A REFERENCE GUIDE

HIGH-PERFORMANCE MATERIALS FOR HEALTHCARE APPLICATIONS

Version 1.0

PATIENTS DEPEND ON DOCTORS

Doctors and other healthcare professionals depend on medical devices to save or improve lives.

Those who design medical devices depend on Covestro, one of the leading producers of high-performance plastics around the world.

COVESTRO — THE MARKET LEADER WITH MORE THAN 50 YEARS' EXPERIENCE IN HEALTHCARE

Polycarbonates from Covestro are part of essential healthcare devices and are being used in the development of next generation life-saving technology. From devices to treat chronic disease — e.g., glucose monitors to manage diabetes, dialyzers to treat kidney failure, respiratory devices to address sleep apnea — to devices used to treat acute medical emergencies — e.g., heart defibrillators, intravenous access components, surgical instruments — Covestro polycarbonates are essential.

Covestro is the global market leader in supplying polycarbonate resins to the Healthcare market, and our continued success is built on four principles:

1. We have over 50 years' experience serving the healthcare market, backed by a deep understanding of the industry's needs.
2. We are a one stop shop for our customer's polycarbonate (and blends) needs
3. We have demonstrated supplier reliability with resin production plants around the world able to produce globally consistent Healthcare grades
4. We are committed to the future of Healthcare customers, offering value added services and developing new products.

TABLE OF CONTENTS

This brochure reviews our polycarbonate-based and thermoplastic polyurethane materials designed for use in healthcare applications. Included are typical applications, their performance requirements and the Covestro materials that may meet those requirements.

Our intent is to provide a general overview of these materials and their performance characteristics specific to the healthcare industry.

MEDICAL GRADES IN COVESTRO'S MARKET LEADING PORTFOLIO MEET THE FOLLOWING CRITERIA:

- Biocompatibility: ISO 10993-1 and USP Class VI for contact of 30 days or less
- Compliance to material requirements of Regulation (EU) 2017/745 on medical devices and (EU) No 722/2012 regarding medical devices manufactured utilizing tissues of animal origin
- Adhere to disclosures in FDA Device Files (MAF) and Drug Master Files (DMF). Letters of authorization available.
- Manufactured at ISO 9001 certified sites that follow GMP standards

This brochure presents Covestro's polycarbonate and TPU medical grade portfolios. Covestro also offers a large portfolio of standard resins which may be used for applications which do not need the stringent requirements of change notification and biocompatibility of a medical grade. Please contact your local Covestro representative for more details.

THE IMPACT OF DISEASE ON GLOBAL HEALTH AND THE ROLE POLYCARBONATE PLAYS

DIABETES

537 million adults in 2021

IDF Diabetes Atlas

Featured Polycarbonate Application:

Insulin delivery device

CANCER

10 million deaths in 2020

World Health Organization

Featured Polycarbonate Application:

Wearable drug delivery device

FLU

145,000 deaths in 2017

The Lancet

Featured Polycarbonate Application:

Diagnostic test

RENAL FAILURE

697.5 million cases in 2017

Nature Reviews

Featured Polycarbonate Application:

Dialyzer

SLEEP APNEA

936 million adults in 2018

The Lancet

Featured Polycarbonate Application:

CPAP machine

SURGERY

143 million procedures/year

The Lancet

Featured Polycarbonate Application:

Surgical trocars

Chronic

Acute

WITH COVESTRO, YOU HAVE CHOICES

Makrolon®, Bayblend®, Makroblend®, and Apec® Medical Grades

With our family of polycarbonate resins and resin blends, you can find the material that best suits the requirements of your medical device or healthcare application. These products are biocompatible per certain ISO 10993-1 test requirements. Below is an overview of these products and their properties. The products are available in granule form and are typically processed by injection molding, extrusion or blow molding.

Makrolon® Polycarbonate

These resins are lightweight and offer a unique combination of impact resistance and rigidity available in transparent, translucent and opaque colors. With a range of grades to meet the needs of medical applications, Makrolon® medical grades can be sterilized by all common methods.

Apec® High-Heat Polycarbonate

This copolymer is characterized by its high transparency, toughness and strength with a higher heat resistance compared to Makrolon® resin. It is suitable for high-heat steam autoclaving up to 143°C.

Bayblend® PC+ABS Blend

These opaque resins are blends of polycarbonate (PC) and acrylonitrile butadiene styrene polymer (ABS) that offer an excellent combination of mechanical and thermal properties, exhibiting high toughness, rigidity, dimensional stability and easy processing.

Makroblend® PC + Polyester Blend

These opaque resins are blends of polycarbonate and polyester (PBT and PET) that offer an excellent combination of toughness and chemical resistance.

Flame Retardant Resins

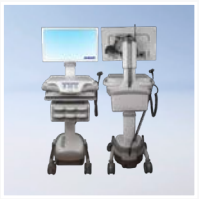
Flame retardant medical Makrolon®, Bayblend® and Makroblend® grades are available with UL94 V-0 ratings down to 1.5mm. Covestro offers the choice of phosphorous based advanced flame retardants.

Covestro Also Offers Texin® Rx Thermoplastic Polyurethane Medical Grades

Biocompatible per certain ISO 10993-1 test requirements, these resins are tough, high tensile materials with good tear strength and excellent resistance to abrasion, fuels, oils and greases. Elastic and resilient, they also offer great cold temperature flexibility, flex fatigue properties, excellent adhesion to various substrates and a Shore hardness range from 70A to 85D. The products are available in granule form and are typically processed by injection molding and extrusion.

APPLICATION CASE STUDIES

IV Access
Customer: Elcam
Product: Marvelous 3-way stopcock
Material: Makrolon® Rx1805 resin
Benefits: Transparent; biocompatible; dimensionally-stable; radiation-resistant
More information on Covestro Solution Center



Electromedical Equipment
Customer: Howard Technology Solutions
Product: HI-Care E 2-tier cart
Material: Makroblend® M525 resin
Benefits: Chemically-resistant; tough; processability; biocompatible
More information on Covestro Solution Center

Drug Delivery
Customer: QS Medical Technology
Product: Quinnocare QS-P insulin pen
Material: Makrolon® Rx1805 resin (ampoule)
Bayblend® FR3050 resin (housing)
Benefits: Transparent; radiation-resistant (ampoule) / Chemical resistance, paint elimination (housing)
More information on Covestro Solution Center

Renal Therapy
Customer: Chengdu OCI Medical Device Co., Ltd.
Product: Dialyzer housing
Material: Makrolon® Rx2440 resin
Benefits: Designed for low-oxygen radiation sterilization; biocompatible; good processability
More information on Covestro Solution Center

Surgical
Customer: Metric Medical Devices, Inc.
Product: Super Staple™ Classic bone fixation device
Material: Makrolon® Rx2530 resin
Benefits: Tough; dimensionally stable
More information on Covestro Solution Center

Respiratory
Customer: Breathe Technologies
Product: Breathe Pillow Interface™
Material: Makrolon® 2458 resin
Benefits: Medium viscosity; easy release; EtO and steam sterilizable; biocompatible
More information on Covestro Solution Center

APPLICATION CASE STUDIES

Animal Health
Customer: RxActuator
Product: Mini-Infuser™ Subcutaneous Constant Rate Infucion (SQ-CRI) pump
Material: Makrolon® Rx1805 resin
Bayblend T85 XF resin
Benefits: Impact resistant; chemical resistant; biocompatible (Makrolon Rx1805)
More information on Covestro Solution Center

