



IDEATION



ENGINEERING



MANUFACTURING



REGULATORY



MARKETING



EDUCATION

# CeramTec Services

expertise • ambition • partnership



# expertise • ambition • partnership

At CeramTec we can proudly look back on more than 45 years of experience in the development and manufacturing of innovative ceramic solutions for medical applications.

To our customers we are a trusted strategic innovation partner in the market. We offer a wide range of value-adding services to our partners to support their ongoing success in a rapidly changing market environment.

## **From Ideation to Education**

Our broad range of services reflects the complete product life cycle workflow of our partners from ideation over engineering, manufacturing, regulatory through marketing and education. Each service can be tailored to our partners' needs to

create the maximum value. Our business partners can book individual services or potentially outsource the entire workflow to CeramTec.

*Challenge us to achieve your desired level of differentiation!*



# POWER YOUR INNOVATION



CeramTec IDEATION SERVICES  
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**CeramTec**  
THE CERAMIC EXPERTS

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The life cycle for medical products is continually getting shorter. Innovation is mandatory for medical device companies to maintain their market share and avoid price pressure.

At the same time, the level of commercial risk for medical device companies is increasing as the regulatory framework gets stricter, time-to-market lengthens, and uncertainty around return on investment increases.

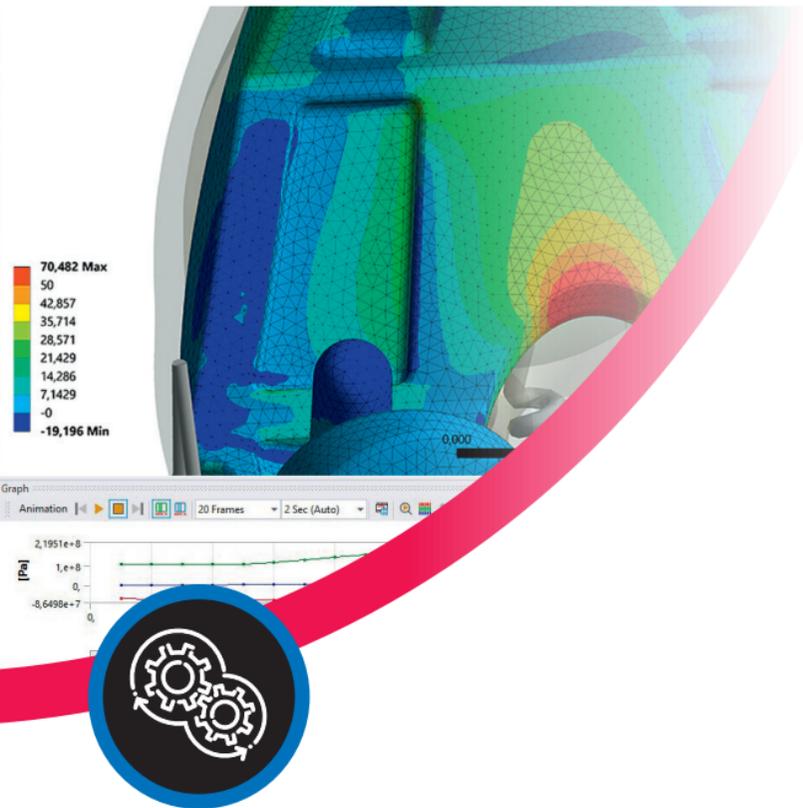
In this context, maintaining internal resources for generating innovative ideas to drive future business growth is financially demanding and the impact of potential failure can be high.

Under the umbrella of “Ideation”, CeramTec offers a range of services to support business partners in their innovation process. We partner with you to find the right solution that aligns with your portfolio strategy and helps to achieve the desired level of differentiation.

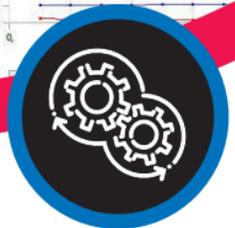
Incorporating technical ceramics from CeramTec as your implant material is an opportunity to think outside the box. Together we can redefine your solution to the clinical problem.

