

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-010

6.5F Tesio® Catheter Set

IMPORTANT INFORMATION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

This SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

Applicable Documents	
Document Type	Document Title / Number
DHF	96067
'MDR Documentation' File Number	MDR-010

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	05OCT2021	26536	RS	Implementation of SSCP	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
2	28JUN2022	27030	RS	Scheduled Update	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
3	05SEP2022	27250	GM	Case numbers sourced from Musumeci et al., 2012 have been corrected to “19” from “21”. This change affects Section 5 (Users / Healthcare Professionals and Patients). Section 8 (Users / Healthcare Professionals) has been updated to match GSPR-010-02_3.	<input checked="" type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
4	10JUL2023	28266	GM	Periodic Update; Updated in Accordance with CER-010, Revision D	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					IIb implantable device
5	01JUL2024	29459	GM	Periodic Update; Updating in Accordance with CER-010, Revision E	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
6	05SEP2025	25-0170	GM	Periodic Update; Updating in Accordance with CER-010, Revision F	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

USERS / HEALTHCARE PROFESSIONALS

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

1. Device identification and general information

Device trade name(s)	6.5F Tesio® Catheter
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Manufacturer single registration number (SRN)	US-MF-000008230
Basic UDI-DI	00884908281ND
Medical device nomenclature description / text	F900202 – Permanent Hemodialysis Catheter and Kits
Class of device	III
Date first CE certificate was issued for this device	1997
Authorized representative name and SRN	European Regulatory Expert Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany SRN: DE-AR-000005009
Notified Body name and single identification number	BSI Netherlands NB2797

The devices in scope of this document are all long-term hemodialysis catheter sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays, in a configuration inclusive of accessories and adjunctive devices (see section “Accessories intended for use in combination with the Device”).

Variant Devices:

Variant Description	Part Number
6.5F Tesio	1398 / 1399

Procedure Trays:

Catalog Code	Part Number	Description
PBFP	1398 / 1399	6.5F Tesio® Catheter Set (Arterial Cuff - 12cm From Tip) (Venous Cuff - 15cm From Tip)

Configurations of Procedure Trays:

Configuration Type	Kit Components
6.5F Tesio® Set	(2) Catheter (2) 1.3mm OD x 1.0mm ID x 70mm (18GA) Introducer Needle (2) 0.97mm x 70cm (.038) Guidewire J (R 3mm) Tip (2) Advancer (2) Tunneler (2) 2.3mm ID x 14cm (7F) Peelable Introducer (1) Arterial Extension Set (1) Venous Extension Set (2) Clamp (2) End Cap (1) Patient ID Card (1) Patient Information Packet

2. Intended use of the device

Intended purpose	6.5F Tesio® Catheters are intended for use in pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for single-use only.
Indication(s)	The 6.5F Tesio® Catheter is indicated for short-term or long-term use where vascular access is required for 14 days or more for the purpose of hemodialysis.
Target population(s)	6.5F Tesio® Catheters are intended for use in pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician.
Contraindications and/or limitations	<ul style="list-style-type: none"> Known or suspected allergies to any of the components of the catheter or the kit. This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.

