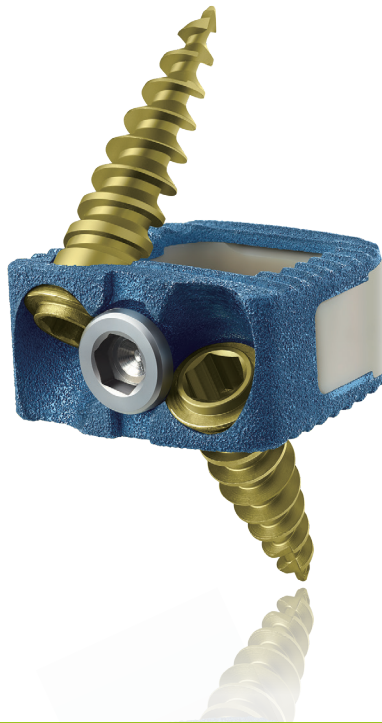


Redmond® Cervical Implants



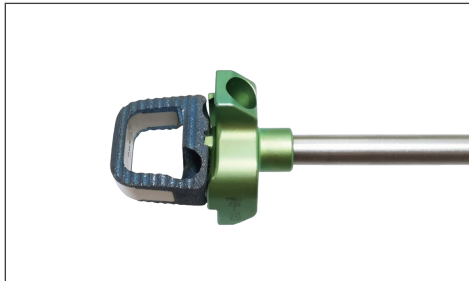
+ Characteristics

- Bioactive
- Stand alone design
- Porous Surface Treatment

Contents



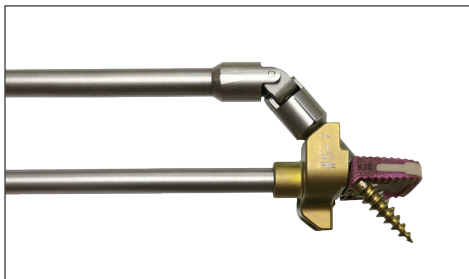
Introduction 2



Indications 2

Contraindications 2

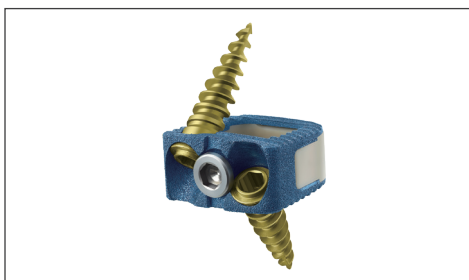
Design Rationale 3



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Introduction

Anterior cervical discectomy and fusion (ACDF) is a commonly employed surgical technique in the treatment of cervical spondylosis. There had been recent attempts to enhance interbody cage implants through the use of composite-designs combining materials titanium (Ti) and polyetheretherketone (PEEK).

Redmond® Cervical Cage utilizes the advantages of titanium and PEEK in one implant.

Indications

- Degenerative disc disease
- Spondylolisthesis and/or retrolisthesis
- Spinal stenosis
- Revision operation
- Pseudarthrosis

Contraindications

- Patients with fever or leukocytosis
- Patients with infections associated with the spine (e.g. spondylodiscitis)
- Patients with a history of material allergy or who tend to react to foreign bodies
- Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomyelitis)
- Spinal fracture
- Spinal tumor

Precautions for use

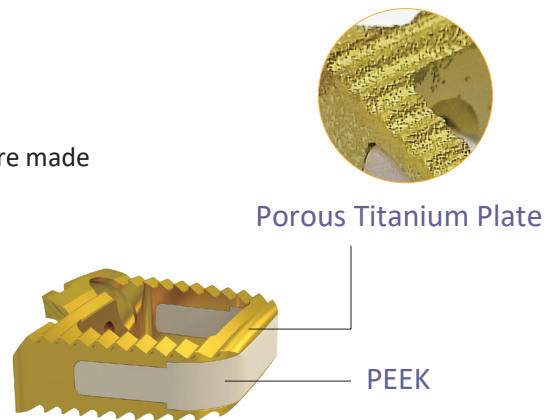
The application of this system is only performed in a sterile surgical environment at the clinic and professional spine center. The product may effect by strength and fatigue. The instruments must be checked for damage during the cleaning and sterilization process and then stored in a dry, dust-free place.

