Medical Polymers from Distrupol

Your world class supplier of medical polymers

Distrupol delivers high quality thermoplastics to the healthcare industry. These thermoplastics are used in the manufacture of demanding components across many different healthcare segments. Distrupol draws on its long-standing experience in materials, application development, technology, safety and regulatory compliance to provide expert support to healthcare product manufacturers, backed by its global polymer supply partners. Depending on the specific application, Distrupol can deliver an appropriate solution from its broad range of standard products, or from its portfolio of medically approved grades, which are differentiated by a greater degree of testing, manufacturing control and regulatory support.
Distrupol is a world class supplier of medical polymers offering a wide range of solutions for the healthcare industry.

Range:
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Depending on the specific application, Distrupol can deliver an appropriate solution from its broad range of standard products, or from its portfolio of medically approved grades, which are differentiated by a greater degree of testing, manufacturing control and regulatory support.

Technical Support:
We can help select a “Fit for Purpose” solution for your applications, recommending the most suitable materials. We understand the numerous requirements and considerations specific for the medical industry enabling you to get it right first time. Our development engineers can also help you with conceptual design, mould flow and tooling, material sampling and process optimisation.

Quality, certification, traceability and confidence:
Authenticity and traceability of materials being used for your components is critical. We can supply you certificates of conformity and analysis with every delivery, and give you full traceability and the confidence that you, and your moulders, are using the right material that is certified and in specification.
Medical & Biocompatibility Tests

What is Biocompatibility?
It is a material’s lack of interaction with living tissue or a living system by not being toxic, injurious, or physiologically reactive, and not causing immunological rejection.

Ultimately, a material’s chemical components will not cause the patient harm. No single test may be sufficient to define biocompatibility.

Two common test regimens are used to measure biocompatibility, United States Pharmacopeia (USP), and ISO 10993, International Organisation for Standardisation, tests for biological evaluation of medical devices.

What is USP Class VI?
The United States Pharmacopeia (USP) is an independent organisation that established a set of standards to ensure the quality of medicines and health care technologies. USP protocols are used to classify plastics in Classes I - VI, based on end use, type and time of exposure of human tissue to plastics, of which Class VI requires the most stringent testing of all the six classes.

- Systemic toxicity tests are used to determine the irritant effect of toxic leachables present in extracts of test materials.
- Intracutaneous tests are used to assess the localised reaction of tissue to leachable substances.
- Implantation tests are used to evaluate the reaction of living tissue to the plastic.

Distrupol Medical:
- USP class VI
- European Pharmacopeia Approved
- ISO 10993
- Drug Master File Listed
- Food Contact Approved
- BPA free
- 2 Year notification of change
- Manufactured to GMP practises
- Worldwide manufacturing locations
- Colour solutions
- Flexible materials
- Tough materials
- Clear materials
- PVC replacement
- Specialised bonding grades
- Specialist tubing grades – solvent bondable
- TPE grades shore 00A up to 60D
- PP & PE
- POM
- PA
- PBT
- TPC-ET
- SMMA
USP Class Plastics Designation

**Surface Devices**

- **Skin**
  - Limited (USP Class I)
  - Prolonged (USP Class I)
  - Permanent (USP Class I)

- **Mucosal Surfaces**
  - Limited (USP Class I)
  - Prolonged (USP Class III)
  - Permanent (USP Class V)

- **Breached or Compromised Surfaces**
  - Limited (USP Class III)
  - Prolonged (USP Class V)
  - Permanent (USP Class VI)

**External Communication Devices**

- **Blood Path Indirect**
  - Limited (USP Class IV)
  - Prolonged (USP Class V)
  - Permanent (USP Class VI)

- **Tissue/Bone/Dentin Communicating**
  - Limited (USP Class IV)
  - Prolonged (USP Class VI)
  - Permanent (USP Class VI)

- **Circulating Blood**
  - Limited (USP Class IV)
  - Prolonged (USP Class VI)
  - Permanent (USP Class VI)

**Implant Devices**

- **All Devices**
  - USP Class VI
**ISO 10993 – Explained**

The International Standards Organisation (ISO, from the Greek word; isos, meaning equal) was established to determine uniform worldwide standards. ISO developed a standard for biological evaluation of medical devices – ISO 10993 in 1995, which is a 20 part standard used to evaluate the effects of medical devices and their component materials on the body.

The most influential guideline for biocompatibility is the first part of this standard, “ISO 10993- Part 1: Evaluation and Testing,” which provides a methodology for choosing the proper biological evaluation test program.

