Kinamed Incorporated
820 Flynn Road, Camarillo, CA 93012 USA
(800) 827-5775 (805) 384-2792 (Fax)
www.Kinamed.com

B00236B
Y998-404

EN English

MD3T™ Multi-Directional Tibial Tubercle Transfer System Instructions for Use

INFORMATION CONCERNING USE OF THE KINAMED MD3T™ MULTI-DIRECTIONAL TIBIAL TUBERCLE TRANSFER SYSTEM (MD3T).

US Patents: 7,794,466 and 8,828,010. www.Kinamed.com/patents

EXPLANATION OF SYMBOLS	
℞ Only	**Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.**
	**Do not use if package is damaged and consult instructions for use.**
	**Do not re-use. 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.**

A. GENERAL REMARKS

The MD3T System is a system of manual instruments that is intended to assist the orthopedic surgeon with a transfer of the tibial tubercle. The MD3T System enables the surgeon to transfer the tibial tubercle in a precise, predictable, and independent manner. Medial and anterior transfer distances are independent of one another. The MD3T System is intended to be used with commercially available bone screw and bone graft substitute implants.

The instruments are made from stainless steel and/or polymer materials. Each package label states the material used for the enclosed instrument. The general principles of patient selection and sound surgical judgment apply to any tibial tubercle transfer procedure.

The preoperative planning and surgical techniques for tibial tubercle transfer have evolved from the surgical experience gained during the development of this and similar techniques over the past century. Many of the methods represent principles that are basic to sound surgical management in orthopedic surgery. Surgeons should not begin the clinical use of this system 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 in medical journals and at regularly scheduled surgical instruction courses for which periodic attendance is advised. It is the surgeon's responsibility to be familiar with relevant publications and consult with experienced practitioners before use.

The patient and surgeon must realize that certain co-morbidities or conditions may reduce the chance of a successful outcome and an increased percentage of risk must be accepted. Kinamed cannot guarantee the outcome of the surgical procedure.

The goal of tibial tubercle transfers is to try to normalize mechanical abnormalities of the patellofemoral joint. To accomplish this goal, patients should be selected who have and will maintain adequate bone support and who are able and willing to follow their surgeon's directions generally, and particularly with respect to activity and weight bearing restrictions during the postoperative period. Patients should be cautioned against heavy labor, active sports, or any activity which places heavy or abrupt loads on the proximal tibia until authorized by the physician.

In addition, the following factors are important but not necessarily sufficient prerequisites for use of this system:

1. Careful selection of patients with regard to activity level and occupation.
2. Surgeon's sound knowledge of knee anatomy and of the biomechanical principles underlying tubercle transfer.
3. Patient's understanding and acceptance of his/her surgeon's instructions (preferably written) for his/her 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.

B. INDICATIONS FOR USE

The MD3T System is indicated for patients that have reached skeletal maturity and are candidates for a tibial tubercle transfer. The flexibility and precision of the MD3T System offers the surgeon the opportunity to address many of the multiple causes of patellofemoral disorders with one instrumentation system. Patients with patellar instability, minimal patellar chondrosis, and tibial tubercle lateralization may benefit from medial transfer alone. For those with more severe chondrosis, appropriate anterior transfer may be added to achieve an anteromedialization or AMZ. If the patient has a shallow sulcus, the MD3T System gives the surgeon the opportunity, if desired, to reduce the Q angle (measured intra-operatively) below its normal value in order to achieve proper balance of the patella in the dysplastic groove. A progressive, distal release of the lateral retinaculum should be considered if the patella remains tethered laterally. In complex cases, the MD3T System allows the addition of MPFL (medial patellofemoral ligament) reconstruction or other appropriate techniques when necessary.

The MD3T System also allows anterior transfer alone (Maquet Procedure) to decompress the patellofemoral joint in those patients who may have patellofemoral chondrosis/arthritis with normal extensor mechanism alignment. Patients with proximal patellar chondrosis and/or predominant trochlear chondrosis should be approached cautiously. As with any reconstructive knee surgery, other factors for consideration should include, but not necessarily be limited to: appropriate alternative treatments and procedures, patient age, occupation, medical condition, psychological profile, current and desired activity levels, etc.

C. CONTRAINDICATIONS

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures. The following are relative contraindications for tibial tubercle transfer: normal patellar articular cartilage with normal patellar alignment, obesity, smoker, diabetes. 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/or after implantation. Tibial tubercle transfer may also be contraindicated where loss of hip abductor musculature, poor bone stock, poor skin coverage around the knee, or neuromuscular disease compromising the affected limb would render the procedure unjustifiable.

D. WARNINGS

Over-correction or over-tightening medially is to be avoided, as this may lead to iatrogenic medial patellar subluxation which can cause the patient to be worse than before surgery. In selected cases the surgeon should consider using selective epidural analgesia along with long-acting local analgesia. This can allow the patient to be awakened during surgery after initial temporary fixation in order to slowly extend the knee to assess patellar excursion and tracking.

Loosening, bending, cracking and/or fracture of the implants (including fixation screws) or bone 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 the implants. For safe and effective use of this system, the surgeon should be thoroughly familiar with the surgical technique.

Accepted practices should be followed meticulously in postoperative care. The patient should be made aware of the limitations of tubercle transfer surgery. Excessive physical activity and trauma affecting the tibia may lead to failure of the reconstruction.

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 surgeon's orders might delay post-operative recovery and aggravate adverse effects.

E. PRECAUTIONS

An implant (such as a bone screw or bone graft substitute) 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.

F. ADVERSE EFFECTS

General risks related to surgery include bleeding, infection, permanent disability, and death. The following complications may occur after tibial tubercle transfer surgery: delayed union or nonunion, tibia fracture (due to the osteotomy cuts creating a stress-riser), loss of fixation, compartment syndrome, skin slough, continued pain and symptoms, painful hardware (bone screws may be removed after healing has occurred), infection, DVT/PE, neurovascular injury, over-correction, patellar instability, under-correction, neuromas, stiffness, cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, and death. Hematomas and delayed wound healing may occur. Other complications may also occur. Tibia 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.

G. PREOPERATIVE PROCEDURES

The amount of medial, anteromedial, or distal transfer needed is based upon the original position of the tubercle and the patella. The tubercle can also be simultaneously transferred proximally or distally to address patella alta or infera.

A thorough physical examination of both lower extremities should be performed focusing on rotational abnormalities, deficient VMO, medial and lateral glide of the patella, standardized Q angle measurement at full extension, location and amount of tenderness, etc.

The following imaging studies will be helpful for surgical planning:

1. A true lateral radiograph allows assessment of patellar height, patellar tilt, and trochlear morphology.
2. A Merchant view radiograph allows assessment of trochlear morphology, patellar tilt and subluxation, and patellofemoral joint space.
3. A knee CT or MRI (including the tuberosity) scan allows measurement of the patellar height, TT-TG distance, and assessment of cartilage morphology.
4. A long-leg weight-bearing radiograph allows assessment of limb alignment and femoro-tibial joint space.

Preoperatively, the patient should go through a lower extremity rehabilitation program with emphasis on isometric progressive resistive quad exercises at 0° (allows quad strengthening without patellar motion and patellofemoral contact) along with core proximal muscle strengthening. This program may be modified according to each particular patient and concomitant procedures.

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

H. INTEROPERATIVE PROCEDURES

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

1. Consistent use of prophylactic antibiotics.
2. Having all operating room personnel–anesthetists, circulators, observers, etc., as well as scrubbed technicians, properly attired to assure sterility at the operating site.
3. Familiarity with and careful attention to the surgical technique are necessary for good results. Improper selection and use of the instrumentation or 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.
4. Protecting instruments from airborne contamination.
5. Use of impermeable draping.

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 instruments should be checked prior to surgery. Bent or damaged instruments may lead to improper technique and result in failure. Thorough familiarity with the surgical technique is essential to ascertain their proper working condition. Refer to Kinamed document B00237 for the MD3T Surgical Technique Guide. Prior to surgery, all packages and implants should be thoroughly inspected for possible damage.

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. During curing of the bone graft substitute, care should be taken to prevent moving the components.

I. POSTOPERATIVE PROCEDURES

Postoperatively, the patient's activity, weight-bearing status, and immobilization will be determined by the surgeon. At six weeks post-op, radiographs are usually obtained to assess healing, and rehabilitation is advanced based on the radiographic results and clinical examination. Nicotine use is contraindicated at all times, as it can interfere with healing. Early protected range of motion exercises are usually prescribed under the direction of the surgeon. With the goal being nearly full motion within the first four weeks. After six weeks, the rehabilitation is determined by clinical examination, radiographs, and the limitations of the concomitant procedures. Rehabilitation is advanced accordingly, with the activities and exercises that stress the extensor mechanism (i.e. stairs, quadriceps strengthening, running, jumping, etc.) to be added cautiously as healing progresses.

