BPS Wrist Fracture System

Titanium

SURGICAL TECHNIQUE

System Description

The OrthoNovis BPS Wrist Fracture System is to be used as an aid to the treatment of certain types of fractures, fusions or osteotomies that lend themselves to the principle of plate and/or screw fixation. Like every type of orthopaedic implant, it cannot be assumed to be uniformly effective without risk. Use of these implants is not a substitute for normal tissue healing. The OrthoNovis BPS Wrist Fracture System is designed to provide additional constraint of movement of a fractured, fused or osteotomized bone and are intended only as an aid to fix the fracture in place during the healing process.

The BPS Wrist Fracture System is indicated for the fixation of simple and complex intra- articular and extra-articular fractures, and for osteotomies of the distal radius in adults. The device is indicated for fixation of Fractures AO types A2, A3, B1, B3, C1, C2, C3. To meet a variety of patient anatomical needs in various sizes, the BPS Wrist Fracture System features distal radius plates as well as various styles of bone screws (locking screws and cortical screws). All implants' plates are manufactured from Commercially Pure Titanium Grade 4 per ASTM F67. All implants' screws are manufactured from Titanium Grade 5 (Ti-6Al-4V ELI) per ASTM F136.

GENERAL CONDITIONS OF USE:

The safe implantation of the BPS Wrist Fracture systems requires an in-depth knowledge of human anatomy as well as common anatomical variations along with a thorough understanding of the specific clinical circumstances. The use of the BPS Wrist Fracture systems should be performed only by experienced surgeons with specific training in the use of internal fixation. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this system. The BPS Wrist Fracture systems should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material.

See IFU for a more detailed description

Indications and Contraindications

Indications for use of BPS wrist fracture system

- The BPS Wrist Fracture System is indicated for the fixation of simple and complex intra-articular and extra-articular fractures, and for osteotomies of the distal radius in adults.

- The device is indicated for fixation of Fractures AO types A2, A3, B1, B3, C1, C2, C3.

Contraindications for use of BPS wrist fracture system

- The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Contraindications may be relative or absolute. Users of this device must carefully weigh the advantages against possible complications and consider the patient's entire clinical exam in addition to the items listed above.

Warnings & Precautions

*Please locate Instructions for Use (IFU at **www.orthonovis.com/ifu** for a complete list of Warnings, Precautions, Potential Risks and Potential Adverse Effects.*

*All non-sterile devices must be cleaned and sterilized before use. Please follow the instructions provided within the Instructions for Use (IFU at **www.orthonovis.com/ifu**)*

These warnings do not include all possible adverse surgical effects, but are particular to metallic fixation devices. Explain general surgical risks to the patient before surgery.

Possible Adverse Effects: In any surgical procedure, the potential for adverse reactions exists. Possible adverse effects particular to orthopaedic devices are listed below. These do not include all adverse effects which can occur with surgical procedures.

1. Loosening, bending, cracking or fracture of any component with or without loss of fixation in bone, possibly in association with blood supply limitations, insufficient quality or quantity of bone, osteoporosis, delayed union, nonunion, excess activity, or any of the factors listed previously.

2. Loss of anatomic position with resulting nonunion, malunion, or delayed union.

3. Infections.

4. Hematoma.

5. Stiffness of the adjacent joint with or without degenerative changes.

6. Tendinitis or tendon rupture.

7. Scarring.

8. Chronic regional pain syndrome.

9. Local bursitis and pain from prominent hardware.

The adverse effects listed here are not specific to the OrthoNovis BPSS Ankle Fracture System and are in principle observed with any implant.

Warnings and Precautions:

1.Use caution in the handling and storage of implants. Cutting, bending, or scratching the surface of metal components impairs the strength and fatigue life of the implant. Implants should be stored away from corrosive agents and environments. If implants appear damaged, they should not be implanted.
2. Implantation in patients with the contraindications specified previously should be avoided. It is important to preoperatively assess the radiographic configuration of the fracture, fusion or osteotomy prior to considering implantation of this device. In addition, all other relevant medical and social factors should be considered in order to determine whether a patient is an appropriate candidate for this device.
3. Allergies to component materials should be considered and tested, if appropriate, prior to using this device. See material composition under the general regulatory information section.
4. A full inventory of instruments and implants should be available prior to initiation of the surgical procedure. Components should be tested in trial assembly prior to implantation.
5. Surgeons are advised to review the product-specific surgical technique prior to performing surgery. Surgeons should also be fully familiar with the biomechanics and surgical principles inherent to the use of this device, and proper selection and placement of the device are important considerations in successful utilization of this device.
6. Any adjacent soft tissue structures should be checked to ensure that abrasive rubbing against components will not occur.
7. Size and position of implants should be checked radiographically prior to completion of the surgical procedure.
8. These devices are intended for single use only. Violation of this could potentially result in loss of performance, function, fit or device failure, and could potentially result in infection.
9. Excessive or improper insertion angle can potentially deform or adversely affect the strength and fatigue life of the implant.
10.OrthoNovis plates should not be bent near the locking screw hole, as it may distort the hole threads which prohibits insertion of the screw.
11.OrthoNovis plates should not be repeatedly bent at the same location or bent to excessive angles as it may potentially lead to premature plate fatigue, loss of performance or breakage in situ.
12.OrthoNovis screws must be inserted by hand, and are not advised to be placed under powered equipment. Possible risks using screws under power include stripping, bending, cracking or fracturing of the implant and/or instrument. For screws where power equipment may be used, the surgeon must carefully control of the speed and power of insertion. It is inappropriate to use power equipment with smaller sizes of OrthoNovis screws. It is the responsibility of the surgeon to ensure safe use.
13.OrthoNovis plates should only be used with the appropriate size OrthoNovis screws. OrthoNovis has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
14.Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative protocol prescribed by the surgeon should be strictly followed to avoid adverse stresses applied to the device.
15. Removal of OrthoNovis plates and screws may be warranted if deemed medically necessary in order to avoid possible adverse effects. Temporary joint spanning plates, such as bridge plates, must be periodically monitored and removed once bone healing has occurred.
16.These devices have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment.

