



Surgical Technique Guide

Plage Anterior Cervical Fusion System

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Rhausler Plage Anterior Cervical Fusion System Surgical Technique Guide

The Rhausler Plage Anterior Cervical Fusion System is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. 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.

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 taped, pulling inferiorly to allow better visualization of the lower cervical spine on fluoroscopy.



fig. 1

The operative fluoroscopy C-arm is positioned at a 45-degree angle above the patient (fig 2) 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 in the exact details of the positioning, taping and draping have evolved.



fig. 2

Either a right (fig. 3) or left approach to the cervical spine is performed according to surgeon preference. Once the skin incision and anterior soft tissue dissection have been performed, allowing visualization of the pathologic levels, a cervical

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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 to aid in aligning the plate before elevating the longus coli muscles.

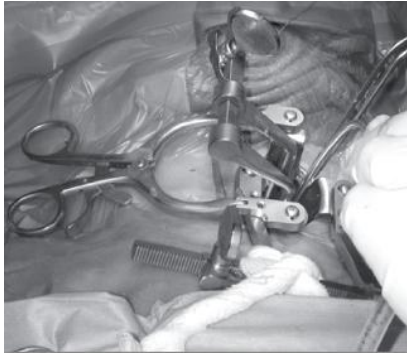


fig. 3

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 anteriorosteophytes 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.

Distraction screws are then placed, in the bodies adjacent to the operated disc space(s) (fig 4), avoiding corpectomy levels under visual and/or fluoroscopy guidance. The distraction screws are placed parallel, but **in offset position**, to allow placement of the Plage into the disc space without interference of the distraction screws, to obtain parallel distraction or angled toward each other to obtain Lordotic correction as per the surgeon's choice and preoperative planning.

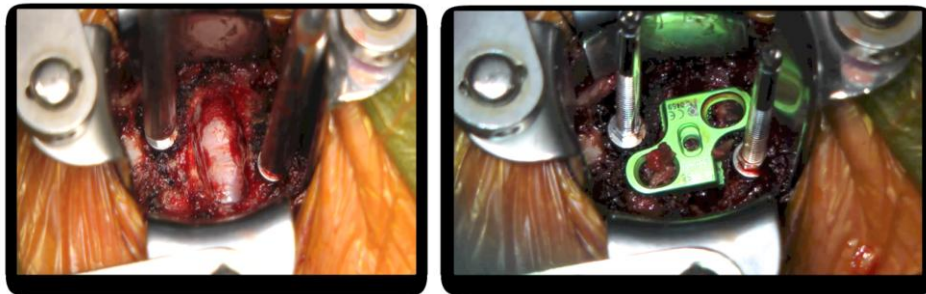


fig. 4

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 preferred. 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.

The intravertebral disc space is prepared for the Plage by removing the cartilage endplate, decorticating the bony endplate and shaping the superior and inferior bony margins in a parallel or slightly lordotic fashion.

Implant Selection

The Rhausler Plage Cervical Fusion System comes in a variety of sizes (fig. 6). The Plages' low-profile medical grade titanium alloy cervical implants are available in a range of sizes from 5mm to 10mm in height and 13mm depth x 14mm width (SML), 15mm depth x 14mm width (STD) and 17mm depth x 16mm width and depth (LRG). The Plage can be

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Note: All Trials, Rasps, Drill Guides and Plages are color coded to Plage height.

Once the Plage Implant size is selected, there are 3 options to place the Plage Implant and bone screws in the Plage to secure it to the vertebral bodies.

Option #1:

Using the Plage Dual Drill Guide Holder D-3201 and Dual Drill Guides D-2466 thru D-2780 or D-2465 Dual Drill Guide with handle (fig 10a):

Secure the color coded Dual Drill Guide from the implant caddy (fig 10b) with the Dual Drill Guide Holder (fig. 11a & 11b), except when using D-2465 Dual Drill Guide for the STD 5mm Silver Drill guide which comes with a handle (fig 10a), then screw in the Dual Drill Guide holder and Guide into the corresponding color coded Plage Implant.



Once firmly attached, the Plage Implant can be inserted into the wound site. It is now ready for drilling of the pilot holes and placement of the bone screws. The appropriate Twist Drill is selected (10, 12, 14, and 16mm lengths) to match the corresponding length of the self-tapping screws. The twist drill can be attached to the Handle for AO Shafts, C-7028 (fig 12),



or a 1,000 rpm power drill. The twist drill is then placed in one side of the Dual Drill Guide and drilled until it no longer advances in the guide (fig 13a & 13b).

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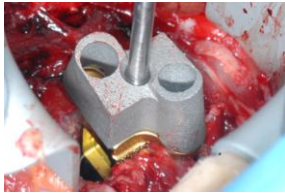


fig. 13a



fig. 13b

The opposite side of the guide is then drilled and the twist drill is removed and disposed of according to hospital protocol for Single Use Items. The associated length bone screw is selected and retrieved with the One Step Locking Screw Driver, C-7025 or Clocked Screw Driver, C-7026. The bone screw is then screwed (fig 14a & 14b) through the drill guide until the screw driver bottoms out and is two finger tightened.

