Implementing ISO 13485 in a Hospital Based Maxillofacial Laboratory

Peter Ll. Evans

Maxillofacial Laboratory Services Manager

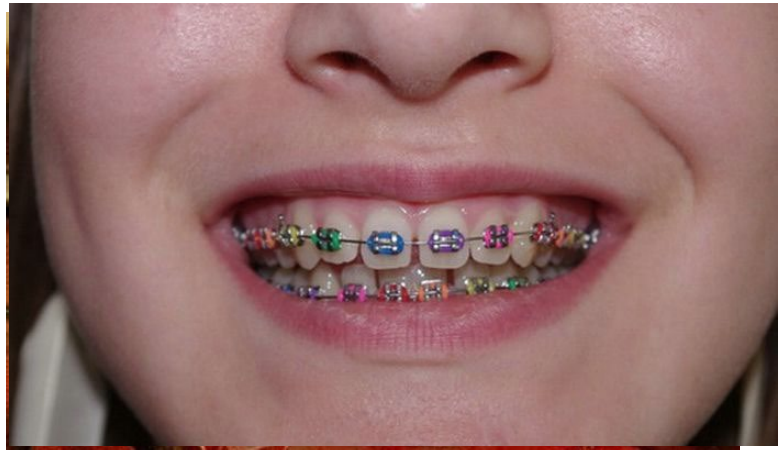
Morriston Hospital Swansea

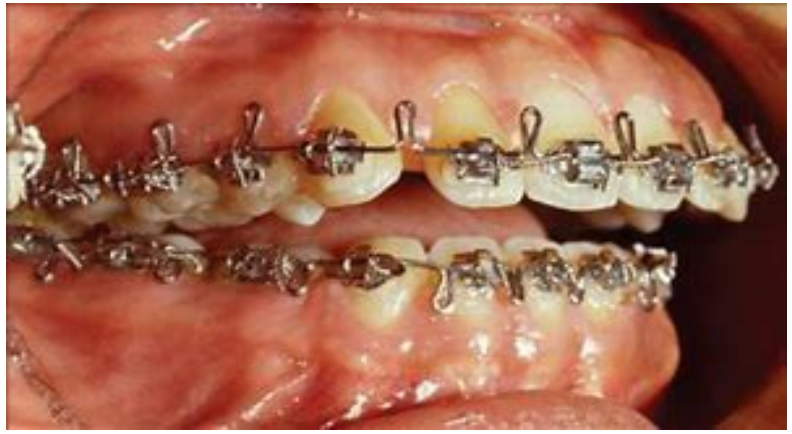
Morriston Hospital

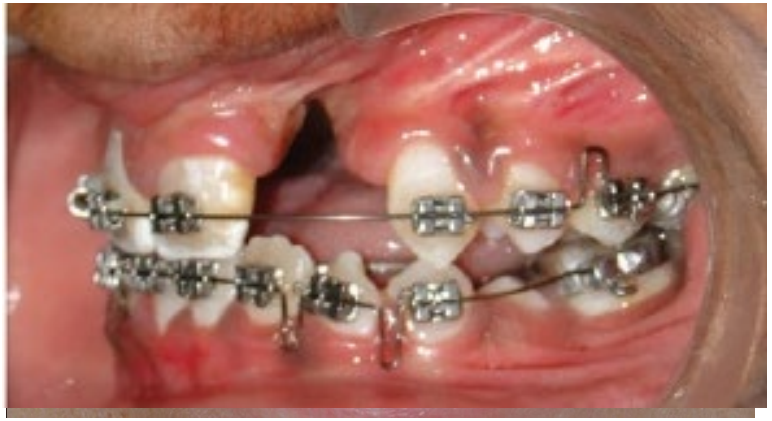
- 750 bed hospital
- First established 1941
- 2nd Trauma centre
- 1st Cardiac centre
- Cleft service
- Burns/Plastics centre
- ALAC
- Maxillofacial

Maxillofacial Unit

- Oral and Maxillofacial Surgery
  - 3 cancer surgeons
  - 2 Craniofacial Surgeons
  - 1 Cleft Surgeon
- Restorative Dentistry
  - 3 Consultant Restorative Dentists
- Orthodontics
  - 3 Orthodontic Consultant Dentists







Maxillofacial Laboratory Service

Ear , Nose and Throat (ENT)

