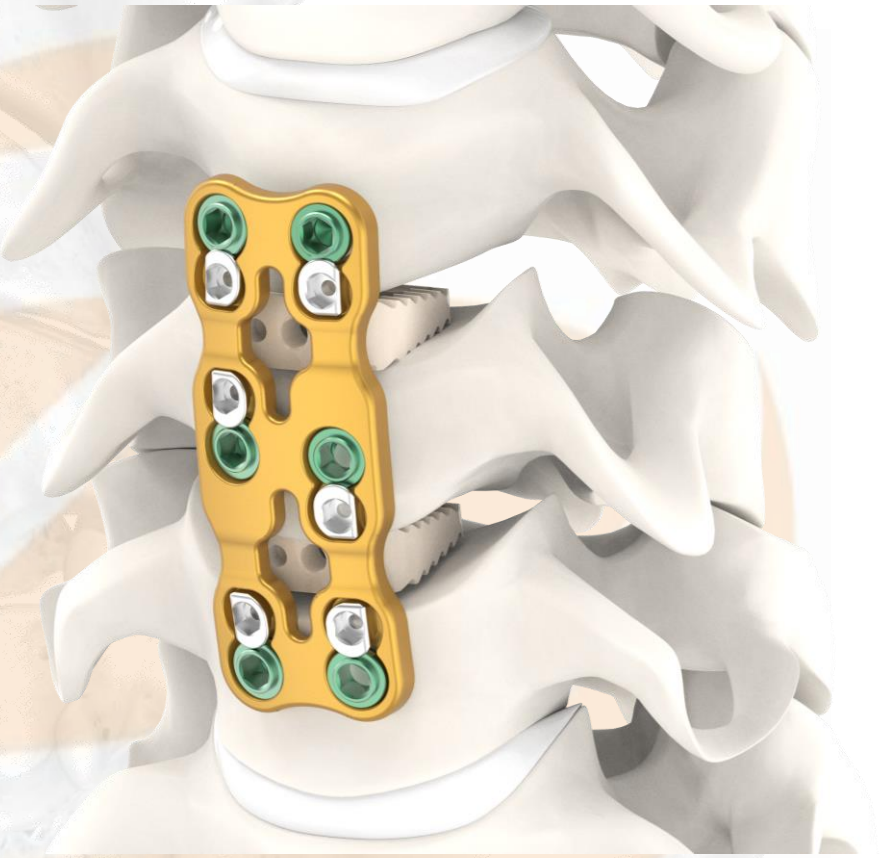
Fortis™

Anterior Cervical Plate System



REV 6 – US ONLY

DIO MEDICAL®

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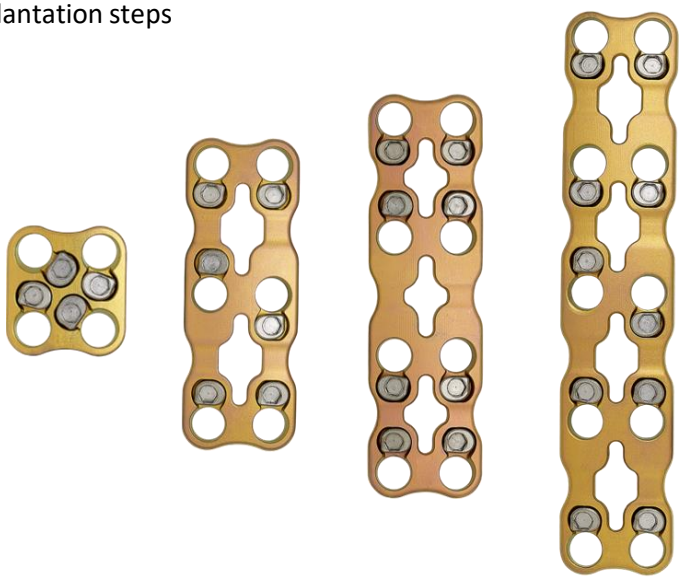
IMPLANT OVERVIEW

