DISTRUPOL
A member of Omya Performance Polymer Distribution

Medical
Product Brochure

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, your supply partner for medical polymers.
Contact us today to find out more.

info@distrupol.com
www.distrupol.com

Distrupol is a world class supplier of medical polymers offering a wide range of solutions for the healthcare industry.

Range:

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 longstanding 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.

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.

For further information please contact us today!
info@distrupol.com | www.distrupol.com

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

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.

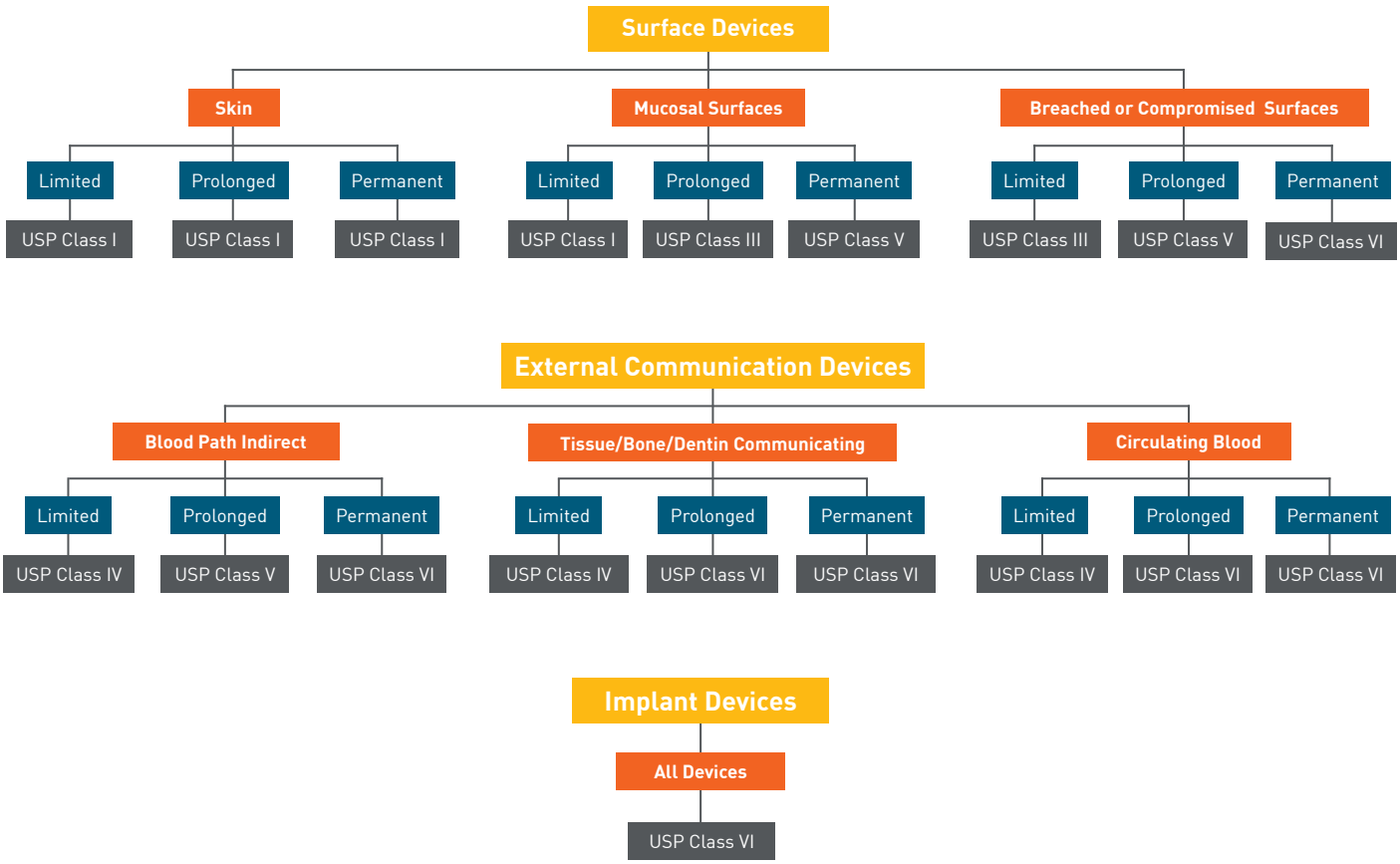
Two common test regimens are used to measure biocompatibility, United States Pharmacopeia (USP), and ISO 10993, International Organisation for Standardisation, tests for biological evaluation of medical devices.

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.

