Operativ®
Advancing joint replacement surgery

UNIVERSAL TIBIA INSTRUMENTATION USER MANUAL

UNIVERSAL TIBIA Instrument Set contains:

Part Number	Description
001647-02	Cut Shim, 2mm Cutting Guide
001647-04	Cut Shim, 4mm Cutting Guide
001648-01	Cutting Guide Capture
001645-01	Extension Guide Assembly
001679-01	Ankle V Mount
001683-01	Ankle Mount Assembly
001650-01	Universal Cutting Guide
001658-01	Stylus
001660-01	5/16 Drop Rod
001661-01	Rod Support
001662-01	3/8 Hex Stud Assembly
001668-01	Spiked Arm Support
001667-01	Spiked Arm Extension

SAFETY AND ACCURACY

INITIALLY PLACE ALL PINS INTO CUTTING GUIDE HOLES BY HAND THEN APPLY POWER TO INSERT THE PIN INTO BONE. THIS WILL AVOID BENDING/SCORING AND BREAKING OF PINS.

*** (3.2 mm pin is a part that is required but not included in this SYSTEM) ***

PRODUCT DESCRIPTION

All UNIVERSAL TIBIA Instruments listed above are supplied as durable instruments. They must be cleaned and sterilized according to the guidelines below.

The UNIVERSAL TIBIA Instruments are manual instruments that are designed to be used to osteotomize the proximal tibia during a unicondylar or total knee arthroplasty. (See disclaimer section for further information)

MATERIAL SPECIFICATIONS

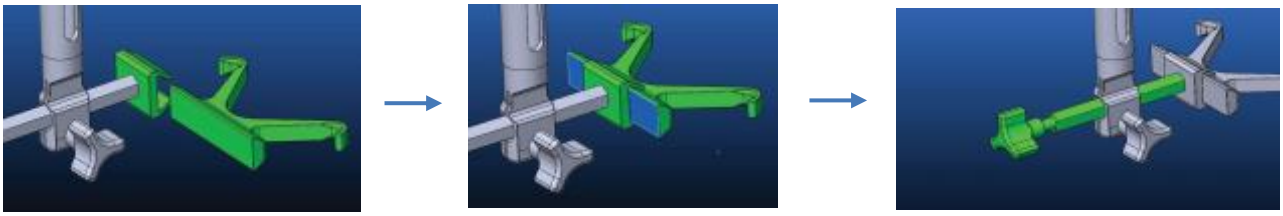
304 stainless steel, 17-4PH stainless steel, Nitronic 60, UHMWPE (Ultra High Molecular Weight Polyethelene).

INTENDED USE/INDICATIONS FOR USE

The UNIVERSAL TIBIA Instruments are indicated for use as a manual orthopedic instrument used to osteotomize the proximal tibia during a unicondylar or total knee arthroplasty.

ASSEMBLY INSTRUCTION

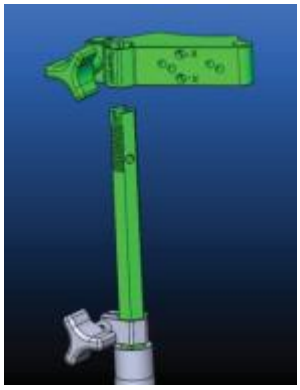
1 Ankle V Mount Assembly



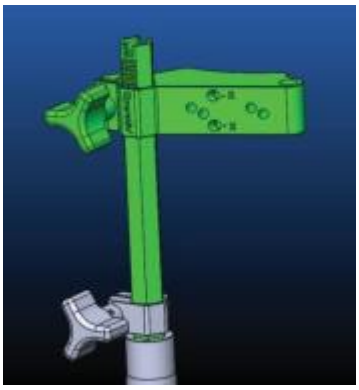
Slide ankle clamp into dovetail.

Tighten trilobe nut to secure ankle clamp.

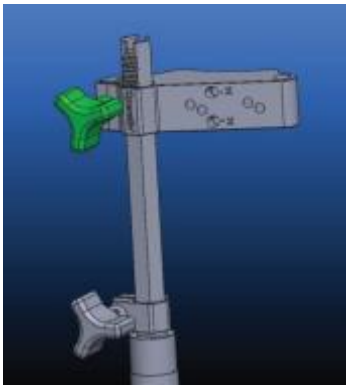
2 Cutting Block



Choose appropriate cutting block side (right or left).

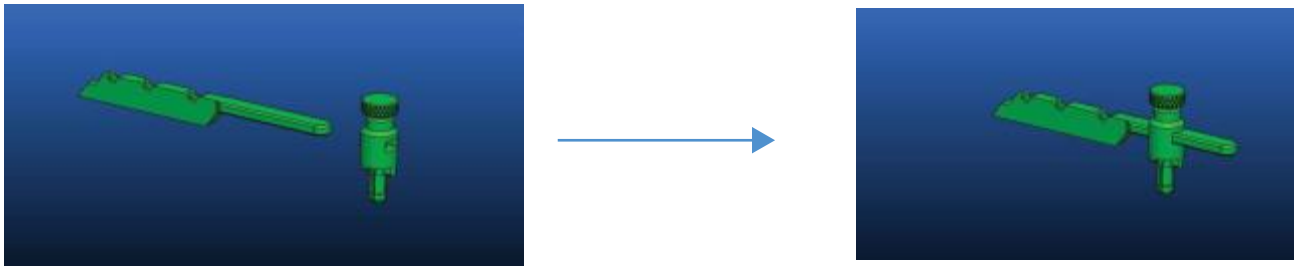


Slide cutting block over post.

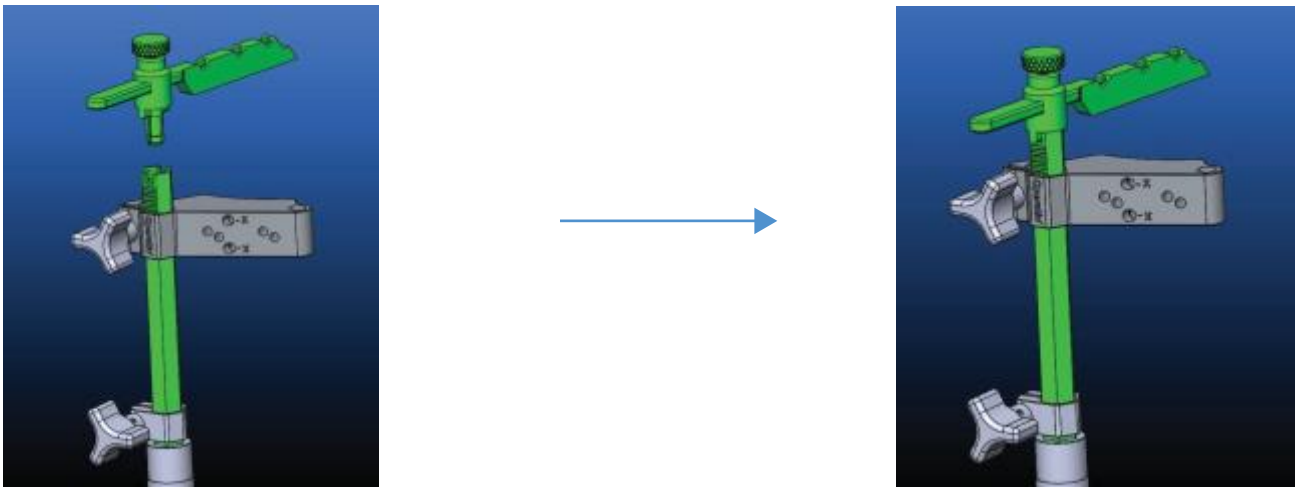


Tighten trilobe nut to secure cutting block.

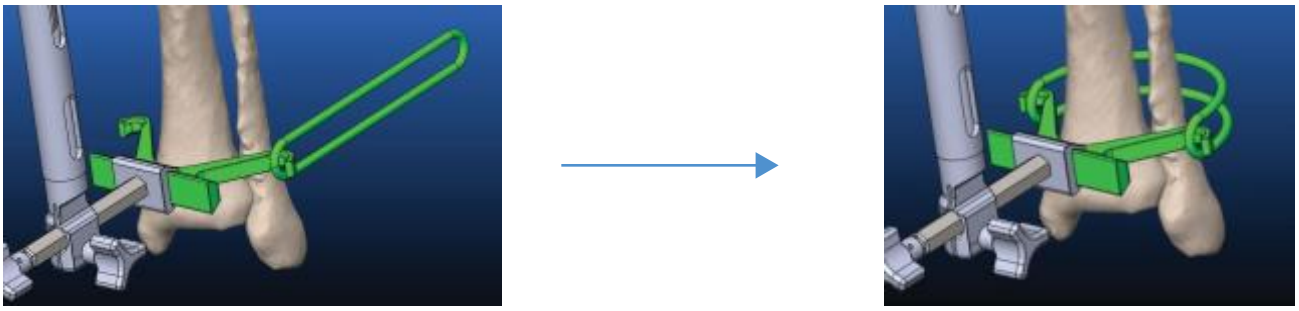
3 Tibial Arm Assembly



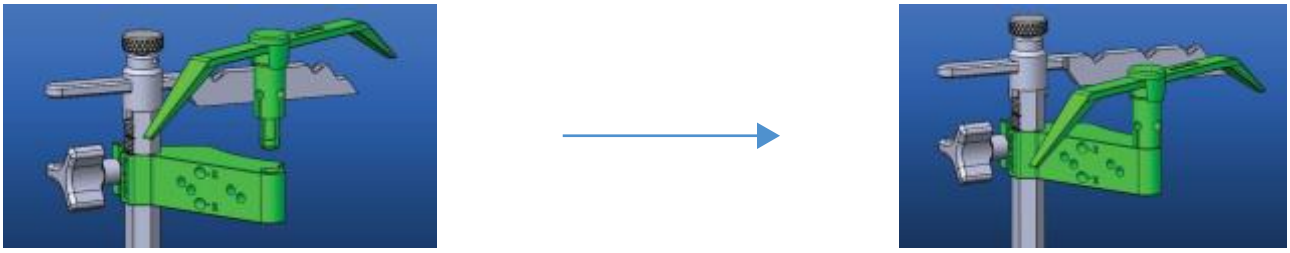
4 Attaching Proximal Tibia Arm



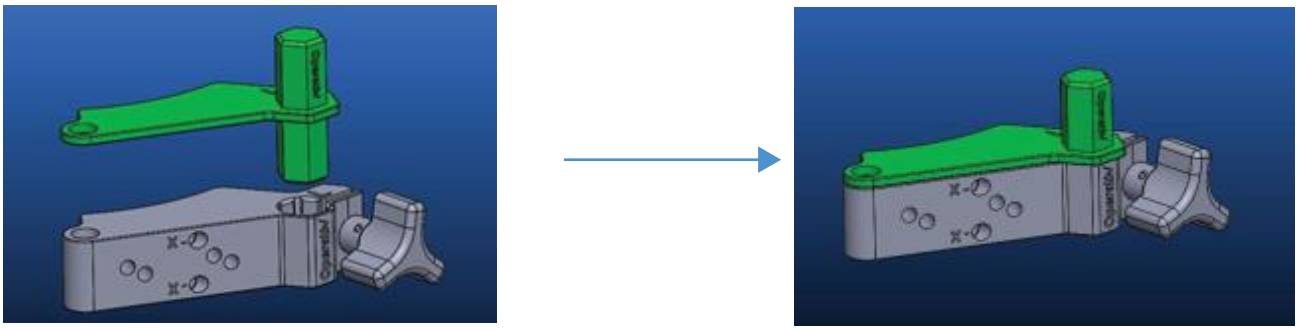
5 Attaching O Ring Band to Ankle V Mount Assembly



