

Patient Information Regarding Clear Aligner treatment consent.

Why you need to sign a consent form.

Your Dentist will require your consent prior to undergoing Clear Aligner orthodontic treatment. You can just agree verbally but if you do agree you will be asked to sign a consent form, which will then become part of your patient records which of course you will have access to.

If you decide that you do not want to go ahead you can withdraw consent at any point throughout the agreed course of treatment. (Even though you may have already signed a consent form).

Prior to making your decision

Prior to deciding that you wish to proceed with your treatment you will need particular relevant information.

Your Clear Aligner dentist will provide you with a “treatment plan” showing the options for treatment & will most likely recommend a detailed course of action from this based on their specific experience in dealing with patients.

You are under NO obligation to accept this opinion & may go for an alternative provided by your Clear Aligner dentist; or indeed any other qualified dentist.

It would be prudent to go to the consultation armed with any specific questions that you may have such as ; will it be painful, how long could I expect the pain to last (if any), how do I deal with my usual dental hygiene regime etc.

Further consent information

Further information regarding consent can be obtained from The Department of Health who produce leaflets about consent ; ***Consent – What I Have A Right To Expect***, If you would like to know more, there are many options available, you can ask for a copy from your Clear Aligner dentist, order a copy from the NHS Response line 08701 555 455, or you can download a copy of the leaflets at www.dh.gov.uk Follow the links to policy & guidance, then select the A-Z option, select “C” & then select “consent” & “consent key documents”.

Who Is Treating You?

Many orthodontic procedures in the NHS or in the Private Sector are carried out by 'dentists in training'. This term covers a very wide range of dentists – from those who have just qualified to those who are almost ready to become specialists. If your procedure is being performed by a dentist in training, he or she will be appropriately supervised. This may mean that a supervisor is standing next to the dentist in training during the whole procedure (where the dentist in training is relatively inexperienced), or it may mean that they are available for advice if necessary (if the dentist in training is experienced in carrying out procedures of this sort).

What If Things Go Wrong?

Things can sometimes go wrong. Often you, the patient, will be the first to notice because it affects you most. If you think something might be wrong (for example, if pain after fitting a Clear Aligner positioner seems to persist for longer than you were told to expect) contact your orthodontist/dentist straight away. The phone number of the clinic where you were treated should be on your appointment card, your appointment letter or on your copy of the consent form.

Questions To Ask The Clinician

You might find it helpful to note down here questions which you want to ask your orthodontist/dentist or other dental health professionals, when you next see them.

Possible questions could include:

- What are the main treatment options available?
- What are the benefits of each of the treatment options?
- What are the associated risks of each of the options?
- What are the risks if I decide to do nothing for the time being?
- Where can I find out more information?
- How will I feel after the Clear Aligner positioner is fitted?

If there is something that particularly matters to you that might be relevant, note it down overleaf so that you remember to tell the health professional – for example, if you have strong views about certain states of health, or certain activities in your life that are important to you. There are some instances in which external factors may affect the decision you reach about your treatment.

Informed Consent For Clear Aligner (Clear Positioner System)

The following information is provided to patients who will be starting with the Clear Aligner positioner system of treatment. Whilst we recognise the benefits of teeth that function well and seem to have a pleasing appearance, a patient should be made aware that Clear Aligner positioner, like any other treatment of the human body, has limitations and inherent risks. The response of a living system cannot be predicted perfectly.

If a patient decides not to proceed with treatment, then the state of their teeth definition can be expected to continue on its present path. Any unwanted changes that are occurring in the mouth can be expected to continue and the rate of these changes are very unpredictable. Dental changes generally tend to be very slow, but as much as we would like to, we cannot predict what may or may not occur if a patient decides not to proceed with our recommendations. A patient must think about and balance the risks of non treatment against risks of treatment. In the majority of cases it would be our opinion that the risks of treatment are not enough to rule against proceeding with the treatment. Nonetheless, a patient should consider any and all risks carefully before making a final decision. It is very important to note that it is not possible to list every circumstance, so the following list is extensive but incomplete.

