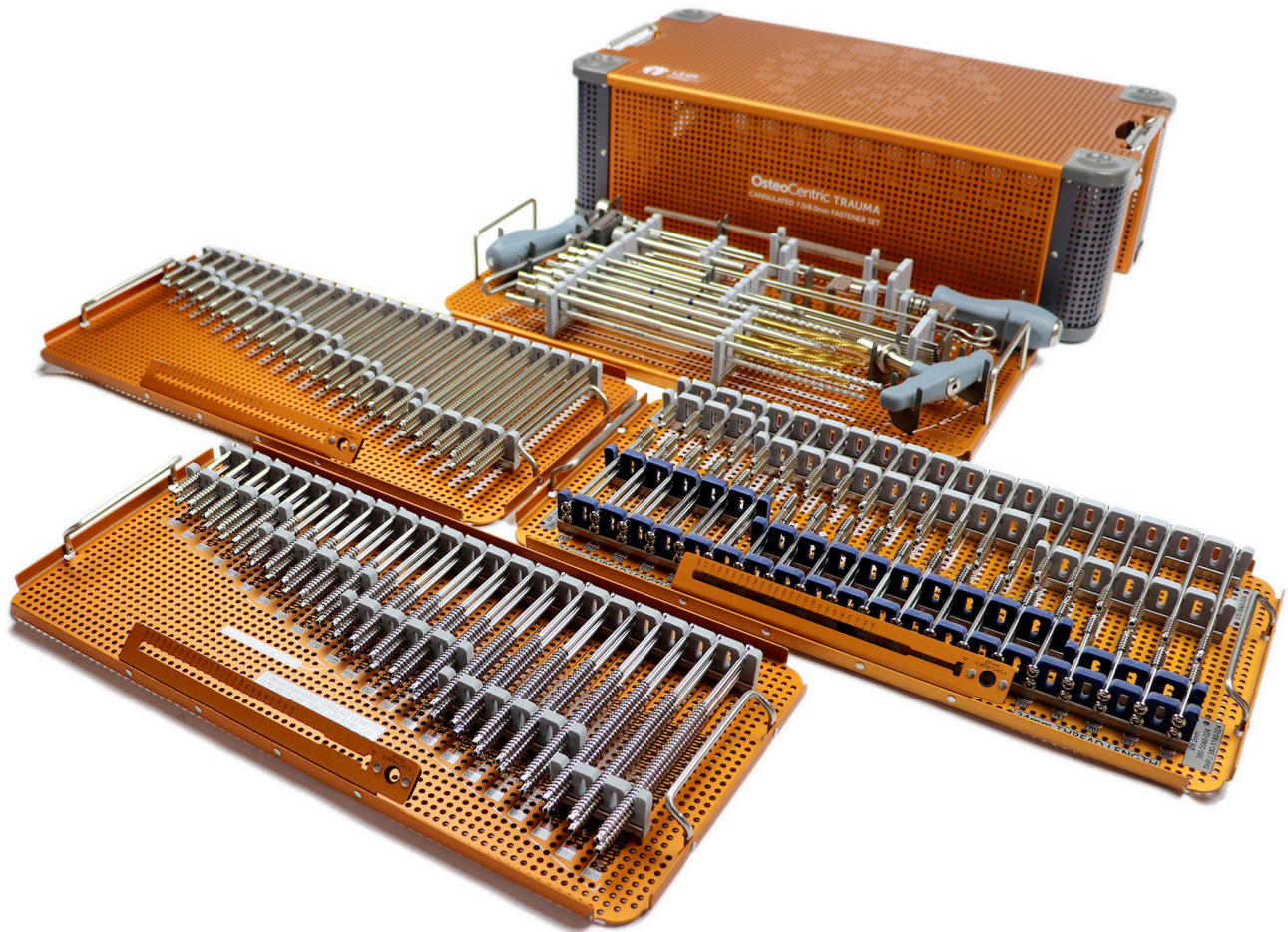


OsteoCentric[®] Trauma

Cannulated Screw Fastener

Surgical Technique



OsteoCentric[®]
TECHNOLOGIES

OsteoCentric Trauma Cannulated Screw Fastener

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Description

The OsteoCentric Trauma Cannulated Screw Fasteners consist of cannulated fasteners in a variety of lengths and diameters to accommodate different procedures and patient sizes. The fasteners are provided non-sterile and are manufactured from Stainless Steel per ASTM F138.