USP Class Plastics Designation



For further information please contact us today!
info@distrupol.com | www.distrupol.com

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>.

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

ISO 10993 Device Categories

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

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 Sterilisation

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.

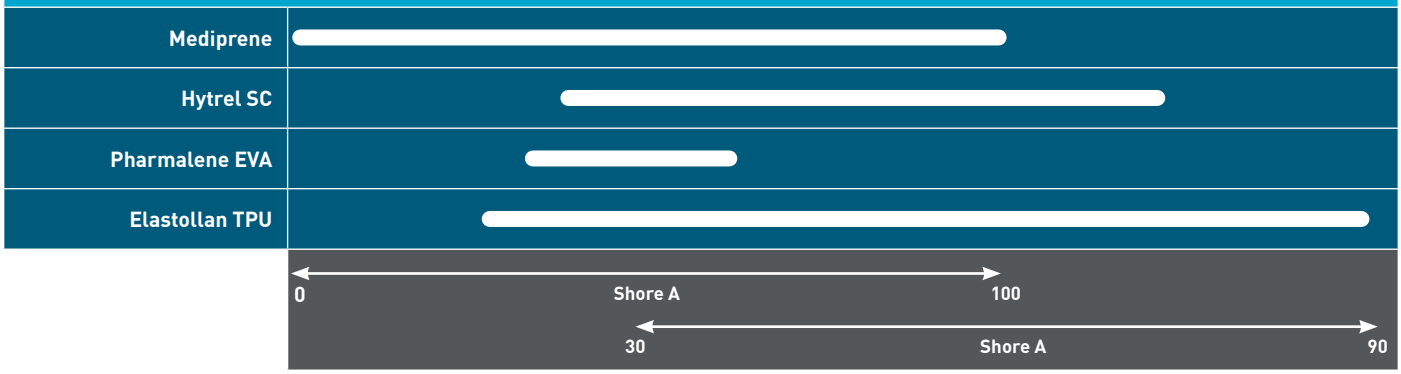
Electron Beam Sterilisation

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.

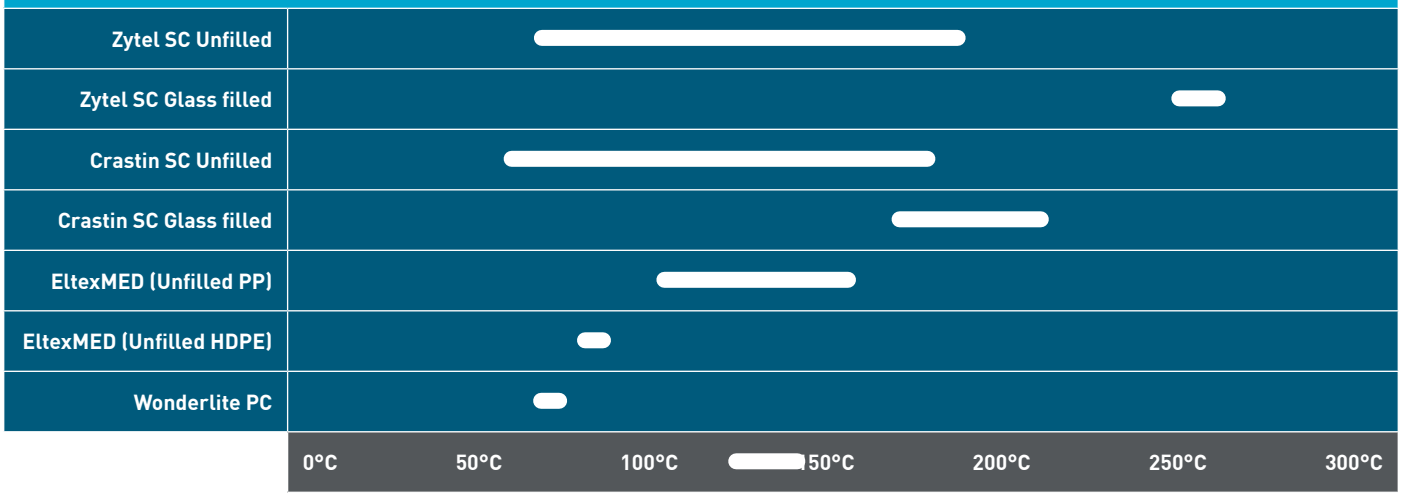
E-beam sterilisation destroys all types of pathogens including viruses, fungi, bacteria, parasites, spores, and moulds.

