

MIRROR™

PARTIAL KNEE SYSTEM

Frequently Asked Questions



MIRROR™

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DESIGN RATIONALE

What is Ligament Guided Surgery (LGS)?

Mirror™ is a partial knee replacement system that reestablishes soft tissue knee kinematics while simultaneously preparing the femoral articular surfaces.

What is Dynamic Distraction?

Dynamic Distraction is a proprietary process using an instrument, the Balancer, that tensions the ligaments to recreate natural knee motion to guide condyle preparation to place the implants where the ligaments want them.

How does this philosophy differ from what I am currently doing?

Other partial knee replacement systems prepare the articular surfaces independent of one another, of soft tissue structures, and preparing each side relative to its own bony landmarks. Mirror™ couples femoral and tibial resection while making the femoral articular cuts in combination with soft tissue kinematics.

IMPLANTS

Describe your implant designs?

The Mirror™ femoral and tibial components have been created after reviewing industry designs with long standing, successful clinical outcomes. The femoral component is universal with two gentle radii, J curve design i.e. a flat on round geometry. These implants are designed for either the medial or lateral side of the knee. The modular Tibial Baseplate is defined by its A/P dimensional length.

Describe the femoral component material, sizing, etc.

The universal, flat on round, femoral component comes in five (5) sizes available in 4mm increments from 38mm to 54mm. The implants are made of CoCr alloy. Sizing is referenced by the distal femoral curvature.

Describe the tibial baseplate component material, sizing, etc. The tibial insert?

The tibial implants are available in two (2) sets of four (4) sizes with one for the right medial/left lateral plateau and the other for the left medial/right lateral plateau. They have a flat articular surface ranging in size from 44mm to 56mm in 4mm increments. The implants are made of titanium alloy with a two (2) peg fixation design.

The poly inserts have a tongue-and-groove capture feature with the baseplate on the posterior end and with a snap-down, one-way locking mechanism on the anterior end. Thicknesses are 8-11mm in one (1) mm increments in left and right configurations.

Are these implants press fit or cement only?

The Mirror™ implants are designed for cement fixation only.

What is the tibial tray made of? CoCr or Ti? Why?

The tibial tray is made of titanium. Strength and load distribution are two reasons titanium is used rather than Cobalt Chromium.

Do you use a cross-linked poly?

No. We use GUR 1080 Poly with ethyl oxide sterilization. Cross linked poly for knee arthroplasty is still a marketing issue. Because of sheer forces across the hip joint cross linked poly has demonstrated superior results over conventional UHMWPE in a recent five (5) year study. It has been shown that ETO (Ethylene Oxide) sterilization provides virtually the same benefit to UHMWPE (Ultra High Molecular Polyethylene) in TKA's. However, further clinical studies are still underway to investigate the performance of highly cross-linked UHMWPE for knee replacement. We feel this is unnecessary in partial or total knee replacement because sheer forces are minimal to the dominant compressive forces.

Why a symmetric femoral component? Why not an anatomic?

An anatomic femur provides no additional coverage, however it does incur substantial cost that gets passed onto the customer.

The femoral component seems more flat on flat than flat on round – is it?

The Mirror femoral component has a very gentle M/L radius. The tibial bearing surface is flat, so it is a round on flat design.

How thick is the femoral component? The poly? The tibial tray?

The articular portion of the femoral component is 4mm thick and the fin is 3mm tall. The polyethylene inserts range from 6 - 9mm and the tibial baseplate is 2mm thick. Final tibial thicknesses are 8, 9, 10, 11mm.

How do you machine a J curve that fits the implant?

Some femoral implants may have a single, uniform radius or C curve. A J curve has two points for its center of rotation as the patient goes through ROM. One radius is longer in extension and because of a tighter curve in flexion the second radius is shorter. So we have a shorter curve from the beginning of flexion to extension then we have longer radius as screw home mechanism is initiated. This is built into the femoral component. Mirror™ uses the patient's own natural biomechanics to accomplish this. From our biomechanical data and surgical experience patient's anatomy can fit these five femoral sizes due to their normal kinematics. The tallest patient that was sized for Tissue Guided Surgery was 6 feet 10 inches tall.

