NORDICS

nexeo plastics

Connecting you to Solutions for the Medical Market

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SUPPORTING A WIDE RANGE OF REQUIREMENTS

In the dynamic world of healthcare, the role of thermoplastics has undergone a remarkable transformation. Today, they stand at the forefront of innovation, driving the development of cutting-edge healthcare products that are safer, more efficient, and environmentally responsible than ever before.

This brochure is your gateway to explore the fascinating realm of plastic materials in healthcare. We delve into the pivotal role that thermoplastics play in shaping the industry, serving as the building blocks for a diverse range of medical devices, packaging solutions, and equipment.

Discover the latest trends and advancements in healthcare plastics, where materials are no longer just passive components but active contributors to patient well-being. From antimicrobial polymers that combat infections to biocompatible materials that seamlessly integrate with the human body, we'll showcase how these innovations are revolutionizing patient care.

Typical Healthcare Requirements

- **Sterilization diversity**: Gamma, E-beam, autoclave and EtO
- **Biocompatibility***: ISO 10993 or USP Class VI or EP
- **Food contact compliance**: US FDA, EU Food Safety Authority (EFSA)
- **Chemical resistance**: Disinfectants, cleaners, lipids and IV solutions
- **Welding and bonding**: Ultrasonic, adhesive and solvent

General Material Considerations

- **Optical clarity, colorability**: View fluids/ contents, rapid identification and visual appeal
- **Impact resistance**: Ductility for practical use conditions and Low-and-high temperature performance
- **Dimensional stability**: Tight tolerance/low creep
- **High flow and enhanced release**: Complex designs, low draft angles, thin wall and flow length capability
- **High-performance specialization:** Added strength, lubricity, shielding and anti-stat
- **Flame retardance**: UL 94-HB, V2, V1, V0, 5VB, 5VA and RoHs flame retardant systems
- **Product stewardship**: REACH compliant products

* Biocompatibility: material evaluated based on ISO 10993 or USP Class VI protocol; supporting information available by Type I or Type II letter.

As a leading provider of thermoplastic resins and compounds, Nexeo Plastics is dedicated to offering unwavering support at every stage of your product's life cycle.
From the initial concept to full-scale commercialization, our extensive range of both commodity and specialty resins, supported by our technical expertise and expansive distribution network, is fully equipped to meet all your application requirements.

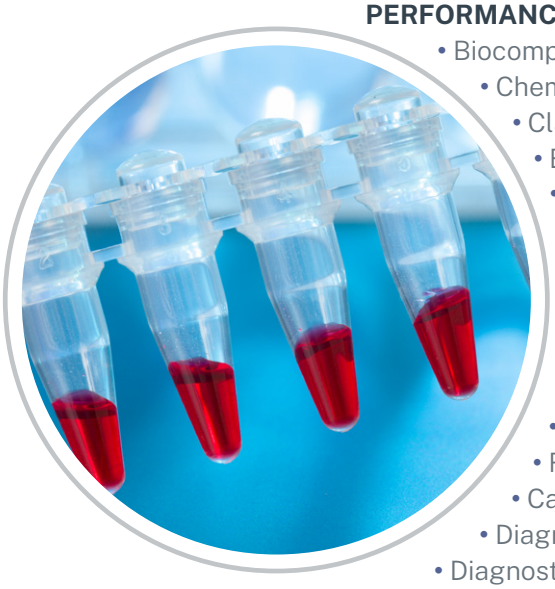
Nexeo Plastics tailor customized solutions to help:

- **Select the Right Material**
- **Improve Profitability**
- **Meet Safety and Compliance Requirements**
- **Ensure Supply Continuity**
- **Enjoy Best-in-Class Service**
- **Achieve Sustainability Goals**

MATERIAL EXPERTISE
FOR DIVERSE MEDICAL SEGMENTS

IVDR (IN VITRO DIAGNOSTICS REGULATION)

This segment encompasses handling and management of blood, such as during cardiovascular and orthopedic surgeries, blood donations and kidney dialysis treatments. Applications include devices to support extracorporeal systems, blood collection and separation, as well as equipment to move, filter and hold blood.



