**Contraindications include,** but are not limited to:

1. Active infection or significant risk of infection (immunos-suppressive).
2. Signs of local inflammation.
3. Fever or leukocytosis.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical condition which could potentially deprive the patient of the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate, anemia, organ failure, elevated white blood count (WBC), or a marked left shift in the WBC differentials.
9. Rapid joint disease, bone absorption, osteoporosis, and/or osteosclerosis.
10. Any condition that, in the opinion of the surgeon, would limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
11. Coagulation disorder.
12. Any case where a bone graft is used.
13. Any case where the implants selected for use would be too large or too small to achieve a successful result.
15. Any patient who, at the surgeon’s discretion, may be a poor candidate for this procedure.
16. Any case not desired by the patient or the operating surgeon.

**Implant Selection**

1. The implant's size, proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the size to the size and shape of human bones. Unless great care is taken in the selection of the proper size and shape of implant, and postoperative maintenance, the implant may not grow to fit, result in failure, or migrate, which may cause severe pain. The surgeon must be aware of the limitations of the device before the surgery begins, and the patient in order to prevent any complications. The surgical procedure should be revised and/or removed immediately before serious injury occurs. The patient should be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
2. Any device should be removed if the patient experiences any of the following conditions:
   - Signs of local inflammation around the implant.
   - Migration of implant position.
   - Infection at the implant site.
   - Fracture or breakage of the implant material.
   - Bone loss due to local stress or implant failure.
   - Increased risk of infection due to the presence of the implant.
   - Bone loss due to stress shielding.
   - Potential short-term and/or long-term effects such as scarring, infection, nerve damage, or infection.

**POSSIBLE ADVERSE EFFECTS**

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible, including, but not limited to:

1. Early or late onset of any of the above.
2. Discomfort, bending, or movement limitations, or change in the surgical site.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from fretting, fretting and/or mechanical degradation), including metallosis, trauma, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from components in patient with inadequate tissue coverage over the operative site or inadequate bone stock or quality.
5. Foreign body (allergic) reaction to implants, debris, corrosion products (from fretting, fretting and/or mechanical degradation), including metallosis, trauma, tumor formation, and/or autoimmune disease.
6. Pressure on the skin from components in patient with inadequate tissue coverage over the operative site or inadequate bone stock or quality.
7. Bone graft must be placed in the area to be fused and graft material must extend from the top of the lowest vertebral segment to be fused.
8. To assure stability, maximum support, two or more cross connectors on two bilaterally-placed, co-axial rod systems should be used whenever possible.
9. Bone cement should not be used because the safety and effectiveness of bone cement has not been established in spinal surgery, and this material will cause migration of the components difficult or impossible. The heat generated from curing bone cement may also cause neurological damage and bone necrosis.
10. Bone graft must be stored in the area to be fused and graft material must extend from the top of the lowest vertebral segment to be fused.

**POSSIBLE ADVERSE EFFECTS**

1. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
2. Any patient who, at the surgeon’s discretion, may be a poor candidate for this procedure.
3. Any case not desired by the patient or the operating surgeon.

**CONTRAINDICATIONS**

Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

1. Active infectious process or significant risks of infection (immuno-compromise).
2. Signs of local inflammation.
3. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
4. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
5. Active infectious process or significant risks of infection (immuno-compromise).
6. Mental illness.
7. Pregnancy.
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