RHAUSLER

A SPINAL IMPLANT COMPANY

Surgical Technique Guide

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The Rhausler Anterior Cervical Vertebrae Plate System

CE 0459

The Rhausler Anterior Cervical Vertebrae Plate System is designed to be used in single and multi-level anterior cervical intravertebral internal stabilization and arthrodesis surgeries from C2 through C7. Surgical indications include degenerative disc disease (neck pain of discogenic origin with degeneration confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumors, pseudoarthrosis and failed previous fusions. The surgical indications and techniques of augmentation of bony stabilization with anterior plate and screw in the cervical spine have been the subject of multiple articles and book chapters.

⚠ ***CAUTION: Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions, etc., which may impact on the performance of the system. Ultimate long-term stability requires bone healing to achieve biologic stability.***

The patient is placed in a supine position, ***(fig. 1)***. Typically, the patient's head is positioned on a horseshoe head holder with 10 pounds of head halter traction. The head is positioned in mild extension and taped to prevent intraoperative rotation. A support is placed under the upper shoulder area in the midline to aid in obtaining the mild extension of the cervical spine. The shoulders are gently taped, pulling inferiorly, to allow better visualization of the lower cervical spine on fluoroscopy.

Figure 1

The operative fluoroscopy C-arm is positioned, ***(fig. 2)*** at a 45-degree angle above the patient to function both as an ether screen and to provide intraoperative images. The base of the fluoroscopy unit is positioned on the opposite side of the skin incision and surgeon. A standard hip drape is used to cover the wound and the C-arm of the fluoroscopy unit, allowing it to be easily rotated into the surgical field when fluoroscopy is desired and rotated out of the surgeon's way otherwise. Many variations

Figure 2

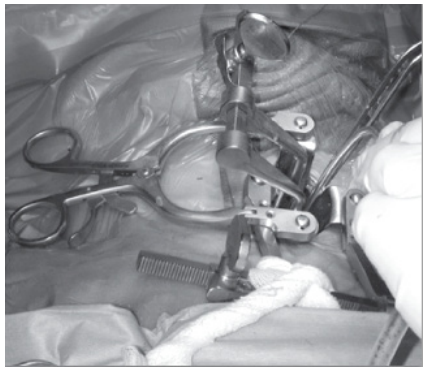

Figure 3

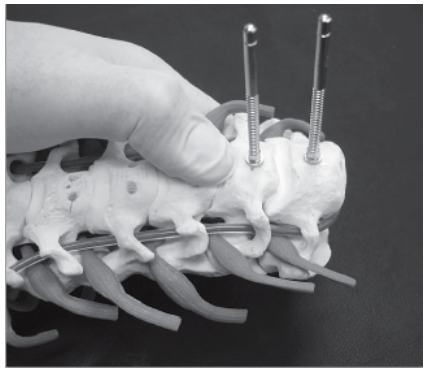

Figure 4

in the exact details of the positioning, taping and draping have evolved.

Either a right ***(fig. 3)*** or left approach to the cervical spine is performed taking into account the clinical situation and surgeon preference. Once the skin incision and anterior soft tissue dissection have been performed, allowing visualization of the pathologic levels, a cervical self-retaining soft tissue retractor is used to maintain exposure to the vertebral column. Marking the easily identified midline superior and inferior to the operated levels with a Bovie is often useful for aiding in aligning the plate before elevating the longus coli muscles.

The correct disc space(s) are verified by radiologic image(s).

In the disc space(s) to be operated on, the anterior longitudinal ligament is incised with a #15 blade and then the overhanging inferior portion of the superior cervical body and anterioros-teophytes are resected with a 3mm Kerrison punch to expose the complete vertical height of the cervical disc. Typically, at this point the anterior 2/3 of the disc is removed with curettes and pituitary rongeurs. Anterior projections of osteophytes are often removed at this stage in preparation for flattening the anterior boney surface for the plate and to make the rest of the discectomy easier.

Distraction screws are then placed ***(fig. 4)*** in the bodies adjacent to the operated disc spaces(s), avoiding corpectomy levels inserted under visual and/or fluoroscopy guidance. The distraction screws are placed parallel to each other to obtain parallel distraction or angled toward each other anteriorly to obtain lordotic correction, according to the surgeon's choice and pre-operative planning. It is often useful to place the distraction screws 2-3mm away from the surgeon and angled 10 degrees medially. This placement and angulation aid in placing the plate stabilization pin in a different position and medial retraction respectively.

The disc space is then distracted using the distraction pins in the standard manner ***(fig. 5)*** and the discectomy completed with curettes and pituitary rongeurs. The uncovertebral joints are removed along with posterior osteophytes with a high-speed drill, Kerrison and/or curette. The disc fragment and/or the posterior longitudinal ligament are removed as per the clinical situation to achieve the desired decompression . In select cases a partial corpectomy or undercutting of the posterior vertebral body margins is necessary for a complete decompression of the spinal cord and exiting nerve roots.

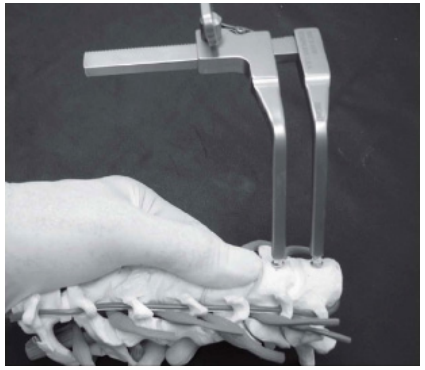

Figure 5

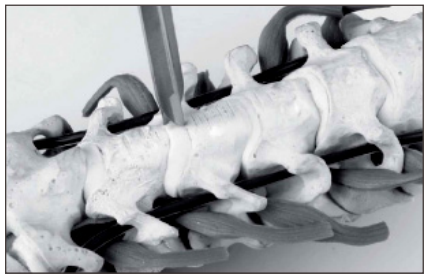

Figure 6
Note: A bone graft screw (C-6005, fig. 10-E) may also be used to affix the bone graft to the plate.

The intravertebral disc space is prepared for the bone graft by removing the cartilage endplate, decorticating the bony endplate and shaping the superior and inferior bony margins in a parallel or slightly lordotic fashion. A Caliper C-7045 ***(fig. 6)*** is used to determine the height of the bony defect at each disc space level for selecting the graft. The graft material is either autologous or allogenic and is shaped to the appropriate dimension and placed into the intravertebral disc space. Alternately, a cervical cage filled with bone graft can be used as an intravertebral support device.

