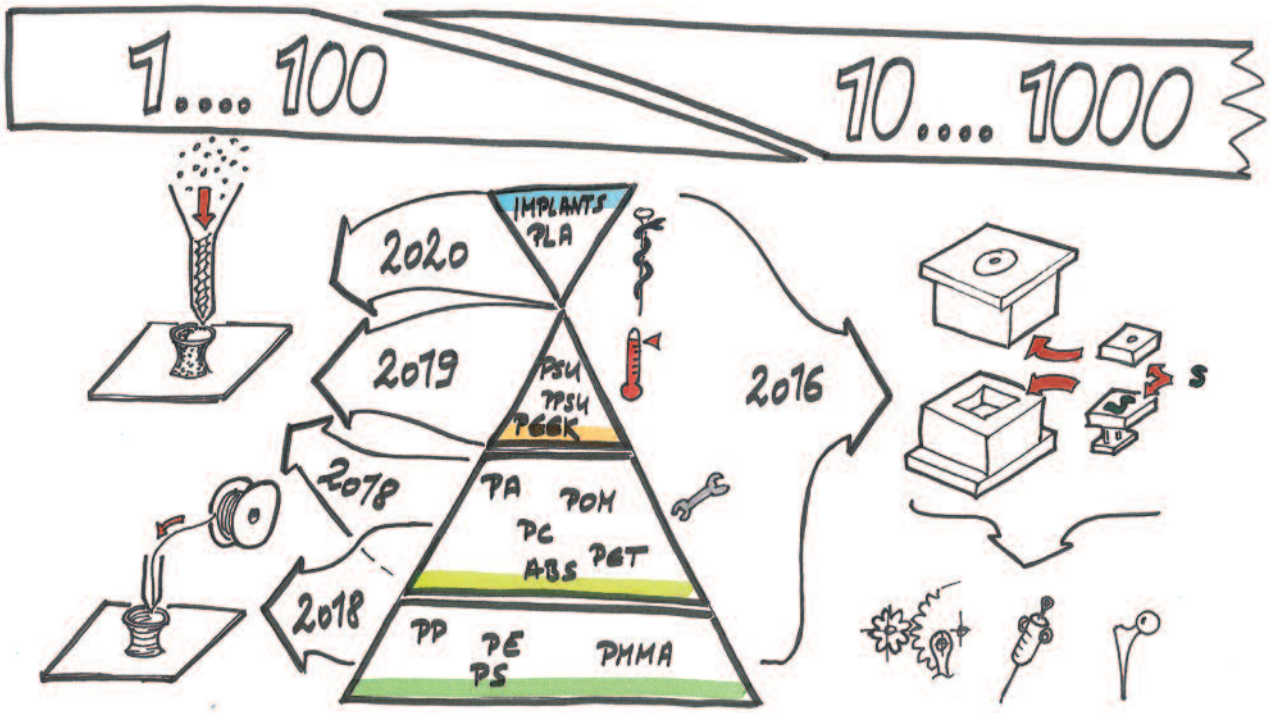
Plastic is the future
... is flexible

SAMAPLAST AG
PLASTICS TECHNOLOGY

PROTOTYPING:
Risk minimisation and manufacturing processes



SAMAPLAST AG –
Production from a batch size of 1

ISO 9001/13485 FDA reg. ANVISA JPAL-OML DIN SPEC 17071

SWISS MADE BY SAMAPLAST AG

www.samaplast.ch

Initial situation

The use of prototypes - a trend that SAMAPLAST AG recognised early on. Their fields of application? Especially in the production of high-precision plastic injection moulded parts for technical products, medical devices and implants.

In 2016 the foundation was laid with the concept "prototypes in 10 days from hardened steel tools". Additive Manufacturing (AM) as a "new" technology was implemented in 2018.

The goal of Additive Manufacturing: the production of products for small series up to batch size 1, and if possible, also for medical devices and implants.

Additive Manufacturing in clean room (ISO 8) in a qualified environment

Today it is impossible to imagine life without this technology, because we use it to implement solutions that would not be possible with the classic injection moulding process.

