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Selective Laser Melting of Ti Orthopedic Implants

Dr. Chris Sutcliffe University of Liverpool
Director Fusion Implants
R+D Director Renishaw AMPD

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Abstract

3D printing has captured the public's attention. People making things at home...surely not...don't we all just drink lattes whilst listening to mp3s on our Ipads contemplating the Ikea catalogue...and watching film on media streaming subscription services. Well you can connect them to your computer you know...really?...and make anything you want...its like a magic machine...print your dreams...

I have 50+ slides 20 minutes

Oh yes I forgot...you can print a bionic man...and perhaps make him work.

Introduction

- AM in the news
- Things am can do
- Hype
- AM in Medicine
- Laser melting
- History
- Orthopaedic implants by SLM
- Porous surfaces
- IP
- In vivo tests
- Patents
- Exploitation
- Opportunities

Picture of RM in the News

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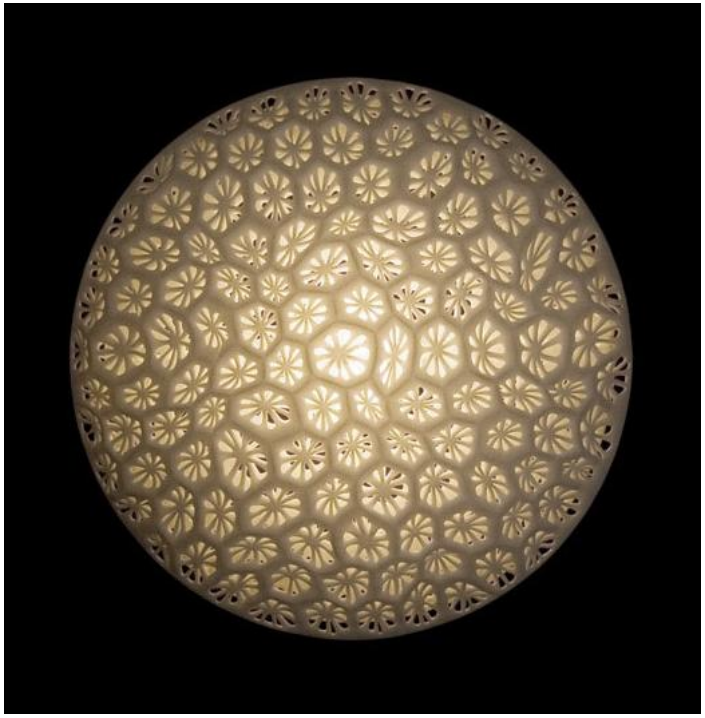
BBC, ITCCLips.net, BBC,Shapeways

Equipment (AM)

What can it do

Consumer Products



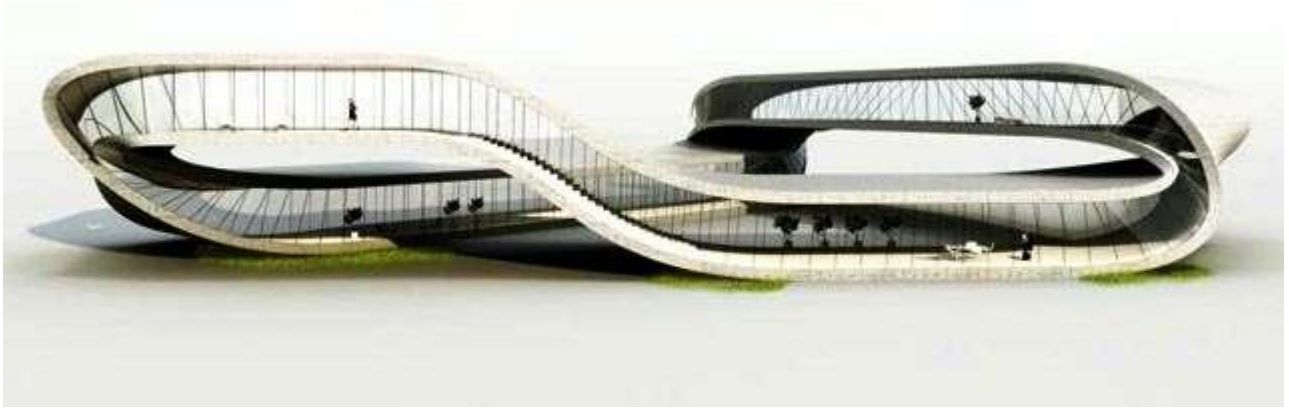
Materialise MGX Freedom of Creation and 3D systems

Consumer Products

Materialise MGX Freedom of Creation and 3D systems

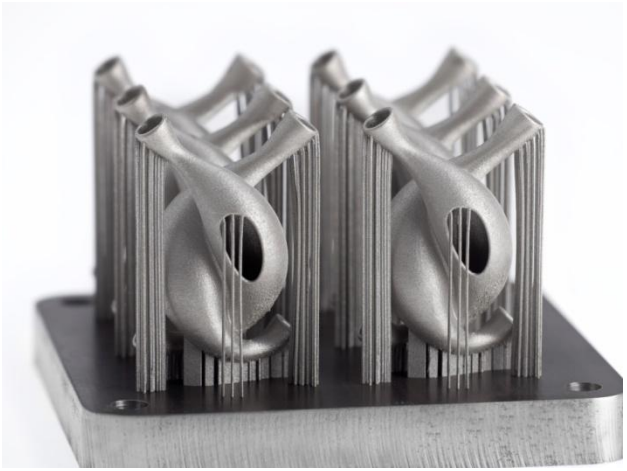
Consumer Products

Large Structures



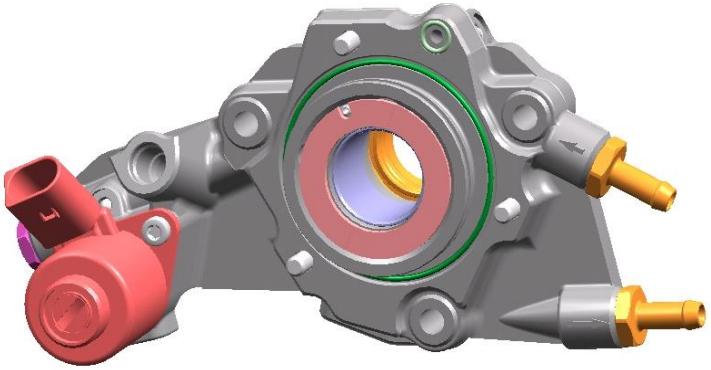
Jewellery

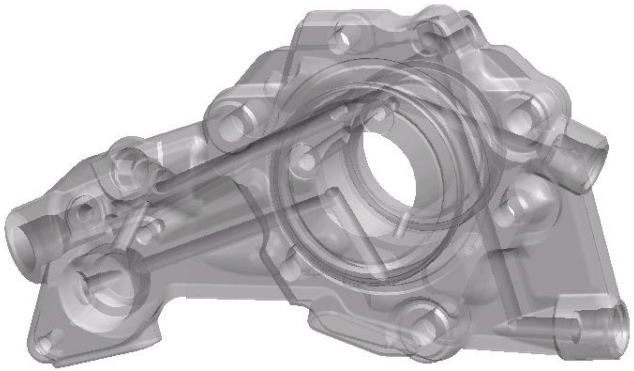
Manufactured by : **CPM**
Designed : Lionel Dean

