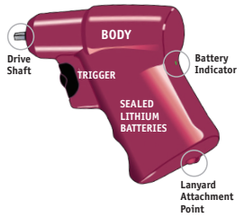
FOLD

ARROW® EZ-IO®
INTRAOSSEOUS VASCULAR ACCESS

ARROW® EZ-IO®
INTRAOSSEOUS VASCULAR ACCESS

PRODUCT INFORMATION



DESCRIPTION:
- The EZ-IO® Power Driver is a sealed, hand-held, lithium battery powered medical device.

PRODUCT INFORMATION:
- Driver Ref. numbers: 9040 (Tactical); 9058 (Civilian); 9059 (Training).
- Applied Parts: EZ-IO® Intraosseous Vascular Access Needles – 15 mm; 25 mm; 45 mm.

SAFETY INFORMATION:
- Indications, contraindications, warnings, precautions, and other safety information are contained in the Instructions for Use for the EZ-IO® Intraosseous Vascular Access System.
- Please consult the Instructions for Use for the EZ-IO® Intraosseous Vascular Access System before applying. If there are questions, or if this information sheet is missing, immediately contact your local Teleflex sales representative.
- Additional product information can be found at EZ-IOaccess.com.
- As with any emergency medical device carrying a backup is a strongly advised protocol.

IMPORTANT INFORMATION FOR USERS:

In order for EZ-IO® Intraosseous Vascular Access System products to perform properly, the following conditions are recommended. Failure to comply with these conditions will void any applicable warranties.
- Use this product only in accordance with this manual and applicable product labeling.
- Adjustments, modifications, technical maintenance or repairs are not allowed.
- Do not connect this product or its components to products not recommended by Teleflex.
- Use only EZ-IO® Intraosseous Vascular Access needle sets with this product.
- Visually inspect driver for cracks and sharp corners before use.
- Avoid spilling fluids on any part of this product.
- Do not use excessive force during insertion. Let the EZ-IO® Power Driver do the work.

STORAGE:
- The EZ-IO® Power Driver and accessories may be stored at temperatures between -20°C to 50°C (-4°F to 122°F).
- Expected shelf life for the EZ-IO® Power Driver is 10 years or approximately 500 insertions.
- Life expectancy is dependent on actual usage (bone density and average insertion time), storage, and frequency of testing.
- When storing the Vascular Access Pak (VAP) remove the trigger guard to prevent accidental activation of the EZ-IO® Power Driver.

BATTERY INFORMATION:
- Drivers are sealed and not intended to be opened.
- Batteries are not replaceable.

INDICATORS & ALERTS:
- EZ-IO® Power Driver LED will be solid green when trigger is activated and has sufficient power.
- EZ-IO® Power Driver LED will blink red when the trigger is activated and has only 10% of battery life remaining.
- Purchase and replace the EZ-IO® Power Driver when the red LED begins blinking.

CARE AND CLEANING:
1. Maintain BSI or PPE precautions.
2. Wipe entire exterior surface of EZ-IO® Power Driver with soft, clean moistened cloth. Use soft bristled brush to remove any visible soil.
3. Spray exterior surface with anti-microbial solution following the solution manufacturer's specific recommendations.
4. Gently wipe exterior surfaces with gauze pads until visible debris is removed.
5. Clean and manipulate trigger using cloth moistened with anti-microbial solution.
6. Using sterile swabs, moisten with anti-microbial solution, gently clean inside opening around metal drive shaft.
7. After cleaning, inspect to ensure no visible debris remains, and no damage has occurred.
8. Dry driver with a soft, clean cloth and return to appropriate location.

Do not immerse or use excessive amount of liquid when performing cleaning and disinfecting. In the unlikely event of a driver failure, remove the EZ-IO® Power Driver, grasp the needle set by hand, and advance the needle set into the medullary space while twisting the needle set.

