Steam Sterilisation

The Gold Standard for Dialyzers

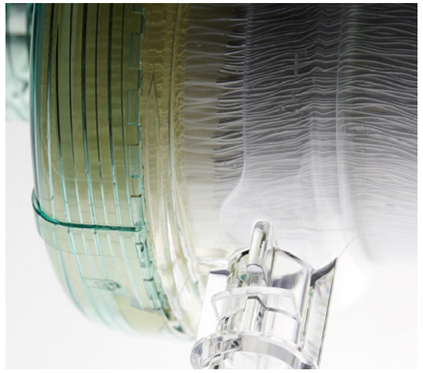
April 2026

Every dialysis session is an exposure—sterilisation method cannot be an afterthought

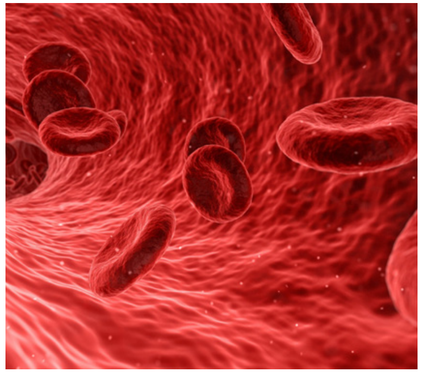
A standard haemodialysis patient undergoes treatment three times per week. The sterilisation method directly determines what chemical residues and biological contaminants the patient's blood encounters during each of these 156 annual sessions.

156

Dialyzer Exposures Per Year



Clearance Performance
Removal of Uremic Toxins



Biocompatibility
Minimising blood-surface contact effects

Material Toxicity
Safety constituent materials

Source: Haroon & Davenport, Hemodialysis International 2018 (ref.1); Allard et al., Le Pharmacien Hospitalier et Clinicien 2013 (ref.5)

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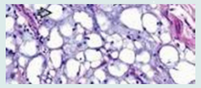
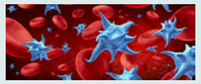
SUMMARY

Steam sterilisation delivers several evidence-based patient safety advantages

WHY

Steam sterilisation provokes less structural polymer degradation (as heat sterilisation is chemically inert).

HOW

	ADVANTAGE	CLINICAL IMPACT	REMEDIES
	**1.** Superior endothelial cell viability	CARDIOVASCULAR	↓ atherosclerosis/CV events ↓ transplant rejection
	**2.** Lower oxidative stress & DNA damage; No MDA release	REDUCED CANCER RISK	↓ anaemia ↑ immune function ↓ exposure
	**3.** Lower PVP elution (>80 % less) in blood	PVP STORAGE DISEASE	↓ bone destruction ↓ anaphylaxis ↓ bone marrow
	**4.** No thrombocytopenia risk	HAEMOSTASIS	↓ bleeding complications

WHAT

Reduced HEPARIN INTAKE:
Thanks to a reduced platelet activation & lower PVP elution, dialyzers are more hemocompatible & require less/no heparin intake.

GREEN DIALYSIS:
Steam sterilisation participates in ‘green dialysis’ as no ozone emission (Staff safety, environmental compliance, sustainability)

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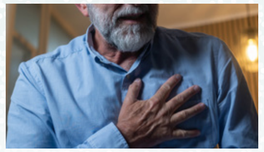
Steam sterilisation preserves endothelial cell viability (ECV) protecting patients from vascular disease progression

- Endothelial dysfunction is the first step in atherosclerosis. Steam-sterilised membranes have been found to improve Endothelial Cell (EC) viability compared to ETO or gamma-sterilised ones.
- No cytotoxic eluates damaging EC.

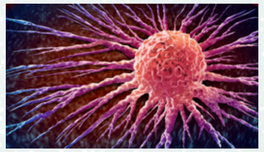
ACCELERATED ATHEROSCLEROSIS

Dialysis patients already carry elevated cardiovascular risk. A dialyser that damages endothelial cells actively accelerates plaque formation and arterial stiffening.



MI& STROKE RISK

Atherosclerosis progression directly increases the risk of acute cardiovascular events — the leading cause of death in the dialysis population



TUMOUR ANGIOGENESIS

Endothelial dysfunction promotes abnormal vascular growth, a prerequisite for tumour progression. Patients may face elevated oncological risk.

