

# EN

## Instructions for Use GC Orthodontics Line

For use only by a dental professional in the recommended indications.

### 1. Intended Use

GC Orthodontics Line is a system for orthodontic corrections. The system consists of brackets, bands, wires and other components.

The system can be complemented by orthodontic products such as implants, class II/III malocclusion appliances and other ancillary orthodontic appliances. Adhesives, orthodontic cements and instruments are required for application of the appliances. Follow manufacturer's instructions for use of all components.

For both function and aesthetics, the GC Orthodontics Line covers the entire spectrum of orthodontic applications.

The GC Orthodontics system can also be used in connection with orthodontic treatments.

### 2. Indications

For the adjustment of teeth, jaw alignment and function, whether required for aesthetic or medical reasons.

### 3. Contraindications

- Deficient patient oral hygiene
- Patient inability to cooperate in treatment plan
- Known allergies to components of the system
- Illness and underlying conditions which preclude orthodontic treatment
- Existing root resorption
- Existing decalcification of tooth enamel

### 4. Disinfection / hygiene

The products are delivered as non-sterile and meet GC Orthodontics Europe GmbH standards of production, handling and logistics and are comprised of medical-grade materials.

If a band has been in a patient's mouth to be appraised for fit, before it may be returned to the band box, it must be sterilized. Follow the below procedure:

- Clean band in ultrasound bath.
- After cleaning, sterilize either by autoclave at 273° F (134° C) for 3 minutes or using hot air sterilization (356° F / 180° C) for a minimum of 30 minutes. Adhere to all regional and national sterilization requirements.

### 5. Warning

The system is designed for single orthodontic use only.

For use by dentists and orthodontists only. Follow all regional and national standards for use of orthodontic appliances. In the event packaging has been compromised, appliance requires pre-processing before use. Products which are damaged, or do not comply with labelling specifications must not be used. For patients with known allergies, select components which will not provoke an allergic response. In the event of an allergic reaction, immediately remove orthodontic appliance.

### 6. Patient information

There is no information available which would preclude the use of commonly available oral healthcare products. Use antibacterial mouthwash.

Chewing hard foods can cause appliances to loosen or come off. Some sports may cause damage to orthodontic appliances being worn, and their presence may increase risk of harm in the event of certain sports-related injuries. When participating in sports, always wear appropriate mouth and/or bracket guards as recommended by the orthodontic specialist.

When scheduling an MRI or other radiology services while wearing orthodontic appliances, always inform MRI or other radiology staff prior to the procedure so that proper coordination of care can be arranged.

### 7. General information for the dentist/orthodontist

As part of developing a treatment plan, and prior to appliance placement, assess the need for interdisciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists.

The use of ceramic brackets and nickel-titanium wires are recommended for patients who may require MRI studies over the course of orthodontic treatment.

Follow manufacturer's instructions for any orthodontic bonding agents, instruments or other materials used in treatment. Orthodontic training in standard procedures will determine appropriate instruments for use during appliance placement and removal.

Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.

Patients using retainers, which can be applied for a longer period, should schedule periodic follow-up visits as recommended by their orthodontist.

For immunocompromised patients, oral hygiene is of particular importance, and should be monitored by the orthodontist and dentist.

In the presence of root resorption, assess whether further treatment is advisable.



Removal of ceramic brackets may cause enamel damage. To avoid damage, carefully follow bracket instructions. Disposal of all orthodontic appliances must follow regional and national regulations.

