

VOLT™ Wrist Plating System

Instructions for Use

Description of the Medical Device

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

- Various bone plates of different shapes and hole configurations.
- Variable angle locking and non-locking screws in various lengths and diameters.

The implants are manufactured from Stainless Steel within the frame of the standard ASTM F138, or from Titanium alloy within the frame of the standard ASTM F136.

The instruments – delivered sterile and non-sterile – are intended to support the implantation of the VOLT Wrist Plating System implants.

Indications for Use

VOLT Wrist Plating System

The VOLT Wrist Plating System includes Distal Radius, Forearm, and Fragment-Specific Plates, which are indicated for fixation of fractures, fusions, non-unions and malunions, or osteotomies of the radius, ulna, and hand.

The VOLT Wrist Plating System is not for spinal use.

Contraindications

- Infection.
- Patient conditions including blood supply limitations, obesity and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

R_X Federal law restricts this device to sale by or on the order of a physician.

Materials

The VOLT Wrist Plating System implants are manufactured from Titanium Alloy (ASTM F136) or Stainless Steel (316L per ASTM F899). The instruments are made of surgical grade stainless steel (ASTM F899), radel (ASTM D6394) and PEEK (ASTM F2026).

Adverse Effects

In all surgical procedures, the potential for complications and adverse reactions exists. The risks and complications with these implants include:

- Fracture of the implant due to excessive loading.
- Incomplete or inadequate healing.
- Implant migration and / or loosening.
- Pain, discomfort or abnormal sensations due to the presence of an implant.
- Nerve damage resulting from surgical trauma.
- Bone necrosis or bone resorption.
- Delayed or nonunion of bone fragments.
- Allergic reaction to the implant materials.

Warnings & Precautions

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Implants must not be re-used or re-sterilized.
- Use only titanium screws with titanium devices and stainless steel screws with stainless steel devices.
- Improper insertion of the device during implantation may result in implant loosening or migration.
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, nonunion and incomplete healing may occur.
- Bending or fracture may occur due to applied excessive stresses and load bearing.
- Failure to follow postoperative care instructions may result in procedure complications or failure.
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition may occur.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The **VOLT Wrist Plating System** has not been evaluated for safety and compatibility in the MR environment. The **VOLT Wrist Plating System** has not been tested for heating or migration in the MR environment.

DEVICE COMPATIBILITY

The VOLT Wrist Plating System is compatible with the Depuy Synthes VOLT Mini Fragment Plating System. The instructions for use of the VOLT Mini Fragment System can be found at <https://www.e-ifu.com/>. Use of the Distal Radius Plating System with implants and instruments for which it is not explicitly compatible may result in injury or device malfunction.

Instructions for Use

1. Using standard dissection techniques, expose the surgical site.
2. Perform the intended osteotomy or identify the fracture location.
3. After reduction of the fracture, choose the proper plate based on the size and type of indication.
4. Place the plate on the fracture/osteotomy site and fix with k-wires. If forming/bending the plate to fit the anatomy – use the proper mini-frag instrumentation for preparation of the proper contour. DO NOT REPEATEDLY BEND THE PLATE – as this will cause a weakened fatigue life of the plate.
5. Utilize the guide block and/or drill guide with proper drill according to screw diameter and drill hole for screw. Repeat hole preparation as necessary for proper fixation of the plate.
6. Utilize the depth gauge to determine proper length of screw in bone anatomy for firm fixation in the opposite bone cortex.
7. Insert desired size screw matching to plate size and bone anatomy. Repeat process on remaining screw(s) with angulation holes – using either locking or cortex screws.
8. Remove k-wires and check plate/screw tightness on bone anatomy fracture/osteotomy site.
9. Using fluoroscopy, confirm the proper plate and screw placement on the bone anatomy. Correct as warranted & re-check.
10. Clean the surrounding area with a pulse lavage.
11. Use the surgeon's preferred method for closing the surgical site.

Postoperative Management

The patient is allowed to ambulate with weightbearing to tolerance on the operated fracture site within limits imposed by postoperative discomfort. The progression to normal use of the digit or limb is limited only by the persistence of postoperative swelling and discomfort.

