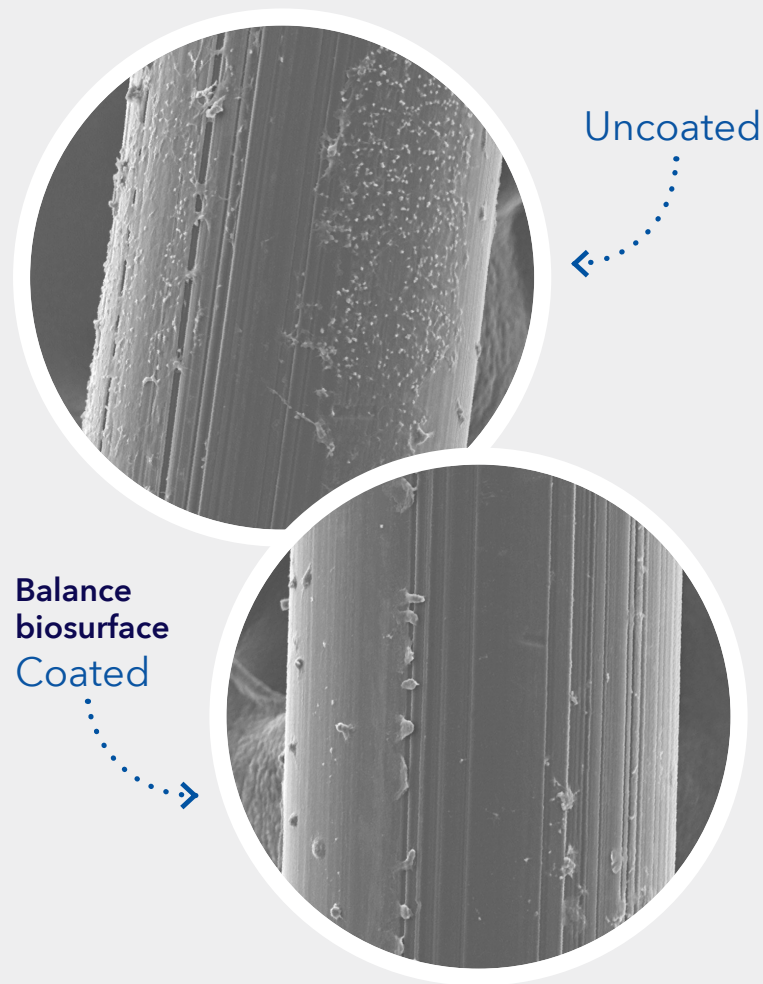
Polyethylene oxide (PEO) hydrophilic polymer is a functional layer component, which creates an “insulating” layer between the blood and device surface.



Schematic provided for illustrative purposes only and is not to scale.

Uncoated oxygenator fiber (SEM top) shows extensive cell deposition on the fiber surface.

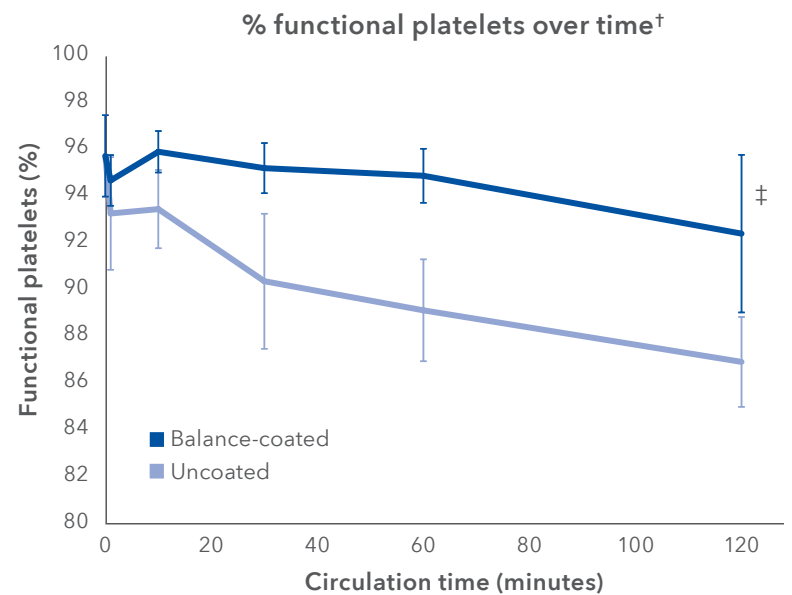
Minimal deposition is seen on the Balance coated fiber (SEM bottom).¹



Scanning electron micrographs (SEM) of oxygenator fiber surfaces after two hours of *in vitro* circulation in a closed circuit using heparinized human blood (200x magnification) visually demonstrate less cell deposition.

