

COORSTEK®

BIOCERAMICS

Technical Overview of Permallon® Tru Alumina Matrix Composite Ceramic Material

White Paper

Permallon®
Tru

**Technical Overview of Permallon® Tru Alumina Matrix Composite
Ceramic Material Manufactured by CoorsTek Bioceramics for
Use as Femoral Heads and Acetabular Liners in Total Hip Arthroplasty**

Author: Jon Haftel
Chief Engineer
CoorsTek Bioceramics

TABLE OF CONTENTS

3	History of Alumina Matrix Composites
3	Permallon® Tru Technical Review
5	Permallon® Tru Material Testing Protocol
7	Product Description
8	Manufacturing Detail for Permallon® Tru ceramic femoral heads and Acetabular Liners
8	Manufacturing Quality Systems and Relevant Regulations
8	Regulatory Clearances and Clinical Performance
9	Product Testing
13	Summary
14	About CoorsTek
14	About the Author
14	Contact Us
15	References
16	Standards

History of Alumina Matrix Composites

The use of ceramic oxide materials for hip arthroplasty was pioneered in France during the 1970's by Prof Pierre Boutin who used Aluminum Oxide (Alumina) femoral heads to provide a solution to high wear rates of metal on polyethylene bearing couples. The combination of low wear rates combined with Alumina's excellent biocompatibility provided a successful approach to reducing clinical issues associated with polyethylene wear⁹.

The latest generation of ceramic materials used for bearing surfaces in Total Hip Arthroplasty are Alumina Matrix Composites that aim to provide the proven properties of Alumina with the added mechanical benefits of Zirconium Oxide (Zirconia) but with greater in-vivo stability. Willmann¹¹ presents a thorough technical overview of Alumina and Zirconia in orthopaedics and the evolution of Alumina Matrix Composites like Permallon® Tru.

Permallon® Tru Technical Review

CoorsTek Permallon® Tru is an implant grade Alumina Matrix Composite ceramic material governed by the ISO 6474-2 (Type X Extra High Strength) material standard. The material is a fully dense 75% Alumina and 25% Zirconia composite ceramic. The microstructure of Permallon® Tru is engineered to incorporate advanced toughening mechanisms to improve the mechanical integrity of the material. The chemical composition and physical makeup of the material is also designed to be biocompatible, stable, and to provide excellent wear performance.

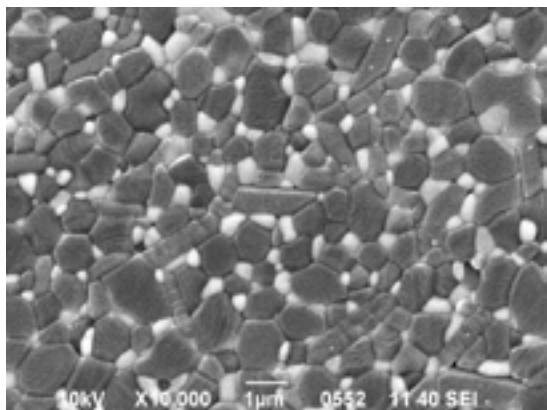
Typical properties including chemical composition, mechanical properties, physical properties, and biological performance are shown in Table 1.

Table 1: Typical Material Properties of Permallon® Tru

TEST	TEST STANDARD	ISO 6474-2 (TYPE X) REQUIREMENT	PERMALLON® TRU
Composition (wt. %)	ISO 12677 / ISO 6474-2	60-90% Al ₂ O ₃ 10-30% ZrO ₂ + HfO ₂ ≤ 10% Additives ≤ 0.2% Impurities	75% Al ₂ O ₃ 25% ZrO ₂ + HfO ₂ ≤ 10% Additives ≤ 0.2% Impurities
Density (% Ultimate)	ISO 18754	≥ 99%	4.37g/cm ³ (100%)
Elastic Modulus (GPa)	ASTM C1198	≥ 320	350
Biaxial Flexural Strength (MPa)	ASTM C1499	≥ 600	1220
Fracture Toughness (MPa m ^{1/2})	ISO 23146	≥ 4.0	6.4
Vickers Hardness (GPa)	ISO 14705	≥ 16.0	17.3
Biocompatibility	ISO 10993 (Permanent Implant)	N/A	Pass

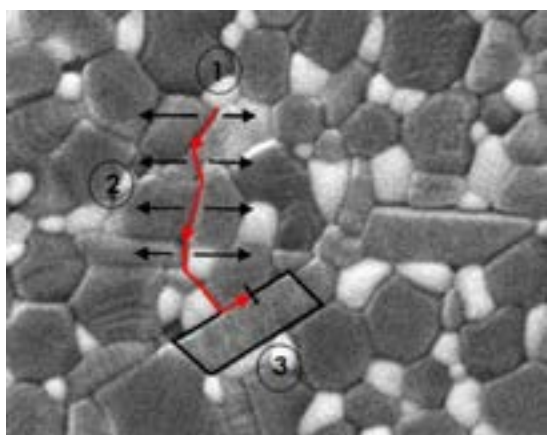
The chart is intended to illustrate typical properties. Specific property values may vary. Data contained herein is not to be construed as absolute and does not constitute a representation or warranty for which CoorsTek Bioceramics assumes legal responsibility.

Figure 1 Permallon® Tru microstructure:



A scanning electron microscope image of Permallon® Tru is shown in Figure 1. In addition to the Alumina Matrix (dark grains) the material also contains β-Alumina platelets (dark-elongated grains) and a Zirconia phase (white grains)—both of which increase fracture toughness. A small amount of Chromium Oxide is incorporated in the chemical composition and by means of solid state solubility into the crystal structure of the Permallon® Tru material. After integration into the crystal structure, the Chromium Oxide provides a mechanism to promote improved environmental stability and low levels have been shown to increase the fracture toughness and hardness in Alumina and Alumina-Zirconia Composites¹⁷⁻²³.

