SURGICAL TECHNIQUE

360 HIP
PATIENT SPECIFIC GUIDES (PSG) SYSTEM

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Parts List

The 360 Hip PSG System consists of parts in Table 1. The parts that are delivered to the hospital will depend on the surgeon's preference and the exact contents will be stated on the packaging label.
The parts listed in Table 1 are SINGLE USE, provided Non-Sterile and must be processed by the Central Sterile Services Department (CSSD) prior to use.

Table 1: 360 Hip PSG System Parts List

	REF No.	Part Name
1	2006-0100-00	Proximal Femur Bone Model (Step Cut)
2	2006-0200-00	Proximal Femur Bone Model (Oblique Cut)
3	2006-0300-00	Proximal Femur Bone Model (Resected)
4	2006-0400-00	Anterior Femur Guide (Step Cut)
5	2006-0500-00	Anterior Femur Guide (Oblique Cut)
6	2006-0600-00	Posterior Femur Guide (Step Cut)
7	2006-0700-00	Posterior Femur Guide (Oblique Cut)
8	2006-0800-00	Proximal Femur Stem Imprint Bone Model (Step Cut)
9	2006-0900-00	Proximal Femur Stem Imprint Bone Model (Oblique)

Consult the Instructions for Use (reference KIC-REC-RA-102) for important information pertaining to the product description, indications for use, contraindications, warnings and precautions, possible adverse effects and storage and handling information.

Please contact your product representative or 360 Med Care (compliance@360med.care) for the *360 Patient Specific Guides System Instructions for Use* (reference KIC-REC-RA-102), *Cleaning and Sterilisation of Single-Use Instruments* instructions (reference KIC-REC-RA-54) or further information.

Product Description

The 360 Hip Patient Specific Guides (PSG) System consists of anterior and posterior Guides and Bone Models.
For each patient, one 3D Visualisation (3DV) Report is provided to the surgeon pre-operatively. The 3DV Report contains 3D images of the requested 360 Hip PSG.

Intended Use

The 360 Patient Specific Guide (PSG) System is intended to be used as patient-specific surgical instruments to assist surgeons in the positioning of orthopaedic components intra-operatively and in guiding the marking and cutting of bone, provided that the required anatomical landmarks can be identified on pre-operative scans in patients requiring orthopaedic surgery.
The 360 PSG System is intended for single use only.

Indications

The 360 Hip PSG System is indicated for use with the outputs of the 360 Orthopaedic Planning and Analysis Software (OPAS).

Contraindications

The 360 Hip PSG System is contraindicated for:

- Patients for which THR is contraindicated
- Insufficient bone structure or quality, which may not allow for rigid attachment of instruments
- Other disorders that affect hip anatomy and bony landmark recognition

Compatible Equipment

- Steinmann pins of 3.175mm diameter are required for the through pin holes of the 360 Hip PSG System.
- A saw blade of thickness 1.27mm must be used with the 360 Hip PSG System.

General Warnings and Precautions

Caution: The 360 Hip PSG are supplied non-sterile to the hospital. It is the responsibility of the healthcare institution to clean and sterilise the 360 Hip PSG before use according to the instructions *Cleaning and Sterilisation of Single-Use Instruments* (reference KIC-REC-RA-54) provided with the device.

Caution: The 360 Hip PSG System is custom-made for a particular patient and must only be used for the patient identified on the packaging and on the parts.

Caution: Check the expiration date prior to use. Using expired 360 Hip PSG could result in non-optimum shape match between the Guide and the patient's bone which could lead to unpredictable outcomes in the orthopaedic surgery.

Caution: The 360 Hip PSG System is indicated for use with the implant system designated on the output of the 360 OPAS for the patient stated. Do not use the 360 Hip PSG System with incompatible pre-operative planning as it may compromise the effectiveness of the joint replacement.

Caution: If any 360 PSG System parts or accompanying information appear faulty or damaged and prevent the safe and effective use of the device, do not use the 360 PSG System, and contact 360 Med Care

Pre-operative Planning

The surgeon will receive a 360 Hip Pre-Operative Plan for each patient pre-operatively. The 360 Hip Pre-operative Plan indicates the component type, sizing and alignment that has been planned according to the surgeon's preferences.

The surgeon's preferences are used to determine the type of osteotomy used for the femoral neck resection i.e. step cut or oblique.