3. Device description

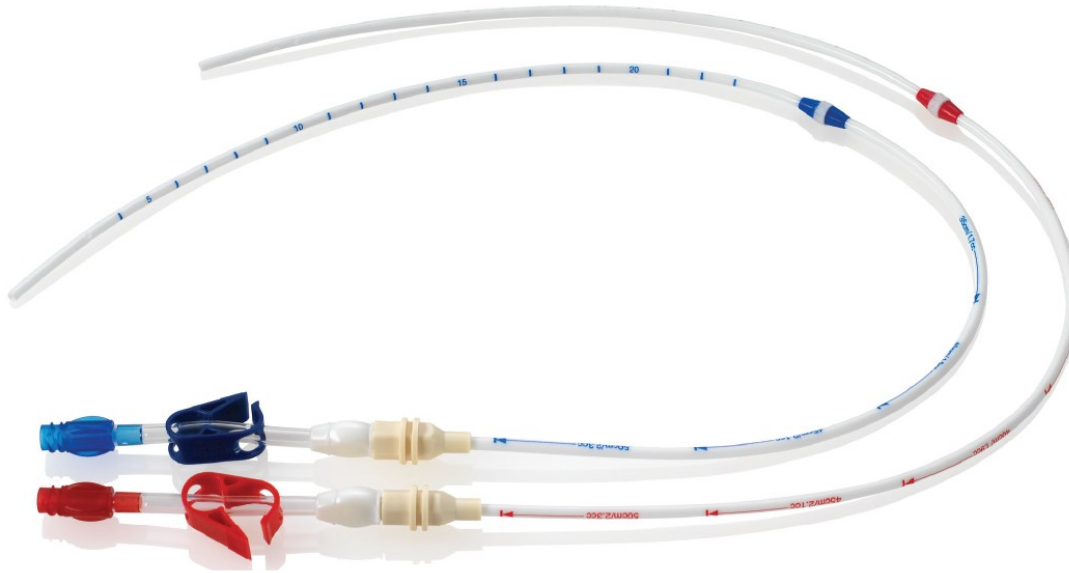


Figure 1: 6.5F Tesio Catheter

Description of device	<p>The 6.5F Tesio® Catheter is a long-term single lumen catheter. Two catheters are inserted into the target vein that are used to remove and return blood through two separate passages (lumens). Priming volume and depth markings are printed on the lumen. A polyester cuff is placed on the catheter's lumen for tissue ingrowth to anchor the catheter. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray. The catheter has been tested at flow rates of up to 250 mL/min.</p>														
Materials / substances in contact with patient tissue	<p>The percentages in the table below are based on the weight of the catheter (9.47g).</p> <table border="1" data-bbox="610 1220 1260 1507"> <thead> <tr> <th>Material</th> <th>Weight % (w/w)</th> </tr> </thead> <tbody> <tr> <td>Polyvinyl chloride</td> <td>32.45</td> </tr> <tr> <td>Acetal copolymer</td> <td>40.63</td> </tr> <tr> <td>Polyurethane</td> <td>20.84</td> </tr> <tr> <td>Barium sulfate</td> <td>3.18</td> </tr> <tr> <td>Polyethylene terephthalate</td> <td>1.60</td> </tr> <tr> <td>Silicone</td> <td>1.30</td> </tr> </tbody> </table> <p>Note: Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.</p> <p>Note: Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</p>	Material	Weight % (w/w)	Polyvinyl chloride	32.45	Acetal copolymer	40.63	Polyurethane	20.84	Barium sulfate	3.18	Polyethylene terephthalate	1.60	Silicone	1.30
Material	Weight % (w/w)														
Polyvinyl chloride	32.45														
Acetal copolymer	40.63														
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Barium sulfate	3.18														
Polyethylene terephthalate	1.60														
Silicone	1.30														
Information on medicinal substances in the device	N/A														

How the device achieves its intended mode of action	Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. This catheter has two separate tubes. The tubes go into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one tube of the catheter. The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second tube. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis. Long-term access may occur in some cases. For example, when there are problems supporting an AV fistula or graft.	
Sterilization Information	Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.	
Previous generations / variants	Name of previous generation	Differences from current device
	7F Tesio® Catheter	N/A
Accessories intended for use in combination with the device	Name of Accessory	Description of Accessory
	Guidewire	For general intravascular use to facilitate the selective placement of medical devices in the vessel anatomy.
	Guidewire Advancer	Aid for introduction of guidewire into target vein.
	Introducer Needle	Used for the percutaneous introduction of guidewires.
	Tunneler	Instrument used to create a subcutaneous tunnel
	Peelable Introducer	Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.
	End Cap	To protect and keep the catheter clean between treatments
Other devices or products intended for use in combination with the device	Name of Device or Product	Description of Device or Product
	Scalpel	A cutting device during surgical, pathology and minor medical procedures
	Tegaderm	Adhesive wound dressing intended to protect the catheter from contamination when not in use
	Syringe	Attached to introducer needle to help capture blood return once introducer needle perforates targeted vein, prevent air embolism

4. Risks and warnings

Residual risks and undesirable effects	<p>As per product IFU (IFU 40775-1BSI), All surgical procedures carry risk. Medcomp has implemented risk management processes to proactively find and mitigate these risks as far as possible without adversely affecting the benefit-risk profile of the device. After mitigation, residual risks and the possibility of adverse events from use of this product remain. Medcomp has determined that all residual risks are acceptable.</p>	
	Residual Harm Type	Possible Adverse Events Associated with Harm
	Bleeding	Bleeding (May be severe) Exsanguination Hematoma Retroperitoneal Bleed Hemorrhage Hemothorax Retroperitoneal bleed Subcutaneous hematoma
	Cardiac Event	Cardiac Arrhythmia Cardiac Tamponade
	Embolism	Air Embolus
	Infection	Bacteremia Endocarditis Exit Site Infection Septicemia Tunnel Infection
	Perforation	Inferior Vena Cava Puncture Laceration of the Vessel Perforation of the Vessel Pneumothorax Right Atrial Puncture Subclavian Artery Puncture Superior Vena Cava Puncture
	Thrombosis	Central Venous Thrombosis Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis
Miscellaneous Complications	Brachial Plexus Injury Femoral Nerve Damage Hemothorax Mediastinal injury Pleural Injury Pneumothorax Thoracic Duct Laceration Venous Stenosis	

