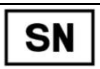
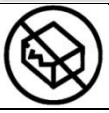
INSTRUCTIONS FOR USE
Triadyme®-C Cervical Total Disc Replacement

Symbols Used on the Device Labeling

	Catalog Number
	Lot Number
	Serial Number
	Use by Date
	Sterilized Using Irradiation
	Do not Reuse
	Consult Instructions for Use
	Manufacturer
	MR Conditional
	Do Not Use if Package is Damaged
	Do Not Re-Sterilize
	Authorized Representative in the European Community
	Double Sterile Barrier System

The Triadyme®-C Cervical Total Disc Replacement is intended for use in cervical arthroplasty (total disc replacement) procedures to replace a degenerated or diseased intervertebral disc in the cervical spine. The device is designed to restore disc height, maintain segmental motion, and preserve biomechanical function at the treated level.

The Triadyme®-C Cervical Total Disc Replacement implant is intended to be used with the Triadyme®-C Cervical Total Disc Replacement instruments. Refer to the Triadyme®-C Cervical Total Disc Replacement Surgical Technique Manual for implantation instructions.

DEVICE DESCRIPTION

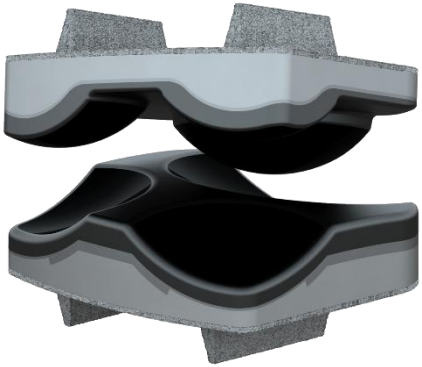
The Dymicron Triadyme®-C Cervical Total Disc Replacement is a two-piece articulating cervical disc prosthesis that is inserted into the intervertebral space as a single unit utilizing an anterior cervical approach. The Triadyme®-C disc, which is inserted into the cervical spine to replace a degenerated native disc removed through a standard decompression procedure, is designed to allow motion of the functional spinal unit following implantation. The Triadyme®-C device is sterile packaged and pre-loaded onto a disposable implant cartridge fitted with a stainless-steel retainer clip that holds the two halves of the disc together before and during implantation. The retainer clip retracts during disc implantation, after which the cartridge assembly can be disposed.

Triadyme®-C Disc and Implant Cartridge

Both endplates of the Triadyme®-C disc contain dual keels, which provide initial fixation of the device onto the superior and inferior vertebral bodies. The keels are press-fit into channels that have been pre-cut into the vertebral bodies using size-specific chisels. A commercially pure titanium plasma spray covers the implant's endplates and keels, accommodating osteointegration for long-term fixation.

The articulation mechanism of the Triadyme®-C disc consists of three spherical lobes mating to three non-congruent, spherical pockets. Motion of the cervical spine segment is approximated by the movement of the three lobes within their associated pockets.

Triadyme®-C Representative Image



The articulating bearing surfaces of the Triadyme®-C disc are comprised of biocompatible Polycrystalline Diamond (PCD), a substance that exhibits the exceptional properties for which natural diamond is known but with significantly enhanced fracture resistance. PCD exhibits very low friction and exceptional wear resistance. Each half of the Triadyme®-C disc is manufactured by sintering the PCD bearing material together with the titanium carbide and titanium alloy substrate materials as a monobloc.

Four different footprint sizes are available for the Triadyme®-C disc, with three different disc heights for each footprint, accommodating a wide variety of vertebral sizes. The implant sizes are identified by 3-digit alphanumeric and color code schemes as illustrated below:

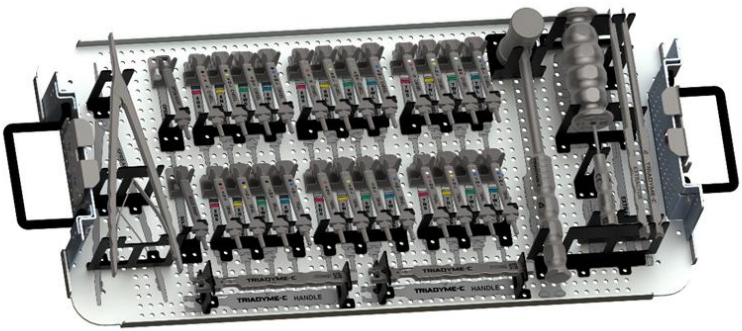
- The first digit identifies the implant height as 5, 6, or 7mm
- A 5mm height implant is color-coded as Black, 6mm as Grey, and 7mm as White
- The second digit identifies the width (N = Narrow, W = Wide)
- The third digit identifies the length (S = Short, L = Long)
- A Narrow-Short (NS) implant is color-coded as Red, Narrow-Long (NL) as Yellow, Wide-Short (WS) as Green, and Wide Long (WL) as Blue

