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ISO 13485
FM75124

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KineMatch® Patello-Femoral Resurfacing Implant

CAUTION

⚠ Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Ⓧ Devices labeled for single use are intended to be used once only, for a single patient, because they may not perform as intended if they are reused. Reuse may lead to failure of the device to perform as intended.

Do not use if package is damaged

A. GENERAL REMARKS

The KineMatch® Patello-Femoral Resurfacing (PFR) Trochlear Implant is a Custom-Made Device intended to provide optimal anatomic coverage of the patello-femoral joint.

The prosthesis is made of Cobalt Chromium Molybdenum alloy (ASTM F-799, ISO 5832-12), providing excellent tribiological properties.

The prosthesis is intended to articulate against the KineMatch® UHMWPe (ASTM F-648, ISO 5834-2) all-polyethylene patella dome implant marketed by Kinamed Inc. The articulating surface of the prosthesis is designed for high contact area and reduced unit load to minimize wear. The patellas are ETO sterilized.

The general principles of patient selection and sound surgical judgment apply to the patello-femoral resurfacing procedure. The device is indicated for use in patients who have reached skeletal maturity.

The preoperative planning and surgical techniques for implantation of the patello-femoral resurfacing procedure evolved from the surgical experience gained during the development of this and similar implants. Many of the methods used represent principles that are basic to sound surgical management in knee replacement. Surgeons should not begin the clinical use of the patello-femoral resurfacing implant before they have familiarized themselves thoroughly with its implantation technique. Certain methods may change with time as further clinical experience is gained. Critical appraisals of such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised.

The patient and physician must realize that any of the circumstances listed (see relevant categories below) may reduce the chance of a successful outcome and an increased percentage of risk must be accepted.

The goal of the patello-femoral resurfacing procedure is to relieve arthritis pain in the front of the knee (patello-femoral joint) thereby increasing a patient's mobility. To accomplish this goal, the patients should be selected: (1) who have and will maintain adequate bone support and (2) who are able and willing to follow their physician's directions generally, and particularly with respect to either no weight-bearing or minimal weight-bearing during postoperative care. Patients should be precautioned against heavy labor, active sports, or any activity which places heavy or abrupt loads on implanted prostheses.

In addition, the following factors are important but not necessarily sufficient prerequisites for use of this product in knee replacement:

1. Careful selection of patients with regard to activity level.
2. Physician's sound knowledge of knee anatomy and of the biomechanical principles underlying knee arthroplasty.
3. Patient's understanding and acceptance of his physician's instructions (preferably written) for his postoperative management, including a regimen of guarded activities with limited loading of the affected extremity.
4. A continuing program of periodic postoperative check-ups of the patient.

Specific prerequisites for unicompartmental (patello-femoral) joint replacement must be strictly adhered to.

1. Significant arthritic disease of the patello-femoral surfaces.
2. Stable or reconstructable ligaments.
3. Physiologic or correctable axial alignment.
4. Intact quadriceps and hamstring mechanisms.
5. Patella bone suitable for accepting a patella component.

B. INDICATIONS AND USAGES

The KineMatch® Patello-Femoral Resurfacing Implant is indicated for patients with degenerative arthritis of the anterior distal femur and patella, a history of patellar dislocation or patella fracture, or failed previous surgery where pain, deformity, or dysfunction persists. The KineMatch® Patello-Femoral Resurfacing Implant is intended to be articulated against the KineMatch® all-polyethylene patella implant. The KineMatch® Patello-Femoral Resurfacing Implant is intended for use with bone cement.

Some of the diagnoses listed above may also increase the chance of complications and reduce the chance of a satisfactory result.

Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief and when there is progressive disability.

