Auxein®

Surgical Technique

APEX - Anterior Cervical Plate System

www.auxein.com

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.

DAIS
Division of Auxein Institute for Surgeons

Organised by: Auxein

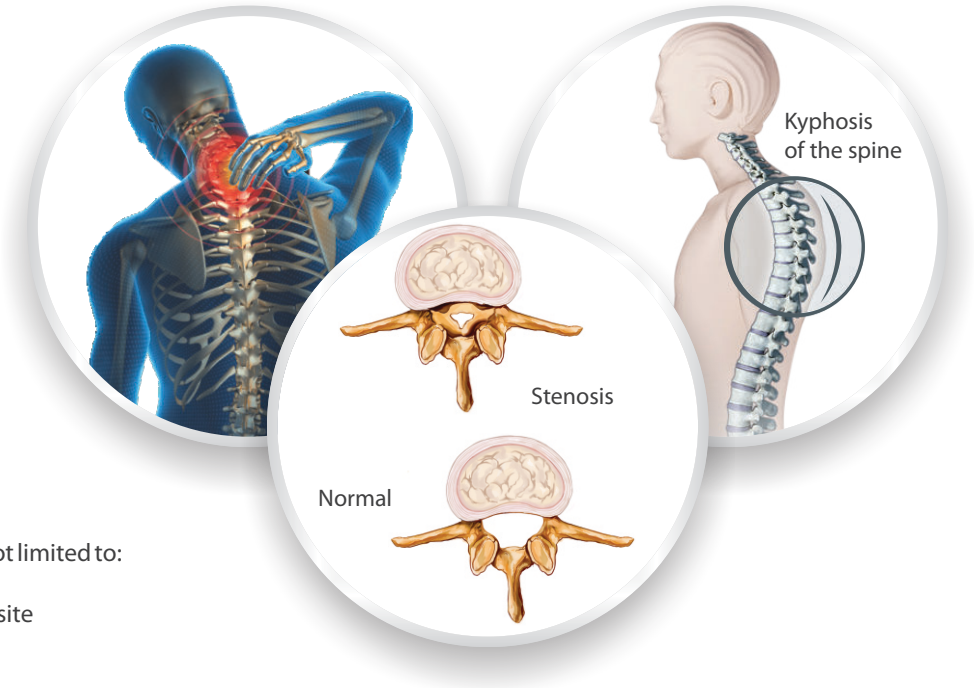
INTRODUCTION

The APEX- Anterior Cervical Plate System is simple to use, low profile plate which maintains the strength according to applicable standard for cervical fixation. It's minimized height and narrow transverse width enhances visualization and plate manipulation for precise plate placement while reducing the amount of traction on trachea and oesophagus.

INDICATIONS:

The APEX- Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for following indications:

- Degenerative Disc Disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and Radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudarthrosis
- Deformity (i.e. kyphosis, lordosis and/or scolosis)
- Trauma
- Deformities or curvatures
- Decompression of the spine cord



CONTRAINDICATIONS:

Contraindications include, but are not limited to:

- Infection, local to the operative site
- Signs of local inflammations
- Fever or leucocytosis
- Morbid Obesity
- Pregnancy
- Mental illness
- Any case not needing a bone graft and fusion or where fracture healing is not required

SURGICAL TECHNIQUE

Patient Positioning:
The Patient is placed in supine position with the head in slight extension as shown in Fig (1). The posterior cervical spine is supported to establish and maintain normal cervical lordosis. The surgeon then must choose a right or left sided approach to the cervical column.
Anterior Approach:
After exposing the cervical spine, the retractor is placed to provide optimal visualization. The Distractor is placed over

