## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>Proven Clinical Heritage of POROCOAT®</td>
<td>4</td>
</tr>
<tr>
<td>Built on the foundations of POROCOAT</td>
<td>5</td>
</tr>
<tr>
<td>Super Textured Asperity Topography (STAT)</td>
<td>6</td>
</tr>
<tr>
<td>High Coefficient of Friction</td>
<td>7</td>
</tr>
<tr>
<td>Gradient, High Volume Porosity</td>
<td>8</td>
</tr>
<tr>
<td>Optimal Pore Size</td>
<td>9</td>
</tr>
<tr>
<td>Manufacturing Process</td>
<td>10</td>
</tr>
<tr>
<td>Clinical Applications</td>
<td>12</td>
</tr>
</tbody>
</table>
GRIPTION® porous coating is an evolutionary development in implant fixation technology designed for patients with an additional need of initial stability or a diminished implant contact area with the host bone.

Introduced in 1977, POROCOAT porous coating has more than 30 years of clinical experience. In 2009 GRIPTION porous coating was introduced to build on the foundation of the POROCOAT porous coating.

GRIPTION exhibits “a superior scratch fit leading to increased primary stability” due to one of the industry’s highest coefficients of friction.
GRIPTION porous coating’s advanced structure is called ‘Super-Textured Asperity Topography’ (STAT) and is a random array of sintered, irregularly shaped, commercially pure titanium (CPT) particles forming a three-dimensional network of interconnecting pores.

GRIPTION exhibits a proprietary gradient porosity which is engineered with a clinically advantageous 80-percent surface volume porosity designed to facilitate bone in-growth\textsuperscript{13,14} and a favorable mechanical loading environment for bone formation.\textsuperscript{15}

GRIPTION has an average pore size of 300 microns\textsuperscript{13,23} which lies within the optimal range for tissue in growth into the structure and enables vascularisation.\textsuperscript{14,16}
Proven Clinical Heritage

POROCOAT Porous Coating is a small-beaded, metal surface coating that sits proud on the surface of the implant and is designed for long-term cementless fixation.

Introduced in 1977, POROCOAT porous coating has more than 30 years of clinical experience.\textsuperscript{1-9} POROCOAT is supported by multiple peer reviewed published clinical papers reporting “excellent results” which is a testament to this well established technology.\textsuperscript{1-9} Peer-reviewed surgeon series of acetabular cups with POROCOAT porous coating show excellent survivorship rates.\textsuperscript{1,2,4} 100% of DURALOC\textsuperscript{®} acetabular implants had bone ingrowth into the porous-coated surface, with 0% aseptic loosening at 16 years,\textsuperscript{1} 100% survivorship at 10 years of the DURALOC 300 cup\textsuperscript{2} and 96.1% survivorship at 8 years with the PINNACLE cup.\textsuperscript{4} These results are supported by multiple National Joint Registry results reporting 10-year survivorship rates of DURALOC at 94% survivorship in the Norwegian\textsuperscript{17} registry. The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man reported 97.19% survivorship at 10 years for ceramic on polyethylene bearings and 96.84% survivorship at 10 years for metal on polyethylene bearings.\textsuperscript{18} POROCOAT Porous Coating is found on a range of contemporary DePuy Synthes Joint Reconstruction products.

POROCOAT is made by sintering (high temperature bonding) a random array of spherical beads of titanium or cobalt chrome to an implant. The sintered beads form a three-dimensional network of interconnecting pores exhibiting optimal morphological properties for bone in-growth. POROCOAT’s high coefficient of friction of 0.8\textsuperscript{10} provides a roughness that enables “very good initial stability and facilitates the scratch fit of the implant”. It is engineered to provide “a high and clinically advantageous ~80% volume porosity at the surface an average pore size of 250 microns”, which is documented in a laboratory studies\textsuperscript{16} to be within the beneficial size range for good bone in-growth.

