INSTRUCTIONS FOR USE

360 PATIENT SPECIFIC GUIDES (PSG) SYSTEM

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Product Description

The 360 Knee Patient Specific Guides (PSG) System consists of femur, tibia and patella patient-specific Guides and Bone Models.

The 360 Hip Patient Specific Guides (PSG) System consists of anterior and posterior patient-specific Guides and reference 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 PSG.

Intended Use

The 360 Patient Specific Guides (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 Knee PSG System is indicated for use with the OMNI Apex Knee System, DePuy Synthes Attune, MatOrtho Saiph or Implanet Madison Knee System, depending on the surgeon's request.

The compatible knee system is identified on the packaging label and on the Guide.

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

Contraindications

The 360 PSG System is contraindicated for:
- Patients for which the applicable joint replacement is contraindicated
- Insufficient bone structure or quality, which may not allow for rigid attachment of instruments
- Other disorders that affect applicable joint anatomy and bony landmark recognition

Parts List

The 360 Knee PSG System consists of parts listed in Table 1.

The 360 Hip PSG System consists of parts listed in Table 2.

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.

All parts are SINGLE USE, provided Non-Sterile and must be processed by the Central Sterile Services Department (CSSD) prior to use.

Table 1: 360 Knee PSG System Parts List

REF No.	Part Name
1507-0500-00	Distal Femur Bone Model
1507-0300-00	Femur Guide
1507-0600-00	Proximal Tibia Bone Model
1507-0400-00	Tibia Guide
1507-0200-00	Patella Bone Model
1507-0100-00	Patella Guide
1811-0700-00	Tibia Drop Rod Attachment
1811-0800-00	Femur Drop Rod Attachment

Table 2: 360 Hip PSG System Parts List

REF No.	Part Name
2006-0100-00	Proximal Femur Bone Model (Step Cut)
2006-0200-00	Proximal Femur Bone Model (Oblique Cut)
2006-0300-00	Proximal Femur Bone Model (Resected)
2006-0400-00	Anterior Femur Guide (Step Cut)
2006-0500-00	Anterior Femur Guide (Oblique Cut)
2006-0600-00	Posterior Femur Guide (Step Cut)
2006-0700-00	Posterior Femur Guide (Oblique Cut)

Please contact your product representative or 360 Med Care (compliance@360med.care), for the *Surgical Techniques* (reference KIC-REC-RA-101, KIC-REC-RA-931), *Cleaning and Sterilisation of Single-Use Instruments* instructions (reference KIC-REC-RA-54) or further information.

Materials

Materials have been selected in accordance with ISO or ASTM standards and are biocompatible for surgically invasive short-term use. The 360 PSG are additively manufactured from polyamide 12 (PA 2200).

Compatible Equipment

- Steinmann pins of the implant system's standard instruments are required for the through pin holes of the 360 Knee PSG System.
- 360 Patella Instruments or equivalent are required to use the 360 Patella Guide.
- 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 Knee and Hip PSG System.

Conditions Affecting Performance, Side Effects and Adverse Effects

Component positioning and orientation is achieved using a patient-specific shape matching Guide designed from patient imaging data. This may be affected by:
- Quality or age of medical scans
- Geometry of native bone not having any significant features to reproduce within the Guide.

Errors of operative technique and improper use of the 360 PSG System may result in:
- Malorientation or maltracking of the implant components, leading to joint pain and/or compromised joint function.

Adverse effects of any orthopaedic procedure include infection, venous thrombosis, pulmonary embolism, cardiovascular disturbances, vascular or nerve injury, osteolysis, periarticular ossification, allergy, pain.

Warnings and Precautions

- The 360 PSG System must be steam sterilised by autoclave only. Do not use other methods of sterilisation. For further information, refer to the *Cleaning and Sterilisation of Single-use Instruments* instructions (reference KIC-REC-RA-54) provided in the device packaging.
- The 360 PSG System is for single use only. Do not re-sterilise for re-use.
- The 360 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.
- Check the expiration date prior to use. Using expired 360 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.
- The 360 PSG are designed from CT-based data. All soft tissue and cartilage must be removed from areas where the Guides contact the patient's anatomy.
- The 360 Knee PSG System is indicated for use with specified TKA implant systems. Do not use the 360 Knee PSG system with incompatible implant systems as it may compromise the effectiveness of the joint replacement.
- 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.
- 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.

Restrictions on Use

- The 360 PSG System must only be used by registered orthopaedic surgeons.
- The 360 PSG System must only be used in a sterile field.
- The 360 PSG System must only be used for the patient identified on the packaging.
- The 360 PSG System must be used within the expiry date specified on the packaging.

Packaging

The 360 PSG System parts are delivered in protective non-sterile packing. The patient-specific Guides and Bone Models must be removed from packaging and placed in an appropriate container or wrap for cleaning and sterilisation. In the event the packaging is damaged, unintentionally opened before use or exposed to sunlight, heat or moisture, then the user must contact a 360 Med Care representative prior to use.

Handling and Storage

The 360 PSG System parts should be stored in surgical trays when not in use to prevent damage.

Parts should be stored in a limited access location, protected from sunlight, heat and moisture. Prior to cleaning and sterilisation, inspect all instruments for visible damage or debris. Damaged instruments must not be used.

Cleaning and Sterilisation

The 360 PSG System parts are provided non-sterile and it is the responsibility of the healthcare institution to clean and sterilise the parts. All parts must be removed from packaging for cleaning and steam sterilisation.

It is important that the autoclave is maintained and calibrated so that the required temperatures and durations of sterilisation cycles are observed. Refer to full instructions *Cleaning and Sterilisation of Single-use instruments* (reference KIC-REC-RA-54) provided in the device packaging.

Operating Instructions

For complete operating instructions of the 360 Knee PSG System, refer to the *360 Knee PSG Surgical Technique* (reference KIC-REC-RA-101).

For complete operating instructions of the 360 Hip PSG System, refer to the *360 Hip PSG Surgical Technique* (reference KIC-REC-RA-931).

Disposal

Any non-functional parts should be immediately returned to 360 Med Care.

Single use parts can be disposed of using the standard clinical waste procedures of the healthcare institution.

Disclosure of Residual Risk

Within the 360 PSG system there remains a risk that the Guides may not fit well on the native bones due to incorrect positioning of the Guides, improper removal of soft tissue or due to the change in bony structures since patient imaging was acquired which could lead to malorientation of the implant components.

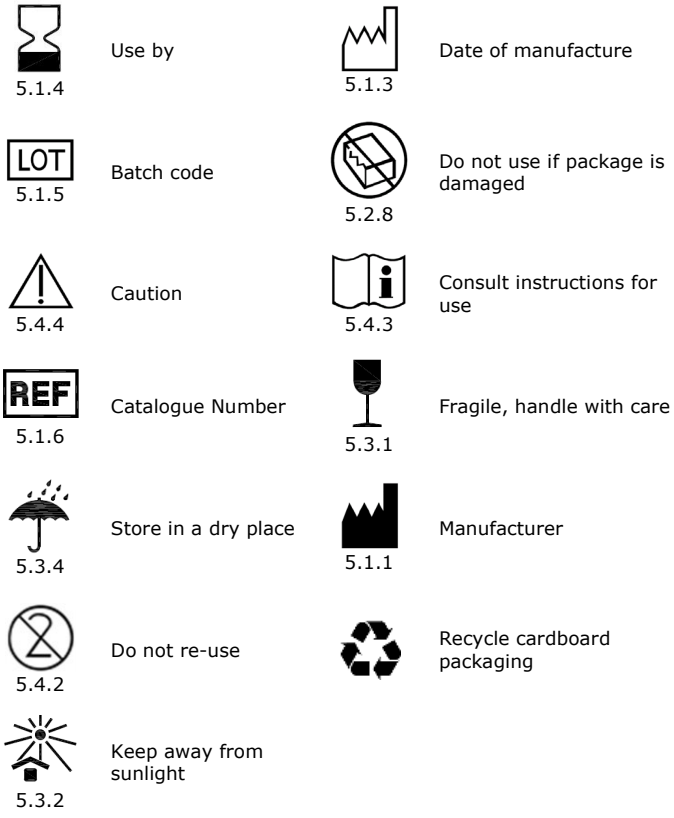
The 360 PSG System must not be used if the Guides do not fit well on the patient's bones.

System Requirements for Viewing 3DV Report

The 3DV Report may be viewed on a personal computer (requires Adobe Acrobat Reader software) or an Apple smart phone or tablet (requires 3D PDF Reader application).
The latest version of Adobe Acrobat Reader can be downloaded from: www.get.adobe.com/reader/.
For Apple smartphones or tablets, the latest version of 3D PDF Reader can be downloaded from your smart phone or tablet app store.
Currently, the 3DV Report is not supported by applications for Android hardware.

Symbols

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



This document is provided in electronic form and in paper form with the device. The *Surgical Techniques* (reference KIC-REC-RA-101, KIC-REC-RA-931) are provided in electronic form. Paper form *Surgical Techniques* can be provided within 7 days of receiving a request.
If provided electronically, it is recommended that these *Instructions for Use*, the *Surgical Techniques* (reference KIC-REC-RA-101, KIC-REC-RA-931) and the *3DV Report* is downloaded 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.