

Custom Device Initiation Form



Patient Consent

Please ensure this section is completed and patient consent has been received prior to sending this form and any CT scans to Signature Orthopaedics. Note, for patients in Australia and the US, verbal consent may be given, but for patients in the EU, QF-73-07-7 must be completed.

The patient has provided verbal consent to release the patient's information to Signature Orthopaedics to allow the design and manufacture of the custom device.

QF-73-07-7 Custom Device Consent Form has been completed - Please attach the completed consent form.

Personal Information

Patient Name

Surgeon Name

Business Address

Requirements of the Device

Target Area Joint

Why is this device required?

(specific details of the condition, prevalence of condition, other relevant information)

Is there a commercially available solution?

Scan Checklist

To ensure that the best possible outcome is achieved, the below details should be supplied to Signature Orthopaedics along with the scan data.

- Radiologist contact
- Surgeon name and contact
- Patient name and age
- Target of supplied scan

Please ensure:

- Scan follows the supplied protocol documented in "141-02-0302 CT Scan Protocol"
- Scan files are in DICOM format
- Supplied scan is the latest available

Device Design Inputs

Initial Surgeon Requirements

Does the device need to interface with an existing device?

(Implant or Instrument - design information may be required in regards to the fitment)

Surgical Approach

Additional relevant information

(existing trauma, implants, soft tissue limitations, etc.)

Signed

Date