iKNEE SURGICAL RETRACTORS
USER MANUAL/IFU

PRODUCTS

Part Number	Description
006021-08	iKnee Narrow Straight Hohman Retractor
006021-18	iKnee Straight Hohman Retractor
006023-01	iKnee Angled Hohman Retractor (set of 2)

PRODUCT DESCRIPTION

All iKnee Surgical Retractors listed above are supplied as durable instruments. They must be cleaned and sterilized according to the guidelines below.

The iKnee Surgical Retractors are manual instruments that are shaped specifically to be gentle to the soft tissues, act like a periosteal elevator and optimize exposure without obstructing visualization during total and uni knee arthroplasty.

MATERIAL SPECIFICATIONS

316L stainless steel and/or 17-4PH stainless steel.

INTENDED USE/INDICATIONS FOR USE

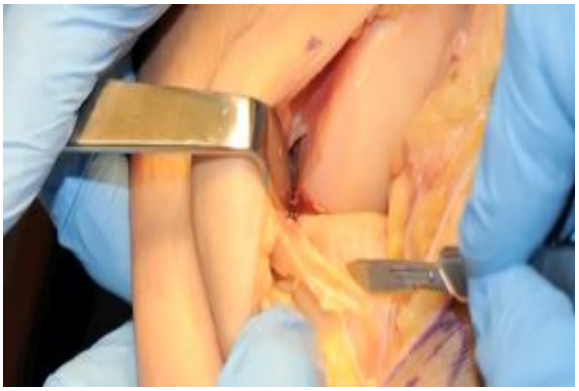
The iKnee Surgical Retractors are intended to be used in TKR/Uni knee replacement to retract and protect the MCL, LCL, PCL and surrounding soft tissues.

INSTRUCTIONS FOR USE

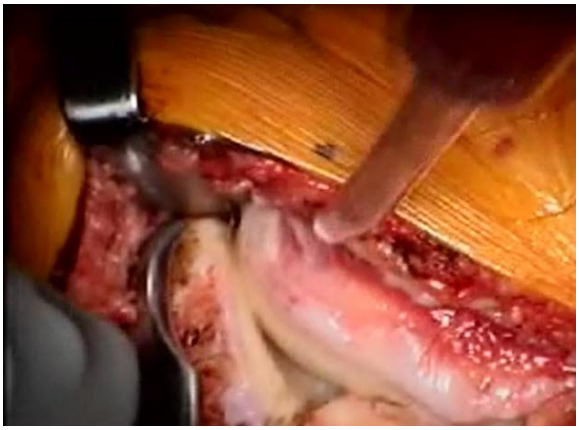
The iKnee Surgical Retractors are designed specifically for MIS total and uni knee replacements. These retractors must be placed strategically and used dynamically to optimize visualization and protect the MCL, PCL, and LCL during surgery. These retractors are also helpful in sequentially releasing the posterior medial corner to aid in exposure in an MIS application. This method decreases the need for more extensile soft tissue dissections without sacrificing exposure.

MEDIAL RELEASE

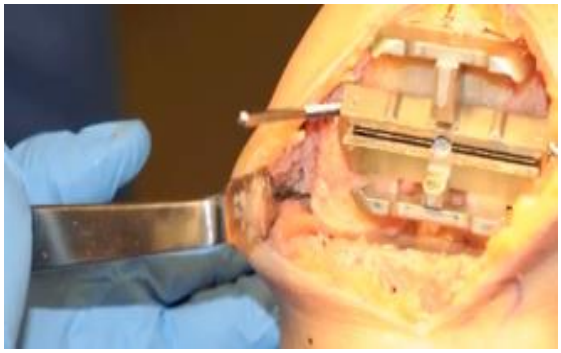
The knee is first placed in the figure of 4 position. The meniscal capsular ligament is put on stretch to start the medial release. With the knee in a figure 4, the medial release can be carried back to the posterior medial corner of the tibia.



The angled retractors can be sequentially placed to allow the surgeon access to the posterior medial corner. There is no need to sublux the joint.

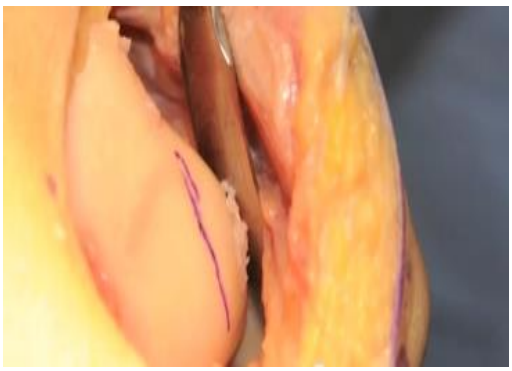


PROTECTION OF THE MCL/LCL/PCL



The key to protecting these ligaments is visualization of the retractor tip sliding between the bone and the ligament. Occasionally, sequential placement of the retractors (picuted above) ensures that the ligaments are protected from the saw blade. If the tip of the retractor is not seen protecting the ligaments reposition and replace the retractors until you are completely sure it is protecting the ligaments.

RETRACTION OF THE PATELLA AND THE PROTECTION OF THE LATERAL COMPLEX



The tip of the angled hohman is placed on the lateral edge of the tibia and in front of the laterally subluxed patella. Special attention by the assistant is needed to make sure the retractor stays on the patella and not the patellar tendon. Exposure and safety will be compromised if this occurs. The tip of the hohman should be placed posterior enough to protect the posterior lateral complex during sawing.

CONTRAINDICATIONS

1. Foreign body sensitivity, known or suspected allergies to iKnee Surgical Retractors 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 retractors can cause injury to the patient and surrounding soft tissues.
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. To ensure proper placement and function/protection operator must visualize the retractor protecting the appropriate structures.

5. If visualization in the placement of the retractor is not possible function of the retractor may be compromised 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 functions properly. Do not use the instruments if there is any loose, broken or misaligned part.
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 iKnee Surgical Retractors 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 iKnee Surgical Retractors.

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 to skin, blood vessels, ligaments and tendons.

CLEANING AND STERILIZATION GUIDELINES

CLEANING

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

STEAM STERILIZATION

WARNINGS

1. Do not use EtO or gamma sterilization.
2. Do not use disinfecting solutions to sterilize the iKnee Surgical Retractors.

Prepare iKnee Surgical Retractors such that all surfaces have direct contact with steam.

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam Unwrapped in a sterilization tray	Pre-Vacuum	270°F (132°C)	4 minutes	10 minutes
Unwrapped in an instrument tray	Flash Gravity	270°F (132°C)	10 minutes (with a 10minute Preheating time)	8 minutes

For sterilization of iKnee Surgical Retractors in a tray, consult guidelines provided with the specific sterilization tray.

CAUTION

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

DISCLAIMER

OPERATIV MAKES NO WARRANTY TO YOU AND HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO THE RETRACTORS, 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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