Instructions for Use

Balanced Knee® System

Manufacturer
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For cemented use only

DESCRIPTION

The Balanced Knee® System (BKS®), BKS TriMax®, and BKS® Revision are multi-compartmental total knee replacement systems providing components for posterior cruciate ligament retaining and substituting procedures. The BKS, BKS TriMax, and BKS Revision are indicated for cemented use only. Choice of specific femoral and tibial components depends on whether the posterior cruciate ligament is retained or excised, and the extent and nature of anterior/posterior (A/P) and medial/lateral (M/L) stabilization.

Cobalt Chromium Femoral Component

The femoral components are cobalt chromium (Co-Cr-Mo).

Femoral components with porous coating are porous coated with cobalt chromium (Co-Cr-Mo).

The semi-constrained posterior stabilizing (PS) femoral components are designed to provide anterior/posterior (A/P) stability but rely on collateral ligament balancing techniques for medial/lateral (M/L) stability.

The cruciate retaining (CR) femoral components are designed for use with a functional posterior cruciate ligament. These components also rely on collateral ligament balancing techniques for medial/lateral (M/L) stability.

The modular femoral components are posterior stabilized with the option of intramedullary stem extensions or femoral sleeves and are designed to provide additional anterior/posterior (A/P) and medial/lateral (M/L) stability if needed or desired.

Titanium Tibial Trays

The titanium tibial trays (Ti-6Al-4V ELI) are available either with or without porous coating of commercially pure titanium (CP Ti).

The porous coated tibial trays are available in two options.
1. The first option is supplied with removable polyethylene screw hole plugs (UHMWPE) for optional screw fixation using cancellous bone screws (Ti-6Al-4V ELI).
2. The second porous coated option is offered with titanium pegs.

The modular tibial trays (Ti-6Al-4V ELI) are supplied with a titanium keel cap (Ti-6Al-4V ELI) which is removable in cases where a stem extension is needed.

The offset tibial trays (Ti-6Al-4V ELI) are used with an offset adapter, offset screw, and stem extension to accommodate various tibial anatomies.

The sleeve tibial trays are offered in standard and 10mm build-up options and are used with a tibial sleeve and/or stem extension to accommodate various tibial anatomies and defects.

Porous Sleeves
The porous sleeves (Ti-6Al-4V ELI) are provided for optional use with the BKS Revision to provide additional metaphyseal fixation. The porous coating (CP Ti) on the porous sleeves is intended for use with and without cement.

Femoral sleeves may only be used with the modular femoral components along with a tapered junction box.

Tibial sleeves may only be used with the sleeve tibial trays in either standard or 10mm build-up options.

Porous Trabecular Tibial Cones
The Porous Trabecular Tibial Cones (Ti-6Al-4V) are provided for optional use with the modular and offset titanium tibial trays to provide additional support to the tibial implant construct when bone voids are present in the proximal tibia.

The porous cone augments are designed for cemented or uncemented fixation with bone and are provided in three configurations: central, full, and half.

Polyethylene Tibial Insert
The polyethylene tibial inserts are available in six variations: BKS Vitamin E Posterior Stabilizing (VPS), E-Vitalize Posterior Stabilizing (EPS), E-Vitalize Cruciate Retaining (ECR), E-Vitalize Ultra Congruent (EUC), PS Plus (PS+), and Semi-Constrained Posterior Stabilizing (CK).

The E-Vitalize Posterior Stabilizing (EPS), BKS Vitamin E Posterior Stabilizing (VPS), E-Vitalize Cruciate Retaining (ECR), E-Vitalize Ultra Congruent (EUC), and PS Plus (PS+) tibial inserts are made of crosslinked Vitamin E polyethylene (Vitamin E XLPE) and are to be used with the matching femoral component variation (ie., PS femoral for EPS insert, CR femoral for ECR or EUC insert, TriMax PS or Modular Femoral for PS Plus (PS+)).

The VPS, EPS, ECR, EUC, and PS Plus (PS+) tibial inserts are compatible with all titanium tibial trays listed above of matching size (i.e.: EPS size 4 with Offset tibial tray size 4).

The CK variation is made of polyethylene (UHMWPE) and includes a titanium (Ti-6Al-4V ELI) reinforcement pin for added stability. The CK tibial insert is to be used with the matching modular femoral component when additional medial/lateral (M/L) stability is required. The CK tibial insert must also be used with the matching modular tibial tray, offset tibial tray, or sleeve tibial tray.

Polyethylene Patella
The E-Vitalize Polyethylene Patella is made of crosslinked Vitamin E polyethylene (Vitamin E XLPE) and is a resurfacing patellar prosthesis.

Titanium Femoral Augments
The titanium femoral augments (Ti-6Al-4V ELI) are provided with a locking screw (Ti-6Al-4V ELI) and a locking ring (Ti-6Al-4V ELI). Femoral augments may only be used with the modular femoral components.

