

Surgical Technique

REGEX Anterior Cervical Plate System

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Our Achievements



Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Please NOTE that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

Warning:

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.



Contents

Product Overview	01
Indications for Use	03
Precautions & Contraindications	04
Surgical Steps	05
Surgical implants & instruments	16

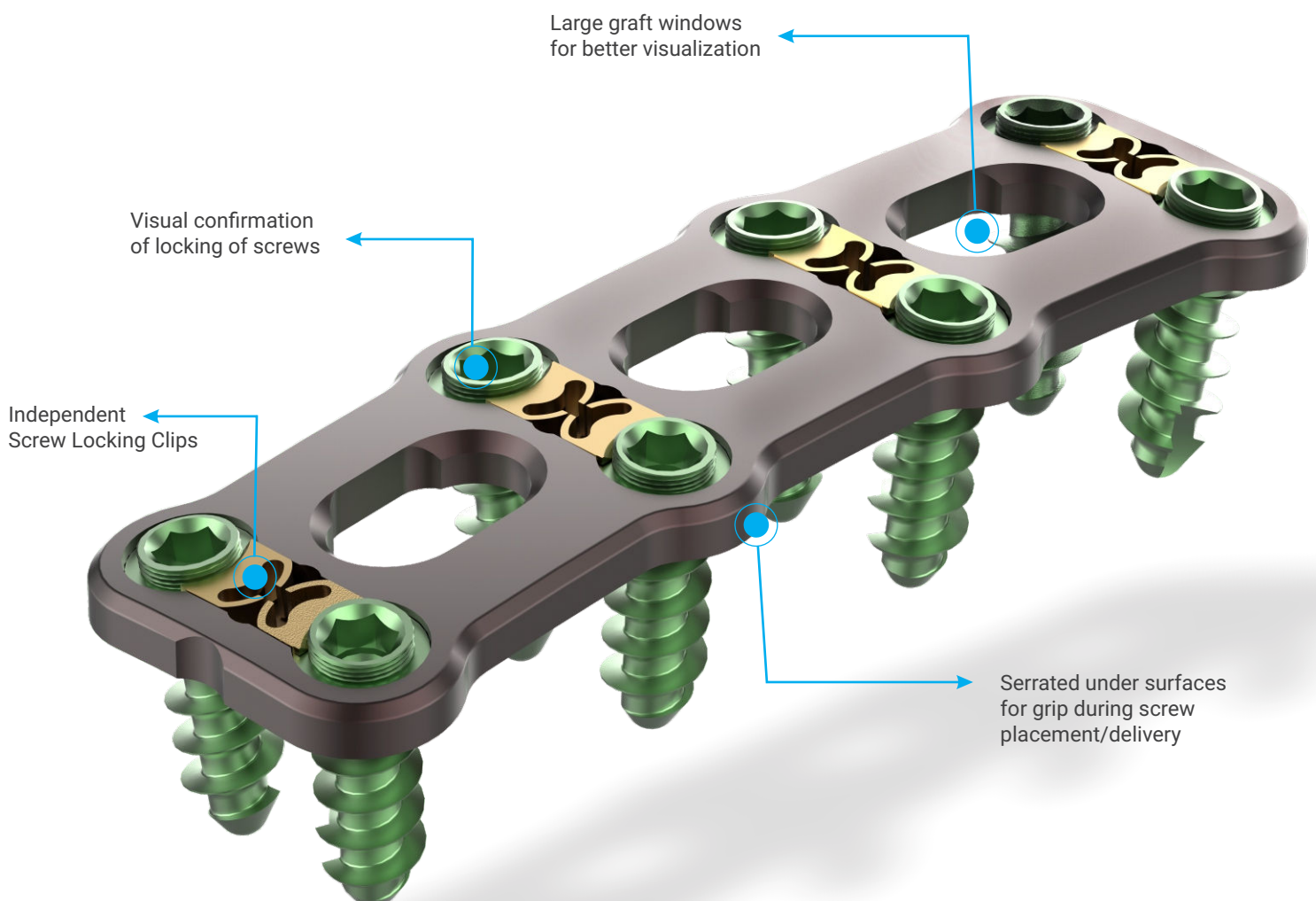
Product Overview

The REGEX System consists of multi-segmented titanium bone plates of various diameters and lengths, and associated instrumentation. REGEX System offers spine surgeons simplicity, efficiency, and versatility. It addresses patients' immediate needs and considers long-term treatment. REGEX System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct for fusion of the cervical spine (C2 to T1).

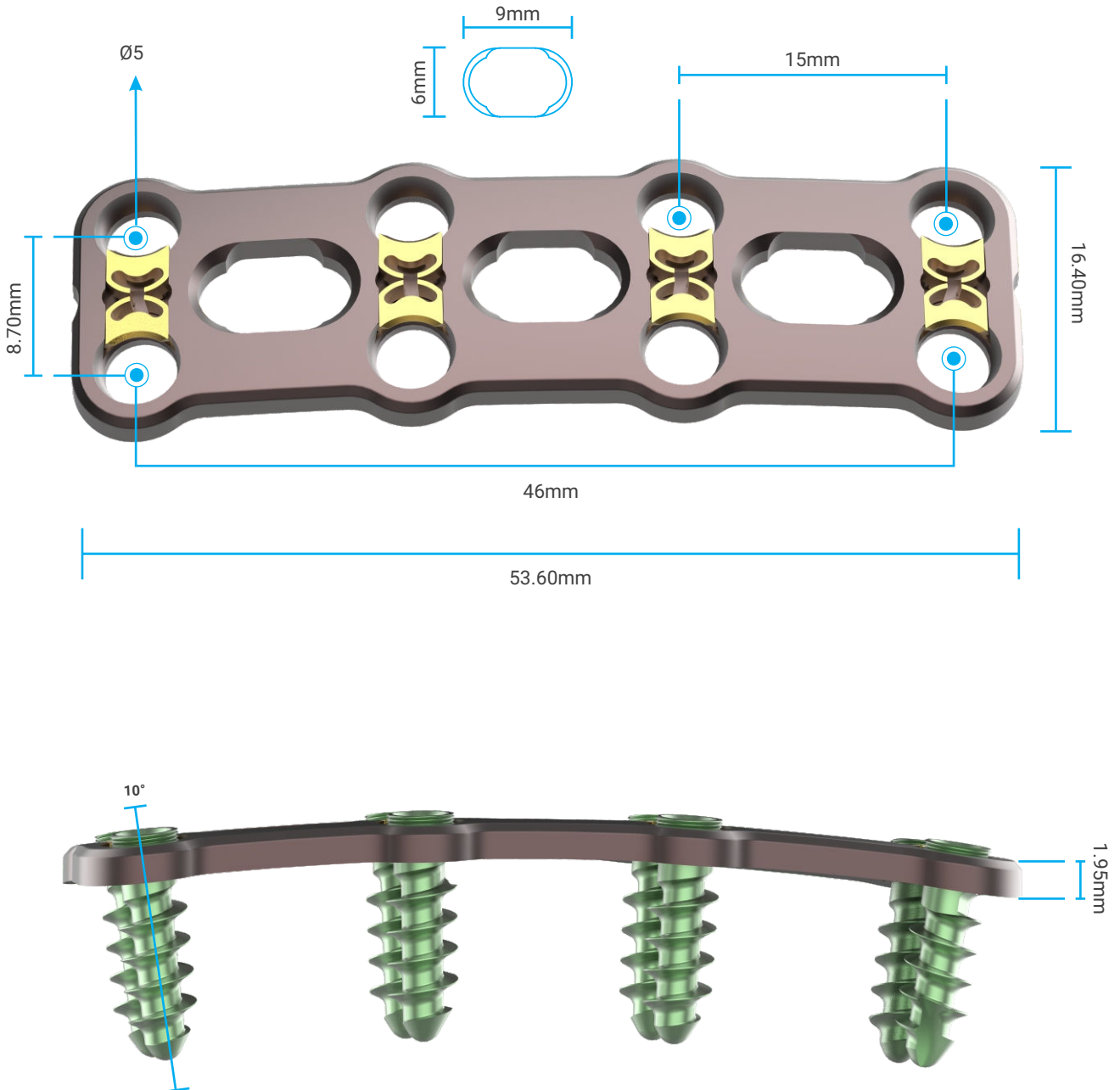
This device is ideal for spinal stabilization after surgically addressing neural compression from soft and bony stenosis of the spinal canal.