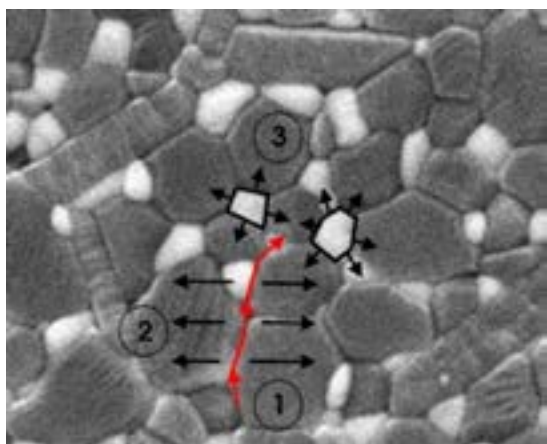
Figure 2: Crack Deflection at the β-Alumina Platelets



The microstructure of Permallon® Tru enhances toughness by two mechanisms: The first toughening mechanism is crack deflection that occurs at the β-Alumina platelets. The second toughening phenomenon is crack compression, which is promoted by the homogeneous distribution of Zirconia particles within the Alumina Matrix. These toughening mechanisms are depicted in Figures 2 and 3.

1: Crack Forms → 2: Crack advances in tensile field → 3: β-Alumina grain deflects the crack away from the tensile field and arrests propagation.

Figure 3: Crack Compression by Zirconia Particles



1: Crack Forms → 2: Crack advances in tensile field → 3: Zirconia particles expand as the crack advances which compresses the fracture and arrests propagation.

Permallon® Tru Material Testing Protocol

Chemical, Physical, and Mechanical Properties

Permallon® Tru material is tested on a batch basis and is certified to meet the requirements for Surgical Implant Grade Alumina Matrix (Ceramic) Composite material per ISO 6474-2 (Type X, Extra High Strength). A list of the baseline testing conducted, and performance criteria follows in Table 2.

Table 2: Testing Protocol per ISO 6474-2 (Type X)

TEST	TEST METHOD / STANDARD	ACCEPTANCE REQUIREMENTS PER ISO 6474-2 (TYPE X)
Average Relative Bulk Density	ISO 18754	≥ 99% Ultimate Density
Chemical Analysis	ICP/XRF ISO 12677 / ISO 6474-2	60 – 90 wt.% Al ₂ O ₃ 10 – 30 wt.% ZrO ₂ + HfO ₂ ≤ 5 wt.% HfO ₂ in ZrO ₂ ≤ 10 wt.% additives ≤ 0.2 wt.% impurities
Microstructure	EN 623-3	
• Grain Size		Alumina: ≤ 1.5 µm Zirconia: ≤ 0.6 µm
• Standard Deviation		Alumina: ≤ 25% Zirconia: ≤ 40%
Material Strength		
• Mean Biaxial Strength	ASTM C1499	≥ 600 MPa
• Weibull Modulus	ASTM C1239	≥ 8
Radioactivity	ISO 13356	≤ 200 Bq/kg
Fracture Toughness	ISO 23146	
• SEVNB (single edge V-notch bending) Test		≥ 4.0 MPa √m
Vickers Hardness	ISO 14705	≥ 16.0 GPa
Young's Modulus	ASTM C1198	≥ 320 GPa
Cyclic Fatigue	ISO 22214	No failure during cyclic loading in 4-point bending, 10 ⁷ cycles at 400 MPa
Accelerated Hydrothermal Aging		
• Mean Biaxial Flexural Strength	ISO 6474-2 / ASTM C1499	Degradation ≤ 20% vs. pre-autoclave. Meet other values noted previously for un-aged
• Cyclic Fatigue	ISO 22214	No failure during cyclic loading in 4-point bending, 10 ⁷ cycles at 320 MPa
• Wear	ISO 6474-2	Wear volume increase ≤ 20% of aged as compared to un-aged

Effects of Hydrothermal Aging

Alumina Matrix Composites that incorporate Zirconia materials (such as Permallon® Tru) can be susceptible to hydrothermal degradation (aging). This degradation process has been shown to take place in vivo over long periods of time, based on retrieval studies of Zirconia femoral heads¹⁰. To address these concerns, the Zirconia-containing ceramics used for implantable applications must be designed in such a manner to reduce the sensitivity of the material to this aging process. In the case of Permallon® Tru, this stabilization is achieved via constraint of the Zirconia phase by the surrounding Alumina matrix.

The international standard for implant grade Alumina Matrix Composites (ISO 6474-2 (Type X)) requires the performance characteristics are successfully maintained after subjecting the material to hydrothermal (accelerated) aging. The protocol detailed in (ISO 6474-2 (Type X)) requires ten hours of hydrothermal aging at 134°C of steam pressure. This simulation has the theoretical effect of 3-4 years of in vivo exposure for every hour of aging¹⁰. Using this theoretical model, the (ISO 6474-2 (Type X)) protocol for hydrothermal aging simulates 30-40 years of in vivo aging. The Permallon® Tru material has been tested and certified to meet the requirements of this hydrothermal accelerated aging test protocol as detailed above.

Biological Properties

A review of available literature investigating the biocompatibility of Alumina Matrix Composite ceramics shows that such ceramics exhibit biocompatibility for implantable applications such as Total Hip Arthroplasty.

Piconi, et al¹⁶ published a complete literature review of biocompatibility studies on Alumina and Zirconia bioceramics, which are the main constituents of Permallon® Tru. This demonstrates that both materials are suitable candidates for human implantation. This is reinforced further by the long clinical history behind the use of such ceramics in dental and orthopaedic applications.

CoorsTek Bioceramics has conducted a full range of biocompatibility testing on Permallon® Tru according to ISO 10993. Tests were chosen based upon guidance given in ISO 10993-1. The testing confirms CoorsTek Bioceramics Permallon® Tru material is biocompatible for long term implantation. A list of tests conducted follows in Table 3.

