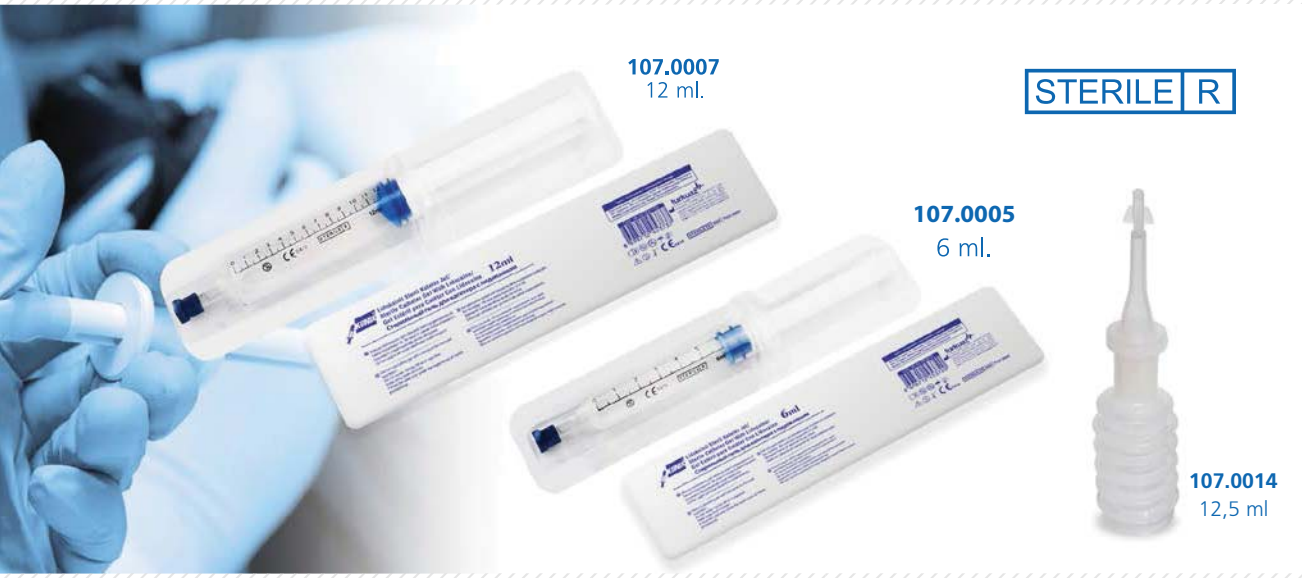
KATETER JEL

CATHETER GEL / GEL POUR CATHÉTER / GEL DE CATÉTER

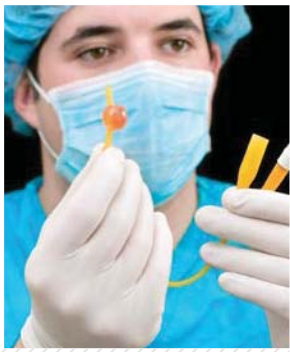


107.0007
12 ml.

107.0005
6 ml.

STERILE R

107.0014
12,5 ml



TR

Özellikler & Kullanım Şekli

Lidokain içeren Konix Steril Kateter Jeli, üretraya kateter, sistoskopi ve/veya başka bir tıbbi alet uygulamadan önce kullanılan steril, berrak, suda çözünen kaydırıcı bir jeldir. Jelin en önemli fonksiyonu kateter veya başka bir tıbbi alet ile üretral mukoza arasında kaydırıcı bir tabaka oluşturarak üretrayı kaplamasıdır. Lidokain içeren Konix Steril Kateter Jelin uygulamasından önce üretral manipulasyonla bağlantılı olan ağrının giderilmesinde yardımcı olmak amacıyla üretranın kaydırılması için kullanılır. Ayrıca anestezik etkisi ile ağrısız bir kateterizasyon sağlar. Konix Steril Kateter Jeli'nin antiseptik etkisi iatrojenik kontaminasyondan dolayı üst bölümü ve mesanede oluşabilecek enfeksiyonlardan hastayı korur.

Saklama Koşulları: 5-30°C'nin arasında ve güneş ışığından uzakta, serin bir yerde muhafaza ediniz.

FR

Propriétés & Utilisation

Cahéter stérile est une lidocaïne stérile contenant du gel clair et soluble dans l'eau qui est utilisé avant l'application de cathéter ou d'autres instruments médicaux sur l'urètre, pour des examens cystoscopiques ou autres. Recouvrir l'urètre en générant une couche lisse entre la muqueuse urétrale et le cathéter ou d'autres instruments médicaux c'est est la plus importante fonction du gel. Konix Gel pour cathéter stérile comprenant de lidocaïne, est utilisé avant l'intervention afin de protéger l'urètre pour atténuer la douleur liée à la manipulation urétrale. En outre, la pose du cathéter devient indolore grâce à son effet anesthésique. L'effet antiseptique du gel protège les patients d'une infection éventuelle qui pourrait se déclarer dans la partie supérieure et de la vessie et due à la contamination iatrogène.

Stockage: Conserver dans un endroit frais et sec entre 5 - 30 ° C à l'abri des rayons soleil.

EN

Properties & Use

Konix Sterile Catheter Gel is a sterile lidocaine contained, clear and water-soluble sort of gel which is used before applying cathether, cystoscopy and/or else medical instrument to urethra. Covering urethra by generating a slick layer between urethral mucosa and catheter or else medical instrument is the most significant function of the gel. Catheter Gel, including Lidocaine, inside, is used before the application in order to replace urethra for the purpose of dulling the pain related to urethral manipulation. Moreover, it provides an indolent catheterization with its anaesthetic effect. Antiseptic effect of the gel insulates patients from the potential infections that may occur within the upper part and urinary bladder due to iatrogenic contamination.

Storage: Store in a cool and dry environment between 5–30 °C away from direct sunlight.

ES

Características y Modo de Empleo

Catéter contiene lidocaína y es un gel lubricante de tipo estéril, transparente y soluble en agua, que se utiliza antes de aplicar el catéter, la cistoscopia y/o otro dispositivo médico a la uretra. La función más significativa del gel es cubrir la uretra mediante la generación de una capa resbaladiza entre la mucosa de la uretra y el catéter u otro dispositivo médico. Konix Gel Estéril de Catéter que contiene lidocaína se utiliza antes, para remplazar la uretra con el fin de evitar el dolor relacionado con la su manipulación. Además, proporciona un cateterismo indolente gracias a su efecto anestésico. El efecto antiséptico de Konix Gel Estéril de Catéter protege a los pacientes de las posibles infecciones que pueden originarse dentro de la parte superior de la vejiga y que es debida a la contaminación iatrogénica.

Almacenamiento: Conservar en ambiente seco y fresco entre 5-30° C fuera del alcance directo de la luz solar

Digitally signed by Bunic Gheorghe
Date: 2019.03.06 21:31:29 EET
Reason: MoldSign Signature
Location: Moldova

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
[illegible]

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 170030

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **TURKUAZSAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLERİSAN.VE TİC, LTD. ŞTİ.**
Yakuplu Mah. Birlik Cad No:34/3 Beylikdüzü, İstanbul, Turkey

for design, manufacturing and final inspection of medical device(s)

Catheter gel with lidocain - class III

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **203303-01 of 30.5.2017**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 05.06.2017 with validity until 04.06.2022.
The validity of this Certificate is limited until: 04.06.2022

05.06.2017

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

203303-01

Certificate

SERTİFİKA

TÜRCERT Sertifikasyon Merkezi
iş bu belge ile/TÜRCERT Certification Body
with this document.

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.

YAKUPLU MAH. BİRLİK CAD. NO:32/1 BEYLİKDÜZÜ İSTANBUL TÜRKİYE

şirketinin;/ of the company

RÖNTGEN SOLÜSYONLARI, TIBBİ CİHAZ DEZENFEKTANLARI VE MEDİKAL CİHAZLAR İÇİN STERİL BUĞU ÖNLEYİCİ SOLÜSYON, STERİL VE STERİL OLMAYAN KAYGANLAŞTIRICI JELLER, DOĞUM JELLERİ, STERİL VE STERİL OLMAYAN ULTRASON JELLERİ, STERİL VE STERİL OLMAYAN BURUN SOLÜSYONLARI, BİT ŞAMPUANI VE SPREYİ VE SMEAR DOKU SABİTLEYİCİ SPREYİNİN TASARIMI, ÜRETİMİ VE SATIŞI

MANUFACTURING AND SALES OF MEDICAL X-RAY SOLUTIONS, MEDICAL DEVICE DISINFECTANT, STERILE ANTIFOG SOLUTION FOR MEDICAL DEVICES, STERILE AND NON-STERILE LUBRICANT GELS, OBSTETRIC GEL, STERILE & NON-STERILE ULTRASOUND GELS, STERILE & NON-STERILE NASAL SOLUTIONS, ANTI-LICE AND NITS SHAMPOO AND SPRAY AND SMEAR SPRAY

belirlenen standardın uygulanması konusunda tıbbi cihazlar için yönetim sistemi yürürlüğe koyduğunu ve uygulamakta olduğunu taahhüt eder./ Effective medical devices management system and guarenteesthat you put in to apply

2018101013284-01MDMS Sayılı rapordaki inceleme ile/
2018101013284-01MDMSwith the nr. examination report;

TS EN ISO 13485:2016

şartlarının sağlanmış olduğu kanıtlanmıştır, iş bu sertifika yıllık ara denetimlerinin yapılması kaydıyla **08.08.2021** tarihine kadar geçerlidir./ Its proven that requirements are provided. This certificate is valid until **08.08.2021** with the condition of surveillance audits done

Sertifika Kayıt No/ Certificate Registration Nr : 2018101013284-01
Sertifika Yayın Tarihi / Date of Issue : 10.10.2018
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 08.08.2021

TÜRCERT

Türcert A.Ş.
Belgelendirme Bölümü Adına

ÖSAS
ÖSTERREICH
Spezielle Akkreditierung Service
austria
ÖSAS Ö-41

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ
Adres : Sanayi Mh. Atatürk Cd. No 57/17 Güngören / İstanbul - Türkiye
Telefon: 0 212 909 35 90 - 0 312 500 00 10 www.turcert.com