Femoral augments are provided for optional use in order to augment either the distal and/or posterior femur with bony deficiencies. Femoral augments are provided in assorted stepped configurations to facilitate surgeon selection for addressing typical bony defects.

Titanium Tibial Augments
The titanium tibial augments (Ti-6Al-4V ELI) are provided with a locking screw (Ti-6Al-4V ELI) and a locking ring (Ti-6Al-4V ELI). Tibial augments may only be used with the modular or offset tibial tray components.

Tibial augments are provided for optional use in order to augment a tibial plateau with bony deficiencies. Tibial augments are provided in assorted hemispherical stepped and angled configurations to facilitate surgeon selection for addressing typical bony defects.

Titanium Stem Extensions
The titanium cemented, fluted, and slotted stem extensions (Ti-6Al-4V ELI), are provided for optional use with the modular femoral components and modular, offset, or sleeve tibial trays to provide increased stability.

Cobalt Chromium Junction Box
The stem junction box is manufactured from cobalt chromium (Co-Cr-Mo), and is used with the modular femoral component when a stem extension is needed

Titanium Junction Boxes
The offset junction box is manufactured from titanium (Ti-6Al-4V ELI) and is used with the modular femoral component when a stem extension is needed. The offset junction box is available in 5mm and 0mm offsets.

The tapered junction box is manufactured from titanium (Ti-6Al-4V ELI) and is used with the modular femoral component. The tapered junction box can mate with a femoral sleeve or stem extension as needed. A locking bolt (Ti-6Al-4V ELI) is required to affix the tapered junction box to the modular femoral component for use with a femoral sleeve.

Titanium Offset Adapter
The titanium offset adapters (Ti-6Al-4V ELI) are provided with one screw (Ti-6Al-4V ELI). Offset adapters must be used with the offset tibial tray and stem extension components.

Titanium Offset Screw
The titanium offset screws (Ti-6Al-4V ELI), are provided for optional use beyond the single screw that is required with the offset adapter. Offset screws may only be used with the offset tibial tray and offset adapter components. One offset screw is required for sufficient fixation of the offset adapter.

INTENDED USE/INDICATIONS

1. Loss of joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities of the knee joint.
6. Revision procedures where other treatments or devices have failed.

The BKS, BKS TriMax, and BKS Revision are intended for total knee arthroplasty procedures.

The BKS is indicated in the salvage of previously failed surgical attempts where bone loss does not require the use of augments or stem extensions and where collateral ligaments may be relied upon for medial/lateral (M/L) stability.

BKS TriMax is intended in the salvage of previously failed surgical attempts where bone loss does not require the use of augments or stem extensions, where collateral ligaments may be relied upon for medial/lateral stability, where post-operative flexion up to 150° may be desirable, and the patient meets all indications/contraindications requirements.

The BKS Revision is indicated in the salvage of previously failed surgical attempts where bone loss may require the use of augments, sleeves, cones, and/or stem extensions.

The BKS Revision CK tibial insert is indicated for use with the BKS Revision modular femoral and modular, offset, or sleeve tibial components where collateral ligaments may not be relied upon for medial/lateral (M/L) stability.

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.

INFORMATION FOR USE

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

Components, trials, and instruments from other knee systems must not be used with components, trials, and instruments from the BKS, BKS TriMax, and BKS Revision 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, BKS TriMax, and BKS Revision 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, tibia, or patella.

Several thicknesses and styles of polyethylene tibial inserts are supplied separately from the tibial tray, but in corresponding sizes to the 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

Components of the BKS, BKS TriMax, and BKS Revision 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.

1. BKS E-Vitalize CR and UC tibial inserts are compatible with BKS TriMax CR or BKS CR femoral components.

1a. BKS PS femoral components are only compatible with BKS Vitamin E PS Inserts (VPS), or E-Vitalize PS tibial inserts (EPS).

2. BKS TriMax PS femoral components are only compatible with E-Vitalize PS tibial inserts and BKS TriMax PS Plus (PS+) tibial inserts. See Compatibility Chart for more details.

3. E-Vitalize PS tibial inserts are only compatible with BKS PS, BKS TriMax PS, and modular femoral components.

4a. BKS Vitamin E PS inserts (VPS) are only compatible with BKS PS and modular femoral components.

4b. BKS TriMax PS Plus (PS+) inserts are only compatible with BKS TriMax PS and modular femoral components.

5. The CK tibial insert may only be used with the modular femoral component and a modular, offset, or sleeve tibial tray.

6. If optional screw fixation is desired with the porous coated tibial tray, use only Ortho Development Corporation cancellous bone screws.

