MEDLINE**UNITE**™ **CANNULATED SCREW SYSTEM**

INSTRUCTIONS FOR USE
Attention Operating Surgeon

DEVICE DESCRIPTION
The MEDLINE UNITE™ Cannulated Screws are manufactured from Titanium Alloy or Stainless Steel. The screws are offered in various diameters ranging from 2.0mm up to 7.5mm and overall lengths ranging from 10mm up to 130mm with various thread lengths. Headed screws, washers, and headless screws are available.

INDICATIONS
The MEDLINE UNITE™ Cannulated Screws are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

INFORMATION FOR USE
The surgeon must select the type of and size implant that best meets the patient's surgical needs.

CONTRAINDICATIONS
1. Any previous or active infection or blood supply limitations.
2. Insufficient quality of bone or soft tissue.
3. Patients who are unwilling or incapable of following postoperative care instructions.
4. Material sensitivity. If suspected, tests should be conducted prior to implantation.
5. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

ADVERSE EFFECTS
1. Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion.
2. Implant migration and/or loosening.
3. Metal sensitivity or histological or allergic reaction resulting from implantation of foreign material.
4. Pain, discomfort, or abnormal sensations due to the presence of an implant.
5. Nerve damage resulting from surgical trauma.
6. Necrosis of the bone or bone resorption.
7. Necrosis of the tissue or inadequate healing.

WARNINGS
1. For safe and effective use, the surgeon must be thoroughly familiar with this type of implant, the method of application, instrumentation, and the recommended surgical technique for this type of device. Improper insertion of the device during implantation can increase the possibility of loosening or migration.
2. The MEDLINE UNITE™ Cannulated Screws are not designed to withstand the stress of weight bearing, load bearing, or excess activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. The postoperative care instructions provided by the surgeon should be strictly followed to avoid adverse stresses applied to the device. The patient must be warned, preferably in writing, that failure to follow postoperative care instructions can cause implant and/or treatment failure.
3. The MEDLINE UNITE™ Cannulated Screws have not been evaluated for safety and compatibility in the MR environment. Additionally, the device has not been tested for heating or migration in the MR environment.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative care.

PRECAUTIONS
1. An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Protect implants from scratching and nicking as such stress concentrations can lead to failure.
2. Instruments, particularly drills, countersinks, and drivers shall be inspected for wear or damage prior to use.
3. The MEDLINE UNITE™ Cannulated Screws are designed specifically for use with Medline instrumentation. The use of other instrumentation is not recommended.

CLEANING AND 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. The provided sterilization recommendations have been developed and tested consistent with ANSI/AAMI ST79. Due to variations in environment, wrap material, or equipment, it must be demonstrated that these recommendations produce clean and sterile devices in your environment.

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.

Manual Cleaning
1. Rinse under cool running tap water to remove gross soil.
2. Bathe in enzymatic detergent per manufacturer's recommendation using lukewarm tap water for 1 minute.
3. Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with enzymatic detergent to remove soil.
4. Rinse under cool running tap water and aggressively flush lumens with a syringe to remove detergent residuals.
5. Bathe in a neutral detergent per manufacturer's recommendation using warm tap water for 3 minutes
6. Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and using a syringe, aggressively flush lumens with neutral detergent to remove soil.
7. Rinse under running reverse osmosis/deionized (RO/DI) water to remove detergent residuals.
8. Sonicate in enzymatic detergent per manufacturer's recommendation for 10 minutes.
9. Rinse under running RO/DI water and aggressively flush lumens with a syringe.
10. Dry with a disposable, lint-free cloth.
11. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

Sterilization
Sterilization should be performed in the provided tray double-wrapped in CSR wrap using the following method:

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

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

Manufactured for and distributed by Medline Industries, Inc., Northfield, IL 60093 USA. **1-800-MEDLINE** RJ16