



**Orthoplastics**  
A MedPlast Company  
*science making a material difference*

**SETTING THE STANDARD FOR  
ORTHOPAEDIC PLASTICS**



## PREMIUM ORTHOPAEDIC COMPONENTS THAT TRANSFORM LIVES

### A WORLD LEADER IN IMPLANTABLE PLASTIC MANUFACTURING

Orthoplastics Limited is dedicated to the medical industry and is a world leader in the development and supply of both implantable-grade plastics and also biocompatible plastics for instrument applications.

Orthoplastics is a leading manufacturer and supplier of UHMWPE and it has led the way in making recognised contributions to the advancement of the product and its applications. Most notably these relate to superior consolidation and elevated purity in addition to the development of Vitamin E blended product, which promise extended product life span and increased quality of life for patients.

## DEDICATED TO THE MEDICAL SECTOR

A producer of the highest quality, premium grade orthopaedic UHMWPE on the market, Orthoplastics is dedicated to the medical sector. It supplies the world's leading orthopaedic device manufacturers and its products are used within a wide range of orthopaedic implants such as applications for hips, knees and shoulders, elbows, ankles and fingers. Its dedication to the medical industry is underpinned by its rigorous quality control systems.

Guided by the requirements of 21 CFR 820, Orthoplastics is accredited to ISO 9001, ISO 13485, ISO 14001 and all process variations are regulated under Validation Control (IQ/OQ/PQ) and FMEA studies. All products conform to allocable product standards and Quality Management processes extend beyond the Documented Quality System and the requirements of International Standards.

## THE COMPLETE SUPPLY CHAIN SOLUTION

Orthoplastics brings together UHMWPE, Crosslinked UHMWPE and Vitamin E UHMWPE, Component Machining, Direct Compression Moulding and Laboratory Services to provide the complete supply chain solution to their customers.

It is the depth and breadth of Orthoplastics specialist knowledge that sets it apart from its competitors within the medical sector and positions it as a valuable resource to its customers when designing and commissioning bespoke implantable devices. Orthoplastics offers its customers the capability to research, design and manufacture their products in one place, with specialised support and guidance to ensure that their custom product precisely meets their needs.



### UHMWPE

A world leader in the supply and manufacture of implantable plastics



### COMPONENT MACHINING

Individual components developed and manufactured to customer specifications



### COMPRESSION MOULDING

Bulk processes UHMWPE and produces implantable material that has increased crosslinking



# INDUSTRY LEADING MANUFACTURING SYSTEMS AND CAPABILITY

Orthoplastics operate four ram-extruders, each with a capacity of 30 tons of UHMWPE rods and two screw extruders of 50 tons capacity.

They have a purpose built 20,000 sq.ft press facility which has an annual capacity in excess of 400 tons of compression-moulded UHMWPE sheet.



## SUPPLYING THE WORLDS LEADING ORTHOPAEDIC DEVICE MANUFACTURERS

The company has an environmentally controlled component machining facility, with several CNC machining centres and lathes, backed up by CMM and surface treatment equipment.

The Orthoplastics finishing shop houses three advanced, computer monitored gas-fired and electric annealing ovens, which are capable of controlling temperatures to exact specifications. This means that when it comes to producing orthopaedic plastics, you can rest assured that its manufacturing systems are the most advanced and specialised systems in the world.



# UHMWPE



For over forty years, UHMWPE has been the primary bearing material for Orthopaedic applications.

## UHMWPE OF SUPERIOR CONSOLIDATION AND ELEVATED PURITY

Its high abrasion resistance and toughness means that it is an exceptionally attractive solution to the complexities of wear. Orthoplastics manufacture UHMWPE from Celanese GUR® 1020, 1050 and 1020-E polymer via two distinct processes: Ram extrusion, which produces a rod shaped product and compression moulding, which produces a large sheet of product.

The company operates ram-extruders each with a capacity of 30 tons of UHMWPE rods and screw



extruders of 50 tons capacity. Their polymer feed systems are fully environmentally controlled, enabling contamination to be reduced to a minimum. The manufacturing process is supported by a finishing area housing three advanced, computer monitored gas-fired and electric annealing ovens, which are capable of controlling temperatures to exacting specifications.

This ensures that the company's manufacturing systems are the most advanced and specialised in the industry.

## A WORLD LEADER IN THE RAM EXTRUSION MANUFACTURING PROCESS

Orthoplastics extrude all variants of Celanese UHMWPE. The difference in molecular weight requires different processing conditions for each.

