BPS Ankle Fracture System

Titanium & Stainless Steel

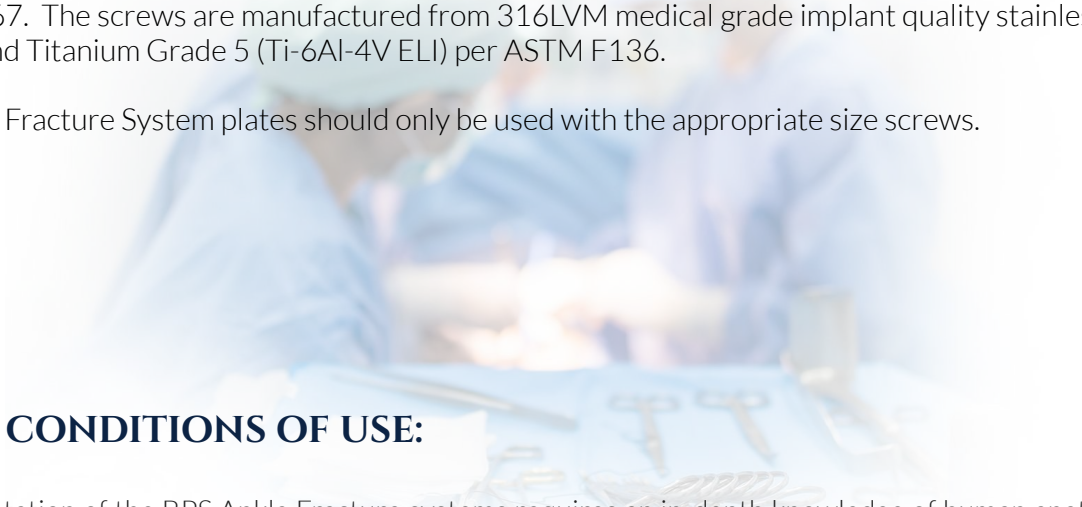
SURGICAL TECHNIQUE

System Description

The BPS Ankle 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 BPS Ankle 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 Ankle Fracture System include implants designed for fixation of certain fractures, fusions or osteotomies. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate variations in patient size and sites of application. The BPS Ankle Fracture System plates are manufactured from 316LVM medical grade implant quality stainless steel per ASTM F138 and commercially Pure Titanium Grade 4 per ASTM F67. The screws are manufactured from 316LVM medical grade implant quality stainless steel per ASTM F138 and Titanium Grade 5 (Ti-6Al-4V ELI) per ASTM F136.

The BPS Ankle Fracture System plates should only be used with the appropriate size screws.



GENERAL CONDITIONS OF USE:

The safe implantation of the BPS Ankle 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 Ankle 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 Ankle 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 ankle fracture system

- The BPS Ankle Fracture System consists of anatomic distal fibula plates, one-third tubular plates and bone screws. The distal fibula plate is intended for use in internal fixation of the distal fibula. The one-third tubular plate is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, distal tibia, fibula, small bones in the ankle, fore, mid-and hind-foot in adult patients. The 3.5mm are compatible screws for the distal fibula and one-third tubular plates and their indications for use. The 4.0mm cannulated screws are intended for fracture fixation of small and long bones. The BPS Ankle Fracture System is not intended for spinal use.

Contraindications for use of BPS ankle 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 Ankle 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 Fibula Plate
One-Third Tubular Plate

The surgical technique is to provide a general overview on the instrumentation and procedure required to implant a plate in the distal fibula. 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. A lateral incision is typically used so a direct reduction and provisional fixation can be achieved.

If an independent lag screw is required prior to plate fixation, this technique starts with reduction achieved by reduction clamps chosen by the surgeon. Using the drill guide (B711-007) and 2.7mm (B711-003) drill bit, it is necessary to drill through both cortices. Screw (Cortical Partial Threaded - K2CP35 or K3CP35) length is measured using the depth gauge (B711-009). When required, use of the countersink (B711-008) provides possible stress rise effects as this can minimize screw head prominence. Screw insertion is completed using the screwdriver assemble detailed within this surgical technique.