	Patient Residual Harm Category	Quantification of Residual Risks	
		PMS Complaints (01 January 2019 – 31 March 2025)	PMCF Events
		Units Sold: 687	Units Studied: 0
		% of Devices	% of Devices
	Allergic Reaction	Not Reported	Not Reported
	Bleeding	Not Reported	Not Reported
	Cardiac Event	Not Reported	Not Reported
	Embolism	Not Reported	Not Reported
	Infection	Not Reported	Not Reported
	Perforation	Not Reported	Not Reported
	Stenosis	Not Reported	Not Reported
	Tissue Injury	Not Reported	Not Reported
	Thrombosis	Not Reported	Not Reported
Warnings and precautions	<p>All warnings have been reviewed against the risk analysis, PMS, and usability testing to validate consistency between the sources of information. As per product IFUs for all brands (IFU 40775-1BSI), the 6.5F Tesio® Catheter have the following warnings:</p> <ul style="list-style-type: none"> • Do not insert catheter in thrombosed vessels. • Do not advance the guidewire or catheter if unusual resistance is encountered. • Do not insert or withdraw the guidewire forcibly from any component. If the guidewire becomes damaged, guidewire and any associated componentry must be removed together. • Do not resterilize the catheter or accessories by any method. • Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE • Do not re-use catheter or accessories as there may be a failure to adequately clean and decontaminate the device which may lead to contamination, catheter degradation, device fatigue, or endotoxin reaction. • Do not use catheter or accessories if package is opened or damaged. • Do not use catheter or accessories if any sign of product damage is visible or the use-by date has passed. • Do not use sharp instruments near the extension tubing or catheter lumen. • Do not use scissors to remove dressing. <p>Precautions listed in the 6.5F Tesio® Catheter IFUs are as follows:</p> <ul style="list-style-type: none"> • Examine catheter lumen and extensions before and after each treatment for damage. • To prevent accidents, ensure the security of all caps and bloodline connections prior to and between treatments. • Use only Luer Lock (threaded) Connectors with this catheter. 		

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.
- Before attempting catheter insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.
- Repeated overtightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- The catheter will be damaged if clamps other than what is provided with this kit are used.
- Avoid clamping near the Luer Lock and hub of the catheter. Clamping of the tubing repeatedly in the same location may weaken tubing.

Additional warnings and cautions listed in the 6.5F Tesio® Catheter IFUs are as follows:

- Physician discretion is strongly advised when inserting this catheter in patients who are unable to take or hold a deep breath.
- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- The length of wire inserted is determined by the size of the patient. Monitor patient for signs of arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.
- DO NOT grasp and pull the guidewire prior to releasing the J-Straightener. Damage to the guidewire may occur if it is pulled against the restraint of the J-Straightener.
- DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.
- Never leave sheaths in place as indwelling catheters. Damage to the vein will occur.
- Do not tunnel through muscle.
- Assure that all air has been aspirated from catheter and the extensions. Failure to do so may result in air embolism.
- Failure to verify catheter placement may result in serious trauma or fatal complications.
- Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

	<ul style="list-style-type: none"> • Only clamp catheter with in-line clamps provided. • Extension clamps should only be open for aspiration, flushing, and dialysis treatment. • Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems. • Only a physician familiar with the appropriate techniques should attempt the following procedures. • Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients. • Do not use excessive force as this may break the catheter. If the catheter does not withdraw from the tunnel after moderate force has been applied, or the catheter is removed without the cuff, the following steps may be taken to remove the catheter. • Do not pull distal end of catheter through incision as contamination of wound may occur.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2020 to 31 March 2025 there were 0 complaints for 612 units sold, giving an overall complaint rate of 0.0%. There were no death related events. No events resulted in recalls during the review period.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

Summary of clinical data related to the subject device			
The below table displays the device insertion case numbers identified and used for clinical performance evaluation in each clinical data source.			
Clinical Literature	PMCF Data	Total Cases	User Survey Responses
37	0	37	0
<p>Clinical performance was measured using parameters including but not limited to dwell time, catheter insertion outcomes, and adverse event rates. Critical clinical parameters extracted from these studies met standards set forth in the guidelines for the State of the Art. There were no unforeseen adverse events or other high occurrences of adverse events detected in any of the clinical activities.</p> <p>Medcomp® catheters are subjected to, and must pass, simulated use testing intended to replicate use 3 times per week for 12 months as part of device development. The 6.5F Tesio® Catheter passed this testing. Although Medcomp® catheters contain no materials which degrade over time, fully functional catheters may be removed for other reasons, such as intractable infection, change of therapy (such as Renal replacement (transplant) or use of an arterio-venous graft/fistula). Published clinical literature does not always focus on the physical lifetime of a catheter for these reasons. In the case of the 6.5F Tesio® Catheter, 11 catheters had a median 244 day [Range: 1 - 344 days] duration of use that has been found in clinical use reported to date. Based on this information, the 6.5F Tesio® Catheter has a 12-</p>			

month lifetime; however, the decision to remove and/or replace the catheter should be based on clinical performance and need, and not any predetermined point in time.

Summary of clinical data related to the equivalent device (if applicable)

An equivalent device was not used for the device's clinical evaluation.

Summary of clinical data from pre-market investigations (if applicable)

No pre-market clinical devices were used for the device's clinical evaluation.

Summary of clinical data from other sources:

Source: Summary of Included Literature

Clinical evidence literature searches have found four published literature articles representing 37 6.5F Tesio® device family specific cases. The articles include two prospective studies (Musumeci et al., 2012, Graziano et al., 2014), one retrospective study (Sheth et al., 2001), and one case study (Duarte et al., 2021).

