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Oxford™ Meniscal Unicompartamental Knee

Attention Operating Surgeon

DESCRIPTION

The Oxford™ Meniscal Unicompartamental Knee is a medial unicompartamental knee replacement system consisting of a femoral component, a tibial component and a freely mobile meniscal bearing.

Materials:

Femoral Components: CoCrMo Alloy

Tibial Component: CoCrMo Alloy

Meniscal Bearing: Ultra-High Molecular Weight Polyethylene (UHMWPE)

INDICATIONS

The Oxford™ Meniscal Unicompartamental 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.

CONTRAINDICATIONS

Contraindications include:

- 1) Infection, sepsis, and osteomyelitis
- 2) Use in the lateral compartment of the knee
- 3) Rheumatoid arthritis or other forms of inflammatory joint disease
- 4) Revision of a failed prosthesis, failed upper tibial osteotomy or post-traumatic arthritis after tibial plateau fracture
- 5) Insufficiency of the collateral, anterior or posterior cruciate ligaments which would preclude stability of the device
- 6) Disease or damage to the lateral compartment of the knee
- 7) Uncooperative patient or patient with neurologic disorders who are incapable of following directions
- 8) Osteoporosis
- 9) Metabolic disorders which may impair bone formation
- 10) Osteomalacia
- 11) Distant foci of infections which may spread to the implant site
- 12) Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
- 13) Vascular insufficiency, muscular atrophy, neuromuscular disease
- 14) Incomplete or deficient soft tissue surrounding the knee
- 15) Charcot's disease

- 16) A fixed varus deformity (not passively correctable) of greater than 15 degrees
- 17) A flexion deformity greater than 15 degrees

WARNINGS

- 1) Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.
- 2) Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
- 3) Do not modify implants.
- 4) Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.
- 5) Malalignment or soft tissue imbalance can place inordinate forces on the components which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required to prevent component failure.
- 6) Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture and loosening due to cement failure has been reported.
- 7) The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

PRECAUTIONS

- 1) As with other surgical procedures, errors of technique are most likely when the method is being learned. To reduce these to a minimum, surgeons are required in the United States and strongly recommended throughout the world, to attend an Instructional Course on the Oxford™ Meniscal Unicompartmental Knee before attempting the operation.
- 2) Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.
- 3) Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and weight gain may contribute to 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 accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks,

possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

- 4) Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure.
- 5) Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

POSSIBLE ADVERSE EFFECTS

A time-course distribution of the adverse events reported in the clinical investigation of the Oxford™ Meniscal Unicompartmental Knee using a standard open surgical technique is provided in Table 1.

Table 1 – Time-Course Distribution of Adverse Events reported in the clinical trial for the Oxford™ Meniscal Bearing Unicompartmental Knee* using a standard open surgical technique.

Adverse Events	Frequency							Percent of Population ¹ (n=125)
	IO	6 mo	1 yr	2 yr	3 yr	4 yr	≥ 5 yr	
Local – Operative Site								
Effusion			1					0.8 %
Deep Infection				1				0.8 %
Degeneration of contralateral condyle						1	3	3.2 %
Loose body and/or osteophyte removal		1		2			1	3.2 %
Soft tissue damage	2							1.6 %
<i>Dislocation</i>				2				1.6 %
<i>Component mal-alignment</i>		1						0.8 %
<i>Patella dislocation</i>				1				0.8 %
<i>Component loosening</i>					1	2	3	4.8 %
Post-operative bone fracture		1						0.8 %
Trauma		1						0.8 %
Mechanical symptoms			1					0.8 %
<i>Instability</i>							1	0.8 %
<i>Persistent pain</i>					1			0.8 %

Wear of bearing due to osteophyte					1			0.8%
Systemic								
Development of rheumatoid arthritis			1					0.8 %

* Phase 2 device design

IO = intraoperatively

¹All percentages for adverse events are based the number of occurrences reported in a patient population of 125 knee cases.

Those events listed in *italics* are considered device related events.

Boldface numbers represent revisions due to the given adverse event. One additional case was revised at 130 months post-operatively, cause unknown.

The following complications have also been reported in the clinical literature for unicompartmental and total knee arthroplasty designs and could potentially occur with the Oxford™ Meniscal Unicompartmental Knee device.

