

Press release

Customized THERMOLAST® M compound for FDA authorized migraine relief wearable
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KRAIBURG TPE supplies custom-colored medical-grade thermoplastic elastomer for Nerivio, an innovative drug-free neuromodulation therapeutic wearable from Theranica

Soft feel and friendly to the skin with biocompatible TPE

Nerivio®, a novel wireless neuromodulation wearable from Theranica for drug-free acute treatment of migraine, features an electronic housing molded in a THERMOLAST® M custom-colored medical-grade thermoplastic elastomer compound from KRAIBURG TPE. The device has passed clinical testing, is FDA-authorized and conforms to all applicable IEC/EN 60601 standards for medical devices, and nerve stimulators. The TPE material provides ISO 10993 certified biocompatibility and is supplied in line with new VDI 2017 guidelines.

Non-pharmacological treatment of migraine and other pain conditions has become a challenge, not just in remote areas without ready access to outpatient care facilities, but also under the constraints of social distancing amid the current COVID-19 pandemic. Theranica (Netanya, Israel) has developed an innovative neuromodulation device – Nerivio® – addressing both issues with a convenient wearable solution for personalized, app-controlled acute treatment of migraine. The electroceutical device is worn on the arm and uses electronic pulses for inducing a drug-free pain inhibition mechanism. The user-friendly app is available for both Android and iOS smartphones and includes a migraine diary that can be shared with healthcare professionals, for better managing this disabling disease.

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“For the outer layer of the Nerivio®, we tested a variety of different biocompatible materials to find the best combination of soft feel, certified dermatological tolerance, processability and surface quality,” says Alon Ironi, President & CEO of Theranica. “Furthermore, the compound had to provide long-term adhesion to double-sided sealing tape, without delamination.”

In close cooperation with AiT Chemicals, a leading local supplier of polymers and KRAIBURG TPE’s distributor in Israel, Theranica selected a THERMOLAST® M medical-grade thermoplastic elastomer (TPE) that offered the ultimate property profile for this device. It delivers a smooth and velvety surface ‘as molded’, with durable abrasion resistance to the securing armband and strap of the device. It is biocompatible and offers irritation-free characteristics while meeting cytotoxicity requirements, which have been certified respectively to ISO 10993-10 and ISO 10993-5 standards. The compound is pre-colored ex works to match the stylish grey surface texture of the armband according to customer requirements. Also, many of KRAIBURG TPE’s portfolio compounds are documented in FDA Drug Master Files. This helps the end customers to speed up regulatory approvals and time-to-market.

“Thanks to our long-standing partnership with AiT Chemicals and our early inclusion in this application project, we were able to supply a custom-tailored TPE that meets all the specifications and requirements of Theranica, from ease of processing to biocompatibility and color,” says Oliver Kluge, Advisor for Medical Products at KRAIBURG TPE.

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Following comprehensive clinical clearance, the Nerivio® device received a De Novo approval from the U.S. Food and Drug Administration (FDA) for clinical use in May 2019. The FDA classified the wearable as a trunk and limb electrical stimulator to treat headache. It conforms to all applicable IEC/EN 60601 standards for the safety and electromagnetic compatibility of medical electrical equipment, nerve, and muscle stimulators.

TIME Magazine acknowledged Nerivio® in its appreciation of '100 Best Inventions' in 2019. The device was selected as one of 10 winners in the Health Care category based on key factors including originality, creativity, influence, ambition, and effectiveness.

In the United States, Nerivio® is already available as a prescribed wearable, including through telemedicine platforms [UpScript](#) and [Cove](#). It is expected to be launched in Europe and other regions in 2021.

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Notes for Editors

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 medical-grade compounds to strict international standards of biocompatibility, purity, and quality. In line with applicable REACH and RoHS requirements, all THERMOLAST® M compounds are free of heavy metals, latex, PVC and phthalates, and offer consistent high purity for cleanroom processing. The quality control of raw materials used in production by KRAIBURG TPE also encompasses their traceability on the suppliers' side. All medical-grade compounds are manufactured in dedicated production lines.

A number of select medical grades have been 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) standards. In addition, the THERMOLAST® M portfolio is listed in the FDA Drug Master Files (DMF). KRAIBURG TPE further ensures alignment with the new guideline for medical grade plastics, VDI 2017, which THERMOLAST M fulfils in full scale, e.g. in regard to change control management as well as the continued availability of individual grades for at least 24 months after any formulation change or withdrawal notification. "This provides customers in the healthcare, pharmaceutical, medical and diagnostics industry segments with a maximum of controlled quality, as well as security of supply," adds Oliver Kluge, a member of the VDI 2017 Guidelines Committee and Advisor for Medical Products at KRAIBURG TPE.

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The company's 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 most thermoplastic resins, including polar materials such as polyamides. Finished parts molded or overmolded in THERMOLAST® M offer high surface aspect and outstanding mechanical properties, including a wide range of scaled hardness ratings. They can be sterilized using ethylene oxide (EtO), superheated steam, gamma or electron beam irradiation. Compounds are supplied in transparent, customer-specific translucent and opaque colors, or can easily be custom-colored during processing.

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The soft-touch and skin-friendly electronic housing of Theranica's novel Nerivio® app-controlled neuromodulation wearable for drug-free and non-invasive migraine relief is molded in a THERMOLAST® M custom-colored medical-grade thermoplastic elastomer compound from KRAIBURG TPE.
(Photos © 2020 Theranica)

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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 for the 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 2019, with over 645 employees worldwide, KRAIBURG TPE generated sales of 190 million euros.

About Theranica

Theranica Bio-Electronics is a prescribed digital therapeutics company dedicated to creating effective, safe, affordable, low-side effect electroceuticals for idiopathic pain conditions. The company's award-winning flagship product, Nerivio™, is the first FDA-cleared smartphone-controlled prescription wearable device for acute migraine treatment. Setting the foundation of an effective first-line therapeutic alternative to pharmacological options within the migraine industry, Theranica is expanding its proprietary technology to offer additional solutions for other pain conditions.

Learn more by visiting our website, www.theranica.com and following us on [LinkedIn](#), [Twitter](#) and [Facebook](#).

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About AiT Chemicals

For over three decades, AiT (www.ait-chemicals.com) has earned its reputation by loyally representing leading global polymer and chemicals manufacturers in the fast-growing Israeli market. The company, based near Netanya, has two divisions focusing on Commodities and the growing Engineering & Specialty Plastics market. As a family-owned company known for its technical expertise and support as well as long term client relationships, AiT is backed by experienced professionals and an extensive network of local industry ties. AiT is known for long term project support and harnessing the full capabilities of their principals to supply client with comprehensive solutions.

This press release and relevant photography can be downloaded from www.PressReleaseFinder.com.

Alternatively for very high resolution pictures please contact Siria Nielsen (snielsen@emg-marcom.com, +31 164 317 036).