Balance biosurface is associated with a greater percentage of functional platelets^{†,1}

Preserved function of circulating platelets^{†,1}



Comparison between Balance-coated and uncoated *in vitro* bench test circuits (ran at device maximum rated flow rate) through percentage of platelets that are activated with adenosine diphosphate (ADP @ 20 μ M) in circulating heparinized human blood over time.

Ask your Medtronic representative today about Medtronic perfusion technologies available with Balance biosurface

[†] Compared to uncoated *in vitro* bench test devices.

[‡] $p \leq 0.02$ at 10, 30, 60, and 120 minutes.

Why use biocompatible surfaces for extracorporeal circulation circuits?

Blood is naturally compatible with vascular endothelium, not artificial surfaces

- The endothelium plays an active role in maintaining balance among the various body defense systems.^{8,9}
- The blood-contacting surfaces of endothelial cells are highly negatively charged, a characteristic that may repel the negatively charged platelets.¹⁰

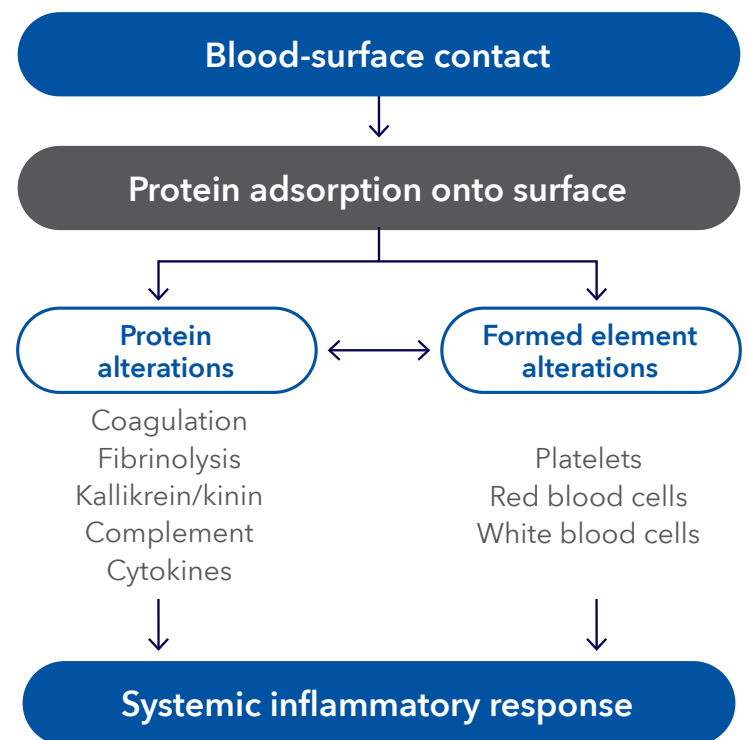
Blood recognizes the extracorporeal circuit surfaces as "foreign"

- Within seconds of blood exposure to artificial surfaces, there is a rapid adsorption of proteins from the blood onto the surface of the foreign material.¹¹

Biocompatible surfaces of Medtronic extracorporeal circulation technologies mimic critical characteristics of the vascular endothelium^{1,3,10,13}

- These biocompatible surfaces mitigate the foreign body response that occurs when blood comes in contact with non-endothelial surfaces.^{1,10}

Responses to blood-material contact^{8,9,11,12}



Risks of ECLS include heart, vessel, or lung damage, hypoxia, anemia, infection, hemorrhage, liver or kidney failure, stroke, and death.

Risks associated with extracorporeal support during CPB may include, but are not limited to, blood loss, embolism, coagulopathy, activation (coagulation/complement), circulatory compromise, infection, ischemia, organ dysfunction, hemolysis and hypovolemia.

1. Medtronic in vitro testing on file, not indicative of clinical performance.
2. Medtronic data on file.
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Caution

Federal law (USA) restricts devices coated with Balance biosurface to sale by or on the order of a physician. For a complete listing of indications, contraindications, precautions, and warnings, please refer to the Instructions for Use that accompany each product.

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UC201005655b EN
08/2024