



ORTHOLOC™ BONE SCREWS

150862-1

The following languages are included in this packet:

English (en)
Español (es)

Deutsch (de)
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Nederlands (nl)
Português (pt)

Français (fr)
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For additional information and translations please contact the manufacturer or local distributor.



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*The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.

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Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION
ORTHOLOC™ BONE SCREWS
(150862-1)

OUTLINE:

DEFINITIONS















DESCRIPTION








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DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation

	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	Non-sterile
	Do not resterilize
	Sterile
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if packaging is ripped or damaged
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

DESCRIPTION

The ORTHOLOC™ Bone Screws are cancellous or cortical, partially or fully threaded screws offered in various diameters and lengths. ORTHOLOC™ Bone screws are available as solid or cannulated. All screws are manufactured from titanium alloy. The implants are single use only devices.

A. INDICATIONS

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

B. CONTRAINDICATIONS

Patients should be warned of these contraindications:

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

C. PRECAUTIONS

Pre-operative Precautions:

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery. The surgeon should contact Wright for product-specific surgical techniques.

The surgeon should also use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level.

Additional conditions presenting increased risk of failure include:

1. uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3. metabolic disorders that may impair bone formation;
4. osteomalacia;
5. poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);

6. pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

Intra-operative Precautions:

Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.

Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

Post-operative Precautions:

The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred.

Periodic follow-up is recommended to monitor the position and state of the implant components, as well as the condition of the bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.

Concerning Magnetic Resonance Environment

ORTHOLOC™ Bone Screws have not been evaluated for safety and compatibility in the MR environment. The ORTHOLOC™ Bone Screws have not been tested for heating or migration in the MR environment.

Recommendations Regarding Device Fragments:

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition, size, and location of the fragment (if known);
 - b. The potential mechanisms for injury, e.g., migration, infection;
 - c. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

D. ADVERSE EFFECTS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

E. HANDLING AND STERILIZATION

The medical devices associated with this package insert may be provided sterile or non-sterile; the individual product's labeling will determine whether or not they are packaged sterile.

Devices provided sterile are sterilized by gamma radiation, ethylene oxide, or gas plasma. The immediate package label should be consulted for specific method of sterilization. Irradiated devices have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation.

Devices provided sterile should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove device from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final

implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

Devices provided non-sterile should be processed according to the recommended cleaning and sterilization parameters below.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to the following: significant degradation in device performance, cross-infection, and contamination.

An implant should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Wright does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

Device Cleaning:

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove any gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.

7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Device Sterilization:

The minimum recommended steam sterilization conditions for the non-sterile or reusable medical devices associated with this package insert are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79:2006 and A1:2008 & A2:2009, Table 5, Row 1 and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

WARNINGS:

- All packaging materials **MUST** be removed from the implant prior to implantation.
- **NEVER** steam sterilize/re-sterilize ceramic, HA, calcium sulfate, plastic, and/or metal/plastic implants.

F. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

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