MULTI-RADIUS
Total Knee System

The MULTI-RADIUS™ Total Knee System

A versatile system which offers a choice

A choice of tibial component designs:

- ☐ Regular components for use when both cruciate ligaments are excised, or for preserving the posterior cruciate only.
- ☐ Cruciate retaining components for use when retaining both cruciates.
- ☐ State-of-the-art Endoskel (internal metal support) components.

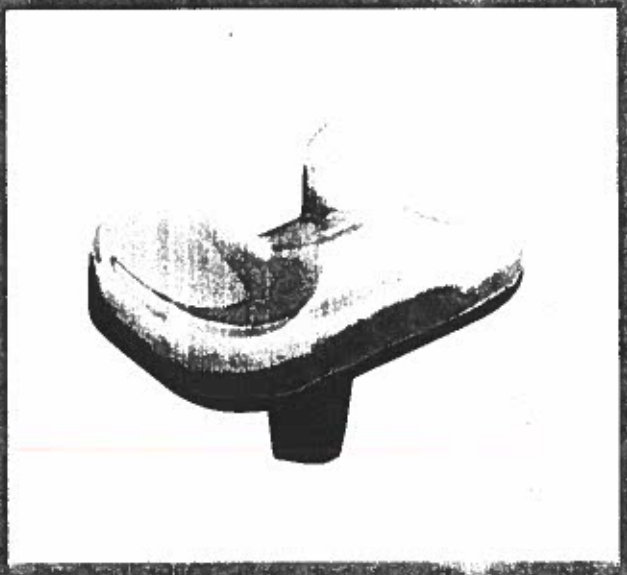
A choice of tibial component materials:

- ☐ Ultra-high molecular weight polyethylene (UHMWPE), or
- ☐ POLY-TWO™ (carbon fiber reinforced UHMWPE) for increased compressive strength and increased resistance to cold flow and wear.

A choice of instrumentation:

- ☐ Surgeon-guided instrumentation.
- ☐ Precision instrumentation.

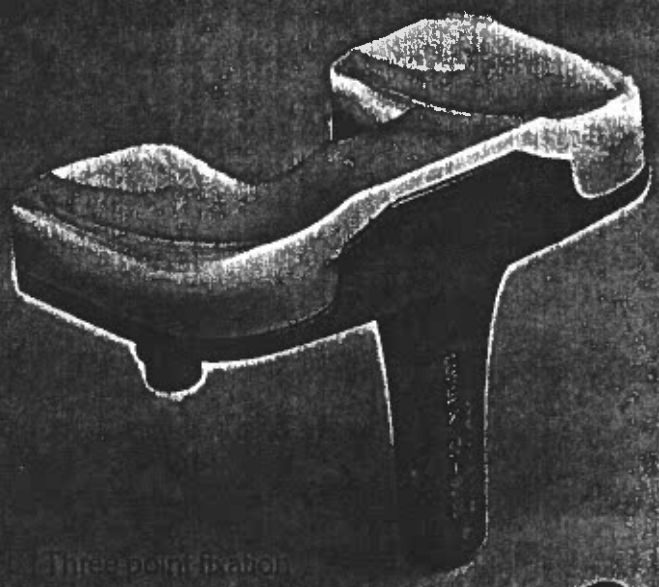
The Cruciate-Retaining design features a larger recess to accommodate the cruciate island when both the anterior and posterior cruciate ligaments are retained. This design also features three-point fixation with an anterior intramedullary post and two short pins on the undersurface of the plateau.



MULTI-RADIUS tibial component design allows retention of the posterior cruciate ligament if desired, and may also be used when both cruciate ligaments are excised.

