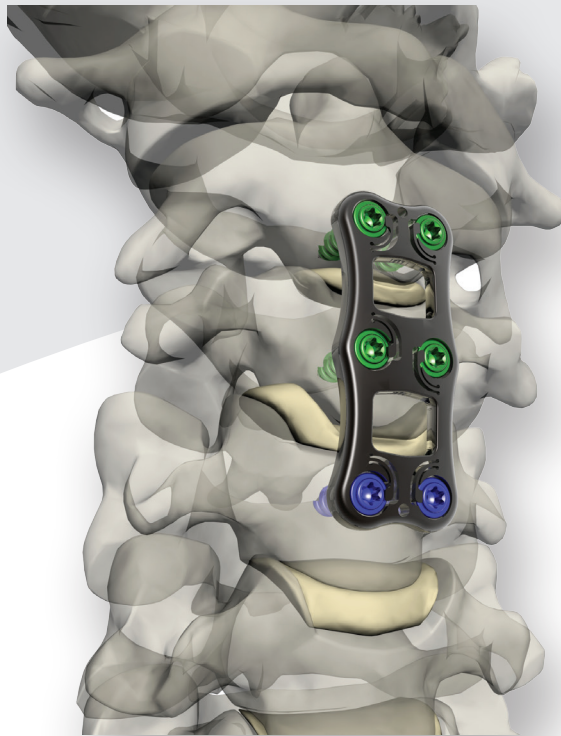


Manta Ray™ ACP*

Surgical Technique



*Anterior Cervical Plate

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The Manta Ray™ ACP

The Manta Ray™ Anterior Cervical Plate was designed by SeaSpine® and practicing surgeons with the goal of delivering a streamlined system.

Design Rationale

The Manta Ray system will accommodate the surgeon who prefers to awl, drill and tap. The system’s integral locking mechanism eliminates the need for additional parts such as fasteners, rings or additional screws. It also provides visual confirmation that screws are locked secure and will remain in place.

The Manta Ray ACP System offers the surgeon the versatility of controlling the characteristics of the plate construct intra-operatively. The 4.0mm and the 4.5mm Fixed Angle and Variable Angle Screws are available as self-drilling or self-tapping.

System Features

Plate Design

The Manta Ray ACP is available in lengths from 18mm to 92mm with screw attachment locations designed to accommodate 1, 2, 3 and 4 levels. The length of the plate is measured end to end.

Large graft viewing windows provide the surgeon excellent intra-operative and post-operative viewing to assess graft placement and anterior cervical fusion.

Integral Retaining Arm helps prevent screw back-out.

During the surgical procedure the posterior spikes stabilize the Manta Ray ACP on the vertebral column.

Screw Design

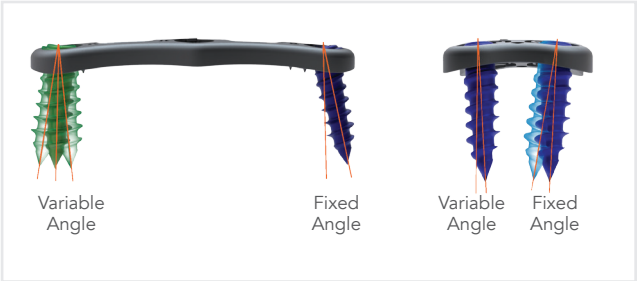
The Manta Ray ACP System offers the surgeon the option of implanting a Constrained Construct (all Fixed Angle Screws) a Semi-Constrained Construct (all Variable Angle Screws) or a Hybrid Construct (two Fixed Angle Screws and two Variable Angle Screws at differing levels).

The Manta Ray ACP System offers the surgeon the versatility of controlling the dynamics of the plate construct intraoperatively. The 4.0mm and 4.5mm (rescue) color-coded Fixed and Variable Angle Screws are manufactured to work seamlessly with the patented Retaining Arm technology.

Caution: A Fixed and Variable Angle Screw should NEVER be used within the same level.

The neutral axis of both the Fixed and Variable Angle Screw is 10° cephalad and caudal perpendicular to the plate’s 195mm lordotic radius and converges 3° medially.

The neutral axis is the fixed position for the Fixed Angle Screw and will remain in this position under loaded conditions. The Variable Angle Screw has the ability to be inserted into the plate at an angle up to 6° in all directions off the screw’s neutral axis.



