



A TRADITION OF QUALITY AND INNOVATION

CANNULATED SCREW SYSTEMTM SURGICAL TECHNIQUE GUIDE

Cannulated Self-Drilling Lag Screws
6.5mm • 7.3mm





SURGICAL TECHNIQUE GUIDE



DANGER indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.



WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.



CAUTION used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

INDICATIONS

The **OSTEOMED** Cannulated Screw Systems are indicated for bone fixation following trauma or osteotomy. The cannulated screws and washers are intended for single use only. The system guide wires are single use instruments.

CONTRAINDICATIONS

Use of the **OSTEOMED** Cannulated Screw Systems are contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation.

WARNINGS

1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
3. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Instruments, guide wires and screws are to be treated as sharps.

CAUTIONS

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

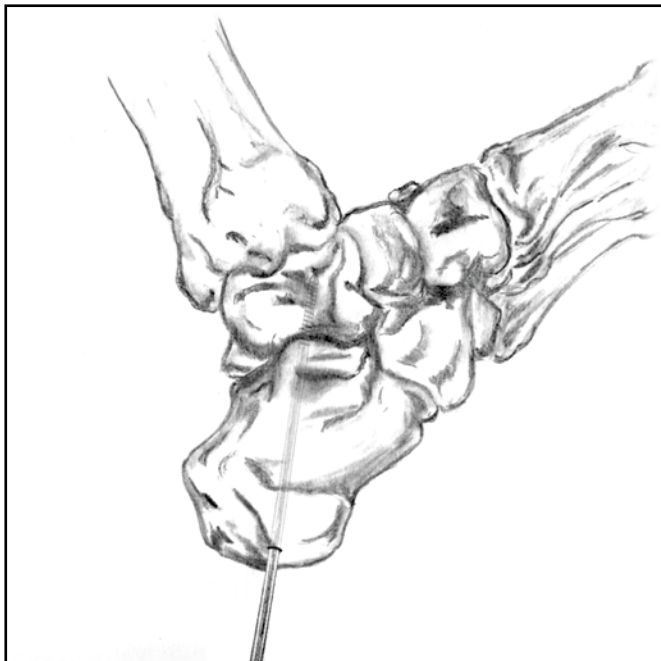
MAINTAINING DEVICE EFFECTIVENESS

1. The surgeon should have specific training, experience, and thorough familiarity with the use of cannulated screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The **OSTEOMED** Cannulated Screws are not intended to endure excessive abnormal functional stresses.
4. The **OSTEOMED** Cannulated Screws are intended for temporary fixation only until osteogenesis occurs.
5. All **OSTEOMED** Cannulated Bone Screws and instrumentation may be required for each surgery. Failure to use dedicated, unique **OSTEOMED** instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
6. Carefully inspect the **OSTEOMED** implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used. They should be replaced or sent to **OSTEOMED** for disposition and repair.
7. **OSTEOMED** recommends the use of **OSTEOMED** products in a sterile environment.

USE OF JACOB'S CHUCK IS ACCEPTABLE

OPEN APPROACH

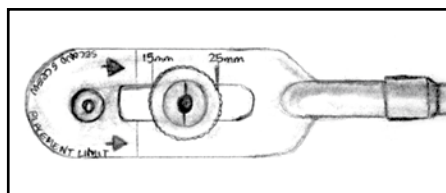
- 1 Insert the 2.8mm Guide Wire (PN 316-0023). Evaluate the placement of the guide wire with intra-operative radiographics. Proper position of the guide wire is critical for screw placement.



