Clariance

Elegance®

ANTERIOR CERVICAL PLATE

Surgical Technique - USA

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INTENDED USE AND INDICATIONS

1. PURPOSE

The Elegance® Anterior Cervical plate device is an anterior cervical plate system, intended for the stabilization of the cervical spine during bone fusion in the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is knowledgeable in the implant's material and surgical aspects and who has been trained as to its mechanical and material applications and limitations.

2. DESCRIPTION

The Elegance Anterior Cervical plate device is designed for use as a cervical plate system. It has a shape which restores the intervertebral height and lordosis. The Elegance Anterior Cervical plate device consists in a variety of shapes and sizes of cervical plates with rounded corners, featuring bone screw's holes ,locking systems and bone screws. The plates go from one (1) to five (5) levels, and the screws are self-drilling or self- tapping, and fixed or variable. The fixation is provided by the bone screws inserted into the vertebral body by means of an anterior approach. The Elegance® plates, as well as the bone screws, are made of compliant ASTM F136 Titanium alloy. It is essential to insert the implants with the instrumentation specifically designed for this purpose. For more description of the instrumentation, read the technical documentation associated to the Elegance® Anterior Cervical plate. Detailed information concerning the surgical technique of the Elegance® Anterior Cervical plate is available upon request, please contact CLARIANCE or its local representative.

3. INDICATIONS

The Elegance Anterior Cervical plate device is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and imaging tests).
2. Spondylolisthesis.
3. Spinal stenosis.
4. Deformities (i.e., scoliosis, kyphosis, and/or lordosis).
5. Pseudoarthrosis.
6. Revision of previous surgery.

4. CONTRA-INDICATIONS

The Elegance Anterior Cervical plate device is not intended for posterior surgical implantation, for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Contraindications include, but are not limited to:

- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any patient having inadequate bone quality or poor bone quality.
- Fever or leukocytosis, infection local to the operative site, signs of local inflammation.
- Any patient unwilling to co-operate with postoperative instructions, having a mental illness , alcoholism or drug abuse, a morbid obesity, pregnancy.
- Where attempted correction exceeds the limits of physiological conditions.

- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication because this condition may limit the degree of obtainable correction.
- Suspected or documented allergy or intolerance to constitutive materials, metal sensitivity, foreign body sensitivity, inadequate tissue coverage over the operative site.
- These devices must not be used for pediatric cases (age < 18 years), or where the patient still has general skeletal growth.
- A requirement for simultaneous anterior and posterior surgery.
- The presence of dysphagia before surgery.

IMPORTANT NOTE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption and osteoporosis, osteomalacia.

5. SECONDARY AND POSSIBLE SIDE EFFECTS

All of the possible adverse events associated with spinal fusion surgery with or without instrumentation are possible but is not limited to the following list:

- Early or late loosening of any or all of the components, disassembly, bending, and/or breakage of components and/or migration of the components.
- Corrosion at the screw/locking interface contributing to breakage, and/or pseudoarthrosis.
- Cessation of any potential growth of the operated portion of the spine, loss of or increase in spinal mobility or function, inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding, graft donor site complications including pain, fracture, collapse or wound healing problems.
- Foreign body (allergic) reaction to implants, debris, corrosion, metallosis, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain, implant or graft extrusion through the skin.
- Bursitis and tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction, instability.
- Infection (paraspinal abscess), dural tears, pseudo-meningocele, fistula, persistent CSF leakage, meningitis.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), C_5 palsy, paraplegia, paraparesis, reflex deficits, irritation, muscle loss.
- Paresthesia, radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits, abnormal sensations.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or retro pulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery, non-union (or pseudarthrosis), delayed union, and malunion.
- Hemorrhage, hematoma, hemothorax, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Dysphagia, esophageal irritation.
- Vocal cord injury (including hoarseness, sore throat, and vocal cord paresis).
- Urinary retention or loss of bladder control or other types of urological system compromise.

- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Change in mental status, death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

6. WARNINGS

Do not use if package is opened or damaged

The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, which may impact on the performance of the device.

