

CE 1639 Rx^{only}



BETTER TRUST BETTER SMILE

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Instructions for Use

Bloomden Dental Zirconia Blank
& Dental Zirconia Pre-Shaded Blank



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BETTER TRUST BETTER SMILE

PRODUCT NAME

Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

DEVICE DESCRIPTION

Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank is composed of yttria-stabilized zirconia. Bloomden Dental Zirconia Blank is white, and it is composed of $ZrO_2+HfO_2+Y_2O_3$ and additional other oxides. Bloomden Dental Zirconia Pre-Shaded Blank is color (containing 20 available Vita shades), and it contains not only the ingredients same as the white zirconia blank but also a very small amount of additional inorganic pigments (Fe_2O_3 , Er_2O_3 , MnO/Co_3O_4). The blank is intended to be processed into dental restorations such as crowns, bridges, veneers, inlays, and onlays based on the anatomical rendering of the patient's teeth using CAD/CAM (computer aided design / computer aided manufacturing) method. The blank is provided non-sterile and it is single use in the "restoration" state.

CLINICAL BENEFIT OF THE PRODUCT

- _ Restoration of missing teeth and masticatory apparatus portions;
- _ Restoration of chewing function.

INTENDED PURPOSE

The blanks are intended to be processed into the custom-made dental restorations such as crowns, bridges, veneers, inlays, and onlays.

TARGET PATIENT POPULATION

Suitable for patients of all ages and genders.

INDICATIONS

HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 14-unit teeth, i.e. the manufacturing of

- _ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);
- _ anatomically reduced and fully anatomical (monolithic) bridges (up to 14 units) in the anterior and posterior tooth range.
- UT, UT-C, UT-ML, UTP, UTP-C, UTP-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 3-unit teeth, i.e. the manufacturing of
- _ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);
- _ anatomically reduced and fully anatomical (monolithic) bridges (up to 3 units) in the anterior and posterior tooth range.

CONTRAINDICATIONS

- _ Hypersensitive to the components;
- _ Insufficient preparation;
- _ Insufficient oral hygiene;
- _ Provisional insertion.

INTENDED USERS

The zirconia blanks shall be processed by dental technicians. And the prepared restorations shall be handled by certified dental professionals.

INTENDED ENVIRONMENT

The zirconia blanks shall be processed in dental laboratories. And the prepared restorations shall be handled in dental departments in hospitals or dental clinics with the environment clean.

CHEMICAL COMPOSITIONS**Table 1 Chemical Compositions**

Model	Composition (in wt%)		
	$ZrO_2+HfO_2+Y_2O_3$	Y_2O_3	Other oxides ¹
HT-plus	≥99%	4.5%~6.0%	<1.0%
ST	≥99%	4.5%~6.0%	<1.0%
ST-C	≥98%	4.5%~6.0%	<2.0%
ST-ML	≥98%	4.5%~6.0%	<2.0%
SHT	≥99%	6.5%~8.0%	<1.0%
SHT-C	≥98%	5.5%~8.0%	<2.0%
SHT-ML	≥98%	5.5%~8.0%	<2.0%
3D-Pro-ML	≥98%	4.5%~8.0%	<2.0%
UT	≥99%	8.0%~10.0%	<1.0%
UT-C	≥98%	8.0%~10.0%	<2.0%
UT-ML	≥98%	8.0%~10.0%	<2.0%
HTP-plus	≥99%	5.0%~6.0%	<1.0%
STP	≥99%	6.0%~7.0%	<1.0%
STP-C	≥98%	6.0%~7.0%	<2.0%
STP-ML	≥98%	6.0%~7.0%	<2.0%
SHTP	≥99%	8.0%~9.0%	<1.0%
SHTP-C	≥98%	7.0%~9.0%	<2.0%
SHTP-ML	≥98%	7.0%~9.0%	<2.0%
3DP-Pro-ML	≥98%	8.0%~9.0%	<2.0%
UTP	≥99%	9.0%~10.0%	<1.0%
UTP-C	≥98%	8.0%~10.0%	<2.0%
UTP-ML	≥98%	8.0%~10.0%	<2.0%

Note: 1 Other oxides mainly include Fe_2O_3 , Er_2O_3 , MnO and Co_3O_4 .