FEATURES & BENEFITS

- Low profile plate
- Visual and tactile confirmation of screw blocking
- Streamlined instrumentation for reduced implantation steps
- Single Driver for both screw and lock plate
- Color coded on screws for easy identification



PLATE

- 1-4 levels
- Thickness: 1.85 mm
- Width: 16 mm (Waist: 13.5 mm)
- Length (hole to hole)
    - 10-26 mm (1 level, 2 mm increments)
    - 26-46 mm (2 level, 2 mm increments)
    - 40-82 mm (3 level, 3 mm increments)
    - 56-112 mm (4 level, 4 mm increments)
- Titanium alloy (Ti-6Al-4V ELI)
- Provides up to 17° of cephalad angulation

1 Level Plate with Variable Drilling Screws

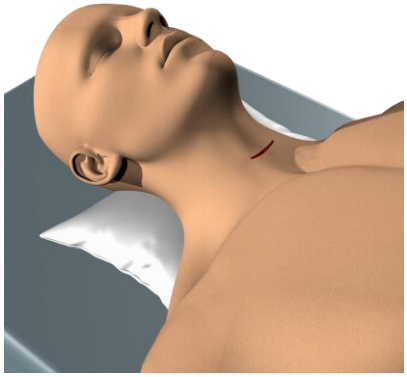
SCREW

- Size: 4.0 mm, 4.5 mm
- Length: 10-18 mm (2mm increments)
- Titanium alloy (Ti-6Al-4V ELI)
- Self-drilling and self-tapping
- Variable and fixed angle screws
- Color coded for easy identification

SURGICAL TECHNIQUE

STEP 1: PATIENT POSITIONING and EXPOSURE

The patient is carefully placed in the supine position on the operating table following the induction of anesthesia. The head is placed in a neutral position. A transverse or oblique skin incision is made, and the incision site is held open by a longitudinal self-retaining retractor.



STEP 2: APPROACH and CAGE PLACEMENT

Expose the appropriate cervical levels for surgical treatment. The distraction pins are positioned midline in the vertebral bodies adjacent to the disc, and the distractor is placed over pins. Distract gently. Refer to the IVA ACIF Surgical Technique Guide for recommended techniques for cage insertion. The surface of the vertebral body may require some preparation by removing anterior osteophytes for flush bone-plate interface.

STEP 3: PLATE PLACEMENT

Select the appropriate plate size. Fortis is available for levels one through four. Plate width is 16mm and the waist is 13.5mm. Plate length is measured from the center of the cephalad bone screw hole to the center of the caudal bone screw hole, ranging from 10 to 22mm, 26 to 46mm, 40 to 82mm, and 56 to 112mm for level one, two, three, and four plates respectively. All plates have prelordotic curvature. Additional contouring may be accomplished to accommodate patient pathology using the plate bender. Once set, place the plate on the vertebral column by using the plate.

Note: Do not bend on the locking plate, this has the potential to compromise the locking plate's ability to hold the screw
Note: Add 7mm for total plate length

STEP 4: BONE SCREW HOLE PREPARATION

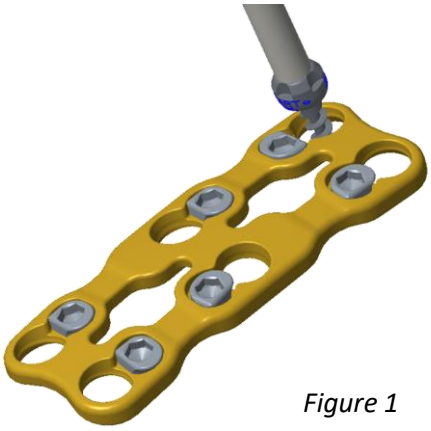


Figure 1

Temporary fixation pins can be used to secure the plate before the addition of screws, using the Screwdriver, 2.3mm Hex. After placement the temporary fixation pin holes may be used as pilot holes for later screw placement. (Figure 1)

Use either the Awl with sleeve (variable angulation) or the Awl for Drill guide (fixed- or variable angulation), for the entry points and to prepare the hole for screw placement. The Awl for Drill Guide can be used with the Drill guide (fixed or variable angle, Figure 2 and 3). The Awl with sleeve protrudes into the bone a maximum of 7mm.

