

Press Release

Surgical electrode with medical compliant TPE

Waldkraiburg/Friedrichshafen, October 2018

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

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

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

Surgical Instrument with Greater Comfort

LED SpA specifies THERMOLAST® M from KRAIBURG TPE for lightweight, ergonomic and reusable SURGEON Pencil S

Specializing in the design and production of premium medical electronic equipment, LED SpA has added an innovative handpiece for use in high-frequency surgery to its portfolio. The SURGEON Pencil S provides a number of outstanding features that benefit from the medical conformity, design freedom and aesthetics of KRAIBURG TPE's THERMOLAST® M thermoplastic elastomer compounds.

Unipolar electrode handpieces are important instrumentals in state-of-the-art high-frequency electrosurgery. Together with different active electrodes, they are used for sensitive cutting and coagulating procedures that require a firm and comfortable grip. The novel SURGEON Pencil S from LED, based in Aprilia near Rome (Italy), meets these requirements with several parts molded in different grades of THERMOLAST® M. The medical thermoplastic elastomer (TPE) from KRAIBURG TPE was chosen by the device manufacturer because of its well-established performance in healthcare along with the supplier's dedicated customer support, including a comprehensive Medical Service Package.

Designed for Fatigue-Free Electrosurgery

"For our advanced medical devices and instruments, we rely on high-performance materials that meet all the strict regulations in healthcare while at the same time offering greater design freedom for functional form and innovation," says Fulvio Clementini style designer manager, LED SpA. "The outstanding property profile of THERMOLAST® M and the excellent cooperation between our team and KRAIBURG TPE made a significant contribution to accelerating the time-to-market of our SURGEON Pencil S product."

Media Contact

Europe, Middle East & Africa

Simone Hammerl

Public Relations EMEA

Phone +49 8638 9810-568

simone.hammerl@kraiburg-tpe.com

International

Marlen Sittner

Head of Corporate Marketing

Phone +49 8638 9810-272

marlen.sittner@kraiburg-tpe.com

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The sleek and ergonomic design of the lightweight (30 g) grey pencil comprises a central handpiece with a screw-on electrode holder, two different-colored CUT/COAG button rings (yellow/blue) and a cable end. The body parts of the tool are two-component moldings with a solid polypropylene core and a THERMOLAST® M soft-touch skin. Apart from excellent long-term, direct adhesion from this combination, the TPE overmolding ensures the secure non-slip grip of the tapered instrument for fatigue-free surgery and comfort even in wet conditions. The convex shape of the button rings forms a supporting area for the surgeon's fingers, and the buttons provide reassuring tactile feedback when engaged or disengaged.

The product accommodates electrodes from 2.4 mm in diameter and above, and complies with the safety requirements of AAMI/ANSI Standard HF18 for electrosurgical devices. In contrast to common single-use electrode handpieces, however, the SURGEON Pencil S can be autoclaved up to 100 times at 134°C thanks to the excellent sterilizability of THERMOLAST® M.

Superior Medical Compliance

KRAIBURG TPE supports customers and molders in healthcare with a unique Medical Service Package that ensures the compliance of its THERMOLAST® M with strict international standards of biocompatibility, purity and quality. All medical compounds are exclusively manufactured on dedicated equipment lines. Selected materials are tested and certified to USP Class VI (Chapter 88), ISO 10993-5 (cytotoxicity), ISO 10993-10 (intracutaneous irritation), ISO 10993-11 (acute systemic toxicity) and ISO 10993-4 (hemolysis), as well as free of heavy metals, latex, PVC and phthalates, and offer consistent high purity. The change control management of raw materials used in compounding also covers full traceability of batches on the side of KRAIBURG TPE's suppliers.

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In addition, all THERMOLAST® M portfolio grades are listed in FDA Drug Master Files (DMF) to document the change control procedure, including prior notification of any changes. KRAIBURG TPE guarantees the continued availability of the original formulation for at least 24 months after notification before such changes come into effect. This provides maximum controlled quality and supply security to customers in the healthcare, pharmaceutical, medical and diagnostic industries.

Excellent Adhesion and Wide Hardness Range

The medical compounds are available in tailored grades for processing on standard injection molding and extrusion equipment. In two-component applications, they offer excellent adhesion to different thermoplastics such as PP, ABS, ABS/PC and PET.

THERMOLAST® M offer high surface aspect and outstanding mechanical properties, including scaled hardness ratings from 10 Shore A to 55 Shore D, and can be sterilized using common ethylene oxide (EtO), superheated steam, as well as beta or gamma irradiation. THERMOLAST® M generally is supplied in transparent or translucent colors but can also be colored customized while keeping basic medical compliance.



The SURGEON Pencil S from LED SpA for high-frequency electrosurgery takes advantage of the superior property profile and medical conformance provided by KRAIBURG TPE's THERMOLAST® M thermoplastic elastomer compounds. (Photo: © 2018 LED SpA)

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AboutLED SpA

With headquarters and extensive facilities covering more than 17,000 m². in Aprilia (Latina, Italy), LED SpA specializes in the design and production of medical electronic devices and instruments. The company was founded in 1982 and is firmly rooted in the creative tradition of superb Italian design. Its original focus was on advanced electrosurgical and electro-physiotherapy equipment. Today, LED's product portfolio also comprises medical home care, wellness and beauty as well as veterinary devices for customers throughout the world. Visit www.led.it for further information.

About KRAIBURG TPE

KRAIBURG TPE (www.kraiburg-tpe.com) is a global manufacturer of thermoplastic elastomers. From its beginning in 2001 as a subsidiary of the historical KRAIBURG Group founded in 1947, KRAIBURG TPE has pioneered in TPE compounds, today being the competence leader in this industry. With production sites in Germany, the U.S., and Malaysia, the company offers a broad range of compounds for applications in the automotive, industrial, consumer, and strictly regulated medical sectors. The established THERMOLAST[®], COPEC[®], HIPEX[®], and For Tec E[®] product lines are processed by injection molding or extrusion and provide numerous processing and product design advantages to manufacturers. KRAIBURG TPE features innovative capabilities as well as true global customer orientation, customized product solutions and reliable service. The company is certified to ISO 50001 at its headquarters in Germany and holds ISO 9001 and ISO 14001 certifications at all global sites. In 2017, KRAIBURG TPE, with 620 employees worldwide, generated sales of 178 million euros.

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Contact person for especially high-resolution images: Siria Nielsen

(snielsen@emg-pr.com, +31 164 317 036)