These devices are provided as single use only implants and are not to be reused or re-implanted regardless of an apparent undamaged condition. This is indicated on the labeling of the implant package by the next symbol 

The reuse of single-use devices can have irreversible consequences on the security and the health of the patients (risk of contamination, risk of failure of the device, etc.). It is therefore strongly prohibited to reuse single use devices.
The Elegance plates and screws are provided in non-sterile state.

If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.

This device system is not intended to be the sole means of spinal support . This spinal implant cannot withstand body loads without the support of bone or cage. In this case, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Because different manufacturers employ different materials, varying tolerances, manufacturing specifications, and differing design parameters, components of the Elegance Anterior Cervical plate should not be used in conjunction with components from any other manufacturer's implant systems. Any such use shall negate the responsibility of CLARIANCE for the performance of the resulting mixed component implant.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

Cervical plate device is intented to be implanted permanently. The lifetime of such devices varies from patient to patient. There are many factors affecting the outcomes and the lifetime of the device. These factors include, but are not limited to, the patient's physical condition, patient's activity level and the progression of the disease.

7. CAUTION OF USE

>Preoperative

- The implantation of the anterior cervical plate system should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient,
- Only patients that meet the criteria described in the indications should be selected, correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery. The size of device for the case should be determined prior to beginning of surgery.
- Proper function of the surgical instruments should be verified prior to every surgical procedure. All instruments must be cleaned and sterilized before use.

>Intraoperative

- The instructions in Elegance Anterior Cervical plate surgical technique manual should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.

> Postoperative

- Detailed instructions on the use and limitations of the device should be given to the patient. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion. It is important that immobilization of union is established and confirmed by x-rays, CT scans examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.
- Elegance® Anterior Cervical plate device are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

!USA FOR US AUDIENCE ONLY

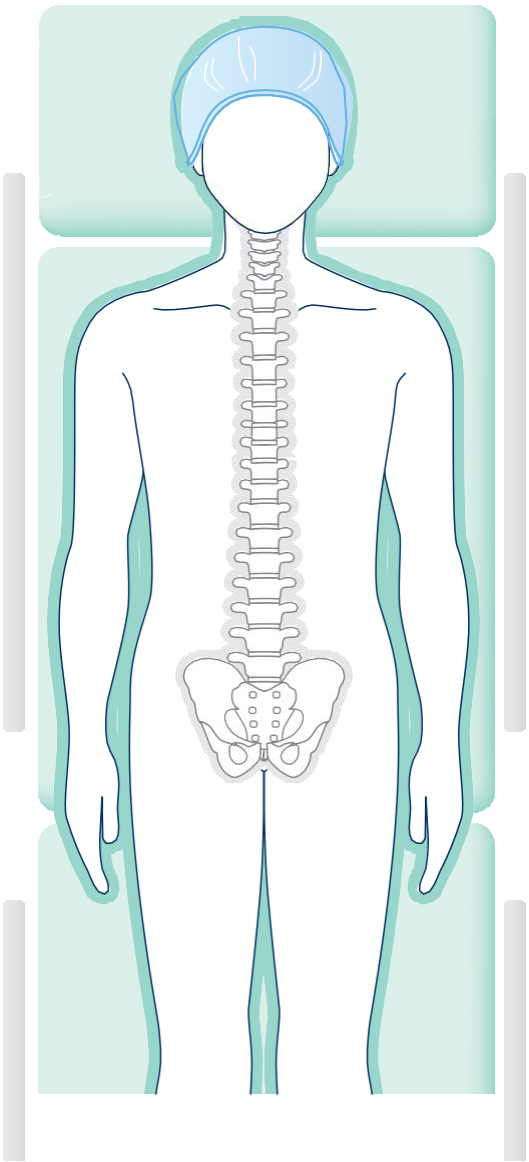
CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Elegance®
ANTERIOR CERVICAL PLATE

CONTENTS

Surgical Technique

Prior to using any Clariance device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.



1 | PATIENT POSITIONING

- The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal cervical lordosis.

Final positioning of the patient and surgical approach are based on known techniques routinely used by surgeons.

