ZIEN Medical Technologies

SAM IO® Intraosseous Access System

PRODUCT FAMILY TECHNICAL DATA SHEET

Finished Product Description

The SAM IO® Intraosseous (IO) Access System facilitates entry into the medullary cavity for infusion of fluids and the administration of medications during medical emergencies.

The SAM IO® is a manually operated intraosseous access system. Catheter placement is achieved by continuously actuating (repeatedly compressing) the driver's trigger assembly while gently guiding the needle assembly into position. Repeated, full trigger actuation creates a rotational spin of the needle assembly which, when combined with gentle downward pressure results in controlled IO placement. Once the needle assembly is properly positioned, the stylet is removed to expose a standard Luer lock connector for extension set connections. With the extension set connected, aspiration verification, flushing and selected treatment(s) may commence.

SAM IO Intraosseous Access System Accessories

- The SAM IO® Needle Set is provided with an extension tubing set and NeedleVISE® sharps protector.
- The SAM IO® Driver is a manually operated reusable handle used to place the IO Needle using repeated actuation.
- The SAM IO® Stabilizer is a sterile protector that can be placed around the IO Needle insertion site to protect the catheter from dislodgement.
- The SAM IO® Adaptor can be used to accommodate competitor needles with the SAM IO Driver.

Indications for Use

The SAM IO Intraosseous Access System provides intraosseous access in the proximal tibia, distal tibia and, humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

Contraindications

1. Fracture in targeted bone.
2. Previous, significant orthopedic procedure at site selected for insertion.
3. Intraosseous catheter placement in targeted bone within past 48 hours.
4. Infection at site selected for insertion.
5. Excessive tissue or absence of anatomic landmarks.

Warnings

The SAM IO® System is not for sternal use.

SAM IO Needle Set, SAM IO Stabilizer, and SAM IO Adaptor are single use only devices and should not be reused. Reuse of the device may cause illness or injury.

Complete product disclosures are listed in the Instructions for Use and available at zienmedical.com/eifu/sam-medical/.

Material Technical Data

Product Material Information

- The SAM IO Needle is composed of a polycarbonate hub and stainless-steel needle.
- The SAM IO Driver is composed of a polycarbonate body, stainless steel spring, and Santoprene front grip handle.
- The SAM IO Stabilizer is composed of polycarbonate, PVC, and acrylic adhesive.
- The SAM IO Adaptor is composed of polycarbonate.

Sterilization and Shelf Life

- The SAM IO Needle and SAM IO Stabilizer are sterilized using ethylene oxide (EO) and have a shelf life of 5 years.
- The SAM IO Driver and Adaptor are non-sterile devices and do not have a defined shelf life.

Instructions for use

- Included in product packaging.
- Complete product information and disclosures are listed in the Instructions for Use and available at zienmedical.com/eifu/sam-medical/.
- Driver: Reusable device following validated cleaning and disinfection process found in the IFU
- Prescription Use Only in the United States

Packaging

- SAM IO Driver is packaged in a single cardboard box with a protective foam insert.
- SAM IO Needle Set and SAM IO Stabilizers are packaged in a single sterile barrier system.
- Multiple units are packaged in a cardboard box.

Packaged Size & Weight

Product Type	Height	Width	Depth	Weight	Quantity
Driver	2 in / 5 cm	6.3 in / 16 cm	7.8 in / 19.8 cm	9.4 oz. / 213 g	1 Unit
Needle (1pk)	0.9 in / 2.3 cm	3 in / 7.6 cm	6 in / 15.2 cm	2.7 oz. / 57 g	1 Pack
Needle (5pk)	3 in / 7.6 cm	4.2 in / 10.7 cm	6 in / 15.2 cm	9 oz. / 255 g	5 Pack
Stabilizer (1pk)	1.8 in / 4.6 cm	6.5 in / 16.5 cm	7 in / 17.8 cm	3.6 oz. / 102 g	1 Pack
Stabilizer (5pk)	5.5 in / 14 cm	6.5 in / 16.5 cm	8.3 in / 21 cm	12.9 oz. / 366 g	5 Pack
Adaptor	0.8 in / 2 cm	3 in / 7.6 cm	4.5 in / 11.4 cm	0.2 oz. / 6 g	1 Unit

*Size and weight may vary by configuration.

Compliance

- ZIEN Medical maintains current EN ISO 13485: 2016 and ISO 13485: 2016/MDSAP certifications.

Needle Set

- United States of America: Class II medical device, K240915 | Product Code: FMI
- Canada: Class 2 Medical Device, License No. 112889
- EU: Class IIa Medical Device, Certificate Number: 28620212805
- GMDN Code: 18009 (intraosseous infusion kit)

SAM IO Intraosseous Access System Products

Customer Product List	
Catalog Number	**Description**
IO705W-1P	15mm Needle Assembly - 1 Pack
IO705W-5P	15mm Needle Assembly - 5 Pack
IO706W-1P	25mm Needle Assembly - 1 Pack
IO706W-5P	25mm Needle Assembly - 5 Pack
IO707W-1P	45mm Needle Assembly - 1 Pack
IO707W-5P	45mm Needle Assembly - 5 Pack
IO742	Adaptor - 1 Pack
IO700	Driver - 1 Pack
IO740-1P	Stabilizer - 1 Pack
IO740-5P	Stabilizer - 5 Pack

SAM IO Intraosseous Access System Training Products

Training Product List	
Catalog Number	**Description**
IO720W	SAM IO Training Kit - Proximal Humerus
IO721W	SAM IO Training Kit - Proximal Tibia
IO722W	SAM IO Training Kit - Distal Tibia
IO723W	SAM IO Training Kit - 3 Bones
IO724	Sawbone Pack, Humerus and Prox Tibia
IO725W	15mm Training Needle; Replacement (each)
IO726W	25mm Training Needle; Replacement (each)
IO727W	45mm Training Needle; Replacement (each)
IO728W	Training Needle; Replacement (15, 25 & 45mm)
IO745-EN	FIELD STORAGE CASE
IO744-EN	IO TRAINING CASE