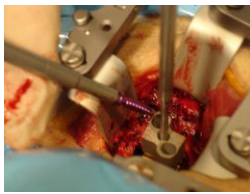


fig. 14a



fig. 14b

The screw driver is removed and the second screw is then placed through the drill guide in the same manner and removed. The Plage Dual Drill Guide Holder with the Dual Drill Guide is also unscrewed and removed. The screw driver is then used for final two finger tightening and locking the bone screw cam mechanism (fig. 15). (See Surgical Technique for the Rhausler Screw Driver C-7025, page 10; or Clocked Screw Driver, page 14)

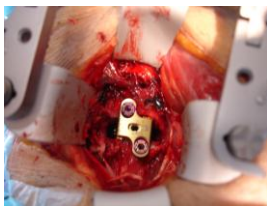


fig. 15

Option #2:

Holder/Impactor Tool, D-3200, and Mallet C-7058

Once the appropriate sized Plage Cervical Implant has been selected, attach the Holder/Impactor Tool D-3200, (fig. 16) to place the Plage in the wound site.



fig. 16

If desired the Mallet (fig. 17) can be used to tap the Holder/Impactor Tool to aid in placement of the Plage implant

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fig. 17

For free hand placement of the self-tapping bone screw and angle, select the Universal Drill Guide, C-7052 (fig. 30) with the associated Universal Twist Drills, 2.0mm, C-7019, C-7034, C-7039, C-7041 & C-7046 (fig. 18) and the Universal Drill Guide Spacer (10, 12, 14, & 16mm heights, fig. 19). The associated spacer (ex. 10mm) is placed on the depth-screw (fig. 20) below the knurled knob and the knurled knob is tightened onto the spacer (see arrow). The Universal Twist Drill is placed in the Universal Drill Guide and the distal tip (fig. 20) is placed in one of the Plages screw holes.

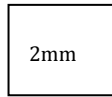


fig. 18

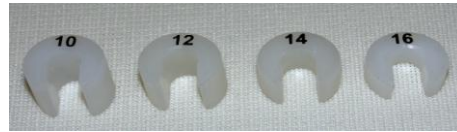


fig. 19

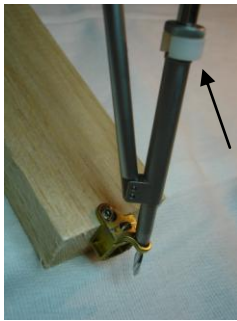


fig. 20

The Universal Twist Drill is then driven either by the Handle for AO Shafts, C-7028, or a 1,000 rpm power drill. Drill until the drill bottoms out into the Plage and use the same technique for the second Plage screw hole. The twist drill is removed and disposed of according to hospital protocol for Single Use Items. Now repeat the same guidelines for bone screw placement and locking.

Option #3:

By selecting a self-drilling, self-tapping bone screw (see fig. 7b), screw placement and screw cam locking can be completed by using the C-7025 One Step Locking Screw Driver, or C-7026 Clocked Screw Driver. **NOTE: Care should be taken if it is deemed that the cortical bone is extremely hard. In that case the 12mm Awl, C-7036 (fig. 21) can be used first to penetrate the cortical bone prior to the screw placement of a self-drilling self-tapping bone screw.**



fig. 21

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Plage Holder/Impactor Tool, D-3200, Plage Holder f/Bone Graft Impacting C-7085 and the Plage Bone Graft Impactor Tool, D-3203.

The Holder f/Bone Graft Impacting is used with the Holder/Impactor Tool. The Holder holds the Plage in place with the Holder/Impactor Tool (fig. 24) while the impactor tool is used to impact the bone inside the Plage prior to implanting (fig. 24a).



fig. 24

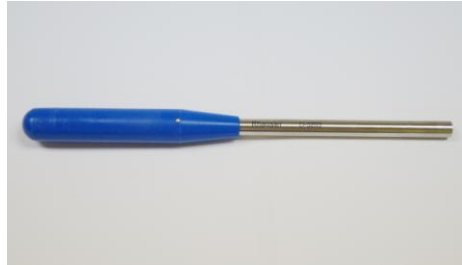


fig. 24a

Plage Slap Hammer, C-7150

The Plage Slap Hammer (fig. 25 & fig. 26) can be attached to the proximal end of the Holder Impactor Tool, Trials and Rasps to assist in their removal from the vertebral body if necessary.



fig. 25



fig. 26

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 Plage in place, the surgeon selects the appropriate twist drill, or Awl for preparing the bone screw pilot holes.

Color Coded Dual Drill Guides

The Color Coded Dual Drill Guides (D-2465 thru D-2780, fig. 27) can be attached to the appropriate color coded Plage Implant using the C-3201 Plage Drill Guide Holder (fig. 28a & 28b).

The SML and STD Plage implants use the 15x14mm Drill Guides (D-2465 thru D-2470) while the LRG Plage implants use the 17x16mm Drill Guides (D-2775 thru D-2780).

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fig. 27

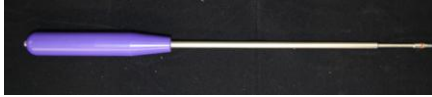


fig. 28a



fig. 28b

The Mallet, C-7058 (see fig. 17), may be used to place the Plage Implant in the desired position. Once the Plage is in position (**Note: this can be confirmed by fluoroscopy**), and the appropriate bone screw has been selected (see fig. 7a, b, & c) using the appropriate length twist drill (fig. 29) attach the twist drill to the AO Handle C-7028 (or 1,000 RPM drill) and place the drill in the drill guide and drill until the stop is reached.



fig. 29

Repeat in the opposite drill guide. The Awl 12mm depth, C-7036 (see fig. 21), can be used instead of the twist drill if desired to break the cortical bone.

