Designed for maximum bone purchase with cam-locking screw head design restricting backing out post-implantation



Selection and Loading

Section 1: Bone Screw Selection and Loading



Bone Screw Selection

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

Bone Screw Loading

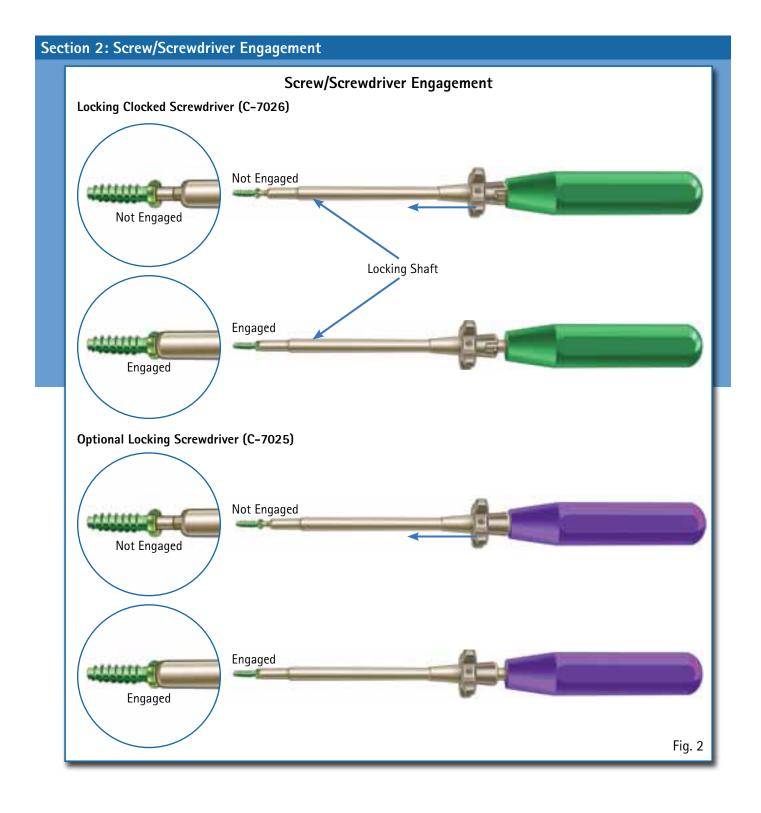
Here are important steps to avoid complications when using the (C-7025/C-7026) Locking Clocked Screwdriver.

 Prior to loading the Screwdriver, be sure that the outer locking mechanism is pulled up flush to the handle

- When engaging the bone screws in the screw caddy, 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. 27)
- Rotate the Driver to a perpendicular position (straight up) and rotate the handle while pushing down lightly to engage the hex in the screw
 - Be sure that the hex of the Driver is fully engaged into the bone screw
- Slide the outer locking shaft down until it seats flush on the bone screw. A slight twist of the shaft may be required to fully seal.

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Screw/Screwdriver Engagement



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Screw Locking

Section 3: Rhausler Bone Screw Locking

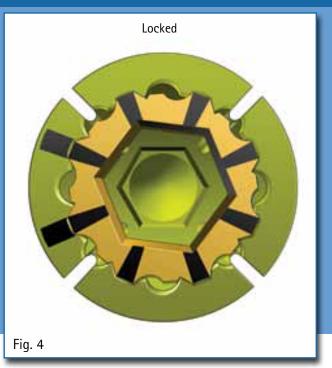


• Once fully engaged, use your free hand to engage the locking mechanism into the bone screws Locking Cam. This is achieved by lightly pushing down and rotating the 4-pronged wheel until the hex of this outer locking mechanism is fully engaged into the hex of the screw Locking Cam.

Re-engaging the Screwdriver

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

■ It can be 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 Retractor arms or any instruments placed in the wound do not interfere when attempting to place the Screwdriver into the bone screw. Any sideward 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 or in any way 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 and once fully engaged, the Locking Mechanism needs to be rotated clockwise 1/16th of a turn to lock the bone screw 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 implant PRIOR to engaging the locking cam. Once the cam is locked, you can further tighten the bone screw into the implant.

There are three (3) confirmations to confirm 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 hears a click as well).
- The SECOND is the black dashes on the Cam no longer line up with the four cuts in the head of the screw.
- 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.

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Removal Technique

Section 4: Implant Removal



Cervical PLAGE Removal

With the cervical vertebral column section containing the PLAGE implant being clearly exposed using a cervical soft tissue retractor, use the Locking Clocked Screwdriver (C-7025/C-7026) to unlock the bone screw locking mechanism by a 1/16 rotation counterclockwise (see section "Technique Self-Retaining One-Step Locking Screwdriver"). Remove each bone screw using the screwdriver by turning the bone screw counterclockwise until the bone screw is completely disengaged from the vertebral body and implant.

Repeat this for the remaining bone screw and properly dispose of the bone screws and implant when completed. If the bone screw cannot be removed using the Self-Retaining One-Step Locking Screwdriver, a Screw Extractor Tool is used. The Screw Extraction Tool is loaded into the Handle for AO Shafts and the distal tip is placed into the center of the bone screw and turned counterclockwise, backing out the bone screw.

Bone Screw Extraction Tool (C-7031)

If the bone screw cannot be removed using the Locking Clocked Screwdriver (C-7026), a Screw Extraction Tool (C-7031) is used.

The screw Extraction Tool is loaded in to the Handle for AO Shafts (C-7028), and the distal tip is placed in to 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.

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- The locked Rhausler Cam prevents expulsion of the screw from the slot
- A Rhausler Screw with a locked cam is still free to slide, angulate and rotate in the slot

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