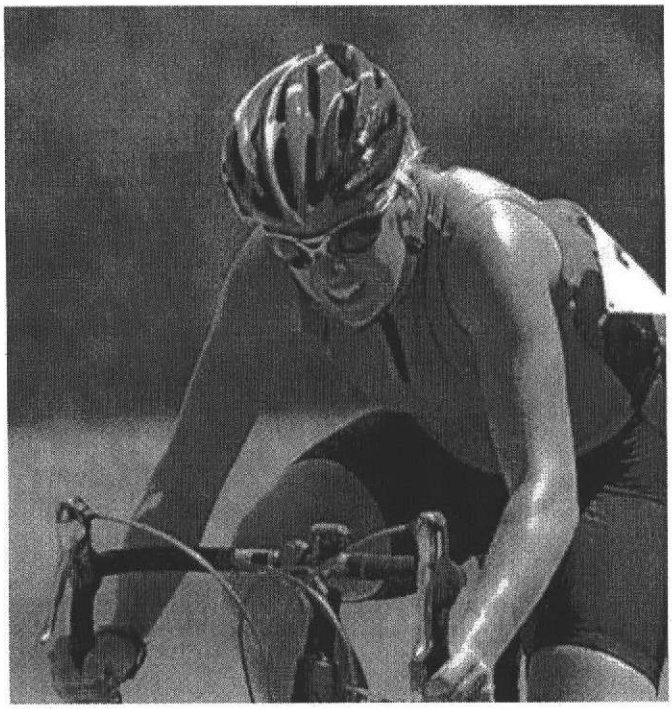
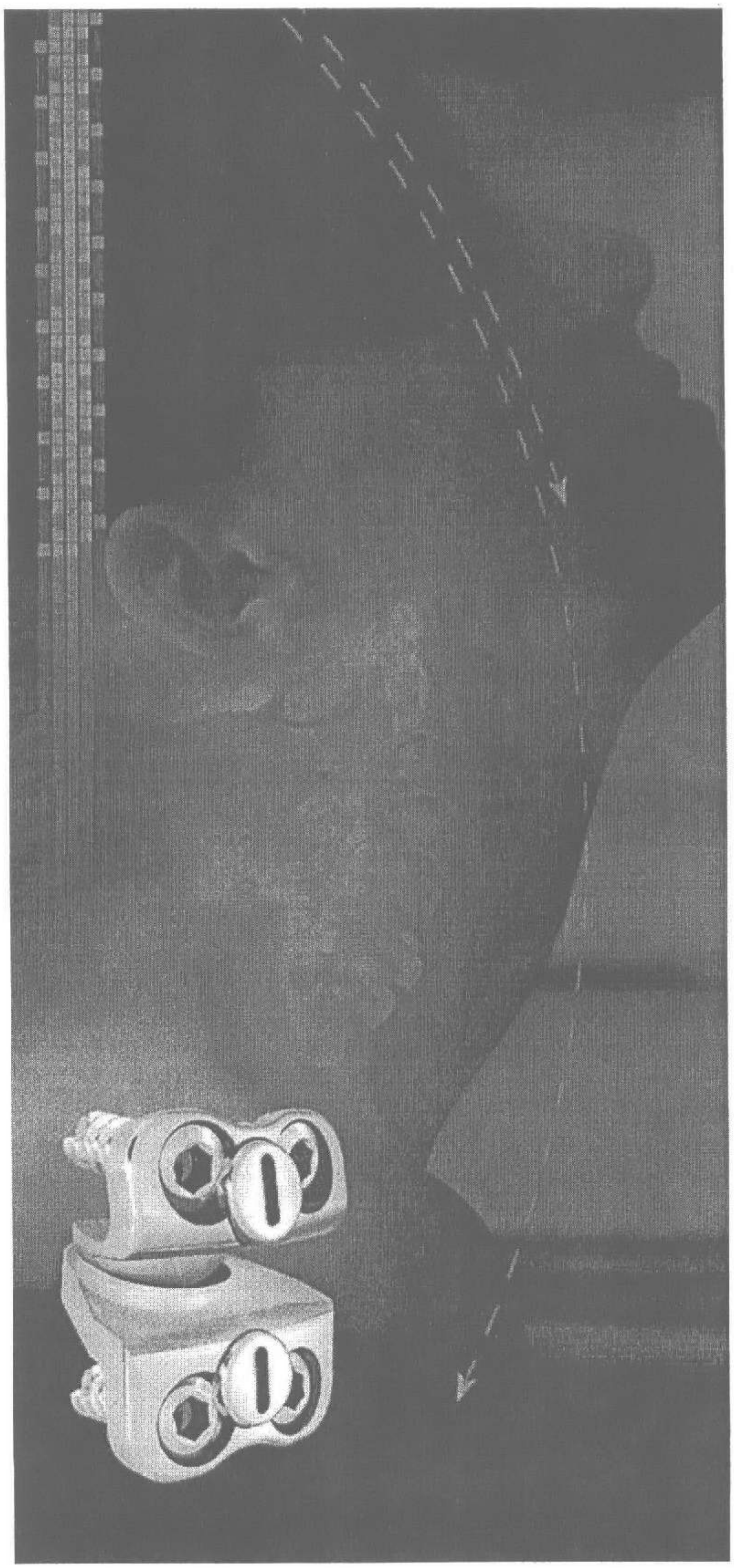
PRESTIGE®
Cervical Disc System



Patient Information

Medtronic



This patient information brochure is designed to help you understand treatment for your neck pain and related problems. Your doctor has recommended you consider surgery to relieve your pain and discomfort using the PRESTIGE® Cervical Disc. The purpose of this brochure is to give you some background about cervical spine (neck) surgery and the PRESTIGE® Cervical Disc.

Your Cervical Spine

The vertebrae (spinal column bones), which encircle and protect your spinal cord, are separated by shock-absorbing discs (Figure 1). The discs give your spine the flexibility to move. Nerves branching from the spinal cord pass through openings in the vertebrae to other parts of your body.

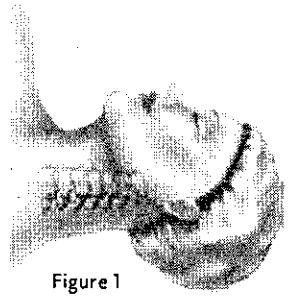


Figure 1

Why do I need surgery?

As discs lose their water content because of disease or age, they lose their height and bring the vertebrae closer together. The consequence is a weakening of the shock absorption properties of the disc and a narrowing of the openings for the nerves in the sides of the spine (Figure 2). Additionally, a loss of disc height may cause the formation of bone spurs, which can push against your spinal cord and/or nerves. When a disc ruptures in the cervical spine, it puts pressure on one or more nerve roots (called nerve root compression) or on the spinal cord; causing pain and other symptoms in the neck and arms. Living with this pain or weakness and tingling in the arms can be disabling.

Disc degeneration

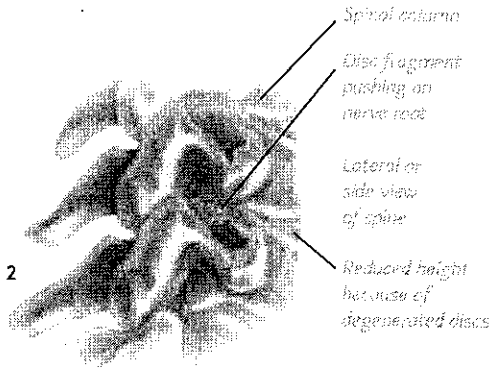


Figure 2

With the advice of your doctor, you may have tried other treatments for some time now which did not relieve your pain or dysfunction. Or perhaps your doctor has determined permanent damage would result without surgery. Your doctor has recommended that you consider the PRESTIGE® Cervical Disc, which provides for motion following surgery, instead of the more common fusion procedure.

What is the PRESTIGE® Cervical Disc?

The PRESTIGE® Cervical Disc is made of two-pieces of articulating, surgical grade, stainless steel. It is inserted into the affected disc space of your neck, acting like a joint, via a ball-and-trough mechanism, similar to that of a ball-and-socket. It is intended to be used in patients with only one diseased disc requiring surgery in their neck.

Who should avoid having cervical disc surgery?

The PRESTIGE® Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.

What warnings should I pay attention to?

Heterotopic ossification (HO) is a fairly common complication associated with artificial hips and knees. The consequence of HO is reduced motion. Not all patients will develop HO. It has been reported in the literature that short-term postoperative use of Non-Steroidal Anti-Inflammatory Drugs

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(NSAIDs), such as ibuprofen, may reduce the instance of HO. HO also has been reported in early cervical disc surgeries outside the United States. NSAIDs were not prescribed in these early cases. Patients in the clinical study were instructed to use NSAIDs for two weeks postoperatively.

This device is placed close to nerves and blood vessels in the cervical spine. There is a risk of nerve damage or serious or fatal bleeding if damage to these structures occurs during or after surgery.

Metallic devices release metallic ions into the body. The long term effect of these ions in the body is not known.

What are the risks and adverse effects of this type of surgery?

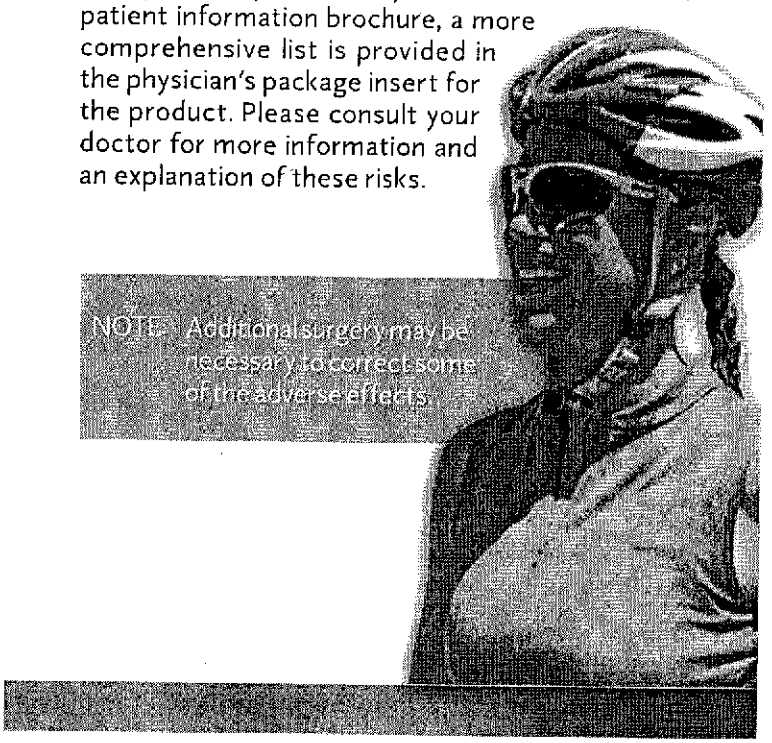
Like any surgery, there are some possible complications that may occur when you receive the PRESTIGE® Cervical Disc. Complications may occur singly or in combination and may include:

- Allergic reaction to the implant material
- Implants bending, breaking, loosening, or moving
- Instruments bending or breaking
- Wound, local, and/or bodily (systemic) infections
- Neck and/or arm pain
- Difficulty swallowing
- Impairment of or change in speech
- Nerve or spinal cord injury, possibly causing impairment or paralysis
- Numbness or tingling in extremities
- Tear in the protective membrane (dura) covering the spinal cord
- Loss of motion or fusion at the treated cervical level
- Development or progression of disease at other cervical levels

- Bleeding or collection of clotted blood (hematoma)
- Blood clots and blood flow restrictions, possibly resulting in stroke
- Tissue swelling
- Reactions to anesthesia
- Changes in mental status
- Complications of pregnancy, including miscarriage and fetal birth defects
- Inability to resume activities of normal daily living, including sexual activity
- Death

There is also the risk that this surgical procedure will not be effective, and may not relieve or may cause worsening of preoperative symptoms.