A central advantage of the prototype process is the reduction of the risk of project failure. Why? Because this method greatly reduces the project lead time and thus also the costs. Therefore, critical function, handling and bio-compatibility tests, e.g. on cytotoxicity, can be carried out on near-production parts as early as the project phase.

Meaningful use of the AM method

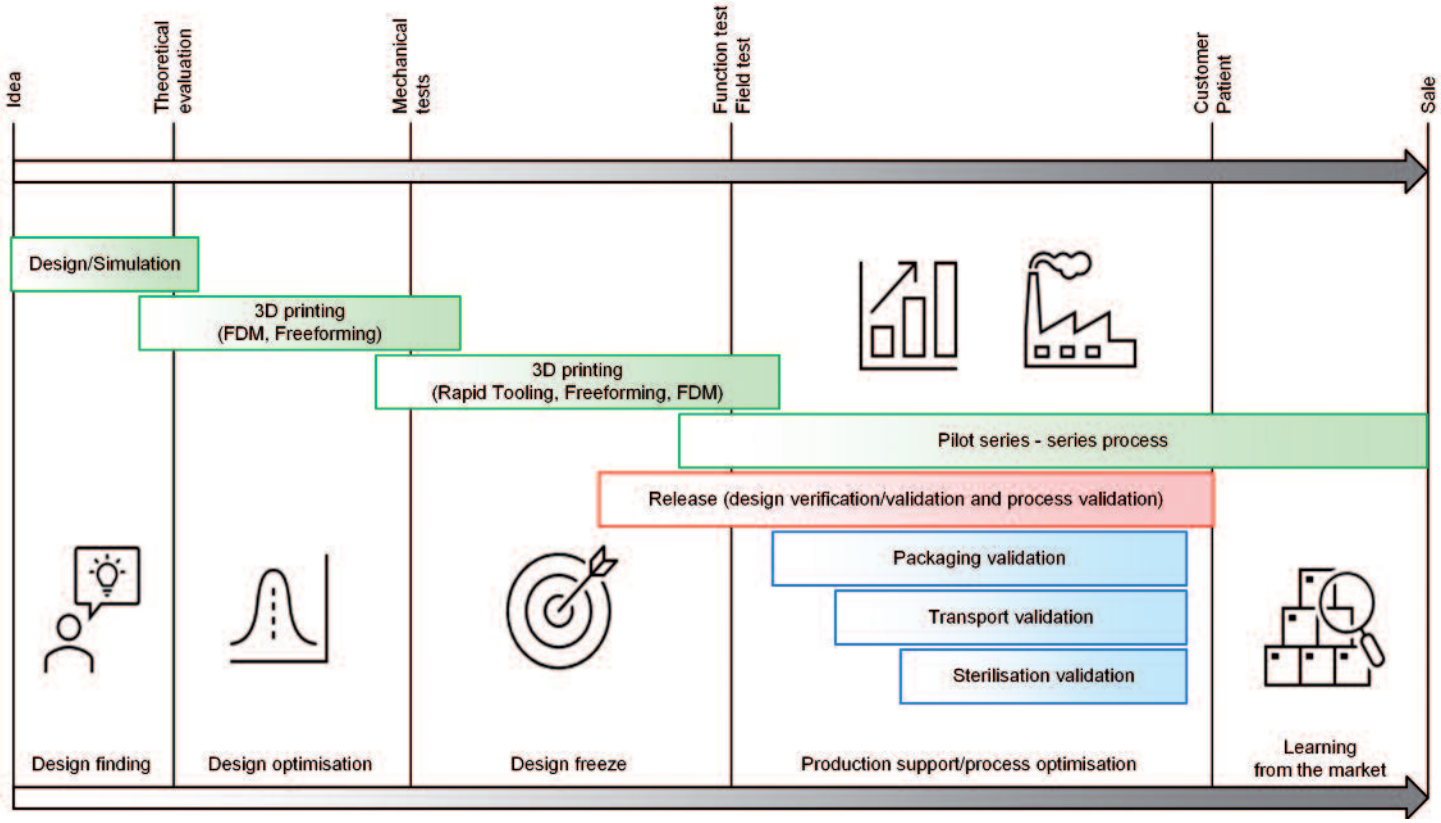
However, 3D printing is not always able to deliver the solution or the success of a project/product idea right away. As with other technologies, those responsibles must first ask themselves the question of feasibility and meaningfulness.