From here it is possible to determine also which test program to utilise depending on the device category of which there are three: Surface, External Communicating and Implant, and the exposure period of the material: Limited (=24 hours), Prolonged (24 hours to 30 days) and Permanent (>30 days). Typically ISO 10993-Part 5 is the most relevant to polymers covering cytotoxicity similar to USP monograph <87>.

<table>
<thead>
<tr>
<th>ISO Part</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Evaluation and testing</td>
</tr>
<tr>
<td>2</td>
<td>Animal welfare requirements</td>
</tr>
<tr>
<td>3</td>
<td>Tests for genotoxicity, carcinogenicity and reproductive toxicity</td>
</tr>
<tr>
<td>4</td>
<td>Selection of tests for interactions with blood</td>
</tr>
<tr>
<td>5</td>
<td>Tests for in vitro cytotoxicity</td>
</tr>
<tr>
<td>6</td>
<td>Tests for local effects after implantation</td>
</tr>
<tr>
<td>7</td>
<td>Ethylene oxide sterilisation residuals</td>
</tr>
<tr>
<td>8</td>
<td>Clinical investigation of medical devices</td>
</tr>
<tr>
<td>9</td>
<td>Framework for identification and quantification of potential degradation products</td>
</tr>
<tr>
<td>10</td>
<td>Tests for irritation and delayed type hypersensitivity</td>
</tr>
<tr>
<td>11</td>
<td>Tests for systemic toxicity</td>
</tr>
<tr>
<td>12</td>
<td>Sample preparation and reference materials</td>
</tr>
<tr>
<td>13</td>
<td>Identification and quantification of degradation products from polymeric medical devices</td>
</tr>
<tr>
<td>14</td>
<td>Identification and quantification of degradation products from ceramics</td>
</tr>
<tr>
<td>15</td>
<td>Identification and quantification of degradation products from metals and alloys</td>
</tr>
<tr>
<td>16</td>
<td>Toxicokinetic study design for degradation products and leachables</td>
</tr>
<tr>
<td>17</td>
<td>Establishment of allowable limits for leachable substances</td>
</tr>
<tr>
<td>18</td>
<td>Chemical characterisation of materials</td>
</tr>
<tr>
<td>19</td>
<td>Physico-chemical, morphological and topographical characterisation of materials</td>
</tr>
<tr>
<td>20</td>
<td>Principles and methods for immunotoxicology testing of medical devices</td>
</tr>
</tbody>
</table>

**ISO 10993 Device Categories**

<table>
<thead>
<tr>
<th>Device Categories</th>
<th>Body Contact</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td></td>
<td>Electrodes, external prostheses, fixation tapes, compression bandages, monitors of various types</td>
</tr>
<tr>
<td>Mucous Membrane</td>
<td></td>
<td>Contact lenses, urinary catheters, intravaginal and intraintestinal devices (stomach tubes, sigmoidoscopes, colonoscopes, gastroscopes), endotracheal tubes, bronchoscopes, dental prostheses, orthodontic devices, IUDs</td>
</tr>
<tr>
<td>Breached or Compromised Surfaces</td>
<td></td>
<td>Uler, burn and granulation tissue dressings or healing devices, occlusive patches</td>
</tr>
<tr>
<td>Blood Path Indirect</td>
<td></td>
<td>Solution administration sets, extension sets, transfer sets, blood administration sets</td>
</tr>
<tr>
<td>Tissue/ Bone/Dentin Communicating</td>
<td></td>
<td>Laparoscopes, arthroscopes, draining systems, dental cements, dental filling materials, skin staples</td>
</tr>
<tr>
<td>Circulation</td>
<td></td>
<td>Intravascular catheters, temporary pacemaker electrodes, oxygenators, extracorporeal oxygenator tubing and accessories, dialysers, dialysis tubing and accessories, hemadsorbsents and immunoadsorbsents</td>
</tr>
<tr>
<td>Tissue/Bone Implant Devices</td>
<td></td>
<td>Orthopedic pins, plates, replacement joints, bone prostheses, cement and intraosseous devices, pacemakers, drug supply devices, neuromuscular sensors and simulators, replacement tendons, breast implants, artificial larynaxes, subperiostealimplants, ligation clips</td>
</tr>
<tr>
<td>Blood</td>
<td></td>
<td>Pacemaker electrodes, artificial arteriovenous fistulae, heart valves, vascular grafts, internal drug delivery catheters, ventricular assist devices</td>
</tr>
</tbody>
</table>
Sterilisation Methods

**Autoclave Steam Sterilisation**
Steam sterilisation, or autoclaving, is a widely used method, it is comparatively easy to control (environmentally friendly) and can be performed with relatively low-cost equipment. An autoclave combines heat and moisture at elevated pressures. Heat sterilization of medical instruments or components with the presence of moisture significantly speeds up heat penetration (steam sterilization). The time and temperature for sterilization depends on pressure and the type of microorganisms to be inactivated. Typical process conditions are 20 min at 121°C or 5 min at 134°C.

