OsteoCentric® Trauma

Long Screw Fastener Set

Featuring

2.7mm & 3.5mm Long Screw Fasteners

Surgical Technique



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Important Note

The OsteoCentric Long Fastener Set (featuring 2.7mm & 3.5mm Long Fasteners) complements the versatile OsteoCentric Small Fragment Set. The instrument and implant sets can be utilized separately or in conjunction.

Reference Surgical Technique Guide TR-001-LBL-0002 for the Osteocentric Small Fragment Set surgical instructions which includes Compression, Reconstruction, 1/3 Tubular, and Distal Fibula plates along with 3.5mm, 3.3mm, and 2.7mm interlocking screw fasteners that work in any plate hole for customized constructs for each patient.



Description

The OsteoCentric Trauma Long Screw Fastener Set consists of cortical fasteners in a variety of lengths and diameters to accommodate different anatomic sizes of patients. This set offers a larger range of implants which better equips physicians to choose the best implant for the anatomy. This set also includes washers and select instrumentation, which has been lengthened to facilitate implantation in anatomies which are located deep within the soft tissue. All implants are made of FDA approved stainless steel per ASTM F138, and all instrumentation materials are FDA approved.

The OsteoCentric Long Fastener Set uses all standard instrumentation familiar to orthopedic surgeons. Fasteners are currently available in stainless steel.

Instrument Set

• Long Hex Driver: 110104

• Long Hex Driver Fixed 300mm: 110703

• 2.5mm Hex Driver Sleeve: 110701

Depth Gauge For Small Frag 150mm: 110206

• Screw Fastener Holding Forceps: 110705

2.7mm Long Screw Fastener Drill Bits

• 2.0mm Drill 145mm, Calibrated: 110039

• 2.7mm Drill Bit 100mm: 110016

3.5mm Long Screw Fastener Drill Bits

• 2.5mm Drill Bit Calibrated 200mm: 110040

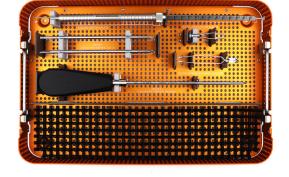
• 3.5mm Drill Bit 110mm: 110028

Long Screw Fastener Taps

• 2.7mm Cortical Screw Fastener Tap 145mm: 110402

• 3.5mm Cortical Screw Fastener Tap 200mm: 110454

Note: Fastener specific Drill Bits and Taps are located in the Screw Fastener implant caddies.



Screw Fastener Implant Caddies

2.7mm Long Screw Fastener

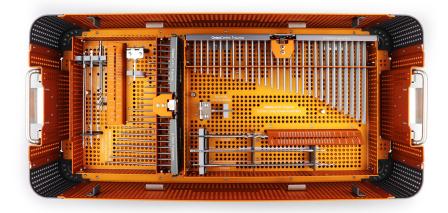
- 34mm 50mm, 2mm increments
- 50mm -110mm, 5mm increments
- 327-1xxx

3.5mm Long Screw Fastener

- 52mm 88mm, 2mm increments
- 90mm 130mm, 5 mm increments
- 335-1xxx

7mm Washer

• 300-0701



Indications for Use

The OsteoCentric Trauma Long Screw Fastener System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including periarticular and intraarticular fractures.

Contraindications

- Active or latent infection
- · Insufficient quantity or quality of bone/soft tissue
- · Material sensitivity If suspected, tests should be performed prior to implantation
- Sepsis
- Patients who are unwilling or incapable of following postoperative care instructions
- Spinal fixation This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine

Potential Adverse Events

Adverse reactions may include but are not limited to:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture of implant, loss of fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- · Allergic reactions to implant material
- Limb shortening due to compression of the fracture or bone resorption
- Necrosis of bone or decrease of bone density
- Injury to vessels, nerves and organs
- Hematoma and/or impaired wound healing; hemorrhage

Ilium or Iliac Wing 3.5mm Long Fastener Technique

Note: If dense, hard bone or excessive insertion torque is encountered, confirm the proper drill bit size has been utilized. If it has, it is recommended to use the appropriately sized Tap to prepare the bone for screw insertion.