Once reduction is achieved, the surgeon can select the proper plate and length desired for the correct internal fixation of the distal fibula. With correct plate (distal fibula or one-third tubular) selected, this can be stabilized by insertion of K-Wires (B711-002) through specifically located K-Wire holes.

Place drill guide (B711-007) into screw hole of selected plate. The drill guide allows for the 2.7mm drills (B711-003) provided within the BPS Ankle Fracture System tray and 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.

Note that the following screws within the BPS Ankle Fracture System tray will use the 2.7mm (B711-003)drill bit. These include: K2C35, K2CP35, MATH35, K2L35, K3C35, K3CP3, MATH35-K3 and K3L35.

The 2.7mm Cannulated (B711-004) drill bit is ONLY for the 4.0 Cannulated Screws when applicable (K2UP40 and K3UP40).

CONTINUED...

Once pilot hole has been established, a depth gauge (B711-009) will be used to measure the correct depth. THe sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring. Failure to do so can result in a false measurement. 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 T10 driver (B711-013) and Ratchet handle (A711-010). Establish the screwdriver assembly by pulling back on the handle sleeve and inserting the AO end of the T10 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.

Surgical Technique

4.0 Cannulated Screw

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

Positioning of the patient shall be determined by the operating surgeon. A lateral incision is typically used so a direct reduction and provisional fixation can be achieved.

Insert Kwire: Using the 1.4mm x 2.7mm double drill guide (B711-005), insert a 1.4mm x 150mm Kwire (B711-002) to appropriate depth determined by surgeon. Repeat procedure when additional wire is necessary. Note that Kwires are single use disposables. Do not reuse Kwires.

Countersink: When further recess of the screw head is required, place the cannulated countersink (B711-008) and rotate the countersink assembly till depth is achieved as determined by the surgeon.

Screw Length Measurement: Slide the cannulated depth gauge (B711-010) over the 1.4mm x150mm Kwire till depth gauge is engaged to the bone. The depth gauge measures direct to the tip of the Kwire.

Pre-Drilling: The 2.7mm Cannulated (B711-004) drill bit is ONLY for the 4.0 Cannulated Screws when applicable (K2UP40 and K3UP40). Slide the AO 2.7mm x 150mm Cannulated Drill Bit over the Kwire and drill to surgeon desired depth.

Insert Screw: Screw insertion is achieved with the instruments T10 cannulated driver (B711-014) and Ratchet handle (A711-010). Establish the screwdriver assembly by pulling back on the handle sleeve and inserting the AO end of the T10 driver and then release the sleeve.

Insert the screw over the selected Kwire and tighten screw till achieved tightness by surgeon. It is recommended to NOT over tighten the screw once it has achieved complete purchase.

Verify Final Reduction: Intra-operative fluoroscopy is performed to confirm appropriate reduction and implant placement. Remove and discard the Kwire. Repeat as necessary for additional screws.

Titanium **Components**

One-Third Tubular Plates

Titanium

Holes	Length	Item Number
2	24.40mm	K213-02
3	36.60mm	K213-03
5	61.00mm	K213-05
7	85.40mm	K213-07
9	109.80mm	K213-09
11	134.20mm	K213-11
13	158.60mm	K213-13

Distal Fibula Plate

Titanium

Left Item Number	Length	Right Item Number
K2DF-13	3 Hole	K2DF-23
K2DF-14	4 Hole	K2DF-24
K2DF-15	5 Hole	K2DF-25
K2DF-17	7 Hole	K2DF-27
K2DF-19	9 Hole	K2DF-29
K2DF-111	11 Hole	K2DF-211

