



Orthopedic implant materials of DSM Biomedical BV

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Belfast 9/9/2010

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DSM Biomedical Products



Biomedical materials	Coatings	Drug delivery
<ul style="list-style-type: none"> • Bionate® Thermoplastic Polycarbonate Urethane • Bionate® II Thermoplastic polycarbonate-Urethane • BioSpan® Segmented Polyurethane • CarboSil® Thermoplastic Silicone Polycarbonate Urethane • Dyneema Purity® High-performance fiber technology • Elasthan™ Thermoplastic Polyether Urethane • PurSil® Thermoplastic Silicone Polyether Urethane • Ultra High Molecular Weight PolyEthylene (UHMWPE) 	<ul style="list-style-type: none"> • ComfortCoat® Hydrophilic coating • ComfortCoat® Silverbased Antimicrobial coating • ComfortCoat® Hemocompatible Antimicrobial coating • VitroStealth® non-fouling coating 	<ul style="list-style-type: none"> • Trancerta™ Drug Delivery platform • Trancerta™ Amino acid based drug delivery systems • Trancerta™ Polythioester based drug delivery systems • Trancerta™ Novel polyesterurethane based drug delivery systems

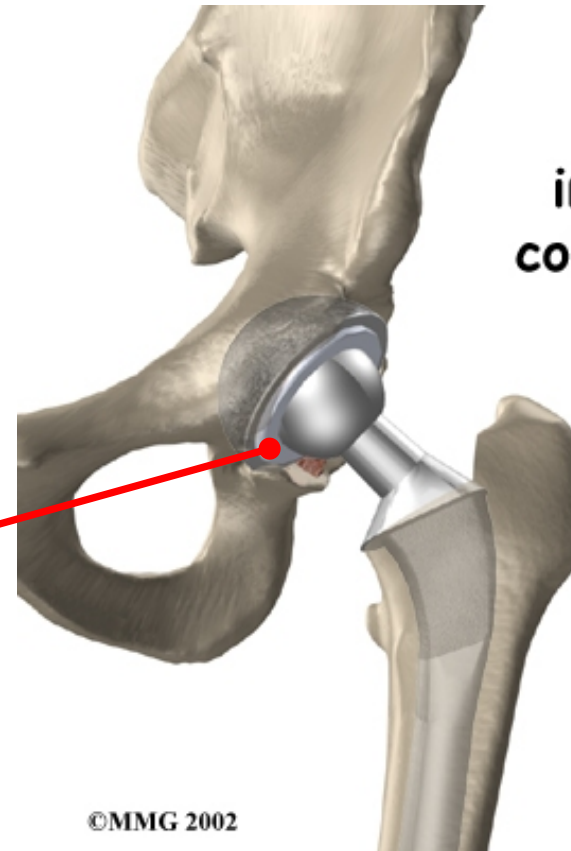


Ultra High Molecular weight PolyEthylene UHMwPE

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Total Hip Replacement



Hip
implant
completed

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Production Scheme UHMwPE



Polymer powder production

Sintering of UHMwPE powder into plates and rods

Gamma radiation with 75kGy creating crosslinks and free radicals

Annealing or remelting to remove “free radicals”

