

Future of Fracture Fixation: A Generative Design Approach to Surgical Implants

Sanjeevan Kanagalingam

Doctoral Researcher

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Peter Champneys

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Technical Specialist



Agenda

ADDITIVE MANUFACTURING

An overview of additive manufacturing, specifically how it is changing the way we design products for the medical industry.

GENERATIVE DESIGN

We'll talk about some of the challenges and opportunities around additive manufacturing. And how we can use generative design as a design tool for additive.

DATA DRIVEN DESIGN PROCESS FOR MEDICAL IMPLANTS

Walkthrough of the process used to create patient specific implants using a data capture, generative design and additive manufacturing workflow.



Peter Champneys

Autodesk – Technical Consultant

Peter is a technical consultant working out of the Autodesk technology center in Birmingham UK. He is a specialist in additive manufacturing and generative design, and works alongside Autodesk customers to help them implement emerging MAKE processes into their day to day workflows.



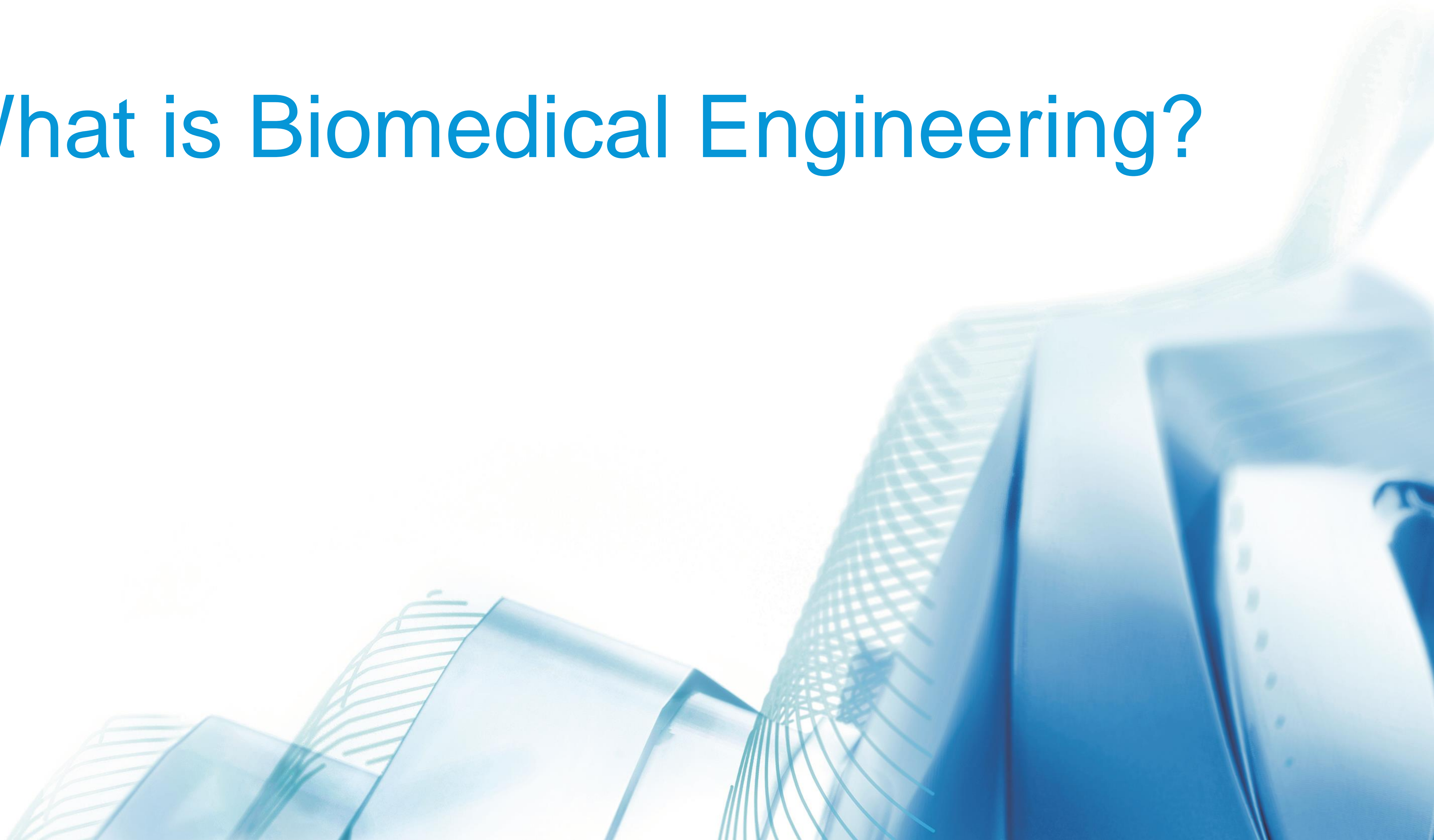
Sanjeevan Kanagalingam

University of Birmingham – Doctoral Researcher

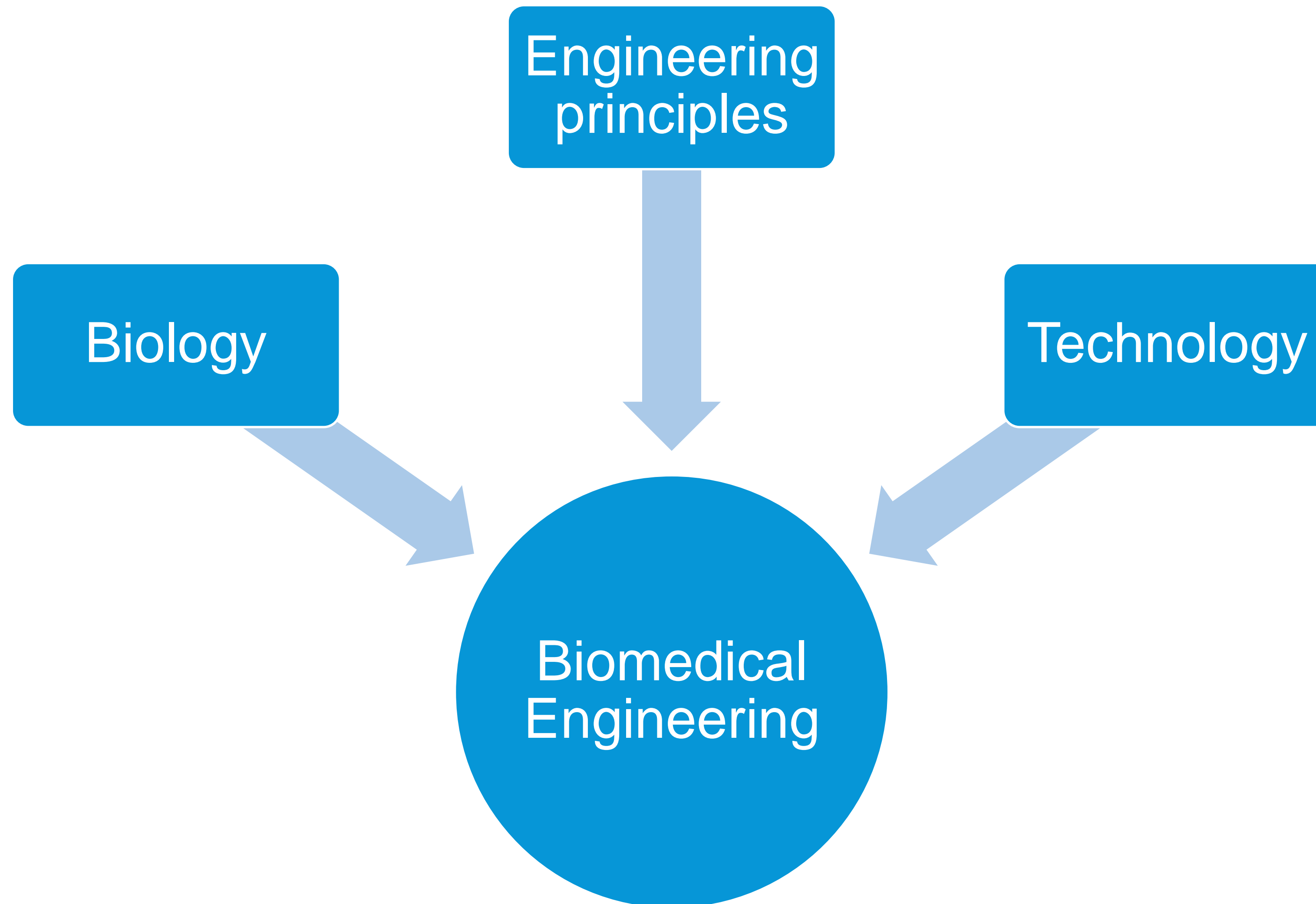
Sanjeevan has a Masters in mechanical engineering, currently pursuing a doctorate with the biomedical engineering group at University of Birmingham. His areas of interest are around the design and application of additive manufacturing in the medical industry, with a particular focus on patient-specific implants.



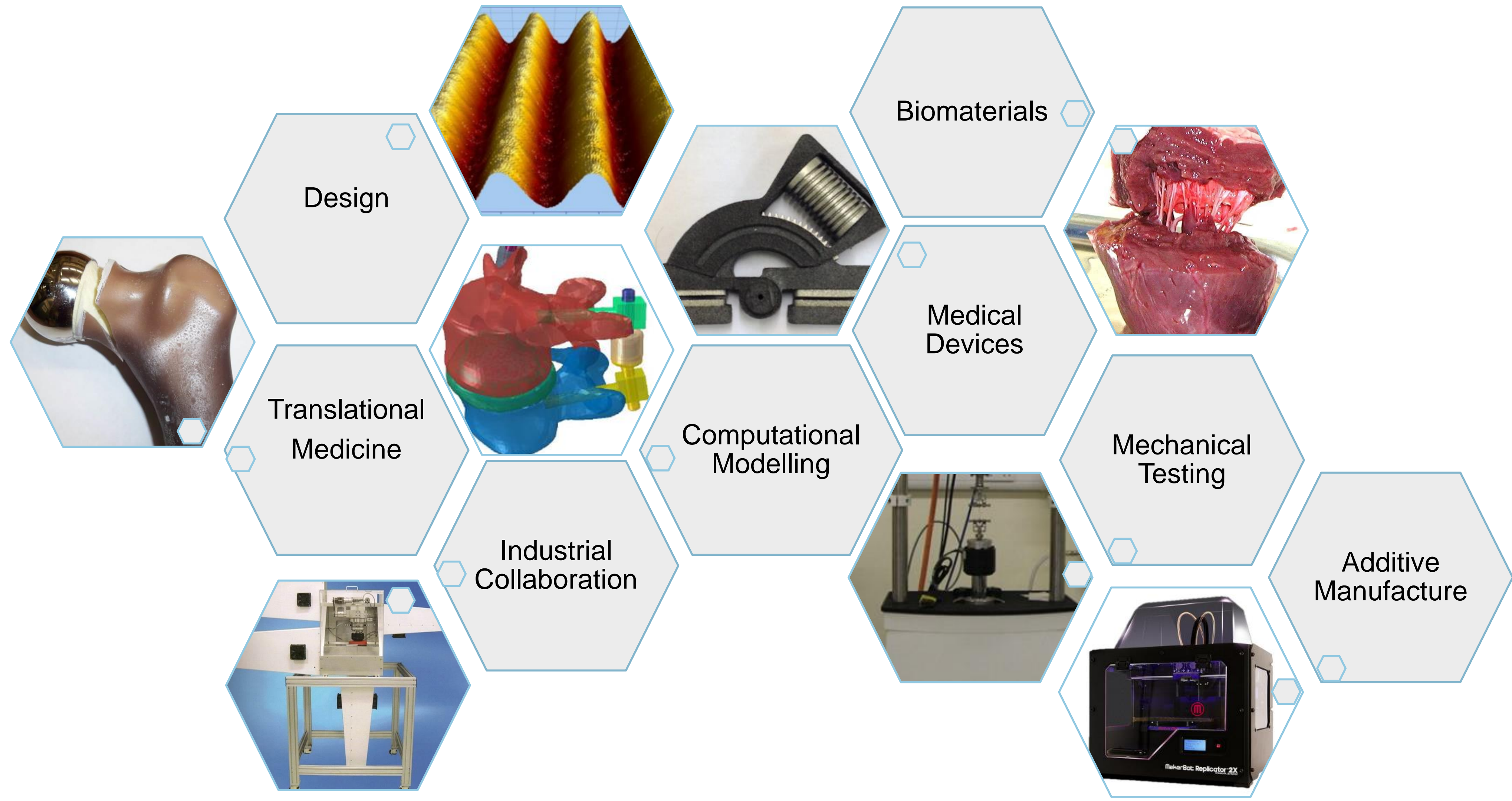
What is Biomedical Engineering?



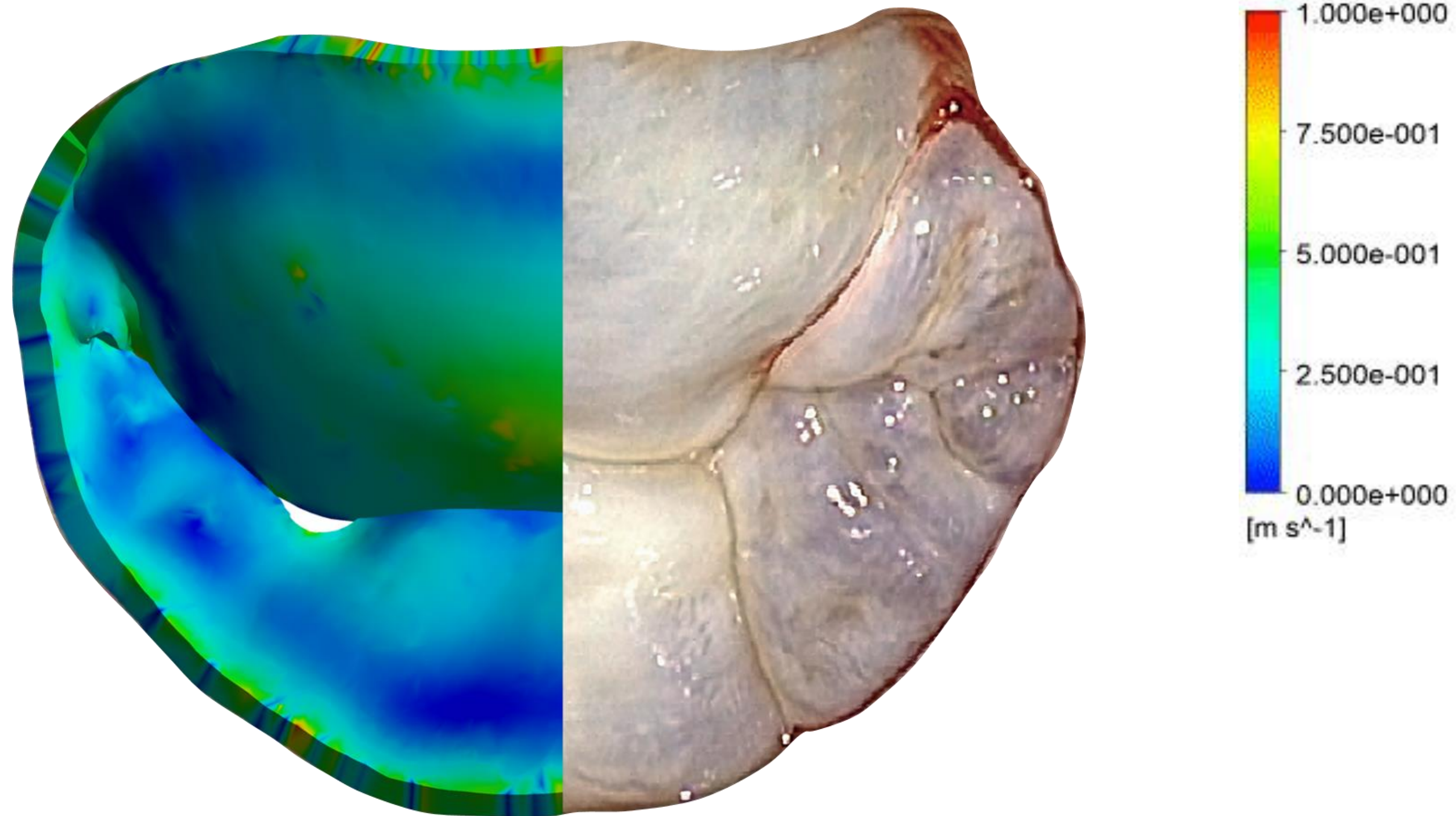
Biomedical Engineering



Biomedical Engineering Research at University of Birmingham



Cardiovascular Research



Understanding Heart Valves

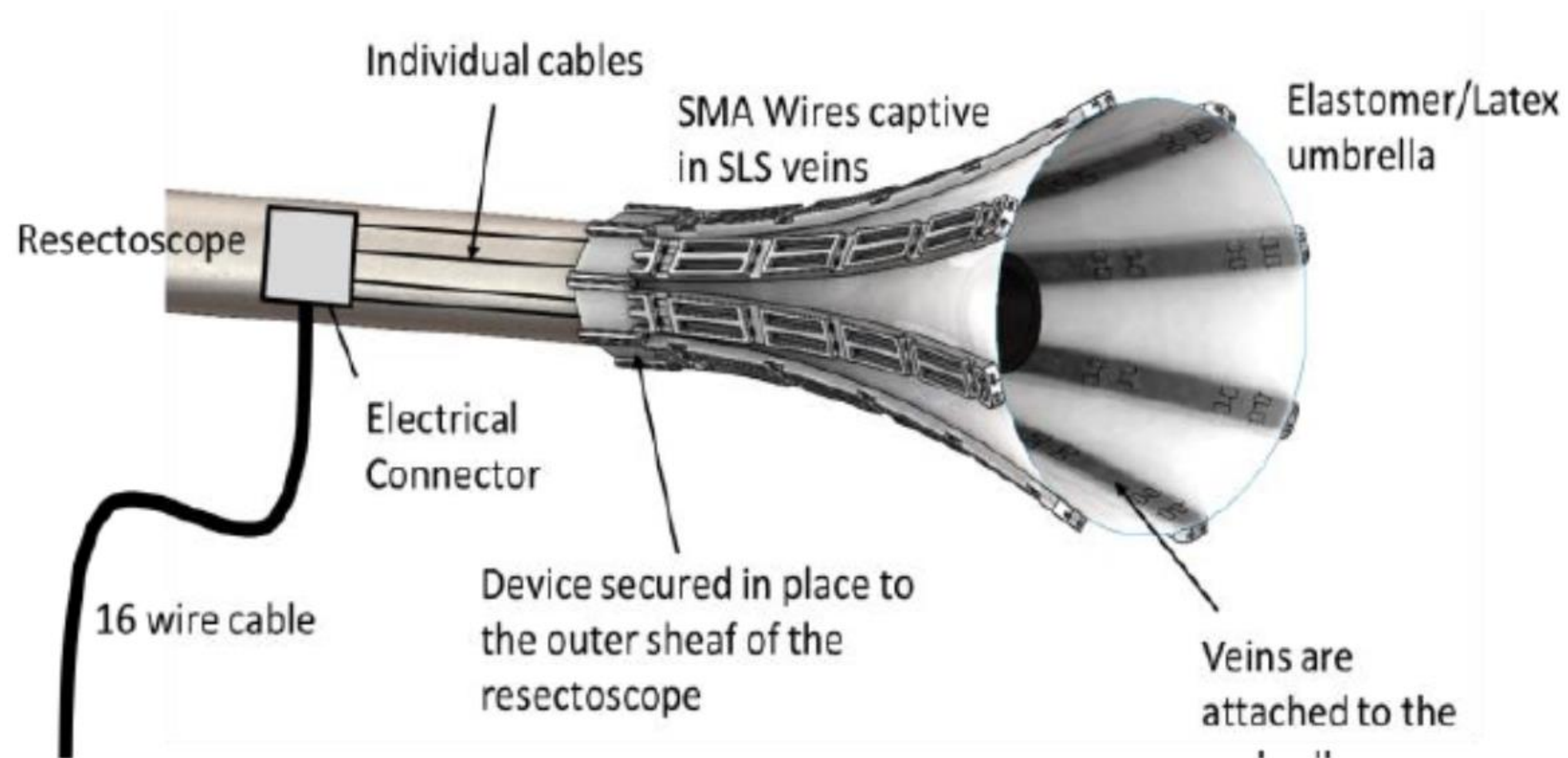
Image courtesy of Diana Oliveira



Predicting Heart Blood Flow

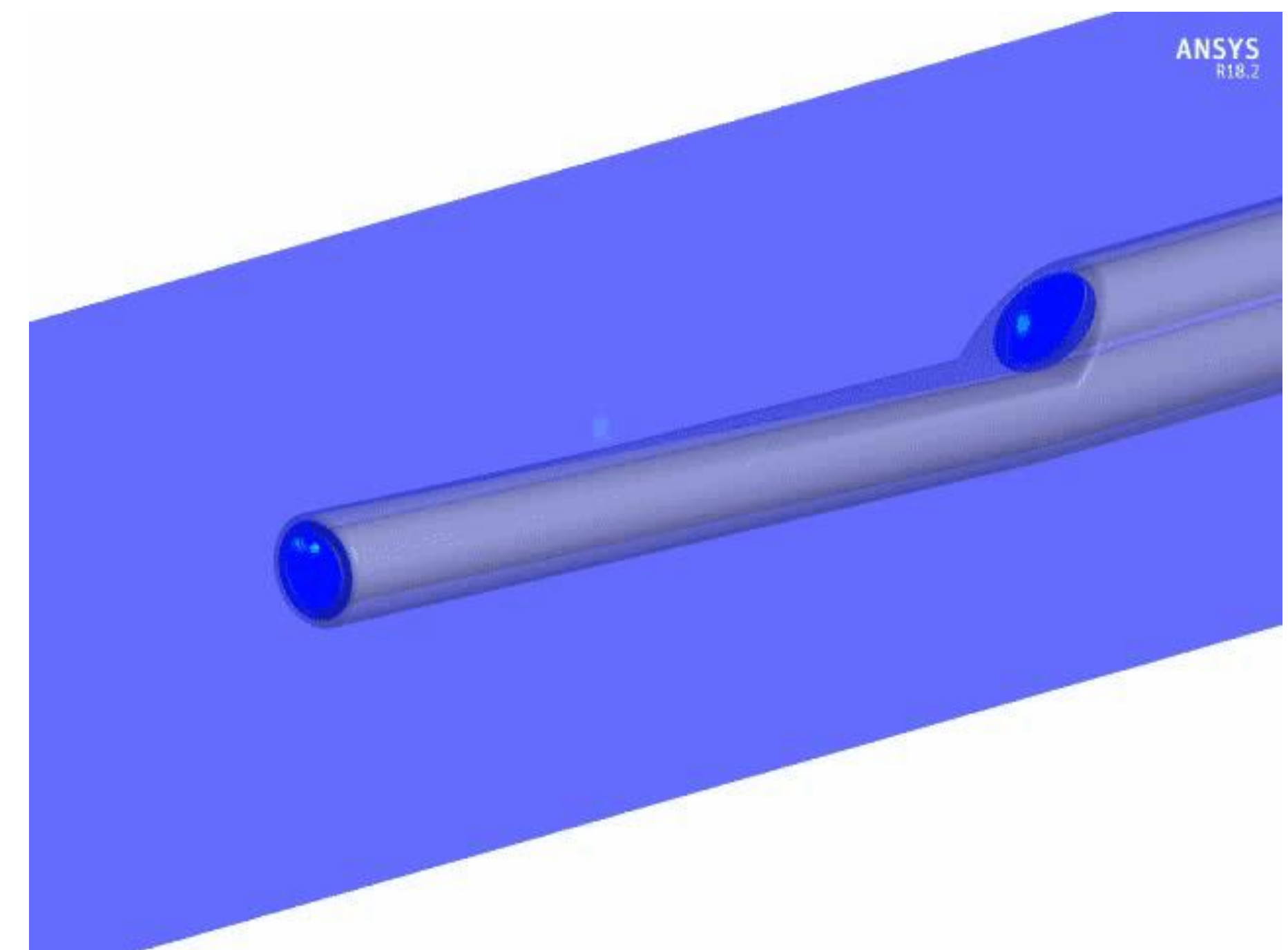
Image courtesy of Diana Oliveira

Medical Devices



Novel Tumour Surgical Device

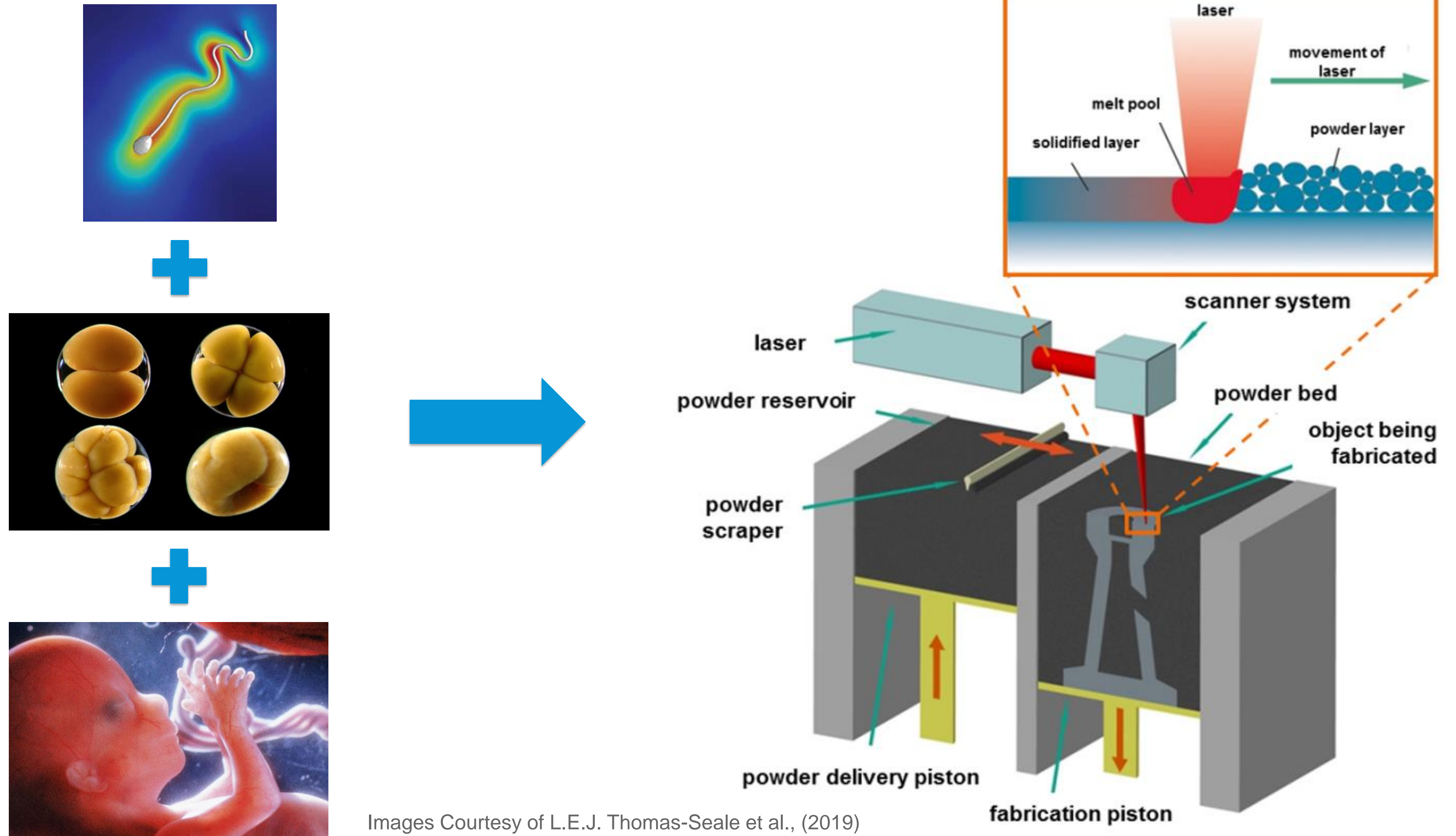
Image courtesy of Cambridge Mechatronics Ltd



Analysing Dialysis Catheters

Image courtesy of David Owen

Design the Future: Developmental Biology and Additive Manufacturing



Images Courtesy of L.E.J. Thomas-Seale et al., (2019)

Design the Future

MECHANICAL ENGINEERING | RESEARCH ARTICLE

The analogies between human development and additive manufacture: Expanding the definition of design

