SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-001

(4.0% and 30.0%) DuraLock-C® Catheter Lock Solution

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	10010, 16012
'MDR Documentation' File Number	TD-001

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**07JUN2021**	**26258**	**GM**	**Implementation of SSCP**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					by the Notified Body as this is a Class IIa or IIb implantable device
2	**16DEC2021**	**26669**	**GM**	**Updated Sections 4, 5, 6 with up to date statistics**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
3	**22AUG2022**	**27204**	**GM**	**Update per 3556675 – Clinical Review - Medical Comp - MDR 734736**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ 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
4	**07MAR2023**	**27870**	**GM**	**Update to QA-CL-200-1 Version 3.00 Template; Aligning Content to 4% DuraLock-C Configuration**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
5	**07MAR2023**	**27871**	**GM**	**Addition of Higher Concentrations of DuraLock-C (30.0% and 46.7%) and accompanying clinical evidence (e.g., summary of published literature, PMCF_DLOCK_211)**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
6	**14AUG2023**	**28369**	**GM**	**Periodic Update in Accordance with CER-001 Rev. E**	☐ Yes, this version was validated by the Notified Body in the following

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
7	**24OCT2023**	**28578**	**GM**	**Update in accordance with MEB review and CER-001 Rev E.1**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
8	**03JUN2024**	**29130**	**GM**	**Update in accordance with MEB review and CER-001 Rev F; 46.7% DuraLock-C® has been discontinued**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					Body as this is a Class IIa or IIb implantable device
9	**23JUL2024**	**29262**	**GM**	**Update in accordance with MEB review**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
10	**29AUG2024**	**29342**	**GM**	**Inclusion of PMCIR-003 Results**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ 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
11	**15JUL2025**	**25-0016**	**GM**	**Periodic Update in Accordance with CER-001 Rev. G**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ 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.

1. Device identification and general information

Device trade name(s)	4.0% DuraLock-C® Catheter Lock Solution 30.0% DuraLock-C® Catheter Lock Solution
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	00884908100ME
Medical device nomenclature description / text	A02010701 – Prefilled Syringes with Sterile Physiological Solution
Class of device	Class III according to Rule 14 of Annex VIII of the European Medical Device Regulation EU (MDR) 2017/745
Date first CE certificate was issued for this device	(4.0%and 30.0%) DuraLock-C was originally sold in ampoules. 30.0% DuraLock-C was first CE marked by DNV in October 2008, and 4.0% DuraLock-C was first CE marked by DNV in September 2010. (4.0% and 30.0%) DuraLock-C was then put into pre-filled syringes. All (3) concentrations of DuraLock-C pre-filled syringes obtained CE mark in August 2012 under DNV. Currently, the Notified Body is BSI. (4.0% and 30.0%) DuraLock-C is now only sold in syringes.
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

This SSCP covers the following devices:

Catalog Code	Description
PFDLC504	4.0% DuraLock-C® Catheter Lock Solution 4.0% Trisodium Citrate Dihydrate
PFDLC530	30.0% DuraLock-C® Catheter Lock Solution 30.0% Trisodium Citrate Dihydrate

2. Intended use of the device

Intended purpose	(4.0% and 30.0%) DuraLock-C® Catheter Lock Solution is intended for use in adult patients with an implanted hemodialysis catheter that is in regular use and where a solution occupying the “dead space” of the lumen between treatments to maintain catheter patency is required, based on the direction of a qualified health professional. DuraLock-C® Catheter Lock Solution is intended to be aspirated prior to treatment and should not be injected into the bloodstream.
Indication(s)	(4.0% and 30.0%) DuraLock-C® Catheter Lock Solution is indicated for use in maintaining patency of Hemodialysis Catheters.
Target population(s)	(4.0% and 30.0%) DuraLock-C® Catheter Lock Solution is intended for use in adult patients with an implanted hemodialysis catheter who require a catheter locking solution regardless of gender or race and who do not have any contraindications. (4.0% and 30.0%) DuraLock-C® Catheter Lock Solution is not intended for use in pediatric patients.
Contraindications and/or limitations	Patients with known or suspected allergies or hypersensitivity to trisodium citrate.

3. Device description

Figure 1: Picture of DuraLock-C® 4.0% and 30.0% Syringes

Description of device	DuraLock-C® Catheter Lock Solution is supplied as a clear, plastic, prefilled syringe, packaged in a pouch. Each DuraLock-C® prefilled syringe contains a sterile, clear and colorless solution containing sodium citrate; pH is adjusted with citric acid. DuraLock-C® Catheter Lock Solution is intended for short-term use, between 24 hours – 72 hours, as a catheter lock solution. The trisodium citrate within Duralock-C® Catheter Lock Solution prevents thrombus formation by chelating ionized calcium into a soluble complex. Calcium is an integral ion involved in the clotting cascade. Local calcium removal by citrate prevents the activation of clotting cofactors, factor X and prothrombin and the ultimate formation of fibrin. Systemic anticoagulation does not occur. Contents are sterile and non-pyrogenic in unopened, undamaged package. Sterilized by gamma irradiation.

