e-Manufacturing Solutions

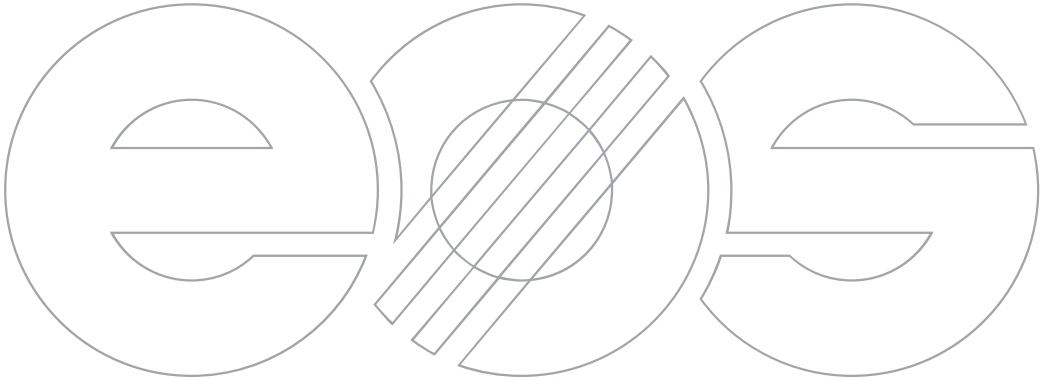
Additive Manufacturing for Medical

e – Manufacturing Solutions

Tom Zhang

Application Engineer

EOS Shanghai



Agenda

e-Manufacturing Solutions

- **EOS – Leader in e-Manufacturing Solutions**
- Additive Manufacturing: “The Manufacturing Technology that will Change the World”
- Additive Manufacturing for Medical

More than 25 years in Additive Manufacturing

EOS HQ in Krailling, Germany

EOS: Technology and market leader for design-driven, integrated e-Manufacturing Solutions

e-Manufacturing Solutions

- Family-owned, founded in 1989 by Dr. Hans Langer
- Focus on end-to-end Solutions for Additive Manufacturing: from part design and data generation to part building and post-processing
- Active in a variety of industries, focus on medical, aerospace, industrial applications
- EOS is committed to: Innovation – Quality – Sustainability
- Revenue FY 15/16: ~ 315 Mio €
- Revenue Increase to FY 14/15: ~ 20%

Dr. Adrian Keppler, Eric Paffrath, Dr. Hans J. Langer, Dr. Tobias Abeln (from left to right)

EOS Headquarters in Krailling, Germany

Global presence: we are, where you need us

e-Manufacturing Solutions

almost
1,000 Employees

EOS
Sales & Service
offices in
11 countries

67 distributor
offices
worldwide

2,400
EOS systems
installed
worldwide

40%
Metal systems

60%
Polymer systems

Agenda

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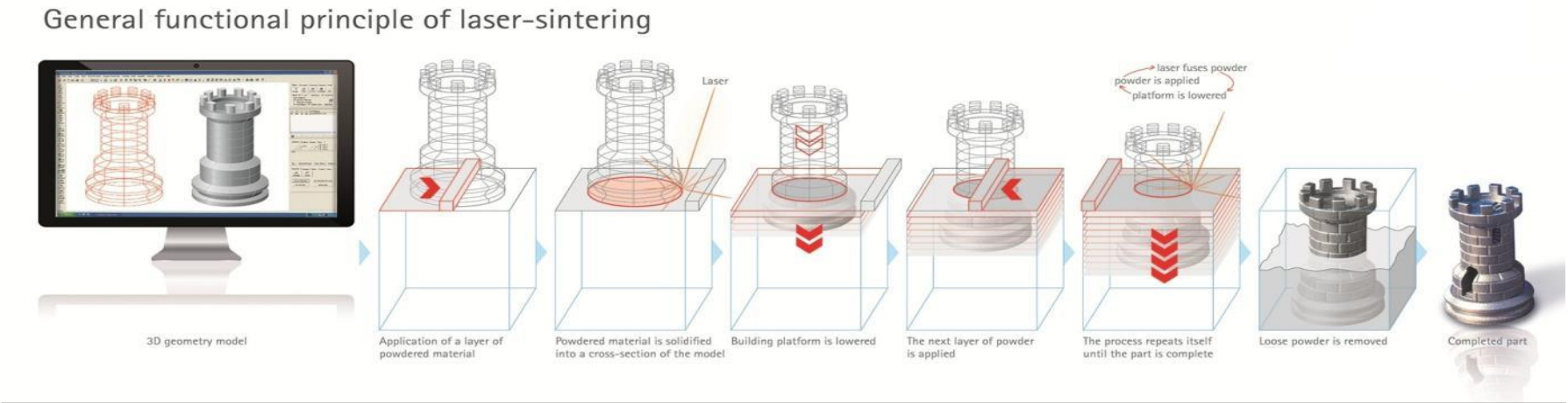
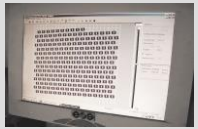
EOS Additive Manufacturing: Functional Principle

e-Manufacturing Solutions

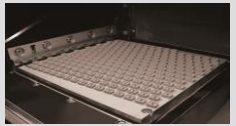




From a 3D CAD model…

- Application of powder
- Exposure by Laser

- Lowering of platform
- Re-application of powder
- Exposure by laser



… to complete parts

Functional principle for polymer and metal materials. Source: EOS

Advantages of Laser Sintering

e-Manufacturing Solutions

Laser Sintering offers various advantages compared to traditional manufacturing processes

