Patient Information and Consent

[Insert Investigator name]

[Insert Investigator address or affiliation]

[Insert Investigator telephone number]

[Insert IRB name]

Study Title: A Prospective Study of Quality of Life in Patients with Chronic Leg Wound(s) Treated with Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel

Protocol No.: OPM-G-H-1506

Sponsor: B. Braun Medical Inc.

Important

This consent (permission) form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information not clear to you.

Joining a research study is an important decision. You should ask the study team any questions you may have about the study and this consent form before making a decision.

Also, you may have your personal doctor call the study doctor to ask any questions he or she feels are necessary to evaluate the study and your possible participation in it.

You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Why is this study being done?

B. Braun Medical Inc. (the Sponsor) has begun a research study of their products called Prontosan® Wound Irrigation Solution (Prontosan solution) and Prontosan® Wound Gel (Prontosan gel) as treatments for chronic leg wounds. These products have been approved by the United States (US) Food and Drug Administration (FDA) for cleaning and moistening chronic wounds. In this study, researchers would like to learn how a patient's quality of life (QoL) changes while using these products to clean and moisten chronic leg wound(s). You are being asked to take part in this study because you have one or 2 chronic leg wound(s). If you do not want to take part in the study, this decision will be respected.

Your participation in this research study is voluntary. If you decide not to take part in this study, you can continue with your current medical care.

The main purpose of this study is to learn how/if a patient's quality of life changes while using Prontosan solution and Prontosan gel to clean and moisten his/her chronic leg wound(s). Also, changes in wound size and wound appearance will be examined.

This form will explain more about the study.

Have these products been used in other studies?

Many studies have already been done with Prontosan solution and Prontosan gel, and these products are currently on the market for cleaning and moistening wounds.

How many people will take part in this study?

This study will be carried out at approximately 5 study centers in the US, in about 52 people with 1 or 2 chronic leg wound(s).

How long will my participation in this study last?

You will be in this study for approximately 6 weeks, and you will need to come to the study center at least 4 times over this period.

What will happen during this study?

Before any study-related tests and procedures can be done, you will be asked to read and sign this consent form.

Study Overview

The study has a screening visit for the study doctor to decide if you meet the requirements of the study, and 3 visits to the study center during the treatment period. Each visit will last about 1 hour. You will need to follow the study doctor's instructions on treating your wound(s) while you are at home.

Screening Visit (Visit 1)

At the first visit, the study doctor or the study doctor's staff will perform the following procedures to determine if you are eligible to take part in the study:

1. You will be asked to sign this informed consent form agreeing to be in the study.

2. You will be asked to complete a short questionnaire (the Wound-QoL questionnaire) about how your wound(s) has/have affected the quality of your life over the past week.
3. Your wound(s) will be looked at and measured.
4. If the study doctor decides that you meet the requirements of the questionnaire and the wound size to be in the study, the following additional procedures will be performed.
5. You will be asked about your general health and the medicines that you have taken and/or are currently taking.
6. You will be asked about your wound(s), including how you got it, how old it is, how often you change the bandage (dressing), and any problems you have had with it.
7. Your blood pressure, heart rate, temperature, height, and weight will be measured.
8. A physical examination will be performed.
9. If you have not had laboratory tests done in the past month, about 2 teaspoons of blood will be taken from your arm using a needle. Your blood will be tested to measure your overall health.

If the study doctor decides that you meet all of the requirements to be in the study, you will be offered the opportunity to schedule a return visit in 1 week for the first treatment visit at Week 1.

Treatment Period

Week 1 (Visit 2)

At the Week 1 visit, the study doctor or the study doctor's staff will perform the following procedures:

1. You will be asked to complete a short questionnaire (the Wound-QoL questionnaire) about how your wound(s) has/have affected the quality of your life over the past week.
2. You will be asked about your health and the medicines that you have taken and/or are currently taking.
3. Your wound(s) will be examined, measured, and photographed before being cleaned.
4. Your wound(s) and wound area(s) will be cleaned with Prontosan solution.
5. After your wound(s) has/have been cleaned, your wound(s) will again be measured, and more pictures of your wound(s) will be taken.
6. Prontosan gel will be applied to the wound(s), and then the wound(s) will be bandaged.
7. You (and/or your caregiver) will be trained on when and how to continue the study treatment at home.
8. You (and/or your caregiver) will be trained on how to record how much of the Prontosan solution and Prontosan gel you use for each treatment. This includes writing the date on a new bottle when it is opened and drawing a horizontal line on each bottle after each use. The line will indicate the amount of solution or gel remaining in each bottle after each use.
9. You will be given enough bottles of Prontosan solution and Prontosan gel to last until the next study visit.
10. You will be given a diary to record the date and time of each study treatment and any reactions you may have to the study treatment.
11. You will be asked to bring back the diary and all used and unused Prontosan solution and gel bottles to the next visit.

