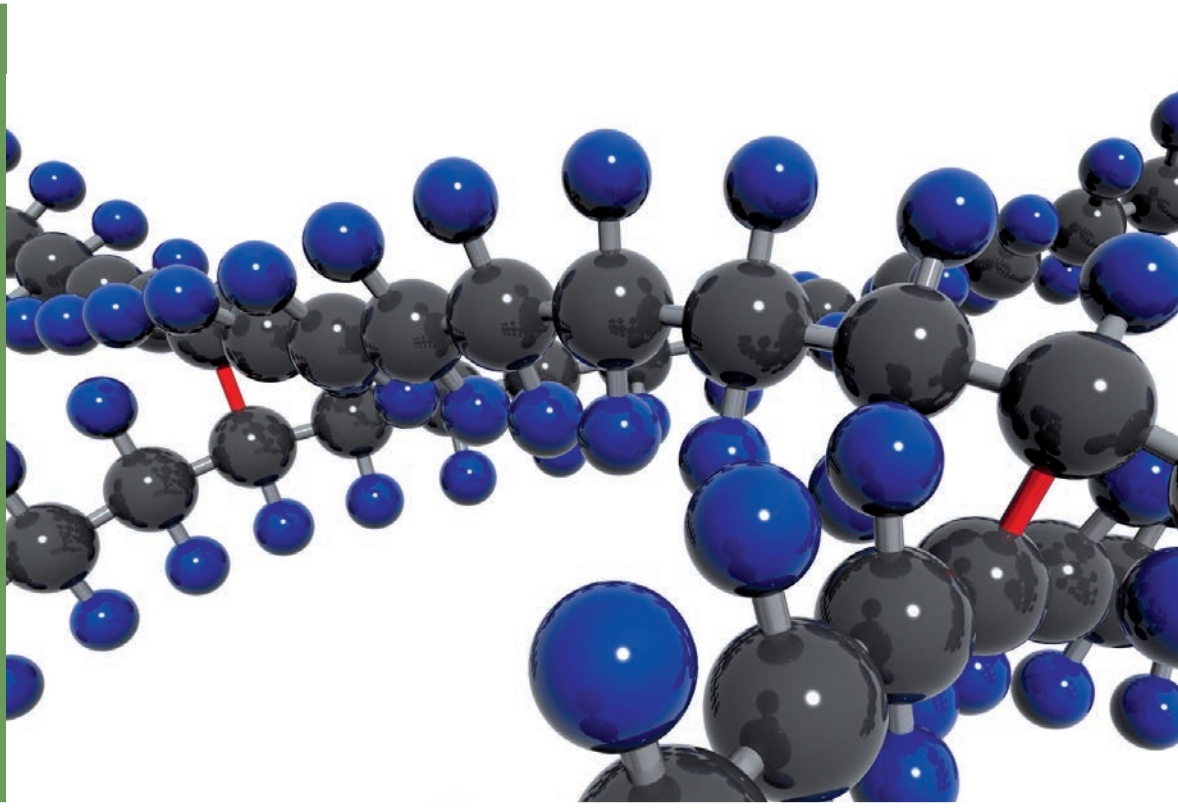
MATHYS
European Orthopaedics

vitamys®

The E-Factor Makes the Difference



vitamys®

Introduction

vitamys is the highly cross-linked polyethylene (HXLPE) from Mathys. Designed for durability and longevity, vitamys meets the highest expectations of a modern orthopaedic implant material. Enriched with vitamin E, this HXLPE heralds the next generation of HXLPE.

Material benefits

- **High oxidation resistance**
- **High ageing resistance**
- **High wear resistance**
- **Excellent mechanical properties**

Radiation cross linking and thermal treatment of ultra-high molecular weight polyethylene (UHMWPE) have aroused intense scientific and commercial interest within the orthopaedic community since the late 1990s. Since 1998, highly cross-linked polyethylenes (HXLPE) are in clinical use. A reduction in wear of 25 % to 83 % after 5 years of implantation has been reported in literature[1]. Despite the improvement over conventional polyethy-lene, previous generations of HXLPE are characterized by some major disadvantages:

- High-energy radiation destroys molecular chains, giving rise to unstable, chemically active areas of damage in the molecules, known as free radicals.
- Subsequent heat treatment causes these radicals to «pair up» more easily with other molecule chains and react with them.
- Heat treatment leads to optimized oxidation resistance but can weaken the mechanical properties of the polyethylene.