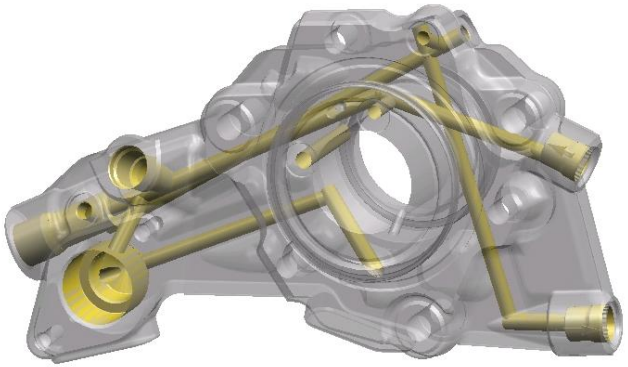


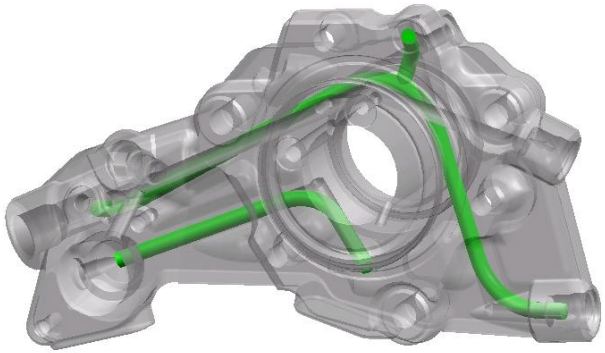
Ecouterre.com, Realizer, Lionel Dean

Optimised Flow Paths

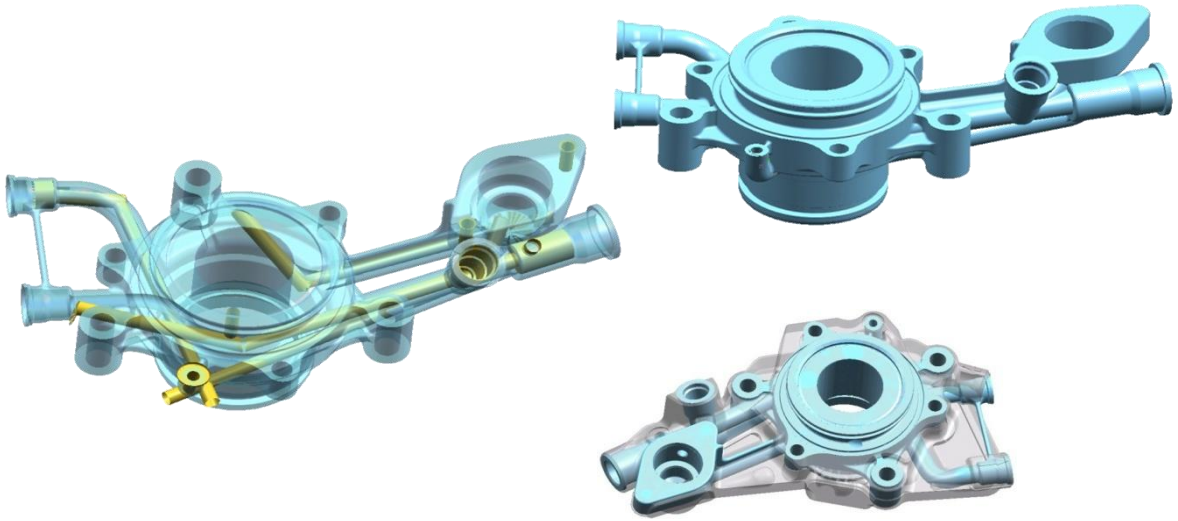




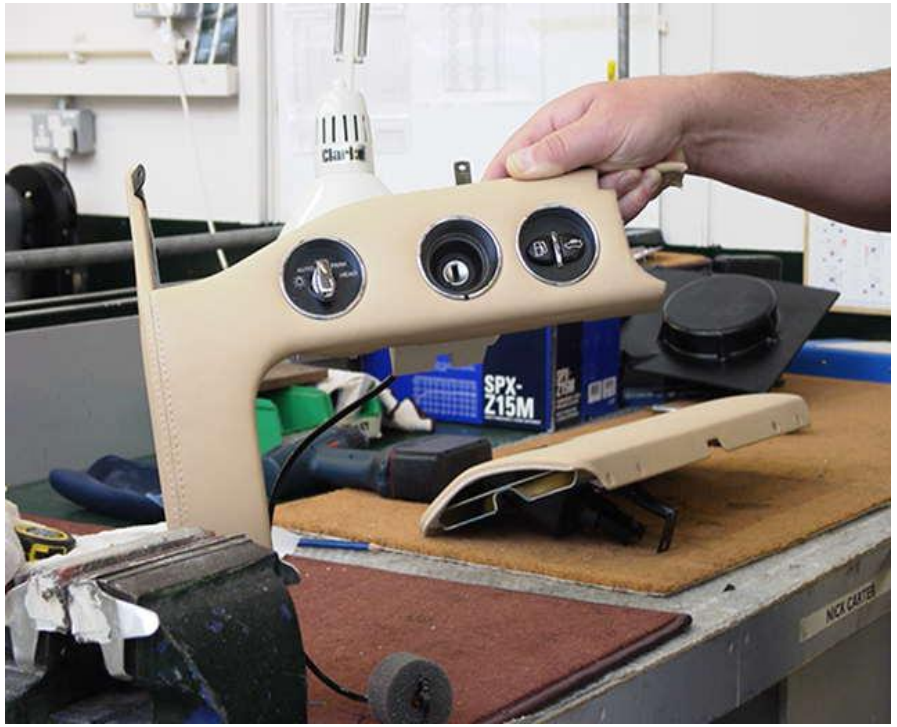




Weight Reduction



Customisation



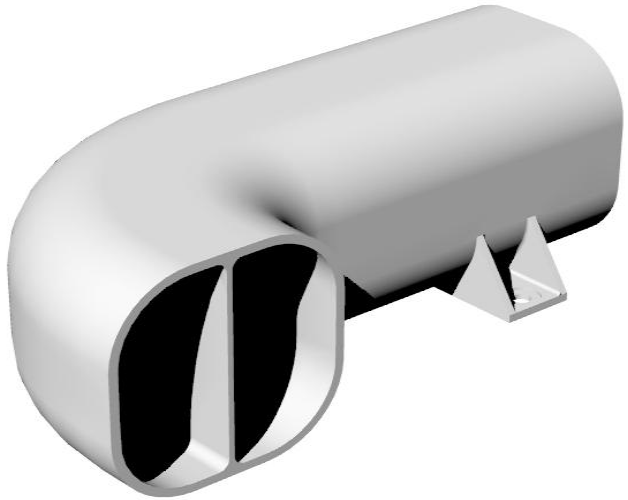
Parts Consolodation

(A) Conventional Duct fabricated from VAC Formed plastic

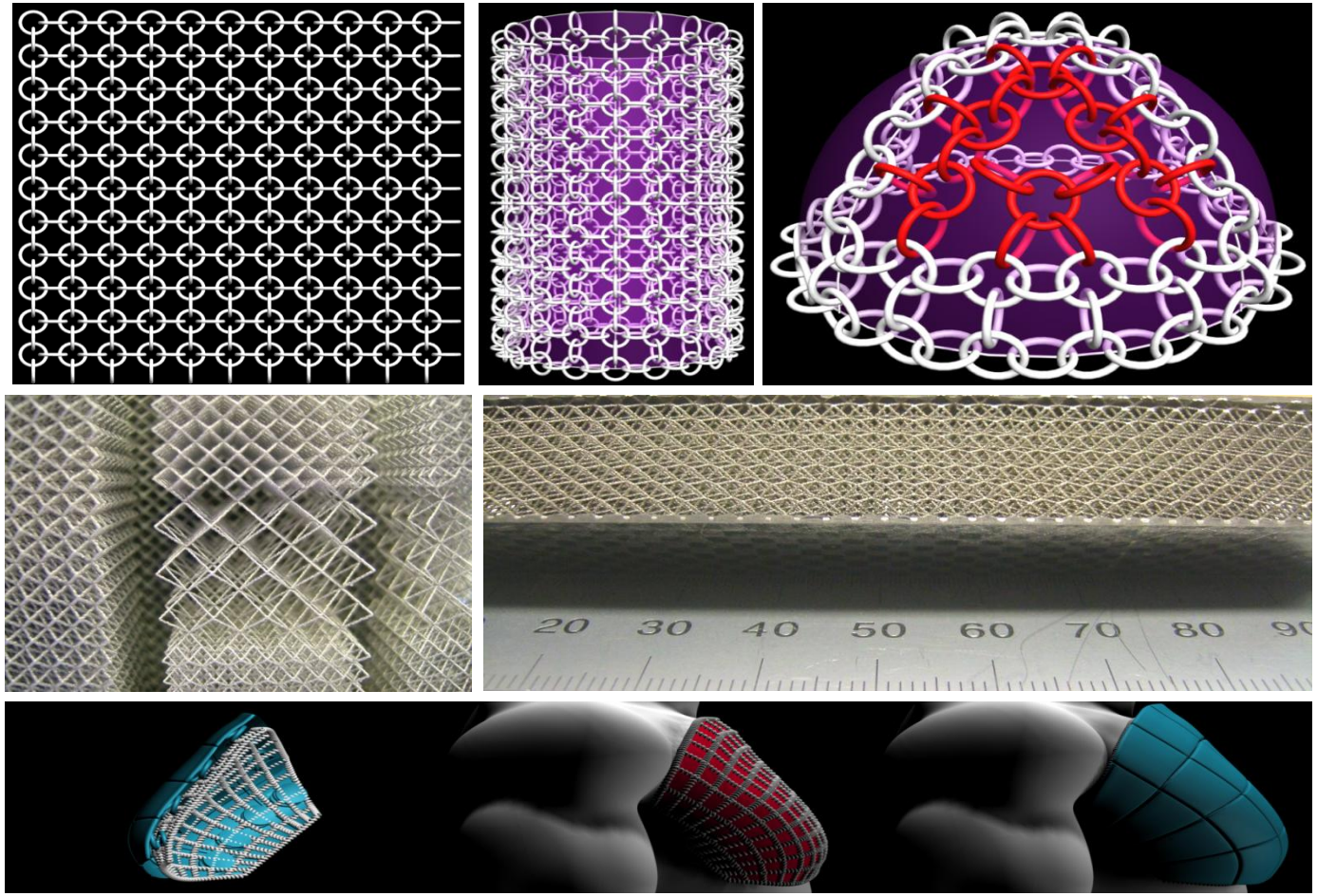
Part Count = 16 (plus glue)

(B) Component modified and consolidated for fabrication via Additive Rapid Direct Manufacture

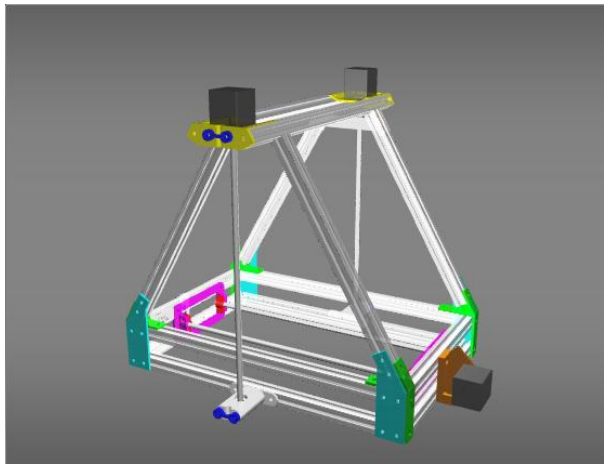
Part Count = 1

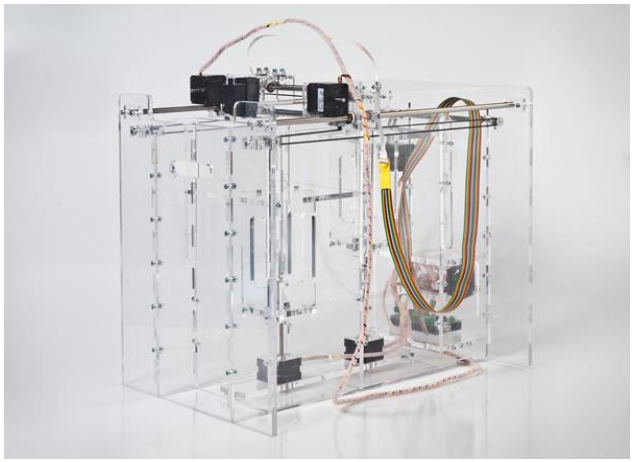


Geometry



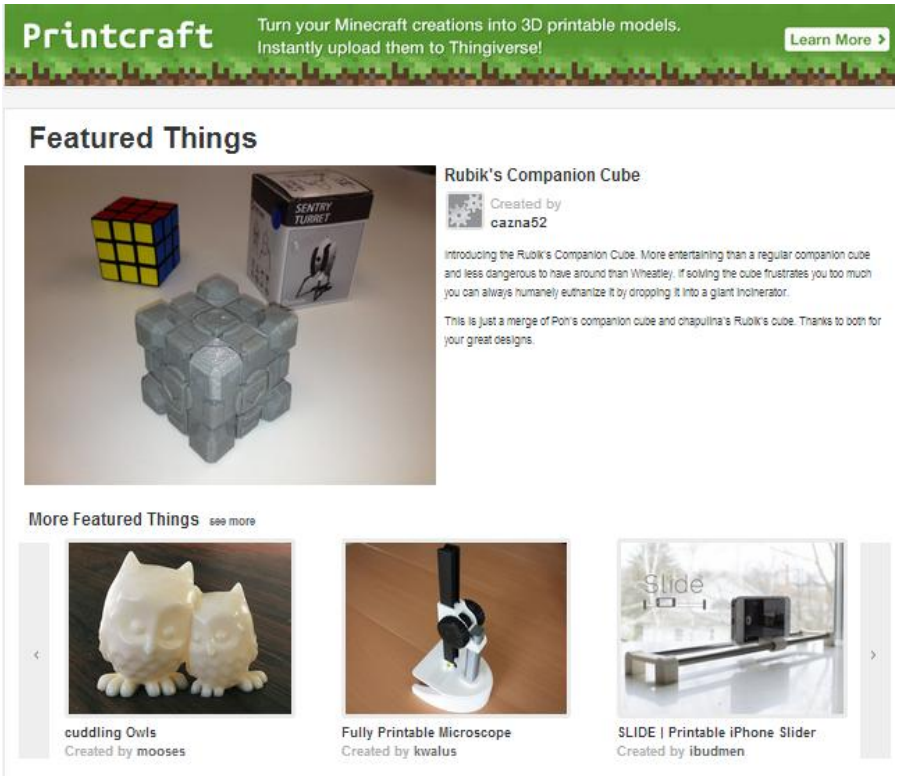
Why now? Democratised 3D Printing

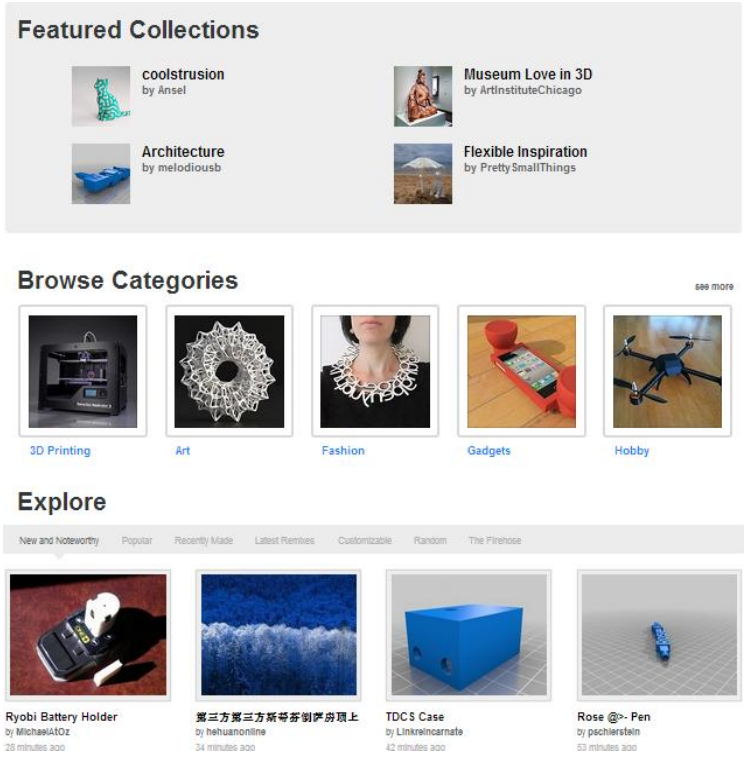




Mendel Max, PWDR, Rostock MAX, Formlabs

Thingiverse





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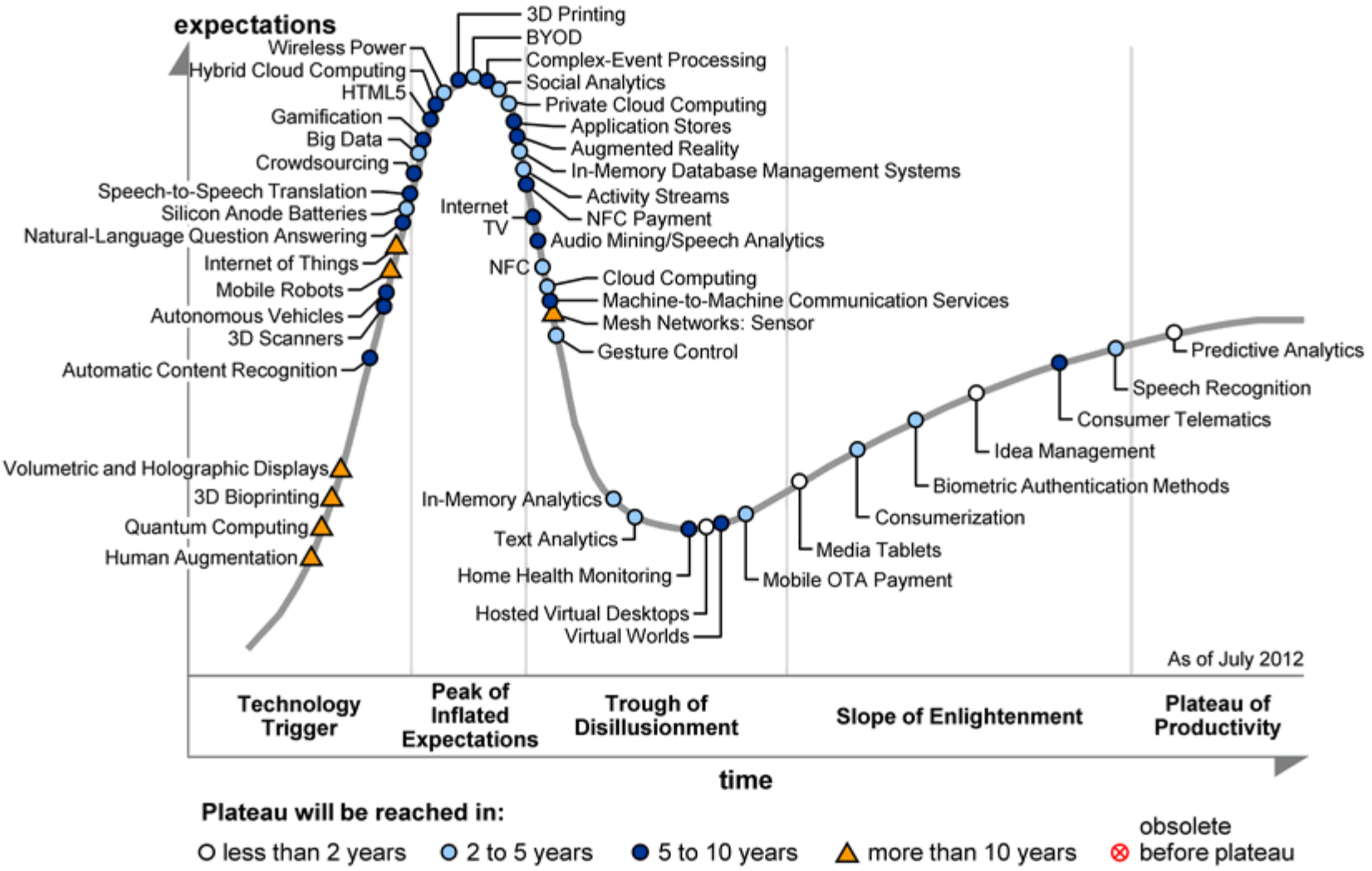
Www.thingiverse.com

