BENGAL® System
CONCORDE® System
CONCORDE® Bullet System
CONCORDE® Inline System
CONCORDE® Curve System
COUGAR® System
DEVEX® System
LEOPARD® System

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The BENGAL®, CONCORDE®, CONCORDE® Bullet, CONCORDE® Inline, CONCORDE® Curve, COUGAR®, DEVEX® and LEOPARD® Systems consist of carbon fiber reinforced PEEK or titanium cages and implantation instrumentation. Cages are available in varying shape and size configurations to match patient anatomy. The carbon fiber reinforced PEEK cage structure is radiolucent with tantalum x-ray markers so that healing can be assessed by normal radiographic methods. The cages have ridges or teeth that resist rotation and migration and have cavities to accept packing of bone graft.

**INDICATIONS**

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) that has appropriate training or experience.

**CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems Indications**

The CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet, CONCORDE Inline,), TLIF (CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

**BENGAL System Indications**

The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an
anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation products may be used.

**CONTRAINDICATIONS**

1. Use of these systems is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.

2. Severe osteoporosis or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.

3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases, are relative contraindications. The decision to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

5. Prior fusion at the level(s) to be treated.

6. Any condition not described in the Indications for Use.

**WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS**

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 devices such as these systems. General surgical risks should be explained to the patient prior to surgery.

These systems are intended to support the vertebral column while fusion is taking place. These implants are intended to be permanent. The recommendations for removal of hardware apply to the supplemental internal fixation implants used in this procedure.
WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. **MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.
2. Correct Handling of the Implant is Extremely Important.
   A. Composite Implants: carbon fiber reinforced PEEK implants are designed to support physiologic loads. Excessive torque, when applied to long-handle insertion tools, can cause splitting or fracture of the carbon fiber reinforced PEEK implants. When a carbon fiber reinforced PEEK implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced. Implants can break when subjected to the increased loading associated with delayed union or nonunion.

   B. Metal Implants: Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid notching, scratching or reverse bending of the implants when contouring.

3. Removal of Supplemental Fixation after Healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implants. Implant removal should be followed by adequate postoperative management to avoid refracture. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. Adequately Instruct the Patient. Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration and damage nerves or blood vessels
5. **Cauterization Near the Implant**: When performing cauterization around an implant, care should be taken to avoid contact with the implant.

6. **Patients with Previous Surgery.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

**ADVERSE EFFECTS**

This list may not include all complications caused by the surgical procedure itself.

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels.
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period.
13. Bending or fracture of the implant. Loosening of the implant.
14. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
15. Death.
17. There is an additional risk if there were to be long term in vivo degradation of the implant resulting in possible local or systemic adverse reactions from any potential degradation products.
18. If a pseudarthrodesis occurs coupled with the implant, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.

19. Subsidence

**IMPORTANT NOTE TO OPERATING SURGEON**

Interbody fusion procedures should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Even for surgeons already experienced in spinal instrumentation or interbody fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications.

**POSTOPERATIVE MOBILIZATION**

Postoperative external immobilization (such as bracing or casting) is recommended, at the surgeon’s discretion. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

**CLEANING AND STERILIZATION**

The BENGAL, CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX and LEOPARD System(s) implants may be provided either sterile or non-sterile and this will be clearly identified on the product labels.

**Sterile Implants**

For the implants supplied sterile, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging, using aseptic technique, only after the correct size has been determined.

**PRECAUTION:** Do not use implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile.

Implants must **not** be resterilized.
Non-sterile Implants
For the implants supplied non-sterile, they will be supplied clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Cleaning instructions
• Enzyme soak
• Rinse
• Ultrasonic cleaning (10-20 minutes)
• Rinse
• Automated cleaning in a washer disinfector with lid on to contain implant components
• Dry

Avoid impact, scratching, bending or surface contact with any materials that might affect the implant surface or configuration.

Special attention shall be paid to recesses since both chemicals and rinse water may be entrapped in them.

Wrap implants in accordance with local procedures using standard wrapping techniques such as those described in ANSI / AAMI ST79:2006.

Implants previously implanted must not be re-used.

RECOMMENDATIONS FOR STEAM STERILIZATION:
In a properly functioning calibrated steam sterilizer, independent testing has shown that effective sterilization may be achieved using the following parameters:

- Cycle: Pre-Vacuum
- Temperature: 270° F (132° C)
- Exposure time: 4 minutes
- Drying time: 45 minutes for BENGAL, CONCORDE, COUGAR, and LEOPARD Systems
  30 minutes for DEVEX, CONCORDE Bullet, CONCORDE Inline, and CONCORDE Curve Systems
Post-sterilization drying of the sterilization load within the sterilization vessel is standard practice in hospitals. ANSI/AAMI ST79:2006, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” provides guidance to hospitals for selecting appropriate drying parameters based on the sterilization cycle that is being conducted. Sterilizer manufacturers also typically provide recommendations for drying parameters for their specific equipment.

Inspect visually for damage or the presence of blood or tissue. If blood or tissue is observed on the implant, it must be thoroughly cleaned manually using a soft brush and neutral pH detergent or discarded.

**MAGNETIC RESONANCE (MR) COMPATIBILITY**

The BENGAL, CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX and LEOPARD System(s) implants have not been evaluated for safety and compatibility in the MR environment. The BENGAL, CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX and LEOPARD System(s) implants have not been tested for heating or migration in the MR environment.

**LIMITED WARRANTY AND DISCLAIMER**

PRODUCTS FROM DEPUY SYNTHES PRODUCTS, INC. 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 TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT DEPUY SYNTHES SPINE FOR CURRENT INFORMATION AT +1-800-365-6633 OR AT +1-508-880-8100.
### SYMBOL TRANSLATION

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<thead>
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<td>REF</td>
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<td>NTI</td>
<td>NEURAL TISSUE INSTRUMENT</td>
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<td>IOM</td>
<td>NEUROMONITORING INSTRUMENTS</td>
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<td>Rx Only</td>
<td>Federal (USA) law restricts this device to sale by or on the order of a physician</td>
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**PEEK/C**

**PEEK/CARBON FIBER COMPOSITE**

Polyether Ether Ketone / Carbon Fiber Composite

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**T Ti**

Titanium and its alloys
* For recognized manufacturer, refer to product label.

**US REP**

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