



The BioBiteCorrector[™] (BBC) is a mandibular protrusion hinge with a screw connector. The BBC can be combined with a removable orthodontic appliance, or with a fixed orthodontic multibracket appliance. The BBC MS version is a rigid-passive appliance without an internal coil spring. The BBC MS is largely based on the functional principle of the Herbst appliance. The BBC SP version has an internal stainless steel coil spring.

INDICATIONS:

- Correction of Class II malocclusions and functional mandibular midline shifts
- Use as anchorage appliance for closing a gap in the posterior teeth of the lower jaw while simultaneously correcting a Class II malocclusion
- Avoidance of dysgnathic surgeries

CONTRAINDICATIONS:

- Severe protrusion of lower incisors

MATERIAL:

- The BioBiteCorrector[™] is manufactured of titanium grade 5
- The BBC SP version has an internal stainless steel coil spring
- The fixing screws and the distance spacers are manufactured of titanium
- The screwdriver is manufactured of stainless steel (sterilizable and re-usable)

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.

FIXATION OF THE BBC on multi-bracket appliance

1. Preconditions

- Precondition for the integration of the BBC is a multi-bracket appliance with a steel archwire with a minimum size of .017" x .025" to maximum .025" x .025" Inch in the upper and lower jaws.
- In the lower jaw the steel archwire must have a cinch back to avoid a proclination of the incisors. For the cinch back we recommend a Twister-Instrument. With the Twister you can bend the arch very simply without risking to remove the bracket from the tooth.

2. Choice of size

Version BBC MS:

- Standard size is used in non-extraction cases.
- Only in extraction cases in the upper jaw small size is used.

Version BBC SP

- BBC SP is delivered only in one standard size.

3. Fixation of the BBC

- The BBC is already pre-assembled. The appliance is distinguished in left and right sides. First the BBC is fixed in the upper jaw and afterwards in the lower jaw.

4. Fixation in the upper jaw

- The upper jaw connecting element is fixed between the first molar and second premolar. The connecting element should have no contact with the bracket of the first molar. The screwdriver should be assured with dental floss to avoid aspiration or swallowing.
- Slide the body on the archwire from lateral and then fix the screw.

5. Fixation in the lower jaw

- After fixing the upper jaw connecting element, the lower jaw connecting element must be fixed between canine and first premolar. Slide the body on the archwire from lateral and then fix the screw. The connecting element should be situated as distal as possible mesially to the bracket of the first premolar. The connecting element must not have any contact with the canine bracket at all. Fix the other side in the same way.

6. 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 shifting the connecting element.

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 provided 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.





BioBiteCorrector® MS & SP

System components / instruments

Made in Germany
Issue date: 06-2023
BBC eIFU MS-SP EN Rev0

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		



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