The trade-off between high oxidation resistance and high mechanical properties has now been solved with vitamys®.

vitamys®

A European development

Patented by Mathys – vitamin E additive replaces heat treatment

The patent-protected procedure by Mathys eliminates the need for heat treatment to quench the free radicals.

In this procedure, the oxidation resistance of HXLPE is assured by the inclusion of the well-known antioxidant vitamin E.

Vitamin E
Vitamin E is a collective term for the group of tocopherols, of which alpha-tocopherol (Fig. 1) shows the best properties as an antioxidant[2]. It exists as a natural substance in the human body and also in diary products; for example in nuts, oils and some fruits such as avocados. The vitamin E content of vitamys is below the recommended daily amount of 10 – 15 mg[3], max. 400 mg. For example, 200 g almonds contain more vitamin E than a vitamys implant. Therefore no systemic reactions are expected.

The highly cross-linked polyethylene of Mathys – vitamys® – is manufactured from UHMWPE Chirulen® 1020 and endowed with 0.1 % of synthetic vitamin E. It is homogeneously mixed with vitamin E, sintered under pressure, and highly cross-linked.

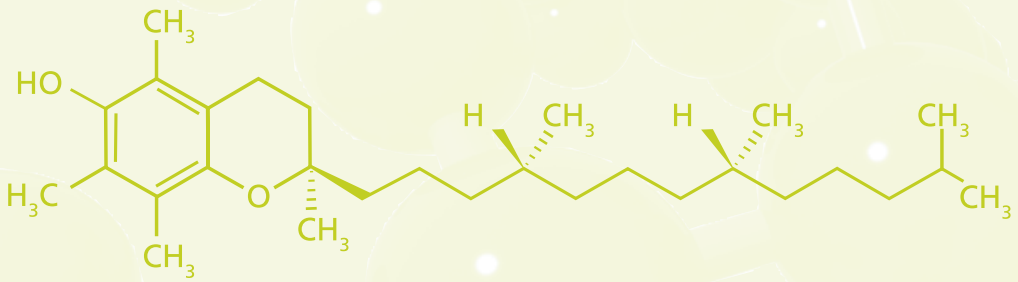


Fig. 1 Molecular structure of α-tocopherol

Homogeneous penetration of vitamin E in the polyethylene matrix
Vitamin E is fully integrated in the polyethylene, thanks to homogeneous mixing with UHMWPE Chirulen 1020 at a very early stage in the production process.[4]

The advantages
- Excellent protection against oxidation already established in the raw material
- No separate heat treatment required to diffuse vitamin E into the polyethylene
- No risk of uneven concentration profiles of vitamin E in the polyethylene[5]

Vitamin E is a stabilizer to prevent the polyethylene from oxidation – the smart solution!

A European development

Function of vitamin E during the cross linking process
Optimal thermal treatment and the addition of vitamin E make vitamys one of the most durable HXLPE available today. The addition of vitamin E as anti-oxidant is a method to preserve mechanical properties and ageing resistance. During and after the cross linking process vitamin E binds oxygen and allows the free radicals to reconnect the carbon-hydrogen (CH_2) chains (Fig. 2).

Unlike most HXLPE on the market, Mathys uses only a stress relieving thermal treatment far below melting temperature to ensure the dimensional stability of the material[6].

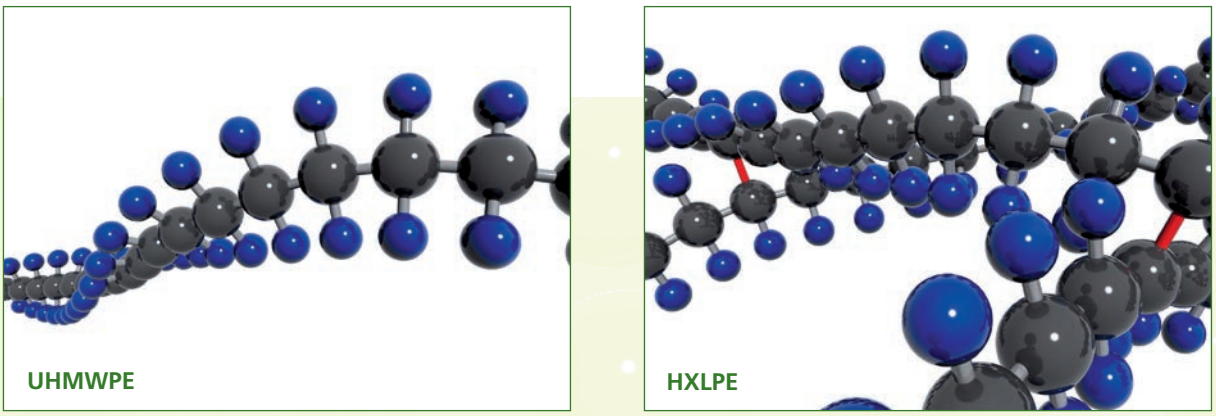


Fig. 2

With vitamys®, no extensive heat treatment is required to preserve high mechanical properties.

