English

Instructions For Use

Cannulated Compression Headless Screw System

Cannulated Screw System +

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DePuy Synthes
COMPANIES OF Johnson & Johnson

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE

The implants – delivered either sterile or non-sterile — are:

- Screws existing in different diameters and length
- Screws have a recess for engaging a driver
- Screws with threads on the head to engage the proximal bone
- Screws made out of Titanium alloy per standards ISO 5832-3 and ASTM F136

INDICATIONS FOR USE

The DePuy Synthes Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

MATERIAL

DePuy Synthes Screws are manufactured from a Titanium alloy (ISO 5832-3 and ASTM F136). The specialized instruments are made of surgical grade stainless steel (ISO 7153-1 and ASTM F899), nickel-cobalt alloy (ISO 5832-6 and ASTM F562) and PAEK.

HOW SUPPLIED

DePuy Synthes Screws and instruments are delivered both **non-sterile and sterile** as specified by the packaging.

All implants and instruments labeled as sterile are exposed to a minimum 25.0 kGy gamma radiation to obtain a minimum Sterility Assurance Level (SAL) of 10^{-6}. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not resterilize.

All non-sterile implants and instruments must be cleaned and sterilized prior to use according to the procedures outlined in this document.
Information on the status of sterilization (sterile or non-sterile) is contained on the product label.

CONTRAINDICATIONS

The implant should not be used in a patient who currently has, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance.

WARNINGS AND POTENTIAL RISKS

The DePuy Synthes Screws are designed for **single patient use only and must never be reused.** As with all other orthopedic implants, the DePuy Synthes Screws should never be re-implanted under any circumstances.

The DePuy Synthes Screws can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who: lacks good general physical conditions; has severe osteoporosis; demonstrates physiological or anatomical anomalies; has immunological responses,sensitization or hypersensitivity to foreign materials; has systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia shouldbe explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

The implantation of screws should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized.

The DePuy Synthes Screw System should never be used with dissimilar materials.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made based on X-Rays, CT scans and other radiological studies.
Only patients that meet the criteria described in the INDICATIONS FOR USE section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight/height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implant surfaces to be damaged.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load-bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load-bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

IMPORTANT: The guide wires included in the DePuy Synthes Screw System are not intended as implants. The guide wires are only intended for use as instruments to facilitate screw insertion.

POSSIBLE ADVERSE EFFECTS

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Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and/or amputation of the limb.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Non-clinical testing has demonstrated the DePuy Synthes Screws are MR Conditional. A patient with these devices can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 3.0 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

Under the scan conditions defined above, non-clinical testing results indicate the DePuy Synthes Screws are expected to produce a maximum temperature rise of 8°C after 10 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the DePuy Synthes Screw when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

DIRECTIONS FOR USE

To implant the DePuy Synthes Screws, use only the provided DePuy Synthes instrumentation. Do not use implants or instruments from any other system or manufacturer.

The DePuy Synthes Screws and instruments are provided either sterile or non-sterile. Non-sterile implants and instruments must be cleaned and sterilized prior to useaccording to the procedures outlined in this document. All DePuy Synthes System components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken DePuy Synthes devices must not be used or processed and should be returned to DePuy Synthes for evaluation.

Before using the DePuy Synthes Screw System for the first time, the surgeon should be thoroughly familiar with the Surgical Technique Guide as well as the functionality and assembly of the various components. Pre-operative planning is performed by the operating surgeon and is solely at their discretion. It should determine the type of implant required and an adequatesupply of the implant sizes should be available prior to surgery, including largerand smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all DePuy Synthes Screws and instruments, please refer to the Surgical Technique Guide (available at no charge upon request).

CARE AND HANDLING

Certain DePuy Synthes Screws and instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

Limitations on Processing

All devices provided and labeled as sterile have undergone two processing procedures: cleaning and gamma radiation sterilization. The devices labeled as single use only are not to be reprocessed under any circumstances.
For devices not labeled as single use only/reusable devices, repeated processing has minimal effect on these implants and instruments. End of life is normally determined by wear and damage due to use.

Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Containment and Transportation

It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

Remove excess soil with a clean, disposable, absorbent Kimwipe, cloth, or equivalent.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the devices by placing under running water and scrubbing with asoft bristle brush to remove major debris. Rinse and scrub each device forat least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other. Load devices in such a way that the parts can drain.
- Use a standard instruments cycle with the following parameters (at a minimum):

Enzyme Wash	Hot 40 - 65 °C (104 - 149 °F) for 3 minutes
Neutral pH Wash	60 °C (140 ° F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90 °C (194 °F) for 1 minute
Dry	82 °C (180 °F) for 6 minutes

- Determine if the devices are dry. If they are not dry, dry with a soft, clean,lint free cloth.
- After drying, devices instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace devices that cannot be cleaned.
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Cleaning (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the devices by placing under running water and scrubbing with asoft bristle brush to remove major debris. Rinse and scrub each device forat least one minute.
- Bathe the devices in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the devices with a soft bristle brush while submerged in the detergent.
- Rinse the devices in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check devices for complete removal of any debris. If necessary, repeat manual cleaning. Replace devices that cannot be cleaned.

Inspection and Function Testing

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged. 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.

Packaging

Instruments may be loaded into the specified DePuy Synthes instrument trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA approved for pre-vacuum steam sterilization.

Sterilization

For components provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to DePuy Synthes.

If not specifically labeled **STERILE**, or if labeled NON-STERILE, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: The manufacturer does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, The manufacturer recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum	
Minimum Temp.	132 °C (270 °F)	132 °C (270 °F)	135 °C (275 °F)
Exposure*	15 min	4 min	3 min
Dry Time	20 minutes		

**The manufacturer has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665-1. 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.*

[1] ENZOL®, a trademark of Advanced Sterilization Products, s used in the cleaning validation
[2] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

The manufacturer recommends following ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

Storage

Devices must be completely dry before storing in designated trays and must be handled with care to prevent damage. Products should be stored in a dry, clean environment which provides protection from dust, insects, pests, chemical vapors, direct sunlight and extremes of temperature and humidity.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact DePuy Synthes Customer Service for return of removed implants.

LABEL SYMBOLS

SYMBOL	MEANING
Rx only	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
REF	Reference Number
LOT	Lot Number
MATL	Material
CC	Date of Manufacture / Country of Manufacture
	Expiration Date
QTY	Quantity
STERILE R	Sterilized using irradiation
	Do not re-use
	Do not use if package is damaged
STERILIZE	Do not resterilize
	Consult instructions for use
	Caution
NON STERILE	Non-sterile
	Distributed by
	Manufacturer
CE 2797	CE Mark
EC REP	Authorized Representative in the European Union
MR	Magnetic Resonance Conditional
MD	Medical Device
	Contains Hazardous Substances
UDI	Unique Device Identifier
	Double Sterile Barrier System
CH REP	Swiss Authorized Representative
	Patient Identification
	Patient Information Website
	Health Care Centre or Doctor
31	Date Information was Entered or Procedure Took Place

CUSTOMER SERVICE

For further information regarding the DePuy Synthes Screw System or a copy of the Surgical Technique Guide, please contact DePuy Synthes or your local DePuy Synthes Distributor.