DESCRIPTION
The Royal Oak Cervical Plate System consists of self-tapping screws, self-drilling screws and plates. Screws are offered in 4.0mm and 4.3mm diameters with overall lengths ranging from 10mm to 20mm. One-, two-, three-, four- and five-level plates are offered. The Royal Oak Cervical Plate surgical technique is available at no charge upon request. For further information, please contact Customer Service at 248-572-9590.

MATERIALS
All components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or commercially pure titanium (Grade 2 or Grade 4) according to ASTM F67.

STERILIZATION
The Royal Oak Cervical Plate System components are supplied clean and not sterile. All implants and instruments should be cleaned and sterilized prior to surgery. AORN recommended practices for in hospital sterilization should be followed. Sterilization testing of components has shown the following recommendations for sterilization are effective to an SAL of 10⁶:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Prevacuum</td>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

CONTRAINDICATIONS
Use of the Royal Oak Cervical Plate System and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotropic diseases, obesity, pregnancy and foreign body sensitivity. See also the WARNINGS, PRECAUTIONS AND POTENTIAL RISKS sections of this insert.

WARNINGS
1. The Royal Oak Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

2. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury. See the Potential Risks section of the package insert for a complete list of potential risks.

PRECAUTIONS
1. PATIENT SELECTION. Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for spinal fixation surgery using the Royal Oak Cervical Plate System. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis. Based upon the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

2. PATIENT EDUCATION. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

3. HANDLING. Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the plate or screw surfaces as these may induce premature failure of the component.

4. IMPLANT SELECTION. The Royal Oak Cervical Plate System components are available in a variety of sizes to insure proper fit of the implanted device. The potential for the success of the fusion is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine.

5. MIXED METALS. The Royal Oak Cervical Plate System is available in titanium. It is imperative that this metal does not come into contact with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.

6. SINGLE USE ONLY. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.

7. DELAYED UNION OR NONUNION. The Royal Oak Cervical Plate System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.

POTENTIAL RISKS
Potential risks identified with the use of this system, which may require additional surgery, include: Bending, fracture or loosening of implant component(s), Nonunion or delayed union, Fracture of the vertebral, Neurological, vascular or visceral injury, Metal sensitivity or allergic reaction to a foreign body, Infection, Decrease in bone density due to stress shielding, Pain, discomfort or abnormal sensations due to the presence of the device, Nerve damage due to surgical trauma, Bursitis, Dural Leak, Paralysis, Death.

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