TRANSPLANT REJECTION

Endothelial dysfunction contributes to transplant rejection. Preserving EC integrity is directly relevant to transplant outcomes for waitlisted patients.

DIABETIC COMPLICATIONS

Dialysers that damage ECs compound vascular injury in diabetic patients, accelerating retinopathy, nephropathy, and peripheral vascular disease.

CHRONIC INFLAMMATION

Damaged ECs contribute to achronic pro-inflammatory state, associated with malnutrition, anaemia, and poor quality of life.

SUPERIOR ECV = REDUCED CARDIOVASCULAR RISK

Source: Haroon & Davenport, Hemodialysis International 2018 (ref.1); El Golli-Bennour et al., Int Urol Nephrol 2011 (ref.2)

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Steam sterilisation generates significantly less oxidative stress & DNA fragmentation

- Independent studies confirm that the sterilisation method directly determines the degree of genotoxic damage experienced by patients.
- No radiation-induced reactive species

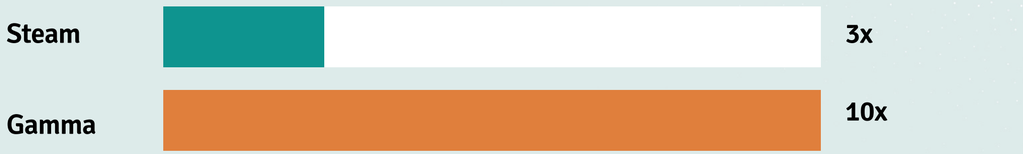
DNA Fragmentation (Post-Dialysis)

Lower is Better

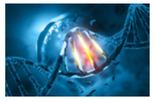
Gamma irradiation results in a ~40% relative increase in DNA damage compared to steam

MDA Levels (Lipid Peroxidation)

Relative to Healthy Baseline



Clinical Consequences



Cumulative DNA Damage & Cancer Risk

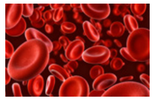
Repeated exposure to gamma-sterilised dialyzers (156 sessions/year) leads to substantial accumulation of genotoxic damage, raising long-term oncological risk.

Oxidative Stress & CVD

Elevated MDA accelerates atherosclerotic plaque instability and cardiovascular disease progression in an already high-risk population.

Cellular Ageing & Immunity

Oxidative stress accelerates cellular senescence and impairs immune function, contributing to high infection rates.



Anaemia Exacerbation

Oxidative damage to red blood cells increases haemolysis, worsening anaemia and increasing ESA requirements.

LESS DNA FRAGMENTATION = REDUCED CANCER RISK

Source: El Golli-Bennour et al., Int Urol Nephrol 2011 (ref.2); El Golli-Bennoura et al., World J Nephrol Urol 2017 (ref.3)

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Gamma irradiation releases a proven carcinogen from dialyzer potting material — steam does not

- Steam does not react with PU potting
- Recent Chinese studies seem to document that MDA leaching seems to remain tolerable

Gamma Irradiation

Polyurethane + Gamma Rays → MDA

Gamma irradiation induces chemical breakdown of polyurethane potting, producing 4,4'-methylenedianiline (MDA).

OUTCOME

Releases Carcinogen (MDA)

Production rises with dose

Steam Sterilisation

Polyurethane + Steam → No Reaction

Steam sterilisation uses heat and moisture and does not degrade polyurethane potting.

OUTCOME

NO MDA Detected

"MDA production NOT found in autoclave"

Direct Carcinogen Exposure

Gamma-sterilised filters can release MDA repeatedly over many sessions.

Regulatory & Liability Risk

A leachable carcinogen raises regulatory concerns versus safer options.

Double Genotoxic Insult

MDA exposure adds to observed DNA fragmentation in affected patients.

