



**VALKYRIE®**

Thoracic Fixation System

HOSPITAL DOCUMENTATION



DEVELOP | DELIVER | EXCEED



**ATTN: HOSPITAL APPROVAL STAFF**  
**RE: VALKYRIE™ THORACIC FIXATION SYSTEM**

Introducing the Valkyrie Thoracic Fixation System: a breakthrough, single-use sternal plating system from Able Medical Devices. The system 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., making it the preferred product among sternal closure.

Valkyrie is a novel PEEK-based sternal plating system that can be easily cut during emergent re-entry. Its radiolucency prevents MRI/CT image scatter and the material can be conformed to meet various patient anatomies. The double lead screws insert into the bone at a faster rate and increase bone purchase, while the HA<sup>nano</sup> surface treatment on the screws recruit cellular adhesion and quickly synthesizes bone to create a more rigid closure. The intuitive instrumentation and minimal packaging help reduce waste to the healthcare system, while its features and benefits are aimed at putting the patient's needs first.

The Valkyrie Thoracic Fixation System is available in multiple plate shapes. Bioactive screws are available in 13mm, 3.0mm diameter, 8mm & 10mm bioactive screws are also available for use in thinner sternums, as well as 3.5mm diameter "rescue" bioactive screws available in both 10mm and 13mm lengths.

All plates are manufactured from medical grade PEEK (ASTM F2026) and the screws are comprised of titanium alloy with hydroxyapatite surface treatment (ASTM F136).

Indications for Use: The Valkyrie Thoracic Fixation System is intended 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.

Kind Regards,

A handwritten signature in black ink, appearing to read "Peter J. Didyk", written in a cursive style.

Peter J. Didyk  
Inventor of Valkyrie  
VP & Managing Director - Cardiothoracic  
PeterD@AbleDev.us

# VALKYRIE®

## Thoracic Fixation System

### PLATE BENEFITS

- Bioinert — Does Not Harbor Infection
- Patient Specific Contouring
- Easy Emergent Re-entry
- No Post-op Image Scatter or Artifacts



### PEEK PLATES

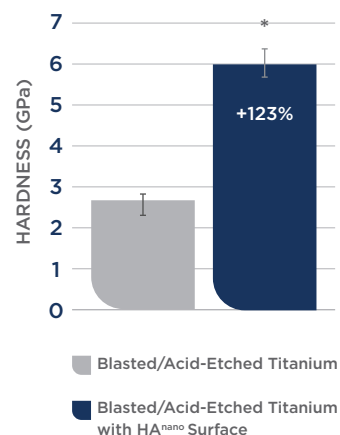
- Low profile radiolucent plate
- Patient specific contouring (without the need for plate bending tools)
- Easily cut for emergent re-entry (without heavy plate cutters)
- Similar stiffness to native bone prevents stress shielding
- Zero-chance cross threading design

### HA<sup>nano</sup>-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)
  - Minimal concern of delamination (2000-4000 times thinner than traditional coatings)

### SINGLE-USE INSTRUMENTATION

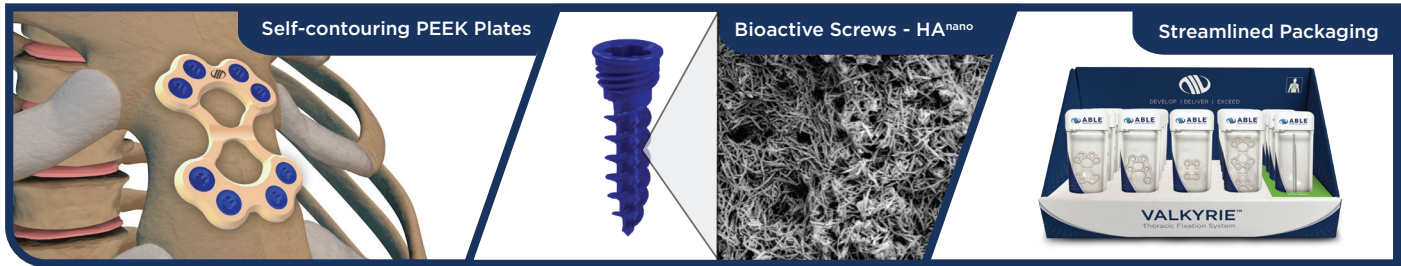
- Pre-loaded MACH™ Screw Clip System eliminates steps in the O.R.
- Power driver option minimizes O.R. time
- Disposable instruments eliminate need for reprocessing and potential for infection
- Driver also acts as screw measurement device guaranteeing optimal screw length every time and eliminating guesswork



Valkyrie's surface modification catalyzes the biological response and has proven to accelerate osseointegration 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%.

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

## VALKYRIE SYSTEM FEATURES

**1 PRODUCT SELECTION AND SCREW CONFIRMATION**

Plates are available in a variety of shapes and sizes. Once the plate(s) are chosen, confirm screw length using the enclosed Driver Bit (Figure 1).

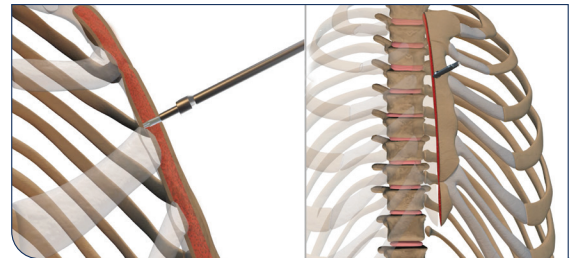


FIGURE 1

**2 PRODUCT PREPARATION**

After a screw size has been selected and sternal approximation is complete (with initial cerclages), snap the pre-loaded screw MACH™ Screw Clip to the appropriate plate (X-Plate is shown in Figure 2).

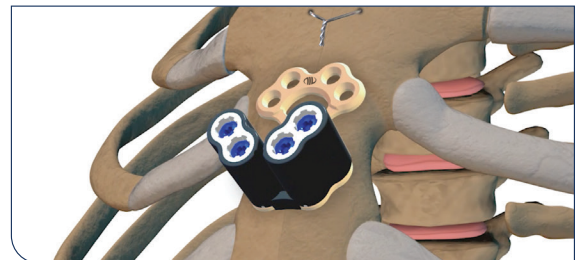


FIGURE 2

**3 BONE SCREW PLACEMENT**

Firmly hold the Screw Clip and with the preferred Driver, insert the first screw into the plate construct but stop prior to the Driver shoulder hitting the Screw Clip (Figure 3). Next, fully seat all screws and then complete seating the first screw.

Following screw insertion, discard Screw Clip and Screw Drivers as well as handles or Power Drivers used during the procedure.

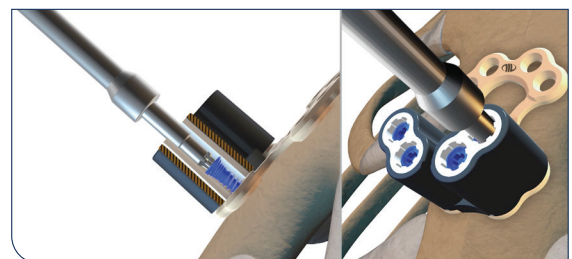


FIGURE 3

**4 CONSTRUCT COMPLETION**

Ensure all screws are fully seated within the plate and construct is properly seated onto the bone.

Close the skin and subcutaneous tissues in routine manner.

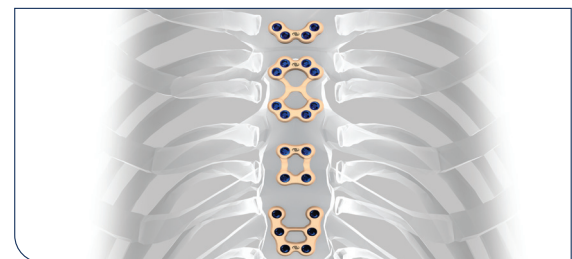


FIGURE 4

See Surgical Technique for complete instructions and limitations related to this device.

## 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 |  |
| 01-100-08   | Valkyrie Straight Plate, 8 hole   | 1 Plate per Pack |  |
| 01-100-16   | Valkyrie Straight Plate, 16 hole  | 1 Plate per Pack |  |

## BIOACTIVE SCREWS

| Part Number  | Description           | Content                                  | Product Image                                                                        |
|--------------|-----------------------|------------------------------------------|--------------------------------------------------------------------------------------|
| 01-3508-HA   | HA Screw, Ø3.5 X 8mm  | 1 Screw per Pack                         |   |
| 01-3510-HA   | HA Screw, Ø3.5 X 10mm | 1 Screw per Pack                         |                                                                                      |
| 01-3513-HA   | HA Screw, Ø3.5 X 13mm | 1 Screw per Pack                         |                                                                                      |
| 01-3010-2-HA | HA Screw, Ø3.0 X 10mm | 2 Screws per Pack<br>(MACH 2 Screw Clip) |   |
| 01-3013-2-HA | HA Screw, Ø3.0 X 13mm | 2 Screws per Pack<br>(MACH 2 Screw Clip) |                                                                                      |
| 01-3008-4-HA | HA Screw, Ø3.0 X 8mm  | 4 Screws per Pack<br>(MACH 4 Screw Clip) |  |
| 01-3010-4-HA | HA Screw, Ø3.0 X 10mm | 4 Screws per Pack<br>(MACH 4 Screw Clip) |                                                                                      |
| 01-3013-4-HA | HA Screw, Ø3.0 X 13mm | 4 Screws per Pack<br>(MACH 4 Screw Clip) |                                                                                      |

## INSTRUMENTATION

| Part Number | Description               | Content    | Product Image                                                                         |
|-------------|---------------------------|------------|---------------------------------------------------------------------------------------|
| 01-01-3035  | Driver Bit                | 1 per Pack |  |
| 01-02-3035  | Disposable Manual Driver* | 1 per Pack |  |
| 01-03-3035  | Disposable Power Driver** | 1 per Pack |  |



**FDA U.S. FOOD & DRUG**  
ADMINISTRATION

March 2, 2021

JM Longyear Manufacturing, LLC D.B.A. Able Medical Devices  
% Nathan Wright  
Engineer & Regulatory Specialist  
Empirical Testing Corp  
4628 Northpark Drive  
Colorado Springs, Colorado 80918

Re: K202889

Trade/Device Name: Valkyrie Thoracic Fixation System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories  
Regulatory Class: Class II  
Product Code: HRS  
Dated: January 25, 2021  
Received: January 26, 2021

Dear Nathan Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmnm.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

For; Shumaya Ali, M.P.H.  
Assistant Director  
DHT6C: Division of Restorative, Repair  
and Trauma Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

### 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. It may be used with or without traditional cerclage (wire or cable).

### INDICATIONS FOR USE

The Valkyrie Thoracic Fixation System is intended 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.
- The Able Medical Valkyrie Thoracic Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Able Medical Valkyrie Thoracic Fixation System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

### PRECAUTIONS

All implants and instruments are single-use only.

- An implant shall never be reused. Previous stresses may have created imperfections which can lead to a device fracture.
- 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.
- Provided instruments shall never be reused. Previous stresses may have created imperfections which may lead to instrument wear or fracture, preventing use as intended.
- Use of instruments other than what is recommended in the surgical technique may result in the construct not functioning as intended.
- If a plate cutter is used on the implant take necessary precautions, 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.

## 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.

## MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

The Able Medical Valkyrie Thoracic Fixation System plates and screws have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Able Medical Valkyrie Thoracic Fixation System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

## 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.

|                                                                                     |                                                                                                                            |                                 |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| <b>MANUFACTURER CONTACT:</b>                                                        | <b>PHONE:</b> (906) 201-5323<br><b>WEBSITE:</b> <a href="http://www.ablemedicaldevices.com">www.ablemedicaldevices.com</a> |                                 |
|  | <b>Manufacturer Address</b><br><b>ABLE MEDICAL DEVICES:</b>                                                                | 512 4th Street, Gwinn, MI 49841 |

*Complete electronic instructions for use available at [www.ablemedicaldevices.com](http://www.ablemedicaldevices.com).*

*See insert for complete labeling limitations related to this device.*



512 4th Street | Gwinn, MI 49841 | Tel: (906) 201-5323  
[www.AbleMedicalDevices.com](http://www.AbleMedicalDevices.com)

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A LONGYEAR COMPANY

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