Bibliography:

Duarte, S.G.G., Alcántara, A., Russo, A., de Sosa, F., Percovich, A.E. (2021). Trans-cells of stent hemodialysis catheter placement in patients with exhausted central venous access Colocación de catéter de hemodiálisis transceldas de stent en paciente con agotamiento de acceso venoso, 73(1), 29

Graziano U, Severino G, Cardone M, Musumeci A, Pecoraro C. Central vascular access by tesio catheters (TC) for chronic hemodialysis in neonates and infants: Beyond the rules. *Pediatric Nephrology*. 2014;29(9):1760.

Musumeci A, Nuzzi F, Graziano U, et al. Use of tesio catheters in infants and children receiving chronic hemodialysis. *Pediatric Nephrology*. 2012;27(9):1801-1802.

Sheth RD, Kale AS, Brewer ED, Brandt ML, Nuchtern JG, Goldstein SL. Successful use of Tesio catheters in pediatric patients receiving chronic hemodialysis. *American journal of kidney diseases : the official journal of the National Kidney Foundation*. 2001;38(3):553-559.

Source: PMCF_Medcomp_211

The Medcomp User Survey acquired responses from healthcare personnel familiar with any number of Medcomp's product offerings.

28 respondents responded that they or their facility have used Medcomp long-term hemodialysis catheters; there were no respondents that have used the 6.5F Tesio® device. There were no differences in mean user sentiments within long-term hemodialysis catheters across State of the Art Performance and Safety Outcome Measures or between device types relating to safety or performance.

The following data points were collected from users of Medcomp long-term hemodialysis catheters (n=28):

- (Mean Likert Scale Response) Catheters function as intended – 4.8 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.8 / 5

- (Mean Likert Scale Response) Benefit outweighs the risk – 4.7 / 5
Dwell Time (n=26) – 167 days (95%CI: 130 – 203)

Overall summary of clinical safety and performance

Upon review of the 6.5F Tesio® Catheter data across all sources, it is possible to conclude that the benefits of the subject device, which is facilitating hemodialysis in patients in whom other therapies or conservative care are not indicated or desirable as determined by the physician, outweigh the overall and individual risks when the device is used as intended by the manufacturer. It is the manufacturer’s and clinical expert evaluator’s opinion that activities both complete and ongoing are sufficient to support the safety, efficacy, and acceptable benefit/risk profile of the 6.5F Tesio® catheters.

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 40 days	↑	244 days (median) (Summary of Included Literature)	ND***
Procedural Outcomes	Greater than 93.3%	↑	100% (Summary of Included Literature)	ND***
Safety				
Catheter Related Blood Stream Infection (CRBSI)	Less than 4.8 incidents of CRBSI per 1,000 catheter days	↓	1.63/1000 catheter days* (Summary of Included Literature)	ND***
Tunnel Infection Rate	Less than 2.8 incidents of tunnel infection per 1,000 catheter days	↓	0.06-2.28/1000 catheter days** (Summary of Included Literature)	ND***
Exit Site Infection Rate	Less than 3.2 incidents of exit site infection per 1,000 catheter days	↓	0.06-2.28/1000 catheter days** (Summary of Included Literature)	ND***
Catheter Associated Venous Thrombus (CAVT)	Less than 3.04 incidents of CAVT per 1,000 catheter days	↓	0.13/1000 catheter days* (Summary of Included Literature)	ND***

* Event rate is an estimate based on the information in the article

** Includes both Exit Site and Tunnel infection rates

*** ND = No data on the clinical outcome parameter

On-going or planned Post-Market Clinical Follow-up (PMCF)			
Activity	Description	Reference	Timeline
Multi-center Patient-Level Case Series	Collect additional clinical data on the device by acquiring case data healthcare personnel familiar with the device.	PMCF_LTHD_241	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of similar devices by reviewing applicable standards, published literature, conference abstracts, guidance documents and recommendations; information relating to the medical condition managed by the device and medical alternatives available for the same target treated population.	SAP-HD	Q2 2026
Clinical Evidence Literature Search	Identify risks and trends with use of the device by reviewing any clinical data relevant to the device from published literature.	LRP-HD	Q2 2026
Global Trial Database Search	Identify ongoing clinical trials involving 6.5F Tesio® catheters.	N/A	Q2 2026
No emerging risks, complications or unexpected device failures have been detected from PMCF activities.			

6. Possible therapeutic alternatives

The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 clinical practice guidelines have been used to support the below recommendations for treatments.

