INSTRUCTIONS FOR USE (ENGLISH)

DEVICE DESCRIPTION

Implants of the A'TOMIC™ Nitinol Fixation System are intended for use as fixation and compression devices to support several surgical techniques (e.g., fracture, osteotomy, joint arthrodesis, and fixation of bone fragments). The implants are made of biocompatible Nitinol and are designed to exhibit superelastic properties at room temperature. The implants are provided sterile packed on retention blocks pre-loaded for insertion.

The system is comprised of various sizes to accommodate individual patient anatomy, varying by leg diameter, bridge length, leg length and number of legs. Leg diameters may be 2.0mm, 2.7mm or 3.2mm. Catalog numbers are descriptive such that 07.27.2118.21A describes an RMR Ortho implant (07) with 2.7mm diameter legs, 21mm bridge, and two 18mm legs.

Instrumentation to assist in the surgical placement of the A'TOMIC™ implants are provided single-use sterile and non-sterile reusable. It is important that the provided instruments are used to ensure the appropriate implantation.

Sterile instruments are provided with and without drills. Facilities may use an appropriately sized drill bit: 2.0 implants require a 2.0mm drill bit; 2.7 implants require a 2.7 or 2.8mm drill bit; 3.2 implants require a 3.2mm drill bit. These drill bits must have a minimum length of 125mm.

IMPLANT MATERIALS

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

INDICATIONS FOR USE

The A'TOMIC™ 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.

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 implant. 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 implant fracture and/or particulate debris. If sterilization is compromised prior to insertion, a different sterile implant 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 implants 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 implant. Modified devices may not perform as intended and could result in patient injury.

POTENTIAL ADVERSE EFFECTS

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

PRECAUTIONS

1. Correct selection of the implant size is important. Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
2. Do not reuse implants. 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 implant removal.
4. Except for appropriately sized drill bits, use only RMR Ortho instruments when handling or implanting RMR Ortho devices.

HOW SUPPLIED

Implants

The implants are provided sterile to the end user. Implant packaging and implants should be inspected to ensure there is no damage. If the implants' packaging or implants' integrity has been compromised use an alternate item and contact the manufacturer for further instructions. **Implants are for single use only.**

Instrument Systems

Instruments are provided sterile or non-sterile to the end user.

Sterile instruments. Sterile instrument packaging and instruments should be inspected to ensure there is no damage. If the instruments' packaging or instruments' integrity has been compromised, contact the manufacturer for further instructions.

Reusable Instruments. Reusable instruments are provided in a sterilization tray for use in healthcare facilities to store and organize RMR Ortho surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. RMR Ortho trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouches or sterilization wraps. The sterilization tray and included components are provided non-sterile to the end user and must be cleaned and sterilized before each use in accordance with the instructions below:

Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.

Cleaning of Reusable Instruments

1. Disassemble all components as per manufacturer instructions (if appropriate).
2. Rinse with cold tap water to remove 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, reclean until it is visibly clean.

The minimum recommended steam sterilization conditions for reusable instruments are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:

1. Double wrap the assembled tray in an FDA-cleared wrap or FDA-cleared sterilization container.
2. Autoclave according to the following parameters:

   Steam Sterilization – PREVACUUM

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 ˚F (132 ˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20-30 minutes

3. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage. These recommendations are consistent with ANSI/AAMI ST79:2010 guidelines and have been developed and tested 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.

OTHER SUPPLIES AND EQUIPMENT NEEDED

- Standard OR equipment used in patient preparation and surgical exposure.
- Power drill with pin driver attachment and AO quick connect attachment.
- FDA-cleared wrap (for reusable tray and instruments only).

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.

1. Expose and prepare surgical site per standard procedure.
2. Reduce or re-approximate fracture, osteotomy, or joint. Apply temporary reduction and fixation.
3. Place the Sizing Guide in the desired position across the fracture, osteotomy, or joint to determine the desired implant bridge length and position.
4. If desired, attach the provided Tamp/Drill Guide Handle to the appropriate Drill Guide. Note that the Tamp/Handle can be placed with a downward or upward angle.
5. To create the first hole, drive the Drill through the Drill Guide into the bone to the far cortex.
6. Insert a Pull Pin through the Drill Guide and into the bone.
7. Repeat Step 5 and 6 to create the remaining hole(s).
8. Remove Drill, Pull Pins and Drill Guide. Pins may be left in place temporarily to mark the position of the drill holes.
9. Select appropriate implant and remove pre-loaded implant from the packaging. Squeeze the wings of the retention block to release the keystone and remove the implant from the retention block.
10. Insert the implant into the pre-drilled holes and pull the slider of the Inserter upwards towards the handle to release the implant.
11. As necessary, lightly tamp the implant with the provided Tamp/Drill Guide Handle to fully seat the implant.
12. Confirm final position using fluoroscopy and proceed with standard closure.

<u>Explant with Removal Tool:</u>
Place the retention springs of the Removal Tool centered on the bridge of the implant. If necessary, use an osteotome to lift the implant 1-2mm from the bone so that the hooks of the retention springs can capture the underside of the implant bridge.
Move slider towards the implant and turn the handle clockwise until the implant can be removed.

<u>Explant without Removal Tool:</u>
Use a small osteotome or curette to lift the implant. If necessary, use a clamp to remove the implant from the bone. The implant bridge may be cut with a pin cutter to release the compression of the implant and allow for ease of implant leg removal if needed.

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 cs@rmrortho.com to arrange training with a qualified instructor.

MRI SAFETY INFORMATION

The A'TOMIC™ 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™ 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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