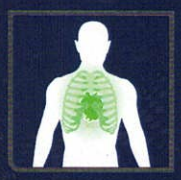
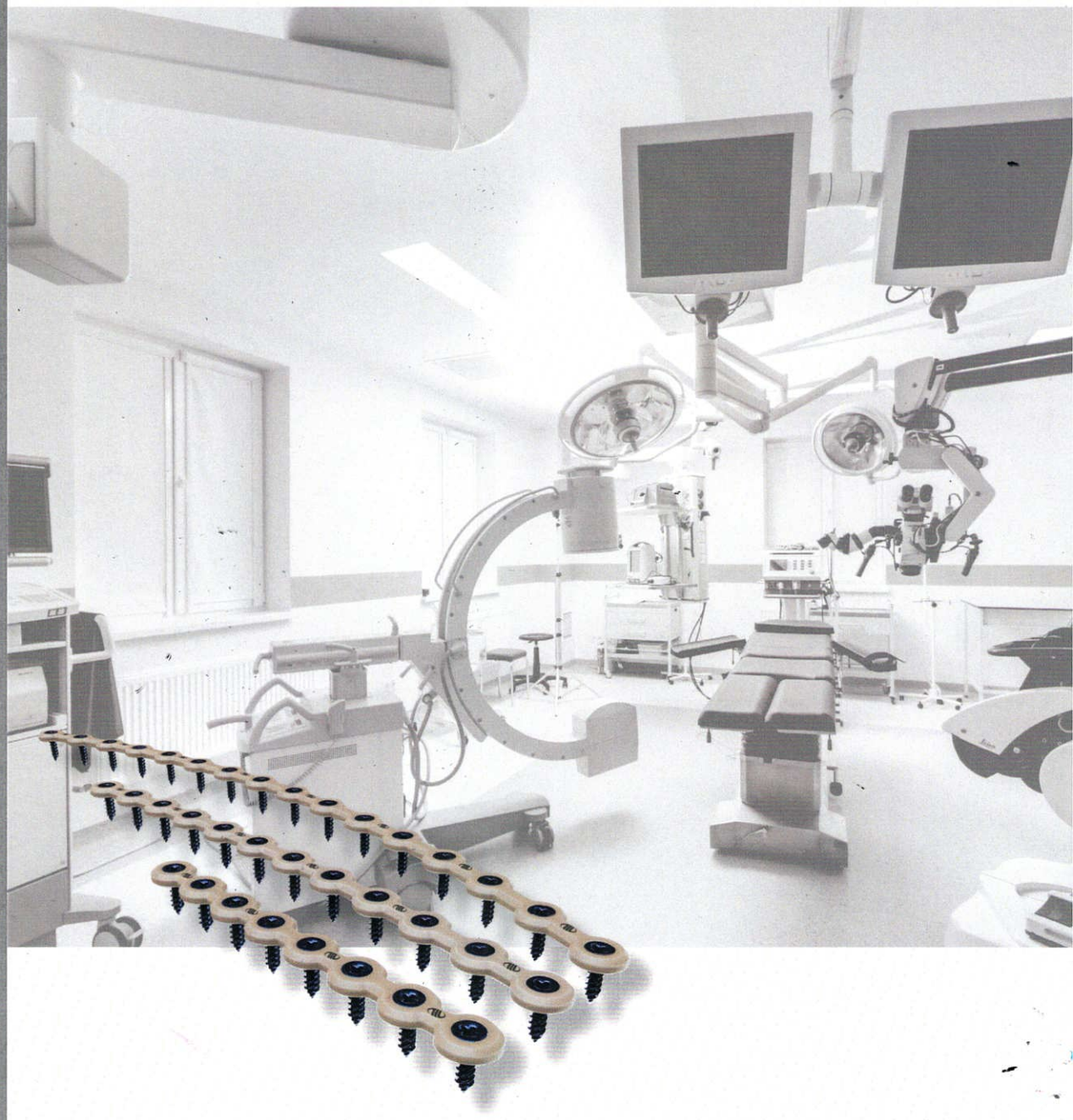
PHASE 1



ABLE MEDICAL



VALKYRIE® RIB

Thoracic Fixation System

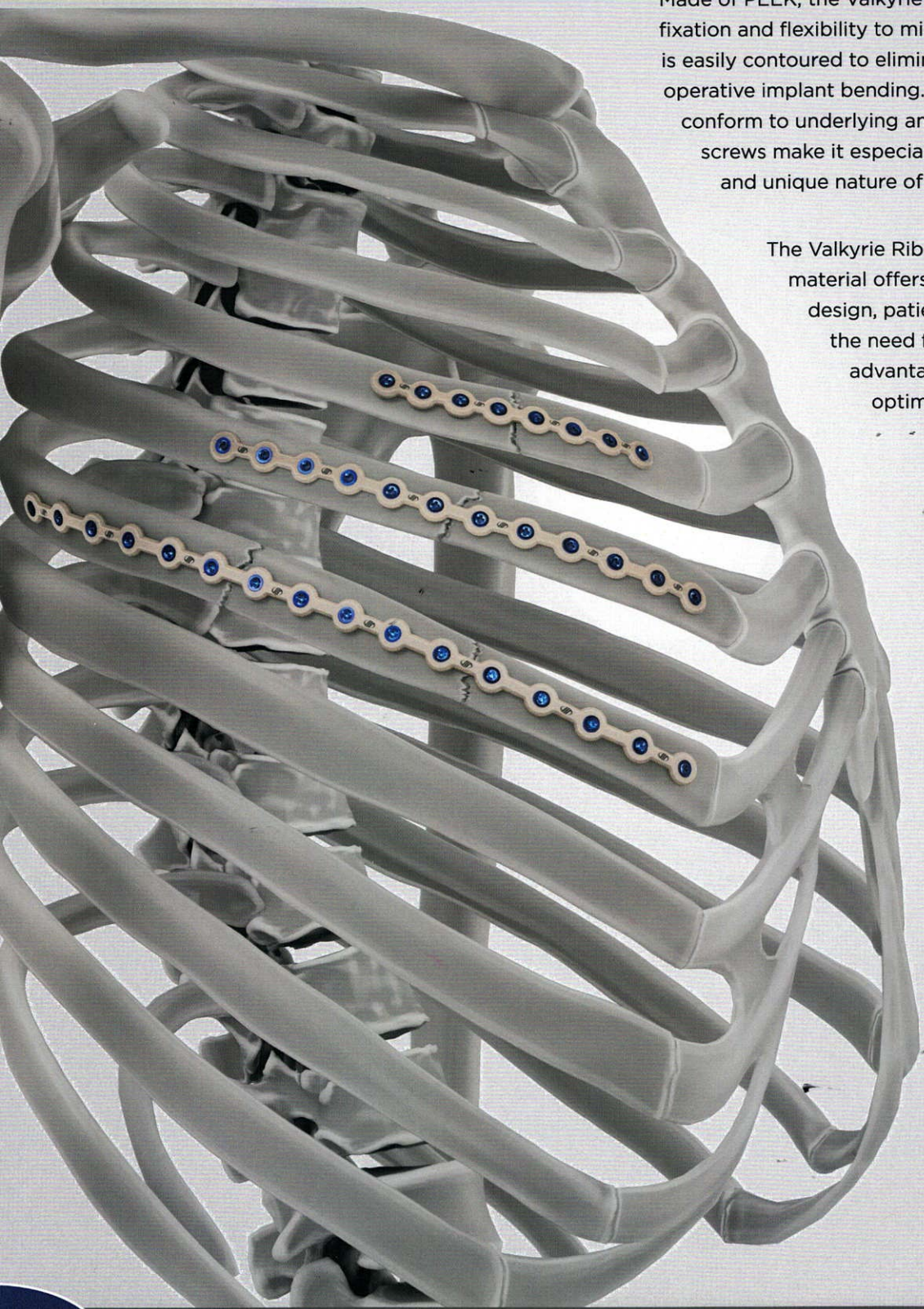
SURGICAL TECHNIQUE

VALKYRIE® RIB
Thoracic Fixation System

The novel single-use, PEEK (PolyEtherEtherKetone) device is an extension of Able's platform technology Valkyrie Thoracic Fixation and is indicated for use in the stabilization and fixation of fractures in the chest wall including reconstructive surgical procedures, trauma, or planned osteotomies.

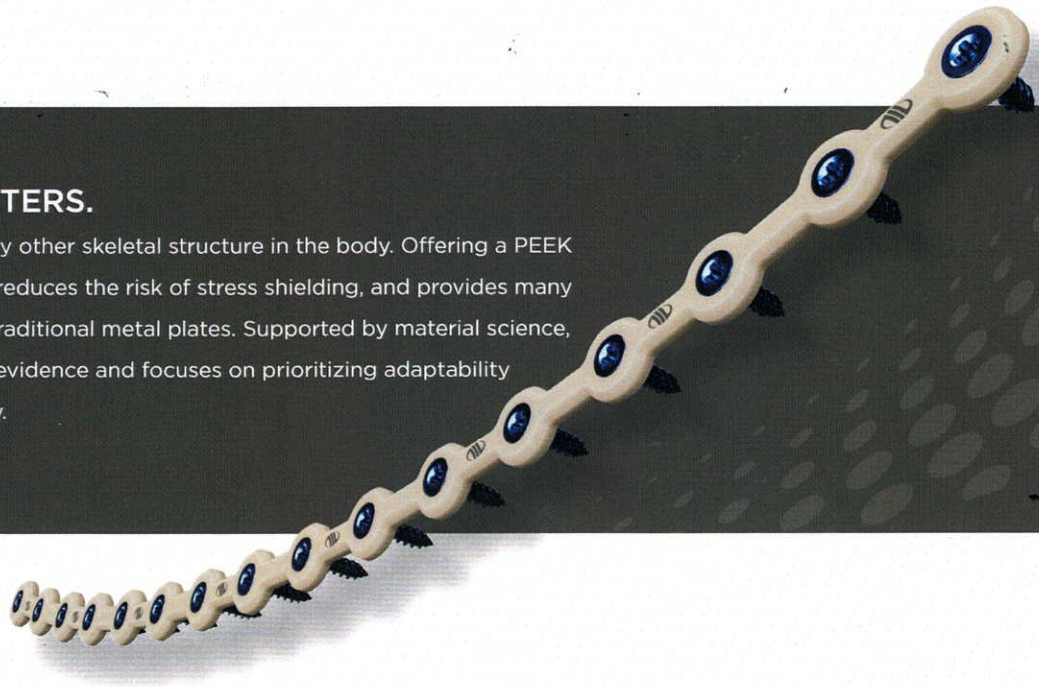
Made of PEEK, the Valkyrie Rib System provides durable fixation and flexibility to minimize stress shielding and is easily contoured to eliminate the complexity of intra-operative implant bending. PEEK's inherent ability to conform to underlying anatomy and to reliably retain screws make it especially well-suited to the challenging and unique nature of rib fracture fixation.

The Valkyrie Rib Thoracic Fixation System's PEEK material offers a zero-chance cross threading design, patient specific contouring (without the need for plate bending tools), the advantage of radiolucency, and the optimal mix of flexibility and stiffness.



MATERIAL SCIENCE MATTERS.

Ribs can elastically bend more than any other skeletal structure in the body. Offering a PEEK material that mimics this native bone, reduces the risk of stress shielding, and provides many additional features and benefits over traditional metal plates. Supported by material science, this novel product is rooted in clinical evidence and focuses on prioritizing adaptability over the conventional norms of rigidity.



FEATURES

- Patient-specific contouring (without the need for plate bending tools)
- ONLY 3 plate SKU's (ambidextrous plating options)
- Enhanced screw retention due to zero-chance cross threading
- Minimizes stress shielding
- Easily cuttable for patient-tailored plates
- Sterile single-use (plates, screws, Driver Bit and Power Driver)
- Radiolucent plates
- Double lead thread screws
- Enhanced screw insertion/cone of angulation

SCREW INTERFACE

Zero-chance cross threading
Screw threads directly into the plate

- Self-drilling screws eliminate need for pre-drilling
- Self-retaining screwdriver
- Locking design for stable construct
- One screw diameter for use with all plates

Low profile design
Plate thickness: **2.3mm**

Allows the screw to sit flush to the plate providing a consistent low-profile construct.

1 EXPOSE RIB

Expose the rib to allow a minimum of three screws on each side of the fracture. Remove any nonviable bone (Figure 1).

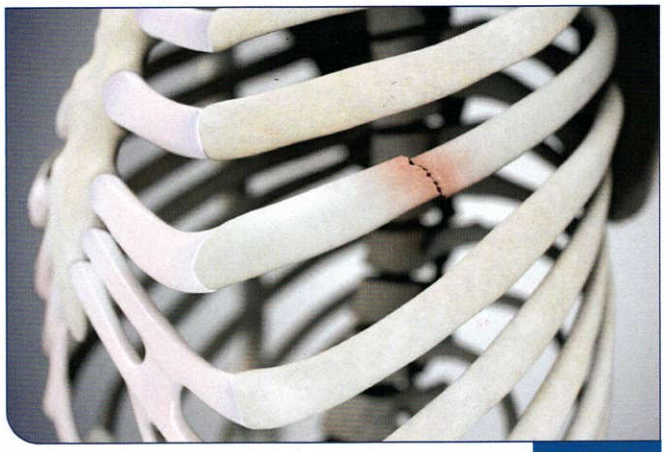


FIGURE 1

2 SCREW SIZING

Determine thickness of the bone using the provided Sizing Caliper. Select the screw length indicated. (Figure 2 & 3).

Note: *The provided Caliper accounts for plate thickness.*

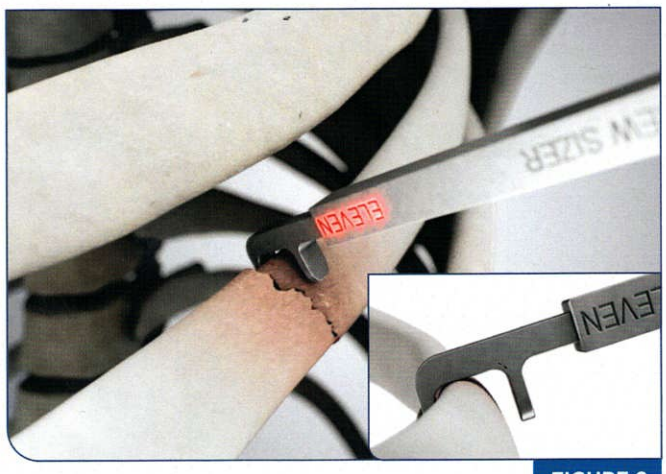


FIGURE 2

FIGURE 3

3 REDUCE FRACTURE

Utilizing Rib Elevators or other instrumentation, ensure the rib fracture is reduced (Figure 4).

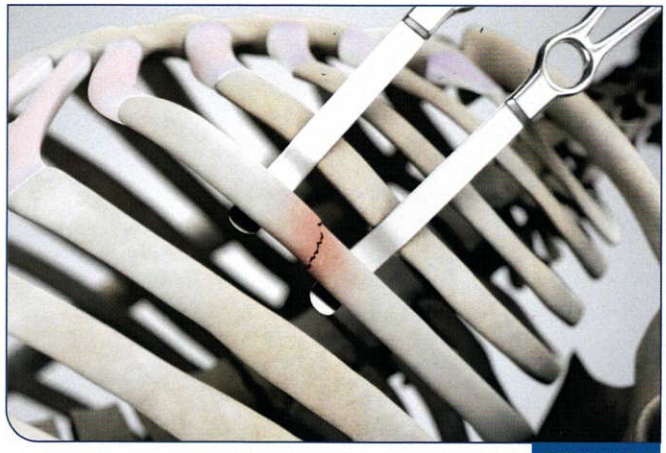


FIGURE 4

4 PRODUCT PREPARATION

Insert the Driver Bit into the preferred Driver (Figure 5).

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

Remove the selected screws from the packaging materials and using the "Stab-&-Grab" feature of the Driver Bit, insert Driver Bit into screw.

FIGURE 5

5 PLATE SELECTION

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

Remove plate from packaging materials.

Insert plate into surgical site and align to preferred location on rib.

Note: *Plates can be cut to better accommodate patient anatomy if needed. If cutting the plate, cut the plate between screw hole locations, allowing for a minimum of three screws on each side of the rib fracture.*

Note: *Plate Holding Forceps or other instrumentation may be used to hold the plate on the rib.*

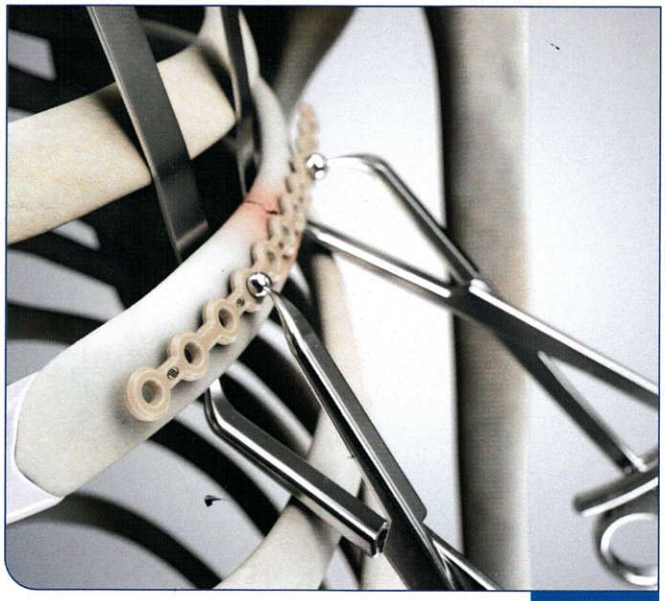


FIGURE 6

6 SCREW INSERTION

Using the preferred Driver, insert the first screw into the plate until the screw head is seated flush to the plate (Figure 7). Repeat, inserting subsequent screws into the plate construct ensuring a minimum of three screws on each side of the rib fracture (Figure 8 & 9).

CAUTION: *Over-tightening the screw may compromise screw purchase in plate and bone.*

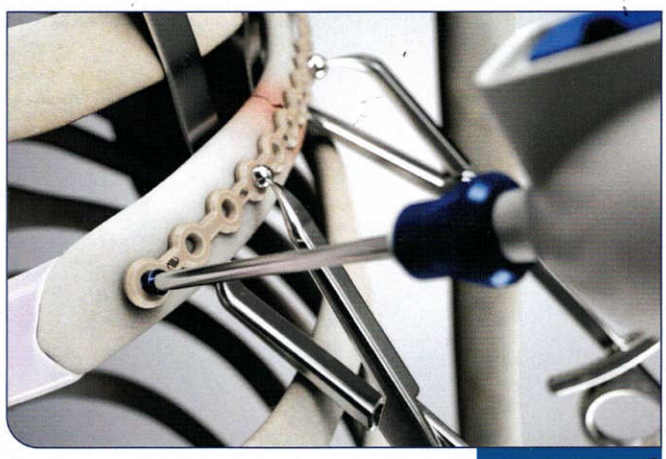


FIGURE 7

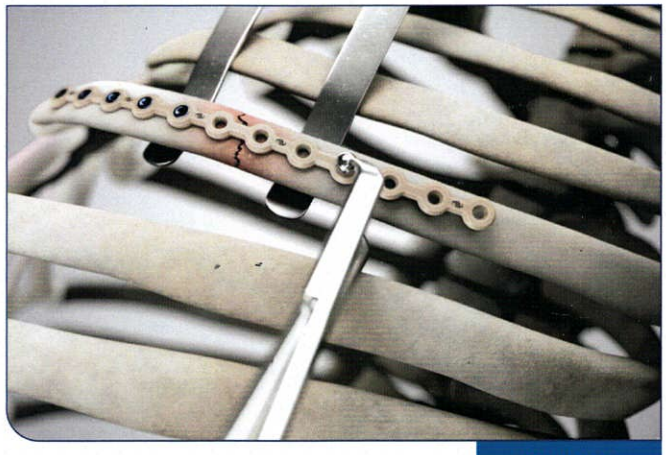


FIGURE 8

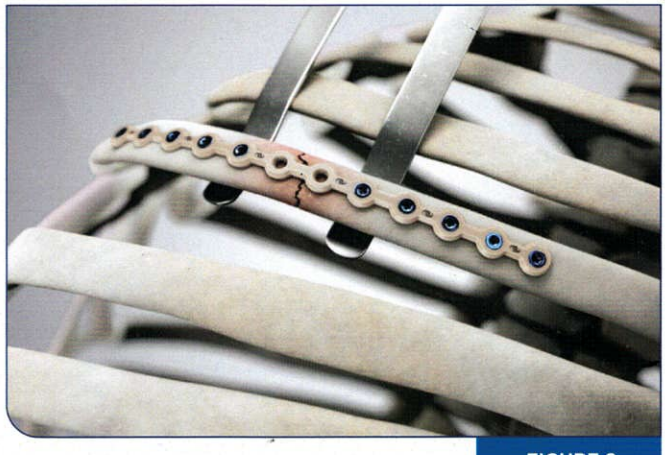


FIGURE 9

7 CONSTRUCT CONFIRMATION

Confirm screws are fully seated within the plate and construct is properly seated onto bone (Figure 10).

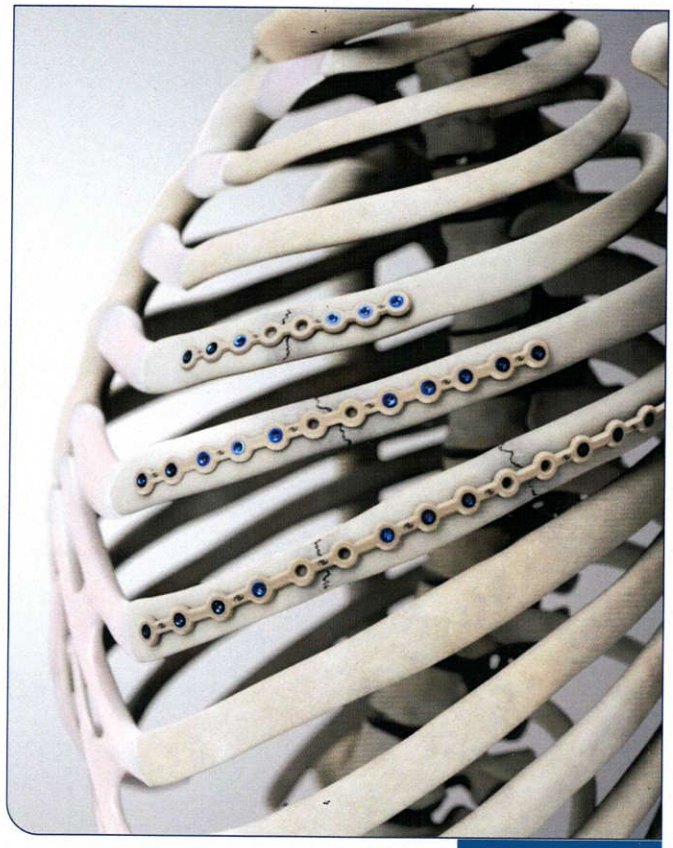


FIGURE 10

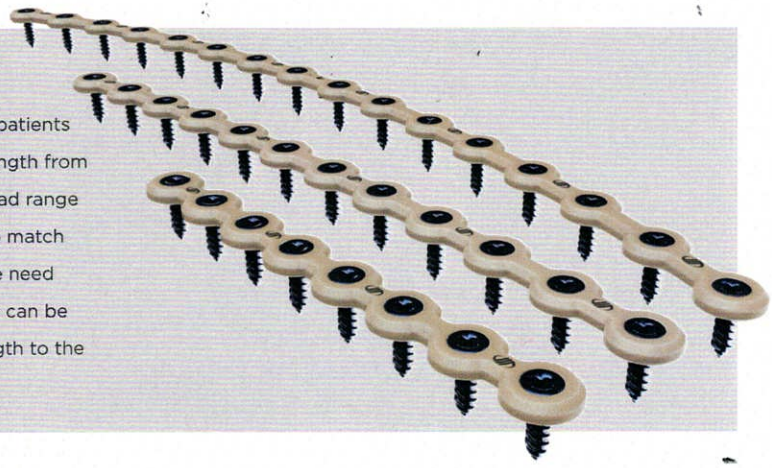
IMPLANT REMOVAL (IF NECESSARY)

EXTRACTION (IF REQUIRED)

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

PEEK PLATES

The Valkyrie Rib Thoracic Fixation System provides "the perfect fit" for patients without the need to pre-contour the PEEK plates. The plates range in length from 80mm-214mm (8 holes-16 holes), allowing the surgeon to address a broad range of fracture patterns. The advanced PEEK material offers the flexibility to match the body's natural curvature in multiple planes of motion eliminating the need for intraoperative bending. Using our universal plate selection; any plate can be applied to any rib (left side or right side) and can be cut to tailor its length to the specific needs of the patient.



8-HOLE STRAIGHT PLATE - 80mm (3.14in.)

Fixation of simple fractures

Hole pattern 10mm apart

12-HOLE SEMI ARC PLATE - 141mm (5.55in.)

Fixation of simple or multiple fractures

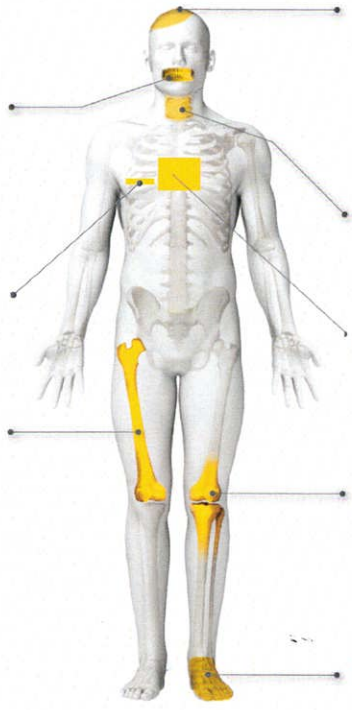
Hole pattern 12mm apart

16-HOLE ARC PLATE 214mm - (8.43in.)

Length allows for bridging of multiple fracture sites and can span multiple fractures to suspend flail segments

Hole pattern 14mm apart

PEEK IN MEDICAL DEVICES



DENTAL
(Restorative and prosthetic dentistry)

THORACIC
(Rib fixation)

ORTHOPEDIC TRAUMA
(Fracture fixation)

CMF
(Craniomaxillofacial (CMF) and more)

SPINE
(Spinal disorders)

STERNUM
(Sternal closure & fixation)

ORTHO
(Joint arthroscopy and arthroplasty)

EXTREMITIES
(Foot & Ankle)

PolyEtherEtherKetone (PEEK) is a high-performance polymer that is located at the top of the polymer pyramid. PEEK is challenging metal as the material of choice in medical devices due to it's numerous advantages, such as:

- **Radiolucent imaging**
- **Patient-specific contouring**
- **Bioinert**
- **Easily cut**
- **Bone-like modulus helps minimize stress shielding**
- **Eliminates the risk of allergies from metal**

A PROVEN HISTORY OF BIOCOMPATIBILITY AND IMPLANTATION

20+ YEARS
of Clinical History

MORE THAN 13,000,000
Devices Implanted

OVER 500
Devices Cleared

Sources:
www.invibio.com

VALKYRIE® RIB THORACIC FIXATION SYSTEM: STERILE PLATES

Part Number	Description	Content	Product Image
05-000-08	Rib Plate, 8-hole Straight	1 Plate per Pack	
05-500-12	Rib Plate, 12-hole Semi-Arc	1 Plate per Pack	
05-300-16	Rib Plate, 16-hole Arc	1 Plate per Pack	

VALKYRIE® RIB THORACIC FIXATION SYSTEM: STERILE SCREWS

Part Number	Description	Content	Product Image
05-2507-1	Rib Screw, Ø2.5 x 7mm, Qty. 1	1 screw	 7mm
05-2507-3	Rib Screw, Ø2.5 x 7mm, Qty. 3	3 screws	
05-2507-8	Rib Screw, Ø2.5 x 7mm, Qty. 8	8 screws	
05-2509-1	Rib Screw, Ø2.5 x 9mm, Qty. 1	1 screw	
05-2509-3	Rib Screw, Ø2.5 x 9mm, Qty. 3	3 screws	
05-2509-8	Rib Screw, Ø2.5 x 9mm, Qty. 8	8 screws	 9mm
05-2511-1	Rib Screw, Ø2.5 x 11mm, Qty. 1	1 screw	
05-2511-3	Rib Screw, Ø2.5 x 11mm, Qty. 3	3 screws	
05-2511-8	Rib Screw, Ø2.5 x 11mm, Qty. 8	8 screws	
05-2807-1	Rib Screw, Ø2.8 x 7mm, Qty. 1	1 screw	
05-2807-3	Rib Screw, Ø2.8 x 7mm, Qty. 3	3 screws	
05-2807-8	Rib Screw, Ø2.8 x 7mm, Qty. 8	8 screws	 11mm
05-2809-1	Rib Screw, Ø2.8 x 9mm, Qty. 1	1 screw	
05-2809-3	Rib Screw, Ø2.8 x 9mm, Qty. 3	3 screws	
05-2809-8	Rib Screw, Ø2.8 x 9mm, Qty. 8	8 screws	
05-2811-1	Rib Screw, Ø2.8 x 11mm, Qty. 1	1 screw	
05-2811-3	Rib Screw, Ø2.8 x 11mm, Qty. 3	3 screws	 13mm
05-2811-8	Rib Screw, Ø2.8 x 11mm, Qty. 8	8 screws	
05-2813-1	Rib Screw, Ø2.8 x 13mm, Qty. 1	1 screw	
05-2813-3	Rib Screw, Ø2.8 x 13mm, Qty. 3	3 screws	
05-2813-8	Rib Screw, Ø2.8 x 13mm, Qty. 8	8 screws	
05-2815-1	Rib Screw, Ø2.8 x 15mm, Qty. 1	1 screw	
05-2815-3	Rib Screw, Ø2.8 x 15mm, Qty. 3	3 screws	 15mm
05-2815-8	Rib Screw, Ø2.8 x 15mm, Qty. 8	8 screws	

VALKYRIE® RIB THORACIC FIXATION SYSTEM: STERILE INSTRUMENTATION

Part Number	Description	Content	Product Image
05-01-2528	Driver Bit	1 per Pack	
05-03-2528	Disposable Power Driver**	1 per Pack	

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

VALKYRIE® RIB THORACIC FIXATION SYSTEM: REUSABLE INSTRUMENTATION

Part Number	Description	Content	Product Image
1103-039NB	Ball-Ended Bone Clamp†	1 Clamp	
111-391	Channel Retractor (Elevators)**	1 Elevator	
111-262	Manual Handle**	1 Manual Handle	
1103-1605	7mm - 9mm Screw Sizer†	1 Screw Sizer	
1103-1606	11mm - 13mm Screw Sizer†	1 Screw Sizer	

† Manufatured by Sontec®

***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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www.AbleMedicalDevices.com

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