MEDICAL &
LIFE SCIENCE

MediTECH® Medical Grade Plastics

Thermoplastic shapes for long-term orthopaedic implants

MITSUBISHI CHEMICAL GROUP

MediTECH®
MEDICAL POLYMERS

Corporate overview & capabilites

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...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 iidentified, 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.

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.

Product quality

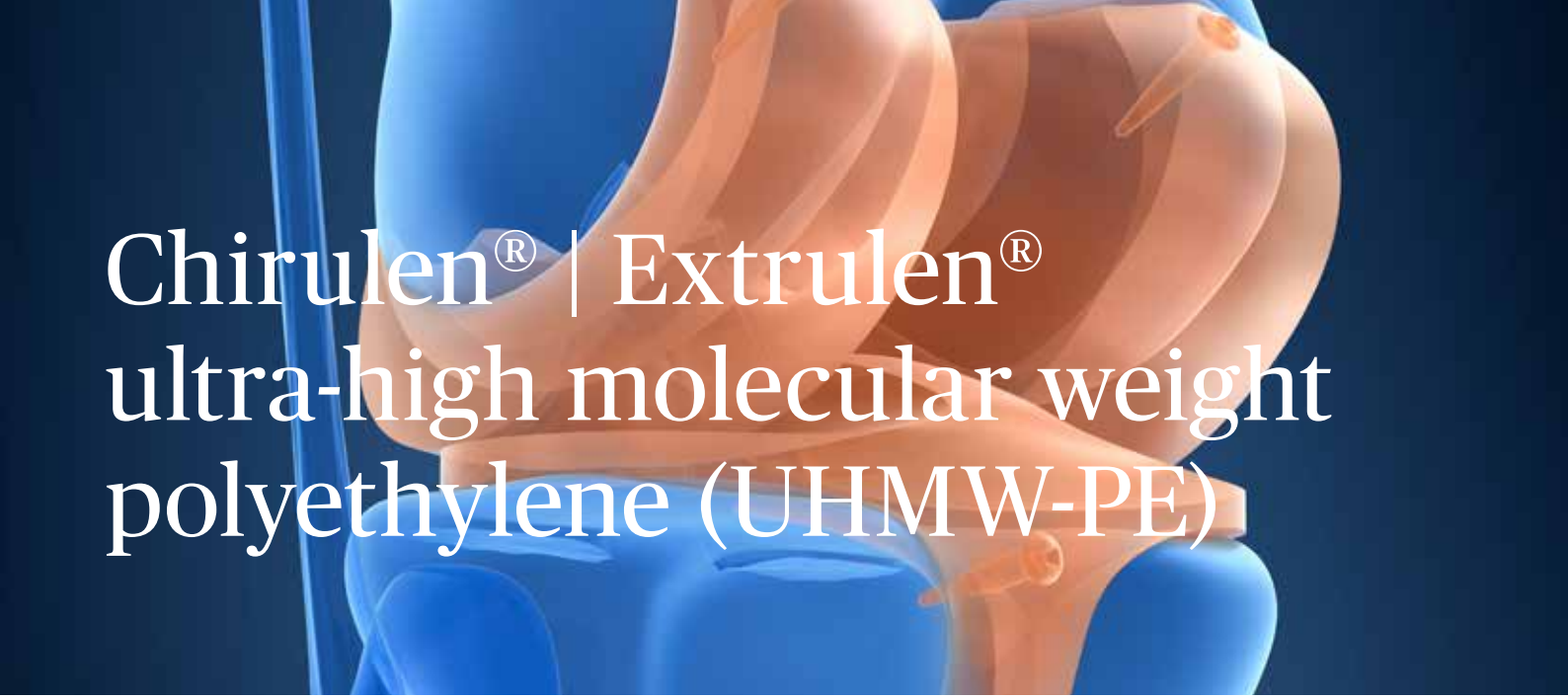
Superior products begin with superior raw materials. MCG Advanced Materials uses certified resins that are compliant for use in surgical orthopaedic implant applications.

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
Ultra-high molecular weight polyethylene (UHMW-PE) is manufactured and supplied by the MediTECH® Implantable Polymers division as thermoplastic shapes to be used in orthopaedics implants. As a polyethylene with a very specialized molecular weight, UHMW-PE is produced as a powder that requires special processing. In the shapes industry, the high pressures generated for Chirulen® UHMW-PE compression molding and for Extrulen® UHMW-PE ram extrusion processes fuse the particles together that is then formed into stock shapes or profiles.

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. The degradation of the material can result in reduced mechanical properties, including reduced wear resistance. Vitamin E, known as an antioxidant, has positive influence on this process and is used as a stabilizer for orthopaedic implants made from UHMW-PE. Tests have proven bio-compatibility and the consistent mechanical properties of UHMW-PE that is blended with Vitamin E.

Expertise in cross-linking
Cross-linking has been shown to eliminate oxidation and improve the wear rate of polyethylene in laboratory studies. MCG Advanced Materials can perform Vitamin E blending together with cross-linking and stabilization according to customer formulation needs. With more than +20 years of clinical history and follow-up, Chirulen® and Extrulen® UHMW-PE are the market leading products for use in today's highly cross-linked polyethylene. The MCG Advanced Materials Division is dedicated to the development of customized cross-linked products in combination with Vitamin E and other anti-oxidants.

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

Typical orthopedic implants

- Shoulder
- Elbow
- Knee Ankle

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

- Chirulen compression molded 1020 & 1050
- Extrulen extruded 1020 & 1050
- Cross-linked
- Vitamin E stablized
- 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.

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

*Custom sizes are available

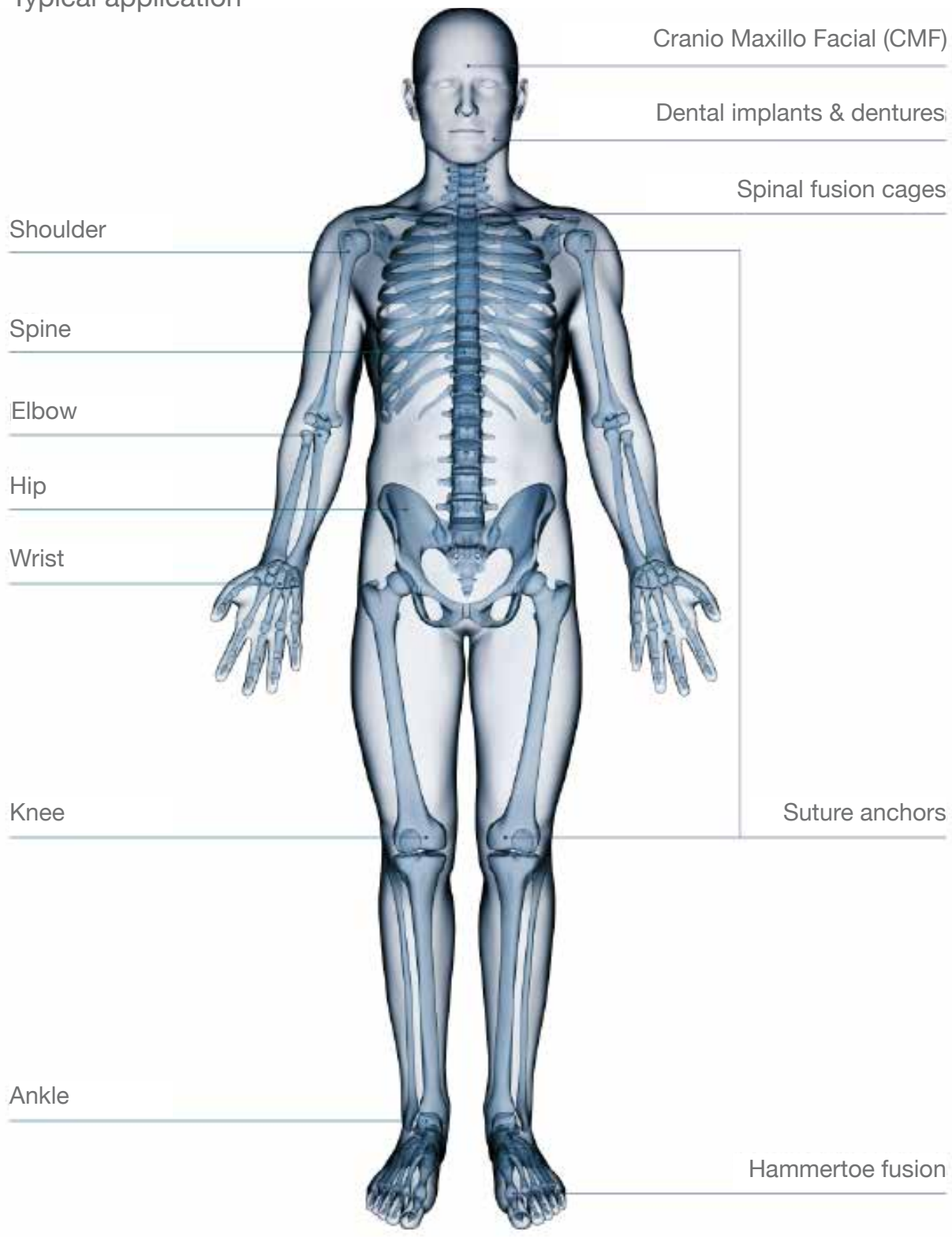
Typical Orthopaedic Applications

Chirulen® & Extrulen® UHMW-PE

Typical application

Zeniva® PEEK

Typical application



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MediTECH® MEDICAL POLYMERS

Get in touch

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