2 | APPROACH

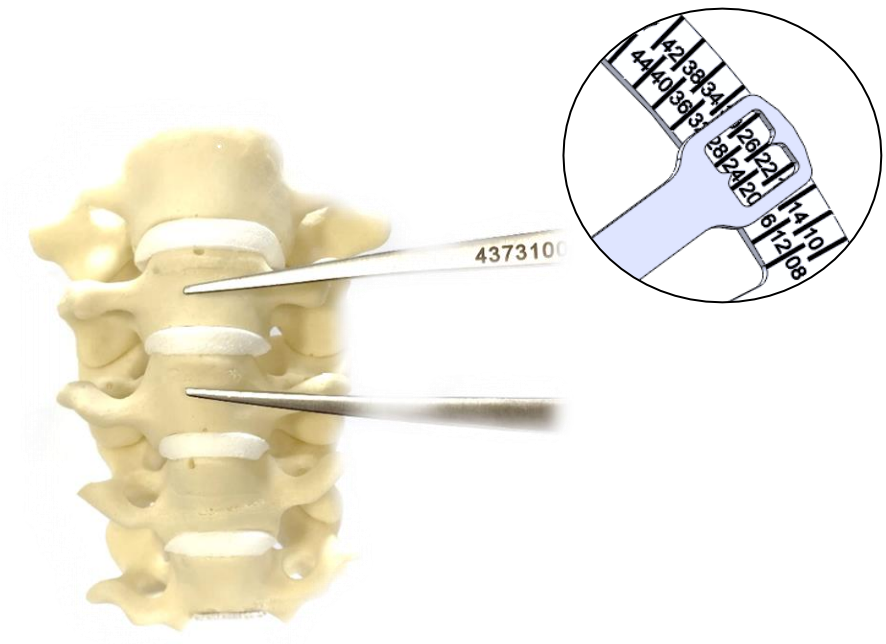
- Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, discography, patient history and physical examination.
- The approach of the treated level(s) can be realized through a standard anterior approach after identifying the treated level(s) under fluoroscopy.

3 | VERTEBRAL SPACE PREPARATION

- Remove anterior osteophytes from the exposed vertebrae so that the plate may sit flush or evenly on the anterior cortex.

4 | PLATE SELECTION

- Determine the appropriate cervical plate length: A properly sized plate will bridge the affected segment(s) without overhanging into the adjacent disc spaces.
- Use the **Cervical Plate Selector** to determine the appropriate plate length.
  - Position one leg of the Cervical Plate Selector at the point where the fixation screws will be inserted into the upper vertebral body and position the other leg on the lower vertebral body where the screw will be inserted.
  - Read the plate size indicated in the window located on the handle and select the corresponding plate size.



CERVICAL PLATE SELECTOR

43731000

PLATE BENDER

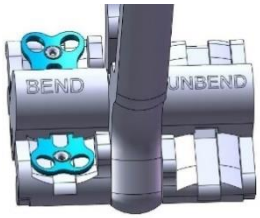
43750001

5 | PLATE PREPARATION (OPTIONAL)

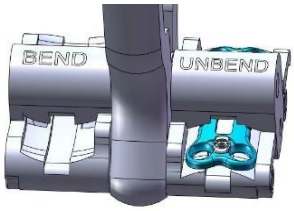
- If needed, it is possible to increase or decrease the in-built lordosis using the plate bender.

- Select the appropriate plate in the implant tray with the size determined in the previous step.
- Place it in the plate bender as described in the picture – refer to laser markings on the instrument.

<u>To increase the lordosis, position the plate as shown:</u>



<u>To reduce the lordosis, position the plate as shown:</u>

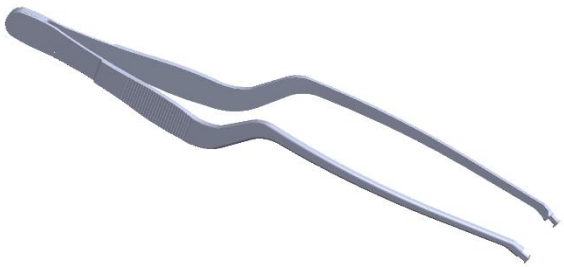


IMPORTANT :

- *Cervical plate bending must be performed between two locking mechanisms, being careful not to damage them.*
- *Do not bend a plate which is shorter than 40 mm.*
- *Never return a bent plate to the implant rack. If it is not suitable for implantation, it must be discarded.*

6 | PLATE POSITIONING

- Use the **Plate Holder** to position the plate.

