RESONATE®

Anterior Cervical Plate System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

RESONATE®

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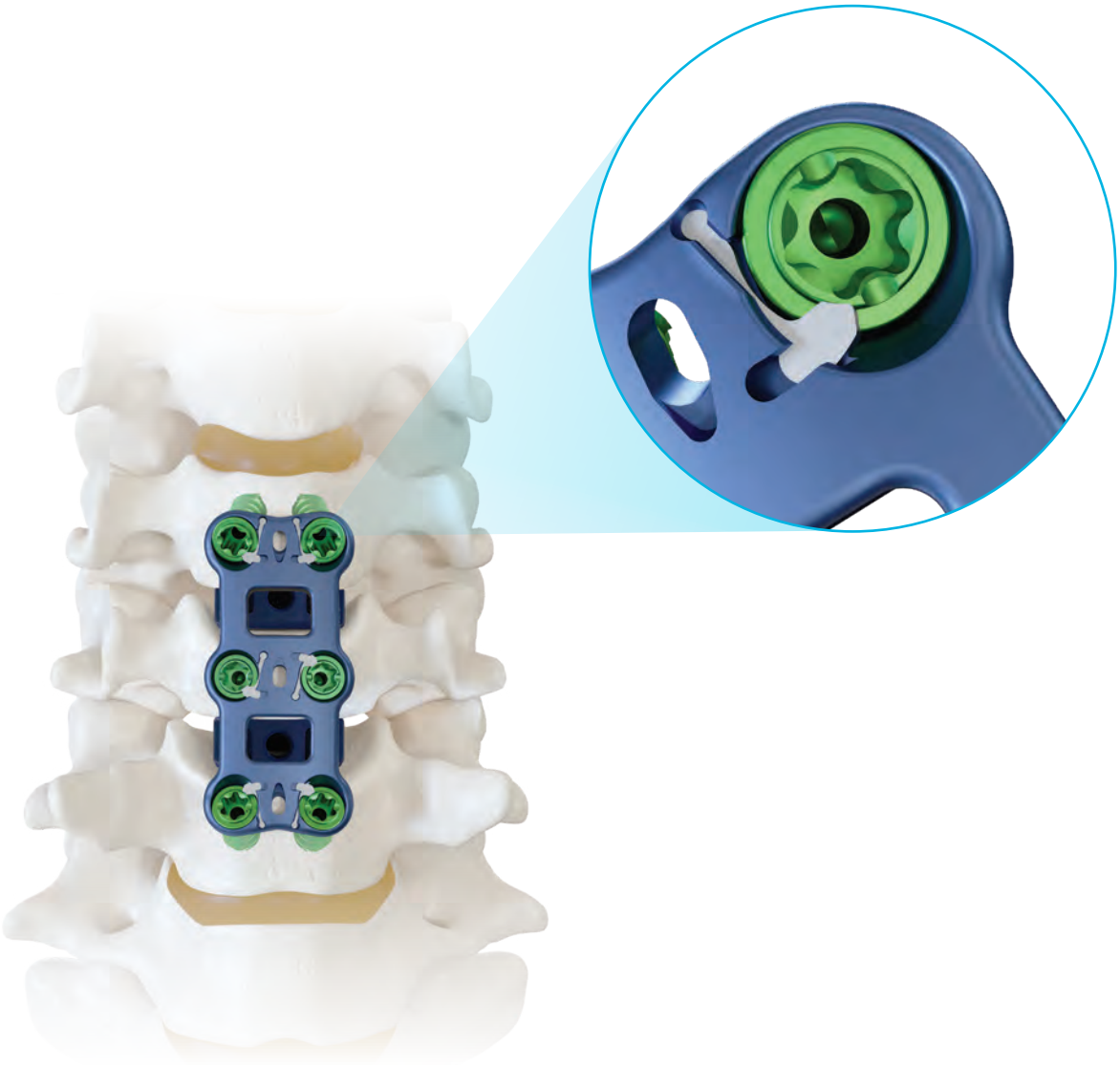
Anterior Cervical Plate System

RESONATE® is an extreme angle ACDF plate designed to maximize screw angulation, ease insertion with automatic screw blocking, and provide optimal plate lengths to minimize overlap on the vertebral body.



Extreme Screw Angulation

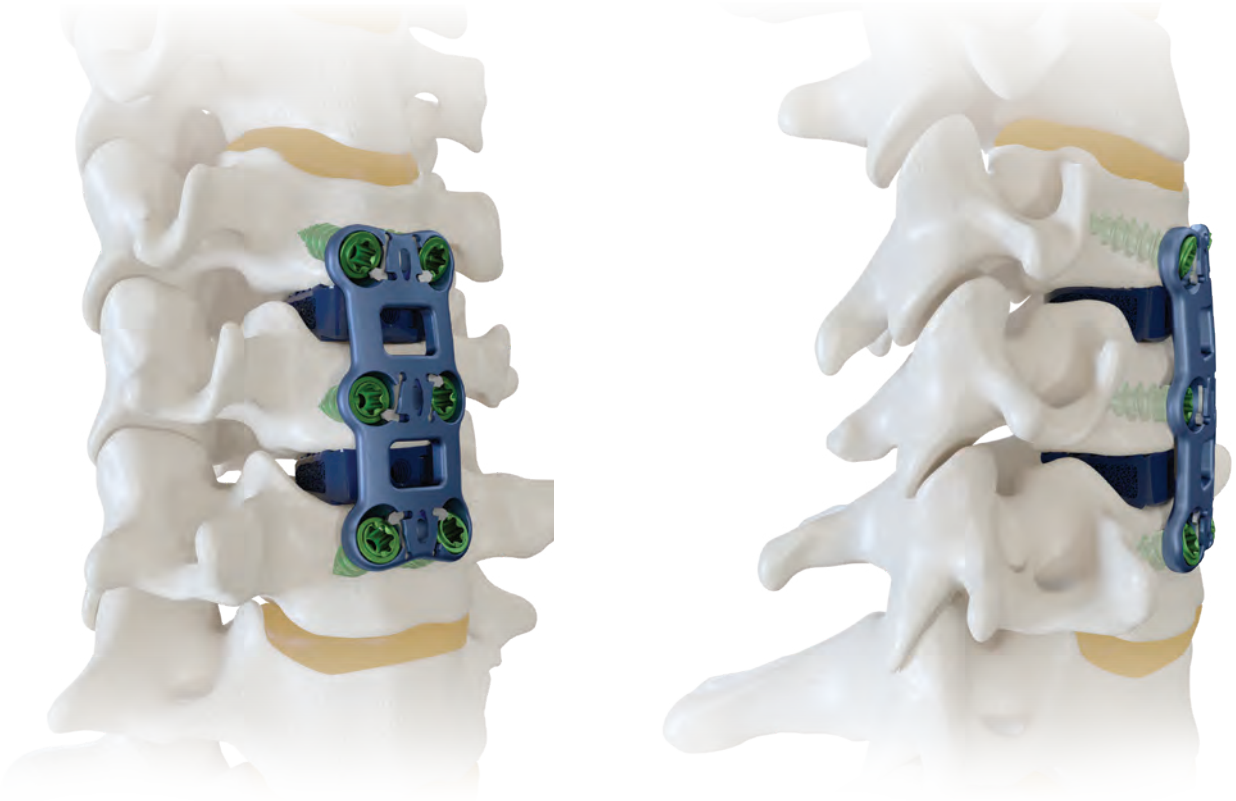
RESONATE® offers a cephalad/caudal range of 5° to 35° when using variable screws. Fixed angle screws allow a preset 25° angle.

Low Profile Design

RESONATE® has a maximum thickness of 2.1mm and a 16.9mm width designed to help reduce soft tissue irritation.

Automatic Blocking Mechanism

Zero-step blocking allows for screw insertion without additional locking steps.

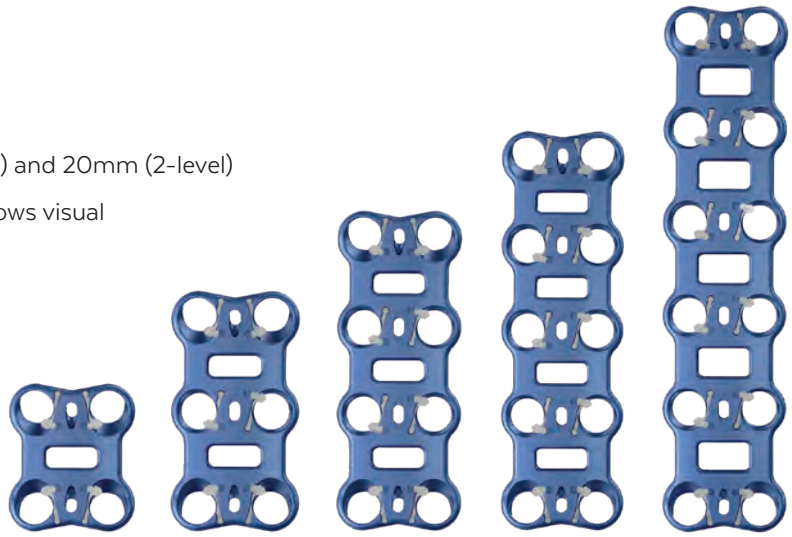


Shown with HEDRON C™ Interbody Spacers

IMPLANT OVERVIEW

RESONATE® Plates

- Shorter length plates available from 8mm (1-level) and 20mm (2-level)
- Unique automatic screw blocking mechanism allows visual confirmation of blocking
- 2.1mm profile
- 16.9mm width
- Large windows for graft visualization
- Available in 1, 2, 3, 4, and 5 level sizes
- Extra lordotic plates available (1, 2, and 3 level)



Screws

- 4.2mm and 4.6mm diameters
- Self-drilling or self-tapping
- Lengths from 12-16mm offered in 1mm increments*
  - Self-tapping screws additionally available in up to 26mm lengths
- Variable or fixed angle

Variable Angle Screw

Fixed Angle Screw

Screw Angulation

- Range of 5° to 35° angulation for variable screws (end holes only)
- Pre-set angulation of 25°
- ±10° angulation on middle levels of multi-level plates
- 6° medial angulation

*18mm self-tapping screws are standard in set.

