

MANUFACTURER

The manufacturer of the DB+; DB+LUX products is:

Bettini S.p.A.

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ITALY

CE MARKING

CE 0476 (notified body)

PRODUCT IDENTIFICATION

Pre-sintered ceramic blanks used to make dental prosthetic frames, through consequent milling and sintering processes. The general codes of the products are DB+, DB+LUX .

USE DESTINATION

Ceramic components (Zirconia, Yttrium stabilized) for construction of dental prosthetic frames, classified as part of class II A of 93/42/CEE rule and supplemented by 2007/47/CEE rule related to medical devices.

Use Environment: dentists, odontologists and dental technicians laboratories, or enabled environment according to rule in force.

Operator Typology: professionals enabled to production and manufacturing of dental prosthetic frames (example: dental technicians) or professionals with milling activity, within enabled environment according to rule in force.

NOTE: the positioning in the oral cavity of the obtained structure is an exclusive task and responsibility of medical personnel, enabled as per laws in force (example: dentists).

Clinical Scope of the device: material for manufacturing of dental prosthetic frames. The DB+, DB+LUX products must only be used for manufacturing of the above mentioned frames, which is to say objects which are put inside the oral cavity and not inserted into gums or bones.

The DB+, DB+LUX products must NOT be used for manufacturing of screws or other components that, because of their use typology and classification, are different than dental prosthetic frames.

Warnings (possible undesirable effects)

At the date of creation of this paper, undesirable effects have not been noticed. In case of appearance of allergenic or other undesirable effects, consult a doctor.

The mechanical and chemical features of the components are achieved after sintering (ref.: sintering curve); **a mechanical machining different than the one suggested in the User's Manual, a sintering curve different than the one suggested in the User's Manual and a not adequate firing of aesthetical coating materials which can be laid upon, may lead to reduced mechanical and chemical features of the device. We do suggest the validation of both machining and sintering systems by enabled operators.**

Contra-indications

The DB+, DB+LUX products must NOT be used for manufacturing of screws or other components that, because of their use typology and classification, are different than dental prosthetic frames.

Even if at the current stage of knowledge, serious allergenic sensitivities have not been reported, it is a duty of the dentist, in presence of a potentially allergic patient, to check the patient compatibility of DB+ , DB+LUX products when placed into its oral cavity.

Product handling

The DB+, DB+LUX products are very brittle; they have to be handled with care.

The DB+ , DB+LUX products must not be ingested.

The DB+, DB+LUX products must be inserted into the oral cavity only after being sintered as per the firing cycle reported into the User's Manual.

SYMBOLS (according to UNI CEI EN 980 : 2009 rule)



CE mark.



Do not expose to humidity and frost.



Store within the temperature range.



Read instructions.



Components lot number.



Non-sterile product

INSTRUCTIONS FOR USE

Description of the device

The device is made of ceramic components (Yttrium stabilized Zirconia) for dental prosthetic frames; these frames are obtained through consequent milling and sintering processes.

Suggested operational steps

The pre-sintered DB+, DB+LUX components have to be machined according to the following suggested procedure:

- 1) Insert the component onto the holding tool of the milling machine (cam)
- 2) Program the milling process according to the wanted final dimension of the structure (for the shrinkage of the material, please refer to the shrinkage calculation)
- 3) Machine the component with tungsten carbide or diamond coated milling tool, “according to the indications suggested by the manufacturer of the system used”.
- 4) During machining operation, clean the structure with air jets, ensuring an appropriate exhausting in the working area.
- 5) Dry the structure with an infrared lamp or with drying oven.
- 6) Visually check the integrity of the structure made, before sintering.
- 7) Place the ceramic structure into the sintering kiln.
- 8) Close the kiln and start the sintering cycle according to the manufacturer’s instructions.
- 9) At the end of the sintering cycle, remove the structure from the kiln, only after the kiln is back to room temperature.
- 10) Test the ceramic structure on the reference model, check its precision and, in case a slight change is necessary, re-finish using diamond coated tools with water cooled turbine.
- 11) The so obtained sintered structure can then be sand-blasted, if necessary using a 60/100 µm aluminium dioxide, at a pressure of 1÷2 bar.
- 12) Hygienize the sintered structure with water. Do not use steam or autoclaves.

