ADVERSE EFFECTS

The surgeon should carefully consider the following when selecting a patient for surgery:

- It is the surgeon's responsibility to determine the best course of action for each patient.

INSTRUMENTATION

- The Medline Cannulated Screws are designed specifically for use with Medline instrumentation.
- Instruments, particularly drills, reamers, and drivers shall be inspected for wear or damage prior to use.

INFORMATION FOR USE

- The surgeon must select the type and size implant that best meets the patient's surgical needs.

CONTRAINdications

- Any previous or active infection or blood supply limitations.
- Insufficient quality of bone or soft tissue.
- Patients who are unwilling or incapable of following postoperative care instructions.
- Material sensitivity. If suspected, tests should be conducted prior to implantation.

The device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

ADVERSE EFFECTS

- Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete or inadequate healing, or excessive force exerted on the implant during insertion.
- Implant migration and/or loosening requiring revision surgery.
- Bone resorption or over-production.
- Metal sensitivity or histological or allergic reaction resulting from implant material.
- Infection or painful, swollen or inflamed implant site.
- Unexpected histological response possibly involving macrophages and/or fibroblasts.

The surgeon must select the type of and size implant that best meets the patient's surgical needs. Screws are intended for single use only.

INDICATIONS

- The Medline UNITE® Cannulated Screws have overall lengths ranging from 10mm up to 130mm with various thread lengths. Headed screws, washers, and headless screws are available.
- The use of other instrumentation is not recommended.
- Prior to cleaning, the depth gauge should be disassembled into 3 pieces by disengaging the knobbed screws.
- Prior to cleaning, the pin distractor should be disassembled into 7 pieces by removing the 3 knobbled screws.
- All instruments, where applicable, must be disassembled prior to cleaning.

Manual Cleaning

- Do not allow excessive debris and soft tissue to dry after use. Begin cleaning process as soon after use as possible. Additional scrubbing may be required if debris and soft tissue dry.
- Prior to cleaning, the device must be disassembled into 7 pieces by removing the 3 knobbled screws.
- Prior to cleaning, the depth gauge must be disassembled into 3 pieces by disengaging the knobbed screws.
- The device shall be thoroughly cleaned and inspected prior to use. Visually inspect the tray for cleanliness. Repeat cleaning process, as necessary, until tray is visually clean.

All instruments, where applicable, must be disassembled prior to cleaning.

CONCERNING MAGNETIC RESONANCE ENVIRONMENT

- The Medline UNITE® Cannulated Screws have 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 the Medline UNITE® Cannulated Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING & STERILIZATION

- All implants and instruments are provided non-sterile in trays or individually packaged and must be adequately cleaned and sterilized prior to use or re-use. A manual cleaning method is provided and has been developed and tested consistent with TIR 30 (manual). The provided sterilization recommendations have been developed and tested consistent with ANSI/AAMI ST79. An implant should never be re-sterilized after contact with human body tissues or fluids. Devices labeled for single use only should never be reused. Reuse of these devices may result in, but are not limited to: decreased performance of the product, cross-infection, and contamination.
- Trays should be thoroughly cleaned and inspected prior to use. Visually inspect the tray for cleanliness. Repeat cleaning process, as necessary, until tray is visually clean.

All instruments, where applicable, must be disassembled prior to cleaning.

Cycle Type | Parameter | Minimum Set Point
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Prevacuum | Exposure Temperature | 270°F (132°C)
 | Exposure Time | 4 Minutes
 | Dry Time | 40 Minutes

Do not stack trays during sterilization.

Ensure that the implants and instruments are at room temperature prior to use.

STORAGE

Store all devices in a clean and dry environment. The devices are manufactured from non-degradable materials. When stored under the recommended conditions, the shelf life of this product is not limited.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

For additional product information, please visit www.medline.com or contact customer service at 1-800-MEDLINE.

www.medline.com

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