ROMD

Royal Oak IBFD System

ROMD, LLC
2967 Waterview Drive
Rochester Hills, MI 48309

System Contents:
- Non-Sterile Implants – Single Use Only
- Non-Sterile Instruments – Reusable

End of usable life for metal surgical instruments is normally determined by wear and tear due to intended surgical use.

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION and INTENDED USE:

The Royal Oak IBFD System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:
Royal Oak IBFD System interbody fusion device(s), which may be implanted
- bi-laterally via a posterior (PLIF) approach;
- as a single device via a transforaminal (TLIF) approach; or
- as a single device via an anterior (ALIF) approach.

INDICATIONS:

When used as a lumbar intervertebral body fusion device, the Royal Oak IBFD System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

CONTRAINDICATIONS:

1. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
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).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:

The Royal Oak IBFD System implant components are made of polyether etherketone (PEEK) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.
The Royal Oak IBFD System is implanted using a combination of device specific and universal Class I instruments manufactured from stainless steel materials that conform to ASTM F899.

CLEANING of INSTRUMENTS:

1. Thoroughly clean all instruments prior to use, and as soon as possible after use. 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. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturer's 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.
3. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. It is recommended to perform manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.
4. Pre-Treatment is required for any instrument(s) heavily soiled and/or containing dried organic material in accordance with **Table 1**.

Table 1 Cleaning Instructions

<table>
<tr><th>Step</th><th>Instructions</th></tr>
<tr><td rowspan="2">1. Pre-Treatment</td><td>Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of tap water. Using a soft bristle brush, clean the instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.</td></tr>
<tr><td>Rinse in warm running tap water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the above steps if necessary. Allow to dry, and then transfer to the cleaning step.</td></tr>
<tr><td>2. Ultrasonic Clean (if required)</td><td>Add one (1) ounce of Enzol (or equivalent) and one (1) gallon of warm tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes.</td></tr>
<tr><td>3. Ultrasonic Rinse</td><td>To remove the detergent, thoroughly rinse each instrument with deionized water including all holes and cannulations. Inspect each instrument for evidence of organic matter. Repeat the sonication and rinse if needed.</td></tr>
<tr><td>4. Automated Washer</td><td>Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load instruments such that contact is avoided and articulating instruments are in the open position.
Automated Cleaning Parameters
<table>
<tr><th>Step</th><th>Time (mm:ss)</th><th>Minimum Temp. (°C)</th><th>Cleaning Agent</th></tr>
<tr><td>Enzymatic Wash</td><td>04:00</td><td>Hot Tap Water</td><td>Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz./gal)</td></tr>
<tr><td>Wash</td><td>02:00</td><td>65.5°C</td><td>Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz./gal)</td></tr>
<tr><td>Rinse</td><td>02:00</td><td>70°C</td><td>Not Applicable</td></tr>
<tr><td>Dry</td><td>15:00</td><td>80°C</td><td>Not Applicable</td></tr>
</table></td></tr>
<tr><td>5. Inspection</td><td>Visually inspect each instrument for evidence of organic matter. Repeat the cleaning process if necessary. If instruments are wet, use a lint-free wipe to dry.</td></tr>
</table>

INSPECTION:

1. Carefully inspect each instrument to ensure all visible blood and soil have been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your ROMD, LLC representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your ROMD, LLC representative for a replacement.

STERILIZATION:

The Royal Oak IBFD System is provided non-sterile and is delivered to the customer in a surgical kit, which is comprised of implant caddies, instrument trays and cases. The following steam sterilization cycle has been validated and shown to result in a SAL of 10^{-6}.

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270ºF (132ºC)
Exposure Time:	4 minutes
Dry Time:	30 minutes
Wrap:	2 times utilizing FDA cleared wrap

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.

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 to 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. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. 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 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 two 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 noncompliant with post-operative guidance is particularly at risk during the early postoperative period.
6. MR ENVIRONMENT. The Royal Oak IBFD System has not been evaluated for safety and compatibility in the MR environment. The Royal Oak IBFD System has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS:

1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior 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.
10. Paralysis.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:

ROMD, LLC warrants all instruments to be free from defects in material or workmanship for 1 year from date of delivery.

Warranty void if product failure resulted from normal wear and tear from instrument use, accident, abuse, misapplication, negligence, or if product has been damaged, altered, or repaired outside of ROMD's facility. Warranty void if purchased from a non-authorized supplier/distributor.

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For product information, questions pertaining to sales and service, or to obtain a copy of the surgical technique manual, please contact your local sales representative or ROMD, LLC customer service.

LC-021 Rev 5 7/7/2022 ECR #1902