C. CONTRAINDICATIONS

The following conditions are contraindications for patello-femoral resurfacing:

1. Local infection, recent or old.
2. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable.
3. Charcot's arthropathy/disease.
4. Paget's disease.
5. Poor bone quality, such as osteoporosis.
6. Elevation of sedimentation rate unexplained by other diseases, elevation of WBC count, or more marked shift in WBC differential count.
7. Patient physical condition that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriate size implant.
8. Blood supply limitations from previous surgery, alcohol agglutination, etc.
9. Insufficient quantity or quality of bone resulting from conditions such as: cancer, congenital dislocation, femoral osteotomy revision, obesity, osteoporosis, etc.
10. Patient's mental or neurological conditions which tend to pre-empt the patient's ability or willingness to restrict activities, especially during the healing period, e.g., drug use, mental illness, senility, and other general neurologic conditions.
11. Physical conditions or activities which tend to place extreme load on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
12. Absence of collateral and cruciate ligament integrity.
13. Any disease affecting the support and fixation of the prostheses.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, tibial osteotomy, resection arthroplasty, patellectomy, tri-compartmental arthroplasty and others.

Additionally, distant foci of infection, such as genitourinary, pulmonary, skin or other sites, are a relative contraindication because hematogenous spread to the implant site may occur. The foci of infection should be treated prior to, during, and after implantation.

Use of this implant is contraindicated where loss of abductor musculature, poor bone stock, poor skin coverage around the knee joint, or neuromuscular disease compromising the affected limb would render the procedure unjustifiable.

D. WARNINGS

Loosening, bending, cracking and/or fracture of implants and other complications may result from failure to observe the following warnings and precautions.

Improper selection, placement, positioning, and fixation of implant components may result in unusual stress conditions and subsequent reduction in the service life of prosthetic implants. For safe and effective use of this system, the surgeon should be thoroughly familiar with the implantation technique (see Utilization and Implantation section).

Accepted practices should be followed meticulously in postoperative care. The patient should be made aware of the limitations of total joint reconstruction and its relatively recent history of usage. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure of the reconstruction by loosening, fracture, and wear of the prosthetic implants.

The long-term safety and effectiveness of this device remains under investigation. The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure:

1. Obesity.
2. Heavy labor.
3. Active sports participation.
4. High general activity level.
5. Likelihood of falls.
6. Alcohol or drug addiction.
7. Other disabilities.

The following physical conditions tend to adversely affect the stable fixation of implants:

1. Marked osteoporosis with poor bone stock and danger of impaired abutment of implants with bone.
2. Systemic and metabolic disorders leading to progressive deterioration of solid bone support for the implant (e.g., diabetes, myelitis, cortisone therapies, immunosuppressive therapies).
3. History of general infectious disease (e.g., erysipelas) or local infectious disease.
4. Severe deformities leading to impaired anchorage or improper positioning of the implant.
5. Tumors of the supporting bone structures.
6. Allergic reactions to corrosion products from implant materials.
7. Tissue reactions to corrosion or wear products.
8. Disablement of other joints, (i.e., hips and ankles).

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions of increased risk. Mental attitudes or personality disorders resulting in patient's failure to adhere to his physician's orders might delay post-operative recovery and aggravate adverse effects.

This device has not been approved for non-cemented application.

E. PRECAUTIONS

Laboratory studies have shown that entrapped bone cement and other wear particles may increase wear rates and lower the service life of prosthetic materials. It is important therefore, to remove any cement debris following cement application.

Meticulous lavage of the prepared bone surface should be observed. Particular care should be taken to insure that the femoral component is not pre-fit onto the femur. Adequate bone cement mantle should be present.

An implant should never be re-used. Although it may appear undamaged, previous handling and in-service stresses may have created imperfections that would reduce the service life of the implant.

Use extreme care in handling and storage of implant components. Cutting, bending or scratching the surface of components may reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected during storage from corrosive environments, such as salt air, etc.

An adequate inventory of patella implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra patella implant components are recommended.

Prior to surgery, all packages and implants should be thoroughly inspected for possible damage.

The use of certain special surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. The femoral preparation instruments should be checked prior to surgery. Bent or damaged instruments may lead to improper implant position and result in implant failure. Thorough familiarity with the surgical technique is essential to ascertain their proper working condition.

F. ADVERSE EFFECTS

The following are generally the most frequent adverse effects of knee arthroplasty.

1. Early or late loosening, bending, cracking, fracture or deformation, of one or more prosthetic components. This is often attributable to factors listed under "WARNINGS." Loosening may also occur due to defective fixation or improper positioning.
2. Early or late infection which may require removal of the implant and a subsequent arthrodesis.
3. Dislocations, subluxation, rotation phenomenon, flexion contracture, or a decreased range of motion caused by improper positioning, or looseness of components.
4. Fractures of the patella, tibia, or femur: Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes and misdirected reaming, and/or inadequacy or maldistribution of cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.
5. Cardiovascular disorders: Wound hematoma, thromboembolic disease, including venous thrombosis and pulmonary embolus.
6. Tissue reactions: Macrophage and foreign body reaction adjacent to implants resulting from foreign material in tissues. Also, myositis ossificans, especially in males with hypertrophic arthritis, limited preoperative range of motion and/or previous myositis. Myositis ossificans is increased with prior surgery or presence of infection.
7. Micro-emboli resulting in decreased pulmonary and mental function.

G. PREOPERATIVE PROCEDURES

The surgeon should discuss all physical and mental limitations particular to the patient and all aspects of the surgery and product with the patient before surgery. The discussion should include the limitations of total joint reconstruction, the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's instructions postoperatively, particularly with regard to limited activity and weight reduction.

An adequate inventory of sterilized patella implant sizes should be on hand at the time of surgery, to include at least one size larger and smaller than the preoperatively determined optimal size.

Allergies and other reactions to device materials, although infrequent, should be considered.

Surgical technique booklets and other documentation are available on request from KINAMED (at no charge), and should be studied prior to initial surgery.

H. INTEROPERATIVE PROCEDURES

There is recent evidence that the potential for deep sepsis following knee arthroplasty may be reduced by:

Consistent use of prophylactic antibiotics.

Having all operating room personnel–anesthetists, circulators, observers, etc., as well as scrubbed technicians, properly attired to assure sterility at the operating site.

Familiarity with and careful attention to the surgical technique are necessary for good results. Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and subsequent reduction in the functional life of the prosthetic implants through loosening, deformation, bending, cracking, fracture, or wear.

Always use a patella trial for any test fit. Trials and their respective implant must have the same configuration.

Proper handling of any implant is mandatory. Prior to surgical use, a visual inspection of each implant for possible imperfections should be performed routinely. Damage or alterations to the implant may produce undesirable stresses and cause defects which could become the focal point for implant failure.

Proper cleaning and preparation of the bone surfaces has been stated to be important in enhancing prosthesis fixation. Bone excision should be limited to the amount necessary to accommodate the implants. Excess bone removal may result in mechanical disturbances and bone resorption with subsequent failure of the procedure due to loosening or deformation of the implant.

Care should be taken not to scratch, bend or cut components during surgery for the reasons stated under Section E (Precautions). Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture.

During curing of cement, care should be taken to prevent moving implant components. A tight fit of implant to cement and cement to bone is essential to prevent motion which may lead to bone resorption and/or cement cracking.

Because of the thickness of the patello-femoral resurfacing prosthesis, it is essential that the implant underside be firmly supported. It is of particular importance that the portion of the implant extending distally towards the intercondylar notch (i.e. tongue of the implant) be supported. Should the implant not be seated in such a manner, there is a risk of implant flexure and fatigue failure. Care must be taken to ensure that the implant is properly seated against the femur to prevent tibial impingement.

Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

An implant should never be reused. Even though the implant appears undamaged, it may be fatigued from previous stresses and may have developed microscopic imperfections which could lead to implant failure.

I. POSTOPERATIVE PROCEDURES

1. Most Common Early Postoperative Adverse Effects:

Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, and death. Hematoma and delayed wound healing. Infected wound. Pneumonia and atelectasis.

