

MEDICAL

ALBIS PLASTIC GMBH

Technical polymers
for medical applications



PERSPECTIVES ON PLASTICS

| | AGENCY APPROVALS | | | | RESISTANCE TO STERILISATION | | | | | | | |
|------------------|------------------|-----------------|--------------|----------------|-----------------------------|------|------|--------------|--------|-------------------|--------------------------|---|
| | FDA 21 CFR | USP CLASS VI | ISO 10993 | DMF LISTING | AUTOCLAVE | | | IR RADIATION | | GAS | TRANSPARENT AVAILABLE | |
| | | | | | 121° | 134° | 143° | GAMMA | E'BEAM | ETHYLENE OXIDE | | |
| | | | | | | | | | | | | |
| Luran® HD | SAN | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Terlux® HD | MABS | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Terluran® HD | ABS | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Lustran® | ABS | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| EASTMAN | | | | | | | | | | | | |
| Eastar® | Copolyester | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Durastar® | Copolyester | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Provista® | Copolyester | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Tritan® | Copolyester | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| | | | | | | | | | | | | |
| Purell® | PP | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ | ✓ |
| Purell® | PE | ✓ | ✓ | ✓ | ✓ | (✓) | | | ✓ | ✓ | ✓ | ✓ |
| | | | | | | | | | | | | |
| AvaSpire® | PAEK | ✓ | | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| KetaSpire® | PEEK | ✓ | | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| | | | | | | | | | | | | |
| Makrolon® | PC | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ | ✓ |
| Desmopan®/Texin® | TPU | ✓ | ✓ | ✓ | | | | | ✓ | ✓ | ✓ | ✓ |
| Apec® | PC-HT | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | | | | | | | | | | | | |
| Ultrason® | PES/PSU/PPSU | ✓ | ✓ | ✓ | | (✓) | (✓) | | ✓ | ✓ | ✓ | ✓ |
| Ultraform® PRO | POM | ✓ | ✓ | ✓ | ✓ | ✓ | (✓) | | (✓) | (✓) | (✓) | |
| | | | | | | | | | | | | |
| Pocan® | PBT | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ | |
| Durethan® T40 | PA6 | | ✓ | ✓ | | | | | ✓ | ✓ | ✓ | ✓ |
| | | | | | | | | | | | | |
| Evoprene® | TPE | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |

✓ A ticked box indicates the availability of one or more grades with an agency approval.

(✓) Resistance can be limited and is dependant upon the application and grade.

Other Agency Approvals

Conformance to additional regulations may be required, for example:

Food contact

2002/72/EC – EEC Countries
NSF 51 – USA National Sanitary Foundation – Plastics used in food equipment

Water contact

WRAS – UK (formerly WRC)
NSF 61 – USA Drinking Water Systems Components – health effects

Toys

EN71 – 3 – European restriction on heavy metal content

Also, European Directive 2002/72/EC defines tests for migration of plastic material in finished products and references a positive list of monomers and additives.

The use of plastics in implant applications is strictly regulated and should always have approval by the material producer.

Summary

Whilst it is quite possible for a manufacturer of a medical device to attain all the necessary approvals on the finished product, there is no question that the process becomes quicker, easier and cheaper when the right information is already in place to support an application. For this reason selection of materials with a recognised medical pedigree is highly advantageous. Most of the major polymer producers have invested in securing the relevant agency approvals for their materials in support of this growing market sector. Many such materials are available through ALBIS as a licensed distributor for several highly reputable polymer manufacturers. The great diversity of materials available to us allows a high degree of impartiality when advising on matters of material selection.

This table outlines the materials available from ALBIS carrying the relevant agency approvals and lists their resistance to commonly used sterilisation methods.

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Definitions

The approvals required to bring a medical device to market vary slightly between Europe and the USA. Devices sold in Europe must comply with the EU Medical Device Directive 93/42/EEC. The Directive uses ISO 10993/EN 30993 (Biological Evaluation of Medical Devices) as a method for testing devices in body contact. Compliance is necessary to achieve a C.E. mark. In the USA similar requirements are laid down by the United States Pharmacopoeia (USP). The standard USP88 (Biological Reactivity Tests) rates plastics in classes I to VI. Class VI encompasses all 6 categories and is a recognised benchmark for a plastic device to attain. The known conformance of a polymer to ISO 10993 and USP Class VI is of significant assistance to a device manufacturer when seeking approval. The European ISO 10993 standard is more detailed than the USP testing and, as such, is generally recognised in the USA. ISO 10993-6 (section 6) measures implant effects in a similar way to USP Class VI.

The FDA (Food and Drug Administration) and ISO 10993

ISO 10993 has many different sections. The relevance of each is determined by the device category and the nature of the contact regime. It is applicable across Europe; however, in the USA (and Japan) the FDA, whilst broadly accepting ISO 10993, chose to further refine part 1 (ISO 10993-1) which provides guidance on the selection of tests for particular categories of device, and introduced some additional requirements. These are listed in an FDA 'Blue Book Memorandum #495-1'. There is therefore a 'European' ISO 10993 and an ISO 10993 'FDA Version' applicable to the USA. Nevertheless, there exists a great degree of common ground. Polymers are often referred to as 'FDA approved'. This is generally a reference to food contact approval under FDA regulation 21CFR. Whilst this is a stringent test, and the use of a plastic carrying this approval is advantageous, it does not define the plastic or the device as suitable for medical use and is a small part of the overall FDA medical requirements.

Drug Master Files (DMF Listings)

When a device is to be sold or used in the USA it will require a DMF listing. This is controlled by the FDA. As part of the application process a DMF can be obtained for the polymers used in the device. A DMF listing for a polymer will firmly establish it as a tried and tested material for use in similar devices and provide a significant shortcut on future projects. As with virtually all approvals a DMF listing relates to specific formulations (including any pigments or additives present) and not merely polymer type.

Material Characterisation

This can be defined as the identification of the chemical, thermal and mechanical make-up of a material. It encompasses the effects of different sterilisation methods and the determination of the presence and nature of leachates. The testing of material characterisation is a high priority for the regulators. ISO working group 18 is developing a new standard to define the information required of material manufacturers when submitting a polymer for medical use. Its conclusions will appear as ISO 10993-18 and will include:

Chemical testing: Infrared analysis, Extraction analysis, Chromatography, Trace metal analysis.

Thermal testing: Differential Scanning Calorimetry (DSC), Determination of melting point and glass transition point.

Mechanical testing: Stress/Strain analysis.

Biocompatibility

This can be defined as the suitability of a material for exposure to the body or body fluids. For a material to be biocompatible it must not cause any of the following:

- Extended Chronic Inflammation
- Cytotoxicity (toxic attack of cells)
- Cell Disruption
- Skin Irritation
- Restenosis (narrowing of blood vessels)
- Thrombosis (formation of blood clots)
- Corrosion of an implant

Tests are carried out "in vitro" (artificial environment) and "in vivo" (in living organisms). The latter relates closely to the test criteria defined in USP Class VI and ISO 10993-6.

Disclaimer

Any information given on the chemical and physical characteristics of our products, including technical advice on applications whether verbally, in writing or by testing the product, is given to the best of our knowledge. However, the information is given without obligation and does not exempt the buyer from carrying out their own investigations and tests in order to ascertain the products specific suitability for the purpose intended. The buyer is solely responsible for the application, utilisation and processing of the product, and must observe the laws and government regulations and the consequential rights of a third party. At all times our Conditions of Sale apply.