Recommendations by the Quality Task Group (48): Decontamination of Plastic Medical Devices or of Devices with Plastic Components (Part 1)

Various materials are used to manufacture medical devices. The type of material used is determined, first, by the intended medical application and requisite features and, second, by issues relating to reuse, and thus to the device's amenability to reliable decontamination. Based on EN ISO 17664, the manufacturer must provide the user with ➜ **DECONTAMINATION INSTRUCTIONS**. In the case of ➜ **CRITICAL MATERIALS** or constructional features, the user must check, or have this verified by a suitable body, whether automated or manual decontamination is possible and whether this should be limited under certain circumstances. If reliable decontamination is not possible, the manufacturer must designate the device for ➜ **SINGLE-USE** only. In such cases, decontamination is carried out at the user´s risk or is forbidden.

Depending on the intended use, there are myriad basic ➜ **CHEMICAL SUBSTANCES** available for manufacturing such devices. In principle a distinction is made between thermoplasts (using heat, these can be reversibly deformed and welded), duroplasts or duromers (close-meshed, networked plastics whose shape can no longer be altered after hardening) and elastomers (wide-meshed, networked rigid plastics that can undergo elastic deformation).

➜ **DECONTAMINATION INSTRUCTIONS** must be provided by the manufacturer based on EN ISO 17664.

➜ **FOR CRITICAL MATERIALS** the user must check whether decontamination is possible.

➜ **FOR DEVICES DESIGNATED AS SINGLE-USE** decontamination is carried out at the user's risk.

➜ **MYRIAD BASIC CHEMICAL SUBSTANCES** are available.

Thermoplasts

Thermoplasts

Thermoplasts are shaped within a particular temperature range using primarily an injection moulding process. Another technique is the extruded bar material method. Thermoplasts can be recycled and reused again and again (but not in medical technology in view of the risk of cross-contamination). However, incorporation of any soils can detract from material resistance (2nd choice). Thermoplasts are divided into two groups: the partially crystalline (melt at high temperature) and the amorphous (become soft at high temperature) thermoplasts.

The partially crystalline thermoplasts include, inter alia, polyethylene (PE), polypropylene (PP), polyamide (PA 6, PA66), polyester (PET), polyether ether ketone (PEEK) and Teflon (PTFE).

The amorphous thermoplasts include, inter alia, polycarbonate (PC), polymethyl methacrylate (PMMA, e.g. plexiglass), polysulphone (PSU) and polyvinyl chloride (PVC).

Duroplasts

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Duroplasts are cast, pressed or injected into shape but unlike thermoplasts this material cannot be deformed again once it has hardened. The duroplasts include, for example, epoxy resin compounds, polyurethane and melamine resin and phenol resin compounds.

Elastomers

Elastomers

Elastomers are mainly cast or injected into shape and then using networking additives (sulphur, platinum catalysts) given a wide-mesh networked structure. The shape of elastomers can be changed when they are exposed to traction and pressure stress, but they later assume their original unformed shape. The elastomers include, inter alia, silicones, polyurethane, rubber, FKM (Viton) etc.

Medical devices made of different types of plastic materials or with plastic components are used and reprocessed in the healthcare sector. In addition to metallic materials, there are various types of synthetic materials. Any mixtures or additives as well as the manufacturing process exert an influence on the properties of the synthetic components. Preservation of the material integrity is of paramount importance for patient safety as well as for economic reasons. If no manufacturer's instructions have been provided or if these are not being observed, the materials can be adversely affected through an ➜ **INCORRECT CHOICE** of detergents, disinfectant and care agents, too high processing temperatures, in particular during drying and sterilisation processes, failure to observe the

➜ **AN INCORRECT CHOICE** of e.g. detergents, disinfectants and care agents can adversely affect materials – often without perceptible evidence of tis damage.

number of reprocessing cycles permitted as well as inappropriate storage conditions. Often, there is no perceptible evidence of this damage. UV light and other influences can give rise to ➜ **PREMATURE "AGEING"** of certain plastics.

➜ **PREMATURE AGEING** can be caused e.g be UV light.

By subjecting materials to specific temperatures, i.e. selective heating and cooling of injection-moulding or stretched components, the service life of certain plastics, e.g. PC connectors, can be prolonged thanks to prevention of premature stress corrosion cracking.

Synthetic materials are also used as a coating, for protection against corrosion and wear as well as for insulation purposes. Coating materials include e.g. Teflon and polyamide.

Selection criteria include:

- Biocompatibility
- Mechanical properties
  - Bending/traction
  - Hardness
  - Impact resistance
  - Stress cracking susceptibility
- Temperature resistance (thermal disinfection, sterilisation)
  - Weight and dimensional stability
- Chemical resistance (chemical disinfection, detergents)
  - Colours/transparency
- Amenability to injection moulding processes
- Electrical properties
- Amenability to gamma sterilisation
- Hydrolysis resistance (steam sterilisation)

Material	Structure	Continuous operating temperature (°C) Short term	Continuous operating temperature (°C) Long term	Hydrolysis resistance	Chemical resistance	Approx. price €/kg
PEEK		> 300	> 250	++	++	70.-
PPS		240	200	–	+	5.-
PPSU		207	207	+	+ susceptible to stress cracking	40.-
Siloxan		Up to 250	Up to 250	+	+	9.-
Harex		Heat resistant	Heat resistant	++	++	1.50

Table 1: Synthetic materials used in medical technology

Thermoplasts such as PEEK are used as partial components for instruments and devices; (silicone) elastomers are used in utensils and containers, and duroplasts such as HAREX for instruments (e.g. handles).

Biocompatibility

The biocompatibility, i.e. the physiological safety of the materials used, must be taken into account, while making a distinction between an instrument used briefly on the patient and an implant. A lack of biocompatibility can cause tissue damage or impaired growth. ➜ **BIOCOMPATIBILITY** can be altered during decontamination, e.g. incorporation of substances. Leaching of certain constituents (solvents) can also take place under certain circumstances. Depending on the respective country, intended use and duration of use, the provisions of ISO 10993 (Europe), the FDA (USA, e.g. USP Class VI), etc. must be complied with.

➜ **BIOCOMPATIBILITY** can be altered during decontamination.

Decontamination Requirements

Pursuant to EN ISO 17664, the ➜ **MANUFACTURER'S INSTRUCTIONS** must be available in the national language. These instructions must be observed for reprocessing and storage. In cases of doubt, the manufacturer must be contacted for clarification. Part 2 of this article will focus on practical recommendations. These have been compiled in cooperation with the manufacturers and experts in the field. ✦

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