# NEW PARADGIGM BIOMEDICAL



## PARA-FIX

External Fixation System Technique Guide

Prescription Use Only. Non-Sterile. Do Not Reuse

## NEW

#### **Device Description**

The NEW PARADIGM BIOMEDICAL (NPB) Para-Fix External Fixation System is intended for use in external fixation of various long bone fractures, including tibial, femoral, pelvic, & humeral fractures in adults. The **Para-Fix** system consists of implants, frame components, & instrumentation for external fixation. The system features implants (Schanz Screws) in various diameters (Ø5 - 6mm) and lengths (120 - 300mm) to accommodate different anatomic sizes of patients.

Schanz Screws are manufactured from medical grade stainless steel per ASTM F138. Para-Fix frame components include clamps and rods. clamps are available in combination (pin to rod, rod to rod) or multi-pin clamp styles. Clamps are manufactured from stainless steel. Ø11mm rods are available in lengths

ranging from 65 – 500mm and are manufactured from carbon fiber. The Para-Fix system is provided non-sterile.

#### **Indications For Use**

The Para-Fix External Fixation System is intended to provide stabilization of open and/or unstable fractures and where tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

#### The specific indications for the Para-Fix External Fixation System include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

#### **Contraindications**

A physician's education, training, and professional judgement are necessary to determine appropriate treatment protocol and patient selection. Contraindications may be relative to each patient, and clinicians should always consider all risks and possible reactions when considering the proper treatment protocol.

Specific contraindications include:

- Material allergies or sensitivities.
- Insufficient quantity or quality of bone/soft tissue.
- use of an external fixator.
- extremity (e.g. psoriatic plaque disease, pyoderma gangrenosum, or administration of anesthesia might be life threatening (e.g. pulmonary, cardiac impairment).
- of underlying pathologic bone conditions.

#### **Para-Fix System Versatility**

By design, the **Para-Fix** External Fixation System is highly versatile, allowing numerous frame configurations to help surgeons meet patient needs. Surgical techniques for Para-Fix Schanz Screw insertion & common frame configurations are contained in this guide:

SECTION	SURGICAL TECHNIQUE	PAGE
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D	Knee Spanning Frame	6
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Presence of extensive internal fracture fixation devices which preclude the

• Preemptive medical conditions including skin conditions of the affected chronic lymphedema), immunosuppressed patients, or patients in which the

 Patients with pathologic bone conditions, including primary or metastatic bone tumors, should not have pins placed at or near the site of such bone lesions. Implants placed in these areas may be ineffective and may complicate treatment

#### **A - Schanz Screw Insertion Surgical Technique**

1. Locate & Prepare Site of Implant Insertion

- Make incision & clear soft tissue at the desired Schanz Screw location.
- Insert appropriately sized Trocar into corresponding Drill Sleeve and guide the assembly onto the bone surface.
- Remove the trocar.

\*NOTE – Take care to avoid major neurovascular structures during incision, drilling, & implant insertion



2. Pre-Drill Bi-cortically (OPTIONAL IF USING SELF-DRILLING SCHANZ SCREWS)

- Connect the appropriate Drill Bit to power and insert the Drill Bit into the Drill Sleeve
- Drill bone bi-cortically
- Remove Drill Bit & Drill Sleeve



Schanz Screw	Drill Bit
Ø5.mm	Ø4.0mm
Ø6.0mm	Ø4.5mm

#### 3. Insert Schanz Screw

- Insert the Schanz Screw, ensuring it obtains bi-cortical purchase
- Repeat steps 1 3 for subsequent Schanz Screws
- \*NOTE Multi-pin clamps may be used with a drill sleeve as a guide for determining Schanz screw spacing between pins that will be clamped in the same multi-pin clamp.

#### **B** - Centrally Threaded Schanz Screw Insertion Surgical Technique

- 1. Locate & Prepare Site

& implant insertion

- 2. Insert Centrally Threaded Schanz Screw

#### **C** - Bi-Lateral Frame Surgical Technique

- to the fracture.
- 2. Insert the second proximal Schanz Screw parallel to the first. A Multi-Pin Clamp may be used to aid in placement of the 2nd Schanz Screw.



3. Place a Multi-Pin Clamp over both Schanz Screws, tighten provisionally. 4. Repeat steps 1 – 3 distal to the fracture.



5. Utilizing Combination Clamps and appropriate-length Ø11mm Carbon Fiber Rods, assemble the remainder of the Bi-Lateral frame. Tighten all clamps provisionally.

 Make incision & clear soft tissue at the desired Schanz Screw location. \*NOTE – Take care to avoid major neurovascular structures during incision,

• Connect the Centrally Threaded Schanz Screw to power & insert using the trocar tip.

1. Utilizing the technique described in Section A, insert a Schanz Screw proximal

6. Perform any adjustments to reduce fracture. Once the fracture is properly reduced, tighten all construct clamps (bolts & nuts) securely.



#### **D** – Knee-Spanning Frame Surgical Technique

1. Utilizing the technique described in Section A, insert two Schanz Screws into the diaphysis of the tibia & diaphysis of the femur.



