Madigan Army Medical Center
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

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KEY INFORMATION FOR PROTOCOL: Effect of Povidone Iodine on the Dental Implant Internal Surface Microbiome

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Detailed information follows this page. Ask the researchers questions you have. If you have questions later, the contact information for the research investigator is below.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

We hope to learn if applying antiseptic to the inside of a dental implant will decrease or alter the types of bacteria inside it which may then decrease the incidence of implant failure associated with bone loss, infection, and other complications. During your implant placement appointment, an antiseptic (povidone iodine) will be applied to the inside one of your two new dental implants, no antiseptic will be applied to your other dental implant (this is what would occur if you choose not to participate in this study), before covering both of them with a cover screw or healing abutment. You will return to the Madigan Oral & Maxillofacial Surgery Clinic 3-6 months later when your implant hardware is removed a swab of the implants internal cavities will be collected. Your participation in this research will last up to 6 months and require one additional minute during both your implant placement and hardware removal appointments.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)

You may benefit from the use of iodine on the dental implant as it may reduce implant failure rate by reducing the frequency of complications such as infection-associated inflammation, bone loss or other complications. It may also decrease the risk of additional surgeries such as explantation of the implant and bone grafting, ultimately delaying care and tooth replacement. However, there is no guarantee that you will benefit from being in this research.

The results from conducting this study may result in the development of information that will affect policy and consequently improve the health of similar patients in the future.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

If you have or suspect you have an allergy to povidone iodine you should not participate in this study. If you participate in this study, you may discover you have a sensitivity to povidone iodine. The incidence of true allergic contact dermatitis due to povidone iodine is 0.4%. The risks for the small volumes of povidone iodine that will be used in this study is unknown. However, for those who do have sensitivity, the reaction to the large volumes of iodine that are used in some oral rinses may include itching, burning, swelling, anaphylaxis. Risks also include dental sensitivity and sinusitis. In rare instances, a coated tongue, desquamation (shedding or peeling of the outermost layer of the skin), dysgeusia (distortion of the sense of taste), erythema (abnormal redness of the skin or mucus membranes), geographic tongue (smooth reddish patches on the tongue), gingivitis (inflammation, redness, and swelling of the gums), glossitis (inflammation and swelling of the tongue), hyperkeratosis (thickening of the skins outer layer), hypersensitivity reaction (exaggerated immune system response to a harmless substance), hypoesthesia (numbness or partial loss of sensation in one or more body parts), mouth irritation, oral lesion, oral mucosa ulcer (small painful sores inside the mouth), paresthesia (sensation of pins and needles in the hands or feet), parotid gland enlargement (swelling of the largest salivary glands located near the jaw and ear), sialadenitis(swollen salivary gland), stomatitis (inflammation in the tissue lining your mouth or lips), tongue changes/edema/irritation, trauma, and xerostomia (dry mouth) may occur

During the course of this study, refrain from using lithium, wound-treatment preparations containing enzymes, octenidine containing antiseptics, mercury containing wound-treatment products, or other products that interact with iodine in the oral cavity.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There may also be other risks of taking part in this study that we do not yet know about.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have at Madigan Army Medical Center if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Kevin Smith. If you have questions, suggestions or concerns about the study, his contact information is: 253-968-0181, and mailing address: 9040 Jackson Avenue, Tacoma, WA 98431-1100.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the Madigan Army Medical Center IRB Office at: 253-968-3524, Department of Clinical Investigation, 9040 Jackson Ave, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research study.

If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you

DETAILED CONSENT:

1. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are an Active-Duty solder between the ages of 18-55, have missing teeth and chose implant therapy to replace at least two of your missing teeth with implants. The purpose of this research study is to learn about the bacteria of the internal cavity of the implant and how our methods influence implant success. Your participation will require one additional minute during your implant placement appointment and one additional minute during your follow-up hardware removal appointment (3-6 months after implant placement).

There will be about 60 people taking part in the study at Madigan Army Medical Center's Oral Maxillofacial Surgery Clinic, over a period of 1-2 years.

At the end of this research study the clinical results, including research results about you will not be shared with you.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". These tests may have been done or this information collected as a part of your regular medical care. The screening process includes clinical chart review and health physical assessment. This is the same screening used for all dental implant patients.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

The study team may have already reviewed your medical and surgical history, imaging and lab results before approaching you about study participation. If you choose to participate you will read and sign this consent form and all of your questions will be answered by a member of the study team.

During your implant placement, a study investigator will apply an antiseptic (povidone iodine) inside one of your two implants before it is covered with a cover screw or healing abutment. This will take less than one minute to complete.

3-6 months after your implant placement appointment you will return to the Madigan Oral & Maxillofacial Surgery Clinic for your follow-up hardware removal appointment. At this appointment, after your implant hardware has been removed, a member of the study team will use a micro brush to collect bacterial samples for testing from both internal implant cavities. This process takes less than one minute to complete.

The study team will collect from your medical records additional information about your medical and surgical history, and laboratory and imaging results (such as grafting and bone loss) that are needed to evaluate the effectiveness of the study's intervention.

Once you have been seen for your 3–6-month follow-up hardware removal appointment and the bacterial samples have been collected, your study participation is complete.

4. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Choosing not to take part in this research study is also an option.

5. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

6. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

7. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study): Kevin Smith, DMD

8. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data): None

9. SOURCE OF FUNDING: Madigan Army Medical Center, Department of Clinical Investigation

10. LOCATION OF THE RESEARCH: Oral & Maxillofacial Surgery Clinic, Madigan Army Medical Center, JBLM, WA 98431

11. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Procedures to protect the confidentiality of the data in this study include but are not limited to: Removal of personal information, computer and data file password protection, and the restriction of access privileges to study personnel. All identifiable information will be stored on computers secured by the government's firewalls. All hard copy data will be stored in a HIPAA approved locked box/cabinet within a locked office. Only approved study personnel will have access to these documents.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, a description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include

information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Only IRB approved study team members will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

12. AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH:

You are being asked for permission to use and disclose your protected health information (PHI) for this research study. Protected health information is defined as individually identifiable health information.

The Health Insurance Portability & Accountability Act of 1996, Public Law 104-191 (also known as HIPAA), establishes privacy standards to protect your health information. This law requires the researchers to obtain your authorization (by signing this document) before they use or disclose your protected health information for research purposes in the study listed above.

WHAT PERSONAL IDENTIFIERS AND/OR PROTECTED HEALTH INFORMATION (PHI) MAY BE USED AND DISCLOSED IN THIS RESEARCH?

The identifiers and/or PHI collected, used, or disclosed are below:

• *Names* • *Dates (except year) directly related to an individual such as birth date* • *DoD ID*	• *Medical history* • *Surgical history* • *Laboratory results* • *Imaging results*

HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

Your name and DoD ID are necessary to associate your lab results with your other data. Dates are needed to determine if age impacts success rates or bacterial content. Medical and surgical history may reveal if factors other than treatment affect surgical outcomes. The lab results identify the bacteria inside the dental implant. The bone x-ray

imaging results taken at your 3–6-month post-implant follow up as part of standard of care will be used determine if the implant was successful or not and to identify the presence of peri-implantitis.

The use and disclosure of your protected health information is necessary in order to be able to conduct the research described. Records of your participation in this research may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 CFR 160 & 164).

Note: Protected health information of military service members may be used or disclosed without your authorization to military command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

By signing this document, you give your permission for information gained from your participation in this research to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

WITH WHOM MAY YOUR PROTECTED HEALTH INFORMATION BE SHARED THROUGH THIS RESEARCH?

- The Madigan Army Medical Center Institutional Review Board
- Madigan Army Medical Center or Department of Defense representatives
- State and Federal Government representatives, when required by law (such as the Food and Drug Administration (FDA))

Those listed above who are covered entities under HIPAA agree to safeguard your protected health information by using and disclosing it only as permitted by you in this Authorization or as directed by state and federal law.

You need to be aware that some parties receiving your protected health information may not have the same obligations to safeguard your protected health information and may re-disclose your protected health information to parties not named above. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

You do not have to sign this document. If you decide not to sign this document:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research.

After signing this document, you can change your mind and:

- Notify the principal investigator in writing that you have withdrawn your permission to disclose or use your protected health information (revoke the Authorization).
- Send your written letter to Kevin Smith, DMD. Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431-1100 to inform him of your decision. Your revocation is not effective until your letter is received.
- Researchers may continue to use and disclose your PHI that was obtained before your revocation became effective to the extent that the researchers have taken action in reliance on your earlier authorization. Researchers may also continue to use or disclose your PHI as necessary to maintain the integrity or reliability of the current research, such as, for example, to account for your withdrawal from the study, to conduct misconduct investigations, or to report adverse events.
- If you withdraw the Authorization, you will not be allowed to continue to participate in the research.

If you have not already received a copy of the brochure entitled "Military Health System Notice of Privacy Practices," you may request one, or it is available on-line at: https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/HIPAA-Compliance-within-the-MHS/Notice-of-Privacy-Practices

If you have any questions or concerns about your privacy rights, you should contact the Madigan HIPAA Privacy Officer, 9040 Jackson Ave, Tacoma, WA, 98431. Telephone: 253-968-1642.

This Authorization does not have an expiration date.

Your signature at the end of this document acknowledges that you authorize Madigan Army Medical Center and the study team members to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

13. USE OF INFORMATION AND SPECIMENS?

During this research study, you could be asked to provide the following types of biological specimens: At the time of hardware removal, the internal cavity of the dental implant will be swabbed.

All identifiers will be removed from your specimens.

Each of your specimens will be labeled with a unique participant ID. Your personal identifiers and health data will be stored in separate electronic files on a password-protected, CAC-enabled government computer, which is protected by DoD firewalls. Only IRB-approved study team members can access the master key that links your ID back to you. For your security, your personal identifiers will never be printed.

Research will not include human whole genome sequencing.

Although research that uses your specimens may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed), there are no plans to share any potential profits with you.

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: Department of Clinical Investigation, Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma WA, 98431-1100.

The data, including your identifiers, and any unused specimens that we obtain from you for this study will be deposited in a repository titled: Antiseptic Effects on the Dental Implant Internal Surface Microbiome. Your de-identified information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

Future studies using your samples or information will be limited to research involving dental disease.

****If you would NOT like your data or specimens collected as part of this research to be kept for possible future research, you should not consent to participate in this research study.****

14. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the Principal Investigator, Kevin Smith. If you decide to no longer participate in this research study, the researcher will destroy your stored specimens and data up and until the master key is destroyed, which contains your identifiers. After the master key is destroyed there will be no way to determine which specimens or data correspond to your information.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization section of this document.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

16. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

CONTACT INFORMATION:

Principal Investigator (PI): The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Kevin Smith, DMD
Phone: 253-968-0181
Mailing Address: Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431-1100.

Madigan Human Research Protection Program (HRPP) Office: The Human Research Protection Program Office staff and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study. Please contact the Madigan HRPP Office at: 253-968-0149, Department of Clinical Investigation, 9040 Jackson Ave, Tacoma, WA 98431-1100.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

IRB NUMBER: 226117
IRB APPROVAL DATE: 08/13/2026