In the U.S. clinical study, there were a number of adverse effects. Some of the most common were trauma, difficulty swallowing, impairment of speech and infection. There may be other risks associated with treatment using the PRESTIGE® device. Although many of the major risks are listed in this patient information brochure, a more comprehensive list is provided in the physician's package insert for the product. Please consult your doctor for more information and an explanation of these risks.



NOTE: Additional surgery may be necessary to correct some of the adverse effects.

What should I expect from the surgery?

This surgical procedure is expected to relieve the symptoms of a nerve root or spinal cord compression caused by the damaged disc. The surgery associated with the PRESTIGE® Cervical Disc is designed to preserve motion at the operated disc level, unlike a fusion surgery that does not allow for motion.

How is this procedure different from a fusion?

Unlike a fusion, which is designed to treat your symptoms by eliminating the motion at the treated level (Figure 3), the PRESTIGE® Cervical Disc is designed to allow motion.

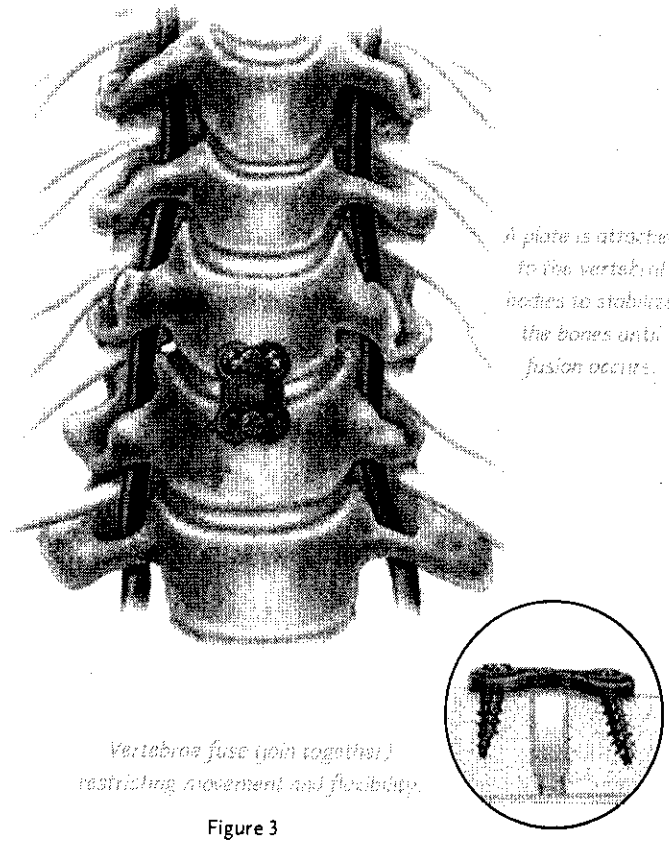
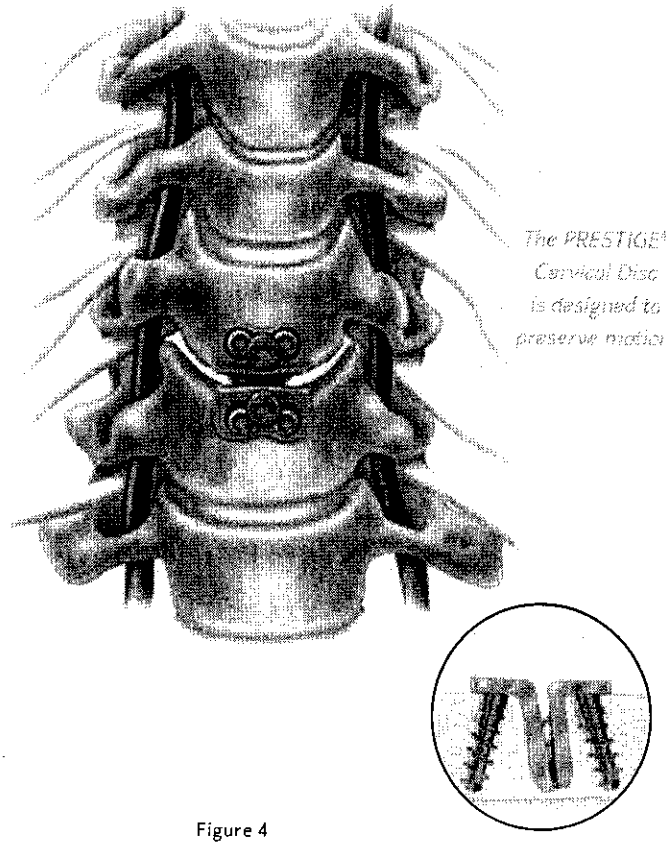


Figure 3

What is involved in a PRESTIGE® Cervical Disc procedure?

This surgery involves the use of a medical device, designed to replace the disc which sits between the vertebrae in your neck (Figure 4). Your disc, which is damaged or diseased, is surgically removed through an incision (cut) made in the front of your neck. Typically, this incision is about an inch long. Your surgeon will prepare a space and insert a PRESTIGE® Cervical Disc into the disc space. The PRESTIGE® Cervical Disc is held in place by four bone screws and two lock screws. The device utilizes a patented ball-and-trough design which allows for motion to be preserved. (Continued on next page)



The PRESTIGE® Cervical Disc is designed to preserve motion

Figure 4

The PRESTIGE® Cervical Disc maintained normal and healthy "segmentally" (naturally divided) motion 24 months after implantation. Patients also showed improvement of their nervous system. A nurse will show you how to care for your wound before you are sent home and your doctor will discuss a program to gradually increase your activity. You may be required to wear a neck brace after surgery. You may be told, while you recover, to avoid any activities that require repeated bending, lifting, twisting, to include athletic activities. Your doctor will schedule office visits to check on how you are doing and to see if anything else needs to be done for your recovery.

Preparing for surgery

You may be told to see your general practitioner before surgery to check your overall health. Tell your doctor what medications you are taking, and ask if you should stop taking any medications before surgery. To make your recovery easier, prepare your home for life after surgery. Place important things within easy reach. Remove safety hazards that might cause you to lose your balance. Arrange for someone to help you at home and around the house after surgery. You will most likely be told not to eat or drink the night before the surgery. Be sure you read and understand this entire booklet. Your surgeon is required to let you know of the potential risks, as well as benefits, of this surgery.

What can I expect after surgery?

Ask your doctor about your specific recovery plan following surgery. It is important to follow your doctor's instructions carefully to recover from surgery as quickly as possible and increase your chances of a successful outcome. Recovering from neck pain and surgery is an ongoing process. How fast you recover depends on the type of surgery you had, your commitment to working closely with your physical therapist, and moving and exercising correctly, as recommended by your doctor.

In most cases, immediately after surgery, your heart and lung function will continue to be monitored, a drainage tube may have been left in your wound and your doctor may prescribe medicines to control pain and nausea.

Contact your doctor immediately if:

- you get a fever
- the wound starts leaking fluids
- you have trouble swallowing or breathing
- you have trouble urinating
- you have new or increased neck or arm pain or numbness

After surgery, your doctor may refer you to a physical therapist who will teach you exercises to improve your strength and increase your mobility. The goal of physical therapy is to help you become active as soon as possible, using safe body movements that protect your spine. This often includes neck strengthening exercises. You may also be taught different ways of positioning your neck to avoid reinjuring your spine.

What are the expected outcomes of the surgery?

Patients in the U.S. clinical study were found to be about 79% successful through two years. Success was based on several factors such as reduced pain, improved function and lack of serious adverse events.

Frequently Asked Questions

Can I shower after surgery?

You will have a dressing on your neck. You may shower quickly but try not to soak the dressing. Do not use a hot tub.

Will I have a large scar?

The incision is usually less than one inch long and usually heals so that it is barely noticeable.

Continued on next page

When can I drive?

For a period of time after your surgery, you may be cautioned about activities such as driving.

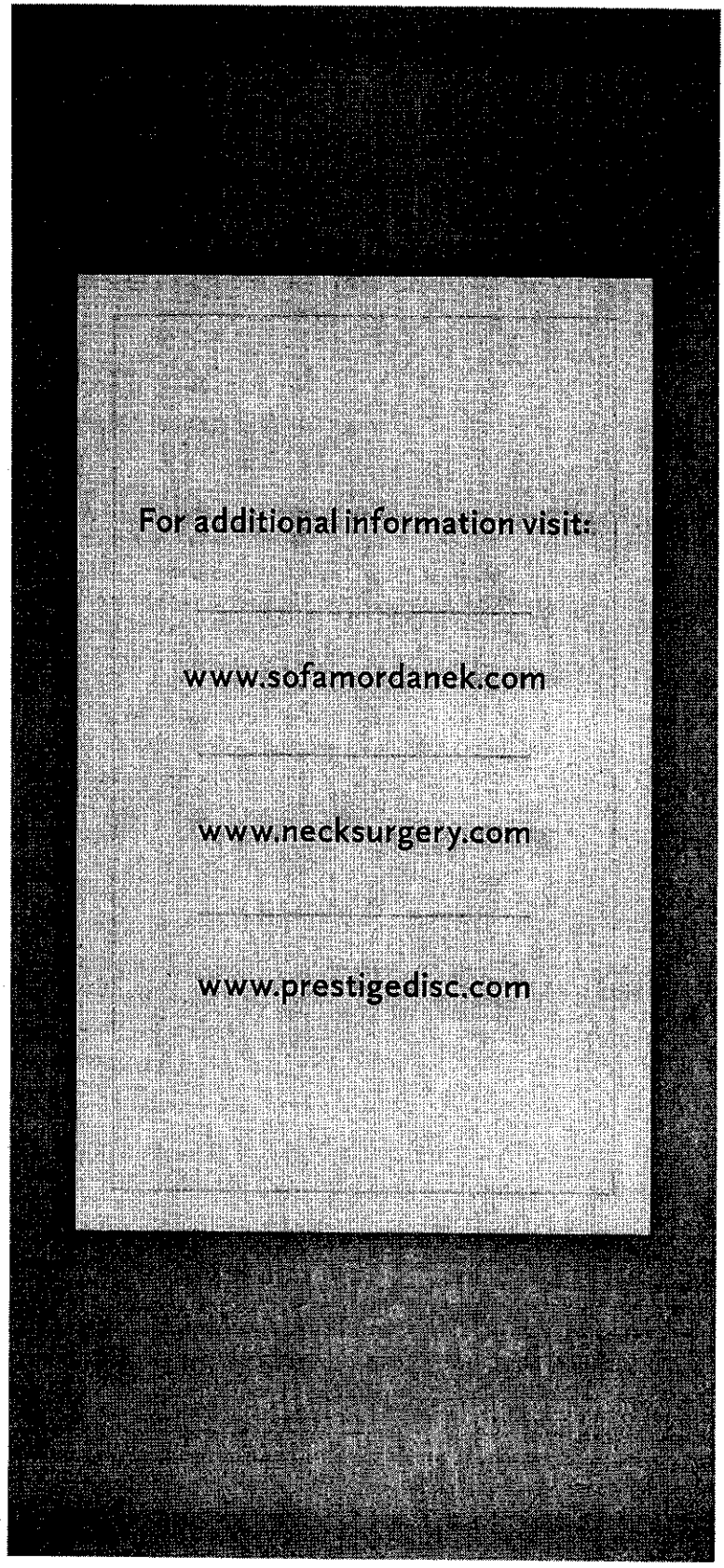
Can I travel?

Because of increased airport security measures, please call your local airport authority before traveling to get information that might help you pass through security more quickly and easily. Ask your surgeon to provide a patient identification card.

