Synthes Spine 1302 Wrights Lane East West Chester, PA 19380 Tel. 610 719-5000 www.synthes.com

ProDisc-C Total Disc Replacement Fact Sheet.

Background Information

- Motion preservation of the cervical spine is recognized as a breakthrough in the field of orthopedics, and is expected to make a significant impact on the surgical treatment of symptomatic cervical disc disease (SCDD) in the United States, as knee and hip replacements did over the last few decades.
- Drs. Rudolf Bertagnoli and Thierry Marnay, designers of the ProDisc-C implant, believed that preserving motion within a diseased vertebral segment could allow the spine to restore its balance and maintain more natural mechanics, which may decelerate degeneration in adjacent vertebral segments in the spine over time.
- The first ProDisc-C Total Disc Replacement surgery was performed in Europe in 2002.
- In the United States, an IDE study was initiated in the summer of 2003. The ProDisc-C Total Disc Replacement was approved by the FDA based on the results of this prospective, randomized, multi-center clinical trial (IDE study) in December of 2007.
- The recent FDA approval of ProDisc-C Total Disc Replacement provides US spine surgeons a clinically proven alternative to fusion surgery for the treatment of intractable symptomatic cervical disc disease (SCDD).
- Spinal fusion is intended to relieve pain by eliminating motion at the diseased vertebral segment, but it can create spinal imbalance, alter the biomechanics of the spine, and increase stresses and motion in adjacent vertebral segments that may accelerate further degeneration. The ProDisc-C Total Disc Replacement provides the potential to restore motion.

Product Description

- The ProDisc-C Total Disc Replacement utilizes a ball and socket design similar to joint replacement devices that have been successfully used for many decades.
- The ProDisc-C implant is comprised of three components: two metal endplates separated by a medical grade plastic core. The endplates are made of cobalt chrome alloy (CoCrMo) and the plastic core is ultra-high molecular weight polyethylene (UHMWPE). The implant is inserted en-bloc and is securely anchored in the spine with patented keel technology.
- The ProDisc-C implant materials have proven biocompatibility in the body. These materials have been used in spinal disc replacement for over two decades and are the most commonly used materials in knee and hip replacements.

Surgical Procedure

- The ProDisc-C Total Disc Replacement is implanted in the cervical spine through a small incision in the patient's neck.
- During the ProDisc-C Total Disc Replacement procedure, the surgeon removes the diseased intervertebral disc, decompresses the neurological elements and inserts a ProDisc-C implant into the disc space.

Synthes Spine 1302 Wrights Lane East West Chester, PA 19380 Tel. 610 719-5000 www.synthes.com

IDE Study Results

- The ProDisc-C Total Disc Replacement was evaluated for safety and effectiveness as part of an FDA-regulated IDE clinical study. The prospective, randomized trial was conducted at 13 centers across the United States. Patients suffering from symptomatic cervical disc disease (SCDD) at a single level from C3-C7 were randomized 1:1 to receive either a ProDisc-C Total Disc Replacement or an anterior cervical decompression and fusion (ACDF) with cortical ring allograft bone and cervical plate.

- In 2003 the first US patient was implanted with the ProDisc-C as part of an FDA Investigation Device Exemption (IDE) clinical study. The study involved 209 patients at 13 centers across the country. Based on the results of this randomized, prospective, multi-center IDE study, the ProDisc-C Total Disc Replacement was approved for use in the United States on December 17, 2007.

- Highlights of IDE study comparing ProDisc-C to anterior cervical decompression and fusion (ACDF):
  - The ProDisc-C Total Disc Replacement was determined to be safe and effective for the treatment of intractable symptomatic cervical disc disease (SCDD) by the FDA.
  - ProDisc-C patients demonstrated a significant improvement in pain and disability, and required fewer re-operations than ACDF patients.
  - Patients receiving the ProDisc-C Total Disc Replacement demonstrated a mean range of motion of 9.4° at the 24 month follow-up.
- Only surgeons who have completed an intensive training program can implant the ProDisc-C Total Disc Replacement.

Indications for Use

The ProDisc-C Total Disc Replacement is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height. The ProDisc-C Total Disc Replacement is implanted via an open anterior approach. Patients receiving the ProDisc-C Total Disc Replacement should have failed at least six weeks of non-operative treatment prior to implantation of the ProDisc-C Total Disc Replacement.

Synthes Spine 1302 Wrights Lane East West Chester, PA 19380 Tel. 610 719-5000 www.synthes.com

Contraindications

The ProDisc-C Total Disc Replacement should not be implanted in patients with the following conditions:

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis defined as DEXA bone density measured T-score ≤ -2.5
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3mm and/or > 11° of rotational difference to either adjacent level
- Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- Severe spondylosis characterized by bridging osteophytes or a loss of disc height > 50% or an absence of motion (<2°), as this may lead to limited range of motion and may encourage bone formation (e.g., heterotopic ossification, fusion)
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion)