Instructions for Use: Lever Action Plate System

LEVER ACTION PLATE SYSTEM®

McGinley Orthopedics
ENGINEERING MEDICAL PROGRESS

Device Overview

The plate system is made up of two distinguished parts: the plate and the beam. The plate is designed to conform to either the diaphysis, the metaphysis, or both parts of the radius. There are at least three types of openings on each plate: the opening for locking or non-locking fixation devices to secure the plate to the bone, the opening for the beam to be inserted to the fracture and connected to the plate, and the opening for the positioning devices to adjust the beam to its proper angle. The holes for the fixation devices have locking compatible threads on them. Using threaded screws allows the plates to be secured to the bone without negatively affecting the fracture. Plates may also have an additional opening to be used for Kirschner wires or K-wires to provide additional fixation. Plates may also have a central window opening to increase visibility when placing the plate and to provide an opening for fill material.

The beam is responsible for engaging the fractured subchondral bone. It can be readjusted by the positioning devices. The beam is an optional feature, and the plate can be used alone if no subchondral bone fixation is needed.

Indication for Use Statement: The Lever Action Plate System® is indicated for:

- Fixation of fractures or non-unions of the distal radius
- Osteotomies of the distal radius to correct malunion

Training

Documents available on request. Please contact support@mcginleyinnovations.com.

Symbols Descriptions

MD Medical Device	Caution - Read IFU before use	Rx only By Prescription Only
Consult Instructions for Use	Please Dispose of Properly	Manufactured By
LOT Lot Number	Do Not Use if Packaging is Compromised	NON STERILE Non-sterile
REF Batch Code		Do Not Reuse

Glossary and Abbreviations

Beam	Variable angle blade that snaps onto plate for restoration of volar tilt.
Beam-Screw	Locking screw that lifts and supports beam into reduced position.
Guide Block	Plate attachment used to direct drill bits and screws to their correct angles.
Guide Block Lock Screw	Used to secure guide block to plate.
Beam Awl	Awl that carves out slot for beam to insert into bone.
Beam Awl Pin Guide	Tool that guides pins into the outer cortex, allowing fenestration in the cortex where the beam awl will be inserted.
Volar Tilt Gauge	Tool that measures the length of beam screw needed to restore distal fragment to reduced position.
Beam Inserter Tool	Tool used to place and attach beam to plate.
Extractor Mallet	Fork-shaped blunt tool used to linearly extract beam awl from radius.

Technical Data

Material for Ti-6Al-4V, medical grade titanium: Iron (0.13-0.14%), Vanadium (4.06-4.08%), Aluminum (6.14-6.16%), Carbon (0.006-0.008%), Oxygen (0.11-0.12%), Nitrogen (0.002-0.003%), Yttrium (<0.0004%), Titanium (remaining)

Plate	Part Number	Length (mm)	Width (mm)	Thickness (mm)	Number of Locking Screw holes
Right Plate, Extra Small, Narrow, 2 Beams, Variable	MCG-RA2V	36.2	25.8	2.0	10
Right Plate, Small, Narrow, 2 Beams, Variable	MCG-RB2V	55.7	25.8	2.0	13
Right Plate, Extra Small, Standard, 2 Beams, Variable	MCG-RC2V	38.9	27.4	2.0	11
Right Plate, Small, Standard, 2 Beams, Variable	MCG-RD2V	54.0	27.4	2.0	14
Right Plate, Extra Small, Wide, 2 Beams, Variable	MCG-RE2V	38.5	31.1	2.0	11
Right Plate, Small, Wide, 2 Beams, Variable	MCG-RF2V	55.0	31.1	2.0	14
Left Plate, Extra Small, Narrow, 2 Beams, Variable	MCG-LA2V	36.2	25.8	2.0	10
Left Plate, Small, Narrow, 2 Beams, Variable	MCG-LB2V	55.7	25.8	2.0	13
Left Plate, Extra Small, Standard, 2 Beams, Variable	MCG-LC2V	38.9	27.4	2.0	11
Left Plate, Small, Standard, 2 Beams, Variable	MCG-LD2V	54.0	27.4	2.0	14
Left Plate, Extra Small, Wide, 2 Beams, Variable	MCG-LE2V	38.5	31.1	2.0	11
Left Plate, Small, Wide, 2 Beams, Variable	MCG-LF2V	55.0	31.1	2.0	14
Right Plate, Extra Small, Narrow, 1 Beam, Fixed	MCG-RA1F	33.0	24.7	2.0	10
Right Plate, Small, Narrow, 1 Beam, Fixed	MCG-RB1F	51.9	24.7	2.0	13
Right Plate, Extra Small, Standard, 1 Beam, Fixed	MCG-RC1F	35.6	25.2	2.0	11
Right Plate, Small, Standard, 1 Beam, Fixed	MCG-RD1F	51.5	25.2	2.0	14
Right Plate, Extra Small, Wide, 1 Beam, Fixed	MCG-RE1F	32.9	29.2	2.0	10
Right Plate, Small, Wide, 1 Beam, Fixed	MCG-RF1F	49.4	29.2	2.0	13
Left Plate, Extra Small, Narrow, 1 Beam, Fixed	MCG-LA1F	33.0	24.7	2.0	10
Left Plate, Small, Narrow, 1 Beam, Fixed	MCG-LB1F	51.9	24.7	2.0	13
Left Plate, Extra Small, Standard, 1 Beam, Fixed	MCG-LC1F	35.6	25.2	2.0	11
Left Plate, Small, Standard, 1 Beam, Fixed	MCG-LD1F	51.5	25.2	2.0	14
Left Plate, Extra Small, Wide, 1 Beam, Fixed	MCG-LE1F	32.9	29.2	2.0	10
Left Plate, Small, Wide, 1 Beam, Fixed	MCG-LF1F	49.4	29.2	2.0	13

