Teleflex 9079T-VC-005 EZ-IOTM Intraosseous Vascular Access System Instruction Manual

Teleflex™

ARROW™ EZ-IO™

INTRAOSSEOUS VASCULAR ACCESS

INTRAOSSEOUS ACCESS TRAY +
SINGLE-USE POWER DRIVER
Instructions for Use

Contents

9079T-VC-005 EZ-IOTM Intraosseous Vascular Access System

INDICATIONS FOR USE:
For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent or medically necessary cases for up to 24 hours.
For patients ≥ 12 years old, the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.
INSERTION SITES:
ADULTS (≥ 22 years old): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≤ 21 years old): proximal humerus, proximal tibia, distal tibia, distal femur
CONTRAINDICATIONS FOR USE:

- Fracture in target bone.
- Previous, significant orthopedic procedure at the site, prosthetic limb or joint.
- IO access (or attempted IO access) in targeted bone within past 48 hours.
- Infection at the area of insertion.
- Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks.

INTENDED USER:
Only practitioners trained in EZ-IO™ Intraosseous Vascular Access System insertion should attempt procedure. Practitioners must be familiar with anatomical landmarks, safe techniques and potential complications before attempting the procedure.
MRI SAFETY INFORMATION:
MR Conditional:
Non-clinical testing has demonstrated that Teleflex's Arrow™ EZ-IO™ Needle Set is MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 4,000 G/cm (40 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).

RF HEATING:
Under the scan conditions defined above, Teleflex's Arrow EZ-IO Needle Set Needles are expected to produce a maximum temperature rise less than or equal to 5.1 ˚C after 15 minutes of continuous scanning.
MR Artifact RF Heating:
In non-clinical testing, the image artifact caused by Teleflex's Arrow EZ-IO Needle Set, extends approximately 6.3 cm from the device when imaged with a spin-echo or gradient-echo pulse sequence in a 3 T MRI system.
WARNINGS AND PRECAUTIONS FOR EZ-IO INTRAOSSEOUS VASCULAR ACCESS SYSTEM:
CAUTIONS:

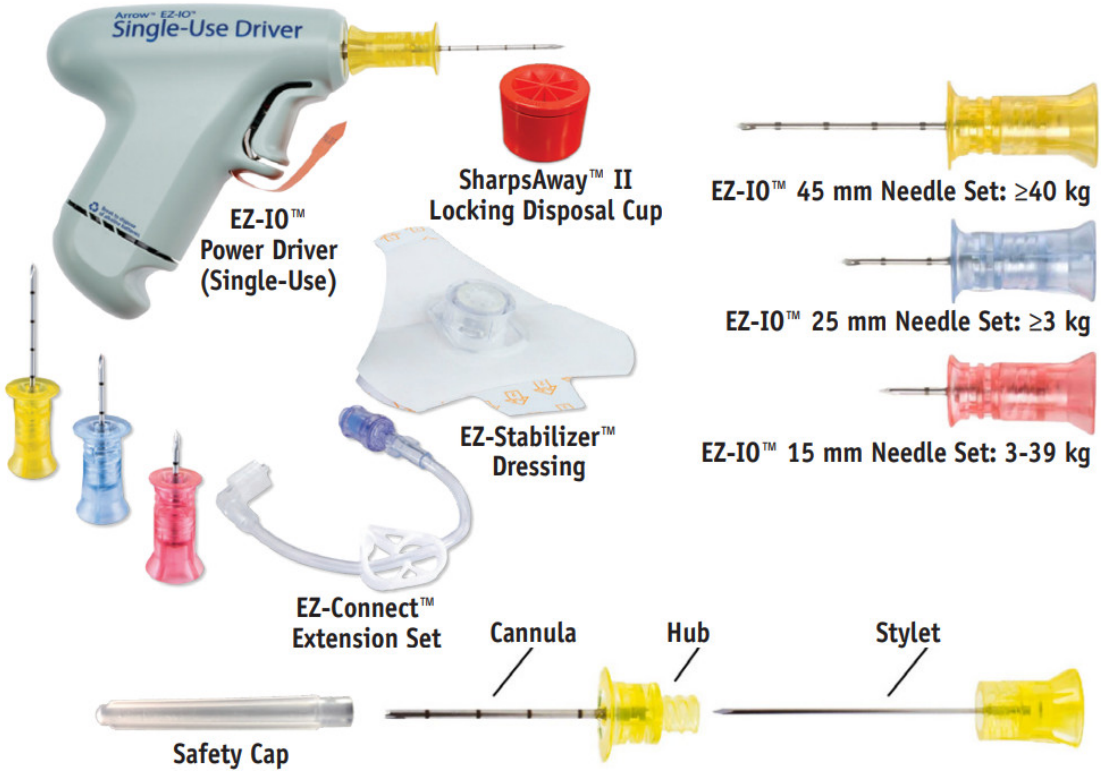
- Use aseptic technique.
- Check skin, adipose and muscle thickness before insertion.
- Extra care should be taken during insertion and site monitoring when used in patients with bone diseases that increase the likelihood of fracture, extravasation and dislodgement.
- Do not recap Needle Sets or reconnect separated components. Use biohazard and sharps disposal precautions. Re-use of contents may cause cross-contamination, leading to patient risk and complication(s).
- Before administering vesicant, toxic, or highly-concentrated drugs, check the IO Cannula again for placement and patency.
- Use caution with chemotherapeutic agents.Monitor IO site/limb/infusion frequently for any signs of extravasation/infiltration, localized inflammation, changes in infusion rates or dislodgement, particularly in the first half hour after insertion, anytime the IO cannula is manipulated or after patient transport, and during infusion of vasopressors, vesicants, and bolus or with high infusion rates and high pressure, but at least hourly during all infusions. This is especially important for all high-risk patients (elderly, pediatric, patients in shock, coagulopathies, decreased immunity, obese, etc).
- Post-IO cannula removal, a delayed complication can occur. Instruct patients and caregivers to return patient to the hospital for any problems in the limb to include a change in the limb appearance (discoloration, swelling), pain, warmth, paresthesias, fever, and prolonged discomfort.
- Complications for individuals with co-morbidities that increase risk of infection or other IO access related complications may be at a higher rate than in patients lacking co-morbidities. This risk may increase with a longer dwell/ time the device is in place.
- Do not leave the Cannula inserted for longer than indicated.
- Needle Sets are single use only; serious medical consequences (e.g. life-threatening infection) and reduced performance (e.g. blunted needles) may occur if compliance to this warning is not followed.
- Read all warnings, precautions, and instructions prior to use. Failure to follow these instructions and associated clinical educational materials may lead to patient or provider injury or death.
- IO infusion pain varies from mild to severe. Pain may be mitigated with a slow infusion of 2% preservative-free and epinephrine-free lidocaine, before initial flush; and other analgesics appropriate to each patient’s clinical situation.
- Potential side effects include pain, inflammation, bleeding at the insertion site, extravasation, infiltration, infection, osteomyelitis, compartment syndrome.

EZ-IO NEEDLE SET DESCRIPTION:

- Comprised of Cannula with Luer-lock connection, Stylet, Safety Cap.
- 15 gauge, 304 stainless steel in 15 mm, 25 mm and 45 mm lengths.
- Intended for use with EZ-IO Power Driver (Single-Use).

EZ-IO INTRAOSSEOUS VASCULAR ACCESS SYSTEM:

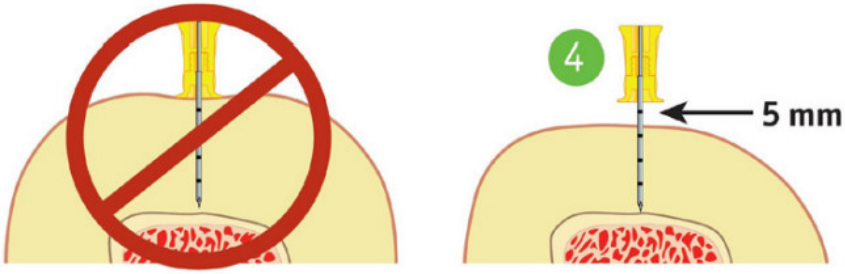
- All components in the tray are sterile via EO sterilization. The fluid path components are non-pyrogenic. All components are in protective packaging.