J. STERILITY

All instruments in the MD3T System are supplied non-sterile and must be cleaned and sterilized by the end user before use. Sterilization of instruments is accomplished by autoclaving per the recommended procedures below. Inspect instruments for dryness prior to sterilization.

Method	Cycle Type	Sterilization Temperature	Full Cycle Time	Dry Time
Steam Autoclave, Double Wrapped[1]	Pre-Vacuum	132°C, (270°F) minimum	4 minutes minimum	45 minutes minimum

[1]Validated with KimGuard® KC600, double wrapped in 1-ply polypropylene wrap. Validated to the following standards: FDA's 21CFR58, ISO 17665-1:2006 and ANSI/AAMI ST79-2010.

The reusable instruments should be visually inspected for wear and tear, routinely and prior to each surgical use. Visual inspection should be performed to look for imperfections or deterioration (such as corrosion, pitting, significant discoloration, cracking, breakage, disassembly, etc.). For reusable instruments that show evidence of such deterioration, the user should first contact Kinamed to determine if repair is possible. If Kinamed determines that repair is possible, the user should thoroughly clean the deteriorated reusable instrument before returning for repair. If Kinamed determines that repair is not possible, then the deteriorated reusable instrument may be discarded using the hospital's normal disposal procedure for similar types of surgical instruments. Note that it is normal and expected for anodized instrument surfaces to show slight discoloration after repeated cleaning and sterilization cycles. Such discoloration is not evidence of deterioration.

K. CLEANING AND MAINTENANCE

All instruments intended for end-user sterilization must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures of contaminant removal and use.

Pre-process Handling: Remove gross soiling by submerging the instrument into cold tap water immediately after use. Instruments should be cleaned within 30 minutes of use to minimize the potential of staining, damage, and drying.

(1) Manual Soak: Completely submerge instruments in neutral pH enzymatic detergent (i.e. Ruhof Endozime® AW Triple Plus®, dilute 1/2 ounce per one (1) gallon (4ml/liter) of warm (20-25°C) tap water) for 5 minutes. Use a soft bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention should be given to hard to clean areas. Visually inspect the instruments for cleanliness and repeat the manual soak step (1) until no visual contamination is present. For reusable instruments that are not visually clean after multiple attempts to repeat the manual cleaning cycle, the user may discard the instrument using the hospital's normal disposal procedure for similar types of surgical instruments. Note that it is normal and expected for anodized instrument surfaces to show slight discoloration after repeated cleaning and sterilization cycles. Such discoloration is not evidence of visual contamination.

Manual Rinse: Remove instruments from the enzymatic solution and rinse thoroughly under running Deionized (DI) water for a minimum of 1 minute. Thoroughly and aggressively brush and flush through cannulated areas using a DI water jet with the exit end submerged for a minimum of 1 minute. Flush instrument for a minimum of 2 minutes with DI water again to clear any debris.

(2) Combination Manual/Automated Soak and Rinse: Same as manual soak and rinse in section **(1)** above. **Washer/Dryer:** Place instruments in a suitable washer basket and load in an automatic washer/dryer. Cycle should be set for a Non Caustic wash cycle according to the table below.

Phase of Automatic Cycle:	Minimum Water Quality / Temperature	Minimum Time	Detergent / Dilution
Pre-Rinse	Tap Water / 31°C	3 minutes	N/A
Wash	Tap Water / 55°C	11 minutes	Ruhof Endozime® AW Plus®, pour directly into detergent reservoir at full strength or set the dispenser to 1/2 ounce per one (1) gallon (4ml/liter) of warm (20-25°C) tap water
Rinse	Tap Water / 34°C	1 minute	N/A
Final Rinse - Thermal Disinfectant Rinse	DI Water / 94°C	2 minutes	N/A
Dry	N/A / 121°C	15 minutes	N/A
Total Cycle Time	N/A	45 minutes	N/A

L. PACKAGING AND LABELING

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

M. SIZING

The MD3T instruments are designed to function across a range of patient sizes. Sterile 4.5mm diameter stainless steel bone screw implants across a range of lengths should be available for each surgery.