Freedom of design

Lightweight
- Static: weight of parts
- Dynamic: moving, accelerated parts

Complex components
- E.g. alternative structures of heat exchangers

Cost advantage

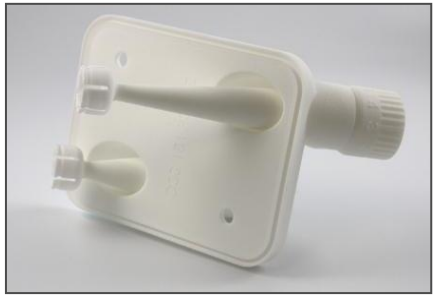
Integrated functionality
- Embedded functionality without assembly
- Material efficiency
- No tooling cost

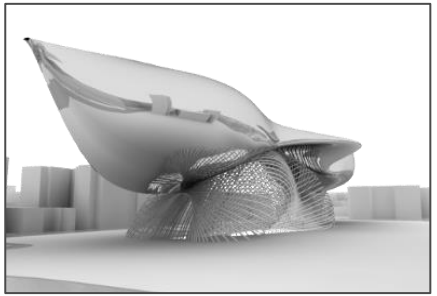
Customisation

Individualised parts
- Customer specific adaptations
- Cost efficient small series up to 'lot size one'

Time to market

Rapid prototyping
- Fast feasibility feedback of virtual models
- Haptic feedback





EOS Additive Manufacturing Medical Applications

e-Manufacturing Solutions

Dental Applications

BEGO USA Dental restorations

- **Challenge:** Economic production of patient-specific restorations made of high-performance alloy
- **Solution:** Manufacturing fully dense restorations w/o porosity using EOSINTM270

Result

- Fast and cost-efficient manufacturing
- Provided accuracy of units is +/- 20 microns
- Restorations are durable, capable and have a consistently high quality

Orthopedic Devices and Implants

Acetabular Cups, WITHIN Labs

- **Challenge:** Production of acetabular cups that pro-motes osseointegration
- **Solution:** EOS DMLS using EOS Titanium Ti64. Design with WITHIN software

Result

- Fully dense sections for stability, lattice structures for better osseointegration
- Both sections produced in a single production step
- Sections merge seamlessly to optimally absorb loads

Surgical Instruments

STarFixMicroTargeting™ platform

- **Challenge:** Manufacturing patient-matched frameless stereotactic fixtures
- **Solution:** Small-batch production of precision surgical components using EOS FORMIGA P 110

Result

- Customised design shortens surgery time
- Parts consolidation resulting in in simpler designs with more features
- Uses less material, faster manufacturing turnaround

Medical Devices

Hettich wash rotor Rotolavit

- **Challenge:** Simplify production of washing rotor ROTOLAVIT
- **Solution:** Laser sintering on EOSINT P 395 with PA 2200 as series material

Result

- High functional integration
- 3 parts (laser-sintered parts plus 1 steel ring) instead of 32 parts
- Finish and assembly effort reduced

Sources Images (left to right): EOS/BEGO USA; WITHIN Labs/3T;L FHC Inc.; Hettich

We are experts
in plastic and metal AM technology …

Key Guideline
innovation with quality

EOS Mission

Provide industrial grade AM **SYSTEM**, **MATERIALS**, **PROCESS** & **SERVICES**.

Polymer Laser Sintering systems

e-Manufacturing Solutions

FORMIGA P 110

Compact system for small and medium sized parts with best detail resolution

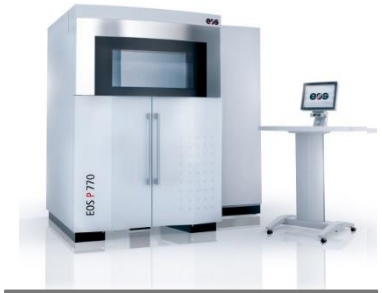
Usable build size
200x250x330 mm

EOS P 396

Fastest polymer laser sintering system in the world! Effectively isotropic part properties.

Usable build size
340x340x600 mm

EOS P 770



Double-head system for high throughput production and/ or large parts.

Usable build size
700x380x580 mm

EOSINT P 800

For high-performance polymer parts.