7. The femoral sleeves may only be used with the modular femoral component and tapered junction box.

8. The tibial sleeves may only be used with the sleeve tibial tray or 10mm build-up sleeve tibial tray.

9. When using a porous tibial cone, ensure the cone does not impinge with the tibial implant construct.

10. The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by the selection of the proper size, shape, and design of the implant. The BKS, BKS TriMax, and BKS Revision have interchangeable part sizes as described by the following chart, where the number in the shaded box refers to the tibial insert size:

A CR insert may be used with a 2 size up or 2 size down CR Femoral Component (2-up/2-down). All E-Vitalize CR inserts are compatible with BKS and BKS TriMax CR Femoral Components.

CR		BKS/BKS TriMax CR Femoral Component Size						
		1	2	3	4	5	6	7
CR Insert & Tibial Tray Size	1	1	1	1				
	2	2	2	2	2			
	3	3	3	3	3	3		
	4		4	4	4	4	4	
	5			5	5	5	5	5
	6				6	6	6	6
	7					7	7	7

A UC insert may be used with a 1 size up or 1 size down CR Femoral Component (1-up/1-down). All E-Vitalize UC inserts are compatible with BKS and BKS TriMax CR Femoral Components.

UC		BKS/BKS TriMax CR Femoral Component Size						
		1	2	3	4	5	6	7
UC Insert & Tibial Tray Size	1	1	1					
	2	2	2	2				
	3		3	3	3			
	4			4	4	4		
	5				5	5	5	
	6					6	6	6
	7						7	7

A PS insert may be used with a 2 size up or 1 size down PS Femoral Component (2-up/1-down). All E-Vitalize PS inserts are compatible with BKS and BKS TriMax PS Femoral Components.

PS		BKS*/BKS TriMax PS Femoral Component Size						
		1	2	3	4	5	6	7
PS/EPS/VPS Insert & Tibial Tray Size	1	1	1	1				
	2	2	2	2	2			
	3		3	3	3	3		
	4			4	4	4	4	
	5				5	5	5	5
	6					6	6	6
	7						7	7

A PS Plus insert may be used with a 2 size up or 1 size down BKS TriMax PS Femoral Component (2-up/1-down).

PS PLUS		BKS TriMax PS Femoral Component Size						
		1	2	3	4	5	6	7
PS Plus Insert & Tibial Tray Size	1							
	2				2			
	3				3	3		
	4				4	4	4	
	5				5	5	5	5
	6					6	6	6
	7						7	7

A PS, PS Plus, or CK insert may be used with a 2 size up or 2 size down Modular Femoral Component (2- up/2-down). All E-Vitalize PS inserts, PS Plus inserts, and CK inserts are compatible with BKSR Modular Femoral Components.

CK		BKSR Modular Femoral Component Size						
		1	2	3	4	5	6	7
CK/PS/PS Plus Insert & Tibial Tray Size	1	1	1	1				
	2	2	2	2	2			
	3	3	3	3	3	3		
	4		4	4	4	4	4	
	5			5	5	5	5	5
	6				6	6	6	6
	7					7	7	7

*Note: The BKS PS Femoral with E-Vitalize PS insert compatibility may be expanded to match the BKSR Modular Femoral and PS insert compatibility (BKS only, not BKS TriMax).

11. The compatibility of the implants vary by what implant is being used. Correct implant choice is crucial in a successful joint replacement. Below is a compatibility chart which refers to the proper implants to be used:

		Tibial Insert and Tray										
		BKS Tibial Tray					BKS Revision Modular, Offset, and Sleeve Tibial Tray					
		VPS	PS+	EPS	ECR	EUC	VPS	CK	PS+	EPS	ECR	EUC
Femoral Component	BKS CR				●	●					●	●
	BKS TriMax CR				●	●					●	●
	BKS TriMax PS		●	●					●	●		
	BKS PS	●		●			●			●		
	Modular Femoral	●	●	●			●	●	●	●		

● = compatible

ADVERSE EFFECTS
Short-term complication rates may be similar to those occurring with any femoral 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, BKS TriMax, and BKS Revision have not been evaluated for safety and compatibility in the MR environment. The BKS, BKS TriMax, and BKS Revision have not been tested for heating or migration in the MR environment. The safety of the BKS, BKS TriMax, and BKS Revision 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 and Vitamin E polyethylene components, are sterilized by a minimum of 25 kGy gamma irradiation. All E-Vitalize and Vitamin E polyethylene components are ethylene oxide sterilized. All gamma irradiated polyethylene tibial inserts are sterilized in a vacuum-sealed foil pouch.

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	132°C (270°F)	4	30

Exceptions by Kit Number:

Kit Number	Kit Description	Cycle Type	Minimum Sterilization Exposure Temperature	Minimum Sterilization Exposure Time (minutes)	Minimum Dry Time (minutes)*
261-9301	BKS Femoral 1	Prevacuum	132°C (270°F)	6	45

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.

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