



 2-2, 88 Jingche Road, Songjiang District
 201611 Shanghai P.R. China
  0086-185 2803 6065
 info@audentalzir.com
 www.audentalzir.com



The Natural Smile Artist

audental

CAD/CAM SOLUTION

CE0197 · ISO 13485 · FDA 510K



Audental Bio-Material Co.,Ltd
www.audentalzir.com

Audental

Company Profile

Audental established in 2007, which is the earliest dental precious metal alloys and reliable zirconia block manufacturer in China. Our production facilities are located in Shanghai and Qinghuangdao, certified by ISO13485, CE 0197 and FDA 510k.

We committed to working in the field of dental bio-materials and focuses on the noble metal alloys and bio-ceramic materials. Audental keeps creating superior value for customers and providing high-quality service. Audental ensures professional and high quality dental products by means of modern production lines, testing equipments, advanced science and technology, strict and full quality control.



January 31, 2020

Qinghuangdao Audental Metal Technology Co., Ltd.
 Mr. Ray Wang
 General Manager
 Beijing Biotech-Med Technology Service Co., Ltd.
 Biao 912, Building #15, Xiyuehuai, No.5, Yifei North Rd.,
 Fengshan District
 Beijing, 100491 CHINA

Re: X192333
 Trade Device Name: Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia
 Registration Number: 21 CFR 872.6660
 Regulatory Name: Precision Powder for Clinical Use
 Regulatory Class: Class II
 Product Code: EHH
 Dated: November 1, 2019
 Received: November 4, 2019

Dear Ray Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although the letter refers to your product as a device, please be aware that some classed products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/cdrh/cdrhfiles/dnprnprodprod.htm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 900. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
 1087 Willow Grove Road
 Blue Spring, MD 21054
 www.fda.gov

EC Certificate
 Directive 93/42/EEC Annex V
 Production Quality Assurance
 Medical Devices

Registration No.: DD 60145841 0001
 Report No.: 50305865 002

Manufacturer: Audental Bio-Material Co., Ltd.
 2-2, 88 Jingche Road, Songjiang District
 201611 Shanghai
 P.R. China

Products: -Dental Alloy
 -Dental Zirconia Ceramic

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class IIc devices covered by this certificate an EC type-examination certificate according to Annex II is required.

Effective Date: 2020-01-21
 Date: 2020-01-21

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
 TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate
 The Certification Body of
 TÜV Rheinland LGA Products GmbH

Notifies that the organization
Audental Bio-Material Co., Ltd.
 2-2, 88 Jingche Road, Songjiang District
 201611 Shanghai
 P.R. China

has established and applies a quality management system for medical devices for the following scope:
Manufacture and Distribution of Dental Alloys and Dental Zirconia Ceramics

Proof has been furnished that the requirements specified in
EN ISO 13485:2016
 are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-21
 Certificate Registration No.: SX 0014942 0001
 An audit was performed. Report No.: 50305865 002
 This Certificate is valid until: 2023-12-27

Certification Body
 TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
 Tel. +49 91 298 1277 Fax. +49 91 298 2800 e-mail: cert@lga.tuev-rheinland.com



3D PRO

ST-Plus Multilayer (Super Translucency Plus)

