

CUT Product Development and 3D Printing Units supporting industry



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Facility(ies): Centre for Rapid Prototyping and Manufacturing, Central University of Technology, Free State 20 President Brand Street, Bloemfontein, 9300 SOLITH AFRICA





Scope of Certificate:	Design, Development and Production of Patient Specific Custom Made Titanium Implants by means of 3D Printing/Additive Manufacturing. Design, Development and Production of Patient Specific Custom Made Proceparative Models, Jag, Cutting Guides in Nyion by means of 3D Printing/Additive Manufacturing. Contract Production of Titanium Implants by means of 3D Printing/Additive Manufacturing. Contract Production of Prosperative Models, Jags, Cutting Guides in Nyion by means of 3D Printing/Additive Manufacturing.
Applied Standard(s):	EN ISO 13485:2012 + AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf





DAkkS

TIN

TÜV SÜD Product Service GmbH - Zertifizierstelle - Ridlerstraße 65 - 80339 München - Germany



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Global Picture

- Metal AM Growth: Wohlers Associates (2018), reports that growth is now approaching exponential.
 - 875% growth in the past five years;
 - 220% growth in the past two years alone.
- Boeing reported that they have 20 sites producing metal parts and that there are over 60,000 AM parts currently in their deployed aircraft.
- GE reported that they have over 1,200 employees operating 1,300 AM machines resulting in over 50,000 parts to date.
- Over 1,000 on-going Metal AM projects are directed at what GE believes is a \$76 billion market opportunity in the next eight years.
- Stryker just finished building a state-of-the-art facility to address growing opportunities in the medical industry and already has over 100,000 Metal AM implants in patients.

Global Picture – FoF / 4th IR





CENTRE FOR RAPID PROTOTYPING AND MANUFACTURING Established in 1997

- CRPM Annually manufactures around 15 000 AM parts as part of >500 projects
 - Have 750 commercial clients
 - Support industries in New Product Development
 - Going from CAD to prototypes and end-use products



LASER MELTING AS PART OF 3D PRINTING

















AM TECHNOLOGIES AT CRPM

- EOS P380
- EOS P385
- EOS P396
- EOS S700



- EOS M280 200W (Ti64)
- EOS M280 400W (MS1)
- EOS M250 Extended
- OBJET CONNEX 350

PLASTIC LASER SINTERING

SAND LASER SINTERING

DIRECT METAL LASER SINTERING



WHY AM FOR MEDICAL APPLICATIONS?



Internationally many reports by large corporations showcase the benefits of Additive Manufacturing (AM), or better known as 3D printing, for healthcare. Aspects like *reduced theatre time* using 3D printed implants, cutting/drill guides and pre-operative planning models are elaborated on. The reduced theatre time has a ripple effect on *faster patient recovery time*.

A particular report by Deloitte called "3D opportunity in medical technology - Additive manufacturing comes to life" highlights how **customization of medical devices** manufactured by 3D printing improves clinical efficacy with better fitting implants at a lower cost.

Large companies like Smith & Nephew, Lima Orthopaedics and 3D Systems realised these advantages and are setting up large 3D printing manufacturing centres that are mass-producing implants and other devices.

Currently 95% of medical devices in South Africa are imported (SAMED 2014 report), which presents an opportunity for localisation, reduced cost and access for more patients to the benefit these provide.

Glenn H. Snyder, Mark Cotteleer, Ben Kotek; 3D opportunity in medical technology, published 28 April 2014 on Deloitte website: https://dupress.deloitte.com/dup-us-en/focus/3d-opportunity/additive-manufacturing-3d-opportunity-in-medtech.html South African Medical Device Industry Association report on The South African Medical Device Industry – Facts. Accessed on 4 October 2017 www.samed.org.za/DynamicData/LibraryDownloads/224.pdf

IMPROVING LIVES



Dr. K. Hoek Dr. W. Hoek



3D PRINTED IMPLANTS



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PRINCESS MOSHOANA



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Princess Moshoana (29) delivers a testimonial at the *Changing faces, changing lives* day at Central University of Technology (CUT).