## 8. Product overview

Click on product type for detailed Instructions for Use, and available part numbers:

- 1-Self-ligating metal brackets
- 2-Self-ligating ceramic brackets
- 3-Standard metal brackets
- 4-Standard ceramic brackets
- 5-Light wire brackets
- 6-Buccal tubes
- 7-Lingual attachments
- 8-Lingual locks (sheaths)
- 9-Bands
- 10-Pre-formed archwires
- 11-Springs
- 12-Auxiliary bracket elements
- 13-Lip-Bumper
- 14-Face bows
- 15-Palatal bows
- 16-Retainer
- 17-Stops and hooks
- 18-Wire ligatures
- 19-Pre-formed labial bows
- 20-Ball Clasp
- 21-Button electrodes

## 9. Symbols description :

 **Manufacturer:** indicates the legal manufacturer of the medical device according to EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

 **Warning:** points out the necessity for the operator to check the operating instructions for important safety-related information such as warnings and precautions which cannot be applied to the medical device itself due to a variety of reasons.

 **LOT number:** Manufacturer's batch number associated with the device.

 **Article number:** indicates the order number of the manufacturer to identify the medical device.

 **Non sterile:** indicates that a medical device was delivered non-sterile.

 **Not for re-use:** indicates that a medical device is designed for single use or use for a single patient during a single procedure.

 **Operating instructions:** refers to the necessity of the operator to consult the operating instructions.

 **Use-by date:** indicates the date after which the medical device may no longer be used.

 **Protect from sunlight:** indicates a medical device which requires protection from light sources.

## 10. Request for instructions in paper form

Identical instructions in paper form can be requested by phone: +492338 801888 or by e-mail [info.gco.germany@gc.dental](mailto:info.gco.germany@gc.dental).

 **GC Orthodontics Europe GmbH**  
Harkortstraße 2  
58339 Breckerfeld  
Germany  
 2797

# 1-Self-ligating metal brackets

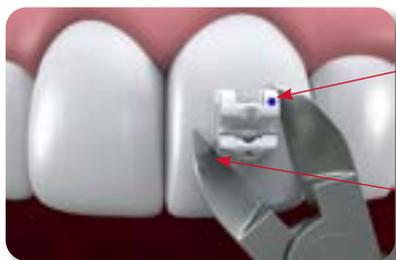
Part numbers	16-XXXX-XXXX    20-XXXX-XXXX 17-XXXX-XXXX    21-XXXX-XXXX 19-XXXX-XXXX    24-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo) Cobalt-Nickel (Co, Ni, Cr, Mo, Fe, Nb, Ti, Mn)
Also available in 16-XXXX-XXXX 17-XXXX-XXXX	Clip coating (Au)
Also available in 19-XXXX-XXXX 24-XXXX-XXXX	Rhodium and gold
Instructions for Use	<p>When bonding the bracket, hold in the mesio-distal orientation to prevent clip from closing (brackets can also be bonded with closed clip): Use conventional orthodontic adhesive following manufacturer's instructions. While bonding, do not allow adhesive to get under the clip. Remove excess adhesive from around the bracket. Remove positioning aid and colored markings after bonding. Once the bow is inserted, press clip shut with fingertip until a click is heard. To open clip, slide from gingival to incisal position with instrument of choice. Using care, the clip may also be opened from the buccal-labial orientation. Do not overstretch the spring clip. When closing clips using a scaler or other pointed instrument, in order to avoid injury to the patient, guide the point with a finger. Do not use excessive force.</p>
Only in 16-XXXX-XXXX 17-XXXX-XXXX 19-XXXX-XXXX 21-XXXX-XXXX 24-XXXX-XXXX 20-XXXX-XXXX	<p>Once the bow is inserted, using the instrument of your choice, or with a finger, gently lift the clip and press clip shut until a click is heard. Using a suitable instrument, insert in the clip recess and rotate to incisal position. Do not overstretch the clip.</p>
Warning	<p>Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion. Adhesive surface of brackets has been sandblasted. To avoid changes to clip flexibility do not sandblast. Do not allow adhesive to get under the bracket in the guide slot. Provide the patient with instructions on how to conduct oral hygiene, as tartar or food debris may impair the function of the bracket. Do not apply excessive force when opening the bracket as the bracket may bend or detach from the tooth. If patient experiences allergic reaction, immediately remove bracket and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.</p>
Also available in 16-XXXX-XXXX 17-XXXX-XXXX	These brackets are not to be used for bite elevation.
Also available in 19-XXXX-XXXX 24-XXXX-XXXX	The coating may discolour due to friction on metal.

