SAM IO Stabilizer





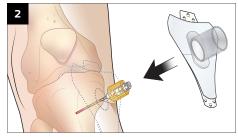
EN INSTRUCTIONS FOR USE



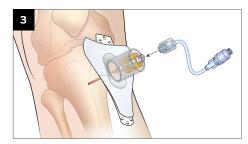
APPLICATION STEPS



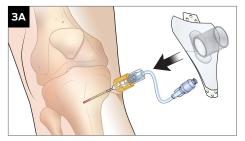
With catheter in position, consider use of Stabilizer.



Place sterile Stabilizer carefully over catheter and against skin.

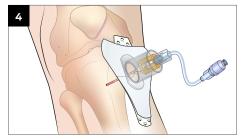


Attach primed extension set to catheter. KEY POINT: Extension set design permits singlehanded tightening to catheter.

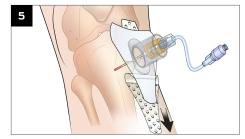


Optional Stabilizer Application Method:

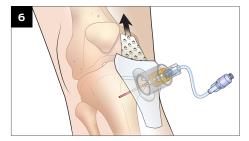
With attached extension set in position gently feed extension set through Stabilizer cylinder. Guide Stabilizer over catheter, and against patient skin.



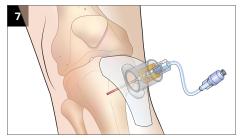
Ensure catheter is centered within Stabilizer.



Hold Stabilizer in position and gently pull Tab 1. By pulling Tab 1 you are removing adhesive backing. This will expose adhesive to patient skin. Gently press exposed adhesive against patient skin.



Hold Stabilizer in position and gently pull Tab 2. By pulling Tab 2 you are removing adhesive backing. This will expose adhesive to patient skin. Gently press exposed adhesive against patient skin.



With Stabilizer in position (and adhesive backing removed) gently smooth all exposed adhesive to patient skin.

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.

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.
Σ	Use-by date (5.1.4 ^[1])	Indicates the date after which the medical device is not to be used.
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.
AZU	Country of Manufacture (5.1.11 ^[1])	To identify the country of manufacture of products.
STERILE EO	Sterilized using ethylene oxide (5.2.3 ^[1])	Indicates a medical device that has been sterilized using ethylene oxide.
TENUZE	Do not resterilize (5.2.6 ^[1])	Indicates a medical device that is not to be resterilized.
®	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.
\bigcirc	Single sterile barrier system (5.2.11 ^[1])	Indicates a single sterile barrier system.
	Single sterile barrier system with protective packaging outside $(5.2.14^{[1]})$	Single sterile barrier system with protective packaging outside.
类	Keep away from sunlight (5.3.2 ^[1])	Indicates a medical device that needs protection from light sources.
<u>*</u>	Keep dry (5.3.4 ^[1])	Indicates a medical device that needs to be protected from moisture.
2	Do not re-use (5.4.2 ^[1])	Indicates a medical device that is intended for one single use only.
eff0	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.
C€	CE Marking (Regulation (EU) 2017/745 Article 20)	Indicates device is approved for sale in the European Community/European Union.
R 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.
1 x30	Package Quantity (No Applicable Reference)	Indicates a quantity of 30 single devices.
5 x6	Package Quantity (No Applicable Reference)	Indicates a quantity of 6 five packs
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







MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland



EC REP







Customer Service:

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

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