**INSTRUCTIONS FOR USE**
**TURBO PRIME™ Interbody Device (IBD)**

**CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.**

**Intended Use:**
**TURBO PRIME IBD** implants are lumbar vertebral Interbody Devices that are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, who have had at least six months of non-operative care for their DDD. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autogenous bone graft material.

**Device Description**
The **TURBO PRIME IBD** is a Titanium metal Interbody Device for use in the lumbar spine to facilitate fusion in patients with Degenerative Disc Disease (DDD).
**TURBO PRIME IBD** implants are available in various sizes to accommodate various disc heights. The upper and lower surfaces of the **TURBO PRIME IBD** are opened to offer optimal contact between the graft and the vertebral endplates. **TURBO PRIME IBD** shape is designed to enhance the stability and area of interaction with the vertebral endplates. The openings on the sides of the **TURBO PRIME IBD** provide for complete filling before insertion. **TURBO PRIME IBD** implants are made of a titanium alloy (Ti-6A1-4V-ELI) that conforms to ASTM F136. **TURBO PRIME IBD** should not be used with components from any other manufacturer.

Custom instruments and trial spacers in the **Turbo MIS TLIF System** are also provided to facilitate implantation of the **TURBO PRIME IBD** devices.

**Indications:**
The **Turbo Prime IBD** (Interbody Device) System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies who have had at least six months of non-operative care for their DDD. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

**Contraindications:**
The **TURBO PRIME IBD** should not be implanted in patients with active infections at the operative site or other active systemic infection, tumor involvement at the operative site or metal sensitivity.

**Warnings and Precautions**

**Warnings** associated with the **TURBO PRIME IBD** include:

- Loss of fixation or fracture of the implants or instruments
- Failure to sufficiently relieve pain or other situations may require a reoperation to remove, reposition, replace or supplement the Turbo Prime IBD implant**.**

The **TURBO PRIME IBD** has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of **TURBO PRIME IBD** in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions: Safety and effectiveness has not been established in the following conditions:

- Gross obesity
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis that is Grade II or greater
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

**TURBO PRIME IBD** implants and **Turbo MIS TLIF System** trial spacers and custom instruments are provided non-sterile and must be steam sterilized prior to use.

No implant should be reused if it has come in contact with blood or other bodily fluids.

All implants, trial spacers and custom instruments should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to the manufacturer.

Potential adverse events may be related to surgery in general, spine surgery or the device. These may include, but are not limited to the following:

> Adverse events related to any surgery: reactions to anesthesia, the anesthetic or other medications, bleeding, infection, ileus, blood vessel damage, nerve or soft tissue damage, atelectasis, pneumonia, hematoma, seroma, wound dehiscence or Incisional hernia, urologic problems, embolism, anemia, colitis, thrombophlebitis, heart attack, stroke or death.
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> Adverse events related specifically to spine surgery: dural tear and CSF leak, nerve damage leading to radiculopathy, myelopathy, paraparesis, parasthesia or paralysis, meningitis, vertebral body damage or fracture, ligament damage, fractured sacrum, or retrograde ejaculation.
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> Adverse events related to the device: implant crack, fracture, failure to achieve fusion, metal sensitivity, migration or dislodgement. Additional surgery may be necessary for implant removal, repositioning or replacement. Additional stabilization at the implanted level or surgery at another disc level may be necessary if non-union or anatomic change at an adjacent level develops.

**Packaging:**

All components of **TURBO PRIME IBD** and the **Turbo MIS TLIF System** are supplied in a single container tray (kit), except in the case of restock. The kit must be closed and sealed; its packaging intact upon receipt. In the case of restock, the set should be carefully checked for completeness.
Storage conditions must maintain the integrity of the implants, associated ancillary instruments and their respective packaging. The condition of all implants and instruments must be checked before use. **Damaged packages or products should not be used and should be returned to SPINAL ELEMENTS.**

**Decontamination, Cleaning, and Sterilization**

All **TURBO PRIME IBD** implants and ancillary instruments of the **Turbo MIS TLIF System** are delivered non-sterile and therefore, must be **decontaminated, cleaned and sterilized** prior to surgical use. Decontamination and cleaning reduces the population of microorganisms and facilitates the subsequent sterilization. **Strict compliance with the instructions for use** pertaining to decontamination, cleaning and sterilization is mandatory. These processes are validated to AAMI standards TIR 12 and TIR 30.

**TURBO PRIME IBD** implants are provided clean, but not sterile. Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized and used.

**-Decontamination and cleaning**

All Turbo MIS TLIF System instruments must first be cleaned and decontaminated using the following method:
Some instruments may need to be disassembled prior to cleaning.
Remove any debris with a water moistened gauze pad, substituting a fresh pad if it becomes soiled.
Immerse in a neutral pH enzymatic cleaning solution such as “Terg-A-Zyme.” Prepare solution in cold tap water following label on the cleaner.
After a 5 minute soak time, clean disassembled instrument using a pipe cleaner or nylon brush on the accessible surfaces until all visible debris is removed.
Thoroughly rinse the instrument using free-flowing warm tap water for a minimum of 15 seconds.
Drain and wipe dry using a sterile gauze pad.
Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage, particularly instruments; these solutions should not be used. All products should be treated with care; improper use or handling may lead to damage and possible improper functioning of the device.

- **Sterilization:** It is imperative to steam-sterilize the kits under the following operating conditions:

**Steam Sterilization**, pre-vacuum, wrapped
Minimum duration: 6 minutes
Minimum temperature: 132˚C (270˚F)

NOTE: **Sterilization does not replace decontamination or cleaning**. **Only a clean product can be correctly sterilized.**

Only sterile implants and instruments may be used for surgery.

**Return of Product:**

All instruments that have been used in surgery must be decontaminated and cleaned using established hospital methods before return to SPINESELECT.

**TURBO PRIME IBD** implants are not to be returned to SPINESELECT after coming into contact with any human tissue or bodily fluid.

**Operative Precautions:**

**TURBO PRIME IBD** should be implanted singly, placed about 5 mm in front of the posterior margin of the vertebrae undergoing arthrodesis, in order to prevent contact with the dura mater and nerve roots. **TURBO PRIME IBD** is not symmetric; therefore care must be taken to position them correctly in the anteroposterior direction. The correct positioning of the **TURBO PRIME IBD** relative to the vertebrae is checked by X-ray. The size and more particularly the height, of **TURBO PRIME IBD** must be chosen on the basis of the patient's anatomy and correction desired.

**TURBO PRIME IBD** is to be filled with autologous bone to promote bone fusion. Special attention must be paid to threading the implant inserter tool into the female threads of the IBD and covering the teeth on the IBD with the sheath attachment during insertion. The instrument must be correctly aligned with the implant during the operation. While still attached to the inserter instrument, adjustment of a **TURBO PRIME IBD** in the inter-vertebral space is possible using slight mallet impaction. Following implantation, the **manufacturing lot number** and **device reference number of the TURBO PRIME IBD** that have been implanted must in all cases be reported in the patient surgical file. **The implants are for single-implant use only**. An explanted implant must never be re-implanted.

****See surgical technique manual for complete details.**

**Product Complaints:**

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any **TURBO PRIME IBD** products should notify SPINAL ELEMENTS, or, where applicable, their distributor. In the event of serious incident, or risk of serious incident, having resulted in, or may potentially result in, the death or severe deterioration in the state of health of a patient or user, SPINAL ELEMENTS or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

**Further Information:**

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