



# BioBiteCorrector® SA & FA

## Directions for Use

Hergestellt in Deutschland  
Ausgabedatum: 06-2023  
BBC eIFU SA-FA EN Rev0

The BioBiteCorrector™ (BBC) is an intermaxillary mandibular protrusion device. In combination with a removable orthodontic appliance, it works as functional Class II appliance. The BBC SA version is a rigid-passive appliance without an internal coil spring. The BBC SA is largely based on the functional principle of the Herbst appliance. The BBC FA version has an internal stainless steel coil spring.

### INDICATIONS:

- Correction of Class II malocclusions and functional mandibular midline shifts

### CONTRAINDICATIONS:

- Severe protrusion of lower incisors

### MATERIAL:

- The BioBiteCorrector™ is manufactured of titanium grade 5
- The BBC FA version has an internal stainless steel coil spring
- The distance spacers are manufactured of titanium
- The screwdriver is manufactured of stainless steel (sterilizable and re-usable)
- The BioBiteCorrector™ is determined for single use only.

### WARNINGS:

- Single patient use only.
- Device contains nickel and may cause allergic reactions.
- Report serious incidents that have occurred in relation to the device to device manufacturer.

### PRECAUTIONS:

- For professional use only. This device is restricted to sale by or on the order of a Dentist.
- Instruct patients not to chew or bite hard on sticky substances such as candy, gum and popcorn.
- Do not reuse the product on another person. Risks of reuse include infection and contamination (i.e. bacterial, viral).
- If an allergic reaction occurs, discontinue use immediately and direct the patient to consult a physician.
- Wear gloves when handling this product at all times.
- If deformation or deterioration is recognized, do not use. Contact manufacturer for assistance.
- Risks of reusing this device with the same patient include possible integrity being compromised and product not functioning as intended.
- The average duration of treatment with BBC is approximately 4-7 months.
- The firmness of the screws must be checked by the doctor in regular intervals to recognize loosened screws and to prevent a loss of the appliance with the danger of swallowing or aspirating the appliance or parts of it. The patient must be instructed for self-control.

- The product range description is included on the product website.

### MANUFACTURING THE DEVICE:

1. Articulate upper and lower jaw model in accordance with the construction bite.
2. Block-out the undercuts on the jaw models.
3. Position determination of the BBC hinges: In the upper jaw, the attachment points should be located at first molar in center and incisal. In the lower jaw, the attachment point should be at first premolars in center and incisal. This procedure guarantees a parallel hinge to occlusal plane. The final position shows a complete closed BBC hinge. The BBC is already pre-assembled. The appliance is distinguished in left and right sides
4. The retentions arms have to be adapted and if necessary reduced. We recommend bending the retention slightly to lingual. This guarantees the greatest movement possibilities.
5. The hinges and ball joints should be protected during the polymerization by silicone wax. The telescope should be completely closed to prevent further retrusion of the mandible. The use of a positioning key for the exact parallelizing of the telescopes isn't necessary.
6. Protect during finishing and polishing the surfaces and ball joints.
7. The wearing time is determined by the doctor. Orthodontics recommend approximately 12-24 hours per day.

### ADJUSTMENT IN NEUTRAL OCCLUSION:

- After both sides are fixed, guide the lower jaw back as far as possible. If there is still distal occlusion the lower jaw can be shifted forward by using distance spacers. These spacers can be crimped on the appliance, whereby the lower jaw can be shifted into neutral occlusion.
- The distance spacers are attached to the thinnest telescope pipe. Fine corrections can be carried out by by screwing the nut.
- The BBC SA can be directly adjust with Infinitely variable calibration by screwing the nut. To be locked in place use the nut as a jam nut against the other nut.

### ADVERSE REACTIONS:

- Severe protrusion of lower incisors, Adverse tooth and jaw movements.

### CLEANING AND DISINFECTING:

- Suitable measures for cleaning, disinfection and if necessary sterilization must be carried out with a validated method before using the

product. Detailed instructions on processing are provide separately and can be requested.

### SAFE DISPOSAL OF DEVICE:

- Used orthodontic appliances may be considered a biohazard. Follow your country-specific laws, directives, standards and guidelines for the disposal of used devices.

### LIABILITY:

- There is no liability for unsatisfying results. Do not use the appliance for other than dental or orthodontic purposes. The dentist or orthodontist is responsible for the use of the appliance. Sterilization must be carried out with a validated method before using the product. Detailed instructions on processing are provide separately and can be requested.



Manufacturer:  
BBC-Orthotec GmbH  
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Url: bbc-orthotec.de





**INSTRUMENTS:**

The instruments needed to insert the implant are provided in an unsterilized state, shrink-wrapped in a foil pouch, and labeled with the corresponding article description. Instruments are made from titanium alloy in accordance with ISO 5832-3 or titanium in accordance with ISO 5832-2 and must be prepared by the user before each procedure. Please follow the specific reprocessing instruction for reusable instruments.

**TITANIUM SPACER 1,0 MM**

Article No. 205-2010-32  
Spacer ring for adjusting the protrusion

**TITANIUM SPACER 1,5 MM**

Article No. 205-2010-33  
Spacer ring for adjusting the protrusion

**TITANIUM SPACER 2,0 MM**

Article No. 205-2010-34  
Spacer ring for adjusting the protrusion

**BBC SCREWDRIVER**

Article No. 205-Q2113, 205-Q2113L  
The screwdriver is available in different lengths. Screwdriver for BBC MS, BBC SP, Titanium Fixing Screw and BBC MS Body with screw

**Q SCREW HANDLE**

Article No. 205-Q2112  
Screwdriver handle for all dental handpiece screwdriver

**TORQUE-RATCHET**

Article No. QX30  
Torque ratchet, support instrument to fix screw with a certain maximum torque

**BBC OPEN END WRENCH**

Article No. 205-2019-55  
Open End Wrench for adjusting the threaded nut of the BBC SA

**BBC MS BODY WITH SCREW**

Article No. 205-2018-11  
Auxiliary element for the laboratory

**TITANIUM FIXING SCREW**

Article No. 205-2010-44  
Replacement screw for BBC MS, BBC SP and BBC MS Body with screw

**BBC SQUARE WIRE**

Article No. 205-W025-18  
Auxiliary element for the laboratory

**BBC SQUARE WIRE SA**

Article No. 205-W039-23  
Auxiliary element for the laboratory

**Sterilization Instruction:**

Temperature: 132°C  
Holding Time: 4 minutes  
Drying Time: 20 minutes

**Packaging:** The products are delivered in non-sterile state. Transport packaging is not suitable for sterilization. Devices must be either packed in suitable steam sterilization packaging systems in accordance with to ISO 11607 and/or AAMI / ANSI ST77:2006 or FDA cleared wrap (e.g.: Steriking-foil: RB51-3P and RB52-3P).

Explanation of symbols used on the label					
	Medical device		European conformity to the essential requirements with notified body DQS Medizinprodukte GmbH / August-Schanz-Straße 21 / 60433 Frankfurt am Main, Germany NB Number: 0297		Use by
	Unique Device Identification		In accordance with US-American federal law, this product can only be sold directly to trained medical practitioners or on their behalf		Non-sterile
	Order number		GS1 Datamatrix - Unique Device Identification		
	Lot number		Caution, consult accompanying documents		
	Manufacturer		Consult instructions for use eIFU: bbc-orthotec.de		
	Manufacturing Date		Do not reuse		