Usable build size
700x380x560 mm

Production scale

SMALL SERIES | FLEXIBLE | LARGE SERIES | LARGE Specialised SERIES

Direct Metal Laser Sintering systems

e-Manufacturing Solutions

EOS M 100

Proven DMLS quality for small-scale production

Build volume:
Ø 100 mm x 95* mm

Laser: 200 W Yb-fiber, focus diameter 40 µm

EOS M 290

Proven DMLS quality with enhanced quality management

Build volume (wxdxh):
250 x 250 x 325* mm

Laser: 400 W Yb-fiber laser, focus diameter 100 µm

EOS M 400

Proven DMLS Quality for the production of large parts

Build volume (wxdxh):
400 x 400 x 400* mm

Laser: 1000 W Yb-fiber, focus diameter 90 µm

EOS M 400-4

Proven DMLS Quality with up to 4x higher productivity

Build volume (wxdxh):
400 x 400 x 400* mm

Laser: 4x 400W Yb-fiber, focus diameter 100 µm

SMALL FRAME | MEDIUM FRAME | LARGE FRAME

Polymer high quality materials

e-Manufacturing Solutions

15 materials: the largest OEM-portfolio of Laser Sintering materials

Family	Material name
PA 12 unfilled	PA 2200
	PA 2201
	PrimePart® PLUS (PA 2221)
PA 12 colored	PA 2202 black
	PA 2105 (gum colored)
PA 12-GB	PA 3200 GF
PA 12-AL	Alumide®
PA 12-CF	CarbonMide®
PA 12-FR	PA 2210 FR
	PrimePart® FR (PA 2241 FR)
PA 11 unfilled	PA 1101
PA 11 black	PA 1102 black
Elastomer (TPE)	PrimePart® ST
Polystyrene (PS)	PrimeCast® 101
Polyaryletherketone (PAEK)	EOS PEEK HP3

Metal high quality materials

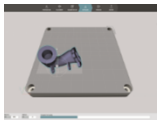
e-Manufacturing Solutions

Currently over 16 powder alloys with more in development

Family	Metal Alloy
Aluminium	EOS Aluminum AlSi10Mg
Cobalt Chrome	EOS CobaltChrome MP1
	EOS CobaltChrome RPD
	EOS CobaltChrome SP2
Maraging Steel	EOS MaragingSteel MS1
Nickel Alloy	EOS NickelAlloy HX
	EOS NickelAlloy IN625
	EOS NickelAlloy IN718
Stainless Steel	EOS StainlessSteel 17-4PH
	EOS StainlessSteel 316L
	EOS StainlessSteel CX
	EOS StainlessSteel GP1
	EOS StainlessSteel PH1
Titanium	EOS Titanium Ti64
	EOS Titanium Ti64ELI
	EOS Titanium TiCP Grade 2

EOS excellent processing program

e-Manufacturing Solutions

High quality materials		Variety of quality approved materials
Validated EOS processes		Validated processes for excellent part quality from the start
Process development tools		Open process development environment
System & Process monitoring		Integrated monitoring suite

Ensuring reliable part quality.

An integrated portfolio of value-adding services

e-Manufacturing Solutions

Technical Services

Installation & Qualification

Maintenance & Repair

Collaboration models

Ensuring optimum system performance

Training Services

Transferring know-how to customers

Additive Minds

Excellence in Industrial 3D printing

» Our fascinating technology offers tremendous possibilities – and our customer enablement offer helps you fully exploit them! «

Agenda

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- **Additive Manufacturing for Medical**
  - **Dental Application**
  - Orthopedic Devices and Implants
  - Surgical Instruments
  - EOS Validation Support

EOS Dental Solutions

e-Manufacturing Solutions

Copings & Bridge Frameworks

Removable Partial Dentures

Dental Models & Surgical Guides

EOS Dental Solutions: Crown & Bridge Frameworks

e-Manufacturing Solutions

Machine:	**EOS M270** | **EOS M100**
Material:	EOS CoCrSP2
Process:	20µm slice thickness – M270 30µm slice thickness – M100

- **Fully certified** and **registered process** by EOS
- High accepted quality: **+90 EOS M270 machines installed** world wide / **5 Million units** produced per year
- **±20µm accuracy** (margin line) for single coping up to eight unit frameworks
- **High productivity** : up to 450 units per job (*about 22h*)
- **Attractive Cost Per Part < 3,-€/unit**

EOS Dental Solutions: Removable Partial Denture (RPD)

e-Manufacturing Solutions

Machine:	**EOS M270**
Material:	EOS CoCrRPD
Process:	40µm slice thickness

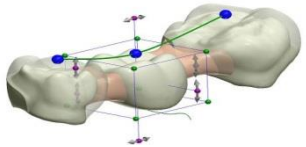
- **Full certified** and **registered process** by EOS beginning of April 2015
- **Sales Release** with SPL scheduled for beginng of May 2015
- **Budget Quotes** with standard M270 Dental SPL until full SPL integration
- **Digital high volume manufacturing** solution compared to traditional fine casting
- Constant **good quality** – low scrap rate
- **Attractive Cost Per Part**

Quality Assurance within the AM Dental process

e-Manufacturing Solutions

Input/Scan

Design



Build

Finish

Dentist/Lab Technician → **Lab Technician** → **Service Provider** → **Lab Technician**