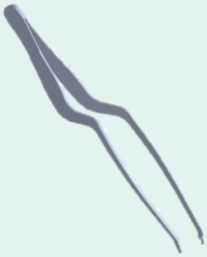


- Grasp the plate in the middle part as shown in the illustration.
- Maintain the plate firmly by squeezing the **Plate Holder** with the fingers.

- Position the plate onto the spine at the level(s) to be treated.

PLATE HOLDER

53713000



TEMPORARY FIXATION PIN

53719000

T10 SCREWDRIVER

53710000

PUNCH AWL

53702000

7 | PLATE STABILIZATION (OPTIONAL)

- To stabilize the plate before screw insertion, Temporary Fixation Pins may be used. The Temporary Fixation Pins are inserted with the T10 Screwdriver.

- Insert the distal part of the screwdriver into the head of the Temporary Fixation Pin.

- Locate the midline and ensure correct positioning of the plate. Insert the Temporary Fixation Pin through the bone screw holes in the plate by turning it clockwise.
- If necessary, the Punch Awl can be used to perforate the cortical bone before inserting the Temporary Fixation Pin.
- To remove the Pins, reinsert the tip of the screwdriver into the head of the pin and turn counterclockwise.

NOTE:

- *To enhance the temporary stability of the Elegance® cervical plate, it is recommended to place the Temporary Fixation Pins diagonally on the cervical plate. When using the double-barrel drill guide, position the Temporary Fixation Pins side by side.*
- *Prior to closure, ensure that all Temporary Fixation Pins have been removed.*

8 | BONE SCREW SELECTION

BONE SCREW SELECTION

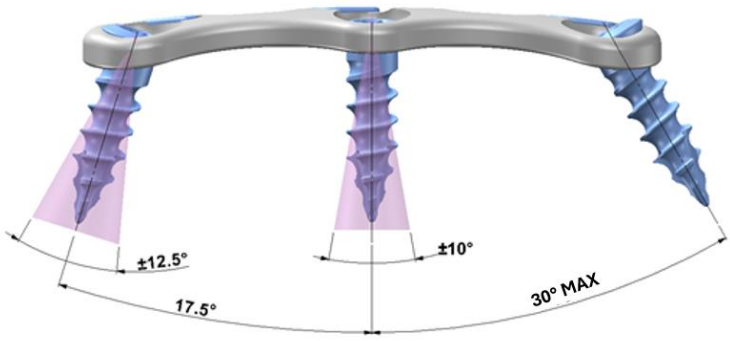
- Select the size and the type of screw that is adapted to the patient anatomy. (See options in the below tables)
- Screws are color coded by length:

Length	Part-number	Image
12MM	530XXX**12**	
14MM	530XXX**14**	
16MM	530XXX**16**	
18MM	530XXX**18**	

- Screw Options:

Angle	Type	Diameter	Part-number
Fixed	Self-Drilling	4.0MM	530**540**1X
	Self-Tapping	4.5MM	530**645**1X
Variable	Self-Drilling	4.0MM	530**340**1X
	Self-Tapping	4.5MM	530**445**1X

- Screw angles:

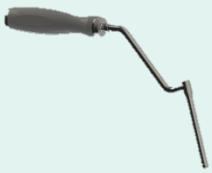


- For self-tapping screws it is recommended to drill prior to screw insertion.