Alternatives for Hemodialysis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> Permanent vascular access solution Lower complication rate than hemodialysis via catheter 	<ul style="list-style-type: none"> Requires time to mature Patients must sometimes self-cannulate 	<ul style="list-style-type: none"> Stenosis Thrombosis Aneurysm Pulmonary hypertension Steal Syndrome Septicemia
Hemodialysis Catheter	<ul style="list-style-type: none"> Useful for quick vascular access without AV Fistula in place Can be used as a bridge dialysis method between other therapies 	<ul style="list-style-type: none"> Not a permanent solution Catheter dysfunction can disrupt regular treatment Benefit is not equal for all patient populations 	<ul style="list-style-type: none"> Post-procedural bleeding Infection Thrombosis Decreased blood flow in dysfunctional catheter Cardiovascular events Fibrin sheath formation around catheter Septicemia
Peritoneal Dialysis	<ul style="list-style-type: none"> Less restrictive diet than hemodialysis Does not require hospitalization, can be done in any clean place 	<ul style="list-style-type: none"> Clearance of impurities is limited by dialysate flow and peritoneal area 	<ul style="list-style-type: none"> Peritonitis Septicemia Fluid overload
Kidney Transplant	<ul style="list-style-type: none"> Better quality of life compared to HD Lower risk of death compared to HD Fewer dietary restrictions compared to HD 	<ul style="list-style-type: none"> Requires a donor which can take time More risky for certain groups (aged, diabetics, etc.) Patient must take rejection medication for life Rejection medication has side effects 	<ul style="list-style-type: none"> Thrombosis Hemorrhage Ureteral blockage Infection Organ rejection Death Myocardial infarction Stroke

Therapy	Benefits	Disadvantages	Key Risks
Comprehensive Conservative Care	<ul style="list-style-type: none"> • Less imposed symptom burden than dialysis • Preserves life satisfaction 	<ul style="list-style-type: none"> • May aggravate clinical condition • Not designed to treat, but to minimize adverse events 	<ul style="list-style-type: none"> • Treatment may not actually minimize risks associated with CKD

Alternatives for Pediatrics:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> • Preferred pediatric vascular access route • Better solute clearance • Lower complication rate than hemodialysis with a catheter • Lower risk of infection and thrombosis 	<ul style="list-style-type: none"> • Technical difficulty in fistula/graft creation in children with small vasculature • Not suitable for certain patient size 	<ul style="list-style-type: none"> • High tendency of vasospasm due to small vessels • Primary failure and early access thrombosis
Hemodialysis Catheter	<ul style="list-style-type: none"> • Great alternative in rapid onset of kidney failure and short period of time until transplantation • Ability to be used in the absence of needle cannulation • Decreased risk of high output cardiac failure 	<ul style="list-style-type: none"> • High infection rates • High failure/replacement rate • Variable blood flow rates leading to potentially poor clearance 	<ul style="list-style-type: none"> • Potential complications with significant morbidity and mortality • Possible Arrhythmia • Permanent damage to central venous system (stenosis/thrombosis) may occur
Peritoneal Dialysis	<ul style="list-style-type: none"> • Most suitable for children due to its almost universal applicability and superior compatibility with lifestyle 	<ul style="list-style-type: none"> • Long-term success is limited by infectious complications and gradual ultrafiltration failure 	<ul style="list-style-type: none"> • Catheter exit site and tunnel infection • Peritonitis

Therapy	Benefits	Disadvantages	Key Risks
	over other modalities		
Kidney Transplant	<ul style="list-style-type: none"> • Enhanced linear growth and potential for remarkable advances in social and intellectual development • Graft survival is about 12-15 years in children. 	<ul style="list-style-type: none"> • Increase in the lifetime risk of cancer for pediatric transplant recipients • Size – newborns and infants may not be large enough to receive a transplant. Patients need to be around 8-10 kg in size generally. 	<ul style="list-style-type: none"> • Infections, post-transplant lymphoproliferative disorders and malignancy • Graft rejection can be difficult to diagnose.

7. Suggested profile and training for users

The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. In certain circumstances, patients who may be suitable for home hemodialysis may manipulate the external connections of the catheter.

As per guidelines stated from the International Society of Hemodialysis, if home dialysis is recommended, each patient will undergo a thorough training in order to obtain optimal results from home dialysis treatments. The objectives of the training program are to (1) provide the appropriate amount of information to ensure that the patient will be able to dialyze safely at home; (2) enable the patient to monitor and manage other elements of his or her chronic kidney disease, such as obtaining samples for lab work and maintaining appropriate nutrition and diet; and (3) help the patient and his or her care partner(s) cope with barriers and fears associated with home HD. During training, the patient will also receive technical education on the operations and maintenance of the water treatment system.

During training, the ideal nurse trainer-to-patient ratio is typically 1:1. An idealized schedule of training is created, with weekly areas of focus and training objectives. In practice, however, training is individualized to address any identified learning barriers or risks for failure.

