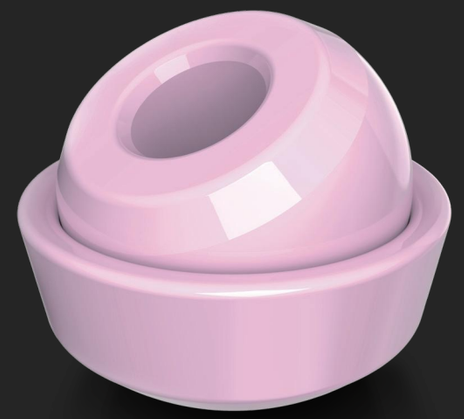
TrendTec



Suzhou TrendTec New Materials Technology Co., Ltd.

WhatsApp

Website: www.trendtec.cn/en/

Tel: +86 512 6661 1181

Address: Room 301, Building 9, No.8, Yandangshan Road, High Tech Zone, Suzhou City, Jiangsu Province, China

Biomedical Ceramic Experts

ABOUT US

8,000+
Facility/m²

300,000+
Production Capacity (units/year)

20+
Technical Accumulation/Years

Suzhou TrendTec New Materials Technology Co., Ltd. (hereinafter referred to as TrendTec) is an enterprise focusing on the design, research and development, manufacturing, and sales of biomedical ceramic materials.

The company is located in Suzhou, specifically in the Science and Technology City of Suzhou High-tech Zone.

The company has modern precision production workshops, a 100,000-class cleanroom, as well as physical and chemical laboratories. The facility exceeds 8,000 square meters, and the annual production capacity of biomedical ceramic components can reach 300,000 units.

TrendTec's Zirconia Toughened Alumina (ZTA) ceramic femoral heads and inserts have successfully passed all mechanical tests required by ISO 6474-2 and biocompatibility tests in accordance with ISO 10993.

TrendTec's Tetragonal Zirconia Polycrystal (TZP) ceramic femoral heads have passed all mechanical tests required by ISO 13556 and biocompatibility tests in accordance with ISO 10993.

TrendTec has obtained the certificates for the following quality management systems:

GB/T 19001-2016 idt ISO 9001:2015

GB/T 42061-2022 idt ISO 13485:2016

FOUNDER

Dr. Lin Zhang Founder

Ph.D. in Materials Science, Tsinghua University
CEO & CTO in orthopedic implant medical device companies

