

# PINNA<sup>®</sup>LE

H I P   S O L U T I O N S

Product Rationale



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# Introduction

Hip reconstruction has become a successful answer for degenerative hip disease in a more demanding patient population.<sup>1</sup> In addition, hip replacement can provide mobility and pain relief to patients with hip dysplasia or posttraumatic arthritis. Experience with total hip arthroplasty has resulted in a more comprehensive understanding of hip anatomy and biomechanics and advances in surgical technique. These advances provide a foundation for the development of more efficient instrumentation and increasingly sophisticated implant design.



# Heritage & Clinical Results

## Heritage

The PINNACLE® Hip Solutions are based on the great heritage of the DURALOC® Acetabular Cup System. Introduced in 1980, DURALOC set the clinical standard for cementless cups. Proven in patients it combined effective fixation with the most advanced polymer and ceramic liners available at the time. This provided the platform for the advanced bearing technology in regard of modularity that we see being used across the world.<sup>2,5</sup>

The introduction of the PINNACLE Hip Solutions in 2000 redefined the standard in the industry. Its design provides proven fixation technologies<sup>2,5</sup>, a broad variety of high performance bearing options and a comprehensive cup platform.

The proven cementless coating fixation technologies<sup>7-9</sup> are based on the outstanding clinical performance<sup>5,6,10</sup> of POROCOAT® Porous Coating, which was introduced with the AML cup in 1977, with the DURALOC cup 1980 and with the PINNACLE cup in 2000. Therefore it has been clinically tracked for over 30 years.<sup>5,6,10,25,26</sup> The DUOFIX® Fixation System was introduced with PINNACLE cups in 2003 being an evolutionary combination of POROCOAT Porous Coating and highly amorphous hydroxyapatite (HA). Finally, in 2009 the GRIPTION® cup fixation technology emulated the reliable foundation of the POROCOAT Porous Coating being also an evolutionary development in implant fixation technology due to an advanced 3D structure.<sup>4-6,10,12,29,38</sup>

The foundation of the polyethylene high performance liners was set by MARATHON™ as the first FDA-cleared, cross-linked polyethylene in the market in 1998, which reduces wear by 83% in a biomechanical study compared to standard polyethylene while eliminating oxidation.<sup>21-23,37</sup> Based on the clinical experience of MARATHON, an adapted and exclusive Altra-Link material enhancement process led to the introduction of the ALTRX™, cross-linked anti-oxidant polyethylene in 2007, with an in-laboratory proven optimised balance of wear reduction<sup>16</sup> and mechanical integrity<sup>17-19</sup> while virtually eliminating oxidation<sup>17-20</sup>. ALTRX polyethylene liners reduce wear by 92%<sup>16,18,19</sup> in comparison to non cross-linked polyethylene and 53%<sup>16</sup> to MARATHON cross-linked polyethylene liners respectively.<sup>21-24</sup>

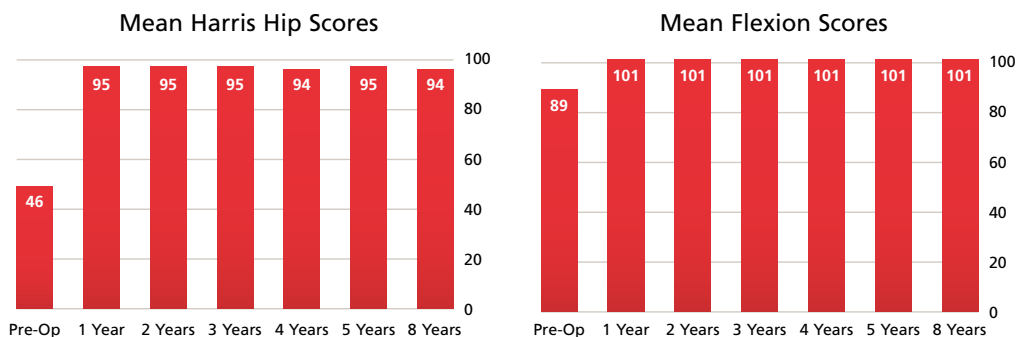
1977	1980	1998	2000	2003	2007	2009
<b>POROCOAT</b>	<b>DURALOC</b>	<b>MARATHON</b>	<b>PINNACLE</b>	<b>DUOFIX</b>	<b>ALTRX</b>	<b>GRIPTION</b>
Initiating the great heritage of porous coating	Setting the clinical standard for cups in cementless total hip replacement with POROCOAT porous coating	The first FDA-cleared, 3rd generation, cross-linked polyethylene in the market	Redefining the clinical standard for cups in cementless total hip replacement with POROCOAT porous coating	Introduction of the evolutionary combination of POROCOAT Porous Coating and highly amorphous hydroxyapatite (HA) to PINNACLE	4th generation cross linked polyethylene with optimised balance of wear reduction	Introduction of the evolutionary development of porous coating technology to PINNACLE due to an advanced 3D structure

