ABC2

Anterior Cervical Plating System Surgical Technique

Aesculap Spine

AESCULAP®
Implant Systems

ABC2

Anterior Cervical Plating System Surgical Technique

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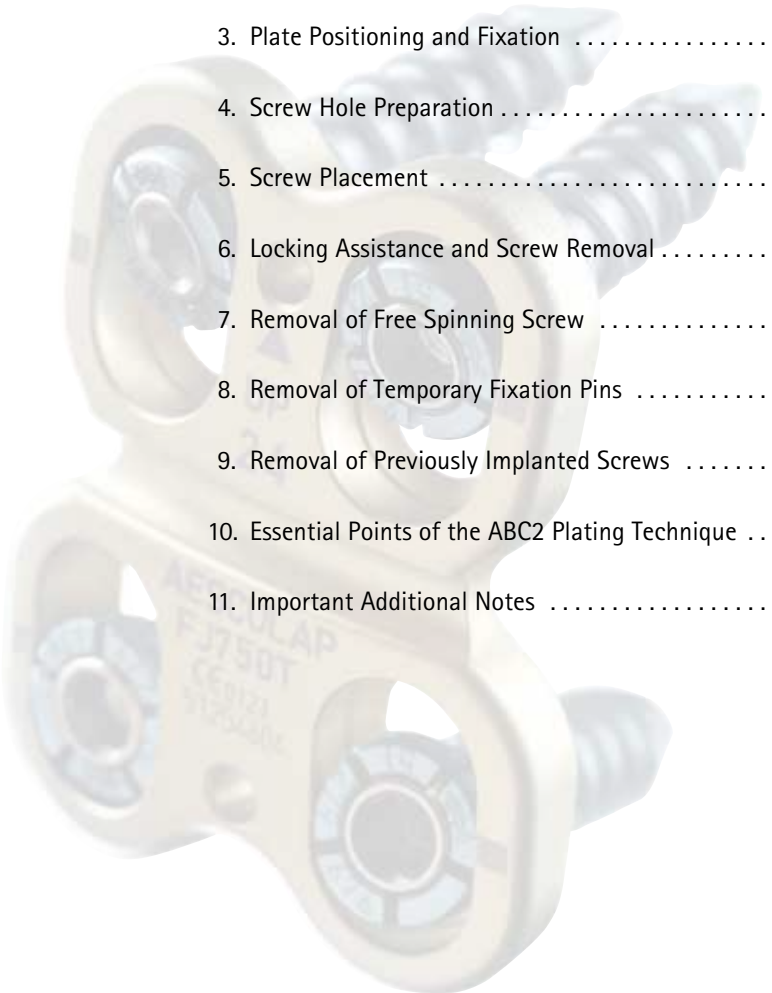
As described by Ronald I. Apfelbaum, M.D.



I. Indications for Use, Contraindications, Warnings and Cautions

Indications for Use

The ABC2 Cervical Plating System is intended for the treatment of cervical spine instability resulting from:

- Degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic
- Trauma (including fractures)
- Tumors
- Posttraumatic kyphosis or lordosis
- Revision operations necessitated by a failed previous fusion

Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

CAUTION

Federal law restricts this device to sale by or on order of a physician!

Indications for use

The ABC Cervical Plating System is intended for the treatment of cervical spine instability resulting from

- Degenerative disc disease (i.e. discogenic pain with degenerated discs, confirmed by evidence from the patient history and by radiographic procedures)
- Trauma (including fractures)
- Posttraumatic kyphosis or lordosis
- Tumors
- Revision operations necessitated by a failed previous fusion.

Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

WARNING

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

System Components

- Bone plate
  - for monosegmental provision, plate length 20—32 mm
  - for multisegmental/bisegmental provision, plate length 34—115 mm
- Bone screws
  - bicortical, 10—28 mm long, 4.0 mm (blue)
  - monocortical, 10—18 mm long, 4.0 mm, self-locking (turquoise)
  - Revision screws, 13—17 mm long, 4.5 mm, self-locking (pink)

Materials

- ISOTAN®F titanium forged alloy Ti6Al4V according to ISO 5832-3
- Phynox® cobalt alloy to ISO 5832-7

The titanium implants are coated with a colored oxide. Slight color changes can occur, but will not have any bearing on the quality of the implant.

ISOTAN®F is a registered trademark of Aesculap AG & Co. KG, 78532 Tuttlingen / Germany.

Phynox® is a registered trademark of Imphy S.A., Paris / France.

Contraindications

Do not apply in the presence of:

- Fever
- Infection:
  - systemic
  - in the spine
  - local
- Pregnancy
- Medical or surgical conditions that could negatively affect the success of the implantation
- Foreign body sensitivity to the implant materials
- Acute osteopenia
- Severe osteoporosis or similar loss of bone density
- Severe damage to the osseous structures preventing the fixation of implant components
- Systemic or metabolic diseases
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- Morbid obesity (adiposity)
- Generally poor condition of the patient
- Inadequate patient compliance
- Cases not listed under indications

Side-effects or Adverse Interactions

- Implant failure resulting from excessive load
  - warping or bending
  - loosening
  - breakage
  - inadequate fixation
  - absence of, or delayed, fusion
  - infection
  - fractured vertebral body or bodies
- Injuries to
  - nerve roots
  - spinal cord
  - blood vessels
  - organs
- Neurological complications due to overdistraction
- Injuries to nerves or vessels
- Loss of disc height due to the removal of load-bearing bone material
- Pseudarthrosis
- Bone graft resorption
- Spondylolisthesis
- Tissue reaction to the implant materials
- Bone atrophy or diminished bone density
- Decreased joint mobility and flexibility
- Arthralgia and decreased tolerance for exercise

Safety Information

- It is the operating surgeon's responsibility to ensure that the operative procedure is performed properly.
- General risks of any surgical intervention are not referred to in these instruction for use.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- Aesculap is not responsible for any complications arising from incorrect

I. Indications for Use, Contraindications, Warnings and Cautions *(continued)*

diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

- The instructions for use of the individual Aesculap implant components must be observed.
- Modular implant components by different manufacturers must not be combined.
- Under no circumstances should damaged components or surgically excised components be used.
- Implants that have already been used must not be reused.
- It is the operating surgeon's responsibility to ensure the correct combination of implant components and their implantation.
- Delayed healing can cause implant components to fracture as a result of metal fatigue.
- The physician in charge decides whether an implant component implanted should be removed, taking into account the potential risks of another surgery and the difficulties involved in the removal of an implant.
- The implant components applied, along with their article numbers, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- Postoperative care should include, apart from motoric and muscle exercise, the individual information of the patient.
- Damage to the force-transmitting bone structures can lead to the loosening of components and bone or implant structures and to other severe complications.
- In order to promote the earliest possible detection of any problems or complications, the surgery's results must be followed up at regular intervals with the aid of appropriate examination procedures.
- A precise diagnosis requires x-rays taken in the directions anterior-posterior and medial-lateral.

