

- su numatyta pakuotės atidarymo vieta



-ant pakuotės pažymėtas produkto galiojimo laikas mėnesiais;

-sterilūs (simbolis ant pakuotės);
-vienkartiniai (pažymėta simboliu);

PAJUNK® GmbH Medizintechnologie | Karl-Hall-Str. 1 | 78187 Geisingen, Germany

Manufacturer – Declaration

COMPATIBILITY

Hereby the PAJUNK® GmbH Medizintechnologie confirms the following:

The cannula Art. No. **221S130200** consist of two major components which is an outer and an inner cannula.

vidinis adatos diametras yra 0,039 coliq. 1mm = 0.039"

The outer cannula has an inner lumen of 1.00 mm. Therefore guide wires up to a max outer diameter of 0.038" ($0.038" \times 25.4 = 0.9652 \text{ mm}$) fit through the outer cannula. The tolerances and the actual outer diameter of the guide wire always has to be taken into consideration.

As executed:

Geisingen, 2020-07-29

Ort, Datum *Issued*



Rosi Schützing

R&D Engineer

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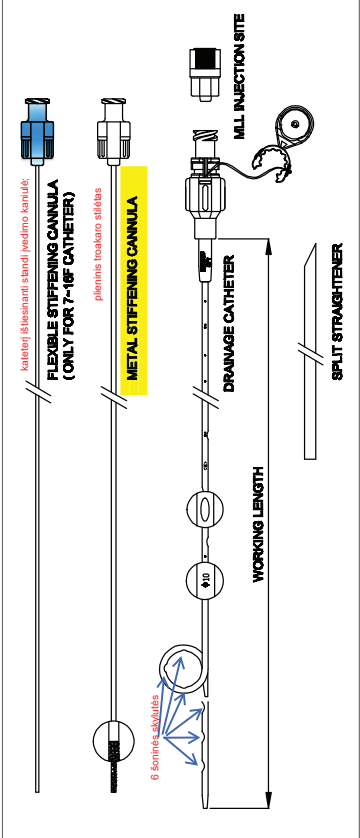
rosi.schuetzinger@pajunk.com _www.pajunk.com

DRAINAGE CATHETER SET-SELDINGER



- Used for biliary drainage; skirtas biliariniam drenažui
- Catheter placement is performed using Seldinger technique; pigtail tipo su užrakinamu galu
- The safety string lock system provides strong fixation of the pigtail; Without SAFETY STRING LOCK
- Hydrophilic coating decreased friction of the distal catheter facilitates easy insertion; padengtas hidrofiline danga
- Supplied sterile in peel-open packages; vienkartinis, sterilus
- Intended for one-time use;

BILIARY CATHETER (BT-PDS-series(B))



