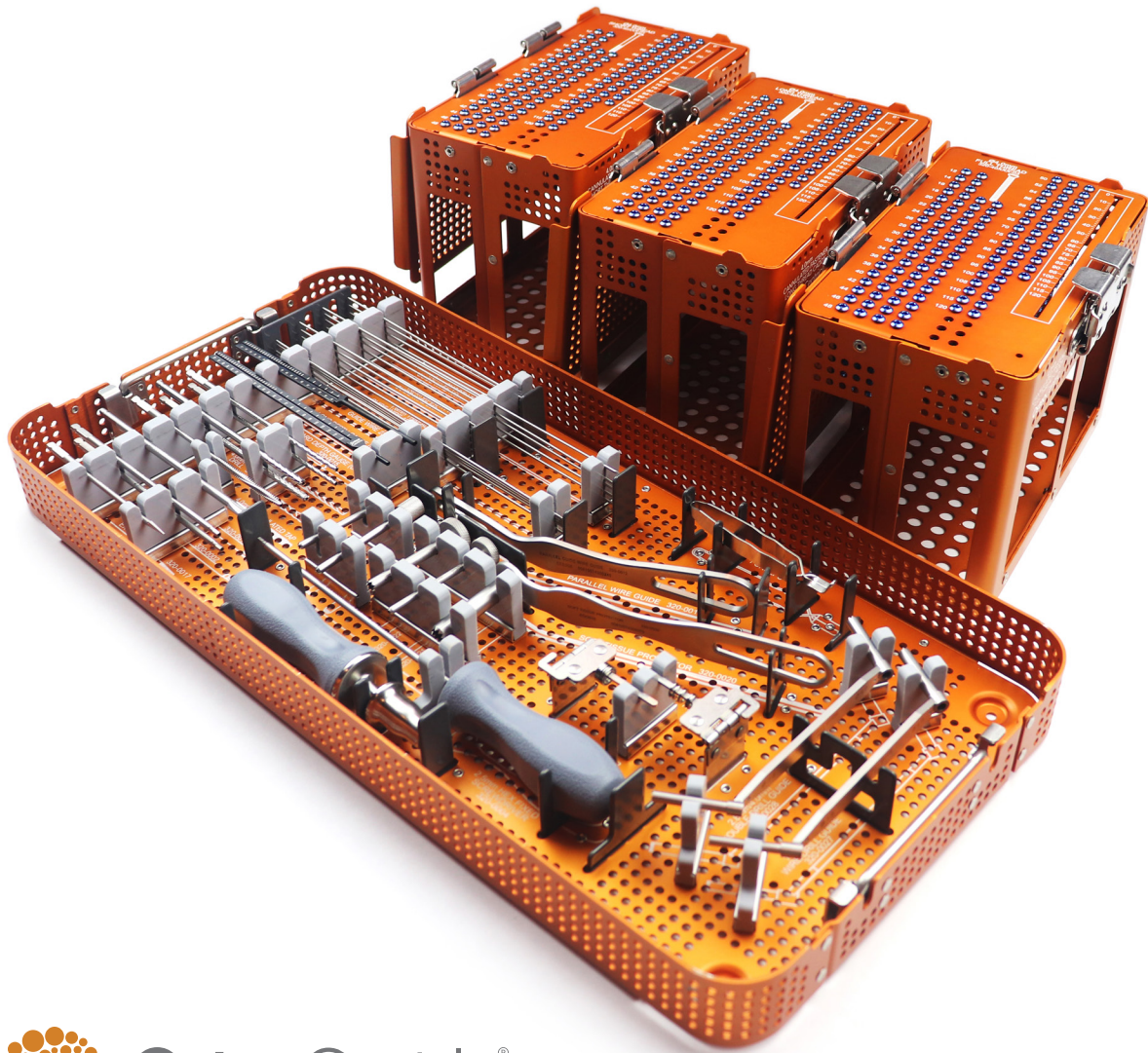


OsteoCentric[®] Trauma

4.0 Cannulated Fastener System

Surgical Technique



OsteoCentric 4.0mm Cannulated Fastener System

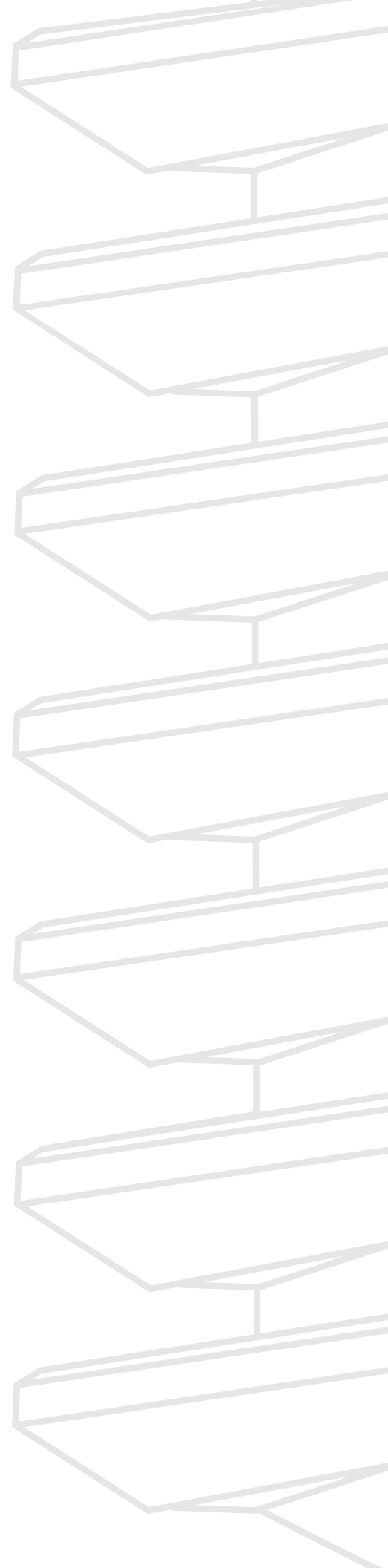
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Note

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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Description

The OsteoCentric Trauma 4.0mm Cannulated 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 Titanium Alloy, Ti-6Al-4V per ASTM F136, and Stainless Steel Alloy, 316LVM 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.



4.0mm - 1/3 threaded length



4.0mm - 3/5 threaded length



4.0mm - full thread

Indications for Use