Implant Selection

The Rhausler Anterior Cervical Vertebrae Plate System offers three cervical plate options, ***Dynamic (fig. 7) Semiconstrained (fig. 8)*** and ***QuickPlate (fig. 9)***. All three low-profile medical grade titanium alloy cervical plates are available in one-, two-, and three- level designs in a range of sizes. The Dynamic and Semiconstrained plates also come as four-level plates. All three of our cervical plating systems utilize the same bone screws and, hence, provide ultimate operative flexibility as the surgeon can modify the type of cervical plate used depending on the intraoperative pathology and bone quality.

Figure 7

Figure 8

Figure 9

The Rhausler Anterior Cervical Vertebrae Plate System contains 4.0mm Diameter Unicortical Locking Self Tapping Medical Grade Titanium Alloy Bone Screws ***(fig. 10-A)*** and 4.0mm Diameter Unicortical Locking Self Tapping Self Drilling Medical Grade Titanium Allow Bone Screws ***(fig. 10-B)***.

The 4.0mm Diameter Unicortical Medical Grade Titanium Alloy Bone Screws are available in:
- 12mm lengths
- 14mm lengths
- and 16mm lengths.

The 4.5mm Diameter Unicortical Oversized Medical Grade Titanium Alloy Bone Screws, ***(fig. 10-C)*** are available in:
- 12mm lengths
- 14mm lengths
- and 16mm lengths.

The 4.0mm Diameter Bicortical Locking, Self Tapping Medical Grade Titanium Alloy Bone Screws, ***(fig. 10-D)*** are also available in:
- 18mm lengths
- 20mm lengths
- and 22mm lengths.

The bone screws may be angulated in variable directions allowing translation and rotation at the plate-screw interface, providing sound biomechanical stabilization and substantially reducing the potential for bone screw back out and breakage. The 3.75mm Diameter Unicortical Locking, Self Tapping Medical Grade Titanium Alloy Bone Graft Screw ***(fig. 10-E)*** is available in a 10mm length for securing the bone graft to the cervical plate if desired.

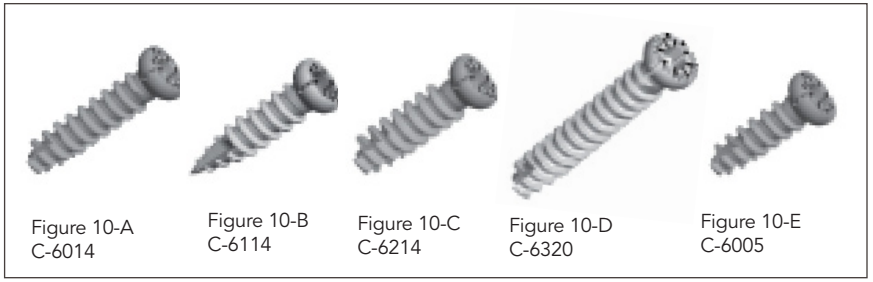

Figure 10-A C-6014 | Figure 10-B C-6114 | Figure 10-C C-6214 | Figure 10-D C-6320 | Figure 10-E C-6005

The Dynamic, Semiconstrained, and QuickPlate Cervical Plates are additionally designed to articulate with one another for situations in which two plates in a long construct are desired.

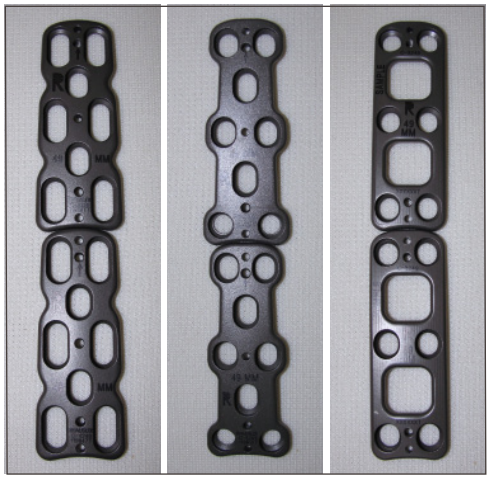
Figure 11

Following graft placement, the surgeon selects the appropriate cervical plate length. The cervical plate should span the vertebral segment using the shortest length possible to avoid contact with the adjacent disc space and allow for settling to occur. The fact that the Dynamic Cervical Plate settles more than the Semiconstrained or QuickPlate cervical plate is inherent in its design. The dynamic cervical plates are typically positioned covering only one-third to one-half of the vertebral body to allow for expected settling. ***Note: The addition of posterior stabilization hardware will limit the extent of settling in all three types of cervical plates.*** The anterior surface of the cervical spine is flattened with a bone biting tool or high-speed burr to prepare a gentle curve for the plate to rest on without wobbling when the ends are digitally rocked. If necessary, the Plate Bender (C-7056) ***(fig. 11)*** may be used to contour the cervical plate to the desired lordotic curve. You can

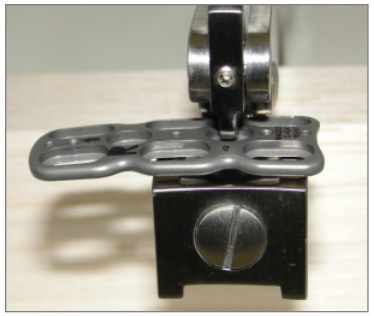

Figure 12A

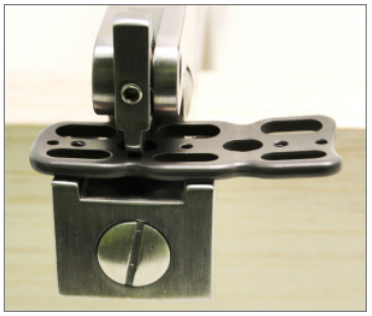

Figure 12B

increase ***(Fig. 12A)*** or decrease ***(Fig. 12B)*** the lordotic bend in the plate. ***Note: The 21, 23 & 25mm plates cannot be contoured with the bender.***

CAUTION: Repeated bending of the cervical plate will cause it to weaken and could compromise its mechanical integrity.

For those cases in which the drill guide is not being used, once the cervical plate is aligned in the desired position Temporary Cervical Plate Tacks ***(C-6400 fig. 13)*** can be inserted in the tack holes in the vertical midine of the plate at its caudal or cephalad ends. The cervical tacks minimize movement of the cervical plate during screw placement.

