



Stock shapes

Plastics used in medical technology

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Ensinger develops and engineers stock shapes, components and profiles made of thermoplastics which are designed to comply with the stringent demands of medical technology. The special demands imposed on these materials such as physiological safety are addressed by the outstanding properties of high temperature plastics:

- Examination of the semi-finished product for biocompatibility
- Very good resistance to cleaning agents and disinfectants
- Resistance against common sterilization methods such as hot steam, hot air, ethylene oxide or gamma radiation
- Compliance examination of the used processing agents
- Attentive storage and shipment with shrink packing

It is the combination of these MT-portfolio attributes that allows this type of high-quality medical products to be used intensively over long periods.

Ensinger quality in the world of medical technology

In the field of medical technology particularly, the demands made on quality, product documentation and product approvals are extremely stringent. Ensinger is certified in accordance with the quality standards set out in DIN EN ISO 13485 in the fields of compounding, stock shape and industrial profile production, as well as injection moulding and machining. Ensinger consequently fulfils a special duty of care when it comes to traceability.

For our customers, using pre-tested semi-finished products simplifies the process of obtaining approvals for their own medical technology products. Therefore all semi-finished stock items of the MT-portfolio have been tested for biocompatibility according to ISO 10993. The issued biocompatibility is order-related and includes not only the raw material conformity but as well the examination results of the semi-finished product according to ISO 10993. With the order-related issuing we ensure a seamless traceability from the customer's order to the semi-finished product and the used raw material.



In many cases, plastics replace metals or ceramics. They often provide the only alternative when it comes to the implementation of unusual technical applications. Ensinger offers a wide portfolio of products for the medical industry.

Plastics in application

MT plastics from Ensinger are generally produced from raw materials conforming to stringent FDA requirements, and are additionally tested on the semi-finished product for biocompatibility at regular intervals.

These properties and their specific resistance to sterilization make them ideally suited to use in the medical and pharmaceutical industry. Our project partners benefit from the compre-

hensive experience we have gathered over decades in wide-ranging areas of medical technology. Our specialists will determine the ideal solution for any concrete application, taking every special requirement precisely into consideration. This application-oriented project management approach covers all the key bases for successful development.

Trauma / Orthopaedics

To determine the right fitting size for a future implant during active surgery on knee, hip and shoulder joints, test implants are used in advance in a variety of colours to assess fitting accuracy. For this application, Ensinger offers a wide selection of colours within its TECAFORM AH MT (POM-C), TECASON P MT (PPSU) and TECAPEEK MT (PEEK) range of materials. Due to their outstanding properties these materials are well suitable for any other kind of instrument used during surgery. TECASON P MT (PPSU), available in a wide range of colours, is particularly suited for this type of application due to its extremely good sterilization resistance.

In the field of traumatology, a guiding device made from TECATEC composite is used, for instance, for positioning fixing nails, and must comply with the very standard of mechanical strength and thermal dimensional stability. The Ensinger materials TECATEC PEEK CW50 offers the ideal property profile for this application. Due to the carbon fibre component of 50 per cent it provides extreme torsional stiffness and is practically immune to warping despite repeated sterilization. All these properties lend the components a long service life and make them ideally suited for the external fixture of fractures.

Surgery

A variety of instruments such as scissors, forceps and clamps are used for surgical procedures in the different surgical disciplines such as vascular, cardiac or thoracic surgery. Ensinger plastics are a key material for use in this type of instrument. Their benefits include a low specific weight and good resistance to sterilization. Coloured plastics also permit easy differentiation.

TECAFORM AH MT (POM-C), TECASON P MT (PPSU) and TECAPEEK MT (PEEK) and other MT materials are used in this area as hand grips, axial grips, ring grips and instrument grips.

These plastics are also used in the field of minimally invasive surgery. Their use also covers components for hand grips, eye pieces and colour coding. Other examples include sliding elements and insulating sleeves for high-frequency cutting instruments using TECAPEEK MT (PEEK).

And last but not least, manufacturers of components for ultrasound surgery also use MT plastics from Ensinger (for instance in handle levers for ultrasound scissors and hooks). Their high level of resistance to sterilization makes TECASON P MT (PPSU) and TECAPEEK MT (PEEK) the materials of choice for this type of application.



Diagnostics

The use of thermoplastics in the world of medical technology begins from instruments used for diagnostic purposes such as endoscopes. Plastics from Ensinger are also used in imaging procedures such as computer tomography (CT) and magnetic resonance tomography (MRT). Due to their high mechanical loading capacity, their transparency and resistance to electromagnetic waves, plastics have proved to be highly successful for components such as the targeting guides used in a CT scanner, or the cardan joint of the positioning system used for head immobilization in an MRT scanner.

TECAPEEK MT black (PEEK) is used in the field of laboratory diagnostics, for example, as a capillary carousel for PCR analysis. The requirements imposed on minimal thermal expansion under rapid temperature change, high processing precision and good chemical resistance are comprehensively met by TECAPEEK MT black (PEEK). The intense deep black pigmentation also permits precise measurement results through accurate adaption of the measurement capillaries for optoelectrical analysis.

Therapy

Engineering plastics from Ensinger have a significant role to play as components of medical products in the treatment of diseases across the various specialist fields of medicine.

In the field of hemodialysis, plastics from Ensinger such as TECASON E (PSE) are used in a component in the secondary circuit of hemodialysis machines. These plastics not only serve as a part of the medical product itself, but can also assume a variety of roles in the manufacture of dialysis machines. From spinning of the hollow fibres through to production of the dialysis machine itself, plastic applications such as rollers or winding cassettes made of TECAFORM AH MT (POM-C) are involved in the successful manufacture of dialysis machines.

For postoperative radiotherapy of soft tissue tumours, for instance, TECAPEI MT (PEI) is a preferred option due to its very good biocompatibility, high transparency and resistance to electromagnetic waves in the irradiation head of the radiotherapy device.

High-performance plastic TECAPEEK MT (PEEK), for instance, performs a therapeutic function as a spring in a support prosthesis. Rods which support leg muscles are significantly lighter and warmer than the alternative made from metal.



Intensive care / ventilation

In the field of intensive care, MT materials play a vital functional role as components in ventilators and therefore guarantee the vital functions. TECAPEEK MT blue (PEEK) is used in the production of dilators for emergency ventilation. Due to its physiological harmlessness in direct contact with human organisms, good electrical insulating properties and a high level of precision for a sharp-edged, completely burr-free thread, this material helps simplify ventilation procedures involving tracheotomy.

Where extreme demands are imposed on a material in terms of its dimensional stability, resistance to anaesthetics, precision, machining properties and sterilization capability, TECATRON (PPS) is the ideal plastic for use in applications such as ventilator respiratory gas blocks. Another application example taken from ventilation medicine are fan impellers made of TECANAT MT (PC) used in CPAP and BiPAP devices for sleep apnoea patients.

Dental medicine

Materials used in devices for dental tartar removal or to harden fillings have to comply with the most stringent demands of repeated sterilization. For suction-irrigation handles, Ensinger plastics offer physiological harmlessness coupled with resistance to repeated sterilization cycles.

Dental healing caps made of TECAPEEK CLASSIX™ (PEEK) are suitable for use up to 30 days or even to in certain cases up to 180 days when made of TECAPEEK CLASSIX™ (PEEK).

Small-scale runs of products such as dentists' couches including instrument holders can be manufactured using large-scale tools with TECARIM (PA 6 C). Through the use of an almost pressureless process, extremely stress-relieved products can be manufactured. In addition, this technique permits larger wall thicknesses than are possible with injection moulded parts.