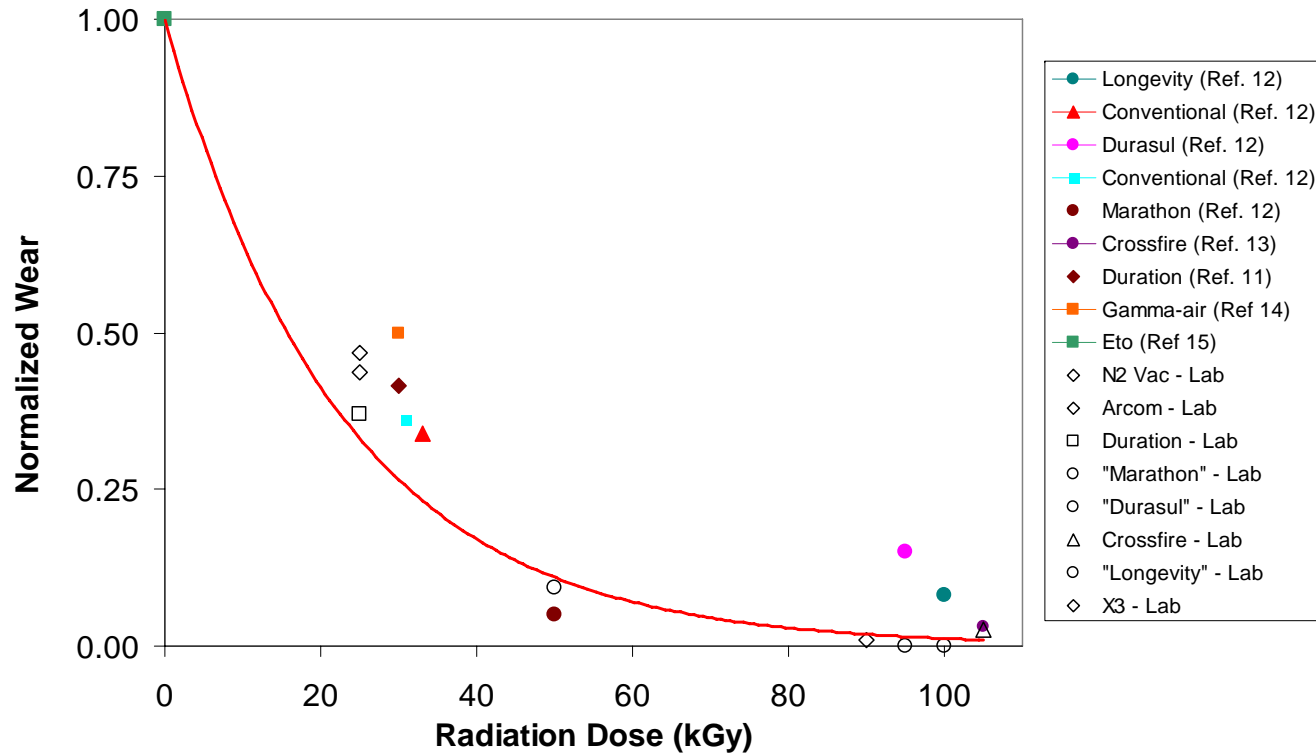
Machining of cups etc

Significant reduction in wear rate



Both **in-vitro** as well as **in-vivo** wear
reduced as function of the Radiation Dose

Laboratory and clinical results



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Edge-Loading Wear of Metal-on-Metal and Metal-on-X3® Highly Crosslinked Polyethylene: Survival of the Fittest
Aiguo Wang, Ph.D., VP, Reconstructive Technologies, Stryker Orthopaedics, Mahwah, New Jersey, USA.

