

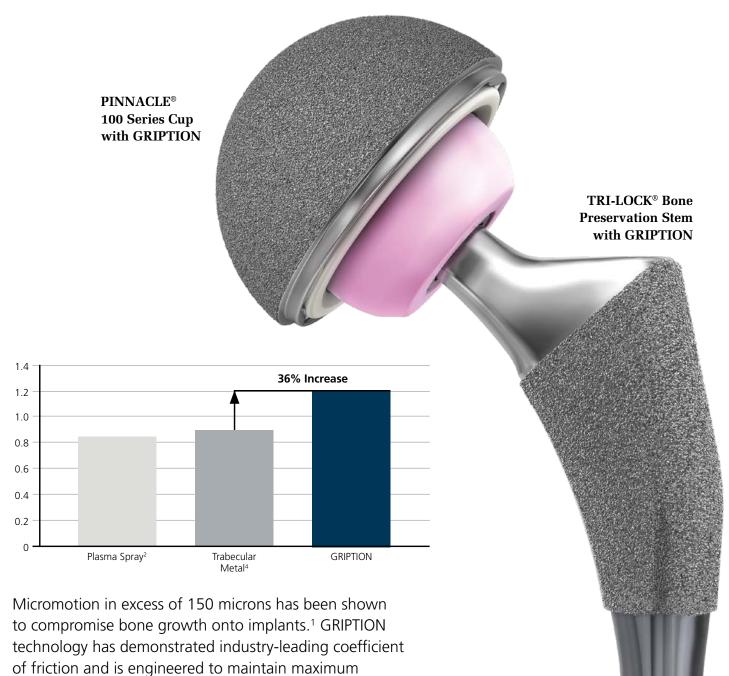
GRIPTION® POROUS COATING

DESIGN RATIONALE



ADVANCED STABILITY

In lab testing, *DePuy Synthes Joint Reconstruction* GRIPTION[®] Porous Coating has demonstrated a 1.2 coefficient of friction, offering a substantial improvement over plasma spray coatings and a 36 percent improvement over a contemporary tantalum cementless interface.^{2,4}



stability even under extreme loading conditions.

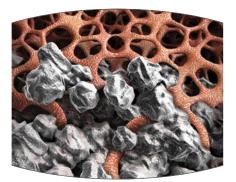
LEADING WITH ADVANCED FIXATION

DePuy Synthes Joint Reconstruction GRIPTION Porous Coating is a significant development in implant fixation technology. This advanced, three-dimensional fixation is designed to maximize initial stability, which leads to long-term biologic fixation.¹ GRIPTION further enhances the solid foundation of *DePuy Synthes Joint Reconstruction* POROCOAT® Porous Coating, which has more than 30 years of clinical heritage.²

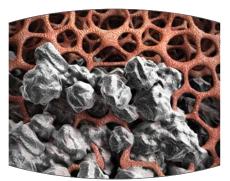


ADVANCED IN-GROWTH

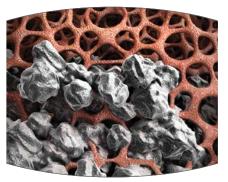
DePuy Synthes Joint Reconstruction's proprietary gradient porosity and pore size is achieved through precision engineering and manufacturing. *DePuy Synthes Joint Reconstruction* GRIPTION Porous Coating is composed of super-textured asperity topography (STAT), which combines macrotexture and microtexture topographies to provide a favorable mechanical loading environment for bone construction, enabling greater cell adhesion and proliferation. Pore size and porosity incrementally increase from the substrate to the bone interface allowing rapid, deep biologic bone in-growth within the implant material. This allows for longer-lasting, secure placement through higher oxygenation and vascularization.³



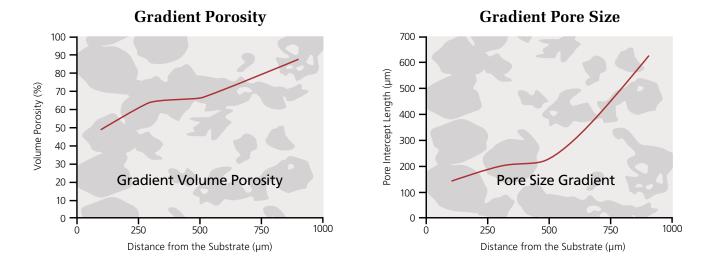
In-growth – 2 weeks



In-growth – 4 weeks



In-growth – 12 weeks



ADVANCED STRENGTH



Bantam 38-46 mm

0

100 Series 44-66 mm



Sector 48-66 mm



Multi-Hole 48-72 mm



Revision 54-80 mm



Deep Profile 54-72 mm

While initial stability and long-term fixation are key elements of GRIPTION's three-dimensional structure, they would not be complete without the strength of the porous matrix itself. Following the proven heritage of *DePuy Synthes Joint Reconstruction's* time-tested Porocoat processing parameters, *DePuy Synthes Joint Reconstruction* GRIPTION is manufactured of CP titanium with a unique gradient porosity. GRIPTION is specifically engineered to maintain mechanical integrity under extreme shear, compression, torsion and tension forces.



Total Hip Prostheses, Self-centering Hip Prostheses and Hemi-hip Prostheses

Important

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications

Total Hip Arthroplasty (THA) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. THA is indicated for a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous hip surgery; and certain cases of ankylosis. Hemi-hip arthroplasty is indicated in these conditions where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem. Hemi-hip arthroplasty is indicated in the following conditions: acute fracture of the femoral head or neck that cannot be reduced and treated with internal fixation; fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation; avascular necrosis of the femoral head; nonunion of femoral neck fractures; certain high subcapital and femoral neck fractures in the elderly; degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement; and pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

Contraindications

THA and hemi-hip arthroplasty are contraindicated in cases of active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; Charcot's or Paget's disease; for hemi-hip arthroplasty - pathological conditions of the acetabulum that preclude the use of the natural acetabulum as an appropriate articular surface. Ceramic heads are contraindicated in revision surgery when the femoral stem is not being replaced or for use with any other than a polyethylene or metal-backed polyethylene cup. In the USA, ceramic heads are not approved for use with metal cups.

Warnings and Precautions

Ceramic-coated femoral stem prostheses are indicated for uncemented press-fit fixation. CAUTION: DO NOT USE BONE CEMENT FOR FIXATION OF A CERAMIC-COATED PROSTHESIS.

Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to adversely affect hip replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, history of infections, severe deformities leading to impaired fixation or improper positioning, tumors of the supporting bone structures, allergic reactions to materials, tissue reactions, and disabilities of other joints.

Adverse Events

The following are the most frequent adverse events after hip arthroplasty: change in position of the components, loosening of components, fracture of components, dislocation, infection, peripheral neuropathies, tissue reaction.

References

1. Jasty M, et al. "In Vivo Skeletal Responses to Porous-Surfaced Implants Subjected to Small Induced Motions." J Bone Joint Surg Am. 1997;79(5):707-714.

- 2. Data on file at DePuy Orthopaedics, Inc.
- 3. Karageorgiou V, et al. "Porosity of 3D Biomaterial Scaffolds and Osteogenesis." Biomaterials. 2005;26(27):5474-5491
- 4. Published literature on file at www.zimmer.com.

Limited Warranty and Disclaimer: DePuy Synthes Joint Reconstruction products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.



companies of Johnson Johnson

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