Wellness
Customer: Apollo Neuroscience
Product: Apollo
Material: Makroblend® M525 resin
Benefits: Impact resistant; chemical resistant; biocompatible
More information on Covestro Solution Center

Dental
Customer: Ningbo Procare Packaging Material Co.
Product: Dental implant sterilization box
Material: Apec® 1745 resin
Benefits: Steam sterilizable at 143°C; colorable; lightweight and cost-effective vs. PPSU;
More information on Covestro Solution Center

Cardiovascular
Customer: Wego New Life Medical Devices
Product: Oxygenator
Material: Makrolon® 2458 resin
Benefits: Transparent; durable; biocompatible; heat resistant; excellent processability
More information on Covestro Solution Center

MATERIAL SHOWCASE

Makroblend® M5005 FR Resin

An FR polycarbonate/polyester blend specifically designed for the healthcare market

Benefits: Chemically resistant; advanced phosphorous based FR UL94 V-0 @ 2.4mm; excellent processability; biocompatible

More information on Covestro Solution Center

Makrolon® M6011 FR Resin

An FR polycarbonate resin specifically designed for the healthcare market

Benefits: Chemically resistant; advanced phosphorous based FR UL94 V-0 @ 1.5mm; biocompatible

More information on Covestro Solution Center

Makrolon® GF Resin Series

A family of six healthcare grades with glass content ranging from 10-30%. Available as high flow and high performance options.

Benefits: Superior rigidity; dimensionally stable; biocompatible; globally available

More information on Covestro Solution Center

Makrolon® LF Resin Series

A family of three opaque healthcare grades with lower surface friction properties

Benefits: Lower deployment forces; dimensionally consistent; biocompatible; globally available

More information on Covestro Solution Center

Makrolon® Rx2235 Resin

A transparent polycarbonate resin for the healthcare market with outstanding high flow properties.

Benefits: Excellent processability; transparent; radiation stabilized; biocompatible

More information on Covestro Solution Center

Makrolon® Rx3440 Resin

A transparent polycarbonate resin for the healthcare market with best in class chemical and oncology drug resistance.

Benefits: Chemically resistant; radiation stabilized; transparent; biocompatible

More information on Covestro Solution Center

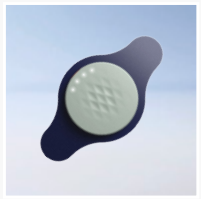
DESIGN STUDIES

Drug Delivery

A connected drug delivery concept device highlighting the benefits of using Covestro materials.

Benefits: Tough and durable; biocompatible; sterilizable; dimensional stability; design flexibility

More information on Covestro Solution Center



Diagnostics

Demonstrating the convergence of healthcare and consumer electronics, this wearable Continuous Glucose Monitor concept combines functionality and fashion

Benefits: Tough and durable; colorable; translucent; design flexibilty; processability; biocompatible

More information on Covestro Solution Center

PRODUCT OVERVIEW OF MEDICAL GRADES

RoweMiniPump from RoweMed AG

PRODUCT OVERVIEW OF MEDICAL GRADES

Standard	Radiation Stabilized	Flame Retardant Blends	Non-Flame Retardant Blends	High Heat	Glass Filled	Low Friction
Makrolon® 2258	Makrolon® Rx2235	Makrolon® M6011 FR[1,2]	Bayblend® M750	Apec® 1745	Makrolon® M410 GF	Makrolon® M204 LF
Makrolon® 2458	Makrolon® Rx2430	Bayblend® M301 FR[2]	Bayblend® M850 XF		Makrolon® M420 GF	Makrolon® M402 LF
Makrolon® Rx1452	Makrolon® Rx2440	Bayblend® M303 FR[2]	Makroblend® M525		Makrolon® M430 GF	Makrolon® M404 LF
Makrolon® Rx1851	Makrolon® Rx2435	Makroblend® M4000 FR[2]			Makrolon® M810 GF	
Makrolon® 2558	Makrolon® Rx2530	Makroblend® M5005 FR[1,2]			Makrolon® M820 GF	
Makrolon® 2658	Makrolon® Rx2635				Makrolon® M830 GF	
Makrolon® 2858	Makrolon® Rx1805					
Makrolon® 3158	Makrolon® Rx3440					
Makrolon® 3258						

[1] Advanced phosphorous based flame retardant formulation
[2] Limited biocompatibility, meets the biocompatibility requirements of ISO 10993-1 testing for contact with uncompromised skin.

PRODUCT OVERVIEW OF MEDICAL GRADES[1]

Makrolon® 2258 resin (MVR 34 cm^3 / 10 min) is a very low viscosity polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx1851 resin (MVR 23 cm^3 / 10 min) is a low viscosity polycarbonate with enhanced release and surface lubricity characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® 2458 resin (MVR 19 cm^3 / 10 min) is a medium/low viscosity polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx1452 resin (MVR 16 cm^3 / 10 min) is a medium/low viscosity polycarbonate with enhanced release and surface lubricity characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® 2558 resin (MVR 14 cm^3 / 10 min) is a medium viscosity polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® 2658 resin (MVR 12 cm^3 / 10 min) is a medium viscosity polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® 2858 resin (MVR 9 cm^3 / 10 min) is a medium viscosity polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® 3158 resin (MVR 6 cm^3 / 10 min) is a high viscosity, high-performance polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® 3258 resin (MVR 5 cm^3 / 10 min) is a high viscosity, high-performance polycarbonate with good release characteristics, suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx2235 resin (MVR 37 cm^3 / 10 min) is a very low viscosity polycarbonate with easy-release characteristics. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx2435 resin (MVR 23 cm^3 / 10 min) is a low viscosity polycarbonate with easy-release characteristics. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx2430 resin (MVR 19 cm^3 / 10 min) is a medium/low viscosity polycarbonate. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

[1] See datasheets for MVR test conditions

PRODUCT OVERVIEW OF MEDICAL GRADES[1]

Makrolon® Rx2440 resin (MVR 19 cm^3 / 10 min) medium/low viscosity polycarbonate. It is stabilized for radiation sterilization of devices in oxygen-free packaging, but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx2530 resin (MVR 15 cm^3 / 10 min) is a medium viscosity polycarbonate. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx2635 resin (MVR 12 cm^3 / 10 min) is a medium viscosity polycarbonate with easy-release characteristics. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx1805 resin (MVR 6 cm3 / 10 min) is a high viscosity, lipid-resistant polycarbonate. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® Rx3440 resin (MVR 4.5 cm^3 / 10 min) is a high viscosity, lipid-resistant polycarbonate with improved oncology drug resistance. It is particularly suitable for sterilization by radiation but may also be sterilized with EtO and steam at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M6011 FR resin (MVR 25 cm^3 / 10 min) is an opaque, uv stabilized, advanced phosphorous based flame retardant (V0 @ 1.5mm) polycarbonate with excellent chemical resistance and easy release characteristics suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Apec® 1745 resin (MVR 17 cm^3 / 10 min) is a high-heat copolycarbonate suitable for repeated steam sterilization up to 143°C. This resin has easy-release characteristics, high softening temperature and good hydrolysis resistance. Biocompatible according to certain ISO 10993-1 test requirements.