## 2-Self-ligating ceramic brackets

Part numbers	10-XXXX-XXXX 11-XXXX-XXXX
Composition	Bracket: Aluminium oxide, PTFE coating Clip: Cobalt-Nickel alloy (Co, Ni, Cr, Mo, Fe, Nb, Ti, Mn) Rhodium coating (rhodium, gold)
Only in 1X-XXXX-ZXXX	Zirconia instead of aluminium oxide
Instructions for Use	<p>When bonding the bracket, hold in the mesio-distal orientation to prevent clip from closing brackets can also be bonded with clip closed.</p> <p>Use conventional orthodontic adhesive following manufacturer's instructions.</p> <p>Do not allow adhesive to get under the clip. Remove excess adhesive after bonding.</p> <p>Remove positioning aid and colored markings after bonding.</p> <p>Once the archwire has been inserted, press clip shut with the fingertip until a click is heard. To open the clip, slide from gingival to incisal position with a suitable instrument.</p> <p>Using care, the clip may also be opened from buccal-labial orientation. Do not overstretch the spring clip.</p> <p>When closing clips using a scaler or other pointed instrument, in order to avoid injury to the patient, guide the point with a finger. Do not use excessive force.</p>
Bracket Removal	<div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 20px;"> <p><b>1</b></p> <p>Remove the archwire.</p> </div> </div> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 20px;"> <p><b>2</b></p> <p>Remove excess adhesive from around bracket.</p> </div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p><b>3</b></p> <p>Insert instrument under the base. Lift in the gingival to incisal position or diagonally.</p> </div> </div>

## 2-Self-ligating ceramic brackets

Bracket removal



Gingival and incisal base chamfer for easy removal.



**4**  
Remove adhesive residue. Clean surface of tooth.

Warning

Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion. Do not allow adhesive to get under the bracket in the guide slot.

Ceramic brackets may abrade opposing arch. Wait to apply ceramic brackets until bite has opened. If necessary, use metal brackets before placement of ceramic brackets.

Provide the patient with instructions on how to conduct thorough oral hygiene, as tartar or food debris may impair the function of the bracket.

Do not apply excessive force when opening the bracket as the bracket may bend or detach from the tooth.

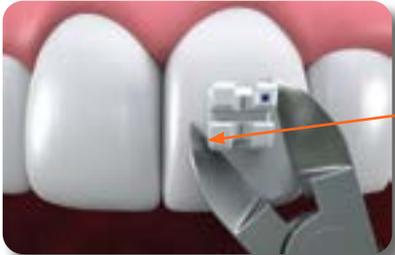
To prevent splintering when removing brackets, use the appropriate instrument.

If patient experiences allergic reaction, immediately remove bracket and advise patient to seek medical care.

