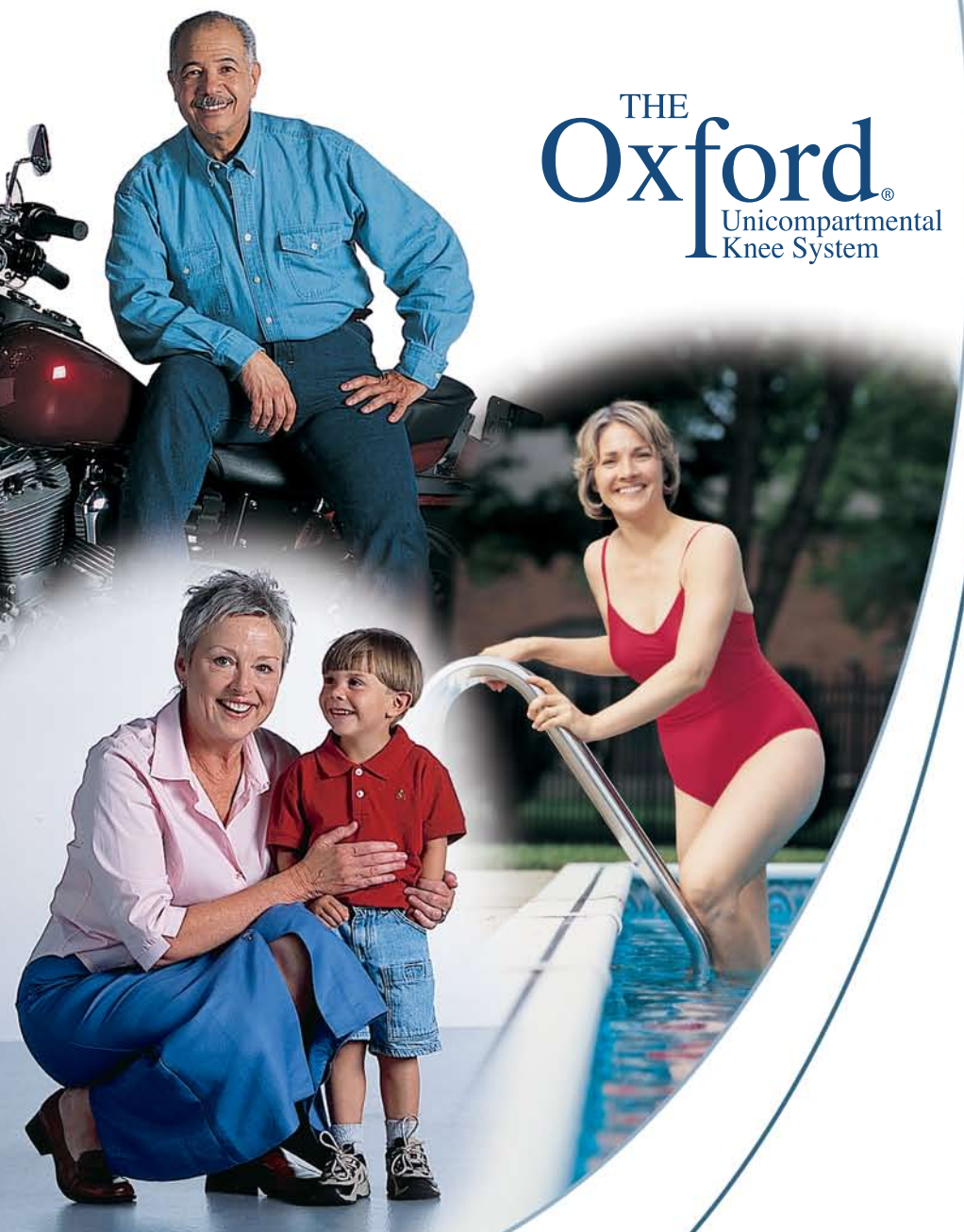
YOUR SURGEON'S

choice of implants

FOR YOUR SURGERY



THE Oxford® Unicompartmental Knee System

YOUR SURGEON'S

choice of implants

FOR YOUR SURGERY

Your surgeon has chosen implants manufactured by Biomet Orthopedics, Inc., for your surgery.

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Your Surgeon Has Chosen the Oxford® Unicompartmental Knee System for You.