**Ethylene Oxide (ETO) Sterilisation**
ETO sterilisation is the gaseous method of sterilisation involving the highly diffusive, permeable and toxic ETO gas. The use of ETO sterilisation evolved for sterilizing heat- and moisture-sensitive medical devices and or devices containing electronic components. The processes of ETO sterilisation involve several stages of gas removal; humidification, ETO exposure and air washes. Process pressures are close to vacuum and temperatures used are circa 50°C. Many plastic materials are compatible with ETO sterilisation.

**Plasma Sterilisation**
Plasma is a gas sterilisation method where different gases can be used, but Hydrogen Peroxide is the most common. Plasma can be considered were an alternative to ETO is required or the high sterilisation temperatures of Autoclave are not suitable. The plasma sterilisation process is safe and easy to use and is typically used for devices that cannot be sterilised with high heat.

**Gamma Ray Sterilization**
Sterilization by gamma radiation uses the radioisotope Cobalt 60 as its energy source. Items for sterilisation pass the radiation field where gamma rays pass readily through plastics and kill bacteria by breaking the covalent bonds of bacterial DNA. They are measured in units called kiloGrays (kGy).

There is no heat or moisture generated during the process and consequently, there is no resulting heat stress and condensate drainage. Most importantly, there is no residual radioactivity after irradiation.

**Electron Beam Sterilisation**
The electron beam sterilization process begins with an electron beam accelerator to create a powerful beam of electrons. The beam is scanned back and forth to create a curtain of fast electrons ensuring a uniform dose of radiation to objects passing the beam.

E-beam sterilisation destroys all types of pathogens including viruses, fungi, bacteria, parasites, spores, and molds.
### Distrupol Medical Elastomer Shore Hardness Range

<table>
<thead>
<tr>
<th>Material</th>
<th>Shore A Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mediprene</td>
<td></td>
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<tr>
<td>Hytrel SC</td>
<td></td>
</tr>
<tr>
<td>Pharmalene EVA</td>
<td></td>
</tr>
<tr>
<td>Elastollan TPU</td>
<td></td>
</tr>
</tbody>
</table>

### Distrupol Rigid Polymer Flexural Modulus Range

<table>
<thead>
<tr>
<th>Material</th>
<th>Modulus Range</th>
</tr>
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<tbody>
<tr>
<td>Zytel SC Unfilled</td>
<td></td>
</tr>
<tr>
<td>Zytel SC Glass filled</td>
<td></td>
</tr>
<tr>
<td>Crastin SC Unfilled</td>
<td></td>
</tr>
<tr>
<td>Crastin SC Glass filled</td>
<td></td>
</tr>
<tr>
<td>Delrin SC (Unfilled)</td>
<td></td>
</tr>
<tr>
<td>EltexMED (Unfilled PP)</td>
<td></td>
</tr>
<tr>
<td>EltexMED (Unfilled HDPE)</td>
<td></td>
</tr>
<tr>
<td>Wonderlite PC</td>
<td></td>
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</table>

### Distrupol Rigid Polymer Heat Deflection Resistance

<table>
<thead>
<tr>
<th>Material</th>
<th>Heat Deflection Resistance</th>
</tr>
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<tbody>
<tr>
<td>Zytel SC Unfilled</td>
<td>0°C to 300°C (0.45mpa &amp; 1.8mpa)</td>
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<tr>
<td>Zytel SC Glass filled</td>
<td></td>
</tr>
<tr>
<td>Crastin SC Unfilled</td>
<td></td>
</tr>
<tr>
<td>Crastin SC Glass filled</td>
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Zytel HTN
### Sterilisation Compatibility