Sterilization

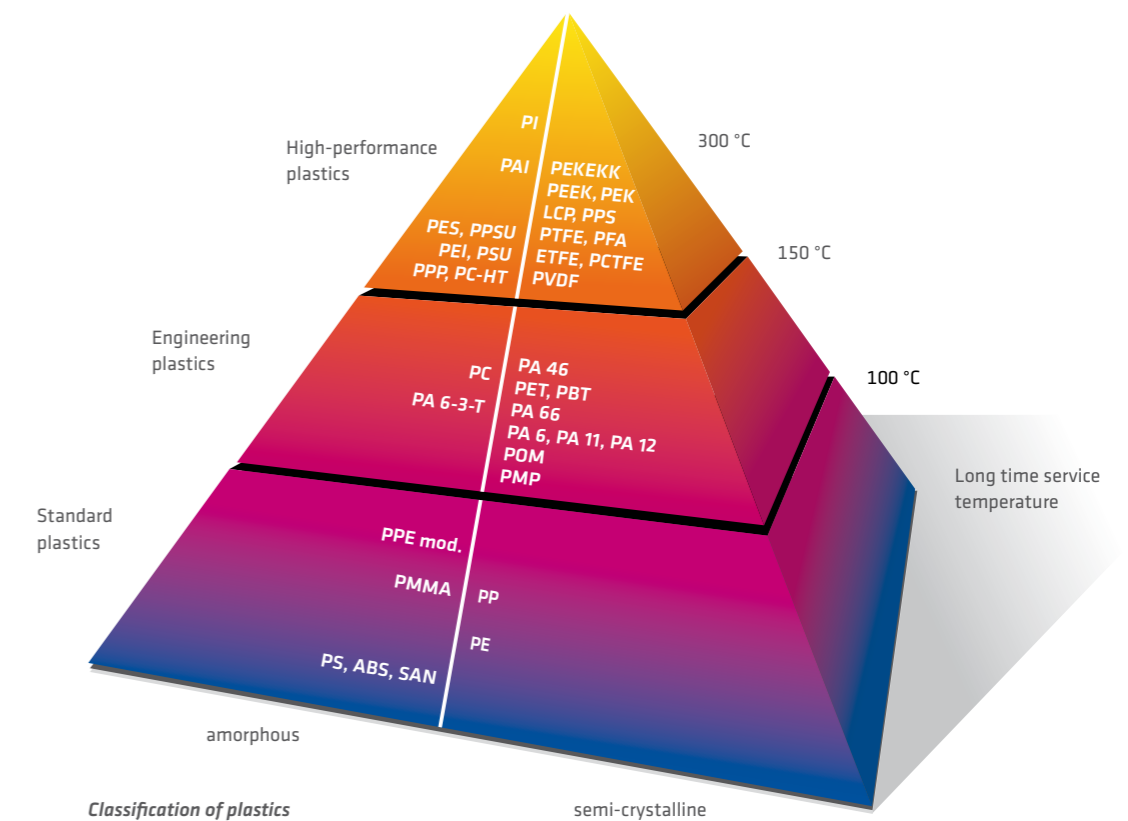
A high proportion of medical products are sterilized after a diagnostic or therapeutic treatment for re-use. Very suitable as materials for sterilization containers are TECASON P VF (PPSU) for deep-drawn shapes, or TECAPRO MT (PP) and TECASON P MT (PPSU) for machined sterilization containers. TECAPRO MT (PP) is resistant to cleaning agents and disinfectant, as well as hydrolysis and hot steam, and its low density permits the manufacture of very lightweight components. In particular its more pleasant feel, good machining properties, low tendency to warp and very good biocompatibility are reinforcing the trend towards the increasing replacement of metals with plastics.



Product portfolio The basis for wide-ranging applications

We offer a wide spectrum of engineering and high-performance materials for medical applications from our standard range. These materials are suitable for applications involving no direct contact with blood or tissue:

- TECAFINE (PE)
- TECAFORM (POM)
- TECAPET (PET)
- TECAMID (PA)
- TECAST (PA 6 C)
- TECANAT (PC)
- TECAFLON (PTFE, PVDF)
- TECASON (PSU, PPSU)
- TECAPEEK (PEEK)
- TECATRON (PPS)
- TECATOR (PAI)
- TECASINT (PI)



Special materials

Sterilization-resistant materials

High number of sterilization cycles

- TECASON P MT (PPSU)
- TECATRON MT (PPS)
- TECAPEEK MT (PEEK)

Function: Very high resistance over a large number of sterilization cycles.

Benefit: Components made of these materials have a long service life, so reducing the cost of repeat purchasing.

Limited number of sterilization cycles

- TECAPRO MT (PP)
- TECAFORM AH MT (POM-C)
- TECANAT MT (PC)
- TECAFINE PMP MT (PE)
- TECANYL MT (PPE)

Function: Sterilization resistance for a limited number of cycles, comparably favourable material costs.

Benefit: Optimized cost ratio for components which are only required to be sterilized and re-used infrequently.

X-ray detectable MT materials

- TECAPEEK MT XRO (PEEK)
- TECASON P MT XRO (PPSU)

Function: Clear visibility under fluoroscopy and X-ray radiation.

Benefit: During image-controlled procedures, the surgeon has an exact picture of the plastic components.

Antimicrobial materials

- TECAPRO SAN (PP)
- TECAFORM AH SAN (POM-C)

Function: Antimicrobial effect by the release of biocides.

Benefit: Reduction of microbes in day-to-day medical and clinical use.

High-strength MT materials

- TECAPEEK CF30 MT (PEEK)
- TECATEC PEEK CW50 (PEEK)
- TECATEC PEKK CW60 (PEKK)

Function: Unusually high mechanical strength and dimensional stability.

Benefit: Extremely accurate and precise operation in the field of orthopaedic surgery.

Transparent MT materials

- TECANAT MT (PC)
- TECASON P VF (PPSU)
- TECAPEI MT (PEI)

Function: Transparency simplifies optical control.

Benefit: Visible components plus biocompatibility.

TECAPEEK MT (PEEK)

- Very good chemical resistance
- Excellent level of resistance to customary methods of sterilization
- Good radiation resistance
- High stress crack resistance
- Good dimensional stability and easy machining properties
- Excellent tribological properties
- Good electrical insulation even under high voltages (does not apply to TECAPEEK MT black)

TECAPEEK CF30 MT (PEEK)

- Very high rigidity and creep strength
- Excellent thermal dimensional stability
- Excellent chemical resistance
- Extremely wear resistant
- Excellent dimensional stability
- Physiological harmlessness
- Good sterilization capability

TECATRON MT (PPS)

- Very good chemical resistance
- Good radiation resistance
- Very good thermal and mechanical properties
- Long-term service temperature up to 230 °C
- Extreme hardness and rigidity
- High dimensional stability and low creep tendency

TECASON P MT (PPSU)

- Extremely good resistance to customary methods of sterilization
- High level of thermal resistance: Long-term service temperature up to 170 °C
- Highly impact resistant, hard and rigid
- Very good electrical insulation (does not apply to TECASON P MT black)
- Low water absorption
- Modification possible for visibility under X-rays

TECAPEI MT (PEI)

- Excellent sterilization resistance
- Permeable to high-frequency electromagnetic waves
- Good thermal and mechanical properties
- Long-term service temperature up to 170 °C
- Good dimensional stability
- Available in a variety of colours

TECANYL MT (PPE)

- Resistant to cleaning agents and disinfectants, hydrolysis and hot steam
- Low density for lighter-weight parts
- Good chemical resistance
- High impact strength
- Available in a variety of colours

TECAFORM AH MT (POM-C)

- Good chemical resistance
- Good electrical insulation (does not apply to TECAFORM AH MT black)
- Very good sliding and abrasion properties
- Rigid, strong and hard
- Easy to machine
- Available in a variety of colours

TECAPRO MT (PP)

- Resistant to cleaning agents and disinfectants, hydrolysis and steam
- Heat stabilization results in improved resistance to sterilization and low warping tendency
- Minimal moisture absorption
- Good sliding properties
- Easy to machine

Many colours for freedom in design

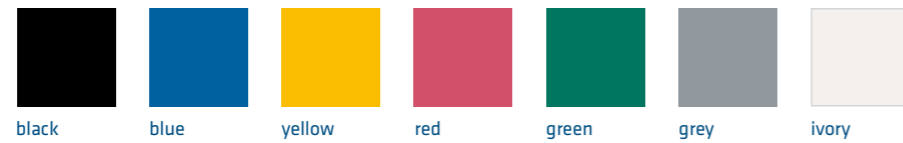
TECAPEEK MT (PEEK)

Standard colours:



TECASON P MT (PPSU)

Standard colours:



Special colours:



TECANYL MT (PPE)

Standard colours:

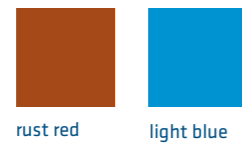


TECAFORM AH MT (POM-C)

Standard colours:

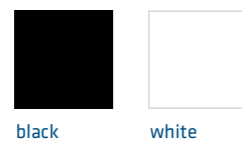


Special colours:



TECAPRO MT (PP)

Standard colours:



Special colours:



The colour fields are only for comparison. We cannot guarantee a colour shade. Dimensions and more information about MT-materials may be found in our stock shapes catalogue.