PERFORMANCE CONSIDERATIONS

- Biocompatible* (devices)
- Chemical resistance
- Clarity (devices)
- EtO, gamma, e-beam, autoclave sterilization (devices)
- Good flow for processing (devices and membranes)
- Light weight (equipment)

TYPICAL APPLICATIONS

- Blood collection and separation bowls
- Blood filter and membrane media
- Blood oxygenators and reservoirs
- Filters (leukocyte/arterial)
- Renal dialyzers
- Cassettes, centrifuges and covers
- Diagnostic machines
- Diagnostic vial transport trays
- Pipettes, vials, tubes

DRUG & FLUID DELIVERY

Drugs come in diverse forms, requiring delivery devices that span a broad set of formats from injection to inhalation. Safety and patient compliance issues have led to increased use of needle-less techniques, focus on improved accuracy/efficiency in drug transfer, as well as aesthetic, miniaturized and ergonomic designs for drug-type identification and consumer appeal/use.

This segment includes handling and management of fluids for use in intravenous therapy and enteral (gastrointestinal) fluid delivery systems. These systems often include various pumps to facilitate fluid delivery to the patient and connection devices that integrate the fluid bag or bottle, pump and tubing into a single system.

PERFORMANCE CONSIDERATIONS

- Biocompatible*
- Clarity and colorability
- Chemical resistance (disposables and pumps)
- EtO, gamma and autoclave sterilization
- Formaldehyde-free valves
- Impact and wear resistance

TYPICAL APPLICATIONS

- Inhalers
- Insulin delivery devices
- Nebulizers
- Needle-less injection devices
- Syringes, bottles, tubes and vials
- Fluid filters
- Infusion sets
- Stopcocks, luers, y-sites and check valves

NONWOVEN DISPOSABLES & MEDICAL PACKAGING

The industry has recognized the importance of good packaging design. Packaging has a significant role, from helping patients comply with medication requirements to helping companies meet regulatory requirements. We see continual innovation and improved material efficiency in this highly regulated industry.

Nonwoven disposables form an integral part of the healthcare market. Resistance, protection levels, disposability and the flexibility offered by materials that meet customer-specific needs are some of the major factors making nonwovens preferred over woven fabrics in hospitals and other contexts.

PERFORMANCE CONSIDERATIONS

- Protects products from moisture, light, oxygen and contaminants
- Solutions also include child-resistance, senior friendly packaging, and foil and non-foil barrier structures
- Colorability
- Sterility
- Strength and weight
- High filtration
- Resistance
- Breathability
- Sustainability/Recyclability

TYPICAL APPLICATIONS

- Bottles
- Caps and closures
- Pouches
- Prefillable inhalers and syringes
- Blisters
- Vials and ampoules
- Medical gowns
- Disposable masks
- Plasters
- Swabs
- Baby nappies
- Incontinence products
- Surgical disposal
- Women's hygiene

RESPIRATORY AND MEDICAL TUBES

These devices and supporting equipment are used for treating respiratory-related illnesses in hospitals, clinics and at home. Respirators, ventilators, positive airway pressure devices and respiratory masks and connecting tubes assist an increasing number of patients who have ongoing therapy needs.

PERFORMANCE CONSIDERATIONS

- Biocompatible* (airflow pathways)
- Clarity (masks)
- EtO, gamma, e-beam, autoclave sterilization (masks and tanks)
- Flame retardance
- Impact and chemical resistance (masks and equipment)

TYPICAL APPLICATIONS

- Humidifier tanks
- Oxygen concentrators
- Positive Airway Pressure (PAP) devices
- Respirators and ventilators
- Respiratory masks and valves
- Respirator parts (filters, tubes, inhalers)

MEDICAL EQUIPMENT

Medical equipment are used in very diverse range of applications from hand-held and small devices, such as pulse oximeters, blood pressure and other patient monitors, to larger transportable devices, such as anesthesia delivery and ultrasound machines, to very large stationary equipment, such as x-ray, CT, MRI and PET imaging machines.

