



BAGUERA® C

Cervical Disc Prosthesis

Patient Information Guide



Welcome to your guide on the **BAGUERA® C Cervical Disc Prosthesis**, a medical device designed to treat certain neck (cervical spine) problems. This guide will help you understand your condition, the BAGUERA® C device, the surgery, and what to expect before and after the procedure.

This guide is not intended as a substitute for an informed discussion with your physician. If you have questions regarding this booklet please write them down so that your doctor or other health care professional can answer them for you.



Table of Contents

Glossary of Key Terms	3
Introduction: Why You Have This Guide	5
Understanding the Cervical Spine and Disc Problems	7
The Cervical Spine Anatomy and Function	7
What is Cervical Disc Degeneration?	9
Initial Treatment Options (Non-Surgical Care)	10
Treatment Options: Fusion vs. Artificial Disc Replacement	11
About BAGUERA® C Cervical Disc Prosthesis	13
What Is BAGUERA® C and What Does It Do?	13
Who Is BAGUERA® C For? (Indications)	17
Who Should NOT Get a BAGUERA® C? (Contraindications)	18
Warnings and Precautions with BAGUERA® C	19
Potential Risks and Adverse Effects	21
General Risks of Anterior Cervical Spine Surgery (any neck surgery from the front):	21
Specific Risks Related to the BAGUERA® C Implant	22
The Surgery: What to Expect	23
Before the Surgery – Preparation	23
During the Surgery – Step by Step	24
After the Surgery	25
Going Home – Recovery and Care After Surgery	26
Expected Outcomes and Benefits of BAGUERA® C Disc Replacement	28
Conclusion and Next Steps	29

Glossary of Key Terms

Understanding a few key terms will make the information in this guide clearer:

- **BAGUERA® C:** An artificial cervical disc prosthesis used to **replace a damaged disc in the neck** while preserving motion. It is intended to relieve neck and/or arm pain caused by a worn-out disc.
- **Cervical Spine:** The upper part of the spine located in your neck, consisting of seven vertebrae (bones) labeled C1 through C7. The cervical spine supports the head and houses the upper spinal cord, allowing neck motion.
- **Intervertebral Disc:** A soft cushioning pad between the vertebrae of the spine in the neck, these discs act as shock absorbers and allow movement. A healthy disc has a soft, gel-like center and a tough outer ring.
- **Symptomatic Cervical Disc Disease (SCDD):** A condition where a cervical disc has deteriorated or been injured and **no longer functions normally, often causing neck and/or arm pain, weakness, or numbness.** It commonly results from aging (degeneration) or disc herniation.
- **Degenerated Disc:** An intervertebral disc that has worn out or dried out over time, losing height and cushioning ability. This can lead to pain and other symptoms when nerves are affected.
- **Disc Herniation:** A condition in which the soft center of a disc bulges or leaks out through a tear in the outer ring, possibly **pressing on nearby nerves or the spinal cord**
- **Anterior Approach:** A surgical technique where the surgeon reaches the spine **from the front of the neck (through a small incision in the throat area).** This is the approach used for cervical disc replacement surgeries like BAGUERA® C.
- **Titanium Alloy:** A strong, lightweight metal commonly used in medical implants. In BAGUERA® C, the two endplates (top and bottom parts) are made of a titanium alloy for strength and biocompatibility.

- **Ultra-High Molecular Weight Polyethylene (UHMWPE):** A medical-grade hard plastic used in implants. BAGUERA® C contains a UHMWPE piece (the nucleus or core) that allows smooth movement between the metal endplates.
- **Facet Joints:** Small joints at the back of each vertebra that connect the bones together and guide spine motion. (These are different from the intervertebral disc in the front of the spine.)
- **Bone Spurs (Osteophytes):** Excess bone that can form around joints or discs due to wear and tear. In the cervical spine, bone spurs can narrow nerve pathways and cause pain or nerve pressure.

If you encounter other medical terms while reading, be sure to ask your doctor to explain them. Now, let's start with an overview of your spine and why you might need the BAGUERA® C disc.



Introduction: Why You Have This Guide

Your doctor has recommended a **BAGUERA® C** cervical disc replacement to treat your neck condition. This guide is provided to help you make an informed decision about your care. It will explain the basics of your cervical spine, what happens when a disc in your neck degenerates, how the BAGUERA® C implant works, and what to expect from the surgery and recovery.

Keep in mind that this brochure is **not a substitute for professional medical advice** – always follow your doctor's guidance for your specific situation. Use this information to discuss any questions or concerns with your healthcare provider.





Understanding the Cervical Spine and Disc Problems

The Cervical Spine Anatomy and Function

Your spine is the structure that supports your body and protects your spinal cord. The **cervical spine (neck)** is the top part of the spine, consisting of seven small bones (vertebrae C1–C7). These vertebrae stack to form a column that supports your head and allows you to nod and turn your head. Between each vertebra is an **intervertebral disc**, which is a soft, compressible cushion. **Each cervical disc acts as a shock absorber and helps your neck move.** The discs maintain the proper spacing between the bones and allow bending and turning of the neck. They also create space for nerves to exit the spinal cord and travel to your arms. A healthy disc has a soft center (nucleus pulposus) and a firmer outer ring (annulus fibrosus). This structure permits flexibility while keeping the bones apart.