Benefits of Unicompartmental Replacement Over Total Knee Replacement

Unicompartmental knee replacement is intended to preserve the healthy knee structures, and is intended to restore normal knee motion and function. Unlike other components, the Oxford® Meniscal Unicompartmental Knee has a fully mobile bearing, which limits the forces and stresses seen by the implant that may often lead to loosening.

The Oxford® Meniscal Unicompartmental Knee is currently the only fully mobile bearing unicompartmental knee system in the United States. Your doctor has selected the Oxford® implant specifically for you based on the unique design of the components, the proven clinical history of the system, and most importantly, your condition.

Reconstruction

The traditional approach to knee reconstruction has been a total knee replacement, which replaces all three compartments of the knee. However, total knee replacement may not be necessary for every patient. Osteoarthritis often develops in only one compartment of the knee, while the other two compartments remain relatively healthy. Patients who have osteoarthritis in only one compartment may not need a total joint replacement. They may be candidates for a unicompartmental knee.

Minimally Invasive Technique for Rapid Recovery

With the Oxford® minimally invasive technique, it is not necessary for your surgeon to make a large incision which would surgically expose healthy parts of the knee. With use of the Oxford® proprietary instruments, the operation may be performed through a small incision with great precision. The system allows accurate balancing of the knee through this small incision avoiding disruption of the thigh muscles (quadriceps), which also contributes to a quicker recovery. [1]

Minimally Invasive Technique for Rapid Recovery, continued

In addition to a less invasive surgery and a smaller incision, the procedure also removes less tissue from both the tibia and femur because only the damaged cartilage is removed.

Most patients walk on their surgical knee the same day as surgery and can possibly be discharged within 24 hours. Some patients may need to use a walker or a cane for the first week. Your condition will determine when you will be discharged.

Frequently Asked Questions

Who can benefit from unicondylar reconstruction?

Adults who show one or more of these symptoms may benefit from this procedure:

- Pain while standing
- Pain while walking a short distance
- Pain changing position, such as sitting to standing
- Persistent knee swelling
- Giving out or locking of the knee
- Failure of the knee to respond to medication

What is the difference between a unicondylar knee replacement and a total knee replacement?

Only part of the joint surface is replaced with a unicondylar knee replacement. A total knee replacement involves resurfacing the entire knee.

Why would I have a unicondylar knee replacement rather than a total knee replacement?

There may be several reasons. A unicondylar knee replacement is typically used for patients who have osteoarthritis in limited parts of their knee. If you have osteoarthritis in more than one area of your knee, a total knee replacement is usually recommended. Of course, there may be other reasons for having a unicondylar knee replacement—feel free to ask your surgeon.

Are there different types of unicondylar knee replacement?

Yes. There are many different designs on the market. The most significant difference is whether the polyethylene (plastic) lining of the new knee is free to move or not. A moving plastic bearing (as in the Oxford® Knee) is known as a mobile bearing type. When the plastic cannot move, the replacement is a fixed bearing type.

Does a unicondylar knee replacement last longer than a total knee replacement?

Not necessarily. All implants have a limited life expectancy depending on an individual's age, weight, activity level and medical condition. Research has shown that the newer types of unicondylar knee replacements, particularly those with moveable plastic bearings like

Frequently Asked Questions, continued

the Oxford® Unicondylar Knee, have exceptionally low wear rates, potentially giving them even longer life expectancies. You can, of course, go on to have a total knee replacement after a previous unicondylar knee replacement, should it become necessary.

What can I expect during and immediately after the surgery?

During surgery, your surgeon will remove small amounts of bone and then fix the Oxford® Knee components to your bone with bone cement. The operation usually lasts about one hour. The recovery time is usually much faster than a total knee replacement because the Oxford® Unicondylar Knee is inserted through a smaller opening in your knee. It is likely that you will be up and walking, although perhaps with some assistance, on the same or next day after the operation. Light activities, such as driving, can normally be resumed in a few weeks.

What activities can I expect to do after the surgery?

The amount of activity you will be able to perform will depend on several variables, including what activities you were able to perform before the operation. It will also depend on how much your surgeon allows. Always follow the advice given by your surgeon or rehabilitation professional.

What can I expect during rehabilitation?

