

Informed Consent

Title of Project: ***The Fully Digital Bruxism Splint; Validation of Efficiency and Efficacy***

Principal Investigator: *Barry E. Goodspeed, DDS, owner of 3D General Dentistry Services, P.C.*

Other Investigators: Birmingham Society for Advancement in Dentistry members

Participant ID: _____

Introduction:

We invite you to take part in this clinical evaluation in Birmingham, AL, which seeks to validate the efficiency and efficacy of a bruxism splint fabricated with the Dentsply Sirona Primeprint 3D printer within a completely digital workflow. This printer and material have been thoroughly tested and proven safe and effective in lab and clinical studies. Taking part in this evaluation is entirely voluntary. If you decide to participate, you must sign this form of consent, and your participation may last 1 year. Approximately (6-12) patients will be included in this evaluation.

Section 1. Purpose of this clinical evaluation

Purpose of this clinical evaluation is to quantify how efficiently a digital bruxism splint is delivered to a patient. A one year follow up with the patient will be used to document the efficacy and durability of this Primeprint printed splint.

Section 2. Procedures

The patient and doctor participation will require an initial digital scan of their teeth, a second visit to adjust and deliver the splint, possible adjustments at 1-2 weeks, and a requested 1 year clinical or telephone follow up evaluation of patient comfort and compliance and the durability of splint. Doctors are asked to provide documentation as listed on documentation sheet.

Section 3. Time Duration of the Procedures and Study

Each of 2-4 visits will require approximately 30 minutes.

Section 4. Discomforts and Risks

The known risks associated with this clinical evaluation are: a patient may feel discomfort with the splint and choose to not use the splint.

Section 5. Potential Benefits to you and to others

The possible benefits you may experience from the described splint include protection of teeth, jaw muscles, and/or jaw joint from the harmful effects of bruxism. The dental profession and their patients may benefit by elevating this efficient method of treatment. Patients will not receive the results of this evaluation. Participating dentists will receive the results of the clinical evaluation.

Section 6. Statement of Confidentiality

Patient names will be confidential. Your clinical evaluation records that are reviewed, stored, and analyzed will be kept in a secured area. Patients will not be identified by name, social security number, address, or phone number. Names of participating doctors may be listed in publications and presentations. If you choose to participate, you are free to withdraw your permission.

Section 7. Costs for Participation

Your dentist will inform you of any costs.

Section 8. Compensation for Participation

There is no monetary compensation for participation to doctors or patients. Doctors will receive CE credit.

Section 9. Research Funding

Funding disclosure: 3D General Dentistry Services, P.C. is supplying the lab funding for this evaluation.

Compensation Disclosure: Barry E. Goodspeed, DDS is an owner of the Dentsply Sirona Primeprint and owner of 3D General Dentistry Services, P.C. No compensation is provided for producing the splints in this evaluation or supervising this clinical evaluation.

Section 10. Voluntary Participation

Taking part in this evaluation is voluntary. If you choose to take part, your major responsibilities will include showing up for the 2-4 appointments.

Section 11. Contact Information for Questions or Concerns

You have the right to ask any questions you may have about this evaluation. Inquiries may be addressed to drbarrygoodspeed@protonmail.com.

Signature and Consent/Permission to be in the Evaluation

Your signature below means that you have received this information, have asked the questions you currently have about the evaluation and those questions have been answered. You may receive a copy of the signed and dated form to keep for future reference.

Participants: By signing this consent form, you indicate that you are voluntarily choosing to take part in this evaluation.

Signature of Patient

Printed Name

Signature of Doctor

Printed Name

Date