

**“Invictus® Spinal Fixation System
Power T Handle, Sterile”**

Battery Powered Driver



PN 17099-S

INS-150A

Intended Use

The Power T Handle® is a single-use battery powered driver intended for using during surgical procedures to power various orthopedic accessories or attachments. The Power T Handle is also intended for use as a non-powered hand-held device for manual use with orthopedic instruments.

Principle of Operation

The Power T Handle® motor is powered by 2 lithium metal-oxide batteries, 4.0 volts each. The batteries are located in the grip portion of the driver. The motor and reducing gears are located in the body of the driver. The output shaft connects to orthopedic accessories through a standard ¼ inch square connection. There is an automatic output shaft locking component that allows the driver to also function as a manual T handle.

Caution

- Federal law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- If package is damaged or open, do not use product.
- Read all instructions prior to use.
- Do not submerge handle in liquid as this may compromise the battery and motor for the driver.

Warning

- This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
- Device is not intended to be modified, serviced, or repaired.
- Do not use in an oxygen-enriched atmosphere.
- Do not incinerate the batteries as this can cause a risk to the environment.
- Do not recharge batteries, put in backwards, or mix with used or other battery types as these actions may cause explosion or leakage leading to personal injury or can cause a risk to the environment.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- Follow Occupation Safety and Health Administration (OSHA) standards or Universal Precautions for blood borne pathogens.
- In order to limit contact with infectious agents from splashing personnel using the device or patient exposed to the Power T Handle must wear personal protective equipment.
- If device becomes objectionably warm during normal operation, discontinue use of device.
- Soft tissue contact with rotating output shaft should be avoided to prevent soft tissue damage.

Operating Conditions

Operating Temperature: 10 degrees C to 40 degrees C

Relative Humidity: 30% to 75% (non-condensing)

Atmospheric Pressure Range: 70kPa - 106kPa

Manufactured By:

Power T Handle, LLC
610 Ocean Hwy W
Supply, NC 28462

Customer SVC: 833-4HANDLE
FAX: 833-4HANDLE
INFO@POWERHANDLE.COM

Distributed By:

ALPHATEC SPINE, INC
1950 Camino Vida Roble
Carlsbad, CA 92008 USA
(760) 431-9286
(800) 922-1356
www.atecspine.com

Operating Instructions

Always review the instructions for use and caution/warning notices. The surgeon should be thoroughly familiar with the proper operation of the power surgical instruments and accessories prior to use. Inspect package prior to use for signs of damage or tampering.

STEP 1: Open the package

The circulating nurse opens the package and delivers the contents onto the sterile field.

STEP 2: Remove the pull tab

Remove the white tab by firmly pulling the tab out of the device. Discard the pull tab.

STEP 3: Install orthopedic instrument

Pull back on the sliding collar on the Power T Handle® output shaft. Align the orthopedic instrument with the shaft so that the corners of the ¼ square end of the attachment line up with the notches on the driver shaft. Insert the orthopedic instrument into the shaft. Release the sliding collar. Sliding collar should return to the starting position. If it does not return fully, the instrument is not fully inserted into the shaft. Check for correct engagement of the orthopedic instrument by pulling it slightly.

STEP 4: For power forward / reverse operation

Select forward ("F") or reverse ("R") on the black switch. Then press and hold the red power button. Rotation in the direction selected on the black switch will continue until the red power button is released or maximum stall torque is produced. This is a non-continuous device with maximum operating time of 15s and a minimum duty off time of 30s.

STEP 5: For manual forward/reverse operation

Grasp the handle of the Power T Handle and turn the entire driver in the forward or reverse direction.

STEP 6: Remove orthopedic instrument

Pull the sliding black collar fully back and remove the instrument from the shaft.

AFTER USE: Battery Removal and Disposal

The batteries, which power the product, may be disposed of separately by unscrewing the six screws (T6) on the undersurface of the driver. The batteries can then be manually removed from the battery clips. Disposal should be done in accordance with applicable regulations, which vary from country to country. Batteries should not be incinerated. Batteries for disposal should be collected, transported, and disposed of in a manner that will prevent short-circuit (terminals taped). Recycling of the batteries should be done in authorized facilities.

Storage Conditions

Ambient temperature out of direct sunlight (10 degrees C to 40 degrees C)

Expiration date of product is printed on the shelf box label and tray label for each unit.

Symbols and Definitions

	Type B Applied Part		Keep Dry
	Sterile, method of sterilization using irradiation		Do not use if sterile package is damaged
	Catalog number		Consult instructions for use
	Use by (Date)		Operating Temperature 10°C 40°C
	Single Use Only		Not made with natural rubber
	Manufacturer		Storage Temperature 10°C 40°C

EMC ACCOMPANYING DOCUMENT

The Power T Handle® (PTH) requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PTH, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

1	Guidance and manufacturer's declaration – electromagnetic emissions		
2	The PTH is intended for use in the electromagnetic environment specified below. The customer or the user of the PTH should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The PTH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
6	RF emissions CISPR 11	Class A	The PTH is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PTH is intended for use in the electromagnetic environment specified below. The customer or the user of the PTH should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 15kV air	+8kV contact + 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PTH is intended for use in the electromagnetic environment specified below. The customer or the user of the PTH should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PTH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = [3.5/3] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [7/3] \sqrt{P} \text{ 800 MHz to 2.7 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PTH is used exceeds the applicable RF compliance level above, the PTH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PTH.

Guidance and manufacturer's declaration – electromagnetic immunity

The PTH is intended for use in the electromagnetic environment specified below. The customer or the user of the PTH should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PTH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = [3.5/3] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [7/3] \sqrt{P} \text{ 800 MHz to 2.7 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PTH is used exceeds the applicable RF compliance level above, the PTH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PTH.

Guidance and manufacturer's declaration – electromagnetic immunity

The PTH is intended for use in the electromagnetic environment specified below. The customer or the user of the PTH should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	<p>MHz – Modulation – Field Strength</p> <p>385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m</p>	<p>MHz – Modulation – Field Strength</p> <p>385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PTH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment as well as mobile RF communications equipment and PTH

The PTH is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PTH can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PTH as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter (m)
----------------------	---

power of transmitter (W)	80 to 800 MHz $d = [3.5/3] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 $d = [6/9] \sqrt{P}$	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 $d = [6/28] \sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.167	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.