Table 3: Biocompatibility Testing on Permallon® Tru Material

ISO 10993-1 REQUIREMENT	TEST METHOD / STANDARD	TESTING CONDUCTED	PERMALLON® TRU RESULT
Cytotoxicity	ISO 10993-5	MEM Elution	Pass: No Reactivity
Sensitization	ISO 10993-10	Maximization Sensitization	Pass: No Sensitization Response
Irritation / Intracutaneous Reactivity	ISO 10993-10	Intracutaneous Reactivity	Pass: Non-irritant
Systemic Toxicity (acute)	ISO 10993-11, ISO 10993-17/18	Acute Systemic Toxicity, Toxicological Risk Assessment	Pass: Non-toxic
Subacute and Subchronic Toxicity	ISO 10993-11	Rabbit Pyrogen, Subacute Intraperitoneal Toxicity	Pass: Non-pyrogenic, Negative for signs of systemic toxicity
Genotoxicity	ISO 10993-3	Mutation Assay (AMES), In Vitro Mouse Lymphoma Assay, In Vivo Mouse Micronucleus	Pass: Non-mutagenic
Implantation	ISO 10993-6	Intra-muscular Implant	Pass: Non-irritant

Product Description

Ceramic femoral heads and acetabular liners are manufactured by CoorsTek Bioceramics from Permallon® Tru Alumina Matrix Composite according to implant grade specifications per ISO 6474-2 (Type X). The heads and liners are precision ground and polished ceramic single-use components designed for replacing the body's natural femoral head and acetabulum. Permallon® Tru ceramic femoral heads and acetabular liners are provided to customers of CoorsTek Bioceramics non-sterile and ready for subsequent processing, including: final cleaning, packaging, labeling, sterilization, and kit assembly. Our customers combine Permallon® Tru ceramic femoral heads and acetabular liners with other components such as acetabular shells and femoral stems to create a total hip replacement system. Such hip replacement systems are indicated for use in primary Total Hip Arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease, trauma, or other indications for use as validated and detailed by Customers of CoorsTek Bioceramics.

Standard product offerings include a line of 12/14 taper femoral heads from 28 to 44mm articulating diameters with -4 to +8mm offsets and 18-degree acetabular liners with 28-44mm articulating diameters and 35-52mm tapers. These products are shown in Tables 4-5.

Table 4: Permallon® Tru 12/14 Taper Ceramic Femoral Heads

ARTICULATION DIAMETER	SHORT OFFSET (S)	MEDIUM OFFSET (M)	LONG OFFSET (L)	EXTRA LONG OFFSET (XL)
28mm	-3.5mm	0mm	+3.5mm	
32mm	-4mm	0mm	+4mm	+7mm
36mm	-4mm	0mm	+4mm	+8mm
40mm	-4mm	0mm	+4mm	+8mm
44mm	-4mm	0mm	+4mm	+8mm

Table 5: Permallon® Tru 18 Degree Acetabular Liners

ARTICULATION DIAMETER	35mm TAPER/OD	37mm TAPER/OD	39mm TAPER/OD	41mm TAPER/OD	44mm TAPER/OD	48mm TAPER/OD	52mm TAPER/OD
28mm	X	X	X	X	X	X	X
32mm			X	X	X	X	X
36mm					X	X	X
40mm						X	X
44mm							X

Figure 5: Permallon® Tru Ceramic Femoral Head and Acetabular Liner



.....

Manufacturing Detail for Permallon® Tru Ceramic Femoral Heads and Acetabular Liners

Ceramic Material Preparation: Ceramic powder is produced including addition of a binder to aid in pressing and forming.

Ceramic Pressing/Forming: The Ceramic powder is pressed into a blank shape and formed to a shape representing the final geometry of the product.

Sintering/Hot Isostatic Pressing: The ceramic component is sintered using heat to achieve full density. The sintering schedule includes a hot isostatic pressing process.

Grinding/Polishing: As precision surfaces are required, the ceramic component is ground and polished. After this process, the ceramic has achieved the final dimensional and finish specification.

Dimensional inspection: Inspection is conducted in accordance with the approved manufacturing control plan to verify the dimensional and finish specifications. The component is measured for conformance to product specifications using calibrated equipment.

Laser Etching: The component is marked with identifying information such as the Articulating Diameter, Offset, and Taper Type (as applicable for femoral heads), Taper Size, Manufacturing Lot, Serial Number, Manufacturer's Logo, and Conforming Material Standard.

Testing/Visual Inspection: The component is tested and visually inspected, including the use of a dye penetrant to analyze for defects.

Cleaning: A cleaning process is utilized to remove processing compounds.

Packaging: After cleaning, the component is packaged to protect from damage during transit.

Quality Assurance Review/Shipment: The component and the manufacturing documentation are reviewed against the applicable standards to ensure conformance to product/process specifications. After the Quality Assurance Review, the component is prepared for shipment, then shipped along with the appropriate certificates, documents, and reports.

Manufacturing Quality Systems and Relevant Regulations

CoorsTek Bioceramics operates a quality system, including inspection processes, which are certified as complying with the requirements of ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes). CoorsTek Bioceramics quality system complies with the applicable requirements of 21 CFR 820 (U.S. FDA Quality System Regulation (QSR)).

Product Testing

Permallon® Tru ceramic femoral heads and acetabular liners have been tested with the objective of assessing the structural integrity, tribological performance, and mechanical fixation required of ceramic components used as bearing surfaces in Total Hip Arthroplasty and have been found to meet the applicable requirements of the orthopaedic industry. A list of the test protocols and acceptance criteria are included in Tables 6-8.

Product Testing Protocols

Structural Integrity

As the ceramics used in hip arthroplasty are subject to in vivo loading, it is important to characterize the strength of the components. This characterization should be conducted such that the components can be reasonably expected to survive the lifetime of the hip system. The testing protocols subject the components to loads that, although sometimes different in orientation, well exceed the expected physiological loading conditions⁴. For example, given a body mass of 75kg (165lbs)⁴, the axial fatigue loading of 14kN is 19 times body weight and static axial compression requirement (based on FDA guidance⁵) of >46kN average is greater than 63 times body weight.

Axial fatigue testing was conducted to determine the resistance of the Permallon® Tru ceramic femoral heads and acetabular liners to repetitive loading. Static Axial Compression (Axial Burst) was also conducted both on as-manufactured components and on post fatigued components to assess the baseline and service strength of the ceramic. These tests are detailed in ISO 7206-10 and FDA guidance⁵. Worst case ceramic geometries were selected for the testing.