The Responsibility Of The Patient

Orthodontic treatment will not be completely successful unless you comply with the following directions. You must make sure that any dental work that will alter the shape or size of your teeth is completed before the Clear Aligner impressions are taken and the positioners are made. You must wear the Clear Aligner positioners 20 to 22 hours per day for them to be effective.

You will move on to the next positioner when your present positioner/s fit your teeth well e.g. (easily fitting in and taking out of the mouth by appearing slightly loose). You must be aware that the loss of a positioner could prevent your treatment from being completed if not replaced or worn as instructed.

Clear Aligner Positioner Description

The system consists of a series of clear removable appliances (positioners) that move your teeth in small increments from their original position to the desired position. Some patients require bonded attachments (small aesthetic tooth-coloured dental composites) and/or elastics on their teeth to facilitate

specific dental movements. You wear the positioner/s in pairs, one on your upper arch teeth and one on your lower arch teeth, unless undertaking single arch treatment. Each positioner/s fully covers your teeth and is virtually invisible when in the mouth.

The total number of positioner/s varies depending on the complexity of your orthodontic problem. The positioner/s are presented on coloured models and worn in sequence. The only time you remove your positioners are to eat, drink and clean your teeth. Approximately every two to three weeks, you will switch to the next positioner/s in the series. Your orthodontist/dentist will monitor your progress through a series of follow-up appointments.

Tooth Decay, Decalcification, Periodical Disease

Bacteria present in plaque (the white substance that is constantly forming on the surface of the teeth) release acids that draws calcium and phosphorous out of the outer surface of the teeth. This will damage a patient's tooth surfaces if the plaque is not removed at least twice each day by thorough brushing, flossing and rinsing. This damage includes tooth decay and permanent markings of decalcification. The bacteria that lives in plaque thrive on carbohydrates, e.g. sugar. Whilst a patient is undergoing Clear Aligner treatment they should minimise the amount and frequency of sugar in their diets. Cleaning by your dentist is necessary during treatment. Daily fluoride mouthwash use is helpful in the maintenance of oral hygiene control.

Treatment Objectives & Treatment Completion

We have tried to establish achievable and realistic objectives for treatment. We know that patients desire the best result that is possible. As you begin treatment, we believe that you will be able to achieve those goals. Unforeseen factors, nevertheless, may interfere with our expectations. As treatment proceeds we will keep the orthodontist/dentist fully informed as to their patient/s treatment progress. If our original goals become unobtainable, we will discuss the alternatives with your orthodontist/dentist who will in turn talk to the patient/s and keep them fully informed of any situations that may arise.

Page 4 of 10

Treatment Duration

Although we give a dentist an estimate of their patient's treatment time, we do not know exactly how long their treatment will take. Individuals vary considerably in their response to orthodontic treatment, so treatment time may be more or less than our estimate. You must be aware poor co-operation in wearing the

positioners or auxiliary elastics for the required hours per day, poor oral hygiene, lost positioners, missed appointments, and other factors can lengthen the treatment time and also dramatically affect the quality of the end result. It is our intention generally to have the treatment move along consistently so that there is minimal discomfort, tissue health is sustained and long term permanent stability maintained.

Enamel Removal/Reduction

Interproximal enamel reduction or removal of the width of teeth (thinning) is often part of the Clear Aligner positioner treatment, it is a procedure to remove a slight amount of enamel between the teeth to create space for the correction of crowded teeth or to enable the teeth in each jaw to come together more efficiently, the enamel is removed with a high speed drill and sand paper in strips of 0.3mm from the mesial and distal surfaces of the perimeter, molars and canines bilaterally as required and this procedure does not require anaesthetic.

Placement Of Attachments

Little composites of tooth coloured acrylic called attachments may be bonded or glued to the front, back or side of specific teeth to give your positioners more grip on your teeth when aiming to move them up or down, changing their tilt or straightening them in order to achieve the correct position, remember these composite attachments are part of your treatment and should only be removed by your orthodontist/dentist when your Clear Aligner positioner treatment is completed.

