Dyneema Purity – A New Ultra-Strong Fibre Available for Innovative Devices

a report by

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A new fibre has recently been introduced into the market and made available to the medical device industry. Called Dyneema Purity, this fibre is made from ultra-high-molecular-weight polyethylene (UHMWPE), a material that is well known within the orthopaedic world. A distinctive property of this fibre is its high strength: weight for weight, 15 times as strong as steel.

Combined with other benefits like flexibility and abrasion resistance, Dyneema Purity is an interesting material for consideration when designing better or completely new devices. Several sports orthopaedic companies have chosen this fibre for use in their new strong orthopaedic sutures. Other implants are being developed by various medical device companies and can be expected on the market soon.

UHMWPE – The Raw Material

UHMWPE is probably one of the best-known biomaterials within the medical community. Introduced clinically for the first time in November 1962 by Sir John Charnley, the material is currently being used in many orthopaedic implants in hip, knee and shoulder surgery. The monitored biocompatibility of the raw material, combined with its toughness and abrasion resistance, makes UHMWPE one of the most frequently used materials for bearing surfaces in orthopaedic implants.

UHMWPE is classified as a linear homopolymer. Polyethylene is formed from ethylene (C_2H_4), a gas with a molecular weight of 28. The generic chemical formula for polyethylene is -(C_2H_4)n-, where n is the degree of polymerisation, i.e. the number of repeat units that form the molecular chain.

For a UHMWPE, the molecular chain can consist of more than 200,000 ethylene repeat units. The average molecular weight typically lies in the range of 2–2.5 million. This extremely high molecular weight is the main reason that special processing techniques need to be applied to form products out of this material. Conventional extrusion processes cannot be applied easily because of the very high viscosity of molten UHMWPE, so typically the material is formed in compression molding and ram extrusion processes. This fact has, for a long time, prevented the material being formed into fibres, until the discovery of the so-called gel spinning process by DSM in the Netherlands.

Forming Fibres – The Gel Spinning Process

The gel spinning process is unique in that it uses a solvent to turn the very tough polymer UHMWPE into a gel-like substance, which subsequently can be spun. In this process, the molecules are dissolved in a solvent and spun through a spinneret. The effect of the solvent is that, within the gel or solution, the molecules that originally formed strong clusters in the solid state now become disentangled. Furthermore, they remain in this disentangled state after spinning when the gel is cooled to give filaments. As the fibre is drawn, a very high level of macromolecular orientation is obtained (see *Figure 1*). This parallel orientation of the molecules is about 98%, which also results in a very high crystallinity of approximately 85%.

Combining these three factors – ultra-long molecular chains, high orientation and crystallinity – leads to fibres with a very high tenacity (strength per weight) and modulus. In the cross-wise direction, however, the fibres behave more or less as normal polyethylene, thus maintaining a very high flexibility. Furthermore, the raw material UHMWPE still retains its properties of high abrasion resistance, toughness and flex fatigue, all of which have been delivered onto the fibre. Thanks to the raw material, the fibre is inert to most chemical solvents such as acids and bases and does not absorb water.

Since being launched in the early 1990s, Dyneema fibres have penetrated a wide variety of high-tech markets worldwide. These fibres have been applied successfully in bullet-resistant products (vests and panels, including those used in the doors of aeroplane cockpits), ropes, fishing nets, cut-resistant gloves, sails, sailing ropes and fishing lines.

Dyneema Purity – The New Fibre

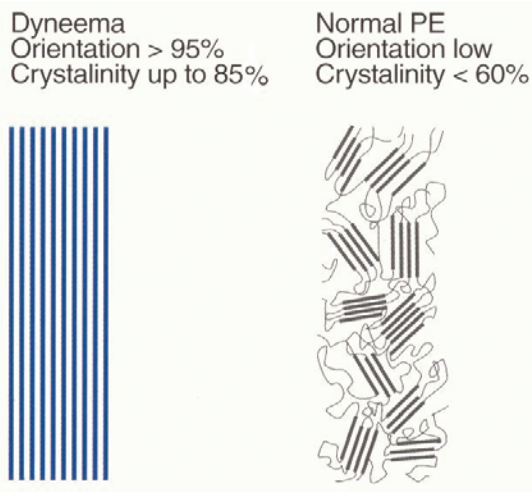
Until recently, UHMWPE fibres have not been available for medical applications. That is because the gel spinning process includes additives that make the industrial fibre less attractive for use inside humans.