## Clinical Results

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The PINNACLE Hip Solution is one of the world's leading modular high performance bearing with a 99.9% survivorship at 5 years and 96.1% at 8 years in a Prospective Multi-Centre Study.<sup>25,26</sup>

### *96.1% 8-Year Survival of the PINNACLE Multi-liner Acetabular Cup in a Prospective Multi-Centre Study*



*CORAIL-PINNACLE is the most implanted cementless combination in the joint registries of England and Wales, and Australia.*



**National Joint Registry for England and Wales  
Annual Report 2012**

With 33% of all implantations, PINNACLE is the most used cup in the UK Joint Registry. Together with CORAIL it is also the most used combination in hip joint reconstruction showing a 95.9% survival rate at 7 years in 54,019 implantations. The cementless CORAIL-PINNACLE ceramic on polyethylene (CoP) bearing combination shows a very high survival rate of 98.6% at 5 years, metal on polyethylene (MoP) 98.3%, ceramic on ceramic (CoC) 97.5% and metal on metal (MoM) 95.7% at 5 years.<sup>27</sup>



**Australian Orthopaedic Association  
National Joint Replacement Registry  
Annual Report 2012**

In the Australian Registry PINNACLE is the second most used cementless acetabular cup. Together with CORAIL it is the most used combination in cementless hip joint reconstruction showing a 96.4% survival rate at 5 years in 14,961 implantations.<sup>28</sup>



# Proven Coating Fixation Technologies

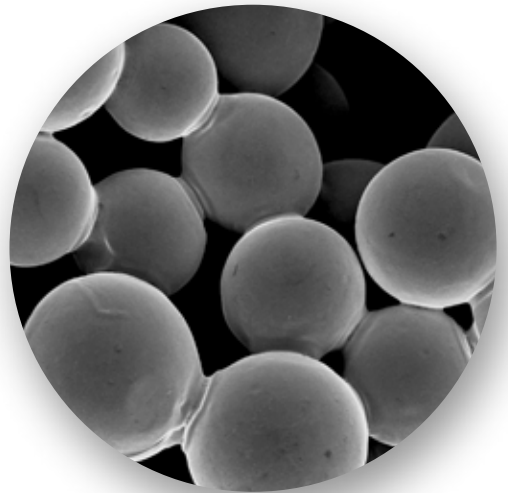
Without initial and long-term component fixation, a surgeon's efforts to restore joint function are lost. With the PINNACLE cup, fixation is achieved through 180° of either POROCOAT, DUOFIX with Hydroxyapatite (HA) or GRIPTION Coating.

## *POROCOAT – Proven Clinical Heritage*

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The proprietary POROCOAT Porous Coating has been unchanged in structure since its introduction in 1977. It is composed of commercially pure titanium sintered metal beads, that allow bone to affix biologically into the porous coating. It has a pore size of 250 microns in average, which is documented in a laboratory study<sup>4</sup> to be a beneficial size for penetration of bone tissue. The high coefficient of friction is designed to enhance the 'scratch-fit' and therefore to improve the initial stability of the PINNACLE acetabular cup.<sup>4</sup>

With more than 30 years of clinical heritage and a recent 5 years follow-up showing a 99.9% and an 8 years follow-up showing 96.1% survivorship, PINNACLE cups with POROCOAT Porous Coating have been successful in achieving stability and long-term fixation.<sup>25,26</sup>