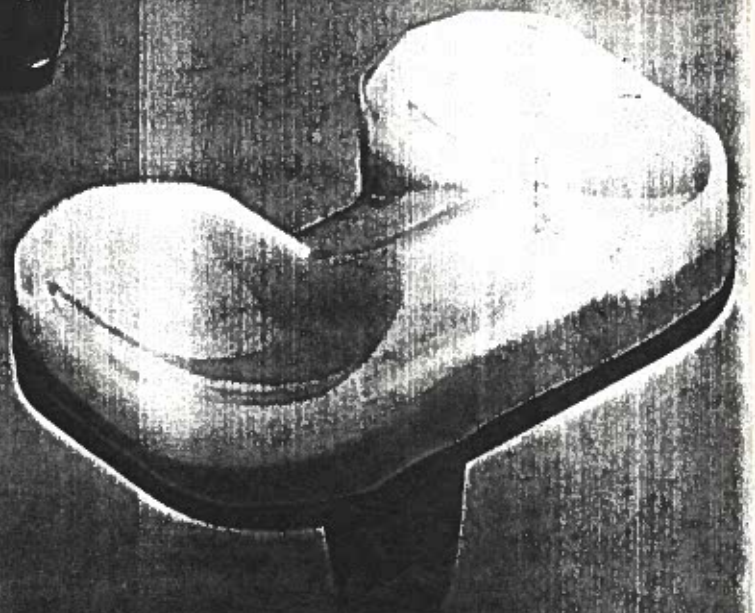
MULTI-RADIUS Endoskel

For improved



MULTI-RADIUS tibial components are available with the Endoskel – internal metal supporting structure designed to support the polyethylene bearing surfaces and reduce cold flow and wear of the plateaus.

Because the polyethylene is molded directly onto the metal retainer, a secure interlock is created which helps prevent the polyethylene from dislodging.



Three point fixation resists rotational forces and transfers the applied load to the anterior tibial cortex.

Single post fixation design affords wide exposure and transmits applied load to the posterior tibial cortex.

Rigid Endoskel tibial retainer of cast ZIMALOY (cobalt-chromium-molybdenum alloy) provides structural support for the molded polyethylene and distributes forces to the tibia more evenly than unsupported plastic tibial components.

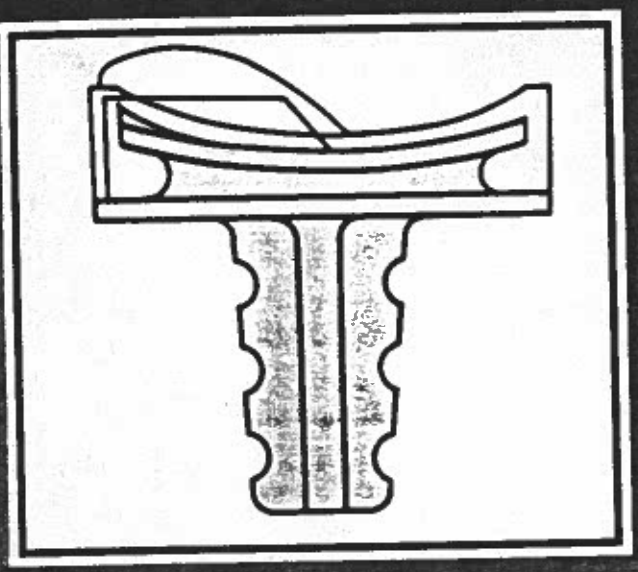
Tibial eminence is slanted posteriorly to reduce the chance of impingement of posterior cruciate ligament.

Molding process produces articulating surfaces with MICRO-FINISH® surface smoothness and dimensional consistency.

Retained Tibial Components

load distribution

The molding process also eliminates machining grooves and other surface inconsistencies inherent with the machining process.



- The tibial eminence is also reinforced by the Endoskel retainer to resist medio-lateral and rotational stresses.
- Internal surfaces of Endoskel retainer are parallel with UHMWPE wear surface to support the plastic against anterior-posterior and rotational stresses.