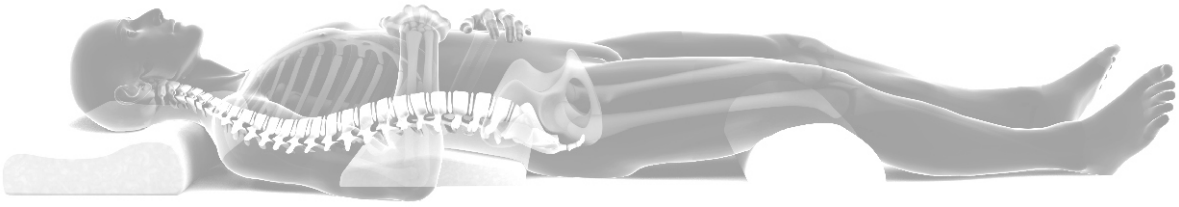


Fig (1)

distraction pins positioned midline in the vertebral bodies and the appropriate amount of distraction is applied as shown in Fig (2).
The Forceps may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament. Bone graft is then positioned between the vertebrae.

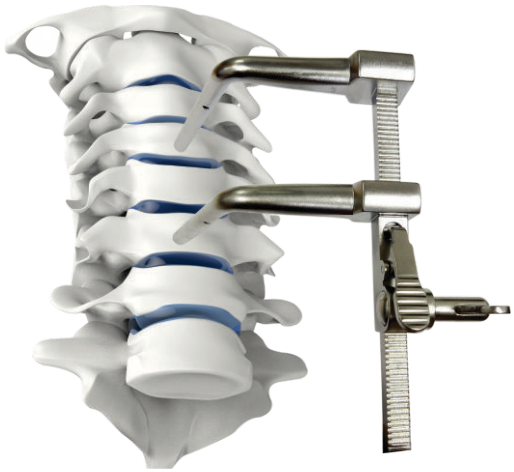


Fig (2)

Plate Selection:

The sizing of the APEX- Anterior Cervical Plate is measured from the center of the cranial hole to center of caudal hole. Measure the distance between appropriate vertebrae and select the corresponding plate. The plate length should be defined according to chosen screw length and angulation, so that it does not interfere with the adjacent unfused disc space.

Increase Lordosis

Fig (3)

Decrease Lordosis

Fig (4)

Plate Contouring:

The plate is designed and manufactured with a lordotic curve. However, the plate bender could be used to increase or decrease the lordosis as per requirement as shown above in Fig (3) & Fig (4). Although it is not recommended to bend the extremities of the plate as it could damage the locking mechanism of the plate.

Plate Positioning:

Plate Holder is used to hold the plate in appropriate position for fixation. To pick up a plate with plate holder, push the button on the proximal end of the plate holder and insert the tip into any screw hole or central slot in the plate. Release the button to engage the plate as shown in Fig (5).

Fig (5)

Fixation pins are used to assist and stabilize the plate in the midline prior to screw insertion. The jaws of "Inserter for fixation pin" are opened by pulling the flange on the shaft towards the handle. The flange is then released to engage the fixation pin. Insert the fixation pin through one of the four small holes along the midline of the plate as shown in Fig (6). Next, insert the second fixation pin into one of the small holes at other end of the plate. Fig (7) displays all the 4 small holes in the plate for fixation pins.

Fig (6)

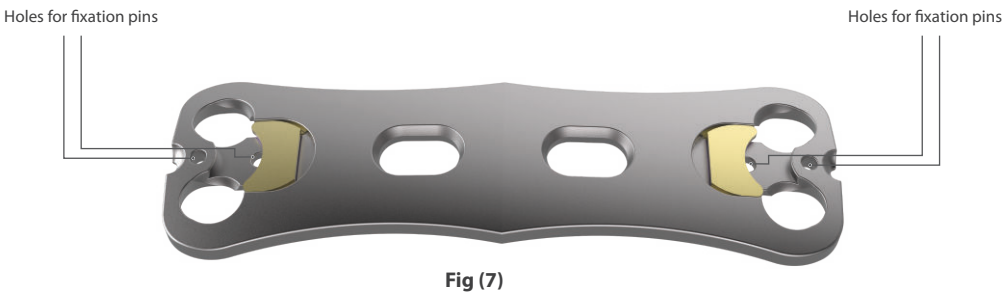


Fig (7)