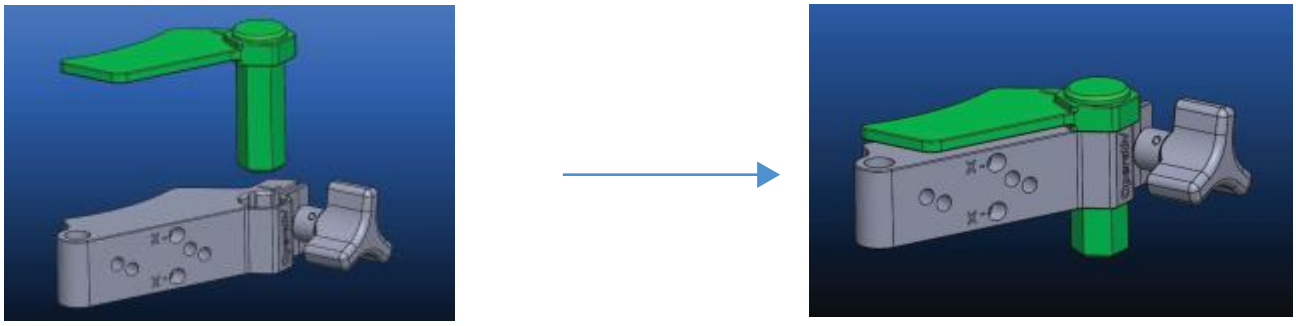
6 Attaching Tibial Stylus



7 Attaching Shims and Capture



The trilobe thumb screw will tighten down onto the 2 mm shim. The shim is right and left. Remember to tighten trilobe thumb screw to secure 2 mm shim.



The trilobe thumb screw will tighten down onto the saw blade capture. The capture is right and left. Remember to tighten trilobe thumb Screw to secure saw blade capture.

NOTES

INSTRUCTIONS FOR USE

SURGICAL PROTOCOL

This surgical technique will cover tibial preparation. The tibia cut can be done first followed by the femoral preparation depending on surgeon preference.

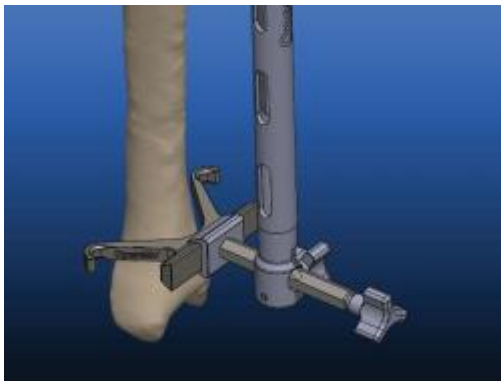
GENERAL INSTRUCTIONS

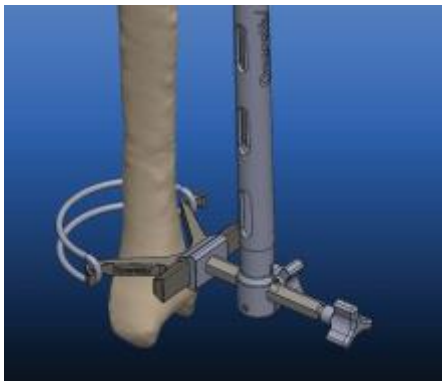
1. Position the leg at 90° of flexion at the knee.
2. The Universal Tibia Instruments can be configured with a RIGHT or LEFT cutting guide. Please make sure the correct side is used.

POSITIONING UNIVERSAL TIBIA GUIDE

01 Place the ankle mount on the front of ankle.

An elastic band is available if further fixation is needed.





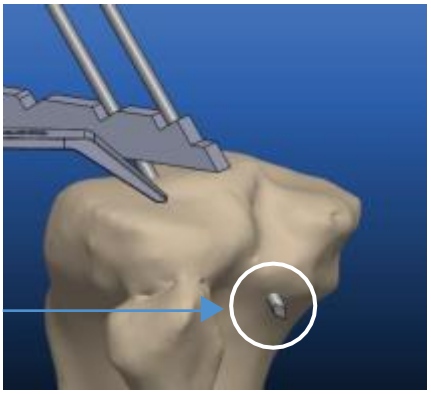
02 Extend the tibial hex rod to the level of the tibial joint line and extend the proximal tibial attachment arm so that it rests on top of the tibia.

03

Place the proximal tibial attachment arm over the top of the tibial spines.

Place threaded pin in the first hole so that it enters the bone between the back part of the tibial spines.

Drill pin into position.

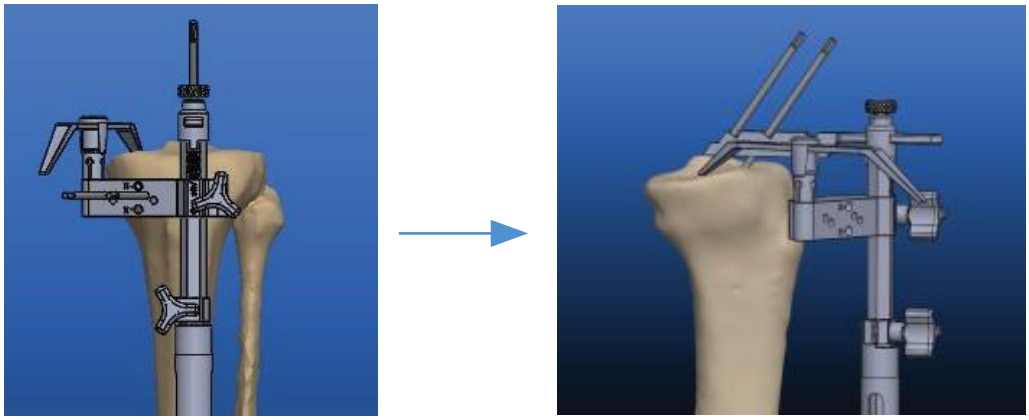


Note: only a few threads are needed to hold the proximal attachment in place. Avoid trauma to posterior blood vessels.

