

GB: GLICE Orthodontics Brackets

1. PRODUCT IDENTIFICATION

The orthodontic brackets manufactured by Sweden & Martina S.p.A. are medical devices intended to be used exclusively in orthodontics procedures for the prevention and treatment of deformations of the dental arches. Orthodontic brackets are medical devices intended for long-term use, single use, provided in non-sterile packaging. Using orthodontic brackets differently from what indicated by Sweden & Martina S.p.A. limits their liability and voids the product warranty (see the later section "Liability for Defective Products and Terms of Warranty"). Sweden & Martina S.p.A. is not liable for the use of non-original orthodontic brackets.

2. INTENDED USE

The orthodontic brackets in sapphire, GLICE brackets, indicated for the orthodontic movement of natural teeth, with the exception of mandibular bicuspid teeth are invasive medical devices intended for long-term use. They are sold in a non-sterile single-use packaging. The function of brackets is to provide orthodontic treatment.

For the purposes of the Directive 93/42 implemented in Italy with D.L. 46/97 of 26/3/97, annex IX, Sweden & Martina declares itself as manufacturer of GLICE orthodontic brackets and identifies the risk class as shown in Table 1. Orthodontic brackets, intended to be used in all subjects who have the appropriate therapeutic indications, must be used exclusively by professional medical personnel with the necessary qualifications.

3. MANUFACTURER'S DETAILS

The manufacturer of GLICE brackets is:

Sweden & Martina S.p.A.
Via Veneto 10 - 35020 Due Carrare (Padova) - Italia
Tel. +39.049.9124300 - Fax +39.049.9124290
e-mail: info@sweden-martina.com - www.sweden-martina.com

4. RAW MATERIAL

The materials used for the production of GLICE orthodontic brackets were selected on the basis of the properties indicated for their intended use, in accordance with Directive 93/42 implemented in Italy with Law 46/97, Annex I Essential Requirements, point 7.1. GLICE aesthetic brackets are made of monocrystalline ceramic (sapphire), a material that makes the bracket highly aesthetic, given its high transparency, and resistant. It is recommended to check with patients for any allergy to raw materials.

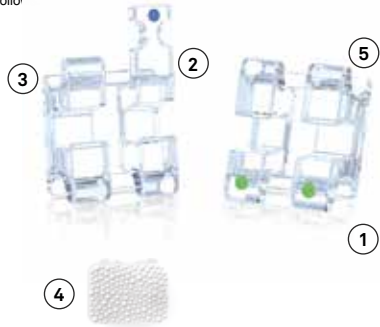
5. DESCRIPTION

Orthodontic brackets are medical devices widely used in orthodontics for the prevention and treatment of deformations of the dental arches. GLICE brackets are characterized by a low profile; all corners, edges and the slot itself are rounded to reduce friction with the orthodontic wire. The surface of the base is treated for better adhesion to the teeth and for a safer detachment, without risking any damage to the enamel. Made of monocrystalline ceramic (sapphire), GLICE is a highly aesthetic and transparent bracket. It is also stain-resistant and is able to maintain its transparency unchanged throughout the entire treatment. The crystalline structure of the material makes GLICE an extremely resistant bracket. GLICE bindings are designed with 4 lateral flaps for any additional ligatures.

Correct positioning of the brackets is of fundamental importance in an orthodontic treatment. The positions of the brackets inside the mouth follow standardized rules recognized by the international community of orthodontists.

On all orthodontic brackets there are clear references, vertical and horizontal, which make their correct positioning easy. The information in these instructions for use completes the information in the catalogs / manuals. The Sweden & Martina GLICE brackets specifically manage the following orthodontic prescriptions: MBT technique: (John Bennett, Richard P Mc Laughlin and Hugo J Trevisi), Roth technique.

The product is composed as follows



N.	Name	Description
1	Slot	Space in which orthodontic wires and / or arches are inserted
2	Marking	color dots for easy identification of the position of the teeth
3	Side flap	part dedicated to the possible application of the bindings
4	Base	part that sticks to the surface of the teeth
5	Hook	part that attaches the rubber bands needed to move the tooth into the ideal position

6. METHOD OF USE

Be careful not to confuse the pieces inside the package. The color code indicated on the back of the lid identifies the correct position and the corresponding tooth. Before use, it is recommended to clean the bracket with alcohol or special products recommended for use with ceramic products. Be careful not to scratch the bracket; if this happens it is recommended to replace the device.

It is recommended to take the brackets with special tweezers and clean the surfaces to be bonded (both the bracket and the tooth surface must be thoroughly clean and dry) to ensure correct adhesion. Check your teeth thoroughly for any damage to the enamel. Observe the specific instructions for use provided by the manufacturer of the adhesive for the bracket used. Sweden & Martina brackets can be glued with any orthodontic adhesive. We recommend the use of adhesives (eg. Ortho Bracket Paste and Ortho One). After applying the etchant both on the surface of the tooth and on the base of the bracket, rinse and proceed with the application of the primer and then the adhesive following the instructions indicated in the instructions for use of the adhesive itself.