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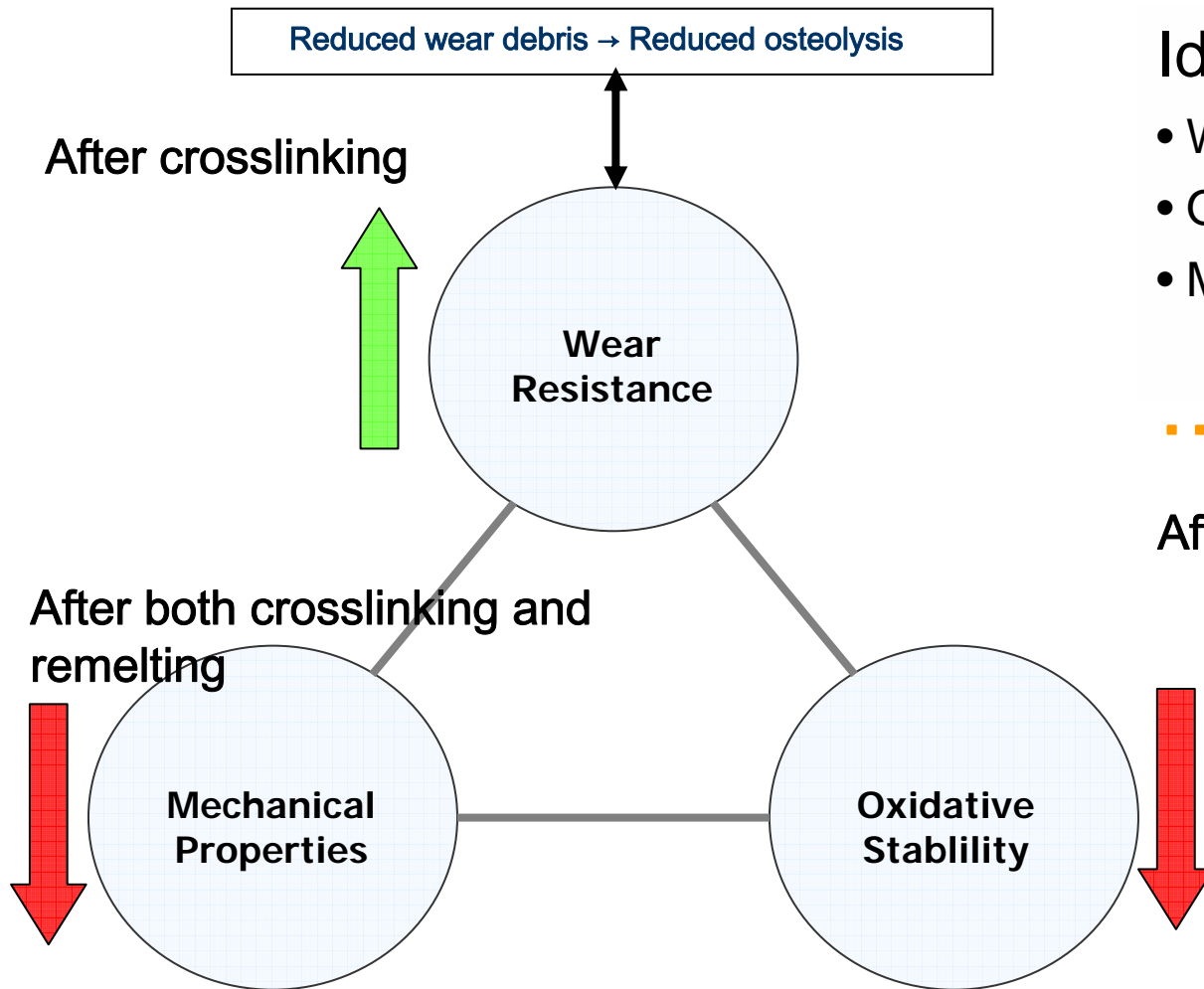
Radicals form new challenge



Macro-radicals are created during irradiation

Macro-radicals react with oxygen - causing oxidative degradation of the bearing material

UHMwPE Paradigm



Ideally

- Wear resistance ↑
- Oxidation resistance ↑
- Mechanical properties ↑

... but in reality

After crosslinking

Goal: Develop a grade that offers combined improvements and beneficial processing possibilities

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Solutions



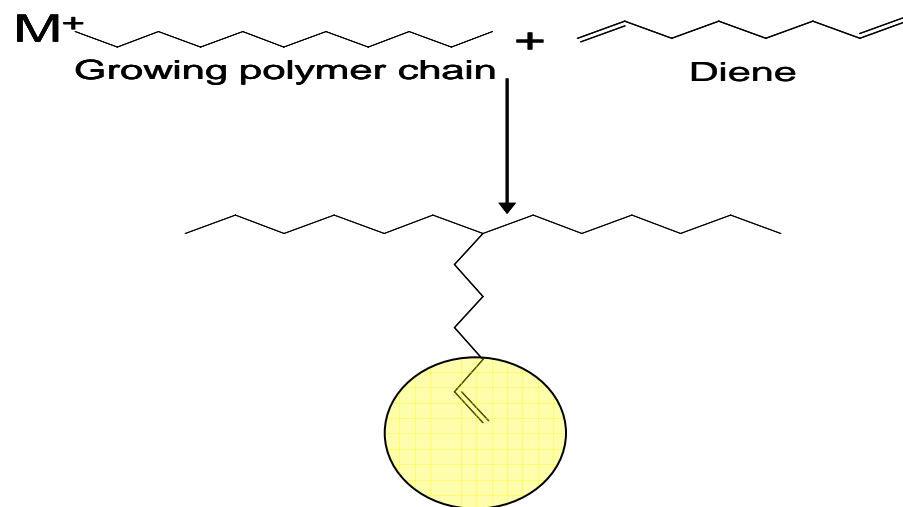
- 1. Use of lower radiation doses → less free radicals**

- 2. Absorb free radicals through a stabilizer (HALS)**

1 Use of lower radiation doses



- By adding diene chemistry more “double” bond end groups are created
- Double bonds require less activation energy to crosslink

