DEFENCATH®
Taurolidine and Heparin Catheter Lock Solution

Limited Population

Protect their central line

Discover which patients are appropriate candidates for DefenCath to help reduce the risk of CRBSIs[1]*

Not actual patients.

INDICATIONS AND USAGE

LIMITED POPULATION: DEFENCATH® is indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). This drug is indicated for use in a limited and specific population of patients.

Limitations of Use

The safety and effectiveness of DEFENCATH have not been established for use in populations other than adult patients with kidney failure receiving chronic HD through a CVC.

*Patient profiles are hypothetical and for illustrative purposes only. They do not intend to offer medical advice. Determination of appropriate use of DefenCath should be made on an individual basis by treating healthcare providers.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DEFENCATH is contraindicated in patients with:

- Known heparin-induced thrombocytopenia (HIT).
- Known hypersensitivity to taurolidine, heparin or the citrate excipient (components of DefenCath), or pork products.

Please see additional Important Safety Information throughout and the full Prescribing Information.

PATIENT PROFILE:
NEW DEFENCATH START*

Mary, age 62

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Living with type 2 diabetes and chronic kidney disease

CLINICAL PRESENTATION

- Type 2 diabetes with poor glycemic control, complicated by chronic kidney disease
- Presented with symptoms consistent with ESRD requiring HD
- Not a suitable candidate for AVF due to peripheral artery disease and vascular insufficiency secondary to diabetes

COURSE OF ACTION

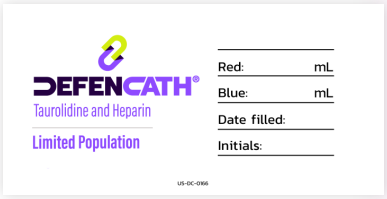
- Underwent temporary non-tunneled CVC placement upon admission to initiate HD, before tunneled CVC placement for outpatient use
- DefenCath instilled in each lumen to reduce the risk of CRBSIs†, with Patient Sticker applied on CVC dressing to indicate use and help ensure continuity of care[1]

MARY'S OUTCOME

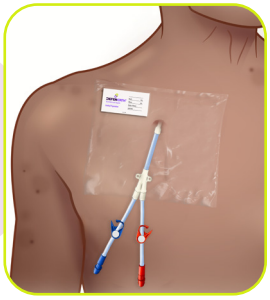
- Outpatient HD continued through the CVC, with DefenCath instilled† after each session to reduce the risk of CRBSIs[1]
- Evaluated for long-term access and now awaiting AVG

Using the Patient Sticker to clearly identify the volume of DefenCath CLS instilled in each lumen can help ensure consistent use to reduce the risk of CRBSIs[1]

PATIENT STICKER



Not actual size



*This case study is hypothetical and for illustrative purposes only. It is not intended to offer medical advice. Determination of appropriate use of DefenCath should be made on an individual basis by treating healthcare providers.

†DefenCath should be aspirated from the catheter and discarded prior to the initiation of the next HD session.[1]

AVF, arteriovenous fistula; AVG, arteriovenous graft; CLS, catheter lock solution; CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; ESRD, end-stage renal disease; HD, hemodialysis.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS

- **Heparin-Induced Thrombocytopenia (HIT):** HIT was reported in patients using heparin, a component of DEFENCATH, as a catheter lock solution. If HIT occurs, discontinue DEFENCATH and institute appropriate supportive measures.

Please see additional Important Safety Information throughout and the full Prescribing Information.

Proven to reduce CRBSI risk by 71%[1,2]

(95% CI [38%, 86%], log-rank *p*=0.0006)

DEFENCATH® Taurolidine and Heparin Catheter Lock Solution | Limited Population

DefenCath is a first-in-class CLS proven to significantly reduce the risk of CRBSIs[1]

The efficacy and safety of DefenCath for reducing the incidence of CRBSI in adult patients with kidney failure receiving chronic HD through a CVC was evaluated in LOCK-IT-100 (NCT02651428), a randomized, double-blind, active-controlled, multicenter trial.[1,2]*

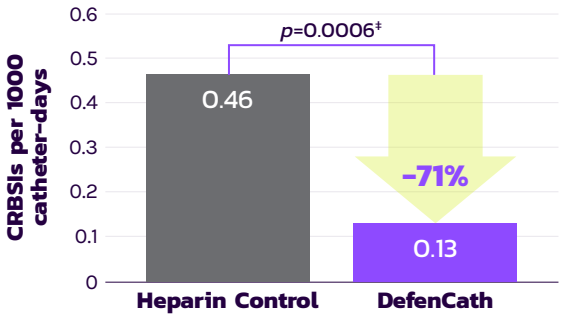
PRIMARY ENDPOINT RESULTS[1]

CAC-adjudicated CRBSI in patients with kidney failure who received ≥1 dose of allocated study CLS[2]

	Heparin Control N=398	DefenCath N=397
CAC-adjudicated CRBSI	32 (8.0%)	9 (2.3%)
Event rate per 1000 catheter-days (95% CI)	0.46 (0.33, 0.66)	0.13 (0.07, 0.26)
Risk reduction (95% CI)†	71% (38%, 86%)	
Log-rank test *p*-value	0.0006	

†Based on 1 - Hazard Ratio.