- 1. Utilize the 2.5mm Fastener Drill Bit to prepare the bone for Fastener insertion.
- 2. Measure Fastener length using the provided Depth Gauge.
- 3. Confirm the appropriate implant length and diameter has been selected and insert the Fastener using the preferred 2.5mm Hex Driver.
- 4. If necessary, insert additional Fasteners as appropriate for the fracture.

Note: If a plate is utilized at the fracture site, a lag screw technique can be used through the plate by overdrilling the near cortex (Figure 1) with the 3.5mm Drill Bit.



Figure 1

Plateau Fracture 2.7mm Long Fastener Technique

Note: If dense hard bone or excessive insertion torque is encountered, confirm the proper drill bit size has been utilized. If it has, it is recommended to use the appropriately sized Tap to prepare the bone for screw insertion.

- 1. Utilize the 2.0mm Fastener Drill Bit to prepare the bone for Fastener insertion.
- 2. Measure Fastener length using the provided Depth Gauge.
- 3. Confirm the appropriate implant length and diameter has been selected and insert the Fastener using the preferred 2.5mm Hex Driver.
- 4. If necessary, insert additional Fasteners as appropriate for the fracture.

Note: If a plate is utilized at the fracture site, a lag screw technique can be used through the plate by overdrilling the near cortex with the 2.7mm Drill Bit.

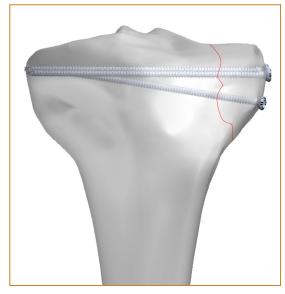


Figure 2

2.7mm Long Screw Fastener Instruments

| Part Number | Description | Set Qty |
|-------------|-------------------------------|---------|
| 110039 | 2.0mm Drill Bit, 145mm | 2 |
| 110016 | 2.7mm Drill Bit, 100mm | 2 |
| 110402 | 2.7mm Bone Screw Fastener Tap | 2 |
| A 2400-01 | 2.7 Fastener Caddy | 1 |

2.7mm Long Screw Fastener Implants

| 9 | | • |
|-------------|------------------------------|---------|
| Part Number | Description | Set Qty |
| 300-0701 | 7mm Washer | 5 |
| 327-1034 | 2.7 x 34mm CORTEX SCREW, ST | 2 |
| 327-1036 | 2.7 x 36mm CORTEX SCREW, ST | 2 |
| 327-1038 | 2.7 x 38mm CORTEX SCREW, ST | 2 |
| 327-1040 | 2.7 x 40mm CORTEX SCREW, ST | 2 |
| 327-1042 | 2.7 x 42mm CORTEX SCREW, ST | 2 |
| 327-1044 | 2.7 x 44mm CORTEX SCREW, ST | 2 |
| 327-1046 | 2.7 x 46mm CORTEX SCREW, ST | 2 |
| 327-1048 | 2.7 x 48mm CORTEX SCREW, ST | 2 |
| 327-1050 | 2.7 x 50mm CORTEX SCREW, ST | 2 |
| 327-1055 | 2.7 x 55mm CORTEX SCREW, ST | 2 |
| 327-1060 | 2.7 x 60mm CORTEX SCREW, ST | 2 |
| 327-1065 | 2.7 x 65mm CORTEX SCREW, ST | 2 |
| 327-1070 | 2.7 x 70mm CORTEX SCREW, ST | 2 |
| 327-1075 | 2.7 x 75mm CORTEX SCREW, ST | 2 |
| 327-1080 | 2.7 x 80mm CORTEX SCREW, ST | 2 |
| 327-1085 | 2.7 x 85mm CORTEX SCREW, ST | 2 |
| 327-1090 | 2.7 x 90mm CORTEX SCREW, ST | 2 |
| 327-1095 | 2.7 x 95mm CORTEX SCREW, ST | 2 |
| 327-1100 | 2.7 x 100mm CORTEX SCREW, ST | 2 |
| 327-1105 | 2.7 x 105mm CORTEX SCREW, ST | 2 |
| 327-1110 | 2.7 x 110mm CORTEX SCREW, ST | 2 |
| | | |