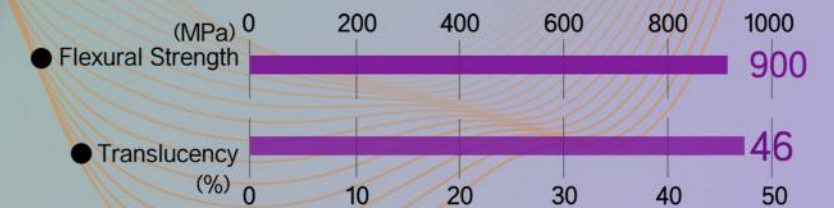


All In One

Flexural Strength (MPa)	650	↔	1100
Translucency (%)	49	↔	42



Born for veneer



Indication



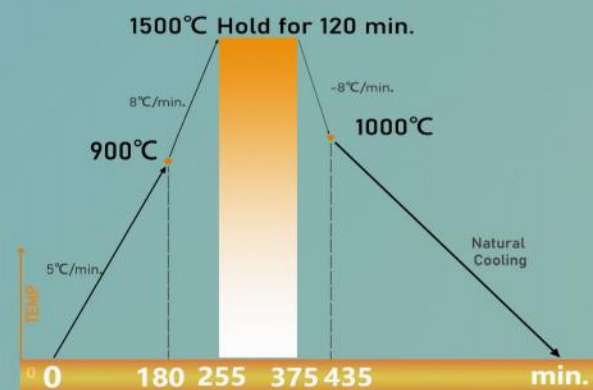
Composition

ZrO₂+ HfO₂+Y₂O₃ > 99%
 Y₂O₃ 5.2%-10%
 Al₂O₃ < 0.15%

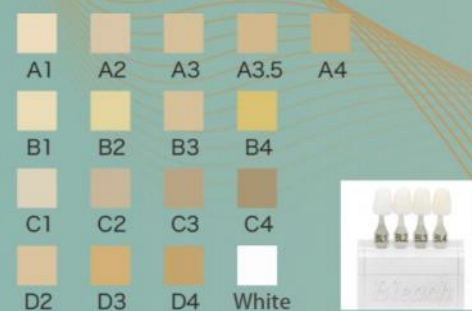
System



Sintering Curve



Shades



Indication



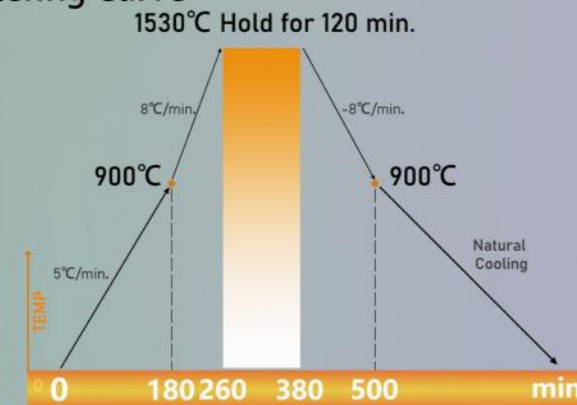
Composition

ZrO₂+ HfO₂+Y₂O₃ > 99%
 Y₂O₃ 7.0%-7.8%
 Al₂O₃ < 0.15%

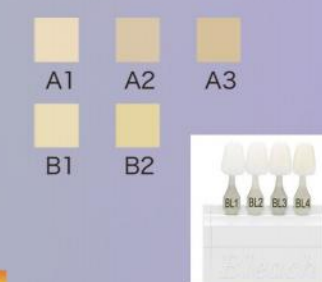
System



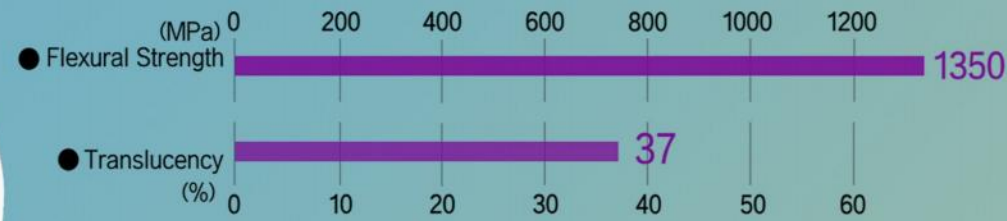
Sintering Curve



Shades



HT White (High Translucency)



Indication



Chemical composition

Components	HT
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥99%
Y ₂ O ₃	4.5%-6.0%
Al ₂ O ₃	<0.25%
Other Oxides	<0.15%

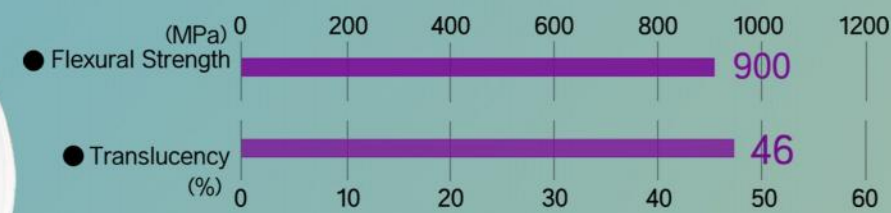
Shapes and Sizes

OD98*10mm	OD98*18mm	OD95*10mm	OD95*18mm		
OD98*12mm	OD98*20mm	OD95*12mm	OD95*20mm	92*75*12mm	92*75*18mm
OD98*14mm	OD98*22mm	OD95*14mm	OD95*22mm	92*75*14mm	92*75*20mm
OD98*16mm	OD98*25mm	OD95*16mm	OD95*25mm	92*75*16mm	92*75*25mm