Technical Details

The BPS Wrist Fracture System has NOT been evaluated for safety and compatibility in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration and image artifacts at or near the implant site.

Surgical Technique

Distal Radius Plate, Volar

The surgical technique is to provide a general overview on the instrumentation and procedure required to implant a plate in the distal radius. Clear identification and classification of the fracture site should first be established pre-operatively using the appropriate methods and visualization.

Preparation of plate requires the surgeon to note that excessive plate bending my lead to failure of the locking mechanism and should be avoided. Do not re-bend plates. In the event plate bending has deformed an oblong hole, please note that there may be potential for a screw to pass through the hole upon insertion.

Positioning of the patient shall be determined by the operating surgeon. Initial incision is typically used so a direct reduction (fracture clamp chosen by surgeon and/or kwires) and provisional fixation can be achieved.

Once reduction is achieved, the surgeon can select the proper plate and length desired for the correct internal fixation of the distal radius. Once the correct plate is selected, this can be stabilized by insertion of K-Wires (A711-001) through specifically located K-Wire holes.

Using the variable angle drill guide (A711-003) and 2.0mm (A711-002) drill bit, it is necessary to drill through both cortices. Screw length is measured using the depth gauge (A711-006). Screw insertion is completed using the screwdriver assemble detailed within this surgical technique.

The drill guide allows for the 2.0mm drills (A711-002), provided within the BPS Wrist Fracture System. is designed to limit drilling to a +/- 15 degree angle. Greater than this angle should be avoided as this may prevent complete locking of screw into the plate.

When using 2.5 Locking Screws (K2L25-XX), use the Static Drill Guide (A711-004). Then using the 2.0mm Drill Bit (A711-002), drill till designated depth is achieved. Remove the drill bit as well the static drill guide.

A depth gauge (A711-006) will be used to measure the correct depth. Obtain the correct screw length and type from the screw caddy and confirm correct measurement using the depth gauge directly on the screw caddy.

Screw insertion is achieved with the instruments T8 driver (A711-009) and Ratchet handle (A711-010). Establish the screwdriver assembly by pulling back on the handle sleeve and inserting the AO end of the T8 driver and then release the sleeve.

Insert the screw into the pre-drilled hole using the screwdriver assembly. As the screw head approaches the plate, it is recommended to NOT over tighten the screw once it has achieved complete purchase within the predetermined hole of the plate. Repeat drilling, measuring and placement of locking and non-locking screws in the remaining holes, as required.

Intra-operative fluoroscopy is performed to confirm appropriate reduction and implant placement.

BPS Wrist Fracture Implants

Volar Distal Radius Plates

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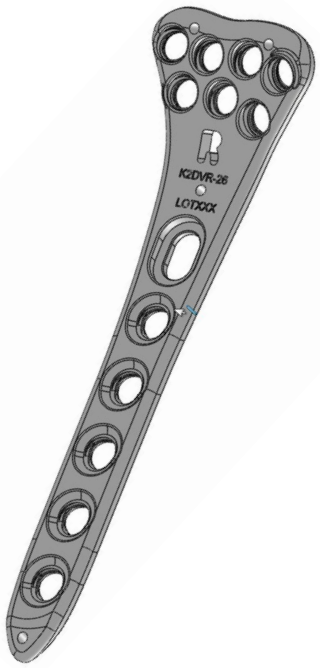
LEFT PLATES

REF	DESCRIPTION
K2DVR-12	Distal Radius Plate, Volar, LEFT, 2 Hole (22mm W / 45mm L)
K2DVR-13	Distal Radius Plate, Volar, LEFT, 3 Hole (22mm W / 54mm L)
K2DVR-14	Distal Radius Plate, Volar, LEFT, 4 Hole (22mm W / 63mm L)
K2DVR-15	Distal Radius Plate, Volar, LEFT, 5 Hole (22mm W / 72mm L)
K2DVR-16	Distal Radius Plate, Volar, LEFT, 6 Hole (22mm W / 80mm L)