Patients in the DefenCath group had a lower incidence of CRBSI events compared with patients in the control group



‡Based on Log-rank test.

For patients like Mary, any time with a CVC in place increases the risk of CRBSIs.[3] Instilling DefenCath CLS in each lumen of the CVC after each HD session can reduce the risk of CRBSIs[1,2§]

*806 patients were randomized in a 1:1 ratio to receive either DefenCath or heparin. Enrollment was not limited to patients with specific types of HD catheters. DefenCath or heparin was instilled into the HD-CVC catheters at the end of all dialysis sessions and withdrawn prior to the initiation of the next dialysis session. CAC definition of CRBSI included 1 positive blood culture (or confirmatory culture for coagulase-negative staphylococci) from a peripheral site or either the arterial or venous catheter hub or the arterial or venous dialysis blood line AND the patient had to have signs and symptoms of infection and no other apparent source of bloodstream infection. The necessary clinical indication for suspicion of infection included one of the following: fever (≥37.8° C) or rigors, often with sweating, as documented by a medical professional, or ≥2 of the following symptoms: tachycardia (heart rate >100 beats per minute), tachypnea (>24 breaths per minute), systolic BP <90 mm Hg or a decrease >30 mm Hg, or a change in mental status from baseline.

§DefenCath should be aspirated from the catheter and discarded prior to the initiation of the next HD session.[1]

BP, blood pressure; CAC, clinical adjudication committee; CLS, catheter lock solution; CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; HD, hemodialysis.

IMPORTANT SAFETY INFORMATION (CONT.)

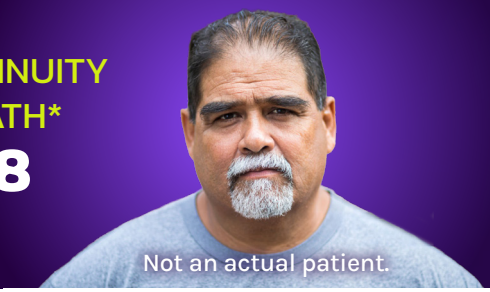
WARNINGS AND PRECAUTIONS (CONT.)

- **Drug Hypersensitivity:** Drug hypersensitivity reactions have been reported in patients using heparin, a component of DEFENCATH, as a catheter lock solution. If a hypersensitivity reaction occurs, discontinue DEFENCATH and institute appropriate supportive measures.

Please see additional Important Safety Information throughout and the full Prescribing Information.

PATIENT PROFILE: CONTINUITY OF CARE WITH DEFENCATH*

Robert, age 68


Not an actual patient.

DEFENCATH® Taurolidine and Heparin Catheter Lock Solution | Limited Population

Hospitalized for myocardial infarction (MI)

CLINICAL PRESENTATION

- ESRD secondary to uncontrolled hypertension and type 2 diabetes
- Receiving HD 3 times per week via a tunneled CVC with DefenCath instilled,† as noted via the sticker on his catheter dressing
- Previous history of CRBSI before initiation of DefenCath
- Currently hospitalized following percutaneous coronary intervention (PCI) for MI

COURSE OF ACTION

- Monitored for complications following PCI and managed post-MI medications
- Continued inpatient dialysis through his HD-CVC, with DefenCath instilled† after every session to reduce the risk of CRBSIs[1]

ROBERT'S OUTCOME

- Successful reperfusion; secondary MI prevention strategies implemented
- Continuous care with DefenCath for inpatient dialysis helped reduce the risk of CRBSIs[1]

Adherence to consistent catheter management practices across care settings is critical to reduce the risk of CRBSIs[4]

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†DefenCath should be aspirated from the catheter and discarded prior to the initiation of the next HD session.[1]

CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; ESRD, end-stage renal disease; HD, hemodialysis.

IMPORTANT SAFETY INFORMATION (CONT.)

ADVERSE REACTIONS

The most frequently reported adverse reactions occurring in ≥2% of patients using DefenCath as a CLS were hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, and thrombocytopenia.

To report SUSPECTED ADVERSE REACTIONS, contact CorMedix Inc at 1-844-424-6345 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and the full Prescribing Information.

