Revcon™ Screw System.

Instructions for use.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Single Use Only

Device description.

The REVCON™ Screws are intended for use in bone reconstruction, osteotomy, arthrodesis, fracture repair, and fracture fixation of bones appropriate for the size of the device, to allow surgeons to perform a bunion osteotomy and fixation of the osteotomy with a minimally invasive surgical technique. The REVCON™ Screw System contains fully threaded, cannulated screws offered in a variety of diameters and lengths. The screws are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI) as per ASTM F136 and are provided non-sterile for end user sterilization.

Indications for use.

The REVCON™ Screw System is indicated for fixation of bone surgery involving reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis.

The REVCON™ Screw System is not intended for spinal use.

Contraindications.

The REVCON ™ Screw System should not be used in the following scenarios:

- Infection
- Physiologically or psychologically inadequate patient
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity
- Vascular insufficiency
- Poor bone quality
- Open epiphyses
- Noncompliant patient
- Allergy to device components
- Possibility for non-surgical treatment

Warnings and precautions.

The surgeon should be familiar with the procedure and use of the REVCON ™ Screw System instruments prior to surgery.

The outcome and results obtained from this surgical procedure, as with any surgery, are highly dependent on the knowledge of surgical techniques, placement and sizes of implants used, management of the patient both pre and post operation, including the general health of the patient.

The implants used in the system are manufactured from medical grade titanium alloy, Ti-6Al-4V (ASTM F-136) and use with implants of other metallic materials is not recommended.

REVCON™ Screw System 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 REVCON™ Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The REVCON™ Screw System implants are single use devices and should never be re-used.

Potential adverse events.

Potential Adverse Events for use of the REVCON™ Screw System includes, but is not limited to.

- Infection, early or late
- Fracture of the implant
- Foreign body (allergic) reaction to implants.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Loosening or dislocation of the implant requiring revision surgery.
- Nonunion, delayed union
- Allergic reaction to the implant material
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

Care and handling of instruments.

The REVCON™ Screw System instruments are provided non-sterile and should be stored in their original packaging until cleaned and sterilized.

Cleaning.

Diligent execution of all steps is extremely important. Before being used for the first time and as soon as possible after each subsequent use, thoroughly clean all instruments and trays, following these steps to ensure safe handling of biologically contaminated instruments:

1. Rinse the devices with distilled water for approximately two (2) minutes while brushing with a soft bristled brush to remove visible gross debris from the device. Pay careful attention to any pivots, threads, recesses, lumens or crevices on the devices.
2. Prepare an ultrasonic bath using distilled water and an Enzymatic Cleaner according to the manufacturer's minimum effective concentration.
3. Completely immerse the devices into the ultrasonic bath and sonicate for five (5) minutes.
4. Scrub the devices with a cleaning brush to remove any visual debris from all crevices. Do not use cleaning agents containing caustic soda, formalin, glutaraldehyde, bleach, or other alkaline cleaners which may damage some devices.
5. Rinse and flush the devices for two (2) minutes with distilled water.
6. Use a lint free cloth to carefully dry the devices until all moisture is removed.

Preparation for sterilization.

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection, and length of operative procedures.

Instruments should be visually inspected and prepared for sterilization following cleaning. If the device is determined to not be visually clean at the end of the cleaning process, the user should repeat the relevant, previous cleaning steps or alternatively, safely dispose of the device.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored, or damaged instruments, as well as worn instruments in which the proper function of the instrument may be compromised.

Sterilization.

The implants and instruments are supplied NON-STERILE and are contained within trays that can be sterilized directly. Replenished implants are provided NON-STERILE in labelled packaging, but will not need cleaning prior to sterilization. Instruments and trays will need cleaning prior to sterilization, as detailed in previous CLEANING section. The system is able to withstand multiple sterilizations. Do not stack trays during sterilization. Instruments should be wrapped in an FDA cleared wrap and sterilized using a pre-vacuum cycle, using the following guidelines:

Method	Temperature
Steam Pre-Vacuum	270˚ F / 132˚ C
Exposure Time	Dry Time
4 Minutes	20 Minutes

The above steam sterilization cycle has been validated through half-cycle and full-cycle tests in accordance with the ANSI/AAMI/ ISO 17665-1:2006 Guidelines. Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. These recommended instructions are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. The recommended instructions provided above have been validated by VOOM Medical Devices. It is the responsibility of the processor to ensure that the processing is performed using appropriate equipment and materials. All users should be qualified personnel and properly trained on applicable policies, procedures, and standards.

Product complaints.

Any healthcare professional (e.g., customer or user) who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify the distributor and/or Voom Medical Devices.

Voom Medical Devices

783 Old Hickory Blvd., Suite 155
Brentwood, TN 37207
+844.372.5489
info@voomdevices.com

When reporting a complaint, please provide the unique device identification number (UDI) or the lot number and serial number, your name and phone number, and the nature of the problem.

The surgical technique is available at no charge upon request.

Symbol (Reference Number)	Description of symbol	Standard of origin
	Indicates the medical device manufacturer	ISO 15223 - 1 Medical Device - Symbols to be used with medical device labels, labelling and information to be supplied - Part: General Requirements
	Indicates the manufacturer's batch code so that the batch or lot can be identified	
	Indicates the manufacturer's catalogue number so that the medical device ca be identified	
	Indicates a medical device that has not been subjected to a sterilization process	
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	
	Indicates the need for the user to consult the instructions for use	
	Indicates that the device is intended for prescription use only	21 CFR 801.109

MEDICAL DEVICES

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