Balteum™

Anterior Lumbar Plate System

REV 1 – US ONLY

DIO MEDICAL®

CONTENTS

IMPLANT OVERVIEW

FEATURES & BENEFITS

- Low profile plate
- Provides up to 30° of cephalad angulation
- 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

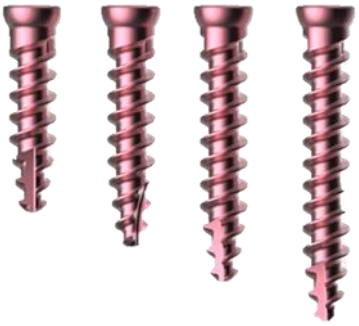
PLATE

- Lumbar and Sacral plate
- 1-2 levels
- Thickness: 3.5 mm
- Width: 26.5 mm (Waist: 24 mm)
- Length (hole to hole)
    - 15-45 mm (1 level, 2 mm increments)
    - 48-99 mm (2 level, 6 mm increments)
- Sagittal curvature
    - Lumbar: 100 mm
    - Sacral: 50 mm
- Titanium alloy (Ti-6Al-4V ELI)
- Single Driver for both screw and lock plate
- Provides up to 30° of cephalad angulation

Sacral Plate (Gold) / Lumbar Plate (Teal)

SCREW

- Size: 5.0 – 6.5 mm (0.5 mm increments)
- Length: 20-30 mm (2mm increments)
  33-60 mm (3mm increments)
- Titanium alloy (Ti-6Al-4V ELI)
- Self-drilling and self-tapping
- Variable and fixed angle screws
- Color coded for easy identification



Variable Tapping Screw

SURGICAL TECHNIQUE

STEP 1: PATIENT POSITIONING and EXPOSURE

Obtain appropriate pre-operative image to identify the surgical approach. Carefully place the patient in the supine position on the operating table following the induction of anesthesia. The operative area is carefully cleaned, and an incision is made at the appropriate fusion level(s). Confirm proper patient position by direct visualization before draping, and by radiograph

STEP 2: APPROACH

Anterior access can be established through variety of approaches including transperitoneal and right or left retroperitoneal, depending on the surgeon's preference and/or patient anatomy. However, a retroperitoneal approach is recommended to minimize the chance of retrograde ejaculation in males and improves exposure for easier and safer retraction of the peritoneal contents.

Expose the appropriate levels for being surgically treated. After the incision at the appropriate fusion level is made, prepare the interbody fusion device, or insert the bone graft into the disc space.

Refer to the IVA™ ALIF Surgical Technique Guide for recommended techniques of the interbody fusion device implant insertion. The surface of the vertebral body may require some preparation by removing anterior osteophytes for bone-plate interface

STEP 3: PLATE SELECTION

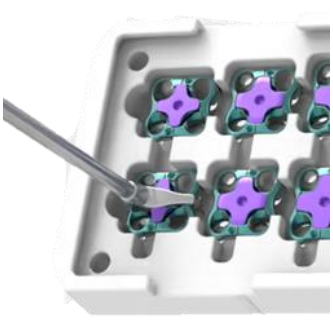
Anterior Lumbar plate is available in one level and two levels. Select the appropriate plate size by trialing different lengths of the plate at the implant site. Plate width is 26.5mm and the waist is 24mm. Plate length is measured from the center of the cephalad hole to the center of the caudal hole, ranging from 15 to 45mm for one level procedure and 42 to 99mm for two level procedure with pre-lordotic options.

STEP 3: PLATE SELECTION (CONT'D)

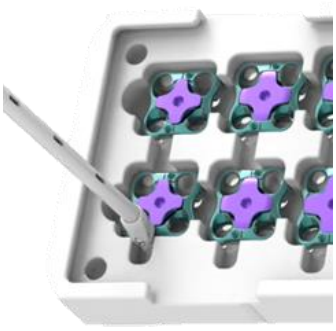
Attach holder onto the plate and place the plate so that the screw holes are in line with cortical rims.

Holder Option 1: Lateral Holder
Place the handle on the holder hole located on each side of the plate.

Holder Option 2: Midline Holder
Place the holder on the bottom hole and bottom side of the plate.



