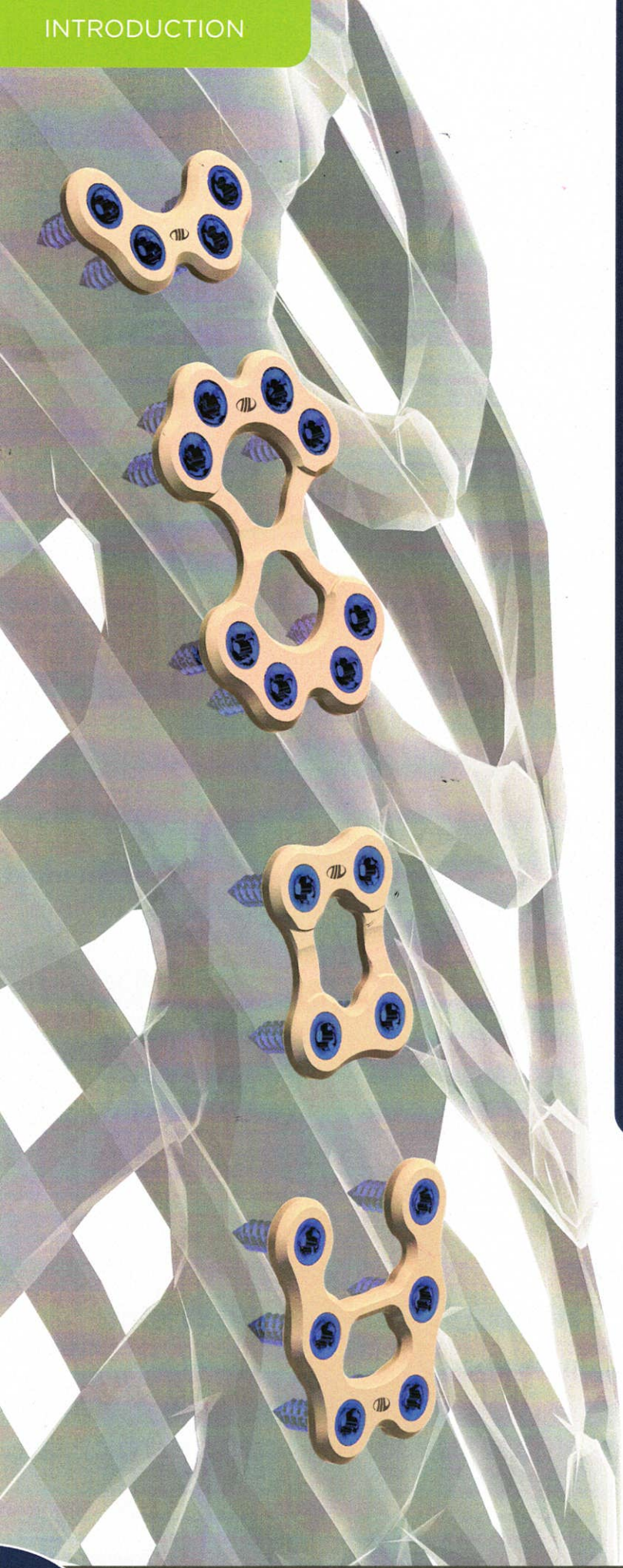
ABLE MEDICAL

VALKYRIE®

Thoracic Fixation System

SURGICAL TECHNIQUE



VALKYRIE®

Thoracic Fixation System

The Valkyrie® Thoracic Fixation System is a fully disposable, single-use plating system designed for ease-of-use and rooted in clinical evidence. Valkyrie features the clinically proven performance of rigid fixation combined with the use of novel materials and the benefits of bioactive science to maximize sternal stability and promote bone healing. Its patient specific design offers intraoperative choices and its minimal instrumentation focuses on speed, efficiency, and simplicity in the O.R.

Valkyrie's bioactive surface treated screws increase fusion rates, improve bone strength, and enhance screw purchase when compared to traditional non-coated devices.

Our PEEK plate material offers a zero-chance cross threading design, patient specific contouring (without the need for plate bending tools) and the advantage of radiolucency, which allows for clear and effective postoperative imaging.

These distinct advantages coupled with a pre-loaded MACH Screw Clip System removes unnecessary steps, simplifies the procedure and maximizes sternal stability.

SYSTEM BENEFITS

- Single-Use System
- Clinically Proven
- Extremely Easy to Use
- Osteoporotic Indications*

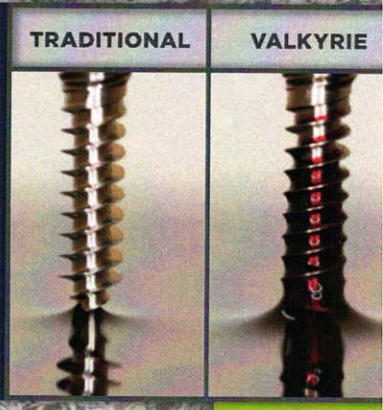


FIGURE A

MORE BONE. FASTER. Valkyrie's HA^{nano} surface on the screws combine several properties known to improve osseointegration in one unique surface modification. The combination of high wettability and optimal surface chemistry with optimized nano-roughness, mediates bioactivity and specific protein adsorption to the implant (Figure A). These properties regulate cell behavior and influence tissue regeneration by increasing the osteoblast functions, thus building more bone faster.