The instrument set includes two Tack Holders ***(C-7015 fig. 16)*** that may be pre-loaded prior to the procedure ***(fig. 15)***. ***Note: The Temporary Tacks (C-6400) cannot be used when the attachable drill guides (C-7100, C-7101 or C-7102 or C-7103) are used.*** When the attachable drill guides are used, the Temporary Threaded Tack, which can be inserted into the plate bone screw hole through the attached drill guide ***(C-6401, fig. 14)*** or the Awl ***(C-7035, C-7036, fig. 35)*** can be used to secure the plate to the verte¬bral body. When an attachable drill guide

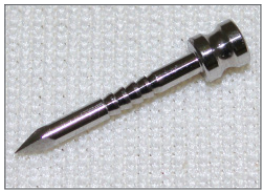

Figure 13

Figure 14

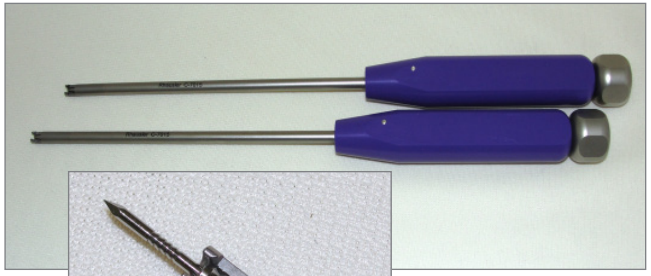

Figure 15

Figure 16

is NOT used, the C-6400 tem¬porary tacks are loaded into each tack holder by insertion into the prongs ***(fig. 16)*** on the open side and then turning the knob at the back end of the handle ***(fig. 17)*** to secure the tack in place and to secure the plate to the vertebral body. ***Note: Do not over tighten tack into tack holder (C-7015).***

Figure 17

The C-6400 Temporary Tacks are typically inserted into both the highest and lowest tack holes using the Tack Holder (C-7015) and advanced into the vertebrae by hand pressure or lightly tapping down on the tack holder with a small mal¬let. ***Note: The cervical tacks (C-6400 & C-6401) are SINGLE USE ONLY and designed for TEMPORARY FIXATION. Tacks should be REMOVED and properly disposed of after bone screw placement and prior to closure.***

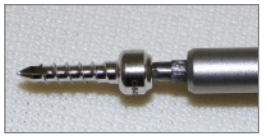

Figure 18

To remove the tacks (C-6400) from the vertebrae, the tack holder is locked on to each tack and the tacks pulled **STRAIGHT** out.

Figure 19

If desired, a Temporary self drilling self tapping Threaded Tack ***(C-6401 fig. 18)*** can be used to hold the plate in place. The threaded tack is placed on any plate screw hole ***(fig. 19)*** and screwed in place by using the Self-Retaining One Step Locking Screwdriver ***(C-7025 fig. 41)***. The threaded tack can be put in place through any attachable drill guides ***(fig. 20)***.

The Temporary Threaded Tack (C-6401) is 1.4mm diameter and has the same screw pitch as all of our bone screws. Remove the threaded tack with the Self-Retaining One Step Locking Screwdriver (C-7025) once a permanent bone screw is ready to be placed. Then properly dispose of the used tack.

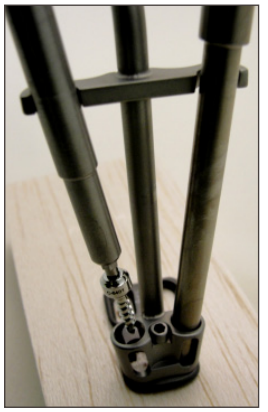

Figure 20

Bone Screw Placement

The type of bone screw selected by the surgeon dictates the specific surgical technique and instrumentation used. Fluoroscopy verifies screw angle, length, and placement. The bone screws should not violate the adjacent disc spaces or project into the spinal canal to compress the spinal cord or nerve roots.

With the cervical plate secured with the temporary tacks, the surgeon selects the

appropriate twist drill or awl for preparing the bone screw pilot holes. Additional temporary cervical plate fixation while drilling can be obtained by applying digital pressure on the plate.

Dynamic Attachable Drill Guides

The instrument set has a selection of drill guides which can be attached to the plate. The Dynamic Cervical Plating Set (C-7075-1) comes with three attachable drill guides: C-7100 Drill Guide 12 Degrees, 16mm wide, f/Top of Plate, purple ***(fig. 21)***; C-7101 Drill Guide12 Degrees, 19mm wide, f/Bottom of the plate, blue ***(fig.22)***; and C-7102 Drill Guide 0 Degrees, 19mm wide, f/Bottom of the plate, Orange ***(fig. 23)***.

Once the desired Dynamic Plate is selected, it is then placed in the plate holder portion of the tray ***(fig. 25)*** and the C-7100 Drill Guide 12 Degrees, 16mm wide put on top of the plate. The drill guide is placed onto the upper holes of the plate, aligning its screw connection perpendicular to the tapped screw hole in the plate ***(fig. 26.)*** The drill guide is attached to the plate using the C-7025 Screw¬driver. ***Note: Attachment Screw must be perpendicular to plate prior to tightening.***

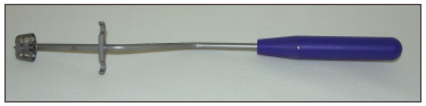

Figure 21
C-7100 – Drill Guide 12 Degrees,
16mm Wide, f/Top of Plate, Purple,
12 Degrees up, Cephalad, on Dynamic,
Semiconstrained or QuickPlate only.

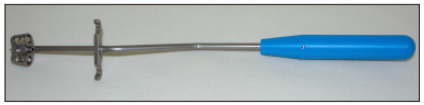

Figure 22
C-7101 – Drill Guide 12 Degrees,
19mm Wide f/Bottom of Plate, Blue,
12 Degrees down, Caudal, Dynamic Plate only.

Figure 23
C-7102 – Drill Guide, 0 Degrees,
19mm Wide, f/Bottom of Plate, Orange,
0 Degrees, Caudal, Semiconstrained Plate only.

Figure 24
C-7103 – QuickPlate Drill
Guide 0 deg, 16mm, f/Btm of Plate,
Yellow, 0 Degrees, Caudal, QuickPlate only.

