



RAPID DESIGN & MANUFACTURING OF SURGICAL GUIDES



'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, Insight Surgery

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.

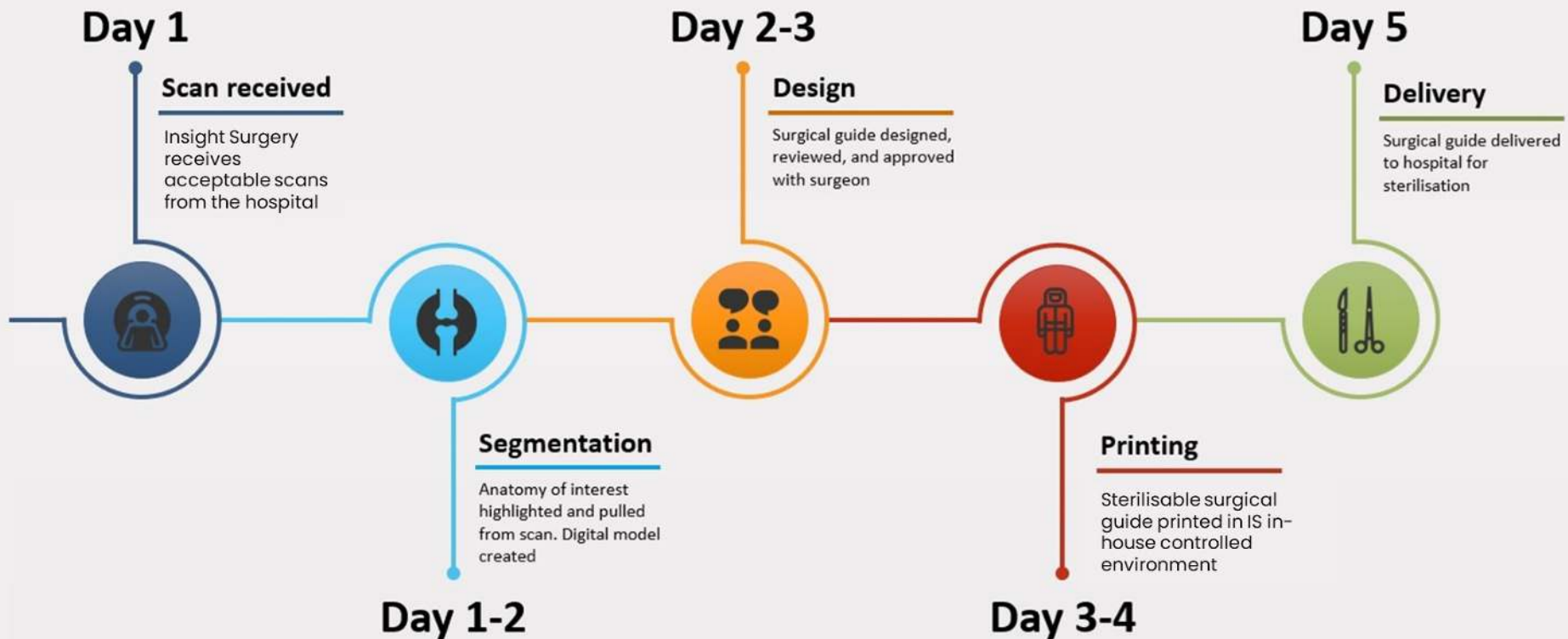
Insight Surgery's Rapid Guide Manufacture can now take your timeline for surgical guides down from weeks to days. For you and your patient, this can mean less time in surgery, greater procedural accuracy and safety, and outcomes more in line with what you envision.



Timeline

Rapid Guide Manufacture Service

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



CASE SUMMARY

This patient presented with a chondrosarcoma and a last minute request was made to Insight Surgery 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, Insight Surgery 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 Insight Surgery's controlled environment facilities located within its Nuffield Orthopaedic Centre hub.

HOSPITAL: NUFFIELD ORTHOPAEDIC CENTRE

PROCEDURE: PII/PIII HEMIPELVECTOMY

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



OUTCOME / BENEFITS

The 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.

