



## **OPERATIV PIN USER MANUAL**

### **STERILE PRODUCTS**

#### **PRODUCTS**

<b>Part Number</b>	<b>Description</b>	
000617-30	Universal Pin, 100 mm length, 3.0 mm diameter	Pack of 2, with 5 packs per box
000617-35	Universal Pin, 150 mm length, 3.0 mm diameter	Pack of 2, with 5 packs per box

#### **PRODUCT DESCRIPTION**

All pins listed above are supplied as single use sterile. If sterile barrier is compromised consider the product not sterile. They must be cleaned and sterilized according to the guidelines below.

Operativ pins are manual instruments that are used as drill bit/smooth pin replacements during total and uni knee arthroplasty.

#### **MATERIAL SPECIFICATIONS**

316L stainless steel (ASTM F138)

#### **INTENDED USE/INDICATIONS FOR USE**

Operativ pins are intended to be used in TKR/Uni knee replacement.

#### **INSTRUCTIONS**

##### **Operativ Pins**

1. By hand, pre-load the pin into desired hole of the orthopedic device.
2. Push the pin through the hole, so the pin tip pierces the near cortex of the bone.
3. Place the pin collet driver of the drill over the top of the pin and then drill the pin into place. Slowly advance the pin into bone to avoid over-drilling.
4. If available, a headless pin driver can also be used for insertion of the pin.

5. Ensure that, upon removal of the pin, the drill is placed in reverse so the pin will not continue through the bone and cause injury to surrounding soft tissues.
6. If any of the pins are bent or scored during use, replace the pin immediately.

## **CONTRAINDICATIONS**

1. Foreign body sensitivity, known or suspected allergies to implant and/or pin materials.
2. Active sepsis or infection.
3. Conditions that tend to limit the patient's ability or willingness to restrict activities or to follow directions during the healing and rehabilitation period.

## **WARNINGS**

1. The pins are extremely sharp. Improper handling of the pins may result in injury.
2. Patient should be advised that product materials may cause allergic reactions, including without limitation foreign body reaction, tissue irritation and inflammation, or other allergic reactions. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to use.
3. Additional warnings include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance to anatomical hazards.
4. Do not apply side or bending loads. Application of side or bending loads may result in breakage of the pins and risk of tissue damage or debris.
5. Do not over-drill the stop pin, as it will result in breakage of the pin, stripping of bone or compression of bone.
6. Beyond a single use, the precision and integrity of the pin could be compromised and cause breakage or incarceration in cutting block.

## **ADVERSE EVENT WARNINGS (please note warnings below)**

*Pin holes alter the stress distribution and decrease the breaking strength of any bone and may cause stress fracture.*

*To minimize the risk of stress fractures, the distal femoral metaphysis and pin placement from lateral to medial is preferred.*

*Avoid placing the Pins into bone sections which are subject to high tensile or torsional stress moments in order to minimize the risk of stress fracture.*

*Transcortical pin fixation is most detrimental to bone strength and may be associated with increased risk of bone necrosis.*

*Pin insertion generates heat. Excessive heat generation may result in bone necrosis. Bone necrosis potentially delays the pin hole healing process and increases the risk of stress fractures. Ensure low drilling speed in order to avoid excessive heat generation. External irrigation should be applied, if possible.*

*Depending on bone stock, pre-drilling with a drill diameter smaller than the intended pin diameter may be indicated.*

## PRECAUTIONS

1. Prior to use, remove all protective packaging and tip protector, if applicable.
2. Inspect the pins prior to use to ensure they are in good physical condition and functions properly. Do not use the pins if there is any loose, broken or misaligned part.
3. Exercise care in the use of the pins to minimize side or bending loads.
4. To avoid damage or breakage during use of the pins, do not use excessive force on the pins.
5. To prevent damage or breakage of the pins, avoid contact with other surgical pins during use.
6. Inspect the pins after use to ensure the pins have not been damaged.
7. The pins are designed for use by surgeons experienced in the appropriate specialized procedures. It is the responsibility of the surgeon to become familiar with the proper techniques for use of the pins.

## ADVERSE EFFECTS

1. Deep and superficial infections.
2. Allergies, tissue irritation and inflammation, and other reactions to materials.
3. Transient local fluid accumulation or sinus formation, arthritis pain or deformity and stiffness.
4. Bone fracture.

## CLEANING AND STERILIZATION GUIDELINES

**Pins are single use and should not be reprocessed.**

### CLEANING (if sterile barrier is compromised)

1. Follow universal precautions for protective apparel when handling and cleaning non-sterile products.
2. Place the pins in a basin with distilled water.  
**NOTE:** Saline solution is not recommended, as it has a corrosive effect on certain metals.
3. The pins should be cleaned using a neutral pH cleaning solution and a non-abrasive brush.
4. Rinse the pins under running water followed by a rinse in distilled water.
5. Dry the pins completely using a clean, lint-free towel.

### STEAM STERILIZATION (if the sterility barrier is compromised)

## WARNINGS

1. Do not use EtO or gamma sterilization.
2. Do not use disinfecting solutions to sterilize the pins.

Prepare pins such that all surfaces have direct contact with steam.

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam (wrapped/unwrapped)	Pre-Vacuum	270°F (132°C)	4 minutes	8 minutes

For sterilization of pins in a tray, consult guidelines provided with the specific sterilization tray.

**CAUTION**

Federal law (USA) restricts this pin to sale, distribution, or use by or on the order of a licensed healthcare practitioner.

**STERILITY**

The pins are sterilized by exposure to gamma radiation. Do not re-sterilize after use. Do not use past expiration date.

**DISCLAIMER**

OPERATIV MAKES NO WARRANTY TO YOU AND HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PINS, LISTED ABOVE, WHETHER ARISING BY COURSE OF DEALING OR PERFORMANCE, CUSTOM, USAGE IN THE TRADE OR PROFESSION OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

**CONTACT INFORMATION**

For more information or a product demonstration, contact your Operativ sales representative, or call 1-425-284-7262 in the United States.



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