16 Colors Liquids



ST-Plus Preshaded (Super Translucency Plus)



Indication



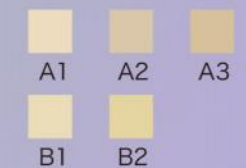
Chemical composition

Components	ST Plus
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥99%
Y ₂ O ₃	7.0%-7.8%
Al ₂ O ₃	<0.15%
Other Oxides	<0.15%

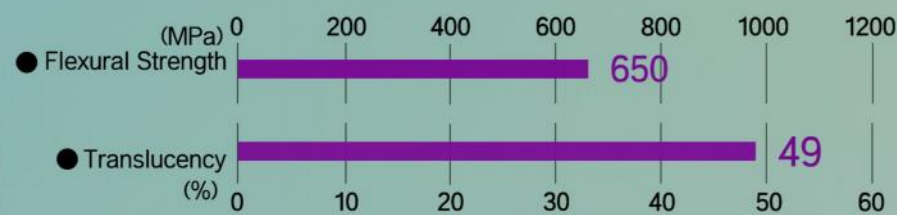
Shapes and Sizes

OD98*10mm	OD98*18mm	OD95*10mm	OD95*18mm		
OD98*12mm	OD98*20mm	OD95*12mm	OD95*20mm	92*75*12mm	92*75*18mm
OD98*14mm	OD98*22mm	OD95*14mm	OD95*22mm	92*75*14mm	92*75*20mm
OD98*16mm	OD98*25mm	OD95*16mm	OD95*25mm	92*75*16mm	92*75*25mm

Preshaded



UT Multilayer (Ultra Translucency)



Indication



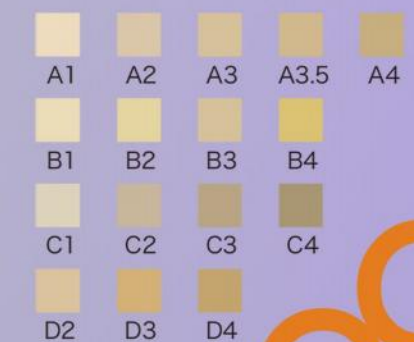
Chemical composition

Components	UT Shaded
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥99%
Y ₂ O ₃	9%-10%
Al ₂ O ₃	<0.5%
Other Oxides	<0.5%

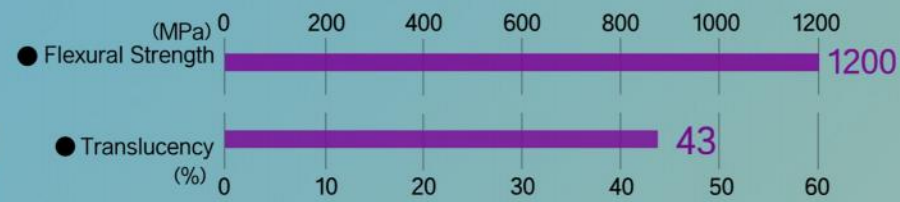
Shapes and Sizes

OD98*10mm	OD98*18mm	OD95*10mm	OD95*18mm		
OD98*12mm	OD98*20mm	OD95*12mm	OD95*20mm	92*75*12mm	92*75*18mm
OD98*14mm	OD98*22mm	OD95*14mm	OD95*22mm	92*75*14mm	92*75*20mm
OD98*16mm	OD98*25mm	OD95*16mm	OD95*25mm	92*75*16mm	92*75*25mm

Preshaded



ST White (Super Translucency)



Indication



Chemical composition

Components	ST
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥99%
Y ₂ O ₃	4.5%-6.0%
Al ₂ O ₃	<0.15%
Other Oxides	<0.15%

