

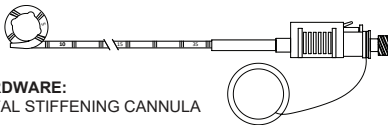
**See the pouch label on this product for specific contents.**

**INTENDED USE:** This product is intended for short-term use (less than 30 days).

- General-purpose (GP/Mini-pigtail)/NEPHRO-CATH Nephrostomy: Percutaneous drainage of abscess, nephrostomy and other fluids.
- CHOLE-CATH Biliary: Percutaneous transhepatic biliary drainage.

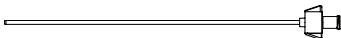
**INTENDED USERS:** This product is intended only for use by trained clinicians.

### LOCKING CATHETER: GP, NEPHROSTOMY AND BILIARY CATHETERS WITH LOCKING PIGTAIL



#### HARDWARE:

METAL STIFFENING CANNULA



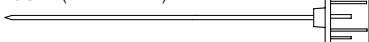
SEPTUM CAP (IF PRESENT)



FLEXIBLE CANNULA (IF PRESENT)



TROCAR (IF PRESENT)



OBTURATOR (IF PRESENT)



**NOTE:** Depth marks (if present) not intended to measure – for reference only

#### INSTRUCTIONS FOR USE:

1. To maximize advantages of the surface, WET THE CATHETER before use.
2. Straighten the catheter when inserting the cannula (and trocar if appropriate). For locking catheters, pull the suture to remove slack before inserting the cannula.
3. Insert the catheter using the over-the-guidewire technique. Tract over-dilation will ease placement. Catheters with a trocar included can also be inserted using direct puncture.
4. For locking catheters, rotate the catheter clockwise while removing the cannula to form the pigtail.
5. When the catheter is properly positioned, remove the hardware.
6. For locking pigtail catheters, pull the suture to close the pigtail. Depending upon whether or not suture storage is desired, lock the pigtail as follows:
  - Option A: Locking the pigtail without storing suture: Move the locking slide proximally until an audible “click” is heard. The suture is now locked. Trim away excess suture at the exit point at the proximal end of the hub. Do not pull suture out of catheter until removing catheter from patient, as this may cause a leak.
  - Option B: Locking the pigtail with suture storage: Wind approximately 15 cm of suture into the suture channel for later use when removing or repositioning the catheter. To wrap the suture, pull it straight and then hook it in the notch at the bottom of the suture channel. After making the last wind, wrap the suture around the suture retention post. Move the locking slide proximally until an audible “click” is heard. The suture is now locked.
7. To remove the catheter, unlock the suture retention mechanism. To unlock the mechanism, depress the tab using an instrument and move the slide distally. If no suture was stored, the suture will now be released. If suture was stored, unwind the suture to complete the release. Cut the suture at the exit point at the proximal end of the hub and pull the catheter out of the patient. In order to maintain control of the suture, do not cut the catheter to release the pigtail.
8. For biliary and nephrostomy catheters, internal drainage can be achieved by placing the septum cap on the catheter hub. The septum cap contains a self-sealing needle puncture port for flushing.

#### CAUTION:

1. When engaging the catheter luer lock, do not overtighten. Do not use instruments to tighten connections. Overtightening the luer can result in luer crack which may require catheter replacement.
2. Dispose of sharps using approved sharps container in accordance with applicable regulations and institutional policy.

**WARNING:** The reuse of this single-use device can lead to patient infection and/or device malfunction.

**SAFE DISPOSAL:** Dispose of used device in container marked for biohazard (i.e. contaminated with potentially infectious substances of human origin).

**REPORTING SERIOUS INCIDENTS:** Any serious incident that has occurred in relation to the device should be reported to UreSil as the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

URESIL, MINI-PIGTAIL, CHOLE-CATH, and Origin are registered trademarks of UreSil, LLC. GP and NEPHRO-CATH are trademarks of UreSil, LLC. U.S. patent no's. 8,177,773; 9,079,006B1.

**REF**

EN Catalog number  
 CS Katalogové číslo  
 DA Katalognummer  
 DE Katalognummer  
 EL Αριθμός καταλόγου  
 ES Número de catálogo  
 FI Luettelonumero  
 FR Numéro de catalogue  
 IT Numero di catalogo  
 NL Catalogusnummer  
 NO Katalognummer  
 PT Referência  
 SK Katalógové číslo  
 SL Kataloška številka  
 SV Katalognummer  
 TR Katalog numarası  
 ZH 产品目录号

**LOT**

EN Batch code  
 CS Kód šarže  
 DA Batchkode  
 DE Chargencode  
 EL Κωδικός παρτίδας  
 ES Código de lote  
 FI Eräkoodi  
 FR Code du lot  
 IT Codice lotto  
 NL Batchcode  
 NO Partikode  
 PT Código do lote  
 SK Kód šarže  
 SL Koda serije  
 SV Batchkod  
 TR Parti kodu  
 ZH 批号