Figure 25

Figure 26

Once the drill guide is secured to the plate, it can be used to place the plate onto the appropriate vertebral body. Once in place, you have the option of using a self drilling self tapping bone screw ***(C-6112, C-6114, C-6116, fig. 10B)***, or an appropriate length twist drill, followed by a self tapping screw ***(C-6012, C-6014, C-6016, fig. 10A)***. Other options are to use the 12mm Awl ***(C-7036, fig. 27)*** to hold the drill guide in place. With the first awl holding the drill guide, a second Awl ***(C-7035, fig. 28)*** can be used to penetrate the cancellous bone in the opposite drill guide hole. Once the cortical bone has been penetrated, a self drilling self tapping bone screw can be placed through the drill guide.

Figure 27

Figure 28

Figure 29

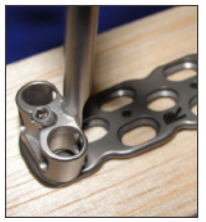

Figure 30

When the appropriate bone screws have been placed in the drill guide ***(fig. 29)***, screw them until they are bottomed out into the plate. Once both screws are firmly in place, the drill guide can be detached from the plate using the screw¬driver, C-7025 ***(fig. 30)***.

The bone screws can now be re-engaged with the Screwdriver (C-7025) and locked and further tightened, if desired, according to the procedure described on Page 16 of "Surgical Technique for the Rhausler Screw Driver" for locking screws. The screws can be locked once seated in the plate groove. Then final tightening can be done.

The C-7101 Drill Guide 12 Degrees, 19mm wide can be attached to the bottom of the plate using the Screwdriver (C-7025). Follow the steps and options above to place the bone screws in the bottom screw holes in the plate.

Semiconstrained Attachable Drill Guides

The instrument set has a selection of drill guides which can be attached to the plate. The Semiconstrained Cervical Plating Set (C-7075-2) comes with two attachable drill guides: C-7100, Drill Guide 12 Degrees up, 16mm wide, Purple, f/Top of plate ***(fig. 21)*** and C-7102 Drill Guide 0 Degrees, 19mm wide, Orange, f/Bottom of the plate ***(fig. 23)*** ***Note: C-7101 Drill Guide 12 Degrees, 19mm wide, f/Bottom of the plate, should not be used for the bottom of the Semiconstrained or the QuickPlate. Follow same steps as shown under "Dynamic Attachable Drill***

Guides" on Pages 10 & 11, and the procedure described on Page 16 "Surgical Technique for the Rhausler Screw Driver" for locking screws.

QuickPlate Attachable Drill Guides

The instrument set has a selection of drill guides which can be attached to the QuickPlate. The QuickPlate Cervical Plating Set (C-7075-3) comes with two attachable drill guides: C-7100, Drill Guide 12 Degrees up, 16mm wide, Purple, f/top of plates ***(fig. 21)*** and C-7103, Drill Guide 0 Degrees, 16mm wide, Yellow, f/bottom of the plate ***(fig. 24)***. ***Note: C-7100, Drill Guide 12 Degrees, 16mm wide, Purple, should not be used for the bottom of the QuickPlate or Semiconstrained Plate. Follow same steps as shown under "Dynamic Attachable Drill Guides" on Page 10 "Surgical Technique for the Rhausler Screw Driver" for locking screws.***

Multi-level Fusions

If two or more levels require fusion, the Green Dual Drill Guide 0 Degree, C-7047 ***(fig. 31)*** is used with the appropriate length 2 or 3mm Twist Drill with Stop (C-7030, C-7033, C-7034, C-7038, C-7039, C-7041, C-7043) ***(fig. 32)*** to drill the bone screw pilot holes ***(fig. 33)***. The Awl, C-7035, C-7036, ***(fig. 34)*** can also be used to perforate the cortical bone. Place the green Dual Drill Guide onto the center plate bone screw holes in multi-level plates. Adjustable arms allow the drill guide to sit in any multi-level bone screw hole. ***Note: Bone screws cannot be placed through the Green Drill Guides.***

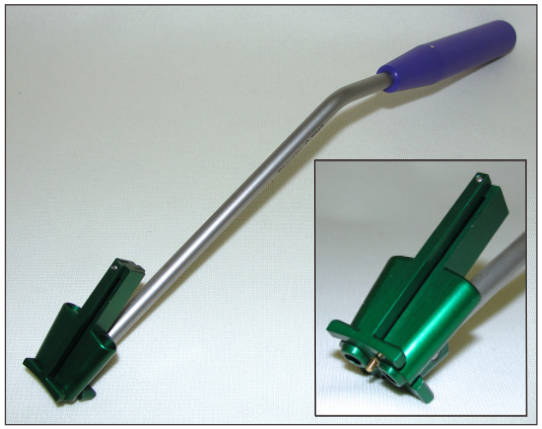

Figure 31

Figure 32

Additional case planning is required if two articulating plates are utilized in a long construct using, for example, two 2-level plates for a 4-level ACDF or one 2 and one 3-level plate for a 5-level ACDF. Four screws are first placed in the medial ver¬tebral body where the plates meet. Decortication of the endplates and vertebral resection should be minimized to assure that the body maintains maximum size for accepting all four screws. In addition, osteophytes should be removed and the anteri¬or surface flattened with a bone biting tool or high-speed burr to prepare a gentle curve for the plates to rest on without wobbling when the ends of the plates are digitally rocked. The top plate should be placed covering approximately one-third of the superior vertebral body and the bottom plate placed below, with the edges touching. Tacks should be used to achieve temporary fixation when the plates are in the desired position. The Dual Drill Guides (C-7100 and C-7101) are designed to place the four screws so that they will not contact

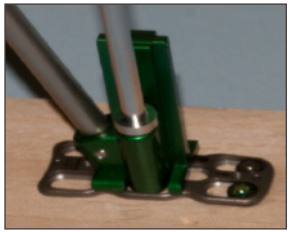

Figure 33

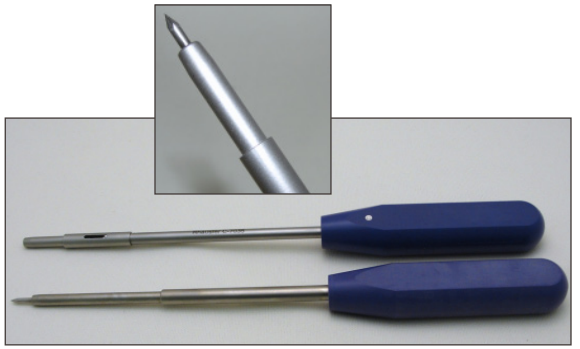

Figure 34

each other ***(fig. 35)***. Screws should first be placed in the caudal/lower holes of the top, followed by placement of the cephalad/top screws in the bottom plate. Fluoroscopy should be used after each screw insertion to verify angle and placement and each screw should be left slightly proud of the plate. The two temporary tacks can be removed in the area where the plates meet. Screw placement is next accomplished in the top hole of the top plate, followed by the center hole in the top plate, the caudal hole of the bottom plate and with the final placement of the center screws in the bottom plate. Screws can be tightened to two-finger tightness and locked into the plate using the procedure described on Page 16 in "Surgical Technique for the Rhausler Screw Driver."

