CARILION CLINIC
CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

TITLE: Clinical Evaluation of a Device for Treatment of Lymphedema of the Upper Extremity

IRB#: IRB-22-1780

INVESTIGATOR: Dr. Ralph Brown, MD, 2900 Lamb Circle, Suite 200, Building A, Christiansburg, VA 24073, 540-230-1022, rdbrown@carilionclinic.org

SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study doctor. A brief summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join this study, you can still stop at any time.
- Do not join this study unless all of your questions are answered.
- This study is being conducted to investigate if and how well a new medical device works to help reduce the swelling associated with lymphedema (the build-up of fluid in soft body tissues when the lymph system is damaged or blocked).
- You may choose to participate in this study to help in this determination, which may eventually allow this device to be more widely used as additional lymphedema therapy.
- In addition to your regularly scheduled lymphedema therapy, at each appointment, the research team will take several measurements and apply a new device to your arm to see if and how well it reduces your lymphedema. Your participation is expected to last four study visits. One visit a week for 4 weeks.
- You will be asked to arrive approximately 45 minutes before your regularly scheduled appointment wearing a tank top or short-sleeved t-shirt to complete the research appointment. (This will make your total appointment time, research and regular appointment, 1 hour and 45 minutes)
- This device is for Research Purposes only and has not yet been evaluated or approved by the FDA.
- We cannot promise any benefits to you or others from your taking part in this research.
- The most likely risks to you are associated with use of the device and include skin tingling sensation, pain, swelling, or soreness, dizziness, headache, nausea, and shortness of breath.
- Options include not participating in the research study.
- Being in the study will not cost anything.

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The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

DETAILED RESEARCH CONSENT

Please read this entire consent form carefully.

WHAT IS INFORMED CONSENT?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

The research is sponsored by the Carilion Clinic and the Virginia Tech Department of Biomedical Engineering and Mechanics. The person running this study locally is Dr. Ralph Brown. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research participant. Being in this study is voluntary.

Be aware that the role of the study doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem in order to help you. The study doctor treats all participants under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to test how effective and safe a new device is in reducing lymphedema-associated swelling and pain. There will be 15 participants from two locations taking part. There will be four research study visits. Each visit will last approximately 45 minutes. These visits will take place before your regularly scheduled appointments. This will make your total appointment time, research and regular appointment, 1 hour and 45 minutes. The length of time you can expect to be in this

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research is approximately 4 weeks. This device is for Research Purposes only and has not yet been evaluated or approved by the FDA.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

- You will come 45 minutes early to your regularly scheduled lymphedema appointment at the Carilion Clinic Outpatient Therapy location (either in Blacksburg or Christiansburg)
- You will need to be wearing a tank top or short-sleeved t-shirt.
- At the beginning of the appointment, a member of the research team will take some measurements, namely the circumference and induration of your upper limb, and administer a survey called the Lymphedema Life Impact Scale (first section only)
    - Circumference: the distance around your arm. This tells us how big your arm is and how much fluid may be in there. This will be measured at 6 points on your arm.
    - Induration: how firm or squishy your arm is. This is another indicator for how much fluid you may have in your arm. This will be measured at 6 points on your arm.
    - The first section of the Lymphedema Life Impact Scale takes less than a minute to complete and asks you questions about the physical symptoms associated with your lymphedema. This survey will be administered three times, at every single research visit
- After these baseline measurements have been made, you will be fitted with your own minimally compressive athletic sleeve, a thin shirtsleeve made of athletic, "dry-fit" fabric, that goes on over your hand to gently cover your arm.

- The experimental study device will be placed over the athletic sleeve and a series of vibrations/compressions will be started that will last approximately 36 minutes. The device will try to imitate the hand movements done by the therapist during standard of care therapy.
- You may ask to stop the research device at any time.
- Afterwards, the device and athletic sleeve will be removed, and the previously conducted measurements and survey will be repeated by a member of the research team.
- Finally, your normal therapist will conduct your normal lymphedema therapy, which will consist of therapy with the vibration tools, massage techniques, stretches, and exercises that are normally used by your therapist. This is your regular appointment and generally takes about 1 hour.
- Afterwards, a member of the research team will repeat the measurements and survey at the end of the visit.
- This will happen once a week for four weeks. Each study visit lasts approximately 45 minutes and occur before your typical lymphedema therapy visit. This will make your total appointment time, research and regular appointment, 1 hour and 45 minutes.

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- Participants will not be asked to be contacted for future research.
- The study treatment is currently in the investigative phase, and will not be available at the end of the study.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

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

- Report any immediate side effects associated with use of the device, which includes, but is not limited to, skin crawling or tingling sensation, pain, soreness, or swelling, dizziness, headache, nausea, and shortness of breath.
- Report any newly diagnosed medical issues to the research team. This may impact your ability to participate in the study.
- Arrive 45 minutes early to your regularly scheduled appointments wearing a tank top or short-sleeved t-shirt to attend research visits.
- Participants should immediately contact the PI/seek emergency medical attention if they have any new bruising or signs of infection (pain, redness, tenderness, discharge) over the arm being treated

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

The risks with participating in this study are thought to be mild to moderate and include the physical risks associated with use of the medical device, including:

- Experiencing a skin crawling or tingling sensation
- Pain, soreness, or swelling in the area being treated or adjacent areas
- Headache
- Dizziness
- Nausea
- Shortness of breath
- There may also be risks of stress, emotional distress, embarrassment, or inconvenience.

