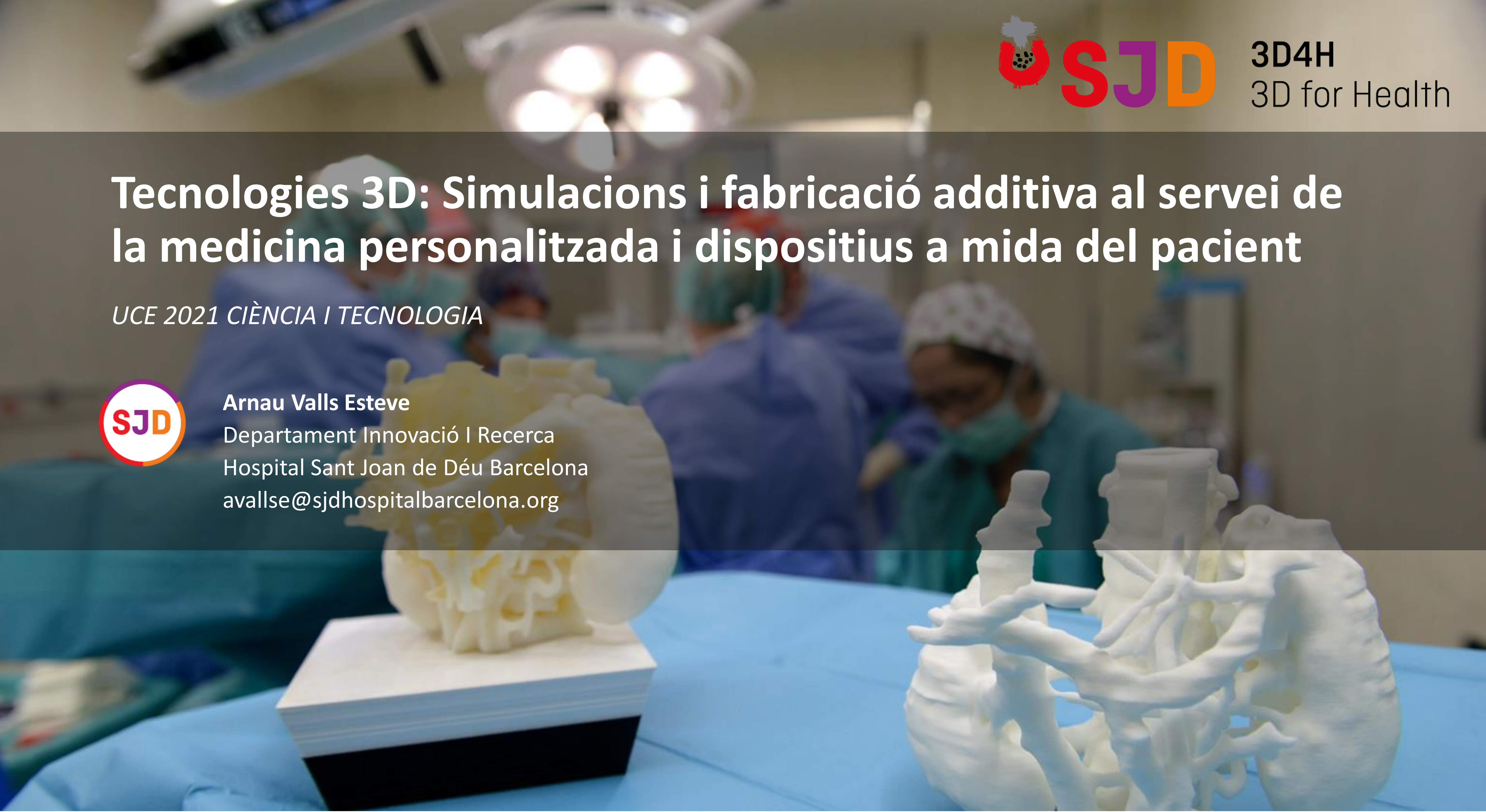
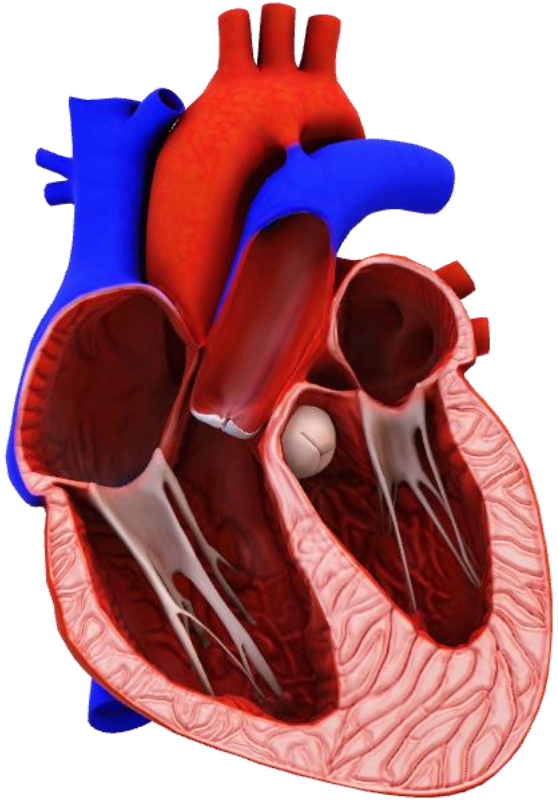


3D4H
3D for Health

Tecnologies 3D: Simulacions i fabricació additiva al servei de la medicina personalitzada i dispositius a mida del pacient

UCE 2021 CIÈNCIA I TECNOLOGIA

Arnau Valls Esteve
Departament Innovació I Recerca
Hospital Sant Joan de Déu Barcelona
avallse@sjdhospitalbarcelona.org



- Introducció
- Introducció a la tecnologia de planificació 3D I fabricació additiva - aspectes més rellevants
- La planificació 3D i les seves aplicacions en salut (exemples pràctics)
- Exemple de Servei 3D en un hospital
- Conclusions, reptes i oportunitats

Sant Joan de Déu
Barcelona · Hospital

SJD Barcelona Children's Hospital

Hospital Sant Joan de Déu

- Hospital materno infantil
- Centre universitari UB
- Privat sense ànim de lucre
- Concertat amb el sistema públic

Hospital Highlights

2020 Activitat

21,947
Altes

272,078 (42,9% homecare)
Consultes externs

14,472
Cirurgies

3,392
Parts

91,243
Urgències

2020 Recursos

2,265
Professionals

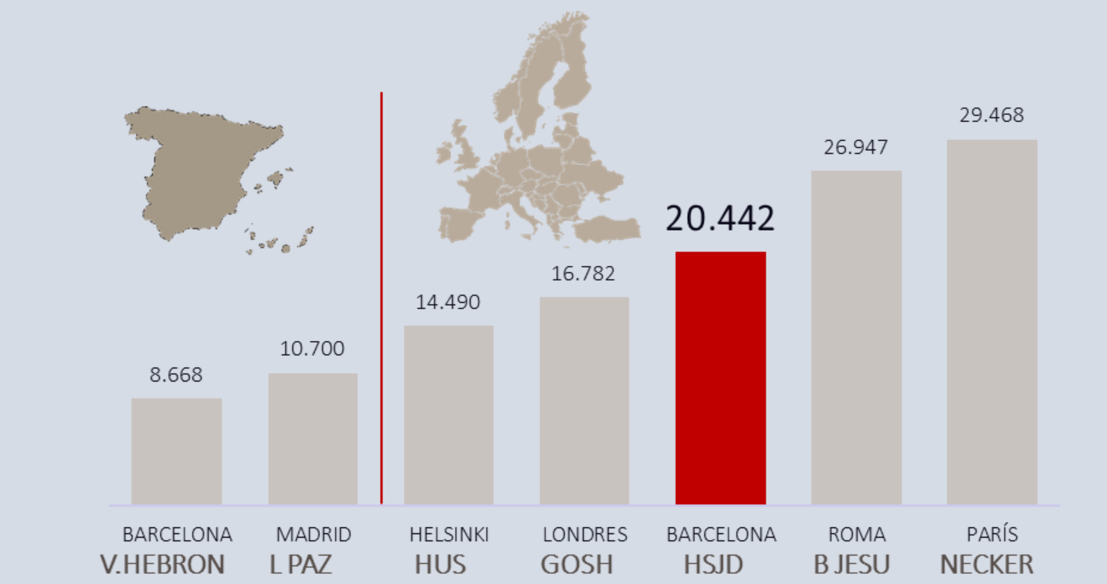
302
Llits

2020 Dades financeres

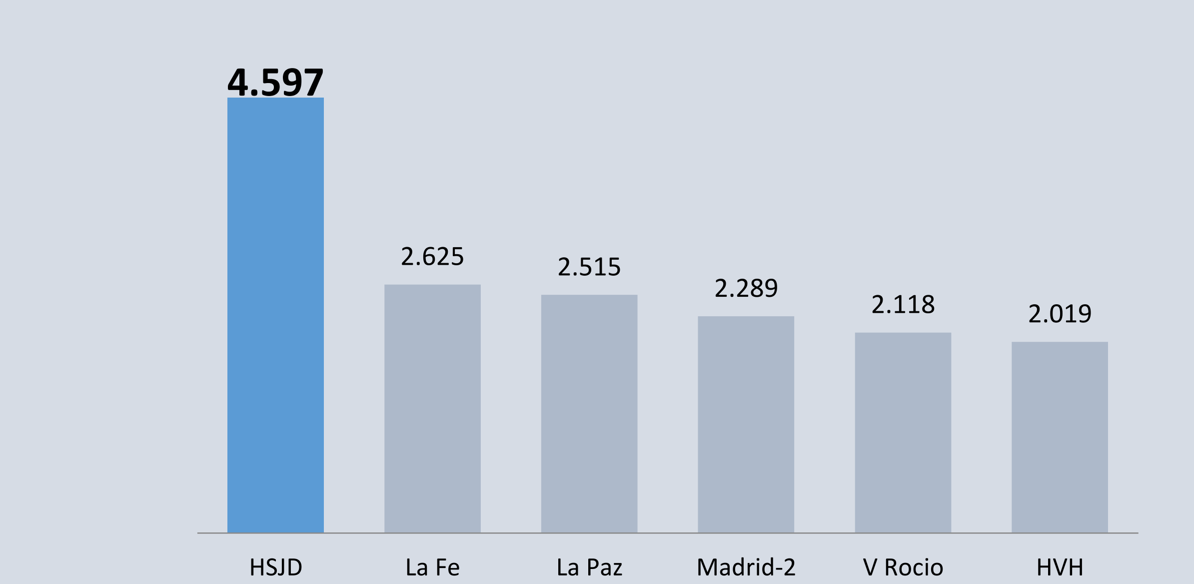
€160.9M
Pressupost anual

€8.5M
Inversions

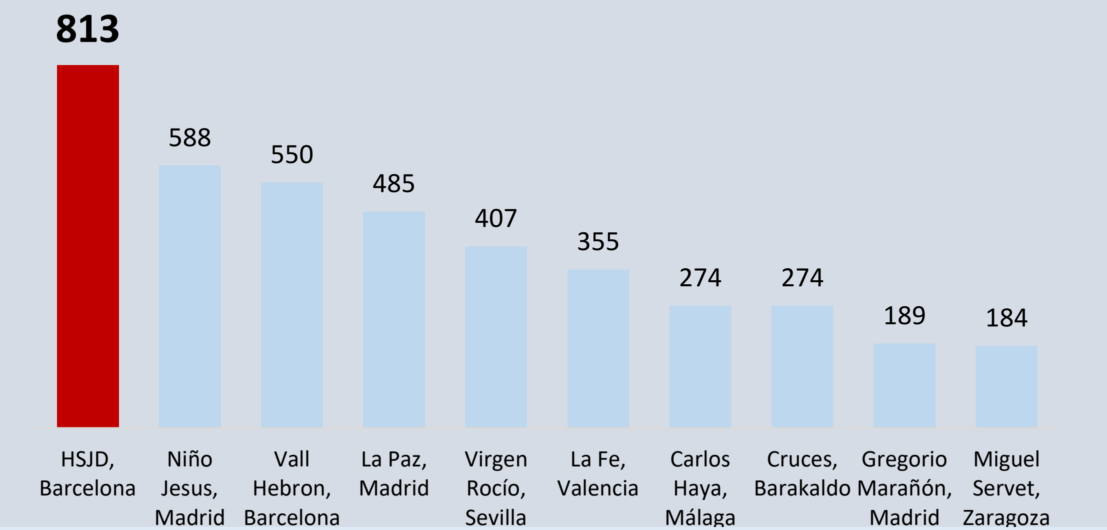
350,000
Pacients/any



Primer centre pediàtric a Espanya i tercer a Europa

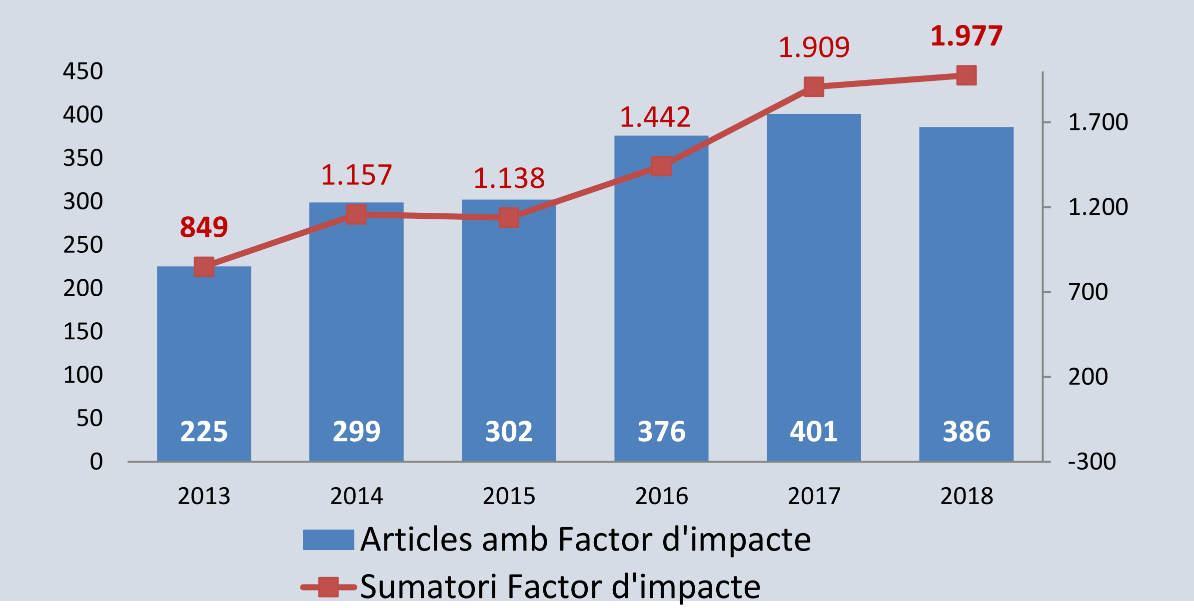


El centre amb més activitat pediàtrica terciària d'Espanya



Líder en tractament de casos de càncer infantil en els darrers 5 anys

(Informe RETI 2019)



INTRODUCCIÓ A LA TECNOLOGIA DE PLANIFICACIÓ 3D I FABRICACIÓ ADDITIVA

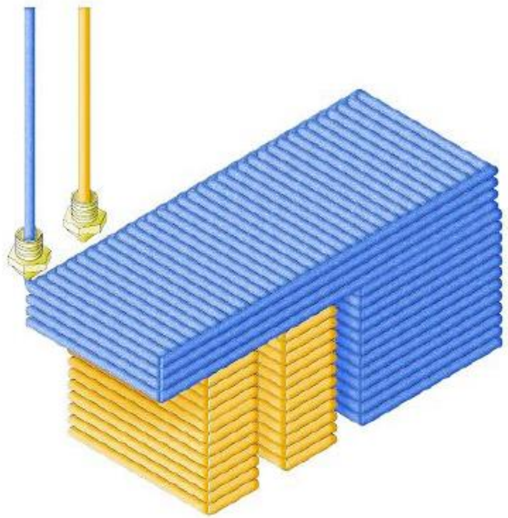
ANTECEDENTS HISTÒRICS

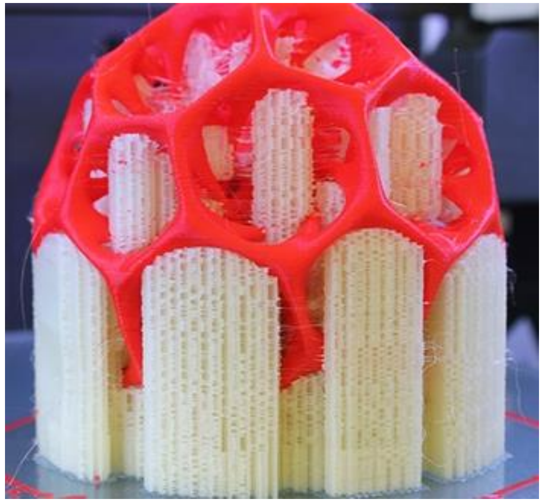
1981	Dr. Hideo Kodama, Institut Municipal de Investigació Industrial, en Nagoya.
1984	Dr. Chuck Hull publica i patenta la primera màquina d'impressió 3D esterolitografia (3D Systems)
1992	Primera publicació mèdica sobre impressió 3D en planificació quirúrgica
1999	El Wake Forest Institute of Regenerative Medicine imprimeix cèl·lules vives amb un medi biocompatible
2002	Lanza et al. bioimprimeixen per primera vegada un model de ronyó en 3D
2005	RepRap Project. Universalització de la impressió 3D
2012	Materials biocompatibles. Primer implant ossi
2013	Primera impressió 3D multimaterial CIR ONC Pediatrica HSJD
2015/16	Creació de la Unitat HSJD 3D4H

PATENT US4575330 A USA

SJD 3D4H
3D for Health

Additive Manufacturing (AM), part of an industrial revolution





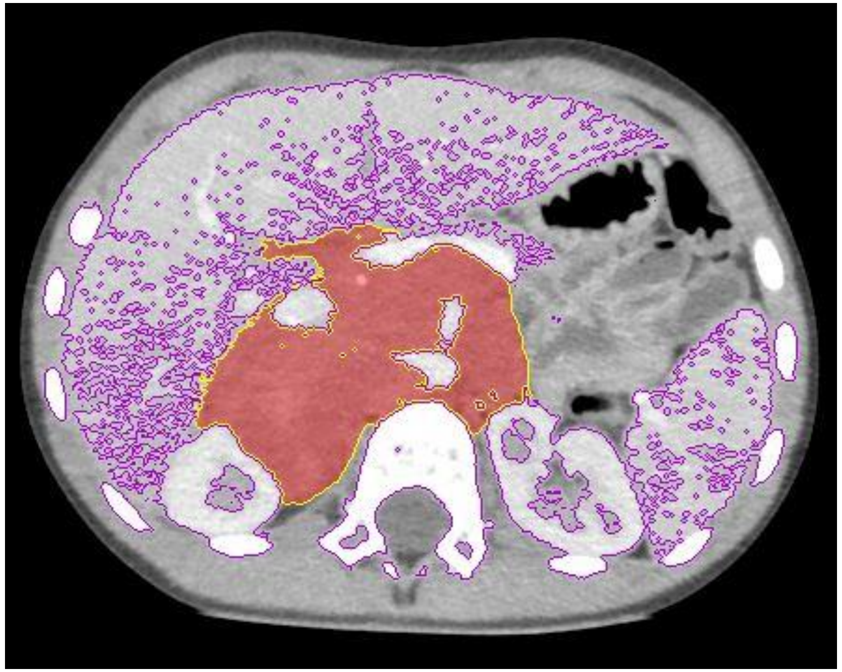
Source: CIM UPC

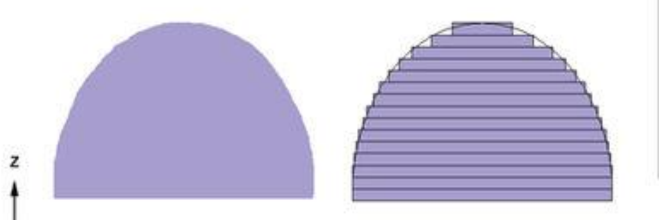
Definition (ISO/ASTM 52900:2015)

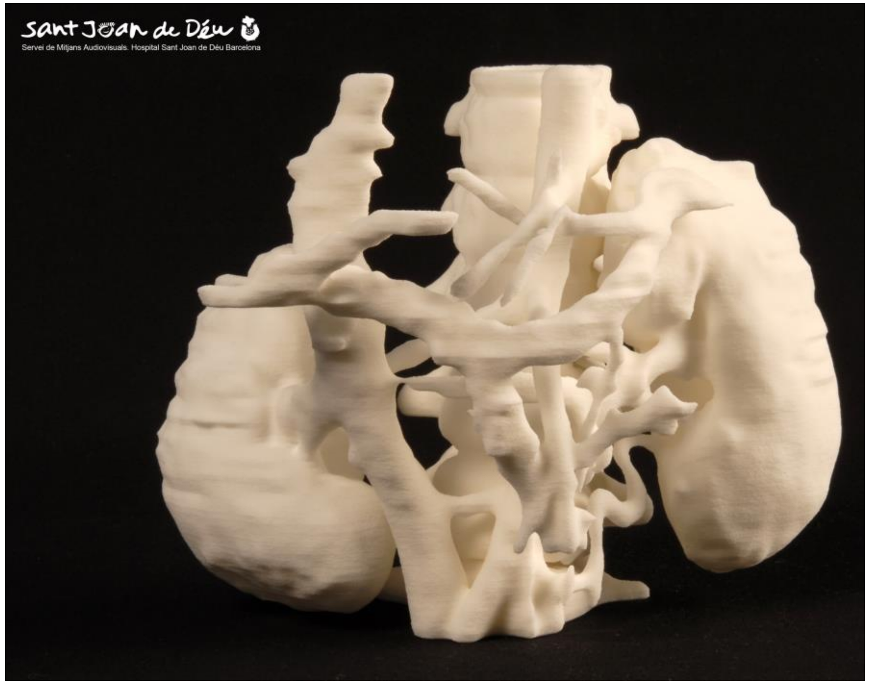
"Process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies"

- Parts or assemblies with "impossible" geometries can be manufactured.
- Different materials can be added in a single part.
- Parts can be customized: unitary production

AM: El camí directe de les dades digitals a la realitat impresa







Source: CIM UPC / HSJD

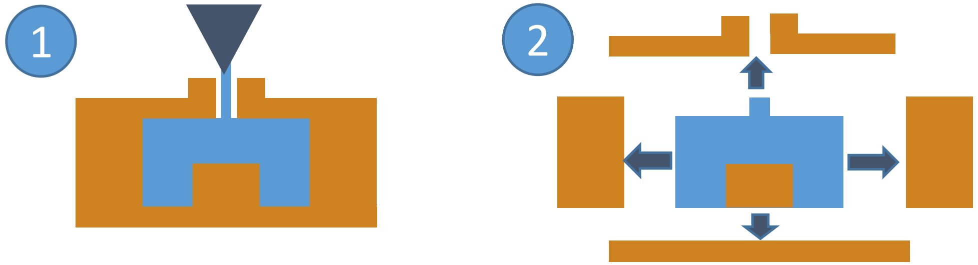
What 3D printing is?

- SUBTRACTIVE MANUFACTURING

- ADDITIVE MANUFACTURING
  3D Printing

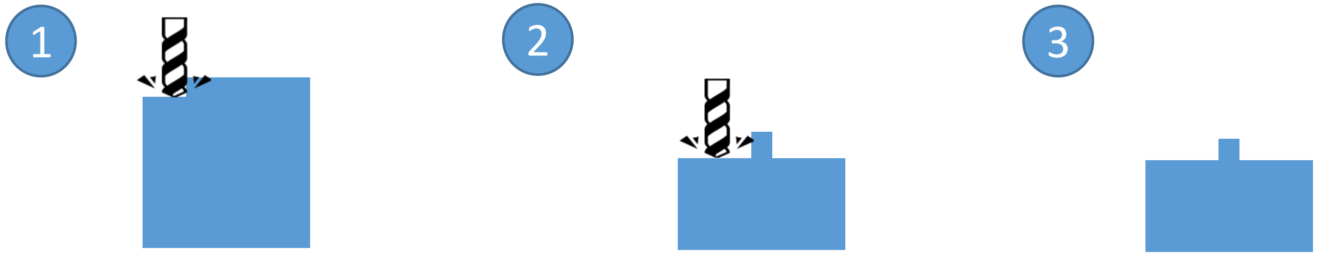
Source: CIM-UPC

Injection moulding



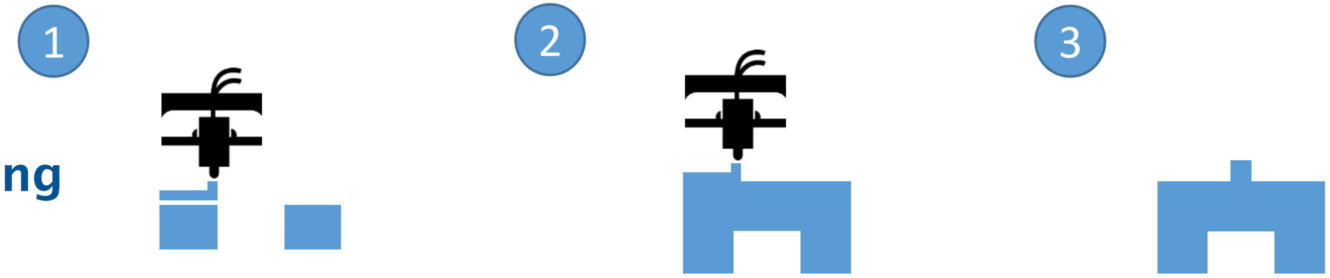
John Wesley Hyatt,
USA, 1872

CNC subtractive machining
(Computer Numeric Control)

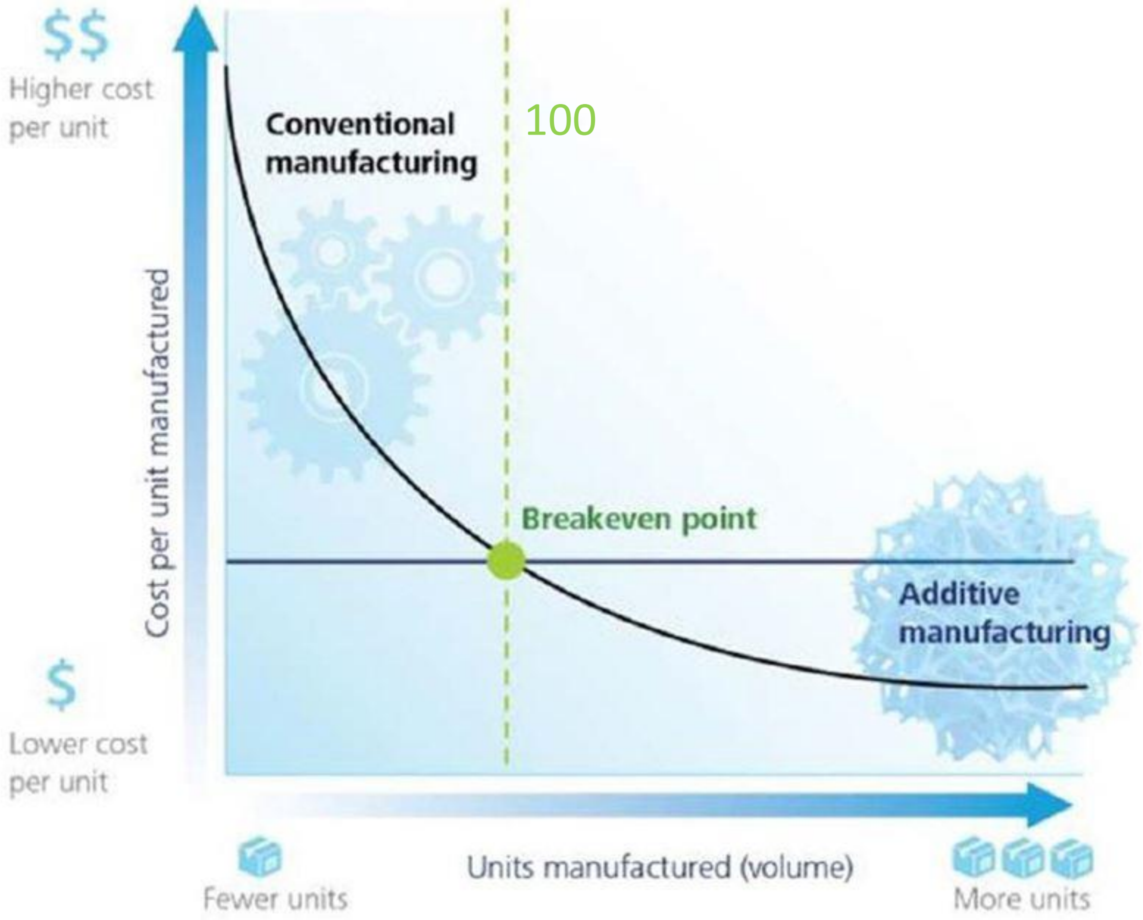


Richard Kegg + MIT,
USA, 1952

Additive Manufacturing



Hideo Kodama,
Japan, 1981



Graphic: Deloitte University Press | DUPress.com

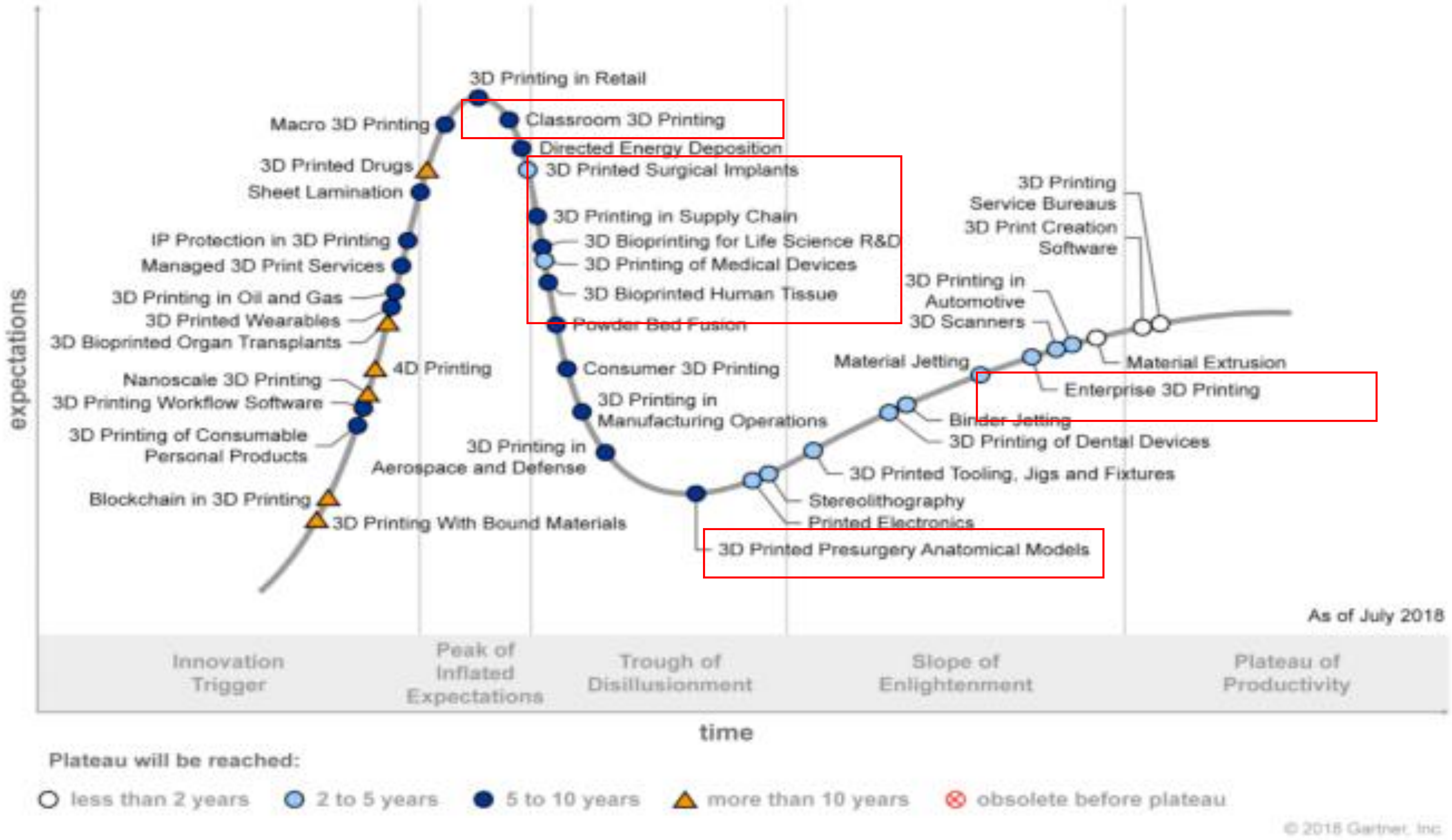
Source: Stuart Trouton, Deloitte

Functional differences Traditional vs AM

1. AM can be used to create complex geometries, even full functional assemblies.
2. Reduction of the steps of the process, going from the digital file to a final fully assembled product.
3. Cost-effective in small scale production.
4. **Decentralized production in the point of demand.**

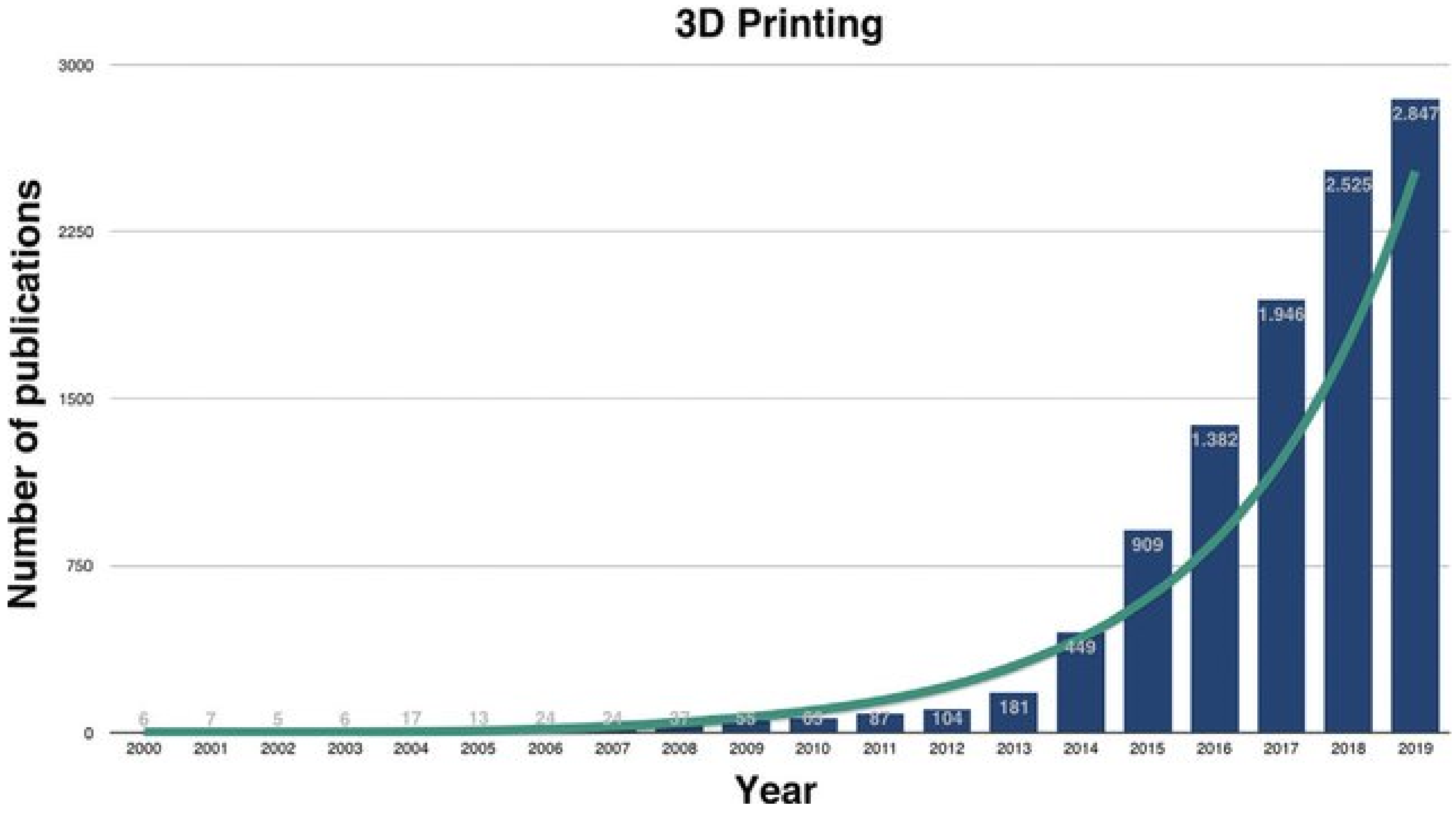
Source: https://proto3000.com/3d-printing/business-considerations-for-production-tooling-conversion-to-additive-manufacturing/

MADURESA PRODUCTIVA DEL 3D



Source: Gartner2019

RECERCA DEL 3D EN SALUD



Nombre de publicacions de PubMed 3DP en medicina per any. Cerca: (impressió 3D O impressió 3D O fabricació additiva) I (assistència sanitària o hospitalització O assistència O medicaments).