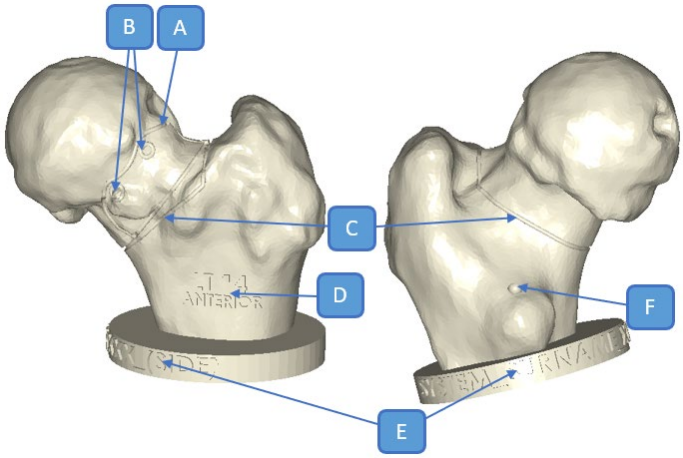
The surgeon must check the 360 Hip Pre-operative Plan and communicate to 360 Med Care if any changes to the planned parameters are required.

360 Hip PSG – Bone Models

Pre-operatively, the provided non-sterile Bone Models may be used by the surgeon for evaluation of anatomical guide positioning and contains traceability information as well as a measure of the perpendicular distance (mm) between the resection and the superior point of the lesser trochanter (in the stem coronal plane). Intra-operatively, sterilised Bone Models may assist in confirming anatomical guide position.

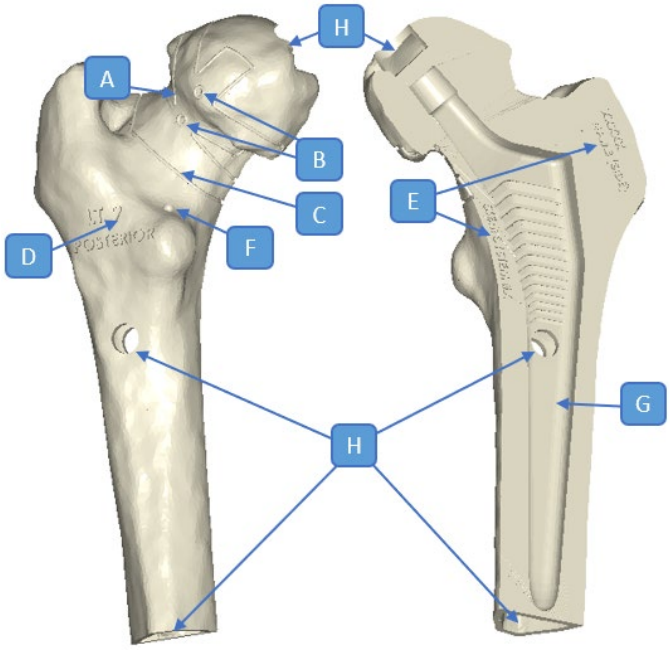
The Standard Bone Models provide the following reference information:

A. Guide registration area represented by continuous line
B. Pin hole locations
C. Planned resection (from the 360 Hip Pre-operative Plan)
D. Resection from lesser trochanter, and type of Guide/approach (Anterior/Posterior)
E. Implant System, Patient ID (Surname and case code number), Operative side (L/R)
F. Lesser trochanter landmark (optional)



The Stem Imprint Bone Models provide the following reference information:

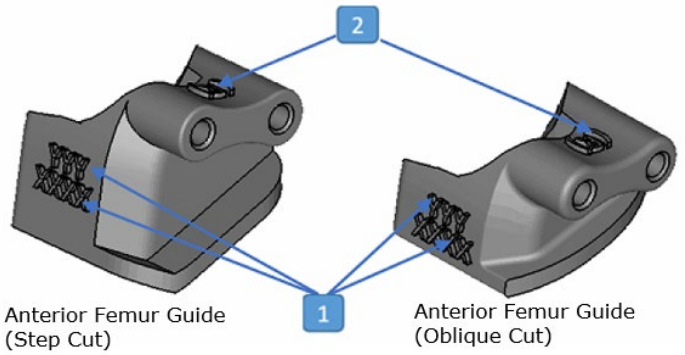
A. Guide registration area represented by continuous line
B. Pin hole locations
C. Planned resection (from the 360 Hip Pre-operative Plan)
D. Resection from lesser trochanter, and type of Guide/approach (Anterior/Posterior)
E. Implant System, Stem Size, Patient ID (Surname and case code number), Operative side (L/R)
F. Lesser trochanter landmark (optional and only available for posterior approach variant)
G. Stem Imprint
H. Ports to facilitate cleaning and sterilisation



360 Hip PSG - Anterior Femur Guide

The Anterior Femur Guide carries the following information:

1. Patient ID (case code number and/or patient's surname)
2. Operative side (L/R)

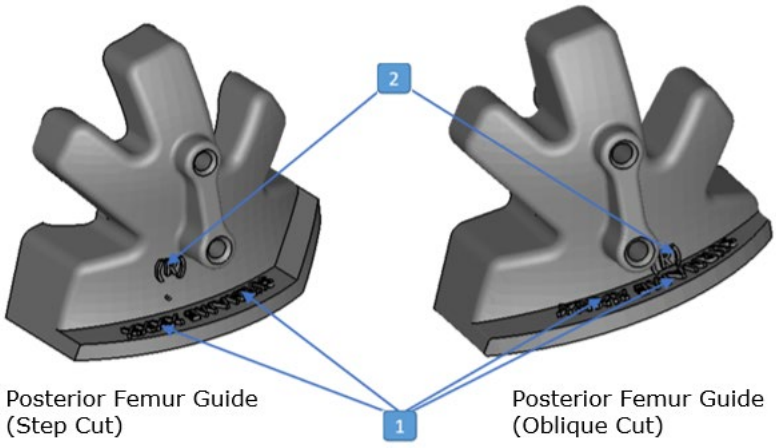


Please verify the accuracy of the patient-specific identifiers on the Anterior Femur Guide prior to use.

360 Hip PSG - Posterior Femur Guide

The Posterior Femur Guide carries the following information:

1. Patient ID (Case code number and/or patient's surname)
2. Operative side (L/R)



Please verify the accuracy of the patient-specific identifiers on the Posterior Femur Guide prior to use.

1. Exposure

Expose the bony anatomy of the proximal femur and prepare by removing as much soft tissue around the proximal femur as needed to allow for good exposure and optimal registration of the Guide.

Caution: Do not remove peripheral osteophytes as the 360 Hip PSG are designed to register on osteophytes.

Caution: The 360 Hip PSG are designed from CT-based data. Therefore, soft tissue around all Guide registration areas must be cleared prior to securing the Guide on the proximal femur to avoid improper seating of the Guide.

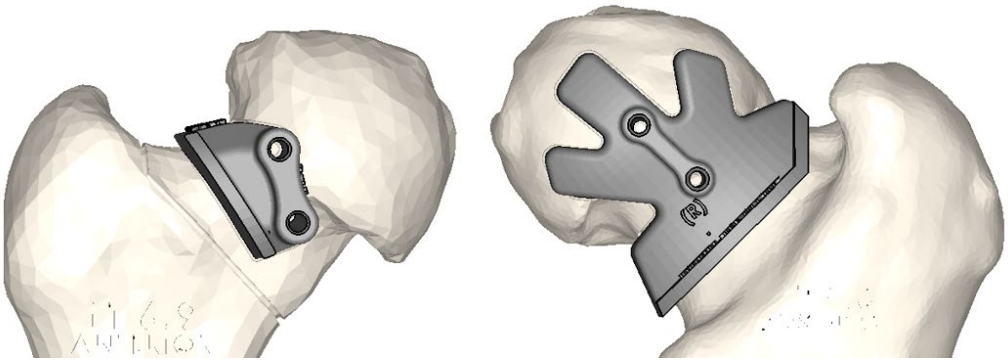
2. Registration

With the proximal femur exposed, register the Guide on the femoral neck.

Note: If the Guide position is questioned in surgery, reference the Femur Bone Model for the planned Guide registration area represented by the outline marked on the Bone Model.

Caution: An inaccurate placement or improper fit of the Guide may lead to cut parameters that do not follow the 360 Hip Pre-operative Plan. The 360 Hip PSG System must not be used if the Guides do not fit well on the patient's bones.

Caution: Pressure should only be applied to the portions of the Guide where in contact with bone.



Once the correct position of the Guide has been located, there should be little or no toggling if pressure is correctly applied.

Hold the Guide firmly in place and secure the Guide to the bone by inserting Steinmann pins (Ø3.175mm) through the two pin holes.

3. Resection

Prior to cutting, confirm the Guide position and resection by checking the Bone Model outlines and the 360 Hip Pre-operative Plan.

Place the saw blade flush onto the cutting surface of the Guide before engaging power. Execute the femoral neck resection.

Note: The resection defined by the Step Cut Femur Guide is designed to replicate the approved 360 Hip Pre-operative Plan. The resection defined by the Oblique Cut Femur Guide is designed to replicate the medial point of the planned resection. The final component position should be validated intra-operatively.

Remove the Steinmann pins and the Guide. Ensure the bone cuts are clean and clear of any under-cut bone fragments.

Caution: Perform the proximal femoral resection using a 1.27mm saw blade.

Symbols

Symbols with a reference number have been sourced from EN ISO 15223-1:2016.


5.1.4 Use by


5.1.3 Date of manufacture


5.1.5 Batch code


5.2.8 Do not use if package is damaged


5.4.4 Caution


5.4.3 Consult instructions for use


5.1.6 Catalogue Number


5.3.1 Fragile, handle with care


5.3.4 Store in a dry place


5.1.1 Manufacturer


5.4.2 Do not re-use


Recycle cardboard packaging


5.3.2 Keep away from sunlight

This document may be provided electronically. Paper-based instructions can be provided within 7 days of receiving a request. If provided electronically, it is recommended to download this document prior to surgery as an internet connection may not be available during use of the 360 PSG System.

This document is intended for the Australian and European market.