- Model Design
- Scanning

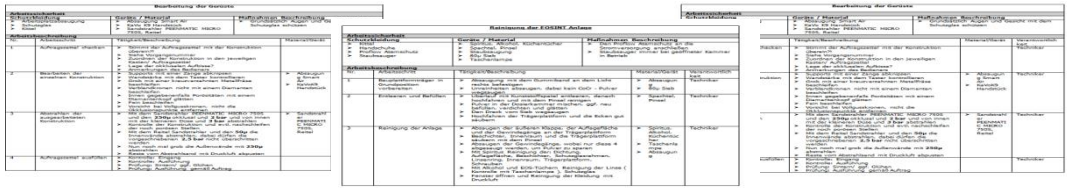
- CAD Design
- Data Management

- Pre & Post Process
- Material handling

- Post treatment
- Compatibility

Quality Assurance through standardized processes and documentation.

Available now at the SPL



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  - Dental Application
  - **Orthopedic Devices and Implants**
  - Surgical Instruments
  - EOS Validation Support

Slovakian healthcare pioneer relies on EOS technology for patient-specific cranial implants

e-Manufacturing Solutions

Medical

- **Challenge**
  Provision of technology and material for the production of precision implants for cranial, jaw and facial bones using Additive Manufacturing.

- **Solution**
  The manufacture of customized, patient-specific implants from biocompatible titanium alloy, using the EOSINT M 280.

- **Results**
  - Patient-specific: form precision leads to reduced side-effects
  - Efficient: lower error-rate during production and constant manufacturing costs with increased precision
  - Approved: implant registered by the Slovakian State Health Authority (SIDC)

Additive manufactured skull implant made of titanium

CEIT biomedical engineering

Source: CEIT Biomedical Engineering, s.r.o.

Alphaform produces hip implant by using additive manufacturing

e-Manufacturing Solutions

Lightweight patient-specific hip implant made of titanium

Challenge

- Design and construct a precision-fitting, lightweight, yet stable hip implant in a short period of time

Solution

- Design of implant:
  - Based on CT images of the patient
  - Integration of lightweight hollow structure
  - Allow for optimal usage of AM manufacturing
- Manufacturing of implant on M280:
  - Material: Ti64 (Grade 5)
  - 11 hours build time
  - Post processing: removal from plate (wire cut) and cleaning (blasting and ultrasonic)

Results

- Successfully implanted in May 2014 in Croatia
- Precise fit
- Short planning and production times for imminent operation
- Minimum weight for high patient comfort

instrumentaria

ALPHAFORM

Source: Alphaform, Instrumentaria

A complex trabecular lattice is applied on a hip cup for improved osseointegration

