OPM

OsteoFab® Technology

Custom Device Design Proposal

Oxford Performance Materials, Inc.

CASE INFORMATION			
Device Name/Description:	Right Triflange	OPM Case #:	OFC0625
Hospital Name:		Physician:	
Country:	USA	Patient Name/Identifier:	
Planned Surgery Date:	04/01/2025	Patient DOB:	

Part Number	Quantity	Brief Description
OFC0625	**2**	**OsteoFab Custom Implant**
OFC0625-CG	**1**	**Cutting Guide**
OFC0625-FG	**3**	**Fixation Guide**
OFC0625-PREOP	**1**	**Model of Pre-Operative Anatomy**
OFC0625-POSTOP	**1**	**Model of Post-Operative Anatomy**

Patient / Case Notes

Background Information: Patient had severe trauma from motor vehicle collision which led to deformation of the pelvis. Patient had infection following multiple previous surgeries. Patient has since cleared infection, and is in need of a custom implant to fill bony defect in pelvis.

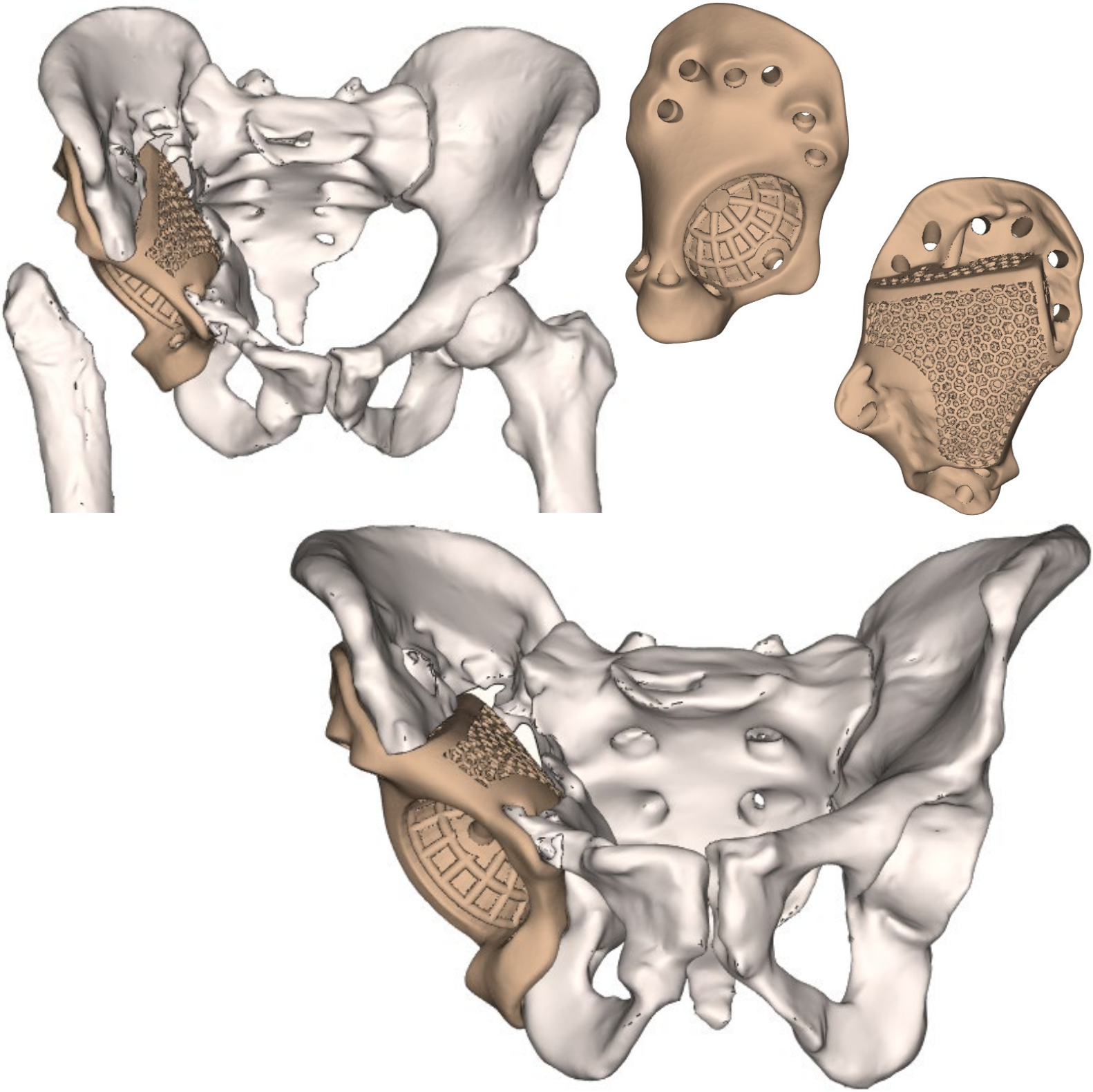
Surgical Plan: Posterior/lateral approach. Remove metal implant and temporary spacer. Minimal additional bone resection of pelvis using cutting guide to remove diseased/damaged bone.

Implant Design: OsteoFab Custom triflange implant to fill bone void. Implant design based on mirror of contralateral anatomy. Implant designed for 40° inclination and 20° anteversion. Solid PEKK implant designed with texture in acetabular cup for cement, and texture on medial/bone facing surfaces. Preplanned holes for fixation into the anatomy.