Surgical Technique

STEP 1 Plate Contouring

The 18mm through 92mm Manta Ray™ **Plates** are designed to be contoured using the **Plate Bender** (22-40-0100). To contour the plate, insert the plate into the **Plate Bender** while aligning the center of the graft viewing windows with the **Plate Bender**.

Apply moderate pressure to the **Plate Bender** handles to increase or decrease the plate curvature. Due to titanium's inherent notch sensitivity, do not attempt to decrease the plate curvature if it has been over-bent.

▶ **Warning:** Do not bend outside of this area as bending on or near a screw hole can compromise the screw retaining mechanism.



STEP 2 Plate Holder

If using the **Plate Holder** (22-40-0800), attach the plate by applying upward pressure on the spring loaded trigger, then align the holding pin on the instrument with the hole on either end of the plate. Release pressure from spring loaded trigger and confirm that plate is securely attached to instrument before inserting plate into the surgical wound.

To remove **Plate Holder** from plate, pull trigger and carefully slide **Plate Holder** cephalad or caudal away from plate.



STEP 3 Plate Holding Technique

Position the plate so that the superior and inferior holes are approximately at the mid-portion of the vertebral body.

3A If using the optional **Plate Holding Pins** (22-40-0500), attach the pins using the **Screwdriver**.

Insert the **Plate Holding Pin** on to the **Screwdriver** and thread the pin into vertebral body.

3B **Plate Holding Pins** are used as follows: Line up screwdriver with the hexalobe inside the **Plate Holding Pin**. Use downward force to engage and retain the **Plate Holding Pin** onto the driver.

Once the pin is engaged on the **Screwdriver**, remove the pin from the screw caddy by pulling upward.

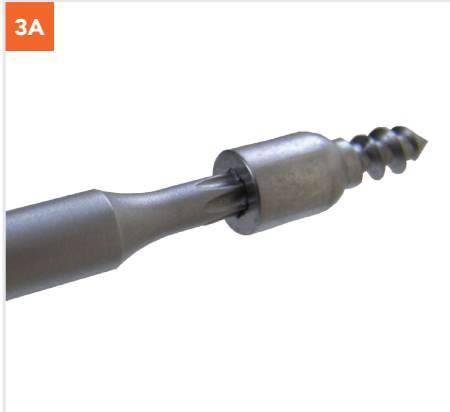
▶ **Note:** The pin is now retained on the end of the screwdriver tip, and should not come off in standard use. The pin is NOT locked on the **Screwdriver**, meaning with some deliberate force, the pin can be pulled off the **Screwdriver**.

Insert the **Plate Holding Pin** through the screw hole in the plate and thread the pin into the vertebral body.

▶ **Note: Over-tightening** the pin may result in stripping of the screw hole and a loss of screw purchase to the bone.

To remove the **Plate Holding Pin**, insert the tip of the screwdriver into the pin and unthread the pin out of the vertebral body in a counterclockwise direction.

▶ **Option:** **Plate Holding Pins** are also available in a non-threaded style. They are inserted by placing downward pressure on the driver.



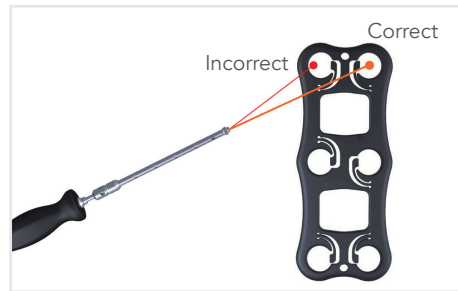
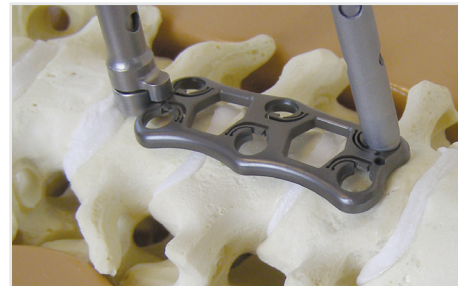
STEP 4 Awl Use

Fixed & Variable Self-Centering Awl Use

Insert the **Fixed** (22-40-0600) or **Variable** (22-40-0650) **Angle Awl** into the screw hole at the desired screw angle and push down while simultaneously twisting the **Awl** handle.

Remove the **Awl** by pulling straight up while maintaining hole and plate alignment.

► **Note:** Awl may be used with the standard 4.0mm or 4.5mm rescue screws.



STEP 5 Drill Use (Optional For Self-Drilling Screws)

In some instances, the use of a **Drill** (22-40-0700) may be preferred prior to screw insertion.