## *DUOFIX – Enhanced Biological Fixation*

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The DUOFIX Fixation System was introduced with the PINNACLE in 2003 and is a combination of POROCOAT Porous Coating and highly amorphous hydroxyapatite (HA). It is composed of commercially pure titanium sintered metal beads, that enable bone to affix biologically into the porous coating. Plasma spray flame applications provide a consistent layer of HA to accelerate osteointegration and aid in achieving early fixation.<sup>38</sup>

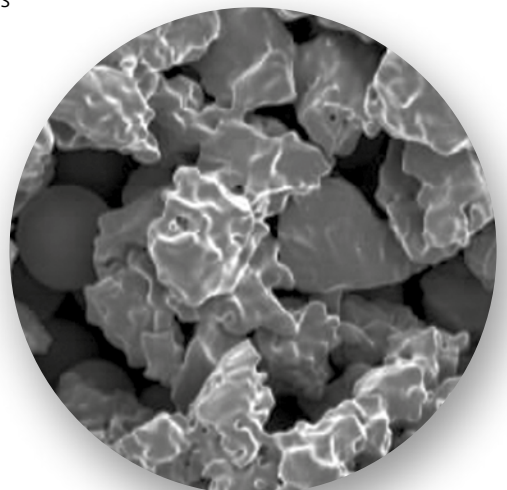


## *GRIPTION – Optimised Fixation*

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GRIPTION fixation technology was introduced in 2009 and emulates the reliable foundation of the POROCOAT Porous Coating. It is an evolutionary development in implant fixation technology. Its advanced 3D structured fixation is designed to maximise initial 'scratch fit' stability due to very high coefficient of friction<sup>12</sup>, leading to long-term biological fixation.<sup>12,29</sup>

It is specifically engineered to maintain a clinically advantageous 80% surface volume porosity and 300-micron pore structure in average.<sup>4,12,29</sup> This makes allowance for good tissue growth and vascularisation onto and around an implant. Combined macrotecture and microtexture topographies can provide a favourable mechanical loading environment for bone reconstitution and enable greater cell adhesion and proliferation.<sup>11</sup>



# High Performance Bearing Options

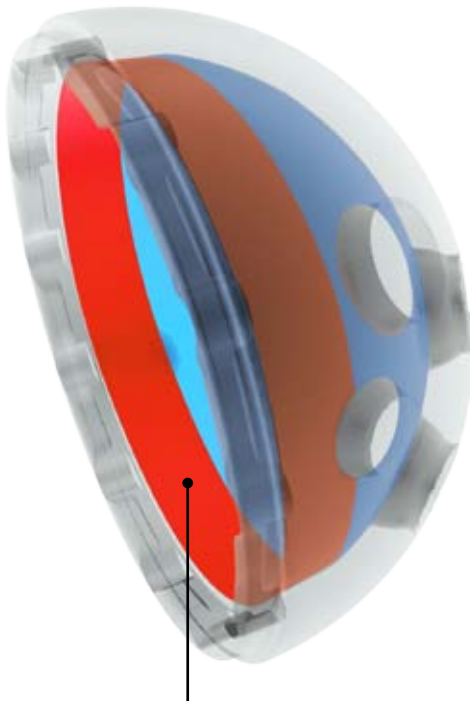
## *VIP Taper*

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Adding enhanced versatility, the PINNACLE cup incorporates the Variable Interface Prosthesis (VIP) taper which supports optimum performance for polyethylene, ceramic and metal liners. For polyethylene liners the VIP taper does not compromise the critical dome loading and for alternative bearing liners (ceramic or metal) it locks the liner tightly to the cup. Anti rotational devices provide rotational stability and resistance to torsional loads for polyethylene liners.

An approach to versatility offers more ways to bring together all the right components and materials for optimised performance. Choose a solution featuring one of three advanced technologies<sup>14-19,21,30-35</sup> available – polyethylene, ceramic or metal liners.