### 3-Standard metal brackets

Part numbers	26-XXXX-XXXX 27-XXXX-XXXX 28-XXXX-XXXX 29-XXXX-XXXX 30-XXXX-XXXX 31-XXXX-XXXX 32-XXXX-XXXX 33-XXXX-XXXX 34-XXXX-XXXX 36-XXXX-XXXX 37-XXXX-XXXX 38-XXXX-XXXX 39-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo) Gold filler (Ag, Au, Cu)
Only in 30-XXXX-XXXX	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo)
Only in 37-XXXX-XXXX	Stainless steel (Fe, Cr, Ni, Mn, Mo)
Also available in 38-XXXX-XXXX, 39-XXXX-XXXX	Rhodium and gold
Instructions for Use	Use conventional orthodontic adhesive following manufacturer’s instructions. Remove excess adhesive from around bracket. Affix wire with elastic or wire ligation on bracket after bonding.
Only in 33-XXXX-XXXX 34-XXXX-XXXX 37-XXXX-XXXX	Weld bracket onto orthodontic band and affix to tooth. Use conventional orthodontic band adhesive following the manufacturer’s instructions. Remove excess adhesive from the band and from the occlusal surface of the tooth.
Only in 30-XXXX-0014	Check the Barbosa brackets in friction-free application more frequently. You can achieve a fixed bracing with these brackets via an 8-ligation.
Only in 37-XXXX-XXXX	Remove the required number of brackets from the strip.
Warning	Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion. Do not apply excess force on the bracket as this may lead to detachment from tooth or band. If patient experiences allergic reaction, immediately remove bracket and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.
Also available in 38-XXXX-XXXX, 39-XXXX-XXXX	The coating may discolour due to friction on metal.

## 4-Standard ceramic brackets

Part numbers	14-XXXX-XXXX
Composition	Aluminium ceramic
Instructions for Use	<p>Use conventional orthodontic adhesive following manufacturer's instructions.</p> <p>Remove excess adhesive from around the bracket.</p> <p>After bonding, remove positioning aid and colored markings from slot. These are easily wiped away with a pellet soaked in alcohol. After bonding, affix wire to bracket with elastomeric or wire ligature. During the initial phase, the application of round Ni-Ti wires such as "Initialloy" is recommended.</p>
Bracket Removal	 <p>1 Remove ligatures and archwires.</p>  <p>2 Remove excess adhesive from around bracket.</p>  <p>3 Mesio-incisal chamfer of base for easier removal.</p>  <p>3 Apply suitable instrument under the base in mesio-distal or diagonal orientation. In the process, use the mesio-incisal chamfer.</p>

## 4-Standard ceramic brackets

Bracket Removal



4  
Remove all remaining adhesive residue and clean surface of tooth.

Warning

Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.  
Do not apply excess force on the bracket as this may lead to detachment from tooth. Premature application of angular bows may lead to fractures of the brackets.  
When removing brackets, correct use of the appropriate instrument will help prevent splintering.  
If patient experiences allergic reaction, immediately remove bracket and advise patient to seek medical care.

## 5-Light wire brackets

Part numbers	35-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo) Gold filler (Ag, Au, Cu) Brass (Cu, Zn, Fe)
Instructions for Use	Use conventional orthodontic adhesive following manufacturer's instructions. Remove excess adhesive from around bracket. After bonding, place wire into slot and hold with a "lock pin". Bend the occlusal end of the pin to fix it.
Warning	Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.  Do not apply excess force on the bracket as this may lead to detachment from tooth. If patient experiences allergic reaction, immediately remove bracket and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 6-Buccal tubes

Part numbers	40-XXXX-XXXX 41-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo) Gold filler (Ag, Au, Cu) Silver filler (Ag, Au)
Instructions for Use	Use conventional orthodontic adhesive following manufacturer's instructions. Remove excess adhesive from around the buccal tube. After bonding, lead wire through tube (main or auxiliary slot). Shorten and bend in the distal direction behind the tube to prevent injury of the mucous membrane. If required, remove the cover of the main slot of all convertible tubes with a suitable instrument and fix the inserted wire with an elastomeric ligature. Face bows and lip bumpers are inserted into the respective .045" auxiliary tube.
Only in 41-XXXX-XXXX	Weld the buccal tube onto an orthodontic band and affix to the tooth. Use conventional orthodontic band adhesive following manufacturer's instructions. Remove excess adhesive from around the band and from the occlusal surface of the tooth.
Warning	Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion. Do not apply excess force on the buccal tube as this may lead to detachment from tooth or band. If patient experiences allergic reaction, immediately remove buccal tube and/or band with buccal tube and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 7-Lingual attachments