Insertion Instructions

For additional clinical educational resources please visit Teleflex.com/EZIOeducation

1. Clean insertion site per institutional protocol/policy.
2. Prepare supplies.
   a. Prime EZ-Connect Extension Set.
   • Ensure clamp is unlocked.
   • Prime set and purge air.
3. Attach EZ-IO Needle Set to EZ-IO Power Driver (Single-Use) and remove Safety Cap from Cannula.
   IMPORTANT: Only handle EZ-IO Needle Set by the plastic Hub.
   IMPORTANT: Control patient movement prior to and during procedure.
4. Remove orange tab from EZ-IO Power Driver (Single-Use) that is labeled “PULL OUT TO USE,” to activate EZ-IO Power Driver (Single-Use) batteries.
5. Push EZ-IO Needle Set through skin until tip touches bone. 5 mm of the Cannula (at least one black line) must be visible outside the skin.



   IMPORTANT: The most accurate determinant of correct needle selection is use of depth markings. Black depth marks on each cannula function as depth measuring guides to determine soft tissue depth overlying bone (see above).
6. Squeeze trigger and apply gentle, steady pressure.
   IMPORTANT: DO NOT USE EXCESSIVE FORCE.

NOTE: If EZ-IO Power Driver (Single-Use) stalls and EZ-IO Needle Set will not penetrate the bone, operator may be applying too much downward pressure to penetrate bone.

NOTE: In the unlikely event of an EZ-IO Power Driver (Single-Use) failure, disconnect the EZ-IO Power Driver (Single-Use), grasp the EZ-IO Needle Set Hub by hand and advance into the medullary space while twisting back and forth.

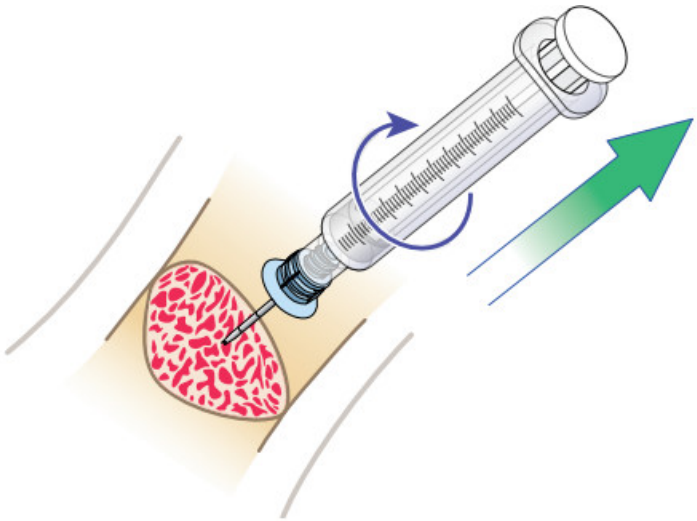
7. Advance EZ-IO Needle Set and release Trigger.
   Pediatrics: Release Trigger when sudden “give” or “pop” is felt, indicating entry into medullary space.
   Adults: Advance EZ-IO Needle Set approximately 1 cm after entry into medullary space; in proximal humerus for most adults Cannula should be advanced until Needle Hub is flush or against the skin (this may be more than approximately 1 cm).
8. Stabilize Needle Set Hub, disconnect EZ-IO Power Driver (Single-Use), and remove Stylet.
9. Place Stylet into Arrow SharpsAway II Locking Disposal Cup for sharps containment.
   NOTE: Place the SharpsAway II Locking Disposal Cup on a flat stable surface. Immediately following use of a needle, use a one-handed technique holding the stylet hub, firmly insert the sharp pointed tip straight down into the opening in the SharpsAway II Locking Disposal Cup until it stops. Do not hold SharpsAway II Locking Disposal Cup with free hand. Dispose of opened sharp into SharpsAway II Locking Disposal Cup whether or not it has been used.
10. Obtain samples for lab analysis, if needed.
    NOTE: Attach a syringe directly to the EZ-IO Cannula Hub when drawing blood for laboratory analysis (stabilize Cannula) or removal.
11. Place EZ-Stabilizer Dressing over Cannula Hub.
    NOTE: Use of the EZ-Stabilizer Dressing is strongly recommended for all EZ-IO Needle insertions.
12. For patients responsive to pain, consider 2% preservative-free and epinephrine-free lidocaine (intravenous lidocaine), follow institutional protocols/policy.
    a. Local anesthetics intended for the medullary space must be administered very slowly until desired anesthetic effect is achieved.
13. Attach a primed EZ-Connect Extension Set to the Hub, firmly secure to Cannula Hub by twisting clockwise, ensure clamp is open.
    NOTE: Do NOT use any instruments to tighten connections.
    NOTE: To prevent valve damage, do NOT use needles or blunt cannula to access the swabable valve. Non-standard syringes or connectors can damage the swabable valve.
    NOTE: Operator may use a sterile alcohol wipe, to swab the EZ-Connect Extension Set valve and let it air dry.
14. Attach EZ-Stabilizer Dressing by pulling the tabs to expose the adhesive and adhere to skin. Secure the affected limb to minimize movement and risk of dislodgement; ambulation is discouraged.
    Use caution moving patients.
    a. Proximal humerus: Secure arm in adducted position (with the patient’s arm close to body), or across the abdomen using immobilizer or alternate method.
    b. Distal femur: Stabilize extremity and secure site with leg outstretched to ensure knee does not bend using leg board or alternate method.
    c. Proximal and distal tibia: Minimize potential for cannula movement when necessary with use of leg board or alternate method in pediatric patients.
15. Flush the EZ-IO Cannula with normal saline (0.9% Sodium Chloride) (5-10 mL for adults; 2-5 mL infant/child).
    a. Prior to flush, aspirate slightly for visual confirmation of bone marrow.