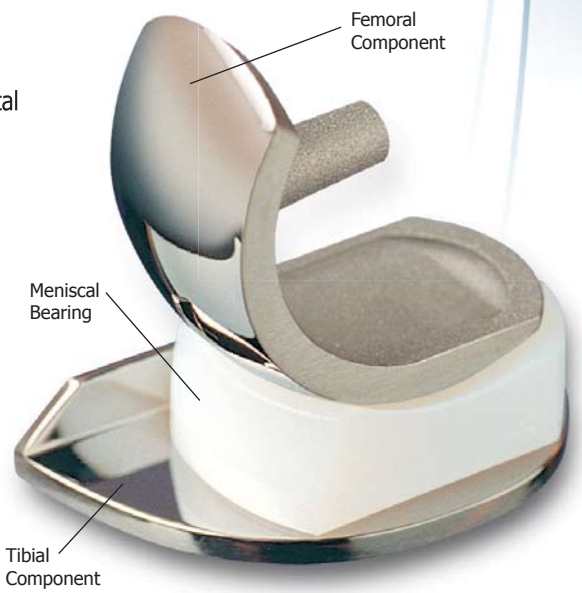
You should follow the exercise program advised by your doctor. This may include visiting a physical therapist. Beside specific exercises to strengthen your knee joint, they will help you learn the best way to perform every day activities such as climbing stairs and rising from a chair.

What can I expect from the device?

The Oxford® Meniscal Unicompartmental Knee is intended to reduce pain and restore function to your knee. As with any artificial joint, this prosthesis will not restore your knee to a normal, undiseased joint.

How do I prepare myself for surgery?

Your doctor will provide you with instructions regarding how to prepare for surgery. You may be required to donate blood before surgery.



Components of the Oxford® Meniscal Unicompartmental Knee

The Knee

The knee is a complex joint consisting of bones and soft tissue (Figure 1). The end of your thighbone (femur) can be compared to a rocking chair. It has two distinct surfaces called compartments, which rest on the shinbone (tibia). A third compartment is found behind the kneecap (patella), and all three compartments are covered with cartilage to help cushion and lubricate the bones during movement.

Knee cartilage is generally very durable, but susceptible to wear over time. As we age, old injuries can become more apparent with activity.

Osteoarthritis is a degenerative process that results in the wearing out of the cartilage that protects the joints. Over time, the cartilage slowly erodes until the underlying bone is exposed. The exposed bone can be painful when the joint moves and bears weight.

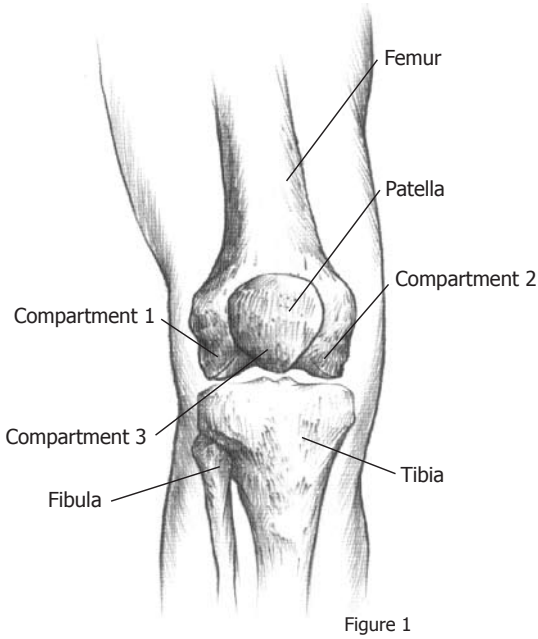


Figure 1

Purpose of the Device:

The Oxford® Meniscal Unicompartmental Knee is intended for use in individuals with osteoarthritis or avascular necrosis limited to the medial compartment of the knee and is intended to be implanted with bone cement.

The Oxford® Meniscal Unicompartmental Knee is unique in that the meniscal bearing is not fixed to the tibial component but free to move as your knee moves.

Description of the Device:

The Oxford® Meniscal Unicompartmental Knee consists of three components: a femoral component; a tibial component; and a meniscal bearing.

The **femoral component** chosen for you is manufactured from a superalloy (cobalt chromium molybdenum). The component has a highly polished, spherical articular surface. A central peg assists in placement of the device in the femur.