PINNACLE Cup Design



VIP taper locks alternative bearing option (ceramic or metal) tightly to the cup

Optimum Polyethylene Performance



VIP taper does not compromise the critical dome loading for polyethylene liners



## Cross-Linked Polyethylene Liners

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### MARATHON

MARATHON polyethylene is the first FDA-cleared, third generation, cross-linked polyethylene in the market and was introduced in 1998. Through the MARATHON process (using a base resin barstock of GUR 1050 and moderately cross-linking it at 5 megarads) it reduces wear by 83% in hip simulator studies compared to standard polyethylene, resists oxidation and exceeds minimum ASTM mechanical standards.<sup>21,22,23,37</sup> With the clinically proven<sup>23,37</sup> wear resistance of MARATHON Cross-Linked Polyethylene, larger head diameters can be used to improve functional range of motion and reduce the risk of dislocation, whilst maintaining adequate thickness of the polyethylene liner.<sup>30</sup>

### ALTRX

ALTRX is built on the proven clinical<sup>21,22,23,36</sup> experience of MARATHON Cross-Linked Polyethylene and was introduced in 2007. Through the exclusive Altra-Link material enhancement process (using a base resin barstock of GUR 1020 and moderately cross-linking it at 7.5 megarads), ALTRX polyethylene is optimised to balance wear reduction and mechanical integrity whilst eliminating oxidation. To address a growing trend toward high demand patients, ALTRX polyethylene liners reduced wear by 92% in an internal laboratory study<sup>16,18,19</sup> versus standard polyethylene and 53%<sup>16</sup> versus MARATHON polyethylene liners.

## Ceramic Liners

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### CERAMAX™

The ceramic material offered with the PINNACLE Hip Solutions is CERAMAX Ceramic, a BIOLOX® *delta* composite material with a unique combination of toughness and structural integrity. Through an exhaustive process of assessment and testing, CERAMAX Ceramic has been developed to incorporate the best characteristics of ceramics as implant materials. The outcome is a material with the wear behaviour and excellent biocompatibility of alumina, but with improved mechanical properties for use in Ceramic-on-Ceramic joints.<sup>31-33</sup>

## Metal Liners

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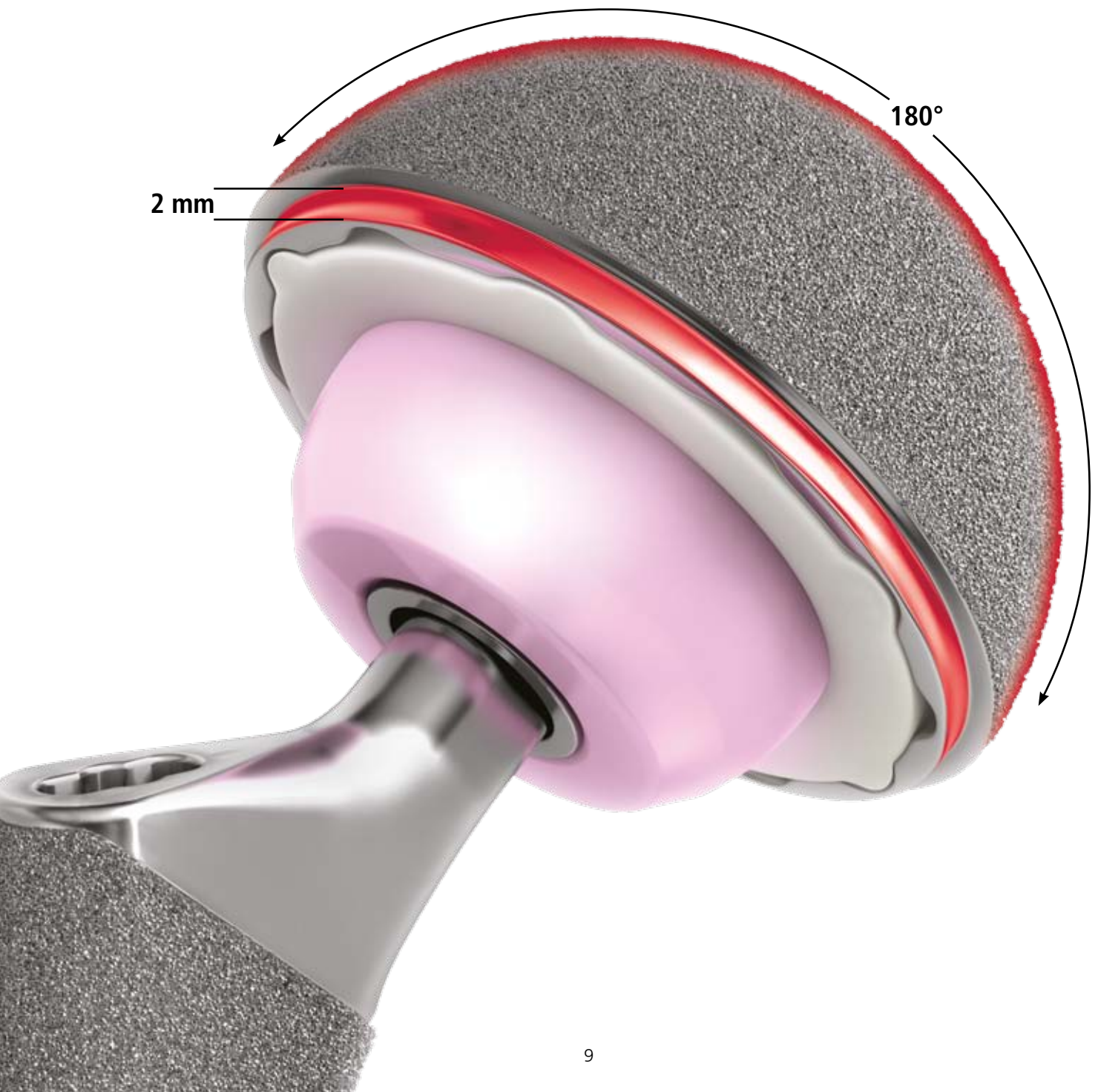
### ULTAMET™

