Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dr. Sheila Hedden Ridner **Revision Date: 9/26/2017**
Study Title: A Pilot Study to Evaluate the Feasibility and Potential Effectiveness of the Flexitouch® System Head and Neck Treatment
Institution/Hospital: Vanderbilt University School of Nursing

This informed consent applies to adults 18 years of age or older.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to be in this research study because you have been previously diagnosed with head and neck cancer and have also been told you have head and neck lymphedema (swelling). This study is being done to see if the Flexitouch® System, a compression pump device, helps reduce lymphedema (swelling) in the head and neck areas.

The study does involve research and it will be explained to you in detail. You will be made aware of possible risks that may make you uncomfortable. The study team member will also discuss other options you have if you choose not to be in the study. You may stop being in the study at any time. You are not being promised any results. You are volunteering to be in this study. If you do not want to be in the study you will receive the normal care for your condition and the same treatment that is available to all patients not in the study.
The study will include approximately 40 participants.

2. What will happen and how long will you be in the study?

Screening: First we will ask you questions about your cancer, swelling, health, and medications. You can answer these questions in person, on the phone, or online with us once you have either signed and returned a paper consent form or completed the informed consent on online. If your answers indicate you are not eligible for the study, then your participation will end. If your answers indicate you are eligible for the study, we will have the study doctor review your information and determine if you are able to be in the study. If the study doctor does not think you should be in the study then your participation will end. If the study doctor thinks you can be in the study then we will schedule a day and time for you to come to the study site for meet with the study team.

Women who are pregnant may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the study.

Baseline Visit (This will take about an hour): First thing we will do is to use a tape to measure your head and neck areas. This will help us fit you for your garments. If the garments do not fit, you will not be enrolled in the study and you can go home. If the garments fit then:

You will fill out forms and answer questions (we will help if you need us to) that ask about:

- Your work, how many years did you go to school where you live, if you have insurance, what is your household income.
- Alcohol and tobacco use. Your medical history such as when you had cancer, when were you told you have lymphedema, and what medications you take.
- Any physical problems you may have such as swallowing, pain, headaches, weight loss, problems talking, lifting, or eating.
- Any emotional problems you have such as feeling sad, not wanting to do things you normally do, poor concentration, and difficulty sleeping.

We will perform a brief physical examination:

- We will take a picture of your face and the sides of your face. We will block out your eyes in the final pictures to protect your identity.
- We will look at your head and neck and touch your head and neck to see if you have any swelling or tight tissues. We will write down what we see.
- We will ask you to turn your head and neck and move your head up and down. We will use a small tool to measure how far you can move your head and write down how far you can move it.
- We will ask you to open your mouth and let us place a small plastic device in your mouth to tell us how far you can open your mouth. We will write down the results.
- We will measure how you can move your shoulders. We will ask you to move your shoulders up and down. We will use a small ruler-like tool to measure how far you could reach and write down the results.
- We will weigh you two times, measure your height two times, take your blood pressure and count your pulse.

Your blood will be drawn;

- The blood taken for the study during this visit will be used to see if your blood shows you have inflammation in your body. We will draw about 1 teaspoon of blood.

If female, you will be asked questions to determine if you might be pregnant.

- If you might be pregnant, we will have you pee on a stick and let the team member see the results on the stick.
- If the stick results are positive, you will be removed from the study.

You will have an Endoscopy:

- A small tube with a mini camera will be put down your nose to look at your throat, this is the same scoping procedure you have done before when you were being treated for cancer. Tetracaine (a topical numbing drug) may be used with Afrin, an over-the-counter spray nasal decongestant, if so desired. This will help us to evaluate internal edema/swelling. This may be done on another day due to scheduling requirements with our study Nurse Practitioner.

After the baseline visit is completed, you will be randomly assigned (like a coin toss) to one of two-groups.