Sterility

- The implant components are supplied in an unsterile condition.
- The implant components are delivered in an individual packaging.

For Implant Components in Original Packaging:

➢ Store the implant components in their original packaging and only remove them from their original and protective packaging immediately prior to application.

➢ Use implant system storage trays for sterilization and sterile setup.

➢ Make certain that the implant components in their implant system storage trays will not get into contact with each other or with instruments.

➢ Make certain that the implant components will not be damaged under any circumstances.

For implant components to be resterilized:

WARNING

Intraoperative contamination with blood, secretions and other fluids may render the affected component unsuitable for resterilization!

➢ Implants that come in contact with bodily tissue can not be resterilized.

➢ Handle the implants with new gloves only.

➢ Keep the implant system storage trays covered or closed.

➢ Put away implant system storage trays separately from instrument trays.

➢ If implant system storage trays are not available, reprocess implant components individually and separately. When doing this, make certain that the implant components do not get damaged.

➢ Mechanically clean and disinfect the implant components.

➢ Carry out the final rinse with distilled, demineralized or fully desalinated water.

➢ Always observe the current hospital guidelines concerning the supply of sterile materials.

Sterilization Method and Parameters

Note

Observe all relevant national regulations and standards concerning reprocessing.

Note

For patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of the products.

Note

Up-to-date information on reprocessing can be found on the Aesculap Extranet at www.aesculap-extra.net

➢ Sterilize with steam, taking note of the following:
The sterilization has to be done according to a validated steam sterilization procedure (e.g. in a sterilizer according to EN285/ANSI/AAMI/ISO11134-1993, ANSI/AAMI ST46-1993 and validated according to EN ISO 17665 or EN 554/ISO 13683). In case of application of the fractionated vacuum procedure the sterilization has to be done using the 134 °C/2 bar program with a minimal holding time of 5 minutes

Sterilization for the US Market

- Sterilization of the implant may be accomplished by steam.
- Aesculap does not recommend the implant be sterilized by "Flash" or chemical sterilization.

I. Indications for Use, Contraindications, Warnings and Cautions *(continued)*

The Recommended Sterilization Parameters are as Follows

		Minimum Exposure Time	
Sterilization Method	Temp.	Wrapped	In a Sterile Container System
Pre-vacuum	270–275°F	4 min	4 min

Application

The operating surgeon shall devise an operation plan that specifies and accurately documents the following:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bones
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite implant components must be ready to hand
- Operating conditions must be highly aseptic
- Implantation instruments including the special Aesculap implant system instruments are complete and in working condition
- The operating surgeon and operation team are familiar with information on the operation technique, the implant set and the instrument set; information materials are complete and are ready to hand
- The operating surgeon possesses detailed knowledge on cervical-spine stabilization and the biomechanical principles of the cervical spine
- The operating surgeon is familiar with the rules of medical practice, current scientific knowledge and the contents of relevant publications by medical authors
- Information was obtained from the manufacturers in case of an ambiguous preoperative situation and if implants are present in the area to be provided for

The operative procedure has been explained to the patient, and the latter's understanding of the following information has been documented:

- The patient is aware of the risks with regard to neurosurgery, general surgery, orthopedics and general anesthesia.
- The patient has been informed of the advantages and drawbacks of implants and has been made aware of possible alternative methods of treatment.
- Delayed or failed bone union can cause breakage and loosening of implants under high load.
- The service life of the implants depends on the patient's body weight.
- The implant components must not be put under strain through extreme exertion, hard physical labor and sports activities.
- In cases of implant loosening, implant breakage and loss of correction, revision surgery may become necessary.
- The patient must undergo medical check-ups of the implant components at regular intervals.

The implantation of the ABC system requires the following steps:

- ➢ Only use ABC instruments provided by Aesculap.
- ➢ Follow the instructions for use of the ABC instruments, the instructions for use of the fixation pins and the O.R. manual.
- ➢ Select implant components according to indication, preoperative planning and the bone situation found intraoperatively.
- ➢ Be sure that stainless steel and titanium components are not combined in one spinal construct.
- ➢ To avoid internal stress on, and weakening of, the implant: avoid scoring or scratching of the implant components.
- ➢ Select the length of the ABC plate according to the following criteria:
  - as short as possible
  - enclosing the area to be fixed
  - allowing for axial settling

Note

Line markings on the ABC plate help in selecting the correct plate length. The lines at the cranial or caudal end of the plate mark the position of the caudal or cranial vertebral body end plate, respectively, of the vertebra in which the screw is to be fixated.

Note

The final determination of the implant length mostly takes place during the operation. The curvature of the ABC plates can be adapted to circumstances or the intended curvature of the spine, respectively.

Note

With long ABC plates, bending should be carried out in steps (bending zone by bending zone) in order to avoid excessive or insufficient lordosation.

WARNING

Damage to, and breakage of, the ABC plate caused by excessive strain on the material.

- ➢ Always bend the ABC plate in one direction only.
- ➢ Do not bend back the ABC plate.
- ➢ Always use the plate bender to bend an ABC plate.
- ➢ Always bend the ABC plate longitudinally and within the bending zone only.
- ➢ Avoid small bending radii, bending back and notching or scratching of the ABC plate.

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I. Indications for Use, Contraindications, Warnings and Cautions *(continued)*

The various types of ABC screws are color-coded:

- Blue = 4.0 mm bicortical
- Turquoise = 4.0 mm monocortical, self-locking
- Pink = 4.5 mm revision screw, self-locking

➢ Select ABC screws for correct type and length.

➢ Check the length of the ABC screw.

➢ To facilitate the intraoperative handling, temporarily fix the ABC plate on the vertebral bodies by means of a fixation pin (through the pinholes on the central line). This prevents the ABC plate from slipping out of place during the drilling procedure, and it allows an easier positioning of the drill holes and insertion of the ABC screws.

➢ Prepare the holes for the ABC screws using ABC drill guides and ABC drills (2.7 mm diameter) or ABC bone awl only. Make sure during this procedure that

– the ABC drill or ABC bone awl is always used in combination with an ABC drilling rule,

– the drill guide is placed correctly in the plate hole.

CAUTION

Damage to the ABC screw by engaging the screwdriver incorrectly when turning the screw into the ABC plate.

➢ Fully insert the tip of the screwdriver into the screw head.

CAUTION

Deficient locking of the ABC screw due to incomplete engaging in the hole of the ABC plate.

➢ Be sure that the ABC screw is fully engaged in the hole of the ABC plate.

➢ When using bicortical ABC screws, precut the thread with a screw tap.

➢ Use special insertion instruments to insert the ABC screws.

➢ Position the ABC screw:

– in the cranial plate holes, cranial as far as possible,

– in the caudal plate holes, as far caudal as possible,

– for multisegmental provision (more than 4 plate holes) centrally in each of the inner plate holes.

➢ Fully screw in the ABC screw into the ABC plate.