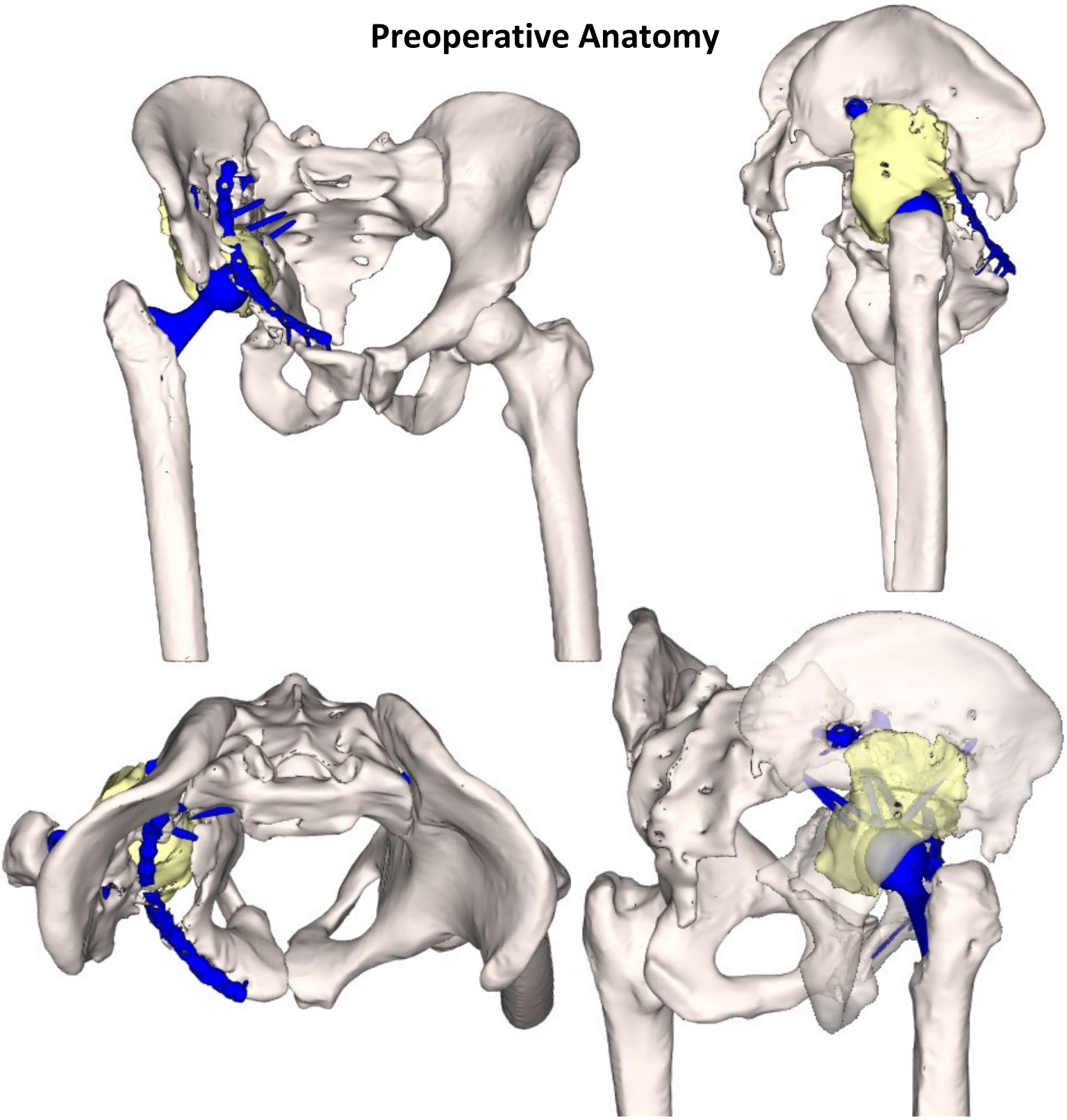
Fixation: Planned fixation with Ø7.0mm OsteoCentric cannulated screws and Ø6.5mm Smith+Nephew solid screws. OsteoCetnric screws will be used as compression screws in the dome and in ischium. All other screws are Smith+Nephew solid screws. Guide provided for placement of Ø2.8mm guidewire for cannulated screws.

Deliverables:
Nominal Implant (quantity 2)
Cutting Guide
Fixation Guide for OsteoCentric cannulated screws (quantity 3)
PreOp Anatomical Model
PostOp Anatomical Model