Source: PubMed.gov

Additive Manufacturing (AM), part of an industrial revolution

PROTOTYPE

Source: BCN3D Technologies

FINAL PART

Source: Under Armour & EOS

Photo is by Adriaan de Groot

Amsterdam's Red Light District.

19 July 2021

A 12-metre 3D-printed stainless steel pedestrian bridge designed by [Joris Laarman]() and built by Dutch robotics company [MX3D]() has opened in [Amsterdam]() six years after the project was launched.

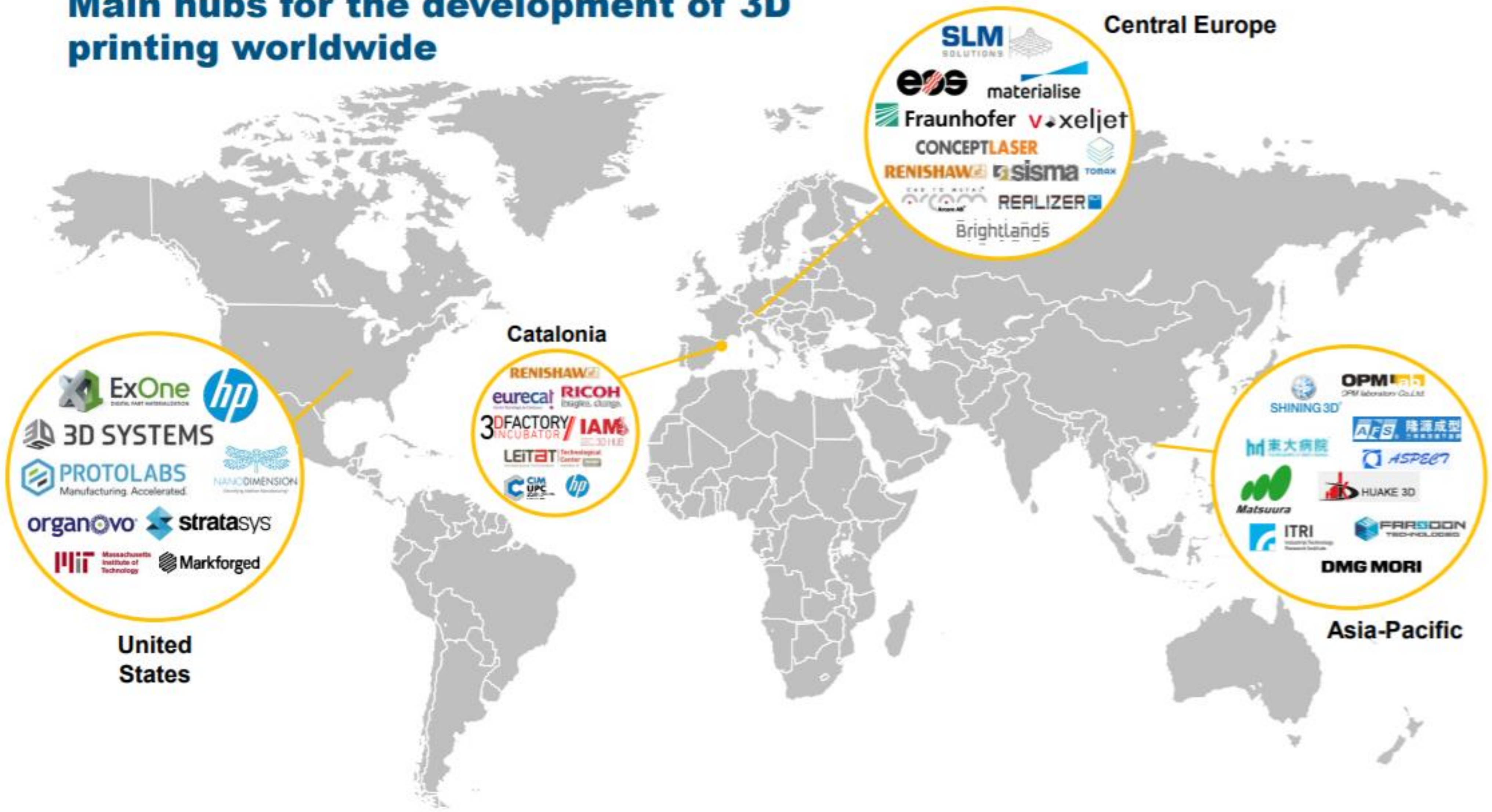
MX3D-Metal 3D-printing 6 axis robot

Business Insider - Joris Laarman

I COM ESTÀ LA INDUSTRIA DE LA FABRICACIÓ ADDITIVA AL MÓN?

I CATALUNYA?

Main hubs for the development of 3D printing worldwide



Source: *EIC (DGI-ACCIÓ) based on Envision Intelligence, Investing News, Aniwaa and the European Commission website.*

3D printing ecosystem companies in Catalonia

Partially illustrative

Technology providers

Software

- alma medical imaging
- materialise innovators you can count on
- }}captae realmente cerca

Materials

- Ercros
- Lubrizol
- mimetis
- BASF SONATRACH PropanChem S.A.
- DOW
- ONYRIO
- Dan*na artificial nature
- ELIX POLYMERS
- TRC THERMAL RECYCLING OF COMPOSITES

Manufacturing of 3D printers

- RENISHAW apply innovation™
- hp
- BCN3D
- MAKNESS
- RICOH imagine. change.
- Fabber
- EPSON EXCEED YOUR VISION
- Roland
- naturalrobotics
- ARBURG

Manufacturing of 3D parts

- FAE
- JABIL
- +GF+
- Polifluor
- protoprenedes
- emes3d
- NOUMENA
- NNOMAQ21
- BALENTEC
- Addwerk
- PANTUR
- 3DHUB
- 3DIGITAL FACTORY
- DIGINCREATE
- SEL MODELS
- ineo prototipos
- ADDIT-ION
- HOFMANN
- MES3D
- ARRK
- 3Du
- eceleni

3D part finishing

- ATOTECH
- CONIEX
- RÖSLER finding a better way ...
- GPAINNOVA
- JOSEP MUNTAL 25
- MECOS DEFORMACIÓN DEL METAL

Main applications

- Home and gifts
- Manufacture
- Food
- Construction
- Education
- Health
- Fashion

Demand

- casals
- TECNITOYS
- MAHLE
- SEAT
- ALSTOM
- FOOD INK.
- LafargeHolcim
- FCC
- REHAU
- ELISAVA
- GAES
- AVINENT Implant System
- Vall d'Hebron
- Sant Joan de Déu
- TOUS

Service providers

Makers fablab and business models

- ZETOFF
- formbytes
- NOVA MEAT
- FAB LAB
- Flubetech
- BDN Lab
- ASCIL
- liq
- TARES
- XKELET
- BonaDrone
- ZER
- PodoTec3d
- BHS30
- TINKERERS
- Tractivus
- ATENEU DE FABRICACIÓ
- M( )B

Engineering, consulting and certification

- 3Dvisual
- INTEGRAL 3D PRINTING
- INTECH3D your 3D partner
- protoprenedes
- Color Sensing
- Applus
- Prometal3D Imagine, Design & Creation
- 3Du
- AVINENT Implant System
- CATALOG INDUSTRY
- SMART ENGINEERING
- drukatt
- Archimedes
- GIRBAU LAB
- TRESD
- VoxeledMaterials Professional Support for the 3D Printing Industry
- OXOLUTIA

Distribution services

- cosedal
- MAQUINSER
- 3DSpider
- 3DZ
- TRESDLAND
- STM
- AsorCAD 3D Engineering & Metrology
- eos
- SOLIDPERFIL3D
- RR3D 3D PRINTING DIVISION
- TRESD
- Join3d
- AyS
- AGFA
- MASTERTEC
- COMHER
- intermaher
- ADVANCED MANUFACTURING
- CENTROTÉCNICA

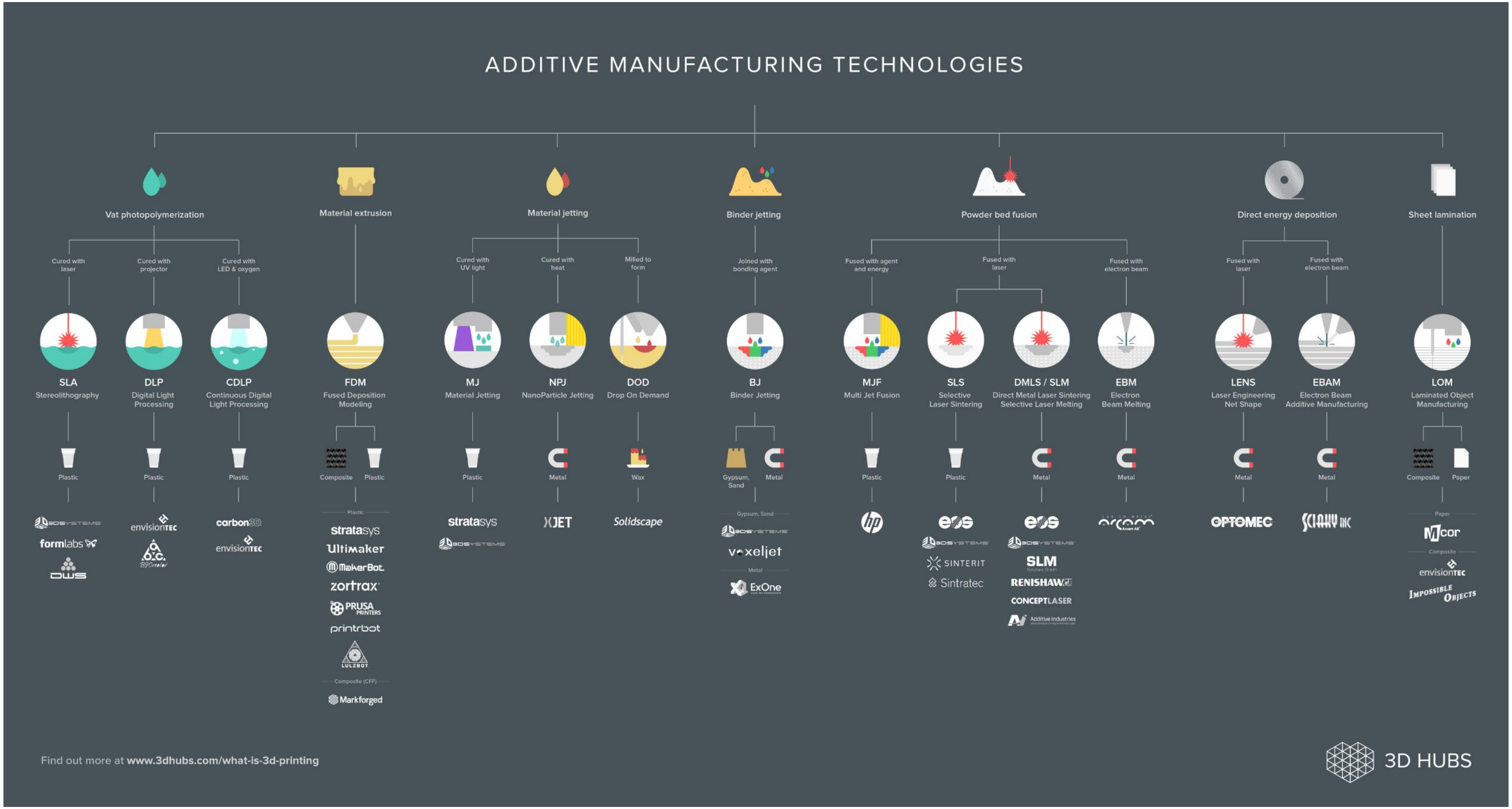
Source: *EIC (DGI-ACCIÓ).*

3D HOSPITALARIA A CATALUNYA i ESPANYA

Source: Estudi efectuat en el marc del grup de treball en Fabricació Aditiva en Salut de ITEMAS

itemas isciii *Plataforma de dinamización e innovación de las capacidades Industriales del Sistema Nacional de Salud*

PRINCIPALS TECNOLOGIES DE FABRICACIÓ ADDITIVA I LES SEVES APLICACIONS



ADDITIVE MANUFACTURING TECHNOLOGIES

- Vat photopolymerization
  - Cured with laser
    - **SLA** Stereolithography
      - Plastic
        - 3D SYSTEMS
        - formlabs
        - DWS
  - Cured with projector
    - **DLP** Digital Light Processing
      - Plastic
        - envisionTEC
        - B9Creator
  - Cured with LED & oxygen
    - **CDLP** Continuous Digital Light Processing
      - Plastic
        - carbon3D
        - envisionTEC
- Material extrusion
  - **FDM** Fused Deposition Modeling
    - Composite
    - Plastic
      - Plastic
        - stratasys
        - Ultimaker
        - MakerBot
        - zortrax
        - PRUSA PRINTERS
        - printrbot
        - LULZBOT
      - Composite (CFF)
        - Markforged
- Material jetting
  - Cured with UV light
    - **MJ** Material Jetting
      - Plastic
        - stratasys
        - 3D SYSTEMS
  - Cured with heat
    - **NPJ** NanoParticle Jetting
      - Metal
        - XJET
  - Milled to form
    - **DOD** Drop On Demand
      - Wax
        - Solidscape
- Binder jetting
  - Joined with bonding agent
    - **BJ** Binder Jetting
      - Gypsum, Sand
      - Metal
        - Gypsum, Sand
          - 3D SYSTEMS
          - voxeljet
        - Metal
          - ExOne
- Powder bed fusion
  - Fused with agent and energy
    - **MJF** Multi Jet Fusion
      - Plastic
        - hp
  - Fused with laser
    - **SLS** Selective Laser Sintering
      - Plastic
        - eos
        - 3D SYSTEMS
        - SINTERIT
        - Sintratec
    - **DMLS / SLM** Direct Metal Laser Sintering Selective Laser Melting
      - Metal
        - eos
        - 3D SYSTEMS
        - SLM Solutions GmbH
        - RENISHAW
        - CONCEPTLASER
        - Additive Industries
  - Fused with electron beam
    - **EBM** Electron Beam Melting
      - Metal
        - arcam Arcam AB
- Direct energy deposition
  - Fused with laser
    - **LENS** Laser Engineering Net Shape
      - Metal
        - OPTOMEC
  - Fused with electron beam
    - **EBAM** Electron Beam Additive Manufacturing
      - Metal
        - SCIAKY INC
- Sheet lamination
  - **LOM** Laminated Object Manufacturing
    - Composite
    - Paper
      - Paper
        - Mcor
      - Composite
        - envisionTEC
        - Impossible Objects

Find out more at **www.3dhubs.com/what-is-3d-printing**

3D HUBS

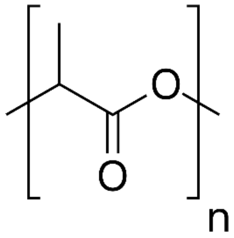
Additive Manufacturing Materials

Polymers

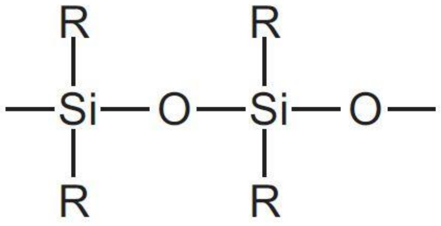
Thermopolymers

Photosensible resins

- PLA (polylactic acid)



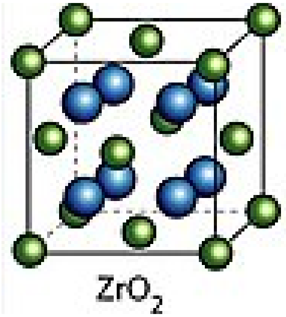
Silicones and hydrogels



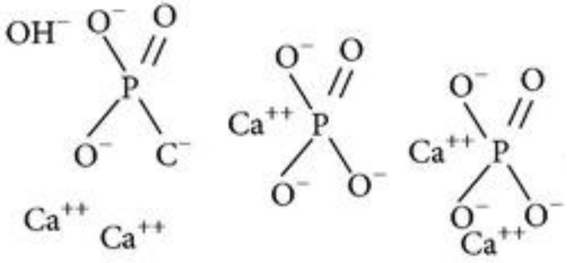
Ceramics

Zirconia

(Zirconium dioxide, ZrO2)

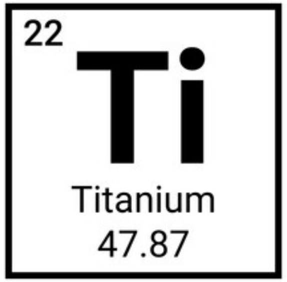


Hydroxyapatite (HA)

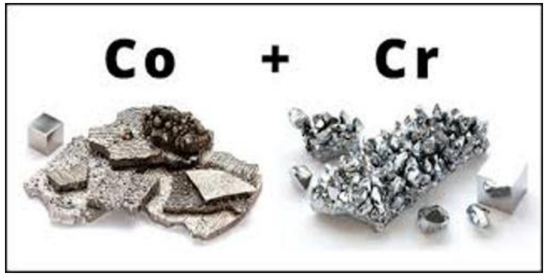


Metals

Titanium



Cobalt-chromium alloy

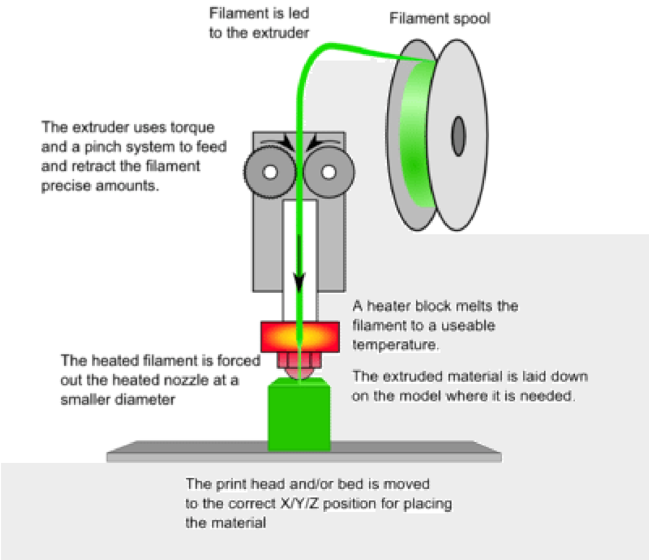


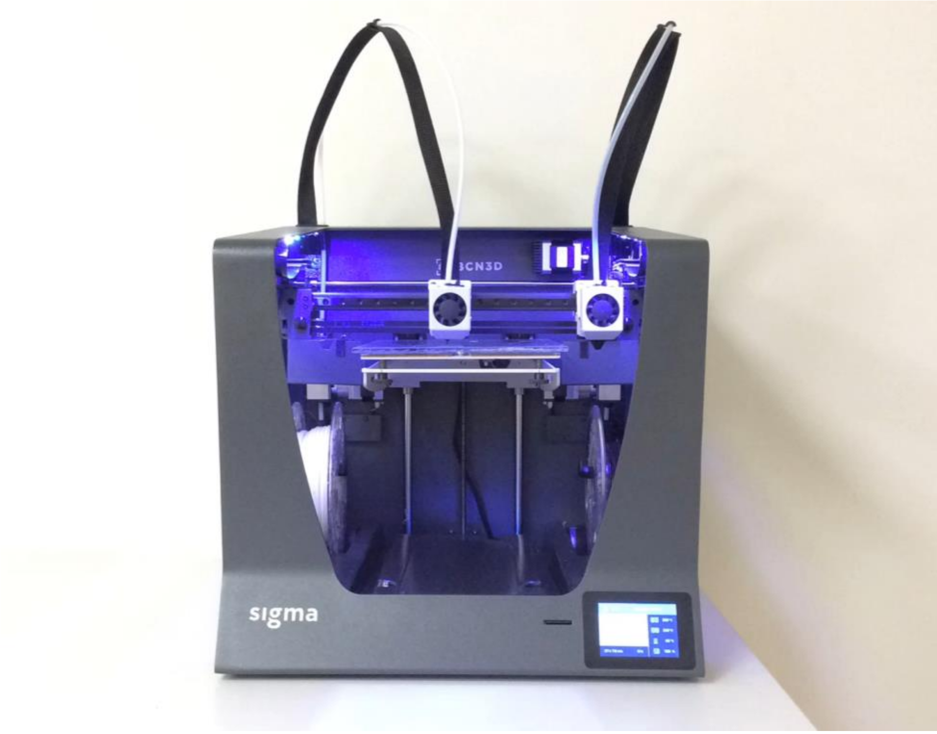
Material extrusion of filaments (FDM/FFF)

Definition:

Extrusion-based printing is a 3D printing technique in which 3D structures are built by melting thermoplastic material out of a nozzle onto a build platform layer-by-layer.

The typical example is Fused Filament Fabrication (FFF).





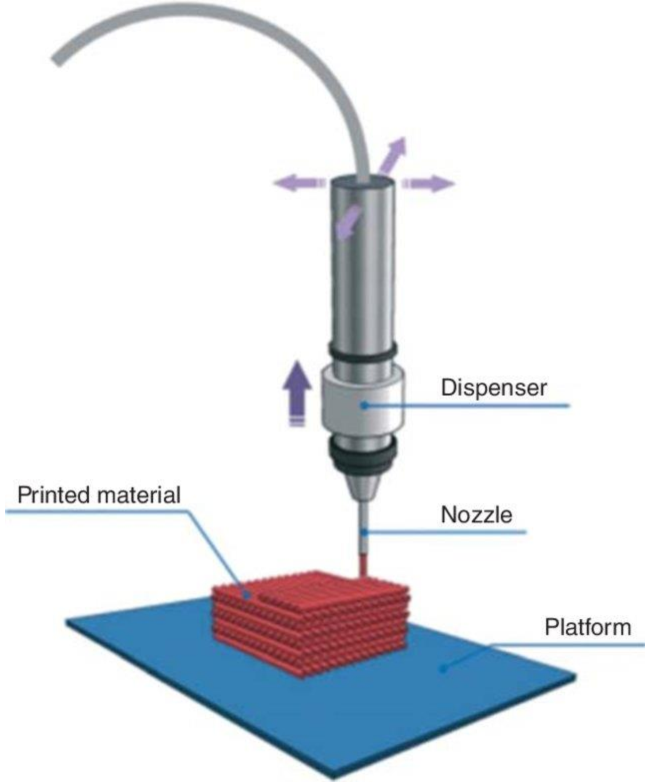
Source: Desktop FFF technology CIM UPC - HSJD

Material extrusion by Robocasting (DIW)

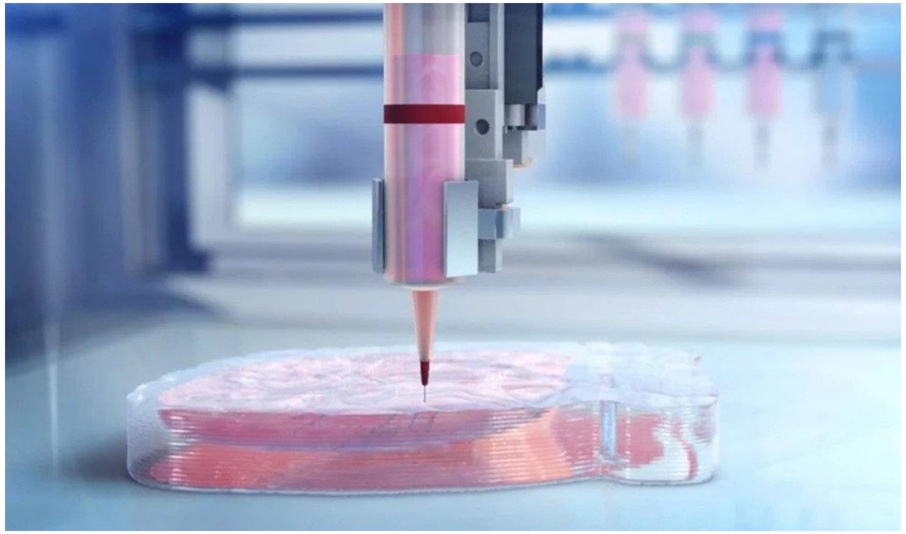
Definition:

It is an additive manufacturing technology based on the direct extrusion of slurry-based materials. Syringes are commonly used as extruder system.

This method is known as Robocasting or Direct Ink Writing (DIW).



Source: Scopigno et al. 2017



Source: all3dp.com

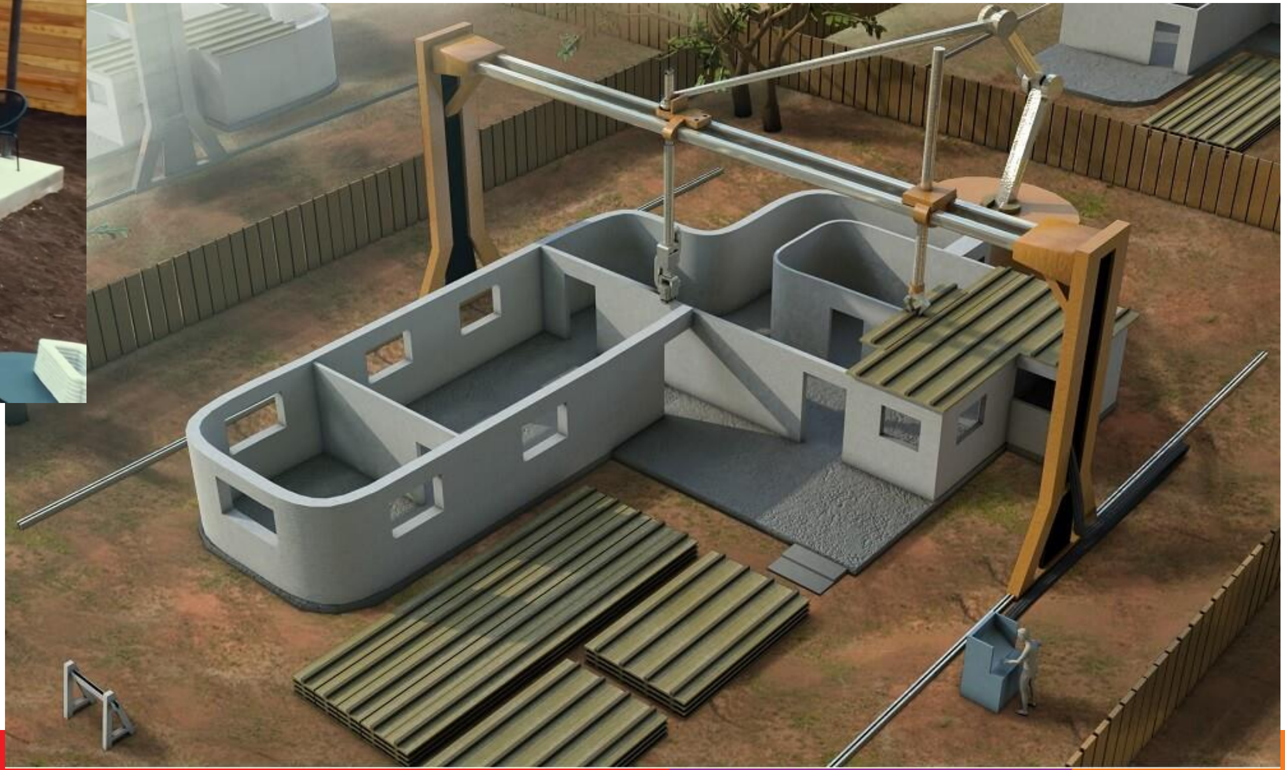
Food Ink placed in La Boscana, Catalonia

Tecnologia: DIW

Source: Foodini

10 houses in just one day

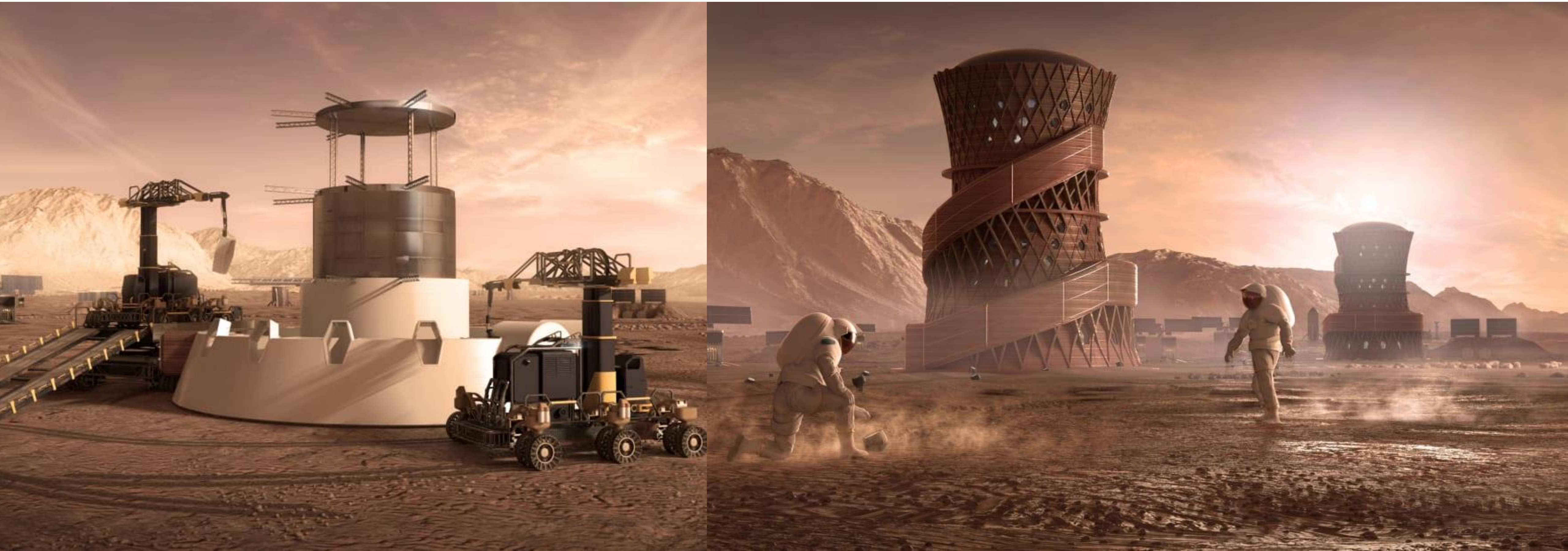
$5000 per house



Source: Sculpteo

Oct 1, 2020

NASA Looks to Advance 3D Printing Construction Systems for the Moon and Mars

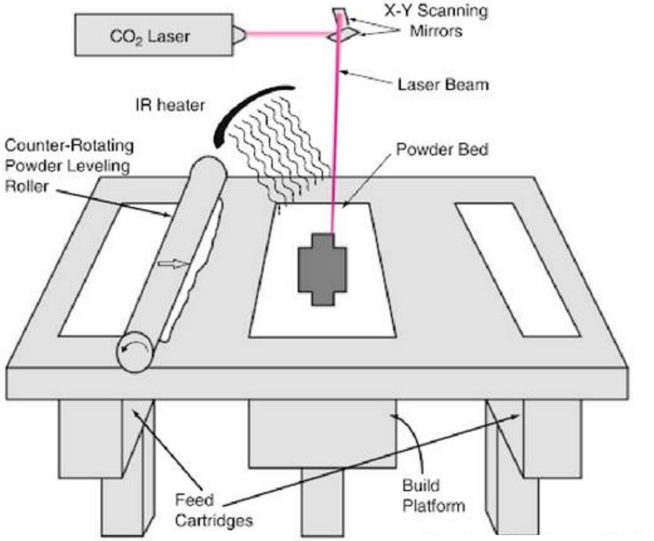


Powder Bed Fusion (PBF) for plastic parts

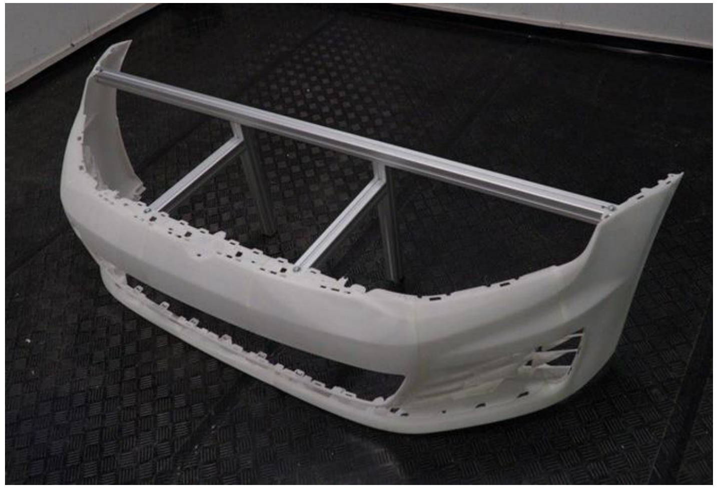
Definition:

Powder Bed Fusion (PBF) for plastic parts is an additive manufacturing technique which creates 3D objects layer by layer from thermopolymeric powdered materials with heat source.