Authors

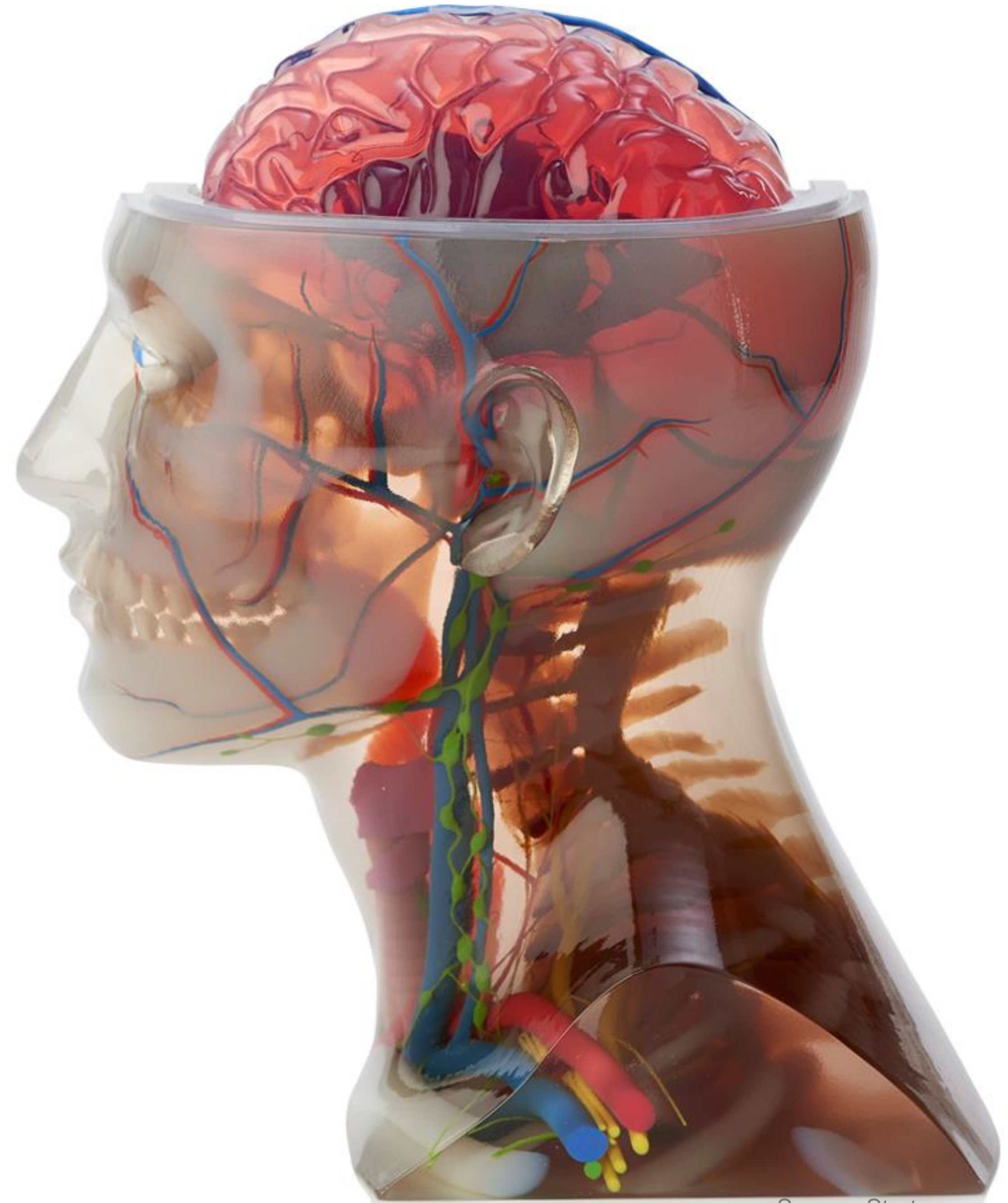
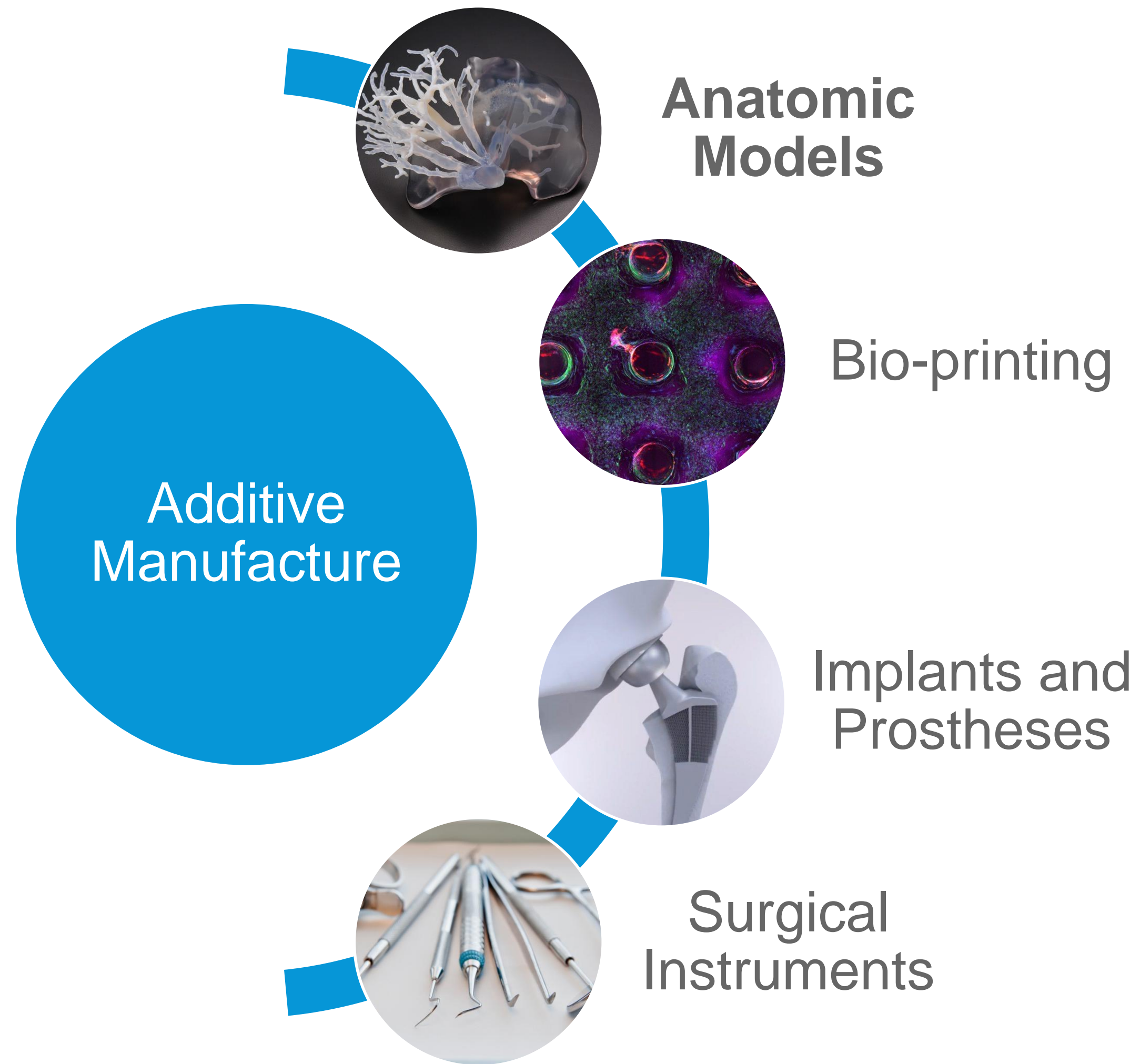
L. E. J. Thomas-Seale, J. C. Kirkman-Brown, S. Kanagalingam, M. M. Attallah, D. M. Espino & D. E. T. Shepherd

(Published 2019)

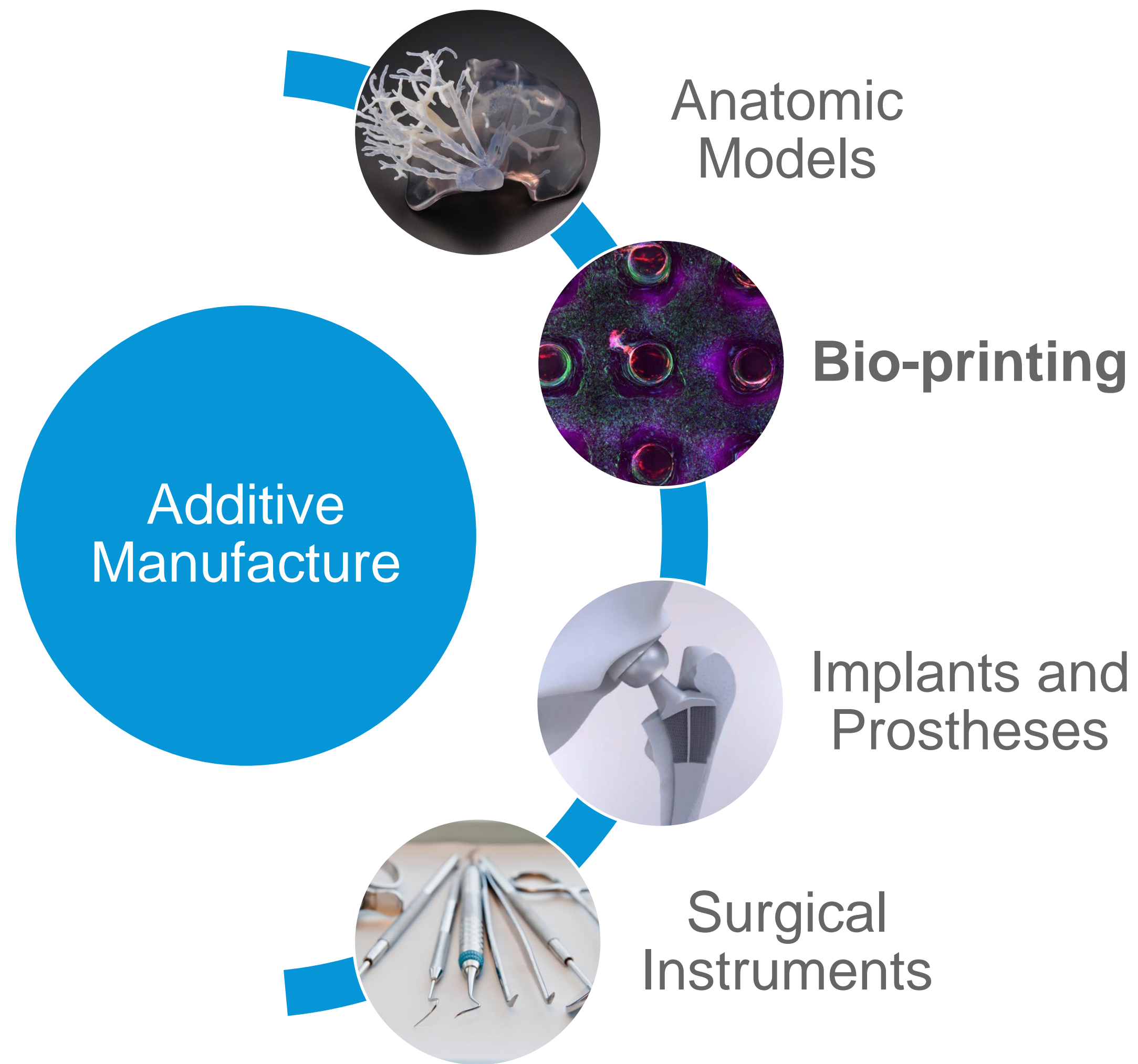
Additive Manufacturing in Medicine



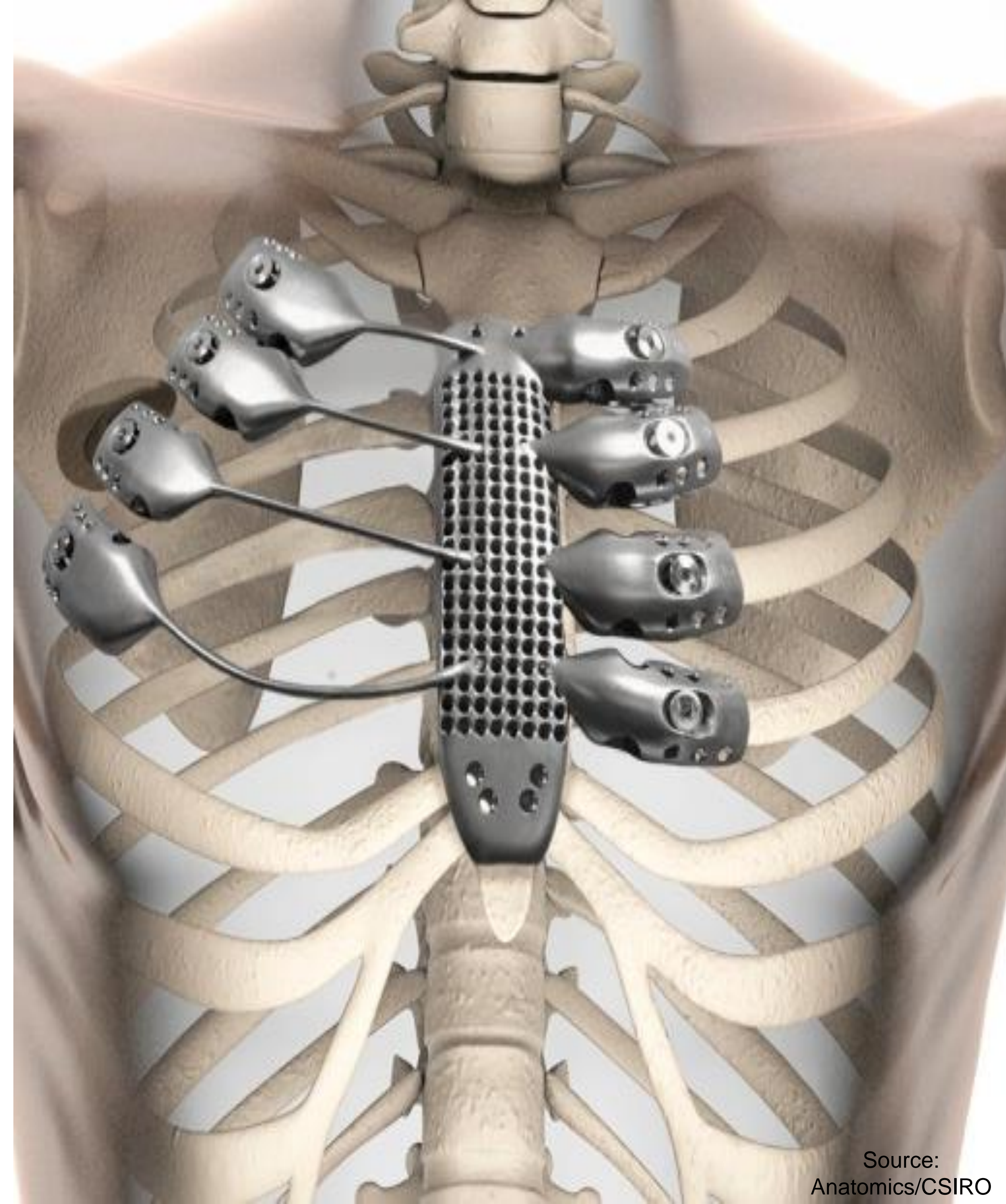
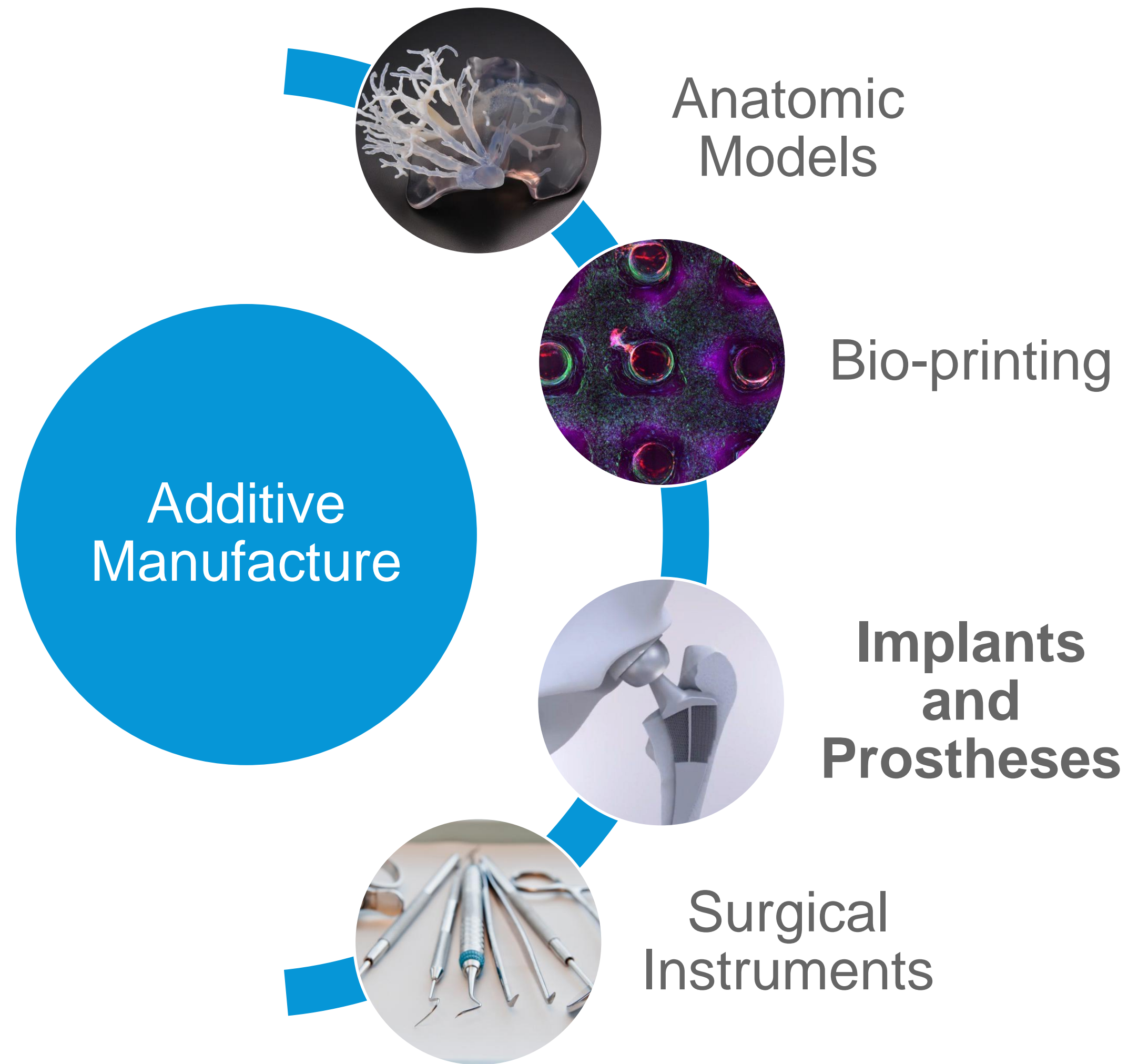
AM in Medicine



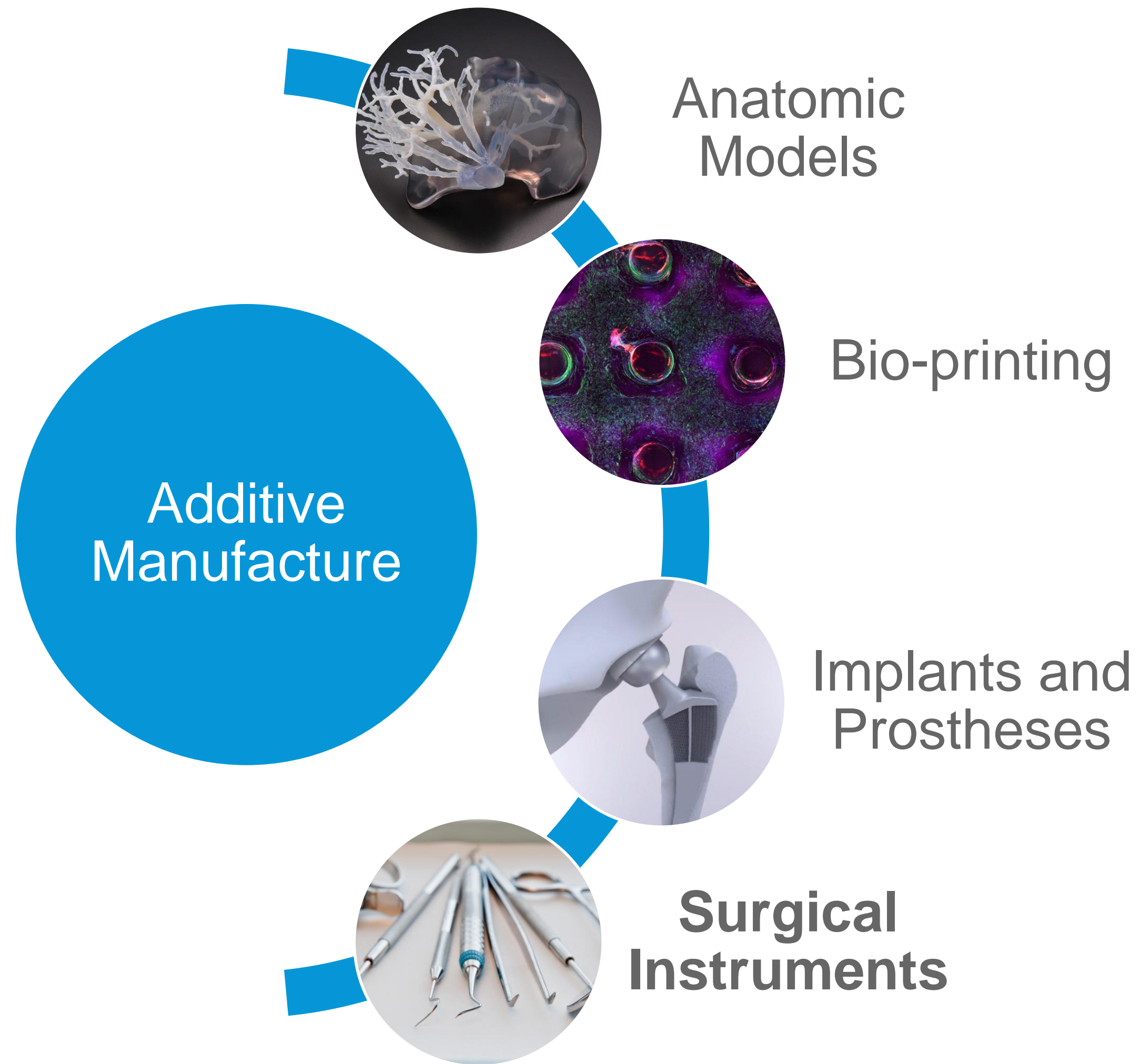
AM in Medicine



AM in Medicine



AM in Medicine



Design for Additive Manufacture



Additive Manufacturing Processes

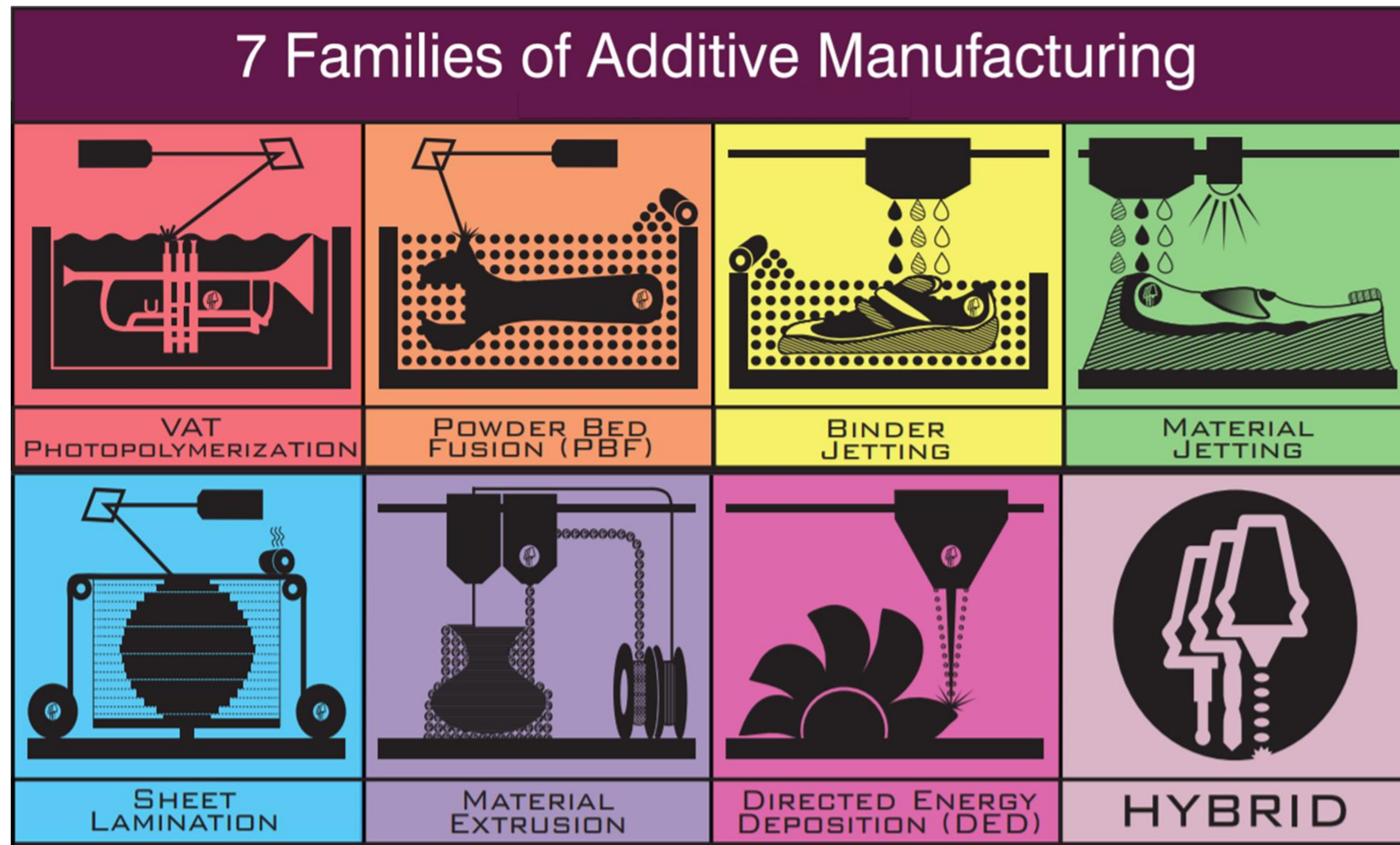
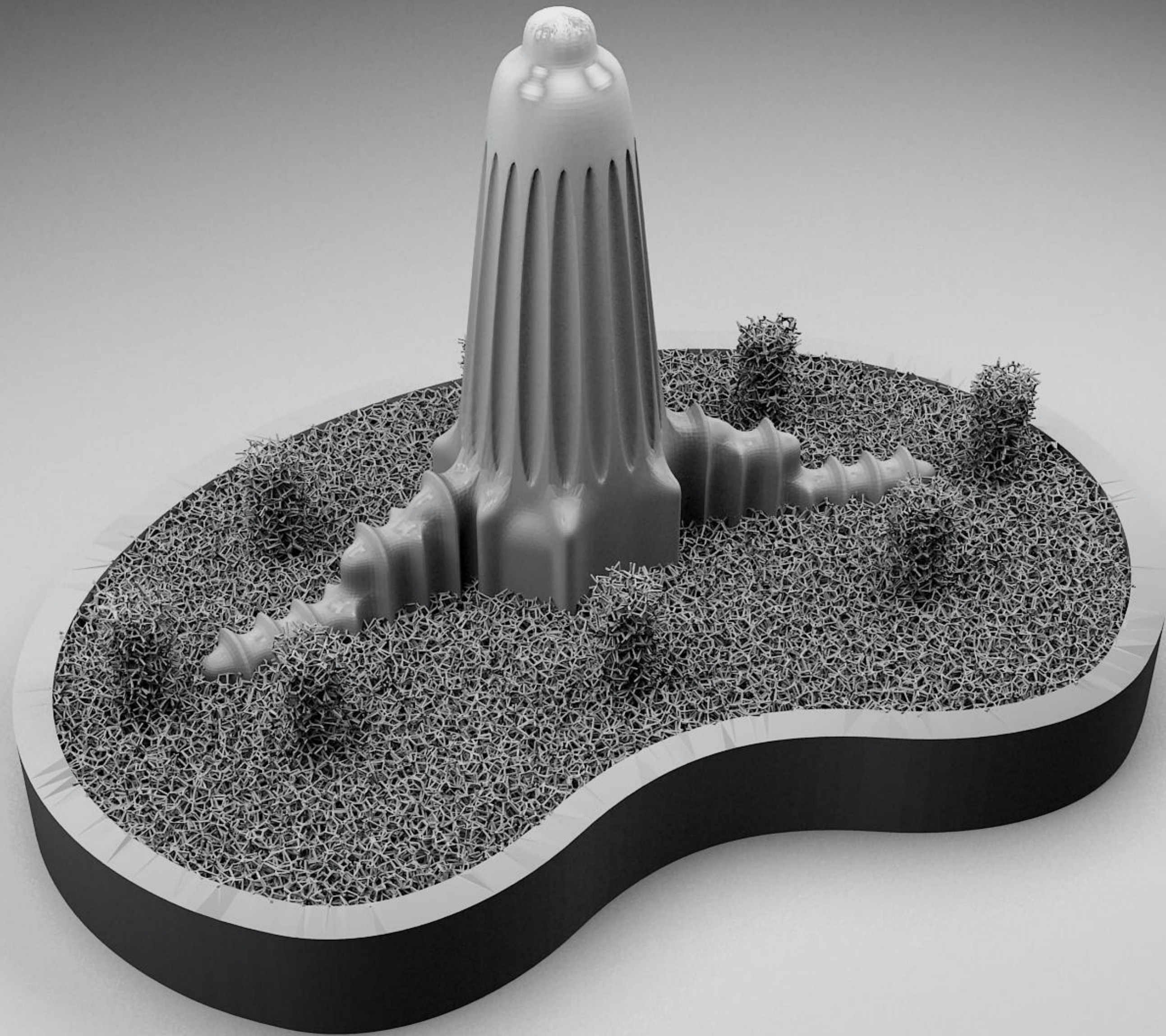


