



MediTECH[®] Medical Grade Plastics

Thermoplastic shapes for long-term
orthopaedic implants



Mitsubishi Chemical
Advanced Materials



Corporate overview & capabilities

The Advanced Materials Division of Mitsubishi Chemical Group (MCG) is a leading global manufacturer of high-performance thermoplastic materials in the form of semi-finished products and finished parts. The company has locations in 19 countries and more than 3,000 employees. Its specialty engineering thermoplastics and composites are superior in performance to metals and other materials and are used in a wide range of applications, primarily in the capital goods industry. The company is continuously developing new areas of applications in close cooperation with industry leaders in a broad variety of customer markets.

Supporting the vision of the parent company, Mitsubishi Chemical Group Corporation (MCGC), MCG Advanced Materials is committed to the realization of KAITEKI, a concept that proposes a way forward in the sustainable development of society and the planet, in addition to serving as a guide for solving environmental and social issues.

Implantable products for today and tomorrow

Under the MediTECH® brand, the Advanced Materials Division of Mitsubishi Chemical Group (MCG) manufactures UHMW-PE implantable thermoplastic polymer shapes compliant to ASTM F648 and ISO 5834-2 and PEEK thermoplastic shapes compliant to ASTM F2026 for use in Class III implants (>30 days). Implantable polymers, like UHMW-PE and PEEK, can be used for orthopedic implant applications such as large joint orthopedics, spinal cages, bone screw, suture anchors, and cranio-maxillofacial (CMF) implants.

Comprehensive R&D strategy

MCG Advanced Materials' R&D strategy focuses on combining knowledge of the global regulatory landscape, industry segments, point of care research, and customer engagement. Once a need is identified, MCG Advanced Materials can initiate a fast-track process of research, testing and support to validate application development. A fully integrated supply chain enables full collaboration with R&D, quality, manufacturing, and material development teams throughout the product development cycle, so customers experience a significant speed to market.

Regulatory management

As a partner with healthcare OEM's for more than 30 years, MCG Advanced Materials understands the stringent industry requirements designed to ensure biological safety and protect the public's health. MCG Advanced Materials offers comprehensive regulatory management.

Global facilities, service & support

With multiple manufacturing locations and global distribution, the MediTECH® Implantable Polymers Division is uniquely positioned to meet increasing demands and ensure surety of supply. The company's dedicated sales and marketing teams enable worldwide coordination while multi-national locations allow for high responsiveness and make it easier for customers to do business with the company.