e-Manufacturing Solutions

Trabecular Lattice Structure

Acetabular cup

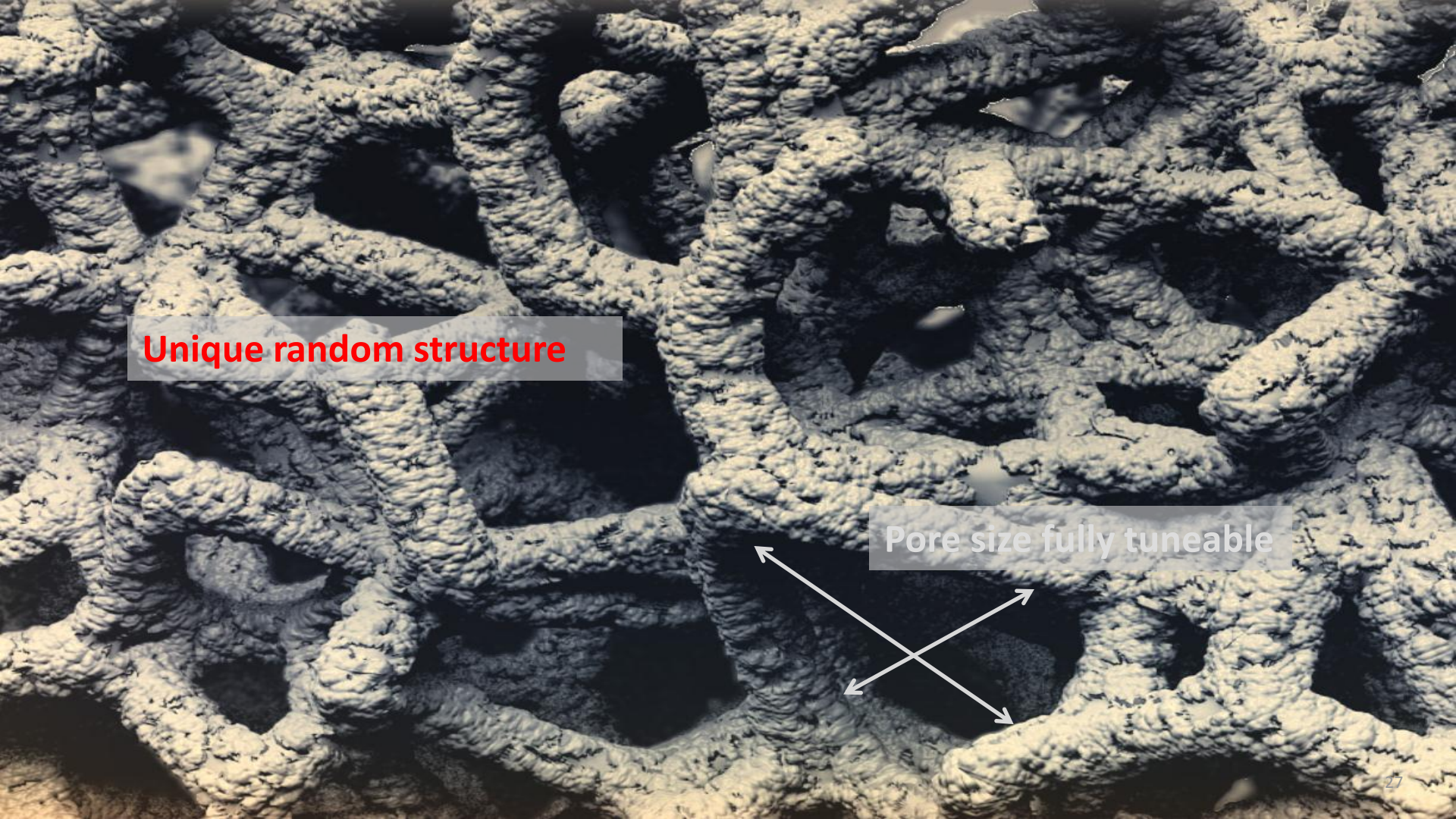
Application

- Trabecular structure to aid osseo-integration
- Autodesk Within Medical Software allows to vary pore size, porosity throughout the implant and surface roughness
- Structural continuity between solid and porous sections
- Material: Ti6Al4V alloy
- FDA 510(k) approval

Advantage

- Stable initial fixation of the implant and improved bony ingrowth

Source: Autodesk, EOS


Unique random structure
Pore size fully tuneable

EOS and partners offer complete solutions dedicated to patient-specific implants

e-Manufacturing Solutions

Implant design and Optimization

- CT/MRI based design (e.g. Materialise Software)
- Use of design software to generate e.g. lattice structures
- SW training by 3rd party
- Support by EOS application team on design rules

e.g. Materialise innovators you can count on; AUTODESK WITHIN MEDICAL; netFabb Software for 3D Printing; simpleware 3D-DOCTOR

1 DESIGN

Implant building process

- EOS offers competitive metal machine and material portfolio
- EOS offers monitoring capability
- EOS offers consultancy for building lattice structures
- EOS offers consultancy for quality assurance concepts

e-Manufacturing Solutions

2 BUILD

Implant post-processing

- Support by EOS application team on heat treatment
- Standard post-processing steps can be applied
- EOS lattice structure design training includes:
  - Recommendations on cleaning of lattice structures
  - Guideline on testing of lattice structures

e.g. MMP TECHNOLOGY

3 FINISH

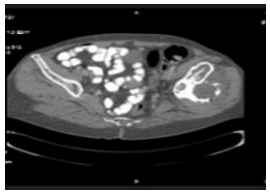
Source: EOS

3rd party software can help users to design for their specific needs

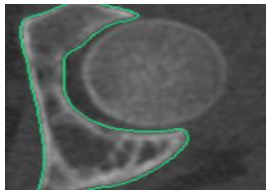
e-Manufacturing Solutions

DESIGN

CT scan

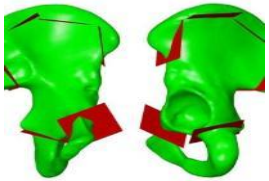


Segmentation process

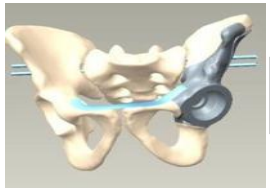


3D CAD bone model

Definition of resection area



Implant design



Design optimization

Design software (examples)

CT scan (DICOM images) to bone model:

- Materialise:
  - Mimics® Innovation Suite (Toolbox for Engineering on Anatomy™)
  - http://biomedical.materialise.com/mis
- Simpleware
  - http://www.simpleware.com/

Design of implant on bone model:

- Materialise:
  - 3-matic of Mimics® Innovation Suite

Design of implant on bone model:

- Materialise:
  - **3-matic STL**

Source: EOS, Instrumentaria, Materialise,

The implants can be produced using the integrated EOS portfolio

e-Manufacturing Solutions

2 BUILD

M 290

EOS metal system

- Laser sintering system to produce complex metal structures
- Build envelope of 250 x 250 x 325 mm
- Systems are geared to high productivity demands of production environment
- Direct interface to standard CAD programs

EOS systems are able to manufacture medical devices. However, EOS cannot offer any guarantee that these devices meet all requirements.
Source: EOS