SURGICAL PROCEDURE**How many steps to the surgical procedure?**

There are 4 steps to the Mirror technique. They are 1. Tibial Resection, 2. Femoral Condyle Preparation, 3. Femoral Sizing and Drill for Peg, 4. Implant Placement & Cement Fixation.

How many Mirror's have been implanted?

Approximately two thousand (2000) cases have been completed to date.

When was the first Tissue Guided Surgery case completed?

The first case completed by Dr. Engh was in 2009.

Do you have any long- term follow-up?

Cayenne Medical has published 2 year data on its first 100 patients with the current implant design.

What has been the key area of failure during your Mirror™ series spanning back over the past three years?

The all poly tibial implants were a source of some failed outcomes. Since releasing the modular tibial component, interest in the all poly tibial component has dramatically fallen off.

Do we recommend any particular leg holder?

No. Leg holders are surgeon preference. Some surgeons prefer the Oxford leg holder, as the surgeon can get very close to the knee to perform the groove cutting and condyle resurfacing steps easier.

Does your system correct knees with severe varus or valgus?

Our system was not designed specifically to correct severe deformities in knees. However, some of our surgeons would typically perform slight releases of the patient's MCL to help correct those knees.

TIBIAL RESECTION

Describe most important cut for tibial resection.

The sagittal cut is the most important and should not have any internal or external rotation.

How does your tibial resection instruments differ from other companies?

The telescoping Upper & Lower Medullary Rods combine with the Ankle Clamp. Two Cutter Blocks, a Left & Right, two Depth Guides (3mm & 5mm) and a Stylus comprise the Tibial Resection Guide (TRG). The TRG can be considered a middle of the road assembly, not too complicated or too simple, when compared to other systems. The goal is to resect accurately and reliably the tibial plateau 90° perpendicular to the long axis of the tibia with a 4°-8° posterior slope.

How much bone do you resect from the tibia?

From a clinician's perspective this is surgeon preference. As with most partial knee systems we want to resect to the defect and take as little bone as necessary. From a biomechanics standpoint resect 3mm below defect.

When resecting the tibia can you maintain the patient's natural varus slope or does it have to be a 90° cut?

When performing the Mirror™ procedure, it is critical to resect the plateau 90° to the long axis of the tibia.

How much posterior slope is too much?

Generally, the anatomic posterior slope varies between 4° & 8° so a resection greater than 8° would be considered as too much bone removal.

What effect, if any, does posterior slope have on the placement of the femoral component?

The greater the slope of the tibial resection, the more likely that the femoral component might be positioned in extension (and vice versa). This has no adverse effect on the orientation of the implants and expected durability of the poly.

Describe the Balancer.

The Balancer, a key instrument in the Mirror System, is placed into the tibiofemoral compartment to tension the cruciate and collateral ligaments so a primary groove can be machined into the femur. When the one (1) mm Shim is attached, the Balancer's range from a collapsed position to fully open is 8mm. Approximately 25 pounds of pressure is applied to the knee joint, well within the biomechanical range, to create a kinematically correct tension for the knee joint. There is a medium indicator line, with additional three lines above and below that guide the clinician's knowledge of the appropriate tensioning for the tibiofemoral compartment. The Balancer maintains a distraction force between femur and tibia so the cutter can prepare a uniform gap. Others may refer to this as the flexion or extension gap, throughout the full range of motion.

If the Balancer is topped out after being placed in compartment, what will be the impact on the groove depth?

If the Balancer is topped out, this illustrates that the surgeon created a deep resection and will likely use a 10mm or 11mm poly insert. The cutter is a fixed distance from bottom of the Balancer, so if the Balancer is fully expanded (no distraction in place), then little to no groove will be milled. If the Balancer is bottomed out, then the deepest groove will be created, ensuring that bone and excess cartilage will be removed.