A-SPINE's instruments are non-sterile, and please refer to "Instruction for Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices"

Design Rationale

■ Titanium and PEEK combined

- Cage components are made of medical grade PEEK (polyetheretherketone) and Ti-6Al-4V EL I
- Teeth on the superior and inferior implant surfaces are made of titanium with Porous treatment
- Excellent early new bone formation
- Provides excellent skeletal attachment



■ Locking Screws

Variable Screws



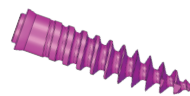
Self Drilling

Diameter: 4.0mm
Length: 12 ~18 mm



Self Tapping

Diameter: 4.0mm
Length: 12~18 mm



Oversized

Diameter: 4.5mm
Length: 12~18 mm
Rescue screws

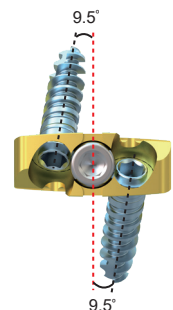
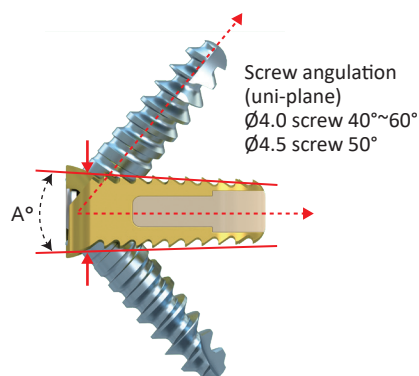
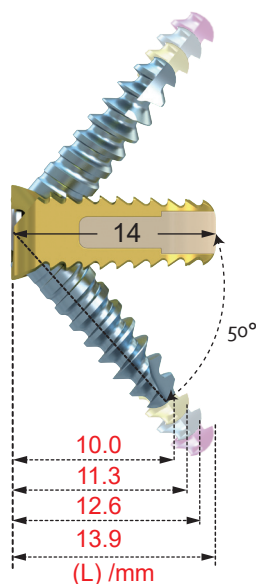


Locking Cap

Diameter: 2.5mm

■ Angulation

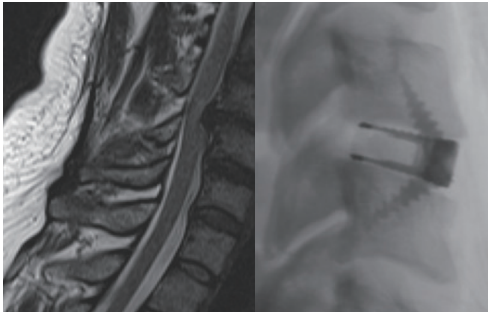
Reference chart for different screws length by cover the body height and length.
Screws length are from 12,14,16,18 mm



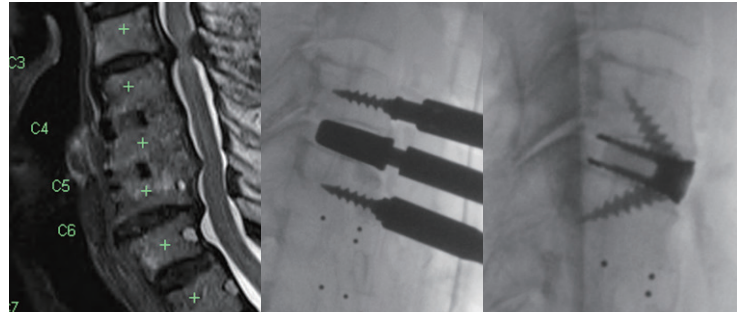
Note:

- The adjustable angle on the 4.0 screw is 40~60 degrees.
- According to the calculated length: Cage length 12 matched with L12 screws; The cage length 14 matched with L14 screws and so forth and so on, its will not exceed the depth of the fusion cage.