High oxidation and ageing resistance

Accelerated ageing through increased temperatures and oxygen content is used to simulate oxidation and ageing over many years of shelf storage. For example, 15 days accelerated ageing under O_2 (70°C, 5 bar) correlates to 10 years in vivo.[7]

In the in-vitro testing as shown in Fig. 3 below, vitamys proved to be long-term oxidation and ageing resistant.[8] With the addition of vitamin E, vitamys demonstrated oxidation resistance for a period of 40 years or more under physiological conditions (extrapolation).

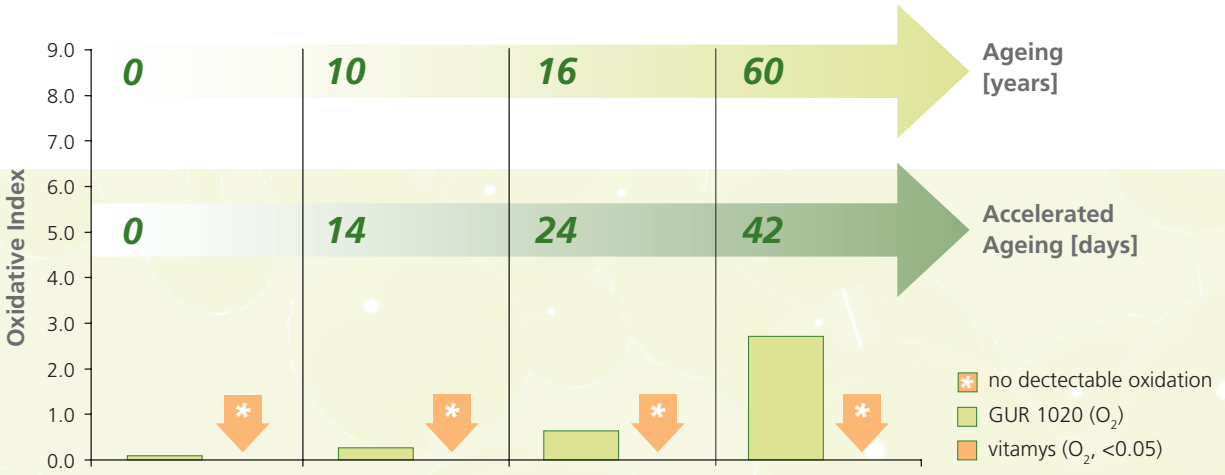


Fig. 3 Accelerated ageing test of vitamys under O_2 (5 bar at 70°C tested at 0, 14, 24, 42 days)

The comparison of conventional UHMWPE made from GUR 1020 and vitamys demonstrated the effect of vitamin E:[8]

- vitamys shows no detectable oxidation tested under O_2 at any time
- vitamys shows 10 times lower oxidation index compared to GUR 1020 tested under H_2O_2

High wear resistance

In hip simulator tests (according to ISO 14242-1:2012) vitamys proves to significantly reduce wear compared to UHMWPE[9,10]. Wear rate of vitamys remained at constant low level even using different head materials and diameters[9].

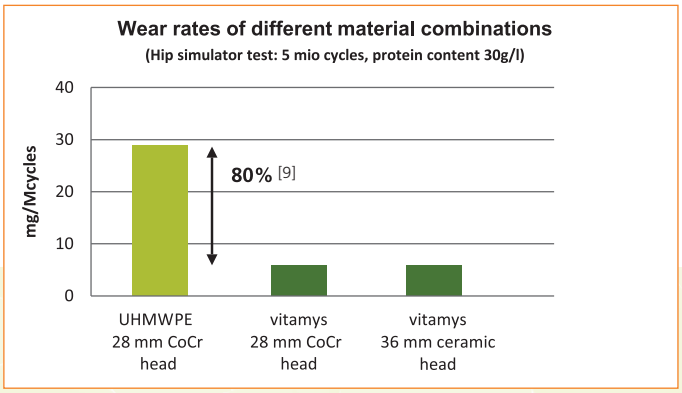


Fig. 4

Wear reduction with vitamys *in vivo*

After 1–2 years the RM Pressfit vitamys Cup clinically showed a significantly lower wear rate than standard UHMWPE[11] and confirms the positive results seen in the simulator studies.