Drilling:

In order to drill, the Drill Guide helps in aligning the Drill bit along the plate screw hole. Following are the two alternatives of Drilling Guide for drilling:

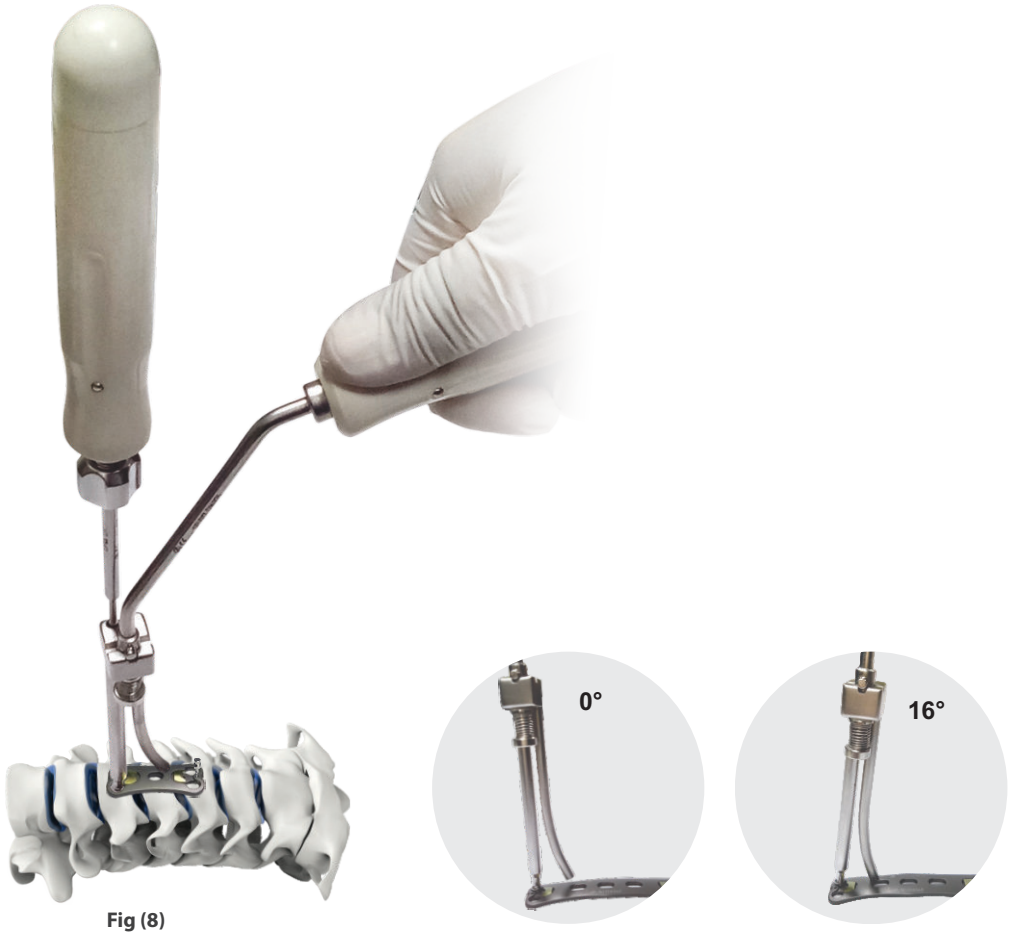


Fig (8)

1. Mono Drilling Guide:

Mono drilling guide is positioned in alignment to bone screw hole in the plate. Then a slight downward pressure is applied until the leg support of the drilling guide comes into contact with the plate as shown in Fig (8). The range of the cranial/caudal angulation ranges from 0° to 16°. The Multifunctional holder is used by loosening the nut and the drill bit is inserted into the handle

Fig (9)

2. Dual Drilling Guide:

Double barrel of the Dual Drilling Guide is placed into the bone screw holes of the plate and is slightly lowered until the leg support sits on the plate as shown in Fig (9).

Both the holes are drilled successively through the drilling guide.

Angulation of the Dual Drilling Guide varies from 0° to 16°.

If required, a Ø3.0mm tap is also available to create the screw thread pattern in the bone

Bone Screw Selection:

The standard bone screw is of 3.5mm diameter and is available both as self-tapping and self-drilling of 12, 14, 16, 18, 20 and 22mm lengths.

While the central slot bone screw is of 4.0mm diameter and is also available both as self-tapping and self-drilling of 12, 14, 16, 18, 20 and 22mm lengths.
Revision screws (APEX- 4.0mm Cancellous Screws) are also available to accommodate the surgeon's need in revision cases.

Sleeve and Screwdriver Shaft are the two main Components of the Screwdriver assembly. The Sleeve is used to pick the bone screw of appropriate diameter and length as shown in Fig (11). The Shaft is placed through the center of the Sleeve to engage the drive in the screw head as shown in Fig (10).

Fig (11)

Fig (10)

Bone Screw Insertion:

Two Bone screws are partially inserted at diagonal position in the plate. Now the fixation pins are removed using the Inserter for Fixation Pin. Finally the remaining two screws are fully inserted followed by the final tightening of the first two partially inserted screws as shown in Fig (12).

Fig (12)

Fig (13)

If intermediate vertebral body or Graft fixation is required while performing a multi-level procedure, the 4.0mm bone screw is used in the central slot of the plate. The pilot hole is drilled perpendicular to the plate slot. The 4.0 mm screw is inserted into the central slot using screwdriver as shown in Fig(13)

Screw Locking:

The Locking cap is used to prevent the movement of the bone screws in the plate and maintain the screws in a specific position. The Locking Cap Pusher is inserted into multifunctional holder and the nut on handle is tightened.

Both Locking cap are translated by inserting the **"LOCK"** tip of the cap pusher in the space between plate and cap and giving instrument a quarter turn as shown in Fig (14). The hemisphere on the lower surface of the cap helps in locking the cap on the plate in a specific position such that it prevents screw migration.

Fig (14)

To unlock the cap, the **"UNLOCK"** end of the Locking Cap Pusher is placed between plate and cap and the instrument is given a quarter turn as shown in Fig (15).

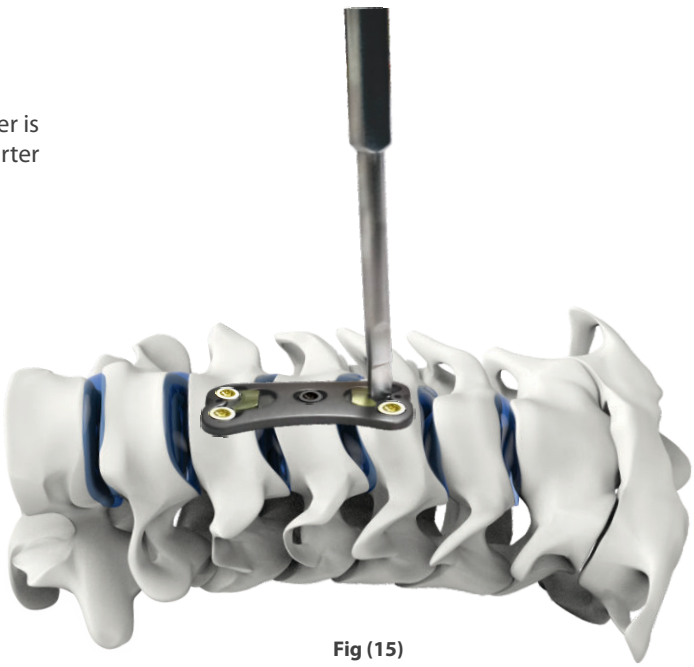


Fig (15)

The following Fig (15) displays the final construct after the surgery:

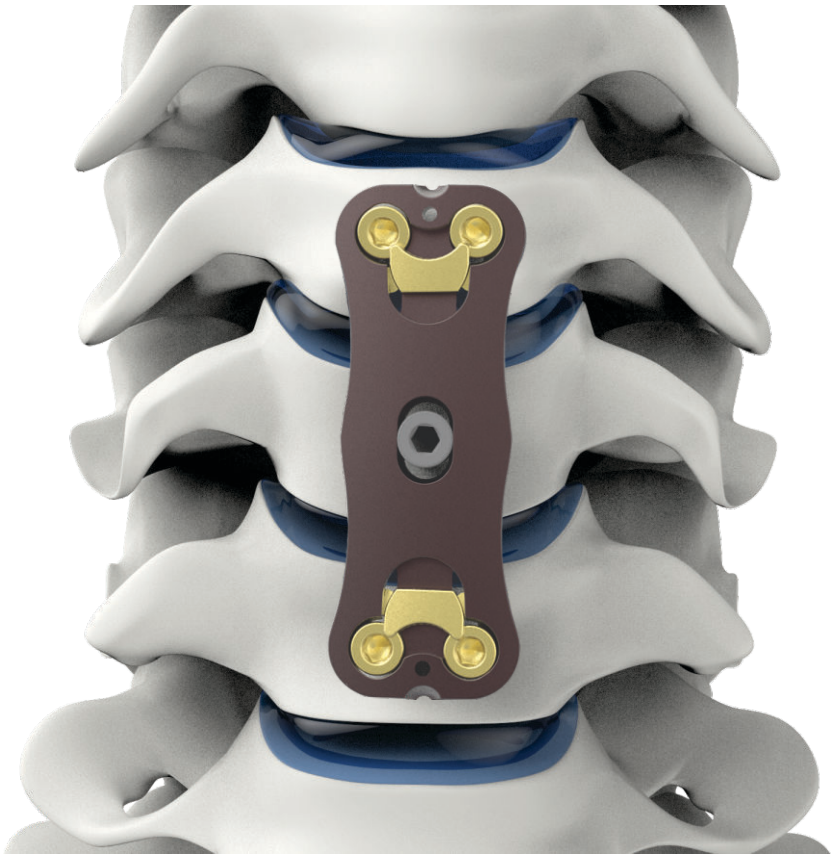


Fig (16)

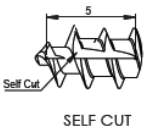
Post Operative Care:

- It is advised not to smoke. Smoking delays healing by increasing the risk of complications (e.g., infection) and inhibits bones' ability to fuse.
- It is not advised to drive for 4 weeks after surgery or until discussed with the Surgeon.
- Avoid sitting for long periods.
- Avoid bending head forward or backwards.
- Avoid lifting heavy things.
- To avoid bending of head a cervical collar is highly recommended.

APEX - Anterior Cervical Plate

Code	Product Specification	Material	
SP-145	Length, 22.5mm	TI	Level-1
SP-146	Length, 25mm	TI	
SP-147	Length, 27.5mm	TI	
SP-148	Length, 30mm	TI	Level-2
SP-149	Length, 32.5mm	TI	
SP-150	Length, 35mm	TI	
SP-151	Length, 37.5mm	TI	
SP-152	Length, 40mm	TI	
SP-153	Length, 42.5mm	TI	
SP-154	Length, 45mm	TI	
SP-155	Length, 47.5mm	TI	Level-3
SP-156	Length, 50mm	TI	
SP-157	Length, 52.5mm	TI	
SP-158	Length, 55mm	TI	
SP-159	Length, 57.5mm	TI	
SP-160	Length, 60mm	TI	
SP-161	Length, 62.5mm	TI	
SP-162	Length, 65mm	TI	
SP-163	Length, 67.5mm	TI	
SP-164	Length, 70mm	TI	

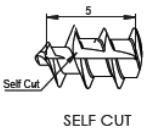
APEX - 3.5mm Cancellous Screws, Self Tapping



SELF CUT

Code	Product Specification	Material
SP-1653	Length, 12mm	TI
SP-188	Length, 14mm	TI
SP-189	Length, 16mm	TI
SP-190	Length, 18mm	TI
SP-1654	Length, 20mm	TI
SP-1713	Length, 22mm	TI