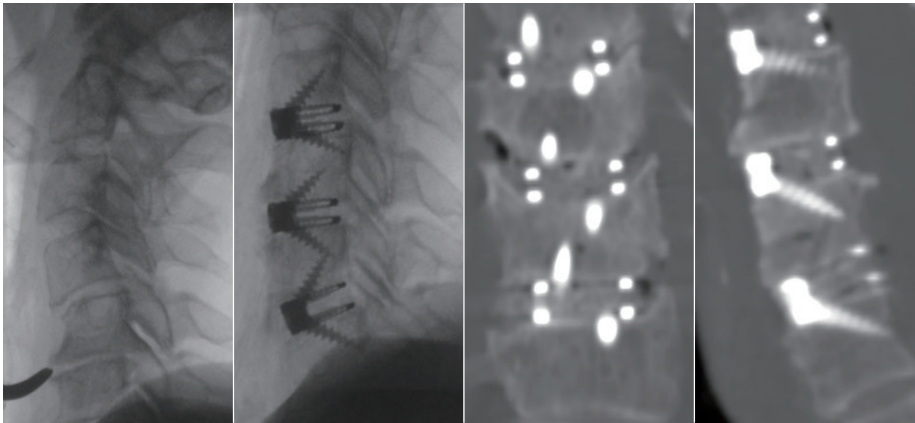
Clinical Outcome



Cord compression with Myelopathy.



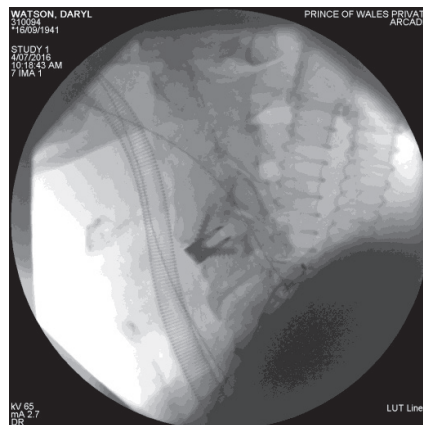
Deformity with multi-level.



Redmond® ACDF Fusion Status.



Clinical case-Postoperative

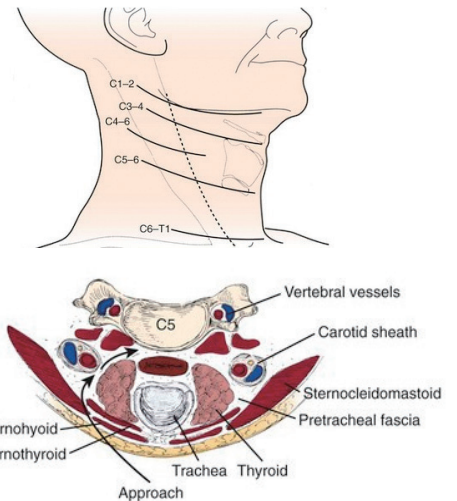


Surgical Technique

Approach

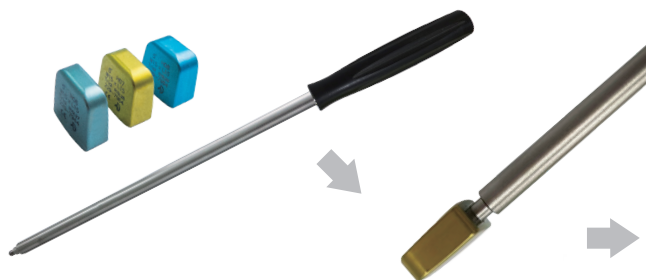
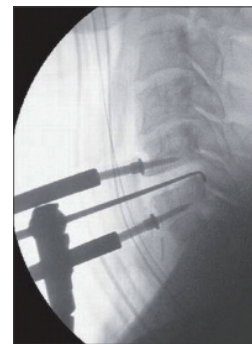
Patient is in a supine position, the correct operative cervical spine level done by radiographic check. Approach and expose the vertebral disc by doing a complete discectomy through the standard anterior approach to the C spine.

Distraction the vertebral body by caspar distractor, perform discectomy then prepare the endplates.



Trial Sizing

The correct size of Redmond® Cervical Implants are determined by inserting the Trials (229-7921 ~ 229-8040) to the disc space. The Trials have the same shape and size as Redmond® Cervical Implants, and choose appropriate height of the Trial from short to high so as not to hurt the vertebral endplate. Use the Universal Insertor (229-1703) connects the Trials from Trial Container (20141-046), put the Trials into the disc space with a proper alignment and carefully check the radiographies.



Note:

It is recommended that you remove the anterior osteophytes to prevent insertion and positioning interference for reducing implantation failure.



20141-046
Trial Container



229-79XX / 229-80XX
Trial

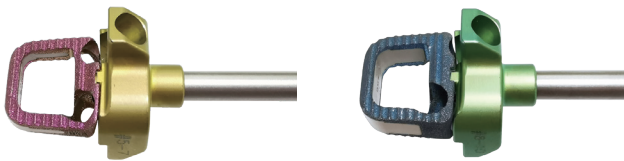


229-1703
Universal Insertor

Implants Preparation

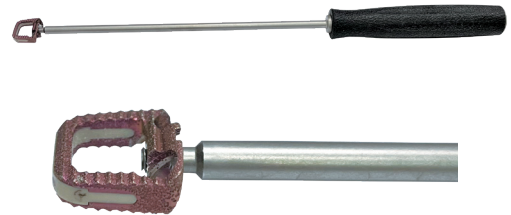
■ Guided Inserter Option 1

It is highly recommended to use #5-7 inserter (229-1701)/#8-10 inserter (229-1702) for cage insertion and preparation; these insertors include guides to limit the screw angle to 50°.



■ Freehand Inserter Option 2

Use Universal Inserter(229-1703) for cage insertion and preparation.



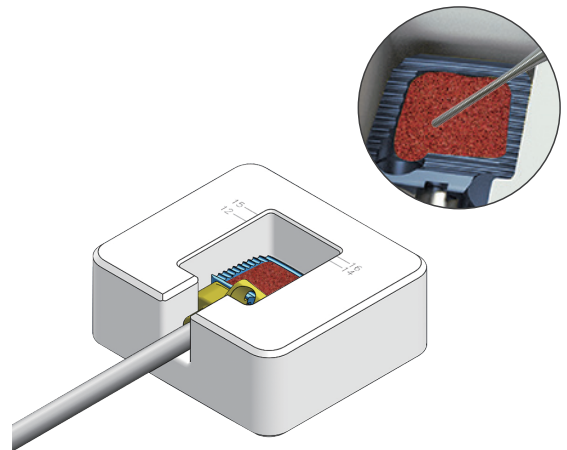
After assembly cage and appropriate inserter, put it onto the Bone Graft Template (229-2901) and fill bone graft in the center by using the Bone Graft Impactor (218-3301).

Implantation

Remove the osteophytes and carefully insert the cage into the distraction segment. When using a small cage (H5-7), it may be necessary to cut some of the front bones to increase the fit between cage and vertebral.

Note:

The implantation position of the Cage must be aligned with the anterior edge of the vertebral body.



