



biomedical
engineering



Additive manufacturing (AM) in medicine

Speaker: **Radovan Hudak**

Authors: **Radovan Hudak, Jozef Zivcak, Bruno Goban**

Co-operating surgeons: **Andrej Jenca, Branislav Kolarovszki, Dagmar Statelova, Bruno Rudinsky....**

Košice, Slovakia, 22.11.2016



R&D AND BUSINESS TEAM

Technical University of Kosice, Faculty of Mechanical Engineering
Department of Biomedical Engineering of Kosice

- 10 employees involved into the medical AM led by professor **Jozef Zivcak** (head of department of biomedical engineering and measurement and co-owner of CEIT Biomedical Engineering, s.r.o.)

CEIT Biomedical Engineering, s.r.o.

- 8 employees involved into the medical AM led by **Bruno Goban**

ADDITIVE MANUFACTURING OR 3D PRINTING?

Process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies. Synonyms are additive fabrication, additive processes, additive techniques, additive layer manufacturing, layer manufacturing, and freeform fabrication (ASTM F2792).

Those from the scientific and technical communities prefer to use *additive manufacturing* when referring to the group of processes that build parts layer upon layer. An important reason is that it is the official standard term according to the **ASTM F42 and ISO TC261 committees** (Wohlers Associates, 2016).

3D printing is, by far, most popular term. Google displays 20-30 times more references for 3D printing (or 3-D printing) compared to additive manufacturing. Today, many individuals and organizations use 3D printing and additive manufacturing interchangeably (Wohlers Associates, 2016).

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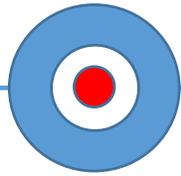
ADDITIVE MANUFACTURING IN MEDICINE



1971

Sir Godfrey Hounsfield

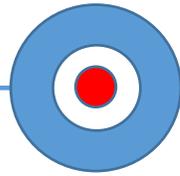
invents the **CT** scan
(Katie Weimer, MS, 2016)



1977

**Raymond Vahan
Damadian**

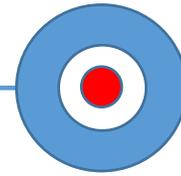
invents an apparatus and
method to use NMR safely
and accurately to scan the
human body (now known
as **MRI**)



1981

**Drs. Jeffrey Marsh &
Michael Vannier**

create 3D models from 2D,
milled slices
(Katie Weimer, MS, 2016)



1983

Chuck Hull

Invents 3D printing via
Stereolithography

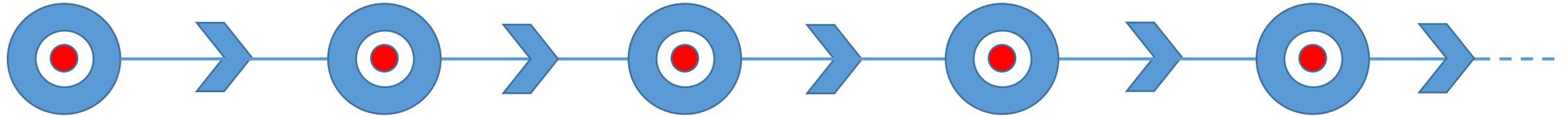


1988

Dr. Mankovich @ UCLA

The first model of anatomy
is produced using 3D
Printing
(Katie Weimer, MS, 2016)

ADDITIVE MANUFACTURING IN MEDICINE



1998

2000

2003

2007

2008

the first selectively colored SLA model in the US, produced in Colorado
(Katie Weimer, MS, 2016)

medical applications of 3D printing date back to the early 2000s, with the production of dental implants and prosthetics
(Gross , Bethany C. at all, 2014).

Dr. Kenneth Salyer
successfully separates conjoined Egyptian twins

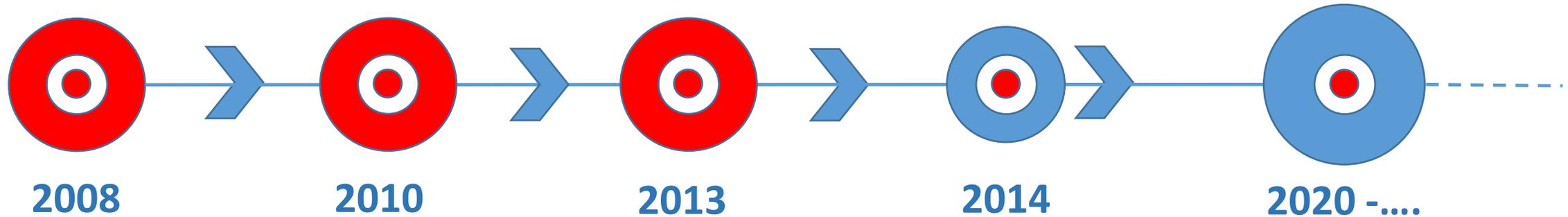
2003

3D Printing in titanium gets its start for implants
(Katie Weimer, MS, 2016)

Virtual Surgical Planning (VSP) gets it start and moves toward becoming the gold standard for surgical planning
(Katie Weimer, MS, 2016)

personalized surgical instruments for total knee surgery become commonplace
(Katie Weimer, MS, 2016)

ADDITIVE MANUFACTURING IN MEDICINE



Radovan Hudák
Jozef Živčák

idea to produce implants
by additive manufacturing
in Slovakia

FDA clears the first 3D
printed metallic implant

2010

The company **CEIT –KE**
was established, later

**CEIT Biomedical
Engineering s.r.o.**

first implant is implanted
designed and produced by

**CEIT Biomedical
Engineering**

Company

anatomical models for
surgical planning in hearts,
kidneys and other organs
becomes common

(Katie Weimer, MS, 2016)

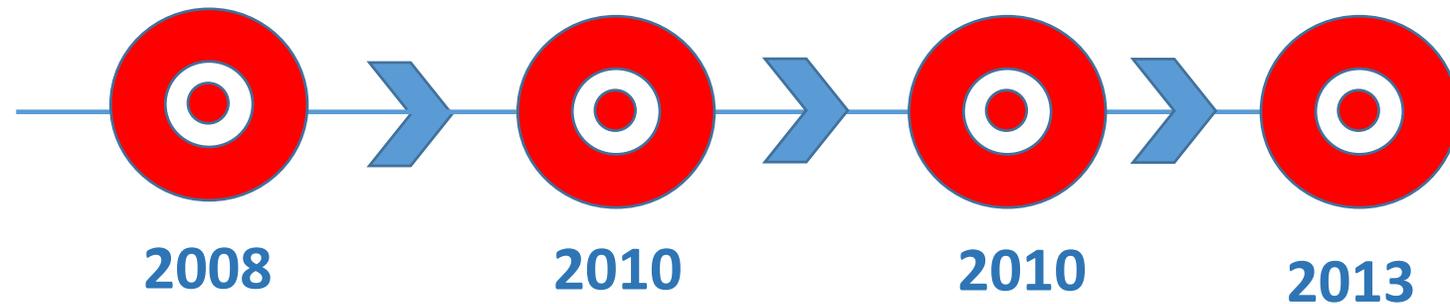
3D printing as a surgery
assist

the increased availability of
biocompatible materials

patent expiry and the
reduced cost of innovation

(Srinath, Aniruddha, June 2016)

IDEA TO REALIZATION



2008

Radovan Hudák
Jozef Živčák

idea to produce implants
by additive manufacturing
in Slovakia

Inspiration from Chicago
(stay in 2006) and
Slovenia (Maribor
University)

2010

CEIT a.s.
TUKE
Jozef Živčák
Radovan Hudák

The spinn-off company
CEIT –KE was established,
later

**CEIT Biomedical
Engineering s.r.o.**
without participation of
TUKE

2010

Preparation of the project
STIMULS FOR R&D
Budget: 2 mil. EUR

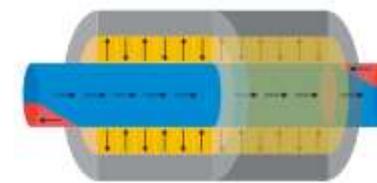
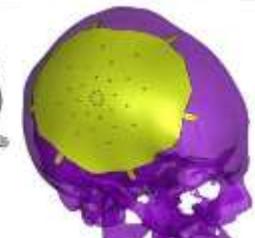
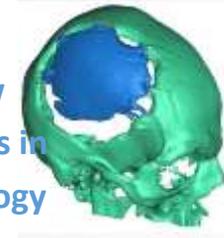
**Research of new
diagnostic methods in
invasive implantology**



2013

Project
**Research of new
diagnostic methods in
invasive implantology**

FINISHED



CEIT Biomedical Engineering

Company was established on 2010 as spin-off company of Technical University of Košice (TUKE) and CEIT a.s. holding (Central European Institute of Technology).

