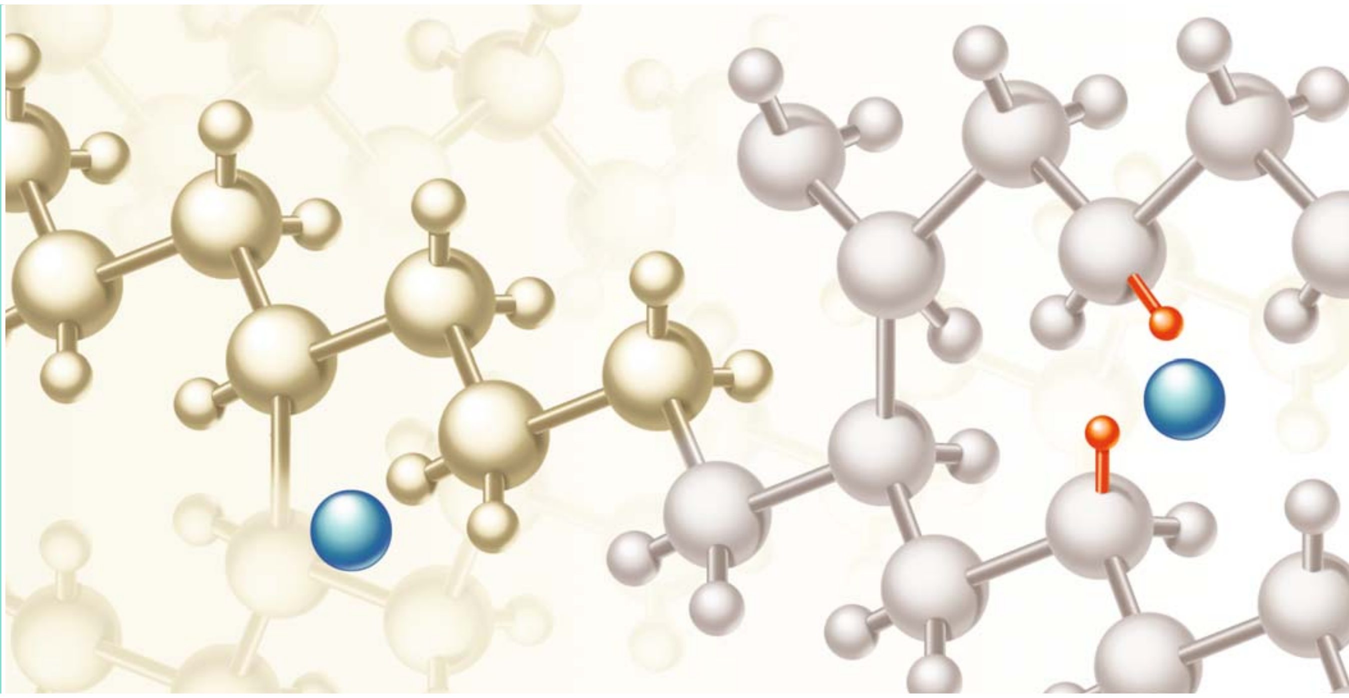
Aesculap® Vitelene®

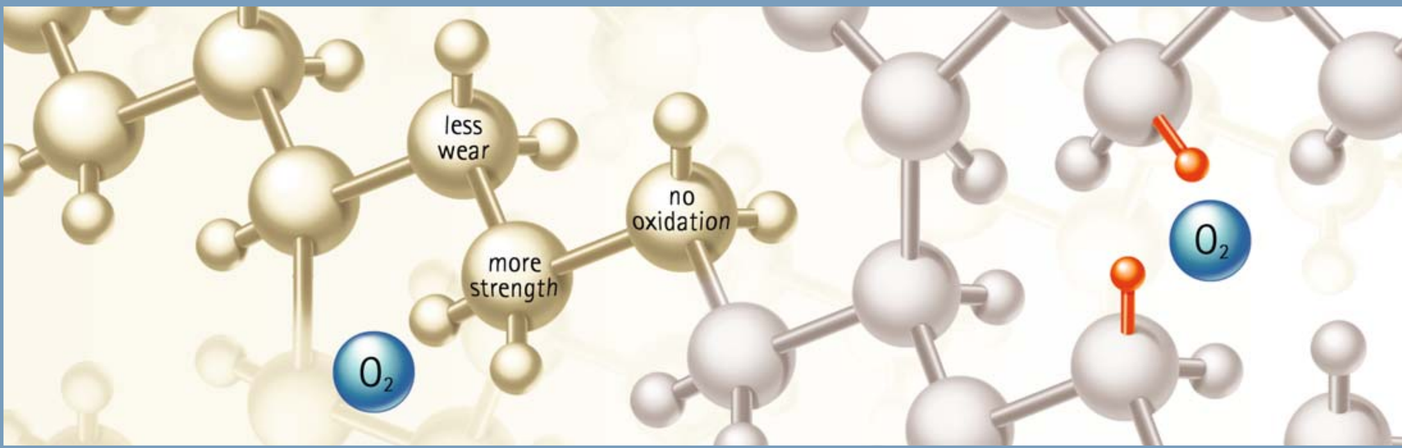
Vitamin E Stabilized Highly Crosslinked Polyethylene