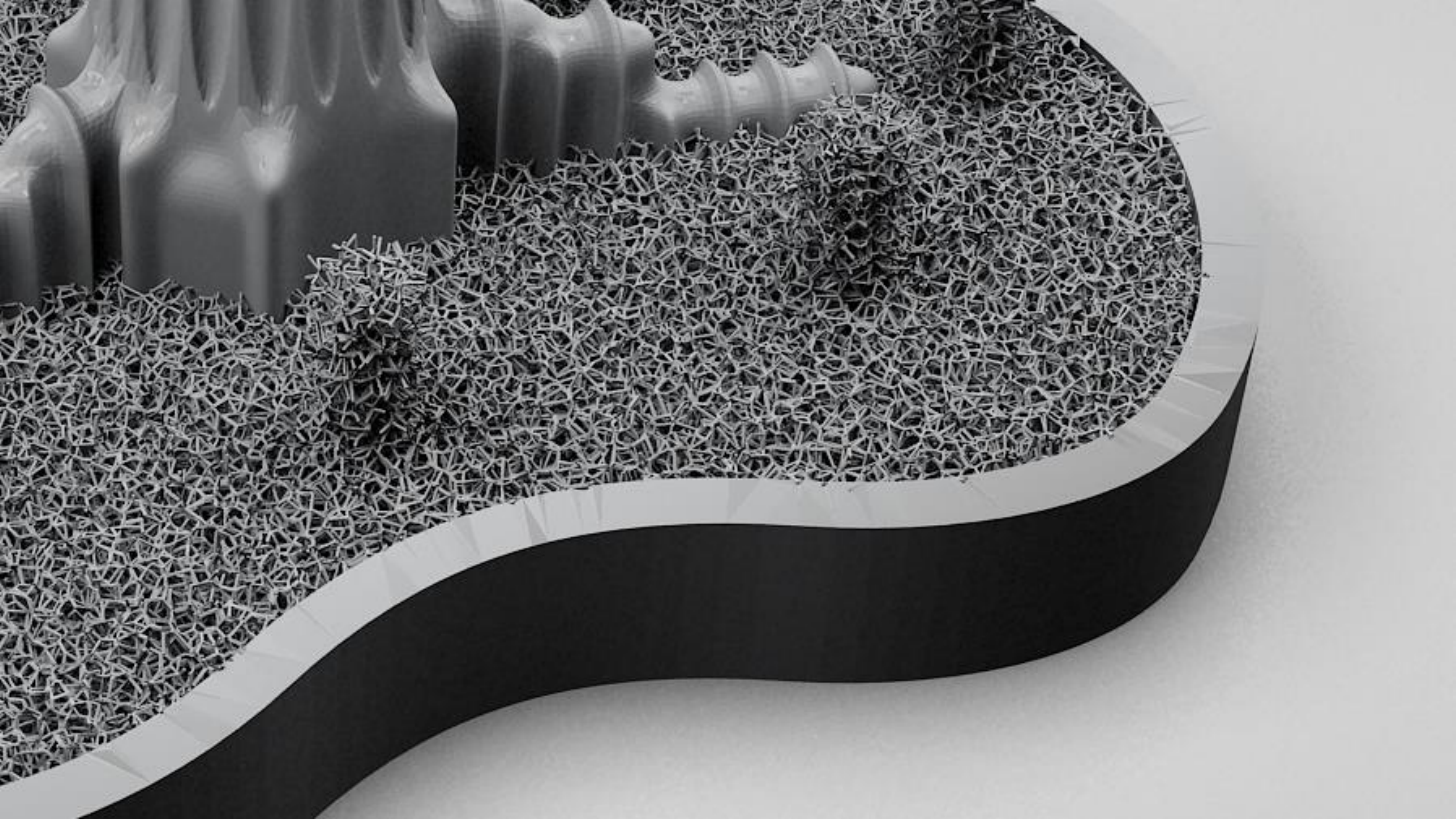
Image courtesy of HMT
<http://www.hybridmanutech.com/>

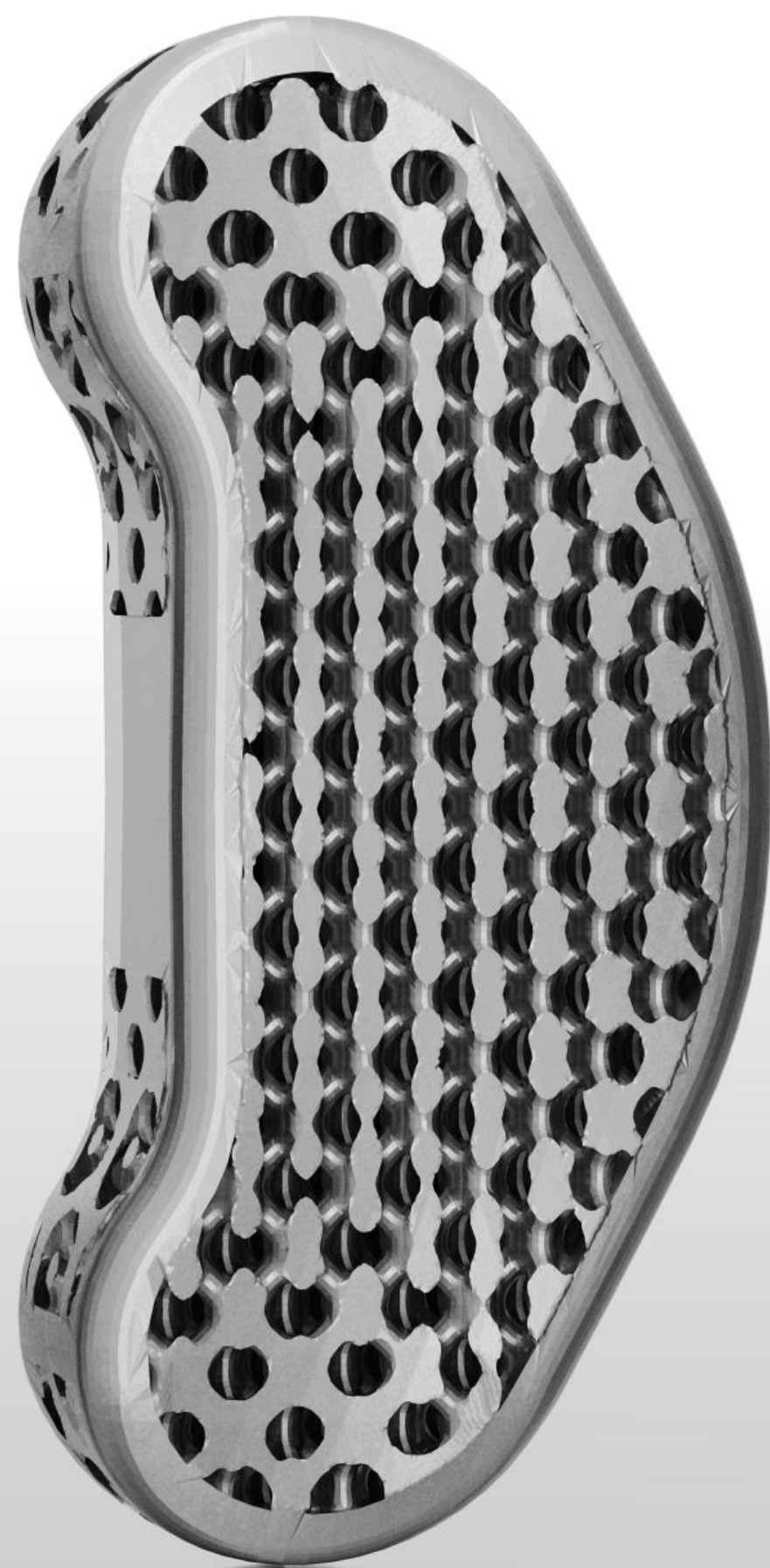
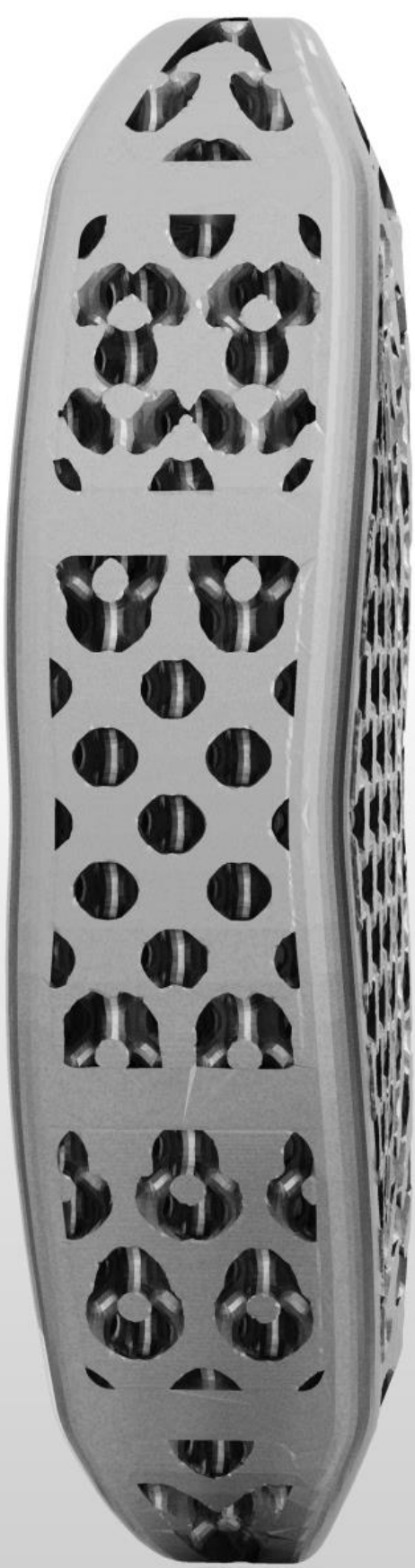
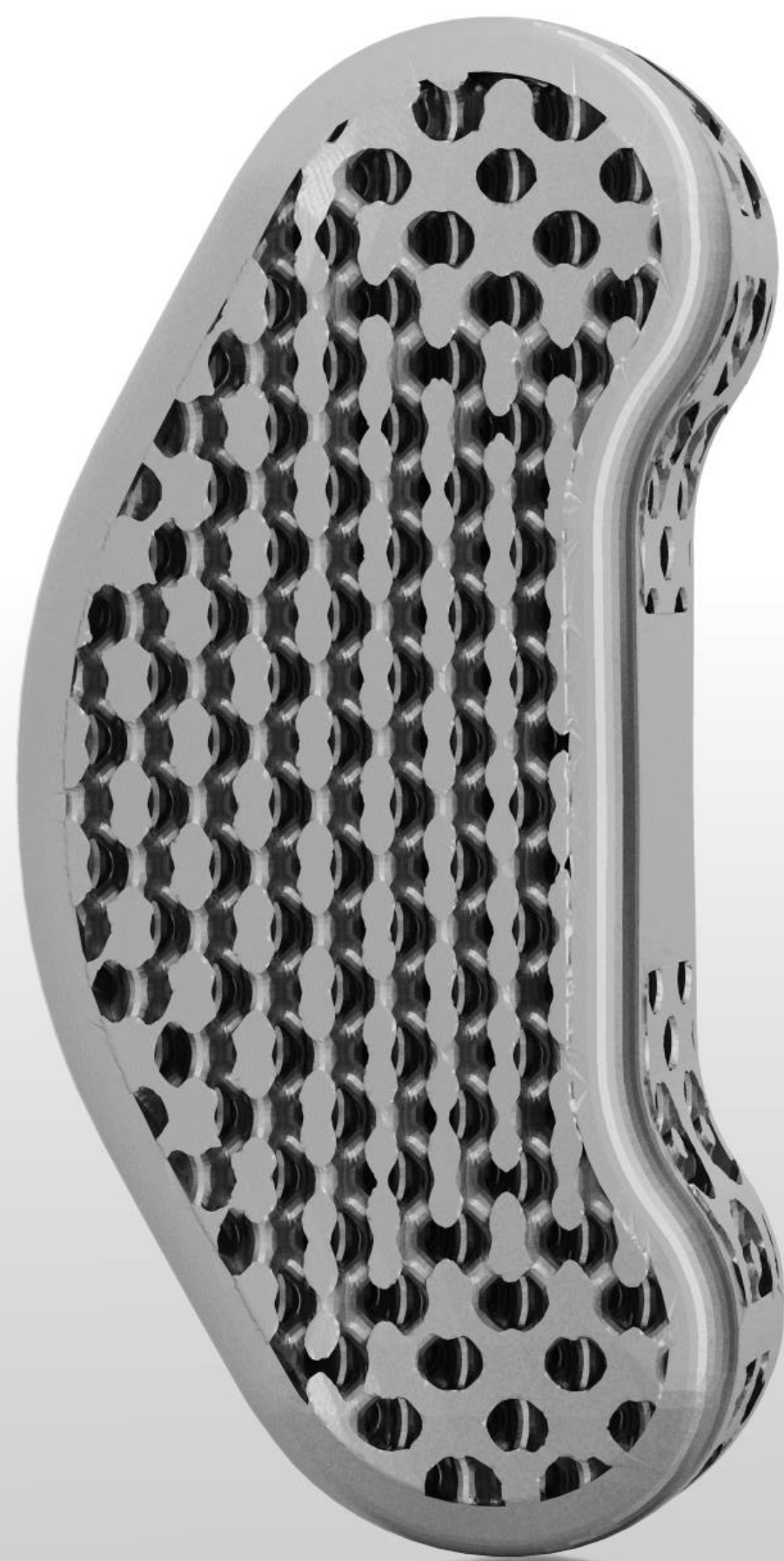
Advantages of Additive Manufacturing

- Part Complexity
 - COMBINE MANY PARTS TO ONE
 - NO ADDED COST
 - INTERNAL STRUCTURES
- Low Production Volume
 - COST
 - LEAD TIME

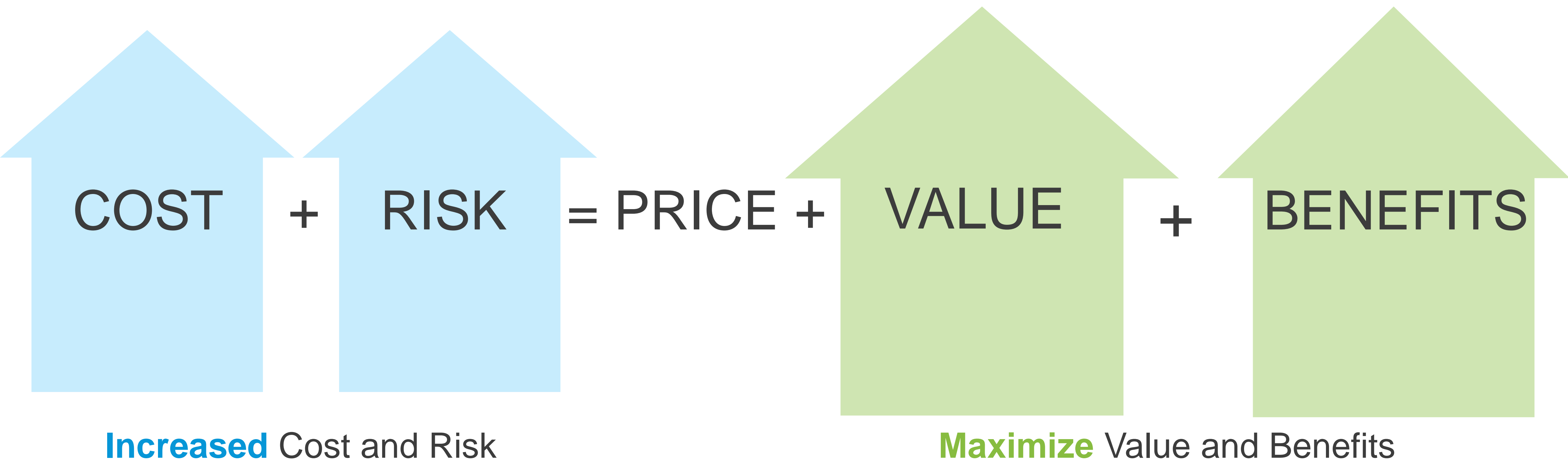








Traditional Manufacturing Approach



The Right Equation for Additive Manufacturing

Minimize Cost and Risk

COST

+

RISK

= PRICE +

VALUE

+

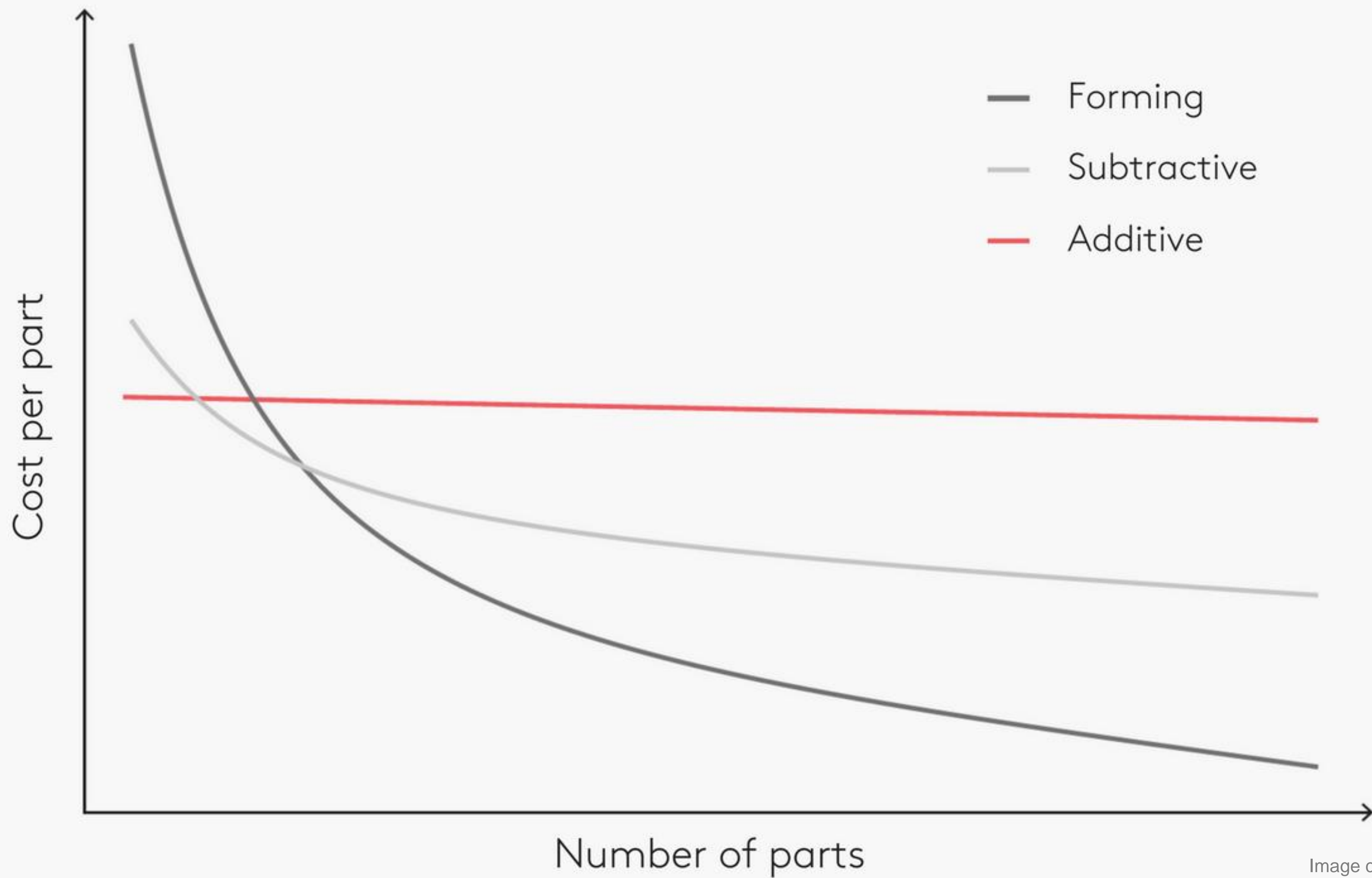
BENEFITS

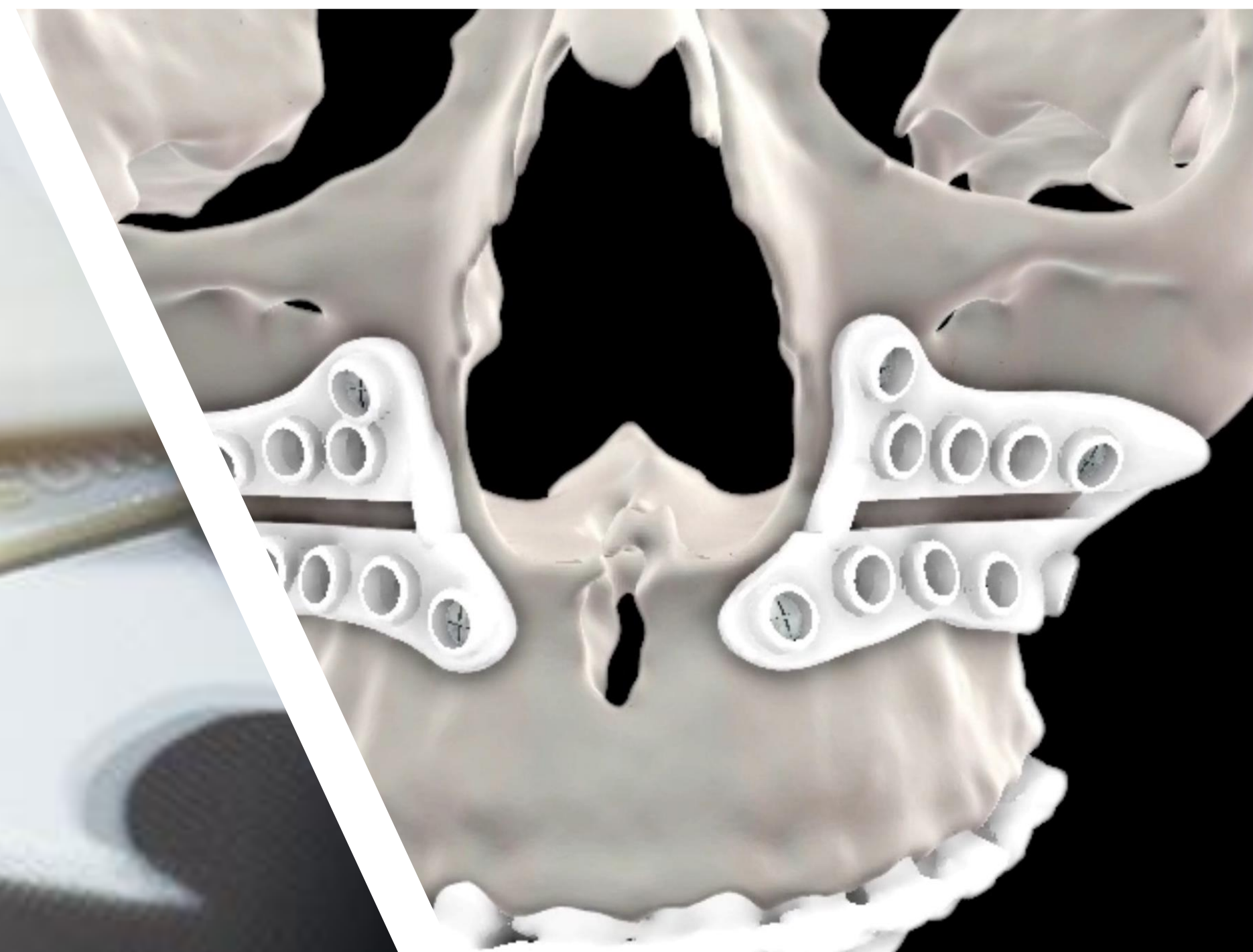
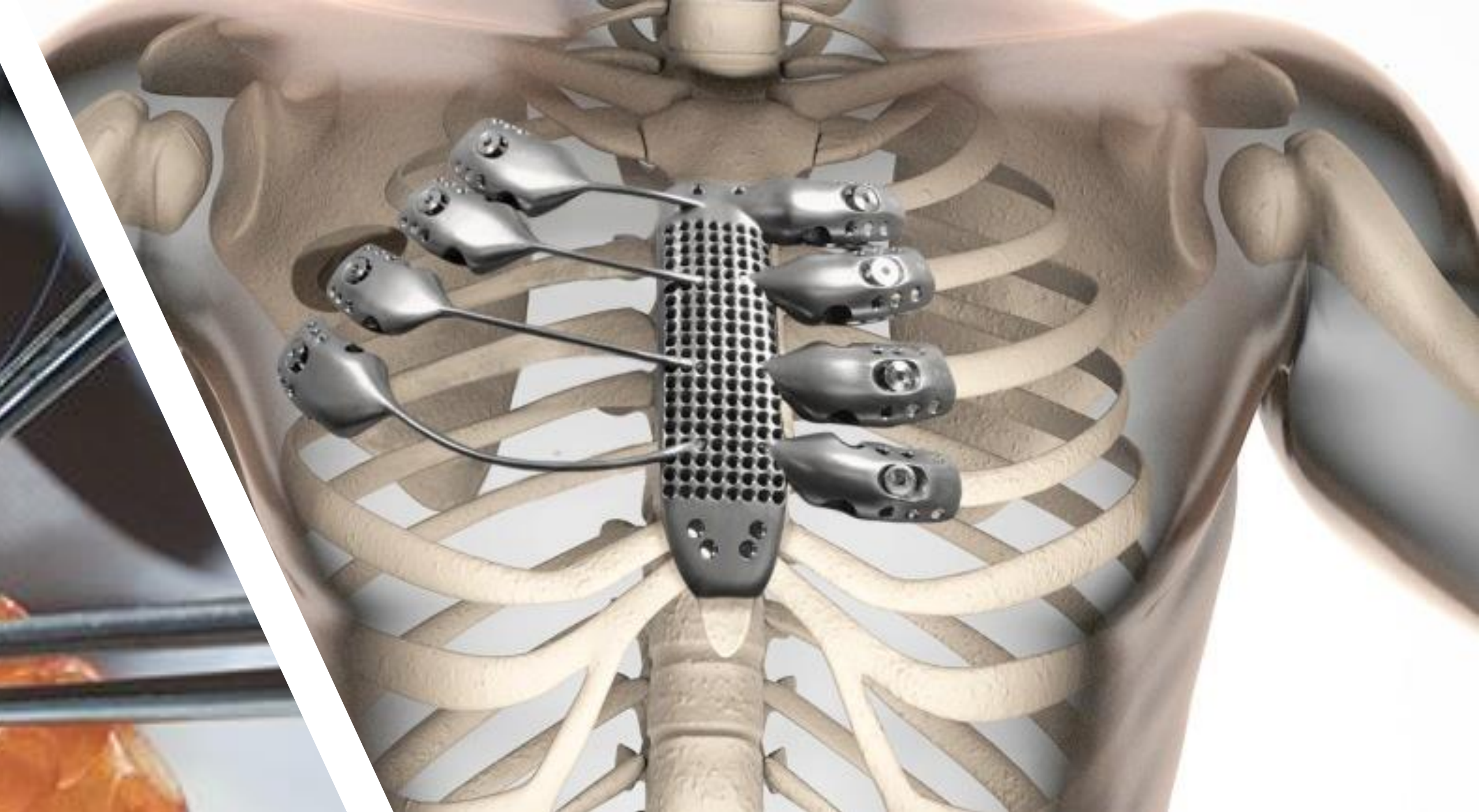
Maximize Value and Benefits

Advantages of Additive Manufacturing

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Challenges in Additive Manufacturing