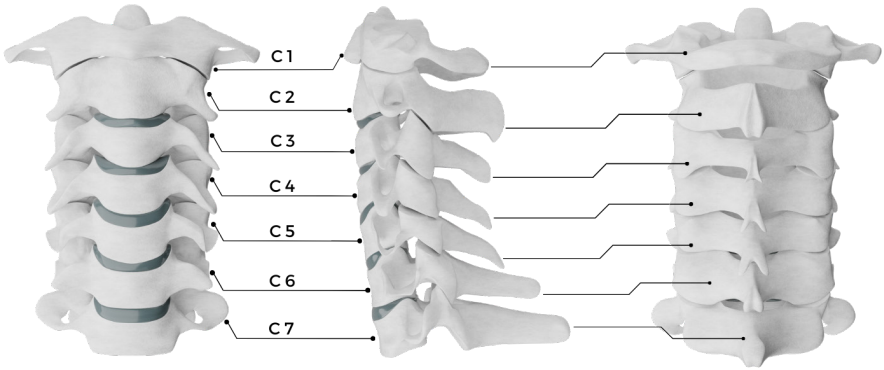
SIDE VIEW OF THE FULL SPINAL COLUMN



FRONT VIEW

SIDE VIEW

BACK VIEW

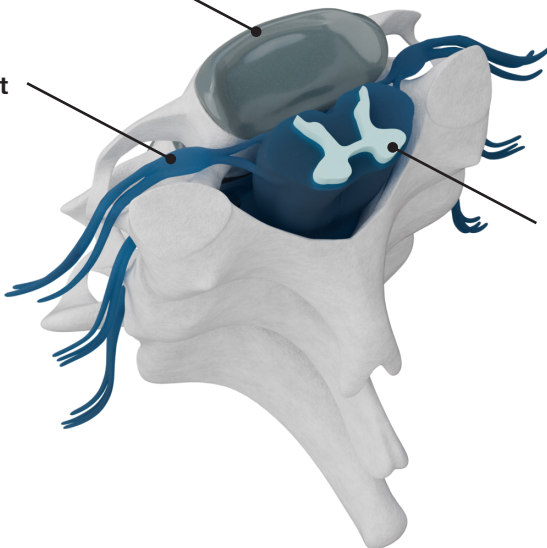


Inside the spinal column runs the **spinal cord**, a bundle of nerves that connects your brain to your body. At each level of the cervical spine, nerve roots branch off from the spinal cord and pass through openings in the vertebrae to reach your shoulders and arms. **These nerves control muscle movements and sensation in your neck, shoulders, arms, and hands.** If something narrows the space for these nerves (for example, a bulging disc or bone spur), it can cause pain or neurological symptoms.

Intervertebral disc

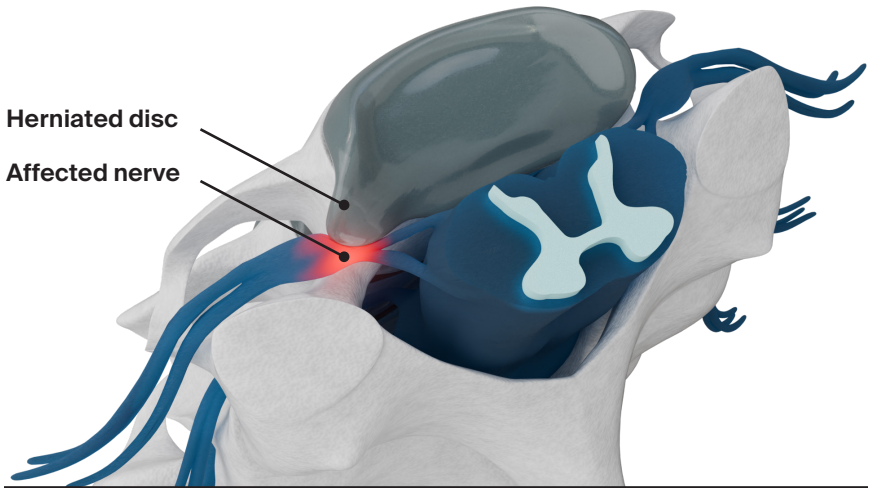
Nerve root

Spinal cord



What is Cervical Disc Degeneration?

Cervical disc degeneration is a natural aging or injury-related process where spinal discs in the neck dry out, flatten, and lose flexibility. This can narrow the space between vertebrae, stressing nearby joints and nerves. The body may respond by forming bone spurs, which can further compress nerve pathways, potentially leading to spinal stenosis. A **herniated disc** may occur when the disc's inner material pushes through a tear in the outer layer, pressing on nerves or the spinal cord—similar to jelly squeezing out of a doughnut.



Symptomatic Cervical Disc Disease (SCDD) occurs when disc degeneration or herniation compresses nerves or the spinal cord, leading to symptoms like neck and arm pain, tingling, numbness, or muscle weakness. In severe cases, spinal cord pressure can affect balance and coordination (myelopathy).

Common symptoms include:

- **Neck pain** (dull, sharp, or burning)
- **Radiating arm/shoulder pain** (radiculopathy)
- **Numbness or tingling** in arms or hands
- **Muscle weakness** in the upper limbs
- **Limited neck motion or stiffness**
- **Balance or walking difficulties** (in advanced cases)

Diagnosis involves a physical exam and imaging (X-ray, MRI, or CT) to identify the affected disc level and confirm nerve involvement.

Initial Treatment Options (Non-Surgical Care)

Most patients start with conservative treatments, which often provide relief without surgery. These include:

- **Medications** (pain relievers, anti-inflammatories, muscle relaxants)
- **Physical therapy** to reduce nerve pressure and improve strength and flexibility
- **Activity modification** to avoid strain
- **Heat or ice therapy** for pain relief
- **Short-term neck brace** for support
- **Epidural steroid injections** to reduce inflammation near affected nerves

A combination of these over at least 6 weeks is typically recommended. If symptoms persist or worsen, surgery may be considered.