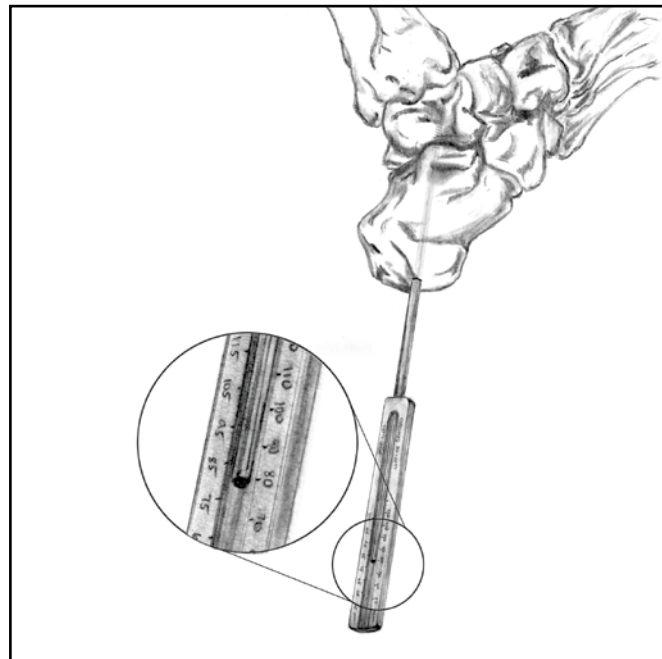
- 2 For parallel screw fixation, parallel guide wires may be placed utilizing the parallel drill guide (PN 316-0018). Place the parallel drill guide over the initial guide pin and rotate it to the desired orientation.

- A) If only a second wire is to be placed: the guide allows a second wire to be placed 8mm away from the first.
- B) If dual screws are to be placed: the guide wires for parallel screw placement should be placed **at least 10mm** apart to eliminate interference between the screw heads (see laser marking on Parallel Drill Guide, PN 316-0018).

NOTE: To avoid screw interference, adjustable arm should be placed past the lasermark.

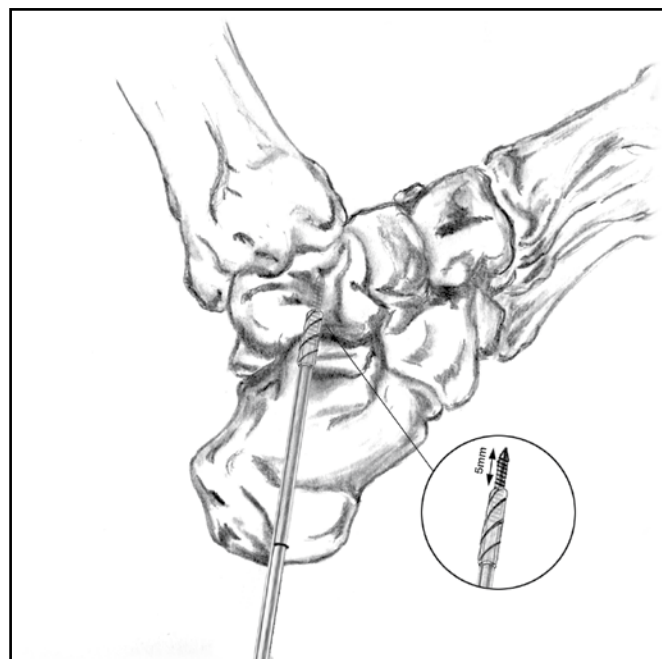


- 3 Place the Depth Gauge (PN 316-0017) over the guide wire, directly against the cortex to ensure accurate measurement.



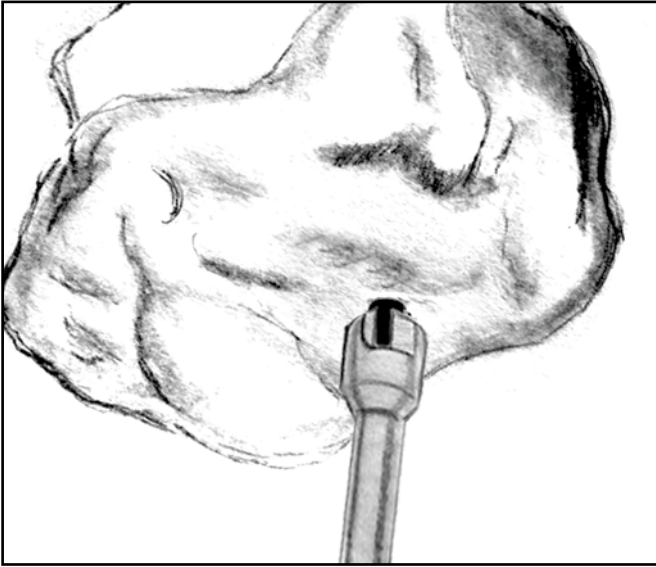
Optional*:

Drilling: If drilling is deemed clinically appropriate, place the calibrated cannulated drill (PN 316-0016) over the guide wire and advance the drill 5mm short of the end of the guide wire. The cannulated drill is calibrated in 10mm increments for reference.