INSTRUMENT OVERVIEW

SCREW PREPARATION INSTRUMENTS

Cervical Awl, with Sleeve 6194.1000

Cervical Awl, for Drill Guide 650.102

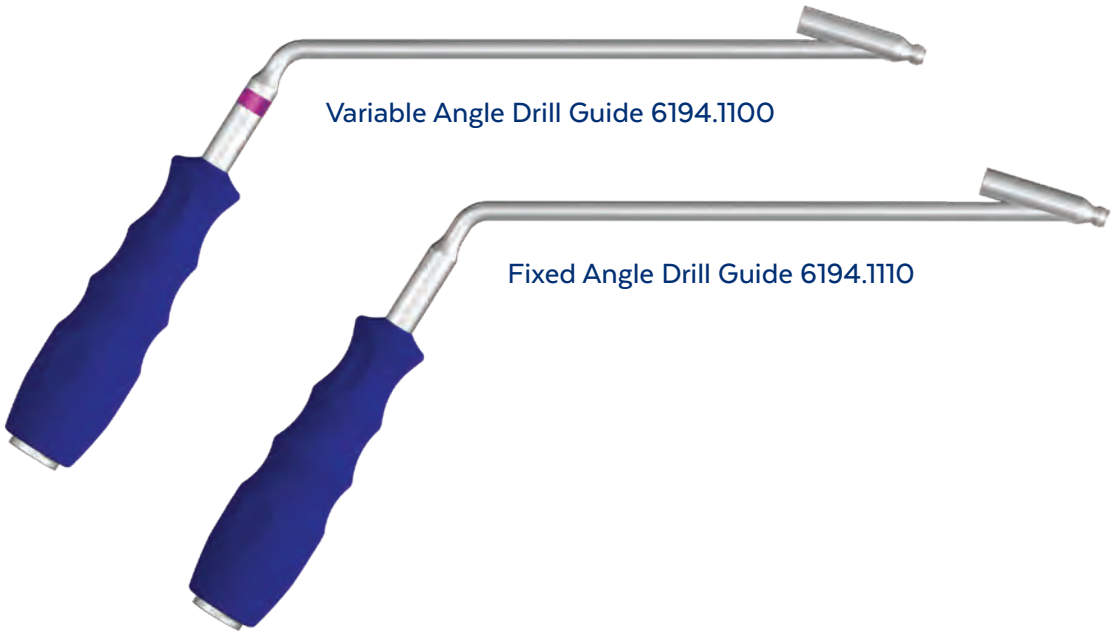
Cervical Tap 650.160

Quick-Connect Handle, Small 6194.3000

Drill Bits			
	Standard Length Part	Short Length Part	Size
	650.110	650.510	10mm
	650.112	650.512	12mm
	650.114	650.514	14mm
	650.116	650.516	16mm
	650.118	650.518	18mm
	650.120	650.520	20mm

Items in gray are additionally available.

DRILL/DTS GUIDES



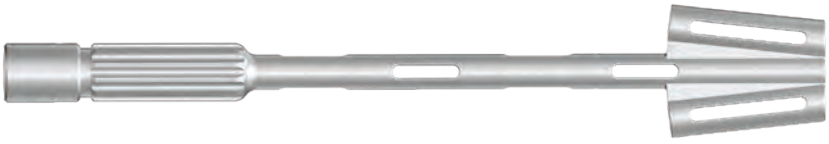
Variable Angle Drill Guide 6194.1100

Fixed Angle Drill Guide 6194.1110

Double Barrel Variable Angle Drill Guide 6194.1102

Double Barrel Fixed Angle Drill Guide 6194.1112

Single Barrel DTS Guide Sleeve, 6194.1150



Double Barrel DTS Guide Sleeve, 6194.1152

Items in gray are additionally available.

TRIAL/DRILL GUIDE AND MODULAR TRIALS

Trial/Drill Guide Sleeve 6194.1050

Inner Shaft, Trial/Drill Guide 6194.1051

14x16mm, 7°	
Height	Part No.
5mm	6194.1005
6mm	6194.1006
7mm	6194.1007
8mm	6194.1008
9mm	6194.1009
10mm	6194.1010
11mm	6194.1011
12mm	6194.1012

SCREW INSERTION

Expandable #15 Hexalobe Screwdriver Sleeve 6194.2000

Inner Shaft, for QC 6194.2001

#15 Hexalobe Self-Retaining Driver, QC 6194.2010

Items in gray are additionally available.

SCREW INSERTION (CONT'D)

Angled Driver Tip, #15 Hexalobe 6194.2418

Angled Driver Tip, #15 Hexalobe, Short 6194.2418

Angled Driver Body 684.415

Backing Nut 684.416

Angled Driver Shaft 684.417

Counter-Torque 684.421

PLATE HOLDER

Forceps Plate Holder 6194.4000

Expandable Plate Holder Sleeve 6194.4010

Inner Shaft, Plate Holder 6194.4011

Items in gray are additionally available.

PLATE BENDER

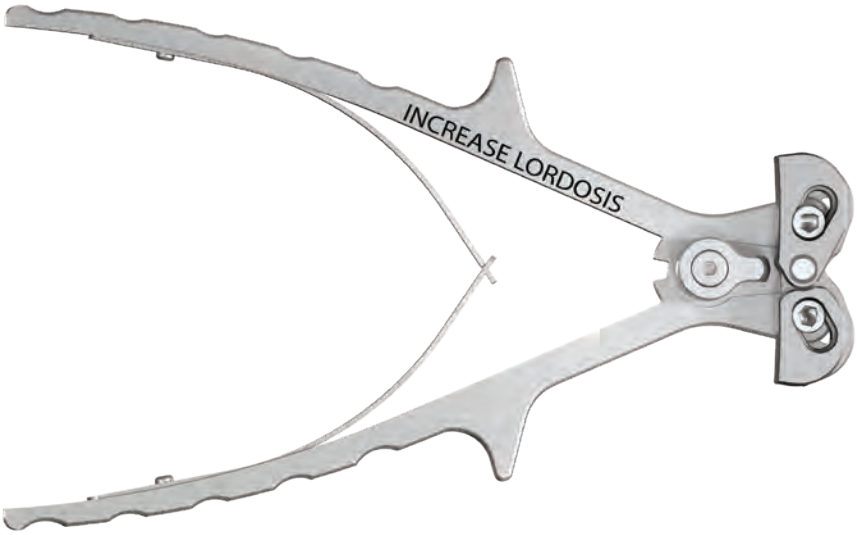


Plate Bender 6194.4400

TEMPORARY FIXATION

Temporary Fixation Pin 6194.5001

Temporary Fixation Screw 6194.5005

Temporary Fixation Pin, Smooth 6194.5002

Temporary Fixation Screw, Long 6194.5006

Fixation Pin Driver Sleeve 6194.5100

Inner Shaft, Fixation Pin Driver 6194.5101

SCREW REMOVAL

Screw Removal Sleeve 6194.7000

Screw Extractor 650.314

#15 Hexalobe Non-Self-Retaining Driver, QC 6194.2015

Items in gray are additionally available.

SURGICAL TECHNIQUE

RESONATE®

Please refer to the product insert printed at the back of this manual for complete description, indications, contraindications, warnings, and precautions associated with this system.

STEP 1 APPROACH

The patient is placed under anesthesia and positioned supine. An anterior cervical approach is used. The operative area is cleaned and an incision is made at the appropriate fusion level(s). RESONATE® plate fixation may be used in the cervical spine from C2 to T1.

Distraction may be accomplished using a standard distractor or other standard methods. Prepare the disc space and insert bone graft or an interbody fusion device. Refer to the following surgical technique guides for recommended products:

- HEDRON C™ 3D Printed ACDF Surgical Technique Guide (GMTGD220)
- COLONIAL® ACDF Surgical Technique Guide (GMTGD27)
- FORGE® Cervical Allograft Surgical Technique Guide (GMTGD40)

Remove anterior osteophytes to allow the plate to sit flush on the vertebral body. AP and lateral C-arm fluoroscopy or other radiographic methods may be used throughout surgery to ensure correct implant placement.