Triadyme®-C Implant Sizing Chart

ID	Height (mm)	Footprint Size (Width x Length)	Catalog Number	
5NS	5	14.5mm x 13mm	CS-5A	● ●
5NL	5	14.5mm x 15mm	CS-5B	● ●
5WS	5	16.5mm x 13.5mm	CS-5C	● ●
5WL	5	16.5mm x 15.5mm	CS-5D	● ●
6NS	6	14.5mm x 13mm	CS-6A	● ●
6NL	6	14.5mm x 15mm	CS-6B	● ●
6WS	6	16.5mm x 13.5mm	CS-6C	● ●
6WL	6	16.5mm x 15.5mm	CS-6D	● ●
7NS	7	14.5mm x 13mm	CS-7A	○ ●
7NL	7	14.5mm x 15mm	CS-7B	○ ●
7WS	7	16.5mm x 13.5mm	CS-7C	○ ●
7WL	7	16.5mm x 15.5mm	CS-7D	○ ●

The Triadyme®-C Instrument Set is designed to assist in implantation of the Triadyme®-C disc. The instruments are reusable and are validated to be cleaned and sterilized per instructions found in the Triadyme®-C Instrument Cleaning and Sterilization Instructions. General purpose manual surgical instruments are also used in the implantation of the Triadyme®-C disc including instruments for cervical distraction and discectomy preparation.

Triadyme®-C Instrument Set



Triadyme®-C Instrument Set Contents

Catalog #	Description
CS-Tr-5A	5NS Trial
CS-Tr-5B	5NL Trial
CS-Tr-5C	5WS Trial
CS-Tr-5D	5WL Trial
CS-Tr-6A	6NS Trial
CS-Tr-6B	6NL Trial
CS-Tr-6C	6WS Trial
CS-Tr-6D	6WL Trial
CS-Tr-7A	7NS Trial
CS-Tr-7B	7NL Trial
CS-Tr-7C	7WS Trial
CS-Tr-7D	7WL Trial
CS-Ch-5A	5NS Chisel
CS-Ch-5B	5NL Chisel
CS-Ch-5C	5WS Chisel
CS-Ch-5D	5WL Chisel
CS-Ch-6A	6NS Chisel

Catalog #	Description
CS-Ch-6B	6NL Chisel
CS-Ch-6C	6WS Chisel
CS-Ch-6D	6WL Chisel
CS-Ch-7A	7NS Chisel
CS-Ch-7B	7NL Chisel
CS-Ch-7C	7WS Chisel
CS-Ch-7D	7WL Chisel
CS-Ex	Extractor
CS-ED	Extractor Pin Driver
CS-Mt	Mallet
CS-SH	Slide Hammer
CS-RH	Quick Release Handle (X2)
CS-Rp-1	Rasp (Solid)
CS-Rp-2	Rasp (Open)
CS-Sr	Spreader
CS-CA	Instrument Case

INDICATIONS FOR USE

The Triadyme®-C Cervical Total Disc Replacement is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, and/or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height compared to adjacent levels. The Triadyme®-C Cervical Total Disc Replacement is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive symptoms

or exhibit progressive neurological symptoms that could lead to permanent impairment prior to implantation of the Triadyme®-C Cervical Total Disc Replacement.

CONTRAINDICATIONS

The Triadyme®-C Cervical Total Disc Replacement should not be implanted in patients with the following conditions:

- Active systemic infection or infection at the operative site
- Allergy or sensitivity to the implant materials (titanium, titanium carbide, cobalt, chromium, aluminum, vanadium, tin, molybdenum)
- Patients with osteoporosis or at an increased risk of osteoporosis/osteopenia, defined as a DEXA bone mineral density T-score of less than -2.5
- Marked cervical instability on radiographs (e.g., radiographic signs of subluxation greater than 3.5 mm or angulation of the disc space more than 11 degrees greater than adjacent segments)
- Significant cervical anatomical deformity or compromised vertebral bodies at the index level(s) (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma)
- Bridging osteophytes or an absence of motion (less than 2 degrees)
- Severe facet disease or facet degeneration
- Intractable radiculopathy or myelopathy necessitating surgical treatment at more than two cervical levels

WARNINGS

Correct installation and placement of the Triadyme®-C device is essential to optimal performance. Implanting the Triadyme®-C device should only be attempted by surgeons who are thoroughly knowledgeable about spinal anatomy and biomechanics, have experience with anterior cervical spinal surgeries, and have hands-on training in the use of this specific device. A lack of adequate experience and/or training may lead to higher incidences of adverse effects, including neurological complications.