MODELS AND SPECIFICATIONS

As shown in Table 2, Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank has 22 models classified by the translucency and color. Each model has three shapes designed for different milling systems, i.e. disc, D-shape, and cube (see Table 3).

Table 2 Product Models and Specifications

Model	Description	Specification			Note
		Color/Shade	Shape	Dimension/mm	
HT-plus	High-plus Translucency	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
ST	Super Translucency	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
ST-C	Super Translucency - Color	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
ST-ML	Super Translucency - Multilayer	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of four gradated shade layers except the bank of 30 mm height consisting of seven layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	

Model	Description	Specification			Note
		Color/Shade	Shape	Dimension/mm	
SHT	Super-high Translucency	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
SHT-C	Super-high Translucency - Color	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
SHT-ML	Super-high Translucency - Multilayer	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of four gradated shade layers except the bank of 30 mm height consisting of seven layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
UT	Ultra Translucency	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	

Model	Description	Specification			Note
		Color/Shade	Shape	Dimension/mm	
UT-C	Ultra Translucency - Color	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
UT-ML	Ultra Translucency - Multilayer	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of four graded shade layers except the bank of 30 mm height consisting of seven layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
3D-Pro-ML	3D-pro -Multilayer	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of five graded shade and translucency layers except the bank of 30 mm height consisting of nine layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
HTP-plus	High-plus Translucency - plus	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	

Model	Description	Specification			Note
		Color/Shade	Shape	Dimension/mm	
STP	Super Translucency - plus	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
STP-C	Super Translucency - Color - plus	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
STP-ML	Super Translucency - Multilayer - plus	Color Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of four graded shade layers except the bank of 30 mm height consisting of seven layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
SHTP	Super-high Translucency - plus	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	

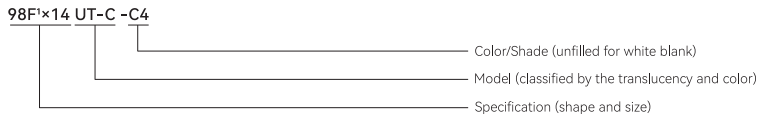
Model	Description	Specification			Note
		Color/Shade	Shape	Dimension/mm	
SHTP-C	Super-high Translucency - Color - plus	Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
SHTP-ML	Super-high Translucency - Multilayer - plus	Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of four graded shade layers except the bank of 30 mm height consisting of seven layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
UTP	Ultra Translucency - plus	White	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
UTP-C	Ultra Translucency - Color - plus	Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The color of the entire blank is identical.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	

Model	Description	Specification			Note
		Color/Shade	Shape	Dimension/mm	
UTP-ML	Ultra Translucency - Multilayer - plus	Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of four graded shade layers except the bank of 30 mm height consisting of seven layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	
3DP-Pro-ML	3D-pro -Multilayer - plus	Available shade: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	DISC	Diameter × Height: 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×30, 98F×10, 98F×12, 98F×14, 98F×16, 98F×18, 98F×20, 98F×22, 98F×25, 98F×30, 95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×30	The blank consists of five graded shade layers except the bank of 30 mm height consisting of nine layers.
			D-shape	Length × Width × Height: 92×75×12, 92×75×14, 92×75×16, 92×75×18, 92×75×20, 92×75×25, 92×75×30	
			Cube	Length × Width × Height: 20×15×14, 20×15×19, 40×15×14, 40×15×19, 55×15×19, 65×25×20, 65×25×22, 65×40×22, 85×40×22	

Table 3 Compatible Milling Systems

Shape		Compatible Milling System
Disc	Diameter of 95mm	Zikronzhan CAD/CAM automatic cutting system
	Diameter of 98mm and 98F	Wieland open cutting system
D-shape		Amann Girrbach CAD/CAM automatic cutting system
Cube		Sirona CEREC CAD/CAM automatic cutting system

Bloomend Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank is designated as follows.