STEP 2 PLATE PLACEMENT

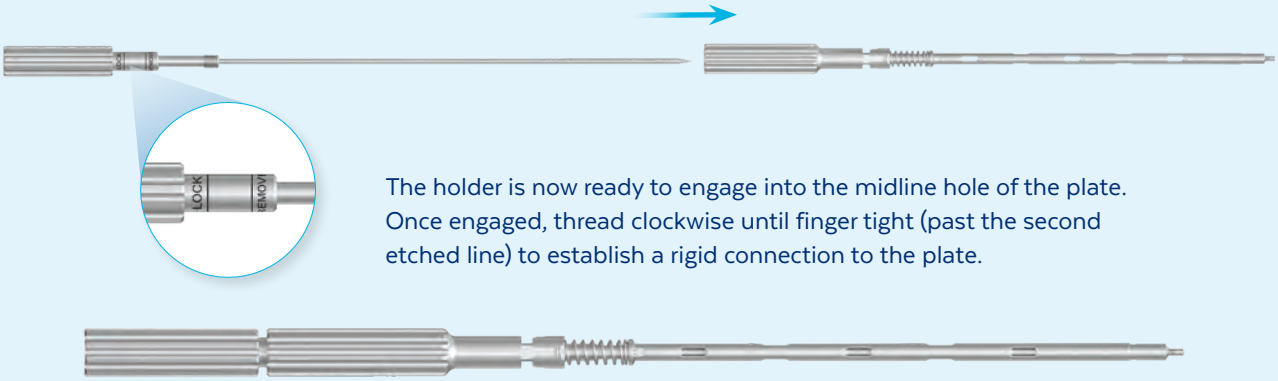
Select the appropriate plate size. Plate length is measured from the center of the cephalad hole to the center of the caudal hole and depends on the number of levels (1-5) to be treated. The appropriate size plate can be measured using a caliper. The plate may be contoured using a plate bender (see page 15 for detailed instruction on plate bending).

Place the plate onto the vertebral bodies using a plate holder. The **Forceps Plate Holder** may be used for plate placement. The **Expandable Plate Holder** assembly may be used if a more rigid connection to the plate is desired.

PLATE PLACEMENT (CONT'D)

EXPANDABLE PLATE HOLDER ASSEMBLY

Insert the **Inner Shaft, Plate Holder** into the **Expandable Plate Holder Sleeve** and thread clockwise to the first etched line on the inner shaft.



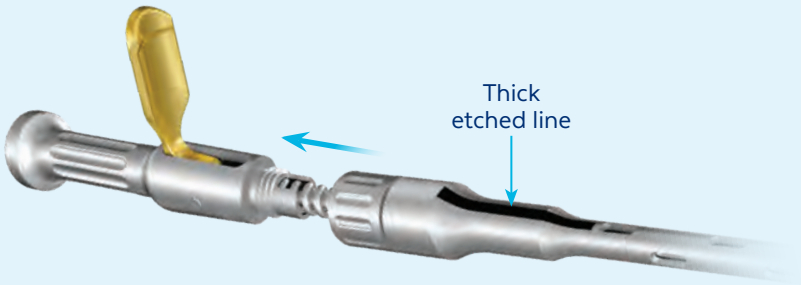
The holder is now ready to engage into the midline hole of the plate. Once engaged, thread clockwise until finger tight (past the second etched line) to establish a rigid connection to the plate.

The plate may be provisionally held in place by **Temporary Fixation Screws**. Use the **#15 Hexalobe Self-Retaining Driver, QC** to insert the screws into the screw holes.

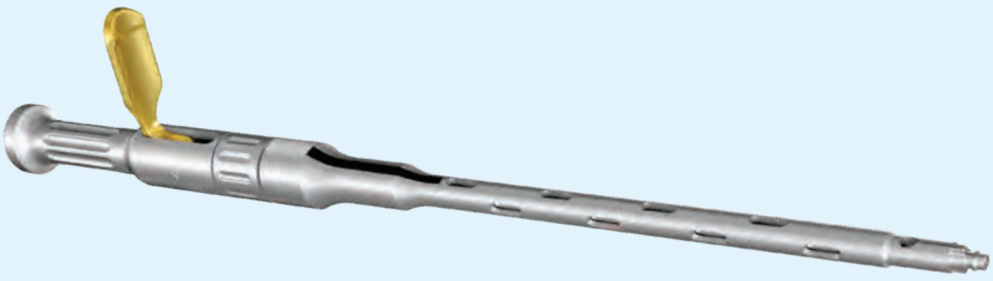
Alternatively, a **Temporary Fixation Pin** may be inserted into a central hole of the plate using the Fixation Driver Assembly.

FIXATION DRIVER ASSEMBLY

Insert the **Inner Shaft, for Fixation Pin Driver** into the **Fixation Pin Driver Sleeve**, aligning the gold lever of the inner shaft with the thick etched line on the sleeve.



Thread the collar clockwise until fully seated. Ensure the lever is disengaged prior to engaging a pin.



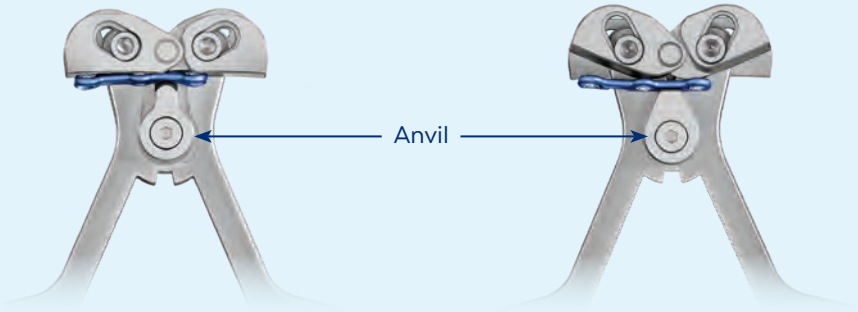
To load a Temporary Fixation Pin, seat the tip of the **Fixation Driver Assembly** into the pin and press the gold lever down to engage the pin. Place the pin into a midline slot and lightly impact to fully seat into bone. Ensure the pin is oriented with the flat areas facing the screw holes. To disengage the driver from the pin, lift the gold lever and pull the driver assembly away.

To remove the pin from the plate, insert the driver assembly into the pin and press the gold lever down to engage the pin. Lightly twist the assembly while pulling upward to remove.

Temporary Fixation Pin aligned

PLATE BENDING

All plates are pre-contoured in the sagittal plane to provide lordosis. Additional contouring may be achieved using the Plate Bender.



Increasing lordosis **Decreasing lordosis**

To add lordosis, place the desired plate face up within the anvil of the plate bender on the side marked INCREASE LORDOSIS. If removing lordosis, place the plate face down into the anvil on the side of the bender marked DECREASE LORDOSIS. Do not place the bender near the slider blocking mechanisms. Compress the handles to achieve the desired curvature.

For multi-level plates, incrementally bend sections and slide the plate along the anvil to the next level. At every level, check to ensure the anvil is not touching any slider blocking mechanisms.

Note: *Avoid bending the plate at the screw holes and slider blocking mechanism by placing the plate in the bender in the correct position.*

Correct Placement **Incorrect Placement**

STEP 3 SCREW HOLE PREPARATION

A fixed angle drill and screw (DTS) guide may be used for drilling and inserting each screw. A variable angle drill guide may be used for drilling only. *Note: Use care when using power tools in screw holes. If damage to the plate or locking mechanism is observed, use a different plate.*

Option A: Pre-Set Angulation

Using the Fixed Angle Drill Guide

The **Cervical Awl, with Sleeve** may be used to create a pilot hole. Insert the awl through the screw hole and break the cortex. If desired, a cervical depth gauge may be used to determine the appropriate screw length. Place the **Fixed Angle Drill Guide** into the desired screw hole. Determine the appropriate screw length using the length gauge on the screw module. The drills are color-coded based on screw length.

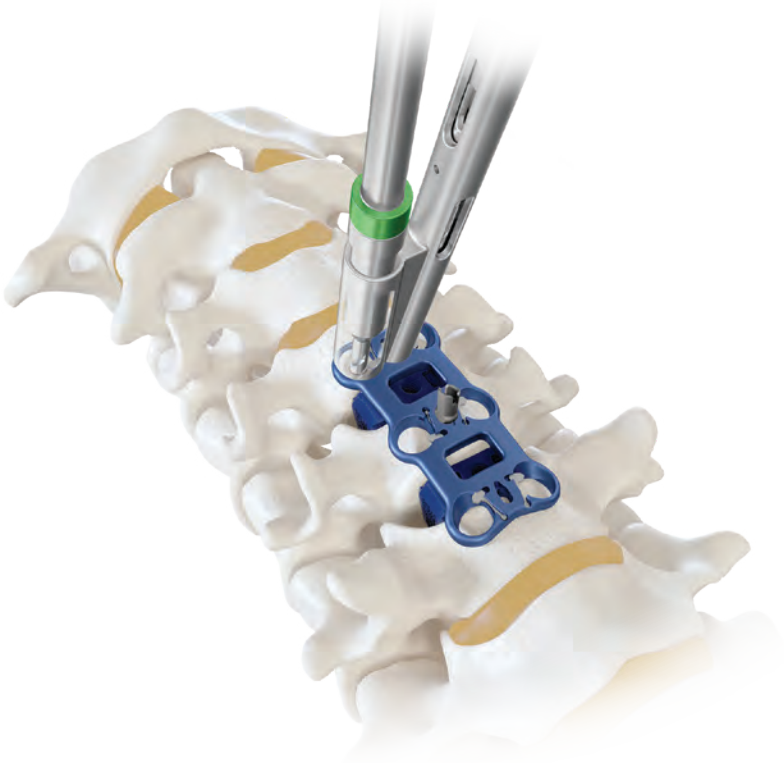
Assemble the selected drill bit onto the **Quick-Connect Handle, Small** and insert into the drill guide. Drill until the stop. Screw holes may be tapped using the **Cervical Tap** once the drill guide is removed. If desired, the **Double Barrel Fixed Angle Drill Guide** may be used to prepare both screw holes with one instrument at each level.

Using the DTS Sleeve

For drilling, tapping, and screw insertion using one instrument, select the desired DTS sleeve. Slide either the **Single Barrel DTS Sleeve** or **Double Barrel DTS Sleeve** onto the **Plate Holder Sleeve** (see page 14 for plate holder assembly steps). Insert the assembly into the central pin hole and rotate the knob clockwise until a rigid connection to the plate is established.

The barrel of the Single Barrel DTS Guide rotates to conveniently switch to the contralateral side. Pull the sleeve up toward the handle, rotate 180°, and release the sleeve to change barrel position.

Lift and rotate sleeve to contralateral side



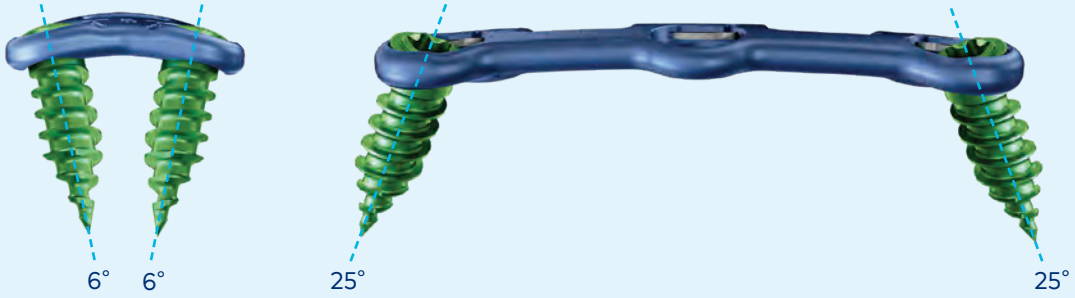
Creating a Pilot Hole

The **Cervical Awl, for Drill Guide** may be used in the DTS sleeve to create a pilot hole. Insert the awl through the screw hole and break the cortex. A cervical depth gauge may be used to determine the appropriate screw length. The drills are color-coded based on screw length. Assemble the selected drill bit onto the Quick-Connect Handle, Small and insert into the drill guide. Drill until the stop. Screw holes may be tapped using the Cervical Tap through the DTS sleeve.

Screws may also be inserted through the DTS sleeve. See Step 4, page 20, for screw insertion. Rotate the knob counterclockwise to release the lock and remove the instrument from the plate.

PRE-SET ANGULATION

DTS and fixed angle drill guides provide a pre-set angle of 25° at the cephalad and caudal screw levels.



Axial Plane **Sagittal Plane**

Using the Trial/Drill Guides

The **Trial/Drill Guide** may be used with the appropriate sized trial to ensure optimal screw entry points on the most cephalad or caudal levels. The trial may be used as a guide for screw hole preparation but is not intended to size the interbody spacer.

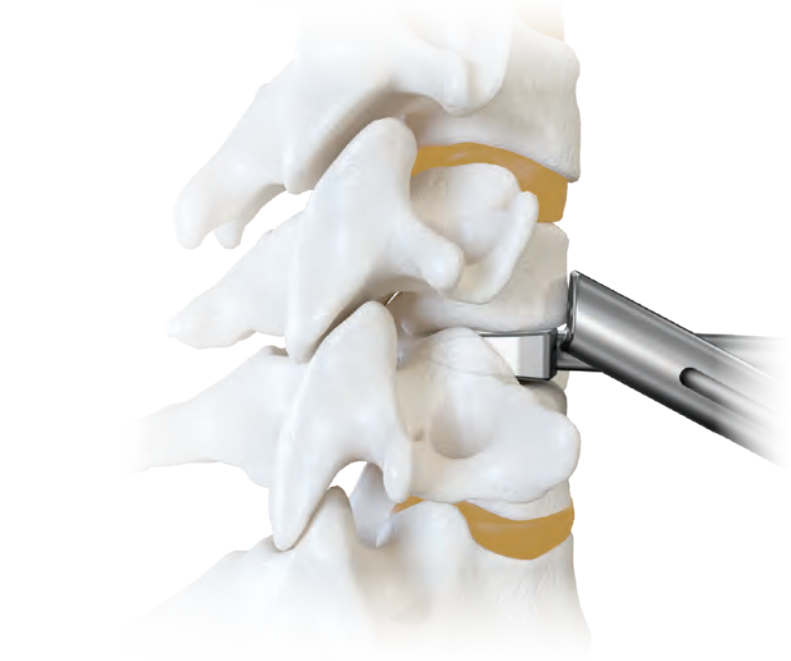
TRIAL/DRILL GUIDE ASSEMBLY

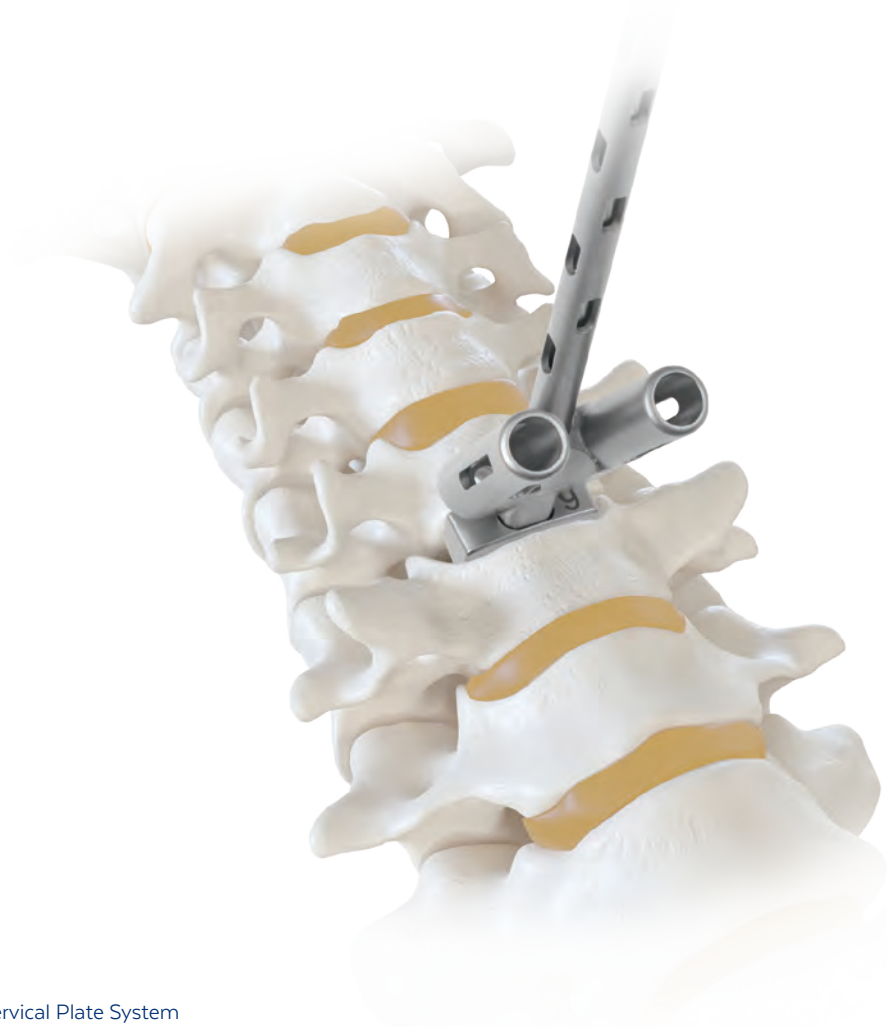
Insert the **Inner Shaft, Trial/Drill Guide** into the **Trial/Drill Guide Sleeve** and thread the knob of the inner shaft clockwise until the first stop. The inner shaft is captured in the sleeve and is ready for the trial to be loaded.

Select the appropriate trial and ensure the etching is facing up. Insert the desired trial into the tip of the sleeve and thread the knob of the inner shaft clockwise until it stops.

Option A: Pre-Set Angulation (Cont'd)

Position the Trial/Drill Guide assembly into the disc space. The screw entry points are located at the edge of the vertebral body. Assemble the selected drill bit onto the Quick-Connect Handle, Small, and insert into the Trial/Drill Guide. Drill until the stop. Repeat for the contralateral side.





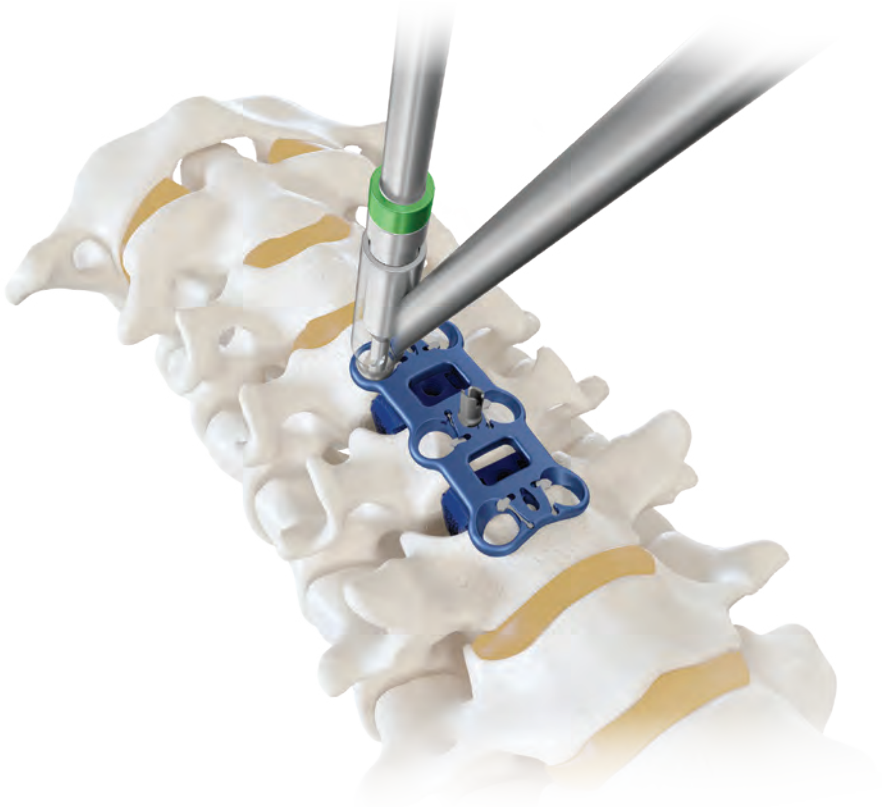
Option B: Variable Angulation

Using the Variable Angle Drill Guide

The Cervical Awl, with Sleeve may be used to create a pilot hole. Alternately, the Cervical Awl, for Drill Guide may be inserted through the Variable Angle Drill Guide. Insert the awl through the screw hole and break the cortex. If desired, a cervical depth gauge may be used to determine the appropriate screw length.

Place the **Variable Angle Drill Guide** into the desired screw hole. Determine the appropriate screw length. A depth gauge may be used if desired. The drill guide permits full angulation of the drill bit through the plate. The drills are color-coded based on screw length. Assemble the selected Drill Bit to the Quick-Connect Handle, Small and insert into the drill guide. Drill until the stop. Screw holes may be tapped using the Cervical Tap once the drill guide is removed.

Note: Variable angle drill guides should not be used to prepare screw holes for fixed angle screws.



ANGULATION WITH VARIABLE ANGLE DRILL GUIDE

Screw Angulation
The Variable Angle Drill Guide allows screw angulation of 5° to 35° for drilling screw pilot holes on the cephalad and caudal ends of the plate, respectively.

STEP 4 SCREW INSERTION

For self-drilling screws, insert the screws using a self-retaining driver. For self-tapping screws, select a drill bit and drill to the appropriate depth. Insert the screws using a self-retaining driver.

Assemble the Expandable Driver and attach to the Quick-Connect Handle, Small. Load the desired screw from the module. Press the gold lever to expand the tip into the hexalobe drive in the screw head. Verify screw length and diameter using the gauges within the screw module.

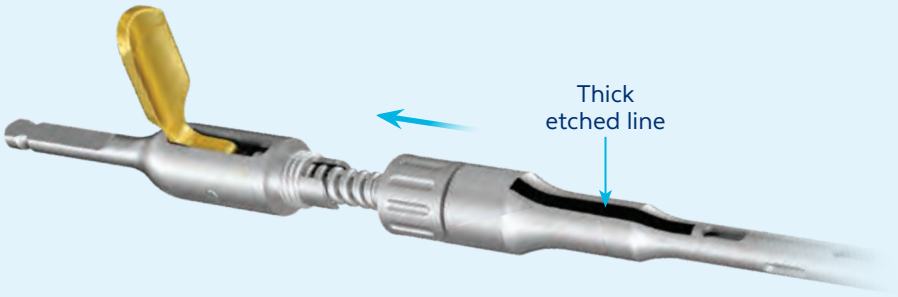
Insert the screw through the screw hole. The slider deflects into the plate as the screw is advanced.

As the screw is inserted, the plate lags to the bone. For proper screw blocking, verify that the screw is fully seated to allow the slider to move back to its original position and block the screw. Lift the lever up to disengage the driver from the screw.

Note: All screw lengths are measured by the amount of bone engagement.

EXPANDABLE DRIVER ASSEMBLY

Insert the **Inner Shaft, for QC** into the **Expandable #15 Screwdriver Sleeve**, aligning the gold lever with the thick etched line on the sleeve.

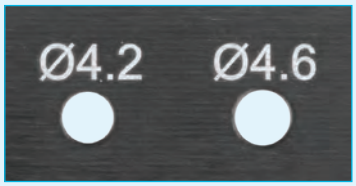


Rotate the collar clockwise until fully tightened. Ensure the lever is disengaged (flipped up) prior to loading a screw.

Alternatively, the **#15 Hexalobe Self-Retaining Driver, QC** may be used for screw insertion. Assemble the desired driver to the Quick-Connect Handle, Small, and follow the same steps above for screw insertion.

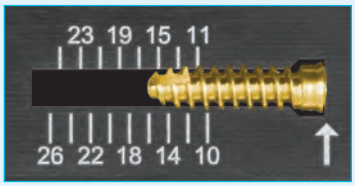
Note: 4.9mm screws are additionally available as secondary rescue screws only for middle level holes in multi-level plates.

USING SCREW GAUGES



Verify screw diameter by inserting selected screw into gauge.

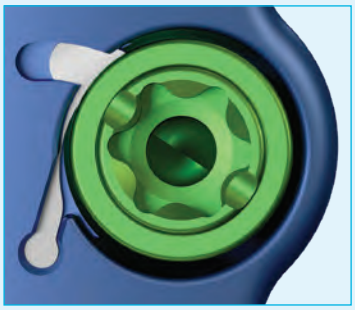
Verify screw type.



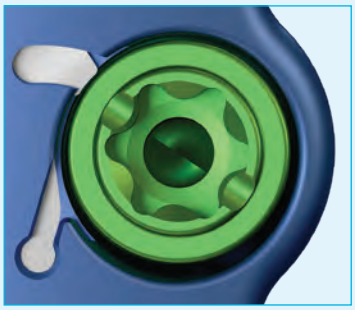
Verify screw length by resting selected screw into length gauge. A 16mm screw is shown.

AUTOMATIC SCREW BLOCKING

The unique blocking mechanism of the RESONATE® plate allows the screws to temporarily deflect the blocking mechanism into the plate during insertion. When the screws are fully seated, the slider automatically returns to its original position, blocking the screws to prevent backout.



Screw prior to contacting slider



Screw contacting slider, which deflects into plate (unblocked)

Screw fully seated and slider returned to original position (blocked)

FINAL CONSTRUCT

RESONATE® final construct with HEDRON C™ Interbody Spacers is shown below.

AP view

FINAL CONSTRUCT

RESONATE® final construct with HEDRON C™ Interbody Spacers is shown below.

Lateral view

OPTIONAL: REMOVAL

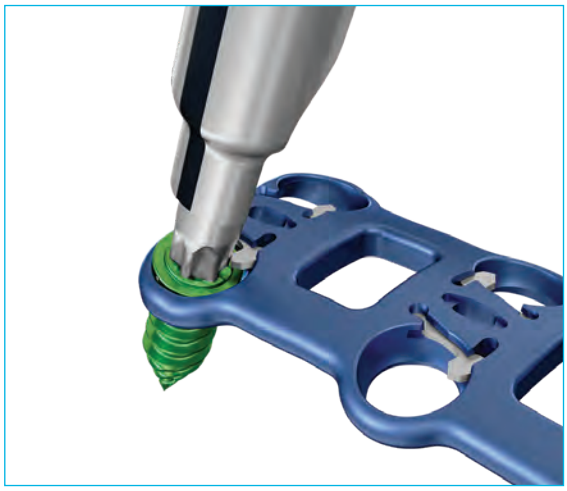
To remove screws, use the **Screw Removal Sleeve** to disengage the slider mechanism from above the screw head. Assemble the #15 Hexalobe Self-Retaining Driver, QC to the Quick-Connect Handle, Small. Slide the removal sleeve onto the driver until the driver tip protrudes from the distal end of the removal sleeve. Engage the driver tip into the hexalobe drive of the screw, ensuring the tab of the removal sleeve is facing away from the slider mechanism. The thick etched line on the sleeve aligns with the tab to provide a visual aid in engaging the slider.

