BAOT Biological Technology Co., Ltd.

Summary of Safety and Clinical Performance

Dental Ceramic

(Model: Metal Ceramic, Zirconia Ceramic)

Table of Contents

Revision History

Version	Changes	Effective date
A/0	New release	Dec. 10, 2023
A/1	Updated documentation	Dec. 10, 2024
A/2	Updated documentation	Feb. 23, 2025

The SSCP is applicable to the following product(s)

Dental Ceramic (Metal Ceramic, Zirconia Ceramic) and Formative Liquid.

Refer to Attachments: Product introduction of Dental Ceramics (Metal Ceramic (JC) series and Zirconia Ceramic (ZCG) series) and Formative Liquid.

Specification/ Model	Category		
Metal Ceramic	Opaque	BOND	
		Wash Opaque	
		Opaque	16 color series, 30 color series
	Dentine	Opacious Dentine	16 color series, 30 color series
		Dentine	16 color series, 30 color series, Dentine Modifier
	Enamel	Semi-transparent	Semi-transparent, Semi-transparent Effect, Cervical, Cervical Effect, Opal Translucent, Pearl Translucent, Luminary, Mamelon, Margin
		Transparent	Transparent, Window, Gingiva
		Glaze	Glaze, Corrective, Stain
Zirconia Ceramic	Dentine	Opacious Dentine	16 color series, 30 color series
		Dentine	16 color series, 30 color series, Dentine Modifier
	Enamel	Semi-transparent	Semi-transparent, Semi-transparent Effect, Cervical, Cervical Effect, Opal Translucent, Pearl Translucent, Luminary, Mamelon, Margin
		Transparent	Transparent, Window, Gingiva
		Glaze	Glaze, Corrective, Stain
Accessory (Formative Liquid)	Modeling Liquid (CFS), Opaque Liquid (OF), Glaze & Stain Liquid (GY)		

Identification of the device

Metal Ceramic (JC) (Powder)

Zirconia Ceramic (ZCG) (Powder)

Metal Ceramic (JC) (Paste)

Zirconia Ceramic (ZCG) (Paste)

Formative Liquid (accessory for Dental Ceramic)

Device Name	Dental Ceramic (Metal Ceramic, Zirconia Ceramic)
Manufacturer	BAOT Biological Technology Co., Ltd. Unit 1, Second Floor, No 12 Building, Yujing Industry Zone,106 Qihao Road, Torch Development District, Zhongshan City, Guangdong Province, P.R.China
Manufacturer SRN	CN-MF-000017164
Basic UDI-DI	697313331CE01BG
EMDN Code	Q010101 - Dental Restoration Devices
Class of device	IIa
Year of first CE Certificate	Certification CN18/41009, NB 0120, Issued date: 2015/09/18 Certification CN19/41078, NB 1639, Issued date: 2019/12/16
Authorised Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany SRN: DE-AR-000000001
Notified Body including identification No.	SGS BELGIUM N.V. Noorderlaan 87, Be-2-3- Antwerpen, Belgium. Identification no.: 1639

Indications, Intended Purpose and Target populations

Intended use / Intended purpose	Dental ceramic (metal ceramic and zirconia ceramic) is used for the fabrication of dental restorations (inlays/onlays, veneers, touch-ups, etc.). Dental ceramic is coated on the surface of the metal crown or zirconia crown, made into the shape of the tooth crown, and then sintered into the form of a restoration in which the inner crown and this dental ceramic are sintered as one, for the restoration of damaged or missing teeth.
Indication	Dental Ceramic is indicated for tooth damage (decayed tooth, damaged tooth, etc.), fixed-bridge restorations for tooth absence, aesthetic restoration for tooth discoloration. Metal Ceramic is a veneering ceramic for metal substructures made of high gold content, reduced gold content as well as non-precious alloys in the conventional CTE range (25~500℃): 13.8~14.9 (x 10^{-6} K^{-1}). Zirconia Ceramic is a special veneering ceramic featuring a fine structure for partially yttrium-stabilized ZrO2 substructures with a CTE range (25~500℃): 10.0~10.6 (×$10^{-6}K^{-1}$).
Applicable Population	Human above 18 years old who need dental prosthesis restoration.
Contraindication	Bruxism and allergic reactions to dental materials / ingredients in this product.
Intended user	All Dental Ceramics (Metal Ceramic, Zirconia Ceramic) are processed through dental laboratories or by dental professionals. Rx only.