The PINNACLE Hip Solutions' ULTAMET Metal-on-Metal Liners are manufactured from forged high-carbon wrought alloy. Precision controlled manufacturing of the bearing surfaces provide specially engineered articular surface clearances. Sophisticated manufacturing and advanced grinding and polishing techniques enable ULTAMET liners to achieve a very low surface roughness.<sup>34-35,37</sup>



# Comprehensive Cup Platform

PINNACLE cups are manufactured from titanium alloy and show a full profile cup design with 180° of POROCOAT, DUOFIX or GRIPTION coating for maximised contact with host bone. A 2 mm peripheral band above the respective coating reduces soft tissue interference when seating the liner. An apical hole is used for cup impaction and for viewing to ensure complete seating of the cup in the acetabulum.



The PINNACLE acetabular cups are offered in a variety of styles to treat both primary and revision cases:



### *100*

- POROCOAT, DUOFIX or GRIPTION coating
- Available in sizes 48-66 mm



### *Sector*

- Three screw holes for optional adjunct fixation - screw hole pattern allows screw access to the ilium and posterior column
- POROCOAT, DUOFIX or GRIPTION coating
- Available in sizes 48-66 mm



### *300*

- Three porous-coated spikes enhance initial fixation - spike length is designed to engage the dome of the acetabulum as the rim of the cup engages the periphery of the acetabulum to enhance directional stability of the cup upon impaction
- POROCOAT coating
- Available in sizes 48-66 mm

### *Multihole*

- 8 -12 screw holes, depending on cup size, for optional adjunct fixation (for more demanding cases or revisions)
- GRIPTION coating
- Available in sizes 48-72 mm



### *Bantam*

- For smaller patients or acetabular dimensions, dysplastic acetabuli (DDH)
- POROCOAT or GRIPTION coating
- Sizes 38-46 mm, Multi-hole style only



### *Revision Standard Profile*

- Revision cup with additional peripheral screw holes
- GRIPTION coating
- Sizes 54-80 mm, accepts hard-on-hard bearings up to 72 mm, MARATHON ES3 inserts up to 80 mm.



### *Revision Deep Profile DPx*

- Revision cup with additional peripheral screws, 4-6 mm offset at the dome.
- GRIPTION coating
- Sizes 54-72 mm, for all bearing options.



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This publication is not intended for distribution in the USA.

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9068-81-050 version 7 Issued: 05/13

CA#DPEM/ORT/1212/0397

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