Aesculap Orthopaedics

B|BRAUN
SHARING EXPERTISE

Vitamin E Stabilized Highly Crosslinked Polyethylene



Vitelene® is a highly crosslinked GUR 1020 polyethylene blended with vitamin E.

Vitamin E provides long-term oxidation protection by binding free radicals through the release of H atoms. Polyethylene powder GUR 1020 is mixed with vitamin E (0.1 % - α-tocopherol) and pressed into sheets.
Afterwards a total dose of 80 kGy electron beam radiation is applied to cross link the blank product.

The Vitelene® inserts are manufactured using CNC technology and sterilized with ethylene oxide.

Vitelene® needs no thermal treatment and has, therefore, balanced mechanical properties. It is characterized by wear and oxidation resistance.

The in vitro wear of a Vitelene® insert in combination with a 36 mm ceramic head is three times below the threshold that is known to cause osteolysis.
Higher wear rates can occur with metal heads, by third-body wear, through cup malpositioning or as a result of implant loosening.

In contrast to polyethylene implants which are doped with vitamin E by diffusion as finished parts, blending of polyethylene by mixing vitamin E already into the raw powder guarantees a vitamin E concentration also in the deep areas of the material.

Thus manufacturing related free radicals could be scavenged also in hardly accessible crystalline areas.

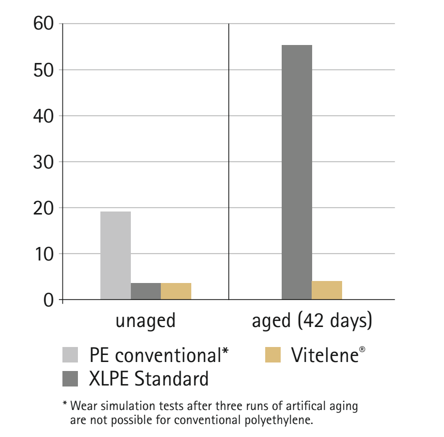
Highly crosslinked polyethylenes without additional antioxidants pass a post-irradiative thermal treatment above the melting point to increase atom mobility and stimulate a recombination of free radicals.
However this thermal treatment destroys the crystalline areas and compromises the mechanical stability of the polyethylene material.

By adding vitamin E a thermal treatment after irradiation is not necessary and the mechanical properties of Vitelene® can be preserved.

Due to its excellent wear and oxidation resistance and balanced mechanical properties, Vitelene® represents a new generation of highly crosslinked polyethylene for total hip arthroplasty.

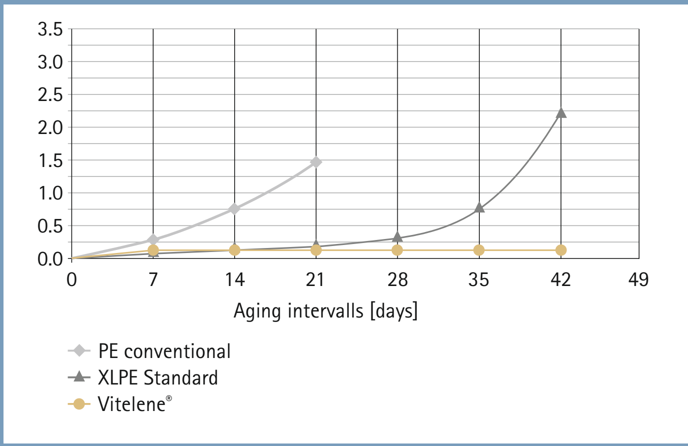
Wear and Oxidation Properties

Gravimetric Wear [mg / Mio. cycles]



Source: Grupp T et al., Biotribology of a vitamin E stabilised polyethylene for hip arthroplasty, EORS 20th Annual Meeting, Amsterdam 2012

Oxidation Index [OI]



Source: Aesculap AG, Tuttlingen

The wear simulation test were performed with 36 mm prosthesis heads. Unaged cup liners of conventional PE, standard XLPE and Vitelene® as well as extremly aged cup liners of standard XLPE and Vitelene® were tested.