The most common technology is also known as Selective Laser Sintering (SLS), where a CO_2 laser beam is used.



Source: Schematic of Selective Laser Sintering (Gibson, Rosen, & Stucker, 2010)

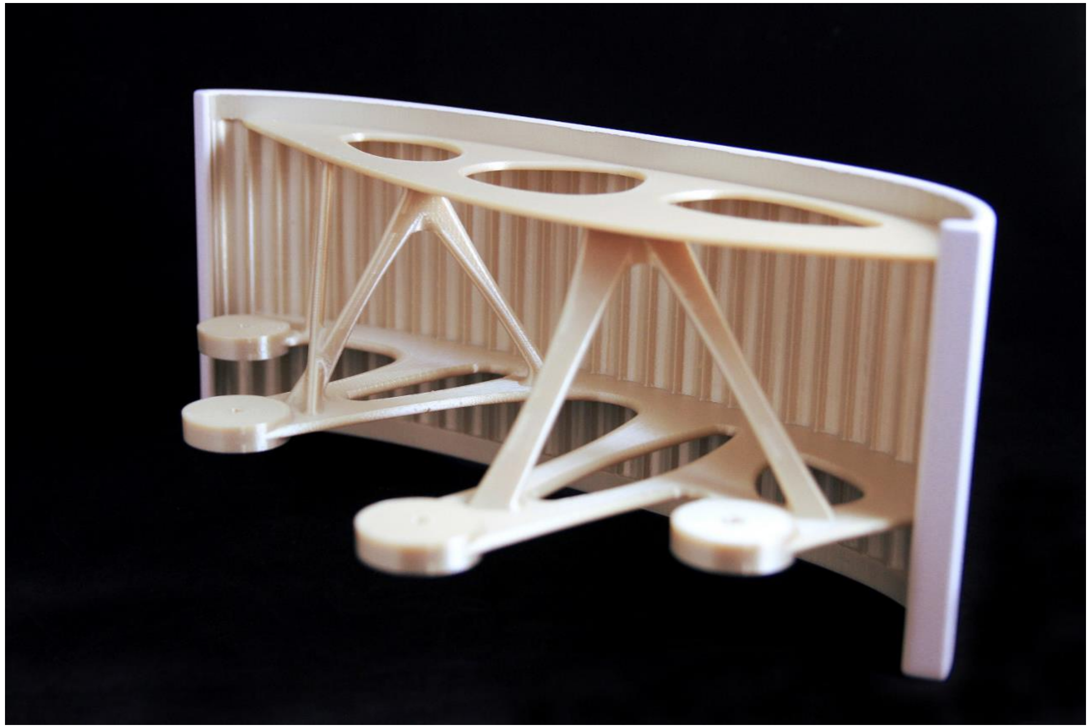


Source: CIM UPC / RICOH

Source:
https://www.3erp.com/3d-print-changing-automotive-industry/
https://www.prodways.com/en/industrial_segment/automotive/

Tecnologia: PBF

Finnair’s A320 aircraft



Materialise produced

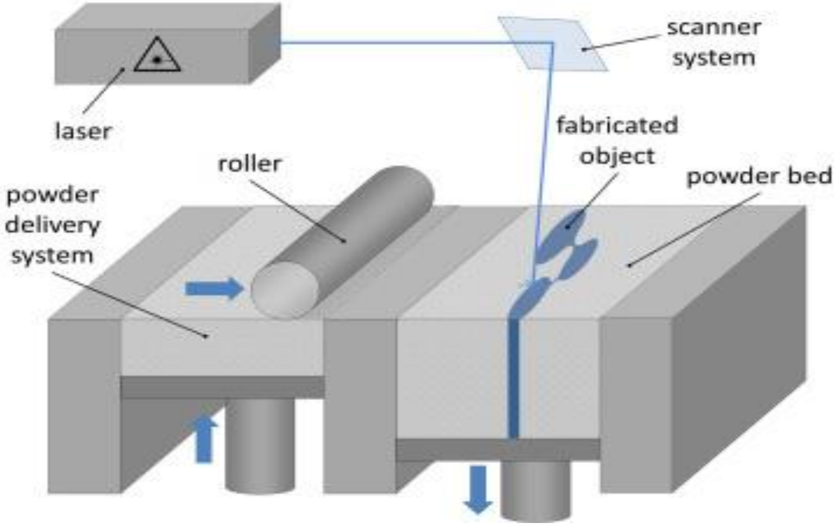
Powder Bed Fusion (PBF) for metal parts

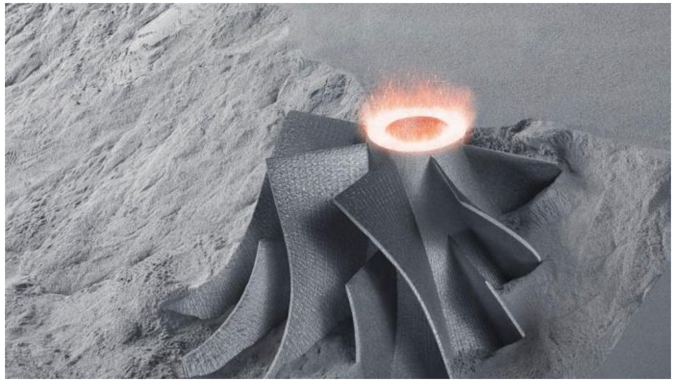
Definition:

Powder Bed Fusion (PBF) for metal parts is also used with metallic powders to form very strong parts, and it has been commonly used to obtain very demanding parts, as for example customized artificial knees and ankles.

It is also known as Selective Laser Melting (SLM).

A laser or an electron beam is used as an energy source.





An air craft peace and a implant part made by metal PBF. Source: 3DNatives and Renishaw

Source: Formula F1
Renishaw

Source: Ring Jewelry
Romanoff West

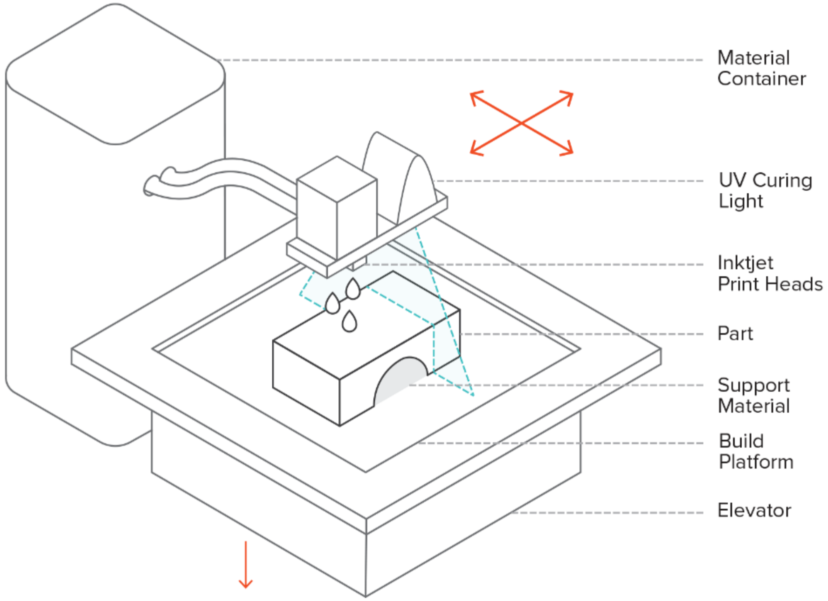
Source: 3DP Dress
http://imprimalia3d.com

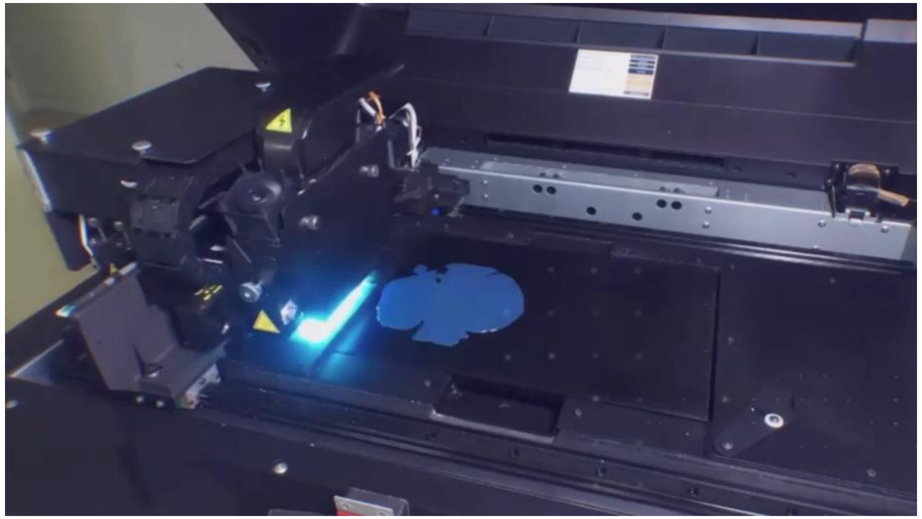
Tecnologia: PBF per metals I PBF amb PA11

Material jetting by Jetted Photopolymer

Definition:

Selective deposition of a mixture of photopolymer material, in drops on a platform. This allows to create layers in a single pass for curing and solidification by UV light.





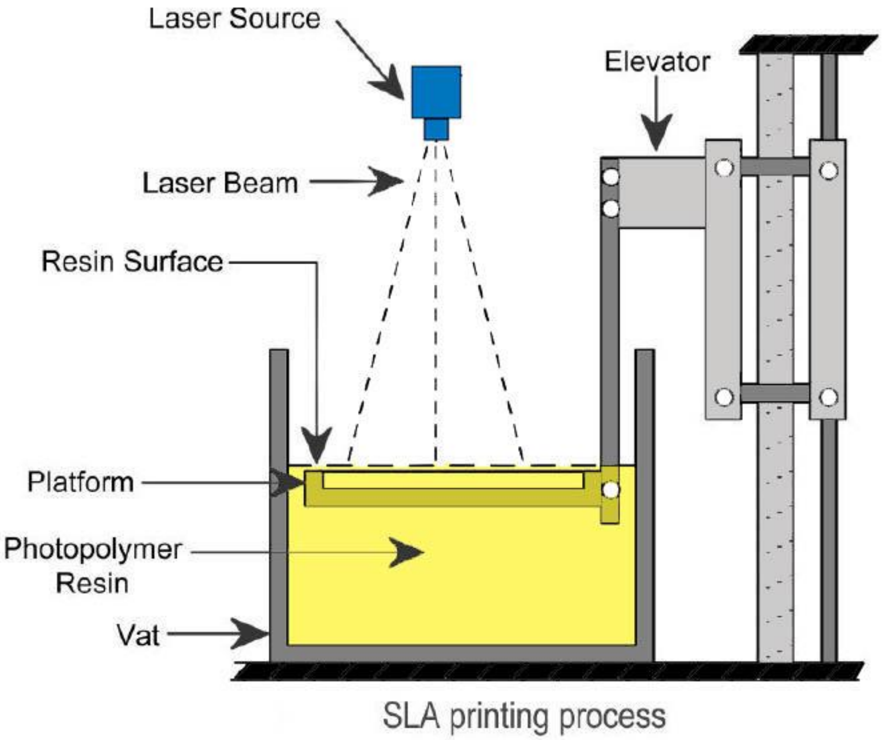
Source: HSJD

Vat-photopolymerization

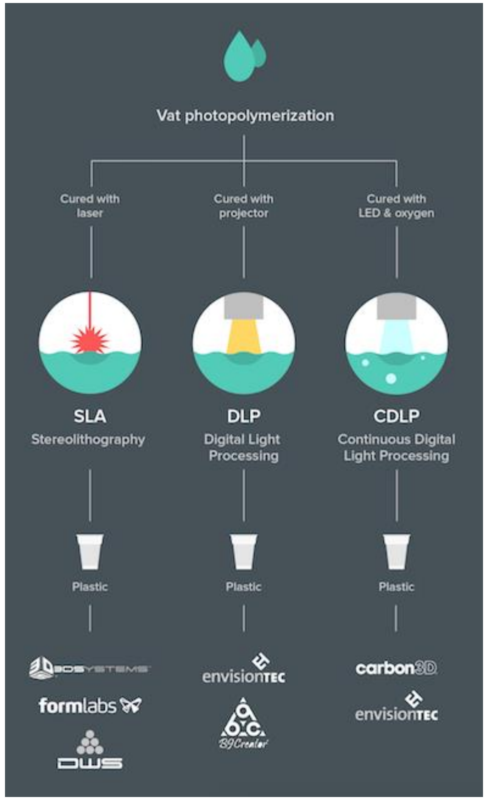
Definition:

It is an additive manufacturing method that uses a UV light (laser, DLP, LCD…) technology which is based on the spatially controlled solidification of a liquid resin by photo-polymerization.

The typical example is Stereolithography (SLA), where the energy source is a laser and the platform moves downwards into the vat. But there other strategies: **platform moving upwards and source energy below the platform**.



SLA printing process



Source: SLA and DLP Process https://www.engineersgarage.com/

SCAN

Ear Impression
+ Desktop Scan
or
In-Ear Scan

DESIGN

3D Model
Edit the STL file
to final form

MANUFACTURE

3D Print
Wash + Post-Cure

Silicone Cast
Cast final material into
3D printed ear mold

POST-PROCESS

Final Product
Finish + Coat

Source: Formlabs

LA PLANIFICACIÓ 3D I LES SEVES APLICACIONS EN SALUT (EXEMPLES PRÀCTICS)

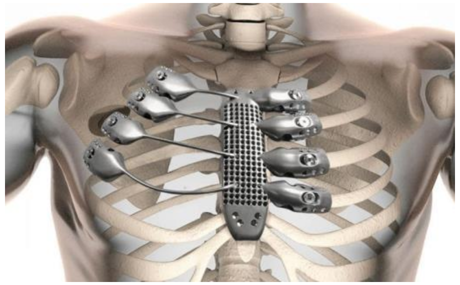
Sant Joan de Déu
Barcelona · Hospital

APLICACIONS DEL 3D EN SALUD

SURGERY PLANNING

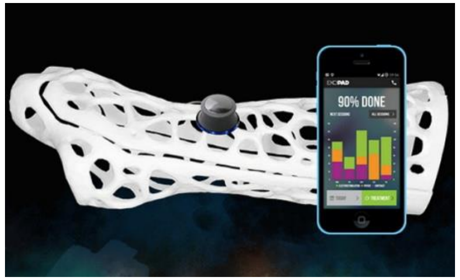
EDUCATION

PROSTHETICS



IMPLANTS

MEDICAL TOOLS AND DEVICES



SPLINTS

BIO-PRINTING

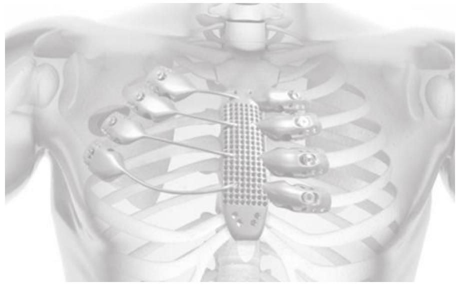
MEDICATION

APLICACIONS DEL 3D EN SALUD

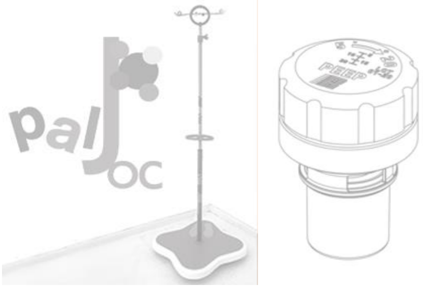
SURGERY PLANNING

EDUCATION

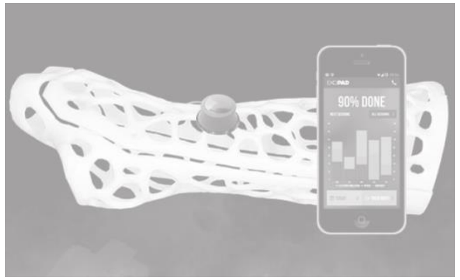
PROSTHETICS



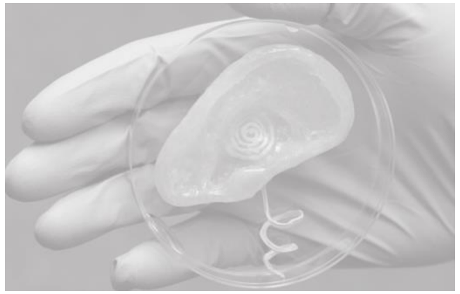
IMPLANTS



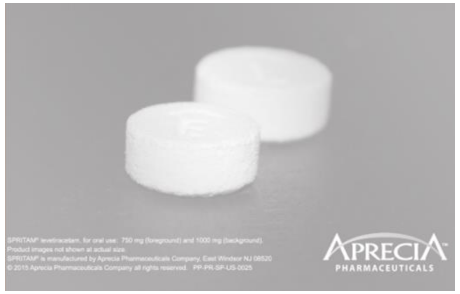
MEDICAL TOOLS AND DEVICES



SPLINTS



BIO-PRINTING



MEDICATION

NOU PROCÉS DE PLANIFICACIÓ QUIRÚRGICA

Image
MRI / CT Scan

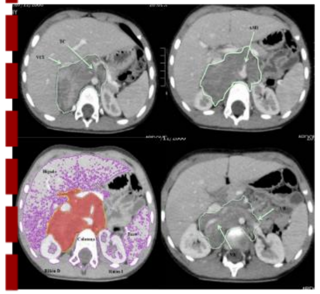
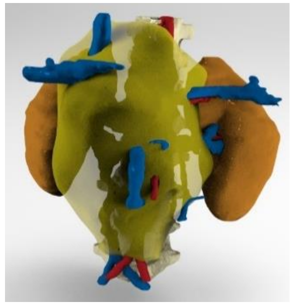
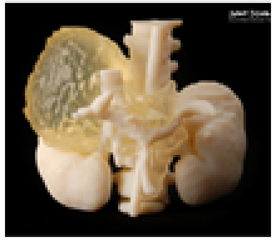
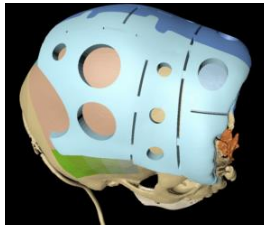
Segmentation
DICOM to STL

Virtual Planning

3D Printing/VR

Review, Training
and Planning

SURGERY

Nous passos en la planificaicó

1er
Estudi

2n
Estudi

Estudi
final

Cirurgia
Guiada

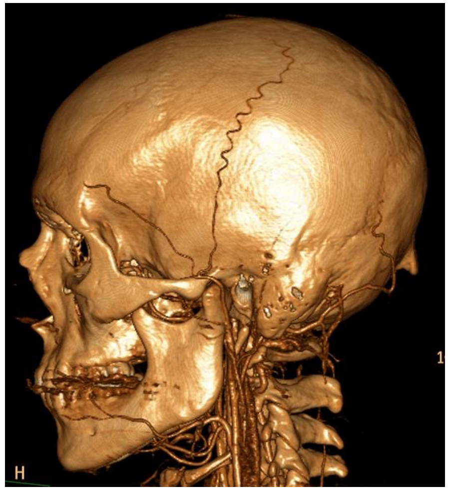
SEGMENTACIÓ (DICOM a STL)

DICOM
(Digital Imaging and Communications in Medicine)

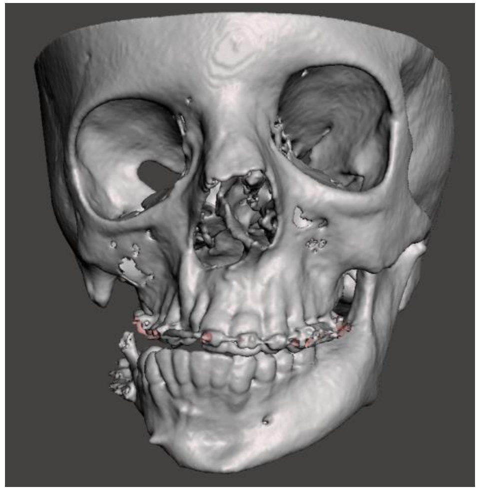
STL File
(Standard Triangle Language)

G-code
(RS-274, G language)

Volume Rendering



Surface Model



Triangulated surface

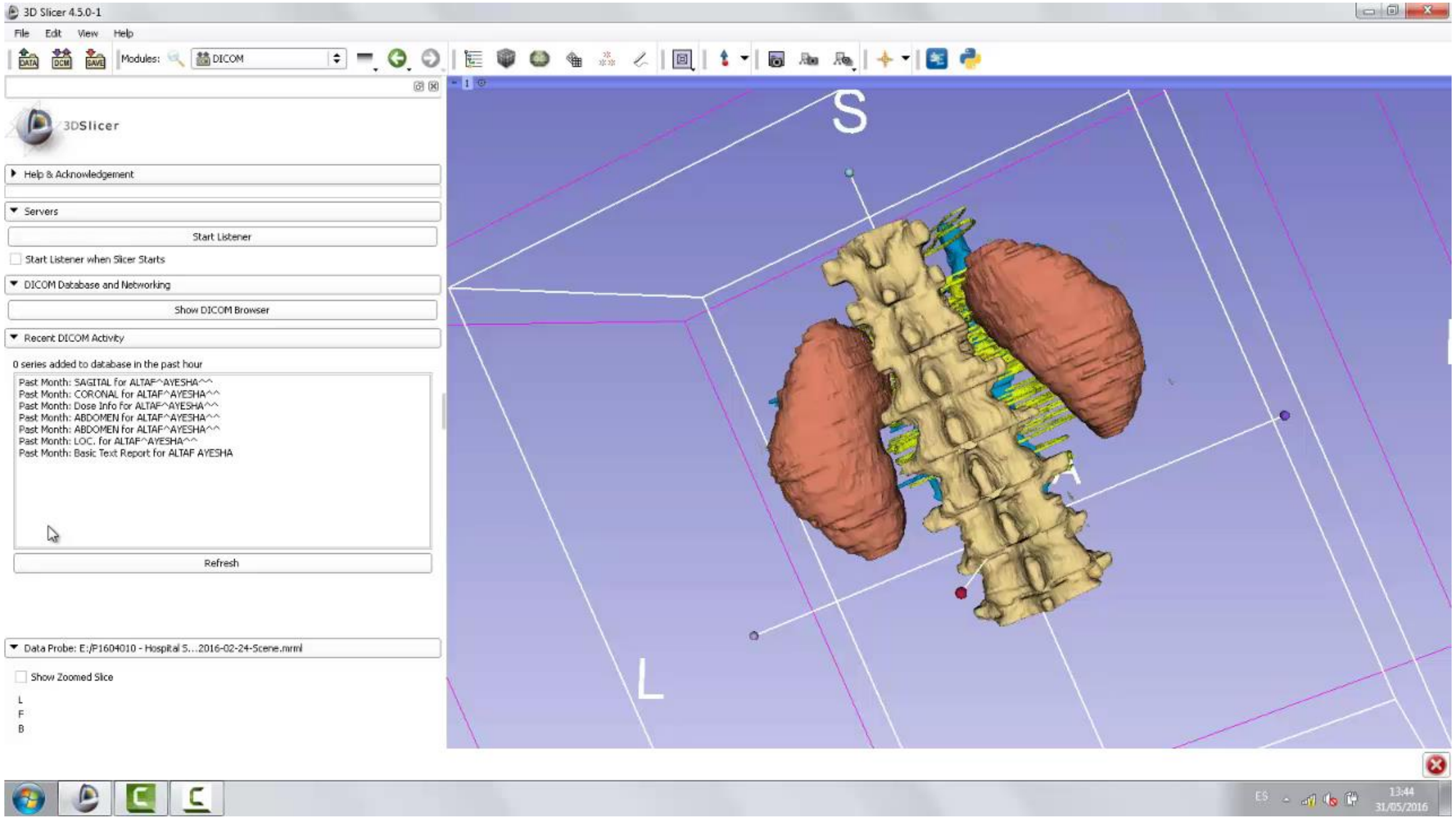
Codes for slicing print

```
M140 S65
M105
M190 S65
M104 S246
M105
M109 S246
M82
G21
G90
M82
M107
G28 X0 Y0
G28 Z0
G1 Z15.0 F9000
G92 E0
G1 F200 E3
G92 E0
```

1 mm a 10 mm de gruix

0.025 mm a 0.3 mm de gruix

SIMULACIÓ CAD (Computed Aided Design)



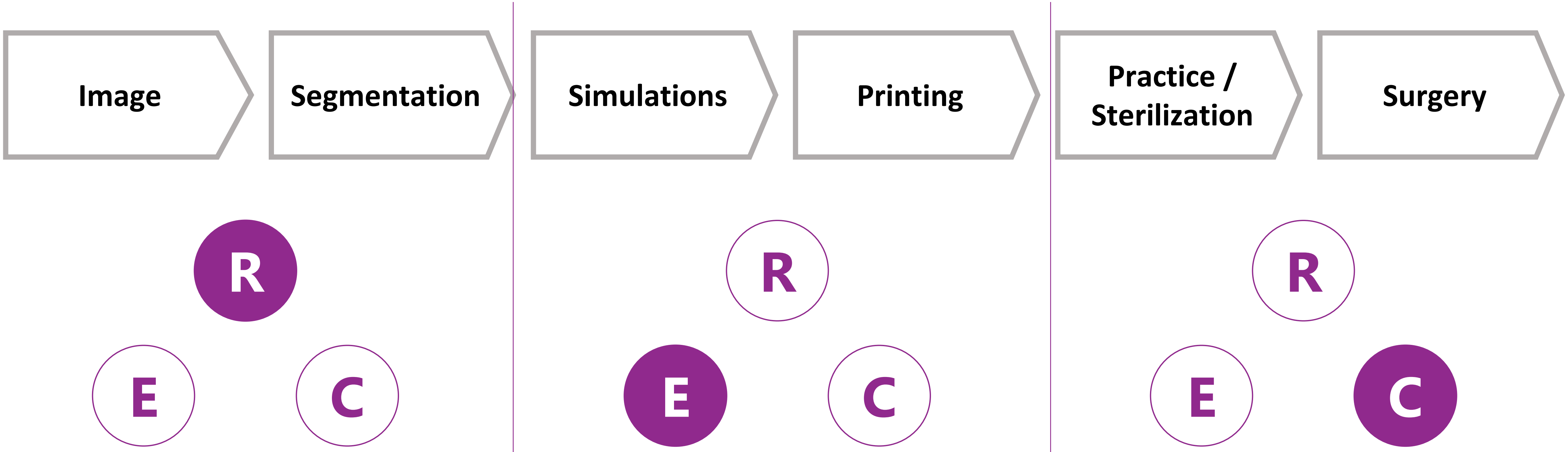
0 series added to database in the past hour

Past Month: SAGITAL for ALTAF^AYESHA^^
Past Month: CORONAL for ALTAF^AYESHA^^
Past Month: Dose Info for ALTAF^AYESHA^^
Past Month: ABDOMEN for ALTAF^AYESHA^^
Past Month: ABDOMEN for ALTAF^AYESHA^^
Past Month: LOC. for ALTAF^AYESHA^^
Past Month: Basic Text Report for ALTAF AYESHA

Data Probe: E:/P1604010 - Hospital S...2016-02-24-Scene.mrml

L
F
B

NOUS PERFILS PROFESSIONALS



R Radiòleg
E Enginyer
C Cirurgià

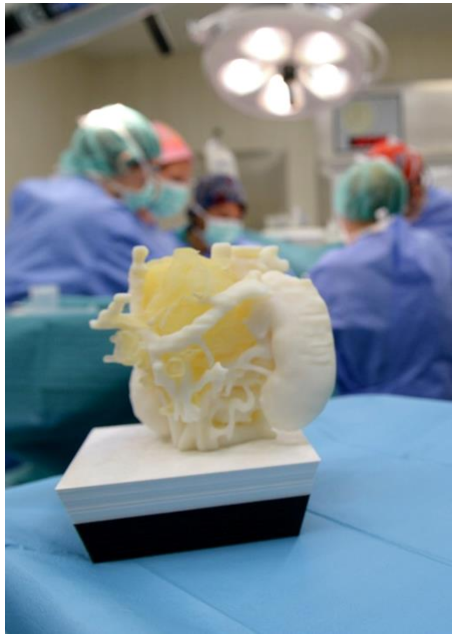
APLICACIONS A CIRURGIA

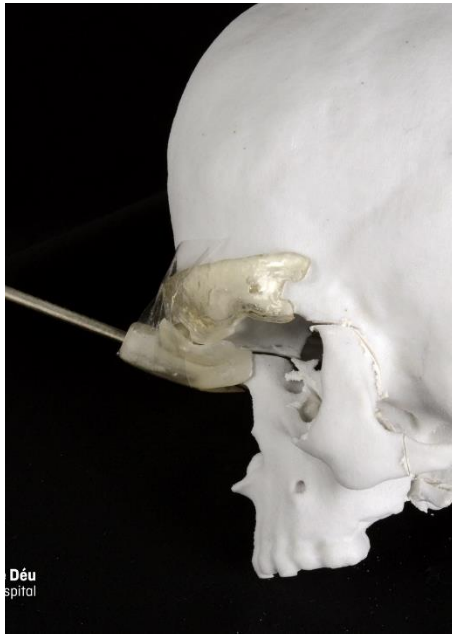
MODEL ANATÒMIC
No invasiu, educatiu
- Class I -

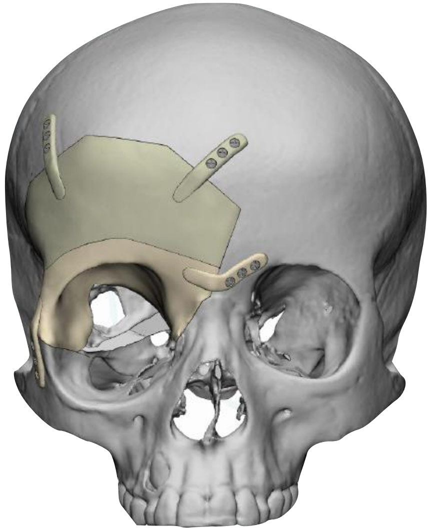
EINES QUIRÚRGIQUES
Invasiu quirúrgicament: ús transitori
- Class II a,b -

IMPLANTS RECONSTRUCTIUS
invasiu quirúrgicament: ús prolongat
- Class III -

BIOIMPRESSIÓ REGENERATIVA
Biomaterials i cèl·lules vives
- Class III -





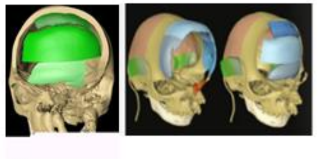


CASOS EXEMPLE

MAXILOFACIAL SURGERY

ONCOLOGICAL SURGERY

NEURO-SURGERY



DENTAL APPLICATIONS

ORTOPEDIC AND TRAUMA SURGERY

CARDIAC SURGERY

PLASTIC SURGERY

FETAL SURGERY

SJD 3D4H
3D for Health

Arnau Valls
INNOVATION & ENG.

Dr. Lucas Krauel
SURGERY

Dr. Josep Rubio
MAXILLOFACIAL SURGERY

Dr. Josep Munuera
RADIOLOGY

Marta Ayats
BIOMEDICAL ENG.