Lateral Holder



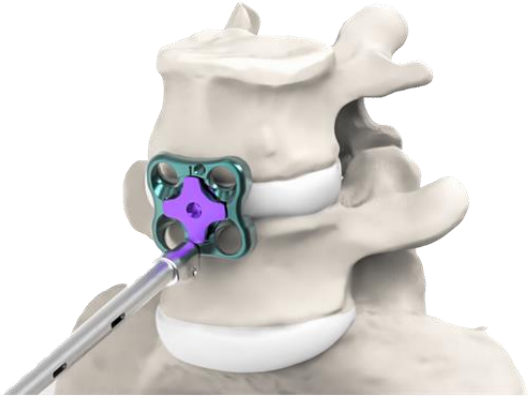
Midline Holder

STEP 4: PLATE PLACEMENT

Place the plate on the vertebral column by using the plate holder.

Note: *Do not bend on the locking plate which will compromise the locking plate ability to lock the screw*

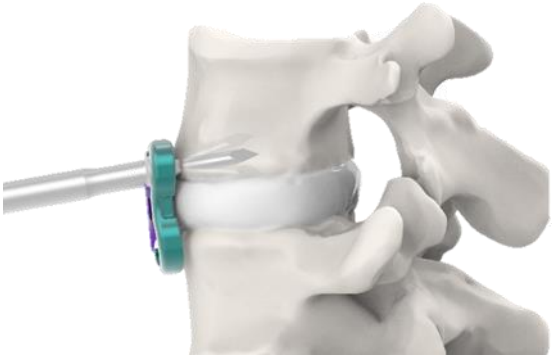
Lateral Holder



Midline Holder

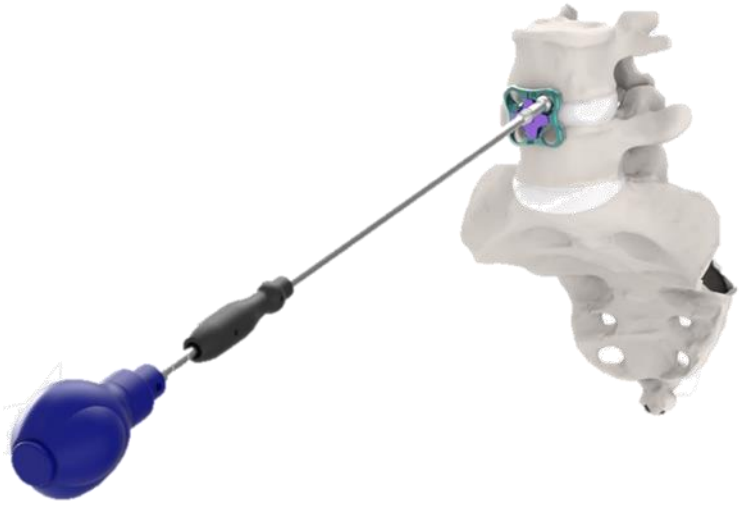
STEP 5: SCREW HOLE PREPARATION

The Awl is introduced to prepare the screw hole. Each screw hole on the plate provides ranges of angular variation for the inserted awl.



Awl for Drill Guide

Use either the Awl for Drill Guide (fixed- or variable angulation) or the Awl with sleeve (variable angulation) for the entry points, or initial pilot hole. The Awl for Drill Guide can be used with either the Fixed Drill Guide or the Variable Drill Guide. The Awl with sleeve protrudes into the bone to a maximum distance of 9mm.



Awl with Sleeve

The Balteum Lumbar Plate System provides multiple lengths of drill bits ranging from 15 mm and 20-28 mm (2 mm increments). Easier screw insertion can be achieved by using a tap.

