MEDNET GmbH • Borkstrasse 10 • 48163 Muenster • Tyskland • Telefon +49 251 32266-0 • Fax +49 251 32266-22 • www.medneteurope.com • info@medneteurope.com

EN

MEDNET

Instructions for Use / Gebrauchsanweisung
Instructions d'Utilisation

Arterial Needle / Arterielle Nadel / Aiguille Artérielle

EN / DE / FR

Part 1 of 6

CE 0482

REV 04 - 2021-11

Instructions for Use

Scope
Non sterile Arterial Needle (PN 1060XX00) for sterilization and subsequent sterile single use.

Intended Use
The Arterial Needle is intended to provide access to the vascular system to insert a guide wire into a blood vessel during a diagnostic or interventional percutaneous procedure.

Sterilization Instructions
To maintain the sterility the products must be packaged in a primary package according to EN 868 / EN ISO 11607. It is the responsibility of the processor that packaging is carried out under suitable conditions concerning cleanroom.
Therefore process validation and routine process monitoring are necessary.

The following EO sterilization process parameters have been validated:

EO concentration:	800 mg/l
Relative Humidity:	30-90 % RH
Temperature:	48-58 °C
Air removal:	max. vacuum -60 kPa
Conditioning:	10 min
EO Injection:	≥ 30 min, max. pressure 40 kPa
EO Exposure Time:	480 min
EO Removal:	-30 kPa
Flushing:	5 air change cycles

The sterilization instructions above have been validated as being capable of preparing the sterile product. It remains the responsibility of the processor to ensure that the sterilization under the processor-specific conditions as actually performed, using equipment, materials, sterilizer load, and product density in the processing facility, achieves the desired result. This requires validation and routine monitoring of the process.

Instructions for Use
Disclaimer:
1. The following indications address the technical requirements of using the product and do not exclude the need for formal training. The indications may not represent all local clinical guidelines and should not substitute the clinician's advice or judgment.
2. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
3. Treatment of the medical waste should be conform to the requirements of the local laws and regulations.

Instructions for Use:
1. The product may only be used in a sterile condition.
2. Open the package and take out the Arterial Needle. Flush with saline or a suitable solution.
3. Carefully remove the protective cover from the needle.
4. Perform any vessel location techniques or an Allen's test required according to local clinical guidelines.
5. Choose the puncture site then make the skin surface aseptic and apply any anesthesia as clinical required.
6. A small cut out on the needle hub indicates the tip side of the needle.
7. Tighten the patient's skin with the left hand and hold the hub of the Arterial Needle with the right hand. Insert the Arterial Needle into the vessel fast from the tip with an angle of 30 to 45 degree between the skin and the needle.
8. Correct placement can be observed by the colour and pressure of blood in the needle hub.
9. Place the straightener, if required, into the Arterial Needle and advance the guide wire into the vessel.
10. Holding the guide wire firmly, withdraw the needle over the end of the guide wire.
11. Discard the needle according to local clinical guidelines.

Precaution
1. Use proper aseptic techniques when handling.
2. The Arterial Needle should not be used with a PTFE coated guide wire.

MEDNET GmbH • Borkstrasse 10 • 48163 Muenster • Tyskland • Telefon +49 251 32266-0 • Fax +49 251 32266-22 • www.medneteurope.com • info@medneteurope.com

EN

MEDNET

Warnings
1. Read any instructions before use.
2. Do not use if the sterile packaging is damaged.
3. The product is intended for SINGLE USE ONLY.
4. Re-use of a single-use device creates a potential risk to the patient or user. This may lead to a contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.
5. The product should not be used for anything other than the intended use.

Storage
Store in the original packaging under clean and dry conditions.