<table>
<thead>
<tr>
<th></th>
<th>Ethylene Oxide</th>
<th>Steam Autoclave (134°C)</th>
<th>Repeat Steam Autoclave (134°C)</th>
<th>Dry Heat (160°C)</th>
<th>Gamma</th>
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<tbody>
<tr>
<td>EltexMED Polypropylene</td>
<td>X</td>
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<tr>
<td>EltexMED LDPE</td>
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<tr>
<td>EltexMED HDPE</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Delrin SC</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Crastin SC</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>Zytel SC</td>
<td>X</td>
<td></td>
<td>X</td>
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<td>X</td>
</tr>
<tr>
<td>Hytrel SC</td>
<td>X</td>
<td></td>
<td>X</td>
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<tr>
<td>Wonderlite</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Mediprene</td>
<td>X</td>
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<tr>
<td>Elastollan TPU</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Pharmalene EVA</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**Key:**
- **Suitable**
- **Suitable in some applications**
- **Not suitable**
### BASF

#### Elastollan® Medical TPU (Thermoplastic Polyurethane)
Elastollan®, a leading brand name in medical TPU elastomers, offering excellent elastic and abrasion properties over a wide range of temperatures. Elastollan® is a versatile material and can be processed with various methods.

**Product Range**
- Ether type 1100 series
- From shore A up to 74 shore D
- Grades tested have passed irritation, sensitisation and cytotoxicity
- Food approved
- Injection moulding
- Extrudable
- Blow mouldable

**Advantages**
- Transparent grades
- Excellent flex fatigue properties
- Suitable for ETO and gamma (with some discoloring)
- Transmits water vapour (selected grades)
- Grades known to pass irritation, sensitisation cytotoxicity testing

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### Chi Mei

#### Polylac® ABS
Polylac ABS is available in both opaque and transparent forms. ABS gives the ideal balance between rigidity, impact strength, surface finish, hardness, and processibility. Polylac ABS is easy to mould and cost effective.

**Product Range**
- Injection moulding grades
- Transparent
- Food approved (EU food for opaque version)

**Advantages**
- Transparent options
- Good toughness
- Easy to mould
- Gamma and ETO resistant (subject to testing)
- Notification of change control
- Good dimensional stability
- Excellent gloss

---

#### Chi Mei

#### Wonderlite® PC - Polycarbonate
Wondelite Polycarbonate is a glass like transparent material designed for the medical market. Standard and gamma irradiation resistant grades are available.

**Product Range**
- Injection moulding grades
- Food approved

**Advantages**
- Glass like transparent
- Excellent impact properties
- Glass like transparent options
- Gamma, ETO and Autoclave resistant (subject to testing)
- High heat properties
- Notification of change control
- Good dimensional stability

---

#### Kibiton® SBC - Q Resin
Kibiton is a possible alternative to brands like K Resin or Styrolux, bringing excellent transparency and flexibility.

**Product Range**
- Injection moulding grades
- Transparent
- Food approved

**Advantages**
- Transparent options
- Good toughness & flexibility
- Easy to mould
- Gamma and ETO resistant (subject to testing)
- Notification of change control
- Good dimensional stability
- Excellent gloss
DuPont

Crasin SC® PBT Thermoplastic Polyester Resin

Crasin® polybutylene terephthalate (PBT) provides exceptional dimensional stability combined with low creep, excellent electrical insulation properties and fantastic surface finishes. Through modifications, physical and technical, a vast range of grades is available for a variety of applications.

**Product Range**
- Unreinforced & Glass Reinforced
- Low warp
- Eur Pharma And USP Class VI
- SC = Special Control for Medical Applications
- Injection Mouldable

**Advantages**
- Stiffness
- Dimensional stability
- Colour stability at elevated temperatures
- Creep resistance
- Eur Pharma And USP Class VI
- High surface gloss
- Gamma, ETO and Autoclave resistant (subject to testing)
- Food Approved
- Super Structural for Glass Reinforced grades

Delrin SC® Acetal Resin (POM)

Delrin® acetal (Polyoxymethylene POM) bridges the gap between metals and plastics with a unique combination of properties. These include low wear/low friction, strength and stiffness, hardness, dimensional stability, toughness, fatigue resistance, solvent and fuel resistance. Delrin® is the stiffest and strongest unreinforced technical engineering polymer available.

**Product Range**
- Low, medium & high flow
- SC = Special Control for Medical Applications

**Advantages**
- Stiffness without reinforcement
- Toughness over wide temperature range
- Wide range of service temperatures
- Fatigue resistance
- Creep resistance
- Dimensional stability
- Low moisture pickup
- Chemical & fuel resistance
- Low friction & wear due to Advanced Lubrication
- ETO and Autoclave resistant (subject to testing)
- Advanced lubrication system

Sorona® EP Thermoplastic Polymer (PTT)

Sorona® EP thermoplastic polymer is produced with 20%-37% renewably sourced material from non-food biomass. The properties of Sorona® EP include good strength, stiffness and dimensional stability with low warpage and excellent surface appearance.

