

Triadyme-C Cervical Total Disc Replacement

Are You a Candidate for this Clinical Study?

You may be eligible for this study if:

- You are ≥21 years old
- If you have been diagnosed with cervical degenerative disc disease that has not responded to conservative therapy (e.g., rest, heat, electrotherapy, physical therapy, chiropractic care, and/or medications)
- Your doctor has recommended cervical spine surgery. If you are still interested, additional screening evaluations will be completed to confirm that you are an appropriate candidate for treatment with Triadyme-C.

Your Responsibilities

If you choose to participate in this study, you will be expected to:

- Follow all medical instructions provided by your study doctor.
- Attend all study-related hospital or clinic visits and complete the scheduled assessments described in the informed consent form.
- Participate in the rehabilitation program prescribed by your study doctor.
- Notify your study doctor or study staff of any changes in your health or medications.
- Inform your study doctor or study staff if you decide to withdraw from the study at any time.
- Notify your study doctor or study staff immediately if you become pregnant.

Possible Risks

The risks associated with surgery, total disc replacement, and the Triadyme-C device are explained in detail in the study's informed consent form. If you decide to participate, you will be asked to carefully review and sign this consent form.

If you have any questions or to learn more about this clinical study, contact your doctor/research staff at:



Additional details about this clinical study are available on clinicaltrials.gov (NCT07287449).

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Caution - Investigational device. Limited by Federal (US) law to investigational use.

Single-Level Clinical Study

Triadyme-C

Cervical Total Disc Replacement

Single-Level Clinical Study

You may be eligible for the Triadyme®-C Single-level Clinical Study. Discuss with your doctor to see if joining this study is right for you.



Triadyme-C may help patients with single-level cervical degenerative disc disease (DDD).

The Triadyme-C implant is currently being studied under an Investigational Device Exemption (IDE) from the United States Food and Drug Administration (FDA). It is not approved by the FDA and is not available for commercial sale in the United States. At this time, the device is only accessible to individuals in the United States who are participating in the clinical study.

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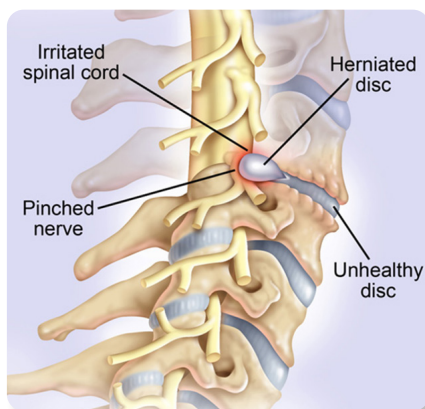
Cervical Degenerative Disc Disease

Cervical degenerative disc disease occurs when one or more of the discs between the bones (vertebrae) in the neck begin to wear down. Over time, this “wear and tear” can lead to symptoms. People may experience neck pain, stiffness, or a reduced range of motion. If a damaged disc presses on nearby nerves, it can also cause pain, tingling, numbness, or weakness that spreads into the shoulders, arms, or hands.

Common Symptoms of Cervical Degenerative Disc Disease

- Neck pain and stiffness, often persistent or recurring, sometimes worse with movement.
- Pain radiating to the shoulders, arms, or hands due to nerve irritation or compression.
- Tingling, numbness, or “pins and needles” in the arms, hands, or fingers.
- Weakness in the arms or hands, making it harder to grip or perform fine tasks.
- Headaches that frequently start in the neck and spread toward the back of the head.
- Reduced range of motion, leading to difficulty turning or tilting the head comfortably.

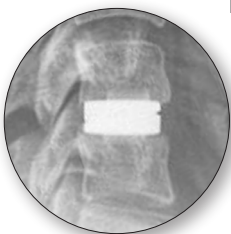
CERVICAL SPINE WITH DISC DEGENERATION



Cervical Total Disc Replacement

If you've been diagnosed with symptomatic cervical disc disease (SCDD), cervical total disc replacement (CTDR) with an artificial disc like the Triadyme-C may be an option. In this procedure, the damaged disc is removed and replaced with an artificial disc that is designed to preserve natural motion of the spine.

For more than 20 years, CTDR devices have been used worldwide as an alternative to spinal fusion. Unlike fusion, which stops motion at the treated spinal level, artificial discs are intended to maintain movement. By restoring normal or near-normal motion, CTDR may not only help reduce pain and improve function, but may also lessen stress on the discs above and below the treated level, potentially reducing future problems at those areas.



Triadyme-C Cervical Total Disc Replacement

The Triadyme-C is an artificial disc made of two parts that is placed between two bones (vertebrae) in your neck. The Triadyme-C's unique three-lobed shape is designed to help keep your spine stable while still allowing movement that is close to normal.

The surfaces that move against each other are made from a special man-made material called polycrystalline diamond. This material is extremely strong and resistant to wear. These properties may enhance the Triadyme-C's durability and wear resistance, allowing it to last longer and continue to perform safely over time.

The Triadyme-C Clinical Study

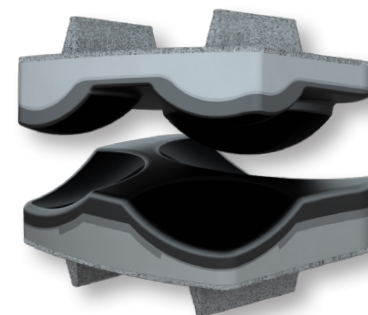
This study is being done to test the safety and effectiveness of the Triadyme-C for treating symptomatic cervical disc disease (SCDD) at one level in the neck.

The procedure involves removing your damaged disc and replacing it with the Triadyme-C. The goal is to stabilize your spine and reduce or even eliminate the pain caused by the diseased disc. Results from this clinical study will be compared to results from earlier studies of other cervical disc replacement devices.

If you join the study, you will be asked to return for follow-up visits to monitor your post-operative progress. You will not be charged extra for any study specific procedures or assessments, and the Triadyme-C device will be provided at no cost to you.

By taking part in this clinical study, you are helping doctors better understand this treatment and potentially helping future patients with the same condition.

You may be eligible for the Triadyme-C Single-level Clinical Study. Discuss with your doctor to see if joining this study is right for you.



Triadyme-C Artificial Disc