Why do you add a Shim to the Balancer?

The Shim is used to increase the height of the Cutter for tibial resections greater than 7mm. Also, use a shim if the Balancer is topped-out as it goes through the choreographing range of motion.

What is the primary femoral groove?

It is the first cut made by the cutter with the femoral Balancer on the femoral condyle. It should remove the methylene blue line as it cuts. The depth of the guide surface is kinematically guided by the patient's unique

knee motion. Subsequent cuts with the Planer references the depth of the Guide Surface to prepare a matching implant support surface.

What do you mean by choreographing?

Choreographing is when the surgeon extends the knee with the Balancer in place without using the Cutter. It is done to ensure that the Cutter will resect along the methylene blue line and that the height of the Balancer remains within the range of the Balancer. One hand is behind the knee and the other should be holding the ankle.

What should you do when you are deviating off methylene blue line?

Turn off the power, bring the leg back to full flexion. Make sure you are holding the leg behind the knee with one hand and at the ankle with the other. There is no need for the surgeon to be holding the power source. The surgeon should monitor cutter progression along the blue line so as to ensure the cutter remains on the line to full extension.

Are there any tips and tricks to staying on the blue line with the cutter bit when creating the groove?

The surgeon can externally rotate the ankle while extending the knee to keep the cutter tip on the blue line.

Is the Femoral Positioner used for determining final sizing?

No, the Femoral Positioner is not used to determine final femoral component size.

What sequence do you use for Planer secondary cutter?

For the Planer, rotate through all steps 1-6.

Why does the Planer sometime “whiff” when resurfacing the most lateral side of the condyle? Should I be concerned if nothing is removed during that step?

The native condyle has a 3° varus slope, which can cause the cutter to not resurface any bone and cartilage on the lateral side. This is fine and the surgeon only needs to ensure that no cartilage remains between the implant surface and the condyle, impeding effective cementing of the component. The surgeon can also add small drill holes in the condyle to improve cementing.

FEMORAL SIZING AND DRILL FOR PEG

Is your Femoral Drill Guide used for determining final sizing?

Yes, start with a larger size and go down in size until the guide does not rock in the sagittal plane.

When performing the femoral cuts is the implant placement considered an onlay or inlay?

The femoral groove and all secondary cuts provide for an onlay placement of the femoral component.

IMPLANT SIZING AND CEMENT FIXATION

When choosing the tibial trial to determine the A/P baseplate, is it better for the surgeon to fully cover the anterior portion of the tibial plateau or the posterior portion of the plateau?

While this is surgeon preference, it is best if the baseplate covers the posterior side of the plateau.

What are major issues when cementing?

The major issue is leaving some cement posteriorly in the knee or soft tissue that could get loose and act as a wear particle between the femoral and tibial components.

What advice can we offer to help remove the tibial trial poly from the baseplate, after cementing the baseplate and femoral component?

Surgeon can place valgus stress on the knee to open up the compartment, creating space for the tibial inserter to remove the poly trial.

How critical is it for the femoral component on x-ray, while perpendicular to tibial baseplate, be centered exactly on the poly and not medial or lateral to the center of the baseplate?

The Mirror system will orient the implants perpendicular to each other and therefore, it is okay if the femoral component is slightly medial or lateral to the center of the tibial baseplate/poly.

Sometimes on a sunrise view x-ray, the femoral component looks rotated and translationally malaligned to the tibia. However, at 30°, the implants look oriented perfectly. How is this explained?

This is normal and confirms that the implants are oriented correctly to each other. The lateral side of the knee moves more forward than the medial side in flexion, causing the femoral condyle to rotate slightly on x-ray.



This guide is an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Cayenne Medical products. The medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature as well as the product's Instructions For Use.

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