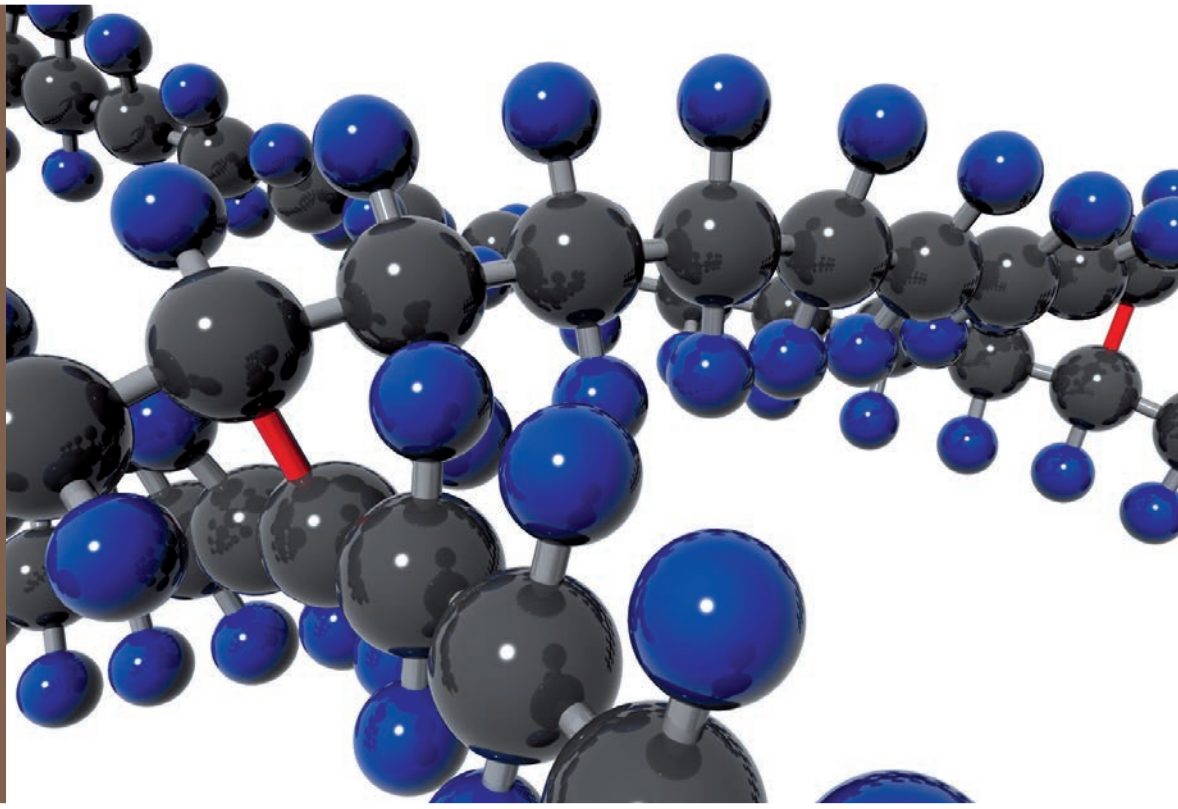
MATHYS
European Orthopaedics

ceramys® & vitamys®

Longevity for the Affinis® Shoulder System



ZrO_2-Al_2O_3

ceramys® & vitamys®

Experience and competence

Fig. 1: Affinis Inverse Inlay ceramys

ceramys®
Since the early 70s, Mathys have been active in the research, development and manufacture of bioceramics because we are convinced of their advantages. Continuous research and development in the field of ceramics results in the steady improvement of our existing materials. A lower risk of osteolysis thanks to reduced polyethylene abrasion, anti-allergic (biologically inert) behaviour and high in-vivo aging resistance are just a few of the properties that make ceramics an ideal treatment solution, not only for young and active patients.

Since 2007, ceramys has yielded successful clinical applications in hip endoprosthetics.

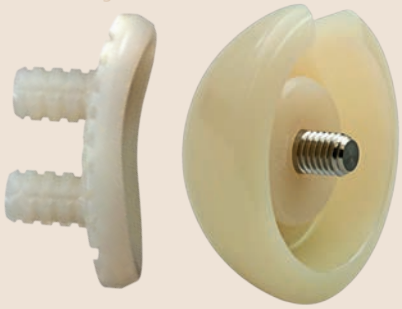


Fig. 2: Affinis Glenoid vitamys cemented and Affinis Inverse Glenosphere vitamys

vitamys®
In the field of polyethylene, too, Mathys focuses on proprietary development. vitamys – a highly cross-linked, vitamin E-enriched polyethylene – is designed for the greatest durability and a long service life, and thus meets the very highest expectations for modern orthopaedic implant materials. This vitamin E-enriched polyethylene represents the latest generation of highly cross-linked polyethylenes (HXLPE).

vitamys has already been in use since 2009 in promising hip-endoprosthetic applications.

ceramys®

A pearl of ceramics

The nanocrystalline dispersion ceramic, ceramys®, consists of a homogenous mixture of 20 % aluminium oxide and 80 % zirconium oxide without any further additives. This composition is unique in the field of joint endoprosthetics.

ceramys is designed for maximum breaking safety: It has the highest breaking strength of all ceramic materials available on the market. With this unique material, Mathys offers a new option in the field of inlays for inverse shoulder prosthetics.