Week 2 (Visit 3)

At the Week 2 visit, the study doctor or the study doctor's staff will perform the following procedures:

1. You will be asked to complete a short questionnaire (the Wound-QoL questionnaire) about how your wound(s) has/have affected the quality of your life over the past week.
2. The diary that you completed at home and all used and unused bottles will be collected.
3. You will be asked about your general health and the medicines that you have taken and/or are currently taking.
4. Your wound(s) will be examined, measured, and photographed before being cleaned.
5. Your wound(s) and wound area(s) will be cleaned with Prontosan solution.
6. After your wound(s) has/have been cleaned, your wound(s) will again be measured, and more pictures of your wound(s) will be taken.
7. Prontosan gel will be applied to the wound(s), and then the wound(s) will be bandaged.
8. You (and/or your caregiver) will be re-trained on when and how to continue the study treatment at home.
9. You (and/or your caregiver) will be re-trained on how to record how much of the Prontosan solution and Prontosan gel you use for each treatment. This includes writing the date on a new bottle when it is opened and drawing a horizontal line on each bottle after each use. The line will indicate the amount of solution or gel remaining in each bottle after each use.
10. You will be given enough bottles of Prontosan solution and Prontosan gel to last until the next study visit.
11. You will be given a diary to record the date and time of each study treatment and any reactions you may have to the study treatment.
12. You (and/or your caregiver) will be trained on how and when to complete the Wound-QoL questionnaire at home. You will be given a few blank Wound-QoL questionnaires to take home, and you will be asked to complete one of them on a specific date during Week 3 and the other one on a specific date during Week 4 (on the same day each week).
13. You will be asked to bring both completed Wound-QoL questionnaires (one for Week 3 and one for Week 4) to the next visit.
14. You will be asked to bring back the diary and all used and unused Prontosan solution and gel bottles to the next visit.

Weeks 3 and 4

During Weeks 3 and 4, the study staff will call to remind you to complete the Wound-QoL questionnaires and record your study treatments and any reactions in the diary. They may also ask you about any changes in medicines that you are taking.

1. During Weeks 3 and 4, you (and/or your caregiver) will continue the study treatment at home as instructed by the study doctor. This will include marking the Prontosan solution and gel bottles after each treatment.
2. You will complete a diary to record the date and time of each study treatment and any reactions you may have to the study treatment.
3. You will complete the Wound-QoL questionnaire on the dates specified by the study doctor.

4. You will need to bring back the completed Wound-QoL questionnaires, the diary, and all used and unused Prontosan solution and gel bottles to the next visit.

Week 5 (Visit 4)

At the Week 5 (final) visit, the study doctor or the study doctor's staff will perform the following procedures:

1. You will be asked to complete a short questionnaire (the Wound-QoL questionnaire) about how your wound(s) has/have affected the quality of your life over the past week.
2. The Wound-QoL questionnaires that you completed at home, the diary, and all used and unused bottles will be collected.
3. You will be asked about your general health and the medicines that you have taken and/or are currently taking.
4. Your blood pressure, heart rate, and temperature will be measured.
5. About 2 teaspoons of blood will be taken from your arm using a needle. Your blood will be tested to measure your overall health.
6. A brief physical examination will be performed.
7. Your wound(s) will be examined, measured, and photographed before being cleaned.
8. Your wound(s) and wound area(s) will be cleaned with Prontosan solution.
9. After your wound(s) has/have been cleaned, your wound(s) will again be measured, and more pictures of your wound(s) will be taken.
10. Prontosan gel will be applied to the wound(s), and then the wound(s) will be bandaged.

What do I have to do?

During the study you will have the following responsibilities:

- Attend all scheduled visits.
- Apply the study treatment as directed at home, and record the date and time of each treatment and any reactions you may have to the study treatment on the diary supplied by the study doctor.
- When a bottle of Prontosan solution or gel is first opened, use the provided marker to write the date the bottle was opened on the space provided on the bottle label.
- After each treatment, using the provided marker, draw a horizontal line to indicate the liquid level remaining and write the date above it on each bottle of Prontosan solution and gel.
- Return the diary and all used and unused Prontosan bottles as instructed by the study staff.
- Complete one Wound-QoL questionnaire during Week 3 and one Wound-QoL questionnaire during Week 4 as instructed by the study staff. Return both of them to the study doctor at the Week 5 visit.
- Follow the study doctor's instructions about whether you may continue to take your regular medicines or other prescribed or over-the-counter therapies during the study.
- Tell the study doctor of any changes to your current medicines, illnesses or injuries, unexpected or troublesome side effects, or problems that occur during the study.
- You should keep all scheduled visits with your personal doctor or any other special doctors that you were seeing before starting the study. This study does not take the place of your regular medical care.

