

Integrated Solutions

**ACCELERATING SPEED TO MARKET IN MEDICAL DEVICE
CONTRACT MANUFACTURING**



Amplify Innovation

At Trelleborg Medical Solutions, we make your medical device and combination product vision a reality. Our fully integrated approach streamlines every step of your journey, from concept to finished product.

Our integrated solutions have a profound impact on device development and ultimately on patients' well-being. By offering a full suite of services from prototyping to sterilization management, we streamline your device development process, saving you valuable time and resources.

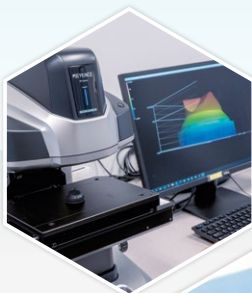
With expertise in product customization, we create tailored solutions that perfectly align with your specifications and requirements. This ensures the devices you develop are of the highest quality, reliable, and safe for patients.

**Supply
chain
continuity**

**Maximum
quality
control**

**Fully
customizable
solutions**

**Product
lifecycle
management**



YOUR ONE-STOP CONTRACT MANUFACTURER

With our comprehensive and collaborative approach, we become an extension of your team, supporting you at all stages from the initial concept through to delivery of the device when, where, and how you need it. By taking care of the details, we allow you to focus on creating innovative solutions to positively impact patients' lives.

HOW OUR INTEGRATED SOLUTIONS HELP

- Support from the earliest development stages, including rapid production-intent prototyping, through to delivery of the finished, sterile packaged product and assembled device
- Facilitate the development of the best design for functional solutions by utilizing our design and material expertise, paired with the latest in 3D model simulation technology
- Improve reliability and design for manufacturability (DfM) issues before a product goes to market
- Optimize business efficiency by consolidating your supply chain, reducing risk and driving savings
- Save costs through bundled purchasing processes and consolidated audits, shipping and logistics

THE INNOVATION CENTER

Bring Products to Life. Faster.

Innovators looking to create high-performing products and measurably reduce go-to-market timelines have a place to collaborate. The Trelleborg Innovation Center provides immersive engineer-to-engineer experiences, along with a fully integrated design-prototype-build-test process.

Find out more

www.trelleborg.com/en/medical/ic



COMBINE A FULL RANGE OF ADVANCED CAPABILITIES TO CREATE CUSTOM SOLUTIONS

- Product engineering and design services, including utilization of advanced simulation tools such as finite element analysis (FEA), DfM, and mold flow analysis
- Material guidance and custom formulations from our library of tailor-made, high-performance materials, ranging from thermoset elastomers and thermoplastics, to implantables and bioabsorbables
- Rapid production-intent prototyping in our Innovation Center accelerates time to market through scalable ramp-up of serial production
- Manufacturing using cutting-edge processes including silicone extrusion, custom molding, overmolding and multicomponent molding, dipping and coating technologies, automated fiber placement for advanced composites, and high-volume automated assembly
- Expertise in drug-elution technologies and formulating active pharmaceutical ingredients (APIs) for combination products
- In-house automation teams support effective scalability and ensure product quality
- Complete assembly services from routine sub-assemblies to automated assembly of finished devices
- Packaging and labelling of both sterile and non-sterile devices

CONTACT US

Looking for a partner for your medical device or combination product project? Reach out to learn how we can support you.

www.trelleborg.com/en/medical/contact-us



Developed in Partnership

We partner with customers to develop life-changing technologies by providing integrated solutions tailored to meet their specific needs, which streamline the development process, saving valuable time and resources.

For nearly 20 years, we have been collaborating with Paxman on the development of a scalp cooling system to help prevent chemotherapy-induced alopecia. We do this through cross-functional integration of design and quality teams and university partners to make the Paxman vision a reality. The cap has evolved over time to optimize efficacy and safety, enable high-volume production and lower costs for patients.