XRO materials

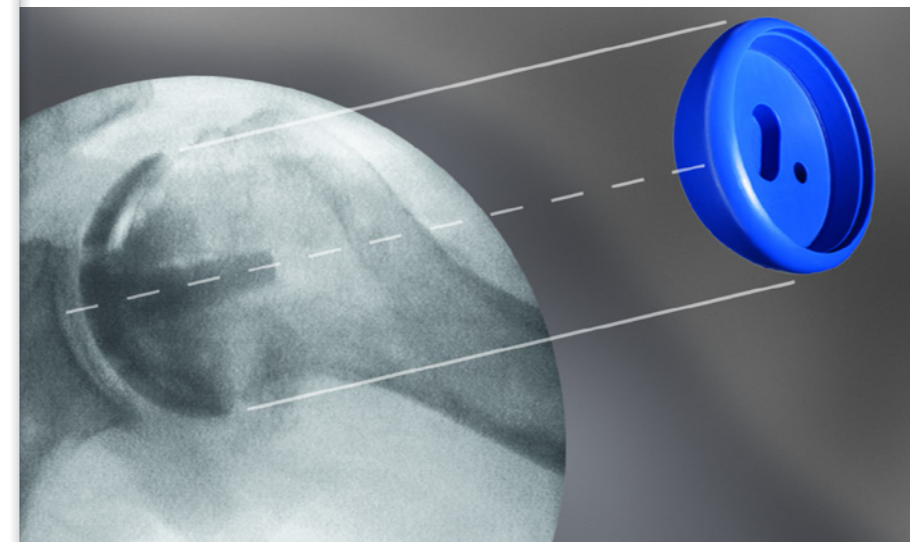
Good visibility in fluoroscopy and radiography

With its X-ray opaque XRO materials, Ensinger meets the challenging demands of minimally invasive and image-controlled surgery. A contrast medium added to the standard product line permits clear visibility of components under fluoroscopy and X-ray radiation. It provides the surgeon with a precise picture of his or her instruments or of orthopaedic test implants during image-controlled procedures.

Available materials:

- TECAPEEK MT XRO (PEEK)
- TECASON P MT XRO (PPSU)

All the listed products have been tested in line with the requirements of ISO 10993 for medical products coming into contact with bodily fluids, bone substance and dentin for up to 24 hours.



Properties

- X-ray impermeable
- Raw material and colour additives are biocompatible
- Resistant to cleaning agents, disinfectants and different solvents
- Resistant to repeated steam autoclaving
- High level of resistance to gamma radiation
- Good hydrolysis resistance
- Excellent dimensional stability, very hard and rigid
- High thermal stability and outstanding mechanical characteristics
- High impact strength and notched impact strength
- Low water absorption
- Very good electrical insulation

Key facts at a glance

Our X-ray opaque XRO plastics allow a precise view of instruments or orthopaedic test implants during image-controlled surgical procedures.

PEEK grades

The fields of application for PEEK grades are many and varied, ranging in the field of medical technology from the FDA conforming material TECAPEEK to PEEK OPTIMA for long-term implants from Invibio® Biomaterial Solutions. In step with the ever more stringent demands imposed on the materials, the level of responsibility and the associated risk for suppliers are also on the increase.

TECAPEEK is characterized by its excellent mechanical properties even under high temperatures. Their FDA conformity makes these products the ideal choice for devices and instruments used in medical technology which do not come into direct contact with blood or tissue. Applications include pumps, housings and dialysis accessories.

Because of its extreme resistance to chemicals and sterilization processes and its ISO 10993 compliance, TECAPEEK MT is suitable for short-term contact with blood or tissue for periods of up to 24 hours. Applications here include, for example, surgical instruments or components for endoscopes.

TECAPEEK CLASSIX™ is used within the Ensinger product range to address the most stringent demands imposed on long-term blood and tissue contact for up to 30 days. This permits the efficient and cost-effective use of components such as catheters or temporary implants in the field of dentistry. On request, the contact period can be extended to up to 180 days.

In case of long-term contact or for implantable products, the material PEEK OPTIMA from Invibio® must be used.



Fields of application for PEEK materials

Equipment	Analysis	Instruments	„Delivery systems“	Long-term implants
<ul style="list-style-type: none"> → Pumps → Housings → Motors → Sterilization equipment 	<ul style="list-style-type: none"> → Chromatography components → Chemicals-contact → Biohazard handling 	<ul style="list-style-type: none"> → Laparoscopy → Handles → Surgical tools → Endoscopy 	<ul style="list-style-type: none"> → Stents → Contact with medicines → Contact with blood (dialysis) → Temporary implants in the field of dentistry 	<ul style="list-style-type: none"> → Orthopaedics → Dental medicine → Neurology → Pharmacy
<p>TECAPEEK</p> <p>FDA conformity, not suitable for direct contact with blood or tissue</p>		<p>TECAPEEK MT</p> <p>ISO 10993 tested, contact: short periods (≤24 hrs.)</p>	<p>TECAPEEK CLASSIX™</p> <p>USP VI conformity, batch-by-batch testing to ISO 10993-5 on raw materials and stock shapes.</p> <p>Contact: Long-term (≤ 30 days) with scope to increase to 180 days (via Invibio®)</p>	<p>PEEK-OPTIMA®</p> <p>For long-term implants, sale only through Invibio®</p>

Increasing risk and responsibility for suppliers

Key facts at a glance

Whether FDA conforming TECAPEEK or TECAPEEK MT and TECAPEEK CLASSIX™ for direct contact with blood and tissue - Ensinger offers just the right product for every application.

TECAPEEK CLASSIX™ (PEEK)

High-performance biocompatible plastic for extended contact with blood and tissue

TECAPEEK CLASSIX™ is a high-performance biocompatible material developed for applications in dentistry and medical technology with blood and tissue contact.

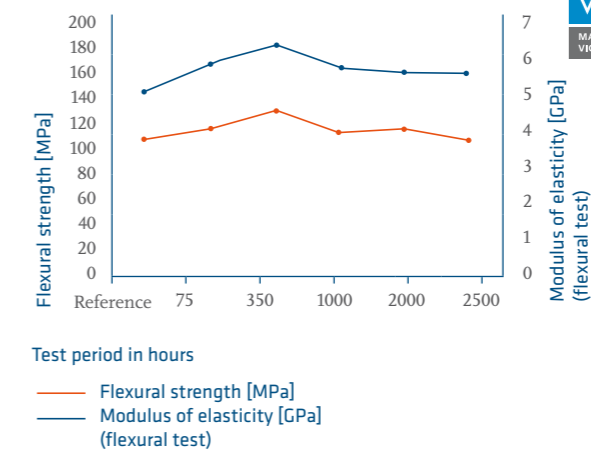
→ For medical applications, it is suitable for contact with tissue for up to 30 days. In dentistry applications, blood and tissue contact can be extended to as much as 180 days on request.

→ FDA conformity and biocompatibility in accordance with USP class VI. Raw material and stock shapes are tested on a batch-by-batch basis for cytotoxicity in accordance with ISO 10993-5.

Properties

- Extreme hydrolysis resistance, even at high temperatures. Repeat sterilization capability using conventional methods
- Outstanding chemical resistance
- Particularly successful combination of strength, rigidity, toughness and hardness
- Excellent abrasion resistance and impact strength
- Standard colour cream white

Extreme hydrolysis resistance: Mechanical properties of TECAPEEK CLASSIX™ under different periods of exposure (hot steam at 200 °C and 14 bar pressure).



Dental healing cap
TECAPEEK CLASSIX™

Key facts at a glance

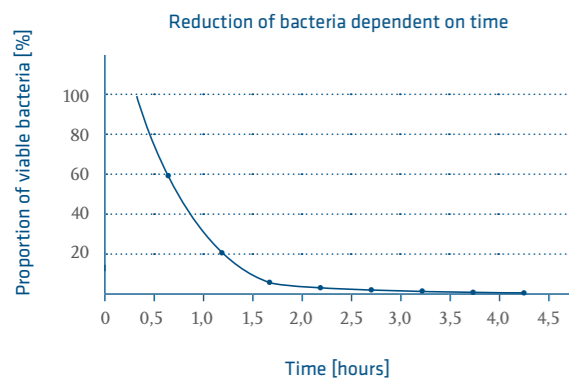
TECAPEEK CLASSIX™ is a high-performance biocompatible material capable of addressing applications in dentistry and medical technology involving blood and tissue contact of up to 30 days / 180 days.