The **tibial component** is also manufactured from cobalt chromium molybdenum. Separate components are designed for the left and right knee. The articular surface is flat and highly

polished with a raised lip running the length of the lateral edge. On the undersurface, there is a a flat fin (keel) to locate the component during insertion.

The **meniscal bearing** is made of ultra high molecular weight polyethylene. The upper articular surface of the bearing is spherically concave and has the same radius as the femoral component. The lower articular surface is flat, to match the tibial component.

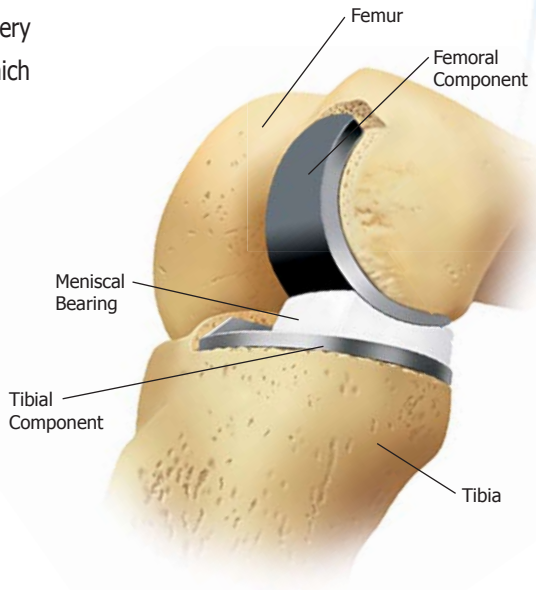
Additional Information

Clinical Studies:

A prospective multi-site clinical investigation of the Oxford® Meniscal Unicompartmental Knee involving 125 knees in 107 patients was conducted in the United States to determine the safety and effectiveness of the device in a standard open surgical procedure. At 2 years following surgery, 72 out of 80 patients (90%) experienced either mild or no pain with 50 of these patients (62%) experiencing no pain at anytime. Also at 2 years after surgery, 74 out of 80 patients (92.5%) required no support when walking. Eight of the 125 knees (6.4%) were removed or replaced (i.e., revised) within 2 years of the initial surgical procedure. After more than 10 years since the last knee in the study was implanted (ranging up to 14 years for all other knees in the study), a total of 23 revisions have been reported.

An additional 328 Oxford® Meniscal Unicompartmental Knees were implanted using a minimally invasive surgical procedure at 3 European medical centers. At 2 years following surgery 5 of the 307 knees (1.6%) for which there was follow-up information had been revised.

Comparison of these clinical results with reports of other types of knee prostheses in the published literature showed the Oxford® Meniscal Unicompartmental Knee to perform similarly or better to other knee devices.



Additional Information, continued

It is important to note that a previous study has shown that hospitals implanting an average of 23 Oxford® Meniscal Unicompartmental Knees per year achieve significantly better results (i.e., lower revision rates) than those centers that implant less than an average of 23 per year.

Adverse events occurring in the clinical investigation of the Oxford™ Meniscal Unicompartmental Knee in the United States were similar to those reported for other commercially available knee components. Adverse events reported with this device included:

- Effusion (1 case reported out of 125 knees)
- Deep infection (1 case reported out of 125 knees)
- Degeneration of the contra-lateral condyle (4 cases reported out of 125 knees)
- Removal of loose body or osteophyte (4 cases reported out of 125 knees)
- Soft tissue damage (2 cases reported out of 125 knees)
- Dislocation (2 cases reported out of 125 knees)
- Component mal-alignment (1 case reported out of 125 knees)
- Patella dislocation (1 case reported out of 125 knees)
- Component loosening (6 cases reported out of 125 knees)
- Post-operative bone fracture (1 case reported out of 125 knees)
- Rheumatoid arthritis (1 case reported out of 125 knees)
- Trauma (1 case reported out of 125 knees)
- Mechanical symptoms (1 case reported out of 125 knees)
- Instability (1 case reported out of 125 knees)
- Persistent pain (1 case reported out of 125 knees)
- Wear of bearing due to osteophyte (1 case reported out of 125 knees)

Alternative Treatment Options:

Depending on your age, general health, and condition of your knee, several alternative procedures are available. These include but are not limited to:

- The use of a conventional total or unicompartmental knee prosthesis
- Fusion of the joint
- Realignment of your knee by removing bone (osteotomy)
- No surgery and your acceptance of the limited movement, pain or deformity

Glossary

Articular Surface: The surface of a joint that moves against another surface.