Talk to your doctor

While this brochure is meant to provide you with information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice.

If you have any questions about the PRESTIGE® Cervical Disc, please call or see your doctor, who is the only one qualified to diagnose and treat your spinal condition. As with any surgical procedure, you should find a doctor who is experienced in performing the specific surgery that you are considering.


For additional information visit:
www.sofamordanek.com
www.necksurgery.com
www.prestigedisc.com

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Notes:

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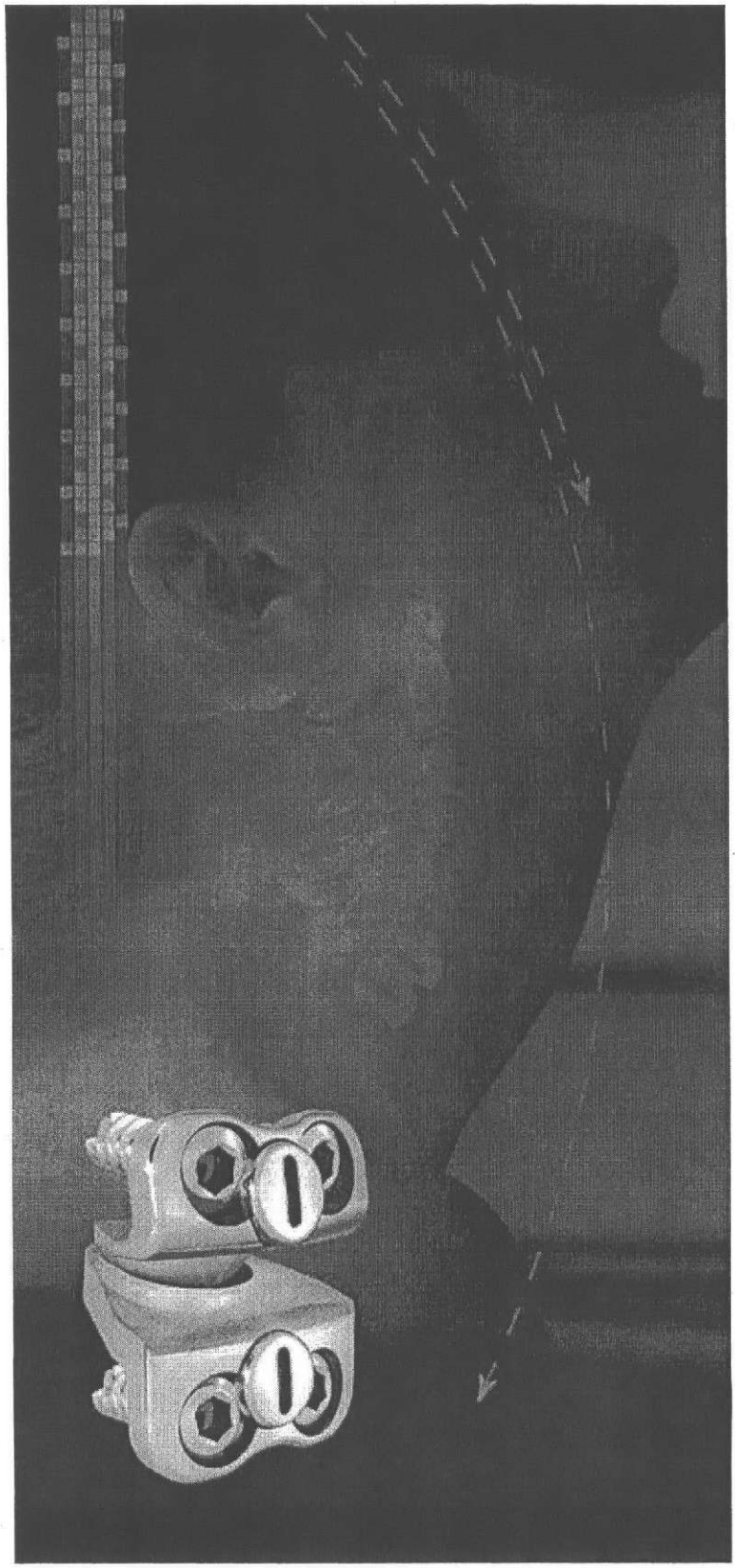

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PRESTIGE® CERVICAL DISC

Implant package contents (superior and inferior disc components, bone screws, lock screws) provided sterile. Instrument set contents provided non-sterile.

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ENGLISH

IMPORTANT INFORMATION ON THE PRESTIGE® CERVICAL DISC

DESCRIPTION

The PRESTIGE® Cervical Disc is a two-piece articulating metal-on-metal device that is inserted into the intervertebral disc space at a single cervical level using an anterior approach. The device is manufactured from wrought type 316 stainless steel (ASTM F-138) and consists of two metal plates which function via a ball and trough mechanism. The superior component of the implant contains the ball portion of the mechanism, and the inferior component incorporates the trough portion. The flat portion of each component, which contacts the vertebral endplate, is roughened through a grit blasting process.

Each component is affixed to the vertebral body by two bone screws through an anterior flange. The bone screws are held in place by a lock screw mechanism. In the implanted disc, the bone screws are divergent in the cephalic/caudal direction and convergent in the medial/lateral direction.

The device assembly was designed to allow the following motions *ex-vivo*: a minimum of 10° motion off the neutral position in flexion/extension and lateral bending, unconstrained axial rotation, and 2 mm of anterior/posterior translation.

The available components are shown in the table below.

Table 1. PRESTIGE® Cervical Disc Device Configurations.

Catalog Number	Component Description
6961260	6 mm x 12 mm Disc Assembly
6961460	6 mm x 14 mm Disc Assembly
6961660	6 mm x 16 mm Disc Assembly
6961270	7 mm x 12 mm Disc Assembly
6961470	7 mm x 14 mm Disc Assembly
6961670	7 mm x 16 mm Disc Assembly
6961870	7 mm x 18 mm Disc Assembly
6961480	8 mm x 14 mm Disc Assembly
6961680	8 mm x 16 mm Disc Assembly
6961880	8 mm x 18 mm Disc Assembly
6960013/6961340*	Self-Tap Bone Screw 4.0 mm x 13 mm
6960015/6961540*	Self-Tap Bone Screw 4.0 mm x 15 mm
6960113/6961345*	Self-Tap Bone Screw 4.5 mm x 13 mm
6960115/6961545*	Self-Tap Bone Screw 4.5 mm x 15 mm
6960120/6961120*	Lock Screw

* Catalog number for screws in implant box / catalog number for separately packaged extra screws, if needed.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS

The PRESTIGE® Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.

CONTRAINDICATIONS

The PRESTIGE® Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.

ADVERSE EVENTS

A multi-center, prospective, randomized, non-inferiority clinical trial of the PRESTIGE® Cervical Disc was conducted in the United States comparing the anterior spinal use of the PRESTIGE® device to fusion using allograft and plating stabilization, the control, in the treatment of patients with symptomatic degenerative disc disease. The adverse effects, as shown in Table 2 below, were reported from the 276 PRESTIGE® device patients and 265 control patients enrolled in the multi-center clinical study. Adverse event rates presented are based on the number of patients having at least one occurrence for a particular adverse event divided by the total number of patients in that treatment group. At the time Tables 2 and 2b below were compiled, all patients had reached the 12-month follow-up visit, and 223 investigational and 198 control patients had completed 24-month follow-up visits. As shown in Table 2b, a minority of the adverse events reported were related to the study treatment.

Table 2. Adverse Events in US IDE Study.[1]

	Surgery		Postoperative 1 day - <4 Weeks		6 Weeks ≥4 Wks - <9 Weeks		3 Months (≥9 Wks - <5 Months)		6 Months (≥5 Mos- <9 Months)		12 Months (≥9 Mos- <19 Months)		24 Months (≥19 Mos- <30 Months)		# of Patients Reporting & Total adverse events	
Complication	Invest.	Control[2]	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest. # Patients (% of 276) Total # Events	Control # Patients (% of 265) Total # Events
Anatomical/Technical Difficulty	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.4) 1	0 (0.0) 0
Cancer	0	0	0	1	0	0	0	0	0	0	2	0	3	1	5 (1.8) 5	2 (0.8) 2
Cardiovascular	0	0	2	1	0	1	2	2	1	0	7	2	3	3	14 (5.1) 15	8 (3.0) 9
Carpal Tunnel Syndrome	0	0	1	1	1	1	3	1	0	0	8	2	1	2	12 (4.3) 14	7 (2.6) 7
Death	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0 (0.0) 0	3 (1.1) 3
Dysphagia/Dysphonia	2	3	16	12	3	3	0	3	1	0	1	1	0	0	23 (8.3) 23	22 (8.3) 22
Gastrointestinal	0	2	4	3	1	1	3	2	4	2	11	11	3	5	25 (9.1) 26	24 (9.1) 26
Implant Displacement/ Loosening	0	0	0	0	0	2	1	0	0	0	0	1	1	1	2 (0.7) 2	4 (1.5) 4
Infection	2	0	6	3	2	4	6	2	3	2	8	4	3	7	27 (9.8) 30	20 (7.5) 22
Neck and/or Arm Pain	1	0	25	17	32	17	27	34	48	38	34	42	23	25	138 (50.0) 190	127 (47.9) 173
Neurological	4	1	8	9	12	5	14	10	14	8	19	18	7	14	66 (23.9) 78	55 (20.8) 65
Non-Union	0	0	0	0	0	1	0	2	0	2	0	1	0	0	0 (0.0) 0	6 (2.3) 6
Other[3]	2	2	18	18	14	12	9	9	19	6	32	18	15	17	70 (25.4) 109	66 (24.9) 82
Other Pain[4]	2	2	4	4	10	5	13	13	14	15	28	18	17	11	69 (25.0) 88	56 (21.1) 68
Pending Non-Union	0	0	0	0	0	0	0	1	0	5	0	7	0	3	0 (0.0) 0	16 (6.0) 16
Respiratory	1	0	1	2	0	1	1	0	1	1	2	3	2	2	8 (2.9) 8	8 (3.0) 9
Spinal Event	0	0	2	2	1	3	6	9	3	9	6	5	0	4	17 (6.2) 18	30 (11.3) 32
Subsidence	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1 (0.4) 1	0 (0.0) 0
Trauma	0	0	4	2	7	8	13	11	17	10	20	6	8	10	59 (21.4) 69	40 (15.1) 47
Urogenital	0	0	0	0	0	0	3	4	2	1	8	1	3	0	15 (5.4) 16	5 (1.9) 6
Vascular Intra-Op	2	1	2	1	1	0	0	0	0	0	0	0	0	0	5 (1.8) 5	2 (0.8) 2
Any Adverse Event															226 (81.9)	212 (80.0)

[1] Based on 24-month cohort at time of interim analysis as pre-specified in IDE protocol.
[2] Control=Single level anterior interbody fusion procedure with allograft and plate stabilization
[3] Other consists of various events that do not fit into another category, such as allergic reaction, depression, or insomnia.
[4] Other Pain consists of non-neck and/or arm pain events such as headache, lower back pain, or leg pain.

Table 2b. Adverse Events Classified as Device-Related or Device/Surgical Procedure-Related in US IDE Study.[1]

	Surgery		Postoperative (1 day - <4 Weeks)		6 Weeks (≥4 Wks - <9 Weeks)		3 Months (≥9 Wks - <5 Months)		6 Months (≥5 Mos- <9 Months)		12 Months (≥9 Mos- <19 Months)		24 Months (≥19 Mos- <30 Months)		# of Patients Reporting & Total adverse events	
Complication	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest.	Control	Invest. # Patients (% of 276) Total # Events	Control # Patients (% of 265) Total # Events
Anatomical/Technical Difficulty	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.4) 1	0 (0.0) 0
Implant Displacement/ Loosening	0	0	0	0	0	1	1	0	0	0	0	1	1	1	2 (0.7) 2	3 (1.1) 3
Infection	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0 (0.0) 0	1 (0.4) 1
Neck and/or Arm Pain	0	0	0	0	1	0	0	0	0	2	0	0	0	0	1 (0.4) 1	2 (0.8) 2
Neurological	0	0	0	0	1	0	1	1	0	0	2	0	0	0	4 (1.4) 4	1 (0.4) 1
Non-Union	0	0	0	0	0	1	0	2	0	2	0	1	0	0	0 (0.0) 0	6 (2.3) 6
Pending Non-Union	0	0	0	0	0	0	0	1	0	5	0	7	0	3	0 (0.0) 0	16 (6.0) 16
Subsidence	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1 (0.4) 1	0 (0.0) 0
Any Adverse Event															9 (3.3)	26 (9.8)

A Bayesian analysis was conducted on the adverse events using non-informative priors. The results are presented in Table 3.

Table 3. Bayesian Comparison of Adverse Events.

Adverse Event	Posterior Adverse Event Rate		There is a 95% probability that adverse event rates will fall within the following range		Probability that the adverse event rate of investigational group is lower than that of the control group (%)
	Inves.	Control	Inves.	Control	
Anatomical/Technical Difficulty	0.007	0.004	0.0% to 1.7%	0.0% to 1.1%	26.0
Cancer	0.022	0.011	0.6% to 3.9%	0.1% to 2.4%	15.6
Cardiovascular	0.054	0.034	2.8% to 8.1%	1.4% to 5.6%	11.9
Carpal Tunnel Syndrome	0.047	0.030	2.4% to 7.2%	1.1% to 5.1%	14.7
Death	0.004	0.015	0.0% to 1.1%	0.3% to 3.0%	94.3
Dysphagia/Dysphonia	0.086	0.086	5.5% to 12.0%	5.4% to 12.1%	49.6
Gastrointestinal	0.094	0.094	6.0% to 12.8%	6.1% to 12.9%	50.1
Implant Displacement/Loosening	0.011	0.019	0.1% to 2.3%	0.5% to 3.5%	79.1
Infection	0.101	0.079	6.6% to 13.6%	4.8% to 11.2%	18.1
Neck and/or Arm Pain	0.500	0.479	44.1% to 55.9%	42.1% to 54.0%	31.5
Neurological	0.241	0.210	19.1% to 29.2%	16.2% to 25.9%	19.0
Non-Union	0.004	0.026	0.0% to 1.1%	0.9% to 4.5%	99.4
Other	0.255	0.251	20.6% to 30.8%	20.0% to 30.4%	45.2
Other Pain	0.252	0.213	20.2% to 30.4%	16.4% to 26.2%	14.4
Pending Non-Union	0.004	0.064	0.0% to 1.1%	3.6% to 9.3%	100.0
Respiratory	0.032	0.034	1.3% to 5.4%	1.4% to 5.6%	53.4
Spinal Event	0.065	0.116	3.6% to 9.3%	7.9% to 15.4%	98.3
Subsidence	0.007	0.004	0.0% to 1.7%	0.0% to 1.1%	26.0
Trauma	0.216	0.154	16.7% to 26.4%	11.2% to 19.8%	3.0
Urogenital	0.058	0.022	3.1% to 8.5%	0.6% to 4.0%	1.5
Vascular Intra-Op	0.022	0.011	0.6% to 3.9%	0.1% to 2.4%	15.6
Any adverse Event	0.817	0.798	77.1% to 86.1%	74.9% to 84.5%	28.9

Table 4 summarizes the secondary surgical interventions in the PRESTIGE® and control treatment groups that occurred at or before the 24 month post-operative interval. Revisions, removals, and supplemental fixations were considered second surgery failures in the clinical study. Table 4 also presents the Bayesian statistical comparison of secondary surgeries between the PRESTIGE® and

control treatment groups. For these safety comparisons, probabilities exceeding 97.5% are considered statistically significant, rather than the 95% criterion used for other endpoints.

Table 4. Secondary Surgical Procedures.

	# Pts ≤ 24 Months		Probability that the second surgery rate of investigational group is lower than that of the control group (%)
	Invest. (N=276)	Control (N=265)	
Revisions (%)	0	5 (1.9)	98.7
Removals (%)	5* (1.8)	9** (3.5)	87.0
Supplemental Fixations (%)	0	8 (3.0)	99.8
Re-operations (%)	4*** (1.4)	2 (0.8)	24.2

*One of these removals occurred following complaints for unresolved neck pain, one occurred following unresolved arm pain, and the other three were related to both neck and arm pain.
**This includes both elective (2) and non-elective (7) removals in the control group.
***Of the four subjects who had re-operations, two occurred prior to 12 months and two occurred after 12 months postoperative. Two of these re-operations followed unresolved neck pain, one followed unresolved arm pain, and one was related to both neck and arm pain.

POTENTIAL ADVERSE EVENTS

Risks associated with the use of the PRESTIGE® Cervical Disc include: 1) those commonly associated with any surgery; 2) those specifically associated with cervical spinal surgery using an anterior approach; and 3) those associated with a spinal implant, as well as those pertaining to the PRESTIGE® Cervical Disc. However, the causality of these adverse events is not exclusive to these categories. There is also the risk that this surgical procedure will not be effective, and may not relieve or may cause worsening of preoperative symptoms. Some of these effects may have been previously reported in the adverse events table.

1. Risks associated with any surgical procedure are those such as abscess; cellulitis; wound dehiscence; wound necrosis; edema; hematoma; heart and vascular complications; hypertension; thrombosis; ischemia; embolism; thromboembolism; hemorrhage; thrombophlebitis; adverse reactions to anesthesia; pulmonary complications; organ, nerve or muscular damage; seizure, convulsion, or changes to mental status; and complications of pregnancy including miscarriage and fetal birth defects.
2. Risks associated with anterior interbody surgery of the cervical spine include dysphagia; dysphasia; dysphonia; hoarseness; vocal cord paralysis; laryngeal palsy; sore throat; recurring aspirations; nerve deficits or damage; tracheal, esophageal, and pharyngeal perforation; airway obstruction; external chylorrhea; warmth or tingling in the extremities; deficit or damage to the spinal cord, nerve roots, or nerves possibly resulting in paralysis or pain; dural tears or leaking; cerebrospinal fistula; discitis, arachnoiditis, and/or other types of inflammation; loss of disc height; loss of proper curvature, correction, height or reduction of the spine; vertebral slipping; scarring, herniation or degeneration of adjacent discs; surrounding soft tissue damage, spinal stenosis; spondylolysis; otitis media; fistula; vascular damage and/or rupture; and headache.
3. Risks associated with implants in the spine, including the PRESTIGE® device, are early or late loosening of the components; disassembly; bending or breakage of any or all of the components; implant migration; malpositioning of implant; loss of purchase; sizing issues with components; anatomical or technical difficulties; implant fracture; bone fracture; skin penetration, irritation, pain, bursitis resulting from pressure on the skin from component parts in patients with inadequate tissue coverage over the implant; foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring; possible tissue reaction; bone resorption; bone formation that may reduce spinal motion or result in a fusion, either at the treated level or at adjacent levels; development of new radiculopathy; myelopathy or pain; cessation of bone growth of the operated portion of the spine; tissue or nerve damage caused by improper positioning and placement of implants or instruments; loss of neurological function; decreased strength of extremities; decreased reflexes; appearance of cord or nerve root injury; loss of bowel and/or bladder control or other types of

urological system compromise; gastrointestinal and/or reproductive system compromise; and interference with radiographic imaging because of the presence of the implant.
4. Wound, local, and/or systemic infections.
5. Surgical instrument bending or breakage, as well as the possibility of a fragment of a broken instrument remaining in the patient.
6. Inability to resume activities of normal daily living, including loss of consortium.
7. Death.

NOTE: Additional surgery may be necessary to correct some of the adverse effects.

WARNINGS

The PRESTIGE® Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, such as neurological complications.

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. Serious or fatal hemorrhage may also occur if the great vessels are eroded or punctured during implantation and are subsequently damaged due to breakage of implants, migration of implants, or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

PRECAUTIONS

The safety and effectiveness of this device has not been established in patients with the following conditions:

- More than one cervical level with DDD;
- Not skeletally mature;
- Clinically significant cervical instability;
- Prior fusion at adjacent cervical level;
- Severe facet joint pathology of involved vertebral bodies;
- Prior surgery at treated level;
- Osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture;
- Spinal metastases;
- Chronic or acute renal failure or history of renal disease;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids);
- Pregnant; and
- Severe insulin dependent diabetes.

In addition, safety and effectiveness of the device has not been established in patients who have not undergone at least six weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care.

Implanted metal alloys release metallic ions into the body (especially those devices with metal-on-metal articulating surfaces). The long term effect of these ions on the body is not known.

Patients in the clinical study were instructed to use non-steroidal anti-inflammatory drugs (NSAIDs) for two weeks postoperatively. It has been reported in the literature that short-term postoperative use of NSAIDs may reduce the instance of heterotopic ossification.

To prevent unnecessary damage to the bearing surfaces, ensure that blood or other debris is not trapped within the assembly.

Correct selection of the appropriate implant size is extremely important to assure the placement and function of the disc. See the surgical technique manual for step-by-step instructions.

Patient selection is extremely important. In selecting patients for a total disc replacement, the following

factors can be of extreme importance to the success of the procedure: the patient's occupation or activity level; a condition of senility, mental illness, alcoholism or drug abuse; and certain degenerative diseases (e.g., degenerative scoliosis or ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially decreased.

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.

Use aseptic technique when removing the PRESTIGE® Cervical Disc Replacement components from the innermost packaging.

Use care when handling a PRESTIGE® component to ensure that it does not come in contact with objects that could damage the implant. Exercise care to ensure that implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable.

PRESTIGE® Cervical Disc Replacement components should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique manual for step-by-step instructions.

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device, including the avoidance of heavy lifting, repetitive bending, and high-impact exercise or athletic activity for 60 days postoperative.

CLINICAL RESULTS

A multi-center, prospective, randomized, non-inferiority clinical trial of the PRESTIGE® Cervical Disc was conducted in the United States comparing the anterior spinal use of the PRESTIGE® device to fusion using allograft and plating stabilization, the control, in the treatment of patients with symptomatic degenerative disc disease.

A total of 541 patients were enrolled in the clinical trial: 276 patients in the investigational PRESTIGE® device treatment group and 265 patients in the control arm.

Inclusion and Exclusion Criteria

Subjects were enrolled in this study according to the following inclusion/exclusion criteria.

Inclusion Criteria

- Degenerative disc disease (DDD) accompanied by neck pain of discogenic origin at a single level between C3 and C7 confirmed by history and radiographic studies. DDD was determined to be present if a herniated disc and/or osteophyte formation were noted;
- At least 6 weeks unsuccessful conservative treatment or signs of progression or spinal cord/nerve root compression with continued non-operative care;
- No previous surgical intervention at involved level or planned procedures at involved or adjacent levels;
- ≥ 18 years of age;
- Preoperative Neck Disability Index score of ≥ 30;
- Preoperative neck pain score of ≥ 20 on Neck and Arm Pain Questionnaire;
- Not pregnant;
- Willing to sign informed consent and comply with protocol.

Exclusion Criteria

- Cervical spinal condition other than symptomatic cervical disc disease requiring surgical treatment at the involved level;
- Documented or diagnosed cervical instability defined by dynamic (flexion/extension) radiographs showing sagittal plane translation > 3.5 mm or sagittal plane angulation > 20°;
- More than one cervical level requiring surgical treatment;

- Fused level adjacent to the level to be treated;
- Severe pathology of the facet joints of the involved vertebral bodies;
- Previous surgical intervention at the involved level;
- Previous diagnosis of osteopenia or osteomalacia;
- Has any of the following that may be associated with a diagnosis of osteoporosis (if Yes to any of the below risk factors, a DEXA Scan will be required to determine eligibility):
    - Postmenopausal Non-Black female over 60 years of age and weighs less than 140 pounds.
    - Postmenopausal female that has sustained a non-traumatic hip, spine, or wrist fracture.
    - Male over the age of 70;
    - Male over the age of 60 that has sustained a non-traumatic hip or spine fracture;
    - If the level of BMD is a T score of -3.5 or a T score of -2.5 with vertebral crush fracture, then the patient is excluded from the study;
- Spinal metastases;
- Overt or active bacterial infection, either local or systemic;
- Severe insulin dependent diabetes;
- Chronic or acute renal failure or prior history of renal disease;
- Fever (temperature > 101°F oral) at the time of surgery;
- Documented allergy or intolerance to stainless steel, titanium, or a titanium alloy;
- Mental incompetence;
- Prisoner;
- Pregnant;
- Alcohol and/or drug abuser currently undergoing treatment;
- Received drugs which may interfere with bone metabolism within two weeks prior to the planned date of spinal surgery;
- History of an endocrine or metabolic disorder known to affect osteogenesis;
- Condition that requires postoperative medications that interfere with the stability of the implant;
- Treatment with an investigational therapy within 28 days prior to implantation surgery or such treatment is planned during the 16 weeks following implantation with the PRESTIGE® device.

Table 5 summarizes the study patient demographics.

Table 5. Study Patient Demographics.

Variables	Investigational (N=276)	Control (N=265)	p-value
Age (years)	43.3 ± 7.6	43.9 ± 8.8	0.435
Height (inches)	67.4 ± 3.9	67.5 ± 4.2	0.767
Weight (lbs.)	181.7 ± 39.7	184.7 ± 41.5	0.389
Sex (% male)	46.4%	46.0%	1.000
Race Caucasian Black Asian Hispanic Other	 260 6 1 7 2	 243 13 2 6 1	0.448
Marital Status Single Married Divorced Separated Widowed	 44 188 36 5 3	 32 204 24 3 2	0.240
Education Level < High School High School > High School	 10 73 193	 14 77 173	0.458
Worker's Compensation	11.6%	13.2%	0.603
Unresolved Spinal Litigation	10.9%	12.1%	0.687
Tobacco Used	34.4%	34.7%	1.000
Alcohol Used	43.5%	53.2%	0.025
Preoperative Work Status	65.9%	62.6%	0.473

Table 6 summarizes the surgical and hospitalization information.

Table 6. Surgical Results.

	Investigational	Control
Mean operative time (hrs)	1.6	1.4
Mean EBL (ml)	60.1	57.5
Hospitalization (days)	1.1	1.0
Spinal level treated		
C_{34} (%)	7 (2.5)	10 (3.8)
C_{45} (%)	14 (5.1)	15 (5.7)
C_{56} (%)	142 (51.4)	149 (56.2)
C_{67} (%)	113 (40.9)	91 (34.3)

The recommended post-operative care included avoidance of heavy lifting, repetitive bending, and high-impact exercise or athletic activity for 60 days postoperatively. Avoidance of prolonged NSAID use (beyond 2 weeks postop) was also specified in the postoperative regimen, although the use of NSAIDs was recommended for the first two weeks postoperatively. The use of electrical bone growth stimulators was prohibited during the 24-month follow-up period. Patients who smoked were also encouraged to discontinue smoking.

Patients were evaluated preoperatively (within 6 months of surgery), intraoperatively, and postoperatively at 6 weeks, 3, 6, 12, and 24 months, and annually thereafter until the last subject enrolled in the study had been seen for their 24-month evaluation. Complications and adverse events were evaluated over the course of the clinical trial. At each evaluation timepoint, the primary and secondary clinical and

radiographic outcome parameters were evaluated. Success was determined from data collected during the initial 24 months of follow-up.

The safety of the PRESTIGE® was assessed by monitoring intraoperative and postoperative complications. Radiographs were examined for evidence of device migration or breakage. Observations of subsidence were reported by investigators as adverse events. All radiographic endpoints were evaluated independently by a core laboratory.

The clinical study was approved for a total of 550 patients. Medtronic performed an interim statistical analysis when 250 implanted subjects had completed their 24-month follow-up visit. At this time all enrolled subjects, i.e. 541 implanted subjects, had reached their 12-month follow-up window. As predetermined at the time of the IDE study initiation, if the results of this interim analysis demonstrated non-inferiority of the subjects receiving the PRESTIGE® device compared to controls, the sponsor would submit a PMA application.

The primary endpoint was determined at 24 months as a composite of the following parameters: pain and functional disability, neurological status, adverse events, secondary surgical interventions, and a radiographic spinal unit height determination. This was termed overall success.

In the approved protocol, individual subject success (i.e. overall success) was defined as attainment of all of the following:

1. An improvement of at least 15 points from the baseline Neck Disability Index (NDI) score;
2. Maintenance or improvement in neurological status;
3. No serious adverse event classified as implant-associated or implant/surgical procedure-associated;
4. No additional surgical procedure classified as "Failure"; and
5. Functional spinal unit (FSU) height maintenance. FSU height was considered maintained if it did not decrease more than 2 mm after 6 weeks following surgery.

Because of difficulty in evaluating FSU, due to anatomical interference with the radiographic image, an alternate overall success determination was made based on the above criteria without the addition of functional spinal unit (FSU) height maintenance.

The table below describes the success probabilities for individual outcome parameters and overall success. All success probabilities were based on the data from the 24-month outcomes and posterior probabilities of success were calculated using Bayesian statistical methods. The conclusions were based on an interim analysis which was pre-defined in the protocol.

Table 7. Posterior Probabilities of Success at 24 Months.

Primary Outcome Variable	Investigational	Control	Posterior Probabilities	
	Posterior Mean (95% HPD Credible Interval)	Posterior Mean (95% HPD Credible Interval)	Non-Inferiority	Superiority
NDI	80.8% (74.7%, 87.0%)	80.8% (74.1%, 86.7%)	98.5%	50.0%
Neurological	92.1% (87.6%, 96.2%)	84.7% (78.6%, 90.5%)	~100%	97.1%
FSU Height	95.4% (91.5%, 98.7%)	93.7% (89.2%, 97.8%)	~100%	71.7%
Overall Success (without FSU)	78.8% (72.1%, 85.0%)	70.0% (62.7%, 77.4%)	~100%	95.9%
Overall Success (with FSU)	80.1% (73.1%, 87.4%)	64.0% (55.3%, 72.8%)	~100%	99.7%

Bayesian analysis was performed utilizing both 12-month and 24-month data to calculate the posterior probabilities in Table 7 above. The number of patients with primary outcome variable data at 12 and 24 months are listed in Table 8 below.

Table 8. Patient Data Available for Bayesian Calculations.

Primary Outcome Variable	12 Months		24 Months	
	Inv	Ctrl	Inv	Ctrl
NDI	263	222	128	121
Neurological	264	226	128	121
FSU Height	205	171	94	88
Overall Success (without FSU)*	263	223	128	122
Overall Success (with FSU)*	205	173	95	90

*If a patient failed based on either a second surgery or serious, possibly implant- or implant/surgical procedure-associated adverse event, the patient was counted as an Overall Success failure and included in the analysis, regardless of whether or not they had the FSU measurement, NDI score, or neurological outcome.

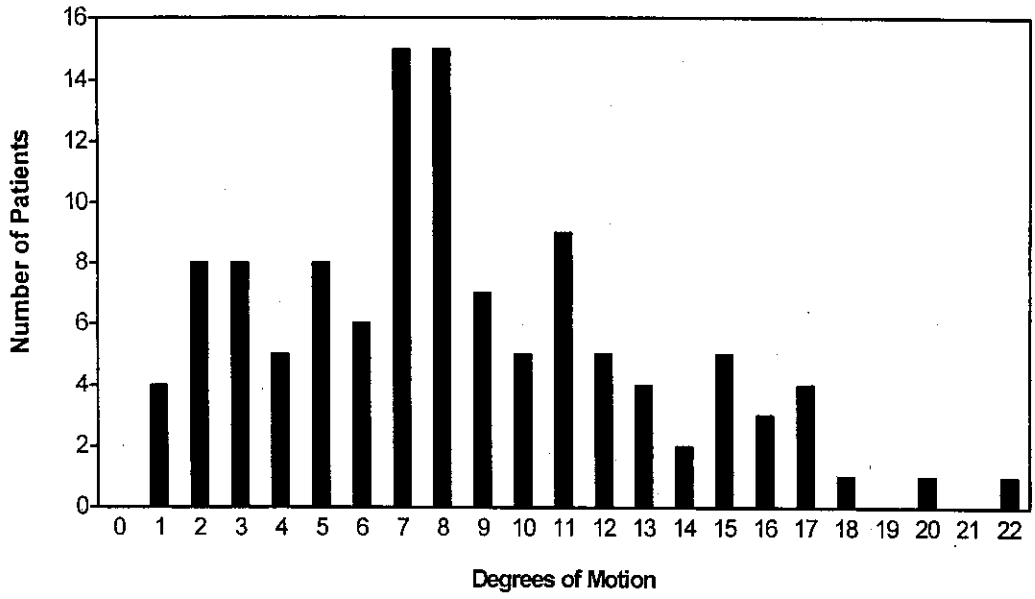
Non-inferiority of the PRESTIGE® group to the control group was demonstrated for all endpoints listed in Table 7 above. Statistical superiority of the PRESTIGE® group to the control group was demonstrated for overall success (both with and without the FSU height component) and the neurological variable. The NDI and FSU components were not found to be statistically superior in the PRESTIGE® group.

Thus, the 95% two-sided confidence interval indicates that the overall success rate for the PRESTIGE® group is within the non-inferiority margin, regardless of which set of study success criteria are used.

The secondary endpoints assessed were Neck Pain, Arm Pain, SF-36 Health Survey, Gait Assessment, Foraminal Compression, Work Status, Patient Satisfaction, Radiographic, Global Perceived Effect, and Doctor's Perception.

For patients receiving the PRESTIGE® device, the mean angular motion values at 12 and 24 months postoperative, respectively, were 7.59° (n=246) and 7.87° (n=116) as compared to a preoperative value of 7.55° (n=216). Based on the interim analysis cohort, the range of motion values measured from flexion/extension radiographs at 24 months for the PRESTIGE® device patients are presented in the histogram below.

Histogram of PRESTIGE® Cervical Disc Angular Range of Motion at 24 Months.



PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to MEDTRONIC. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.
Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

The contents of the implant package for the PRESTIGE® Cervical Disc, including the superior and inferior disc components, bone screws, and lock screws, are provided sterile via gamma irradiation. The contents of instrument sets are provided non-sterile.

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

Table 9. Sterilization Parameters.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. No implant should be re-used once it comes into contact with human tissue or body fluid. Always immediately clean and re-sterilize instruments that have been used in surgery. This process must be performed before handling or (if applicable) returning to MEDTRONIC.

CONFORMANCE TO STANDARDS

The PRESTIGE® Cervical Disc is manufactured from type 316 stainless steel per ASTM F138.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested. Complaints may also be reported directly to Medwatch at http://www.fda.gov/medwatch.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC.

DEVICE RETRIEVAL EFFORTS

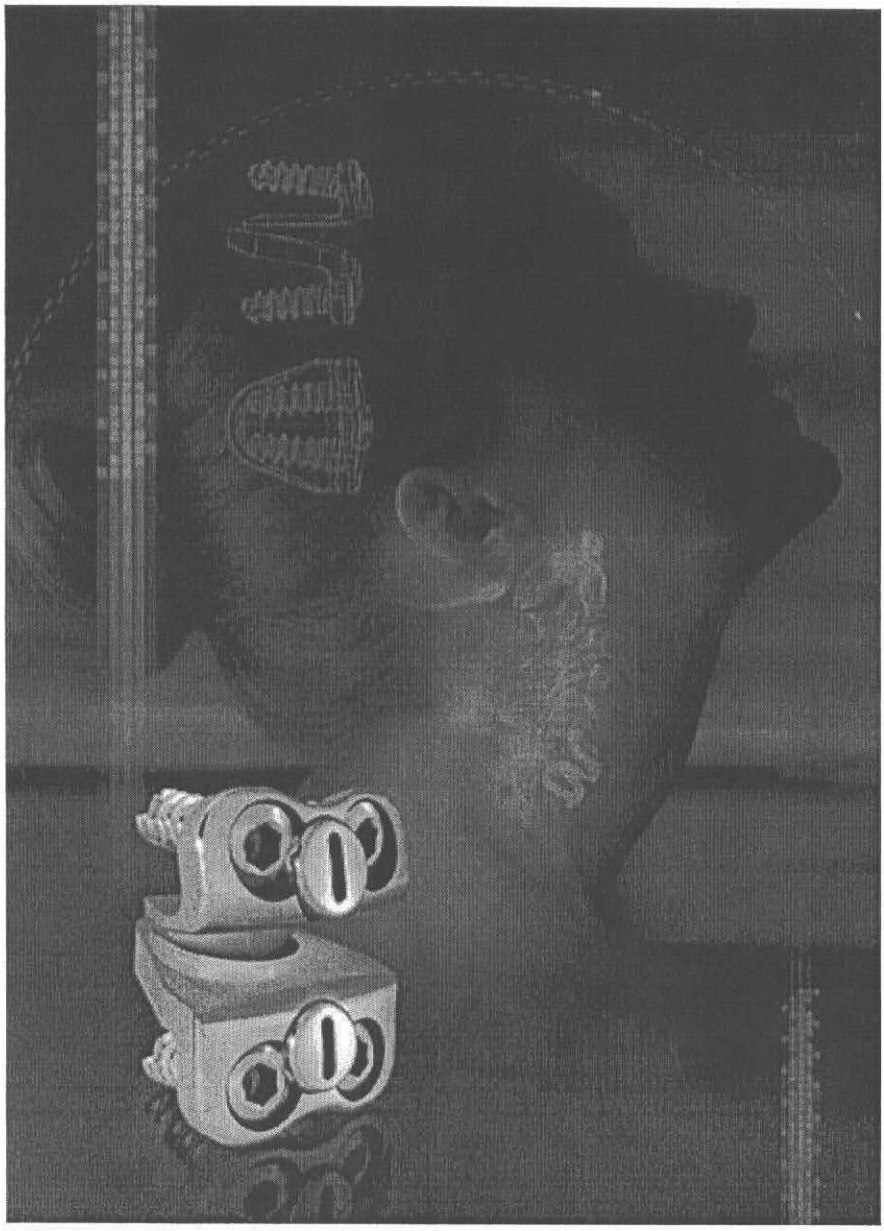
Should it be necessary to remove a PRESTIGE® Cervical Disc device, please call MEDTRONIC prior to the scheduled surgery for product/tissue retrieval information.

[USA] FOR US AUDIENCES ONLY
CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

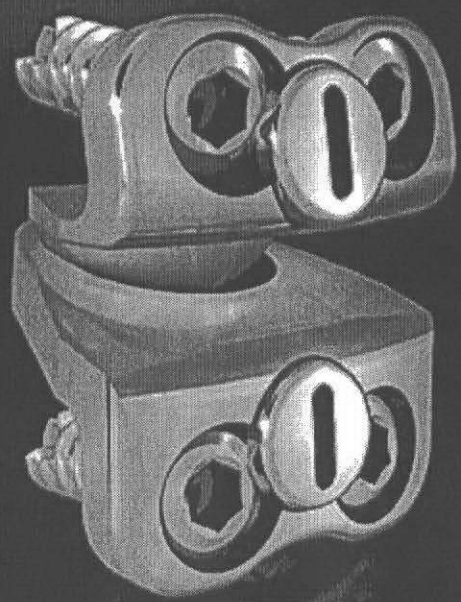
Medtronic

PRESTIGE®

Cervical Disc System Surgical Technique



PRESTIGE®
Cervical Disc System



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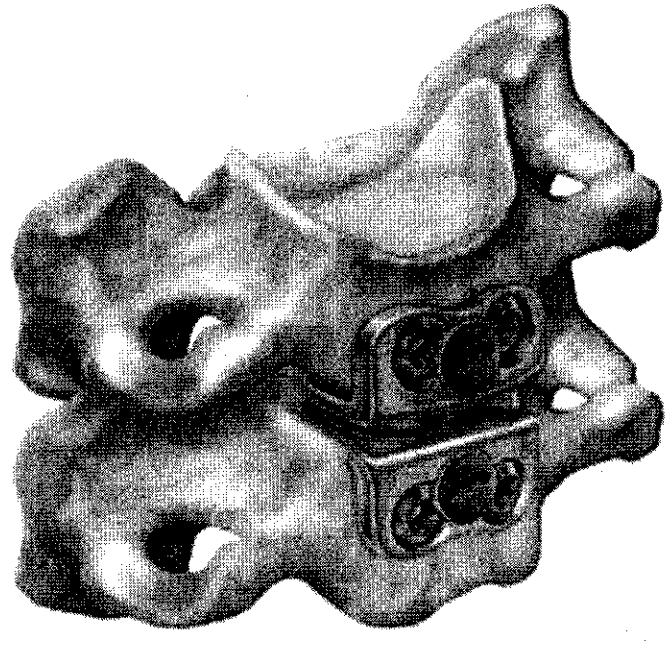

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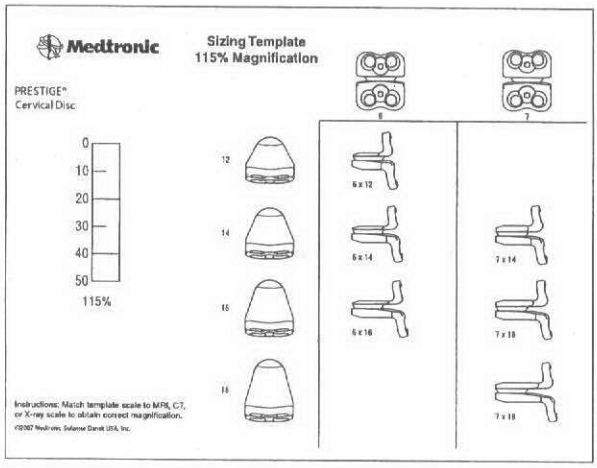
Introduction

The surgical benefits of an anterior approach to the cervical spine in the management of the intractable symptoms and physical findings associated with cervical degenerative disc disease are well known. Usually, the symptomatic functional spinal unit (FSU) is mobile and mechanically stable. Anterior cervical disc fusion, though providing symptomatic relief, has the disadvantage of converting the operated segment to a non-functional spinal unit.

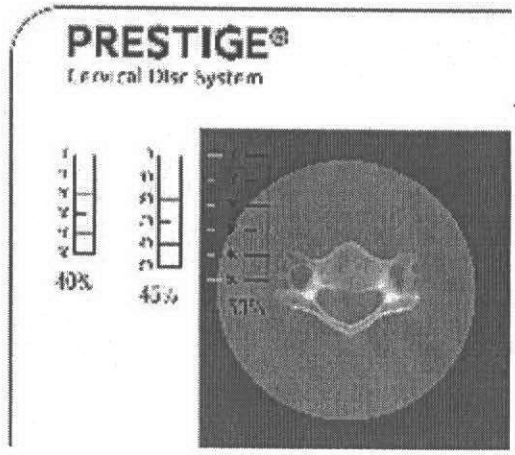
Cervical disc arthroplasty is intended to preserve the motion segment, reduce return to work time, and reduce reoperations due to pseudoarthrosis.

Using a computed tomography (CT) or magnetic resonance image (MRI) obtained so that the slices are parallel to the vertebral body endplates, determine the dimensions of the two vertebral body endplates at the target disc space. Do not include spurs or ridges that will be removed in the subsequent burring/decompression process. Determine the magnification factor of the image using the Template Set (*Figure 1a*). Choose the prosthesis template corresponding to the measured magnification factor, and follow the instructions on the template to select the prosthesis size (*Figure 1b*). This templating process determines the appropriate footprint of the implant, but not the height (*Figure 1c*).

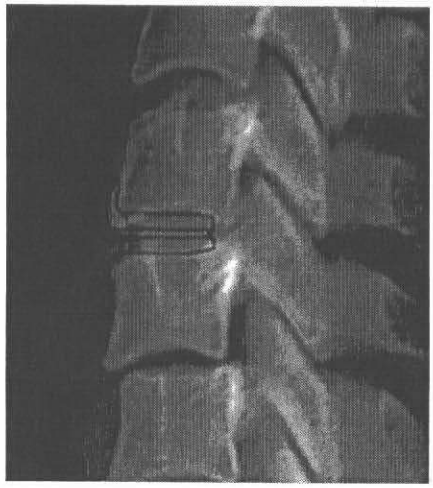
Note: Templating provides only approximate sizing. This initial assessment may vary because of magnification factors inherent in CT or MRI images. The appropriate implant should approximate the height of healthy adjacent discs. The depth should maximize endplate coverage. The final selection of implant size should be based on clinical judgement, disc space preparation, and trialing.



(Figure 1a)



(Figure 1b)



(Figure 1c)

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The patient is placed in the supine position with the head and neck in a neutral position (*Figure 2*). The posterior cervical spine should be supported to establish and maintain this position. Head halter traction may be applied to stabilize and open the disc space. A standard right-sided or left-sided approach may be used. Both shoulders may be pulled down and secured for better visualization of the lower cervical spine. It may be necessary to perform a fusion procedure if visualization of the target disc space does not allow for an optimal lateral view.

Note: A preoperative, straight lateral film can be used as a guide for achieving neutral position on the operating table. Failure to reproduce a preoperative, neutral neck position may result in improper implant position or improper sagittal balance of the cervical spine at the operative level.

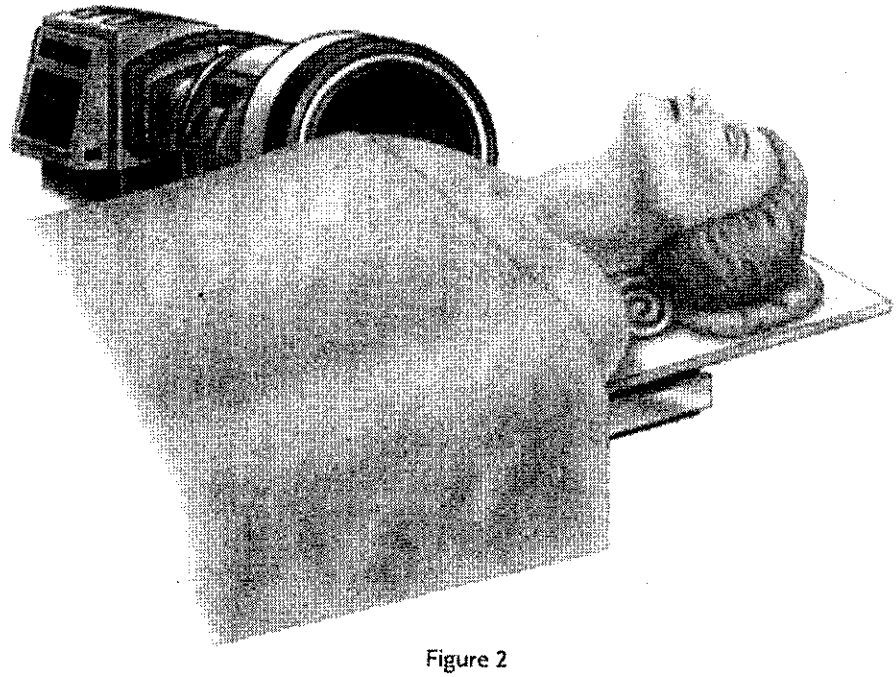

Figure 2

Typically, a transverse skin incision is made. An avascular dissection plane is developed between the trachea and the esophagus medially, and the carotid sheath laterally. Hand-held retractors are utilized to provide exposure of the anterior vertebral column and the adjacent longus colli muscles (*Figure 3*).

After the anterior vertebral column has been exposed, the longus colli muscles are subperiosteally elevated off of the vertebral bodies and the medial/lateral, self-retaining retractor blades are positioned beneath them.

Note: The presence of anatomical abnormalities and/or deformities, such as the presence of scoliosis or kyphosis or abnormal segmentation, may reduce the ability to ensure proper placement of the instrumentation and/or prosthesis. Under such circumstances, it may be necessary to perform a fusion procedure.

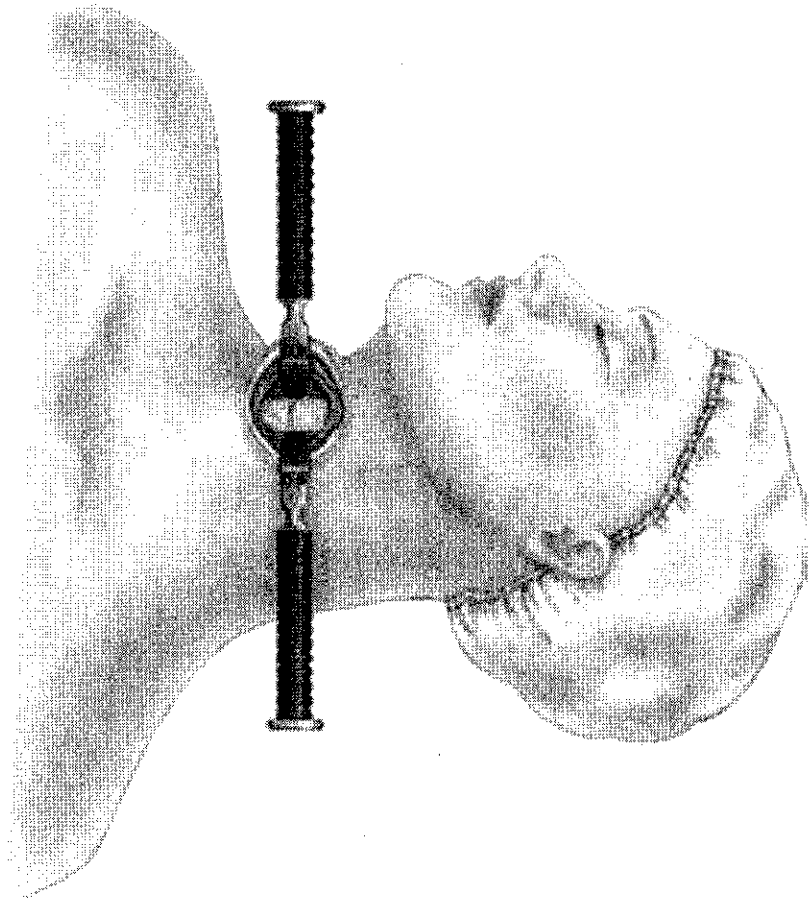

Figure 3

If Caspar distraction is used, vertebral body distraction pins are positioned midline in the vertebral bodies adjacent to the discectomy. The distractor is placed over the pins and the appropriate amount of distraction is applied. The discectomy is completed at the indicated level. Pituitaries, curettes, and kerrisons may be used to remove the disc material and cartilage and to expose the posterior longitudinal ligament (*Figure 4*). A high-speed drill with a burr (match tip/round) may be utilized for removal of the posterior disc and osteophytes to achieve neural decompression. The posterior longitudinal ligament is carefully removed exposing the underlying dura. Prepare the anterior surface of the vertebral bodies with the burr to remove any soft tissue and bony protrusions to create a flat surface.

This technique accomodates for halter, intradiscal, or pin distraction.

NOTE: Great care is taken to preserve the bony vertebral endplates.

NOTE: A complete and thorough discectomy and bilateral decompression are essential.

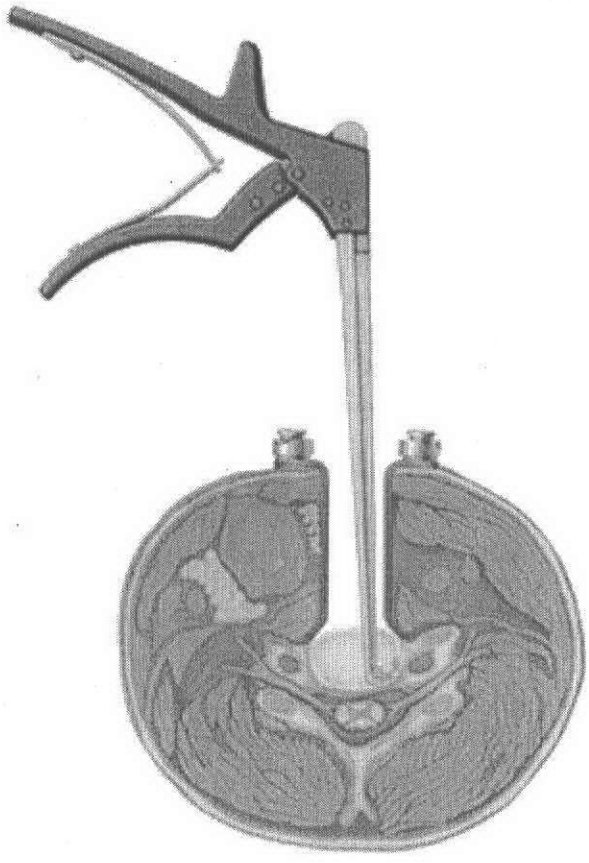

Figure 4

After the discectomy and decompression is complete, using either a round or cylindrical burr (surgeon preference), prepare the endplates so that they are flat and parallel (*Figures 5a and 5b*). Take care to preserve as much cortical bone as possible. It is important to complete the endplate preparation to the posterior aspects of the vertebral bodies to ensure maximum implant–endplate interface.

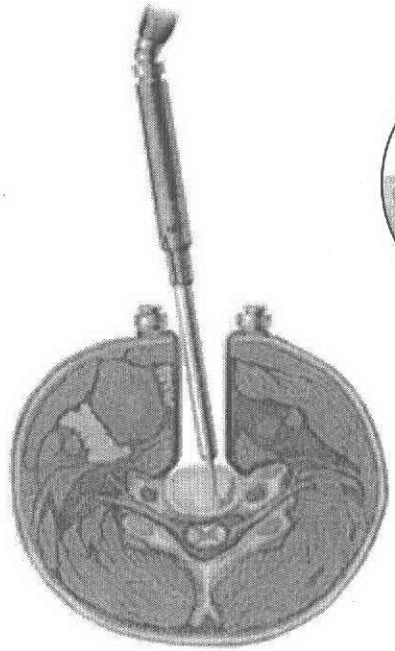

Figure 5a

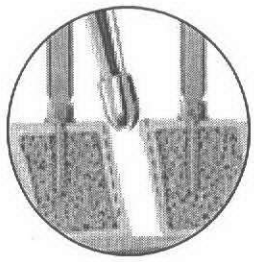

Figure 5b

Any protruding anterior osteophytes should be carefully removed to ensure a flush interface with the anterior flanges of the PRESTIGE® Cervical Disc *(Figures 6 and 7)*.

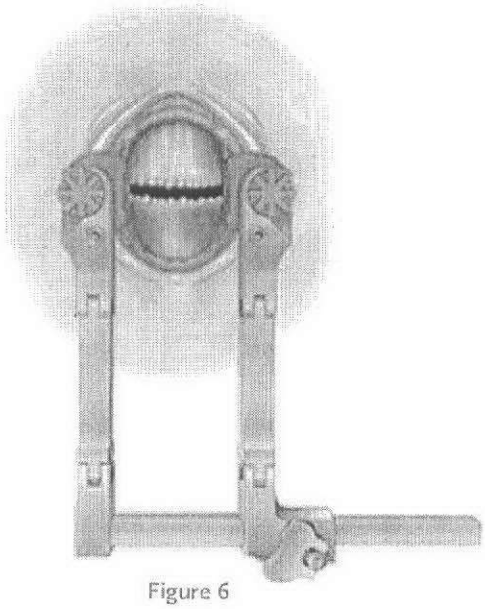

Figure 6

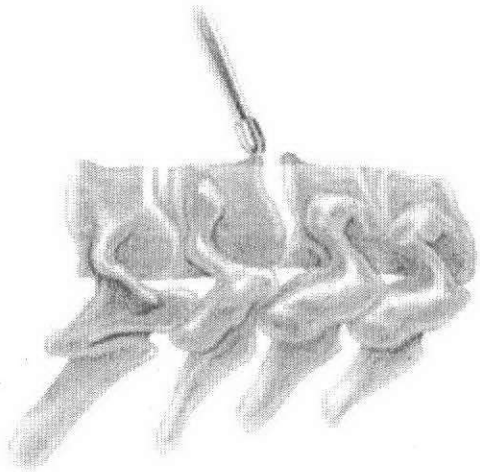

Figure 7

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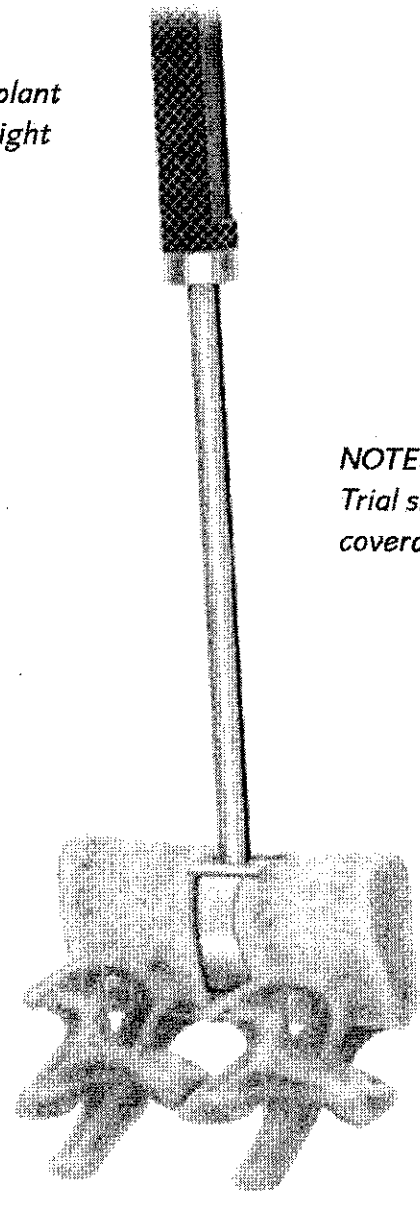
STEP 5 • Implant Size Selection

Utilize the Implant Trial to ensure accuracy of the prepared disc space. The Implant Trial features the same footprint as the corresponding PRESTIGE® Cervical Disc. After all distraction has been removed, it should slide into the prepared disc space with mild resistance. (*Figure 8*). Flouroscopy will confirm the appropriate measurement of anatomic disc space height.

NOTE: Appropriate height Implant Trial should fit snug, but not tight in the disc space. Do not over stuff.



NOTE: Appropriate depth Implant Trial should maximize endplate coverage.

Figure 8

Utilise the corresponding Profile Trial to ensure accuracy of the anterior surface preparation and the angles relative to the disc space (*Figures 9 and 10*). Confirm under lateral flouroscopy that anterior surfaces of the Profile Trial are flush with anterior vertebral bodies. Additional anterior bone removal may be required to ensure a flush fit.

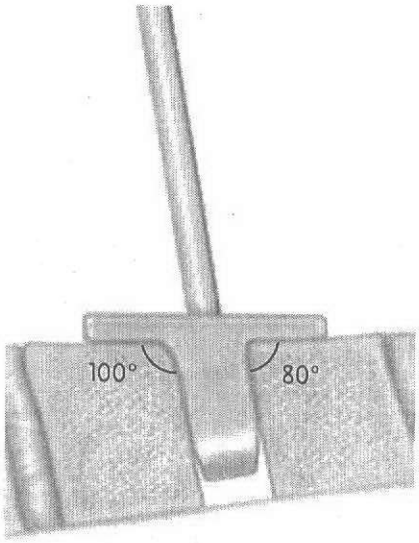


Figure 9

NOTE: The corner (edge) must be removed with a burr to match radius of implant.

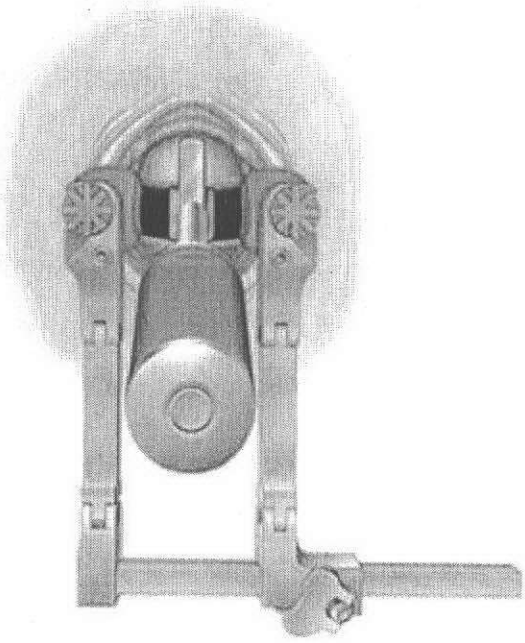


Figure 10

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From the packaging (*Figure 11*), load the appropriately sized PRESTIGE® Cervical Disc onto the bottom of the Implant Inserter by aligning the flanges of the disc between the superior and inferior components of the Implant Inserter. Tighten each pin by rotating it in a clockwise manner. The Implant Inserter and package are marked for proper superior/inferior orientation.

NOTE: Before placing the PRESTIGE® Cervical Disc into the prepared disc space, ensure the ball of the construct is placed cephalad (Figure 12). The disc should slide into the prepared disc space with only minor resistance (Figure 13).

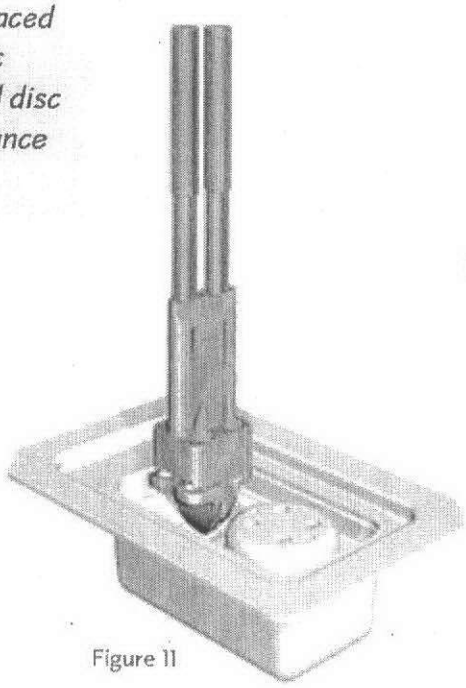

Figure 11

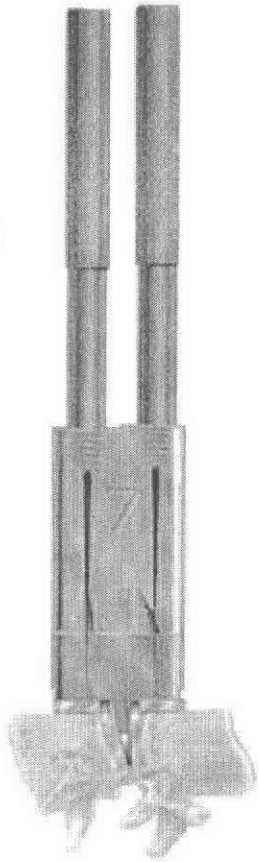

Figure 12

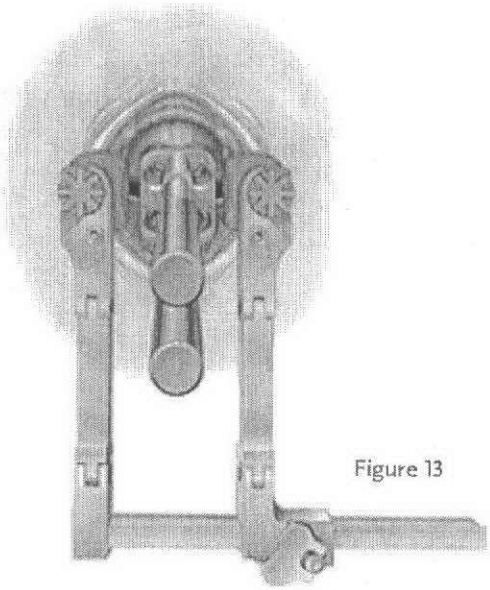

Figure 13

Drill and Insert Bone Screws and Lock Screws

With Implant Inserter in place, drill all four bone screw holes using the Drill Guide and 13mm drill (*Figure 14*). Make sure the Drill Guide properly aligns with the implant to ensure appropriate screw trajectory.

Remove the Drill Guide and place Bone Screws through the Implant Inserter (do not fully tighten). Bone Screws should be tightened sequentially until all four are completely tight (*Figure 15*).

After final tightening of the Bone Screws, remove Implant Inserter by unscrewing the pins counterclockwise. Tilt the Implant Inserter cephalad/caudal to release it from implant.

Place and tighten the Lock Screws over the heads of the Bone Screws (*Figure 16*).

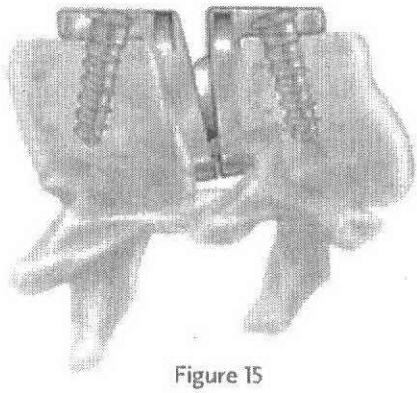

Figure 15

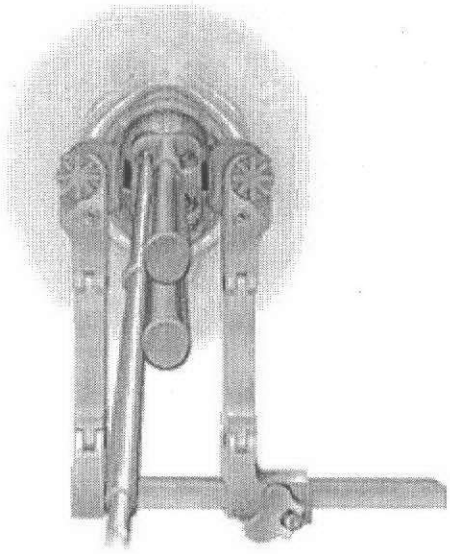

Figure 14

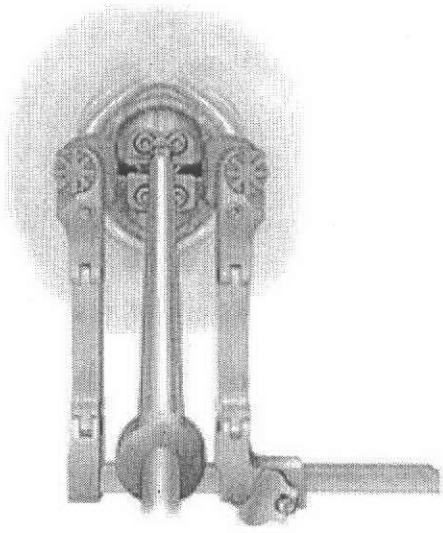

Figure 16

Following final disc insertion (*Figure 17*), lateral and A/P flouroscopy should be taken to verify proper placement. Complete the surgery using standard anterior cervical disc closure procedures.

If explantation of the PRESTIGE® Cervical Disc is required, use the Lock Screwdriver to remove the Lock Screws and the Screwdriver to remove the Bone Screws. A separation of the implant from the endplate can be achieved using standard surgical instruments.

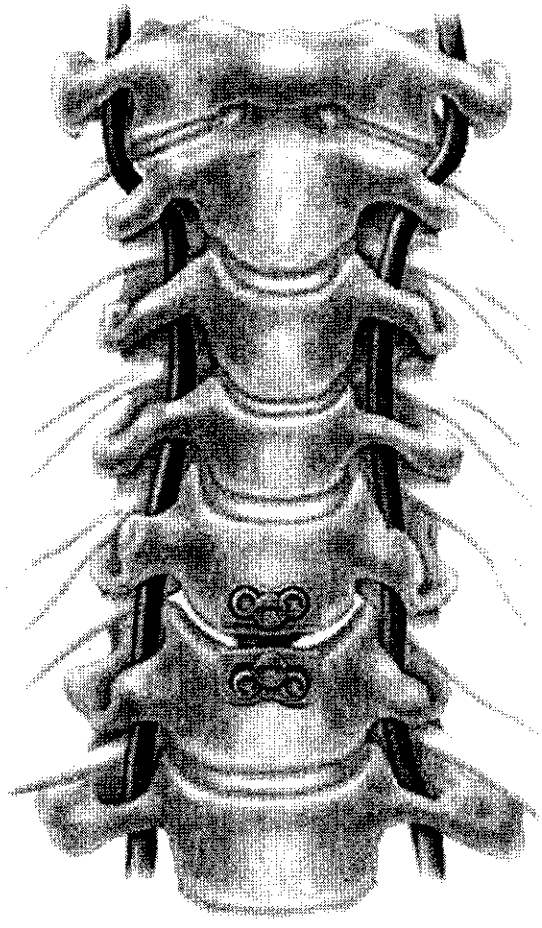

Figure 17

PRESTIGE® Cervical Disc System		
Part #	Description	Qty
6972226	Implant Trial 6x12	1
6972246	Implant Trial 6x14	1
6972266	Implant Trial 6x16	1
6972247	Implant Trial 7x14	1
6972267	Implant Trial 7x16	1
6972287	Implant Trial 7x18	1
6961326	Profile Trial 6mm	1
6961327	Profile Trial 7mm	1
6961266	Implant Inserter 6mm	1
6961267	Implant Inserter 7mm	1
6961215	Drill Guide	1
6971117	Universal Handle	2
6961241	Drill Bit (Sterile)	1
6961275	Screwdriver	1
6961285	Lock Screwdriver	1
6960281	Lock Screw Holder	1
6971419	Tray Base	1
6971420	Inner Tray	1
6971421	Tray Lid	1

Package insert will be placed here upon approval

Package insert will be placed here upon approval

Notes

listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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