Invictus® Power T Handle
INSTRUCTIONS FOR USE

INDICATIONS FOR USE
The Invictus Power T Handle is a single-use battery powered driver intended for use during surgical procedures to power various orthopedic accessories or attachments. The Invictus 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 Invictus 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.

WARNINGS/CAUTIONS/PRECAUTIONS:
1. 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.
2. 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.
3. Device is not intended to be modified, serviced, or repaired.
4. Do not use in an oxygen-enriched atmosphere.
5. Do not incinerate the batteries as this can cause a risk to the environment.
6. 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.
7. 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.
8. Follow Occupation Safety and Health Administration (OSHA) standards or Universal Precautions for blood borne pathogens.
9. In order to limit contact with infectious agents from splashing, personnel using or patient exposed to the Invictus Power T Handle must wear personal protective equipment.
10. If device becomes objectionably warm during normal operation, discontinue use of device.
11. Soft tissue contact with rotating output shaft should be avoided to prevent soft tissue damage.
12. Federal law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
13. If package is damaged or open, do not use product.
14. Read all instructions prior to use.
15. Do not submerge handle in liquid as this may compromise the battery and motor for the driver.
16. Power T Handle operates at a continuous amperage which does not allow for speed control and is not torque-limiting. Do not use Power T Handle with torque-sensitive devices.

OPERATING CONDITIONS:

- Operating Temperature: 10 degrees C to 40 degrees C
- Relative Humidity: 30% to 75% (Non-condensing)
- Atmospheric Pressure Range: 70kPa - 106kPa

PREOPERATIVE/ INTRAOPERATIVE MANAGEMENT:

1. Always review the instructions for use and caution/warning notices.
2. The surgeon should be thoroughly familiar with the proper operation of the power surgical instruments and accessories prior to use.
3. Inspect package prior to use for signs of damage or tampering.
4. The circulating nurse opens the package and delivers the contents onto the sterile field.
5. Remove the white tab by firmly pulling the tab out of the device. Discard the pull tab.
6. Pull back on the sliding collar on the Invictus 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.
7. Check for correct engagement of the orthopedic instrument by pulling it slightly.
8. 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 noncontinuous device with maximum operating time of 15s and a minimum duty off time of 30s.
9. Grasp the handle of the Invictus Power T Handle and turn the entire driver in the forward or reverse direction.
10. Pull the sliding black collar fully back and remove the instrument from the shaft.

POSTOPERATIVE MANAGEMENT:

Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.

1. The batteries, which power the product, may be disposed of separately by unscrewing the six screws (T6) on the undersurface of the driver.
2. The batteries can then be manually removed from the battery clips.
3. Disposal should be done in accordance with applicable regulations, which vary from country to country.
4. Batteries should not be incinerated.
5. Batteries for disposal should be collected, transported, and disposed of in a manner that will prevent short-circuit (terminals taped).
6. 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.

INSPECTION:

- Inspect each instrument, container, and tray to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.

- Drill bits, reamers, rasps, and other cutting instruments should be inspected after processing with alkaline detergents.
- Inspect instruments for any other damage, wear, and/or corrosion.

ELECTROMAGNETIC COMPATIBILITY:

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**	**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.** **Recommended separation distance:** **d = [3.5/3] √P 80 MHz to 800 MHz** **d = [7/3] √P 800 MHz to 2.7 GHz** **where P is the maximum output power rating of the transmitter in wats (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:** 
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 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	MHz – Modulation – Field Strength 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	MHz – Modulation – Field Strength 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	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. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in wats (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: 
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 power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	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 wats (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 from structures, objects, and people.

The Invictus 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 the below tables.

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.**

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**	**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.** **Recommended separation distance** **d = [3.5/3] √P 80 MHz to 800 MHz** **d = [7/3] √P 800 MHz to 2.7 GHz** **where P is the maximum output power rating of the transmitter in wats (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:** 
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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.			

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

UDI CONSTRUCTION

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING / REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@atecspine.com.

For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc., Customer Service directly at customerservice@atecspine.com.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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