Tapping: If tapping is deemed clinically appropriate, place the cannulated tap over the guide wire and advance.

- 4 Place the cannulated countersink (PN 316-0020) over the guide wire and create a recess in the bone to seat the head of the screw. (Head height = 4 mm)

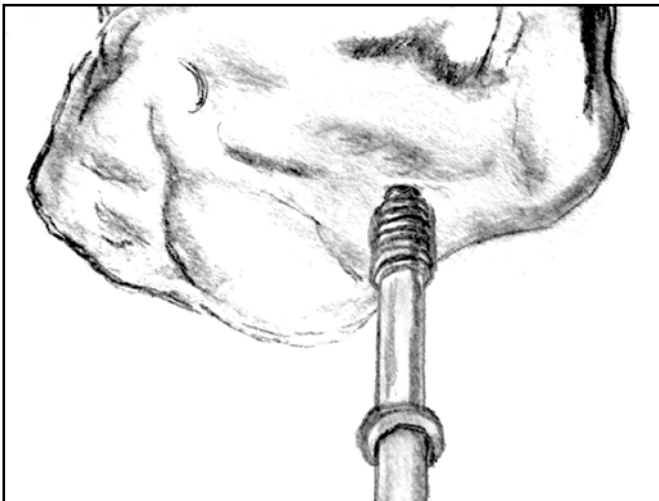


NOTE: Overall screw lengths of the 6.5mm and 7.3mm Cannulated Screws are measured from the top of the head to the tip of the screw. The head height (4mm) should be considered when countersinking.

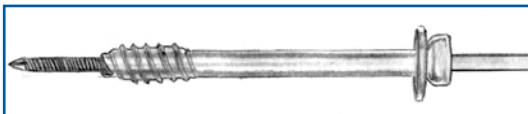
- 5 Verify screw length using screw length gauge.
- 6 Place the appropriate screw over the guide wire.



- 7 Drive the screw.



Optional: If deemed clinically appropriate, place a washer over the guide wire prior to placing the screw.



CAUTION

* OsteoMed's 6.5mm/7.3mm Cannulated Screws can be inserted over the guide pin without predrilling or pretapping. In dense bone, however, predrilling and pretapping are recommended to facilitate screw insertion.

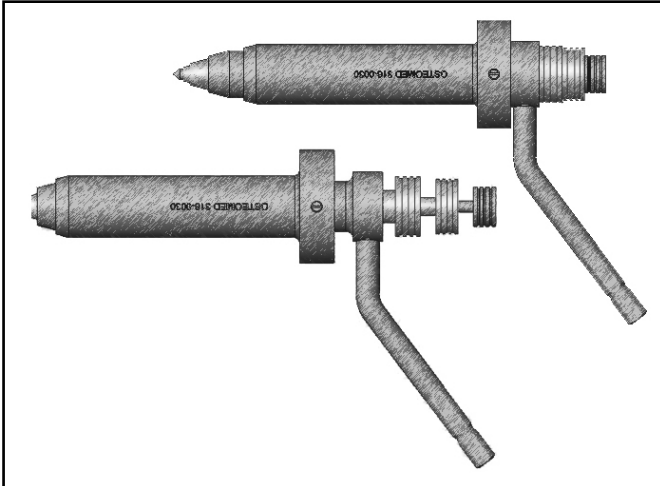
SCREW EXTRACTION

Screw extraction should be performed with the cannulated driver shaft manually. If complications arise during screw extraction, the screw can be removed with the Cannulated Screw Extractor (PN 316-0024). The screw extractor is turned counterclockwise into the cannulation of the screw. The screw extractor will thread into the inner wall of the screw and become bound within the cannulation. When the screw extractor has become bound within the screw, continue to turn the screw extractor counterclockwise to facilitate removal.

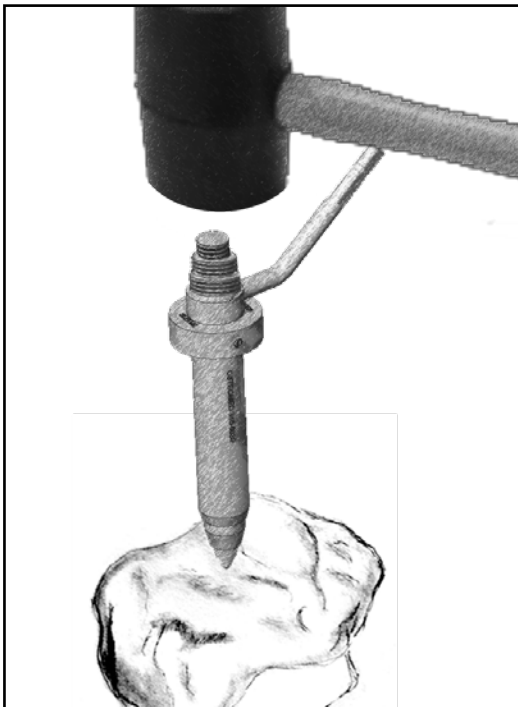
USE OF JACOB'S CHUCK IS ACCEPTABLE

PERCUTANEOUS APPROACH

- 1 Assemble percutaneous screw sleeve assembly. Place trocar tip through skin incision, directly in contact with bone.



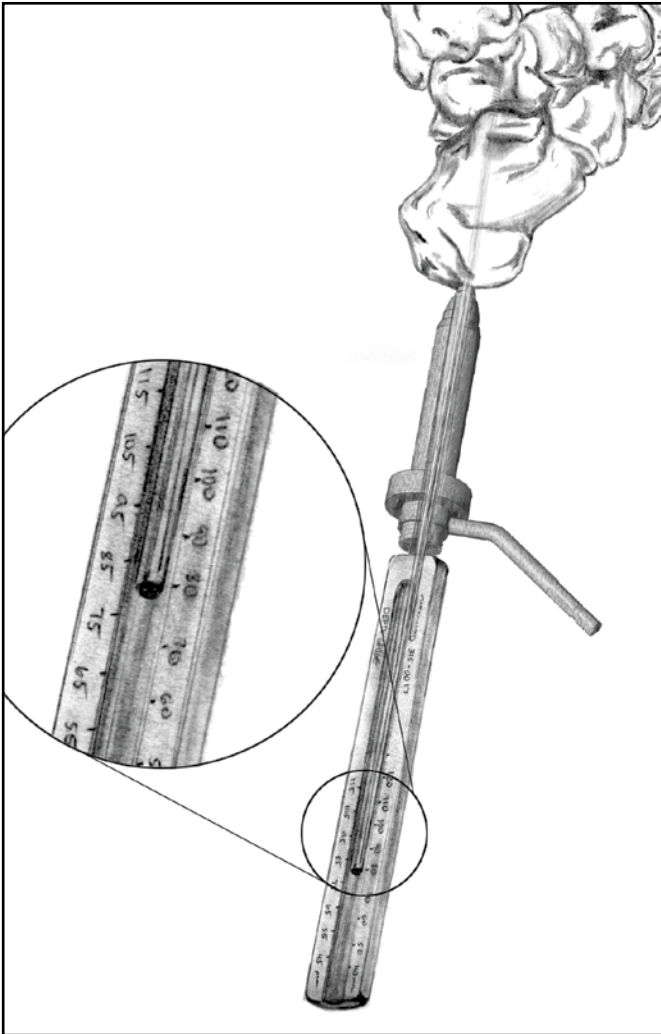
- 2 Tap the 2.8mm trocar with a mallet to dimple the bone.



- 3 Remove the 2.8mm trocar and advance the guide pin into the bone through the guide pin sleeve. Evaluate the placement of the guide wire with intra-operative radiographics. Proper position of the guide wire is critical for screw placement.