The bracket is normally applied to the center of the affected tooth, and any excess adhesive left around the tooth must be removed before the adhesive hardens completely. This operation will simplify the debonding phase at the end of the treatment. Absolutely avoid points of contact with antagonists which could cause dental abrasion and / or cause premature detachment of a bracket. Possibly create an occlusion elevation. Once the adhesive has hardened (see hardening times of the adhesive used), fix the orthodontic arch in the "slot" of the bracket with a binding wire or elastic wire. The procedures to be followed are however at the discretion of the dentist. To remove the bracket it is necessary to use special tools, always following the procedures that avoid if any possible damage to the enamel.

6.1 Instructions relating to the handling and storage of the product

Before use it is recommended to clean the bracket. The tooth surface must be clean, dry and insulated. Keep the brackets dry before adhesion. It is recommended to place them in the correct position on the tooth, following the recommended procedures. Each bracket corresponds to a specific tooth. Incorrect placement on the tooth can compromise treatment or create problems. The brackets are for single use only and should not be reused. Even in case of detachment from the tooth surface, they must be replaced with new brackets. The reuse of a bracket, in addition to no longer having any guarantee of integrity and seal in the treatment adopted, can cause damage to the tooth surface. Brackets must always be used by personnel specialized in orthodontic treatments. Instruct patients to avoid chewing on hard-consistency materials and foods such as ice, candy, etc. It is important to instruct the patient to follow a correct cleaning of the same throughout the period of orthodontic treatment. Store the orthodontic brackets at room temperature or lower, keeping them in the original packaging or in a special hermetic packaging that avoids knocks and contact with external agents.

Pay attention to the removal of orthodontic brackets, help yourself with the use of special tools. If any remaining fragments of ceramic material remain, use a diamond bur to remove them. Once removed, the brackets must be disposed of. Dispose of orthodontic brackets according to the sanitary disposal procedures in place at the dental office.

7. CONTRAINDICATIONS

Technical information such as torque, angle, size, etc. are shown on the product label. I'm not known side effects (allergic reactions), and / or contraindications for Sweden & Martina brackets. In case of allergic reactions, skin reactions, irritation, dermatitis, remove the medical device immediately and consult the attending physician.

Brackets should not be used on teeth with compromised enamel surfaces, on porcelain teeth, or on patients suffering from dental mucosal diseases. The use of orthodontic brackets on damaged teeth can cause further damage to the tooth.

8. WARNINGS

Orthodontic brackets Sweden & Martina S.p.A. are single use medical devices sold in non-sterile packaging. Do not use if package is damaged. The code, the description of the contents and the lot number are printed on each package. These same data are also indicated on the labels placed inside the packages and must always be quoted by the doctor for any communication on the matter. The packaging complies with European standards.

Law restricts this device to sale by or on the order of an orthodontic professional. Be careful not to confuse the pieces inside the package. The color code indicated on the back of the lid identifies the correct position and the corresponding tooth. Avoid placing orthodontic brackets in occlusion to avoid erosion of the enamel.

9. CHEMICAL COMPOSITION

Raw Material	Monocrystalline alumina	Criteria	Test Results
Composition	Al ₂ O ₃	≥ 98,4	99,85
	SiO ₂	≤ 0,06	0,042
	Fe ₂ O ₃	≤ 0,03	0,017
	Na ₂ O	≤ 0,70	< 0,010
Information Danger Elements Informazioni	Ni	≤ 0,1	< 0,001
	Cd	≤ 0,1	< 0,001
	Pb	≤ 0,1	< 0,001
	Be	≤ 0,1	< 0,001

10. LEGAL REFERENCES

The design and production of GLICE brackets is carried out in compliance with the most up-to-date harmonized directives and standards regarding the materials used, the production processes, the information provided and the packaging.

11. WASTE DISPOSAL PROCEDURES

Orthodontic brackets, if removed from the oral site due to a biological or mechanical failure, must be assimilated for their disposal with biological waste, according to local regulations.

12. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY

Optimal patient care and attention to their needs are necessary conditions for orthodontic success and it is therefore necessary to carefully select the patient, inform him of the inherent risks and duties associated with the treatment and encourage him to cooperate with the dentist for a good outcome. of the treatment itself. It is therefore necessary that the patient maintain good hygiene, confirmed during check-ups and control appointments; it must always be ensured and documented as, moreover, the pre and post-operative indications and prescriptions must be observed and documented.

The instructions provided by Sweden & Martina are available at the time of treatment and accepted by the dental practice; they must be observed and applied at all stages of care: from the patient's medical history to post-operative check-ups.

The warranty only covers ascertained manufacturing defects, after sending the piece identified by item code and lot, within the warranty period. The warranty clauses are available on the website www.sweden-martina.com.











13. DATE AND VALIDITY OF INSTRUCTIONS FOR USE

These Instructions for Use have validity and effect from the month of May 2019.

Table 01

Device	Packaging	Directive 93/42	Rule	Risk Class
GLICE Orthodontic Brackets	Single-use packages	Invasive devices in relation to the orifices of the body other than surgical devices, used in the oral cavity up to the pharynx, intended for a long-term use.	5	Ila

Key of symbol used

	Attention, read instructions for use
	Batch number
	Code
	European Union CE conformance marking
	Do not re-use
	Not sterile
	Manufacturer
	Consultare le istruzioni per l'uso https://www.sweden-martina.com/en_gb/
	Do not use if package is damaged
	Manufacturing date