

Osteosynthesis

AxSOS Locking Plate System

Operative Technique

Small Fragment Basic Fragment



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Introduction

The AxSOS Periarticular Locking Plate System is Stryker's range of axially stable locking plates with locking screws designed to treat peri- or intraarticular fractures. Indications include the Proximal Humerus, Distal Femur, and Proximal and Distal Tibia.

The conventional SPS Small and Basic Fragment Sets are standard plating systems which offer a broad range of plates and screws to treat a variety of indications. The system includes Compression Plates, T-Plates, L-Plates, Buttress Plates, Clover Leaf Plates, Reconstruction Plates, One-Third Tubular Plates, Calcaneal Plates, and a complete range of Cortical and Cancellous ISO Screws.

Stryker has combined these systems to offer you the AxSOS Small and Basic Fragment Locking Plate Systems. The System includes 3mm Threaded Hole 1/3 Tubular Plates; 4 and 5mm Threaded Hole Reconstruction Plates; and 4 and 5mm Compression Plates.

The Compression Plates can act as conventional compression plates or can be converted to locking plates by using the appropriate Locking Inserts.

The Threaded Hole Reconstruction Plates are made of annealed stainless steel; therefore, they can be bent to fit the anatomical structures in long bones and the pelvis.

The 1/3 Tubular Plate is designed to treat fractures in the fibula, metatarsals, and metacarpals.

In general, these locking plates are indicated for fractures requiring additional stability (e.g. osteoporotic bone, severely comminuted fractures, etc.).



Features & Benefits

4 and 5mm Compression Plates

Compression and/or Locking Plate Option

• The Locking Inserts and Locking Screws give you the choice.

Innovative Locking Screw Design

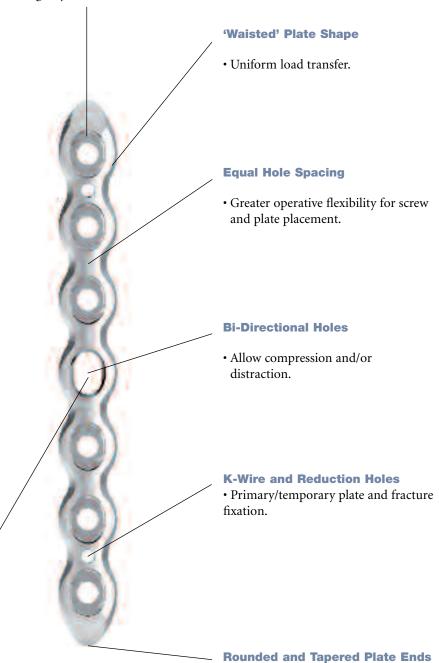
• Screw is guided into the Locking Insert.



Self-Tapping Locking or Cortical Screws

Standard Cortical or Cancellous Screw Hole Options

• Flexibility when using the plate in conventional or locking/non-locking hybrid applications.



Features & Benefits

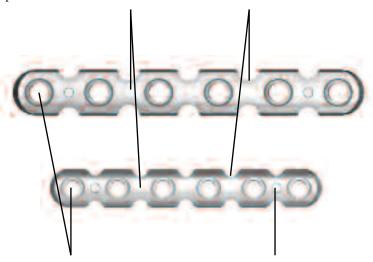
Reconstruction and 1/3 Tubular Locking Plates

Annealed Stainless Steel

• The reconstruction plates are made of annealed stainless steel, which facilitates three dimensional bending of the plate for an anatomical fit.

Special Plate Shape

• The plate shapes are specifically designed to be bent.



Threaded Locking Holes

• The holes in the plates accept a Self Tapping Locking Screw. This adds stability to the plate/screw construct.

K-Wire and Reduction Holes

• Primary/temporary plate and fracture fixation.





Full Range of Locking Screws

• 3, 4, and 5mm Self Tapping Locking Screws can be used for bi-cortical or mono-cortical fixation.

Modular Case Design

• The AxSOS Small and Basic Fragment Systems can be combined with the conventional Stryker SPS Plating Systems into a complete locking and non-locking Small Fragment Set or Basic Fragment Set.

