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Drip chambers – the problem with plasticizers

Manufacturers of medical devices deal intensively with the materials to be used before the development phase. In the field of plastics, PVC has proven itself for many medical applications. As for infusion systems. Each system comprises a pin, a drip chamber, a transparent infusion line, a flow controller and a connector. The material is inexpensive, easy to process and has good functional properties.This material is increasingly subject to criticism, e.g. because of problems with plasticizers. It has been proven that plasticizers are released comparably easily. When PVC has direct contact with medication, various interactions need to be examined in detail beforehand. After all, some active ingredients are in fact incompatible with PVC. The problem here is often two-fold: on the one hand, the solubilizers in PVC can cause plasticizers to be released from the material. On the other hand, certain medical substances settle on the PVC surface. Such adsorption is then accompanied by undesirable loss of material, resulting in lower dosage.

Furthermore, some phthalates are regarded as being harmful to human health. The problem is that plasticizers in items made of PVC often need to be used in high concentrations. As they are not chemically bound to the PVC, a certain volume is constantly emitted through outgassing or leaching – depending on the respective pressure and chemical environment. Studies have shown that the general public absorbs a significantly higher volume than previously assumed and even so much that harmful impacts cannot be ruled out. Risk groups (pregnant women, preterm/newborn babies, children during puberty, dialysis patients, patients who have received several blood transfusions) are in particular danger.

Consideration must, therefore, be given to PVC-free solutions.

Trend reversal – the current situation

Medical products that are produced in very large numbers must, on the one hand, be economical to manufacture despite the highest demands on product safety and hygiene. On the other hand, the requirements are constantly increasing. Ultimately also to ensure the health of staff and patients.

In an effort to comply with this requirement profile, there is a growing tendency to rely on alternative materials instead of PVC. There has long been a shift in people's thinking in favor of PVC-free solutions. There are numerous initiatives that provide information about the problem of PVC and also warn not simply substituting other plasticizers that are classified as questionable. On the one hand, not all alternative plasticizers have been investigated and documented as extensively as is the case with DEHP; on the other hand, this by no means solves the environmental problem that arises when disposing of PVC. The goal must be to entirely dispense with PVC and all plasticizers. An example is provided in the form of the HCWH Europe (Healthcare without Harm) organization, which not only publishes helpful fact sheets in the form of the PVC/DEHP Phase-Out initiative, but also reports extensively on numerous clinics, hospitals and hospital organizations, including in Scandinavia, France, Austria, Czech Republic, Slovakia and Denmark, which are already successfully using mostly medical products without PVC/DEHP.

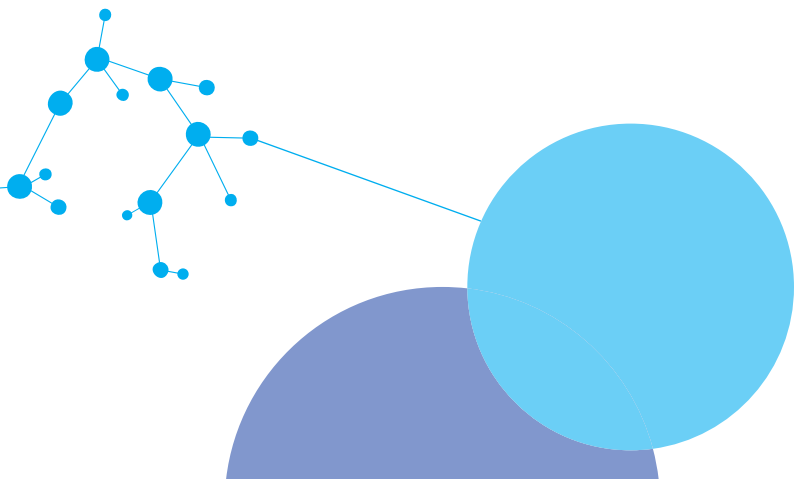
Alternatives to PVC: TPE – thermoplastic elastomers

TPE (thermoplastic elastomers) refer to materials which combine the properties of classic elastomers with those of thermoplastics. Unlike "normal" elastomers, where linking is not possible without decomposition of the material, thermoplastic elastomers are materials whose elastic polymer chains are integrated in thermoplastic material. They can be processed in a purely physical process by combining high shear forces and heat exposure followed by cooling. Renewed exposure to heat and shear forces leads to melting and reforming of the material.