- You are the only person who should receive the study treatment. These products are for external use only and for your chronic wound(s) only. Make sure that the study treatment is kept out of the reach of children and people who have a limited capacity to read or understand.
- Contact the study doctor if you find you have any questions about the study after you sign this form.

What are the benefits of being in this study?

There is no guarantee that you will receive any benefits from the study treatment. However, you may feel that you are benefitting in the following ways:

- Your wound(s) will be checked as long as your participation in the study lasts.
- You will be helping others by contributing to medical research.

What are the risks and possible discomforts?

Any clinical study has both known and unknown risks, which may include things that could make you feel sick, make you feel uncomfortable, or harm you. You might experience side effects related to the study treatment while participating in the study. All research participants in the study will be watched carefully for any side effects.

Your taking part in this study involves possible risks or discomforts as noted below:

- The study treatment may cause side effects or reactions. Prontosan solution and Prontosan gel have been on the market for many years with very few side effects. In rare cases, there has been a mild burning feeling after putting it on that went away after a few minutes. Also, allergic reactions such as itching and rashes have been reported. In very rare cases (less than 1 person out of 10,000), anaphylactic shock (a serious, life-threatening allergic reaction) has been reported.
- Blood sampling will be done. Taking blood from a vein in your arm may cause faintness and/or swelling, pain, redness, bruising, or infection (infection rarely happens) at the site where the needle is inserted.

What other options are available if I do not take part in this study?

You do not have to take part in the study to treat your chronic wound(s). There are other wound care options. Your personal doctor or the study doctor can answer any questions you have about other therapies.

Who is paying for this study?

This study is being funded by the Sponsor. The study doctor will be paid for his or her work in carrying out this study.

What are the costs?

The study treatment will be given to you at no cost, and you will not be charged for any doctor's visits, laboratory work, or procedures that are needed for the study.

Will I be paid for being in the study?

You will receive no payment for taking part in this study.

What if I get sick or hurt?

If you require medical care for an illness or injury that is a direct result of using the study treatment, the Sponsor will pay for reasonable and routine costs of such care if the following conditions are met:

- The study doctor and the Sponsor agree that the illness or injury was a result of taking part in the study.
- Any part of the costs of care is not covered by any other health insurance, government health program, or others providing coverage for health care.

The Sponsor does not offer to provide compensation other than that described above.

Neither payment nor reimbursement for such things as pre-existing conditions, illnesses or diseases totally unrelated to the study, lost wages, property damage, disability, or discomfort is available. You or your insurance company will be responsible for payment for any tests or care done outside the scope of the study.

Can I leave the study after it has begun?

Yes. Taking part in this study is voluntary, and you can leave the study at any time for any reason. You will not be punished in any way. There will also not be any penalty or loss of benefits to which you are entitled at the study center if you decide not to take part or if you decide to leave the study.

If you decide to leave the study, you should contact the study doctor who will explain the safest way to end participation, which may involve the completion of some final procedures. You should also contact your personal doctor so he or she can provide the best course of continuing care.

The study doctor or the Sponsor can remove you from the study, without your permission, for any reason. Possible reasons for doing so include the following:

- Any change in your medical condition that might be harmful to you.
- Your failure to follow the study doctor's instructions.
- It is discovered that you no longer meet the study requirements.
- The study is stopped for any reason.
- Administrative purposes.

What will happen to the samples I give?

Your blood samples will be used only for specific tests that are needed for this study. Your blood samples will be destroyed as soon as possible after the specific tests are performed according to the standard procedures of the laboratory.

What happens when this study stops?

When the study stops, you will return to only the care of your personal doctor. Since you will no longer be involved in this study, the Sponsor will no longer provide you with the study product for the treatment of your wound(s). You and your personal doctor will decide the best treatment for the continued care of your wound(s).

If you wish, the study center will provide your medical information to your personal doctor or to other appropriate medical personnel who are responsible for your welfare.

Will my records be kept private?

During this clinical study, the study center and the Sponsor will process and record your personal data, including information regarding your health, age, ethnicity, race, and gender, in order to carry out the study.

Every effort will be made to keep all information about you private. Therefore, all information which is sent or provided outside of the study center will show only a coded patient identification number instead of your name. You have the right to review, copy, and rectify (wrong) personal data concerning you by contacting your Study doctor.

