DEPARTMENT OF RADIATION ONCOLOGY
Yuhchyau Chen, M.D., Ph.D.
Richard T. Bell Professor and Chair

NCT# 04238728

CONSENT FORM

An unblinded, open-label study evaluating the safety of Silverlon® to manage radiation dermatitis

Principal Investigator: Julie Ryan Wolf, PhD, MPH

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.You are being asked to take part in this study because your doctors have recommended that you receive a course of radiation therapy as part of the treatment for your breast cancer.
- The purpose of this study is to see whether a silver-nylon dressing (Silverlon®) is useful for the prevention and treatment of radiation dermatitis.
- The dressing is not approved by the Food and Drug Administration (FDA) for this indication.
- Your participation in this study will last for about five months.
- Procedures will include the wearing of the Silverlon dressing against the skin of the breast being treated for cancer around the clock.
- There are risks from participating:
  - The most common risk is a worsening of skin irritation.
- You might not benefit from being in this research study. The potential benefit to you might be less skin irritation, pain or itching at the radiation sites.
- If you do not want to take part in this study, you can choose the standard therapy for skin irritation.

Purpose of Study

The purpose of this study is to see if a silver-nylon dressing (Silverlon®, Argentum Medical) is useful for the prevention or treatment of radiation dermatitis in patients receiving radiation therapy to the breast. The dressings have FDA clearance for use in burns, traumatic injuries and acute and chronic wounds. The dressings are not currently approved for use in treatment of radiation dermatitis in patients receiving radiation therapy to the breast.

Approximately 80% of patients diagnosed with breast cancer will receive radiation therapy at some point in their course of treatment. Of these, approximately 95% will experience skin side-effects of radiation therapy, collectively termed ***radiation dermatitis***. At present, there is no known treatment that will reliably prevent radiation dermatitis. There are a number of drugs and dressings that are used to treat radiation dermatitis once it occurs.

Description of Study Procedures

If you decide to take part in this study, you will be asked to wear a silver-nylon dressing during the course of your radiation therapy.

You will start wearing the dressing on the first day of radiation therapy starts and will continue to wear the dressing for two weeks after the completion of radiation therapy.

- You will take off the dressing when bathing and during the radiation treatment sessions.
- For maximum benefit, you should wear the dressing as much as possible around-the clock. You will follow the written instructions for using the dressing provided to you by a member of the research team.
- You will be provided with a form and will be asked to document how long you are wearing the dressing every day.
- You will be given two silver-nylon dressings. You should wear the same dressing for 7 days. If the dressing becomes soiled or damaged, you can change to the second new dressing provided according to instructions.
- You will meet with a member of the research team for two new dressings, instructions sheet, and new form every 7 days. You will bring in your used dressings and form each time. The number of times you meet with study personnel every 7 days will depend on your prescribed course of radiation therapy.

In addition to the brief meetings to obtain new dressings, you will meet with a member of the research team for four study visits where more data will be collected:

- Before you begin your radiation treatment
- At the midpoint of your radiation treatment
- At the end of your radiation treatment
- Two weeks after you finish your radiation treatment

At these study visits you will:

- Fill out short questionnaires
- Have photographs taken of the skin on your breast.

During these study visits the Radiation Oncologist will complete the usual examination and also fill out a short form. This will add up to 20 minutes of additional time to your regular visit for these four sessions. All meetings and study visits will be scheduled and conducted during your scheduled course of radiation therapy. There will not be additional study visits required outside of your course of radiation therapy. There will be no additional procedures, x-rays, scans, or bloodwork obtained because of participation in this study.

A member of the research team will contact you weekly to ask you a few questions regarding the silver-nylon dressing during radiation therapy. Additionally, a member of the research team will contact you by phone, MyChart and/or mail at 90 days after the start your radiation treatment to ask you a few questions about the healing of your skin after radiation therapy. Answering these questions will take less than 10 minutes. Your participation on the study will end 90 days after the start of your radiation treatment.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Approximately thirty (36) subjects will take part in this study. The study will be performed at The University of Rochester Medical Center. All subjects will receive the same study treatment.

Risks of Participation

This study involves no more than minimal risk, which means it is no riskier than the activities you would do in a normal day.