Benefits:

- Graft visualisation
- Pre contoured plates with low profile
- Low profile plates may help reduce post-operative discomfort. Integrated set screws maintain the plate's low profile and smooth surface.



REGEX-Anterior Cervical Plate, Level-III 46mm



Note: The technical details mentioned above are specifically based on the REGEX-Anterior Cervical Plate, Level-III 46mm implant. The dimensions will vary as per the size & Level of the implant.

Indications for Use:

The REGEX ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The REGEX ACP System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis
- Failed previous fusions
- Spondylolisthesis
- Spinal Stenosis



Precautions:

1. Surgical Implants must never be reused.
2. Contouring of metal implants should be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the device when contouring. Alterations will produce defects in the surface finish and internal stresses may become the focal point for eventual breakage. Do not use an implant if damage is suspected.
3. Excessive torque applied to the screws when seating the plate may cause failure of the bone resulting in stripped threads and/or compromised screw purchase.
4. Based on fatigue testing results, when using the REGEX ACP System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Contraindications:

1. Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis
2. Insufficient quality of quantity of bone which would inhibit rigid fixation.
3. Previous history of infection
4. Excessive local inflammation & open wounds
5. Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
6. Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
7. Patients having inadequate tissue coverage of the operative site.
8. Pregnancy
9. A condition of senility, mental illness, or substance abuse. These conditions, among others may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
10. Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

Surgical Steps:

Step 1: Preoperative Planning

The patient is placed in the supine position on the operating table. A standard anterior approach to the cervical spine is performed using one of several incision techniques. A transverse incision parallel to the skin folds of the neck can be utilized for one- or two-level procedures. An oblique incision along the anterior border of the sternocleidomastoid can be utilized for longer level procedures.

The anterior cervical spine is exposed through tissue dissection and fascial plane release. A discectomy or corpectomy is performed and the interbody fusion area prepared. A bone graft or PEEK anterior cervical interbody implant is then inserted into the prepared disc space.

Step 2: Plate Selection

To select the appropriate REGEX Anterior Cervical Plate, the center of the cephalad hole to the center of the caudal hole can be measured using the REGEX- Caliper (7-025-20). The distance between the desired xation points on the appropriate vertebrae is measured and corresponds to the appropriate plate. In the event the distance measured fall between the two sizes, it is usually recommended to use the smaller size to prevent interference with adjacent disc



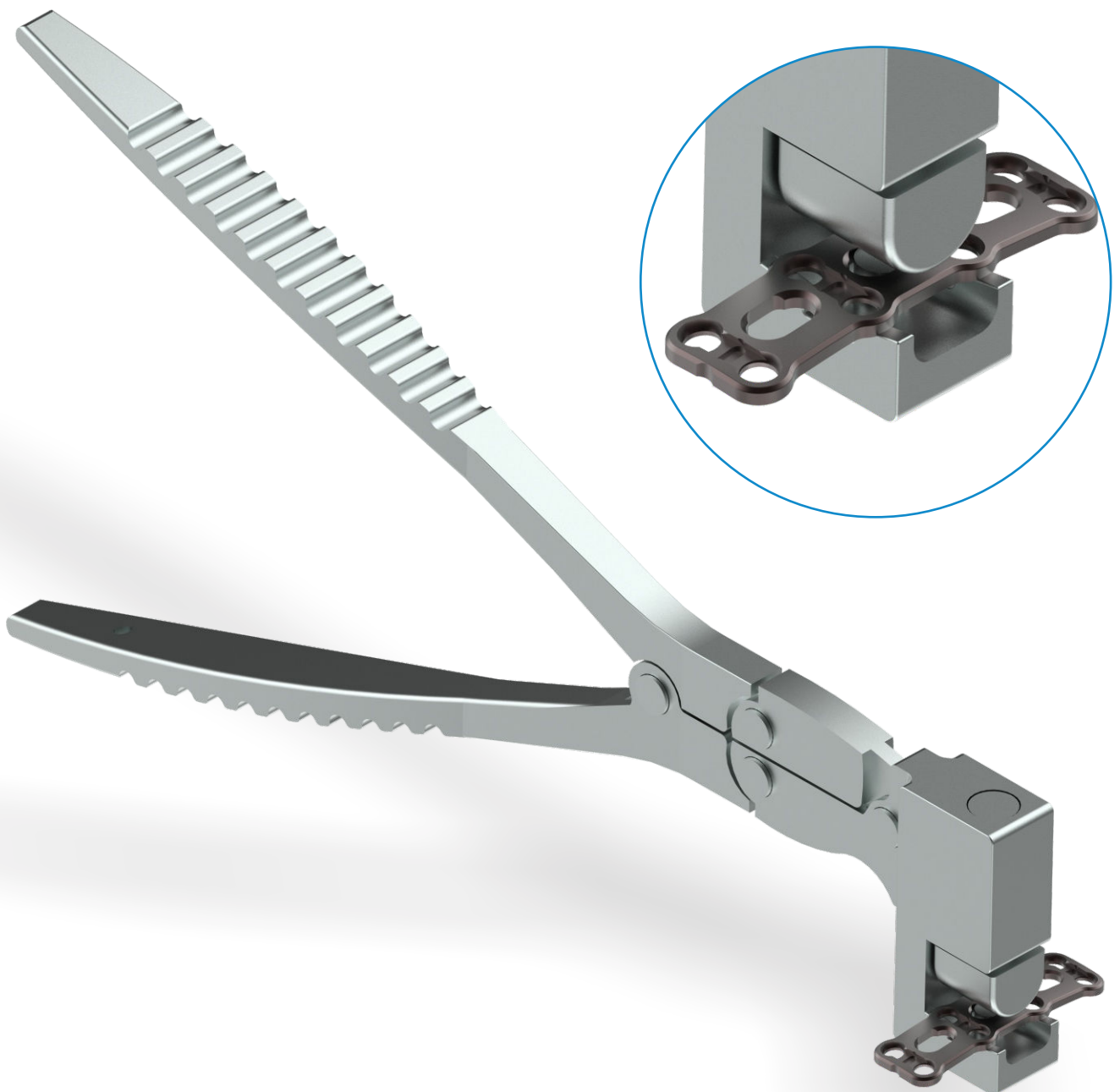
Step 3: Plate Placement

Once the appropriate size plate has been selected, use the REGEX-Plate Holder (7-025-07) to grip the cervical plate and check to ensure that the plate fits the anatomy. The Plate holder grips the plate in the two cut-outs of the instrument, making it possible to hold and insert the implant without personal contact to the patient.