NO MDA RELEASE = REDUCED CANCER RISK

Source: Shintani & Nakamura, J Analytical Toxicology 1989 (ref.4); Allard et al., Le Pharmacien Hospitalier et Clinicien 2013 (ref.5) , Chen You (ref. 15)

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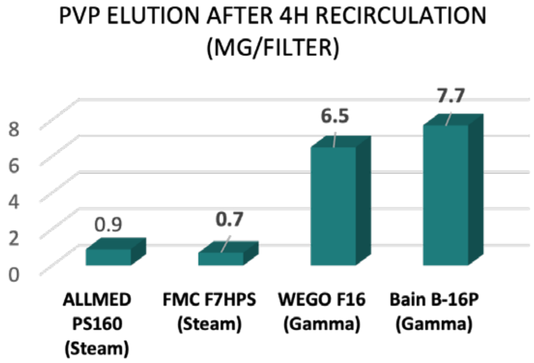
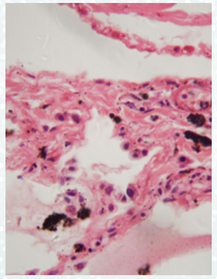
PVP is an allergenic compound that can trigger anaphylaxis & accumulate in organs — causing irreversible damage

- The sterilisation method has a dramatic effect on how much PVP is eluted from the membrane into the patient's blood during dialysis.
- A patient using a gamma-sterilised dialyser returns home after each session with significantly more PVP in their body than one using a steam-sterilised filter (releasing up to 7× more PVP into the patient's bloodstream).
- Heat sterilisation preserves the PVP chain integrity.

700% More PVP in the body after a Gamma session





Chronic Risk: PVP Storage Disease

High molecular weight PVP cannot be excreted from the body. It accumulates in histiocytes, leading to "PVP storage disease".

Consequences:	Bone destruction, skin lesions, arthritis, polyneuropathy, bone marrow failure, and myelofibrosis.
Systemic Impact:	Deposits found in kidney, bone marrow, GI tract, lymph nodes & skin.
Outcome:	Severe organ dysfunction and fatal outcomes in the most affected patients.

Acute Risk: Anaphylaxis

PVP is a recognised allergenic compound that can be released into the patient's circulation during haemodialysis.

Consequences:	Severe, life-threatening anaphylactic reactions induced by PSu-PVP membranes have been documented.
Systemic Impact:	Sensitisation can develop rapidly: cases documented after as few as 9 sessions with the same membrane.
Outcome:	Risk is directly proportional to the amount of PVP eluted.

GAMMA = PVP RELEASE = PVP STORAGE DISEASE & ANAPHYLAXIS

Source: Comparative Study on Elution of PVP on Dialyzers Using UV Analysis and Iodine Method, ASAIO Journal 2022 ASAIO Journal 2022; Nefrologia 2014; Hemodialysis International 2011; Am J Hematology 1998; Human Pathology 116

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E-beam sterilised dialysers are associated with significant thrombocytopenia — steam carries no such risk

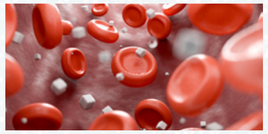
- Steam sterilization has no documented association with thrombocytopenia.
- E-beam induces platelet destruction.

EVIDENCE:

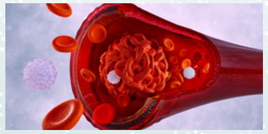
JAMA 2011 Cohort Study
Kiaii et al., Canada

> **“The use of e-beam sterilized dialyzers was associated with significant thrombocytopenia following dialysis.”**

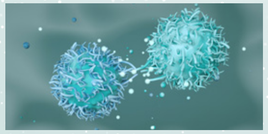
Significant Thrombocytopenia Defined:
Post-dialysis platelet count < 100×10^3 AND > 15% decrease in platelet count.



Bleeding Risk
Low platelet counts increase the risk of spontaneous bleeding, including GI haemorrhage and intracranial bleeding.



Haemostasis Impairment
Compromises clotting ability, creating risk during vascular access procedures, surgery, and trauma.



Diagnostic Confusion
Unexplained thrombocytopenia triggers costly haematological workups before the dialyser is identified as the cause.

E-BEAM = THROMBOCYTOPENIA = HAEMOSTASIS PROBLEMS

Source: Kiaii et al., JAMA 2011 (ref.6)

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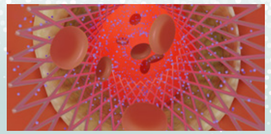
Steam-sterilising dialyzers reduces heparin intake

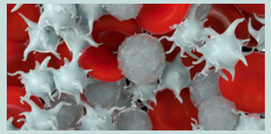
- **There is strong evidence, particularly from recent dialyzer studies, that **steam sterilisation** significantly improves the hemocompatibility profile of dialysis membranes. By reducing PVP elution and minimizing platelet activation, these dialyzers facilitate **reduced heparin requirements** and support safer **heparin-free** treatments compared to gamma-sterilised alternatives.**

OBSERVATIONS:



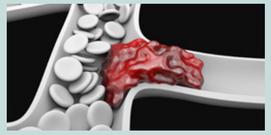
Lower PVP elution

Compared steam-sterilised with gamma-sterilised dialyzers and found significantly lower PVP elution in steam-sterilized models.