Part numbers	42-XXXX-XXXX 43-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo) Gold filler (Ag, Au, Cu)
Instructions for Use	Use conventional orthodontic adhesive following manufacturer's instructions. When bonding directly, secure the attachments via an 8-ligature or thread to prevent accidental swallowing. Remove excess adhesive from around the attachment point. After bonding the elastic chains, elastomeric ligatures, 8-ligatures or other ancillary elements can be hooked or tied to the attachment.
Only in 43-XXXX-XXXX	Weld the attachment to an orthodontic band and affix it to the tooth. Use conventional orthodontic adhesive following manufacturer's instructions. Remove excess adhesive from around the band and from the occlusal surface of the tooth.
Only in 43-0340-0000 43-0350-0000	These attachments (positioning flaps) are only designed to assist positioning during the adaptation and bonding of the band and are not able to accommodate ancillary elements.
Warning	Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion. Do not apply excess force on the lingual attachment as this may lead to detachment from tooth or band. If patient experiences allergic reaction, immediately remove attachment and/or band with attachment and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 8-Lingual locks (sheaths)

Part numbers	43-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb)
Instructions for Use	<p>Weld the lingual sheath to an orthodontic band and affix to the tooth.</p> <p>Use conventional orthodontic band cement following manufacturer's instructions.</p> <p>Remove excess cement from around the band and the occlusal surface of the tooth. Palatal bows, lingual bows, quad-helix or similar auxiliary equipment can be inserted into the sheath after bonding.</p> <p>In case of prefabricated bows, use the appropriate size as determined by the model. Bend it according to the palatal or lingual size and shape.</p> <p>If you manufacture the palatal bow yourself, a wire with a diameter of 0.9 mm is best suited for 180° bending.</p> <p>Press the retentions of the prepared bow with the aid of a pair of Howe pliers from mesial orientation into the sheath.</p> <p>If the sheath possesses a stop notch, you should be able to clearly feel it click into the retention.</p> <p>In order to prevent slipping, affix the inserted bow into the lock using elastomeric or wire ligature (if applicable on the existing hook). This will decrease risk of accidental swallowing.</p> <p>Using Howe pliers from distal to mesial orientation, press the retention out of the sheath to remove the bow.</p>
Warning	<p>Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.</p> <p>Do not apply excess force on the lingual sheath as this may lead to detachment from tooth or band.</p> <p>If patient experiences allergic reaction, immediately remove band with lock and advise patient to seek medical care.</p> <p><b>NICKEL Warning</b> This product contains nickel, a chemical known to the State of California to cause cancer.</p>

## 9-Bands

Part numbers	80-XXXX-XXXX 81-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn)
Instructions for Use	<p>Weld or solder the required attachments, such as buccal tubes, lingual attachments or sheaths, to the band in accordance with your treatment plan.</p> <p>Please maintain exact positioning of the attachments as well as the correctly executed weld to ensure that attachments do not detach from the band.</p> <p>Select the best fitting band. Use conventional orthodontic band cement following manufacturer's instructions. Place it using the instrument of your choice.</p> <p>Remove excess cement from around the band and from the occlusal surface of the tooth.</p> <p>After bonding, bows, wires, chains, elastics or other auxiliary equipment can be attached in and on the welded attachments.</p>
Warning	<p>When using a band pusher, exercise caution to prevent the instrument from slipping from the band thus injuring the patient's mucous membrane.</p> <p>If patient experiences allergic reaction, immediately remove band and advise patient to seek medical care.</p> <p><b>NICKEL Warning</b> This product contains nickel, a chemical known to the State of California to cause cancer.</p>