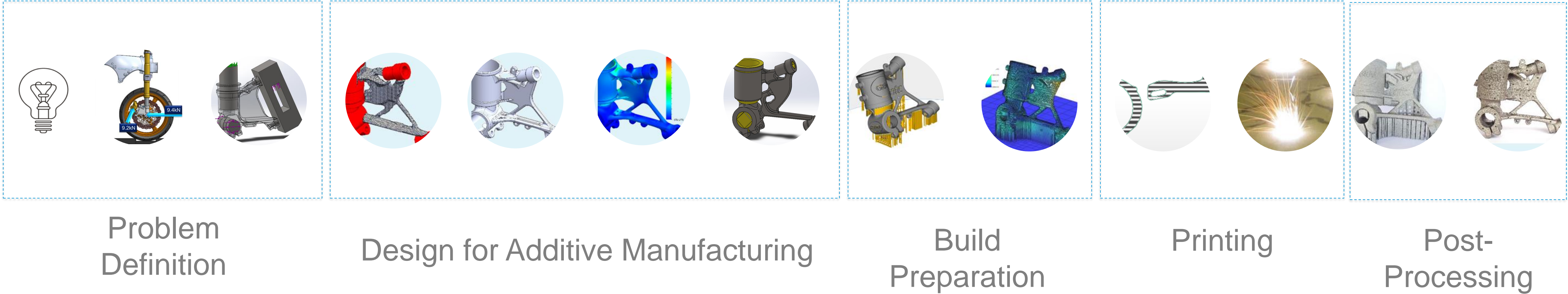


DESIGNING COMPLEX,
ORGANIC FORMS

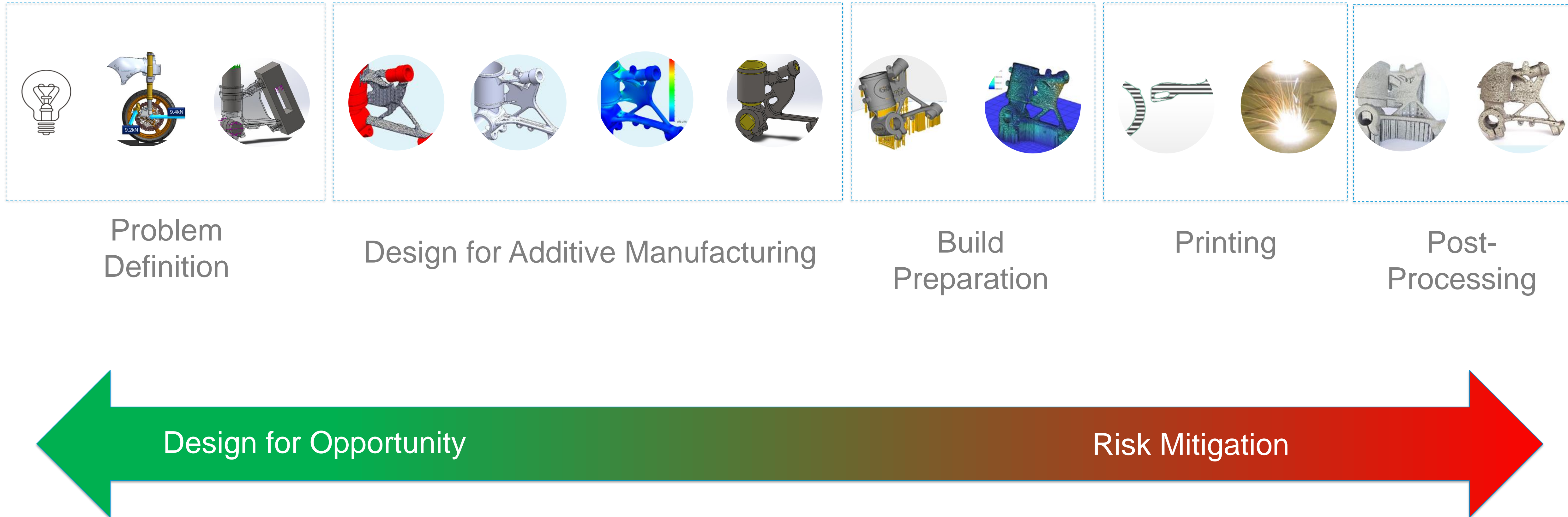


PART DISTORTION AND
PRINT FAILURES

Additive Manufacturing Workflow



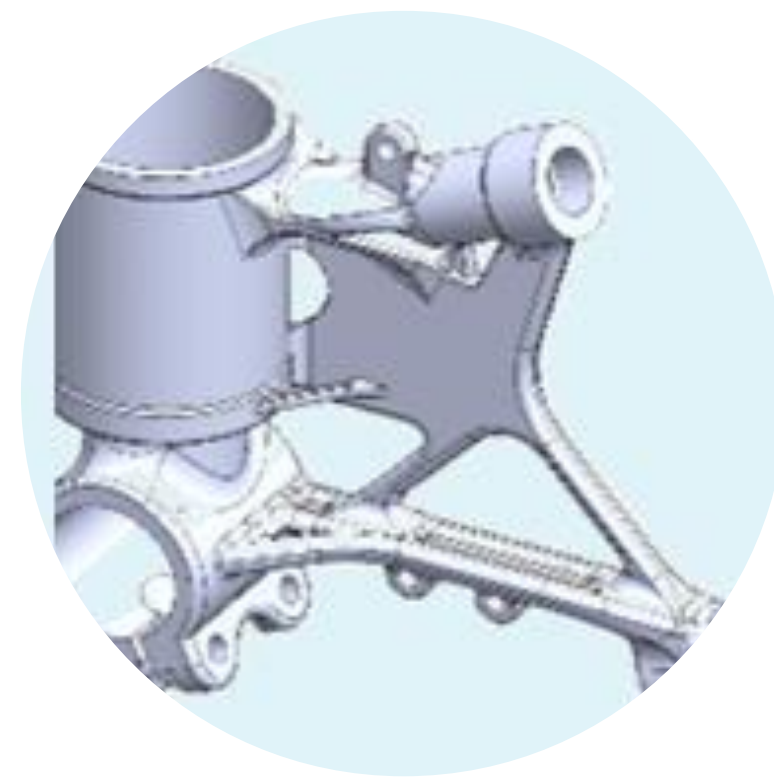
Additive Manufacturing Workflow



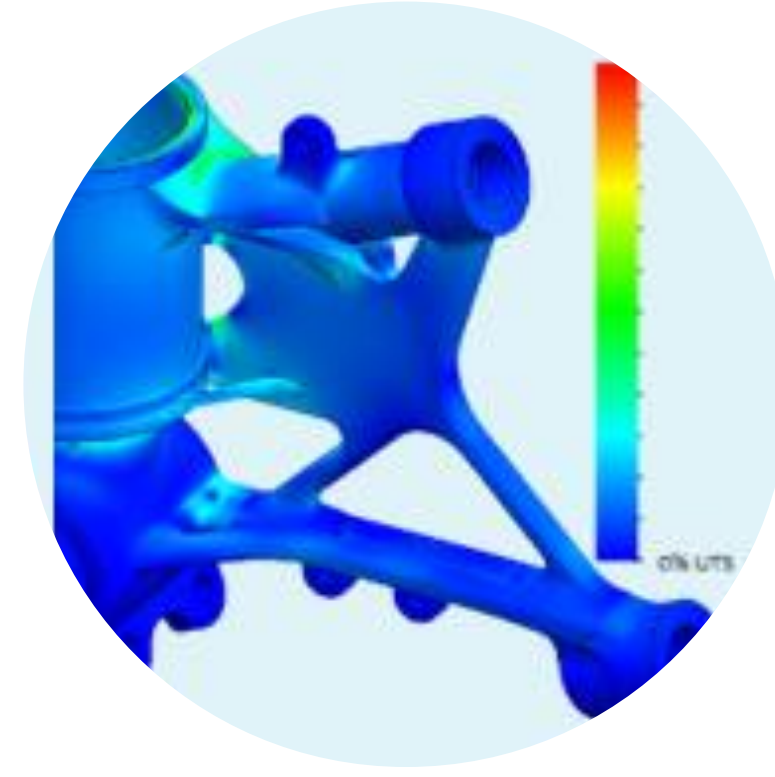
Design for Additive Manufacturing



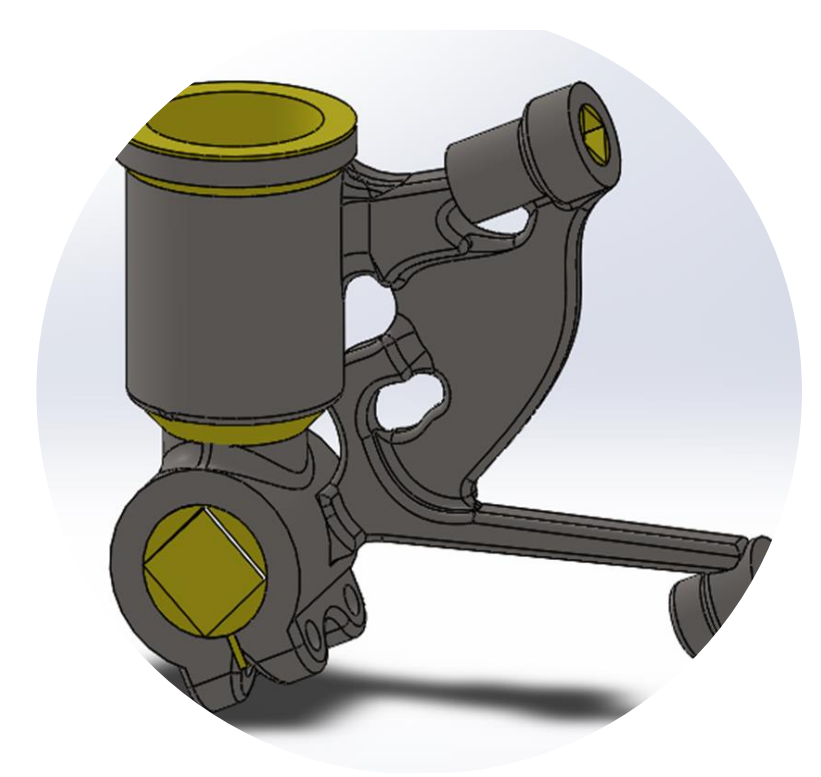
Concept Generation



Remodeling

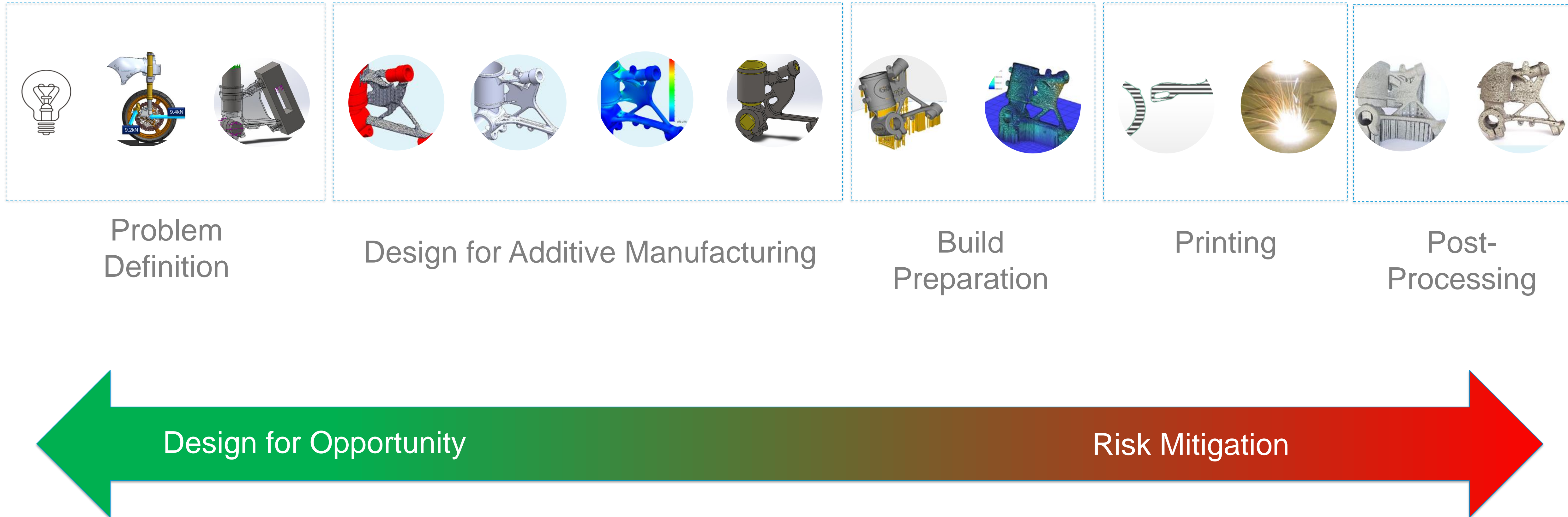


Validation



Design for Manufacture

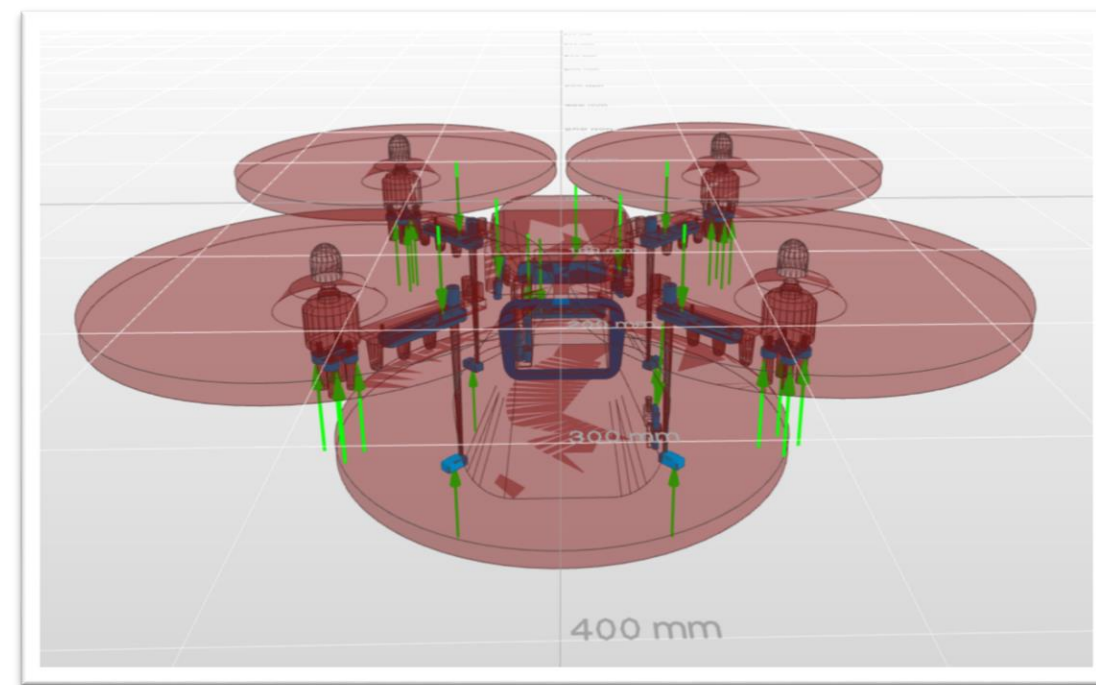
Additive Manufacturing Workflow



Generative Design as a Design Tool for Additive Manufacturing



Generative Design Workflow



Define

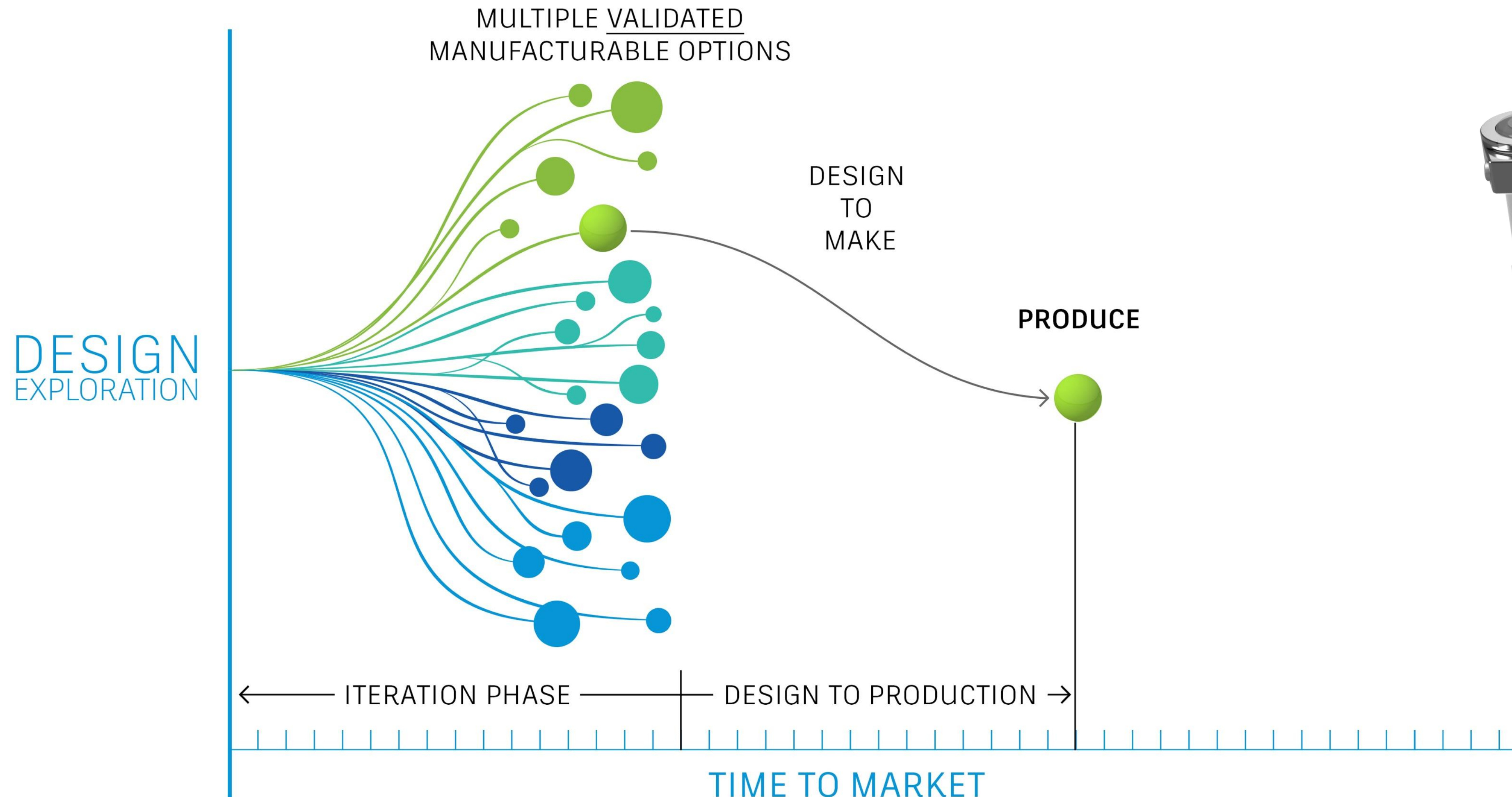


Generate

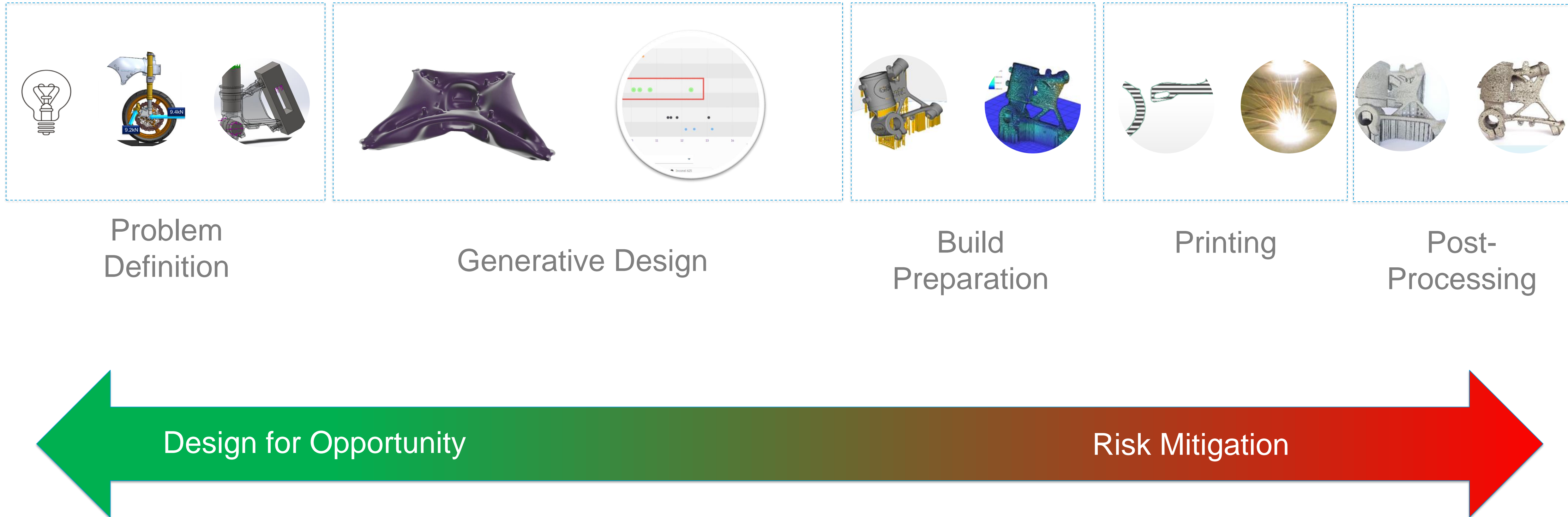


Explore

Generative Design Workflow



Additive Manufacturing Workflow





Generative Design Case Study

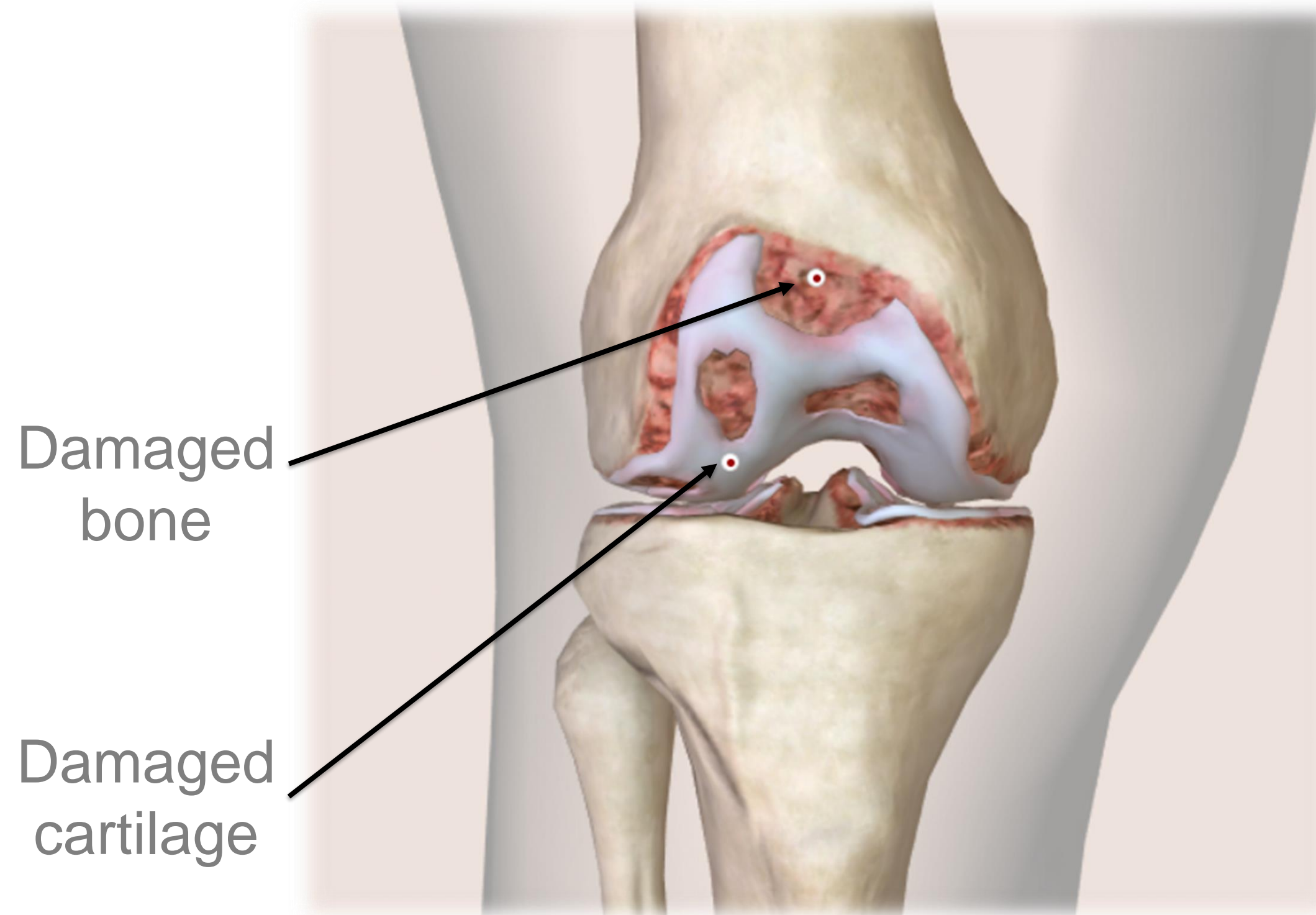
Osteoarthritis (OA)

- OA affects 27 million Americans and 240 million people globally
- Annual cost per patient ~ \$15K
- Causes and risk factors
 - Aging
 - Genetics
 - Infection
 - Obesity
 - Overuse
 - Trauma