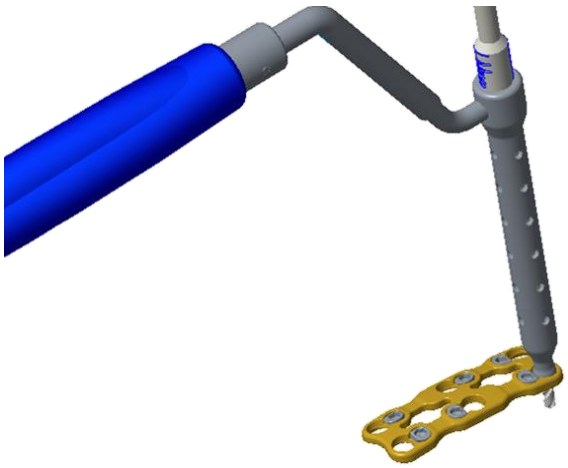


Figure 2

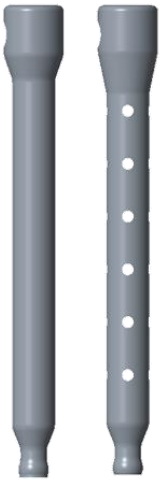


Figure 3

Left: Fixed Drill Guide
Right: Variable Drill Guide

The Fortis System provides drill bits (Figure 4) for the screw pocket with 10mm, 12mm, 14mm in the standard set. The drill bit length can be distinguished by the laser marking towards the proximal end.

Figure 4

STEP 5: SCREW INSERTION

After selecting the desired screw type and size, remove the screw from the screw caddy using 2.3mm Hex self-retaining Screwdriver (Figure 5). If a 2-, 3-, or 4-level plate is chosen for use, it is recommended that the bone screws be inserted sequentially at opposite corners initially, followed by insertions working towards the center of the plate. Use fluoroscopic imaging to confirm the final trajectory of screw and plate position before bone screws are fully tightened.

