

PINNACLE TECH






Technical Specification Sheet



The OsteoMed Pinnacle Driver is a handheld, cordless, software driven, battery operated driver for high speed insertion of screws and drilling pilot holes.

Performance Rating:

- Seats 1.6mm x 4mm OsteoMed Neuro screws in less than one second
- Driver weighs less than one pound

		RPM
Forward 		2,000 +/- 10 RPMs
Reverse 		275 +/- 10 RPMs

Smart Software:

Pinnacle's torque limiting software is optimized to seat the following OsteoMed screws:

Diameter	Length	Screw Type
1.2mm	4mm - 6mm	AutoDrive
1.6mm	4mm - 6mm	Standard & AutoDrive
2.0mm	5mm - 18mm	Standard

*contraindicated for use in poor bone quality

Accessories:

Only OsteoMed Hex Shank attachment accessories

- Driver Stems (114-xxxx)
- Twist Drills (111-xxxx)

Chemistry:

Lithium Nickel Cobalt Oxide

Operating Conditions:

- Temperatures between 50°F - 95°F
- Relative humidity non-condensing between 30% - 75%
- Only operate at altitudes below 3000m
- For indoor use only

Batteries:

- Single-use / Disposable
- Sterile Packed
- Available in two configurations:
 - o Single: 110-1000-SP (qty 1)
 - o Double: 110-1000-02-SP (qty. 2)



Modes:

DRIVE – Green



DRILL – Blue



FAULT – flashing Red



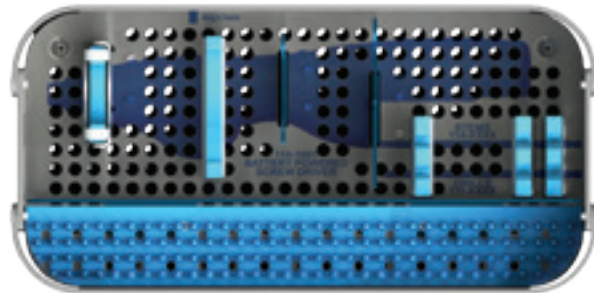
510(k) Cleared System

Pre-Vacuum Steam Sterilization

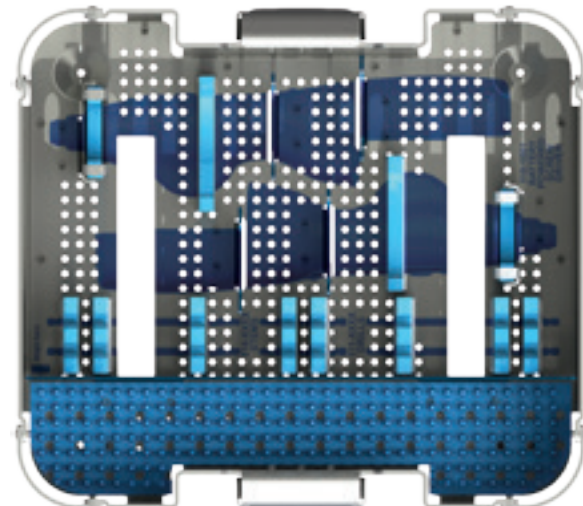
Sterilization Case:	Hand piece Only (No Case)	1-Driver Case (110-1011)	2-Driver Case (110-1012)
Minimum Temperature:	270° F (132° C)	270° F (132° C)	
Cycle	4 minutes	4 minutes	
Minimum Dry Time:	30 minutes	30 minutes	
Minimum Open Door Time:	N/A	N/A	
Minimum Cool-Down Time:	N/A	N/A	
Configuration	Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques.	Unwrapped using a rigid sterilization container (Aesculap – 510(k) K053389 or equivalent)	
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.			
Note: Biological indicator of <i>G. stearotherophilus</i> was used in sterilization validation.			
Note: If the specified wrap is not available, only FDA cleared wraps should be used to wrap the subject device.			



110-1001 Pinnacle Battery Powered Screw Driver



110-1011 – Pinnacle Sterilization Tray, 1BPS



110-1012 – Pinnacle Sterilization Tray, 2BPS

510(k) Cleared System