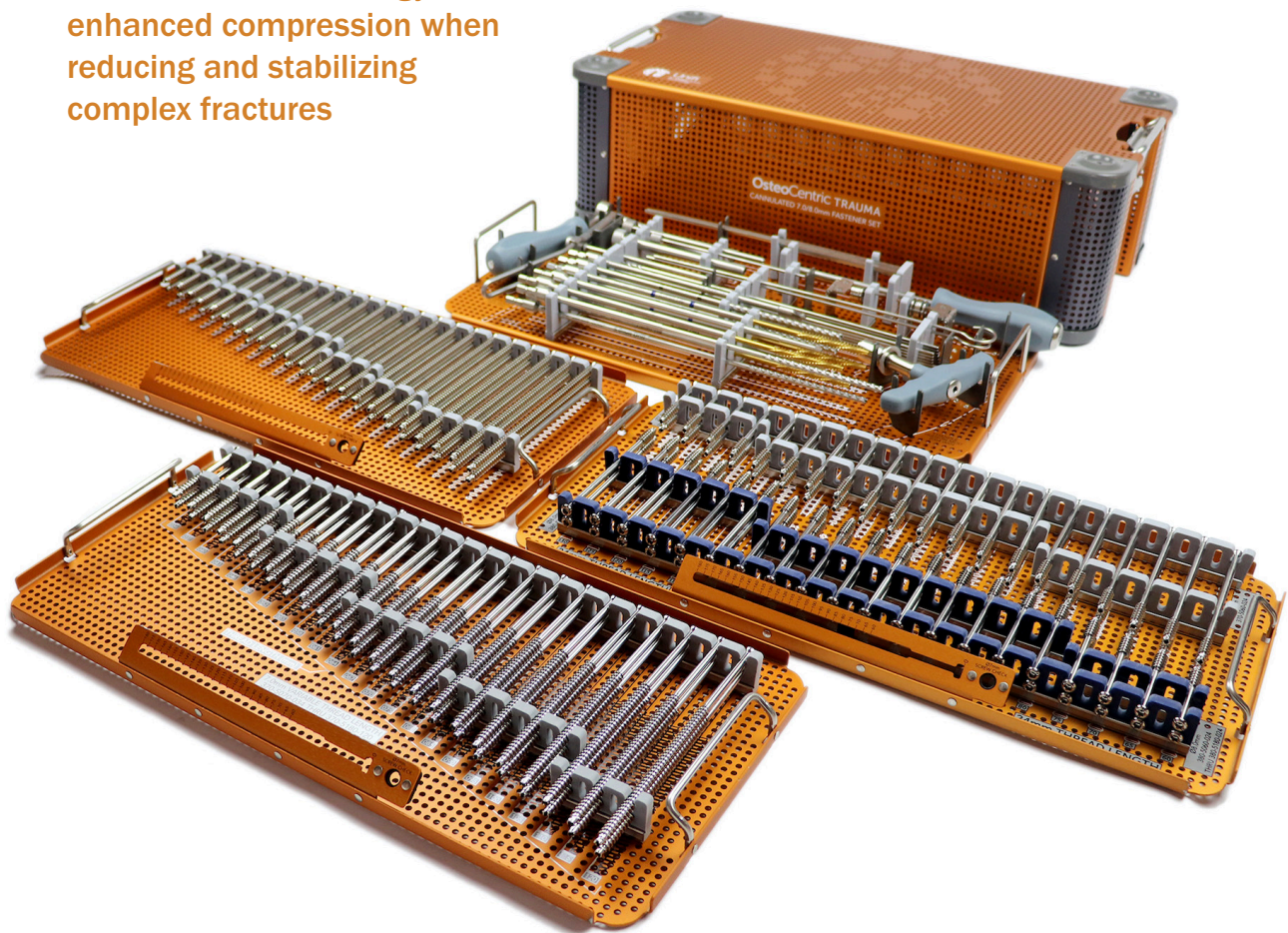


OsteoCentric Trauma

Cannulated Fastener Nut Technology

Auxiliary Surgical Technique Guide

Featuring Optional Cannulated Fastener Nut Technology for enhanced compression when reducing and stabilizing complex fractures



OsteoCentric
TECHNOLOGIES



OsteoCentric Trauma Cannulated Screw Fastener

Table of Contents

Description	3
General System Information	3
Indications for Use	3
Implant Overview	4
Cannulated Fastener Nut Implant Description	5
Cannulated Fastener Nut Indications for Use	6
Contraindications	6
Cannulated Fastener Nut Surgical Technique	7
Implants	8
Instruments	12



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.

