

## Press release

Extremely soft and custom-made compounds for medical devices

Waldkraiburg, October 2024

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KRAIBURG TPE GmbH & Co. KG  
Friedrich-Schmidt-Strasse 2  
84478 Waldkraiburg  
Germany

Phone +49 8638 9810-0  
Fax +49 8638 9810- 310

info@kraiburg-tpe.com  
www.kraiburg-tpe.com

### **KRAIBURG TPE provides supersoft compounds for medical devices**

The demand for ultrasoft TPEs has been increasing across various industrial sectors. The reasons for this are obvious. Whether they are intended for key products such as orthopedic equipment or applications in prosthetics – their particularly soft surface feel, combined with a soft grip, make the compounds particularly suitable for a variety of application segments. KRAIBURG TPE is now meeting these requirements globally.

Waldkraiburg, October 15, 2024 – Due to a substantial increase in the demand for extremely soft thermoplastic elastomers (TPEs), KRAIBURG TPE successfully launched NEXT GENERATION Supersoft TPEs in spring 2021. Since then, the company has been able to appreciate – and satisfy in even greater detail – the complex requirements that customers from a wide range of industrial sectors have for the “super” soft compounds. Most recently, the TPE manufacturer has expanded its range of supersoft products by additional hardness degrees. The focus here is on the THERMOLAST® M series, designed for medical devices. This means that the potential applications have become even more diverse, especially for the heavily monitored and regulated medical sector.

#### **Press contact**

*Europe, Middle East, Africa & Americas*

Juliane Schmidhuber

PR & Communications Manager

Phone +49 8638 9810568

[juliane.schmidhuber@kraiburg-tpe.com](mailto:juliane.schmidhuber@kraiburg-tpe.com)

*Asia Pacific*

Bridget Ngang

Marketing Manager Asia Pacific

Phone: +6039545 6301

[bridget.ngang@kraiburg-tpe.com](mailto:bridget.ngang@kraiburg-tpe.com)

*Americas*

Mirna Pina

Marketing Coordinator

Phone: +1 470 514- 2458

[mirna.pina@kraiburg-tpe.com](mailto:mirna.pina@kraiburg-tpe.com)

#### **Communications agency**

EMG

Vera Kiseleva

Phone: +31 645 092 735

[vkiseleva@emg-marcom.com](mailto:vkiseleva@emg-marcom.com)

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Their specific properties make these TPEs particularly suitable for prostheses and orthotic devices. The soft material is characterized by hardness values ranging from 30 to 50 Shore 00 and/or 45 to 70 VLRH. While TPEs in this hardness range tend to oil out and produce sticky surfaces, the extremely soft compounds from KRAIBURG TPE make a convincing impression with their pleasantly dry and velvety feel. Combined with their elastic properties, these TPEs are often used for applications with one-sided compressive loads such as orthopedic damping elements. Tests in accordance with the ISO 10993-10 standard also confirm that permanent contact with the skin surface does not lead to and/or cause allergic reactions.

Supersoft compounds are mainly processed using standard injection molding. In developing the extremely soft TPEs, the focus was on achieving a flawless dosing capability and/or flowability of the granules, uncomplicated processing as well as easy ejection. The additional option of using the materials in 3D printing opens up new avenues toward customized therapeutic products.

The properties of these THERMOLAST® M compounds also correspond to those of medical grade plastics in accordance with the VDI 2017 standard and have passed the biocompatibility tests in accordance with ISO 10993-5 (cytotoxicity) and ISO 10993-10 (skin sensitization) as well. The Medical Service Package ensures that THERMOLAST® M compounds are produced on a dedicated production line. KRAIBURG TPE assures formulation and process stability (change control).

In addition, the compounds comply with the ISCC PLUS requirements and thus enable customers to use TPEs with a reduced product carbon footprint (PCF) also in strictly regulated markets such as the medical sector.

The supersoft compounds for medical devices are available worldwide from KRAIBURG TPE.

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**Image:** Extremely soft and custom-made compounds for medical devices  
(Image: KRAIBURG TPE)

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### Information for press representatives



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### About KRAIBURG TPE

KRAIBURG TPE ([www.kraiburg-tpe.com](http://www.kraiburg-tpe.com)) is a global manufacturer of custom thermoplastic elastomers. KRAIBURG TPE was founded in 2001 as an independent business unit of the KRAIBURG Group and is now the industry's competence leader in the field of TPE compounds. The company's goal is to provide safe, reliable and sustainable products for customer applications. With more than 660 employees worldwide and production sites in Germany, the USA and Malaysia, the company provides a large product portfolio for applications in the automotive, industrial and consumer goods industries, as well as for the strictly regulated medical sector. The established THERMOLAST®, COPEC®, HIPEX®, and For Tec E® product lines are processed by injection molding or extrusion and offer manufacturers numerous advantages not only in processing but also in product design. KRAIBURG TPE is characterized by its innovative strength, global customer orientation, customized product solutions and reliable service. The company is ISO 50001 certified at its headquarters in Germany and holds ISO 9001 and ISO 14001 certifications at all its sites worldwide.