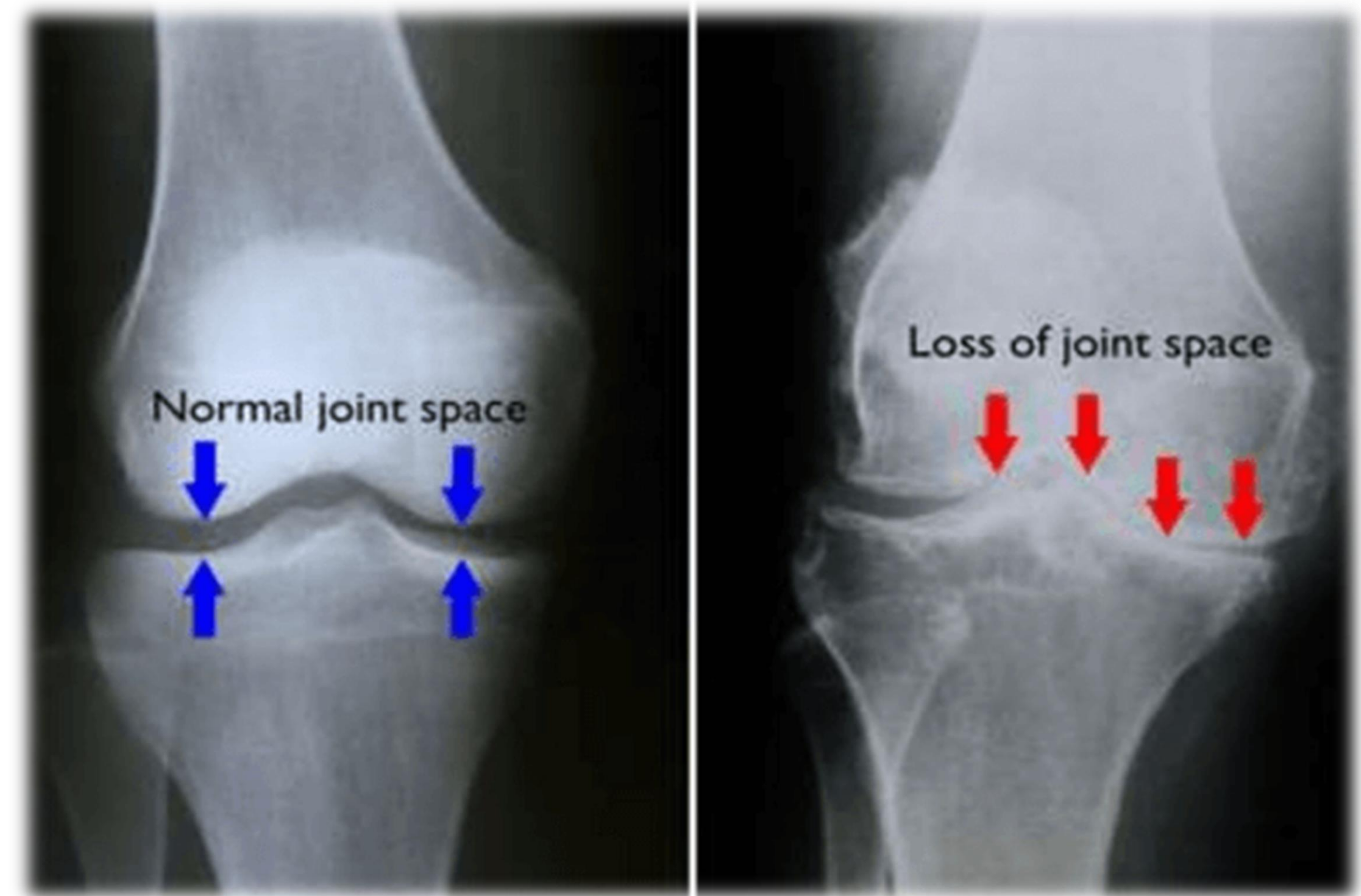
Knee Osteoarthritis

DAMAGED CARTILAGE AND BONE



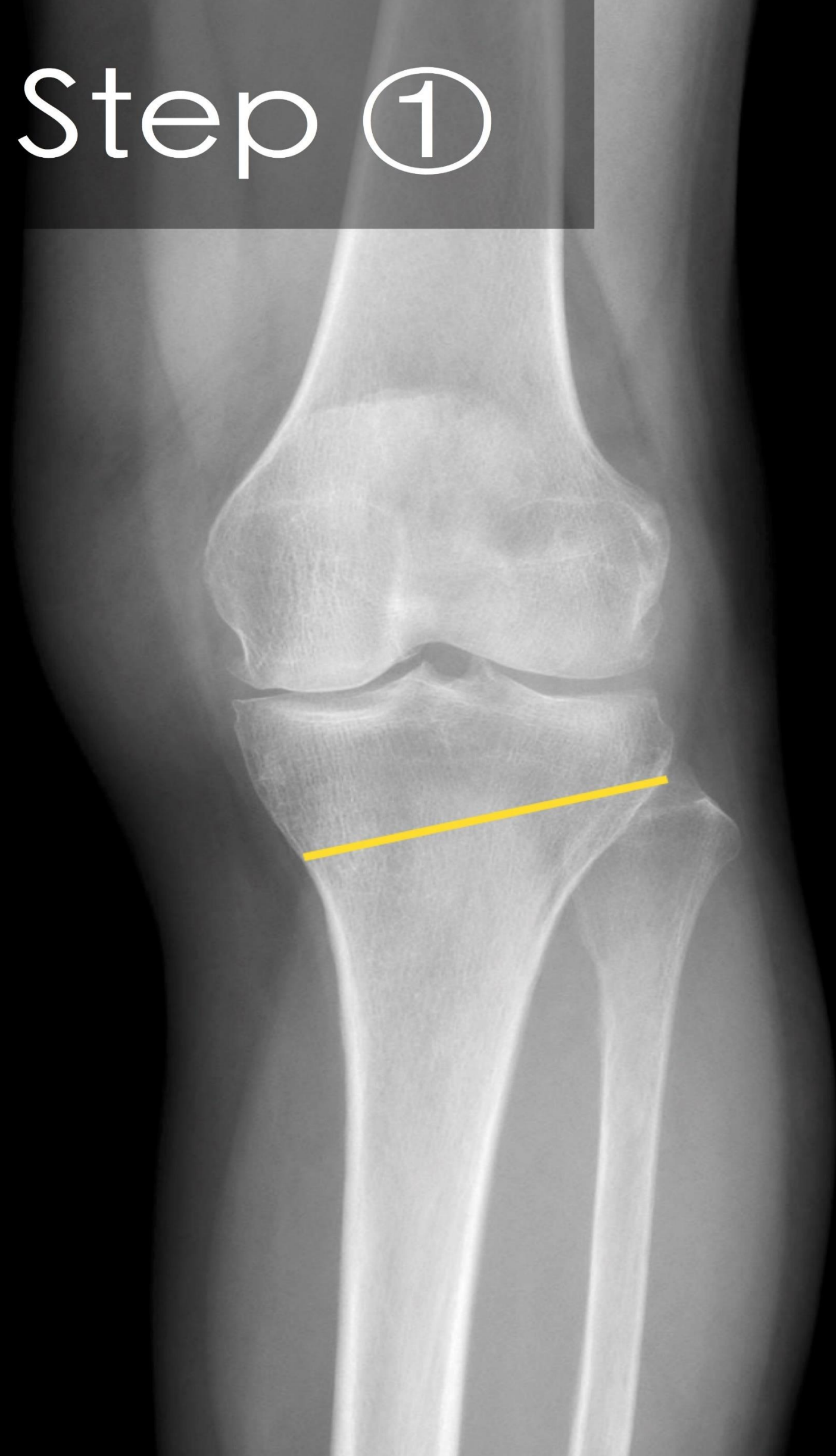
Source: BioDigital
<https://www.biodigital.com/>

UNEVEN WEIGHT DISTRIBUTION

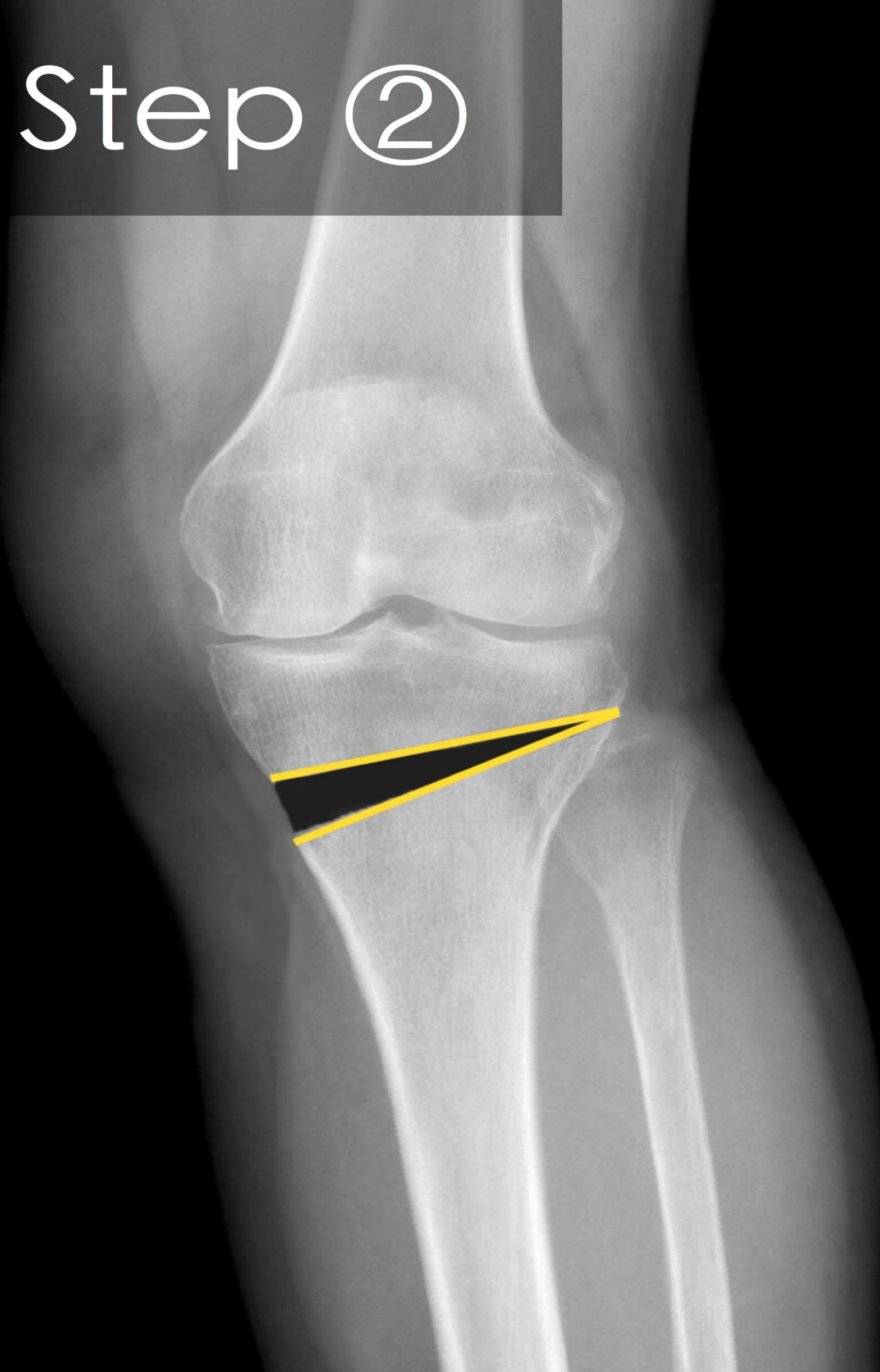


Source: American Association of Orthopaedic Surgeons
<https://orthoinfo.aaos.org/>

Step ①



Step ②



Step ③



Image courtesy of Taipei Veterans General Hospital

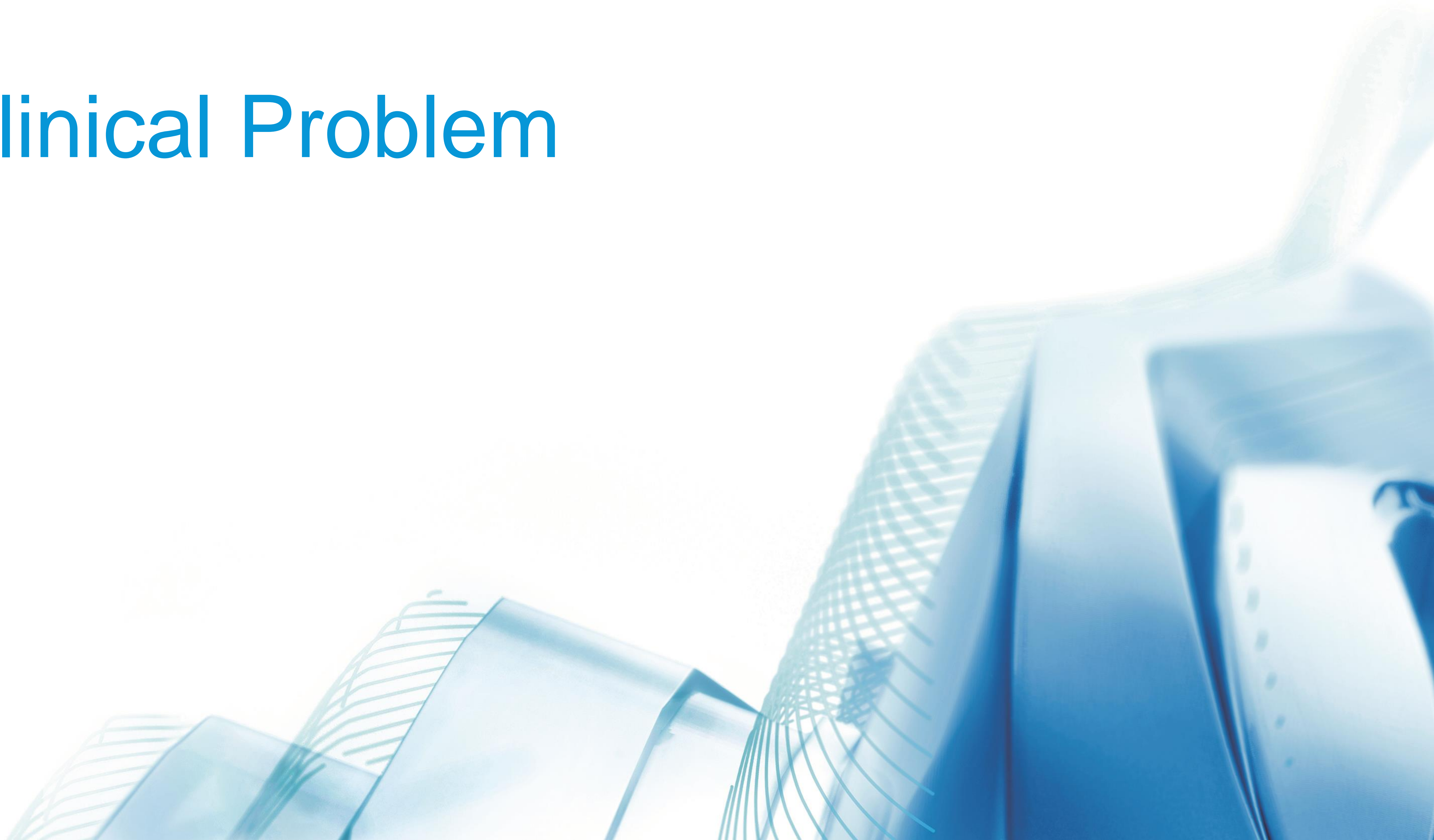
High Tibial Osteotomy (HTO)

High Tibial Osteotomy (HTO)

- HTO realigns the knee joint with an induced fracture (open wedge)
- The open wedge redistributes weight-bearing loads at the knee, relieving pain and preventing further damage to the joint.
- HTO is a preventive measure for osteoarthritis and/or delays the need for a knee replacement.



Clinical Problem



Bone Remodelling

- Bone is a living material, actively constructed and remodelled throughout life
- Remodelling is triggered by mechanical stimuli (force or pressure)
- Absence of mechanical stimuli leads to loss of bone density in critical areas of the skeleton

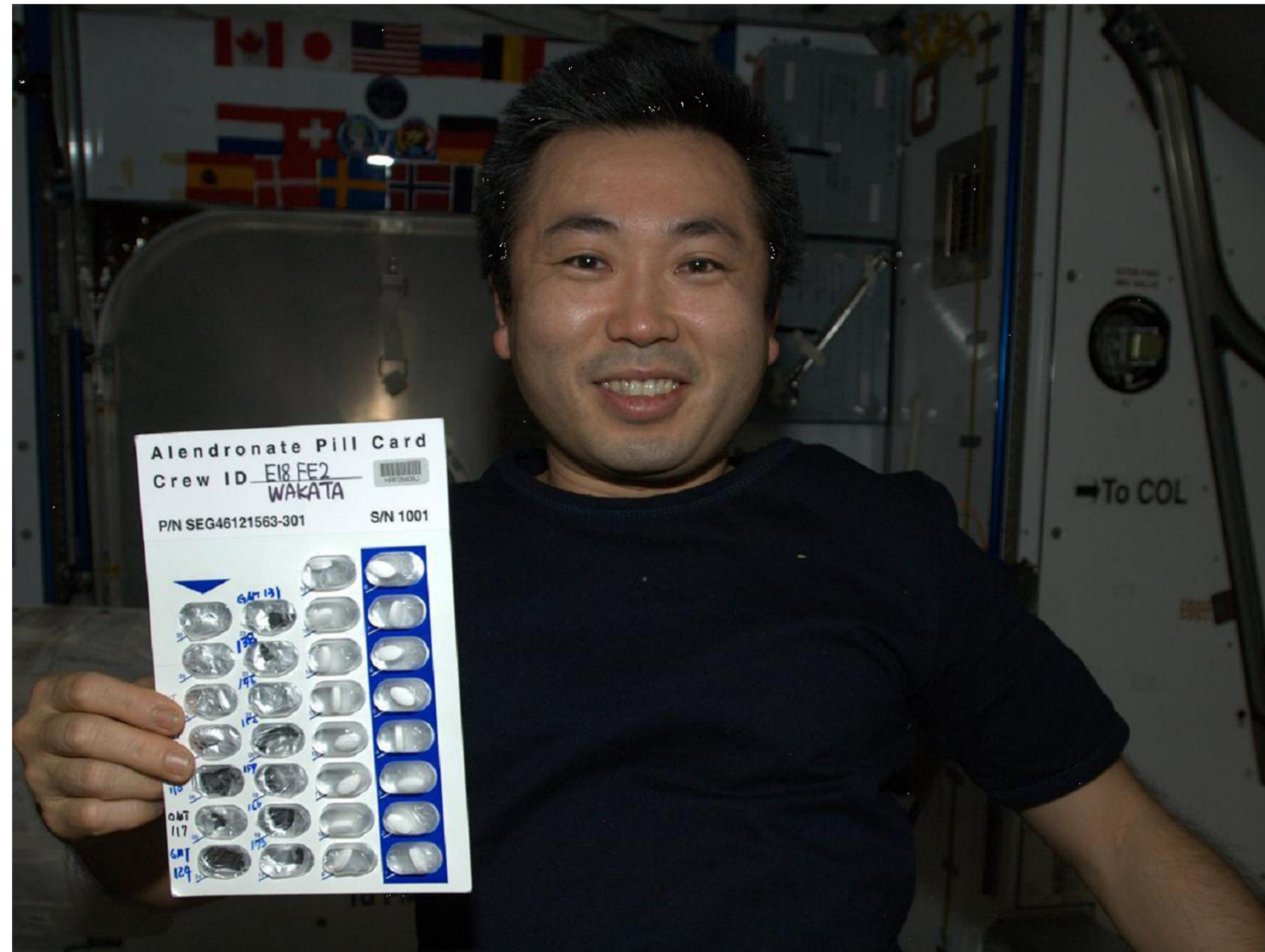


Microgravity Affects Bone Density



Source: NASA

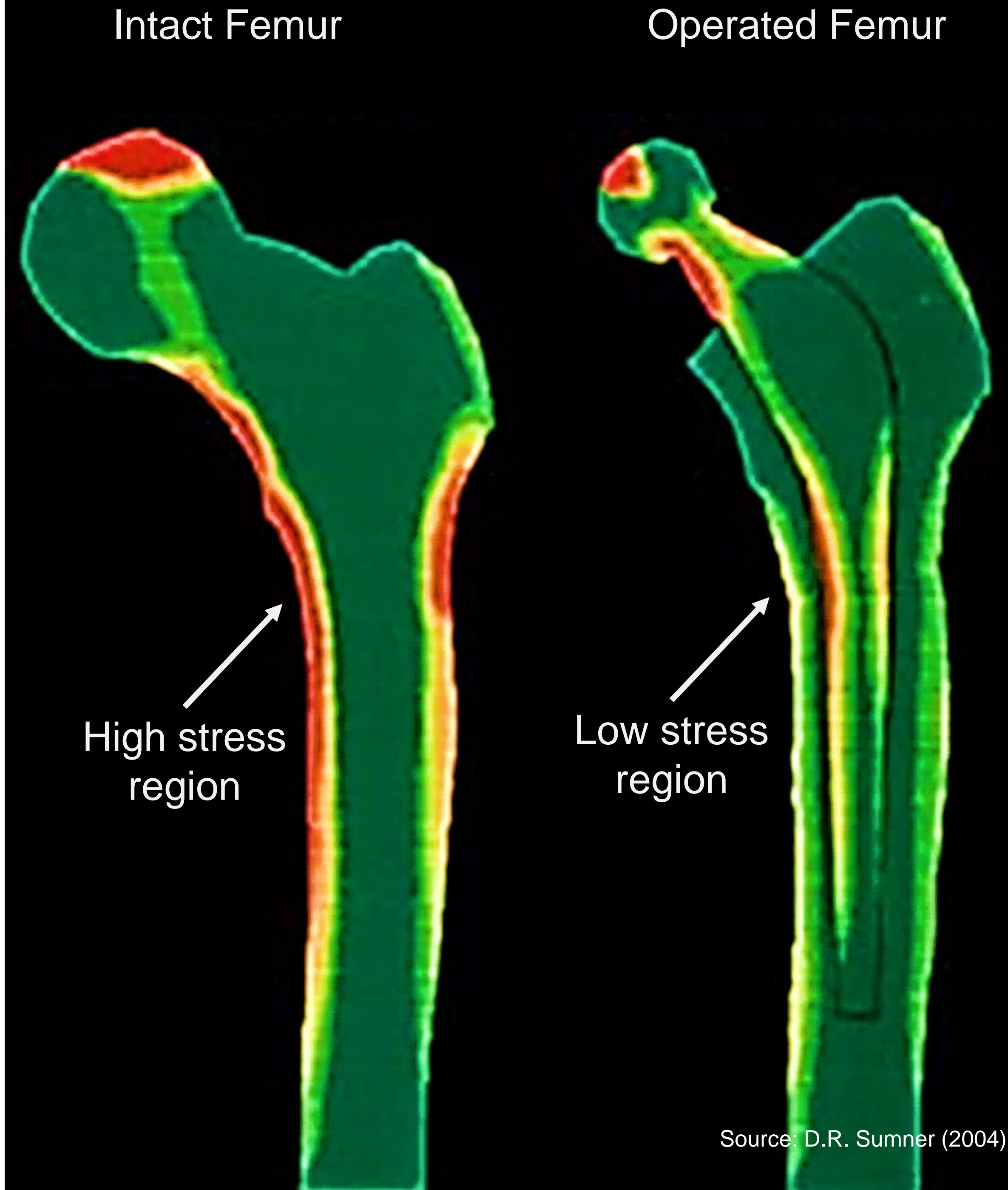
Calcium Supplementation for Astronauts



Source: European Space Agency

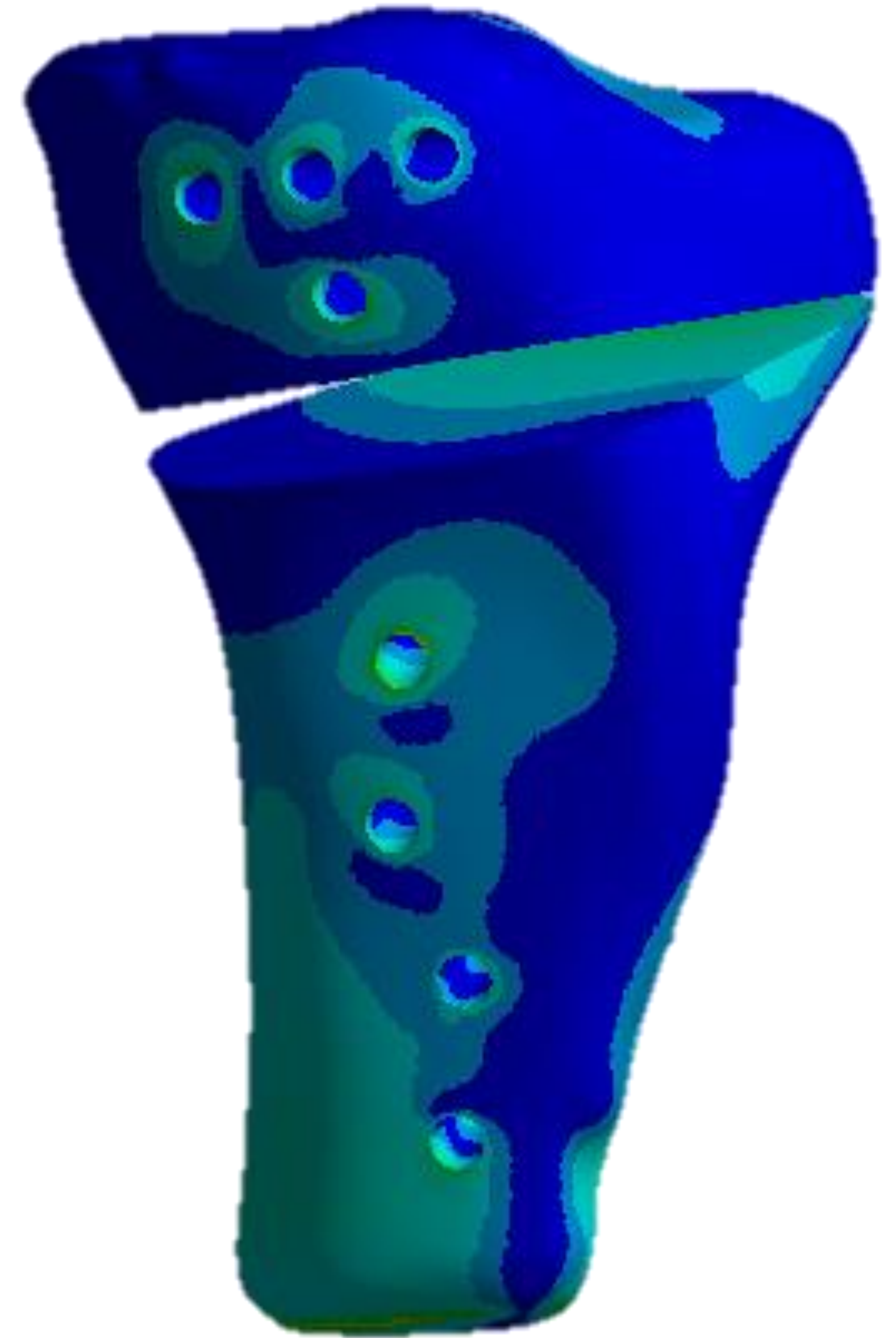
1. Stress Shielding

- Metal implants are 10 times stiffer compared to Bone (20 GPa)
 - Stainless steel - 200 Gpa
 - Titanium – 120 Gpa
- Physiological load on a bone is shielded by the implant
- Stress shielding affects the natural remodelling process and thus bone resorption and loss in bone density



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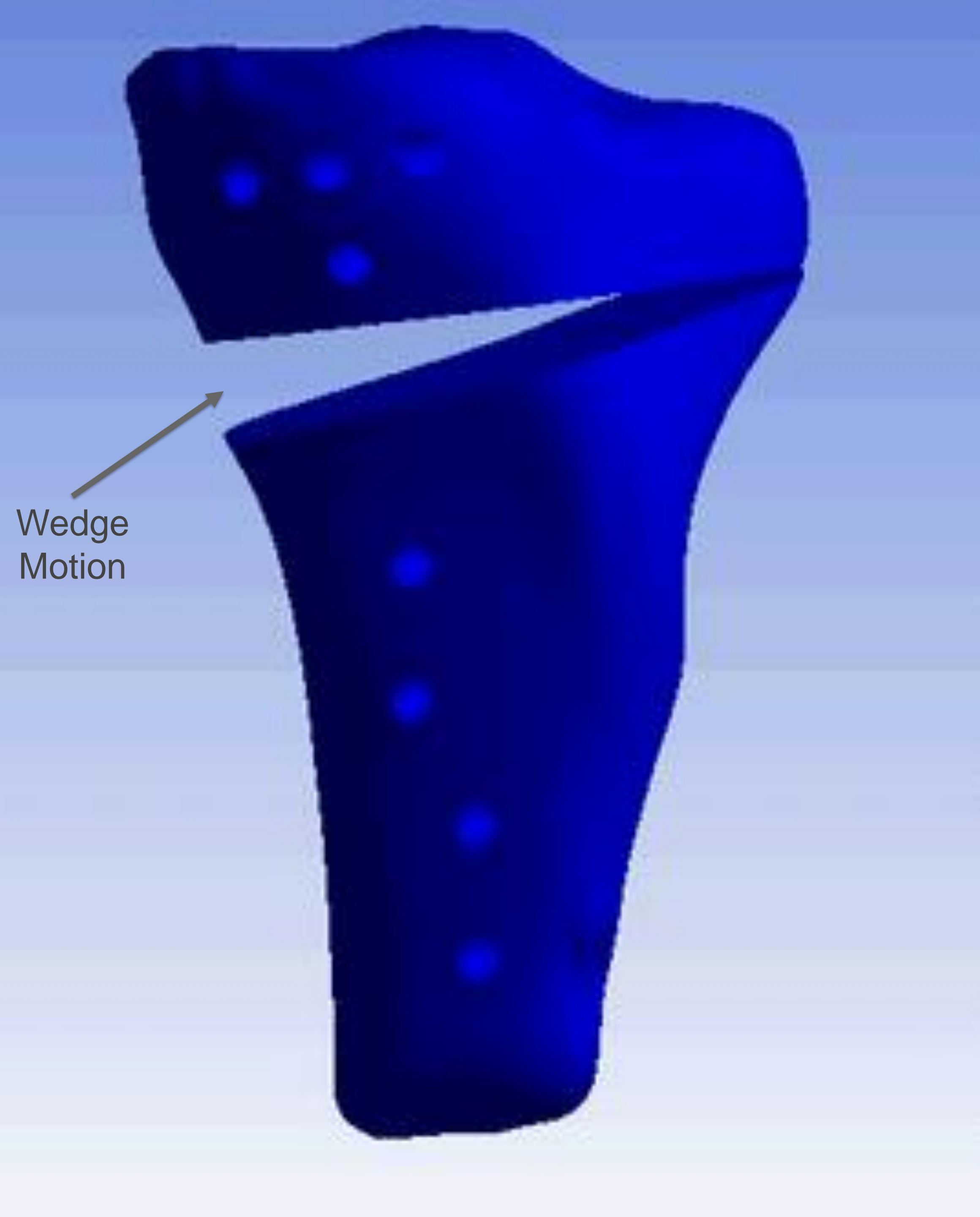
2. Relative Motion

- Stiff implants induce minimal movement around the open wedge (absolute stability)
- **Absolute stability** impedes the reconstruction of bone around the open wedge
- **Relative motion (1mm)** between the bone and implant is necessary to provide optimal conditions for biological healing to take place



2. Relative Motion

- Stiff implants induce minimal movement around the open wedge (absolute stability)
- **Absolute stability** impedes the reconstruction of bone around the open wedge
- **Relative motion (1mm)** between the bone and implant is necessary to provide optimal conditions for biological healing to take place



High stiffness of implants induce stress shielding and inhibit biological healing of the bone

Ideal Implant for HTO?

