A. Description and Specifications

NutriLock™ is a catheter lock solution indicated for patients who use a port or a silicone or polyurethane catheter-based device as vascular access for parenteral nutrition or medication. NutriLock™ is to be instilled in the device lumens between treatments in order to make the internal flow passages hostile to bacterial and fungal growth. The solution must be withdrawn prior to initiating the next treatment. NutriLock™ is to be used by healthcare professionals and users trained by healthcare professionals. NutriLock™ contains an antimicrobial substance. Active ingredient in NutriLock™ is taurolidine. Other components include water for injection and PVP. The pH is adjusted with sodium hydroxide. The product is supplied as a clear, sterile and non-pyrogenic solution.

Note: For complete details of catheter-based vascular access products, consult the manufacturer's instructions or clinician's manual.

B. Intended Purpose

NutriLock™ is a catheter lock solution to be used with devices for venous access (catheter-based vascular access device or ports). It is to be instilled into the device at the termination of a treatment to ensure patency and provide infection control in the device.

C. Contraindications

NutriLock™ is contraindicated for patients with a known allergy to taurolidine or any of the other ingredients, or when a patient is currently taking medication with known adverse interaction to taurolidine.

D. Cautions

1. As a consumable NutriLock™ is for single use only. Once instilled into the catheter the solution must not be used again after aspiration. Reuse creates a potential contamination risk for the patient.
2. NutriLock™ is not for systemic injection. NutriLock™ must be used as a catheter lock solution as described in the access device's instruction for use. Failure to adhere to these instructions may result in inadvertent systemic injection of the solution.
3. Data for NutriLock™ use in dialysis catheters are insufficient. Therefore we do not recommend the use of NutriLock™ in dialysis catheters.
4. In the event that access device patency is compromised, follow institutional protocol for restoring flow. In addition, heparin may be used as an accessory to NutriLock™ in these events to decrease the incidence of blood clots. If heparin is used as an additive do not add more than 0.6 mL volume of heparin to 3 mL volume of NutriLock™. The maximum concentration of heparin used is 25,000 IU/mL. If heparin is added, the combined solution should not be flushed into the bloodstream due to the systemic effect of heparin. Note: In case of patency problems, ready-to-use solutions such as TauroLock™, TauroLock™-HEP100, TauroLock™-HEP500 or TauroLock™-U25.000, which contain additional anticoagulant or fibrinolytic agents, are available.
5. If aspiration is not possible or if healthcare professional decides that aspiration of NutriLock™ is not appropriate (blood in the catheter, e. g. in parenteral nutrition), slow flushing of the catheter lock solution may be considered. Taurolidine does not induce any systemic effect. In infants and children less than two years of age flushing should only be performed if aspiration is not possible. If the access device has previously been blocked with non-antimicrobial lock solutions (e.g., with heparin, low concentrated citrate or saline) there is an increased probability of a presence of biofilm with viable organisms and endotoxins. This should be considered if it is decided to flush a catheter lock solution like NutriLock™.
6. The concentration of the antimicrobial compound is near to saturation. If not stored or transported according to the instructions under section H, precipitation can occur in the product. Do not use such a precipitated product.

E. Adverse Effects

Assessment of adverse effects is based on the following definitions of incidence:

Very common	Common	Uncommon	Rare	Very rare	Not known
≥ 1/10	≥ 1/100 - < 1/10	≥ 1/1.000 - < 1/100	≥ 1/100.000 - < 1/1.000	< 1/100.000	cannot be estimated from the available data

The following undesired effect(s) may occur: Anaphylaxis (very rare). There are no known risks associated with concomitant systemic antibiotic therapy or exposure to magnetic fields.

F. Instillation of NutriLock™

Follow the manufacturer's instructions that accompany the particular vascular access product utilized. Specific catheter lock volumes are associated with each device.

1. Flush the device with 10 mL of saline.
2. Withdraw NutriLock™ from the container using an appropriate syringe.
3. Instill NutriLock™ slowly (not more than 1 mL per second) into the access device in a quantity sufficient to fill the lumen completely. **Consult the manufacturer's instructions for the specific fill volume or specify fill volume during implantation. The volume has to be strictly respected.** NutriLock™ will remain inside the access device until the next treatment (up to a maximum of 30 days).
4. Prior to the next treatment, NutriLock™ must be aspirated and discarded in accordance with the institution's policy for infectious waste disposal.
5. Flush the device with 10 mL of saline.

G. Special patient groups

No data are available for pregnant and breastfeeding women. For safety reasons NutriLock™ should not be used during pregnancy and breastfeeding. The safety and efficacy of NutriLock™ have not been investigated in children before skeletal maturity.

H. Storage and shipment

NutriLock™ must be stored at a temperature of 15 to 30°C and must not be shipped at freezing temperature. Do not store in a refrigerator.

I. Packaging configuration

The following packaging configuration is available for NutriLock™: 10 x 3 mL NutriLock™ ampoules (single dose container).

J. Further Information

Please refer to the following address for additional information regarding safety and clinical performance:
https://ec.europa.eu/tools/eudamed *(Basic UDI-DI 426018822-07-TA)*

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MD Medical Device.

Contains a medicinal substance.

Do not use when package is damaged.

Non-pyrogenic.

Read instruction for use.

Single use. The ampoule is a single dose container.

STERILE

Sterilized using steam or dry heat, single sterile barrier system.

CE 0123

CE acc. Regulation (EU) 2017/745 (EU MDR), notified body:
TÜV SÜD PRODUCT SERVICE GmbH.