



**SAMAPLAST AG**  
PLASTICS TECHNOLOGY

**Plastic is the future  
... is flexible**



SWISS MADE BY SAMAPLAST AG



[www.samaplast.ch](http://www.samaplast.ch)



# The future is today. We'll face it. Together.

High-quality plastic products, made by SAMAPLAST AG:

Technical plastic injection moulded parts/assemblies, medical devices  
and implants leave our location in St. Margrethen/SG every day.

For already over 60 years. We are proud of that.



## What distinguishes us

### Strength >

### Core competency

#### **SAMAPLAST AG - Specialist in plastics**

Innovation, precision, flexibility - that's what makes us special, both in production and in customer service. With six decades of experience, we permanently maintain our know-how in the processing of high-tech plastics and absorbable materials at the highest level. That is our aspiration.

### Quality >

### Quality management

#### **Quality is our job**

Developing products and bringing them to market maturity is one of our tasks. Another is the optimal quality of these products, on which you can always rely.

Therefore, quality management according to EN ISO 9001, EN ISO 13485 and MDR 2017/745, 21 CFR Part 820 (FDA), ANVISA and JPAL has top priority at SAMAPLAST AG.

### Lean >

### 5S / LEAN

#### **Process optimisation through sustainable lean management**

Based on the highest process and product quality, we continuously improve our processes and procedures. We consistently use a wide variety of lean tools, such as set-up time optimisation, value stream analyses and shop floor management.

This enables us to implement all customer requirements flexibly, efficiently and cost-effectively in our optimised production facility. This is what we are committed to day after day.

### Risk >

### Risk management

#### **Risk management without compromise**

Risk management is an important part of our daily work. We bear a great responsibility in the production of our medical devices, because ultimately life depends on them.

For this reason, a functioning risk management system based on EN ISO 14971 is one of our central tasks. Since this area is of existential importance, we face up to this responsibility: for our customers, for our employees, for our company.



# Engineering – a component is created

## From the idea to the implementation

Do you have your own ideas for your component? Then we are your partner: Because we leave nothing to chance and develop a tailor-made and market-driven product from your ideas and wishes.



## Prototypes - quickly to the test model

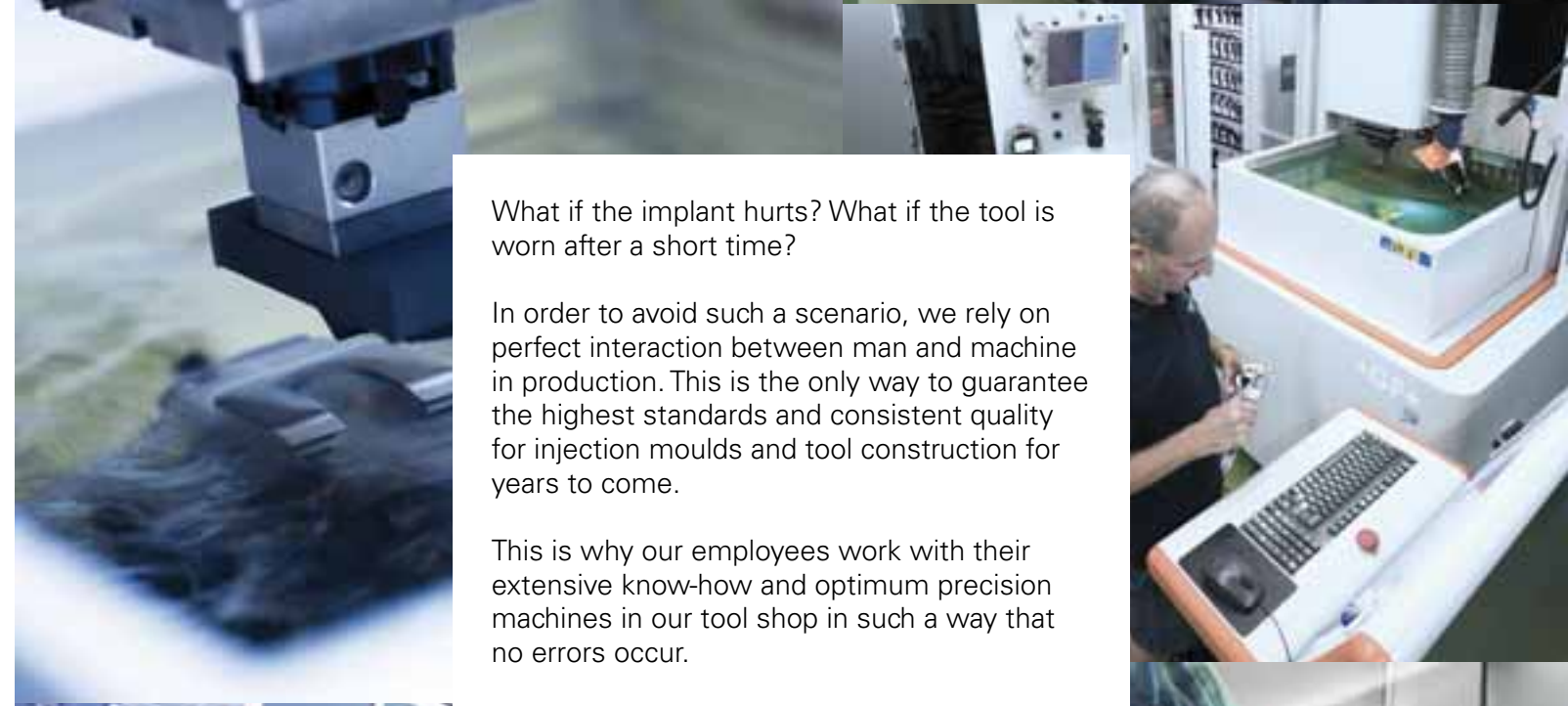
So that you can test your design ideas quickly, we can produce your prototypes for you using i.e. our Stratasys 3D printer.



