i=FACTOR™
Peptide Enhanced Bone Graft

PATIENT INFORMATION BROCHURE

CERAPEDICS
Enhancing the Science of Bone Repair

PATIENT INFORMATION BROCHURE

This brochure is designed to help you make an informed decision about your surgery. Please read this entire document carefully. Keep this document because you may want to read it again. If you have additional questions, talk to your doctor. Only your doctor can determine the types of treatment that may be appropriate for you. Please speak to your doctor about using this procedure, and about individualized recommendations for you.

TABLE OF CONTENTS

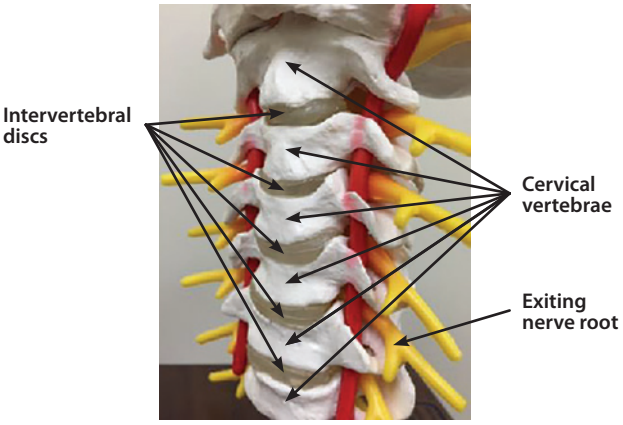
GLOSSARY

Allograft bone
Bone that is taken from another person. Also called 'banked bone'.

Anorganic bone mineral (ABM)
Structural component of i-FACTOR™ Peptide Enhanced Bone Graft. ABM is a mineral component manufactured to leave only the non-living (inorganic) material, eliminating the potential for disease transmission.

Autologous bone graft (autograft)
Bone that is taken from one part of your body and placed into a different part of your body to promote bone healing.

Cervical (spine)
Includes the first seven vertebrae of the spinal column (neck).



Model of the cervical spine

Degenerative disc disease (DDD)
A term used to describe degenerative changes in the intervertebral disc(s) due to aging and wear-and-tear, which may result in chronic pain and restricted movement.

Fusion
When two bones grow together to stop movement.

GLOSSARY

Incision
A cut in the skin made during surgery.

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.

Nerve roots
Bundles of nerve fibers extending out from the spinal cord.

Ring allograft (structural)
A ring-shaped bone graft that holds i-FACTOR™ Bone Graft in place in the disc space.

Physical therapy
Using exercise and massage to help regain movement.

Spinal cord
Bundles 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.

Spinal disc
Soft pad of cartilage between each vertebra of the spine. The discs hold the vertebrae apart, act as a cushion, and allow the vertebrae to move.

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

PATIENT DIAGNOSIS

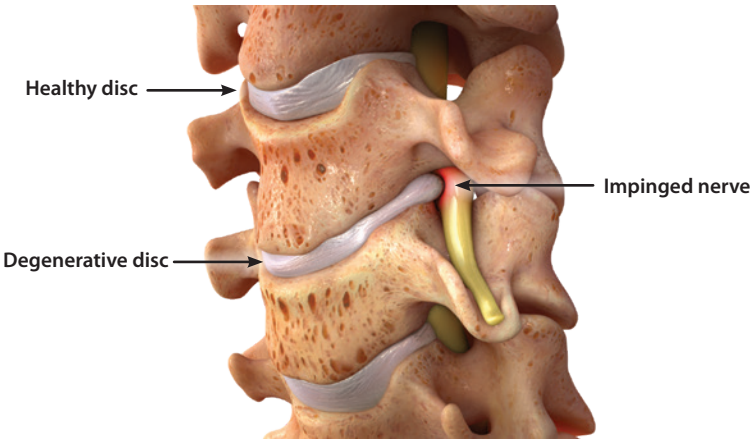
You have been given this brochure because you have been diagnosed with cervical degenerative disc disease (DDD) and have not responded to at least six weeks of non-operative treatment. Your doctor has determined that you should have a region of your cervical spine fused and that you may benefit from the use of i-FACTOR™ Bone Graft as part of this procedure.

WHAT IS CERVICAL DEGENERATIVE DISC DISEASE?

The bone segments in your spine are separated and cushioned by 'spinal discs'. These discs are what make your spine flexible, allowing it to bend. The term degenerative disc disease (DDD) refers to changes in spinal discs that occur in most people as they age. DDD can occur at different locations in your spine, and sometimes results in pain or difficulty with daily activities that may be treated with surgery.

WHY DOES CERVICAL DDD NEED TO BE TREATED?

Cervical DDD can cause nerve roots to become irritated or pinched, causing pain, weakness, or tingling down the arm and possibly into the hands. DDD also can irritate the spinal cord causing a loss of feeling or movement. DDD may have an impact on your ability to conduct daily functions.



HOW CAN CERVICAL DDD BE TREATED?

There are several options for treating cervical DDD. Physical therapy is a non-surgical option. Several surgical options also exist. The first type of surgery involves removing the damaged spinal disc and filling its space with bone graft. The goal of this surgery is to fuse the two bones that surround the disc to prevent them from moving and pressing against your nerve roots or spinal cord. Another surgical option is to remove the damaged spinal disc and replace it with a disc replacement implant. The goal of this surgery is to try and maintain motion at that region of your neck.

You have not responded to at least six weeks of physical therapy and your doctor has determined that the most appropriate treatment for you is fusion surgery.

HOW IS i-FACTOR™ PEPTIDE ENHANCED BONE GRAFT USED IN THE TREATMENT OF DDD?

In the surgical procedure, your physician will remove the degenerated disc that is causing pain. After removing the disc, your physician will place an allograft ring containing i-FACTOR™ Bone Graft (to keep i-FACTOR™ Bone Graft in place) in the disc space to help promote fusion of the cervical spine. After i-FACTOR™ Bone Graft and the allograft ring are in place, your doctor will use screws to connect a metal plate to the two bones that surround your damaged disc. This will hold them still while the bones are fusing.

WHAT IS i-FACTOR™ PEPTIDE ENHANCED BONE GRAFT MADE OF?

The main ingredients of i-FACTOR™ Bone Graft are a synthetic version of a naturally occurring protein segment found in everyone's body called P-15, and calcium phosphate particles called 'anorganic bone mineral' or ABM. The calcium phosphate provides a structure for new bone growth and i-FACTOR™ Bone Graft encourages cells to attach to the structure as the bones in the damaged part of your neck fuse. These materials are suspended in a gel carrier that aids in the placement and containment of i-FACTOR™ Bone Graft at the treatment site.

Below are images of i-FACTOR™ Bone Graft and how it is placed inside the allograft ring:

WHO SHOULD NOT RECEIVE i-FACTOR™ BONE GRAFT (CONTRAINDICATIONS)?

i-FACTOR™ Bone Graft should not be used if:

- You are hypersensitive to any of the i-FACTOR™ Bone Graft ingredients such as the synthetic P-15 protein segment
- You have an infection near the area of the surgical site or a systemic infection
- Your neck area near the surgical site is subject to a great deal of impact or stress
- You do not have enough load-bearing structural support in your neck near the area where you are to be treated
- You have any bone disorders that may affect bone healing or wound healing
- Your kidneys do not function normally

You should speak to your doctor to determine if the above conditions apply to you or if other conditions may make you ineligible to use i-FACTOR™ Bone Graft.

WHAT ARE SOME WARNINGS FOR USING i-FACTOR™ BONE GRAFT?

i-FACTOR™ Bone Graft has not been tested in pregnant women or nursing mothers.

If you are a woman of child-bearing potential, you should wait at least one year after getting i-FACTOR™ Bone Graft before trying to get pregnant.

If you have significant blood vessel damage, there is a greater risk that cervical fusion using i-FACTOR™ Bone Graft may not be successful.

WHAT ARE SOME PRECAUTIONS FOR USING i-FACTOR™ BONE GRAFT?

i-FACTOR™ Bone Graft should only be used by doctors who are trained in using it and have experience performing cervical spine fusion.

i-FACTOR™ Bone Graft has not been tested in patients with bleeding disorders.

i-FACTOR™ Bone Graft has not been tested in patients who have had immunosuppressive therapy, high-dosage radiation therapy, or long-term steroidal therapy.

i-FACTOR™ Bone Graft has not been tested in patients who have liver (hepatic) or kidney (renal) disorders.

i-FACTOR™ Bone Graft has not been tested in patients with metabolic bone disease. Metabolic bone diseases are disorders of bone strength, usually caused by abnormalities of minerals (such as calcium or phosphorus), vitamin D, bone mass or bone structure. The most common include osteoporosis, osteomalacia, and Paget's disease.

The potential for the use of i-FACTOR™ Bone Graft to result in an immune response (allergic reaction) has not been established. Immune responses have not been observed in studies using i-FACTOR™ Bone Graft in animals (sheep) and in humans.

WHAT ARE POTENTIAL COMPLICATIONS OR SIDE EFFECTS I SHOULD BE AWARE OF?

As with any surgery, spine surgery of the neck is not without some risks. Various complications arising out of the surgery or the use of i-FACTOR™ Bone Graft may occur. Some complications may be severe, affecting the overall outcome of surgery. It is possible that the surgery may not be effective in relieving your symptoms or may cause worsening of your symptoms. Sometimes you may need additional surgery to correct complications or in order to help you feel better.

Some of the possible complications include:

- Side effects from anesthesia or the surgical approach, including difficulty swallowing or hoarseness
- Bleeding, which may require a blood transfusion
- Wound complications, including infection, drainage, collection of blood at the surgical site
- Scar formation or other problems with the surgical incision
- Movement of i-FACTOR™ Bone Graft from where it is placed, as is possible with any bone graft, which may result in pain, decrease or loss in physical functioning, and may require additional surgery
- Failure of the bones of the cervical spine to fuse
- Temporary increase in calcium levels which may cause muscle weakness
- Difficulty swallowing, partial or complete vocal cord paralysis (hoarseness)
- Degeneration of the bones of the cervical spine next to the treated level
- Allergic reactions to the ingredients of i-FACTOR™ Bone Graft
- Pain or discomfort in the neck, arms, and/or shoulders
- Damage to tissues or nerves near the surgical site
- Abnormal bone formation in an unintended location
- Excessive or incomplete bone formation
- Mild to severe swelling
- Arthritis or other disorders in bone formation
- Breathing (respiratory) problems
- Kidney (renal) problems
- Nervous system problems
- In rare situations, heart attack, stroke, or death

Please speak to your doctor if you have any questions about possible complications, or think you may be experiencing any of the above.

WHAT WILL HAPPEN DURING SURGERY?

Prior to the surgery, your doctor will instruct you of any special care or instructions to follow the day before the operation. This procedure is usually completed in one day. Your doctor will give you specific information about your individual procedure and recovery plan. When you get to the hospital, your doctor will explain the relevant procedures to you. During surgery, an incision is made in your neck at the area of the damaged disc, and the damaged disc will be removed.

Your physician will prepare an allograft ring with i-FACTOR™ Bone Graft in place, and this will be positioned into your spine. A metal plate will then be attached with screws to the bones to help keep this part of your neck from moving while the bones fuse.

WHAT CAN I EXPECT AFTER SURGERY?

Your doctor will provide you with specific recovery procedures that you should follow. Following these steps will help ensure your chances of a successful surgery. Be sure to ask your doctor if you have any questions regarding whether certain activities are permissible after surgery, as these directions will vary for each individual.

Contact your doctor immediately if:

- you get a fever
- you do not feel well after your surgery
- you experience pain
- you experience tenderness or swelling of the skin or surgery site
- you experience itching, redness, or drainage at surgery site
- you experience nausea and vomiting
- you have problems with swallowing (dysphagia), talking (dysphonia), or breathing
- you have more tingling, numbness, pain, or weakness in the arms or neck than you had before surgery
- you experience anything else that is making you feel unwell even if it is not on this list

ARE THERE CLINICAL DATA FOR i-FACTOR™ BONE GRAFT?

The safety and effectiveness of i-FACTOR™ Bone Graft has been tested in a total of 319 patients undergoing cervical spine fusion surgery in 22 different locations including 3 in Canada. Patients were divided into two groups: a Treatment group that received i-FACTOR™ Bone Graft (165 patients), and a Control group that received their own bone (154 patients). The key study results were assessed at 12 months after surgery and almost all patients have been followed at least 24 months after surgery. Many patients have been followed for 5 years after surgery.

The patients who received i-FACTOR™ Bone Graft experienced equal success rates to those patients receiving the standard surgical treatment. The standard treatment used an allograft ring filled with autograft taken from the area of the damaged disc. Both groups experienced similar decreases in pain and improvement in ability to function compared to their condition before surgery. The great majority of patients in both groups (close to 90%) achieved fusion of the bones of the cervical spine by one year after surgery.

In the clinical study, 69% of i-FACTOR™ Bone Graft patients and 57% of the Control patients achieved 'overall success', which required all four of the following:

- fusion of the bones of the cervical spine;
- improvement in their pain and function compared to before the surgery;
- no decrease in their neurological status;
- no serious adverse events (complications) related to the device or re-operation.

The difference in overall success rate was significantly higher in the i-FACTOR™ Bone Graft group compared to the Control group.

Complications were observed with both the Control and i-FACTOR™ Bone Graft groups. However, patients receiving i-FACTOR™ Bone Graft did not experience complications that were different or more frequent than the patients in the Control group.

You should ask your doctor about the potential complications associated with your individual procedure.

ARE THERE ALTERNATIVES TO USING i-FACTOR™ BONE GRAFT?

Surgery will likely be recommended by your doctor if other non-operative methods have not been successful at reducing your pain. You may wish to ask your doctor about other exercises, physical therapy, or medications that might help improve pain as alternatives to surgery. Several other surgical options also exist.

The first type of surgery involves removing the damaged spinal disc and filling its space with bone graft. The goal of this surgery is to fuse the two bones that surround the disc to prevent them from moving and pressing against your nerve roots or spinal cord. Another surgical option is to remove the damaged spinal disc and replace it with a disc replacement implant. The goal of this surgery is to try and maintain motion at that region of your neck.

Please ask your doctor for more information on possible alternatives to the use of i-FACTOR™ Bone Graft.

TALK TO YOUR DOCTOR

This pamphlet is meant to give you useful information and knowledge about i-FACTOR™ Bone Graft. However, it is not intended to replace medical advice or instruction from your healthcare professional.

Your doctor or physician is the only person responsible and qualified to appropriately diagnose and treat your health condition. Should you have any questions about i-FACTOR™ Bone Graft or its relevance to your course of treatment, please contact your healthcare professional.

i-FACTOR™
Peptide Enhanced Bone Graft

For additional information about
i-FACTOR™ Peptide Enhanced Bone Graft,
visit our website at:
www.cerapedics.com

Corporate Headquarters
11025 Dover Street, Suite 1600
Westminster, CO 80021 USA

P: (303) 974-6275
F: (303) 974-6285
E: info@cerapedics.com

www.cerapedics.com

CERAPEDICS
Enhancing the Science of Bone Repair

LS 40024-00-2