Universal Single Drill Guide

The Universal Single Drill Guide (C-7052) ***(fig. 36)*** with Nylon Depth Stop Spac¬ers – 10mm, 12mm, 14mm and 16mm (C-7053) can be used with either the 2mm (C-7046) or the 3mm (C-7033) Universal Twist Drills ***(fig. 37)*** in preparation

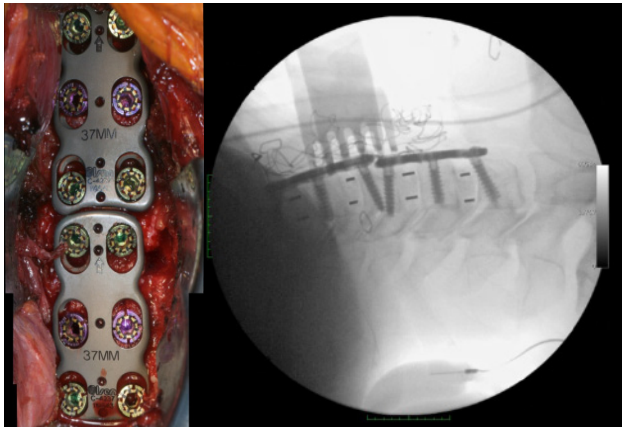

Figure 35

for bone screw placement. This drill guide can be used to vary the angle of the bone screws and fluoroscopy can be used to verify the correct angle prior to drilling after placement in the plate. Adjust the Universal Twist Drill depth in the guide by placing the Nylon Depth Stop Spacer on the guide ***(fig. 38)*** corresponding to the selected screw length. Next, tighten the top of the drill guide to secure the adjuster and the drill guide body. ***Note: Confirm the length of the Twist Drill and the distal end of the Universal Drill Guide using caliper C-7045 (fig. 39). Twist drills are SINGLE use only and need to be properly disposed of after use.***

Once the twist drill depth is confirmed, the Universal Drill Guide can be used to drill through the plate into the vertebral body. ***(fig. 40).***

4.0mm Diameter Locking Self Tapping Medical Grade Titanium Alloy Bone Screws (C-6012, C-6014, C-6016)

If the surgeon selects the self-tapping bone screw, it is inserted onto the Self-retaining One-Step Locking Screwdriver, C-7025 ***(fig. 41)***. The screwdriver, with the bone screw, is placed in the desired guide angle hole.

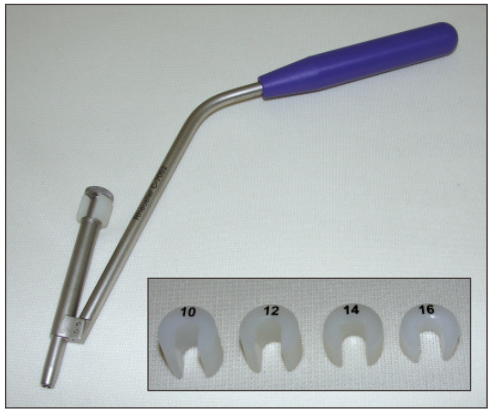

Figure 36

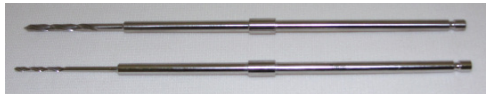

Figure 37

Figure 38

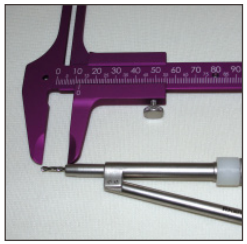

Figure 39

Figure 40

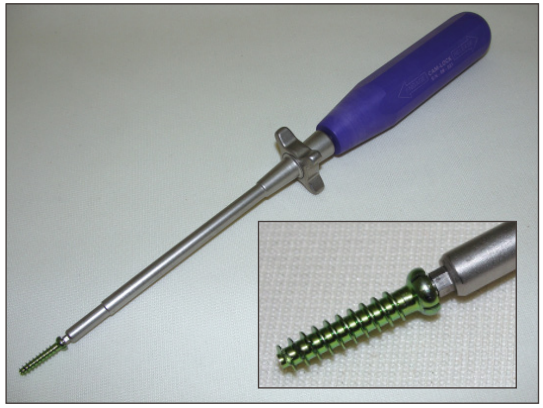

Figure 41

Surgical Technique for the Rhausler Screwdriver C-7025

Here are important steps to avoid complications when using the C-7025 Screwdriver:

Loading the Bone Screws

- Prior to loading the screwdriver, be sure that the outer locking mechanism is pulled up flush to the handle ***(fig. 42)***.
- When engaging the bone screws in the screw caddie, bring the hex end of the screwdriver to the selected bone screw at a 45-degree angle while holding the back end of the handle with one hand ***(fig. 43)***.
- Rotate the screwdriver to a perpendicular position (straight up) and rotate the handle while pushing down lightly to engage the hex in the screw ***(fig. 44)***.
- Be sure that the hex of the screwdriver is fully engaged into the bone screw. ***(fig. 45)***.

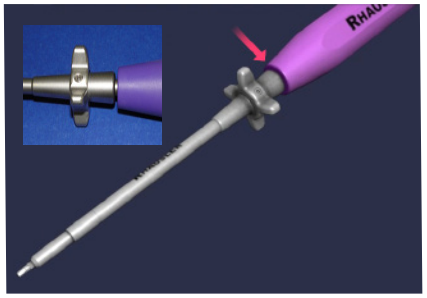

Figure 42

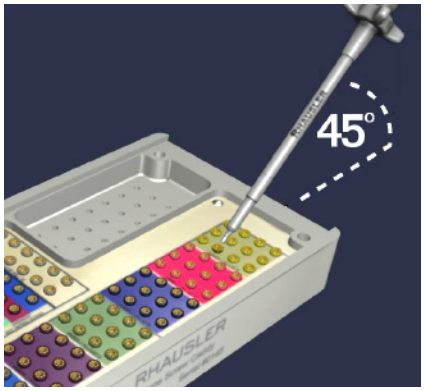

Figure 43

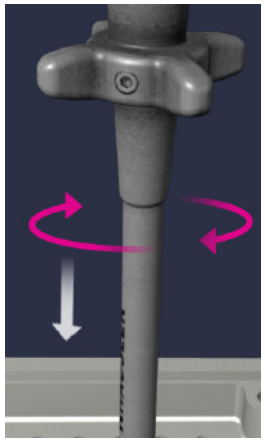

Figure 44

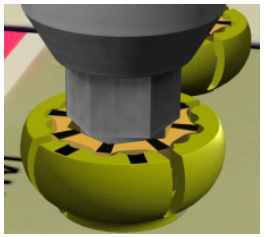

Figure 45

- Once fully engaged, use your free hand to engage the locking mecha¬nism into the bone screw locking cam. This is achieved by lightly pushing down and rotating the four-pronged wheel until the hex of this outer locking mechanism is fully engaged into the hex of the bone screw locking cam. ***(fig. 46)***.
- The screwdriver is now ready to be passed to the surgeon.

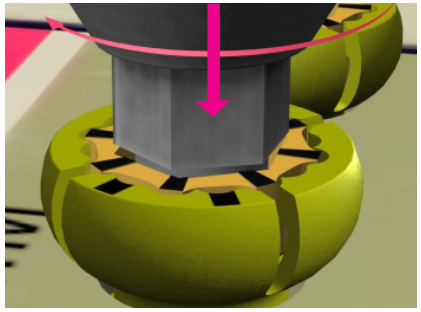

Figure 46

Re-engaging the Screwdriver

When the surgeon re-engages the screwdriver into bone screw which has already been placed into the plate ready for final tightening and locking, there are a few steps to keep in mind.

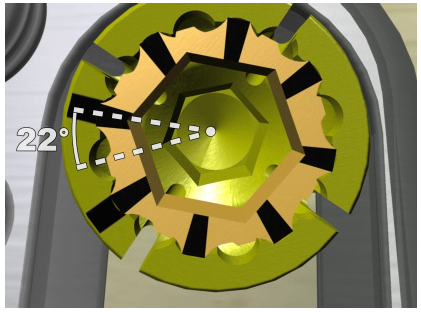

Figure 47

- It can be very difficult to re-engage the screwdriver into the bone screw if it is not positioned coaxial to the head of the bone screw (aligned straight in). It also is critical that the cervical retractor arms, or any instruments placed in the wound, do not interfere when attempting to place the screwdriver into the bone screw. Any lateral pressure will cause the screwdriver NOT to cleanly engage the bone screw. If any part of the retractor is interfering with the screwdriver placement, you MUST hold the retractor away from touching and keep anything from interfering with the screwdriver shaft.
- Once the screwdriver is fully engaged into the bone screw (while continuing to avoid any lateral pressure/interference) the locking shaft needs to be lightly pushed down and rotated into the cam mechanism. Once fully engaged, the locking mechanism needs to be rotated clockwise 1/16th of a turn to lock the bone screw in place. ***Note: The bone screw head must be past the top of the plate's screw hole ridge and not fully tightened into the bottom of the plate prior to engaging the locking cam. Once cam is locked, you can further tighten the bone screw into the plate.***
- There are three confirmations to assure that the locking cam is locked. FIRST, the surgeon will feel a tactile click once the locking shaft is rotated 1/16th of a turn (usually a click is heard as well). SECOND, the black dashes on the cam no longer line up with the four cuts in the head of the bone screw ***(fig. 47)***. THIRD, use a small probe or dissector, push side to side on the cam ring and if there is

no movement of the ring, the bone screw is locked.

The removal of the Screwdriver

The removal of the screwdriver after bone screw placement or locking of the bone screw can be difficult unless the following steps are taken:

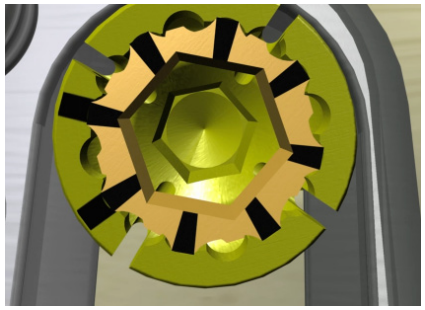

Figure 48

- Be sure that there are NOT any instruments, such as the muscle/tissue retractors placing any lateral pressure on the screwdriver shaft.
- The screwdriver must be pulled straight out, coaxial, from the bone screw.
- If the surgeon is having difficulty removing the screwdriver from the bone screw, it is usually because there are instruments such as the retractor frame placing side/lateral pressure on the screwdriver shaft, or the surgeon has a full hand grasp of the screwdriver handle and is trying to force the release by pulling up hard. This has a negative effect because the surgeon is applying a lateral twisting motion, which will NOT allow the release of the screwdriver from the screw. The surgeon needs to release the grip on the screwdriver. The screwdriver will stand up on its own, which indicates that it is engaged into the bone screw. The surgeon needs to gently hold the end of the handle with a thumb and two-finger grip, then gently wiggle and pull straight out, coaxial, to disengage the screwdriver from the bone screw.

Figure 49

4.0mm Diameter Locking Self-Tapping & Self-Drilling Medical Grade Titanium Alloy Bone Screws (C-6112, C-6114, C-6116)

If the surgeon selects the self-tapping self-drilling bone screws, they can be placed by first using the Awl with Spring Loaded Tip, (C-7035, ***(fig. 34)*** or Awl without Guard, 12mm length ***(C-7036 , fig. 34)***, to penetrate the cortical bone. The awl can be used with the Dual Drill Guides (C-7100, C-7101, C-7102, C-7103, C-7047) or by placing the awl tip directly into the plate.

The appropriate length bone screw is selected and inserted in the Self-Retaining One-Step Locking Screwdriver, C-7025 ***(fig. 41)***. The screwdriver is placed in the hex of the bone screw. The bone screw should then be advanced into the holes of the plate until firmly in place.

This process is repeated for each bone screw. Once all the bone screws are in place, the surgeon verifies that the cervical plate and bone screws are in the desired position before the final tightening and engaging of the bone screw locking mechanism.