Company employes are mostly biomedical, material and quality engineers who were students of TUKE, Faculty of mechanical engineering, Department of biomedical engineering and measurement.

free form
modelling
& development
of prototypes

manufacturing
of certified
medical products,
custom-made
& in series

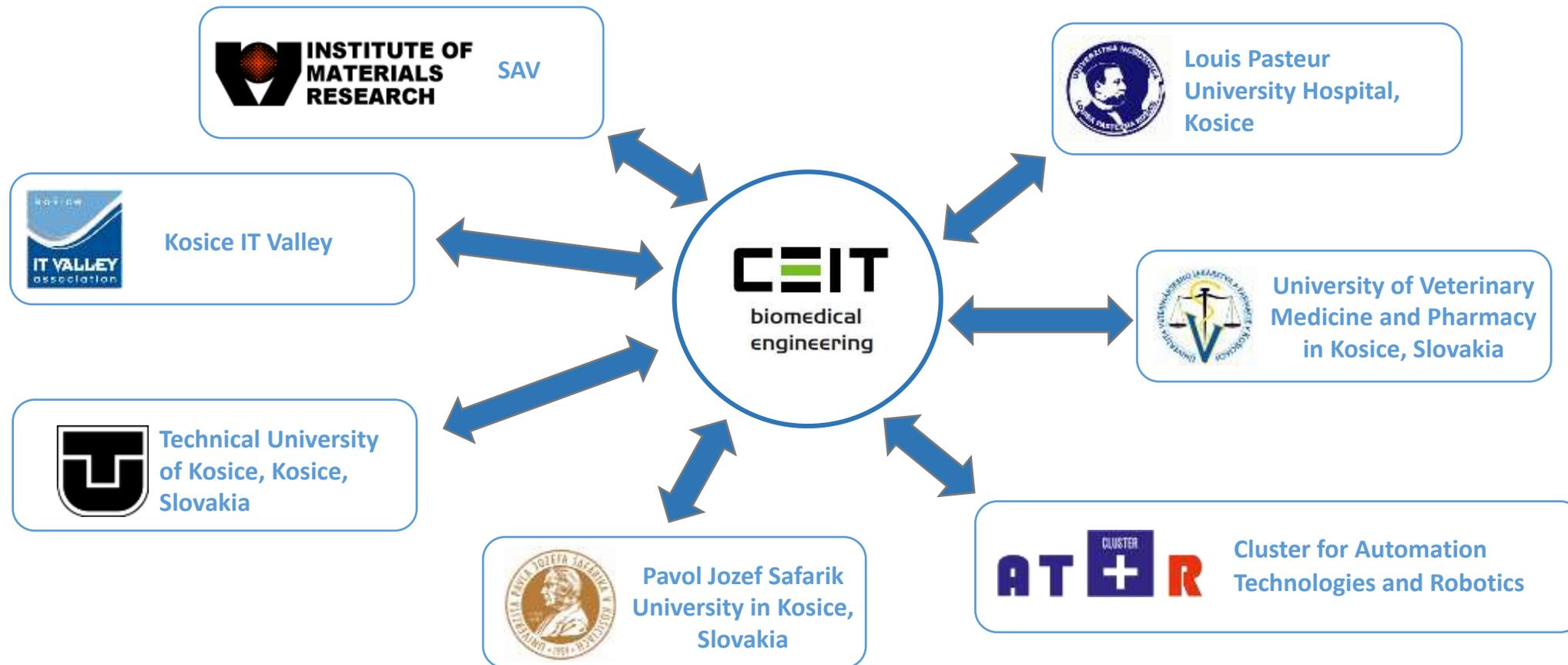
research
& development
of medical
products

CEIT Biomedical Engineering

custom implants made of titanium alloy (Ti-6Al-4V) (Grade 5)
manufactured by the 3D printing technology
plastic and metal prototypes manufactured by the 3D printing
technology, manufacture of anatomic models
3D scanning, digitalisation and modelling of medical products
medical data processing and adjustment
verification and validation of medical products medical metrology
and diagnostics
science and research in the field of implantology, implant
manufacturing and medical sensorics

- Company is accredited producer of CMF custom-made implants: SIDC code – SK-13-0224
- Approved medical devices:
 - Custom-made cranial implant P91710
 - Custom-made maxillo-facial implant P91709
 - Custom-made cranio-maxillo-facial implant P91708
 - Custom implant for chest surgery

CEIT Biomedical Engineering



MEDICAL AM WORKFLOW

An aerial photograph of a city at night, showing a grid of streets and illuminated buildings. A bright, glowing light source is positioned in the upper right quadrant, with numerous thin, radiating lines extending outwards, resembling a starburst or a signal. The overall color palette is dark blue and black, with the city lights providing a contrast.

*AM/ step by step

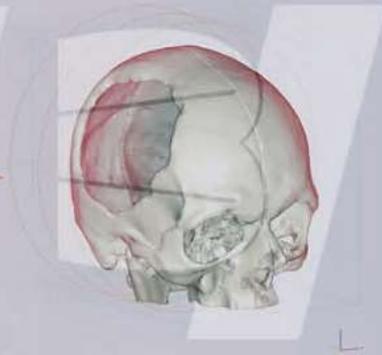
MEDICAL AM WORKFLOW



diagnostics



input data (CT, MRI)



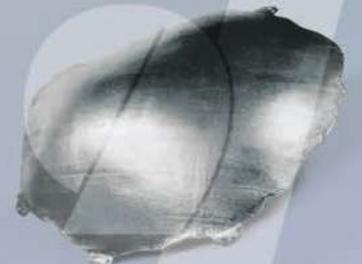
referential model



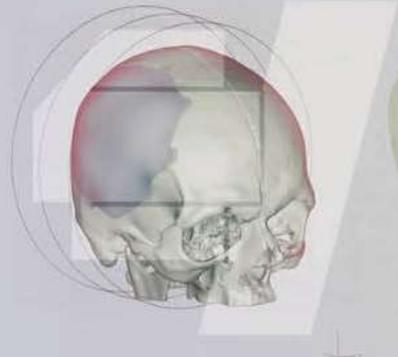
additive manufacture (AM)



postprocessing



implant Ti-Al6-V4 (Grade 5)



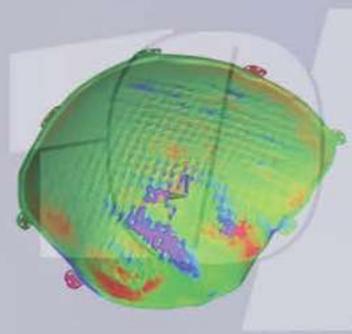
implant modelling



3D printing of prototypes



consulting



validation-metrotomography



surgery



after the reconstruction

MEDICAL AM WORKFLOW – INPUT DATA



Body surface:

Optical and laser scanning



Bones:

CT/MRI/
DICOM data



Inner organs:

CT/MRI/USG DICOM
data

MEDICAL AM WORKFLOW – PRODUCTION TECHNOLOGY



Building volume

(including building platform)
250 mm x 250 mm x 325 mm

Laser type

Yb-fibre laser, 200 W

Precision optics

F-theta-lens, high-speed scanner

Scan speed

up to 7.0 m/s (23 ft./sec)

Variable focus diameter

100 - 500 μm (0.004 - 0.02 in)

Material:

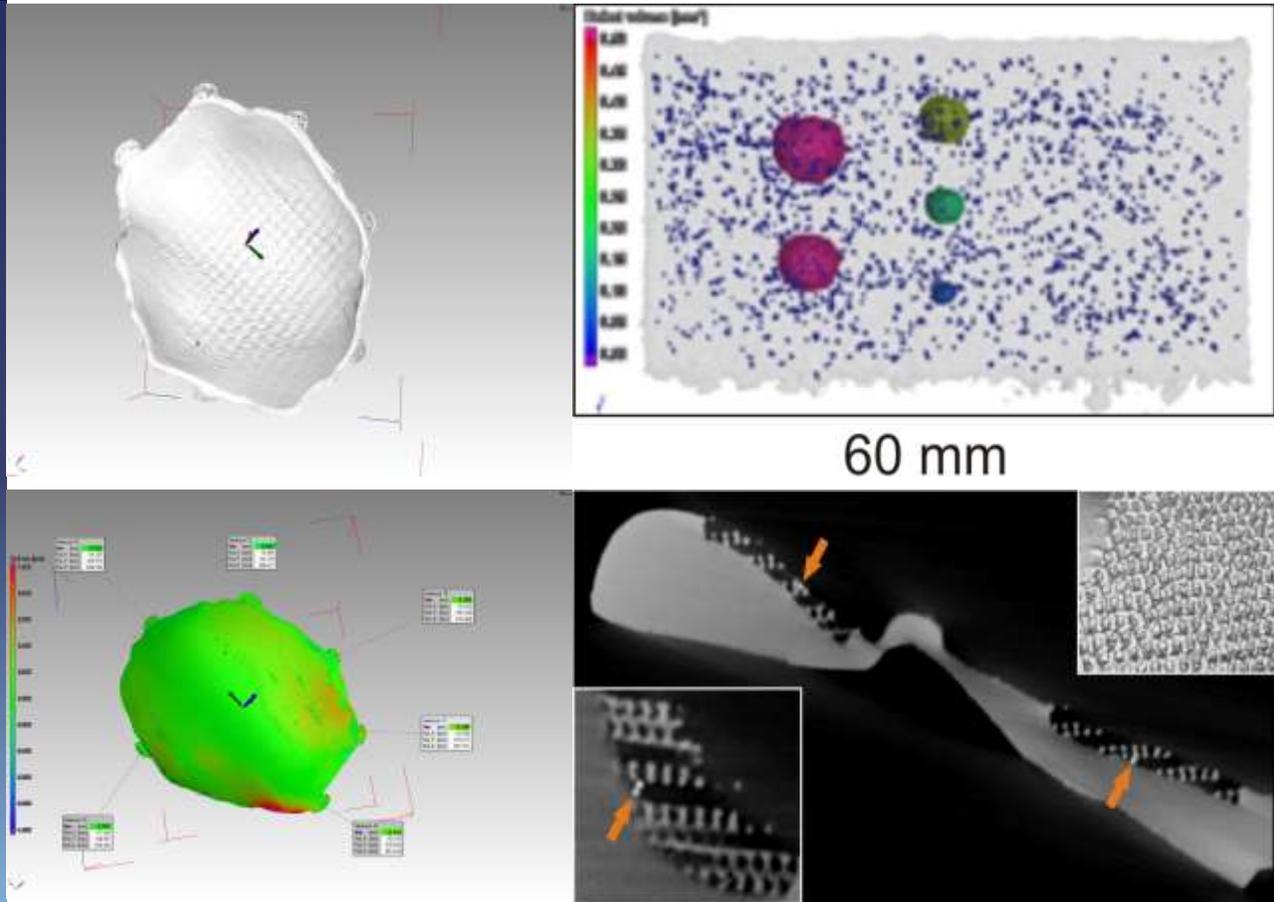
Ti-6Al-4V (Grade 5), Ti-6Al-4V ELI (Grade 23)

MEDICAL AM WORKFLOW – PRODUCTION TECHNOLOGY



MEDICAL AM WORKFLOW – QUALITY CONTROL

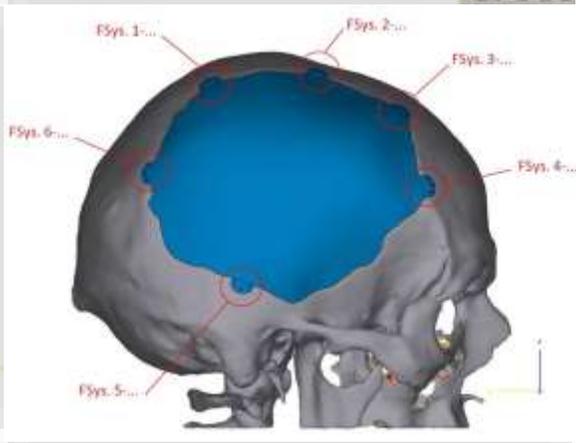
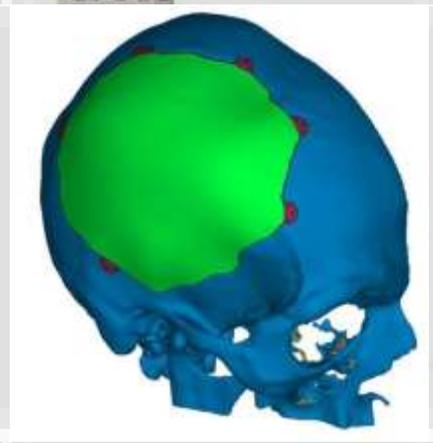
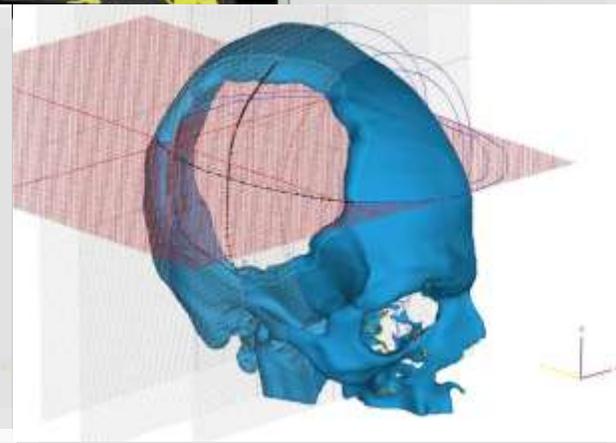
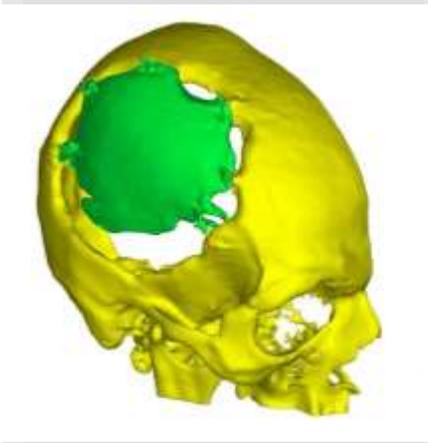
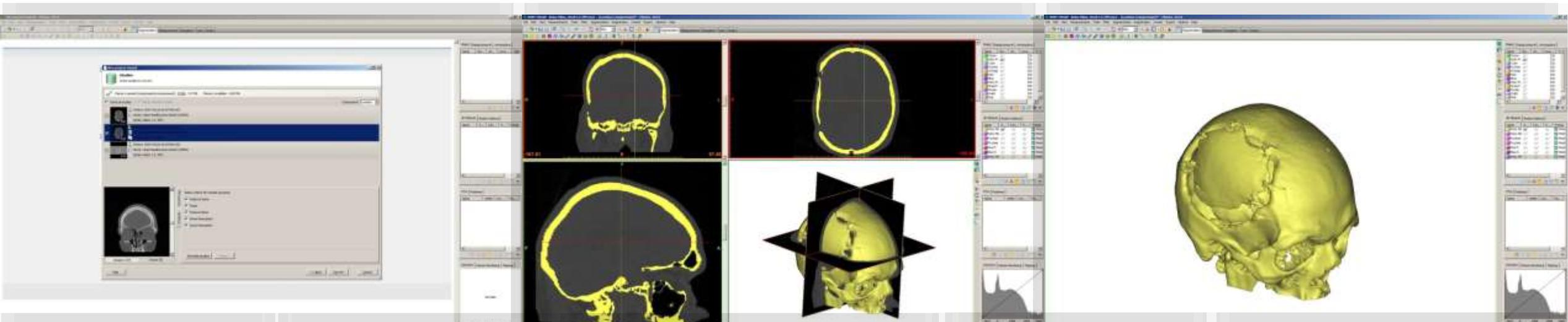
METROTOM 1500, Carl Zeiss, Germany