Device description

a) Description of the medical device(s)

Dental Ceramic (Ceramic powder) is a kind of ceramic materials used for dental restoration, sintering molding imitating human oral biology tooth by the denture production company. Ceramic powder is composed of inorganic material, made through sintering, crushing and coloring, Production equipment used in the production process mainly include: ball mill, low temperature furnace and high temperature furnace, industrial ovens. According to the different dental crowns porcelain powder divided into metal crown porcelain powder and zirconia crown porcelain powder, it is often called metal ceramic powder and Zirconia Ceramic powder.

The structure of Dental Ceramic: inner crowns (Inner Alloy Crown or Zirconia Crown), Bonding layer, Body layer and Enamel layer, refer to the fig.1, fig.2.

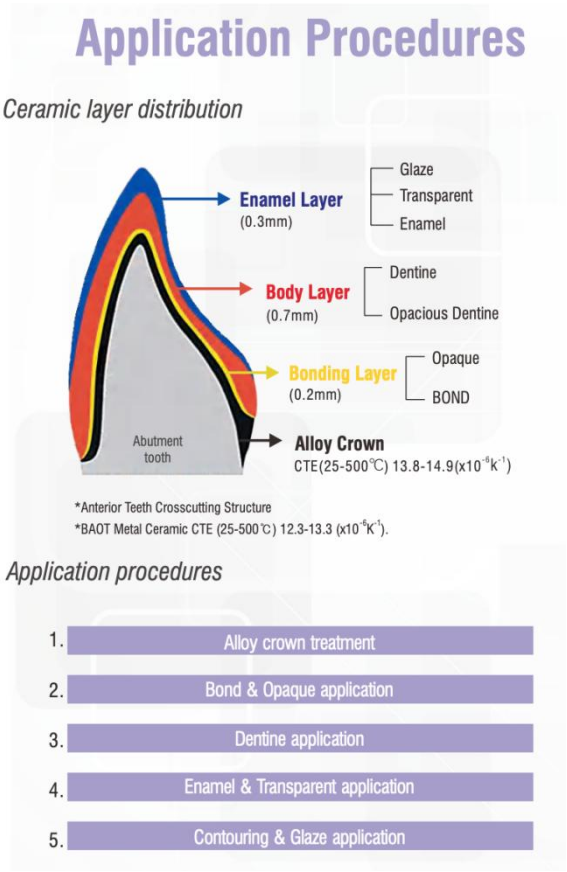

Figure 1. Metal Ceramic

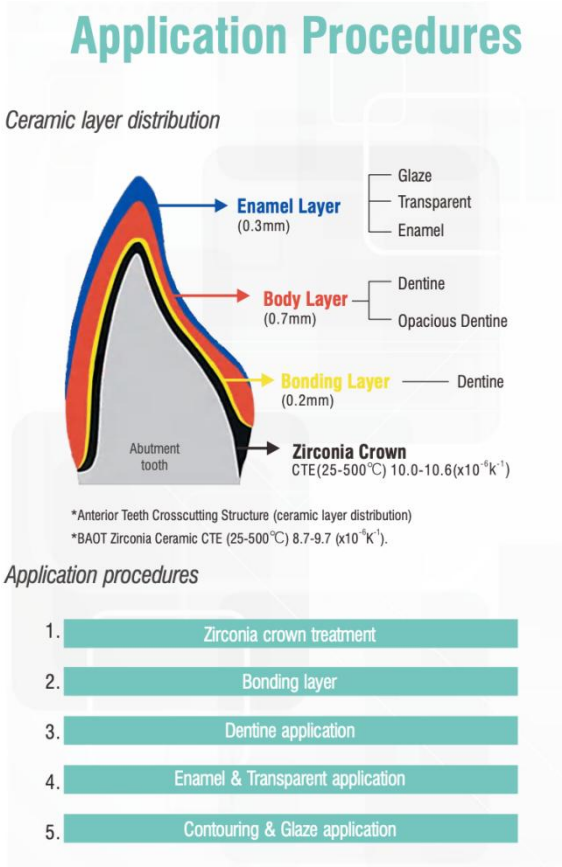

Figure 2 Zirconia Ceramic

Dental Ceramic is made of potassium feldspar ($K_2O \cdot AL_2O_3 \cdot 6SiO_2$), potassium oxide ($K_2O$), sodium oxide ($Na_2O$), aluminum oxide ($Al_2O_3$), calcium oxide (CaO), barium oxide (BaO), strontium oxide (SrO), boron oxide (B_2O_3), zirconium silicate ($ZrSiO_4$), zinc oxide (ZnO), lithium carbonate (Li_2CO_3), silicate glass ($Na_2O \cdot CaO \cdot 6SiO_2$) and inorganic pigments. The formative liquid is composed of water (H_2O), 1,3 butanediol ($C_4H_{10}O_2$) and 1,5 pentanediol ($C_5H_{12}O_2$).

Chemical Composition of Dental Ceramic