Note: 1 Only for Disc 98F, which indicates the blank has a "Frame".

PHYSICAL CHARACTERISTICS

Table 4 Performance Characteristics and Applications

Model	Classification (per ISO 6872:2024)		Performances			
	Type	Class	CTE (25-500°C) ($\times 10^{-6} \text{ K}^{-1}$)	Flexural strength after sintering (MPa)	Chemical solubility after sintering ($\mu\text{g}\cdot\text{cm}^{-2}$)	Radioactivity (Bq.g ⁻¹)
HT-plus	II	5	10.5±0.5	≥800	< 100	≤1.0
ST	II	5				
ST-C	II	5				
ST-ML	II	5				
SHT	II	5				
SHT-C	II	5				
SHT-ML	II	5				
3D-Pro-ML	II	5				
HTP-plus	II	5				
STP	II	5				
STP-C	II	5				
STP-ML	II	5				
SHTP	II	5				
SHTP-C	II	5				
SHTP-ML	II	5				
3DP-Pro-ML	II	5				
UT	II	4	10.0±0.5	≥500	< 100	≤1.0
UT-C	II	4				
UT-ML	II	4				
UTP	II	4				
UTP-C	II	4				
UTP-ML	II	4				

INSTRUCTION FOR USE

1. Take the zirconia blank from the packaging and confirm that the blank does not have a crack or other damage.
 2. Fix the zirconia blank in the suitable milling machine (see Table 3).
 3. Start the milling process following the milling system's technical instructions.
 4. After milling, remove the restorations from the blank with a diamond disc, and inspect the restorations carefully to ensure that they can the following criteria:
 - There should be no visible discoloration.
 - The material should show no signs of chipping.
 - There should be no visible cracks.
 5. Remove the dust from the restoration with a gentle air stream.
 6. Color the restorations with the coloring liquid, final-dry the restorations under infrared lamp following the instructions for use of the coloring liquid.
- Note: This step only applies to the white zirconia blank, i.e. HT-plus, ST, SHT, UT, HTP-plus, STP, SHTP, and UTP.
7. Place the restorations into the sintering furnace.
 8. Select the appropriate sintering schedule (see Table 5, 6 and 7) and start sintering.

Table 5 Sintering Schedule for HT-plus/ST/ST-C/ST-ML/SHT/SHT-C/SHT-ML/
HTP-plus/STP/STP-C/STP-ML/SHTP/SHTP-C/SHTP-ML/3DP-Pro-ML/UTP/UTP-C/UTP-ML

Step No.	Initial Temperature (°C)	Heating Rate (°C/min)	Final Temperature (°C)	Holding Time (min)
1	Room temperature	5.0	900	-
2	900	8.0	1530	120
3	1530	-5.0	900	-
4	900	Free cooling	Room temperature	-

Table 6 Sintering Schedule for 3D-Pro-ML

Step No.	Initial Temperature (°C)	Heating Rate (°C/min)	Final Temperature (°C)	Holding Time (min)
1	Room temperature	5.0	900	-
2	900	8.0	1480	120
3	1480	-5.0	900	-
4	900	Free cooling	Room temperature	-

Table 7 Sintering Schedule for UT/UT-C/UT-ML

Step No.	Initial Temperature (°C)	Heating Rate (°C/min)	Final Temperature (°C)	Holding Time (min)
1	Room temperature	5.0	900	-
2	900	8.0	1450	120
3	1450	-5.0	900	-
4	900	Free cooling	Room temperature	-

Note: The sintering furnace are recommended to be calibrated to ensure the accuracy of the sintering temperature. Otherwise, the set sintering temperature may need to be adjusted according to the actual conditions of the sintering furnace.

9. After sintering, check frame on working model for sitting and margin fit. Adjust the restorations with a diamond grinder and polisher if required.