1. Reduced stiffness to minimise stress shielding
2. Allow 1mm wedge motion for optimal healing
3. Low profile to avoid implant prominence
4. Support physiological loading





Image courtesy of DePuy Synthes



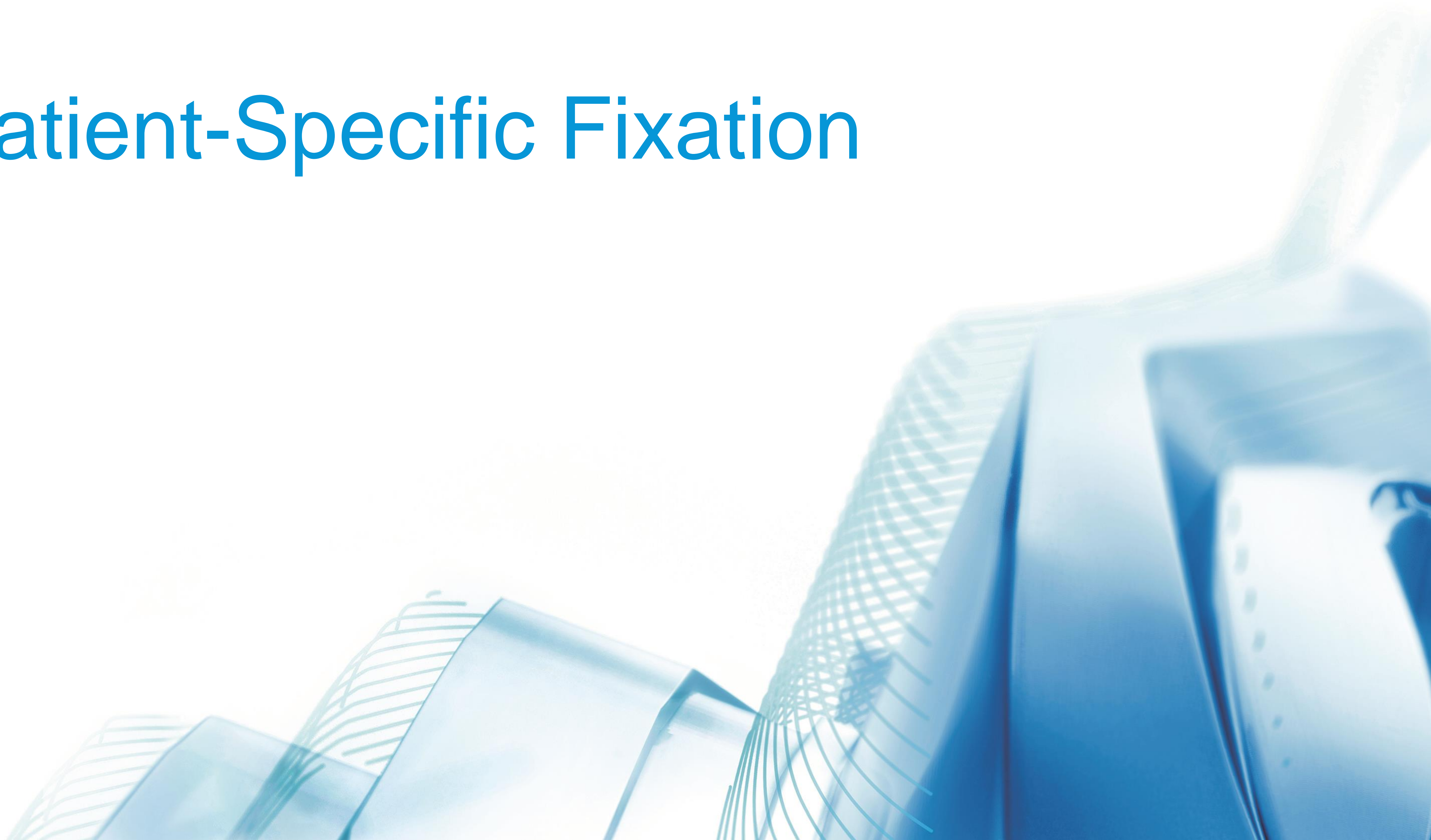
Source: NEWCLIP



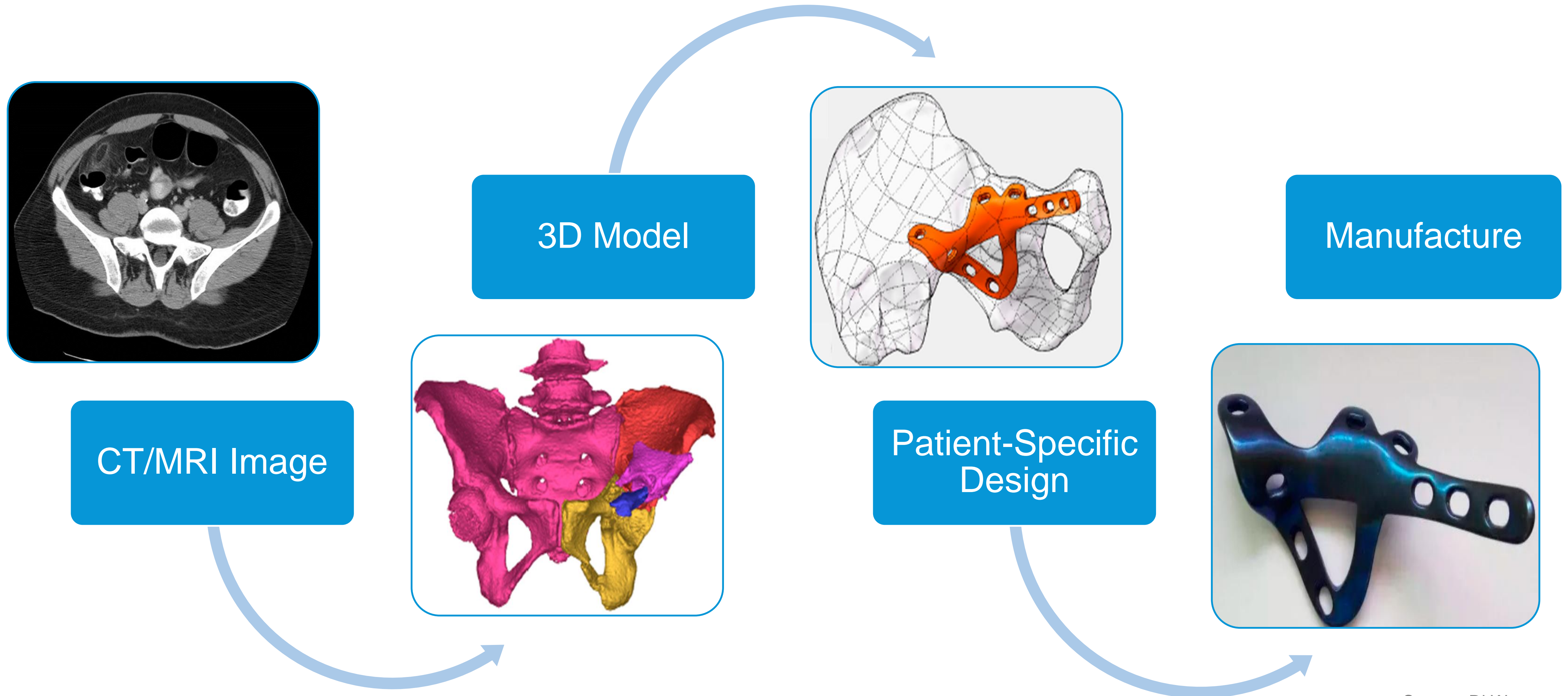
Source: Arthrex

ONE-SIZE-FITS-ALL

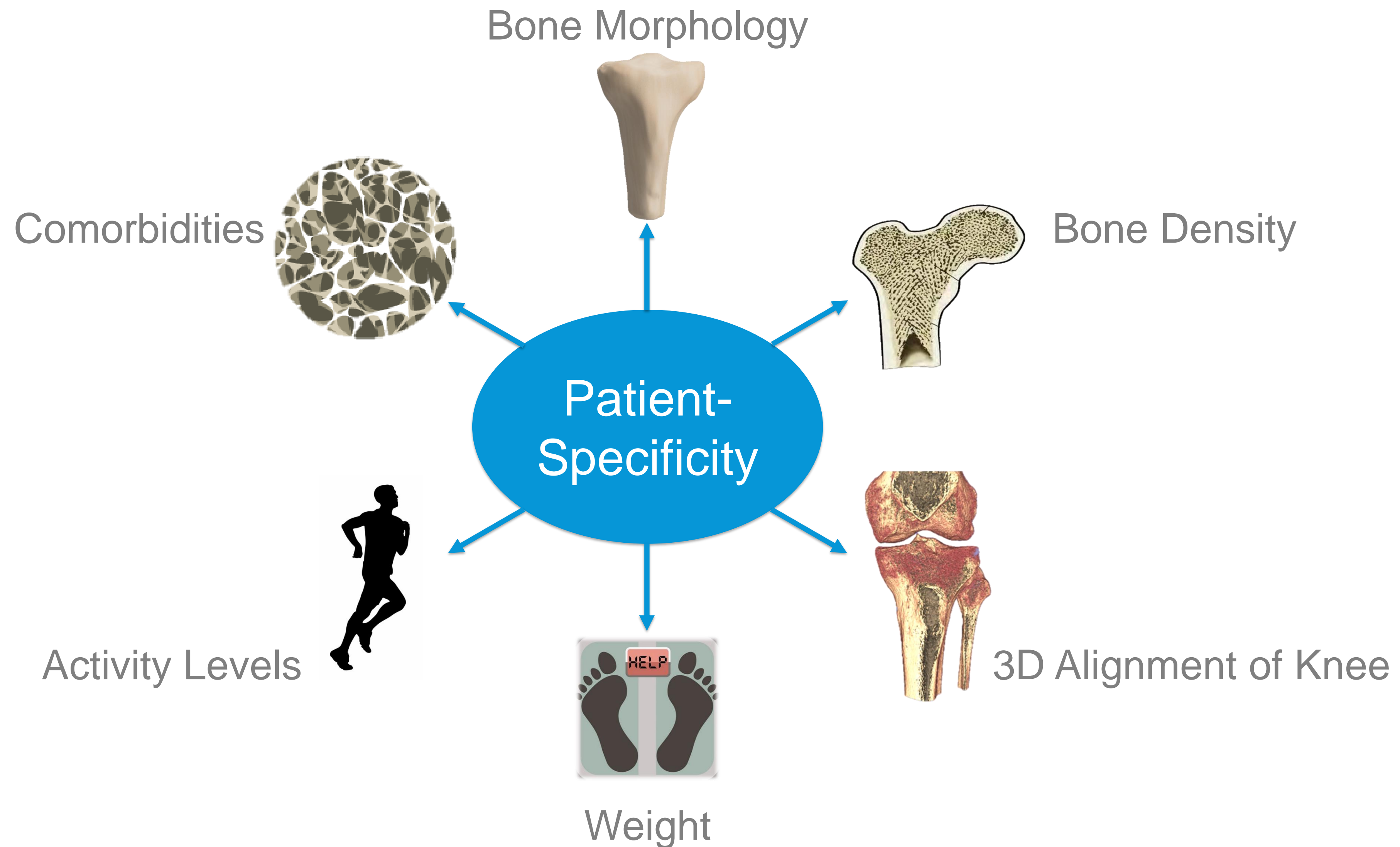
Patient-Specific Fixation



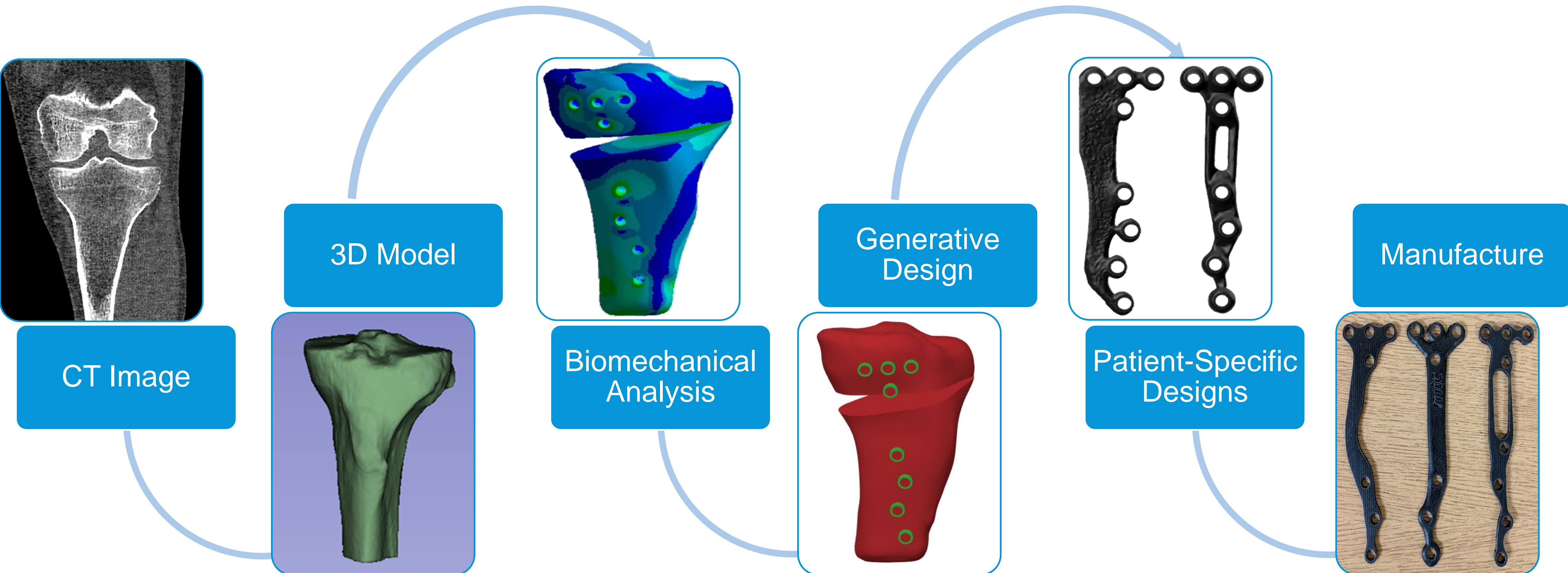
Standard Patient-Specific Fixation



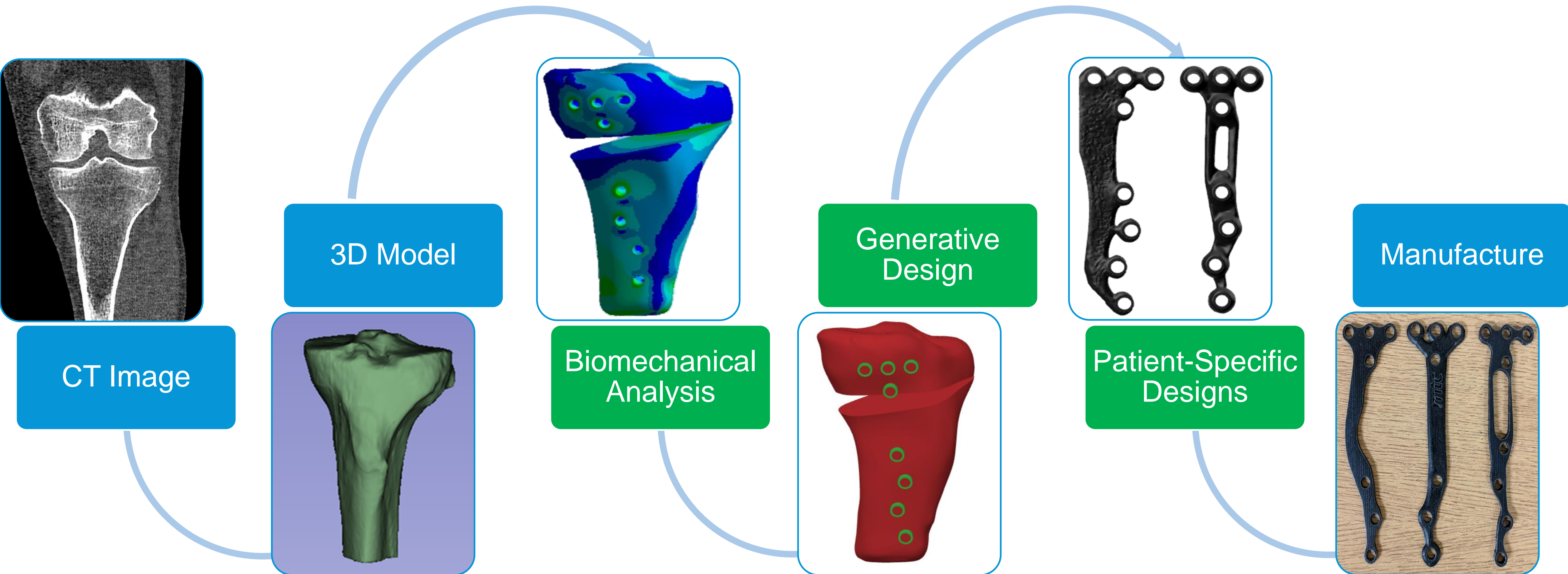
Patient-Specific Biomechanics



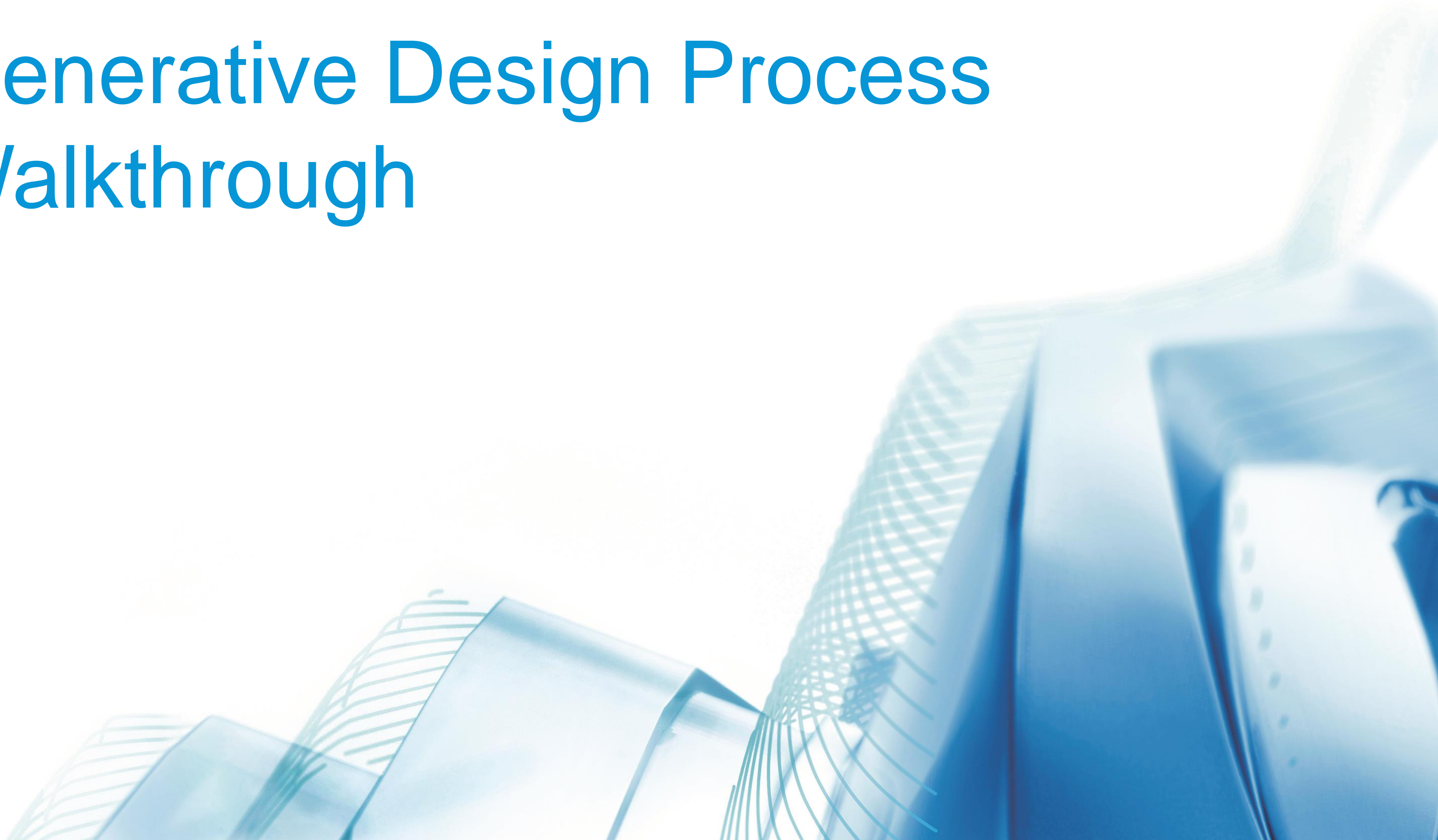
Patient-Specific Fixation via Generative Design



Patient-Specific Fixation via Generative Design



Generative Design Process Walkthrough



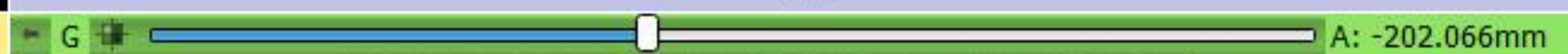


Patient CT Scan

A CT scan is taken of the patients knee. This provides information about the geometry of the bone itself, as well as mechanical information such as bone density



B: 2: LEFT KNEE cropped



Geometry Reconstruction

Multiple 2D scans are pieced together to create a 3D model of the patients knee joint



Biomechanical Analysis

Mechanical analysis which takes into account patient specific bone density, activity levels, age, weight etc. is performed in order to generate load cases to take into generative design