ACCELERATING PRODUCT DEVELOPMENT

Getting to market quickly is critical. During the nearly two-decade partnership, our engineers worked closely with the Paxman design teams and university partners to design, develop and optimize the cooling cap. This included:

- Providing design support by combining custom engineering with DfM to develop initial and new designs
- Production-intent prototype tooling and processes delivered prototypes in the same material used for production, saving time and facilitating testing of fully functional products early in the process
- Once prototypes were available, product performance tests were performed to assess cap design, analyze tubing flow rate and verify material properties

Collaboration early in the development process accelerates the timeline from prototype to scale-up. Our expertise ensures the right selection of material and design for a functional integrated solution and improves future production yields.

INDUSTRY-LEADING MATERIAL EXPERTISE

Utilizing our in-house compound formulation capabilities, experts worked directly with Paxman to determine the best compounds for the cap and tubing. Considerations were:

- Thin-walled design adapts better to head shape, increasing comfort and efficacy by maximizing scalp contact
- Enhance tear-strength by formulating more robust materials to lower patient risk
- Compliance with ISO 10993, BfR CFR 21 177.2600 and USP Class VI requirements
- Compatibility with cooling media and cleaning regimens

We excel at finding innovative solutions to challenges through our understanding of material interactions, the manufacturing environment and the application. This gives us the ability to create complex devices of the highest standard.



ABOUT PAXMAN

Paxman have been pioneering scalp cooling technology for over a quarter of a century to support patients and minimize hair loss during chemotherapy. Their clinically proven scalp cooling system helps tens of thousands of cancer patients every year, in more than 60 countries worldwide, to retain their hair during chemotherapy.

paxmanscalpcooling.com

ADVANCED MANUFACTURING PROCESSES

Our facilities are equipped with state-of-the-art production technologies to exceed unique customer requirements. From prototype to scaled-up production, our manufacturing experts collaborated closely with the Paxman quality engineering team to produce the cooling cap and optimize manufacturing processes using innovative capabilities:

- Extrusion of silicone tubes in custom sizes to match the Paxman pump fittings and flow rate requirements
- Combined overmolding with coreless molding technologies to produce the blue cap, which is fully bonded to the tubing
- Advanced tooling capabilities facilitated the transition from 3D printed tools to metal-filled 3D printed tools and most recently to steel molded tools, enabling faster manufacturing and significantly improving quality

We have an in-depth understanding of the challenges our customers must overcome. This enables us to reliably develop and manufacture innovative, precision components and assemblies. Our scalable processes enable prototype and small-batch production through to fully automated cells for high-volume production.

MINIMIZING RISK BY ENSURING THE HIGHEST QUALITY

Maintaining consistent quality and minimizing risk are essential for devices. Together with Paxman quality engineers, we designed a customized quality assurance program focusing on two areas:

- Testing and inspection – using a unique, customer-specific, in-house test rig, we inspect the cooling caps for leaks, flow rate and other performance criteria. Our rig mirrors test equipment at Paxman to allow for test method correlation when the cap is incorporated into the scalp cooling system.
- Traceability – serial numbers are molded into each cooling cap, enabling full traceability of each device. These numbers are documented in patient files and in the case of a defect, we can track the cap components and materials.

Through our comprehensive, unified quality management system (QMS), our OneQMS initiative provides consistency, efficiency and reduced risk across all manufacturing operations globally. This simplifies your supplier auditing process and ensures the highest quality standards are met to protect patient lives.

REDUCING COMPLEXITY THROUGH VALUE-ADDED SERVICES

Our fully integrated solutions streamline supply chain processes. A tailored package of post-fabrication services provided Paxman with a complete cooling cap, simplifying and accelerating their logistics operations:

- Optimized cap forming technology reduces assembly time and costs
- Fully assembled, packed and labeled device
- Documentation on regulatory compliance

With our integrated solutions portfolio, we are your single point of contact, ensuring a seamless process from start to finish.



Trelleborg is a world leader in engineered polymer solutions that protect essential applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Medical Solutions partners with the world's leading medical device and biopharmaceutical companies, collaborating from concept to commercialization to bring to market impactful solutions that improve patient quality of life. It leverages decades of design and manufacturing experience, in-depth knowledge of polymer materials to deliver pioneering, engineered solutions for transformative health technologies.

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