## Analysis and optimisation

Implementation is good, optimisation is important. Because there's nothing that can't be made any better. With our Moldflow filling simulation programme and external FEM analyses, we get to the bottom of the components in your product and optimise the manufacturing process.

# Toolmaking – long life through precision



What if the implant hurts? What if the tool is worn after a short time?

In order to avoid such a scenario, we rely on perfect interaction between man and machine in production. This is the only way to guarantee the highest standards and consistent quality for injection moulds and tool construction for years to come.

This is why our employees work with their extensive know-how and optimum precision machines in our tool shop in such a way that no errors occur.





# Prototypes and additive manufacturing (AM)

## Testing made easy

Experience has shown that market analysis and functional tests follow ideas, development and optimisation. So that you can quickly test your products in the market, we internally manufacture prototypes and small series.

With our Stratasys and Kumovis PEEK 3D printer or Arburg Freeformer, you can have your prototype in your hands in no time at all. On request, we can also produce it from hardened steel tools in 10 days. Because we develop solutions.



## Additive Manufacturing (AM) – a step into the future

Keyword prototypes and small series: The market is increasingly demanding the production of small batch sizes for medical devices and implants. For this reason, the machinery at SAMAPLAST AG was expanded to include Freeformer and PEEK 3D printer, as well as a clean room (ISO Class 8 in operation).

Freeformer is a system type for additive manufacturing that combines the basic functions of an injection moulding machine with those of a 3D printer. With our 3D printers, generatively manufactured components can be produced with standard material from batch size 1, if necessary also patient-specific.





# Injection moulding – part of our core competence

We process all thermoplastics and absorbable materials on our state-of-the-art injection moulding machines. Our work is based on decades of experience, innovative strength and precision.

In addition, we are able to produce plastic parts from 0.01 – 1000 g piece weight. This is the foundation for long-lasting, trusting customer relationships.



### We'll get to the bottom of it

For us, man and machine form a unit that gets to the bottom of the specific tasks. Modern analysis tools for the characterisation of flow behaviour and for the detection of residual moisture support our specialists in their daily work. This also includes the quality control of raw materials and a possible damage analysis.



«Innovation in processing for optimal products.»



# Further processing



The production of plastic injection moulded parts is only one of our fields of activity.

In addition, we are also specialists in their further processing and fully automated production.