		DuraLock-C® 4.0%	**DuraLock-C® 30.0%**
	Composition	Pouch Contains: (2) 3mL Syringes w/ 2.5mL Trisodium Citrate Dihydrate 40mg/mL Solution Contains: Trisodium Citrate Dihydrate, Citric Acid Anhydrous, Water	Pouch Contains: (2) 3mL Syringes w/ 2.5mL Trisodium Citrate Dihydrate 300mg/mL Solution Contains: Trisodium Citrate Dihydrate, Citric Acid Anhydrous, Water
		Sterile, clear and colorless solution containing sodium citrate Supplied as a clear, plastic, prefilled syringe, packaged in a pouch	
	pH	pH is adjusted with citric acid.	

	Name of previous generation	Differences from current device
Previous generations / variants	DuraLock-C® Catheter Lock Solution	DuraLock-C® was originally sold in 5 mL ampoules. The devices have been sold as pre-filled syringes since August 2012.
	46.7% DuraLock-C®	46.7% DuraLock-C® was discontinued in May 2024. Clinical evaluation of the product will continue for the device through the shelf life and expected lifetime of the device, concluding after 09 February 2026.
Accessories intended for use in combination with DuraLock-C 4.0% and 30.0%	Name of Accessory	Description of Accessory
	N/A	N/A
Other devices or products intended for use in combination with DuraLock-C	Name of Device or Product	Description of Device or Product
	N/A	N/A

4. Risks and warnings

Residual risks and undesirable effects	Complications and serious adverse events associated with the use of Duralock-C® Catheter Lock Solution are rare and are often related to inadvertent direct infusion of the product through failure to follow instructions for use carefully, especially with respect to priming volumes. Complications of the trisodium citrate within Duralock-C® Catheter Lock Solution are primarily due to systemic effects of hypocalcemia. Systemic hypocalcemia and other citrate-induced metabolic abnormalities may affect cardiac function and may cause severe cardiac arrhythmias. Major bleeding may also occur. Patients in whom Duralock-C® Catheter Lock Solution is often used commonly suffer from end stage renal disease, the presence of which may

alter circulating calcium levels, and thus the effect of trisodium citrate infusion may be more pronounced than in a healthy individual.

Despite instillation of catheter lock solution in line with the user instructions, some spillage of catheter lock solution might occur resulting in side-effects that are transient and generally mild. Inadvertent over injection has been associated with severe cardiac arrhythmias and should be avoided. 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. This should be weighed against the expected clinical benefit of the DuraLock-C® Catheter Lock Solution.

Residual Harm Type	**Possible Adverse Events Associated with Harm**
Adverse Reaction*	Dysgeusia Hypotension Paresthesia Perioral Numbness
Air Embolism	Air Embolus
Allergic Reaction	Allergic Reaction Intolerance Reaction to Implanted Device
Bleeding	Bleeding Systemic Anticoagulation Unexplained Thrombopenia
Cardiac Event	Cardiac Arrest Cardiac Arrhythmia Cardiac Event
Infection	Bacteremia Septicemia
Thrombosis	Catheter Obstruction Central Venous Thrombosis Fibrin Sheath Formation Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis
Miscellaneous Complications	Muscle Cramps Nausea Seizure Tetany Risks Normally Associated with Vascular Access User Injury

Possible side effects related to the trisodium citrate within DuraLock-C® Catheter Lock Solution are transient in nature, immediately following instillation of the solution and generally lasting 1 – 3 minutes and include:

- tingling fingers (paresthesia)

- metallic tastes (dysgeusia)
- perioral numbness
- hypotension

These side effects have been reported at rates as low as 1.1 per 1,000 catheter days and as high as 3.72 per 1,000 catheter days in published literature.

Serious adverse events, including cardiac arrhythmias, have been reported rarely.

