The current and future market for thermoplastic elastomers in medical and healthcare applications

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It is estimated that the global market for thermoplastic elastomers (TPEs) for medical and healthcare applications will be of the order of 375,0000 t in 2019. It is likely that this market will grow with a CAGR of 8.5 % to 565,000 t by 2024. This represents the highest growth rate of all thermoplastic elastomers. The reason for such growth is a combination of a growing number of the world's population seeking medical care as well as a move to replace a number of incumbent materials, in particular PVC. In addition, certain vulcanised elastomers are also likely to be replaced by thermoplastic elastomers at the same time. The main driving force behind these changes is the need to supply the market with products which have a much higher degree of purity. In Europe in particular, the introduction of the EU medical device and in vitro regulations 2017/745/EU and 2017/746/EU, which will come into force in 2020, will drive the producers of medical devices to examine alternative materials, which fully comply with these new regulations. Other geographical regions will also be forced to comply with these regulations, since from 2020 it will be very difficult to supply the European Union, unless all their products comply as well.

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1 TPEs in medical and healthcare applications

Table 1 gives a list of the various TPE applications in the medical sector and common competitors. **Table 2** gives the global market for TPEs in 2014 and an estimate for 2019, as well as a forecast for 2024.

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All figures and tables, unless otherwise stated, have been kindly provided by the author.

TPS is by far the most important TPE used in medical and healthcare applications. In 2014, it represented 56.1 % of the market, which is estimated to grow to 60.5 % by the end of 2019 and is forecast to be 63 % by 2024. Its advantage is a wide combination of properties with a Shore A hardness from 90 down to 5, and it is now possible to produce grades of TPS with a Shore hardness measured on the 00 scale. Its sterilisation potential, as well as its ease of processing gives it a secure advantage over vulcanised elastomers.

Recycling of medical waste is now becoming an important issue. There is no problem with recycling TPS, and it is very easy to modify its properties to suit a particular application. It can be sterilised by all common systems (EtO, steam, radiation) and can be produced with very high levels of transparency. TPS can be RF-welded and solvent-bonded, which are two important advantages over polyolefin-based thermoplastic elastomers. It is also now possible to cross-link SEBS; the main ingredient of TPS. This increases TPS' heat resistance and reduces its compression set. Both these properties are of extreme importance for medical applications. It has excellent chemical resistance to most hospital cleaning liquids. In addition, it can be produced to comply with all pharmacopeia regulations, as well as the new European Union regulations. Incineration is no problem, since it is a hydrocarbon in composition. It can easily be pyrolyzed into hydrocarbons, which can either be used as fuel, or converted back to TPEs.

Other TPEs are of course used in the production of medical and healthcare applications. TPVs also have excellent compression sets and good temperature resistance. They are mainly based on cross-linked EPDM for the moment. There is now a move to produce TPVs with much higher heat resistance than it previously was possible. These are capable of being steam sterilised it higher temperatures than before. They tend to be more expensive than TPS grades but are suitable for certain critical applications. TPOs are mainly used in applications such as clogs, kidney dishes, trays, hospital furniture and other less demanding applications. TPOs are now vul-

nerable to competition from metallocene-catalysed plastomers, which are now able to match the properties of TPOs, but at a lower price. The use of TPUs shows the lowest growth, the main applications being tubing, hospital furniture and catheters, as well as other intrusion applications.

2 PVC replacement programmes

It is estimated that the global consumption of PVC in medical and healthcare applications is likely to be of the order of 2.4 million t in 2019 and that the compound average growth rate (CAGR) is forecast to be 4.3 %, over the 2019 – 2024 period. PVC represents approximately 35 % of all thermoplastics used in medical and healthcare applications. Since the end of the last century, there has been a growing movement to replace PVC in medical and healthcare applications, which has so far not resulted in a real reduction in PVC usage. The major reason was to replace phthalate plasticisers with so-called safe plasticisers. This has granted PVC a lease of life, given the success of this change. Of all the candidates for PVC replacement, TPEs are considered to have the best chance. The PVC lobby is extremely powerful and is constantly coming up with arguments against PVC replacement. The main arguments cited are the ease of processing of PVC, as well as the advantage presented by its solvent and RF-welding possibilities. A major argument put forward is its relatively low price and ready availability. PVC in medical and healthcare applications only represent about 0.5 % of its overall availability, which eliminates any question of possible PVC shortages. The fact that it is only based on about 50 % of petroleum resources, remains one of its strongest arguments. Given that the use of plasticised PVC is the main product used in medical and healthcare applications, the non-petroleum content drops to about 25 % - but the argument is still very strong, for all that.