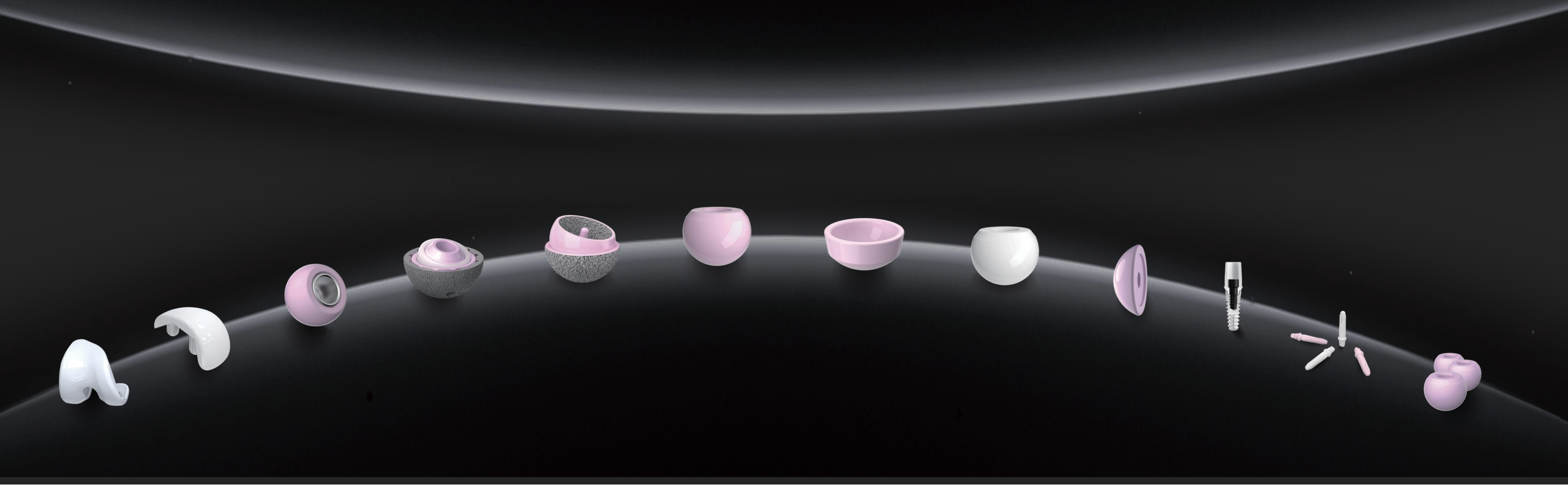
Dr. Xiaogang Cao Co-founder

Ph.D. in Materials Science, Tsinghua University
Beijing Senior Engineer (Medical Device)

BIOMEDICAL CERAMIC PRODUCT PORTFOLIO

TrendTec provides a comprehensive biomedical ceramic product portfolio, designed to meet the stringent demands of modern orthopedic and dental implant applications.

Based on the material properties of ZTA and TZP ceramics,
We develop thinner, larger, more refined, and complex-shaped components, empowering medical device manufacturers to push the boundaries of design and performance.