➢ Check that the locking pin of the ABC screw is visible and sits flush with the screw head. If that is not the case, use the special locking instrument to pull up the pin and thereby lock the screw.

➢ Remove the temporary fixation pin as soon as the ABC plate has been fixed with the ABC screws.

CAUTION

Damage to the revision instrument (for bicortical screws) and the ABC screw due to improper application.

➢ Never use the revision instrument to screw in or unscrew fixated ABC screws.

➢ Only use the revision instrument to screw in or unscrew free-spinning ABC screws, whose screw heads will not snap out of the hole in the ABC plate.

CAUTION

Damage to the screw-out sleeve and to the self-locking ABC screw due to improper application.

➢ Always use the ABC screwdriver to unscrew fixated ABC screws.

➢ Only use the screw-out sleeve for free-spinning screws on the screwdriver to unscrew free-spinning ABC screws, whose screw heads will not snap out of the hole in the ABC plate.

➢ To remove an implanted ABC screw:

– Push down the locking pin of the ABC screw with the ABC screwdriver.

– Use the screwdriver to loosen the ABC screw.

➢ If the screw head of a freely spinning screw does not snap out of the hole of the ABC plate, use the special revision instrument (for bicortical screws) or the special screw-out sleeve (for self-locking screws):

– Insert the revision instrument (for bicortical screws), as far as it will go, into the slots between the screw head segments.

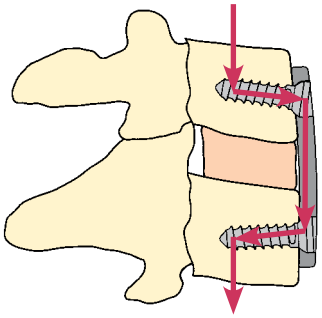
- or -

– Slide the screw-out sleeve (for self-locking screws) over the screwdriver. Guide the screwdriver with the screw-out sleeve attached over the screw and fully insert the screwdriver tip into the screw. Push forward the outer sleeve.

– Remove the ABC screw by simultaneously pulling and turning it anticlockwise.

II. Principles of Dynamic Osteosynthesis

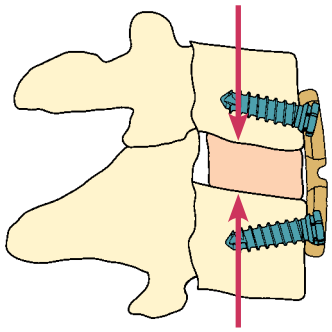
Stress Shielding



Loading forces applied with constrained (rigid) construct

Fig. 1: Traditional plating systems stress shield the graft site, preventing contact between the endplates and the graft during graft incorporation

Load Sharing



Loading forces applied with dynamic construct

Fig. 2: Fig. 2: ABC2 dynamic system avoids stress shielding and allows for full load sharing

WOLFF's law states that: "Every change in the function of a bone is followed by definitive changes in its internal architecture and secondary alterations in its external confirmation". This means that osseous tissues remodel in direct response to the stresses placed upon them.

Traditional plating systems stress shield the graft, thereby preventing continuous load transfer between the end plates and the graft after surgery (Fig. 1).

The ABC2 dynamic system is designed to take full advantage of Wolff's law by avoiding stress shielding and allowing full load sharing. This can result in earlier and more substantial graft incorporation (Fig. 2).

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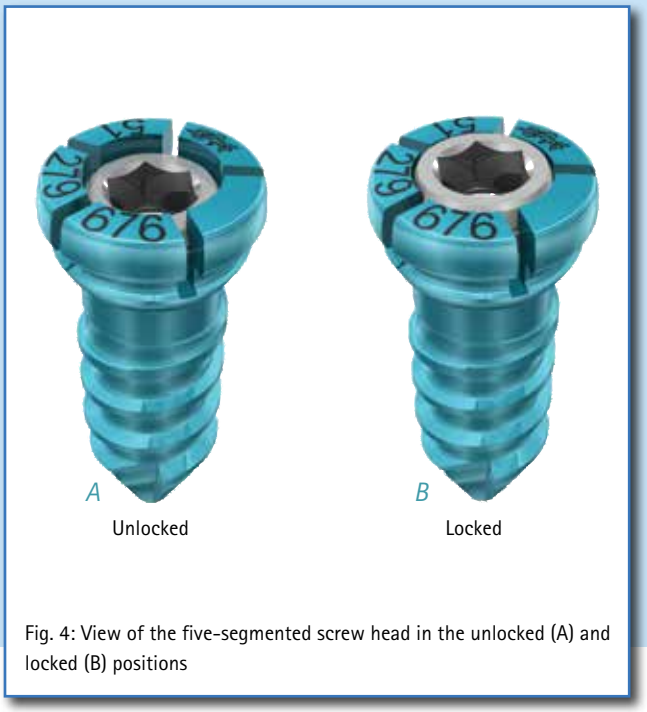
III. ABC2 Cervical Plating System

Fig. 3: ABC2 implant construct



Unlocked Locked

Fig. 4: View of the five-segmented screw head in the unlocked (A) and locked (B) positions

The ABC2 system consists of a variety of anterior cervical plates as well as unicortical and oversized screws. All implants are manufactured from a titanium alloy (Ti6Al4V) and phynox[1] in accordance to ISO 5832-3.

Axial settling, which allows full load sharing capability, occurs because the screws are free to move in the plate slots (Fig. 3). The settling distance is determined by the amount of graft resorption not the restriction of the plate screw interface.

The ABC2 screw head (Fig. 4) consists of five segments or petals, which compress (in the unlocked position) as the screw head enters the plate slot and then returns to its original configuration as the screw reaches its final position. In the locked position, the petals are blocked from compressing but are not expanded. They can therefore slide in the slots in the plate and toggle. Therefore, the system allows unrestricted axial settling while preventing screw back-out.

[1]Phynox is a cobalt chromium nickel alloy with very high strength. It is non-metallic and therefore MR safe.

III. ABC2 Cervical Plating System *(continued)*

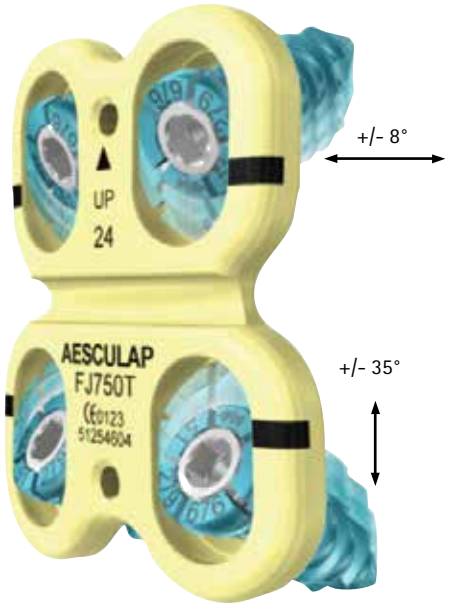


Fig. 5: Range of screw angulation

The design allows screw angulation of plus or minus 35 degrees in the vertical axis as well as plus or minus 8 degrees medial or lateral in the coronal axis (Fig. 5).