Patient Residual Harm Category	4.0% DuraLock-C® Quantification of Residual Risks	
	PMS Complaints (01 January 2019 – 30 April 2025)	PMCF Events
	Units Sold: 5,971,879	Units Studied: 13,647*** Catheter Cases: 161
	% of Devices	% of Devices
Adverse Reaction**	Not Reported	0.073%
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	0.029%
Thrombosis	Not Reported	0.103%

***All adverse reaction events are "Hypotension" reported from PMCF activity PMCF_DLOCK_214. It is not known whether these related to the instillation of DuraLock-C®.*
****Exact number of instillations (units studied) from PMCF activity PMCIR-003 is an estimate based on the formula "catheter days / 3".*

Patient Residual Harm Category	30.0% DuraLock-C® Quantification of Residual Risks	
	PMS Complaints (01 January 2019 – 30 April 2025)	PMCF Events
	Units Sold: 5,758,079	Units Studied: 509,982*** Catheter Cases: 11,006
	% of Devices	% of Devices
Adverse Reaction**	Not Reported	0.039%
Allergic Reaction	Not Reported	0.002%
Bleeding	0.00002%	0.012%
Cardiac Event	Not Reported	0.001%
Embolism	Not Reported	0.0002%
Infection	Not Reported	0.21%
Thrombosis	Not Reported	0.398%

***Adverse reaction events include "Hypotension" reported from PMCF activity PMCF_DLOCK_214 and "Paresthesia" reported from PMCF activity PMCIR-003. It is not known whether these related to the instillation of DuraLock-C®.*
****Exact number of instillations (units studied) from PMCF activity PMCF_DLOCK_211 and PMCIR-003 is an estimate based on the formula "catheter days / 3".*

Warnings and precautions	All warnings and precautions have been reviewed against the risk analysis, PMS, and usability testing to validate consistency between the sources of information. Warnings listed in the DuraLock-C® Catheter Lock Solution IFUs are as follows: • Do not inject catheter lock solution into the bloodstream. Inadvertent intravenous administration of DuraLock-C® can result in serious adverse events as described in 'POTENTIAL COMPLICATIONS'. Only in the event locking solution cannot be aspirated due to catheter dysfunction despite maximal efforts, an attempt to inject 0.1 to 0.2 ml of the luminal content of DuraLock-C® may be carefully considered, but only at a slow rate over **several minutes** while carefully monitoring the patient. This should be followed by further attempts to aspirate the catheter lock solution (see last bullet point of Warnings). • Do not use when exact catheter lumen volumes are not known. • Do not inject more of the solution than the known volume of the catheter lumen. • Do not apply by direct intravenous injection or added to an infusion. • Do not use if prefilled syringe solutions show haziness, particulate matter, precipitate, discoloration, or leakage. • Do not use if the cap on the syringe is not intact or damaged. • Do not use if package is opened or damaged or the expiration date located on pouch and syringe label has passed. • Do not re-use. Single use only. Re-use of single use devices creates a potential risk of contamination. This may lead to patient infection, which may cause illness or death of the patient or user. • Do not flush existing catheter lock solution into the patient. Only in the event locking solution cannot be aspirated due to catheter dysfunction despite maximal efforts, an attempt to inject 0.1 to 0.2 ml of the luminal content of DuraLock-C® may be carefully considered, but only at a slow rate over **a minute** while carefully monitoring the patient. This should be followed by further attempts to aspirate the catheter lock solution. If both lumens cannot be aspirated, leave several minutes between the first and the second lumen. If the patient mentions side effects as described in 'POSSIBLE SIDE EFFECTS' the injection should be stopped. Precautions listed in the DuraLock-C® Catheter Lock Solution IFUs are as follows: • For patients with severe liver failure or significantly reduced muscle perfusion, consider one or a combination of the following interventions: using lower concentrations of trisodium citrate, implementing close monitoring for diminished citrate clearance, or employing an alternative locking solution. Medical consultation is strongly recommended in these cases. • In patients with hypocalcemia or hypomagnesemia, 30.0% DuraLock-C® has to be used cautiously. Consider one or a combination of the following interventions: using lower concentrations of trisodium citrate or employing an

	alternative locking solution (Honore et al., 2018). Medical consultation is strongly recommended in these cases. • If a patient reports side effects listed in the 'POSSIBLE SIDE EFFECTS' section, these symptoms could be due to a reduced effective priming volume of the catheter, possibly caused by biofilm or tip thrombus. In such cases, consider gradually reducing the locking volume by 0.1mL per session and continue to monitor the patient for symptoms. • If catheter is not sufficiently locked, clots can form and thrombosis may occur. • For use with adult patients only. • Use aseptic technique. • For prescription use only and to be used by a skilled or trained medical professional only. • Before using, ensure that catheter lumen, extensions and luer do not contain cracks, swelling or other signs of damage before and after each treatment session. • If skin contact occurs, clean per facility's procedures. • Based on experimental animal studies and limited human experience, citric acid is not expected to increase the risk of birth defects (Reprotox 2020). It should be noted, however, that DuraLock-C® has not been tested in pregnant and/or lactating women.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	The overall complaints / sales numbers for a period of 01 May 2024 to 30 April 2025 for DuraLock-C® Catheter Lock Solution are listed below by concentration: 4.0% DuraLock-C®: There were 0 complaints for 1,579,564 units sold, giving an overall complaint rate of 0.000%. 30.0% DuraLock-C®: There were 0 complaints for 177,340 units sold, giving an overall complaint rate of 0.000%. 46.7% DuraLock-C®: There were 2 complaints for 78,660 units sold, giving an overall complaint rate of 0.0002%. For a period from 01 May 2024 to 30 April 2025, there were 0 reportable events (none reported in the EU region). There were no death-related events. No events resulted in field safety corrective actions or 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