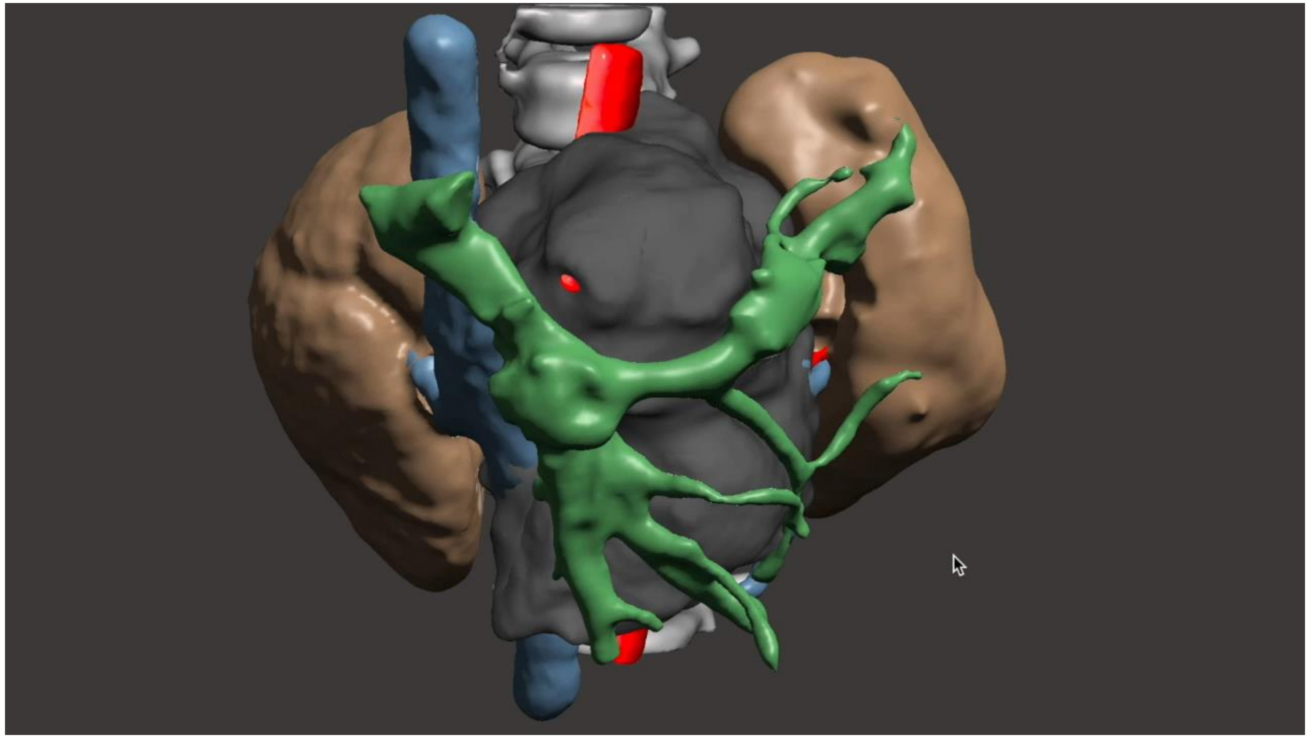
Dr. José Mª Quintilla
TEACHING SIMULATION

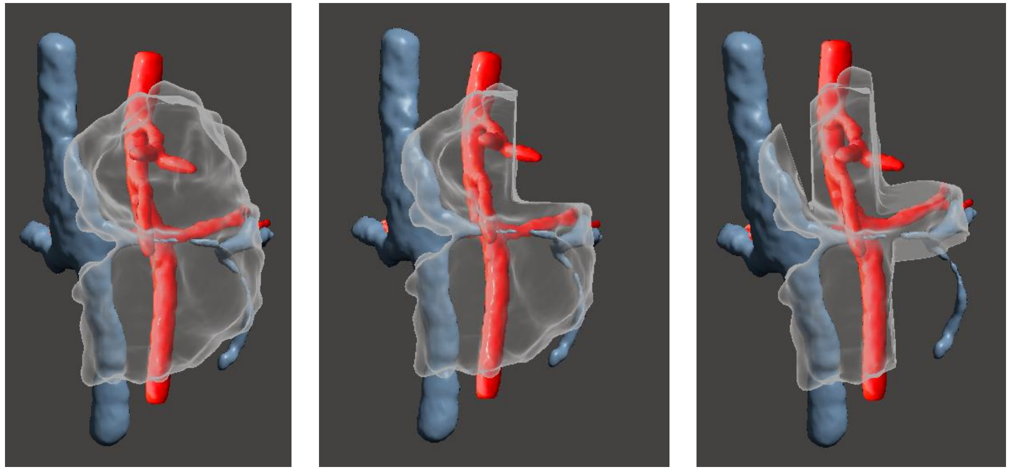
Carmen de la Gala
TEACHING SIMULATION

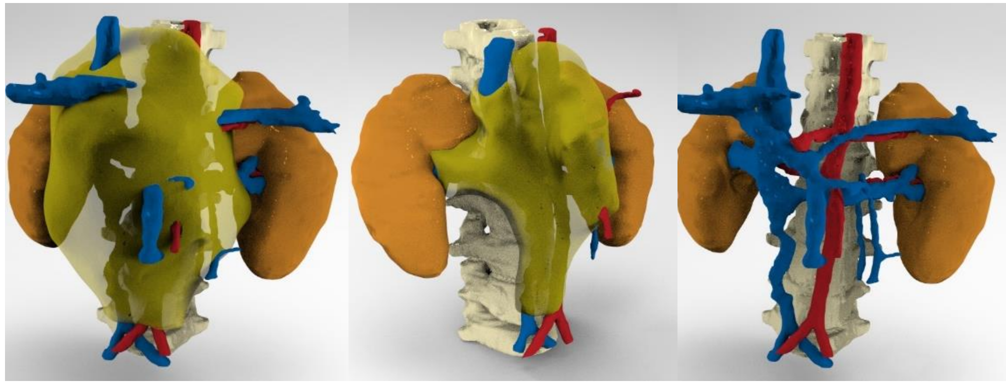
Marta Millet
ECONOMY AND FINANCE

Simulació virtual

Cirurgia Oncològica *Ex. Neuroblastoma*





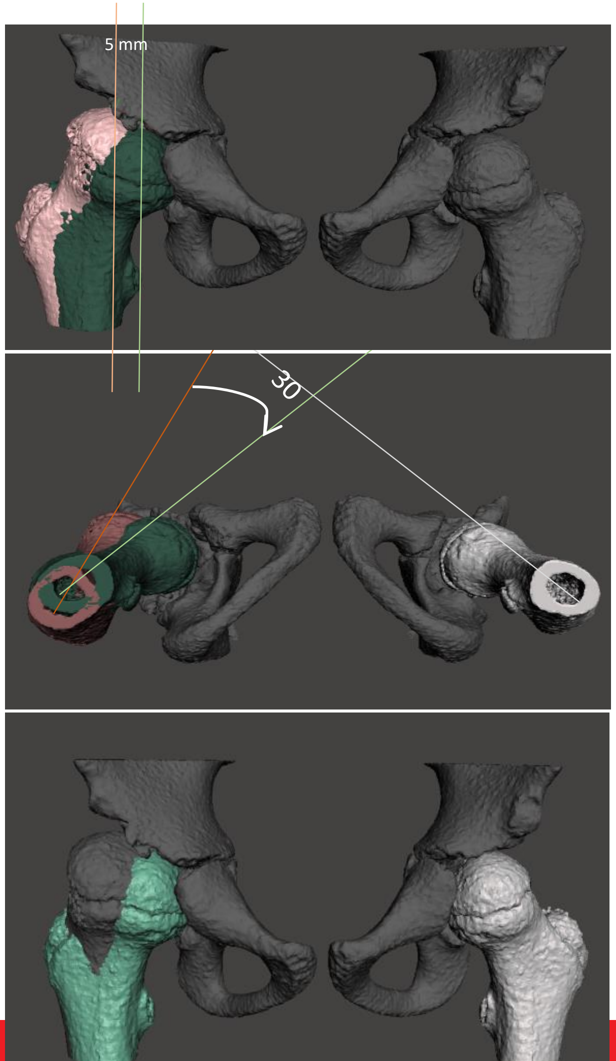


- Càlcul del volum de resecció
- Simulació de diferents escenaris
- Anàlisi de la imatge 3D

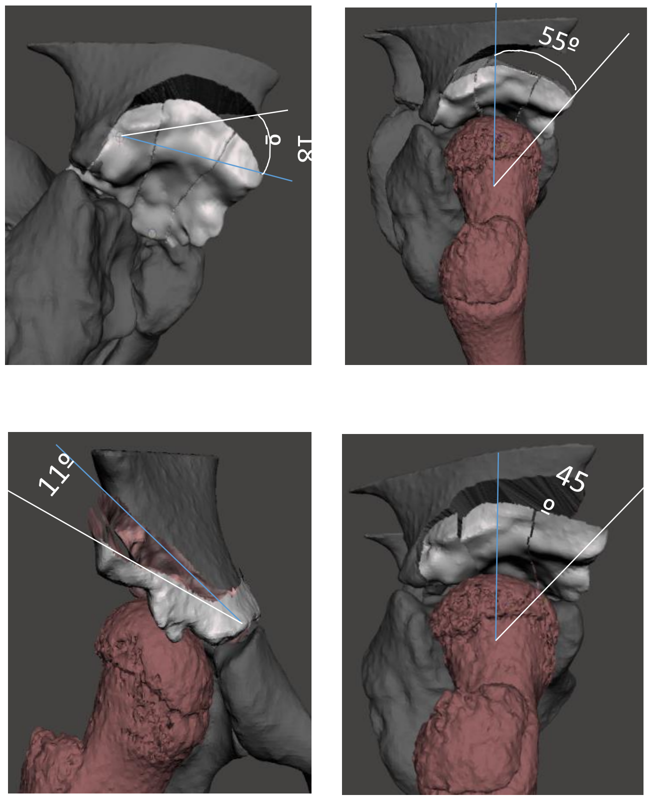
Predir i Protocolitzar:

Estandarditzar processos quirúrgics

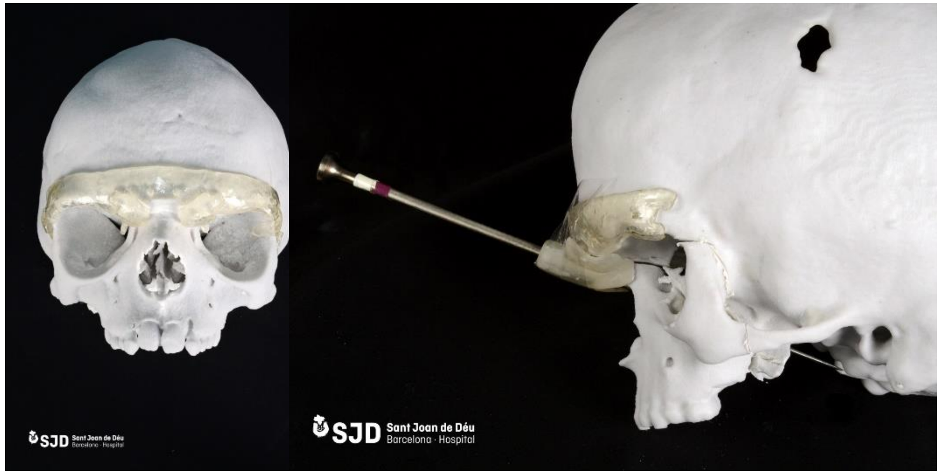
Càlculs de posicionament / Simetries

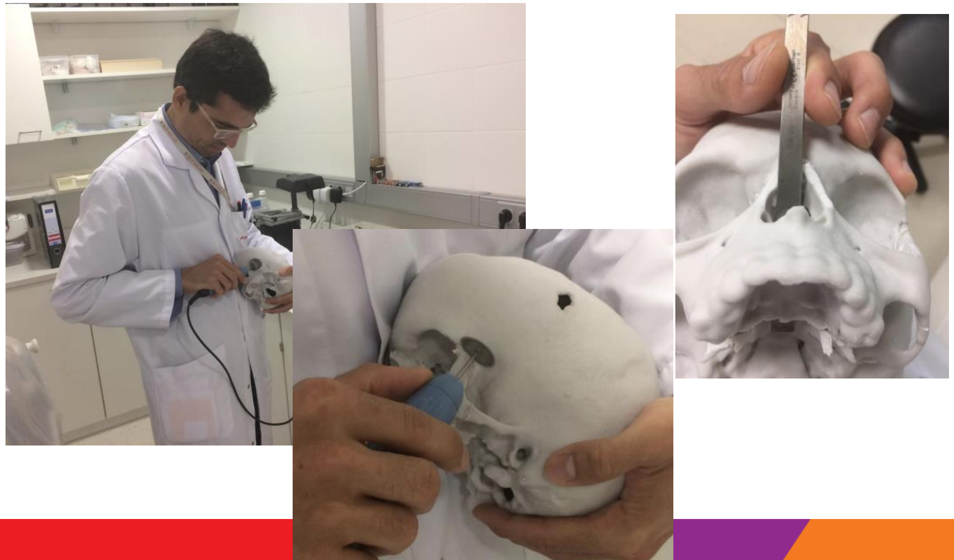


Simulació abordatges



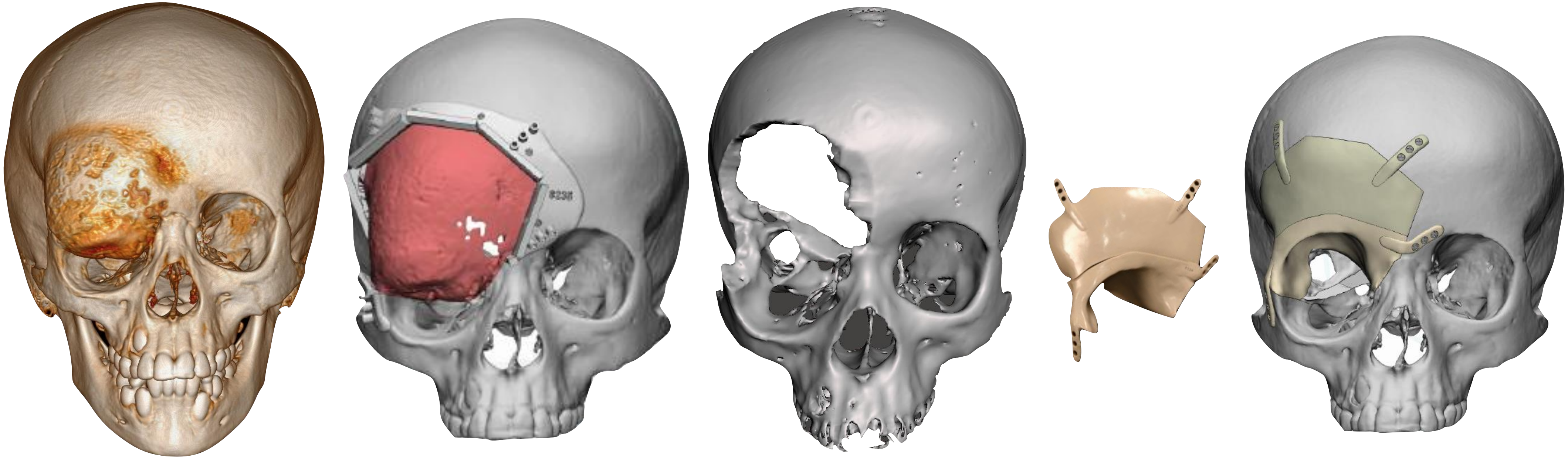
Guiatge

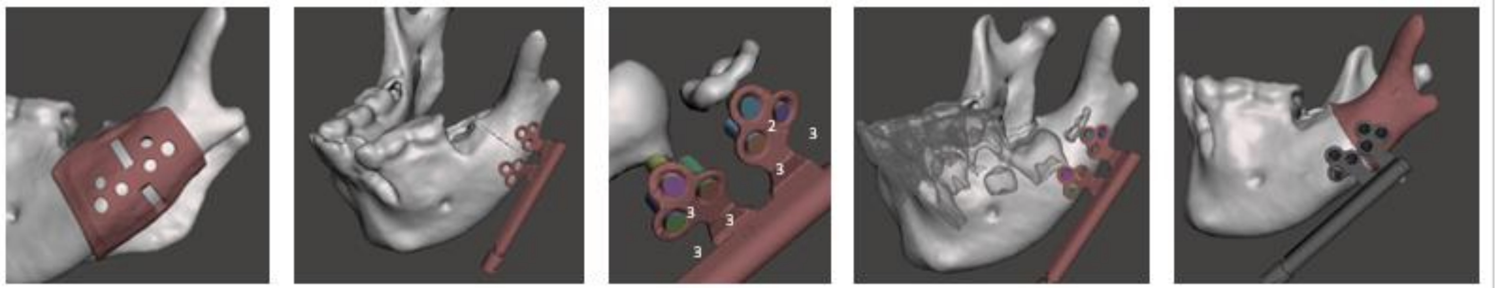


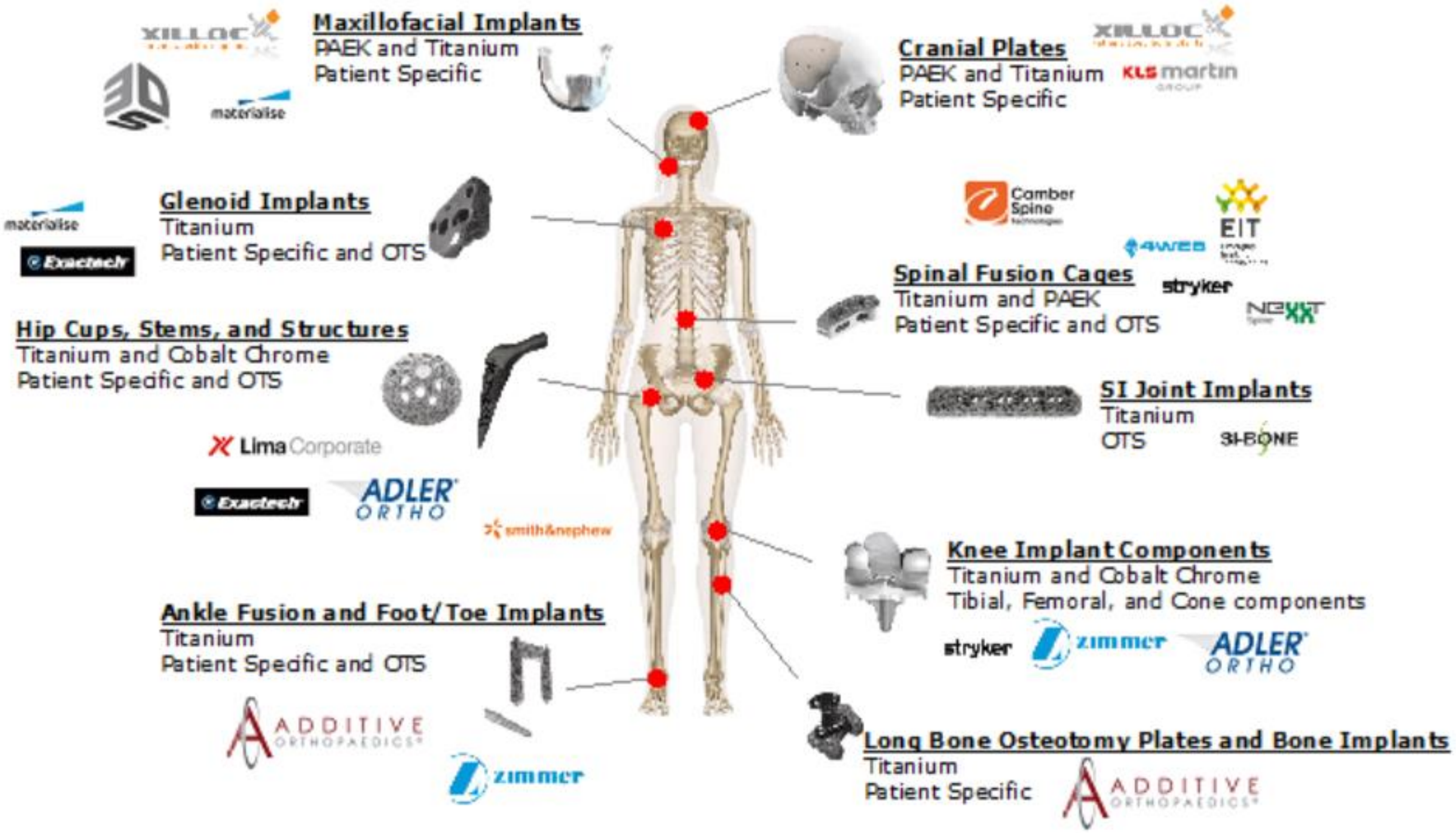


Guiar i minimitzar complicacions:

Guies de Tall / Guies de Posicionament







Maxillofacial Implants
PAEK and Titanium
Patient Specific

Cranial Plates
PAEK and Titanium
Patient Specific

Glenoid Implants
Titanium
Patient Specific and OTS

Spinal Fusion Cages
Titanium and PAEK
Patient Specific and OTS

Hip Cups, Stems, and Structures
Titanium and Cobalt Chrome
Patient Specific and OTS

SI Joint Implants
Titanium
OTS

Knee Implant Components
Titanium and Cobalt Chrome
Tibial, Femoral, and Cone components

Ankle Fusion and Foot/Toe Implants
Titanium
Patient Specific and OTS

Long Bone Osteotomy Plates and Bone Implants
Titanium
Patient Specific

Source: SmarTech Analysis

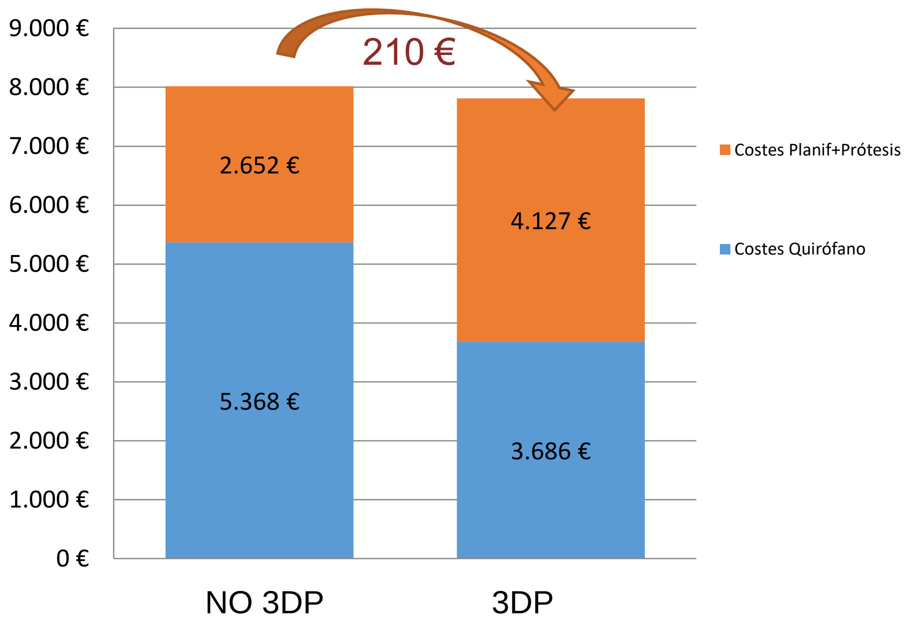
IMPACTE

< 30%

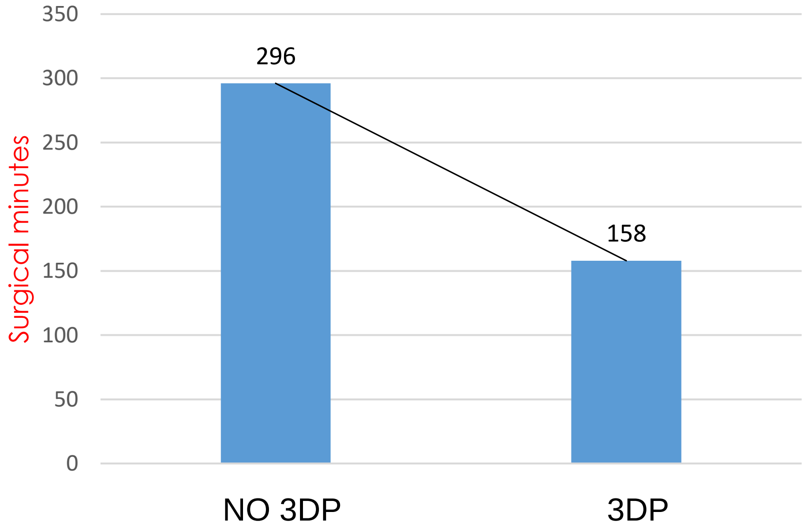
Reducció cost procés global

30%

Reducció del temps global



Costs surgery of a mandibular distraction with and without 3D planning



Surgical times
mandibular distraction

BENEFICIS

1. SEGURETAT

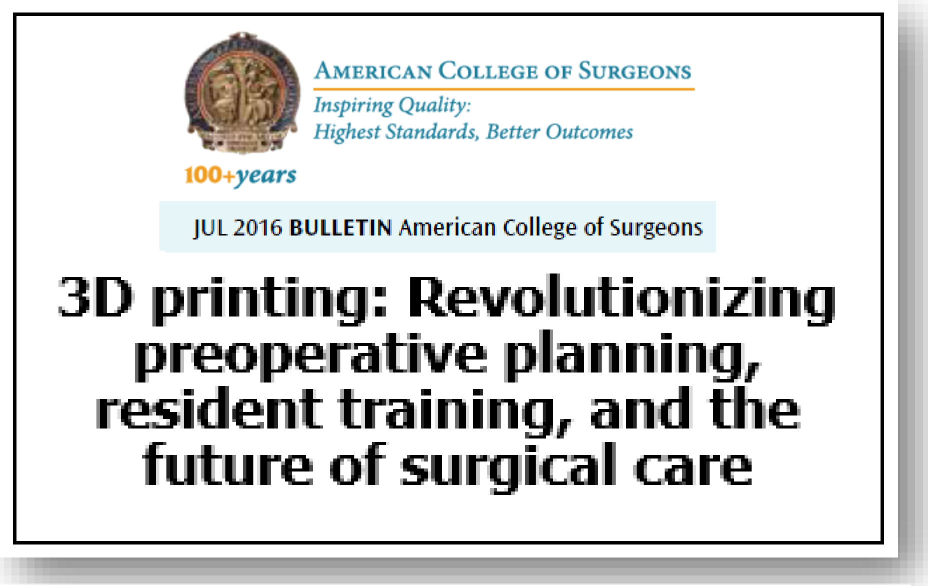
- Temps de anestèsia i isquèmia
- Simulació i pràctica prèvia amb tots sentits: Reducció de complicacions

2. EFICIÈNCIA i EFICÀCIA

- Reducció en el temps de intervenció
- Reducció de costos

3. MILLORA EN ELS RESULTATS/ QUALITAT

- Precisió en l’abordatge
- Reducció en reintervencions



AMERICAN COLLEGE OF SURGEONS
Inspiring Quality:
Highest Standards, Better Outcomes
100+years

JUL 2016 **BULLETIN** American College of Surgeons

3D printing: Revolutionizing preoperative planning, resident training, and the future of surgical care

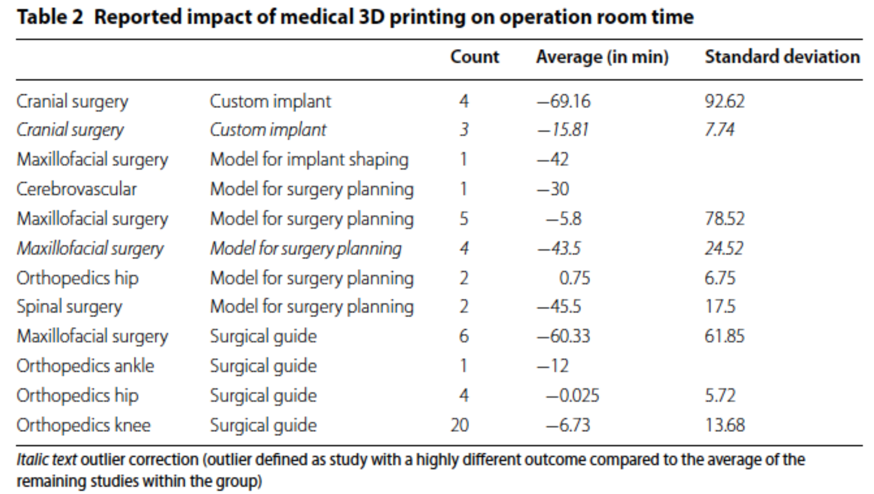


Table 2 Reported impact of medical 3D printing on operation room time

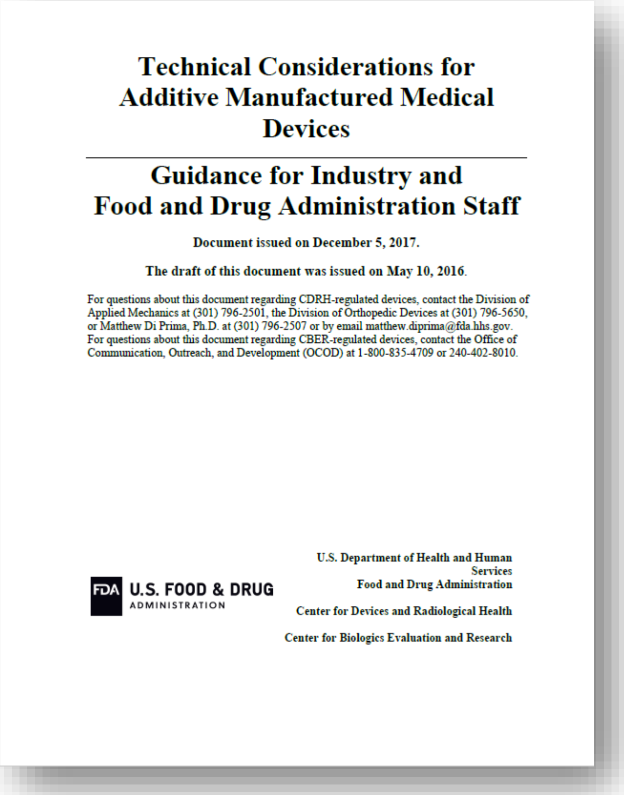
		Count	Average (in min)	Standard deviation
Cranial surgery	Custom implant	4	−69.16	92.62
Cranial surgery	*Custom implant*	*3*	*−15.81*	*7.74*
Maxillofacial surgery	Model for implant shaping	1	−42	
Cerebrovascular	Model for surgery planning	1	−30	
Maxillofacial surgery	Model for surgery planning	5	−5.8	78.52
Maxillofacial surgery	*Model for surgery planning*	*4*	*−43.5*	*24.52*
Orthopedics hip	Model for surgery planning	2	0.75	6.75
Spinal surgery	Model for surgery planning	2	−45.5	17.5
Maxillofacial surgery	Surgical guide	6	−60.33	61.85
Orthopedics ankle	Surgical guide	1	−12	
Orthopedics hip	Surgical guide	4	−0.025	5.72
Orthopedics knee	Surgical guide	20	−6.73	13.68

Italic text outlier correction (outlier defined as study with a highly different outcome compared to the average of the remaining studies within the group)

MDR – NOVA REGULACIÓ

FDA U.S. FOOD & DRUG ADMINISTRATION

CE



Technical Considerations for Additive Manufactured Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

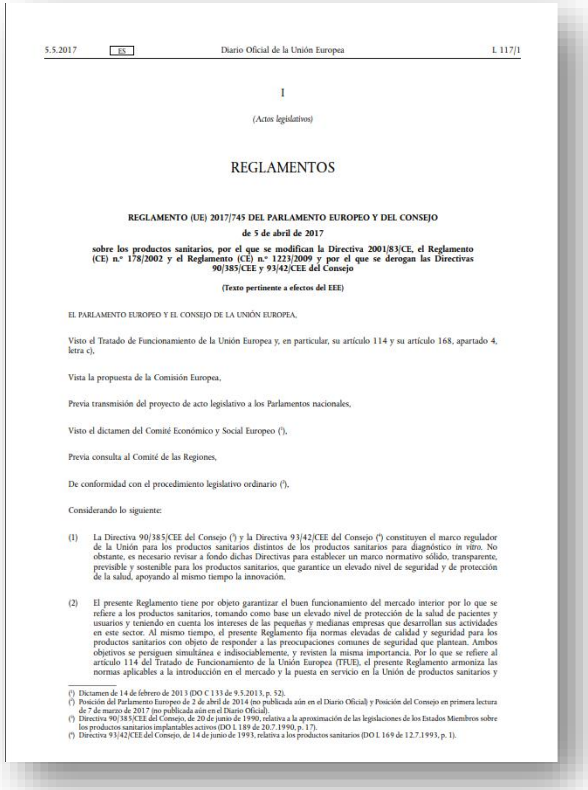
Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research



5.5.2017 ES Diario Oficial de la Unión Europea L 117/1

I

(Actos legislativos)

REGLAMENTOS

REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 5 de abril de 2017

sobre los productos sanitarios, por el que se modifican la Directiva 2001/83/CE, el Reglamento (CE) n.º 178/2002 y el Reglamento (CE) n.º 1223/2009 y por el que se derogan las Directivas 90/385/CEE y 93/42/CEE del Consejo

(Texto pertinente a efectos del EEE)

EL PARLAMENTO EUROPEO Y EL CONSEJO DE LA UNIÓN EUROPEA,

Visto el Tratado de Funcionamiento de la Unión Europea y, en particular, su artículo 114 y su artículo 168, apartado 4, letra c),

Vista la propuesta de la Comisión Europea,

Previa transmisión del proyecto de acto legislativo a los Parlamentos nacionales,

Visto el dictamen del Comité Económico y Social Europeo (1),

Previa consulta al Comité de las Regiones,

De conformidad con el procedimiento legislativo ordinario (2),

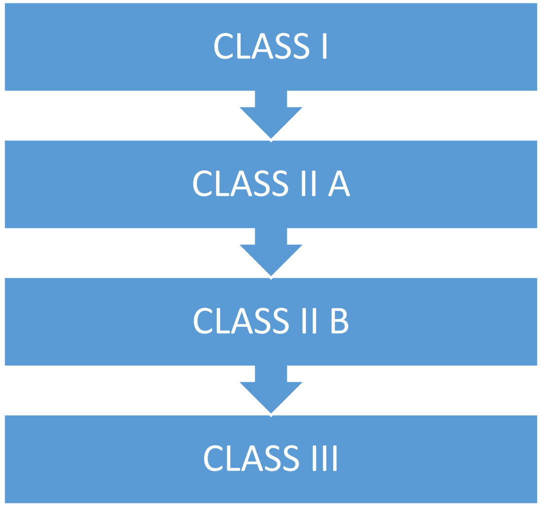
Considerando lo siguiente:

(1) La Directiva 90/385/CEE del Consejo (3) y la Directiva 93/42/CEE del Consejo (4) constituyen el marco regulador de la Unión para los productos sanitarios distintos de los productos sanitarios para diagnóstico *in vitro*. No obstante, es necesario revisar a fondo dichas Directivas para establecer un marco normativo sólido, transparente, previsible y sostenible para los productos sanitarios, que garantice un elevado nivel de seguridad y de protección de la salud, apoyando al mismo tiempo la innovación.

