PERSONALIZED SURGERY SOLUTIONS RAPID DESIGN & MANUFACTURING OF SURGICAL GUIDES

### **3D LIFEPRINTS**

### **Rapid Guide Manufacture**



## 'A surgical guide in five days'

"We received word of this urgent incoming osteosarcoma case on a Friday. The scans were with us Monday. The surgeon had our fully segmented, digital model for virtual surgery by Tuesday. With cuts agreed, our engineer had the surgical guide designed, manufactured, and ready for sterilisation by the hospital Thursday morning. The guide was used in surgery that day."

Henry Pinchbeck, CEO, 3D LifePrints

#### **Developing Rapid Guide Manufacture**

When it came to urgent osteosarcoma, maxillofacial, trauma, or limb reconstruction cases, we recognised the growing need for precise surgical guides delivered as fast as possible.

Our work with Oxford University Hospitals and other leading osteosarcoma centres around the UK, combined with our new manufacturing facilities at our hub in the Nuffield Orthopaedic Centre, allowed us to refine our service.

3D LifePrints' Rapid Guide Manufacture can now take your timeline for surgical guides down from weeks to days. For you and your patient, this can mean less time in surgery, greater procedural accuracy and safety, and outcomes more in line with what you envision.



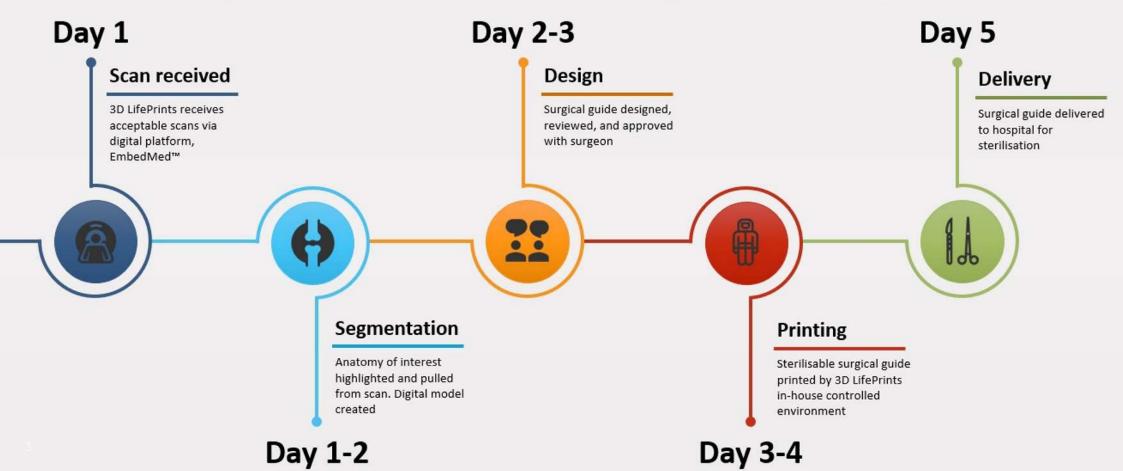
### **Rapid Guide Manufacture**



### Timeline

## Rapid Guide Manufacture Service

5 day turnaround service dependent upon on extreme level of surgical urgency and scan quality being compatible with 3D LifePrints' protocols designed to ensure quality medical devices that adhere to our ISO 13485 standards. Typical service time of 10 working days advised.



This patient presented with a chondrosarcoma and a last minute request was made to 3D Lifeprints to provide sterilisable surgical cutting guides to aid in a PII/PIII resection of the right hemipelvis. The scans were segmented, surgery planned, and model and guide approved, manufactured and sterilised inside 72 hours of receipt of the scans and instruction.

### **Description**

Upon receiving the patient's PET CT scan, 3D LifePrints segmented the imagery to build the virtual model of the pelvis and tumour. The tumour boundary was grown by a 10mm margin, as instructed. The optimal cutting planes were then agreed upon by the surgeon and the biomedical engineer.

