

Reflex™

Surgical Technique

Anterior Cervical Plate



Surgical Technique

Acknowledgement:

Stryker® Spine extends their thanks to the following surgeons for their participation in the development of the Reflex™ system:

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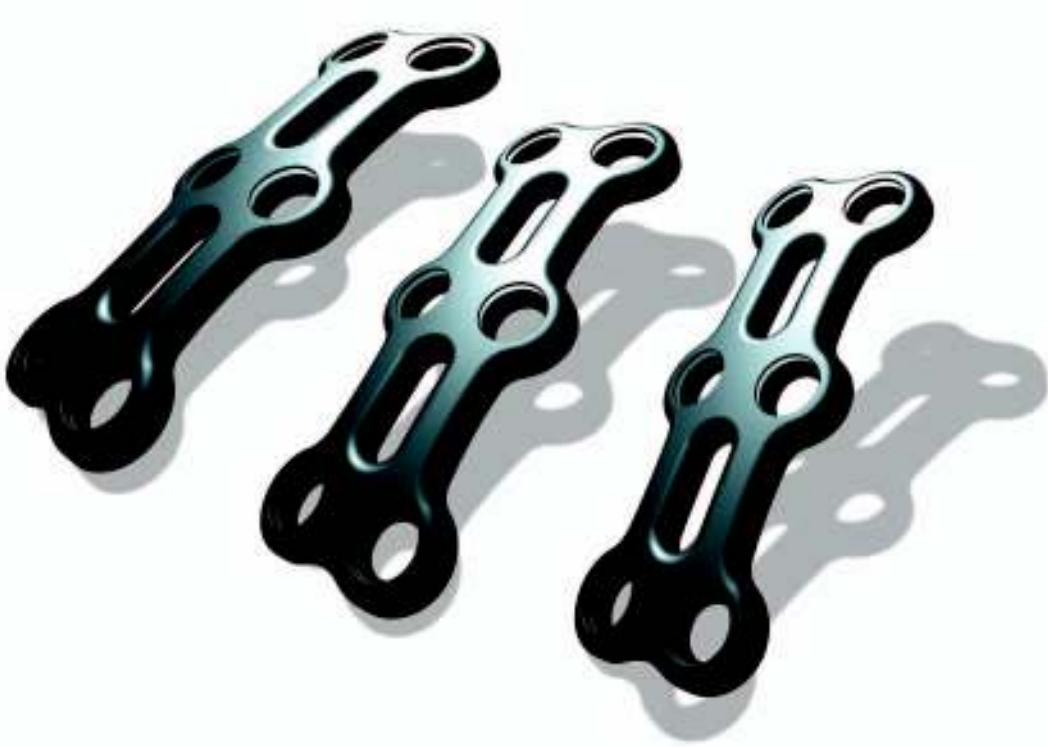
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The Reflex™ system has been designed not only to be clinically effective but also simple to use. The notes in this manual provide suggestions regarding surgical technique and instructions on implanting the Reflex™ system during major spinal surgical procedures. This manual concentrates on operative technique and implant configurations of particular relevance to the Reflex™ system.

Table of Contents

Surgical Technique

Preparation and Exposure	4
Implant Selection	5
Plate Bending and Fixing	6
Pilot Hole Preparation	8
Screw Insertion	10
Graft Screw Insertion (Optional)	12
Closing and Postoperative Care	13
Disassembly	13

Instrumentation

Instrument Guide	14
Implant Guide	15

Preparation and Exposure

The Reflex™ Anterior Cervical Plating system is designed to provide an immediate stabilization of the cervical spine in the case of cervical arthrodesis up to 4 levels from C2 to T1 in:

- Degenerative Disc Disease
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The system includes plates available in various lengths for surgeries involving one, two, three or four levels.

The plates are fixed to the vertebral column by screws interlocked to the plate with a blocking mechanism.

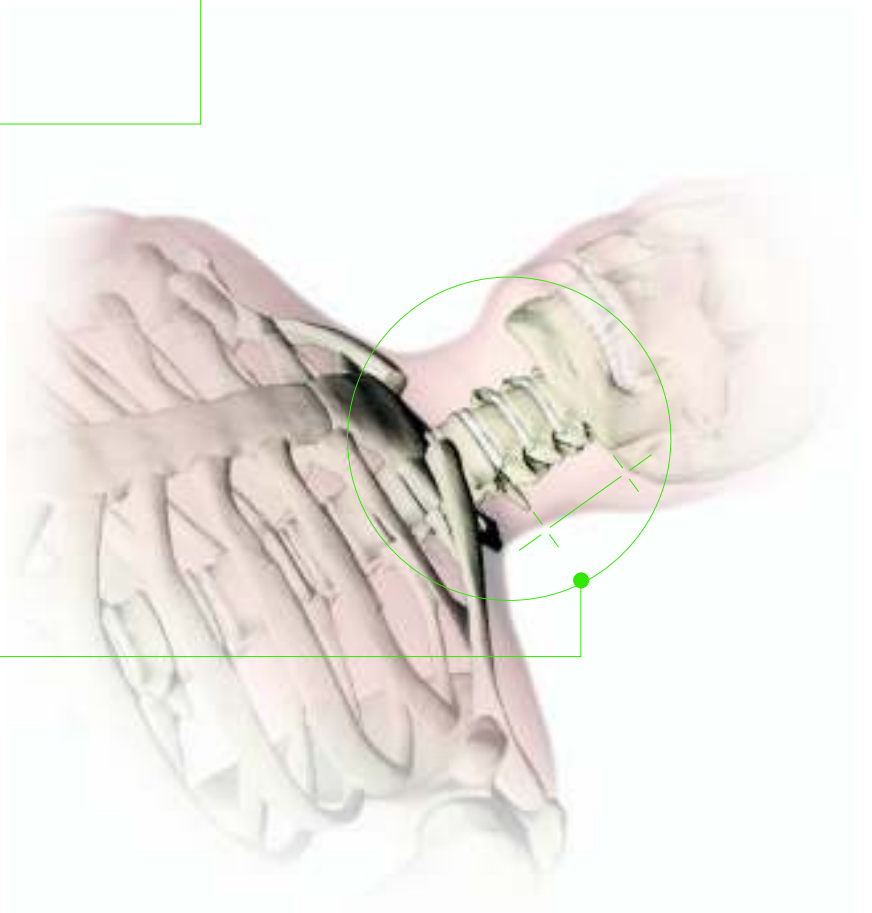
Appropriate positioning of the patient is essential for optimal exposure of the anterior cervical spine.

Traction may be necessary in the event of an unstable trauma.

Depending on the level(s) to arthrodesis, a transverse or longitudinal incision is made to allow access to the anterior face of the cervical vertebral column (C2 to T1).

A discectomy and/or corpectomy is performed, depending on the indication.

The choice and use of interbody graft is dependent upon surgeon's preference.



Implant Selection

The length of the plate will depend on the number of levels to be fixed (1, 2, 3 or 4). Using a caliper, the distance between the middle of the cranial vertebra and the middle of the caudal vertebra can be measured.

From the caliper measurement, it is then easy to match the appropriate plate length to accommodate the indicated levels of fusion.

The selected plate is held from its tray using the plate holder. The forceps has notches to hold the plate tightly. The plate is then placed on the vertebral column to confirm that the length of the plate is appropriate.