For further information please contact us today!
info@distrupol.com | www.distrupol.com

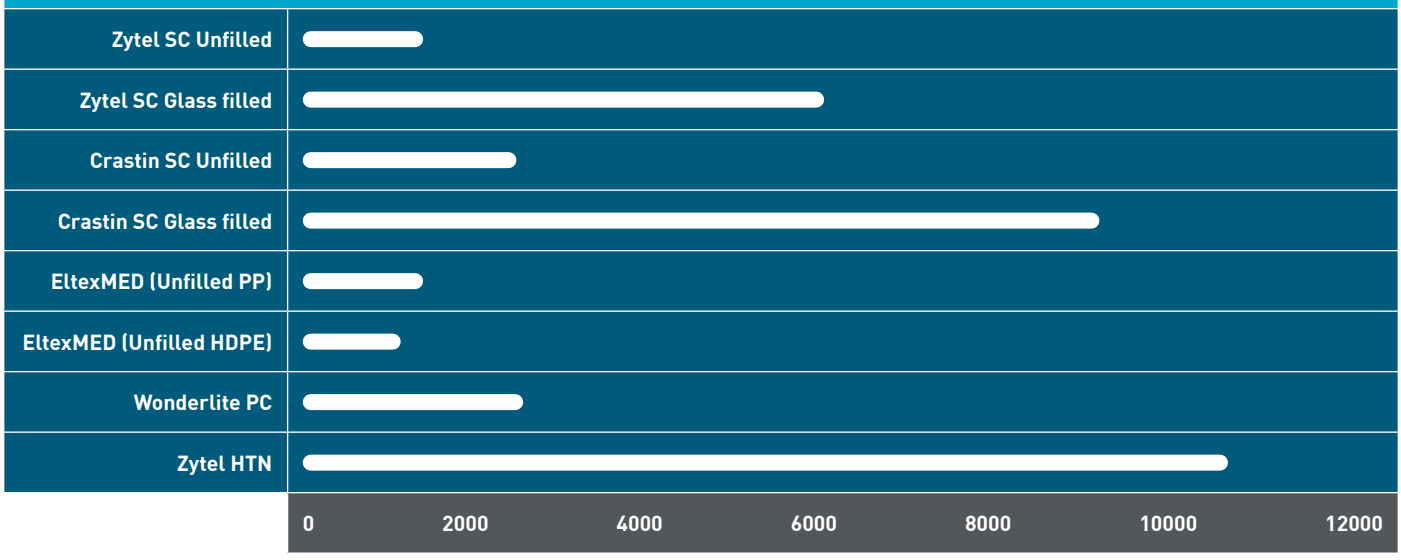
Distrupol Medical Elastomer Shore Hardness Range



Distrupol Rigid Polymer Heat Deflection Resistance
(0.45mpa & 1.8mpa)



Distrupol Rigid Polymer Flexural Modulus Range



Sterilisation Compatibility

	Ethylene Oxide	Steam Autoclave (134°C)	Repeat Steam Autoclave (134° C)	Dry Heat (160°C)	Gamma
EltexMED Polypropylene	●	○	○	✕	○
EltexMED LDPE	●	✕	✕	✕	●
EltexMED HDPE	●	○	✕	✕	●
Crastin SC	●	○	○	○	●
Zytel SC	●	●	●	●	●
Hytrel SC	●	○	○	✕	●
Wonderlite	●	○	✕	✕	●
Mediprene	●	○	○	✕	●
Elastollan TPU	●	✕	✕	✕	○
Pharmalene EVA	●	✕	✕	✕	●
Key:	● Suitable	○ Suitable in some applications	✕ Not suitable		

For further information please contact us today!
info@distrupol.com | www.distrupol.com

Medical Product Range (by Supplier)

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 upto 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 discolouring)
- Transmits water vapour (selected grades)
- Grades known to pass irritation, sensitisation cytoxicity testing

ChiMei

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

ChiMei

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

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

Celanese

Crastin® SC PBT Thermoplastic Polyester Resin

Crastin® 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

Hytrel® SC TPC-ET Thermoplastic Polyester Elastomer

Hytrel® thermoplastic polyester elastomers provide the flexibility of rubbers, the strength of plastics and the processibility of thermoplastics.

Hytrel® combines resilience, heat and chemical resistance with strength and durability.

