

POLICY - STATEMENT OF RECEIPT OF INFORMATION AND CONSENT

STATEMENT OF RECEIPT OF INFORMATION AND CONSENT FOR ORTHODONTIC TREATMENT WITH A CUSTOMIZED FLEXILIGNER MEDICAL DEVICE

Dear patient, this form summarizes the terms (Policy) related to your treatment with a customized medical device from FlexiLigner, which have already been verbally expressed during the dental visit, so that you also have written confirmation of your consent to the preventive therapies, as required by the ethical code. The reasons for providing you with this form, to be signed by both parties, are:

- a) To obtain your consent to orthodontic treatment and the processing of your data for purely therapeutic purposes.
- b) To inform you about the proposed therapy and the necessary precautions during and/or after its execution.

The following key points are summarized:

1. The FlexiLigner orthodontic methodology involves the application of transparent aligners designed to correct dental malocclusion and align teeth.
2. These aligners, applied to both or just one of the dental arches, must be worn for 22 hours out of 24 (they should only be removed for eating and brushing your teeth).
3. Every 15 days, the aligners are replaced with new ones until the treatment is completed, as planned in the treatment plan.
4. It is often necessary, to facilitate proper dental alignment, to apply small buttons (attachments) of the same color as the patient's teeth on some teeth to achieve specific dental movements.
5. It is frequently necessary to create small spaces between teeth (0.2-0.5 mm) using slightly abrasive strips or small calibrated drills (using a dental drill), which do not damage the enamel. This is done to avoid the need for tooth extraction when space is required for alignment.
6. If the patient does not wear the aligners for the recommended number of hours or does not agree to the application of the buttons and/or the creation of spaces with interproximal reduction (IPR), the expected dental movements cannot be guaranteed, nor the quality and precision of the result.
7. The duration of treatment is entirely individual and depends on the severity of the malocclusion and the alignment of the teeth, as well as the number of aligners needed.
8. The treatment typically includes a set number of aligners (based on the malocclusion present) as planned, and the need for one or more refinements, also as initially planned. Refinement refers to the addition of more aligners to perfect the result. The refinements (x) are included in the orthodontic treatment cost estimate.

It is important to note that if the expected dental movements do not occur due to the patient's lack of cooperation, and new impressions and a new series of aligners are needed, there will be an additional charge of € _____ compared to the agreed-upon estimate.

If the treatment timeline and any refinements are delayed due to the patient's lack of cooperation or missed appointments, FlexiLigner Srl will apply an additional charge of € _____.

At the end of the treatment, there is a retention phase that involves wearing either the last aligners used or specific retention aligners for at least 1 year, every night. Depending on the patient's age and the severity of the initial malocclusion, a further retention phase (at least two nights per week) will follow indefinitely.

Failure to follow these instructions correctly may compromise the stability of the orthodontic result.

OBJECTIVES OF THE ORTHODONTIC TREATMENT

The objectives of orthodontic treatment are:

a) Achieving good dental alignment and a proper relationship between the arches, respecting the soft tissues and the temporomandibular joint.

For the favorable progress and success of the therapy, the patient must:

1. Attend scheduled appointments.
2. Keep the teeth clean.
3. Wear the appliances according to the prescribed methods and times, carefully following the given instructions.
4. Promptly report any changes in the fit of the appliance.
5. Carefully follow the retention phase.

RISKS AND INFORMATION ABOUT ORTHODONTIC TREATMENT

Orthodontic treatment, like any medical procedure, involves certain risks that may occur even during perfectly executed therapy, specifically:

1. The presence of the appliance may cause discomfort in daily life, particularly in eating and speaking, especially during the initial phases of therapy.
2. Pressure on the cheeks and lips may cause discomfort, especially in the early days of appliance use, but this typically subsides after the initial adaptation phase.
3. A sensation of pain of varying intensity may occur 2-3 hours after each activation of the orthodontic appliance and may last for about 2-3 days.
4. Unidentified allergies to the materials used may require treatment interruption.
5. The detachment or breakage of orthodontic appliances should be immediately reported, as fragments may be accidentally swallowed, inhaled, or cause injury to the gums and cheeks.
6. Cavities, gum inflammation, and enamel decalcification may occur if food consumed contains excessive sugar, and/or if proper and continuous dental hygiene is not maintained.
7. Orthodontic appliances themselves do not cause tooth decay or gum inflammation but allow for maintaining good oral hygiene.
8. Shortening of tooth roots can occur in some cases during orthodontic treatment. This usually does not cause consequences but may occasionally lead to a significant reduction in the longevity of the affected teeth.
9. The appearance of pain or noises in the temporomandibular joint must be immediately reported to the orthodontist. These issues can occur during orthodontic treatment or at any other time in life.
10. Teeth may have a tendency to move after orthodontic alignment.

BROKEN OR LOST ALIGNERS AND DEVICES

If an aligner breaks, it will be replaced free of charge, provided a photo showing the breakage is supplied to the doctor.

In the case of a lost aligner, a replacement can be requested at a cost.

If the FlexiVibe auxiliary device is prescribed and malfunctions, it will be replaced free of charge upon submitting detailed photos of the device and returning it to the doctor for replacement.

RETENTION

1. To maintain the results achieved with the transparent aligners, it is essential to use the retention device provided at the end of the therapy. Other factors beyond the orthodontist's control (e.g., infantile swallowing, mouth breathing, wisdom teeth eruption, skeletal growth, or harmful habits) may cause significant changes. For these reasons, the retention phase is just as important as the active therapy phase and must last as long as possible.
2. Wisdom tooth extraction may become necessary, even long after the end of orthodontic treatment, if there is insufficient space for proper eruption of the wisdom teeth.
3. Oral hygiene is crucial. Patients undergoing orthodontic treatment must maintain meticulous oral hygiene. The orthodontic appliance is rarely the cause of gum inflammation and overgrowth (swelling), and it is never responsible for cavities. Orthodontic appliances tend to trap plaque more easily, which is responsible for dental and gum problems. However, with careful and prolonged daily oral hygiene, these risks can be minimized.
4. Normally, orthodontic appliances do not interfere with the ability to perform sports or other activities (e.g., playing wind instruments). If the specialist deems it necessary, the use of a mouthguard may be recommended for high-contact sports to minimize trauma risks. Small injuries to the mucous membranes of the cheeks and lips are physiological during orthodontic treatment, as small sports-related or everyday traumas are unpredictable.

DOCTOR'S OPINION

Not undergoing orthodontic treatment may result in one or more of the following consequences:

1. Worsening of the existing malocclusion.
2. Chewing and digestion problems.
3. Oral mucosa infections (gum inflammation, periodontitis, etc.).
4. Aesthetic compromise of the face.
5. Disorders of the temporomandibular joint.

The treatment may require a longer period than initially expected.

Excessive or insufficient bone growth, delayed eruption of permanent teeth, poor oral hygiene, failure to wear the devices for the recommended number of hours, broken appliances, and missed appointments can prolong the treatment and compromise the result.

It is strongly recommended to carefully follow the instructions given for using the orthodontic appliances, as improper use may cause serious injuries (e.g., to the face, eyes, cheeks, etc.).

The undersigned patient (indicate personal details and tax code)

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declares to have been informed and to have understood the purpose and nature of the orthodontic therapy with the FlexiLigner device, to have received all further requested information regarding the treatment plan, and to be aware of the risks and complications that could arise or be associated with the procedure.

Therefore, I consent to the orthodontic therapy, which has been thoroughly explained, shown, and illustrated with impressions, photographs, X-rays, and the treatment plan.

Date and location:

Patient's signature

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Parents' or legal guardian's signature (attach a copy of the identity document)

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Doctor's signature

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I also accept the cost estimate and the proposed payment terms:

Cost:

Payment schedule:

Patient's signature

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Parents' or legal guardian's signature (attach a copy of the identity document)

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Doctor's signature

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