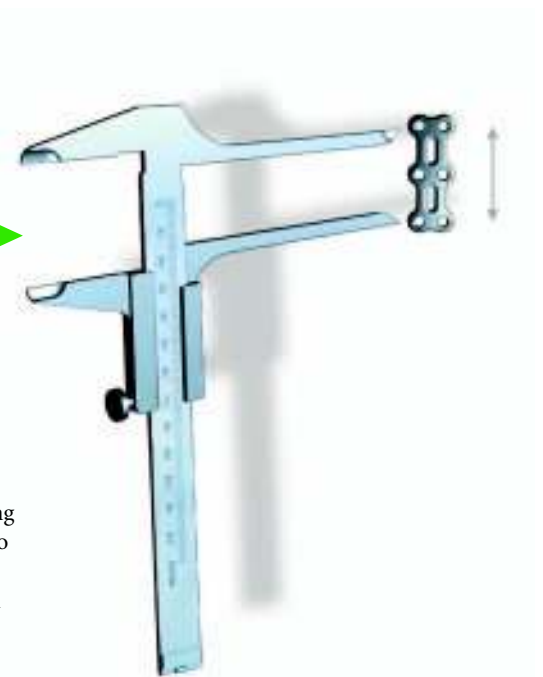
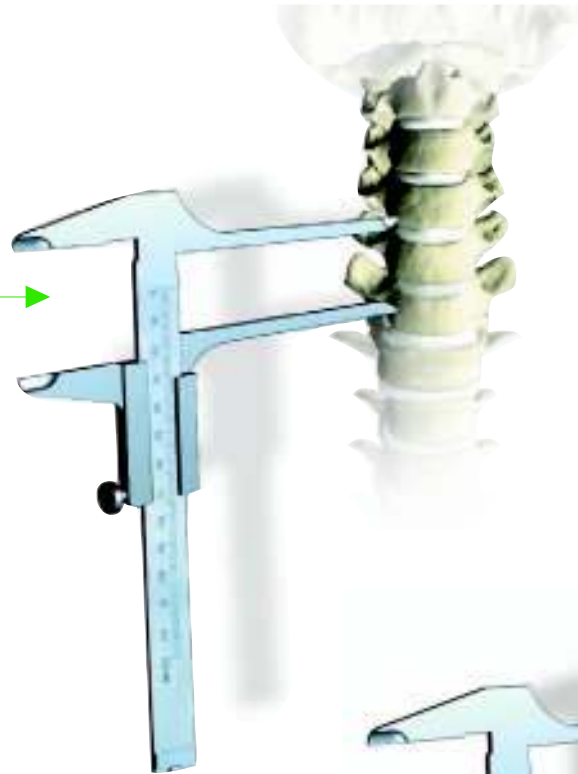
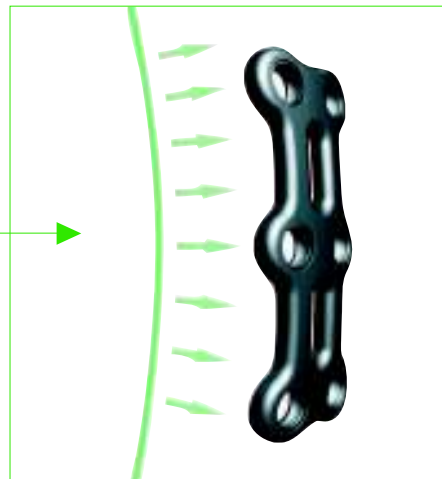


Plate Bending and Fixing

Reflex plates are machined with a slight sagittal and axial bend.



Depending on the curvature of the cervical segment to undergo osteosynthesis, the plate may be bent to conform to the anatomy using the plate bender.

It is recommended to make several slight bends along the length of the plate, between the screw holes, to obtain a consistent curvature radius.



Osteophytes, often found in the degenerative vertebral column, can be removed manually or with a power tool so the plate can be seated on the anterior face of the vertebral bodies.



The plate is held by the plate holder and placed on the vertebral column.

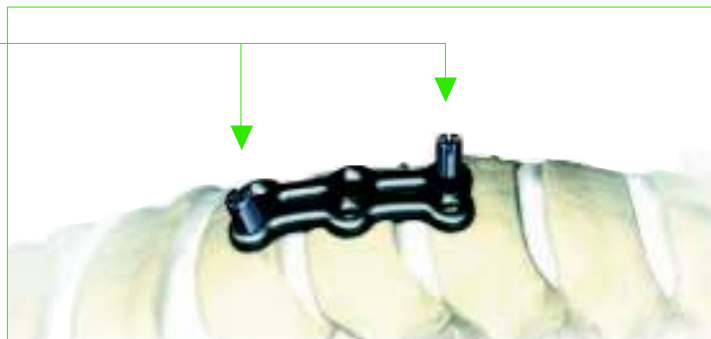
To make the subsequent steps easier, the plate is temporarily fixed to the vertebral column using small pins screwed into the cortical wall.