SUGGESTED TIPS FOR MACHINING OF DENTAL ARCS OR SINGLE TEETH

Having the requirement to make a multiple extended prosthetic frames or a complete dental arc it is necessary to preserve the integrity of all the surrounding material. This is possible having the care to keep the surrounding material in union with the structure, by leaving small “junctions” or “connectors” which will be cut after sintering. This is useful in order to avoid deformation of the machined structure during the sintering process, and for its positioning on the firing plate of the kiln, avoiding undesirable contacts.

Having the requirement to get several prosthetic frames or single teeth from the same blank, it is necessary to provide time by time to the filling of the generated cavities, using materials able to damp vibrations during the milling operation (example: wax, plaster, silicone, etc.). The vibrations might effect the integrity of the not yet used pre-sintered ceramic material.

SHRINKAGE CALCULATION

The pre-sintered ceramic material is subjected to a shrinkage during sintering process, which will reduce its initial dimensions. In order to make a milling on a pre-sintered material is necessary, first of all, to know the dimensions of the final dental prosthesis:

- a) in case the method of the multiplying coefficient is used; each dimension of the final prosthesis has to be multiplied by this coefficient. Its value is indicatively **1,250 ± 0,007**, each single lot has its multiplication coefficient specified on the package.
- b) In case the method of shrinkage percentage is used, whose formula is $[(presint. - sint.) / (presint.)] * 100$, each dimension of the final prosthesis has to be multiplied by the following value: **100 / (100-shrinkage percentage)**, specified on the package for each single lot.

The so obtained values(for each dimension, following one of the above methods) are the dimensions that the prosthesis must have, before its sintering in the kiln.

The values of the shrinking coeff. are based on Bettini's experience which was developed according to several testing based on machineability and density of the material at green and sintered stages.

The coefficient of shrinkage is determined (see quality flow chart) as the difference of shrinkage between pre-sintered and sintered samples on which are made visual, weight and dimensional testing.

WARNINGS

Apply an adequate exhausting system when machining, in order to avoid the inhalation of powders. Do not use continuously the air jet for cleaning while machining, in order to avoid spreading of powders in the air.

Protect the respiratory apparatus by using a suitable thin powders protective mask.

Use security glasses during direct machining.

Do not ingest the product.

The DB+, DB+LUX products have to be placed into the oral cavity only after being sintered as per sintering cycle reported on the User's Manual.

The DB+ and DB+LUX products are sold non sterilized.

For sterilization:

Zirconia (Zirconia stabilized with sintered Yttrium), is a polymorphous material. In order to avoid quality decay due to phase transformation, the material must not be sterilized with steam or autoclaves or chemical products(except ethylene oxide). The use of gamma ray may cause chromatic change in the product.

The sterilization of the zirconia components takes place during the sintering cycle as the maximum temperature of sintering is 1450 C° for two hours (sintering atmosphere: air). This process ensures that any bacteria or viruses (potentially present in the ceramic parts) are completely decomposed and destroyed by the high temperature and that any potential pyrolyzed carbon residuals are burned away completely by the air in the kiln.

The dental technicians, sintering kilns, denture packaging machines including bags and kiln and machine locations must all be under strict sterile conditions, as already provided by health regulations.

Note: the sterilization process must be performed only once.

STORAGE AND LIFE

Do not expose to humidity and frost.
Do not exceed 50°C and do not fall below 5°C.