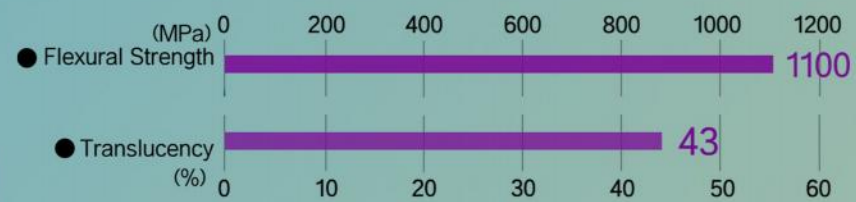
Shapes and Sizes

OD98*10mm	OD98*18mm	OD95*10mm	OD95*18mm	
OD98*12mm	OD98*20mm	OD95*12mm	OD95*20mm	92*75*12mm 92*75*18mm
OD98*14mm	OD98*22mm	OD95*14mm	OD95*22mm	92*75*14mm 92*75*20mm
OD98*16mm	OD98*25mm	OD95*16mm	OD95*25mm	92*75*16mm 92*75*25mm

16 Colors Liquids



ST Preshaded (Super Translucency)



Indication



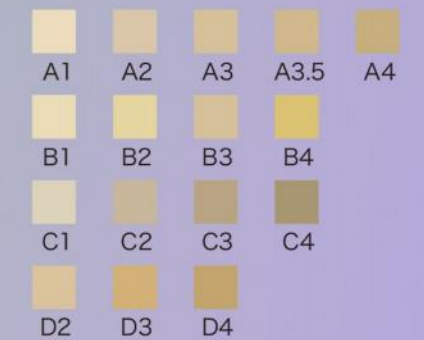
Chemical composition

Components	ST Shaded
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥99%
Y ₂ O ₃	4.5%-6.0%
Al ₂ O ₃	<0.5%
Other Oxides	<0.5%

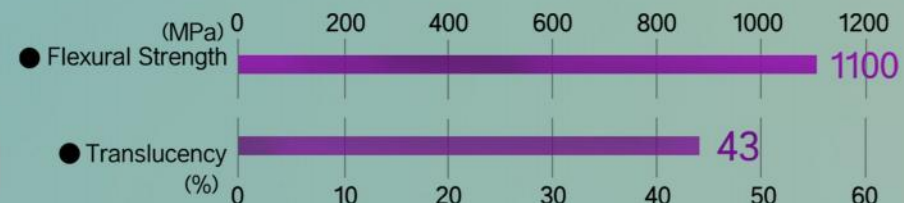
Shapes and Sizes

OD98*10mm	OD98*18mm	OD95*10mm	OD95*18mm	
OD98*12mm	OD98*20mm	OD95*12mm	OD95*20mm	92*75*12mm 92*75*18mm
OD98*14mm	OD98*22mm	OD95*14mm	OD95*22mm	92*75*14mm 92*75*20mm
OD98*16mm	OD98*25mm	OD95*16mm	OD95*25mm	92*75*16mm 92*75*25mm

Preshaded



ST Multilayer (Super Translucency)



Indication



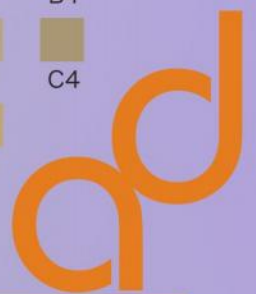
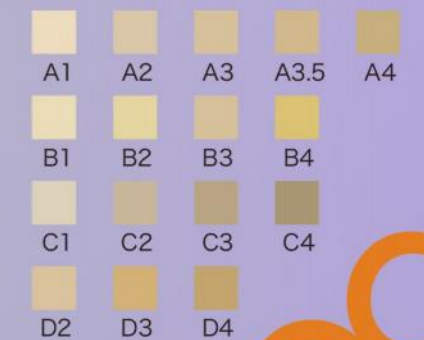
Chemical composition

Components	ST Multilayer
ZrO ₂ +HfO ₂ +Y ₂ O ₃	≥99%
Y ₂ O ₃	4.5%-6.0%
Al ₂ O ₃	<0.5%
Other Oxides	<0.5%