PERFORMANCE CONSIDERATIONS

- Chemical resistance to cleaners/disinfectants
- Colorability and indoor UV stability
- Durability, lightweight, and impact resistant
- Flame retardance and EMI/RFI shielding
- WEEE and RoHS complaint

TYPICAL APPLICATIONS

- Anesthesia delivery and monitoring
- OTC blood glucose meters
- Imaging equipment (e.g., MRI, CT, PET and x-ray)
- Patient monitors
- Portable monitoring devices

MEDICAL TRAYS

Trays are used to transport instruments after surgery and to hold them during sterilization. In manufacturing, trays are used to transport vials and other items throughout the facility. Common to all types of trays is impact resistance to withstand unintended drops.

PERFORMANCE CONSIDERATIONS

- Autoclave sterilization
- Biocompatible*
- Chemical resistance
- Colorability
- Impact, crack, and craze resistance

TYPICAL APPLICATIONS

- Dental instrument trays
- Microsurgery and scope trays
- Surgical instrument trays
- Vial transport and storage trays

ORTHOPAEDICS

Orthopaedic devices support surgical and non-surgical techniques to preserve and/or restore the musculoskeletal system, limbs, etc. These devices use external fixators to immobilize the position of bones throughout the healing process.

PERFORMANCE CONSIDERATIONS

- Biocompatible*
- Colorability
- Dimensional stability
- EtO, gamma, e-beam, autoclave sterilization
- Impact and chemical resistance

TYPICAL APPLICATIONS

- Bone cement mixers
- External bone fixation devices
- Instrument handles
- Trays and cases

SURGICAL INSTRUMENTS

Due to the breadth of surgical techniques,a variety of tools have been developed to support specific procedures. These range from access devices to hand/mechanical and powered instruments for open and minimally invasive surgeries. As devices become smaller and more complex, the need for miniaturized components calls for specialized materials to achieve strength, durability and freedom of design.

PERFORMANCE CONSIDERATIONS

- Biocompatible*
- Ductility and toughness
- EtO, gamma and autoclave sterilization
- Precision fit and high dimensional tolerance
- Smooth part interaction and low wear
- Strength and stiffness

TYPICAL APPLICATIONS

- Access devices
- Trocars, retractors and speculums
- Hand Instruments
- Staplers, forceps and clip appliers
- Powered Instruments
- Electrosurgical

3DP TECHNOLOGY IN HEALTHCARE

3D printing is becoming increasingly present in healthcare. Use of this technique is visible from conceptual modeling and prototyping of novel devices to training parts, advanced packaging and instruments. 3DP is also being incorporated in the production of end-use parts, facilitating a less expensive alternative to classical production, especially for small quantities and personalized patient-specific medical support.

PERFORMANCE CONSIDERATIONS

- Biocompatible*
- EtO, Gamma and Steam (autoclave) sterilization
- Clarity or colorable
- Flame retardance
- Toughness and dimensional stability
- Traceability

TYPICAL APPLICATIONS

- Hearing aids
- Dental applications
- Models for virtual surgical planning and teaching
- PPEs
- Small production parts and replacements for medical devices
- Orthopaedics

OUR HEALTHCARE PRODUCTS LINE CARD

Product	Brand Name	Sterilization			Producer
		Ethylene Oxide (EtO)	Steam Autoclave	Radiation	
GPPS	Styron*	✓		50kGy	TRINSEO
MABS	Toyolac*	✓			TORAY
PA6	Akulon* Care	>2	>25	44.5kGy	ENVALIOR
	Akulon* Care 30%GF	>2	>100	44.5kGy	ENVALIOR
PBT	Arnite* Care	>2	>25	44.5kGy	ENVALIOR
PC	Iupilon*	✓	✓		MITSUBISHI
POM	Iupital*	✓	✓		MITSUBISHI
PPA	ForTii* Care 30%GF	>2	>100	44.5kGy	ENVALIOR
PP Homo	MedSelect*	✓	✓	25kGy	INVISTA
PP Random	MedSelect*	✓	✓	25kGy	INVISTA
PVC	Mixvil	✓	✓	25kGy	TPV COMPOUNDS
TPC	Arnite* Care	>2		44.5kGy	ENVALIOR
TPE-S	Medalist	✓	✓	50kGy	TEKNOR APEX
TPV	Medalist	✓	✓	50kGy	TEKNOR APEX