Product quality

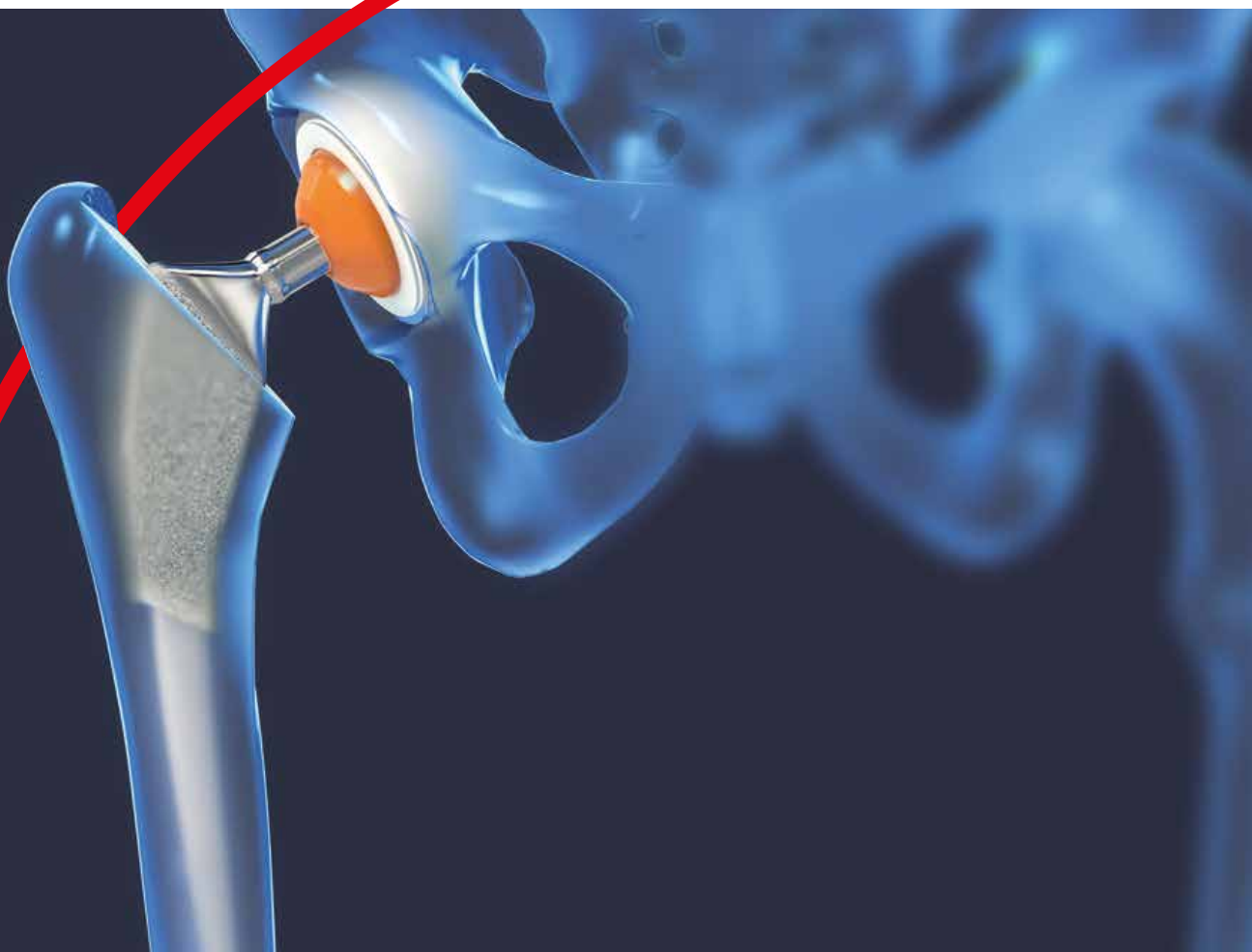
Superior products begin with superior raw materials. MCG Advanced Materials uses certified resins that are compliant for use in surgical orthopaedic implant applications

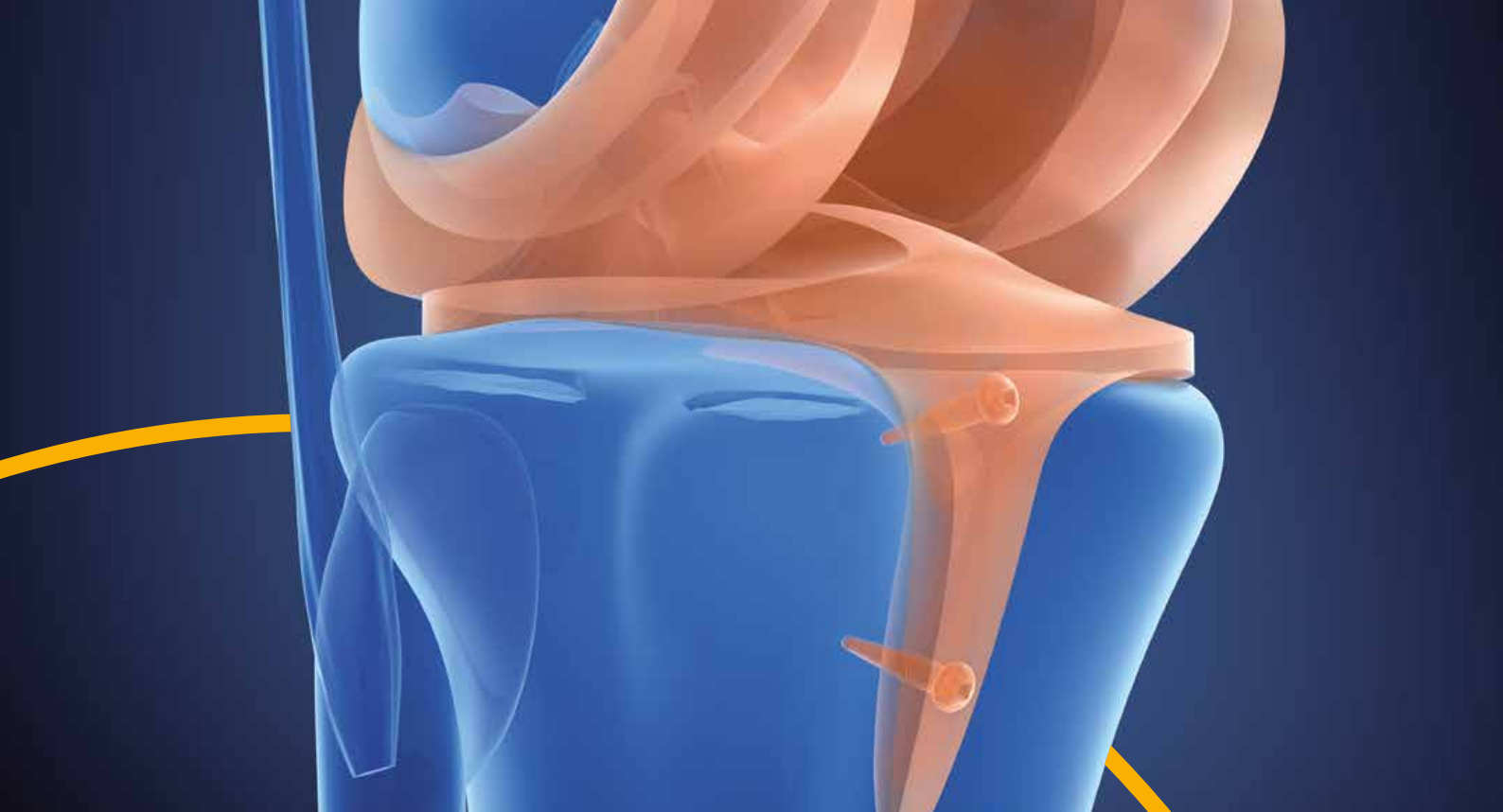
MCG Advanced Materials has robust inspection procedures to produce thermoplastic shapes:

- Required ASTM and ISO standards
- Proven regulatory compliance from global manufacturing facilities
- ISO 9001 and ISO 13485 certification
- ISO 17025 lab accreditation
- GMP compliant
- Validated processes
- Robust product traceability throughout manufacturing process

Testing capabilities to support product development

A vital part of the MediTECH® technology continues to be our state-of-the-art polymer research, analysis, and testing lab. Recent investments in the lab with specimen fabrication, testing equipment and capabilities position the MediTECH® lab to be the solution provider for customer product testing needs, test method evaluation and development. The lab is ISO 17025 accredited, adding to the level of quality and service that the lab is capable to provide.





Chirulen[®] | Extrulen[®] ultra-high molecular weight polyethylene (UHMW-PE)

Overview

As a polyethylene with a very specialized molecular weight, UHMW-PE is produced as a powder that requires special processing. The MediTECH[®] Implantable Polymers Division of Mitsubishi Chemical Group manufactures the resin as thermoplastic shapes to be used in orthopaedic implants. Chirulen[®] UHMW-PE is our compression molding grade and Extrulen[®] UHMW-PE is processed by ram extrusion.

UHMW-PE blended with vitamin E

Cross-linking by irradiation bears the risk of free radical formation in the UHMW-PE product and can result in vivo oxidation and material degradation. Such degradation can cause a loss in mechanical performance, including reduced wear resistance. Vitamin E, known as an antioxidant, has positive influence on this process and is used as a stabilizer for orthopaedic UHMW-PE implants.

