LINK®

MobileLink

Acetabular Cup System

Product Rationale

System Description

Many years of experience with successful implant systems and fixation concepts as well as the latest material and coating technologies have been taken into account and used in the design of this acetabular system. The result is the versatile cementless MobileLink Acetabular Cup System.

The MobileLink Acetabular Cup System comes in two different versions: A cluster-hole press-fit cup and a multi-hole press-fit cup. Both versions of the shells are available in a PlasmaLink, a TiCaP double coating or a TrabecuLink surface.

The TiCaP double coating combines a porous surface for primary fixation with our osseoconductive HX calcium phosphate coating.[7] This combination is designed to give optimal primary and secondary stability through accelerated osseointegration.

The 3-dimensional TrabecuLink structure, with its pore size, porosity and type of structure, also provides an excellent basis for promoting osseoconduction and microvascularization, taking into account the requirements for the cell-adhesive protein layer (fibronectin - vitronectin - fibrinogen).[12,13]

The MobileLink Acetabular Cup System can be used with ceramic or UHMWPE inserts. UHMWPE inserts are available in X-LINKed and E-DUR (highly crosslinked, Vit-E PE) versions. All UHMWPE inserts are available in a standard version and 5mm shoulder option (protection against luxation).

The MobileLink Acetabular Cup System can be combined with modular offset and/or inclining Shell/Insert Adapters (Face Changer). The adapters allow restoration of the anatomy in revision cases and necessary adjustments. In addition, the adapters permit the use of ceramic inserts in revision arthroplasties as well.

The MobileLink Acetabular Cup System can be transformed into a modular dual mobility system, with the use of Dual Mobility Inserts made from EndoDur. The DM Insert is to accommodate poly DM Liners from the BiMobile Dual Mobility System.

The dual mobility concept was developed by Prof. Gilles Bousquet in the 1970s with the aim of avoiding recurrent hip luxations. A modular Dual Mobility System is composed of a Dual Mobility Insert with a highly polished inner surface placed in a Shell in which a mobile polyethylene Liner with a pressed-in Prosthesis Head is articulates.

Features and Advantages of the Dual Mobility System:

- Dual mobility leads to reduced risk of dislocation and increased range of motion (RoM)[1]
- Polished inner surface[2,3]
- Elevated shoulder to facilitate removal of the liner in case of revision
- Self-centering Liner promotes even wear patterns and enhances dislocation resistance[4]

Shells

TrabecuLink
Cluster Hole

TrabecuLink
Multi Hole

TiCaP
Cluster Hole

Inserts

E-DUR

E-DUR
(with 5 mm shoulder)

X-LINKED

Shell/Insert Adapter (Face Changer)

Neutral

Offset

Dual Mobility Insert & Liner

Dual Mobility Insert
EndoDur

TiCaP
Multi Hole

PlasmaLink
Cluster Hole

PlasmaLink
Multi Hole

X-LINKED
(with 5 mm shoulder)