TIBIAL COMPONENTS

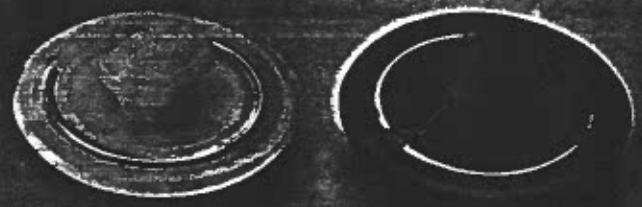
SIZE	THICKNESS (mm)	CRUCIATE RETAINING		POSTERIOR CRUCIATE RETAINING			
		UHMWPE/ ENDOSKEL	POLY II ENDOSKEL	UHMWPE	UHMWPE/ENDOSKEL	POLY II	POLY II/ENDOSKEL
SMALL	5.0			5060-53		5060-51	
	7.5				5060-76		5060-46
	10.0	5066-02	5066-07		5060-74	5060-62	5060-44
	12.5	5066-03	5066-08	5060-64	5060-72		5060-42
	15.0	5066-04	5066-09		5060-75	5060-36	5060-45
	20.0			5060-67	5060-77	5060-37	5060-47
				5060-68			
REGULAR	5.0			5060-58		5060-51	
	7.5				5060-78		5060-48
	10.0	5066-12	5066-17		5060-70	5060-52	5060-40
	12.5	5066-13	5066-18	5060-54	5060-73		5060-43
	15.0	5066-14	5066-19		5060-71	5060-38	5060-41
	20.0			5060-65	5060-79	5060-39	5060-49
				5060-66			
LARGE	5.0						
	7.5				5060-44		5060-50
	10.0				5060-28		5060-29
	12.5				5060-55		5060-56
	15.0				5060-80		5060-81
	20.0				5060-96		5060-97

FEMORAL COMPONENTS

5060-10	Regular, Right
5060-11	Regular, Left
5060-20	Small, Right
5060-21	Small, Left
5060-18	Large, Right
5060-19	Large, Left
5060-57	Ex. Large, Right
5060-58	Ex. Large, Left

- Femoral articulating surface closely approximates the natural femoral condyle to re-establish function.
- Patellar trochlear is anatomically offset 7° to promote proper tracking of natural or prosthetic patella.

UNIVERSAL PATELLAR DOMES



5068-01 5068-02

MULTI-RADIUS™ TOTAL KNEE

Brief Summary of Package Insert **Issued: February, 1979**

DESCRIPTION

This partially constrained device replaces the natural tibiofemoral joint to afford stability and a normal range of motion. The contour of the femoral condyles provides changing instant centers of rotation. The design allows for retention of the intact posterior cruciate and collateral ligaments, for minimal bone removal, and for future alternative procedures.

The femoral component is manufactured from ZIMALOY® (cast cobalt-chromium-molybdenum alloy). It is designed with an accentuated patellar groove at 7° offset to permit more normal patellar articulation (right and left prostheses are required) or with the ZIMMER® Universal Patellar Dome. Medial and lateral posts and undercuts provide for cement fixation. Small and regular sizes are available (See How Supplied).

Either molded ultra-high molecular-weight (UHMW) polyethylene or POLY TWO™ (carbon reinforced UHMW polyethylene) is used for the tibial component. The tibial component is a single unit with two concave parallel tibial plateau surfaces linked by a tibial spine. This spine enhances mediolateral stability. A fluted central stem with a series of cannulations located anteroposteriorly provides for cement fixation. Raised projections on the under surface increase the surface area between the prosthesis and acrylic cement. Radiographic wires are integrally molded into the tibial component for determining its position postoperatively. The tibial component is also available with a metal retainer. The cast cobalt-chromium retainer distributes forces more effectively than unsupported plastic tibial components and is used where additional support is necessary.

INDICATIONS

Total knee arthroplasty has been proved effective in reducing or relieving pain and in restoring functional knee motion. Such surgical procedures have been used in the management of severe gonarthropathy as in: (1) Painful disabling bicompartmental joint disease secondary to osteoarthritis, rheumatoid, or traumatic arthritis; (2) Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion or dysfunction; (3) Moderate valgus, varus or flexion deformities.

The device may also be indicated in the salvage of previously failed surgical attempts.

CONTRAINDICATIONS

Overt infection is an absolute contraindication. Every effort should be made to rule out the possibility of preoperative sepsis in a patient who has one or more of the following abnormalities; (1) fever and/or local inflammation signs; (2) rapid joint destruction or bone absorption apparent on roentgenograms; and (3) elevation of sedimentation rate unexplained by other diseases, elevation of WBC count, or marked shift in WBC differential count.

Additionally, distant foci of infection such as genitourinary, pulmonary, skin, etc., are a relative contraindication because hematogeneous spread to the implant site may occur.

Severe instability secondary to the absence of collateral ligament integrity is a contraindication.

Use of this implant is contraindicated where marked bone loss, osteoporosis, loss of musculature or where neuromuscular disease compromising the affected limb would render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).

A stable painless arthrodesis in a satisfactory functional position may be a relative contraindication for use of this device.

WARNINGS

In cases of major bone loss (greater than can be compensated for by the thickness of the prosthetic components) and subsequent gross instability or marked angular deformity, total knee replacement prostheses of the non or partially constrained type may be insufficient to provide complete correction.

For safe and effective use of this implant, the surgeon should be familiar with the recommended implantation procedure for the device (See Utilization and Implantation).

In every case, accepted surgical practices should be followed in postoperative care. The patient should be made aware of the limitations of total joint reconstruction, and its 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/or wear of the prosthetic implants. The patient should be cautioned to govern his activities accordingly, protecting the replaced joint from unreasonable stresses.

PRECAUTION

An implant should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce the service life of the implant.

ADVERSE EFFECTS

Fracture of the tibial or femoral condyles may occur if the implant site has been improperly prepared, or excessive force is used to seat the implant.

Transient peroneal palsy secondary to surgical manipulation and increased joint movement have been reported following total knee arthroplasty. This is more likely to occur in patients with severe flexion and valgus deformities.

Patellar tendon rupture, subluxation, ligamentous laxity, dislocation, infection, and loosening have also been reported with use of partially constrained implants for total knee arthroplasty.

Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The actual clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the normal wound healing process.

Metal sensitivity reactions in patients following total joint replacement have been rarely reported. The significance and effects of sensitization await further clinical evidence and evaluation.

UTILIZATION AND IMPLANTATION

Special instruments and femoral provisionals are available to assist in the accurate installation of this knee system. The Tibial Alignment Guide (1360-30) marks the line of resection at right angles to the long axis of the tibia. The Spacer Guides (5060-02, 03, 04; 05) serve as a template for choosing the correct tibial component size. Determination of tibial height is based on ligamentous laxity. It is important that the femoral and tibial components are positioned with their bearing surfaces parallel to the weight bearing surfaces with tension restored through the two collateral ligaments. Oblique implantation increases the shear forces acting at the bone/acrylic interface. A ½ in. Twist Drill (5060-09) is used in conjunction with the spacers to seat the tibial component (proper depth should be determined from the tibial stem length). The Tibial Broach (5060-08) is required to remove additional bone following use of the drill.

Femoral Resection Guides (5060-06, 07) mark the anteroposterior depth of the femoral component and locate the proper positions for the femoral posts. The posterior portion is utilized as a marker for resecting the posterior condyles.

A grossly distorted patella may not properly track in the groove of the femoral component during flexion/extension. If necessary, the Universal Patellar Dome (1338-61, 62) is available for resurfacing the patella. The surface of this prosthesis is designed to articulate with the patellar groove of the Multi-Radius Total Knee.

Surgical Technique (TR-208) is available upon request.

STERILITY

Metal implant components and all instruments must be sterilized prior to surgical use. Steam autoclaving is recommended.

Ultra-high molecular-weight polyethylene components are presterilized by prior exposure to a minimum of 2.5 Mrad gamma irradiation. Resterilization by any method is not recommended. Repeated irradiation may result in degradation of the material. Exposure to high temperatures as they are encountered in autoclaving, dry heat sterilization, or boiling will result in warping or shrinkage. While resterilization by exposure to ethylene oxide, or use of liquid chemosterilant may not be damaging, safe and proper procedures have not been established.

CAUTION

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

zimmer
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