- 1) Major surgical risks associated with anesthetic including, brain damage, pneumonia, blood clots, heart attack, and death.
- 2) Cardiovascular disorders including venous thrombosis, pulmonary embolism, and myocardial infraction.
- 3) A sudden drop in blood pressure intraoperatively due to the use of bone cement.
- 4) Damage to blood vessels, hematoma, delayed wound healing and/or infection.
- 5) Temporary or permanent nerve damage may result in pain and numbness.
- 6) Material sensitivity reactions.
- 7) Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
- 8) Early or late postoperative, infection, and allergic reaction.
- 9) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
- 10) Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
- 11) Periarticular calcification or ossification, with or without impediment of joint mobility.
- 12) Inadequate range of motion due to improper selection or positioning of components.
- 13) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
- 14) Fatigue fracture of components can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
- 15) Fretting and crevice corrosion can occur at interfaces between components.
- 16) Wear and/or deformation of articulating surfaces.
- 17) Valgus-varus deformity.

- 18) Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
- 19) Patellar tendon rupture and ligamentous laxity.
- 20) Persistent pain.

PATIENT SELECTION

Positive selection factors to be considered include:

- 1) ACL and PCL functionally intact
- 2) Cartilage and bone erosions limited to the anterior and middle parts of the medial compartment. The posterior part of the medial compartment and the lateral compartment having cartilage of normal thickness
- 3) Medial collateral ligament not structurally shortened (i.e. varus deformity correctable)
- 4) Patellofemoral joint damage limited to (or greater on) the medial facets
- 5) Fixed flexion deformity of less than 15 degrees
- 6) Flexion possible to 110 degrees under anaesthetic
- 7) Need to obtain pain relief and improve function
- 8) Ability and willingness of the patient to follow instructions, including control of weight and activity level
- 9) A good nutritional state of the patient, and
- 10) The patient must have reached full skeletal maturity.

CLINICAL STUDIES

A prospective multi-site clinical investigation of the Oxford™ Meniscal Unicompartmental Knee involving 125 knee devices in 107 patients (see Tables 2 and 3) was conducted in the United States to determine the safety and effectiveness of the device when implanted using a standard open surgical technique. All clinical results and adverse events for this investigation were derived from the Oxford™ Meniscal Unicompartmental Knee Phase 2 device, a previous version of the current Phase 3 device, that had a single femoral component size, a universal (left and right) design tibial component of few sizes, and a universal design meniscal bearing component with extended sizes.

Table 2 – Patient Demographics for the Oxford™ Clinical Study (Phase 2 Device)

	All Oxford Knees Enrolled
Total # Knees (# Patients)	125 (107)
Mean Age in years (range)	63±10.6 (29-85)
Sex	Males – 60 Females - 65
Indications	Osteoarthritis – 114 Post-Traumatic Arthritis – 10 Avascular Necrosis - 1
Side	Left – 56 Right – 69
Compartment	Medial – 119 Lateral – 6
Mean Height in Inches (range)	67.0±3.9 (59-77)
Mean Weight in Pounds (range)	187±38.6 (105-256)

Table 3 – Device Accounting for the Oxford™ Clinical Study (Phase 2 Device) based on number of completed clinical follow-up examinations.

	6 months	1 year	2 year	3 year	4 year	5 year
¹ Theoretically Due	125	125	125	113	102	84
² Deaths	0	0	1	2	2	2
³ Revisions	3	4	8	11	13	15
⁴ Expected	122	121	116	100	87	67
⁵ Clinical Follow-Up	100	110	80	83	69	51
⁶ Percent Follow-up	82.0%	90.9%	69.0%	83.0%	79.3%	76.1%

¹Based on the cut-off date when the last patient enrolled reached their 2 year post-operative anniversary

²Cumulative over time

³Any component removed, cumulative over time

⁴Theoretically Due – (Deaths + Revised)

⁵Cases with complete clinical data (i.e., HSS, radiographic), obtained at the specified time point

⁶Clinical Follow-Up / Expected

Each patient was evaluated pre-operatively, and at the immediate and 6, 12, and 24 month post-operative intervals, and annually thereafter until the last patient enrolled had achieved their 24 month follow-up. All operative and post-operative complications, device related or not, were recorded for patients enrolled into the investigation (see Table 1).

Clinical results were evaluated using the Hospital for Special Surgery (HSS) knee scoring system and radiographic data. At each follow-up visit an HSS knee score and anterior/posterior and lateral radiographs were obtained. Radiographs were reviewed by the implanting surgeon. See Table 4 for clinical study results.

A patient was defined as a success if they met all of the following criteria:

- 1) A Good/Excellent HSS score, i.e., > 70 points,
- 2) No radiolucent lines > 1 mm in width surrounding > 50% of the component after 1 year in-situ,
- 3) No progressive radiolucencies, and
- 4) No revision/removal of any components.