Fixed & Variable Self-Centering Drill Use

Choose either the **Fixed Angle Drill Guide** (22-40-0425), **Variable Angle Drill Guide** (22-40-0475) or **Double Barrel Cannula** (22-40-0480).

6A Set desired drill depth by depressing button and sliding the depth stop to the proper depth.

6B Insert the **Drill** through the Guide. Engage the **Drill** into the cortex of the vertebral body by turning the **Drill** handle in a clockwise direction.

Once the stop on the **Guide** is reached, the **Drill** is now at the appropriate depth. Remove the **Drill** from the vertebral body by turning the **Drill** counter clockwise.

► **Note:** Drill may be used for the standard 4.0mm or 4.5mm rescue screws.



STEP 6 Tap Use (Optional)

In some instances, the use of a **Tap** (22-40-0750) may be preferred prior to screw insertion.

6A Choose either the **Fixed** or **Variable Angle Drill Guide**. Set depth.

6B Insert the **Tap** through the **Guide**. Engage the **Tap** into the cortex of the vertebral body by turning the Tap handle in a clockwise direction.

Once the stop on the **Guide** is reached, turn the **Tap** handle counterclockwise to remove the **Tap** from the vertebral body.

► **Note:** Taps should be checked prior to each surgery to ensure that they are sharp.

► **Note:** Tap may be used for the 4.0mm or 4.5mm rescue screws.



STEP 7 Screw Verification

Screws are color-coded based on the screw diameter and variability.

4.0mm FIXED: Light Blue

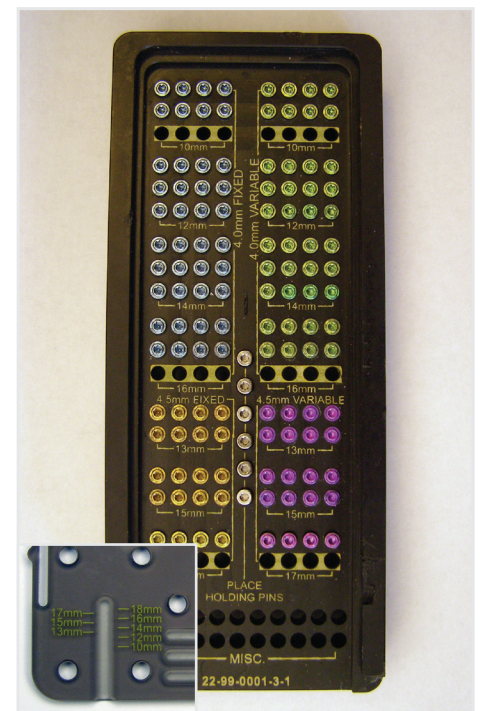
4.5mm FIXED RESCUE: Gold

4.0mm VARIABLE: Green

4.5mm VARIABLE RESCUE: Magenta

With the **Fixed** or **Variable Angle Screw** attached to the end of the screwdriver, the screw length and diameter can be verified using the **Screw Gauge** located on the **Screw Caddy** cover.

► **Note:** 4.5mm diameter screws are "rescue screws" and should only be used when 4.0mm diameter screws do not provide enough purchase to the bone.



STEP 8 Split Tip Inserter

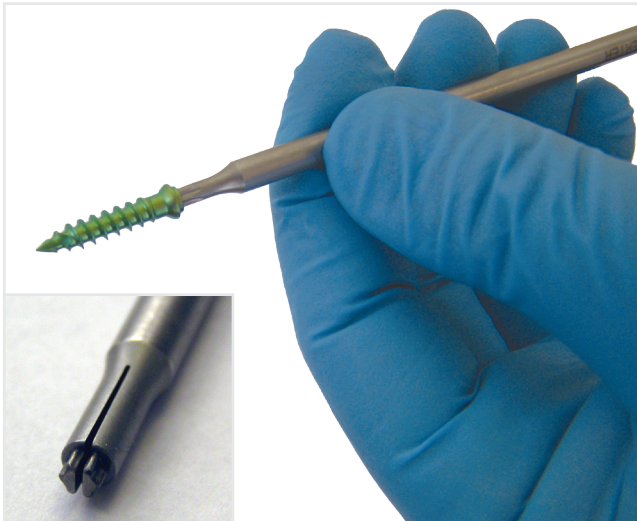
The **Split Tip Inserter** (22-40-0305) uses a hexalobe tip to retain the screw. This Inserter is used for initial screw insertion, and is not recommended for final screw tightening.