Ceramic
BIOLOX delta*

Ceramic
CeraDur

10° Inclination

20° Inclination

Dual Mobility Liner
UHMWPE

Dual Mobility Liner
E-DUR

* BIOLOX delta is made by CeramTec GmbH, Plochingen, Germany

Wide range of sizes
- 42 - 72 mm
- 74 - 80 mm, on request

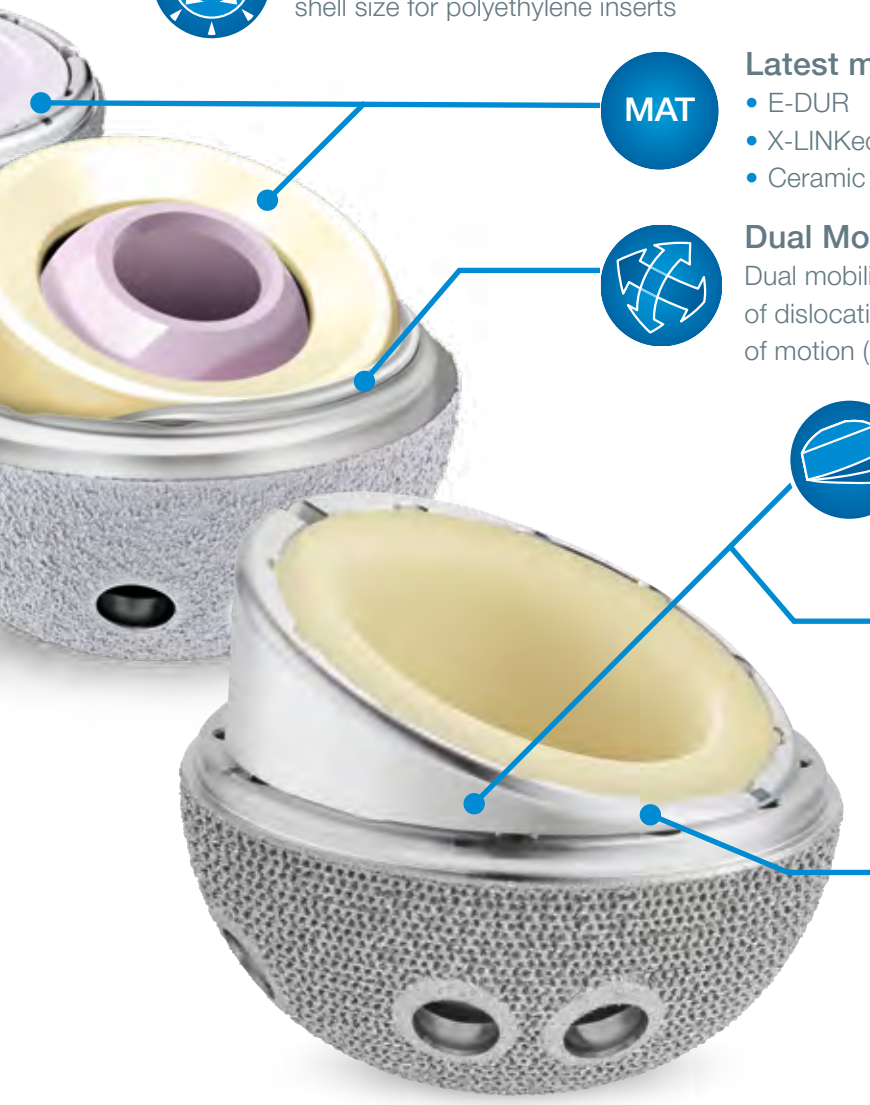
Triple locked inserts
Secure fixation of polyethylene insert to shell by a “snap-lock mechanism”, conical coupling and antirotation tabs

Variable bone screw options
- Cluster Hole Shell screw holes are pre-closed with removable caps.
- +/-15° screw angulation possible

Color coding
for streamlined workflow

3 dimensional TrabecuLink structure
Porosity of 70%, pore size of 610-820 µm and structure depth of 1mm designed for effective cell ongrowth.[12,13,14]

Rough Titanium-Plasma + HX Coating → TiCaP
Double layer coating.



50/36 – Outside small, inside big
36 mm prosthesis heads starting from 50 mm shell size for polyethylene inserts

Latest material selection
- E-DUR
- X-LINKed
- Ceramic

Dual Mobility Insert
Dual mobility leads to reduced risk of dislocation and increased range of motion (RoM)[1]

Face Changer
Shell/Insert Adapter (Face Changer) to adjust inclination or/and offset

Secure fixation of Face Changer
to Shell by a conical coupling, antirotation tabs and a fixation screw (except the neutral Face Changer)

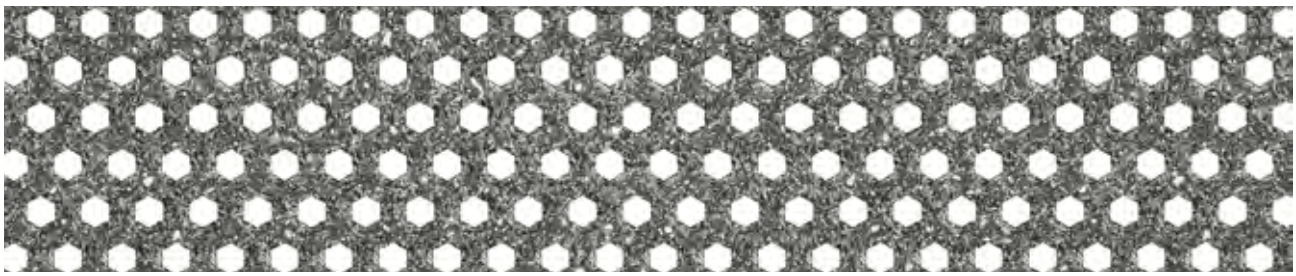
Great versatility, reduced inventory
due to size grouping of inserts and introduction of Face Changers, great versatility with limited amount of polyethylene inserts