The three-dimensional, gradient structure of POROCOAT Porous Coating is designed to provide a favourable mechanical loading environment for bone formation.\textsuperscript{15} POROCOAT Porous Coating is manufactured with a coating tensile strength >23 Mpa to minimise coating delamination. The coating process has an average thickness of 0.762 (± 0.254 mm). This tolerance variance is intentional because it adds to the overall roughness of the coating. Research\textsuperscript{20} has demonstrated that virtually all bone growth onto and into an implant is at the outermost surface (only about 1-1.5mm deep into the pore structure), which reinforces the design characteristics of a sintered bead coating.
Built on the Foundations of POROCOAT

GRIPTION Porous Coating builds on the characteristics of POROCOAT and hence emulates some of its proven properties:

- **GRIPTION** has a pore size of 300 microns\(^{13,21}\) versus 250 microns for POROCOAT. Both POROCOAT and GRIPTION are documented in laboratory studies\(^{14,16}\) to be within the beneficial size range for good bone in-growth and vascular reconstitution.

- **GRIPTION** features a favourable three-dimensional, gradient structure, which is designed to provide a favorable mechanical loading environment for bone reconstitution.\(^{15}\) The microtexture additionally enables greater cell adhesion and proliferation due to its morphology.\(^{14}\)

- **GRIPTION**’s manufacturing principles and mechanical attributes are virtually identical to POROCOAT and therefore replicate many mechanical properties such as the resistance to delamination with a coating tensile strength >32 Mpa.\(^{22}\)

- The GRIPTION Porous Coating is applied by first preparing the surface of the cup to accept a coat of the same spherical titanium beads as used for POROCOAT Porous Coating. Once these spherical beads are applied to the surface, multiple coats of irregularly shaped particles of titanium are applied directly over the top. The result is a high porosity, high friction GRIPTION surface.\(^{10,13,21}\)

- **GRIPTION** exhibits a high co-efficient of friction for initial ‘scratch fit’ designed to increased primary stability based on one of the industry’s highest coefficients of friction at 1.2.\(^{10-12}\)

- **GRIPTION** is engineered to feature “a clinically advantageous gradient and very high porosity (80-percent at the surface)”\(^{13}\)

### Comparison of the physical characteristics of POROCOAT and GRIPTION porous coatings

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>POROCOAT(^{10})</th>
<th>GRIPTION(^{10,13,21,22})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pore Size (Gradient Pore Size)</td>
<td>~250 microns (average)</td>
<td>~300 microns (average)</td>
</tr>
<tr>
<td>Volume Porosity</td>
<td>~80% (surface), 45% (average)</td>
<td>~80% (surface), 63% (average)</td>
</tr>
<tr>
<td>Thickness</td>
<td>0.762 (average)</td>
<td>0.889 (average)</td>
</tr>
<tr>
<td>Coating Tensile Strength</td>
<td>&gt;23 Mpa*</td>
<td>&gt;32 Mpa*</td>
</tr>
<tr>
<td>Coefficient of Friction</td>
<td>0.8</td>
<td>1.2</td>
</tr>
</tbody>
</table>

* Actual values associated with failure of the coating were not obtained. The highest strength result obtained with no coating failure is indicated, as cohesive failure occurred between the outer surface of the porous coating and the testing medium in all cases.
Super Textured Asperity Topography

GRIPTION incorporates a proprietary Super-Textured Asperity Topography (STAT). STAT is a random array of irregularly shaped, commercially pure titanium (CP Ti) sintered particles forming a three-dimensional network of interconnecting pores. STAT is comprised of two differentiated structures; a macrotexture and a microtexture.

The microtexture comprises a series of peaks and troughs on the irregularly shaped titanium particles. This microtexture may improve the osteoblasts’ ability to stick to the surface, increasing adhesion strength and enabling cell proliferation on the coating surface.14
The proprietary Super-Textured Asperity Topography (STAT) of GRIPTION Porous Coating features initial ‘scratch fit’ stability due to one of the industry’s highest coefficients of friction of 1.2\textsuperscript{10-12}.

Implant micromotion exceeding 150 microns results in fibrous attachment and poor bone formation onto and around an implanted device\textsuperscript{19}. Bearing this in mind, a superior coefficient of friction and therefore enhances initial ‘scratch-fit’ stability may be crucial with regards to long-term fixation for a cementless implant. This may be especially important with regard to cases with a smaller host bone contact area (this may include revision or unusual primary cases), where the coefficient of friction may be an important factor for initial stability and long-term fixation of the implant.