Metal Ceramic	SiO_2 (50-60%), Al_2O_3 (14-17%), K_2O (7-12%), Na_2O (7-10%), CaO (1-4%), BaO < 3%, SrO < 2%, B_2O_3 < 1%, Others < 2%.
Zirconia Ceramic	SiO_2 (52-62%), Al_2O_3 (14-16%), K_2O (7-10%), Na_2O (7-10%), CaO (1-4%), BaO < 3%, SrO < 2%, B_2O_3 < 1.5%, Others < 2%.

Ingredient information of Formative Liquid

Name	Category	Code	Ingredient proportions		
			1,3-Butanediol $C_4H_{10}O_2$	1,5-Pentanediol $C_5H_{12}O_2$	Pure water H_2O
Formative Liquid	Modeling Liquid	CFS	30%	/	70%
	Opaque Liquid	OF	100%	/	/
	Glaze & Stain Liquid	GY	/	100%	/

Firing Parameters

Model	Type	Initial Temp (℃)	Drying Time (min)	Heating Time (min)	Heating Rate (℃/min)	Firing Temp. (℃)	Holding Time (min)	Cooling Time (min)	Cooling Temp. (℃)	Vacuum Start (℃)	Vacuum End (℃)
Metal Ceramic	Bond	550	2	2	60	960	1	4	550	550	960
	Opaque	550	3	3	60	940	1	4	550	550	940
	Margin	550	3	3	55	930	1	4	550	550	930
	Body*	550	3	3	55	920	1	4	550	550	920
	Add on	550	2	2	55	910	1	4	550	550	910
	Glaze & Stain	550	2	2	55	890	1	4	550	-	-
Zirconia Ceramic	Heat treatment	500	2	2	50	960	1	4	550	550	960
	Body*	500	3	3	50	920	1	4	550	550	920
	Add on	550	2	2	50	910	1	4	550	550	910
	Glaze & Stain	500	2	2	50	890	1	4	550	-	-

Note:

Please kindly note, as the manufacturer recommended, the inner alloy crown for Metal Ceramic should be in the conventional CTE range: CTE (25~500℃): 13.8~14.9(x 10^{-6} K^{-1}). The inner zirconia crown for Zirconia Ceramic should be in the conventional CTE range (25~500℃): 10.0~10.6 (×$10^{-6}K^{-1}$).

(1) *Body: including Cervical, Opacious Dentine, Dentine, Enamel, Transparent, Gingiva.

(2) Add on: the second add-on porcelain material.

