GC Orthodontics Line

Instructions for Use - English

TOMY

Smile for the World

Since 1921

100 years of Quality in Dental

Instructions for Use

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

1. Description

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 orthodontics, 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. The GC Orthodontics Line covers the entire field of fixed orthodontic treatments, both from functional and esthetic facial aspects.

2. Intended Use

The purpose of the GC Orthodontics Line is to treat orthodontic problems diagnosed by experts such as orthodontists or dentists. These can be a wide range of clinical diagnoses such as malocclusions or dysgnathia.

3. Indications

For the adjustment of teeth, jaw alignment and function.

4. Contraindications

Absolute 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

Relative Contraindications

- Existing root resorption
- Existing decalcifications of tooth enamel
- Existing bone metabolism disorders
- Existing periodontal diseases

5. Warning

The system is designed for single orthodontic use only. Re-use of the product is likely to cause deformation, deterioration or reduction of strength and poses risk of infection.

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.
As with any other orthodontic product line, adverse events may occur during treatment with GC Orthodontics line products. These are

- Ingestion of parts
- Allergic reactions
- Root resorption
- Decalcification of the tooth structure
- Injury to the inside of the cheek
- Pain

6. Patient information

Fixed orthodontic appliances require very good dental hygiene. Follow orthodontic professional's instructions and adhere to regular check-ups. 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. For product-specific MR safety warnings, refer to the relevant information provided in the following tables for each individual product.

7. General information for the dentist/orthodontist

As part of developing a treatment plan, and prior to appliance placement, assess the need for inter-disciplinary 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.
The products are delivered as non-sterile and meet GC Orthodontics Europe GmbH standards of production, handling and logistics. Any necessary preparation, including sanitization and sterilization of devices, lies within the responsibility of dental professional or orthodontist.
Disposal of all orthodontic appliances must follow regional and national regulations.

8. Reporting of undesired effects

If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, including those not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the proper authority of your country accessible through the following link: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en as well as to our internal vigilance system: vigilancegcortho@gc.dental. In this way you will contribute to improve the safety of this product.

9. Disclaimer of liability

This product is part of a family of orthodontic products developed by GC and should be used only according to instructions provided by GC. To the extent permitted by law, GC rejects any liability for any direct, indirect or consequential damages or loss of any kind in connection with this product, regardless of whether the legal demands made are related to assets or liabilities or are of another nature and regardless of whether the damages arise out of, or in connection with, errors in professional judgment or practice when using GC products.

10. 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-Buccal tubes
6-Lingual attachments
7-Lingual locks (sheaths)
8-Bands
9-Pre-formed archwires
10-Springs
11-Lip-Bumper
12-Palatal bows
13-Retainer
14-Stops and hooks
15-Wire ligatures

11. Explanation of symbols:

Manufacturer: indicates the legal manufacturer of the medical device according to EU Directives 90/385/EEC, 93/42/EEC, 2017/745/EC and 98/79/EC.

Attention: 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.

MRI safety conditional: indicates that a medical device is safe for use in MRI environment only under specific conditions.

Cobalt: indicates that a medical device contains Cobalt, which is classified as a CMR substance.

12. 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.

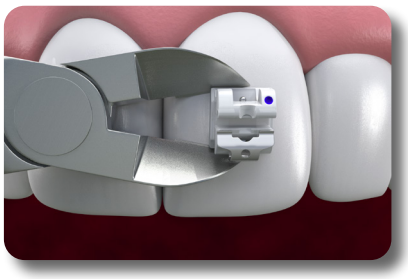
GC Orthodontics Europe GmbH
Harkortstraße 2
58339 Breckerfeld
Germany