The artificial aging of polyethylene liners is realized in a pressure container filled up with pure oxygen. Under pressure conditions of 5 bar and a temperature of 70°C these environment correlates after 14 days approximately to five years real aging according to ISO standard 5834-3. The wear simulation tests were conducted after triple artificial aging of the liners.

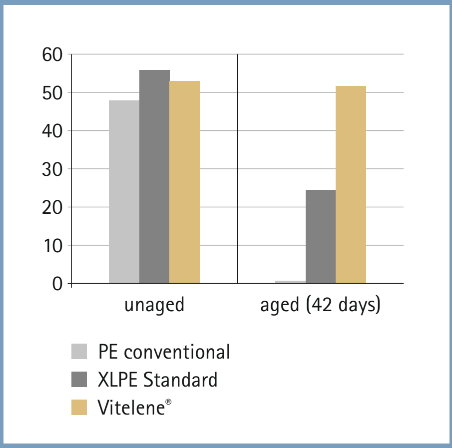
The oxidation index shows the part of oxidized bonds on the surface of the material. For Vitelene® the oxidation index is considerably lower compared to conventional and standard XLPE. Even after three aging cycles the oxidation index of Vitelene® is below the detection threshold.

The wear rate of Vitelene® is very low even after extreme artificial aging. The vitamin E concentration is still sufficient to eliminate oxidative reactions and therefore reducing wear throughout the whole lifespan of the total hip arthroplasty.

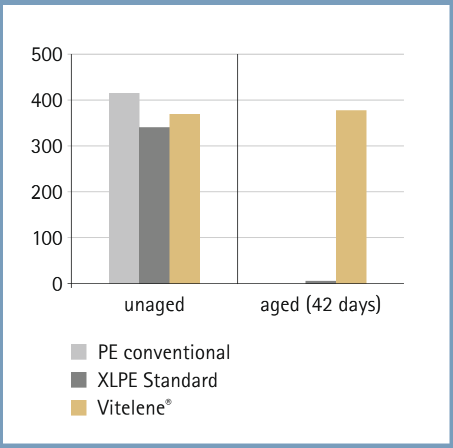
Oxidation leads to degradation of polyethylene. Vitamin E increases the resistance of polyethylene against oxidative processes and strengthens the bearing material throughout the lifespan of the total hip arthroplasty.

Mechanical Properties

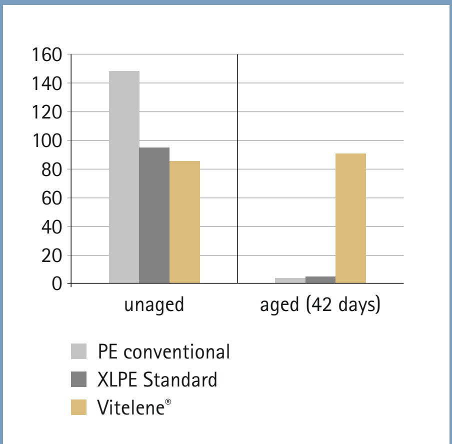
Tensile Strength [MPa]



Elongation [%]



Impact Strength [kJ / m²]



Source: Aesculap AG, Tuttlingen

Tensile strength is the maximum power which can be applied to a material in relation to the stressed test surface and is measured in Megapascal (MPa).

It is determined in a tensile test according to ISO 527. Under unaged conditions all materials: conventional PE, standard XLPE (remelted) and Vitelene® show comparable values within the measurement accuracy.

Only Vitelene® preserves the original stability after aging.
The unstabilized polyethylene variations demonstrated a significant reduction.

> The mechanical properties impact strength, tensile strength and elongation of Vitelene® are unchanged even after 42 days of artificial aging. Thus the laboratory tests show an excellent longterm stability of Vitelene® against mechanical stress.

The elongation is also determined by the tensile test according to ISO 527 and describes the maximum deformation of a test sample til a break occurs.

The detected elongation is indicated in % in relation to the original sample length. The higher the elongation is, the lower is the probability of material fracture.

Under unaged conditions there is no significant difference between conventional PE, standard XLPE (remelted) and Vitelene®. However, after 42 days of artificial aging, only Vitelene® holds the elasticity of unaged polyethylene.

The impact strength of a material shows its resistance against abrupt stress. The lower the viscosity is, the more brittle the material is, thereby leading to a higher risk of material failure. Impact strength is detected with a pendulum impact tester according to the method of Charpy ISO 11542-2 and is indicated in kj / m².

The crosslinking by irradiation causes an extreme reduction of viscosity due to the formation of a rigid polyethylene matrix.

Therefore both highly crosslinked polyethylenes in the unaged state show a lower viscosity than the conventional one. However, oxidative reactions during the aging process lead to a significant embrittlement of the unstabilized polyethylene which is blocked by vitamin E in Vitelene®.

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