SAN materials

Safety for medical technology

SAN materials from Ensinger offer additional safety through their antimicrobial effect. This effect is based on the continuous release of biocides to the surface of the plastic component. This supplements the necessary mechanical and chemical cleaning steps by an additional safety stage. The antimicrobial effect of Ensinger SAN materials depends heavily on other processing operations and fields of application of the final product. The use of production techniques and production additives, as well as the component geometry and surface can impact on the effectiveness of SAN materials. Every customer is therefore responsible for testing its own finished product to determine the extent to which antimicrobial effects are still present. We are unable to issue any guarantees of this. Our semi-finished products have been positively tested in compliance with the ISO 22196:2007 standard. Before testing, the extrusion skin was removed from the semi-finished test specimen.

Typical performance of antimicrobial surfaces on bacteria



Key facts at a glance

The antimicrobial effect of our SAN materials is designed to supplement mechanical and chemical cleaning processes in medical technology by an additional safety stage.

The following materials are currently equipped with antimicrobial properties as standard:

- TECAFORM AH SAN (POM-C)
- TECAPRO SAN (PP)

Properties

- Higher degree of material purity
 - Due to reduced bacterial contamination during downtimes
 - Decreased formation of biological films on the material surface
 - Decreased formation of bacteria accumulation in critical machine geometries (corners, hollows etc.)
- Even distribution of the active substance over the material surface
- Cleaning or low surface abrasion results in continuous renewal of antimicrobial effect
- Harmless to humans as the active substance is neither toxic nor does it migrate; no degradation into toxic substances takes place
- No thermal damage to the active substance takes place in the temperature range of normal applications

Notes

It is not possible to dispense with necessary and customary cleaning measures. Extreme chemical contamination can result in impaired action of the antimicrobial surfaces.

SAN materials are generally active against a wide spectrum of micro-organisms (bacteria, fungi, algae, viruses). However, they must still be tested for the specific application.

TECATEC™

Thermoplastic composites with excellent strength

Components made from the highly-filled carbon fibre composite material TECATEC™ are characterized by an extraordinary degree of mechanical strength and high thermal dimensional stability.

Stock shapes made using the new product range comprise a thermoplastic matrix and a woven fabric of carbon fibre bundles. This combination ensures significantly higher tensile and flexural strength compared to fibre-reinforced extruded materials. These lightweight composites offer good chemical resistance and are also permeable for X-rays, making them ideal for use in medical applications.

The matrix polymer used in TECATEC™ PEEK CW50 is Victrex® PEEK™, which is compressed with woven carbon fabric mats. A special coating on the fabric reduces the number of faults. The carbon fibre component of 50 per cent offers very high torsional rigidity.



Target arm
TECATEC PEEK CW50
Courtesy Stryker Trauma GmbH

Even after multiple sterilization processes, the material has a very low tendency to warp, resulting in a long service life of components.

TECATEC™ PEKK CW60 comprises a polyetherketoneketone matrix (PEKK), compressed with carbon fibre fabric. The manufacturing process achieves excellent fibre and matrix integration. Because of its high glass transition point (165 °C), PEKK is highly resistant to repeated autoclave cycles, and its enhanced carbon fibre component (60%) ensures optimum dimensional stability and rigidity.

Properties

- Outstanding strength
- Excellent thermal dimensional stability
- Good dimensional stability
- Low water absorption
- Corrosion resistance
- Excellent chemical resistance
- Excellent resistance to hot steam autoclaving
- Physiologically harmless

Fields of application

- Medical technology (surgery, orthopaedics)

Applications

- Targeting arms used in medical technology
- External fixing aids
- Structural elements

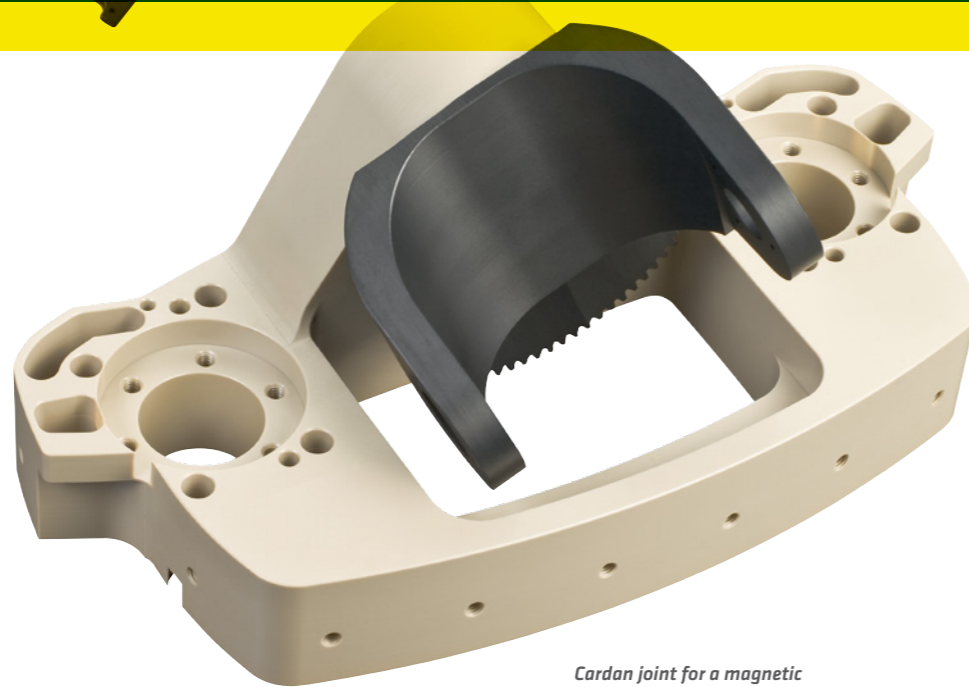
Application examples



Storage container
TECAPRO MT (PP)
High strength.
Sterilization resistant.
Minimal weight.



Trial knee implant
TECASON P MT green
(PPSU)
Resistant to steam sterilisation.
Biocompatible.



**Cardan joint for a magnetic
resonance tomography machine**
TECAPEEK MT/TECAPEEK PVX
(PEEK/PEEK CF CS TF)
Self-lubricating.
High rigidity.
Good power transmission.



Trial hip implant
TECAFORM AH MT
(POM-C)
Resistant to steam sterilisation.
Biocompatible.