b. Failure to appropriately flush the EZ-IO Cannula may result in limited or no flow. Repeat flush as needed.

c. Once EZ-IO Cannula has been flushed, administer fluids or medications as indicated.

16. Confirm Cannula placement with the following recommended methods:
    - Stability of Cannula in the bone.
    - Ability to aspirate after flush.
    - Adequate flow rate.
17. Document date/time of insertion and apply wristband.

    CAUTION: Monitor insertion site frequently for extravasation.
18. For removal of alkaline batteries refer to Battery Information section for the EZ-IO Power Driver (Single-Use).
    - To remove EZ-IO Cannula from patient:
    - Remove EZ-Connect Extension Set.
    - Lift and remove EZ-Stabilizer Dressing.
    - Attach Luer-lock Syringe to Hub of Cannula. Maintain axial alignment and rotate clockwise while pulling straight out. Do NOT rock or bend the Cannula. Improper technique may cause cannula to break.
    - Once removed, immediately place syringe/Cannula in appropriate sharps container.
    - Dress site per institutional protocol/policy.



NOTE: If the Cannula or Needle Set breaks during or after placement in the patient, attempt to grasp the Cannula that remains in the patient with a hemostat and remove by gently pulling while simultaneously rotating. If broken Cannula is not accessible, obtain x-ray and have physician determine if and how it should be removed as a foreign body.

CLINICAL STUDY SUMMARY:

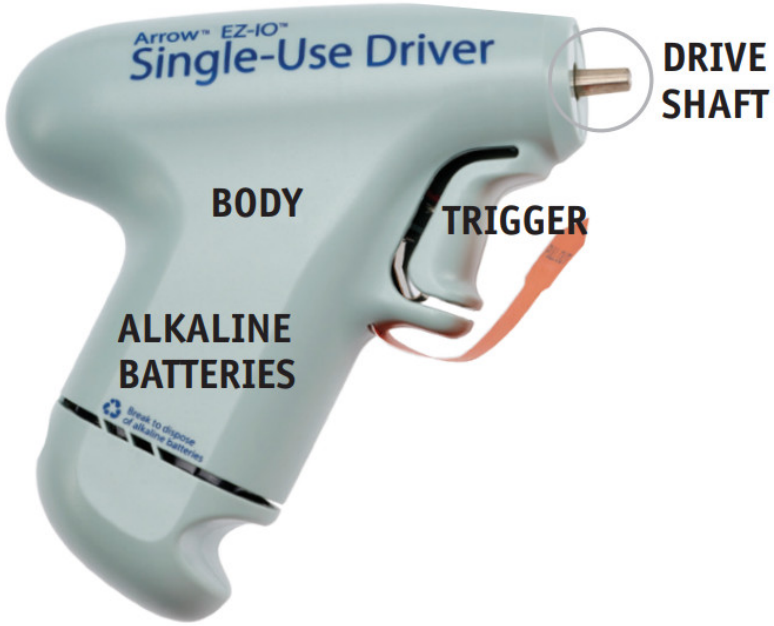
A US single-site, prospective clinical IDE trial was performed to study use of the EZ-IO Intraosseous Vascular Access System for up to 48 hours indwelling time; the primary study endpoint was the absence of serious complications resulting from intraosseous (IO) cannula retention over a 48 hour period.