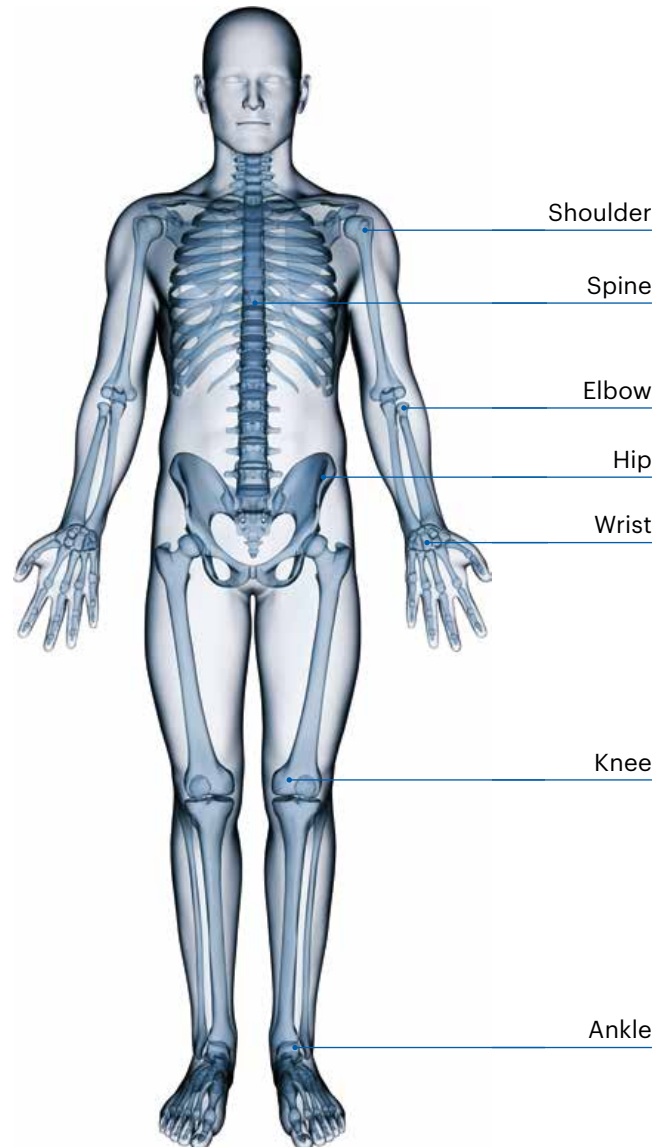
Chirulen® & Extrulen® UHMW-PE Typical applications

Expertise in cross-linking

Crosslinking of UHMW-PE products has demonstrated to increase the wear resistance of orthopedic implants. For example, the balance of wear and mechanical strength is affected by the level of crosslinking and is specified by the energy dose provided. MediTECH Division can supply products across the full span of irradiation levels to meet customer specific preferences. The crosslinking methods are also customizable with Gamma, E-Beam, and X-Ray potentials to meet customer requirements and application needs.

UHMW-PE product benefits

- Exceptionally high notched impact strength
- High energy absorption capacity at high stress rate
- Excellent wear resistant properties
- Low coefficient of friction



MediTECH Chirulen® / Extrulen® UHMW-PE thermoplastic shapes*

- Chirulen® compression molded 1020 & 1050
- Extrulen® extruded 1020 & 1050
- Cross-linked
- Vitamin E stabilized
- Vitamin E cross-linked
- Near net shapes available in multiple conversion technologies

*Custom sizes are available

Zeniva[®] PEEK (Polyetheretherketone)

Overview

Zeniva[®] PEEK is a high-performance specialty polymer with high strength and advanced stiffness that offers extreme toughness and reliability for use in structural, load-bearing implantable medical devices. This bio-stable plastic has excellent fatigue and creep resistance. The unique properties of Zeniva[®] PEEK allow implantable devices to withstand continuous strain and repeat loading. In addition, it offers numerous advantages over metals, such as a reduction of stress shielding, no heavy metal allergy or ion erosion, and has radiolucent properties that allow X-ray and CT scanning procedures without interference.

