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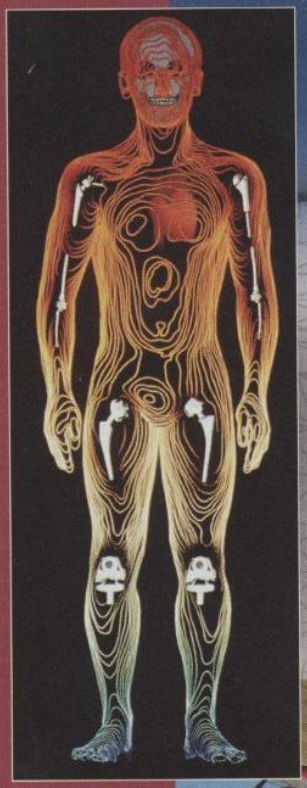
JANUARY 2007



TECHNICAL AND BUSINESS NEWS FOR THE MEDICAL DEVICE INDUSTRY

INCLUDES:

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- University Research
- Thermoplastic Urethane for Load Bearing Implants
- Business Briefs

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Thermoplastic Urethane for

A new thermoplastic polyurethane has excellent mechanical fatigue and load bearing properties while being bio-stable and biocompatible.

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After three years of research and development on a TPU for its lumbar spine artificial disc known as the eDisc (Fig.1), Theken Disc has developed a proprietary material for this high load, high fatigue application. The material is characterized by superior mechanical and biological properties when compared to similar commercially available materials. With a focus on improving material fatigue, biodurability, and compression-set resistance, TH200 outperforms commercially available TPU implant grade materials. The main reason for this has been the ability to tailor the chemistry to suit its performance requirements. In addition, superior quality of raw materials along with tight process controls has resulted in an improved and consistent material. Table 1 lists the important mechanical properties and Table 2 lists the important chemical properties.

Fig 1 — Theken eDisc in the vertebral space provides superior mechanical and biological properties.

Polyurethanes have a unique chemistry that can be tailored for properties ranging from soft elastomers to rigid plastics. Thermoplastic or melt-processible polyurethanes comprise the most important group of polyurethanes for implantable devices, and are made of poly-dispersed blocks of soft and hard segments. They consist of long-chain linear polymers without cross-links, which allows them to be melt-processed by extrusion and injection molding.

Macrodiol forms the soft segment and provides flexibility, while di-isocyanate linked with a chain extender forms the hard segment and provides high strength. Although the hard and soft segments mix to some degree, the two phases are generally separate, resulting in a structure that consists of hard-segment domains dispersed in a soft-segment matrix.

Biostability testing

In long-term implant load-bearing applications, it is important for the implant to not only have good properties initially, but also to retain them over the life of the implant. Hydrolysis and oxidation are the two main modes of TPU degradation. In-vitro tests, designed to simulate and accelerate in-vivo conditions for hydrolysis and oxidative degradation, have shown that TH200 functions significantly better than some commercial materials (Fig. 2 and 3).

Another important requirement is that little or no material leach out after they have been extracted in polar and nonpolar solvents. TH200 is made without additives, and thus its biological safety is increased because no catalysts, lubricants, or processing aids can ultimately leach. Tests per the ISO10993 guidelines in polar and nonpolar solvents have shown no leachates at the parts per million level (ppm).

Crack-growth resistance

The test method ASTM D-624 measures the tear strength of an elastomer in a static test.

Table 1 — Mechanical properties

Property	Test method	Value
Hardness (Shore A)	ASTM D-2240	82 typical
Compression Set	ASTM D395A	3% max.
Ultimate Tensile Strength, psi	ASTM D412	4000 – 5000 typical
Ultimate Tensile Strain, %	ASTM D412	350- 450 typical .
25% Modulus, psi	ASTM D412	350-500 typical
100% Modulus, psi	ASTM D412	800-1050 typical
Tear die C (lbf/in.)	ASTM D624	400-500 typical
Tear die T (lbf/in.)	ASTM D624	300-400 typical

Table 2 — Chemical properties

Properties	Test method	Value
Dilute solution viscosity, dl/g	ASTM D2857	0.95 to 1.05
Molecular weight, Mw, Daltons	ASTM D5259	130,000 to 170,000
Glass transition temperature, Tg	ASTM D4092	-20 to -30°C typical

Load-Bearing Implants

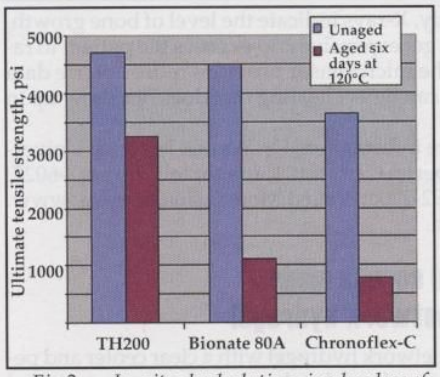

Fig 2 — In-vitro hydrolytic aging has less ef-

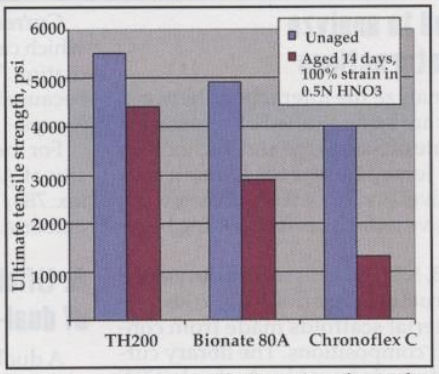

Fig 3 — In-vitro oxidative aging shows that