CE 2797

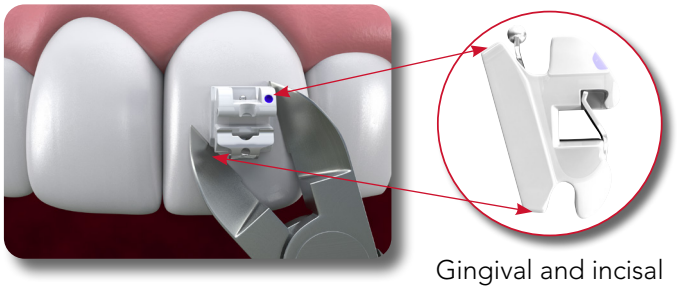
1-Self-ligating metal brackets

Part numbers	16-XXXX-XXXX 20-XXXX-XXXX 24-XXXX-XXXX 17-XXXX-XXXX 21-XXXX-XXXX 19-XXXX-XXXX 22-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb+TA, Co, 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	For bondable: 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. For weldable: Weld the welding flange to a band, and fit the band to the tooth after applying band cement inside the band. Remove positioning aid and colored markings after bonding. Once the Archwire 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 opening 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.
Only in 16-XXXX-XXXX 17-XXXX-XXXX 19-XXXX-XXXX 21-XXXX-XXXX 22-XXXX-XXXX 24-XXXX-XXXX 20-XXXX-XXXX	Once the archwire 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.
Warning	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. (not applicable for items familly 22-XXXX-XXXX). 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 clip 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.
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	11-XXXX-XXXX 12-XXXX-XXXX
Composition	Bracket: Aluminium oxide, PTFE coating (Not applicable for zirconia items) 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	When bonding the bracket, hold in the mesio-distal orientation to prevent clip from closing (brackets can also be bonded with clip closed). Use conventional orthodontic adhesive following manufacturer's instructions. Do not allow adhesive to get under the clip. Remove excess adhesive after bonding. Remove positioning aid and colored markings after bonding. 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. Using care, the clip may also be opened from buccal-labial orientation. Do not overstretch the spring clip. When opening 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.
Bracket Removal	 1 Remove the archwire. 2 Remove excess adhesive from around bracket.  3 Insert instrument under the base. Lift in the gingival to incisal position or diagonally.

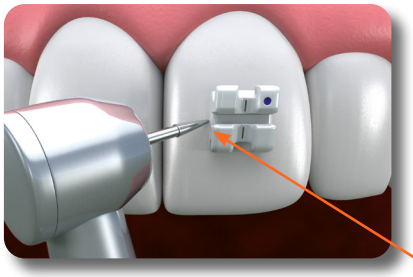
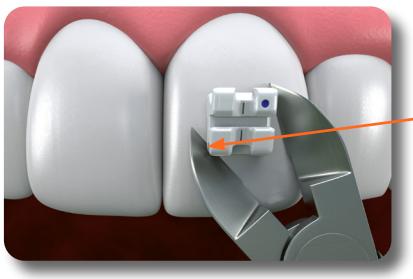
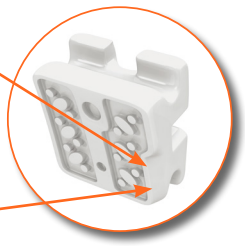
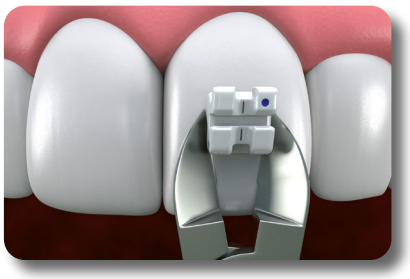
2-Self-ligating ceramic brackets

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 clip as the bracket may break 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. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

3-Standard metal brackets

Part numbers	23-XXXX-XXXX 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, Co) Gold filler (Ag, Au, Cu)
Only in 28-XXXX-XXXX	Stainless steel (Fe, Cr, Ni, Cu, Mn, Mo, Nb+Ta) Gold filler (Ag, Au, Cu)
Only in 30-XXXX-XXXX	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb+Ta, Mo)
Only in 37-XXXX-XXXX	Stainless steel (Fe, Cr, Ni, Mn, Mo, Co)
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 ligature on bracket after bonding.
Only in 23-XXXX-XXXX 33-XXXX-XXXX 34-XXXX-XXXX 37-XXXX-XXXX	Weld bracket onto orthodontic band and affix to tooth. Use conventional orthodontic band cement following the manufacturer´s instructions. Remove excess cement 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 (not applicable for weldable product). 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 15-XXXX-XXXX
Composition	Alumina ceramic
Instructions for Use	Use conventional orthodontic adhesive following manufacturer's instructions. Remove excess adhesive from around the bracket. After bonding, remove positioning aid and colored markings from slot. 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.
Bracket Removal	 1 Remove ligature and archwire.  2 Remove excess adhesive from around bracket.   Mesio-incisal chamfer of base for easier removal.  3 Apply suitable instrument under the base in mesio-distal or diagonal orientation. In the process, use the mesio-incisal chamfer.