Drill Guide with Drill

STEP 6: SCREW INSERTION

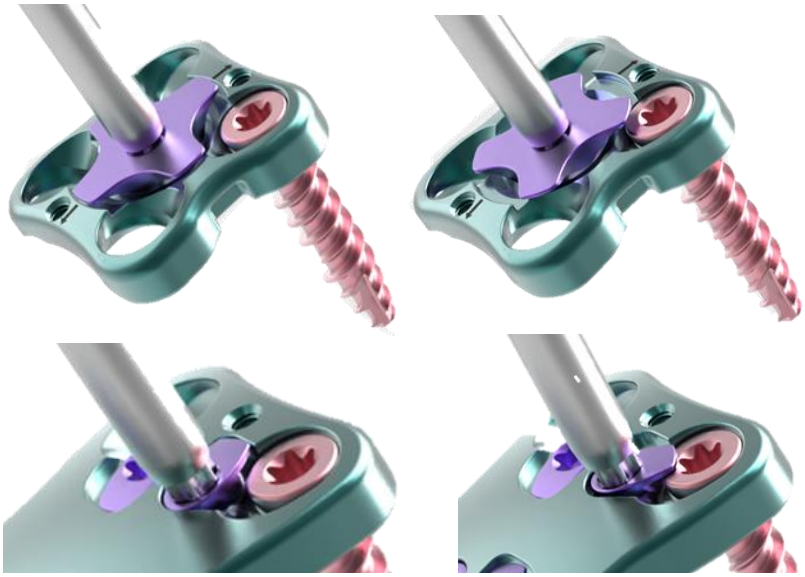
After selecting suitable screw type and size, grab the screw from the screw caddy using the Self-retaining Screwdriver T20. If the plate is longer than a 2-level plate, it is recommended that bone screws to be placed at the intermediate levels first. Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before bone screws are fully tightened.

Note: *Avoid insertion angulation of the screws greater than 30° to ensure optimal locking of the screw to the plate.*
Note: *All screw lengths are measured by bone engagement, not overall length.*

STEP 7: LOCKING

Once the bone screws are fully tightened, lock the lock plate by turning clockwise 90˚ using the Self-retaining Screwdriver T20 until a hard stop is reached. The locking step will provide tactile and visual confirmation.

Note: *Assure to turn the lock plate until hard stop.*



Unlock (left, top) and Lock (right, top) position of plates 15-19 mm, and
Unlock (left, bottom) and Lock (right, bottom) position of the rest of plates

Fully locked

STEP 8: CLOSURE

Confirm the final position of the plate before closure. The operative site should be closed per hospital protocol and the surgeon's discretion.

STEP 9: POSTOPERATIVE CARE

Following are few of the recommended steps:

- Prior to adequate fusion, the physician may prescribe additional external support (e.g., braces) to accommodate full load bearing.
- Take anteroposterior and lateral X-rays to ensure correct positioning of the cages and pedicle screws before mobilization of the patient.
- 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 10: REMOVAL (OPTIONAL)

The screws/plate can be extracted using the screwdriver/plate holder respectively, by following the implantation process in the reverse order. Optionally, forceps or other manual surgical instruments may be used to grasp and extract the plate.

SURGICAL SET OVERVIEW

Plate

1 level Anterior Lumbar Plate

Part No.	Set Quantity
AL.PL.0115	2
AL.PL.0117	2
AL.PL.0119	2
AL.PL.0121	2
AL.PL.0123	2
AL.PL.0125	2

Screw

Variable-angle screws (self-tapping), Ø5.5

Part No.	Set Quantity
AL.VT.5520	8
AL.VT.5524	10
AL.VT.5528	10
AL.VT.5533	8

Variable-angle screws (self-tapping), Ø6.5

Part No.	Set Quantity
AL.VT.6520	6
AL.VT.6524	6
AL.VT.6528	6
AL.VT.6533	6

Instrument

Standard Configuration

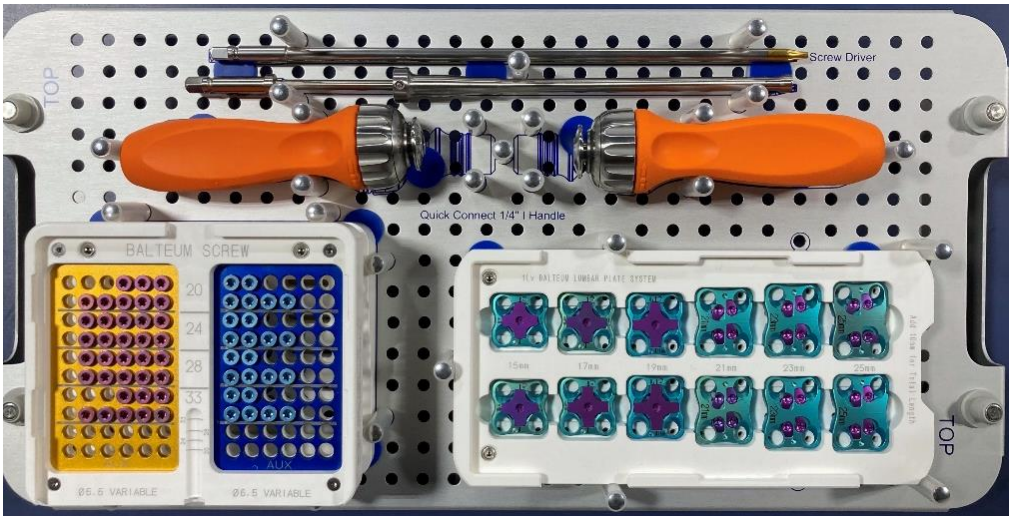
Part No.	Set Quantity
Screwdriver, Self-Retaining	2
Plate Holder (Lateral or Midline)	1
Variable angle Drill Guide	1
Drill Bit Ø3.5 x 15 mm	1
Drill Bit Ø3.5 x 20 mm	1
Awl, with Sleeve	2
Awl, for Drill Guide	1
Ratchet I-Handle	2
Plate Caddy case 1 level	1
Screw Caddy case (Variable 5.5 & 6.5)	1
AL Case	1

