

A. V. FISTULA NEDDLE SET INSTRUCTIONS

1. INTENDED USE:

"BIOTEQ" A.V. Fistula Needle Sets are intended to be used as blood vessel puncture and channel for hemodialysis vascular access.

2. Intended Population:

Intended Users:

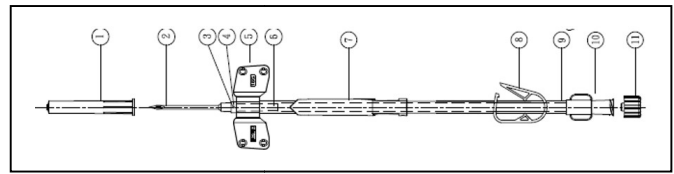
- "Bioteq" A.V. Fistula Needle set shall be manipulated by a trained registered professional Nephrology physician and nurse.

Intended Patient:

"Bioteq" A.V. Fistula Needle set is indicated for patients that have the indications related to Renal Failure, Acid-base problems, Electrolyte problems, Intoxications, and Overload fluid. Uncooperative or hemodynamically unstable patients are contraindications of hemodialysis. Pregnant should be evaluated the benefit-risk by Nephrology physicians before using.

3. INSTRUCTION MENU:

1. Before use, the doctor or nurse should evaluate the blood vessel of patient and select a needle of size. (BT-109series-14G/BT-110series 15G/BT-111series 16G/BT-112-17G)
2. Remove cover 1 and insert needle 2 into patient's blood vessel.
3. Use tape to fix wing 5 on the skin.
4. Remove cover 11 and then connect FLL 10 to a syringe.
5. Open clamp 8 and then use syringe to remove the air in the tube.
6. Remove the syringe and then connect FLL 10 to Hemodialysis Blood Tubing Set to start hemodialysis.
7. Push the blood in which the tube into patient's blood vessel by using the syringe with normal saline after hemodialysis.
8. Block the needle site by slipping the safe flex 7 after drawing out the needle 2 from the patient's blood vessel to avoid the injuries by needle-sharp.




4. PRECAUTIONS:

1. "Bioteq" A.V. Fistula Needle Set shall be stored in the environment of the temperature between 15°C to 25°C as well as the humidity between 15% to 85%.
2. Please notice the various specification of with/ without back eye as well as fixed/ rotated wings.
3. Safety flex can protect the user from needle-sharp if used.
4. "Bioteq" A.V. Fistula Needle Set is made of DEHP-Free plasticizer.
5. A.V. Fistula Needle Set does neither contain animal tissue origin nor any drug contents.

5. WARNING:

1. Do not reuse.
2. Discard the A.V. Fistula needle set after use.
3. Do not use if package is damaged.
4. Unpack and operate under aseptic condition.
5. Check the connections before priming process.
6. Do not store at extreme temperature and humidity.
7. Using of this device should be supervised by the doctor and trained nurse.
8. If blood leak during operation, change entire set.
9. After used, this product may be a potential biohazard. Handle or dispose following with local government laws and regulation

 **U.S. Federal Law restricts the sale of the device to use under physician's prescription only.**

 A.V. Fistula Needle Set is intended for single use. The reprocessing and reuse of single-use products pose the hazards of bacterial growth and contamination as well as the risks of patient serious injuries or even death. The infectious disease may be transmitted between patients by faulty clean, resterilization, and test, which also possibly alter the mechanical properties of the device lead to the risk of product failure. It is the end user's responsibility to read and understand the important warnings and to ensure the single-use of A.V. Fistula Needle Set which is single patient use only and must be replaced for each patient.

6. Manufacturer:


BIOTEQUE CORPORATION.

 Address: 5F-6, No. 23 Sec. 1, Chang-An E. Road, Taipei 104, Taiwan
Tel: +886-2-2571-0269 Fax: +886-2-2536-1967

MADE IN TAIWAN

PE-32-000189

REV. D(2020-08-18)

 MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany














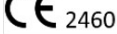



 FOR SINGLE USE

 STERILE EO



 CE 2460



	Catalogue number
	Batch code
	Date of manufacture
	Use-by date
	Manufacturer
	Do not re-use
	Authorized representative in the European community
	Sterilized using ethylene oxide
	Consult instructions for use
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Temperature limit
	CE mark
	Fragile,handle with care
	Non-pyrogenic
	Do not re-sterilize

DRAWING NO:PE-32-000189 PARTS NAME:內康管翼狀針說明書/DEHP Free/英文版 REV : D
APPROVED BY:游川倍 2020/08/18 CHECKED BY:林春來 2020/08/18 DESIGNED BY:吳曉寧 2020/08/18
備註：版面規格為 270*210mm ±10mm / 雙面印刷 / 模造紙 60lb 紙 / 白底黑色印刷