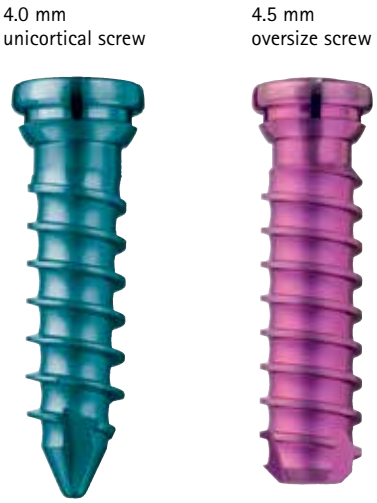


Fig. 6: Color-coding helps to distinguish screw types

The screws (Fig. 6) are offered in two different versions:

- The 4.0 mm **unicortical** screws are self-drilling, self-tapping colored turquoise for easy identification, and available in 10, 12, 14, 16 and 18 mm lengths*.
- The 4.5 mm **oversized** screws are colored purple and available in lengths 13, 15 and 17 mm. They serve as rescue screws for cases where a standard unicortical screw does not provide a firm hold (e.g. in osteoporotic bone or when a screw has been over-tightened and is free spinning).

*Screw length refers to the length of the screw protruding below the plate, which is the actual length within the bone.

Note: 4.0 mm bicortical screws are available upon request. *They are colored blue, flat tipped to maximize thread purchase in the distal cortex without protruding into the spinal canal and available in one millimeter increments from 10 to 28 mm.*

III. ABC2 Cervical Plating System *(continued)*

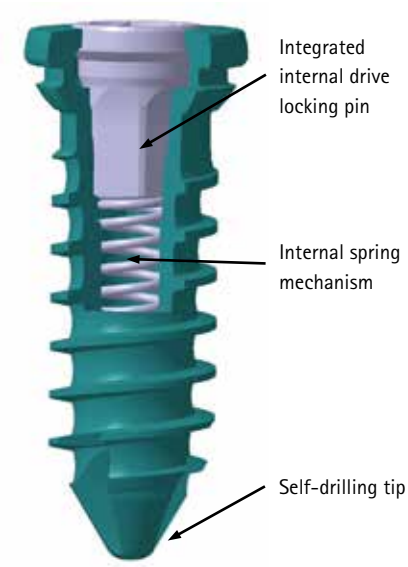


Fig. 7: Cutaway view of the screw

All screws feature ABC2's **unique internal self-locking mechanism** which is automatically activated after the screw is in its final position (Fig. 7).

The integrated internal drive locking pin of the screw is activated by an internal spring mechanism that pushes the pin up into the head of the screw. As the screw is being inserted, the downward pressure of the screwdriver automatically pushes the pin into the unlocked position, (Fig. 8.1) allowing the petals to compress and the screw to be seated into the plate (Fig. 8.2). As the driver is removed/ disengaged from the screw head, the spring pushes the pin up to the locked position (Fig. 8.3). In this locked position, compression of the screw head petals is blocked, thereby preventing screw back-out from the plate. Since the petals are not expanded in the locked position, the system allows settling or axial translation in the slot of the plate, which avoids stress shielding of the graft.

Note: *Refer to Aesculap's ABC2 brochure DOC576 for the detailed implant range.*

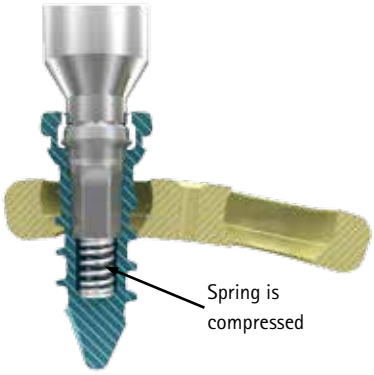


Fig. 8.1: Spring is compressed by downward pressure with the screwdriver, which unlocks the screw.

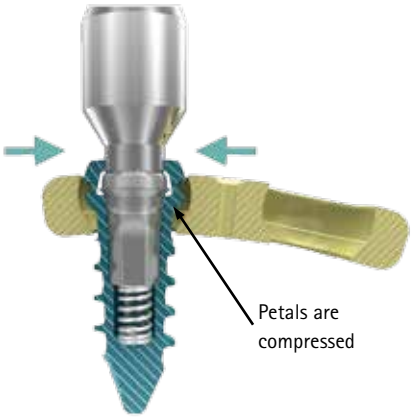


Fig. 8.2: Petals compress as screw passes into slot.

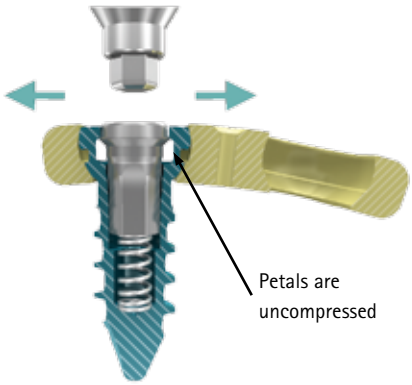


Fig. 8.3: Once in the slot, the petals return to original uncompressed state. Upon screwdriver removal, spring forces the pin into the locked position.

Surgical Technique

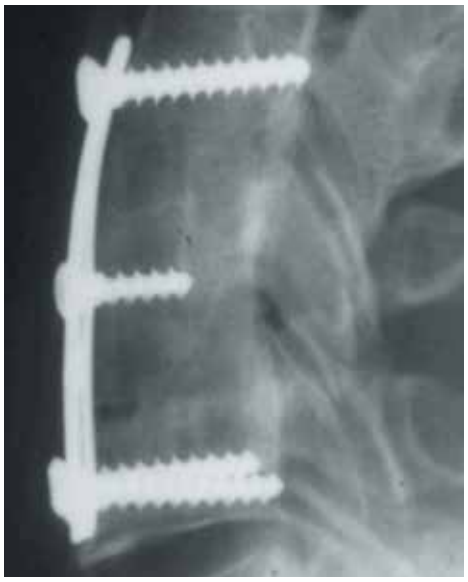
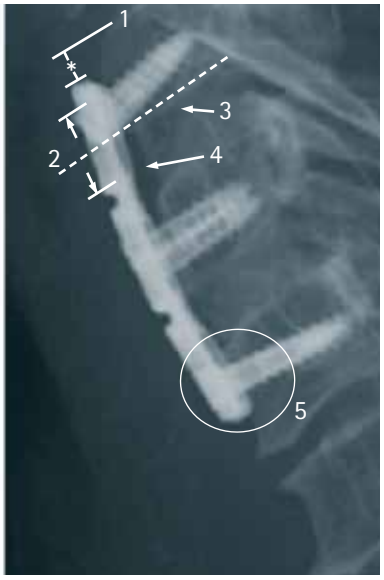


Fig. 9A: First generation Caspar plate



1. Distance between the end of the plate and the vertebral body
2. 50% overlap allows for dynamic settling
3. Graft vertebral body interface
4. Inferior end of the upper slot
5. ABC2 screw placement is at the most distal ends of the plate slots

Fig. 9B: ABC2 plate

Patient positioning, approach, exposure, distraction, decompression, bone graft site preparation, as well as bone graft harvesting are performed using the standard methods.