Screws & Beams	Part Number	Diameter (mm)	Length (mm)	Screws & Beams	Part Number	Diameter (mm)	Length (mm)
Locking Screw	MCG-L2510	2.5	10	Non-Locking Screw	MCG-N2520	2.5	20
Locking Screw	MCG-L2511	2.5	11	Non-Locking Screw	MCG-N2522	2.5	22
Locking Screw	MCG-L2512	2.5	12	Non-Locking Screw	MCG-N2524	2.5	24
Locking Screw	MCG-L2513	2.5	13	Snap Beam	MCG-B16	N/A	16
Locking Screw	MCG-L2514	2.5	14	Snap Beam	MCG-B19	N/A	19
Locking Screw	MCG-L2516	2.5	16	Snap Beam	MCG-B22	N/A	22
Locking Screw	MCG-L2518	2.5	18	Beam Screw	MCG-S12	3.5	12
Locking Screw	MCG-L2520	2.5	20	Beam Screw	MCG-S13	3.5	13
Locking Screw	MCG-L2522	2.5	22	Beam Screw	MCG-S14	3.5	14
Locking Screw	MCG-L2524	2.5	24	Beam Screw	MCG-S15	3.5	15
Non-Locking Screw	MCG-N2510	2.5	10	Beam Screw	MCG-S16	3.5	16
Non-Locking Screw	MCG-N2511	2.5	11	Beam Screw	MCG-S17	3.5	17
Non-Locking Screw	MCG-N2512	2.5	12	Beam Screw	MCG-S18	3.5	18
Non-Locking Screw	MCG-N2513	2.5	13	Beam Screw	MCG-S19	3.5	19
Non-Locking Screw	MCG-N2514	2.5	14	Beam Screw	MCG-S20	3.5	20
Non-Locking Screw	MCG-N2516	2.5	16	Beam Screw	MCG-S21	3.5	21
Non-Locking Screw	MCG-N2518	2.5	18	Beam Screw	MCG-S22	3.5	22

Contraindications

- This device is contraindicated for use on patients with known allergies to the material composition.
- This device is contraindicated for use on patients with physical conditions that may inhibit proper healing or support of the implant. Physical conditions include, but are not limited to poor quality of bone, poor quality of skin, insufficient quantity of bone, insufficient blood supply, etc.

Warnings and Precautions

- This device should not be used on patients with the previously listed contraindications.
- A Surgical Technique Guide is provided, and surgeons are advised to review the device's intended implant procedure before use.
- The surgical team should ensure the implants and instruments are at full inventory before beginning a procedure.
- The surgeon should check the location of the intended implant to ensure soft tissue structures will not be disturbed by the device.
- The surgical team should inspect devices for damage prior to use. Abrasions on the device can affect the strength and service life of the component. Use caution when handling and storing the device.
- Do not bend device in locations near locking screw holes.
- Implants in the system are strictly single use only.
- The device must be sterilized before use.

