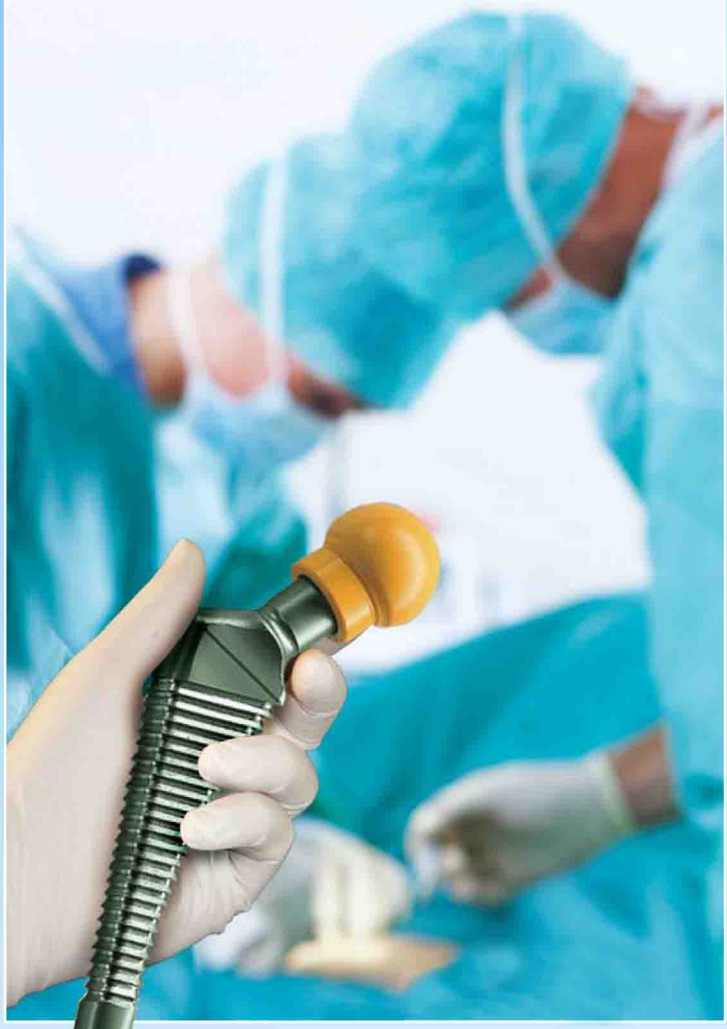
MEDICAL GRADE PLASTICS



INTERSTATE PLASTICS
PLASTICS FOR LIFE

interstateplastics.com

USP 23 Class VI
& ISO 10993
Compliant Plastics

INTERSTATE PLASTICS

PLASTICS FOR LIFE

Interstate Plastics is a full line distributor of sheet, rod, tube, and film. Founded in 1980, we have provided products and services to meet, and exceed, the expectations of our customers. As a **proven industry leader of medical materials**, our experienced sales staff provides solutions for the most complex applications and development projects. We are one of the nation's largest stocking distributors of **Medical Grade** plastics and have extensive training in materials, applications, and certifications.

Interstate Plastics carries a complete line of **Medical Grade** plastics for products such as surgical instruments, diagnostic equipment, orthopedic sizing and trial implants, dialysis units, drug delivery systems, surgical carriers, caddies and trays, dental equipment, instruments, and healing caps. **We stock plastic grades that are FDA, USP class VI, and ISO 10993 approved.** We also offer a variety of plastics with a radio opacifer (XRO) that are x-ray opaque for clear visibility of a component on fluoroscopy and x-rays. This accommodates some of the new challenges created by minimally invasive and image guided surgery.

Interstate Plastics works hand in hand with our manufacturers who can provide the expertise needed to assist engineers, designers, fabricators, and job shops with all their needs. These include help with new or existing materials, applications, specifications, and machining guidelines. We have **complete lot and batch traceability and can provide all test data** including, FDA conformity, biocompatibility, resistance to sterilization, and product thermal, electrical, chemical resistance, and mechanical properties.

Interstate Plastics has grown for over 25 years developing a reputation of providing high quality products, excellent customer service, and superior technical support. With over seven stocking locations throughout the country, **we are committed to serving the medical industry**.