Group 1 Immediate Treatment Group: You will be taught how to use the device by the research team. You will be loaned a device to take home and use for 8 weeks. You will be seen at the research site weeks 1, 4, and 8. These visits will take about 45-60 minutes.

You will complete 2 treatment sessions daily using the Flexitouch® head and neck device during your 8 week participation. Eachtreatment will take approximately 25-43 minutes and the first treatment will be observed by study staff.

You will be asked to complete a daily diary, a weekly self-care checklist, and continue your home care regimen which may include:

- self-MLD
- exercise
- skin care
- wearing an appropriate compression garment, if applicable

You will bring your diary and checklists to each visit for review by the study team and complete the following activities:

You will fill out forms and answer questions (we will help if you need us to) that ask about:

- Changes in your health and medications since your last visit.
- Any physical problems you may have such as swallowing, pain, headaches, weight loss, problems talking, lifting, or eating.
- Any emotional problems you have such as feeling sad, not wanting to do things you normally do, poor concentration, and difficulty sleeping.

We will perform a brief physical examination:

- We will take a picture of your face and the sides of your face. We will block out your eyes in the final pictures to protect your identity.
- We will look at your head and neck and touch your head and neck to see if you have any swelling or tight tissues. We will write down what we see.
- We will ask you to turn your head and neck and move your head up and down. We will use a small tool to measure how far you can move your head and write down how far you can move it.
- We will ask you to open your mouth and let us place a small plastic device in your mouth to tell us how far you can open your mouth. We will write down the results.
- We will measure how you can move your shoulders. We will ask you to move your shoulders up and down. We will use a small ruler-like tool to measure how far you could reach and write down the results.
- We will weigh you two times, take your blood pressure and count your pulse.

At week 4 and 8:

If female, you will be asked questions to determine if you might be pregnant.

- If you might be pregnant, we will have you pee on a stick and let the team member see the results on the stick.
- If the stick results are positive, you will be removed from the study.

At week 8 only:

You will have an Endoscopy that will take about an hour:

- A small tube with a mini camera will be put down your nose to look at your throat, this is the same scoping procedure you have done before. This will help us to evaluate internal edema/swelling. This may be done on another day due to scheduling requirements with our study Nurse Practitioner.

Your blood will be drawn:

- The blood taken for the study during this visit will be used to see if your blood shows you have inflammation in your body. We will draw about 1 teaspoon of blood.

You will leave the device with the study team and complete forms that ask about how well you liked the device.

Group 2 Wait for Treatment Group: You will be seen at the research site weeks 1, 4, and 8. These visits will take about 45-60 minutes.

You will be asked to complete a weekly self-care checklist and continue your home care regimen which may include:

- self-MLD
- exercise
- skin care
- wearing an appropriate compression garment, if applicable

You will bring your checklists to each visit for review by the study team and complete the following activities:

You will fill out forms and answer questions (we will help if you need us to) that ask about:

- Changes in your health since your last visit and what medications you take.
- Any physical problems you may have such as swallowing, pain, headaches, weight loss, problems talking, lifting, or eating.
- Any emotional problems you have such as feeling sad, not wanting to do things you normally do, poor concentration, and difficulty sleeping.

We will perform a brief physical examination:

- We will take a picture of your face and the sides of your face. We will block out your eyes in the final pictures to protect your identity.
- We will look at your head and neck and touch your head and neck to see if you have any swelling or tight tissues. We will write down what we see.
- We will ask you to turn your head and neck and move your head up and down. We will use a small tool to measure how far you can move your head and we will write down how far you can move it.
- We will ask you to open your mouth and let us place a small plastic device in your mouth to tell us how far you can open your mouth. We will write down the results.
- We will measure how you can move your shoulders. We will ask you to move your shoulders up and down. We will use a small ruler-like tool to measure how far you could reach and we will write down the results.
- We will weigh you two times, take your blood pressure and count your pulse.

At week 4 and 8:

If female, you will be asked questions to determine if you might be pregnant.