The manufacturing process has been developed to minimise stress and improve dimensional stability, by finely controlling production using the latest manufacturing technology; a world leading achievement. Ram extruded UHMWPE rods are available in both 1020 and 1050, and can be supplied in an extruded or doweled form.

## THE COMPRESSION MOULDING MANUFACTURING PROCESS

Compression moulding is a common method of bulk processing UHMWPE.

Orthoplastics mould both grades of polymer in lengths of up to 3 metres, and to a maximum thickness of 115mm, in 'pressed sheets'. Sheets can be cut to order, produced as rectangular blocks, or machined to give a rounded/or other shaped profile, up to the maximum size.



# CROSSLINKED UHMWPE & VITAMIN E UHMWPE

## ORTHOPLASTICS ROUTINE TEST METHODS

All UHMWPE bars are certified in-plant for crosslink density, oxidation index and mechanical properties to ensure conformance to the highest standards achievable.

Our standard tests are:

- Crosslink Density using SRT to ASTM F2214
- Small punch test to ASTM F2183
- Trans Vinylene Index to ASTM F2381
- Oxidation index to ASTM F2102 (ISO 5834-4)

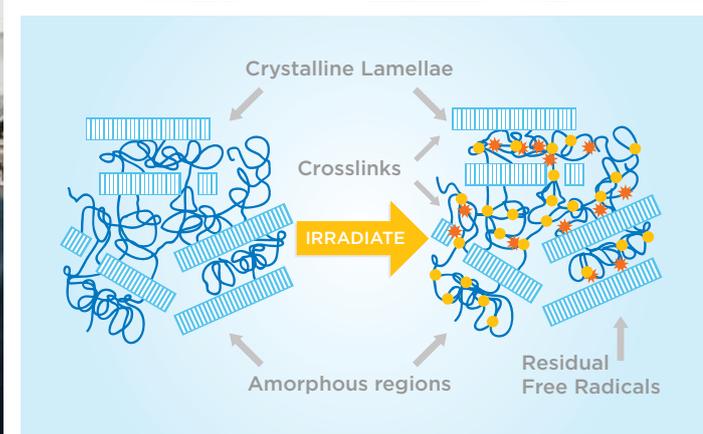
## VITAMIN E UHMWPE, A REVOLUTIONARY TECHNOLOGY IN ORTHOPAEDIC APPLICATIONS

The addition of vitamin E to UHMWPE promises increased implant lifespan. Vitamin E is an effective oxygen scavenger, which reduces oxidation following irradiation.

Vitamin E is a collective term for the group of tocopherols, of which alphatocopherol shows the best properties as an antioxidant. Alphatocopherol acts as a radical scavenger and thus reduces long term in-vivo oxidation.

The material is produced in accordance with ASTM F2965. All mechanical properties remain unchanged compared to the original GUR UHMW-PE premium grades. The blend follows the typical high standards of product cleanliness and shows a very uniform vitamin E distribution.





Orthoplastics manufacture Crosslinked UHMWPE which offers significant wear reduction. Crosslinking is achieved by exposing standard UHMWPE to ionising radiation.

## SIGNIFICANT WEAR REDUCTION

By controlling the dose to +/-10kGy in validated processes, wear performance and mechanical strength are more uniform throughout the cross-section of the product

Free radicals generated during the irradiation processes are minimised via post cross-linking thermal treatment and removal of exposed surfaces after the

process, this is extremely important in reducing the possibility of long term in-vivo oxidation.

The timescale between irradiation and annealing to prevent the proliferation of free radicals and subsequent testing using Fourier Transform Infrared Spectroscopy (FTIR) verifies the level of oxidation prior to supply.



# COMPONENT MACHINING



Orthoplastics is a World leading UHMWPE machining and manufacturing expert that guides you through compliance, increases speed to market and reduces costs.

## OVER 30 YEARS' EXPERIENCE OF ORTHOPAEDIC COMPONENT MACHINING

Many new orthopaedic product ideas simply don't get past the concept stage due to the technical, regulatory and cost barriers that exist. Orthoplastics helps you take back control of your business.

By working with a World leader in implantable plastic manufacturing and component machining, this will navigate you through the complexities of production, compliance and accreditation, getting your products to



market quickly, saving you valuable time and money.

Orthoplastics are experts in all aspects of CNC machining of implantable grade plastics and have an impressive portfolio of high-end CNC machines and unrivalled machining know-how. With in-house testing, on site plastics manufacturing, design, quality assurance, supply chain and project management, they are the complete solution.

## COMPLETE PRODUCT DEVELOPMENT SOLUTION

By choice, Orthoplastics machining capabilities relate only to plastics, both implant grade and instrument, where we can offer the latest CNC machining centres and lathes.

Investment in new machinery is continuous so a plant list is maintained and provided separately. Supporting the company's machinery are Mitutoyo CMM's and various surface treatments, which are engineered to exceed customer specifications.

## WIDE RANGE OF SOLUTIONS & PRECISION CAPABILITIES

If you need CNC expertise in milling, turning, grinding and drilling of implantable grade plastics then speak to the leader in orthopaedic component machining.

Orthoplastics has developed strong partnerships with its customers, visiting their sites or end user's sites, to provide bespoke orthopaedic engineering solutions.

With a skilled workforce, industry leading state of the art equipment, it takes pride in being able to produce high quality, complex components quicker and more cost effectively than its competitors.



# DIRECT COMPRESSION MOULDING

## THE ORTHOPLASTICS INSERT MOULDING PROCESS

Although Direct Compression Moulding is a relatively expensive method of sintering the polymer, it produces components with a high gloss finish.

Orthoplastics, has focused on advancing this method of manufacturing UHMWPE to ensure that components produced this way are optimised. It has pioneered the development of an 'insert moulding' process, which allows UHMWPE to be moulded onto or into, another steel, titanium or ceramic part.

## DIRECT COMPRESSION MOULDING QUALITY CONTROL

All processes used in the manufacture of medical grade products are validated with all data stored for a minimum of 30 years and quality standards are also applied such as ISO 9001, ISO 13485 and ISO 14001. Full product trace-ability techniques are employed during the manufacture of all medical grade material.

In addition, visual inspection techniques are employed to determine the product quality along with non-destructive ultrasonic testing; product batch testing is completed in accordance with ISO 5834-2, ASTM F648 and customer specifications; certification of conformance is supplied with every shipment of product in accordance with standard requirements or customer specifications.





Direct Compression Moulding of UHMWPE ensures the consolidation of the materials is a direct result of the heat, pressure and time combination used by the presses but on a small scale.

## ALLOWS MEDICAL GRADE MOULDING OF INDIVIDUAL COMPONENTS

Each orthopaedic implant is moulded directly. This enables the manufacture of a component with a highly polished direct moulded surface by removing the machining surface definition present on the articulated surface of conventionally machined products.

By undertaking the compression moulding operation

over a smaller projected area greater control is attained over the pressure and temperature cycles, which improves the properties of the product.

Consolidated product is heat treated in air circulating (fan assisted) ovens under controlled conditions, thus compensating for thermal dwell through the otherwise insulating layers of the product to the core region.

# LABORATORY SERVICES



The Orthoplastics laboratory is UKAS accredited & the majority of its projects are carried out in accordance to ISO17025.

## INDUSTRY LEADING LABORATORY SERVICES TO SUPPORT CUSTOMER PRODUCT DEVELOPMENT

Orthoplastics' industry leading laboratory facilitates the materials characterisation for; material suppliers, processors, manufacturers & end users in addition to research and development.

Consulting with its clients, referring to the applicable standards and their extensive experience, it designs test programmes to meet the requirements for applications such as CE and 510k submissions.



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The quality systems employed at Orthoplastics meet the highest standards required within its main service sector, namely implantable medical devices.

The company's commitment to research and development is unrivalled within the orthopaedic implantable plastics industry and ensures that its depth and breadth of technical expertise is available to support its customers product development programmes.

## CUSTOMER PRODUCT DEVELOPMENT

Orthoplastics works in conjunction with its customers design/development teams to accelerate the design process and ensure products meet the application, specification and mechanical designs demanded.

Its research and development laboratory is comprehensively equipped and has extensive experience of testing materials and products manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE), Polyether ether ketone (PEEK) and other polymers primarily within the medical device sector.

## EQUIPPED TO MEET YOUR SPECIFIC ORTHOPAEDIC REQUIREMENTS

In addition to the essential equipment for certification the research and development laboratory is equipped with the following:

- Nicolet FTIR Avatar 360 with microscope
- Netzsch DSC 200 PC
- Cambridge Polymer Group Swell Ratio Tester SRT-1
- 'Small Punch Test' (Multi-axis Tensile Test) from Exponent
- Oxygen bomb for artificial ageing





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