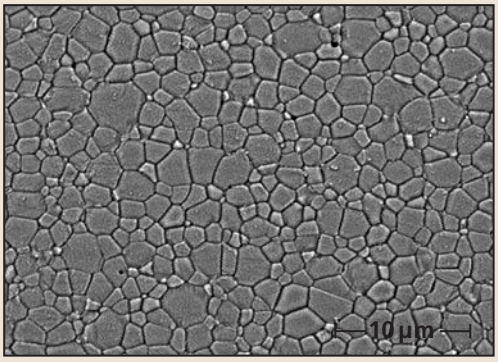
ceramys can be combined with standard polyethylene and vitamys.

Advantages of ceramys

- ceramys offers maximum breaking safety thanks to unsurpassed material properties
- ceramys is completely resistant to aging
- ceramys is characterised by reduced abrasion
- ceramys contains no nickel, chromium or cobalt

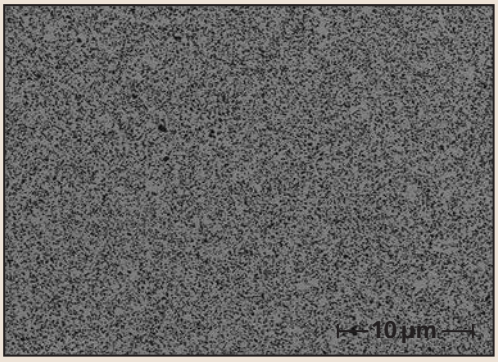
Mathys ceramics – microstructure and material properties

Aluminium oxide ceramic



Grain size
D50 (Al_2O_3) = 2.3 µm

ceramys®



Grain size
D50 (Al_2O_3) = 0.4 µm
D50 (ZrO_2) = 0.4 µm

Material properties	Aluminium oxide ceramic	ceramys
Al_2O_3 [% by weight]	100	20
ZrO_2 [% by weight] with yttrium oxide	0	80
Theoretical density [g/cm^3]	3.99	5.51
Mean grain size [µm]	2.3	0,4
Biaxial bending strength [MPa]	≥350	≥900
Fracture toughness (SEVNB) [MPa√m]	≥3	≥7

vitamys®

The E factor makes the difference

The highly cross-linked, vitamin E-stabilised polyethylene vitamys® is designed for the greatest durability and a long service life and meets even the most demanding expectations for modern orthopaedic implant materials. The manufacturing process patented by Mathys protects the polyethylene against oxidation through its entire life cycle.

The material
- High oxidation resistance
- High aging resistance
- Excellent wear resistance
- Extraordinary mechanical properties

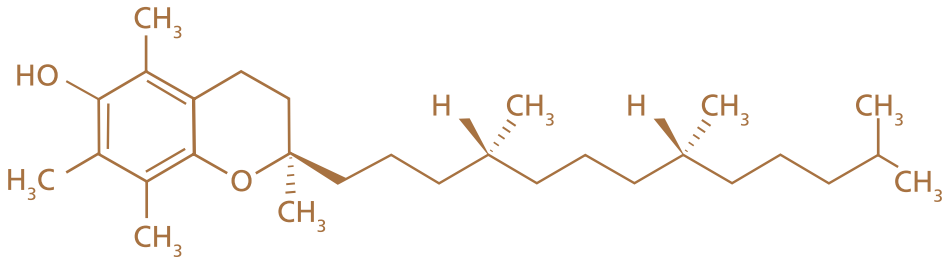


Fig. 3: Molecular structure of alpha-tocopherol (vitamin E)

Vitamin E
Vitamin E is a general term for the tocopherol group, of which alpha-tocopherol (Fig. 3) has the best antioxidant properties[1]. It occurs as a natural substance in the human body, but also in foodstuffs such as nuts and oils. The vitamin E content of a vitamys implant is below the recommended daily dose of 10 – 15 mg, maximum 400 mg[2]. No systemic reactions are therefore to be expected.

Manufacture of vitamys and the function of vitamin E
vitamys is manufactured from UHMWPE Chirulen 1020. Vitamin E, in a concentration of 0.1 %, is homogenously mixed, sintered under pressure and highly cross-linked directly with the powdery raw material.

An optimal sintering process and the enrichment with vitamin E make vitamys one of the most durable HXLPE materials of our time. The addition of vitamin E as an antioxidant eliminates the negative effect of free radicals. This is currently the most efficient method of maintaining the mechanical properties and increasing aging resistance. During and after the cross-linking process, the vitamin E reacts with oxygen, interrupts the oxidation cycle and thus effectively minimises the oxidation of the polymer. Contrary to most of the HXPLE materials on the market, vitamys requires no heat treatment to eliminate free radicals. vitamys thus meets all requirements in terms of yield stress, breaking resistance and elongation at break. These mechanical properties are of utmost importance for the short and long-term performance of the material.