229-1701 / 229-1702

#5-7 Inserter
#8-10 Inserter



229-1703

Universal Inserter



229-2901

Bone Graft Template



218-3301

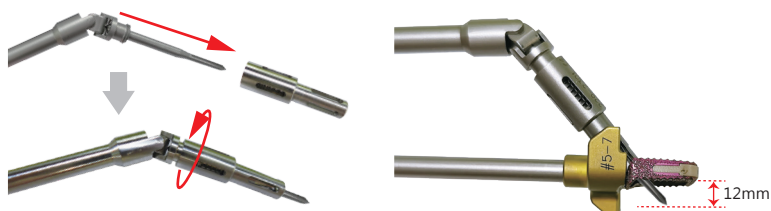
Bone Graft Impactor

Screw Hole Preparation Option

Step 1 Screw hole preparation

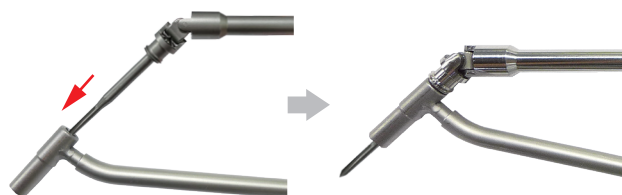
■ Guided inserter Option

The use of the #5-7 Inserter/#8-10 Inserter,awl and tap must be matched with Telescopic Sleeve (229-2301) to ensure that the preparing trajectory is correct.



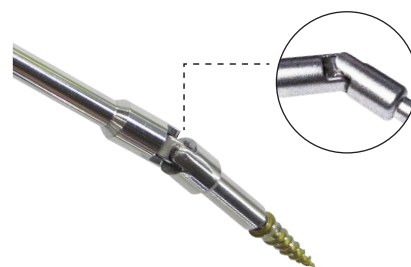
■ Freehand inserter Option

If the Universal Inserter is used, the Angle Guide(229-1101) can be used as a guide to prepare the screw trajectory.



Step 2 Bone Screw Insertion

Use the Flexible Screw Holder (229-1301) to load the screw from the Screw Container (20141-040) and insert screw into trajectory.

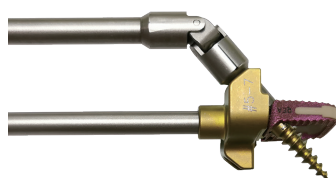


Note:

If the selected screw length exceeds the length of the cage, there must be at least 2 mm of space between the cage and the posterior edge of the vertebral body to avoid nerve damage.

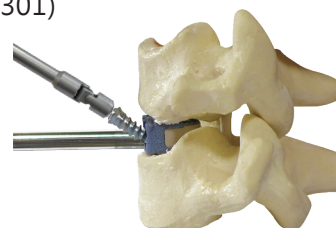
■ Guided Screw Insertion Option

Use the Flexible Screwdriver (229-3301) to tighten the screws.



■ Freehand inserter Option

Use the Universal Inserter (229-1703) to connect the implant and tighten the screw by Flexible Screwdriver (229-3301)



229-2301

Telescopic Sleeve



229-1101

Angle Guide



229-1301

Flexible Screw Holder



229-3301

Flexible Screwdriver

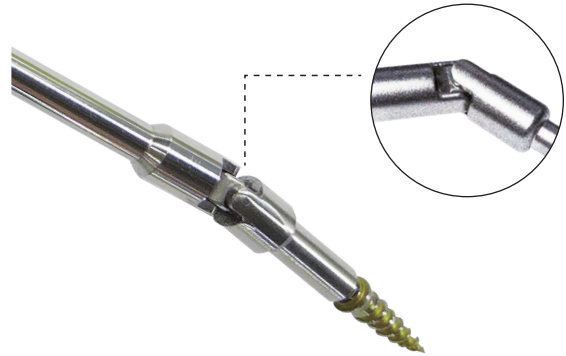


229-3302

Screwdriver

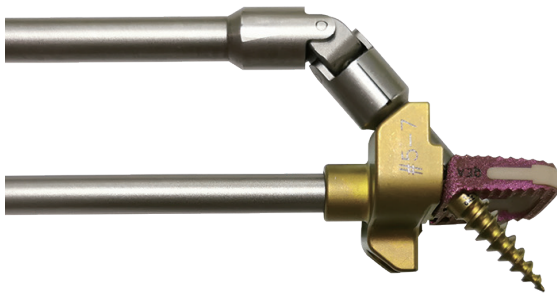
Direct Screw Insertion Option

Use the Flexible Screw Holder (229-1301) to load the screw from the Screw Container (20141-040) and insert screw into trajectory.