FDA CONFORMITY

The American Food and Drug Administration (FDA) inspects the suitability of materials for 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-conforming.

BIOCOMPATIBILITY

Biocompatibility is the measure of the compatibility of a material with the tissue or physiological system of the patient. Assessment takes place after a number of investigations as defined in USP 23 (U.S. Pharmacopeia) Class VI or ISO 10993. Biocompatibility depends not only on the type of material, but also on:

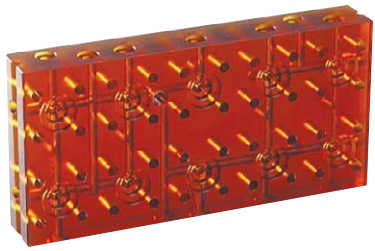
- Where it is used (skin, mucus membranes/ blood, tissue)
- The intended function (superficial contact with the body, contact with the interior of the body, product for implantation)
- The length of time that the material remains in the body (< 24 hours, < 30 days, indefinitely)

Comparison of the testing methods according to USP 23 Class VI and ISO 10993.

Raw Material	DIN*	Material	FDA**	BIO***
INVIBIO® PEEK®	PEEK	Tecapeek™ Classix™	✔	✔
VICTREX® PEEK®	PEEK	Tecapeek™ MT	✔	1
HOSTAFLON, TEFLON®	PTFE	Tecaflon™ PTFE	✔	2
FORTRON®	PPS	Tecatron™ MT PPS	✔	2
RADEL® A	PES	Tecason™ E	✔	-
UDEL®	PEI	Tecapei™ MT	✔	3
RADEL® R	PPSU	Tecason™ P MT	✔	1
ULTEM®	PSU	Tecason™ S PSU	✔	2
SOLEF, KYNAR®	PVDF	Tecaflon™ PVDF	✔	2
-	PPP	Tecamax™ SRP	in testing	
LEXAN®, MAKROLON®	PC	Tecanat™ PC	✔	2
ARNITE, CRASTIN	PET	Tecadur™ PET, Tecapet™	✔	-
-	PA 66	Tecamid™ 66™	✔	2
CELCON®	POM-C	Tecaform™ AH MT	✔	2
-	PP	Tecapro™ MT	✔	3

*DIN Abbreviation
**FDA Conformity
***Biocompatibility

1 = Applies to MT Black, other colors on request
2 = On request
3 = Applies to natural, colors on request



MEDICAL GRADE PLASTICS

High temperature plastic possess properties which enable them to meet specific hygiene standards.

- Biocompatibility and FDA conformity provide the required physiological safety.
- Very high resistance to:
  - Cleaning agents, disinfectants and many solvents.
  - Common sterilization processes using super-heated steam, ethylene oxide, hot air or gamma rays.
- Suitable electrical properties: Good electrical insulation in high-frequency surgery.
- Precision and stability of the finished parts and components.

The combination of these properties contributes to the long useful life of quality instruments that are used frequently, thus reducing the costs of procurement and disposal.

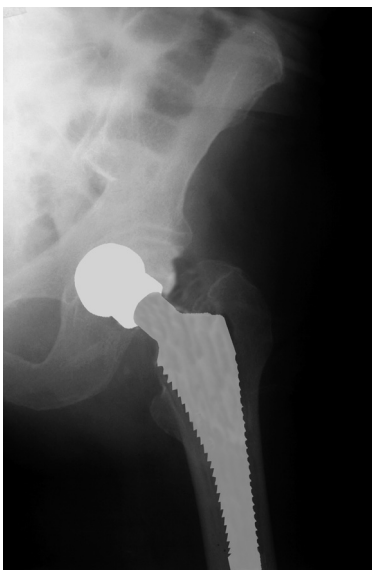
CLEAN ROOM PRODUCTION

Production with clean room technology is becoming more important in medical technology, especially for materials used in diagnostic and therapeutic applications. ENSINGER has vast experience in clean-room production. The current investments in a high-purity production building of clean-room class 100.000 adds to this competence.

Catheter pump for surgical use. CELCON (Tecaform AH MT) is flexible and biocompatible, with a non-polar surface and high resilience (unbreakable).