The first guide provided allowed for an accurate tri-planar cut through the acetabulum from the lateral aspect. The accuracy of the cuts allowed the surgeon to keep enough bone stock for an effective reconstruction. A second guide for the Pubic Symphysis was created but only used as a reference template for the osteotomy. The guides and models were designed and printed in 3D LifePrints' controlled environment facilities located within its Nuffield Orthopaedic Centre hub. Optimally, we would ask for 10-14 days to complete this service, having the facility onsite allows us to meet very tight turnarounds in emergency situations.

Blade - 0.89mm

### **3D LIFEPRINTS**

### **CASE STUDY**

# ONCOLOGICAL PRE-SURGICAL PLANNING, VIRTUAL SIMULATION, SURGICAL GUIDE

**HOSPITAL** NUFFIELD ORTHOPAEDIC CENTRE

PROCEDURE PII/PIII HEMIPELVECTOMY

**DEVICE** 3D PRINTED PATIENT SPECIFIC ANATOMICAL MODEL AND SURGICAL GUIDE (POLYAMIDE)



## OUTCOME / BENEFITS

Use of the model in pre-surgical planning, and the surgical guide in theatre, meant the surgical approach could be limited to posterior extensile Kocker Langenbeck approach. Significant operative time was saved and bone stock was preserved, excluding use of augments to support the Lumic Cup (Implantcast).

Clear margins were confirmed in post operative tests, confirming complete removal of the tumour tissue.

This patient presented with a non-symptomatic Grade I chondrosarcoma that had been picked up in a routine scan for a separate investigation. The tumor was small and localised in their left ilium, and the surgeon planned to do a targeted, bone-conserving resection that preserved the integrity of the ilium whilst maintaining safe margins.

3D LifePrints was asked to design and deliver a novel sterilizable surgical drill guide that allowed for this.

### **Description**

Simpleware Medical ScanIP was used to segment both bony structures from the patient's CT scan (a 1 mm slice of the left ilium) and tumor structres from the MRI. These were combined in Simpleware to create a virtual model. The tumor was then grown digitally by 10mm to create a safe surgical margin and highlighted for better visualization.

The consultant determined their ideal path for resection and 3D LifePrints' devised a patient-specific, circular drilling channel guide for use in theater.

The surgical guide was printed in Biomed Clear, a biocompatible, sterilizable material on a Formlabs 3B Printer, and delivered to the surgical team alongside a 3D printed anatomical model for intra-operative reference. The guide was printed in 3D LifePrints' controlled environment facilities, located within its Nuffield Orthopaedic Centre hub (UK).

### **3D LIFEPRINTS**

### **CASE STUDY**

# ONCOLOGICAL PRE-SURGICAL PLANNING, VIRTUAL SIMULATION, SURGICAL GUIDE

**HOSPITAL:** NUFFIELD ORTHOPAEDIC CENTRE **PROCEDURE:** TARGETED RESECTION OF ILIUM

**DEVICE:** 3D PRINTED PATIENT SPECIFIC ANATOMICAL MODEL AND SURGICAL GUIDE



## OUTCOME / BENEFITS

The surgery was extremely straightforward and completed within an hour. The guide fitted well and once the drill holes were made the surgeon was able to easily complete the osteotomy with a uni sawblade. The surgical team appreciated the level of precision the guides enabled and were able to salvage all of the sacroiliac joint, whilst also avoiding disturbance of any neurovascular structure. Sectioning of the tumor showed good margins.

Post-operatively, the patient experienced a quick rehabilitation period and was able to return home after 48 hours.

A request was made to 3D LifePrints by the Nuffield Orthopaedic Centre to provide sterilizable surgical guides to assist in the partial removal of a patient's pelvis (left side) due to it being compromised by tumorous tissues.

A fast-track service was required to meet the urgent surgery date for the resection of the sarcoma.

### **Description**

3D LifePrints used Simpleware Medical ScanIP to segment the patient's latest CT and MRI scans to build a virtual model of the left hemipelvis. The sarcoma within was digitally grown by a 15mm margin and highlighted in order for the consultant to determine optimum surgical cutting planes.