SAMAPLAST AG currently uses 3D printing for the following tasks:

- Design finding ➞ development of product ideas
- Design optimisation ➞ minimisation of the risk
- Material specification/testing ➞ quality
- Production support ➞ biocompatible handling systems and devices in lightweight construction
- Production of tools ➞ printed tool inserts for injection moulds
- Process optimisation ➞ DoE as a basis for process validation and the process freeze
- Series production ➞ GMP-compliant production of medical devices

Your way to the customer/patient

Today, the path from the first design idea to the consumer/patient practically always leads via prototype production:



Project management - the way to the customer/market

How do established manufacturers get ideas or optimisation proposals for new or existing technical applications, medical devices or implants directly from the market? This mainly takes place in the form of market observations or customer evaluations. If a new product idea develops from this, it is simulated in a first step in the theoretical evaluation and discussed in advance with experts.

Fast design freeze with 3D printing

What opportunities does SAMAPLAST AG have?

Using the FDM 3D printer "Stratasys F170", we are able to produce dimensionally stable components from 3D data with the highest possible precision and reproducibility from a wide range of the most common thermoplastics (PLA, ABS, ASA).

This enables our development/design team to support the customer at an early stage in the definition of the design. This reduces lead times and project costs and thus minimises the residual risk. The result? The confirmation of the design idea of the customer.

This enables us to implement our customers' ideas quickly, manufacture them just-in-time, test them on the same day and produce them ready for the market faster.

FDM 3D printer F170

Why not "test it right" from beginning on?

Once the "theoretical evaluation" has been completed, the market pushes for product samples that are tangible as quickly as possible. The best way to do this is to shape and type the final product to make the first functional tests.

Among other things, SAMAPLAST AG has successfully implemented the concept "prototypes in 10 days from hardened steel tools".

This solution closes the gap between generatively or conventionally produced prototypes and parts from injection-moulded series tools.

Testing on the "serial part" is now possible without high costs and long delivery times.

This opens up new possibilities, because the necessary evidence and tests can be started at an early stage.

The "time to market" is thus significantly reduced.

Rapid Tooling concept

SAMAPLAST AG
PLASTICS TECHNOLOGY

Rapid Tooling - saves time and costs

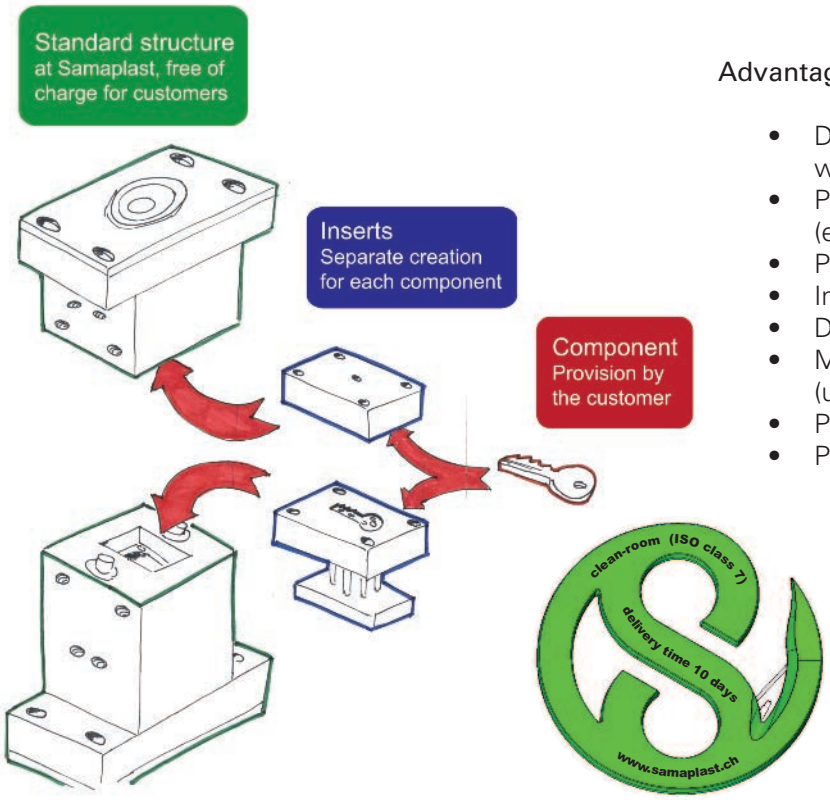
In Rapid Tooling, bearing, prefabricated and hardened inserts made of approved materials are used and, after production of the tool inserts, samples are taken in suitable master moulds. Clamping devices and tools are standardised.

