Domat/Ems, October 12, 2021

PRESS INFORMATION

Fakuma Press Release

High-performance polymers in medicine

Polymers are among the most widely used materials in the medical industry today. It is estimated that more than half of all medical products currently in use are made of polymer materials. The ability to see through products or to check the flow of a medium or the filling level: transparency, for example, is just one of many key properties that make polymers such sought-after materials for medical products.

Polymers can be used in a myriad of different ways. Due to their low weight and ease of processing, for example, they not only make work easier in general, but also are also incredibly safe when used by patients and medical personnel due to being absolutely resistant to breakage. Used for disposable products such as syringes, containers, catheters, and respiratory masks, they are indispensable given the high hygiene requirements in hospitals. But nowadays, medical instruments for use during surgery and even prostheses are made of polymers.
In addition, polymers can be manufactured in almost any colour, which makes it easier to distinguish between similar-looking products and prevents confusion. Specialty polymers, all of which are adapted to their specific purpose, have found their way into healthcare technology.

Transparent polyamides prove their worth in the operating theatre
Polymers in reusable medical devices can be sterilised and reused relatively easily. However, the demands placed on the material are considerably high, as conventional polymer materials often malfunction in practice. Medical professionals often complain that polymer components malfunction after the parts have been exposed repeatedly to solvents. The components can exhibit cracking, become discoloured or, at worst, even break. Chemicals can affect a polymer in various ways. For example, a polymer material may be resistant to one chemical (i.e. suffer no loss of their properties or become discoloured) but can break easily when exposed to a different chemical. This phenomenon can occur, for example, when medical devices are repeatedly wiped with disinfectants. The table given in Fig. 1 illustrates the resistance of transparent polymers to cleaning agents and disinfectants commonly used in healthcare.

In contrast to plastics such as PC and ABS, transparent polyamides are not susceptible to stress cracking due to their high chemical resistance. After various tests with the above-mentioned disinfectants, the surfaces of the polyamide samples remained unchanged. All other plastics tested exhibited stress cracking, discolouration, or deformation after coming into contact with a number of test media.

Reusable over disposable
Reusable medical devices or medical instruments carry a certain risk of cross-contamination, which is often why only single-use products are used. This creates a large amount of waste. If a product is to be reusable, it must be reliably rid of germs. To ensure this, the instruments and products must be sterilised.

There are various ways to do this when working with reusable products: ethylene oxide, gamma radiation, plasma or hot steam. The law prescribes exactly which methods may be used for which applications.

For further information please contact: Janne Egli Tel: +41 81 632 72 62
janne.egli@emsservices.com

Transparent plastics such as PC, ABS, PMMA, PS and SAN, but also ordinary amorphous PA, for example, are not suitable for repeated steam sterilisation. The number of transparent plastics that are able to withstand steam sterilisation multiple times is very small. Known conditionally transparent plastics are PSU, PEI and PESU. EMS-GRIVORY has now developed a new highly transparent high-performance polyamide for precisely this purpose, which can be steam sterilised several hundred times and is therefore reusable.

The degree of reusability of medical devices and instruments determines the choice of polymer used in their manufacture. If the polymers selected are sterilised no more than five times, all products listed in 'Fig. 2' are suitable. PSU and TR HT 200 are suitable for multiple sterilisation (≤ 500 cycles), whereby TR HT 200 has better transparency, is significantly more ductile and easier to process. Components made of PC have a similar transparency to TR HT 200 but can only be steam sterilised to a limited extent (≤ 5 cycles).

Highly transparent and sterilisable
This makes Grilamid TR HT 200 the world's first transparent polyamide that can be steam sterilised several hundred times. This product is a BPA-free, transparent high-performance polyamide that can be easily processed using thermoplastic processing methods.

The core properties of the new Grilamid TR HT 200 are:

- Crystal-clear transparency
- High mechanical stability and toughness
- High chemical resistance
- Easy processability
- High-temperature resistance
- Biocompatibility in accordance with ISO 10993 and USP Class VI

For these reasons, the new Grilamid TR HT 200 can be used in a wide range of applications. It can be utilised for example, for reusable applications that require high transparency, such as respiratory masks, protective visors, pump containers, filters, valves, containers, boxes and toolboxes, inspection windows and much more.
In this way, Grilamid TR HT 200 contributes in general to a longer service life of medical applications.

* * * * * *

Resistance to disinfectants ASTM D543, 1% elongation	Birex	CaviCide 1	Cidex OPA	Sani-Cloth AF3	Sani-Cloth Plus	MetraCide Plus	Virex TB	Virex II 256	Wexice 128	Cl Bleach (6 % unverdünnt)	Clorex Health Care H_2O_2	70 % Isopropyl alcohol
PA transparent	●	●	●	●	●	●	●	●	●	●	●	◗
PA (TR HT 200)	●	●	●	●	●	●	●	●	●	●	●	◗
PC	○	◗	●	○	○	●	○	○	○	○	○	●
ABS	○	○	●	○	○	◗	○	◗	○	●	○	○
PC/ABS	○	○	◗	○	○	◗	○	○	○	◗	○	○

○ <69 % ◗ >70 % bis <94 % ● >95 %.

Fig. 1: Comparison of disinfectant resistance, retention of tensile strength in percent

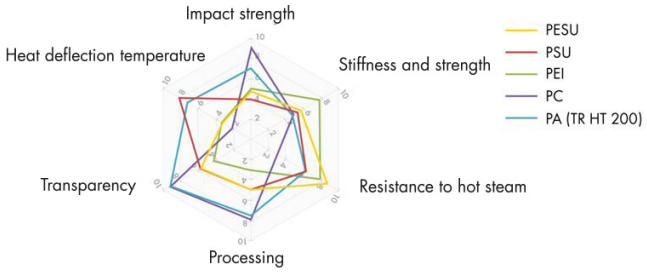

Fig. 2: Overview of transparent materials for medical applications

Sterilising agent / Material	Ethylene oxide (EtO)	Gamma rays < 40 kGy	Hydrogen peroxide (H_2O_2) 50°C, 54 minutes	Steam cycles 134°C, 18 minutes
PESU	+	+	+	≤ 100
PSU	+	+	+	≤ 500
PEI	+	+	+	≤ 100
PC	+	+	+	≤ 5
PA transparent	+	+	+	≤ 3
PA (TR HT 200)	+	+	+	≤ 500

Fig. 3: Comparison of resistance to sterilisation

Contact for technical inquiries

For further information please contac

Nikolai Lamberts
Product Management, EMS-GRIVORY
Tel. +41 81 632 74 34

Contact for the press

Janne Egli

Communication

Tel.: +41 81 632 72 62

Email: janne.egli@emsservices.com