PUNCH AWL
53702000

VARIABLE DRILL-GUIDE

53706000



FIXED DRILL-GUIDE

53706001

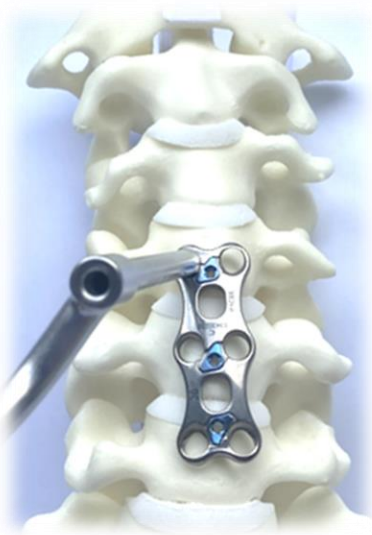
9 | SCREW PATHWAY PREPARATION

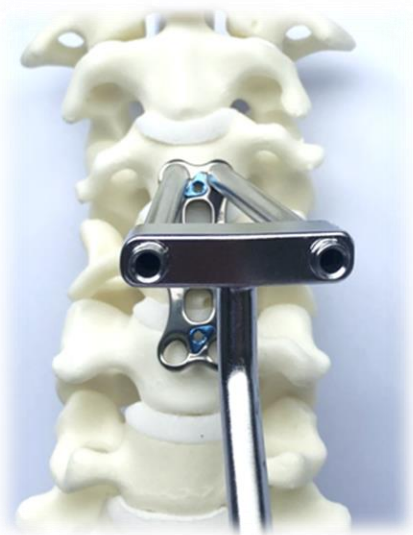
PUNCHING

- Place the punch awl in the first bone screw hole and push down the handel to breach the cortical bone. The diameter of the awl is 1.8 mm and the length of the deployed awl is 9 mm. After Punching the self-drilling screws may be inserted directly.

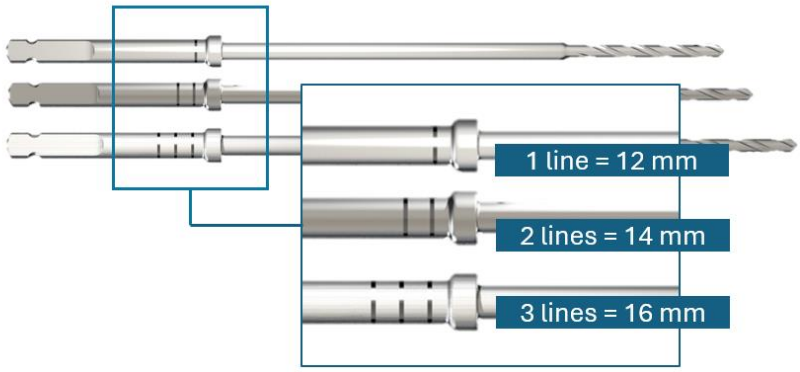
DRILLING (OPTIONAL)

- Use the **Punch Awl** as described above to break the cortical bone prior to drilling.
- Use the **Variable Drill-Guide (single barrel)** if variable-angle screws are used or the **Fixed Drill-Guide (double barrel)** if fixed-angle screw are used.





- Select the **Drill Bit** corresponding to the desired length, which could be equal or smaller to the screw length. The **Drill Bits** are marked with lines for quick identification of length.



- Assemble the selected **Drill Bit** onto one of the **AO Handles**.

Insert the assembled **Drill bit** into the selected **Variable** or **Fixed Angle Drill Guide**.

Advance the **Drill** by rotating it clockwise until the positive stop on the Drill bit contacts the **Variable Drill**.

Once completed, remove both instruments.

DRILL BIT

43700212	12MM
43700214	14MM
43700216	16MM

AO HANDLE

99783001	Fixed
99783005	Ratcheting

TAPPING (OPTIONAL)

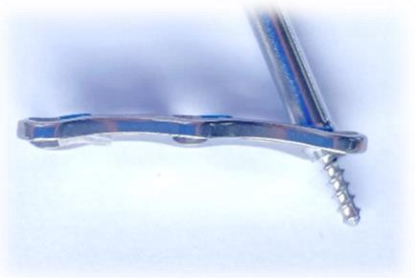
Although the bone screws are self-tapping, optional tapping may be performed according to the surgeon's preference.

TAP

43701035

- The tap is designed for under-tapping and features a diameter of 3.5 mm and the length is 12 mm. Assemble the Tap with one of the AO Handles.

- Position the **Variable** or **Fixed Drill Guide** on the previously drilled hole.
- Insert the Tap into the selected **Drill Guide**. Advance by rotating clockwise until the positive stop contacts the Variable Drill.
- Once contact is made you must STOP rotating clockwise. Rotate the Tap counterclockwise until it is free from the bone and remove it from the **Drill Guide**.