Hype


expectations
Wireless Power
Hybrid Cloud Computing
HTML5
Gamification
Big Data
Crowdsourcing
Speech-to-Speech Translation
Silicon Anode Batteries
Natural-Language Question Answering
Internet of Things
Mobile Robots
Autonomous Vehicles
3D Scanners
Automatic Content Recognition
Volumetric and Holographic Displays
3D Bioprinting
Quantum Computing
Human Augmentation
3D Printing
BYOD
Complex-Event Processing
Social Analytics
Private Cloud Computing
Application Stores
Augmented Reality
In-Memory Database Management Systems
Activity Streams
NFC Payment
Internet TV
Audio Mining/Speech Analytics
NFC
Cloud Computing
Machine-to-Machine Communication Services
Mesh Networks: Sensor
Gesture Control
In-Memory Analytics
Text Analytics
Home Health Monitoring
Hosted Virtual Desktops
Virtual Worlds
Mobile OTA Payment
Media Tablets
Consumerization
Biometric Authentication Methods
Idea Management
Consumer Telematics
Speech Recognition
Predictive Analytics
As of July 2012
Technology Trigger
Peak of Inflated Expectations
Trough of Disillusionment
Slope of Enlightenment
Plateau of Productivity
time
Plateau will be reached in:
less than 2 years
2 to 5 years
5 to 10 years
more than 10 years
obsolete before plateau

So its just another manufacturing method…

- Design freedom
- No tools
- You can build anything you can draw
- You can make smart parts
- You can make them at home
- Let’s have a look what it can do now

Surgical Devices and Tools

FEATURE

By Peter Zelinski

Movable Components, No Assembly Required

A medical device maker produces a 13-piece articulating section with zero assembly work, thanks to DMLS's ability to make the free-moving section as one complete piece.

The crucial component of a medical device currently under development is a flexing, snaking, stainless steel section like the ones seen on this page. The tentacle-like section has to move with enough force and control to precisely manipulate human tissue. Assembling this small, intricate moving element has proven to be challenging, time-consuming and expensive—so what if it could be made without any assembly at all?

That is, what if this snaking metal section could simply be produced on demand, at the push of a button, with all of the freedom of motion built in? Manufacturers are used to thinking of part-making cycles producing solid pieces, not moving collections of pieces. Yet a company specializing in additive manufacturing has now realized exactly this possibility for the device, successfully "printing out" an articulating section that is both free-moving and complete, right out of the direct metal laser sintering (DMLS) machine. The accomplishment has important implications for both the end product and the medical technology company that is busy inventing it.

BaroSense is the startup company in Redwood City, California, that is pioneering this device, which will provide an endoscopic alternative to surgery affecting the stomach. The promise of this device is that physicians will be able to reach through the patient's mouth and esophagus to access the stomach, avoiding surgery and its trauma. If the small, precise, articulating section that is so vital to this device can be made without the cost of

4 — AM Supplement

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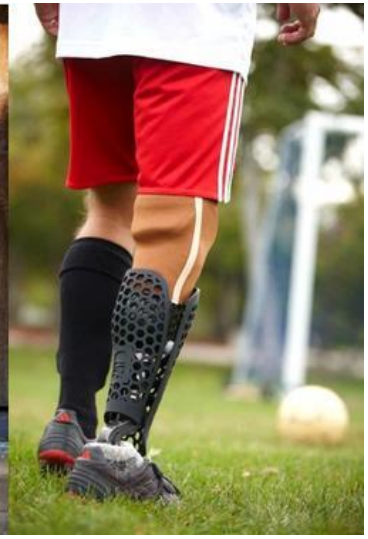
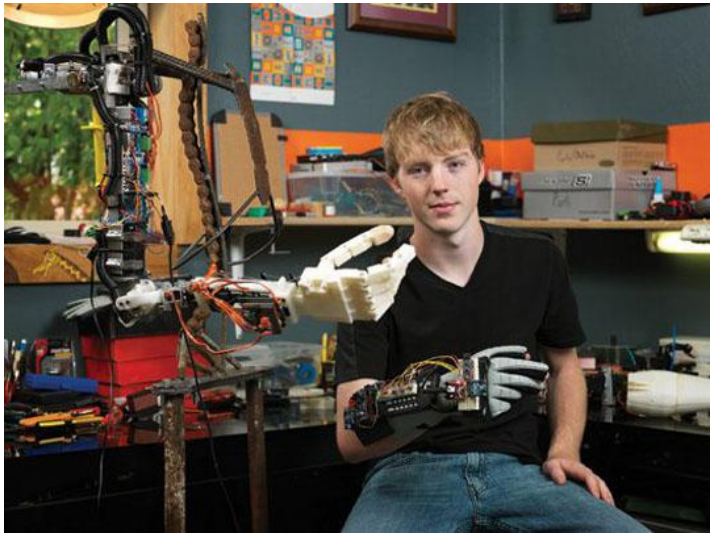
Materialse, Startasys, BaroSense 3D Systems

Prosthetics and Orthotics

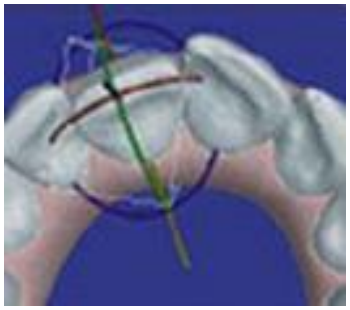





3D Systems, Popular Science, Fripp Design, Prof Kenny Dalgarno

Dentistry

Impressions are taken of your teeth by your doctor.

The impressions are used to make plaster models of your teeth.



Plaster models converted into 3D digital image.

A movie depicting the movement of your teeth from the beginning to the final position is created

All Pictures Courtesy of Invisalign www.invisalign.com

A customized set of aligners is made from these models

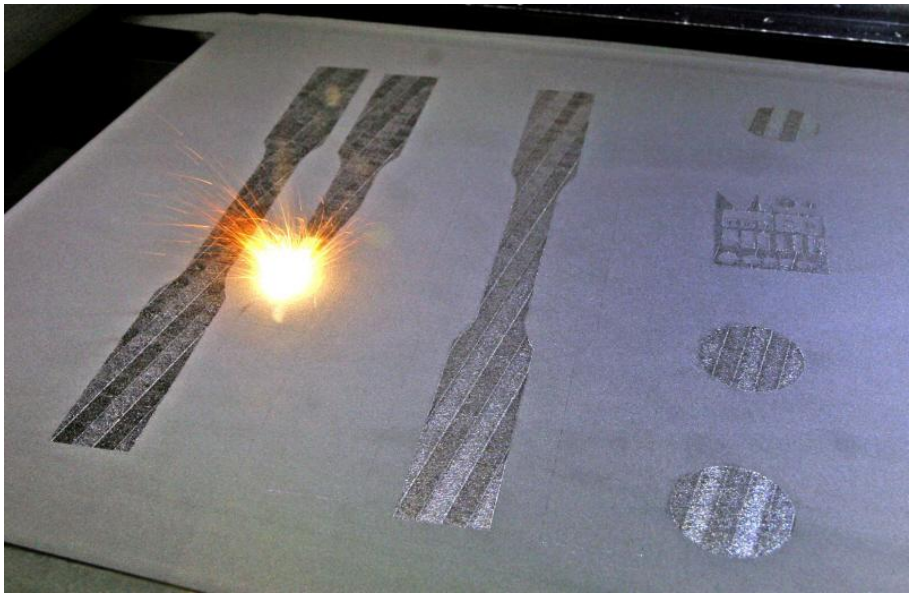
SLA is used to build models that reflect each stage of your treatment plan.

