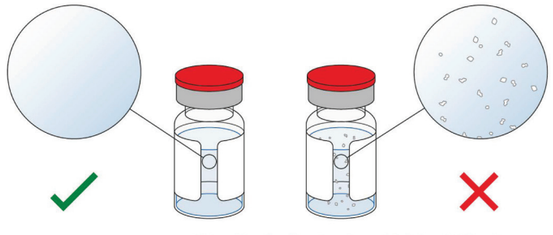
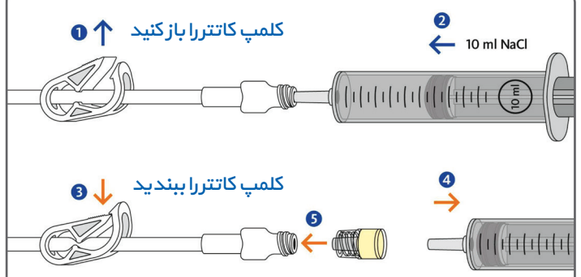
TauroSept®

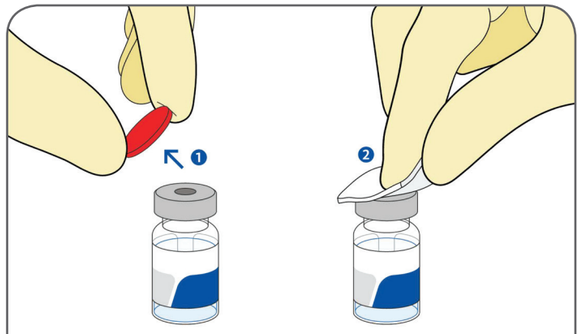
Geistlich Pharma



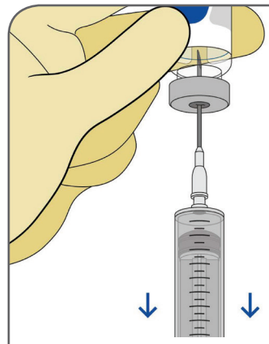
۱ قبل از هر بار استفاده، تاروسپت را از لحاظ وجود ذرات قابل رویت، بررسی کنید. درصورت مشاهده ذرات، از مصرف تاروسپت خودداری شود.



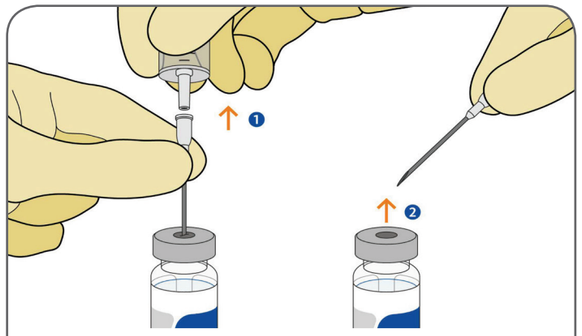
۲ کاتتر را قبل از استفاده از تاروسپت (اینستالیشن تاروسپت)، با ۱۰ میلی‌لیتر محلول سرم فیزیولوژیک استریل شستشو دهید.



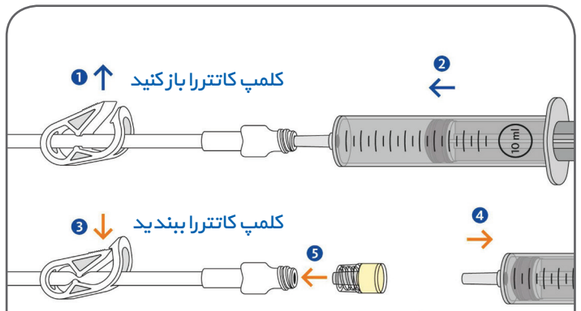
۳ قبل از استفاده از تاروسپت، سطح ویال را با یک ماده ضدعفونی‌کننده که پایه یدی نداشته باشد، ضدعفونی کنید.



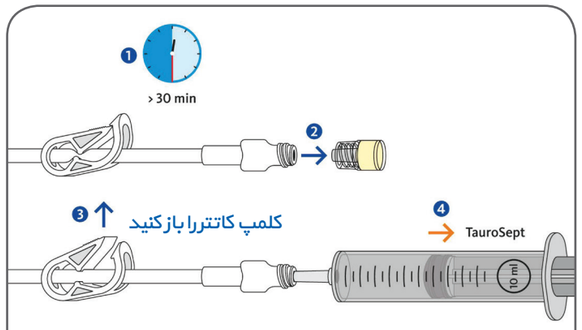
۴ حجم مورد نیاز از تاروسپت را با یک سرنگ استریل از ویال آن بکشید.



۵ سوزن را از درپوش جدا کنید.



۶ لومن کاتتر را از تاروسپت پرکنید. سرعت اینستالیشن تاروسپت نباید بیشتر از یک میلی‌لیتر در هر ۲ ثانیه باشد.



۷ اجازه دهید تاروسپت حداقل ۳۰ دقیقه در کاتتر بماند. قبل از استفاده مجدد، تاروسپت قبلی را از داخل لومن کاتتر تخلیه کنید.

شرایط نگهداری و استفاده

- شست‌وشوی تاروسپت موجود در لومن کاتتر، بدون هیچ عارضه سیستمیکی قابل انجام است.
- از ترکیب کردن تاروسپت با مواد اکسیدکننده نظیر سدیم هیپوکلراید، پویدون آیدون و هیدروژن پراکسید پرهیز شود.
- تاروسپت در مطالعات حیوانی و در محدود مطالعات انسانی، تداخلی با هپارین نداشته است.
- ویال تاروسپت را پس از اولین استفاده، می توان تا ۴۸ ساعت نگهداری کرد؛ لازم به ذکر است که محتویات ویال فقط برای یک بیمار و حداکثر تا ۴۸ ساعت پس از اولین نوبت استفاده، قابل مصرف است.
- ویال تاروسپت باید در دمای ۱۵ تا ۲۵ درجه سانتی‌گراد نگهداری شود. از نگهداری تاروسپت در یخچال (حتی پس از اولین نوبت استفاده) خودداری شود.
- کلیه مراحل آماده سازی و استفاده از تاروسپت باید در شرایط استریل انجام شود.