(2) El presente Reglamento tiene por objeto garantizar el buen funcionamiento del mercado interior por lo que se refiere a los productos sanitarios, tomando como base un elevado nivel de protección de la salud de pacientes y usuarios y teniendo en cuenta los intereses de las pequeñas y medianas empresas que desarrollan sus actividades en este sector. Al mismo tiempo, el presente Reglamento fija normas elevadas de calidad y seguridad para los productos sanitarios con objeto de responder a las preocupaciones comunes de seguridad que plantean. Ambos objetivos se persiguen simultánea e indisociablemente, y revisten la misma importancia. Por lo que se refiere al artículo 114 del Tratado de Funcionamiento de la Unión Europea (TFUE), el presente Reglamento armoniza las normas aplicables a la introducción en el mercado y la puesta en servicio en la Unión de productos sanitarios y

---

(1) Dictamen de 14 de febrero de 2013 (DO C 133 de 9.5.2013, p. 52).
(2) Posición del Parlamento Europeo de 2 de abril de 2014 (no publicada aún en el Diario Oficial) y Posición del Consejo en primera lectura de 7 de marzo de 2017 (no publicada aún en el Diario Oficial).
(3) Directiva 90/385/CEE del Consejo, de 20 de junio de 1990, relativa a la aproximación de las legislaciones de los Estados Miembros sobre los productos sanitarios implantables activos (DO L 189 de 20.7.1990, p. 17).
(4) Directiva 93/42/CEE del Consejo, de 14 de junio de 1993, relativa a los productos sanitarios (DO L 169 de 12.7.1993, p. 1).



CLASS I

CLASS II A

CLASS II B

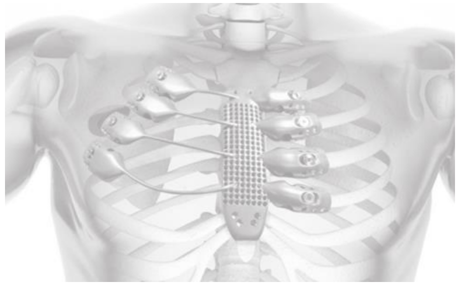
CLASS III

APLICACIONS DEL 3D EN SALUD

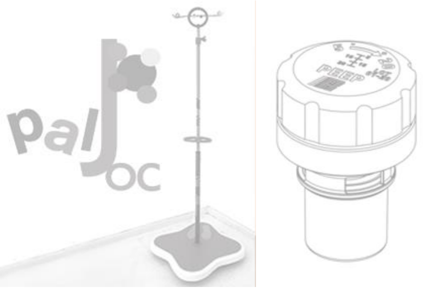
SURGERY PLANNING

EDUCATION

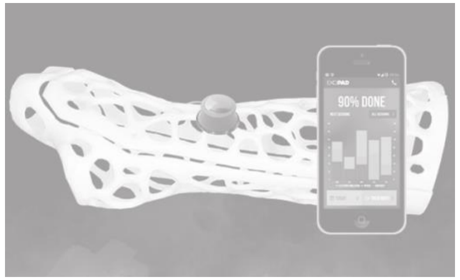
PROSTHETICS



IMPLANTS

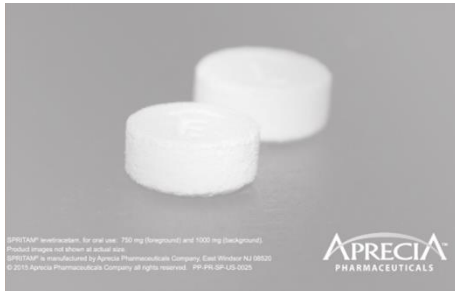


MEDICAL TOOLS AND DEVICES



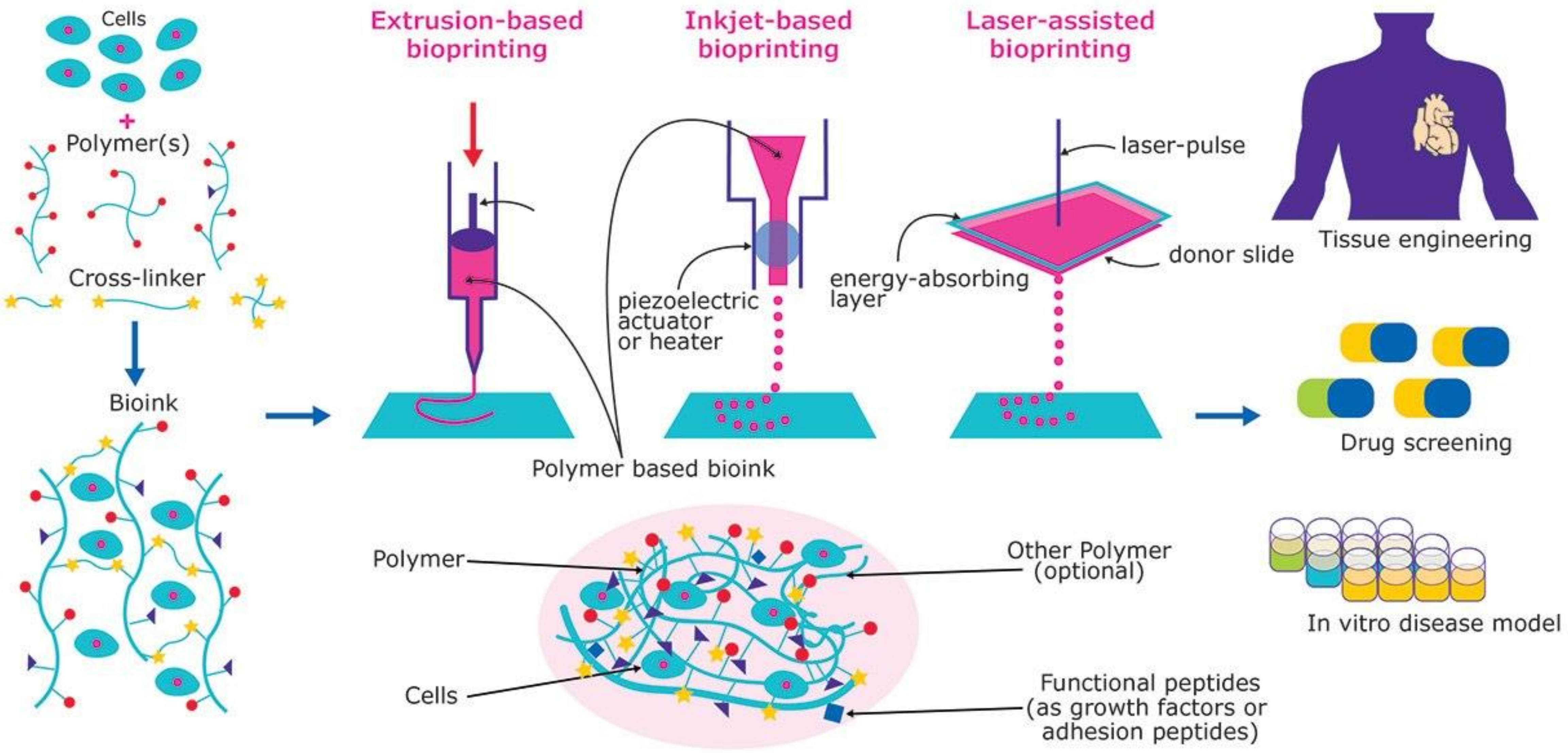
SPLINTS

BIO-PRINTING



MEDICATION

Printing Process: Material extrusion (DIW): 3D Bioprinting



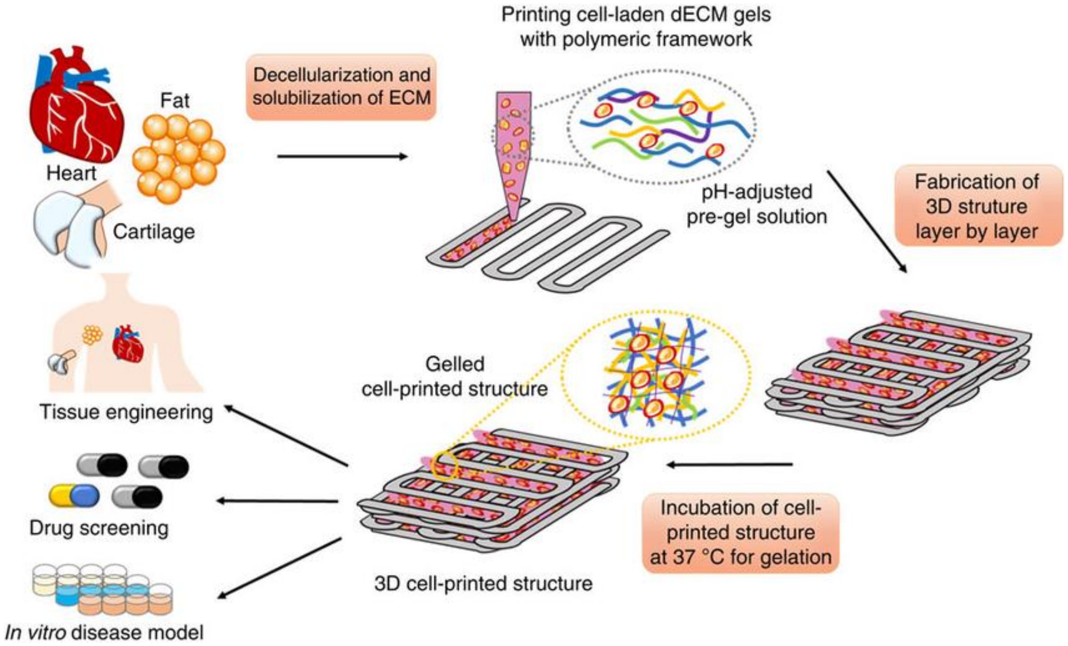
Source: https://www.sigmaaldrich.com/ES/es/technical-documents/technical-article/cell-culture-and-cell-culture-analysis/3d-cell-culture/3d-bioprinting-bioinks

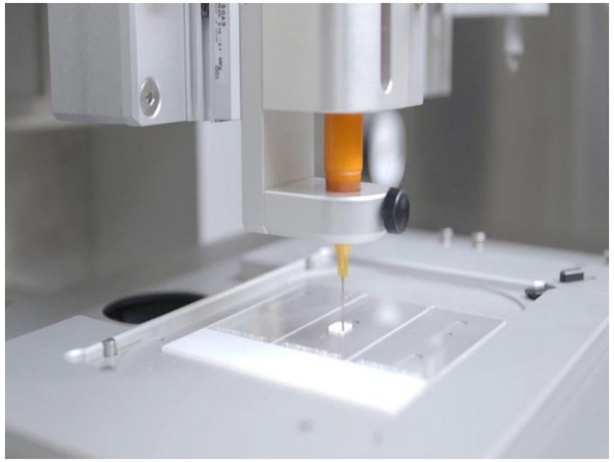
Printing Process: Material extrusion by Robocasting (DIW): 3D Bioprinting

Definition:

Is the process in which bioinks are used for the manufacturing of 3D structures which are implanted in the human body. These bioinks are a mix of cells, material corresponding to extracellular matrix (ECM biocompatible with the human body, most of them organogels) and growth factors.

Normally the structures are printed by extrusion.



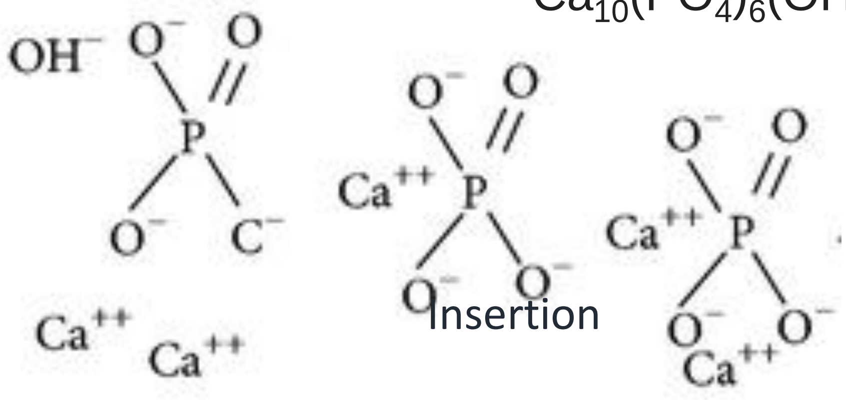


Bioprinting is a “trend” on research. The path to 3Dprinted tissues is open, but there is a lot of work to be done. Source: IBEC

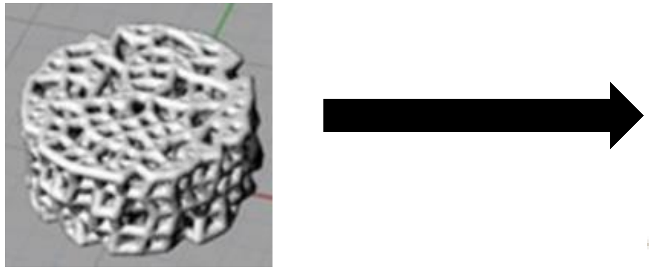
Printing materials: Silicone, alginate (hydrogel), generation cells (chondrocytes) and for bones and scaffolding ceramics (Hydroxyapatite (HA))

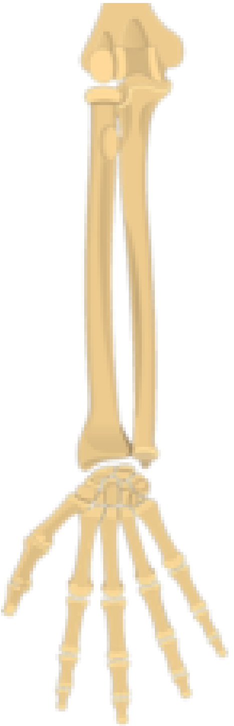
Ceramics: Hydroxyapatite (HA)

$Ca_{10}(PO_4)_6(OH)_2$



Insertion





Definition

Hydroxiapatite, which is a CaP (Calcium Phosphate) bioceramic, is an inorganic composite which is part of the human and animal bones composition.

HA is not only highly biocompatible but also non-toxic and osteoconductive. Therefore, it is an ideal biomaterial for fracture healing.

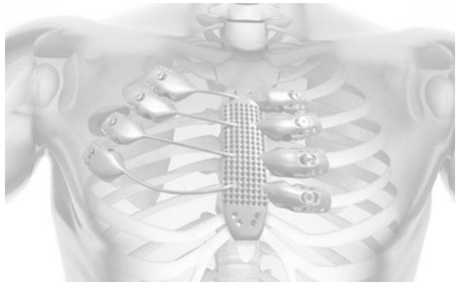
Source: Buj-Corral, I., Bagheri, A., & Petit-Rojo, O. (2018). 3D printing of porous scaffolds with controlled porosity and pore size values. *Materials*, *11*(9), 1532.

APLICACIONS DEL 3D EN SALUD

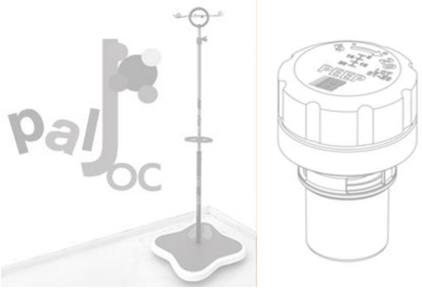
SURGERY PLANNING

EDUCATION

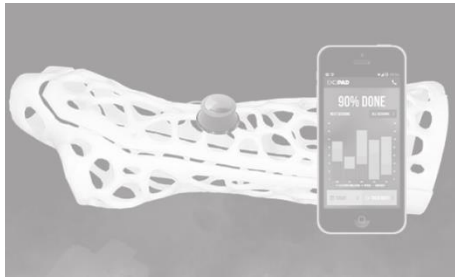
PROSTHETICS



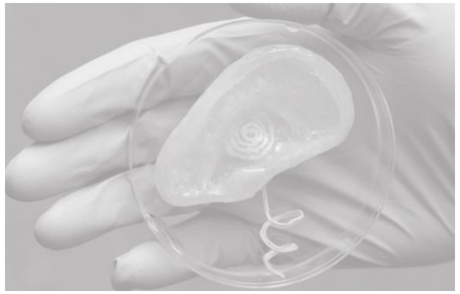
IMPLANTS



MEDICAL TOOLS AND DEVICES



SPLINTS



BIO-PRINTING

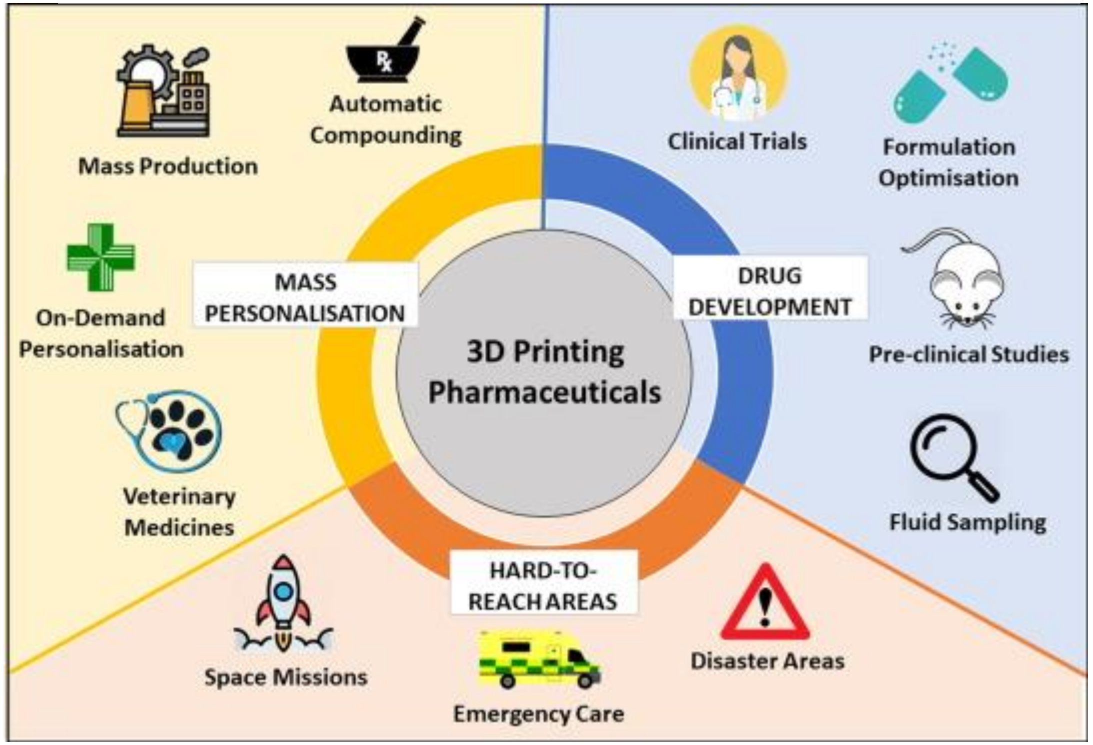
SPRITAM® levetiracetam, for oral use: 750 mg (foreground) and 1000 mg (background).
Product images not shown at actual size.
SPRITAM® is manufactured by Aprecia Pharmaceuticals Company, East Windsor NJ 08520
© 2015 Aprecia Pharmaceuticals Company all rights reserved. PP-PR-SP-US-0025

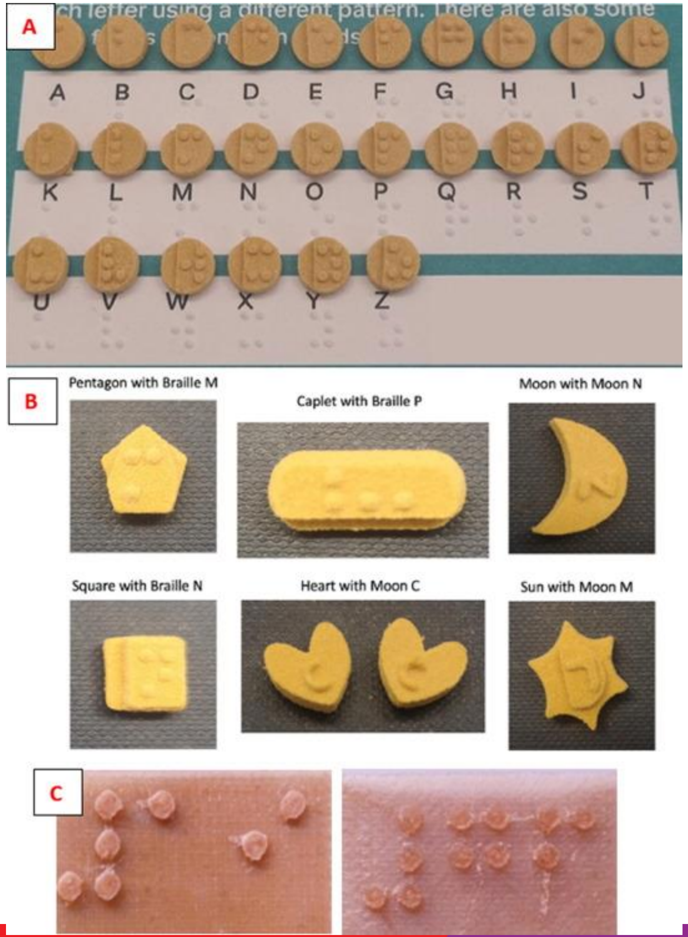
MEDICATION

Advanced Drug Delivery Reviews
Volume 174, July 2021, Pages 553-575

Translating 3D printed pharmaceuticals: From hype to real-world clinical applications

Iria Seoane-Viaño [a, 1], Sarah J. Trenfield [b, 1], Abdul W. Basit [b, c], Alvaro Goyanes [b, c, d]





https://www.sciencedirect.com/science/article/pii/S0169409X21001599?dgcid=coauthor#f0100

FDA U.S. FOOD & DRUG ADMINISTRATION

Source: *Creative Commons Data Base*

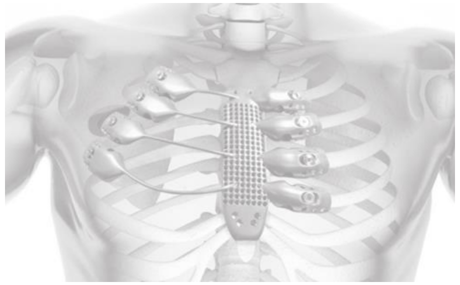
https://www.3dprintingmedia.network/university-glasgow-students-build-chemical-mp3-player-3d-printed-drugs/

APLICACIONS DEL 3D EN SALUD

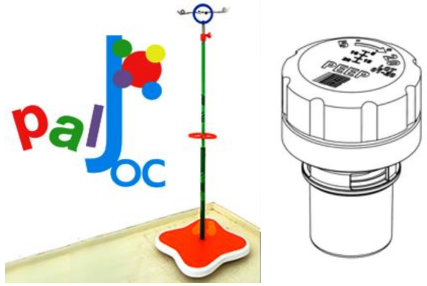
SURGERY PLANNING

EDUCATION

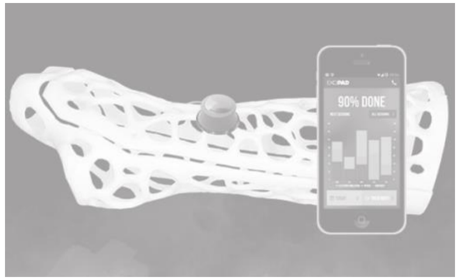
PROSTHETICS



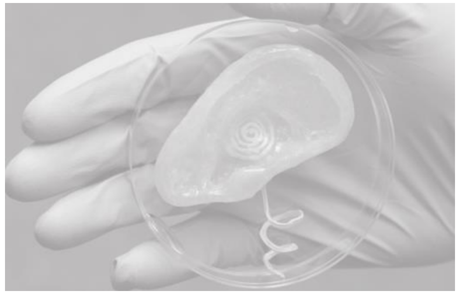
IMPLANTS



MEDICAL TOOLS AND DEVICES



SPLINTS



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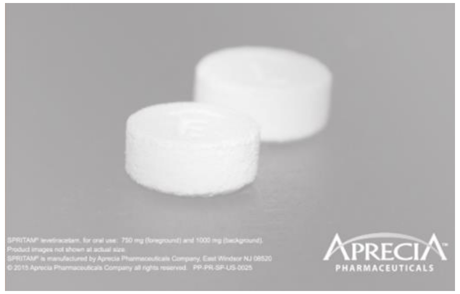
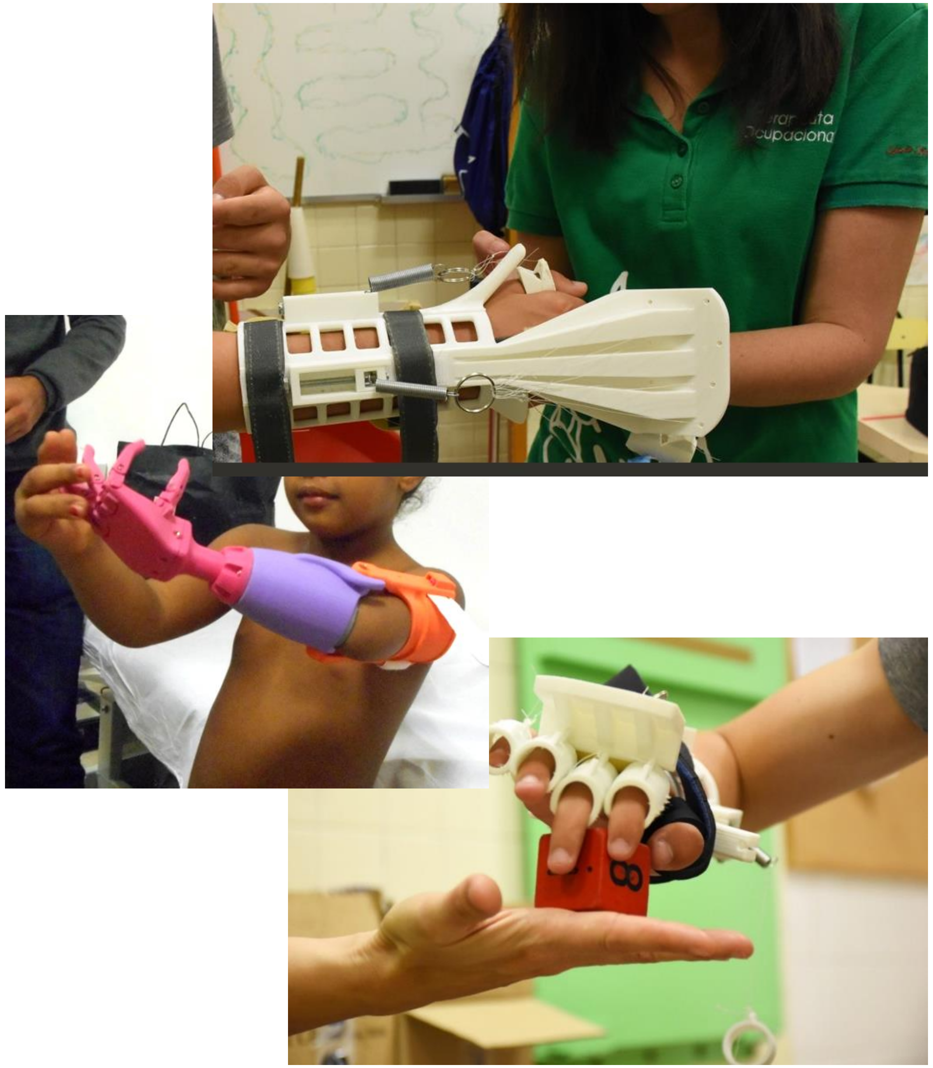
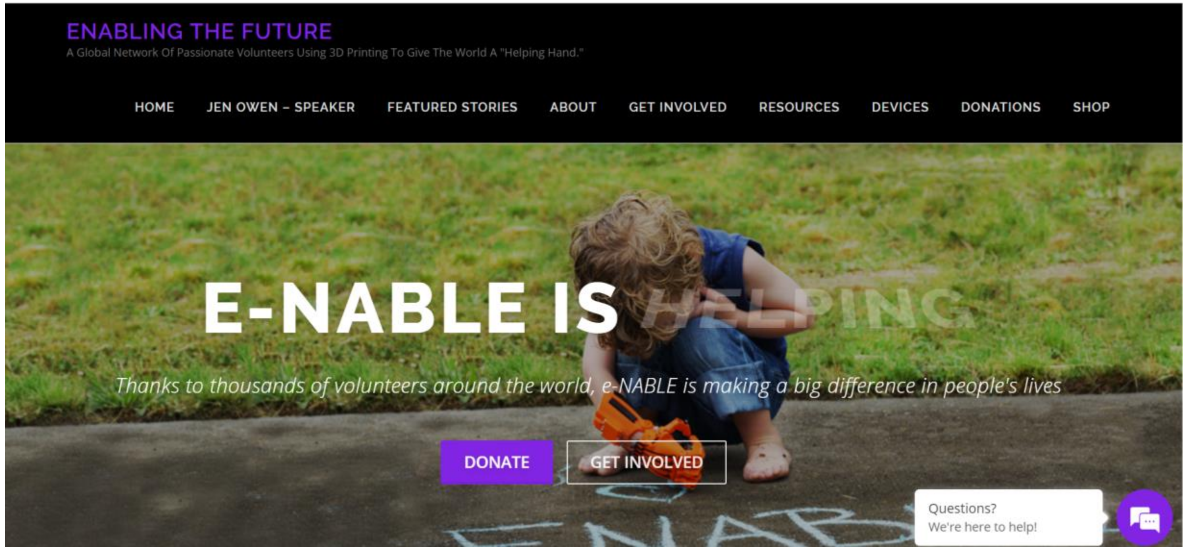


MEDICATION

Prototipat de dispositius

palJoc





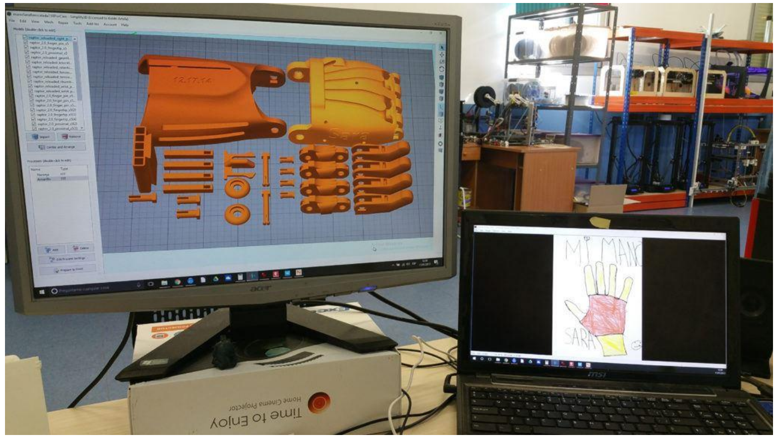
ENABLING THE FUTURE

A Global Network Of Passionate Volunteers Using 3D Printing To Give The World A "Helping Hand."

E-NABLE IS HELPING

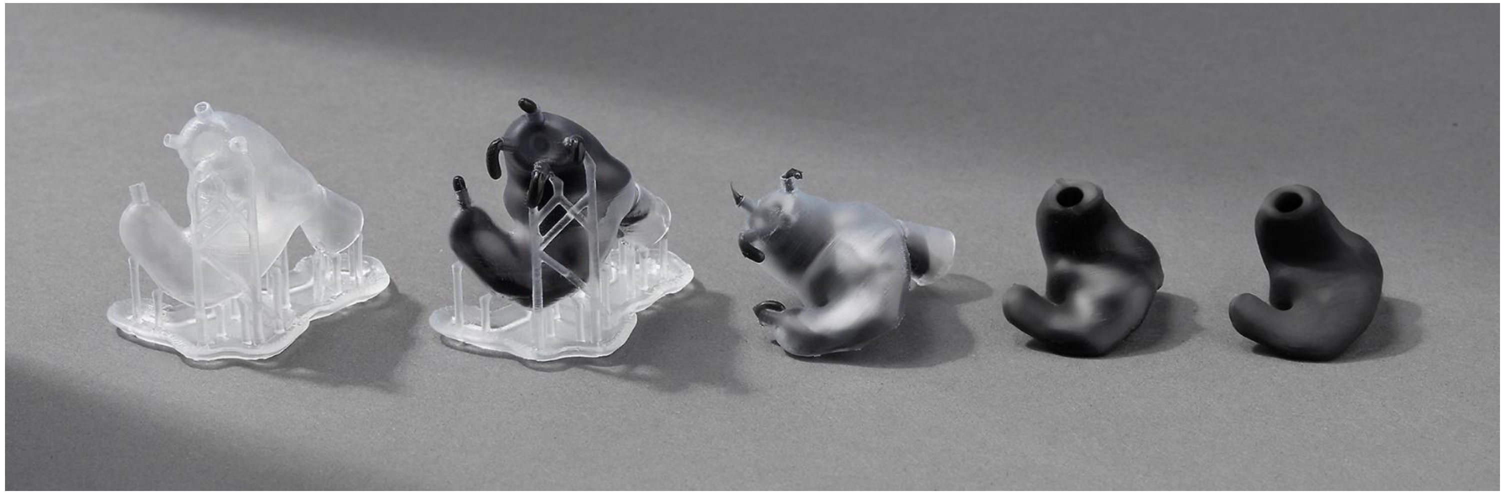
Thanks to thousands of volunteers around the world, e-NABLE is making a big difference in people's lives

Questions?
We're here to help!