Bayblend® M750 resin (MVR 11 cm^3 / 10 min) is an opaque, medium viscosity, PC+ABS blend. This resin is biocompatible according to certain ISO 10993-1 test requirements.

Bayblend® M850 XF resin (MVR 25 cm^3 / 10 min) is an opaque, low viscosity, PC+ABS blend. This resin is biocompatible according to certain ISO 10993-1 test requirements.

Bayblend® M301 FR resin (MVR 25 cm^3 / 10 min) is an opaque, low viscosity, advanced phosphorous based flame retardant (UL94 V-0 @ 1.5mm), PC+ABS blend. This resin meets the biocompatibility requirements of certain ISO 10993-1 testing for contact with uncompromised skin.

Bayblend® M303 FR resin (MVR 11 cm^3 / 10 min is an opaque, medium viscosity, advanced phosphorous based flame retardant (UL94 V-0 @ 1.5mm), PC+ABS blend. Suitable for extrusion. This resin meets the biocompatibility requirements of certain ISO 10993-1 testing for contact with uncompromised skin.

Makroblend® M525 resin (MVR 21 cm^3 / 10 min) is an opaque, low viscosity, PC+PBT blend with exceptional low temperature impact. This resin meets the biocompatibility requirements of certain ISO 10993-1 testing for contact with uncompromised skin.

[1] See datasheets for MVR test conditions

PRODUCT OVERVIEW OF MEDICAL GRADES[1]

Makroblend® M4000 FR resin (MVR 25 cm^3 / 10 min) is an opaque, medium/low viscosity, PC+PBT blend. UL94 listed V-0 @ 2.0mm. This resin meets the biocompatibility requirements of certain ISO 10993-1 testing for contact with uncompromised skin.

Makroblend® M5005 FR resin (MVR 35 cm^3 / 10 min) is an opaque, medium/low viscosity, PC+PBT blend. Advanced phosphorous based flame retardant UL94 listed V0 @ 2.4mm. UV-stabilized and meets the biocompatibility requirements of certain ISO 10993-1 testing for contact with uncompromised skin.

Makrolon® M410 GF resin (MVR 12 cm^3 / 10 min) is a medium/low viscosity 10% glass filled polycarbonate. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M420 GF resin (MVR 9 cm^3 / 10 min) is a medium/low viscosity 20% glass filled polycarbonate. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M430 GF resin (MVR 7 cm^3 / 10 min) is a medium/low viscosity 30% glass filled polycarbonate. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M810 GF resin (MVR 4 cm^3 / 10 min) is a high viscosity 10% glass filled polycarbonate. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M820 GF resin (MVR 3.5 cm^3 / 10 min) is a high viscosity 20% glass filled polycarbonate. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M830 GF resin (MVR 3 cm^3 / 10 min) is a high viscosity 30% glass filled polycarbonate. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M204 LF resin (MVR 34 cm^3 / 10 min) is a very low viscosity polycarbonate with excellent low friction properties. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M402 LF resin (MVR 19 cm^3 / 10 min) is a medium/low viscosity polycarbonate with good low friction properties. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

Makrolon® M404 LF resin (MVR 19 cm^3 / 10 min) is a medium/low viscosity polycarbonate with excellent low friction properties. It is suitable for EtO sterilization and steam sterilization at 121°C. Biocompatible according to certain ISO 10993-1 test requirements.

[1] See datasheets for MVR test conditions

PRODUCT OVERVIEW OF STANDARD GRADES

Standard grades for medical applications (non-biocompatible)

The following flame-retardant Bayblend® grades are used in applications such as device housings where flame-retardancy is needed, yet ISO 10993-1 biocompatibility is not required.

Please contact your local Covestro representative to discuss these and other alternative materials.

Bayblend® FR3010 resin (PC+ABS) Blend; flame retardant; Vicat/B 120 temperature = 110 °C; increased heat resistance; UL94 V-0 at 1.5 mm; glow wire temperature (GWFI): 960 °C at 2.0 mm; improved chemical resistance and stress cracking behavior

Bayblend® FR3010 HF resin (PC+ABS) Blend; flame retardant; easy flowing; Vicat/B 120 temperature = 108 °C; UL94 V-0 at 1.5 mm; glow wire temperature (GWFI): 960 °C at 2.0 mm; optimized processability

STERILIZATION METHODS

Medical devices typically require sterilization before use. There are three sterilization methods most prevalent in the medical industry:

1. Ethylene oxide (EtO gas)
2. Steam autoclave
3. Irradiation with high-energy radiation (gamma or e-beam)

The table below shows which Makrolon®, Bayblend®, Apec® or Makroblend® grades are suitable for each sterilization method. However, the resistance to the different sterilization methods and the number of sterilization cycles a medical device can withstand will vary depending upon the type/grade of Makrolon®, Bayblend®, Makroblend® and Apec®, part design, processing parameters and other factors. The manufacturer of the medical device must determine the suitability of the sterilization method in each individual case.

Sterilization Method	Makrolon® 2258 Rx1851 2458 Rx1452 2558 2658 2858 3158 3258	Makrolon® Rx2235 Rx2435 Rx2430 Rx2440 Rx2530 Rx2635 Rx1805 Rx3440	Makrolon® M6011 FR	Apec® 1745	Bayblend® M301 FR M303 FR M750 M850 XF	Makroblend® M525 M4000 FR M5005 FR	Makrolon® M410 GF M420 GF M430 GF M810 GF M820 GF M830 GF	Makrolon® M204 LF M402 LF M404 LF
Ethylene oxide	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Steam 121 °C	Yes	Yes	No	Yes	No	No	Yes	Yes[2]
Steam 134 °C	No	No	No	Yes	No	No	No	No
Steam 143 °C	No	No	No	Yes	No	No	No	No
Gamma radiation	Yes[1]	Yes	Yes[1]	Yes[1]	Yes[1]	Yes[1]	Yes[1]	Yes[1]
E-beam	Yes[1]	Yes	Yes[1]	Yes[1]	Yes[1]	Yes[1]	Yes[1]	Yes[1]

[1]See information under "Sterilization by high energy radiation (gamma/e-beam) on page 19"
[2]Single sterilization cycle only

STERILIZATION METHODS

Sterilization by ethylene oxide (EtO gas)

Ethylene oxide when used for sterilization can be either used undiluted or in an inert gas mixture containing between 10 to 20% EtO.

During sterilization the temperature should not exceed 65°C. Tests have shown that frequent sterilization can lead to slight brittleness and crack formation. Tests carried out on specimens treated with pure ethylene oxide at 55°C showed that, after 50 cycles of 6 hours each, the impact strength is unchanged compared with the starting level despite slight crack formation.

Sterilization by steam (saturated steam)

The sterilization temperature should not exceed 125°C for Makrolon® resin, otherwise the molded parts can become deformed. Parts made of Apec® 1745 may be sterilized in steam up to 143°C. Care must also be taken to ensure that the Makrolon® or Apec® resin part is not damaged by any substances added to the boiler feed water, such as alkaline corrosion inhibitors, and that the article is positioned correctly so that no condensation can accumulate inside it.

As a rule, it is possible to sterilize molded parts made of Makrolon® and Apec® resins many times before gradual chemical decomposition reduces the mechanical strength to a level where it is no longer adequate for certain applications. Sterilization tests on on Apec® test specimens have shown that even after 100 cycles of 30 minutes each at 120 to 125°C, the parts retain comparatively good impact strength. Medical articles made of Makrolon® or Apec® resins which are intended for single use are not suitable for multiple use.