3.5mm Long Screw Fastener Instruments

| Part Number | Description | Set Qty |
|-------------|----------------------------------|---------|
| 110028 | 3.5mm Drill Bit 110mm | 2 |
| 110040 | 2.5mm Drill Bit Calibrated 200mm | 2 |
| 110104 | Long Hex Driver | 2 |
| 110206 | Long Depth Gauge | 1 |
| 110454 | 3.5mm Screw Fastener Tap 200mm | 1 |
| 110701 | 2.5mm Hex Driver Sleeve | 1 |
| 110703 | Long Hex Driver Fixed 300mm | 1 |
| 110705 | Screw Fastener Holding Forceps | 1 |

3.5mm Long Screw Fastener Implants

| Part Number | Description | Set Qty |
|-------------|---|---------|
| 300-0701 | 7mm Washer | 4 |
| 335-1052 | 3.5mm Screw Fastener Self-Tapping 52mm | 2 |
| 335-1054 | 3.5mm Screw Fastener Self-Tapping 54mm | 2 |
| 335-1056 | 3.5mm Screw Fastener Self-Tapping 56mm | 2 |
| 335-1058 | 3.5mm Screw Fastener Self-Tapping 58mm | 2 |
| 335-1060 | 3.5mm Screw Fastener Self-Tapping 60mm | 2 |
| 335-1062 | 3.5mm Screw Fastener Self-Tapping 62mm | 2 |
| 335-1064 | 3.5mm Screw Fastener Self-Tapping 64mm | 2 |
| 335-1066 | 3.5mm Screw Fastener Self-Tapping 66mm | 2 |
| 335-1068 | 3.5mm Screw Fastener Self-Tapping 68mm | 2 |
| 335-1070 | 3.5mm Screw Fastener Self-Tapping 70mm | 2 |
| 335-1072 | 3.5mm Screw Fastener Self-Tapping 72mm | 2 |
| 335-1074 | 3.5mm Screw Fastener Self-Tapping 74mm | 2 |
| 335-1076 | 3.5mm Screw Fastener Self-Tapping 76mm | 2 |
| 335-1078 | 3.5mm Screw Fastener Self-Tapping 78mm | 2 |
| 335-1080 | 3.5mm Screw Fastener Self-Tapping 80mm | 2 |
| 335-1082 | 3.5mm Screw Fastener Self-Tapping 82mm | 2 |
| 335-1084 | 3.5mm Screw Fastener Self-Tapping 84mm | 2 |
| 335-1086 | 3.5mm Screw Fastener Self-Tapping 86mm | 2 |
| 335-1088 | 3.5mm Screw Fastener Self-Tapping 88mm | 2 |
| 335-1090 | 3.5mm Screw Fastener Self-Tapping 90mm | 2 |
| 335-1095 | 3.5mm Screw Fastener Self-Tapping 95mm | 3 |
| 335-1100 | 3.5mm Screw Fastener Self-Tapping 100mm | 3 |
| 335-1105 | 3.5mm Screw Fastener Self-Tapping 105mm | 3 |
| 335-1110 | 3.5mm Screw Fastener Self-Tapping 110mm | 3 |
| 335-1115 | 3.5mm Screw Fastener Self-Tapping 115mm | 3 |
| 335-1120 | 3.5mm Screw Fastener Self-Tapping 120mm | 3 |
| 335-1125 | 3.5mm Screw Fastener Self-Tapping 125mm | 3 |
| 335-1130 | 3.5mm Screw Fastener Self-Tapping 130mm | 3 |
| A2200-01 | Large Case Lid | 1 |
| A2400 | Long Fasteners Outer Case | 1 |
| A2400-02 | 3.5mm Long Fastener Caddy | 1 |
| A2400-03 | Instrument Tray Long Fasteners | 1 |

Note

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