**Definition of Coefficient of Friction**

The Coefficient of Friction is defined by the ratio of the force that maintains contact between an object and a surface and the frictional force that resists the motion of the object.

\[ \text{Coefficient of Friction} = \frac{\text{Force to dislodge}}{\text{Force that maintains contact}} \]

\[ \text{A Coefficient of Friction of 1.2 (GRIPTION Porous Coating) implicates that for each 1 kilogram of weight applied downward, it needs 1.2 kilograms of force to dislodge it.} \]
A property that is proprietary to DePuy Synthes porous coatings is its gradient porosity¹³ (see chart right).

GRIPTION like POROCOAT was designed with a gradient porosity.¹³ The intent of this gradient porosity is to assist with load sharing. The gradient coating design gives rise to highest density of metal at the substrate or surface of the cup and the lowest density of metal at the outer surface of the coating.¹³ This provides a smooth transition in porosity and metal density as bone grows through the coating from bone to substrate. The outermost surface of the coating being more porous results in more open space for vascularisation and good bone in growth. This gives a strong bone-to-implant interface, and might aid in stress shielding with the transition to lower porosity providing a favorable mechanical loading environment for bone formation.¹⁵,²³ The outermost pores are typically filled with scraped bleeding bone upon impaction of the component.

GRIPTION is engineered to maintain a high and clinically advantageous 80-percent volume porosity¹³ at the surface for good bone in-growth.¹⁴ This 80-percent volume porosity is equal to or better when compared to the volume porosity of other advanced coating surfaces in the market.¹¹-¹³

**Definition of Volume Porosity**

Porosity is a measure of the void spaces in a material and is a fraction of the volume of voids over the total volume, expressed as a percentage between 0–100%.

→ A surface volume porosity of 80%¹³ (GRIPTION Porous Coating) indicates, that 80% of the area is void space at the bone implant interface.
Optimal Pore Size

GRIPTION has an average pore size of 300 microns,\textsuperscript{13,21} which is documented in laboratory studies to be within the beneficial size range of 50-400 microns for good bone in-growth and vascular reconstitution.\textsuperscript{16}

Pores below 50 microns may hinder uniform maturation of tissue: in larger pores, 400 microns and above, in-growth may be slow, inconsistent and tends to be fibrous.\textsuperscript{16}

Definition of Pore Size

Pore size is a measure of the average diameter of a material’s pores (this usually includes a definition of the range of pore sizes).

→ GRIPTION Porous Coating has an average pore size of 300 microns.\textsuperscript{13,21}
The manufacturing process for PINNACLE cups with GRIPTION Porous Coating is very similar to the manufacturing process for coating with POROCOAT.

**Raw Forging**
The PINNACLE Shell forging is essentially a “blank” that can be made into almost any PINNACLE cup design including the 100, 300, Sector, Multihole or Bantam series.

**Outer Diameter Machined**
The forging is machined at this stage to include the apical hole and any screw holes.

**GRIPTION Porous Coating Applied**
The surface of the cup is prepared to accept a coat of the same spherical titanium beads as used for POROCOAT Porous Coating. Once these spherical beads are applied to the surface, multiple coats of irregularly shaped particles of titanium are applied directly over the top. The result is a high porosity, high friction GRIPTION surface.\(^{10,13,23}\) (Were this a cup with POROCOAT Porous Coating, only spherical beads would be applied.)

**Inner Diameter Machined**
Following the sintering process (sintering is the process of high temperature bonding of the beads to the implant creating a strong metallurgical bond between the implant and the fused beads), the PINNACLE shell’s inner diameter is machined to accept the liners.\(^{26}\)

**Finished Pinnacle Cup**
PINNACLE Cups with GRIPTION Coating are checked against specification and are cleaned, boxed and sterilised.
Clinical Applications

There are three groups of patients that may stand to gain the most from GRIPTION’s high coefficient of friction, high gradient volume porosity and optimal pore size:

- **Atypical Primary Patients** (in the case of a diminished contact area of the implant with the host bone)
  This may include DDH, rheumatoid protrusio, prior fusion, severe natural anteversion or retroversion deformity, or tumour.

- **Traditional Revision Patients**
  This may include revisions of failed cemented cups, minor to moderate protrusio, migrated shell, osteolytic defects and false acetabulum, where a loss of host bone may compromise primary fixation.

- **Primary Patients with an Additional Need for Initial Stability**
  Any other primary patients where surgeons feel an improved initial scratch fit is of benefit.
References


22. DePuy Synthes Data on File, WR070087,070065.