04

Obtain desired rotation for tibial guide and place second pin in next pin hole.

Note: only a few threads are needed to hold proximal attachment in place. Avoid trauma to posterior blood vessels as noted above.

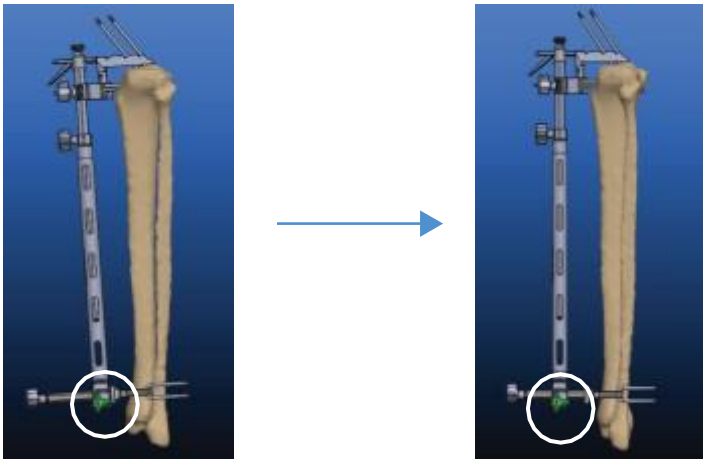


05

Adjust tibia guide to achieve desired slope by using trilobe thumb screw.

Note: Correct slope is achieved when the long axis of the tibial guide is parallel to the long axis of the fibula.

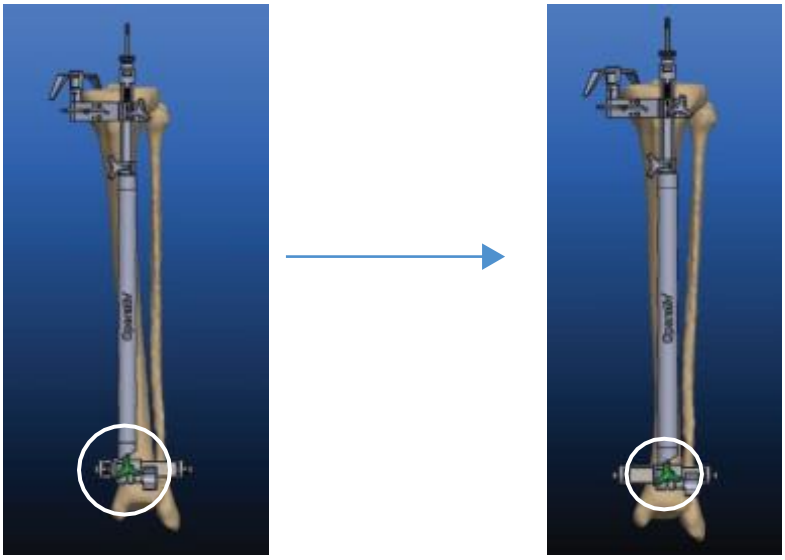
Tighten tri-lobe screw so position is maintained.



06

Adjust tibia guide to achieve desired varus/valgus alignment by using the trilobe thumb screw.

Note: Correct varus/valgus alignment is achieved when the shaft of the tibial guide is in the center of the tibia. Tighten trilobe screw by hand so position is maintained.

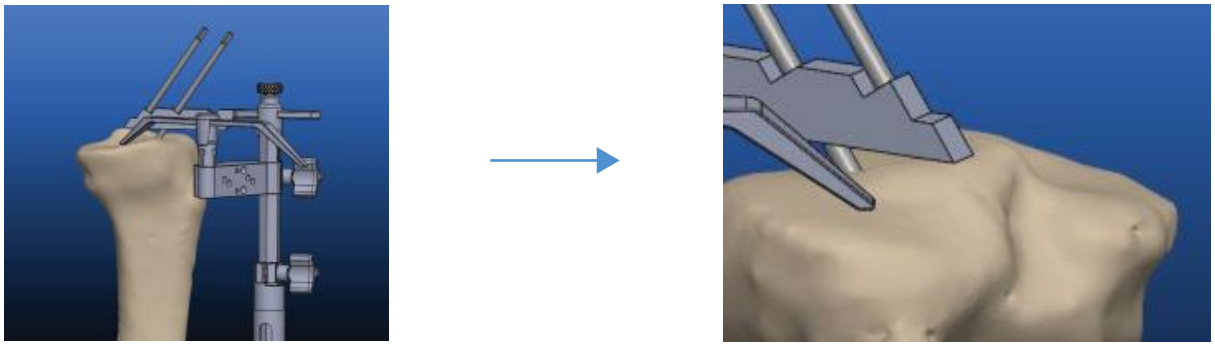


07

Adjust resection level to achieve the desired depth of cut.

The tibial stylus attaches to the cutting block. The 2 mm tip of the stylus is used when referencing the lowest level of the affected compartment of the tibia (usually the medial side). If using the unaffected side (usually the lateral side) use the 9 mm tip.

If the 2 mm tip of the stylus is used 2 mm of bone will be resected, alternatively if the 9 mm tip of the stylus is used 9 mm of bone will be resected below the stylus.