Step 4: Plate Bending

The Plate Bender is designed for single hand operation to adjust the curvature of the plate. Place the cervical plate REGEX-Plate Bender (7-025-18). By depressing the instrument handles the plate is bent to the desired curvature based on incremental location changes and the amount of compression applied to



Step 5: Temporary Fixation

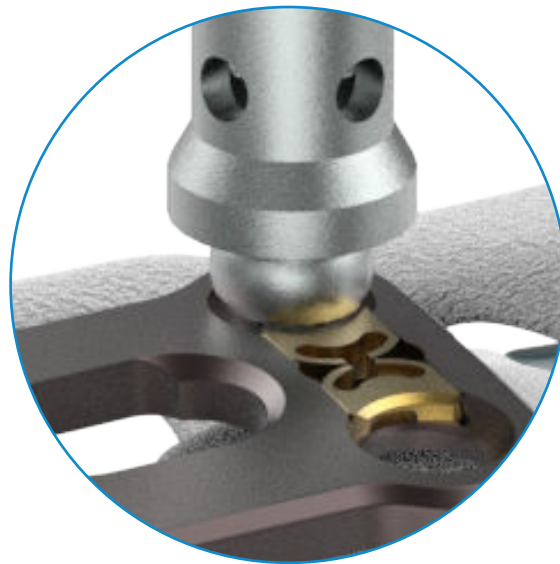
Temporary stainless steel non-implantable REGEX- Fixation Pin (**7-025-21**) are available to hold the plate on the vertebral bodies during preparation of the screwholes. Two threaded pins are inserted into diagonally opposite screwholes. After the REGEX- Fixation Pin (**7-025-21**) are inserted, screws are placed in the remaining holes. Once the screws are secure, remove the REGEX- Fixation Pin (**7-025-21**) and insert the screws into the vacant hole

Temporary stainless steel non-implantable Cage REGEX- Fixation Pin (**7-025-21**) are available in 7mm and 10mm lengths to hold the plate on the cervical interbody fusion device during screw hole preparation and screw insertion. The threaded Cage REGEX- Fixation Pin (**7-025-21**) is inserted into the cervical interbody fusion device through the plate graft window. After the Cage REGEX- Fixation Pin (**7-025-21**) is inserted, screw holes are prepared and screws are inserted into the plate. Once the screws are secure, remove the Cage



Step 6: Pilot Hole Preparation

Use the REGEX-Variable Awl Sleeve (7-025-02) or REGEX-Fixed Awl Sleeve (7-025-03) along with the REGEX-Awl (7-025-01) to create the pilot holes enabling smooth insertion of the screws in the bone.

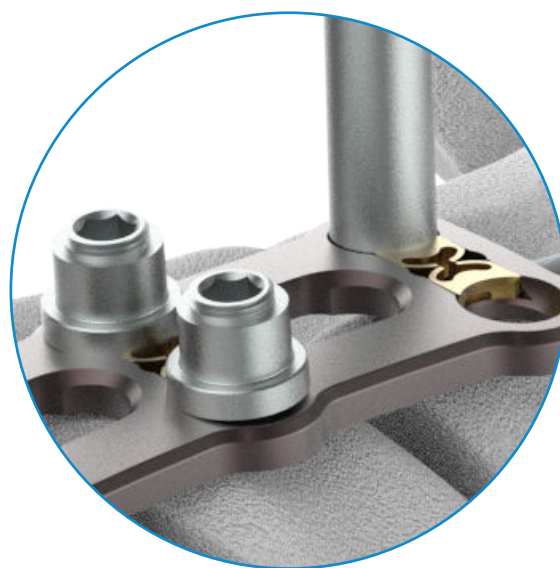


Step 6a: Screw Hole Preparation (using single barrel guide)

There are a variety of options available for screw-hole preparation. It is important to ensure that the REGEX- Single Barrel Fixed Drill Guide (7-025-09) corresponds to the type of screw being implanted. Drill Guides are available in REGEX- Single Barrel Fixed Drill Guide (7-025-09) and REGEX- Double Barrel Variable Drill Guide (7-025-08) option. The Drill Guide consists of one cannula for the Single Barrel and two cannulas for the Double Barrel. The Drill Guide must be securely affixed to the plate prior to preparation of the screw hole.

To ensure the REGEX-Single Barrel Fixed Drill Guide (7-025-09) fixation to the plate, the cannula of the guide was designed with a spherical surface to match the screw-hole of the plate.

There are variety of options available for drilling purpose. Use the appropriate REGEX- 10.0mm Drill (7-025-12) with the REGEX-Quick Release Handle (7-025-04) to drill or enlarge the plot hole.



Step 6b: Screw Hole Preparation (using double barrel guide)

To ensure REGEX- Double Barrel Variable Drill Guide (**7-025-08**) fixation to the plate, the cannulas of the guide were designed to match the outside profile of the plate. Ensure the REGEX- Double Barrel Variable Drill Guide (**7-025-08**) is properly mated to the plate prior to hole preparation.

After the correct Drill Guide is chosen, prepare the screw hole using the drill or REGEX-Awl (**7-025-01**). If using self-drilling screws, use the awl to prepare the hole. Pre-drilling of the hole is not required for self-drilling screws. A tap is also available if needed or desired.