The first guide allowed for a bilateral cut through the ilium for the lateral aspect. The second guide allowed for a single cut through the pubis. The third guide directed a single cut through the ischium.

All three guides were printed in Biomed Clear, a clear, sterilizable material on a Formlabs 3B printer, at 3D LifePrints' controlled environment facilities, housed within its Nuffield Orthopaedic Centre hub (UK).

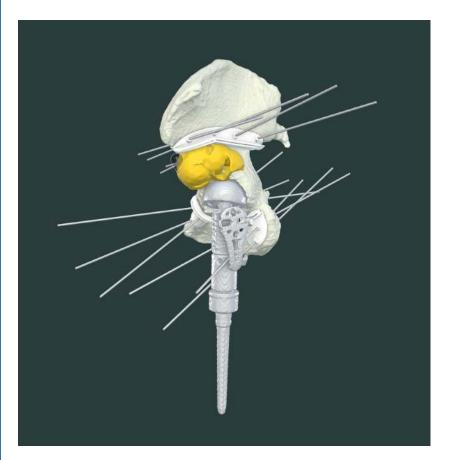
### **3D LIFEPRINTS**

### **CASE STUDY**

## ONCOLOGICAL PRE-SURGICAL PLANNING, VIRTUAL SIMULATION, SURGICAL GUIDE

**SPECIALITY:** ORTHOPAEDIC ONCOLOGY **PROCEDURE:** PI/II HEMIPELVECTOMY

**DEVICE:** 3D PRINTED PATIENT SPECIFIC ANATOMICAL MODEL AND SURGICAL GUIDES



### OUTCOME / BENEFITS

- Rapid turnaround of the design and manufacture of the model and guides was achieved (within one week)
- Pre-operatively, the surgical team used the anatomical model and guides to engage the patient with thorough discussion regarding tumor re-recurrence and the metastasis of the tumour.
- Intra-operatively, the guides fitted optimally and allowed for a single posterior extensile approach to be used. Significant operative time was saved.

A patient's previous fracture had malunited, causing reduced range of motion in their wrist.

3D LifePrints were asked to provide a patient-specific open wedge osteotomy cutting guide to allow the surgeon to accurately realign articulating cartilage with the carpals of the hand in an effort to restore mobility in the wrist.

A standard plate would also be implanted using 3D LifePrints' predetermined drilling locations to secure realignment.

### **Description**

3D LifePrints used Simpleware Medical ScanIP to segment CT scans of both the patient's left and right (affected) wrist anatomy. The left side was mirrored and the right side orientated to match the radiocarpal alignment present in the left side.

The optimum location of the cutting planes were identified by the surgeon and converted by the biomedical engineer into a surgical guide which would allow accurate recreation of the cuts in theater.

The guide was printed in Biomed Clear, a biocompatible, sterilisable material on a Formlabs 3B printer, and delivered to the surgical team. The guide was printed in 3D LifePrints' controlled environment facilities, located within its Nuffield Orthopaedic Centre Hub (UK).

### **3D LIFEPRINTS**

### **CASE STUDY**

# ORTHOPAEDIC PRE-SURGICAL PLANNING, VIRTUAL SIMULATION, SURGICAL GUIDE

**SPECIALITY: ORTHOPAEDIC** 

PROCEDURE: RADIOCARPAL REALIGNMENT VIA OPEN WEDGE OSTEOTOMY

DEVICES: 3D PRINTED PATIENT SPECIFIC ANATOMICAL MODEL AND SURGICAL GUIDE



### **OUTCOME / BENEFITS**

Pre-surgical planning with the virtual model, and use of the patient-specific guide intra-operatively, resulted in time saved during theater. Accuracy in the cuts to the bone, and securing of the implant, also improved the procedural outcome.

Realignment surgery proved to be a success with post-op x-rays showing good placement of the plate and alignment of the radiocarpals.

A patient presented with an atypical impending fracture, potentially caused by bisphosphonate infusion. A closing wedge osteotomy for tri-planar correction was required to restore biomechanical function of the femur.

The orthopaedic surgeon requested patient-specific anatomical models for pre-surgical planning and simulation, as well as surgical cutting guides which would be used in theatre.

