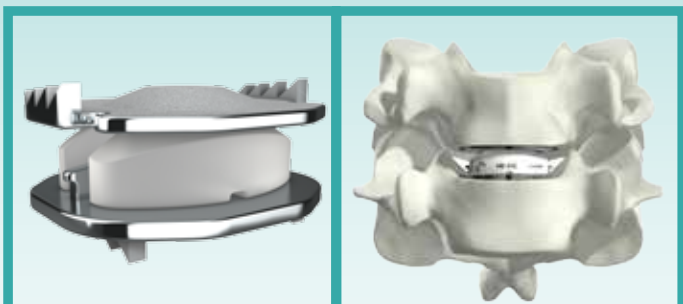


Mobi-C[®] Cervical Artificial Disc Patient Education





This patient education book explains:

- How the neck works.
- What happens when a cervical disc wears out.
- What are the risks and benefits of cervical artificial disc surgery.
- How the Mobi-C® Cervical Disc (Mobi-C) may help your arm pain and related problems.

Your doctor may have said that surgery using the Mobi-C could help reduce your arm pain and/or neurologic symptoms (such as weakness or numbness). This book will help answer questions on what to expect before, during, and after surgery.

Reading this book should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your neck or arm problems.

The Mobi-C has been used outside the United States since 2003 in thousands of cases. In 2013, the Mobi-C was approved for use in the United States by the Food and Drug Administration (FDA).

Table of Contents

Glossary	4
The healthy neck	6
Degenerative cervical spinal pathology.....	7
The Mobi-C Cervical Disc	8
Who <u>should</u> receive a Mobi-C?.....	10
Will my doctor recommend Mobi-C surgery for me ?...	11
Who should <u>not</u> receive a Mobi-C (contraindications)?	11
What are the:	
Warnings for using the Mobi-C?	12
Precautions for using the Mobi-C?	13
Potential risks and adverse effects for using the Mobi-C?	16
What are the benefits of surgery with the Mobi-C?	19
What are the expected outcomes and benefits of the Mobi-C?	20
Preparing for your Mobi-C surgery	22
What happens during Mobi-C surgery?	22
What happens after Mobi-C surgery?	23
How does surgery using the Mobi-C compare to fusion?	25
When should I call the doctor after surgery?	26
For more information on the Mobi-C	27

Glossary

annulus fibrosus - The outer protective ring of a spinal *disc*, which covers the soft center (*nucleus pulposus*). Made from strong rings of fibers.

ACDF - Anterior cervical discectomy and fusion (ACDF) is a fusion surgery where an unhealthy cervical disc is removed and replaced with bone or an implant. For more information see page 25.

artificial disc - A medical *implant* used to replace a worn out *disc*.

blood vessels - Flexible tubes that carry blood throughout the body.

cervical spine - Includes the first seven *vertebrae* of the spinal column (neck).

CT - Computerized tomography (CT) is *an x-ray* procedure that combines many images to create cross-sectional images (like slices) of the body.

degeneration - Deterioration of tissue which may include loss of function.

disc - Soft pad of cartilage between each *vertebrae* of the *spine*. The discs hold the *vertebrae* apart, act as cushions, and allow the *vertebrae* to move.

facet joint - *Joint* in the back (posterior part) of the *spine* that connect the *vertebrae* together.

fluoroscopy - An *x-ray* procedure used to take moving pictures of a body part.

Food and Drug Administration (FDA) - Part of the United States government. The FDA makes rules for companies that protect the patients who need medicine or medical *implants*. The FDA also helps decide which and how *implants* can be used.

fusion - When two bones grow together stopping movement.

heterotopic ossification - Unintended bone formation around or across the *disc* space between the *vertebrae*.

implant - A device that is put in the body to fix or take the place of a damaged body part.

incision - A cut in the skin made during *surgery*.

joint - Where two or more bones meet, normally to allow movement.

ligament - A short strip of strong, flexible *soft tissue* that connects two bones.