Correct selection of the appropriate implant size is extremely important to assure the proper placement and function of the Triadyme®-C disc. The Triadyme®-C surgical technique manual provides step-by-step instructions for selecting and implanting an appropriately sized Triadyme®-C disc.

Due to the proximity of vascular structures, neurological structures, and major organ systems to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage and/or injury to adjacent

organs with the use of the Triadyme®-C device. Care must be taken to identify and protect these structures.

There is a risk of heterotopic ossification associated with artificial cervical discs, which could lead to reduced cervical motion or fusion.

PRECAUTIONS

The clinical outcomes of this device may be affected in patients with the following conditions:

- Skeletally immature patients or patients under 21 years old
- Prior surgery at the level(s) to be treated, except laminotomy with less than one-third facetectomy
- Axial neck pain as solitary symptom
- More than one level anterior cervical fusion
- Neck or arm pain of unknown etiology
- Systemic disease, including AIDS, HIV or Hepatitis
- Taking medication known to potentially interfere with bone or soft tissue healing (e.g., steroids)
- Severe, insulin-dependent diabetes
- Paget's disease, osteomalacia, or other metabolic bone disease
- Current or extended use (>6 months) of any drug that may interfere with bony/soft tissue healing (e.g., steroids)
- Extreme obesity, as defined by the NIH Clinical Guidelines Body Mass Index (i.e., a BMI of 40 or greater)
- Rheumatoid arthritis or other autoimmune disease
- Active malignancy
- Chronic or acute renal failure or history of renal disease

Pre-operative

Patient selection is extremely important. In selecting patients for a total disc replacement, the following factors can be of extreme importance to the success of the procedure: the patient's occupation, activity level, and general health, as well as the presence of senility, mental illness, alcoholism, or drug abuse. In addition, certain degenerative diseases (e.g., degenerative scoliosis or ankylosing spondylitis) may be so advanced at the time of implantation that the expected useful life of the disc is substantially decreased. Medical conditions such as Alzheimer's disease and emphysema may affect postoperative management.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all comorbidities, past and present medications, previous treatments, etc. Surgeons should screen patients to determine if a bone

mineral density measurement (DEXA) is necessary. If DEXA is performed, the patient should not receive the Triadyme®-C device if the DEXA bone mineral density T-score is equal to or less than -2.5 (as noted in the contraindications above).

Patients should be informed of the potential adverse effects (i.e., risks and/or complications) contained in this document.

Information on the proper implant site preparation, implant size selection, use of surgical instrumentation, and implantation technique for the Triadyme®-C device is provided in the surgical technique manual and should be reviewed prior to surgery.

Examine all instruments prior to surgery for wear or damage. Instruments that have excessive wear or damage may not be adequate for their intended function or be more likely to break. Replace any worn or damaged instruments.

Intra-operative

Use aseptic technique when removing the Triadyme®-C device from the innermost packaging. Carefully inspect each device and its packaging for any signs of damage, including damage to the sterile barrier. Do not use the Triadyme®-C device if the packaging is damaged or if the implant shows signs of damage.

Upon removal from its packaging, carefully inspect the Triadyme®-C disc to ensure that it is fully seated in the implant cartridge. Do not remove the Triadyme®-C disc from the implant cartridge or retract the retainer clip holding the two implant halves together. Should a Triadyme®-C disc become loose or removed from the implant cartridge prior to implantation, do not attempt to reassemble it, but use a new implant.

The Triadyme®-C device must not be used with instruments of spinal systems from other manufacturers.

Excessive removal of endplate cortical bone may result in sub-optimal outcomes.

Take care to ensure that tissue or other debris is not trapped between the bearing surfaces of the Triadyme®-C disc.

Ensure proper alignment and placement of the Triadyme®-C disc as misalignment or improper placement of the device may impede the proper function and/or lead to failure of the disc.

The Triadyme®-C disc must never be re-used or re-implanted. Although the disc may appear undamaged, it could have small defects and/or internal stress patterns that may lead to early breakage.