Sterilization by high-energy radiation (gamma/e-beam)

Makrolon® and Apec® resins have a high resistance to the effects of high-energy radiation. Assuming that 28 kGy of energy is required to sterilize Makrolon® or Apec® resins, the resin can be sterilized 10 to 20 times before any appreciable reduction in mechanical strength occurs. Standard Makrolon® and Apec® however become more yellow with each sterilization cycle. Makrolon® Rx2235, Rx2435, Rx2430, Rx2440, Rx2530, Rx2635, Rx1805 and Rx3440 resins are high-energy radiation stable grades. The color of these grades shifts to a neutral tint after a typical sterilization dose of high-energy radiation. The degree of color shift depends on the sterilization dose. Makrolon® Rx2440 resin has been designed for devices sterilized by radiation in oxygen-free packaging. Parts made from Bayblend® or Makroblend® resins can become more yellow and exhibit decreased impact resistance after sterilization with high-energy radiation.

CHEMICAL RESISTANCE

Parts molded from Makrolon®, Bayblend®, Apec® and Makroblend® resins are resistant to mineral acids, including a large number of organic acids (e.g., carbonic acid, lactic acid, oleic acid and citric acid), to oxidizing and reducing agents, neutral and acidic saline solutions, a range of greases and oils, saturated aliphatic and cycloaliphatic hydrocarbons and also alcohols, with the exception of methanol. Makrolon®, Bayblend®, Apec® and Makroblend® resins are severely degraded by alkaline/caustic solutions, ammonia gas and its solution and amines. Makrolon®, Bayblend®, Apec® and Makroblend® resins will dissolve in a number of industrial solvents such as dichloromethane or tetrahydrofuran (THF).

Other organic compounds, such as benzene or acetone, cause them to swell. A number of chemical substances may cause stress cracking. Chemical resistance depends both on the internal molded-in stresses and on the external stresses to which the part is exposed (see "Makrolon® - Stress Crack Test"). In the case of Makrolon® resins, the higher-viscosity grades generally offer better resistance to chemicals. Makroblend® grades can provide even higher levels of chemical resistance.

The tables which follow list test results after exposure to various chemicals which may be encountered by medical devices.

As is the case with any compatibility test, the results are dependent on such variables as concentration, time, temperature, part design and residual stresses, and should serve only as a guideline. It is imperative that production parts be evaluated under actual application conditions prior to commercial use.

In addition to the resins listed below, industrial resins may be used in some applications where neither biocompatibility nor formulation control is required. Some of these grades are listed in the tables at the end of this guide. For more information about these and other grades, including chemical compatibility, please contact your Covestro representative.

CHEMICAL RESISTANCE

Resins for Medical Devices
Medical devices often come into contact with a variety of substances from medical tubing, drugs, IV-fluids and antiseptics. The table below summarizes the resistance of medical grade products to examples of these media.

The method used to determine degree of chemical resistance reported in the tables below was as follows:

ISO 527 tensile specimens were continuously exposed to chemicals for 24 hours or repeatedly wiped (10× wet-to-dry) at fixed flexural strains of 1.0% and 0.6%.

Pass criteria: (1) no visible cracking upon close inspection, (2) tensile yield strength fully retained: >98%, and (3) yield behavior preserved with >10% nominal strain at break.

R "resistant": passed evaluation at 1.0% strain

L "limited resistance": passed evaluation at 0.6% strain, failed at 1.0% strain

N "not resistant": failed evaluation at 0.6% strain

Media	Makrolon®			Apec®
	Rx3440	2858	Rx2530	1745
Dioctyl phthalate	L	L	L	L
Trioctyl trimellitate	R	R	L	L
20% lipid solution	R	L	L	L
1% saline solution	R	R	R	R
Deionized water	R	R	R	R
Betadine	R	R	R	R
3% hydrogen peroxide	R	R	R	L

R Resistant L Limited resistance N No resistance

RESINS FOR ELECTROMECHANICAL HOUSINGS

Housings encounter a greater variety of substances than medical devices. In addition to media described in the table above, the surfaces of housings are often cleaned with aggressive disinfectants. The following table summarizes the chemical resistance of our medical resins for electro-mechanical devices.[1]

Disinfectants	Bayblend®				Makroblend®			Makrolon®			
	M301 FR	M303 FR	M750	M850 XF	M4000 FR	M525	M5005 FR	2458	2858	Rx3440	M6011 FR
CaviCide™	R	R	R	R	R	R	R	R	R	R	R
Clorox Healthcare® Bleach Wipes	R	R	R	R	R	R	R	R	R	R	R
Lysol® Disinfecting Wipes (Lemon & Lime)	R	R	R	R	R	R	R	R	R	R	R
Opti-Cide®3 Surface Wipes	R	R	R	R	R	R	R	R	R	R	R
Oxivir® Tb	N	N	L	N	R	R	R	L	L	R	R
Sporicidin®	R	R	R	R	R	R	R	R	R	R	R
Super Sani-Cloth® Germicidal Wipe	R	R	R	R	R	R	R	R	R	R	R
Virex® II 256	R	R	R	R	R	R	R	R	R	R	R

R Resistant L Limited resistance N No resistance

Disinfection with UVC light

An emerging disinfection technology for housings in hospitals is to use UVC light (wavelength 200 – 280 nm). UV light in this range is absorbed by the pathogen's DNA/RNA, disrupting their cell replication processes and inhibiting their spread. UV light can also affect the appearance and mechanical performance of plastics.

Depending on amount of UVC exposure, the color and mechanical properties of the material may be affected. Preliminary testing has demonstrated that when exposed to a typical cumulative dose of 120 J/m^2, mechanical properties of our resins are retained. Please consult with your local Covestro representative for more information.

[1] See also the white paper *Compatibility with disinfectants used against SARS-CoV-2*

RESINS FOR WEARABLES

The emergence of wearable medical devices presents unique challenges for material selection. Parts often need to be durable enough to withstand being worn 24 hours a day while being exposed to chemicals such as sunscreen and lotions. The table below summarizes the effect of these substances on our products.

Consumer Products	Bayblend®				Makroblend®			Makrolon®			
	M301 FR	M303 FR	M750	M850 XF	M4000 FR	M525	M5005 FR	2458	2858	Rx3440	M6011 FR
Aveeno® Daily Moisturizing Lotion	L	R	R	L	R	R	R	R	R	R	R
Banana Boat® Sunscreen, Ultra Sport™, SPF 50+	N	L	R	L	L	L	N	R	R	R	R
Goo Gone® Original Goo & Adhesive Remover	N	R	R	N	R	R	R	L	R	R	R
Hand Soap (Softsoap®)	R	R	R	R	R	R	R	R	R	R	R
Isopropanol, 70% (v/v)	R	R	R	R	R	R	R	R	R	R	R
Purell® Advanced Hand Sanitizer	R	R	R	R	R	R	R	R	R	R	R
Sebum (synthetic, ASTM D4265)	L	R	R	L	R	R	R	R	R	R	R
Skin Tac™ Adhesive Barrier Wipes	L	R	R	R	R	R	R	R	R	R	R

R Resistant L Limited resistance N No resistance

COVESTRO MEDICAL GRADES & REGULATORY INFORMATION

Guidance on Use of Covestro Products in a Medical Application

All Covestro polycarbonate thermoplastics, sheets, and films (herein after "products") that are designated as "Medical Grade" meet certain biocompatibility test requirements of USP Plastics Class VI and/ ISO 10993-1 (table on right).