Discomfort Or Pain In The Joint Of The Jaw

Discomfort and pain may be experienced during orthodontic treatment and clicking or popping noises may occur in or near the joint of the jaw at any time during the treatment, just as with any joint discomfort the possible causes vary. It is important that we are told about temporal mandibular joint/jaw problems so that we may deal with them appropriately and promptly.

Page 5 of 10

Loss Of Tooth Vitality (Nerve Damage)

It is possible for the nerve of a tooth to die during orthodontic treatment, especially if a tooth was previously injured, bumped or impacted. It is therefore helpful when monitoring the health of each tooth for a patient to tell their orthodontist/dentist about any previous injury or stress to their teeth. Sometimes minor bumps can result in nerve damage that is unknown to the

patient. Such injuries cannot always be detected during the orthodontic diagnostic process. As a result it is vitally important that the orthodontist/dentist highlights and informs the company Clear Aligner of any such injuries that occur, are occurring or have occurred. Root canal treatment may be recommended if such a problem occurs, extraction is rarely necessary, however the patient must be aware that it is an option in extreme cases.

Speech

For many patients, orthodontic treatment affects their speech temporarily and they may experience a lisp, most speech impediments caused by positioners usually disappear within a couple of days.

Injury From Positioners

Positioners are designed to have a minimal amount of injury potential and a maximum amount of strength. Nevertheless, accidents can occur. It is also possible, albeit unlikely, for a patient to swallow or inhale parts of the appliances or attachments. The cheeks, lips and gums may be scratched or irritated by the positioner, occasionally tender teeth should be expected after changing to the next positioner in the series. The period of sensitivity or tenderness varies from patient to patient.

Unexpected Tooth Problems

A tooth can become ankylosed (tightly bound), occasionally, to its surrounding bone, it may not be possible to remove the tooth at all. A change in the plan of treatment may be necessary if a tooth ankyloses.

Enamel Wear

The tooth's enamel surface is made up of a crystalline structure and like other crystals it can have undetected fracture lines and defects within it. The enamel may also erode if a patient were to grind their teeth to an excessive extent.

Page 6 of 10

Oral Surgery

Tooth removal or orthognathic surgery, jaw surgery is sometimes necessary in conjunction with orthodontic treatment. Especially to correct severe jaw misalignments/imbances or crowding. These procedures would only be recommended if it improves the prospect for successful treatment. The risk involved with treatment and anaesthesia should be discussed with the patients orthodontist/dentist or oral surgeon before making a decision to undertake this procedure.

Use Of Tobacco

Orthodontic patients are at a greater risk of oral cancer and periodontal gum disease when they undertake the use of tobacco. It is proven that tobacco reduces the blood flow to the tissue of the mouth at a time when optimum blood flow is needed for tooth movement. We recommend that all tobacco users cease the practice of tobacco use and seek advice from their orthodontist/dentist or general practitioner.

General Medical Conditions

General medical conditions can affect orthodontic treatment. The patient is obligated to and should advise their orthodontist/dentist of any medical conditions or allergies they have or subsequently encounter or of any changes in their medical condition/s that occur during treatment with the Clear Aligner positioner system.

Root Resorption

Usually this affect is mild and does not compromise the teeth, however, sometimes this root resorption can be extensive and may then endanger the teeth as periodontal (bone and gum support) can be lost at some future time. It is recognised that some patients are prone to this happening and some are not. It is not possible to predict which teeth may be affected and may need your orthodontist/dentist to take regular progress x-rays of their patients teeth during the treatment process to evaluate whether root resorption is occurring.

Example: Orthodontic forces can initiate a cellular response in the supporting tissue surrounding the roots of the teeth. It's this cellular response that allows the teeth to move, sometimes, this response becomes confused resulting to damage at the ends of the roots of the teeth.

Page 7 of 10

Treatment Success

It is our intention and that of your orthodontist/dentist to do everything possible to provide the very best treatment result. However, we cannot guarantee that the proposed treatment will be successful to a patients complete satisfaction. Individual patient differences create the possibility of unstable or incomplete results. Therefore, selective pre-treatment at additional fees may be necessary despite the very best of care. A limited period of braces may occasionally be recommended to achieve an optimal result.

