Facebows

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. 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.

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-Face bows

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.

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.

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CE 2797

Facebows

Part numbers	62-XXXX-XXXX
Composition	Stainless steel (Fe, Cr, Ni, Mn, Mo, Co) Silver filler (Ag, Au, Cu, Sn)
Also available in 62-X2XX-XXXX	Nylon, PVC
Application	Assembled with neck strap, safety modules and extra-oral headgear for distalization, 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: 1. Always insert the distal ends into the tubes first and then hook up the pulling mechanism. 2. When removing, always release the pulling mechanism first, then pull the face bow out of the tubes. 3. Do not allow other persons to touch or wear the equipment supplied. 4. Never pull in front of the eyes. 5. Do not use during sports. 6. Monitor the condition of bedclothes so the external bow does not catch during sleep. Note: The power module manufacturer's instructions supersede any others. NICKEL WARNING: This product contains nickel, a chemical known to the State of California to cause cancer.

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