

Instruction for Use (Fistula Needle)

	<h2>Fistula Needle</h2>	English
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Medica Middle East for Advanced Medical Industries

Manufactured / Sterilized by:



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A-Intended purpose

Aseptic removal of blood for delivery to and return from an extracorporeal circuit for haemodialysis. Fistula Needles are used for all types of renal replacement therapies such as haemodialysis, hemofiltration and hemodiafiltration. Sterile single use Fistula Needle.

B. Recommendations

It is important to match needle gauge to blood flow rate

Note: These are minimum recommended gauges for the stated Blood Flow Rate (BFR) settings. Larger needles, when feasible, will reduce (make ↓ negative) the pre-pump arterial pressure.

Recommended Blood Flow Rate	Recommended Needle Gauge
< 300 ml/min	16-17-gauge
300 – 350 ml/min	16-gauge
> 350 - 500 ml/min	15-16-gauge

C. Warning

- (1) The female luer lock cap must be closed during vie puncture.
- (2) Safety has not been approved for nursing women, pregnant, and children to use this device.

D. Caution

- (1) Don't start session without using heparin connection.
- (2) Consider evaluating the arterial venous fistula within 10 days of surgery by stethoscope examination and signs of infection.
- (3) Use of the Fistula Needles may be associated with various, recognised complications including: Haematoma; Thrombosis, Bleeding, Ischemia, Pain, Erosion, Stenosis (especially in immature Fistula Needle).
- (4) Fistula Needles should only be used by physicians or under physician's instructions.
- (5) Aseptic technique is required to insert a Fistula Needle.
- (6) Visual inspections to discover blood leaks to avoid blood loss are high recommended

Doc Ref	Issue Date	Effective Date	Page No	Issue No
IFU-DI-05	20/02/2023	20/02/2023		14

Doc Ref	Issue Date	Effective Date	Page No	Issue No
IFU-DI-05	20/02/2023	20/02/2023		14

E-Procedure

General procedure

- a. The luer-lock connection must be made by applying the correct mechanical force. Excessive forces may crack the connection and create blood leaks.
- b. Fixation of the inserted needle and the flexible lumen should be inserted to avoid any kinking which results in high pressures in the extracorporeal circuit.
- c. If there are any disinfection solutions which may cause a loosening between the needle and the plastic housing it should be mentioned to avoid blood loss.
- d. Identify the correct side for insertion of needle in accordance to the opening of the needle
- e. Keep the connector cap on the needle during insertion to avoid any entry of air.
- f. Determine the suitability of the area by vein compression, continuity, distension, depth of location, palpable pulse or other method such as imaging (Duplex Ultrasound).
- g. Ensure the diameters of the vein and artery to be used for creation of the Fistula Needle is adequate.
- h. Prepare the area of skin according to local recommended practice.
- i. Align the cannula of the arterial venous Fistula Needle with the vessel, ensuring the bevel faces upward, cannulate at an appropriate angle, then lower the angle of cannulation once flashback of blood becomes visible.
- j. Tape the Fistula Needle and proceed with haemodialysis according to local practice.
- k. Evaluate the fistula according to local recommended post-operative practices.

Connecting the patient with arterial venous Fistula Needle in haemodialysis

- a. Perform a complete physical assessment of the arterial venous fistula and document the findings.
- b. Select the cannulation sites carefully. Consider straight areas, and needle orientation.
- c. Sites should be selected in an area without aneurysms, and with a minimum of two inches between the tips of the needles.
- d. Remove any scabs over the cannulation sites.
- e. Disinfect the cannulation sites per facility protocol.
- f. Using a sharp arterial venous Fistula Needle, grasp the needle wings, and remove the tip protector. Align the needle cannula, with the bevel facing up, over the cannulation site and pull the skin taut (Figure 1).

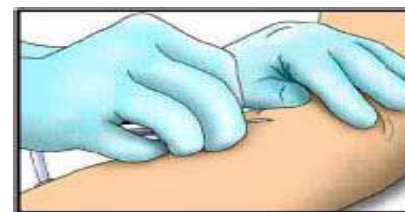


Figure (1)

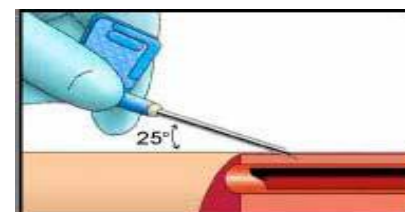


Figure (2)



Figure (3)

- a. Cannulate the site at a 25° angle (Figure 2). It is important to cannulate the developing constant-site in the exact same place, using the same insertion angle and depth of penetration each time.
- b. A flashback of blood indicates the needle is in the access. Lower the angle of insertion. Continue to advance the needle into the arterial venous fistula until it is appropriately positioned within the vessel (Figure 3).

F-Availability

Size	Length/cm
15 G	15 to 30
16 G	15 to 30
17 G	15 to 30

G-Connectors

Connectors' specifications are in accordance with ISO 80369-7

Doc Ref	Issue Date	Effective Date	Page No	Issue No
IFU-DI-05	20/02/2023	20/02/2023		14

Doc Ref	Issue Date	Effective Date	Page No	Issue No
IFU-DI-05	20/02/2023	20/02/2023		14

EC REP

Qualitech Internatonl B.V.	
Add.	SIRIUSDREEF 17, 2132WT HOOFDORP, The Netherlands,
Web	http://www.qt-int.uk/



Symbols

	Medical device
	Caution
	Do not re-use
	Temperature limit
	Batch code
	Date of manufacture / Country of Manufacture
	Use-by date
	ETO sterilization
	Do not re-sterilize
	Non-pyrogenic

Doc Ref	Issue Date	Effective Date	Page No	Issue No
IFU-DI-05	20/02/2023	20/02/2023		14

	Consult instructions for use
	Model Number
	Do not use if package is damaged and consult instructions for use
	Manufacturer
	Authorized representative in the European European Union/ Community
	Single sterile barrier system
	Unique Device Identifier
	Fragile, handle with care
	Keep away from sunlight
	Keep dry

Doc Ref	Issue Date	Effective Date	Page No	Issue No
IFU-DI-05	20/02/2023	20/02/2023		14