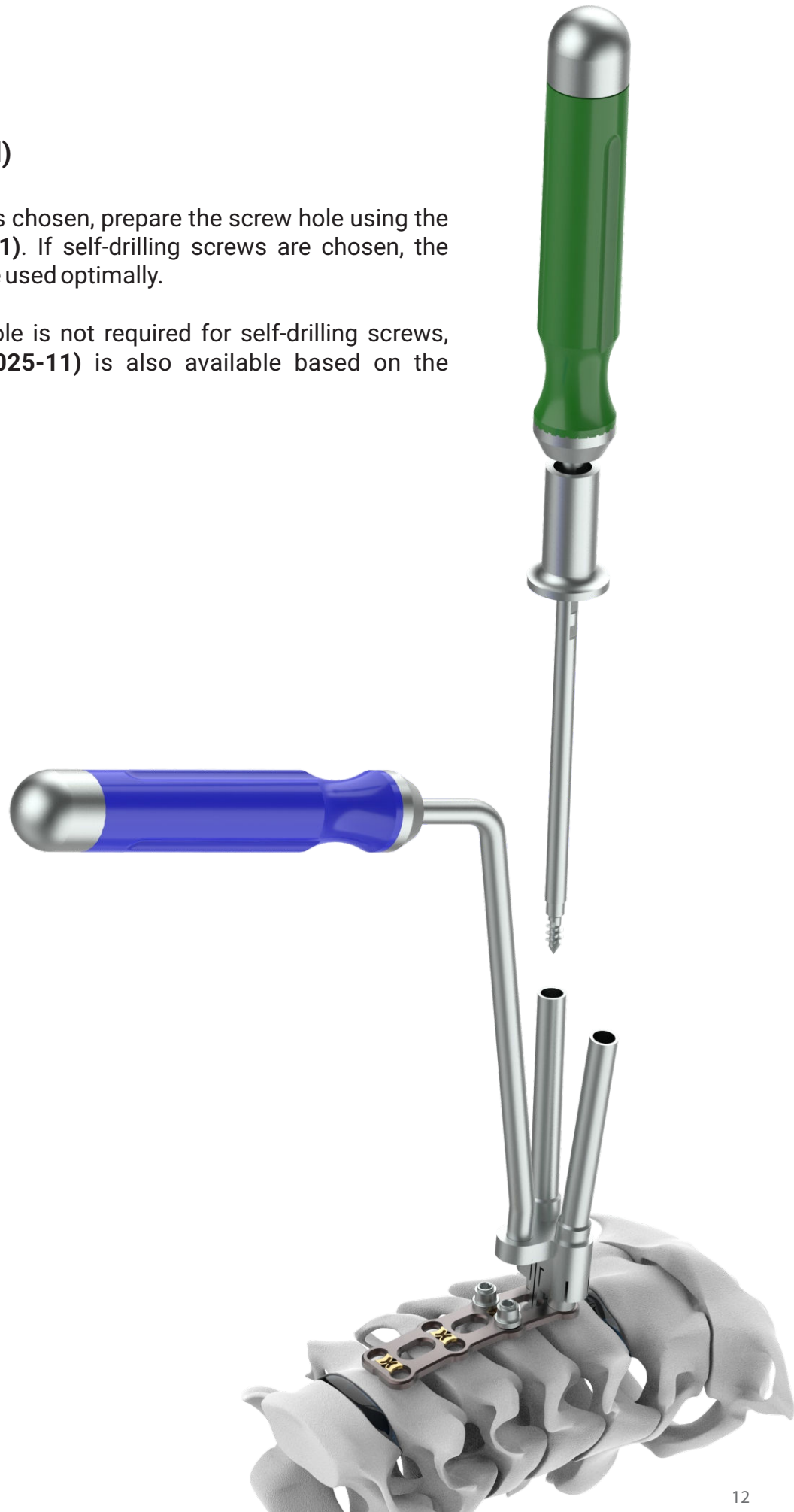
(NOTE: Drills, REGEX-Awl (7-025-01**), and REGEX-Tap (**7-025-11**) will work with all of the Drill Guide options.)**



Step 7: Tapping (Optional)

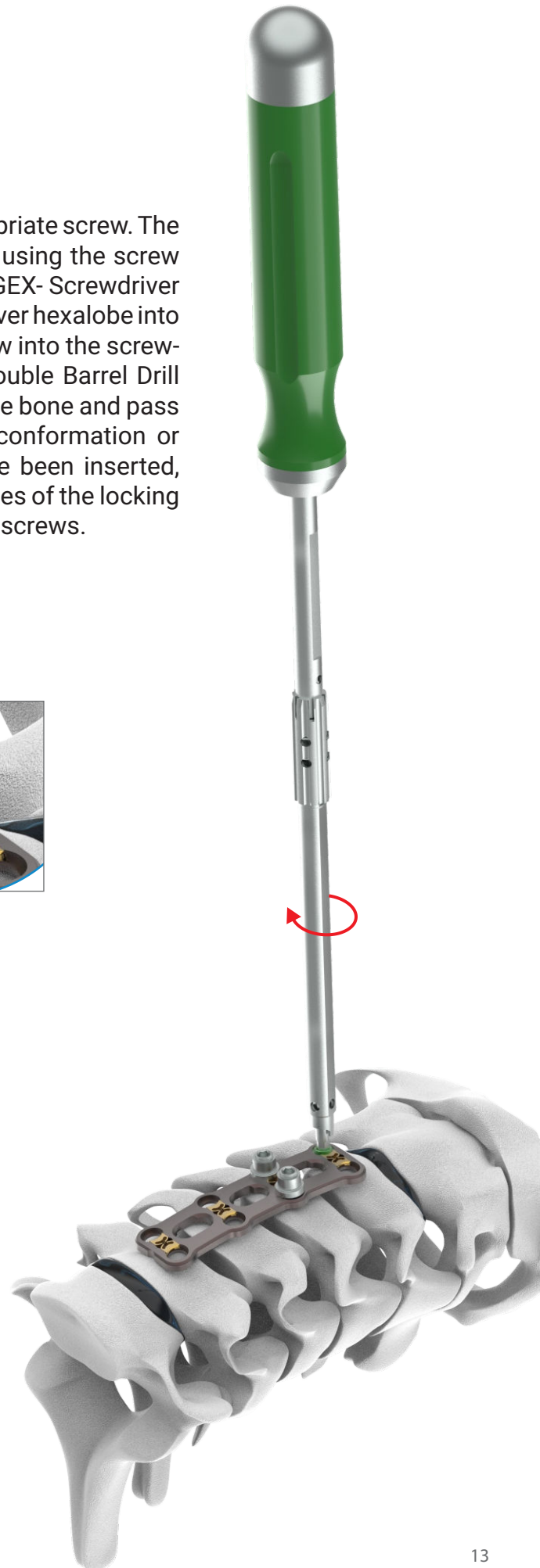
After the correct Drill Guide is chosen, prepare the screw hole using the drill or REGEX-Awl (7-025-01). If self-drilling screws are chosen, the REGEX-Awl (7-025-01) will be used optimally.

NOTE: Pre-drilling of the hole is not required for self-drilling screws, although a REGEX-Tap (7-025-11) is also available based on the discretion of the surgeon.



Step 8: Screw Insertion:

Once the screw hole has been prepared, select the appropriate screw. The length and diameter of the screw can be confirmed by using the screw gauges on the screw caddy. Attach the screw to the REGEX- Screwdriver for Screw Insertion (**7-025-06**) by inserting the Screwdriver hexalobe into the screw. Insert the Screwdriver with the attached screw into the screw-hole on the plate. Screws can be inserted while the Double Barrel Drill Guide is still fixed to the plate. Advance the screw into the bone and pass the locking spring on the plate until a tactile, visual conformation or audible click is felt or heard. Once all the screws have been inserted, locking should be ensured by viewing that the lateral edges of the locking springs are positioned over the proximal shoulders of the screws.