Once the holes have been drilled, select the appropriate length **4.0mm Diameter Unicortical Locking Self-Tapping Medical Grade Titanium Alloy Bone Screws (C-6010, C-6012, C-6014, C-6016)**, or **4.0mm Diameter Unicortical Locking Self-Tapping Self-Drilling Medical Grade Titanium Alloy Bone Screws (C-6010, C-6112, C-6114, C-6116)**, and place the screw through the Dual Drill Guide until the screw is firmly in place. Repeat in the second Dual Drill Guide hole. Once screws are in place, remove the Dual Drill Guide by unscrewing the drill guide shaft from the implant. Then engage the One Step Locking Screw Driver C-7025 or Clocked Screw Driver C-7026; and lock the screw locking cam by turning the Locking Screw Drive by turning the locking Mechanism 1/16 of a turn to the right (clockwise, see section **"Surgical Technique for the Rhausler One Step Locking Screw Driver C-7025"** page 10; or **Clocked Screw Driver, C-7026** page 14). You may also finish tightening the bone screws after they are locked. If the Awl is used, it is recommended that you use a Self-Drilling Self-Tapping Bone Screw (see fig. 7b).

Universal Drill Guide

The Universal Single Drill Guide (C-7052) with Nylon Depth Stop Spacers, 10, 12, 14 and 16mm (C-7053) (fig. 30) can be used as a drill guide to vary the bone screw placement angle. Fluoroscopy can be used to verify the correct bone screw angle desired prior to drilling and after placement in the Plage implant.

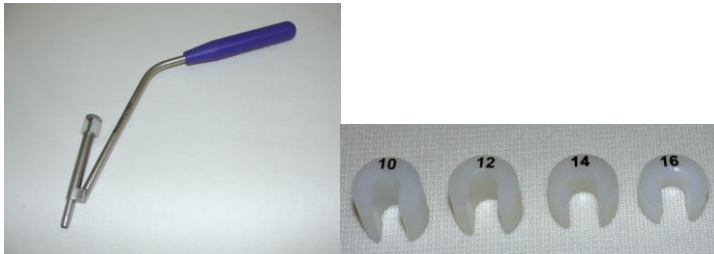


fig. 30

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Adjust the drill guide by placing the nylon depth stop spacer on the guide (fig.31) corresponding to the selected screw length. Next, tighten the adjuster to secure the spacer between the adjuster and the drill guide body.



fig. 31

Surgical Technique for the Rhausler One Step Locking Screw Driver C-7025

Here are important steps to **avoid complications** when using the C-7025 One Step Locking Screw Driver;

Loading the Bone Screws

- Prior to loading the Screw Driver, be sure, that the outer locking mechanism is pulled up flush to the handle (fig. 32).

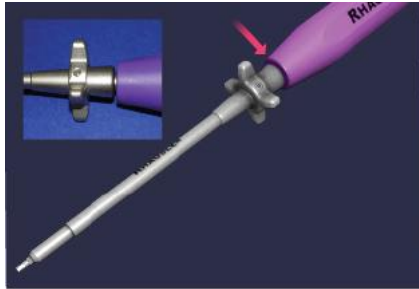


fig. 32

When engaging the Bone Screws in the screw caddy, bring the hex end of the Screw Driver to the selected Bone Screw at a 45 Degree angle while holding the back end of the handle with one hand (fig. 33)

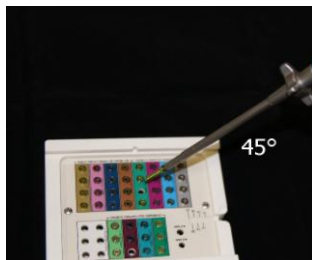


fig. 33

- Rotate the Driver to a perpendicular position (straight up) and rotate the handle while pushing down lightly

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to engage the hex in the screw (fig. 34).

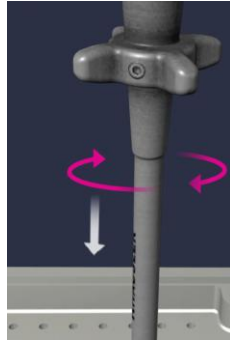


fig. 34

- Be sure that the hex of the Driver is fully engaged into the Bone Screw (fig. 35).

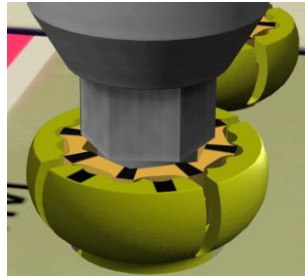


fig. 35

- Once fully engaged, use your free hand to engage the locking mechanism into the Bone Screws Locking Cam. This is achieved by lightly pushing down and rotating the 4-pronged wheel (fig.36a) until the hex of this outer locking mechanism is fully engaged into the hex of the Bone Screw Locking Cam (fig. 36b).

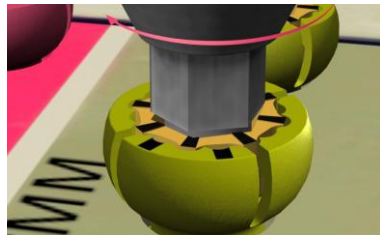


fig. 36a

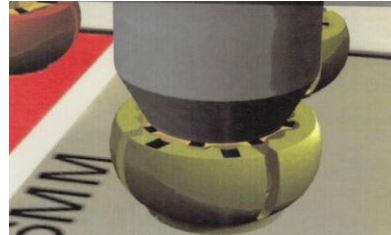


fig. 36b

- The Screw Driver is now ready to be passed to the surgeon.

Re-engaging the Screw Driver

When the surgeon re-engages the Screw Driver back into the Bone Screw, which has been already placed into the Plage ready for final tightening and locking, there are a few steps to keep in mind.

- It can be difficult to re-engage the screw driver 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 Retractor arms or any instruments placed in the wound do not interfere when attempting to place the Screw Driver into the Bone Screw. Any sideward pressure will cause the screw driver **NOT** to cleanly engage the Bone Screw. If any part of the Retractor is interfering with the Screw Driver placement you **MUST** hold the retractor away from touching or anyway interfering with the Screw Driver shaft.

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- Once the Screw Driver 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, and once fully engaged the Locking Mechanism needs to be rotated clockwise 1/16th of a turn to lock the Screw Bone in place. **Note: At least 1/3 of the bone screw head (depending on the angle of placement) must be past the top of the plate's screw hole ridge and not fully tightened into the bottom of the Plage *PRIOR* to engaging the locking cam. Once the cam is locked, you can further tighten the bone screw into the Plage.**

There are three (3) methods to confirm that the Locking Cam locked.

- FIRST, the surgeon will feel a tactile click once the Locking Shaft is rotated 1/16th of a turn (usually hears a click as well).
- The SECOND is that the black dashes on the Cam no longer line up with the four cuts in the head of the Bone Screw (fig. 37).



- The THIRD is to use a small probe or dissector, push side to side on the cam ring and, if there is no movement of the cam ring, the Bone Screw is locked.

The removal of the Screw Driver

It can be difficult to disengage the Screw Driver from the Bone Screw after Bone Screw placement or Locking of the Bone Screw unless the following steps are taken.

Be sure that there are **NOT** any instruments, such as the muscle/tissue Retractors, placing any lateral pressure on the Screw Driver shaft. The Screw Driver must be pulled straight out from the bone screw.

If the surgeon is having difficulty removing the Screw Driver from the Bone Screw, it is usually because there are instruments such as the Retractor Frame placing side/lateral pressure on the Screw Driver shaft, or the surgeon has a full hand grasp of the Screw Driver handle and is trying to force the release by pulling up hard. This has a negative effect because the surgeon may be applying a lateral twisting motion which will NOT allow the release of the Screw Driver from the screw. Ask the surgeon to release their grip of the Screw Driver. The Screw Driver will stand up on its own, which indicates that it is engaged into the bone Screw. Have the surgeon gently hold the end of the handle with a thumb and two finger grip. Then gently wiggle and pull straight up to disengage the Screw Driver from the Bone Screw.

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Bone Screw removal tool C-7031

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.38).



fig. 38

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 and turned **counterclockwise**, backing out the bone Screw. Once the bone Screw is removed, the bone screw must be properly discarded.

4.5mm Diameter Unicortical Locking Self Tapping Oversized Medical Grade Titanium Alloy Bone Screws (C-6210, C-6212, C-6214, C-6216)

In the event a hole becomes stripped, an oversized 4.5mm Diameter Unicortical Locking Self-Tapping Oversized Medical Grade Titanium Alloy Bone Screw, (see fig. 7-C) may be utilized to insure adequate cervical Plage compression. Oversized bone screws are available in 10, 12, 14, and 16mm lengths.

Note: the 4.5mm bone screw is slightly larger than the Plage implant screw holes and must be screwed through the hole of the Plage when used.

Cervical Plage Removal

With the cervical vertebral column section containing the Plage clearly exposed with a cervical self-retaining soft tissue retractor, use the Self-Retaining One-Step Locking Screwdriver (C-7025) to unlock the screw locking mechanism by a 1/16 rotation counterclockwise (see section "**Surgical Technique for the Rhausler Self-Retaining One-Step Locking Screw Driver C-7025**" page 10). Remove each bone screw using C-7025 by turning the bone screw counterclockwise until the bone screw is completely disengaged from the vertebral body and Plage.

Repeat this for the remaining bone screw and properly dispose of the bone screws and Plage when completed. If the bone screw cannot be removed using the Self-Retaining One-Step Locking Screwdriver (C-7025) or Clocked Screw Driver C-7026, a Screw Extractor Tool (C-7031) is used (see fig. 38). 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 and turned counterclockwise, backing out the bone screw.