Source: E-Nabling the future, Domotek, CIM UPC, BCN3DTechnologies, HSJD

Source: MIT and Shanghai Jiao Tong University



SCAN

Ear Impression
+ Desktop Scan
or
In-Ear Scan

DESIGN

3D Model
Edit the STL file
to final form

MANUFACTURE

3D Print
Wash + Post-Cure

Silicone Cast
Cast final material into
3D printed ear mold

POST-PROCESS

Final Product
Finish + Coat

Source: Formlabs

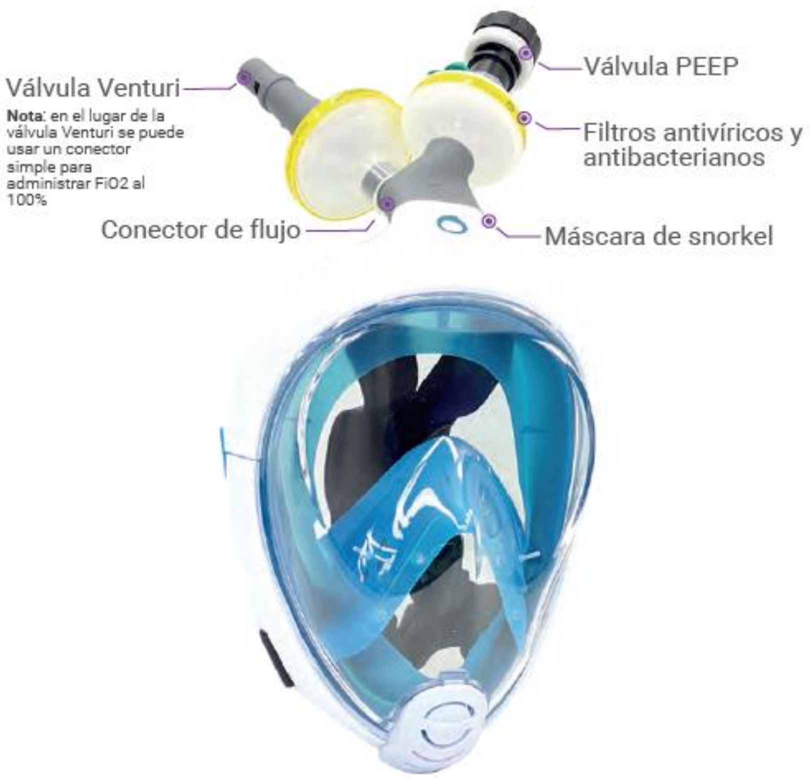
Source: https://proto3000.com/3d-printing/business-considerations-for-production-tooling-conversion-to-additive-manufacturing/

COVID19: Què ens ha permès tenir 3D4H?

ECPAP

1. **ECPAP** – CPAP Ventilació no Invasiva (VNI)

El dispositivo ECPAP está compuesto por los siguientes componentes esenciales:



En el projecte ECPAP s'han desenvolupat 2 components clau: La vàlvula de Venturi i la Vàlvula de PEEP (en 3 versions: 18 mm, 22 mm i 30 mm). Comercialitzables com a dispositius independents.

1 Válvula Venturi para regular el 02

PATENTED

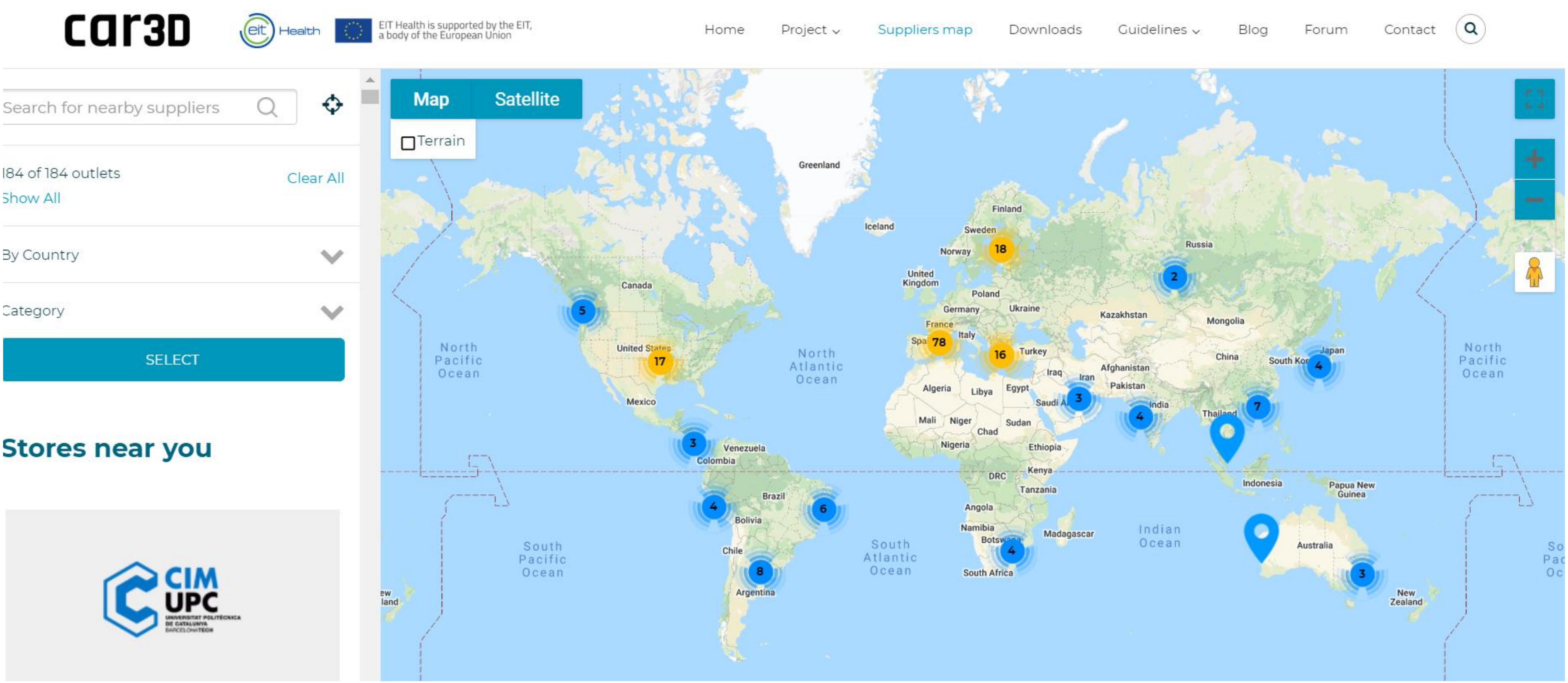
1 Vávula PEEP

Llicenciat a:

REDFLUID S.L.
REGULACION DE FLUIDOS

2. Equipament de Protecció Individual (EPIS)

CAR3D – Máscares i pantalles de protecció: Projecte finançat pel EIT Health de creació de màscares i pantalles de protecció i un web (https://car3d-project.eu/)



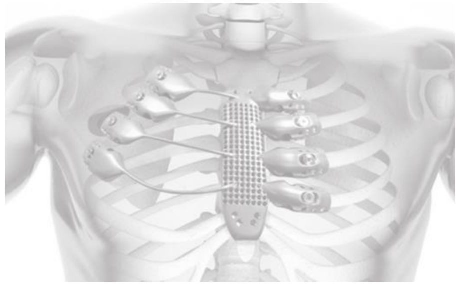
Source: https://car3d-project.eu/suppliers/

APLICACIONS DEL 3D EN SALUD

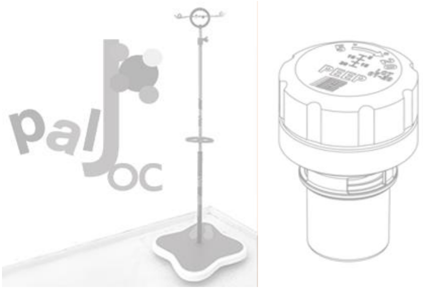
SURGERY PLANNING

EDUCATION

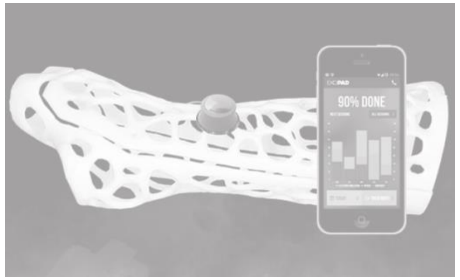
PROSTHETICS



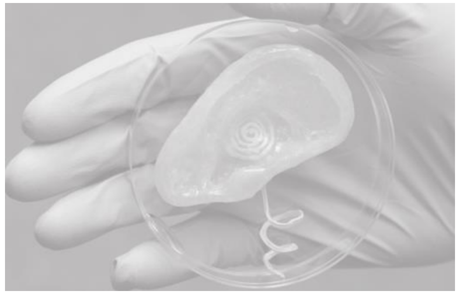
IMPLANTS



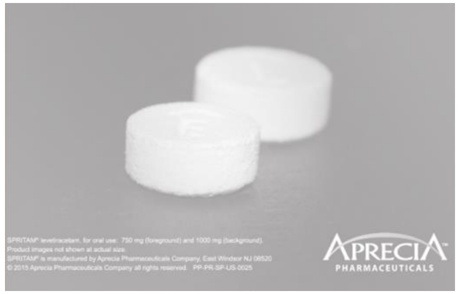
MEDICAL TOOLS AND DEVICES



SPLINTS



BIO-PRINTING



MEDICATION

Forbes, January 2018

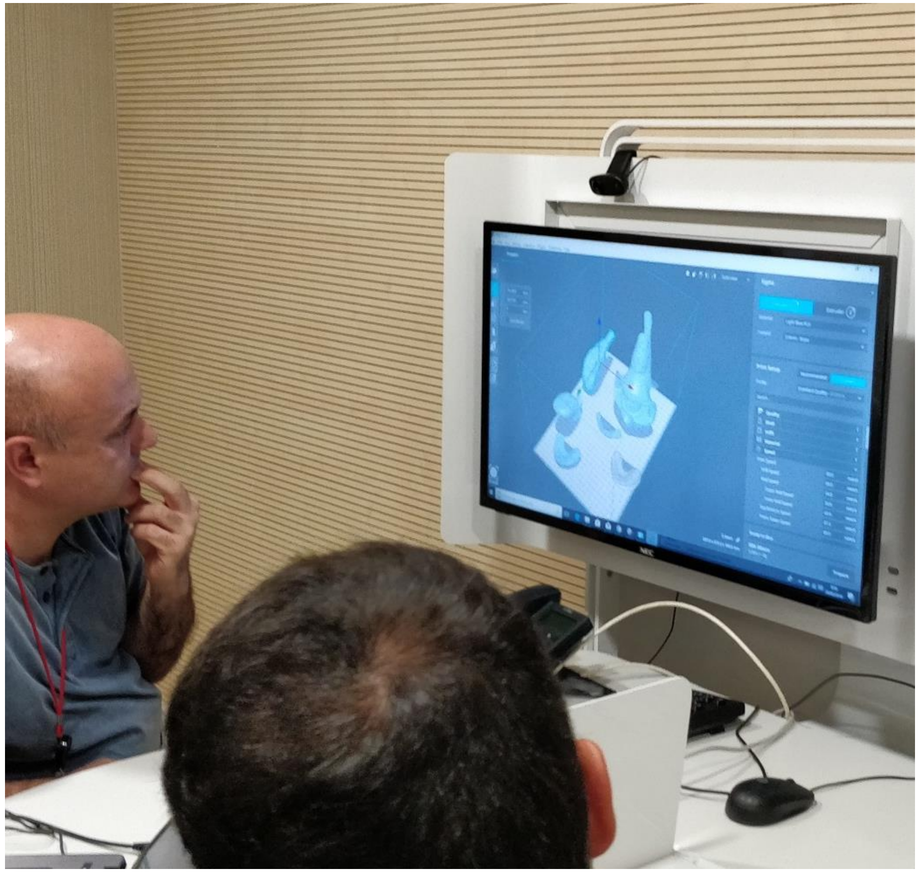
Frost & Sullivan’s: jobs that are likely to come in the near future:

1. **Reconstructive Surgery 3D Printing Specialist**
2. Voice Assistant Healthcare Content Specialists
3. Robotic Clinical Documentation Scribes Virtual Hospital Manager
4. Precision Medicine Compounding Pharmacist
5. Epigenetic Counselors
6. Health Finances Planner
7. Brain Neurostimulation Specialist Health Data Hacker
8. Biological Terrorist

Sant Joan de Déu
Barcelona · Hospital

Advanced Simulation – Darwin Center

Construcció de simuladors parcials



SIMULACIÓ I ENTRENAMENT

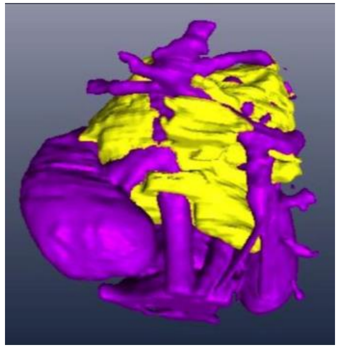
Sant Joan de Déu
Barcelona · Hospital

3D4H
3D for Health

Unitat de planificació 3D i simulació avançada de cirurgies

Use of 3D prototypes for complex surgical cases

(Dr. Lucas Krauel – Paediatric Surgical Oncology and CIM UPC)



CIM UPC
UNIVERSITAT POLITÈCNICA DE CATALUNYA BARCELONATECH

First case: 2013

3D4H HISTORY

2013: First Case

2015: Creation of a multidisciplinary team for the study:

1. State of the art
2. Clinical impact (outcomes)
3. Economic viability
4. Safety and regulations

2016: Study and follow-up of 16 pilot cases. The results targeted the benefits of creating a 3D based hospital planning service.

End of 2016: 3D printing unit implanted

2018 Consolidation

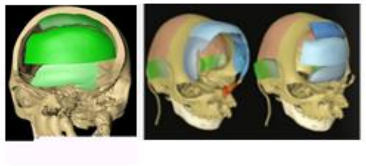
2021 Today!

3D PLANNING IN HSJD

MAXILOFACIAL SURGERY

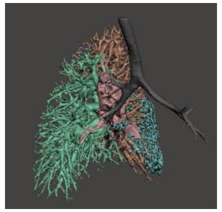
ONCOLOGICAL SURGERY

NEURO-SURGERY



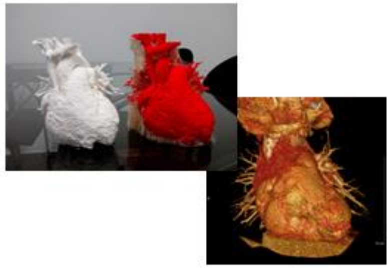
DENTAL APPLICATIONS

General Surgery



ORTOPEDIC AND TRAUMA SURGERY

CARDIAC SURGERY



PLASTIC SURGERY

FETAL SURGERY

Funcionament


Arnau Valls
Enginyer innovació


Dr. Lucas Krauel
Cirurgià

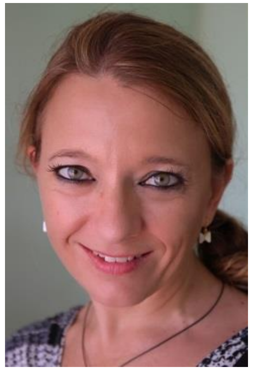

Dr. Josep Rubio
Cirurgià maxil·lofacial


Dr. Josep Munuera
Radiòleg


Marta Ayats
Enginyera Biomèdica


Dr. José Mª Quintilla
Docència i simulació


Carmen de la Gala
Docència i Simulació


Marta Millet
Economia i finances

Equip multidisciplinari

1 Reunió mensual

Col·laboració en I+D i docència

“Saleta Innovació”

2015

“La cuineta”

2017

“3D + Simulació”

2019

“3D + Simulació”

2021

On estem?

Assistència

I+D

Docència

On estem?

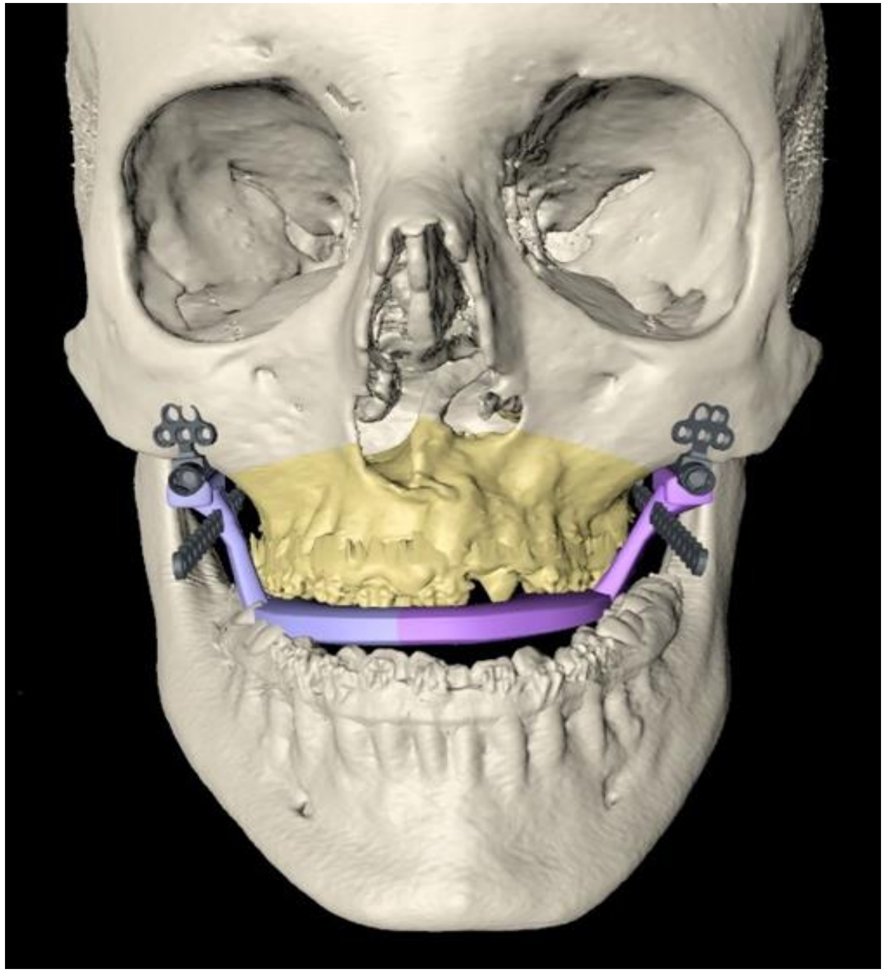
Assistència

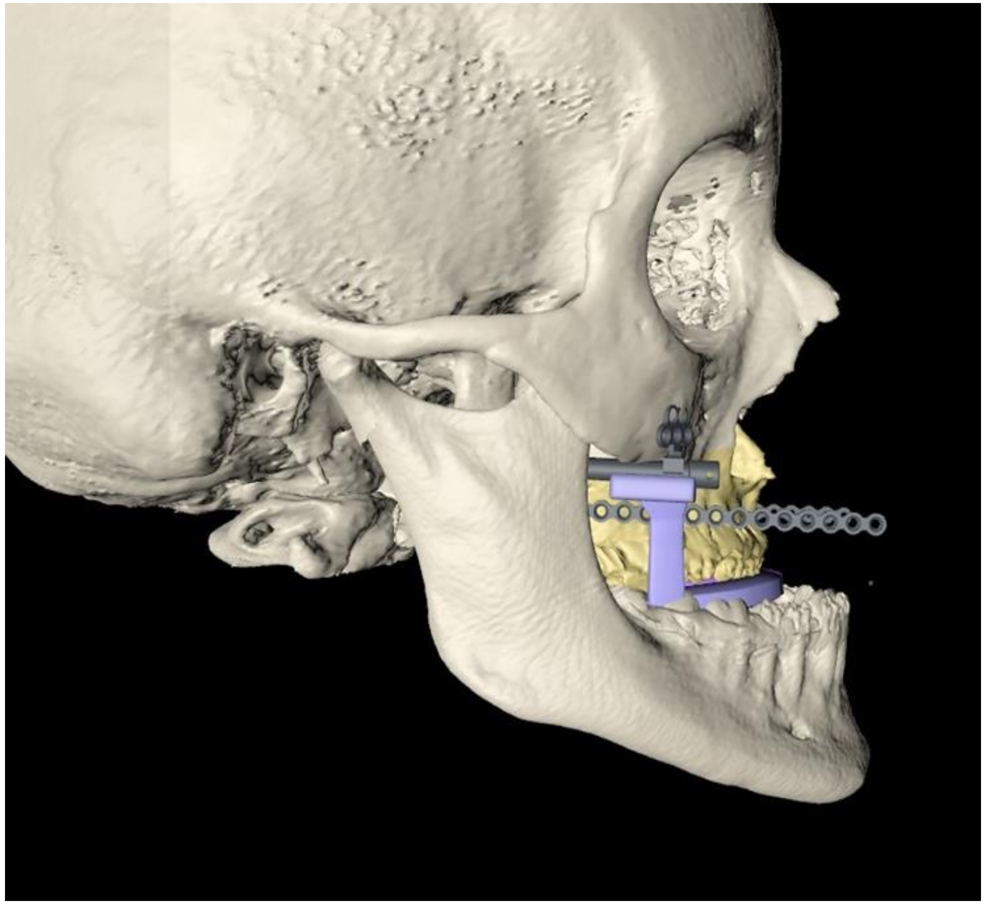
I+D

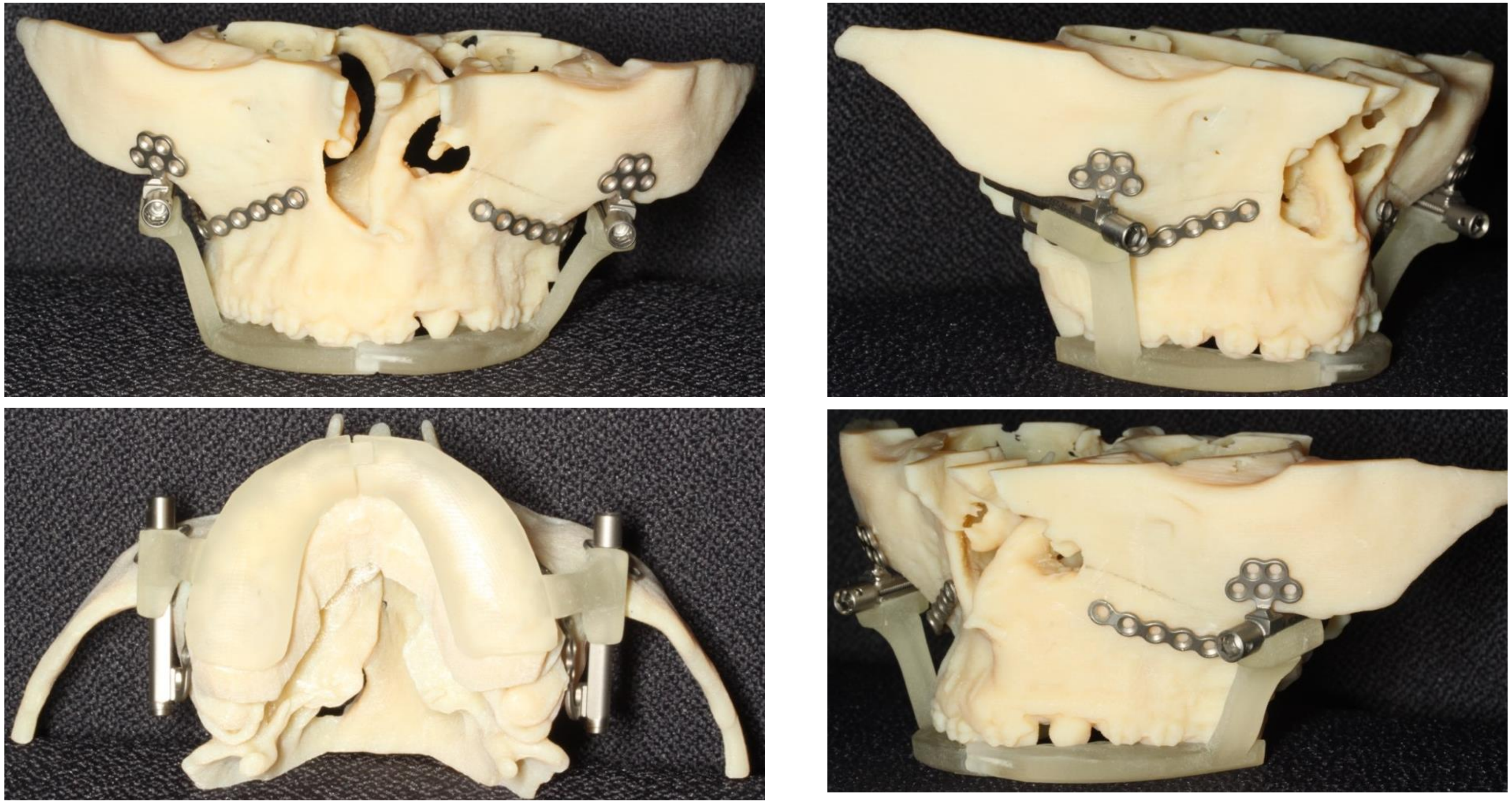
Docència

3D planning in maxillofacial surgery

(Dr. Josep Rubio – Cirugía Maxilofacial)

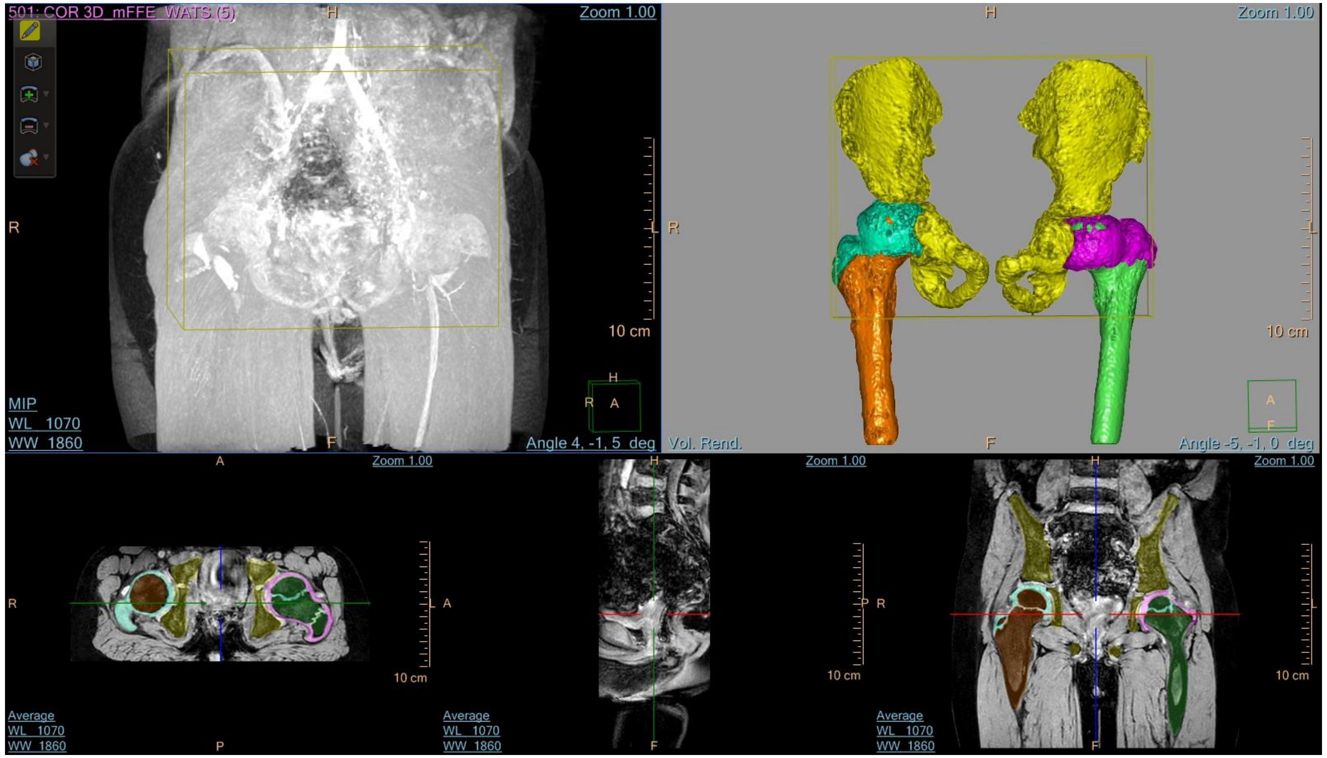


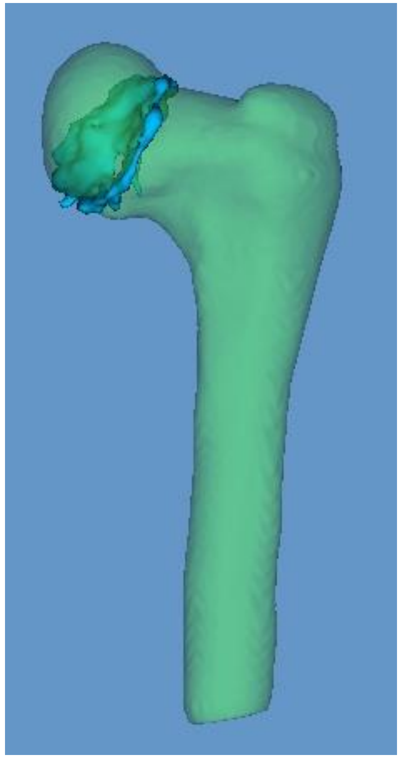




Casos Exemple

COT – Intervenció de correcció de pont fisari



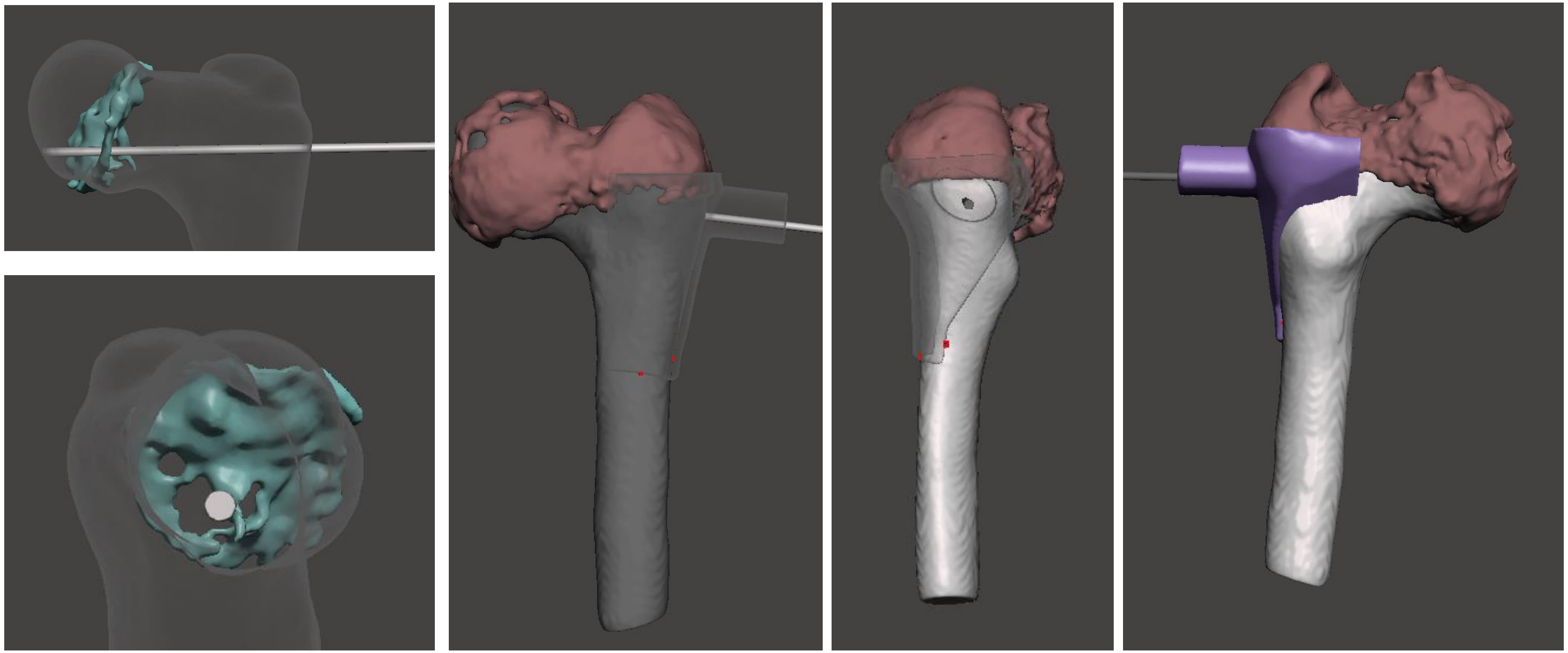


- Segmentació de les diferents estructures per RM
- Visualització 3D de la lesió i el context

Guies de localització de pont fisari (lesió traumàtica del cartílag del creixement) en cap del fèmur

Casos Exemple

COT

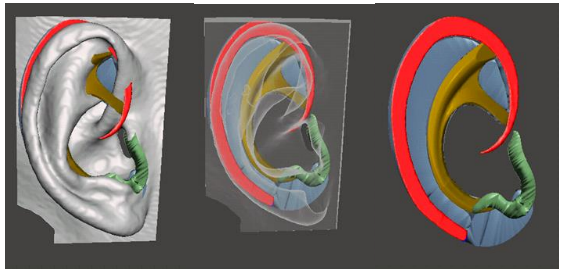


- Disseny guia de posicionament d'agulla de Kirschner per la localització del centre de la lesió

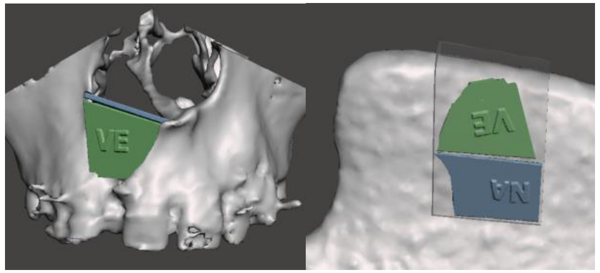
Guies de localització de pont fisari en cap del fèmur