PEEK PLATES

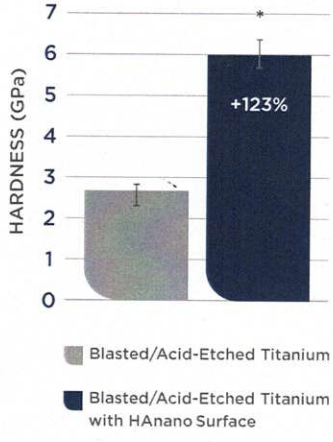
- Low profile radiolucent plate
- Patient specific contouring (without the need for plate bending tools)
- Easily cut for emergent re-entry (without heavy plate cutters)
- Similar stiffness to native bone prevents stress shielding
- Zero-chance cross threading design

HA^{nano}-MODIFIED TITANIUM SCREWS

- Double lead threads reduce insertion time
- Stab-and-grab retention
- Surface-modified screws compared to traditional non-treated screws*
  - Minimal fusion time (2 week osseointegration begins)
  - Increased screw retention (67%)
  - Increased bone strength (123%)
  - Clinical evidence (300,000+ implants, 30+ in vivo and in vitro studies)
  - Bacterial resistant
  - Minimal concern of delamination (2000-4000 times thinner than traditional coatings)

SINGLE-USE INSTRUMENTATION

- Pre-loaded MACH Screw Clip System eliminates steps in the O.R.
- Screw Clip keeps screws on axis when inserting into plate
- Disposable instruments eliminate need for reprocessing and potential for infection
- Driver has a positive stop on the Screw Clip guaranteeing optimal screw insertion every time and eliminating guesswork



Valkyrie's surface modification catalyzes the biological response and has proven to accelerate osseo-integration of implants to enhance early bone growth in more than 30 pre-clinical studies. The nano-thin surface modification has been shown to increase the anchoring of titanium implants by 35% and increase tissue density by 123% at 3 weeks.

* *Complete labeling and technical data available at Able Medical.*

1 EXPOSURE

Beginning medially, dissect all soft tissue from the surface of the sternum to allow for complete visualization; this may decrease the likelihood of an off mid-line sternotomy. Optimally, the costal cartilage on both sides of the sternum is revealed. Perform a sternotomy (Figure 1).

FOR SECONDARY CLOSURE OF THE STERNUM

Remove existing wires. Debride the involved sternal edges until they are free of devitalized tissue and hemostasis has been obtained. To allow for proper anatomical reduction and plate placement, bony calluses should also be removed from the midline and sternal surface (in addition to sternal soft tissue dissection in a revision surgery). A rib curette may be used to remove any nonviable cartilaginous rib tissue.

Note: *A sternal bone specimen should be sent to pathology to assess for osteomyelitis, and sent to microbiology for culturing. This may help the infectious disease consultant determine the appropriate antibiotic treatment if necessary.*

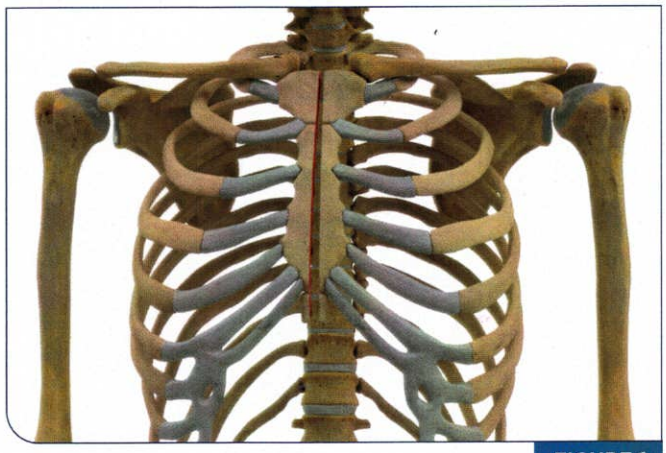


FIGURE 1

2 PRODUCT SELECTION

Plates are available in a variety of shapes and sizes. Choose the plate(s) that appropriately fit(s) the patient's anatomy.

Note: *A combination of plates should include a minimum of five bridges to promote a stable closure.*

Using the Driver Bit, gauge the depth of the sternum and choose the corresponding screw length.

Screws are available in separate packages, including 3.0mm (standard) and 3.5mm (rescue) diameters, in lengths of 8mm, 10mm & 13mm.

