Arrow™ EZ-IO™ Intraosseous Vascular Access Needle
MR Conditional Safety Status Labeling
FAQ

The Arrow™ EZ-IO™ Intraosseous Vascular Access Needle has received 510(k) clearance from the U.S. Food and Drug Administration for use in an MRI environment.

The EZ-IO™ System is indicated 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.

1. **What are the MR Conditional parameters in the updated EZ-IO™ Needle Set IFU?**
   MR Conditional

   Non-clinical testing has demonstrated Arrow™ EZ-IO™ Needles are MR Conditional. A patient with this device inserted for intraosseous (IO) vascular access can be safely scanned in an MR system that meets 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, EZ-IO™ 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

   In non-clinical testing, the image artifact caused by EZ-IO™ Needles 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.

2. **Does the MR Conditional status apply to product in stock already?**
   Yes, the updated Instructions for Use may be applied to customers' in-stock product as the design (dimensions, materials, etc.) of the device did not change in support of the MR Conditional clearance.

3. **What is the clinical benefit of the MR Conditional labeling of the EZ-IO™ System?**
   The ability to utilize the EZ-IO™ System for difficult vascular access patients in urgent, emergent, and medically necessary cases who require MRI offers clinicians an additional access option via the intraosseous route. This route delivers fast[1] and effective[2] access, and with the MR Conditional safety status, it allows clinicians to leave an inserted EZ-IO™ Needle in place when MRI scans are needed, removing a barrier to expedient patient care.

4. **Can the EZ-IO™ Needle cannula be pulled out of a patient's bone in the indicated MR environment?**
   Results from non-clinical performance testing and an internal cadaveric study determined the gravitational and deflection forces in the MR environment are approximately 700 times less than the removal force required to pull an EZ-IO™ needle cannula out of the bone.

5. **Will the use of an EZ-IO™ Needle cannula in the MR environment cause an unsafe maximum temperature rise when used as labeled?**
   Based on non-clinical performance testing, the increase in temperature when used in the MR environment is within a safe and reasonable range. The maximum temperature rise is less than or equal to 5.1ºC after 15 minutes of continuous scanning.

6. **How long can a patient be exposed to the MR environment with an EZ-IO™ Needle cannula in place?**
   Obtain imaging for no longer than 15-minute increments and then allow a nine-minute cool-down period between scans.

References:
1. Davidoff J, Fowler R, Gordon D, et al. Clinical evaluation of a novel intraosseous device for adults: prospective, 250-patient, multi-center trial. *JEMS* 2005;30(10):s20-3. Research sponsored by Teleflex Incorporated.
2. Cooper BR, Mahoney PF, Hodgetts TJ, Mellor A. Intra-osseous access (EZ-IO®) for resuscitation: UK military combat experience. *J R Army Med Corps*. 2007;153(4):314-316.

Rx Only.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
The Arrow® EZ-IO® Needle Set is Sterile, Single Use: Do not reuse, reprocess, or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Refer to Instructions for Use for complete warnings, indications, contraindications, precautions, and potential complications.

This material is not intended to replace standard clinical education and training by Teleflex Incorporated and should be utilized as an adjunct to more detailed information which is available about the proper use of the product. View educational resources at Teleflex.com or contact a Teleflex clinical professional with any detailed questions related to product insertion, maintenance, removal, and other clinical education information.