CE 0123

Instruction for use

State 1/2020

1. General:

SOLIBOND C *plus* blanks, powder and CoCr sintering blanks are clinical proved nickel and beryllium free Cobalt-Chrome alloy for application in dental area. Present documents contains instructions which have to be followed for secure production and proper usage of the products. It is absolutely essential to read this instructions the before usage.
SOLIBOND C *plus* blanks and CoCr sintering blanks are predestinated for processing of objects from digital data in milling machines.
Solibond C *plus Powder* is specified for laser melting because of it micro-fine powder structure .

1.1. Product description/ Delivery:

Laser melting	**Art.**	**969-5000**	**Solibond C plus Powder**	**5000g**
Milling	**Art.**	**969-9010**	**Solibond C plus blank**	**10 mm**
Milling	**Art.**	**969-9012**	**Solibond C plus blank**	**12 mm**
Milling	**Art.**	**969-9013**	**Solibond C plus blank**	**13,5mm**
Milling	**Art.**	**969-9015**	**Solibond C plus blank**	**15 mm**
Milling and sintering	**Art.**	**969-9110**	**CoCr sintering blank**	**10 mm**
Milling and sintering	**Art.**	**969-9112**	**CoCr sintering blank**	**12 mm**
Milling and sintering	**Art.**	**969-9114**	**CoCr sintering blank**	**14 mm**
Milling and sintering	**Art.**	**969-9116**	**CoCr sintering blank**	**16 mm**
Milling and sintering	**Art.**	**969-9118**	**CoCr sintering blank**	**18 mm**
Milling and sintering	**Art.**	**969-9120**	**CoCr sintering blank**	**20 mm**

1.2. Manufacturer:

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2. General information

Biocompatible Cobalt-Chrome dental alloy and sintering alloy with less oxide film, to be used only by dental technicians for dental restorations in the patient's mouth. Medical product according RL 93/42 EWG. This dental alloy serve for the production of custom-made alloy constructions according the instructions of a dentist. Keep away from frost, contamination, protected against shock and impact. Store blanks which were started to mill in original package.

3. Indikation

For production of dental restorations such as crowns and bridges using milling machine for processing of CoCr sintering blanks and Solibond C plus blanks or using laser melting machine for Solibond C plus powder.
Thickness of crown walls and connectors, as well as whole construction are based on the expert knowledge of qualified dental specialists. For CoCr sinering blanks design construction with not more than 2 connectors in posterior area.
Preparations in form of chamfer or rounded steps with 1 mm contact area. Substance removal occlusal and incisal 1,5-2 mm, edge radius 0,7 mm, preparation angle 6-8°.

3.1 Information for usage Rx only

Only educated and experienced dental technicians fulfils the requirements for the proper use of this medical product. For the bridge constructions it is advisable to make the sufficient size of connections and to strength the construction by garland. Sufficient wall thickness always have to be taken in account. We advice the thickness of at least 0,35 mm for Solibond C plus blanks and Solibond C plus powder.
For CoCr sintering blanks we advice during construction to take in account following information.
Anterior teeth: Wall thickness 0,4 mm, cross section of connectors 6 mm²
Posterior teeth/Abutment teeth: Wall thickness 0,6 mm, cross section of connectors 9 mm²
The bridge have to be constructed in accordance with necessities of ceramics application.

3.2 Digital processing of blanks

Unpack CoCr sintering blank carefully. Cecke it, pay attention that the blank must have no traces of shocks, cracks or demolitions. Fix sintering blank in the milling machine carefully, dont clamp it too firmly. Follow the instructions of machine producer strictly. Set the data which corresponds to the file of processing of CoCr sintering alloys. Process the blank as stated. Pay attention that suction unit is working properly during milling. Operator should wear goggles and a dust mask.
We advice to use radius milling cutter with three cutters and cross section of 2 mm for processing of Solibond C plus blanks and Co Cr sintering blanks. For finishing use radius milling cutter with two cutters and a cross section of 1 mm. Always set correct enlargement factor for CoCr sintering blanks.

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For constructions with four and more connectors we advice to use generously dimensioned sintering bar and connectors of sufficient dimensions.
Separate connectors with cross-toothed milling cutters and remove chips with fine brush. Protect for humidity, do not use steamer or ultrasonic for cleaning.

Solibond C plus powder is suitable for common laser melting machines with similar alloy grain size. Laser parameter have to be setted individualy and structural density of produced objects have to be proofed.
To avoid the material tension we advise a firing for constructions with 4 and more units according the instructions of the machine producers and, if possible, using argon gas.

3.2.1 Sintering (only for CoCr sintering blanks)
Milled objects should be sintered immediately after milling to reduce the influence of air humidity and of temperature changes. Place the objects in stable way but without pressure onto sintering beads or sintering plate. Do not clamp any beads in interdental space.
Sintering process takes place with usage of Argon starting by 500°C, take in account following recommendations. Sintering time is ca. 4 hours, sintering object has even silvergrey colour. After sintering cool the object down to the room temperature before processing.
For finishing use ceramic-bonded grinding tools or cross-toothed milling cutters for hard alloys and clean the construction (steamer, ultra sonic, distillated water) bevore application of ceramics. das Gerüst gut säubern (Dampfstrahler, Ultraschallgerät mit dest. Wasser) bevor die Keramik aufgetragen wird. Use artery forcepts and do not touch the construction with finger after cleaning.

	°C/min	Temperature	Hold time
1.	14°C	1130°C	0 min.
2.	5°C	1280°C	30 min.
3,	25°C	700°C	0 min.
4.	50°C	400°C	0 min.