Case Overview

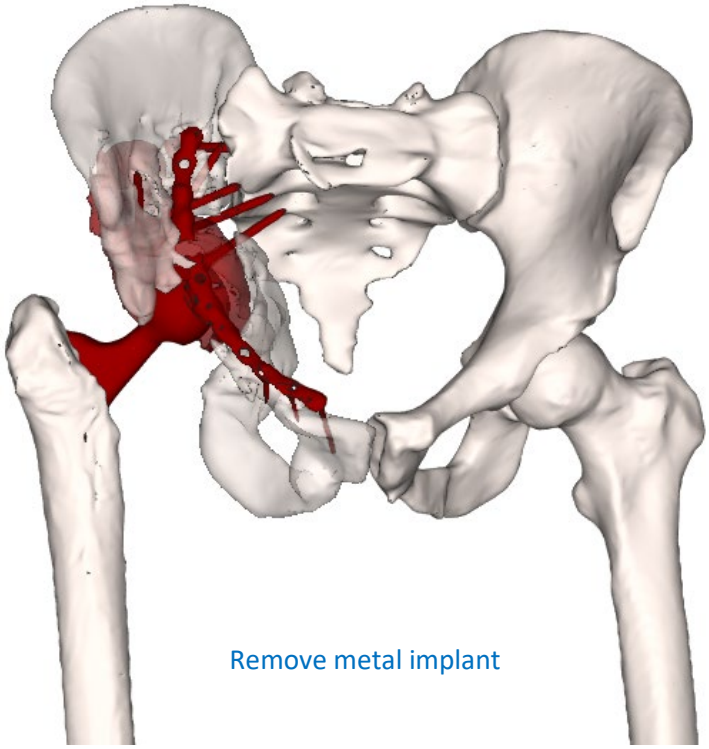


Preoperative Anatomy

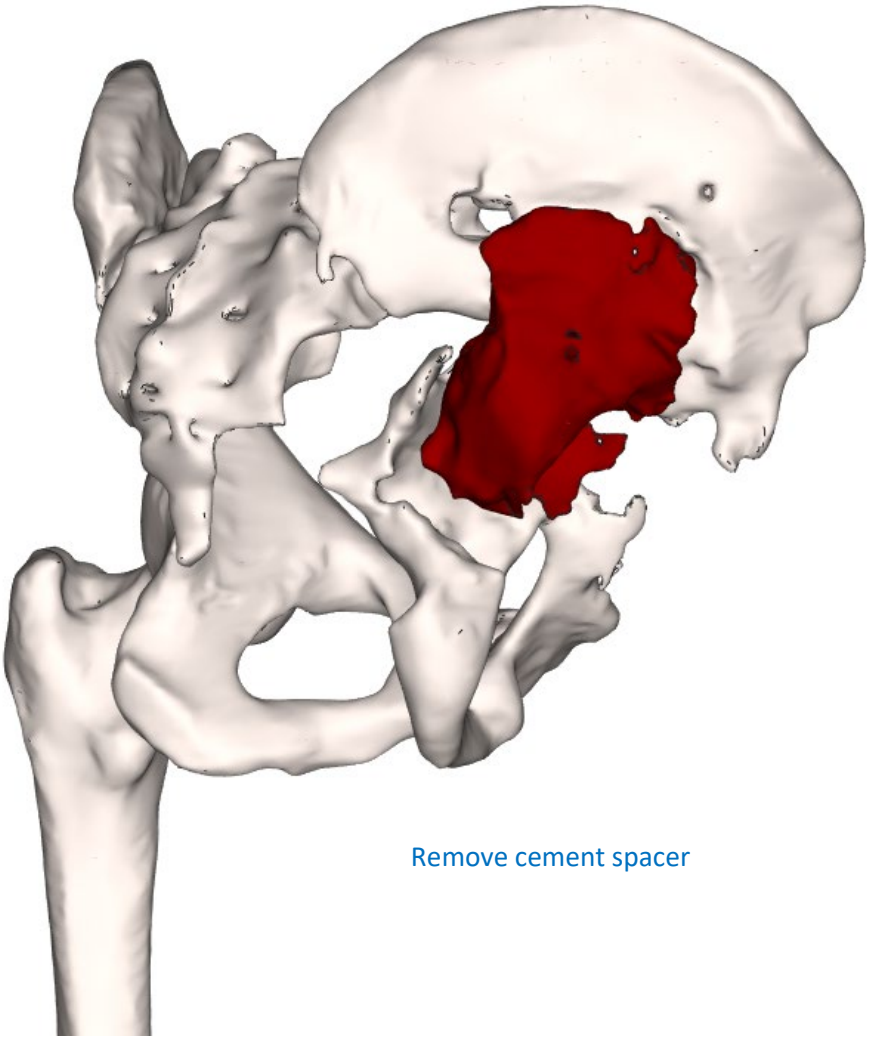


Proposed Anatomy Resection

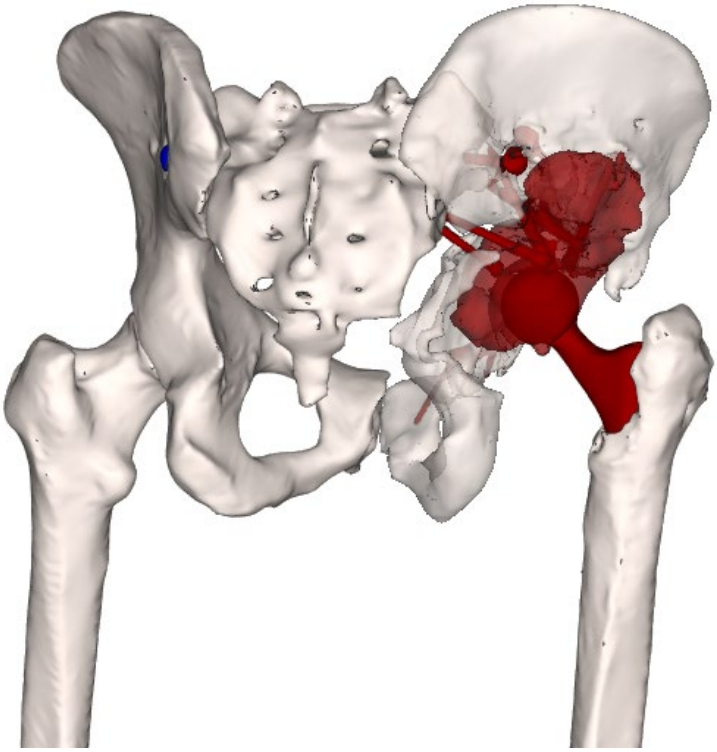
(Red indicates resected anatomy)