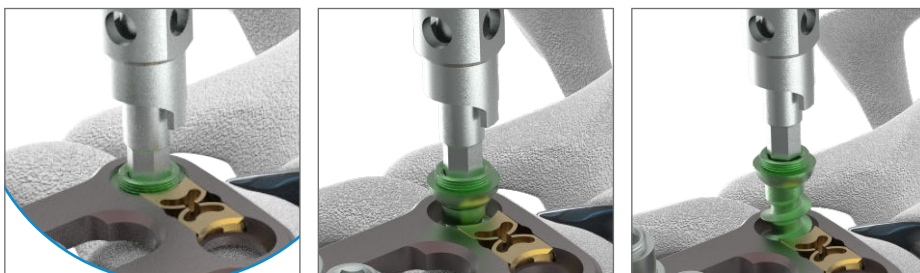
Note: Repeat all the previous steps to screw all the plate holes.

Step 9: Screw Removal

If a screw has been locked in place but needs to be removed the Screw Removal Tool is to be utilized.

Attach the REGEX- Screwdriver for Screw Removal (**7-025-05**) Tool to the implanted screw by inserting the Screw Removal Tool hexalobe into the screw. The position of Screw Removal Tool should be placed in such that Screw Removal Tool sleeve should be on the lateral side of the locking spring on the plate. As you rotate the Screw Removal Tool counter clockwise to remove the screw, the Screw Removal Tool sleeve comes in contact with the locking spring on the plate. The locking spring will move laterally and the proximal shoulders of the screw will pass the locking spring on the plate. Keep advancing the screw counter clockwise for removal.

(**NOTE:** Care should be taken in placing the Screw Removal Tool sleeve in the correct orientation. The screw might need prior adjustment/rotation to aid in the engagement of the Screw Removal Tool sleeve.)



Plates

REGEX-Anterior Cervical Plate, Level-I

Code	Length
4-033-12TI	12mm
4-033-14TI	14mm
4-033-16TI	16mm
4-033-18TI	18mm
4-033-20TI	20mm
4-033-22TI	22mm
4-033-24TI	24mm



REGEX-Anterior Cervical Plate, Level-II

Code	Length
4-034-26TI	26mm
4-034-28TI	28mm
4-034-30TI	30mm
4-034-32TI	32mm
4-034-34TI	34mm
4-034-37TI	37mm
4-034-40TI	40mm
4-034-43TI	43mm
4-034-46TI	46mm



REGEX-Anterior Cervical Plate, Level-III

Code	Length
4-035-40TI	40mm
4-035-43TI	43mm
4-035-46TI	46mm
4-035-49TI	49mm
4-035-52TI	52mm
4-035-55TI	55mm
4-035-58TI	58mm
4-035-61TI	61mm
4-035-64TI	64mm
4-035-67TI	67mm



REGEX-Anterior Cervical Plate, Level-IV

Code	Length
4-036-60TI	60mm
4-036-64TI	64mm
4-036-68TI	68mm
4-036-72TI	72mm
4-036-76TI	76mm
4-036-80TI	80mm
4-036-84TI	84mm



Screws

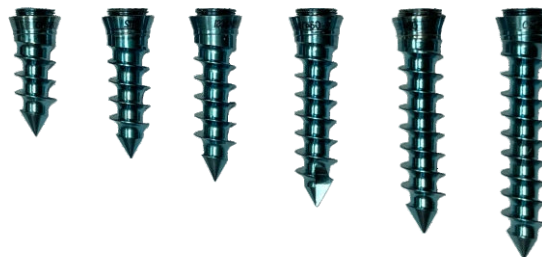
4.0mm REGEX-Bone Screw, Self-Drilling, Variable Angled

Code	Length
4-037-10TI	10mm
4-037-12TI	12mm
4-037-14TI	14mm
4-037-16TI	16mm
4-037-18TI	18mm
4-037-20TI	20mm



4.0mm REGEX-Bone Screw, Self-Drilling, Fixed Angled

Code	Length
4-038-10TI	10mm
4-038-12TI	12mm
4-038-14TI	14mm
4-038-16TI	16mm
4-038-18TI	18mm
4-038-20TI	20mm



4.5mm REGEX-Bone Screw, Self-Drilling, Variable Angled

Code	Length
4-039-12TI	12mm
4-039-14TI	14mm
4-039-16TI	16mm
4-039-18TI	18mm
4-039-20TI	20mm



4.5mm REGEX-Bone Screw, Self-Drilling, Fixed Angled

Code	Length
4-040-12TI	12mm
4-040-14TI	14mm
4-040-16TI	16mm
4-040-18TI	18mm
4-040-20TI	20mm



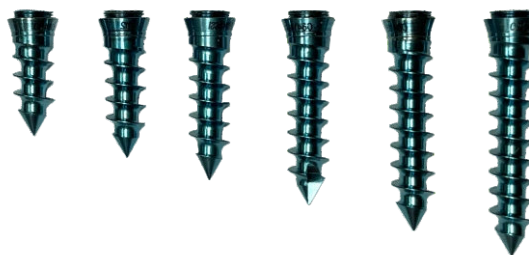
4.0mm REGEX-Bone Screw, Self-Tapping, Variable Angled

Code	Length
4-087-10TI	10mm
4-087-12TI	12mm
4-087-14TI	14mm
4-087-16TI	16mm
4-087-18TI	18mm
4-087-20TI	20mm



4.0mm REGEX-Bone Screw, Self-Tapping, Fixed Angled

Code	Length
4-088-10TI	10mm
4-088-12TI	12mm
4-088-14TI	14mm
4-088-16TI	16mm
4-088-18TI	18mm
4-088-20TI	20mm



4.5mm REGEX-Bone Screw, Self-Tapping, Variable Angled

Code	Length
4-089-12TI	12mm
4-089-14TI	14mm
4-089-16TI	16mm
4-089-18TI	18mm
4-089-20TI	20mm