Possible Adverse Effects

With any surgical procedure, there is a potential for adverse effects associated with the implant device. Possible adverse effects include:

- High stress fractures and loosening of implants or fixation devices.
- Damage to implants can be attributed to contraindications, excessive activity, etc.
- Discomfort to hardware
- Infections
- Tendinitis
- Stiffness of joint
- Scarring
- Bleeding
- Loss of position

MRI Safety Information

The Lever Action Plate System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Lever Action Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Operation

See Surgical Technique Guide.

Manual Cleaning Procedure

1. Use proper PPE during cleaning process. Instruments should be cleaned as soon as possible. Do not allow blood and debris to dry on instruments. If cleaning cannot be performed immediate, keep the instruments moist.
2. Wipe soiled devices using a soft, low-lint wipe.
3. Prepare a warm (32-43°C / 90-110°F) detergent solution using a pH neutral, enzymatic detergent (such as STERIS PROLYSTICA® HP Enzymatic Manual Cleaner) according to manufacturer's recommended instructions.
4. Soak soiled devices in the prepared enzymatic detergent solution for ≥ 1 minute.
5. Using a soft nylon bristle brush, scrub the exposed surfaces of each device while submerged for a minimum of 30 seconds or until all visible soil has been removed.
6. Using 1 Channel brushes, scrub each interior lumen for ≥ 3 complete passes (in and out) clearing any visible soil from brush bristles after each pass.
7. Rinse cleaned devices under flowing, warm (32-43°C / 90-110°F) utility water for ≥ 30 seconds.
8. Rinse cleaned devices under flowing critical water (deionized or reverse-osmosis) for ≥ 30 seconds.
9. Allow devices to dry in a clean environment.
10. For sterilization tray cleaning, see document "MCG2019-4 Tray IFU."
11. For container cleaning, see document "MCG2019-4 Container IFU."

Automatic Cleaning Procedure

1. Use proper PPE during cleaning process.
2. Pre-clean devices under flowing, warm (20-25°C / 68-77°F) utility water for ≥ 1 minute using a soft-bristled nylon brush and/or gloved hands to remove all visible soil.
3. Load devices into a wire mesh basket. Place a wire mesh lid on top of the devices to prevent movement while washing. NOTE: Arrange devices to allow for draining.
4. Place basket(s) of devices into an automated washer / disinfector with the **motor speed set on high**, detergent delivered at the manufacturer's recommended concentration and programmed as follows:

Phase	Minimum Recirculation Time (minutes)	Temperature
Pre-wash	00:15 - 15:00	Cold utility water
Enzyme wash	04:00 - 15:00	Hot utility water
Wash	02:00 - 15:00	60 - 82.2°C / 140 - 180°F
Neutralization*	01:00 - 15:00	60 - 82.2°C / 140 - 180°F
Rinse	00:15 - 15:00	43.3 - 82.2°C / 110 - 180°F
Thermal Rinse	01:00 - 10:00	82.2 - 95.0°C / 180 - 203°F
Hot Air Dry	00:00 - 60:00	82.2 - 98.8°C / 180 - 210°F

*Neutralization is omitted for neutral pH detergents.

NOTE: Lubrication is not recommended.

5. Unload basket(s) of devices from washer / disinfector.
6. Visually inspect each device for remaining soil.
7. If visible soil remains, repeat steps 2 – 6 until all visible soil has been removed.

Sterilization Requirements

ON-SITE STERILIZATION IS REQUIRED PRIOR TO USE.

1. Always use proper PPE during the cleaning process.
2. Follow this chart for sterilization settings

Sterilizer Type:	Pre-vacuum
Precondition Pulses:	4
Temperature:	132°C
Full Cycle Exposure Time:	4 minutes
Dry Time:	30 minutes

Maintenance Requirements

After each use, visually inspect the instruments for any defects.

Warranty

Please contact customer service at support@mcginleyinnovations.com or 307.315.6403 for details.

Special Handling Instructions

The Lever Action Plate System is single use and shall be sterilized per the instructions in this manual prior to use.
Store the Lever Action Plate System in a manner common to industry practice, including storing in a dry place.
Store the Lever Action Plate System in such a way as to maintain sterility after sterilization process.
Implants arrive individually in protective packaging.

Manufactured By:

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