### ECiMa<sup>™</sup>

Vitamin E technology Overview

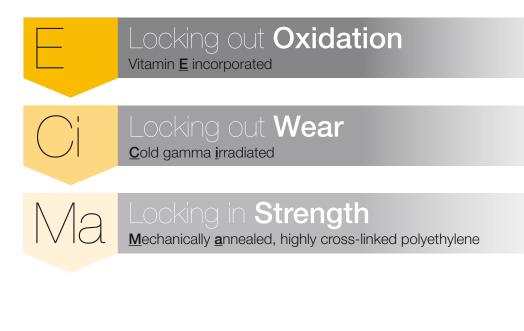
# Locking in Life\*



### ECiMa<sup>™</sup>

Ultra High Molecular Weight Polyethylene (UHMWPE) has proven itself over many decades as the gold standard bearing choice in total joint arthroplasty<sup>1</sup>. Several developments have been proposed to address ongoing issues surrounding wear, fracture and mid-term oxidation<sup>1</sup>. Advances in material and manufacturing technologies have attempted to address these issues, however challenges still persist in relation to long-term oxidation and material strength<sup>2,3,4</sup>.

ECiMa<sup>™</sup> has been developed in conjunction with Massachusetts General Hospital, Boston, to address some of these long standing clinical issues, and is designed to provide an advanced, high performance, oxidation resistant bearing technology.





E

Vitamin <u>E</u> blend Mechanical blending of vitamin E with UHMWPE prior to consolidation allows irreversible grafting of vitamin E during the radiation process.

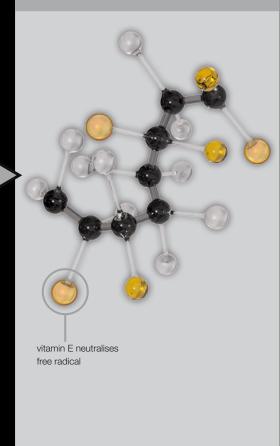


cross-linking

**<u>C</u>old gamma <u>i</u>rradiated** This excites molecules to create cross-links, improving wear resistance of the material.



<u>Mechanical annealing</u> This proprietary compression process below re-melt temperature creates extensive cross-links, while maintaining strength.





### Novel manufacturing process

### Locking out Oxidation

Modern generation vitamin E polyethylene products provide an antioxidant solution helping to prevent *in vivo* oxidation. However...

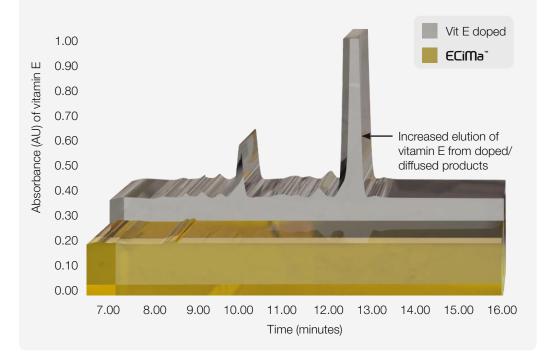
# **not all** vitamin E polyethylenes are **equal**

Whilst some companies use a diffusion or doping process, ECiMa<sup>™</sup> uses a proprietary blending and consolidation process, grafting the vitamin E to the polyethylene molecule at the start of the manufacturing process. This offers two distinct advantages:

- allows uniform distribution of vitamin E throughout the polyethylene<sup>5</sup>
- minimises the vitamin E elution effect seen in diffused or doped vitamin E products<sup>5</sup>.

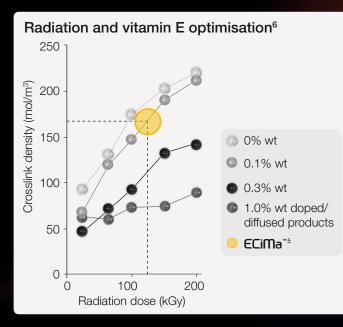
#### Elution rates from vitamin E polyethylenes

Increased elution of vitamin E from doped/diffused vitamin E polyethylene observed utilising a high performance liquid chromatography technique (non-polar solvent extraction)<sup>5</sup>.