Reduced platelet activation

Showed lower complement activation and reduced platelet activation compared to conventional dialyzers.



Lower thrombogenicity

Steam-sterilized dialyzers show the lowest decrease in Activated Clotting Time (ACT), indicating the lower thrombogenicity.

CLINICAL IMPLICATIONS:

The improved hemocompatibility of steam-sterilized dialyzers allows clinicians to:

- Perform heparin-free dialysis more safely in patients at high risk of bleeding.
- Reduce the maintenance dose of heparin for chronic patients, potentially decreasing long-term side effects such as osteoporosis or lipid metabolism disturbances.
- Minimize dialyzer-induced thrombocytopenia, which is often triggered by PVP elution or ETO residues.

STEAM = IMPROVED HAEMOCOMPATIBILITY = REDUCED HEPARIN INTAKE

Source: Zawada et al. (2021) Compared steam-sterilized (FX CorAL) with gamma-sterilized dialyzers. Ehlerding et al. (2021) Randomized controlled trial (RCT) evaluating the FX CorAL dialyzer (steam-sterilized) Zawada et al. (2026) In vitro thrombogenicity evaluation of various dialyzers. Pachmann et al. (2025)** | Longitudinal study on heparin use in hemodialysis

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Irradiation sterilisation releases ozone into the atmosphere — steam does not

Gamma / E-Beam

Releases Ozone (O_3)

EMISSION

Steam Sterilisation

Physical Heat & Moisture

ZERO OZONE

The Ozone Paradox

"Good up high, bad nearby"

↑Stratospheric (Good)

Located 15-35km high. Acts as a shield, protecting life on Earth from harmful UV-B radiation. We want more of this.

↓Ground-Level (Bad)

Located where we breathe. A toxic super-pollutant formed by industrial processes (like irradiation) and traffic. We want less of this.

Human Health

Ground-level ozone permanently damages lung tissue and triggers asthma. It is responsible for an estimated 1 million premature deaths annually (CCAC).

Climate Impact

SLCP

Classified as a Short-Lived Climate Pollutant. It is a powerful greenhouse gas that warms the atmosphere significantly more than CO_2 in the short term.

Agriculture

A highly reactive oxidant that reduces crop yields by impeding photosynthesis. It costs the global economy tens of millions of tons in lost food production.

STEAM STERILISATION = GREENER DIALYSIS AS NO OZONE EMISSION (Staff safety, environmental compliance, sustainability)