Intraoperative flexibility
One instrument platform for primary and revision surgery

Streamlined surgical experience
through simple, ergonomic instruments and color coding

TrabecuLink
3-dimensional structure for biologic fixation

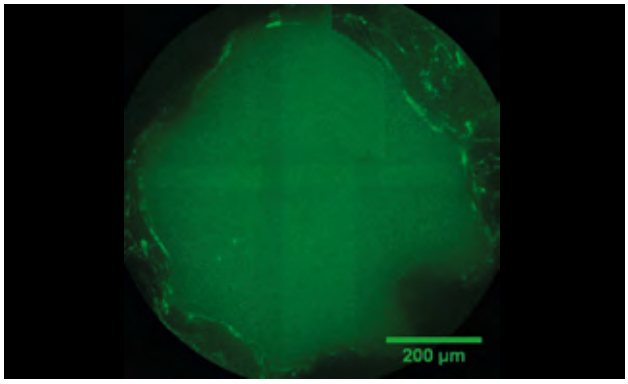
- Porosity of 70%, pore size of 610-820 µm and structure depth of 1mm designed for ensures excellent cell ongrowth.[12,13,14]

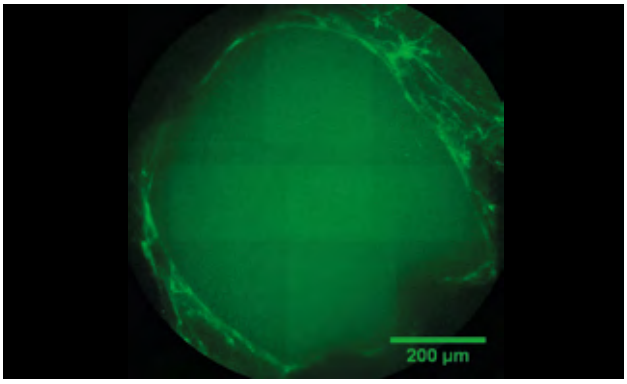


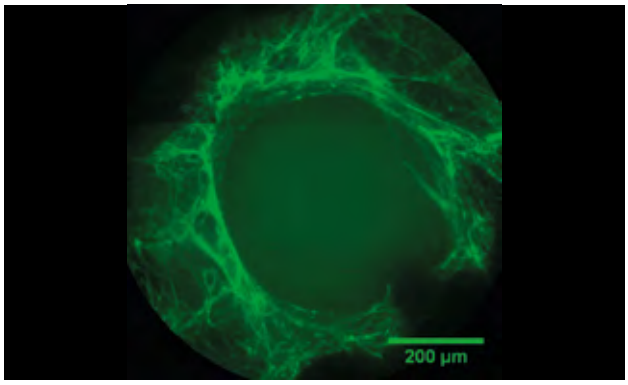
TrabecuLink pore filling

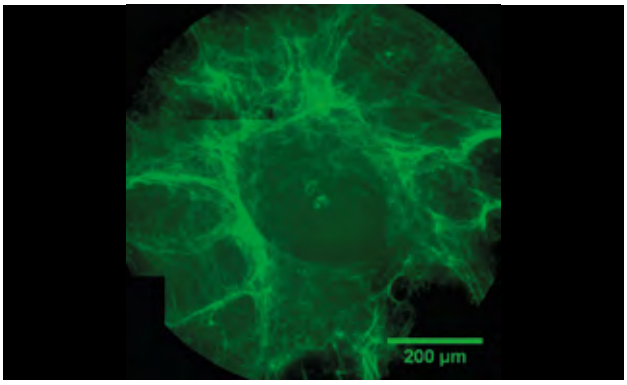
The sequence of images shows a pore of the TrabecuLink structure being filled with tissue under in-vitro cell culture conditions. The fibronectin laid down by human fibroblasts and continually reorganized over a period of eight days is visible as green fibers.

Fibronectin is a component of the extracellular matrix that is formed at an early stage of the healing process. It forms a basis for the embedding of collagen, which is essential for mineralization of the tissue and ingrowth of bone into the structure. Apart from the accumulation of fibronectin, which increases over time, a clear contraction of the matrix towards the center of the pore can be observed. This contraction mechanism, which is attributable to the cellular forces acting in the tissue, accelerates the rate at which the pore is filled with tissue, compared to a layer-by-layer tissue growth.