The OsteoCentric 4.0mm Cannulated Screws are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodesis of the carpals and phalanges, osteochondritis dissecans, and ligament fixation.

Implant Overview

The OsteoCentric Trauma Cannulated 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 titanium alloy. The OsteoCentric Trauma Cannulated Screw Fasteners System includes:

Ø4.0mm Cannulated Screw Fasteners

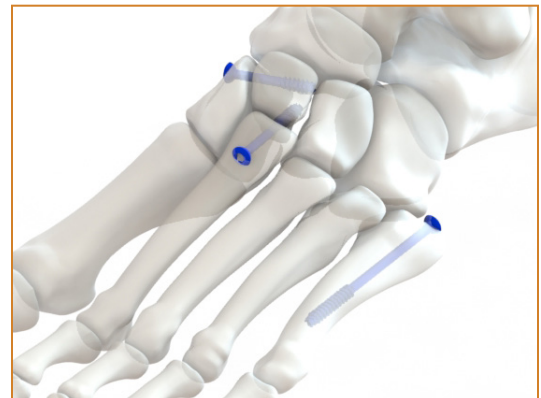
- Self-Tapping
- Self-Drilling
- Short Thread (1/3 threaded length)
- Long Thread (3/5 threaded length)
- Full Thread
- 12-60mm lengths in 2mm increments
- 65-120mm lengths in 5mm increments
- Ti-6Al-4V per ASTM F136

The part number layout is as follows: 320-40XXX-XX

- 40XXX- Indicates 4.0mm fastener and XXX indicates the length of the fastener.

