Sterile from A to Z
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Those responsible for packaging solutions for sterile medical products require a great deal of imagination and perception concerning the risks to which packaging is exposed from commencement of production through to the time of use. Packaging is exposed to an enormous level of stress en route to patients with numerous potential hazards lurking during the production process in the factory, the packaging process and transport. In the development of new products in medical technology, it is therefore necessary that right from the start the aspects of packaging, sterilization, transport and storage are complied with in order to eliminate any potential hazards endangering sterility.

Even the raw materials for manufacturing medical packaging and medical products must be sterilisable just as the same applies for thermoplastic elastomers as a group of materials.

Ulterior proceedings are the choices of sterilisation processes. Apart from electron and X-radiation, ethylene oxide (EtO), gamma irradiation or hot vapor in the autoclave are also used as sterilisation methods in medical technology. When applied as designated, each of these methods is regarded as both effective and safe.

Ethylene oxide sterilisation is a low-temperature method which kills microorganisms at 10 °C by forming a compound with the protein molecules and destroying them. As the sterilisation time depends on the temperature – the higher the temperature, the shorter the sterilisation time – a temperature range of 37 to 60°C is usually applied. Combined with a low process temperature, this method is suitable for many thermoplastic materials and is applied in particular for disposable items such as syringes, compresses, swabs and medical products which are sensitive to temperature.

Sterilization with hot vapor is at 121 or 134°C and overpressure of up to three bar in the autoclave. When the vapor condenses on the item to be sterilised, energy is released which damages the microorganisms. Hot vapor sterilisation at 134°C is the most popular method of sterilizing reusable medical products.

High-energy, ionizing gamma irradiation deactivates the microorganisms. When this low-temperature method is applied, the minimum radiation dose must be observed. But not all plastics are suitable for multiple sterilisation by gamma rays: this method is only applied industrially and almost exclusively for disposable items.

All of these methods can prevent biological contamination. But they each have advantages and disadvantages and above all significant effects on the material used. In order to prevent any negative impacts, the material formulae need to be compiled very carefully using stabilisers and other supporting ingredients – as is the case with the
ProvaMed portfolio offered by Actega DS. Extensive tests of the various variants comparing gamma irradiation, autoclaving and gassing with ethylene oxide indicate the resistance displayed by these materials to signs of wear such as swift ageing, brittleness, discoloration or changes in mechanical properties possible in the case of high-energy gamma irradiation, for example, while hot-vapor sterilization can cause shrinkage, deformation or even melting of the plastic.

Tests on ProvaMed compounds indicate that tensile strength remains virtually unaffected even after irradiation with 50 kGy. The high temperatures in the autoclave can even have a positive effect on the relaxation and crystallisation processes of some polymers contained in the TPE recipe. This can increase tensile strength and elongation at break. Similar effects have been detected when gassing with ethylene oxide.