Note: *The length of the Driver Bit beyond the Distal Step represents a 10mm screw. If bone extends past the tip of the Driver Bit, a 13mm screw is recommended (Figure 2). If bone rests at tip of the Driver Bit, a 10mm screw should be used (Figure 3).*

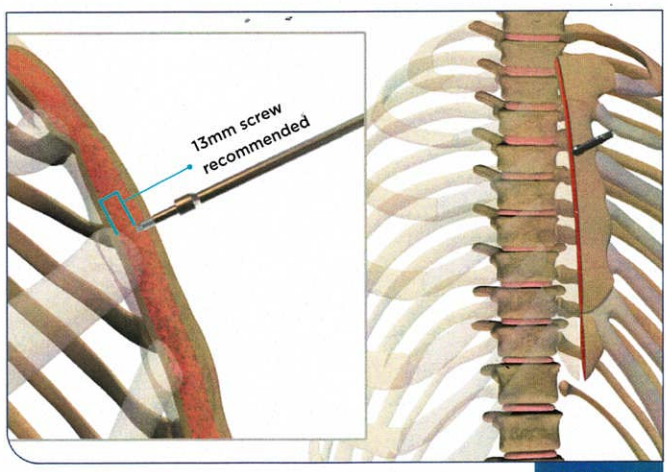


FIGURE 2

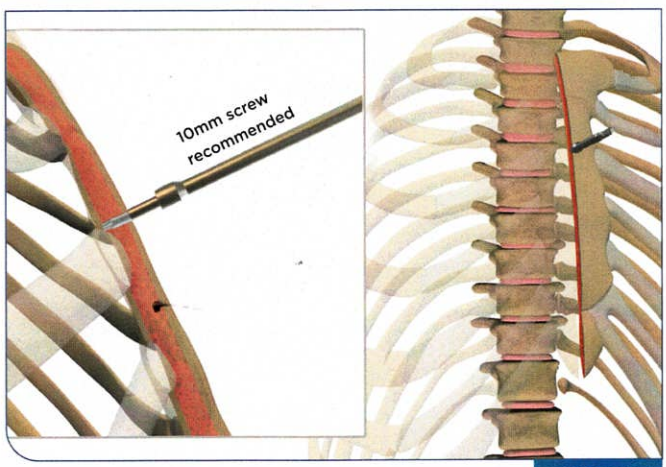


FIGURE 3

3 STERNAL APPROXIMATION

The osteotomy can be reduced with a traditional cerclage closure (wire or cable) at the Xyphoid and Manubrium (Figure 4). During reduction, observe the midline for protruding internal tissue and proper bony alignment.

Note: *Sternal approximation and stability must be determined by tactile assessment. Optimal cerclage tension is dependent on proper assessment of the patient's bone quality.*

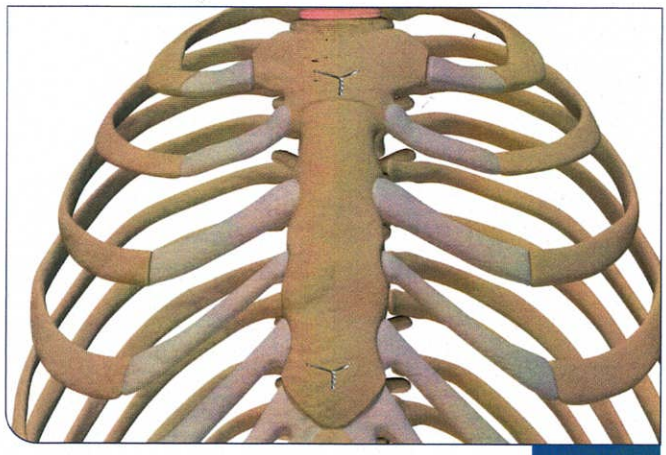


FIGURE 4

4 PRODUCT PREPARATION

Insert Driver Bit into preferred driver (Figure 5).

Note: *Rotating the Driver Bit may be necessary until proper orientation is achieved.*

Select appropriate screw configuration and MACH Screw Clip.

Note: The Straight Plates and Hex Plate do not work with the MACH Screw Clips. The Box Plate and M-Plate work only with the MACH 2 Screw Clip. The M-10 plate uses both MACH 2 screw clips and a MACH 4 screw clip. All other plate configurations work only with the MACH 4 Screw Clip.

To attach the MACH Screw Clip to selected plate, align holes of the MACH Clip with the holes on the plate and snap the MACH Clip onto the plate (Figure 6).