Post-operative

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. Patients should be advised to avoid activities that require repeated bending, lifting, and twisting, such as athletic activities, for a period of weeks to months. Gradual increases in physical activity will depend on individual patient progress and monitoring the Triadyme®-C disc for stability and proper functioning.

POTENTIAL ADVERSE EVENTS/COMPLICATIONS

Potential risks associated with the use of the Triadyme®-C device include those commonly associated with any surgery as well as those specifically associated with cervical spinal surgery using an anterior approach including those associated with a spinal implant including the Triadyme®-C device.

Possible, anticipated, procedure-related risks that are associated with any surgery include, but are not limited to:

- Superficial (shallow) infection
- Deep wound infection
- Pneumonia (lung infection)
- Atelectasis (collapsed lung)
- Septicemia (blood poisoning)
- Injury to blood vessels
- Soft tissue damage
- Phlebitis (inflammation of the blood vessel in your leg)
- Thromboembolus (blood clot in the legs)
- Pulmonary embolism (blood clot in the lung)
- Hemorrhage (excessive bleeding)
- Respiratory distress or depression (slow, shallow, or difficulty breathing)
- Pulmonary edema (abnormal collection of fluid in the lungs)
- Reactions to the drugs or anesthesia used during and after surgery
- Reactions to blood transfusions
- Failure of the tissue to heal properly (e.g., hematoma [a pocket of blood caused by bleeding from a broken blood vessel]; seroma [buildup of clear body fluid in the tissue]; wound dehiscence

[failure of the incision to completely heal which may allow it to reopen]), which may require drainage, aspiration (removing a substance using suction), debridement (surgery to clean foreign material and dead tissue out of a wound), or other treatment
- Pain at the incision
- Myocardial infarction (heart attack)
- Stroke
- Death

Complications that are known to occur with spinal implant surgery, including surgery with Triadyme®-C device:
- Damage to nerves that may result in changes in the sensation and/or muscle weakness in your neck, legs, arms, and/or shoulders
- Paralysis (loss of ability to move muscles with the loss of feeling)
- Paresthesia (a sensation of pricking, tingling, or creeping on the skin)
- Dysphagia (trouble swallowing)
- Dysphonia (trouble with the voice or speaking)
- Dysphasia (trouble with speech generation and potential comprehension of speech)
- Dysarthria (difficulty articulating speech that is otherwise linguistically normal)
- Otitis media (inflammation of the middle ear)
- Recurring aspirations (inhaling foreign substances into the lungs)
- Fistula formation (an abnormal passage)
- Tracheal, esophageal, and/or pharyngeal perforation (penetration of the windpipe, the tube that goes from the throat to the stomach, and/or the area between the mouth and esophagus that performs the swallowing action)
- Airway obstruction (blockage of the airway)
- Spinal stenosis (narrowing of the nerve passages that go from the spine to the rest of your body)
- Hardening or tearing of the tissue surrounding the implant
- Spondylosis
- Worsening of the degenerative disc disease condition at adjacent levels
- Discitis (inflammation of the disc), arachnoiditis (inflammation of middle layer of the tissues that cover the spinal cord), or other types of inflammation
- External chylorrhea
- Hoarseness
- Vocal cord paralysis

- Damage to nerves, blood vessels, and nearby tissues including, for example, muscle and/or ligament injury
- Epidural bleeding (bleeding around the membrane covering the tissue surrounding your spinal cord that may require a blood transfusion or another operation)
- Epidural hematoma (a pocket of blood caused by a broken blood vessel or bone bleeding in the membrane covering the nerves or the tissues surrounding your spinal cord)
- Epidural fibrosis (scar tissue formation on the membrane covering the nerves)
- Instability of the operated or adjacent vertebrae
- Blindness by prolonged pressure on the eye during the operation
- Urinary or fecal incontinence
- Surgery at the wrong level of your spine
- Loss of bone around the implant (osteolysis related to debris from implant wear)
- Injury to the spinal cord or the nerves leaving or entering the spinal cord
- Disc herniation ("slipped disc")
- Injury to blood vessels
- Injury of the membrane (dura) surrounding the spinal nerves which may or may not result in leakage of spinal fluid
- Impaired muscle or nerve function (symptoms like clumsiness, numbness, foot drop, neurological weakness, etc.)
- Hemorrhage (bleeding)
- Fracture of the vertebra, spinous process (the part of your spine that you can feel through the skin on your back), or other damage to bony structures during or after surgery
- Deterioration of the facet joints in the adjacent vertebrae (worsening of the condition)
- Postoperative muscle and tissue pain
- The chance that the surgery will not reduce the pain or symptoms felt before the surgery
- Pain and discomfort resulting from the presence of implants or reaction to the metal used in the implant, as well as the cutting and healing of tissues
- Spontaneous fusion (unplanned, self-generated fusion of the vertebra)
- Unfavorable changes or deterioration at the operated level(s) of the spine and/or the levels above and below including loss of proper spinal curvature, correction, height, and/or reduction, or malalignment, which may require another surgery