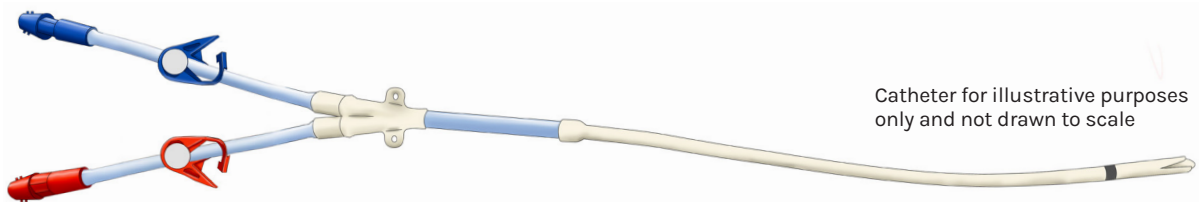
Protect the central line from end-to-end[1,2]

DEFENCATH® Taurolidine and Heparin Catheter Lock Solution | Limited Population

Patients with kidney failure receiving HD-CVC are at risk for developing hospital-acquired bloodstream infections (HA-BSIs)[5,6*]

When compared with patients who do not develop HA-BSIs, these patients are associated with[5,6†]: longer median hospital length of stay, longer median ICU length of stay, greater median total hospital costs, and greater 90-day all cause mortality.

When instilled into the catheter, DefenCath protects the entire length of the lumen, with broad spectrum activity and no known antimicrobial resistance[1,2,7‡]



Catheter for illustrative purposes only and not drawn to scale

Robert is at increased risk for HA-BSIs. Continuing DefenCath and clearly identifying use via the Patient Stickers can help ensure continuity of care upon discharge[1,2]

*Analysis of Premier Healthcare Database (2020-2022) comparing HD-CVC patients with CRBSI versus HD-CVC patients without a CRBSI.

†Limitations of the analysis: These retrospective analyses were performed using medical claims data and should be interpreted with caution. Individual patient medical records were not reviewed, and important clinical details may be missing or misclassified. As these are observational, retrospective analyses, associations identified do not establish causality. The results may be subject to confounding factors and biases inherent in claims data. Further prospective, controlled studies are necessary to validate and confirm these findings.

‡The following in vitro data are available, but their clinical significance is unknown. Taurolidine has been shown to be active against most isolates of the following microorganisms[1]: gram-positive bacteria (*Staphylococcus aureus* [including methicillin-sensitive *Staphylococcus aureus* (MSSA) and methicillin-resistant *Staphylococcus aureus* (MRSA)], *Staphylococcus epidermidis*, and *Enterococcus faecalis*); gram-negative bacteria (*Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*); and fungi (*Candida albicans*, *Candida glabrata*, and *Candida auris* [*Candida auris* in vitro data were not submitted and reviewed by the FDA]). No known antimicrobial resistance.

CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; FDA, US Food and Drug Administration; HD, hemodialysis; ICU, intensive care unit.

IMPORTANT SAFETY INFORMATION (CONT.)

CONTRAINDICATIONS

DEFENCATH is contraindicated in patients with:

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You're their **front line**

Protect the **central line**

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Limited Population

Any time with a CVC in place increases the risk of CRBSIs, making reduction of infection risk critical[3]

When instilled, **DefenCath demonstrates broad-spectrum activity and protects the entire length of the lumen**[1,2,7]*

DefenCath significantly reduces the risk of CRBSIs by 71% vs heparin control (95% CI [38%, 86%], log-rank p=0.0006)[1,2]

To reduce the risk of CRBSIs, consider the risk factors that help determine whether your patients are appropriate candidates for DefenCath

SCAN OR CLICK TO LEARN MORE

*The following in vitro data are available, but their clinical significance is unknown. Taurolidine has been shown to be active against most isolates of the following pathogens: gram-positive bacteria such as *Staphylococcus aureus* (including MSSA and MRSA), *Staphylococcus epidermidis*, and *Enterococcus faecalis*; gram-negative bacteria such as *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*; and fungi such as *Candida albicans*, *Candida glabrata*, and *Candida auris* (*Candida auris* in vitro data were not submitted and reviewed by the FDA).

CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; FDA, US Food and Drug Administration; MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*.

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References: 1. DefenCath® (taurolidine and heparin) catheter lock solution Prescribing Information, CorMedix, Berkeley Heights, New Jersey. **2.** Agarwal AK, Roy-Chaudhury P, Mounts P, Hurlburt E, Pfaffle A, Poggio EC. Taurolidine/heparin lock solution and catheter-related bloodstream infection in hemodialysis: a randomized, double-blind, active-control, phase 3 study. *Clin J Am Soc Nephrol*. 2023;18(11):1446-1455. **3.** Shingarev R, Barker-Finkel J, Allon M. Natural history of tunneled dialysis catheters placed for hemodialysis initiation. *J Vasc Interv Radiol*. 2013;24(9):1289-1294. **4.** Lok CE, Huber TS, Lee T, et al. KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. *Am J Kidney Dis*. 2020;75(4 Suppl 2):S1-S164. **5.** Michaud M, et al. Impacts of hospital-acquired bloodstream infections in patients undergoing hemodialysis through a central venous catheter. Poster presented at: Society for Healthcare Epidemiology of America Spring Conference; April 16-19, 2024; Houston, TX. **6.** Data on File, CorMedix Inc. **7.** Reidenberg BE, Jenkins SG, Crandon JL, et al. *In vitro* activity of taurolidine against clinical *Candida auris* isolates: relevance to catheter-related bloodstream infections. *Antimicrob Agents Chemother*. 2024;68(7):e0038124.

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