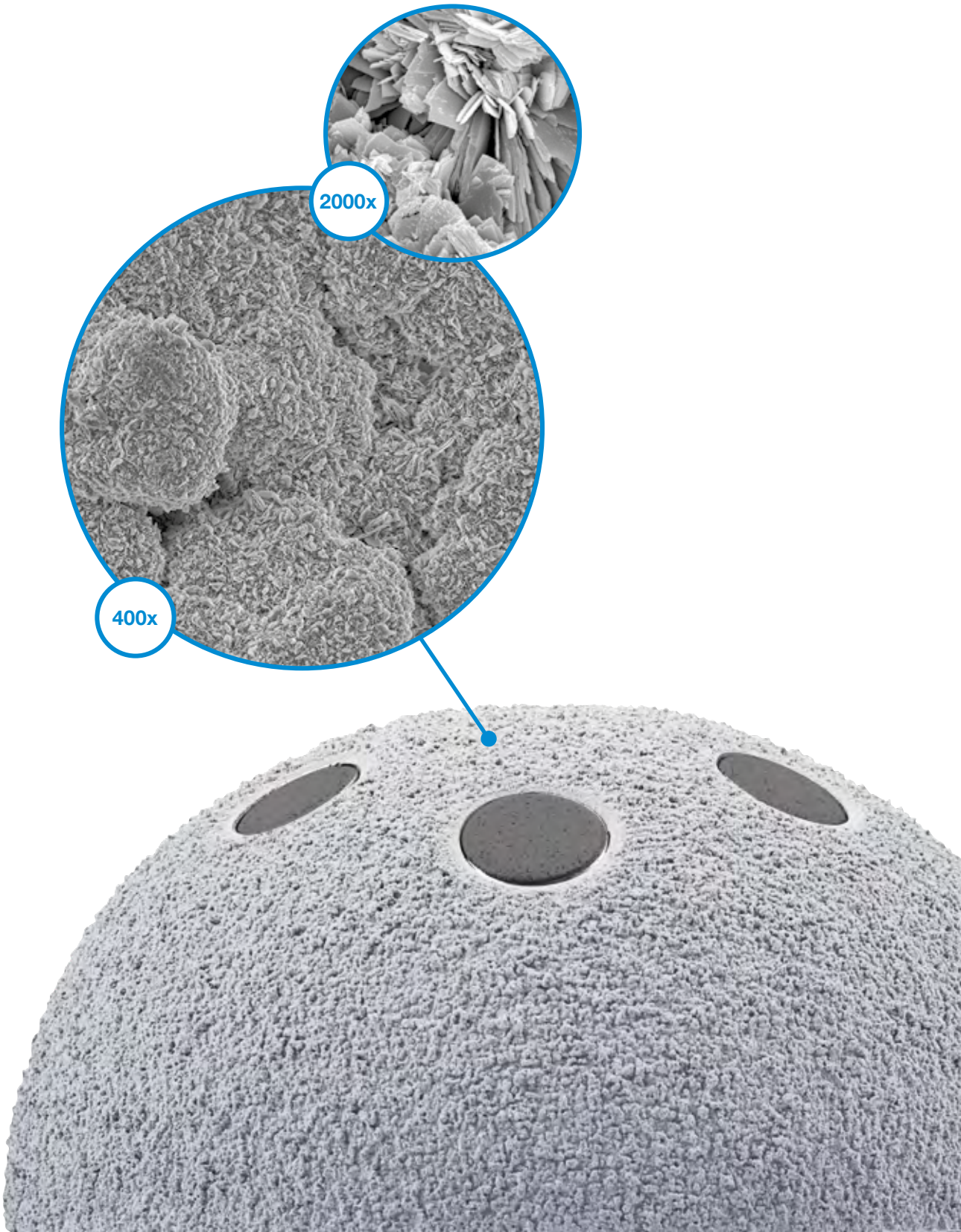




(Reference: Joly P et al., PLOS One 2013; https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0073545). Julius Wolff Institute, Charité - Universitätsmedizin Berlin

TiCaP Double Coating:
Titanium (Ti)/Calcium Phosphate (CaP)

The TiCaP coating is applied by first vacuum plasma spraying a highly dense adhesive layer of titanium, approximately 450 µm thick, onto the surface of the implant. In a second step, on top of this roughened surface, an approx. 15 µm thick HX layer of mechanically stable calcium phosphate is deposited in an electrochemical process.