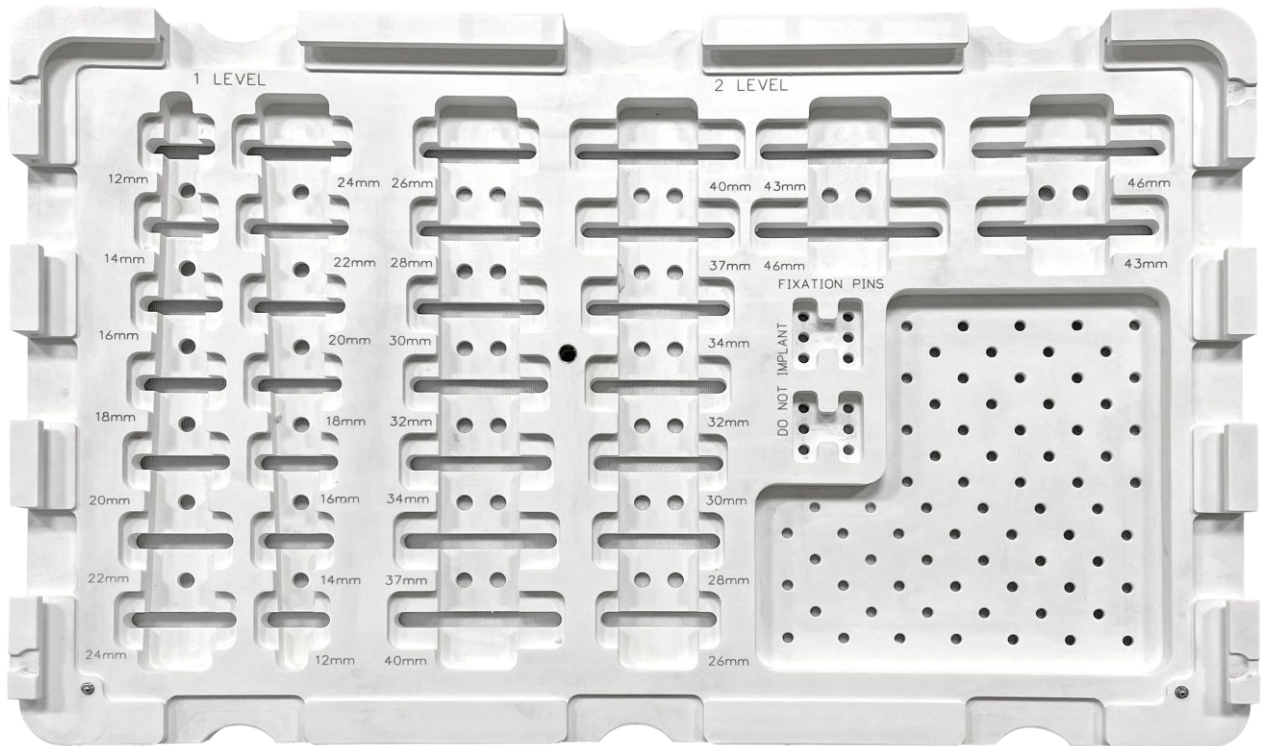


4.5mm REGEX-Bone Screw, Self-Tapping, Fixed Angled

Code	Length
4-090-12TI	12mm
4-090-14TI	14mm
4-090-16TI	16mm
4-090-18TI	18mm
4-090-20TI	20mm



4-041-01 REGEX Implant Tray Level 1 & 2 Plates

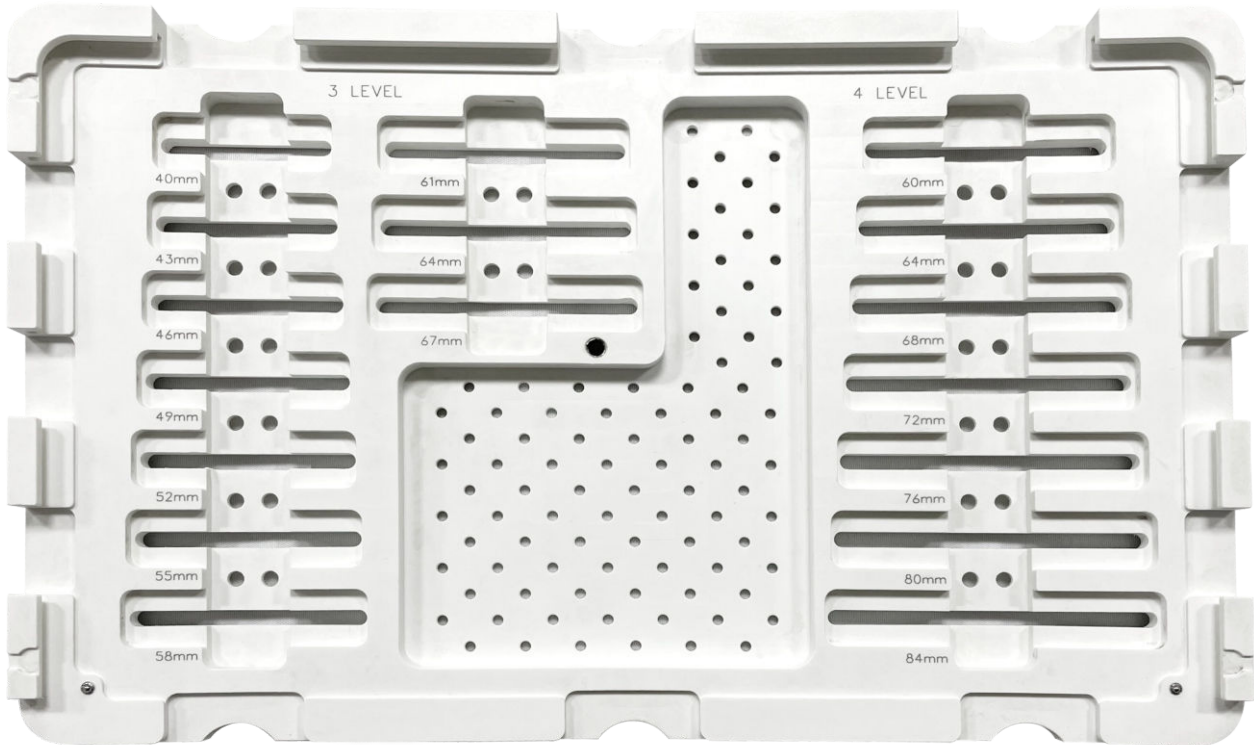


Level 1

Code	Length	Qty.
4-033-12TI	12mm	2
4-033-14TI	14mm	2
4-033-16TI	16mm	2
4-033-18TI	18mm	2
4-033-20TI	20mm	2
4-033-22TI	22mm	2
4-033-24TI	24mm	2

Level 2

Code	Length	Qty.
4-034-26TI	26mm	2
4-034-28TI	28mm	2
4-034-30TI	30mm	2
4-034-32TI	32mm	2
4-034-34TI	34mm	2
4-034-37TI	37mm	2
4-034-40TI	40mm	2
4-034-43TI	43mm	2
4-034-46TI	46mm	2

4-041-02 REGEX Implant Tray Level 3 & 4 Plates

Level 3

Code	Length	Qty.
4-035-40TI	40mm	1
4-035-43TI	43mm	1
4-035-46TI	46mm	1
4-035-49TI	49mm	1
4-035-52TI	52mm	1
4-035-55TI	55mm	1
4-035-58TI	58mm	1
4-035-61TI	61mm	1
4-035-64TI	64mm	1
4-035-67TI	67mm	1