Additionally Available

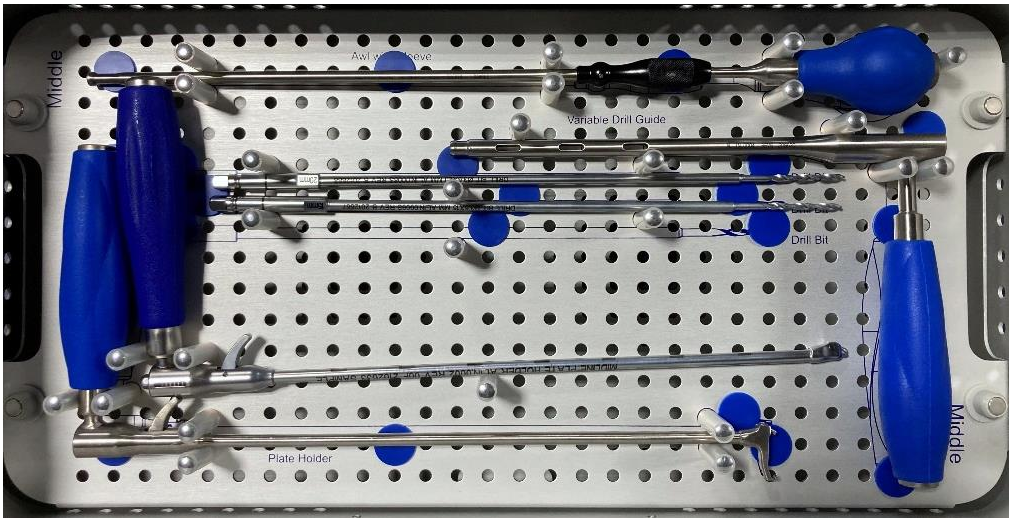
Description
Temporary Fixation Pin
Drill bit 22-28 mm
Tap 5.5
Tap 6.5

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

SURGICAL SET IMAGE



Tray, Top



Tray, Middle

***Note:** Tray, Bottom is for Extra space for AUXs or custom devices*

INDICATION and CONTRAINDICATIONS

Indications For Use

The BALTEUM™ Lumbar Plate System is intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved

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:

- Infection, systemic, spinal or localized; Signs of local inflammation;
- Morbid obesity;
- Fever or leukocytosis; Metal sensitivity/allergies to the implant materials;
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC) or a marked left shift in the WBC differential count;
- Grossly distorted anatomy due to congenital abnormalities;
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft);
- Any case not needing a bone graft and fusion or where fracture healing is not required;
- Any case requiring the mixing of metals from different components;
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
- Any case not described in the indications;
- Any patient unwilling to cooperate with the postoperative instructions;
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

Caution

- The BALTEUM™ Lumbar Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Instruments designed for use with implantation of the BALTEUM™ Lumbar 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 intervertebral body fusion device.
- The implantation of the device 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 fusion device, 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
- Rx only, Federal law restricts this device to sale by or on the order of a physician.

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:

- Bending, loosening or fracture of the implants or instruments;
- Loss of fixation;
- Sensitivity to a metallic foreign body, including possible tumor formation; Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
- Nonunion or delayed union;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
- Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
- Pain or discomfort;
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra);
- Hemorrhage of blood vessels and/or hematomas;
- Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
- Bursitis; Bone graft donor site pain; Inability to resume activities of normal daily living;
- Reoperation or revision
- Infection; Death.

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

NOTE

Indications

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lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

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