- XX- the remaining two digits indicate the thread length: (short thread -01, long thread -02, full thread -03).

For Example: Part number 320-40070-01 indicates that it is the 4.0mm fastener with an overall length of 70mm and short thread (1/3 threaded length) configuration.



Surgical Technique

Insertion of an OsteoCentric Trauma Cannulated Fastener

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

Dissect Down to Bone and Reduce the Fracture:

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

Place the Appropriate CoCr Guide Wire in the Desired Orientation.

Choose short 150mm (6") or long 230mm (9") wire. Smooth trocar and Threaded trocar tips are available.

Nested Soft Tissue Protectors are Available

(320-0020, -21 & -22). (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.



Figure 3

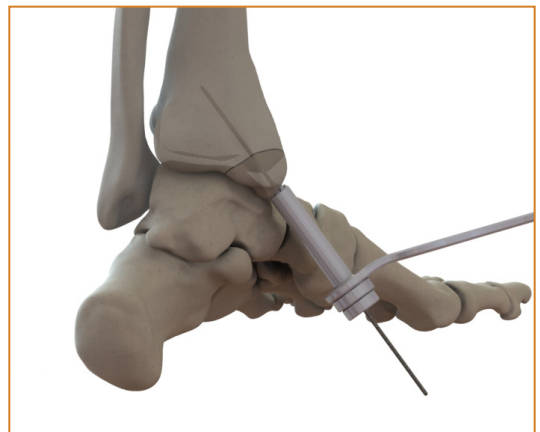


Figure 4

Measure the Fastener Length

Place Standard Depth Gauge (320-0015) over the guide wire and advance to bone. The Standard Depth Gauge measures to the tip of the guide wire to determine working length of the fastener. The indicated length on the depth gauge shows the corresponding fastener to select from the caddy. (Figure 5)

*See footnote below for further explanation

For fastener sizes 95-120mm, use the Long Depth Gauge (320-0014).

Select the appropriate size fastener keeping in mind 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.

Drill Using the Appropriate Cannulated Drill Bit

Expose the bone with appropriate aseptic surgical technique.

Drill the near cortex with the 2.8mm Cannulated Drill (320-80021). (Figure 6)

For lag technique, use the 4.0mm Cannulated Drill (320-80023).

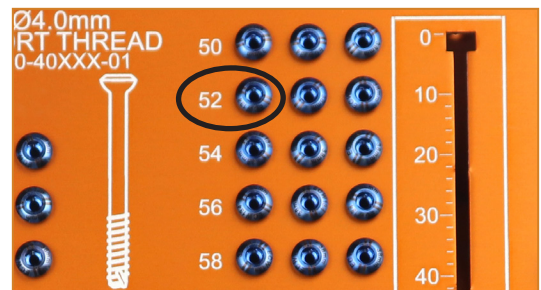


Figure 5

See Warning and Precaution Page 5

***Note:** The Cannulated Depth Gauge measures to the tip of the guide wire to determine working length of the fastener. The reading on the depth gauge adds the head height to the measured working length. Therefore, the reading indicates the tip-to-tip length of the fastener which corresponds to its length description in the caddy

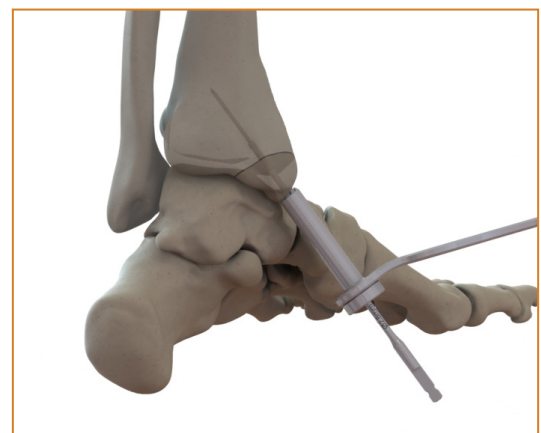


Figure 6

Tap

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.

