DESIGN FRAMEWORK

COMPLEX CRANIOFACIAL RECONSTRUCTIONS

VERSION 2.0

DOCUMENT REVISIONS

List in date-ascending order:

REVISION:	DATE:	AUTHOR:	SUMMARY OF CHANGES:
V1	13/12/16	Anon	First draft completed.
V2	15/12/16	Anon	Edited to remove repetitions, and context or software-specific elements.

DESIGN PRO-FORMA

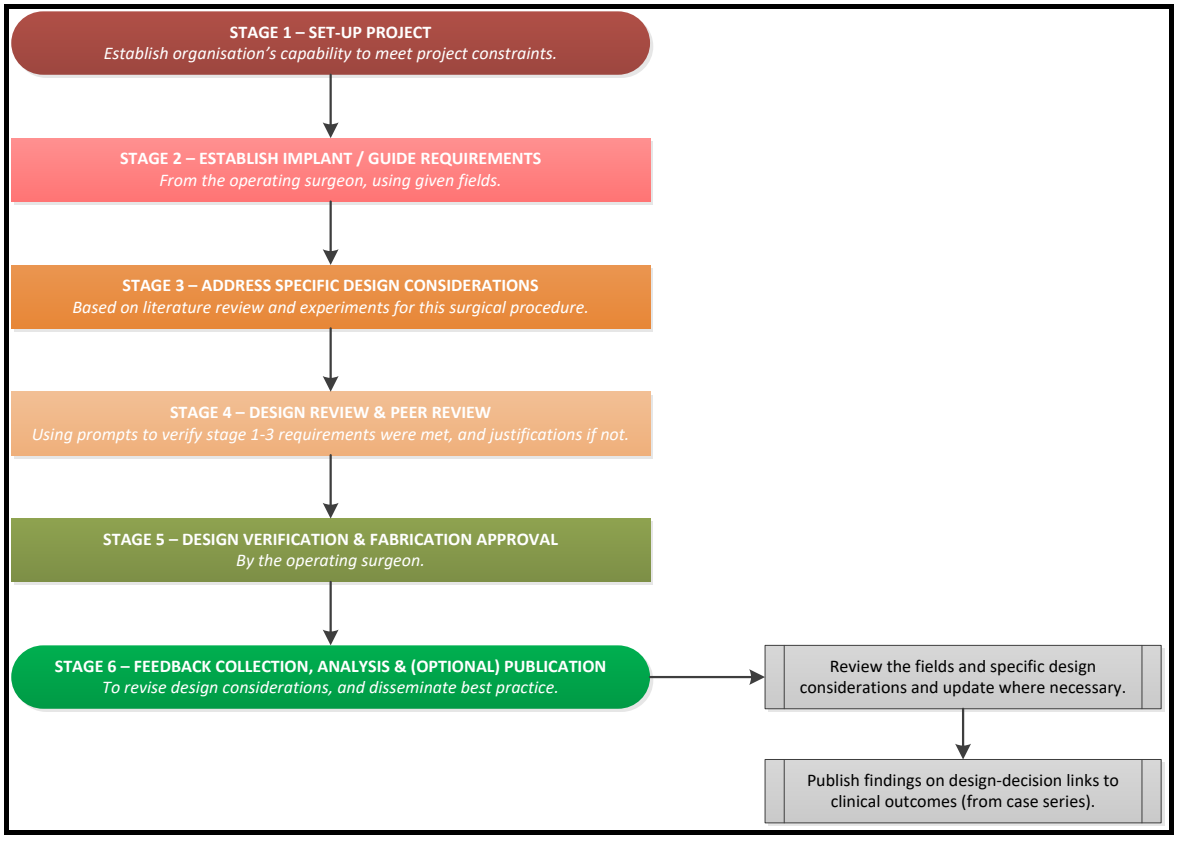
PURPOSE / SCOPE

This framework is for use by design engineers, biomedical engineers, and clinicians who are undertaking computer-aided **design** of patient-specific 3d-printed (titanium) or machined (PEEK) complex craniofacial reconstructive implants. Missing information, required to populate the fields, should always be sought from the operating surgeon (not an intermediary). Fabrication should be controlled separately. Production quality control should be addressed separately.