10 | SCREW INSERTION

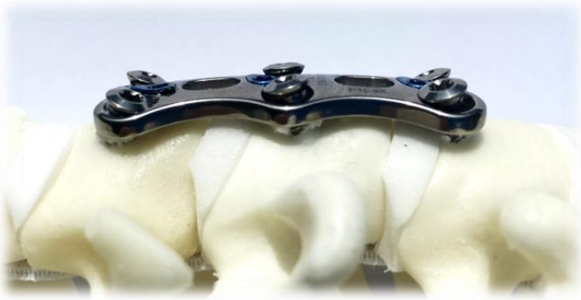
SCREW INSERTION

- Select the **T10 screwdriver** according to surgeon preferences. If one of the AO drivers is used, assemble the screwdriver with one of the AO handles prior to use.

- Insert the tip of the **T10 Screwdriver** into the selected screw using downward pressure on the driver to secure the screw to the driver tip. The screwdrivers are self-retaining.

- Following the prepared path, insert the screw.

- Take care to leave the screwheads over the locking mechanism as shown below.

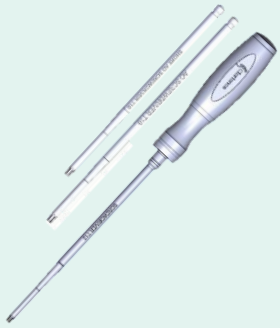


IMPORTANT:

Prior to closure, confirm that all Positioning Pins used in bone screw holes have been replaced by bone screws.

T10 SCREWDRIVER

53710000	Fixed
53710001	AO
53710001	AO Short



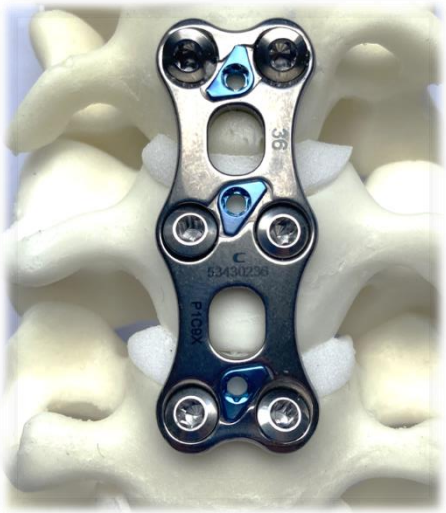
AO HANDLE

99783001	Fixed
99783005	Ratcheting

11 | LOCKING

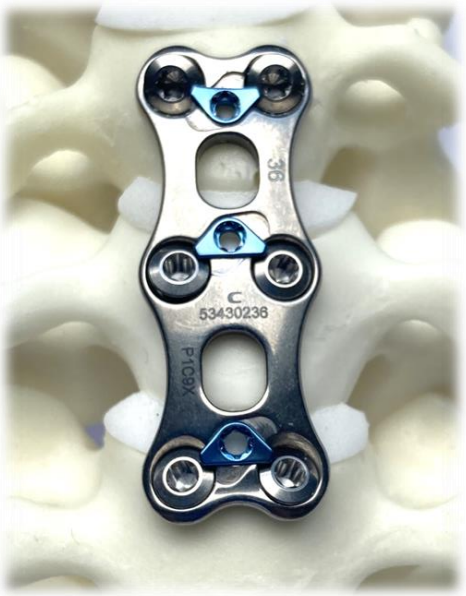
FINAL SCREW PLACEMENT

- Once all bone screws have been inserted in the plate, use fluoroscopy to confirm the trajectories of the screws.
- Once screw positions and trajectories are confirmed, perform final positioning of all the bone screws with one of the **T10 screwdriver** options. Advancing the bone screw heads until they are located inferior to the locking mechanisms, as shown below.



FINAL LOCKING AND CONTROL

- Use the T10 Screwdriver to turn the locking mechanisms until all screwheads are covered by the clips.



IMPORTANT :

- Correct positioning of the locking mechanism is confirmed when a visual control of each screw head seating under the locking mechanism has been performed.

- Each bone screw head is seated under the locking mechanism, using fluoroscopy, perform final visual control to confirm all bone screws are fully seated in the plate….

If repositioning of a bone screw is necessary, refer to the section, “Revision”.