Note: *Ensure proper orientation of plate with the MACH Screw Clip.*

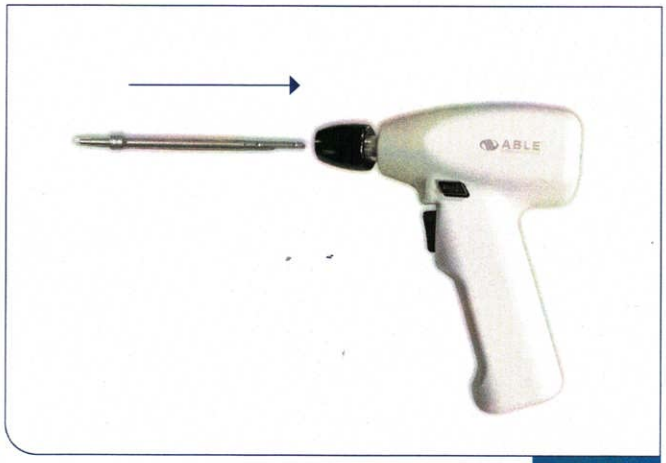


FIGURE 5

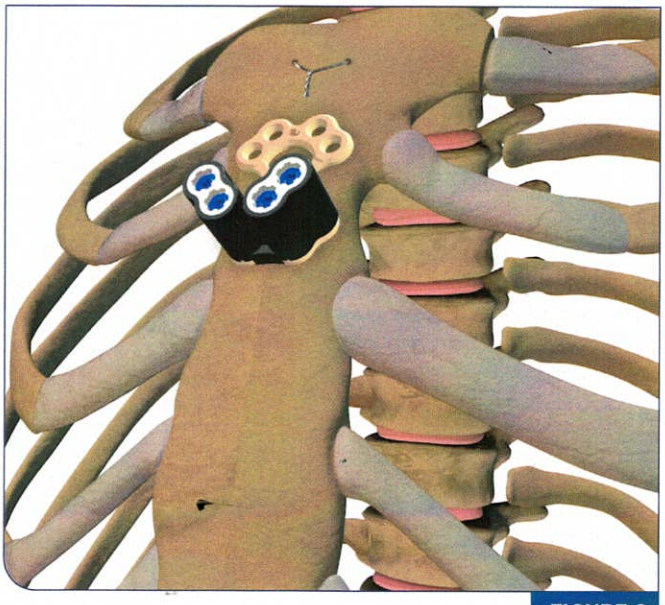


FIGURE 6

5 BONE SCREW PLACEMENT

After placing Plate with Screw Clip on sternum, firmly hold the Screw Clip and using the preferred Driver, insert the first screw into the plate construct but stop prior to the Driver shoulder hitting the Screw Clip (Figure 7).

Then, insert subsequent screws into the plate construct until Driver shoulder hits the top of Screw Clip (Figure 8).

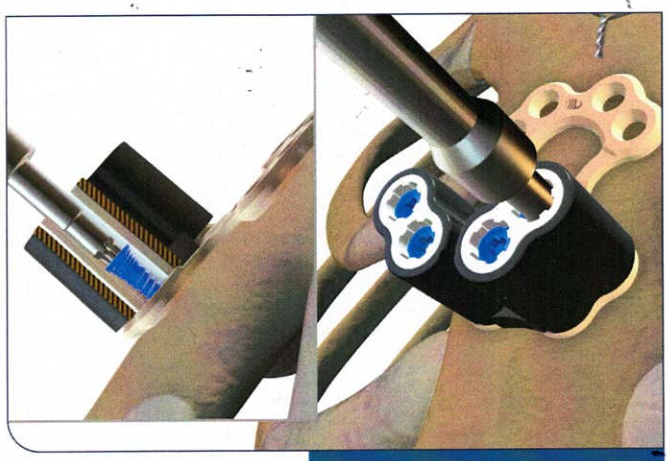
Finally, fully seat the first screw.

Following screw insertion, detach Screw Clip by pulling away from implant construct (Figure 9).

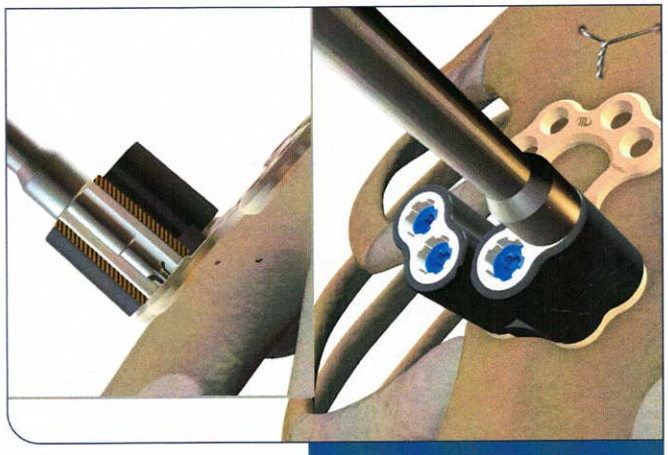
Note: *The Valkyrie Thoracic Fixation System is compatible with Stainless Steel or Titanium cerclages.*

Note: *If desired, screws can be inserted into the plate without the Screw Clip.*

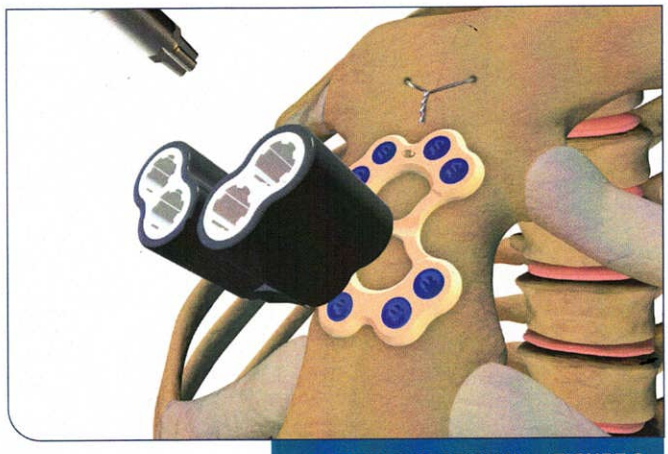
CAUTION: *If driving screws without the use of a Screw Clip, over-tightening the screw may compromise screw purchase.*



INSERT SCREW - FIGURE 7



SEAT FLUSH - FIGURE 8



SCREW CLIP REMOVAL - FIGURE 9

6 CONSTRUCT CONFIRMATION

It is important to be aware of the overall stability of the closure and use as many plates as necessary to achieve adequate fixation based on surgeon's assessment of each patient. Confirm screws are fully seated within plate and construct is properly seated onto bone (Figure 10).

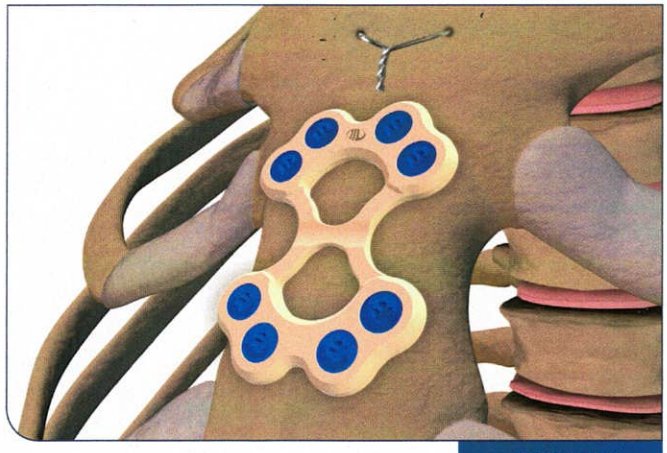


FIGURE 10

7 IMPLANT REMOVAL (IF NECESSARY)

EXTRACTION (IF REQUIRED)

To remove the screws, insert the Driver into the head of the screw and rotate counter-clockwise while exerting downward pressure.

EMERGENT RE-ENTRY (IF REQUIRED)

Use a preferred Wire or Plate Cutter to cut the plate through the main support locations (as shown with dotted line in Figure 11) and cut any remaining cerclages.

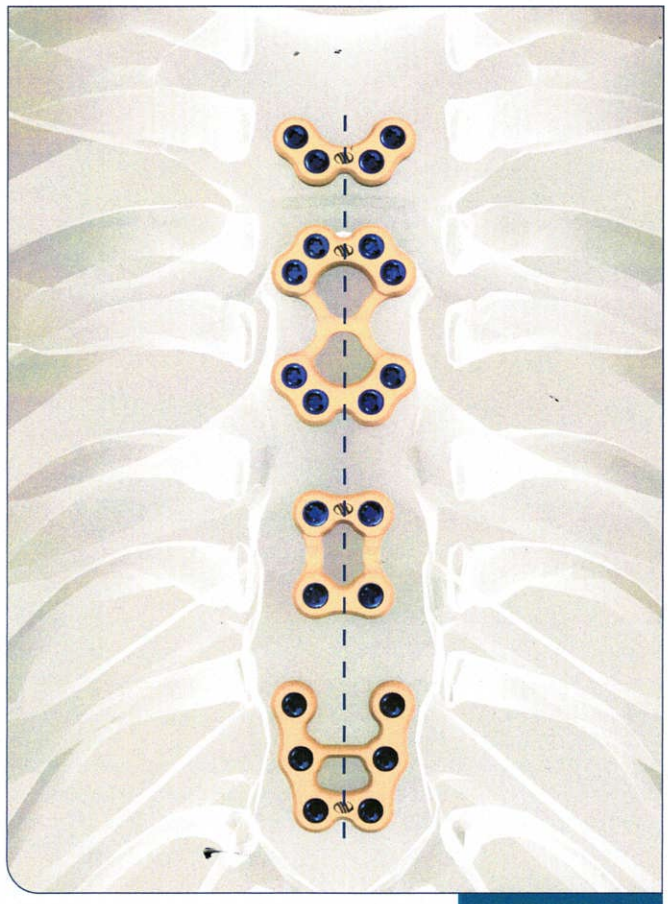
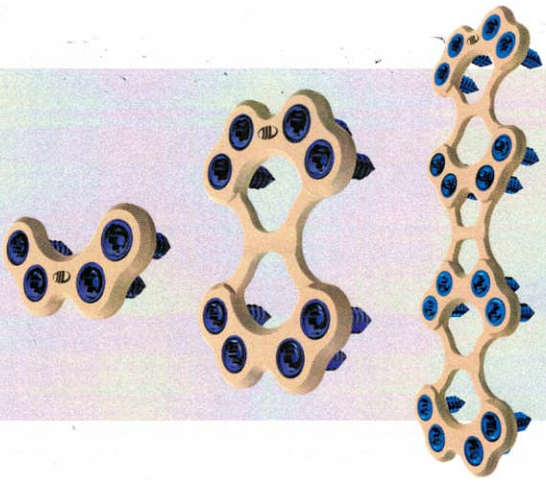


FIGURE 11



V-PLATE, X-PLATE AND LADDER PLATE

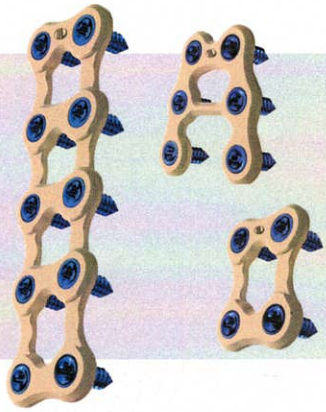
Traditionally, the V-Plate is placed on the manubrium or xyphoid; the X-Plate and Ladder Plate are recommended to be placed on the body of the sternum.