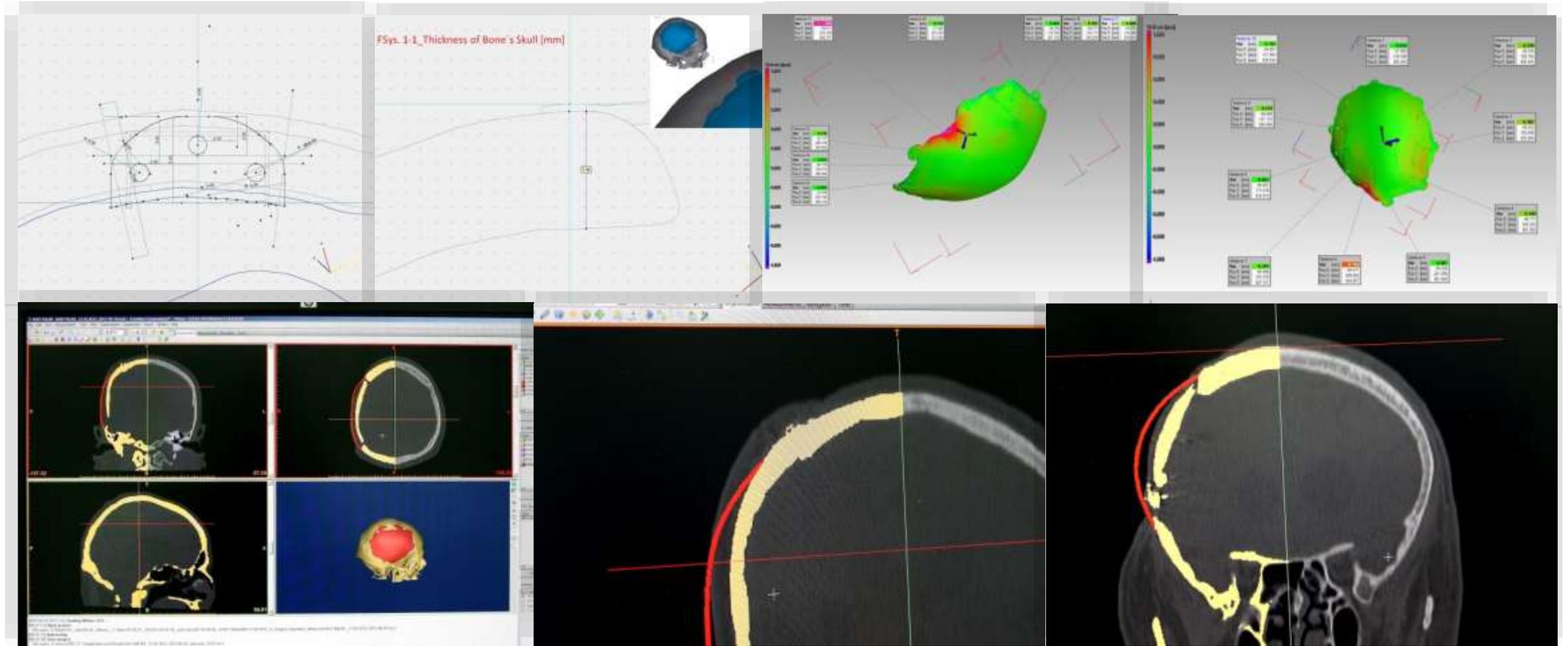
MEDICAL AM WORKFLOW – QUALITY CONTROL



MEDICAL AM – CASE STUDY 1



MEDICAL AM – CASE STUDY 1



MEDICAL AM – CASE STUDY 1



MEDICAL AM – CASE STUDY 1



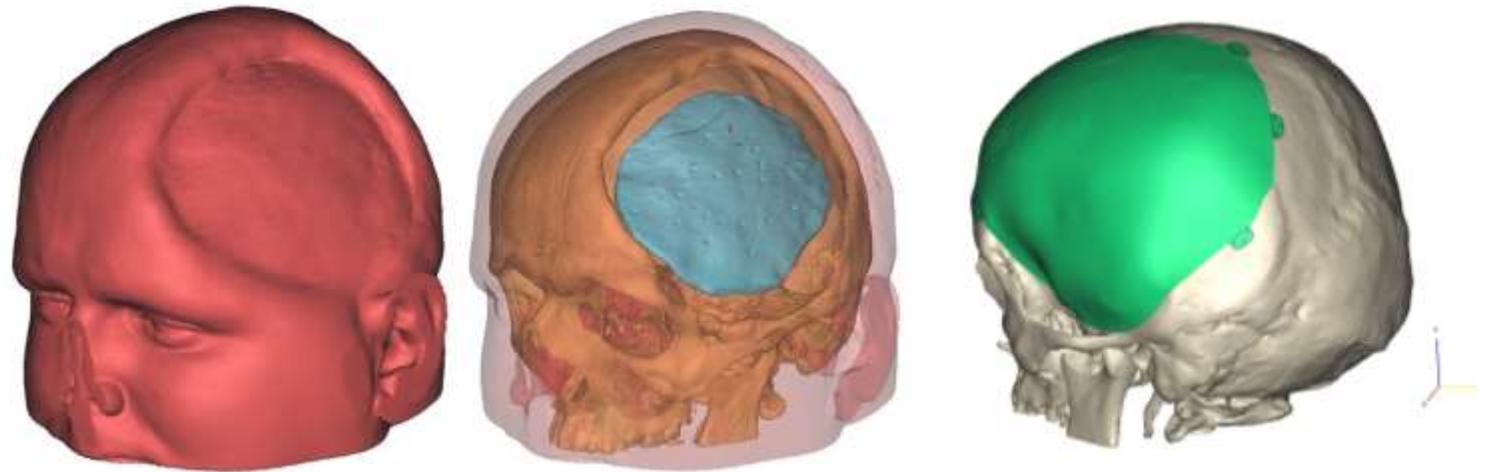
MEDICAL AM – CASE STUDY 2



Age: 30
Cause of the injury: fall from the building (9 year ago)
In coma after the accident
Difficulty to walk and speak
Large cranial defect: 33,8%



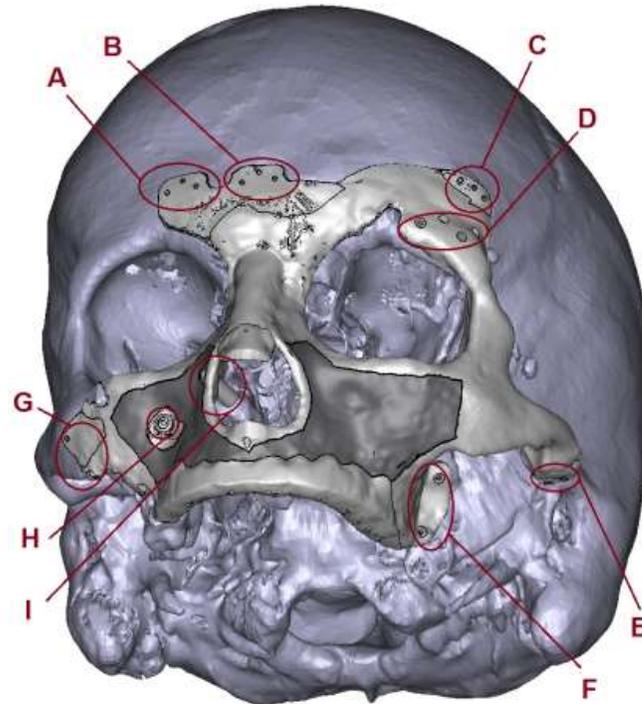
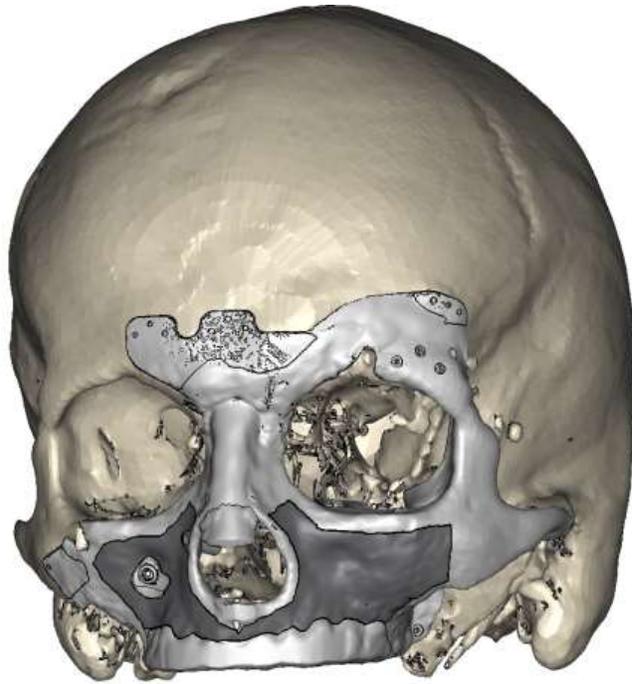
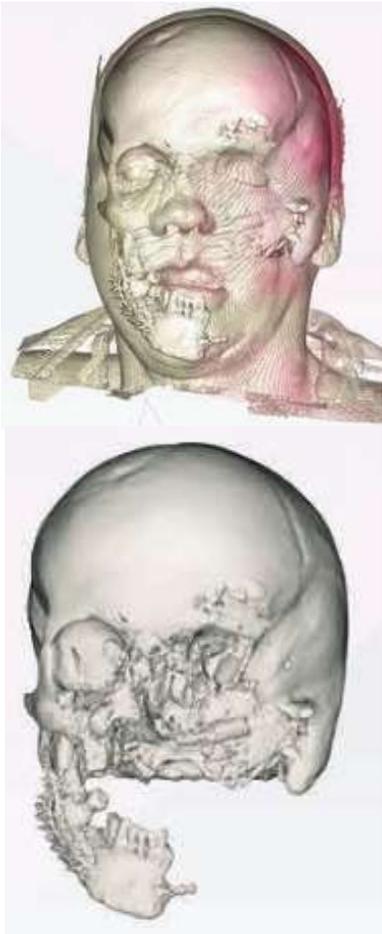
Material: Ti-6Al-4V (Grade 5) titanium alloy
Weight: 125 g
Size: 120 cm²
Technology: DMLS
Fixation: 21 screws, f 1,2 mm



