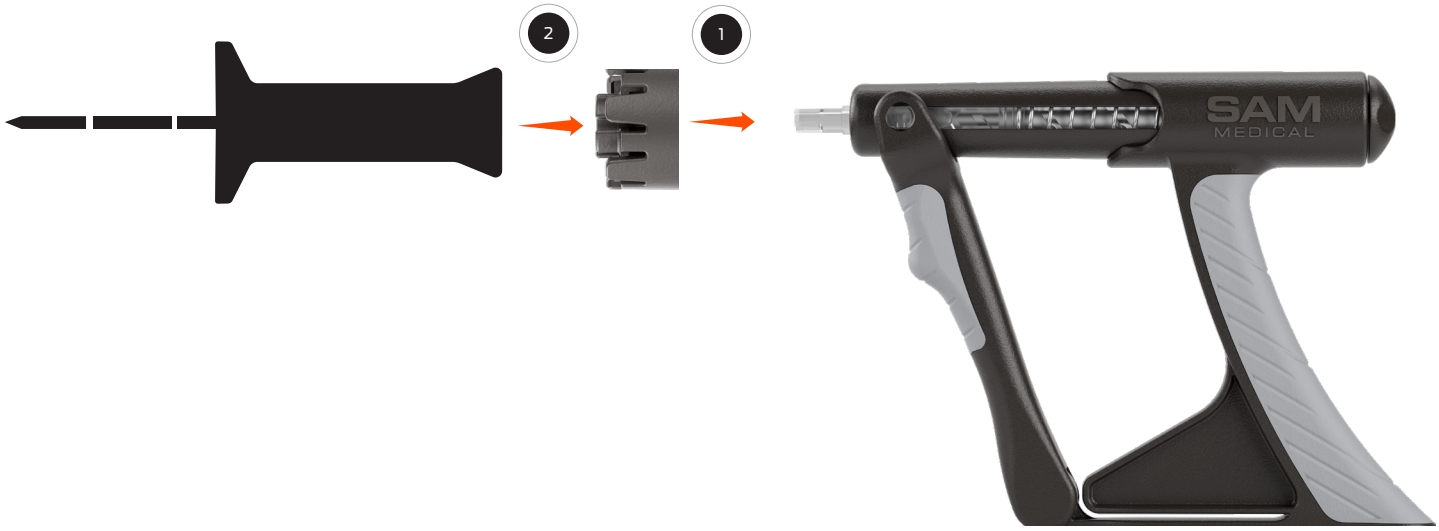
SAM IO® Adaptor

EN INSTRUCTIONS FOR 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 or region in which the user and/or patient is established.

Consult all relevant instructions for use.
Not for sternal use.
Single use only. Reuse may result in illness.

REF IO742

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,
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ZIEN Medical Technologies, Inc.
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SYMBOL GLOSSARY:

Symbol	Title (Reference)	Description
	Manufacturer (5.1.1[1])	Indicates the medical device manufacturer.
EC REP	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.
LOT	Batch Code (5.1.5[1])	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	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.
USA	Country of Manufacture (5.1.11[1])	To identify the country of manufacture of products.
	Do not use if package is damaged and consult instructions for use (5.2.8[1])	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
2	Do not re-use (5.4.2[1])	Indicates a medical device that is intended for one single use only.
eIFU	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.
MD	Medical Device (5.7.7[1])	Indicates the item is a medical device.
UDI	Unique Device Identifier (5.7.10[1])	Indicates a carrier that contains unique device identifier information.
CE	CE Marking (Regulation (EU) 2017/745 Article 20)	Indicates device is approved for sale in the European Community/European Union.
Rx only	Prescription Only (21 CFR 801.109)	Caution: Federal law restricts this device to sale by or on the order of a physician.
CH REP	Swiss Authorized Representative (Section 3[2])	Indicates the authorized representative in Switzerland.
x10	Package Quantity (No Applicable Reference)	Indicates a quantity of 10 single devices.
Not For Sternal Use	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

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