TauroSept®,Medical device for treatment and prevention of catheter infections, **Device description Composition:** Active ingredient: Taurolidine 2%. **Excipients:** Polyvinylpyrrolidone 5% (PVP-17); water for injection, traces of hydrochloric acid or sodium hydroxide to permit pH adjustment to 7.3. **Properties:** TauroSept® contains taurolidine 2%, an antimicrobial chemotherapeutic agent that exhibits activity against a wide range of pathogenic microorganisms including aerobic and anaerobic, gram-negative and gram-positive bacteria, yeasts and moulds. Taurolidine also inhibits staphylococcal coagulase and reduces microbial adherence to cells and surfaces of biomaterials. Bacterial resistance has never been observed and is unlikely to occur because of the mechanism of action of taurolidine on the cell wall. **Intended use / indications:** TauroSept® is intended for instillation in intravascular catheters between treatments in order to prevent bacterial and fungal growth leading to microbial infection in the catheter lumen as well as to maintain device patency and to avoid staphylococaglase-induced clotting of blood. TauroSept® can also be used as adjuvant treatment in infected catheters. Contraindications There are no contraindications to date. **Warnings:** TauroSept® is not to be used for systemic injection. The solution should be withdrawn from the catheter before next use. If withdrawal of TauroSept® is not possible for technical reasons, e. g. with totally implantable venous access systems (portacaths), or clinically not wanted, e. g. in parenteral nutrition, the flushing of TauroSept® can be done without systemic effect. **Precautions:** • TauroSept® should be handled with caution in patients with known allergic predisposition and when patients are concomitantly treated with products which are known to interact with taurolidine. • TauroSept® must not be mixed with oxidizing agents such as Dakin's solution (sodium hypochlorite), povidone iodine, or hydrogen peroxide because of oxidation to formic acid. The risk can be considered to be very low as these agents are not used in the catheter but only on the surrounding skin. • TauroSept® does not impair the anti-coagulant effect of heparin as shown in in-vitro studies, animal experiments, and in a limited number of patients in clinical trials. However, in individual cases decreased patency of the catheter may occur. In clinical practise, tissue plasminogen activator (r-tPA) was successfully applied when thrombolytic intervention was required in taurolidine containing lock solutions. • TauroSept® must be instilled into the access device as described in the product's user manual. Failure to comply with these instructions may result in inadvertent systemic injection of the taurolidine solution. • The TauroSept® solution must only be instilled once and the withdrawn residue must be disposed of. Reuse may result in decreased efficacy of the device. • Do not use TauroSept® if the vial is damaged. **Adverse events:** No adverse events have been reported to date as a result of the intended use of TauroSept®. There are no known risks associated with concomitant antibiotic therapy. Intraperitoneal administration or false injection of taurolidine into subcutaneous or intra-muscular space can cause severe stinging pain. In non anesthetized patients or if anaesthesia is not deep enough, these pain reactions can cause blood pressure decrease or increase with corresponding changes in pulse rate. This risk can be considered to be very low since only very small volumes are used in the catheter and flushing of the catheter content into patient's circulation is rather unlikely. In animal experiments, considerable scarring and necrosis have been observed after subcutaneous or intra-muscular administration of taurolidine. **Instruction for use:** TauroSept® can be used with any vascular access device. Follow the manufacturer's instructions for the particular catheter utilized. Specific catheter volumes are associated with each device and must be strictly followed. Before each use, TauroSept® should be inspected for the presence of visible particles. Do not use TauroSept® if particles are visible. Flush the catheter with 10 ml sterile physiological saline solution before instillation of TauroSept®. Disinfect the surface of the septum of opened vials with a noniodine based disinfectant immediately before using TauroSept® Transfer the required volume of TauroSept® from the vial with a sterile syringe and fill the lumen of the catheter with TauroSept®. Remove the needle from the vial cap. Allow TauroSept® to remain inside the catheter for at least 30 minutes. If treating an infected catheter allow TauroSept® to remain inside the catheter for 12 hours and replace the product every 12 hours until the desired effect is achieved. Withdraw if possible and discard TauroSept® before the next use of the catheter. **Pregnancy / Lactation:** Data on the use of the product during pregnancy or lactation are not available. **For safety reasons:** women who are pregnant or breastfeeding should not be treated with TauroSept®. The safety and efficacy of TauroSept® have not been investigated in children before skeletal maturity. **Storage:** TauroSept® should be stored in a horizontal position at a controlled temperature of 15 to 25 °C. Do not store in the refrigerator. Do not use after the indicated expiry date. **Other Information:** The product is sterile. The content of a vial is for a single patient only and must be used within 48 hours after the first puncture. Write time and date the vial was opened on the vial label. Re-sterilisation is not possible! Dispose of unused portions of the solution and withdrawn residues from access systems. Do not use if the packaging is damaged. If the packaging is opened and no date and time indicating 1st opening are legible on the vial, the product must not be used. Status of the Information 06/2015

Packs and prices: Country specific
Legal classification: Country specific

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Phone +41 41 492 56 25, **Fax** +41 41 492 67 14, TauroSept@geistlich.ch, www.geistlich-medical.com

Adverse event should also be reported to Phone +9821 26 76 18 35

Reference
TauroSept® – Instructions for Use, 06/2015.

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