NorthShore University HealthSystem

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CONSENT FORM

A Phase 1 Clinical Trial to Assess the Performance and Safety of a Novel Ostomy Ring (OstoRing®) to Improve Ileostomy and Colostomy Management

Principal Investigator: Eugene Yen, MD

Principal Investigator telephone number: 847-657-1900

Sponsor: GoDuRn, LLC

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to assess the safety and performance of the OstoRing® as it relates to your current pouching system wear time and degree of leakage.
- **Duration.** It is expected that your participation will last 75 days.
- **Procedures and Activities.** You will be asked to be fitted for the OstoRing®, complete questionnaires during study visits, and take photos of your skin in between pouch changes.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include allergic reaction or worsening of the peristomal (skin surrounding stoma) skin condition from the OstoRing®. You may feel upset or be uncomfortable answering some of the questions.
- **Benefits**. You may or may not benefit from using the OstoRing® device along with your pouching system. Some of the benefits may be longer wear times between pouch changes and reduction of leakage.
- **Alternatives.** As an alternative to participation, you could continue to use your standard of care pouching system without the OstoRing®.

Detailed Information about this Study:

Introduction: You are being asked to volunteer for this clinical research study because you have undergone an ostomy surgery and are now using an external pouch to collect bodily waste. Ostomy surgeries remove the colon, rectum, and/or portions of the small intestine. After surgery, bodily waste is excreted from the body through the stoma (hole created in the abdomen.) It was estimated in 2012 that there are 1 million people in the U.S. and Canada living with ostomies. An additional 100,000 new ostomies are created per year in the U.S.
This Consent Form gives information about the study that you can talk about with your doctor and/or family. You are being given this information to help you make your decision. If you have any questions, you can ask the study doctor or staff.

Why is this Study Being Done?

You are currently using a Hollister 2-piece pouch system to collect bodily waste, which consists of a separate skin barrier and pouch. The flange located on the skin barrier interlocks with the pouch to snap together and form a seal.

The OstoRing® is a stainless steel ring device intended to be used between the skin barrier and pouch. The device tries to create a flat and even seal between the flange and pouch in an attempt to reduce the risk of leakage and increase wear time. The purpose of this study is to evaluate the OstoRing® for pouching system wear time and degree of leakage. Subjects who first use their original pouching system and then after with the OstoRing® device will be evaluated at every study visit. It is hypothesized that this device will increase the quality of life and ease of use in patients that wear a pouch system.

The OstoRing® is considered investigational (not approved for general use) by the Food and Drug Administration (FDA) for use in standard of care pouching systems.

This study will include a total of 32 subjects. Of those subjects, all will be from NorthShore University HealthSystem (NorthShore).

What Will Happen During the Study?

If you agree to participate in this study, you will be asked to sign this consent form before any research-related activities are done. You will be given further instructions for use of the OstoRing® with your existing system.

The study will follow 32 adult subjects who have had an ileostomy or colostomy for at least 6 months. If you agree to participate, you will be asked to use your standard 2-piece New Image Hollister pouching system without the OstoRing® for 28 days, then on day 29 will be switched to the OstoRing® regimen until day 56. Subjects will be evaluated in person at Days 0, 28, 56 and 75. Using the OstoRing® device alongside your normal pouch system will be an investigational procedure.

The study includes the following visits:

- Day 0 screening and enrollment visit #1
  - Your medical history will be reviewed to confirm enrollment into study and you will wear your standard device for 28 days and go about your normal pouch changing routine.
- Day 28 OstoRing® fitting visit #2
  - The study doctor and/or nurse will ensure you are using the proper size OstoRing® based on the corresponding size of the Hollister 2-piece system. You will be given pouch changing instructions along with how to care and clean for your device.
- Day 56 visit #3
  - The study doctor will assess and evaluate your skin and pouch system. You will decide if you want to continue wearing the OstoRing® device along with extending wear time (by 1-4 days if possible) between pouch changes. If you choose not to continue wearing the OstoRing®, you will return the device back to the study staff.
- Day 75 follow-up visit #4
  - You will return to the study office for follow-up if you continued wearing the OstoRing® device and return the device to the study team at this visit. The study team will ask you to describe your experience and wear time between pouch changes. If you did not continue wearing the OstoRing®, the study staff will contact you via telephone to ask you follow up questions about your experience using the device.