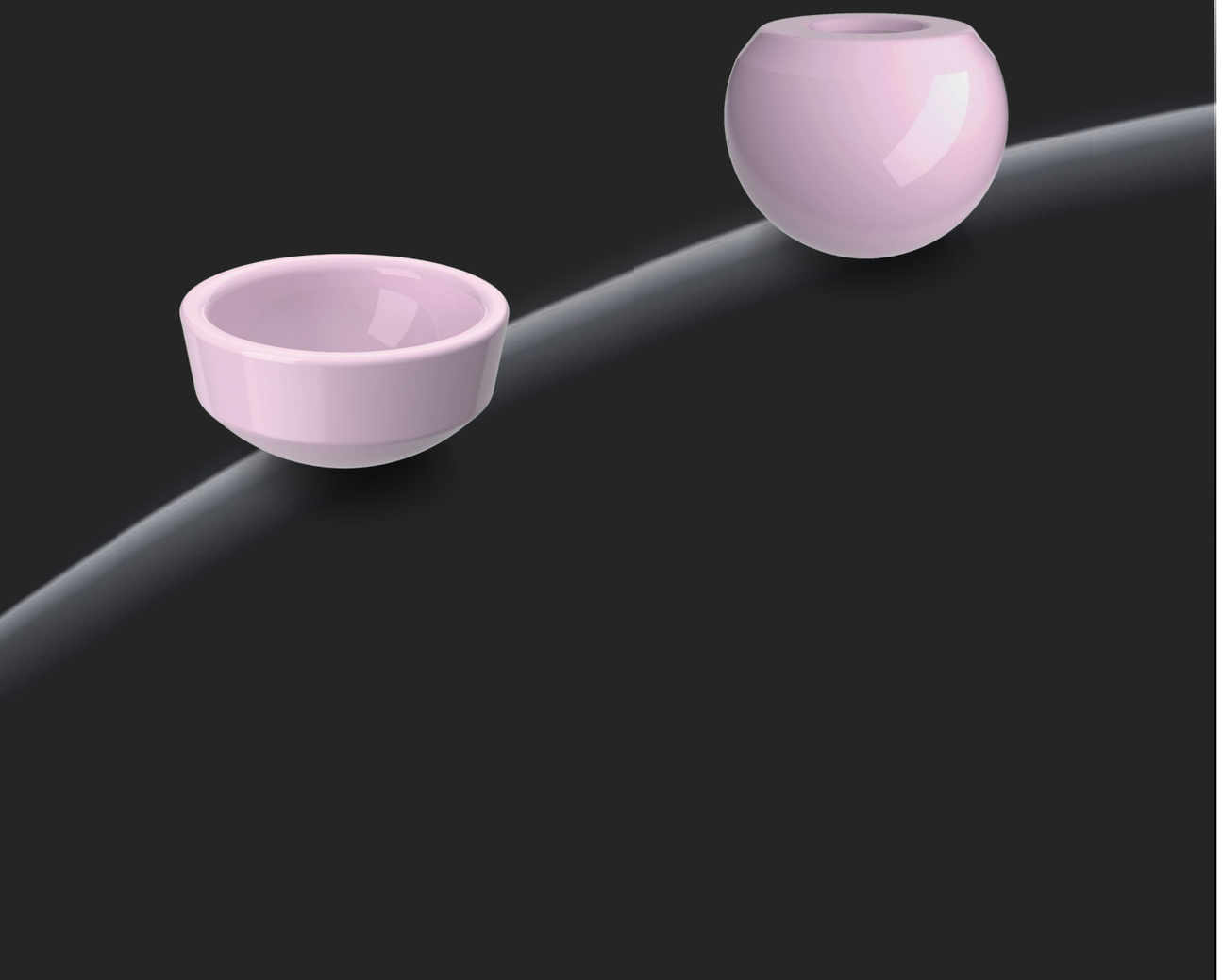


- **Primary Hip Replacement**
  A full range of ceramic femoral heads and inserts, fully compatible with existing implant systems.
- **Revison THA**
  Revision ceramic heads with a metal sleeve are available for use in revision THA.
- **Dual Mobility THA**
  Dual mobility THA with a ceramic insert can prevent dislocation while decreasing fretting/corrosion.
- **Resurfacing THA**
  For young and active patients, ceramic resurfacing THA can help to prevent dislocation, increase range of motion, and reduce bone resection.

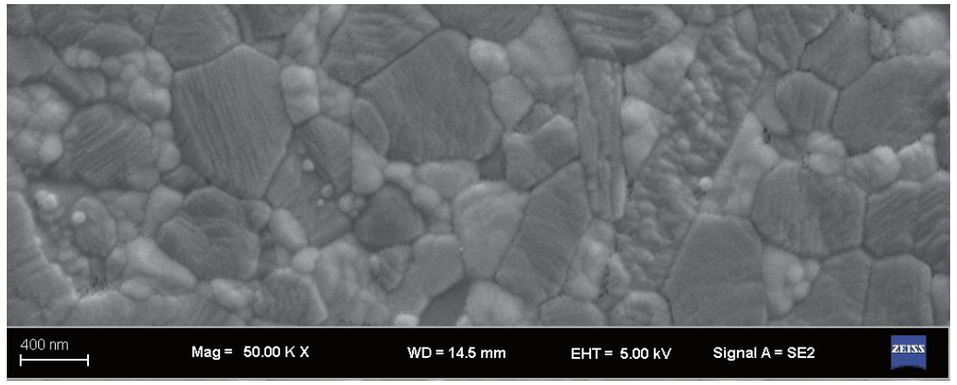
- **Knee Joint**
  With outstanding toughness and strength, our ceramic materials enable the production of knee components such as femoral condyles and unicondylar implants.
- **Shoulder Joint**
  Ceramic materials offer a novel solution for patients with metal allergies, providing superior biocompatibility.
- **Dental Implants**
  Ceramic implants significantly reduce the risk of peri-implantitis and related complications.
- **Veterinary Applications**
  Ceramic femoral heads for animal THA effectively resolve dislocation issues and improve animal welfare.

TOUMIC®

ZTA CERAMIC COMPONENTS



FINE MICROSTRUCTURE



Zirconia Toughened Alumina (ZTA) ceramics are composed of alumina (Al_2O_3), yttria-stabilized zirconia (ZrO_2), and strontium aluminate ($SrAl_{12}O_{19}$).

By precisely controlling chemical composition and optimizing forming and sintering parameters, a dense and uniform microstructure is achieved, in which zirconia and strontium aluminate crystals are evenly dispersed within the alumina matrix. The material reaches over 99.5% of theoretical density, ensuring outstanding mechanical performance and long-term stability.

