UNIVERSITY OF MINNESOTA

Twin Cities Campus

Division of Orthodontics
School of Dentistry

6-320 Moos Health Sciences Tower
515 Delaware Street S.E.
Minneapolis, MN 55455
Office: 612-625-5110
Fax: 612-626-2571

CONSENT FORM

Clinical performance of a new esthetic, self-ligating orthodontic bracket

You/your child are invited to participate in a research study that evaluates the performance of a new tooth-colored, self-ligating orthodontic bracket. Brackets are part of the braces that allow us to move teeth. Self-ligating brackets use some form of door or clip to hold the wire in place, eliminating the need for conventional ligatures. You/your child were selected as a possible participant because you/your child are seeking or undergoing orthodontic treatment at the University of Minnesota. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Thorsten Gruenheid, DDS, Dr med dent, PhD and Brent Larson, DDS, MS, researchers at the University of Minnesota, Division of Orthodontics, Department of Developmental and Surgical Sciences. It is funded by 3M Oral Care, the manufacturer of the new bracket.

Study Purpose

The purpose of this study is to assess the stability of the bracket door that holds the wire in place, the ability of the bracket to correct rotations and inclinations of teeth, and patient and clinician satisfaction with the bracket.

Study Procedures

If you/your child agree to participate in this study as a new patient, we will ask you/your child to have the new brackets bonded to your/your child's four lower incisors. Bonding orthodontic brackets to your/your child's teeth is required for orthodontic treatment, regardless of your/your child's participation in this research study. If you/your child already have braces and choose to participate in the study, you/your child will be asked to have the old brackets on the four lower incisors replaced with new study brackets. All other brackets will remain in place.

During treatment, you/your child will be asked to be seen at intervals of 4–8 weeks for adjustment of the orthodontic appliance. During these adjustment visits, correction of tooth rotations and possible bracket failure will be recorded. An extra time of 1–2 minutes per adjustment visit is estimated to be needed for these activities. Adjustment of the orthodontic appliance at regular intervals is necessary to achieve an adequate treatment result regardless of your/your child's participation in this research study. You/your child will also be asked to complete a short survey to assess patient comfort and satisfaction with the new bracket. The time needed to complete the survey is estimated to be less than 3 minutes. Study participation does not involve withholding the standard of care, which includes bonding orthodontic brackets to your/your child's teeth as outlined above.

Risks of Study Participation

The risks associated with the new bracket include wear of enamel surfaces of teeth in contact with the bracket, increased risk of bracket fracture (especially upon bracket removal), and losing fractured portions of the bracket in the patient's mouth. However, these risks are not specific to the study and are associated with the use of other ceramic orthodontic brackets as well. Similar to most orthodontic brackets on the market, the door locking mechanism of the new bracket contains nickel and chromium (0.01%). A small percentage of the population is known to be allergic to nickel and/or chromium.

A risk associated with record keeping is breach of confidentiality. All efforts will be made to keep your/your child's information private. Moreover, your/your child's name will be made anonymous and replaced with a unique identification number. All data will be reported using this number and only the investigators will know which identification number corresponds to which individual.

Benefits of Study Participation

There is no direct benefit to you/your child for participating in this study. However, future orthodontic patients could benefit from the results of this study as they may help develop better orthodontic materials.

Alternatives to Study Participation

If you/your child choose not to participate, your/your child's status to receive orthodontic treatment will not be affected.

Study Costs/Compensation

You/your child will not incur any costs as a result of study participation. If you/your child currently do not have braces, you will not be compensated for participation but can be treated with tooth-colored ceramic brackets without additional charge ($239 value). If you/your child currently have braces and choose to participate in the study, you/your child will be given a $150 gift card at the end of the study as compensation for the time, expense and inconvenience associated with replacing the old brackets on the four lower incisors with new study brackets.

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your/your child's insurance company. The sponsor of this study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you/your child have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the researchers know right away.