Chemical resistance

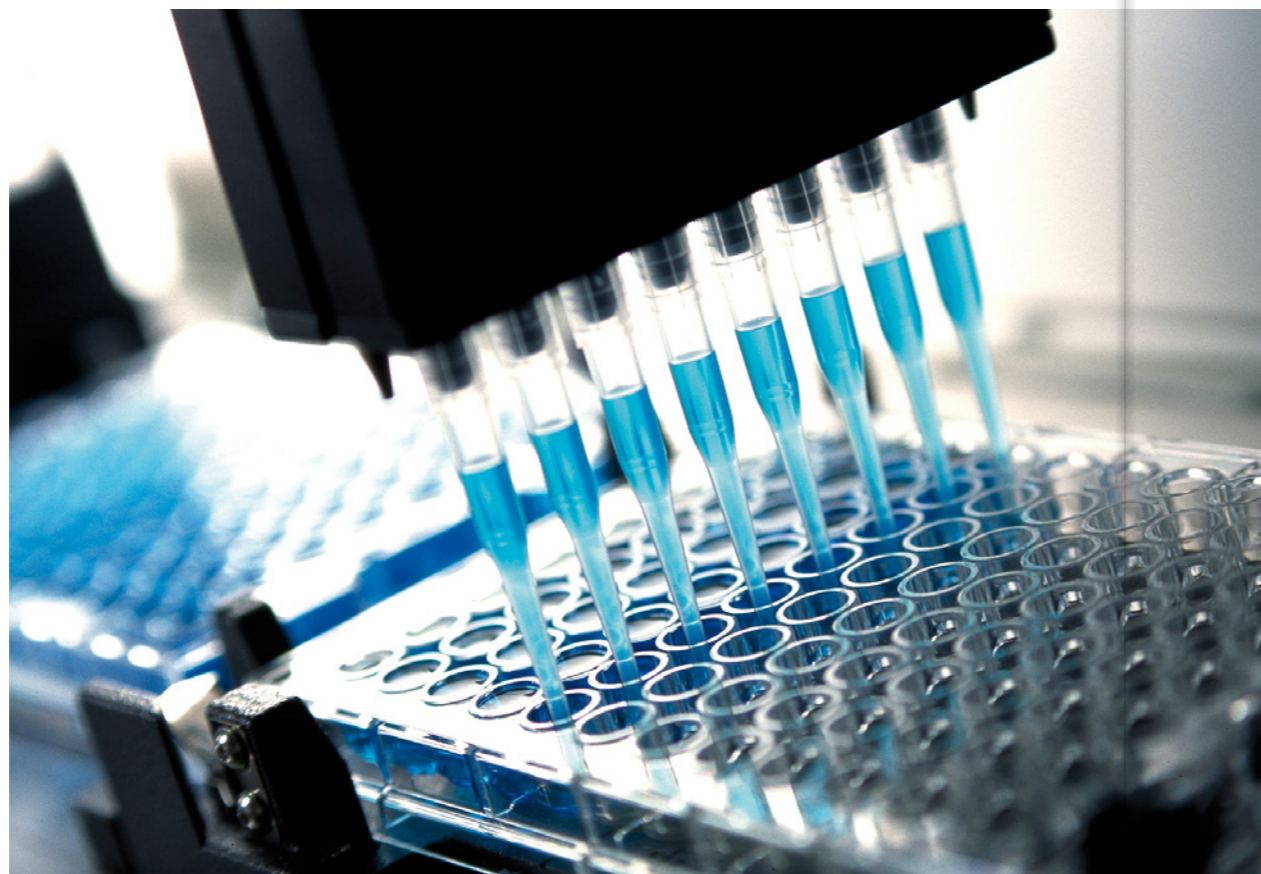
Consequently, temperature, the concentration of agents, exposure periods and also mechanical load are all important criteria when testing for chemical resistance. The following table lists resistance to different chemicals. This information is provided to the best of our current knowledge and is designed to provide data about our products and their applications. Consequently it is not intended to provide any

legally binding assurance or guarantee of the chemical resistance of our products or their suitability for a concrete application. For a more concrete application, we recommend producing your own verification. Standard tests are performed under normal climatic conditions 23/50 in accordance with DIN 50 014.

	TECAPEEK MT (PEEK)	TECATRON MT (PPS)	TECASON P MT (PPSU)	TECAPEI MT (PEI)	TECANYL MT (PPE)	TECAFORM AH MT (POM-C)	TECAPRO MT (PP)	TECANAT (PC)
Acids - weak	+	+	+	+	+	+	+	(+)
Acids - strong	(+)	+	(+)	(+)	(+)	(+)	(+)	-
Alkalis - weak	+	+	+	-	+	+	+	-
Alkalis - strong	+	+		-		-	+	-
Solvents - alcohol	+	+	+	+		+	+	(+)
Solvents - ester	+	+				(+)	(+)	-
Solvents - ether	+	+				(+)	(+)	-
Ketone	+	+	-	-		(+)	(+)	-
Water - cold	+	+	+	+	+	+	+	+
Water - hot	+	+	+	+	+	+	+	(+)

+ = resistant
(+) = limited resistance
- = not resistant

A comprehensive overview of the chemical resistance of our products is provided at www.ensinger-online.com



Sterilization resistance levels

Resistance to sterilization

The deliberate sterilization of devices and components made of plastic is designed to destroy as far as possible all living micro-organisms such as bacteria, viruses, algae and their spores.

Steam

In accordance with DIN EN 285, all surfaces of the objects being sterilized must be exposed to pure saturated water vapour at 134 °C for at least three minutes. Steam sterilization or autoclaving is regarded as the safest and cheapest of all the sterilization methods. However, the high process temperatures involved make it less suitable for materials sensitive to heat and hydrolysis.

Hot air

With hot-air sterilization, germs are killed off by means of dry heat under high thermal load (180 °C) over a period of at least 30 minutes. This process is no longer permissible due to a large number of uncertainty factors, and has therefore been replaced in most cases today by other methods.

Plasma

Sterilization with hydrogen-peroxide plasma is suitable for all plastics, but it is costly and requires elaborate equipment. Highly reactive hydroxy and hydroxyl radicals kill off the micro-organisms at temperatures of only 45 °C over periods of 45 to 80 minutes; the plasma is removed by ventilation. The risk of corrosion is almost non-existent, and there is no toxic residue that would require prolonged degassing.

Formaldehyde and ethylene oxide

Sterilization by means of a microbicidal gas such as formaldehyde or ethylene oxide is always carried out at temperatures between 48 and 60 °C. Because of the low temperatures, this process is suitable for temperature-sensitive materials. The efficiency of formaldehyde is comparable with that of ethylene oxide, but its lower toxicity permits shorter degassing times. Both are mainly used for disposable articles.

Sterilization by radiation

Sterilization by radiation is a gentle method which is suitable for almost all types of plastic, and uses either gamma rays or a beam of greatly accelerated electrons. These processes are cost and equipment intensive, so they are mainly used for the sterilization of disposable products on an industrial scale.

	TECAPEEK CLASSIX™ (PEEK)	TECAPEEK MT, CF30 MT (PEEK)	TECATRON MT (PPS)	TECASON P MT, P VF (PPSU)	TECAPEI MT (PEI)	TECANYL MT (PPE)	TECAFORM AH MT (POM-C)	TECAPRO MT (PP)	TECAFLON PTFE (PTFE)	TECASON E (PES)	TECASON S (PSU)	TECAFLON PVDF (PVDF)	TECANAT (PC)	TECAPET (PET)
Steam (134 °C)	++	++	++	+	+	+	(+)	(+)	++	+	+	+	-	-
Hot air (appr. 180 °C)	++	++	++	+	+	-	-	-	++	+	(+)	-	-	-
Plasma	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Formaldehyde	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Ethylene oxide	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Gamma radiation	++	++	++	+	+	+	-	-	-	+	+	+	+	+

++ = very resistant (practically no or very low change of weight)
+ = resistant (low change of weight possible)
(+) = limited resistance (short contact with medium weight change possible)
- = no resistance (weight changes > 5%, strong decline in mechanical properties)

Quality management

Certification

EN ISO 13485

The demands placed on quality management systems for medical technology are specified by ISO 13485. This international standard describes both the supply of medical devices as well as the associated services. A primary aim is the harmonization of legal requirements for the quality management systems of medical devices.

In doing so, Ensinger not only satisfies the legal requirements, but the customer also has the assurance of a certified quality management system.

The following Ensinger divisions are certified according to ISO 13485:

- Stock shapes
- Injection moulding
- Industrial profiles
- Compounding
- Machining

Medical quality management

All MT materials in stock are produced using a prescribed formulation. This provides the guarantee that the material you receive for your medical application is always identical, comparable and approved. Our Quality Management System conforming to ISO 13485 allows us to ensure that all requirements imposed on this type of material for medical applications are adhered to, monitored and documented. Consequently, a change history is documented for each MT product. In addition, this ensures that the biocompatibility tests are performed on semi-finished products at regular intervals or after every change in the formulation or any other significant changes to the production sequence.

Packaging

The packaging for medical products is an important aspect to protect the product from corrosion, contamination and damage. The product should be protected from high air humidity, dust and dirt, extremes of temperature and direct sunlight during transportation and storage at Ensinger or on the customer's premises. Depending on the customer's requirements this is provided by using film or sleeve packaging. They can be adapted flexibly to the product, to some extent even shrunk or used in multiple layers. The product can be cleaned or washed and sterilised as required.

Certification

Experienced quality management is also reflected in a seamless system of traceability. This principle is particularly significant in the fields of medicine and pharmaceutical technology. By ensuring consistent documentation of individual process steps, seamless product traceability is assured at Ensinger. To secure this, Ensinger only issues certificates of conformity on an individual order-specific basis. This establishes a direct link between the certificate and the delivered goods.

This minimizes the risk that non-standard production materials which are not in conformity with biocompatibility requirements could unintentionally be certified and so gain access to the market.

Traceability

Due to product coding and statements of conformity Ensinger has direct traceability of the delivered semifinished product.