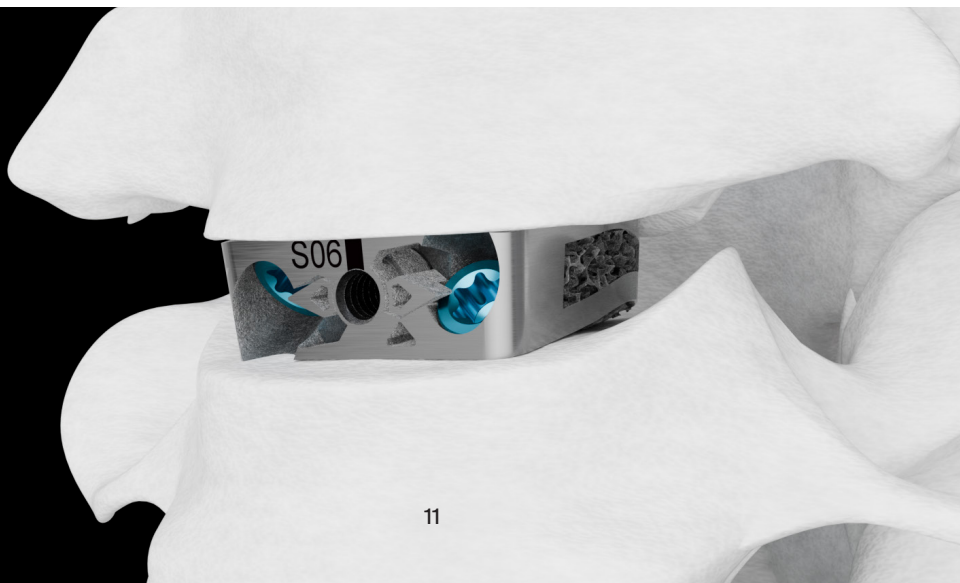
Treatment Options: Fusion vs. Artificial Disc Replacement

When conservative treatments don't provide relief, surgery becomes an option. The two main surgical approaches to address a problematic cervical disc are:

1. **Anterior Cervical Discectomy and Fusion (ACDF)** – the traditional surgery.
2. **Artificial Cervical Disc Replacement** – the newer approach, which includes devices like BAGUERA® C.

Both procedures are done from the front of the neck (an anterior approach) under general anesthesia, and both relieve pressure on the nerves by removing the problematic disc. The right option depends on many factors, including the specifics of your condition, overall health, and your surgeon's evaluation.

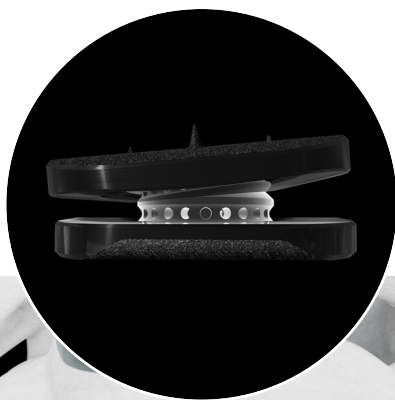
ACDF is a common surgery where the damaged disc is removed to relieve nerve or spinal cord pressure. A spacer is inserted between the vertebrae (as shown below), and the vertebrae are fused together using screws and sometimes a plate, eliminating motion at that level. While effective for pain relief, fusion reduces neck flexibility and may stress nearby discs and cause future issues. Rarely, the bones may not fuse properly, leading to complications.





Artificial Disc Replacement (ADR) involves removing the damaged disc and inserting a movable implant, like the **BAGUERA® C**, instead of fusing the bones. This preserves natural motion and disc height, helping maintain neck flexibility and reduce stress on adjacent levels. Unlike fusion, ADR doesn't require a bone graft or healing time for bone fusion.

Both non-surgical and surgical treatments are designed to relieve your painful symptoms. Your surgeon will help determine if you are a good candidate for an artificial disc replacement like **BAGUERA® C**.



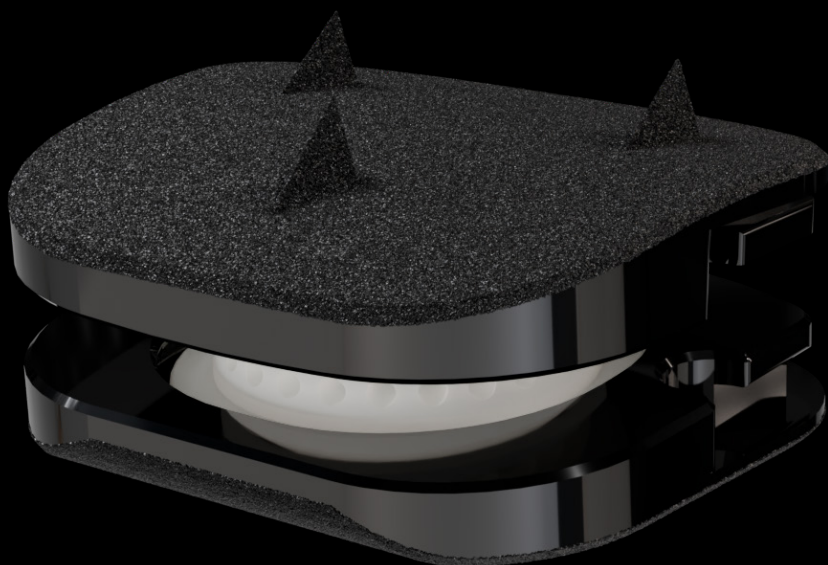
About BAGUERA® C Cervical Disc Prosthesis

What Is BAGUERA® C and What Does It Do?