EN Caution  
 CS Upozornění  
 DA Forsigtig  
 DE Achtung  
 EL Προσοχή  
 ES Precaución  
 FI Huomio  
 FR Avertissement  
 IT Attenzione  
 NL Opgelet  
 NO Advarsel  
 PT Atenção  
 SK Upozornenie  
 SL Pozor  
 SV Varning  
 TR Dikkat  
 ZH 注意



EN Country of manufacture/ Date of manufacture  
 CS Země výroby/ Datum výroby  
 DA Fremstillingsland/ Fremstillingsdato  
 DE Herstellungsland/ Herstellungsdatum  
 EL Χώρα κατασκευής/ Ημερομηνία κατασκευής  
 ES País de fabricación/ Fecha de fabricación  
 FI Valmistusmaa/ Valmistuspäivä  
 FR Pays de fabrication/ Date de fabrication  
 IT Paese di produzione/ Data di produzione  
 NL Land van productie/ Productiedatum  
 NO Produksjonsland/ Produksjonsdato  
 PT País de fabric/ Data de fabrico  
 SK Krajina výroby/ Dátum výroby  
 SL Država proizvodnje/ Datum proizvodnje  
 TR Ambalaj hasarlıysa ürünü kullanmayın ve kullanım talimatlarına başvurun/ Tillverkningsdatum  
 SV Tillverkningsland/ Üretim tarihi  
 ZH 产地/ 生产日期



EN Quantity  
 CS Množství  
 DA Antal  
 DE Menge  
 EL Ποσότητα  
 ES Cantidad  
 FI Määrä  
 FR Quantité  
 IT Quantità  
 NL Hoeveelheid  
 NO Antall  
 PT Quantidade  
 SK Množstvo  
 SL Količina  
 SV Kvantitet  
 TR Miktar  
 ZH 数量



EN Not made with natural rubber latex  
 CS Není vyrobeno z latexu z přírodního kaučuku  
 DA Ikke fremstillet med naturgummilætex  
 DE Nicht aus Naturkautschuklatex hergestellt  
 EL Δεν κατασκευάζεται με λατέξ από φυσικό καουτσούκ  
 ES No fabricado con látex de caucho natural  
 FI Ei ole valmistettu luonnonkumilateksista  
 FR Non fabriqué avec du latex de caoutchouc naturel  
 IT Non realizzato con lattice di gomma naturale  
 NL Niet gemaakt van natuurlijk rubberlatex  
 NO Skal ikke brukes med naturlig gummilætex  
 PT Não fabricado com látex de borracha natural  
 SK Neobsahuje prírodný latex  
 SL Ni narejeno iz naravnega kavčuka  
 SV Inte tillverkad med naturlig gummilætex  
 TR Doğal kauçuk lateksten yapılmamıştır  
 ZH 并非天然乳胶材质



EN Do not re-use  
 CS Nepoužívejte opakovaně  
 DA Må ikke genbruges  
 DE Nicht wiederverwenden  
 EL Να μην επαναχρησιμοποιηθεί  
 ES No reutilizar  
 FI Älä käytä uudelleen  
 FR Ne pas réutiliser  
 IT Non riutilizzare  
 NL Niet hergebruiken  
 NO Ikke til gjenbruk  
 PT Não reutilizar  
 SK Nepoužívajte opakovane  
 SL Ne uporabite znova  
 SV Får inte återanvändas  
 TR Yeniden kullanmayın  
 ZH 不可重复使用



1-800-538-7374 (U.S.A.)



1-847-982-0106



EN Telephone Number  
 CS Telefonní číslo  
 DA Telefonnummer  
 DE Telefonnummer  
 EL Αριθμός τηλεφώνου  
 ES Número de teléfono  
 FI Puhelinnumero  
 FR Numéro de téléphone  
 IT Numero di telefono  
 NL Telefoonnummer  
 NO Telefonnummer  
 PT Número de telefone  
 SK Telefónne číslo  
 SL Telefonska številka  
 SV Telefonnummer  
 TR Telefon Numarası  
 ZH 电话号码

EN Fax Number  
 CS Číslo faxu  
 DA Faxnummer  
 DE Faxnummer  
 EL Αριθμός φαξ  
 ES Número de fax  
 FI Faksinumero  
 FR Numéro de fax  
 IT Numero di fax  
 NL Faxnummer  
 NO Faksnummer  
 PT Número de fax  
 SK Faxové číslo  
 SL Številka faksa  
 SV Faxnummer  
 TR Faks Numarası  
 ZH 传真号码

EN Do not re-sterilize  
 CS Neresterilizujte  
 DA Må ikke reesteriliseres  
 DE Nicht erneut sterilisieren  
 EL Να μην αποστειρωθεί εκ νέου  
 ES No reesterilizar  
 FI Älä steriloï uudelleen  
 FR Ne pas restériliser  
 IT Non risterilizzare  
 NL Niet opnieuw steriliseren  
 NO Skal ikke reesteriliseres  
 PT Não reesterilizar  
 SK Nesterilizujte  
 SL Ne sterilizirajte znova  
 SV Får inte omsteriliseras  
 TR Yeniden sterilize etmeyin  
 ZH 不可重复消毒



EN Do not use if package is damaged and consult instructions for use  
CS Nepoužívejte, pokud je obal poškozený, a přečtěte si návod k použití  
DA Må ikke bruges, hvis pakken er beskadiget, og se brugsanvisningen  
DE Nicht verwenden, wenn die Verpackung beschädigt ist, und Gebrauchsanweisung beachten  
EL Μην χρησιμοποιείτε το προϊόν εάν η συσκευασία έχει υποστεί ζημιά και συμβουλευτείτε τις οδηγίες χρήσης  
ES No utilizar si el envase está dañado y consultar las instrucciones de uso  
FI Älä käytä, jos pakkaus on vahingoittunut, ja katso käyttöohjeet  
FR Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi  
IT Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso  
NL Niet gebruiken als de verpakking beschadigd is. Raadpleeg de gebruiksaanwijzing  
NO Ikke bruk hvis pakke er skadet, og les bruksanvisningen  
PT Não utilizar se a embalagem estiver danificada e consultar as instruções de utilização  
SK Nepoužívať, ak je obal poškodený, a prečítajte si návod na použitie  
SL Ne uporabljajte, če je embalaža poškodovana, in glejte navodila za uporabo  
SV Använd inte produkten om förpackningen är skadad och se bruksanvisningen  
TR Ambalaj hasarlıysa ürünü kullanmayın ve kullanım talimatlarını başvurun  
ZH 包装如有损坏不可使用，请参考使用说明书



EN Sterilized using ethylene oxide/ Single sterile barrier system  
CS Sterilizováno ethylenoxidem/ Jednoduchý sterilní bariérový systém  
DA Steriliseret ved anvendelse af ethylenoxid/ Enkelt steril barrieresystem  
DE Mit Ethylenoxid sterilisiert/ Einfaches Sterilbarrieresystem  
EL Αποστειρώθηκε με χρήση αιθυλενοξειδίου/ Σύστημα μονού αποστειρωμένου φραγμού  
ES Esterilizado con óxido de etileno/ Sistema de barrera estéril simple  
FI Steriloitu etyleenioksidilla/ Yksittäinen steriili estojärjestelmä  
FR Stérilisé à l'oxyde d'éthylène/ Système de barrière stérile unique  
IT Sterilizzato con ossido di etilene/ Sistema di barriera sterile singola  
NL Gesteriliseerd met ethyleenoxide/ Enkelvoudig steriel barrieresysteem  
NO Sterilisert med etylenoksid/ System med enkelt steril barriere  
PT Esterilizado por óxido de etileno/ Sistema de barreira estéril simples  
SK Sterilizované etylénoxidom/ Systém jednej sterilnej bariéry  
SL Sterilizirano z etilen oksidom/ Enojni sterilni sistem pregrad  
SV Steriliserad med etylenoxid/ Sterilt barriärsystem med ett lager  
TR Etilen oksit kullanılarak sterilize edilmiştir/ Tek steril bariyerli sistem  
ZH 使用环氧乙烷消毒/ 单一无菌屏障系统



EN Locking pigtail  
CS Zajišťující pigtail  
DA Låsende grisehale  
DE Pigtail-Verriegelung  
EL Άκρο τύπου pigtail με δυνατότητα κλειδώματος  
ES Pigtail de bloqueo  
FI Lukittava letkukatetri  
FR Verrouillage en queue de cochon  
IT Bloccaggio "a coda di maiale" (pigtail)  
NL Pigtail met vergrendeling  
NO Låsende grisehale  
PT Pigtail de retenção  
SK Uzamykací pigtail  
SL Zaklepni jeziček  
SV Låsande pigtail-koppling  
TR Kilitli pigtail  
ZH 锁定猪尾管



EN Working length  
CS Pracovní délka  
DA Arbejds længde  
DE Arbeitslänge  
EL Λειτουργικό μήκος  
ES Longitud de trabajo  
FI Työskentelypituus  
FR Longueur de travail  
IT Lunghezza di lavoro  
NL Werklengte  
NO Arbeidslengde  
PT Comprimento de trabalho  
SK Pracovní dĺžka  
SL Delovna dolžina  
SV Arbetslängd  
TR Çalışma uzunluğu  
ZH 工作长度