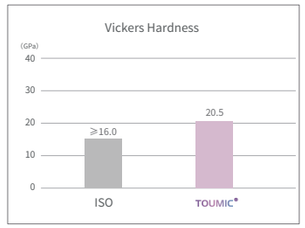
Average alumina grain size: **0.5~0.8**μm

Average zirconia grain size: **0.2~0.4**μm

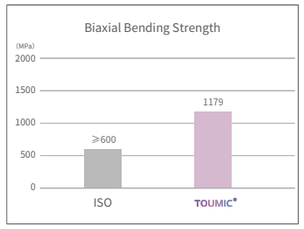
Average strontium aluminate crystal length: **0.8~1.2**μm

Density: ⩾**99.5**%TD

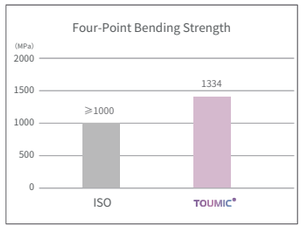
TECHNICAL DATA



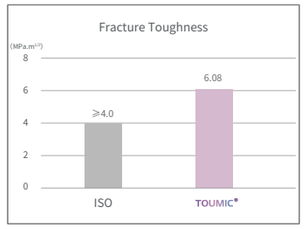
Vickers Hardness 20.5GPa



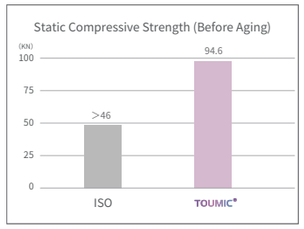
Biaxial Bending Strength 1179MPa



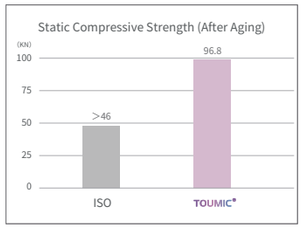
Four-Point Bending Strength 1334MPa



Fracture Toughness 6.08MPa.m$^{1/2}$



Static Compressive Strength (Before Aging)
94.6 KN (Model 28L, Worst Case)



Static Compressive Strength (After Aging)
96.8 KN (Model 28L, Worst Case)

MASS PRODUCTION & MANUFACTURING

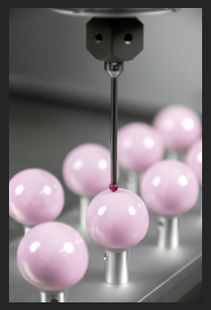
Manufacturing

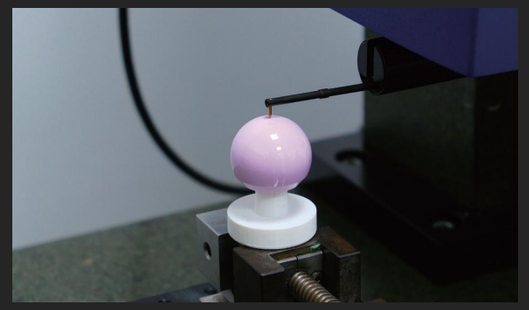
Backed by over 20 years of R&D experience, TrendTec has mastered the entire manufacturing process of ZTA ceramics — from powder preparation, sintering, hot isostatic pressing (HIP), precision machining, polishing, to final inspection.

In 2024, TrendTec established an 8,000+ m^2 modern precision manufacturing base, equipped with Germany and Switzerland high-precision CNC grinders, a dedicated HIP furnace, and nano-level polishing equipment, achieving highly automated full-process production.

Additionally, a 100,000-class cleanroom is established in our plant. Currently, the entire production line enables us to have an annual capacity of 300,000 ceramic components.

Furthermore, sufficient workshop space is also reserved to rapidly expand production capacity to 600,000 units, thereby meeting growing global demand. With years of effort, TrendTec has successfully transitioned from lab research to stable, large-scale industrial production of biomedical ceramic components.





HIGH-TECH CERAMICS

Quality Inspection

Adhering to the core principle of "Excellence at Delivery", TrendTec ensures that every component meets identical standards of premium quality.

Our 100% inspection is a non-negotiable commitment, enforced by industry-leading 3D coordinate measuring machines (CMMs) and other sophisticated inspection equipments, making consistent quality a part of our DNA.

Our rigorous testing meets all requirements of ISO 6474-2 for mechanical performance — including wear and fatigue resistance—as well as ISO 10993 for biocompatibility.