Dyneema Purity has been developed with a specific view to obtaining high levels of quality and purity. The fibre is therefore produced using a proprietary adapted gel spinning process. The process is tightly controlled to meet high specifications with respect to mechanical properties and composition.

While developing this process, DSM Dyneema was able to make use of the expertise in other parts of the DSM organisation. DSM is active worldwide in both performance materials and life sciences. The company therefore sees Dyneema Purity as the fruitful product of a collaboration of these two widely different disciplines. This specific fibre can now be offered to medical device companies for use in medical applications.

Some typical values for the fibre properties are given in *Table 1*. various biocompatibility tests have been performed on the on Dyneema Purity fibre, as given in *Table 2*.

Figure 1: A Schematic View of the Macromolecular Orientation of Normal Polyethylene (left) and Dyneema Purity Fibres (right)



Normal polyethylene has a low orientation and crystallinity generally below 60%; Dyneema Purity has an orientation of approx. 98% and crystallinity up to 85%.

Table 1: Typical Product Data – Dyneema Purity

Property	***Unit***	***Value***
Density	*g/cm^3*	*0.97*
Strength		
Tenacity	*N/tex*	*3.2*
Tenacity	*G/den*	*36*
Tensile strength	*Gpa*	*3.1*
Modulus		
Specific modulus	*N/tex*	*101*
Specific modulus	*G/den*	*1,144*
Modulus	*Gpa*	*98*
Elongation at break	***%***	***3.4***

Table 2: Biocompatibility Tests Performed with Dyneema Purity

Biocompatibility Test	***Standard***
Cytotoxicity	*ISO 10993-5*
Irritation	*ISO 10993-10 (2002)*
Reverse Mutation Assay	*ISO 10993-3 (1992)*
Delayed Type Hypersensitivity	*ISO 10993-10 (2002)*

High Strength – Making Things Stronger or Smaller

The high strength of Dyneema Purity is used to improve devices in two ways. Obviously, using a stronger material in a construction will result in that construction becoming stronger. On the other hand, devices can also be redesigned to deliver the same strength in smaller dimensions.

Minimal invasive techniques like, for instance, arthroscopic soft tissue repairs enjoy becoming increasingly popular. They offer numerous benefits, including shorter hospitalisation time and a faster recovery rate, which benefits the comfort of the patient and leads to a lower total cost of care. Many specialised tools and implants are being developed for these kinds of techniques, often making use of stronger materials that enable miniaturisation of the devices. The new ultra-strong fibre Dyneema Purity has been seen to play a significant role within such an innovative area.

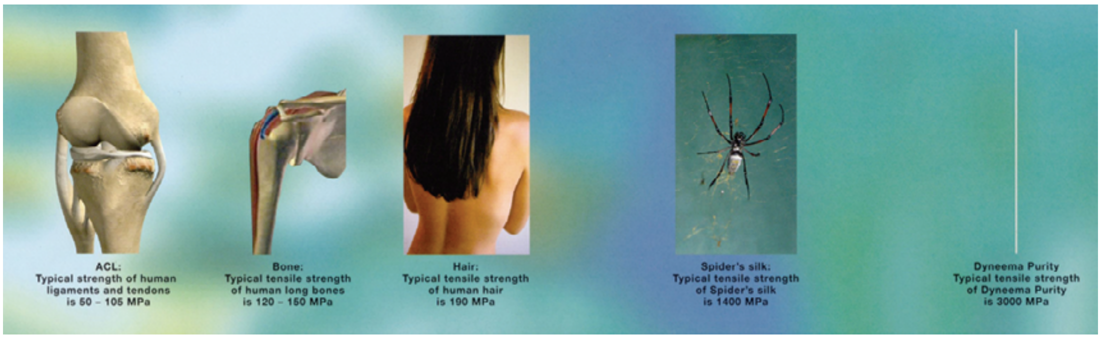
The benefits of the higher strength can best be explained by looking at the differences with other materials.