Plastic Surgery

Burns Surgery

Occupational Therapy

Orthopaedics

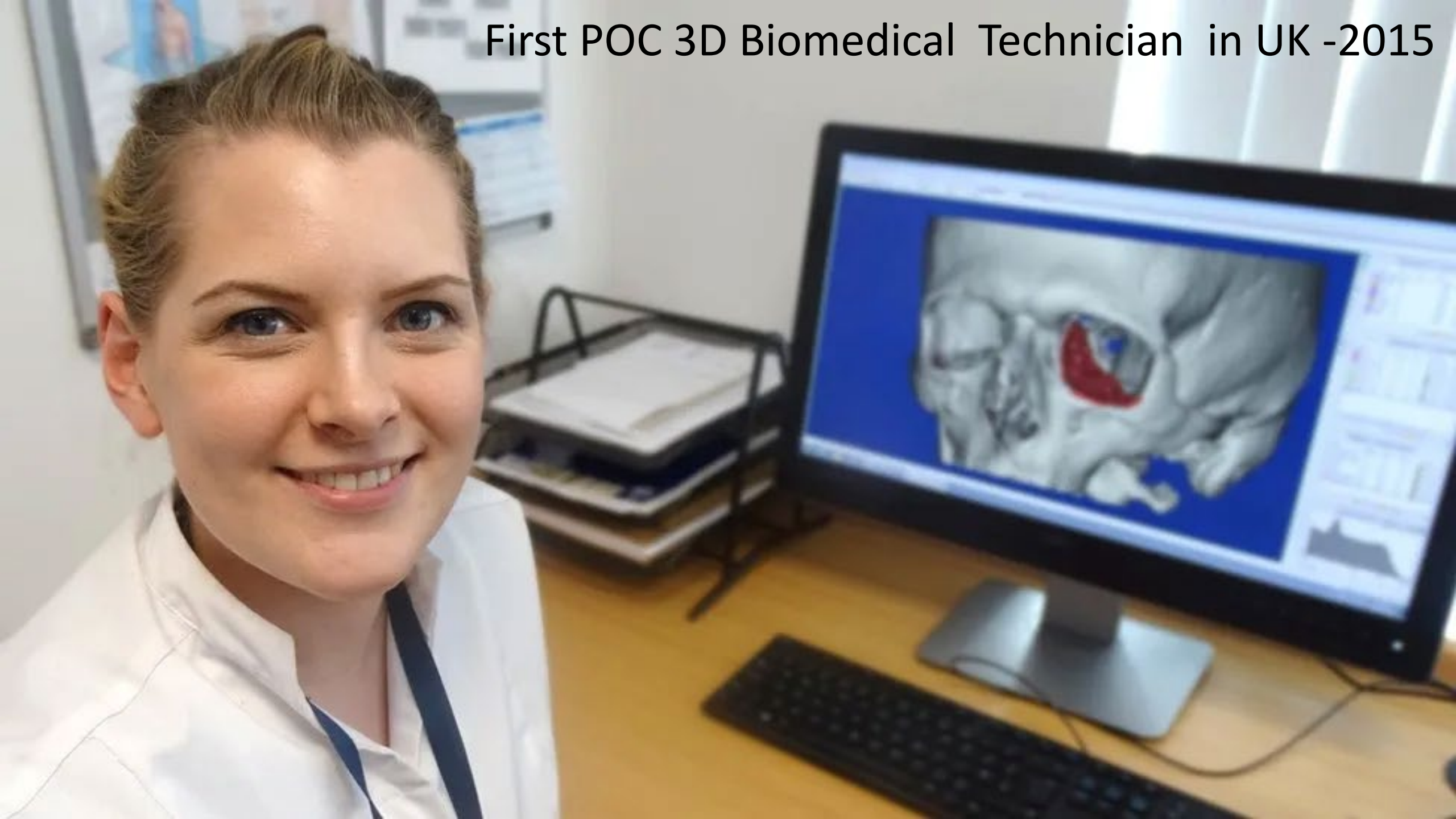
Cardio Thoracic

Lymphedema services

Rehabilitation Engineering

Maxillofacial Laboratory Service

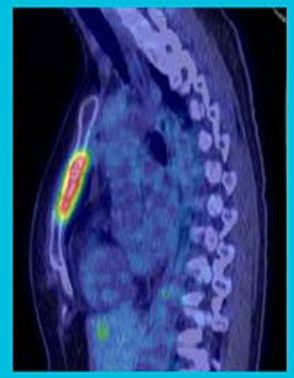
- Mimics, Materialise since 2003
- Freeform Plus since 2004
- In house printing – 3 Formlabs and 1 PLA printer
- 1st established 3d post in the UK
- 1st Implanted rib cases manufactured in UK
- 1st Lab to achieve ISO certification for design and manufacture


First POC 3D Biomedical Technician in UK -2015

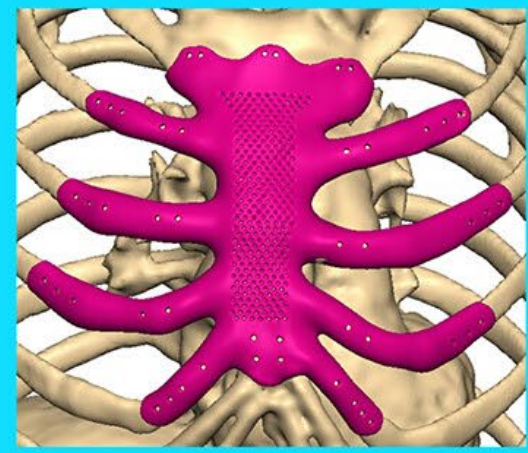
3D Printing Technology for Chest Wall Reconstruction With a Sternum-Ribs-Cartilage Titanium Implant: From Ideation to Creation

INTRODUCTION

Resection of sternum, adjoining cartilages, and ribs for sternal malignancy results in large chest wall defect, requiring complex chest wall reconstruction



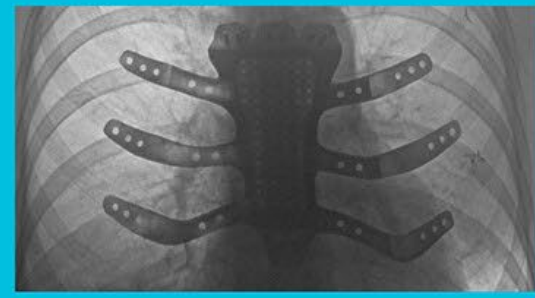
INTERVENTION



3D printed, novel, customized, anatomically designed titanium implant was manufactured to reconstruct the chest wall

OUTCOME

Implant slotted in place perfectly, easily secured with sutures



No pain, paradoxical movement, or dislocation at follow-up & anatomical shape and function of chest wall was preserved

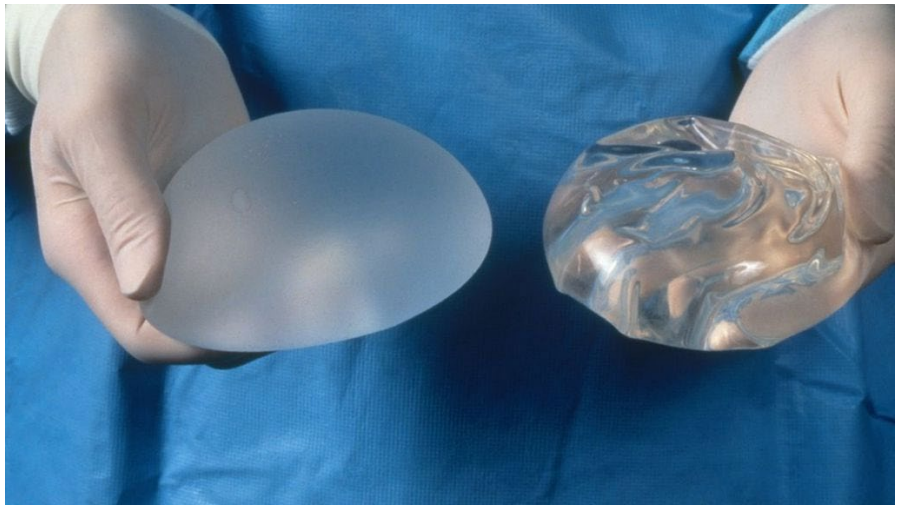
INNOVATIONS

TECHNOLOGY AND TECHNIQUES IN CARDIOTHORACIC AND VASCULAR SURGERY

Goldsmith et al. *Innovations*. January/February 2023.

Regulations

- In 2017 EU regulations on Medical Devices Regulations (MDR) proposed in reaction to a series of manufacture issues.
- Maxillofacial labs needed to comply by May 2021



- Post Brexit , UKCA (UK Conformity Assessed) under the MHRA

- Two routes –

1. Health Institute Exemption (HIE) Put device in service
2. Place a device on market.

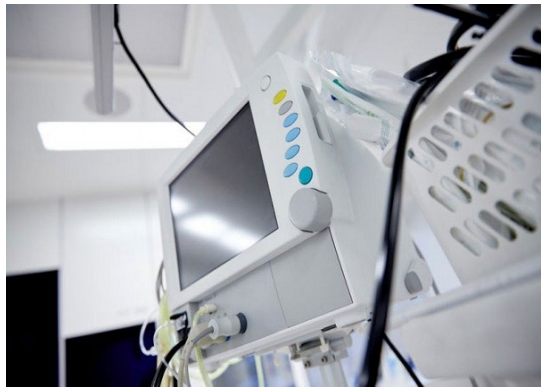
- All laboratories required to have a quality management system in place, ideally ISO 13485

ISO 13485 MEDICAL

Quality Management System (QMS)

A quality management system (often referred to as a QMS) is defined as a formalised system that documents the processes, procedures and the responsibilities for achieving quality policies, objectives and requirements of standards

Pathology
ISO 15189



Medical Equipment
ISO 9001

Sterile Services
ISO 13485

Maxillofacial Laboratory
ISO 13485

Annual External Audit

bsi.

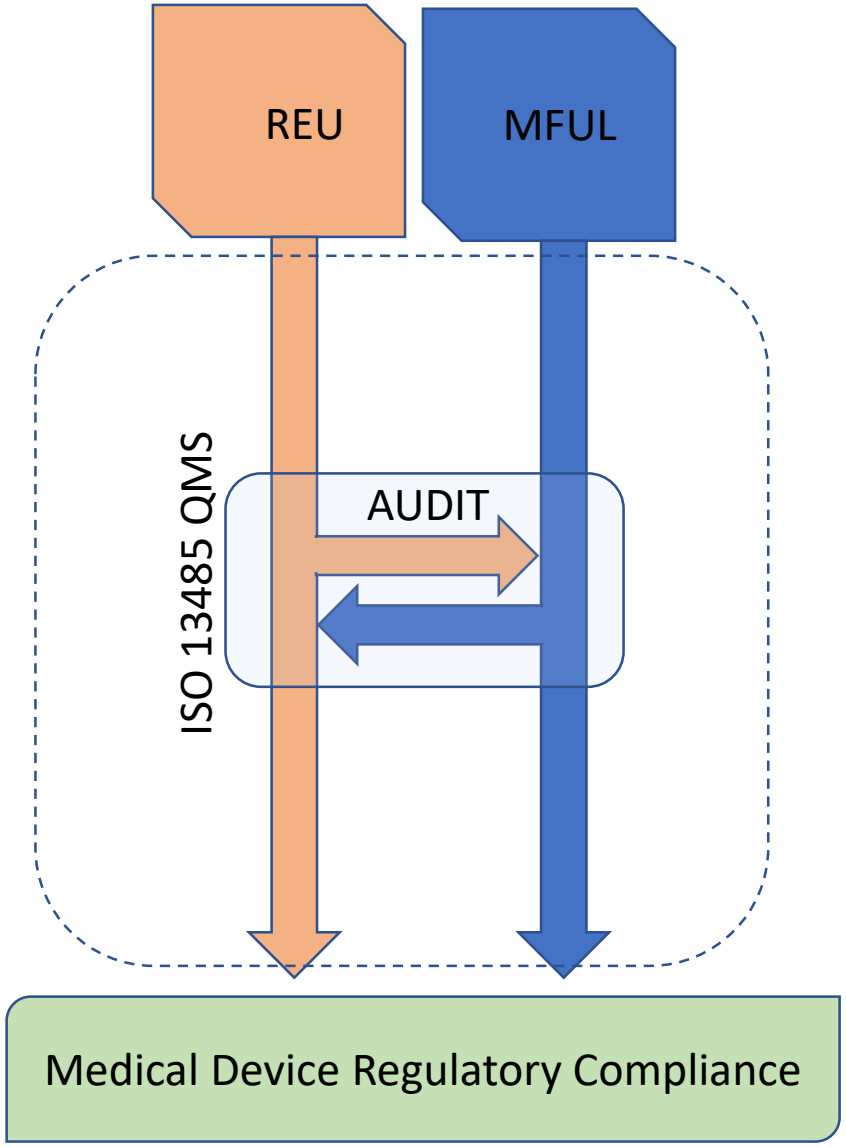
SGS

Notified Bodies

Accredited Bodies

How did we get there?

Recognition	Assessment	Action	Goal
Joint problem Recognised by REU and MFUL Dec 17	Report directed future path and QMS requirement November 18	Joint appointment of Quality System Implementation Manger Sept 2019 Joint appointment of Quality System Implementation Manger Sept 2019	Successful Accreditation with Certification Body for ISO 13485 April 2021




Quality Manual
QMS Scope, policy and objectives
Training and Competence
Non Conformity & Corrective Action
Infrastructure and Equipment Management
Document Control Control of Records
Purchasing and Suppliers
Communication and Feedback
Internal Audit
Software
Device Technical Files
Family Description
Risk Classification
Safety and Performance Requirements (GSPR)
Risk Management Plan
Service Procedures-
Cross Infection
Dress Code
Health and Safety
Management review

Document Control -Maxillofacial Families

4 families -26 devices (whole laboratory 43 families 130 devices)

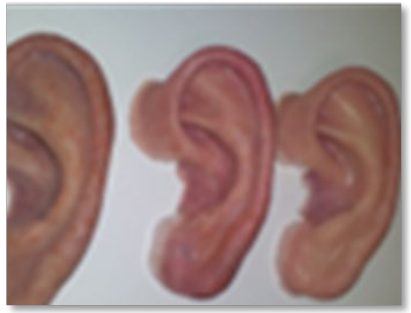
Facial Prosthetics		
1.	**Adhesive Ear Prosthesis Family** (Maxillofacial Laboratory – General 109)	**Class I** (Maxillofacial Laboratory – Laboratory 152)
2.	**Adhesive Orbital Prosthesis Family** (Maxillofacial Laboratory – Laboratory 121)	**Class I** (Maxillofacial Laboratory –Laboratory 135)
3.	**Adhesive Nasal Prosthesis Family** (Maxillofacial Laboratory – Laboratory 118)	**Class I** (Maxillofacial Laboratory – Laboratory 151)
4.	**Spectacle-retained Orbital Prosthesis Family** (Maxillofacial Laboratory – Laboratory 129)	**Class I** (Maxillofacial Laboratory – General 111)
5.	**Spectacle-retained Nasal Prosthesis Family** (Maxillofacial Laboratory – Laboratory 128)	**Class I** (Maxillofacial Laboratory – Laboratory 149)
6.	**Craniofacial Bar Family** (Maxillofacial Laboratory – Laboratory 119)	**Class IIb** (Maxillofacial Laboratory – Laboratory 132)
7.	**Craniofacial Retained Ear Prosthesis Family** (Maxillofacial Laboratory – Laboratory 153)	**Class I** (Maxillofacial Laboratory – Laboratory 154)
8.	**Craniofacial Retained Orbital Prosthesis Family** (Maxillofacial Laboratory – Laboratory 156)	**Class I** (Maxillofacial Laboratory – Laboratory 157)
9.	**Craniofacial Retained Nasal Prosthesis Family** (Maxillofacial Laboratory – General 112)	**Class I** (Maxillofacial Laboratory – Laboratory 155)
10.	**Temporary / Surgical Nasal Prosthesis Family** (Maxillofacial Laboratory – Laboratory 130)	**Class IIa** (Maxillofacial Laboratory – Laboratory 149)
11.	**Septal Button Family (Nasal Septal Prosthesis)** (Maxillofacial Laboratory – Laboratory 126)	**Class IIa** (Maxillofacial Laboratory – Laboratory 148)