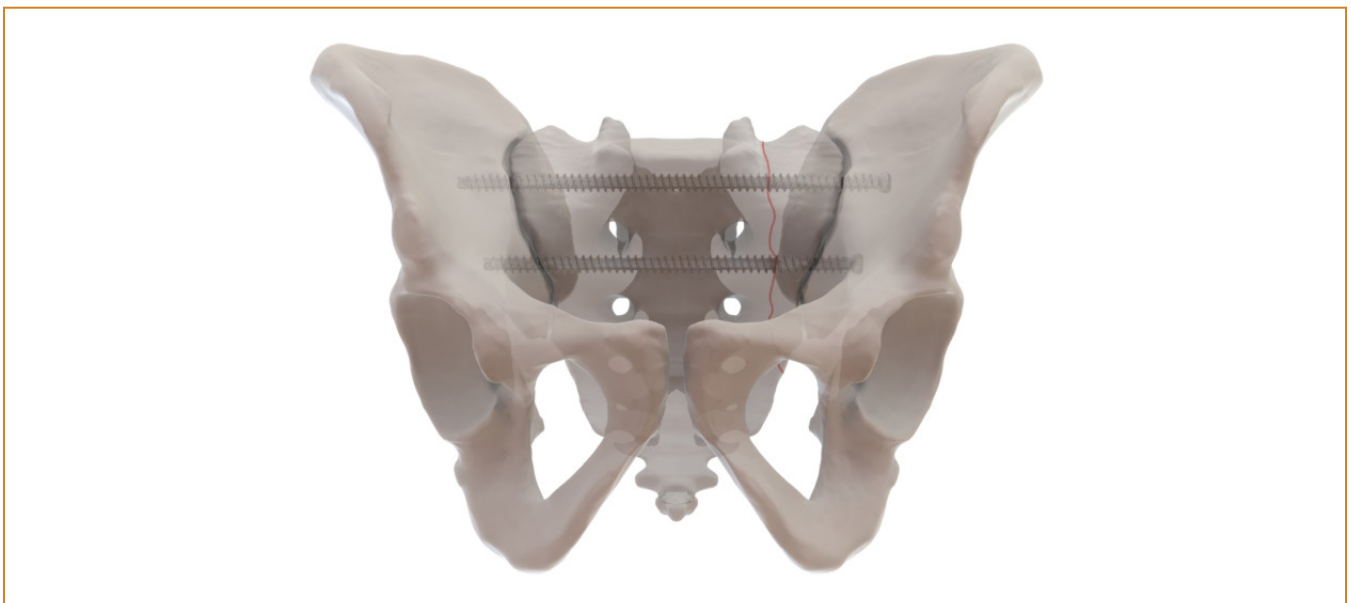
General System Information

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 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.

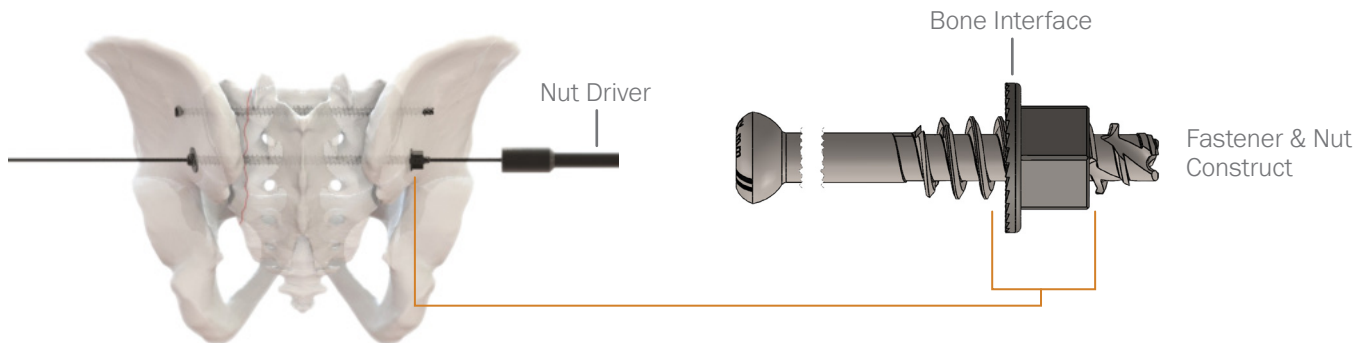
For Example: Part number 370-5130-070 indicates that it is the 7.0mm fastener with an overall length of 130mm and has a variable thread length of 70mm.

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.

Cannulated Fastener Nut Implant Description

The Cannulated Fastener Nut System was designed to provide additional compression when reducing and stabilizing complex fractures. This addition complements the extra-large washers included in the system which also provides additional compression.



Benefits

- Complements UnifiMI™ fracture fixation and repair site compression.
- Evenly distributes the compressive load across the implant to bone interface.
- Freely rotates and easily tightens.

The OsteoCentric Cannulated Fastener Nut System includes:

- 2004-2000-11 Cannulated Nut Caddy
- 370-7000 7.0mm Nut
- 380-7000 8.0mm Nut
- 2004-0030 Nut Driver
- 2004-0031 2.7mm Guide Wire Drill Tip SS 600mm



Cannulated Fastener Nut Indications for Use

The OsteoCentric 7.0mm & 8.0mm Cannulated Nut is indicated for fracture fixation where fracture compression is desired, and where insertion of the nut-and-bolt system does not increase the risk of morbidity due to the need for surgical access to both sides of the compressed area. The device may also be used when compression between separate bones is desired (i.e.: the syndesmosis) as long as there is not increased morbidity associated with the insertion of a nut-and-bolt system, as discussed above.