In addition to the axial static and fatigue testing above, a system level anatomical fatigue and post fatigue axial burst test was conducted to assess the mechanical integrity associated with the physiological (inclined) orientation of the hip implant. This test was conducted on worst case ceramic geometries using fatigue parameters established in ASTM WK28883 “Standard Test Method for Environmental Fatigue Testing for Acetabular Devices for Total Hip Replacement” including a 60° acetabular liner alignment from horizontal to facilitate adverse edge loading created from surgical mal-positioning. These ceramics were gamma irradiated to

simulate the effect of sterilization on the material prior to testing. To address hydrothermal stability, the Permallon® Tru ceramic femoral heads and acetabular liners used for this test were also subjected to the hydrothermal (accelerated) aging protocol defined in ISO 6474-2 prior to this test. After the anatomical fatigue testing, the system (as an assembly) was tested to failure in axial compression to assess the long-term service strength. The testing protocol and acceptance criteria are summarized in Tables 6-7 and the outcome of the testing is presented in the Discussion section below.

Tribological Performance

As the primary function of the ceramic components in hip arthroplasty is to restore motion to the joint, the wear performance of the materials must be developed and understood. The chosen method for this evaluation was a hip simulator study with the Permallon® Tru ceramic femoral heads and acetabular liners. The ceramic-on-ceramic system was studied, as this will create a hard surface of opposing contact for the femoral head and challenge the wear performance of the ceramic—versus studies of the ceramic-on-polyethylene system in which the wear mechanism is focused on the polymer liner material.

First, a study was conducted under standard simulated use loading and kinematics. This “standard gait” testing is detailed in the ISO 14242-1 procedure. In addition to standard gait testing (to 5 million cycles), an additional adverse condition study was conducted (to 3 million cycles). The adverse condition study was conducted using the motion and loading of ISO 14242-1 as the basis with a translation of centers (microseparation) between the femoral head and acetabular liner of 0.5mm induced during the swing phase of the gait under a 50N load. In addition to the microseparation, the face of the acetabular liner was angled at 60° to the horizontal to simulate a surgical mal-positioning of 15°. This mal-positioning increases the likelihood of edge loading by the femoral head near the equator of the acetabular liner. This study is similar to the work performed by Al Hajjar et al^{1,3}. Both the 28 and the 44mm ceramic-on-ceramic systems were studied, as this encompasses the smallest and largest articulating diameters. The testing protocol and acceptance criteria is summarized in Table 8 and the outcome of the wear testing is presented in the Discussion section below.

Mechanical Fixation

It is important that the modular interfaces between the femoral stem and head and the acetabular liner and shell are adequately fixed to eliminate the possibility of dissociation of the ceramic hip system during use. In service, the predominant forces generated are compressive, and therefore will work to keep the modular components attached. However, there are some frictional forces and adverse conditions that apply small torsional or tensile loads to the ceramic hip system. To assess the integrity of the fixation mechanism, tests were conducted applying both torsional and axial loads to dissociate the modular interface between the metal and ceramic tapers. For the Permallon® Tru ceramic femoral head these tests included a Pull Off test (static tension) in which a load is applied along the axis of the taper connection (detailed

in ISO 7206-10) and a Torsional Resistance test in which torque is applied around the axis of the taper connection (detailed ISO 7206-13). The Permallon® Tru acetabular liners were subjected to an Axial Disassembly test in which a load applied in the axis of the taper connection is used to remove the liner from the shell, an Offset Pullout test in which an axial load is applied at the equatorial inner surface of the liner to create a torsional load transverse to the axis of the taper connection, and finally a Torsional test that applies torque around the axis of the taper connection. The tests for the acetabular liners and shells are detailed in the ASTM F1820. Testing was conducted on the worst-case ceramic geometries. The testing protocols and acceptance criteria for Mechanical Fixation are summarized in Tables 6-7 and the outcome of the testing is presented in the Discussion section below.

Table 6: Permallon® Tru Ceramic Femoral Head Testing Protocol

TEST	TEST STANDARD	ACCEPTANCE REQUIREMENTS
Axial Burst Test	ISO 7206-10	Avg > 46kN, Min 20kN (FDA Guidance for femoral heads ⁵)
Axial Fatigue	ASTM F2345	10 Million cycles at 14kN without failure (FDA Guidance for femoral heads ⁵)
Post Fatigue Axial Burst	ISO 7206-10	Min 20kN (FDA Guidance for femoral heads ⁵)
Pull Off	ISO 7206-10	>250 N criteria for predicate Ceramic Hip Systems ⁴
Resistance to Torque	ISO 7206-13	>4 Nm criteria for acetabular liners on predicate Ceramic Hip Systems ^{4,6}

Table 7: Permallon® Tru Acetabular Liner/System Testing Protocol

TEST	TEST STANDARD	ACCEPTANCE REQUIREMENTS
Axial Burst Test	ISO 7206-10*	Avg > 46kN, Min 20kN (Criteria on Predicate Ceramic Hip Systems ⁴ and FDA guidance for femoral heads ⁵)**
Axial Fatigue	ISO 7206-10*	10 million cycles at 14kN without failure (FDA Guidance for femoral heads ⁵)**
Post Fatigue Axial Burst	ISO 7206-10*	Min 20kN (FDA Guidance for femoral heads ⁵)**
Hydrothermally Aged Anatomical Fatigue	ASTM WK28883	10 million cycles at 5.34kN without failure
Hydrothermally Aged Anatomical Post Fatigue Axial Burst	ISO 7206-10*	Min 20kN (FDA Guidance for femoral heads ⁵)**
Axial Disassembly	ASTM F1820	>200 N (Criteria on Predicate Ceramic Hip Systems ⁴)
Offset Pullout	ASTM F1820	>400N (Based on historical comparisons)
Torque Out	ASTM F1820	>4 Nm (Criteria on Predicate Ceramic Hip Systems ⁴ and per Historical FDA guidance on acetabular liners ⁶ with safety factor)

*Follows test lab protocol, as standard is not established. General configuration is per ISO 7206-10 using an axial arrangement and loading conducted using a ceramic femoral head.

