



Precautionary Statement (01-50-0942)

Biomet UK Ltd. **01-50-0942**

Waterton Industrial Estate Date: 04/04

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Oxford™ Meniscal Partial Knee

DESCRIPTION

The Oxford™ Meniscal Partial Knee is a medial partial 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 Partial 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 Partial 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 Partial 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 Partial Knee* using a standard open surgical technique.

Adverse Events	Frequency							Percent of Population ¹ n=125
	Visit	IO	6 mo	1 yr	2 yr	3 yr	4 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%
Dislocation				2				1.6%
Component mal-alignment		1						0.8%
Patella dislocation				1				0.8%
Component loosening					1	2	3	4.8%
Post-operative bone fracture		1						0.8%
Trauma		1						0.8%
Mechanical symptoms			1					0.8%
Instability							1	0.8%
Persistent pain					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 partial and total knee arthroplasty designs and could potentially occur with the Oxford™ Meniscal Partial 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 Partial 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 Partial 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 years	4 years	5 years
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 > 1mm		6/108 (5.5%)	2/80 (2.4%)	2/83 (2.4%)	2/68 (2.9%)	2/51 (2.9%)
Tibial Lucencies > 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 Partial 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 partial 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 of 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 3N = 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<SUP.1<td>	6.8% (8/117)	1.6% (5/307)	2.0% (4/196)	2.7% (1/37)	0% (0/74)
	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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