## 10-Pre-formed archwires

Part numbers	<p>70-XXXX-XXXX Nickel-titanium alloy (Ni, Ti)</p> <p>71-XXXX-XXXX Nickel-titanium alloy (Ni, Ti)</p> <p>72-XXXX-XXXX Nickel-titanium alloy (Ni, Ti)</p> <p>73-XXXX-XXXX Beta-titanium alloy (Mo, Zr, Sn, Ti)</p> <p>74-XXXX-XXXX Nickel-titanium alloy (Ni, Ti)</p> <p>76-XXXX-XXXX Nickel-titanium alloy (Ni, Ti)</p> <p>77-XXXX-XXXX Nickel-titanium alloy (Ni, Ti)</p> <p>78-XXXX-XXXX Stainless Steel (Fe, Cr, Ni, Mn)</p> <p>79-XXXX-XXXX Stainless Steel (Fe, Cr, Ni, Mn)</p>
Also available in 74-XXXX-XXXX 76-XXXX-XXXX 79-XXXX-XXXX	Rhodium-plating (Rh, Au)
Application	Element providing power for tooth movement
Instructions for Use	<p>Insert the archwire in the slot of the brackets and buccal tubes and fix it with an elastomeric or wire ligature.</p> <p>When using self-ligating brackets, close according to manufacturer's instructions.</p>
Warning	<p>When gripping and holding archwire, only use instruments/pliers without sharp edges or serrated surfaces. Scratches and scuffing of the archwire caused by such instruments can lead to the archwire breaking in the mouth. Excessive force and/or repeated bending of the archwire and the use of cutting pliers can lead to breakage. If patient experiences allergic reaction, immediately remove archwire and advise patient to seek medical care.</p> <p>NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.</p>

## 11-Springs

Part numbers	60-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) Exception: 60-X2XX-XXXX stainless steel (Fe, Cr, Ni, Mn) 61-XXXX-XXXX Nickel titanium alloy (Ni, Ti) Exception: 61-XXXX-0000 stainless steel (Fe, Cr, Ni, Mn)
Application	Tooth movement either through pulling or pressing force.
Instructions for Use	Cut the spring to the desired length and thread it onto the bow. Compress the spring until the windings are closed. Place the spring in the bracket gap or between a stop on the bow and the bracket.
Only in 60-X2XX-0000	Hang the spring on the hooks of the brackets and buccal tubes or the stops applied to the bow. The springs can be activated at a length of 15 mm.
Warning	To prevent springs from detaching, instruct patient to exercise care while eating or brushing teeth. Do not repeatedly activate the springs throughout an inappropriately long treatment period as they may break in the mouth. If patient experiences allergic reaction, immediately remove spring and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.
Only in 60-X2XX-0000	The spring can be activated at a length of 15 mm; do not overstretch the spring as it may lose its reset force.

## 12-Auxiliary bracket elements

Part numbers	69-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn)
Only in 69-37XX-XXXX	Nickel-titanium alloy (Ni, Ti)
Application 69-14XX-XXXX	To attach auxiliary elements such as elastomerics, chains and springs in conjunction with vertical slot brackets.
Instructions for Use 69-14XX-XXXX	Place the V-slot Omni hooks from gingival orientation into the vertical slot of the bracket. Bend the occlusal end under occlusal tie-wings to secure.
Application 69-15XX-XXXX	Rotation of teeth by way of pre-activated leaf spring
Instructions for Use 69-15XX-XXXX	Use the wire ligature to affix the rotation spring in a mesial or distal direction. Shorten the twisted end of the ligature with the aid of a ligature tucking instrument. Bend behind tie wing of the bracket.
Application 69-37XX-XXXX	Pre-bent wire elements for the separation of teeth
Instructions for Use 69-37XX-XXXX	With a suitable instrument (e.g. needle holder) thread the wire element through the appropriate space below the contact point. Adjust the wire elements occlusally so they are supported within the appropriate space. Shorten the twisted end and bend.
Warning	Excessive force, repeated bending, and the use of cutting pliers can lead to breakage. If patient experiences allergic reaction, immediately remove respective component of the appliance and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

