



# Frequently Asked Questions

## Carpentier-Edwards ThermaFix advanced tissue process

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### ***How can tissue treatments reduce calcification?***

According to available literature, there are two major binding sites for calcium — tissue phospholipids and residual or “unstable” glutaraldehyde molecules, which lead to tissue calcification. While other tissue treatments may extract or coat one of these two calcium binding sites, only the ThermaFix advanced tissue process extracts both sites.<sup>1-6</sup>

### ***How is a tissue treatment different from glutaraldehyde fixation?***

Glutaraldehyde fixation is only the first step in the tissue treatment process. It helps in tissue preservation, sterility, improved biocompatibility and structural stability. An effective tissue treatment also specifically targets calcification.<sup>7</sup>

### ***Why is extraction better than coating?***

Unlike the ThermaFix advanced tissue process which extracts phospholipids and unstable and residual glutaraldehyde molecules, other tissue treatments may only coat these calcium binding sites. As a result, their anticalcification effect may be reversible.<sup>9</sup>

### ***Does the ThermaFix process affect the mechanical properties of tissue?***

Testing has shown that the biomechanical properties of leaflet tissue treated with the ThermaFix advanced tissue process remain unchanged. Additionally, *in vitro* hydrodynamic and accelerated-wear testing show no changes in functional valve performance.<sup>4,5</sup>

## ***Why Compromise durability and tissue treatment?***

The ThermaFix advanced tissue process is available on the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis, which is designed with 20-year unparalleled durability data.<sup>8</sup>

## ***What results has the ThermaFix advanced tissue process achieved?***

As the only tissue treatment to extract both major calcium binding sites, the proprietary ThermaFix advanced tissue process reduced calcium uptake by up to 81% over glutaraldehyde controls in small animal studies.<sup>5</sup>

No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.

### **References:**

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8. Carpentier-Edwards PERIMOUNT Aortic Pericardial Bioprosthesis 20-year Results. Data on file at Edwards Lifesciences 2003.
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