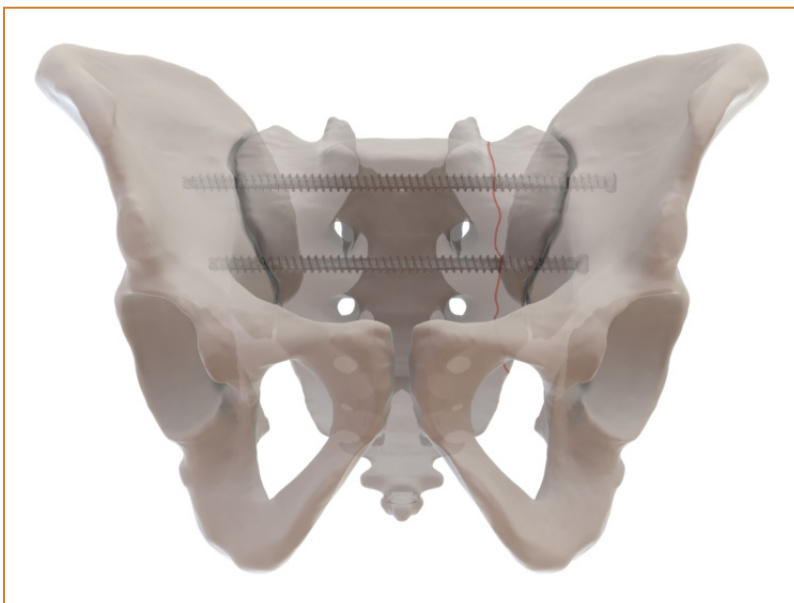
General System Information

The surgeon must select the type and size of the implant that best meets the patient's surgical needs. Refer to the Instructions for Use for indications, contraindications, precautions, warnings and cleaning instructions. To obtain these materials or to obtain more information about products, go to www.osteocentric.com or please contact Customer Service at (800) 969-0639.



Indications for Use

The OsteoCentric 7.0mm to 8.0mm Cannulated Screws are intended for fracture fixation of long bones and long bone fragments, long bone osteotomies, femoral neck fractures, slipped capital femoral epiphyses as an adjunct to treatment with a dynamic hip screw (DHS) in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, SI joint disruptions, fixation of pelvis and iliosacral joints, and subtalar arthrodesis.



Implant Overview

The OsteoCentric Trauma Cannulated Screw Fasteners consist of cannulated fasteners in a variety of lengths and diameters to accommodate different procedures and patient sizes. The fasteners are provided non-sterile and are manufactured from stainless steel.

The OsteoCentric Trauma Cannulated Screw Fasteners System includes:

Ø7.0mm Cannulated Screw Fasteners

- Self-Tapping
- Full Thread, 24mm Partially Threaded, and Variable Threaded options
- 60mm – 180mm lengths in 5mm increments
- Stainless Steel per ASTM F138



Figure 1: 7.0 x 100 Variable Thread

Ø8.0mm Cannulated Screw Fasteners

- Self-Tapping
- Full Thread, 24mm Partially Threaded, and Variable Threaded options
- 60mm – 180mm lengths in 5mm increments
- Stainless Steel per ASTM F138



Figure 2: 8.0 x 24mm Partial Thread

NOTE: Please pay special attention to the part numbers for the Variable thread fasteners.

