Circumferential Vertebral Reconstruction of Osteoporotic Compression Fractures Using a Novel Bipedicular Peek Implant (RECONSTRUCT)
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STUDY INFORMATION:

Study Title: Circumferential vertebral RECONSTRUCTion of osteoporotic compression fractures using a novel bipedicular peek implant (RECONSTRUCT)

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai West, Mount Sinai Queens

Lead Researcher (Principal Investigator): Michael Travis Caton, MD

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to collect information about the use of the V-STRUT©, a vertebral implant. This device is used for the treatment of vertebral compression fractures (occurs when one or more bones in the spine weaken and crumple). The V-STRUT© device is a medical device that has received FDA clearance to treat these compression fractures. You may only receive treatment using this device if you agree to participate in this study.

If you choose to take part, you will be asked to

- Allow your data (such as dates relevant to you and your procedure, and your medical information) to be collected.
- Attend all of your regular follow-up visits. These visits will occur at around 14 days, 30 days, and 6 months post-procedure.

- Complete questionnaires regarding your level of pain following surgery. The physician will ask questions pertaining to your *pain.*
- You will not be paid for taking part in this study. Being in this study will not cost you anything extra. Researchers will not pay you for your travel or the time it will take for you to be in the study.

If you choose to take part, the main risk to you is the risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. Please see the Possible Risks and Discomforts section below for further information. Other risks pertaining to the surgery include cement leakage, displacement of bone fragments and other risks outlined in detail in the Possible Risks and Discomforts section below.

You will not benefit directly from taking part in this research.

Instead of taking part in this research, it may be possible to treat your spine with this device without enrolling in this study, outside of the Mount Sinai Health System, but it is not available elsewhere in New York. There are other devices available to treat compression fractures that also require a surgical procedure, anesthesia and radiation.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you may have an osteoporotic, pedicle, or malignant compression fractures of the thoracolumbar spine (T1 – L5) that you and your doctor have already agreed will be treated using the V-STRUT© device as part of your regular medical care. The V-STRUT© device is a medical device that has received FDA clearance to be used to treat these particular fractures. You may only receive treatment using this device if you agree to participate in this study.

Your participation in this research study is expected to last approximately six months after the procedure and placement of the device.

There are 30 people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Queens, Mount Sinai West, and across all other sites.

Funds for conducting this research study are provided by the manufacturer of the device, Hyprevention.

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.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

You will receive the V-STRUT device as part your routine medical care. This will take place at the Mount Sinai location you schedule with your physician as part of your normal course of care. There are no experimental procedures. While there are no experimental procedures, this a newly FDA cleared device, and that is why we are collecting information.

Before and after the procedure, medical information will be collected and documented as part of the study. This will involve reviewing your medical records.

By agreeing to be in this study you will:

1. Allow collection and documentation of your medical information before and after your procedure. This will involve reviewing your medical records. A study team member at The Mount Sinai Hospital will collect this data.
2. Agree to attend all of you regular follow-up visits. These visits will occur at around 14 days, 30 days, and 6 months post-procedure.
3. Complete two short research-related health questionnaires at the follow-up visits. These questionnaires will take approximately 15 minutes to complete.

Because this research study involves the use of an investigational medical device, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If "Yes", please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA AND/OR SAMPLES:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

1. Following the instructions of your doctor.
2. Telling the doctor or research staff about any side effects, medications, doctor visits or admissions to a hospital.
3. Attending all of you regular follow-up visits. These visits will occur at around 14 days, 30 days, and 6 months post-procedure. If it is necessary to miss an appointment, please contact the doctor or research staff to reschedule as soon as you know you will miss the appointment.
4. Completing two short research-related health questionnaires at the follow-up visits. These questionnaires will take approximately 15 minutes to complete.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra. Researchers will not pay you for your travel or the time it will take for you to be in the study.

Mount Sinai will be purchasing the device from the study sponsor, Hyprevention. This will be billed and covered by your insurance.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, possible future benefits to others include a better understanding of how and when to use this treatment for patients with VCF.

POSSIBLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.

The use of this device requires surgery, the use of anesthesia and radiation. These risks are not different when placing this device as compared to similar device. They will be explained in more detail when we ask your permission to do the surgery.

The use of this device may be associated with the following adverse events:

- The device can break, detach from the spine and move. The cement used may leak and move.
- The bone can break and pieces can move.
- While placing the device it is possible that nerves or blood vessels in the area may be damaged.
- While placing the device there may be a leak of the fluid that surrounds the spinal cord.
- While placing the device there may be bleeding and swelling of the surrounding area.
- Infection
- Allergic reaction to the bone cement. This may be local or general, which may be life threatening.

Depending on the seriousness of the event they may require prolonged surgery, reoperations or medication treatment. They may not be totally reversible. Additionally, unexpected risks are possible.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.
Instead of being in this research study, your choices may include:

- Outside of the Mount Sinai Health System, it may be possible to treat your spine with this device without enrolling in this study, but it is not available elsewhere in New York. There are other devices available to treat compression fractures that also require a surgical procedure, anesthesia and radiation. The risks are believed to be similar to the device used in this study.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number (212) 241-1297.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Dr. Reade De Leacy (a Mount Sinai faculty member and global lead investigator for this study) is an equity owner in Hyprevention, the study sponsor and manufacturer of the VStut vertebral implant study device. Dr. DeLeacy will not be on the research team here at Mount Sinai.

The company sponsoring this research study makes the device being tested and has a financial interest that could be affected by the outcome of this research study.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, medical record number, telephone number, dates directly related to the individual (birth, admission, discharge, date of death, etc.). The researchers will also get information from your medical record from Mount Sinai Health System.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.

- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use): Hyprevention
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration.

In all disclosures outside of Mount Sinai, you will not be identified by name, medical record number, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI? Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information
If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human

Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time
_____	_____	_____	_____

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time
_____	_____	_____	_____

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time
_____	_____	_____	_____