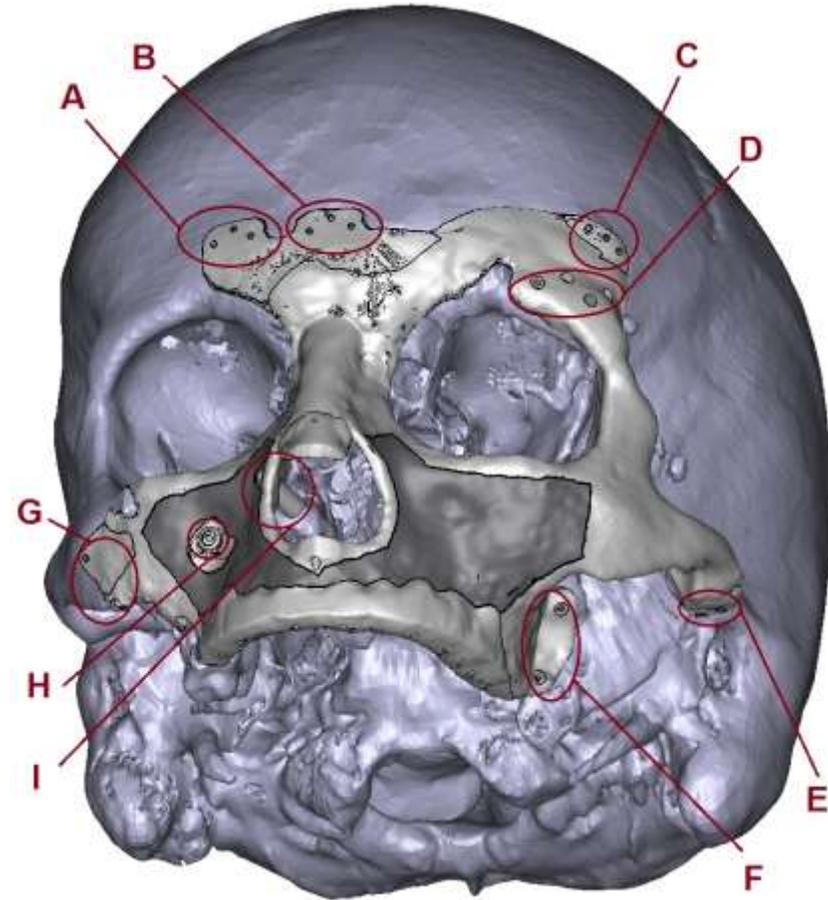
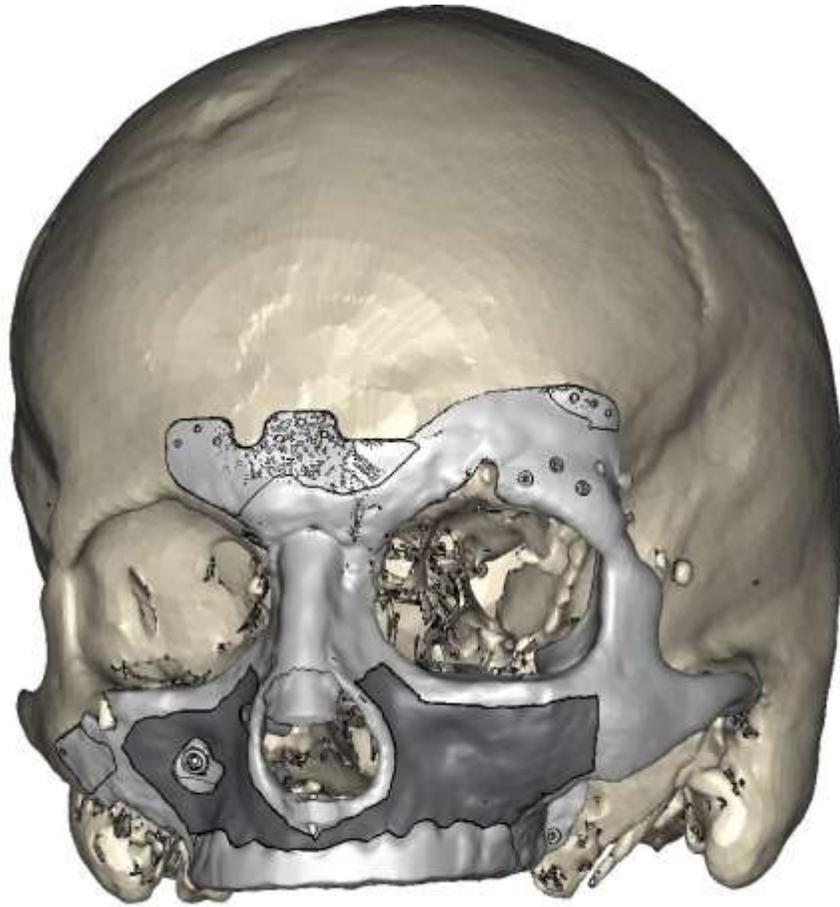
MEDICAL AM – CASE STUDY 2