BAGUERA® C is an artificial cervical disc implant that replaces a damaged disc in the neck while preserving natural motion and disc height. for the long term, though regular check-ups are advised.

Product Description – How BAGUERA® C Is Constructed: The BAGUERA® C prosthesis has three main parts (components): **two metallic endplates and one plastic core (nucleus).**

- The endplates are metal pieces (one fits against the upper vertebra and one against the lower vertebra at the treated level). They are made of a titanium alloy – a strong, lightweight metal commonly used in implants. These plates have a special coating of pure titanium on their outer surfaces (the sides that touch your bone) to encourage the bone to grow onto the implant surface for stability in the long-term. On the inside, the plates have an **amorphous carbon coating** that reduces wear against the plastic core.
- The core or **nucleus** is a piece made of **ultra-high molecular weight polyethylene (UHMWPE)**, a very durable medical plastic, that is highly cross-linked (networking of the polymer chains within the material) and stabilized using an antioxidant to enhance its strength and durability. This core fits between the two metal plates and acts like the cushion whilst allowing movement.
- The design is similar to a guided ball-and-socket joint: **the top metal plate can slide over the plastic core, and the core can slide within the cavity of the bottom metal plate.** This allows movement in multiple directions (bending, rotating, etc.) similar to a natural disc's movement.



**Porous Titanium
Coating for long-term
fixation**

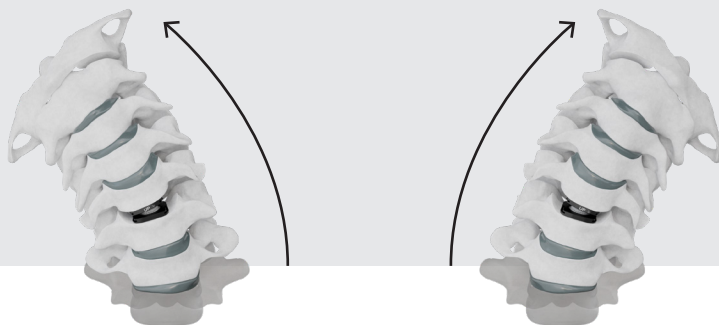
**Fins for initial
stability**

**Superior Titanium
Endplate with
Diamond-Like-
Carbon coating**

**Vitamin-E stabilised,
Highly Crosslinked
Ultra High Molecular
Weight Polyethylene**

**Inferior Titanium
Endplate with
Diamond-Like-
Carbon coating**

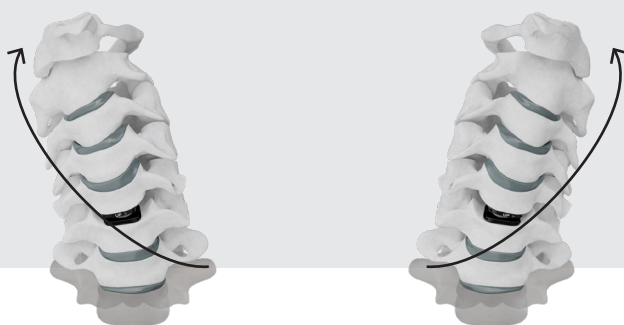
**Front view of cervical spine with BAGUERA® C
at C5-C6 bending side to side**



**Right side view of cervical spine with
BAGUERA® C at C5-C6 extending and flexing**



**Front view of cervical spine with BAGUERA® C
at C5-C6 twisting to the right and left**



In simpler terms, once implanted, the BAGUERA® C's metal plates are firmly attached to your vertebrae above and below, and the plastic core between them lets the two bones move smoothly. There are small teeth or fins on the metal plates to help grip the bone initially. Over time, your bone should grow onto the plates' surface, further securing them in place.

Reliability of Materials: Titanium alloys and medical-grade polyethylene have been used in other orthopedic implants (like hip and knee replacements) for decades, so they have a long history of safe clinical use in the human body. The combination of these materials in BAGUERA® C is specifically engineered for the cervical spine's demands. There is **no need for any bone graft** with BAGUERA® C, since the implant itself maintains the space.

If you receive a BAGUERA® C disc, you will be given a patient implant card with details of the device (such as the model and size) to keep for your records. Always carry this card or know where it is, in case you need to show it to healthcare providers in the future.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.



Who Is BAGUERA® C For?

(Indications)

The **BAGUERA® C Cervical Disc Prosthesis** is indicated for use in skeletally mature patients for reconstruction of the disc at one or two contiguous levels from C3-C7 following single-level or two-contiguous-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level or two-contiguous-level abnormality localized to the level of the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic resonance imaging (MRI)): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. Patients receiving the BAGUERA® C Cervical Disc Prosthesis should have failed at least six weeks of non-operative treatment or have the presence of progressive symptoms (e.g., numbness or tingling) prior to implantation. The BAGUERA® C Cervical Disc Prosthesis is implanted via an open anterior approach.

Proper patient selection is important for the success of this procedure. Your doctor will ensure that your symptoms truly come from the disc problem identified. If you have issues at two adjacent levels, BAGUERA® C could be placed at both levels during one surgery (two-level disc replacement), if appropriate.