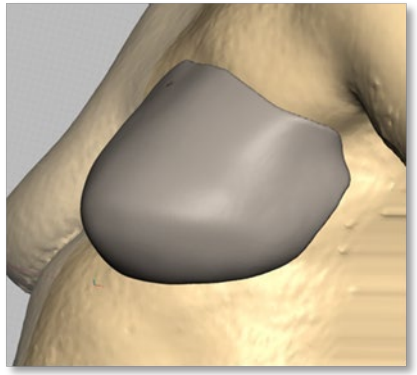
Body Prosthetics		
1.	**Breast Prosthesis Family** (Maxillofacial Laboratory – Laboratory 160)	**Class I** (Maxillofacial Laboratory – Laboratory 162)
2.	**Finger / Thumb / Toes Prosthesis Family** (Maxillofacial Laboratory – Laboratory 158)	**Class I** (Maxillofacial Laboratory – General 164)
3.	**Facial / Body Prosthesis – Other** (Maxillofacial Laboratory – Laboratory 239)	**Class I**

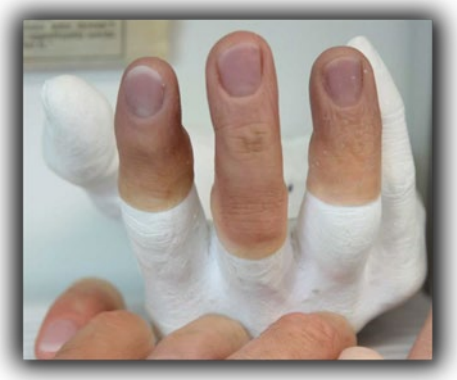
Surgical / Surgical Support		
1.	**Osteotomy Wafer Family** (Maxillofacial Laboratory – Laboratory 125)	**Class IIa** (Maxillofacial Laboratory – Laboratory 147)
2.	**Surgical Guide Family** (Maxillofacial Laboratory – Laboratory 159)	Highest Risk -> **Class IIa** Lowest Risk -> **Class I** (Maxillofacial Laboratory – Laboratory 163)
3.	**Silver Disimpaction Plate Family** (Maxillofacial Laboratory – Laboratory 127)	**Class I** (Maxillofacial Laboratory – Laboratory 146)
4.	**Prebent Archbar Family** (Maxillofacial Laboratory – Laboratory 122)	**Class IIa** (Maxillofacial Laboratory – Laboratory 145)
5.	**Eyelid Weight Family** (Maxillofacial Laboratory – Laboratory 123)	**Class IIb** (Maxillofacial Laboratory – Laboratory 136)
6.	**Oral Healing Plate Family** (Maxillofacial Laboratory – Laboratory 120)	**Class IIa** (Maxillofacial Laboratory – Laboratory 133)
7.	**Custom Titanium Implant (Facial) Family** (Maxillofacial Laboratory – Laboratory 243)	**Class IIb**
8.	**Custom Titanium Implant (Body) Family** (Maxillofacial Laboratory – Laboratory 242)	**Class IIb**
9.	**Silicone Custom Implants Family** (Maxillofacial Laboratory – Laboratory 237)	**Class IIb**

Splints		
1.	**Pressure Formed Splint Family** (Maxillofacial Laboratory – Laboratory 124)	**Class IIa** (Maxillofacial Laboratory – Laboratory 134)
2.	**Burns Facial Splint Family** (Maxillofacial Laboratory – Laboratory 161)	**Class IIa** (Maxillofacial Laboratory – Laboratory 165)
3.	**Burns Hand Splint Family** (Maxillofacial Laboratory – Laboratory 241)	**Class IIa**

