Consumer Information on: SECURE-C Artificial Cervical Disc - P100003

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: SECURE®-C Artificial Cervical Disc
Manufacturer: Globus Medical, Inc
Address: 2560 General Armistead Avenue, Audubon, PA 19403
Approval Date: September 28, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100003a.pdf [1]

What is it? The SECURE®-C Artificial Cervical Disc consists of two metal (cobalt-chrome alloy) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (vertebrae) to replace a diseased cervical disc [2] that is causing arm pain and/or weakness or numbness.

How does it work? The implanted device is designed to restore the distance between the two vertebrae (disc height) and allow motion at the treated level as the plastic core moves against the metal endplates.

When is it used? The SECURE®-C Artificial Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy [3] or myelopathy [4]) at

only one level.

What will it accomplish? The device should help stabilize the operated disc in the neck. Unlike a fusion procedure [5], the SECURE®-C Artificial Cervical Disc is designed to allow motion at the operated disc. The effects of the diseased disc removal should include pain relief and improved function.

When should it not be used? You should avoid having surgery with the SECURE®-C Cervical Artificial Disc if you have any of the following conditions:

- Whole body (active systemic) infection or an infection at the operating site, as undergoing surgery could interfere with your ability to heal and could increase the chance of spreading or worsening the infection.
- Thin or weak bones resulting from a loss of calcium (osteoporosis or osteopenia) because this condition could increase the risk of bone fracture, or could cause the device to loosen.
- Allergy to the metals in the device (cobalt, chromium, molybdenum, or titanium), or to the type of plastic used in the device (polyethylene) because this could cause an allergic reaction.
- An unstable cervical spine as seen on X-rays and determined by your doctor, because the SECURE®-C Artificial Disc surgery involves removal of the disc without the use of a stabilizing plate (as is routinely done for fusion) and this may cause further instability.
- Advanced spinal arthritis (severe spondylosis) as determined by your doctor, as your disc may have begun to turn into bone, which could severely limit any motion that could be achieved.
- Severe deterioration of the facet joint between each vertebra (facet joint arthropathy) as determined by your doctor, which is not treated by the replacement of the disc.
- Weakened bones at the affected level due to current or past trauma as determined by your doctor, which could increase the risk of the device loosening.
- More than one cervical disc requiring treatment, as the device has only been evaluated in patients with one cervical disc requiring treatment.

Additional Information: The Summary of Safety and Effectiveness Data and labeling [6] are available online.

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