Part Number	**IFU-1394**
Revision	03
Description	Instruction For Use, Arcus
Notes	N/A

Revision History

Rev	Effective Date	Summary of Change	DCO#	Author
00	10/8/15	Initial Release	15-069	S. Hartle
01	3/11/16	Added statement if product was re-used.	16-020	S. Hartle
02	8/25/17	Added new Emergo Address	17-082	S. Hartle
03	4/11/18	Updated Warning using MRI	18-041	S. Hartle

Arcus™
Staple System

DESCRIPTION

The Nextremity Solutions, Inc. Arcus™ Staple System is indicated for fixation of bone fractures, bone reconstruction, ligaments, soft tissue and tendon in the foot and hand. The Arcus™ Staple System consists of multiple sized staples that may be stacked for added fixation. The system is provided with a set of accessory instruments designed for preparation of the implant site and inserting the implant into bone.

SYSTEM COMPONENTS

Arcus™ Implant Kit

Staple:	Implantable Ti-6Al-4V ELI
Drill:	Surgical-grade stainless steel
Stabilization Pin:	Surgical-grade stainless steel
Drill Guide:	Surgical-grade stainless steel
Staple Inserter:	Polyarylamide and surgical-grade stainless steel

Arcus™ Sizing Template Kit

Sizing Star:	Polycarbonate

INDICATIONS

The Nextremity Solutions, Arcus™ Staple System is indicated for fixation of bone fractures, bone reconstruction, ligament, soft tissue and tendon. Examples included:

- Fixation of bone fragments or small bones fractures
- Fracture management in the foot and hand

CONTRAINDICATIONS

- Patient conditions including insufficient quantity or quality of bone.
- Blood supply limitations and previous or active infections that may inhibit healing.
- Surgical procedures other than for the indications listed.
- Patients with conditions that limit their ability or willingness to follow postoperative care instructions.
- The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature.
- Foreign-body sensitivity. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to implantation.

POTENTIAL ADVERSE EFFECTS

- Infection, deep and superficial
- Loosening or migration of the implant
- Nerve damage due to surgical trauma

- Inadequate healing
- Pain, soft tissue discomfort or abnormal sensation due to the presence of the device
- Allergies or other reactions to implant materials

PRECAUTIONS

- It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective surgical technique and implants used.
- Surgical instruments and implants may only be used for surgeries for which the designated application of the instrument and implant is explicitly necessary and defined.
- The trained expert staff is obligated to examine the surgical implant and its sterile packaging for damage prior to use. In case of the implant or its packaging being damaged or deformed, it is not to be used.
- Only Nextremity Solutions, Inc. specially manufactured instruments and implants (contained in the respective set) are to be used. If using other instruments and implants, function, warranty and liability are omitted.

WARNINGS

- This product may only be used with accessories from the respective Arcus™ Staple System kit.
- Application and use of other instruments or implants is not permitted.
- Cutting edges, blades, tips etc. can be very sensitive to mishandling. Thus, these instruments must be handled with care.
- Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.

MRI SAFETY INFORMATION

- The Arcus™ Staple System has not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration or image artifact in the MRI environment. The safety of the Arcus Staple System in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTION FOR USE

Warning: The Arcus™ Staple System is available and should only be used with the supplied, dedicated instruments.

Arcus™ Surgical Technique

1. Create osteotomy on subject bone.
2. Measure for the implant, using the intra-operative Arcus™ Sizing Template Kit provided in a separate box.

3. Select appropriate Implant Kit, based on results from step 2.
4. Reduce osteotomy. Place drill guide over the osteotomy while ensuring appropriate angle for drilling. Drill the first hole and insert stabilization pin.
5. Drill the second hole. Remove stabilization pin and drill guide. (Surgical marker can be used to mark holes after drilling if needed for visualization)
6. Align tips of the tines of the Arcus™ staple over the pre-drilled holes and at the same angle as the pre-drilled holes. Press the Arcus™ staple into pre-drilled holes. Remove the inserter by tilting inserter in the direction of the staple tines. (Some tapping using a mallet on the end of the inserter may be required in harder bone to ensure the Arcus™ staple is fully seated).
7. Remove Inserter from Staple by twisting knob counter-clockwise until lever arm is free, then tilt Inserter forward or backward.
8. To check placement, fluoroscopy may be used.

Stacking (Optional)

1. Create your osteotomy or prepare the joint and then reduce. Insert the first Arcus™ staple as indicated in the surgical technique.
2. Based on the size of the first **Arcus™ staple**, select a second Arcus™ staple that will appropriately stack. The separate Sizing Template Kit may be used to help determine the appropriate size of staple.
3. Using the selected size Arcus™ Implant Kit, place the corresponding drill guide over the osteotomy site while ensuring appropriate angle for drilling.
4. Drill the first hole and insert stabilization pin.
5. Drill the second hole. Remove stabilization pin and drill guide. (Surgical marker can be used to mark holes after drilling if needed for visualization)
6. Align tips of the tines of the Arcus™ staple over the pre-drilled holes and at the same angle as the pre-drilled holes. Press the Arcus™ staple into pre-drilled holes. Some tapping using a mallet on the end of the inserter may be required in harder bone to ensure the Arcus™ staple is fully seated.
7. Remove inserter from staple by twisting knob counter-clockwise until lever arm is free, then tilt Inserter forward or backward.
8. To check implant placement, fluoroscopy may be used.

CAUTION: If the device must be removed, do not reuse any portion of the device.

HOW SUPPLIED

The Arcus™ Staple System is available as a sterile surgical kit(s). The components of the Arcus™ Staple System are for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. If product is re-used it may cause infection and may compromise the mechanical integrity of the product which may lead to failure.

The Arcus™ staple is non-pyrogenic.

STORAGE AND HANDLING

Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments.

PACKAGING AND LABELING

1. Nextremity Solutions devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Nextremity Solutions™ and Arcus ™ are trademarks of Nextremity Solutions, Inc. These products are covered by one or more U.S. and international patents pending.

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