Confidentiality

The records of this study will be kept private. Any publications or presentations that may result from this study will not include any information that will make it possible to identify you/your child as a subject. However, your/your child's study records may be reviewed by the study sponsor and University departments with appropriate regulatory oversight. Study information will not be recorded in your/your child's orthodontic record. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

Protected Health Information (PHI)

Your/your child's PHI created or received for the purposes of this study is protected under the federal regulation known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your/your child's decision whether or not to participate will not affect your/your child's current or future relations with the University. If you/your child decide to participate, you/your child are free to withdraw at any time without affecting those relationships.

Contacts and Questions

If you have questions about research appointments, the study, research results, or other concerns contact the researchers. You may ask any questions you have now, or if you have questions later, you are encouraged to contact them:

Researcher Names: Thorsten Gruenheid, DDS, Dr med dent, PhD and Brent Larson, DDS, MS
Phone Number: 612-625-5110

To share feedback privately about your research experience, including any concerns about the study, call the Research Participants Advocate Line: 612-625-1650 or give feedback online at www.irb.umn.edu/report.html. You may also contact the Human Research Protection Program in writing at D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455. You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of patient/parent/guardian	Date
Signature of person obtaining consent	Date

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ASSENT FORM

Clinical performance of a new esthetic, self-ligating orthodontic bracket

We are asking you to participate in a research study that will help us find out how well a new tooth-colored orthodontic bracket works for straightening teeth. An orthodontic bracket is the part of your braces that is glued to your teeth.

If you agree to be in this study, we will assess the stability of the door that holds the wire in the bracket, the ability of the bracket to rotate teeth, and your satisfaction with the bracket. During your treatment, we will see you every 4–6 weeks to adjust your braces. At these adjustment visits, we will check if all brackets are still in place and intact. In case that a study bracket is broken, we expect the adjustment visit to take an extra 1–2 minutes. We will also ask you to complete a short survey about how happy you are with the new bracket. We estimate this to take less than 3 minutes.

None of the activities involved in the study will hurt. It may just take some extra time at your regular clinic visit as we need to collect some extra information.

We have also asked your parents for permission and we will show you the brackets we will use in the study before we put your braces on. If you want, your parents can be in the room with you at all times. If there is anything you do not like during the study, you can ask us to stop at any time. You can also ask us questions about the study at any time. If you think of any questions later, you may call us at 612-625-5110.

By signing below, you confirm that you have read this form with us, we have explained your role in the study, and that you are willing to participate. Remember, being in this study is up to you. Nobody will be offended if you do not want to participate or if you change your mind later.

Signature of participant	Date
Signature of person obtaining assent	Date

HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

1. Purpose. As a research participant, I authorize Thorsten Gruenheid, DDS, Dr med dent, PhD and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled "Clinical performance of a new esthetic, self-ligating orthodontic bracket."

2. Individual Health Information to be Used or Disclosed. My individual health information that may be used or disclosed to conduct this research includes information on clinical performance (*e.g*. door stability, ability to correct rotations of teeth) of orthodontic brackets bonded to my teeth and my satisfaction with these brackets.

3. Parties Who May Disclose My Individual Health Information. The researcher and the researcher's staff may obtain my individual health information s from hospitals, clinics, health care providers, and health plans that provide my health care during the study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information disclosed by parties listed in item 3 and information disclosed by me during the course of the research may be received and used by Thorsten Gruenheid, DDS, Dr med dent, PhD, the researcher's staff, and 3M Oral Care for product development and improvement. Also, if I receive compensation for participating in this study, identifying information about me may be used or disclosed as necessary to provide compensation.

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign, I may not be allowed to participate in this study or receive any research-related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to Thorsten Gruenheid, DDS, Dr med dent, PhD, University of Minnesota, 515 Delaware Street S.E., Minneapolis, MN 55455 to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the health information already collected for this study. No further health information about me will be collected by or disclosed to the researcher for this study.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this study and no longer covered by this authorization. However, the research team and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect privacy and limit the disclosure of identifying information. There are other laws that may require individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities, and public health measures.

This authorization does not have an expiration date.

I am the research participant or personal representative authorized to act on behalf of the participant. I have read this information, and I will receive a copy of this authorization form after it is signed.

Signature of research participant or personal representative	Date
Printed name of research participant or description of personal representative's authority to act on behalf of the research participant	Date

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.