Line up the **Split Tip Inserter** with the hexalobe inside the screw. Use a downward force to engage and retain the screw onto the driver.

Once the screw is engaged on the **Split Tip Inserter**, remove the screw from the screw caddy by pulling upward.

► **Note:** The screw is now retained on the end of the Inserter tip, and should not come off in standard use. The screw is NOT locked on the Inserter, meaning with some deliberate force, the screw can be pulled off the Inserter.

► **Note:** The **Split Tip Inserter** (22-40-0305) is not recommended to be used for final screw tightening.



STEP 9 Force Tip Inserter (Optional)

9A The **Force Tip Inserter** (22-40-0306) can be used as a secondary Inserter and also as a final tightening tool.

Place the screw on the tip of the **Inserter**. Ensure **Draw Rod** is removed prior to insertion.

► **Note:** This Inserter is not self-retaining until the **Draw Rod** is engaged.

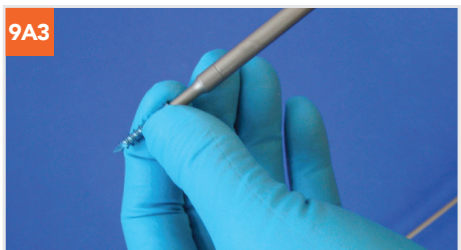
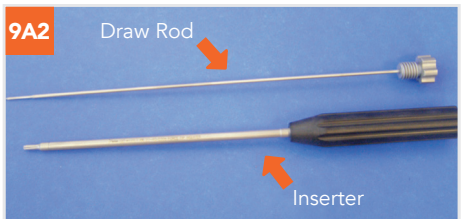
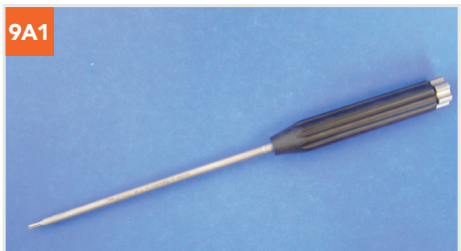
9B Insert the **Draw Rod** into the Inserter. Rotate **Draw Rod** clockwise until tight. The screw will then be engaged with the Inserter.

9C ► **Note:** Do not tighten **Draw Rod** prior to screw placement on Inserter. This is noted on the top of the Draw Rod.

To disengage the Inserter, rotate the **Draw Rod** counterclockwise.

Remove the **Draw Rod** from the Inserter prior to instrument cleaning and sterilization.

► **Note:** The **Force Tip Inserter** may be used as a final tightening tool. Remove the **Draw Rod** from the Inserter. Engage the **Force Tip Inserter** into the head of the screw. Turn the **Draw Rod** clockwise until tightened.



STEP 10 Screw Inserter (Optional)

The **Screw Inserter** (22-40-0300) uses a hexalobe tip to retain the screw. This **Inserter** is used for initial screw insertion and final screw tightening.

Line up the **Screw Inserter** with the hexalobe inside the screw. Use a downward force to engage and retain the screw onto the driver.

Once the screw is engaged on the **Screw Inserter**, remove the screw from the screw caddy by pulling upward.

► **Note:** The screw is now retained on the end of the **Inserter** tip, and should not come off in standard use. The screw is NOT locked on the Inserter, meaning with some deliberate force, the screw can be pulled off the Inserter.



STEP 11 Screw Insertion

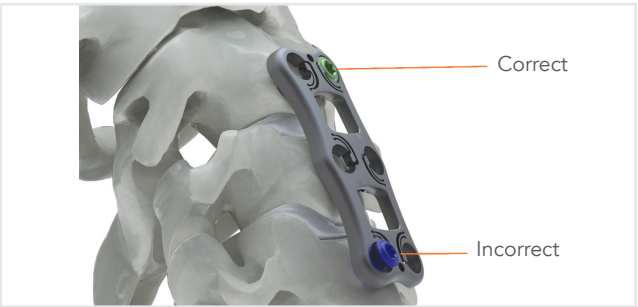
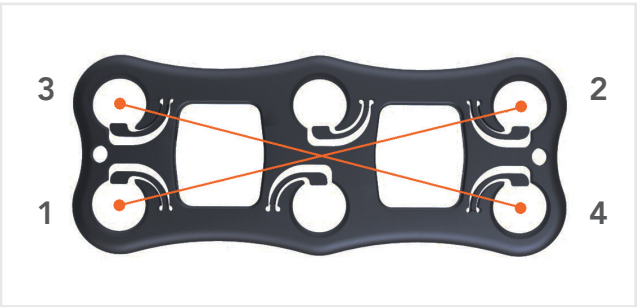
After penetrating cortex with the **Fixed** or **Variable Angle Awl** or **Drill** (depending on screw type), insert the bone screw through the plate into the vertebral body until the lock tab on the **Retaining Arm** visually occludes the periphery of the screw head. The screw is now retained by the plate. Release the screw with slight upward force, and remove the **Screwdriver** from the **Guide**.