These pins are inserted through the screw holes using the standard screwdriver.

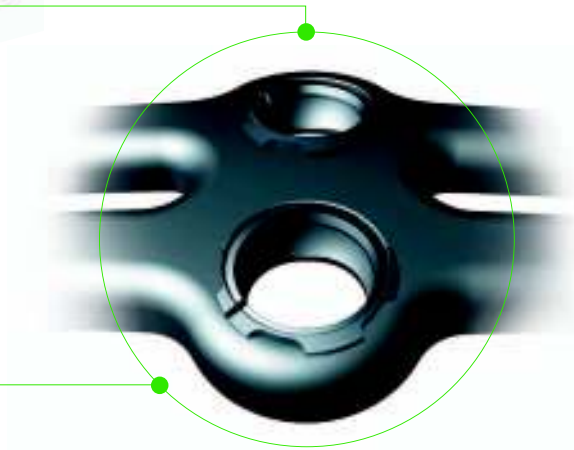


They have a self-cutting thread and can be inserted without any special preparation. To achieve sufficient temporary stability, it is recommended to place two pins diagonally.

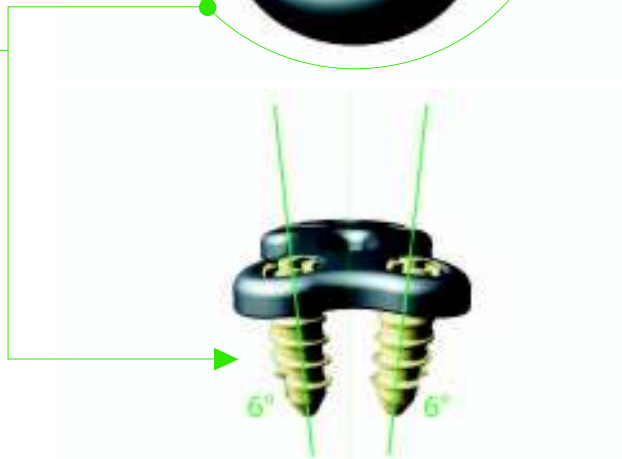


Pilot Hole

Preparation



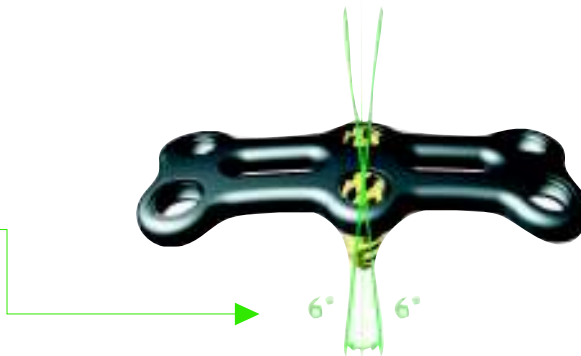
The integrated locking mechanism is designed in such a way as to direct the screws with a convergence of 6° in the axial plane.



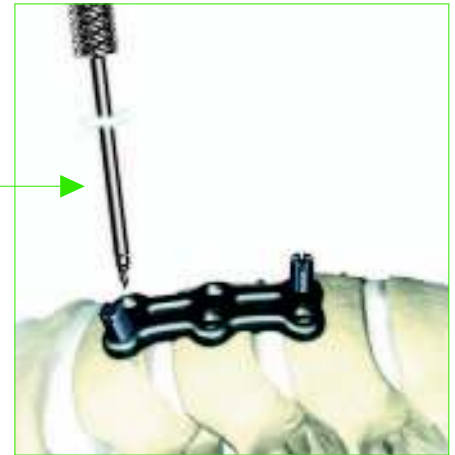
The design of the screw and its connection to the plate allow a sagittal angulation of the end screws: 0° to $+10^\circ$ for the cranial end and 0° to -10° for the caudal end



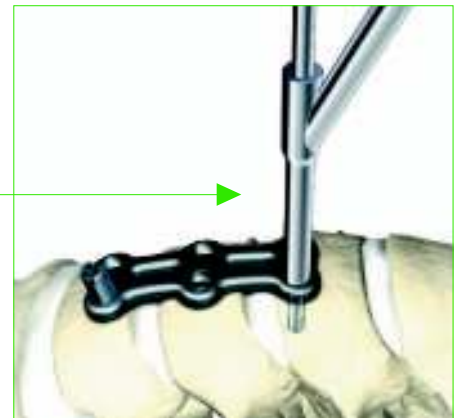
The screws placed in the intermediary screw holes have a free angulation of $+6^\circ$ to -6° in the sagittal plane.



An awl is available for perforation of the cortex, or as an alternative to drilling. When inserted into the screw hole, the tip of the outer sleeve has been designed to limit the pathway and the resulting screw angulation to 0 to +/- 10° in the sagittal plane and to 6° of convergence in the axial plane, which is the optimal range to ensure optimal functioning of the locking ring. When the awl is positioned outside of these limits, the sleeve will disengage from the plate. To activate the instrument, push and gently rotate the awl clockwise and counter-clockwise while continuing to apply pressure. The spring-loaded sleeve of the awl limits the depth of perforation to a maximum of 10mm. Since the bone screws of the Reflex™ system have been designed as self-tapping (but not self-drilling), additional drilling may be necessary based on the bone quality and surgeon's preference.

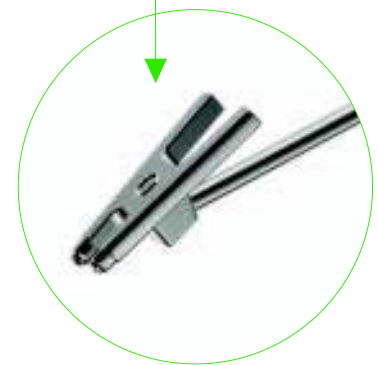


Two drill guides – a single and a double barrel option – are available for screw hole preparation. The tip of the single barrel drill guide has been designed to provide the same angulation constraints as those described above.



The double barrel drill guide is used to prepare both screw holes at a certain plate level at the same time. The guide provides the necessary degree of angulation in the sagittal plane, while the barrels are fixed in the position corresponding to the 6-degree axial convergence. After drilling both holes, the double barrel drill guide is removed for subsequent tapping and/or screw insertion.

The 2.5mm drill bits, which can be used manually with a quick release handle or connected to an AO type power equipment, are used for both 4.0 and 4.5mm diameter screws. The drill bits come in various lengths corresponding to the lengths of the screws, and they are color coded for easy identification, e.g., a 12mm drill bit with a blue ring will be used to prepare for the blue 12mm screw.

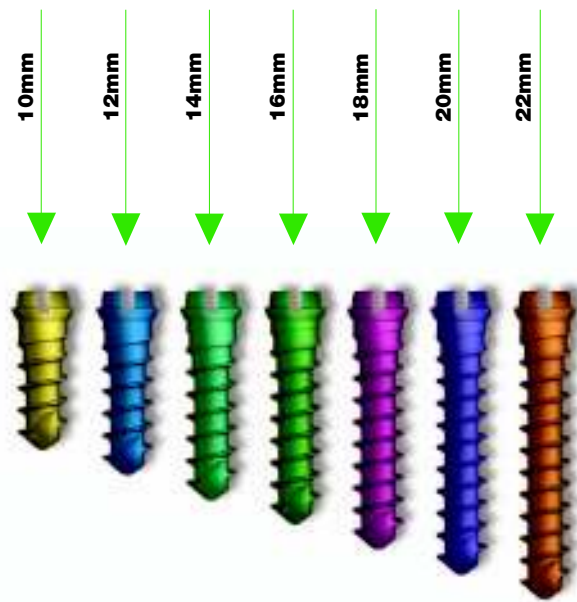


A tap may be used, particularly in the case of a hard bone, to prepare the passage of the screw. However, screws feature a self-tapping thread and tapping is therefore not always necessary.

Screw

Insertion

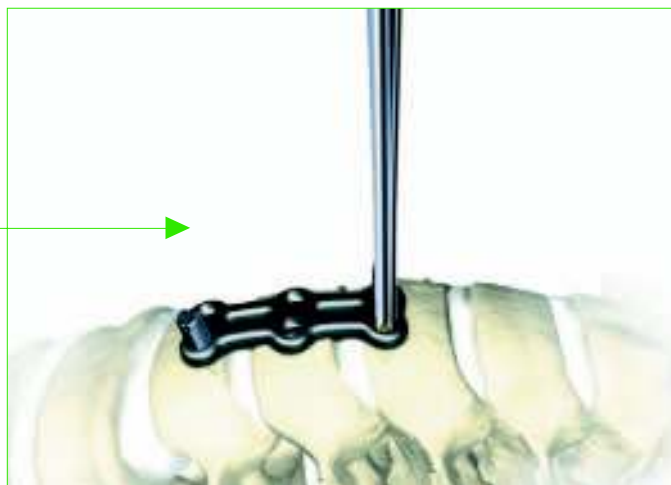
Two screw diameters are available to accommodate different bone qualities: 4.0mm for standard use, and 4.5mm for inferior quality bone or as a replacement of a previously placed 4.0mm screw. The screws are offered in 10, 12, 14, 16, and 18mm lengths in the 4.0mm diameter, and in 12, 14, 16, and 18mm lengths in the 4.5mm diameter. Additional lengths (20 and 22mm screws) are available if bicortical application is desired. The screws are color coded for easy identification.



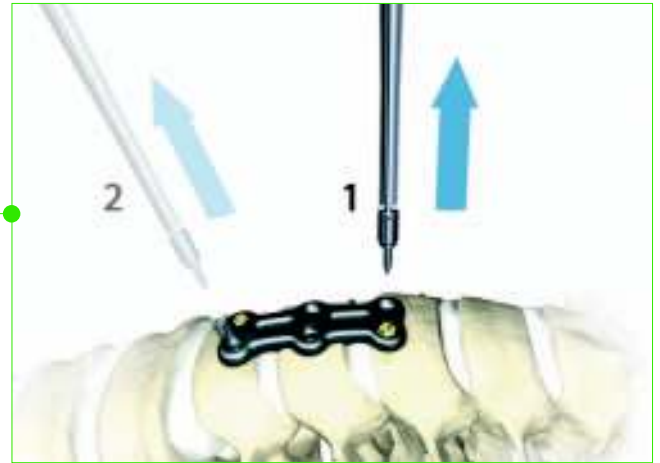
The selected screw size is taken directly from the tray using the standard screwdriver.



The screw is inserted into the prepared pilot hole. The screw is then tightened until it is sufficiently seated and locked into the plate.



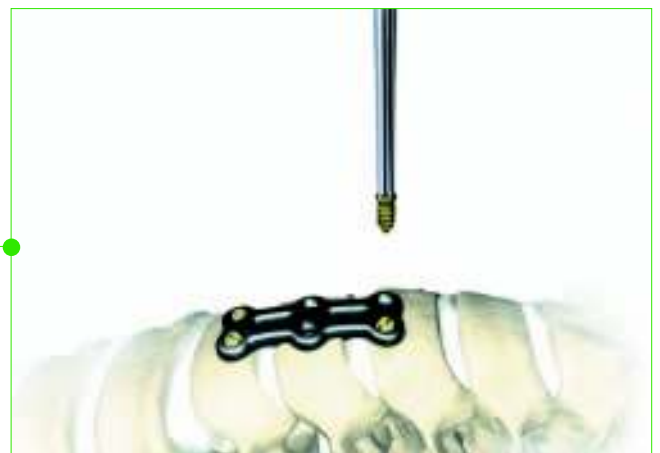
The temporary pins are removed using the standard screwdriver.



The paths for the remaining screws are prepared in the same way as previously described.



The standard screwdriver is then used for the final tightening of the screws.



Detail of the blocking ring after the screw has been fully inserted. When the screw has been properly seated, the entire blocking ring should be visible. A partial ring indicates that the angle of the screw may be outside of the optimal limits and the blocking feature may not be fully engaged.



Graft Screw Insertion (Optional)

In the case of a corpectomy, the graft can be secured to the plate using standard 4.0 mm screws placed in the intermediary screw holes. The preparation and insertion of the screws are carried out as previously described.



Closing

and Postoperative Care

Closing is performed at the involved levels. Postoperative care as well as physical therapy schedule depends on surgeon's preference.

Disassembly

If it becomes necessary to remove a fully seated screw from the plate, a special revision screwdriver must be used.

The tip of the revision screwdriver spreads the blocking ring to unlock the bone screw so that it can be removed from the plate. It is important that the tip of the revision screwdriver is fully inserted into the head of the bone screw to spread the blocking ring. For best results, align the shaft of the revision screwdriver at the same angle the bone screw was inserted.

A knob at the top of the revision screwdriver handle allows the surgeon to screw an inner threaded shaft into the central thread of the screw head (screwing action clockwise). The threaded shaft is used to add extra stability at the instrument interface. To back out the screw, turn the revision screwdriver counter-clockwise while pulling gently upward.



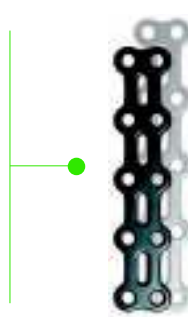
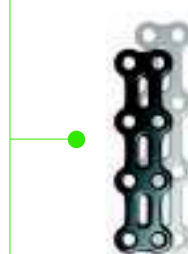
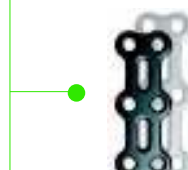
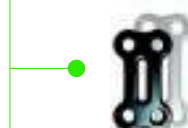
Instruments

Description	Part No.	Qty / Set	
Container	4850004	1	
Caliper	48500100	1	
Plate bender	48500200	1	
Plate holder	48500300	1	
Pin	48500401	4	
Drill guide	48500500	1	
Double barrel drill guide	48500505	1	
Quick release handle	48500600	2	
Drill Length 10mm	48500610	2	
Drill Length 12mm	48500612	1	
Drill Length 14mm	48500614	1	
Drill Length 16mm	48500616	1	
Drill Length 18mm	48500618	1	
Drill Length 20mm	48500620	1	
Drill Length 22mm	48500622	1	
Tap	48500700	1	
Awl	48500705	1	
Screwdriver	48500800	2	
Revision screwdriver	48500900	1	

Implants

	Description	Part No.
	Gold 4.0mm x 10mm	48624010
	Blue 4.0mm x 12mm	48624012
	Turquoise 4.0mm x 14mm	48624014
	Green 4.0mm x 16mm	48624016
	Fuchsia 4.0mm x 18mm	48624018
	Purple 4.0mm x 20mm	48624020
	Orange 4.0mm x 22mm	48624022
	Blue 4.5mm x 12mm	48624512
	Turquoise 4.5mm x 14mm	48624514
	Green 4.5mm x 16mm	48624516
	Fuchsia 4.5mm x 18mm	48624518
	Purple 4.5mm x 20mm	48624520
	Orange 4.5mm x 22mm	48624522

Description	Part No.
1 Level Size 12mm	48610112
1 Level Size 14mm	48610114
1 Level Size 16mm	48610116
1 Level Size 18mm	48610118
1 Level Size 20mm	48610120
1 Level Size 22mm	48610122
2 Level Size 24mm	48610224
2 Level Size 26mm	48610226
2 Level Size 28mm	48610228
2 Level Size 30mm	48610230
2 Level Size 32mm	48610232
2 Level Size 34mm	48610234
2 Level Size 37mm	48610237
2 Level Size 40mm	48610240
2 Level Size 43mm	48610243
2 Level Size 46mm	48610246
3 Level Size 39mm	48610339
3 Level Size 42mm	48610342
3 Level Size 45mm	48610345
3 Level Size 48mm	48610348
3 Level Size 51mm	48610351
3 Level Size 54mm	48610354
3 Level Size 57mm	48610357
3 Level Size 60mm	48610360
3 Level Size 63mm	48610363
3 Level Size 66mm	48610366
3 Level Size 69mm	48610369
4 Level Size 60mm	48610460
4 Level Size 64mm	48610464
4 Level Size 68mm	48610468
4 Level Size 72mm	48610472
4 Level Size 76mm	48610476
4 Level Size 80mm	48610480
4 Level Size 84mm	48610484





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