Relative Indications & Contraindications

Relative Indications

The indications for use of AxSOS Small Fragment System include:

Fractures of the Clavicle, Distal Humerus, Radius, Ulna, Metacarpals, Distal Tibia, Fibula, and Metatarsals.

The indications for use of the AxSOS Basic Fragment System include: Fractures of the Humerus, Pelvis, Femur, and Tibia.

Relative Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.

- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Detailed information is included in the instructions for use being attached to every implant.

See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Caution:

Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Technical Details - Compression Plates

The AxSOS Small and Basic Fragment Systems function in the same general operative manner as the SPS Small and Basic Fragment Systems in the conventional non-locking mode. For a detailed Operative Technique, please refer to the SPS Small Fragment Brochure (REF 982181) or the SPS Basic Fragment Brochure (REF 982183).

The procedure below illustrates how to convert an AxSOS Plate Hole from a compression mode to an un-locked mode.

AxSOS Compression Plates or SPS Compression Plates

The AxSOS Compression Plate should not be confused with the SPS Compression Plate. The standard SPS Plate cannot be locked, and therefore should not be used with Locking Screws, Locking Inserts, or Cable Plugs.

The AxSOS Compression Plate can be used both in compression and/or locking mode.

Each system has its own Reference Numbers, and there are 2 visible differences between the plates. The AxSOS plate has a matt finish, while the SPS plate has a polish finish. Second, the plates have different tapers at the plate ends as illustrated in Figure 1.

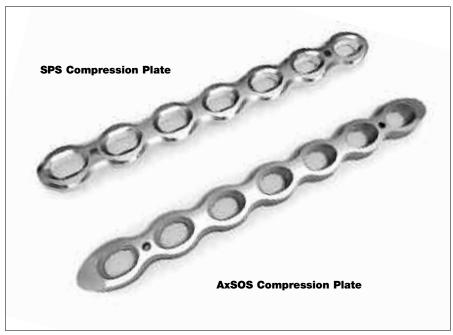


Fig. 1

Bending

If the plate is used in a fully locked mode, plate bending is not recommended due to possible hole deformity and inability of Locking Insert placement (Fig. 2).

If the plate is used in a hybrid mode (compression with appropriate cortical screws and locking screws, (see table below), the plate should only be bent above the fracture line between the compression holes (Fig. 3).

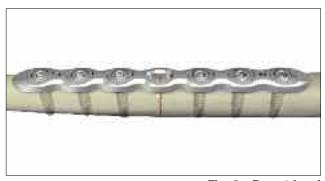


Fig. 2 - Do not bend

AxSOS Compression Plates	Cortical Screws	Locking Screws
Small Fragment	3.5mm	4.0mm
Basic Fragment	4.5mm	5.0mm

Hybrid Mode Screw Insertion

When using the plate in a hybrid mode (Fig. 3), it is essential to insert the Cortical Screws for axial compression before inserting any Locking Screws.

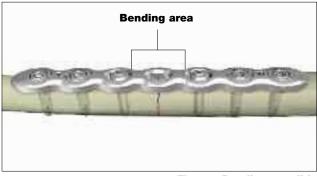


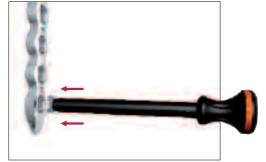
Fig. 3 - Bending possible

Technical Details - Compression Plates

Locking Insert Application

If an AxSOS Plate is used in a locking mode, pre-operative insertion of Locking Inserts is required.
A Locking Insert (4mm - REF 370002 / 5mm - REF 370003) is attached to the Locking Insert Inserter (4mm - REF 702762 / 5mm - REF 702763) and placed into the chosen hole(s) of the plate (Fig. 4). Ensure that the Locking Insert is properly placed. The Inserter should then be removed (Fig. 5).

Do not place Locking Inserts with the Drill Sleeve.







Fia. 5

Locking Screw Insertion

Locking Screws can be placed in plate holes provided there is a pre-placed locking insert. The appropriate Drill Sleeve is threaded into the Locking Insert to ensure initial fixation of the Locking Insert into the plate. This will also facilitate subsequent screw placement.

A 3.1mm or 4.3mm Drill Bit is used to drill through both cortices. Avoid any angulation or excessive force on the drill, as this could dislodge the Locking Insert. The screw measurement is then taken.

The appropriate sized Locking Screw is then inserted. Locking Screws should initially be inserted manually to ensure proper alignment. If the Locking Screw thread does not immediately engage the plate thread, reverse the screw a few turns and re-insert the screw once it is properly aligned.

Using the Solid Screwdriver together with the Torque Limiting Attachment and T-Handle, final tightening is performed. Maximum stability of the Locking Insert is achieved once the screw head is fully seated and tightened to 4Nm for the 4.0mm system, respectively 6Nm for the 5.0mm system. This procedure is repeated for all holes chosen for locked fixation.

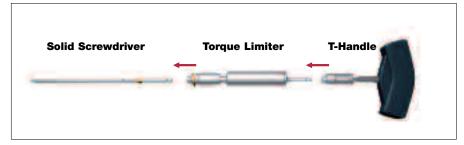


Fig. 6 - 4mm Instruments for Final Tightening

Locking Insert Extraction

Should removal of a Locking Insert be required for any reason, then the following procedure should be used. Thread the central portion (A) of the Locking Insert Extractor (4mm - REF 702767 / 5mm - REF 702768) into the Locking Insert that you wish to remove until it is fully seated.

Then turn the outer sleeve/collet (B) clockwise until it pulls the Locking Insert out of the plate (Fig. 7). The Locking Insert must then be discarded, as it cannot be reused.

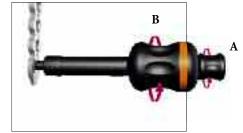




Fig. 7

Operative Technique - Reconstruction Plates

Clear identification classification of the fracture should first be established using proper imaging methods. The appropriate anatomical reduction should be carried out before any definitive fixation. X-Ray Templates are available to help choose the length of the plate intra operatively. Bending Templates are available to help determine the proper bend of the plate.

Step 1 - Bending

Since the holes in the plate are threaded, it is important to bend only between the holes. Bending the holes will cause a deformation which may cause the screw to not properly seat in the hole. Three types of bending may be performed on the plates with the bending irons (Fig. 1).



After the proper implant has been selected and bent accordingly, the plate is temporarily fixed to the bone using K-Wires and/or reduction forceps (Fig. 2).

Step 3 - Locking Fixation

The AxSOS Reconstruction Plates act only in the locking mode. Screw "Lagging" is not possible through the plate. If Lagging is desired, use an independent lag screw, and note that the lag screw must not interfere with screw trajectory of the locking screws in the plate.

Using the appropriate Drill Sleeve (4mm – REF 702707 / 5mm – REF 702708) and ø3.1 or ø4.3 Drill Bit (4mm – REF 702742 / 5mm – REF 702743), drill the hole on each side of the fracture line.

Measure the depth of the hole using the Depth Gauge (REF 702884), and insert the screws using the Solid Screwdriver (4mm – REF 702747 / 5mm – REF 702748) and Screw Holding Sleeve (4mm – REF 702732 / 5mm – REF 702733) (Fig. 3).



Fig. 1 – Rotational Bending



Fig. 1 – Anterior Posterior Bending



Fig. 1 – Medial Lateral Bending

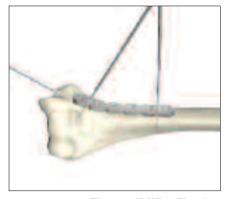


Fig. 2 - K-Wire Fixation

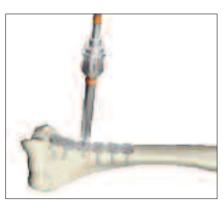


Fig. 3 - Screw Insertion

Final tightening of Locking Screws should always be performed manually using the Torque Limiting Attachment (4mm – REF 702750 / 5mm – REF 702751) together with the Solid Screwdriver (4mm – REF 702753 / 5mm – REF 702754) and the T-Handle (4mm – REF 702427 / 5mm – REF 702430).

Repeat the above technique until all desired holes in the plate are filled (Fig. 4).



Fig. 4

Operative Technique - 1/3 Tubular Plate

Clear identification classification of the fracture should first be established using proper imaging methods. The appropriate anatomical reduction should be carried out before any definitive fixation. The most common indication for the 1/3 Tubular Plate is a fracture of the fibula.

Step 1 - Bending

Since the holes in the plate are threaded, it is important to bend only between the holes. Bending the holes will cause a deformation which may cause the screw to not properly seat in the hole (See Step 1 of the Reconstruction Plate Operative Technique).

Step 2 - Primary Plate Fixation

After the proper implant has been selected, the plate is temporarily fixed to the bone using K-Wires and/or reduction forceps (Fig. 1).

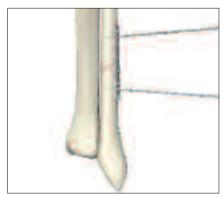


Fig. 1 - K-Wire Fixation

Step 3 - Locking Fixation

Using the Drill Sleeve (REF 702706) and Ø2.3 Drill Bit (REF 702741), drill the hole on each side of the fracture line.

Measure the depth of the hole using the Depth Gauge (REF 702883), and insert the screws using the Torque Limiting Screwdriver (REF 702759) and Screw Holding Sleeve (REF 702731) (Fig. 2).

Repeat the above technique until all desired holes in the plate are filled.

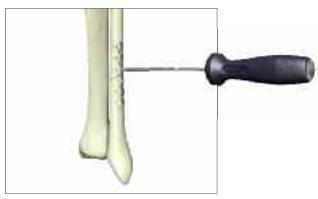
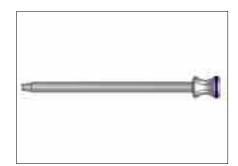


Fig. 2 - Screw Insertion

Additional Tips

1. Always use the threaded Drill Sleeve when drilling for Locking Screws (threaded plate hole or Locking Insert).

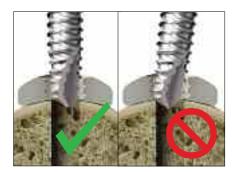


Free hand drilling will lead to a misalignment of the Screw and therefore result in screw jamming during insertion. It is essential, to drill the core hole in the correct trajectory to facilitate accurate insertion of the Locking Screws.

2. Always start inserting the screw manually to ensure proper alignment in the plate thread and the core hole.

It is recommended to start inserting the screw using "the two finger technique" on the Teardrop handle. Avoid any angulations or excessive force on the screwdriver, as this

could cross-thread the screw.



If the Locking Screw thread does not immediately engage the plate thread, reverse the screw a few turns and re-insert the screw once it is properly aligned.

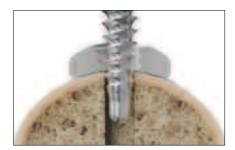
3. If power insertion is selected after manual start (see above), use low speed only, do not apply axial pressure, and never "push" the screw through the plate! Allow the single, continuous threaded screw design to engage the plate and cut the thread in the bone on its own, as designed.
Stop power insertion approximately 1cm before engaging the screw head in the plate.



Power can negatively affect Screw insertion, if used improperly, damaging the screw/plate interface (screw jamming). This can lead to screw heads breaking or being stripped.

Again, if the Locking Screw does not advance, reverse the screw a few turns, and realign it before you start re-insertion.

4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a Locking Screw.



The spherical tip of the Tap precisely aligns the instrument in the predrilled core hole during thread cutting. This will facilitate subsequent screw placement.

5. Do not use power for final insertion of Locking Screws. It is imperative to engage the screw head into the plate using the Torque Limiting Screwdriver. Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening. If the screw stops short of final position, back up a few turns and advance the screw again (with torque limiter on).



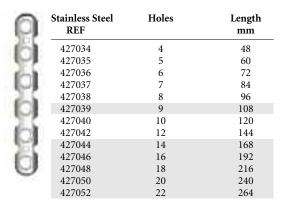
Ordering Information - Small Fragment Implants

The following ordering information lists the AxSOS Implants and Instruments. To order standard SPS Screws and Instruments, please refer to the SPS Small Fragment Brochure (REF 982181) or SPS Basic Fragment Brochure (REF 982183) for details.