Your dentist reviews the file and if necessary, makes adjustments

Hearing Aids

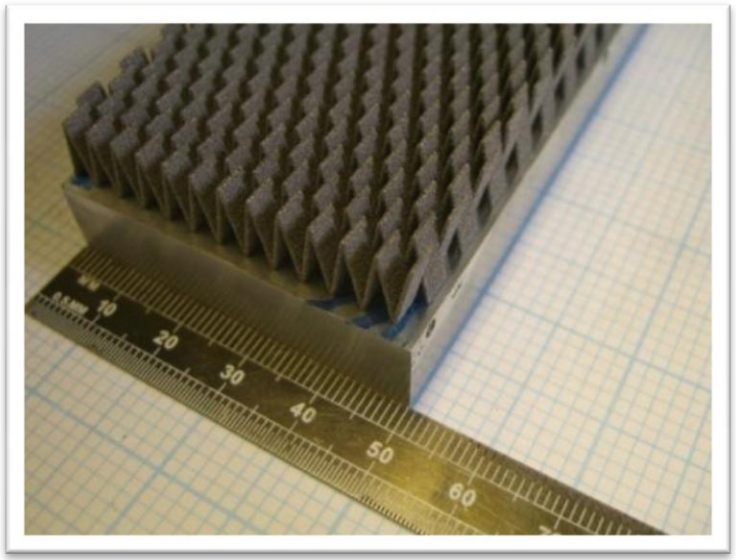
Phonak and Materialse

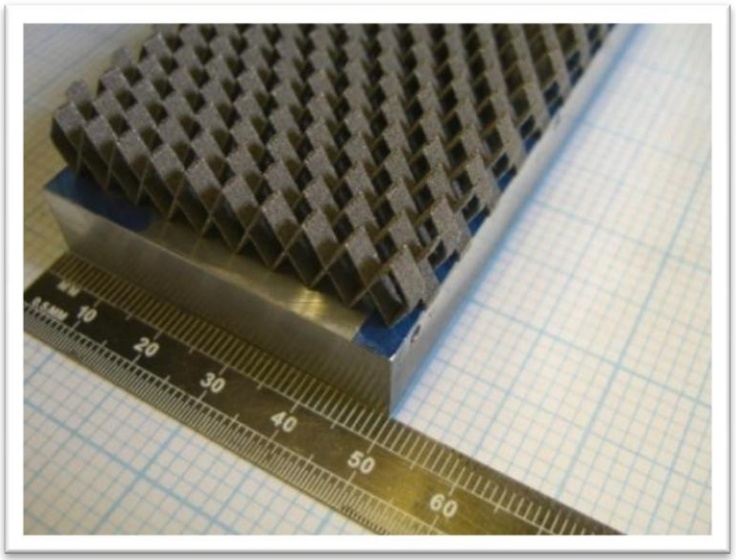
Laser Melting

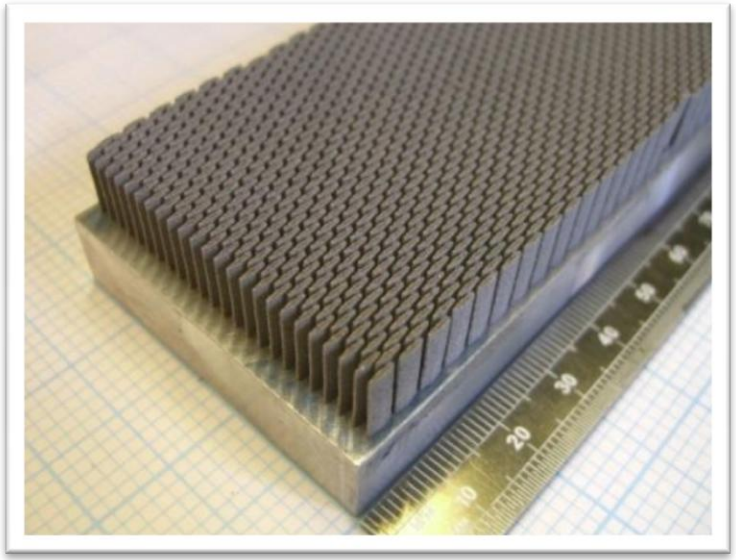


History Early Years SLM Development

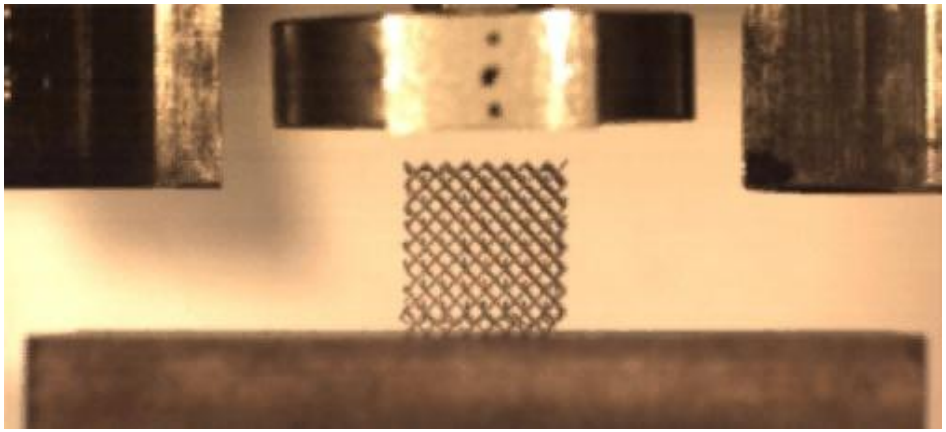
Typical Aluminium Heat Sinks



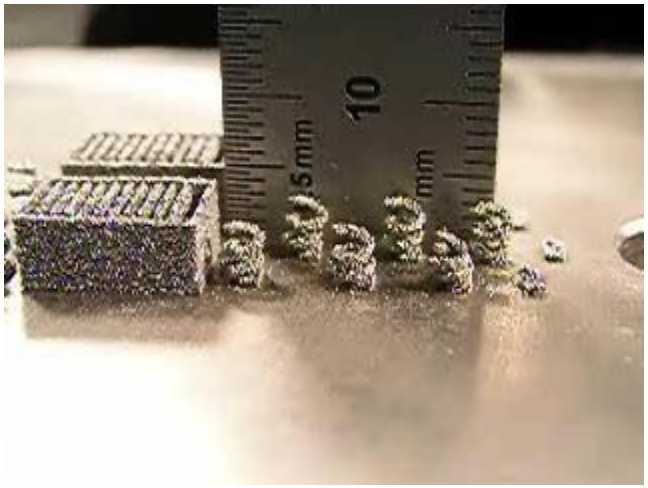




Structured components and functional materials

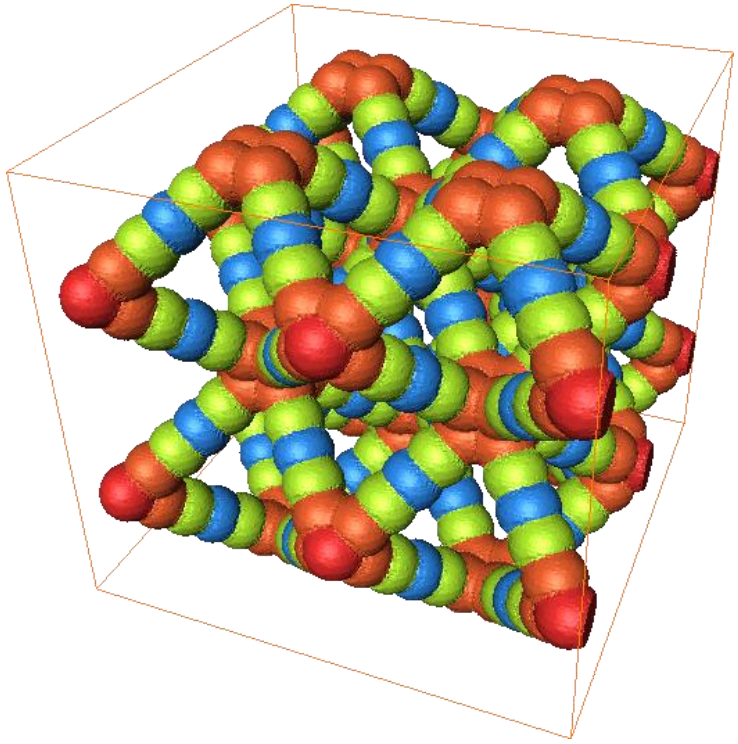


- Lightweight parts
- Medical implants
- Thermal management parts
- Substitution of solid mass to boost production
- Engineered materials
- Actuation



Implantable devices from 2000

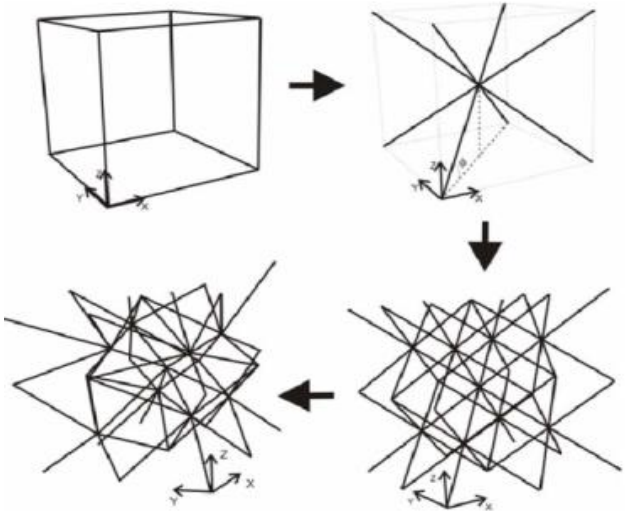
The model (reconstructed from machine input files) shows how a unit cell is constructed with each ball representing a lasered spot 6 of which form a strut and 8 struts form an octahedral shape contained in a unit cell. Many unit cells are joined together (tessellated) to form the final porous structure. There are 10's of millions of these spots in each implant.

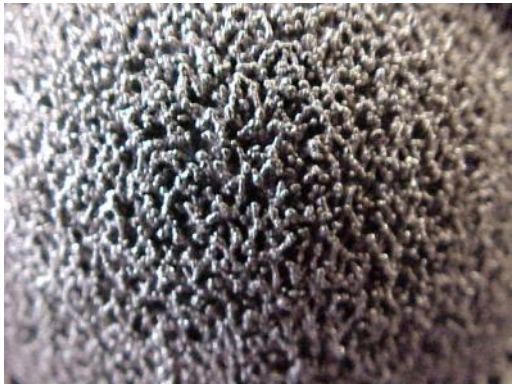


Standard CAD can not produce these structures. Our developed software techniques have or is currently being ported to commercial software

Implantable devices

- Developed software at the university
- Developed hardware at the university and with partners
- Invented techniques and know-how
- Transferred technology via out PhD cohort





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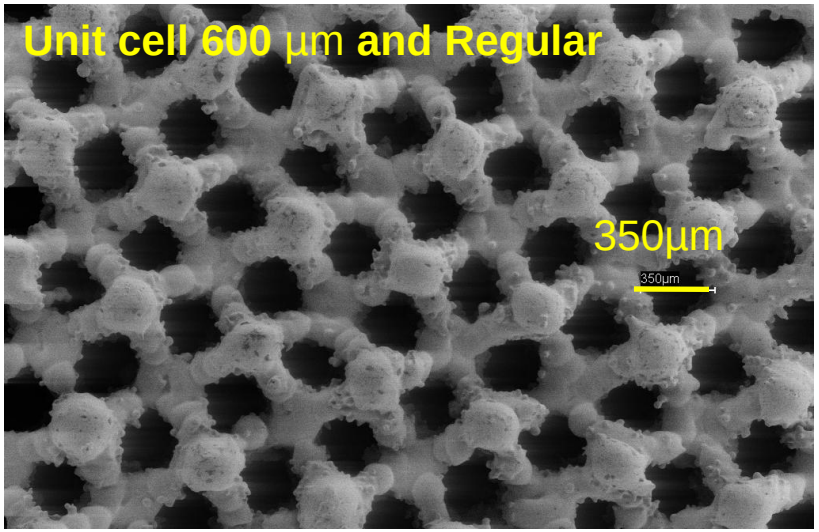
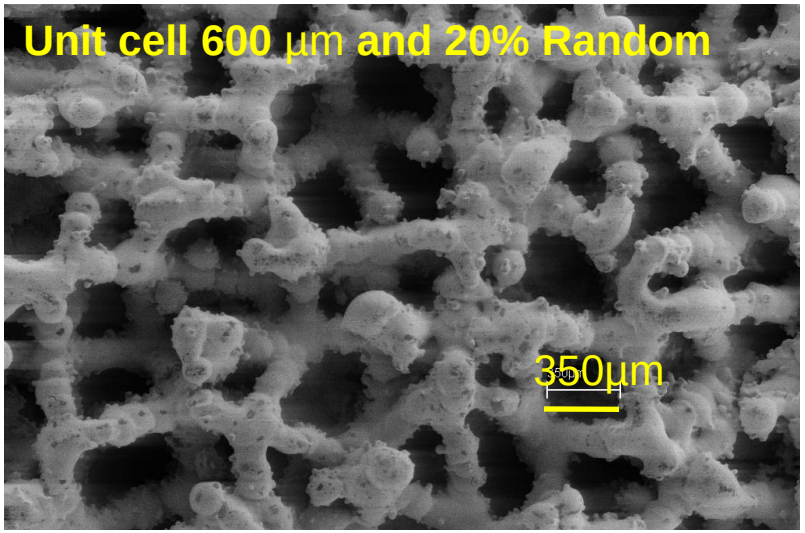
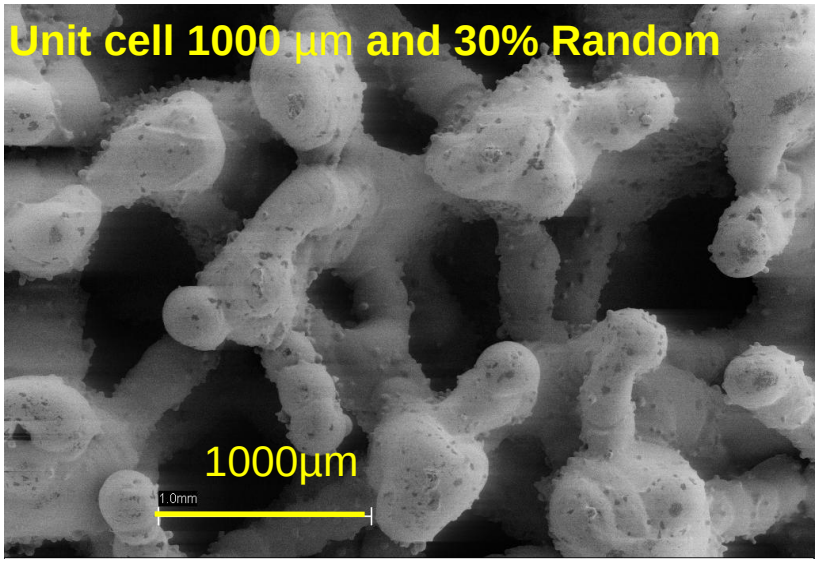
Implantable Devices

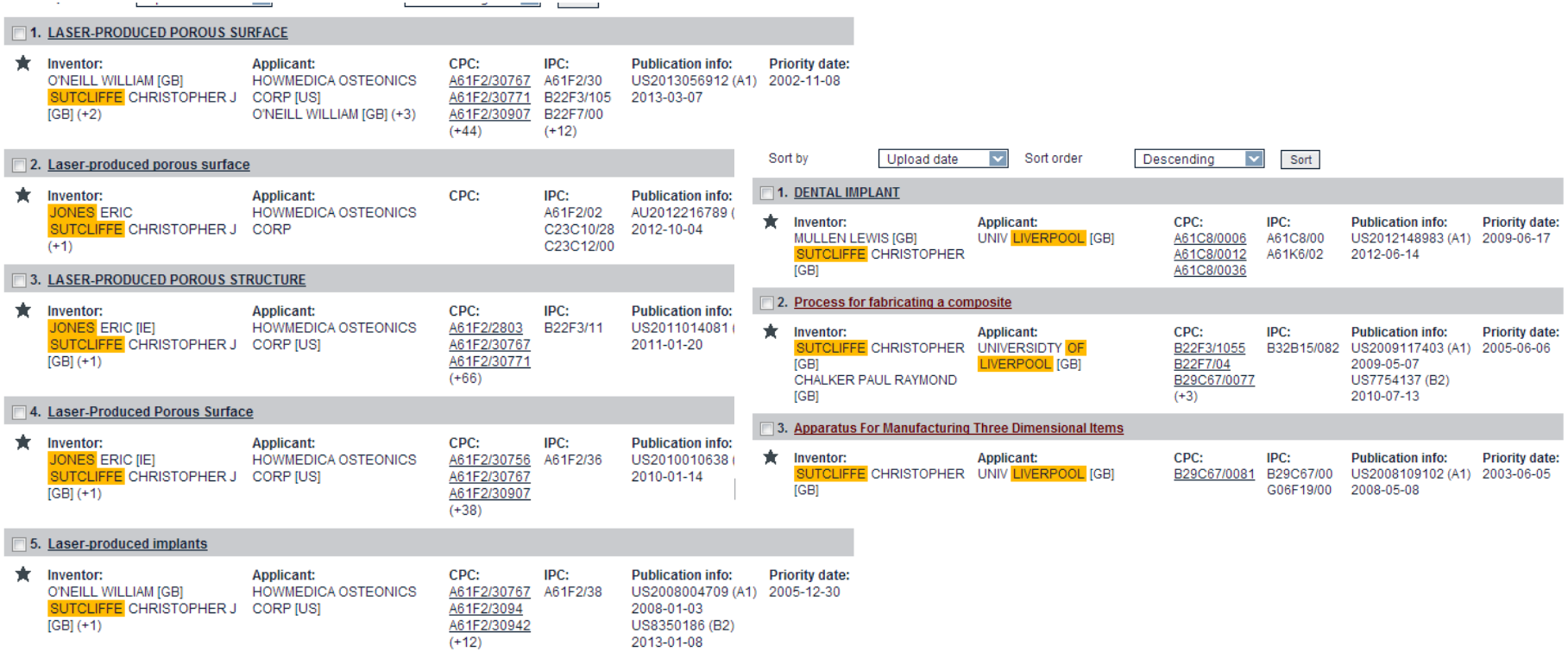






IP Portfolio

- Extensive patent portfolio of 7 families with 25 issued patents and 22 pending patents which include strategic continuations