Custom Devices

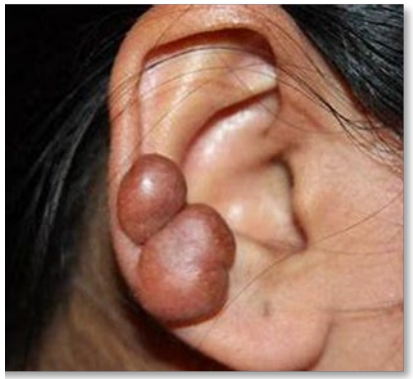


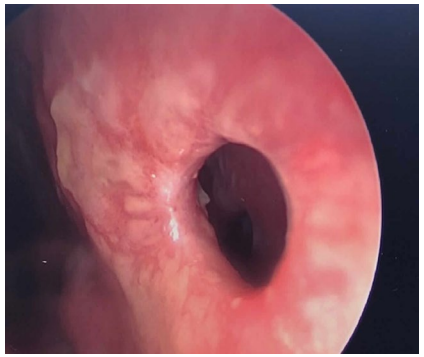




Prosthetics

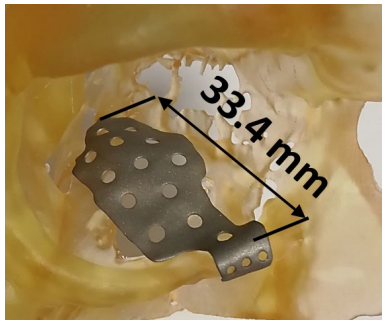
Class 1

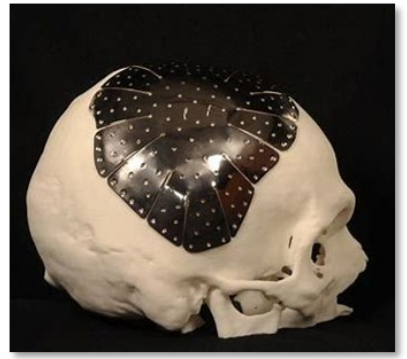


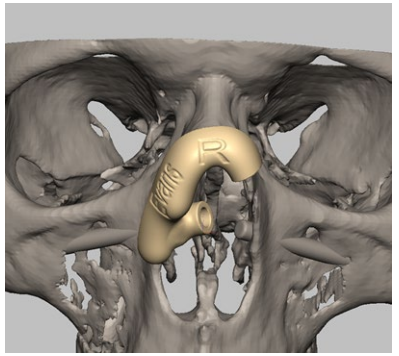


Splints

Class 2a



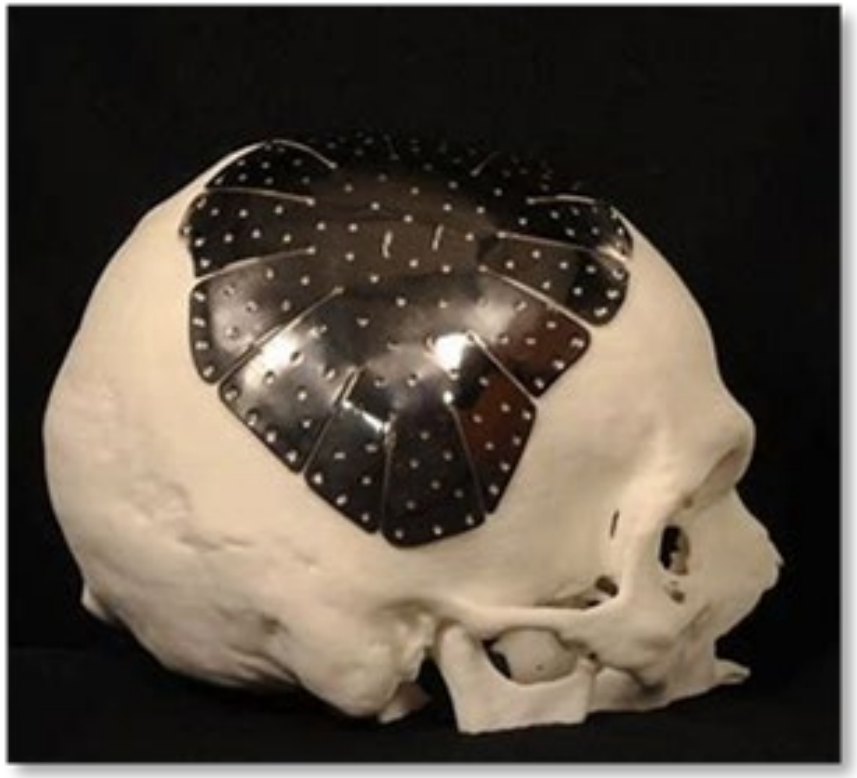


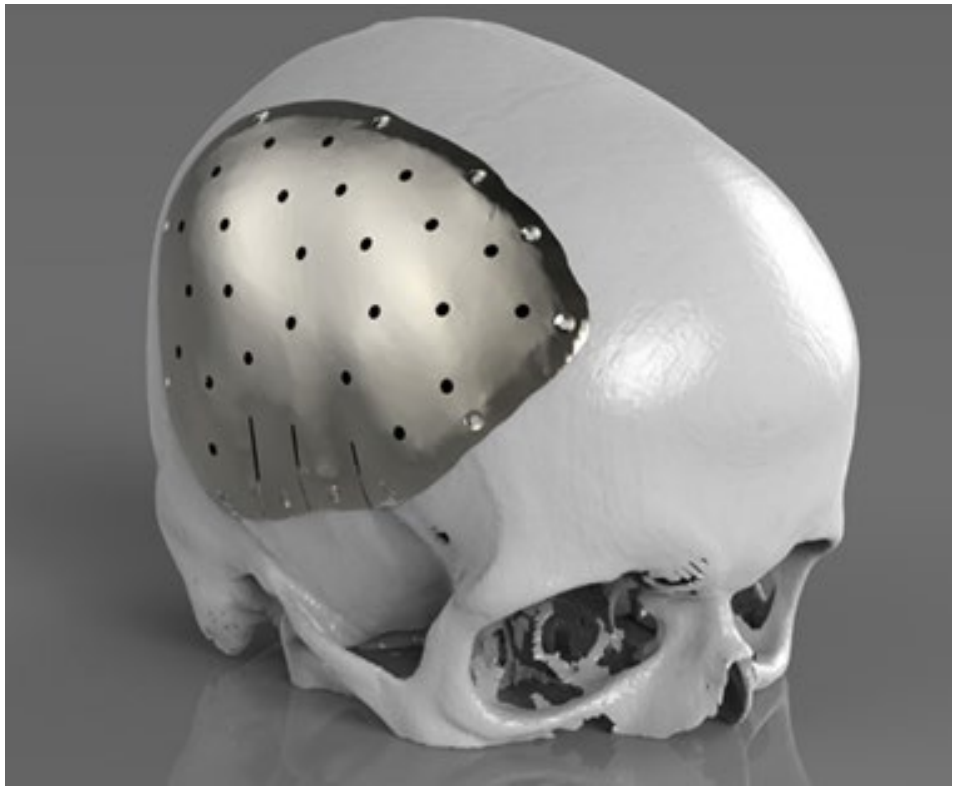


Implants

Class 2b

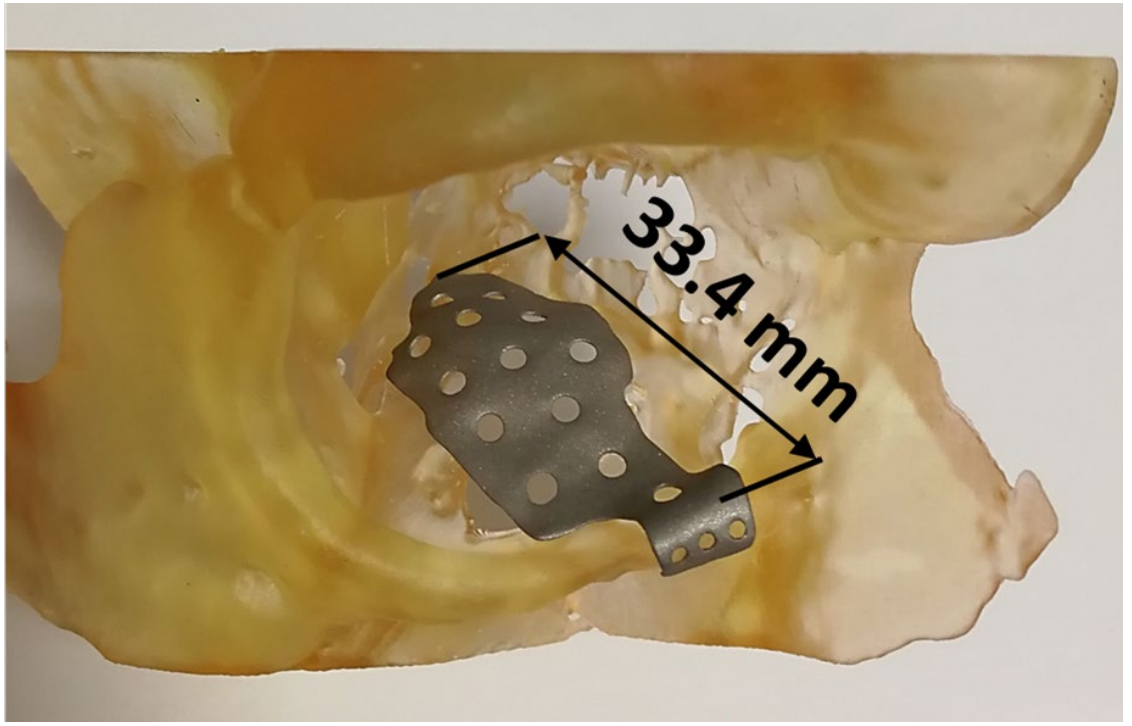
The effects of ISO 13485





Pressed cranioplasty plate versus printed/milled

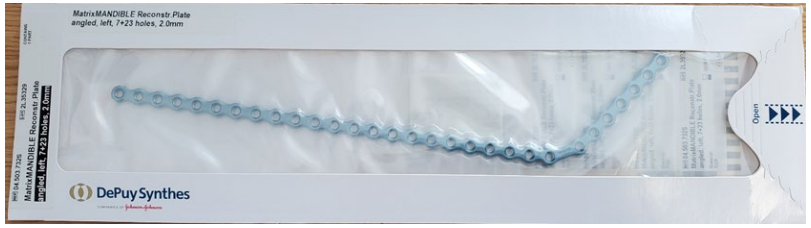
The effects of ISO 13485



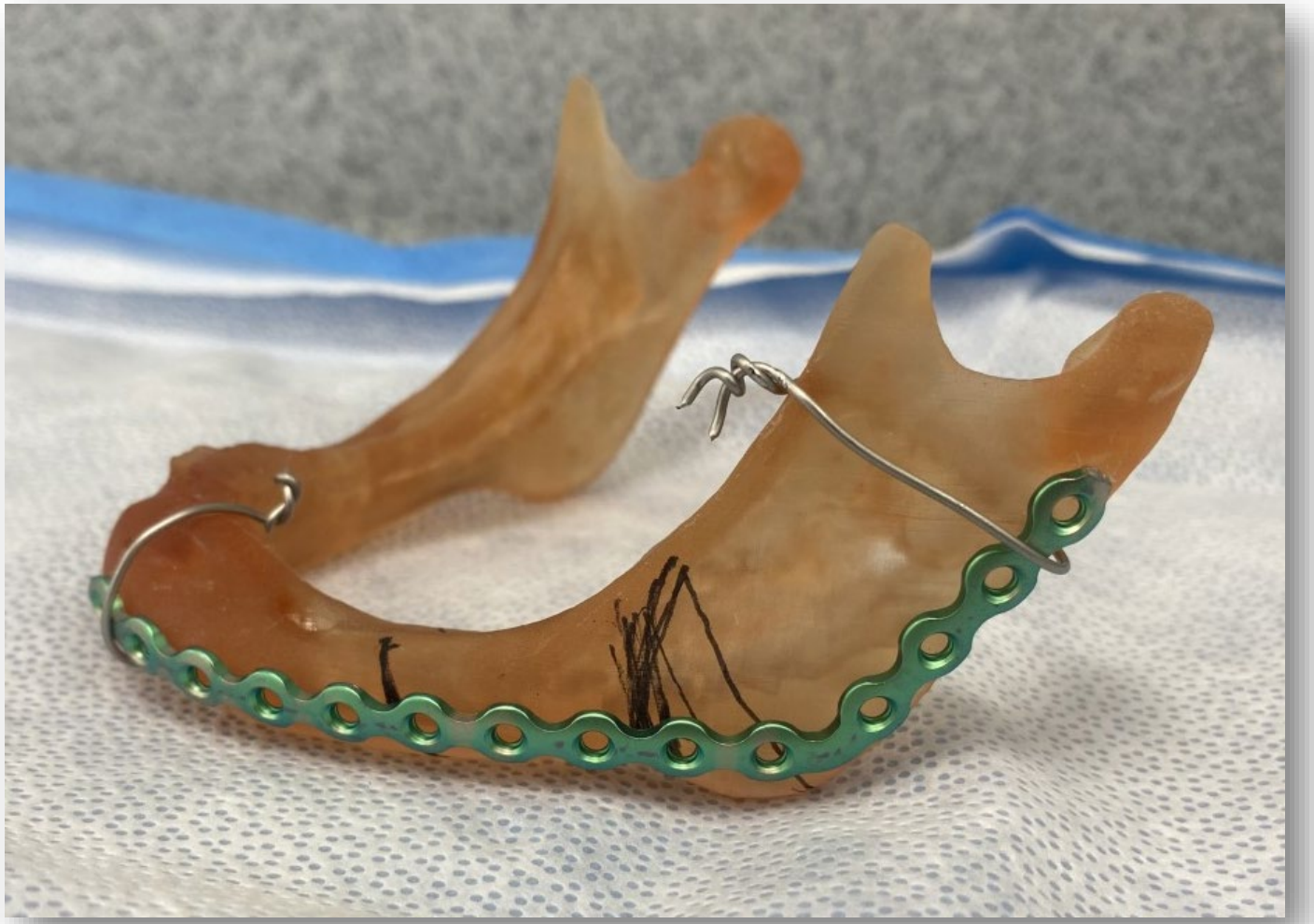