#### The 'Goldilocks Enigma'

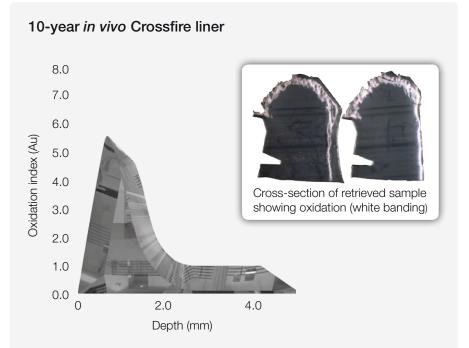
The radiation dose and vitamin E content have been optimised with ECiMa<sup>TM</sup>, providing excellent crosslink density for the radiation dose. In comparison, conventional infused vitamin E polyethylenes use up to 1% weight vitamin E which yields a lower crosslink density and poorer wear properties for a given radiation dose<sup>6</sup>.



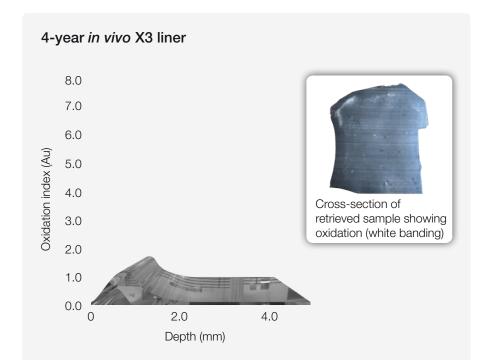
### Optimising wear resistance

### Locking out Oxidation

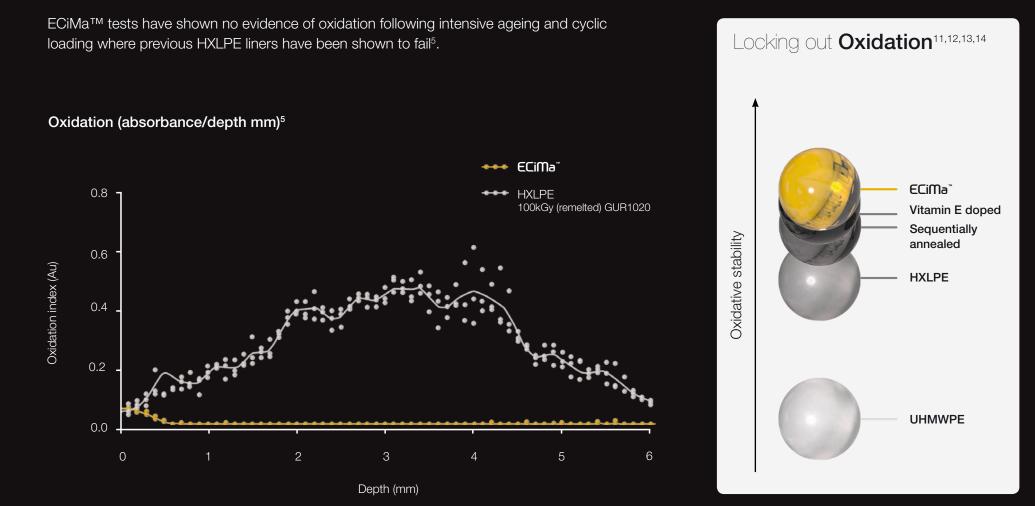
Whilst first generation HXLPEs were designed to minimise oxidation, recent research has demonstrated that cyclic loading and absorption of lipids such as squalene result in the generation of free radicals *in vivo*, causing oxidation<sup>7,8</sup>. The vitamin E grafted to the polyethylene acts as a reservoir able to quench free radicals, minimising the potential for *in vivo* oxidation<sup>9</sup>.