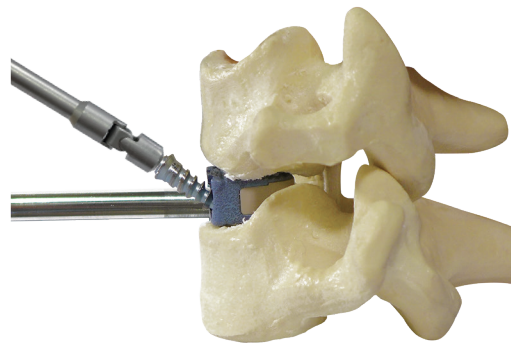
Guided Screw Insertion Option

Use the Flexible Screwdriver (229-3301) to tighten the screws.



Freehand Screw Insertion Option

Use the Universal Insertor (229-1703) connects the implant and tighten the screw by Flexible Screwdriver (229-3301)

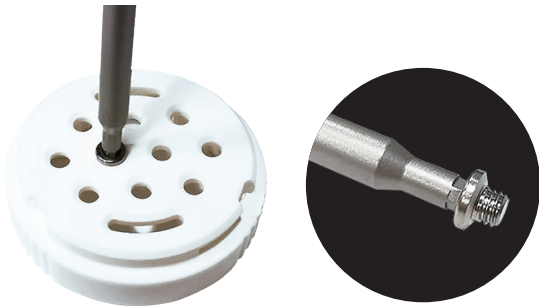


Note:

Flexible Screw Holder cannot be used for final tightening.

Cat.No.	Description	
229-1301	Flexible Screw Holder	
20141-040	Screw Container	
229-3301	Flexible Screwdriver	
229-3302	Screwdriver	
229-1701 229-1702	#5-7 Insertor #8-10 Insertor	
229-1703	Universal Insertor	

Securing the Locking Cap

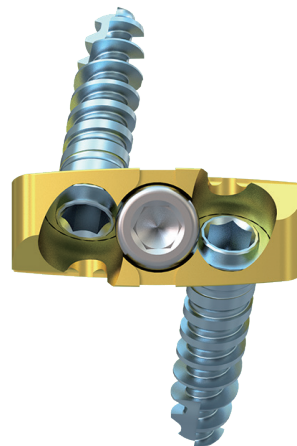


Use the Cap Holder (229-1302) to capture the Locking Cap from the Locking Cap Container (18140-046) and screw to the central hole of Redmond® Cervical Implant for preventing screws back-out. The locking cap is finally tightened by the screwdriver.

Note:

The Cap Holder cannot be used for final tightening, otherwise it will damage the grab function.

Cat.No.	Description	
229-1302	Cap Holder	
18140-046	Locking Cap Container	



STERILIZATION

The Redmond cervical instruments and screws are delivered non sterile. Before use needed cleaned and sterilized recommended to be steam sterilized by the hospital using the following process parameters:

Steam Wrapped Gravity Cycle at 121 °C/ 250 °F for 30 minutes, dry time for 30 minutes.