For production of lattice structures for implants different materials are available

e-Manufacturing Solutions

BUILD

Trade name	Description
EOS Titanium Ti64, grade 5 and 23 (ELI)	▪ Ti6Al4V alloy , grade 5 and grade 23 (ELI) ▪ Laser-sintered parts fulfil ASTM F1472 (for Ti6Al4V) and ASTM F136 (for Ti6Al4V ELI) regarding maximum concentration of impurities
EOS CobaltChrome MP1	▪ CoCr-based superalloy ▪ Fulfils the mechanical and chemical specifications of ISO 5832-4 and ASTM F75 for cast CoCrMo implant alloys
EOS StainlessSteel 316L	▪ Chemical composition corresponding to ASTM F138 “Standard Specification for Wrought 18Cr-14Ni-2.5Mo Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

EOS metal materials

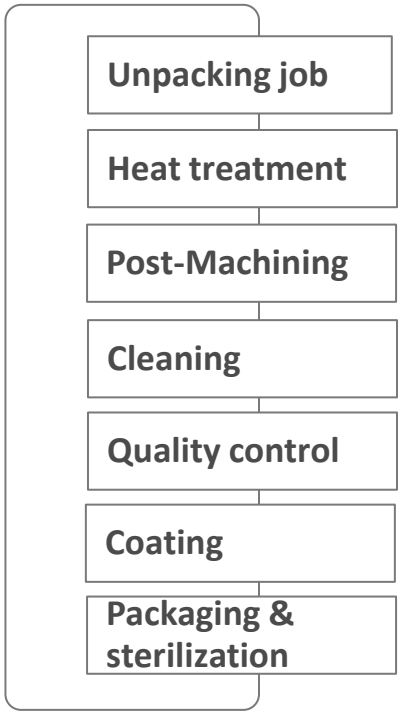
- Materials comply to high EOS quality standards
  - Analysis of **chemical composition** for every batch
  - Analysis of **density and static properties** for every batch
  - **Mill-test-certificate** for every batch, delivered with the powder
  - **Traceability** of powder batches
- Database of different **static and dynamic properties** according to heat treatments available
- Continued innovating portfolio for new materials

EOS systems are able to manufacture medical devices. However, EOS cannot offer any guarantee that these devices meet all requirements.
Source: EOS

Several finishing methods can be applied to the laser-sintered implants with lattice structure

e-Manufacturing Solutions

3 FINISH



- Air blasting or shaking to remove loose powder particles from the manufactured components
- Usually a heat treatment takes place before parts are separated from the platform with a band saw or wire EDM
- If applicable, selected areas can be finished by milling, turning, polishing etc.
- Different cleaning methods can be applied, e.g. blasting, ultrasonic
- EOSTATE quality reports (laser power monitoring, oxygen content, …)
- The part can be coated with e.g. hydroxyapatite
- The packaged part can be sterilized, by e.g. gamma sterilization

Source: EOS

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  - Orthopedic Devices and Implants
  - **Surgical Instruments**
  - EOS Validation Support

Again, EOS and partners strive to offer complete solutions

e-Manufacturing Solutions

Instrument design

- Software to process patient's CT data to 3D model provided by e.g. Materialise (Mimics)
- Software to design the patient-specific instrument provided by e.g. Materialise (3matic)

Instrument building process

- Production of instruments using the integrated EOS portfolio
  - Systems
  - Materials
  - Services

Instrument post-processing

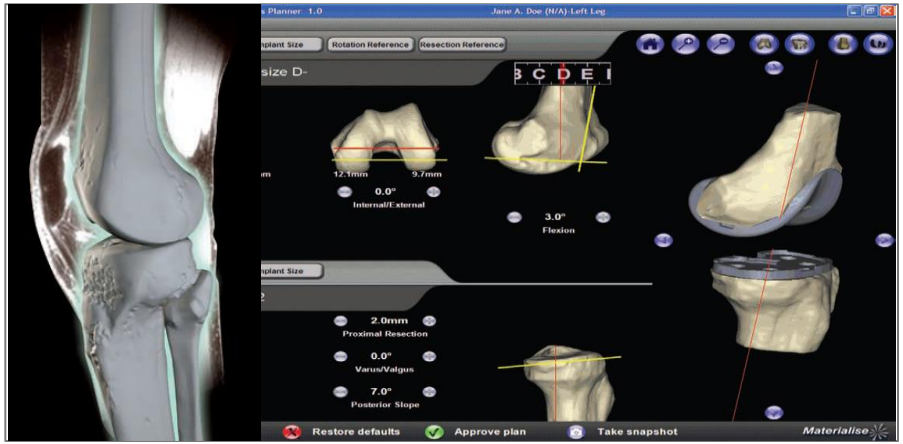
- Finishing of instruments
- Additional possibilities, e.g.
  - Cleaning
  - Sterilization etc.

