CE 0476

EN: Removable Orthodontic Appliances

1. PRODUCT IDENTIFICATION
The removable orthodontic appliances manufactured by Sweden & Martina are medical devices intended to be used to correct the position of one or more teeth.
Any use of such devices other than their intended purpose, limits Sweden & Martina S.p.a.'s liability and voids the product warranty (see section "Liability for Defective Products and Terms of Warranty"). Sweden & Martina isn't liable for the use of non-original orthodontic devices.

2. INTENDED USE
The Sweden & Martina's orthodontic removable appliances are medical invasive devices intended for long term use in the oral cavity. They are sold in NON- sterile package. They must be used only in a single patient undergoing orthodontic treatment. They are indicated for the alignment of teeth during orthodontic treatments for malocclusions and are available only with a medical prescription.
In compliance with Directive EEC 93/42, implemented with L.D. 46/97 dated 24/02/1997, annex IX, Sweden & Martina declares that is the manufacturer of these orthodontic devices and attributes the risk classes given in Tab. 1.
Sweden & Martina orthodontic devices are intended to be used in all subjects who need orthodontic treatment and satisfy the appropriate therapeutic indications. They must be used only by professional, medically - qualified personnel having the necessary qualifications and approvals.

3. MANUFACTURER'S DETAILS
The manufacturer of these orthodontic device is:

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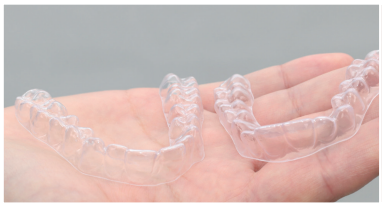
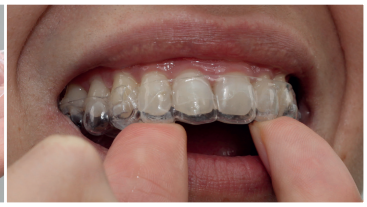
4. RAW MATERIALS USED
The materials used for manufacturing orthodontic devices are selected on the basis of the properties required for their intended use, in accordance with Regulation (EU) 2017/745.
Sweden & Martina orthodontic removable devices are produced in plastic material. It is recommended to check with patients for any allergies to raw materials.

5. DESCRIPTION
The orthodontic treatment for teeth alignment consists of a series of removable orthodontic appliances, commonly called aligners, designed to the specific characteristics of the individual patient.
The aligners allow to move the patient's teeth with small movements from their original position to an optimal position.

6. METHOD OF USE
a. Give the aligners to patient inside envelope number one, together with their container, the Patient User Manual and the copy of Declaration of Conformity.
b. Insert aligner number one and position it correctly, checking that the edge is comfortable for the patient. Use the rubber polishers in case the aligner requires finishing.
c. after removing them from packaging and before use, rinse the new aligners with cold water.
d. if the treatment plan includes the extraction of a tooth, it would be best to discuss the most appropriate time to being aligner therapy with your tutor.
e. if a new aligner doesn't fit perfectly in mouth, check the level of patient's collaboration with previous one. If cooperation has been less than required, ask the patient to continue wearing the old one until the next check-up.
f. it is necessary to carry out the IPR that is forecasted and indicated on the medical prescription with great precision, using a dental feeler gauge to measure it correctly. At each appointment, for correct execution of planned movements check that the contact points are clear, using dental floss.
g. At each appointment, to supervise the progresses and to control that the aligners have a perfect fit with teeth, check the treatment plane.
h. Delivery the next set of aligners to patient. The patient should have a sufficient number of aligners until next following appointment.

Application of grip points, if required
F22 started kit contains a special template for placement of grip points. Check on virtual set-up or on case documentation to see where grip points should be applied. Position the template on patient's teeth, to verify proper fit. Once the template has been removed, it is necessary to clean and dry the surface of the teeth to apply grip points. The indirect adhesive technique involves steps of etching, rinsing, drying and applying adhesive on teeth and then polymerization. Make sure the template is clean and dry. Insert composite, in an excess quantity, into concavities at grip points on the ineer surface of the template. Insert the template on dental arch and polymerize the composite. Remove the template, lifting edge using scaler. Make sure the grip points are firmly attached to the teeth. Remove any excess composite and finish grip points with finishing bur.

Perform any necessary interproximal reduction (IPR)
F22 recommends mechanical IPR using abrasive strips of increasing roughness to be mounted on a right-angle or handpiece with a speed of 10.000-12.000 RPM. Once displayed the amount of IPR required, on which teeth and on which wall of virtual set-up, create a guide using an abrasive strip manually to avoid the formation of steps on the enamel. After an adhesive strip has passed through the contact point, it is easier and more effective to use a diamond disk. Even when not specifically required, IPR of 0.1 mm is recommended at a level of teeth where the movements obtained do not correspond to those programmed digitally.

