PRESTIGE® CERVICAL DISC SYSTEM

EC REP
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: + 31 45 566 80 00

1800 Pyramid Place
Memphis, TN 38132
Telephone 800 876 3133 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax 901 396 0356

ENGLISH

IMPORTANT INFORMATION ON THE PRESTIGE® CERVICAL DISC SYSTEM

DESCRIPTION

The PRESTIGE® Cervical Disc is available in various sizes and consists of two articulating components, four bone screws, and two locking screws. Available depths (anterior to posterior) range from 12 mm to 18 mm, and heights range from 6 mm to 8 mm. The device is made of stainless steel.

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

INDICATIONS

The PRESTIGE® Cervical Disc is indicated in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C3-C7. DDD is defined as intractable radiculopathy and/or myelopathy 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. The PRESTIGE® device is to be implanted via an open anterior approach.

CONTRAINDICATIONS

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

ADVERSE EVENTS

The adverse effects, as shown in the table below, were reported from the 276 PRESTIGE® device patients and 265 control patients enrolled in the multi-center clinical study of the PRESTIGE® Cervical Disc. The control treatment was a single level anterior interbody fusion procedure with allograft and plate stabilization. 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.

Table 1. Adverse Events in Pivotal Study.

ADVERSE EVENTS[1]																
	Surgery		Postoperative 1 day - <4 Weeks		≥4 Wks - <9 Weeks 6 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	Inves.	Control	Inves.	Control	Inves.	Control	Inves.	Control	Inves.	Control	Inves.	Control	Inves.	Control	**Investig. # 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	2	2	18	18	14	12	9	9	19	6	32	18	15	17	70 (25.4) 109	66 (24.9) 82
Other Pain	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)

The reported rates of several adverse events were greater than 10% in both the investigational and control groups. These events included neck and/or arm pain, neurological, other, other pain, and trauma. Spinal events occurred in 11.3% of the control patients but 6.2% of the investigational patients.

Some of the reported adverse events required surgical interventions subsequent to the initial surgery. The investigational group had a statistically lower rate of secondary surgical procedures related to implant revisions and supplemental fixations. Investigational patients also experienced a lower rate of implant removals, but it was not statistically different. These findings resulted in a lower second surgery failure rate for investigational patients.

[1] Based on 24-month cohort.

The incidence of most adverse events that were considered to be implant- or implant/surgical procedure-associated, including implant displacement/loosening and neck and/or arm pain, were greater in the control group compared to the investigational group. However, the rates of all these events were low in both groups. Six serious (WHO Grade 3 or 4), implant- or implant/surgical procedure-associated adverse events were reported; all of these occurred in control patients. No deaths were reported among investigational patients. Three control group deaths were reported, all of which were due to myocardial infarction or cardiac arrest.

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. 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 adverse reactions to anesthesia; pulmonary complications such as pneumonia or atelectasis; infection of the wound; systemic infection; abscess; cellulitis; wound dehiscence; swelling; wound hematoma; thrombosis; ischemia pulmonary embolism; thromboembolism; hemorrhage; thrombophlebitis; organ, nerve or muscular damage and death.
2. Risks associated with anterior interbody replacements of the cervical spine include dysphagia; dysphasia; dysphonia; otitis media; recurring aspirations; fistula; nerve deficits or damage; malunion of the mandible; tracheal, esophageal, and pharyngeal perforation; airway obstruction; external chylorrhea; hoarseness; vocal cord paralysis; warmth or tingling in the extremities; neural damage; damage to the spinal cord or nerve root; or graft in the neural canal; dural tears or leaking; loss of disc height; loss of proper curvature, correction, height or reduction of the spine; vertebral slipping; nerve root trauma; scarring, herniation or degeneration of adjacent discs; nerve damage possibly resulting in paralysis or pain, and surrounding soft tissue damage, vascular damage; spinal stenosis; and spondylolysis.
3. Risks associated with any implants in the spine are early or late loosening of the components; disassembly; bending or breakage of any or all of the components; implant migration; loss of purchase; implant fracture; bone fracture; foreign body reactions to the implant including allergic reaction; infection; possible tissue reaction; bone absorption; tumor formation or graft rejection; bone resorption; development of new radiculopathy; myelopathy or pain; cessation of bone growth of the operated portion of the spine; decreased strength of extremities; decreased reflexes; appearance of cord or nerve root injury; pseudoarthrosis; fracture of the vertebral body. Additionally, there is the possibility of misdiagnosis or missed diagnosis with radiographic imaging of the spine when implants are present.
4. Early or late loosening or movement of the device.
5. Implant migration.
6. Breakage of any or all of the components or instruments.
7. Foreign body reaction to the implants including possible tumor formation, auto immune disease, metallosis, and/or scarring.
8. Pressure on the surrounding tissues or organs, possibly resulting in oesophagas or trachea breakdown from component parts where there is inadequate tissue coverage over the implant. Implant or graft extrusion can lead to fistular complications.
9. Loss of proper spinal curvature, correction, height, and/or reduction.
10. Infection.
11. Bone fracture or stress shielding at, above, or below the level of surgery.
12. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis or other types of serious injury. Cerebral spinal fluid leakage.
13. Haemorrhage and/or hematomas.
14. Discitis, arachnoiditis, and/or other types of inflammation.
15. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
16. Inability to resume activities of normal daily living.