Remove metal implant

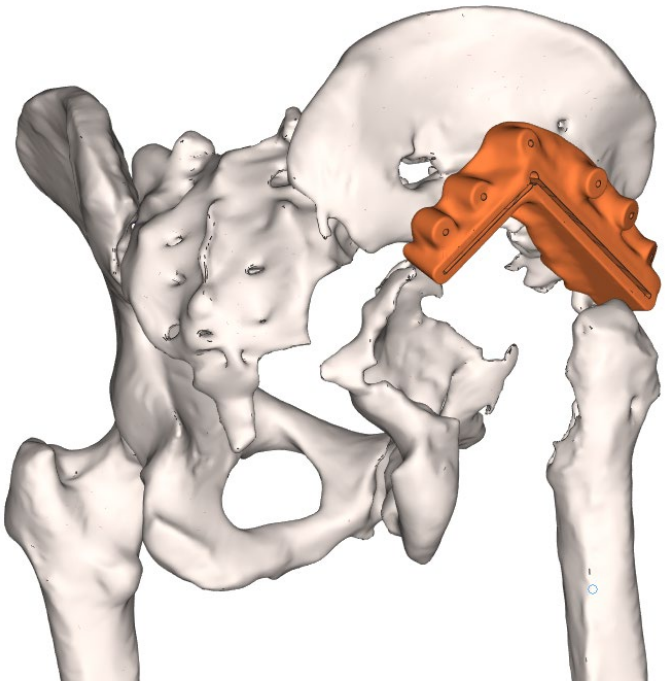


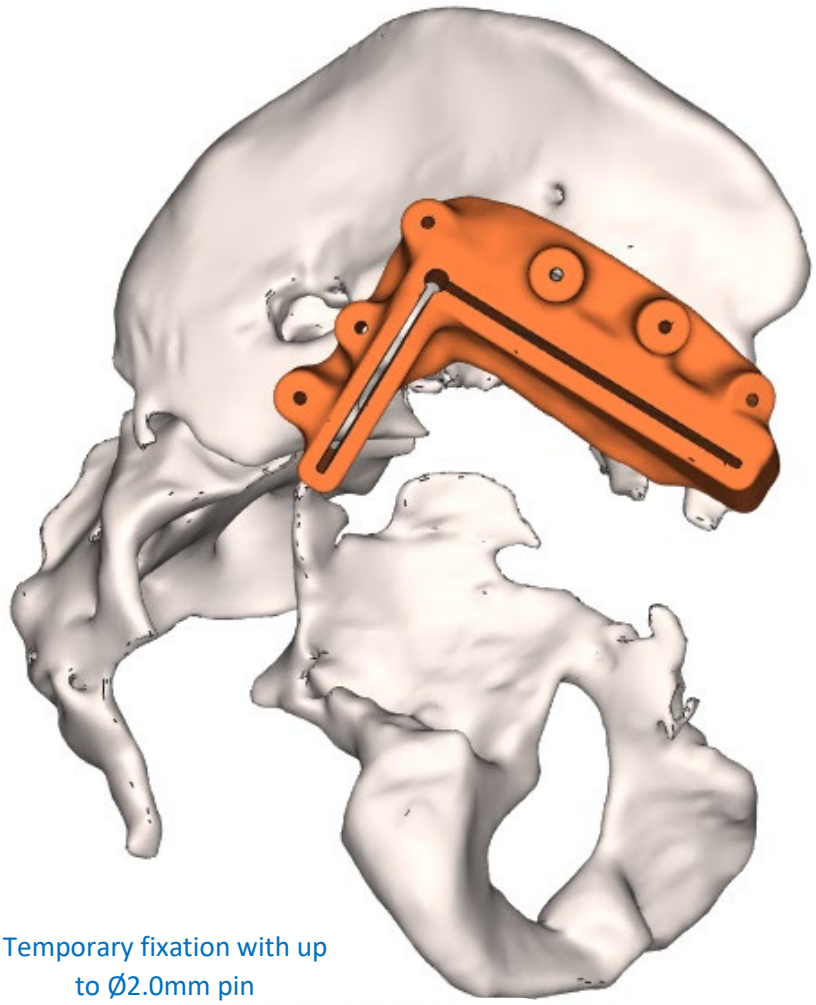
Remove cement spacer

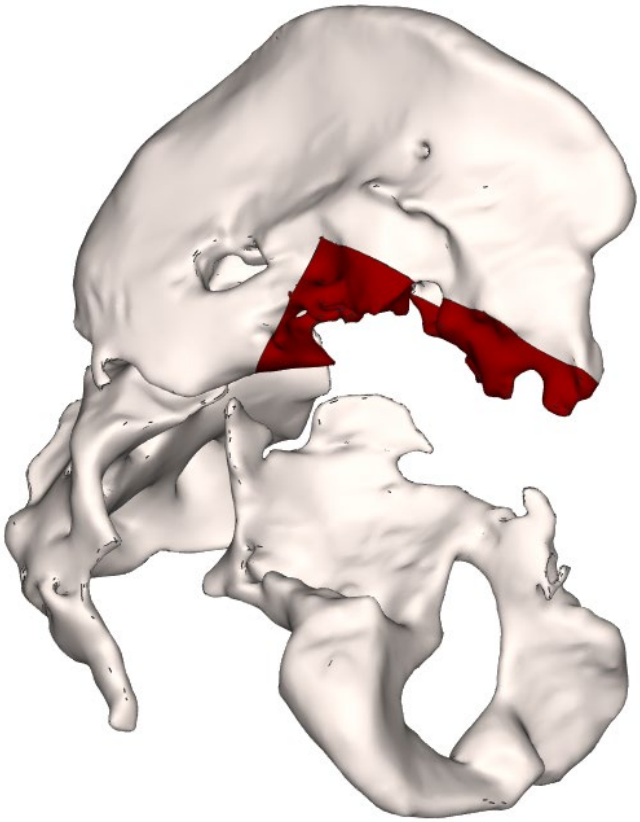


Proposed Anatomy Resection

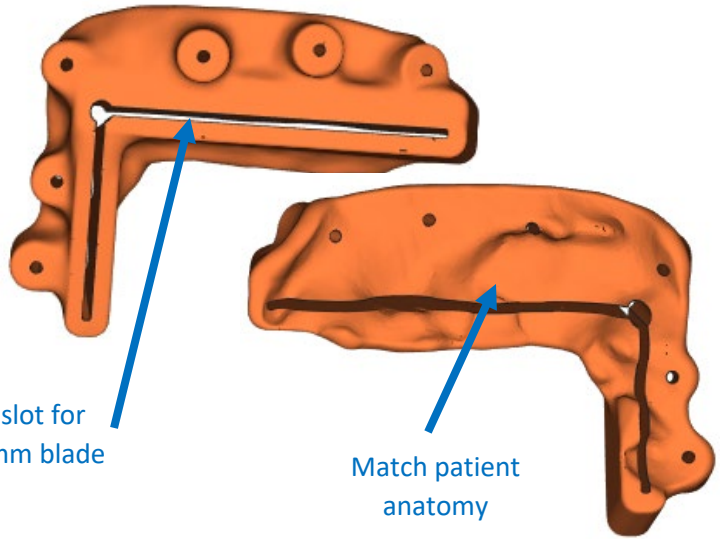
(Red indicates resected anatomy)