Lateral views of two different plating cases are shown in Fig. 9. A first generation Caspar plate was used in Fig. 9A and an ABC2 plate was used in Fig. 9B.

A shorter length ABC2 plate was used as compared to the first generation Caspar plate (Fig. 9A) to allow for axial settling.

Choosing a shorter plate ensures the plate will not overlap into the adjacent interspaces as settling occurs (Fig. 9B).

In Fig. 9B, note the screw placement in the most distal ends of the plate slots (5). The asterisk in Fig. 9B denotes the distance between the end of the plate and the vertebral body endplate (1). This distance allows for settling during graft resorption/incorporation.

As shown in Fig. 9B, the inferior end of the upper slot in the plate is marked by the longer blue arrow (4), while the graft-vertebral body interface is indicated by the shorter blue arrow (3).

Practical Tip: *As shown in Fig. 9B, with optimal plate length selection and proper plate positioning, the upper and lower screw holes in the plate will, in most cases, overlap the bone graft by approximately 50% (2). This allows for dynamic settling.*

Surgical Technique *(continued)*

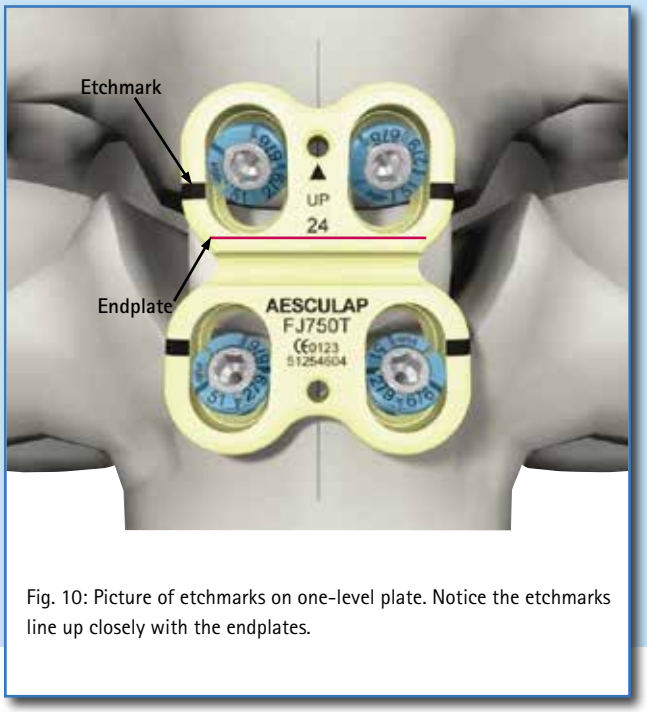


Fig. 10: Picture of etchmarks on one-level plate. Notice the etchmarks line up closely with the endplates.

Fig. 11: Different hole configurations in plates of the same length are available. In the example above, the same length plate could be used for 2 or 3 level (3 or 4 vertebrae) application.

1. Plate Length Selection

As a rule of thumb, select the shortest plate that most closely lines up the etch marks with the end plates (Fig. 10).

> **Note:** *In the event that the etch marks are not on the plate, select a plate length that allows the upper and lower screw holes in the plate to overlap the bone graft by approximately 50 percent.*

All ABC plates have a trapezoid shape and are clearly marked with an "up" arrow to distinguish the upper or narrow end of the plate (Fig. 10). To properly place the plate, always insure the "up" arrow points cranially.

To allow maximum flexibility of selection, plate lengths are available in 2 mm increments from 20 to 34 mm and in 3 mm increments from 34 to 115 mm. The number of intervening holes also vary to allow for segmental fixation when appropriate and desired. Some plate lengths may be available with two different hole configurations. For example, the 52, 55, and 58 mm lengths are available in both six and eight-hole versions (Fig. 11).

Surgical Technique *(continued)*

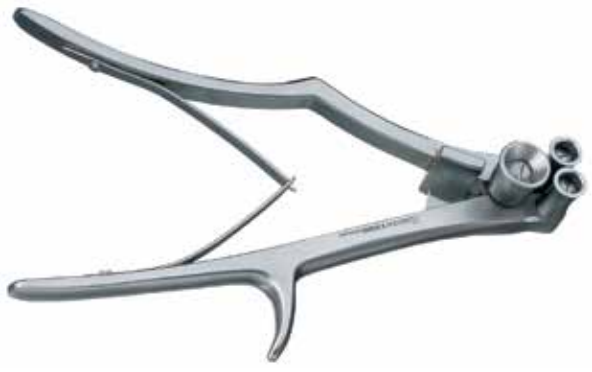


Fig. 12: Bending tool FJ826R is used to optimize plate contour (Item No. FJ826R).

Fig. 13: Bending zones of the plates

2. Plate Contouring

The ABC2 plates are pre-bent to an optimal angle of cervical lordosis. If needed, they should be further optimized to sit flush on the vertebrae without gaps or without rocking as digital pressure is alternately applied to either end or from side to side.

To optimize the plate curvature, a bending tool (Fig. 12) is provided. **Bending will only occur within the bending zones of the plate** (Fig. 13). Increased lordotic curvature is achieved through a series of small incremental corrections along the plate. (Fig. 14). A reduction of lordotic curvature can also be achieved within these regions (Fig. 15).

Surgical Technique *(continued)*

Fig. 14: Using the bender in this manner increases the lordosis of the plate.

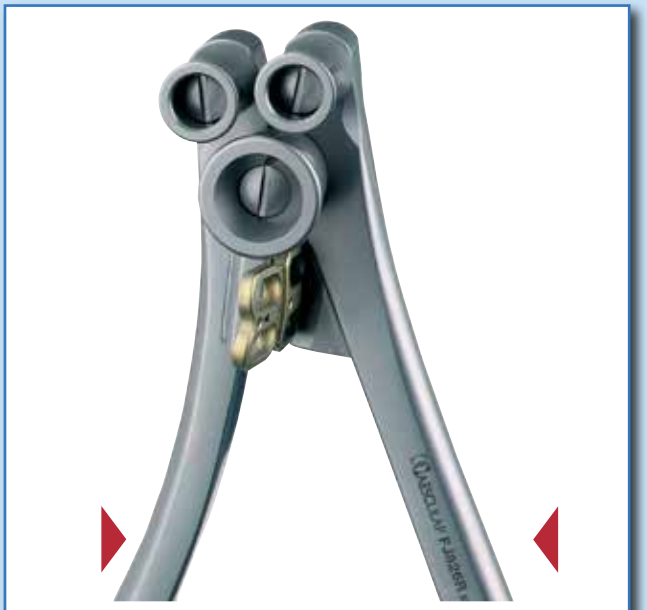


Fig. 15: Plate curvature can be reduced by using the bender in this manner.