(3) According to the characteristics of different porcelain ovens, the firing parameters can be adjusted appropriately, and attention should be paid to test and confirm the firing situation before production.

b) Previous generations of the medical device(s)

Previous Generation Device: Dental Ceramic

Model: Metal Ceramic (JC) series , Zirconia Ceramic (ZCG) series

Dental Ceramic have been on the market for decade, comparing with legacy device, following changes have been made:

- Based on the requirement of optimizing the manufacturing technology, CTE has been updated.
- More color shades have been added in order to cover as much aesthetical requirements as possible.

c) Accessories / other products which are intended to be used with the medical device(s)

Name of Accessory: Formative liquid

As an auxiliary material for denture shaping, formative liquid is made of Pure water(H_2O), 1,3-Butanediol ($C_4H_{10}O_2$), 1,5-Pentanediol ($C_5H_{12}O_2$) and it is divided into modeling liquid(CFS), opaque liquid (OF), glaze & stain liquid(GY). Formative Liquid is used for mixing Dental Ceramic.

Name	Category	Code	Spec(ml/bottle)
Formative Liquid	Modeling Liquid	CFS	15, 50, 240
	Opaque Liquid	OF	15, 50, 240
	Glaze & Stain Liquid	GY	5, 15, 50, 240

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
The therapeutic alternative of crown can be made from lithium disilicate-based glass ceramic.	Lithium disilicate glass ceramic has higher success rate / survival rate than feldspathic ceramic [*] e.g. BAOT Dental Ceramic.
The therapeutic alternative of crown can be a purely monolithic metal restoration without subsequent staining or further characterization.	The risk of a purely monolithic restoration compared to a classical metal-ceramic crown with e.g. BAOT Metal Ceramic is a less aesthetic appearance - which could play a role especially in single-tooth restorations in the anterior region.
The therapeutic alternative of crown can be a purely monolithic zirconia restoration pre-shaded without subsequent staining.	The risk of a purely monolithic restoration compared to a classical zirconia-ceramic crown with e.g. BAOT Zirconia Ceramic is a less aesthetic appearance - which could play a role especially in single-tooth restorations in the anterior region.

[*] Saavedra, G., et al. (2021). "Feldspathic and Lithium Disilicate Onlays with a 2-Year Follow- Up: Split-Mouth Randomized Clinical Trial." Braz Dent J 32(2): 53-63.

Reference to harmonized standards and CS applied

No.	Standard/Directive Reference	Title
01	MDR (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
02	EN ISO 13485:2016 ISO 13485:2016	Medical devices-Quality management systems – Requirement for regulatory purposes.
03	EN ISO 14971:2019 ISO 14971:2019	Medical Devices - Application of Risk management to medical devices
04	EN ISO 15223-1:2021 ISO 15223-1: 2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
05	EN ISO 20417:2021 ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
06	EN 62366-1:2015+A1:2020 IEC 62366-1:2015/Amd 1:2020	Medical devices – Application of usability engineering to medical devices
07	EN 1641:2009	Dentistry - Medical devices for dentistry - Materials
08	EN ISO 7405:2018 ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
09	EN ISO 6872-2015 ISO 6872-2015	Dentistry — Ceramic materials
10	EN ISO 7491:2000 ISO 7491:2000	Dental materials — Determination of colour stability
11	EN ISO 9693-1:2012	Dentistry — Compatibility testing — Part 1: Metal-ceramic systems
	EN ISO 9693:2019 ISO 9693:2019	Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems
12	EN ISO 10993-1:2020 ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
13	EN ISO 10993-3:2014 ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
14	EN ISO 10993-5:2009 ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
15	EN ISO 10993-6:2016 ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
16	EN ISO 10993-10:2023 ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
17	EN ISO 10993-11:2018 ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
18	EN ISO 10993-23:2021 ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
19	MEDDEV 2.7/1 rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
20	MEDDEV 2.12/1 rev 8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM

No.	Standard/Directive Reference	Title
21	ASTM D 4169:2016	Standard Practice for Performance Testing of Shipping Containers and Systems
22	EN ISO 10993-17:2024 ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
23	EN ISO 10993-18:2023 ISO 10993-18:2020/Amd 1:2022	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
24	MDCG 2018-1 Rev.4	Guidance on BASIC-UDI and changes to UDI-DI
25	MDCG 2019-4	Timelines for registration of device data elements in EUDAMED
26	MDCG 2019-5	Registration of Legacy Devices in EUDAMED
27	MDCG 2019-7	Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
28	MDCG 2019-9	Summary of safety and clinical performance
29	MDCG 2020:6	Guidance sufficient clinical evidence
30	MDCG 2020-3	Guidance on significant changes
31	MDCG 2020-7	Guidance on PMCF Plan Template
32	MDCG 2020-8	Guidance on PMCF Evaluation Report Template
33	MDCG 2021-1 Rev.1	Guidance solution until EUDAMED is fully functional
34	MDCG 2021-19	Guidance note integration of the UDI within an organization‘s quality management system
35	MDCG 2021-25	application of MDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2021
36	MDCG 2022-4 Rev. 2	Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD
37	MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
38	Regulation (EC) No 1272/2008 Annex VI, Part 3	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)
39	Regulation (EC) No 1907/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Summary of clinical evaluation

Since the subject device is a WET legacy device and it has been previously marketed under MDD, and there is no equivalent device on the market under MDR, the clinical evaluation route was determined to be based on the assessment of PMS data (Clinical evidence Rank 7 – MDCG 2020-06) and comprehensive analysis of SOTA and similar devices (Clinical evidence Rank 6 – MDCG 2020-06).

We have used key words of the device under evaluation, similar device, state of the art and general phrase: dental ceramic for the literature searching for the past 10 years. The databases used includes Pubmed, Embase, Google Scholar, and Cochrane CENTRE trial registry. Of all databases, 28167 literatures were hit after initial search, and 37 of them were included for clinical evaluation. The literatures have been divided into study of short-term (no longer than 5 years) and long-term (longer than 5 years). The survival rate was defined as no catastrophic problem occurs that may need to replace the prosthesis and the success rate was defined as the rate that no any complications occur. After analysing the survival rate and success rate for dental ceramics in short-term is 93.27% and 78.62% respectively. For the follow-up period over 5 years, the survival rate and success rate are 90.64% and 73.14% respectively. The main happened complication is chipping. By considering the overall survival rate and success rate of all types of dental prosthesis of all time, the survival rate and success rate are 92.02% and 77.16% respectively. Since we have defined that the safety endpoint and performance endpoint as the survival rate over 90%, and success rate over 75%, so the safety and performance of the device under evaluation can be demonstrated.

As for the post market data, we have performed 3 activities except scientific literature searching. The first is to distribute surveys to importers and dealers. This activity is mainly for products sold overseas, which will lead to difficulty of collecting information from patient and user themselves. So instead, we let importers and dealers to collect information and which will be reported through this survey. In Sept. 2022, we selected 14 distributors, deliver them total 3842 copies questionnaires as estimated (100copies, 1800copies,1942copies), and conduct surveys on the use of the products from Oct. 2022 to Oct. 2023. 100copies questionnaires were delivered, and 8copies have returned, and total 3cases reported from Imports and dealers, that white mist on the appearance of the restorations, light color (color difference), and cracked after fired. As tested the sample batches, no same problem reported. comes the determination that the cases above were not related the product quality defect, but related to the operation and production control by dental technician. And the problems also have been solved under the instruction by technician, take no further CAPA.

In Oct. 2023, we selected 15 distributors, deliver them 2546 copies questionnaires (100copies, 1800copies, 646copies as estimated), and conduct surveys on the use of the products from Nov. 2023 to Oct. 2024. 100copies questionnaires were delivered, 12copies have returned, including 4cases reported from Imports and dealers from US, Egypt, Brazil, and Turkey. Cases including Formative liquid leakage, an empty bottle for porcelain powder found, damaged shipping carton, and IFU missing. For those feedbacks in PMCF questionnaires, also had been recorded as PMS data instantly already for those complaints in feedbacks and CAPAs had been taken for each tracking ID. And those problems

also have been solved and the clients have taken the solutions, so for those results in PMCF activities, no need to take new CAPA.

The second is to distribute surveys to patients, dental professionals, and dental technicians. This survey is mainly for product sold within China where the manufacturer can get access to the terminal of each product. In Sept. 2022, we have delivered 1800 copies for Dental Technicians, 1942 copies for patients and dental professionals to investigate the use of products from 2022-2023. 20copies and 10copies from dental technicians, and patients and dental professionals respectively have returned, so far, there is no feedback related to recalls, even no any adverse events or complains.

