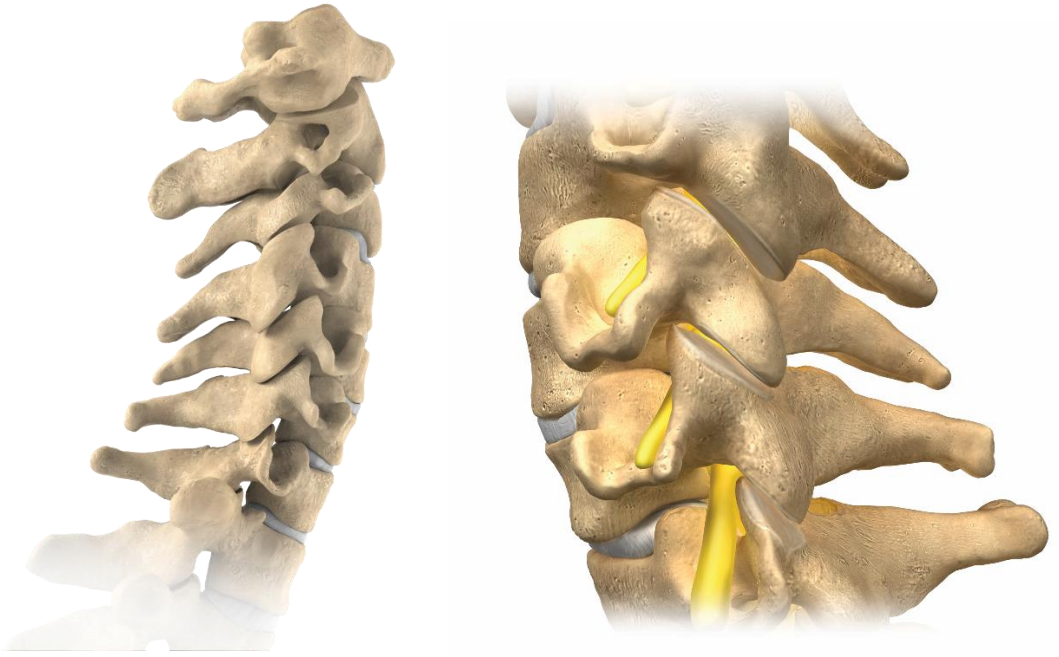
Simplify Disc Patient Information Leaflet

Device Name: Cervical Total Disc Replacement Prosthesis

Model: NuVasive Simplify Disc

Anatomy of Spine:
The human cervical spine is made up of 7 bones or vertebrae. Vertebrae are connected by several joints, which allow for bending and twisting. The main joint between the two vertebrae is called an intervertebral disc. The disc is made of two parts, a tough and fibrous outer layer (annulus fibrosis) and a soft, gelatinous center (nucleus pulposus). These two parts work in conjunction to allow the spine to move.



At each level of the cervical spine, spinal nerves exit the bony spine then extend throughout the body.

What causes pain?
There are several possible causes of spine problems. Symptoms can be caused by either instability or by disc, bone, or ligaments putting pressure on (compressing) the nerve roots or spinal cord or by inflammation.

What are treatment options?
Many symptoms can be treated without surgery including rest, heat, ice, medication, injections, and physical therapy.

If symptoms do not improve with conservative treatment, physicians may recommend spinal surgery. Surgery is reserved for those who do not gain relief from nonoperative forms of treatment, patients whose symptoms are increasing or worsening, and/or patients that present with a spinal condition which indicates the need for surgery. It is important to speak with a physician about the best option.

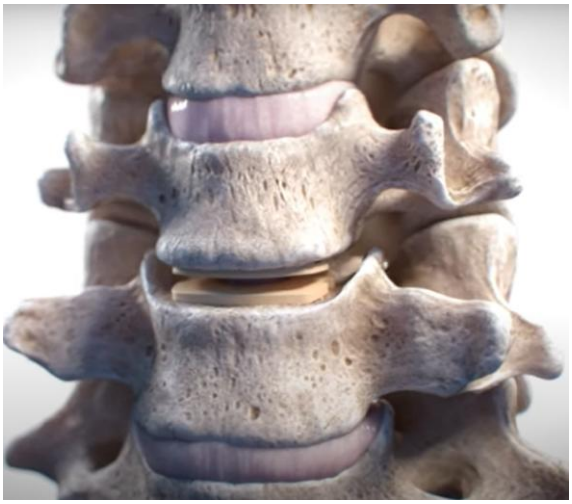
The surgical option

Cervical disc replacement is a surgical treatment option for degenerated or damaged disc(s) in the neck. The procedure is designed to reduce or alleviate the symptoms, while maintaining motion at the treated segment.

Simplify Disc is indicated for use in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single level discectomy for cervical degenerative disc disease.

The Simplify Disc is a 3-part cervical intervertebral prosthesis with two polyetheretherketone (PEEK, a medical-grade plastic) endplates and a zirconia-toughened alumina ceramic core (a material commonly used in orthopedic devices). There is no metal on the articulating surfaces, and the device is Nickel-free. The endplates are coated with titanium plasma on their bone-contacting surfaces, which promotes bony on-growth. Long-term clinical experience of the use of these materials has shown that an acceptable level of biological response can be expected, if the materials are used in appropriate applications.