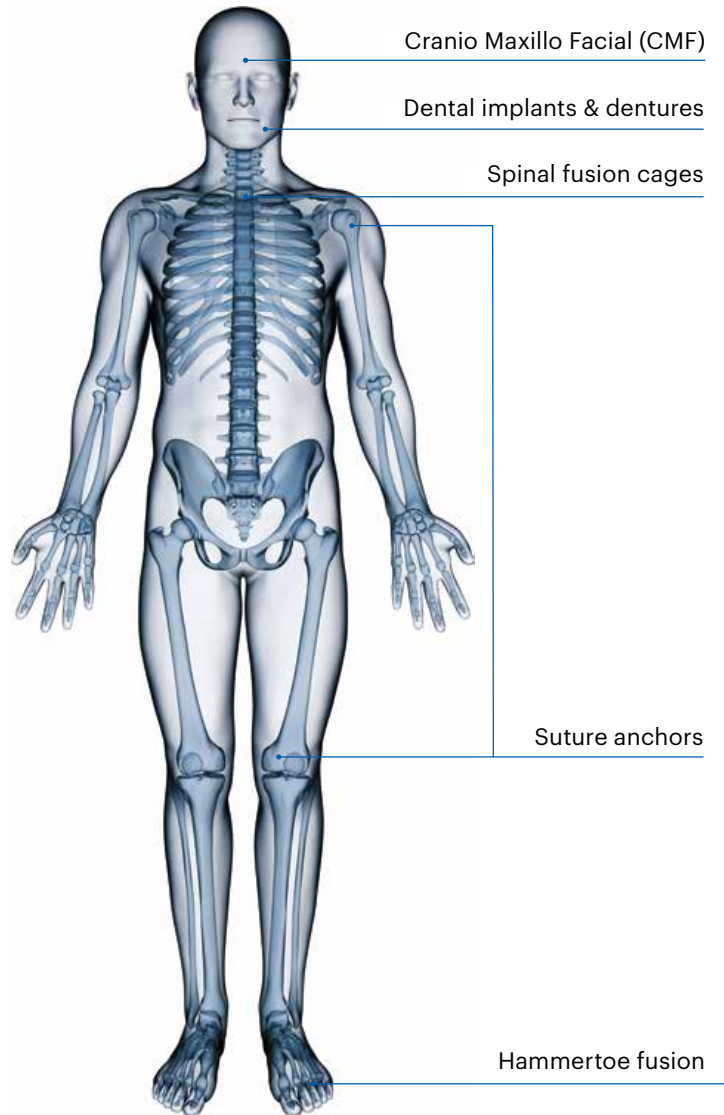
Solvay license agreement

The MCG Advanced Materials Division is the exclusive global converter and supplier for Solvay's Zeniva[®] PEEK thermoplastic shapes. This agreement expands MediTECH's existing role in the longstanding partnership between the two companies, with the goal of bringing additional value to the customer channel.



Zeniva® PEEK

Typical applications



Long-term implantation

Additional performance benefits of Zeniva® PEEK shapes include high strength and stiffness, fatigue resistance, and exceptional dimensional stability. Zeniva® PEEK shapes are ideal for the close tolerance machining of finished components, and for prototypes used in injection molding applications.

Typical orthopaedic implants

- Spinal - spinal cages and spacers for anterior and posterior lumbar interbody fusions
- Supports fixations in anterior and posterior cervical interbody fusions and disc height restoration
- Suture anchors and bone screws
- Dental
- Trauma and large joints



MediTECH® thermoplastic shapes made from Zeniva® PEEK - Size range*

- ZA-500 Rods:
80 mm, 70 mm, 60 mm, 50 mm, 40 mm,
36 mm, 32 mm, 30 mm, 25 mm, 20 mm,
16 mm, 13 mm, 9 mm, 6 mm
- ZA-500 Plates:
15 x 150 x 400 mm
40 x 500 x 1000 mm

Mitsubishi Chemical Advanced Materials

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It is the customer's responsibility to determine the suitability of Mitsubishi Chemical Advanced Materials' products in any given application.

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