

JAN 27 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K964357

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Natural-Hip™ System CoCr Stem.

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Classification Name: Hip-joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis, 21 CFR 888.3353.

Common/Usual Name: Total Hip Prosthesis - Femoral Component

Trade/Proprietary Name: Natural-Hip System CoCr Stem

PRODUCT DESCRIPTION

The Natural-Hip System CoCr Stem is a straight stem employing a proximal wedge shaped design. The stem is available in both a collared and collarless design. The proximal one-third of the stem's surface is grit blasted. Normalization steps are also located on the proximal portion of the stem. The grit blasted surface and normalization steps enhance cement compression and bonding for optimal fixation of the hip stem in the femoral canal.

The Natural-Hip System CoCr Stem employs a Sulzer 12/14 configured neck trunnion for attachment to Intermedics Orthopedics, Inc.'s femoral heads, including Biolox and Zirconia ceramic heads, featuring a Sulzer 12/14 configured bore.

The Natural-Hip System CoCr Stem has a hole in the distal portion of the stem to allow the use of a distal centralizer for correct distal alignment. The stem also employs proximal PMMA centralizers which, along with the distal centralizer, provide for an even cement mantle. This device is intended for single use only.

The Natural-Hip System CoCr Stem is intended to be used in conjunction with the following Intermedics Orthopedics, Inc. devices that have been cleared for marketing by the FDA:

- IOI metallic femoral bearing heads [510(k)s K905781 and K913060],
- IOI Biolox Bearing Heads [510(k)s K923734, K942330],
- Zirconia Bearing Heads [510(k) K944209],
- IOI bipolar components [510(k)s K833404 and K873815],
- IOI unipolar components [510(k)s K833403 and K934159],

- IOI acetabular components [510(k)s K850793, K920955, K933203, K942406, K941617, K955033 and K955739].

DIAGNOSTIC INDICATIONS

The Natural-Hip System CoCr Stem is intended to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. The Natural-Hip System CoCr Stem is intended for *cemented application only*. The general indications associated with the use of Natural-Hip System CoCr Stem in total hip arthroplasty include:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity or dysfunction persists.
3. Revision of previously failed arthroplasty.

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient, and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

SUBSTANTIAL EQUIVALENCE

The Natural-Hip System CoCr Stem is substantially equivalent to the Natural-Hip System - DRG Hip Stem (Intermedics Orthopedics, Inc.), the Premier Hip Stem (Intermedics Orthopedics, Inc.), the ODC Hip Stem (Osteonics Corporation), and the Perfecta IMC Stem (Orthomet Inc.).