Concentration	Clinical Literature	PMCF Data	Total Cases	User Survey Responses
4.0% DuraLock-C®	0	161	161	27
30.0% DuraLock-C®	10,689	11,006	11,006*	31

**The 10,689 cases from PMCF_DLOCK_214 and Miller et al., 2025 are from the same study, but are represented in both the clinical literature and PMCF data.*

The case numbers above are representative of the total number of catheters that were used in conjunction with DuraLock-C® Catheter Lock Solution. It is estimated that the results of PMCF activities are based on 13,647 4.0% DuraLock-C® instillations and 509,982 30.0% DuraLock-C® instillations.

Clinical performance and safety were measured using parameters including but not limited to dwell time and adverse event rates. There were no unforeseen adverse events or other high occurrences of adverse events detected in any of the clinical activities.

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 Published Literature

Clinical evidence literature searches have found no articles relating to DuraLock-C® 4.0% and one retrospective study (Miller et al., 2025) relating to DuraLock-C® 30.0% representing 10,689 specific cases. Miller et al., 2025 analyzes the same cases as PMCF_DLOCK_214. Three published literature articles are known to the manufacturer representing 303 46.7% DuraLock-C® (discontinued in May 2024) specific cases. The articles include two randomized controlled trials (Power et al., 2009, Hermite et al., 2012) and one retrospective cohort study (Parienti et al., 2014).

Bibliography:

Hermite L, Quenot J-P, Nadji A, et al. Sodium citrate versus saline catheter locks for non-tunneled hemodialysis central venous catheters in critically ill adults: a randomized controlled trial. *Intensive Care Med*. 2012;38(2):279-285. doi:10.1007/s00134-011-2422-y

Miller, G., Feuersenger, A., Ogujiofor, K., Arens, H. J., Blanco, M., Fatima, R., & Zabaleta, I. (2025). Adverse Events in Hemodialysis Patients With Venous Catheters Locked With 30% Trisodium Citrate Versus Alternative Locking Solutions. *Hemodialysis International*.

Parienti J-J, Deryckère S, Mégarbane B, et al. Quasi-experimental study of sodium citrate locks and the risk of acute hemodialysis catheter infection among critically ill patients. *Antimicrob Agents Chemother*. 2014;58(10):5666-5672. doi:10.1128/AAC.03079-14

Power A, Duncan N, Singh SK, et al. Sodium citrate versus heparin catheter locks for cuffed central venous catheters: a single center randomized controlled trial. Am J Kidney Dis 2009;53:1034–41.

Source: PMCF_DLOCK_211

The Netherlands 2021A data report is intended to assess safety and performance outcome information from collected data on Medcomp Long-Term Hemodialysis Catheters, Short-Term Hemodialysis Catheters, and 30.0% Duralock-C Locking Solution for use in EU MDR clinical evaluation. These outcome measures include dwell time, reasons for removal, exit site infection rates, catheter related blood stream infection (CRBSI) rates, and catheter associated venous

thrombosis (CAVT) rates. Product family identification information was also included in the collected data. The dataset was provided by Marcel C. Weijmer, MD, PhD the head of the Department of Internal Medicine and Nephrology at OLVG located in Amsterdam, Netherlands. The dataset is comprised of consecutive cases from January 2010 to October 2019.

At least partial data was collected on 315 catheters that were routinely locked with 30.0% Duralock-C Catheter Lock Solution. 27 of these catheters were long-term (tunneled, cuffed) hemodialysis catheters, and 288 were short-term (nontunneled, uncuffed) hemodialysis catheters. The rate of catheter related blood stream infection was 0.48 per 1,000 catheter days in the long-term hemodialysis catheter cohort, and 0.73 per 1,000 catheter days in the short-term hemodialysis catheter cohort. The report equated catheter associated venous thrombus rates to the number of urokinase lock incidents found in the database, which allowed for a catheter associated venous rate of 1.79 per 1,000 catheter days in the long-term hemodialysis catheter cohort, and 4.90 per 1,000 catheter days in the short-term hemodialysis catheter cohort. The dataset focused on flow problems, and not the etiology of those problems – which may have arisen from tip malposition, tip migration, catheter kinking, fibrin sheath formation or thrombus formation.

