

Dentist's manual



Indications for use

The F22 system is indicated for the alignment of teeth during orthodontic treatments for malocclusions, and is available only with a dental prescription.

Contraindications

Like any other orthodontic treatment, the F22 system is contraindicated in cases of periodontal pathologies, radicular resorption and pharmacological therapies or systemic conditions that may affect tooth movement.

Sending a case

Before starting to plan a treatment with F22 aligners, check that the patient's mouth is in a satisfactory condition of health and that prostheses and restorations are adequate and require no modifications.

a) **Collecting orthodontic data**

An orthopantomography must be prescribed for the patient, and it is also advisable to perform a latero-lateral telerradiography of the cranium. Any further radiographic examinations (e.g. CBCT, hand and wrist X-rays, radiographic status) must be decided by the dentist on a case-by-case basis. Frontal, resting and smiling photos must be taken of the patient's face, together with the left and right profiles smiling and at rest. Frontal, left, right and occlusal intraoral photos with maximum intercuspation of the upper and lower arches (using a mirror) and of the overjet must be taken.

b) **Taking impressions with polyvinyl siloxane**

Impressions must contain all the molars of the arch. Impressions of both arches are necessary, even if the treatment involves only one arch. It is advisable to use the two-stage method. In the first stage, apply the putty (heavy body material) in the impression tray and cover it with transparent film (for food uses), so that an individual impression tray is created. In the second stage, use a dosing syringe to apply the light body material over the spaces left free by the transparent film. The single-use impression tray should be used for this procedure. The tray will not be returned when the case is sent.

c) **Occlusal registration in maximum intercuspation with polyvinyl siloxane**

Remove excess saliva from the arches using a suction tube or blower.

It is advisable to use silicone applied with a syringe. Apply the material starting from the lower rear molars, then covering the occlusal surface of the molars and premolars on one side, the margins of canines and incisors, and then up to the occlusal surface of premolars and molars on the other side.

Instruct the patient to close the mouth in maximum intercuspation, keeping the arches tight until the material has hardened. Follow the hardening times indicated on the product packaging, remove the registration obtained without deforming it.

d) **Creation of an F22 case online**

Register on **www.f22aligner.com** and fill in the prescription.

Upload the digital photos saved in “.jpg”. Otherwise they will not be recognized by the software. For Apple® users, all extensions, must be changed “.jpeg” in “.jpg”.

e) **Printing out forms**

Print out and complete the consent form for processing of the patient's personal data (available online), and have it signed by the patient.

These forms must be included in the pack containing the impressions and the occlusal registration.

Print out the acceptance and informed consent form to be signed by the patient before treatment, and retain in your documentation.

This form must not be sent.

f) **Sending the case**

The impressions, the registration of the bite, the form for the processing of the patient's personal data and the patient report must be sent to:

Sweden & Martina S.p.A. F22 Aligner Dept.,
Via Veneto 9, 35020 Due Carrare (PD), tel. 049.9124300

Please indicate the name of the sender.

Contact our office in Crawley Toll Free: 0800 112 3575 to arrange for the package to be collected free of charge.

g) **F22 reception**

The aligners will be sent shortly after the case has been received by Sweden & Martina SpA.

Instructions for use

- Give the patient the aligner holder contained in the initial kit, the instructions for use and maintenance of the F22 aligner and the patient's copy of the Declaration of Conformity.
- Rinse the new aligners thoroughly with cold water before use, after removing them from their packaging.
- If an extraction has been performed as part of the treatment, keep the space open while the area is healing. Attachments must be positioned only after the extraction area has fully healed.
- Each set of aligners is designed to be replaced after being worn for 20–22 hours a day for approximately two weeks (about 300 hours for each aligner). In case of difficult tooth movements, the current aligners can be worn for up to three weeks.
- Position aligner no. 1 on the patient's teeth, and visually check that there are no impacts against soft tissues. If necessary, cut the aligners. After cutting the aligners, polish them using EZ-Trim™ polishers or a similar product.

- If a new aligner does not fit the patient's mouth perfectly, check that the previous aligner has not been worn for too short a time, limiting movement, or if it has been worn incorrectly, and has therefore been deformed.
In these cases, a new impression should be taken to request new aligners. In the meantime, the patient should wear the most recent pair of aligners.
- At every appointment, check the teeth to identify any close interproximal contacts and to perform IPR if envisaged. Check that the aligners corresponding to the current phase are being used, and that they adhere correctly. Review the treatment plan to monitor the progress with treatment. Check that attachments have not been detached or worn by colouring them with a pencil.
- Consign the next pair of aligners. The patient must have a sufficient number of aligners to last until the next appointment.
- If extra aligners are necessary, new impressions may be required.