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Inservice for Surgeons on the proper use of the Rhausler Clocked Screw Driver C-7026

Here are important steps to know prior to using the C-7026 Clocked Screw Driver

LOADING AND ENGAGING THE BONE SCREW

Step 1

- Prior to loading the bone screw on to the Screw Driver, be sure that the outer locking mechanism is pulled up to the handle until the pin stop (fig 1)

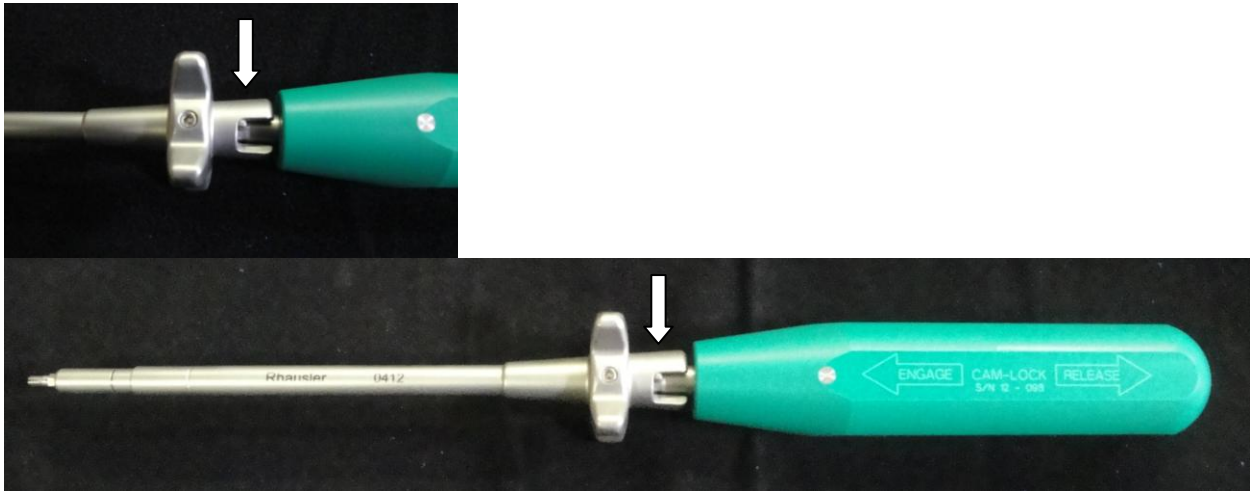


fig 1

Step 2

- When engaging the Bone Screws in the screw caddy, bring the hex end of the Screw Driver to the selected Bone Screw (C-6010 thru C-6216) at a 45 Degree angle while holding the back end of the handle with one hand (fig. 2)

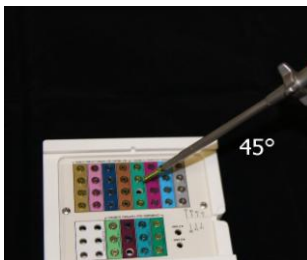


fig 2

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Step 3

- With a small back and forth motion (clockwise –counterclockwise motion), rotate the Screw Driver while bringing the screw driver to a perpendicular position (straight up) and pushing down lightly to guide the engagement of the inner hex in to the head of the bone screw (fig. 3).



fig. 3

Step 4

- Be sure that the inner hex portion of the Clocked Screw Driver is fully engaged into the Bone Screw (fig.4) and seated to a hard stop.

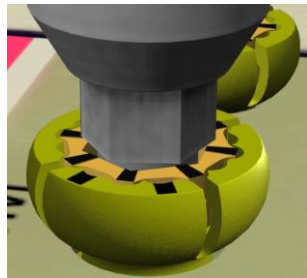


fig. 4

Step 5

- Use your free hand to engage the outer screw shaft hex of the Clocked Screw Driver into the screw cam. This is achieved by lightly pushing down and slightly rotating back and forth (clockwise –counterclockwise motion) the 4-pronged wheel (fig.5a) until the hex of this outer locking mechanism is fully engaged into the hex of the Bone Screw Locking Cam (fig. 5b) to a hard stop.

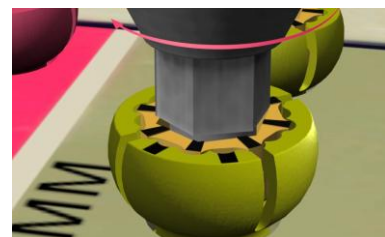


fig. 5a

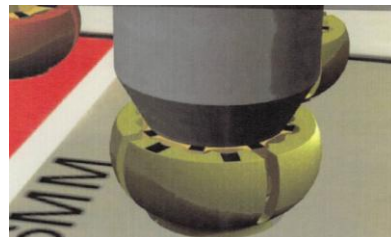


fig. 5b

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Step 6

- Using a motion perpendicular to the plane of the top of the screw caddy, pull the clocked screw driver with the attached screw and engaged cam straight up from the Caddy. The screw is now engaged in the clocked screw driver ready for insertion to the Plage and the locking cam mechanism is also engaged and ready to lock the screw (fig 6).