2. Plate Contouring *(continued)*

Caution: *To avoid damaging the ABC2 plate, only use the special ABC2 bending tool. Under no circumstances should the plate be straightened once it has been bent. Small sequential corrections are preferred since repeated bending and unbending will weaken any metallic device.*

Practical Tip: *To accomplish optimal plate fit, remove osteophytic ridges with rongeurs or with the Microspeed high-speed drill. If necessary, a prominent bony midline keel can also be trimmed. Care must be taken during bone trimming not to weaken the paramedian screw fixation sites.*

Surgical Technique *(continued)*

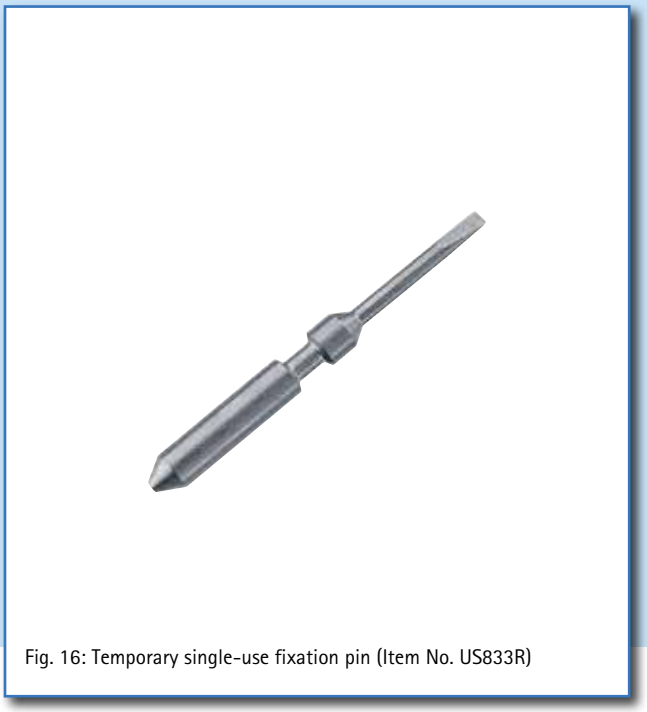


Fig. 16: Temporary single-use fixation pin (Item No. US833R)

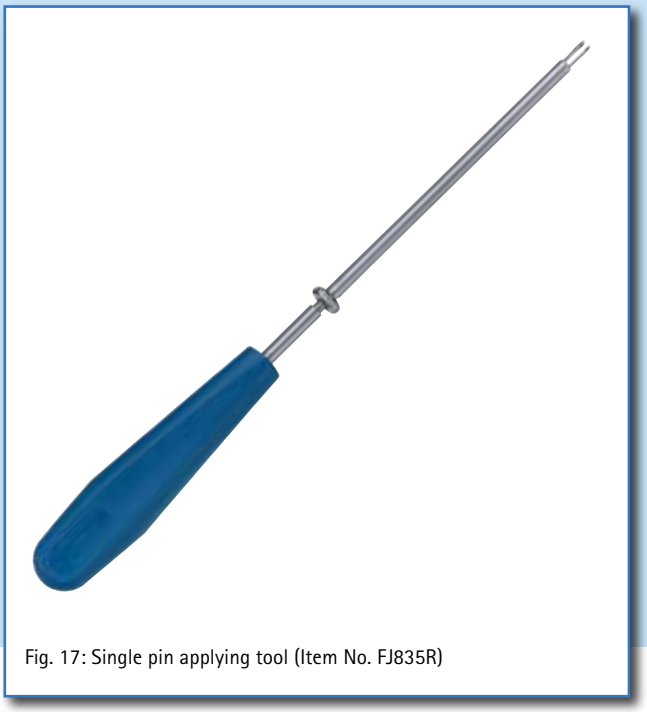


Fig. 17: Single pin applying tool (Item No. FJ835R)

3. Plate Positioning and Fixation

Position the plate so the lines are aligned as close to the end plates as possible. Once the plate is in its final position, set the fixation pin (Fig. 16) with a gentle mallet tap on the single pin applying tool (Fig. 17). Repeat the process at the opposite end for the second fixation pin.

Pin site location need not be at the ends of a multilevel plate but can be placed in any intermediate position based on the anatomy and the surgeon's best judgment.

It is strongly recommended that temporary ABC fixation pins (Fig. 16) are used in all cases.

Using the fixation pin allows optimization of screw placement because the drill guides can be angled and firmly pressed against the slots without the plate migrating during drilling.

Practical Tip: *To assist in vertical alignment, it may be helpful to mark the midline above and below the plate placement site. This can be easily accomplished during the initial spine exposure by making a small cut with the electro-cautery in the midline between the longus colli muscle bellies and then marking the two locations with a marking pen. This leaves a mark that will help identify the midline later when the plate is being positioned.*

Surgical Technique *(continued)*

Instrument Overview

Fig. 18: Single adjustable drill guide (Item No. FJ822R Double barrel adjustable drill guide (Item No. FJ823R)Double barrel 14 mm fixed depth drill guide (Item No. FJ834R).

Fig. 19: The direction to turn the drill barrel to adjust for more (+) or less (-) drill penetration is clearly marked on the drill guide barrels (Item No. FJ823R).

4. Screw Hole Preparation

Awl/Drill Guides

With the ABC2 self-drilling screws, the surgeon has the option to drill or to use the awl to puncture the cortical bone. In either case, an awl/drill guide **MUST** be utilized.

- Both single and double barrel awl/drill guides are available (Fig. 18). Usually the latter will be used to optimize the angle of convergence of the screws to each other. By converging them, pullout strength is greater than if a straight anterior-posterior path is chosen.
- For simplicity, a fixed (14 mm depth of penetration) double awl/drill guide is available for use with unicortical screws (Fig. 18). It has a green handle to readily distinguish it from the blue handled variable depth awl/drill guide. It may be used when placing screws unicortically to a depth of 10, 12, 14, 16, or 18 mm, as long as the tip of the self-drilling screw remains in the central cancelleous bone. If strong resistance to screw tightening is encountered, indicating denser bone posteriorly, consideration should be given to either drilling deeper with the adjustable depth drill guide (Fig. 19) or switching to a shorter screw.

Practical Tip: *The double drill guide will optimize the screw angulation and maximize pull out resistance by placing the two screws in a converging direction.*

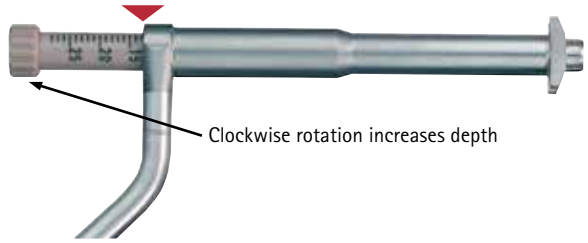


Fig. 20: Drill guide with calibrated adjustable barrel for depth control (Item No. FJ822R)

Fig. 21: Drill guide with the fixture in the proper position, (tips are placed inside the plate slots)

4. Screw Hole Preparation *(continued)*

Awl/Drill Guides:

- The adjustable awl/drill guides (Fig. 20) have calibrated barrels that allow for 1/2 mm incremental adjustments during drilling (felt as a click when turning).
- Counter-clockwise rotation increases depth; clockwise rotation decreases depth. This reverse threading is for safety and assures that the depth will not be inadvertently increased during drilling.
- The awl/drill guides have tips and fixtures at the ends that engage the plate slots. This ensures the maximum range of longitudinal angulation is achieved without exceeding the range of which plate screw locking is possible (Fig. 21).

It is absolutely mandatory to use a awl/drill guide. This ensures the correct centric placement of the screw holes within the plate slots and helps to ensure the activation of the self-locking mechanism (Fig. 22). If the screw is placed off center, the segments or petals of the screw head may be deformed during screw insertion. In such a case, the locking mechanism may fail.

Fig. 22: Correct, centric screw hole placement can only be achieved by using the ABC2 drill guides.

Surgical Technique *(continued)*

Fig. 23: The awl (Item No. FJ913R)

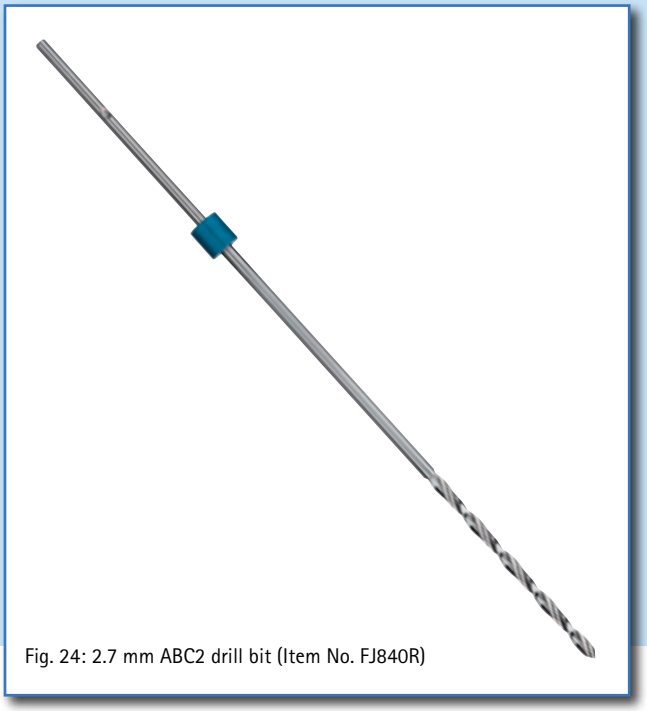


Fig. 24: 2.7 mm ABC2 drill bit (Item No. FJ840R)

4. Screw Hole Preparation *(continued)*

Awl:

- If the surgeon chooses not to drill, the awl must be used with a awl/drill guide to puncture the cortical bone (Fig. 23).
- The awl is incorporated with a depth stop at 14mm.

Note: *All ABC2 screw sizes can be inserted into the vertebral body with the 14 mm depth stop puncture.*

Drilling with the 2.7 mm ABC drill bit (Fig. 24) can either be performed under power using a micro drill hand piece or manually with the ABC hand twist drill (Fig. 25).

The correct screw length is based on depth information obtained during drilling. For unicortical screws, it is recommended that the selected length traverse at least 75 percent of vertebral body depth.

Fig. 25: ABC2 hand twist drill (Item No. FJ839R)

Fig. 26: ABC screwdriver (Item No. FJ910R)

Fig. 27: Screw holding sheath (Item No. FJ821R)

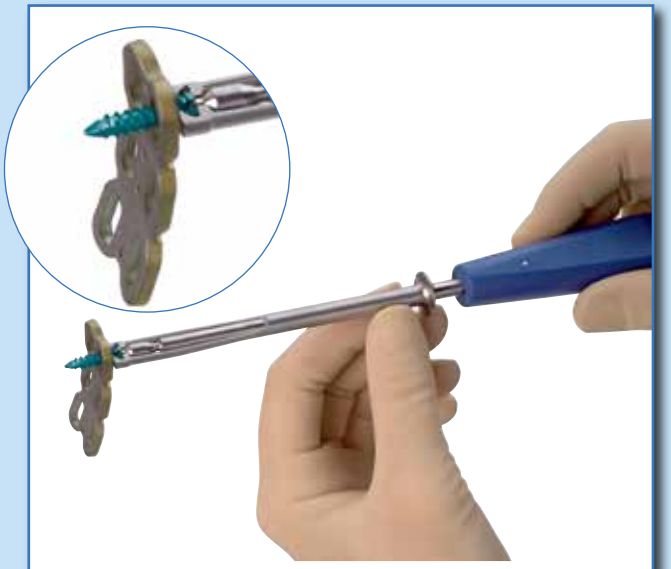


Fig. 28: Guiding and stabilizing the screwdriver by the screw holding sheath facilitates easy insertion of the screws.

5. Screw Placement

The ABC2 screwdriver (Fig. 26) tip has a hexagonal shape to account for the shape of the internal locking pin. The tip fits inside the shaft of the locking pin, which drives the screw without placing stress on the screw head petals.

The screw holding sheath (Fig. 27) is used to hold the screw during initial placement. Once the screw begins to engage the bone, the sleeve should be retracted. To help stabilize the screwdriver as the screw is being placed, grasp the sleeve with one hand while rotating the screwdriver with the other (Fig. 28).

During screw insertion, it is important that the tip of the screwdriver remain fully inserted within the screw head and a constant downward pressure is applied during screw insertion. Once the screw is implanted, removal of the driver from the screw automatically activates the internal spring which pushes the pin into the locked position.

At this time, the surgeon should verify that the screw is locked by checking that the internal pin sits flush with the top of the screw head (Fig. 29).

All screws should be tightened firmly but not in excess. If inadequate screw torque is achieved with a unicortical screw, or the screw is free spinning, consider using the next longer size screw or rescue screw. Over tightening may result in a deformation of the screw head or stripping of the screw, which may prevent the locking mechanism from engaging.

