Can the world’s strongest medical grade fiber help you to design your next device?

Cláudia Vaz
Who is DSM?
DSM Company profile

- Active worldwide in performance materials & life sciences
- Among global leader in approximately 75% of businesses
- History of 100+ years. Highly ranked in Dow Jones Sustainability Index
- Focus on growth by means of innovation

**DSM key data**

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>~ Euro 8800 mln</td>
</tr>
<tr>
<td>EBIT</td>
<td>~ Euro 825 mln</td>
</tr>
<tr>
<td>Workforce</td>
<td>~ 24000 (9% R&amp;D)</td>
</tr>
<tr>
<td>Material research</td>
<td>&gt; 300 people</td>
</tr>
</tbody>
</table>
Examples of business areas

Food

Pharmaceutics

Anti-infectives

Biomedical materials

Electronics

Constructions

Automotive
DSM biomedical material portfolio

With the acquisition of Polymer Technology Group (PTG), DSM can present a broad portfolio of biomaterials

- DSM UHMWPE Fiber Dyneema Purity®
- DSM UHMWPE Homopolymer MG003
- DSM Hydrophilic coatings
- DSM Antimicrobial coatings
- DSM Microspheres for local drug delivery

- DSM-PTG BioSpan® segmented polyurethane
- DSM-PTG Elasthane™ polyether urethane
- DSM-PTG Bionate® polycarbonate urethane
- DSM-PTG CarboSil® silicone-polycarbonate urethane
- DSM-PTG PurSil® silicone polyether-urethane
- DSM-PTG Tailor-made polymers
What is Dyneema® and Dyneema Purity®?
Dyneema Purity® on market since 2004

CASE: Rotator cuff repair

Strong, thin and pliable sutures play an important role in Rotator Cuff repair¹:

- Minimizes suture breakage during tightening
- Reduces need for additional procedures
- Reduces patient discomfort

Switch to Dyneema Purity®

High strength sutures made with Dyneema Purity® have become the new ‘golden’ standard within 4 years.

Dyneema Purity® on market since 2004

CASE: ACL repair

Fixation of ligament replacement in knee
- Endoscopic, minimally invasive procedure
- Reduces patient discomfort and costs
- Strength and compliance essential

Switch to Dyneema Purity®

Various constructions of Dyneema Purity® are used today to secure the soft tissue transplant, providing strength and stiffness.
The basics

- Dyneema Purity® is a fiber made from Ultra High Molecular Weight Polyethylene (UHMWPE), with a very high purity, dedicated for medical applications.

  Normal Polyethylene, low orientation, low molecular weight, crystalinity < 60%

  Dyneema Purity®, very high molecular orientation and weighth, crystalinity approximately 95%
How is Dyneema Purity® produced?

- Proprietary product and production process developed by DSM Dyneema to obtain highest level of purity dedicated for medical applications
- Production of Dyneema Purity® is ISO13485:2003 compliant
DSM Dyneema in a nutshell…

• Large, global material supplier.
• Global leadership position in UHMWPE fiber technology.
• Producing the strongest medical grade fiber in the world (ISO13485).
• Committed to develop new and innovative Dyneema Purity® grades.

• Providing to medical device companies:
  • Multiple Dyneema Purity® grades in various sizes.
  • Knowhow on fiber properties. Dyneema Purity® FDA Masterfile.
  • Experience with development of fiber constructions.
  • Laboratory and technical assets for prototyping and testing.
What are the mechanical properties?
Dyneema Purity® typical properties

- Extremely strong
- Soft as silk
- High pliability
- Hydrophobic
- Low melting point (~150°C)
- High fatigue resistance
- High chemical resistance
- High abrasion resistance
- Low density
- Creeps under constant load
- Cut and tear resistance
- Low coefficient of friction
- Electrical insulator
- Biocompatible; low irritation rate
- Low elongation
- Low elongation
Benchmarking Dyneema Purity® strength

At similar weight, Dyneema Purity® is about 15x stronger than steel.

At similar volume, Dyneema Purity® is about 4x stronger than titanium.

At similar volume, Dyneema Purity® is about 3x stronger than polyester.
## Typical mechanical properties