1. LASER-PRODUCED POROUS SURFACE

Inventor:	Applicant:	CPC:	IPC:	Publication info:	Priority date:
O'NEILL WILLIAM [GB] SUTCLIFFE CHRISTOPHER J [GB] (+2)	HOWMEDICA OSTEONICS CORP [US] O'NEILL WILLIAM [GB] (+3)	A61F2/30767 A61F2/30771 A61F2/30907 (+44)	A61F2/30 B22F3/105 B22F7/00 (+12)	US2013056912 (A1) 2013-03-07	2002-11-08

2. Laser-produced porous surface

Inventor:	Applicant:	CPC:	IPC:	Publication info:
JONES ERIC SUTCLIFFE CHRISTOPHER J (+1)	HOWMEDICA OSTEONICS CORP		A61F2/02 C23C10/28 C23C12/00	AU2012216789 (2012-10-04

3. LASER-PRODUCED POROUS STRUCTURE

Inventor:	Applicant:	CPC:	IPC:	Publication info:
JONES ERIC [IE] SUTCLIFFE CHRISTOPHER J [GB] (+1)	HOWMEDICA OSTEONICS CORP [US]	A61F2/2803 A61F2/30767 A61F2/30771 (+66)	B22F3/11	US2011014081 (2011-01-20

4. Laser-Produced Porous Surface

Inventor:	Applicant:	CPC:	IPC:	Publication info:
JONES ERIC [IE] SUTCLIFFE CHRISTOPHER J [GB] (+1)	HOWMEDICA OSTEONICS CORP [US]	A61F2/30756 A61F2/30767 A61F2/30907 (+38)	A61F2/36	US2010010638 (2010-01-14

5. Laser-produced implants

Inventor:	Applicant:	CPC:	IPC:	Publication info:	Priority date:
O'NEILL WILLIAM [GB] SUTCLIFFE CHRISTOPHER J [GB] (+1)	HOWMEDICA OSTEONICS CORP [US]	A61F2/30767 A61F2/3094 A61F2/30942 (+12)	A61F2/38	US2008004709 (A1) 2008-01-03 US8350186 (B2) 2013-01-08	2005-12-30

Sort by: Upload date | Sort order: Descending | Sort

1. DENTAL IMPLANT

Inventor:	Applicant:	CPC:	IPC:	Publication info:	Priority date:
MULLEN LEWIS [GB] SUTCLIFFE CHRISTOPHER [GB]	UNIV LIVERPOOL [GB]	A61C8/0006 A61C8/0012 A61C8/0036	A61C8/00 A61K6/02	US2012148983 (A1) 2012-06-14	2009-06-17

2. Process for fabricating a composite

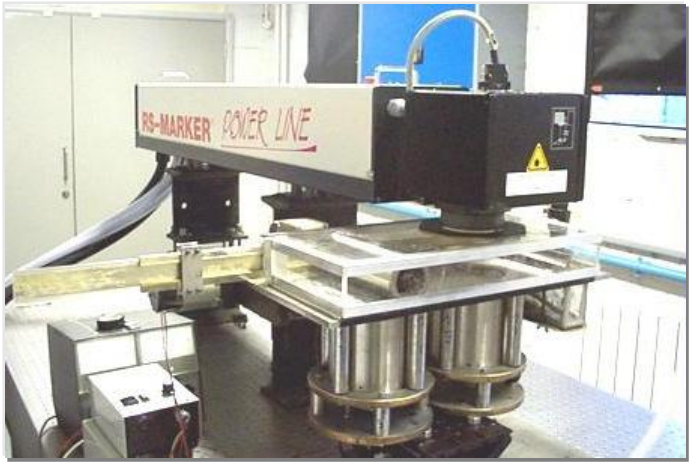
Inventor:	Applicant:	CPC:	IPC:	Publication info:	Priority date:
SUTCLIFFE CHRISTOPHER [GB] CHALKER PAUL RAYMOND [GB]	UNIVERSIDTY OF LIVERPOOL [GB]	B22F3/1055 B22F7/04 B29C67/0077 (+3)	B32B15/082	US2009117403 (A1) 2009-05-07 US7754137 (B2) 2010-07-13	2005-06-06

3. Apparatus For Manufacturing Three Dimensional Items

Inventor:	Applicant:	CPC:	IPC:	Publication info:	Priority date:
SUTCLIFFE CHRISTOPHER [GB]	UNIV LIVERPOOL [GB]	B29C67/0081	B29C67/00 G06F19/00	US2008109102 (A1) 2008-05-08	2003-06-05

Medical Parts

Machine Development



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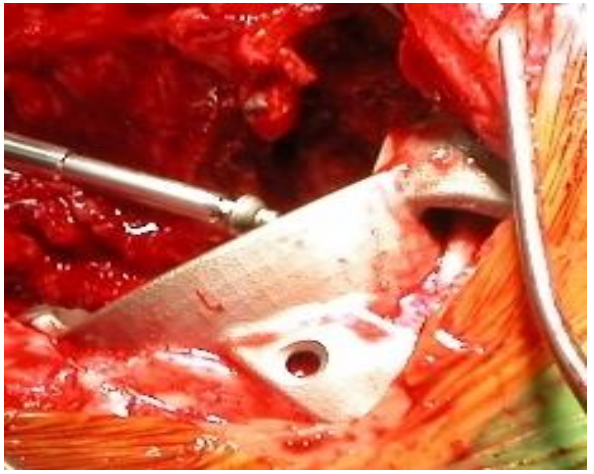
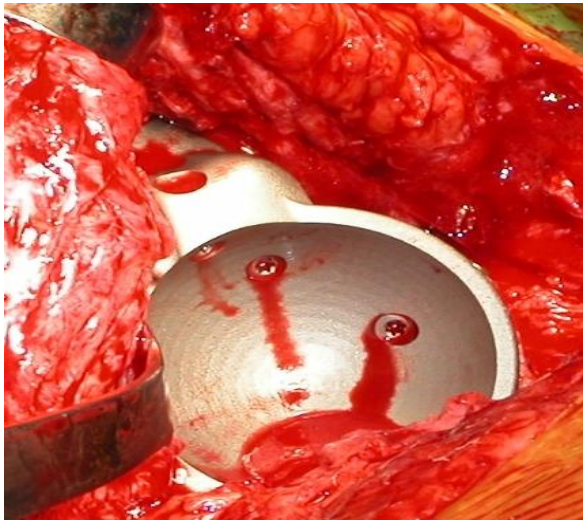
RENISHAW
apply innovation™

Implantation





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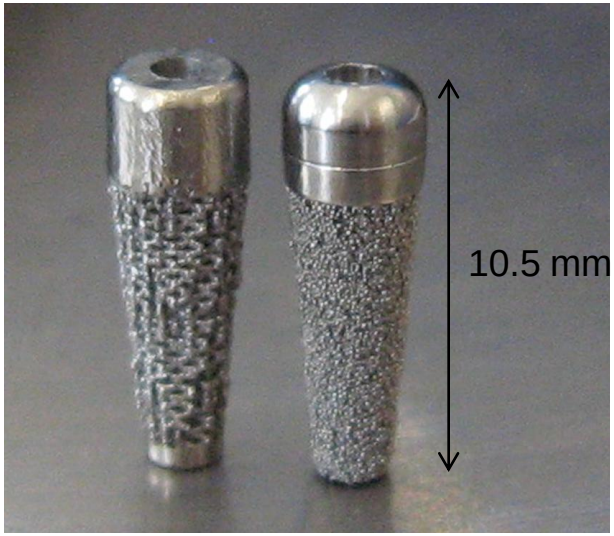
Royal Perth Hospital/MTT 2006

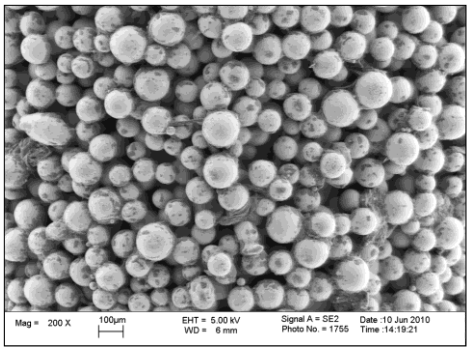
Summary

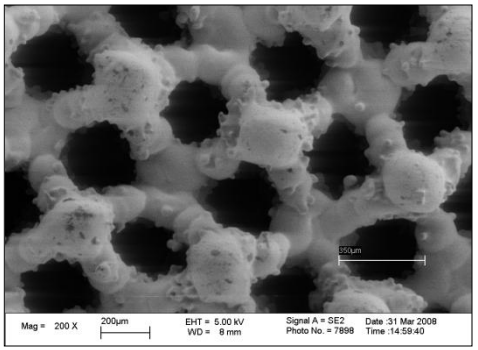
- The implants are produced from CP Grade 1 Titanium
- Constructed as an integral build of solid and porous sections
- Can have co moulded bearing surfaces
- Optimising both strength and biological performance.
- The bone ingrowth region is optimised to 65 % fully interconnected porosity
- 100-600 µm pore size distribution.
- We have 3 software tools to allow us to manufacture the parts so we aren’t reliant on commercial software
- We have a developed set of expertise to allow us to manufacture these porous devices to high (FDA) standards

In Vivo Studies



SLM implant (lhs) and Endopore (rhs)

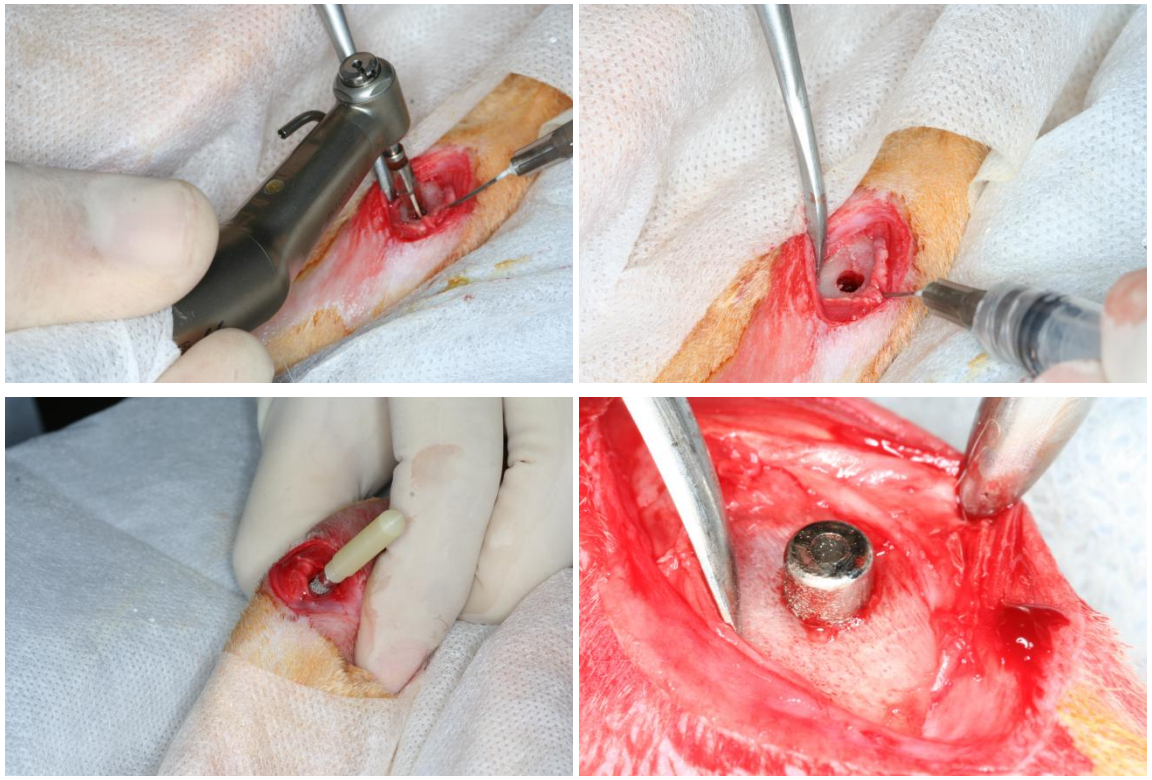




Surface characteristics	SLM	Bone	Endopore
Interconnectivity	Fully	Fully	Partially
Porosity (%)	60	60-70	35
Average pore size (µm)	200	300	100
Pore size distribution (µm)	100-300	100-600	50-150