Crossfire shows 45x increase in oxidation compared to base level at 10 years<sup>10</sup>.



X3 shows 15x increase in oxidation compared to base level at 4 years<sup>10</sup>.



### Locking out Wear

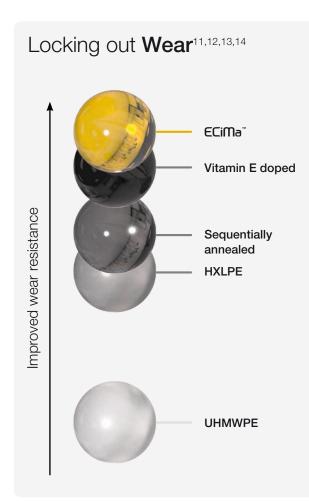
Post irradiation processing combined with high vitamin E dosage can reduce the cross-linking density of polyethylene. Whilst low temperature processes minimise cross-linking density, high temperature processes decrease material strength.

A proprietary mechanical annealing process combined with low vitamin E dosage allows optimisation of cross-linking density, improving the wear resistance of ECiMa<sup>™</sup> over conventional HXLPE and infused vitamin E products.

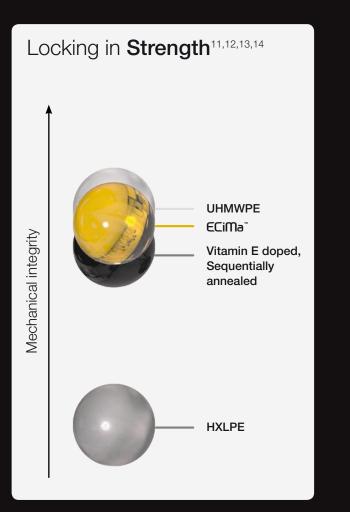
- 41% reduction compared to infused vitamin E products<sup>12</sup>
- 83% reduction compared to HXLPE<sup>11</sup>
- 95% reduction compared to UHMWPE<sup>11</sup>

#### Wear rate<sup>11,12</sup>



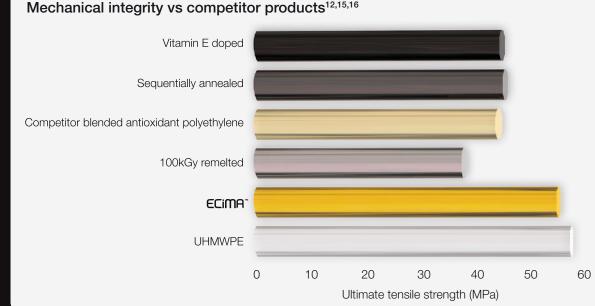


# Locking in Strength



Unlike most other antioxidant and HXLPE materials, ECiMa™ utilises a mechanical annealing process which quenches free radicals at below melt temperature, maintaining the mechanical integrity of the material<sup>13,14</sup>.

- 45% increase in ultimate tensile strength compared with conventional HXLPE<sup>11</sup>
- 17% increase in ultimate tensile strength compared with modern generation antioxidant and sequentially annealed HXLPE<sup>12</sup>



#### Mechanical integrity vs competitor products<sup>12,15,16</sup>

# ECiMa<sup>™</sup>



### Locking out **Oxidation**

Blended vitamin E provides an 'oxidative shield' actively stabilising the polyethylene insert from oxidation<sup>11</sup>.

### Locking out Wear

Cold irradiation allows cross-linking at the optimal radiation dose, providing 95% reduction in wear compared with conventional polyethylene<sup>11</sup>.

### ocking in Strength

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Mechanical annealing below the melt temperature provides a 45% increase in ultimate tensile strength compared to conventional HXLPE<sup>11</sup>.

# Locking in Life\*

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### \*Locking in the life of the polyethylene through the incorporation of vitamin E to prevent oxidation and minimise wear<sup>5</sup>



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