INSIGHT SURGERY
CASE STUDY

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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 /
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CASE SUMMARY

This patient presented with a non-symptomatic Grade 1 chondrosarcoma that had been picked up in a routine scan for a separate investigation. The tumour 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.

Insight Surgery were 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 tumour structures from the MRI. These were combined in Simpleware to create a virtual model. The tumour 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 Insight Surgery's devised a patient-specific, circular drilling channel guide for use in theatre.

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 Insight Surgery's controlled environment facilities, located within its Nuffield Orthopaedic Centre hub (UK).

INSIGHT SURGERY 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 tumour showed good margins.

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

CASE SUMMARY

A request was made to Insight Surgery 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

Insight Surgery 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 Insight Surgery's controlled environment facilities, housed within its Nuffield Orthopaedic Centre hub (UK).

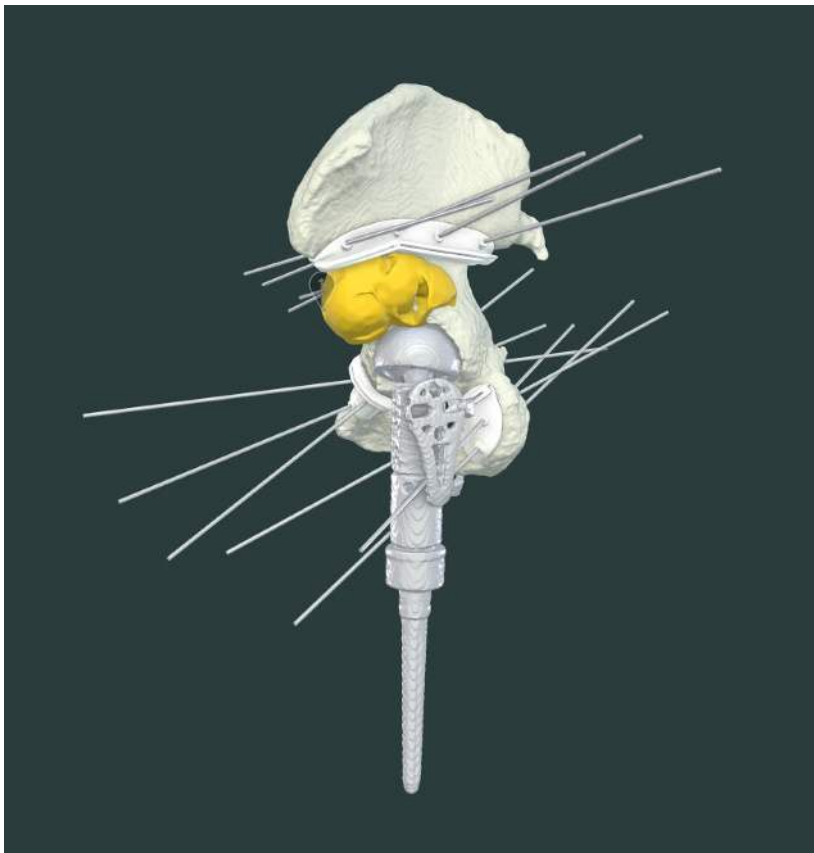
INSIGHT SURGERY CASE STUDY

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 in a thorough discussion regarding tumour 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.

CASE SUMMARY

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

Insight Surgery was 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 Insight Surgery's predetermined drilling locations to secure realignment.

DESCRIPTION

Insight Surgery extrapolated the anatomical region of interest from the CT scans of both the patient's left and right (affected) wrist anatomy. The left side was mirrored and the right side was orientated to match the radiocarpal alignment present on 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. The surgery was simulated using bone-mimicking material to imitate use of the guide and allow accurate recreation of the cuts in theater.

The surgical guide was 3D printed in Insight Surgery's in-hospital cleanroom manufacturing center and delivered to the surgical team for sterilization ahead of theater.

Blade - 1mm
Fixation - 1.6mm K-wires

INSIGHT SURGERY CASE STUDY

ORTHOPEDIC PRE-SURGICAL PLANNING, VIRTUAL SIMULATION, SURGICAL GUIDE

SPECIALTY: ORTHOPEDIC

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, physical model and the use of the patient-specific guide intra-operatively resulted in time saved during theater. In addition, this improved accuracy of the cuts to the bone, and securing of the implant, as well as an improved 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.

