MATHYS
European Orthopaedics

Preservation in motion

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ceramys

A pearl of ceramics

History of Mathys ceramics

Since 1970, ceramic materials have been playing an important role in the area of joint replacement. In the early 1970s, the «Keramische Werke Hermsdorf, Bioceramics Department», later Mathys Orthopädie GmbH, were one of the first companies worldwide that developed and sold bioceramics for endoprosthetics. [1, 2]

Ongoing research and development by Mathys result in continuous improvement of our existing materials.

In 2007, Mathys introduced dispersion ceramic – ceramys – (ATZ – Alumina-Toughened Zirconia) for use in hip endoprosthetics.

All Mathys ceramics are developed, produced and tested in-house.

Building on our heritage
Moving technology forward
Step by step with our clinical partners
Towards a goal of preserving mobility
Preservation in motion

As a Swiss company, Mathys is committed to this guiding principle and pursues a product portfolio with the goal of further developing traditional philosophies with respect to materials or design in order to address existing clinical challenges. This is reflected in our imagery: traditional Swiss activities in conjunction with continuously evolving sporting equipment.

40 years of history, shaped by Mathys

1970 — *Development of bioceramics at* ***«Keramische Werke Hermsdorf»,*** *Germany*

1972 — ***Ceramic tibial plateau prosthesis***

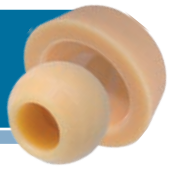
1978 — ***Femoral head made of Bionit*** *(ultrapure alumina)*

1991 — ***Founding of KERAMED Medizintechnik GmbH,*** *Germany*

1997 — ***Ceramic-on-ceramic pairing made of*** *Bionit for a 28 mm articulation*

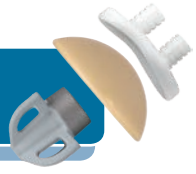
2000 — ***Articula*** *shoulder prosthesis with Bionit head*

2002 — ***Integration of KERAMED into Mathys Medical Ltd***

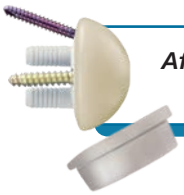


2003 — ***Ceramic-on-ceramic pairing made of Bionit*** *for 32 mm and 36 mm articulations*

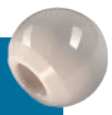
2007 — ***ceramys*** *(ATZ – Alumina Toughened Zirconia)*



2009 — ***Affinis Short*** *Shoulder prosthesis with Bionit head*



2014 — ***Affinis Inverse*** *Shoulder prosthesis with ceramys inlay*



2015 — ***symarec*** *(ZTA – Zirconia Toughened Alumina)*

ceramys – a pearl of ceramics

The dispersion ceramic **ceramys** consists of a homogenous mixture of 20 % alumina and 80 % yttria-stabilised zirconia without additions. ceramys has high fracture resistance and offers additional solutions in the area of femoral heads for revisions

ceramys can be combined with the Mathys polyethylenes and all Mathys ceramics.

ceramys – a material that combines the advantages of zirconia and alumina.

Advantages of ceramys

- High fracture strength [3]
- Reduced risk of chipping and surface roughening in the event of recurrent dislocations [4]
- Resistant to ageing [5]

ceramys – Material characteristics

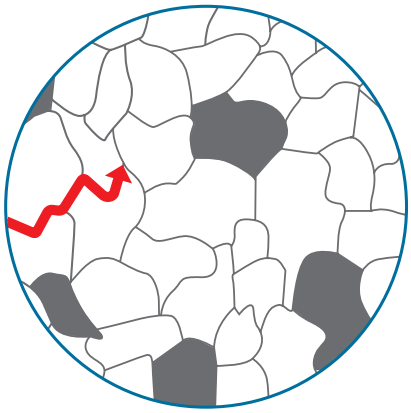
Material characteristics	ceramys (ATZ)
Al_2O_3 [% w/w]	20
ZrO_2 [% w/w] yttria-stabilised	80
Theor. density [g/cm³]	5.51
Average grain size [µm]	0.4
Biaxial bending strength [MPa]	≥900
Fracture toughness (SEVNB) [MPa√m]	≥7

Reinforcement power of zirconia

If a micro crack crosses the ceramys matrix, some of the zirconia particles will transform from tetragonal into monoclinic crystalline structure. This leads to an increase in volume, resulting in a local compressive stress field surrounding the crack tip. Hence, the crack propagation will be inhibited, resulting in enhanced fracture toughness.