Bone screws should then be tightened sequentially until flush with the cervical plate ***(fig. 48 & fig.49)***. ***Note: Use the two finger tightening method to avoid stripping the bone screw placement.***

Locking Bone Screws

Final locking of the bone screws to the cervical plate is performed by using the Self-Retaining One-Step Locking Screwdriver ***(C-7025, fig. 41). Note: The outer shaft of the Locking Screwdriver should be flush to the bone screw head during the locking procedure. Otherwise, damage might occur to the tip of the outer shaft. Hold the screwdriver handle firmly while rotating the locking mechanism to avoid advancing the bone screw.***

Final locking of the bone screws to the cervical plate is performed by turning the Self-retaining One-Step Locking Screw Driver (C-7025) 1/16 rotation clockwise to engage the bone screw lock and 1/16 rotation counterclockwise to disengage the bone screw lock. There are three ways to confirm that the bone screw is locked:

- Tactile – a click is felt when the cam is moved to the locked position. The surgeon will also feel a tactile click once the locking shaft is rotated 1/16th of a turn (usually hears a click, as well).
- Visual – the etched lines on the inner cam are no longer in alignment with the four slots on the outer screw ***(fig. 50)***
- Visual – there is no movement of the cam lock when a small probe or dissector is used to push side to side on the cam ring in the head of the bone screw.

The appropriate length bone screw is selected and inserted in the Self-Retaining One-Step Locking Screwdriver ***(C-7025, fig. 41)***. The screwdriver is placed into the hex of the bone screw. The bone screw should then be advanced into the drilled holes until the head of the bone screw is in the plate. This process is repeated for each bone screw. Once all the bone screws are in place, the surgeon verifies that the cervical plate and bone screw are in the desired position before final tightening and activation of the

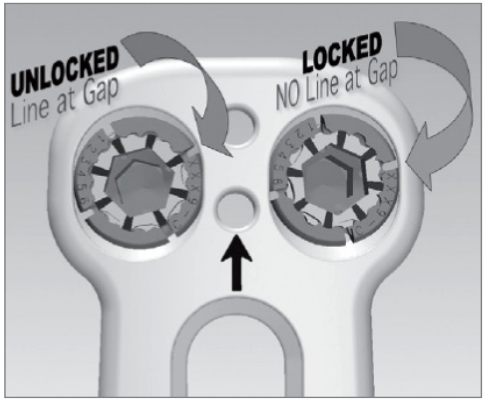

Figure 50

bone screw locking mechanism. ***Note: Blue Screw head once angled in the plate, up to 15 degrees, will have a portion of the bone screw head protruding above the plate. The bone screw can be locked in place as long as no more than 1/2 of the bone screw head protrudes above the plate.***

Bone screws should then be tightened sequentially until flush with the cervical plate ***(fig. 49)*** working clockwise from a superior to inferior direction to ensure equal compression of the cervical plate to the vertebral body. ***Note: Use the two finger tightening method to avoid stripping the bone screw placement.***

Final locking of the bone screws to the cervical plate is performed by using the Self-retaining One-Step Locking Screwdriver ***(C-7025, fig. 41)***. ***Note: The outer shaft of the Locking Screwdriver should be flush to the bone screw head during the locking procedure; otherwise, damage might occur to the tip of the outer shaft. Hold the screwdriver handle firmly while rotating the locking mechanism to avoid advancing the bone screw.***

Final locking of the bone screws to the cervical plate is performed by turning the Self-retaining One-Step Locking Screw Driver (C-7025) 1/16 rotation clockwise to engage the bone screw lock and 1/16 rotation counterclockwise to disengage the bone screw lock. There are three ways to confirm that the bone screw is locked:

- Tactile – a click is felt when the cam is moved to the locked position. The surgeon will also feel a tactile click once the locking shaft is rotated 1/16th of a turn (usually a click is heard as well).
- Visual – the etched lines on the inner cam are no longer in alignment with the four slots on the outer screw ***(fig.50)***
- Visual – there is no movement of the cam lock when a small probe or dissector is used to push side to side on the cam ring in the head of the bone screw.

If a bone screw needs to be removed, turn the shaft 1/16 rotation counter-clockwise to disengage the screw locking mechanism lock before removing the bone screw. If the bone screw cannot be removed using the Self-Retaining One-Step Locking Screwdriver (C-7025), a Screw Extraction Tool (C-7031) is used ***(fig. 51)***. The Screw Extraction Tool is loaded in to the Handle for AO Shafts (C-7028), and the distal tip is placed into the center of the bone screw and turned counter-clockwise, backing out the bone screw. Once the bone screw is removed, the bone screw must be properly discarded.

Figure 51

4.5mm Diameter Locking Self Tapping Oversized Medical Grade Titanium Alloy Bone Screws (C-6212, C-6214, C-6216)

In the event a hole becomes stripped, an oversized 4.5mm Diameter Locking Self Tapping Oversized Medical Grade Titanium Alloy Bone Screw ***(fig. 10-C)*** may be utilized to ensure adequate cervical plate compression. Oversized bone screws are available in 12mm, 14mm and 16mm lengths. ***Note: the 4.5mm bone screw is slightly larger than the Dynamic, Semiconstrained, and QuickPlate Cervical Plate screw holes and must be screwed through the hole of the cervical plate.***

Cervical Plate Removal, Dynamic, Semiconstrained or QuickPlate

With the cervical vertebral column section containing the plate clearly exposed, use the Self-Retaining One-Step Locking Screwdriver ***(C-7025, fig. 41)*** to unlock the screw locking mechanism and engage the screwdriver. Then en¬gage the locking mechanism by a 1/16 rotation counter-clockwise of the locking mechanism and unlock the screws ***(fig. 50)***. Remove each bone screw using C-7025, by turning the bone screw counter-clockwise until the bone screw is completely disengaged from the vertebral body and cervical plate. Repeat this for all remain¬ing bone screws (on the Semiconstrained and QuickPlates, remove the screws from the two inferior holes first) and properly dispose of all screws and plates when completed. If the bone screw cannot be removed using the Self-Retaining One-Step Locking Screwdriver (C-7025), a Screw Extraction Tool (C-7031) is used ***(fig. 51)***. The Screw Extraction Tool is loaded into the Handle for AO Shafts (C-7028), and the distal tip is placed into the center of the bone screw hex and turned counter-clockwise, backing out the bone screw.