XRO GRADE PLASTIC

A radio opacifer is added to the standard line of colored extruded rod for orthopedic sizing trials and other instrument devices allowing for clear visibility of the component on flouroscopy and x-ray. This accommodates some of the challenges created by minimally invasive and image guided surgery.



CELCON (Tecaform AH MT)
Sizing trials for hip implants. Different colors allow easy differentiation of sizes.

LEXAN® (Tecanat, PC)

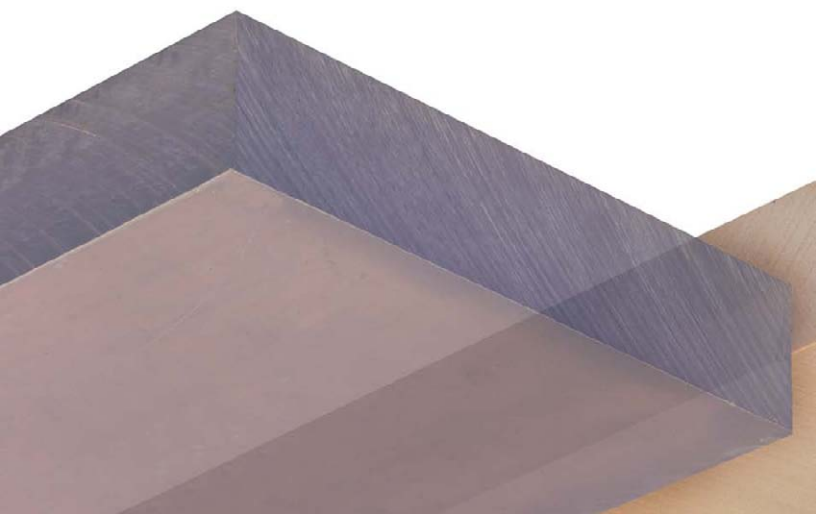
Extremely tough and unbreakable. Excellent electrical insulation. Easy to machine and polish.

TECANAT PC sealing strips for the SIEMENS CT scanner. ENSINGER engineering has made a reliable production process possible by ultrasonic welding of different extruded profiles. The material is transparent, extremely tough, and resistant to radiation.

TECANYL™ MT

TECANYL™ MT is a new shape offering and is produced from GE Plastics' NORYL® HNA055 resin. In-house specimen testing performed at GE has demonstrated that NORYL® HNA055 resin is an excellent material candidate for medical device applications destined for the repeated exposures of autoclaving cycles. It has good impact properties and easily machined. NORYL® HNA055 BL3B234F resin has been subjected to several biological tests covered in ISO 10993 including systemic toxicity, intracutaneous toxicity, implantation test, cytotoxicity, hemolysis, pyrogenicity and maximization sensitization test.

xray • opaque
XRO



RADEL® R (Tecason P MT, PPSU)

FDA conforming PPSU with excellent resistance to common methods of sterilization. High thermal stability. Very tough, hard and rigid.

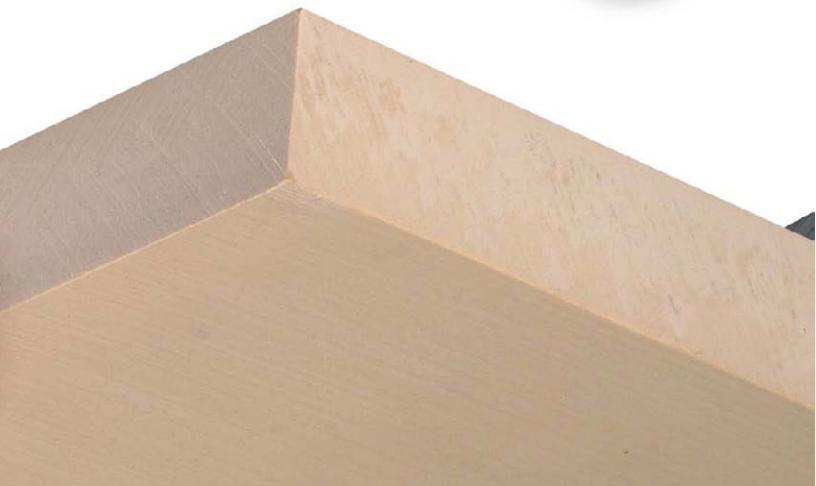
YL3-528 Yellow	GN4-232-1 Green	BL033 Blue	RDI-638 Lavender	OR2-773 Rust Brown	NT 15 Bone
OR040 Orange	RD099 Red	GY061 Grey	937 Black	BN029 Brown	NT Natural Transparent

Lid for caddy for surgical instruments. High dimensional stability even after many sterilizations cycles.