10. Confirm that the restorations have no cracks.

11-1. FCZ (Full contour zirconia):

➤ Glaze baking: Create a high shine surface by polishing, especially on the contact areas then apply the glaze on all surfaces following the instructions for use of the glaze.

➤ Hand polishing: Create a high shine surface on the entire restoration by polishing without using the glaze.

11-2. Frameworks: Build-up the dental porcelain on the frameworks following the instructions for use of the dental porcelain.

12. Fixing

The restorations may either be cemented using traditional cements (such as zinc phosphate or glass ionomer cement) or adhesively bonded using conventional or self-adhesive composite resin cements following the instructions for use of the cements. Ensure that surfaces are retentive and that stump height is at least 3 mm.

COMPATIBLE DEVICES AND EQUIPMENT

The devices intended to be used in combination with our zirconia blanks include:

- 1) Coloring liquid;
- 2) Glaze and dental porcelain: check the coefficient of thermal expansion in their labeling to confirm compatibility;
- 3) Cements: traditional cements such as zinc phosphate or glass ionomer cement, or conventional or self-adhesive composite resin cements.

Please choose and use the legally marketed devices. Before use, please read their instructions for use to ensure that they can be used with zirconia restorations.

The equipment used in processing our zirconia blanks into the restorations includes:

- 1) Milling system: choose the compatible milling system as shown in Table 3;
- 2) Sintering furnace: check its user manual to ensure that it can provide the specified sintering schedule for our zirconia blank;
- 3) Mechanic handpieces with different grinding heads.

Please choose and use the legally marketed equipment during processing our zirconia blanks into the restorations. Before use, please read their user manuals to ensure that they can be used to process zirconia restorations.

STORAGE

The product should be stored in the original packaging, in a dry place, at room temperature and away from the direct sunlight.

SHELF LIFE

Five years.

UNDESIRABLE SIDE EFFECTS/RESIDUAL RISKS

_ Mechanical failure (fracture of the restoration, chipping of the ceramic veneer or detachment of the restoration/loss of retention) with low risk of possible ingestion or reversible mucosal injuries.

_ Biological incompatibility (plaque accumulation, intolerance reactions, marginal/secondary caries, loosening of the supporting teeth) resulting in possible loss of the restoration.

WARNINGS

If the patient or the dental professional demonstrates a hypersensitivity reaction, such as rash, dermatitis etc., discontinue use of the product and seek medical attention immediately.

CAUTIONS

1. Do not use products beyond the expiration date.

2. Please storage the products in the conditions as specified in "STORAGE", otherwise the performances of the product may be affected.

3. The product is fragile, avoid shock and vibration when handling.

4. When choosing the devices and equipment in combination, please strictly comply with the requirements in "COMPATIBLE DEVICES AND EQUIPMENT". Otherwise, the performance of restorations may be affected.

5. Don't apply to patients before the material is fully sintered.

6. The product is a partially sintered ceramic material and shrinks during sintering, so it is vital to take into account the appropriate shrinkage factor during milling to ensure the precise fit of the restoration. The specific shrinkage factor is labeled on each blank.

7. This product shall only be handled by the dental specialist.

8. When milling the blank or cutting, grinding and polishing the restorations, wear an approved dust respirator to protect your lungs from inhaling dust.

9. When milling the blank or cutting, grinding and polishing the restorations, wear safety glasses to prevent the dust from getting into your eyes. If the dust gets into your eyes, immediately rinse with water and consult a physician.

10. Ensure that the following thicknesses are still present after finishing (see Table 8).

Table 8 Recommendation for Wall Thickness

Model	Location & Indication	Wall thickness (mm)
HT-plus/HTP-plus	Anterior crown or bridge	0.4 or more
	Veneer	0.4 or more
	Posterior crown or bridge	0.5 or more
	Inlay or onlay	0.5 or more
ST/ST-C/ST-ML/SHT/SHT-C/SHT-ML /3D-Pro-ML/UT/UT-C/UT-ML/STP/STP-C /STP-ML/SHTP/SHTP-C/SHTP-ML /3DP-Pro-ML/UTP/UTP-C/UTP-ML	Anterior crown or bridge	0.8 or more
	Veneer	0.4 or more
	Posterior crown or bridge	1.0 or more
	Inlay or onlay	1.0 or more