Source: Climate & Clean Air Coalition (CCAC); WHO Air Quality Guidelines

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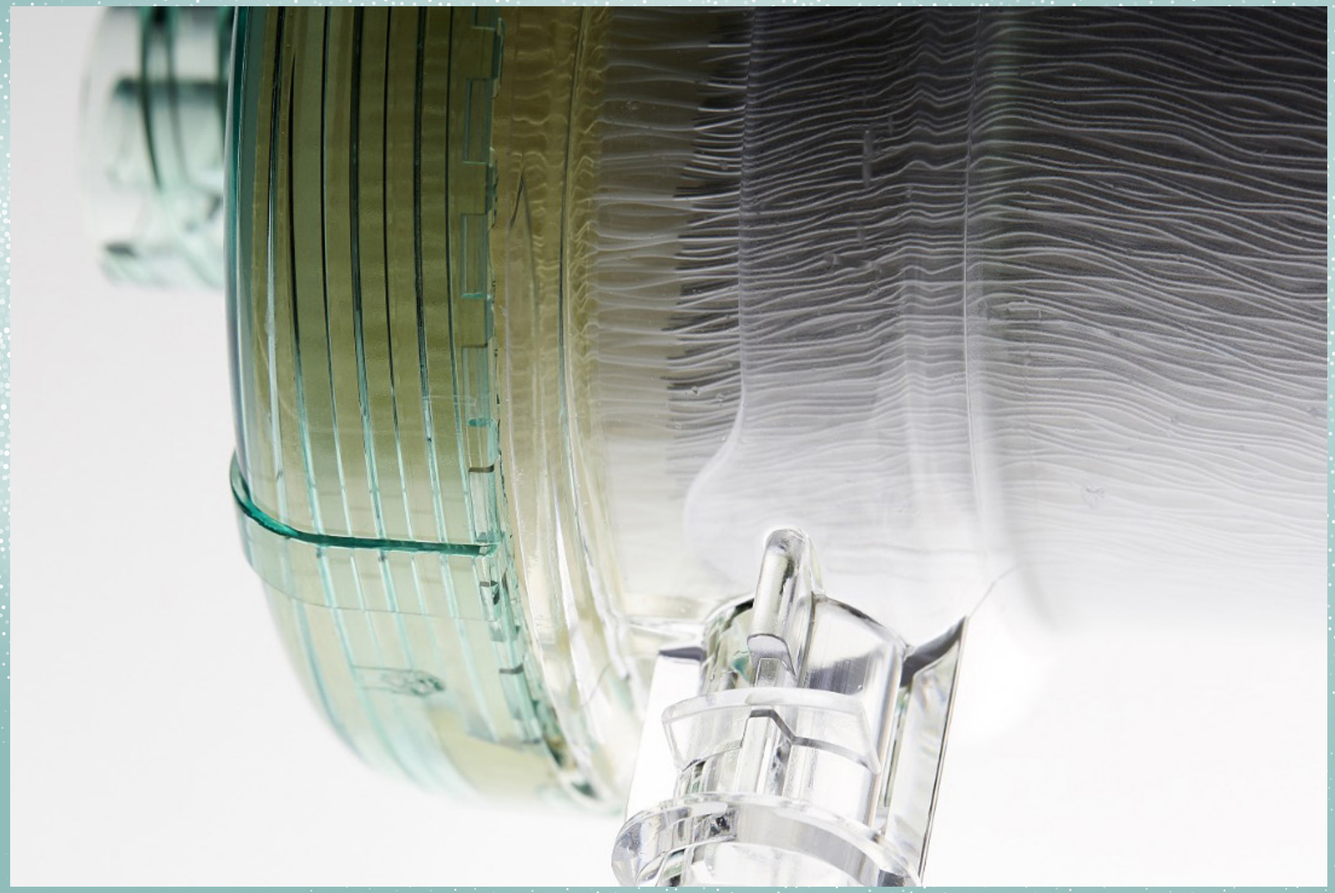
Back-Up



Gamma irradiation structurally degrades dialyser polymers — steam sterilisation leaves membrane integrity intact

Radiation sterilisation physically and chemically alters the polymers that constitute the dialyser membrane and housing. Steam sterilisation achieves sterility without structural modification.

POLYMER	GAMMA IRRADIATION EFFECT
Polysulfone (PSU)	Simultaneous chemical bridging AND splitting reactions above 25 kGy.
Polyurethane (PUR)	Release of mutagenic compounds, especially from aromatic polyurethane.
PAN Membranes	Increased permeability of high molecular weight molecules.
PMMA	Splitting of molecular structure; decreased permeability of high MW molecules.
PVC	Splitting, browning, hydrochloric acid release, unpleasant smell, accelerated ageing.
Polyethylene (EVAL)	Chemical bridging; release of hydrocarbon aldehydes and organic acids.
Polycarbonate	Browning (visual indication of degradation).

ALTERED PERMEABILITY

Structural changes in membranes change pore size and selectivity, potentially allowing passage of molecules that should be retained.

CYTOTOXIC RELEASE

Splitting reactions release fragments and by-products into the blood circuit, contributing to oxidative stress.

ACCELERATED AGEING

Gamma irradiation compromises the mechanical integrity and performance consistency of the dialyser.

The Steam Advantage

Steam sterilisation is chemically inert. It is the reference for security of thermostable materials and removes manufacturing waste—something irradiation cannot do.

Source: Allard et al., Le Pharmacien Hospitalier et Clinicien 2013 (ref.5); Uhlenbusch-Körver et al.