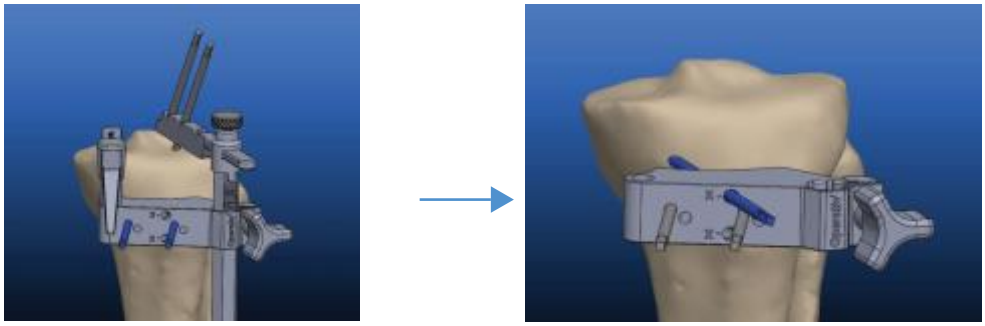
08

Secure the cutting block to the tibia.

Place one threaded pin into either the 0 or +2 hole on the cutting block.

Make sure you place a second pin into the corresponding hole on the other side.

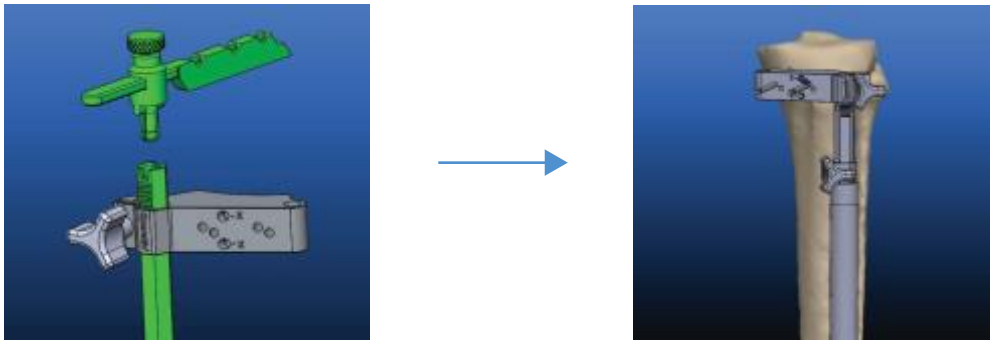
Note: The surgeon can use the 2 mm or 4 mm shims to adjust the depth of cut on the tibia if needed.
The "x" pin hole can be used to keep the cutting block from moving by using another threaded pin.



09

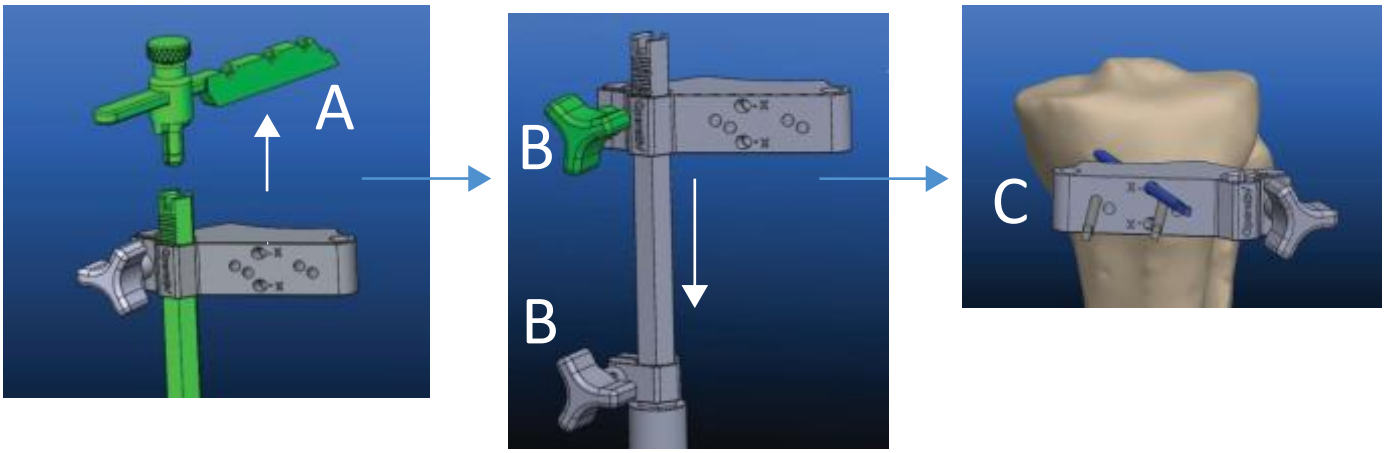
To make the tibial cut the surgeon has two options to choose from.

1) The surgeon can choose to keep the EM tibia assembly together by removing the threaded pins from the tibia arm assembly, remove tibial arm assembly, and loosen the trilobe thumb screw of the cutting block and lowering the vertical hex bar below the surface of the cutting guide and retightening the trilobe thumb screw. (See below)

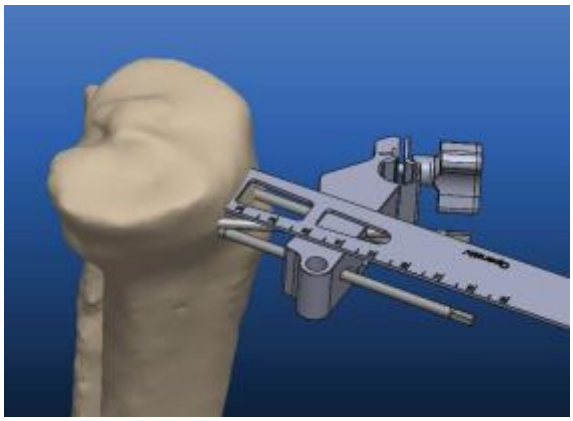


2) The surgeon can choose to remove EM tibia assembly leaving only the tibial cutting guide in place.