This coded information from this study will be sent to the Sponsor and third parties (individuals and/or companies) that act on their behalf, including inVentiv Health Clinical or another agent of the Sponsor. Additionally, this information may also be submitted to governmental agencies (such as the FDA).

Some of the entities above may be based in countries outside the country where you live, including other countries in different parts of the world, whose data protection and privacy laws may be less strict than in your own country.

Your involvement in this study must be noted in your medical records. Medical records that identify you and/or the consent form signed by you may be inspected by the following parties:

- B. Braun Medical Inc. (the Sponsor)
- inVentiv Health Clinical or another agent of the Sponsor
- FDA
- Department of Health and Human Services (DHHS) agencies in the US
- (*Insert IRB name*), a group that reviews and approves research studies

Your personal data may be re-disclosed and no longer protected under the HIPAA privacy rule once it is disclosed by your Study doctor to these other parties

Your personal data and medical findings will be maintained per local laws and regulations.

Results of this research study may be presented at meetings or in publications; however, your identity will never be made known (disclosed) in these meetings or presentations.

A description of this clinical study will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

The recording, forwarding, storage, and analysis of your personal data are subject to legal provisions and require the following voluntary consent prior to participation in the study; without the following consent, you are unable to take part in the clinical study.

The consent regarding the collection and processing of the information about your health cannot be reversed. Your authorization for the uses and disclosures of your personal data does not have an expiration date. You have already been informed that you can end your participation in the clinical study at any time. In the event of withdrawal, you hereby give your consent that your data stored up to this point may continue to be used if necessary. The data will not identify you by name.

By signing this consent form, you (or your legally acceptable representative) give permission (authorize) for access to this private information.

What if I have a question or concern?

You should feel free to ask questions about the study and your rights as a research subject before, during, and after the study.

Whom can I call?

If you have any questions about this research study or if at any time you believe that you have a research-related injury or a reaction to the study treatment, you should contact (*insert Investigator and phone number*).

If you have any questions regarding your rights as a research subject, you may contact (*insert IRB name and phone number*).

Important

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Signing your name to this consent form means that you voluntarily agree to take part in this study.

This agreement can be withdrawn by you at any time.

Consent to Participate

I have read and I understand this consent form. I have also been given the chance to ask any questions I had about the study, and all questions I asked were answered to my satisfaction. I understand the risks and benefits of taking part in this study as described in this consent form. I freely consent to be treated with Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel under the study doctor's care. To the best of my knowledge, I also confirm that all information I have given about my medical history is true and correct.

I understand that I am free to withdraw from the study at any time for any reason. I will tell the study doctor if I decide to withdraw so that my participation may end in an orderly manner, and my future care can be discussed.

I understand that I will be told of any information that might relate to my willingness to continue in the study.

If I have any physical or psychiatric (mental health) symptoms or problems, I will tell the study doctor.

I understand that I will receive a signed and dated copy of this consent form for my records.

By signing this form, I consent to the processing of my personal data as well as the transfer of such data outside the US for the purposes of the study, in accordance with the terms and mechanisms specified in the information notice provided by means of this document.

I authorize the inspection of my medical records by B. Braun Medical Inc., inVentiv Health Clinical, the FDA, DHHS agencies, and [*insert IRB name*]**.**

My consent to participate in this research study does not take away any legal rights in the case of negligence (carelessness) or other legal fault of anyone who is involved with this study. Nothing in this consent form is intended to change any applicable federal, state, or local laws regarding informed consent.

_____
Name of Participant (Print)

_____ _____
Signature of Participant Date

_____ _____
Signature of Study Doctor or Person Administering Consent Date

Caregiver Consent (if needed)

As the caregiver for _____, I have read and I understand this consent form. I have also been given the chance to ask any questions I had about the study, and all questions I asked were answered to my satisfaction. I agree to assist him or her in the study.

_____
Name of Caregiver (Print)

_____ _____
Signature of Caregiver Date

Legal Guardian/Authorized Representative Consent (if needed)

As the legal guardian/authorized representative for _____,
I have read this consent form. I have also been given the chance to ask any and all questions I had about the study, and all the questions I asked were answered to my satisfaction.
I understand the risks and benefits of taking part in the study, as described in this consent form.
I affirm that I have the legal right to sign this form on behalf of _____ _____.

I give my consent for _____to take part in this study under the conditions stated above.

_____
Name of Legal Guardian (Print)

_____ _____
Signature of Legal Guardian Date

Witness (if needed)

I am a witness and was present during the entire informed consent discussion. I attest that the information in this consent form was accurately explained to, and apparently understood by, _____, and that he or she freely gave consent to participate.

_____
Name of Witness (Print)

_____ _____
Signature of Witness Date