



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.





**INSTRUMENTS:**

Les instruments nécessaires à la mise en place de l'implant sont fournis non stérilisés, emballés dans une pochette en aluminium et étiquetés avec la description de l'article correspondant. Les instruments sont fabriqués en alliage de titane conformément à la norme ISO 5832-3 ou en titane conformément à la norme ISO 5832-2 et doivent être préparés par l'utilisateur avant chaque procédure. Veuillez suivre les instructions de retraitement spécifiques pour les instruments réutilisables.

**TITANIUM SPACER 1,0 MM**

Réf. 205-2010-32  
Bague d'espacement pour le réglage de la protrusion

**TITANIUM SPACER 1,5 MM**

Réf. 205-2010-33  
Bague d'espacement pour le réglage de la protrusion

**TITANIUM SPACER 2,0 MM**

Réf. 205-2010-34  
Bague d'espacement pour le réglage de la protrusion

**BBC SCREWDRIVER**

Réf. 205-Q2113, 205-Q2113L  
Le tournevis est proposé en différentes longueurs. Tournevis pour BBC MS, BBC SP, Titanium Fixing Screw et BBC MS Body with screw

**Q SCREW HANDLE**

Réf. 205-Q2112  
Poignée de tournevis pour tous les tournevis avec prise de contre-angle

**TORQUE-RATCHET**

Réf. QX30  
Clé à cliquet dynamométrique, instrument auxiliaire permettant de visser des vis avec un couple maximal déterminé

**BBC OPEN END WRENCH**

Réf. 205-2019-55  
Clé à fourche pour le réglage de l'écrou fileté du BBC SA

**BBC MS BODY WITH SCREW**

Réf. 205-2018-11  
Élément auxiliaire pour le laboratoire

**TITANIUM FIXING SCREW**

Réf. 205-2010-44  
Vis de rechange pour BBC MS, BBC SP et BBC MS Body with screw

**BBC SQUARE WIRE**

Réf. 205-W025-18  
Élément auxiliaire pour le laboratoire

**BBC SQUARE WIRE SA**

Réf. 205-W039-23  
Élément auxiliaire pour le laboratoire

**Instructions pour la stérilisation:**

Température: 132°C  
Temps de maintien: 4 minutes  
Temps de séchage: 20 minutes

**Emballage:** les produits sont livrés non stérilisés. L'emballage de transport n'est pas adapté à la stérilisation. Les produits doivent être emballés soit dans des systèmes d'emballage de stérilisation à la vapeur appropriés conformément à la norme ISO 11607 et/ou AAMI / ANSI ST77:2006, soit dans des emballages agréés par la FDA (par ex. : film Steriking : RB51-3P et RB52-3P).

Explication des symboles utilisés sur l'étiquette					
	Produit médical		Conformité européenne aux exigences essentielles avec organisme notifié DQS Medizinprodukte GmbH / August-Schanz-Straße 21 / 60433 Frankfurt am Main, Germany NB Number: 0297		Utilisable jusqu'à
	Numéro UDI (Identification unique de l'appareil)		Selon la loi fédérale américaine, ce produit ne peut être vendu que directement à des professionnels de la santé formés ou en leur nom		Non stérile
	Référence de l'article		GS1 Datamatrix - Identification unique de l'appareil		
	Numéro de lot de fabrication, lot		Consulter l'encart d'information		
	Fabricant		Respecter le mode d'emploi Mode d'emploi électronique eIFU: bbc-orthotec.de		
	Date de fabrication		Non réutilisable		