If your clinical environment requires sterilization, the EZ-IO® Power Driver can be sterilized using the STERRAD® 100S System, NX® System, and 100NX® System. STERRAD® Systems are products of ©ADVANCED STERILIZATION PRODUCTS, Division of Ethicon Inc., a Johnson & Johnson company.

WARNING: No modification of this equipment is allowed.

FOLD

FOLD

EZIOaccess.com

EMERGENCY NUMBER:

1.800.680.4911

Teleflex®

Customer Service: 1.866.479.8500

EC REP
European Authorized Representative Service

VIDACARE LLC
4350 Lockhill Selma Road, Suite 150
Shavano Park, TX 78249
United States

EMERGO EUROPE
Molenstrat 15
2513 BH, The Hague
Netherlands

AUSTRALIAN SPONSOR
Emergo Australia
Level 20, Tower II Darling Park
201 Sussex Street
Sydney NSW 2000
Australia

At the completion of the Power Driver's service life, proper disposal is the responsibility of the institution or service (directive 2012/19/EU).

4001639

Rx ONLY This device is restricted for sale by or on order of a physician.

SN Serial Number

Degree of protection against electric shock BF Applied part.

CE 0086 The System Conforms to the Medical Device Directive (93/42/EEC)

Consult Instructions For Use

8047 Rev D (07/2014)

FOLD

FOLD

ARROW® EZ-IO®
INTRAOSSEOUS VASCULAR ACCESS

EZ-IO® POWER DRIVER

Instructions for Use

Teleflex

FOLD

FOLD

Declaration-Electromagnetic Emissions

The EZ-IO® Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the EZ-IO® Power Driver should assure that it is issued in such an environment.

Emission Test	Compliance	Compliance
RF Emissions CISPR 11	**Group 1**	The EZ-IO® Power Driver uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	**Class B**	The EZ-IO® Power Driver 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.
Harmonic emissions IEC 61000-3-2	**Not applicable**	
Voltage fluctuations/flicker emissions IEC 61000-3-3	**Not applicable**	

Declarations – Electromagnetic Immunity

The EZ-IO® Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the EZ-IO® Power Driver should assure that it is issued in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV Contact +/- 8 kV air	+/- 6 kV Contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input. output lines	Not applicable (battery powered) Not applicable (no I/O lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	Not applicable (battery powered)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% Ur (>95% dip in Ur) for 0.5 cycles 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (95% dip in Ur) for 5 sec	Not applicable (battery powered)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EZ-IO® Power Driver requires continued operation during power mains interruptions, it is recommended that the power driver be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in typical commercial or hospital enviroment.

NOTE: Ur is the a.c. mains voltage prior to application of the test level.

FOLD

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

The EZ-IO® Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the EZ-IO® Power Driver should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Not applicable (battery powered) 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the driver including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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, *a* should be less than the compliance level in each frequency range.*b* 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.

a 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 EZ-IO® Power Driver is used exceeds the applicable RF compliance level above, the EZ-IO® Power Driver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EZ-IO® Power Driver. *b* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

FOLD

Recommended separation distances between portable and mobile RF communications equipment and the EZ-IO® Power Driver

The EZ-IO® Power Driver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EZ-IO® Power Driver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EZ-IO® Power Driver 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		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
.01	0.12	0.12	0.23
.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service accordingly to the EMC information provided in this manual.
- Portable and mobile RF communications can affect medical electrical equipment.
- The use of accessories, transducers, and cables other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the EZ-IO® Power Driver.
- The EZ-IO® Power Driver should be observed to verify normal operation in the configuration it will be used.
- The EZ-IO® Power Driver is designed and tested to run intermittently with a duty cycle of 30 seconds on, 1 minute off for 5 consecutive cycles. Allow 1 hour cool down time.

