Instructions for Use

Manufacturer
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For cemented use only

DESCRIPTION

The Balanced Knee® System (BKS®) Uni is a single compartment knee replacement. The BKS Uni is indicated for cemented use only.

Cobalt Chromium Femoral Component

The femoral components are cobalt chromium (Co-Cr-Mo). The femoral components are right and left specific, and are intended for cemented use only.

Titanium Tibial Trays

The titanium tibial trays (Ti-6Al-4V ELI) are left and right specific, and are intended for cemented use only.

Polyethylene Tibial Insert

The E-Vitalize Uni Knee tibial insert is manufactured from crosslinked Vitamin E Ultra High Molecular Weight Polyethylene.

INTENDED USE/INDICATIONS

1. Non-inflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, avascular necrosis
2. Traumatic arthritis
3. Previous tibial condyle or plateau fracture with loss of anatomy or function
4. Varus deformities
5. Revision of the tibial bearing insert of a previously implanted unicompartmental knee system provided that the tibial tray locking mechanism is not compromised and femoral and tibial tray components remain well fixed and undamaged.

The BKS Uni is intended for unicompartmental knee arthroplasty procedures. The system is single-use and intended for implantation with bone cement.

CONTRAINDICATIONS

1. Any patient not experiencing a compromised quality of life by loss of joint function and/or joint configuration, or pain from arthritis disease.
2. Any patient whose knee cannot be returned to normal function and normal stability through reconstructive procedures, including ligamentous balancing.
3. Active infection in or near the knee joint, fever and/or local inflammation signs, and elevation of sedimentation rate unexplained by other diseases should not be treated unless preoperative infection is ruled out.
4. Distant foci of infection, such as genitourinary, pulmonary, skin (chronic lesions or ulcerations), and other sites, that may result in hematogenous spread to the implant site.
5. Rapid joint destruction or bone absorption apparent on roentgenograms.
6. Neuromuscular disorders in which the potentially adverse effects on prosthesis function are not outweighed by the benefits gained by the patient from usage of the prosthesis.
7. Mental disorders that would compromise essential patient post-operative care.
8. A painless, stable arthrodesis in a functional position.
9. Allergic reactions to implant materials and/or tissue reactions to the products of corrosion or wear.
10. Skeletal immaturity.
11. Collateral ligament deficiency.

INFORMATION FOR USE

To ensure proper placement and fit, BKS Uni instruments and trials manufactured by Ortho Development Corporation should only be used to implant the BKS Uni components.

Components, trials, and instruments from other knee systems must not be used with components, trials, and instruments from the BKS Uni and vice versa, unless specifically labeled for such use. Different engineering specifications and dimensional incompatibilities among the various systems may cause premature wear or loosening of the implant.

Components of the BKS Uni are not compatible with the components of any other knee system.

Optimal fixation and implant stability are achieved by maximizing bone coverage. Components are provided in a variety of sizes. The largest available components should be chosen that cover, but do not overhang, the femur and tibia.

The BKS Uni has universal compatibility between the BKS Uni femoral component and BKS Uni tibial insert. The largest size femoral component is fully compatible with the smallest size tibial insert. The thickness of the tibial insert is not a limiting contributor to the compatibility with the femoral component.

The BKS Uni tibial insert is compatible with the BKS Uni tibial tray, size for size. Each thickness of a particular size tibial insert is compatible with the same size corresponding tibial tray. The surgeon should choose an insert of appropriate thickness and style to restore the original joint line and to achieve proper ligament tension.

PRECAUTIONS

Preoperative:

The surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. The surgeon should instruct patients as to the limits of the prosthesis and the impact of excessive loading through patient weight or activity. Patients should also be taught to govern and/or restrict their activities accordingly.

Strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize the success of the procedure and the service life of the implant.

Intraoperative:
If the implant site has been improperly prepared or excessive force is used to seat the implant, fracture of the proximal tibia or femoral condyles may occur.

Polyethylene tibial inserts can be removed after they have been snapped into place. Once removed, however, they must be discarded, as the removal process deforms the plastic and reduces attachment strength. Use trials to determine proper tibial insert sizing.

An implant should never be reused. Any implant, once used, should be discarded. Though it appears undamaged, it may have small defects and internal stress patterns that may eventually lead to failure. Likewise, care must be taken in handling new implants to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening, such as marring, nicks, or notches caused by contact with metal or abrasive objects.

If loose fragments of bone cement become detached, they can act as an abrasive on the contact surfaces of the implant, greatly accelerating the wear rate of the prosthesis. Care should be taken to remove all excess cement from around the implant and its surfaces.

WARNINGS

1. Components of the BKS Uni are not compatible with the components of any other knee system. Different specifications and dimensional compatibilities among the various systems may cause premature wear or loosening of the implant.
2. The correct selection of the implant is extremely important. The potential for success in partial joint replacementis increased by the selection of the proper size, shape, and design of the implant.

ADVERSE EFFECTS
Short-term complication rates may be similar to those occurring with any partial joint replacement such as:

1. Changes in position and loosening of the implant.
2. Dislocation of implant.
3. Infection.
4. Reduced range of motion.
5. Heterotopic bone formation.
6. Incomplete pain relief.

MAGNETIC RESONANCE (MR)
The BKS Uni has not been evaluated for safety and compatibility in the MR environment. The BKS Uni has not been tested for heating or migration in the MR environment. The safety of the BKS Uni in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING AND STERILITY
All implants are sterilized to Sterility Assurance Level 10^{-6}. All implants, except for the E-Vitalize Vitamin E polyethylene components, are sterilized by a minimum of 25 kGy gamma irradiation. All E-Vitalize VitaminE polyethylene components are ethylene oxide sterilized.

Sterile product packaging should be inspected for flaws before and after opening. In the presence of a flaw, assume the product is non-sterile and do not implant it into a patient.

INSTRUMENT STERILITY
All instruments should be thoroughly cleaned prior to sterilization. Please refer to Ortho Development Reusable Instrument Care Manual for instrument cleaning and sterilization details.

Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Sterilization Exposure Time (minutes)	Minimum Dry Time (minutes)
Prevacuum	132º C (270º F)	4	30

PRODUCT HANDLING
Always store implants unopened in their respective protective packages. Prior to use, inspect the packaging for damage, which may compromise sterility. When removing the implant from its packaging, observe relevant aseptic techniques. Protect the prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development Corporation. If any of the implants or instruments "malfunction" (i.e., do not meet any of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death, serious injury of the patient, or serious deterioration in state of health, Ortho Development Corporation should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

CAUTION
Federal Law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.