Apply any necessary attachments

The F22 initial kit contains a specific template for the transfer of attachments. Check where attachments must be positioned on the virtual set-up or in the case documentation.

Try the template on the teeth, and make any necessary modifications to ensure its correct insertion.

The teeth to which attachments will be applied must be cleaned with pumice.

The indirect adhesive method includes the phases of acid-etching, rinsing, drying, the application of a layer of adhesive on the teeth and polymerization.

Check that the template is clean and dry.

Insert an excess quantity of composite into the recess on the internal surface of the template. Fit the template onto the dental arch and polymerize the composite.

Remove the template by raising the edges with a scaler.

Check that attachments are firmly glued to the teeth.

Remove any excess composite and trim the attachments using finishing drills.

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 to 12,000 rpm.

After having assessed the quantity of IPR necessary, and on which teeth and which wall of the 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 the level of the 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

After treatment has ended, it is highly recommended to use the final F22 aligners for containment during the night.

Correct oral hygiene

The patient must be instructed in basic oral hygiene procedures to ensure the correct conservation of aligners:

1. Aligners must always be removed for eating or drinking. Aligners need not be removed to drink cold water. Coloured drinks (e.g. coffee, tea, red wine) should NOT be drunk, to avoid staining the aligners;
2. Always remove your aligners if you wish to smoke, to prevent yellow stains on them;
3. Brush the teeth and pass dental floss between them after every meal or snack, before inserting your aligners again. If you are temporarily without your usual dental hygiene system or a toothbrush, rinse your mouth and clean the aligners with running cold water;
4. Consult your dentist for all questions about oral hygiene techniques;
5. Dental check-ups and cleaning should be performed periodically to guarantee the health of teeth and gums.

Instructions for use and responsibilities of the client

Sweden & Martina SpA does not provide medical, dental, health or similar services, and does not perform medical or dental procedures or provide medical opinions.

Sweden & Martina SpA manages only the contact platform and manufactures products in accordance with the indications provided by the dentist.

The implementation of any suggestion made by Sweden & Martina SpA is left exclusively to the discretion of the dentist, who is the only party who may decide on the treatment methods to be used with patients.

Any liability for the therapeutic choices made and treatment plans applied will be attributed solely to the dentist.

Some products and/or treatment options incorporate predefined or pre-established treatment protocols, which are accepted by the dentist with the approval of the digital simulation of treatment. Information on treatment protocols are available on the **F22aligner.it** or when the order is sent.

The order will become binding only after acceptance by Sweden & Martina SpA, which reserves all rights in this respect.

Sweden & Martina SpA treatment options are intended solely for officially accredited dentists who have successfully followed the interactive online course in the reserved area of the F22aligner.it website. Sweden & Martina SpA treatment options are available only for dentists who are up-to-date with their payments and who work in conformity with the corporate policies and practices adopted by Sweden & Martina SpA.

At the end of treatment, Sweden & Martina SpA reserves the right to ask dentists for feedback on the treatment of their patients with the F22 system.

Caution

- In rare cases, some patients may be allergic to the plastic from which aligners are made.
- In rare cases, in patients affected by hereditary angioedema (HAE), rapid local swelling of subcutaneous tissues may occur, including the tissues of the larynx, because HAE may be activated by slight stimuli such as dental treatments.
- In this case, the treatment must be suspended, immediately examining the patient.
- Orthodontic devices or parts of them may be accidentally swallowed or sucked in, with harmful consequences.

A series of 18 horizontal dotted lines for writing.



IFU-ORTO-F22-E

rev. 03-17
v.01



Sweden & Martina S.p.A.

Via Veneto, 10
35020 Due Carrare (PD), Italy
Tel. +39.049.9124300
Fax +39.049.9124290
info@sweden-martina.com
www.sweden-martina.com

Sweden & Martina Ltd

Unit 45
Basepoint Business Centre Metcalf
Way, Crawley,
West Sussex, RH11 7XX, UK
Toll free 0800 1123575
info.uk@sweden-martina.com

Sweden & Martina Mediterranea S.L. - España

info.es@sweden-martina.com

Sweden & Martina Lda - Portugal

info.pt@sweden-martina.com

Sweden & Martina Inc. - United States

info.us@sweden-martina.com

F22 aligners are "custom-made" medical devices. Sweden & Martina is registered with the Italian Health Ministry as a manufacturer of "custom-made" medical devices.
The Declaration of Conformity consigned to the client guarantees the conformity of the product.



Contents are correct at the time of publication. Please contact Sweden & Martina SpA for information on any subsequent updates.