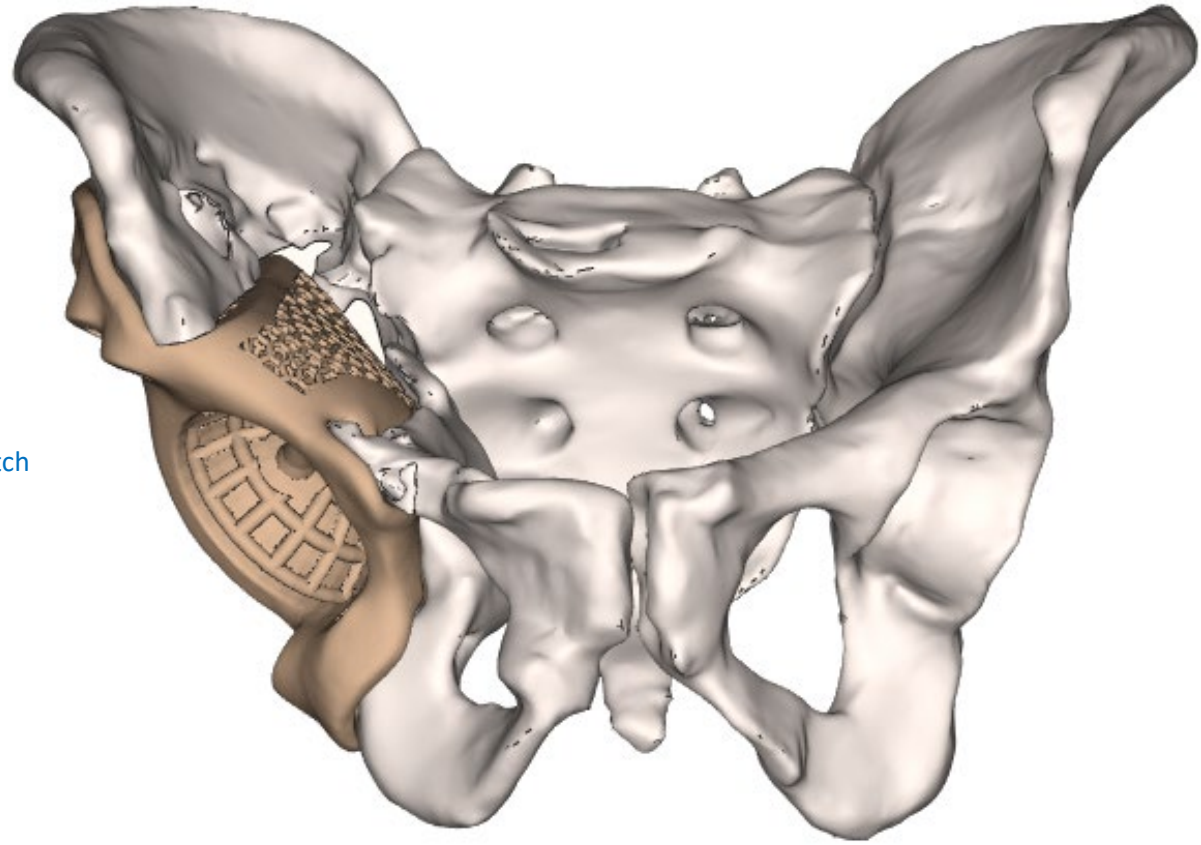


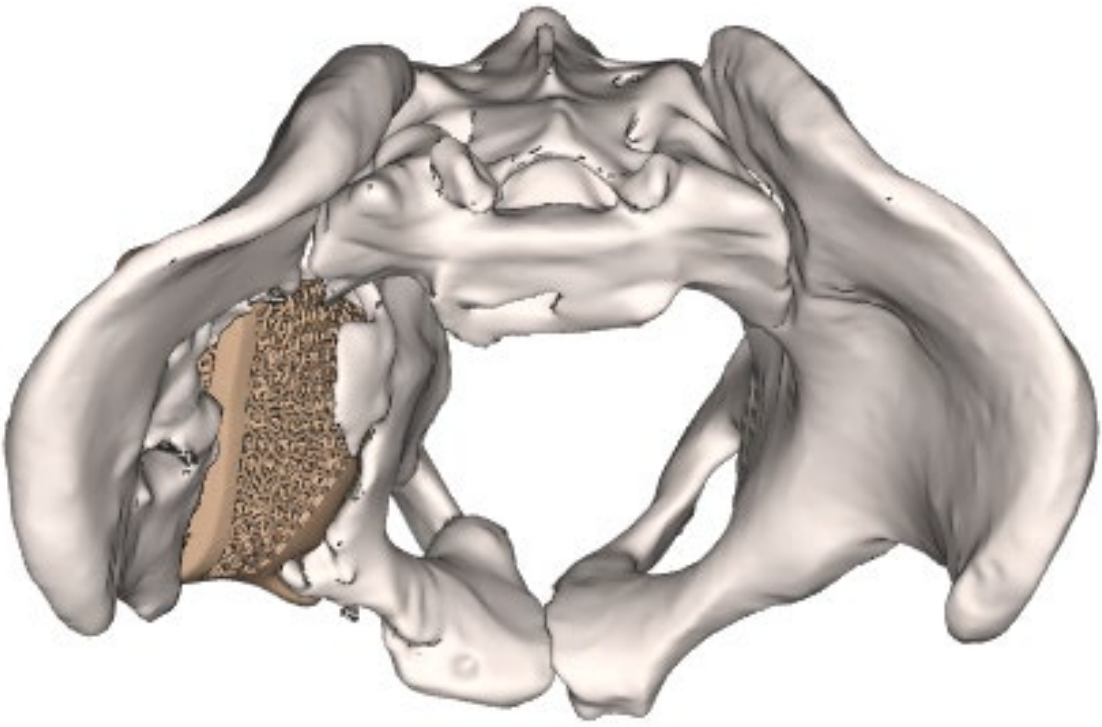
Temporary fixation with up to Ø2.0mm pin



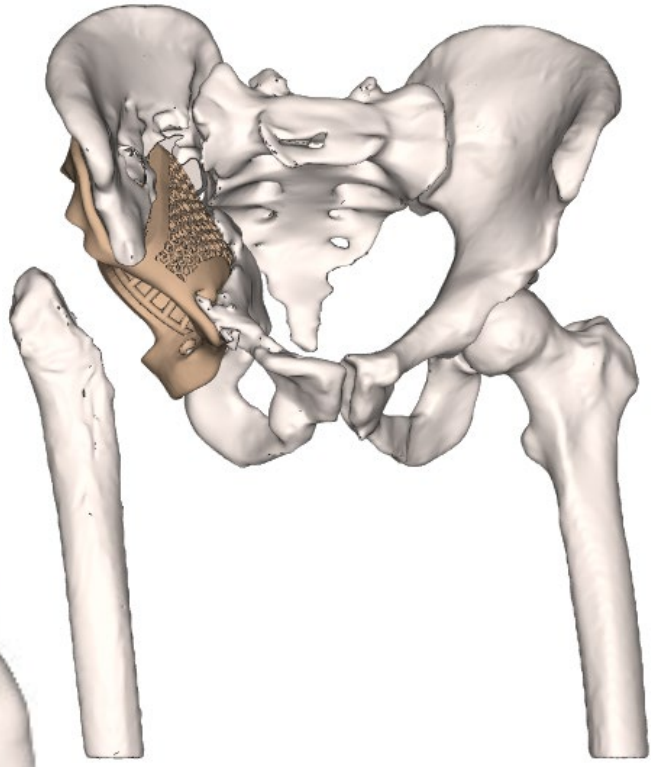
Proposed Implant

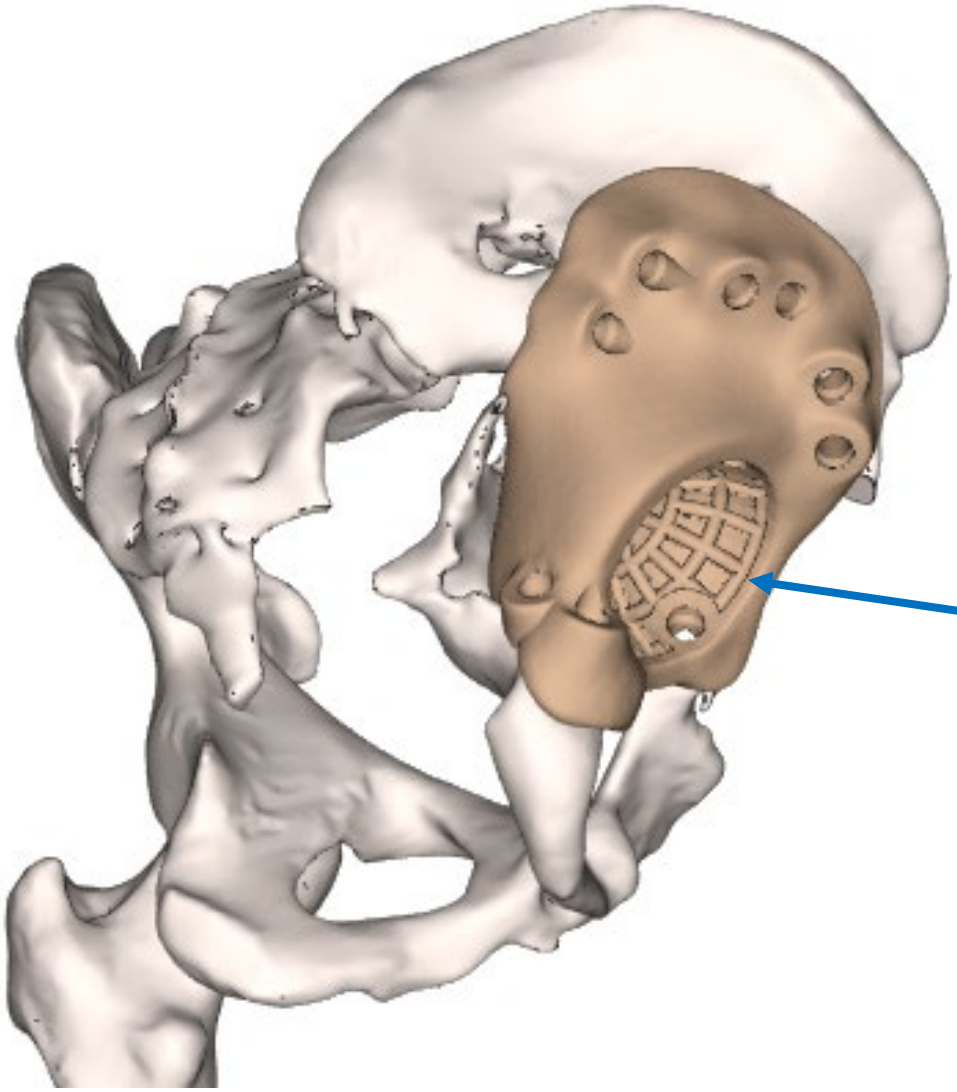
Cup axis designed to match
Left/Healthy side
Inclination: 40°
Anteversion: 20°