(4.0mm Tap, 320-0007) (Figure 7)

See Warning and Precaution Page 5



Figure 7

Insert Fastener

Attach the appropriately sized fastener to the cannulated screwdriver.

Washers are available if desired.

(7mm, 320-10007) & (9mm, 320-10009)

Advance the fastener by turning the 2.5mm Hex Driver clockwise until firmly seated in the bone.

Do not use excessive force as the fastener threads may strip.

See Warning and Precaution Page 5

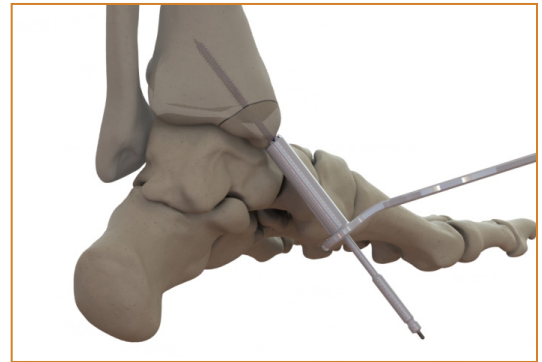


Figure 8

Fastener Insertion into Bone

(Figure 9)

See Warning and Precaution Page 5



Figure 9

Final Construct in Bone

(Figure 10)



Figure 10

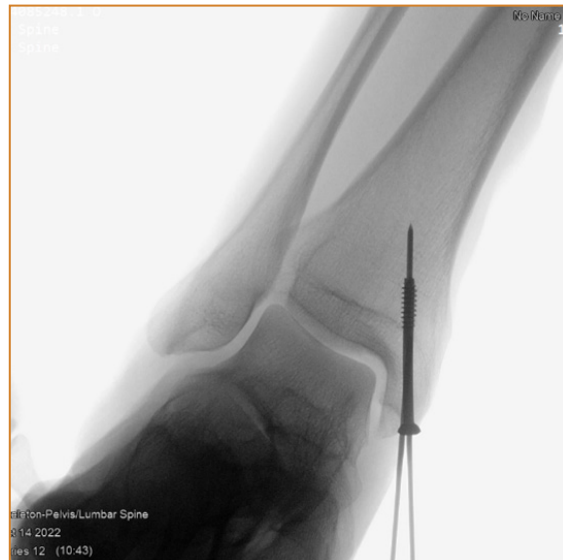
Fastener Extraction

Insert extractor into cannula and turn counterclockwise to remove the fastener.

***Note:** Soft tissue may interfere with the extractor engaging with the inside of the cannula. Ensure that soft tissue is cleared out of the cannula if possible. This can be done by inserting a guide wire into the cannulation prior to extraction.



Figure 11



4.0mm Fastener System Instrument List

Instruments are made from various materials approved per ASTM F899. (Stainless Steel), and ASTM F90 (CoCr).

Part Number	Description
320-90000	4.0mm Cannulated Tray Base
320-90001	4.0mm Cannulated Instrument Tray
320-90002	4.0mm Cannulated Short Thread Caddy
320-90003	4.0mm Cannulated Long Thread Caddy
320-90004	4.0mm Cannulated Full Thread Caddy
A2200-01	Lid
320-80031	1.6mm Guide Wire Trocar CoCr 150mm
320-80032	1.6mm Guide Wire Trocar CoCr 230mm
320-80041	1.6mm Guide Wire Thd Trocar CoCr 150mm
320-80042	1.6mm Guide Wire Thd Trocar CoCr 230mm
320-80021	2.8 x 125mm Drill Bit Cann AO
320-80023	4.0 x 125mm Drill Bit Cann AO
320-80024	2.8 x 180mm Drill Bit Cann AO
320-0002	2.5mm Hex Driver Cann AO 125mm
320-0004	2.5mm Hex Driver Cann Fixed
320-0007	4.0mm Tap Cann AO 125mm
320-0010	Small Cannulated Countersink AO
320-0012	Parallel Guide Wire Guide
320-0014	Long Depth Gauge
320-0015	Standard Depth Gauge
320-0017	Small Cannulated Screw Extractor AO
320-0020	Soft Tissue Protector
320-0021	Small Guide Wire Sleeve
320-0022	Small Drill Sleeve
320-0027	1.6/2.8 Wire/Drill Guide
320-0026	Driver handle, AO coupling
320-10007	7mm Washer Ti
320-10009	9mm Washer Ti
320-11007	7mm Washer SS
320-11009	9mm Washer SS
110705	Screw Holding Forceps

4.0mm Fastener Implant List

All implant components are manufactured from Ti-6Al-4V per ASTM F136, and SS 316LVM per ASTM F138.