In Vivo Studies

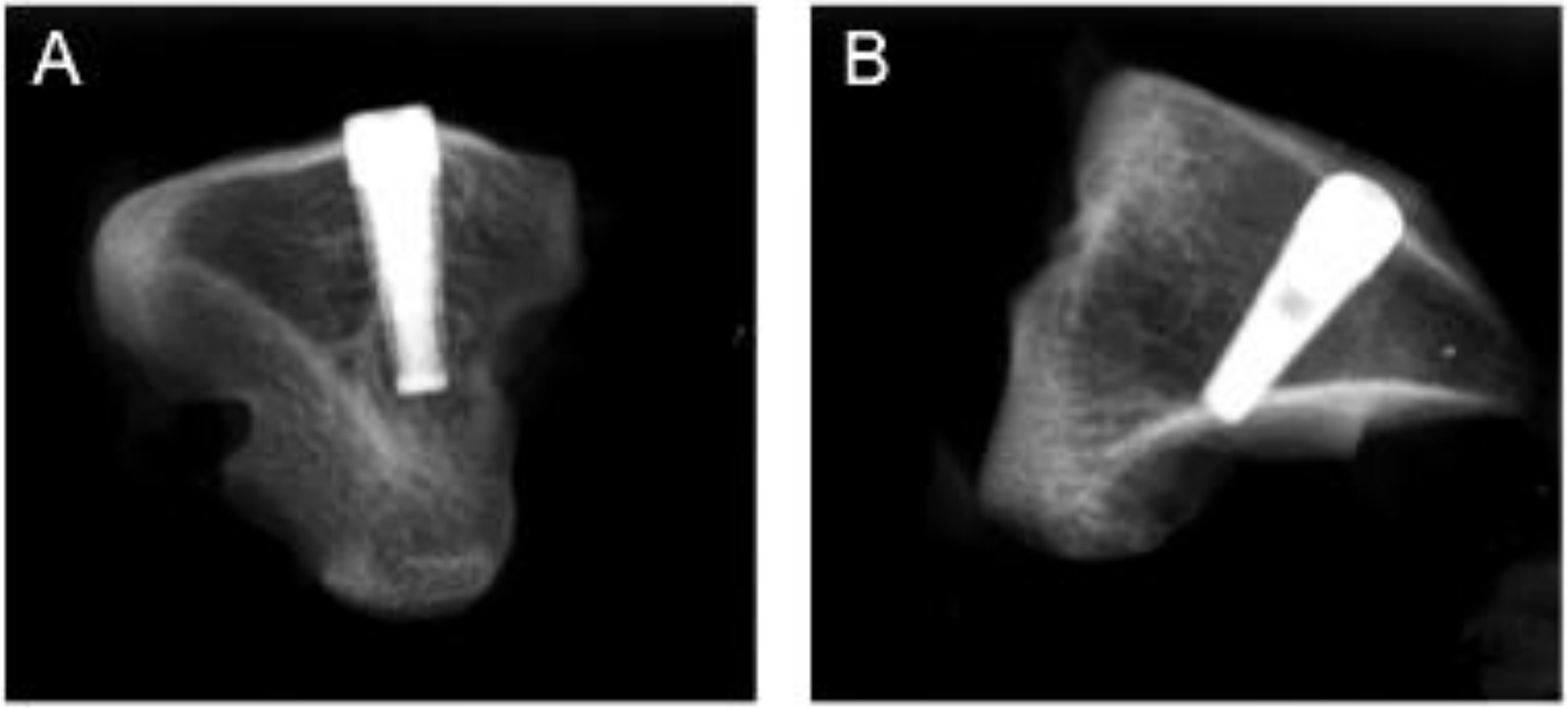
Two time periods 4 and 8 weeks



Surgical procedure for implant placement

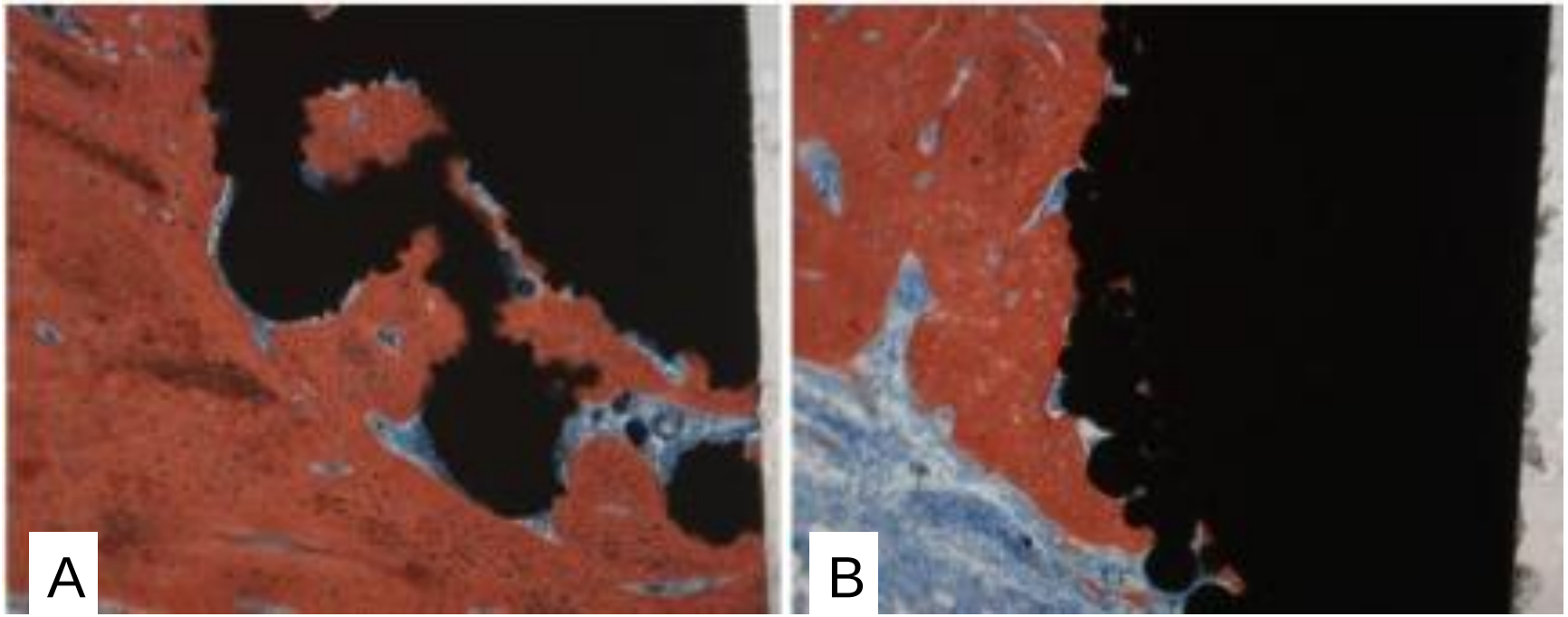
An incision was made to expose the tibia and lubricated drilling of the bone was carried out in accordance with the Endopore protocol, prior to implant placement.

In Vivo Studies



SLM (LHS) and Endopore (RHS) showing the position of the implants in the rabbit tibia.

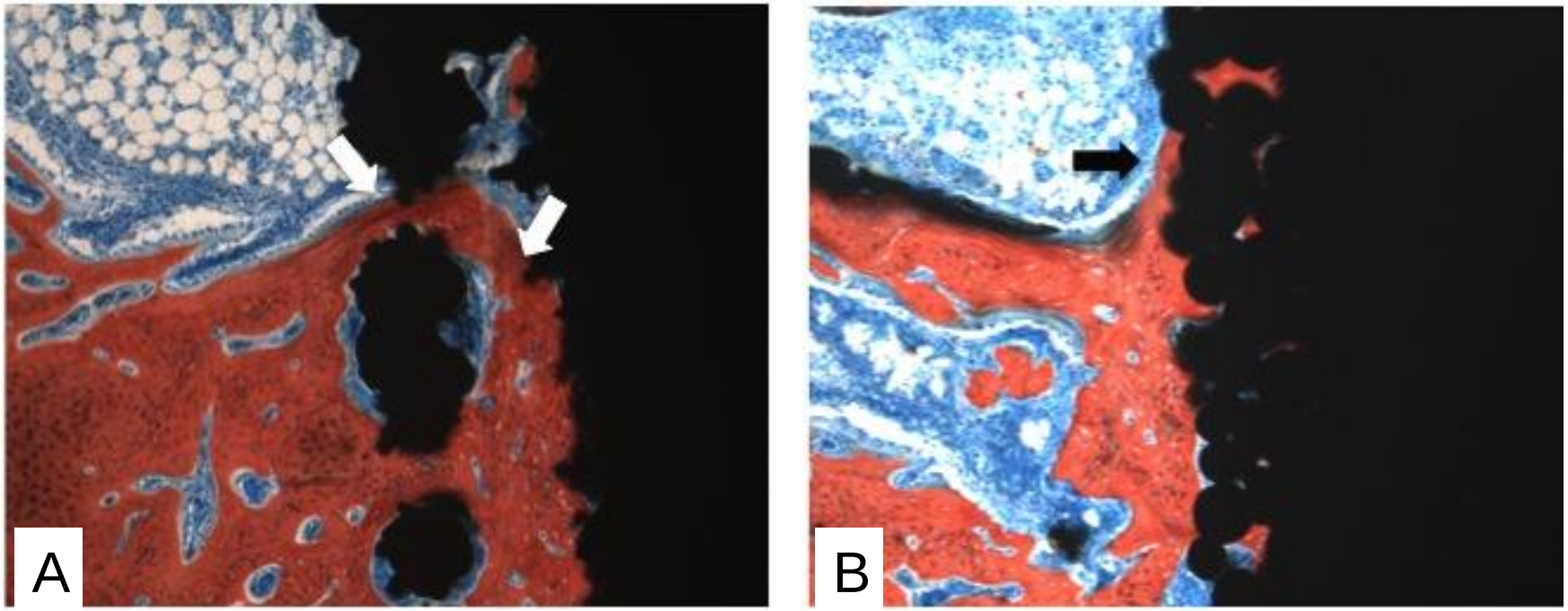
In Vivo Studies



Cross sections of SLM and Endopore implants after 4 weeks at a magnification of 20 x

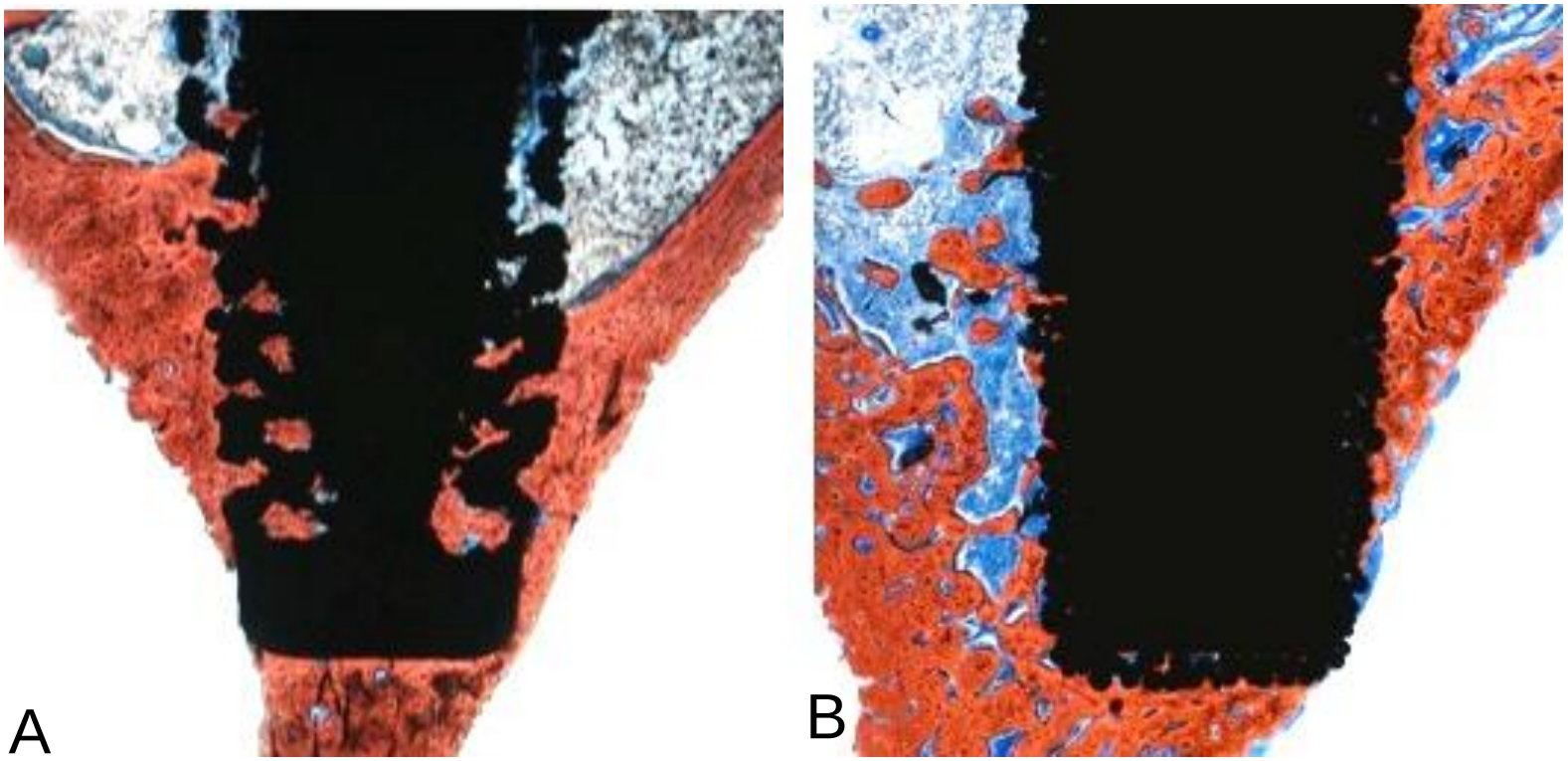
Stevenel's blue (soft tissue) and Alizarin red S (bone) staining