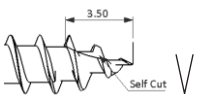
APEX - 4.0mm Cancellous Screws, Self Tapping



SELF CUT

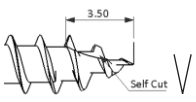
Code	Product Specification	Material
SP-1655	Length, 12mm	TI
SP-191	Length, 14mm	TI
SP-192	Length, 16mm	TI
SP-193	Length, 18mm	TI
SP-1656	Length, 20mm	TI
SP-1714	Length, 22mm	TI

APEX - 3.5mm Cancellous Screws, Self Drilling



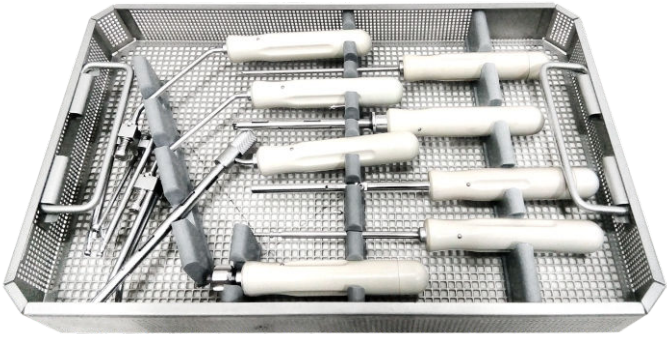
Code	Product Specification	Material
SP-1657	Length, 12mm	TI
SP-1494	Length, 14mm	TI
SP-1495	Length, 16mm	TI
SP-1496	Length, 18mm	TI
SP-1658	Length, 20mm	TI
SP-1715	Length, 22mm	TI

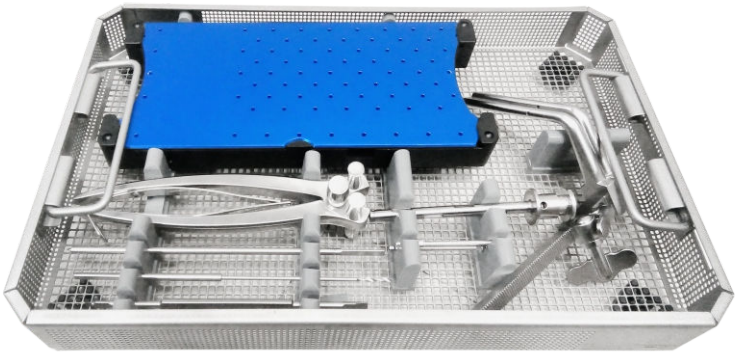
APEX - 4.0mm Cancellous Screws, Self Drilling



Code	Product Specification	Material
SP-1659	Length, 12mm	TI
SP-1497	Length, 14mm	TI
SP-1498	Length, 16mm	TI
SP-1499	Length, 18mm	TI
SP-1660	Length, 20mm	TI
SP-1716	Length, 22mm	TI

SP-001 : APEX Anterior Cervical Instrument Set





Code	Product Specification	Qty.
SP-003	Fixation Pin	2
SP-004	Plate Bender	1
SP-005	Screwdriver Sleeve	1
SP-006	Position Rod	2
SP-007	Distractor	1
SP-008	Awl,2.0mm	1
SP-009	Drill Bit, Φ2.2mm	1
SP-010	Screwdriver	1
SP-011	Locking Cap Pusher	1
SP-012	Inserter for Position Rod	1
SP-013	Multifunctional Holder	1
SP-014	Inserter for Fixation Pin	1
SP-015	Plate Holder	1
SP-017	Mono Drilling Guide	1
SP-016	Dual Drilling Guide	1
SP-018	Tap Ø3.0mm	1
SP-002	Container	1

Auxein®

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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, Sonepat - 131028, Haryana
Tel: +91 99106 43638 | Fax: +91 86077 70197
Email: info@auxein.com

www.auxein.com