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Press Article

What is a “Medical Grade” Polymer?
Why a clarification would benefit both material suppliers and device manufacturers

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The healthcare and medical device industry is heavily regulated to ensure quality, sustainability and most importantly safety of human life. Hence, device development is a long and complex undertaking, with strict compliance regulations, long-term tests, quality checks and certifications. Nonetheless, one seemingly simple question has not been answered yet: What is a “medical grade” polymer? The Association of German Engineers, VDI, has embarked on defining a standard. First draft is expected in April 2018.
Siobhan Bastiansen, Market Manager Medical Plastics at VELOX GmbH, depicts the current situation and explains why material suppliers as well as device manufacturers would benefit from a clarification. She also shows how specialised medical polymer producers have risen to the challenge to create indispensable value for processors and OEMs.

From orthopedic and surgical instruments to diagnostic equipment, drug-delivery systems and implants to vision aids, polymers have been used in the healthcare and medical industry for decades. Meeting constantly new requirements like weight and size reduction, easier processing, flexibility, biocompatibility, stricter sanitation or the need for single-use instruments would be practically impossible without the use of polymers. Hence, it comes as no surprise, that an estimated 50 percent of all materials used in medical device manufacturing consist of plastics.
However, when it comes to the right polymer choice for a specific medical or pharmaceutical application, things can get complicated. Despite strict international and national regulations as well as demanding requirements for medical polymers, one extra difficulty in this choice is the fact that there has been no universally accepted definition of “medical-grade” polymers so far.

The challenges of the past
In recent years, the so-called “PIP scandal”, where the French implant device manufacturer Poly Implant Prothèse (PIP) used industrial silicone instead of surgical-grade silicone for breast implants, has been affecting the medical industry, with far-reaching financial, judicial and personal consequences for PIP, the material suppliers, Notified Bodies and for the patients. The scandal came to light in 2010 after high rates of rupturing were reported. To this day, this case keeps the courts busy. Only in February 2017, the European Union Court of Justice decided in the case of TÜV Rheinland that whilst Notified Bodies do have to protect end users of medical devices, they are not legally liable.

The PIP scandal from 2010 is only the most recent of the failures that took place in the past decades causing great outcry throughout the industry. It once again showed the extent of unresolved questions and uncertainties on all sides.

In the 1990s, many polymer suppliers decided to withdraw from the medical market as a consequence of similar affairs. To stop the drying-up of the market in the United States, the US Congress passed "The Biomaterials Access Assurance Act of 1998", which stipulated that raw material suppliers were not to be held liable for any product failure as long as they "meet applicable contractual requirements or specifications"[1]. Since then, medical device manufacturers have had to invest heavily to make sure their products comply with regulatory requirements and are safe for the intended application.
However, a national or international definition of "medical-grade" polymer or plastic is yet to be put into place.

Application restrictions as self-protection for polymer suppliers
Following several high-profile and costly litigations in the '90s, companies that actively market their polymers for medical applications typically have developed policies regarding restricted or permitted applications. "There is a wide variety of 'rules' from polymer producers concerning which applications are allowed. Often the restrictions may not be related to expected performance of the polymer in the target application, but rather reflect the corporate environment and legal department's decisions. The restrictions can have much more to do with perceived risk exposure to litigation down the line", says Siobhan Bastiansen

Some examples of guidelines are:

- not permitted to be used in medical applications
- skin contact only
- no direct contact with fluids entering the blood stream
- maximum 24 hours inside the body
- maximum 29 days inside the body

Of course, it is very challenging for medical device manufacturers and OEMs, especially the specialised small and medium-sized businesses, to keep track of all the different and complex policies and disclaimers. "As a specialist medical polymer distributor, we see our role as the critical bridge between our polymer principals and our customers, the device manufacturers, to make the right polymer choice process a safe, successful, sustainable and convenient one."

For instance, currently, there are very few polymer choices for medical device manufacturers designing products to remain in the body longer than 30 days, and where the customer wants the confidence and support of the raw material supplier. "Our partner Lubrizol LifeSciences is one of the very few polymer suppliers who do not restrict the use of their TPUs to 30 day implants but instead have a disclaimer reminding that the choice of polymer is up to the device manufacturer. Medical device designers are free to select from a wide TPU portfolio the most suitable grades to be tested and considered for each specific application", explains Bastiansen. "On the other hand, if we have a customer who has very low volume of demands for a coloured material for a non-invasive device, we can offer a

[1] Charles F. Walter, Ph.D. and Edward P. Richards, III, 18 IEEE Engineering In Medicine And Biology Magazine #2, 125-7 (1999). Articles on Law, Science, and Engineering, https://biotech.law.lsu.edu/IEEE/ieee31.htm

range of options advising MOQs of coloured resins direct from the producer, or assist in finding a long-term sustainable solution with our medical compounding partner IPC".

MDR and its impact for medical device manufacturers
While polymer producers have determined their own individual set of characteristics to define what a medical grade is, medical device manufacturers have been theoretically free to choose any polymer, as long as they followed existing regulations, while carrying the risks involved with product liability. Many device manufacturers have relied on compliance with applicable standards such as USP Class VI and ISO 10993, with regard to biocompatibility when choosing the material for their application.