In Oct. 2023, we have delivered 1800 copies for Dental Technicians, 646 copies for patients and dental professionals to investigate the use of products from 2023-2024. 23copies and 10copies for each group have returned, so far, there are 2 cases from dental technicians in China, and 5 feedback from Patients/Dentists in China, no feedback related to recalls. For those 3 cases in PMCF activities (Survey 2), also have been recorded in PMS data, and No CAPA need. For those 5 feedbacks from patients/dentists, so far, no CAPA need, just clinical use follow-up.

The last one is to review case reports which may reveal misuse or off-label use. Identifying possible systematic misuse or off-label use of the device. View such incidents by reviewing the results of the questionnaire and the feedback and complaint information collected by the company. In all surveys distributed, we have found no case on misuse or off-label use.

From all the results get from different activities of CER, it can be concluded that the safety and performance of the device under evaluation can be demonstrated.

Suggested profile and training of users

BAOT Dental Ceramic are designed for use by professional users. This specification is made clear by the labeling of BATO products with the symbol "Rx only". The specialist users are dentists and dental technicians who have excellent prior knowledge in the use of our products due to their many years professional training and/or university education. Follow-up training is the responsibility of the expert users and is offered by BAOT specifically for BAOT products. This guarantees safe handling of BAOT products at every point in the application process.

Information on residual risks, undesirable effects and warnings and precautions

a) Residual Risks

Possible complications and residual risks of Dental Ceramic (Metal Ceramic, Zirconia Ceramic) in general, and not specific to BAOT materials, are:

• Peeling and loosening of the restoration, resulting in possible choking

• Marginal gaps

• Plaque deposits

• Periodontitis

• Irritation of and damage to the mucosa

• Intolerance and potential allergic reaction

• Breakage

These risks must be communicated to the patient by trained personnel (e.g., dental professionals).
Please be aware, that these are possible complications and residual risks of the dental product group in general, and not specific to BAOT's Dental Ceramic materials.
These risks must be communicated to the patient by trained personnel (e.g., dental professionals).

b) Undesirable effects

There are no known undesirable effects for the products.

c) Warnings and precautions

When working with the products, wear suitable safety goggles/face protection, gloves and safety clothing.
These warnings and precautions can also be found in the corresponding instructions for use of the product(s).
The attentions for operation can be found in the IFUs: WI-TC-JC-026 A/1.pdf, WI-TC-ZCG-026 A/1.pdf.

Attachment 1: Product introduction of Metal Ceramic (JC) series

Category			Shades	State	Spec. (g)
Opaque	BOND		BOND	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
	Wash Opaque		WO	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
	Opaque	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
Dentine	Opacious Dentine	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Dentine	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Dentine Modifier	DM-1A DM-1B DM-1C DM-1D DM-1E DM-1F DM-1G DM-1H	Powder	2, 5, 7, 10, 15, 50, 100, 200

Enamel	Semi-transparent	Semi-transparent	E-1A E-1B E-1C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Semi-transparent Effect	EE-1A EE-1B EE-1C EE-1D EE-1E EE-1F EE-1G EE-1H	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Cervical	C-1A C-1B C-1C C-1D C-1C 003	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Cervical Effect	CE-1A CE-1B CE1-C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Opal Translucent	OT-1A OT-1B OT-1C OT-1D OT-1E	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Pearl Translucent	PL-1A PL-1B PL-1C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Luminary	LM-1A LM-1B LM-1C LM-1D LM-1E LM-1F LM-1G LM-1H	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Mamelon	MM-1A MM-1B	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Margin	M-1A M-1B M-1C M-1D	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Transparent	Transparent	T-1 T-1A T-1B T-1C T-1 061 T-1 062 T-1 064 T-1 063 T-1 065 T-1 068 T-1 071 T-1 075	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Window	WIN-1	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Gingiva	GIN-1A GIN-1B GIN-1B 073 GIN-1B 074 GIN-1B 076 GIN-1B 077	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Glaze	Glaze	G-1 G-1A	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		Corrective	COR-1A COR-1B COR-1C COR-1D	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		Stain	S-1A S-1B S-1C S-1D S-1A 011 S-1A 012 S-1A 013 S-1A 014 S-1B 021 S-1B 022 S-1B 023 S-1B 024 S-1B 025 S-1B 026 S-1B 027 S-1B 028 S-1C 031 S-1C 032 S-1C 033 S-1C 034 S-1C 035 S-1D 041 S-1D 042 S-1D 043 S-1D 044 S-1D 045 S-1D 046 S-1D 047 S-1D 048 S-1D 049	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15

Attachment 2: Product introduction of Zirconia Ceramic (ZCG) series

Category			Shades	State	Spec. (g)
Dentine	Opacious Dentine	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Dentine	16 color series	A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4	Powder	2, 5, 7, 10, 15, 50, 100, 200
		30 color series	B1M1 BL1 B1M1 BL2 B1M1 BL3 B1M1 BL4 B1M1 B1M2 B2L1.5 B2L2.5 B2M1 B2M2 B2M3 B2R1.5 B2R2.5 B3L1.5 B3L2.5 B3M1 B3M2 B3M3 B3R1.5 B3R2.5 B4L1.5 B4L2.5 B4M1 B4M2 B4M3 B4R1.5 B4R2.5 B5M1 B5M2 B5M3	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Dentine Modifier	DM-2A DM-2B DM-2C DM-2D DM-2E DM-2F DM-2G DM-2H	Powder	2, 5, 7, 10, 15, 50, 100, 200
Enamel	Semi-transparent	Semi-transparent	E-2A E-2B E-2C E-2A 201	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Semi-transparent Effect	EE-2A EE-2B EE-2C EE-2D EE-2E EE-2F EE-2G EE-2H	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Cervical	C-2A C-2B C-2C C-2D C-2C 203	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Cervical Effect	CE-2A CE-2B CE-2C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Opal Translucent	OT-2A OT-2B OT-2C OT-2D OT-2E	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Pearl Translucent	PL-2A PL-2B PL-2C	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Luminary	LM-2A LM-2B LM-2C LM-2D LM-2E LM-2F LM-2G LM-2H	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Mamelon	MM-2A MM-2B	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Margin	M-2A M-2B M-2C M-2D	Powder	2, 5, 7, 10, 15, 50, 100, 200
	Transparent	Transparent	T-2 T-2A T-2B T-2C T-2 261 T-2 262 T-2 263 T-2 264 T-2 265 T-2 268 T-2 271 T-2 275	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Window	WIN-2	Powder	2, 5, 7, 10, 15, 50, 100, 200
		Gingiva	GIN-2A GIN-2B GIN-2B 273	Powder	2, 5, 7, 10, 15, 50, 100, 200

	Glaze	Glaze	G-2 G-2A	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		Corrective	COR-2A COR-2B COR-2C COR-2D	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15
		Stain	S-2A S-2B S-2C S-2D S-2A 211 S-2A 212 S-2A 213 S-2A 214 S-2B 221 S-2B 222 S-2B 223 S-2B 224 S-2B 225 S-2B 226 S-2B 227 S-2B 228 S-2C 231 S-2C 232 S-2C 233 S-2C 234 S-2C 235 S-2D 241 S-2D 242 S-2D 243 S-2D 244 S-2D 245 S-2D 246 S-2D 247 S-2D 248 S-2D 249	Powder	2, 5, 7, 10, 15, 50, 100, 200
				Paste	2, 3, 5, 7, 10, 15

Attachment 3: Accessories of Dental Ceramic (Formative Liquid)

Specifications and models of Formative Liquid

Name	Category	Code	State	Spec(ml/bottle)
Formative Liquid	Modeling Liquid	CFS	Liquid	15, 50, 240
	Opaque Liquid	OF	Liquid	15, 50, 240
	Glaze & Stain Liquid	GY	Liquid	5, 15, 50, 240