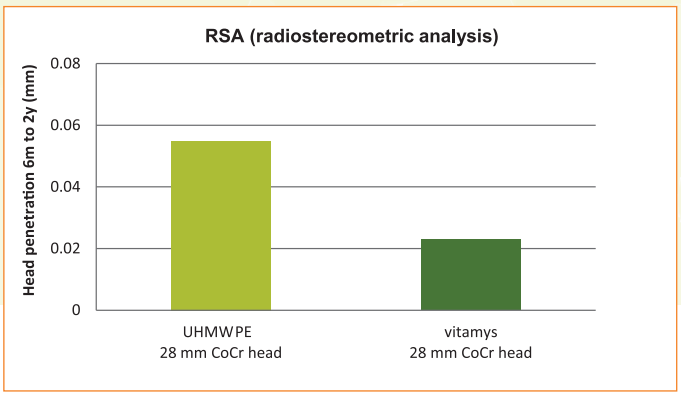


Fig. 5

Excellent mechanical properties

Excellent mechanical properties
vitamys is a highly cross-linked polyethylene used in total hip replacement that is equivalent to the best PE type 1 classification (according to ISO), meeting all requirements for yield strength, ultimate tensile strength and elongation at break. These mechanical properties are most important for long-term performance of the material.

The figure below shows vitamys in comparison to the different PE types according to ISO. vitamys shows excellent values. Other HXLPE may only meet PE Type 2 or 3 categories due to decreased tensile strength or elongation.

Although second generation HXLPE materials are convincing in terms of wear resistance, the mechanical properties of other HXLPE have not yet met the most stringent requirements. Extensive heat treatment which is necessary to get rid of free radicals weakens the mechanical properties of polyethylene [12].

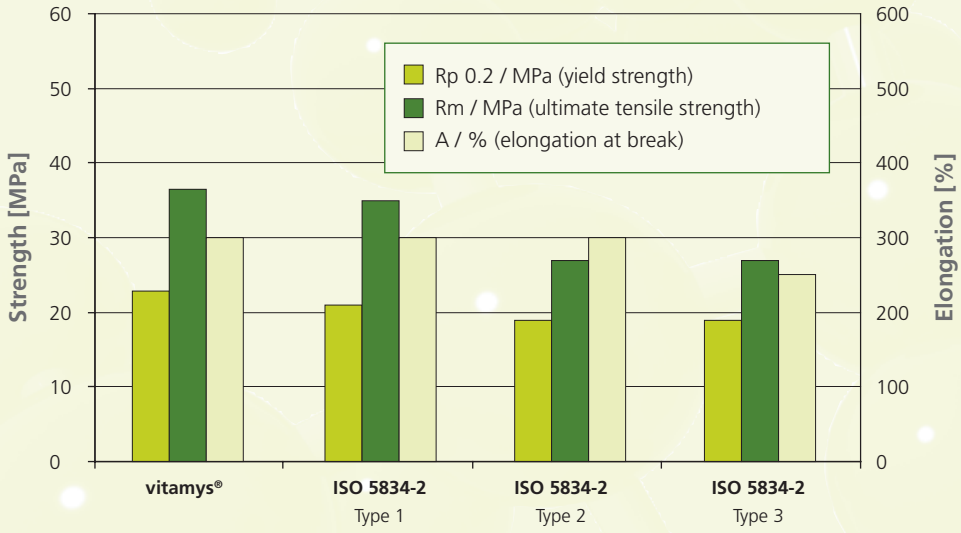


Fig. 6 vitamys in comparison to ISO standards [13]

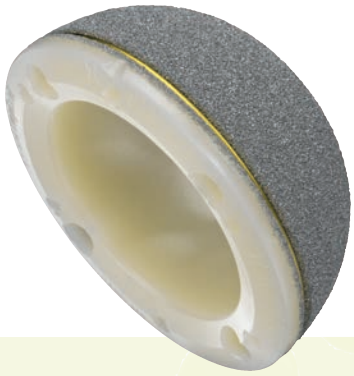
Solutions with vitamys®

vitamys is a high wear resistant alternative to hard/hard bearings for young and active patients. Used in combination with our ceramic heads there is no risk of increased ion levels or risk of chipping/fracture of the inlay – a truly «forgiving» combination.

RM Pressfit vitamys® Cup
The RM Pressfit vitamys implant is a cementless, 100 % PE acetabular cup and is the first cup of this type to combine the advantages of low rigidity (similar to cancellous bone, thus preventing stress shielding) with resistance to wear and ageing, and clinically proven biologic anchorage.

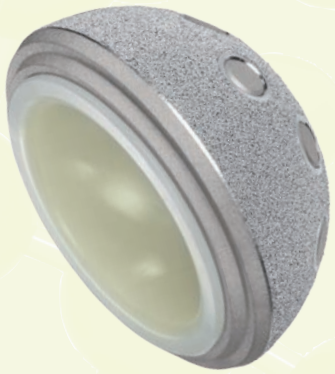
The benefits of vitamys allow a reduction in the polyethylene wall thickness and larger articulation diameters which can be used with smaller cups: a 32 mm articulation with a cup diameter of 48 mm and a 36 mm articulation with 52 mm cups.

The RM Pressfit vitamys Cup is characterised by
- Extraordinary combination of implant design and material properties
- High wear and ageing resistance
- Proven concept of elasticity
- Easy surgical technique, MIS adapted instruments



RM Pressfit vitamys®

seleXys® vitamys® Inlays
The successful modular cup system seleXys is offered with vitamys inlays in addition to conventional UHMWPE inlays. Articulations of 28, 32 and 36mm are available.



seleXys® PC vitamys®

vitamys® – The E-Factor Makes the Difference

Literature

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[3] www.diabetes-news.de/info/ernaehrung/vitamine/vitamin-e.htm

[4] Patent No. WO0049079; Data on file

[5] Oral E et al, Wear Resistance and Mechanical Properties of Highly Cross-linked, Ultrahigh-Molecular Weight Polyethylene Doped With Vitamin E, Journal of Arthroplasty Vol.21 No.4 2006: 580-91

[6] Annealing: Annealing is a heat treatment process below melting temperature wherein a material is altered, causing changes in its properties such as strength and hardness. It is used to induce ductility, relieve internal stresses, refine the structure by making it homogeneous

[7] Zurbrügg D et al, 18th European Conference on Biomaterials, 2003, Stuttgart, Germany

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[13] ISO Standard 3834-2

MATHYS
European Orthopaedics

Australia
Mathys Orthopaedics Pty Ltd
Lane Cove West, NSW 2066
Tel: +61 2 9417 9200
info.au@mathysmedical.com

Austria
Mathys Orthopädie GmbH
2351 Wiener Neudorf
Tel: +43 2236 860 999
info.at@mathysmedical.com

Belgium
Mathys Orthopaedics Belux N.V.-S.A.
3001 Leuven
Tel: +32 16 38 81 20
info.be@mathysmedical.com

France
Mathys Orthopédie S.A.S
63360 Gerzat
Tel: +33 4 73 23 95 95
info.fr@mathysmedical.com

Germany
Mathys Orthopädie GmbH
«Centre of Excellence Sales» Bochum
44791 Bochum
Tel: +49 234 588 59 0
sales.de@mathysmedical.com
Hotline: +49 1801 628497 (MATHYS)

«Centre of Excellence Ceramics» Mörsdorf
07646 Mörsdorf/Thür.
Tel: +49 364 284 94 0
info.de@mathysmedical.com

«Centre of Excellence Production» Hermsdorf
07629 Hermsdorf
Tel: +49 364 284 94 110
info.de@mathysmedical.com

Japan
Mathys KK
Tokyo 108-0075
Tel: +81 3 3474 6900
info.jp@mathysmedical.com

New Zealand
Mathys Ltd.
Auckland
Tel: +64 9 478 39 00
info.nz@mathysmedical.com

Netherlands
Mathys Orthopaedics B.V.
3905 PH Veenendaal
Tel: +31 318 531 950
info.nl@mathysmedical.com

P. R. China
Mathys (Shanghai) Medical Device Trading Co., Ltd
Shanghai, 200041
Tel: +86 21 6170 2655
info.cn@mathysmedical.com

Switzerland
Mathys Ltd Bettlach
2544 Bettlach
Tel: +41 32 644 1 644
info@mathysmedical.com

United Kingdom
Mathys Orthopaedics Ltd
Alton, Hampshire GU34 2QL
Tel: +44 8450 580 938
info.uk@mathysmedical.com

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