



Universa® Firm Ureteral Stent

Used for temporary internal drainage. The stent is made of a soft, sensitive stent material providing comfort and ease of stent indwelling. The stent position is visible by the visibility of the positioner tip. See Figure 1.

CAUTION: Periodic evaluation of the stent is required every 12 months.

Global Product Number	Order Number	Fr	Length cm
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Set

G54378	UFI-522	5.0	22
G54448	UFI-626	6.0	26
G54446	UFI-628	6.0	28
G54379	UFI-726	7.0	26
G54440	UFI-728	7.0	28

Stent and Positioner

G54418	UFI-522-R	5.0	22
G54416	UFI-524-R	5.0	24
G54414	UFI-526-R	5.0	26
G54412	UFI-528-R	5.0	28
G54410	UFI-622-R	6.0	22
G54408	UFI-624-R	6.0	24
G54407	UFI-626-R	6.0	26
G54404	UFI-628-R	6.0	28
G54400	UFI-724-R	7.0	24
G54398	UFI-726-R	7.0	26
G54396	UFI-728-R	7.0	28

Stent Set with Roadrunner® Wire Guide and Lockable Pusher

G54435	UFI-526-RPC-LP	5.0	26
G54432	UFI-528-RPC-LP	5.0	28
G54430	UFI-624-RPC-LP	6.0	24
G54429	UFI-626-RPC-LP	6.0	26
G54428	UFI-628-RPC-LP	6.0	28
G54426	UFI-724-RPC-LP	7.0	24
G54425	UFI-726-RPC-LP	7.0	26
G54424	UFI-728-RPC-LP	7.0	28

Stent with Pigtail Sideports Only

G54422	UFI-726-P	7.0	26
G54421	UFI-728-P	7.0	28

Français **Set d'endoprothèse urétérale rigide Universa®**

Utilisé pour effectuer un drainage interne temporaire entre la jonction pyélo-urétérale et la vessie. Le matériau thermosensible de l'endoprothèse offre l'avantage de la rigidité lors de la mise en place et de la souplesse lorsque l'endoprothèse est à demeure. Le positionneur d'endoprothèse comporte une bande radio-opaque qui améliore la visibilité sous radioscopie de l'extrémité du positionneur. Le set comprend une endoprothèse, un guide et un positionneur.

MISE EN GARDE : Une évaluation périodique est recommandée ; l'endoprothèse ne doit pas rester à demeure pendant plus de 12 mois.

Deutsch **Universa® Firm Ureter Stentset**

Dient zur vorübergehenden internen Drainage aus dem pyeloureteralen Übergang in die Blase. Das thermosensible Stentmaterial bietet bei der Platzierung die Vorzüge eines festen Stents und nach der Platzierung die Vorzüge eines weichen, anpassungsfähigen Stents. Der Stent-Positionierer hat einen röntgendichten Streifen, der die Darstellung der Spitze des Positionierers unter Durchleuchtung verbessert. Das Set enthält einen Stent, einen Führungsdraht und einen Positionierer.

VORSICHT: Eine regelmäßige Überprüfung ist angeraten. Der Stent darf nicht länger als 12 Monate verweilen.

Italiano **Set con stent ureterale rigido Universa®**

Utilizzato per il drenaggio interno temporaneo dalla giunzione ureteropelvica alla vescica. Il materiale termosensibile dello stent offre le caratteristiche di posizionamento di uno stent rigido assieme ai vantaggi di uno stent cedevole durante la permanenza. Il posizionatore per stent è dotato di una banda radiopaca che migliora la visibilità della punta del posizionatore stesso in fluoroscopia. Il set include uno stent, una guida e un posizionatore.

ATTENZIONE - Si consiglia di eseguire una valutazione periodica; la permanenza dello stent non deve superare i dodici mesi.

Español **Equipo de stent ureteral rígido Unversa®**

Se utiliza para el drenaje interno temporal desde la unión ureteropélvica hasta la vejiga urinaria. El material termosensible del stent proporciona las ventajas de un stent rígido en cuanto a la colocación y de un stent blando amoldable en cuanto a la permanencia. El posicionador de stent dispone de una banda radiopaca que mejora la visibilidad fluoroscópica de la punta del posicionador. El equipo incluye: stent, guía y posicionador.

AVISO: Se recomienda realizar evaluaciones periódicas; el stent no debe permanecer colocado más de 12 meses.

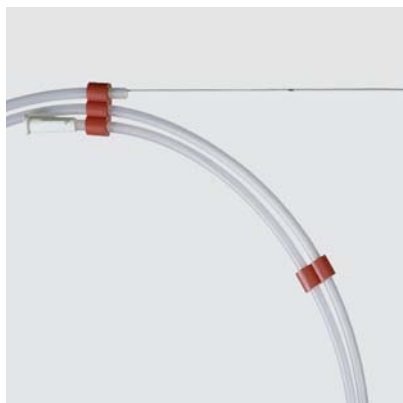
Русский **Набор твердых мочеточниковых стентов Universa®**

Применяется для временного внутреннего дренажа из лоханочно-мочеточникового сочленения в мочевой пузырь. Термочувствительный материал стента сочетает преимущества жесткого стента при установке и мягкого податливого стента при нахождении в организме. Позиционирующее устройство стента имеет рентгеноконтрастную полосу, которая облегчает рентгеноскопический контроль положения его кончика. В набор входят стент, проводник и позиционирующее устройство. **ОСТОРОЖНО:** Рекомендуется периодическое обследование; стент не должен находиться в организме пациента более 12 месяцев.

Polski **Zestaw sztywnego stentu moczowodowego Universa®**

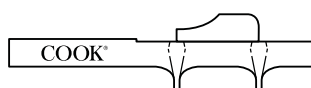
Stosowany do czasowego drenażu wewnętrznego moczu z poziomu połączenia miedniczkowo-moczowodowego do pęcherza. Termicznie czuły materiał stentu ma tę zaletę, że stent jest sztywny w czasie wprowadzania, jednak po wprowadzeniu do ciała pacjenta staje się miękki i elastyczny. Pozycjoner stentu posiada cieniobłą opaskę, która poprawia wizualizację fluoroskopową końcówki pozycjonera. Zestaw zawiera stent, przewodnik i pozycjoner.

PRZESTROGA: Zaleca się okresową kontrolę; nie wolno utrzymywać założonego stentu bez wymiany przez okres dłuższy niż 12 miesięcy.



Roadrunner® Hydrophilic PC Wire Guide

Used to gain ureteral access, to establish a tract, and to assist in the placement, replacement, and exchange of medical devices during urological procedures. It may also be used for catheter positioning and exchange in a tortuous or kinked ureter, traversing a large stone en route to the kidney, or in cases demanding enhanced control and high radiopacity. The Roadrunner has a nitinol core, a flexible, platinum tip, and one-to-one torque. The AQ® coating is a microthin layer of hydrophilic polymer that, when activated, attracts and holds water and other liquids to the wire guide, creating a low-friction surface. Choose between standard- and stiff-body options. This product is not intended for PTCA use.



Order Number	Reference Part Number	Diameter inch	Length cm	Tip Configuration	Tip Length cm	Coating
Standard-Body Wire Guide						
G17540	RFSPC-035145	0.035	145	angled	3	Slip-Coat®
G17541	RFSPC-038145	0.038	145	angled	3	Slip-Coat
G17542	RFSPC-035145-0	0.035	145	straight	3	Slip-Coat
G17539	RFSPC-038145-0	0.038	145	straight	3	Slip-Coat
Standard-Body Wire Guides with Ink Marks and AQ® Coating						
G18629	RFSPC-035145-0-I-AQ	0.035	145	straight	3	AQ
Stiff-Body Wire Guides*						
G34132	RPC-035145-5	0.035	145	angled	8	Slip-Coat
G34130	RPC-038145-5	0.038	145	angled	8	Slip-Coat
G34131	RPC-035145-0-5	0.035	145	straight	8	Slip-Coat
G34129	RPC-038145-0-5	0.038	145	straight	8	Slip-Coat

*Sold in boxes of 5.

Slip-Coat is a registered trademark of Angiotech Biocoatings Corp.

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Delivery for details.

Please see product risk information in the IFU at cookmedical.eu.



REGISTRUL DE TAT AL DIPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			ufi			cook	eric		
DM000207565	TENT URETERAL	Cook® Universa®	UFI-628-R	G54404	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207564	TENT URETERAL	Cook® Universa®	UFI-628-P	G54452	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207567	TENT URETERAL	Cook® Universa®	UFI-728	G54440	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207566	TENT URETERAL	Cook® Universa®	UFI-628-RPC-LP	G54428	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207569	TENT URETERAL	Cook® Universa®	UFI-728-R	G54396	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207570	TENT URETERAL	Cook® Universa®	UFI-728-RPC-LP	G54424	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207568	TENT URETERAL	Cook® Universa®	UFI-728-P	G54421	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207560	TENT URETERAL	Cook® Universa®	UFI-528	G54447	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207561	TENT URETERAL	Cook® Universa®	UFI-528-R	G54412	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019
DM000207562	TENT URETERAL	Cook® Universa®	UFI-528-RPC-LP	G54432	Irlanda	COOK IRELAND LIMITED	ERICON .R.L.	A07.P -01.Rg04-106	26-04-2019

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Product Service

Certificate

No. Q5 033038 0038 Rev. 01

Holder of Certificate: Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick
IRELAND

Facility(ies): Cook Ireland Limited
O'Halloran Road, National Technology Park, Limerick, IRELAND

See Scope of Certificate

Certification Mark:**Scope of Certificate:**

Design, Development, Manufacture and Distribution of Disposable Devices for Use in Pulmonary, Urological, Gastroenterological and Obstetric/Gynaecological Procedures - Including Catheters, Introducers, Wires, Drainage Sets, Electrosurgical and Non-Active Instruments, Stents, Stent Grafts, Needles, Cannulae, Self Expandable Vascular Stents and Delivery Systems, Drug Eluting Peripheral Stents with Delivery Systems and Vascular Needles and Connecting Tubes.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5 033038 0038 Rev. 01

Report No.: 75950473

Valid from: 2021-12-22

Valid until: 2024-06-21

Date, 2021-12-17

Christoph Dicks

Head of Certification/Notified Body