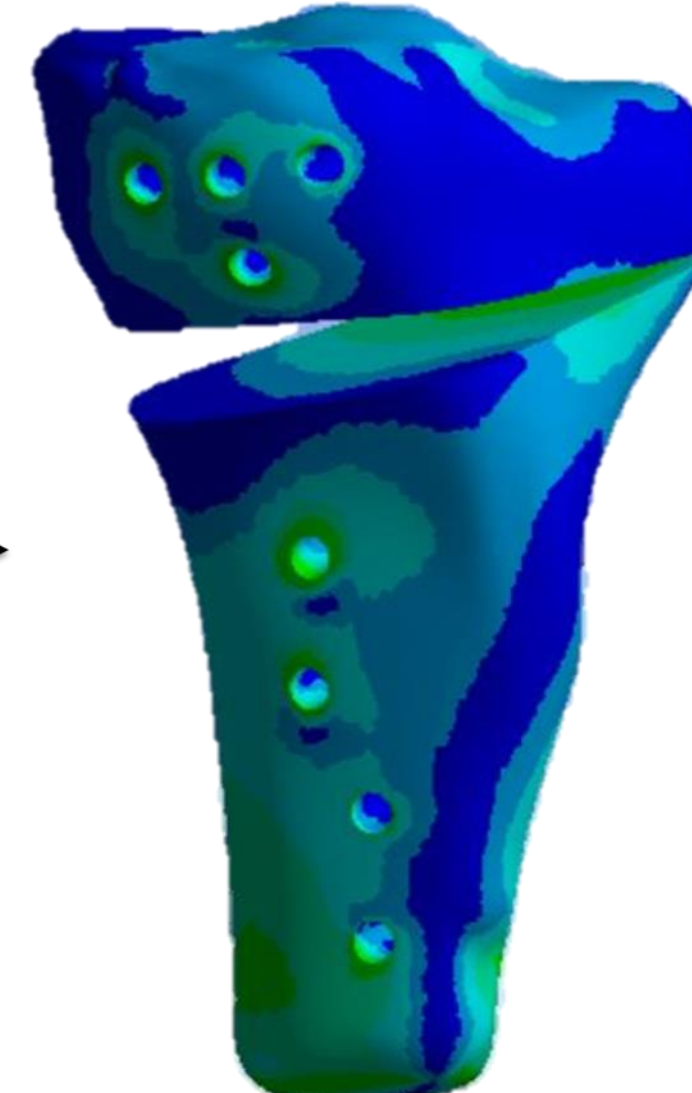
Patient-Specific HTO Design Process



Patient CT scan



3D Geometry
Reconstruction

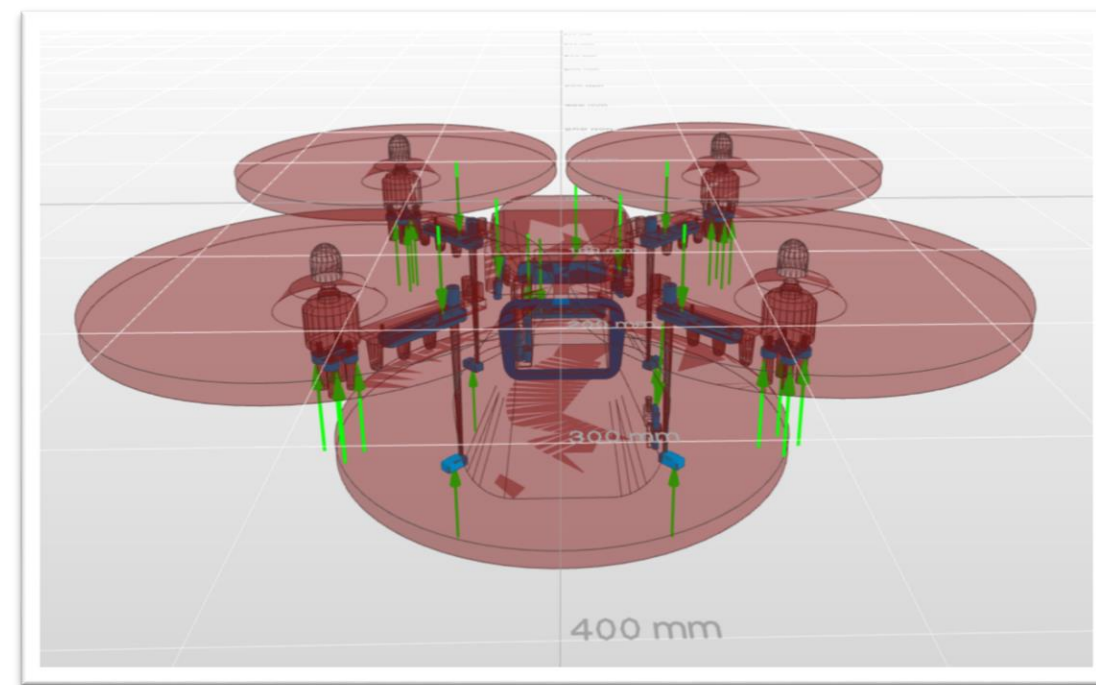


Biomechanical
Analysis



Generatively Designed
Implant

Generative Design Workflow



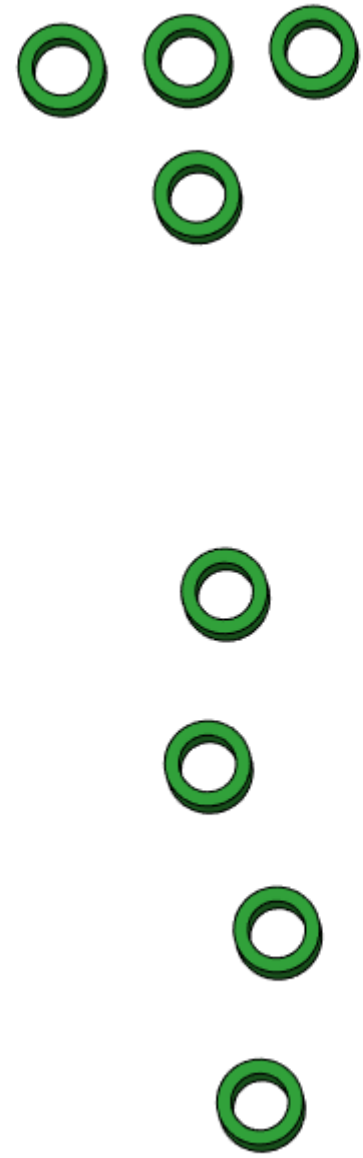
Define



Generate

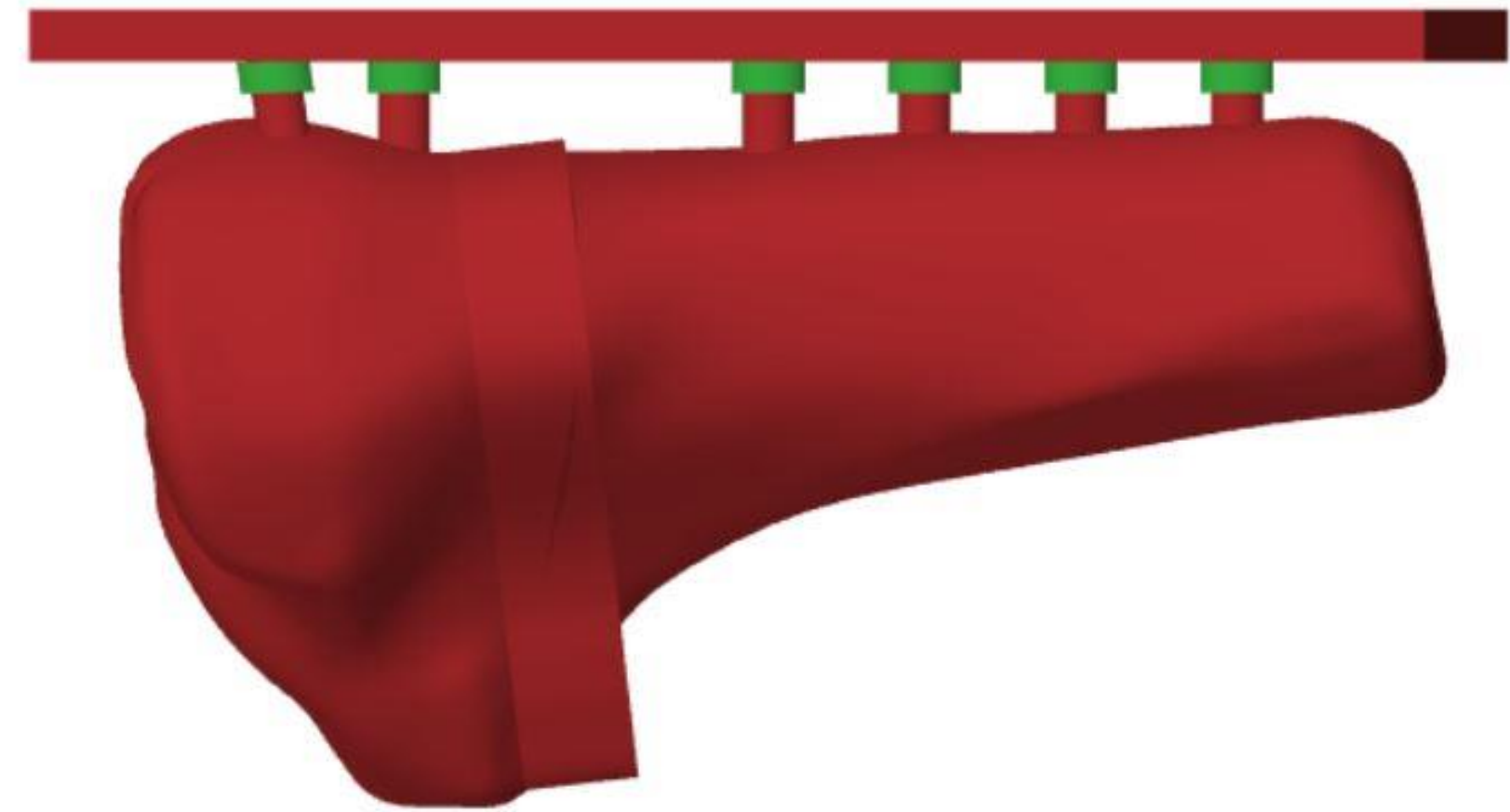


Explore



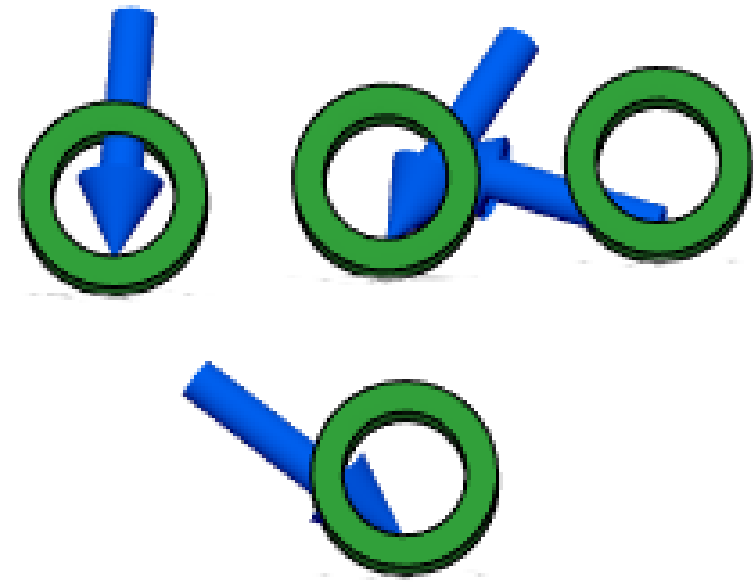
Fixation Points

The fixture needs to be securely fastened to the bone, the orientation and position of these connection points can be kept as default, or oriented on the bone by the operator in order to avoid previous fracture sites



Vasculature, Bone and Soft Tissue Avoidance

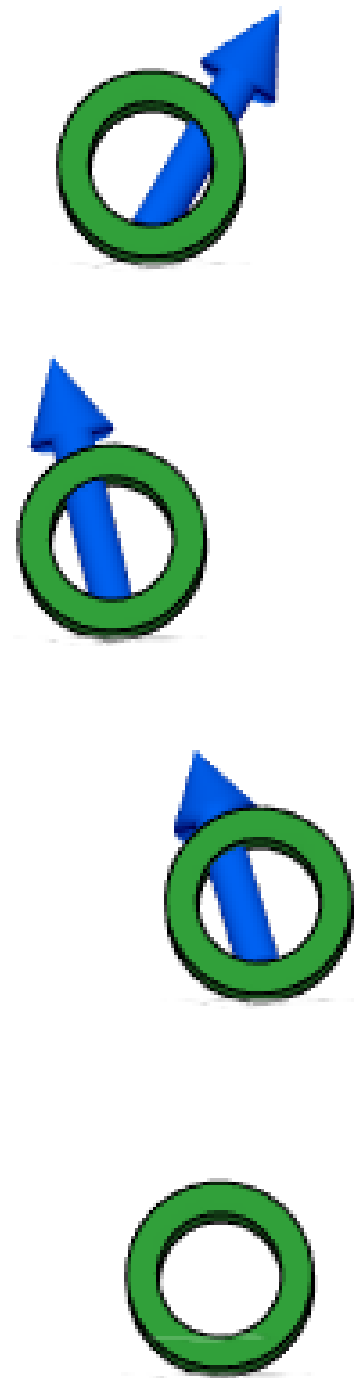
Ligaments and muscle attachments bond the upper and lower limb. Arteries supplying blood and nerves providing sensation and muscle control to the lower limb. It is vital that these structures are preserved during surgery and not impeded on by the implant



Biomechanical Loading

Information about the types of forces acting on the implant are taken from the Biomechanical analysis, to simulate realistic load cases which are specific to the patient.

These forces are able to take into account factors such as bone density and patient age, weight and degree of activity.





Manufacturing Methods

The manufacturing methods which are available to the designer can be selected as constraints. Each design outcome created, will have a unique manufacturing goal in mind, the parameters of which can be customized to the users liking.



Generate

Once the problem is fully defined, results can be generated simultaneously using the power of cloud computing.

GENERATIVE DESIGN



DISPLAY ▾



FINISH EXPLORE ▾

Sort by Processing status

Sort by

Processing status

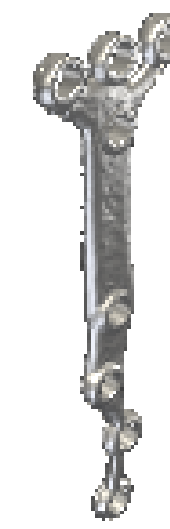
Converged



Study 3 - Generative - Outcome 1



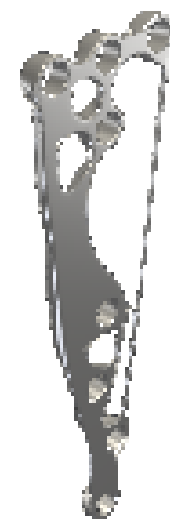
Study 3 - Generative - Outcome 2



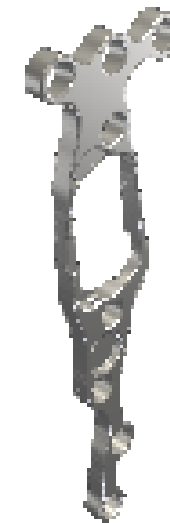
Study 3 - Generative - Outcome 4



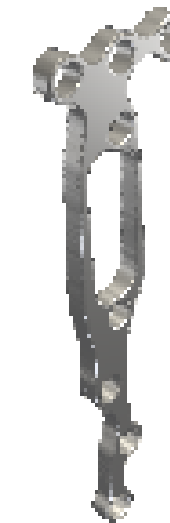
Study 3 - Generative - Outcome 5



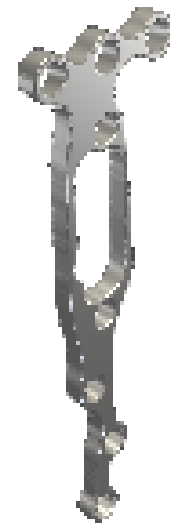
Study 3 - Generative - Outcome 6



Study 3 - Generative - Outcome 8



Study 3 - Generative - Outcome 9



Study 3 - Generative - Outcome ...
Converged

EXPLORE

GENERATIVE
DESIGN

DISPLAY

FINISH EXPLORE

Outcome filters

Processing status

- ☒ Converged (16)
- ☒ Completed (4)

Study

- ☒ Study 3 - Generati...
- ☒ Study 4 - SS Gene...

Visual similarity

- ☒ Ungrouped (20)

Design file

- ☒ Created from outcome
- ☒ Not created from outcome

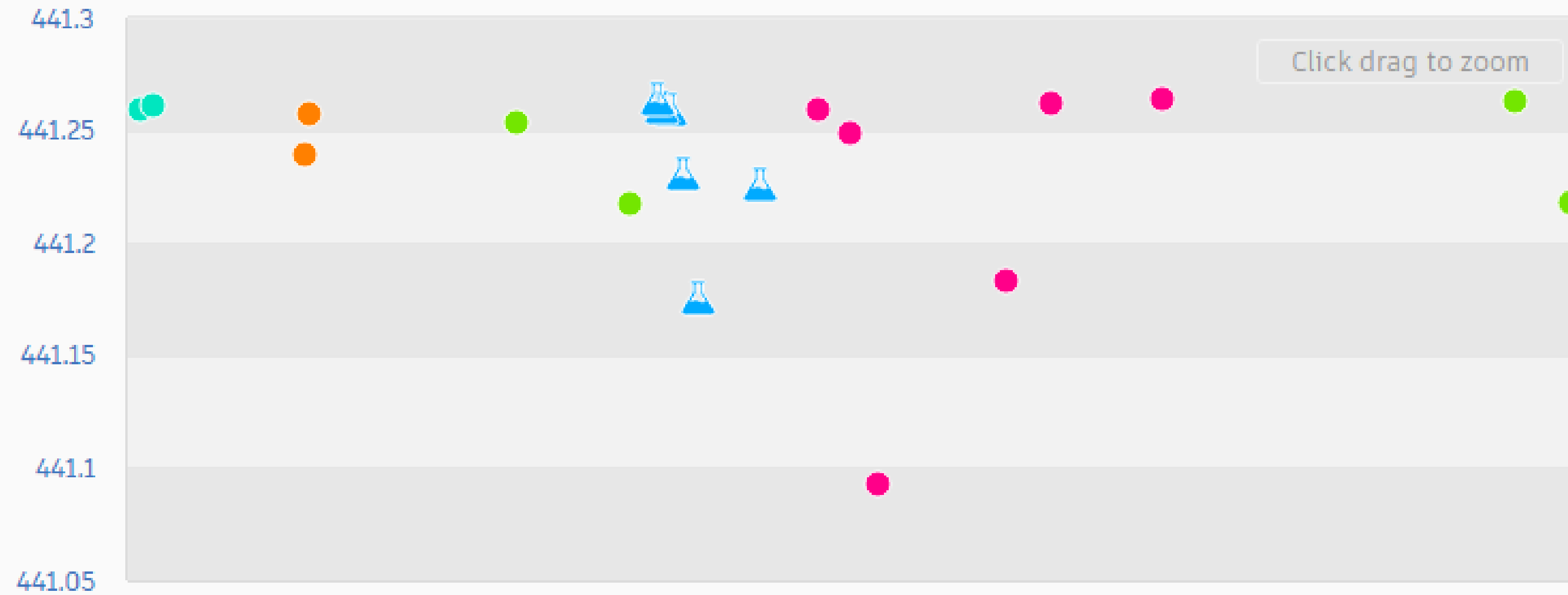
Tech-Preview

- ☒ Tech-Preview
- ☒ Not Tech-Preview

Manufacturing method

- ☒ Unrestricted
- ☒ Additive

Max von Mises stress (MPa)



Mass (kg)

Symbols

Manufacturing method

2.5 axis milling

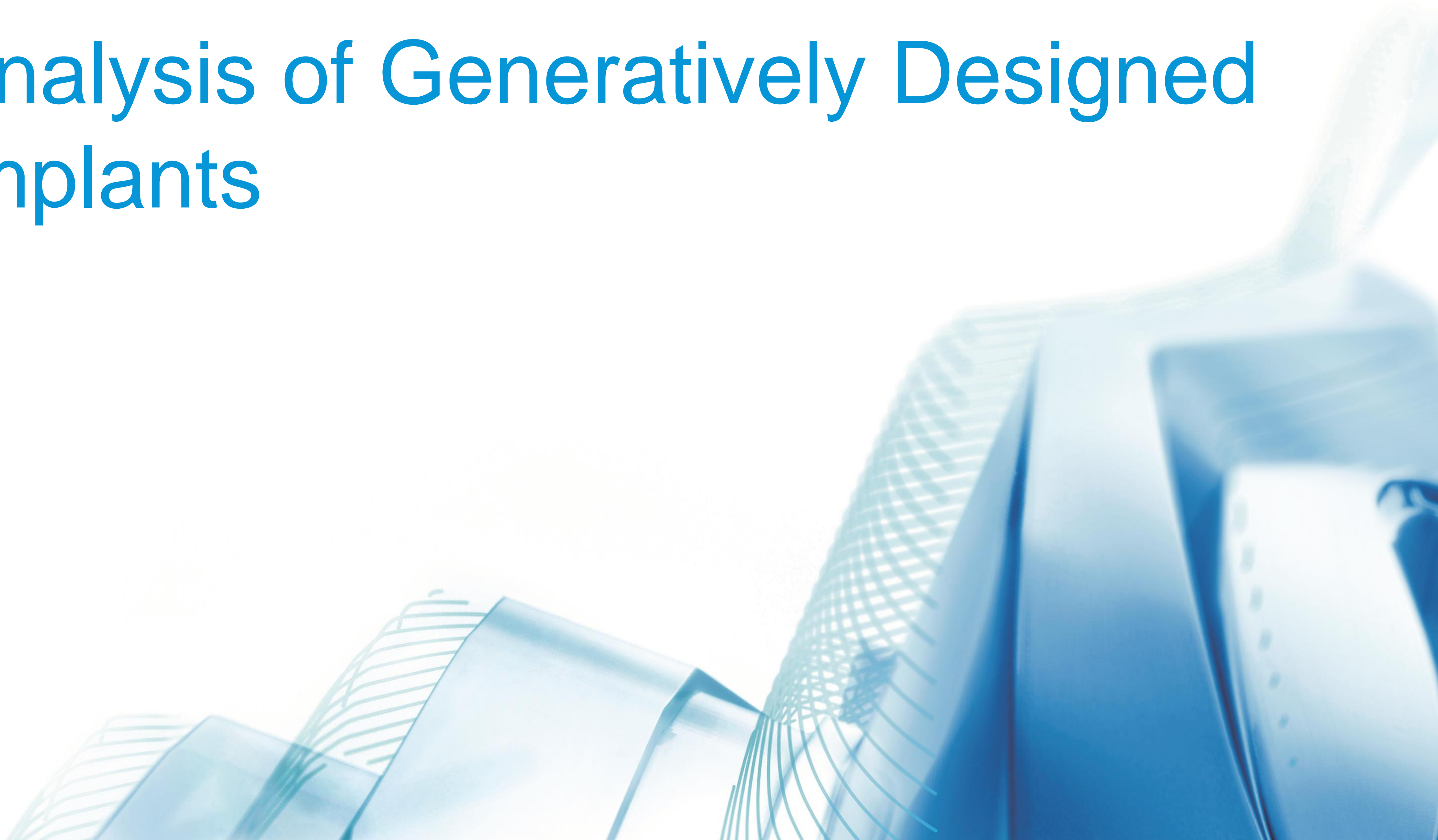
3 axis milling

5 axis milling

Additive

Unrestricted

Analysis of Generatively Designed Implants



Standard vs Generative Comparison



Standard



Outcome 1



Outcome 2



Outcome 3

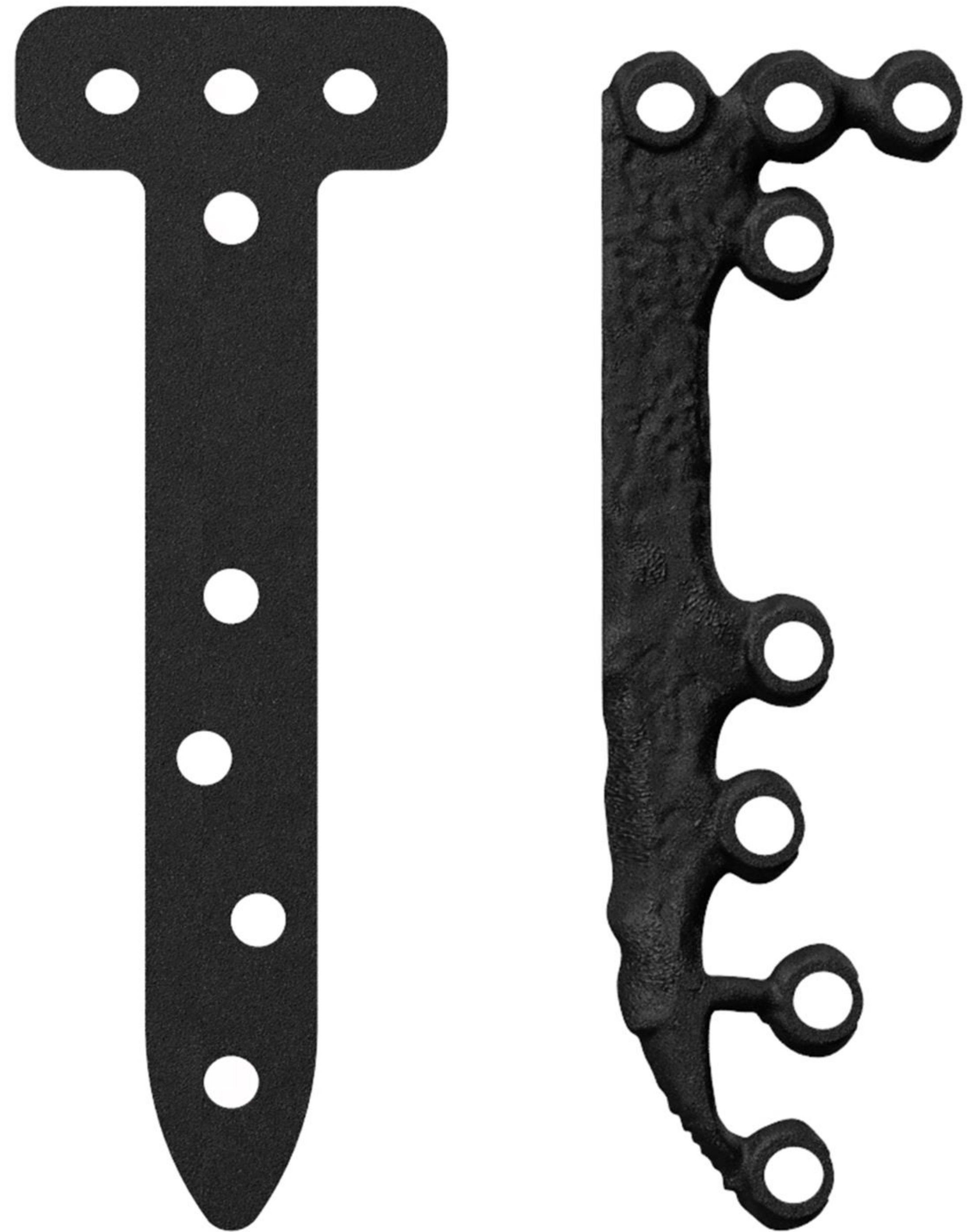
Implant prominence

- 80% reduction in implant mass



Implant prominence

- 80% reduction in implant mass
- 40% reduction in overall area

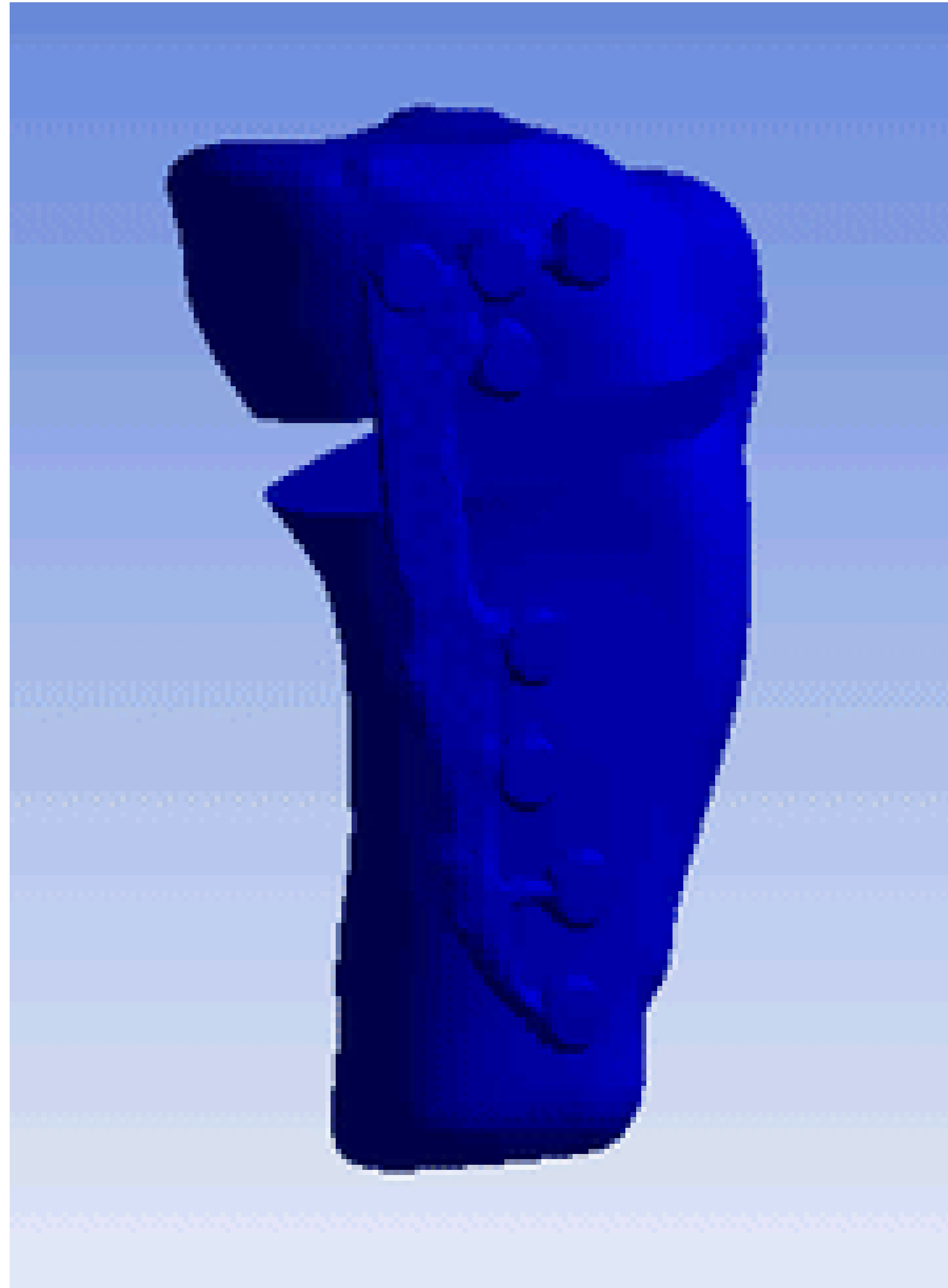


Implant prominence

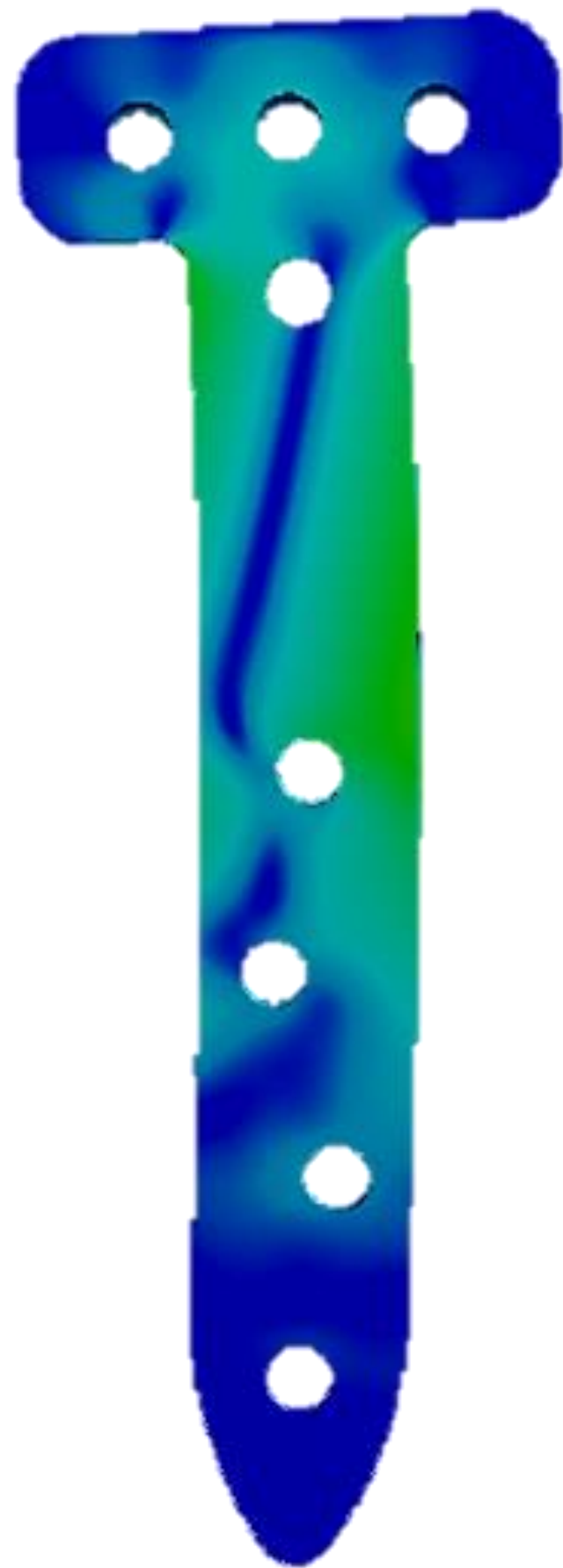
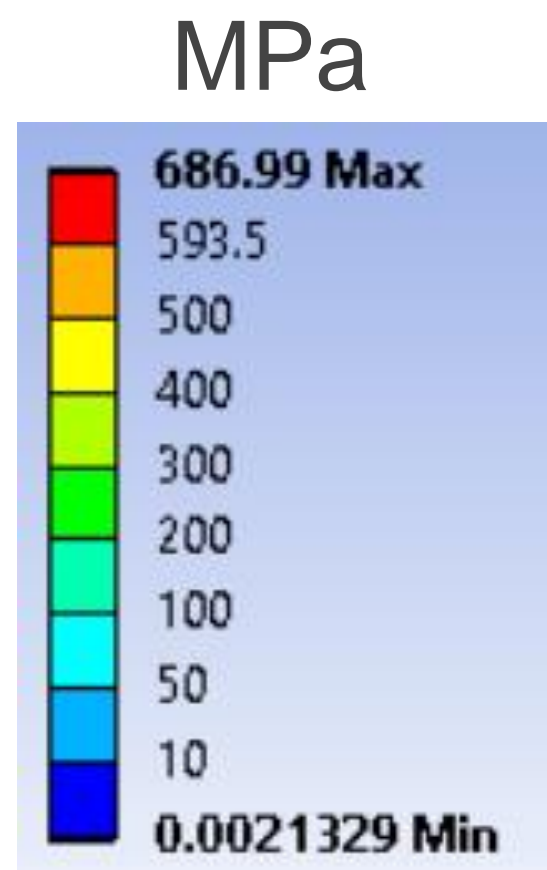
- 80% reduction in implant mass
- 40% reduction in overall area
- **Low profile plates reduces discomfort and skin infection**



Physiological Loading (3 x body weight)