All production processes are optimised. Want some examples

- Quotation preparation within one working day
- Data preparation in 3D-CAD with CAM connection
- Milling of the mould sections overnight
- Injection moulding process on series machines in the chosen environment

Risk minimisation through injection moulded prototypes

- Use of the injection moulding material without limitation
- Sampling of different materials
- Exact reproduction of the manufacturing process for the series
- Freely selectable ambient conditions (e.g. clean room production)
- Production of larger quantities in constant quality (pilot series, field test...)
- No surprises with industrialisation
- Early testing and optimisation of the serial process
- Production on existing injection moulding machines
- In-house expertise
- Reliable results during the function test
- Assessment of handling and appearance
- Biocompatibility tests (e.g. cytotoxicity, sensitisation, irritation) are possible



Concept "prototypes in 10 days from hardened steel tools"

Advantages of Rapid Tooling

- Delivery time for first samples from 10 working days
- Practically all plastics can be processed (e.g: PEEK, PCU and resorbable plastics)
- Part size: up to 70x70x30mm
- Inserts
- Detailed production
- Minimum corner radii of 0,15mm (up to 0.05mm)
- Process control as in series production
- Production in clean room

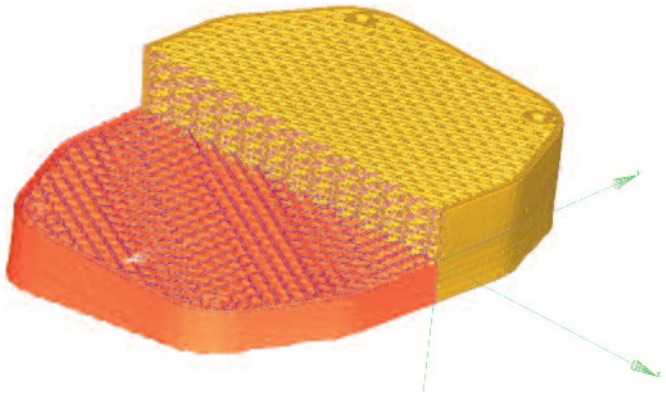
From design optimisation to pilot series

Another exciting approach to finding an optimal design for the "intended use" of a medical device is the use of tools like DoE (Design of Verwendung von Tools wie DoE (Design of Experiment) or CT (computed tomography).

After the design freeze, prototypes with various filling structures are produced with the 3D printer based on the DoE process and then counter-checked with CT analyses for manufacturing precision.

Want some examples?
Cage made of resorbable material, SEBS pads with filling structures for dentures, Y-plates made of PEEK.

With this procedure it is possible to fix the design and provide proof of design verification for a part manufactured in the AM process, which is required by the FDA's "Waterfall Design Process".



CT image cage made of resorb material

Requirements for AM production - DIN SPEC 17071

The first step is the procurement and qualification of equipment, the necessary process know-how and efficient project planning. Subsequently, a risk analysis is carried out throughout the entire manufacturing process, the critical influencing variables and their effects are determined and processed step by step.
A central aspect is AM production within the defined framework of a management system that guarantees certification according to DIN SPEC 17071. The interfaces to EN ISO 9001/13485 must be observed and transferred into a holistically functioning system.
At SAMAPLAST AG, certification according to DIN SPEC 17071 will be completed by the end of 2020.