# 13-Lip-Bumper

Part Numbers	63-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo) polypropylene Nylon Gold filler (Ag, Cu, Zn, Sn)
Application	Averting lip pressure to rectify narrow positions. Usage of lip pressure for expansion and distancing.
Instructions for Use	Select the suitable size with the aid of the model. Activate the Omega loops so that the distance of the lip bumper to the row of teeth (brackets) is 2-3 mm. Insert the lip bumper into the buccal tubes with the aid of an elastomeric ligature instrument to prevent it from slipping out.
Only in 63-1XXX-XXXX	Insert the lip bumper into the buccal tubes and with the aid of a ligature, prevent it from slipping out. For this purpose, stretch the ligature from the hook of the lip bumper to the hook at the buccal tube.
Warning	The lip bumper may not contact enamel, brackets or working wire. Do not apply excess force during activation as this may cause the lip bumper to break. If patient use experiences allergic reaction, immediately remove lip bumper and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 14-Face bows

Part numbers	62-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo) Gold filler (Ag, Au, Cu, Sn)
Also available in 62-X2XX-XXXX	Nylon, PVC
Application	Assembled with neck strap, safety modules and intra-oral headgear for distancing, intrusion or extrusion of molars, and expansions.
Instructions for Use	Select the suitable size with the aid of the model. Ensure that the inner bow has sufficient distance to the row of teeth. Guide the ends of the inner bow in the provided buccal tubes and hang the pulls of the safety modules onto the ends of the outer bow. Set traction at 200 and 300 g per side.
Only in 62-XXUN-XXXX	Position the stops to the interior bow at the required location and affix with pliers. Weld the stops to the bow and shorten the distal ends appropriately.
Warning	It is imperative to use the safety module. The patient must be informed of the function and risks of the equipment. Follow the power module manufacturer's instructions to prevent injury to the eyes. If patient experiences allergic reaction, immediately remove face bow and advise patient to seek medical care
Patient Instructions	According to the face bow manufacturer, patients should be given the following instructions: <ol style="list-style-type: none"> <li>1. Always insert the distal ends into the tubes first and then hook up the pulling mechanism.</li> <li>2. When removing, always release the pulling mechanism first, then pull the face bow out of the tubes.</li> <li>3. Do not allow other persons to touch or wear the equipment supplied.</li> <li>4. Never pull in front of the eyes.</li> <li>5. Do not use during sports.</li> <li>6. Monitor the condition of bedclothes so the external bow does not catch during sleep.</li> </ol> <p>Note: The power module manufacturer's instructions supersede any others.</p> <p>NICKEL WARNING: This product contains nickel, a chemical known to the State of California to cause cancer.</p>

## 15-Palatal bows

Part numbers	64-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn)
Application	Retention and anchoring as well as rotation of molars in combination with ligature locks on bands.
Instructions for Use	<p>Select appropriate size palatal bow with the aid of the model. Bend according to palatal or lingual circumstances.</p> <p>Press the retentions of the prepared bow using Howe pliers from mesial orientation into the lock. If the lock possesses a stop notch, you should feel clearly as it clicks into the retention.</p> <p>To prevent slipping and accidental swallowing, affix the inserted bow to the lock using elastomeric or wire ligature.</p> <p>Using Howe pliers, remove the bow by pressing the retention out of the lock from distal to mesial orientation.</p>
Warning	<p>Use GC Orthodontics Line bows combined with GC Orthodontics Line lingual locks for optimal fit. Affix the bow to the lock with a ligature.</p> <p>Excessively strong and repeated bending or the use of cutting pliers to bend the bow can lead to the bow breakage.</p> <p>If patient experiences allergic reaction, immediately remove bow and advise patient to seek medical care.</p> <p><b>NICKEL Warning</b> This product contains nickel, a chemical known to the State of California to cause cancer.</p>