### **Description**

3D LifePrints segmented the patient's CT scan to build a virtual model of the patient's femur. In collaboration with the surgeon, optimum cutting planes for the osteotomy were decided upon.

The biomedical engineer then designed a surgical cutting guide which would allow the surgeon to recreate these cuts accurately in theatre. The guide was printed in sterilisable material at 3D LifePrints' controlled environment and delivered to the hospital's team for sterilisation.

A replica of the femur was printed in wood-like material to allow the surgeon to practice the procedure with a dummy guide before live surgery.

### **3D LIFEPRINTS**

### **CASE STUDY**

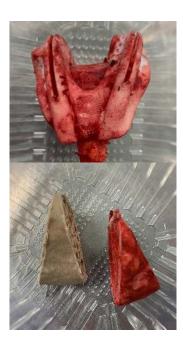
# ORTHOPAEDIC PRE-SURGICAL PLANNING, SIMULATION, SURGICAL GUIDE

SPECIALITY: ORTHOPAEDIC

**PROCEDURE:** CLOSING WEDGE OSTEOTOMY

**DEVICES:** 3D PRINTED PATIENT SPECIFIC ANATOMICAL MODEL AND SURGICAL GUIDE





### OUTCOME / BENEFITS

The combination of advanced pre-surgical planning, active procedural simulation, and use of the custom surgical guides in theatre saved significant time during the actual procedure.

Post-op X-rays showed a tight fit between the proximal and distal sections of the femur, owing to guide use, with the large surface area of both halves lining up well for better osseointegration as the patient recovers.

A femoral stem was also put in place and a total hip replacement successfully carried out in a single staged surgery.

### **3D LIFEPRINTS**

### **Rapid Guide Manufacture**



## Ensuring quality manufacturing



## Controlled environment

3D LifePrints is able to manufacture 3D printed sterilisable surgical guides and anatomical models within its controlled environment facilities in the Nuffield Orthopaedic Centre, Oxford.

The controlled environment undergoes regularly scheduled cleaning, monitoring, and maintenance to ensure adherence to ISO 13485 standards, so that our customers can rely on our rapid service.

### ISO 13485 Certification

3D LifePrints achieved the vital ISO 13485 quality certification in 2021, ensuring it meets the most current regulatory requirements specific to the design, manufacture, and distribution of medical devices.

It is underpinned by 3D LifePrints' Digital Platform, EmbedMed™, which forms the backbone of its Quality Management System by guiding our engineers' design and production of any medical device through strict processes.

The in-house controlled environment and ISO certification have brought our ability to provide surgical guides down from weeks to days.

### **3D LIFEPRINTS**

### **Rapid Guide Manufacture**



## EmbedMed - Digital management of production

**Secure Cloud-based Platform** accesible over a wide variety of technologies

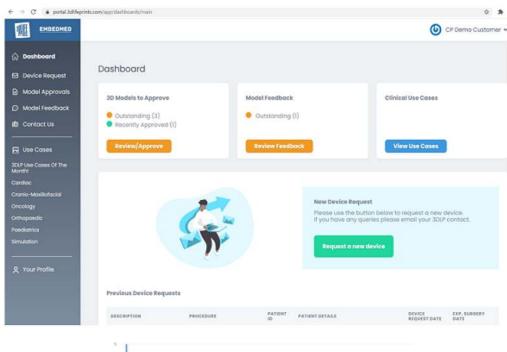
Surgeons can **easily order new medical devices** such as Anatomical Models and Surgical Guides

Apprved cutting planes and footprints from virtual surgery shown within client portal following virtual

Pre and post op-visualisation available

Advanced visualisation capabilities for surgeons to **review and approve** segmented patient data and virtual models

Case by case **feedback functionality**, capturing the benefits of the device used during the procedure, including time saved and improved outcomes







## RAPID GUIDE SERVICE

WE PRIDE OURSELVES
ON PROVIDING
OUTSTANDING CLIENT
SERVICE, AND ARE
ALWAYS AVAILABLE FOR
A DISCUSSION

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