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AIMPLAS www.aimplas.es

AZM www.azm.nl

BEGO www.bego.com

Degradable Solutions www.degradable.ch

ENTE www.ente.com.pl

EOS www.eos.info

Fraunhofer ILT www.ilt.fraunhofer.de

Fundación INASMET www.inasmet.com

IBV www.ibv.org

Icotec www.icotec.ch

Innalox www.innalox.com

Laser Med <http://mitr.p.lodz.pl/biomat/overview.html>

Materialise www.materialise.com

Neos www.neosurgery.com

PlastiaSite www.plastia.com

Sant Pau www.santpau.es

Smithers Rapra www.rapra.net

SPMC www.spmcgroup.com

Suprapolix www.suprapolix.com

TNO www.tno.nl

UDIAT www.tauli.cat

Xpand www.progentix.com

For further information on Custom IMD, please visit the project website:

www.customimd.eu



CUSTOM IMD - BEST PRACTICE GUIDE:

USING FUSED DEPOSITION MODELLING FOR RAPID PROTOTYPING MODELS IN MEDICAL APPLICATIONS

INTRODUCTION

In order to give adequate support to organisations who plan to (or already do) use FDM Rapid Manufacturing models for making medical implantable parts, it was decided to provide a document which can be used as a *best practice guide*. The objective of this document is to give an overview, written by experts in the field, to give their opinion and appreciation of developments from a user point of view.

Since there are various documents available on the Custom IMD Extended Services website - <http://www.customimd.eu/CustomIMDES/> which extensively describe relevant technical details (e.g. manufacture, material and part handling, sterilisation procedures), this report will give a complementary overview of elements and issues that are not mentioned elsewhere.

The report starts with a technical overview of the experimental manufacturing method of FDM employed by Custom IMD partners as a basis. In addition to this, the report also describes some case studies from FDM medical parts. By doing so, one can learn and be inspired to follow a suggested route for manufacturing a particular part which resembles your own part the most.

STATE OF THE ART

Rapid Manufacturing Technologies have been around for approximately 20 years and have been used in a wide range of applications. Over the last 10 years the use of Rapid Manufacturing Technologies in the medical industry has played an important role in the development of new materials and new systems that are specifically aimed at medical implants.

The drive for this development is obvious in that functional medical parts have always been required in the production of prototypes at a very early stage of the design process. Traditionally, the medical components were CNC machined if only one was required (e.g. PMMA), however this is not beneficial for larger batches. This could be a costly process bearing in mind the size of the metal billet that was required and the machine programming and machine time involved.

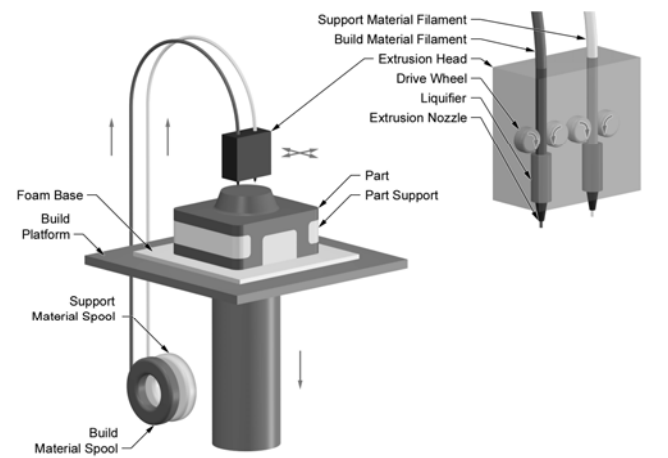
Other materials such as those developed in Custom IMD are more elastomeric and require other technologies for processing. One very suitable technology is FDM or micro extrusion, where by direct deposition of medical material, a fully functional (i.e. implantable) part is made. The following chapter highlights FDM technology with the focus on medical materials. Please note that although FDM is very versatile, it does not claim to be the optimal answer to all medical parts manufacturing.

