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Conversion of polymers – properties and processing

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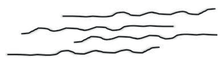
RAUMEDIC® *Lifeline to Health*

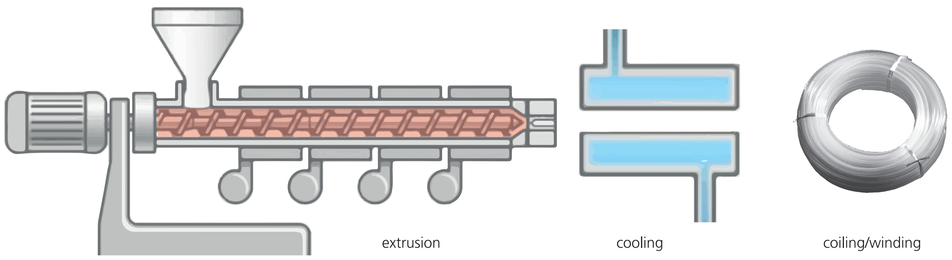
The requirements for products, being supplied to the pharmaceutical and medical industry are getting higher almost every day. Clean room production, FDA-Certification, and several other certifications according to different standards is the base of new products and developments.
No matter if the product is used in final filling applications, medical devices or as long-term implants. Only with a very high level of material expertise and application experience it is possible to supply to such highly regulated markets.

Thermoplastic Polymers

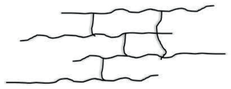


Raw material is melted in the extruder using temperature and shearing energy from the screw. Using a ring/pin-dye the hot melt is shaped and cooled in water. Finally coiled or cutted in short pieces. This gives the opportunity to fullfill individual customer requests.
The choice of raw-materials is always based on the final application. Key properties of thermoplastics are linear molecule chains without cross links, shape- and re-shapeable with heat, "easy" to deform mechanically. Sealable and weldable.

Most important processing steps: Heating/plastification, shaping, cooling, coiling/winding

