



Metal or plastics, TPE or PVC - an increasing number of customers are requesting material solutions which are free of PVC and plasticizers.

According to the German Federal Statistical Office, 55000 tracheotomies and 1,300 laryngectomies are carried out annually therefore 40000 patients receive tracheostoma care provided by specialized homecare experts.

TPE FOR TRACHEOSTOMY TUBES

Performed since ancient times, a tracheotomy is a surgical procedure during which an opening is made into the trachea through the soft tissues of the neck. Also known as a tracheostomy, this opening into the windpipe becomes necessary, e.g. when the swallowing reflex is impaired or long-term ventilation is necessary after accidents or operations, during radiation treatment of the head or neck, larynx palsy or full removal of the larynx (laryngectomy).

These procedures lead to the loss of the function of the upper airways such as filtering, warming and moistening breathing air through to voice loss and extreme limitations in terms of the senses of smell and taste. Tracheostomy tubes and speaking aids are absolutely essential and for which the professional industry offers an extensive range of ultra-modern tubes and aids optimally tailored to the respective demands and requirements of each individual patient, which are distinctive in terms of function, material, design and accessories – in line with defined requirement profiles.



While metal tubes are offered with thin walls which are rigid and have a comparably large inner volume, silicone and plastic tubes featuring thicker walls minimally limit inner volume and are distinguished by a high degree of wearing comfort and lighter weight.

Most tube wearers can benefit from tracheal tubes made from lightweight, soft plastic material as these lead to less irritation of the sensitive tracheal mucus membranes and less mechanical irritation of the tracheostoma, but also because metal tubes may not be inserted during radiotherapy. Reflections on the tracheostomy tubes could prevent the calculated radiation dose from being applied or they can cause uncontrolled radiation exposure through to burns of healthy tissue.

As in many areas of medical technology, most plastic-based tracheostomy tubes are manufactured from PVC. But criticism of this material is not letting up and an increasing number of customers are requesting solutions which are free of PVC and plasticizers from manufacturers of medical technology.

This request leads to the material group of thermoplastic elastomers (TPE), such as the PROVAMED® TPE from Actega DS, whose good processability makes them ideal for all conventional injection-molding and extrusion plants but also on account of their very low emissions, reusability and cost effectiveness. Furthermore, they can be sterilized, are conformant with the FDA, ISO and USP classes, and display very good sealing and adhesion properties. Features which are helpful or even necessary when it comes to manufacturing tracheostomy tubes.

Tracheostomy tubes are typically manufactured in extrusion or injection-molding processes. Their material properties need to be adapted accordingly. Extrusion requires exact setting of the material flow properties to the processing method while injection-molding offers the possibility of manufacturing the tracheostomy tubes and neck flange in a single step. Multi-component injection-molding enables economic manufacturing of multiple components such as a connector made from a thermoplastic and the soft components made using TPE. This is particularly applicable when the material's adhesion properties need to comply with the connector material, thereby requiring optimization. PROVAMED® TPE display perfect adhesion to polystyrene and ABS.

Another area of focus is represented by solvent bondability. Micro-tubes are often inserted through the neck flange, e.g. in the case of transporting air to the cuff (inflatable sleeve at the lower end of the endotracheal tube or a tracheostomy tube for sealing the space between the tube and the tracheal wall) or for optional secretion removal, whereby the micro-tubes need to be bonded to the outer tubes. Conventional solvents are used for this. Here, too, an excellent solution has been found for the PROVAMED® portfolio. One which has been examined in an extensive range of tests featuring frequently used solvents.

Manufacture and printing (this printing capability also needs to be considered when developing the plastic material) are followed by sterilization, usually with EtO or Gamma. TPE can display their particular advantages as only minimal changes in terms of mechanics and optics can be ascertained after sterilization, even after 50 kGy Gamma sterilization.

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