1 Invoice / delivery note

The order and invoice number is shown on the invoice / delivery note, for semi-finished products the batch number is also shown on the delivery note. This allows goods to be traced back using these numbers. A certificate to ISO 10204 is issued on an order-specific basis.

2 Semi-finished products

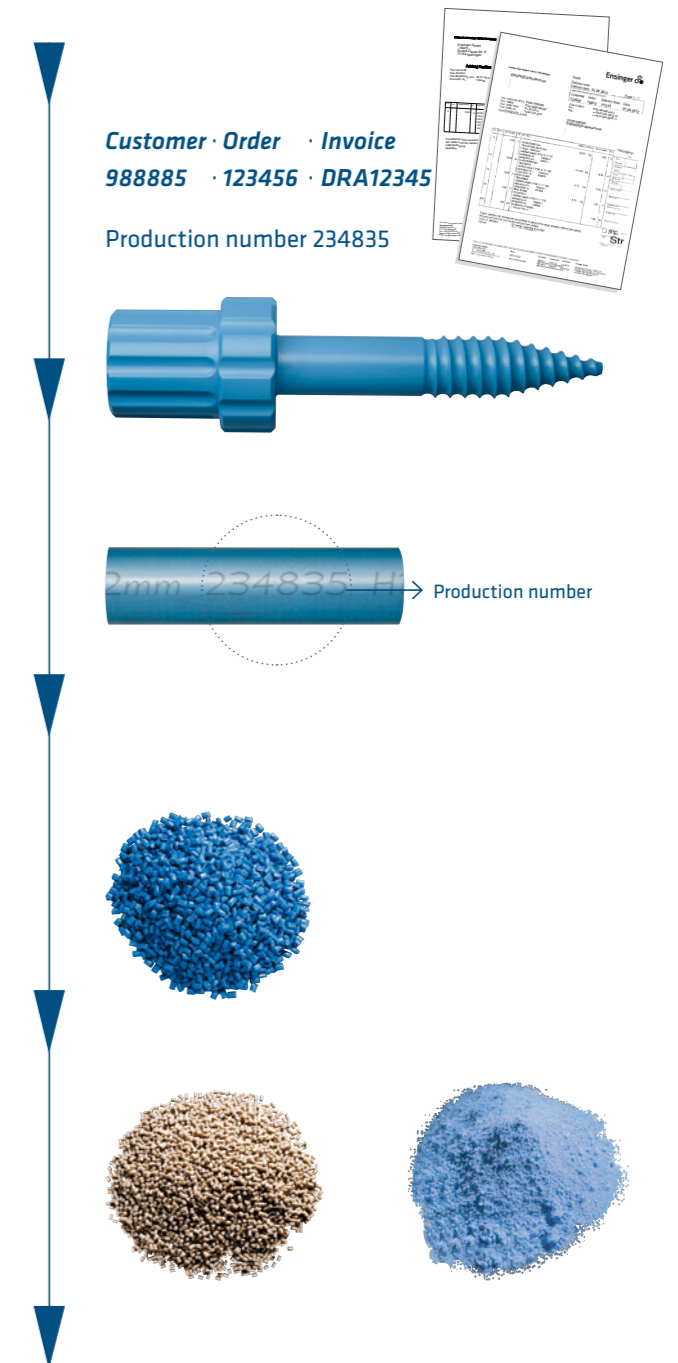
The production and manufacturing number is located on the semi-finished product. Starting with the production or manufacturing number data from the production process can be traced (production data, production protocol, control cards).

3 Compounds

The lot number of the compound can be determined from the production / manufacturing number of the semi-finished product.

4 Raw materials

The lot number of the compound is traceable back to the formulation and so to the delivered raw material batch, the relevant raw material specification and the safety data sheet.



Key facts at a glance

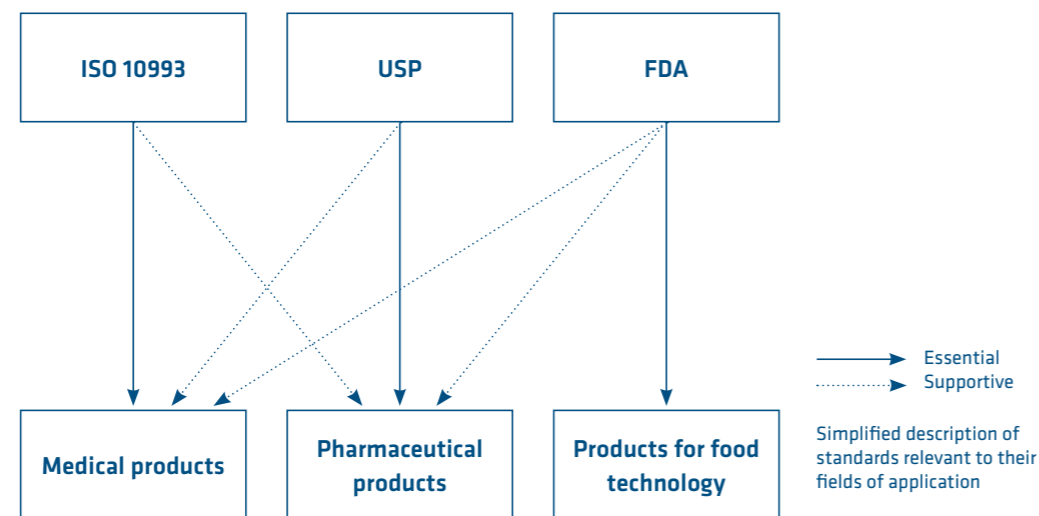
Ensinger secures foolproof traceability from the delivery note to the raw material

Regulations

Biocompatibility

Biocompatibility is the measure of the compatibility of a material with the tissue or physiological system of the patient. It provides information on whether a plastic or its degradation products give off toxic products or provoke an allergic reaction. In principle, the function of both ISO 10993 and USP is to verify the biological qualification of a material or product. As

FDA assessments can also provide information on the compatibility of a material, this information is frequently requested. Depending on the product in question and the field of application, the following standards are determining factors or can provide valuable assistance in evaluating a product or material.



ISO 10993

The international standard ISO 10993 is of relevance particularly to manufacturers of medical products and test laboratories, and is now the acknowledged guideline for medical products. The aim of this standard is to evaluate the materials used in terms of their suitability for direct body contact. The described strategy for biological qualification applies initially to medical products, but can also be used for evaluation and assessment of their pre-products (such as plastic semi-finished products). This allows the material to be pre-qualified before its use in a medical product, reducing the risks entailed in subsequent application.

For biological-toxicological assessment of medical products in compliance with ISO 10993-1, it makes sense to start with a product categorization to determine the hazard level and the requirement profile for the material in the relevant medical application. The available toxicological data relating to the used material is then checked in order to analyse and evaluate the possible biological effects in a step by step process. On the basis of the results, a decision is then taken as to which toxicological tests are necessary for a final evaluation and whether an alternative material may have to be used.

Alongside the description of biological-toxicological tests, since 2003 the ISO 10993 standard has also included physical-chemical tests for the identification of potentially toxic and allergenic materials or substances. In concrete terms, the ISO 10993 standard is subdivided into sections 1-20 from the preparation of samples and evaluation of tests through the chemical characterization of materials to immunotoxicological tests. The requirements imposed on the biological qualification of medical products in accordance with ISO 10993 depend not only on the type of medical product, but at the same time also

- on the place of use
(skin, mucous membrane, blood, tissue)
- on the intended function
(contact with body surfaces, internal body contact, implantable product) and
- on the period of use
(< 24 hours, < 30 days, unlimited)

USP

The United States Pharmacopeia Convention (USP) is an organization for the evaluation of packaging used for pharmaceutical products. It compiles with standards relating to quality, purity and identity, and checks products manufactured world wide and generally sold, consumed or used in the USA. The USP is a fundamental requirement specifically for pharmaceutical products and their manufacturing technologies. However, for medical products, the role of the USP is only to provide a supportive statement for qualification. Statements on the biological risk assessment of a material in accordance with USP tests can be derived from alternative tests in compliance with ISO 10993. This leads to a situation where, in the case of new developments in particular, the USP has been increasingly superceded by the ISO 10993 in recent years.

The USP <87> and <88> can be consulted for the assessment of components / products made of plastic. USP <87> describes the cytotoxicity test which does, however, differ in certain details from the ISO 10993-5. The USP

<88> divides products into categories I-VI, whereby the products of category VI have to comply with the most stringent requirements and consequently have to complete extensive testing. This so-called "in-vivo screening" for the fundamental assessment of the biocompatibility of a plastic are used to test acute systemic toxicity, irritation and also includes a short-term implant test.

FDA-compliance

Alongside the evaluation of a material's suitability for contact with food, FDA compliance is frequently also used in the field of medical technology to provide users with important information on risk assessment. However, it is not a binding requirement for the use of materials in the medical or pharmaceutical field. The American Food and Drug Administration (FDA) assesses the suitability of materials for direct and indirect contact with food. Raw materials, additives and properties of plastics are specified by the FDA in the "Code of Federal Regulations" CFR 21. Materials that meet the relevant requirements are regarded as FDA compliant. A FDA-compliant formulation is valid without time limitation, as long as the raw materials are not changed. For this reason, only the manufacturer of a product may issue this FDA certificate, as only he/she knows the formulation and can guarantee that FDA-compliant raw materials are used. As raw materials for use in the medical sector mostly comply with the requirements of the FDA, this can be certified accordingly on an order-by-order basis in order to guarantee seamless traceability.

Procedure to assess the biocompatibility of semi-finished products

By definition, semi-finished products are not medical or pharmaceutical products, but pre-products used in their production. As there is consequently no standardized requirement to evaluate the biological suitability of semi-finished products, Ensinger has made its own selection from the wide spectrum of different biocompatibility tests contained in ISO 10993 and USP. This is intended to provide our customers with the greatest possible support in the approval process for their medical or pharmaceutical end products. For this reason, Ensinger subjects its stocked MT semi-finished products intended for use in medical products which are suitable for a contact period of <24h to regular combined tests: Cytotoxicity / growth inhibition (ISO 10993-5), hemolysis (ISO 10993-4), chemical analysis / "fingerprinting" (ISO 10993-18) and their biological-toxicological evaluation (ISO 10993-1) and so follows the recommendations of ISO 10993-1 in respect of step-by-step biological qualification.

By means of in-vitro tests for cytotoxicity (ISO 10993-5) and hemolysis (ISO 10993-4) steps are taken to ensure that the products demonstrate sufficiently inert properties in contact with blood and tissue, and have a defined toxicological profile. In this process, the cytotoxicity / growth inhibition test, which is regarded as the standard test and basic biological test for all medical products, represents the basis for toxicological evaluation of the material. Through the use of cell cultures, it is possible to verify the presence of toxic substances which could migrate from the material during use in accordance with the intended purpose. This test supplies the information required for the biological compatibility of medical products or the materials used. For plastic materials which could under certain circumstances have come

into contact with a patient's blood, the hemolysis test is performed. Here, the influence of materials and substances which could migrate from the material are evaluated for their compatibility with blood.

In addition, the chemical analyses performed in accordance with ISO 10993-18 identify any organic, soluble substances contained in the product or surface contamination and metallic substances which are subsequently compared to toxicological experience values and assessed. Using these analytical methods it is not only possible to obtain a statement as to whether the material has a biological - toxicological influence, but also to directly identify the cause.

Through the use of modern analytical methods, it is also possible to achieve highly sensitive verification limits, permitting a significantly higher level of product safety in the assessment than is the case with extensive toxicological studies.

In addition, in this way it is possible to bypass the influence exerted by the immune system of an animal, which can exert an impact on the results of a toxicological study. In order to extract even the smallest quantities of harmful substances, the use of solvents is possible for analytical processes which would cause allergic reactions in any animal.

When issuing order-specific certificates, Ensinger indicates additional tests which have also been performed on the relevant raw material. These can vary depending on the raw material concerned and are always checked for their topicality and validity on our suppliers' premises on the basis of the Ensinger Compliance Management system.

Key facts at a glance

Ensinger tests all MT materials in accordance with ISO 10993-1, -4, -5, -18 and follows the step-by-step approach stipulated in the standard for biological risk assessment, so avoiding unnecessary animal testing.

Frequently asked questions

What does biocompatible mean?

Biocompatibility is the measure of the compatibility of a material with the tissue or physiological system of the patient. It provides information on whether a plastic or its degradation products gives off toxic products or provokes an allergic reaction.

Which biocompatibility tests are necessary on semi-finished products for my application?

Generally speaking, no biocompatibility tests are required on semi-finished products for an application, as the finished components have to be tested and approved at the end of all the processing steps. However, qualification of semi-finished products does provide an aid to ensuring product quality and subsequent approval of the final medical product.

Can I use MT materials from Ensinger as implants?

These materials are not generally speaking suitable for use as long-term implants. In principle, all MT materials from the Ensinger portfolio are approved for direct body contact for up to 24 hours. One exception to this is the material TECAPEEK CLASSIX™, which is approved for direct body contact as a temporary implant for up to 30 days or 180 days.

Are MT materials produced by Ensinger completely traceable?

Using a coding system for its semi-finished products and by means of order-specific certificates, Ensinger ensures the capture and documentation of all product and process data and consequently traceability back to the original material. In this process, all integrated procedures are included - from the raw material to the used finished part. In the unlikely case of a claim, this allows the possible fault to be quickly localized.

What does the suffix "similar to RAL" mean in connection with the colour designation?

By processing the plastic materials to create semi-finished products, it is not possible to directly match specific RAL colours. Certain deviations can occur for production-related reasons. For this reason, it is only possible to provide a colour indication which is similar to RAL.

The information relating to chemical resistance and sterilization resistance is only provided in the form of a relative value. What does this mean for me?

It is not possible to provide a definitive statement on resistance to chemicals and to sterilization. The information provided relating to resistance refers to test results and can differ depending on application conditions. To determine the definitive suitability of a material, practically based tests must be carried out.

Does the coding ink exert an influence on the physiological properties of a plastic?

Semi-finished products marked with coding ink have been tested in accordance with ISO 10993-5. During this testing process, all inks used are tested. The results show that all sections comply with the requirements of ISO 10993-5 and are consequently physiologically harmless.

Why are MT materials specially packaged?

Semi-finished products suitable for medical use are welded into transparent film and so protected from contamination and dirt - from the moment they leave the production line through storage to transport and arrival on your premises. This eliminates the need for labour-intensive cleaning of semi-finished products. In addition, the film comes with a handy perforation which makes it particularly easy to open.

Do you have any other questions?

Please do not hesitate to contact our technical application advice service: techservice.shapes@de.ensinger-online.com or by telephone on +49 7032 819 101