Source: PMCF_DLOCK_214

The Duralock-C EuCliD (European Clinical Patient Surveillance Database) Data Collection report is intended to assess collected performance outcome information and review existing safety information on 4.0% and 30.0% DuraLock-C Catheter Lock Solution for use in EU MDR clinical evaluation. EuCliD is maintained by Fresenius Medical Care.

Real-world performance data on the use of DuraLock-C Locking Solution was measured against potential acceptance criteria derived from State of the Art safety and performance outcome measures from published literature. These acceptance criteria were based on non-inferiority to the worst-case margin of the confidence interval of outcome-data from literature, and therefore reflect the lowest level of acceptability. The majority of information was specific to DuraLock-C 30.0% (18,162 catheters in 10,689 patients), but also included significant numbers relating to DuraLock-C 4.0% (217 catheters in 157 patients) and the discontinued DuraLock-C 46.7% (206 catheters in 143 patients). This information was also compared to a large data set relating to the use of non-DuraLock-C catheter lock solution (65,144 catheters in 40,554 patients). Overall, this report summarizes information relating to 9,682,587 catheter days and 3,461,027 catheter locking solution instillations across 25 countries in populations representative of the total population of patients with implanted hemodialysis catheters that would be instilled with catheter lock solution.

The rate ratios for both uncensored (0.6) and censored (0.53) adverse events between DuraLock-C and Non-DuraLock-C affirm that DuraLock-C is State of the Art in regard to safety. Across all three DuraLock-C concentrations, two adverse events exceeded the minimum rate found in published literature. “Patient failed to attend” was considered a censored adverse event as it is unrelated to the safety and performance of a device; the rate (2.43 events per 1,000 catheter days) was also below the maximum rate found in published literature (3.72 events per 1,000 catheter days). The rate of “Poor blood flow” (1.58 events per 1,000 catheter days) was also below the maximum rate found in published literature. Overall, flow related complications and catheter associated venous thrombus (CAVT) rates were within State of the Art parameters.

The rates of catheter related blood stream infection (CRBSI) and catheter associated venous thrombus (CAVT) were found to be within State of the Art safety and performance outcome measure parameters (reflecting the lowest level of acceptability as defined by the manufacturer) for all three concentrations of DuraLock-C separately and collectively. The rates of CRBSI and CAVT affirm that DuraLock-C is State of the Art in regard to performance.

Source: DuraLock-C® Survey Report

The purpose of the DuraLock-C® Survey Plan was to assure consistency when creating surveys, distribution of the surveys and in analyzing the data collected. The results are reviewed and tabulated to ensure that the product remains safe and effective when used as instructed. The survey was distributed to all customers that ordered DuraLock-C® from 01 July 2017 to 31 July 2018. Medcomp anticipated a minimum 90% positive response rate on safety and efficacy questions based on a minimum of 10% response rate from all surveys sent.

The DuraLock-C® Survey was provided electronically to clinicians who use the product worldwide by the product distributors. The survey received responses from 76 clinicians from 24 countries including Australia, Bermuda, Canada, Croatia, Ecuador, Finland, Germany, Greece, Holland, Ireland, Italy, Kuwait, Malaysia, Mexico, Panama, Philippines, Portugal, Saudi Arabia, Singapore, South Africa, Sweden, Switzerland, United Arab Emirates, and United Kingdom. DuraLock-C® Survey Report was finalized on 17 September 2018.

Survey responses were stratified by concentration as follows:

- 4.0% DuraLock-C® Catheter Lock Solution – 26 Responses
- 30.0% DuraLock-C® Catheter Lock Solution – 30 Responses

The below are the results of the survey responses against their anticipated minimum response rate as defined in DuraLock-C® Survey Protocol.