Products:

Cervical Titanium Plates

- QuickPlate™
- Dynamic plates
- Semiconstrained plates

Bone Screws

Single Use Only

Instruments

Cervical Titanium Plates

QuickPlates

ITEM#	DESCRIPTION	LEVEL
C-3121	21 mm	1
C-3123	23 mm	1
C-3125	25 mm	1
C-3127	27 mm	1
C-3129	29 mm	1
C-3131	31 mm	1
C-3133	33 mm	1
C-3135	35 mm	1
C-3237	37 mm	2
C-3240	40 mm	2
C-3243	43 mm	2

ITEM#	DESCRIPTION	LEVEL
C-3246	46 mm	2
C-3249	49 mm	2
C-3252	52 mm	2
C-3255	55 mm	2
C-3354	54 mm	3
C-3357	57 mm	3
C-3360	60 mm	3
C-3363	63 mm	3
C-3366	66 mm	3
C-3369	69 mm	3
C-3372	72 mm	3
C-3375	75 mm	3
C-3378	78 mm	3

Dynamic Plates

ITEM#	DESCRIPTION	LEVEL
C-4121	21 mm	1
C-4123	23 mm	1
C-4125	25 mm	1
C-4127	27 mm	1
C-4129	29 mm	1
C-4131	31 mm	1
C-4133	33 mm	1
C-4135	35 mm	1
C-4237	37 mm	2
C-4240	40 mm	2
C-4243	43 mm	2
C-4246	46 mm	2
C-4249	49 mm	2
C-4252	52 mm	2
C-4255	55 mm	2
C-4354	54 mm	3
C-4357	57 mm	3
C-4360	60 mm	3

ITEM#	DESCRIPTION	LEVEL
C-4363	63 mm	3
C-4366	66 mm	3
C-4369	69 mm	3
C-4372	72 mm	3
C-4375	75 mm	3
C-4378	78 mm	3
C-4469	69 mm	4
C-4473	73 mm	4
C-4477	77 mm	4
C-4481	81 mm	4
C-4485	85 mm	4
C-4489	89 mm	4
C-4493	93 mm	4
C-4497	97 mm	4
C-4501	101 mm	4
C-4505	105 mm	4
C-4509	109 mm	4

Semiconstrained Plates

ITEM#	DESCRIPTION	LEVEL
C-5121	21 mm	1
C-5123	23 mm	1
C-5125	25 mm	1
C-5127	27 mm	1
C-5129	29 mm	1
C-5131	31 mm	1
C-5133	33 mm	1
C-5135	35 mm	1
C-5237	37 mm	2
C-5240	40 mm	2
C-5243	43 mm	2
C-5246	46 mm	2
C-5249	49 mm	2
C-5252	52 mm	2
C-5255	55 mm	2
C-5354	54 mm	3
C-5357	57 mm	3
C-5360	60 mm	3

ITEM#	DESCRIPTION	LEVEL
C-5363	63 mm	3
C-5366	66 mm	3
C-5369	69 mm	3
C-5372	72 mm	3
C-5375	75 mm	3
C-5378	78 mm	3
C-5469	69 mm	4
C-5473	73 mm	4
C-5477	77 mm	4
C-5481	81 mm	4
C-5485	85 mm	4
C-5489	89 mm	4
C-5493	93 mm	4
C-5497	97 mm	4
C-5501	101 mm	4
C-5505	105 mm	4
C-5509	109 mm	4

Bone Screws

ITEM#	DESCRIPTION	
C-6005	Rhausler	3.75 x 10 mm Ti Bone Graft Screw, Self-tapping, Dark Gold
C-6012	Rhausler	4.0 x 12 mm Ti Bone Screw, Self-tapping, Light Blue
C-6014	Rhausler	4.0 x 14 mm Ti Bone Screw, Self-tapping, Magenta
C-6016	Rhausler	4.0 x 16 mm Ti Bone Screw, Self-tapping, Light Green
C-6112	Rhausler	4.0 x 12 mm Ti Bone Screw, Self-drilling, Self-tapping, Dark Blue
C-6114	Rhausler	4.0 x 14 mm Ti Bone Screw, Self-drilling, Self-tapping, Pink
C-6116	Rhausler	4.0 x 16 mm Ti Bone Screw, Self-drilling, Self-tapping, Gold
C-6212	Rhausler	4.5 x 12 mm Ti Oversized Bone Screw, Teal
C-6214	Rhausler	4.5 x 14 mm Ti Oversized Bone Screw, Grape
C-6216	Rhausler	4.5 x 16 mm Ti Oversized Bone Screw, Sea Foam Green

Single Use Only

ITEM#	DESCRIP-	TION
C-7030	Rhausler	3.0 x 12mm Drill, Single use only
C-7031	Rhausler	Screw Removal Tool, Single use only
C-7033	Rhausler	3.0mm Universal Twist Drill, Single use only
C-7034	Rhausler	2.0x14mm Drill, Single use only
C-7038	Rhausler	3.0x14mm Drill, Single use only
C-7039	Rhausler	2.0x12mm Drill, Single use only
C-7041	Rhausler	2.0x16mm Drill, Single use only
C-7043	Rhausler	3.0x16mm Drill, Single use only
C-7046	Rhausler	2.0mm Universal Twist Drill, Single use only
C-6400	Rhausler	Temporary Cervical Plate Tack, Single use only
C-6401	Rhausler	Temp. Plate Holder, Threaded, Single use only

Instruments

ITEM#	DESCRIPTION	
C-7015	Rhausler	Tack Holder
C-7025	Rhausler	Self-retaining One-step Locking Screw Driver
C-7028	Rhausler	Handle for AO Shafts
C-7035	Rhausler	Awl w/spring loaded tip
C-7036	Rhausler	Awl
C-7045	Rhausler	Caliper
C-7047	Rhausler	Dual Drill Guide, Green, 0 Deg.
C-7052	Rhausler	Single Drill Guide, Universal
C-7053	Rhausler	Universal Drill Guide Spacer Set 10, 12,14 ,16, 18, 20mm
C-7056	Rhausler	Plate Bender, w/Anvil
C-7075	Rhausler	Bone Screw Caddy
C-7089	Rhausler	Plate Caddy
C-7090	Rhausler	Sterilization Tray
C-7100	Rhausler	Drill Guide 12 Degrees,16mm Wide, f/Top of Plate, Purple
C-7101	Rhausler	Drill Guide 12 Degrees,19mm Wide, f/Bottom of Plate, Blue
C-7102	Rhausler	Drill Guide 0 Degrees,19mm Wide, f/Bottom of Plate, Orange
C-7103	Rhausler	QuickPlate Drill Guide 0 Deg,16mm Wide, f/Btm of Plate, Yellow

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Email: info@rhausler.com

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Caution: US Federal law restricts this device to sale by or on the order of a physician.

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