8. Reference to any harmonized standards and Common Specifications (CS) applied

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices	Full
EN ISO 10555-1	2013+A1:2017	Intravascular catheters. Sterile and single-use catheters. General requirements	Full
EN ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Central venous catheters	Full
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes	Full
MEDDEV 2.7/1	Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC	Full
EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-18	2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	Full
EN ISO 10993-7	2008+ A1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants	Full
EN ISO 11135	2014 + A1: 2019	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices	Full
ISO 14644-1	2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	Full
ISO 14644-2	2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices	Full
EN ISO 11737-1	2018 + A1: 2021	Sterilization of health care products. Microbiological methods. Determination of a population of microorganisms on products	Full
EN ISO 20417	2021	Medical Devices - Information supplied by the manufacturer	Full
EN ISO 15223-1	2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Full
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	Full
ISO 594-2	1998	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock Fittings	Full
80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications	Full
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
ASTM D4332-14	2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Full
ASTM D4169-16	2016	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
ASTM F2503-20	2020	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Full
EN ISO 11070	2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires	Full
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers	Full
MEDDEV 2.12/2	Rev. 2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		MANUFACTURERS AND NOTIFIED BODIES	
MDCG 2020-7	2020	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies	Full
MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies	Full
MDCG 2022-9	2022	Summary of safety and clinical performance	Full
MDCG 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Full
EN ISO 11138-1	2017	Sterilization of health care products — Biological indicators Part 1: General requirements	Full
ISO 11138-2	2017	Sterilization of health care products— Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes	Full
ISO 11138-7	2019	Sterilization of health care products. Biological indicators - Guidance for the selection, use and interpretation of results	Full
EN ISO 11140-1	2014	Sterilization of health care products — Chemical indicators Part 1: General requirements	Full
EN ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories	Full
Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council	Full

PATIENTS

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Revision: SSCP-010 Rev. 6

Date: 05SEP2025

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

IMPORTANT INFORMATION

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

This SSCP is not intended to replace an Implant Card or the Instructions for Use to provide information on the safe use of the device.

1. Device identification and general information

Device trade name(s)	6.5F Tesio® Catheter
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908281ND
Date first CE certificate was issued for this device	1997

The devices in scope of this document are all long-term hemodialysis catheter sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays. The procedure tray is a configuration including accessories.

Variant Devices:

Variant Description	Part Number
6.5F Tesio	1398 / 1399

Procedure Trays:

Catalog Code	Part Number	Description
PBFP	1398 / 1399	6.5F Tesio® Catheter Set (Arterial Cuff - 12cm From Tip) (Venous Cuff - 15cm From Tip)

Configurations of Procedure Trays:

Configuration Type
6.5F Tesio® Set

2. Intended use of the device

Intended purpose	6.5F Tesio® Catheters are intended for use in pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for single-use only.
Indication(s)	The 6.5F Tesio® Catheter is indicated for short-term or long-term use where vascular access is required for 14 days or more for the purpose of hemodialysis.
Intended patient group(s)	6.5F Tesio® Catheters are intended for use in pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician.
Contraindications	<ul style="list-style-type: none"> • Known or suspected allergies to any of the components of the catheter or the kit. • This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.