Material standard values

Material		TECAPEEK CF30 MT	TECAPEEK MT	TECAPEEK MT black	TECAPEEK MT yellow	TECAPEEK MT bright red	TECAPEEK MT green	TECAPEEK MT blue	TECAPEEK MT ivory	TECASON P MT black	TECASON P MT coloured
Polymer		PEEK	PEEK	PEEK	PEEK	PEEK	PEEK	PEEK	PEEK	PPSU	PPSU
Fillers		carbon fibres									
Density (DIN EN ISO 1183)	[g / cm ³]	1,42	1,31	1,31	1,38	1,36	1,32	1,34	1,42	1,31	1,31
Mechanical properties											
Modulus of elasticity (tensile test) (DIN EN ISO 527-2)	[MPa]	6000	4200	4200	4400	4200	4100	4300	4400	2300	2300
Tensile strength (DIN EN ISO 527-2)	[MPa]	115	116	114	113	108	116	113	114	81	81
Tensile strength at yield (DIN EN ISO 527-2)	[MPa]	115	116	114	113	108	116	113	114	81	81
Elongation at yield (DIN EN ISO 527-2)	[%]	5	5	5	5	4	5	5	4	7	7
Elongation at break (DIN EN ISO 527-2)	[%]	5	15	13	10	6	17	11	12	50	50
Modulus of elasticity (flexural test) (DIN EN ISO 178)	[MPa]	6000	4200	4100	4300	4500	4200	4300	4400	2300	2300
Flexural strength (DIN EN ISO 178)	[MPa]	188	175	171	169	177	172	173	171	107	107
Compression modulus (EN ISO 604)	[MPa]	4500	3400	3400	3400	3500	3400	3400	3400	2000	2000
Compressive strength (1% / 2%) (EN ISO 604)	[MPa]	23 / 44	23 / 43	23 / 44	17 / 35	22 / 40	17 / 35	17 / 35	24 / 44	18 / 30	18 / 30
Impact strength (Charpy) (DIN EN ISO 179-1eU)	[kJ / m ²]	58	n.b.	n.b.	n.b.	50	n.b.	n.b.	n.b.	n.b.	n.b.
Notched impact strength (Charpy) (DIN EN ISO 179-1eA)	[kJ / m ²]		4	5	5		4	7	4	13	13
Ball indentation hardness (ISO 2039-1)	[MPa]	318	253	243	257	244	250	248	250	143	143
Thermal properties											
Glass transition temperature (DIN 53765)	[°C]	146	150	151	151	151	151	151	150	218	218
Melting temperature (DIN 53765)	[°C]	341	342	341	341	341	341	341	340	n.a.	n.a.
Service temperature, short term	[°C]	300	300	300	300	300	300	300	300	190	190
Service temperature, long term	[°C]	260	260	260	260	260	260	260	260	170	170
Thermal expansion (CLTE), 23 - 60 °C (DIN EN ISO 11359-1;2)	[10 ⁻⁵ K ⁻¹]	5	5	5	5	5	5	5	5	6	6
Thermal expansion (CLTE), 23 - 100 °C (DIN EN ISO 11359-1;2)	[10 ⁻⁵ K ⁻¹]	5	5	5	5	5	5	5	5	6	6
Specific heat (ISO 22007-4:2008)	[J / (g*K)]	1,7	1,1	1,1	1,1	1,1	1,1	1,1	1,1	1,1	1,1
Thermal conductivity (ISO 22007-4:2008)	[W / (m*K)]	0,59	0,27	0,3	0,28	0,27	0,28	0,28		0,25	0,25
Electrical properties											
Specific surface resistance (DIN IEC 60093)	[Ω]	10 ² -10 ¹⁰	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴
Surface resistance (DIN IEC 60093)	[Ω*cm]	10 ³ -10 ^{11(e)}	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴
Miscellaneous data											
Water absorption 24h / 96h (23 °C) (DIN EN ISO 62)	[%]	0.02 / 0.03	0.02 / 0.03	0.02 / 0.03	0.02 / 0.03	0.02 / 0.03	0.02 / 0.03	0.02 / 0.03	0.02 / 0.03	0.1 / 0.2	0.1 / 0.2
Resistance to hot water / bases		+	+	+	+	+	+	+	+	+	+
Resistance to weathering		-	-	-	-	-	-	-	-	(+)	-
Flammability (UL94) (DIN IEC 60695-11-10;)		VO(f)	VO(f)	VO(f)	VO(f)	VO(f)	VO(f)	VO(f)	VO(f)	VO(f)	VO(f)

Data generated directly after machining (standard climate Germany). For polyamides the values strongly depend on the humidity content.



Test specimen to DIN EN ISO 527-2

- + good resistance
- (+) limited resistance
- poor resistance (depending on concentration, time and temperature)
- n.b. not broken
- n.a. not applicable

- (a) Glass transition temperature testing according to DIN EN ISO 11357
- (b) Thermal conductivity testing according to ISO 8302
- (c) Thermal conductivity testing according to ASTM E1530
- (d) Surface resistance testing according to ASTM D 257
- (e) Surface resistance testing according to DIN EN 61340-2-3
- (f) No listing at UL (yellow card). The information might be taken from resin, stock shape or estimation. Individual testing regarding application conditions is mandatory.

Material		TECAFORM AH MT black	TECAFORM AH MT coloured	TECAPRO MT white	TECAPRO MT black	TECANYL MT black	TECANYL MT coloured	TECANAT MT	TECATEC PEEK CW50	TECATEC PEKK CW60
Polymer		POM-C	POM-C	PP	PP	PPE	PPE	PC	PEEK	PEKK
Fillers				heat stabilized	heat stabilized					
Density (DIN EN ISO 1183)	[g / cm ³]	1,41	1,41	0,93	0,92	1,05	1,08	1,19	1,49	1,61
Mechanical properties										
Modulus of elasticity (tensile test) (DIN EN ISO 527-2)	[MPa]	2800	2800	2000	2000	2400	2400	2200	53200	54300
Tensile strength (DIN EN ISO 527-2)	[MPa]	69	69	34	37	65	65	69	491	585
Tensile strength at yield (DIN EN ISO 527-2)	[MPa]	70	70	34	37	67	67	69		
Elongation at yield (DIN EN ISO 527-2)	[%]	15	15	5	5	4	4	6		
Elongation at break (DIN EN ISO 527-2)	[%]	30	30	67	34	8	8	90		
Modulus of elasticity (flexural test) (DIN EN ISO 178)	[MPa]	2800	2800	1800	2000	2400	2400	2300	48900	50900
Flexural strength (DIN EN ISO 178)	[MPa]	94	94	54	56	95	95	97	813	960
Compression modulus (EN ISO 604)	[MPa]	2200	2200	1600	1600	2100	2100	2000	4050	5100
Compressive strength (1% / 2%) (EN ISO 604)	[MPa]	18 / 32	18 / 32	16 / 26	16 / 26	17 / 30	17 / 30	16 / 29		51 / 509
Impact strength (Charpy) (DIN EN ISO 179-1eU)	[kJ / m ²]	n.b.	n.b.	140	160	70	70	n.b.		
Notched impact strength (Charpy) (DIN EN ISO 179-1eA)	[kJ / m ²]	9	9	5	5			14		
Ball indentation hardness (ISO 2039-1)	[MPa]	158	158	100	100	140	140	128		
Thermal properties										
Glass transition temperature (DIN 53765)	[°C]	-60	-60	-10	-10	174	171	149	143	165
Melting temperature (DIN 53765)	[°C]	169	169	165	161	n.a.	n.a.	n.a.	343	380
Service temperature, short term	[°C]	140	140	140	140	110	110	140		
Service temperature, long term	[°C]	100	100	100	100	95	95	120	260	260
Thermal expansion (CLTE), 23 - 60 °C (DIN EN ISO 11359-1;2)	[10 ⁻⁵ K ⁻¹]	14	14	14	14	8	8	8		
Thermal expansion (CLTE), 23 - 100 °C (DIN EN ISO 11359-1;2)	[10 ⁻⁵ K ⁻¹]	14	14	14	14	8	8	8		
Specific heat (ISO 22007-4:2008)	[J / (g*K)]	1,4	1,4			1,3	1,3	1,3		
Thermal conductivity (ISO 22007-4:2008)	[W / (m*K)]	0,39	0,39			0,21	0,21	0,25		
Electrical properties										
Specific surface resistance (DIN IEC 60093)	[W]	>10 ¹²	>10 ¹²	10 ¹⁴	10 ¹²	10 ¹⁴	10 ¹⁴	10 ¹⁴		
Surface resistance (DIN IEC 60093)	[W*cm]			10 ¹⁴	10 ¹⁴	10 ¹⁴	10 ¹⁴			
Miscellaneous data										
Water absorption 24h / 96h (23 °C) (DIN EN ISO 62)	[%]	0.05 / 0.1	0.05 / 0.1	0.01 / 0.02	0.01 / 0.02	0.02 / 0.04	0.02 / 0.04	0.03 / 0.06		
Resistance to hot water / bases		(+)	(+)	(+)	(+)	(+)	(+)	-	+	+
Resistance to weathering		-	-	-	(+)	(+)	-	(+)	-	-
Flammability (UL94) (DIN IEC 60695-11-10;)		HB(f)	HB(f)	HB(f)	HB(f)	HB(f)	HB(f)	HB(f)	VO(f)	VO(f)

The corresponding values and information are no minimum or maximum values, but guideline values that can be used primarily for comparison purposes for material selection. These values are within the normal tolerance range of product properties and do not represent guaranteed property values. Therefore they shall not be used for specification purposes. Unless otherwise noted, these values were

determined by tests at reference dimensions (typically rods with diameter 40-60 mm according to DIN EN 15860) on extruded, cast, compression moulded and machined specimens. As the properties depend on the dimensions of the semi-finished products and the orientation in the component (esp. in reinforced grades), the material may not be used without separate testing under individual circumstances.

Data sheet values are subject to periodic review, the most recent update can be found at www.ensinger-online.com

Technical changes reserved.

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Thermoplastic engineering and high performance plastics are used today in all important industries. They often replace other materials due to their economic and power benefits.