11. Use the following cross-sectional areas for connectors when fabricating bridges (see Table 9).

Table 9 Recommendation for Connector Cross-sectional Area

Model	Location & Indication	Connector cross-section area (mm ²)
HT-plus/HTP-plus	Anterior, 2-or 3-unit bridges	7 or more
	Anterior, more than 3-unit	9 or more
	Posterior, 2-or 3-unit bridges	9 or more
	Posterior, more than 3-unit	9 or more
ST/ST-C/ST-ML/SHT/SHT-C /SHT-ML/3D-Pro-ML/STP /STP-C/STP-ML/SHTP /SHTP-C/SHTP-ML/3DP-Pro-ML	Anterior, 2-or more unit bridges	12 or more
	Posterior, 2-or more unit bridges	16 or more
UT/UT-C/UT-ML /UTP/UTP-C/UTP-ML	Anterior, 2- or 3-unit bridges	12 or more
	Posterior, 2- or 3-unit bridges	16 or more

12. It is advised not to use coolant during the milling process as it may lead to color changes and/or loss of transparency.

13. Do not use the blank if there is a crack after removing it from the package.

14. If you find a crack in the restorations, do not use.

15. Please check and confirm the arrow direction on the label on the zirconia blank, which indicates the incisal edge for the prosthesis, when processing ST-ML, SHT-ML, UT-ML, 3D-Pro-ML, STP-ML, SHTP-ML, UTP-ML, and 3DP-Pro-ML.

16. Do not reuse the restoration. There may be cracks in the reused restorations, even invisible small cracks may bring the risk of fracture of the restoration. In addition, if a restoration is reused between different patients, there are mainly two additional risks: 1) cross-infection, 2) mismatch between the restoration prepared for one patient and the base teeth of another patient, which can badly effect the restoration.

17. Please keep the paper IFU for reference. You can also obtain the electronic instruction for use by scanning the QR code (eIFU) on the label with the "scan" function of a browser using a mobile device.

DISPOSAL

The material is not hazardous to the environment.

The residual zirconia blanks and restorations that have not been used in the patient's mouth can be disposed of together with house hold waste, but do not dispose of them into sewer systems.

If the restorations have been used in the patient's mouth, please disposed of them as medical waste according to the National and regional regulations.

EUROPEAN REPRESENTATIVE

Name: Wellkang Ltd

Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland

Tel No: +44(20)3287 6300

Email: AuthRep@CE-marking.eu

Please note that this section is only relevant to the MDR version of Instructions for Use .



















MANUFACTURER

Name: Bloomden Bioceramics (HuNan) Co., Ltd

Address: No.301, 5th Building, Hi-tech Int'l Enterprise Port, LianDong U Valley, Linyu Rd, Dongfanghong Street, Hi-tech Development Zone, Changsha, HuNan, China

Phone: +86-731-84210831

EXPLANATION OF SYMBOLS AND ABBREVIATION

	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE		WARNING
	DATE OF MANUFACTURE		UNIQUE DEVICE IDENTIFIER		BATCH CODE
	USE-BY DATE		PRESCRIPTION ONLY		KEEP DRY
	F VALUE		SHRINKAGE FACTOR		COEFFICIENT OF THERMAL EXPANSION
	EUROPEAN REPRESENTATIVE		CE MARKING 1639: IDENTIFICATION NUMBER OF NOTIFIED BODY		MEDICAL DEVICE
	ARROW DIRECTION INDICATES THE INCISAL EDGE FOR THE PROSTHESIS		FRAGILE		DO NOT REUSE

NOTE

The product shall be used only by trained personnel. The manufacturer is not liable for any erroneous results, since we have no control if this instruction is properly followed or if the product is appropriately used. Any claims for damages therefore shall be limited exclusively to the commercial value of our products.

Please make sure that the dentist has received all of the necessary information for the correct use of the product.