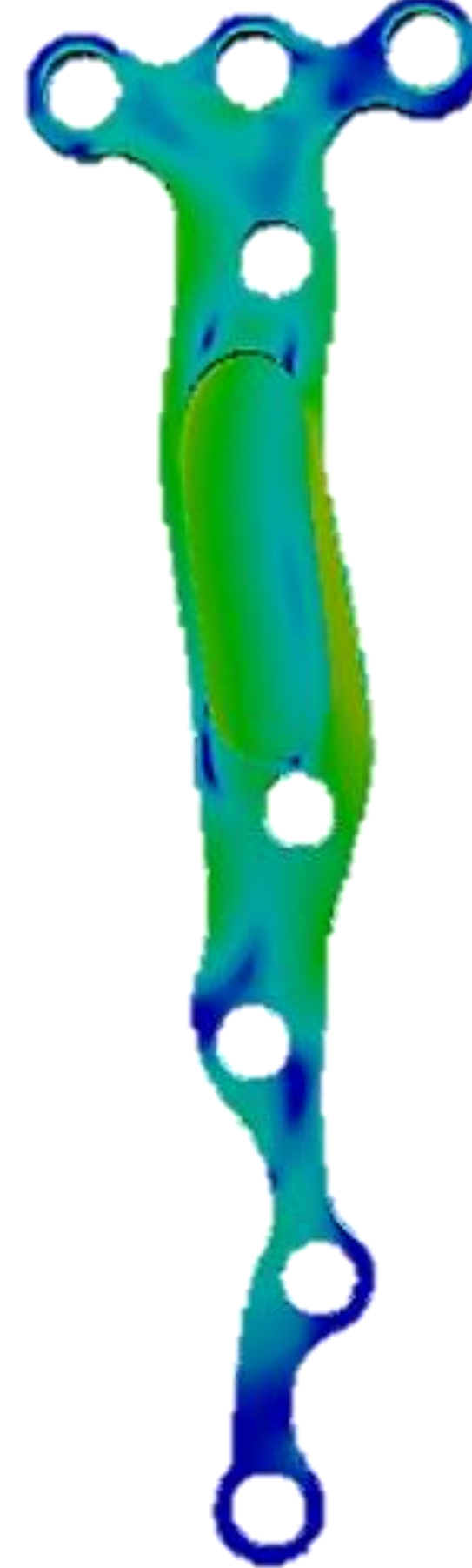
Physiological Loading (3 x body weight)



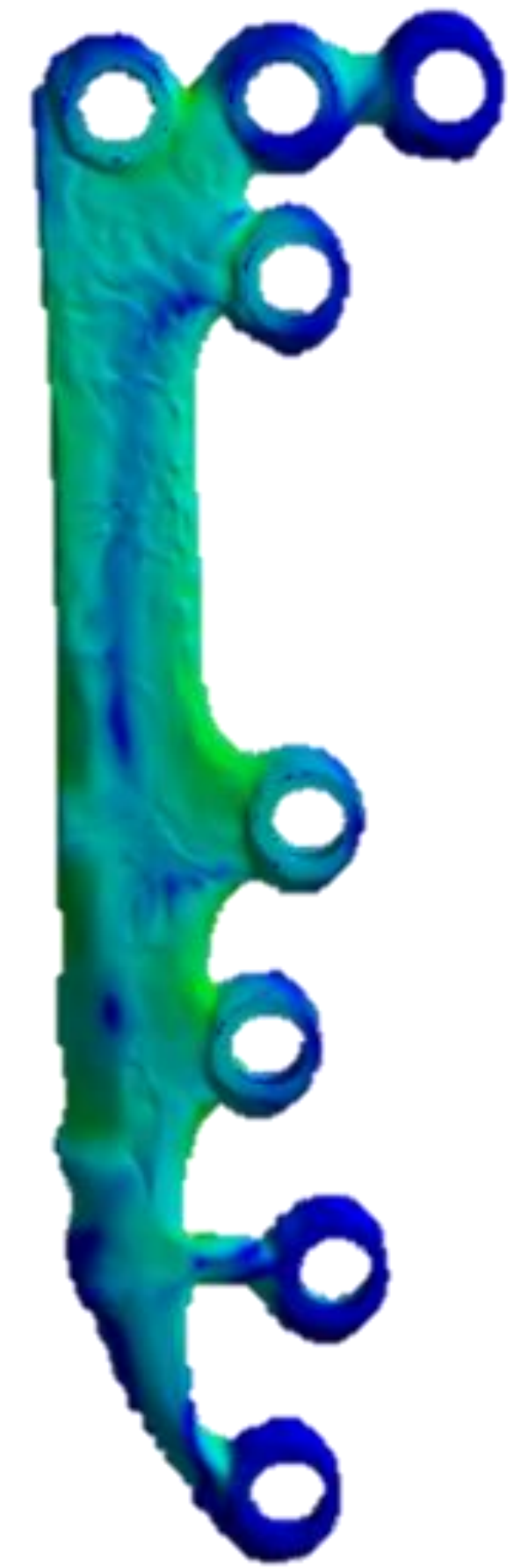
Standard



Outcome 1

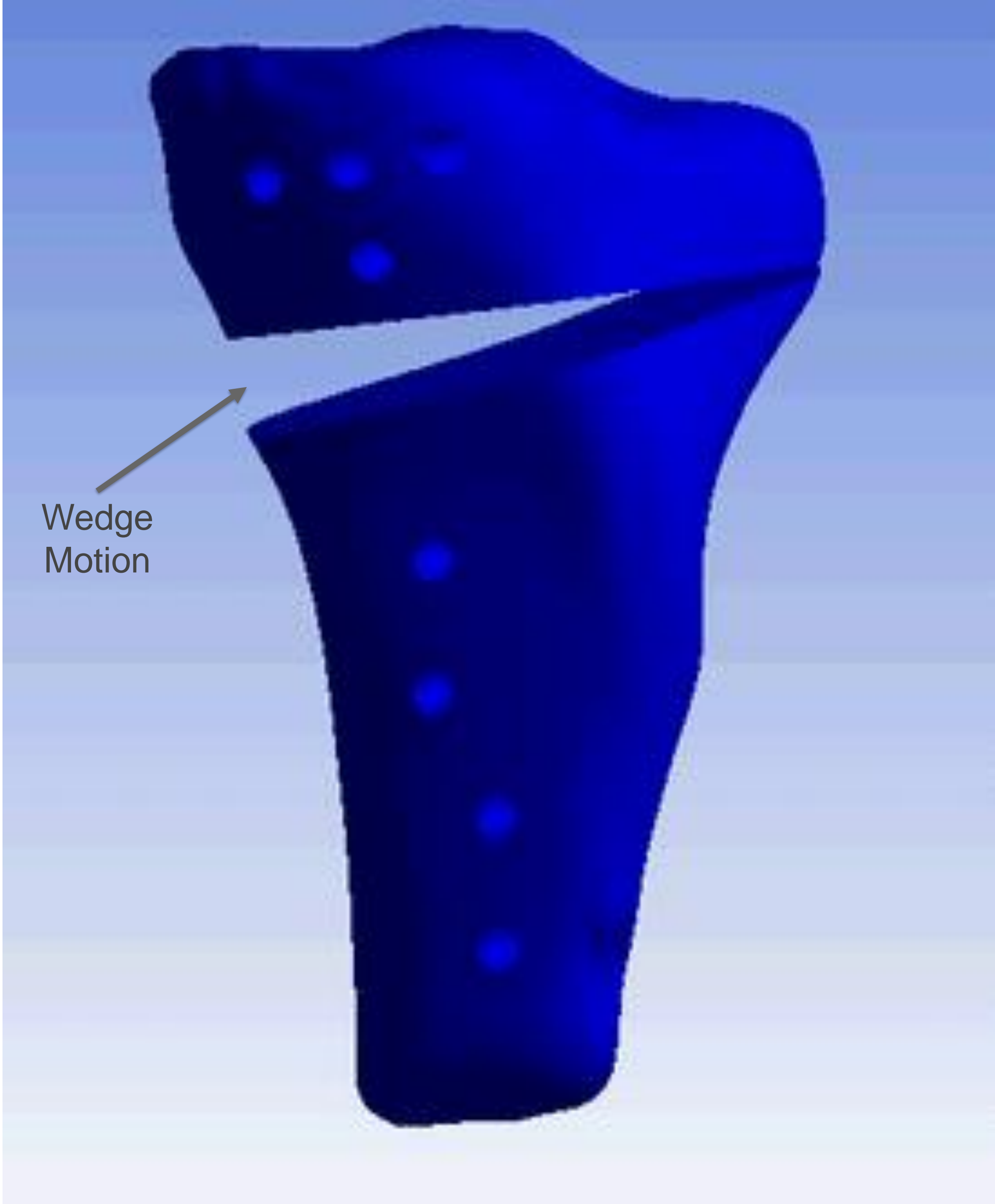
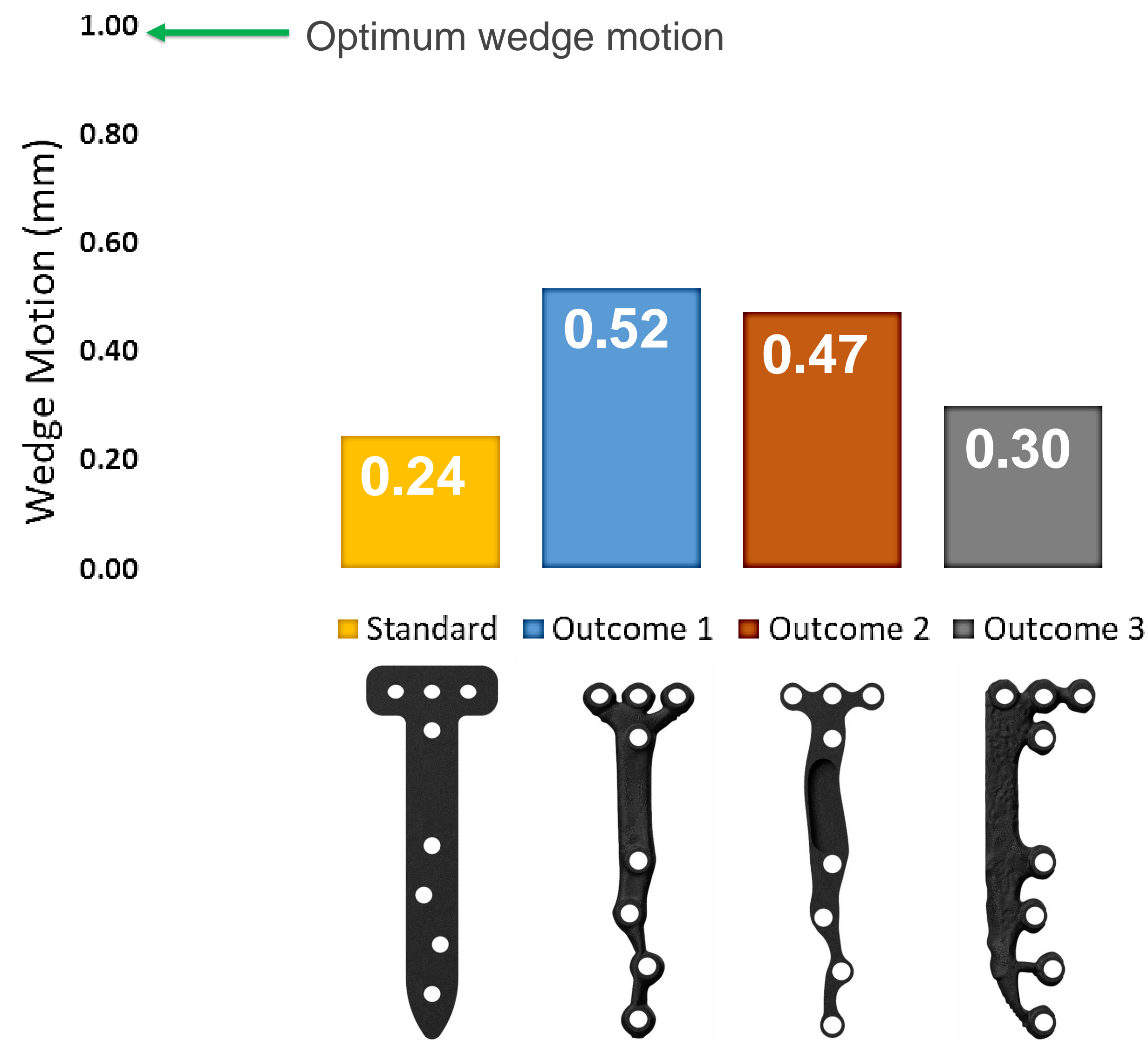


Outcome 2



Outcome 3

Implant Stiffness



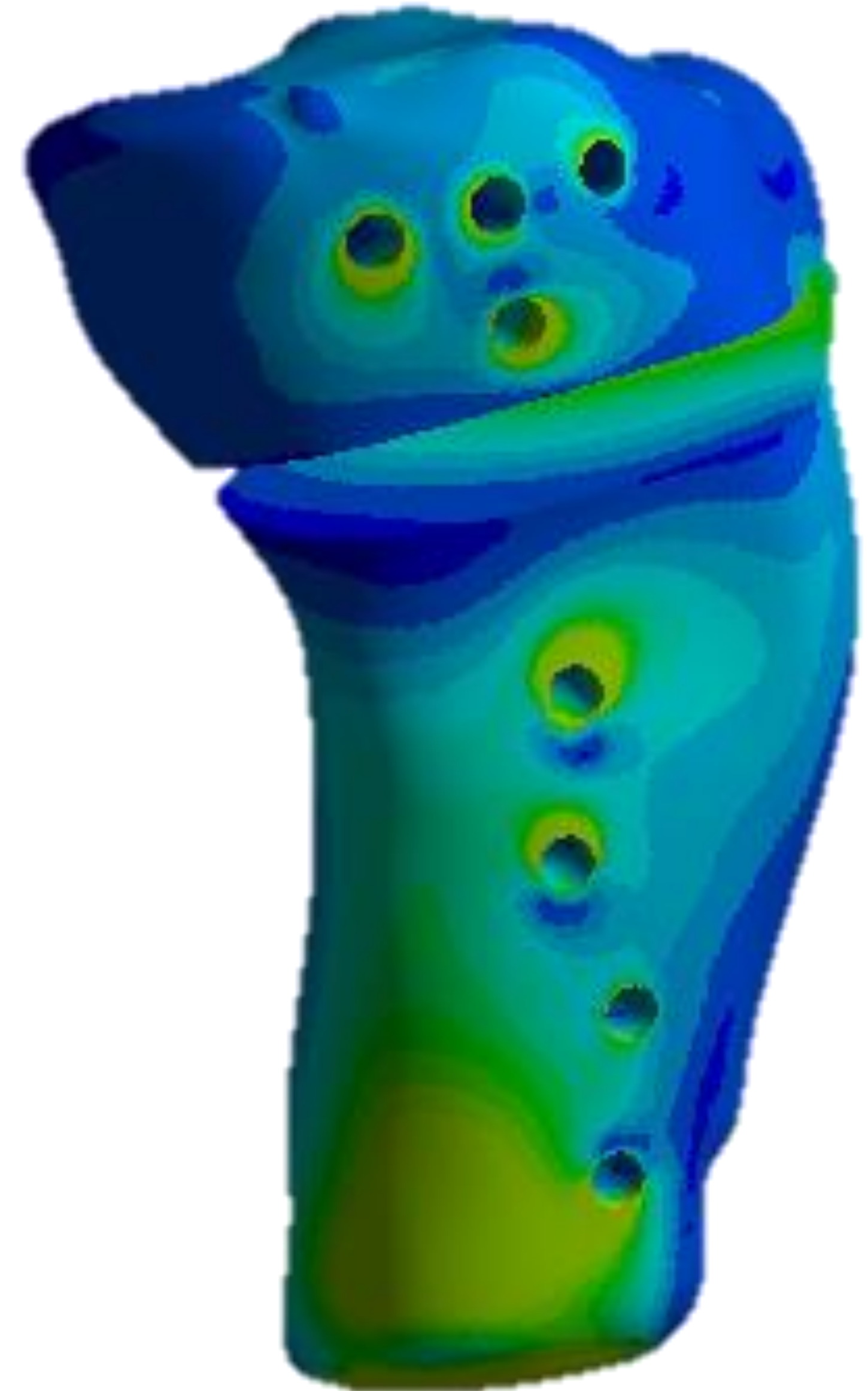
Implant Stiffness

- Optimal wedge motion **1mm**
- Standard (0.24mm) vs Outcome 1 (**0.52mm**)
- **117%** increase in wedge motion with generative design - much improved healing environment for bone compared to standard implant
- Reduced implant stiffness allows for bone to undergo higher stresses, minimising stress shielding effect and thus preserve bone density



Bone-Screw Interface

- Average strain around bone-screw interface has reduced
- Reduced risk of implant loosening and thus revision surgeries can be avoided



Pre-operative Planning



Summary

STANDARD IMPLANT

“One-Size-Fits-All” plate

High stiffness affects physiological loading of the bone

Absolute stability inhibit biological healing

Soft tissue irritation

Implant loosening, refracture and increased risk of revision surgery

GENERATIVELY DESIGNED IMPLANT

Personalised plate with patient-specific biomechanics

Reduced stiffness allow physiological stresses and thus preserve the bone remodelling process

Increased flexibility provides an optimal healing environment

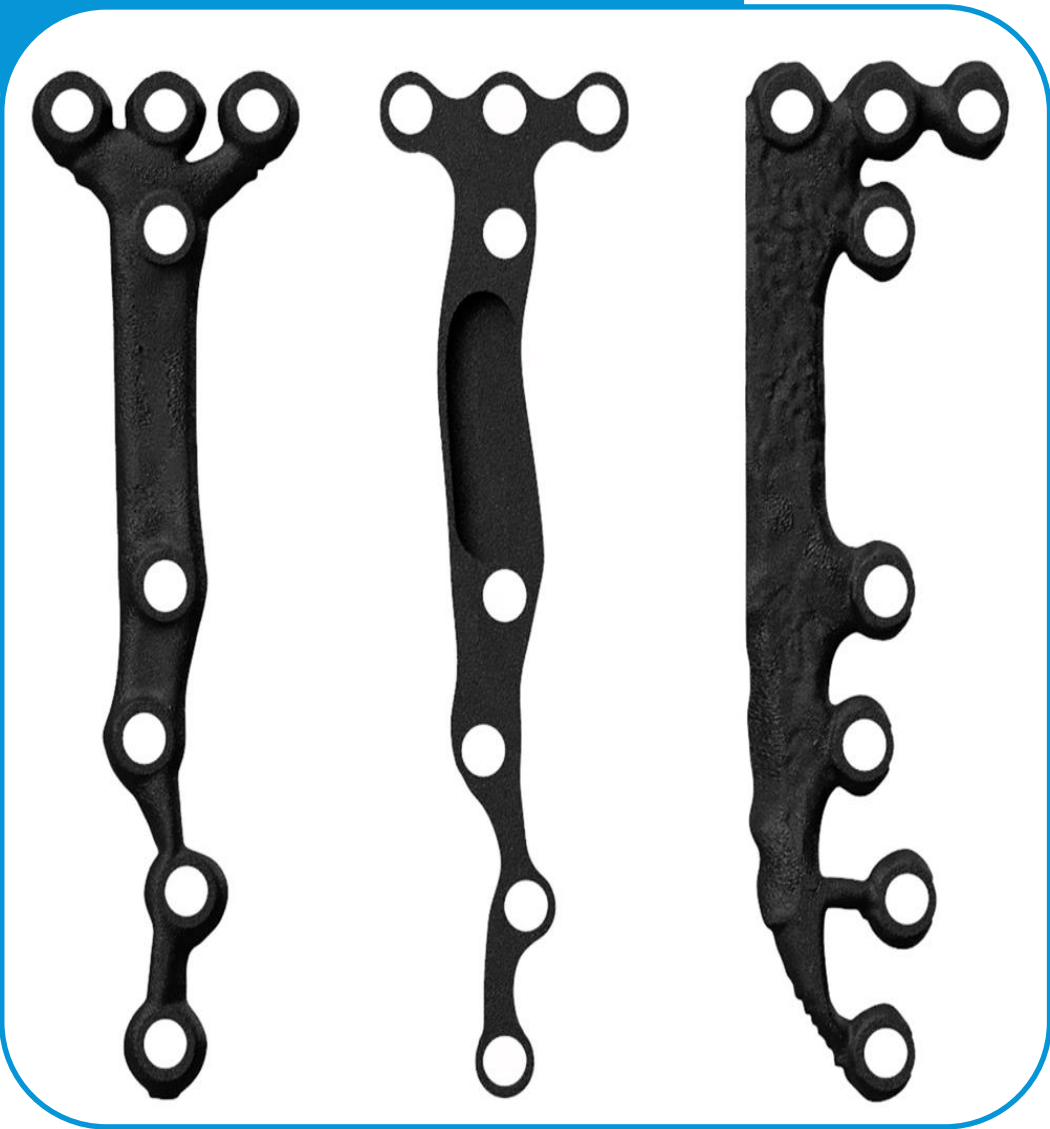
Reduced risk of infection and discomfort

Minimised risk of implant loosening and revision surgery

Pre-operative planning flexibility

Future Work

Detailed
Design



Additive
Manufacture



Mechanical
Testing



Image Courtesy of S.Miramini et al., (2015)

Computational
Validation

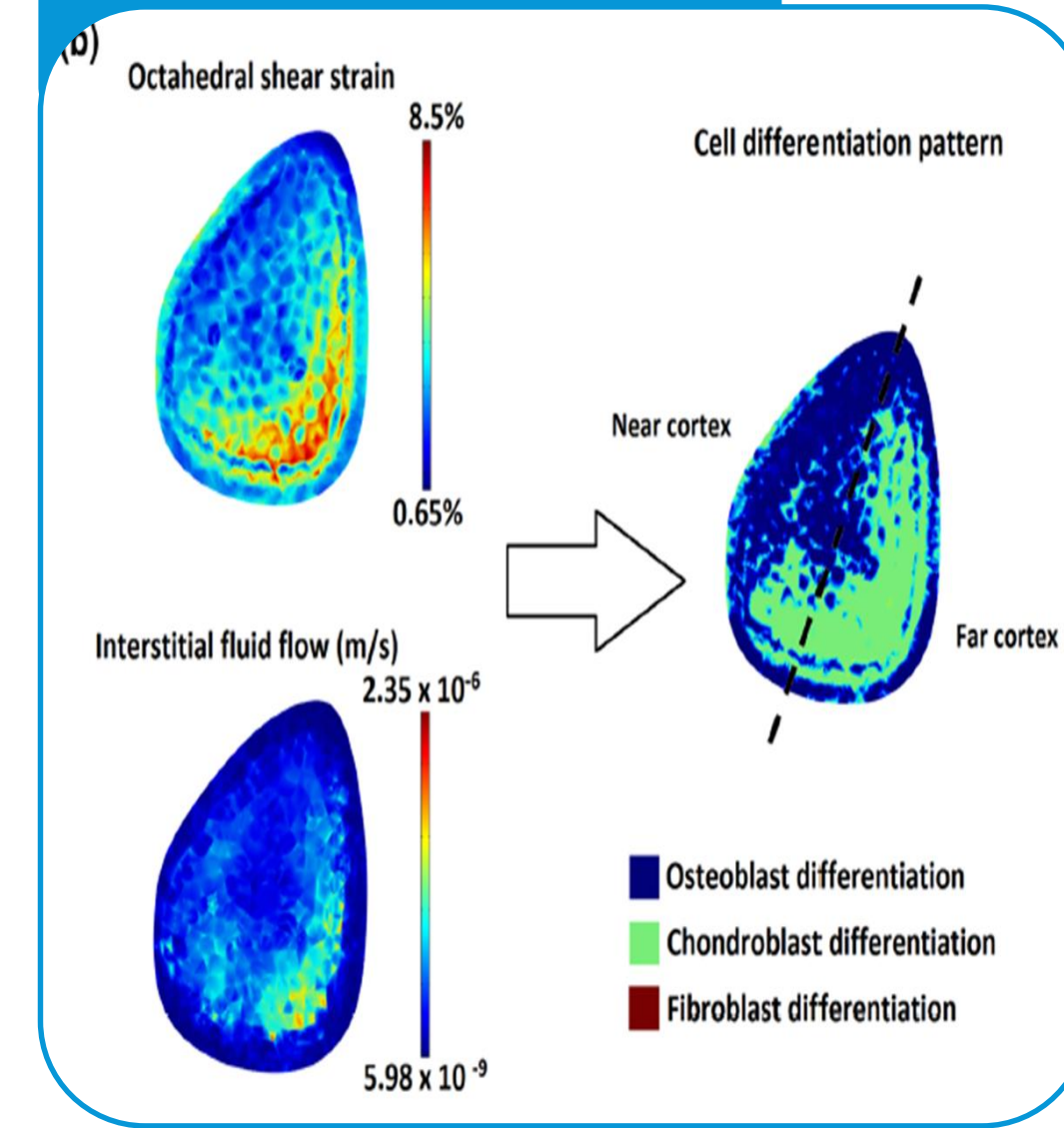


Image Courtesy of S.Miramini et al., (2015)



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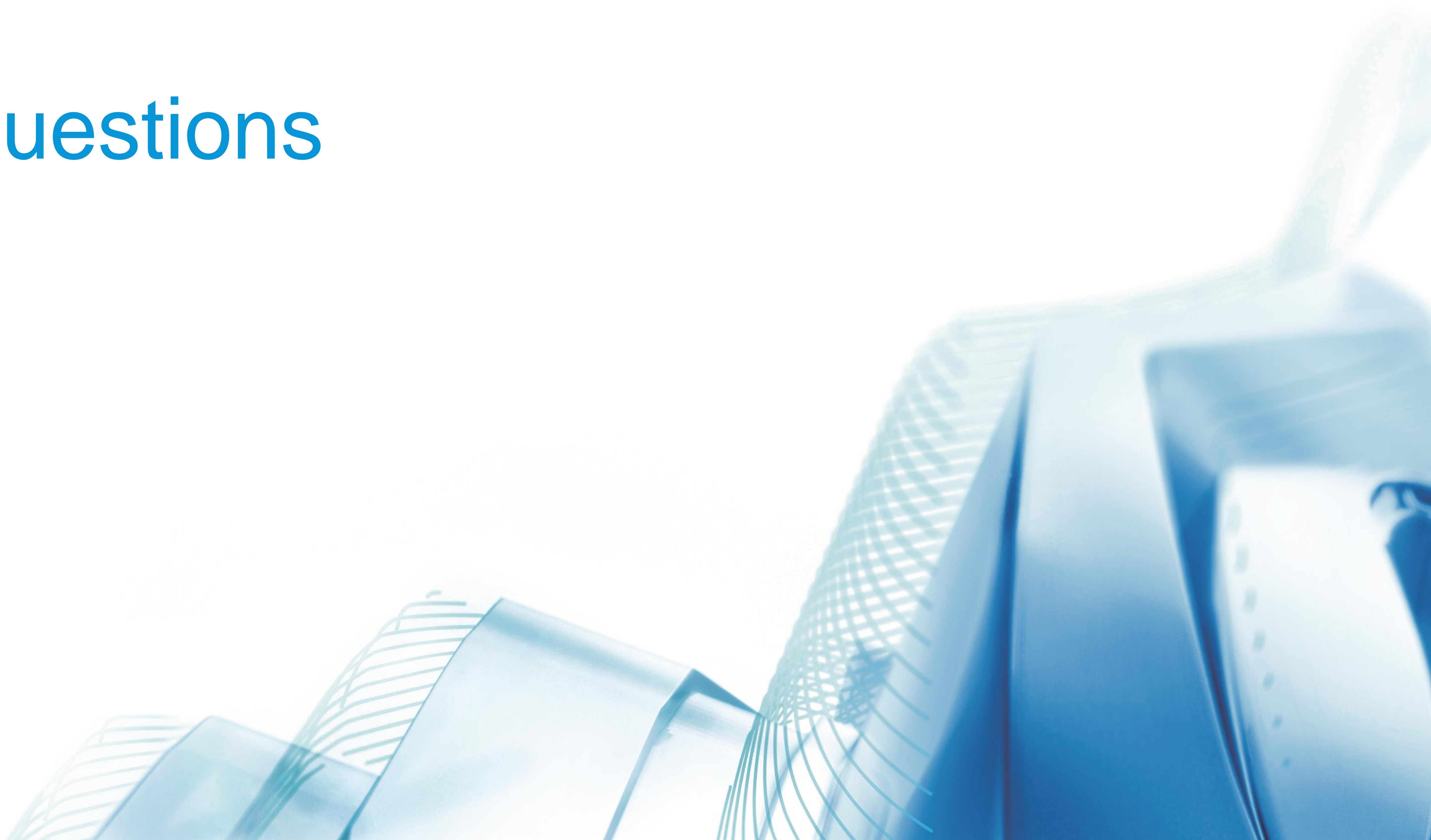
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Questions





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