Furthermore, we conduct additional 10 million-cycle fatigue limit testing after Gamma irradiation and autoclave aging, ensuring exceptional long-term reliability.

Registration No. 04724Q10298R0S

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that:

Suzhou TrendTec New Materials Technology Co., Ltd.

Registered address: **Room 301, Building 9, No.8, YanDangShan Road, High tech Zone, Suzhou**
Manufacturing address: **Room 101-301, Building 9, No.8, YanDangShan Road, High tech Zone, Suzhou**

Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 idt ISO 9001:2015

For the following scope:

The Design, Development, Production and Service of ceramic components for the application in medical technology (supporting the use on medical devices).

Date of issue: **May 20, 2024**
Date of expiry: **May 19, 2027**
Date of change: **May 12, 2025**

General manager:

BEIJING HUAXUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information is available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 3rd floor of Zhong Lian building, No.jia08, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62211993

Registration No. 04724Q10000298

CERTIFICATE OF QUALITY MANAGEMENT
SYSTEM FOR MEDICAL DEVICES

This is to certify that:

Suzhou TrendTec New Materials Technology Co., Ltd.

Registered address: **Room 301, Building 9, No.8, YanDangShan Road, High tech Zone, Suzhou**
Manufacturing address: **Room 101-301, Building 9, No.8, YanDangShan Road, High tech Zone, Suzhou**

Operates a Quality Management System which complies with the requirements of:

GB/T 42061-2022 idt ISO 13485:2016

For the following scope:

The Design, Development, Production and Service of ceramic components for the application in medical technology (supporting the use on medical devices).

Date of issue: **May 20, 2024**
Date of expiry: **May 19, 2027**
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HIGHLY RELIABLE

TrendTec has passed dual quality management system certifications:

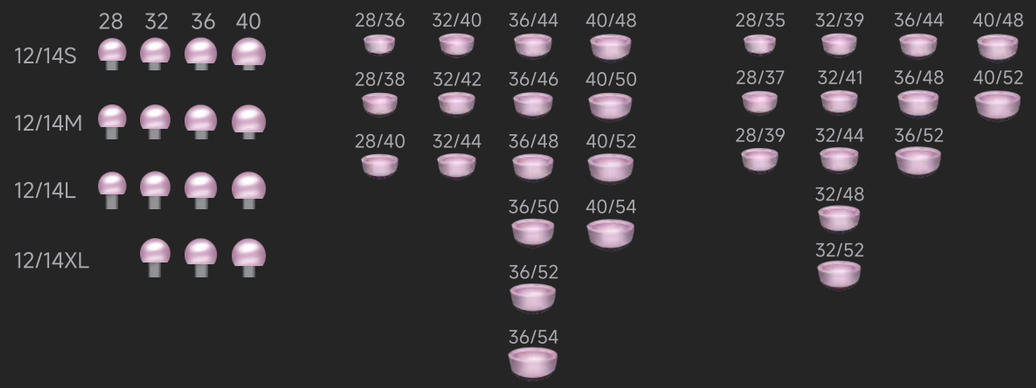
GB/T 19001-2016 idt ISO 9001:2015

GB/T 42061-2022 idt ISO 13485:2016

We have obtained biocompatibility test reports issued by authorized laboratories and comprehensive performance test reports based on ISO 6474-2. These reports can be directly used for FDA, CE, and registration applications in Latin American and Asian countries.

FULL PORTFOLIO

Comprehensive Model Range



TOUMIC® Femoral Heads		
Specification	Diameter (mm)	Offset (mm)
28S	28	-3.5
28M		0
28L		3.5
32S	32	-4.0
32M		0
32L		+4.0
32XL		+7.0
36S	36	-4.0
36M		0
36L		+4.0
36XL		+8.0
40S	40	-4.0
40M		0
40L		+4.0
40XL		+8.0

TOUMIC® Insert (0 Series)		
Specification	Inner∅ (mm)	Outer∅ (mm)
28/36	28	36
28/38		38
28/40		40
32/40	32	40
32/42		42
32/44		44
36/44	36	44
36/46		46
36/48		48
36/50		50
36/52		52
36/54		54
40/48	40	48
40/50		50
40/52		52
40/54		54