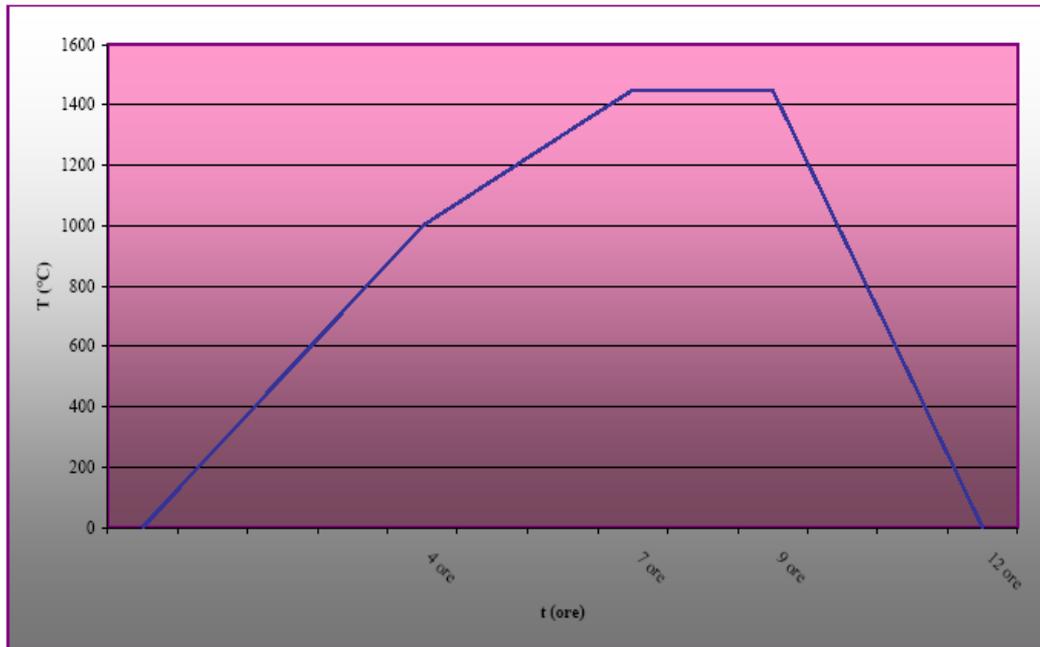
NOTE: The final machining on the sintered material may alter biological, chemical, physical, mechanical properties of the product: the temperature achieved during machining (milling) on the sintered DB+SINT and DB+LUX SINT; DB+ and DB+LUX(in case of slight correction on sintered components) must not exceed 70°C⁴

Use(when machining) a water jet in order to cool down the ceramic structure.

Suggested sintering cycle fo DB+, DB+LUX components

Atmosphere:	air
Stand by at 1450°C:	2 hours

The mechanical properties, reported on technical data, have been obtained according to the following cycle; different cycles than this will have to be validated by enabled operators.



Alarms and warnings

There are not devices for alarm warnings.

Procedures for re-use (device cleaning and installed components, controls)

The DB+ and DB+SINT; DB+LUX and DB+LUX SINT products are not re-usable: from a single blank is possible to obtain several prosthesis (if allowed by its dimensions); once the prosthesis have been installed onto a patient, they must not be transferred onto another patient.

Wasting

Waste according to law in force.

PRECAUTIONARY MAINTENANCE AND REPAIRING

The product is not repairable.

In case of damage (cracks, breakage etc...) the product must not be further machined and must not be inserted into the oral cavity.

TECHNICAL CHARACTERISTICS AND/OR REFERENCE RULES

The above products are ceramic components to be used to obtain ceramic dental prosthetic frames to be inserted into the oral cavity (after their milling and sintering); the products have excellent characteristics of chemical inertia, mechanical resistance and bio-compatibility.

NON-CONFORMITY REPORTS

In order to maintain high level of customer's satisfaction, dentists and dental technicians are asked to report any possible non-conformity found on DB+, DB+LUX products; they have to indicate the batch number, the code number and the reason for complaint. A sample has to be sent to the manufacturer who will carry out, at his charge, the relevant analysis.

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