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WHAT DO YOU DO IF YOU DO NOT HAVE ACCESS TO GUIDED SURGERY TO REMOVE CYST BEHIND AN EYE?







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7-year old girl with cyst behind right eye Possibility of loosing sight within 14 day window





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MAXILLARY PATIENT



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- Female patient with Myxoma of the mid-facial region (Kimberley)
- Customised mid-facial implant design Materialise software
- Customised LS mid-facial implant in TI64
 printed on EOS M280
- Maxillary frame designed to restore facial profile and symmetry
- Placement of obturator and dental bar restored mastication and speech functionality









State patients – June 2017



PATIENT 3

PATIENT 4



PATIENT 5

Acknowledgements





CARE

IMPLANT

3D PRINTED TITANIUM IMPLANT

3D VIRTUAL MODEL























FOLLOW-UP: 6 MONTHS













https://www.youtube.com/watch?v=nLKksq2ZSwM





MANDIBULAR IMPLANT



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MANDIBULAR IMPLANT



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Customised Pelvectomy



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Acknowledgement Prof George Vicatos (UCT)









Customised Ankle Implant



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FACIAL PROSTHESIS



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AURICULAR PROSTHESIS - 8



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IMPACT OF 3D PRINTING



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NEW INNOVATIONS





NEW APPLICATIONS



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NEW PARTNER







NEW APPLICATIONS



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3D PRINTED SPINAL CAGES



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NEW APPLICATIONS



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PATIENTS ON WAITING LIST



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Qualification of Additively Manufactured Medical Implants







National Collaborative CPAM Resource Network



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Qualification Process Chain Generating Validation Data



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CENTRE FOR RAPID PROTOTYPING AND MANUFACTURING



CRPM Strategic Focus within CPAM







ISO 13485 CERTIFICATION



- The centre received ISO 13485 certification for 3D printing
 of medical devices in 2016
- This is a quality management system which is only granted after a rigorous audit of all processes. This means that the products produced at the centre conform to the International Standards and accreditation
- This will open the doors for commercial manufacturing of medical devices here in South Africa and also offer global export opportunities





Scope of Certificate



- Design, development and production of patient specific custom made titanium implants by means of 3D Printing/Additive Manufacturing
- Design, development and production of patient specific custom made preoperative models, jigs, cutting guides in nylon by means of 3D Printing/Additive Manufacturing
- Contract production of titanium implants by means of 3D Printing/Additive Manufacturing
- Contract production of preoperative models, jigs, cutting guides in nylon by means of 3D Printing/Additive Manufacturing





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THE NEWLY ESTABLISHED DSI & CUT FUNDED:



Bridging the Innovation Chasm in the Medical Device Industry through Additive Manufacturing



MEDICAL DEVICE ADDITIVE MANUFACTURING TECHNOLOGY DEMONSTRATOR



Central University of Technology is the leading South African university in the application of AM for the design and production of customised medical implants. For South Africa to compete internationally, the local medical device industry needs to be supplemented with the latest technology, infrastructure, expertise and skills. This can be aided by a technology demonstrator for additive manufacturing of medical devices.

It is envisaged that MedAdd will:

- enhance the current equipment and capabilities at CUT enable CUT, academic partners and local companies to demonstrate reproducibility and scale-up of innovative medical device products. be available for small companies to industrialise new products, de-
- risking their innovative development before fully-fledged commercialisation. enable students, researchers and industry personnel to develop the
- enable students, researchers and industry personnel to develop the required skills for the development of this new technology and new industry.

Success will be achieved through a comprehensive approach, using a combination of conventional and AM techniques. Initial Key Performance metrics are:

- research, development and manufacturing of medical devices;
- training of users; and
- stakeholder engagement.

Established Key Performance metrics are to:

- assist companies; and
 - to create new joint-venture companies.