These tests are conducted under Good Laboratory Practices as defined by the FDA in 21 CFR Part 58. Prior to testing, skin contact Medical Grades were treated with alcohol swabs; all other medical products were sterilized by ethylene oxide and gamma radiation. Only Medical Grade products may be considered candidates for applications requiring biocompatibility. No "Medical Grade" product will be available for sale until successfully assessed for biocompatibility.

"Medical Application" means all applications of medical devices wherein the medical device is manufactured with a Covestro product(s) and is intended under normal use to be brought into direct contact with the patient's body (e.g., skin, body fluids or tissues, including indirect contact to blood).

Covestro products designated as "Medical Grade" shall not be considered candidates for bioabsorbable or long-term (greater than 30 days) implant applications unless Covestro explicitly agrees, in writing, to sell such products for such applications.

The biocompatibility testing referenced above cannot assure the biocompatibility of final or intermediate products made from Covestro products or the suitability of such products for their use in a Medical Application, i.e., the test data cannot be used to conclude that any medical devices manufactured from the Covestro products meet the necessary requirements of ISO Standard 10993-1. It is the sole responsibility of the manufacturer of final end-use product to conduct all necessary tests (including biocompatibility tests) and inspections and to evaluate the final product under actual end-use requirements.

The designation as "Medical Grade" does not mean that Covestro has determined the product is suitable for use in any particular Medical Application. Covestro makes no representations regarding the suitability of a Covestro product for a particular Medical Application or final end-use product.

A determination that the Covestro product is suitable for use in a particular Medical Application or final end-use product can only be made by the purchaser of the Covestro product who utilizes it in a Medical Application and conducts all necessary testing and evaluation to support such a determination.

Only virgin Medical Grade Covestro products have been assessed for biocompatibility. Any use of regrind, for example, runners from mold flow channels or trim pieces, must be evaluated by the medical device manufacturer for suitability.

"Biological Evaluation of Medical Devices" Selected Tests May Include

1. Cytotoxicity
2. Sensitization
3. Intracutaneous Injection
4. Acute Systemic Toxicity
5. Pyrogenicity
6. Genotoxicity
7. Implantation
8. Hemolysis (Direct and Indirect)
9. In-vitro Hemocompatibility
10. USP Physicochemical Test
11. Heavy Metals Analysis (Acid Digest and Extraction)

COVESTRO MEDICAL GRADES & REGULATORY INFORMATION

Appropriate Use of Covestro Products In a Medical Application

Covestro has not performed clinical medical studies concerning the use of Covestro products. Moreover, Covestro has neither sought nor received approval from the United States Food and Drug Administration (FDA) or other competent authorities from other regions for the use of Covestro products in a Medical Application.

Covestro makes no representations or warranty regarding (and accepts no responsibility for determining) either: (a) the suitability of a Covestro product for a particular Medical Application or final end-use product or (b) the adequacy of any warning relating to a Covestro product or particular Medical Application or final end-use product.

The suitability of a Covestro product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, method of manufacture, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final end-use product to determine the suitability (including biocompatibility) of all raw materials and components, including any Covestro products, in order to ensure that the final product:

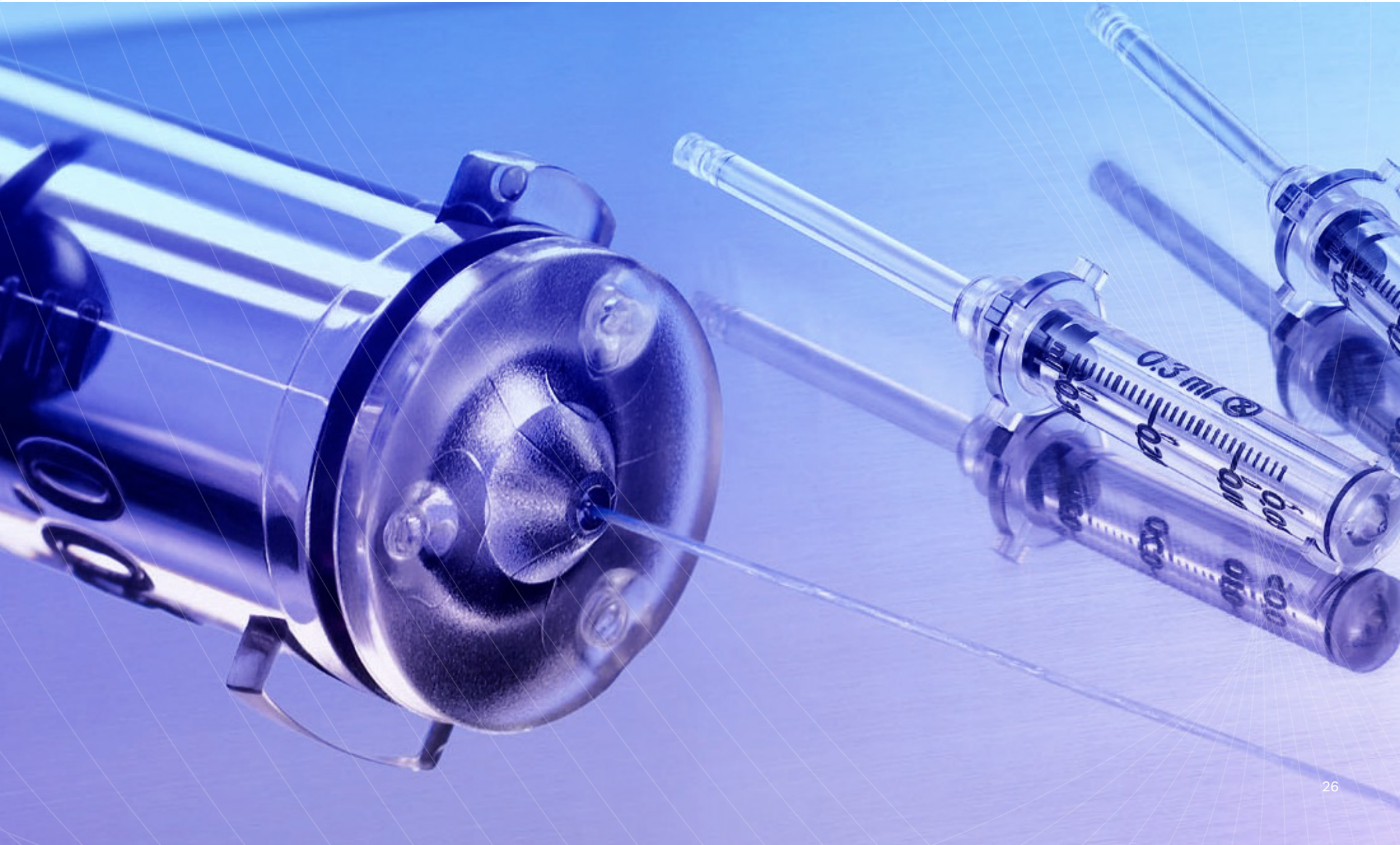
- meets relevant biocompatibility requirements and is otherwise safe for its end-use
- performs or functions as intended
- is suitable for its intended use
- complies with all applicable FDA and other regulatory requirements.

It also is the sole responsibility of the manufacturer of the final end-use product to conduct all necessary tests and inspections and to evaluate the final product under actual end-use requirements and to adequately advise and warn purchasers, users and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any post-market surveillance obligations.

Any decision regarding the appropriateness of a particular medical product in a particular clinical or Medical Application should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician. Covestro cannot weigh the benefits against the risks of a medical device and cannot offer a medical or legal judgment on the safety or efficacy of the use of a Covestro product in a specific Medical Application.

Sterilization: Parts molded or extruded from Texin Medical Grade TPU resins can be sterilized using ethylene oxide, radiation or dry heat. The use of steam autoclaving or boiling water sterilization techniques may hydrolyze polyurethane materials to their corresponding precursor diamines (for example, aromatic polyurethanes based on diphenylmethane diisocyanate (MDI) may hydrolyze and produce methylene dianiline (MDA). This condition needs to be considered by the device manufacturer in defining sterilization conditions. The sterilization method and the number of sterilization cycles a medical device made from Texin® resins resin can withstand will vary depending upon type/grade of product, part design, processing parameters, sterilization temperature and chemical environment. Therefore, the manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

TYPICAL PRODUCT VALUES



TYPICAL PRODUCT VALUES

				Biocompatible Makrolon® Resins for Medical Applications Requiring EtO and Steam Sterilization								
				2258	**Rx1851**	**2458[1]**	**Rx1452**	**2558**	**2658[2]**	**2858[3]**	**3158[4]**	**3258[5]**
MVR	ISO 1133	300°C/1.2 kg	cm^3/10 min	34	23	19	16	14	12	9	6	5
Molding Shrinkage, Parallel	ISO 294-4	60x60x2 mm; 500 bar	%	0.65	0.70	0.65	0.60	0.65	0.70	0.70	0.70	0.70
Molding Shrinkage, Normal	ISO 294-4	60x60x2 mm; 500 bar	%	0.65	0.70	0.70	0.65	0.70	0.75	0.75	0.75	0.75
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	2400	2400	2400	2400	2400	2400	2400	2400	2400
Yield Stress	ISO 527-1, -2	50 mm/min	MPa	65	65	65	68	66	66	66	66	66
Yield Strain	ISO 527-1, -2	50 mm/min	%	6.0	6.0	6.1	6.0	6.1	6.1	6.1	6.2	6.2
Notched Izod Impact (3mm)	b.o. ISO 180-A	23°C	kJ/m^2	65	65	75	65	80	80	85	70	75
Notched Izod Impact (3mm)	b.o. ISO 180-A	-30°C	kJ/m^2	12	12	14	12	14	14	14	15	20
Temperature of Deflection under Load	ISO 75-1, -2	1.80 MPa	°C	124	121	125	120	124	124	125	126	127
Temperature of Deflection under Load	ISO 75-1, -2	0.45 MPa	°C	137	134	139	132	136	137	137	138	139
Coefficient of Linear Thermal expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
Coefficient of Linear Thermal Expansion, Transverse	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
Density	ISO 1183-1	—	kg/m^3	1200	1200	1200	1200	1200	1200	1200	1200	1200

[1]Makrolon® 2408 resin also available — equivalent grade without release agent
[2]Makrolon® 2608 resin also available — equivalent grade without release agent
[3]Makrolon® 2808 resin also available — equivalent grade without release agent
[4]Makrolon® 3108 resin also available — equivalent grade without release agent
[5]Makrolon® 3208 resin also available — equivalent grade without release agent
For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

TYPICAL PRODUCT VALUES

				Biocompatible Makrolon® Resins for Medical Applications Requiring Gamma and E-beam Sterilization							
				Rx2235	**Rx2435**	**Rx2430**	**Rx2440**	**Rx2530**	**Rx2635**	**Rx1805**	**Rx3440**
MVR	ISO 1133	300°C/1.2 kg	cm^3/10 min	34	23	19	19	15	12	6	4.5
Molding Shrinkage, Parallel	ISO 294-4	60x60x2 mm; 500 bar	%	0.5-0.7[1]	0.65	0.60	0.60	0.60	0.6-0.8[1]	0.70	0.70
Molding Shrinkage, Normal	ISO 294-4	60x60x2 mm; 500 bar	%	0.5-0.7[1]	0.65	0.65	0.65	0.65	0.6-0.8[1]	0.70	0.70
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	2400	2400	2400	2400	2400	2400	2400	2300
Yield Stress	ISO 527-1, -2	50 mm/min	MPa	65	67	67	67	67	67	67	65
Yield Strain	ISO 527-1, -2	50 mm/min	%	5.9	6.1	6.1	6.1	6.1	6.1	6.3	6.4
Notched Izod Impact (3mm)	b.o. ISO 180-A	23°C	kJ/m^2	10	75	70	75	70	65	80	80
Notched Izod Impact (3mm)	b.o. ISO 180-A	-30°C	kJ/m^2	8	12	14	12	14	12	15	14
Temperature of Deflection under Load	ISO 75-1, -2	1.80 MPa	°C	117	120	122	120	122	121	126	126
Temperature of Deflection under Load	ISO 75-1, -2	0.45 MPa	°C	131	132	134	132	134	135	138	139
Coefficient of Linear Thermal expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
Coefficient of Linear Thermal Expansion, Transverse	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
Density	ISO 1183-1	—	kg/m^3	1200	1200	1200	1200	1200	1200	1200	1200

For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

[1] Value range based on general practical experience

TYPICAL PRODUCT VALUES

				Biocompatible Low Friction Makrolon® Resins for Medical Applications		
				M204 LF	**M402 LF**	**M404 LF**
MVR	ISO 1133	300°C/1.2 kg	cm^3/10 min	34	19	19
Molding Shrinkage, Parallel	ISO 294-4	60x60x2 mm; 500 bar	%	0.7	0.7	0.7
Molding Shrinkage, Normal	ISO 294-4	60x60x2 mm; 500 bar	%	0.7	0.7	0.7
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	2200	2150	2100
Yield Stress	ISO 527-1, -2	50 mm/min	MPa	60	60	60
Yield Strain	ISO 527-1, -2	50 mm/min	%	5.8	6.1	6.0
Notched Izod Impact (3 mm)	b.o. ISO 180-A	23°C	kJ/m^2	50	60	60
Notched Izod Impact (3 mm)	b.o. ISO 180-A	-30°C	kJ/m^2	10	12	12
Temperature of Deflection under Load	ISO 75-1, -2	1.80 MPa	°C	122	122	122
Temperature of Deflection under Load	ISO 75-1, -2	0.45 MPa	°C	137	138	137
Coefficient of Linear Thermal Expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65	0.65	0.65
Coefficient of Linear Thermal Expansion, Transverse	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65	0.65	0.65
Density	ISO 1183-1	-	kg/m^3	1200	1200	1200