Question	Anticipated Minimum Response Rate	Survey Results	Rationale (if anticipated minimum response rate not met)
Have you experienced any difficulty in connecting the syringe to the catheter or instilling solution into the catheter lumen?	> 85% No	97.3% No	N/A
Do you use DuraLock-C® to prevent catheter-related thrombosis by maintaining catheter patency?	> 90% Yes	88.1% Yes	Of the 10 respondents that did not indicate “Yes” to the question: 9 clinicians still answered that the product was safe and effective, 1 clinician did not answer the question. In conclusion, even though the 90% positive response rate was not met, based on overall safety and performance rating, the DuraLock-C® product performs as intended.
Do the pouches with pre-filled syringes increase efficiency?	> 85% Yes	88.1% Yes	N/A
Do the volume markings on the syringe prevent overfilling by accurately identifying priming volume?	> 85% Yes	94.7% Yes	N/A

Do the color-coded caps provide safer delivery of accurate priming to the lumens?	> 85% Yes	96.0% Yes	N/A
Known Complications	N/A – Identification of Safety Information	Cardiac Event, Clinician Injury, Dysgeusia, Paraesthesia, Bleeding, Allergic Reaction, Thrombosis	N/A
Please rate the overall Safety and Performance of DuraLock-C®	>90% Positive Response	97.3% Positive Response	N/A

Source: PMCF_DLOCK_213

The objective of the study is to test the in-vitro antimicrobial potential of all concentrations of DuraLock-C® Catheter Lock Solution. Medcomp, with assistance from NAMSA, created whitepapers to contextualize and apply a scientific narrative to the results of the Antimicrobial in vitro Study (PMCF_DLOCK_213, NAMSA Project # US033993).

"Antimicrobial Activity and Safety of the Following Dialysis Catheter Locking Solutions: 4.0% DuraLock-C®, 30.0% DuraLock-C®, 46.7% DuraLock-C® and Heparin. A Comprehensive Evaluation" concluded that solutions of Trisodium Citrate Dihydrate available as DuraLock-C® is effective at preventing some bacterial formation of biofilm in dialysis catheters. DuraLock-C® solutions of Trisodium Citrate Dihydrate dissolved in water at the concentrations at 4.0%, 30,0% and 46.7% weight to volume were very effective at reduction of microorganisms ability to colonize and form biofilm when tested in direct contact with catheters in this study. This is the first study that reports on the direct ability of Trisodium Citrate Dihydrate to directly affect the viability of microorganisms that have colonized the surface of the catheter. This study further shows that the ability of microorganism to colonize catheters is species and catheter material specific. Solutions of Trisodium Citrate Dihydrate at clinically used concentrations may have limited value against MRSA, Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecalis and Escherichia coli. Whereas Pseudomonas aeruginosa and Candida albicans viability were highly susceptible to reduction of viability to solutions of Trisodium Citrate Dihydrate.

Source: PMCF_DLOCK_212

The objective of the study is to test the in-vitro antithrombotic potential of all concentrations of DuraLock-C® Catheter Lock Solution. Medcomp, with assistance from NAMSA, created whitepapers to contextualize and apply a scientific narrative to the results of the In vitro Blood Loop Assay (PMCF DLOCK_212, APS Study ID QOI001-HE29).

"Evaluation of Dialysis Catheter Locking Solutions Using Multiple Concentrations of DuraLock-C® Compared to Heparin with an Innovative in-vitro Test Method for Antithrombotic Activity." which uses the findings of the In vitro Blood Loop Assay (APS Study ID QOI001-HE29) concluded that all concentrations of DuraLock-C® performed as anticipated with single phase type of activity. DuraLock-C® was active when compared to controls at all concentrations, with the two highest concentrations performing equally, but better than the lowest. Drugs or compounds with multiphasic responses (like heparin) are much more difficult to predict clinical outcomes. DuraLock-C® is an effective alternative to heparin as a locking solution.

Source: PMCIR-003

Three study sites were instructed to enroll thirty patients and collect specific data. Each site observed the use of one of the three concentrations of Duralock-C®. No randomization was employed. There was a ninety day follow up period with a primary endpoint of catheter related blood stream infection and secondary endpoints including catheter patency and catheter dysfunction.

The following recruitment totals were achieved: 4.0% DuraLock-C®: 4 Subjects, 30.0% DuraLock-C®: 2 Subjects. 46.7% DuraLock-C®: 12 Subjects (11 that began treatment). SAEs recorded were catheter dysfunction (1 event in the 4.0% group and 1 event in the 30.0% group), peritoneal carcinosis (1 event in the 4.0% group), and paresthesia (1 event in the 30.0% group). Only paresthesia was determined by the investigator to be related to DuraLock-C. AEs described as possibly related to the device were catheter occlusion (1 event in the 4.0% group) and catheter fibrin sheath formation (1 event in the 30.0% group). Due to the limited availability of data due to missing predefined recruitment targets the results have limited significance in terms of evaluating the safety and performance of DuraLock-C® 4.0%, 30.0%, and 46.7%.