Table 4 – Oxford™ Clinical Study Results* (Phase 2 Device) using a standard open surgical technique.

	Preop	1 year	2 years	3 year	4 year	5 year
Cases with complete HSS	123	110	80	83	69	51
Average HSS Score	59.5	89.3	90.0	90.6	90.7	90.4

¹ Cases Rated as Good/Excellent HSS	20/123 (16.3%)	105/110 (95.5%)	77/80 (96.3%)	82/83 (98.8%)	64/69 (92.8%)	50/51 (98.0%)
Femoral Lucencies \geq 1mm		6/108 (5.5%)	2/80 (2.4%)	2/83 (2.4%)	2/68 (2.9%)	2/51 (2.9%)
Tibial Lucencies \geq 1mm		5/108 (4.6%)	6/80 (7.5%)	8/83 (9.6%)	7/68 (10.3%)	3/51 (5.9%)
Number of G/E cases with radiolucent lines >1mm around >50% of component		0	0	0	0	1 (femoral)
Number of G/E cases with progressive radiolucencies		0	0	0	1 (tibial)	0
² Revisions		4	8	11	13	15
³ Cumulative Survivorship		96.75%	93.34%	90.73%	88.83%	86.82%
⁴ Successful Cases		105	77	82	63	49
⁵ Percent Successful		92.5% (105/114)	87.5% (77/88)	87.2% (82/94)	76.8% (63/82)	74.2% (49/66)

*Based on the cut-off date when the last patient enrolled reached their 2 year post-operative anniversary

¹Hospital for Special Surgery score > 70

²Number of components removed at specified time point

³Kaplan-Meier Life Table results

⁴A successful case required a Good/Excellent HSS score, no revision/removal of any component, no radiolucent lines > 1 mm in width surrounding > 50% of the component, *and* no progressive radiolucencies.

⁵Denominator includes cases with complete HSS and radiographic data, *and* revisions.

There were a total of 23 revisions reported for the Oxford™ study group (over a follow-up period of at least 9 years), with 8 of these occurring within the first 2 years of implantation. Of the 8 revisions reported at 2 years, 2 were for tibial bearing dislocation, 1 for patellar dislocation, 1 for infection, 1 for component malalignment, 1 for recurrent arthritis due to trauma, 1 for onset rheumatoid arthritis, and 1 for femoral loosening and fracture at the bone-cement interface. In all but 1 case the knees were revised to a total knee prosthesis. For the remaining 15 revisions reported after 2 years, 6 were due to loosening, 4 to progression of osteoarthritis in the lateral compartment, 1 to persistent pain, 1 to instability, 1 to impingement on an osteophyte and subsequent wear of the tibial bearing, 1 to impingement of an osteophyte on the femur, and 1 failed to report a reason. Revisions in this latter group occurred from 2 to 12 years post-operatively.

The survival rate for the Oxford™ Meniscal Unicompartmental Phase 2 device study group at 2 years post-operatively is 93.38%, based on the endpoint of revision/removal of any component. Table 5 displays the Kaplan-Meier life table for survivorship through 8 years post-operatively for the Oxford study group. Survivorship rates for the study group are comparable to those rates seen in the literature for other unicompartmental knee devices and the rates seen in other studies of the Oxford™ Phase 2 device.

Table 5: Survivorship for Oxford™ Clinical Study (Phase 2 Device)

Interval Since Operation (years)	Number in Beginning of Interval	Number of Revisions at End of Interval	% Interval ¹ Survival	% Cumulative ² Survival	95% Confidence Interval
0-1	125	4	96.75%	96.75%	(93.61 - 99.98)
1-2	117	4	96.52%	93.38%	(88.95 - 97.82)
2-3	109	3	97.16%	90.73%	(88.50 - 95.95)
3-4	99	2	97.91%	88.83%	(83.08 - 94.57)
4-5	90	2	97.74%	86.82%	(80.57 - 93.07)
5-6	85	0	100%	86.82%	(80.57 - 93.07)
6-7	65	3	94.92%	82.41%	(75.21 - 89.60)
7-8	50	1	97.87%	80.65%	(73.35 - 87.95)

¹ Percent survival for that interval only, taken at the end of the interval.

² Percent cumulative survival taken at the end of the interval.