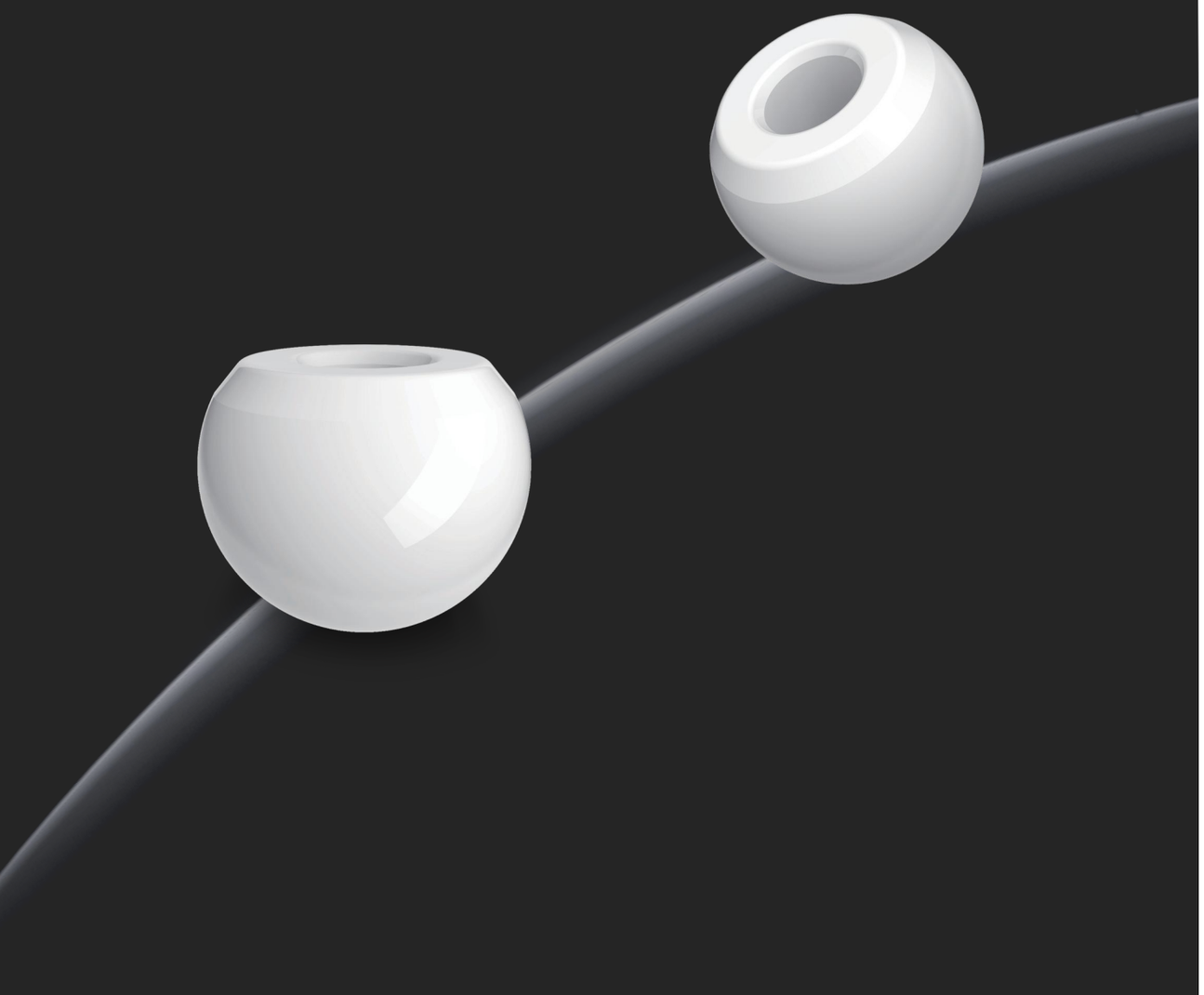
TOUMIC® Insert (18 Series)		
Specification	Inner∅ (mm)	Outer∅ (mm)
28/35G	28	35
28/37G		37
28/39G		39
32/39G	32	39
32/41G		41
32/44G		44
32/48G		48
32/52G		52
36/44G	36	44
36/48G		48
36/52G		52
40/48G	40	48
40/52G		52