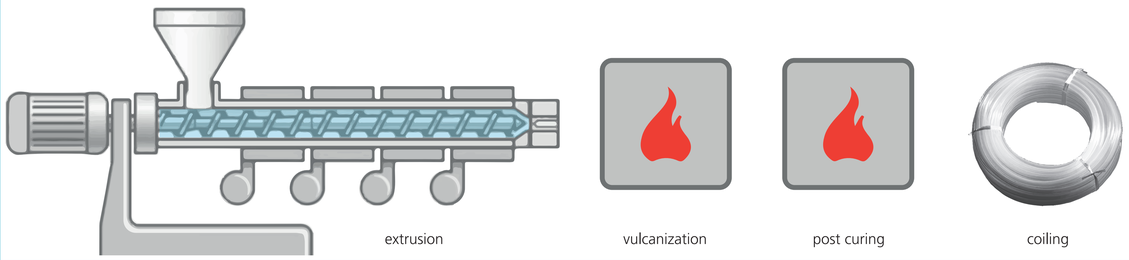


Silicone Elastomers

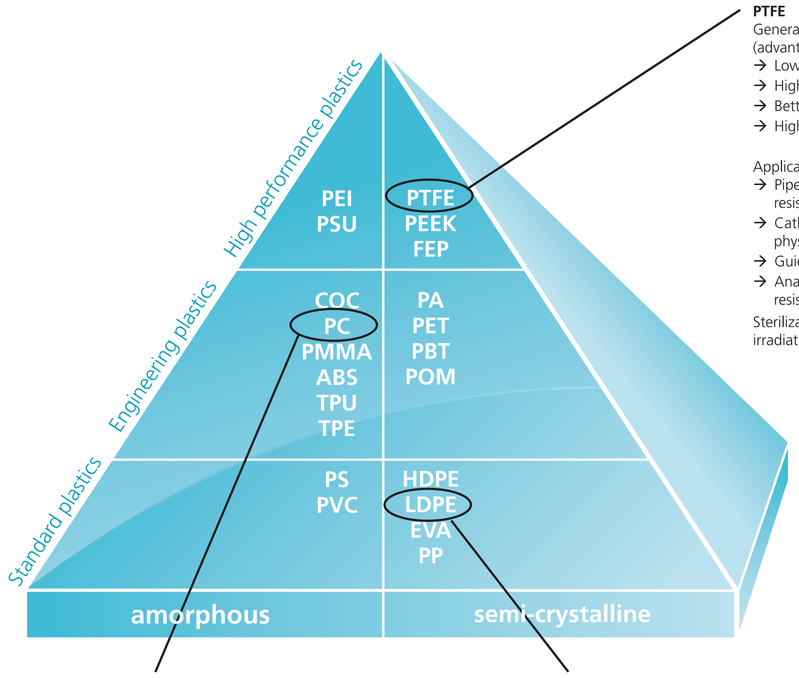


Mixing of raw-material and crosslinker, using a ring/pin-dye mixture is shaped at room temperature and heated in an oven to initiate cross linking. The post-curing/tempering process reduces substancially the content of extractables before the tube is coiled/cut in cut-length. Key properties of silicone are linear molecule chains with cross links, not re-shapeable, rubberlike properties (retention forces), no additives like antioxidants or plasticizers necessary.

Most important processing steps: Mixing, shaping, heating/cross linking, post curing, coiling



RAUMEDIC processes the whole range of polymers. The three highlighted examples are very interesting for the pharmaceutical industry because of their properties.



PTFE
General properties
(advantages towards FEP):
→ Lower coefficient of friction
→ Higher operating temperature
→ Better chemical resistance
→ Higher density (> better barrier function)

Application:
→ Pipettes & Tubing (excellent chemical resistance)
→ Catheters (Low fritction & good physiological properties)
→ Guide wires & coatings (low friction)
→ Analytics (excellent chemical resistance)

Sterilization: ETO, autoclave, irradiation

PC
General properties:
→ Very high trancparency
→ Rigid and stiff material
→ Solvent bondable
→ Susceptible to crack with some solvents

Application:
→ Connectors
→ Tubing (for single use filling needles, protection tubing)

Sterilization: ETO, autoclave*, irradiation*

LDPE
General properties:
→ Very inert material
→ Excellent drug compatibility
→ Good pressure resistance
→ Very good barrier properties (oxygen, air)
→ Not solvent bondable

Application:
→ Infusion lines
→ Pressure monitoring lines
→ Catheters (angiography)
→ Connectors
→ Protection tubes

Sterilization: ETO, autoclave*, irradiation*

* depending on raw material

All silicones processed by RAUMEDIC are tested very comprehensively with several bio.-tox. tests including USP Class VI and ISO 10993. Furthermore post-curing after production is obligatory in order to achieve a save and high quality product.

Peroxid cured silicone	Platinum cured silicone
+ Higher degree of cross-linking	+ Almost no migrable substances
+ Better retention forces	+ Shorter post-curing time
+ Better pump performance (durability, flow rate accuracy)	+ Almost inert material
+ Higher tensile strength	+ Less sticky surface
- More migrating substances	+ Higher elongation at break

The choice of the cross-linking system is usually not only based on one single property but on several factors being influenced by final material properties. Questions can be: Is the tube mainly used in pumping application with a high flow rate accuracy and durability? Is the overall extractable profile the most important factor? Are special mechanical or chemical properties needed? Is blood or tissue compatibility during long or short term implantation a topic?

The combination of thermoplastic components (extruded and injection molded) and silicone tubing allows the assembly of transfer sets, sampling devices, filling needles, sets, and other system products. The range of fluid handling applications can cover ECC (extracorporeal circulation), pharmaceutical production processes, infusion or drainage during and after surgery. Catheter applications can also be part of this product range. For providing high quality system products it is compulsory to know every raw material used, very well.

Supply Chain

Raw material supplier → Converter (RAUMEDIC) → Set assembly (Sartorius Stedim Biotech) → Final user

For better product development and to serve customer needs, it is very important to integrate as much parties as possible within the whole supply chain.
A very good example is the cooperation between Sartorius Stedim Biotech and RAUMEDIC.

sartorius stedim biotech