Pressed orbital floor plate versus printed/milled

Non Custom Devices ready 24 -48 hours

Open Tray Kit



Sterile Packaging

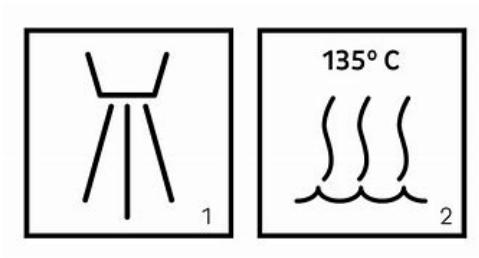


DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

KLS martin
GROUP

Supplier ?

Manufacturer ?



Sterile Services

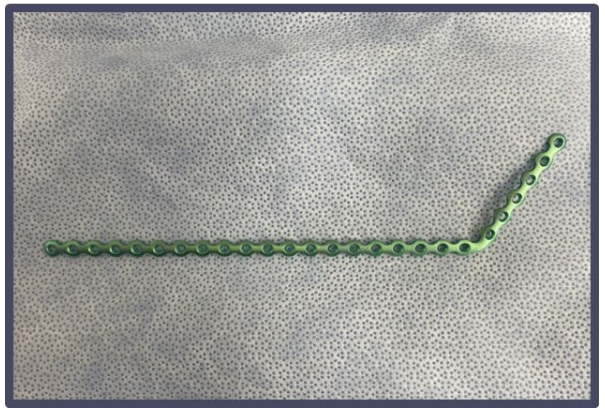
User

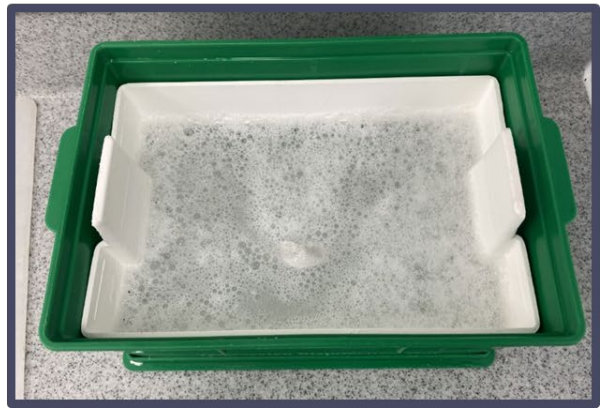
Maxillofacial Laboratory, Swansea Bay University Health Board

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

IMPT INSTITUTE OF MAXILLOFACIAL PROSTHETISTS & TECHNOLOGISTS

Healthcare Science Cymru
Delivering tomorrow, today!