Final Stability Of Teeth

The positions of the teeth achieved at the end of treatment may not be perfectly stable. The retainers that the patient wears, will enhance the stability of the final result. However even diligent wear of the retainers may not keep a patient's teeth exactly as they were at the end of treatment.

The teeth and jaw structure are a system that is constantly changing throughout one's life. Orthodontic treatment does not make a patient immune to this process. Maturity changes that occur after active orthodontic treatment may alter the quality of the end result.

The wearing of the retainers long term or permanently will minimise changes. If a patient decides to stop wearing their retainers at some point, their teeth may change and some of the original problems may re-emerge. A life time commitment to retainers would be necessary to stabilise the position of the teeth long term and permanently.

Possible Alternatives

Alternatives included, but not limited to can include:-

- No treatment
- Extraction versus treatment without extraction
- Orthographic surgery (jaw surgery) versus treatment without surgery
- Conventional brace, prosthetic teeth (artificial replacement) or compromised solutions

Page 8 of 10

PATIENT CONSENT FORM (part 1 of 3)

To be completed by the patient or a person with parental responsibility if the patient is a child unable to give a valid consent (or if a competent child wishes their parent to sign as well)

I,----- (Print Name) consent to undergoing orthodontic treatment with Clear Aligner positioners and confirm that I have read and understood the content of this document.,

Signature-----

Date-----

Relationship To Child (if applicable)-----

To be filled in by the clinician(s) providing information to the patient:

I confirm that I have explained the treatment to the patient, along with the significant risks and the possible alternatives. I also confirm that I have the necessary competence to provide this information.

Name (Print)----- Date-----

Signature----- Position-----

If a second clinician is involved in providing information please complete:

Name (Print)----- Date-----

Signature----- Position-----

If interpreter present: I have interpreted the information of this informed consent to the patient to the best of my ability and in terms which I believe he/she understands.

Name (Print)----- Date-----

Signature-----

Page 9 of 10

PATIENT CONSENT FORM (part 2 of 3)

To be completed by the patient or a person with parental responsibility if the patient is a child unable to give a valid consent (or if a competent child wishes their parent to sign as well)

I,----- (Print Name) consent to undergoing orthodontic treatment with Clear Aligner positioners and confirm that I have read and understood the content of this document.,

Signature----- Date-----

Relationship To Child (if applicable)-----

To be filled in by the clinician(s) providing information to the patient:

I confirm that I have explained the treatment to the patient, along with the significant risks and the possible alternatives. I also confirm that I have the necessary competence to provide this information.

Name (Print)----- Date-----

Signature----- Position-----

If a second clinician is involved in providing information please complete:

Name (Print)----- Date-----

Signature----- Position-----

If interpreter present: I have interpreted the information of this informed consent to the patient to the best of my ability and in terms which I believe he/she understands.

Name (Print)----- Date-----

Signature-----

Page 9 of 10

PATIENT CONSENT FORM (part 3 of 3)

To be completed by the patient or a person with parental responsibility if the patient is a child unable to give a valid consent (or if a competent child wishes their parent to sign as well)

Please read this form carefully. If your treatment has been planned in advance you should already have been given your own copy of the diagnostic report which describes the proposed treatment. If you have any further questions, do ask the person who is asking you to sign this form. You have the right to change your mind at any time including after you have signed this form.

I agree To what has been explained to me by the person(s) named on this form.

I understand That the procedure may not be undertaken by the person who has been treating me or my child so far

I have been advised of additional procedures which may be necessary, I have listed below those which I do not wish to be carried out without further consultation and consent.

Name-----
(print)

Relationship to child-----
(if applicable)

Signature-----

Date-----

To be completed by the clinician confirming the patient's consent:

On behalf of the team treating the patient I have consulted with the patient and confirmed that he/she wants to procedure to go ahead. I have also answered any/all additional questions that the patient had and have checked their understanding of procedure and terminology.

Name (Print)-----

Date-----

Signature-----

Position-----

If a second clinician is involved in providing information please complete:

Name (Print)-----

Date-----

Signature-----