Equipment Classification

Type of protection against electric shock	NA internal powered equipment
Degree of protection against electric shock	Type BF applied part
Degree of protection against ingress of water	IPX0 Ordinary protection
Degree of safety or application in the presence of a flammable anesthetic mixture	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

FOLD

ARROW EZ-IO®
INTRAOSSEOUS VASCULAR ACCESS

WARRANTY INFORMATION

VIDACARE LIMITED EXPRESS WARRANTY AND DISCLAIMERS

Vidacare warrants to the original end user of the Products only ("***End User***") that during the applicable Warranty Period: (a) the hardware Products will conform with Vidacare's written product specifications for such Products in all material respects for the shorter of (i) one year after shipment to End User or (ii) the number of uses of such hardware Product as are specified by Vidacare in its written product specifications, and (b) the disposable Products will conform with Vidacare's written product specifications for such Products in all material respects until the expiration date designated therefor on such disposable Products (collectively, the "***Warranty Period***"), unless the Products have been subjected to physical abuse, misuse, abnormal use, use not consistent with Vidacare's published directions and instructions for use, fraud, tampering, unusual physical stress, negligence or accidents ("***Express Warranty***"). Vidacare does not guarantee that the operation of a hardware Product will be uninterrupted or error-free. Vidacare will, in its discretion, repair, replace or refund the purchase price to End User for Product determined by Vidacare to be non-conforming ("Remedies"), provided that End User returns the nonconforming Product to Vidacare during the applicable Warranty Period, at End User's expense and first gives prompt written notice to Vidacare so that Vidacare can issue a Return Material Authorization ("***RMA***") number. Products sent to Vidacare for warranty replacement without a valid RMA number displayed on the outside of the shipping container may, in Vidacare's discretion, be returned to End User at End User's expense. All returned nonconforming Product become the property of Vidacare. To the extent permitted by law, Vidacare may repair or replace nonconforming hardware Products (a) with new or previously used Products or parts equivalent to new in performance and reliability, or (b) with equivalent Products to an original Product that has been discontinued. Replacement Products (or parts thereof) are warranted for the remainder of the Warranty Period of the Product they are replacing. THE REMEDIES DESCRIBED HEREIN SHALL BE END USER'S SOLE AND EXCLUSIVE REMEDY FOR A FAILURE OF A PRODUCT TO CONFORM TO THE EXPRESS WARRANTY. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE EXPRESS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY AND GIVEN IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY OR SUITABILITY. IF THE DISCLAIMER OF ANY IMPLIED WARRANTY IS NOT PERMITTED BY APPLICABLE LAW, SUCH EXPRESS WARRANTY IS LIMITED TO NINETY (90) DAYS FROM THE DATE OF ORIGINAL PURCHASE. OTHER THAN THE EXPRESS WARRANTY, THE PRODUCTS ARE PROVIDED "AS IS" AND ARE DESIGNED FOR USE SOLELY BY QUALIFIED HEALTHCARE PERSONNEL USING REASONABLE MEDICAL DISCRETION IN MEDICALLY NECESSARY SITUATIONS. VIDACARE DISCLAIMS ALL LIABILITY WITH RESPECT TO THE PRODUCTS ARISING FROM ANY USE OF THE PRODUCTS THAT IS INCONSISTENT WITH VIDACARE'S PUBLISHED DIRECTIONS AND INSTRUCTIONS FOR USE. IN NO EVENT SHALL VIDACARE BE LIABLE TO END USER, ANY CUSTOMER OR ANY OTHER THIRD PARTY ("CLAIMANT") IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, WHETHER ARISING UNDER CONTRACT OR TORT LAW (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY),REGARDLESS OF THE FORM OF LEGAL ACTION EVEN IF VIDACARE IS AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE. VIDACARE'S TOTAL AGGREGATE LIABILITY IN CONNECTION WITH THE PURCHASE OR USE OF THE PRODUCTS SHALL NOT EXCEED THE SUM OF THE AMOUNTS PAID BY CLAIMANT TO VIDACARE DURING THE TWELVE (12) MONTHS IMMEDIATELY PRECEDING THE DATE OF THE EVENT GIVING RISE TO A CLAIM AGAINST VIDACARE.

FOLD