For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

TYPICAL PRODUCT VALUES

				Biocompatible Glass Filled Makrolon® Resins for Medical Applications					
				M410 GF	**M420 GF**	**M430 GF**	**M810 GF**	**M820 GF**	**M830 GF**
MVR	ISO 1133	300°C/1.2 kg	cm^3/10 min	12	9	7	4	3.5	3
Molding Shrinkage, Parallel	ISO 294-4	60x60x2 mm; 500 bar	%	0.5	0.3	0.2	0.55	0.3	0.2
Molding Shrinkage, Normal	ISO 294-4	60x60x2 mm; 500 bar	%	0.5	0.5	0.5	0.55	0.55	0.55
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	3800	5800	8000	3600	5600	7800
Yield Stress	ISO 527-1, -2	5 mm/min	MPa	80	105	128[1]	77	100[1]	121[1]
Yield Strain	ISO 527-1, -2	5 mm/min	%	3.8	3.0	2.8[2]	4.1	4.0[2]	3.3[2]
Notched Izod Impact	b.o. ISO 180-A	23°C	kJ/m^2	7	12	14	12	16	18
Notched Izod Impact	b.o. ISO 180-A	-30°C	kJ/m^2	6	11	13	10	14	16
Temperature of Deflection under Load	ISO 75-1, -2	1.80 MPa	°C	135	138	140	136	140	142
Temperature of Deflection under Load	ISO 75-1, -2	0.45 MPa	°C	142	143	144	145	146	147
Coefficient of Linear Thermal Expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.4	0.3	0.3	0.4	0.3	0.2
Coefficient of Linear Thermal Expansion, Transverse	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.4	0.4	0.4	0.4	0.4	0.4
Density	ISO 1183-1	-	kg/m^3	1270	1340	1420	1270	1340	1420

[1]Stress at break
[2]Yield at break
For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

TYPICAL PRODUCT VALUES

				Biocompatible High Heat Apec® for Medical Applications
				1745
MVR	ISO 1133	330°C/2.16 kg	cm^3/10 min	17
Molding Shrinkage, Parallel	ISO 294-4	60x60x2 mm; 500 bar	%	0.8
Molding Shrinkage, Normal	ISO 294-4	60x60x2 mm; 500 bar	%	0.8
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	2400
Yield Stress	ISO 527-1, -2	50 mm/min	MPa	70
Yield Strain	ISO 527-1, -2	50 mm/min	%	6.8
Notched Izod Impact	b.o. ISO 180-A	23°C	kJ/m^2	13
Notched Izod Impact	b.o. ISO 180-A	-30°C	kJ/m^2	10
Temperature of Deflection under Load	ISO 75-1, -2	1.80 MPa	°C	148
Temperature of Deflection under Load	ISO 75-1, -2	0.45 MPa	°C	160
Coefficient of Linear Thermal Expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65
Coefficient of Linear Thermal Expansion, Transverse	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.65
Density	ISO 1183-1	-	kg/m^3	1170

For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

TYPICAL PRODUCT VALUES

				Biocompatible Resins and Blends for Medical Applications							
				Makrolon®	Makroblend®			Bayblend®			
				M6011 FR[1]	**M4000 FR[1]**	**M5005 FR[1]**	**M525[1]**	**M301 FR[1]**	**M303 FR[1]**	**M750[2]**	**M850 XF[2]**
MVR	ISO 1133	300°C/5 kg	cm^3/10 min	25	-	-	-	-	-	-	-
MVR	ISO 1133	240°C/5 kg	cm^3/10 min	-	-	-	-	25	-	-	-
MVR	ISO 1133	260°C/5 kg	cm^3/10 min	-	18	35	21	-	11	11	25
Molding Shrinkage, Parallel	b.o. ISO 2577	Value range based on practical experience	%	0.6-0.8	0.7 - 0.9	0.7 - 0.9	0.7 - 0.9	0.5 - 0.7	0.5 - 0.7	0.7 - 0.9	0.55-0.75
Molding Shrinkage, Normal	b.o. ISO 2577	Value range based on practical experience	%	0.6-0.8	0.7 - 0.9	0.7 - 0.9	0.7 - 0.9	0.5 - 0.7	0.5 - 0.7	0.7 - 0.9	0.55- 0.75
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	2300	2300	2300	2000	2600	2650	2000	2500
Yield Stress	ISO 527-1, -2	50 mm/min	MPa	61	56	55	55	60	69	47	62
Yield Strain	ISO 527-1, -2	50 mm/min	%	5.9	4.3	4	4.5	4	5	4.8	4.9
Notched Izod Impact	ISO 180-A	23°C	kJ/m^2	70	40	45	60	35	40	45	48
Notched Izod Impact	ISO 180-A	-30°C	kJ/m^2	20	12	13	20	8	10	35	15
Temperature of Deflection under Load	ISO 75-1, -2	1.80 MPa	°C	113	85	77	75	85	98	104	109
Temperature of Deflection under Load	ISO 75-1, -2	0.45 MPa	°C	128	115	89	100	95	115	127	127
Coefficient of Linear Thermal Expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.7	0.8	0.9	0.9	0.8	0.7	0.85	0.7
Coefficient of Linear Thermal Expansion, Transverse	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.7	0.8	0.9	0.9	0.8	0.7	0.85	0.7
Density	ISO 1183-1	-	kg/m^3	1190	1340	1250	1220	1190	1190	1120	1140
Burning behavior UL 94 [UL recognition]	UL94	V-0	mm	1.5	2.0	2.4	-	1.5	1.5	-	-
Burning behavior UL 94 [UL recognition]	UL94	5VA	mm	-	3.0	-	-	3.0	3.0	-	-

[1]Skin contact biocompatibility for uncompromized skin
[2]Biocompatible for non-implant applications
For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