Our customers get everything from a single source – in the highest quality and precision.

«We don't take any half measures in plastic.»

# Final packaging | sterilisation

## Final packaging of medical devices

Medical devices must be designed, manufactured and packaged in such a way that it is assured - according to the information provided by the manufacturer - that their characteristics and performance do not change during storage and transport.



## Validated standard packaging

In order to minimise the time and costs involved in the development process and project management, SAMAPLAST AG has determined standard medical packaging for bags and blisters of various sizes and materials and validated them in accordance with EN ISO 11607.

## Sterilisation

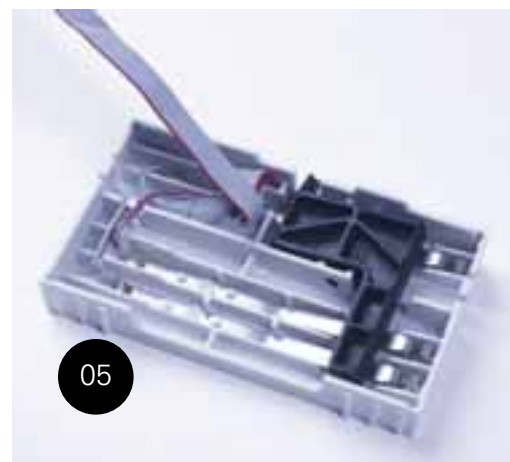
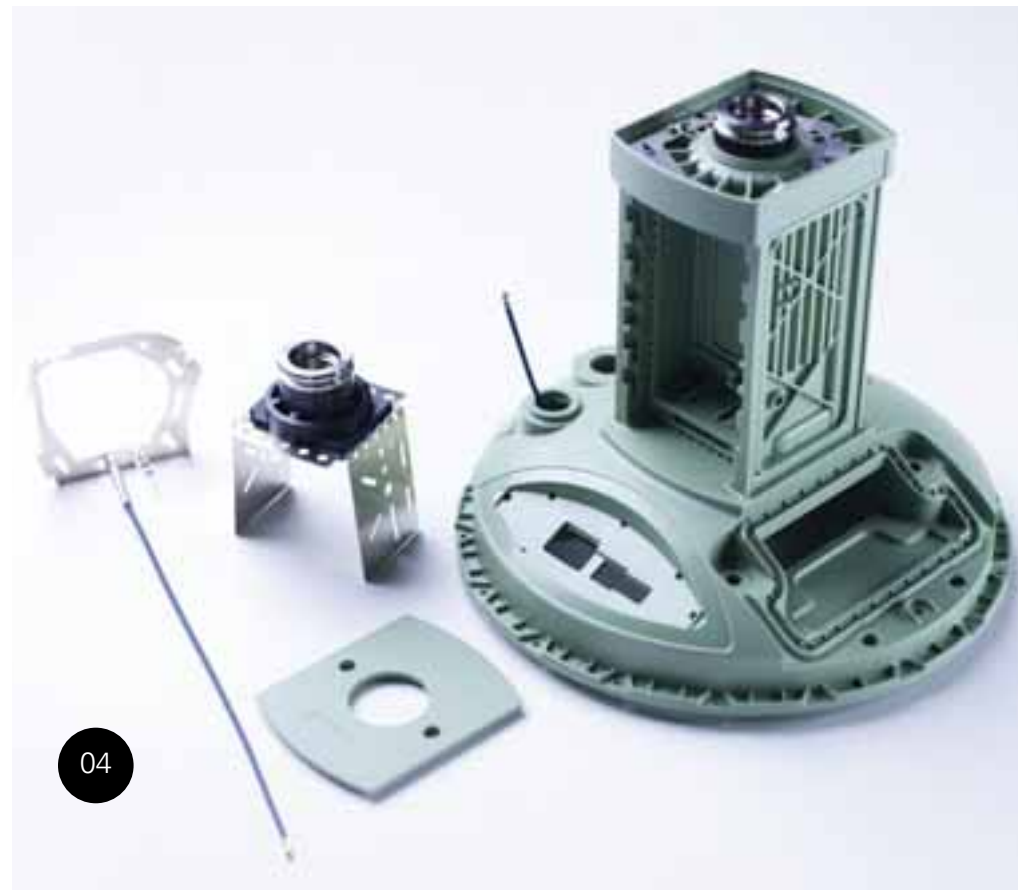
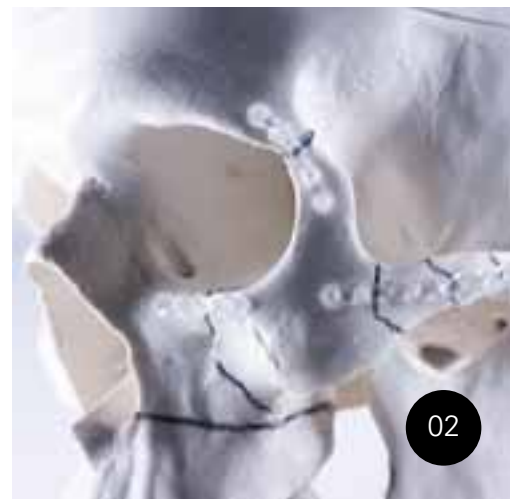
To achieve the sterility of the final packaged medical devices, SAMAPLAST AG offers in cooperation with its partners the execution of sterilisation (e.g. gamma or ETO) in accordance with the standards.