Engagement with other initiatives, such as the Cape Health Technology Park, South African Medical Technology Industry Association, Medical Device Manufacturers of South Africa and the National Medical Devices and Diagnostic Technology Innovation Cluster, will ensure that MedAdd can have a national impact.

www.cut.ac.za =

Applications	Number of products/units												
	Current	nt 2019		2020		2021		2022		2023		Total	
		Product/Projects	Units	Product/Projects	Units	Product/Projects	Units	Product/Projects	Units	Product/Projects	Units	Product/Projects	Units
Maxillofacial	20	20	50	25	60	30	75	40	90	50	110	165	385
Orthopaedics	7	100	500	200	1000	250	1250	300	1500	350	1750	1200	6000
Dental	0	10	20	25	50	50	100	75	150	100	200	260	520
Other	25												
(assistive		50	100	60	200	72	300	87	400	103	500	372	1500
devices etc.)													
Total	52	180	670	310	1310	402	1725	502	2140	603	2560	1997	8405
Definition		Product/Project: Each instance mentioned below counts as one											
Product	Develop	ment	of a pi	roduct									
Product	Redesign of existing product after extensive testing (new version)												
Project	Patient-specific case for example <i>maxillofacial and dental applications</i> (1 project, but consists of multiple units)												
Product	Product that is being reproduced for commercial sales												
Product	Contract to manufacture specific components or provide a high level service for a medical device product (tube processing for external manufacturer, CNC milling of implants or devices, 3D scanning of patients or implants, ect.)												
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Table 6: Estimated number of implants/devices to be manufactured over the next 5 years

Table 8 shows the expected numbers of users trained for the first five years after the establishment of MedAdd. In order to estimate these numbers, the following assumptions have been made:

- Training will cover aspects such as design for AM, application (part orientation, support generation), machine operation and post processing;
- Training will be in the form of short courses, workshops and experiential learning.

In addition, it should be noted that additive manufacturing forms part of newly developed Honours degree in Advanced Manufacturing in Mechanical Engineering. These students are not included in the numbers below.

User	2019	2020	2021	2022	2023	Total
Students (CUT)	20	30	40	45	50	185
Student and interns (other)	10	15	20	20	20	85
Researchers	20	25	25	25	25	120
Industry – engineers and clinicians	10	20	35	50	50	165
Total	60	90	120	140	145	555

Table 8: Estimate of users trained

The numbers of users trained is a key measure of impact for the facility. This facility will be unique in South Africa and in order to build a thriving medical device industry, students, entrepreneurs and existing industry need to understand how the equipment and the expertise at MedAdd can assist them in developing or growing their business.



CUT AM INNOVATION CHAIN



Commercialization Process







HOW ARE WE SUPPORTING INDUSTRY WITH PRODUCT DEVELOPMENT?



LEATLES PROTOTYPING APPLICATIONS



The DBX 3.0 All-Mountain bicycle helmet is designed to carry you safely across any terrain.

Leatt DBX 3.0 All Mountain Helmet



Tooling cost for three different sizes = \$350 000 3D printed cost = R25 to 35k

TOPOLOGY OPTIMIZATION AND LATTICE DESIGNS









Courtesy: Prof Anton du Plessis Stellenbosch University











GAS TURBINE WITH 3D PRINTED EXHAUST NOZZLE



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3D PRINTED DRONES





not make up the value that high-

quality optics can deliver.

Thermal and still mapping ideal GIS meta data to images.

> 1080P HD CAMERA Recording up to

24 MB STILLS For mapping imagery.



PDTS is hosted by Central University of Technology, Free State



PDJ55MEDICAL MEDICAL DEVICE PRODUCT DEVELOPMENT



Product Development Technology Station

Rural Mobility







Description:

African countries such as South Africa face a large problem concerning mobility of persons with disability in rural communities. To supply the large need of people in rural areas, the government and organizations import cheap basic folding wheelchairs. Theses wheelchairs seldom come with or have available spare parts. This is concerning as these wheelchairs are not intended for the environmental challenges faced by South African disabled persons. This rural mobility project as seen in the figures, aimed to build a sustainable reliable solution to improve mobility of persons with disability in rural areas. A wheelchair incorporates a clip on hand cycle or free wheel to help with mobility and reliability of wheelchairs in rural areas and long distance traveling. A person with disability will have a reliable wheelchair to move around indoors but has a clip on hand cycle or free wheel to improve mobility on rough rural roads and over long distances.

