

## INFORMED CONSENT FOR DNA APPLIANCE THERAPY

You have been diagnosed by your general dentist with craniofacial underdevelopment. There are several options to treat this condition, including no treatment, consultation with a specialist in orthodontics or surgery.

**What is DNA Appliance™ therapy?** *Please initial paragraphs:*

\_\_\_\_\_ I understand that DNA appliance therapy for mid-facial development is a relatively new therapy, and not practiced by all dentists, but significant maxillary development has occurred in most of the patients in treatment to date.

Although DNA appliance therapy has effectively treated many patients, I understand that there are risks, and I accept the risks that a new modality of treating mid-facial abnormalities may entail, such as the need to apply secondary orthodontic therapy in the form of clear aligners, wires and brackets, and any other auxiliary treatment.

I understand there are no guarantees that DNA appliance therapy will be effective for me, as everyone is different and there are many factors influencing the development of the maxilla and that the full effect of the DNA appliance is still yet to be determined.

The DNA appliance has been described as a biomimetic appliance that tries to mimic normal function and, therefore, encourages normal re-development of the jaws, and I therefore understand that to resolve my problem takes time. The average time for development is approximately 18 months, but is affected directly by the severity of an individual patient's problem with other unknown factors and may take 24 months or longer.

### Side Effects and Complications of Oral Appliance Therapy

Published studies show that short-term side effects of oral appliance use in general may include excessive salivation, difficulty swallowing (with the appliance in place), sore jaws, sore teeth, jaw joint pain, dry mouth, gum pain, sore spots in the palate, loosening of teeth, and short-term changes in the bite. I am willing to suffer these side effects should they occur, and will report them so that the doctor can resolve them with adjustments.

There are reports of dislodgment of dental restorations. I accept the cost of repairs should this occur.

\_\_\_\_\_ I am willing to accept long-term complications which include: changes in the bite that may be permanent, resulting from tooth movement or jaw joint repositioning (which is the desired effect with this particular appliance therapy). I understand that these complications may or may not be fully reversible once appliance therapy is discontinued.

I understand that the desired effect of the DNA appliance specifically, in most cases, is to remodel the jaw bone and move the teeth and jaw position to enhance craniofacial development, but if not fully achieved, restorative dental treatment, orthodontic intervention or other treatments may be required, for which I will be responsible.

**Follow-up Visits and Testing**

\_\_\_\_\_ I understand that follow-up visits every few weeks or months in our office are mandatory to: insure proper fit; to assure a healthy condition and maximum, timely development of my mouth and jaw.

\_\_\_\_\_ I understand that following the approximately 18-24-month development protocol, scans and images are required to test the position of your jaw and teeth and that periodic photographic documentation will also be required, which is included in the cost of this appliance therapy, and that depending on the amount of development, Dr. Taylor/Dr. Carroll will reassess my case and may consider alternative treatment modalities and continue with longer treatment time.

**Alternative Treatments**

\_\_\_\_\_ I understand that other accepted treatments for my condition include orthodontics by a specialist, and/or various surgeries, but it is my decision to choose DNA appliance therapy to treat my condition, and am aware that it may not be completely effective for me.

\_\_\_\_\_ I understand that the DNA appliance will not work if I do not wear it 12-16 hours per day, and I am ready to commit to this time investment.

\_\_\_\_\_ I understand that it is my responsibility to report the occurrence of side effects and to address any questions with the doctor.

\_\_\_\_\_ I understand that although this appliance may open the breathing airway and relieve symptoms of obstructive sleep apnea, no guarantee or expectation exists that this will occur.

\_\_\_\_\_ I understand that I will be required to pay the full fee for any treatment I receive at Dental Sleep Northwest, and I am fully responsible for the cost of my care.

\_\_\_\_\_ I understand and accept all risks known and unknown involving the wearing of a DNA appliance, and I understand all the terms contained in this Informed Consent.

\_\_\_\_\_ I consent to the release of my medical photos and radiographs for documentation and research purposes.

\_\_\_\_\_ I consent / do not consent (*circle one*) to the use of my photos for marketing purposes.

I hereby certify that I have read and received a copy of this document on the date listed below, and that I have read the Informed Consent regarding my treatment and fully understand all the terms.

*(Do not sign this before you read it or if it contains blank spaces. You are entitled to an exact copy of the paper you sign if you request it.)*

Patient \_\_\_\_\_

Date \_\_\_\_\_

Witness \_\_\_\_\_

Date \_\_\_\_\_

Doctor \_\_\_\_\_

Date \_\_\_\_\_