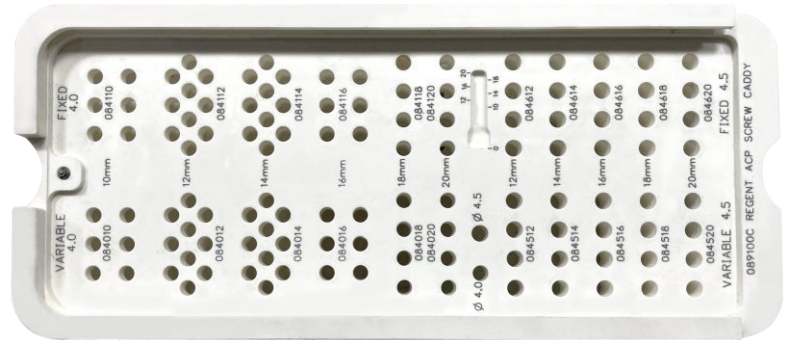
Level 4

Code	Length	Qty.
4-036-60TI	60mm	1
4-036-64TI	64mm	1
4-036-68TI	68mm	1
4-036-72TI	72mm	1
4-036-76TI	76mm	1
4-036-80TI	80mm	1
4-036-84TI	84mm	1

4-041-03 REGEX Implant Screws Tray

4.0mm REGEX-Bone Screws, Self-Drilling, Variable Angled

Code	Length	Qty.
4-037-10TI	10mm	6
4-037-12TI	12mm	10
4-037-14TI	14mm	10
4-037-16TI	16mm	6
4-037-18TI	18mm	4
4-037-20TI	20mm	4



4.0mm REGEX-Bone Screws, Self-Drilling, Fixed Angled

Code	Length	Qty.
4-038-10TI	10mm	6
4-038-12TI	12mm	10
4-038-14TI	14mm	10
4-038-16TI	16mm	6
4-038-18TI	18mm	4
4-038-20TI	20mm	4

4.0mm REGEX-Bone Screws, Self-Tapping, Variable Angled

Code	Length	Qty.
4-087-10TI	10mm	6
4-087-12TI	12mm	10
4-087-14TI	14mm	10
4-087-16TI	16mm	6
4-087-18TI	18mm	4
4-087-20TI	20mm	4

4.0mm REGEX-Bone Screws, Self-Tapping, Fixed Angled

Code	Length	Qty.
4-088-10TI	10mm	6
4-088-12TI	12mm	10
4-088-14TI	14mm	10
4-088-16TI	16mm	6
4-088-18TI	18mm	4
4-088-20TI	20mm	4

4.5mm REGEX-Bone Screws, Self-Drilling, Variable Angled

Code	Length	Qty.
4-039-12TI	12mm	4
4-039-14TI	14mm	4
4-039-16TI	16mm	4
4-039-18TI	18mm	4
4-039-20TI	20mm	4

OR

4.5mm REGEX-Bone Screws, Self-Tapping, Variable Angled

Code	Length	Qty.
4-089-12TI	12mm	4
4-089-14TI	14mm	4
4-089-16TI	16mm	4
4-089-18TI	18mm	4
4-089-20TI	20mm	4

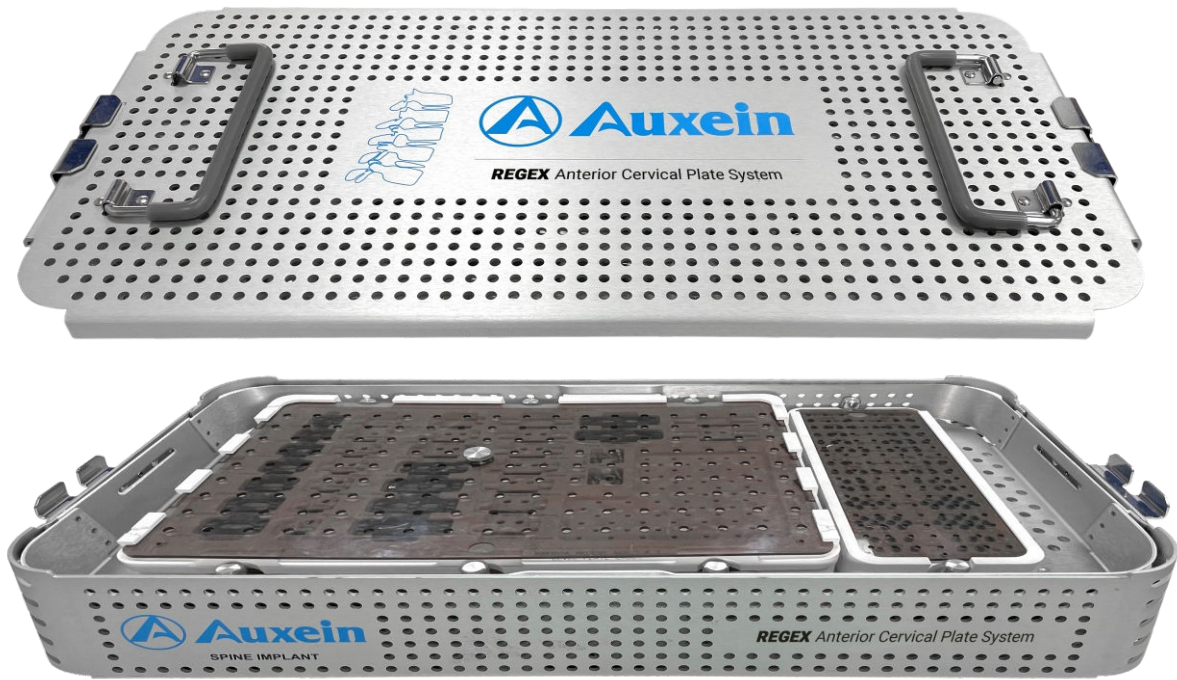
4.5mm REGEX-Bone Screws, Self-Tapping, Fixed Angled

Code	Length	Qty.
4-090-12TI	12mm	4
4-090-14TI	14mm	4
4-090-16TI	16mm	4
4-090-18TI	18mm	4
4-090-20TI	20mm	4

4.5mm REGEX-Bone Screws, Self-Drilling, Fixed Angled

Code	Length	Qty.
4-040-12TI	12mm	4
4-040-14TI	14mm	4
4-040-16TI	16mm	4
4-040-18TI	18mm	4
4-040-20TI	20mm	4