**FDA guidance is for ceramic femoral heads but is routinely used to evaluate ceramic acetabular liners as standard acceptance criteria has not been established.



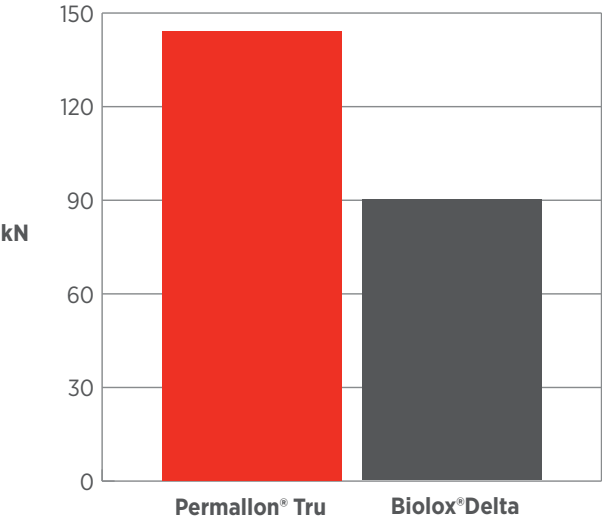
Table 8: Permallon® Tru Hip Simulator Testing Protocol

TEST	TEST STANDARD	ACCEPTANCE REQUIREMENTS
Hip Simulator, Ceramic-on-Ceramic, Standard Gait Cycle at 5 million Cycles	ISO 14242-1 / ISO 14242-2	Comparable to or less than values from literature on predicate materials
Hip Simulator, Ceramic-on-Ceramic, Adverse Conditions at 3 million Cycles	ISO 14242-1 / ISO 14242-2	Comparable to or less than values from literature on predicate materials

Discussion of Product Testing
Structural Integrity

Permallon® Tru ceramic femoral heads met the acceptance criteria for mechanical strength testing. The worst-case ceramic 28-12/14 L (+3.5mm) against the titanium test taper has a 144kN mean and 130kN minimum axial burst strength. This exceeds the FDA Guidance⁵ of >46kN mean and >20kN minimum by a safety factor of 3.1X and 6.5X respectively. The axial burst strength of the Permallon® Tru ceramic femoral head at 144kN compares favorably to BioloX®Delta 28-12/14 L (+3.5mm) ceramic heads with a 90kN mean¹³ (both tested against Titanium tapers) as shown in Figure 6. All Permallon® Tru ceramic femoral head samples passed fatigue testing and are well in excess of the FDA Guidance⁵ for post fatigue burst.

**Figure 6: Axial Burst Strength (ISO 7206-10)
28-12/14 L (+3.5mm) / Titanium Taper**



The Permallon® Tru acetabular liners met all acceptance criteria for mechanical strength testing and are well in excess of the FDA Guidance⁵ for axial compressive (burst) strength. The Permallon® Tru acetabular liners met all fatigue and post fatigue burst requirements as detailed in Table 7. The Anatomical Fatigue test was designed to represent the worst-case configuration with respect to implant geometry/configuration, surgical mal-position, and hydrothermal aging. The Permallon® Tru ceramic femoral heads and acetabular liners survived the fatigue loading of 10 million cycles at 5.34kN in a 0.9% saline solution (per ASTM WK28883). Post fatigue axial burst testing of the Permallon® Tru ceramic femoral heads and acetabular liners used for the Anatomical Fatigue test were also well in excess of the FDA Guidance⁵.

The Permallon® Tru ceramic femoral heads and acetabular liners were subjected to loading that exceeds physiological conditions⁴. In addition, these components are well in excess of the industry standards for strength. Given these results and clinical observations, the Permallon® Tru ceramic femoral heads and acetabular liners are expected to provide adequate structural integrity for the lifetime of the hip implant system⁴.

Tribological Performance

As no standardized acceptance criteria has been developed for wear, the results of the study in question have been compared to similar testing on the Alumina Matrix Composite material Biolox®Delta which has been used in predicate ceramic hip systems⁴. Permallon® Tru ceramic-on-ceramic wear couples of 28 and 44mm articulating diameters were tested as detailed above. The first five million cycles were conducted using the standard gait profile and loading per ISO 14242-1, and the results were determined according to ISO 14242-2 using the gravimetric method to determine wear. The results of the standard gait testing are shown in Figure 7 with a comparison to the published literature on Biolox®Delta^{2,12}. The wear couples were then subjected to three million cycles of adverse conditions as detailed above. The results for this adverse condition testing are shown in Figure 8 with a comparison to similar testing conducted on Biolox®Delta material.

As literature was not available for the 44mm size, the 36mm Biolox®Delta wear couple was used for comparison purposes on the adverse conditions test. As can be seen (and shown in Figures 7-8), the wear rates under normal and adverse conditions for Permallon® Tru are favorable with respect to Biolox®Delta. The wear rates of Permallon® Tru ceramic-on-ceramic bearings also surpass the performance of Alumina-Alumina^{1,4,7,8}, Metal-Metal^{1,3,4,7}, and Metal-Cross Linked Polyethylene^{1,4} in standard gait and microseparation as shown in Figures 9-10. The low level of wear debris generated from the Permallon® Tru ceramic femoral heads and acetabular liners under standard and adverse conditions is not expected to result in adverse tissue reactions⁸. When coupled with clinical observations, these components are expected to provide the required tribological performance for the lifetime of the hip implant system.