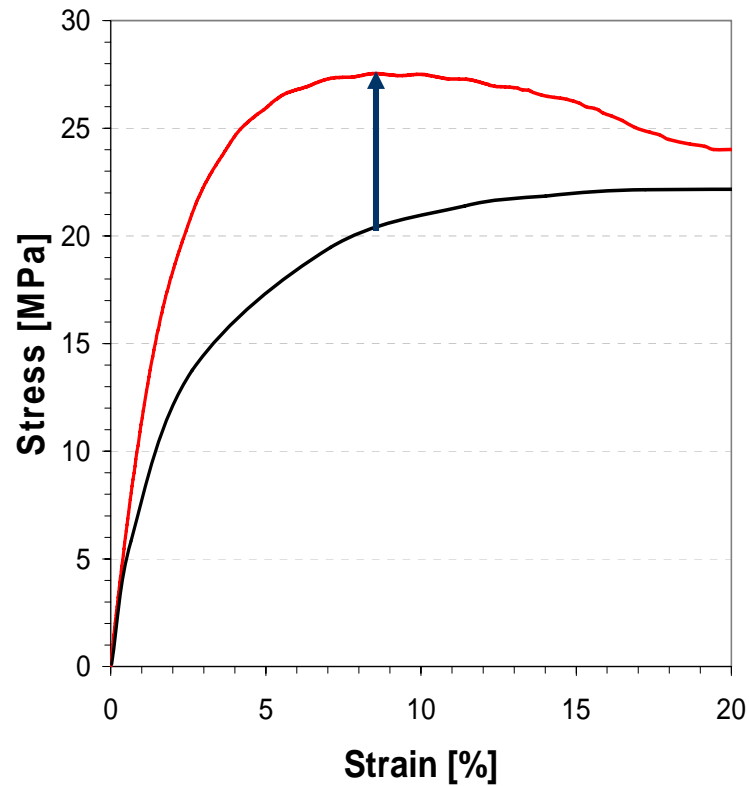


Results Easy –XL™



test	Xylene Swelling @ 130 °C g/mol	Wear factor	Oxygen levels at 1 mm from surface (6 wks in 70 C air	Free radical conc.
Material				
Standard 75KGy	4000	0.9	0.4	2-3
Standard 25KGy Sterilization load	6200	2.5	0,1	1
Easy-XL™ 25 kGy	3800	0,7	0.1	1

Better Mechanical Properties



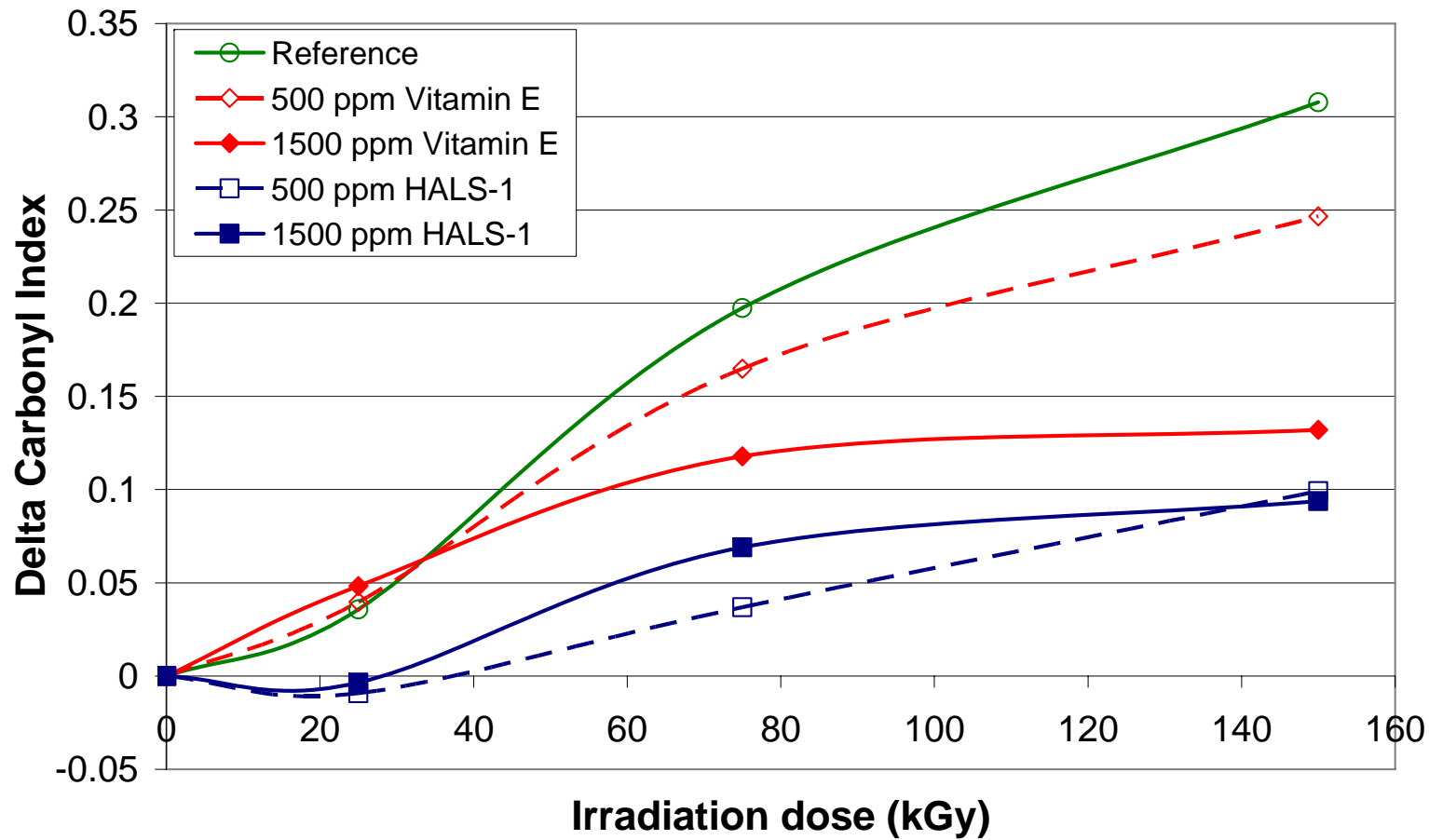
Easy-XL™ is a stronger material:
- a.o. 30% higher Yield Stress