- Exposure closure following surgeon's habits.

T10 SCREWDRIVER

53710000

12 | REVISION

REVISION SCREWDRIVER

53710003

AO HANDLE

99783001 Fixed
99783005 Ratcheting

PLATE HOLDER

53713000

In case of revision, follow the instructions below:

Assemble the **Revision Screwdriver** with one of the AO Handles.

- Unlock the screws by turning the locking mechanism using either the **T10 Screwdriver** or the **Revision Screwdriver** until all screw-heads are free.

- Use the **T10 Screwdriver** or the **Revision Screwdriver** to remove all the screws from the plate.
  - Insert the tip into the screw head.
  - Maintain the cervical plate with the **Plate Holder** until removal of the last screw.

- Once all screws are removed, remove the plate from the incision using the **Plate Holder**.

CAUTION:
Performing this step may result in damage to the implant(s) making it unsuitable for clinical use.

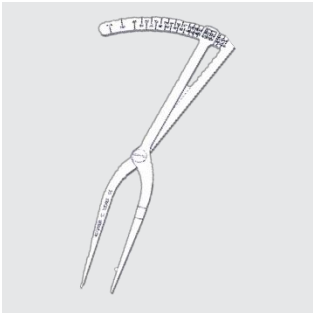
IMPORTANT :

If the Torx shape of the locking mechanism is damaged and the locking mechanism cannot turn, use the Revision Screwdriver to turn it.

Instruments

ELEGANCE INSTRUMENT BASE

53991007	**Base**
53991008	**Lid**
53991009	**Tray**



CERVICAL PLATE SELECTOR

43731000

PLATE BENDER

43750001

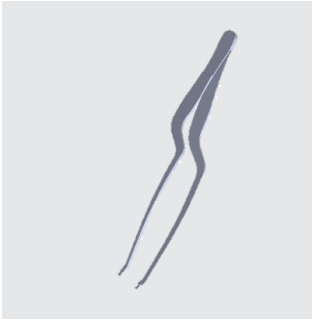


PLATE HOLDER

53713000

PUNCH

53702000

TAP

43701035

FIXED GUIDE

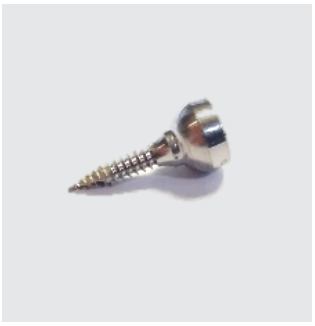
53706001

VARIABLE DRILL

53706000

DRILL Ø 2,00

43700212	12MM
43700214	14MM
43700216	16MM



TEMPORARY FIXATION PIN

53719000

AO RATCHETING HANDLE

99783005

AO MEDIUM CYLINDRICAL HANDLE

99782008

T10 SCREWDRIVER

53710000

T10 A/O SCREWDRIVER

53710001

T10 A/O SHORT SCREWDRIVER

53710002

REVISION SCREWDRIVER

5371003

Implants
Non-Sterile

Product availability may vary upon markets. Please check with your Clariance representative.

ELEGANCE PLATES 1LEVEL

REFERENCE	DESIGNATION	QTY
53430108	ELEGANCE 1 LEVEL CERVICAL PLATE 8MM	2
53430109	ELEGANCE 1 LEVEL CERVICAL PLATE 9MM	-
53430110	ELEGANCE 1 LEVEL CERVICAL PLATE 10MM	2
53430111	ELEGANCE 1 LEVEL CERVICAL PLATE 11MM	2
53430112	ELEGANCE 1 LEVEL CERVICAL PLATE 12MM	2
53430113	ELEGANCE 1 LEVEL CERVICAL PLATE 13MM	2
53430114	ELEGANCE 1 LEVEL CERVICAL PLATE 14MM	2
53430115	ELEGANCE 1 LEVEL CERVICAL PLATE 15MM	-
53430116	ELEGANCE 1 LEVEL CERVICAL PLATE 16MM	2
53430118	ELEGANCE 1 LEVEL CERVICAL PLATE 18MM	-
53430120	ELEGANCE 1 LEVEL CERVICAL PLATE 20MM	2
53430122	ELEGANCE 1 LEVEL CERVICAL PLATE 22MM	-

ELEGANCE PLATES 2 LEVEL

REFERENCE	DESIGNATION	QTY
53430220	ELEGANCE 2 LEVEL CERVICAL PLATE 20MM	2
53430222	ELEGANCE 2 LEVEL CERVICAL PLATE 22MM	-
53430224	ELEGANCE 2 LEVEL CERVICAL PLATE 24MM	2
53430226	ELEGANCE 2 LEVEL CERVICAL PLATE 26MM	-
53430228	ELEGANCE 2 LEVEL CERVICAL PLATE 28MM	2
53430230	ELEGANCE 2 LEVEL CERVICAL PLATE 30MM	2
53430232	ELEGANCE 2 LEVEL CERVICAL PLATE 32MM	2
53430234	ELEGANCE 2 LEVEL CERVICAL PLATE 34MM	2
53430236	ELEGANCE 2 LEVEL CERVICAL PLATE 36MM	2
53430238	ELEGANCE 2 LEVEL CERVICAL PLATE 38MM	-
53430240	ELEGANCE 2 LEVEL CERVICAL PLATE 40MM	2

ELEGANCE PLATES 3 LEVEL

REFERENCE	DESIGNATION	QTY
53430338	ELEGANCE 3 LEVEL CERVICAL PLATE 38MM	2
53430341	ELEGANCE 3 LEVEL CERVICAL PLATE 41MM	-
53430344	ELEGANCE 3 LEVEL CERVICAL PLATE 44MM	2
53430347	ELEGANCE 3 LEVEL CERVICAL PLATE 47MM	2
53430350	ELEGANCE 3 LEVEL CERVICAL PLATE 50MM	2
53430353	ELEGANCE 3 LEVEL CERVICAL PLATE 53MM	2
53430356	ELEGANCE 3 LEVEL CERVICAL PLATE 56MM	2
53430359	ELEGANCE 3 LEVEL CERVICAL PLATE 59MM	-
53430362	ELEGANCE 3 LEVEL CERVICAL PLATE 62MM	2

ELEGANCE SCREW (VARIABLE)

REF	DESIGNATION	QTY
53044512	ELEGANCE VARIABLE SCREW Ø4.5x12MM SELF-TAPPING	2
53044514	ELEGANCE VARIABLE SCREW Ø4.5x14MM SELF-TAPPING	6
53044516	ELEGANCE VARIABLE SCREW Ø4.5x16MM SELF-TAPPING	6
53044518	ELEGANCE VARIABLE SCREW Ø4.5x18MM SELF-TAPPING	4
53044520	ELEGANCE VARIABLE SCREW Ø4.5x20MM SELF-TAPPING	-
53034012	ELEGANCE VARIABLE SCREW Ø4.0x12MM SELF-DRILLING	12
53034014	ELEGANCE VARIABLE SCREW Ø4.0x14MM SELF-DRILLING	20
53034016	ELEGANCE VARIABLE SCREW Ø4.0x16MM SELF-DRILLING	18
53034018	ELEGANCE VARIABLE SCREW Ø4.0x18MM SELF-DRILLING	8
53034020	ELEGANCE VARIABLE SCREW Ø4.0x20MM SELF-DRILLING	-

ELEGANCE SCREW (FIXED)

REF	DESIGNATION	QTY
53064512	ELEGANCE FIXED SCREW Ø4.5x12MM SELF-TAPPING	-
53064514	ELEGANCE FIXED SCREW Ø4.5x14MM SELF-TAPPING	-
53064516	ELEGANCE FIXED SCREW Ø4.5x16MM SELF-TAPPING	-
53064518	ELEGANCE FIXED SCREW Ø4.5x18MM SELF-TAPPING	-
53054012	ELEGANCE FIXED SCREW Ø4.0x12MM SELF-DRILLING	-
53054014	ELEGANCE FIXED SCREW Ø4.0x14MM SELF-DRILLING	-
53054016	ELEGANCE FIXED SCREW Ø4.0x16MM SELF-DRILLING	-
53054018	ELEGANCE FIXED SCREW Ø4.0x18MM SELF-DRILLING	-

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