Who Should NOT Get a BAGUERA® C? (Contraindications)

BAGUERA® C is **not right for everyone**. There are certain conditions and situations where this implant should not be used. **You should not receive a BAGUERA® C cervical disc if you have:**

- Diseases or deformity that may affect your spine such as rheumatoid arthritis or ankylosing spondylitis
- Degeneration or disease of the facets (small joints behind the spinal disc)
- Medical imaging showing that the areas of the spine at the neck is not stable enough
- An active infection in the body or at the location of the body near where surgery will take place
- Osteoporosis/osteopenia
- Allergy or sensitivity to the implant materials (e.g., titanium, vanadium, polyethylene)

It's important to discuss your full medical history with your surgeon. If you have any of the above conditions, your doctor will weigh the risks and may steer you to alternative treatments. The success of a cervical disc replacement partly depends on careful patient selection.



Warnings and Precautions with BAGUERA® C

Following your surgeon's instructions and understanding the precautions can improve the success of your surgery. Below are the warnings relating to the BAGUERA® C Cervical Disc Prosthesis:

- BAGUERA® C 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 the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the BAGUERA® C 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 ensure the placement and function of the device. Information regarding proper implant size selection, implant site preparation, and the use of the instrumentation before, during, and after BAGUERA® C surgery is provided in the BAGUERA® C Surgical Technique Manual. Users are advised to read and understand the surgical technique manual and instructions for use prior to surgery.
- Removal of the disc may be required during device re-positioning or for other surgical considerations. This process could cause damage that is not visually apparent – if a disc is removed during the implantation procedure, a new device should be implanted in its place
- Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this 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 at either the treated level(s) or adjacent levels.

The safety and effectiveness of the BAGUERA® C Cervical Disc Prosthesis has not been established in patients with the following conditions:

- Skeletally immature patients, pediatric or adolescent children (<22 years old), or those over the age of 69;
- Previous anterior cervical spine surgery at the index level(s);
- More than two diseased or immobile cervical spine level requiring surgical intervention;

- Disc height less than 3mm measured from the center of the disc in a neutral position;
- Axial neck pain as the solitary symptom or neck or arm pain of unknown etiology;
- Intractable radiculopathy or myelopathy due to pathology at more than two levels;
- History of an endocrine or metabolic disorder (e.g., Paget's disease) known to affect bone and mineral metabolism;
- Current or extended use (>6 months) of any drug that may interfere with bony/soft tissue healing
- Active malignancy;
- Diabetes mellitus requiring daily insulin management;
- Pregnancy;
- Clinical extreme obesity (class III) as defined by the NIH Clinical Guidelines Body Mass Index (i.e. BMI >40);
- Systemic disease including AIDS, HIV, and Hepatitis;
- Neuromuscular disorders such as muscular dystrophy, spinal muscular atrophy, or amyotrophic lateral sclerosis;
- Acute mental illness or substance abuse.

Discuss with your doctor if any of the following apply:

- Over the age of 69
- History of low bone quality, condition affecting bone growth or any auto-immune condition
- Previous cervical spine surgery, whether anterior or posterior.
- Only symptoms are neck muscle soreness
- Neck feels stiff indicating two or more of your vertebrae may already be fused.
- Use of any medication with an impact on bone growth or soft tissue healing.
- Diabetes

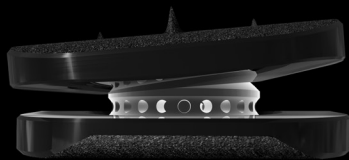
By understanding and following these precautions, you can help ensure the best outcome from your BAGUERA® C surgery. Always feel free to discuss any specific concerns or lifestyle questions (like “Can I ride rollercoasters?” or “Can I lift my heavy suitcase?”) with your doctor during follow-ups.

Potential Risks and Adverse Effects

All surgeries carry some risks, and it's important to be aware of them. Below we outline general risks of cervical spine surgery as well as risks specifically associated with the BAGUERA® C implant. **Keep in mind that serious complications are not common, but it's still important to know what they are.** Your surgical team will take many precautions to minimize these risks.

General Risks of Anterior Cervical Spine Surgery (any neck surgery from the front):

- **Anesthesia reactions:** Rare allergic responses, managed by anesthesiologists.
- **Infection:** Can occur at the incision or deeper; usually prevented with antibiotics.
- **Bleeding or hematoma:** Rare but serious if it affects the airway.
- **Nerve or spinal cord injury:** May cause numbness or weakness; minimized with careful technique and monitoring.
- **Blood clots:** Low risk, reduced by early movement and sometimes blood thinners.
- **Injury to esophagus/trachea:** Rare and typically repairable if it occurs.
- **Voice or swallowing issues:** Usually temporary; rarely long-term.
- **Incomplete symptom relief:** Some symptoms may persist or return.
- **Adjacent level degeneration:** Possible over time, even with motion-preserving implants.
- **Serious complications:** Extremely rare events like stroke or heart attack.



Risks Related to Cervical Disc Replacement Implants:

While the above risks apply to fusion or disc replacement alike, cervical disc replacements like BAGUERA® C have some specific potential risks:

- **Migration:** The implant may shift from its position, potentially requiring revision surgery.
- **Subsidence:** The implant may sink into soft bone, reducing disc height and possibly compressing nerves.
- **Wear or breakage:** Over time, moving parts may wear down, though this is rare with modern materials.
- **Heterotopic ossification:** Excess bone growth around the implant may limit motion, sometimes leading to unintended fusion.
- **Adjacent level degeneration:** Other spinal levels may still deteriorate naturally.
- **Allergic reaction:** Rare, but possible if sensitive to implant materials.
- **Persistent or new pain:** Some patients may not achieve full relief or may develop new discomfort.
- **Need for further surgery:** A small number may require additional procedures due to complications.