In addition, 2 year clinical data from 328 knee cases implanted with the current Phase 3 device, implanted using the minimally invasive surgical technique and minimally invasive surgical instruments specifically developed for the Phase 3 device, was collected from 3 European sites (2 U.K., 1 Holland). European clinical results were evaluated using the Knee Society Score (KSS) scoring system. At 2 years following surgery 5 of the 307 knees (1.6%) with available data had been revised (see Table 6).

Table 6: Results at 2 years for Phase 2 Device using an open surgical technique and Phase 3 Device using a minimally invasive surgical technique.

Clinical Parameters	Oxford Study Phase 2 N = 125 knees	Combined European Data* Oxford Phase 3 N = 328 knees	European Site 1 Oxford Phase 3 N = 208 knees	European Site 2 Oxford Phase 3 N = 40 knees	European Site 3 Oxford Phase 3 N = 80 knees
Revision Rate ¹	6.8% (8/117)	1.6% (5/307)	2.0% (4/196)	2.7% (1/37)	0% (0/74)
Percent with a Good or Excellent Knee Score ²	N = 80 96.3% ³ (77/80)	N = 271 83.0% ⁴ (225/271)	N = 160 83.1% ⁴ (133/160)	N = 37 86.5% ⁴ (32/37)	N = 74 81.0% ⁴ (60/74)

*Combined data from European Site 1, Site 2, and Site 3.

European Site 1 = Nuffield Orthopaedic Centre (U.K.), Site 2 = Macclesfield Hospital (U.K.), and Site 3 = Groningen Hospital (Holland).

¹Revision rate (%) at 2 years = cumulative number of revisions / (N - # deaths - # lost to follow up).

²Percent with Good or Excellent HSS or KSS knee score at 2 years.

³Based on HSS knee scoring system.

⁴Based on KSS knee scoring system.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

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THE
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Unicompartmental
Knee System

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Oxford™ Meniscal Unicompartmental Knee Patient Labeling

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Glossary:

- Articular Surface:** The surface of a joint that moves against another surface.
- Atrophy:** A wasting away of tissue, frequently related to decrease use or decrease 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.
- 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.
- 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 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.

Descriptive Information

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.

Description of the Device:

The Oxford™ Meniscal Unicompartmental Knee is a medial, unicompartmental knee prosthesis consisting of three components: a femoral component; a tibial component; and a meniscal bearing.

The **femoral component** is manufactured from metal (cobalt chromium molybdenum alloy). 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 manufactured from metal (cobalt chromium molybdenum alloy). 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 keel (a flat fin) to locate the component during insertion. The component is approximately semicircular in shape extended in the front for better bone coverage.



Components of the Oxford™ Meniscal Unicompartmental Knee

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

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.

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
- 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 can not correct by pushing on it) of greater than 15 degrees.
- If you have a flexion deformity greater than 15 degrees.

Benefits of Unicompartmental Replacement over Total Knee Replacement:

Unicompartmental knee replacement is designed to have some advantages over total knee replacement. It is intended to preserve more of the normal knee structures, and is intended to restore more normal knee motion and function. By replacing only one compartment of your knee, there is more of your natural bone left if removal of the Oxford™ prosthesis and replacement with another implant ever becomes necessary.

The Oxford™ Meniscal Unicompartmental Knee has a fully mobile bearing surface which limits the forces and stresses seen by the implant that may often lead to loosening.

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.

What You Can 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.

Preparing for Surgery:

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

What to Expect During Surgery:

The operation usually lasts about one hour. During surgery, your surgeon will remove small amounts of your bone using specialized instruments. The surgeon will then place the femoral and tibial components into your knee, fixing them to your bones with bone cement, a plastic grouting material. The meniscal bearing will be placed between the femoral and tibial components. When your surgeon is happy with the placement of your knee prosthesis, he will close your knee with stitches.

What to Expect After Surgery:

Most patients can walk on their surgical knee the same day as surgery and can possibly be discharged within 24 hours of surgery. Some patients may need to use a walker or cane for the first week. Your surgeon will provide you with instruction on the care of your knee and for any medications he/she prescribes.

What to 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.

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 this knee.

Additional Information:**Clinical Studies:**

A prospective multi-site clinical investigation of the Oxford™ Meniscal Unicompartamental 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 Unicompartamental 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 Unicompartamental Knee to perform similar to other knee devices. The Oxford™ Meniscal Unicompartamental Knee showed a similar rate of occurrence of problems.

It is important to note that a previous study has shown that hospitals implanting an average of more than 23 Oxford™ Meniscal Unicompartamental 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:

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 the bearing due to an 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

User Assistance 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: _____

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