Figure 7: Wear Comparison of Alumina Matrix Composite Ceramic-Ceramic Couples after 5 Million Cycles (ISO 14242) of Standard Gait Simulation^{2,12}

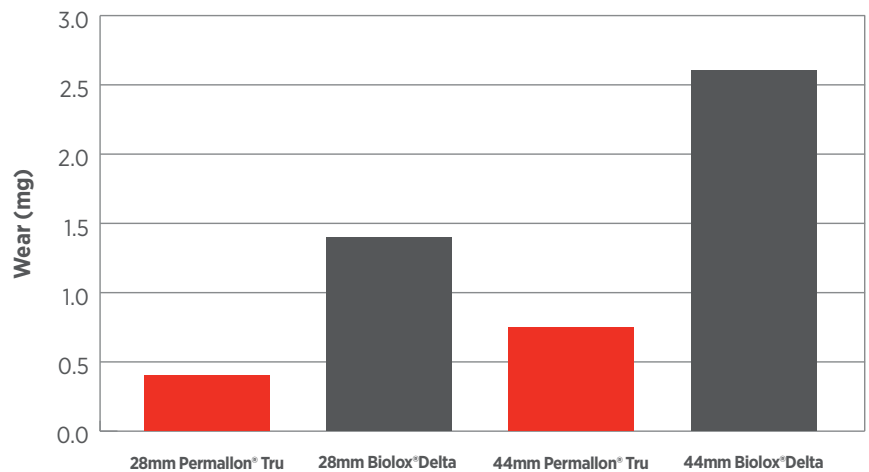


Figure 8: Wear Comparison of Alumina Matrix Composite Ceramic-Ceramic Couples after 3 Million Cycles of Microseparation and High Inclination Angle Simulation^{1,3}

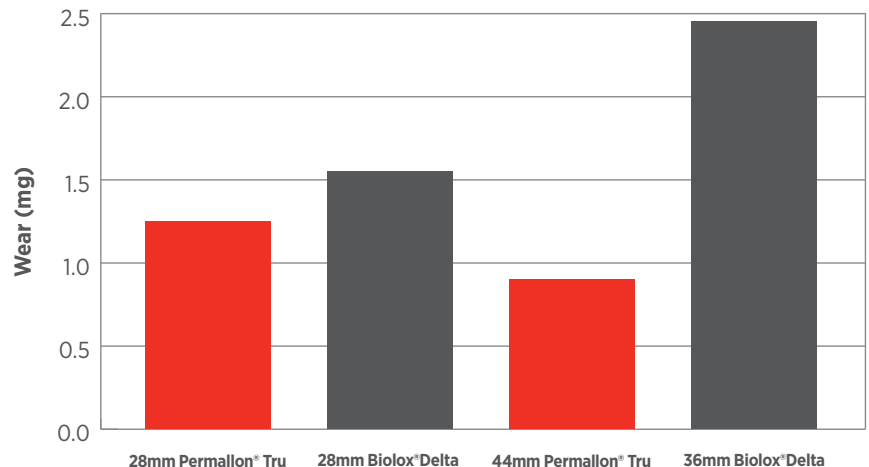


Figure 9: Comparison of Reported Wear Rates on Hip Simulator Studies of Materials Used for Bearing Surfaces in Hip Arthroplasty (Standard Gait Testing)

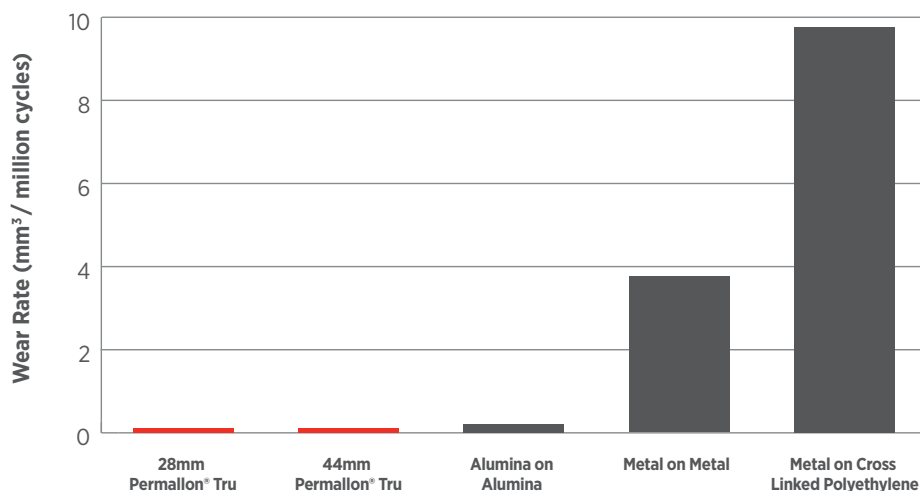
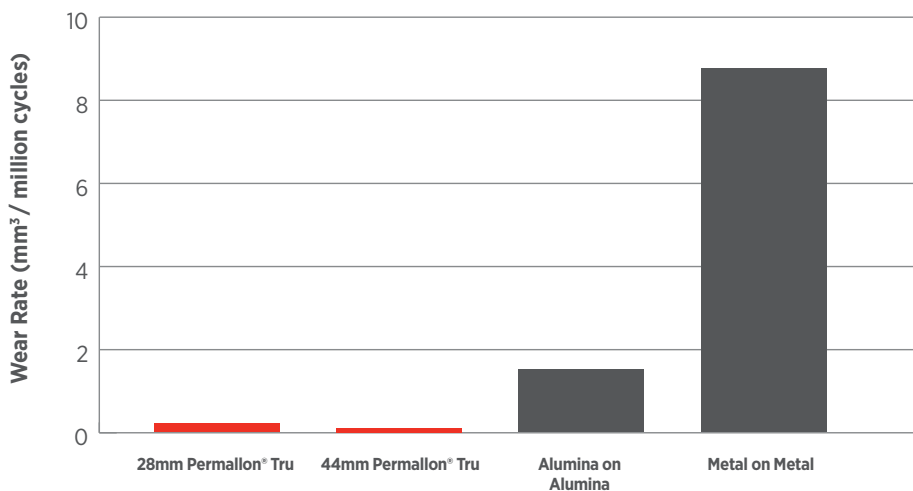


Figure 10: Comparison of Reported Wear Rates on Hip Simulator Studies of Materials Used for Bearing Surfaces in Hip Arthroplasty (Microseparation Testing)



Mechanical Fixation

All samples met the acceptance criteria for mechanical fixation. The performance of the Permallon® Tru ceramic femoral heads and acetabular liners has been shown to exceed expected physiological conditions^{4,6}, and is comparable to available historical test data from predicate ceramic hip systems⁴. These results along with performance from wear testing, fatigue testing, and clinical observations support proper mechanical fixation of the Permallon® Tru ceramic femoral heads and acetabular liners in Total Hip Replacement systems.