MEDICAL AM – CASE STUDY 3



MEDICAL AM – CASE STUDY 3



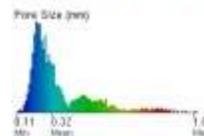
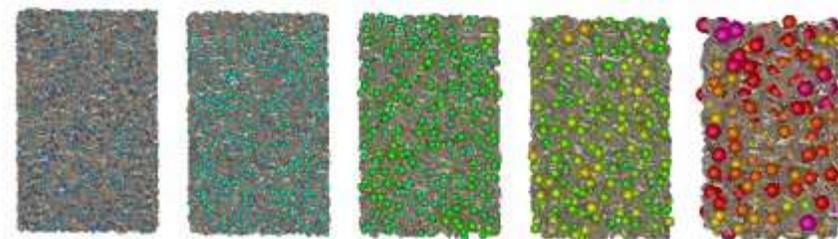
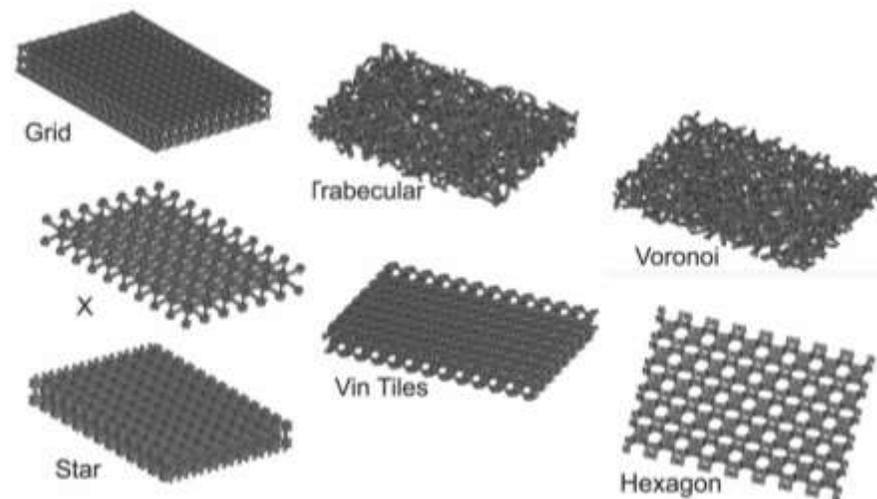
MEDICAL AM – CASE STUDY 3



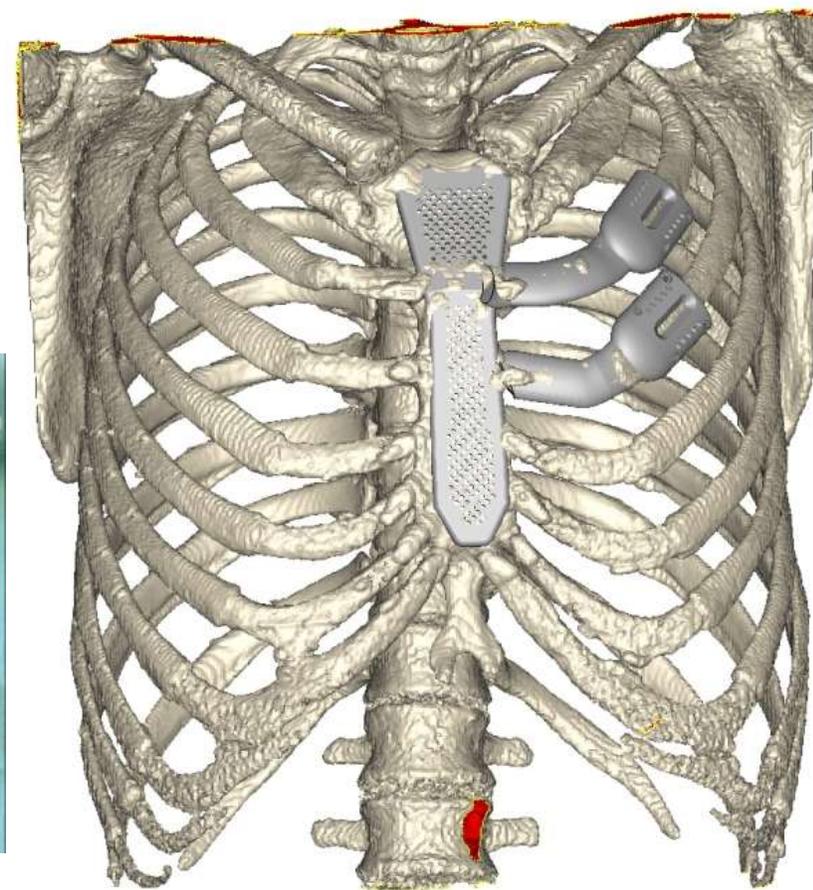
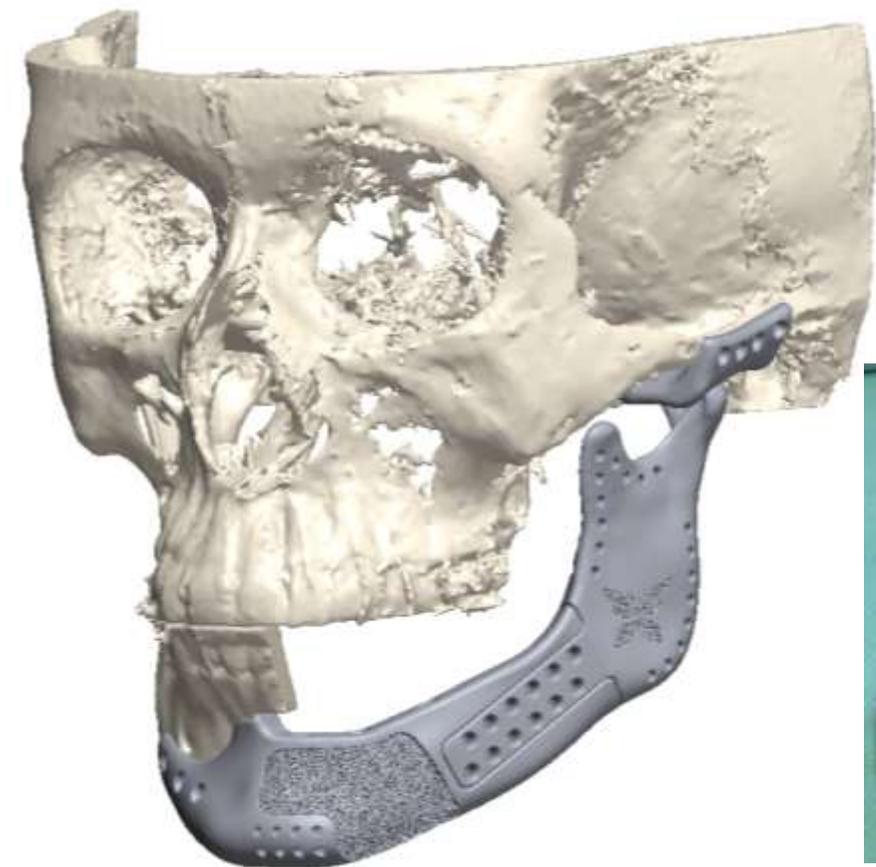
MEDICAL AM – POROUS STRUCTURES



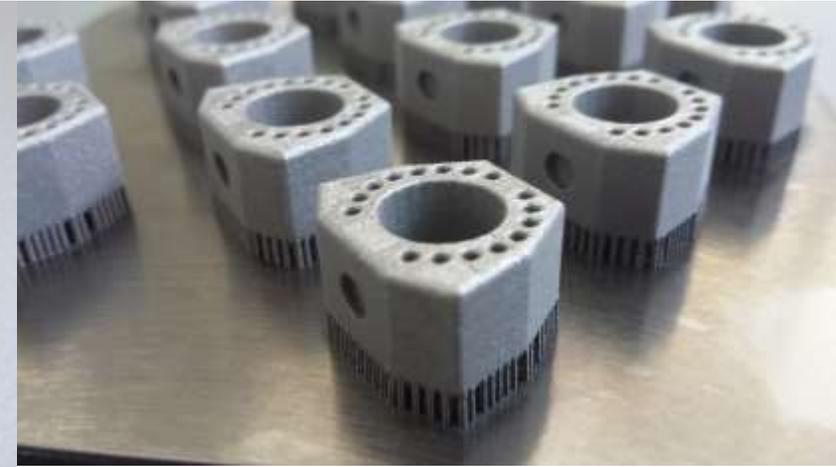
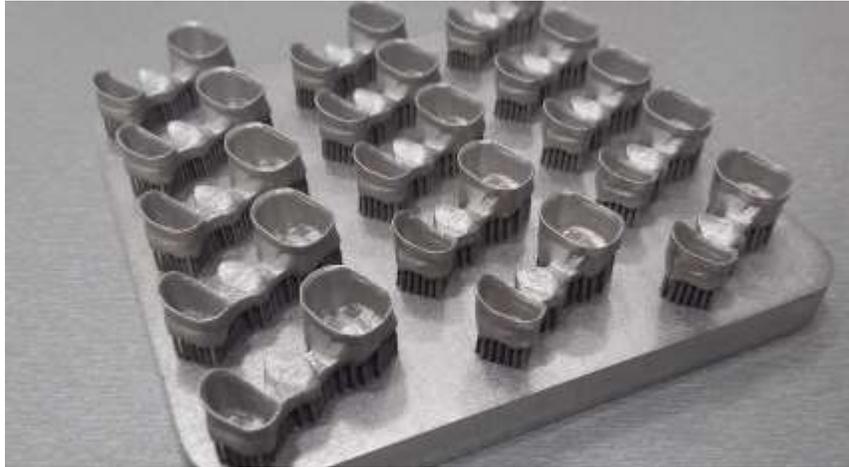
porous structure is manufactured with various geometric shapes and pore sizes