Client:

Schalk van der Merwe - Manufacture of wheelchairs and hand cycles





Rural Mobility







Hand cycle

Wheelchair

Free wheel





Qbell Bed Management System





Description:

South Africa's health care system is under enormous pressure concerning hospital bed communication and management, this problem is further highlighted in the public health care system. Qsystems in collaboration with PDTS have produced a product that is more cost effective than international competitors, while improving functionality in African environments. The first development of the Qbell was funded by Qsystems, funding received from SAB. The Qbell is a TPU soft button that can be triggered by multiple body movements (not limited to finger pressing, this is ideal for patients without hand function). The communication and reporting systems is developed by the PDTS electronic department, funded by the PDTS medical device unit through TIA funding. A wireless radio communication system was developed, this allows for a flexible bed management system and reporting of nurse productivity and response times.

Client:

Hienrich Williams - Entrepreneur (Qsystems)





Qbell Bed Management System



Hardware





Qbell Bed Management System



Software and Reporting





Non-Assisted Patient Transfer







Description:

Transferring from a sitting position to standing is essential for rehabilitation and daily task, often performed multiple times a day. Common transfers, including transfers from bed to chair/wheelchair, toilet or washbasin. Performed incorrectly or with out equipment, transferring can put both patient and caregiver at risk of injury. The patient transfer device ensures that sit-to-stand transfers can be carried out safely, quickly and with ease. Reducing the load on both therapists and care givers. The PDTS patient transfer device allows patients of all sizes to be safely transferred. The seat paddles are able to adjust forward and backwards to accommodate a variety of people. The paddles easily swing away to help with a quick and safe transfer. Medical grade caster wheels also ensure smooth movement in a home and hospital environment. The width of the device is specifically designed to accommodate standard wheelchair sizes in transfer, while a non-slip standing surface further improves the transfer.

Client:

Nurture Health Hillandale Physical Rehabilitation Hospital





Adult Standing Frame



Description:

Standing frames are used by persons who rely on a wheelchair for mobility. A standing frame provides alternative positioning to sitting, by supporting the person in the standing position. Standing promotes healthy bone maintenance, leg muscle stretching, spasticity reduction, improved internal organ functions, improved posture, and overall range of motion improvement. These benefits are not just physical, but also psychological. The PDTS standing frame comes with a host of adjustable features that accommodate a wide range of body types. Localised manufacturing dramatically improves the retail price.

Client: GreyMil Physical Rehabilitation Hospital





Multi Functional Walking Frame



Description:

A major problem faces by retirement homes and care centres is older patients falling at night on their way to the toilet. Conventionally a commode is used to solve this problem. Currently patients cannot buy a walking frame and commode on medical aids together. Commodes are usually priced at R1300 – R3200. The proposed device, clip on commode, is an add on to a standard walking frame. The device will retail for R350 –R450 and is seen as a walking frame accessory.

Client:

Nurture Hillandale Physical Rehabilitation Hospital

Patient Specific Dynamic Hand Splint

Description:

This project aims to develop a patient specific dynamic hand splint that will enable persons with tendon injuries or spasticity of the hand caused by a stroke to achieve appropriate hand rehabilitation. One of the major drivers of this project is to produce dynamic hand splints through the use of additive manufacturing (AM), specifically selective laser sintering (SLS). AM allows for a dimension driven CAD file to be manufactured that exhibits biomechanical function and appropriate fit. Insuring cost effective local production of complex hand splints that will be custom fitted to the client's specific needs.

Client:

Frans Klienhans Orthotics & Prosthetics

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