In Vivo Studies



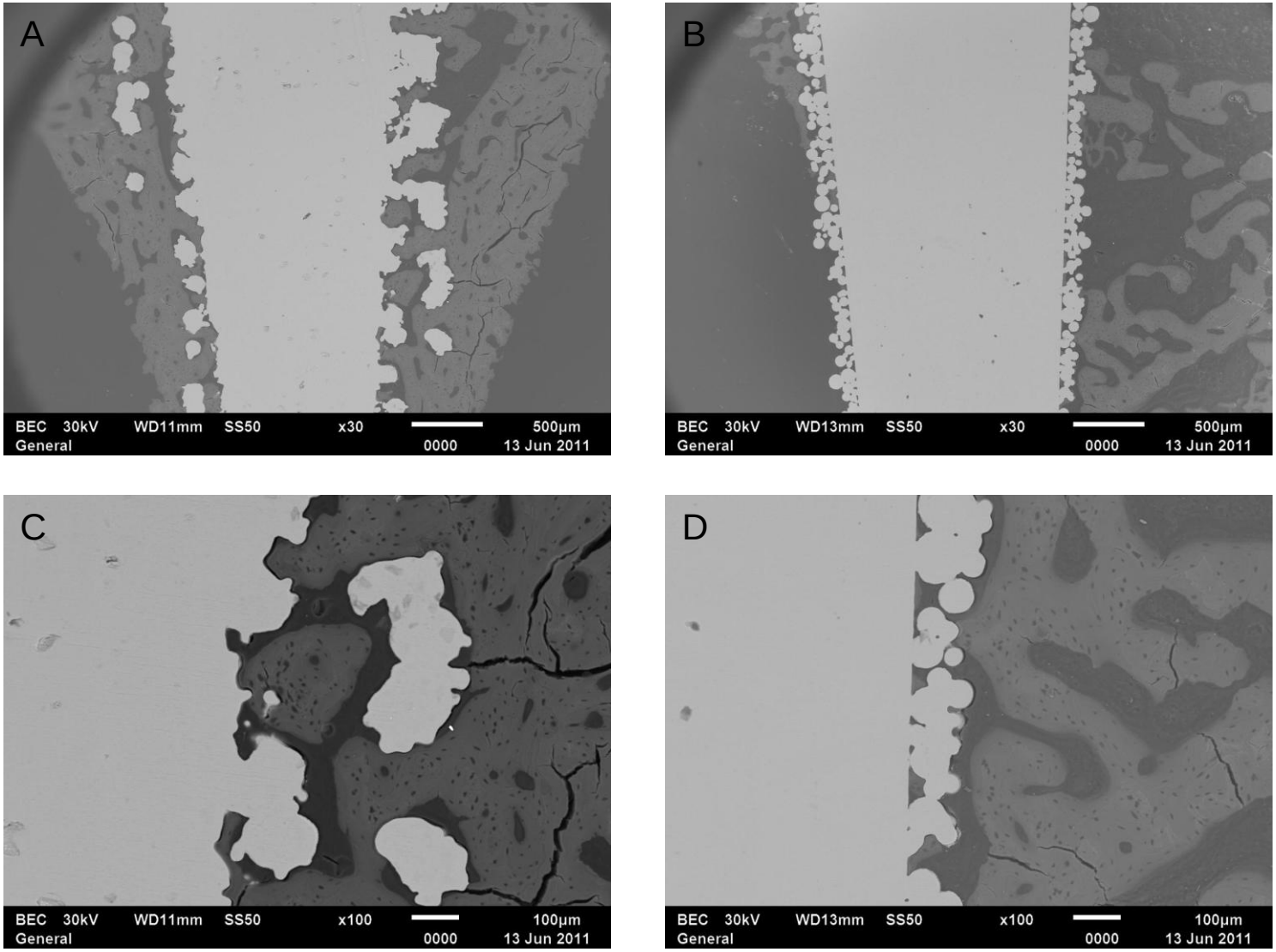
Longitudinal sections of SLM and Endopore implants after 4 weeks at magnification of 10 x

In Vivo Studies



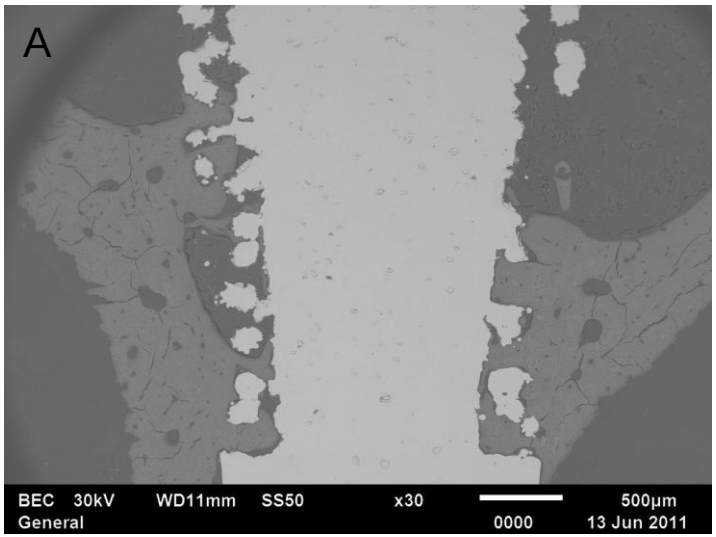
Longitudinal sections of SLM and Endopore implants after 8 weeks at magnification of 5 x.

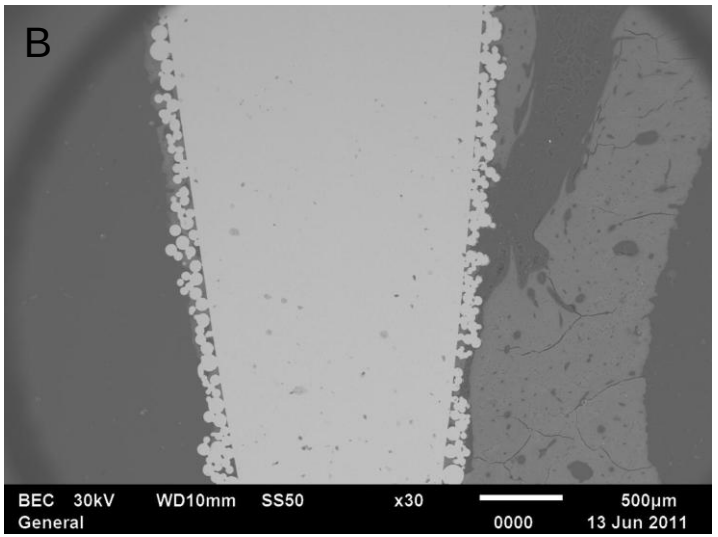
BS-SEM Bone Formation

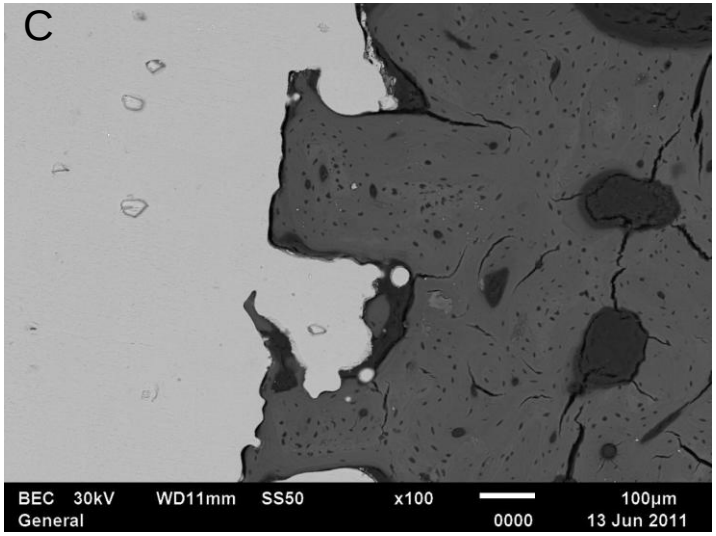


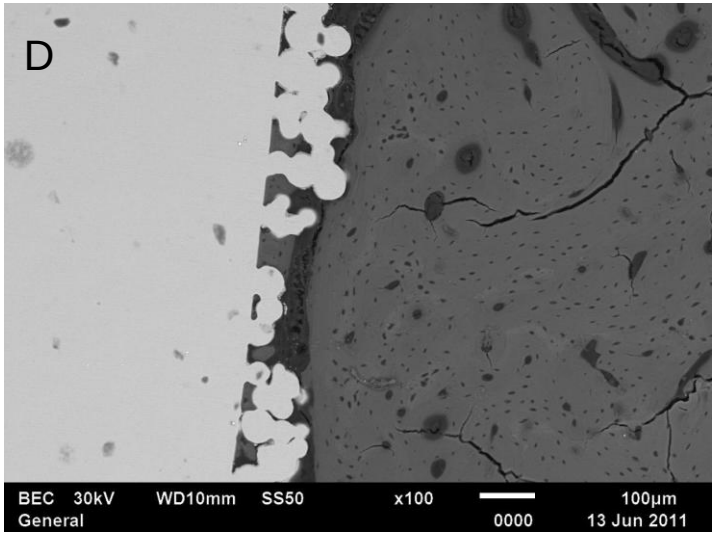
4 week SLM (a) and Endopore (b) implants x 30, SLM (c) and Endopore (d) implants x 100.

BS-SEM Bone Formation





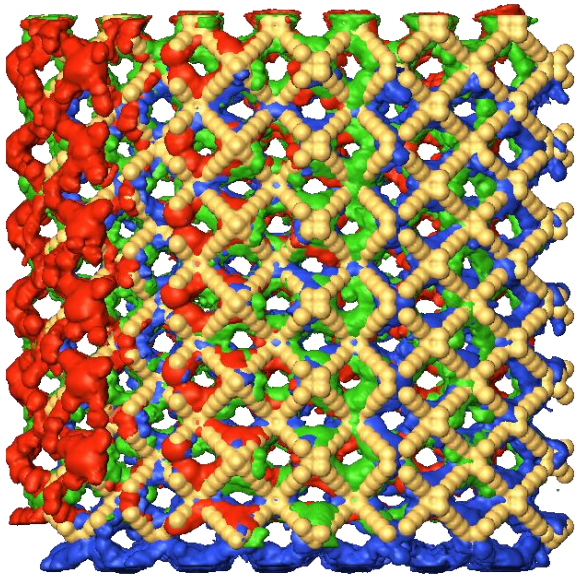


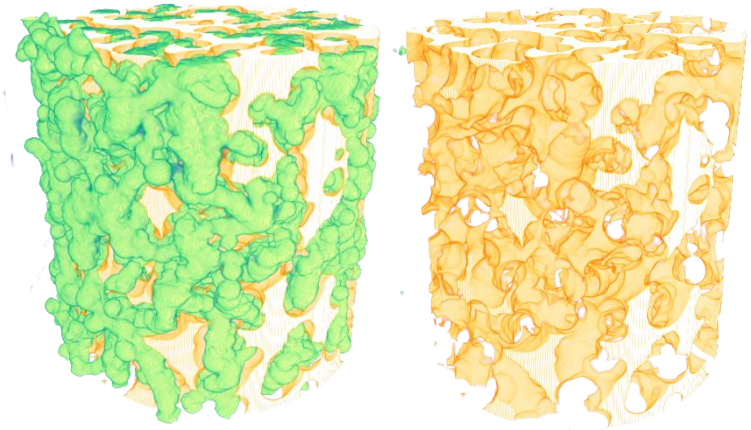


8 week SLM (a) and EP (b) implants x 30, SLM (c) and Endopore (d) implants x 100

Metrology and Process Control

- How do we improve part accuracy?
- Which measurement do we take and how do we feed the data back to the process?
- Can we use the data to inform
- Or can we use the data to control