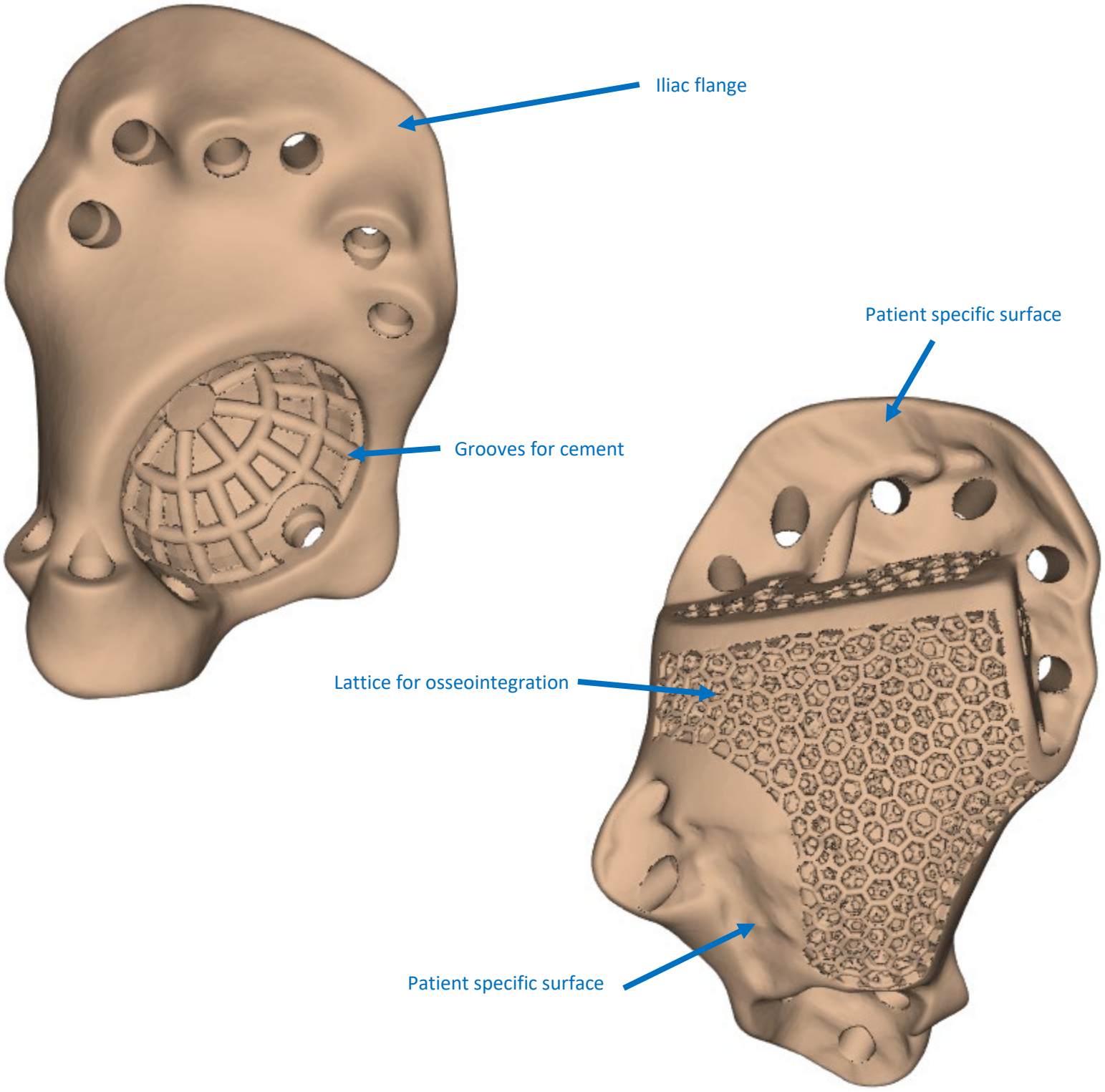


Proposed Implant

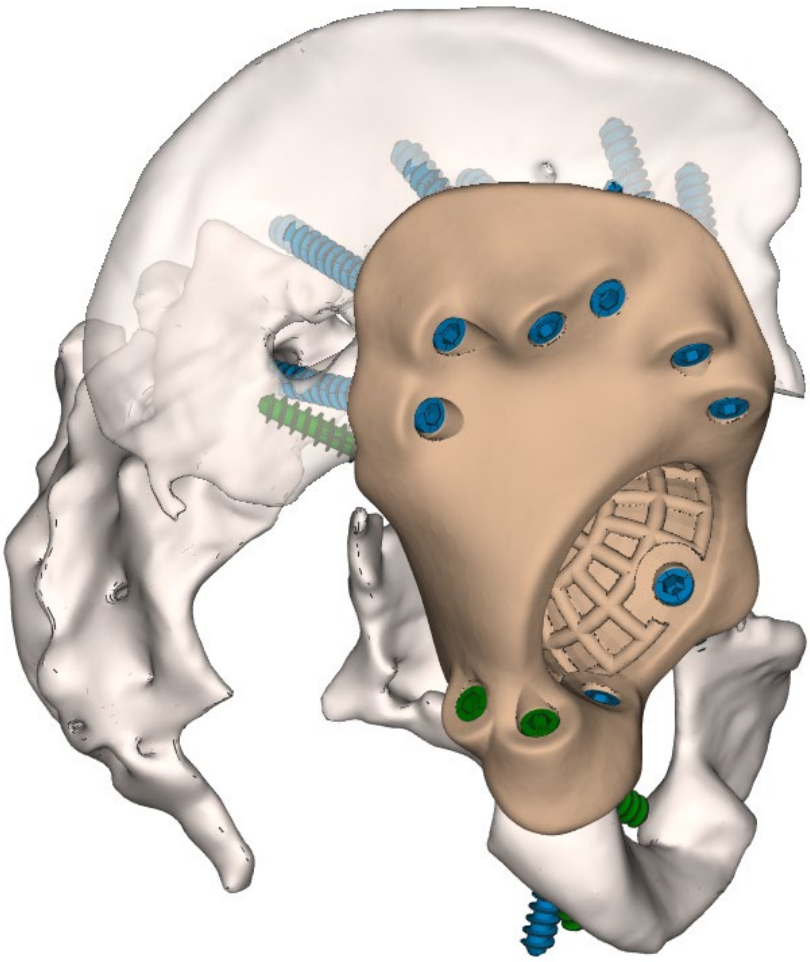




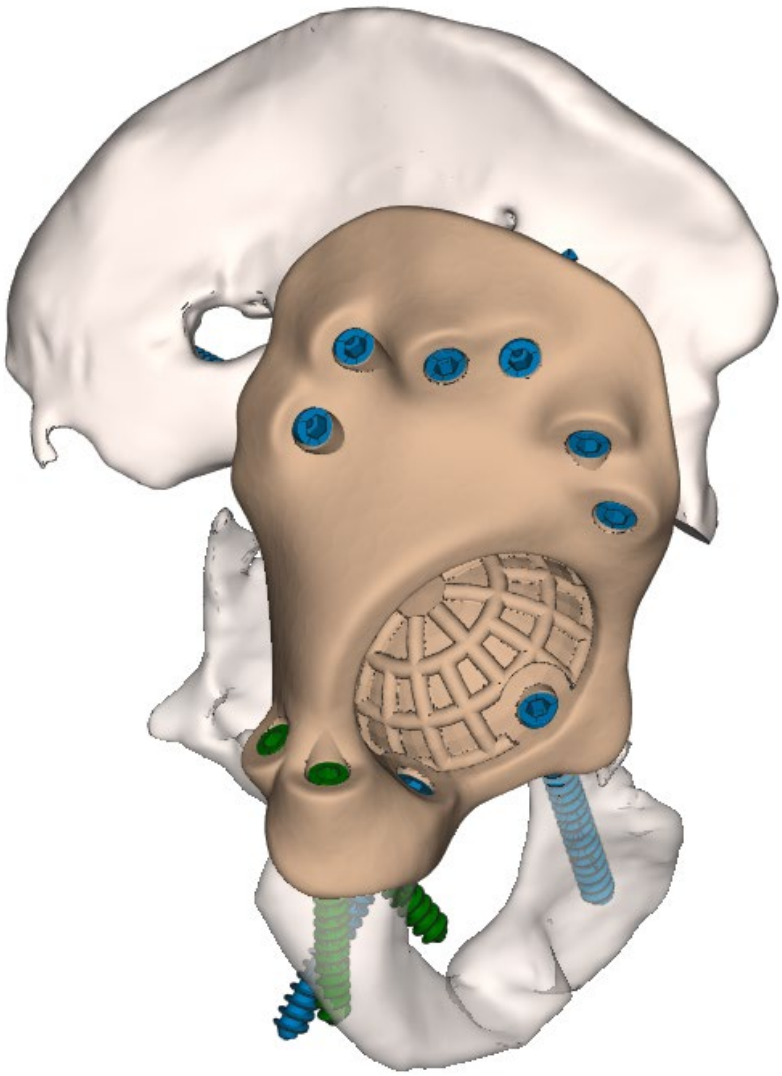
Proposed Implant