The new European Union Medical Device Regulation 2017/745 (MDR), which came into force on 25th May 2017 and will be mandatory from 26th May 2020, places a strong emphasis on risk management and safety. Compared with previous medical device guidelines as MDD 93/42/EEC, that the new MDR will replace, it comprises 100 additional articles and two more appendices, new classification rules as well as extra surveillance and safety reports. It also reinforces the position of notified bodies, "with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification."[2]
"Especially for many small and medium-sized medical device manufacturers, the new, more demanding law may sound the death knell, as it will make the market entry for their products extremely difficult and expensive", Bastiansen comments.

Still, when it comes to an industry-wide, standard definition for medical-grade polymer, the new MDR, like MDD before, remains silent. Hence, there is no compulsory use of medical polymers for medical applications, as long as conformity with existing regulations is given.

First step towards binding definition of medical grades
In Germany, things are moving. In December 2016, the Association of German Engineers, VDI, has implemented a committee for defining a standard for medical-grade polymers. As VDI stated, "The aim is to define the requirements for the polymers for use in medical devices and thus to develop a standard that can be used as a guideline for raw material producers and manufacturers of medical devices. The directive covers development, logistics, procurement and purchasing equally."[3] It is expected that VDI will present a first draft of the guideline at the VDI symposium "Plastics in Medical Technology", taking place from 10 to 11 April in Friedrichshafen, Germany.

"We are fully supportive of the VDI aim, and think that a standard definition would bring more reliability, stability and long-term commitment for all sides. This is what polymer manufacturers and medical device producers alike need", comments VELOX' medical plastics expert Bastiansen.

Change management and long-term commitment as key differentiators
In the meantime, specialised medical polymer producers have already taken the opportunity to create indispensable value for medical plastics processors and OEMs.

[2] Official Journal of the European Union, Volume 60, 5 May 2017, Legislation, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:117:FULL&from=EN

[3] VDI-Richtlinienausschuss "Medical Grade Plastics" zu Gast bei B.Braun Melsungen AG, https://www.vdi.de/technik/fachthemen/materials-engineering/artikel/vdi-richtlinienausschuss-medical-grade-plastics-zu-gast-bei-bbraun-melsungen-ag/

To understand the peculiarity, one has to recall that only up to three percent of the worldwide polymer production ends up in medical and healthcare applications. “This is really a drop in the ocean”, says Bastiansen. For many polymer suppliers that serve diverse high-volume industries like automotive, food, packaging, construction etc., it may make no economic sense to invest in a market with such small potential volumes. However, several of these ‘industrial grade’ resins have made their way into products that are considered as medical devices and as such are subject to MDR or FDA conformity. For medical device manufacturers, on the other hand, this holds several risks and challenges; once they have carefully chosen and tested a material to comply with all the complex laws and guidelines for medical plastics, and to meet the requirements for their specific application, they need to rely on long-term supply and predictability. Sudden delivery stops or changes in the raw material production without notification of the device manufacturer, that are common in the industrial polymer sector, can be fatal as the medical device producers may have to repeat the whole complicated and expensive gauntlet of tests, qualification and certification processes that can take years.

“Polymer suppliers that develop and provide specialised polymers for medical applications have discovered a significant gap in this complicated situation to add value for the manufacturers”, highlights Bastiansen. “Suppliers like Repsol or Lubrizol LifeSciences that we have been cooperating with for many years have put transparent mechanisms into place to ease the process of change control for the OEMs and to also secure a long-term supply.” This way, both parties benefit from a close cooperation with mutual insight and knowledge exchange and protect their business and products from expensive failures.

Therefore, it is important for these manufacturers to understand the “landscape” of typical polymer producers. Cristina Martinez from VELOX’ partner Repsol, Healthcare division, explains the challenge precisely: “The typical dynamic in chemical plants producing hundreds of thousands of tonnes such as we have for our PE, PP and EVA resins, is to strive for continuous improvement in efficiencies, quality, innovation and economics. By implication, things are always changing – new grades bring advantages and old grades become obsolete – which is great for our industrial customers but can be a nightmare for medical customers. The challenge in setting up our Repsol Healthcare® portfolio has not been of a technical nature in developing innovative new grades. The much bigger task has been to understand the needs of medical and pharma companies and to put the necessary product stewardship in place across all the stakeholders within the organisation. This means production, purchasing, logistics, R&D as well as sales and marketing.”

“So knowing your supplier and being sure that they know you and your application is the ideal scenario”, sums up Siobhan Bastiansen from VELOX. “They can give the right support, advise you and be there for the long term, which is crucial for success across the lifetime of the product. This is even more true with regard to the regulations of the new MDR.”

About VELOX GmbH:

VELOX GmbH is a leading pan-European distributor of raw material specialities and solution provider for the plastics, composites, rubber, paints and coatings industries. Founded in 1993 by Bernard Goursaud and N. Max Schlenzig, VELOX is headquartered in Hamburg, Germany. The company has 21 offices throughout Europe and employs over 230 experienced employees to support its customers across Europe and beyond.

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