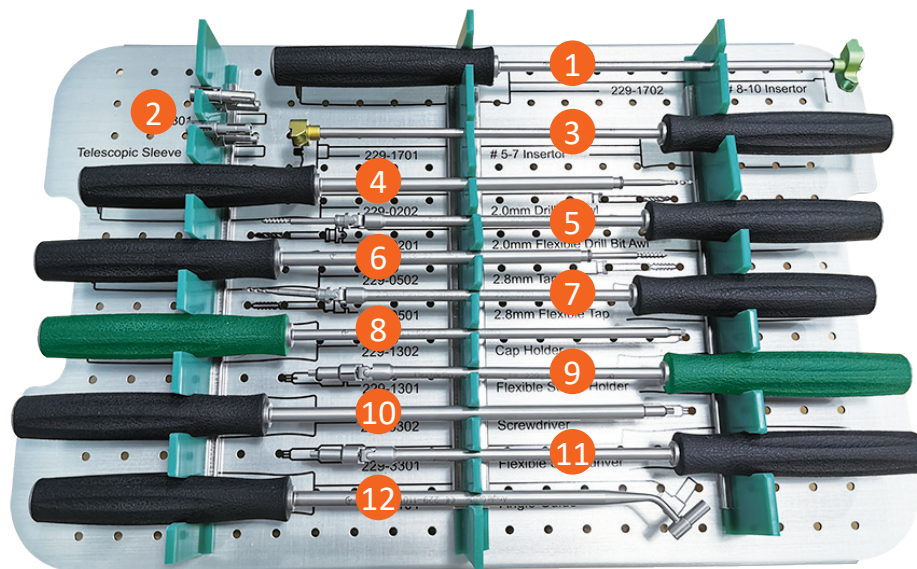
Steam Wrapped Dynamic-Air-Removal (Pre-vacuum) Cycle at 132 °C/ 270 °F for 4 minutes, dry time for 30 minutes.

The cage had been sterilized by gamma radiation at least 25 kGy dose.

It should avoid contaminating while operation process. It is necessary to exchange our product if the packaging has been broken without reason.

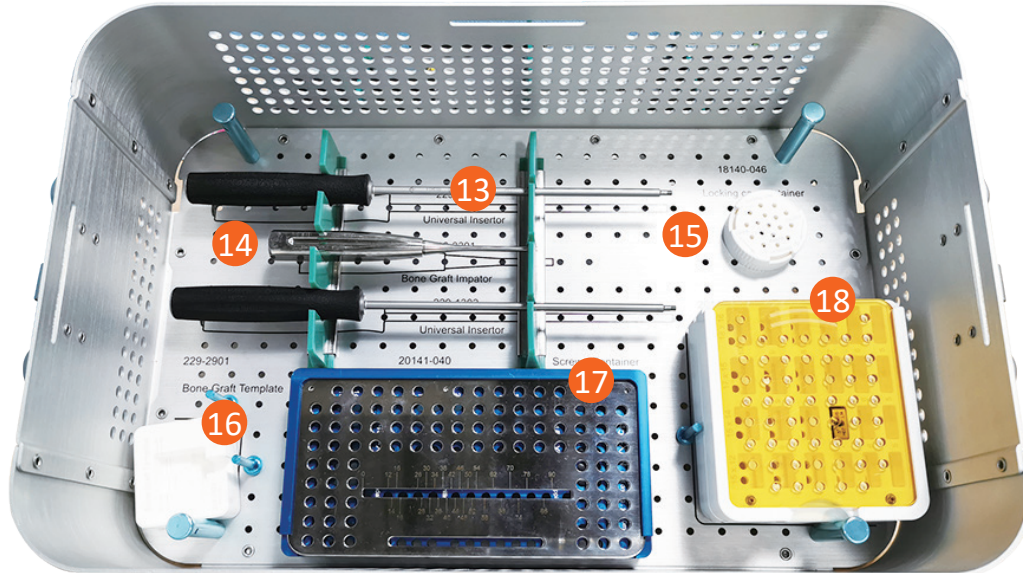
If need more function, please refer to "Reprocessing Manual" from A-SPINE's website (<http://www.aspine.com.tw/>).

Instrument Set



Instrument Tray 1

Cat.No.	Description	Q'nty
① 229-1702	#8-10 Insertor	1
② 229-2301	Telescopic Sleeve	4
③ 229-1701	#5-7 Insertor	1
④ 229-0202	2.0mm Drill Bit Awl	1
⑤ 229-0201	2.0mm Flexible Drill Bit Awl	1
⑥ 229-0502	2.8mm Tap	1
⑦ 229-0501	2.8mm Flexible Tap	1
⑧ 229-1302	Cap Holder	1
⑨ 229-1301	Flexible Screw Holder	1
⑩ 229-3302	Screwdriver	1
⑪ 229-3301	Flexible Screwdriver	1
⑫ 229-1101	Angle Guide	1