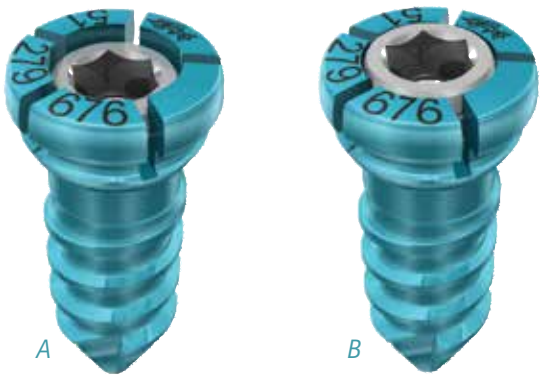


Fig. 29: View of the five-segmented screw head in the unlocked **(A)** and locked **(B)** positions

Surgical Technique *(continued)*

Fig. 30: Locking assistance tool (Item No. FJ911R)

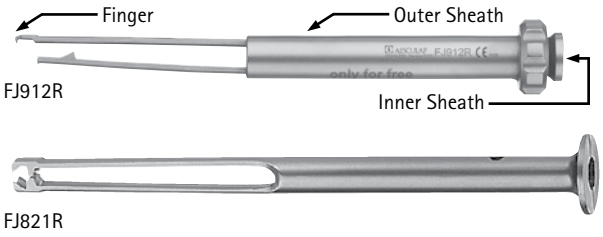


Fig. 31: The free spinning screw removal tool (Item No. FJ912R) and the ABC2 screw holding sheath (Item No. FJ821R)

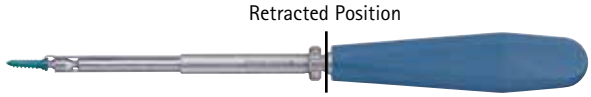


Fig. 32: Insert the screwdriver through the sheath and move the sheath to a retracted position.

Fig. 33: Screw holding sheath in locked position

6. Locking Assistance and Screw Removal

If for any reason the self-locking mechanism does not engage, the ABC2 locking assistance tool (Fig. 30) can be threaded into the locking pin to manually pull the pin into the locked position.

Should it be necessary during the initial procedure to remove a screw, the screwdriver will normally suffice. If the screw has self-locked, reinsert the screwdriver and push down on the pin. This will deactivate the locking mechanism and allow the screw to be removed. While applying firm downward pressure, rotate the screwdriver counter clockwise.

Note: *For removal of previously implanted screws; see page 18.*

7. Removal of Free Spinning Screw

If a screw is stripped and spinning within the bone, a special free spinning screw removal tool (Fig. 31) is available.

Caution: Special attention should be made to the difference in design between the free spinning screw removal tool and the ABC2 screw holding sheath (Fig. 31) The free spinning screw removal tool should only be used with the ABC2 screwdriver (FJ910R) to remove free spinning screws.

- To remove a free spinning screw, insert the ABC2 screwdriver (Cat No. FJ910R) through the sheath of the free spinning screw removal tool and move the outer sheath to a retracted position (Fig. 32).
- Insert the ABC2 screwdriver into the screw head
- Line up the finger of the free spinning screw removal tool with the plate slot
- In one fluid motion, push forward on the outer sheath until the free spinning screw removal tool reaches the midline of the ABC2 screwdriver (Fig. 33)
- Pull screw out
- Replace with an oversize screw

Surgical Technique *(continued)*

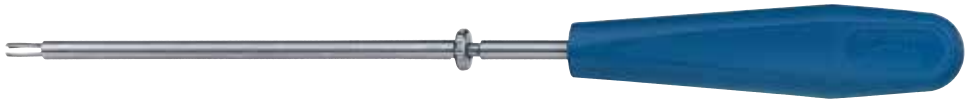


Fig. 34: Single pin applying tool (Item No. FJ835R)

8. Removal of Temporary Fixation Pins

After completing the screw placement at both ends of the plate as well as at any desired intermediate levels or into any strut grafts, the temporary fixation pins must be removed with the single pin applying instrument (Fig. 34).

9. Removal of Previously Implanted Screws

Removing a previously implanted screw may require significant torsional force. In order to keep the screwdriver properly seated within the screw, apply firm downward pressure with one hand, while rotating the screwdriver counter clockwise with the other hand. Slowly increase the torsional force while maintaining downward pressure until the screw-bone interface is released.

Practical Tip: *Prior to screw removal, it may be useful to rotate the screwdriver clockwise one-quarter turn to help disengage the screw from any bony adhesion.*

ABC2

Anterior Cervical Plating System Surgical Technique

Surgical Technique *(continued)*

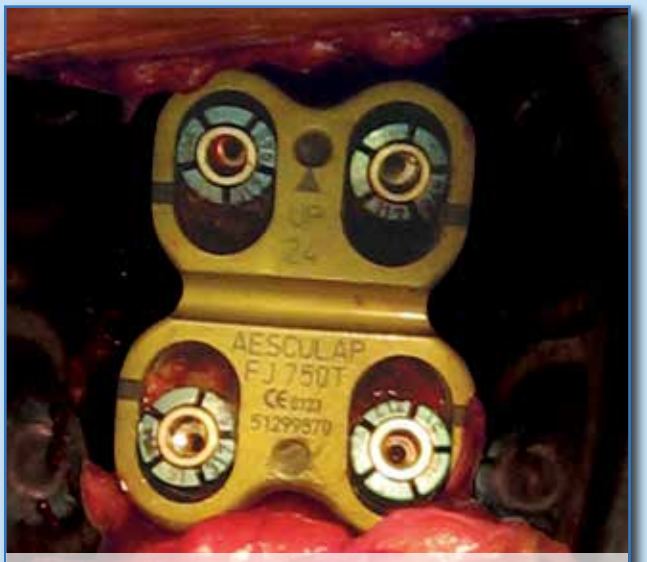


Fig. 35: ABC2 plate in position with all screws locked. As shown above, the silver internal locking pins are flush with the top of the screws, thereby providing a visual confirmation of successful locking of the locking pin.

: View of the five-segmented screw head in the unlocked **(A)** and locked **(B)** positions

10. Essential Points of the ABC2 Plating Technique

- **Ensure all screws are loaded by verifying that the locking pin is flush with the petals.**
- Always select a shorter plate as compared to other systems. This avoids overlap of adjacent disc spaces and allows for axial settling.
- If plate contouring is necessary, always bend in the appropriate bending zones with the supplied ABC2 bending tool. Avoid bending and unbending the plate.
- To avoid migration of the plate during drilling and screw insertion, always use the ABC2 temporary fixation pins.
- Place Awl/Drill holes at the most distal ends of the screw slots.
- Use the ABC2 Awl/Drill guides to properly align the entry hole in a centered position within the plate slot.
- Tighten each screw fully before removing the screwdriver. Avoid over tightening.
- Remove temporary fixation pins once all the screws have been inserted.

The driving mechanism for the ABC2 screws and the corresponding screwdriver is six-sided (hexagonal) shape. Therefore, ABC2 screws must be removed using the ABC2 screwdriver.

11. Important Additional Notes

Warning: *The ABC2 cervical plating system is not approved for screw attachment or fixation to the posterior element (lamina mass/pedicles) of the cervical, thoracic or lumbar spine. There are certain labeling limitations. See package insert for further information.*

Caution: *Federal Law (USA) restricts this device for sale by or on the order of a physician.*

Notes

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