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ALTIUS® RT
ACUTE

Instructions for Use

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INTENDED USE

Sterile single use device indicated for use in attaining short term access (less than 30 days) for haemodialysis or aphaeresis.

DEVICE DESCRIPTION

Altius RT is a double lumen acute haemodialysis catheter made of radiopaque polyurethane. The catheter tubes are colour coded, where blue indicates the venous and red indicates the arterial lumen. The catheter tip is tapered with a softer material. The flexible Altius RT catheter tube can be shaped to be a straight tube and extension, straight tube and J shape extension or pre-curved tube and straight extension.

Intelligent grooves around the side holes prevent them sticking to the vessel walls. The product is also equipped with integrated haemostatic valves instead of the normal luer lock connectors. Haemostatic valves provide security by automatically sealing the lines, hence clamping the catheter lines is not required at any stage of the procedure.

Kit components

Each Altius RT kit consists of a unique Altius RT haemodialysis catheter and the following accessories:

- 1 × 7cm, 18 Ga Y introducer needle
- 1 × 5 ml syringe
- 1 × 70 cm, 0.035'' Nitinol guidewire in a guidewire advancer with cap
- 1 × 12 Fr hydrophilic coated dilator
- 1 × 14 Fr or 16 Fr hydrophilic coated dilator
- 1 × No. 11 scalpel
- 1 × 12 Fr or 14 Fr stiffener

Depending on the size, length and type of the catheter, different variations of dilators and stiffeners are provided in the sets. Dimensions of the components are also indicated on the product label.

How supplied

All contents are supplied sterile and non-pyrogenic in unopened and undamaged packaging. The device is sterilised by ethylene oxide. Do not use catheter if sterile package has been damaged or has been opened. Do not re-use or re-sterilise the device.

Storage

Protect from direct sunlight, any source of heat, and moisture. Store at room temperature and do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to expiration date on package label.

CONTRAINDICATIONS

The devices are contraindicated as follows:

- The catheter should not be placed in patients with bleeding disorders
- When the presence of other device related infection, bacteraemia or septicaemia is known or suspected
- Post irradiation of prospective insertion site

- If previous episodes of venous thrombosis or vascular surgical procedure at the prospective insertion site have occurred
- Local tissue factors which may prevent proper devices stabilisation and/or access, like allergic reaction, or any dermatological disease

WARNING

- **This product is sterile and for single use only. Do not re-use, reprocess or re-sterilise. Do not use catheter or accessories if any sign of damage is visible.**
- **Re-processing or re-sterilisation of the kit may damage the catheter and affect its integrity which may, when re-used, lead to severe deterioration in health and safety of patients.**
- **The catheter does not have any metallic components and can be exposed to various environmental conditions including thermal ignition source (during MRI) as long as no metal component is attached to it.**

WHICH VEIN TO CANNULATE?

The preferred insertion site for dialysis catheters is the right internal jugular vein. Other options include the right external jugular vein, left internal and external jugular veins, subclavian veins and femoral veins. Subclavian access should be used only when no other upper-extremity or chest-wall options are available.

Table 1 – Patient evaluation prior to access placement

Consideration	Relevance
History of previous CVC	Previous placement of a CVC is associated with central venous stenosis.
Dominant arm	To minimize negative impact on quality of life, use of the non-dominant arm is preferred.
History of pacemaker use	There is a correlation between pacemaker use and central venous stenosis.
History of severe CHF	Placement of catheter may alter haemodynamic and cardiac output.
History of arterial or venous peripheral catheter	Previous placement of an arterial or venous peripheral catheter may have damaged target vasculature.
History of diabetes mellitus	Diabetes mellitus is associated with damage to vasculature necessary for internal accesses.
History of anticoagulant therapy or any coagulation disorder	Abnormal coagulation may cause clotting or problems with haemostasis of access site.
Presence of co-morbid conditions, such as malignancy or coronary artery disease, that limit patient's life expectancy	Morbidity associated with placement and maintenance of certain accesses may not justify their use in some patients.
History of vascular access	Previously failed vascular accesses will limit available sites for access; the cause of a previous failure may influence planned access if the cause is still present.
History of heart valve disease or prosthesis	Rate of infection associated with specific access types should be considered.
History of previous arm, neck or chest surgery/trauma	Vascular damage associated with previous surgery or trauma may limit viable access sites.