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 rectangular archwires may lead to fractures of the brackets. When removing brackets, correct use of the appropriate instrument will help prevent splintering.

5-Buccal tubes

Part numbers	40-XXXX-XXXX 41-XXXX-XXXX
Composition	Stainless steel (Fe, Co, Cr, Ni, Cu, Mn, Nb, Mo, Ta) 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 cement following manufacturer's instructions. Remove excess cement 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.
Warning	A patient with Buccal Tubes may be safely scanned under following conditions. Failure to follow these conditions may result in injury to the patient. · Instructions to be followed before MRI exam: o Do not enter the MR examination room with removable orthodontic appliance o Remove any other detachable metallic objects · Static Magnetic Field Strength: o 1.5 or 3T · MRI System (RF) Operating mode: o Normal Operating Mode Failure to follow these conditions may result in injury to the patient. Notes: · Under the scan conditions defined above, Buccal Tubes are not expected to produce a temperature rise that can harm patients. · It cannot be excluded that artefacts may be caused by the orthodontic work. Adaptation of the scanning protocol and parameters may be required to compensate for the artefact.

6-Lingual attachments

Part numbers	42-XXXX-XXXX 43-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo, Co) 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 cement following manufacturer's instructions. Remove excess cement 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.

7-Lingual locks (sheaths)

Part numbers	43-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Co)
Instructions for Use	Weld the lingual sheath to an orthodontic band and affix to the tooth. Use conventional orthodontic band cement following manufacturer's instructions. 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 banding. 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. If you manufacture the palatal bow yourself, a wire with a diameter of 0.9 mm is best suited for 180° bending. Press the retentions of the prepared bow with the aid of a pair of Howe pliers from mesial orientation into the sheath. If the sheath possesses a stop notch, you should be able to clearly feel it click into the retention. 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. Using How pliers from distal to mesial orientation, press the retention out of the sheath to remove the bow.
Warning	Do not apply excess force on the lingual sheath as this may lead to detachment from band. If patient experiences allergic reaction, immediately remove band with lock 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-Bands

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

Instructions for reprocessing	Scope of reprocessing instructions These instructions contain the instructions for reprocessing (cleaning, disinfection and sterilization) of any GC Orthodontics Bands which are provided in non-sterile condition and designed for single use. 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 reprocessed according to the following instructions. Read these instructions for reprocessing carefully and completely. Keep the instructions for reprocessing for future reference. Failure to observe the instructions for reprocessing may result in injury to the patient or damage to the device. Safety instructions For reasons of hygiene and health protection, all single-use bands that have been in a patient's mouth to be appraised for fit must be cleaned and sterilized before it may be returned to the band box. The hygiene regulations of the individual national and international legal provisions of dental/medical practices, hospitals and dental laboratories must be complied with. Only devices with a validated procedure may be used for cleaning, disinfection and sterilization. The following parameters for cleaning, disinfection and sterilization must be complied with, as these have been subjected to a validated process. The cleanliness of the medical devices cannot be guaranteed if the reprocessing is carried out with deviating parameters. Cleaning, disinfection and sterilization All reprocessing must be carried out by trained personnel in a room specially equipped for this purpose with a clean and unclean zone. The cleaning agents must not contain aldehydes.

Instructions for reprocessing

Manual Cleaning

1. Place all medical devices to be cleaned in a liquid instrument cleaner (e.g., Komet DC Evo cleaning and disinfecting agent) for 30 minutes immediately after use, but after 30 minutes at the latest.
2. Remove any other visible residues with a nylon instrument brush and a lint-free disposable towel. Cavities, feedthroughs and constrictions must be treated twice. Move the product around the welding at least twice in all directions while cleaning.
3. Rinse all medical devices under cold, running water (drinking quality).
4. Visually check the cleanliness of all individual medical devices. Magnifying glasses can be used for support.

