Titanium 3D Printed Treatment of Sleep Apnoea
John E. Barnes, Director, High Performance Metals Technologies
Adjunct Professor, Royal Melbourne Institute of Technology
S. Gulizia, V. Nguyen, D. Fraser, M. Bolger, C. Hart, N. Anderson & C. Henry
International Titanium Association | Chicago | September 2014
- We pull resources from the overall pool of 5,000 dedicated employees of CSIRO.
- The HPMI Program taps into the skills of 100 CSIRO scientists and engineers.
- We strive to assist industry to be more efficient and affordable.
Background

• Oventus approached CSIRO to help with development of a manufacturing method of their novel device
• Jointly, we have developed oral appliances that provide breathing assistance – increased airflow - for people at “work, rest and play”.
• Novel = breathing port + airway = bypass obstructions
• Customised using 3D printing technology
The Need

• 60% of adult suffer from nasal obstruction
• For obstructive sleep apnea (OSA) especially moderate to severe cases, Continuous Positive Airway Pressure (CPAP) is still the gold standard
• Currently there is no appliance therapy or CPAP therapy that bypasses nasal, soft palate and tongue obstructions at the same time
• 50% of patients stop treatment in first year
• Number of OSA patients growing – serious side effects
• For mild to moderate sleep apnea oral appliances are gaining increasing acceptance.
The Solution

• Deep **Sleep-3D** – is a customised 3D printed oral appliance that *bypasses* obstructions of the mandible, soft palate, tongue and nose

• It is a combination device – a CPAP can be connected to the airway ie. patients can “graduate” to CPAP if their condition worsens or replace masks for existing patients

• It is comfortable and does not result in the jaw pain or teeth wear or teeth loosening
# Current Oral Appliance Market Size

<table>
<thead>
<tr>
<th>Region</th>
<th>CAGR</th>
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<tbody>
<tr>
<td>North America</td>
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<tr>
<td>Europe</td>
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<td>Asia</td>
<td>19</td>
</tr>
<tr>
<td>ROW</td>
<td>17.2</td>
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**Expected Market Growth ($)**

- 2014
- 2015
- 2016
- 2017
Why, Why, Why?

**Why Additive Manufacturing?**
- Design requires a complex channel that is difficult to produce – affordably - using conventional means
- Each patient’s mouth is custom fit which is a hallmark advantage of AM
- AM enables a completely new design that is customized to the individual which provides a high degree of value

**Why Titanium?**
- Corrosion resistance, Lightweight & Strong (= thin)

**Why CSIRO?**
- We run the nation’s Additive Manufacturing Innovation Centre
Additive Manufacturing Strategy

Casting & Welding
- Simulation
  - New Material Development
  - Distortion Management

Alloys + TiRO + Processing
- Feedstock
  - Novel Sources
  - Physical Modification
  - The AX - Powder Flow

Industry Engagement
- AM Network
- Build, Consult, SIEF
LAB22 – Australia’s 3DP Innovation Centre

What we’ve heard

• Over the last three years, we’ve heard industry tell us that they do not have enough need to buy a machine and no one machine will satisfy their potential requirement in the near term

What we’re doing about it

• Introducing an “innovation centre” concept where CSIRO takes the risk of acquiring equipment which does not already exist in country
• Allowing industry to access the equipment by the day, week or month
• Partner with service bureaus, services and users

When are we doing it?

• Official opening Q1 of 2015 (but we’re already open)
Topology and Design Optimisation
Design for the Process = Less Weight, Less $$
Development of Deep Sleep-3D

- Bypass obstructions of the nose that cause non-compliance
- No leakage
- Light weight, allows easier travel
- Substantially lower pressures and air flow rates needed
Clinical Strategy

• Following CSIRO campaign over 400 people have approached Oventus to be part of clinical trials

• Next trial focussing on snoring and sleep apnea currently being readied for ethics committee

• A further study is planned for moderate to severe patients with and without a CPAP
Technical and Pre-clinical Achievements

- **Product design:**
  - 3D printing ✓
  - Coating ✓

- **Patient customisation:**
  - 3D print 40 appliances at a time ✓
  - Inserts ✓
  - Software – automation from patient to 3D print

- **Testing:**
  - Clinical proof of concept ✓
  - Mechanical – in progress
  - Biocompatibility (confirmation) – in progress
  - Cleaning – ultrasonic ✓
2011 winner, Callaghan Forsyth, an Honours Industrial Design student at Swinburne University in Melbourne, VIC for his concept of an advanced radiator.

Matt Troup is the 2012 winner from the University of Canberra for his concept of the Ti Pack.

Afshin M.Hosseini, Ph.D. Candidate from Swinburne University, is the 2013 winner for his Unitized Impeller concept.

Andrew Haselgrove is the 2014 winner from QUT for his ConVert Vertebral Body Replacement System concept.
Metals by system

**TRUMPF**
- Monash
- RMIT
- Swinburne

**CONCEPT LASER**
- Monash (X1000)
- CSIRO (M2)

**v|oxeljet**
- CSIRO (VX1000)

**EOS**
- Monash (280)
- Race Dental (250)
- Breseight (270 & 280)

**SLM Solutions GmbH**
- RMIT (250HL)
- Deakin (125)
- UWA (100)
- UoW (50)
- DoD (250)

**Arcam AB**
- CSIRO (A1)

**PHENIX SYSTEMS**
- Adelaide Uni

**OPTOMECS**
- CSIRO

**SULZER**
- CSIRO
- Rosebank

**Laserline**
- Hardchrome
- Brenco
- Jarvie
- Laser Bond

**RENYSHAW**
- apply innovation

**ExOne**
- DIGITAL PART MATERIALIZATION
“Additive Manufacturing Network”

VISION – Provide an industry driven collaborative network of organisations that will foster and grow the additive manufacturing sector.

Goals & Objectives
The Ten Point Plan:

- Communication
- Knowledge
- Implementation
- Value
- Marketing
- Networking
- Research
- Partnerships
- Investment
- Sustainability

For more information, please contact:
Shane Infanti - AMTIL Chief Executive Officer
+61 3 9800 3666
sinfanti@amtil.com.au

Universities, CSIRO

3D Printing, Design, Sub Contractors, Post Processing

CRC’s, Entrepreneur Infrastructure Program

3D Printing Equipment Suppliers, Manufacturing Technology Suppliers, Software Providers

OEM’s, End Users

Additive Manufacturing HUB

Research Institutes

Service Providers

Government Mechanisms

Technology Providers

Industry Participants
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  - Chris Hart - Medical Director
  - Michael Slater - Manufacturing Director
  - Neil Anderson – CEO

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  - Stefan Gulizia, Vu Nygun, Darren Fraser, Matt Bolger & Chad Henry