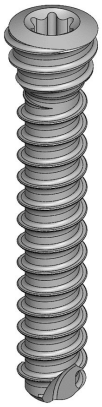
3.5mm Non-Locking Screws

Titanium

Size	Item Number
10mm	K2C35-10
12mm	K2C35-12
14mm	K2C35-14
16mm	K2C35-16
18mm	K2C35-18
20mm	K2C35-20
22mm	K2C35-22
24mm	K2C35-24
26mm	K2C35-26
28mm	K2C35-28
30mm	K2C35-30
32mm	K2C35-32
34mm	K2C35-34
36mm	K2C35-36
38mm	K2C35-38
40mm	K2C35-40
42mm	K2C35-42
44mm	K2C35-44
46mm	K2C35-46
48mm	K2C35-48
50mm	K2C35-50
55mm	K2C35-55
60mm	K2C35-60
65mm	K2C35-65

3.5mm Locking Screws

Titanium



Size	Item Number
10mm	K2L35-10
12mm	K2L35-12
14mm	K2L35-14
16mm	K2L35-16
18mm	K2L35-18
20mm	K2L35-20
22mm	K2L35-22
24mm	K2L35-24
26mm	K2L35-26
28mm	K2L35-28
30mm	K2L35-30
32mm	K2L35-32
34mm	K2L35-34
36mm	K2L35-36
38mm	K2L35-38
40mm	K2L35-40

Titanium **Components**

Continued...

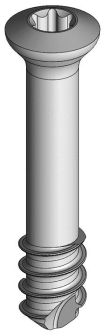
4.0mm Cannulated Partial Thread Screws

Titanium

Size	Item Number
14mm	K2UP40-14
16mm	K2UP40-16
18mm	K2UP40-18
20mm	K2UP40-20
22mm	K2UP40-22
24mm	K2UP40-24
26mm	K2UP40-26
28mm	K2UP40-28
30mm	K2UP40-30
32mm	K2UP40-32
34mm	K2UP40-34
36mm	K2UP40-36
38mm	K2UP40-38
40mm	K2UP40-40
42mm	K2UP40-42
44mm	K2UP40-44
46mm	K2UP40-46
48mm	K2UP40-48
50mm	K2UP40-50
52mm	K2UP40-52
54mm	K2UP40-54
56mm	K2UP40-56
58mm	K2UP40-58
60mm	K2UP40-60
65mm	K2UP40-65
70mm	K2UP40-70

3.5mm Partial Thread Non-Locking Screws

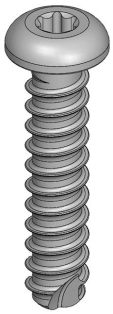
Titanium



Length	Item Number
14mm	K2CP35-14
16mm	K2CP35-16
18mm	K2CP35-18
20mm	K2CP35-20
22mm	K2CP35-22
24mm	K2CP35-24
26mm	K2CP35-26
28mm	K2CP35-28
30mm	K2CP35-30

3.5mm Cortical Screws

Titanium



Length	Item Number
14mm	MATH35-14
16mm	MATH35-16
18mm	MATH35-18
20mm	MATH35-20
22mm	MATH35-22
24mm	MATH35-24
26mm	MATH35-26
28mm	MATH35-28
30mm	MATH35-30

Stainless Steel **Components**

One-Third Tubular Plates

STAINLESS STEEL

Holes	Length	Item Number
2	24.40mm	K313-02
3	36.60mm	K313-03
5	61.00mm	K313-05
7	85.40mm	K313-07
9	109.80mm	K313-09
11	134.20mm	K313-11
13	158.60mm	K313-13

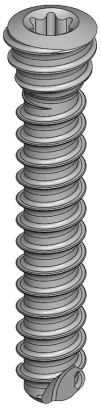
3.5mm Non-Locking Screws

STAINLESS STEEL

Size	Item Number
10mm	K3C35-10
12mm	K3C35-12
14mm	K3C35-14
16mm	K3C35-16
18mm	K3C35-18
20mm	K3C35-20
22mm	K3C35-22
24mm	K3C35-24
26mm	K3C35-26
28mm	K3C35-28
30mm	K3C35-30
32mm	K3C35-32
34mm	K3C35-34
36mm	K3C35-36
38mm	K3C35-38
40mm	K3C35-40
42mm	K3C35-42
44mm	K3C35-44
46mm	K3C35-46
48mm	K3C35-48
50mm	K3C35-50
55mm	K3C35-55
60mm	K3C35-60
65mm	K3C35-65