Atrophy: A wasting away of tissue, frequently related to decreased use or decreased blood supply.

Avascular Necrosis: A condition resulting from the temporary or permanent loss of blood supply to the bone, causing the bone tissue to die and the bone to collapse.

Bone Cement: A plastic grouting material used to hold joint replacement prosthesis to the natural bone.

Cartilage: A tough, fibrous connective tissue attached to the articular surfaces of bones.

Charcot's Disease: A condition where joint destruction is caused by loss of normal sensation/feeling.

Compartment: One side of the knee joint.

Component: One piece of a multi-piece device.

Condyle: The rounded surface of a bone that allows movement of a joint.

Contra-lateral: Pertaining to the opposite side (i.e. the left leg is contra-lateral to the right leg).

Degeneration: Breakdown of the natural tissue.

Dislocation: The condition of the components of your knee joint not lining up correctly. May also refer to bones that are not lined up correctly.

Effusion: Draining of liquid.

Femur: The large bone of the thigh that runs between your hip and your knee.

Femoral Component: Artificial device used to replace portions of the femur.

Fixation: The condition of being held in a fixed position.

Fixed Varus Deformity: The abnormal positioning of your leg. In the case of the knee, a varus deformity would cause bowed legs.

Flexion Deformity: The inability to fully straighten or extend your leg.

Fracture: A break.

Implant: (Noun) An artificial device used to replace a part of the body (same as prosthesis).

Implant: (Verb) To place a foreign object into the body.

Inflammatory Joint Disease: A disease that causes the swelling of the joint lining.

Lateral: The side toward the outside of the body.

Ligament: A sheet or band of tough, fibrous tissue that connects bones or cartilage.

Loose Body: Any piece of material (bone, metal or plastic) that is not attached to the joint surface.

Loosening: The condition when the metal components of the knee device are no longer firmly attached to the bone.

Mal-alignment: The failure of the knee components and/or bone surfaces to be properly lined up with one another.
Medial: The side toward the midline of the body.
Meniscus: The crescent shaped, rubbery cushion of cartilage attached to the inner and outer surface of the tibia in the knee joint. The meniscus helps the knee joint carry weight, glide, and turn. It also keeps the femur and tibia from grinding together.
Meniscal Bearing: An artificial replacement for the meniscus of the knee.
Mobile Meniscal Bearing: Bearing which is not fixed, but free to move as the knee moves.
Neuromuscular Disease: An abnormal condition of the muscles and nerves.
Osteoarthritis: A condition where the cartilage covering the bone end gradually wears away from extensive use over time. It is accompanied by joint inflammation causing pain and swelling.
Osteomalacia: The adult form of rickets causing reduction in bone strength.
Osteophyte: An abnormal growth of bone.
Osteoporosis: A condition resulting in the reduction of the quantity of bone.
Patella: Your kneecap.
Post-Operative: Following placement of your knee device.
Post-Traumatic Arthritis: A condition where the cartilage covering the bone end gradually wears away as a result of prior damage to the knee. It is accompanied by joint inflammation causing pain and swelling.
Prosthesis: An artificial device used to replace a part of the body (same as Implant).
Resorption: The loss of bone.
Revision Surgery: The removal of the components of the knee device.
Rheumatoid Arthritis: A disease affecting the entire body causing swelling of the joint lining which destroys the joint surface.
Soft Tissue: The parts of your knee joint not made up of bone.
Tendon: A band of tough, fibrous tissue that connects a muscle with a bone.
Tibia: The larger of the two bones in the lower leg. The shinbone.
Tibial Component: Artificial device used to replace portions of the tibia.
Tibial Plateau Fracture: A break or crack at the top surface of the shinbone.
Total Knee Replacement: An artificial device used to replace all surfaces of the knee.
Ultra High Molecular Weight Polyethylene: A type of plastic used for bearing surfaces in joint replacement prostheses; often referred to as Polyethylene or UHMWPE.
Unicompartmental: Pertaining to one side of the knee joint (same as Unicondylar).
Unicondylar: Pertaining to one side of the knee joint (same as Unicompartmental).
Unicompartmental or Unicondylar Knee Replacement: An artificial device used to replace one side of the knee.
Upper Tibial Osteotomy: Realignment of the knee joint by cutting and removing bone from the upper portion of the shinbone.
Wear Particles: Small pieces of the metal or plastic from the knee device that rub off over time.