- If you might be pregnant, we will have you pee on a stick and let the team member see the results on the stick.
- If the stick results are positive, you will be removed from the study

At week 8 only, you will have an Endoscopy that will take about an hour:

- A small tube with a mini camera will be put down your nose to look at your throat, this is the same scoping procedure you have done before. This will help us to evaluate internal edema/swelling. This may be done on another day due to scheduling requirements with our study Nurse Practitioner.

Your blood will be drawn:

- The blood taken for the study during this visit will be used to see if your blood shows you have inflammation in your body. We will draw about 1 teaspoon of blood.

At week 8, and after your Endoscopy, you will be asked if you want to take a device home to use for 8 weeks. If you say no, your time in the study is over. If you say yes, the following will take place:

You will be taught how to use the device by the research team. The twice daily treatment will take approximately 25-43 minutes and the first treatment will be observed by study staff.

You will be seen at weeks 9, 12, and 16 for safety checks. These visits will take about 30 minutes.

- You will have your blood pressure taken, your pulse recorded, your head and neck examined to determine tightness and swelling, and be asked if you have any concerns or problems related to using the device. We will conduct these checks the same way we did when you were waiting for the device.

At weeks 8 and 12 only, if female, you will be asked questions to determine if you might be pregnant.

- If you might be pregnant, we will have you pee on a stick and let the team member see the results on the stick.
  If the stick results are positive, you will be removed from the study.

At week 16, you will leave the device with the study team.

Study Activities are Summarized Below:

	Screening/ Randomization	Baseline Visit	Follow Up Week 1	Follow Up Week 4	Final Week8
Patient Characteristics					
Medical History	√				
Height		√			
Weight		√	√	√	√
Garment Fitting	√				
Vital Signs (BP, Pulse)*		√	√	√	√
Demographics	√				
Pregnancy Testing*	√			√	√
Fidelity					
Adherence-Diary**			√	√	√
Barriers-Dairy**			√	√	√
Self-care Checklist		weekly			
Safety					
Adverse Events-CTCAEV4.0*			√	√	√
Satisfaction					
Pretreatment survey**		√			
Post treatment survey **					√
Swelling/Inflammation					
Internal- Endoscopy/Patterson Scale		√			√
Digital Photography		√	√	√	√
Grading and Staging*	√	√	√	√	√
Cytokines		√			√
Function					
Range of motion-jaw, shoulder, neck		√		√	√
Patient Reported Outcome-Neck Disability Index		√		√	√
Patient Reported Outcome-Voice Handicap Index		√		√	√
Symptoms					
Vanderbilt H and N Symptom Survey		√		√	√
Lymphedema Symptom Intensity and Distress Scale		√		√	√
Quality of Life					
Linear Analog Self-Assessment		√		√	√

*=safety checks at week 9, 12, &16 for wait-list group opting to use the device

**=intervention group only

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study other than the cost of coming for your study visits.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

There are minimal side effects expected from the treatment you will receive in this study. The expected risks are often a failure to respond to the study treatment and are not related to the study treatment itself. In some cases, side effects due to head and neck lymphedema can be serious, long lasting, or may be permanent.

The risks listed are symptoms of head and neck lymphedema and may be reported by all patients with head and neck lymphedema:

Common (10%):

- Odd feelings such as heaviness, pain, or tightness in the swollen area
- Increased swelling
- Difficulty moving your head and neck and swallowing

:

Uncommon (<10%):

- Difficulty Breathing
- Inability to Swallow
- Cellulitis – Infection of the skin which may include swelling, redness, and tenderness of the infected area.

Tape Measure and Physical Examination: There are no known risks to being measured with a tape measure, the plastic jaw card, or having your skin examined.

Blood Draws: Soreness, skin irritation, or bruising at the place where your blood is drawn.