- An unfavorable reaction where the bone and the implant meet
- Implant malposition or orientation (the implant could be improperly positioned)
- Adverse reaction or foreign body reaction to implant materials (possible allergic reaction to the metal, or metallosis) or wearing of the implant material against bone or another part of the implant that creates very small particles; it is possible that these particles may eventually cause adverse reactions with the local tissues such as bone, nerves, and nearby soft tissue
- Placement of the device at the wrong level of the spine
- Implant may become loose, deform (permanently change shape), fail, break, wear out, or move, which may require another surgery to correct the problem and/or remove the implant
- Instruments used to insert the implant may break or malfunction in use, which may cause damage to the surgical site or surrounding tissues
- Pain, discomfort, and/or abnormal sensations caused by the presence of the implant
- Subsidence (the implant may sink into the bone) or migration
- Implantation of the incorrect size, which may cause the device to be less effective or safe
- Failure of the implant to maintain or improve range of motion
- Actual or perceived noise or other audiologic sensation generated by motion of the implant

HOW SUPPLIED

The Triadyme®-C device is sterile-packaged and pre-loaded onto a disposable implant cartridge. This cartridge is fitted with a stainless-steel retainer clip that holds the two halves of the implant together before and during implantation. Each Triadyme®-C device is packaged in a double sterile packaging system that includes an inner and outer peel pouch. The implant/cartridge assembly is contained within a protective sleeve inside the inner pouch. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. The use-before-date is provided on the external package labeling. Remove the Triadyme®-C implant/cartridge assembly from its packaging using aseptic technique only after the correct size implant has been determined.

The Triadyme®-C instrument case and associated surgical instruments are supplied non-sterile and must be cleaned and sterilized prior to use according to the instructions found in the Triadyme®-C Cervical Total Disc

Replacement Instrument Set Cleaning and Sterilization Instructions. The instruments are shipped and stored in the instrument case. Instruments should be securely placed in their specifically marked spaces within the instrument case. The sterilization case may be stored in normal hospital environmental conditions.

IMPLANT RETRIEVAL

Should it be necessary to remove a Triadyme®-C disc, please contact Dymicron for instructions regarding data to be collected, including histopathological, patient, and adverse event information. All explanted discs must be returned to Dymicron for analysis. Please refer to the Triadyme®-C Cervical Total Disc Replacement Surgical Technique Manual for instructions on the proper surgical technique for disc removal.

COMPLAINTS

Any health care professional (e.g., customer or user of this system), who has experienced dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify Dymicron. If the Triadyme®-C implant or instruments ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended) or may have caused or contributed to the death or serious injury of a patient, Dymicron should be notified immediately.

LIMITED WARRANTY

The manufacturer warrants that reasonable care has been used in the manufacture of this device. There are not express or implied warranties, including fitness for a particular purpose, for the Triadyme®-C Cervical Total Disc Replacement. Any description or specifications provided are solely to describe the product at the time of manufacture and do not constitute any express or implied warranties. The manufacturer is not responsible for any direct, incidental, special, or consequential loss, damage or expense based on any defect, failure, or malfunction of this product, other than as expressly provided by mandatory provisions of applicable law. No person has the authority to bind the manufacturer to any representation or warranty except as provided in this Limited Warranty.

MRI SAFETY INFORMATION

The Triadyme®-C Cervical Total Disc Replacement is MR Conditional. A patient with the Triadyme®-C Cervical Total Disc Replacement implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition of Use/Information
Nominal Values of Static Magnetic Field	1.5 Tesla or 3.0 Tesla
Maximum Spatial Field Gradient	100 T/m (10,000 Gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no Transmit Coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive Knee RF coil, etc.)
Operating Mode of MR system	Normal Operating Mode
Maximum Whole-Body Averaged SAR	2 W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole-body averaged SAR of 2 W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. Therefore, carefully select pulse sequence parameters if the implant is in the area of interest. The artifact may extend approximately 1.0 cm from the implant.

TRIADYME®-C
POWERED BY TRI-LOBE TECHNOLOGY

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