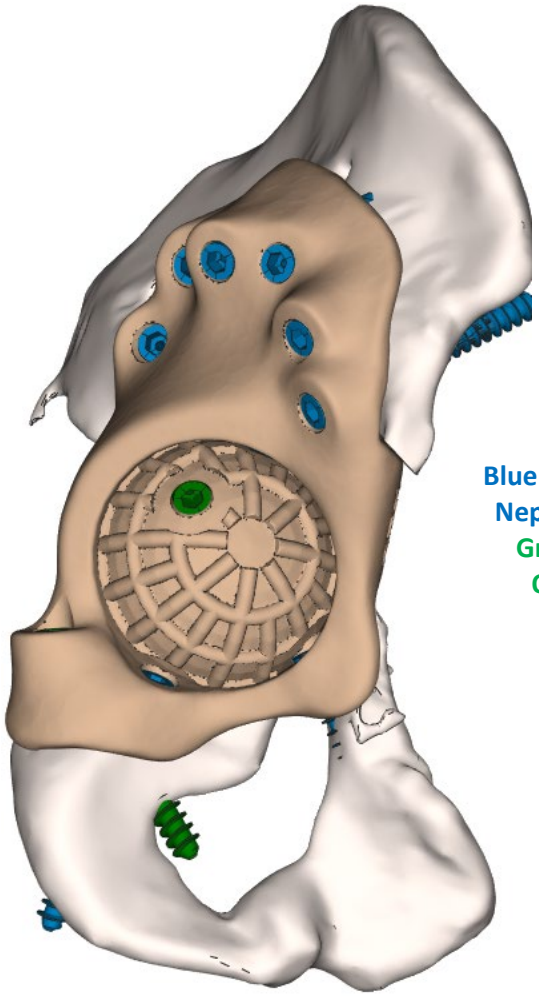
Implant Fixation



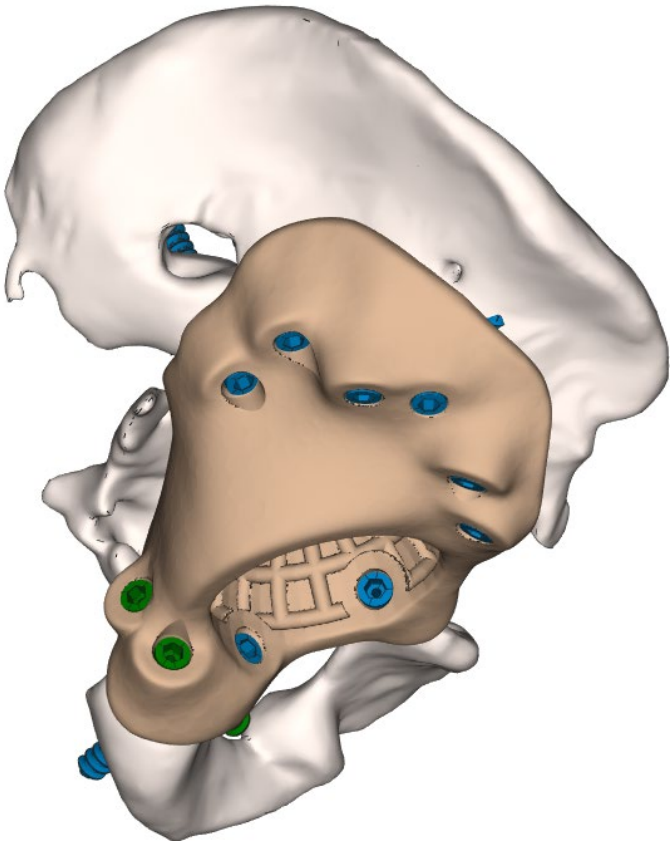
Blue: Mock Ø6.5mm Smith-Nephew Screw (L=60mm)
Green: Mock Ø7.0mm OsteoCentric Screw (L=60mm)