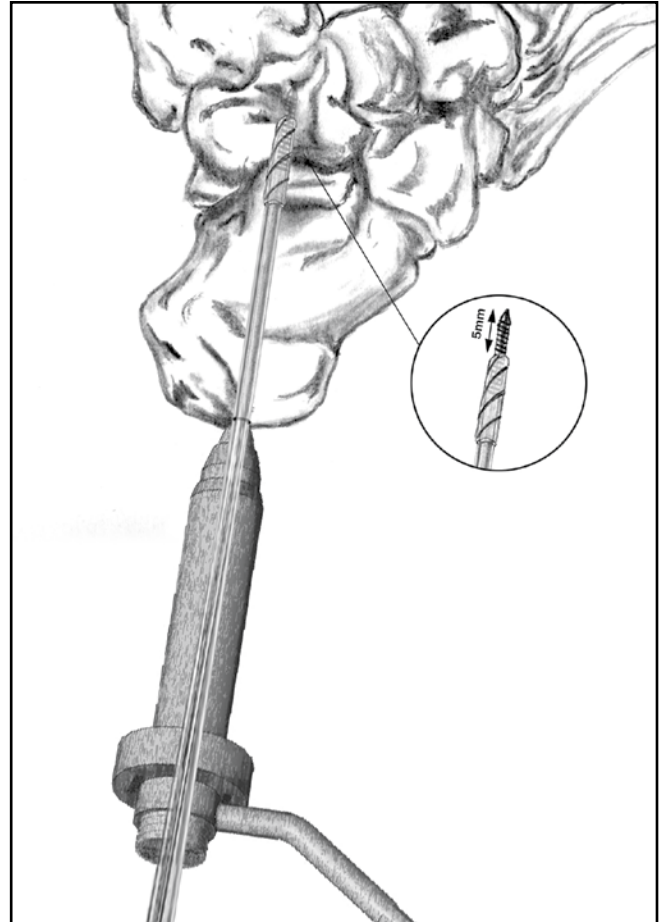


- 4 Remove the guide wire sleeve and introduce the depth gauge over the guide wire through the drill sleeve. Place the depth gauge directly against the cortex to ensure a correct screw length reading.



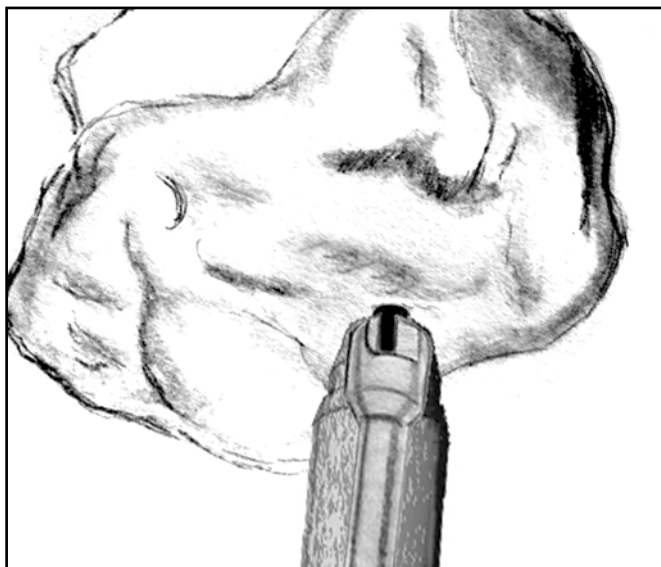
5 **Optional*:**

Drilling: If drilling is deemed clinically appropriate, place the cannulated drill through the drill sleeve and advance 5mm short of the end of the guide wire. The cannulated drill is calibrated in 10mm increments for reference. Remove the drill sleeve.



Tapping: If tapping is deemed clinically appropriate, place the cannulated tap through the screw sleeve and advance.

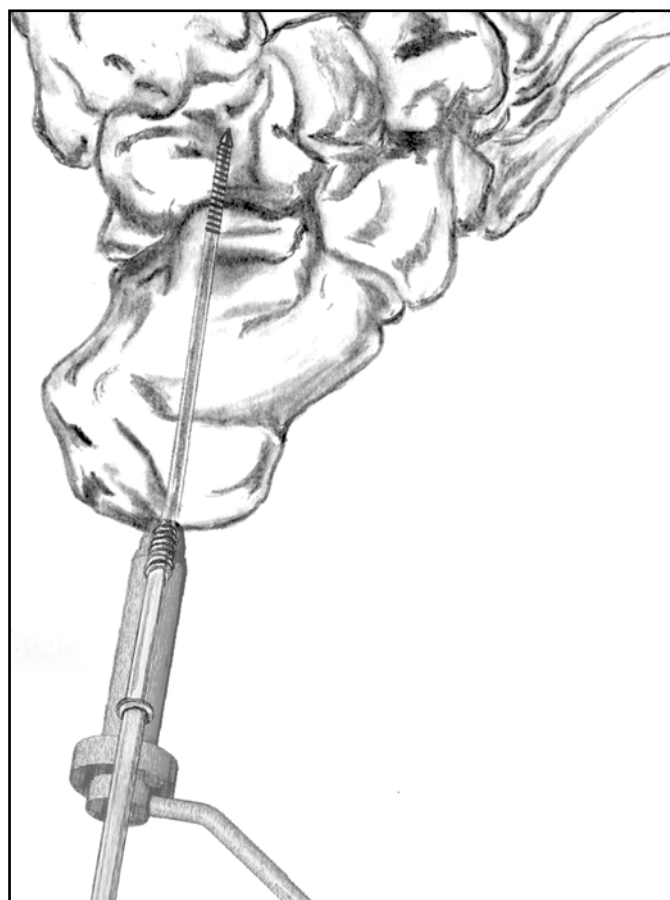
- 6 Place the cannulated countersink over the guide wire and through the screw sleeve to create a recess in the bone to seat the head of the screw. (Head height = 4 mm)