Slide the sleeve toward the plate until it bottoms out on the screw. Rotate the removal sleeve so the tab deflects the slider. While holding the removal sleeve in this position, rotate the driver counterclockwise until the screw fully passes the slider.

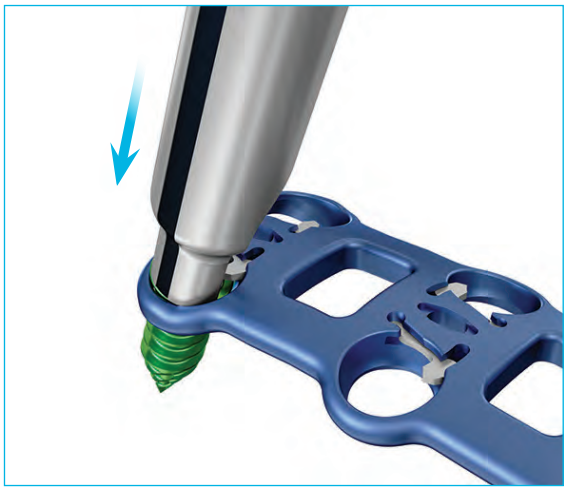
The **#15 Hexalobe Non-Self-Retaining Driver, QC** may be used if non-self-retention of the screws is desired.

After all screws are removed, grasp the plate with the plate holder and remove.

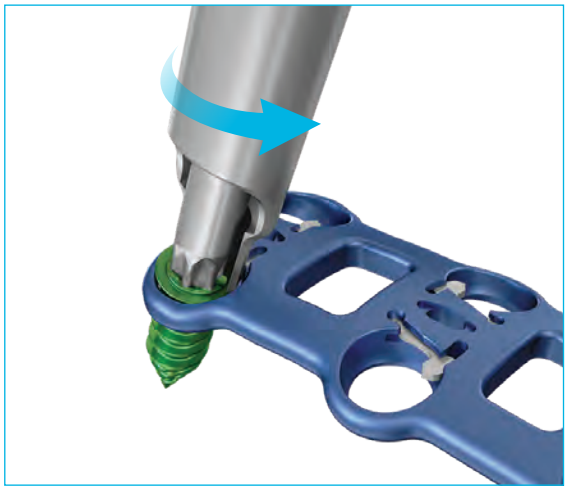
To disassemble the Screw Removal Sleeve from the driver assembly, reverse assembly steps.



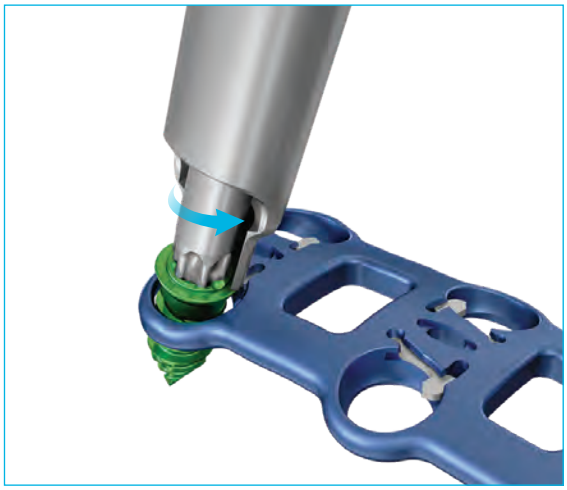
Engage hexalobe feature in screw



Slide removal sleeve towards plate



Rotate sleeve towards slider



Rotate driver counterclockwise while holding sleeve to remove screw

RESONATE®
1- AND 2-LEVEL PLATE SET 9194.9012

1-Level Plates

Part No.	Length	Qty
1194.1008	8mm	1
1194.1009	9mm	1
1194.1010	10mm	1
1194.1011	11mm	1
1194.1012	12mm	1
1194.1013	13mm	1
1194.1014	14mm	1
1194.1015	15mm	
1194.1016	16mm	1
1194.1017	17mm	
1194.1018	18mm	1
1194.1020	20mm	1
1194.1022	22mm	1
1194.1024	24mm	
1194.1026	26mm	

Extra Lordotic

Part No.	Length	Qty
1194.1108	8mm	
1194.1109	9mm	
1194.1110	10mm	1
1194.1111	11mm	
1194.1112	12mm	1
1194.1113	13mm	
1194.1114	14mm	1
1194.1115	15mm	
1194.1116	16mm	
1194.1118	18mm	

2-Level Plates

Part No.	Length	Qty
1194.2016	16mm	
1194.2018	18mm	
1194.2020	20mm	1
1194.2022	22mm	1
1194.2024	24mm	1
1194.2026	26mm	1
1194.2028	28mm	1
1194.2030	30mm	1
1194.2032	32mm	1
1194.2034	34mm	1
1194.2036	36mm	1
1194.2038	38mm	1
1194.2040	40mm	1
1194.2042	42mm	
1194.2044	44mm	
1194.2046	46mm	

Extra Lordotic

Part No.	Length	Qty
1194.2120	20mm	
1194.2122	22mm	
1194.2124	24mm	
1194.2126	26mm	1
1194.2128	28mm	1
1194.2130	30mm	1
1194.2132	32mm	1
1194.2134	34mm	
1194.2136	36mm	

MODULE

Part No.	Description
9194.0012	RESONATE® 1- and 2-Level Plate Module

Items in gray are additionally available.

RESONATE®
3-LEVEL PLATE SET 9194.9030

3-Level Plates

Part No.	Length	Qty
1194.3027	27mm	
1194.3030	30mm	
1194.3033	33mm	1
1194.3036	36mm	1
1194.3039	39mm	1
1194.3042	42mm	1
1194.3045	45mm	1
1194.3048	48mm	1
1194.3051	51mm	1
1194.3054	54mm	1
1194.3057	57mm	1
1194.3060	60mm	1
1194.3063	63mm	
1194.3066	66mm	
1194.3069	69mm	

Extra Lordotic

Part No.	Length	Qty
1194.3133	33mm	
1194.3136	36mm	
1194.3139	39mm	
1194.3142	42mm	1
1194.3145	45mm	1
1194.3148	48mm	1
1194.3151	51mm	
1194.3154	54mm	

MODULE

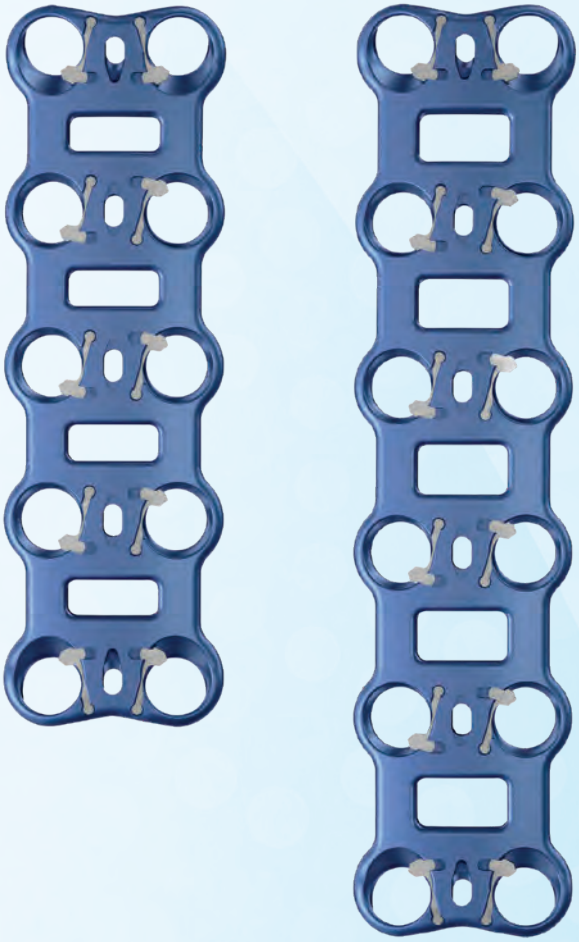
Part No.	Description
9194.0030	RESONATE® 3-Level Plate Module

Items in gray are additionally available.