### Dyneema Purity® SGX grades

<table>
<thead>
<tr>
<th>SGX Grades</th>
<th>Filament Nr</th>
<th>Density [dtex]</th>
<th>Size [µm]</th>
<th>Load at break</th>
<th>Tenacity at break</th>
<th>E-modulus</th>
<th>Elongation at break</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 dtex</td>
<td>25</td>
<td>2.2</td>
<td>17</td>
<td>18 N</td>
<td>33 cN/dtex</td>
<td>1100 cN/dtex, 107 GPa</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4 pounds</td>
<td>3.2 GPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>110 dtex</td>
<td>50</td>
<td>2.2</td>
<td>17</td>
<td>36 N</td>
<td>33 cN/dtex</td>
<td>1000 cN/dtex, 97 GPa</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8 pounds</td>
<td>3.2 GPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>165 dtex</td>
<td>65</td>
<td>2.5</td>
<td>20</td>
<td>50 N</td>
<td>31 cN/dtex</td>
<td>1000 cN/dtex, 97 GPa</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 pounds</td>
<td>3.0 GPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>220 dtex</td>
<td>100</td>
<td>2.2</td>
<td>17</td>
<td>66 N</td>
<td>30 cN/dtex</td>
<td>1000 cN/dtex, 97 GPa</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15 pounds</td>
<td>2.9 GPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>440 dtex</td>
<td>200</td>
<td>2.2</td>
<td>17</td>
<td>140 N</td>
<td>32 cN/dtex</td>
<td>1000 cN/dtex, 97 GPa</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30 pounds</td>
<td>3.1 GPa</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Typical mechanical properties

### Dyneema Purity® UG and TG grades

<table>
<thead>
<tr>
<th>UG Grades</th>
<th>Filament</th>
<th>Load at break</th>
<th>Tenacity at break</th>
<th>E-modulus</th>
<th>Elongation at break</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nr</td>
<td>Density [dtex]</td>
<td>Size [μm]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>110 dtex</td>
<td>200</td>
<td>0.55</td>
<td>9</td>
<td>45 N</td>
<td>1300 cN/dtex</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10 pounds</td>
<td>126 GPa</td>
</tr>
<tr>
<td>165 dtex</td>
<td>300</td>
<td>0.55</td>
<td>9</td>
<td>66 N</td>
<td>1300 cN/dtex</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15 pounds</td>
<td>126 GPa</td>
</tr>
<tr>
<td>440 dtex</td>
<td>800</td>
<td>0.55</td>
<td>9</td>
<td>172 N</td>
<td>1300 cN/dtex</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>39 pounds</td>
<td>126 GPa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TG Grade (provisional)</th>
<th>Filament</th>
<th>Load at break</th>
<th>Tenacity at break</th>
<th>E-modulus</th>
<th>Elongation at break</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nr</td>
<td>Density [dtex]</td>
<td>Size [μm]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 dtex</td>
<td>25</td>
<td>1</td>
<td>12</td>
<td>10 N</td>
<td>1250 cN/dtex</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 pounds</td>
<td>120 GPa</td>
</tr>
</tbody>
</table>

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Benchmarking Dyneema Purity® size

Profile reduction at same strength

Two constructions with **similar strength**, 23x magnification (SEM micrograph)

- **USP#2 suture made with Dyneema Purity®**
- **USP#5 Ethibond Excel™ polyester suture**
Fatigue resistance

Conclusion

Dyneema® fibers will not easily break or lose their strength when subjected to cyclic or fluctuating loads.
The number of cycles obtained in abrasion testing is very dependent on the set-up of the test. Results presented above show an example that Dyneema® fiber outperforms other synthetic fibers. If abrasion is relevant in an application design, it is recommended to perform test per application to determine the absolute cycles to failure in the specific case.
Conformity

- Polyethylene cables conform to bone surfaces. Metal cables have a narrow contact surface and hence show high focal loads. Focal loads can cause cables to cut through bone\(^2\).

- Polyethylene cables flatten when placed under tension. This property may make the use more desirable for soft, osteoporotic or cartilaginous bone (i.e. in elderly or young children)\(^2\).

\(^2\) From SPINE, Volume 22, Nr. 6, pp. 596-604, 1997:
Coefficient of friction - ASTM D3108 yarn on metal

Yarn to Solid Material, load 22.2 mN/tex

- Low coefficient of friction contributes to ‘soft touch’ feeling.
- Because of its low coefficient of friction, products made with Dyneema Purity® fibers slide more easily through tissue.

Data filed at DSM

<table>
<thead>
<tr>
<th>Material</th>
<th>Dry Coefficient of Friction</th>
<th>Wet Coefficient of Friction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyneema Purity® SGX</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Aramid</td>
<td>0.30</td>
<td>0.25</td>
</tr>
<tr>
<td>Polyester</td>
<td>0.25</td>
<td>0.20</td>
</tr>
<tr>
<td>Polyamide</td>
<td>0.20</td>
<td>0.15</td>
</tr>
<tr>
<td>PTFE</td>
<td>0.10</td>
<td>0.05</td>
</tr>
</tbody>
</table>
Stopping power

- Dyneema Purity® has a very low elongation:
  - Elongation at break typically is around 3-4% whereas elongation of PET typically is around 15-20%.
  - Dyneema Purity® is used in medical applications for its stopping power needed to prevent dimensions or structures go beyond a pre-specified range.
  - Modulus of Dyneema Purity® is 130N/tex or 126GPa
What about the chemical and biological properties?
## ISO10993 Biocompatibility testing