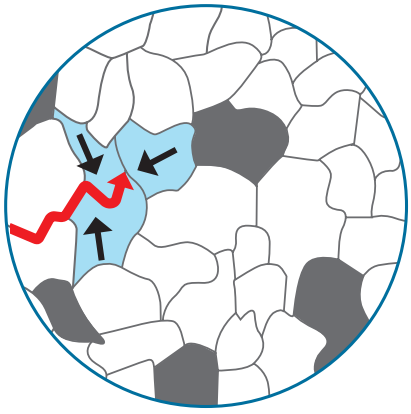
1.

Crack crossing ceramys matrix



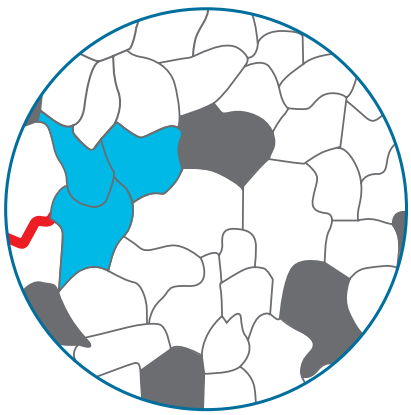
2.

ZrO_2 transforms into monoclinic, high volume structure



3.

Crack is compressed and propagation stopped



Al_2O_3

Tetragonal ZrO_2

Crack

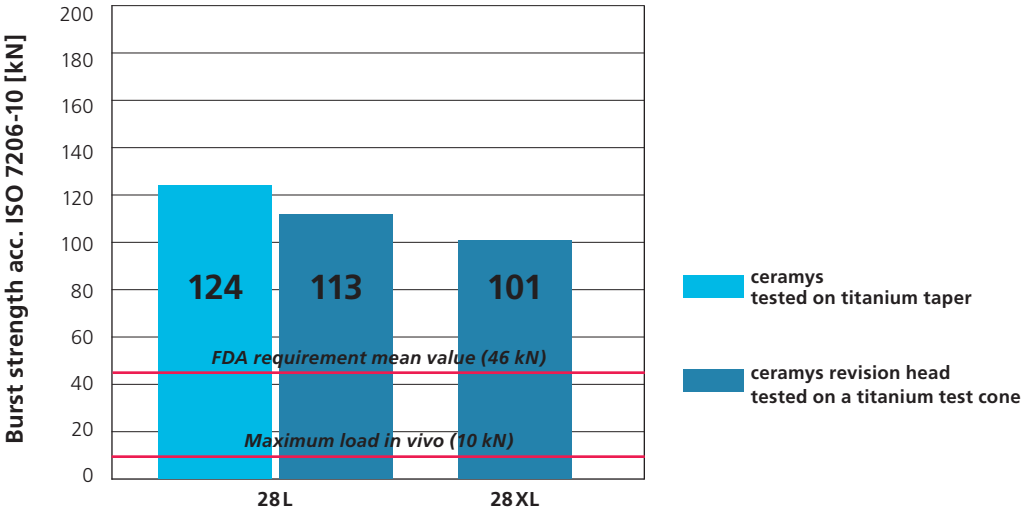
ZrO_2 during transformation into monoclinic crystalline phase

Monoclinic ZrO_2

High strength

Despite all the advantages that a ceramic articulation offers,[3–11] such as low wear rates, high strength and toughness, low risk of surface roughening, good wettability and biologically inert behaviour, there is, however, still a concern regarding ceramic materials:
They are relatively brittle and therefore have a residual risk of fracture. In the case of ceramys, this risk is reduced due to the combination of zirconia and alumina. When handled properly, ceramys offers high fracture resistance.

Burst strength of Mathys ceramic femoral heads (28 L, XL) on cones made of titanium alloy[6]



During the burst strength testing according to ISO 7206-10, the ceramic heads are axial loaded until head fracture occurs. In vivo a load of around 10 kN = 1 t can occur.[7] Even the ceramys head with the lowest strength due to the design (ceramys revision head 28 XL[6]) withstands stresses of up to 100 kN – thus ten times the in vivo loading. The burst strength raises with increasing head diameter and decreasing neck length. A ceramys head size 36 S for example has a burst strength > 170 kN.[6]

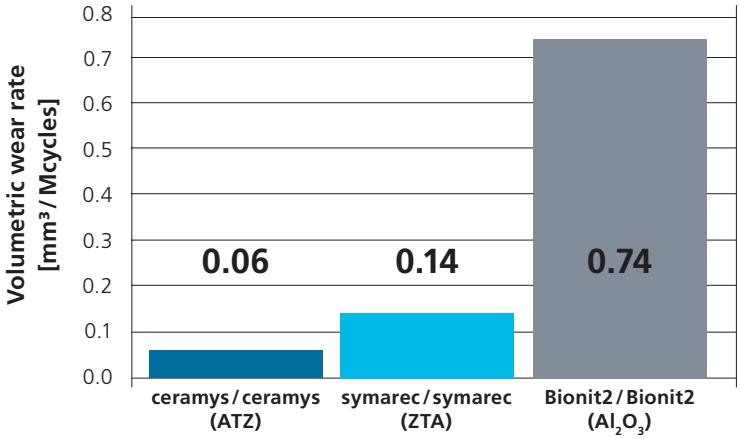
High wear resistance

The advantage of ceramic materials is their low wear rates.

Hip simulator test under microseparation conditions [8]
Independent wear tests in the hip simulator test under microseparation conditions show 58 % lower wear rates of ceramys pairings in comparison to ZTA pairings and 91 % less wear in comparison to alumina pairings.

Allergies or tissue reactions are not to be expected, since ceramys forms exclusively biologically inert wear particles.

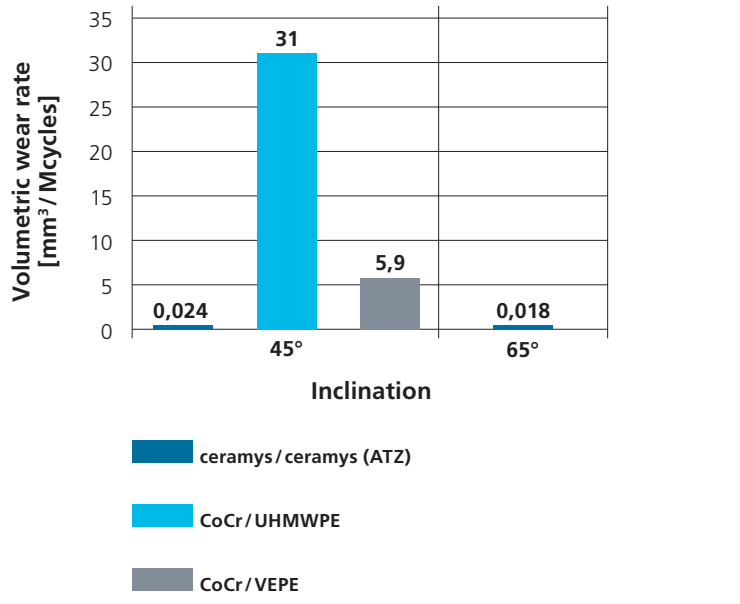
Wear rates in the hip simulator test with microseparation [8]



Hip simulator test under edge loading [9]
Various material combinations were tested with a 28 mm articulation at the standard and the highest possible angle of inclination in the hip simulator (according to ISO 14242-1).

- At an inclination of 45°, ceramys-on-ceramys pairings have 1000 times less wear than CoCr-on-UHMWPE and 200 times less wear than CoCr-on-highly crosslinked vitamin E polyethylene (VEPE) pairings
- Edge loading does not show any negative influence on the wear behaviour of ceramys
- No surface roughening can be detected in the case of the ceramys pairing after 5 million cycles

Hip simulator test under edge loading [9]



ceramys revision heads – wear-resistant solution for demanding situations

28 mm **32 mm** **36 mm**

One system – many options

ceramys revision heads offer a revision solution with decreased invasiveness.[10] In the case of a cup and/or femoral head revision, the surgeon has the option of putting a wear-resistant ceramic head onto a hip stem that is still in situ and firmly anchored.

- Available in four neck lengths: S, M, L and XL
- Femoral head and cup replacement without stem revision for all Mathys stem systems with a 12/14 cone
- Combination with the Mathys polyethylenes and Mathys ceramics

Indication

Undamaged cone | Cone with slight abrasion

Contraindication

Significant metal abrasion | Deep scratches with pronounced ridges | Deformed cone tip

Use also in case of slight wear of the surface of the cone

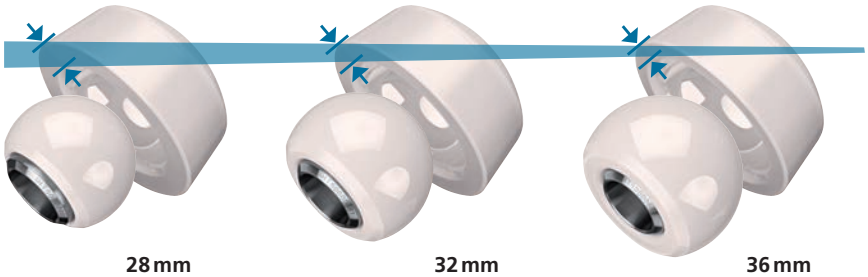
During the revision surgery, minor abrasions on the surface of the cone may occur, e. g. due to the extraction of the head.

ceramys revision heads have high fracture resistance. They are indicated for undamaged cones and cones with minor abrasion.

A contraindication for the revision head is heavy wear or damage to the stem cone, as it can occur e. g. after a ceramic head fracture. In this case, the stem must be replaced.

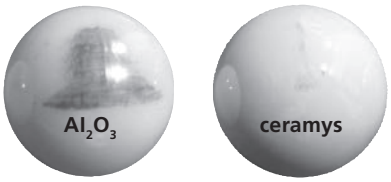
ceramys inlays – reduced risk of surface roughening

ceramys inlays can be combined with the modular seleXys and aneXys cup system. The design and wall thickness of these shells are based on the requirements of the ceramic inlays.



28 mm **32 mm** **36 mm**

The resistance against surface damage of the 28 mm ceramic articulation partners (head and liner) was investigated using a special luxation apparatus. With the use of ceramys, the risk of damage to the ceramic components from hard-on-hard pairings in cases of repeated postoperative dislocations or subluxations could be significantly reduced in comparison to alumina ceramics[4, 12] (see figures on the right).



Reduced surface roughening with ceramys

Recommendations for the safe use of ceramys heads and inlays

1. The cone of the stem and the shell must be dry and free of any foreign bodies (e. g. soft tissues or bone or cement particles)

- A cone contaminated with fluids or fats can lead to reduction in strength by up to 60 % and increase the risk of premature implant failure. [13]

2. Handle all ceramic components with care

- Ceramic heads are to be fixated with positive fit onto the cone (applying rotation and axial pressure). No metal hammer may be used for fixation.
- When using the ceramys revision head, first the head – undamaged and clean – is placed on the sleeve. Then the assembled ceramys revision head is fixated with positive fit onto the cone (applying rotation and axial pressure). No metal hammer may be used for fixation.
- Ceramic inlays are manually placed into and centred in the shell. With a stroke on the plastic impactor, the inlay is secured in the shell.
- Ceramic implants that have fallen onto the floor or onto a hard surface must not be used.

3. Cup positioning

- Inclination between 40 and 50°
- Recommended anteversion between 10 and 20°

Outside of these limit values, the range of motion may be restricted, which can lead to impingement of the implant components and subluxation and/or dislocation of the femoral head out of the cup. In such a case, a hard-on-soft pairing is to be used.

4. Trial components

In the case of ceramic-on-ceramic pairings, use of trial implants is always recommended. No ceramic-on-ceramic pairings may be used if there is a risk of impingement between the hip stem and cup. In such a case, a hard-on-soft pairing is to be used.

Please note that ceramic components must not be resterilised. Before using an implant manufactured by Mathys Ltd Bettlach, familiarise yourself with the warnings, safety information and recommendations listed in the package insert and surgical technique.

Ceramic portfolio

Cup size	Head size		
	28 mm	32 mm	36 mm
44			
46			
48			
50			
52			
54		*	
56		*	
58		*	
60		*	
62		*	
64		*	
66		*	*
68		*	*
70		*	*
Heads	S M L XL	S M L XL	S M L XL

ceramys inlay

ceramys head

symarec head

ceramys revision head

* Available only for the aneXys cup system

Mathys ceramic inlays may be combined exclusively with **Mathys ceramic heads** and ceramys revision heads.

Mathys ceramic heads and ceramys revision heads can be combined with cups and inlays by Mathys that are made of ceramic or polyethylene. Combination with ceramic inlays by other manufacturers or with inlays made of metal is not permitted.

How to proceed in case of a revision

Pairing options for revision cases following ceramic breakage

Ceramic-Ceramic (CoC): Combination with low risk of wear

Ceramic-PE (CoPE): Acceptable combination, but increased wear may occur in comparison to a primary ceramic-on-ceramic or ceramic-on-PE pairing. CoPE can be used after ceramic failure whereas CoC may not be implanted.

After ceramic breakage, no metal-on-metal pairings or metal-PE pairings may be used, since these can lead to increased metal wear. [14]

It is not permissible to insert a new ceramic inlay into an already implanted shell, since the cup may be damaged. Replacement of the cup is necessary if another ceramic-on-ceramic pairing is to be used.

Mathys is one of the world's few manufacturers of orthopaedic ceramic implants. Mathys combines high competence in bioceramics and long-term experience in orthopaedic technologies in one company.

Development of innovative ceramics, modern production, as well as competent and direct customer support – this is what Mathys stands for!

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