3MM ONE THIRD TUBULAR PLATES

4MM RECONSTRUCTION PLATES

Stainless Steel REF	Holes	Length mm
427062	2	24
427063	3	37
427064	4	50
427065	5	63
427066	6	76
427067	7	89
427068	8	102
427069	9	115
427070	10	128
427072	12	154
427074	14	180



4MM WAISTED COMPRESSION PLATES

Stainless Steel REF	Holes	Length mm
427002	2	32
427003	3	45
427004	4	58
427005	5	71
427006	6	84
427007	7	97
427008	8	110
427009	9	123
427010	10	136
427011	11	149
427012	12	162
427014	14	188
427016	16	214
427018	18	240
427020	20	266

4MM LOCKING INSERT AND CABLE PLUG

	Stainless Steel REF	Description
	370002	4mm Small Fragment Locking Insert
0	370004	4mm Small Fragment Cable Plug

Ordering Information - Basic Fragment Implants

5MM RECONSTRUCTION PLATES

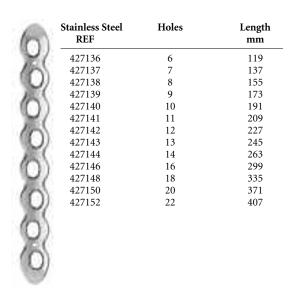
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Stainless Steel REF	Holes	Length mm
427164	4	62
427166	6	94
427168	8	126
427170	10	158
427172	12	190
427174	14	222
427176	16	254

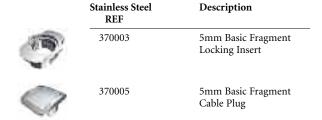
5MM BASIC FRAGMENT WAISTED COMPRESSION PLATES - NARROW

0	Stainless Steel REF	Holes	Length mm
MIC.	427102	2	43
(1)	427103	3	61
9	427104	4	79
150	427105	5	97
	427106	6	115
ALC:	427107	7	133
((1))	427108	8	151
9	427109	9	169
150	427110	10	187
((1)	427112	12	223
墨(427114	14	259
(C)	427116	16	295
9/	427118	18	331
M	427120	20	367
((1)	427122	22	403
1000			

5MM BASIC FRAGMENT WAISTED COMPRESSION PLATES - BROAD



5MM LOCKING INSERT AND CABLE PLUG



Ordering Information – AxSOS Locking Screws

3.0MM LOCKING SCREWS, SELF TAPPING T8 DRIVE

Stainless Steel Length REF mm

4.0MM LOCKING SCREWS, SELF TAPPING T15 DRIVE

	inless Steel REF	Length mm
3'	71514	14
3	71516	16
3	71518	18
3	71520	20
3'	71522	22
3	71524	24
3	71526	26
3'	71528	28
3'	71530	30
3	71532	32
3	71534	34
3	71536	36
3	71538	38
3	71540	40
3	71542	42
3	71544	44
3	71546	46
3	71548	48
3	71550	50
3	71555	55
3	71560	60
3	71565	65
3	71570	70
3	71575	75
3	71580	80
3	71585	85
3	71590	90
3	71595	95

5.0MM LOCKING SCREWS, SELF TAPPING T20 DRIVE

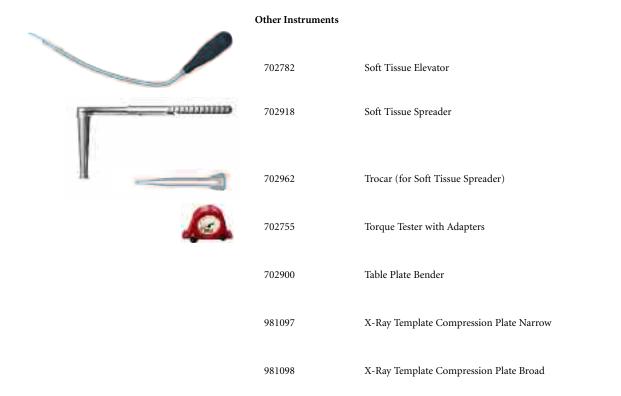
Ħ	Stainless Steel REF	Length mm
目	371314	14
- 14	371316	16
118	371318	18
E3	371320	20
- 84	371322	22
E8	371324	24
- 13	371326	26
2.2	371328	28
軽	371330	30
15	371332	32
12	371334	34
13	371336	36
155	371338	38
5.0	371340	40
146	371342	42
40	371344	44
	371346	46
	371348	48
	371350	50
	371355	55
	371360	60
	371365	65
	371370	70
	371375	75
	371380	80
	371385	85
	371390	90
	371395	95