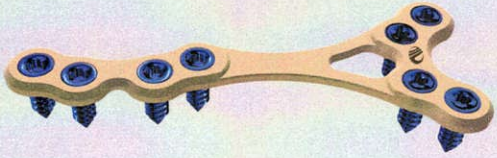
- Each plate employs a MACH 4 Screw Clip offering 4 Bioactive Screws in 8mm, 10mm & 13mm lengths.
- The plates are made of PEEK; designed to conform to the surface of the patient's sternum.
- The V-Plate uses one MACH 4 Screw Clip, the X-Plate uses two MACH 4 Screw Clips and the Ladder Plate uses four MACH 4 Screw Clips.

RECTANGLE PLATE, M-PLATE AND BOX PLATE

Traditionally, the M-Plate is placed on the manubrium or xyphoid while the Rectangle Plate and Box Plate are recommended to be placed on the body of the sternum.

- Each plate employs a MACH 2 Screw Clip offering 2 Bioactive Screws in 10mm & 13mm lengths.
- The plates are made of PEEK; designed to conform to the surface of the patient's sternum.
- The Box Plate uses two MACH 2 Clips, the M-Plate uses three MACH 2 Clips and the Rectangle Plate uses five MACH 2 Clips.





T-PLATE

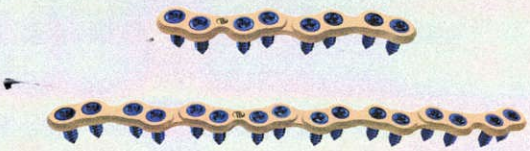
Traditionally, the T-Plate is used in a mini-thoracotomy approach and attaches the rib to the sternum.

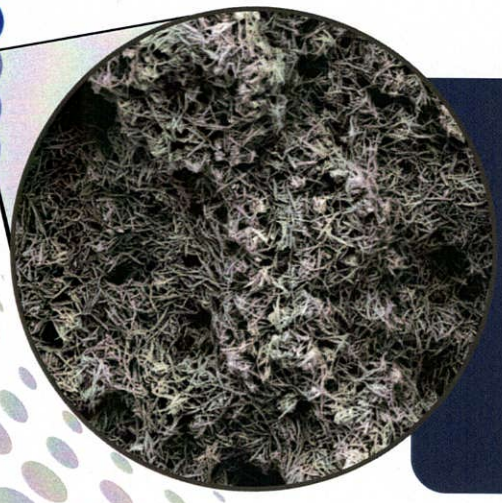
- The plate employs a MACH 4 Screw Clip offering 4 Bioactive Screws in 10mm & 13mm lengths as well as 8mm for rib placement.
- The plate is made of PEEK; designed to conform to the surface of the patient's thoracic anatomy.
- The T-Plate uses Screw Clip over the sternal portion of the plate but allows screw insertion to the ribs without the need of a Screw Clip.

8 HOLE AND 16 HOLE STRAIGHT PLATES

Straight Plates can be placed vertically on the body of the sternum, placed horizontally for rib-to-rib connections that span the sternum, or used as rib plates for bony fractures of the chest wall.

- Each plate accommodates Bioactive screws in 8mm, 10mm & 13mm lengths.
- The plates are made of PEEK; designed to conform to the surface of the patient's thoracic anatomy.
- The Straight Plates do not use Screw Clips to minimize tissue trauma during access.





BIOACTIVE TREATMENT

All Valkyrie Bioactive screws are modified with the advantages of HA^{nano} Surface

These advantages include:

- Omni-cortical screw purchase (vs. Uni-cortical or Bi-cortical screw purchase)
- Superior hydrophilicity resulting in faster osseointegration
- Bacterial resistant
- Ultra-thin layer (0.02 µm) meaning no dimensional changes to implants and minimal risk of delamination
- 510(k) clearances with FDA masterfile
- 300,000+ implants, 30+ in vivo and in vitro studies

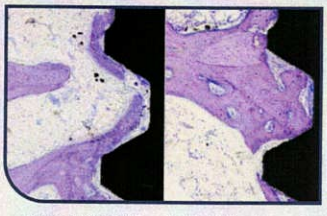
EARLY OSSEOINTEGRATION

2 & 4 week in vivo-study in rabbit tibia bone

- Titanium screws
- 2 & 4 weeks in rabbit tibia
- Histological analysis

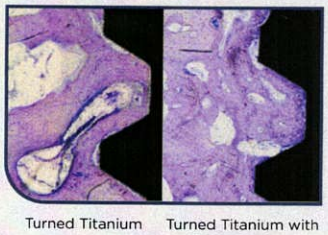
RESULTS: Surface modification improved initial bone integration at both 2 and 4 weeks by +22 & 37% respectfully

2 Weeks



Turned Titanium | Turned Titanium with HA^{nano} Surface

4 Weeks



Turned Titanium | Turned Titanium with HA^{nano} Surface

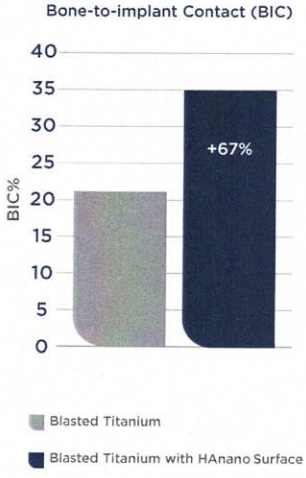
Jimbo R (2011), 'Histological and three-dimensional evaluation of osseointergration.