We support you with flexible solutions to reduce project risk at an early stage, through design workshops or stand-alone feasibility projects. CeramTec has the resources and expertise to bring a different perspective that will enhance your innovation process.

- Large R&D team of over 50 specialists dedicated to medical products
- Dedicated team with experience in design-thinking
- Demonstrated customer-centric and solution-oriented thinking
- Recognized expertise in design of ceramic components
- Decades of experience in design of component-implant interfaces and design optimization for cost-effective ceramic manufacturing
- Over 300 patents and other IP rights granted to CeramTec



# INCREASE LIKELIHOOD OF SUCCESS



CeramTec ENGINEERING SERVICES  
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**CeramTec**  
THE CERAMIC EXPERTS

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Developing a new product or system is a complex process. Each component needs to be designed while balancing desired functionality and manufacturing costs. The interaction of components influences safety and performance of the system as well.

Frequently, interfaces bear significant failure risk but also present opportunities for superior performance.

In today's high paced environment, a single R&D department can no longer deal with such complexity. It requires effective and efficient collaboration with other professionals throughout the process.

CeramTec has identified the importance of expertise and collaboration across component interfaces and process steps.

Therefore, we offer a wide range of engineering services from 3D scanning, CAD modeling and design evaluation through FE Analyses, risk assessment, and rationales for regulatory purposes, to standard testing, product-specific setups, and statistics.

After a product's successful market introduction, we offer continuous engineering support, *e.g.*, market surveillance, retrieval analyses, and design changes. CeramTec helps you to achieve superior product performance while meeting your scheduled deadlines.

- Over four decades of experience in designing ceramic components and interfaces for implants
- Established development process frequently audited by notified bodies, FDA, and other authorities
- Test lab certified according to ISO17025 for a multitude of standardized mechanical tests
- Comprehensive database with results of > 5,000 tests and > 3,000 retrieval analyses
- Expertise in design and validation of test setups published in peer-reviewed literature
- Short communication channels based on our one-stop-shop philosophy



# REALIZE YOUR PRODUCT VISION



CeramTec **MANUFACTURING SERVICES**  
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**CeramTec**  
THE CERAMIC EXPERTS

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Successful new product introduction requires efficient, goal-driven processes while maintaining the highest quality standards. This applies equally to the manufacturing of prototypes, pilot, and large scale production.

Valuable time can be saved or lost at the interface between design definition and serial manufacturing. It is often an evolving process of optimization of pilot production processes, techniques, tooling, tolerances and as a result, subsequent changes to the design and technical drawings.

Reducing the number of iterations to optimize new implant and component manufacturing is highly relevant for medical device companies as it directly translates into time-to-market.

CeramTec supports business partners with outstanding manufacturing know-how and material expertise to address the challenge between design work and serial production.

Customers can benefit from ISO-audited manufacturing equipment and production capacity specifically for prototype and contract manufacturing.

We offer flexible solutions to realize new product concepts and enable your plans, free of internal production capacity limitations or quality management investments. This includes all your manufacturing needs from one-off, individual manufacturing, or made-to-order batch production through pilot series and large scale production.

- State of the art machine park manufacturing equipment dedicated to developing prototypes and made-to-order batches or pilot series
- Manufactured components range from micro size with the finest radius and tolerances to large, highly complex products with free form surfaces
- Tooling and manufacturing fixture requirements are developed internally based upon a very broad skill set
- Team consisting of specialists with decades of experience in the field of ceramic implant process development
- Highly structured processes for developing prototypes and made-to-order products ensuring best-in-class results



# SPEED-UP MARKET ENTRANCE



CeramTec REGULATORY SERVICES  
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**CeramTec**  
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In today's reality, new products have to comply with a multitude of different regulations and it becomes difficult to keep up with the current status.

The variety of requirements worldwide is increasingly complex. Therefore the regulatory pathway often becomes as time and cost consuming as the development of the product itself.

The experience and even capacity of regulatory departments can allow them to become gate keepers to successful market entrance for new devices.