The example part number layout is as follows;

370-5XXX-XXX

- 370- Indicates that it is the 7.0mm Fastener.
- 5XXX- Indicates the overall length of the Fastener.
- XXX- the remaining three digits indicate the thread length.

For Example: Part number 370-5130-070 indicates that it is the 7.0mm fastener with an overall length of 130mm and has a variable thread length of 70mm.

The overall length of the fastener is identified in the faster tray in black lettering.

The variable thread length of the fastener is identified in the fastener tray in white lettering.

Insertion of an OsteoCentric Trauma Cannulated Screw Fastener

1. Select the appropriately sized fastener for the operative procedure

- a. Prior to surgery, ensure that the instrument set is complete with fasteners and instrumentation (i.e. guide wires, drill bits, taps, and screwdrivers).

2. Dissect down to bone and reduce the fracture

- a. Reduce the fracture using standard techniques and instrumentation. (Figure 3)



Figure 3

3. Place the appropriate guide wire in the desired orientation. Nested soft tissue protectors are available (2004-0001-01, -03, & -04).

(Figure 4)

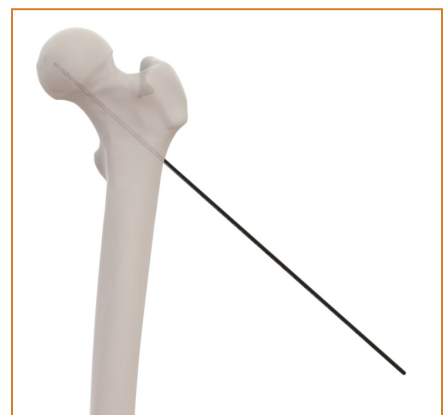


Figure 4

Warning and Precaution

As with any system using guidance wires, special care should be taken to ensure the position of the guide wire, using fluoroscopy.

Guide Wire placement should be verified periodically especially while using rotating instrumentation. The guide wire can become lodged in an instrument for various reasons, causing the guide wire to drive forward beyond the original placement, introducing unintended consequences and risk for the patient.

4. Measure the fastener length

- a. Place the depth gauge (2004-0016) over the guide wire and advance to bone. The indicated length shows the depth of the guide wire tip and the corresponding fastener to use. (Figure 5)

Note: The Cannulated Depth Gauge measures to the tip of the guide wire. This allows the final screw position to correspond with the initial tip position of the guide wire. The reading indicates the working length of the fastener which is measured from just under the head to the tip of the fastener.

Select the appropriate size fastener keeping in mind subtracting for any anticipated interfragmentary compression. Length is particularly important if the tip is near the articular surface.

If using a counter sink, this should be done prior to inserting the cannulated depth gauge.

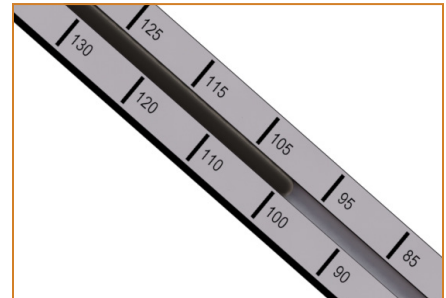


Figure 5

5. Drill using the appropriate cannulated drill bit

- a. Expose the bone with appropriate aseptic surgical technique.
- b. Drill the near cortex with the appropriately sized cannulated drill bit.
- c. For both 7.0 and 8.0mm fasteners, the appropriate drill is the 5.0mm drill bit (2004-0008). (Figure 6)

See Warning and Precautions pg 5



Figure 6

6. Tap

- a. With the self-tapping fasteners, tapping is not required in most instances. In specific cases such as hard bone, tapping may be utilized by using the appropriately sized cannulated tap to prepare the bone for fastener insertion. (7.0mm Tap, 2004-0007) and (8.0mm Tap, 2004-0021) (Figure 7)

See Warning and Precautions pg 5



Figure 7

7. Insert fastener (Figure 8)

- a. Attach the appropriately sized fastener to the cannulated screwdriver.
- b. Washers are available if desired.
(13mm, 300-1302) & (16mm, 300-1601)
- c. Advance the fastener by turning the 4.0mm Hex Driver clockwise until firmly seated in the bone.
- d. Do not use excessive force as the fastener threads may strip.