There are risks from participating in this or any other research study. The most common risk and the most serious risk might be a worsening of your skin irritation. Given the extensive experience with silver-nylon dressings over the last 15 years, and the experiences of other investigators using silver-nylon dressings for radiation therapy to the groin, head and neck and breast, the possibility of this risk is extremely small.

During this study you will not be able to use standard of care treatment, such as lotions for dryness of the skin, for any radiation dermatitis on the whole breast you may develop on the study. The Silverlon dressing will be applied to the whole breast area receiving radiation therapy during the study. Standard of care treatments, such a moisturizing lotions, may be used on other areas of radiation dermatitis outside of the whole breast area covered by the Silverlon dressing (i.e., certain node irradiation sites).

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 website at any time.

This study is registered as: NCT04238728.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you might be less skin irritation, pain or itching at the radiation sites.

Alternatives to Participation

If you do not want to take part in this study then you will receive the standard skin care that is prescribed by the radiation oncologists at the University of Rochester Medical Center.

Compensation for Injury

If you are directly injured by the device being studied, or by medical procedures needed because of this study (exclusive of your radiation therapy), and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

Neither Argentum Medical, LLC, nor the Biomedical Advanced Research Development Authority will provide compensation for any injury claimed as a result of participation in this study.

Costs

There will be no cost to you to participate in this study. Several sets of silver-nylon dressings will be supplied to you at no cost. There will be no additional scans, lab tests, blood work or x-rays required as a result of participation in this study.

Costs associated with your radiation therapy are not included as a part of this study. All of the tests/procedures/exams [radiation therapy] you will receive are standard care. You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

Payments

You will be paid $200.00 for taking part in this study. Payment will be based on the number of study visits completed. You will be paid $20 for completion of the Baseline visit (i.e., before the start of radiation therapy), $60 for completion of the mid-radiation therapy visit, $60 for completion of end of radiation therapy visit, and $60 for completion of the two-week post-radiation therapy visit. Payment will be either by check or a Visa card, and will be given at the completion of each of the four study visits.

Payment received for participation in research is considered taxable income. If you receive payment for your participation in studies at the University of Rochester and its affiliates of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You will be asked to complete a W-9 form, which includes your Social Security Number.

You will not receive any money that may result from any commercial tests or products that are developed as a result of this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will follow all University regulations and applicable laws regarding the protection of patient information. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The sponsors and funding agencies of this study: Argentum Medical, LLC and the Department of Health and Human Services, Biomedical Advanced Research Development Authority
- The US Food and Drug Administration, as a component of an application for the additional indication of radiation dermatitis for Argentum Medical dressings (silver-nylon / Silverlon®)
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely. The investigators plan to destroy the data from this study at 5 years after completion of the study, or at a longer interval if required by the FDA.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Circumstances for Dismissal

You may be withdrawn from the study if you do not consent to photographs of your skin, if you do not wear the silver-nylon garment continuously except when bathing or undergoing radiation treatments, for failure to fill out the questionnaires, or for failure to fill out your dressing–use log book.

You may be withdrawn from the study if your disease becomes worse or if your doctor feels that staying in the study is harmful to your health.

Early Termination

There are no known health consequences for subject self-withdrawal. If you choose to withdraw from the study, your skin care will switch from silver-nylon to the standard of care prescribed by radiation oncologists at the University of Rochester Medical Center. You will continue to receive the course of radiation therapy prescribed by your attending radiation oncologist and will receive your normal follow-up care from them.

New Study Information

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support

The University of Rochester is receiving payment from Argentum Medical, LLC under a research contract funded by the US Department of Health and Human Services, Biomedical Advanced Research Development Authority (BARDA).

Financial Disclosure Statement

No members of the University of Rochester research team, including the Principal Investigator have a conflict of interest involving the study sponsor.

Commercial Profit

Information from this study will be submitted to the US Food and Drug Administration in support of an application for an additional indication for Silverlon® silver-nylon dressings for the treatment of radiation dermatitis. You will not receive money from the sale of any such product.

Return of Research Results

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Sughosh Dhakal, M.D. at (585) 276-3578.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Use of E-mail for Communication in Research

Study team members may contact you by email with study-related matters.

When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received.

You and the researcher should understand the following conditions, instructions and risks of e-mail use:

Conditions for e-mail use:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for e-mail use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of e-mail use:

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

Signatures/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____

Signature of Person Obtaining Consent Date