RESONATE®
4- AND 5-LEVEL PLATE SET 9194.9045

4-Level Plates

Part No.	Length	Qty
1194.4042	42mm	
1194.4045	45mm	
1194.4048	48mm	1
1194.4051	51mm	1
1194.4054	54mm	1
1194.4057	57mm	1
1194.4060	60mm	1
1194.4063	63mm	1
1194.4066	66mm	1
1194.4069	69mm	1
1194.4072	72mm	1
1194.4075	75mm	1
1194.4078	78mm	1
1194.4081	81mm	1
1194.4084	84mm	1
1194.4087	87mm	1
1194.4090	90mm	
1194.4093	93mm	



5-Level Plates

Part No.	Length	Qty
1194.5065	65mm	
1194.5068	68mm	
1194.5071	71mm	1
1194.5074	74mm	1
1194.5077	77mm	1
1194.5080	80mm	1
1194.5083	83mm	1
1194.5086	86mm	1
1194.5089	89mm	1
1194.5092	92mm	1
1194.5095	95mm	1
1194.5098	98mm	1
1194.5101	101mm	
1194.5104	104mm	

MODULE

Part No.	Length
9194.0045	RESONATE® 4- and 5-Level Plate Module

Items in gray are additionally available.

RESONATE®
SCREW SET 9194.9060

Self-Drilling Screws

	Fixed Angle Screws		Variable Angle Screws	
	10mm	**Qty**	**10mm**	**Qty**
4.2mm	1194.6210	-	1194.7210	-
4.6mm	1194.6610	-	1194.7610	-
	11mm		**11mm**	
4.2mm	1194.6211	-	1194.7211	-
4.6mm	1194.6611	-	1194.7611	-
	12mm		**12mm**	
4.2mm	1194.6212	6	1194.7212	10
4.6mm	1194.6612	4	1194.7612	8
	13mm		**13mm**	
4.2mm	1194.6213	6	1194.7213	10
4.6mm	1194.6613	4	1194.7613	8
	14mm		**14mm**	
4.2mm	1194.6214	8	1194.7214	10
4.6mm	1194.6614	4	1194.7614	8
	15mm		**15mm**	
4.2mm	1194.6215	8	1194.7215	10
4.6mm	1194.6615	8	1194.7615	8
	16mm		**16mm**	
4.2mm	1194.6216	8	1194.7216	10
4.6mm	1194.6616	4	1194.7616	8
	17mm		**17mm**	
4.2mm	1194.6217	-	1194.7217	-
4.6mm	1194.6617	-	1194.7617	-
	18mm		**18mm**	
4.2mm	1194.6218	-	1194.7218	-
4.6mm	1194.6618	-	1194.7618	-
	19mm		**19mm**	
4.2mm	1194.6219	-	1194.7219	-
4.6mm	1194.6619	-	1194.7619	-
	20mm		**20mm**	
4.2mm	1194.6220	-	1194.7220	-
4.6mm	1194.6620	-	1194.7620	-

Self-Tapping Screws

	Fixed Angle Screws		Variable Angle Screws	
	10mm	**Qty**	**10mm**	**Qty**
4.2mm	1194.8210	-	1194.9210	-
4.6mm	1194.8610	-	1194.9610	-
	11mm		**11mm**	
4.2mm	1194.8211	-	1194.9211	-
4.6mm	1194.8611	-	1194.9611	-
	12mm		**12mm**	
4.2mm	1194.8212	6	1194.9212	8
4.6mm	1194.8612	4	1194.9612	6
	13mm		**13mm**	
4.2mm	1194.8213	6	1194.9213	10
4.6mm	1194.8613	4	1194.9613	6
	14mm		**14mm**	
4.2mm	1194.8214	8	1194.9214	10
4.6mm	1194.8614	6	1194.9614	8
	15mm		**15mm**	
4.2mm	1194.8215	8	1194.9215	10
4.6mm	1194.8615	6	1194.9615	8
	16mm		**16mm**	
4.2mm	1194.8216	8	1194.9216	10
4.6mm	1194.8616	6	1194.9616	8
	17mm		**17mm**	
4.2mm	1194.8217	-	1194.9217	-
4.6mm	1194.8617	-	1194.9617	-
	18mm		**18mm**	
4.2mm	1194.8218	4	1194.9218	4
4.6mm	1194.8618	4	1194.9618	4
	19mm		**19mm**	
4.2mm	1194.8219	-	1194.9219	-
4.6mm	1194.8619	-	1194.9619	-
	20mm		**20mm**	
4.2mm	1194.8220	-	1194.9220	-
4.6mm	1194.8220	-	1194.9620	-

4.9mm Variable Angle Screws are also available upon request.

Items in gray are additionally available.

RESONATE®
SCREW SET 9194.9060 (CONT'D)

Additionally Available Self-Tapping Screws

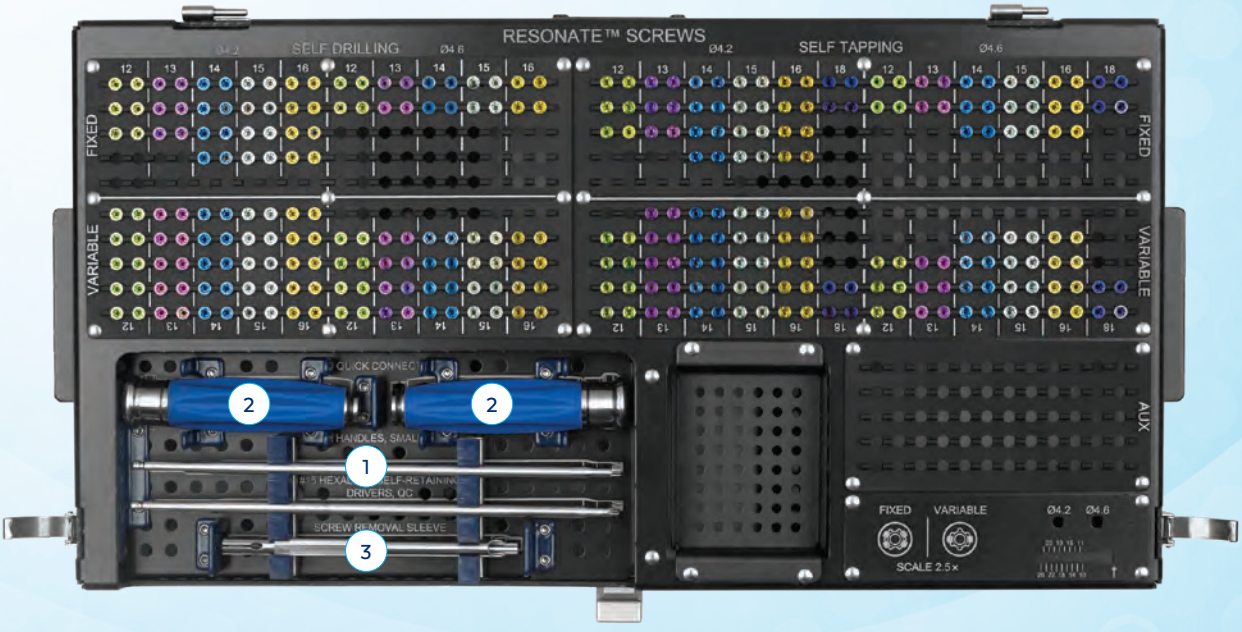
	Fixed Angle Screws	Variable Angle Screws
	21mm	**21mm**
4.2mm	1194.8221	1194.9221
4.6mm	1194.8621	1194.9621
	22mm	**22mm**
4.2mm	1194.8222	1194.9222
4.6mm	1194.8622	1194.9622
	23mm	**23mm**
4.2mm	1194.8223	1194.9223
4.6mm	1194.8623	1194.9623
	24mm	**24mm**
4.2mm	1194.8224	1194.9224
4.6mm	1194.8624	1194.9624
	25mm	**25mm**
4.2mm	1194.8225	1194.9225
4.6mm	1194.8625	1194.9625
	26mm	**26mm**
4.2mm	1194.8226	1194.9226
4.6mm	1194.8626	1194.9626

INSTRUMENTS

	Part No.	Description	Qty
1	6194.2010	#15 Hexalobe Self-Retaining Drive, QC	2
2	6194.3000	Quick-Connect Handle, Small	2
3	6194.7000	Screw Removal Sleeve	1

MODULE

Part No.	Description
9194.0060	RESONATE® Screw Module



Items in gray are additionally available.