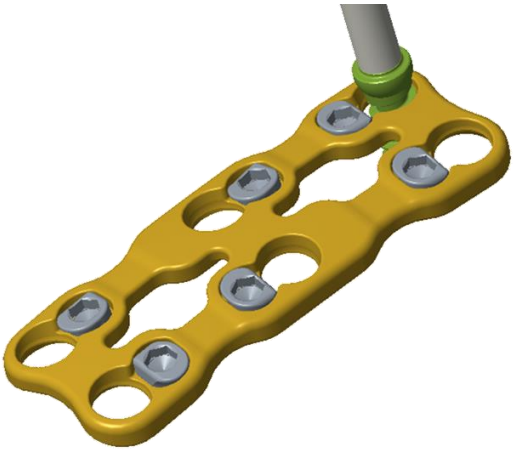


Figure 5

STEP 6: LOCKING

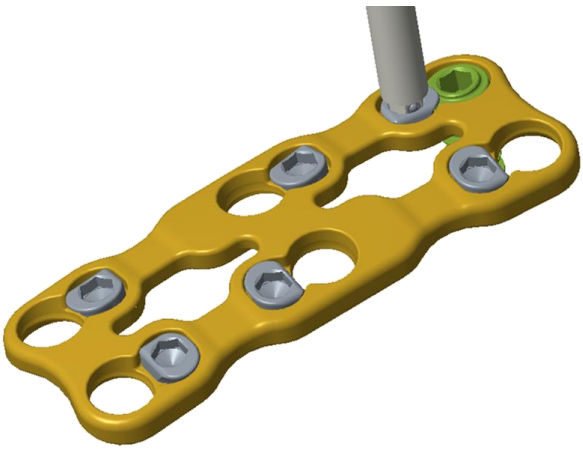


Figure 6

Once the bone screws are fully tightened, lock the lock-plates by turning clockwise 90˚ using 2.3mm Hex Lock-plate driver (Figure 6). The lock plate will stop after you turn the lock-plate 90˚. The locking mechanism will provide tactile and visual confirmation. Confirm the final position of the implant under fluoroscopy imaging.

STEP 7: CLOSURE and POSTOPERATIVE CARE

Following are few of the recommended steps:

- The operative site should be closed per hospital protocol and the surgeon's discretion. Prior to adequate fusion, the physician may prescribe additional external support (e.g. braces) to accommodate full load bearing
- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient per hospital protocol and the surgeon's discretion
- Pain Medication per hospital protocol and the surgeon's discretion
- Diet is restricted to small amounts of liquids until return of bowel function per hospital protocol and the surgeon's discretion
- The patient is encouraged to ambulate as soon as possible based on the activity level determined by the individual surgeon.

STEP 8: REMOVAL (OPTIONAL)

The insertion instruments can be used to engage the implant securely in-situ. The implant can then be extracted by following the implantation process in the reverse order. Optionally, forceps or other manual surgical instruments may be used to grasp and extract the implant. If necessary, distract the vertebrae inferior and superior to the implant for removal.

SURGICAL SET OVERVIEW

Plate

1-3 level

Part No.	Set Quantity
TP.PL.0110	2
TP.PL.0112	2
TP.PL.0114	2
TP.PL.0116	2
TP.PL.0118	2
TP.PL.0120	2
TP.PL.0226	2
TP.PL.0228	2
TP.PL.0230	2
TP.PL.0232	2
TP.PL.0234	2
TP.PL.0236	2
TP.PL.0343	1
TP.PL.0346	1
TP.PL.0349	1
TP.PL.0352	1
TP.PL.0355	1
TP.PL.0358	1

Instrument

Standard Configuration

Part No.	Set Quantity
Screwdriver, Self-Retaining	2
Plate Holder	1
Plate Bender	1
Variable angle Drill Guide (single barrel)	1
Pre-set angle Drill Guide (single barrel)	1
Drill bit - 12 mm	1
Drill bit - 14 mm	1
A-O Quick Connect Handle, Swivel	2
Cervical Awl, for Drill Guide	1
Temporary Fixation pin	4
Plate Caddy case 1 lvl	1
Plate Caddy case 2 lvl	1
Plate Caddy case 3 lvl	1
Screw Caddy case	1
AL Case	1

Screw

Variable-angle (self-drilling), Ø4.0 and 4.5

Part No.	Set Quantity
TP.VD.4012	8
TP.VD.4014	10
TP.VD.4016	10
TP.VD.4018	8
TP.VD.4512	6
TP.VD.4514	6
TP.VD.4516	6
TP.VD.4518	6