Instrument Tray 2

Cat.No.	Description	Q'nty
13 229-1703	Universal Insertor	2
14 218-3301	Bone Graft Impactor	1
15 18140-046	Locking Cap Container	1
16 229-2901	Bone Graft Template	1
17 20141-040	Screw Container	1
18 20141-046	Trial Container	1

Instruments

Cat.No.	Description	
229-0201	2.0mm Flexible Drill Bit Awl	
229-0202	2.0mm Drill Bit Awl	
229-0501	2.8mm Flexible Tap	
229-0502	2.8mm Tap	
229-3301	Flexible Screwdriver	
229-3302	Screwdriver	
229-1701 229-1702	#5-7 Insertor #8-10 Insertor	
229-1703	Universal Insertor	
229-1101	Angle Guide	
229-1301	Flexible Screw Holder	
229-1302	Cap Holder	
229-2301	Telescopic Sleeve	
218-3301	Bone Graft Impactor	

Instruments

Cat.No.	Description	
18140-046	Locking Cap Container	
229-2901	Bone Graft Template	
20141-040	Screw Container	
20141-046	Trial Container	
99900-046	Redmond Cervical Case with Metal Lid	
99901-046	Redmond Cervical Instrument Case * (Optional with plastic lid)	



Category	Trials (Angle 5°)					Trials (Angle 8°)		
	W / 15mm		W / 17mm	W / 18mm	W / 20mm	W / 15mm	W / 17mm	W / 18mm
H / mm	L / 12mm	L / 14mm	L / 15mm	L / 16mm	L / 18mm	L / 14mm	L / 15mm	L / 16mm
5	229-7921	229-7923	229-7934	229-7940				
6	229-7941	229-7943	229-7954	229-7960		229-8263	229-8274	229-8280
7	229-7961	229-7963	229-7974	229-7980	229-8401*	229-8283	229-8294	229-8300
8	229-7981	229-7983	229-7994	229-8000	229-8402*	229-8303	229-8314	229-8320
9	229-8001	229-8003	229-8014	229-8020	229-8403*	229-8323	229-8334	229-8340
10	229-8021	229-8023	229-8034	229-8040		229-8343	229-8354	229-8360

*Coming soon

Implants

Redmond® Cervical Implants Specification

Angle 5°

Category	W / 15mm		W / 17mm	W / 18mm	W / 20mm
H / mm	L / 12mm	L / 14mm	L / 15mm	L / 16mm	L / 18mm
5	1051-55528H	1051-55548H	1051-55758H	1051-55868H	
6	1051-56528H	1051-56548H	1051-56758H	1051-56868H	
7	1051-57528H	1051-57548H	1051-57758H	1051-57868H	1051-57088H*
8	1051-58528H	1051-58548H	1051-58758H	1051-58868H	1051-58088H*
9	1051-59528H	1051-59548H	1051-59758H	1051-59868H	1051-59088H*
10	1051-50528H	1051-50548H	1051-50758H	1051-50868H	

*Coming soon

Angle 8°

Category	W / 15mm	W / 17mm	W / 18mm
H / mm	L / 14mm	L / 15mm	L / 16mm
6	1051-86548H	1051-86758H	1051-86868H
7	1051-87548H	1051-87758H	1051-87868H
8	1051-88548H	1051-88758H	1051-88868H
9	1051-89548H	1051-89758H	1051-89868H
10	1051-80548H	1051-80758H	1051-80868H

Variable Screw

Ø /mm	Cat.No	Self-Drilling
4.0	1053-128	
	1053-148	
	1053-168	
	1053-188	

Ø /mm	Cat.No	Self Tapping
4.0	1054-128	
	1054-148	
	1054-168	
	1054-188	

Ø /mm	Cat.No	Oversized
4.5	1057-128	
	1057-148	
	1057-168	
	1057-188	

Locking Cap

Cat.No	
1052-03038	





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