Instructions for Use
Cancellous Bone Screw

Manufacturer
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DESCRIPTION

The Cancellous Bone Screw is intended for use in conjunction with the Tri-plus® Acetabular System and the Balanced Knee® System for adjunct fixation. The screw is available in a 6.5mm diameter in various lengths and is fabricated from Ti-6Al-4V (ASTM F-136).

INDICATIONS/ CONTRAINDICATIONS

In using the Cancellous Bone Screw, refer to the **Indications** and **Contraindications** for the Tri-plus® Acetabular System and the Balanced Knee® System. Refer to the Tri-plus® Acetabular System Product Insert for use with the Tri-plus® Acetabular System. Refer to the Balanced Knee® System Product Insert for use with the Balanced Knee® System.

WARNINGS AND PRECAUTIONS

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. Total joint replacement requires careful seating and adequate bone support and should be restricted to limited functional stress. The following factors may tend to impose risk of implant failure:

1. Severe osteoporosis.
2. Local tumors of the bone.
3. Obesity.
4. History of infectious disease or falls.
5. Drug addiction and/or abuse.
6. Systemic and metabolic bone disorders.
7. Active sports participation.

ADVERSE EFFECTS

Short term complication rates may be similar to those occurring with any total joint replacement.

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

PACKAGING AND STERILITY

All implants have been sterilized by a minimum of 25 kGy gamma irradiation, Sterility Assurance Level 10^{-6}. Sterile product packaging should be inspected for flaws before and after opening. In the presence of a flaw or if the implant sterility has been compromised the product must be considered non-sterile and should not be implanted.

PRODUCT HANDLING

Implants should always be stored unopened in their respective protective packages. Prior to use, inspect packaging for damage which may compromise sterility. When removing the implant from its packaging, the relevant

aseptic techniques must be observed. Protect the prosthesis from contact with objects which may damage the surface finish. Inspect each implant prior to use for visual damage. Do not implant this or any device that has been used, even if it appears undamaged.

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 does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, 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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