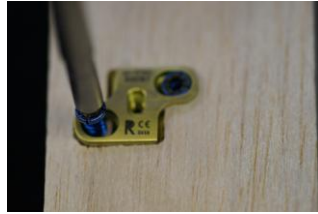


fig 6

Step 7

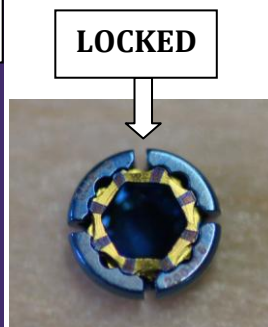
- Once the head of the screw is in the groove of the Plage tab, the 4 prong portion of the outer Locking Mechanism near the handle is rotated to the right (clockwise rotation as sighted down the screw driver shaft) until an audible "click" is heard and/or a lessening of rotation force is noted as verification of the cam moving into a LOCKED position. It is not always necessary to go all the way to the mechanical stop. (The C-7026 Clocked Screwdriver is designed to lock at $1/16$ of a full circle ($\{360 \text{ degrees}\}/16 = 22.5 \text{ degrees}$). (fig 7)



fig 7

Step 8

- Disengage the clocked screw driver by pulling straight out of the screw (coaxial with the trajectory of the screw) upwards with the screwdriver handle (see fig 1). This straight upward pull disengages both the inner hex in the screw and the outer hex in the cam. Bone Screw cam will now be in the locked position (see fig 8)



Locked position fig 8

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- You can confirm that the Locking Cam is locked with these three (3) methods:
 - FIRST, an audible and tactile click is noticed when the outer Locking Shaft of the clocked screw driver is rotated 1/16th (22.5 degrees) of a full turn at the time of locking.
 - SECOND once the clocked screw driver is removed the black dashes on the Cam are noted to no longer line up with the four cuts in the head of the Bone Screw (fig. 9).



fig. 9

THIRD the cam is firmly fixated in position. This firm fixation is verified with the use of a small probe, sucker or dissector, placed inside the cam and attempting to push the cam side to side. Lack of movement verifies that the cam is in the locked position in the screw head.

UNLOCKING AND DISENGAGING THE BONE SCREW

Begin following Steps 3-5 above

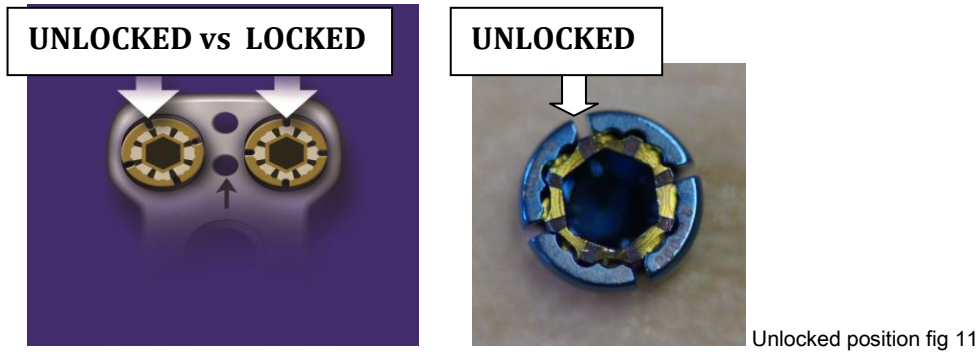
- Once engaged, rotate 1/16th (22.5 degrees) of a full turn the locking mechanism wheel to the left (clockwise rotation as sighted down the screw driver shaft) until you hear or feel the cam click into the UNLOCKED position. It is not always necessary to go all the way to the mechanical stop. C-7026 Clocked Screwdriver is designed to lock at 1/16 of a full circle ($\{360 \text{ degrees}\}/16 = 22.5 \text{ degrees}$). (fig 10)



fig 10

- Disengage the locking mechanism wheel by pulling the wheel up to the screwdriver handle until the pin stop (see fig 1). Then with a straight upward pull, disengage the screwdriver from the bone screw. Bone Screw cam will now be in the unlocked position (see fig 11)

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Rhausler Bone Screw Insertion Instructions

Step by Step – the bone screw insertion and cam locking is one action on a screw-by-screw basis. It is not necessary to insert all bone screws and then return to lock all bone screws as with most other systems.

- 1) Surgeon gets the desired bone screw in the UNLOCKED position with both the central hex fully engaged and the cam locking mechanism (outer sleeve) inserted into the cam.
- 2) Surgeon inserts the bone screw into the groove (screw hole) in the Dynamic, Semiconstrained or QuickPlate plates or PLAGE with visual identification that the widest part of the bone screw head is in the groove. At this point the 4 pedals in the unlocked position will have moved in slightly and then returned to the unstressed and neutral position in the groove. The surgeon on advancing the bone screw cannot feel this slight movement of the pedals. The bone screw head is specifically not tightened to the bone at this point.
- 3) Surgeon now LOCKS the cam in the bone screw in the groove in an “untightened” to the bone position. The bone screws are dynamic in the slots and can freely slide and rotate in the slots. A common misconception is that the cam lock expands the pedals of the bone screw head. The cam lock only holds the bone screw head pedals in the neutral position and it is the shape of the groove that “locks” the bone screw in the groove as the cam prevents the pedals from the inward movement necessary to come out of the groove. If the bone screws are mechanically tightened to the bone before the locking cam is moved into the locked position, then the force needed to lock is greatly increased and may exceed the force that the “clocked” tightener can apply. Slightly unscrewing this bone screw by a fraction of a turn removes the bone tightening force on the bone screw head, which removes the distortion of the bone screw head pedals, and allows the locking cam to be moved to the locked position easier.
- 4) All the bone screws of the construct are placed in a like manner.
- 5) Once all the bone screws are placed and locked in the slot, they are sequentially tightened to the bone for final tightening using only the inner hex. The bone screw heads are “locked” in the plate groove but can freely turn in these slots. This turning does not affect the locking mechanism.