- 2. Using appropriate length Carbon Fiber Rods & Combination Clamps, complete knee spanning frame. Tighten all clamps provisionally.
- 3. Perform any adjustments to reduce fracture. Once the fracture is properly reduced, tighten all construct clamps (bolts & nuts) securely.



### **E** – Ankle-Spanning Frame Surgical Technique

1. Utilizing the technique described in Section A ,insert a Schanz Screw into the calcaneus.

2. Insert the second Schanz Screw into the calcaneus parallel to the first. A Multi-Pin Clamp may be used to aid in

3. Insert two Schanz Screws into the diaphysis of the tibia, again using the Multi-Pin Clamp as a guide as necessary.

4. Place Multi-Pin Clamps over the calcaneal and tibial pins. Remove any Multi-Pin Clamp Rods as necessary. Tighten clamps provisionally.







- 5. Utilizing Combination Clamps and appropriate-length Ø11mm Carbon Fiber Rods, assemble the remainder of the ankle-spanning frame. Tighten all clamps provisionally.
- 6. Perform any adjustments to reduce fracture. Once the fracture is properly reduced, tighten all construct clamps (bolts & nuts) securely.

#### **F** – Pelvic Frame Surgical Technique

1. Utilizing the technique described in Section A, insert two Schanz Screws into the iliac crest.

\*NOTE – ensure all Schanz Screws remain in the ilium as they are inserted.

2. Repeat for the opposite side.



all construct clamps (bolts & nuts) securely.









4. Using appropriate length Carbon Fiber Rods & Combination Clamps, complete pelvic frame.

5. Perform any adjustments to reduce fracture. Once the fracture is properly reduced, tighten



#### PARA-FIX SCHANZ SCREWS

Part #	Description	Thread Diameter (mm)	Thread Length (mm)		
	5mm Schanz Screws				
0201-50120	5 X 120mm Self-Drilling Schanz Screw	5	120		
0201-50125	5 X 125mm Self-Drilling Schanz Screw	5	125		
0201-50130	5 X 130mm Self-Drilling Schanz Screw	5	130		
0201-50135	5 X 135mm Self-Drilling Schanz Screw	5	135		
0201-50140	5 X 140mm Self-Drilling Schanz Screw	5	140		
0201-50145	5 X 145mm Self-Drilling Schanz Screw	5	145		
0201-50150	5 X 150mm Self-Drilling Schanz Screw	5	150		
0201-50155	5 X 155mm Self-Drilling Schanz Screw	5	155		
0201-50160	5 X 160mm Self-Drilling Schanz Screw	5	160		
0201-50165	5 X 165mm Self-Drilling Schanz Screw	5	165		
0201-50170	5 X 170mm Self-Drilling Schanz Screw	5	170		
0201-50175	5 X 175mm Self-Drilling Schanz Screw	5	175		
0201-50180	5 X 180mm Self-Drilling Schanz Screw	5	180		
0201-50185	5 X 185mm Self-Drilling Schanz Screw	5	185		
0201-50190	5 X 190mm Self-Drilling Schanz Screw	5	190		
0201-50195	5 X 195mm Self-Drilling Schanz Screw	5	195		
0201-50200	5 X 200mm Self-Drilling Schanz Screw	5	200		
0201-50205	5 X 205mm Self-Drilling Schanz Screw	5	205		
0201-50210	5 X 210mm Self-Drilling Schanz Screw	5	210		
0201-50215	5 X 215mm Self-Drilling Schanz Screw	5	215		
0201-50220	5 X 220mm Self-Drilling Schanz Screw	5	220		
0201-50225	5 X 225mm Self-Drilling Schanz Screw	5	225		
0201-50230	5 X 230mm Self-Drilling Schanz Screw	5	230		
0201-50235	5 X 235mm Self-Drilling Schanz Screw	5	235		
0201-50240	5 X 240mm Self-Drilling Schanz Screw	5	240		
0201-50245	5 X 245mm Self-Drilling Schanz Screw	5	245		
0201-50250	5 X 250mm Self-Drilling Schanz Screw	5	250		