Fixed-angle screws (self-drilling), Ø4.0 and 4.5

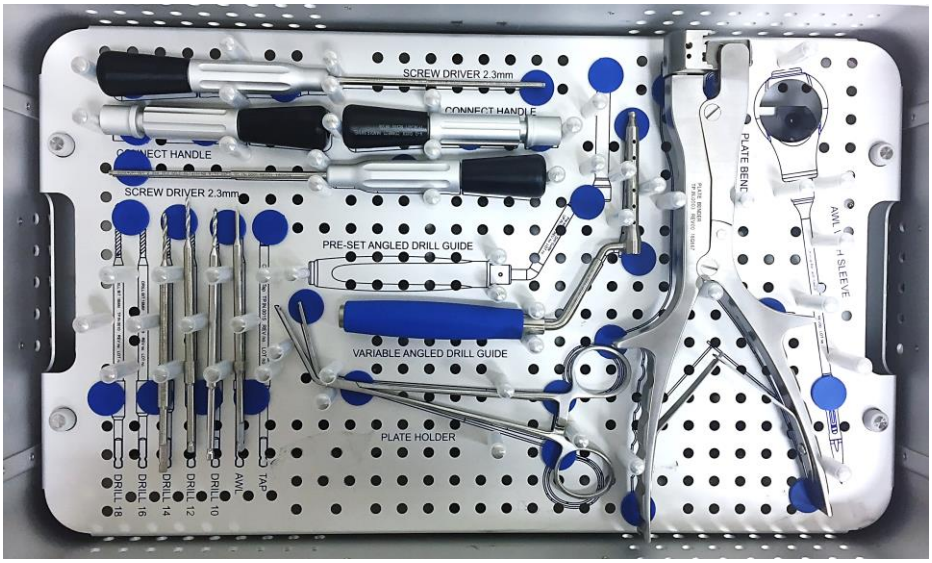
Part No.	Set Quantity
TP.FD.4012	8
TP.FD.4014	10
TP.FD.4016	10
TP.FD.4018	8
TP.FD.4512	6
TP.FD.4514	6
TP.FD.4516	6
TP.FD.4518	6

Additionally Available

Description
TP.PL.0456
TP.PL.0460
TP.PL.0464
TP.PL.0468
TP.PL.0472
TP.PL.0476
TP.VD.4010
TP.VD.4510
TP.FD.4010
TP.FD.4510
Drill bit - 10 mm
Plate Caddy case 4 lvl

Note: *Additionally available instruments should be requested in advance and please contact Dio Medical to confirm the set configurations which may vary depending on locations.*

SURGICAL SET IMAGE



Tray, Top

Tray, Bottom

INDICATION and CONTRAINDICATIONS

Indications

The FORTIS and HANA Anterior Cervical Plate System is intended for anterior fixation to the cervical spine C2-C7. The specific clinical indications include: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational
- activities.
- Use with components from other systems
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.
- Prior fusion at the level(s) to be treated.
- metals from different components;

These contra-indications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

Caution

- Instruments designed for use with implantation of the FORTIS and HANA Anterior Cervical Plate System are
- provided non-sterile and must be sterilized prior to use.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight,
- patient activity level, other patient conditions, etc. Which may impact the performance of the FORTIS and HANA
- Anterior Cervical Plate System.
- The implantation of the FORTIS and HANA Anterior Cervical Plate System must 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.
- Potential risks identified with the use of this FORTIS and HANA Anterior Cervical Plate System, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebrae, neurological injury, and vascular or visceral injury.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to
- those without a previous surgery.
- The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of HUVEXEL for the performance of the resulting mixed component implant.
- Federal law restricts this device to sale by or on the order of a physician/surgeon (Rx only).

Pre-Operative Precautions

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.

INDICATION and CONTRAINDICATIONS

- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

Intra-Operative Precautions

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Huvexel.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

Adverse Effects

Include but are not limited to:
Early or late loosening of any or all of the components. Disassembly, bending, and/or breakage of any or all of the components. Late bone fusion or no visible fusion mass and pseudarthrosis;
While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone;
Superficial or deep-set infection and inflammatory phenomena;
Allergic reactions to the implanted materials, although uncommon, can occur;
Decrease in bone density due to stress shielding;
Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
Cessation of growth of the fused portion of the spine;
Loss of proper spinal curvature, correction, height and/or reduction;
Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs.
In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs;
Neurological from surgical trauma;
Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain. Serious complications may occur with any spinal surgery. These complications include, but are not limited to, disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death. Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form. Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock. Adverse effects may necessitate reoperation or revision.

The surgeon must warn the patient of these adverse effects as deemed necessary.

NOTE

Indications

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