Extensive Compatibility

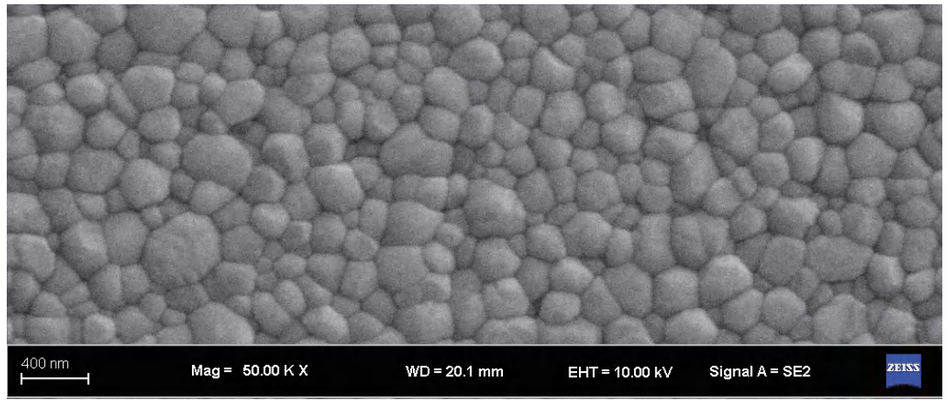
TrendTec offers a comprehensive range of femoral heads and inserts; multiple diameters and offsets are available to meet the diverse needs of primary and revision hip replacement surgeries, fully compatible with existing hip replacement systems in the market.

CLEAMIC®

TZP CERAMIC HEAD



FINE MICROSTRUCTURE

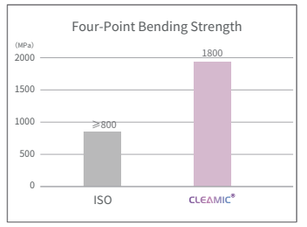


The zirconia ceramic femoral head is composed of fully dense tetragonal zirconia polycrystal (TZP). Through precise control of the content and distribution of the stabilizer yttrium oxide (Y_2O_3) and sintering aid aluminum oxide (Al_2O_3), combined with optimized forming and sintering processes, a fine microstructure with an average grain size of 0.1–0.3 μm and a density of 99.6% of the theoretical value is achieved.

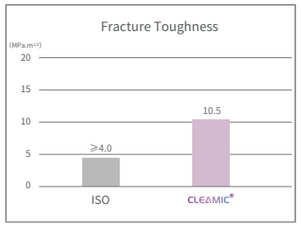
Average grain size: **0.1~0.3**μm Density: ⩾**99.6**%TD

TECHNICAL DATA

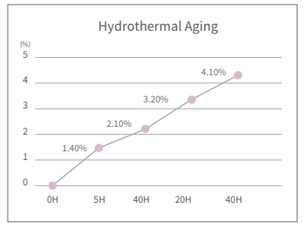
Vickers Hardness 12.5GPa



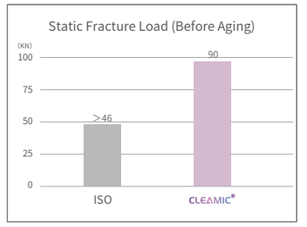
Four-Point Bending Strength 1800MPa



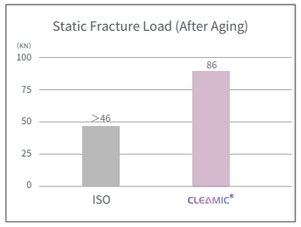
Fracture Toughness 10.5MPa.$m^{1/2}$



Hydrothermal Aging 4.1%
(monoclinic phase content after 40 h)

