RESEARCH SUBJECT CONSENT FORM

Title:	Evaluation of Micro Water Jet Technology and the Progression of Wound Healing: A Prospective Cohort Evaluating the Efficacy of Micro Water Jet Technology in the debridement and healing of Chronic Lower Extremity Ulcers
Protocol No.:	MDX-DEB-001
Sponsor:	Medaxis LLC
Investigator:	Stephanie Wu, DPM 3471 Green Bay Road North Chicago, IL 60064 USA
Study-Related Phone Number(s):	847-578-8423 847-473-4357 (24 hours)

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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you do not take part, it will not be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last up to 20 weeks. Your participation may end earlier if your wound has completely healed.

Why is this research being done?

The purpose of this research is to assess how effective the mirco water jet debridement device is in debridement and healing of chronic wounds.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include cleaning your wound with the micro water jet debridement device. This device uses only water pressure to clean your wound of unhealthy tissue instead of using instruments such as scalpels and curettes.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include discomfort from the water pressure and as with any wound; there is the risk of infection or wound deterioration. In regards to the discomfort from the water pressure, you will be able to have your hand sprayed with sterile water so you can only feel the amount of pressure that will be used on your wound. Wound infection or deterioration with a chronic wound is always a possibility but the wound will monitored for signs of infection and you will be taught what signs to look for. Infection and wound deterioration will be addressed with appropriate antibiotics.

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Will being in this research benefit me?

The potential benefits may include potentially less painful debridement experience and a potentially better way to have your wound debrided as the water jet debridement removes the need to touch your wound by the health care provider during debridement to minimize possible cross-contamination. Possible benefits to others include knowledge of whether water debridement may be less painful and results in faster healing than traditional debridement with instruments.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include your regular wound care visit with either standard debridement using instruments or a debridement tool as chosen by your doctor. Being in this research is voluntary.

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DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to assess the how effective the micro water jet debridement device is in debridement and healing of chronic wounds.

About 20 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last up to 20 weeks or less if, your wound heals faster.

What happens to me if I agree to take part in this research?

The Food and Drug Administration (FDA) has cleared Debritom+, the micro water jet debridement device.

If you have agreed to participate and have signed this consent form, the following will be done at the visits:

Screening/Treatment Day 0

- The study staff will obtain information about you such as age, date of birth from your medical chart.
- Information about your ulcer and about your medical history will also be obtained from your medical chart.
- Information from your physical exam that will include checking the nerves in your legs, checking the blood flow of your legs and your vital signs (vital signs are pulse, breathing

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rate, and blood pressure) and height and weight documented in your medical chart will be obtained.
- Your wound will be evaluated, measured and photographed to ensure you qualify.
- If available, an image of your wound before and after debridement may be taken with a special near-infrared camera.
- You will be asked to assess the pain from your ulcer
- If you are still eligible, your wound will be debrided using micro water technology. Before beginning the debridement on your wound, you will have the opportunity to have your hand sprayed with the micro water jet debridement device so you can know what to expect on your wound.
- Your will be asked to assess pain and give comments about the micro water jet technology after the debridement has been completed.
- Your wound will be bandaged.

Visits 1 – 20 (will occur every one to two weeks (+/- 2 days)

- You will be asked to assess the pain from your ulcer.
- Your wound will be evaluated and photographed.
- Your wound will be debrided using micro water jet technology if necessary.
- If available, an image of your wound before and after debridement may be taken with special near-infrared camera.
- Your wound will be bandaged.

End of Study Visit (at the end of 20 weeks or when your wound heels)

- Your wound will be evaluated and photographed.
- You will be asked to assess the pain from your ulcer.
- Your wound will be debrided if applicable.
- If available or applicable, an image of your wound before and after debridement may be taken with a special near-infrared camera.
- Your wound will be bandaged.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff about any changes in the medicines you take.
- Tell the study doctor or study staff if you want to stop being in the study at any time.
- Returning for all visits, unless you chose to withdraw consent. If you want to withdraw consent, you should tell study staff you are removing consent.

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Could being in this research hurt me?

You may experience pain during the evaluation and debridement of the wound. The study doctor and study personnel will assess your pain. If your pain becomes severe, you should tell the study staff immediately.

It is possible that your wound could become infected. The study personnel will monitor your wound for signs of infection. If an infection is present, you could be withdrawn from participation in this study. The study staff will prescribe further therapy.

Your condition may not get better or may get worse during this study.

Will it cost me money to take part in this research?

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You do not have to pay for the study product or study research procedures. They will be provided free of charge during the study.

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

The Sponsor or the study site has no plans to compensate you for injury- or illness-related costs, such as lost wages. You are not waiving any legal rights by participating in this study. To ask questions about this, talk to the study doctor or study staff.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include possibly a less painful way to have your wound debrided and a potentially better way to have your wound debrided as the water jet debridement removes the need to touch your wound during debridement to minimize possible cross-contamination.

We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include finding improved debridement methods with potentially faster healing.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include:

Standard wound debridement that includes the use of instruments. Potential other types of debridement that your wound doctor may deem appropriate for you.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Who can answer my questions about this research?

If you have questions, concerns, complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 232-9570, info@neirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

Your participation is voluntary. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. Your ongoing medical care will not be affected by your decision to be in this study or to withdraw from the study. If you decide to withdraw from the study, please talk to your study doctor to make sure this is done safely.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $50. Your compensation will be paid at the end of the study. If you leave the study early, you will be compensated $2.50 for each week you were in the study.

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 the results. You can search this Web site at any time.

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Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

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