The excellent suitability of UHMWPE as a bearing material for joint replacement is accepted since the 60s.[5,6,7]

The following features characterize UHMWPE:
- Biocompatibility
- High wear resistance
- Impact resistance
- Fatigue and crack resistance

With these characteristics the national and international standards for implant materials are fulfilled.[6,7]

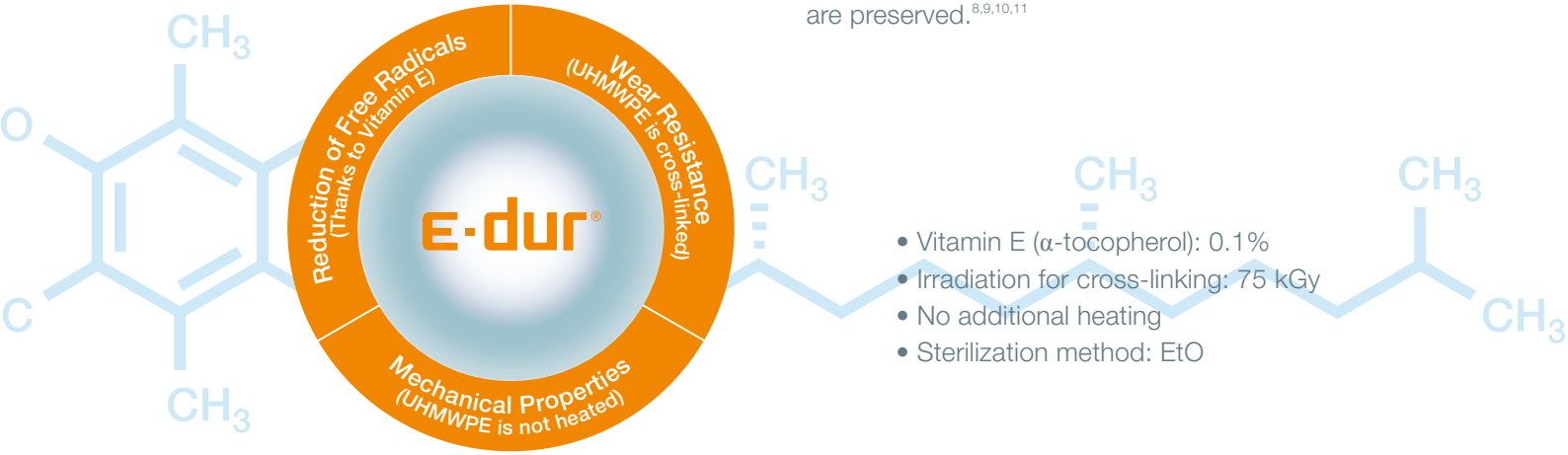
UHMWPE was developed to be the "Gold Standard" for articulating surfaces in endoprostheses reconstructions.

The "Gold Standard" has since taken additional steps to further improve mechanical properties and longevity of the material. By cross-linking the material, the wear resistance improved substantially. The enrichment with Vitamin E protects against oxidation.[15]

For the E-dur® Vit-E Inserts the Vitamin E is used as an antioxidant to neutralize the free radicals during the process of the cross-linking.[8,9,10,11]

Due to the cross-linking process the wear resistance of the UHMWPE material is improved. The enrichment of Vitamin E counteracts the aging process.[15]

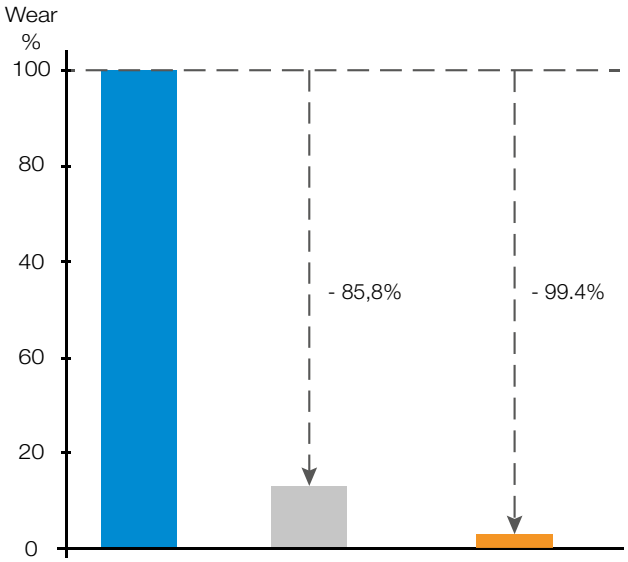
The mechanical properties and the biocompatibility are preserved.[8,9,10,11]



- Vitamin E (α-tocopherol): 0.1%
- Irradiation for cross-linking: 75 kGy
- No additional heating
- Sterilization method: EtO

Wear Resistance[15]

in vitro wear comparisons of UHMWPE materials reported in literature



Method

Hip Simulator, 5 million cycles, Ø 36 Aluminia.