Overall summary of clinical safety and performance

Duralock-C Catheter Lock solution has been demonstrated to maintain patency of the hemodialysis catheter between treatments, allowing continued use of the catheter. There are no studies that enable a direct comparison of the different strengths of Duralock-C® (either 4.0% or 30.0%). If the device is used as intended by the manufacturer, adverse events including dysgeusia, paresthesia, perioral numbness and hypotension are short-lasting and occur in up to 3.72 events per 1,000 catheter days. Inadvertent over instillation of Duralock-C® 30.0% has been associated with severe cardiac arrhythmias.

Outcome Parameters for 4.0% DuraLock-C® Catheter Lock Solution Across Post-Marketing Clinical Follow-up (PMCF) Data Sources

Outcome	PMCF Data
Catheter Dwell Time (Expressed as Catheter Days)	62.6 days[1] 85.5 days[2]
Catheter Related Blood Stream Infection (CRBSI)	0.221 per 1,000 catheter days[1] 5.26 per 1,000 catheter days[2]
Catheter Associated Venous Thrombus (CAVT)	0.957 per 1,000 catheter days[1]
Treatment-Emergent Adverse Events (TEAEs)	0.00 incidents of Air Embolus per 1,000 catheter days[1] 0.00 incidents of Bleeding per 1,000 catheter days[1] 0.00 incidents of Hemostasis Problems per 1,000 catheter days[1] 0.22 incidents of Cramps per 1,000 catheter days[1] 0.07 incidents of Dysrhythmia per 1,000 catheter days[1] 0.00 incidents of Neurological Symptoms per 1,000 catheter days[1] 0.736 incidents of Hypotension per 1,000 catheter days[1]

1 – PMCF_DLOCK_214. Data source included data on 217 Central Venous Catheters (60.7% long-termtunneled, 39.6% short-term untunneled) in 157 patients.2 – PMCIR-003. Data source included data on 4 Central Venous Catheters (long-term tunnelled) in 4 patients.

Outcome Parameters for 30.0% DuraLock-C® Catheter Lock Solution Across Post-Marketing Clinical Follow-up (PMCF) Data Sources

Outcome	PMCF Data
Catheter Dwell Time (Expressed as Catheter Days)	83.1 days[1] 152 days[2] 76 days[3] 1204.5 days[4]

Catheter Related Blood Stream Infection (CRBSI)	0.695 per 1,000 catheter days[1] 0.48 per 1,000 catheter days[2] 0.73 per 1,000 catheter days[3] 0 per 1,000 catheter days[4]
Catheter Associated Venous Thrombus (CAVT)	1.303 per 1,000 catheter days[1] 1.79 per 1,000 catheter days[2] 4.90 per 1,000 catheter days[3]
Treatment-Emergent Adverse Events (TEAEs)	0.0007 incidents of Air Embolus per 1,000 catheter days[1] 0.04 incidents of Bleeding per 1,000 catheter days[1] 0.014 incidents of Hemostasis Problems per 1,000 catheter days[1] 0.05 incidents of Cramps per 1,000 catheter days[1] 0.01 incidents of Dysrhythmia per 1,000 catheter days[1] 0.01 incidents of Neurological Symptoms per 1,000 catheter days[1] 0.131 incidents of Hypotension per 1,000 catheter days[1]

1 – PMCF_DLOCK_214. Data source included data on 18162 Central Venous Catheters (CVCs; 36.0% long-term tunneled, 64.0% short-term untunneled) in 10689 patients.
2 – PMCF_DLOCK_211. Results of 27 long-term CVCs, from a data source that included 315 CVCs (27 long-term tunneled, 288 short-term non-tunneled.)
3 – PMCF_DLOCK_211. Results of 288 short-term CVCs, from a data source that included 315 CVCs (27 long-term tunneled, 288 short-term non-tunneled.)4 – PMCIR-003. Data source included data on 2 Central Venous Catheters (long-term tunnelled) in 2 patients.

On-going or planned Post-Market Clinical Follow-up (PMCF)

Activity	Description	Reference	Timeline
Multicenter Patient-Level Case Series	Collect additional clinical data on the device	PMCF_DLOCK_231	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of catheter lock solutions	SAP-DuraLock	Q2 2026
Clinical Evidence Literature Search	Identify risks and trends with use of the device	LRP-DuraLock	Q2 2026
Global Trial Database Search	Identify ongoing clinical trials involving DuraLock-C®	N/A	Q2 2026

No emerging risks, complications or unexpected device failures have been detected from PMCF activities.