Shapes and Sizes

OD98*10mm	OD98*18mm	OD95*10mm	OD95*18mm	
OD98*12mm	OD98*20mm	OD95*12mm	OD95*20mm	92*75*12mm 92*75*18mm
OD98*14mm	OD98*22mm	OD95*14mm	OD95*22mm	92*75*14mm 92*75*20mm
OD98*16mm	OD98*25mm	OD95*16mm	OD95*25mm	92*75*16mm 92*75*25mm

Preshaded



Cobalt SLM Powder

Selective Laser Melting 3D Printing



Composition

Co 61.5 % • Cr 58.1 % • W 5.43% • Mo 5.0 % •

Technical properties

Density: 8.6 g/cm³
 Tensile strength (Rm): 8%
 Vickers hardness: 365
 Liquidus temperature : 1,350 -1,385° C
 Coefficient of thermal expansion : 14.5x10⁻⁶K⁻¹

Indication

Frames for partially; crowns and bridges up to 16 units
 Two-piece abutments
 C&B tertiary frame

Lithium Disilicate Block

Matching the Esthetics of Natural Teeth



Composition

Lithium disilicate

Technical properties

Thermal Expansivity (25-500°C)[10-6/K]: 10.5±0.5
 Bending Strength: 418 Mpa
 Density: 2.47±0.05g/cm³
 Chemical Solubility: National standard/ISO<2000 μg/cm²
 Color: HT/LT A1 A2 A3 A3.5 B1 B2 C1 C2 C3 D4 BL1-4

Indication

Veneers, Inlays, onlays,
 Partial crowns, Crowns,
 Three-unit bridges

PMMA

Mono; Multilayer; Denture Base; Flexible



Composition

Methyl acrylate

Technical properties

Flexural strength: 114Mpa
 Modulus of elasticity: 2500Mpa
 Water absorption: 11 μg/mm³
 Solubility: 0.2 μg/mm³
 Thickness: 10mm-30mm
 Shade: Clear, Pink, A0, Vita 16, Bleach1-4

Indication

Temporary crowns and bridges; verification of the bridge on the plater model/ mouth; full dentures; partial dentures; bite guards; herapeutic splints; drilling templates; frameworks

Wax

CAD CAM Milling Block; Burnout without waste



Composition

Wax

Technical properties

Softening point: 105 °C
 Melting point: 140 °C
 Density: 0.89-0.93
 Diameter: 95mm 98mm 100mm
 Thickness: 10mm-30mm
 Color: White Blue Green

Indication

Precise casting or
 pressing of metal and all ceramic, framework

Metal Alloys Disc

CAD CAM System Dental Implant

Composition

Titanium Gr2, Gr5 or CoCr alloy,

Technical properties

Density: $8.5\text{g/cm}^3 \pm 0.5\text{g/cm}^3$

Tensile strength (Rm): $>560\text{Mpa}$

PFM Bonding Strength $\geq 25\text{ Mpa}$

Diameter: 95mm, 98mm

Height: 10-25mm

Indication

Metal crown and bridge of denture porcelain restoration;
abutments;
C&B tertiary frame etc.



Milling Bur



Mill Machine	Roland	VHF	Wieland Zenotec	Yenadent /Origin	Zirkonzahn M5
Head Φ mm	0.6, 1.0, 2.0	0.6, 1.0, 2.0	0.3, 0.6, 1.0, 2.5	0.6, 1.0, 2.0	0.6, 1.0, 2.0
Shank Φ mm	4mm/6mm	3mm	3mm	4mm	3mm/6mm
Total Length	50mm	35mm/40mm	35mm/40mm	43mm	57mm
Coating	DLC/Diamond	DLC	DLC/Diamond	DLC	DLC/No coating

PEEK

High-Performance Thermoplastic Technopolymer

Composition

Polyetheretherketon: 100%

Technical properties

Flexural Strength: 150 MPa

Density: 1.32 - 1.51g/ml

Flexural Modulus: 4 - 5.8 GPa

Water Solubility: insoluble

Thickness: 10mm - 25mm

Color: Natural Grey Pink White

Indication

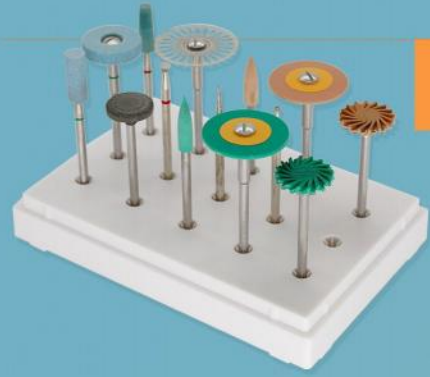
Crowns & bridges (max. 3 units)
Secondary and telescope restorations
Attachment restorations or screw-retained
Implant-supported super structures