Awl, drill and insert the second **Bone Screw** diagonal to the initial screw position. Prepare remaining screw sites. **Awl**, drill, and tap (if necessary) and insert the remaining screws.

► **Note:** Over-tightening the screw will result in stripping of the screw hole and a loss of screw purchase to the bone.

► **Warning:** The **Variable Angle** instruments have built in stops to prevent trajectories that result in over angulations of the screw(s). Over angulations of the screws may result in the inability of the locking tabs to adequately retain the screws.

► **Warning:** Do not leave screw head proud (above **Retaining Arm**) before proceeding to next screw.



INCORRECT: Screw Head is Proud



INCORRECT: Locking Tab is Displaced but has Not Snapped Over Screw Head

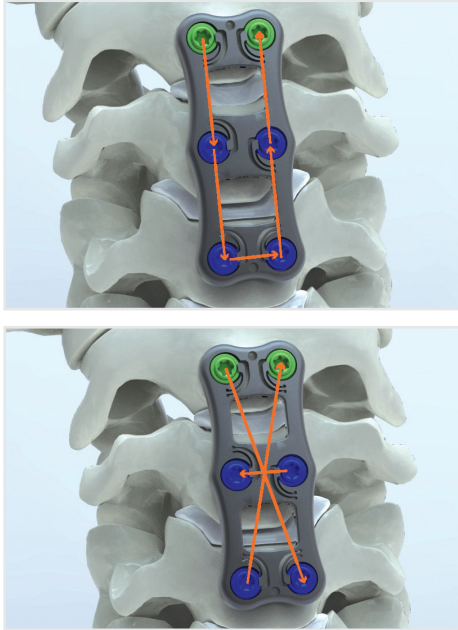


CORRECT: Locking Tab is Snapped Over Screw Head

STEP 12 Final Screw Tightening

Once all screws have been inserted below the locking tabs, the surgeon should now perform final screw tightening with the **Screw Inserter** or **Force Tip Inserter**.

Final tightening can be performed in any sequence.



STEP 13 Screw Removal

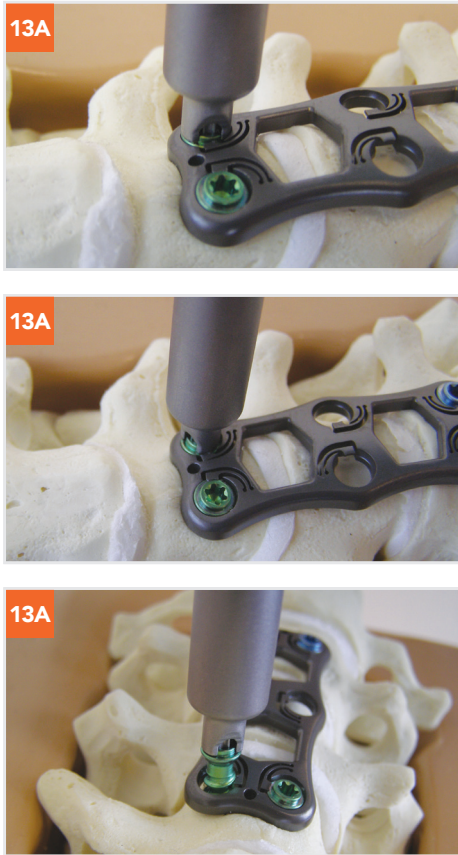
Use the **Screw Removal Tool** (22-40-0350) to remove a screw from the **Manta Ray Plate**.

13A Place the **Inserter** or **Split-Tip Inserter** down the center of the **Screw Removal Tool**. Place **Screw Removal Tool** with either the **Split-Tip Inserter** or **Screw Inserter** on the screw head with the window over the locking tab of the **Retaining Arm**.

13B Turn the **Removal Tool** clockwise or counterclockwise 90° to displace locking tab away from screw head.