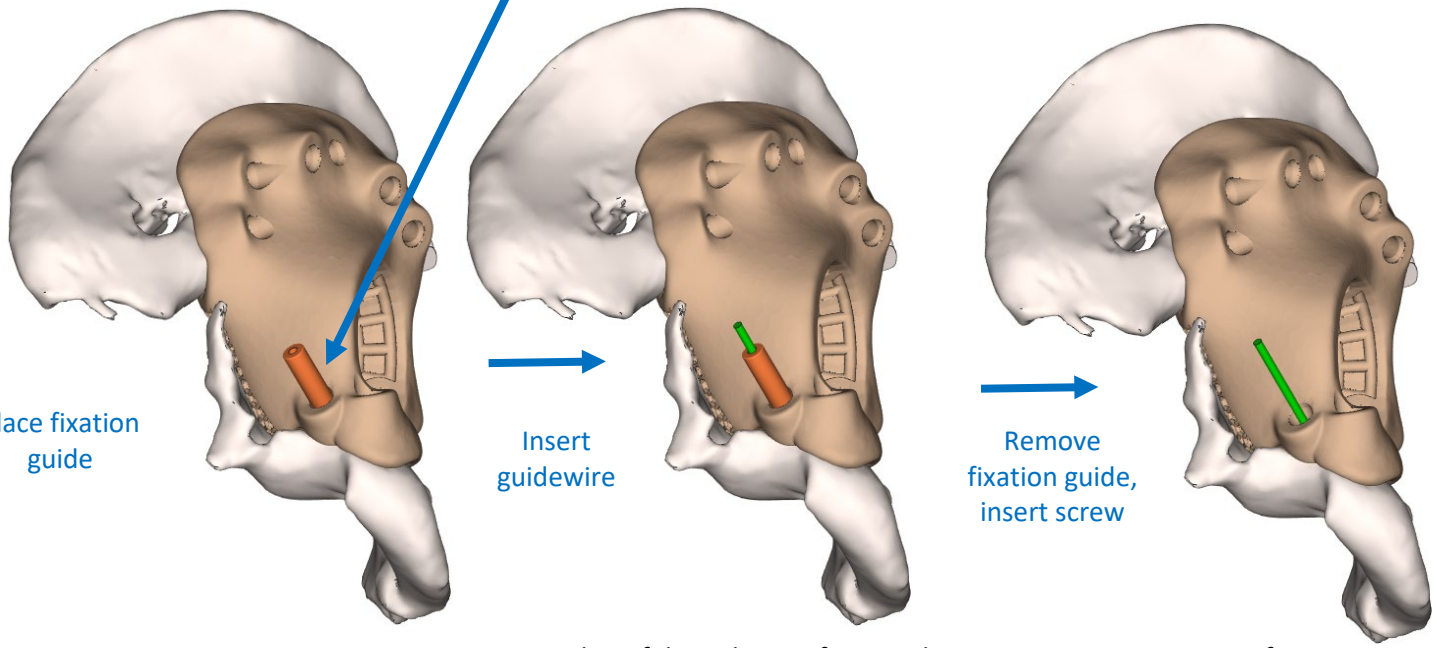
Implant Fixation



Blue: Mock Ø6.5mm Smith-Nephew Screw (L=60mm)
Green: Mock Ø7.0mm OsteoCentric Screw (L=60mm)



Guide for placement of Ø2.8mm guidewire for cannulated screws



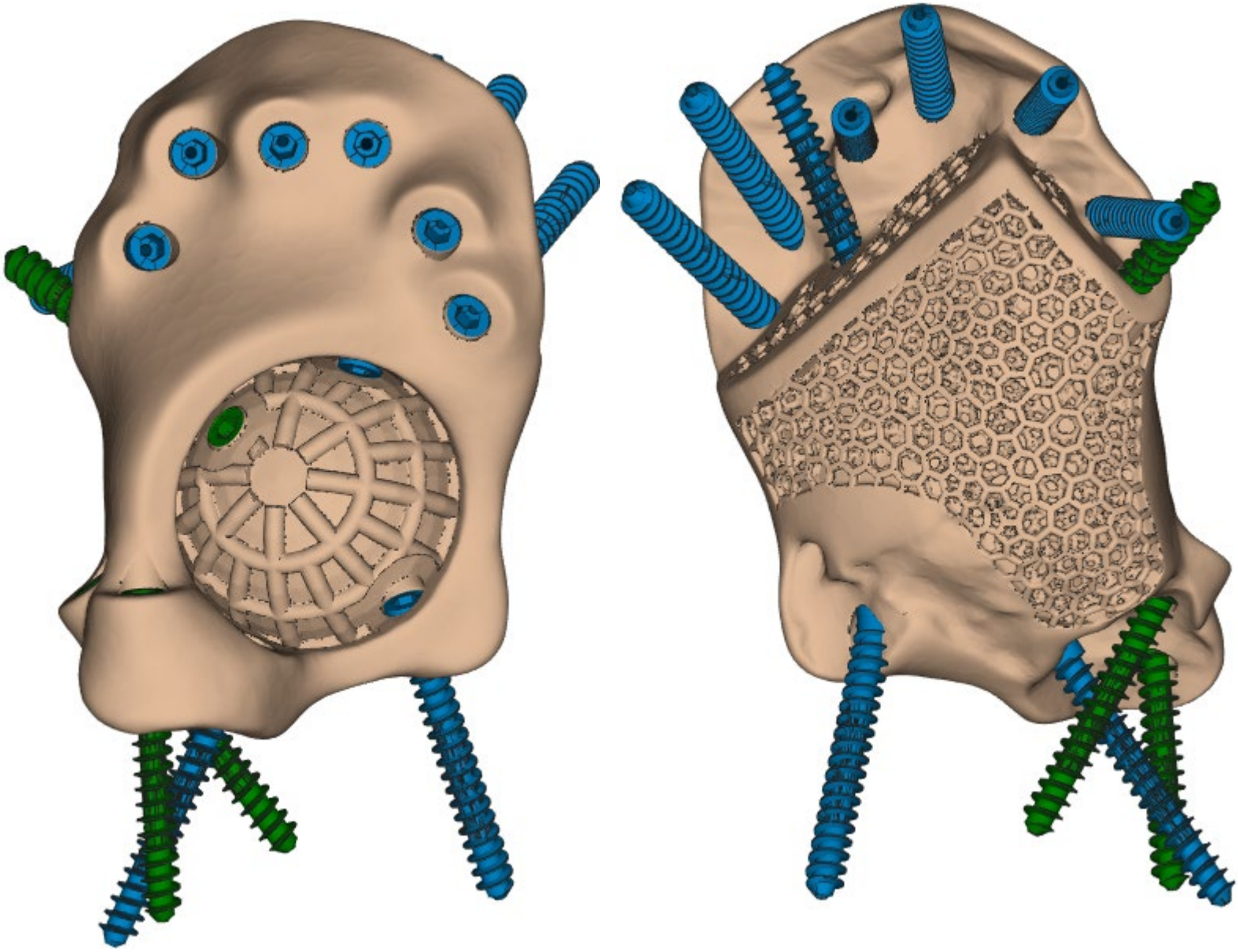
Place fixation guide

Insert guidewire

Remove fixation guide, insert screw

Implant Fixation

Blue: Mock Ø6.5mm Smith-Nephew Screw (L=60mm)
Green: Mock Ø7.0mm OsteoCentric Screw (L=60mm)



Notes to Physician

Planned fixation with Ø7.0mm OsteoCentric cannulated screws and Ø6.5mm Smith+Nephew solid screws.

It is recommended to pre-drill holes in OsteoFab implant, using the drills associated with the fixation of choice.

For best results, use irrigation when predrilling fixation through implant.

It is not recommended to drill/fixate through the latticed areas of the implant.

OsteoFab® Custom Device Design Approval

CASE INFORMATION			
Device Name/Description:	Right Triflange	OPM Case #:	OFC0625
Hospital Name:		Physician:	
Country:	USA	Patient Name/Identifier:	
Planned Surgery Date:	04/01/2025	Patient DOB:	

Part Number	Quantity	Brief Description
OFC0625	**2**	**OsteoFab Custom Implant**
OFC0625-CG	**1**	**Cutting Guide**
OFC0625-FG	**3**	**Fixation Guide**
OFC0625-PREOP	**1**	**Model of Pre-Operative Anatomy**
OFC0625-POSTOP	**1**	**Model of Post-Operative Anatomy**

Signature indicates approval of the final design for the Personalized Medical Device / Custom Device, which was prescribed in writing. Physician recognizes this device is only for the individual for whom it is prescribed and accepts responsibility for its proper application and use. Signing of this form indicates a request that Oxford Performance Materials proceed with the manufacturing of the OsteoFab Custom Device.

Surgeon Signature: _____ **Date: _____**