17. Death.

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

WARNINGS AND PRECAUTIONS
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.

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

CLINICAL RESULTS
A multi-center equivalency[2] 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 clinical trial had a prospective, randomized, controlled design.

Inclusion criteria for the clinical trial included symptomatic degenerative disc disease as noted by intractable neck and/or arm pain, functional deficit, and/or neurological deficit, with positive diagnostic imaging finding(s); a preoperative Neck Disability Index score of ≥30; a preoperative neck pain score of ≥20 based on a modified visual analog scale; single level symptomatic involvement from C3-C7;. Specifically excluded from the study were patients who: had a previous surgical intervention at the involved spinal level or a previous fusion at an adjacent level; had instability at the involved cervical level; had osteopenia, osteoporosis, or osteomalacia; or had conditions or were receiving medications which could interfere with bone metabolism.

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

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.

Individual subject success (i.e. overall success) was defined in the study protocol as success in certain clinical outcome parameters. Success for these parameters included:

1. An improvement of at least 15 points from the baseline Neck Disability Index score;
2. Maintenance or improvement in neurological status;
3. No serious adverse event classified as implant-associated or implant/surgical procedure-associated; and
4. No additional surgical procedure classified as “Failure.”

In addition, an alternate overall success determination was made based on the above criteria with the addition of 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.

Study success was expressed as the number of individual subjects categorized as a success divided by the total number of subjects evaluated. The table below describes the success rates for individual outcome parameters and overall success. All success rates were based on the data from the 24-month

[2] PRESTIGE® device statistically no worse than the control.

follow-up evaluation 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 2. Posterior Probabilities of Success at 24 Months.

	Investigational	**Control**
Primary Outcome Variable	Posterior Mean (95% HPD Credible Interval)	Posterior Mean (95% HPD Credible Interval)
NDI	80.8% (74.7%, 87.0%)	80.8% (74.1%, 86.7%)
Neurological	92.1% (87.6%, 96.2%)	84.7% (78.6%, 90.5%)
FSU Height	95.4% (91.5%, 98.7%)	93.7% (89.2%, 97.8%)
Overall Success (without FSU)	78.8% (72.1%, 85.0%)	70.0% (62.7%, 77.4%)
Overall Success (with FSU)	80.1% (73.1%, 87.4%)	64.0% (55.3%, 72.8%)

Bayesian statistical analyses yielded a posterior probability of non-inferiority at 24 months of approximately 100%. The posterior probability of superiority was found to be 95.9%.

With FSU height included in the overall success criteria, the probability (also called the posterior probability) that the 24-month overall success rate for the investigational group was equivalent to the 24-month success rate for the control group was 100%. The posterior probability of superiority was 99.7%.

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 SOFAMOR DANEK.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC SOFAMOR DANEK 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 SOFAMOR DANEK. 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

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:

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 SOFAMOR DANEK.

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 SOFAMOR DANEK. 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 SOFAMOR DANEK 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.

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 SOFAMOR DANEK.

DEVICE RETRIEVAL EFFORTS

Should it be necessary to remove a PRESTIGE® Cervical Disc device, please call MEDTRONIC SOFAMOR DANEK.