The discs come in a variety of sizes and heights, designed to match a broad range of patient anatomies. The unique design of the Simplify Disc is designed to mimic the motion a healthy spine.



Warnings, Cautions and Precautions:

- Simplify Disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone hands on training in the use of this device. Only surgeons who are familiar with Simplify Disc components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

- Correct selection of the appropriate implant size is extremely important to assure the placement and function of the device. Information regarding proper implant size selection is provided in the Simplify Disc Surgical Technique Guide.

- 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 Simplify Disc. 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 at either treated level or adjacent levels.

- Preoperative

  In order to minimize the risk of atraumatic periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. Upon reviewing all relevant information, the surgeon must determine whether a bone density (DEXA) scan is prudent. If DEXA is performed, the patient should not receive the device if the DEXA bone mineral density T-score is <-1.5, as the patient may be osteoporotic or osteopenic.

- Intraoperative

  Use aseptic technique when removing Simplify Disc from the innermost packaging. Ensure Simplify Disc does not come into contact with hard objects that may damage the implant and render the implant functionally unreliable.

  Correct selection of the appropriate implant size is extremely important to ensure the optimal placement and functionality of Simplify Disc. See the Simplify Disc Surgical Technique Guide for step-by-step instructions.

  Surgical implants must never be re-used or re- implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Simplify Disc must not be used with instruments of spinal systems from other manufacturers.

- Post-operative

  Follow your surgeon's scheduling and instructions for post-operative care monitoring and be advised of the importance of adhering to these instructions for successful treatment with the device. Heavy lifting should be avoided for 6 weeks, and impact sports should be avoided for 3 months.

  It is recommended that you contact your health care professional / spine surgeon if you experience any

new or increased pain or neurological symptoms, such as an irritated nerve root (radiculopathy) or spinal cord (myelopathy).

Please ask your health care professional/spine surgeon should you have any concerns following surgery.

Contraindications:
Simplify Disc should not be implanted in patients with the following conditions:

- An active systemic infection or an infection at the operative site,
- Degenerative disc disease (DDD) symptoms necessitating surgical treatment at more than one cervical level,
- Osteoporosis/osteopenia defined as DEXA bone mineral density T-score equal to or worse than -1.5,
- Known allergy to the implant materials (PEEK, ceramic, titanium),
- Severe facet disease or facet degeneration,
- Bridging osteophytes,
- Marked cervical instability on radiographs (e.g., radiographic signs of subluxation >3.0mm or angulation of the disc space more than 11° greater than adjacent segments),
- Significant cervical anatomical deformity at the index level or clinically compromised cervical vertebral bodies at the index level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis)
- Non-discogenic neck pain or non-discogenic source of symptoms (e.g., tumor, rotator cuff injury, etc.)
- Less than 2 degrees of motion at index level
- Prior surgery at the level to be treated
- Prior fusion or artificial disc replacement at any cervical level
- More than one neck surgery via anterior approach
- Previous trauma to the C3-C7 levels resulting in compression or burst fractures
- Free nuclear fragment at other cervical levels
- Axial neck pain only
- Severe myelopathy
- Any paralysis
- Recent history (within previous 6 months) of chemical or alcohol dependence
- Prior disc space infection or osteomyelitis in the cervical spine
- Any terminal, systemic, or autoimmune disease
- Metabolic bone disease (e.g. gout, osteomalacia, Paget's disease)

- Any disease, condition or surgery which might impair healing, such as
    - Diabetes mellitus requiring daily insulin management,
    - Active malignancy,
    - History of metastatic malignancy.
- Current or extended use (> 6 months) use of any drug known to interfere with bone or soft tissue healing
- Arachnoiditis
- Currently experiencing an episode of major mental illness (psychosis, major affective disorder, or schizophrenia) or manifesting physical symptoms without a diagnosable medical condition to account for the symptoms
- Pregnancy
- Use of spinal stimulator at any cervical level prior to surgery
- Currently a prisoner
- Currently involved in spinal litigation which may influence the reporting of the patient's symptoms
- Participation in any investigational drug, biologic, or medical device study within the last 30 days prior to surgery

This list above does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

Device Lifetime Information:
The expected device lifetime is at least 10 years. Follow your surgeon's instructions for postoperative activities and be advised of the importance of adhering to these procedures for successful treatment with the device. Heavy lifting should be avoided for 6 weeks, and impact sports should be avoided for 3 months.

It is recommended that you continue to remain vigilant for any symptoms such as new or increased pain or neurological symptoms.

MRI Safety Information:
The Simplify Disc was tested for compatibility with magnetic resonance imaging (MRI) and was determined to be safe when the patient is scanned according to the following Simplify Disc MR Conditional labeling:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 30 T/m.

- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:

  o 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.

  o 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

Under the scan conditions defined above, Simplify Disc is expected to produce a maximum temperature rise of less than 3 ºC after 15 minutes of continuous scanning.

Consult your surgeon for further information related to magnetic field interference from magnetic resonance imaging devices.

Incident Reporting:
Any serious incident that occurs in relation to the device should be reported to the manufacturer and the Therapeutic Goods Administration.

Name and Address of Manufacturer:

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