These risks may be uncommon and may not require medical treatment. In addition to these risks, taking part in this research may harm you in unknown ways. The risks should go away once treatment with this new device is stopped. Currently available devices, which are used with therapist-led treatment, have similar side effects.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening. (see "What about confidentiality ?" section below).

The study may have additional risks that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

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WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

We cannot promise any benefits to you or others from your taking part in this research.

Choosing to participate in this study may benefit other lymphedema patients down the line, as this is the first step in the testing of this product, which may eventually be widely used as an adjunct therapy for lymphedema.

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?

Options include manual decongestive therapy, the standard of care for lymphedema, other research studies, or you may choose not to treat your condition at all. Your doctor will discuss all of the choices with you.

WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?

In general, we will not give you any individual results from the study of the samples you give us because these measurements are not routinely used in providing care to lymphedema patients and do not significantly impact clinical care.

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. If you decide you no longer wish to participate, they will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

WHAT ABOUT CONFIDENTIALITY?

Research records, including ANY information that is obtained from you over the course of this study (including measurements and answers to survey questions), will be stored on a secure, Carilion-based computer server. This information is password protected, and only members of the research team will be able to assess it. Your identity will not be used in any sort of published report.

Identifiers on your research data might be removed so that your identity can no longer be linked to them. Your private information may then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Even though your identifiers will be removed, there still may be a chance that someone could figure out that the information is about you.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers such as name, telephone number, and medical record number
- Your social security number (required to receive compensation for your participation in the study)
- Current and past medications or therapies
- Other personal health information that will be obtained from other sources to use in the research, including past medical history, tests or records from other sites.
- Information from surveys or questionnaires done specifically for this study

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Laboratories and other individuals and organizations that analyze your health information in connection with this research.
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.
- Researchers at the following non-Carilion facilities:
    - Virginia Polytechnic and State University (Virginia Tech)

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share

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other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form. Refusing to sign will not affect the present or future care you receive at Carilion.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not directly cost you any money.

Taking part in this research may lead to added costs to you, such as an increased length of your lymphedema treatment appointments, leading to more time away from your other daily activities.

You or your insurance company will be billed ONLY for your lymphedema therapy appointment. The additional use of the proprietary device will NOT cost you any money.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

For taking part in this research and to compensate you for the time and effort of participating, you may be compensated up to a total of $20. At the conclusion of your four study sessions, you will be awarded you're a $20 Kroger gift card as compensation.

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If you do not complete all study visits, you will be paid for the portion that you complete at the scheduled end of the study. For each study visit that you complete, you will receive $5. For example, if you complete 2 out of 4 of the scheduled visits, you will receive a $10 compensation for your time and effort.

Payments made to you as compensation for your participation will be tracked by the research team. This information will be submitted to Carilion's financial department for central tracking. If you receive greater than $600 from Carilion in a calendar year, this is considered taxable compensation and will be reported to the Internal Revenue Service (IRS). You will be issued a 1099 tax form by Carilion if you meet this reporting threshold.

This research may lead to new medical knowledge, tests, treatments, or products. This research could have some financial value and result in commercial profit. There are no plans to provide financial payment to you or your relatives should this occur.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion. If you decide to leave this research, contact the research team so that the investigator can directly inform the provider and the rest of your research team of your decision. You will not be asked again to engage in any study-related activities.

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
- If you suffer from a serious adverse event
- You are unable to keep your scheduled appointments

The reason for any exclusion will be explained to you.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If you need emergency care, call 911 or go to your nearest hospital or emergency room right away. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

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The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

Call the person in charge of this study as soon as you are able. They will need to know that you are hurt or ill.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

The device itself was developed with funding from Carilion Innovations by engineers at Virginia Tech. Some researchers conducting this research are inventors of the device being studied. The researchers and Carilion Clinic may benefit financially if the device is found to be helpful and is made available for sale. This project has been carefully reviewed by research oversight officials at Carilion Clinic. They believe that the possible financial benefits to the person performing this research is not likely to affect your safety and/or the scientific quality of the research. Any questions you might have about this will be answered fully by the researchers or by the Human Protections Administrator of Carilion Clinic at (540) 224-5478.

WHO ARE THE CONTACT PERSONS?

If you encounter complications or have any questions about the study, you may call:

Please direct clinical concerns or questions to **Dr. Ralph Brown (540-230-1022)**
Please direct questions about study procedures (such as missing a session or study compensation) to **Jenia Molotkova (678-435-3316)**

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 (540) 224-5878 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 participant.

IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research participants. One job of the IRB is to make sure the research is done in a way

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that is respectful to participants. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.
_____ No, I do not want Carilion IRB to send me such a survey.

ClinicalTrials.gov:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

CONSENT SIGNATURES:

- **Research Participant Box** must always be completed.
- **Person Obtaining Consent Box** must always be completed.
- **Signatures must be obtained/documented on the same date, prior to enrollment.**

- **Participants must receive a signed copy of this consent form.**

RESEARCH PARTICIPANT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time.

_____
Printed Name of Research Participant (18 years or older)

_____ _____
Participant's Signature Date

RESEARCH TEAM MEMBER OBTAINING CONSENT - WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES: I certify I was present for the informed consent discussion. The participant had an opportunity to ask questions about and appeared to understand the information presented. The participant agreed to take part voluntarily in the research and I obtained his/her signature.

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Research Team Member Obtaining Consent Date

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