To remove the EM tibia assembly remove the threaded pins in the tibia arm assembly and remove the tibial arm assembly (a). Loosen the trilobe thumb screws (b). The vertical hex bar will drop below the cutting block (b) and can be removed from the tibia leaving only the cutting block (c).

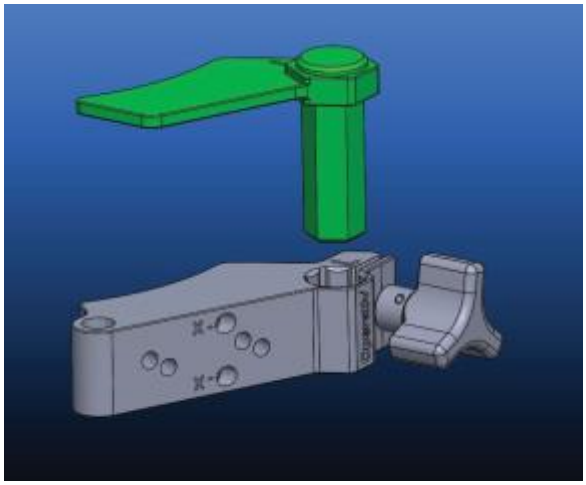


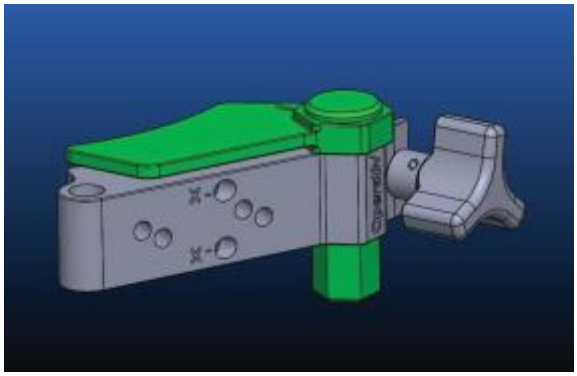
10 The surgeon can choose to use the cutting block as an open block or use the captured guide.

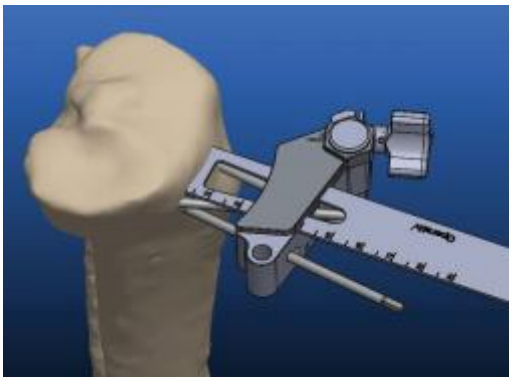


Without the EM tibial guide in place

With the EM tibial Guide in place







CONTRAINDICATIONS

1. Foreign body sensitivity, known or suspected allergies to the UNIVERSAL TIBIA Instruments and UNIVERSAL TIBIA Instrument 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. If used improperly, the instruments can result in component mal-position, misalignment of the leg, fracture, and other injury to the patient.
2. Patients should be advised that product materials may cause allergic reactions, including, but not limited to foreign body reaction, tissue irritation and inflammation, other allergic reactions. Where material sensitivity is suspected, appropriate testing should be performed prior to use.
3. Additional warnings include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards.
4. To ensure proper placement and function, the operator must visualize the position of the UNIVERSAL TIBIA Instruments on the proximal end of the tibia and protect the surrounding structures.
5. If visualization during the placement of the UNIVERSAL TIBIA Instruments is not possible, the UNIVERSAL TIBIA Instruments may malfunction and patient injury may occur.

PRECAUTIONS

1. Prior to use, remove all protective packaging and tip protector, if applicable.
2. Inspect the instruments prior to use to ensure they are in good physical condition and function properly. Do not use the instruments if there are any loose, broken or misaligned parts.
3. Exercise care in the use of the instruments to ensure proper function.
4. Please read and understand the instructions of use to ensure proper function and patient safety.
5. The UNIVERSAL TIBIA Instruments are designed for use by surgeons experienced in specialized procedures. It is the responsibility of the surgeon to become familiar with the proper techniques for use of the UNIVERSAL TIBIA Instruments.

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.
5. Soft tissue injury.

INSTRUCTIONS FOR CARE, MAINTENANCE, CLEANING AND STERILIZATION OF OPERATIV MEDICAL DEVICES

PURPOSE

This document was prepared to provide instructions for the care, maintenance, cleaning and sterilization of the medical devices produced by Operativ. These methods were developed using standard equipment and practices common to health care facilities. Validation testing to support these instructions was based on recognized guidelines and standards for reusable devices and containment devices from the following organizations:

Association for the Advancement of Medical Instrumentation (AAMI)

SCOPE

These instructions apply to all instruments that are sold by Operativ for reuse.

- Detergents - Low foaming detergents with a pH range between 6.0 and 8.0 are recommended.
- Detergents with a pH outside this range can have an adverse effect or be damaging to some instruments and containment devices.
- Enzymatic detergents can aid in the removal of organic soil such as blood and tissue. Detergents should be used at the concentration and temperature recommended by the detergent manufacturer.
- Water - The quality of water should be carefully considered for use in cleaning reusable devices. Water hardness is a concern because deposits left on medical devices may result in ineffective cleaning and sterilization. Final rinsing should be carried out using demineralized water.
- Automatic washer/disinfector Washer - Disinfectors are not only used to clean devices, but also to provide intermediate to high level disinfection with a hot water rinse. Cleaning is dependent upon thorough coverage of the devices and the force of the water spray. Therefore, all sections of the device must be accessible for ease of cleaning and penetration of cleaning agents. The automatic washer/disinfector equipment should be operated following the manufacturer's instructions for use.
- Manual cleaning tools necessary include: surgical scrub brushes, chenille pipe cleaners, soft low lint cloths, cotton tip applicators, and several size and length brushes.
- Do not use abrasive cleaning tools (i.e. scouring pads or metal brushes).
- Cleaning tools must be cleaned and inspected between uses. Cloths should be clean, lint free and changed frequently.
- Brushes should be clean. Discard worn brushes and disposable cleaning tools.
- Safety precautions - Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated devices. PPE includes: gown, mask, goggles or face shield and shoe covers.

Note: All hospital personnel that work with contaminated or potentially contaminated devices should observe universal precautions. Caution should be exercised when handling devices with sharp points or cutting edges.

Definitions: Universal Precautions - Universal Precautions are standards of infection control practices designed to reduce the risk of transmission of blood borne infections.

IMPORTANT INFORMATION/ RECOMMENDATIONS FOR USE

RECOMMENDED CLEANING INSTRUCTIONS

Cleaning is the single most important step in preparing a device for reuse. Effective cleaning must be carried out to achieve proper disinfection/sterilization. Thorough cleaning and rinsing are vital to reprocessing reusable medical devices. Furthermore, thorough rinsing is important for the removal of any residual-cleaning agents from the medical devices. The purpose of cleaning and rinsing is to remove all adherent visible soil and to reduce the number of particulates, microorganisms, and pyrogens. The recommended cleaning instructions in this document are manual procedures. The cleaning processes presented in this brochure have been validated. Other methods of cleaning may be suitable but must be validated by the user of the device.

WARNINGS

- It is the responsibility of the user to ensure that the cleaning process is performed by following these procedures, to achieve the desired result. These procedures do not apply to single-use devices. Operativ has not validated the cleaning of single use devices and does not support the reuse of single-use devices.
- All cleaning should be performed in a manner designed to minimize exposure to bloodborne pathogens. Manual cleaning should be done while the instrument is immersed.
- Limitations of cleaning instructions- These recommended procedures are intended as a general guide for cleaning of medical devices.
- Limitations of reprocessing- Repeated reprocessing of a reusable medical device have minimal effect on the device.
- End of life is normally determined by wear and damage due to use.

PREPARATIONS AT THE POINT OF USE PRIOR TO PROCESSING

Keep instruments moist after use to prevent soil from drying on them. Follow Universal Precautions for handling and transporting contaminated instruments to the designated cleaning area. Contaminated instruments should be transported to the area for cleaning in a way that avoids contamination of personnel and hospital. Prior to cleaning, gross soil should be removed from the surfaces, crevices, mating surfaces, cannulas, joints and all other hard-to-clean design features. Dried on soil is difficult and sometimes impossible to remove with manual washing.

Instruments should be cleaned as soon as possible after use to prevent blood from drying on the devices.

Preparation for cleaning Devices capable of disassembly must be disassembled prior to cleaning.

Note: If you have questions concerning the disassembly of any Operativ device, contact your Operativ Sales Representative.

OVERVIEW OF PRODUCTS FOR REUSABLE DEVICE CLEANING

Cleaning reusable devices is dependent upon product design features. The cleaning methods for Operativ reusable devices are based on design features that present a similar challenge to cleaning.

OVERVIEW OF PRODUCT DEVICES FOR REUSABLE DEVICE CLEANING

Device categories for cleaning:

- Devices WITHOUT challenging design features.
- Devices WITH challenging design features.

RECOMMENDED CLEANING PROCEDURES

MANUAL CLEANING PROCEDURES

Devices WITHOUT challenging design features:
tibia shims (001647-04) (001687-02), capture for guide (001648-01), drop rod (001660-01)

1. Rinse in cold water (<43ºC) with enough volume and time to remove gross debris and to prevent coagulation of blood.
2. Immerse and soak for a minimum of 5 minutes in enzymatic detergent.
3. Use a surgical scrub brush to remove visible soil.
4. Rinse thoroughly with warm water.
   Note: Final rinsing should be carried out using demineralized water.
5. Check for visible soil. Repeat cleaning if soil is visible.

Devices WITH challenging design features:
(extension guide assembly (001645-01), cutting guide (001678-01), stylus (001658-01), rod support (001675-01), hex stud assembly (001662-01), spiked arm assembly (001668-01), spiked arm extension (0016667-01), ankle retention band (001688-xx), ankle v mount (001679-01), ankle dove-tail slide (001683-01), ankle locking pin (001685-01))

1. Rinse in cold water (<43ºC) with enough volume and time to remove gross debris and to prevent coagulation of blood.
2. Immerse and soak for a minimum of 14-15 minutes in enzymatic detergent.
3. Remove additional soil from challenging design features (i.e. holes, lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common hospital cleaning tools.

a. Move and/or retract all moveable parts and remove soil using a brush.

b. Scrub lumens or holes with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. Small diameter lumens may be irrigated with the cleaning solution using a syringe.

c. Open hinged devices and scrub hinged area with a brush.

d. Scrub crevices with a brush.

Rinse thoroughly with warm water, making sure to irrigate the challenging design features.
Note: Final rinsing should be carried out using demineralized water. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.

4. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

AUTOMATIC WASHING AND THERMAL DISINFECTING PROCEDURES

Devices WITHOUT challenging design features:
tibia shims (001647-04) (001687-02), capture for guide (001648-01), drop rod (001660-01)

1. Manual pre-cleaning:
   NOT REQUIRED if the device does not have dried-on soil. Place the device directly into the automatic washer for cleaning.
   REQUIRED if the device does have dried on soil. Follow the manual cleaning steps prior to placing the device in the automatic washer for cleaning.
2. Place the device in the automatic washer and run the recommended automatic washer steps (see Section "Automatic Washing Cycle Steps and Parameters.")
   Note: Final rinsing should be carried out using demineralized water.