Casos estandarditzats

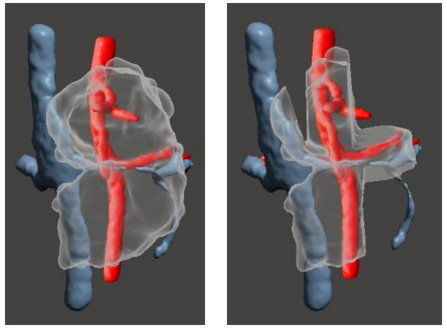
Reconstrucció pavelló auricular



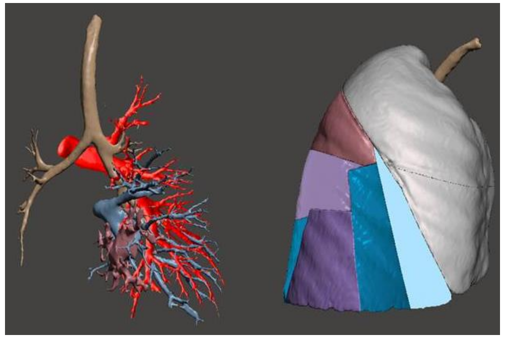
Correcció fissura alveolar



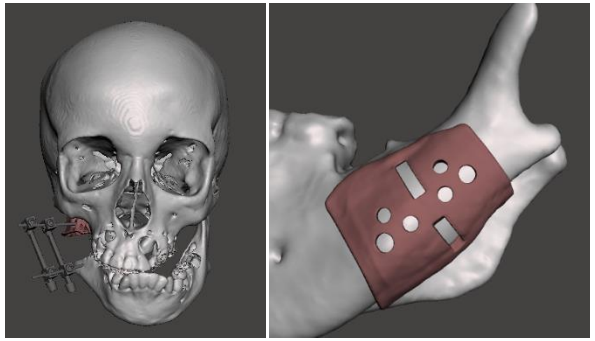
Neuroblastomes complexes



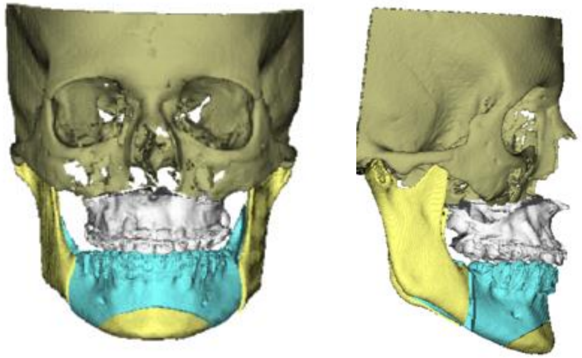
Segmentectomíes pulmonars



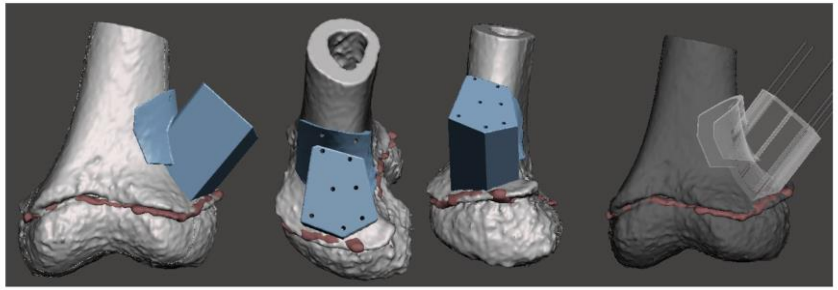
Distraccions mandibulars



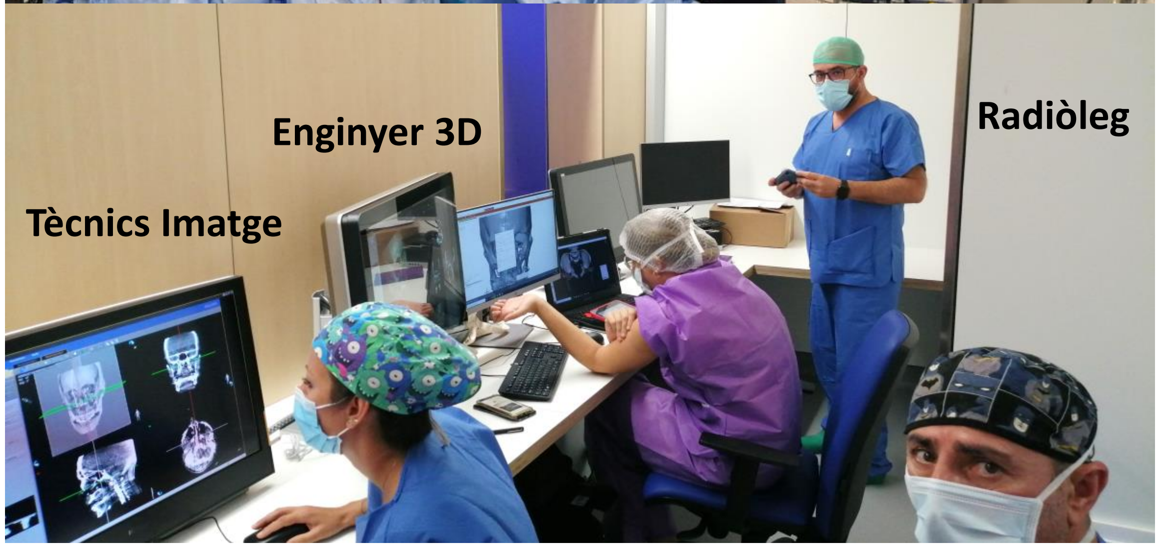
Cirurgia ortognàtica



Correcció pont fissari

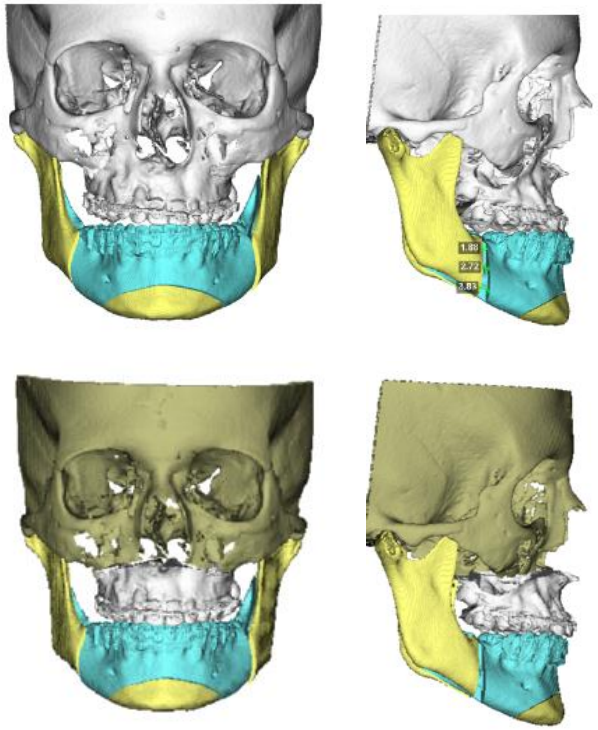


Unitat 3D4H al Bloc Quirúrgic

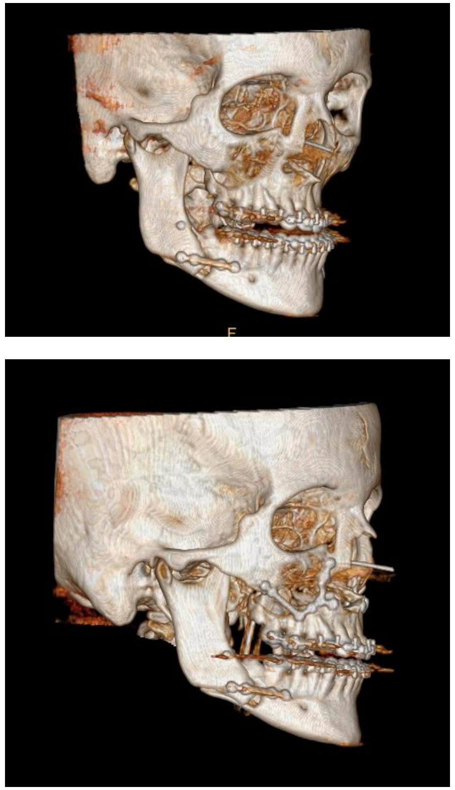


Unitat 3D4H al Bloc Quirúrgic

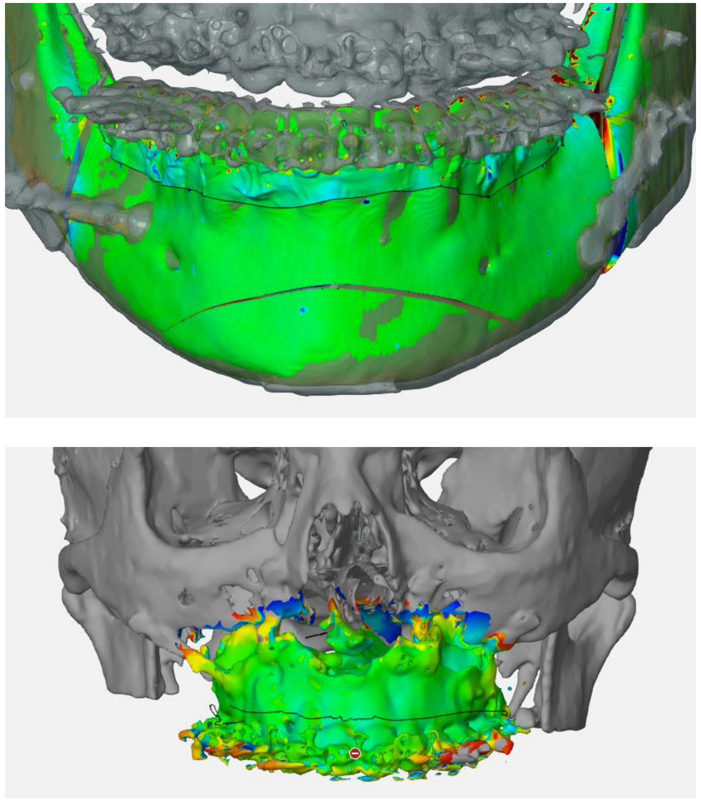
1. Planificació



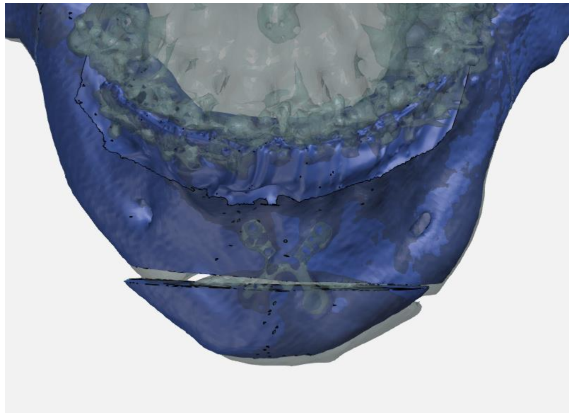
2. Cirurgia – TC Control



3. Cirurgia – Comparativa

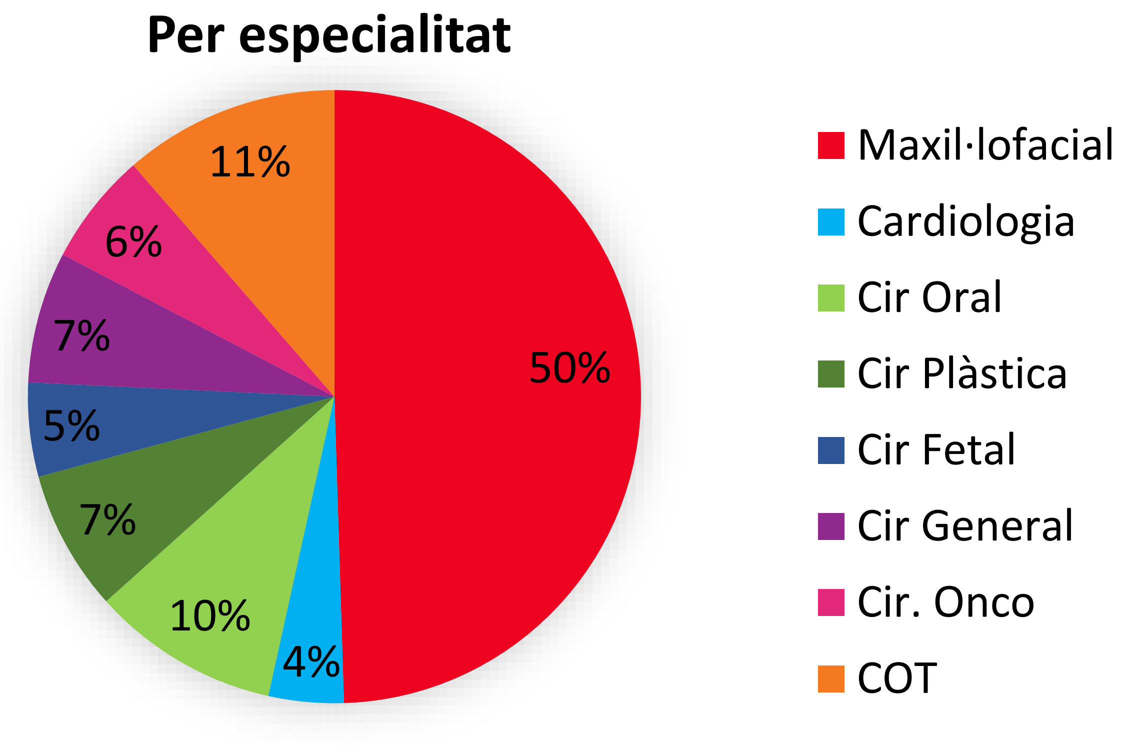


4. Anàlisi i aplicació de punts de millora



Implementació d'un circuit assistencial de comparativa del resultat final de la cirurgia amb el resultat de la planificació quirúrgica

La Unitat 3D4H en xifres



122
casos
2020

60
2021

12
casos
externs

Parc Sanitari Sant Joan de Déu

egarsat

CLÍNICA CORACHAN

althaia
Xarxa Assistencial Universitària Manresa

On estem?

Assistència

I+D

Docència

Recerca

16

Publicacions

4

Projectes Europeus

2

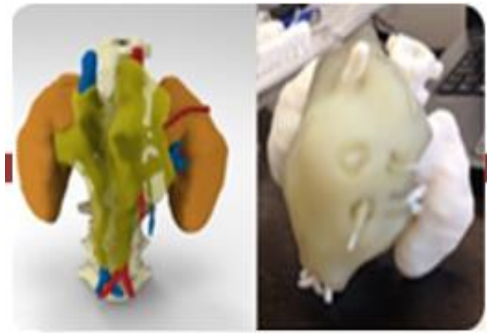
Tesis Doctorals

+4

en marxa

LLAVOR 3D

LLAVOR 3D
Comunitat RIS3CAT



CIRURGIA CRÍTICA: Models mimètics d’assaig, simulació quirúrgica i visualització avançada.

Casos d’ús:

a) **Oncològica**: Hepàtiques.

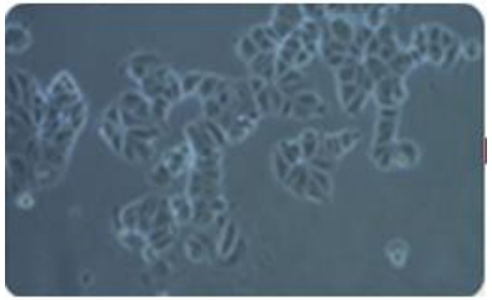
b) **Cardiovascular**: Malformacions cardíaques complexes.

CIRURGIA REGENERATIVA: Generació d’estructures biocompatibles implantables. Implants bio-actius i regeneració de teixit ossi.

Casos d’ús:

a) **Traqueal:** Stents traqueals per traquio-bronquiomalàcies, estenosis traqueals i esofàgiques.

b) **Traumatològica:** Falques bio-actives per regeneració òssia.



CIRURGIA RECONSTRUCTIVA: Generació i millora d’eines personalitzades de suport a la cirurgia: guies de tall, guies de posicionament, altres eines.

Casos d’ús:

a) **Maxil·lofacial:** Guies de tall i posicionament amb marcatge biocompatible i comportament avançat.

b) **Traumatològica:** Guies de tall i posicionament amb marcatge biocompatible i comportament avançat.

Prospectiva de projectes col ·laboratius BASE 3D

P1- LIGHT3D: Tecnologies de Làser i altra Llum

P2 - FUSE3D: Tecnologies per a deposició de material semifos

P3 – INK3D: Tecnologies per a la deposició de tintes continues

P4 – HYBRI3D: Tecnologies per a hibridació multimaterial

Codi SIFECAT: 001-P-001646
Nom de l'agrupació: BASE3D
Nom breu del programa d'actuacions: BASE3D
Entitat coordinadora: CIM-UPC
Entitats beneficiàries:

- CIM-UPC
- ICIQ
- IBEC
- EURECAT
- LEITAT
- IREC
- CD6
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- CIMNE
- HSJD
- GEMAT IQS
- GREP UdG
- DIOPMA UB
- BBT UPC
- CDAL UPC
- CEPHIS (UAB)
- CIEFMA UPC
- CTTC UPC
- IMEM UPC
- NEMEN UPC
- POLTEPO UPC
- REMM UPC
- TECNOFAB UPC
- PROCOMAME

Estudi de caracterizació dels teixits

Anàlisis de la duresa dels diferents teixits del cos humà.
Amb Anatomia Patològica HSJD i H. Clínic

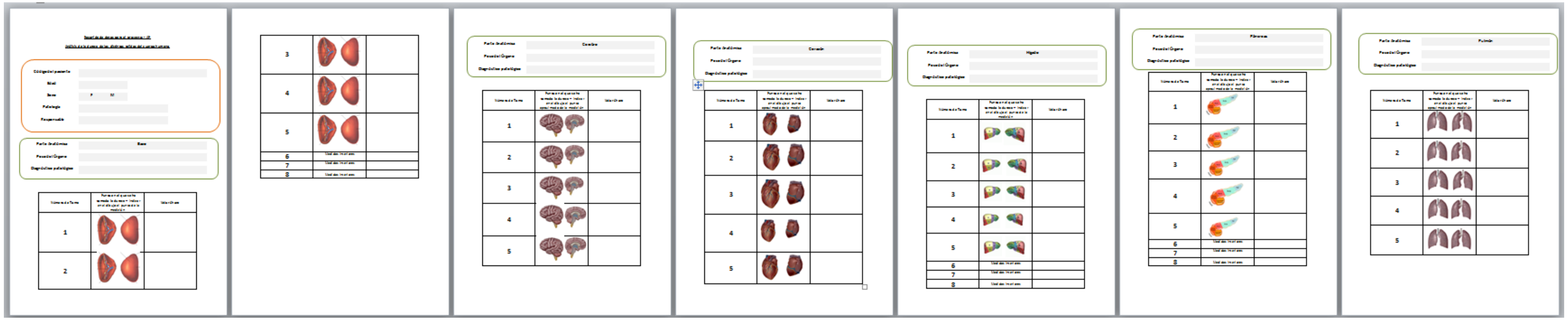
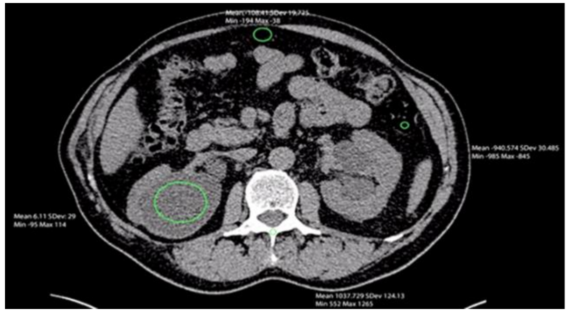
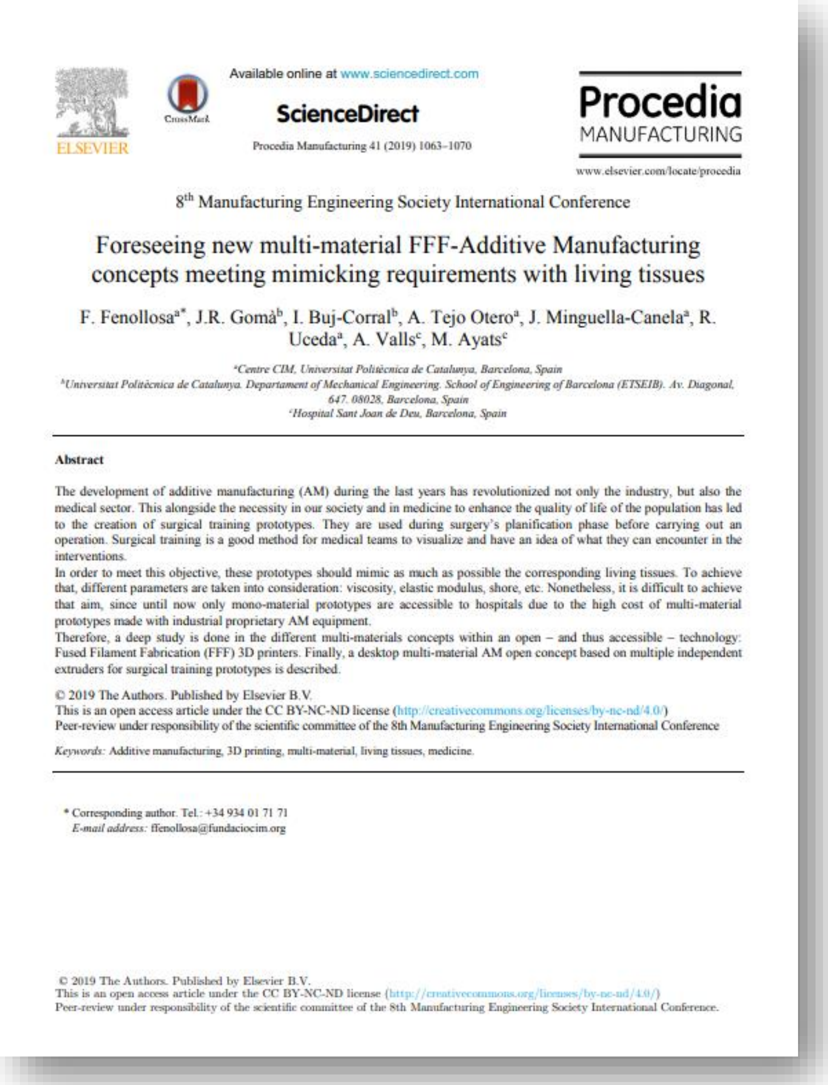


Table 1. Characteristics of the different living tissues.

Organ	Density (kg/m^3)	Hardness	Elastic modulus (kPa)	Shear modulus (kPa)	Bulk modulus (MPa)
Lung	394	40 Shore OOO – 10 Shore OO	2.85	0.95	355
Liver	1079	52 Shore OOO – 25 Shore OO	6.55	2.185	2713
Breast adipose tissue	911	54 Shore OOO – 35 Shore OO	9.90	3.3	1890
Kidney	1066	56 Shore OOO – 40 Shore OO	12.66	4.22	2608
Pancreas	1087	58 Shore OOO – 45 Shore OO	14.40	4.8	2752
Breast fiberglandular tissue	1041	56 Shore OO – 10 Shore A	22.50	7.5	2358
Parotid gland	1048	60 Shore OO – 13 Shore A	31.14	10.38	2549
White matter brain	1041	70 Shore OO – 20 Shore A	40.80	13.6	2509
Breast tumor	1050	30 Shore O – 22 Shore A	45	25	2678
Muscle	1090	35 Shore O – 25 Shore A	49.80	16.6	2750



HU - radiodensity



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Procedia Manufacturing 41 (2019) 1063–1070

Procedia
MANUFACTURING

www.elsevier.com/locate/procedia

8th Manufacturing Engineering Society International Conference

Foreseeing new multi-material FFF-Additive Manufacturing concepts meeting mimicking requirements with living tissues

F. Fenollosa[a*], J.R. Gomà[b], I. Buj-Corral[b], A. Tejo Otero[a], J. Minguella-Canela[a], R. Uceda[a], A. Valls[c], M. Ayats[c]

[a]Centre CIM, Universitat Politècnica de Catalunya, Barcelona, Spain
[b]Universitat Politècnica de Catalunya. Departament of Mechanical Engineering. School of Engineering of Barcelona (ETSEIB). Av. Diagonal, 647. 08028, Barcelona, Spain
[c]Hospital Sant Joan de Deu, Barcelona, Spain

Abstract

The development of additive manufacturing (AM) during the last years has revolutionized not only the industry, but also the medical sector. This alongside the necessity in our society and in medicine to enhance the quality of life of the population has led to the creation of surgical training prototypes. They are used during surgery's planification phase before carrying out an operation. Surgical training is a good method for medical teams to visualize and have an idea of what they can encounter in the interventions.

In order to meet this objective, these prototypes should mimic as much as possible the corresponding living tissues. To achieve that, different parameters are taken into consideration: viscosity, elastic modulus, shore, etc. Nonetheless, it is difficult to achieve that aim, since until now only mono-material prototypes are accessible to hospitals due to the high cost of multi-material prototypes made with industrial proprietary AM equipment.

Therefore, a deep study is done in the different multi-materials concepts within an open – and thus accessible – technology: Fused Filament Fabrication (FFF) 3D printers. Finally, a desktop multi-material AM open concept based on multiple independent extruders for surgical training prototypes is described.

Peer-review under responsibility of the scientific committee of the 8th Manufacturing Engineering Society International Conference

Keywords: Additive manufacturing, 3D printing, multi-material, living tissues, medicine.

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Peer-review under responsibility of the scientific committee of the 8th Manufacturing Engineering Society International Conference.

Material: Filaflex, PLA…

Source: HSJD / CIM UPC

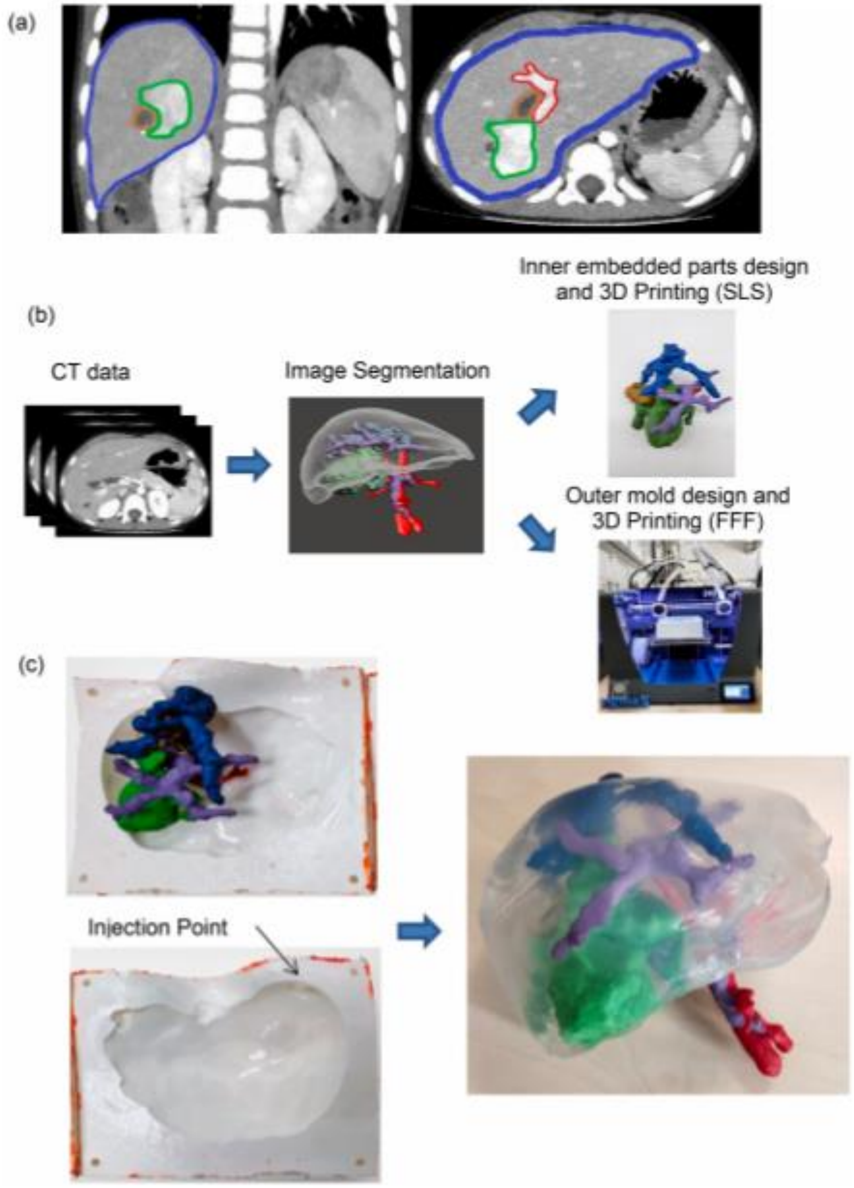

Fig. 3. (a) CT image of a liver with the different parts pointed out: (1) Liver is circled with blue color; (2) Portal system is circled with red color; (3) Dilated intra-hepatic biliary tract -tumor- is circled in brown color; and (4) the rest of the tumor, which origin is the biliary tract, is circled in green color. (Left) Coronal or frontal plane. (Right) Axial plane. (b) Workflow for the design of the model. (c) The two outer molds and one with the inner embedded parts placed inside. The 1%wt agarose 3D manufactured surgical planning prototype. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

journal of the mechanical behavior of biomedical materials 109 (2020) 103844

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: http://www.elsevier.com/locate/jmbbm

3D printed soft surgical planning prototype for a biliary tract rhabdomyosarcoma

A. Tejo-Otero [a,*], P. Lustig-Gainza [a], F. Fenollosa-Artés [a,c], A. Valls [b], L. Krauel [b], I. Buj-Corral [c]

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[b] *Hospital Sant Joan de Déu, Barcelona, Spain*
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ARTICLE INFO

Keywords:
Additive manufacturing
Mimicking
Soft living tissues
Surgical planning
Biliary tract rhabdomyosarcoma
Liver

ABSTRACT

Biliary tract rhabdomyosarcoma is a soft tissue malignant musculoskeletal tumor which is located in the biliary tract. Although this tumor represents less than 1% of the total amount of childhood cancers, when localized, a >70% overall 5-year survival rate, the resection is clinically challenging and complications might exist during the biliary obstruction. Although surgery remains a mainstay, complete tumor resection is generally difficult to achieve without mutilation and severe long-term sequelae. Therefore, manufacturing multi-material 3D surgical planning prototypes of the case provides a great opportunity for surgeons to learn beforehand what they can expect. Additionally, practicing before the operation enhances the probability of success. That is why different compositions of materials have been characterized to match the mechanical properties of the liver. To do this, Dynamic Mechanical Analysis (DMA) tests and Shore hardness tests have been carried out. Amongst the material samples produced, 6%wt PVA (poly vinyl alcohol)/1%wt PHY (Phytagel)-1FT (Freeze-Thaw cycles) and 1%wt agarose appear as the best options for mimicking the liver tissue in terms of viscoelasticity. Regarding the Shore hardness, the best solution is 1%wt agarose. Additionally, a surgical planning prototype using this last material mentioned was manufactured and validated using a CT (Computed Tomography) scanner. In most of the structures the difference between the 3D model and the organ in terms of dimensions is less than 3.35 mm, which represents a low dimensional error, around 1%. On the other hand, the total manufacturing cost of the 3D physical model was €513 which is relatively low in comparison with other technologies.

1. Introduction

Additive Manufacturing (AM) has been widely used in different fields such as electronics, aerospace, motor vehicles and medicine. 3D printing is starting to bloom in this last sector, as it is nowadays used in different applications: tissue engineering (Bose et al., 2013), (Buj-Corral et al., 2018), implants (Liuet al., 2016), (Buj-Corral et al., 2019), or in the creation of surgical planning prototypes (Adamset al., 2017; Tejo-Otero et al., 2019; Muguruza Blanco et al., 2019; Fenollosa-Artés et al., 2019).

Regarding the last application, in recent years most of the surgical planning prototypes manufactured were not only monomaterial but also monocolor, as FFF (Fused Filament Fabrication) based 3D printers were mainly used (Chae et al., 2015). These do not offer the opportunity to print with two or more materials at the same time. Therefore, it was difficult to identify the different anatomical structures (soft and hard tissues) within the surgical planning prototype. Despite that, most of the surgical planning prototypes were produced entirely in FFF (Krauelet al., 2016; Rankin et al., 2014; Starosolski et al., 2014), since it is a cost-effective technology. However, it does not offer the best mimicking of living tissues since most of the filaments used in FFF are hard and rigid.