Sizing trials for knee capstrial implants in RADEL®.

SOLEF, KYNAR® (Tecaflon PTFE, PTFE)

Maximum resistance to chemicals. Resistant to common methods of sterilization (except high-energy radiation). Sustained use at a temperature of 260 °C. Excellent sliding and electrical properties.



TECAPRO MT (PP)

An antimicrobial additive gives more security to parts made of TECAFORM AH SAN or TECAPRO MT SAN in medical or food technology. It effects antibactricid on the surface of the plastic parts. Applications: Grips, containers, components in medical, food and sanitary technology.

Container made of TECAPRO MT.

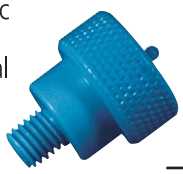
ULTEM® (Tecason S, PSU)

Translucent. Resistant to electromagnetic waves and gamma rays. Hydrolysis resistant. Good electrical insulation. Good thermal and mechanical properties.

xray • opaque XRO

ARNITE, CRASTIN (Tecadur PET, Tecapet, PET)

Good resistance to chemicals. Good dielectric properties. Low susceptibility to wear in moist or dry surroundings, high dimensional stability through relatively low thermal expansion, low moisture absorption.



UDEL® (Tecapei MT, PEI)

Translucent. Transparent to high-frequency electromagnetic waves. Good thermal and mechanical properties. Sustained use at temperatures up to 170 °C. High dimensional stability.

FORTRON® (Tecatron, PPS)

Very high resistance to chemicals. Good resistance to radiation. Very good thermal and mechanical properties. Sustained use at temperatures up to 230 °C. Very hard and rigid. Very stable dimensionally with low susceptibility to creeping.

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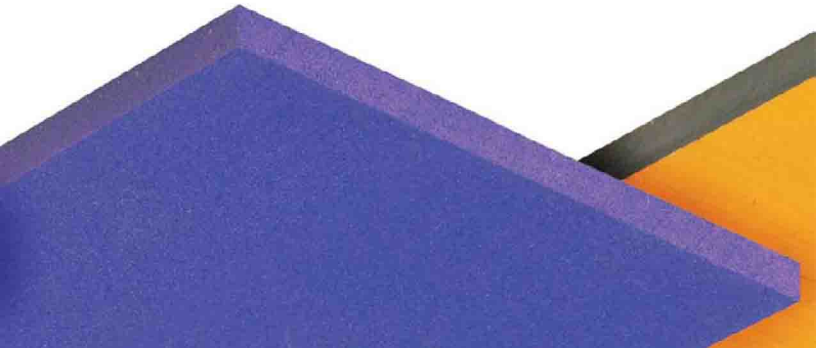
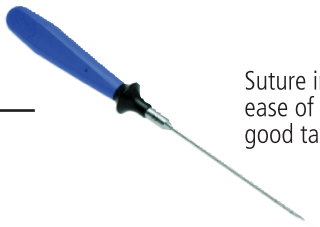


CELCON® (Tecaform AH MT, POM-C)

Good resistance to chemicals. Good electrical insulation. Very good sliding and abrasion properties. Stiff, strong and hard. Easy to machine. Available in different colors.