2 . Absorb free radicals through a stabilizer

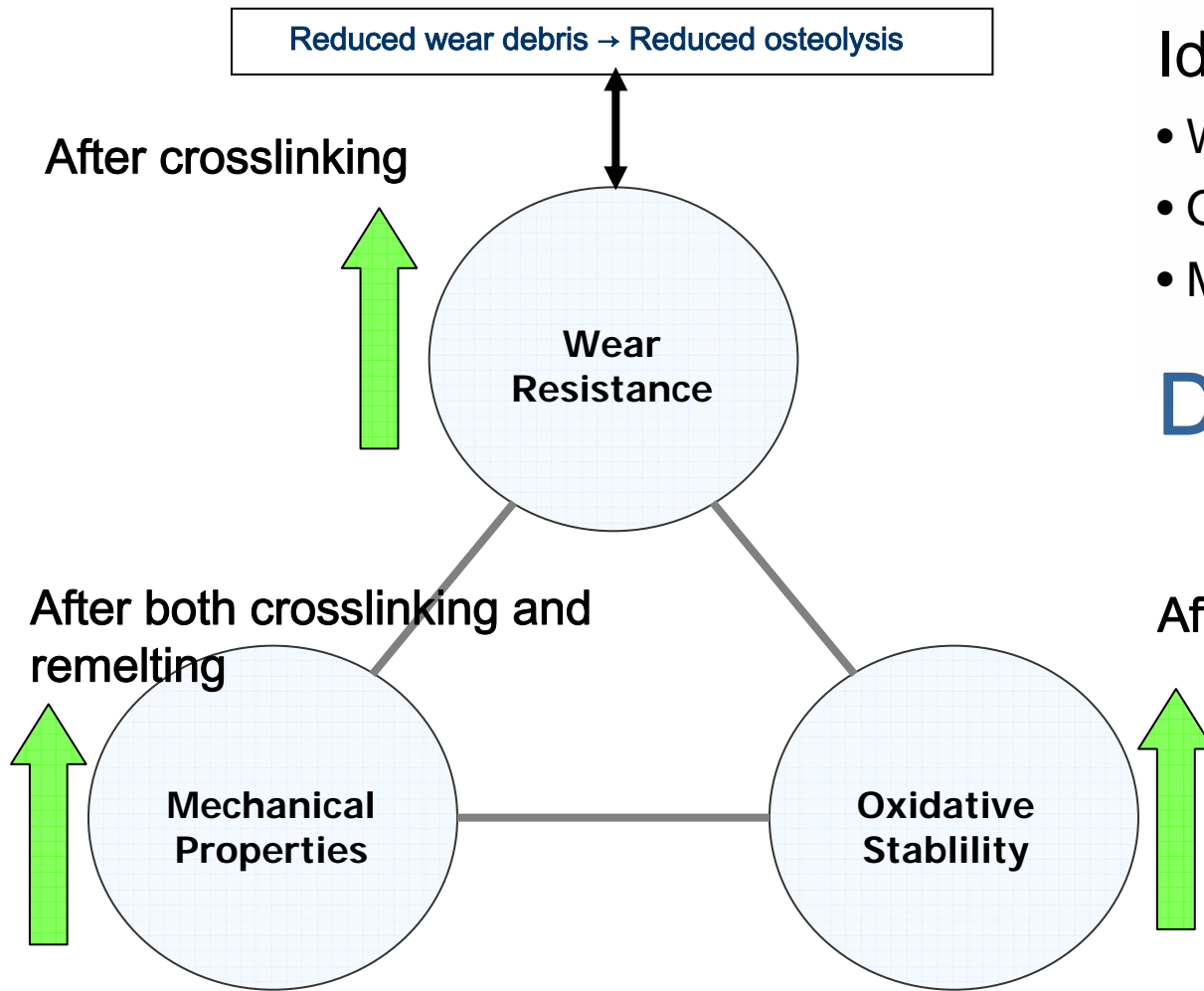


- **Currently Vitamin E is used as a stabilizer**
 - **Vitamin E is consumed in the radiation process**
 - **Alternative: Hindered Amine Light Stabilizers (HALS)**
 - **Concentration remains constant during radiation**
- More effective stabilizer**

Absorb free radicals through a stabilizer (HALS)



Conclusion



Ideally

- Wear resistance ↑
- Oxidation resistance ↑
- Mechanical properties ↑

DSM results:



Innovation in Thermoplastic Urethanes

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DSM Biomedical Polyurethane Family



Bionate[®] thermoplastic polycarbonate-urethane (PCU)

CarboSil[®] thermoplastic silicone-polycarbonate-urethane (TSPCU)

BioSpan[®] segmented polyurethane (SPU)