**4-041-04 REGEX Anterior Cervical Plate System
Implant case with Lid**



7-025-01

REGEX- Awl



7-025-02

REGEX- Variable Awl Sleeve



7-025-03

REGEX- Fixed Awl Sleeve



7-025-04

REGEX- Quick Release Handle



7-025-05

REGEX- Screwdriver for Screw Removal



7-025-06

REGEX- Screwdriver for Screw Insertion



7-025-07

REGEX- Plate Holder



7-025-08

REGEX- Double Barrel Variable Drill Guide



7-025-09

REGEX- Single Barrel Fixed Drill Guide



7-025-10

REGEX- Single Barrel Variable Drill Guide



7-025-11

REGEX- Tap



7-025-12

REGEX- 10.0mm Drill



7-025-13

REGEX- 12.0mm Drill



7-025-14

REGEX- 14.0mm Drill



7-025-15

REGEX- 16.0mm Drill



7-025-16

REGEX- 18.0mm Drill



7-025-17 REGEX- Universal Drill Guide



7-025-18 REGEX- Plate Bender



7-025-19 REGEX- Revision Screwdriver



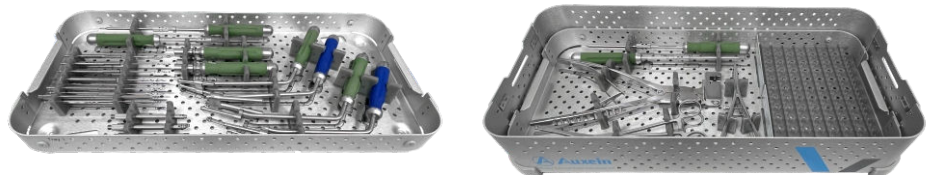
7-025-20 REGEX- Caliper



7-025-21 REGEX- Fixation Pin



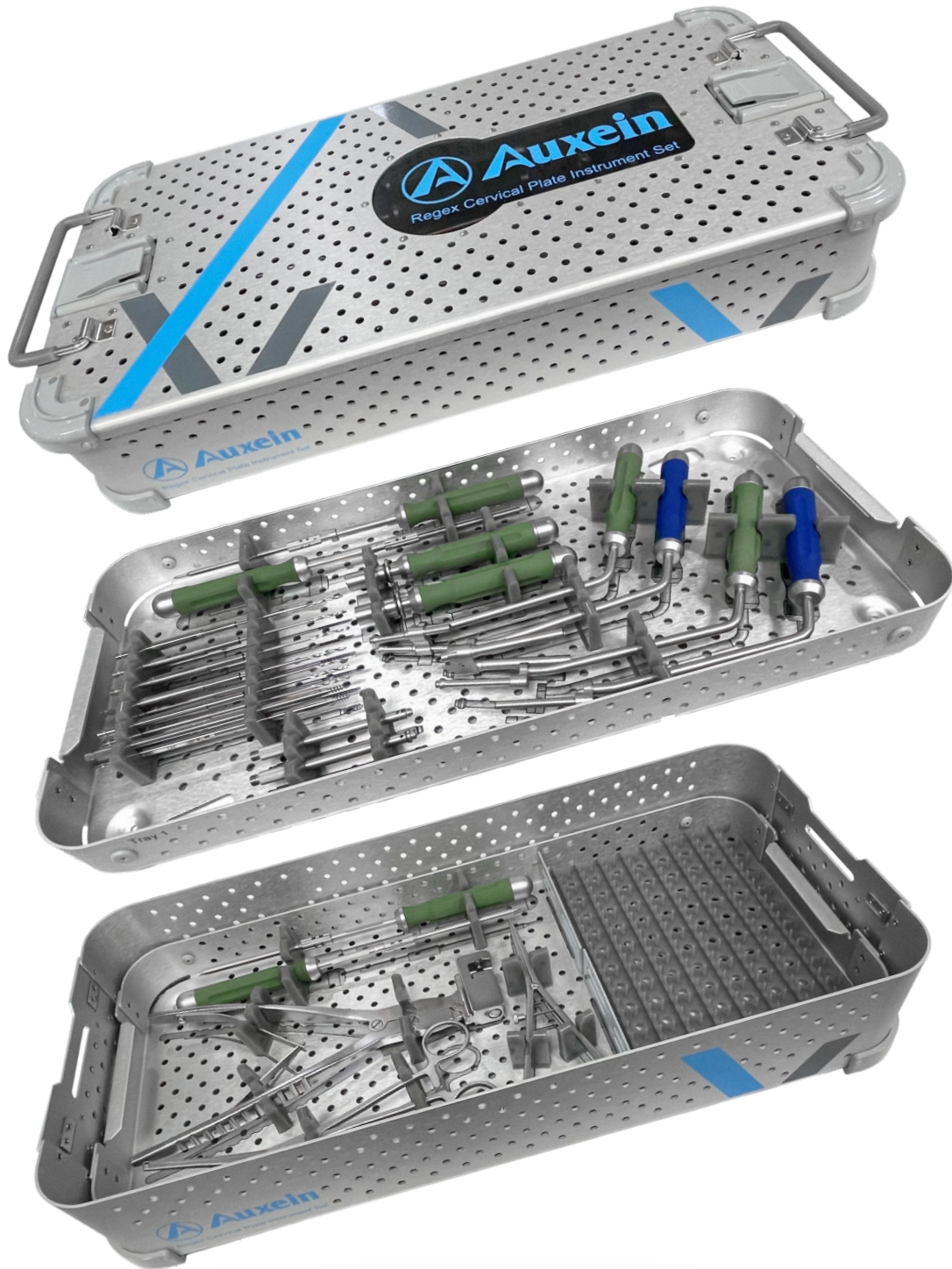
7-025-22 Instrument Tray for REGEX-Anterior Cervical Plate Instrument Set



7-025-23 Container with Tray for REGEX- System



7-025 REGEX-Anterior Cervical Plate Instrument Set



7-025 REGEX-Anterior Cervical Plate Instrument Set

Code	Set Consisting of	Qty.
7-025-01	REGEX- Awl	1
7-025-02	REGEX- Variable Awl Sleeve	1
7-025-03	REGEX- Fixed Awl Sleeve	1
7-025-04	REGEX- Quick Release Handle	2
7-025-05	REGEX- Screwdriver for Screw Removal	1
7-025-06	REGEX- Screwdriver for Screw Insertion	2
7-025-07	REGEX- Plate Holder	1
7-025-08	REGEX- Double Barrel Variable Drill Guide	1
7-025-09	REGEX- Single Barrel Fixed Drill Guide	1
7-025-10	REGEX- Single Barrel Variable Drill Guide	1
7-025-11	REGEX- Tap	2
7-025-12	REGEX- 10.0mm Drill	2
7-025-13	REGEX- 12.0mm Drill	2
7-025-14	REGEX- 14.0mm Drill	2
7-025-15	REGEX- 16.0mm Drill	2
7-025-16	REGEX- 18.0mm Drill	2
7-025-17	REGEX- Universal Drill Guide	1
7-025-18	REGEX- Plate Bender	1
7-025-19	REGEX- Revision Screwdriver	1
7-025-20	REGEX- Caliper	1
7-025-21	REGEX- Fixation Pin	10
7-025-22	Instrument Tray for REGEX-Anterior Cervical Plate Instrument Set	2
7-025-23	Container with Tray for REGEX- System	1



USA

Auxein Inc.
1500 Nw 89th Court, Suite 107-108
Doral, Florida 33172
Tel: +1 305 395 6062
E Fax: +1 305 395 6262
Email: USoffice@auxein.com

MEXICO

Auxein México, S.A. de C.V.
Tepic 139 int 801, Colonia Roma Sur,
Alcaldía Cuauhtémoc, CDMX,
México, C.P. 06760
Tel: +521 55 7261 0318
Email: info@auxein.mx

INDIA

Auxein Medical Pvt. Ltd.
Plot No. 168-169-170, Phase-4,
Kundli Industrial Area,
HSIIDC, Sector-57, Sonapat - 131028, Haryana
Tel: +91 99106 43638 | Fax: +91 86077 70197
Email: info@auxein.com