CR33345	CE33391	CE7430	CV33822	CN33827	CY33828
CN7540	CL33402	CL33247	CH33619	CG34096	CG33836
CJ33269	CJ33826	CJ34045	CS33273	CD7068	CC34031

xray • opaque
XRO

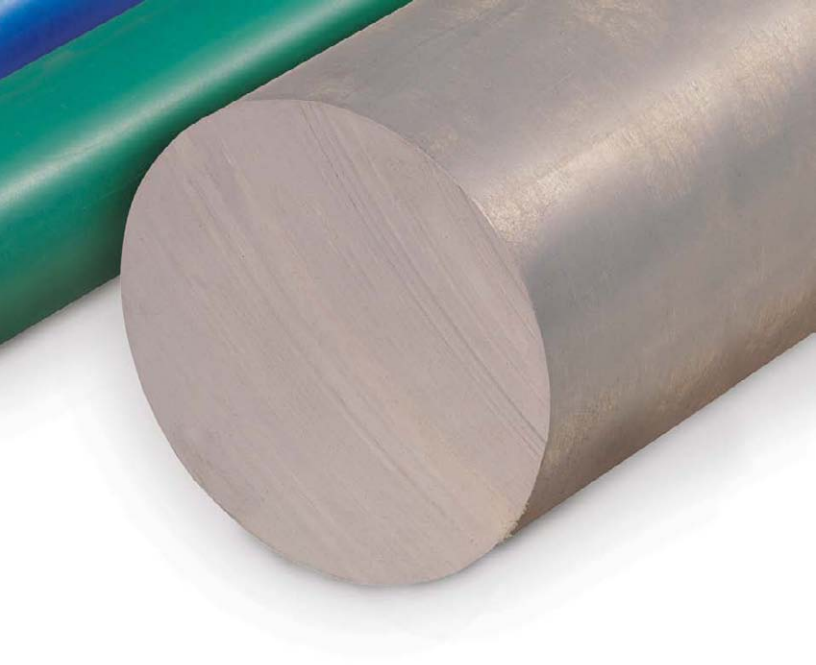


Suture instrument requires ease of cleaning and very good tactile properties.

VICTREX® PEEK® (Tecapeek MT)

Very high resistance to chemicals. Excellent resistance to common methods of sterilization. Good electrical insulation, event at high voltage. Good resistance to radiation. Low susceptibility to stress cracking. High dimensional stability and easy to machine. Excellent tribological properties.

victrex®
MADE WITH VICTREX PEEK POLYMER



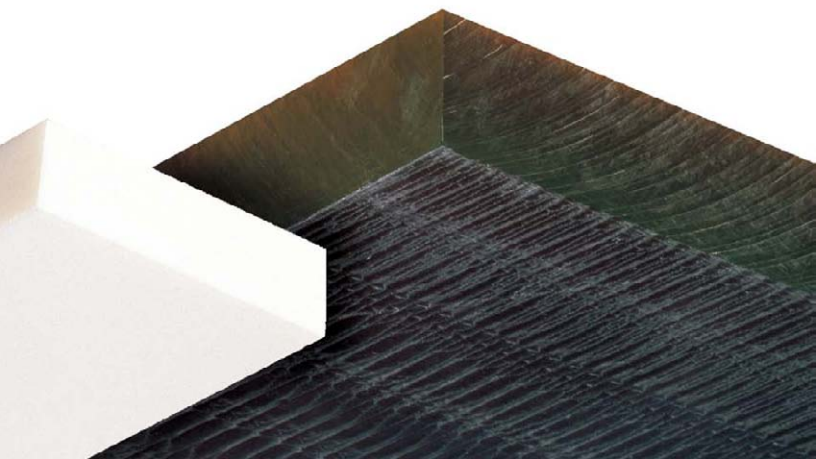
INVIBIO® PEEK® (Tecapeek Classix™)

TECAPEEK CLASSIX™ is suitable for medical-technical applications up to 30 days contact with tissue. Excellent resistance to chemicals. Conforms with FDA, and is biocompatibility-tested as defined USP Class VI. Semi-finished and raw material is batch tested for cytotoxicity according to ISO 10993. Extremely high resistance to hydrolysis, even at high temperatures. Capable of repeated sterilization using conventional methods. Particularly good combination of strength, stiffness, toughness and hardness. Excellent toughness with regard to abrasion and impact. Applications: temporary dental implants, healing caps, catheters, surgical instruments, analysis units, drug dosing systems and devices for contact with tissue. Standard color at present cream white; other colors and modifications on request.

PEEK- CLASSIX™ Made by Invibio® biomaterial solutions

xray • opaque XRO

Dental Healing Cap



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