3. Device description

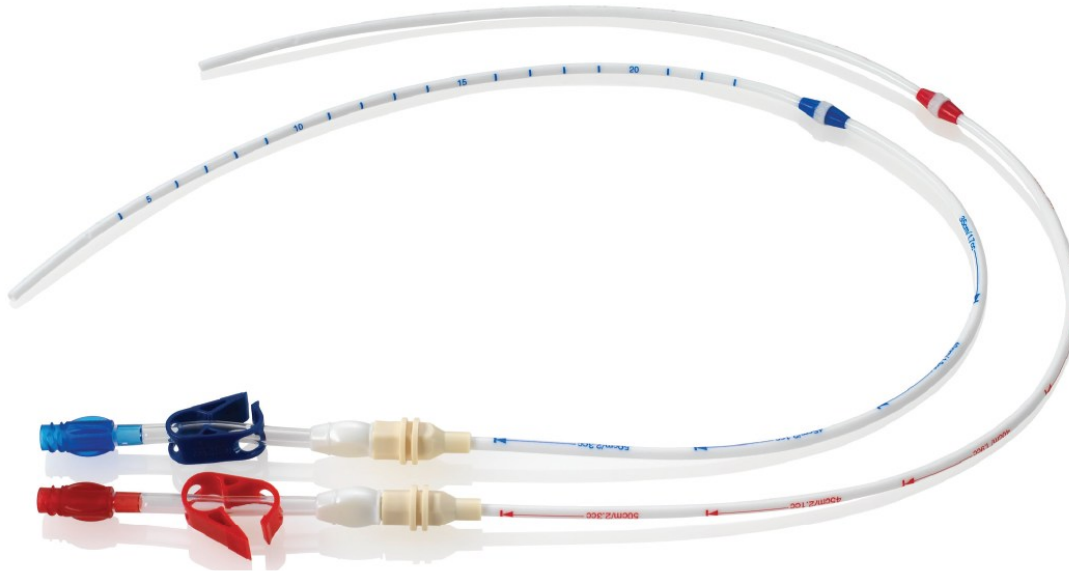


Figure 1: 6.5F Tesio Catheter

Description of device	The 6.5F Tesio® Catheter is a long-term catheter. The catheter is single tubed. Two catheters are inserted into the target vein. The catheters remove and return blood through two separate lines. Priming volumes are printed on the lumen.														
Materials / substances in contact with patient tissue	<p>The percentage below is based on catheter weight. The catheter weighs 9.47 grams.</p> <table border="1" data-bbox="652 1178 1302 1465"> <thead> <tr> <th>Material</th> <th>Weight % (w/w)</th> </tr> </thead> <tbody> <tr> <td>Polyvinyl chloride</td> <td>32.45</td> </tr> <tr> <td>Acetal copolymer</td> <td>40.63</td> </tr> <tr> <td>Polyurethane</td> <td>20.84</td> </tr> <tr> <td>Barium sulfate</td> <td>3.18</td> </tr> <tr> <td>Polyethylene terephthalate</td> <td>1.60</td> </tr> <tr> <td>Silicone</td> <td>1.30</td> </tr> </tbody> </table> <p>Note: The device should not be used if you are allergic to the above materials.</p> <p>Note: Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</p>	Material	Weight % (w/w)	Polyvinyl chloride	32.45	Acetal copolymer	40.63	Polyurethane	20.84	Barium sulfate	3.18	Polyethylene terephthalate	1.60	Silicone	1.30
Material	Weight % (w/w)														
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Information on medicinal substances in the device	N/A														
How the device achieves its intended mode of action	Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. This catheter has two separate tubes. The tubes go into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one tube of the catheter.														

	The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second tube. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis. Long-term access may occur in some cases. For example, when there are problems supporting an AV fistula or graft.	
Sterilization Information	Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.	
Description of accessories	Name of Accessory	Description of Accessory
	Guidewire	Acts as a path for other components.
	Guidewire Advancer	Helps guidewire introduction.
	Introducer Needle	Placed into the target vein to gain access.
	Tunneler	Creates a pocket in between muscle and skin for catheter.
	Peelable Introducer	Used to get central venous access.
	End Cap	To keep the catheter clean between treatments.

4. Risks and warnings

Contact your healthcare professional if you believe you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document does not replace a consultation with your healthcare professional if needed.

How potential risks have been controlled or managed	<p>There have been 612 devices sold since January 2020. There are side effects and risks associated with the device. These include:</p> <ul style="list-style-type: none"> • Infection • Bleeding • Catheter Removal • Catheter Replacement <p>These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is access for hemodialysis when alternatives are not suitable. These benefits outweigh the risks.</p>
Remaining risks and undesirable effects	<p>The 6.5F Tesio® catheter is associated with risks. These include:</p> <ul style="list-style-type: none"> • Procedural Delays • Thrombosis • Infections • Perforations

- Embolism
- Cardiac Event
- Dissatisfaction

These risks are consistent with risks of other dialysis catheters. They are not unique to the Medcomp product. Some of the most common reactions include infection. Infection may be associated with general surgical procedure and hospitalization. Infection may not always be device-related.

Patient Residual Harm Category	Quantification of Residual Risks	
	PMS Complaints (01 January 2019 – 31 March 2025)	Post Market Clinical Follow-Up Activity Events
	Units Sold: 687	Units Studied: 0
	# of Cases Per Event	# of Cases Per Event
Allergic Reaction	Not Reported.	Not Reported.
Bleeding	Not Reported.	Not Reported.
Cardiac Event	Not Reported.	Not Reported.
Embolism	Not Reported.	Not Reported.
Infection	Not Reported.	Not Reported.
Perforation	Not Reported.	Not Reported.
Stenosis	Not Reported.	Not Reported.
Tissue Injury	Not Reported.	Not Reported.
Thrombosis	Not Reported.	Not Reported.

Warnings and precautions

The below are warnings, precautions, or measures to be taken by patient:

- To reduce the risk of bacteria entering the catheter, wear a mask over your nose and mouth whenever the catheter is accessed.
- Keep the catheter dressing clean and dry. The dressing should be changed by a medical professional at each dialysis session.
- Avoid letting the catheter or catheter site go under water. Moisture near the catheter site can potentially lead to an infection.
- Ask the doctor to explain the signs and symptoms of catheter infection.

	<ul style="list-style-type: none"> • Never remove the cap at the end of the catheter. The cap and clamps of the catheter must be kept closed when not being used for dialysis.
Summary of any field safety correction action (FSCA)	There were no recalls for the device between 01 April 2024 to 31 March 2025.

5. Summary of clinical evaluation and post-market clinical follow-up

Clinical background of the device
<p>The 6.5F Tesio® was marketed previously as the 7F Tesio® catheter. The 6.5F Tesio® catheter has been available since 1997. The CE Mark was received in 1997. US FDA clearance was in February 1999. All models included are planned for distribution in the European Union.</p>
Clinical evidence for CE-marking
<p>The clinical literature review found 4 articles relating to the safety and/or performance of the subject device when used as intended. These articles include approximately 37 cases.</p> <p>Findings from the clinical literature support the performance of the subject device. All data on the 6.5F Tesio® catheter has been evaluated. The benefits of the subject device outweigh the risks when the device is used as intended. The benefit of the device is allowing hemodialysis in patients in whom other therapies or conservative care are not desirable by the physician.</p>
Safety
<p>There is sufficient data to prove conformity to the applicable requirements. The device is safe and performs as intended and claimed by Medcomp. The device is state of the art for allowing long-term vascular access for hemodialysis in pediatric patients.</p> <p>Medcomp has reviewed:</p> <ul style="list-style-type: none"> • Post-Market Data • Medcomp Information Materials • Risk Management Documentation <p>The risks are appropriately displayed and consistent with the state of the art. The risks associated with the device are acceptable when weighed against the benefits. There were 0 complaints for 612 units sold from 01 January 2020 to 31 March 2025. The complaint rate is 0.000%.</p>

6. Possible therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation. The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 clinical practice guidelines have been used to support the below recommendations for treatments.