13C While keeping the **Removal Tool** in place, turn the **Inserter** in a counterclockwise direction to remove the screw from the plate and vertebral body.

► **Note:** The **Force Tip Inserter** cannot be used with the **Screw Removal Tool**.



STEP 14 Double Barrel Cannula (Optional)

14A The **Double Barrel Cannula** (22-40-0480) can be used to drill, tap and screw. It provides the surgeon with specific trajectory for placement of fixed and variable angle screws.

14B Insert the **Draw Rod** fully into the **Draw Rod Tube**. Line up one end of the desired plate with the **Draw Rod**. Rotate the **Draw Rod** clockwise until the **Double Barrel Cannula** is tight to the plate.

Insert a **Depth Stop** into each **Cannula**. Rotate each **Depth Stop** clockwise until the locking pin is fully engaged in the corresponding slot in the **Cannula**. Using the **Double Barrel Cannula**, place the plate in the desired location on the vertebral body.

14C Insert the **Drill** through the **Depth Stop**. While applying downward pressure, rotate the **Drill** clockwise until the **Drill** contacts the top of the **Depth Stop**.

Awl, drill and insert the second bone screw diagonal to the initial screw position. Prepare remaining screw sites. Awl, drill, and tap (if necessary) and insert the remaining screws.

► **Optional:** Repeat above steps if using **Tap**.

Repeat steps for the other screw hole.

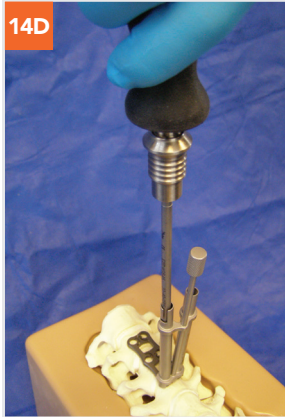
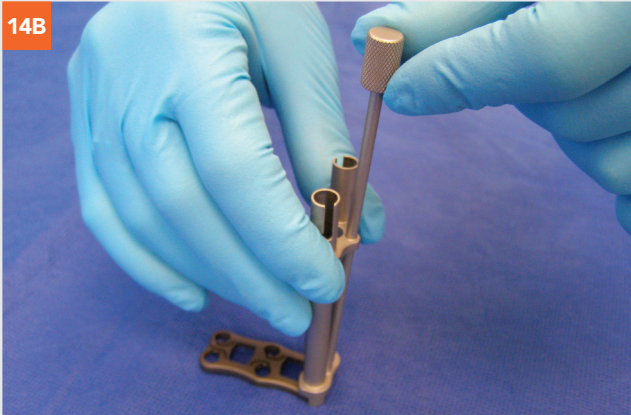
Once drilling and tapping is complete, rotate the **Depth Stops** counterclockwise and remove them from the **Cannula**.

14D Attach the desired screw to the **Screw Inserter** and insert the screw through the **Cannula** into the vertebral body. While applying a slight downward force, rotate the **Screw Inserter** clockwise until the screw is tight to the plate.

Repeat step for the other screw hole.

Remove the **Double Barrel Cannula** by rotating the **Draw Rod** counterclockwise until the **Double Barrel Cannula** can be removed from the plate.

If desired, repeat steps for the other end of the plate.



Set Configuration

Plates

Part Number	Description
22-20-0118	1 Level — 18mm long
22-20-0120	1 Level — 20mm long
22-20-0122	1 Level — 22mm long
22-20-0124	1 Level — 24mm long
22-20-0126	1 Level — 26mm long
22-20-0128	1 Level — 28mm long
22-20-0130	1 Level — 30mm long
22-20-0132	1 Level — 32mm long
22-20-0134	1 Level — 34mm long
22-20-0231	2 Level — 31mm long
22-20-0234	2 Level — 34mm long
22-20-0237	2 Level — 37mm long
22-20-0240	2 Level — 40mm long
22-20-0243	2 Level — 43mm long
22-20-0246	2 Level — 46mm long
22-20-0249	2 Level — 49mm long
22-20-0252	2 Level — 52mm long
22-20-0348	3 Level — 48mm long
22-20-0351	3 Level — 51mm long
22-20-0354	3 Level — 54mm long
22-20-0357	3 Level — 57mm long
22-20-0360	3 Level — 60mm long
22-20-0363	3 Level — 63mm long
22-20-0366	3 Level — 66mm long
22-20-0369	3 Level — 69mm long
22-20-0372	3 Level — 72mm long
22-20-0375	3 Level — 75mm long
22-20-0468	4 Level — 68mm long
22-20-0472	4 Level — 72mm long
22-20-0476	4 Level — 76mm long
22-20-0480	4 Level — 80mm long
22-20-0484	4 Level — 84mm long
22-20-0488	4 Level — 88mm long
22-20-0492	4 Level — 92mm long

Self-Drilling Screws

Part Number	Description
22-11-4010	4.0 Dia Fixed—10mm long
22-11-4012	4.0 Dia Fixed — 12mm long
22-11-4014	4.0 Dia Fixed — 14mm long
22-11-4016	4.0 Dia Fixed — 16mm long
22-13-4513	4.5 Dia Fixed — 13mm long
22-13-4515	4.5 Dia Fixed — 15mm long
22-13-4517	4.5 Dia Fixed — 17mm long
22-21-4010	4.0 Dia Variable — 10mm long
22-21-4012	4.0 Dia Variable — 12mm long
22-21-4014	4.0 Dia Variable — 14mm long
22-21-4016	4.0 Dia Variable — 16mm long
22-22-4513	4.5 Dia Variable — 13mm long
22-22-4515	4.5 Dia Variable — 15mm long
22-22-4517	4.5 Dia Variable — 17mm long

Self-Tapping Screws

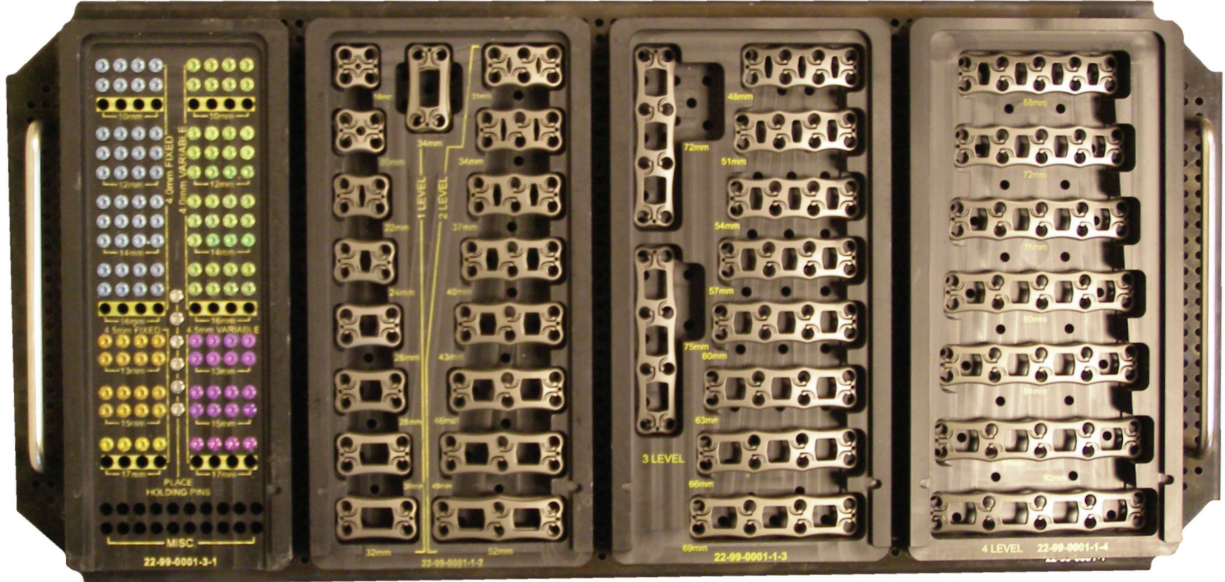
Part Number	Description
22-15-4010	4.0 Dia Fixed — 10mm long
22-15-4012	4.0 Dia Fixed — 12mm long
22-15-4014	4.0 Dia Fixed — 14mm long
22-15-4016	4.0 Dia Fixed — 16mm long
22-17-4513	4.5 Dia Fixed — 13mm long
22-17-4515	4.5 Dia Fixed — 15mm long
22-17-4517	4.5 Dia Fixed — 17mm long
22-23-4010	4.0 Dia Variable — 10mm long
22-23-4012	4.0 Dia Variable — 12mm long
22-23-4014	4.0 Dia Variable — 14mm long
22-23-4016	4.0 Dia Variable — 16mm long
22-24-4513	4.5 Dia Variable — 13mm long
22-24-4515	4.5 Dia Variable — 15mm long
22-24-4517	4.5 Dia Variable — 17mm long

Set Configuration

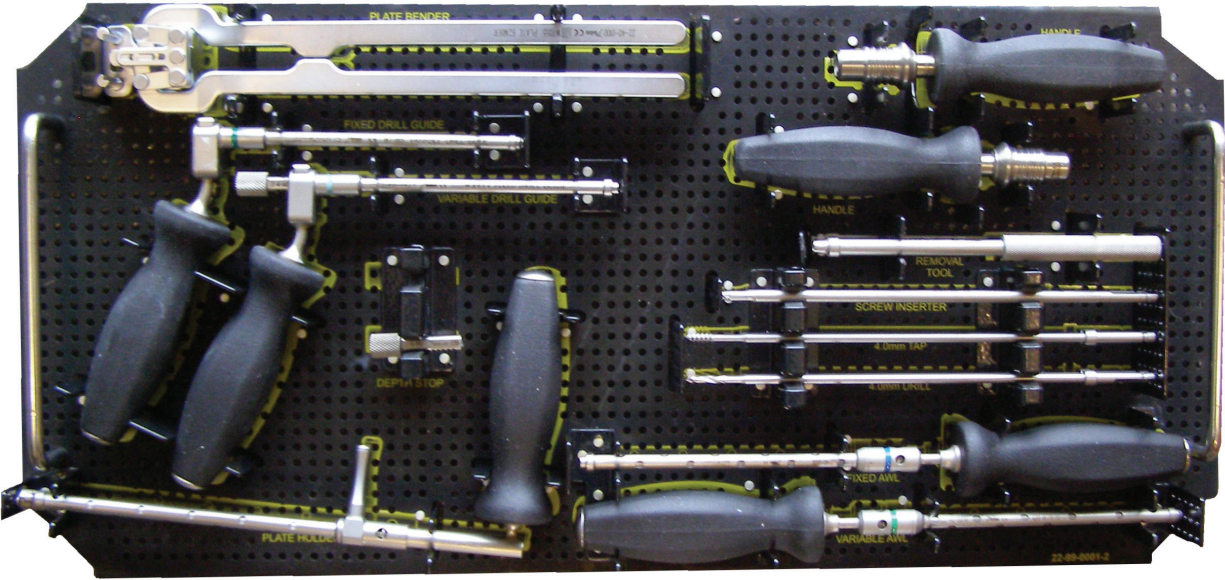
Instruments

Part Number	Description
22-40-0100	Plate Bender
22-40-0200	AO Inline Handle
22-40-0305	Split Tip Inserter
22-40-0306	Force Tip Inserter
22-40-0350	Screw Removal Tool
22-40-0425	Fixed Drill Guide
22-40-0425-3	Depth Stop
22-40-0475	Variable Drill Guide
22-40-0480	Double Barrel Cannula
22-40-0300	Screw Inserter
22-40-0500	Plate Holding Pin
22-40-0600	Fixed Awl
22-40-0650	Variable Awl
22-40-0700	4.0 mm Drill
22-40-0750	4.0 mm Tap
22-40-0800	Plate Holder (Trigger)
22-99-0001	Case

Trays



Implant Tray



Instrument Tray

Indications for Use

The Manta Ray™ ACP System is an anterior cervical plate that is intended for temporary stabilization of the cervical spine from C2-C7 for the following indications:

- DDD (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture/dislocation)
- Tumor
- Spinal stenosis
- Deformity (i.e. scoliosis, kyphosis and/or lordosis)
- Pseudoarthrosis
- Failed previous fusion


Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the efficacy of the procedure:

- Widely disseminated metastatic tumors of adjacent vertebral bodies
- Severe osteoporosis
- Overt infection of the involved vertebral bodies
- Any entity or condition which totally precludes the possibility of successful fusion such as cancer, kidney dialysis, or osteopenia. Other relative contraindications include, but are not limited to, obesity, certain degenerative diseases, and foreign body sensitivity. The patient's activity level, mental condition, or occupation may be factors relative to the surgery. Other conditions, including alcoholism and drug abuse may also place excessive stresses on the device.
- Do not use this device in the presence of any neural or vascular deficits or compromising pathology that may be further injured by device application.

This is not a comprehensive list. Please refer to instruction for use.

As the manufacturer of this device, SeaSpine Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

 **Caution:** federal law restricts this device to sale by or on the order of a physician or practitioner.



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