Complications and Risks

Complications and risks are associated with any major surgery. These include, but are not limited to:

- Infection
- Blood vessel and/or nerve damage
- Bone breakage during the procedure
- Inflammation of the veins of the leg (phlebitis)
- Swelling and/or drainage from your wound
- Delayed wound healing
- Risks associated with anesthetic including brain damage, pneumonia, blood clots, heart attack, and death
- Cardiovascular disorders including blood clots (venous thrombosis), clots in the arteries or veins near the lungs (pulmonary embolism) and heart attack (myocardial infarction)

The following risks are associated with joint replacement prostheses:

- The prosthesis could break
- The components of your prosthesis could dislocate from one another
- The bone cement used to hold your prosthesis in place may break down
- The bone around your implant may disappear (resorb)
- The surfaces of the prosthesis may experience wear
- You may have an allergic reaction to the prosthesis materials
- You could have persistent pain and/or loss of motion
- A sudden drop in blood pressure during surgery due to the use of bone cement
- The prosthesis may become loose or move within the joint due to loss of fixation, trauma, mal-alignment, loss of bone or excessive activity
- Formation of extra bone within the joint
- Improper alignment of your knee
- Tearing of the tendons or failure to fully stretch out the ligaments around the knee joint

Some complications may cause prolonged illness, a draining wound, the need for blood transfusions, the need for other major surgery, removal of the prosthesis, or permanent pain and deformity. Any one of these complications alone or in combination might result in death. There may be some risks that are not known at this time. You can reduce the risk of some adverse events by following your doctor's instructions.

When the Device Should Not Be Used

You should not consider having an Oxford® Meniscal Unicompartmental Knee implanted into your knee if you are experiencing any of the following conditions:

- If you have an infection, even if it is not located in your knee
- If you have rheumatoid arthritis or other forms of inflammatory joint disease in your knee
- If you have had an implant in your knee before
- If you have had a failed upper tibial osteotomy or post-traumatic arthritis after tibial plateau fracture

When the Device Should Not Be Used, continued

- If you have damaged or missing ligaments in your knee
- If you have disease or damage to the lateral compartment of your knee
- If you can not follow your doctor's instructions
- If you have osteoporosis and your doctor feels it may affect your knee prosthesis
- If you have a disease or metabolic disorder such as osteomalacia, vascular insufficiency, muscular atrophy, neuromuscular disease, or Charcot's disease, which may impair bone formation and affect the outcome of your knee implant surgery.
- If you have rapid joint destruction, marked bone loss, or bone resorption visible on an X-ray.
- If you have incomplete or deficient soft tissue surrounding the knee
- If you have a fixed varus deformity (which your surgeon cannot correct by pushing on it) of greater than 15 degrees.
- If you have a flexion deformity greater than 15 degrees.

General Warnings and Precautions

WARNING:
You should not participate in vigorous sports, such as jogging and heavy lifting. These activities may place unusual stresses (forces) on your knee device, which could lead to breakage, excessive wear or dislocation of the components, which may result in additional surgery. You can increase the chance of success with this knee joint if you limit your activity.

WARNING:
Avoid excessive activity, trauma, and weight gain as these could cause premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as damage to bone making successful revision surgery more difficult.

PRECAUTION:
Listen to your doctor. Your doctor will provide you with important postoperative instructions. You will be advised as to the limitations of the prosthesis and the need for protection of the implant from full load bearing until adequate fixation and healing have occurred. Your failure to follow these postoperative care instructions involving rehabilitation will reduce your success with the knee.

Further Information

Your doctor should be able to answer any questions you may have regarding the Oxford® Meniscal Unicompartmental Knee and the potential use of this device for treatment of your knee. If there are any questions that your doctor is unable to answer, you may contact Biomet, Inc., the manufacturer of this device at 1-800-348-9500.

Your Doctor: _____

Phone Number: _____

Reference

1. Keys, G.W.: "Reduced Invasive Approach for Oxford II Medial Unicompartmental Knee Replacement—A Preliminary Study." *The Knee*, Vol. 6; No.3: 193–196, 1999.

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