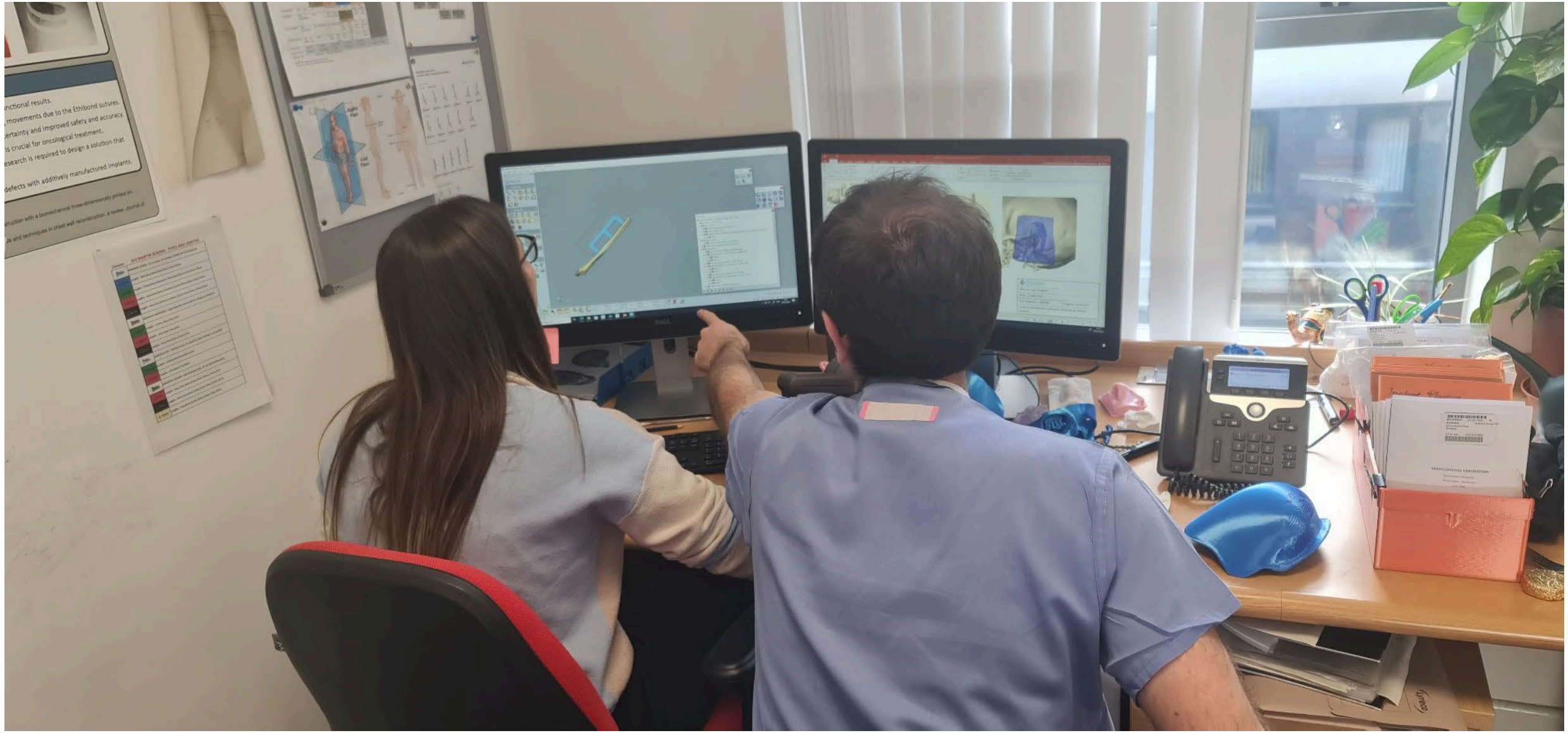
Maxillofacial Laboratory, Swansea Bay University Health Board

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

IMPT INSTITUTE OF MAXILLOFACIAL PROSTHETISTS & TECHNOLOGISTS

Healthcare Science Cymru
Delivering tomorrow, today!

Access to planning services

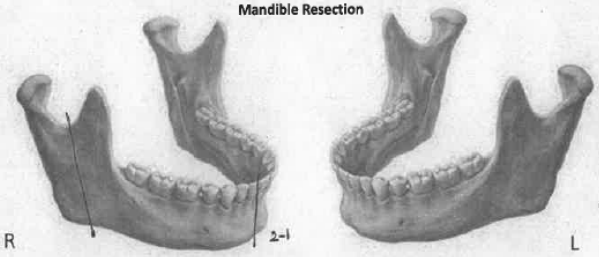


Maxillofacial Laboratory Mandible/Fibula Planning Request

Patient label

Surname	First Name	
Hospital Number	DOB / /	
Address		
Request consultant 1 NW	Request consultant 2 KS	Request date 6 / 3 / 24
CT Head available (Y) N	Download date 2 / 3 /24	Lab Number 12345.
CT Leg available (Y) N	Download date 4 / 3 /24	Notes 2 procs fib.

Mandible Resection

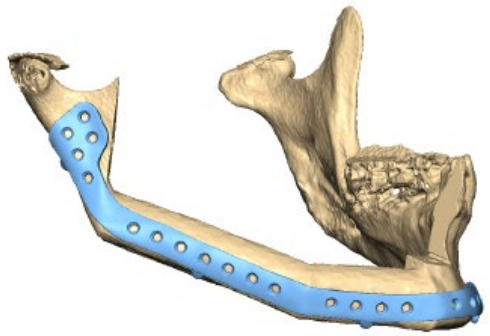


Left / Right leg (circle)	Plan agreed and confirmed (initials) MHZ
Surgery date 12 / 3 / 24	Working days available for completion 6
Pre-bent plate Manufacturer size	Custom Plate Manufacturer orthoscape.
Design/Plan Revisions	Colin Number

date / /	Description
	Initials
date / /	Description
	Initials
date / /	Description
	Initials

Medical Device for Print Approval

Patient Initials	PE
Patient Lab Number	12345
Surgery Date	7/3/24
Surgery Description	fibula free flap
Manufacturer Reference (if known)	Orthoscape



Design version 1

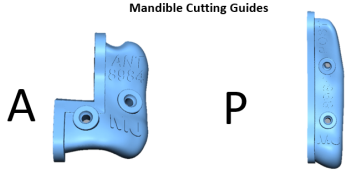
I would like to change the design or stop production ○

I approve the above design for manufacture ●

DA form version 2 .0 23/1/24

Free Flap Plan - **HEAD**

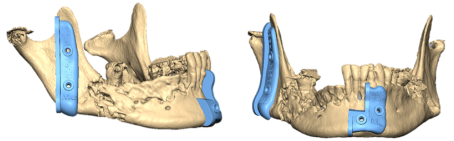
Mandible Cutting Guides



Guide Screw Hole Diameter: *2.0 mm*

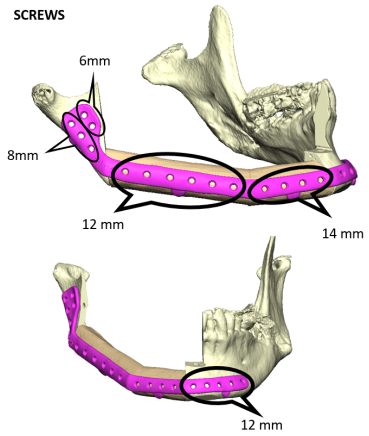
Guide Screw Hole Length: *8mm*

Guides In Place



Patient: evans
Hospital Number:12345
Plan Number: CN8984 & CN9473
Date: 28/02/24
Surgery Description: Mandibular Reconstruction with fibula

