UROMED »HYDROPUR®« SELDINGER-TECHNIK

REF 4445 – 4449

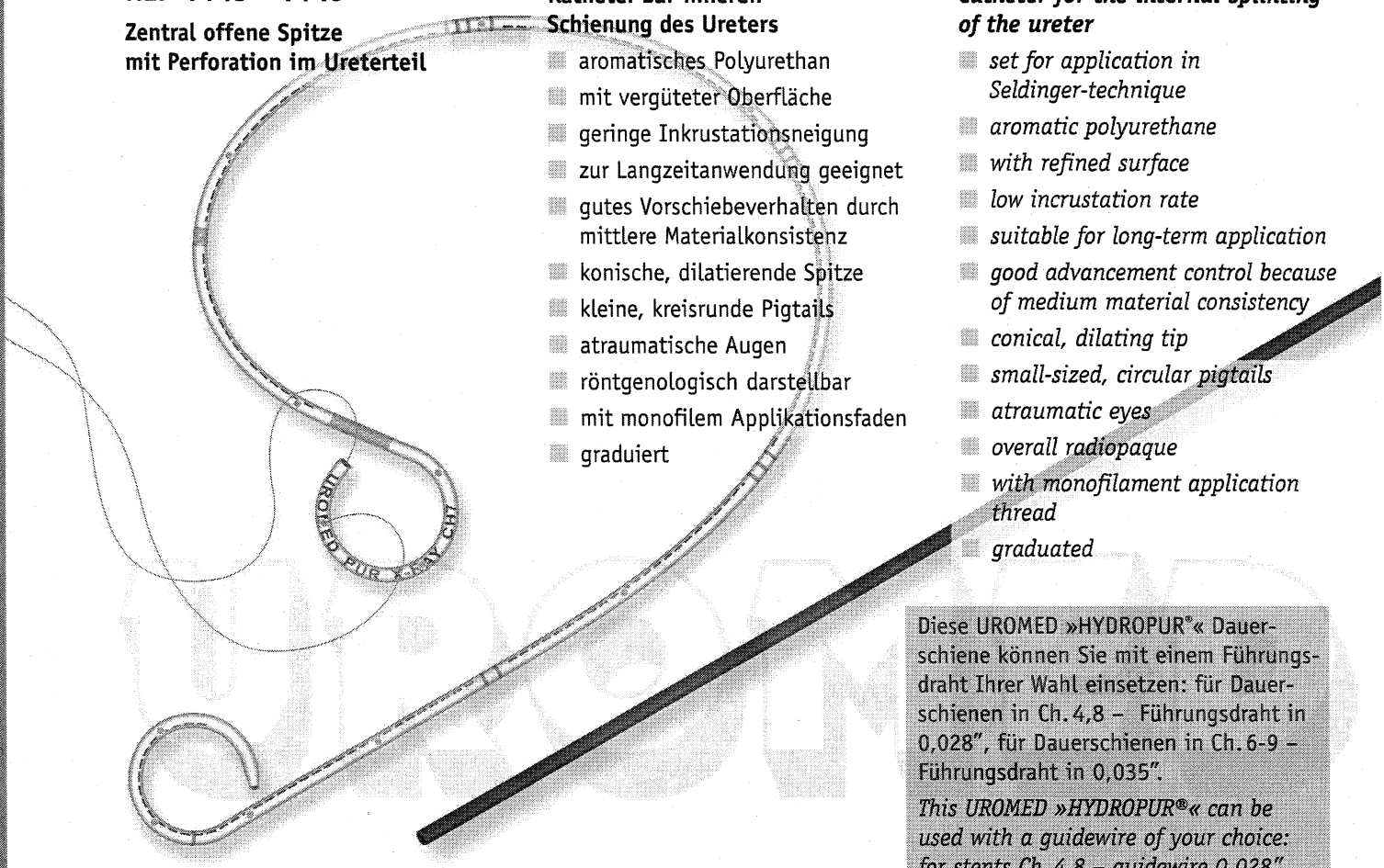
Zentral offene Spitze mit Perforation im Ureterteil

Katheter zur inneren Schienung des Ureters

- aromatisches Polyurethan
- mit vergüteter Oberfläche
- geringe Inkrustationsneigung
- zur Langzeitanwendung geeignet
- gutes Vorschiebeverhalten durch mittlere Materialkonsistenz
- konische, dilatierende Spitze
- kleine, kreisrunde Pigtails
- atraumatische Augen
- röntgenologisch darstellbar
- mit monofilem Applikationsfaden
- graduiert

Catheter for the internal splinting of the ureter

- *set for application in Seldinger-technique*
- *aromatic polyurethane*
- *with refined surface*
- *low incrustation rate*
- *suitable for long-term application*
- *good advancement control because of medium material consistency*
- *conical, dilating tip*
- *small-sized, circular pigtails*
- *atraumatic eyes*
- *overall radiopaque*
- *with monofilament application thread*
- *graduated*



Diese UROMED »HYDROPUR®« Dauerschiene können Sie mit einem Führungsdraht Ihrer Wahl einsetzen: für Dauerschienen in Ch. 4,8 – Führungsdraht in 0,028", für Dauerschienen in Ch. 6-9 – Führungsdraht in 0,035".

This UROMED »HYDROPUR®« can be used with a guidewire of your choice: for stents Ch. 4,8 – guidewire 0,028", for stents Ch. 6-9 – guidewire 0,035".

Ureter-Dauerschiene
beidseitiger Pigtail
ureteral stent, double pigtail central open tip, with perforation in the ureteral part

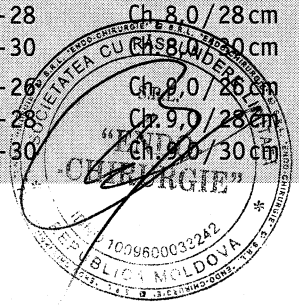
Nachschiebeschlauch
Länge 45 cm bzw. 70 cm bei Ch. 4,8
pusher length 45 cm and 70 cm for Ch. 4,8

Unmittelbar nach Positionierung der Ureter-Dauerschiene ist der Applikationsfaden zu entfernen.

Right after positioning of the ureteral stent the application thread has to be removed.

REF *REF*	**Dauerschiene** *Stent*	**PZN** *PZN*
4445-24	Ch. 4,8/24 cm	11371225
4445-26	Ch. 4,8/26 cm	11371231
4445-28	Ch. 4,8/28 cm	11371248
4446-24	Ch. 6,0/24 cm	11371254
4446-26	Ch. 6,0/26 cm	11371260
4446-28	Ch. 6,0/28 cm	11371277
4446-30	Ch. 6,0/30 cm	11371283

REF *REF*	**Dauerschiene** *Stent*	**PZN** *PZN*
4447-24	Ch. 7,0/24 cm	11371308
4447-26	Ch. 7,0/26 cm	11371314
4447-28	Ch. 7,0/28 cm	11371320
4447-30	Ch. 7,0/30 cm	11371337
4448-26	Ch. 8,0/26 cm	11371343
4448-28	Ch. 8,0/28 cm	11371372
4448-30	Ch. 8,0/30 cm	11371389
4449-26	Ch. 9,0/26 cm	11371395
4449-28	Ch. 9,0/28 cm	11371426
4449-30	Ch. 9,0/30 cm	11371432



Verpackung: doppelt, steril
Original-Karton: 10 Stück

Packing: *double, sterile*
Original carton: *10 pieces*

MEDCERT®
Certification. Medical Only.

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 — 20355 Hamburg — Germany

herewith confirms that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

With the facilities as per attachment 1

has introduced, applies and maintains a Quality Management System in the area of:

Design, manufacture, final inspection and distribution of Medical devices for

- **Urology**
- **Gynecology**
- **Radiology**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 12 March 2020

Report No.: 1202PS25F
Process No.: QS – 1202
Certificate No.: 1202GB445190614

Hamburg, 14 June 2019

MEDCERT Certification Body
(Dr. Andreas Search)

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

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EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

This certificate is valid until 12 March 2022

Report No.: 1202PS25F
Process No.: QS – 1202
Certificate No.: [illegible]202GB410190617

Hamburg, 17 June 20[illegible]

MEDCERT Certification Body
(Dr. Andreas Schich)

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To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB410190617

List of products / product categories included in the scope of certificate

Medical devices for Urology

- **Biopsy gun**
- **Catheter and catheter sets**
- **Implants**
- **Guide wires**
- **Stone baskets**
- **Cannulas and dilators**
- **Biopsy cannulas**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

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