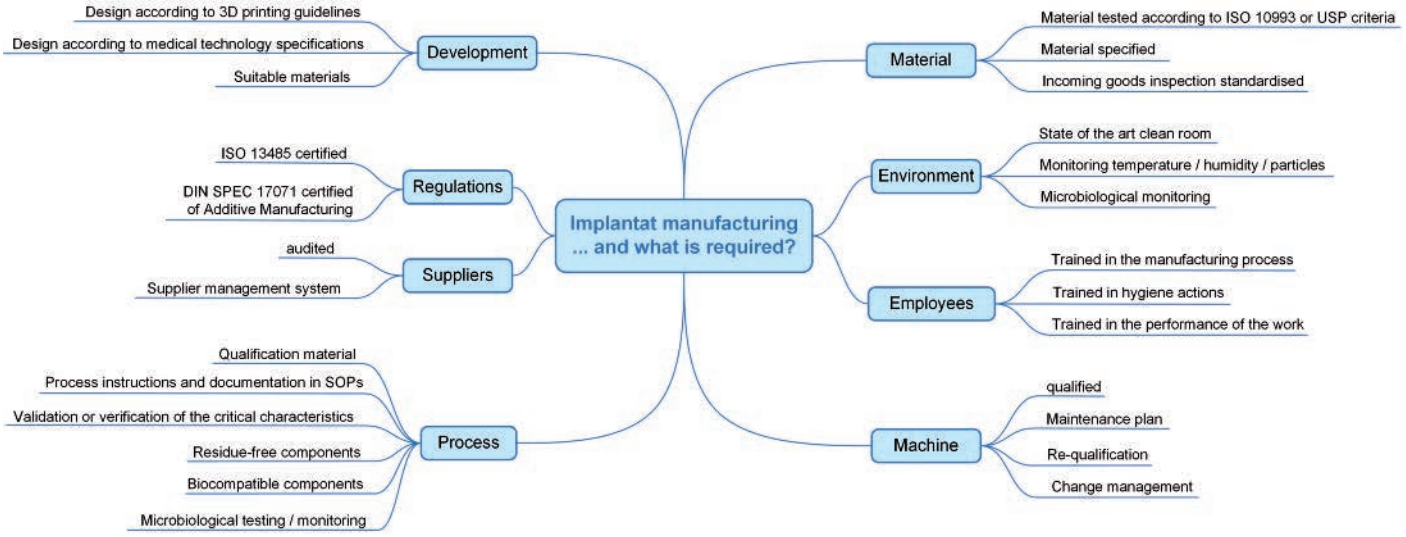
Another important aspect is the absence of residues and bio-compatibility of the components. The possible risk of error due to the necessary carrier plates and materials is carefully checked and eliminated. The basic requirements for this are qualified machines and controlled environmental conditions such as a clean room.
In addition, close cooperation with material suppliers is an advantage. The best results with carrier plates? These are assured with the basic material glass with specific pretreatment.

Glass plate as carrier material for Freeforming of resorbable C and Y plates

The art of the Additive Manufacturing process

The AM process is based on 3 pillars: the 3D data, the 3D printer and the material. It appears simple, but requires high precision. In injection moulding, function and precision are controlled by the injection mould. With 3D printing, this is done exclusively through the component design, the strategy of the component construction and the fine tuning of the parameters. And it is precisely this fine tuning that determines success or failure.

Only precise knowledge of the process and raw material guarantees printed components with the required reproducible quality over a long period of time and over several productions. This procedure is comparable with a process validation in the classical sense.



Critical influencing variables and measures for AM production

Production support/process optimisation with AM

Another exciting approach that is pursued with the AM process is the production support or process optimisation of manufacturing processes. This concerns injection moulding, but also subsequent processes, e.g. component assembly or the fulfilment of bio-compatibility for medical products.

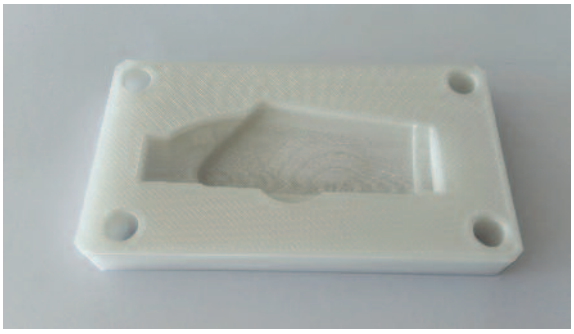
For example, the AM process can be used to produce printed tool inserts for injection moulding. These can be used in the design or pilot series phase.

However, they are also suitable for very small series, for which a wide range of shapes and sizes are required and for which the AM process is not economical.

Thanks to AM, complex moulds according to POKA YOKE can be produced individually and cost-effectively - also in lightweight construction. A plastic fixture also reduces the risk of damage to the part.

In both applications, the risk of cross-contamination from the use of the same or similar medical materials is eliminated and also promotes bio-compatibility.

PEEK mould insert for an injection mould



Bio-compatible POKA YOKE device in lightweight construction

SAMAPLAST AG
PLASTICS TECHNOLOGY

Freeforming - components made of original plastic additive

The Arburg Freeformer is used to produce prototypes and small series from original material quickly and at low cost without an injection mould.

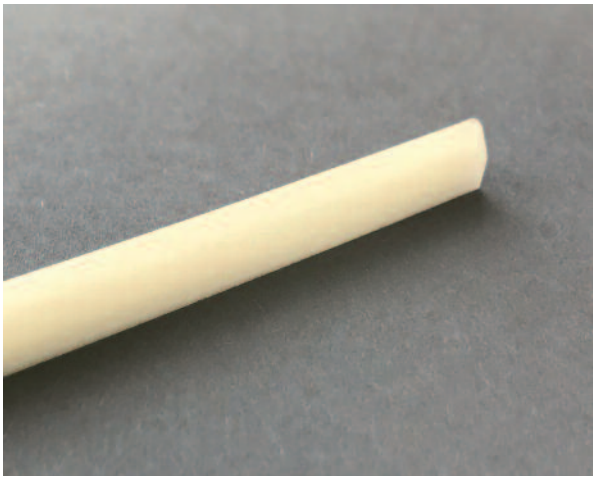
The parts produced with the Freeformer can be used for various purposes:

- Design optimisation
- Verification before the final design and process freeze for strength test (tensile, pressure or torsional strength)
- Handling or assembly tests
- Functional tests
- Biocomp. tests
- Clinical trials

The basis for this is a qualification or validation of the materials used. This requires appropriate know-how in the determination of process parameters and the processing of a wide variety of materials.

SAMAPLAST AG has developed this know-how through intensive cooperation with the machine manufacturer Arburg and material suppliers. But also the large number of tests on existing products and new projects with different materials (PCU, MBS, SBS, Resomer) have contributed to this knowledge advantage.

2K-PCU spiral



PCU bar

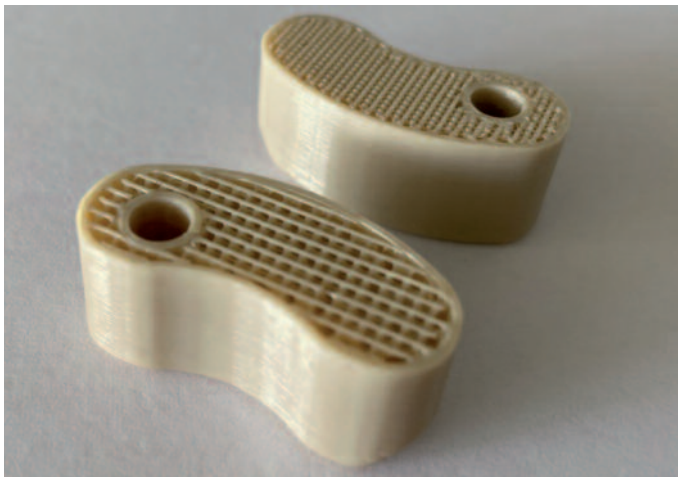
3D printing with implementable PEEK

What cannot be produced with the Freeformer today - the processing of PEEK - is implemented at SAMAPLAST AG with the Kumovis 3D PEEK printer.

This was purchased in 2019, qualified in accordance with experience, defined processes and SOPs and made fit for medical production.

Up to now, a wide variety of product ideas have been produced to customer specifications, but also existing products have been constructively optimised, printed and compared with commercially produced parts.

The results are also promising here.



Printed PEEK cages