Type of PE

- Standard UHMWPE, γ-ster 30kGy, aged
- Highly Crosslinked UHMWPE, γ-irr 75kGy, remelt, Eto-ster, aged
- Highly Crosslinked UHMWPE + Vit-E, blended 0.1% Vit-E, β-irr 80 kGy, Eto-ster, aged

Literature

1 Stroh, D. Alex, et al. „Dual-mobility bearings: a review of the literature.“ Expert review of medical devices 9.1 (2012): 23-31.

2 Long, M., & Rack, H. (1998). Titanium alloys in total joint replacement—a materials science perspective. Biomaterials, 19(18), 1621-1639

3 Loving L, Herrera L, Banerjee S, Heffernan C, Nevelos J, Markel DC, Mont MA. 2015. Dual mobility beari ngs withstand loading from steeper cup-inclinations without substantial wear. J Orthop Res. 33(3):398-404.

4 Fabry C, Kaehler M, Hermann S, Woernle C, Bader R. 2014. Dynamic behavior of tripolar hip endoprostheses under physiological conditions and their effect on stability. Medical Engineering & Physics 36:65– 71.

5 S. M. Kurtz, „The Origins and Adaptations of UHMWPE for Knee replacement“, in UHMWPE Biomaterials Handbook, S. M. Kurtz, Ed., Burlington, MA Academic Press 2009.

6 S. M. Kurtz, „Advances in th the processing, sterilization, and crosslinking of ultra-high molecular weight polyethylene for total joint arthroplasty“, Biomaterials 1999; 20:1659-1687.

7 E. M. Brach del Prever, „UHMWPE for arthroplasty: past ot future?“, J Orthopaed Traumatol 2009;10:1-8.

8 E. Oral, „Characterization of irradiated blends of α-tocopherol and UHMWPE“, Biomaterials 2005; 26(33):6657-6663.

9 E. Oral, „Highly Crosslinked UHMWPE Doped with Vitamin E“, in UHMWPE Biomaterials Handbook, ´S. M. Kurtz, Ed., Burlington, MA Academic Press 2009.

10 S. M. Kurtz, „Vitamin-E-Blended UHMWPE Biomaterials“, in UHMWPE Biomaterials Handbook, S. M. Kurtz, Ed., Burlington, MA Academic Press 2009.

11 S. M. Kurtz, „Trace concentration of vitamin E protect radiation crosslinked UHMWPE from oxidative degradation“, J Biomed Mater Res A 2008; 549-563.

12. Cecile M. Bidan, Krishna P. Kommareddy, Monika Rumpler, Philip Kollmannsberger, Yves J.M. Brechet, Peter Fratzl, John W.C. Dunlop et al. (2012) How Linear Tension Converts to Curvature: Geometric Control of Bone Tissue Growth. PLoS ONE 7(5): e36336

13. Pascal Joly, Georg N. Duda, Martin Schöne, Petra B. Welzel, Uwe Freudenberg, Carsten Werner, Ansgar Petersen et al. (2013) Geometry-Driven Cell Organization Determines Tissue Growths in Scaffold Pores: Consequences for Fibronectin Organization. PLoS ONE 8(9): e73545. https://doi.org/10.1371/journal.pone.0073545

14. Steinemann SG: Compatibility of Titanium in Soft and Hard Tissue – The Ultimate is Osseointegration; Materials for Medical Engineering, WILEY-VCH, Volume 2, Page 199-203

15. Gigante, Antonio, et al. “Effectiveness of Vitamin-E-Doped Polyethylene in Joint Replacement: A Literature Review.” PubMed Central (PMC), 8 Sept. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4598683

16. Ullmark, Gösta, Jens Sörensen, and Olle Nilsson. “Analysis of bone formation on porous and calcium phosphate-coated acetabular cups: a randomised clinical [18F] fluoride PET study.” Hip International 22.2 (2012)

Waldemar Link GmbH & Co. KG, Hamburg

Waldemar Link GmbH & Co. KG

Barkhausenweg 10 · 22339 Hamburg · Germany
Phone +49 40 53995-0 · info@link-ortho.de
www.link-ortho.com