Ordering Information – AxSOS Instruments

	Dpc	Description
	REF 3mm	Description Small Fragment Locking Instruments
	702741	Drill Ø2.3mm x 125mm
	702771	Tap Ø3.0mm x 130mm
	702731	Screw Holding Sleeve
	702706	Drill Sleeve
	702883	Direct Depth Gauge for Locking Screws
	702759	Torque Limiter Screwdriver T8 / 3.0mm
	4mm Small Fragmen	t Locking Instruments
	702742	Drill Ø3.1mm x 204mm
-	702772	Tap Ø4.0mm x 140mm
	702747	Screwdriver T15, L200mm
	702753	Solid Screwdriver T15, L115mm
	702732	Screw Holding Sleeve
	702707	Drill Sleeve
	702884	Direct Depth Gauge for Locking Screws
	702750	Universal Torque Limiter T15 / 4.0mm
	702762	Locking Insert Inserter 4.0mm
	702767	Locking Insert Extractor
	702427	T-Handle Small, AO Fitting
	702756	Bending Irons (x2)
	Other Instruments	
	981096	X-Ray Template Compression Plate
	702782	Soft Tissue Elevator
T gaman	702919	Soft Tissue Spreader
M.	702961	Trocar (for Soft Tissue Spreader)
	702755	Torque Tester with Adapters

Ordering Information – AxSOS Instruments

	REF	Description
	Basic Fragment Lock	ing Instruments
	702743	Drill Ø4.3mm x 289mm
CHARA	702773	Tap Ø5.0mm x 140mm
	702748	Screwdriver T20, L300mm
	702754	Solid Screwdriver Bit T20, L180mm
	702733	Screw Holding Sleeve L118mm
	702708	Drill Sleeve L143mm
	702884	Direct Depth Gauge for Locking Screws 14-120mm
	702751	Universal Torque Limiter T20 / 5.0mm
	702763	Locking Insert Inserter
	702768	Locking Insert Extractor
	702430	T-Handle Medium, AO Fitting
	702906	Bending Irons for Recon Plate and Narrow Compression Plate (x2)



Ordering Information – AxSOS Cases

REF	Description
Basic Fragment Sy	stem Cases and Trays
902821	Metal Base – Instruments
902822	Lid for Base – Instruments
902823	Instrument tray 5.0mm
902824	Generic Tray
902825	Silicon Mat (Bottom)
902826	Silicon Mat (Generic)
902827	Plate Rack with Lid – AxSOS™ Compression Plates
902832	Screw Rack with Lid − 5.0mm AxSOS™ Locking Screws
902827–2	Lid for Plate Rack – 5.0mm AxSOS™ Compression Plates
902829	Plate Rack With Lid – Generic
902830	Metal Base – Implants
902831	Lid for Base – Implants
902828	Plate Rack with Lid – Special Plates
902828–2	Lid for Plate Rack – Special Plates
902929–2	Lid for Plate Rack – Generic
902836	Screw Rack with Lid – Standard

Small Fragment System Cases and Trays

902801	Metal Base – Instruments
902802	Lid for Base – Instruments
902803	Instrument tray 4.0mm
902805	Generic Tray
902806	Silicon Mat (Bottom)
902807	Silicon Mat (Top)
902808	Silicon Mat (Generic)
902809	Plate Rack with Lid – 4.0mm AxSOS $^{\text{\tiny TM}}$ Compression Plates
902813	Screw Rack with Lid – 4.0mm AxSOS $^{\text{\tiny TM}}$ Locking Screws
902809–2	Lid for Plate Rack – 4.0mm AxSOS $^{\text{\tiny TM}}$ Compression Plates
902811	Metal Base – Implants
902812	Lid for Base – Implants
902804	Instrument tray 3.0mm
902810	Plate Rack with Lid – Special Plates
902810-2	Lid for Plate Rack – Special Plates

Notes



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US Patents Pending

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