If you agree to participate in this study, you will be asked to do the following:

- Allow study doctor and/or nurse to investigate skin around pouch system and take photos during study office visits which will last for approximately 1 hour
- Complete paper questionnaires during study visits related to Quality of Life and Ostomy Evaluation which will take around 15 minutes
- At every pouch system change, fill out an evaluation record to describe your experience between pouch system changes and take accompanying pictures of the stoma and adhesive site which will add another 10 minutes to your pouch change routine
- Contact the study team if you have any allergic reactions or other adverse events due to either pouch system or OstoRing® device. Your regular primary care physician will be notified of any adverse event reporting.

During this study, the research team will collect information about you for the purposes of this research. This includes your name, telephone number, medical record number, date of birth, medical records that include surgical and medication history, dates of study entry and study procedures, and results of tests and procedures done as part of the study.

How Long Will I Be in the Study?

Your participation in the study is expected to last 75 days.

What Other Choices Do I Have?

You can receive your standard care pouching system without the OstoRing® and not participate in this study.

Are There Benefits to Taking Part in the Study?

This study may allow doctors to learn more about how this OstoRing® works in conjunction with standard pouching systems.

What Side Effects or Risks Can I Expect?

The OstoRing® device used in this study might have undesired effects. However, doctors do not know all the effects that may happen. Side effects may be mild or very serious. Some effects may go away soon after you stop using the study device. The study doctor will watch you carefully and will provide treatment for any effects. This may include taking you off the study or giving you other medications.

Some side effects of the OstoRing® device may include: allergic reaction to the ring, worsening of the peristomal skin condition, increased risk of leakage, prolonged time needed in changing the ostomy pouching device, or possible damage to the OstoRing® device.

Some of the questions may remind you of your illness or other upsetting memories. If you become anxious or upset during the study, the study staff can refer you to a counselor.

You will only be given one OstoRing® device to use for the duration of the study. Please contact the study staff if your device breaks or needs replacement during the study.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the NorthShore Institutional Review Board, other medical personnel at NorthShore who are involved in your care, or by the Food and Drug Administration (FDA).

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.

Will my information be used for research in the future?

Information collected from you for this research study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared.

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “protected health information (PHI).” In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

- Past, present and future medical records, including information housed in the Electronic Medical Record called "Epic," which is maintained by NorthShore University HealthSystem
- Information about research procedures, including research office visits, medical tests, procedures, interviews and questionnaires

Who may see, use and share my PHI and why may they need to do so?

- NorthShore research staff involved in this study
- Non-research staff within NorthShore who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The NorthShore IRB board that oversees the research and the NorthShore research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research)
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do work for us, such as data storage companies, insurers and lawyers
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside NorthShore, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study

information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Will I Be Paid for Participating?

You will not be paid for being in this study.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will not be charged for OstoRing® device or any of the study visits and procedures as outlined in this consent form. You will still be responsible for all costs that you would normally incur as part of routine care for your standard ostomy pouch system.

What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at NorthShore. You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. You can ask for more information from the Research Institute of NorthShore.

Health insurance plans (including Medicare) may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Can I Withdraw from the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can still get medical care as usual. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. You can take off the study device at any point and use your normal pouch system as usual.

Your doctor/the sponsor may stop this study or take you out of the study without your permission. If this happens, it might be the result of a bad reaction you have. There could also be new information that your doctor learns about the safety or helpfulness of this treatment.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

Who Can I Call with Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Eugene Yen, MD, at telephone: 847-570-3890.

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INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	