Repeat steps 1 to 4 if residues are still visible on the medical devices.

Maintenance, Inspection and Testing

Afterwards, check the medical devices for intactness. The medical devices must be free from corrosion, other contamination, wear or damage.

Medical devices that show a loss of function and/or corrosion/defects must be removed from use immediately and must not be used on patient.

Packaging

All non-sterile medical devices supplied must not be sterilized in their original packaging.

1. The medical devices are packed individually in a sterile bag according to EN ISO 11607-1 and sealed using a suitable sealing machine.

Care must be taken to ensure that the medical devices in the sterile pouch are not under tension. This can lead to damage to the sterile barrier and thus to a loss of sterility.

2. Sterilization is carried out in a class B small steam sterilizer with fractionated pre-vacuum (in accordance with EN 13060 and CE certification). Sterilization parameters other than those listed below are not covered by the manufacturer's validation. Therefore, no guarantee can be given that sterile-status will be achieved.

Type	Temperature	Holding Time	Drying Time
B	134°C	≥ 3 Min.	≥ 5 Min.

3. The labelling of the (re)processed, packaged medical devices must include the following information:
   a. designation of the device(s), size information if applicable;
   b. information on release;
   c. release decision;
   d. sterilization cycle and sterilization date;
   e. expiry date and sterile supply storage period.

Disposal

The medical devices must be disposed of in accordance with the locally applicable regulations and environmental regulations. The degree of contamination of the medical devices must be considered – decontamination prior to disposal therefore may be necessary.

9-Pre-formed archwires

Part numbers	70-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) 71-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) 72-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) 73-XXXX-XXXX Beta-titanium alloy (Mo, Zr, Sn, Ti) 74-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) 76-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) 77-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) 78-XXXX-XXXX Stainless Steel (Fe, Cr, Ni, Mn) 79-XXXX-XXXX Stainless Steel (Fe, Cr, Ni, Mn)
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	Insert the archwire in the slot of the brackets and buccal tubes and fix it with an elastomeric or wire ligature. When using self-ligating brackets, close according to manufacturer's instructions.
Warning 	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. NICKEL Warning This product contains nickel, a chemical known to the State of California to cause cancer.

10-Springs

Part numbers Composition	60-XXXX-XXXX Nickel-titanium alloy (Ni, Ti) Exception: 60-X2XX-XXXX stainless steel (Fe, Cr, Ni, Mn, Co) 61-XXXX-XXXX Nickel titanium alloy (Ni, Ti) Exception: 61-XXXX-0000 stainless steel (Fe, Cr, Ni, Mn, Co)
Application	Tooth movement either through pulling or pressing force.
Instructions for Use	Cut the spring to the desired length and thread it onto the archwire. Compress the spring until the windings are closed. Place the spring in the bracket gap or between a stop on the archwire 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 archwire. 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.

11-Lip-Bumper

Part Numbers	63-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo , Co) Nylon/ polypropylene Silver 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 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.

12-Palatal bows

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

13-Retainer

Part numbers	65-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Cu, Mn, Nb, Mo, Co) 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.

14-Stops and hooks

Part numbers	66-XXXX-XXXX 69-14XXX-XXXX
Composition Co	Stainless steel (Fe, Cr, Ni, Mn, Mo, Co)
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 archwire dimension being used. Place the product on the required location of the archwire 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.

15-Wire ligatures

Part numbers	67-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Co)
Also available in 67-XX4X-XXXX 67-XX5X-XXXX 67-XX6X-XXXX	Polyether ether ketone (PEEK) coating
Application	Placing archwire in bracket slot. Affix ancillary appliances in and on brackets, buccal tubes, archwire 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 archwire 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 archwire.
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, archwire and ligature as well as chipping of the coating. When twisting ligature with an instrument, do not scratch the archwire or its coating. 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.

GC Orthodontics Line

Instructions for Use - English

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