## 16-Retainer

Part numbers	65-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo) Gold filler (Ag, Au, Cu)
Application	Long-term retention after conclusion of active orthodontic treatment.
Instructions for Use	Using model, select appropriate size retainer. Adapt wire to the lingual surfaces of teeth. Use conventional orthodontic adhesive following manufacturer's instructions. It is also possible to use light-cured cement for retainers with a perforated base.
Warning	Do not touch bonding surfaces with bare fingers since skin oils may diminish adhesion.  Detachment of bonded appliances can occur during long-term retention due to aging of the adhesive material and changes in the position of teeth.  If patient experiences allergic reaction, immediately remove retainer and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 17-Stops and hooks

Part numbers	66-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo)
Also available in 66-XX1X-XXXX	Gold filler (Ag, Au, Cu)
Application	Passive elements to attach and fix auxiliary equipment such as elastics, chains and springs.
Instructions for Use	Select the stops and hooks to suit the bow dimension being used. Place the product on the required location of the bow and affix using crimping pliers.
Warning	To prevent detachment and accidental swallowing, ensure correct attachment. If patient experiences allergic reaction, immediately remove respective component of the appliance and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 18-Wire ligatures

Part numbers	67-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn)
Also available in 67-XX4X-XXXX 67-XX5X-XXXX 67-XX6X-XXXX	Polyether ether ketone (PEEK) coating
Application	Placing bow in bracket slot. Affix ancillary appliances in and on brackets, buccal tubes, bows or other attachments.
Also available in 67-XX2X-XXXX 67-XX5X-XXXX	Loop to hook up elastic auxiliary equipment.
Instructions for Use	Place the wire ligature over the bow and under bracket wings and twist the end with a suitable instrument (e.g. needle holder) until the desired attachment has been achieved. Shorten the twisted end and bend it with the aid of a ligature adapter close to the bracket behind the bow.
Only in 67-X3XX-XXXX	Cut the ligature wire to the desired length.
Warning	Use a cloth to protect patient's face from possible injury caused by ligature ends. When using ligature cutter to size ligature, exercise caution not to injure the lips or mucus membrane of the patient. If wire ligature is twisted too tightly, it may cause deformation and breakage of bracket, bow and ligature as well as chipping of the coating. When twisting ligature with an instrument, do not scratch the archwire or its coating. Follow manufacturer's instructions when using a Twist-Mate. If patient experiences allergic reaction, immediately remove ligature and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 19-Pre-formed labial bows

Part numbers	92-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn)
Application	Wire element for removable equipment
Instructions for Use	Fit the loops of the labial bow into the space between the teeth on the working model and bend the wire toward lingual orientation. Shorten the end of the wires as needed and shape into a loop. Work the labial bow into the plastic base of the equipment following standard procedures.
Warning	Excessively strong and repeated bending or use of cutting pliers can lead to labial bow breakage. If patient experiences allergic reaction, immediately remove labial bow and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 20-Ball Clasp

Part numbers	92-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn)
Application	Support wires for removable appliances
Instructions for Use	Fit the ball into the space between the teeth on the working model and bend the wire over the occlusal surface to lingual orientation of the tooth. Shorten the end of the wire as needed and shape into a loop. Work the ball clasp into the acrylic base of the appliance following standard procedures.
Warning	Excessively strong and repeated bending or use of cutting pliers can lead to ball clasp breakage. If patient experiences allergic reaction, immediately remove appliance with ball clasp and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

## 21-Button electrodes

Part numbers	92-XXXX-XXXX
Composition	Brass wire (Cu, Zn, Fe) Silver filling (Ag, Cu, Zn, Sn)
Application	Soldering on bows to establish hooks
Instructions for Use	Solder the button electrodes onto the bow, positioning between the brackets. If necessary, shorten to the required length.
Warning	The wire material of button electrodes contains copper. Do not overheat bow during soldering, as button electrodes may lose elasticity. If patient experiences allergic reaction (e.g. to copper), immediately remove equipment with button electrodes and advise patient to seek medical care. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.