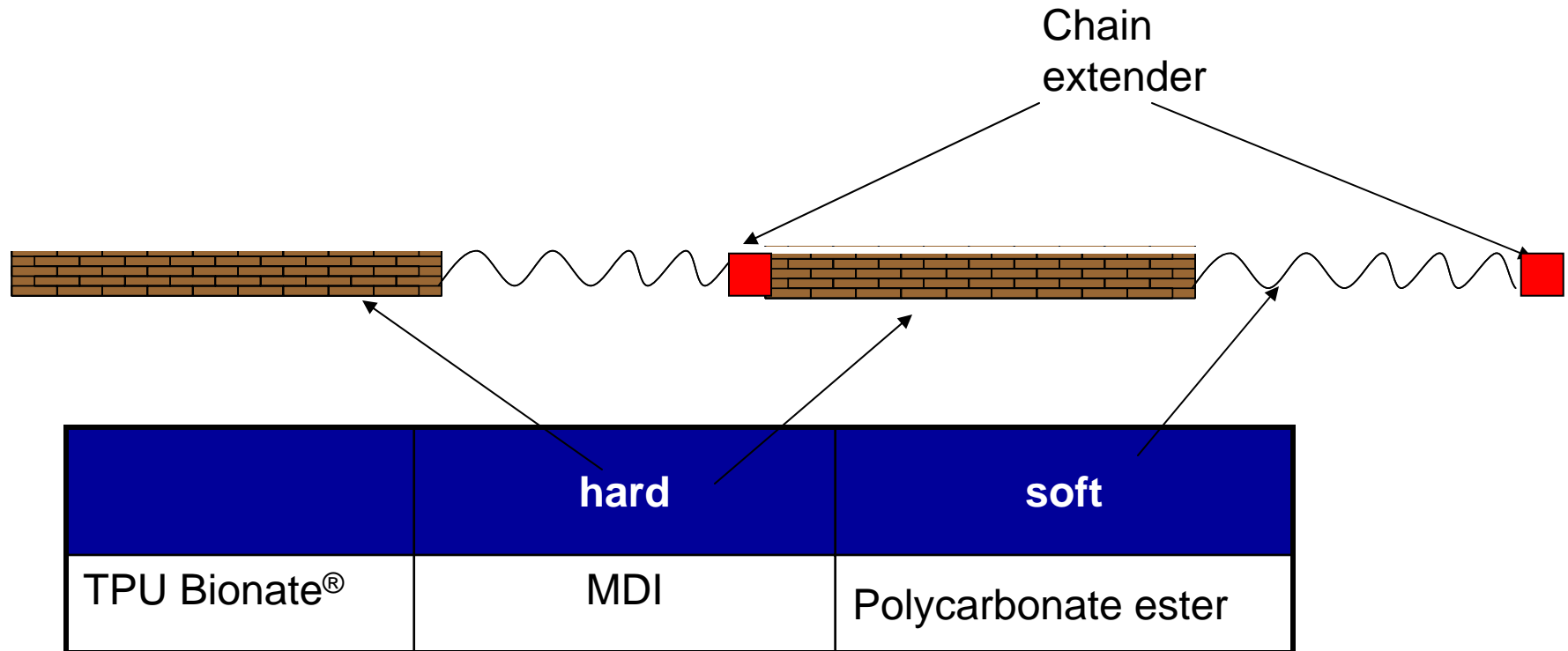


All polymer families have extensive FDA Master Files

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Thermoplastic elastomers DSM Biomedical

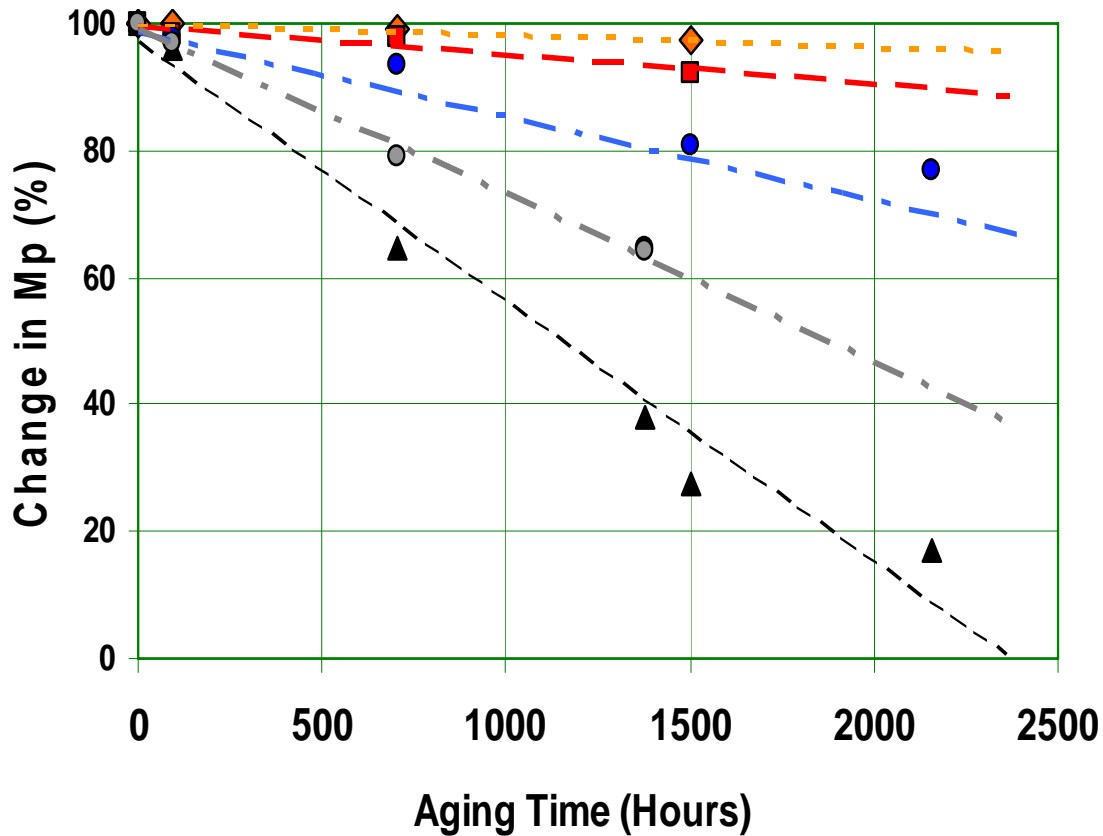


Biostability polyurethanes



- **Soft block chemistry determines biostability against free radicals**
- **Typical simulation testing is performed in 20% hydrogen peroxide at 37 °C catalyzed by CoCr**

Results Biostability Testing



- ◆ Bionate® II PCU 55D
- Bionate® PCU 55D UR
- Elasthane™ TPU 55D MR
- ▲ Elasthane™ TPU 80A
- Elasthane™ TPU 80A with SAME®

Portfolio



Material	Tensile Modulus ISO-527 1B/A MPa	Bionate® PCU	Bionate® II PCU
80A Bionate® PCU	19	x	x
90A Bionate® PCU	42	x	x
55D Bionate® PCU	100	x	x
65D Bionate® PCU	1460	x	-
75D Bionate® PCU	2016	x	-

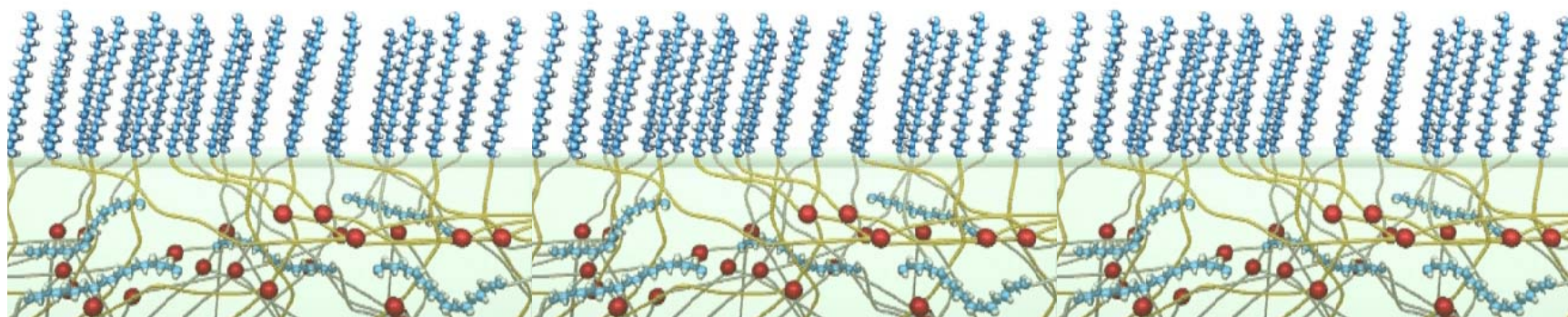
Bionate® II PCU is surface modified Bionate® PCU
advantages: easier processing + improved biostability

DSM Surface Modification Technology Applications



Integrated surface characteristics

- Passive thrombo-resistance
- Enhanced biostability
- Improved abrasion resistance
- Reduced self adhesion of device surfaces
- Enhanced lubricity
- Antimicrobial activity
- Covalently-bound, non-leaching processing aids




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Application example Dynesys



- 15 years application history
- No change in material composition observed on explants
- Pass ISO 10993 testing
- Material Bionate® PCU 55D

Test	Universal Spacer 
Extractables ISO 10993-5, USP 24	PASS: Non-toxic
Cytotoxicity ISO 10993-5, USP 24	PASS: Non-toxic
Acute Systemic Toxicity ISO 10993-11/12, USP 24/26	PASS: Non-toxic
Irritation ISO 10993-10/12, USP 24/26	PASS: Non-irritant
Mutagenicity ISO 10993-3/12	PASS: Non-mutagenic
Genotoxicity ISO 10993-3/12	PASS: Non-mutagenic
Sensitization ISO 10993-10/12, ASTM F720-81	PASS: Non-sensitizing
Pyrogenicity ISO 10993-11/12, USP 25	PASS: Non-pyrogenic
Subcutaneous Implantation (12 wks) ISO 10993-6/12	PASS: Non-irritant



Dynesys® Dynamic Stabilization Device

Courtesy Zimmer

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Application: Freedom total disc replacement



- Damping element for lumbar spine
- CE approved
- Material: CarboSil® TSPCU



AxioMed Freedom® Lumbar Disc

Application : cup for total hip arthroplasty



- Wear resistance similar to X-linked UHMwPE
- Improved wetting of surface with synovial fluid creating elasto-hydrodynamic lubrication
- Better distribution of stresses
- CE approval in Europe
- Material: Bionate[®] PCU 80A



Active Implants Hip Cup

Material	Contact angle degrees
UHMwPE	104
Bionate [®] PCU 80A	78.5

www.dsmbiomedical.com