Devices WITH challenging design features:
(extension guide assembly (001645-01), cutting guide (001678-01), stylus (001658-01), rod support (001675-01), hex stud assembly (001662-01), spiked arm assembly (001668-01), spiked arm extension (0016667-01), ankle retention band (001688-xx), ankle v mount (001679-01), ankle dove-tail slide (001683-01), ankle locking pin (001685-01))

1. Manual pre-cleaning:
   REQUIRED for all devices in this product group. Follow the manual cleaning steps prior to placing the device in the automatic washer for cleaning.
2. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and lumens and holes positioned to drain).
3. Run the recommended automatic washer steps (see Section "Automatic Washing Cycle Steps and Parameters.")
   Note: Final rinsing should be carried out using demineralized water.
4. Check instruments for visible soil (see "Verifying cleaning"). Repeat cleaning if soil is visible and re-inspect.

VERIFYING CLEANING

1. After cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.
   Note: Rinse the instruments thoroughly with warm water (>85°C) until all visible bubbles are gone (following hydrogen peroxide testing).
3. Repeat cleaning if not visibly clean and re-inspect.

INSPECTION AND FUNCTION TESTING

All reusable devices should be visually inspected for damage or wear.
Hinged instruments should be checked for smooth movement of hinge without excessive "play."
Mating parts should be checked to make sure that mating parts fit together without complications.
Metal surfaces should be inspected for corrosion and major deformation.

MAINTENANCE AND CARE FOR DEVICES WITH HINGES

Surgical-grade lubricant should be added to the hinged area while in the open position.
Discard or repair damaged instruments.

RECOMMENDED STERILIZATION INSTRUCTIONS

WARNINGS

It is the responsibility of the user to ensure that the sterilization process as it is actually performed using the equipment, materials and personnel, achieves the desired result. Operativ recommends consulting the Immediate-Use Sterilization statement in AAMI ST 79 2012 for guidance on IUSS. Steam is the only method that has been validated for reprocessing by Operativ to a 10-6 Sterility Assurance Level (SAL). Sterrad or hydrogen peroxide based gas systems have not been validated.

These recommended procedures are intended as a general guide for sterilization of reusable medical devices sold by Operativ. It is the responsibility of the user to validate their sterilization equipment to ensure that the recommended parameters are achieved.

Note: The pre-vacuum steam sterilization cycle is approved for Operativ devices. Most reusable devices are sold non-sterile. It is critical to properly clean all reusable devices prior to sterilization.

Note: The sterilization of containment devices is validated with the instruments placed and positioned in the predetermined placement locations of the containment device.

A single absorbent towel (i.e.; a huck towel) can be placed under the containment device to aid in drying.

PREPARATION FOR STERILIZATION REUSABLE DEVICES

It is important that adequate cleaning be carried out prior to sterilization.

Reusable devices should be placed in suitable packaging for the sterilization process (i.e. central supply wrap [CSR], paper/plastic pouches, rigid containers, etc.) and sterilized prior to surgical use.

Prior to sterilization of the device, remove all original packaging and labeling inserts. Place the device in its designated location in the containment device. It is important that adequate cleaning be carried out prior to sterilization.

Containment devices can be wrapped with an approved CSR wrap or placed in an approved reusable rigid container for sterilization. Aesculap SterilContainerTM with perforated bottoms has been approved for use with Operativ instrument sets. These rigid containers are not approved for Immediate Use Steam Sterilization (IUSS) (Flash Sterilization).

Note: **US CUSTOMERS** - Sterilizers and wraps used in your sterilization process must be FDA cleared.

RECOMMENDED STERILIZATION

- Dynamic air removal (prevacuum)
- Exposure temperature: 132ºC (270ºF)
- Exposure time: 4 minutes
- Minimum drying time: 20 minutes

Time and temperature parameters for dynamic-air-removal steam sterilization cycles in health care facilities

Item	Exposure time at 132 °C (270 °F)	Exposure time at 135 °C (275 °F)	Minimum drying time
Wrapped instruments	4 minutes		20 minutes
		3 minutes	16 minutes
Textile packs	4 minutes		5 to 20 minutes
		3 minutes	3 minutes
Wrapped utensils	4 minutes		20 minutes
		3 minutes	16 minutes
Unwrapped instruments	3 minutes	3 minutes	NA
Unwrapped nonporous and porous items in mixed load	4 minutes	3 minutes	NA

The Sterilization Recommendation's is based on AAMI protocols

REFERENCES

ANSI/AAMI/ISO 17665-1: 2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and control of a sterilization process for medical devices. (FDA standard 14-261)

ISO 17665-2:2009 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1 (FDA standard 14-376)

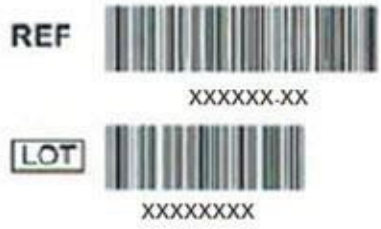
ANSI/AAMI ST79:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. (FDA standard 14-394)

AAMI/ANSI/ISO 11138-01:2006/(R) 2010, Sterilization of Health Care Products - Biological Indicators - part 1: General Requirements. (FDA standard 14-296)

AAMI/ANSI/ISO 11737-2:2009, Sterilization of Medical Devices-Microbiological Methods - Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process. (FDA standard 14-287)

NOTES

Universal Tibial Instruments
Stainless Steel Durable Medical Instruments



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