

# Balancing Act between Viscosity and Stiffness

## *Glass-Fiber-Reinforced ABS in Healthcare Applications*

Novodur HD M203FC G3 is the first glass-fiber-filled ABS polymer grade which is certified as biocompatible. The grade delivers a significantly increased stiffness combined with a high melt flowability making it the material of choice for applications in the healthcare industry like medical spikes and other applications requiring structural stability. An application example shows how manufacturers can reduce the risk of failing biocompatibility certification with their newly launched products by using certified materials.

Glass-fiber-reinforced ABS grade for the development of a new generation of medical spikes

(© Fleima-Plastic)



**M**edical device manufacturers are required by law to conduct regulatory compliance tests on their final application. Since Ineos Styrolution Group, Frankfurt/Main, Germany, test their materials against these same standards medical device manufacturers can have greater confidence when these products are used in their final application. They can significantly reduce the risk of failure when introducing new applications in the medical market since their key raw materials are already compliant. Working with a pre-certified raw material leads to a reduction in time and cost for the application provider.

For applications requiring a high structural stability the glass-fiber-reinforced acrylonitrile butadiene styrene (ABS) Novodur HD M203FC G3 was developed. The glass fiber content has been optimized for the right ratio of flowability and stiffness. It is certified against the relevant parts of the biocompatibility standard ISO 10993 and USP class VI and offered with Ineos Styrolution's "Full Service HD package" which includes regulatory documents along with an up to 36 months notification of change (NOC) with a signed long-term supply contract.

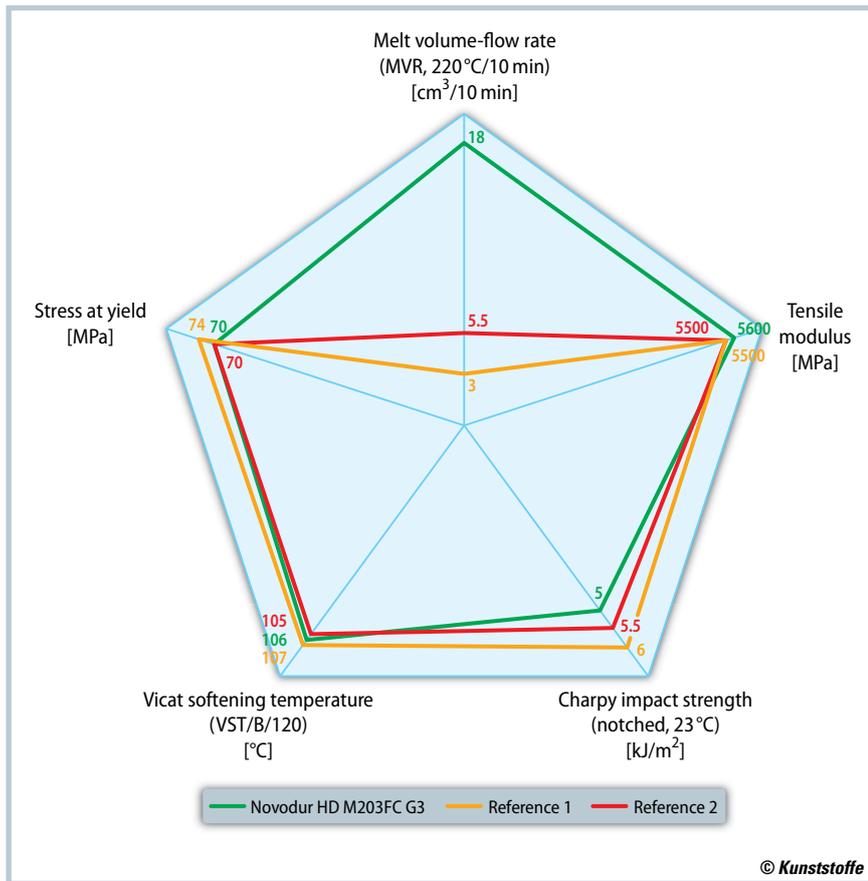
Consistency in formulation provides another level of assurance to medical de-

vice designers that their efforts in qualifying new materials and obtaining the corresponding biocompatibility documentation will be valid for the years to come.

### *Product Characteristics*

The material's characteristics such as good impact strength, surface quality and processability mean that it can be used to produce complex injection molded geometrics.

The melt volume-flow rate (MVR, **Fig. 1**) shows the very good flowability of the new material. Novodur M203FC G3 delivers a significantly increased melt



**Fig. 1.** Properties of Novodur HD M203FC G3 at a glance: The reference materials used are similar to those used in the automotive industry, but not certified for medical applications

(source: Ineos Styrolution)

flow rate compared to commonly used materials combined with the required stiffness. Flexural and tensile strength are shown in **Figure 2**.

The development of this glass-fiber-filled Novodur HD grade was performed in close cooperation with Fleima-Plastic GmbH, Wald-Michelbach, Germany, member of the Masterflex Group since 2004. The company is a manufacturer of spikes and caps made of ABS. Fleima-Plas-

tic launched their first regulatory compliant application in parallel to Ineos Styrolution's product launch – indicating fast regulatory approval cycles.

Testing raw materials against common biocompatibility standards (i.e. ISO 10993 and USP class VI) helps medical device manufacturers to significantly reduce the risk of failure when introducing new applications in the medical market. They have two advantages: An effective abbrev-

viation of the process and, perhaps more importantly, a more reliable source material with which it is possible to obtain certifications with a much higher probability than with other, non-certified materials. The probability of (unanticipated) delays is therefore significantly lower and the chance to be earlier on the market is higher. This is also shown by the example of the processor Fleima-Plastic.

### First Applications in Medical Spikes

Fleima-Plastics started to use Novodur HD M203FC G3 immediately after the public announcement of the new material for the development of a new generation of medical spikes (**Title figure**). Ismael Dogru, Key Account Manager at Fleima-Plastic, explains: "Thanks to these special glass fibers, this ABS material has a high E-modulus and a significantly improved compression, bending, tensile and impact strength". A decisive property is the surface coating of the material with optimized adhesion to ABS. He concludes: "As there is currently no other fiber-glass-reinforced ABS with corresponding approvals available across the world, we expect the new material to develop as standard for applications in the field of medical technology and especially in the development of medical spikes."

In addition to the use of the new material in spikes, it is also suitable for a whole range of other medical applications where robust properties are required. Examples are the handles of special surgical equipment. ■

## The Author

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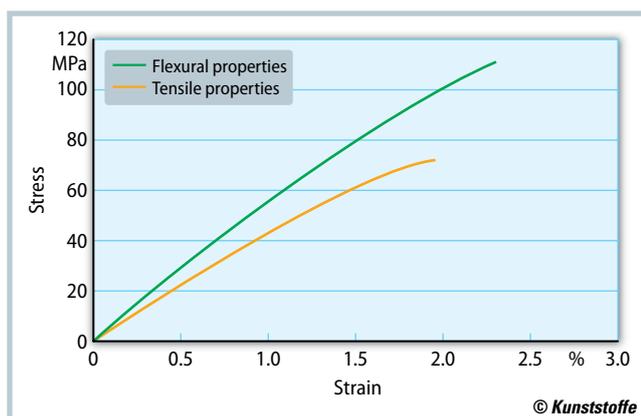
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**Fig. 2.** Overview of the flexural and tensile properties of Novodur HD M203FC G3

(source: Ineos Styrolution)