Connecting You to Solutions for the **Healthcare Market**

We connect healthcare OEMs and processors with world-class quality products

We Tailor Customized Solutions to Help You:

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

nexeo® plastics

Performance materials support a wide range of requirements

IMPORTANT
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 your healthcare or other applications.

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, European Food Safety Authority (EFSA), others

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
- 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
- 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.

MATERIALS EXPERTISE FOR DIVERSE HEALTHCARE SEGMENTS

- Cardiovascular and blood care
- Drug delivery
- Fluid delivery
- Lab ware
- Nonwoven disposables
- Medical packaging
- Medical trays
- Monitoring and imaging
- Respiratory and medical tubes
- Orthopaedics
- Surgical instruments
- 3DP Technology in Healthcare

Cardiovascular and blood care

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 and autoclave sterilization (devices)

-Good flow for processing (devices and membranes)

TYPICAL APPLICATIONS

-Blood collection and separation bowls

-Blood filter and membrane media

-Blood oxygenators and reservoirs

-Filters (leukocyte/arterial)

-Renal dialyzers

Drug 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.

PERFORMANCE CONSIDERATIONS

-Biocompatible*

-Clarity and colorability

-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 delivery

This segment includes handling and management of fluids for use in intravenous (IV) 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* (disposables)

-Chemical resistance (disposables and pumps)

-Clarity (disposables)

-EtO, gamma/E-beam sterilization (disposables)

-Impact resistance (pumps)

TYPICAL APPLICATIONS

-Fluid filters

-Infusion sets

-Stopcocks, luers, y-sites and check valves

Lab ware

The segment includes instruments and accessories for the analysis and diagnosis of patient samples, as well as for pharmaceutical and biopharmaceutical research. Applications range from disposable vials and containers for sample collection, to hand-held instruments, such as pipettors, for sample preparation, to clinical diagnostic equipment for rapid processing and evaluation of multiple samples.

PERFORMANCE CONSIDERATIONS

-Biocompatible* (disposables)

-Clarity (disposables)

-Gamma and/or autoclave sterilization

-Impact and chemical resistance

-Light weight (equipment)

TYPICAL APPLICATIONS

-Cassettes, centrifuges and covers

-Diagnostic machines

-Diagnostic vial transport trays

-Pipettes, vials, tubes

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Nonwoven disposables

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

-Colorability

-Sterility

-Strength and weight

-High filtration

-Resistance

-Breathability

-Sustainability/Recyclability

TYPICAL APPLICATIONS

-Medical gowns

-Disposable masks

-Plasters

-Swabs

-Baby nappies

-Incontinence products

-Surgical disposal

-Women's hygiene

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.

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

TYPICAL APPLICATIONS

-Bottles

-Caps and closures

-Pouches

-Prefillable inhalers and syringes

-Blisters

-Vials and ampoules

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

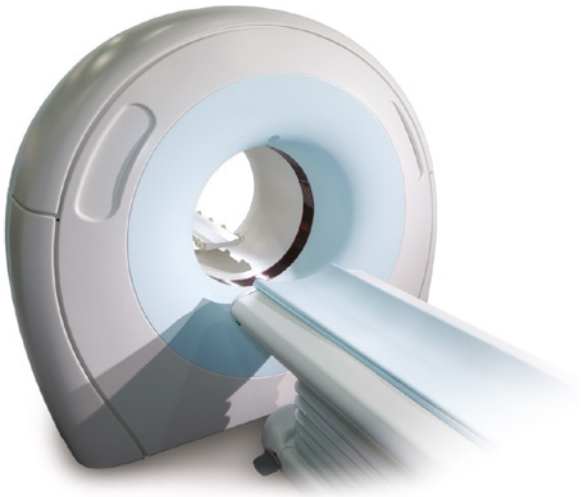
-Microsurgery and scope trays

-Surgical instrument trays

-Vial transport and storage trays

Monitoring and imaging

Monitoring and imaging devices 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

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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 a increasing number of patients who have ongoing therapy needs.

PERFORMANCE CONSIDERATIONS

-Biocompatible* (airflow pathways)

-Clarity (masks)

-EtO and autoclave sterilization (masks and tanks)

-Flame retardance

-Impact and chemical resistance (masks and equipment)

TYPICAL APPLICATIONS

-Humidifier tanks

-Oxygen concentrators

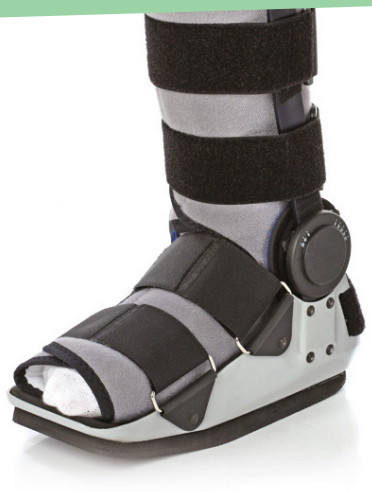
-Positive Airway Pressure (PAP) devices

-Respirators and ventilators

-Respiratory masks and valves

-Respirator parts (filters, tubes, inhalers)

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 and 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