6. Possible therapeutic alternatives

The following clinical practice guidelines have been used to support the below recommendations for treatments:

- KDOQI Clinical Practice Guideline for Vascular Access (KDOQI 2019)
- Diagnosis and Treatment of CRBSI: Clinical Guidelines of the Spanish Society of Clinical Microbiology and Infectious Diseases (SEIMC) and the Spanish Society of Intensive Care Medicine and Coronary Units (SEMICYUC) (Chaves 2018)
- Guidelines for the Prevention of Intravascular CRIs (O'Grady 2011)

Lock Solution	Advantage	Drawback
Trisodium Citrate	Reduction of biofilm, anticoagulant, antithrombotic properties	Transient side effects Systemic injection can lead to hypocalcemia and/or cardiac arrhythmia
Heparin	Cheap, easily available	Systemic anticoagulation, heparin-induced thrombocytopenia, no anti-microbial effect
Antibiotic	Decrease CRBSI rate	Selection of drug-resistant bacteria
Ethanol	Theoretically antiseptic	No difference in CRBSI rate vs. placebo, biocompatibility issues with catheter material
Taurolidine	Decrease CRBSI vs. 4% citrate in hemodialysis patients, Decrease recombinant tissue plasminogen activator (r-TPA) use	Different associations (heparin, citrate, urokinase), with different properties, expensive
Sodium Bicarbonate	Potential good safety profile and advantageous benefits involving antithrombotic and antimicrobial properties	Inferior to heparin and is associated with a high rate of catheter-related thrombosis

7. Suggested profile and training for users

For use by a qualified, licensed physician or other qualified health care professional under the direction of a physician.

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

Standard, Common Specification, or 'Other Source'	Revision	Description	Compliance (Full/Partial)
EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices	Full
EN 1041	2008 + A1:2013	Information Supplied by the Manufacturer of Medical Devices	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
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
MEDDEV 2.7.1	Rev. 4; June 2016	Guidelines on Medical Device: Clinical Evaluation: A Guide for Manufacturers and Notified	Full

Standard, Common Specification, or 'Other Source'	Revision	Description	Compliance (Full/Partial)
		Bodies Under Directives 93/42/EEC and 90/385/EEC	
EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Full
USP-791	2012	pH Test Method	Full
USP-85	2011	Pyrogen & Endotoxins	Full
Ph. Eur. 2.6.14	01/2010 Reissued Date 01/2014	Bacterial Endotoxins Testing	Full
Ph. Eur. 5.1.10	01/2010 Reissued Date 01/2014	Bacterial Endotoxins Testing	Full
EN ISO 11137-2	2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	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 (ISO 14644-2:2015)	Full
EN 556-1	2001/AC: 2006	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices	Full
ISO 594-2	2nd edition, 1998 (Gap Analysis for EN ISO 80369-7: 2017, DuraLock-C EN ISO 80369-7:2017 Transition Plan)	Conical Fittings w/ 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment	Full
EN ISO 7886-1	2018	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use	Full
MEDDEV 2.1/5	June 1998	Guidance Document – Medical devices with a measuring function	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

Standard, Common Specification, or 'Other Source'	Revision	Description	Compliance (Full/Partial)
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council	Full
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 2019-9	2022	Summary of safety and clinical performance	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
MEDDEV 2.12/2	Rev. 2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	Full

9. Revision History

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**07JUN2021**	**26258**	**GM**	**Implementation of SSCP**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					not validated by the Notified Body as this is a Class IIa or IIb implantable device
2	**16DEC2021**	**26669**	**GM**	**Updated Sections 4, 5, 6 with up to date statistics**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
3	**22AUG2022**	**27204**	**GM**	**Update per 3556675 – Clinical Review - Medical Comp - MDR 734736**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					implantable device
4	**07MAR2023**	**27870**	**GM**	**Update to QA-CL-200-1 Version 3.00 Template; Aligning Content to 4% DuraLock-C Configuration**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
5	**07MAR2023**	**27871**	**GM**	**Addition of Higher Concentrations of DuraLock-C (30.0% and 46.7%) and accompanying clinical evidence (e.g., summary of published literature, PMCF_DLOCK_211)**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
6	**14AUG2023**	**28369**	**GM**	**Periodic Update in Accordance with CER-001 Rev. E**	☐ Yes, this version was validated by the Notified Body in the

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
7	**24OCT2023**	**28578**	**GM**	**Update in accordance with MEB review and CER-001 Rev E.1**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
8	**03JUN2024**	**29130**	**GM**	**Update in accordance with MEB review and CER-001 Rev F; 46.7% DuraLock-C® has been discontinued**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					Notified Body as this is a Class IIa or IIb implantable device
9	**23JUL2024**	**29262**	**GM**	**Update in accordance with MEB review**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
10	**29AUG2024**	**29342**	**GM**	**Inclusion of PMCIR-003 Results**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ 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
11	**15JUL2025**	**25-0016**	**GM**	**Periodic Update in Accordance with CER-001 Rev. G**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

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