MEDICAL AM – OTHER CUSTOM IMPLANTS



MEDICAL AM – R&D&CO-OPERATIONS



WITHIN

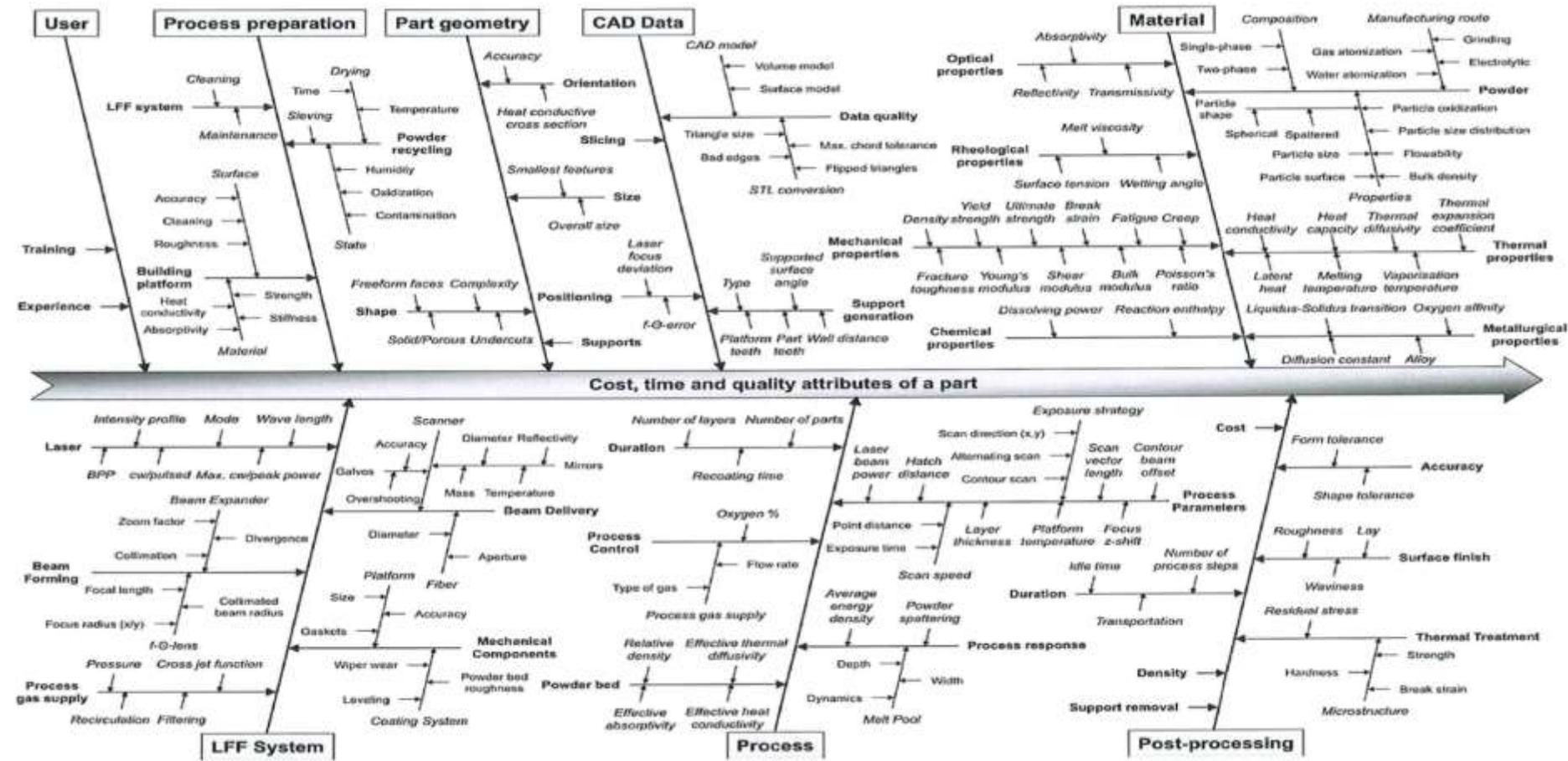


BEZNOSKA

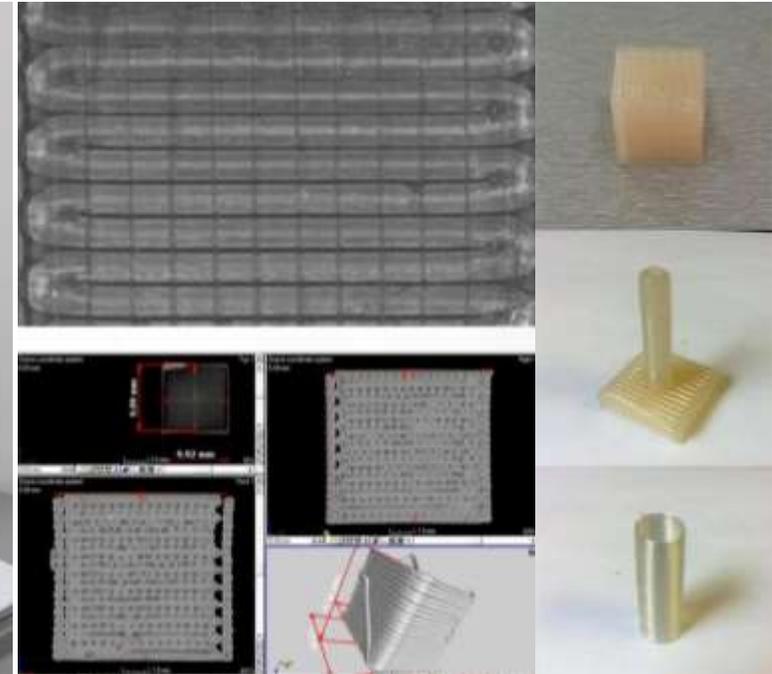
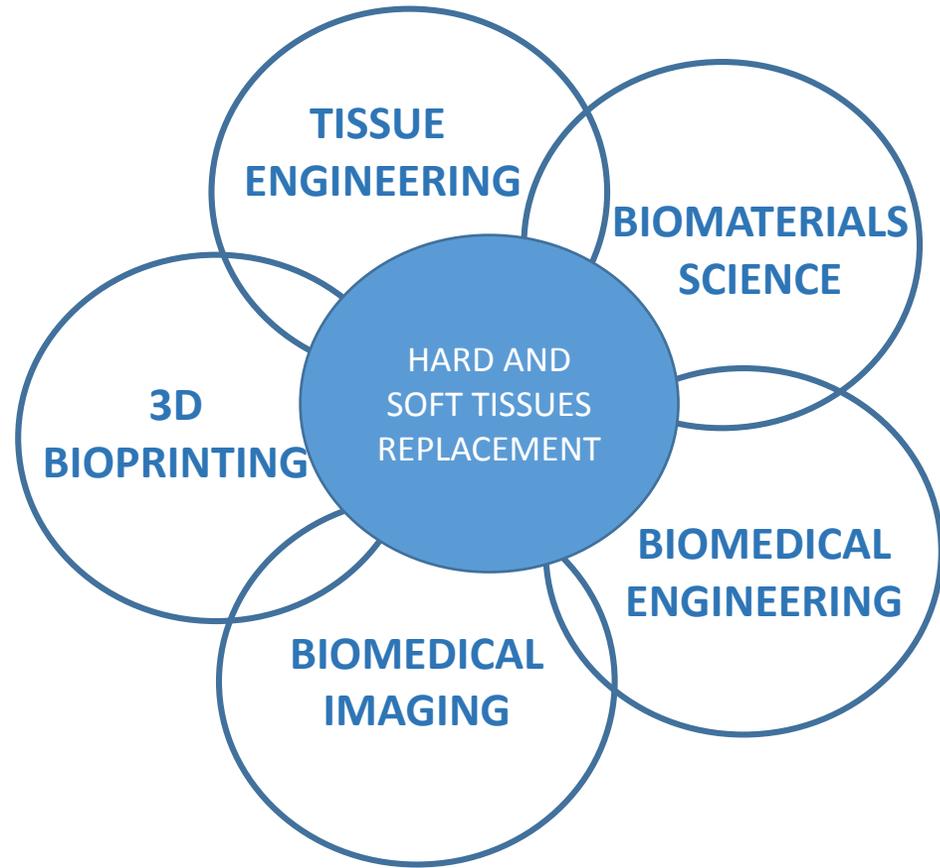


enbicore

AM PARAMETERS OPTIMIZATION COMPLEXITY - EXPERIENCES



FUTURE OF MEDICAL ADDITIVE MANUFACTURING



FUTURE OF MEDICAL ADDITIVE MANUFACTURING

ACTIVE PROJECTS

Manufacturing and testing of custom made bone scaffolds made of hydroxyapatite (HA) by use of 3D printing technology