4.0mm Titanium Cannulated Fastener Short Thread

Part Number	Description	Size (mm)
320-40012-01	4.0 X 12mm	12
320-40014-01	4.0 X 14mm	14
320-40016-01	4.0 x 16mm	16
320-40018-01	4.0 X 18mm	18
320-40020-01	4.0 X 20mm	20
320-40022-01	4.0 X 22mm	22
320-40024-01	4.0 X 24mm	24
320-40026-01	4.0 X 26mm	26
320-40028-01	4.0 X 28mm	28
320-40030-01	4.0 X 30mm	30
320-40032-01	4.0 X 32mm	32
320-40034-01	4.0 X 34mm	34
320-40036-01	4.0 X 36mm	36
320-40038-01	4.0 X 38mm	38
320-40040-01	4.0 X 40mm	40
320-40042-01	4.0 X 42mm	42
320-40044-01	4.0 X 44mm	44
320-40046-01	4.0 X 46mm	46
320-40048-01	4.0 X 48mm	48
320-40050-01	4.0 X 50mm	50
320-40052-01	4.0 X 52mm	52
320-40054-01	4.0 X 54mm	54
320-40056-01	4.0 X 56mm	56
320-40058-01	4.0 X 58mm	58
320-40060-01	4.0 X 60mm	60
320-40065-01	4.0 X 65mm	65
320-40070-01	4.0 X 70mm	70
320-40075-01	4.0 X 75mm	75
320-40080-01	4.0 X 80mm	80
320-40085-01	4.0 X 85mm	85
320-40090-01	4.0 X 90mm	90
320-40095-01	4.0 X 95mm	95
320-40100-01	4.0 X 100mm	100
320-40105-01	4.0 X 105mm	105
320-40110-01	4.0 X 110mm	110
320-40115-01	4.0 X 115mm	115
320-40120-01	4.0 X 120mm	120

4.0mm Titanium Cannulated Fastener Long Thread

Part Number	Description	Size (mm)
320-40012-02	4.0 X 12mm	12
320-40014-02	4.0 X 14mm	14
320-40016-02	4.0 x 16mm	16
320-40018-02	4.0 X 18mm	18
320-40020-02	4.0 X 20mm	20
320-40022-02	4.0 X 22mm	22
320-40024-02	4.0 X 24mm	24
320-40026-02	4.0 X 26mm	26
320-40028-02	4.0 X 28mm	28
320-40030-02	4.0 X 30mm	30
320-40032-02	4.0 X 32mm	32
320-40034-02	4.0 X 34mm	34
320-40036-02	4.0 X 36mm	36
320-40038-02	4.0 X 38mm	38
320-40040-02	4.0 X 40mm	40
320-40042-02	4.0 X 42mm	42
320-40044-02	4.0 X 44mm	44
320-40046-02	4.0 X 46mm	46
320-40048-02	4.0 X 48mm	48
320-40050-02	4.0 X 50mm	50
320-40052-02	4.0 X 52mm	52
320-40054-02	4.0 X 54mm	54
320-40056-02	4.0 X 56mm	56
320-40058-02	4.0 X 58mm	58
320-40060-02	4.0 X 60mm	60
320-40065-02	4.0 X 65mm	65
320-40070-02	4.0 X 70mm	70
320-40075-02	4.0 X 75mm	75
320-40080-02	4.0 X 80mm	80
320-40085-02	4.0 X 85mm	85
320-40090-02	4.0 X 90mm	90
320-40095-02	4.0 X 95mm	95
320-40100-02	4.0 X 100mm	100
320-40105-02	4.0 X 105mm	105
320-40110-02	4.0 X 110mm	110
320-40115-02	4.0 X 115mm	115
320-40120-02	4.0 X 120mm	120