CARE AND HANDLING

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

Limitations on Processing

Repeated processing has minimal effect on these implant 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, thorough cleaning, and sterilization of biologically contaminated devices.

Containment and Transportation

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

Preparation for Cleaning

Note: Implants are supplied cleaned from the manufacturer and do not require cleaning prior to initial use.

Where instruments interface with other devices, disassemble prior to cleaning. Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Disassembling of Depth Gauge:

1. Press the hook tip down to allow for retraction into sleeve cannula.
2. Slide the insert out of the metal sleeve. The insert will stop at the key feature.
3. Turn the insert 180 degrees counterclockwise with gentle pressure on the insert shaft until another stop is felt and the shaft has advanced slightly.
4. Turn the insert another 180 degrees clockwise with gentle pressure on the insert shaft and the insert should be free to be fully removed from the sleeve.

Automated Cleaning

Equipment: Automated washer, soft bristle brush, enzymatic detergent, and neutral pH detergent.

- Preclean the devices by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at 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, check devices for complete removal of any debris. If necessary, repeat cycle or use manual cleaning.
- Final rinse shall be performed, using reverse osmosis or distilled water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.

Manual Cleaning

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).

Instrument Manual Cleaning Instructions:

- Preclean the devices by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- Bathe the device in the enzymatic solution for 5 minutes; where appropriate, the device 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 using reverse osmosis or distilled 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.

After Cleaning

Where instruments have been disassembled prior to cleaning, reassemble prior to use. Visually inspect cleaned devices to ensure cleaning was effective. Perform cleaning again on any device that is not visually clean. Replace any device that cannot be cleaned.

Inspection and Function Testing

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. Verify the legibility of all markings. Replace any device that has unreadable markings. Replace affected devices as needed to ensure proper operation before proceeding with sterilization.

INSTRUMENT REPLACEMENT

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

WARNING: Do not attempt to repair any instrument.

If your instrument requires repair or maintenance, please contact DePuy Synthes Customer Service for return of the instrument.

Packaging

Instruments may be loaded into the specified VOLT Wrist Plating System instrument trays, or general-purpose trays. Visually inspect the tray before loading implants and/or instruments. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared for pre-vacuum steam sterilization.

Sterilization

For components provided Sterile, the sterilization method is noted on 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 the sterile barrier has been broken, return the component to DePuy Synthes.

WARNING: Please note that a single-use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.

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

WARNING: DePuy Synthes 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} , Tyber Medical recommends the following parameters:

METHOD	TIME	TEMPERATURE	DRY TIME
Pre-Vacuum	4 minutes	270° F (132° C)	20 MINUTES
	3 minutes	275° F (135° C)	
Gravity	15 minutes	270° F (132° C)	20 MINUTES

DePuy Synthes 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

VOLT Wrist Plating System devices must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in 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.

Disposal

Observe internal hospital/institution procedures, practice guidelines, and/or government regulations for proper handling and disposal of the VOLT Wrist Plating System Devices.

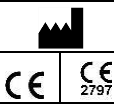
CUSTOMER SERVICE

For further information regarding the VOLT Wrist Plating System or a copy of the Surgical Technique Manual, please contact DePuy Synthes Customer Service, +1 (800) 523-0322.



Tyber Medical
83 South Commerce Way Suite
310
Bethlehem, PA 18017
Phone: +1 (866) 761-0933
Fax: +1 (866) 889-9914

Symbol Glossary

SYMBOL	MEANING
	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
	Reference Number
	Lot Number
	Material
	Country and Date of Manufacture
	Expiration Date
	Quantity
	Sterilized Using Irradiation
	Do Not Re-Use
	Do Not Use If Package Is Damaged
	Do Not Re-Sterilize
	Consult Instructions for Use
	Caution
	Non-Sterile
	Hazardous Substance
	Distributor
	Manufacturer
	CE Mark / CE Mark with Notified Body
	Authorized Representative in the European Union
	Authorized Representative in Switzerland
	Unique Device Identifier
	Medical Device
	Double Sterile Barrier