RIGHT PLATES

REF	DESCRIPTION
K2DVR-22	Distal Radius Plate, Volar, RIGHT, 2 Hole (22mm W / 45mm L)
K2DVR-23	Distal Radius Plate, Volar, RIGHT, 3 Hole (22mm W / 54mm L)
K2DVR-24	Distal Radius Plate, Volar, RIGHT, 4 Hole (22mm W / 63mm L)
K2DVR-25	Distal Radius Plate, Volar, RIGHT, 5 Hole (22mm W / 72mm L)
K2DVR-26	Distal Radius Plate, Volar, RIGHT, 6 Hole (22mm W / 80mm L)

BPS Wrist Fracture Implants

2.5mm Locking Screws

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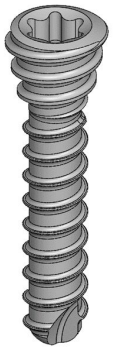
Size	DESCRIPTION
K2L25-10	2.5mm Locking screw, 10mm
K2L25-12	2.5mm Locking screw, 12mm
K2L25-14	2.5mm Locking screw, 14mm
K2L25-16	2.5mm Locking screw, 16mm
K2L25-18	2.5mm Locking screw, 18mm
K2L25-20	2.5mm Locking screw, 20mm
K2L25-22	2.5mm Locking screw, 22mm
K2L25-24	2.5mm Locking screw, 24mm
K2L25-26	2.5mm Locking screw, 26mm
K2L25-28	2.5mm Locking screw, 28mm
K2L25-30	2.5mm Locking screw, 30mm



2.5mm Non-Locking Screws

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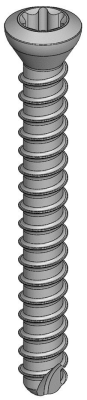
Size	DESCRIPTION
K2C25-10	2.5mm Non-locking screw, 10mm
K2C25-12	2.5mm Non-locking screw, 12mm
K2C25-14	2.5mm Non-locking screw, 14mm
K2C25-16	2.5mm Non-locking screw, 16mm
K2C25-18	2.5mm Non-locking screw, 18mm
K2C25-20	2.5mm Non-locking screw, 20mm
K2C25-22	2.5mm Non-locking screw, 22mm
K2C25-24	2.5mm Non-locking screw, 24mm
K2C25-26	2.5mm Non-locking screw, 26mm
K2C25-28	2.5mm Non-locking screw, 28mm
K2C25-30	2.5mm Non-locking screw, 30mm



2.5mm Cortical Screws

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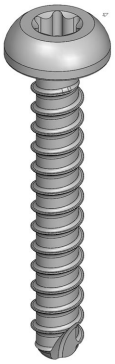
Size	DESCRIPTION
MATH25-10	2.5mm Cortical screw, 10mm
MATH25-12	2.5mm Cortical screw, 12mm
MATH25-14	2.5mm Cortical screw, 14mm
MATH25-16	2.5mm Cortical screw, 16mm
MATH25-18	2.5mm Cortical screw, 18mm
MATH25-20	2.5mm Cortical screw, 20mm
MATH25-22	2.5mm Cortical screw, 22mm
MATH25-24	2.5mm Cortical screw, 24mm
MATH25-26	2.5mm Cortical screw, 26mm
MATH25-28	2.5mm Cortical screw, 28mm
MATH25-30	2.5mm Cortical screw, 30mm



Components for the BPS Wrist Fracture System

Part No.	Description
A711-001	1.0mm x 100mm Kwire
A711-002	2.0mm AO Drill Bit
A711-003	2.0mm Variable Angle Drill Guide
A711-004	2.0mm Static Drill Guide
A711-005	Cannulated Countersink 2.5/3.5/4.0mm
A711-006	Depth Gauge
A711-007	Screw Pickups
A711-008	Screw Holding Sleeve
A711-009	T8 AO Driver
A711-010	AO Handle Cannulated
A711-011	0.8Nm Torque Limiting Adapter AO
A711-013	Lobster Clamp
3B	BPS Base Tray
3WL	BPS Wrist Tray Lid
325C	BPS 2.5mm Screw Caddy
3WSL	BPS 2.5mm Screw Caddy Lid
3WC	BPS Wrist Plate Caddy

Components (cont.)

GENERAL GUIDELINES FOR PRE-DRILLING

- Always pre-drill with a new, sharp drill
- All drills are single-use only
- Drill slowly to help prevent thermal injury
- When placed through an exposed bone surface, irrigating the interface can reduce heating

Screw Diameter	Screw Length	Thread Length	Drill Bit
2.5mm	10mm to 30mm	Full	2.0mm

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