See Warning and Precautions pg 5



Figure 8

8. Fastener Insertion into Bone (Figure 9)

See Warning and Precautions pg 5



Figure 9

9. Final Construct in Bone (Figure 10)



Figure 10

Contraindications:

The physician's education, training, and professional judgment are necessary to determine the appropriate treatment protocol and patient selection. Contraindications may be relative to each patient, and clinicians should always consider all risks and possible reactions when considering the proper treatment protocol.

Specific contraindications include:

- Allergies and sensitivities to materials in the device
- Active or latent infection
- Obesity
- Pathologic fractures
- Skeletal immaturity
- Osteoporosis or other disease resulting in osteopathology
- Previous implantation
- Tissue viability at or near the operative site
- Compromised blood flow at or near the operative site
- Mental or neuromuscular disorders
- Patient compliance
- Spinal fixation – this device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Note:

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice.

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Implants

All implant components are manufactured from Stainless Steel per ASTM F138.

Part Number	Description	Size (mm)
2004-2000	Cannulated Screw Fastener Set	
2004-2000-01	Cannulated 7.0/8.0mm Outer Case	
A2200-01	Lid	
2004-2000-03	7.0mm Full Thread Tray	
300-1302	13mm Washer	
300-1601	16mm Washer	
370-5070-001	7.0 X 70mm Cann Screw Fastener Full Thd	70
370-5075-001	7.0 X 75mm Cann Screw Fastener Full Thd	75
370-5080-001	7.0 X 80mm Cann Screw Fastener Full Thd	80
370-5085-001	7.0 X 85mm Cann Screw Fastener Full Thd	85
370-5090-001	7.0 X 90mm Cann Screw Fastener Full Thd	90
370-5095-001	7.0 X 95mm Cann Screw Fastener Full Thd	95
370-5100-001	7.0 X 100mm Cann Screw Fastener Full Thd	100
370-5105-001	7.0 X 105mm Cann Screw Fastener Full Thd	105
370-5110-001	7.0 X 110mm Cann Screw Fastener Full Thd	110
370-5115-001	7.0 X 115mm Cann Screw Fastener Full Thd	115
370-5120-001	7.0 X 120mm Cann Screw Fastener Full Thd	120
370-5125-001	7.0 X 125mm Cann Screw Fastener Full Thd	125
370-5130-001	7.0 X 130mm Cann Screw Fastener Full Thd	130
370-5135-001	7.0 X 135mm Cann Screw Fastener Full Thd	135
370-5140-001	7.0 X 140mm Cann Screw Fastener Full Thd	140
370-5145-001	7.0 X 145mm Cann Screw Fastener Full Thd	145
370-5150-001	7.0 X 150mm Cann Screw Fastener Full Thd	150
370-5155-001	7.0 X 155mm Cann Screw Fastener Full Thd	155
370-5160-001	7.0 X 160mm Cann Screw Fastener Full Thd	160
370-5165-001	7.0 X 165mm Cann Screw Fastener Full Thd	165
370-5170-001	7.0 X 170mm Cann Screw Fastener Full Thd	170
370-5175-001	7.0 X 175mm Cann Screw Fastener Full Thd	175
370-5180-001	7.0 X 180mm Cann Screw Fastener Full Thd	180
2004-2000-04	7.0mm Variable Thread Tray	
370-5070-034	7.0 X 70mm Cann Screw Fastener 34mm Var Thd	70
370-5075-037	7.0 X 75mm Cann Screw Fastener 37mm Var Thd	75
370-5080-040	7.0 X 80mm Cann Screw Fastener 40mm Var Thd	80
370-5085-043	7.0 X 85mm Cann Screw Fastener 43mm Var Thd	85
370-5090-046	7.0 X 90mm Cann Screw Fastener 46mm Var Thd	90
370-5095-049	7.0 X 95mm Cann Screw Fastener 49mm Var Thd	95