STRONGER ANCHORING OF IMPLANTS

4 week in vivo-study in rabbit tibia bone

- Blasted titanium implants
- 4 weeks in rabbit tibia
- Histological analysis

RESULTS: BIC improvement by +67% with surface modification



Meirelles L (2008), 'The effect of Chemical and Nanotopographical Modification on the early stages of osseointegration'

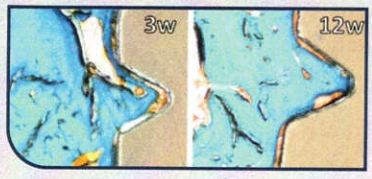
FASTER FUSION

3 & 12 week in vivo-study in rabbit tibia bone

- PEEK screws with hole
- 3 & 12 weeks in rabbit tibia
- Histological analysis

RESULTS: Surface modification showed on average +21 & 32% more bone-to-implant contact and +49 & 74% improvement in bone to surface coverage

Modified on PEEK



Unmodified on PEEK

Johansson P (2015), Nanosized Hydroxyapatite Coating on PEEK Implants Enhances Early Bone Formation

VALKYRIE® THORACIC FIXATION SYSTEM

Part Number	Description	Content	Product Image
01-010	Valkyrie V-Plate, 4 hole	1 Plate per Pack	
01-020	Valkyrie X-Plate, 8 hole	1 Plate per Pack	
01-030	Valkyrie M-Plate, 6 hole	1 Plate per Pack	
01-040	Valkyrie T-Plate, 8 hole	1 Plate per Pack	
01-050	Valkyrie Box Plate, 4 hole	1 Plate per Pack	
01-060	Valkyrie Ladder Plate, 16 hole	1 Plate per Pack	
01-070	Valkyrie Rectangle Plate, 10 hole	1 Plate per Pack	
01-080	Valkyrie H-Plate, 6 hole	1 Plate per Pack	
01-090	Valkyrie Hex Plate, 6 hole	1 Plate per Pack	
01-100-08	Valkyrie Straight Plate, 8 hole	1 Plate per Pack	
01-100-16	Valkyrie Straight Plate, 16 hole	1 Plate per Pack	
01-110	Valkyrie M10 Plate, 10 hole	1 Plate per Pack	

HA-COATED BIOACTIVE SCREWS, Ø3.0

Part Number	Screw Length	Description	Clip Type	Product Image
01-3010-2-HA	10mm	2 screws in preloaded clip	MACH 2	
01-3013-2-HA	13mm	2 screws in preloaded clip	MACH 2	
01-3015-2-HA	15mm	2 screws in preloaded clip	MACH 2	

MACH 2
SCREW CLIP SYSTEM

MACH 2 SCREW MULTI-CLIPS

01-3010-2-HA-2	10mm	4 screws in 2 preloaded clips	MACH 2: x2
01-3010-2-HA-3	10mm	6 screws in 3 preloaded clips	MACH 2: x3
01-3013-2-HA-2	13mm	4 screws in 2 preloaded clips	MACH 2: x2
01-3013-2-HA-3	13mm	6 screws in 3 preloaded clips	MACH 2: x3
01-3015-2-HA-3	15mm	6 screws in 3 preloaded clips	MACH 2: x3

Part Number	Screw Length	Description	Clip Type	Product Image
01-3008-4-HA	8mm	4 screws in preloaded clip	MACH 4	
01-3010-4-HA	10mm	4 screws in preloaded clip	MACH 4	
01-3013-4-HA	13mm	4 screws in preloaded clip	MACH 4	
01-3015-4-HA	15mm	4 screws in preloaded clip	MACH 4	

MACH 4
SCREW CLIP SYSTEM

MACH 4 SCREW MULTI-CLIPS

01-3010-4-HA-2	10mm	8 screws in 2 preloaded clips	MACH 4: x2
01-3010-4-HA-4	10mm	16 screws in 4 preloaded clips	MACH 4: x4
01-3013-4-HA-2	13mm	8 screws in 2 preloaded clips	MACH 4: x2
01-3013-4-HA-4	13mm	16 screws in 4 preloaded clips	MACH 4: x4
01-3015-4-HA-2	15mm	8 screws in 2 preloaded clips	MACH 4: x2
01-3015-4-HA-4	15mm	16 screws in 4 preloaded clips	MACH 4: x4

INSTRUMENTATION

Part Number	Description	Content	Product Image
01-01-3035	Driver Bit	1 per Pack	
01-03-3035	Disposable Power Driver**	1 per Pack	

OPTIONAL INSTRUMENTATION

1103-1604	Screw Sizer/Plate Holder	1 per Pack	
1103-1601	Plate Holder	1 per Pack	

Manual driver available upon request. Contact customer service.