SCREWS

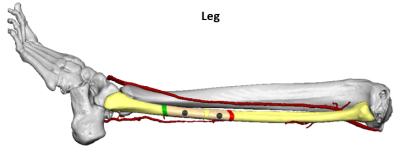


Screw Manufacture: *Synthes*
Screw Type: *Non-Locking*
Screw Length:
2 x 6 mm
3 x 8 mm
11 x 12 mm
4 x 14 mm

Patient: evans
Hospital Number: 12345
Plan Number: CN8984 & CN9473
Date: 28/02/24
Surgery Description: Mandibular Reconstruction with fibula

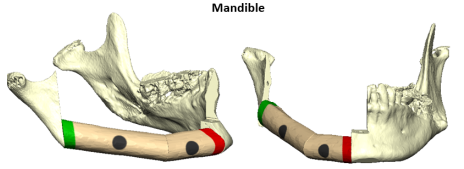
PEDICLE DIRECTION

Leg



Leg Side: *Left*
Pedicle Direction: *Anterior*

Mandible



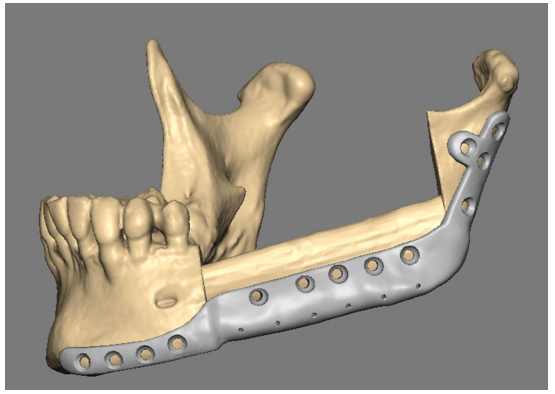
Patient: evans
Hospital Number: 12345
Plan Number: CN8984 & CN9473
Date: 28/02/24
Surgery Description: Mandibular Reconstruction with fibula

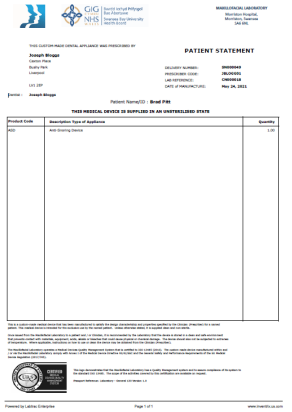
Custom Devices (Class 2b)

- Manufactured specifically in accordance with a written prescription of a registered medical practitioner.

- Supply a statement to the patient with details of clinician, manufacturer etc.

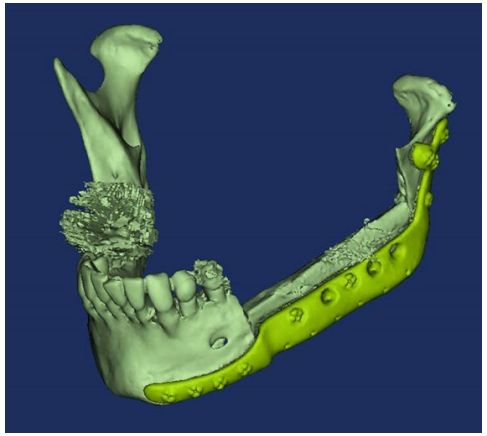
- Have evidence of post market surveillance





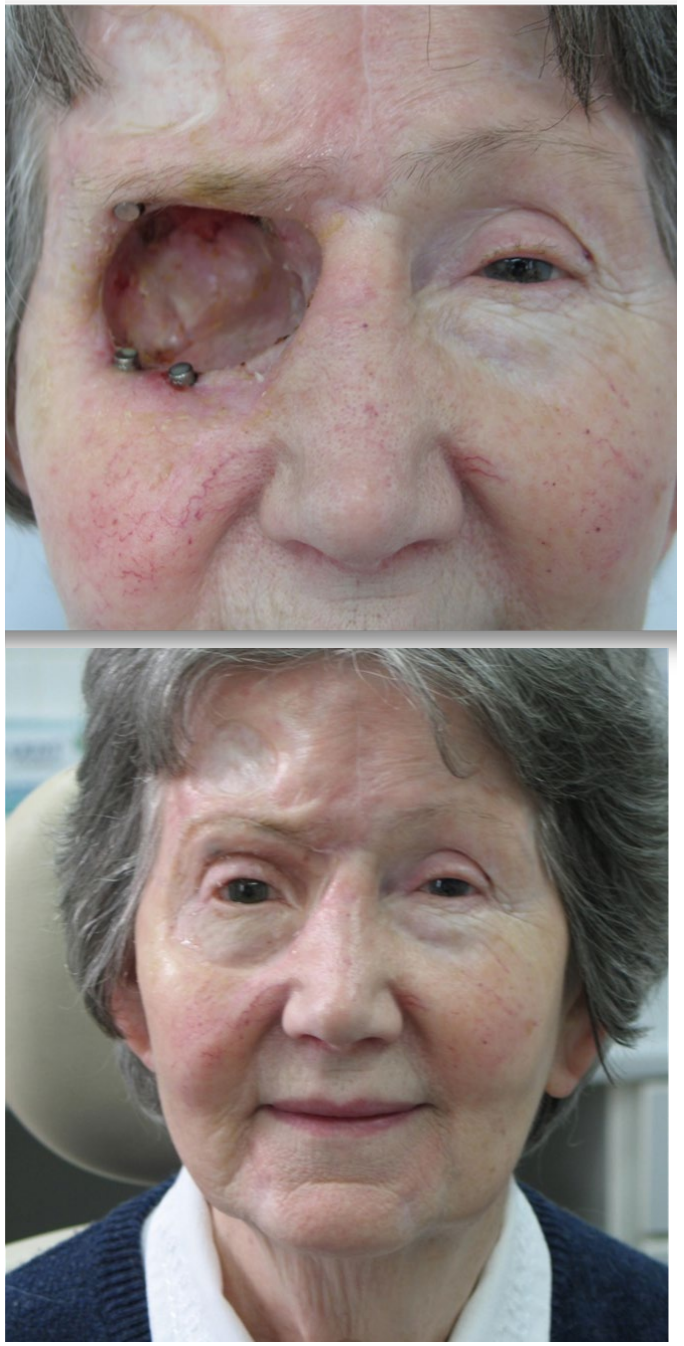
PATIENT STATEMENT

THIS MEDICAL DEVICE IS SUPPLIED IN AN UNSTERILISED STATE



Conclusions

- Iso certification….a journey!
- Need to flexible and the QMS needs to work for us
- Has been an increase in manufacturing times
- Innovation ?



Diolch yn fawr Vielen Dank

Thank you