Part Number	Description	Size (mm)
370-5100-052	7.0 X 100mm Cann Screw Fastener 52mm Var Thd	100
370-5105-055	7.0 X 105mm Cann Screw Fastener 55mm Var Thd	105
370-5110-058	7.0 X 110mm Cann Screw Fastener 58mm Var Thd	110
370-5115-061	7.0 X 115mm Cann Screw Fastener 61mm Var Thd	115
370-5120-064	7.0 X 120mm Cann Screw Fastener 64mm Var Thd	120
370-5125-067	7.0 X 125mm Cann Screw Fastener 67mm Var Thd	125
370-5130-070	7.0 X 130mm Cann Screw Fastener 70mm Var Thd	130
370-5135-075	7.0 X 135mm Cann Screw Fastener 75mm Var Thd	135
370-5140-080	7.0 X 140mm Cann Screw Fastener 80mm Var Thd	140
370-5145-085	7.0 X 145mm Cann Screw Fastener 85mm Var Thd	145
370-5150-090	7.0 X 150mm Cann Screw Fastener 90mm Var Thd	150
370-5155-095	7.0 X 155mm Cann Screw Fastener 95mm Var Thd	155
370-5160-100	7.0 X 160mm Cann Screw Fastener 100mm Var Thd	160
370-5165-105	7.0 X 165mm Cann Screw Fastener 105mm Var Thd	165
370-5170-110	7.0 X 170mm Cann Screw Fastener 110mm Var Thd	170
370-5175-115	7.0 X 175mm Cann Screw Fastener 115mm Var Thd	175
370-5180-120	7.0 X 180mm Cann Screw Fastener 120mm Var Thd	180
2004-2000-05	7.0/8.0mm 24mm Thread Tray	
370-5060-024	7.0 X 60mm Cann Screw Fastener 24mm Thd	60
370-5065-024	7.0 X 65mm Cann Screw Fastener 24mm Thd	65
370-5070-024	7.0 X 70mm Cann Screw Fastener 24mm Thd	70
370-5075-024	7.0 X 75mm Cann Screw Fastener 24mm Thd	75
370-5080-024	7.0 X 80mm Cann Screw Fastener 24mm Thd	80
370-5085-024	7.0 X 85mm Cann Screw Fastener 24mm Thd	85
370-5090-024	7.0 X 90mm Cann Screw Fastener 24mm Thd	90
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370-5100-024	7.0 X 100mm Cann Screw Fastener 24mm Thd	100
370-5105-024	7.0 X 105mm Cann Screw Fastener 24mm Thd	105
370-5110-024	7.0 X 110mm Cann Screw Fastener 24mm Thd	110
370-5115-024	7.0 X 115mm Cann Screw Fastener 24mm Thd	115
370-5120-024	7.0 X 120mm Cann Screw Fastener 24mm Thd	120
370-5125-024	7.0 X 125mm Cann Screw Fastener 24mm Thd	125
370-5130-024	7.0 X 130mm Cann Screw Fastener 24mm Thd	130
380-5060-024	8.0 X 60mm Cann Screw Fastener 24mm Thd	60
380-5065-024	8.0 X 65mm Cann Screw Fastener 24mm Thd	65
380-5070-024	8.0 X 70mm Cann Screw Fastener 24mm Thd	70
380-5075-024	8.0 X 75mm Cann Screw Fastener 24mm Thd	75