NOTE: Overall screw lengths of the 6.5mm and 7.3mm Cannulated Screws are measured from the top of the head to the tip of the screw. The head height (4mm) should be considered when countersinking.

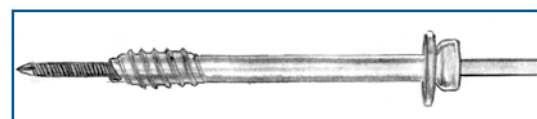
- 7 Verify screw length using screw length gauge.

- 8 Place the appropriate screw over the guide wire through the screw sleeve, the screwdriver stem is used to advance the screw manually or via a Jacob's chuck.



- 9 Drive the screw.

Optional: If deemed clinically appropriate, place a washer over the guide wire prior to placing the screw.



CAUTION

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SCREW EXTRACTION

Screw extraction should be performed with the cannulated driver shaft manually. If complications arise during screw extraction, the screw can be removed with the Cannulated Screw Extractor (PN 316-0024). The screw extractor is turned counterclockwise into the cannulation of the screw. The screw extractor will thread into the inner wall of the screw and become bound within the cannulation. When the screw extractor has become bound within the screw, continue to turn the screw extractor counterclockwise to facilitate removal.

INSTRUMENTS



316-0023 Partially Threaded Guide Wire, 2.8mm X 300mm



316-0019 Cannulated Tap for 6.5mm Screws



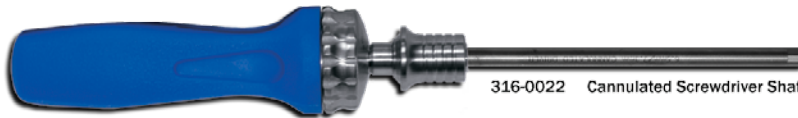
316-0031 Cannulated Tap for 7.3mm Screws



316-0016 Cannulated Drill, 6.5mm / 7.3mm



316-0017 Depth Gauge, 6.5mm / 7.3mm



316-0022 Cannulated Screwdriver Shaft, 6.5mm / 7.3mm

316-0021 Cannulated Non-slip Screwdriver Body, 6.5mm / 7.3mm

316-0032 Ratchet Cannulated Screwdriver Body, 6.5mm / 7.3mm



316-0024
Screw Extractor



316-0020 Cannulated Countersink, 6.5mm / 7.3mm

316-0021 Cannulated Non-slip Screwdriver Body, 6.5mm / 7.3mm

316-0032 Ratchet Cannulated Screwdriver Body, 6.5mm / 7.3mm



316-0018
Adjustable Parallel Drill Guide, 6.5mm / 7.3mm

316-0021 Cannulated Non-slip Screwdriver Body, 6.5mm / 7.3mm



316-0026 Trocar, 2.8mm



316-0027 Guide Pin Sleeve, 6.5mm / 7.3mm



316-0028 Drill Sleeve, 6.5mm / 7.3 mm



316-0030
Washer Sleeve, 6.5mm / 7.3mm



316-0021 Cannulated Non-slip Screwdriver Body, 6.5mm / 7.3mm

316-0029
Screw Sleeve, 6.5mm / 7.3mm



316-0025
Washers for 6.5mm/7.3mm Screws



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