The study participants were either healthy or health-compromised adult volunteers with mild to moderate renal disease (NHANES Stage 1 to 3) and/or controlled diabetes (HbA1C ≤8). There were 121 evaluable subjects enrolled in the study; 79 were in the healthy subset, 39 were in the diabetes only subset, and 3 in the diabetes with renal insufficiency subset. Placement site was randomized with 61 proximal tibia and 60 proximal humerus insertions. Subjects were infused with 0.9% sodium chloride at a rate of 100 mL/hr for the initial eight hours then a rate of 30 mL/hr. Pain control during the study was managed with a slow infusion of 2% preservative-free and epinephrinefree lidocaine before initial flush; and analgesics. An IO aspirate culture was obtained before cannula removal, followed by an x-ray of the site. After 30 days, subjects returned for examination and repeat x-ray.

Three subjects were discontinued from the 48 hour procedural portion of the study: one with pain and left arm swelling after 10 hours; and two adverse events (AE) between 30-32 hours, swelling secondary to extravasation; and leaking at the hub of the device and accidental dislodgement. Four subjects withdrew following IO needle

insertion before 48 hours due to inability to control pain or pain and fever.
Study follow-up was performed at 30 days. There were no serious AEs or complications, or unexpected AEs reported for any of the subjects randomized into the study. AEs determined to be related/and or possibly related to the device included: pain, swelling; elevated white blood cell counts and neutrophils; skin demarcation/ scar; fever; local skin allergy; and vasovagal response during initial insertion.
Under the conditions of the study, IO access can be maintained for 48 hours without significant risk of serious adverse events. Pain associated with cannula dwell and infusion can be well-managed, and a slow infusion of 30 mL/hour maintains patency for 48 hours.
Education and training materials available at **ArrowEZIO.com**

EZ-IO POWER DRIVER (SINGLE-USE)
Instructions for Use
PRODUCT INFORMATION



DESCRIPTION:

- The EZ-IO Power Driver (Single-Use) is a single-use, hand-held, alkaline battery powered medical device.
- Sterile via EO sterilization, in protective packaging.

PRODUCT INFORMATION:

- Applied Parts: EZ-IO Intraosseous Vascular Access Needle Sets – 15 mm; 25 mm; 45 mm.

SAFETY INFORMATION:

- Additional product information can be found at **ArrowEZIO.com**.
- In the unlikely event of a EZ-IO Power Driver (Single-Use) failure, remove the EZ-IO Power Driver (Single-Use), grasp the Needle Set by hand, and advance the Needle Set into the medullary space while twisting the Needle Set.

IMPORTANT INFORMATION FOR USERS:
In order for EZ-IO Intraosseous Vascular Access System products to perform properly, the following conditions are recommended.

- Use this product only in accordance with this manual and applicable product labeling.
- 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.
- Avoid spilling fluids on any part of this product.
- The EZ-IO Power Driver (Single-Use) may not be cleaned or resterilized.
- Do not use excessive force during insertion. Let the EZ-IO Power Driver (Single-Use) do the work.
- The EZ-IO Power Driver (Single-Use) is designed and tested to run for up to 30 seconds. The EZ-IO Power Driver (Single-Use) is not for reuse.
- Remove orange tab from EZ-IO Power Driver (Single-Use) that is labeled “PULL OUT TO USE,” to activate EZ-IO Power Driver (Single-Use) batteries.