This form prompts consideration of routine, and overlooked key factors – with a view to minimising design iterations, minimising risks, and improving patient outcomes - based on evidence and informed risk-management. It also ensures good record keeping. **This version of the framework tool is constrained to orbito-temporal disease excision and reconstruction**. In future, it will be expended – with evidence based prompts for other procedures.

This framework can contribute to meeting the requirements of ISO 13485 for the **design** of medical devices – when used as part of an organisation's own Quality Management System. It is intended for continuous referencing and updating throughout project activity (including after surgery and during clinical follow-up). For best results, do not progress to the next project stage(s) until the current section has been completed.

Stages 1 and 2 establish the project and product requirements by prompting, and making explicit, answers to key fields – information which will be required during the 3D modelling of implants and guides. **Stage 3** prescribes specific considerations for some of those fields based on published evidence. **Stage 4** prompts reviews of the design by the project manager and by a relevant peer. **Stage 5** prompts the processes of obtaining "customer" (or, operating surgeon) sign-off. **Stage 6** prompts the collection of useful feedback – and encourages later publication. The flow diagram below provides an overview of the stages in this framework.



STAGE 1: SET-UP PROJECT (PRE-SCAN-DATA PROCESSING / PRE-DESIGN):

Establish the fundamental project details, and evaluate yours / your organisation's ability to deliver within the stated constraints.

PROJECT SETUP	
Patient / project name / identifier:	
Your name: *[Acting as project manager / project designer]:*	
Your employed role:	
Operating clinician name: *[If different to you]:*	
Operating clinician role: *[If different to you]:*	
(Operating clinician) email address(es):	
(Operating clinician) phone number(s):	
(Operating clinician) typical meeting availability:	
DEADLINES	
Today's date: *[Project starts]:*	
Finished (clean, not sterile) devices required on or before:	
Estimated fabrication and post-processing timescale:	
Full delivery address / restrictions:	

AIMS

Patient condition / procedure / background / future: *[including, e.g. scheduled radiotherapy]:*					
Service(s) required:	*Digital surgical planning meeting:*		*Custom implant design:*		
	Custom guide design:		*Medical model design:*		
Ideal custom device(s): *[Item(s) & purpose]:*					
Ideal clinical outcome(s):					
Billing arrangements in-place? *[Where necessary, detail]:*					

CAPABILITY CHECK

Capable of delivering device design services? *[In terms of: timeframe / capacity / technical capability / skills.]*	*Yes:*		*Yes:* *[With support which is achievable within the deadline]:*		*No:* *[Abandon project]:*

STAGE 2: ESTABLISH IMPLANT / GUIDE REQUIREMENTS (PRE-SCAN-DATA PROCESSING / PRE-DESIGN):

Request specific details about the operating clinician's implant and guide requirements – and note them against all of the relevant fields. Where the clinician prompts or agrees to requirements updates through the project (perhaps after design review, further discussion, a design experiment, or a change in project circumstances), note any refined requirements in the third column.

CUSTOMER & IMPLANT / GUIDE REQUIREMENTS		
Requirements:	**Design Implications & Requirements Version 1:**	**(Optional) Version 2:** *[If refined / changed]:*
	Context	
Any accommodation required for potential defect alterations between the scan and surgery?		
Any scan-data modifications required before design work? *[E.g. Remove existing devices / grafts?]*		
Any requirements from surgeon experience (and therefore expectations) from using analogous devices?		
Any project requirements from the surgical team having relevant additional needs? *[E.g. accommodating colour blindness?]*		
	Material and Texture	
Device(s) materials:		
Device(s) surface finish(es): *[Including desirability of osseointegration]:*		

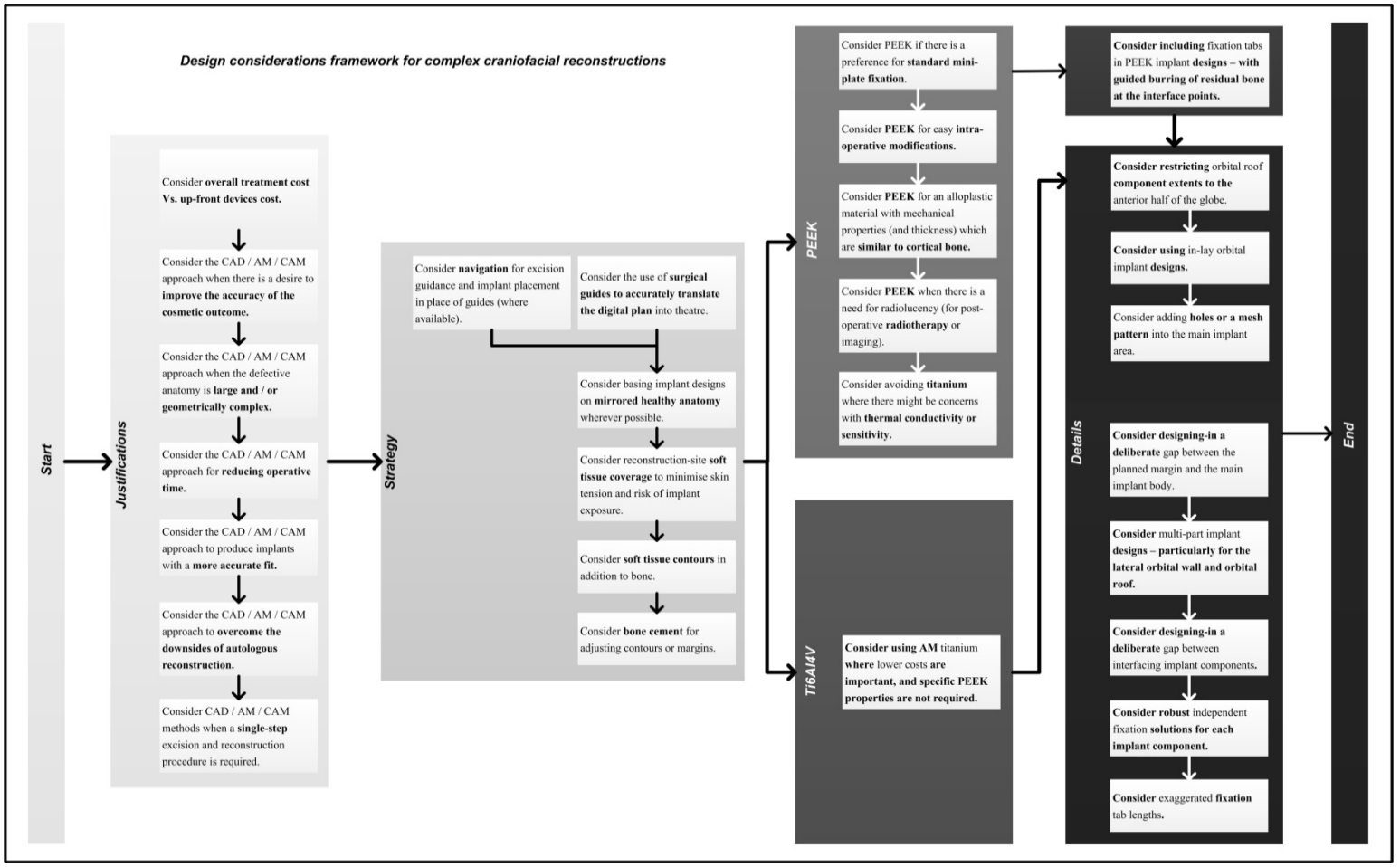
Basic Geometry		
Device(s) extents:		
Device(s) thickness:		
Device(s) shape:		
Morphology and Safety		
Device(s) fit: *[Including inlay vs.onlay]:*		
Device(s) insertion paths:		
Device(s) soft-tissue considerations:		
Number of components / nature of the interface between components:		
Device(s) fixation methods: *[Incl. specify screws]:*		
Delicate anatomy handling / manipulation:		
Device handling:		

Anatomical engagement:		
Clinician / support-staff safety:		
Intuitive? [Or functional labelling?]		
Other		
Other product requirements:		

STAGE 3: ADDRESS SPECIFIC DESIGN CONSIDERATIONS (PRE-DESIGN / DURING DESIGN):

After defining and refining the operating surgeon's product requirements during **STAGE 2**, address the specific design considerations listed in the table on the following page below. Check the boxes when each issue has been addressed, or note a justification for those which are deliberately overlooked, or deemed irrelevant.

For ease-of-reference, the flow-diagram below presents the considerations in summary form. The table however, provides details on evidence and justifications.



SPECIFIC DESIGN CONSIDERATIONS CHECKLIST

Consideration / Outcome:	Evidence / Source:	Implemented?	Notes / Justifications:
Design Decisions			
Consider multi-part implant designs – particularly for the lateral orbital wall and orbital roof. *To enable easy manipulation of the components into the correct (pre-planned) positions.*	Peel S, Bhatia S, Eggbeer D, Morris DS, Hayhurst C. Evolution of design considerations in complex craniofacial reconstruction using patient-specific implants. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2017; 231: 509-24.		
Consider robust independent fixation solutions for each implant component. *To build-in functional independence in case one component is omitted from the final reconstruction.*			
Consider exaggerated fixation tab lengths. *To provide margin flexibility when excisions are larger than planned.*			
Consider designing-in a deliberate gap between the planned margin and the main implant body. *To provide margin flexibility when excisions are smaller than planned.*			
Consider designing-in a deliberate gap between interfacing implant components. *To provide positioning flexibility and avoid chain-tolerance errors in the event that one or more components is fixed sub-optimally.*			
Consider using in-lay orbital implant designs. *To lower the risk of reducing the orbital volume.*			
Consider restricting orbital roof component extents to the anterior half of the globe. *To lower the risk of reducing the orbital volume.*			
Consider including fixation tabs in PEEK implant designs – with guided burring of residual bone at the interface points. *To offer a more stable fixation option – or when preferred over mini-plates.*			

Consider using AM titanium where specific PEEK properties are not required. *To achieve similar benefits at lower cost.*			
Consider providing extra holes in the temporal region. *To provide suturing points for the temporalis muscle.*			
Consider slightly flattening the reconstruction contours. *To produce a plate which is not overly bulbous – therefore ensuring good skin flap coverage.*	*Peel, S., Eggbeer, D., Burton, H., Hanson, H., & Evans, P. L. (2018) Additively manufactured vs. conventionally pressed cranioplasty implants - an accuracy comparison. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine (Accepted - In Press)*		
Consider removing plate material around areas of potential temporalis muscle-dura fusion. *To maintain implant viability in the event of muscle-dura fusion in the weeks and months following craniotomy.*	Peel S, Eggbeer D. Additively manufactured maxillofacial implants & guides - achieving routine use *Rapid Prototyping Journal*. 2016; 22: 189 - 99.		
Manufacturing (Metal AM)			
Consider adhering to the supplier's minimum part thickness guidelines (Renishaw PLC = 0.4mm). *To prevent the need to redesign areas or components downstream.*	Manufacturer correspondence.		
Consider the differences in surface finish achievability for: where a grit blast stream can reach, and where a polishing tool can reach, and where a polishing tool can reach. *To prevent the need to reduce the range of available surface finishes downstream.*			
Consider ensuring the residual material remaining after modelling countersinks in device designs is at least 0.3mm thick. *To adhere to the supplier's guidelines and guarantee the integrity of the fixation solution.*			

Consider making transitions between part thickness values smooth. *To mitigate issues with distortion and stress during part cooling.*			
Consider chamfering or smoothing sharp corners where possible. *To mitigate issues with support structure modelling.*			
Manufacturing (Machined PEEK)			
Consider adhering to the supplier's minimum part thickness guidelines (DePuy Synthes = 3-4mm except for slight local thinning for onlay implants). *To prevent the need to redesign areas or components downstream.*	Manufacturer correspondence.		
Consider the ability of a machine tool to access undercut areas of a PEEK device design. *To prevent the need to redesign areas or components downstream.*			
Regulatory Requirements			
Consider how to minimise contamination opportunities through the design of the devices. *By, e.g. improving the ease of cleaning, sterilisation, packaging damage prevention.*			
Consider how to minimise risks of leakage from the designed device(s). *By, e.g. ensuring the designed geometry has unintended gaps filled.*			
Consider how to minimise risks of substance ingress into the designed device(s). *By, e.g. ensuring the designed geometry has unintended gaps filled.*			
Consider how to ensure part identification and traceability. *By, e.g. ensuring packaging is labelled if labelling the devices physically is difficult.*			

STAGE 4: DESIGN PEER REVIEW (POST-DESIGN):

Now, the proposed design(s) must be reviewed by you, and by another member of the technical or design team against the requirements list which was compiled in **STAGE 2**, and against the recorded considerations in **STAGE 3**. Use the checkboxes to verify the design solution(s) and confirm that each requirement and relevant consideration has been accommodated. Where a requirement has been deliberately overlooked, or a relevant consideration omitted, note the justification in the spaces provided.

PEER REVIEW					
Peer- reviewer:					
Peer-reviewer job role:					
	Designer Review			**Peer Review**	
Date of reviews:					
Name(s) of reviewed file(s): *[Finished device STL's / IGES]:*					
Do the design outputs match the requirements from STAGE 2 and the justifications from STAGE 3?	*Yes:*		*No:*	*Yes:*	*No:*

If not, why not?	*Not enough detail in recorded notes:*		*Changes to design required:*		*Not enough detail in recorded notes:*		*Changes to design required:*	
	Recorded notes are not current:		*Other:* *[Detail below].*		*Recorded notes are not current:*		*Other:* *[Detail below].*	
If not, recommended corrective actions:								
Corrective actions undertaken satisfactorily?			*Yes:*				*Yes:*	

DESIGN APPROVAL

The design outputs address STAGE 2 requirements and STAGE 3 considerations, or have omissions justified.	*Project manager signature:*		*Reviewer signature:*	

STAGE 5: DESIGN VERIFICATION & FABRICATION APPROVAL (POST-DESIGN)

Present the peer-approved final designs to the operating clinician for approval. If requirements have changed, or modifications are requested, update the previous sections of this form, and undertake the revisions. After obtaining a verification signature from the operating surgeon, begin an appropriately controlled and certified fabrication process.

	VERIFICATION MATERIAL						
Checklist – have you documented and communicated these details to the operating surgeon?	*List of final product requirements:*		*Images of the 3D reconstructions of the processed scan-data:*		*Multiple views of designed devices:*		*Images showing device contours overlaid against key scan-data slices:*
	List of specifically addressed design considerations from stage 3:		*Images of scan-data modifications /digital anatomical repairs:*		*Multiple views of designed devices in-situ on virtual model of anatomy:*		
	CHANGE REQUESTS						
Operating clinician design verification?	*Yes:*				*No:*		
If not, requested modifications:							
Corrective actions undertaken satisfactorily?	*Yes:*						
	DESIGN VERIFICATION & FABRICATION APPROVAL						
The design outputs address STAGE 2 requirements and STAGE 3 considerations, or have omissions justified.	*Operating surgeon signature:*				*Date:*		

STAGE 6 – FEEDBACK COLLECTION, ANALYSIS & (OPTIONAL) PUBLICATION (POST-DESIGN TRANSFER)

Gather feedback on the designed devices, their design details, their performance, and any links to surgical outcomes - by prompting the operating clinician for thorough comments after key milestones. Record this feedback under your own organisation's systems. Where a case study or a case series demonstrates new design considerations, or require revisions of existing considerations, consider updating this framework (after peer-review in your organisation). Wherever possible, this new evidence should be disseminated through conferences or journal papers to advance the development of design rules across the field.

FEEDBACK PROMPTS

Have you requested feedback after:

Surgery: ☐ *3 months:* ☐ *6 months:* ☐

12 months: ☐ *Longer:* ☐

RECEIVED FEEDBACK

Feedback receipt date:

Feedback medium: *Letter:* ☐ *Form:* ☐ *Email:* ☐ *Verbal:* ☐

Original (or transcribed) correspondence attached (or filed)?

[Details]:

FEEDBACK CLASSIFICATION:

Complaint? (If yes, follow your organisation's procedure). ☐

[- A device failure related to the design of the device,
- a criticism of the product or service for which the customer requests compensatory action,
- or something requiring an immediate response]:

Feedback? ☐

[- Information which can be used to formulate new or revised considerations, form frameworks, or work instructions]:

DISSEMINATION

Does this project demonstrate potential for inclusion in a presentation or publication?

[Details]: