enhatch

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This document contains general instructions for use of United Orthopedic Knee Patient Specific Instrumentation. For detailed instructions, please refer to the user manual.

℞ Only

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a Physician.

DESCRIPTION

United Orthopedic Knee Patient Specific Instrumentation (PSI) is comprised of following components: United Orthopedic (UO) surgical guides (hardware), anatomical models (physical replica), Intelligent Surgery Knee CT Segmentation Engine (software), Intelligent Surgery Knee X-ray Segmentation Engine (software), and Intelligent Surgery Knee Implant Recognition Engine (software). Enhatch is responsible for design and development of all three components of the system. The surgical guides and anatomical models designed within the United Orthopedic Knee Patient Specific Instrumentation are manufactured by an SLS additive process from DuraForm ProX PA (Nylon 12, White). Subject device is intended to facilitate the implantation of the knee prostheses developed and distributed by United Orthopedic Corporation: U2 Cemented Total Knee System and U2 PF+ Cementless Total Knee System.

INDICATIONS

The United Orthopedic Knee Patient Specific Instrumentation is indicated as an orthopedic instrument system to assist in the positioning of compatible total knee arthroplasty systems. It is comprised of surgical planning software (Intelligent Surgery Knee CT Segmentation Engine / Knee X-ray Segmentation Engine, and Implant Recognition Engine) intended to preoperatively plan the surgical placement of the United Orthopedics U2 Knee implants on the basis of provided patient radiological images and 3D reconstructions of bones with identifiable anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the to aid in placement of the implant components intra-operatively per the surgical plan. The United Orthopedic Knee Patient Specific Instrumentation is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia.

The instruments are intended for use with the U2 Total Knee System when the clinical evaluation complies with its cleared indications for use. The instruments are intended for single use only.

CONTRAINDICATIONS

United Orthopedic Knee PSI contraindications are the same as the situations when a total knee replacement is contraindicated. Refer to the instructions for use of the Knee products distributed by United Orthopedic Corporation as listed in the description for full contraindications of the implant and instrument systems.

Do not use if the patient currently or has a history of sensitivity/allergy to the material of which the surgical guides are manufactured (DuraForm ProX PA, Nylon 12, White).

United Orthopedic Knee PSI is contraindicated in patients:

- With the presence of osteochondroma around articular surfaces
- With failed osteotomies, displaced fractures, unicompartmental replacement, and previous total knee replacement
- With active infections of the knee joint
- With Hip-Knee-Ankle (HKA) alignment deformities larger than 15° varus or valgus

MATERIALS

Patient contact materials used in the guides and templates have been tested and shown to be biocompatible in accordance with ISO 10993-1. The materials used to manufacture guides and templates are nylon blends.

ADVERSE EFFECTS

Potential adverse effects include infection, decreasing range of motion, loosening of the components, breakage or bending of the components, or malalignment of the components. Dislocation can occur due to inappropriate patient activity, trauma, or other biomechanical considerations. Loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment, osteolysis or trauma.

Breakage or bending may result due to inadequate support of the component by the underlying bone or poor component fixation. Wear of polyethylene components has occurred, and literature reports have associated its occurrence with bone absorption, loosening and infection. Other potential adverse effects of total knee surgery include genitourinary disorders; gastrointestinal disorders; neurovascular damage, embolism, myocardial infarction, and other less common adverse effects. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb. Due to the many biological, mechanical, and physicochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

WARNINGS ⚠

Formal United Orthopedic Knee Patient Specific Instrumentation training is recommended prior to use of the system. Please contact caseorder@enhatch.com for more information and training for the United Orthopedic Knee Patient Specific Instrumentation and its surgical technique.

Discard all damaged or mishandled components. Never reuse an implant. Reuse of implants will cause the risk of cross infection and unpredictable health threat. Keep bearing areas clean and free of debris prior to assembly. Components of the United Orthopedic Knee System should not be used with those of another manufacturer's total knee component since articular and dimensional compatibility cannot be assured. Except general instruments, United Orthopedic Knee System components may only be implanted combined with United implants by using United Orthopedic Knee Patient Specific Instrumentation or the instruments released by United Orthopedic. Intentional removal of the plastic tibial insert after its assembly into the tibial tray results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial tray during insert removal. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize more than one time.

