



# Ready for the Medical Future

**S**AMAPLAST conducted complementary experiments with resorbable materials such as resomer L210S, LR 704, LR 706 S, LG 855 S, C209 and X206S. It has been shown that the process also has only minor IV reductions compared to traditional injection moulding.



PCU test part made of various shore hardnesses

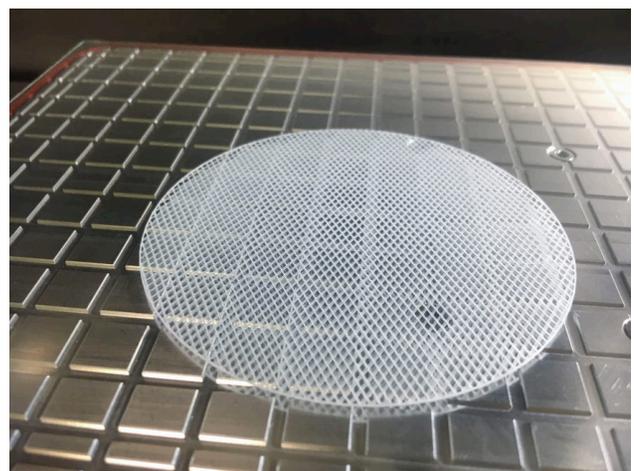
With regard to the material PCU, various materials such as Bionate 80A, 75D, 65D, but also Corbthane 75D and Chronoflex 75D were qualified on the basis of the machine qualification (DQ, FAT, IQ, OQ) of Arburg Freeformer.

Since the end of 2018, after the first tests on an existing PCU spine permanent implant with long-term strength tests and resorbable materials to reach with additive manufacturing the same quality as with injection moulding regarding inherent viscosity (IV), SAMAPLAST worked intensively on making AM fit for the medical future.

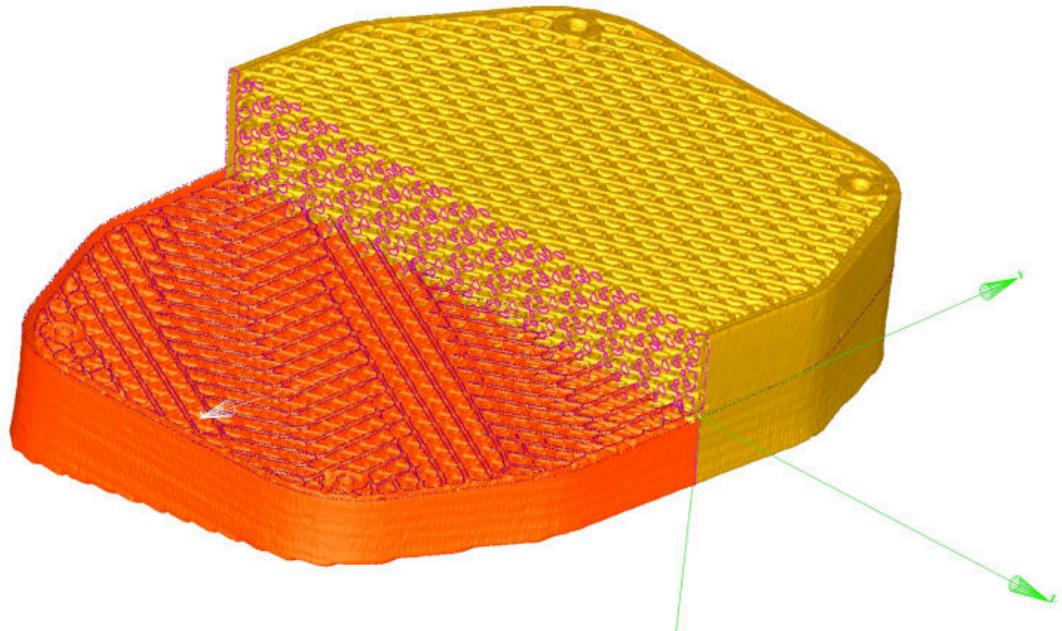
## Risk-based approach as the key to success

Based on a risk analysis and discussions with machine manufacturers, raw material suppliers and customers, SAMAPLAST AG determined the critical input parameters (key points) for the additive production of medical products at the beginning of 2019 and initiated and implemented the following measures:

- + Material validation of various raw materials based on a DoE process (Design of Experiment) = expansion of process know-how
- + Optimisation of up- and downstream processes (incoming goods inspections, maintenance, controlled conditions, carrier materials ...)
- + Tests to remove the carrier material without leaving any residue
- + Rethinking process in the constructive design of the components, based on numerous geometry tests in combination with various materials
- + Additive manufacturing as a cost-effective decision-making process with regard to material selection for the injection moulding process
- + 2K components can easily be manufactured at low cost
- + Devices (e.g. assembly or testing devices) or instruments can be manufactured quickly and cost-effectively from bio-compatible material
- + Optimisation of the adhesion of the material to the construction panel versus residue-free detachment of the material from the construction panel



Net construction made of resomer X206S




CT image cage made of resorbable material

### Project progress at SAMAPLAST AG

SAMAPLAST AG continued to work on the projects launched in 2018 in parallel with the processing of measures from the risk analysis. For example, 2k tests with PCU implants based on the excellent strength values from long-term studies have been implemented with blunt, 45°, shanked and sheathed connection variants. The long-term strength tests are in implementation.

At the same time, a large number of further tests and material validations were carried out and tested. The results are promising.

- + Basic experiments with MBS and SEBS to determine and test the influence of the connection and processing
- + Meshes of resorbable materials to explore new construction possibilities
- + Alternative support materials (e.g. Mowiflex) have been tested
- + Material qualification of SEBS Mediprene Shore 35 has been completed

An exciting approach is also the use of various tools to determine and confirm the correct and optimal design with regard to the intended use of a medicinal product. SAMAPLAST AG



Cage made of resorbable material

created various prototypes with Arburg Freeformer with various filling structures (e.g. cage made of absorbable material, SEBS pads with filling structures for prostheses) after the first design draft.

The prototype was then checked and also confirmed for manufacturing precision using CT analyses. With this procedure it would be possible to provide proof of design verification for a part manufactured using the additive process, which is a requirement in the design phase of the FDA's Waterfall Design Process.

### The future remains exciting

SAMAPLAST AG continues to work on expanding the existing additive process into a validated prototyping process and as a future manufacturing process for medicinal products, on exploiting new geometric possibilities for small series up to batch sizes of 1 piece and on offering combinations from prototype projects to OEM projects for customers.

In addition, a PEEK printer was purchased and qualified for this purpose. Also, a new clean room (ISO 8 in operation according to ISO 14644) was built and qualified for additive manufacturing, in which medicinal products and devices, but also assemblies combined from purchased parts, injection moulded parts and AM products can be manufactured with low microbiological contamination and according to the normative specifications. ■



SAMAPLAST AG  
Neugrütstr. 3  
CH-9430 St. Margrethen

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