METHOD OF INSERTION

General preparation to obtain haemodialysis access

The basic preparation and equipment required for venous cannulation are the same regardless of the route or technique chosen. Clinicians who insert dialysis catheters should be taught the technique by an experienced colleague. If this is not possible then the access routes associated with the fewest complications are the femoral vein.

Equipment required for venous access

- Sterile dressing
- Syringes and needles
- Tilting bed, trolley or operating table
- Sterile pack and antiseptic solution
- Appropriate catheter for age and purpose
- Local anaesthetic (e.g. 5 ml lignocaine 1% solution)
- Saline or heparinised saline to prime and flush all lumens on the line after insertion
- Shaving equipment for the area if very hairy (especially if femoral access is required)
- Suture in case of fixation by suturing is determined (e.g. 2/0 silk on a straight needle)

Steps prior to catheter insertion

- Prepare the Altius RT catheter for insertion by priming the catheter lumens and inserting the stiffener in the venous (blue) lumen.
- Follow instructions on how to insert the stiffener to prevent from kinking.
- Once the stiffener is inserted, it also needs to be primed by flushing.

WARNING

- **The implantation technique has a significant influence on the complications and outcome of the device. Implantation must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon.**

PRECAUTION

- **Ultrasound should be used in the placement of catheters.**
- **The position of the tip of any central venous catheter should be verified by radiological means (e.g. X-ray) and monitored routinely as per institution policy.**
- **Do not use absolute alcohol or acetone based product on the catheter. 2% chlorhexidine or iodine based solution is recommended as antiseptic solution.**
- **It is not recommended to use antimicrobial ointments or solutions on the catheter as it may cause degradation of the catheter material.**

GENERAL INSERTION TECHNIQUE FOR ALL ROUTES

1) Confirm that central venous access is needed and select the most appropriate route. Explain the procedure to the patient.

2) Shave the needle insertion area if very hairy.

3) Using a strict aseptic technique, prepare and check all the equipment for use. Read the instructions provided with the catheter.

4) Prepare the skin and drape the area.

5) Infiltrate the skin and deeper tissues with local anaesthetic. In cases where difficulty is anticipated use the small local anaesthetic needle to locate the vein before using the larger needle. This reduces the risk of trauma to other structures.

6) Position the patient appropriately for the selected route. Trendelenburg position is preferred for neck placement to reduce risk of air embolism. Avoid long periods of head down, particularly in breathless patients.

7) Identify the anatomical landmarks for the chosen route and insert the Y needle at the recommended point. After the needle has penetrated the skin, aspirate gently whilst advancing the needle as directed until the vein is entered. If the vein is not found, slowly withdraw the needle whilst gently aspirating; often the vein has been collapsed and transfixed by the entry of the needle.

8) Advance the guidewire (using Seldinger technique) through the Y needle valve port using the guidewire dispenser, into the vein.

9) Advance the guidewire to an equivalent length to the desired position of the catheter tip.

10) Once the guidewire is in the vessel, remove the Y needle together with the guidewire dispenser and the syringe. If that is not possible, then remove the guidewire dispenser first before removing the Y needle and the syringe.

11) It may be necessary to dilate the hole in the skin. Use the scalpel, with the blade facing away from the guidewire, and make a small incision in the skin and fascia where the guidewire enters the patient. Thread the dilator over the wire into the vein with a twisting motion. Ensure the dilator is not over-inserted (usually 4-6 cm maximum). Rotating the dilator may make insertion easier. Excessive force should not be needed. There are two dilators provided in every kit, a 12 French and one which is 2 French size larger than the catheter (14 or 16 French). It is recommended to start with the 12 French dilator and progress to the larger one based on the judgement of the Clinician. Both dilators are hydrophilic coated and it is recommended to dip them in saline before insertion to activate the coating.

12) Remove the dilator taking care not to dislodge the guidewire.

13) Thread the catheter over the guidewire until the end of the wire protrudes from the end of the stiffener and whilst holding the wire still advance the catheter into the vein. Take care not to allow the wire to be pushed further into the vein whilst advancing the catheter. Rotating the catheter may make insertion easier.

14) Once the catheter is in place, unlock the stiffener from the catheter and remove it together with the guidewire.

15) Check that blood can be aspirated freely from all lumens of the catheter and flush with saline following a push-pause technique and positive pressure disconnection.

16) Secure the catheter in place with the suture and cover with a sterile dressing. Tape any redundant tubing carefully avoiding any kinking or loops which may snag and pull out the catheter.

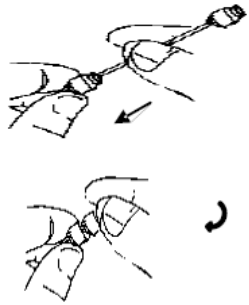
17) Connect the catheter to a bag of intravenous fluid or flush both lumens with appropriate anti-thrombotic.

WARNING

- **If any resistance is felt, then the needle should be pulled out with the wire still inside and the procedure repeated. This reduces the risk of entangling of the guidewire or its end being cut off by the needle tip.**
- **Over advancement of the guidewire can result in serious injuries or arrhythmias.**
- **Over advancement of the catheter can result in serious injury or arrhythmias.**

PLACEMENT OF ALTIUS RT USING THE STIFFENER

Altius RT catheters shall be inserted with the stiffener provided to aid in its insertion and prevent vessel damage. The stiffener consists of a LuerSafe haemostatic valve attached to a plastic mandrill. This plastic mandrill can kink, if too much force is applied during insertion.



1) Insert the stiffener tip into the slit of the LuerSafe valve at the venous (blue) lumen.
2) Gently advance the stiffener inside the catheter lumen until it reaches the catheter tip, while holding the stiffener not more than 5 cm or 1 inch away from the LuerSafe valve.
3) Secure the male luer valve of the stiffener to the female luer valve of the catheter (Figure 1).

Figure 1

USE OF SWABABLE INTEGRATED HAEMOSTATIC VALVES

1) Prior to accessing the haemostatic valves, swab the silicone seal in accordance with facility protocol (Figure 2).

Figure 2

2) To attach a Male Slip Luer (Figure 3) or a Male Luer Lock (Figure 4) to the haemostatic valve, grasp the clear polycarbonate body of the connector and push the luer/syringe straight into the silicone valve by using a twisting motion.

Figure 3

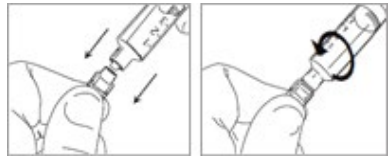


Figure 4

3) Flush the lines after each use, in accordance with facility protocol, using a push-pause and positive pressure disconnection technique.
4) To disconnect from the valve, grasp the valve and twist the syringe or blood tubing set connector clockwise until loose, then pull away from the valve connector. The valve closes and seals once a connector is removed, therefore capping is optional.

WARNING

- **DO NOT twist the integrated haemostatic valves and DO NOT grasp the catheter line when attaching a luer/syringe otherwise the line may be damaged.**
- **DO NOT clamp the catheter line. Haemostatic valves automatically seal the line when devices are being attached or detached.**
- **Do not attempt to insert the luer/syringe at an angle.**
- **Never use a needle to access the haemostatic valves, and there is no need to pry open the slit.**

FIXATION BY SUTURE WING

1) Take the flexible part of the moveable wing and spread the wings until the internal slit is opening. Position it on the catheter at the desirable place.
2) Snap the rigid part of the moveable wing over the flexible wings.
3) Suture the wings through the holes to the skin of the patient.

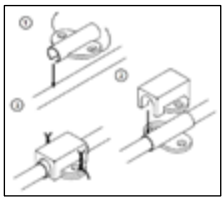


Figure 5

PRECAUTION

- **Always ensure there is secure fixation of the catheter to the patient.**
- **Always ensure that the fixation is not causing catheter obstruction.**

CHECKS BEFORE USING THE CATHETER

1) Ensure that fluid runs in freely and that blood draws back freely.
2) Take a chest X-ray (ideally erect) to check the position of the catheter tip and to exclude a pneumo-, hydro- or haemothorax. An early radiograph may not show up abnormalities and it may be best to wait 3-4 hours unless symptoms develop. The tip of the catheter should lie within the right atrium.
3) Ensure that the patient will be nursed and their access can be supervised. Give appropriate written instructions regarding how, and what it is to be used for, and who to contact if there is a problem between dialysis sessions.

PRACTICAL PROBLEMS COMMON TO MOST INSERTION TECHNIQUES

The table below lists some problems that may occur during dialysis sessions.

Table 2 – Problems during haemodialysis cannulation.

