INSTRUCTIONS FOR USE (ENGLISH)

DEVICE DESCRIPTION

The A'TOMIC PULSE™ Nitinol Fixation System, which consists of the A'TOMIC PULSE™ implants and associated instruments, is intended for use for fixation and compression and supports several surgical techniques (e.g., fracture, osteotomy, joint arthrodesis, and fixation of bone fragments). The staples are made of implant-grade Nitinol and are designed to exhibit superelastic properties at room temperature. This allows for continued compression to be applied across bone segments, thus enhancing long-term stability and promoting fusion. Each staple is pre-loaded on an inserter for implantation and sterile packed. The staples are available in multiple sizes, varying by bridge length and leg length, to accommodate individual patient anatomy.

Disposable Instrumentation is provided to assist in the surgical placement of the Extremity Staple.

IMPLANTS AND ASSOCIATED INSTRUMENTATION MATERIALS

All implants are made of implant-grade Nickel-Titanium Alloy (Nitinol) per ASTM F2063-18. The disposable instrumentation is made from medical grade stainless steel and plastic.

INDICATIONS FOR USE

The A'TOMIC PULSE™ Nitinol Fixation System is indicated for use in fracture, osteotomy fixation and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that precludes staple placement). The device is intended for use in short, long, or flat bones. The A'TOMIC PULSE™ Nitinol Fixation System is intended for single use only.

CONTRAINDICATIONS

- Infection
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone that would impair the ability to securely fix the implant.
- Comminuted bone surface that would hinder staple placement.
- Foreign body sensitivity to metals. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

WARNINGS

1. This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this staple. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/ hypersensitivity to these materials.
2. Do not re-sterilize this device. Re-sterilization could lead to mishandling and surface damage that could result in staple fracture and/or particulate debris. If sterilization is compromised prior to insertion, a different sterile staple and/or associated instrument(s) will need to be used. Product cannot be re-sterilized due to the heat lability of the medical grade plastic materials.
3. Re-operation to remove or replace staples may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
4. Do not modify the staple. Modified devices may not perform as intended and could result in patient injury.
5. Do not attempt to reload or adjust staples retained on the inserter to increase/decrease alignment. Any attempts will result in an unusable device and may require opening another package.

POTENTIAL ADVERSE EFFECTS

- Fracture of staple due to excessive activity, prolonged loading upon the device, incomplete or inadequate healing, or excessive force exerted on the staple during insertion.
- Staple migration and/or loosening requiring revision surgery.
- Metal sensitivity or histological or allergic reaction resulting from staple material.
- Infection or painful, swollen, or inflamed implant site
- Pain, discomfort, or abnormal sensations due to the presence of the staple.
- Necrosis of the bone or surrounding tissue.
- Nerve damage resulting from surgical trauma.

PRECAUTIONS

1. Correct selection of the staple size is important. Use of an undersized staple in areas of high functional stresses may lead to fracture and failure of the staple.
2. Do not reuse staples. Re-use of devices indicated as single-use can result in decreased mechanical and clinical performance of devices.
3. The surgeon must make the final decision regarding staple removal.
4. Use only RMR Ortho instruments when handling or implanting RMR Ortho devices.

HOW SUPPLIED

The A'TOMIC PULSE™ Nitinol Fixation System and associated instruments are provided sterile (using gamma irradiation) for single-use only. Carefully inspect the sterile packaging for damage prior to use. If the sterile packaging is found to be damaged or opened, do not use the device, or attempt to re-sterilize. Call your RMR Ortho sales agent or RMR Ortho customer service for a replacement.

RECOMMENDED PROCEDURE

It is the responsibility of the surgeon to be familiar with the procedure before use of these products. As the manufacturer of this device, RMR Ortho does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient. Expose and prepare surgical site per standard procedure.

1. Expose and prepare fusion surfaces using standard technique.
2. Reduce bone segments: Use the 1.1mm k-wires located in the instrument kit as needed for temporary fixation. Temporary fixation should be placed in such a way as to prevent interference while drilling.

   NOTE: If using the precision drilling option, the cannulated drill kit (07.20.CDK) contains 1.1mm K-wires that may be used for provisional fixation.

3. Determine the correct implant bridge length using the drill guides: Place the drill guide across the fusion site to determine the desired implant bridge length. If necessary, place the drill bits into the drill guide and note the location and trajectory of the drill bits visually and/or using fluoroscopy.
4. Attach handle to selected drill guide: Slide the handle into the dovetail feature on the drill guide. The use of the handle is

optional. Proceed to Step 7 if using the cannulated drilling option.

Standard Drilling Method:

5. Create first hole: Create the first hole using a 2.0mm quick disconnect drill bit.
6. Create second hole: Insert a pull pin and create the second hole. The second pull pin may be used to assist in locating the position of the drill holes after removing the drill guide. Proceed to Step 10. NOTE: Implant selection may be facilitated by using a standard depth gauge to determine leg length.

Cannulated Drilling Option:

7. Place both drill bits into the tubes in the drill guide.
8. Insert guide wires: Drill the 0.9mm guide wires through the drill bits and verify position using fluoroscopy. Alternatively, the first guide wire may be inserted into the expected position of one of the legs of the implant. Once position is confirmed using fluoroscopy, the drill guide and long drill bit may be placed over the guide wire.
9. Using a pin driver drive the drill bits into bone to the far cortex and determine implant leg length by noting the location of the laser bands on the drill bit in relation to the top of the drill guide. The bands correspond to 8, 10, 12, 14 and 16mm, respectively. Use the smallest measurement to determine the implant leg length
10. Remove Inserter Assembly from Retention Block: Lightly squeeze the wings of the retention block just enough to release the keystone. Remove the implant from the retention block.
11. Insert implant into pre-drilled holes: Align the implant legs with the trajectory of the pre-drilled holes and insert the implant fully.
12. Release the implant and tamp: Pull the slider on the inserter assembly to release the implant. Use the tamp as necessary to fully seat the implant. Confirm final implant position using fluoroscopy

Explant Information: Use a small osteotome or curette to lift the implant. If necessary, use a clamp to remove the staple from the bone. The implant bridge may be cut with a pin cutter to release compression of the implant and allow for ease of removal of the implant legs.

TRAINING

Surgeons may obtain training from a qualified instructor prior to implantation of this device to ensure thorough understanding of instrumentation, implantation, and removal techniques. Please contact RMR Ortho Customer Service toll-free in the U.S. at (833) 210-2529 or email customersupport@rmrortho.com to arrange training with a qualified instructor.

MRI SAFETY INFORMATION

The A'TOMIC PULSE™ Nitinol Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or imaging artifact in the MR environment. The safety of the A'TOMIC PULSE™ Nitinol Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CAUTION

U.S federal law restricts this device to sale by or on the order of a physician.

SYMBOLS

Refer to package labels to determine which symbols are relevant to the device in the package.

REF	Catalog Number
LOT	Lot Number
CONT	Contents of package
	Use By: YYYY-MM-DD (YYYY is year; MM is month; DD is day)
STERILE R	Sterilized Using Irradiation
SBS	Single Sterile Barrier with Protective Packaging Inside
	Do not reuse
	Do Not Use if Package Has Been Damaged or Opened
℞ ONLY	Prescription Only - Device Restricted to Use By or On The Order of a Physician
	Temperature Limitation
	Consult Instructions for Use (available on RMR Ortho website)
	Manufacturer

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