

Frequently Asked Questions

RESTORIS[®] **UniCompartmental Knee System**



- **Who manufactures RESTORIS® implants?**

Sandvik Medical Solutions (formerly Doncasters Medical Technologies), a division of Sandvik Materials Technology, manufactures the femoral component and the tibial baseplate. Orchid Macdee manufactures the ultra-high molecular weight polyethylene (UHMWPE) tibial onlay insert and the tibial inlay. All of these components are manufactured per the specifications of MAKO Surgical Corp.

- **How do we know they are reputable manufacturers?**

Sandvik and Orchid Macdee have been manufacturing implants for the leading orthopedic companies for many years.

- **How are RESTORIS implants manufactured?**

The femoral and baseplate implants are manufactured from castings of cobalt chromium (CoCr), a bio-compatible metal alloy commonly used in orthopedic implants. After casting, the parts are heat treated to relieve stress, the articular surface (of the femoral implant) is polished for kinematic performance and wear resistance, and the cement-contacting surfaces are grit blasted to aid in fixation to bone cement. The RESTORIS inlay and onlay poly implants are machined from compression molded resin GUR 1050 ultra-high molecular weight polyethylene (UHMWPE), a durable polymer used in many orthopedic implants.

- **Why are RESTORIS poly implants made from compression molded UHMWPE?**

Two of the major processing methods for medical grade UHMWPE are ram extrusion and compression molding. There is a perception among some surgeons that implants machined from ram extruded polymer possess inferior wear properties than those made from compression molded polymer. The basis for concern in the 1990's was the use of calcium stearate as a lubricant in the ram extrusion process, as it was shown to interfere with consolidation of the polyethylene molecular chains, potentially resulting in delamination.

Though manufacturers who employ ram extrusion have discontinued the use of calcium stearate, the lingering negative perception of ram extrusion among some surgeons has influenced many orthopedic companies to use compression molded polymer for their implants instead.

- **How are RESTORIS implants sterilized?**

RESTORIS implants are sealed in packaging and exposed to 2.5-4.0 Mrad of gamma radiation. For the UHMWPE components, the packaging is filled with inert gas to purge environmental oxygen (air) prior to sealing and sterilization, to minimize the chance of oxidation.

- **What does "cross-linked" mean?**

UHMWPE is made of very long molecular chains of a polymer called polyethylene. Each molecule resembles a very long strand of spaghetti. These strands are not chemically bonded to each other, so when an external force is applied they are able to slide past each other, albeit restrictedly. This is standard behavior for a polymer.

When polymers are cross-linked their molecular chains become attached at certain points, prohibiting them from sliding past each other. This affects the mechanical properties of the polymer. For example, when an external force is applied there is less "give" in a cross-linked polymer, it is stiffer and has less impact toughness. A stiffer material will produce a

smaller contact patch in an articulating joint surface, which increases stress in the material. Reduction of impact toughness increases the risk of polyethylene fracture.

Cross-linking has been shown to reduce the volume of abrasive wear in laboratory studies. However, cross-linking produces a higher percentage of small wear particles which have been shown to be more biologically reactive, causing an inflammatory response which increases the risk of osteolysis. Studies have not confirmed that having fewer but more biologically reactive particles produces better long-term clinical outcomes.

- **Why doesn't MAKO Surgical Corp. use cross-linked UHMWPE?**

Cross-linked UHMWPE is the standard of care in hip arthroplasty applications. This is an appropriate application because traditional hip arthroplasty implants have large contact areas and high wear rates, and cross-linking reduces volumetric wear as described above.

Some orthopedic companies have begun to use cross-linked UHMWPE in total knee arthroplasty (TKA) implants. TKA implants are designed to have more inherent mechanical stability and contact area than unicompartmental knee arthroplasty (UKA) implants.

Cross-linked UHMWPE for TKA implants may eventually prove to have beneficial long-term outcomes. However, since UKA implants have smaller contact areas, the benefits of wear reduction may be offset by cross-linked UHMWPE's inferior mechanical properties which could lead to early implant failure. Moreover, failure of knee arthroplasty implants due to abrasive wear is not as common as in hip arthroplasty.

Therefore, MAKO Surgical Corp. has taken a conservative approach and determined that cross-linked UHMWPE for UKA implants is not appropriate at this time.

• **What are the features and benefits of RESTORIS implants?***

Implant	Feature	Benefit
Femoral	Similar to Repicci II® design**	Similar to a proven, longstanding implant design
	J-curve	Approximates natural articulating surface through range of motion (ROM)
	Peg	Cross-shaped peg offers greater surface area for contact with bone cement
	Keel	Provides stability while being implanted with bone cement
Inlay poly	Similar to Repicci II® design**	Similar to a proven, longstanding implant design
	Cement groove/channel	Designed for enhanced cement retention, fixation, and resistance to subsidence
	D-shaped dovetail undercut on bottom of implant	Designed for enhanced fixation during implantation with bone cement
	3 thicknesses	For joint gap adjustment
Baseplate	Peg	Helps secure the implant in bone
	Keel	Helps secure implant in bone, in particular helps prevent unwanted movement in the ML direction and axial rotation
	Undercut retaining feature	Retains the poly insert for a secure fit
Onlay insert	Flexible tabs	Allows the insert to snap into the baseplate for a secure fit
	3 thicknesses	For joint gap adjustment

* For further details, refer to the RESTORIS Technical Data Sheet (PN 200808)

** Repicci II® is a registered trademark of Biomet, Inc.



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MAKO Surgical Corp.

2555 Davie Road | Fort Lauderdale, FL 33317 | 866.647.6256 | www.makosurgical.com