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Additional tips:

- 1) If the cam locking mechanism of the screwdriver becomes disengaged from the bone screw head and the bone screw is inserted into the slot and then tightened, the bone screw head pedals can become slightly distorted making the reengagement of the cam locking part of the insertion screwdriver into the cam difficult or impossible. The bone screw can be loosened slightly to leave the screw head in the groove to lessen the bone screw pedal distortion, and then insert the cam locking mechanism. If necessary you can change out the bone screw.
- 2) If the screwdriver is removed from the bone screw head in the wound, the easiest way to reestablish the bone screw hex and the cam locking mechanism is to:
 - a. Disassemble the screwdriver by pulling off the outer cam locking mechanism from the screwdriver body.
 - b. Insert the cam locking mechanism into the bone screw cam, apart from the screwdriver body. Once inserted the cam locking mechanism will stand on its own.
 - c. Insert the body of the screwdriver hex through the engaged cam locking mechanism and rotate until it goes into the hex of the bone screw. The screwdriver and the cam locking mechanism are engaged to lock the cam and to tighten the bone screw to the bone.
- 3) To avoid the scrub nurse/tech from passing a locked bone screw to the surgeon, the scrub nurse/tech needs to load the bone screw from the bone screw caddy. The screwdriver outer cam locking mechanism needs to be pulled up tight toward the handle. Then bring in the screwdriver at a 45 degree to the caddy to engage the bone screw hex. Once the hex of the screwdriver is on top of the bone screw hex, while bringing the screwdriver up to a perpendicular position, slightly rotate the screwdriver with downward pressure to fully engage the bone screw hex. Once the hex of the screwdriver is engaged into the bone screw now rotate with downward pressure the outer cam locking mechanism. Once the cam locking mechanism is engaged in the cam the bone screw is now ready to be removed from the caddy by pulling the screwdriver straight up from the caddy.

Note: The scrub nurse/tech should be specifically instructed to engage the hex of the screwdriver and to engage the cam locking mechanism into the cam and NOT to rotate the cam locking mechanism so that the cam is turned to the locked position or to force the screwdriver hex and locking sleeve into the bone screws. When loading the screwdriver, it must be placed at a 45-degree angle at the top of the bone screw hex and then raised into a perpendicular position while gently pushing the hex of the bone screwdriver into the bone screw hex. Once in place the outer cam-locking sleeve should be advanced into the cam of the bone screw. Once in place the bone screw can be removed for placement into the cervical implant.

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PRODUCTS:

Item #	Product Description	QTY
	SET #1	
C-7091	Plage Implant and Instrument Sterilization Tray	1
C-7086	Plage Implant Caddy, 15mmx14mm STD	1
C-7087	Plage Implant Caddy, 17mmx16mm LRG	1
C-7088	Plage Bone Screw Caddy	1
	Plage Cervical Implant (Depth x Width x Height)	
D-1165	Plage, Lordotic 13x14x5mm, Silver, 0 Deg. SML	2
D-1166	Plage, Lordotic 13x14x6mm, Blue, 0 Deg. SML	2
D-1167	Plage, Lordotic 13x14x7mm, Copper, 0 Deg. SML	2
D-1168	Plage, Lordotic 13x14x8mm, Green, 0 Deg. SML	2
D-1169	Plage, Lordotic 13x14x9mm, Violet, 0 Deg. SML	2
D-1170	Plage, Lordotic 13x14x10mm, Gold, 0 Deg. SML	2
D-1465	Plage, Lordotic 15x14x5mm, Silver, 0 Deg., STD	2
D-1466	Plage, Lordotic 15x14x6mm, Blue, 0 Deg., STD	2
D-1467	Plage, Lordotic 15x14x7mm, Copper, 0 Deg., STD	2
D-1468	Plage, Lordotic 15x14x8mm, Green, 0 Deg., STD	2
D-1469	Plage, Lordotic 15x14x9mm, Violet, 0 Deg., STD	2
D-1470	Plage, Lordotic 15x14x10mm, Gold, 0 Deg., STD	2
D-1775	Plage, Lordotic 17x16x5mm, Silver, 0 Deg., LRG	2
D-1776	Plage, Lordotic 17x16x6mm, Blue, 0 Deg., LRG	2
D-1777	Plage, Lordotic 17x16x7mm, Copper, 0 Deg., LRG	2
D-1778	Plage, Lordotic 17x16x8mm, Green, 0 Deg., LRG	2
D-1779	Plage, Lordotic 17x16x9mm, Violet, 0 Deg., LRG	2
D-1780	Plage, Lordotic 17x16x10mm, Gold, 0 Deg., LRG	2
	Bone Screws	
C-6010	4.0x10mm Ti Self-Tapping Screw, Silver	4
C-6012	4.0x12mm Ti Self-Tapping Bone Screw, Light Blue	4
C-6014	4.0x14mm Ti Self-Tapping Bone Screw, Magenta	4
C-6016	4.0x16mm Ti Self-Tapping Bone Screw, Light Green	4
C-6110	4.0x10mm Ti Self Drilling Self-Tapping Screw, Copper	4
C-6112	4.0x12mm Ti Self-Drilling Self-Tap. Bone Screw, Dark Blue	4
C-6114	4.0x14mm Ti Self-Drilling Self-Tap. Bone Screw, Pink	4
C-6116	4.0x16mm Ti Self-Drilling Self-Tap. Bone Screw, Gold	4
C-6210	4.5x10mm Ti Oversized Self-Tapping Screw, Green	3
C-6212	4.5x12mm Ti Oversized Self-Tapping Bone Screw, Teal	3
C-6214	4.5x14mm Ti Oversized Self-Tapping Bone Screw, Grape	3
C-6216	4.5x16mm Ti Oversized Self-Tapping Bone Screw, Sea Foam Green	3
	Single Use Only	
C-7019	2.0x10mm Twist Drill, Single Use Only	1
C-7034	2.0x14mm Twist Drill, Single Use Only	1
C-7039	2.0x12mm Twist Drill, Single Use Only	1
C-7041	2.0x16mm Twist Drill, Single Use Only	1
C-7031	Bone Screw Removal Tool, Single Use Only	1
C-7046	2.0mm Universal Twist Drill, Single Use Only	1