Summary

Permallon® Tru material has been tested and found to meet the requirements for chemical, physical, mechanical, and biological performance related to the intended use as a permanent load

bearing implant. The material has been evaluated from a technical standpoint and the results exceed the requirements for implant grade Alumina Matrix Composites. Femoral heads and acetabular liners produced from Permallon® Tru material have been tested using applicable protocols, worst case configurations, comparisons to predicates, and industry standardized acceptance criteria. These tests verify the performance of Permallon® Tru products with respect to the biological, mechanical, and tribological demands of ceramic femoral heads and acetabular liners used in Total Hip Arthroplasty. These results, in combination with the clinical feedback and observations from our customer's products since 2011 supports the use of Permallon® Tru as a state-of-the-art ceramic bearing material for use in Total Hip Arthroplasty.

About CoorsTek

CoorsTek is a leading global manufacturer of technical ceramics and advanced materials. With over 400 proprietary material formulations, vast process capabilities, and vertically integrated systems, CoorsTek is the international partner of choice for companies requiring the unique, high-performance properties of technical ceramics.

For over 100 years, industry leaders have turned to CoorsTek for solutions to the world's most perplexing engineering and manufacturing challenges. CoorsTek meets these challenges with unsurpassed expertise in materials engineering, broad research and development capabilities, operational excellence, and a commitment to building reliable, collaborative relationships. We collaborate with industry leaders to engineer next-generation technology applications.

With locations across three continents, CoorsTek expertise is available to help design better, more efficient, and longer-lasting products.

Learn more at www.coorstek.com.

CoorsTek Bioceramics

Located in Grand Junction Colorado, USA, CoorsTek Bioceramics is dedicated to state-of-the-art manufacturing of technical ceramics for the medical device industry. Since its inception in 2005, CoorsTek Bioceramics has manufactured over six million critical implantable ceramic components under an ISO 13485 certified and FDA compliant quality system. Our focus is orthopaedic reconstruction with a primary concentration on ceramic bearing components for Total Hip Arthroplasty. Additionally, CoorsTek Bioceramics components can be found in other implantable devices such as Spinal Disc Replacements, Cochlear Implants, Pacemakers, and Neurostimulators.

The manufacture of Permallon® Tru ceramic femoral heads and acetabular liners facility begins with the production of the raw material and continues all the way to the testing and inspection of the finished components. This vertical integration allows for the finest control of the manufacturing process, guaranteeing consistent, high-quality performance.

Devices incorporating CoorsTek Bioceramics products are registered by our customers. Check for regulatory approval in your area: www.coorstek.com/bioceramics-regulatory.

Learn more at www.permallon.com.

About the Author

Jon Haftel has been in the technical ceramics industry since 1996, and has a wide range of experience in ceramics processing and ceramic material engineering/development. He has spent his career in Engineering and Manufacturing Operations, and has managed projects for a variety of industries including health care, semiconductor, and electronics. Jon has been responsible for the engineering of materials and processes since the launch of CoorsTek Bioceramics (formerly C5 Medical Werks) in 2005, and currently manages the technical and operational aspects of the business. Jon received a Bachelor of Science in Mechanical Engineering with honors from Colorado State University, where he worked on research of biomedical materials. He also holds a Masters Degree in Metallurgical and Materials Engineering from the Colorado School of Mines, with a focus on Advanced Ceramic Materials and graduate research on ceramic-metal seals. Jon is involved with his local community in Grand Junction, Colorado supporting the Engineering Program at Colorado Mesa University where he provides industry guidance, assistance with material laboratories, and sponsors student engineering projects.

To learn more about CoorsTek Bioceramics and Permallon® Orthopaedic Ceramics, contact us:

CoorsTek Bioceramics
info@coorstek.com
+1 303 271 7100
+1 855 929 7100 (toll free in North America)