Pore diameter > 100 µm
Volume percentage (>100 µm) = 90%

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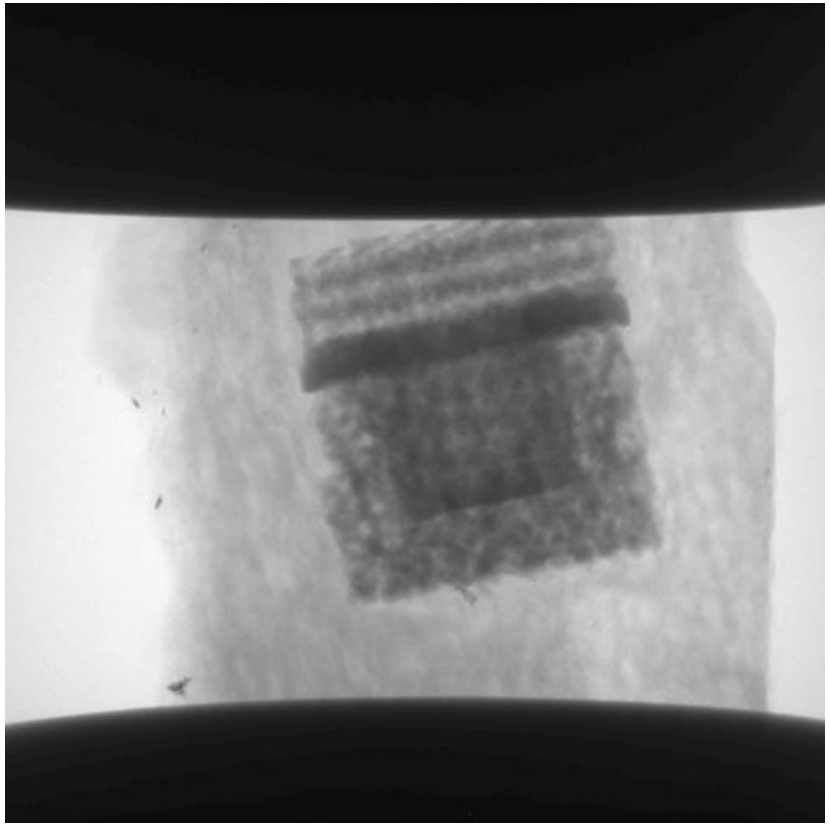
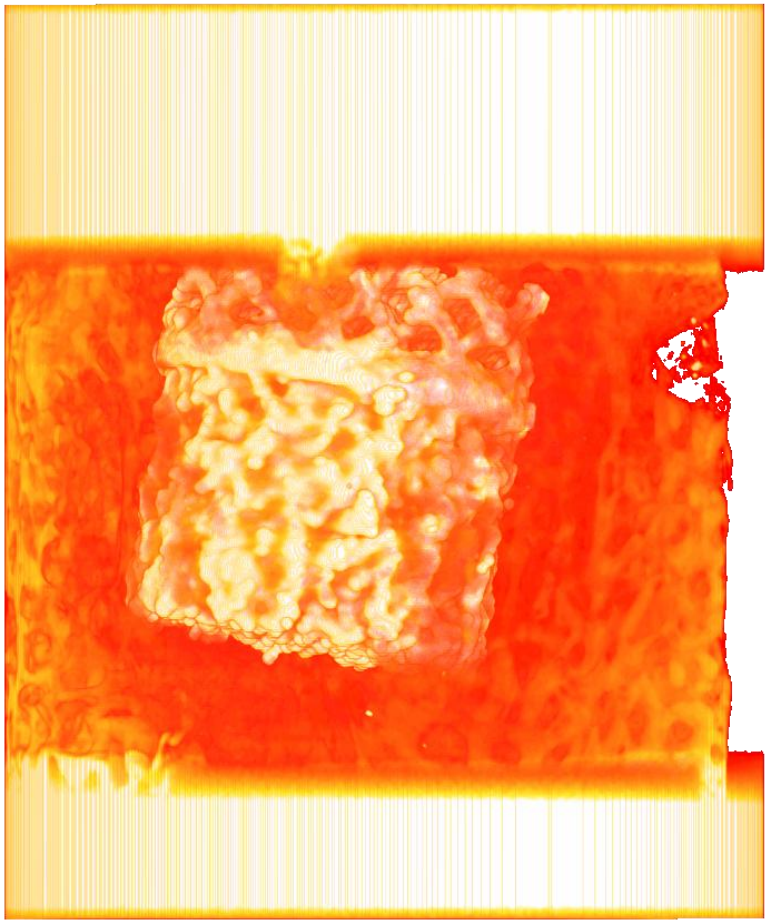
Interrupted in situ compression test





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Opportunities Exploited

Plant 5 Years ago

Opportunities Exploited

Stryker

- **3-D Printed Implants Hit The Market, Pave The Way For More Personalized Devices**
  Health News Daily – 11/04/2013

  Companies have recently started to launch implants constructed via 3-D printing to increase product customization and to save on costs. FDA says the additive manufacturing techniques are a promising form of personalized medicine. Multiple companies have recently used 3-D printing to make implantable devices that are customized to specific patients or to improve manufacturing precision and efficiency. is one large orthopedic firm that has recently starting using 3-D printing to manufacture its implants. It employed the technique for its *Triathlon Tritanium Tibial Baseplate* device, which was launched in June following 510(k) clearance. The baseplate is used with the company's *Triathlon Total Knee System* for total knee arthroplasty. The device is made using laser rapid manufacturing. Stryker CEO Kevin Lobo specifically highlighted the product and the promise of 3-D printing, particularly as a cost-saving tool, during the firm's 2013 analyst meeting on Sept. 5. 3-D printing has "really exciting potential for us," Lobo said. "The potential for significant cost savings is real, but it's an industry that's kind of in its infancy. So it will take time to play out.""3-D printing provides us with design and manufacturing flexibility, simplicity and the potential to reduce time to market" – Stryker's Patrick Treacy.

Opportunities Exploited

- Fusion Implants Ltd formed in March 2013
- Company structure set up
- Design and manufacture of veterinary devices
- Sales will comprise instruments and implants
- Online web shop
- Clean, package and dispatch from Liverpool HQ
- Develop the UK market in Y1
- Establish distribution networks in EU and US inY2
- Expand into EU and US in Y3

Opportunities Exploited

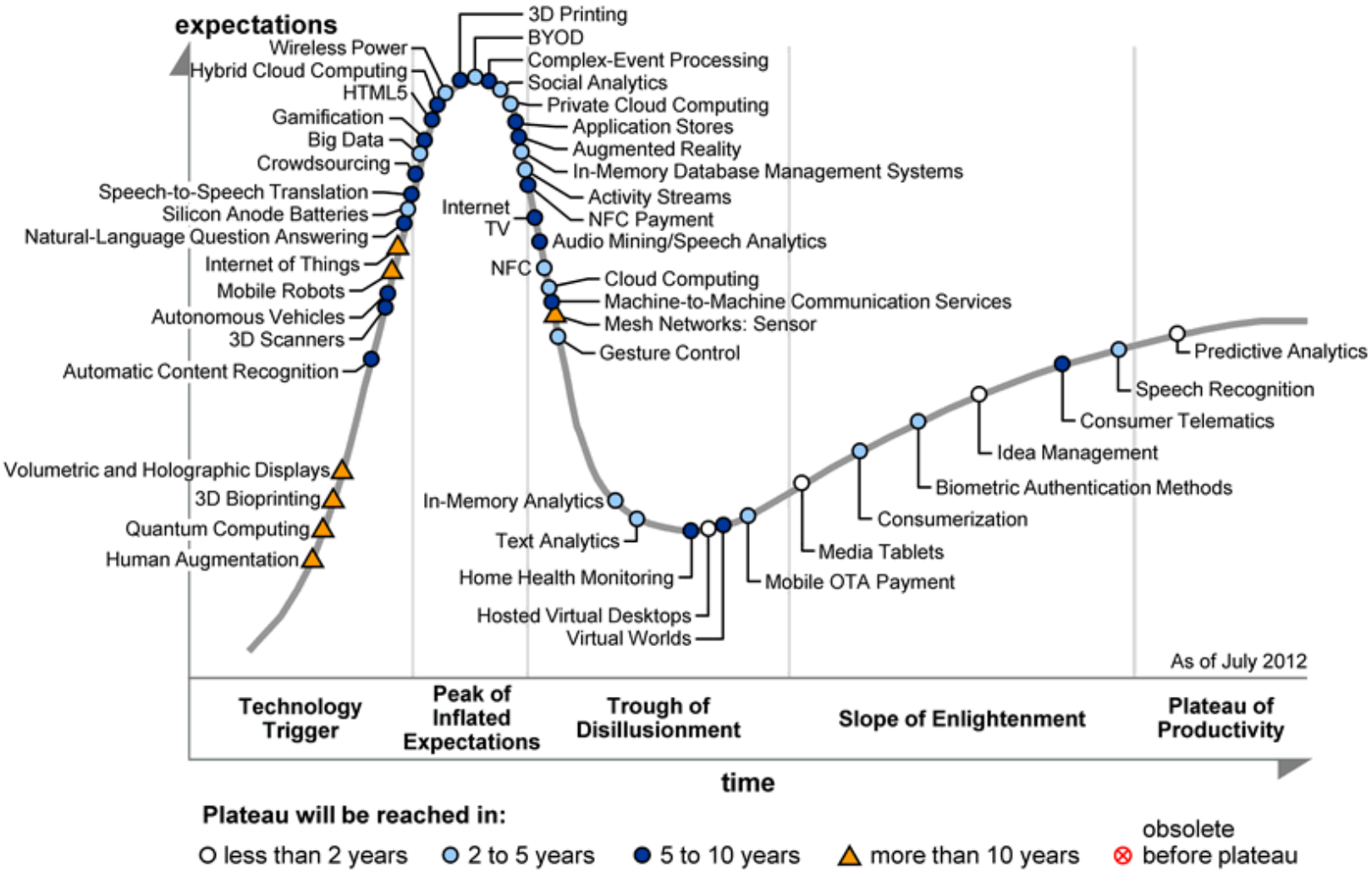
- Panel of 3 vets all highly qualified orthopaedic specialists
- Implant design development
- Process development
- “Sawbone” models
- 3 Cadaver trials
- Final design release
- Ethical approval
- Clinical evaluation
- Packaging sterilisation and delivery

Opportunities Exploited

Opportunities Available Dental Implants

- Exclusive license opportunity for a proprietary, patented method of producing **porous titanium** dental implants by Laser Rapid Manufacturing (**LRM**—generically referred to as 3D printing or additive manufacturing) co-developed by the University of Liverpool and Stryker Corporation
- Extensive patent portfolio of 7 families with 25 issued patents and 22 pending patents which include strategic continuations
- Provides the clinical advantage of initial stability through its porous titanium structure in a solid one-piece implant (not a coating)
- Unique opportunity to gain access to an enabling technology in the dental implant market leveraging expert technical experience in additive manufacturing and orthopaedic clinical experience
- Additive Manufacturing provides a capability for cost efficient future designs for implant manufacturing

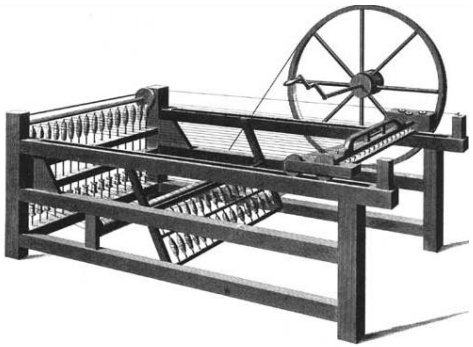
So why is that important Chris?



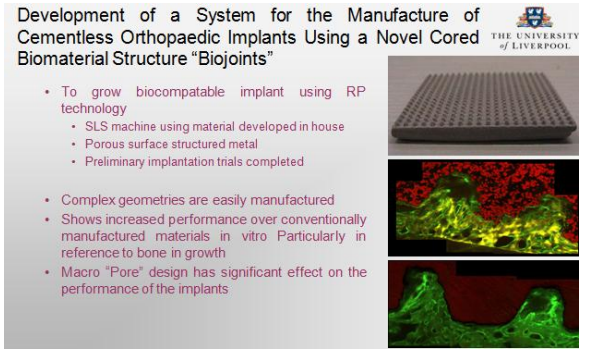
Further Comments

- Sometimes I'm a bit of a luddite.
- Next Industrial revolution…well it's the slowest one so far
- In or near the patient…let's regulate that
- Customised implants, that's the easy part the FDA are quite concerned
- Now try and make money out of it

Stanhill, Stanhill Lane c1955 Ref: S814005




This TV commercial shows a young boy ordering a football online and, after peering inside expectantly for a few minutes, catching the ball as it literally pops out of the family "fabber."
Courtesy United Parcel Service (UPS)
Via Marshall Burns Ennex Corp



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