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	Plage Drill Guides (Depth x Width x Height)	
D-2465	Plage, Dual Drill Guide 14x5mm, Silver, w/ Handle SML & STD, 0 and 6 Deg	1
D-2466	Plage, Dual Drill Guide 14x6mm, Blue, SML & STD, 0 and 6 Deg	1
D-2467	Plage, Dual Drill Guide 14x7mm, Copper, SML & STD, 0 and 6 Deg	1
D-2468	Plage, Dual Drill Guide 14x8mm, Green, SML & STD, 0 and 6 Deg	1
D-2469	Plage, Dual Drill Guide 14x9mm, Violet, SML & STD, 0 and 6 Deg	1
D-2470	Plage, Dual Drill Guide 14x10mm, Gold, SML & STD, 0 and 6 Deg	1
D-2775	Plage, Dual Drill Guide 16x5mm, Silver, 0 Deg. LRG	1
D-2776	Plage, Dual Drill Guide 16x6mm, Blue, 0 Deg. LRG	1
D-2777	Plage, Dual Drill Guide 16x7mm, Copper, 0 Deg. LRG	1
D-2778	Plage, Dual Drill Guide 16x8mm, Green, 0 Deg. LRG	1
D-2779	Plage, Dual Drill Guide 16x9mm, Violet, 0 Deg. LRG	1
D-2780	Plage, Dual Drill Guide 16x10mm, Gold, 0 Deg. LRG	1
	Instruments	
D-3200	Holder/Impactor Tool	1
D-3201	Plage Drill Guide Holder	2
D-3203	Plage Bone Graft Impactor Tool	1
C-7052	Universal Drill Guide	1
C-7053	Universal Drill Guide, Spacers 10, 12, 14, and 16mm	2
C-7025	Locking Screw Driver	2
C-7026	Clocked Screw Driver	2
C-7028	Handle for AO Shafts	1
C-7036	Awl, 12mm	1
C-7058	Mallet	1
C-7085	Packing Block f/Plage Implants	1
C-7086	Plage Implant Caddy 15X14mm STD	1
C-7087	Plage Implant Caddy 17X16mm LRG	1
C-7088	Plage Bone Screw Caddy	1
	SET #2	
C-7092	Plage Trial and Rasp Sterilization Tray	1
	Rasps (Depth x Width x Height)	
D-3000	Serrated Rasp 15x14x4.5mm, Silver, STD	1
D-3001	Serrated Rasp 15x14x5.5mm, Blue, STD	1
D-3002	Serrated Rasp 15x14x6.5mm, Copper (Red), STD	1
D-3003	Serrated Rasp 15x14x7.5mm, Green, STD	1
D-3004	Serrated Rasp 15x14x8.5mm, Violet, STD	1
D-3005	Serrated Rasp 15x14x9.5mm, Gold, STD	1
D-3010	Serrated Rasp 17x16x4.5mm, Silver, LRG	1
D-3011	Serrated Rasp 17x16x5.5mm, Blue, LRG	1
D-3012	Serrated Rasp 17x16x6.5mm, Copper (Red), LRG	1
D-3013	Serrated Rasp 17x16x7.5mm, Green, LRG	1
D-3014	Serrated Rasp 17x16x8.5mm, Violet, LRG	1
D-3015	Serrated Rasp 17x16x9.5mm, Gold, LRG	1
	Trials (Depth x Width x Height)	
D-3100	Trial 15x14x5mm, Silver, STD	1
D-3101	Trial 15x14x6mm, Blue, STD	1
D-3102	Trial 15x14x7mm, Copper (Red), STD	1
D-3103	Trial 15x14x8mm, Green, STD	1

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D-3104	Trial 15x14x9mm, Violet, STD	1
D-3105	Trial 15x14x10mm, Gold, STD	1
D-3110	Trial 17x16x5mm, Silver, LRG	1
D-3111	Trial 17x16x6mm, Blue, LRG	1
D-3112	Trial 17x16x7mm, Copper (Red), LRG	1
D-3113	Trial 17x16x8mm, Green, LRG	1
D-3114	Trial 17x16x9mm, Violet, LRG	1
D-3115	Trial 17x16x10mm, Gold, LRG	1
C-7150	Slap Hammer	1

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Rhausler Instrument Sets are Patented



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

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