Alternatives for Hemodialysis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> • Permanent solution. • Lower complication rate than catheter. 	<ul style="list-style-type: none"> • Requires time. • Patients must sometimes self-needle stick. 	<ul style="list-style-type: none"> • Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	<ul style="list-style-type: none"> • Useful for quick access. • Can be used as a bridge between therapies. 	<ul style="list-style-type: none"> • Not permanent. • Catheter dysfunction can happen. • Benefit may not be the same for everyone. 	<ul style="list-style-type: none"> • Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Peritoneal Dialysis	<ul style="list-style-type: none"> • Less restrictive diet than hemodialysis. • Does not require hospitalization. 	<ul style="list-style-type: none"> • Clearance of impurities is limited by flow and space. 	<ul style="list-style-type: none"> • Peritonitis • Septicemia • Fluid overload
Kidney Transplant	<ul style="list-style-type: none"> • Better quality of life. • Lower risk of death. • Fewer dietary restrictions. 	<ul style="list-style-type: none"> • Requires a donor. • More risky for certain groups. • Patient must take medication for life. • Medication has side effects. 	<ul style="list-style-type: none"> • Thrombosis • Hemorrhage • Ureteral blockage • Infection • Organ rejection • Death • Myocardial infarction • Stroke
Comprehensive Conservative Care	<ul style="list-style-type: none"> • Less imposed symptom burden. 	<ul style="list-style-type: none"> • May aggravate clinical condition. 	<ul style="list-style-type: none"> • Treatment may not actually minimize risks

Therapy	Benefits	Disadvantages	Key Risks
	<ul style="list-style-type: none"> Preserves life satisfaction. 	<ul style="list-style-type: none"> Not designed to treat. 	<ul style="list-style-type: none"> associated with CKD.

Alternatives for Pediatrics:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> Preferred pediatric vascular access. Better solute clearance. Lower complication rate than catheter. Lower risk of infection and thrombosis. 	<ul style="list-style-type: none"> Technical difficulty in children with small veins. Not suitable for certain patient size. 	<ul style="list-style-type: none"> High tendency of vasospasm due to small vessels. Primary failure and early access thrombosis.
Hemodialysis Catheter	<ul style="list-style-type: none"> Great alternative in rapid onset of kidney failure. Ability to be used in the absence of needle sticks. Decreased risk of cardiac failure. 	<ul style="list-style-type: none"> High infection rates. High failure/replacement rate. Potentially poor treatment. 	<ul style="list-style-type: none"> Potential complications with significant morbidity and mortality. Possible Arrhythmia Permanent damage to central venous system.
Peritoneal Dialysis	<ul style="list-style-type: none"> Most suitable for children. 	<ul style="list-style-type: none"> Long-term success is limited by infectious complications and gradual ultrafiltration failure. 	<ul style="list-style-type: none"> Catheter exit site and tunnel infection Peritonitis
Kidney Transplant	<ul style="list-style-type: none"> Enhanced linear growth and potential for remarkable advances in social and intellectual development. Graft survival is about 12-15 	<ul style="list-style-type: none"> Increase in the lifetime risk of cancer. Newborns and infants may not be large enough to receive a transplant. Patients need to be around 8-10 kg in size generally. 	<ul style="list-style-type: none"> Infections, post-transplant lymphoproliferative disorders and malignancy Graft rejection can be difficult to diagnose.

Therapy	Benefits	Disadvantages	Key Risks
	years in children.		

7. Suggested training for users

The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. In certain circumstances, patients who may be suitable for home hemodialysis may manipulate the external connections of the catheter.

Consult International Society of Hemodialysis guidelines. If home dialysis is recommended, you will undergo thorough training. The objectives of the training program are:

- 1) Give you information to dialyze safely at home.
- 2) Enable you to monitor and manage your disease.
- 3) Help you cope with fears and restrictions of home hemodialysis.

The ideal nurse trainer-to-patient ratio is typically 1:1. A training schedule will be created. Training will be individualized to your needs.

Abbreviation	Definition
AV	Arteriovenous
CE	Conformité Européenne (European Conformity)
CKD	Chronic Kidney Disease
cm	centimeter
CMR	Carcinogenic, mutagenic, reprotoxic
dba	Doing Business As
F	French (thickness of catheter)
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
KDOQI	Kidney Disease Outcomes Quality Initiative
PA	Pennsylvania
SSCP	Summary of Safety and Clinical Performance
USA	United States of America
w/w	Weight over Weight

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