MRI - Magnetic Resonance Imaging (MRI) is a radiographic procedure that uses magnets to create cross-sectional images (like slices) of the body.

nerves - Fibers that move messages to and from the brain. Nerves control feeling and movement. Nerves connect the skin, organs, and *muscles* through the *spinal cord* to the brain.

nucleus pulposus - The soft center of a spinal *disc*.

osteopenia - A condition in which the bones are somewhat thin or weak, which may develop into *osteoporosis*.

osteoporosis - A condition in which the bones are thin or weak and become brittle and fragile.

physical therapy (PT) - Using exercise and massage to help regain movement.

skeletal muscle - A strong tissue that makes movement for the body.

soft tissue - Connects, supports, or surrounds the organs and other structures of the body.

spinal cord - Bundle of spinal *nerves*. The spinal cord starts at the bottom of the brain and runs to the lower back. The spinal cord moves messages between the brain and the body.

spine - The 33 *vertebrae* starting under the skull and ending in the small of the back. Grouped into three sections: *cervical* (upper), *thoracic* (middle), and *lumbar* (lower). Protects the *spinal cord* and provides body support.

surgery - An operation on the body to fix, remove, or replace diseased or injured tissue.

vertebrae - The bones that form the spinal column, with a hole for the *spinal cord* to pass through.

x-ray - A tool used by doctors to take a picture of a patient's bones.

The healthy neck

The neck (cervical spine) is made up of the bones (vertebrae), spinal cord, nerves, muscles, ligaments, and the system that carries blood (blood vessels).

The top seven vertebrae make up the cervical spine and begin at the base of the skull. The vertebrae of the cervical spine protect the spinal cord and support the skull. A disc between each vertebra helps to cushion the vertebrae from moving together with the load of the body.



Side-view of a cervical spine

Each disc has a strong outer ring (annulus fibrosus). The outer ring helps keep the disc's soft center (nucleus pulposus) in place. Disc problems can start from over-use, an accident, or just the wear and tear of every day life.



Healthy cervical spine

The vertebrae and the discs allow a healthy cervical spine to:

- Bend side-to-side (lateral bend) (Figure A).
- Bend forward-to-back (flexion and extension) (Figure B).
- Turn left-to-right (rotation) (Figure C).



Figure A



Figure B



Figure C

Degenerative cervical spinal pathology

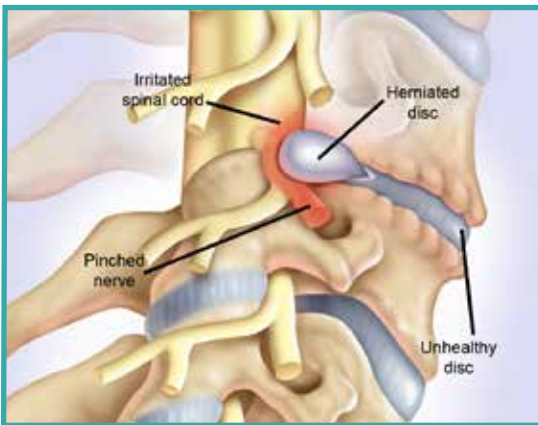


Side-view of a cervical spine showing progressive examples of disc degeneration

Degenerative cervical spinal pathology may result in a damaged disc that can cause pain.

When a disc degenerates, the disc:

- Loses water. With less water, the disc becomes thinner and has less padding to absorb movement. The disc may become less flexible.
- May have tiny tears or cracks in the outer layer (annulus fibrosus) of the disc.



Side-view of cervical vertebrae showing the effect of disc degeneration

Disc degeneration can cause the:

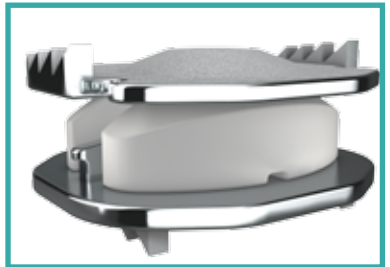
- Inner disc (nucleus pulposus) to squeeze through the outer disc (disc bulge or disc herniation).
- Spinal canal to narrow and pinch the cord and nerves (spinal canal stenosis).
- Spinal cord to be irritated causing a loss of feeling or movement (myelopathy).
- Nerve roots to be irritated or pinched causing pain, weakness, or tingling down the arm and possibly into the hands (radiculopathy).

The Mobi-C Cervical Disc

The Mobi-C is an artificial disc for the neck. The Mobi-C has three parts: two metal plates and a plastic insert in the middle.

The plates are made of a mix of metals commonly used in spine surgery (cobalt, chromium, and molybdenum). The plates have teeth on the top and bottom that help hold the plates to the vertebrae. The teeth are pressed into the bone with no bone cut out, which makes the Mobi-C design and technique bone sparing.

The outside of the plates are sprayed with a coating (hydroxyapatite). This coating helps the vertebrae to grow and attach to the metal plates for long term stability.



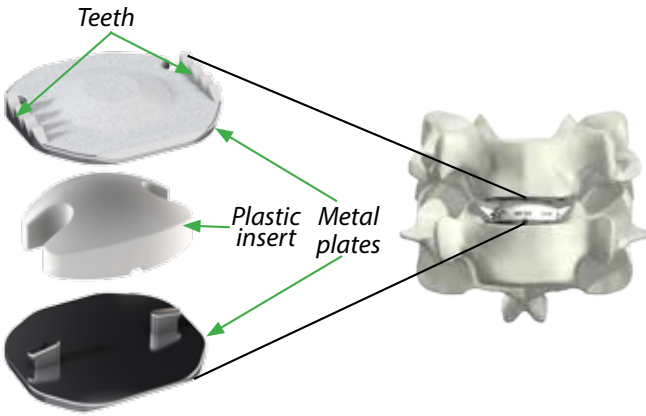
Mobi-C

The plastic insert is made from polyethylene. The insert is flat on the bottom and round on the top. The insert is made to move as you move your neck.

The Mobi-C comes in many different sizes. Your doctor will choose the size that best fits your disc.



How does the Mobi-C move?



The top plate moves over the insert. The insert slides across and twists over the bottom plate.

The muscles and soft tissue in your neck move the vertebrae and the attached Mobi-C plates. With vertebrae and muscle movement, the Mobi-C is free to twist and slide left-to-right and front-to-back. This allows the vertebra above and below the Mobi-C to move.



Side view of a cervical spine showing the Mobi-C in flexion and extension



Front view of a cervical spine showing the Mobi-C lateral bending

Who should receive a Mobi-C?

The Mobi-C Cervical Disc:

- **Is for adults;** the vertebrae must be mature (age range, 21-67 years).
- **Takes the place of one damaged cervical disc** from levels C3-C7.
- **Is for patients with arm pain and/or neurological symptoms** such as weakness or numbness with or without neck pain. The damaged disc may be irritating the:
 - Spinal cord (myelopathy) or nerve roots (radiculopathy). This can cause a loss of feeling, loss of movement, pain, weakness, or tingling down the arm and possibly into the hands.
- **Disc damage needs to be proven** by your doctor's review of your CT, MRI, or X-ray images. Images of the neck should show at least one of the following:
 - Inner disc squeezing through the outer disc (herniated nucleus pulposus).
 - Degeneration of the spine from wear and tear (spondylosis). There may be boney growth (osteophytes) on a vertebra.
 - Loss of disc height compared to the levels above and below.
- **Is for people who have not responded to non-surgical care.** Patient should either have:
 - Tried at least six weeks of other medical treatments such as physical therapy and medicine before having surgery; or
 - Have signs or symptoms that their condition is getting worse even with other medical treatments.



Will my doctor recommend Mobi-C surgery for me?

Non-surgical treatment, such as physical therapy, injections, and possibly a neck brace, will be prescribed first by your doctor. If these treatments do not relieve your pain or dysfunction, you and your doctor may determine that you are a candidate for artificial disc replacement.

Talk to your doctor about the risks and benefits of surgery using the Mobi-C to treat your condition. Surgery with the Mobi-C may help stop your pain and other problems from a damaged cervical disc.

Who should not receive a Mobi-C (contraindications)?

If you have any of the following, you should **NOT** have surgery with the Mobi-C:

- An active **whole body (systemic) infection**, such as pneumonia.
- An **infection at the surgery site**, such as a skin rash or infected cut.
- A known **allergy to what Mobi-C is made of**: cobalt, chromium, molybdenum, titanium, hydroxyapatite, polyethylene, and other trace elements. Talk to your doctor if you have a metal allergy.
- **Damaged cervical vertebrae** from an accident (trauma) at the level of the surgery.
- An **unhealthy shape (deformity) of the cervical vertebrae** at the level of the surgery. Deformity could be caused by an inflammatory disease where the vertebrae swell or grow together and limit movement, such as ankylosing spondylitis and rheumatoid arthritis.
- **A cervical spine that shows an unhealthy amount of extra movement** (instability). This can be measured by X-rays taken from your side when the spine is still and bending.
- **Low bone mineral density**, such as osteoporosis or osteopenia (defined as a DEXA bone mineral density T-score < -1.5). This condition could increase the risk of bone breaking or cause the implant to loosen.
- Severe **disease or degeneration in the joints in the back of the cervical vertebrae** (facet joints).

What are the warnings for using the Mobi-C?

Take time to understand the possible dangers from artificial disc surgery. Talk to your doctor about the **possible dangers and complications of Mobi-C surgery**.

Possible danger

Implanting an artificial disc in the neck is serious surgery. There are blood vessels and nerves very close to where the implant enters the body. Your doctor will take care to find and protect the blood vessels and nerves.

Consequence

- A small cut to a blood vessel could **cause a dangerous loss of blood** (hemorrhage) or even death.
- Damage to a nerve can cause **long-term loss of movement (paralysis) or feeling**.

Possible complication

As with any artificial disc surgery, there are steps your doctor should take to make the surgery safe. **The Mobi-C should only be used by doctors**, who:

- Are skilled in neck surgery.
- Are trained in the proper use of Mobi-C, how it works, and how to choose the correct size Mobi-C.
- Understand the risks and complications of disc surgery.

Consequence

If your doctor does not have quality experience or training, there could be a higher chance of problems from surgery,

Possible complication

Bone tissue could form outside the vertebrae (heterotopic ossification (HO)). HO can happen after artificial cervical disc surgery and causes less cervical motion.

Consequence

If HO forms, it has not been shown to cause harmful results in Mobi-C patients.

What are the precautions for using the Mobi-C?

The safety and effectiveness of the Mobi-C has not been tested in patient with the following conditions:

- The young (younger than 21) and the elderly (older than 67).
- Previous cervical spine surgery, including a repeat surgery at the same level.
- More than one cervical spine level that is damaged or stopped moving that needs surgery.
- Short disc height, defined as a disc height less than:
 - 3mm measured from the center of the disc.
 - One-fifth of the front-to-back measurement of the lower vertebra.
- An unhealthy curving of the cervical spine (kyphosis or reversal of lordosis).
- Active cancer (malignancy).
- Diseases of the bone caused by low mineral levels or genetic problems (Paget's disease, osteomalacia, or other metabolic bone diseases).
- Taking medicine that is known to get in the way of bone or soft tissue healing, such as steroids.
- Pregnancy.
- Diabetes that needs medicine (insulin) given every day.
- Very overweight (obese) (based on the NIH Clinical Guidelines Body Mass Index (BMI greater than 40)).
- Neck or arm pain from an unknown source.

What are the precautions for using the Mobi-C? (continued...)

The safety and effectiveness of the Mobi-C has not been tested in patients with the following conditions (continued):

- Whole body (systemic) diseases, including AIDS, HIV, and hepatitis.
- Findings which suggest an irritated nerve root (radiculopathy) or spinal cord (myelopathy) where there is a poor match between the image findings (CT, MRI, or X-ray) and the physical examination.
- A previous fusion at a level above or below the surgery level.
- Only neck pain with no arm pain.
- Diseases that cause the vertebrae to swell or grow together and limit movement, such as rheumatoid arthritis or other autoimmune diseases.
- Diseases that affect muscle movement because of problems with the nerves or muscles (neuromuscular disorders). Disease examples include: muscular dystrophy, spinal muscular atrophy, and amyotrophic lateral sclerosis.
- Serious mental illness or drug abuse.

Before surgery

Your medical history is very important in your doctor's decision to choose the Mobi-C for you. Before recommending the Mobi-C, your doctor will take into account your past and present health, such as:

- Your job and activity level.
- Past injury or ongoing illness.
- Alcoholism or drug abuse.
- Medicine use.
- Previous treatments.

You may be asked questions to help decide if you have a risk of low bone mineral density. Based on your answers, your doctor may order a bone test (DEXA measurement). The Mobi-C has not been tested in patients with a DEXA T score less than -1.5. This level of DEXA score shows the patient may be osteoporotic or osteopenic.

Your doctor will choose the best Mobi-C size for your body. A correctly sized Mobi-C helps the implant stay in place and work right. Your doctor should not start surgery without the right implant size or instruments in good working order.

Ask your doctor to see the full list of risks and complications in the insert.

During surgery

Your doctor will keep the Mobi-C clean (sterile) and undamaged.

After surgery

Take care to follow your doctor's directions. Right after surgery, you should not:

- Do any heavy lifting.
- Bend your neck multiple times.
- Do any long or difficult activity. You may need to limit activity for weeks to months depending on your level of healing.

What are the potential risks and adverse effects for using the Mobi-C?

Complications may occur when you are treated with the Mobi-C, as with any surgery. Possible complications may include, but are not limited to the following.

Risks from any surgery:

- Problems with the wound healing including pain.
- An allergic attack or infection.
- Problems with the heart (cardiovascular) or blood movement (circulation). This could include: loss of blood, a reaction to a blood transfusion, problems with circulation, or problems with blood forming into clumps (clotting).
- A sickness to the drugs used to put you asleep during surgery (anesthesia).
- Problems with the stomach and intestines (gastrointestinal).
- Problems with the urinary or genital systems (urogenital).
- Problems breathing (respiratory). Respiratory problems could include: lung infection (pneumonia), lung tissue collapsing (atelectasis), or swelling in the neck (edema).
- In rare situations, heart attack, stroke, or death.

Risks from anterior cervical spine surgery:

- Damage, infection, swelling, and problems healing at or anywhere near the surgery site. This could affect, for example, the blood vessels, nerves, spinal cord, trachea, esophagus, disc, vertebrae, and skin.
- Neck and/or arm pain.
- Headaches: weak to strong.
- Pain or damage to the organ that allows you to talk (dysphonia).
- Pain or damage to the muscles that allow swallowing (dysphagia).
- Problems with feeling, movement, or response time (neurological issues) in the upper arm, neck, back, leg, or other area.
- In rare situations, loss of movement (paralysis).

Risks specific to cervical artificial discs including the Mobi-C:

- Less neck movement than before surgery due to:
 - Stiff ligaments (spinal ligament ossification).
 - An overgrowth of bone (heterotopic calcification) at the surgery level.
 - Vertebrae fusing together.
- The implant breaking, moving, or wearing.
- Needing additional neck surgery after disc replacement.
- The development of a recurrent spinal problem at the surgery level, as well as the development of a new spinal problem above or below the treated spinal level.

There is also the risk that the surgery may not be effective in relieving your symptoms or may cause worsening of your symptoms. If this occurs, you may need another surgery in order to help you feel better.

What are the potential risks and adverse effects for using the Mobi-C? (continued...)

Adverse effects

Throughout the Food and Drug Administration (FDA) clinical study, patients reported health related problems to their doctors. Some of the events listed on the previous page occurred in the FDA study. Some of the more common study events for the Mobi-C and the Anterior Cervical Discectomy and Fusion (ACDF) patients include:

- Neck pain in 41.3% of Mobi-C (74 out of 179 patients) and 45.7% of ACDF (37 out of 81 patients).
- Arm (extremity) pain in 25.7% of Mobi-C (46 out of 179 patients) and 24.7% of ACDF (20 out of 81 patients).
- Back pain in 24.6% of Mobi-C (44 out of 179 patients) and 22.2% of ACDF (18 out of 81 patients).
- Shoulder pain in 21.8% of Mobi-C (39 out of 179 patients) and 25.9% of ACDF (21 out of 81 patients).
- The feeling of pins and needles in the arms (sensory disturbance) in 37.4% of Mobi-C (67 out of 179 patients) and 39.5% of ACDF (32 out of 81 patients).
- Headache in 25.1% of Mobi-C (45 out of 179 patients) and 32.1% of ACDF (26 out of 81 patients).
- Difficulty swallowing (dysphagia) in 10.6% (19 out of 179 patients) and 18.5% of ACDF (15 out of 81 patients).

Two patients (1.2%) treated with Mobi-C and five patients (6.2%) treated with ACDF had additional surgery at the same level within 2 years after their surgery. One patient (0.6%) treated with Mobi-C and three patients (3.7%) treated with ACDF, had surgery at an adjacent level within 2 years after surgery. **No mechanical failures of the Mobi-C device were observed in any study patients.**

A comprehensive list of risks is provided in the package insert for the device, which your doctor has received. **Please ask your doctor for more information about any additional risks that could be related to your planned surgery.**

What are the benefits of surgery with the Mobi-C?

This patient brochure describes many possible problems. These facts are given to help you make the right choice about artificial disc surgery.

There are good reasons, however, to choose an artificial disc. The Mobi-C may help end or lessen your pain and discomfort.

The surgery with Mobi-C:

- Will replace your worn out disc.
- May help keep neck movement:
 - Bending forward-to-back.
 - Bending side-to-side.
 - Turning left-to-right.
- Matches disc height to the levels above and below. This can help un-trap nerves.
- May lessen your neck and/or arm pain.
- May lessen any arm tingling.
- May help you return to your normal life of work, family, and fun.



What are the expected outcomes and benefits of Mobi-C?

In order to be used in the United States, the Mobi-C went through major testing and review with the Food and Drug Administration (FDA). In the US study, 179 patients were treated with Mobi-C and 81 patients were treated with ACDF (anterior cervical discectomy and fusion). Some of the study results at two years after surgery are described below. The clinical benefit beyond two years has not been measured. Ask your doctor for more details about the clinical study and its results.

Two years after surgery, 115 out of 156 Mobi-C patients (73.7%) achieved overall study success, compared to 49 out of 75 ACDF patients (65.3%). This shows that Mobi-C achieved similar outcomes to ACDF.

Other key results from the study at two years after surgery include:

- Of Mobi-C patients, 130 out of 155 (83.9%) had four or more degrees of motion while bending the head forward to backward (flexion-extension). Additionally, 106 of 155 Mobi-C patients (68.3%) had either the same or more motion in flexion-extension at two years as before they were treated.
- The rate of major complications was lower for Mobi-C patients (13 out of 164 (7.9%)) compared to ACDF patients (12 out of 81 (14.8%)). Major complications included: diminished neurologic status, spontaneous fusion in the Mobi-C group or failure to fuse in the ACDF group, and adverse events determined to be major complications and related to the study device.
- Another surgery at the treated level was needed for 5 out of 81 ACDF patients (6.2%), compared to 2 out of 164 Mobi-C patients (1.2%); **a rate five times higher for ACDF patients.**
- Of the Mobi-C patients, 151 out of 154 (98.1%) had the same or improved neurologic status, compared to 68 out of 70 ACDF patients (97.1%).

At two years 123 out of 155 Mobi-C patients (79.4%) demonstrated meaningful improvement in an outcome measure designed to evaluate patient function known as the NDI (Neck Disability Index), compared to 54 out of 70 ACDF patients (77.1%). Importantly, NDI scores are higher at early time points for Mobi-C patients compared to ACDF.

The patients in this study will continue to be followed for 7 years after surgery.



Preparing for your Mobi-C surgery

Follow your doctor's directions when getting ready for your surgery. Here is a list with examples of things to-do before surgery. Your doctor's directions may be different:

- Check that the medicine(s) you are taking will still be OK to take after having surgery on your neck.
- Take time before going to the hospital to arrange your life for after surgery:
 - Move anything you use a lot to an easy to reach spot.
 - Arrange to have family or friends around to help you.
- You will likely to be told not to eat or drink the night before the surgery.
- Ask your doctor to tell you what to expect from this surgery.

What happens during Mobi-C surgery?

In the operating room:

- You will lie on your back on a table and be put into deep sleep (anesthesia). Once asleep, your neck area is washed. A clean (sterile) sheet is taped around your neck.
- A cut (incision) is made on your neck. Your doctor will move the muscles, the airway (trachea), the esophagus, and blood vessels to the side. This makes a tunnel to the spine.
- Using a special X-ray (fluoroscopy), your doctor will pass a thin needle into the damaged disc to check the level for surgery.
- Your doctor will remove the damaged disc and put in the Mobi-C. Fluoroscopy may be taken during surgery to check Mobi-C placement.
- The muscle and skin incisions will be sewn together with surgical thread (sutures). A small bandage or biologic glue will be placed across the incision.
- While asleep, you will be moved to a new area (Recovery Room). Nurses will check your blood pressure, heart rate, and breathing. If you are in pain, you may be given medicine. Once awake, you will be moved to a different room.

What happens after Mobi-C surgery?

Ask your doctor to describe how you will feel and what you will need to do after surgery. Replacing your disc with the Mobi-C is a major surgery. Getting better will take time. How fast you get better depends on your age, your general health, and the reason for the surgery. **Your doctor may recommend exercise with the help of a physical therapist. As with any surgery, it is extremely important to follow your doctor's direction after surgery.**

Here are some examples of directions to follow after surgery. Your doctor's directions may be different.

- Stay one night in the hospital.
- Sit, stand, and walk the night after surgery.
- Wear a neck collar to lessen neck movement for around a week after the surgery.
- Take medicine (by mouth) for pain or sickness of the stomach (nausea) as needed.
- Put a new, clean bandage on the cut five days after surgery. The doctor or nurse may show you how to change the bandage.
- Set up a time to visit your doctor to check your healing. Your doctor may take X-rays to look at the Mobi-C placement in your neck.
- Get direction from your doctor on when it is OK to return to your normal neck bending and turning. Talk to your doctor about a physical therapy plan.

What will my surgery cut (incision) look like?

The cut will likely be a short incision in the front (anterior) part of the neck. The doctor normally makes the cut in a line you already have in the skin on your neck. The cut generally heals so that it is difficult to see.

What happens after Mobi-C surgery? (continued...)

When can I shower after Mobi-C surgery?

You will need to keep your incision dry immediately after surgery. Some doctors allow early showering. Patients normally take baths for 1-2 weeks after surgery. Get direction from your doctor on when it is OK to start showering.

When can I drive after Mobi-C surgery?

Ask your doctor when you can start driving after surgery. The timing varies from patient to patient.

Will my Mobi-C affect travel through airport security?

It is very unlikely that the metal in the Mobi-C will set off airport security detectors. However, the Transportation Security Administration (TSA) rules state, "TSA Security Officers will need to resolve all alarms associated with metal implants."



How does surgery using the Mobi-C compare to fusion?

Before artificial discs, most often a patient would get an anterior cervical discectomy and fusion (ACDF). In this fusion surgery, the doctor removes the unhealthy disc. The empty disc space is filled with a bone spacer or plastic implant. The implant helps match the disc height to the levels above and below. Restoring the disc height can help remove pressure on the nerves and/or spinal cord.

Then, a metal plate with screws is placed on the front of the neck. The plate helps:

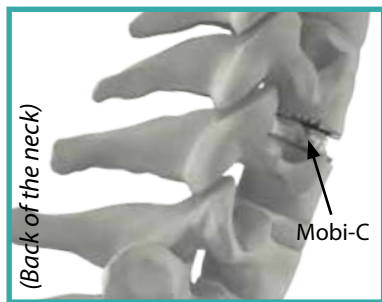
- Keep the spacer in place.
- Stop movement at that level. This helps new bone grow between the vertebrae (fusion).

Both a fusion and Mobi-C artificial disc surgery:

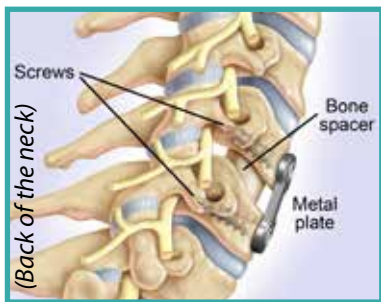
- Replace the damaged disc.
- Try to match a healthy disc height to help un-trap any nerves.

Only the Mobi-C implant:

- Tries to maintain neck movement.
- Fits entirely within the disc space.



Mobi-C



Fusion

When should I call the doctor after surgery?

Ask your doctor to describe how you will feel after surgery. Some pain and discomfort is normal. The problems you had before surgery may not lessen right away. Talk to your doctor about **when to call with problems after surgery**.

If you have any of these problems at any point after surgery, call your doctor.

- Signs that your cut (incision) may not be healing (infection):
 - The incision is draining. Although, you can expect some wetness.
 - The skin around the incision becomes red, warm, swollen, or increasingly painful.
 - You have a fever.
- Pain or problems with swallowing (dysphagia), talking (dysphonia), or breathing. It is common to experience some mild, temporary discomfort with swallowing.
- More tingling, numbness, pain, or weakness in the arms or neck than you had before surgery.

For more information on the Mobi-C

www.ldrmedical.com

www.cervicaldisc.com

LDR USA

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Indications:

The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level 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 Mobi-C® Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis.

Reading this book should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your neck or arm problems.

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