CASE SUMMARY

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

Insight Surgery 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 in Insight Surgery's 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.

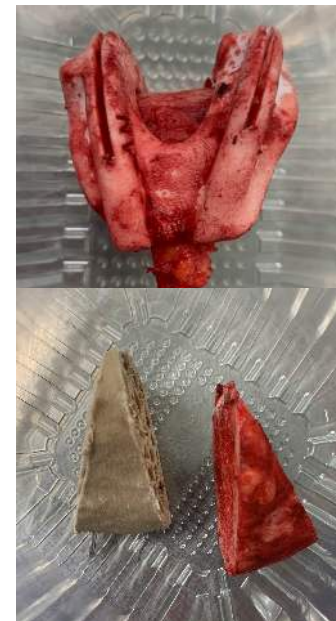
INSIGHT SURGERY CASE STUDY

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.

Ensuring quality manufacturing



Controlled environment

Insight Surgery 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

Insight Surgery 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 Insight Surgery's 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.

EmbedMed - Digital management of production

Secure Cloud-based Platform accessible over a wide variety of technologies

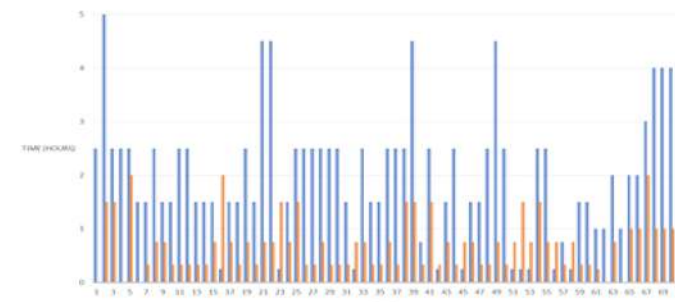
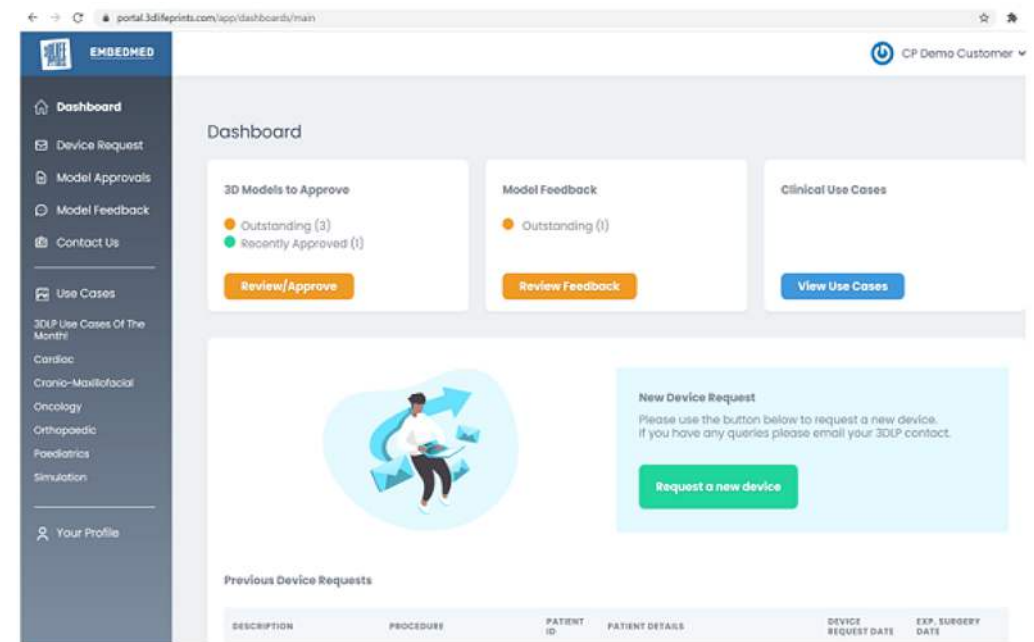
Surgeons can **easily order new medical devices** such as Anatomical Models and Surgical Guides

Approved **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





SURGICAL GUIDES

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

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