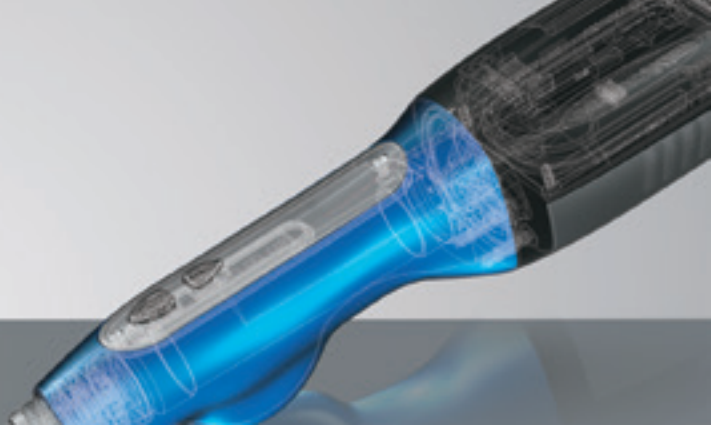


PINNACLE FAQ

Frequently Asked Questions



How do I access the battery?

After removing the plastic tray from the black shelf box, use the “Peel Here” corner to remove the Tyvek® lid. Bend back the ribbed corner of the tray with one hand and pull back the corresponding corner of the plastic lid slowly. The sterile battery will now be accessible.

How do I insert the battery?

Align the battery contacts and dovetail slots of the battery with the mating dovetail boss on the hand piece. Fully insert the battery until an audible snap is heard and the battery adjoins the battery contact face of the hand piece. At battery insertion, the mode button will illuminate **green**, and the hand piece will be ready to use.

What if the mode button fails to illuminate when the battery is inserted?

Pull the battery off and reinsert, making sure the battery dovetail slots are correctly aligned with the mating bosses and battery contacts are connected. If the button still fails to illuminate, remove the battery and replace with a new, unused battery and repeat insertion. If the driver continues to fail to respond, contact your local OsteoMed representative.

What if the mode button flashes red after the battery is inserted?

If the mode button immediately illuminates a flashing red, remove the battery and replace with a new, unused battery and repeat battery insertion. If the mode button again illuminates a flashing red, this indicates the device is in a FAULT mode. Immediately contact your local OsteoMed representative.

Can the Pinnacle accessories be loaded prior to inserting the battery?

Yes. The driver is fully operational regardless of the order in which the OsteoMed Hex Shank accessories and battery are loaded.

What accessories are compatible with the Pinnacle?

All OsteoMed Hex Shank attachment twist drills and driver stems are compatible with the Pinnacle Driver.

How do I load an accessory?

After selecting the appropriate size driver stem or twist drill, pull the collet towards the hand piece, insert the accessory, rotate the hex shank until aligned with the mating feature inside the collet, and then fully seat it in the collet. Release the collet to allow it to spring forward into a locked position, and ensure the driver stem or twist drill is properly captured by gently pulling the accessory away from the collet.

How do I remove an accessory?

To remove a driver stem or twist drill, pull the collet towards the hand piece and remove the accessory from the collet.

How do I load a screw onto the driver stem?

Select the desired screw and confirm the loaded driver stem is compatible. Align the driver stem tip with the screw head cruciform and push down to engage the screw.

How do I drive a screw?

With the mode button illuminated **green** (in drive mode), position the screw and press the forward drive button. The Pinnacle Driver will rapidly insert the screw and the torque limiting software will halt motor operation when the screw is fully seated.

What if the motor stops before the screw is fully seated?

Hold the reverse button to remove the screw, before placing the screw back in the desired location and pressing the forward button. If the motor again stops before the screw is fully seated, the software may be reacting to the bone density. Use a manual screwdriver to finish seating the screw.

What if the motor stops before a bi-cortical screw is fully seated?

When driving bi-cortical screws, the torque limiting software may prevent full insertion of the screw as the screw tip approaches the second cortical layer. In this situation, after the motor operation delay concludes, the Pinnacle Driver can be used to then fully seat the screw.

Can the Pinnacle Driver remove screws?

Yes. To remove screws, engage the driver stem tip with the screw head cruciform and push the reverse button. If the screw does not reverse, help initiate screw removal by manually rotating the hand piece counter-clockwise while holding down the reverse button.

What screws are compatible with the Pinnacle Driver?

The Pinnacle software is optimized for driving OsteoMed 1.6mm standard and autodriven screws in lengths from 4mm to 6mm. The software is also capable of driving OsteoMed 2.0mm standard screws in lengths from 5mm to 18mm, and 1.2mm screws in lengths from 4mm to 6mm.

How do I switch the Pinnacle Driver to Drill Mode? Then back to Drive Mode?

To switch from drive to drill mode, press and hold the center of the mode button for at least 2 seconds until the mode button illuminates **blue**, indicating drill mode. To return to drive mode, repeat the process by holding down the mode button for at least 2 seconds until the button illuminates **green**. Or pull the battery off the driver, wait at least 4 seconds and re-insert the battery.

What is the best way to drill pilot holes with the Pinnacle Driver?

Position the drill in the desired location and push the forward button. The Pinnacle Driver will rapidly activate the drill. Use a "pick & peck" technique by slowly advancing the drill bit, and then pulling it back out of the bone to allow bone fragments to be removed, preventing jamming or breaking of the drill. Use irrigation if necessary in dense bone. Continue until the desired pilot hole depth is achieved.

When drilling a pilot hole, the motor stopped. What do I do?

The Pinnacle Driver is most likely still in drive mode. Check the back mode button to ensure it is illuminated **blue**. If the button is illuminated **green**, the torque-limiting software is still engaged and causing the motor to halt. Press and hold the center of the mode button for at least 2 seconds until the mode button illuminates **blue**, indicating drill mode.

How can the Pinnacle Driver be sterilized?

The Pinnacle Driver and accessories are provided non-sterile and can be sterilized by steam sterilization/autoclaving contained in the single driver case (110-1011) or double driver case (110-1012) within an Aesculap container, or wrapped separately. For full sterilization requirements refer to the Surgical Technique Guide.

Are the batteries resterilizable/reusable?

No. The batteries come sterile packaged, and should be disposed of following each use.

Can the Pinnacle Driver be completely submerged?

Do not immerse the Pinnacle Driver in any solution. Immersing will render the device inoperable.

Does the Pinnacle have a clutch?

No. The Pinnacle Driver features OsteoMed's torque-limiting software. Programmed based on an exhaustive OsteoMed screw characterization, the software recognizes the torque curve of the screw type and length that is being driven into bone and automatically stops once the screw is fully seated.

Is the Pinnacle Driver cleared by the FDA for use?

Yes. The Pinnacle Driver is 510(k) cleared by the FDA.