3.5mm Locking Screws

STAINLESS STEEL



Size	Item Number
10mm	K3L35-10
12mm	K3L35-12
14mm	K3L35-14
16mm	K3L35-16
18mm	K3L35-18
20mm	K3L35-20
22mm	K3L35-22
24mm	K3L35-24
26mm	K3L35-26
28mm	K3L35-28
30mm	K3L35-30
32mm	K3L35-32
34mm	K3L35-34
36mm	K3L35-36
38mm	K3L35-38
40mm	K3L35-40

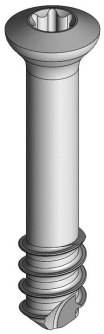
Stainless Steel **Components**

Continued…

4.0mm Cannulated Partial Thread Screws
STAINLESS STEEL

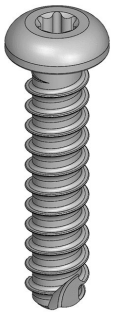
Size	Item Number
14mm	K3UP40-14
16mm	K3UP40-16
18mm	K3UP40-18
20mm	K3UP40-20
22mm	K3UP40-22
24mm	K3UP40-24
26mm	K3UP40-26
28mm	K3UP40-28
30mm	K3UP40-30
32mm	K3UP40-32
34mm	K3UP40-34
36mm	K3UP40-36
38mm	K3UP40-38
40mm	K3UP40-40
42mm	K3UP40-42
44mm	K3UP40-44
46mm	K3UP40-46
48mm	K3UP40-48
50mm	K3UP40-50
52mm	K3UP40-52
54mm	K3UP40-54
56mm	K3UP40-56
58mm	K3UP40-58
60mm	K3UP40-60
65mm	K3UP40-65
70mm	K3UP40-70

3.5mm Partial Thread Non-Locking Screws
STAINLESS STEEL



Length	Item Number
14mm	K3CP35-14
16mm	K3CP35-16
18mm	K3CP35-18
20mm	K3CP35-20
22mm	K3CP35-22
24mm	K3CP35-24
26mm	K3CP35-26
28mm	K3CP35-28
30mm	K3CP35-30

3.5mm Cortical Screws
STAINLESS STEEL



Length	Item Number
14mm	MATH35-K3-14
16mm	MATH35-K3-16
18mm	MATH35-K3-18
20mm	MATH35-K3-20
22mm	MATH35-K3-22
24mm	MATH35-K3-24
26mm	MATH35-K3-26
28mm	MATH35-K3-28
30mm	MATH35-K3-30

Instruments

Part No.	Description
B711-001	1.4mm Kwire
B711-002	1.4mm Threaded Kwire
B711-003	2.7mm Drill Bit
B711-004	2.7mm Cannulated Drill Bit
B711-005	1.4mm/2.7mm Double Drill Guide
B711-006	2.7mm Double Drill Guide
B711-007	2.7mm Static Drill Guide
B711-008	Cannulated Countersink, 2.5/3.5/4.0mm
B711-009	Depth Gauge
B711-010	Cannulated Depth Gauge
B711-011	Screw Pickups
B711-012	Screw Holding Sleeve
B711-013	T8 AO Screwdriver Shaft
B711-014	T8 AO Cannulated Screwdriver Shaft
A711-010	AO Cannulated Ratchet Handle
B711-016	1.5Nm Torque Limiting Adapter
B711-017	Cleaning Stylus
B711-018	Point to Point Clamp
B711-019	Lobster Clamp
B711-022	Screw Caddy
B711-023	Plate Caddy
B711-024	Outer Tray
B711-025	Tray Lid

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
3.5mm	10mm to 65mm	Partial or Full	2.7mm
4.0mm	14mm to 70mm	Partial	2.7mm (cannulated)

PLEASE SEE COMPLETE IFU AT WWW.ORTHONOVIS.COM/IFU

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