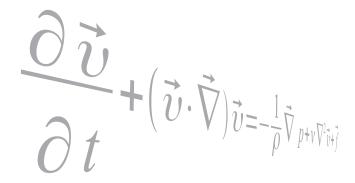


# Implants



# Challenge >>

Implants are the most sophisticated of all medical devices. They remain in the patient for a long period – maybe even for life – and must reliably perform their task.



## Approach >>

A certified development process takes into consideration the creative phase of finding a solution as well as the systematic verification and validation of a new product through first-in-human studies.

#### Services >>

- Development of invasive medical devices and implants. Our interdisciplinary team will accompany you for the entire development process, starting with the first idea until marketing approval.
- Feasibility studies and concepts. Thanks to our own production facilities, we are able to manufacture functional models, prototypes, or even small batches in a fast and cost-effective manner.
- Accessories and packaging. A clinically effective implant together with intuitive and user-friendly accessories are critical for market success. We offer you a wide range of experience with delivery instruments and packaging systems.
- Long-term testing. In the laboratory and, upon request, under physiological conditions we are able to build test systems tailored to your products.
- Reviews. Often, «another set of eyes» can provide important and valuable contributions. Our specialists can take part in your reviews.
- \_ In-vivo validation. Certain issues can only be solved using an animal model. We can help you chose the right model and plan, conduct, and analyze in-vivo tests.
- Expert feedback. Feedback from clinical opinion leaders is essential for the eventual success of a product. You can profit from our existing relationships with key opinion leaders or let us help you build your own network.
- Risk management. Together with your specialists, we will compile a tailor-made risk management plan pursuant to EN ISO 14971 and assist you with the risk analysis, e.g. with a FMEA.

- Clinical evaluations. We will show you how to conduct your clinical evaluations in accordance with Annex X of the Medical Devices Directive and guideline MEDDEV 2.7.1.
- Biodegradable materials. Biodegradable materials open up a new spectrum of interesting applications. We are able to assist you in identifying potential compounds, and in the handling, storage, and processing of these sophisticated materials.

#### Trust >>

Our experience includes, among others, class III products from the fields of cardiology and neurosurgery. All of our processes are certified in accordance with EN ISO 13485

### Uniqueness >>

A leading interdisciplinary team in Switzerland is working for you – practically based and target-oriented.

Do you wish to advance the development of your implants in a fast and cost-effective manner without sacrificing safety?



Contact >>

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Carag is a leading Swiss engineering company and point of contact for physicians, developers, and medtech companies developing high-quality products for cutting-edge medical applications. Carag has an experienced, performance-driven, interdisciplinary team consisting of engineers, physicians, medical technicians, electronic technicians and software developers. The broad range of specialized engineering and consulting services starts with technical feasibility checks and continues with product development through marketing approvals, regardless of the regulatory complexity.