SLS (Selective Laser Sintering) has also been used, but some materials such as PP (polypropylene) are even more rigid (Krauelet al., 2016). However, it is worth highlighthing that it offers other, more elastic, materials like TPU (Thermoplastic Polyurethane), TPE (Thermoplastic Elastomer) or PA (Polyamide) (Dadbakhsh et al., 2016). These technologies only provide the opportunity to have an idea about the model, in other words, identifying the different anatomical structures. Additionally, material jetting technology 3D printers have been used in the

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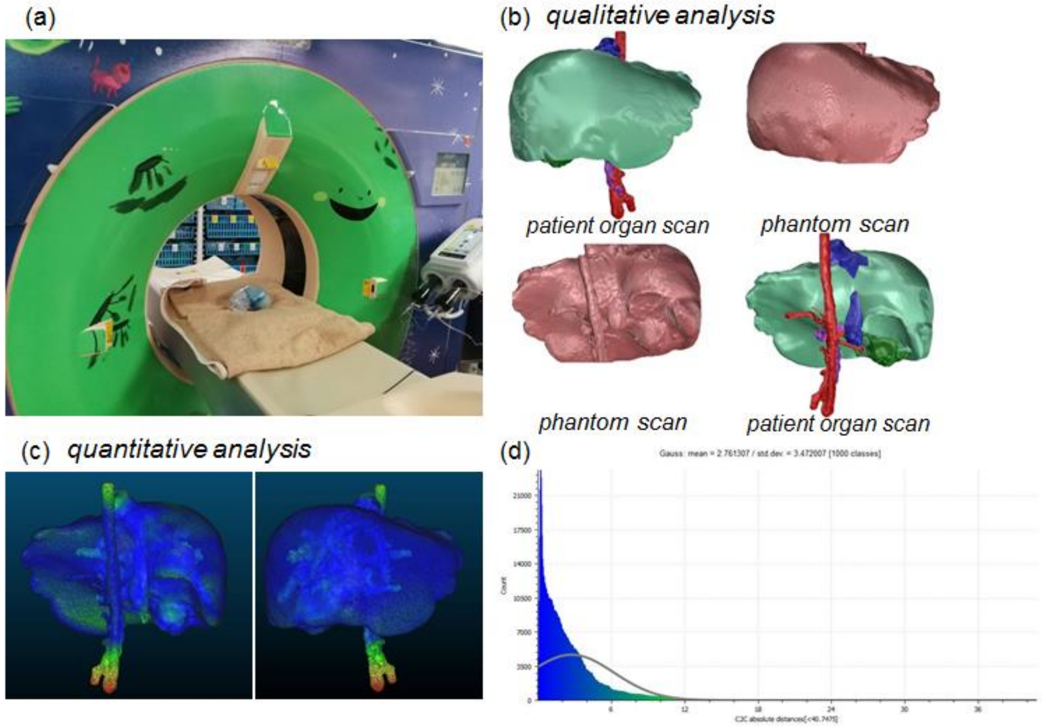
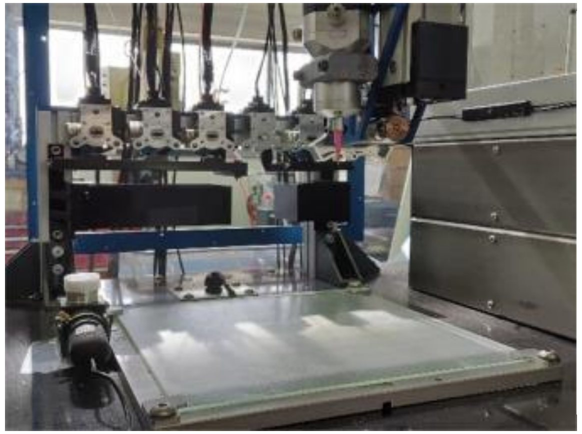
Received 1 October 2019; Received in revised form 8 April 2020; Accepted 28 April 2020
Available online 11 May 2020

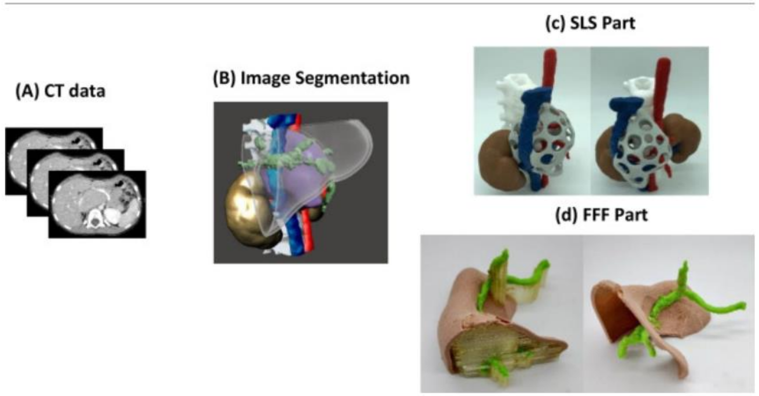
Qualitative Validation

Quantitative Validation

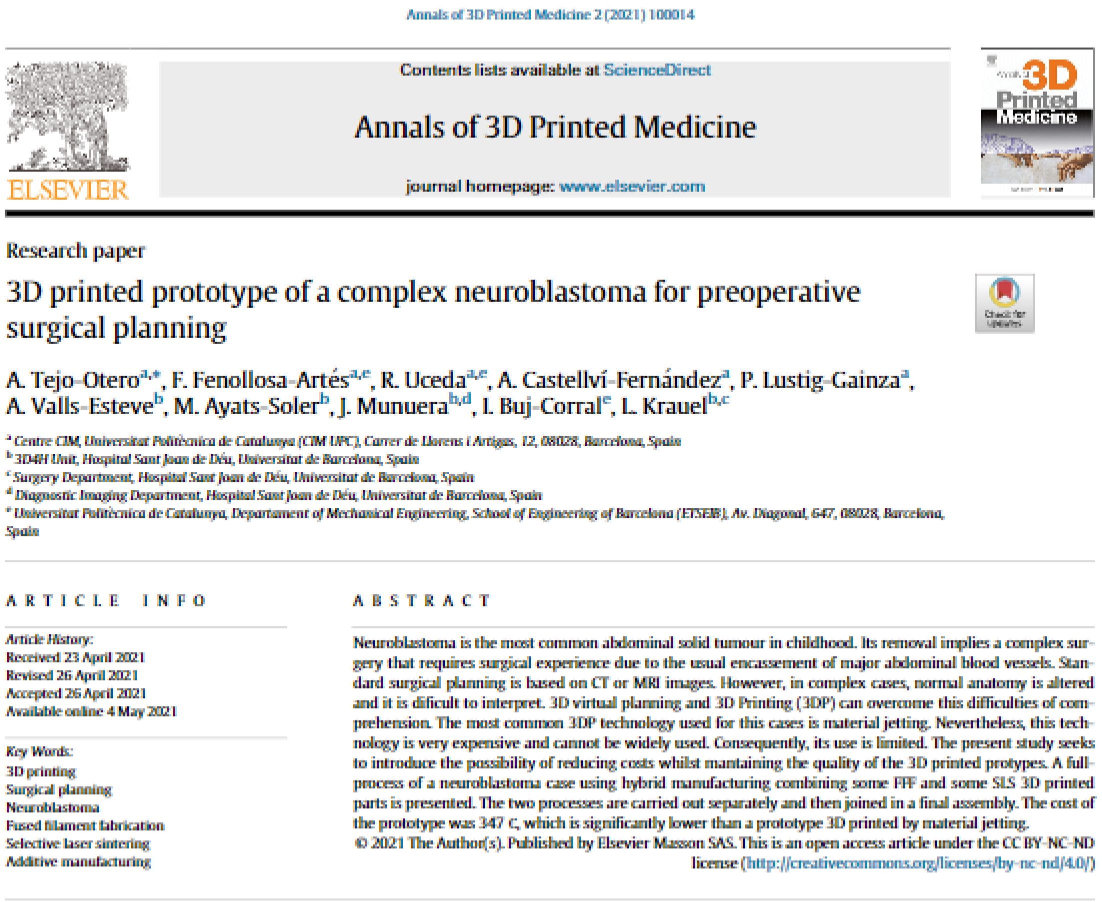




Source: Màquina instal.lacions CIM UPC



Source: Procés de fabricaciço moedl multi-material



Annals of 3D Printed Medicine 2 (2021) 100014

Contents lists available at ScienceDirect

Annals of 3D Printed Medicine

journal homepage: www.elsevier.com

Research paper

3D printed prototype of a complex neuroblastoma for preoperative surgical planning

A. Tejo-Otero[a,*], F. Fenollosa-Artés[a,e], R. Uceda[a,e], A. Castellví-Fernández[a], P. Lustig-Gainza[a], A. Valls-Esteve[b], M. Ayats-Soler[b], J. Munuera[b,d], I. Buj-Corral[e], L. Krauel[b,c]

[a] Centre CIM, Universitat Politècnica de Catalunya (CIM UPC), Carrer de Llorens i Artigas, 12, 08028, Barcelona, Spain
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[c] Surgery Department, Hospital Sant Joan de Déu, Universitat de Barcelona, Spain
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ARTICLE INFO

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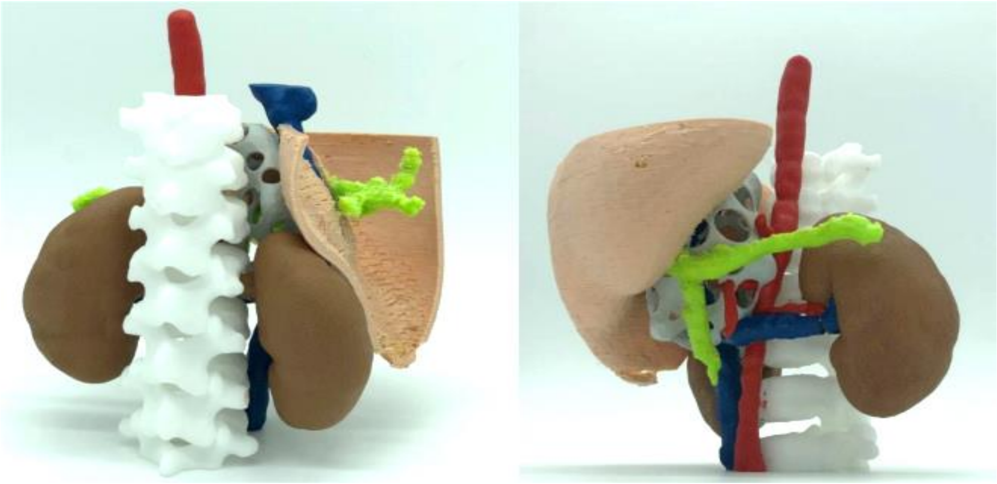
3D printing
Surgical planning
Neuroblastoma
Fused filament fabrication
Selective laser sintering
Additive manufacturing

ABSTRACT

Neuroblastoma is the most common abdominal solid tumour in childhood. Its removal implies a complex surgery that requires surgical experience due to the usual encassement of major abdominal blood vessels. Standard surgical planning is based on CT or MRI images. However, in complex cases, normal anatomy is altered and it is dificult to interpret. 3D virtual planning and 3D Printing (3DP) can overcome this difficulties of comprehension. The most common 3DP technology used for this cases is material jetting. Nevertheless, this technology is very expensive and cannot be widely used. Consequently, its use is limited. The present study seeks to introduce the possibility of reducing costs whilst mantaining the quality of the 3D printed protypes. A full-process of a neuroblastoma case using hybrid manufacturing combining some FFF and some SLS 3D printed parts is presented. The two processes are carried out separately and then joined in a final assembly. The cost of the prototype was 347 €, which is significantly lower than a prototype 3D printed by material jetting.



Source: Model anatòmic multi-material HSJD

On estem?

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I+D

Docència

SJD Sant Joan de Déu Barcelona · Hospital

On estem?

Decència

Docència

Expert3D

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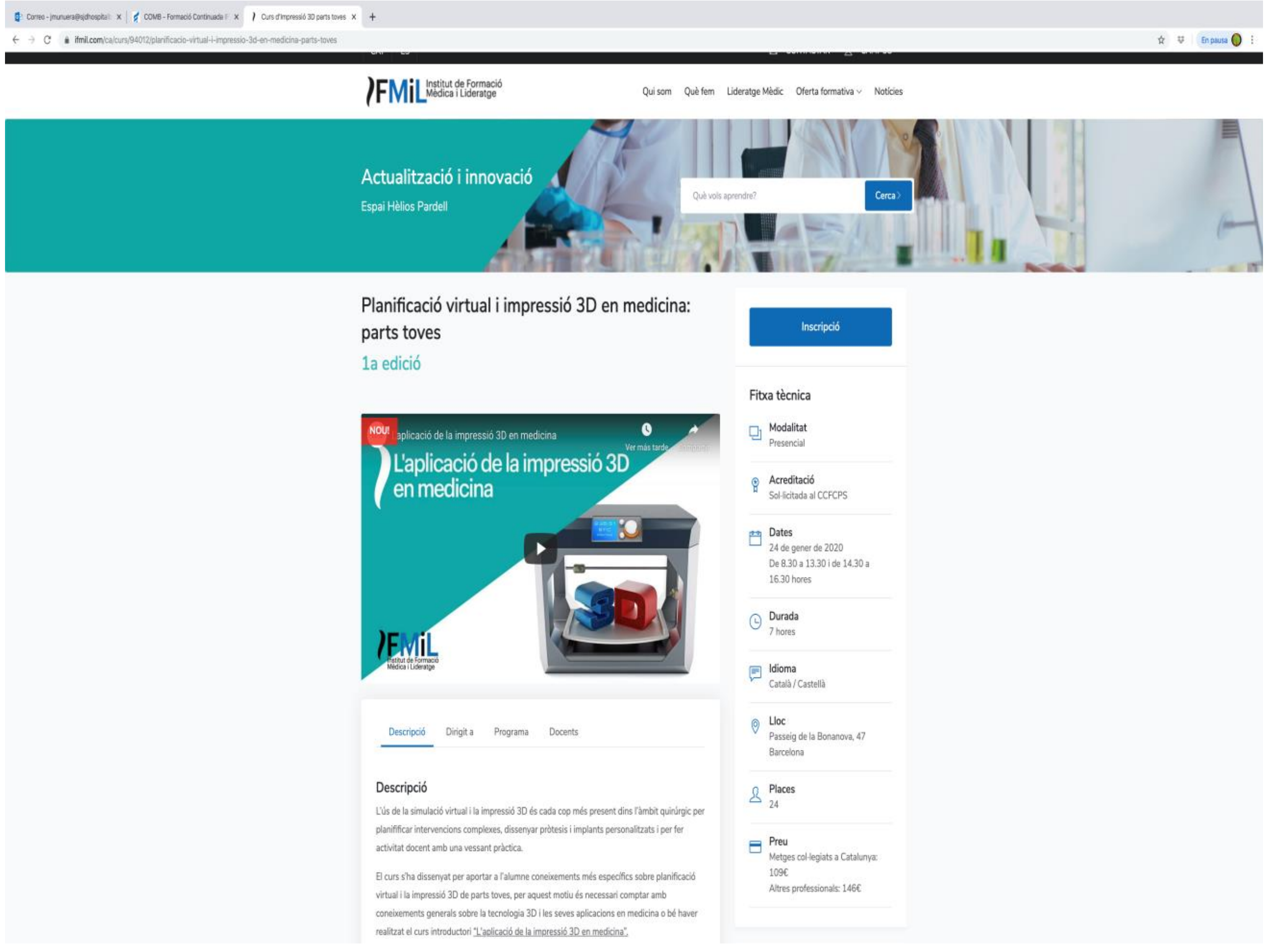
Poland	3	Iran	2	Mexico	2
Uruguay	3	Andorra	1	Colombia	2

Docència



Planificació virtual i impressió 3D en medicina: parts toves

1a edició

Fitxa tècnica

Modalitat
Presencial

Acreditació
Sol·licitada al CCFCPS

Dates
24 de gener de 2020
De 8.30 a 13.30 i de 14.30 a 16.30 hores

Durada
7 hores

Idioma
Català / Castellà

Lloc
Passeig de la Bonanova, 47
Barcelona

Places
24

Preu
Metges col·legiats a Catalunya: 109€
Altres professionals: 146€

Descripció

L'ús de la simulació virtual i la impressió 3D és cada cop més present dins l'àmbit quirúrgic per planifificar intervencions complexes, dissenyar pròtesis i implants personalitzats i per fer activitat docent amb una vessant pràctica.

El curs s'ha dissenyat per aportar a l'alumne coneixements més específics sobre planificació virtual i la impressió 3D de parts toves, per aquest motiu és necessari comptar amb coneixements generals sobre la tecnologia 3D i les seves aplicacions en medicina o bé haver realitzat el curs introductori "L'aplicació de la impressió 3D en medicina".

Participants al curs:

- Lucas Krauel
- Arnau Valls
- Josep Munuera
- Marta Ayats
- Ignasi Barber
- Josep Maria Quintillà
- Francesc Parri

CHALLENGES AND BARRIERS

1. MATERIALS AND PRINTERS

- Physiological models (real tissue behaviour)
- Combination of technologies in one model
- Printing time

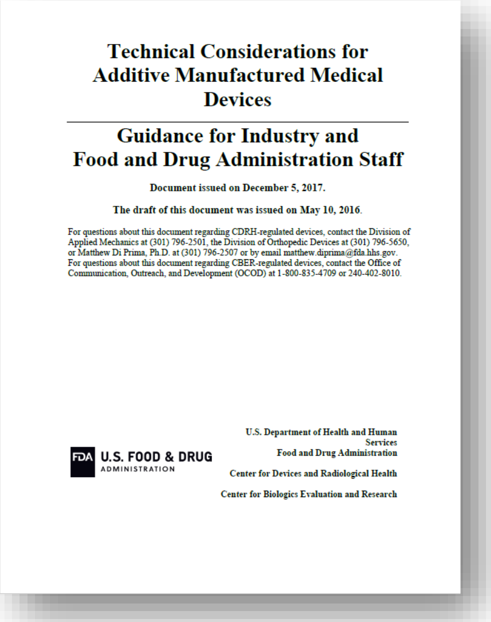
2. COSTS

- Reduction of materials and printers' costs.
- Planning and post-processing automation.

3. REGULATION

4. ADMINISTRATIVES

- Refund (not currently reimbursed by the Centers for Medicare and Medicaid Services (CMS) in the US or in most EU countries)



Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

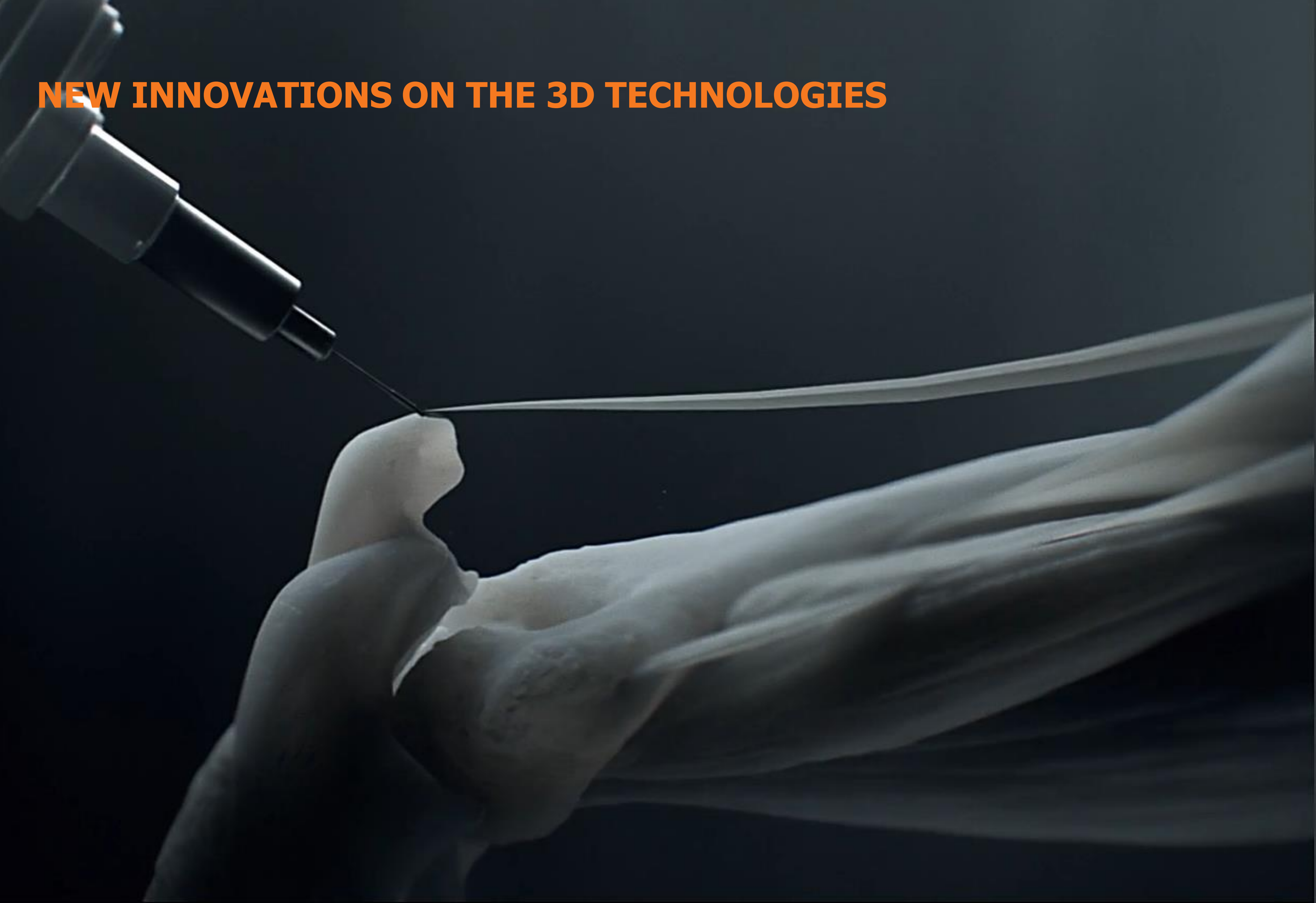
U.S. FOOD & DRUG ADMINISTRATION

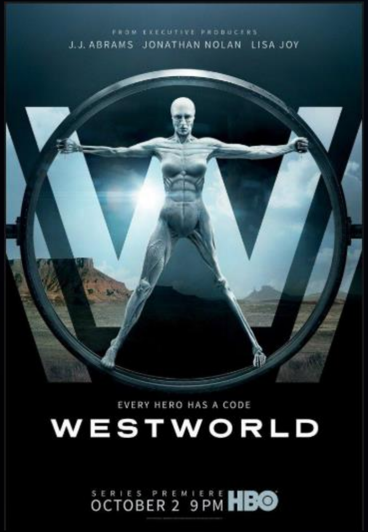
U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

NEW INNOVATIONS ON THE 3D TECHNOLOGIES

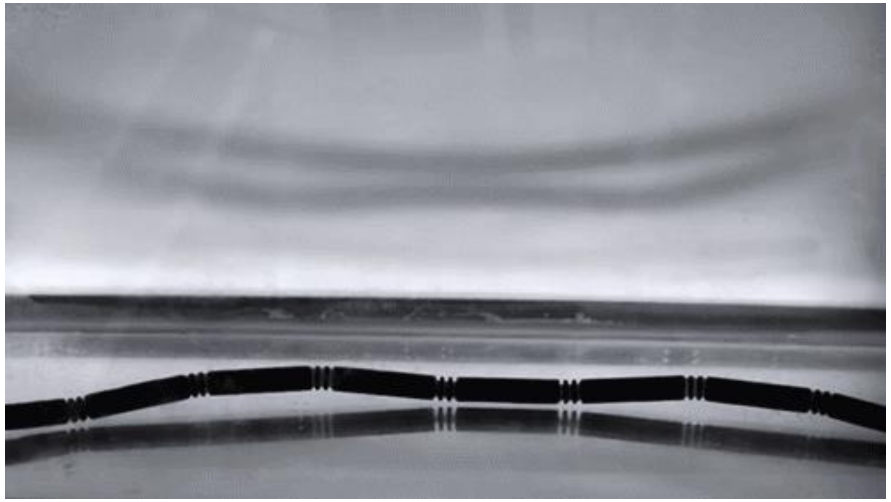


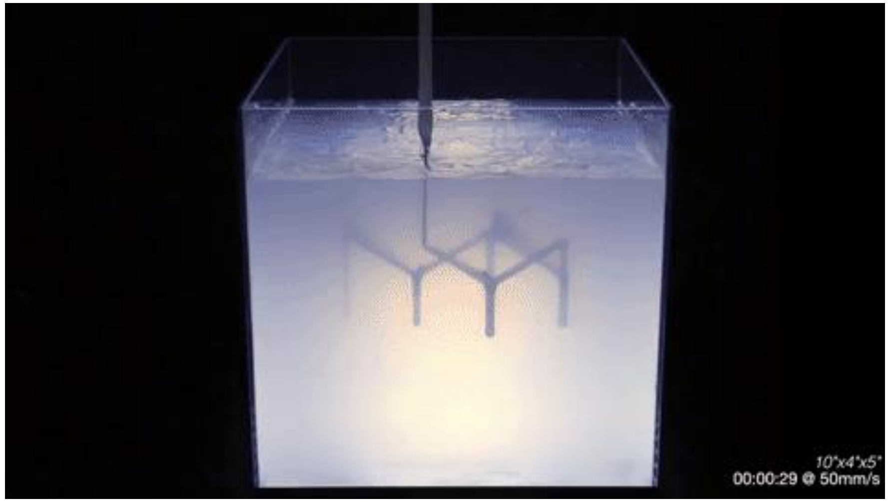


3D printing farming parallelization

Source: CIM-UPC

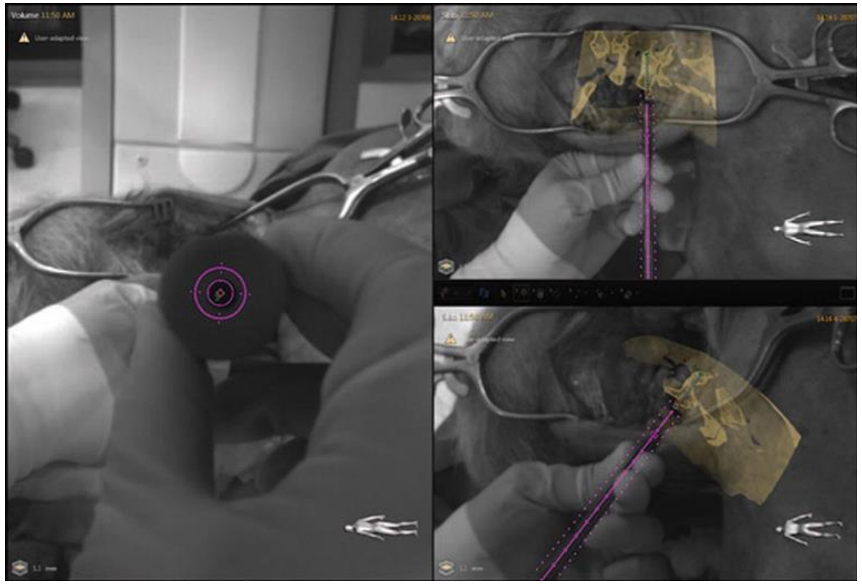
4D PRINTING





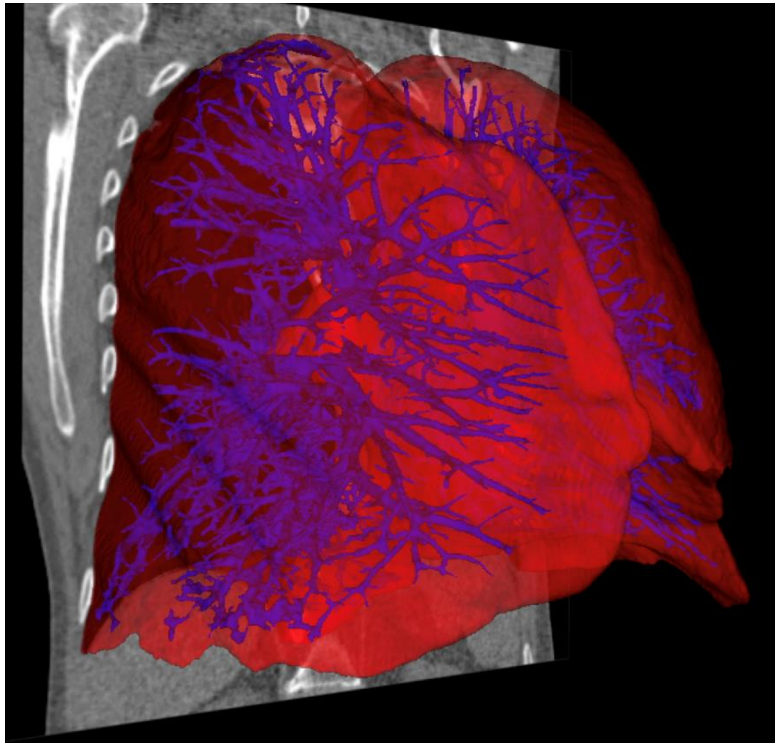
Augmented Reality Navigation

Patient and Device Tracking



Organ bio-printing

3D PRINTING + ARTIFICIAL INTELIGENCE?

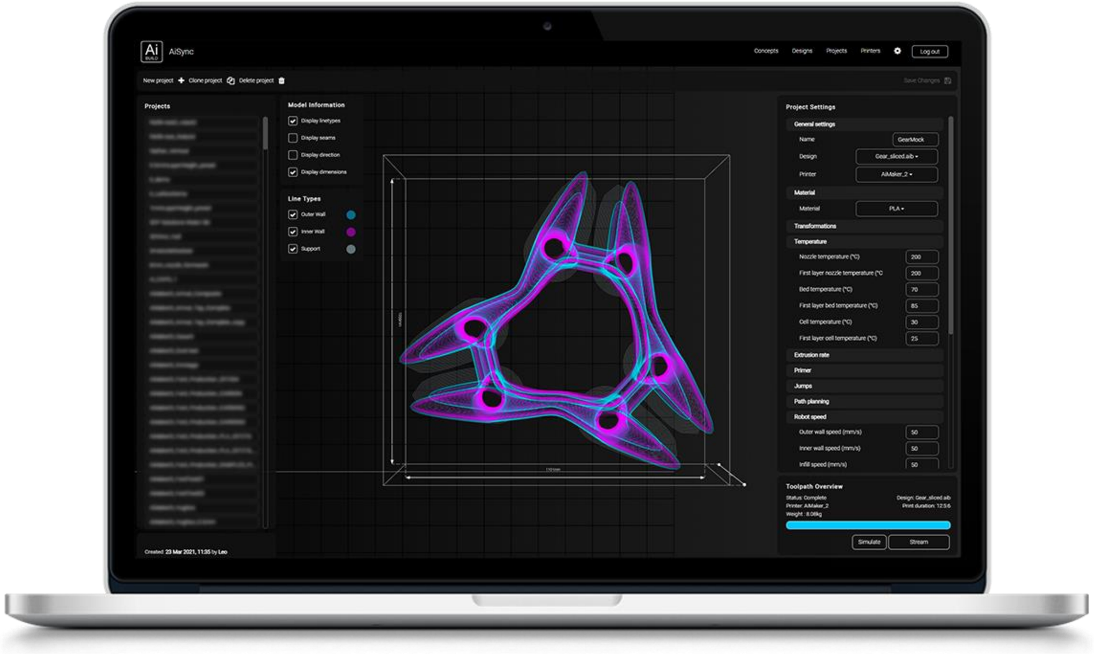


MEDICAL IMAGES BECOME PRINTABLE ORGANS AT THE PUSH OF A BUTTON

Aether's new Automatic Segmentation and Reconstruction ("ASAR") process uses adaptable deep learning models, dynamically combined with an array of AI and image processing techniques. ASAR enables users to segment organs and tissues, and reconstruct them as digital 3D models, which can be used for fabrication, analysis, and other applications.

The process is completely automatic with no editing tools, calibration, or human intervention required.

Source: http://www.prweb.com/releases/2018/04/prweb15401486.htm



AI Build, a company in London developed an automated AI-based 3D printing technology, with a smart extruder, allowing to detect problems: "AiMaker" a high precision robotic end-effector that attaches to industrial robotic arms and is able to 3D print large objects at high speed with great accuracy.

Source: https://ai-build.com/

Conclusions

1. **Tecnologia madura en procés de millora i evolució constant**
   - Models semblants a la fisiològia (comportament real dels teixits)
   - Combinació de tecnologies en una sola impressió
   - Temps d'impressió

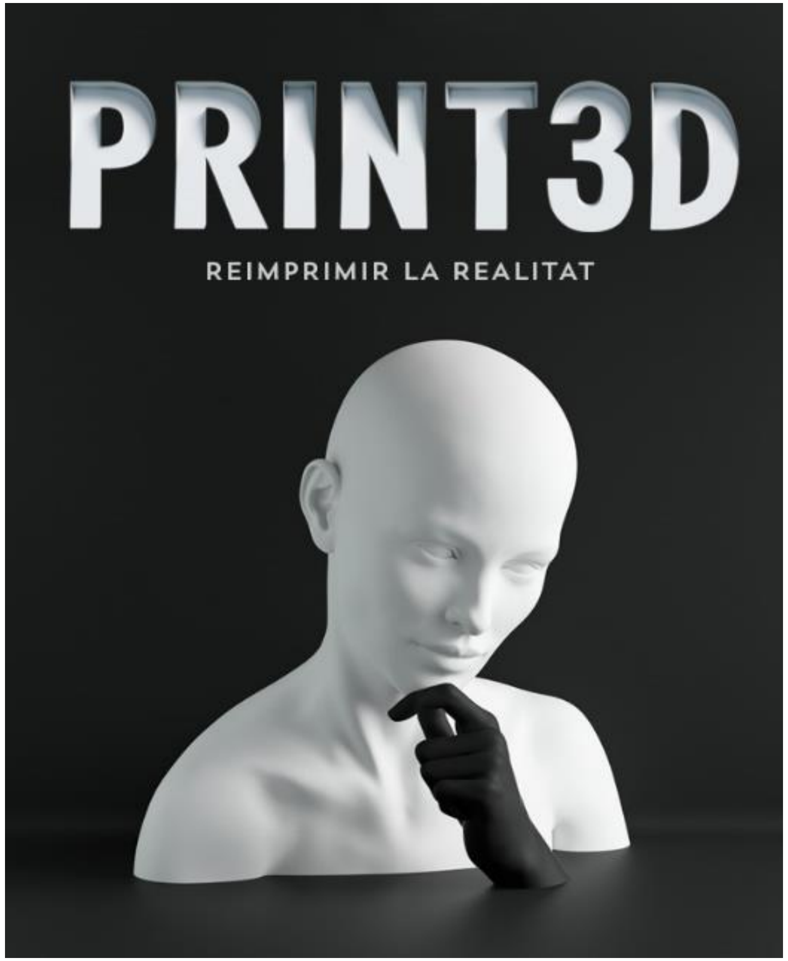
2. **Els equips multidisciplinars són clau amb nous perfils com els enginyers biomèdics formant part de l'equip assistencial**
   - Radiòleg pel coneixement de la imatge i l'anatomia
   - Enginyer per la part de disseny I fabricació
   - Cirurgià com a usuari final i líder clinic en les intervencions

3, Queden reptes per la seva implantació completa en el sistema sanitari
- Reemborsament
- Nova regulació MDR

Sant Joan de Déu
Barcelona · Hospital

Exposició CosmoCaixa: PRINT3D

https://cosmocaixa.es/ca/p/print3d_a11353685



EIT Health is supported by the EIT,
a body of the European Union

Postgraduate Programme / 20 ECTS

Expert3D

https://www.expert3d.eu/

GRACIES


Arnau Valls
Enginyer innovació


Dr. Lucas Krauel
Cirurgià


Dr. Josep Rubio
Cirurgià maxil·lofacial


Dr. Josep Munuera
Radiòleg


Marta Ayats
Enginyera Biomèdica


Dr. José Mª Quintilla
Docència i simulació


Carmen de la Gala
Docència i Simulació


Marta Millet
Economia i finances

3D

KEEP
CALM
THE BEST
IS YET
TO COME