RESONATE®
INSTRUMENT SET 9194.9001

	Part No.	Description	Qty
1	650.110	Drill Bit, 10mm	1
2	650.112	Drill Bit, 12mm	1
3	650.114	Drill Bit, 14mm	1
4	650.116	Drill Bit, 16mm	1
5	650.118	Drill Bit, 18mm	1
	650.120	Drill Bit, 20mm	
6	6194.1000	Cervical Awl, with Sleeve	1
7	6194.1100	Variable Angle Drill Guide	1
	6194.1102	Double Barrel Variable Angle Drill Guide	
8	6194.1110	Fixed Angle Drill Guide	1
	6194.1112	Double Barrel Fixed Angle Drill Guide	
9	6194.1150	Single Barrel DTS Sleeve	1
	6194.1152	Double Barrel DTS Sleeve	
10	6194.2000	Expandable #15 Hexalobe Screwdriver Sleeve	2
11	6194.2001	Inner Shaft, for QC	2
12	6194.3000	Quick-Connect Handle, Small	1
13	6194.4000	Forceps Plate Holder	1
14	6194.4010	Plate Holder Sleeve	1
15	6194.4011	Inner Shaft, Plate Holder	1
16	6194.4400	Plate Bender	1
17	6194.5001	Temporary Fixation Pin	2
	6194.5002	Temporary Fixation Pin, Smooth	
18	6194.5005	Temporary Fixation Screw	2
	6194.5006	Temporary Fixation Screw, Long	
19	6194.5100	Fixation Pin Driver Sleeve	1
20	6194.5101	Inner Shaft, Fixation Pin Driver	1
	9194.0001	RESONATE® Instrument Graphic Case	

Additionally Available Instruments

Screw Prep Instruments

Part No.	Description
650.102	Cervical Awl, for Drill Guide
650.160	Cervical Tap
650.314	Screw Extractor
650.510	Small Drill Bit, 10mm
650.512	Small Drill Bit, 12mm
650.514	Small Drill Bit, 14mm
650.516	Small Drill Bit, 16mm
650.518	Small Drill Bit, 18mm
650.520	Small Drill Bit, 10mm

Angled Screwdriver Instruments

Part No.	Description
684.415	Angled Sleeve
684.416	Angled Sleeve Backing Nut
684.417	Angled Driving Shaft
684.421	Counter-Torque, Angled Instrument
6194.2418	Angled Driver Tip, #15 Hexalobe
6194.2425	Angled Driver Tip, #15 Hexalobe, Short

Trial/Drill Guide Instruments

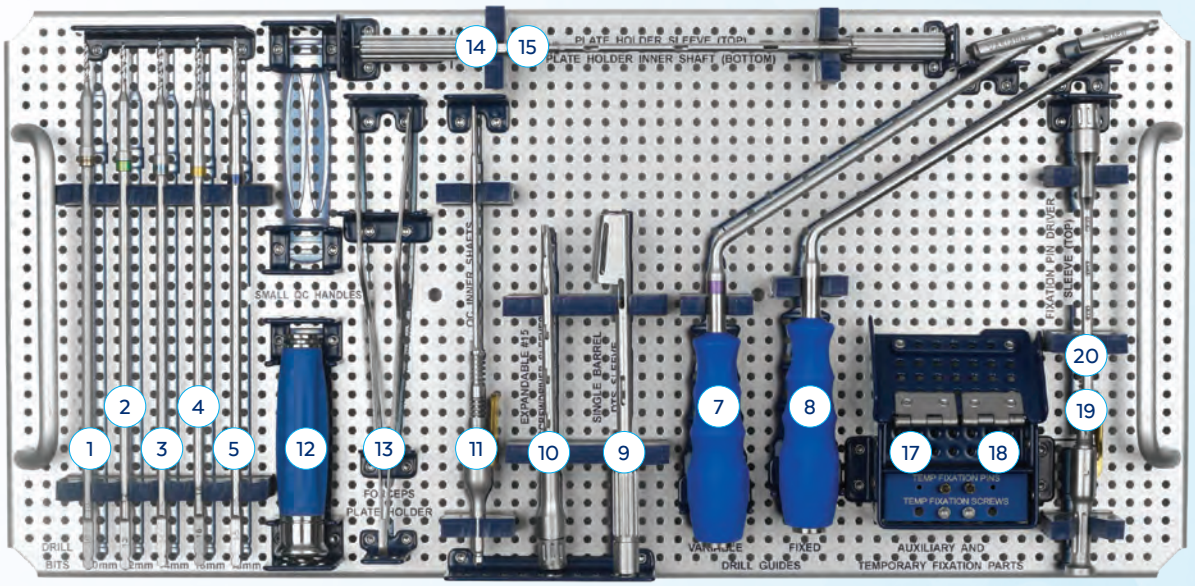
Part No.	Description
6194.1005	Modular Trial Head, 14x16, 7°, 5mm
6194.1006	Modular Trial Head, 14x16, 7°, 6mm
6194.1007	Modular Trial Head, 14x16, 7°, 7mm
6194.1008	Modular Trial Head, 14x16, 7°, 8mm
6194.1009	Modular Trial Head, 14x16, 7°, 9mm
6194.1010	Modular Trial Head, 14x16, 7°, 10mm
6194.1011	Modular Trial Head, 14x16, 7°, 11mm
6194.1012	Modular Trial Head, 14x16, 7°, 12mm
6194.1050	Trial/Drill Guide Sleeve
6194.1051	Inner Shaft, Trial/Drill Guide

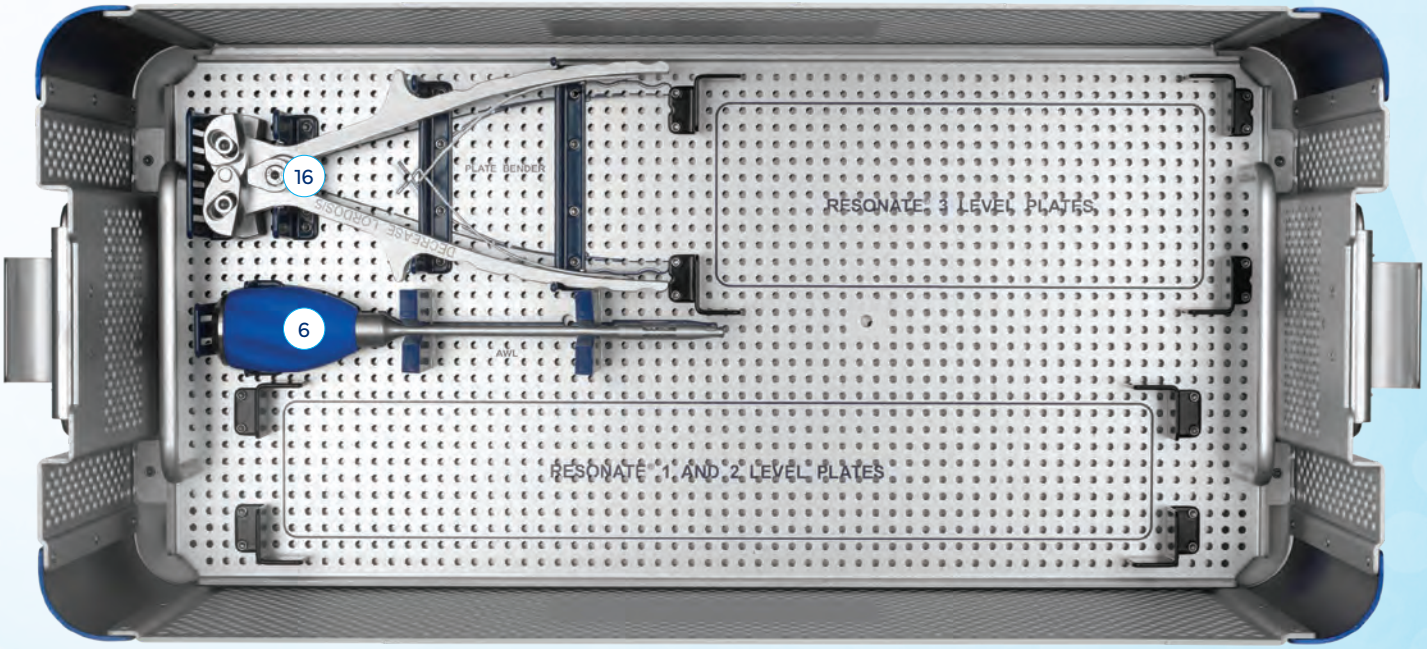
Alternative Screwdrivers

Part No.	Description
6149.2700	#15 Hexalobe Pushbutton Driver
6194.2015	#15 Hexalobe Non-Self-Retaining Driver, QC

Items in gray are additionally available.

RESONATE®
INSTRUMENT SET 9194.9001 (CONT'D)





IMPORTANT INFORMATION ON THE RESONATE® ANTERIOR CERVICAL PLATE SYSTEM

DESCRIPTION

The RESONATE® Anterior Cervical Plate System consists of standard or extra lordotic plates of various lengths to be used with either variable angle screws, fixed angle screws, or a combination of the two. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-T1). RESONATE® screws are available as fixed angle or variable angle and are self-drilling or self-tapping. The implants and screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The slider blocking mechanism is manufactured from Nitinol (nickel titanium alloy), as specified in ASTM F2063.

INDICATIONS

The RESONATE® Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury.

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

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Possible adverse effects that may occur include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTION

The implantation of screw and plate systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size, screw diameter and length.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Adequately instruct the patient. Mental or physical impairment that compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

CONTRAINDICATIONS

- Use of this system is contraindicated in patients with the following conditions:
- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any condition not described in the indications for use.

MRI SAFETY INFORMATION

RESONATE® Anterior Cervical Plate Systems are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Quadrature Body Coil only

Under the scan conditions defined above, the RESONATE® Anterior Cervical Plate Systems are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

The image artifact is not expected to extend beyond 55mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

PACKAGING

The implants and instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.

IMPORTANT INFORMATION ON THE RESONATE® ANTERIOR CERVICAL PLATE SYSTEM

6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments are available nonsterile.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes
Steam	Pre-vacuum	134°C (273°F)	3 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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NOTES

NOTES

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

GMTGD236
10.21 Rev C