4.0mm Titanium Cannulated Fastener Full Thread

Part Number	Description	Size (mm)
320-40012-03	4.0 X 12mm	12
320-40014-03	4.0 X 14mm	14
320-40016-03	4.0 x 16mm	16
320-40018-03	4.0 X 18mm	18
320-40020-03	4.0 X 20mm	20
320-40022-03	4.0 X 22mm	22
320-40024-03	4.0 X 24mm	24
320-40026-03	4.0 X 26mm	26
320-40028-03	4.0 X 28mm	28
320-40030-03	4.0 X 30mm	30
320-40032-03	4.0 X 32mm	32
320-40034-03	4.0 X 34mm	34
320-40036-03	4.0 X 36mm	36
320-40038-03	4.0 X 38mm	38
320-40040-03	4.0 X 40mm	40
320-40042-03	4.0 X 42mm	42
320-40044-03	4.0 X 44mm	44
320-40046-03	4.0 X 46mm	46
320-40048-03	4.0 X 48mm	48
320-40050-03	4.0 X 50mm	50
320-40052-03	4.0 X 52mm	52
320-40054-03	4.0 X 54mm	54
320-40056-03	4.0 X 56mm	56
320-40058-03	4.0 X 58mm	58
320-40060-03	4.0 X 60mm	60
320-40065-03	4.0 X 65mm	65
320-40070-03	4.0 X 70mm	70
320-40075-03	4.0 X 75mm	75
320-40080-03	4.0 X 80mm	80
320-40085-03	4.0 X 85mm	85
320-40090-03	4.0 X 90mm	90
320-40095-03	4.0 X 95mm	95
320-40100-03	4.0 X 100mm	100
320-40105-03	4.0 X 105mm	105
320-40110-03	4.0 X 110mm	110
320-40115-03	4.0 X 115mm	115
320-40120-03	4.0 X 120mm	120

4.0mm Stainless Steel Cannulated Fastener Short Thread

Part Number	Description	Size (mm)
320-11012	4.0 X 12mm	12mm
320-11014	4.0 X 14mm	14mm
320-11016	4.0 X 16mm	16mm
320-11018	4.0 X 18mm	18mm
320-11020	4.0 X 20mm	20mm
320-11022	4.0 X 22mm	22mm
320-11024	4.0 X 24mm	24mm
320-11026	4.0 X 26mm	26mm
320-11028	4.0 X 28mm	28mm
320-11030	4.0 X 30mm	30mm
320-11032	4.0 X 32mm	32mm
320-11034	4.0 X 34mm	34mm
320-11036	4.0 X 36mm	36mm
320-11038	4.0 X 38mm	38mm
320-11040	4.0 X 40mm	40mm
320-11042	4.0 X 42mm	42mm
320-11044	4.0 X 44mm	44mm
320-11046	4.0 X 46mm	46mm
320-11048	4.0 X 48mm	48mm
320-11050	4.0 X 50mm	50mm
320-11052	4.0 X 52mm	52mm
320-11054	4.0 X 54mm	54mm
320-11056	4.0 X 56mm	56mm
320-11058	4.0 X 58mm	58mm
320-11060	4.0 X 60mm	60mm
320-11065	4.0 X 65mm	65mm
320-11070	4.0 X 70mm	70mm
320-11075	4.0 X 75mm	75mm
320-11080	4.0 X 80mm	80mm
320-11085	4.0 X 85mm	85mm
320-11090	4.0 X 90mm	90mm
320-11095	4.0 X 95mm	95mm
320-11100	4.0 X 100mm	100mm
320-11105	4.0 X 105mm	105mm
320-11110	4.0 X 110mm	110mm
320-11115	4.0 X 115mm	115mm
320-11120	4.0 X 120mm	120mm

