# SAM IO® Driver

## EN INSTRUCTIONS FOR USE

**DESCRIPTION:**
The SAM IO Intraosseous Access System utilizes a manually operated driver handle. The driver functions by continuously actuating (repeatedly compressing) the trigger assembly. Repeated, full trigger actuation creates rotational spin with a passive ratcheting mechanism designed to place the SAM IO needle assembly.

**PRODUCT INFORMATION:**
- Driver part number: IO700
- Applied Parts: SAM IO Intraosseous Access needles; 15 mm, 25 mm, 45mm

**SAFETY INFORMATION:**
- Indications, contraindications, warnings, precautions, and other safety information are contained in the Instructions for Use for the SAM IO Intraosseous Access System.
- Please consult the Instructions for Use for the SAM IO Intraosseous Access System before applying. If there are questions, Immediately contact your local SAM Medical sales representative.
- Additional product information can be found at sammedical.com

**IMPORTANT INFORMATION FOR USERS:**
For SAM IO Intraosseous Access System products to perform properly, the following conditions are recommended.
- 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 SAM Medical.
- Visually inspect driver for deficiencies before use. If driver is soiled, discard or clean according to the method below:
    - Maintain personal protective equipment precautions.
    - Wipe exterior surfaces of the SAM IO driver with soft, clean moistened cloth.
    - Use a soft bristled brush dampened with a 1% Alconox solution to remove visible soil. Clean all surfaces that make contact with the hand during use, with particular attention paid to the rubberized grip on the front of the driver.
    - Rinse the IO driver under running tap water, but do not rinse the driver's internal components.
    - Dry driver with a soft, clean cloth.
    - After cleaning, inspect to ensure no visible debris remains and no damage has occurred to the driver. If soils remain on the driver, repeat steps above or discard SAM IO Driver.
    - Spray or wipe exterior surface with anti-microbial solution or towelettes (e.g. Super Sani-Cloth® or equivalent intermediate level EPA registered disinfectant agent) following the manufacturer's recommendations.
    - Actuate the driver 1-3 times and ensure no tactile or visible damage is felt or seen before returning the driver to its storage location. If tactile or visible damage is noted, discard the driver.
- Do not immerse or use excessive amount of liquid when performing cleaning and disinfecting.
- Unless mechanically damaged, there is no known expiration of the driver. Mechanical damage ending the useful life of the product will be readily identified as fractures, bends, or other visibly obvious damage. Before attachment of the needle, actuate driver 1-3 times and if no tactile or visible damage is felt or seen the driver is viable for use.

**Do not use excessive force during insertion. The mechanical rotation of the needle by handle actuation and the cutting edge of the needle should be the PRIMARY mechanisms to penetrate the bone, NOT the downward pressure.**

**In unlikely event of driver failure, needle assembly can be used manually. Please refer to SAM IO Needle Instructions for Use (step 5).**

**Not for Sternal use.**

**Notice:**
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authority/competent authority of the Member State region in which the user and/or patient is established.

## SYMBOL GLOSSARY:

| Symbol | Title (Reference) | Description |
|---|---|---|
|  | Manufacturer (5.1.1[1]) | Indicates the medical device manufacturer. |
|  | Authorized representative in the European Community (5.1.2[1]) | Indicates the authorized representative in the European Community/ European Union. |
|  | Date of Manufacture (5.1.3[1]) | Indicates the date when the medical device was manufactured. |
|  | Batch Code (5.1.5[1]) | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | Catalogue Number (5.1.6[1]) | Indicates the manufacturer's catalog number so that the medical device can be identified. |
|  | Importer (5.1.8[1]) | Indicates the entity importing the medical device into the locale. |
|  | Country of Manufacture (5.1.11[1]) | To identify the country of manufacture of products. |
|  | Consult instructions for use or consult electronic instructions for use (5.4.3[1]) | Indicates the need for the user to consult the instructions for use. |
|  | Medical Device (5.7.7[1]) | Indicates the item is a medical device. |
|  | Unique Device Identifier (5.7.10[1] ) | Indicates a carrier that contains unique device identifier information. |
|  | CE Marking (Regulation (EU) 2017/745 Article 20) | Signifies European technical conformity. |
|  | Prescription Only (21 CFR 801.109) | Caution: Federal law restricts this device to sale by or on the order of a physician. |
|  | Swiss Authorized Representative (Section 3[2]) | Indicates the authorized representative in Switzerland. |
|  | Package Quantity (No Applicable Reference) | Indicates a quantity of 1 device. |
|  | Package Quantity (No Applicable Reference) | Indicates a quantity of 10 single devices. |
|  | Not For Sternal Use (No Applicable Reference) | Indicates device is not to be used on the sternum. |

[1] ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
[2] Swissmedic, Obligations Economic Operators CH, VM-ID: MU600_00_016e/V4.0/mea/pmi/06.04.2023

REF **IO700**

CE

CH REP
**MedEnvoy Switzerland**
Gotthardstrasse 28
6302 Zug
Switzerland

EC REP
**CS Life Sciences Europe Ltd**
The Black Church, St. Mary's Place
Dublin 7, Dublin
D07P4AX, Ireland,
eurep@cslifesciences.com

**ZIEN Medical Technologies, Inc.**
2490 South 300 West
Salt Lake City, UT 84115 USA

**MedEnvoy**
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands

SAM® MEDICAL

**Customer Service:**
Tel: +1.503.639.5474 (USA)
technical.support@sammedical.com
**sammedical.com**



SAM04100-EN REV A
ISSUE DATE: 2025-05-08