WARNING: Adjustments, modifications, technical maintenance or repairs are not allowed.
STORAGE:

- The EZ-IO Power Driver (Single-Use) and accessories may be stored at temperatures between 15°C to 30° C (59° F to 86° F) at a non-condensing relative humidity of 30 to 85%.

ENVIRONMENTAL CONDITIONS OF USE:

- -20° to + 40°C; 30 to 85% Relative Humidity.

BATTERY INFORMATION:

- Batteries are not replaceable.
- Once insertion is complete break the battery compartment of the EZ-IO Power Driver (Single-Use) to remove batteries and dispose per institution policy.

Guidance and manufacturer’s declaration – electromagnetic emissions

The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is intended for use in the The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the Teleflex Incorporated EZ-IO electromagnetic environment specified below. The customer or the user of the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver should assure that it is used in such an environment.Intraosseous Access Tray + Single-Use Power Driver should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver 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.
RF emissions CISPR 11	Class A	The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity

The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver 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.

NOTE: UT is the A.C. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity
The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver 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 Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [3.5/10] √P 80 MHz to 800 MHz d = [7/10] √P 800 MHz to 2.7 GHz 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.
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 Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is used exceeds the applicable RF compliance level above, the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use 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 Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver.

Guidance and manufacturer's declaration – electromagnetic immunity
The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver should assure that it is used in such an environment.

Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment – guidance
	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	

IMMUNITY to proximity fields from RF wireless communications equipment	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz	27 V/m 28 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$
IMMUNITY to proximity magnetic fields IEC 61000-4-39	0.134213.560.030	2.1kHz 50kHz CW	65 A/m 7.5 A/m 8 A/m	0.134213.560.030	2.1kHz 50kHz CW	65 A/m 7.5 A/m 8 A/m	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: 

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 RF wireless communications equipment and the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver.

The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver 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] VP	800 MHz to 2.7 GHz d = [7/3] VP	s 710, 745, 780, 5240, 5500, 5785 MHz d = [6/9] VP	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz d = [6/28] VP
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	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.
The Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver 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 Teleflex Incorporated EZ-IO Intraosseous Access Tray + Single-Use Power Driver, 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: This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.
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.
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.

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 and particulate	IP21 – Protection against solids greater than 12mm in diameter and against vertically dropping water or condensation
Degree of safety or application in the presence of aflammable anesthetic mixture	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

For Instructions for Use visit: **www.teleflex.com/IFU**
ARROWEZIO.COM
EMERGENCY NUMBER: 1.800.680.4911
Model #/ REF #:

9018T-VC-005: 15 mm EZ-IO Single-Use Intraosseous Access Tray + Single-Use Power Driver
9001T-VC-005: 25 mm EZ-IO Single-Use Intraosseous Access Tray + Single-Use Power Driver
9079T-VC-005: 45 mm EZ-IO Single-Use Intraosseous Access Tray + Single-Use Power Driver

Customer Service: 1.866.479.8500
Teleflex Medical
IDA Business & Technology Park,
Dublin Rd, Athlone,
Co. Westmeath, Ireland
Rx only

Caution	Consult instructions for use	Refer to instruction manual/ booklet	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Keep away from sunlight	Keep dry
Do not use if package is damaged	Not made with natural rubber latex	Store between 15°C to 30° C (59° F to 86° F)		Humidity limitation	Atmospheric pressure limitation	MR conditional	No sternal use
Type BF Applied part	800723 ANSI/AAMI ES60601-1 CSA C22.2 No. 60601-1		Catalogue number	Lot number	Use by	Manufacturer	Date of manufacture

Documents / Resources

	Teleflex 9079T-VC-005 EZ-IOTM Intraosseous Vascular Access System [pdf] Instruction Manual 9079T-VC-005 EZ-IOTM Intraosseous Vascular Access System, 9079T-VC-005, EZ-IOTM Intraosseous Vascular Access System, Intraosseous Vascular Access System, Vascular Access System, Access System, System

References

- ArrowEZIO.com
- IFU
- User Manual