Gamma/X-ray sterilisation process	Standard	Ethylene oxide sterilisation process	Standard
Method 1, sterilisation dose: 14,2–36,3kGy	ISO 11137-2	Half-cycle method (Overkill)	ISO 11135-1
VD <sub>max</sub> <sup>25</sup> -method, sterilisation dose: 25kGy	ISO 11137-2	Ethylene oxide sterilisation residues	ISO 10993-7
VD <sub>max</sub> <sup>15</sup> -method, sterilisation dose: 15kGy	ISO 11137-2		



«Packaging and sterilisation – critical for safe medical devices.»





That's our strength: We offer complete solutions from idea to prototype to marketability. This applies to technical injection moulded parts and assemblies, injection moulded medical devices and implants to the sterile packed end product. Thus, we unite all competences in our company.

### Implants

In addition to technical and medical devices, SAMAPLAST AG also manufactures a wide range of implants, e. g. spinal prostheses to replace intervertebral discs, components for knee and hip implants or port catheters, and much more.

01 / 02 Implant

### Medical devices

In the dental industry, but also in many other areas, our medical devices are in demand. They are used, among other things, for external fixations or instruments for a wide range of tasks.

03 / 06 Medical device

### Technical parts

SAMAPLAST AG has been successfully developing products and solutions in the fields of technology, medical devices and implants for many years. Especially for surveying technology, the food industry, floor cleaning or mechanical engineering, our know-how and our competences lead to individual solutions.

04 / 05 Technical part





## Production without ambient noise

Clinically pure products – a necessity for many areas. For this purpose, we at SAMAPLAST AG have set up two clean rooms (ISO 7 in operation according to EN ISO 14644) in which we manufacture these products and carry out their subsequent operations in the required quality. You can rely on that.



## Monitoring – a must

To ensure that production and further processing are demonstrably carried out under the required parameters, we at SAMAPLAST AG have set up a monitoring system that completely documents the individual parameters. In this way, we meticulously comply with the manufacturing instructions (device master record etc.) and guarantee comprehensive and complete hygiene measures. In order to permanently meet the high quality level, we have implemented further monitoring: hygiene monitoring. So you can be sure that we have all hygiene requirements and regulations under control.

## Cleaning with ultrapure water

However, we do not manufacture all our products in a clean room, but also outside it. Nevertheless, these products must also be pure at the end. We achieve this with our ultrapure water washing machine, which connects the producing dirty area with the clean room via a sluice. In addition to our ultrapure water washing machine, we also have a water treatment plant with which we can treat HPW water (Highly Purified Water) according to Pharm. Eur. We need this water to feed our washing machine. This process is, of course, also optimised and certified.





## Clean room – competence at its finest

Working in a clean room is essential at SAMAPLAST AG.  
This is why we have built up know-how over decades that  
is always up to date. Our customers trust in it.

