Pace Surgical Ultra™ Compression Screw System

Instructions for Use:
Attention Operating Surgeon

Device Description:
The Pace Surgical Ultra™ Compression Screw System includes solid and cannulated screws in various diameters ranging from 2 to 8mm and multiple length options, each available in partial and fully threaded variants. Headed screws, headless screws, and washers are available. All screws and washers are manufactured from Titanium Alloy (ASTM F136).

Indications:
The Pace Surgical Ultra™ Compression Screw System is intended for the internal fixation and stabilization of arthrodeses, osteotomies, fractures, and nonunions of the foot and ankle. The System is specifically indicated for:

Fractures and Osteotomies

- Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
- Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
- Talar fractures
- Ankle fractures
- Navicular fractures
- Fractures of the fibula, malleolus, and calcaneus
- Metatarsal and phalangeal osteotomies
- Weil osteotomy
- Calcaneal osteotomy

Fusion resulting from neuropathic osteoarthropathy (Charcot), example:

- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

Arthrodesis and Deformity Correction

- 1st MTP arthrodesis
- Metatarsal deformity correction
- Tarsometatarsal joint arthrodesis
- Naviculocuneiform joint arthrodesis
- Talonavicular arthrodesis
- Subtalar joint arthrodesis
- Triple arthrodesis
- Medial column arthrodesis
- Subtalar joint distraction arthrodesis
- Ankle arthrodesis
- Lateralizing calcaneal osteotomy
- Lateral column lengthening
- Hammertoe

Hallux Valgus Correction

- Fixation of osteotomies (i.e. Akin, Scarf, Chevron)

- Interphalangeal (IP) arthrodesis
- Proximal, midshaft, or distal osteotomy
- Lapidus arthrodesis

Information for Use:
The surgeon must select the type and size of implant that best meets the patient's surgical needs.

Contraindications:
1. Any previous 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 Events:
1. Fracture of implant due to excessive activity, prolonged loading up on 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 Pace Surgical Ultra™ 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. Any decision to remove the device should take into consideration the potential risk to 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 Pace Surgical Ultra™ Screws are designed specifically for use with Pace Surgical instrumentation. The use of other instrumentation is not recommended.

Cleaning & Sterilization:
All implants and instruments are provided non-sterile in trays or individually packaged and must be adequately sterilized prior to use or re-use (in the case of instruments). The provided sterilization recommendations have been developed and tested with ANSI/AAMI ST79. Due to variation 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 contract with human body tissues or fluids. Devices labeled for single use only should never be reused. In addition, all instruments must be adequately cleaned.

Instrument Inspection

- All markings are legible.
- No cracks are present in any part of the instrument.
- No cuts or gouges in any silicone handle.
- There is no damage to working ends or tips, free from damage, cracks, or gouges. Where applicable, the working end should be sharp.
- There is no damage to threads.
- There is no discoloration, corrosion, stains or rust present.
- Cannulated instruments are visually checked for obstruction.
- Any moving parts move freely without binding or sticking.
- The instrument will function as intended with appropriate mating parts.
- Ratcheting mechanisms are functional.
- Driver tips are not worn beyond functional used and mate as intended with the appropriate part.

If an instrument does not meet these inspection criteria (where applicable), discard the instrument and do not use.

Instruments Point of Use:

1. Remove all visible soil from instruments.
2. Instruments should be thoroughly cleaned within 30 minutes of use to minimize the potential for drying.
3. If the instruments cannot be processed immediately, keep the devices moist during transport.
4. Place the instruments in a tray of softened tap water, if available, or cover with damp towels.

Instruments Only 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 style 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 manufacture's recommendation using warm tap water for 3 minutes.
6. Scrub thoroughly with a soft bristled bush 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 reverse osmosis/deionized (RO/DI) water to remove detergent residuals.
8. Sonicate in enzymatic detergent per manufacture'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 with an FDA-cleared wrap using the following method:

Cycle Time	Parameter	Minimum Set Point
	Exposure Temperature	270F (132C)
Prevacuum	Exposure Time	4 minutes
	Dry Time	30 minutes

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 by sale by or on the order of a physician.

MRI Safety Information
The Pace Ultra Compression Screw System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Pace Ultra Compression Screw System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Manufacturer Information

Pace Surgical
7 Great Valley Parkway, Suite 295
Malvern, PA 19355
Pace-surgical.com
1-610-952-0462

Symbol	Standard Title and Designation	Symbol Title (Reference Number)	Explanatory
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Manufacturer (5.1.1)	Indicated the medical device manufacturer
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Catalog number (5.1.6)	Indicates the manufacturer's catalog number so that the medical device can be identified
	§801.109 Prescription devices	Prescription Use	United States Federal law restricts this device to sale by or on the order of a physician
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Do not use if package is damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened
	IEC 60601-1 Edition 3.1 2012-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Batch code/ Lot number (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Do not re-use/ Single use only (5.4.2)	Indicates a medical device that is intended for one single use only.
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Consult instructions for use or consult electronic instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.

Symbol	Standard Title and Designation	Symbol Title (Reference Number)	Explanatory
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Fragile, handle with care (5.3.1)	Indicates a medical device that can be broken or damaged if not handled carefully
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process
	ISO 15223-1 Fourth edition 2021-07 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Unique Device Identifier (5.7.10)	Indicates a carrier that contains Unique Device Identifier information.