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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Device: Konstruct Patellar Component

Classification Name: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer (888.3560)

Intended Use: The Konstruct Patellar Component is indicated for patients suffering from severe knee pain and disability. Specific indications include patellar replacement in patients who require implantation due to degenerative bone disease such as rheumatoid arthritis or osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis, pseudo-gout or complications from a failed prosthesis.

The device is for use with bone cement only and for supplemental fixation by means of suture attached. Supplemental suture attachment is used in cases where soft tissues (tendons, ligaments) have ruptured or require reattachment.

Device Description:

This component is made of Ultra-High-Molecular Weight Polyethylene (UHMWPE), a material commonly used for this type of implant. The Konstruct patella is designed for cemented use. The dome shaped topography is a standard design and is compatible with the TC-IV and Performance Total Knee Systems which received marketing clearance in 1986 and 1988, respectively.

The implants are of a uniform 9 mm thickness and have suture holes that allow for fixation supplemental to the standard acrylic fixation if necessary. The partially drilled suture holes surround the component's periphery and grooves in the articular surface allow the sutures to be countersunk so as not to contact the femoral surface. The addition of partially drilled suture holes does not effect the functioning of this device in total knee arthroplasty. What it does do is provide a mechanism for reattachment of soft tissue such as tendons or ligaments using standard suturing techniques. The Konstruct Patellar Component allows for treatment of these soft tissue complications without necessity of revising the entire knee replacement.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to the bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

Substantial Equivalence: In function and overall design, the Konstruct Patellar Component is equivalent to other knee components on the market. These include:

AGC Total Knee System Patellar Component (Biomet, Inc., Warsaw, IN)
Total Condylar Knee Prosthesis (Howmedica, Inc., Rutherford, NJ)