MEDICAL FDM

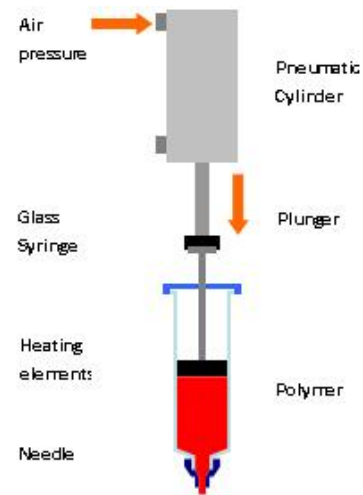
Commercial parts created by Fused Deposition Modelling, a process developed and manufactured by Stratasys Inc, can also be used in the production of medical implants. For this, a medical-grade ABS material can be used, however for limited time of use in the body only. More details can be found at the Stratasys website - www.stratasys.com.

Other medical materials used in Custom IMD are more elastomeric and cannot be processed with a conventional FDM system.

The Micro Extrusion Depositing technique developed for the Custom IMD project is derived from this process, a schematic of the process is given in the figures below.



Fused Deposition Modeling Process from Stratasys inc, copyright © 2008.
Image courtesy of www.CustomPartNet.com



Micro Extrusion Depositing Process developed for Custom IMD

Two Micro Extrusion depositing units are mounted onto an XYZ manipulator. The extrusion force needed to process the heated material is generated by a pneumatic cylinder. By using disposable syringes and needles, it is possible to work in a clean environment and to process small amounts of polymers.

The material can be fed into the system as a granule or pellet shape. The temperature of the material is controlled by a digital temperature controller. Different temperatures are measured and can be set for the material stock and the nozzle tip.

TEST PROCEDURE/PROCESS PARAMETERS – MICROEXTRUSION

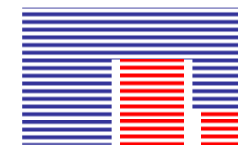
The first step in the experimental test is to get an indication of the melting point of the materials to be processed. These will be used as initial temperature settings of the system. When this is set, the system is run to produce a solid molten wire, which should be of constant quality. As a medium for the building platform, mostly a glass plate is used. Once the ability of extrusion of the material has been demonstrated, and the target temperature has been set, several process parameters are set. One important parameter is the setting of the trackwidth by varying the flow/cruising speed ratio by means of a test geometry. Also variation is possible in layer thickness and ambient temperature.

Experiments show that uncontrolled flow of the material can occur, due to humidity of the material (in case of hygroscopic material). Conditioning of the material always needs to be considered, as well as differences in batches.

The flow characteristics of the material to be processed are determined at several processing temperatures in combination with different extrusion nozzle diameters.

SUPPORT MATERIAL

Due to the layered manufacturing, a structure is needed to support overhanging features. This support structure can be achieved by using the building material itself or with an additional support material.



Support Structure under overhanging structures.



Angle when support is needed is approximately 45°.



No support needed.

The support structure must be easily removed afterwards. This can be done by breaking or dissolving the material. Therefore, the material must be brittle or soluble. Another issue is the adhesion between the building material and the support material. This must be strong enough to hold the part in place during the manufacturing process, but not too strong to prevent removal of the support. Several biocompatible materials are investigated that might be suitable as support.

EXPERIMENTAL RESULTS

At an early stage a partial section of a skull implant has been printed with a demonstrator medical material. In this case no support structure was needed due to the vertical build.



Printing Skull Implant.



Clear view of extrusion nozzle.



Detailed view of implant.

In case a support structure is needed, which is dependent on the part geometry, the use of both nozzles is required. Some typical parts are given below as an example of how the structure comes from the FDM machine.



SP60 Scaffold printed onto a PEG support layer.



ABS scaffold with support structure.



Partial printed 3D Cranial Implant.

CONCLUSIONS

Several 3D scaffold structures have been built by the Micro Extrusion process. Besides process development of the micro extruders, research has been conducted to determine the processing characteristics of different models and support materials. The manufactured objects show that porous structures from bioresorbable polymer can be produced. These structures have sufficient strength to be suitable for a wide variety of medical implants. The technology can also be used to process other elastomeric materials into free-form shapes, which makes it a very versatile technology.

Traditional medical device manufacturing techniques can also benefit from the use of Rapid Manufacturing Technologies. The addition of complicated geometrical sections of medical devices that have been manufactured on any one of the Rapid Manufacturing systems can very quickly speed up lead-times. Entire medical devices can also be built on the systems prior to being traditionally finished.