Problem type	Description
Arterial puncture	Usually obvious but may be missed in a patient who is hypoxic or hypotensive. Withdraw the needle and apply firm direct pressure to the site for at least 10 minutes or longer if there is continuing bleeding. If there is minimal swelling then retry or change to a different route.
Suspected pneumothorax	If air is easily aspirated into the syringe (note that this may also occur if the needle is not firmly attached to the syringe) or the patient starts to become breathless. Abandon the procedure at that site. Obtain a chest radiograph and insert an intercostal drain if confirmed. If access is absolutely necessary, then try another route ON THE SAME SIDE. DO NOT attempt either the subclavian or jugular on the other side as bilateral pneumothoraces are produced. Alternatively, vascular access can be obtained using either femoral vein.
Arrhythmias during the procedure	Usually from the catheter or wire being inserted too far (into the right ventricle). The average length of catheter needed for an adult internal jugular or subclavian approach is 15cm. Withdraw the wire or catheter if further than this.
The wire will not thread down the needle	Check that the needle is still in the vein. Flush it with saline. Try angling the needle so the end of it lies more along the plane of the vessel. Carefully rotate the needle in case the end lies against the vessel wall. Reattach the syringe and aspirate to check that you are still in the vein. If the wire has gone through the needle but will not pass down the vein it should be very gently pulled back. **If any resistance is felt, then the needle should be pulled out with the wire still inside and the**

Problem type	Description
	procedure repeated. This reduces the risk of the end of the wire being cut off by the needle tip.
Persistent bleeding at the entry	Apply firm direct pressure with a sterile dressing. Bleeding should usually stop unless there is a coagulation abnormality. Persistent severe bleeding may require surgical exploration if there is an arterial or venous tear.

POSSIBLE COMPLICATIONS

The table below lists some of the possible complications that can occur during the early and late stages of dialysis sessions.

Table 3 – Potential early and late complications

Early	Late
Arterial puncture	Venous thrombosis
Bleeding	Cardiac perforation and tamponade
Cardiac arrhythmias	Infection
Injury to the thoracic duct	Hydrothorax
Injury to surrounding nerves	
Air embolism	
Catheter embolus	
Pneumothorax	

CONNECTION TO THE DIALYSIS MACHINE

1) Connect the catheter to the blood line of the dialysis machine. The blood line is a set of arterial and venous lines.

2) After swabbing the LuerSafe haemostatic valves, insert the male luer of the blood tube. Ensure that the male luer is fully protruding by retracting the movable collar of the bloodline as much as possible.

3) Insert the luer end into the LuerSafe. To ensure that the movable collar on the blood tubing is fully engaged, check that the split-septum valve within the LuerSafe is open (Figure 6).

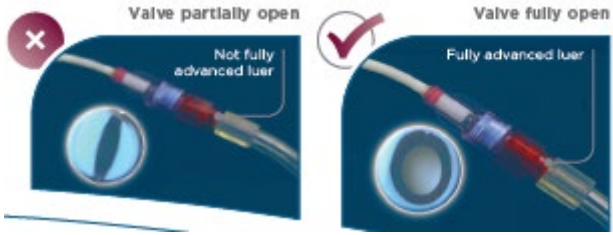


Figure 6

4) Ensure that the catheter allows a free flow of fluids. Free flow is usually indicated by flow of blood within the accepted venous and arterial pressure in the extracorporeal circuit of the dialysis machine.

DISCONNECTION FROM THE DIALYSIS MACHINE

1) Pull out the blood tube from the catheter LuerSafe by twisting the male luer of the blood tube.

2) Connect the flushing device to the catheter LuerSafe and flush the catheter, using a push-pause and positive pressure technique according to hospital protocol.

3) Use of dry gauze dressing combined with skin disinfection, using either chlorhexidine or povidone iodine solution, followed by povidone iodine ointment or mupirocin ointment at the catheter exit site are recommended at the end of each dialysis session.

PRECAUTION AGAINST MISUE

The catheter can be affected by the following actions:

- Improper positioning of the catheter tip.
- Misconnection of catheter extension line(s) by connecting the venous line of the dialysis blood line to catheter extension line that is dedicated to the arterial line and marked red. This can lead to high recirculation rate and inefficient dialysis.
- Improper heparinization during the dialysis may result in blood clotting and obstruction of the catheter.
- Improper heparinization of the catheter between dialysis may result in thrombus formation.
- Inserting male luer aggressively or over tightening may crack catheter female luer.

CARE OF THE CATHETER BETWEEN DIALYSIS SESSIONS

Insertion site should be inspected for possible bleeding.