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

Dedicated Healthcare Grades

Supplier	Product Type	Grade	Medical Regulation (1)	
				Steam
Flint Hills Resources	PP-Homo	P4G3Z-039	DMF, USP	Yes
Flint Hills Resources	PP-Homo	P4G4A-053	DMF	Yes
Flint Hills Resources	PP-Homo	P4C5N-046	USP, DMF, ISO 10993	Yes
Flint Hills Resources	PP-Homo	P4C6B-134a	DMF	Yes
Flint Hills Resources	PP-Random	23R2A	USP, DMF, ISO 10993	Yes
Flint Hills Resources	PP-Random	23M2A	USP, DMF, ISO 10993	Yes
Flint Hills Resources	PP-Random	P5M4K-046	USP, DMF	Yes
Flint Hills Resources	PP-Random	13T25A	USP, DMF, ISO 10993	Yes
Flint Hills Resources	PP-Random	P5M6K-080	USP, DMF, ISO 10993	Yes
Flint Hills Resources	PP-Random	P5M6K-048	USP, DMF	Yes
Lyondell Basell	PP-Homo	Pro-fax PF511	REACH, USP, DMF, EP	Yes
Lyondell Basell	PP-Homo	Pro-fax PF531	REACH, USP, DMF, EP	Yes
Lyondell Basell	PP-Homo	Pro-fax PD702	REACH, USP, DMF, EP	Yes
Mitsubishi	POM	Iupital™ MAS20	USP, DMF, ISO 10993	No
Mitsubishi	POM	Iupital™ MAS30	USP, DMF, ISO 10993	No
Mitsubishi	POM	Iupital™ MAH25	USP, DMF, ISO 10993	No
Mitsubishi	POM	Iupital™ MAL20	USP, DMF, ISO 10993	No
Toray*	ABS	Toyolac™ 500-322M	ISO 10993	No
Toray*	MABS	Toyolac™ 950 ME1	USP, DMF, ISO 10993	No
Toray*	MABS	Toyolac™ 950 ME2	USP, DMF, ISO 10993	No
SABIC 3DP Filament	PEI	ULTEM™ AMHU1010F	USP, ISO 10993	Yes
BASF 3DP Resin	Urethane photopolymer	Ultracur3D® RG35	ISO 10993	Yes
BASF 3DP Resin	Urethane photopolymer	Ultracur3D® ST45	ISO 10993	Yes
BASF 3DP Resin	Urethane photopolymer	Ultracur3D® ST80	ISO 10993	Yes

(1) -Approval statement available on application via email: techrequest@nexeoplastics.com
* Toray, available in France, Italy & United Kingdom only

USP = USA Pharmacopeia
EP = European Pharmacopia
DMF = Drug Master files

Sterilisation Technique		MFR	Conversion Technique	Special Feature
EtO	Gamma			
Yes	No	5	IM	
Yes	No	12	IM	LTHA
Yes	No	20	IM	NU
Yes	No	35	IM	AS, NU
Yes	Yes	2	EBM, IM	RAD
Yes	No	2	EBM, BFS, IM	
Yes	No	10	IM	AS
Yes	No	25	IM	
Yes	Yes	27	IM	RAD
Yes	No	35	IM	
Yes	Yes	20	IM, EBM	Rad
Yes	Yes	27	IM, EBM	Rad
Yes	No	35	IM, EBM	
Yes	No	9	IM	Standard
Yes	No	27	IM	High Flow
Yes	No	15	IM	High Rigidity
Yes	No	8.6	IM	Low-Friction
Yes	Yes	20	IM	High Rigidity
Yes	Yes	18	IM	High Flow
Yes	Yes	7	IM	High Chemical Resistance
Yes	Yes		3DP	RAD
Yes	No		3DP	
Yes	No		3DP	
Yes	No		3DP	

BFS = Blow-Fill-Seal
EBM = Extrusion Blow Moulding
IM = Injection Moulding
IBM = Injection Blow Moulding
ISBM = Injection Stretch Blow Moulding

Nu = Nucleation
Rad = Radiation
AB = Anti-block
AS = Anti-static
LTHA = Long-term heat acclimation

Key Suppliers for other Applications and Markets

Pan - European Suppliers

BOREALIS Keep Discovering

DUPONT

FLINT HILLS resources

KINGFA

lyondellbasell

Mitsubishi Engineering-Plastics Corp.

NEVICOLOR

parx materials

stordenso

TRINSEO

3DP Pan-European Suppliers

BASF We create chemistry FORWARD AM

covestro

JABIL

LEHVOSS Group

sabic

Nexeo Plastics key suppliers are:
Leaders in quality and reliability, focused on investing in their businesses, growth-oriented and connected globally.

Local Suppliers *

بروج
Borouge

COLLOIDS
THE MAKERS OF MASTERBATCH
A MEMBER OF THE TOSAF GROUP

INVISTA™

KuibyshevAzot
PUBLIC JOINT-STOCK COMPANY

beyond the best
KUMHO PETROCHEMICAL

Mexichem
Specialty Compounds

MITSUI & CO. EUROPE PLC

OQ

RESILIA
A KEM ONE COMPANY

sasol
reaching new frontiers

SUMITOMO CHEMICAL EUROPE

TORAY
Innovation by Chemistry

Volgalon
KuibyshevAzot | DSM

WANHUA

* Not all the local suppliers are available in every country

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.

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) No 10/2011 for plastics used in food contact applications.

Implant policy

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

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.

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.

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.

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 diphenyl ethers (PBDEs), unless specifically exempted. We offer materials that allow manufacturers to avoid the use of these hazardous substances in healthcare applications.

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

One of the most widely accepted flammability performance standards for plastic materials are UL 94 ratings. These ratings are intended to identify 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 retardants, 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.

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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
-Healthcare dedicated ADEs (Application Development Engineers)
-Flexibility to meet changing demand
-Efficient management & available inventory

◆ Warehouses
● Sales office

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