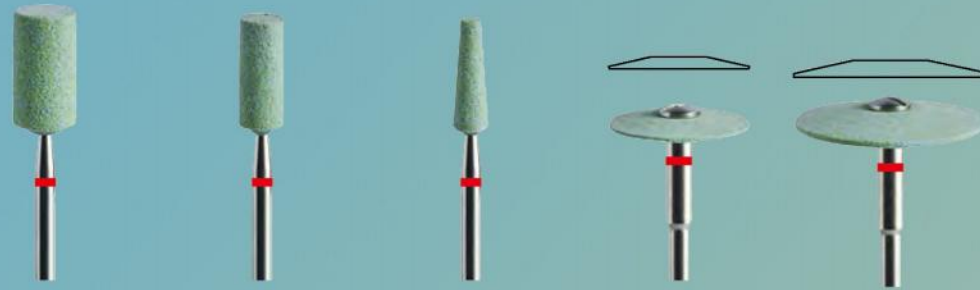
Mill Machine	Sirona	Imes-icores	Arum	Amann Girbach Ceramill
Head Φ mm	0.5, 1.0, 2.0, 2.5	0.6, 1.0, 2.0, 2.5, 3.0	0.6, 1.0, 1.5, 2.0, 2.5, 3.0	0.6, 1.0, 2.5
Shank Φ mm	3mm	3mm 6mm	4mm 6mm	3mm
Total Length	44mm	48mm/50mm/53mm	44mm, 47mm/50mm	47mm
Coating	DLC	DLC	DLC	DLC/Diamond coated

Contact for more

Diamond Turbo Grinder



-  Fine Grit
-  8000-15000 rpm
-  max:25000 rpm
-  1 pc







Order No.	TG01	TG02	TG03	TG06	TG07
Size \varnothing 1/10mm	0.65	050	045	160	220
Length in mm	13.0	13.0	13.0	1.5	2.0

-  Fine Grit
-  8000-15000 rpm
-  max:25000 rpm
-  1 pc







Order No.	TG08	TG09	TG10	TG11	TG12
Size \varnothing 1/10mm	220	150	130	220	150
Length in mm	4.5	3.5	2.0	2.0	2.0

-  Extra Fine
-  8000-15000 rpm
-  max:25000 rpm
-  1 pc



Order No.	TF10	TF02	TF03
Size \varnothing 1/10mm	130	050	045
Length in mm	2.0	13.0	13.0

Diamond Polisher

-  medium
-  7000-15000 rpm
-  max:20000 rpm
-  1pc






Order No.	HG07M	HG06M	HG03M	HG10M
Dimensions(mm)	26*2	20*1	4*13	12*2

-  fine
-  7000-15000 rpm
-  max:20000 rpm
-  1pc

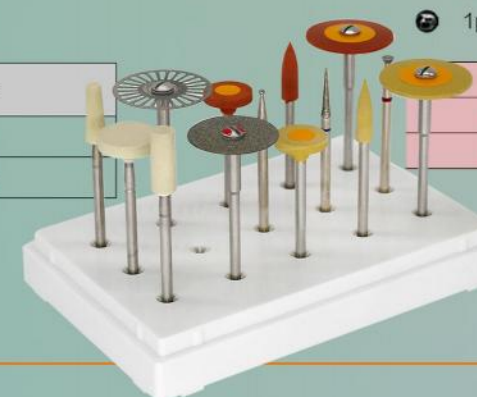


Order No.	HG07F	HG06F	HG03F	HG10F
Dimensions(mm)	26*2	20*1	4*13	12*2

-  10000-15000 rpm
-  max:20000 rpm
-  1pc



Grit:	very coarse	coarse	medium	extra-fine	ultra-fine
NO.:	RDH021	RDH023	RDH024	RDH026	RDH025
Size (mm):	26x2	26x2	26x2	26x2	26x2



Contact for more