TPEs, especially TPS, are the strongest candidate for plasticised PVC replacement. The main arguments for TPEs versus PVC are:

- Lower specific gravity, taking their volume price closer to that of plasticised PVC
- Higher heat resistance, allowing steam sterilisation to be used
- Excellent weldability and solvent adhesion which allows TPS to be a drop-in for most plasticised PVC applications
- Lower water vapour transmission than PVC, allowing for longer storage times of liquid products, such as blood, glucose solutions and irrigation water
- High transparency and good UV stability
- Higher CO_2 transmission. Blood platelets produce high levels of CO_2, which if allowed to accumulate, will lower the pH of blood, adversely effecting blood platelets
- Lower sub-zero properties, which allows lower temperature storage of blood, which extends its useful life
- No plasticiser migration; high purity medical grade paraffinic oil is used as to modify TPE's flexibility
- Fully recyclable
- Can be easily incinerated, without production of noxious gases

Despite the above arguments, it will still take some time before TPEs replace PVC, but the plasticiser migration appears to be the strongest argument. This factor alone will probably decide PVC's future in medical and healthcare applications.

3 Elastomer replacement programme

The introduction of the new medical and food contact regulations, as mentioned above, will also affect the use of vulcanised elastomers in medical and healthcare applications. Though the potential for replacement by TPEs is smaller than that for PVC, it is nevertheless real. The main elastomer scheduled for replacement by TPEs is butyl rubber. It is currently used for the production of syringe plungers and vial stoppers. This market is expanding rapidly, due to needs to reduce infection, especially in hospitals and clinics. Butyl rubber was chosen for its

Tab. 1: Typical TPE applications in the medical and healthcare sector

Application	TPE	Competition
Blood bags	TPS	PVC
Blood sample container stoppers	TPV	Butyl rubber
Catheters	TPU	Silicone elastomers
Dialysis sets	TPS	PVC
Dispensing systems	TPO	PVC, LDPE, HDPE, PP
Disposable respirator Systems	TPS	PVC, silicone elastomers
Drapes	TPS	PVC
Drip chambers	TPS	PC
Equipment (seals, gaskets)	TPV	Natural rubber, EPDM, Butyl rubber
Infusion bags	TPS	PVC
Medicine bottle seals	TPV	Butyl rubber
Surgical instrument handles	TPS, TPV (soft touch)	PP
Sterile water containers	TPO	HDPE
Syringe plunger tips	TPV	Butyl rubber
Toothbrush, razor handles	TPS (soft touch)	No competition
Tubes (dialysis, endocrinal, feeding sets, IV sets)	TPS	PVC, silicone elastomers
Urine incontinence bags	TPS	PVC
Vacuum-formed packaging	TPS	PET, PVC
Vial stoppers	TPV	Butyl rubber
Note: Many TPE applications under development		

Tab. 2: Global market for TPEs by product, 2014, 2019 (E) and 2024 (F) (thousand tonnes)

TPE	2014	2019 (E)	2024 (F)
TPS	139.6	228.4	356.2
TPO	52.5	75.8	107.4
TPV	28.6	39.8	57.1
TPU	14.7	21.0	28.8
TPC	1.5	3.6	6.6
TPA	0.8	2.3	4.6
Others	2.9	4.3	4.5
Total	**240.7**	**375.2**	**565.3**
Note: E = estimate, F = forecast			

low oxygen transmission and good compression set. Being a vulcanised rubber, certain by-products are produced during the vulcanisation process. These are now considered as substances of very high concern (SVHC) and are banned by the REACH regulations which are coming into force in 2020. Certain TPEs have been suggested as replacements, among which is butyl rubber-based TPV. The vulcanisation process used in this TPV does not produce SVHCs which allows for its use in medical and healthcare applications. Other TPVs have been suggested, for example TPVs based on cross-linked SEBS. This latter product has been available from Kuraray for some time now and recently Asahi Kasei also introduced such a product to the market. The compression set properties of TPVs based on these speciality SEBS elastomers is equal and, in some cases, better than that of both butyl rubber and TPVs based on butyl rubber. Thus, there is no apparent barrier to their usage. Moisture and gas transmission results are also encouraging; ironically better than butyl rubber in some cases.

The growth of TPEs in medical and healthcare applications is set for serious growth in the next few years

Source: Kraiburg TPE

4 Conclusions

The growth of TPEs in medical and healthcare applications is set for serious growth in the next few years. Despite certain barriers to the use of TPEs, they are slowly but surely taking over from the current incumbents. Their ability to comply with existing and new medical and healthcare regulations is assisting their growth. Doubts about the validity of some plasticisers used in the production of flexible PVC compounds will also allow the continued introduction of TPEs to the growing medical and healthcare markets.

This article is an extract from Smithers Rapra's recently published global market study entitled **The Future of Thermoplastic Elastomers to 2024.**

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