TRANSGLOBAL QUALITY ASSESSORS LLP

Management System Certificate

Certificate No. MD.QMS.91.006.06.16

This is certify that

Marflow AG

at

Soodstrasse 57, CH-8134 Adliswil, Zürich, Switzerland.

has been found to conform to Management System Standard

ISO 13485: 2003

This certificate valid for the following product / service ranges:

DESIGN AND MANUFACTURE OF NON-ACTIVE AND ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES FOR UROLOGY AND GASTROENTEROLOGY

Internal Certification : 23.06.2016
Valid until : 22.06.2019

(Authorized Signatory)
Transglobal Quality Assessors LLP

This is an accredited certificate authorised for issue by Accreditation Services for certifying bodies (Europe) Limited, who have assessed Transglobal Quality Assessors LLP Located at PUNE, INDIA, against defined criteria and in cognisance of ISO 17021, "Conformity Assessment Requirements for bodies providing audit and certification of management systems". This certificate is only valid when confirmed by register listed in the International register of Quality Assessed Organisation : www.irqao.com

Nottingham One-Step Dilator (70cm length)

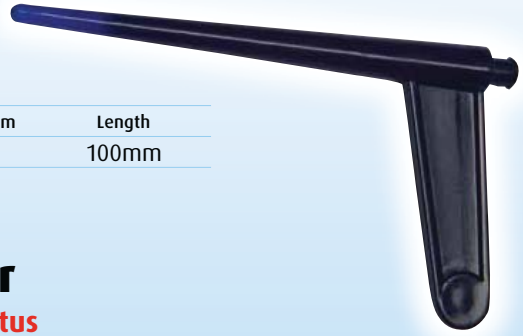
Hydrophilic coated, to dilate ureter

Taper length 6cm, accepts 0.038" guidewire
Class IIa device
For single use only

Art. No.	Shaft Size (Fr/CH)	Taper Size (Fr/CH) from
NOT 6-10	10	6 to 10
NOT 6-12	12	6 to 12

Female Dilator

To dilate the female urethra



Class IIa device
For single use only

Art. No.	Taper Size (Fr/CH) from	Length
FUD	3 to 10mm	100mm

Meatal Dilator

To dilate urethral meatus

Paediatric or adult model available
Class IIa device
For single use only

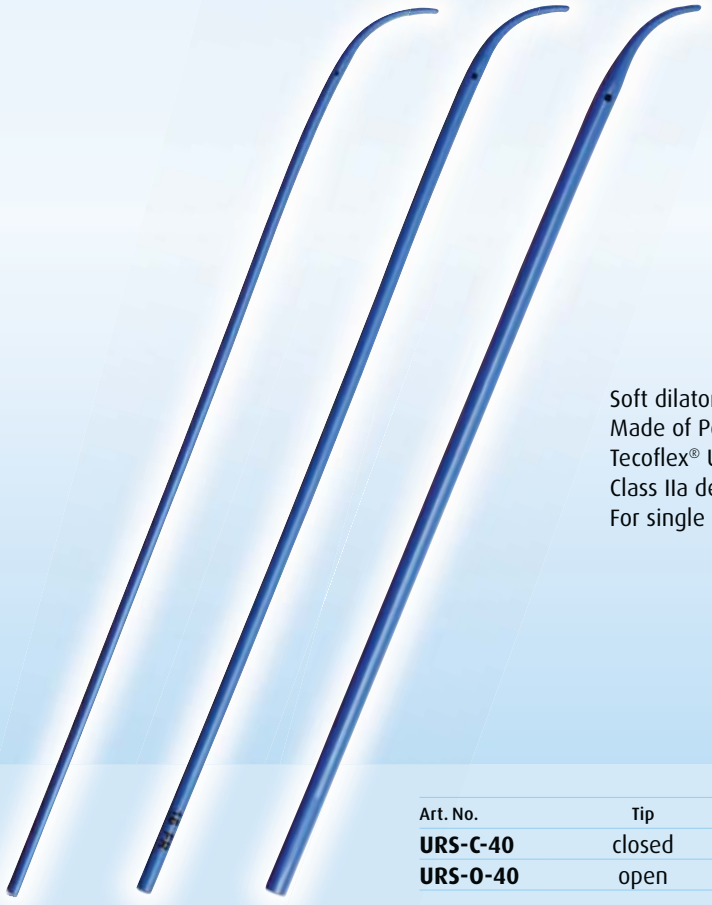
Art. No.	Tapersize	Length
MDA	2 to 8mm	45mm
MDP	1 to 4mm	20mm

Urethra Dilator Set Curved (40cm length)

For the dilation of the urethra

Set with 3 dilators
12Fr, 16Fr and 20Fr

Available with
open or closed tip



Soft dilators
Made of Polyurethane
Tecoflex® USA
Class IIa device
For single use only

Art. No.	Tip	Length (cm)
URS-C-40	closed	40
URS-O-40	open	40