Actual product markings and size may differ from images shown

***Manufactured by JEIL Medical Corporation*
55, Digital-ro 34 Guro-gu, Seoul Korea

IMPORTANT

This information is intended to aid in using this system and is not a reference for surgical technique. Refer to the surgical technique manual for instructions for proper implantation and removal, including selection of suitable implant sizes, accessories, and related devices, and ways to avoid or minimize risks associated with implantation.

DESCRIPTION

The Valkyrie Thoracic Fixation System includes plates and screws in a variety of configurations used to temporarily fixate fractured bone during healing. Plates are comprised of PEEK; screws are comprised of Titanium Alloy with or without Hydroxyapatite surface treatment. The system also includes instruments necessary for the insertion of the device. When used for sternal closure, The Valkyrie Thoracic Fixation System may be used with or without traditional cerclage (wire or cable).

INDICATIONS FOR USE

The Valkyrie Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality.

CONTRAINDICATIONS

Contraindications for this system are active or latent infection, sepsis, insufficient quantity or quality of bone/soft tissue, and material sensitivity. If metal sensitivity is suspected, tests should be performed prior to implantation.

Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for this device.

WARNINGS

- For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the methods of application, the instruments, and the recommended surgical technique for this device.
- Surgeons must carefully consider the likelihood of tissue healing being achieved when plating fractures, osteotomies, or reconstructions of the chest wall. This system is only designed to withstand loading during a reasonable healing time period and is not intended to be a permanent tissue replacement.
- Confirm screws are fully seated within the plate and construct is properly seated onto bone. Improper insertion of the device during implantation can increase the possibility of loosening or migration.
- Device damage or breakage can occur when the implant is subjected to increased loading associated with trauma, delayed union, nonunion or incomplete healing. Device breakage in such circumstances is expected and could lead to additional surgery and device removal.
- The patient must be cautioned about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or unwanted outcomes as a result of loose fixation and/or loosening, stress, excessive activity, or continuous load bearing past the average healing time (6-8 weeks), particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete bone healing.
- The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail, including fracture of the device and/or migration.
- As with any surgical implantation there is a possibility of nerve, bone or soft tissue damage related to either trauma associated with surgery or the individual patient response to the presence of the implant.

PRECAUTIONS

All implants and instruments are single-use only.

  - o An implant shall never be reused. Previous stresses may have created imperfections which can lead to a device fracture.
  - o Sterile instruments shall never be reused. Previous stresses may have created imperfections which may lead to instrument wear or fracture, preventing use as intended.

- Extreme or repeated bending or contouring of the implants can cause stresses that may lead to premature device fracture.
- Visually inspect implants for damage prior to installation; use of a damaged implant may lead to device fracture.
- Use of instruments other than what is recommended in the surgical technique may result in the construct not functioning as intended.
- If cutting the plate, take necessary precautions as a sharp edge may have been created.
- During use of a driver, cutting or installing plates and inserting screws, take necessary precautions when in close proximity to sharp edges and points, and be aware that debris/fragments can be generated. Remove any observed debris/fragments from the surgical field with suction or manually, and dispose of appropriately.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

ADVERSE EFFECTS

Possible adverse effects include:

- Pain, discomfort, or abnormal sensations due to the presence of an implant.
- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
- Implant fracture, nonunion, delayed union, migration and/or loosening may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. These types of adverse effects could lead to additional surgery and device removal. Selection of screws which are longer than the depth of the sternum may cause possible impingement of structures internal to chest wall including vessels, pleura and other structures, leading to perforation of the vessels and/or blood loss.
- Formation of seromas
- Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate/incomplete healing may result from the presence of an implant or due to surgical trauma.
- A histological or allergic reaction resulting from the implantation of a foreign material in the body may occur.
- The implant contains metal that may induce an allergic reaction in patients with an allergy or sensitivity to metallic components.
- Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

MRI Safety Information:

The Valkyrie Thoracic Fixation System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field	1.5 T or 3.0 T
Maximum magnetic field spatial gradient	20 T/m (2,000 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no RF Transmit Coil restrictions.
Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode
Maximum Whole Body Averaged SAR	2 W/kg
Maximum Scan Duration	60 minutes

The presence of this implant may produce an image artifact.

STERILIZATION

Sterilized by irradiation. Do not use if package is open or damaged. Do not re-sterilize. This is a single use device. Products intended for single-use must not be re-used in a subsequent procedure. Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

PACKAGING AND STORAGE

The devices are packed in protective packaging that is labeled to its contents. All implants and instruments are supplied sterile. Always store the devices in the original protective packaging. Store the devices in a dry and dust-free place (standard medical device storage and hospital environment).

MAINTENANCE, INSPECTION, AND TESTING

Before use, inspect the implant/instrument box carefully. Do not use when sterile barrier is visually damaged; return immediately to manufacturer. Do not use expired product.

MANUFACTURER CONTACT INFORMATION

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

MANUFACTURER CONTACT:	**PHONE: (906) 201-5323** **WEBSITE: www.ablemedicaldevices.com**	
	**Manufacturer Address** **ABLE MEDICAL DEVICES:**	**512 4th Street, Gwinn, MI 49841**

Complete electronic instructions for use available at www.ablemedicaldevices.com.

ABLE™ MEDICAL

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