Part #	Description	Thread Diameter (mm)	Thread Length (mm)
	6mm Schanz Screws		
0201-60120	6 X 120mm Self-Drilling Schanz Screw	6	120
0201-60125	6 X 125mm Self-Drilling Schanz Screw	6	125
0201-60130	6 X 130mm Self-Drilling Schanz Screw	6	130
0201-60135	6 X 135mm Self-Drilling Schanz Screw	6	135
0201-60140	6 X 140mm Self-Drilling Schanz Screw	6	140
0201-60145	6 X 145mm Self-Drilling Schanz Screw	6	145
0201-60150	6 X 150mm Self-Drilling Schanz Screw	6	150
0201-60155	6 X 155mm Self-Drilling Schanz Screw	6	155
0201-60160	6 X 160mm Self-Drilling Schanz Screw	6	160
0201-60165	6 X 165mm Self-Drilling Schanz Screw	6	165
0201-60170	6 X 170mm Self-Drilling Schanz Screw	6	170
0201-60175	6 X 175mm Self-Drilling Schanz Screw	6	175
0201-60180	6 X 180mm Self-Drilling Schanz Screw	6	180
0201-60185	6 X 185mm Self-Drilling Schanz Screw	6	185
0201-60190	6 X 190mm Self-Drilling Schanz Screw	6	190
0201-60195	6 X 195mm Self-Drilling Schanz Screw	6	195
0201-60200	6 X 200mm Self-Drilling Schanz Screw	6	200
0201-60205	6 X 205mm Self-Drilling Schanz Screw	6	205
0201-60210	6 X 210mm Self-Drilling Schanz Screw	6	210
0201-60215	6 X 215mm Self-Drilling Schanz Screw	6	215
0201-60220	6 X 220mm Self-Drilling Schanz Screw	6	220
0201-60225	6 X 225mm Self-Drilling Schanz Screw	6	225
0201-60230	6 X 230mm Self-Drilling Schanz Screw	6	230
0201-60235	6 X 235mm Self-Drilling Schanz Screw	6	235
0201-60240	6 X 240mm Self-Drilling Schanz Screw	6	240
0201-60245	6 X 245mm Self-Drilling Schanz Screw	6	245
0201-60250	6 X 250mm Self-Drilling Schanz Screw	6	250

#### PARA-FIX SCHANZ SCREWS

#### PARA-FIX SCHANZ SCREWS

Part #	Description	Thread Diameter (mm)	Thread Length (mm)
	Centrally Threaded Schanz Screws		
0201-70200	4/5 X 200mm Centrally Threaded Schanz Screw	5	200
0201-70210	4/5 X 210mm Centrally Threaded Schanz Screw	5	210
0201-70220	4/5 X 220mm Centrally Threaded Schanz Screw	5	220
0201-70230	4/5 X 230mm Centrally Threaded Schanz Screw	5	230
0201-70240	4/5 X 240mm Centrally Threaded Schanz Screw	5	240
0201-70250	4/5 X 250mm Centrally Threaded Schanz Screw	5	250
0201-70260	4/5 X 260mm Centrally Threaded Schanz Screw	5	260
0201-70270	4/5 X 270mm Centrally Threaded Schanz Screw	5	270
0201-70280	4/5 X 280mm Centrally Threaded Schanz Screw	5	280
0201-70290	4/5 X 290mm Centrally Threaded Schanz Screw	5	290
0201-70300	4/5 X 300mm Centrally Threaded Schanz Screw	5	300
0201-80200	5/6 X 200mm Centrally Threaded Schanz Screw	6	200
0201-80210	5/6 X 210mm Centrally Threaded Schanz Screw	6	210
0201-80220	5/6 X 220mm Centrally Threaded Schanz Screw	6	220
0201-80230	5/6 X 230mm Centrally Threaded Schanz Screw	6	230
0201-80240	5/6 X 240mm Centrally Threaded Schanz Screw	6	240
0201-80250	5/6 X 250mm Centrally Threaded Schanz Screw	6	250
0201-80260	5/6 X 260mm Centrally Threaded Schanz Screw	6	260
0201-80270	5/6 X 270mm Centrally Threaded Schanz Screw	6	270
0201-80280	5/6 X 280mm Centrally Threaded Schanz Screw	6	280
0201-80290	5/6 X 290mm Centrally Threaded Schanz Screw	6	290
0201-80300	5/6 X 300mm Centrally Threaded Schanz Screw	6	300

### Frame Component List

Part #	Description
0201-0001	Combination Clamp
0201-0002	Multi-Pin Clamp
0201-11065	11 X 65mm Carbon Fiber Rod
0201-11100	11 X 100mm Carbon Fiber Rod
0201-11150	11 X 150mm Carbon Fiber Rod
0201-11200	11 X 200mm Carbon Fiber Rod
0201-11250	11 X 250mm Carbon Fiber Rod
0201-11300	11 X 300mm Carbon Fiber Rod
0201-11350	11 X 350mm Carbon Fiber Rod
0201-11400	11 X 400mm Carbon Fiber Rod
0201-11450	11 X 450mm Carbon Fiber Rod
0201-11500	11 X 500mm Carbon Fiber Rod

#### **Instrument List**

#### PARA-FIX INSTRUMENTATION

Part #	Description
0201-5001	5mm Trocar
0201-5002	5mm Drill Sleeve
0201-5003	5mm Tissue Sleeve
0201-6001	6mm Trocar
0201-6002	6mm Drill Sleeve
0201-6003	6mm Tissue Sleeve
0201-40200	4 X 200mm Drill Bit AO QC
0201-45200	4.5 X 200mm Drill Bit AO QC
0201-0003	AO QC to 10mm Hex Adapter
0201-0004	AO QC T-Handle
0201-0005	10mm Combination Wrench
0201-0006	Sterilization Case
0201-0007	Sterilization Case Lid

#### PARA-FIX FRAME COMPONENTS



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