APPENDIX D – Insert and Labeling

BUECHEL–PAPPAS™ TOTAL ANKLE REPLACEMENT

COMPONENTS

The Buechel- Pappas Total Ankle Replacement, consists of the following components; a Titanium-Nitride coated, Titanium alloy tibial and talar components, and a UHMWPe bearing.

TIBIAL COMPONENT

Manufactured of Ti-6Al-4V alloy with UltraCoat® TiN coating. The tibial component consists of a flat plate with a short fixation stem on the superior face. The fixation stem and superior surface of the plate are coated with a sintered porous bead coating with a mean pore size of 350 microns and a porosity of 35%, Biocoat®. The inferior surface is polished, and the TiN coating is applied to the entire part.

TALAR COMPONENT

Manufactured of Ti-6Al-4V alloy with UltraCoat TiN coating. The talar component in the lateral plane is a segment of a cylinder. In the frontal plane, the component is a composite three curve structure, containing two identical medial and lateral concave segments, and a central convex sulcus. The inferior surface of the component contains two, short fixation fins and porous coating which is identical to the tibial component. The device is used to "resurface" the dome of the talar. In cases where talar erosion is significant, either in revision cases or patients' normal pathology, an alternate, thick talar component is available. This component is identical to the previous, with the exception of a horizontal, flat inferior surface, instead of a cylindrical type. Where grafting or cement alone will not provide the adequate base for support because talar erosion is so severe, or there is too much bone loss, the thick talar component should be used. Also, in some cases the lateral view of the talus may look flat (almost horizontal) instead of its normal curved shaped. In this situation, it may not be feasible to fashion the talar dome to receive the talar component. It is important that the underside of the prosthesis be supported by the appropriate bone stock. This is defined as healthy bone, which matches the underside shape of the component to ensure proper loading and fixation. In these cases where the talar component may only be supported on the anterior and posterior edges due to the lack of talar curvature and/or ability to fashion this curvature, the thick prosthesis should be used to allow full area contact of the bone/prosthesis interface.

BEARING

The bearing is manufactured from GUR-1050 UHMWPe and is placed between these two components. It articulates with the flat surface of the tibial component and the curved talar component. This allows all surfaces to be totally congruent throughout all ranges of motion.
The superior surface is flat and mates with the flat tibial component. The inferior surface contains the same profile as the talar component. When properly installed, the bearing resists medial/lateral dislocation by engaging the deep sulcus of the talar component. This congruency will lower the contact stress, thereby lowering the wear rate. Also, total ankle replacements have been plagued by torsional loosening of the components due to the ankles, "corkscrew" type motion patterns. By allowing the bearing to "float" between the two components, the only torsional loads transmitted to the prosthesis are through friction.

STERILIZATION

All titanium implant components are provided pre-sterilized by exposure to a minimum of 25 Kilograys of gamma radiation. All UHMWPe components are provided pre-sterilized by exposure to ethylene oxide. If package is damaged, contents should not be used and Endotec, Inc. should be contacted.

INDICATIONS

1. Patients may have a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis
2. Patients may have correctable varus or valgus deformity (under 20°)
3. Patients having intact ankle dorsiflexors and plantarflexors
4. Patients may have a previous failed total ankle arthroplasty provided the medial and lateral malleoli and ligamentous structures are intact
5. Viable or reconstructable ligamentous and malleoli supports
6. Patients may have pseudoarthrosis

CONTRAINDICATIONS

1. Reduced vascular circulation in the affected limb (e.g. diabetes with peripheral vascular involvement of the foot)
2. Severe (over 20°) varus or valgus talar tilt
3. Subjects with distant foci of infection should be treated preoperatively to avoid hematogenous spread of the infection to the implant site
4. Neuromuscular compromise
5. Unreconstructable ligamentous or Malleoi supports
6. Patient in the opinion of the surgeon is extremely obese, and this fact may compromise the function of the device
7. Is mentally incompetent
8. Patient has a history of endocrine or metabolic disorder known to affect osteogenesis

PRECAUTIONS

Before clinical use, the surgeon should be familiar with all aspects of the surgical procedure. Patients should be instructed in the limitations of the prosthesis and should be taught to govern their activities accordingly. Sizing between components should only be performed as indicated in the surgical procedures.

WARNINGS

Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in the service of the prosthetic implants.

Accepted practices should be followed meticulously in postoperative care and the patient should be made aware of the limitations of total joint reconstruction. Heavy labor, active sports, or other disorders of the hip or knee could increase loading of the ankle and decrease its function.

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STERILE R

BUECHEL-PAPPAS™

TIBIAL COMPONENT

BIOCOAT® and ULTRA COAT®

MATERIAL Ti-6Al-4V

US Patent 4,309,778

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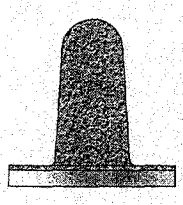
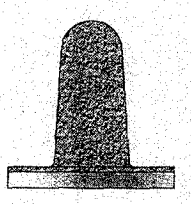


STERILE R

MATERIAL Ti-6Al-4V

TIBIAL COMPONENT

BIOCOAT® and ULTRA COAT®



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STERILE EO

BUECHEL-PAPPAS™

ANKLE BEARING

MATERIAL UHMWPe

US Patent 4,309,778

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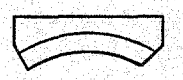

STERILE EO

MATERIAL UHMWPe

ANKLE BEARING

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TERILE R

BUECHEL-PAPPAS™

TALAR COMPONENT

BIOCOAT® and ULTRA COAT®

MATERIAL Ti-6Al-4V

US Patent 4,309,778

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STERILE R

TALAR COMPONENT
COAT® and ULTRA COAT®

MATERIAL Ti-6Al-4V

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STERILE R

BUECHEL-PAPPAS™

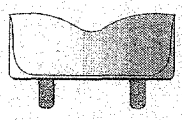
TALAR COMPONENT, THICK

BIOCOAT® and ULTRACOAT®

MATERIAL Ti-6Al-4V

CE 0120

US Patent 4,309,778

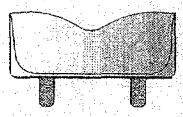


STERILE R

MATERIAL Ti-6Al-4V

TALAR COMPONENT, THICK

BIOCOAT® and ULTRACOAT®



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