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Most dialyzers are sterilised by irradiation — steam is the clinically superior minority

PRODUCER	DIALYZER FAMILY	STERILISATION
Allmed	**POLYPURE, VAPURE, BIOREMA series**	**BIOSTEAM**
Fresenius	FX series	In-line Steam
Baxter	Polyflux / Revaclear	Steam (strongly reduced market presence)
Fresenius	Optiflux	E-Beam
Serumwerk	VitaPES	E-Beam
Nipro	Elisio / Surelyzer	Gamma
BBraun	Diacap / Xevonta	Gamma
Asahi	APS / VitabranE-ViE	Gamma
Toray	Toraysulfone	Gamma
Bain	Dora	Gamma
Wego	PS series F, MF, HF	Gamma

Method:	Steam	Gamma	ETO
Chemical Residues:	None	None	Potential for allergic reactions
Polymer Degradation:	Minimal	High (PVP elution	Low
Hemocompatibility:	Excellent	Moderate	Variable
Heparin Need:	Lowered	Standard	Standard

STEAM STERILISATION IS THE GOLD STANDARD THAT THE MAJORITY OF THE MARKET HAS NOT ADOPTED

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Independent peer-reviewed research consistently concludes: steam is the preferred sterilisation method for dialysers

STUDY / YEAR	JOURNAL	KEY CONCLUSION
Haroon & Davenport 2018	Hemodialysis International	Steam membranes improve endothelial cell viability vs ETO and Gamma
El Golli-Bennour et al. 2011	Int Urol Nephrol	Steam-sterilisation may improve biocompatibility of PS membranes
El Golli-Bennoura et al. 2017	World J Nephrol Urol	Steam offers considerable safety advantages compared to gamma
Shintani & Nakamura 1989	J Analytical Toxicology	MDA releases carcinogen, which is NOT produced in autoclave sterilisation
Allard et al. 2013	Le Pharmacien Hospitalier	Moist heat sterilization to be favoured for dialyzers with equivalent performance
Kiaii et al. 2011	JAMA	E-beam-sterilised dialyzers associated with significant thrombocytopenia
Allmed / ASAIO 022	ASAIO Journal	Steam-sterilised dialyzers release appr. 7 times less PVP than gamma-sterilized equivalents

Other References

1.	**Haroon S, Davenport A.** Haemodialysis membranes: The importance of the sterilisation method. Hemodialysis International. 2018.
2.	**El Golli-Bennour K et al.** Cytotoxicity of modified polysulfone membranes sterilised by steam and gamma irradiation. Int Urol Nephrol. 2011.
3.	**El Golli-Bennour K et al.** Genotoxicity of sterilization methods: A comparative study. World J Nephrol Urol. 2017.
4.	**Shintani H, Nakamura A.** Formation of 4,4'-methylenedianiline in polyurethane potting materials by gamma-ray irradiation. J Analytical Toxicology. 1989.
5.	**Allard et al.** Impact of sterilization on the physicochemical properties of hemodialysis membranes. Le Pharmacien Hospitalier et Clinicien. 2013.
6.	**Zawada et al. (2021)** Compared steam-sterilized (FX CorAL) with gamma-sterilized dialyzers.
7.	**Ehlerding et al. (2021)** Randomized controlled trial (RCT) evaluating the FX CorAL dialyzer (steam-sterilized)
8.	**Kiaii M et al.)** A prospective cohort study of the association between e-beam sterilized dialyzers and thrombocytopenia. JAMA. 2011.
9.	**GIPA & iia.** A comparison of sterilization methods for medical devices. White Paper. August 2017.
10.	**Namekawa K et al.** PVP elution from polysulfone membranes: Impact of sterilization. ASAIO Journal. 2022.
11.	**Müller TF et al.** Biocompatibility of steam-sterilized vs. gamma-sterilized polysulfone membranes. Nefrologia. 2014.
12.	**Uhlenbusch-Körver et al.** Understanding polymer degradation in sterilization processes. Biomaterials. 2010.
13.	**Zawada et al. (2026)** In vitro thrombogenicity evaluation of various dialyzers.
14.	**Pachmann et al. (2025)** Longitudinal study on heparin use in hemodialysis
15.	**Chen Yun et al. (2025)** The acceptable impact

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Thank you