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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Cannulated Fastener Nut Surgical Technique

1. Place 600mm Guide Wire across the pelvis in desired location, stopping the Guide Wire at the lateral cortex on the far side of the pelvis.
2. Measure the distance to the far cortex using the 2004-0016 Depth Gauge.
3. For nominal thread engagement add 15mm to the measured length and select the fastener closest to this total length.
4. Pre-drill the hole using the 5.0mm Drill Bit.
5. Use the appropriate Tap as necessary.

Note: 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.

6. Using the selected Fastener/Washer combination and the 4.0mm Hex Driver, advance the fastener across the pelvis until the washer is fully seated against the near ilial cortex.

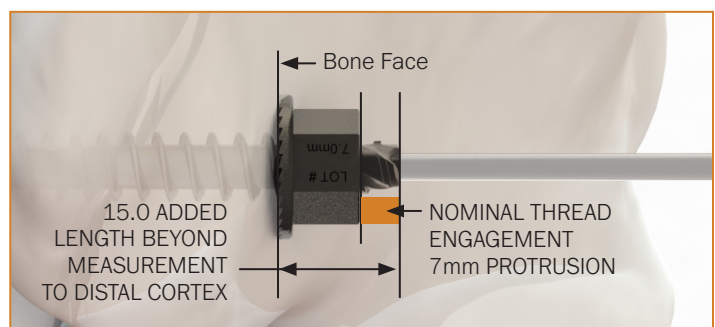
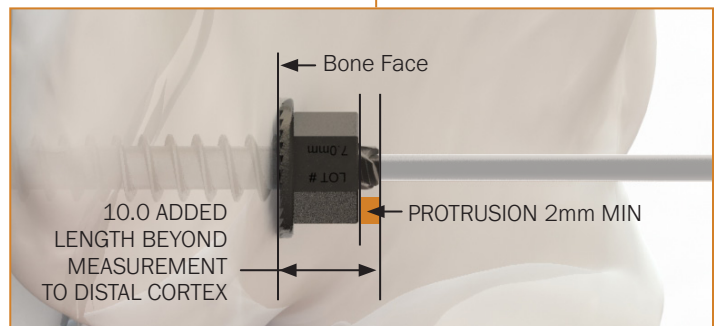
7. Ensure the Guide Wire is visible on both sides of the patient's pelvis for the next step.

8. Place the Cannulated Fastener Nut over the Guide Wire and slide it down until initial engagement with the implanted fastener is achieved.

9. Place the Cannulated Nut Driver over the Guide Wire and advance the Nut onto the fastener until fully seated against the bone, ensuring intermittent fluoroscopic views are utilized to confirm Nut engagement with bone and that appropriate fastener protrusion has been achieved.

NOTE: It is recommended to have the 4.0mm Hex Driver engaged with the fastener head on the contralateral side..

NOTE: The fastener threads should protrude 2mm - 7mm beyond the nut and 10mm - 15mm from the ilial wall during final seating.



Implants

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

Part Number	Description	Size (mm)
2004-2000-11	Cannulated Nut Caddy	
370-7000	7.0mm Nut	
380-7000	8.0mm Nut	
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	
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

Part Number	Description	Size (mm)
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
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
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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
380-5100-024	8.0 X 100mm Cann Screw Fastener 24mm Thd	100
380-5105-024	8.0 X 105mm Cann Screw Fastener 24mm Thd	105
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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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370-5165-024	7.0 X 165mm Cann Screw Fastener 24mm Thd	165
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	
380-5040-001	8.0 X 40mm Cann Screw Fastener Full Thd	40
380-5045-001	8.0 X 45mm Cann Screw Fastener Full Thd	45
380-5050-001	8.0 X 50mm Cann Screw Fastener Full Thd	50
380-5055-001	8.0 X 55mm Cann Screw Fastener Full Thd	55
380-5060-001	8.0 X 60mm Cann Screw Fastener Full Thd	60
380-5065-001	8.0 X 65mm Cann Screw Fastener Full Thd	65
380-5070-001	8.0 X 70mm Cann Screw Fastener Full Thd	70
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Part Number	Description	Size (mm)
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380-5180-001	8.0 X 180mm Cann Screw Fastener Full Thd	180
2004-2000-10	8.0mm Variable Thread Tray	
380-5070-034	8.0 X 70mm Cann Screw Fastener 34mm Var Thd	70
380-5075-037	8.0 X 75mm Cann Screw Fastener 37mm Var Thd	75
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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
2004-0030	Nut Driver
2004-0031	2.7mm Guide Wire Drill Tip SS 600mm
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
300-1302	13mm Washer
300-1601	16mm Washer
2004-0014	2.70mm Guide Wire Drill Tip 300mm SS
2004-0015	2.70mm Guide Wire Threaded Trocar Tip 300mm SS
2004-0017	2.70mm Guide Wire Drill Tip 450mm SS
2004-0018	2.70mm Guide Wire Threaded Trocar Tip 450mm SS
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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