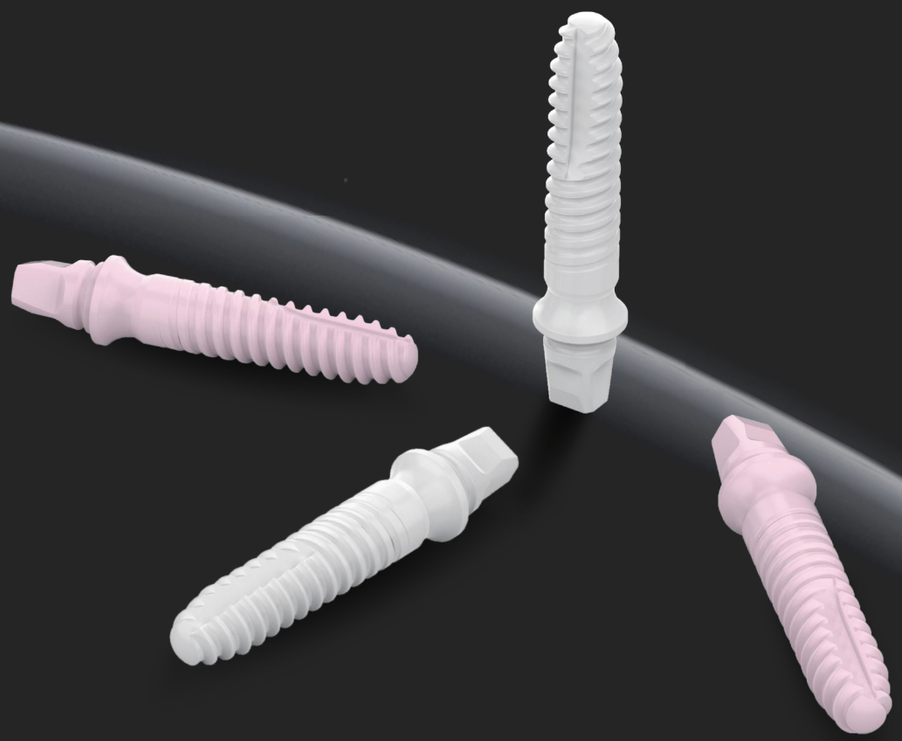


Static Fracture Load (Before Aging)
90 KN (Model 28L, worst case)

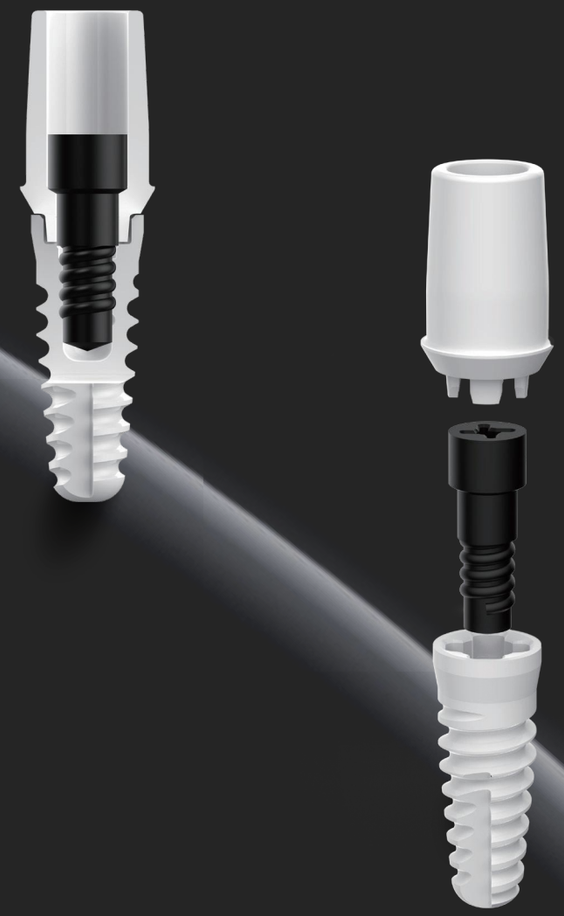


Static Fracture Load (After Aging)
86 KN (Model 28L, worst case)

CERAMIC DENTAL IMPLANTS



ONE-PIECE
CERAMIC DENTAL IMPLANT



TWO-PIECE
CERAMIC DENTAL IMPLANT