Part Number	Description	Size (mm)
380-5080-024	8.0 X 80mm Cann Screw Fastener 24mm Thd	80
380-5085-024	8.0 X 85mm Cann Screw Fastener 24mm Thd	85
380-5090-024	8.0 X 90mm Cann Screw Fastener 24mm Thd	90
380-5095-024	8.0 X 95mm Cann Screw Fastener 24mm Thd	95
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380-5115-024	8.0 X 115mm Cann Screw Fastener 24mm Thd	115
380-5120-024	8.0 X 120mm Cann Screw Fastener 24mm Thd	120
380-5125-024	8.0 X 125mm Cann Screw Fastener 24mm Thd	125
380-5130-024	8.0 X 130mm Cann Screw Fastener 24mm Thd	130
2004-2000-07	7.0mm 24mm Thread Tray 135mm-180mm	
370-5135-024	7.0 X 135mm Cann Screw Fastener 24mm Thd	135
370-5140-024	7.0 X 140mm Cann Screw Fastener 24mm Thd	140
370-5145-024	7.0 X 145mm Cann Screw Fastener 24mm Thd	145
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370-5170-024	7.0 X 170mm Cann Screw Fastener 24mm Thd	170
370-5175-024	7.0 X 175mm Cann Screw Fastener 24mm Thd	175
370-5180-024	7.0 X 180mm Cann Screw Fastener 24mm Thd	180
2004-2000-09	8.0mm Full Thread Tray	
380-5070-001	8.0 X 70mm Cann Screw Fastener Full Thd	70
380-5075-001	8.0 X 75mm Cann Screw Fastener Full Thd	75
380-5080-001	8.0 X 80mm Cann Screw Fastener Full Thd	80
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380-5140-001	8.0 X 140mm Cann Screw Fastener Full Thd	140
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380-5150-001	8.0 X 150mm Cann Screw Fastener Full Thd	150
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380-5075-037	8.0 X 75mm Cann Screw Fastener 37mm Var Thd	75
380-5080-040	8.0 X 80mm Cann Screw Fastener 40mm Var Thd	80
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380-5170-110	8.0 X 170mm Cann Screw Fastener 110mm Var Thd	170
380-5175-115	8.0 X 175mm Cann Screw Fastener 115mm Var Thd	175
380-5180-120	8.0 X 180mm Cann Screw Fastener 120mm Var Thd	180

Instruments

Instruments are made from various materials approved per ASTM F899.

Part Number	Description
2004-2000-06	Cannulated 7.0/8.0mm Instrument Tray
2004-0001-01	Fastener Sleeve With Handle
2004-0001-03	Drill Sleeve 5.0mm
2004-0001-04	Guide Wire Sleeve 2.7mm
2004-0001-05	Trocar
2004-0002	Parallel Wire Guide
2004-0003	Trocar Tip Reduction Tool
2004-0004	7.0mm Countersink Cann Hudson-Mod
2004-0005	4.0mm Hex Driver Cann Hudson-Mod 270mm
2004-0006	4.0mm Hex Driver Solid Hudson-Mod
2004-0007	7.0mm Screw Fastener Tap Cann Hudson-Mod 300mm
2004-0008	5.0mm Drill Bit Cann Hudson-Mod 330mm
2004-0009	T-Handle Hudson-Mod
2004-0010	4.0mm Hex Driver Cann Fixed
2004-0011	Stylet 285mm
2004-0016	Depth Gauge For 7.0/8.0mm
2004-0020	7.0mm Drill Bit Cann Hudson-Mod 270mm
2004-0021	8.0mm Screw Fastener Tap Cann Hudson-Mod 300mm
2004-0022	2.70mm Guide Wire Drill Tip 300mm CoCr
2004-0023	2.70mm Guide Wire Threaded Trocar Tip 300mm CoCr
2004-0024	2.70mm Guide Wire Drill Tip 450mm CoCr
2004-0025	2.70mm Guide Wire Threaded Trocar Tip 450mm CoCr



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