Advantages of vitamys
- vitamys was specifically developed for the stress conditions in the shoulder
- vitamys incorporates the excellent antioxidant protection (vitamin E) in homogenous distribution in the raw material
- vitamys requires no separate heat treatment for the diffusion of vitamin E into the polyethylene
- vitamys undergoes no changes in mechanical properties due to material aging
- vitamys solves the problem of combining high oxidation resistance with good mechanical properties without needing to compromise

Reduction of wear and tear

In simulator tests, both the ceramys Inlay and the vitamys Glenosphere showed significantly lower wear and tear compared to UHMWPE or cobalt-chromium (CoCr) components. The reduction in wear and tear of the best possible vitamys/ceramys pairing versus the CoCr/UHMWPE pairing is approximately 80 % (Fig. 4).

As shoulder endoprostheses meet with increasing acceptance, the number of implantations is steadily rising – especially among younger patients. As a result, higher survival rates are needed. Mathys is aiming to raise the service life of shoulder prostheses to at least 15–20 years with the new materials.

Tribological wear of Affinis Inverse sliding pairings

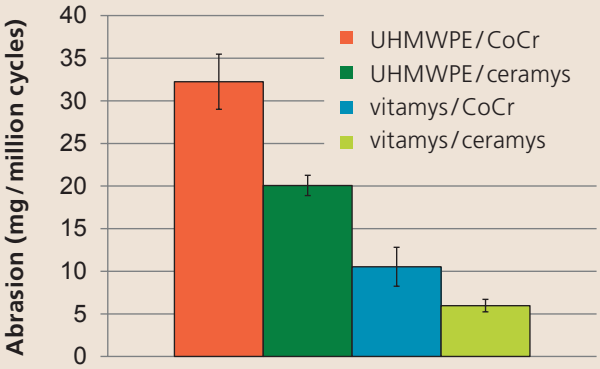


Fig. 4: Affinis Inverse with vitamys Glenosphere and ceramys Inlay

ceramys® & vitamys®

The new solutions

ceramys and vitamys represent a highly abrasion and aging-resistant solution especially for young and active patients, but it is not only this patient group which benefits from their outstanding material properties.

With ceramys and vitamys, 95 % of the implant-related causes of shoulder endoprosthesis revision published in the 2013 Australian implant registry are addressed[3]. The survival rate of glenoids, based on glenoid loosening as an end point, is 98 % after five years and 62.5 % after ten years. At 24 %, glenoid loosening was the most frequent complication leading to component revision[4].

Affinis Glenoid vitamys cemented

Advantages of Affinis Glenoid vitamys

- Mathys in-house material research and manufacture
- Several years of in-vivo experience in hip endoprosthetics with vitamys
- Better wear resistance thanks to cross-linking
- High oxidation and aging resistance thanks to the addition of vitamin E as an antioxidant
- Enhanced delamination behaviour thanks to high aging resistance
- Increased implant survival rate due to aging-resistant material properties
- Lower edge load to prevent implant failure thanks to improved rounded edge design
- Improved cement-implant bonding due to undercut and continuous cement grooves
- Greater wall thickness at the centre of the glenoid implant due to constant cement groove depth

Affinis Inverse Glenosphere vitamys and ceramys Inlay

Advantages of Affinis Inverse with ceramys and vitamys components

- Mathys in-house material research and manufacture
- Several years of experience in hip endoprosthetics with both implant materials
- Known biomechanical behaviour because no design adjustments to the implants were made
- Greater wear resistance thanks to cross-linking
- High oxidation and aging resistance thanks to the addition of vitamin E as an antioxidant
- Nickel, cobalt and chromium-free implant components thanks to the ceramic material
- Less abrasion (80 %) in vitro compared to the conventional pairing of CoCr with UHMWPE versus ceramys with vitamys
- No additional costs and regulatory barriers for custom designs for allergic patients, since the implants are standard products

References

[1] Oral E, Malhi AS, Wannomae KK, Muratoglu OK. Highly cross-linked ultrahigh molecular weight polyethylene with improved fatigue resistance for total joint arthroplasty: recipient of the 2006 Hap Paul Award. J Arthroplasty. 2008 Oct; 23 (7): 1037–44.

[2] www.diabetes-news.de/info/ernährung/vitamine/vitamin-e.htm

[3] Australian Orthopaedic Association National Joint Replacement Registry. Annual Report 2013. Table SR3. Available from URL: https://aoanjrr.dmac.adelaide.edu.au/annual-reports-2013

[4] Denard PJ, Raiss P, Sowa B, Walch G. Mid- to long-term follow-up of total shoulder arthroplasty using a keeled glenoid in young adults with primary glenohumeral arthritis. J Shoulder Elbow Surg. 2013 Jul; 22 (7): 894–900.

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