Even though the performances and characteristics of the plastic device are deemed not to be affected by the passage of time, it is required to use the guides within 6 months from the date of scan acquisition on which they are based or within 3 months from the date of manufacture as indicated on the product label. If the patient's anatomy has changed significantly since the time of the imaging, the guides should not be used, even if the time period of 6 months is not expired.

Be aware that the anatomical models provided are derived from the images of the patient. If the patient's anatomy has changed significantly since the time of the images, the surgical plan should not be used. This product is not intended to be used on patients with skeletal immaturity. The use of larger than 1mm inter-slice distances is not recommended. The quality of the images in the Segmentation Engine – Knee module depends on the quality of the scanned images. To obtain optimal results, please use the scan parameters specified in the scanning protocol. 3D models generated from x-ray images are a product of extrapolation using an algorithmic model and may not be representative of the patient's anatomy. Presence of metallic implants at the anatomical area of interest may decrease the quality of the patient bone reconstruction due to imaging artifacts. Use the surgeon's clinical judgment and experience in evaluating the acceptability of outputs. Ensure that scans are free from motion artifacts. Image distortion from patient motion can compromise accuracy. Imaging must be within 6 months of acquisition date in order to be processed.

Ensure that the delivered Disposable United Orthopedic Knee Patient Specific Instruments correspond to the intended patient. A copy of the approved surgical plan is provided in the United Orthopedic Knee Patient Specific Instrumentation packaging. Only use the Disposable United Orthopedic Knee Patient Specific Instruments if the PSI Case ID marking are both legible on the United Orthopedic Knee Patient Specific instrument guides and bone models and match the PSI Case ID specific to the intended patient. If the two PSI Case ID markings do not match, DO NOT USE the Disposable United Orthopedic Knee Patient Specific Instruments on the patient and notify your Enhatch representative.

PRECAUTIONS ⚠

United Orthopedic Knee PSI components are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use. To ensure that damage has not occurred during shipping and handling, inspect all guides and templates for damage prior to use. Do not use if the templates or guides are broken, cracked or otherwise damaged. To avoid material toxicity reactions, contact time for DuraForm ProX PA should be limited to ≤24 hours. If you experience difficulties with the United Orthopedic Knee PSI guides intraoperatively, stop using the guides and revert to the standard United Orthopedic metal instrument system surgical technique.

CLEANING & STERILIZATION

United Orthopedic Knee Patient Specific Instrumentation are provided in non-sterile condition. Cleaning and sterilization are required prior to use.

Manual Cleaning Method:

1. Prepare neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device into the prepared detergent and allow the device to soak for 20 minutes.
3. While immersed, use a soft bristle brush to brush this device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas for a minimum of 30 seconds.
5. Rinse the device in cold tap water for a minimum of 3 minutes.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Ultrasonically clean fully soak the device and ensure all surfaces have contact with the prepared detergent for 30 minutes at 45-50 kHz.
8. Rinse the device in cold tap water for a minimum of 3 minutes until no visible debris, soil, enzyme cleaning solution remains on the device.
9. Final rinse the instruments in warm deionized water for a minimum of 3 minutes to irrigate challenging design features.
10. Wipe dry with sterilized lint free cloth or wipes.

Automated Cleaning Method

Manual Pre-Cleaning:

1. Prepare neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device into the prepared detergent and allow the device to soak for 20 minutes.
3. While immersed, use a soft bristle brush to brush this device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas for a minimum of 30 seconds.
5. Rinse the device in cold tap water for a minimum of 3 minutes.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Ultrasonically clean fully soak the device and ensure all surfaces have contact with the prepared detergent for 30 minutes at 45-50 kHz.
8. Rinse the device in cold tap water for a minimum of 3 minutes until no visible debris, soil, enzyme cleaning solution remains on the device.
9. Transfer the test articles onto rack system contained inside the washer for processing.

10. Automatic Cleaning Parameters:

Phase	Recirculation Time (Min)	Temperature	Detergent Type and Concentration
Pre-Wash 1	02:00	<40°C	Tap water
Wash 1	05:00	30-44°C	Enzymatic solution
Wash 2	05:00	66°C	Neutral pH Detergent solution
Rinse	10:00	>44°C	Deionized water
Drying	30:00	100°C	N/A

Sterilization Method / Instructions:

1. Packaging: Wrap parts using an FDA cleared sterilization wrap (e.g. Kimguard® Sterilization Wrap, P/N KC600)
2. Cycle Type: Dynamic-Air-Removal Sterilization (Pre-Vacuum / Steam)
3. Preconditioning Pulses: 4
4. Cycle Temperature: 132°C
5. Cycle Time: 4 min
6. Dry Time/Cool Time: 30-minute dry time, 30-minute cool down for DuraForm ProX PA guides and templates
7. Storage in Sterile State: Product is intended for use immediately after sterilization only. Do Not Unwrap until ready for use.

Consult the United Orthopedic Knee Patient Specific Instrumentation surgical technique for use of surgical guides and anatomical models. The Instructions for Use for Intelligent Surgery Knee can be supplied in electronic form in PDF format via email request at caseorder@enhatch.com.

SEGMENTATION ENGINE MODULE DESCRIPTION

The Intelligent Surgery Knee CT Segmentation Engine and X-ray Segmentation Engine are web-based applications used to detect and extract region of interest (ROI) information, specifically femur and tibia, from medical imaging data (DICOM). The Segmentation Engines generate 3D models which can be used for treatment planning, design of surgical guides or be utilized for generation of 3D printed anatomical models. The Intelligent Surgery Knee Segmentation Engine consists of two imaging modalities, CT and X-ray. Each

modality has an independent deep learning algorithm used to extract the regions of interest from the data.

IMAGING SCANNER COMPATIBILITY

Scanner Compatibility		
Modality	Manufacturer	Model
CT	Siemens	Emotion16
	GE Medical	Discovery710
	Toshiba	AquilionPRIME
X-ray	Kodak	ClassicCR
	Konica Minolta	13
	Swissray	ddrFormula
	Canon Inc	CXDIControlSoftwareNE

IMPLANT RECOGNITION ENGINE MODULE DESCRIPTION

The Implant Recognition Engine is a web application used as a treatment planning tool for total knee arthroplasty. It assists in selecting implant size and position, from a range of implants of a total knee implant system, using a range of run parameters based upon the TKA surgical technique of that system. The software identifies anatomical landmarks of the patient's bony anatomy and articular surface topographies to reference the position and alignment of the femoral and tibial implant components. This positioning and alignment in turn allows or design of surgical guides and of the United Orthopedic Knee Patient Specific Instrumentation.

The Knee Implant Recognition Engine web application works with the knee anatomy utilizing optimization functions. The software consists of search parameters and loss functions, capturing distance measurements of the bone and sections of the implant to determine an optimal implant size and position.

CYBERSECURITY CONSIDERATIONS

Intelligent Surgery Knee is served using various AWS Cloud Technologies and thus considers Cloud Platform Security Strategy on AWS. The AWS Shared Responsibility Model is disclosed in product labeling to detail AWS' responsibility for protecting the infrastructure of AWS Cloud services, Enhatch's responsibility to perform configuration and management tasks as determined by AWS Cloud services, and finally the end user's responsibility to understand that Enhatch is responsible for the management of the guest operating system (including updates and security patches), any application software or utilities installed by Enhatch on the instances, and the configuration of the AWS-provided firewall (security group) on each instance. Additionally, Enhatch's Privacy and Security Policy is provided on the Enhatch website at https://www.enhatch.com/ privacy-policy. This policy outlines to the end user information collected, how information is used, information sharing and disclosure, and customer data information.

SYMBOL LEGEND

Warning
Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.

Caution
Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.

Manufacturer

Date of Manufacture

Non-Sterile

Do Not Re-Use

Catalog Number

Prescription Only

Batch Code

Consult Instructions for Use