(Budget: 250k €)

Analysis of the PEEK polymer and the additive manufacturing possibilities

(Budget: 250k €)

Design and complex characterization of biocompatible tubular 3D-scaffolds made of biosynthetic extracellular matrix intended as potential substitutes of damaged human urethra

(Budget: 250k €)

All projects are supported by Slovak Research and Development Agency (SRDA), Ministry of Education, Science, Research and Sport of the Slovak Republic

FUTURE OF MEDICAL ADDITIVE MANUFACTURING

PROJECTS IN PREPARATION PHASE

Project H2020: Distribute – Digitalization of supply chain and manufacturing digital transformation

MBP-22-2017 Business models and industrial strategies supporting novel supply chains for innovative product-services”.

Applicant: *Aalto University School of Engineering, Department of Engineering Design and Production, Finland*

Partner: *CEIT Biomedical Engineering, Kosice, Slovakia*

Project INTERREG: INNOMED3D

Applicant: *Ortotip, d.o.o., Maribor, Slovenia*

Partner: *CEIT Biomedical Engineering, Kosice, Slovakia*

FUTURE OF MEDICAL ADDITIVE MANUFACTURING

Gartner hype cycle for 3D printing

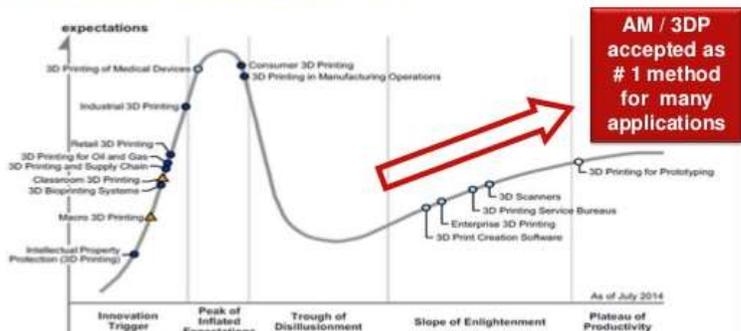


Figure 4.16 Spain: 3D Printing Market for Healthcare Revenue Forecast (\$m), 2016-2026

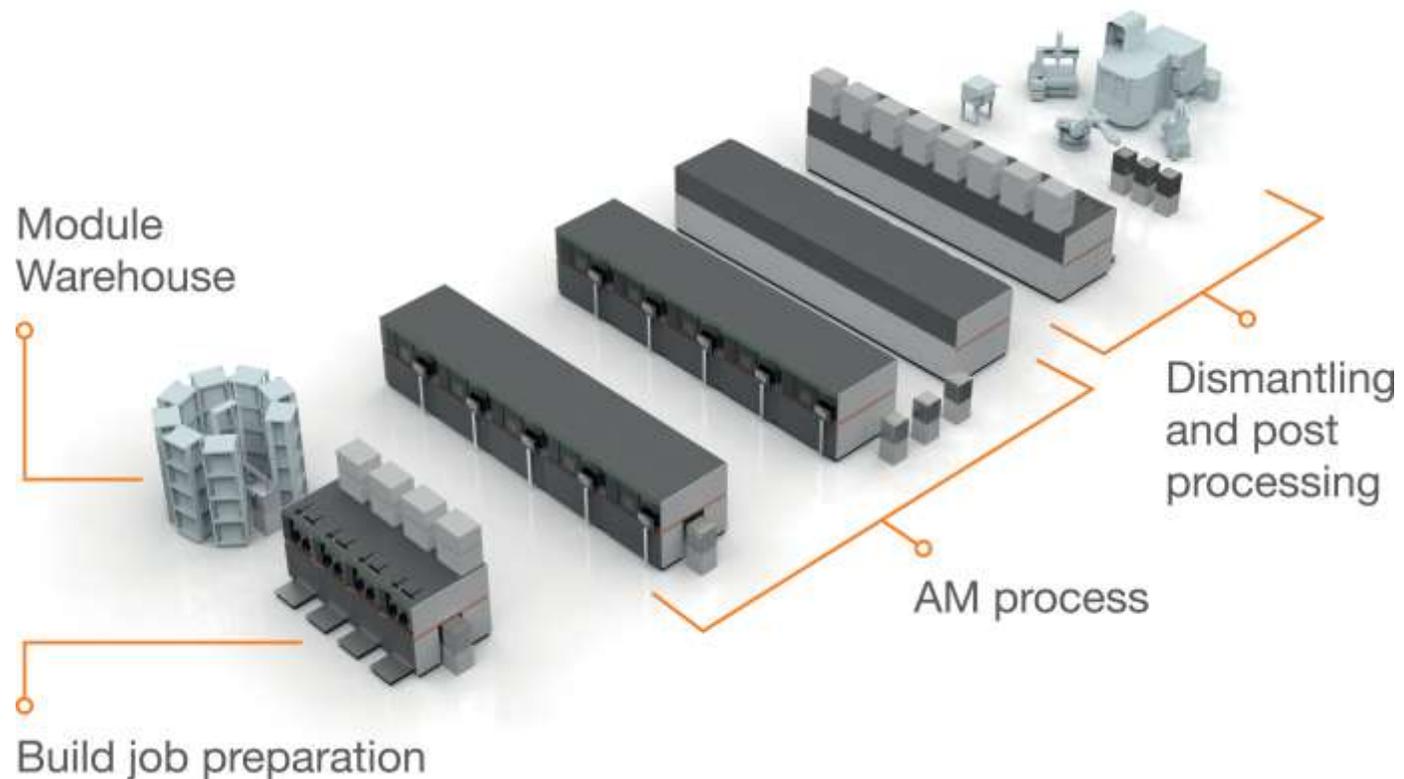
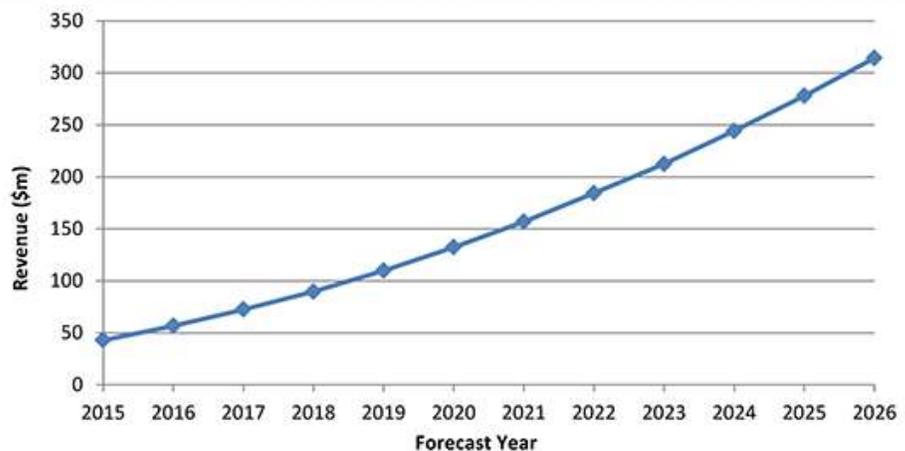


Photo courtesy of Concept Laser GmbH, May, 2016

FUTURE OF MEDICAL ADDITIVE MANUFACTURING



MORE INFORMATION

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Tel.: +421 905 820734