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Ask us for more technical information

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***Discover more products available**
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welcome@nexeoplastics.com
Tel: +46 20881393
www.nexeoplastics.com

SUPPORTING DATA AND REGULATORY INFORMATION

Medical Devices Regulation (MDR) – EU Directive 2017/745/EU

The MDR, which aims to ensure a high level of quality and safety of medical devices, whilst supporting innovation, sets forth rules related to the market launch and commercialization of medical devices for human use and accessories for such devices and also applies to clinical investigations concerning such devices and accessories.

U.S. FDA Food Contact Compliance

FDA grades comply with the requirements of the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations set forth by the FDA, covering substances used as basic components of food contact surfaces.

European Union (EU): EU food contact grades comply with the compositional requirements of Regulation (EU) N° 10/2011 for plastics used in food contact applications.

In-vitro Diagnostics Regulation (IVDR) – EU Directive 2017/746/EU

The IVDR establishes a regulatory framework for in-vitro diagnostic devices, which aims to improve transparency and to maintain a high level of safety and quality for end users of these devices, while trying to balance the interests of the small and medium-sized enterprises that are active in this sector. The IVDR establishes general requirements of quality and safety for in vitro diagnostic medical devices in order to address common safety concerns in regard to such products.

Resin Biocompatibility

Typically, a set of tests are performed on a resin to determine if the resin or its extractables will cause potential harm to the human body.

Many of our suppliers' biocompatible grades have passed USP/USP Class VI biological tests or tests from the ISO 10993 "Biological Evaluation of Medical Devices."

Nexeo Plastics does not support the use of material grades not designated as "biocompatible supported" in healthcare applications requiring biocompatibility.

U.S. Food and Drug Administration (FDA) Drug Master File (DMF) and/or Device Master File (MAF)

Nexeo Plastics works with our suppliers to obtain U.S. FDA Drug Master Files and/or Device Master Files within the FDA's documentation centers for our healthcare products, where available. A Letter of Authorization (LoA) for the customer's reference of our Master Files and for the FDA's review of our Master Files may be provided upon request.

UL 94, EN 60695-11-10/20, IEC 60695-11-10/20

One of the most widley accepted flammability performance standards for plastic materials are UL 94 ratings. These ratings are intended to identify a a material's ability to extinguish a flame, once ignited. Several different ratings can be applied based on the rate of burning, time to extinguish, ability to resist dripping and whether or not drips are burning.

Each material tested may receive several ratings based on color and/or thickness. When specifying a material for an application, the UL rating should be applicable for the thinnest wall section in the plastic part, and the UL rating should always be reported with the thickness. EN 60695-11-10 is the European equivalent of UL 94; IEC 60695-11-10/20 is the international equivalent of UL 94.

Waste Electrical and Electronic Equipment (WEEE) — EU directive 2012/19/EU

WEEE aims to promote sustainable production, efficient use of resources (including recycling), and reducing the environmental impact of WEEE. This Directive requires OEMs and component and sub-assembly producers providing electrical/electronics (E&E) products to the EU to collect, recover and treat these products at the end of life. Certain substances, mixtures, and components, including plastics using brominated flame retardant, must be removed from any collected WEEE and treated separately.

To help customers simplify recovery and recycling at end of life, we offer materials that are inherently flame-retardant or that do not contain brominated or chlorinated flame retardants.