**Product Range**
- Food approved only
- Vert high gloss
- Sublimation printable

**Advantages**
- Excellent surface finish
- Good UV resistance
- Stronger & stiffer than PBT
- 37% renewable biomass
- 40% less energy to produce than PBT
- Works with 3D print techniques

Zytel SC® Nylon Resin

Zytel® polyamide has been an industry leader for more than 70 years. Zytel® offers high mechanical strength, stiffness and quality.

**Product Range**
- Unreinforced
- Glass fibre reinforced
- Heat stabilised
- Flexible
- Heat stabilised
- SC = Special Control for Medical Applications
- Food Approved

**Advantages**
- Strength
- Toughness
- Fatigue resistance
- Creep resistance
- Chemical resistance
- Thermal resistance
- Easy to process
- Eur Pharma And USP Class VI
- Gamma, ETO and Autoclave resistant (subject to testing)
Ineos

**ELTEX® MED (PP & PE)**

Eltex® MED is an enhanced range of products dedicated to the medical market. Eltex® MED has a proven track record in meeting the needs of high-value applications for medical & pharmaceutical products.

**Product Range**
- PPH
- RCP
- HDPE
- LDPE

**Advantages**
- European Pharmacopoeia composition compliance
- United States Pharmacopoeia USP class VI
- Drug Master File Listed
- Formula disclosure under secrecy agreement
- Controlled pharma certificates
- Continuity of supply and formulation
- 2 years Notification of Change

DuPont

**Zytel® HTN - High Performance Polyphthalamide**

Zytel® HTN High performance polyamide bridges the gap between engineering and high performance specialty polymers. Zytel® HTN is modified to withstand extreme conditions such as long term exposure to heat, chemicals, and moisture.

**Product Range**
- Glass fibre reinforced
- Heat stabilised
- Food approved only
- Hydrolysis resistant
- Low warp

**Advantages**
- Stiffness
- Property retention with moisture content
- High service temperature (150°C-200°C)
- Creep resistance
- Chemical resistance
- Dimensionally stable
- Eur Pharma And USP Class VI
- Gamma, ETO and Autoclave resistant (subject to testing)
- Excellent flow properties

**Versalis**

**Pharmalene® Medical PE**

Pharmalene®, a new range of medically approved Polyethylene based products to serve the medical market. Uses are varied but could include syringes, medical packaging and tubing.

**Product Range**
- HDPE
  - Injection moulding grades
  - Extrusion grades
- LDPE
  - Injection moulding grades
  - Extrusion grades
- EVA
  - Injection moulding grades
  - Extrusion grades

**Advantages**
- Compliance with European Pharmacopoeia and USP
- DMF (Drug, Master File, type 111-FDA for all products
- Prior notice if product changes occur
- Availability for plant audits
- Long term sample retention and documentation

Hexapol

**Mediprene® TPE - SEBS & SBS**

Mediprene thermoplastic elastomers are suitable for a wide variety of uses in the medical and pharmaceutical market and new applications are being developed all the time.

Mediprene compounds combine the performance of vulcanised rubbers with the processing properties of thermoplastics, delivering sophisticated design opportunities through a wide and flexible range of products.

**Product Range**
- Injection moulding grades
- Extrusion grades
- Blown film extrusion grades
- Blow moulding grades
- From 0 shore A upto 60 shore D
- USP Class VI & Eur Pharma Compliant
- Food approved
- 2K adhesion grades to PP, ABS, PC, PBT, PA and POM

**Advantages**
- Good elastic properties
- Standard and custom made grades
- Glass like transparent options
- Gamma, ETO and Autoclave resistant (subject to testing)
- Low kink properties for tubing applications
- Plasticiser free options
- Easy to process and colour
- Solvent dissolvable / solvent bonding grades
An Integrated Process
From concept to manufacture

DESIGN
Concept and part design
Market Research and knowledge sharing
Material selection
Process optimisation
Testing and trialling
Tooling and part review
Design verification

DEVELOP
Moldex3D
Finite Element Analysis (FEA)
Tooling
Sampling and performance

DELIVER
Manufacture method
Localised logistic support
ISO 9001:2015 certified
25kg bags to FTL deliveries
European distribution points
Material repacking

Further Information
For further information please contact your local Distrupol representative or email:
E: info@distrupol.com

Design, Develop & Deliver
Distrupol, your polymer solutions partner.
Our highly experienced sales and technical team will support you with mould design, polymer selection, testing and process optimisation.