Stronger and Thinner – Orthopaedic Sutures

Take, for instance, the example of (very) thin braids like sutures. The Dyneema braid will be about half as thick as a similar polyester product but offer the same strength. This volume factor becomes even more significant if one looks at the size of the knot with which the suture is fixated. In *United States Pharmacopoeia* (*USP*) terms, one could say that, on a strength basis, a #5 polyester suture can be replaced by a #2 suture made from Dyneema Purity.

Various companies have introduced strong orthopaedic sutures based on Dyneema Purity fibres.

Figure 2: A Strength Comparison Between the Tensile Strengths of Various Body Parts, Spider Silk and the New Dyneema Purity Fibre



The sutures have created a lot of interest since they distinguish themselves clearly from 'ordinary' polyester sutures. A lot of the sutures are loaded on suture anchors, which are used to repair shoulder injuries to the rotator cuff.

Approximately six million people each year visit their doctor complaining of shoulder pain. About 25% of them will finally obtain specialist treatment for rotator cuff tears or related injuries. These injuries prevent these people from continuing physical activities in a pain-free manner (for example swinging a golf club or tennis racket, gardening or even reaching for an item on a high shelf).

The Dyneema sutures are appreciated in this area since they provide a stronger, more pliable suture material for arthroscopic and open repairs of ligaments and tendons. The smoothness of the fibre material helps to improve the way in which the sutures slide through both tissue and anchors; furthermore, the abrasion resistance of the UHMWPE offers higher resistance to fraying.

Dyneema Purity has been the choice of several medical device companies for the development of these orthopaedic sutures. One of these is Teleflex Medical – a company that recently acquired the Deknatel™ suture brand. The well-known Tevdek® polyester suture is a product of this company. Through its Deknatel™ brand, Teleflex Medical has a wealth of experience in developing and manufacturing specialty sutures and fibres. Using Dyneema Purity, Teleflex Medical has developed a special flat-braid suture. The flat construction helps improve the knotting behaviour of the slick polyethylene fibre and also adds to the total flexibility of the final suture. The result is a new suture with increased flexibility, knot sliding and strength.

The company reports both a tensile strength and a knot break strength for its (#2) suture more than 2.5 times that of the state-of-the-art polyester suture.

Figure 3: The new strong orthopaedic sutures on the basis of Dyneema Purity also come preloaded on Suture Anchors as they are commonly used in shoulder procedures.

Steel-like Strength – Moving Towards Softer Cables?

As mentioned previously, the strength of Dyneema Purity is, weight for weight, 15 times as strong as steel. Obviously, weight reduction is not the primary concern for most medical implants, yet size-wise, if Dyneema Purity is braided into a cable, this cable would be around the same thickness as a steel cable of the same strength. Steel cables, however, have certain disadvantages: the products are rather inflexible and, when cut, they give sharp edges, posing a serious blood-contamination risk during operations. They also tend to fail when twisted or bent because of the high bending fatigue properties of metals. Compared with metal, Dyneema Purity can provide cables that are much more flexible and soft. In addition, the flex fatigue of Dyneema Purity is lower than for metals. In surgical terms, this means that the risk of fracture during or after an operation can be much smaller when using Dyneema Purity products, because they don't break easily or lose their strength when bent, twisted or stretched. In addition to the sutures already mentioned, surgical cabling could also be an attractive application area for Dyneema Purity.

First Step – Orthopaedics

DSM expects Dyneema Purity to be chosen for use in several different medical applications. Its most obvious use is in orthopaedics, as Dyneema Purity's strength presents an immediate benefit. Following the introduction of the orthopaedic sutures, other orthopaedic implants are also being developed by various medical device companies and can be expected on the market soon. ■

The contents of this article are informative only. Suitability of any particular grade of Dyneema Purity for any application should be assessed in each individual case by a specialist in the area of the specific application targeted.

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