Source: EOS

Different software products can help users to design patient-specific disposable instruments

e-Manufacturing Solutions

1 DESIGN



Mimics

- Software to process patient's CT data to 3D model

3matics

- Software to design the patient-specific instrument according to the anatomical 3D model

Software products

- 3D modeling from CT or MRI images captures true patient anatomy
- Based on the 3D model the surgical guide is designed
- Preoperatively, the surgeon can view the patient's anatomy and adjust the surgical plan

Advantages

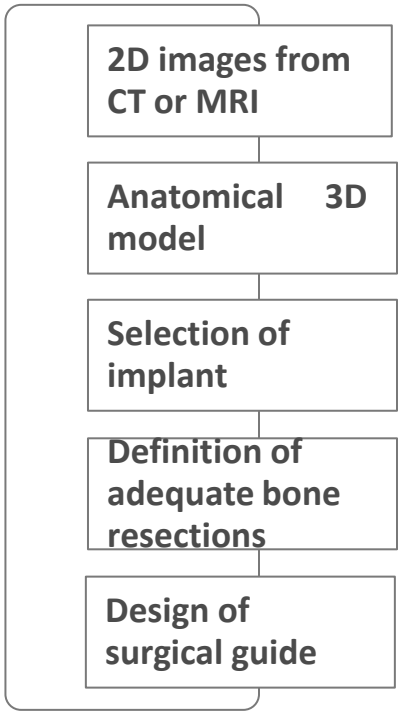
- **Time to market** (new designs, patient specific designs)
- **Ease of use**
- **Control of the surgeon**

Source: Materialise, EOS

The overall design process, from the patient's 2D data to the instrument design is established

e-Manufacturing Solutions

1 DESIGN



- Hospital creates CT or MRI (2D) images of the patient's bones about 3-5 weeks before surgery
- Patient's 2D data is send to the manufacturer
- CT or MRI images are reconstructed to produce a 3D model of the patient's bones
- The dimensions of the knee are measured and the most appropriately sized prosthetic components are selected
- Information is uploaded onto pre-operative planning SW
- SW proposes the adequate bone resections taking into account the orientation (axis alignment etc.) of the bones
- The surgeon can then visualize the proposal and make adjustments
- Based on this input, the patient-specific instrument is designed with e.g. "3matic", a computer-assisted design SW from Materialise
- Implant size, patient name etc. can be clearly labeled

Source: EOS

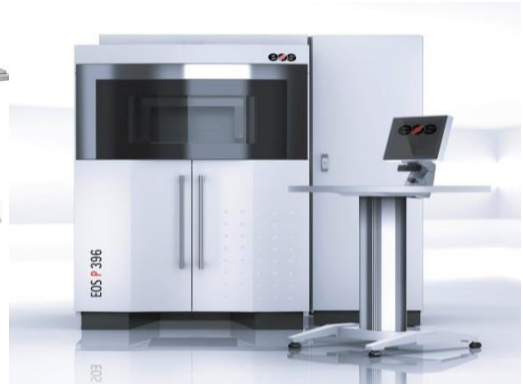
The disposable instruments can be produced using the integrated EOS portfolio

e-Manufacturing Solutions

2 BUILD

P 760

P 110



P 396

EOS plastic systems

- Laser sintering systems to produce plastic grippers and components almost without geometric limitations
- Three different system sizes available up to a build envelope of 700 x 380 x 580 mm
- Systems are geared to high productivity demands of pro-duction environment
- Direct interface to standard CAD programs

Source: EOS

For disposable instrument production biocompatible material is available

e-Manufacturing Solutions

BUILD

Trade name	Composition
PA 2200	PA 12

EOS plastic material

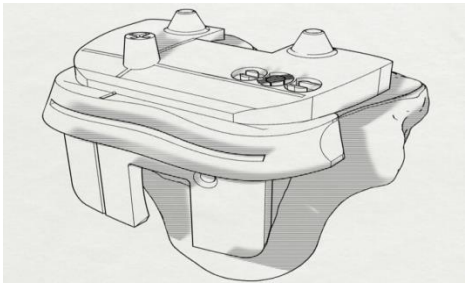
- Material complies to high EOS quality standards
- Proper storage according to EOS specifications to avoid electrostatic charge
- Refreshing of powder according to EOS specifications
- Disposable instruments requirements matched:
  - high strength and stiffness
  - high detail resolution
  - various finishing possibilities (e.g. sterilization possible)
  - biocompatible[1)] according to EN ISO 10993-1 and USP/level VI/121 °C

1) Biocompatibility test available for intended use of disposable guides (for new powder and 50%/50% mix).
Source: EOS

The disposable instruments can be produced using the integrated EOS portfolio

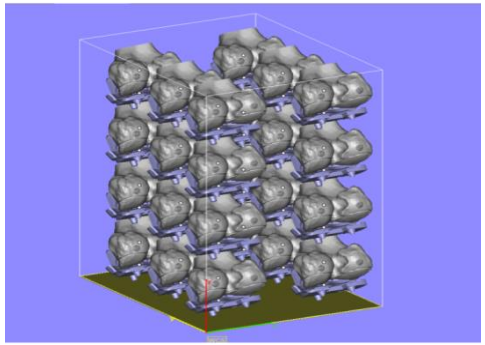
e-Manufacturing Solutions

2 BUILD



Sample geometry set consisting of

- Disposable guide and
- corresponding bone section



24 guide sets packed into one P110 job

EOS economic production

- Layer thickness can be adjusted to find the right balance of detail resolution and cost per part
- EOS application team can consult to optimize work flow

Sample calculation for knee guide set:

- P110, 120µm:
  - 24 sets/job
  - 18 h/job
  - 23 €/set[1)]
- P396, 120µm:
  - 80 sets/job[2)]
  - 21h/job
  - 18 €/set[1)]

1)Including system list price with standard configuration, 5 years machine depreciation, 3% interest, maintenance contract, medium user (3500 h/year) and standard list price PA2200 .