References

1. Al-Hajjar, M., Leslie, I. J., Tipper, J., Williams, S., Fisher, J., & Jennings, L. M. (2010). Effect of cup inclination angle during microseparation and rim loading on the wear of BioloX®Delta ceramic-on-ceramic total hip replacement. *Journal of Biomedical Materials Research Part B: Applied Biomaterials*, 95B(2), 263-268.
2. Pandorf, T. (n.d.). Wear of large Ceramic Bearings. *Ceramics in Orthopaedics Bioceramics and Alternative Bearings in Joint Arthroplasty*, 91-97.
3. Al-Hajjar, M., Fisher, J., Tipper, J. L., Williams, S., & Jennings, L. M. (2013). Wear of 36-mm BioloX®Delta ceramic-on-ceramic bearing in total hip replacements under edge loading conditions. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, 227(5), 535-542.
4. "Summary of Safety and Effectiveness" Premarket Approval (PMA) Numbers: P000013, P030022, P030027, P040023, P040048, P040051, P050009, P050039 and P070026. *U.S. Food and Drug Administration*.
5. "Guidance Document for The Preparation of Premarket Notification for Ceramic Ball Hip Systems". *U.S. Food and Drug Administration*, 10 January 1995.
6. "Guidance Document for Testing Acetabular Cup Prostheses". *U.S. Food and Drug Administration*, 1 May 1995.
7. Fisher, J. (2013). Wear of Hard-on-Hard Bearings in the Hip: The Influence of Loss of Conformity Under Edge Loading. *Total Hip Arthroplasty*, 191-195.
8. Fisher, J.; Nevelos, J.; Hatton, A.; Tipper, J.; Ingham, E.; Doyle, C.; Streicher, R.; Nevelos, A. (2001). Wear Debris Generation in Alumina-Alumina Total Hip Joints, an In Vivo and In Vitro Comparison. *Proceedings of the 47th Annual Meeting, Orthopaedic Research Society*.
9. Boutin, P. (1971 [79]), Alumina and its use in surgery of the hip. *Presse Med*, 639-640.
10. Chevalier, J. (2006). What future for zirconia as a biomaterial? *Biomaterials*, 27(4), 535-543.
11. Willmann, G. New Generation Ceramics, *Ceramtec BioloX 5th Symposia*, 127-135.
12. Kaddick, C., Pfaff, H.G. Wear Study in Alumina-Zirconia System. 146-150.
13. Ceramic ball heads BioloX®Forte BioloX®Delta, CeramTec GmbH, MT-00022-1702-EN-02, 8.2017
14. Traina, F., Fine, M. D., Martino, A. D., & Faldini, C. (2013). Fracture of Ceramic Bearing Surfaces following Total Hip Replacement: A Systematic Review. *BioMed Research International*, 2013, 1-8.
15. Massin, P., Lopes, R., Masson, B., & Mainard, D. (2014). Does BioloX®Delta ceramic reduce the rate of component fractures in total hip replacement? *Orthopaedics & Traumatology: Surgery & Research*, 100(6). 5317-5321.
16. Piconi, C., Maccauro, G., Muratori, F., & Brach Del Prever, E., (2003 [1]) Alumina and Zirconia Ceramics in Joint Prosthesis, Jn. Appl. Biomater. *Biomec.* 19-32.
17. Pezzotti, G., Munisso, M., Porporati, A., Lessnau, K., "On the role of oxygen vacancies and lattice strain in the tetragonal to monoclinic transformation in alumina/zirconia composites and improved environmental stability", *Biomaterials* 31(2010), p6901-6908.
18. Riu, D., Kong, Y., Kim, H., "Effect of Cr2O3 addition on microstructural evolution and mechanical properties of Al2O3", *Journal of the European Ceramic Society* 20 (2000), p1475-1481.
19. Magnani, G., Brillante, A.; "Effect of the composition and sintering process on mechanical properties and residual stresses in zirconia-alumina composites", *Journal of the European Ceramic Society* 25 (2005), p3383-3392.
20. Burger, W., Richter, H., "High Strength and Toughness Alumina Matrix Composites by Transformation Toughening and 'In Situ' Platelet Reinforcement (ZPTA) - The New Generation of Bioceramics", *Key Engineering Materials Vols. 192-195 (2001)*, p545-548.
21. Azhar, A., Mohamed, H., Ratnam, M., Ahmea, Z., "The effects of Cr2O3 Addition on Microstructure and fracture toughness of ZTA ceramic composite", *Journal of nuclear and related technologies, Volume 10, No. 2 December 2013*, p9-15.
22. Burger, W., Gernsheimer, S., Andersch, H., Friederich, K., Lehmann, S., Schneider, J., Fripan, M., "Sintered Molding", *United States Patent 5,830,816 November 3, 1998*.
23. Bradt, R., "Cr2O3 Solid Solution Hardening of Al2O3", *Journal of the American Ceramic Society, Vol. 50, No. 1, 1967*, p54-55.

Standards

21 CFR 820 "Quality System Regulation" U.S. Food and Drug Administration

ASTM C1198 "Standard Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance"

ASTM C1239 "Standard Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics"

ASTM C1499 "Standard Test Method for Monotonic Equibiaxial Flexural Strength of Advanced Ceramics at Ambient Temperature"

ASTM F1820 "Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device"

ASTM F2345 "Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads"

ASTM WK28883 "Standard Test Method for Environmental Fatigue Testing for Acetabular Devices for Total Hip Replacement"

EN 623-3 "Advanced technical ceramics - Monolithic ceramics - General and textural properties - Part 3: Determination of grain size and size distribution (characterized by the linear intercept method)"

ISO 10993 "Biological Evaluation of Medical Devices"

ISO 12677 "Chemical analysis of refractory products by X-ray fluorescence (XRF) - Fused cast-bead method"

ISO 13356 "Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)"

ISO 13485 "Medical devices - Quality management systems - System requirements for regulatory purposes"

ISO 14242-1 "Implants for surgery - Wear of total hip prostheses - Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test"

ISO 14242-2 "Implants for surgery - Wear of total hip joint prostheses - Part 2: Methods of measurement"

ISO 14705 "Fine ceramics (advanced ceramics, advanced technical ceramics) - Test method for hardness of monolithic ceramics at room temperature"

ISO 18754 "Fine ceramics (advanced ceramics, advanced technical ceramics) - Determination of density and apparent porosity"

ISO 22214 "Fine ceramics (advanced ceramics, advanced technical ceramics) - Test method for cyclic bending fatigue of monolithic ceramics at room temperature"

ISO 23146 "Fine ceramics (advanced ceramics, advanced technical ceramics) - Test methods for fracture toughness of monolithic ceramics - Single-edge V-notch beam (SEVNB) method"

ISO 6474-2 "Implants for surgery - Ceramic materials Part 2: Composite materials based on a high-purity alumina matrix with zirconia"

ISO 7206-2 "Implants for surgery - Partial and total hip joint prostheses - Part 2: Articulating surfaces made of metallic, ceramic and plastics materials"

ISO 7206-10 "Implants for surgery - Partial and total hip prostheses - Part 10: Determination of resistance to static load of modular femoral heads"

ISO 7206-13 "Implants for surgery - Partial and total hip joint prostheses - Part 2: Articulating surfaces made of metallic, ceramic and plastics materials"

COORSTEK

Data contained herein is not to be construed as absolute and does not constitute a representation or warranty for which CoorsTek assumes legal responsibility. CoorsTek and CoorsTek Bioceramics are registered trademarks of CoorsTek, Inc.

Americas

+1 303 271 7100 tel
+1 855 929 7100 toll free in USA
coorstek.com
info@coorstek.com

Europe

+49 160 530 3768
infoeurope@coorstek.com

Japan

+1 81 3 5437 8411
japaninfo@coorstek.com

China

+86 21 6232 1125
info_shanghai@coorstek.com

Korea

+82 31 613 2946
koreainfo@coorstek.com