Product Range

- Shore 30D - 82D
- SC = Special Control for Medical Applications
- Injection moulding
- Extrusion
- Food Approved

Advantages

- High impact strength at low temperatures
- Excellent fatigue resistance
- Flexible at low temperatures
- Wide range of service temperatures (-40°C-125°C)
- Good noise & vibration dampening
- No plasticizer
- Eur Pharma And USP Class VI
- Easy to process and Colour
- Gamma, ETO and Autoclave resistant (subject to testing)

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)

Celanese

Zytel® HTN - High Performance Polyphthalamide

Zytel® HTN High performance polyamide bridges the gap between engineering and high performance speciality 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

Zytel® SC Long Chain Polyamides (LCPA)

Zytel® Long Chain Polyamides (LCPA) PA6.12 . Zytel® (LCPA) grades offer excellent thermal, flexible, chemical and hydrolysis resistance properties.

Product Range

- PA6.12
- SC = Special Control for Medical Applications
- Injection moulding
- Food Approved

Advantages

- Gamma, ETO and Autoclave resistant (subject to testing)
- Flexible
- Tough
- Excellent chemical resistance
- Hydrolysis resistant
- Excellent thermal properties

For further information please contact us today!
info@distrupol.com | www.distrupol.com

HEXPOL TPE

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
- Plasticisier free options
- Easy to process and colour
- Solvent disolvable / solvent bonding grades

INEOS

ELTEX® MED (PP & PE)

Eltex® MED. 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

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

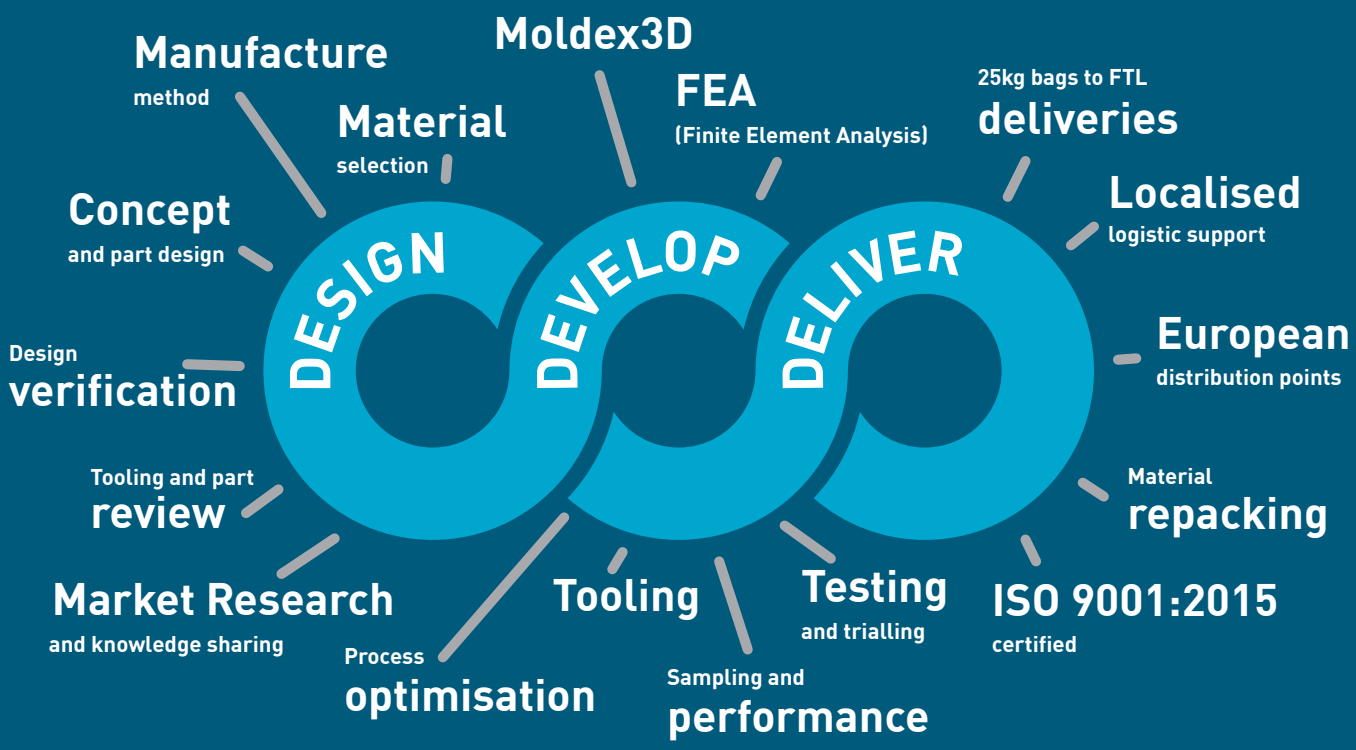
DISTRUPOL
A member of Omya Performance Polymer Distribution

www.distrupol.com

An Integrated Process

From concept to manufacture

DESIGN
DEVELOP
DELIVER



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.