2)Full job would be 112 sets/job in 29 hours , BUT due to workflow and processing time it is recommended to build max 5 layers (= 80 sets) per job!

Source: EOS

Several finishing methods can be applied to the laser-sintered disposable instruments

e-Manufacturing Solutions

3 FINISH

- Shot peening with PA 2200 powder is used to free the laser sintered part from remaining powder
- Cleaning of holes with a bench drilling machine
- High-pressure water jetting and industrial dishwasher can be used for final cleaning
- Quality control of functional surfaces with e.g. stripe-light scanners

- Transport into cleanroom
- Steam autoclave sterilization (Gamma and ETO sterilization also possible)[1)]

1) We have test results available .
Source: EOS

Agenda

- EOS – Leader in e-Manufacturing Solutions
- Additive Manufacturing: “The Manufacturing Technology that will Change the World”
- **Additive Manufacturing for Medical**
  - Dental Application
  - Orthopedic Devices and Implants
  - Surgical Instruments
  - **EOS Validation Support**

70+ Additively Manufactured Medical Devices Cleared Through the 510(k) Pathway in the US

e-Manufacturing Solutions

Patient matched implants	Patient matched surgical guides	Orthopedic devices	Dental
▪ Skull plate	▪ Craniofacial	▪ Hip cups	▪ Temporary bridges
▪ Maxillofacial implants	▪ Knee	▪ Spinal cages	▪ Reconstructive surgery support
▪ Knee implants	▪ Ankle	▪ Knee trays	

FDA: „AM devices are regulated through the same pathways as non-AM devices. The FDA regulates medical devices based on intended use, indications for use, and technological characteristics within a risk-based framework regardless of specific manufacturing process.“

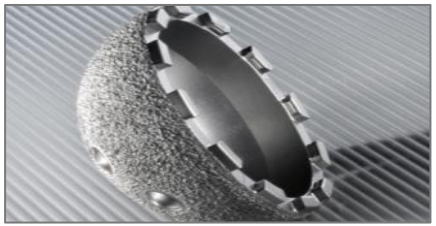
iTotal® TKR by ConforMIS

http://www.accessdata.fda.gov/cdrh_docs/pdf12/K122870.pdf

VSP® by Medical Modeling

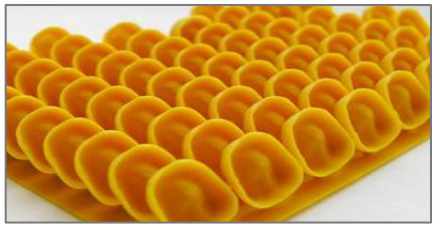
http://www.accessdata.fda.gov/cdrh_docs/pdf12/K120956.pdf

Novation Crown, Exactech



http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102975.pdf

e-DENT Temporary Resin, DeltaMed GmbH



http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102776.pdf

Source: FDA – Presentation during RAPID workshop on May 18, 2015 in Long Beach, USA.

EOS understands customers‘ Quality challenges

Requirements from validation processes

Customers with high quality standards

- pass through extensive validation processes.
- often need certifications from external bodies to release their products.
- sometimes lack the AM specific know-how to implement adequate Quality Management processes.

EOS provides Services to support customers in their validation processes.

We understand the challenges of customer validation processes

e-Manufacturing Solutions

Execusiton by EOS

1. **FAT**
   Factory Acceptance Test
2. **IQ Support Service**
   Installation Qualification

- EOS has a proven process for Standard FAT and IQ.
- EOS can customise both services to address specific customer requests.

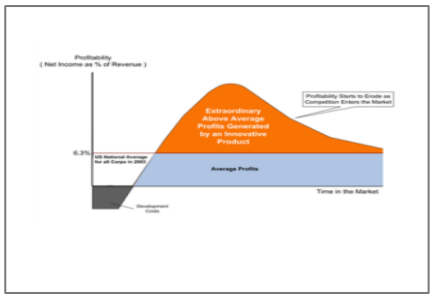
Consulting by EOS

3. **OQ Support Service**
   Operational Qualification
4. **PQ Support Service**
   Performance Qualification

- OQ and PQ are largely determined by customers' internal Quality Management processes.
- EOS can provide Consulting services.

Customer benefits from Validation Support

e-Manufacturing Solutions

1 Quality Assurance / Risk Management	2 Compliance with external obligations	3 Time to market	4 Cost efficiency
			

Learning curves are costly for customers –
We make sure they are short!

Thank you for your attention!

www.eos.info