Patients may not experience serious complications, but being informed helps you recognize issues early. Your surgical team take extensive control measures to minimize risks. Minor issues, such as temporary swallowing difficulty, usually resolve with conservative care. Rare complications like implant displacement or nerve injury may require further treatment or surgery. Your surgeon will explain risks specific to your health (e.g., diabetes or osteoporosis). Asking questions and following recovery instructions—like avoiding smoking and doing breathing exercises—can support a smoother recovery.

The Surgery: What to Expect

If you and your doctor decide that BAGUERA® C cervical disc replacement is the best option, it's helpful to know how the process will go. This section walks you through **what to expect before, during, and after the surgery.**

Before the Surgery – Preparation

In the weeks leading up to surgery, your healthcare team will prepare you:

Review your scans and health to confirm the surgical plan and ensure you're fit for anesthesia.



Discuss options and obtain consent, ensuring you understand the procedure and alternatives.



Adjust medications as needed (e.g., pause blood thinners) and review your full medication list.



Advise quitting smoking, as it can hinder healing.



Provide fasting instructions (usually no food or drink after midnight before surgery).



Help you plan logistics, including transportation and home setup for recovery.



Answer your questions about hospital stay, recovery time, and return to work.



By the day of surgery, you should feel as ready as possible, knowing what's ahead and having prepared your mind and environment for the recovery period.

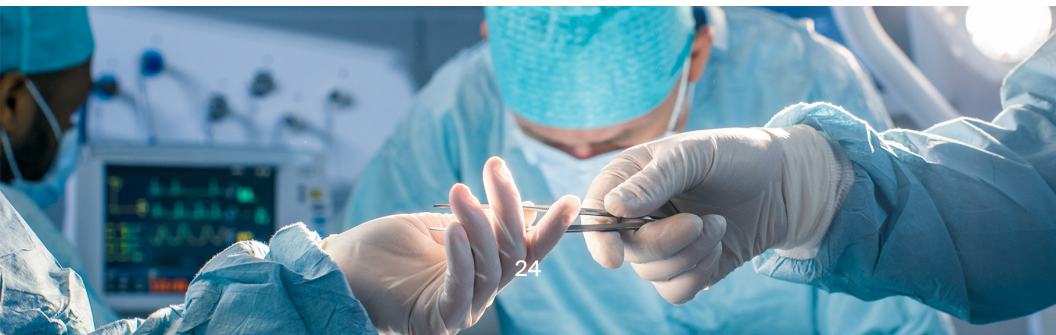
During the Surgery – Step by Step

Cervical artificial disc replacement surgery with BAGUERA® C will likely follow these general steps:

- 1 Anesthesia** You'll be put under general anesthesia and may have a breathing tube during surgery.
- 2 Incision** A small cut is made in the front of your neck to access the spine without disturbing back muscles.
- 3 Disc Removal** The damaged disc and any bone spurs are removed to relieve nerve pressure.
- 4 Trialing** The space is measured to choose the correct size BAGUERA® C implant.
- 5 Implant Insertion** The implant is placed between the vertebrae, restoring disc height and allowing motion. X-rays confirm proper placement.
- 6 Closure** The incision is closed with stitches or glue. A bandage is applied, and a drain may be used temporarily if needed.

The entire surgery for a single-level disc replacement can take around 1 to 2 hours, depending on complexity. It may be slightly longer for two levels.

You will then be moved to a recovery area where anesthesiology staff will wake you up and monitor you as you begin to recover from the anesthesia.



After the Surgery

Immediately after surgery, you will be in the recovery room (post-anesthesia care unit) for observation as you wake up. Nurses will check your vital signs (blood pressure, heart rate, breathing, temperature) and level of pain. You might feel groggy and have a sore throat (from both the incision and the breathing tube). It's common to feel neck soreness and some pain at the incision, but severe pain is usually managed with IV medications initially.

Once you are stable, you'll be moved to a regular room for the rest of your stay. **Most patients typically go home the same day or about one day after** a single-level cervical disc replacement. This is to ensure pain is under control and there are no immediate complications.

During your stay, expect the following:

- **Neck Collar:** If used, it's typically a soft collar for short-term comfort.
- **Eating:** Start with clear liquids, then progress to solids as tolerated. Swallowing may be mildly difficult at first.
- **Pain Management:** Pain is usually moderate and managed with IV and oral medications. Throat and muscle soreness are common.
- **Mobility:** Walking is encouraged soon after surgery to aid recovery and prevent clots—avoid heavy lifting or neck strain.
- **Drains/IV:** Any surgical drain is usually removed the next day; IVs stay until you can eat and take meds by mouth.
- **Monitoring:** Staff will check for complications like swelling, breathing issues, or nerve problems before discharge.

If everything looks good (which it does for the vast majority of patients), you will be cleared to go home, typically within 24 hours after surgery.

Before you are discharged, you'll receive important instructions for caring for yourself at home.