General Disclaimer

Nexeo Plastics does not support certain healthcare applications, including Class III medical devices and implants. As such, all potential or known healthcare applications must be reviewed by Nexeo Plastics' personnel pursuant to Nexeo Plastics' Healthcare Applications Policies in advance. Nexeo Plastics' technical team is available to help you evaluate the characteristics of the materials we supply that may be used for your proposed applications; however, Nexeo Plastics does not warrant the suitability or efficacy of the materials that we supply, and, ultimately, you are responsible for and must make your own independent evaluation and judgment concerning the safety and efficacy of any materials supplied by Nexeo Plastics for use in healthcare or other applications

Implant policy

Nexeo Plastics does not support applications that involve implantation. Please refer to Nexeo Plastics' Healthcare Applications Policies for more details.

Restriction of Hazardous Substances (RoHS) — EU Directive 2011/65/EU

RoHS restricts the "use of certain hazardous substances in electrical and electronic equipment," including, but not limited to, lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated ethers (PBDEs), unless specifically exempted. We offer materials that allow manufacturers to avoid the use of these hazardous substances in healthcare applications.

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NEXEO PLASTICS Europe

Nexeo Plastics prides itself on providing its Customers with:

- Superior customer service (ISO certified)
- Broad product portfolio from world-class manufacturers
- Competitive pricing
- Geographic coverage
- Strong / long-term relationships
- Small / medium / large quantities
- Technical expertise in end applications
- Flexibility to meet changing demand
- Efficient management & available inventory

◆ Warehouses
● Sales office

Nexeo Plastics European Central Office
Carrer Luis Muntadas, 5
08940 Cornellà de Llobregat
Tel: +34 93 480 91 25
plastics.europe@nexeoplastics.com

Austria
Tel: +49 711 490 96087
nexeodach@nexeoplastics.com

Benelux
Nexeo Plastics Europe B.V.
nexeobenelux@nexeoplastics.com

CEE
Tel: 00 48 601 652 757
nexeoCEE@nexeoplastics.com

CZ, HU, SK
Tel: 00 420 602 218 084
nexeoCEE@nexeoplastics.com

Denmark
Tel: +46 303 72 95 00
plasticsnordics@nexeoplastics.com

Finland
Tel: +46 303 72 95 00
plasticsnordics@nexeoplastics.com

France
55 Avenue de Colmar 92 500
Ruel Malmaison, France
Tel: +33 (0) 141 192 920
nexeofrance@nexeoplastics.com

DACH
Curiestr. 2,
D-70563 Stuttgart, Germany
Tel: +49 711 490 96087
nexeodach@nexeoplastics.com

Ireland
Nexeo Plastics Europe BV
Tel: +44 177 352 06 66
nexeoireland@nexeoplastics.com

Italy
Nexeo Plastics Italy srl
Via Maso n.27
42045 Luzzara (Reggio Emilia)
Tel : +39 0522 1215875
nexeoItaly@nexeoplastics.com

LT, LV
Tel: +48 601 336 544
nexeoCEE@nexeoplastics.com

Norway
Tel: +46 303 72 95 00
plasticsnordics@nexeoplastics.com

Poland
Nexeo Plastics Poland Sp. z o.o.
Ruchliwa 15, 02-182 Warszawa
Tel: +48 22 575 56 15
nexeoCEE@nexeoplastics.com

Portugal
Accolade Portugal, Unipessoal Lda
nexeoIberia@nexeoplastics.com

RO, BG
Nexeo Plastics BV
Tel: 00 40 721 106 659
nexeoCEE@nexeoplastics.com

Spain
Nexeo Plastics Spain SLU
Luis Muntadas N° 5, 3ª Planta 08940
Cornellá de Llobregat
Barcelona, Spain
Tel: +34 934809125
nexeoIberia@nexeoplastics.com

Nordics
Nexeo Plastics Sweden AB
Hyllie Stationstorg 31 MALMO,
SE 215 32 Sweden
Tel: + 46 20881393
plasticsnordic@nexeoplastics.com

Switzerland
Tel: +49 711 490 960 87
nexeodach@nexeoplastics.com

UK
Nexeo Plastics UK Limited
Pure Offices, Lake View Drive,
Sherwood Park, Annesley,
Nottingham. NG15 0DT
Tel: +44 177 352 0666
nexeouk@nexeoplastics.com

NEXEOPLASTICS.COM

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