ORTHONOVIS
ELEVATING SURGERY™

OrthoNovis BPS Cannulated Screw Instructions for Use

For the most current instructions for use and symbol glossary visit www.orthonovis.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact cs@orthonovis.com

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Description
The OrthoNovis BPS Cannulated Screw System is a headed cannulated bone screw manufactured from titanium available in multiple diameters and lengths.

Material
6-4 Eli Titanium (ASTM F136)

Indications for use:
Bone fractures, Osteotomies, Arthrodesis, Osteochondritis, and tendon re-attachment. It is intended for but not limited to hand surgery, plastic surgery, and podiatric surgery, but is not intended for use in the spine.

Contra-indications:
1. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. Comminuted bone surface that would mitigate against screw placement.
3. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the screw.
4. Foreign body sensitivity to metals specifically titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Precautions and Handling:
- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and screws should not be used if blister or seal is damaged.
- The screws are a single use device
- Do not autoclave screws

Potential Complications and Adverse Effects:
- Allergic reactions to metal
- Delayed or Non-union of bone
- Delayed Healing
- Screws may bend or break
- Screws may extrude or back out of the surgical site

Contact surgeon if a change in performance or pain level is noticed.

MR Safety Information
The OrthoNovis BPS Cannulated Screw has been evaluated for safety and compatibility in the MR environment and is MR conditional. Contact OrthoNovis for MR parameters.

Sterile:


Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

Instructions for use:
Please note that the screw packaging features a color-coding system that coordinates screw diameter with drill diameter. Always ensure the drill diameter chosen matches the color code on the screws packaging.

1. Tightly oppose bone segments and drive the appropriately sized guide wire to the far cortex.
2. Countersink and measure in one step with the included appropriately sized depth gauge.
3. If necessary, over drill the proximal aspect of the surgical site with included, appropriately sized, drill bit.

4. Assemble the appropriate hex driver into the ratchet handle. Slide the screw over the wire and drive to depth. Ensure that the screw head seats flush into the countersunk hole created in step two, using care to not overtighten and strip the screw.

Sterilization Guidelines for Instrument Trays

These guidelines are intended to provide a better understanding of the care and handling of OrthoNovis surgical instruments. These guidelines are not intended for use with electrical, pneumatic, or other powered surgical instruments. All instruments are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use.

General Care and Handling
Use instruments only for their intended purpose, such as cutting, holding, retracting, torquing, etc. Avoid undue stress or strain when handling or cleaning. Always transport contaminated or soiled items in or on a cart. Tap water can contain many minerals that may discolor and stain surgical instruments; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting. For instruments contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning. Placing instruments in water until cleaning can prevent drying.

NOTE: Ensure that any instrument inserted into the handle is disassembled prior to cleaning.

Cleaning: Follow these steps to thoroughly clean all instruments
1. Submerge instruments in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the instruments for ten (10) minutes in the protein solubilizing detergent.
2. Scrub the submerged instruments with a soft sponge and agitate.
3. Use a pipe cleaner or brush in any lumens and crevices.
4. Rinse in warm (38-49 degree C) tap water for one (1) minute.
5. Thoroughly flush all lumens and other difficult to reach areas.
6. Ultrasonically clean the instruments for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
7. Rinse the instruments with clean tap water for at least one (1) minute, repeat twice.
8. Dry the instruments thoroughly with a clean, lint free cloth.
9. Visually Inspect instruments for any damage or remaining contaminates instruments should be visually clean.
10. Repeat cleaning procedure if necessary if contamination remains. The instrument must be thoroughly clean.
11. Contact OrthoNovis if any instruments are damaged.

Sterilization
Following the cleaning process, place a sterilization indicator in each instrument tray along with the instruments. Instrument tray is to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:
Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time

Examination Prior to Use
All instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change.
Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of the manufacturer.

Warnings and Precautions
- Devices must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Improper use may result in breakage of the instrumentation during operation.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

Orthonovis Item #	Description	GTIN
FBS18163	H2.0 Cannulated Screw 8mm	810169312391
FBS18164	H2.0 Cannulated Screw 10mm	810169312407
FBS18165	H2.0 Cannulated Screw 12mm	810169312414
FBS18166	H2.0 Cannulated Screw 14mm	810169312421
FBS18167	H2.0 Cannulated Screw 16mm	810169312438
FBS18168	H2.0 Cannulated Screw 18mm	810169312445
FBS18169	H2.0 Cannulated Screw 20mm	810169312452
FBS18170	H2.0 Cannulated Screw 22mm	810169312469
FBS18171	H2.0 Cannulated Screw 24mm	810169312476

FBS18187	H3.0 Cannulated Screw 10mm	810169312483
FBS18188	H3.0 Cannulated Screw 12mm	810169312490
FBS18189	H3.0 Cannulated Screw 14mm	810169312506
FBS18190	H3.0 Cannulated Screw 16mm	810169312513
FBS18191	H3.0 Cannulated Screw 18mm	810169312520
FBS18192	H3.0 Cannulated Screw 20mm	810169312537
FBS18193	H3.0 Cannulated Screw 22mm	810169312544
FBS18194	H3.0 Cannulated Screw 24mm	810169312551
FBS18195	H3.0 Cannulated Screw 26mm	810169312568
FBS18196	H3.0 Cannulated Screw 28mm	810169312575
FBS18197	H3.0 Cannulated Screw 30mm	810169312582
FBS18198	H3.0 Cannulated Screw 32mm	810169312599
FBS18199	H3.0 Cannulated Screw 34mm	810169312605
FBS18200	H3.0 Cannulated Screw 36mm	810169312612
FBS18201	H3.0 Cannulated Screw 38mm	810169312629
FBS18202	H3.0 Cannulated Screw 40mm	810169312636
FBS18321	H2.0 Cannulated Depth Gauge H2/H3	810169312889
FBS18323	H2.0 Cannulated Hex Driver	810169312872
FBS18324	H3.0 Cannulated Hex Driver	810169312919
FBS18329	H3.0 Cannulated Kwire 1.1mm	810169313015
FBS18330	H2.0 Cannulated Kwire 0.8mm	810169313008
FBS18333	H3.0 Cannulated Drill 2.0mm	810169312971
FBS18400	Tray - Headed Cannulated Instrument	810169313060
FBS19092	H2.0 Cannulated Drill 1.7mm	810169312964
FBS19106	H2.0 Cannulated Kwire 0.8mm STERILE	810169312858
FBS19108	H3.0 Cannulated Kwire 1.1mm STERILE	810169312896
FBS19234	H2.0 Cannulated Drill 1.7mm STERILE	810169312865
FBS19235	H3.0 Cannulated Drill 2.0mm STERILE	810169312902

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