TYPICAL PRODUCT VALUES

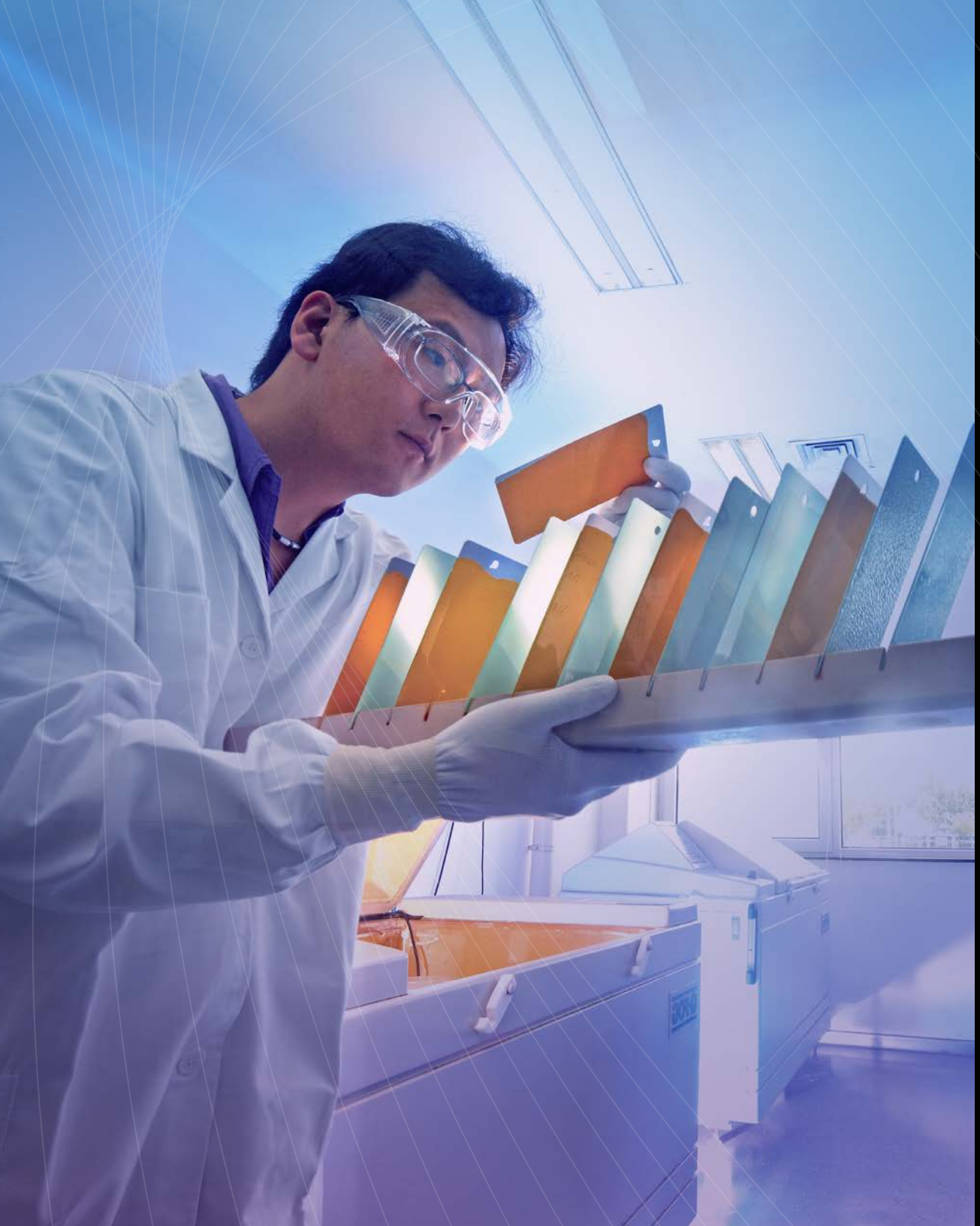
				General Purpose Resins for Medical Applications (Non-biocompatible)	
				Bayblend®	
				FR3010	**FR3010 HF**
MVR	ISO 1133	240°C/5 kg	cm^3/10 min	15	25
Molding Shrinkage, Parallel	b.o. ISO 2577	Value range based on practical experience	%	0.5-0.7	0.5-0.7
Molding Shrinkage, Normal	b.o. ISO 2577	Value range based on practical experience	%	0.5-0.7	0.5-0.7
Tensile Modulus	ISO 527-1, -2	1 mm/min	MPa	2700	2600
Yield Stress	ISO 527-1, -2	50 mm/min	MPa	60	60
Yield Strain	ISO 527-1, -2	50 mm/min	%	4	4
Notched Izod Impact	b.o. ISO 180-A	23°C	kJ/m^2	35	35
Notched Izod Impact	b.o. ISO 180-A	-30°C	kJ/m^2	10	10
Temperature of Deflection Under Load	ISO 75-1, -2	1.80 MPa	°C	90	90
Temperature of Deflection Under Load	ISO 75-1, -2	0.45 MPa	°C	100	100
Coefficient of Linear Thermal Expansion, Parallel	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.76	0.76
Coefficient of Linear Thermal Expansion, Normal	ISO 11359-1, -2	23 to 55°C	10^{-4}/K	0.8	0.8
Density	ISO 1183-1	-	kg/m^3	1180	1180
Burning behavior UL 94 [UL recognition]	UL94	V0	mm	1.5	1.5
Burning behavior UL 94 [UL recognition]	UL94	5VA	mm	3.0	3.0

For more information on the grades listed above, check the Product Finder on the Covestro Solution Center

TYPICAL PRODUCT VALUES

			Biocompatible High-Performance Thermoplastic Polyurethanes for Healthcare Applications								
			Texin®								
			RxT70A	**RxT80A**	**RxT85A**	**RxT90A**	**RxT50D**	**RxT65D**	**RxT76D**	**RxS285**	**RxS292**
Shore Hardness	ISO 868	-	70A	84A	85A	90A	50D	65D	76D	85A	92A
Tensile Stress at 100% Elongation	ISO 37	MPa	3.4	5.3	5.5	7.6	14.0	25.0	29.0	5.3	9.7
Tensile Strength	ISO 37	MPa	26	27	37	41	48	52	46	38	40
Tear Strength	ISO 34	kN/m	60	88	88	136	131	210	257	88	129
Vicat A	ISO 306	°C	75	80	80	106	128	138	133	91	88
Flex Modulus	ISO 178	MPa	14	27	27	41	114	421	1467	28	73
Taber Abrasion	ISO 4649	mg loss	7	30	30	25	75	75	62	35	27
Clarity	-	-	Good	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent

For more information on the grades listed above, check the Product Finder on the Covestro Solution Center



APPLICATION DEVELOPMENT

Our Capabilities, Engineering, and Application Development Support.

- Part and Mold Design Reviews
- Teardowns and Part/Assembly Design
- Concept Development
- Feasibility Studies / Cost Estimation
- Material Selection
- CAE Design and Analysis (Structural, Mold filling, etc.)
- Mold & Injection System Design & Analysis
- Failure Analysis
- On-Site Technical Support and Troubleshooting
- New Mold/Material Trials
- Advanced Processing Feasibility & Support
- Component/System Testing Evaluations
- Technical Literature

ADDITIONAL RESOURCES

White papers available on the Covestro Solution Center

HEALTHCARE TOPICS

- Adhesion of TPEs on polycarbonates for medical wearables
- Balanced filling in thermoplastic medical molding
- Compatibility with disinfectants used against SARS-CoV-2
- Enhancing impact resistance and toughness in molded medical parts
- Eye protection for welders
- Influence of UVC LED disinfection on polycarbonate materials
- Photo-elastic stress analysis of polycarbonate medical parts
- Thermoplastic polyurethanes for medical applications
- Understanding flow hesitation in molded medical parts

GENERAL TOPICS

Injection Molding & Mold Design

- Calculating the mold-filling process for thin-walled injection moldings
- Determining the dryness of Makrolon® by the TVI test
- Gate design for high-quality surface finish
- Injection molding - production equipment and machinery
- Injection molding of high-quality molded parts-drying
- Optimized mold temperature control
- Overmolding with polycarbonate and polycarbonate blends
- Part and mold design brochure
- Process variables - injection molding
- Purging compounds for use when molding thermoplastics
- Shrinkage and deformation of glass fiber reinforced thermoplastics
- The fundamentals of shrinkage in thermoplastics
- Understanding and optimizing weld lines in thermoplastic molding

Secondary Options

- Joining techniques design guide
- Laser marking thermoplastics
- Laser transmission welding
- Marking products made of technical thermoplastics
- Self-tapping screws for thermoplastics
- The insertion of connecting elements using ultrasound

Part Performance

- Addressing molded-in stresses and part durability
- Environmental stress cracking - Bend strip test
- Makrolon® - stress crack test
- Makrolon® - chemical resistance

Part Design

- Design with Makrolon® thermally conductive polymers
- Designing with light
- Snap-fit joints for plastic - A design guide

Material Selection

- Makrolon® for LED lighting
- Makrolon® for optical data storage
- Materials and packaging solutions for energy storage systems used in electromobility
- Optical properties of Makrolon® and Apec®
- Polycarbonate and polycarbonate blends for the electrical and electronics industries
- Shaping LED diffuser performance

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