PREVENTION AND TREATMENT OF CATHETER DYSFUNCTION

Select catheter length in relation to the catheter insertion site. It is normally accepted to be 15 to 20 cm for right side insertion and 20 to 25 cm for left side insertion. For femoral insertion a minimum 25 cm long catheter is recommended, as lower flow rates are expected as a result of selecting catheters shorter than that.

Altius RT is a very flexible catheter and it is recommended to start dialysis treatment from flows of 80 ml/min and gradually build up to require flows to prevent catheter abutting against vessel wall.

Catheters should be evaluated when they become dysfunctional. Dysfunction is defined as failure to attain and maintain an extracorporeal blood flow of 300 ml/min (for adult size catheter) or greater at a pre pump arterial pressure more negative than –250 mm Hg.

Signs of catheter dysfunction – assessment phase

- Blood pump flow rates <300 ml/min
- Arterial pressure increases (< –250 mm Hg)
- Venous pressure increases (>250 mm Hg)
- Conductance decreases (<1.2): the ratio of blood pump flow to the absolute value of pre-pump pressure
- Unable to aspirate blood freely (late manifestation)
- Frequent pressure alarms - not responsive to patient repositioning or catheter flushing

Causes of early catheter dysfunction

- Mechanical compression (pinch off syndrome in subclavian catheter)
- Malposition of catheter tip
- Kinks
- Catheter migration
- Occlusion of side holes due to clotting or fibrin sheath formation or drug precipitation (some antibody locks or IV IgG)
- Patient position, especially if the catheter has not been well positioned and secured
- Loss of catheter integrity by infection

Methods that should be used to treat dysfunctional or non-functional catheter include

- Repositioning of a malpositioned catheter. Change patient position, ask them to cough or vigorously flush the catheter (if no resistance is felt) to try and dislodge side holes away from vein wall.
- Fibrin sheath stripping using a snare is a fibrin sheath is present.
- Exchanging the thrombosed catheter over a guidewire if a fibrin sheath is present or if the catheter is malpositioned or of inadequate length.
- Use of thrombolytics, as per hospital protocol.
- Treatment of an infected haemodialysis catheter should be based on the type and extent of infection.
- All catheter-related infections, except for catheter exit-site infections, should be addressed by initiating parenteral treatment with an antibiotic(s) appropriate for the organism(s) suspected. Definitive antibiotic therapy should be based on the organism(s) isolated.
- Catheters should be exchanged as soon as possible and within 72 hours of initiating antibiotic therapy in most instances, and such exchange does not require a negative blood culture result before the exchange. Follow-up cultures are needed 1 week after cessation of antibiotic therapy.
- At the end of the dialysis session inject heparin or other anti-thrombotic in each lumen (according to lumen priming volume) within the catheter via the injection caps.

CARE OF THE CATHETER BETWEEN DIALYSIS

- Insertion site should be inspected for possible bleeding.
- Anti-thrombotic should be regularly injected to the catheter to prevent catheter thrombus and obstruction.

CATHETER REMOVAL

Remove any dressing and suture material. Ask the patient to inhale and fully exhale afterwhich they should hold their breath. Remove the catheter with a steady pull and apply firm pressure to the puncture site for at least 5 minutes to stop the bleeding. Excessive force should not be needed to remove the catheter. If it does not come out, try rotating it whilst pulling gently. If this still fails, cover it with a sterile dressing and ask an experienced person for advice.

CATHETER DISPOSAL

Used catheters should be disposed of in a sanitary container or according to hospital protocol to prevent possible contamination and cross infection.

DESCRIPTION OF THE MARKING SYSTEM

In order to achieve the required length, the catheter tube is marked with numerical numbers every 5 cm with dots every 1 cm in between, apart from the first 5 cm which is not marked.

5 • • • • 10 • • • • 15 • • • • 20 • • • • 25 • • • •
Illustration purposes only, not to scale.

SUMMARY SAFETY AND CLINICAL PERFORMANCE (SSCP)

The Summary of Safety and Clinical Performance (SSCP) can be referenced on the Eudamed public website (https://ec.europa.eu/tools/eudamed) or can be requested directly from Kimal (regulatory_department@kimal.co.uk)

BASIC UDI

The basic UDI for the Altius RT range of Haemodialysis Catheters is 5032932KSP-203JE.

SERIOUS ADVERSE EVENTS

If a serious adverse event occurs, please report it to Kimal at vigilance@kimal.co.uk and to your national competent authority.

EC REP

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