IN:C2 Spinal Fixation System

INDICATIONS:
The IN:C2 Spinal Fixation System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. IN:C2 is a stand-alone device intended to be used with an anterior cover plate and a minimum of two bone screws angled both cephalad and caudal with a minimum of one screw into each vertebral body. The implants are to be used with autogenous bone graft and implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS:
1. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
2. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
3. Known allergic sensitivity to PEEK-OPTIMA.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g., cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).

MATERIALS:
IN:C2 implants are manufactured from PEEK-OPTIMA LT1 and Titanim. Surgical instruments provided with the IN:C2 implants are manufactured from stainless steel.

CLEANING of INSTRUMENTS:
1. Clean all instruments prior to use, and as soon as possible after use. Specific cleaning instructions are included in the System Surgical Technique, 1199-0002-MRK available through SpineSmith Customer Service. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.
3. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturers instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes.
4. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. SpineSmith recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.

STERILIZATION:
All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. In compliance with AAMI ST79, the following sterilization cycle will be validated prior to marketing and is expected to result in a SAL of 10⁻⁶:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
<th>Wrap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>20 minutes</td>
<td>2 times utilizing FDA cleared wrap</td>
</tr>
</tbody>
</table>

Instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be re-sterilized after surgery. Implants should not be used as templates in surgery. If an unwanted implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

POSTOPERATIVE MOBILIZATION:
The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.
WARNINGS:
Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.

b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.

c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.

d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.

e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS
1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.

2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.

3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.

6. THE IN:C2 DEVICE HAS NOT BEEN EVALUATED FOR SAFETY AND COMPATIBILITY IN THE MR ENVIRONMENT. The IN:C2 device has not been tested for heating or migration in the MR environment.

7. IMPLANTS FROM THIS SYSTEM AND ANOTHER SYSTEM NOT BE MIXED. The compatibility of dissimilar materials and proper interfaces with other similar systems and has not been established and should not be used.

POSSIBLE ADVERSE EFFECTS
1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:
SpineSmith products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issuance/revision of this document, and the date of patient consultation, contact SpineSmith for current information.

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