Making divots
Use the special forceps to make divots. Divots must have a minimum depth of 1.3 mm. To simplify the positioning of divots, the surfaces of all teeth are subdivided into nine areas in the treatment summary attached to the documentation of each case and a colour code indicates the vestibular or lingual area.

Containment
It is highly recommended that the F22 Fix retention templates be used at the end of the treatment. Required patient collaboration should gradually be reduced until the aligners only need to be used at night.

7. CONTRAINDICATIONS
F22 system is contraindicated in case of periodontal pathologies, radicular resorption and pharmacological therapies or systemic conditions that may affect tooth movement.
The aligners must always be removed before eating. It is not necessary to remove them to drink cold water. However, it is strongly recommended not drinking coloured or hot drinks (e.g., coffee, tea, red wine) to avoid staining or deforming removable orthodontic appliances.
Always remove your aligners if you wish to smoke, to prevent yellow stains of them. Brush your teeth and pass dental floss after every meal or snack, before inserting your aligners again. If you are temporary without your usual dental hygiene system or a toothbrush, rinse your mouth and clean the aligners with running cold water. Thoroughly clean them as soon as possible. Never use sharp objects, nor bend or twist the aligners when removing them. Dental check-ups and cleaning should be performed periodically to guarantee the health of teeth and gums.

8. CAUTION
In rare case, some patients could be allergic to the plastic from which the aligners are made.
In rare case, in patients affected by hereditary angioedema (HAE), rapid local swelling of subcutaneous tissues may occur, including the tissues of the larynx, because the HAE may be activated by slight such as dental treatment.
In this case, the use of aligners must be suspended and consult the doctor immediately.
The orthodontic devices or part of them may be ingested accidentally or sucked in, with harmful consequences.

9. PRECAUTIONS
1. Aligners must not be exposed to hot water and chemical materials.
2. Aligners must be kept out of reach of children and animals.
3. Store the aligners in a cool, dry place before delivering them.
4. When aligners alone may not be sufficient to achieve the desired outcome, additional orthodontic treatment may be necessary for more complicated treatment plans including the use of fixed buttons, orthodontic elastics, auxiliary dental devices (e.g. temporary anchorage devices), removable or fixed appliances and/or dental reconstruction procedures or severe cases of open bite, mixed dentition and/or narraw jaw.
5. If the patient has hybrid solutions containing metal parts, these may invalidate the outcome of diagnostic testing such as MRI. Whether such parts shuold be removed before performing the test, you should discussed with the specialist.
6. Oral surgery may be necessary to correct dental crowding or severe mandibular asymmetries which were already present before using the F22 product. Should oral surgery be required, the risks associated with anaesthesia and correct healing of relevant tissues involved must be taken into consideration prior to treatment.
7. Already existing dental restorations (e.g. crowns or bridges) may move, making it necessary to re-cement or in some cases replace them.
8. The aligners cannot be used to move dental implants.
9. The patient's general medical conditions and the use of medicines may interfere with the orthodontic treatment.
10. Some teeth sensiviity may be experienced when passing on to the next aligner. Some people may complain about a slight temporary discomfort for some days at the beginning of each treatment phase, when a new aligner is worn: this is a normal condition, usually described as a sensation of pressure. It is a sign thet the aligners are working and are gradually moving the teeth towards the final result. The discomfort generally disappears within a couple of days.
11. Aligners may have a temporary effect on pronunciation and cause a slight lisp, even though any speech defects caused by using F22 tend to disappear within one or two weeks. The majority of patients have reported no effects on their pronunciation. Neverless, as with all conventional orthodontic devices, there is an initial adaptation period associated with the presence of a foreign body in the oral cavity.
12. Poor patient collaboration in not using the aligners for the prescribed number of daily hours, not following the doctor's advice, tooth eruption, teeth with atypical shapes and failure to keep appointments could extend the treatment period and compromise the desired final result.
13. Gingivae, cheeks and lips may be scratched or irritated by the device.
14. To facilitate tooth movements and/or aligner retention, attachments may be temporarily fixed to one or more teeth, or divots may be created on aligners during treatment. The protuberances are located at points where the aligner adheres to the attachment positioned on teeth by dentist. The attachments are small elements made of composite materials that the dentist fixes onto the teeth at points where they engage the aligner's protuberances. Divots are thin indentations situated on aligner surface wich are made by dentist using special forceps. Dentists use one or both of these techniques to obtain the desidered tooth movements. Such attachments are removed after treatment.
15. An interproximal reduction should be required in order to create the necessary spaces for dental movements, the risks associated with this technique should be take into account.
16. Periodontal problems, the formation of caries, gingival inflammation or permanent marks due to staining and tooth decalcification may affect patients who consume foods or drinks with a high sugar content and/or who do not clean their teeth frequently and thoroughly before wearing F22 aligners. Orthodontic devices do not cause caries or gingival inflammation, but their presence may give rise to a greater accumulation of bacterial plaque. It is therefore essential to scrupulously respect oral hygiene routines.
17. The bite may change during treatment and cause a temporary discomfort for the patient.
18. At the end of treatment, the bite may require additional adjustments by the dentist ("balanced occlusion").
19. The teeth may change position after the treatment has ended. It is advisable to use containment techniques. Teeth may tend to move after the treatment has ended. The constant use of containment aligners at the end of treatment will reduce this risk. However, there may be other causes beyond the orthodontist's control that can even cause major changes. Hence, the containment phase is just as important as the treatment phase and must last as long as possible. Teeth that are not at least partially covered by the aligner may be subject to super-eruptions
20. Teeth that are not at least partially covered by the aligner may be subject to super-eruptions.
21. The use of aligners may cause a temporary increase in salivation or xerostomia and some medicines may increase this tendency.
22. Periodontal problems (gingivae and supporting bone) may occur or worsen during the orthodontic treatment due to several factors, especially if one does not observe a proper oral hygiene. The dentist must therefore perform regular check-ups every 2-30 months to monitor the health of the periodontium, also ensuring that the patient maintains high standards of oral hygiene. If this regime is followed, the orthodontic treatment will not have any negative effects and it may even improve the overall oral situation, also due to the greater ease of cleaning correctly aligned teeth. If it is impossible to control the periodontal problems, the orthodontic treatment must be interrupted before completion.
23. The roots of teeth may become shorter during the orthodontic treatment. This does not normally have any consequences, but very rarely it may constitute a problem, with a loss of pulp vitality and a significant decrease in the useful lifespan of the tooth or teeth affected by this shortening.
24. Very rarely, problems with the temporomandibular joint may also be encountered, with joint pains, headaches or ear problems. Such ailments may be experienced during the orthodontic treatment as well as at any other moment of one's life. The role of contact between teeth is unclear, since currently there is no scientific evidence that indicates its importance in the onset of this pathology.
25. If the patient is affected by acute pain or severe discomfort, have to stop using of aligners and undertake further diagnostic examinations, also consulting the F22 tutor.
26. In some very rare case, patients may have allergic reactions to the aligner material. In these cases, treatment should be suspended and referred the patient to a specialist.
27. Orthodontic devices or part of them could be swallowed or sucked, with damaging effects.

10. WASTE DISPOSAL PROCEDURES
The orthodontal devices, if removed from oral cavity as a result of a biological or mechanical failure, must be treated as organic waste for their disposal, according to the laws that apply locally.

11. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY
For orthodontic success it is necessary an excellent patient care and attention to his needs. Therefore, It is necessary to select the patient carefully, inform him about inherent risks and the duties associated with the treatment, encouraging collaboration with the dentist. Therefore, the patient must maintain a good level of oral hygiene, confirmed of regular check-ups and following appointments; that must be guaranteed and documented, along with the pre-and post-surgical directions and prescriptions.
The instructions provided by Sweden & Martina are available at the moment of treatment and accepted by the Dental Practice. These instructions must be observed and applied during all care phases: from the patient medical history to the post surgy check-ups.
The liability covers only the defects of the production, if the device, identified by item code and batch number, is sent within the guarantee period. The guarantee conditions are available at www.sweden-martina.com

12. DATE AND VALIDITY OF INSTRUCTIONS FOR USE
These Instructions for Use have validity and effect from the month of July 2021.

Table 01

Device	Packaging	Classification	Classification Rule	Risk Class
Removable Orthodontic Devices	Single-use package	Invasive device in relation to body orifices other than surgical-type devices, used in the oral cavity up to the pharynx, intended for long-term use. Specific Patient	5	IIa

Explanation of symbols		
REF	Code	✓
UDI	UDI code, Unique Device Identification	✓
LOT	Batch number	✓
	Manufacturer	✓
IT	Country of manufacture	✓
	Caution! See instruction for use	✓
MD	Medical Device	✓
#	Model number	✓
	Consult instruction for use www.sweden-martina.com	✓
CE	CE marking *Where applicable: The identification number of the Notified Body shall follow this symbol.*	✓
	Do not use if the packaging in damaged	✓
NON STERILE	Non-sterile product	✓
1	Single patient, multiple use	✓

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