# 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, Titanium within the frame of the standard ASTM F67, 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.

℞ 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), Titanium (ASTM F67), or Stainless Steel (316L per ASTM F138). 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 is MR Conditional and may only be used in an MR environment under specific conditions.

The patient should consult with their healthcare providers before an MR exam and inform the MRI site personnel that they have an MR Conditional device before the MR exam.

The following tables provide the MR conditions for which the VOLT Distal Radius Plating System may be safely scanned in the MR environment.

Failure to adhere to these conditions may result in injury or device malfunction.

A MR Patient Implant Card is available at https://dpswrist.info/ . This should be completed using the label of the implanted device and provided to the patient as part of their postoperative care.

| **MRI Safety Information**<br>  <br>A patient with the VOLT Distal Radius Plating System (plate/screw construct) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient. | |
|---|---|
| **Name/Identification of device** | VOLT Distal Radius Plating System |
| **Nominal value(s) of Static Magnetic Field [T]** | 1.5 T or 3 T |
| **Maximum Spatial Field Gradient [T/m and gauss/cm]** | 20 T/m (2000 gauss/cm) |
| **RF Excitation** | Circularly Polarized (CP) |
| **RF Transmit Coil Type** | **Body Coil:** See scan limitations below.<br>**Local Coils**: No restrictions on local transmit-receive coils that the device is not within. |
| **Operating Mode** | Normal Operating Mode |
| **Maximum Whole Body SAR** | See details below |
| **Maximum Head SAR** | 3.2 W/kg (Normal Operating Mode) |
| **RF Conditions** | **1.5 T MRI Systems**<br>$B_1^+$RMS ≤ 3.40 μT for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)<br>or<br>Whole body average SAR ≤ 1.0 W/kg for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) |
| | **3 T MRI Systems**<br>$B_1^+$RMS ≤ 1.45 μT for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)<br>or<br>Whole body average SAR ≤ 0.8 W/kg for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) |
| **MR Image Artifact** | The presence of this implant may produce an image artifact of 68 mm. |
| If information about a specific parameter is not included, there are no conditions associated with that parameter. | |

**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**

Provide the patient with their completed MR Patient Implant Card.

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 cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

**Limitations on Processing**

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, 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.**

Remove excess soil with a clean, lint-free, disposable, absorbent Kimwipe, cloth, 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.

The depth gauge is intended to be cleaned, sterilized, and stored disassembled. For reassembly instructions, please refer to the Surgical Technique Guide.

**Automated Cleaning**

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

- 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.

[1] ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

[1] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

- Use a standard instruments cycle with the following parameters (at a minimum):

| | |
|---|---|
| **Enzyme Wash** | Hot (40° – 65° C)<br>(104° – 149° F)<br>for 3 minutes |
| **Neutral pH Wash** | 60° C (140° F)<br>for 3 minutes |
| **Rinse** | Ambient temperature<br>for 1.5 minutes |
| **Thermal Rinse** | 90° C (194° F)<br>for 1 minute |
| **Dry** | 82° C (180° F)<br>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. Replace devices that cannot be cleaned.

**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).

**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 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 an instrument that cannot be cleaned.

**Inspection and Function Testing**

Visually inspect all instruments under normal lighting to ensure the cleaning was effective. Inspect for surface damage and wear. Check for staining, discoloration, corrosion, misalignment, burrs, bent, or fractured tips. Where instruments interface with other devices, inspect to ensure that instruments properly interface.
Mechanically test the working parts to verify that each instrument functions correctly. Replace any instrument that is not functioning.
Verify the legibility of all markings. Replace any instrument that is unreadable.
Repeat the cleaning and/or replace affected devices as needed to ensure proper operation before proceeding with sterilization.

**DEVICE 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 device is defective or damaged, please contact DePuy Synthes Customer Service for return of the device.

**Packaging for Steam Sterilization**

For sterilizing non-sterile instruments, the devices may be loaded into the specified VOLT Wrist Plating System instrument trays, or general-purpose caddies/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. Do **not** re-sterilize.

**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 $10^{-6}$, DePuy Synthes 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.


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**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 |
|  | Country of Manufacture / Date of Manufacture |
|  | Expiration Date |
|  | Sterilized Using Irradiation |
|  | Do Not Re-Use |
|  | Do Not Use If Package Is Damaged |
|  | Do Not Re-Sterilize |
|  | Consult Instructions for Use |
|  | Non-Sterile |
|  | Contains Hazardous Substances |
|  | 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 |
|  | Single Sterile Barrier |
|  | MR Conditional |