<table>
<thead>
<tr>
<th>Property</th>
<th>Unit Typical Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity</td>
<td>Non-cytotoxic (L929 cells response after extraction @ 37 ºC/24 hrs)</td>
</tr>
<tr>
<td>ISO 10993 - 5</td>
<td></td>
</tr>
<tr>
<td>Sensitization</td>
<td>No sensitizing properties for polar and non-polar extracts (Guinea pig maximization test)</td>
</tr>
<tr>
<td>ISO 10993 - 10</td>
<td></td>
</tr>
<tr>
<td>Irritation</td>
<td>Non-irritant/corrosive properties for polar and non-polar extracts (intradermal application in NZW rabbits)</td>
</tr>
<tr>
<td>ISO 10993 - 10</td>
<td></td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>Non-mutagenic in the bacterial reverse mutation assay (Ames assay using <em>Salmonella Typhimunium</em>)</td>
</tr>
<tr>
<td>ISO 10993 – 3</td>
<td></td>
</tr>
<tr>
<td>Hemocompatibility</td>
<td>Non-hemolytic by contact with human blood red cells Slightly higher hemostasis activation (clotting time and TAT complex formation) when compared w negative control (similar in terms of kinetic and intensity to polyester)</td>
</tr>
<tr>
<td>ISO 10993 - 4</td>
<td></td>
</tr>
<tr>
<td>Implantation</td>
<td>No adverse effects. See slides</td>
</tr>
<tr>
<td>ISO 10993 - 6</td>
<td></td>
</tr>
</tbody>
</table>

ISO 10993 tests have been executed by various specialized, independent third party institutes. Reports available at DSM.
### ISO10993 Biocompatibility testing

<table>
<thead>
<tr>
<th>Property</th>
<th>Unit Typical Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Carcinogenicity &amp; Reproductive/Developmental toxicity</strong> ISO 10993 – 3</td>
<td>No components can leach out that can cause carcinogenic response. UHMWPE is IARC classified under Group 3 (non classifiable as to carcinogenicity to human) Extended long term biological safety literature of UHMWPE as used for decades in various kinds of implants</td>
</tr>
<tr>
<td><strong>Systemic (acute) toxicity</strong> Sub-acute/sub-chronic toxicity Chronic toxicity ISO 10993 - 11</td>
<td>Extended long term biological safety literature of UHMWPE as used for decades in various kinds of implants</td>
</tr>
<tr>
<td><strong>Pyrogenicity USP30 NF25</strong></td>
<td>Non-pyrogenic (no substances were detected inducing a rise in temperature in rabbits after intravenous injection of material’s extract)</td>
</tr>
<tr>
<td><strong>Leaching test ISO 10993 - 12</strong></td>
<td>Concentration of leachables &lt; 150 µg/kg in both polar and non-polar extracts</td>
</tr>
</tbody>
</table>

ISO 10993 tests have been executed by various specialized, independent third party institutes. Reports available at DSM.
Implantation ISO 10993 - 6

**Materials**

<table>
<thead>
<tr>
<th>Material</th>
<th>Suture Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHMWPE fiber (Dyneema®)</td>
<td>Braid: USP#2 suture (16<em>1</em>110 dtex)</td>
</tr>
<tr>
<td>Polyester Fiber (Dacron®)</td>
<td>Braid: USP#2 suture (16<em>1</em>112 dtex)</td>
</tr>
</tbody>
</table>

**Animal model:** rattus norvegicus (304-372 g)

**Time:** 28 days

**Histology**

- Infiltrate / Inflammation
- Colonization
- Neo-vascularization
- Irritation Score

**Histomorphometry**

- Encapsulation

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Implantation test - results

$\text{GT} = \left[2 \times (\text{inflammation score} + \text{encapsulation score} + \text{necrosis score} + \text{fibroplasia score} + \text{fibrosis score} + \text{fatty infiltrate score})\right]$
Implantation test - conclusions

Conclusions for braids made with Dyneema Purity® SGX

- Milder presence giant cells and macrophages
- Less inflammatory reaction
- Less irritant (Irritation score* -9 compared to PET)
- Both implant materials present the same level of encapsulation (~23 μm capsule)
- Similar level of formation of fibro-connective tissue

* Irritation Score = GT (Dyneema Purity®) – GT (PET)
What can we conclude?
• Dyneema Purity® provides extreme strength and many additional features
• Dyneema Purity® brings new design options to medical device companies
• Many patients in the world have devices with Dyneema Purity® implanted

• Produced conform ISO13485 by DSM, a large and global company
• DSM offers extensive support program and prototyping facilities
Questions? Suggestions? Ideas?

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