The first thermoplastic elastomer was launched in 1959. Many new variations have been developed since then. Six main groups of TPE are now available:

- TPE-O – Thermoplastic olefines (blend of hard and soft phases)
- TPE-S – Styrene block copolymers (SBS, SEBS or SEPS)
- TPE-V – Vulcanized (linked) PP/EPDM compounds
- TPE-E – Copolyester compounds
- TPE-U – Thermoplastic polyurethanes
- TPE-A – Thermoplastic polyamides

As not all TPE groups are suitable for drip chambers – solely by virtue of the high degree of transparency required – the following descriptions are restricted to the group of TPE-S plastics.



TPE from the perspective of sustainability

Compared to other materials, TPE do well in terms of environmental and sustainability aspects. Complete recyclability is of course one of the most important aspects here. Neither PVC, nor thermosetting plastics nor latex can be recycled simply or completely. In addition, PVC and thermosetting plastics generate large amounts of waste during production and processing, and plasticizers can be released from PVC. Plasticizers can be released from PVC. Even during the production of the granulate, the energy consumption is lower than with soft PVC. With TPE granules, the potential for the migration of undesirable substances is minimized.

Medical, technical and regulatory requirements

Flexible TPE for medical technology need to comply with the highest requirements on purity, hygiene and safety. The materials offer a safe solution for the high demands made of medical products in terms of performance and safety. They also facilitate the work of manufacturers of medical technology products with regard to regulatory qualification and compliance with the MDR.

Drip chambers and medical tubes need to be distinguished by their health safety and transparency. A good balance of flexibility and rigidity is also required. Transparency ensures that the dripping process can be regulated visually and the fluid level can be easily and swiftly adjusted. Furthermore, sterilizability is imperative in order to guarantee 100 percent sterility and therefore safety for patients and the environment. The standard sterilization processes with ethylene oxide (EtO) and Gamma rays must neither impair the material properties nor change the optics. All bonding and assembly connections must also remain impeccable. Another important aspect is represented by the bonding capacity with standard solvents, e.g. the drip chamber with other components of the infusion set, such as the tube, or TPE components with PVC components. This makes it possible to reduce the overall percentage of PVC and the debate on plasticizers can be largely avoided.

Various test results concerning biocompatibility in accordance with ISO 10993 and USP Class VI must also be available for medical-grade materials. In order to obtain USP Class VI classification, the following tests on the actual material as well as various extracts of this material are conducted in external laboratories:

Acute systemic toxicity: Determining the acute irritation effect on contact with the skin, inhalation and ingestion

Intracutaneous reactivity: The test material is brought into direct contact with the tissue for which it is designated in standard use.

Implant test: Test of the reaction after implant in the tissue of a living organism. The time span is generally five days.

These tests are carried out for specified exposure times and temperatures in order to ensure comparability of the results. Apart from the biocompatibility test on the finished medical product, it is important for the manufacturer that all output materials used are tested and that they meet the requirements of the end product.

Other property profiles and TPE solutions

Pleasant to the touch, a safe and non-slip grip – these are the properties hospital personnel want when holding the drip chamber for pumping and testing. Such properties can be examined and adjusted using test plates during the development phase.

As the drip chamber is repeatedly compressed while pumping, it must be able to swiftly return to its original shape. On the other hand, the pressing motion required for pumping must not be too strenuous for personnel. This requires a balanced relationship between rigidity and recovery capacity. This is also ensured while developing the formula, specifically while adjusting the material mechanics.

In order to ensure that the material can be feasibly processed in an injection-molding process and that it helps to achieve very good cycle times, importance is attached to the flow properties and processability even during the formula development phase.

Even prior to the new EU Medical Products Ordinance, manufacturers of medical technology faced the difficult task of being obliged to subject their products to extensive regulatory qualifications and submit comprehensive documentation prior to launching them onto the market. This requires time and expertise as well as a partner availing of this knowledge who supports the manufacturers and projects from development right through to market launch.

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