Endoscopy:
Common (>10%):

- Feeling of pressure during the procedure

- Gaging

Uncommon (<10%):

- Allergic reactions to the anesthesia or decongestant if these are used
- Tetracaine, a numbing drug, and Afrin, an over-the-counter spray nasal decongestant have an awful taste and cause a strange feeling in the mouth. There is a risk that these drugs may cause problems with heart rhythm.
- Nosebleed or other bleeding
- Sore throat
- Fainting
- Headache
- Chipped teeth

Device:

- Feeling of being confined or claustrophobic (due to the garment covering your head)

The effects of the study device on a developing fetus are unknown. Because of that reason, you are not permitted to take part in this study if you are pregnant, think that you may be pregnant, or are trying to get pregnant. You may be asked to take a pregnancy test.

5. Risks that are not known:

There may be risks that we do not know about at this time. However, you will be made aware of any significant new findings that develop during the course of the study.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator or the Sponsor that an injury occurred as a direct result of the tests or treatments that are done for research alone, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.

7. Good effects that might result from this study:

This study may or may not benefit you, but taking part may help others in the future. The possible benefit of this study is treatment of your Head and Neck Lymphedema. There is no guarantee that taking part in this research will result in any improvement in your condition.

8. Other treatments you could get if you decide not to be in this study:

You can choose not to take part in the study. You will receive the normal care at this facility for patients with your condition(s), even if you choose not to participate. The current standard of care in the treatment Head and Neck Lymphedema is manual lymph drainage, exercise and compression garments (as needed).

9. Payments for your time spent taking part in this study or expenses:

You will be paid for your time each time we see you as listed below.

Baseline Visit	Week 1	Week 4	Week 8	End of Optional Device Use
$10	$10	$15	$20	$20

If you complete the visits outlined above, you will have the option to keep your study garments at the end of the study in case you decide to obtain the device for long term care at a later time.

10. Reasons why the study doctor may take you out of this study:

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit you must return the device you are using so other people in the study can use it.

11. What will happen if you decide to stop being in this study?

Your participation in this study is voluntary. You may decide not to participate in this study. If you do participate, you may freely withdraw your consent to take part in this study at any time. Your decision will not result in penalty or loss of benefits, for which you are entitled, nor will it change your future medical care at this site.

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Sheila H. Ridner at 615-322-0831. If you cannot reach the research staff, please page the study doctor at 615-835-9499.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry:

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the web sit will include a summary of the results. You can search this website at any time.

14. Confidentiality:

You will be assigned a study ID number. It is necessary for the study team to know your name and ID number during the study to coordinate visits/data collection. We will keep an electronic folder with your first name and last initial on it while on study. Any hard copy data collection forms will be stored in a locking cabinet at the Vanderbilt School of Nursing while you are in the study. When you finish the study the first name and initials will be deleted from the electronic folder.

Dr. Ridner will maintain a list of names and study ID numbers in a password protected computer file. The list will be accessible only to her and the team members and will be destroyed when the study is closed. Medical record information created during this study, such as the results of the endoscopy, will become part of the medical record. Hard copy records of research data will be kept at least 6 years by Dr. Ridner; however, these records will not have your name on them.

Tactile Medical and Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Tactile Medical, Vanderbilt, Dr. Sheila H. Ridner and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Sheila H. Ridner and her study team may share the results of your study and/or non-study linked study specific information including and not limited to Medical and research records, records about phone calls, records about your study visits, records of physical exams, laboratory, x-ray, and

other test results, diaries and questionnaires, records about medications, records about any study device you received, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Institutional Review Board, U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), and Governmental agencies in other countries. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private. The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Sheila H. Ridner in writing and let her know that you withdraw your consent. Her mailing address is 525 Godchaux Hall, 461 21st Ave. S. Nashville, TN 37072. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

_____
Printed Name

Consent obtained by:

_____ _____
Date Signature

_____ _____
Printed Name Time

Date of IRB Approval: 11/07/2017
Date of Expiration: 09/25/2018

Institutional Review Board
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