Data for HTS Metal furnace of Mihm-Vogt GmbH & Co KG Germany. For other sintering furnaces adapt this data individually.

3.5. Ceramics firing
Oxide firing is advisable and should be processed for objects from Solibond C plus blanks and Solibond C plus powder at 960°C for 5 min. For objects from CoCr sinter blanks we adviser 980°C and 1 min. hold time. After it blast with aluminium oxide of 100-250 my size and on 3-4 bar. Clean with water or steamer. Never strip the non precious alloys. Make ceramic firing and colling in accordance with instructions of ceramics producer.
Outgoing of previous experience, long time cooling down for dentin, correction and glaze firing is not necessary for K2LF or PoM (press over melall).

3.6 Soldering
SOLIBOND C plus blank and Solibond C plus powder can be soldered with **LOT UNIVERSAL** Art. 960-0000. Do not use Gold or Palladium soldering.
CoCr sintering blanks can be laser welded or soldered with cobalt based lot. Do not use Gold or Palladium soldering.

4 . Storage information
CoCr sinter blanks metallic grey and Solibond C plus blanks & powder metallic silber can be applied until the product are completely used.
In case of shock sintering blank can get cracks or brake. We advise
- keep it in original packinging in dry condition between 5° and 50°C. Avoid direct sun light
- be careful in handling, avoid shocks or impacts
- CoCr sintering blank should have no contact with chemicals or solvents
- visual check of complete surface (cracks), in case of doubt do not use it after shock. There is high probability of cracks in alloy during sintering.

5.0 Contradictions
Do not use in case of intolerances or allergical reactions in the mouth on components of this alloy. Can not be used by not sufficiently trained or unexperienced in construction dental technicians.
Follow the limitation of connectors quantity and do not use the sintering blank if any damages are visible.
Prepared tooth stumps shorter than 3mm can not be used.

6.0 Safety instruction
Alloy dust is hazardous, use exhaust system while working. Take in account possible hypersensitivity against the alloy components.
Above-mentioned instructions are based on own experience. Damage claims basd on our recomendation can not be higher than the value of delivered goods.

Cleaning and desinfection of patient mouth have to be maken in accordance with clinical praxis before placement of the constructions. For fixation use commercially available cements or with glass ionomer cement for preparations higher than 3 mm.

7.0 Warranty

For sintering blanks there ist the warranty of one year on manufacturing faults due to faulty materials. The warranty voids in case of:

- improper use because of non-observance of this instructions
- non-conform use, negligence while processing or mistakes in design and cosntruction
- force majeure or transit damage on delivered shipmen, where this damage can not be covered by transport company insurance.

In warranty case Yeti Dentalprodukte GmbH makes free of charge replacement of the unprocessed material. Condition is the sending to Yeti defective parts for analyse. Further compensation for damages is excluded.

7.1 Customer service:

In case of possible problems during processing or for improvement suggestions we advice you to note the lot number and to contact Yeti Dentalprodukte GmbH.

7.2 Disposal:

After the placement in the patient mouth the product should be disposed as hazardous medical waste. Please adhere to national and regional regulations.

8. For your attention

All regulatory requirements and local regulations for ordering, processing and disposal should be taken in account and fulfilled.

9. Symbols

	**Producer**
	**CE sign with number of notified body**
	**Consult operating instructions**
	**FOR DENTAL PROFESSIONALS ONLY (USA)**
	**Non-sterile product**
	**Order number**
	**Lot number**
	**Production date**
	**Warning**
	**Protect from sunlight**

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Certificate

Product name: **SOLIBOND**

Indication: **Metal to ceramic Co Cr alloy**

Delivery form:

Art. 969-5000	**Solibond C plus Powder**	**5000g**
Art. 969-9010	**Solibond C plus Blank**	**10 mm**
Art. 969-9012	**Solibond C plus Blank**	**12 mm**
Art. 969-9013	**Solibond C plus Blank**	**13,5mm**
Art. 969-9015	**Solibond C plus Blank**	**15 mm**
Art. 969-9110	**CoCr sintering Blank**	**10 mm**
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Art. 969-9116	**CoCr sintering Blank**	**16 mm**
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Chemical composition Solibond C plus powder according to **EN 10204 – 2.2**

Co %	Cr %	W %	Mo %	Nb %	Si %	
63	24	8,1	2,9	0,9	1,1	

Chemical composition Solibond C plus blank according to **EN 10204 – 2.2**

Co %	Cr %	Mo %	Si %	Fe %	Mn %	Nb
63	29	5,8	1,2	< 0,1	< 0,1	< 0,1

Chemical composition CoCr sintering blank according to **ICP-OES DIN 51086-2**

Co %	Cr %	Mo %	Mn %	Fe % + C %	Si %	Ni %
63,5-66,5	27,5-29,5	5,5-6,5	< 0,1	< 0,1	< 0,1	< 0,1

Technical Data:	**Solibond C Plus powder**	**C Plus blank**	**CoCr sintering blank**
Density g/cm³	8,3	8,2	7,9-8,0
Melting point°C:	1310-1370	1290-1370	1390-1415
Casting / sintering temperature °C	1430		1260
Coefficient of Expansion 10^{-6} K^{-1}	14,0	14,4	14,1
Vickers Hardness HV 10	280	330	285
Modul of Elasticity Mpa/Gpa	210	200	190
Breaking elongation %	10,1	6,5	10
0,2% elongation limit Mpa	550	480	

Norm:

Alloy type 2-4 **DIN EN ISO 22674**