CeramTec has recognized that additional regulatory support is becoming increasingly important for our clients in return for driving innovation. Therefore, we offer a wide range of regulatory services for different markets.

Our services include customized projects and regulatory pathway planning, device classification and evaluation of predicate devices, technical file preparation and submission, as well as negotiations and communication with the responsible national authorities.

Even after successful approval, we offer ongoing regulatory service, *e.g.*, support of change notifications.

- Professional regulatory competence and detailed experience, enabled by a small and highly specialized, cross-functional team
- Up-to-date knowledge of changing global regulations, ensured through continuous exchange with authorities and notified bodies
- Proven quality of support provided to clients, confirmed during reviews by authorities worldwide
- Efficient communication channels, based on our one-stop-shop philosophy
- Reduced time-to-market, by taking advantage of our services from the start of product development activities



# ACCELERATE YOUR BUSINESS

CeramTec MARKETING SERVICES  
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**CeramTec**  
THE CERAMIC EXPERTS

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After costly product development and regulatory activities come product roll out, production ramp-up and investment recuperation. As the product life cycle continually gets shorter, the window of opportunity for a successful product launch shortens while the complexity increases.

Market entry challenges for a new device can include generating clinical evidence and proof of cost-effectiveness. Ideally, this information is communicated through key opinion leaders by sharing their clinical experience.

In this context, a mutually beneficial relationship with a supplier who can enhance your launch & marketing activities with global brand power will positively impact your sales growth.

Business partners can benefit from CeramTec's portfolio of highly recognized global brands, which have the power to enhance market visibility and drive user perception. To reinforce the brand strength, CeramTec has identified biocompatibility and immunological response to ceramics as a fundamental competitive advantage.

We offer business partners a wide range of marketing services to facilitate and accelerate successful launches and reinforce brand visibility. Our services include the use of premium brands, clinical benefit assessments, dedicated scientific affairs, and market access expertise.

We offer further layers of services beyond the launch, such as ongoing education and literature updates for internal users and the end-customer.

- Globally recognized premium branding developed over decades, supported by a wealth of data and broad perception
- A strong global presence across key media channels for collaboration and leverage
- Evidence-based and up-to-date clinical and scientific input for Global Value Dossiers, ensured through continuous exchange with our international scientific and registry network
- Worldwide co-marketing support provided to clients, enabled by our global commercial and education network
- Professional marketing competence in medical and dental devices, enabled by an experienced international marketing and market access team



# FOSTER COMMERCIAL SUCCESS



CeramTec EDUCATION SERVICES  
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**CeramTec**  
THE CERAMIC EXPERTS

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The demands in professional circles of the medical industry are increasing. Physicians in particular are obliged to train on correct and safe handling of medical products and update their qualifications on a continual basis.

Distributors and their sales forces, however, are obliged to pass to end-users on their complete product portfolio knowledge in a consistent and professional manner. Ultimately, they have to communicate their products' advantages in an understandable way allowing the end-user to perceive the added value.

This requires comprehensive knowledge of all relevant aspects in the value-added process, including information from the supplier.

CeramTec provides all relevant information about its materials, from scientific basics to practical handling instructions. Respective trainings are offered first hand. Our educational offering is not only directed at medical professionals but also at the communication, marketing and sales teams of our customers.

Learning can be tailored to the educational format and customized to cover specific topics of interest, for example on the topic of safe handling of ceramic components.

Furthermore, CeramTec provides information on interactions between the implant material and target tissue, the clinical outcome, and lastly, the cost-effectiveness of ceramics. The overall goal is joint commercial success.

- Information about ceramics taken from our 100 years of experience with technical ceramics and more than 45 years of experience in the medical device industry
- A multidisciplinary team of immunologists, clinical researchers and health economists coordinate activities in the area of "Medical and Scientific Affairs"
- Provided knowledge based on extensive literature studies and numerous self-initiated or accompanied studies
- Active collaboration with scientific bodies and initiatives with registries ensure our up-to-date knowledge
- Training sessions following defined concepts with experienced instructors from CeramTec or external specialists, who provide training on site