2. Postoperative:

Postoperative direction and warnings to patients by physicians, and patient care are extremely important. Unsupported weight bearing after surgery is not recommended. This may delay normal healing of bone which would provide proper bone support. Evidence suggests adequate healing may require four months or longer, and a period shorter than this increases the possibility of loosening, bending, cracking, and/or fracture of implants.

A postoperative rehabilitation program is imperative. Patient should be precautioned against unassisted activity, particularly use of toilet facilities and other activities requiring walking.

Use extreme care in patient handling. Support should be provided to the operative knee when moving the patient. While placing the patient on bedpans, changing dressings, clothing, and similar activities, precautions should be taken to avoid placing any load on the operated part of the body.

The patient should be cautioned to govern his activity level, protecting the replaced joint from unreasonable stresses. Postoperative therapy should be structured to prevent excessive loading of the operated knee.

The patient should be released from the hospital with complete instructions and warnings (preferably written) regarding further exercise and therapies. The patient should be encouraged to report to his physician any unusual changes in the operated extremity.

Postoperative therapy should be structured to prevent loading of the operative knee. Periodic x-rays are recommended for comparison with postoperative conditions to detect long-term evidence of changes in position, loosening, bending and cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.

In every case, accepted practices should be followed in postoperative care. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure of the reconstruction by position change, fracture, and/or wear of the implant. The functional life expectancy of prosthetic implants is, at present, not clearly established.

3. Late Postoperative:

Patella fracture can result from trauma or excessive loading, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects from previous surgery, reaming or bone resorption, or improper implant placement.

Tissue reactions, allergic reactions, and loosening may be caused by metallic corrosion products, the accumulation of wear debris from the metal/polyethylene couple or loose cement particles.

J. UTILIZATION - INFORMATION FOR USE

Many of the methods used represent principles that are commensurate with sound surgical judgment in total knee replacement. Surgeons should not begin using this system before they have familiarized themselves thoroughly with its implantation technique.

Special instruments are available to assist in the accurate installation of the implant components. With knee and hip disease, generally operate on hips prior to knees and on the more diseased side of each pair of joints first, in order to make rehabilitation more effective.

NOTE: The cementing technique is extremely important: a uniform, thin cement mantle should surround the patello-femoral resurfacing implant components.

Bone scanning may help identify postoperative problems such as infection, loosening, or ectopic bone formation. However, most postoperative complications can be identified on periodic routine A-P and lateral x-rays.

In revision surgery, it is important to adequately remove the fibrous membrane which encapsulates the failed prosthesis. If not removed, this residual fibrous membrane may impede the required acrylic cement interdigitation (into cancellous bone interstices) necessary for mechanical fixation.

There is recent evidence that deep sepsis following knee arthroplasty may be minimized by:

1. Consistent use of adequate preventative antibiotics.
2. Utilizing a laminar flow clean air system.
3. Having scrubbed operating room personnel attired in individual respiratory evacuating systems, i.e., helmet aspirators.
4. Protecting instruments from airborne contamination.
5. Impermeable draping.

Note: Surgical technique available upon request.

K. STERILITY AND HANDLING

1. Metal Components

Unless supplied sterile, the metallic implant must be sterilized prior to surgical use. The recommended method of sterilization is autoclaving which employs saturated steam under pressure at a minimum of 121°C (250°F) for a minimum of 30 minutes after the temperature of the metallic components being sterilized reaches 121°(250°F).

Metal instruments must be sterilized prior to surgical use. Steam autoclaving is recommended.

2. Plastic Components

Caution: Sterilization of polyethylene components by autoclave is not recommended; autoclaving, dry heat or boiling may warp or shrink the material and preclude usage. Do not resterilize the patella components using radiation.

L. PACKAGING AND LABELING

Implant should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact.

M. SIZE MATCHING SCHEME

The KineMatch® Patello-Femoral Resurfacing Implant is designed to mate with the KineMatch® all-polyethylene patella dome marketed by Kinamed. Patellar components, which are available in multiple sizes, all have a 1 inch (25.4 mm) radius articulating curvature.