4.0mm Stainless Steel Cannulated Fastener Long Thread

Part Number	Description	Size (mm)
320-12012	4.0 X 12mm	12mm
320-12014	4.0 X 14mm	14mm
320-12016	4.0 X 16mm	16mm
320-12018	4.0 X 18mm	18mm
320-12020	4.0 X 20mm	20mm
320-12022	4.0 X 22mm	22mm
320-12024	4.0 X 24mm	24mm
320-12026	4.0 X 26mm	26mm
320-12028	4.0 X 28mm	28mm
320-12030	4.0 X 30mm	30mm
320-12032	4.0 X 32mm	32mm
320-12034	4.0 X 34mm	34mm
320-12036	4.0 X 36mm	36mm
320-12038	4.0 X 38mm	38mm
320-12040	4.0 X 40mm	40mm
320-12042	4.0 X 42mm	42mm
320-12044	4.0 X 44mm	44mm
320-12046	4.0 X 46mm	46mm
320-12048	4.0 X 48mm	48mm
320-12050	4.0 X 50mm	50mm
320-12052	4.0 X 52mm	52mm
320-12054	4.0 X 54mm	54mm
320-12056	4.0 X 56mm	56mm
320-12058	4.0 X 58mm	58mm
320-12060	4.0 X 60mm	60mm
320-12065	4.0 X 65mm	65mm
320-12070	4.0 X 70mm	70mm
320-12075	4.0 X 75mm	75mm
320-12080	4.0 X 80mm	80mm
320-12085	4.0 X 85mm	85mm
320-12090	4.0 X 90mm	90mm
320-12095	4.0 X 95mm	95mm
320-12100	4.0 X 100mm	100mm
320-12105	4.0 X 105mm	105mm
320-12110	4.0 X 110mm	110mm
320-12115	4.0 X 115mm	115mm
320-12120	4.0 X 120mm	120mm

4.0mm Stainless Steel Cannulated Fastener Full Thread

Part Number	Description	Size (mm)
320-13012	4.0 X 12mm	12mm
320-13014	4.0 X 14mm	14mm
320-13016	4.0 X 16mm	16mm
320-13018	4.0 X 18mm	18mm
320-13020	4.0 X 20mm	20mm
320-13022	4.0 X 22mm	22mm
320-13024	4.0 X 24mm	24mm
320-13026	4.0 X 26mm	26mm
320-13028	4.0 X 28mm	28mm
320-13030	4.0 X 30mm	30mm
320-13032	4.0 X 32mm	32mm
320-13034	4.0 X 34mm	34mm
320-13036	4.0 X 36mm	36mm
320-13038	4.0 X 38mm	38mm
320-13040	4.0 X 40mm	40mm
320-13042	4.0 X 42mm	42mm
320-13044	4.0 X 44mm	44mm
320-13046	4.0 X 46mm	46mm
320-13048	4.0 X 48mm	48mm
320-13050	4.0 X 50mm	50mm
320-13052	4.0 X 52mm	52mm
320-13054	4.0 X 54mm	54mm
320-13056	4.0 X 56mm	56mm
320-13058	4.0 X 58mm	58mm
320-13060	4.0 X 60mm	60mm
320-13065	4.0 X 65mm	65mm
320-13070	4.0 X 70mm	70mm
320-13075	4.0 X 75mm	75mm
320-13080	4.0 X 80mm	80mm
320-13085	4.0 X 85mm	85mm
320-13090	4.0 X 90mm	90mm
320-13095	4.0 X 95mm	95mm
320-13100	4.0 X 100mm	100mm
320-13105	4.0 X 105mm	105mm
320-13110	4.0 X 110mm	110mm
320-13115	4.0 X 115mm	115mm
320-13120	4.0 X 120mm	120mm



Additional Information

To learn more about the full line of innovative OsteoCentric Technologies surgical solutions, please contact us by calling **1-800-969-0639** or visiting our website at OsteoCentric.com

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