Going Home – Recovery and Care After Surgery

Recovery at home is a crucial phase of the healing process. Your surgical team will provide specific instructions, but here are common guidelines and what to expect:

- **Pain Management:** Prescription pain meds are used initially, then tapered to over-the-counter options as healing progresses.
- **Wound Care:** Keep the neck incision clean and dry. Follow instructions on showering and watch for signs of infection.
- **Collar Use:** A soft collar may be used briefly for comfort, depending on your surgeon's advice.
- **Activity Restrictions:** Avoid heavy lifting, strenuous activity, and prolonged neck strain. Gentle movement is encouraged. Don't drive until cleared and off narcotics.
- **Physical Therapy:** May begin a few weeks post-op to restore motion and strength.
- **Return to Work:** Desk jobs may resume in 1–2 weeks; physical jobs may take 6–8 weeks with medical clearance.
- **Follow-Up:** Attend all scheduled visits to monitor healing and implant position, including X-rays and long-term checkups.

It's normal to feel tired for a while; your body is healing. Each week you should notice improvement – perhaps a little more neck mobility, a little less pain, and returning strength. Nerve symptoms like numbness or weakness may take weeks or even months to fully recover as nerves heal slowly.



When to Contact Your Doctor

While recovering, be vigilant and know the warning signs for when to seek medical attention. Contact your doctor right away (don't wait for a scheduled visit) if you experience any of the following:

- **Fever over 101°F (38.5°C) or chills**
- **Redness, warmth, or unusual drainage** at the incision
- **Worsening swallowing or breathing issues**, or visible neck swelling
- **New or worsening neck/arm pain or numbness**
- **Sudden weakness** in arms or legs
- **Severe headache** that improves when lying down
- **Chest pain, shortness of breath, or leg pain/swelling**
call emergency services
- **Loss of bladder or bowel control**

In general, if something just “doesn't feel right” and you're concerned, it's better to call your surgeon's office and ask. They can determine if you should come in sooner or go to the ER. It's always better to err on the side of caution.



Expected Outcomes and Benefits of BAGUERA® C Disc Replacement

Most patients undergoing cervical disc replacement with BAGUERA® C can expect **significant improvement in their symptoms and a good functional recovery**. The intended benefits of the BAGUERA® C prosthesis and the surgery include:

- **Pain Relief:** Most patients experience significant reduction in arm and neck pain, often immediately after surgery.
- **Nerve Recovery:** Numbness or weakness in the arms or hands typically improves over weeks to months as nerves heal.
- **Restored Disc Height:** The implant restores spacing between vertebrae, improving alignment and relieving pressure.
- **Preserved Motion:** Unlike fusion, BAGUERA® C maintains natural neck movement, aiding daily activities like driving.
- **Less Stress on Nearby Discs:** By preserving motion, the implant may reduce degeneration of adjacent spinal levels over time.
- **High patient satisfaction:** Many cervical disc replacement patients report being satisfied with their surgeries and would have the surgery again for the same condition. Pain relief and restoration of function contribute to this.

It's also worth noting what **BAGUERA® C does not do**: it does not guarantee that you will never have neck issues again. It addresses the specific level and issue that was problematic. Other levels in your neck could still develop wear over time (as part of natural aging), though the hope is that preserving motion at one level will delay or minimize that. Maintaining a healthy lifestyle, good posture, and perhaps doing neck exercises (as taught in physical therapy) can help keep your cervical spine healthy overall.

Long-Term Outlook: The BAGUERA® C is designed to last a lifetime. There is **no set “expiration date”** for the implant. However, long-term follow-up (beyond 10-20 years) data is still being gathered since cervical disc replacements haven't been around as long as hip replacements for example. If, many years down the road, a problem arises (like significant wear or bone fusion), a secondary procedure might be considered, but many patients continue to do well decades later.

Discuss with your surgeon if you're interested in specific statistics or how your personal health might affect your outcome. They can provide the most relevant expectation for you.

Conclusion and Next Steps

The BAGUERA® C Cervical Disc Prosthesis offers a promising solution for people suffering from cervical disc degeneration who meet the criteria. It is designed to alleviate pain, restore nerve function, and preserve motion in the neck, thereby helping you return to your normal activities and improve your quality of life.

By replacing a diseased disc and maintaining movement, BAGUERA® C aims to combine the pain relief of traditional surgery with the benefit of ongoing flexibility. Many patients who undergo this surgery experience significant improvement and are able to get back to work, hobbies, and time with family without the constant distraction of pain or numbness.

However, it's important to remember a few final points:

- **Informed Decision:** Only you and your spine surgeon can decide if this surgery is the right choice for you. This guide provides general information, but **your doctor's advice tailored to your individual situation is paramount.** Feel comfortable seeking a second opinion if you desire – any reputable surgeon will support that.
- **This Guide is Educational:** While we aim to cover all key aspects of BAGUERA® C and the surgery, this guide is not a replacement for professional medical advice. It serves as a reference to help you understand and formulate questions. Always rely on consultations with your healthcare providers for medical decisions.

Important: If you have any **questions or uncertainties**, bring them up with your doctor. No question is too small when it comes to your health and peace of mind.

- **Adhere to Instructions:** If you proceed with the surgery, carefully **follow all the pre- and post-operative instructions** given by your care team. These instructions significantly contribute to a smooth recovery and optimal outcome.
- **Report Problems:** If you ever suspect a problem with your implant or your recovery, notify your doctor immediately. As mentioned, any serious incident related to a medical device like BAGUERA® C should also be reported to the manufacturer and regulatory bodies– your healthcare providers will facilitate this reporting.
- **Lifestyle and Prevention:** After recovery, take steps to maintain spine health – regular exercise, good neck posture (especially with computers and phones), and avoiding smoking all help prolong the benefits of your surgery and protect your spine.

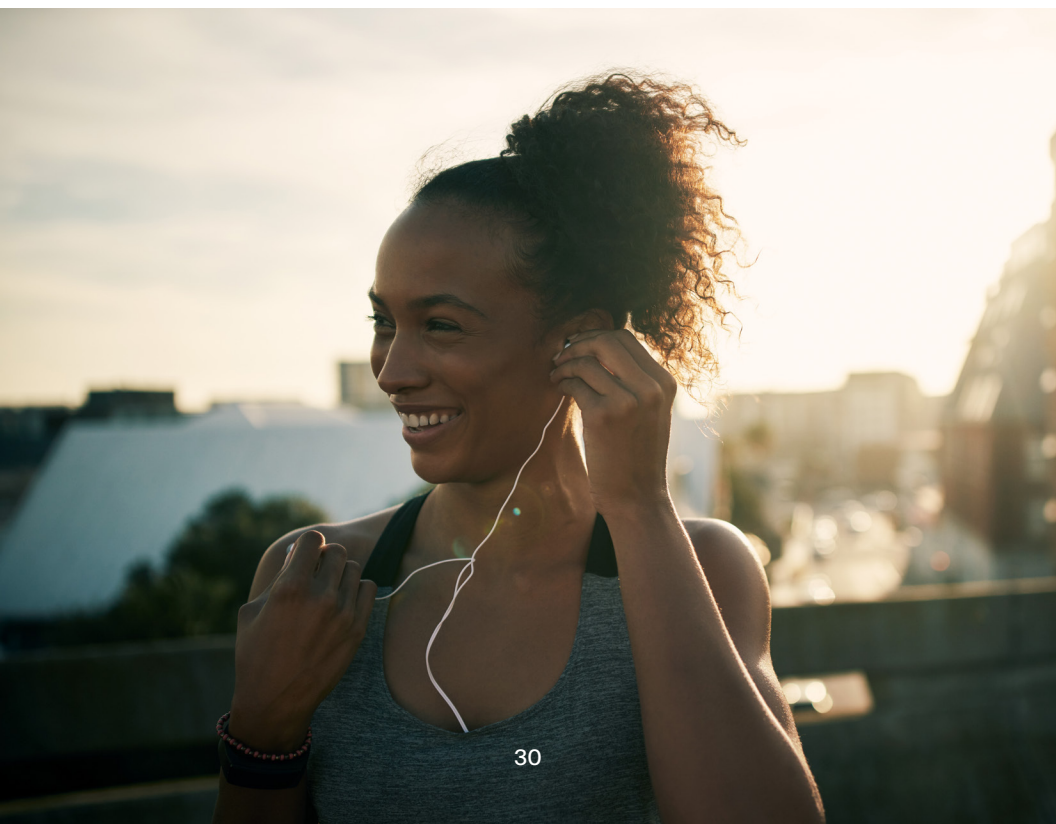
Many patients find it helpful to connect with others who have undergone similar surgeries, whether through a support group or an online forum. Hearing experiences (both challenges and successes) can provide realistic expectations and moral support. Ask your medical team if they know of any local support resources.

Finally, keep the **patient implant card** that you receive (with details like the implant's lot number and model) in a safe place, such as your wallet. This card is useful for:

- Informing other doctors or emergency personnel that you have an artificial disc.
- Airport security, if needed, to explain that you have metal in your body.
- Any future scans or medical procedures, to quickly convey what implant you have.

With knowledge, preparation, and the support of your surgical team, you are well-equipped to navigate the journey through cervical disc replacement surgery.

We wish you the best in your treatment and recovery.





[illegible]

[illegible]

Manufacturer Information and Getting More Help

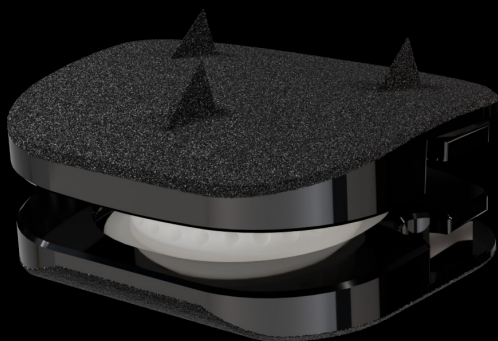
The BAGUERA® C Cervical Disc Prosthesis is manufactured by **Spineart SA**, a medical device company. If you need more information about the implant outside of what your doctor provides:

- **Legal Manufacturer:** Spineart SA, Chemin du Pré-Fleuri 3, 1228 Plan-les-Ouates, Switzerland.
- This patient information content is available from Spineart (e.g., via their website) for reference. Your surgeon may have given you a copy, or you can download it from the Spineart website or regulatory page.
- For any concerns or to report issues with the device, you or your healthcare provider can contact Spineart.

Always keep open communication with your healthcare providers.

They are your first resource for any questions about your condition or the BAGUERA® C device. If after reading this guide you have questions like “What is the exact level you will operate on?” or “How much improvement can I personally expect?”, note them down and discuss with your surgeon.

Your spine care team’s goal is the same as yours – **to reduce your pain and improve your function safely**. With the BAGUERA® C cervical disc prosthesis, you have a state-of-the-art option that has helped many patients with cervical disc disease. We hope this guide has given you a clearer understanding and confidence as you take the next steps towards a healthier neck and life.





SPINEART

MANUFACTURED BY:
SPINEART SA
CHEMIN DU PRE-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

DISTRIBUTED BY:
SPINEART USA INC
23332 MILL CREEK DR. SUITE 150
LAGUNA HILLS, CA 92653
USA

SEP-2025-REF-BAG-CE-PG-US