With SAFETY STRING LOCK

Order Number	Size	Accepts Guide Wire Dia.	Working Length	Order Number	Size	Accepts Guide Wire Dia.
BT-PDS-0620-W(B)	6F	0.35 inch (0.89mm)	19 cm (XX=20)	BT-PDS-1020-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0625-W(B)	6F	0.35 inch (0.89mm)	24 cm (XX=25)	BT-PDS-1025-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0630-W(B)	6F	0.35 inch (0.89mm)	29 cm (XX=30)	BT-PDS-1030-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0635-W(B)	6F	0.35 inch (0.89mm)	34 cm (XX=35)	BT-PDS-1035-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0640-W(B)	6F	0.35 inch (0.89mm)	39 cm (XX=40)	BT-PDS-1040-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0645-W(B)	6F	0.35 inch (0.89mm)	44 cm (XX=45)	BT-PDS-1045-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0650-W(B)	6F	0.35 inch (0.89mm)	49 cm (XX=50)	BT-PDS-1050-W(B)	10F	0.38 inch (0.97mm)
BT-PDS-0720-W(B)	7F	0.35 inch (0.89mm)	19 cm (XX=20)	BT-PDS-1220-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0725-W(B)	7F	0.35 inch (0.89mm)	24 cm (XX=25)	BT-PDS-1225-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0730-W(B)	7F	0.35 inch (0.89mm)	29 cm (XX=30)	BT-PDS-1230-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0735-W(B)	7F	0.35 inch (0.89mm)	34 cm (XX=35)	BT-PDS-1235-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0740-W(B)	7F	0.35 inch (0.89mm)	39 cm (XX=40)	BT-PDS-1240-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0745-W(B)	7F	0.35 inch (0.89mm)	44 cm (XX=45)	BT-PDS-1245-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0750-W(B)	7F	0.35 inch (0.89mm)	49 cm (XX=50)	BT-PDS-1250-W(B)	12F	0.38 inch (0.97mm)
BT-PDS-0820-W(B)	8F	0.38 inch (0.97mm)	19 cm (XX=20)	BT-PDS-1420-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0825-W(B)	8F	0.38 inch (0.97mm)	24 cm (XX=25)	BT-PDS-1425-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0830-W(B)	8F	0.38 inch (0.97mm)	29 cm (XX=30)	BT-PDS-1430-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0835-W(B)	8F	0.38 inch (0.97mm)	34 cm (XX=35)	BT-PDS-1435-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0840-W(B)	8F	0.38 inch (0.97mm)	39 cm (XX=40)	BT-PDS-1440-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0845-W(B)	8F	0.38 inch (0.97mm)	44 cm (XX=45)	BT-PDS-1445-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0850-W(B)	8F	0.38 inch (0.97mm)	49 cm (XX=50)	BT-PDS-1450-W(B)	14F	0.38 inch (0.97mm)
BT-PDS-0920-W(B)	9F	0.38 inch (0.97mm)	19 cm (XX=20)			
BT-PDS-0925-W(B)	9F	0.38 inch (0.97mm)	24 cm (XX=25)			
BT-PDS-0930-W(B)	9F	0.38 inch (0.97mm)	29 cm (XX=30)			
BT-PDS-0935-W(B)	9F	0.38 inch (0.97mm)	34 cm (XX=35)			
BT-PDS-0940-W(B)	9F	0.38 inch (0.97mm)	39 cm (XX=40)			
BT-PDS-0945-W(B)	9F	0.38 inch (0.97mm)	44 cm (XX=45)			
BT-PDS-0950-W(B)	9F	0.38 inch (0.97mm)	49 cm (XX=50)			

Organ Biopsy

PAJUNK®

Initial puncture cannula with ultrasonic tip

Nerūdijančio plieno punkcinė adata echo pozityviu galiuku

The initial puncture cannula with ultrasonic tip made of high-grade stainless steel is especially suitable for the nephrostomy and all percutane punctures with guide- wires. There are 2-parts as well as 3-parts designs available, with and without graduation. Its outer cannula is round-blunt and is aligned with the internal stylett cannula.

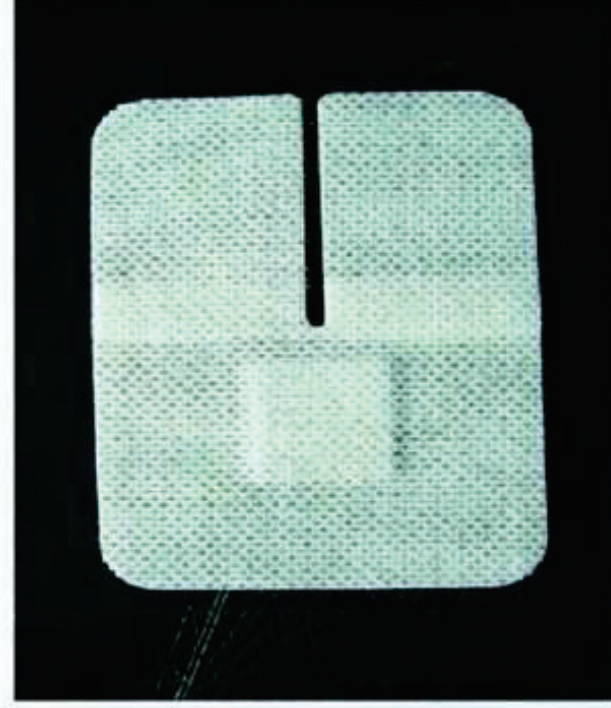


Size	Working length	Description	Item no.	Item no.	PU
			[double reflection]	[graduated]	
18 G	200 mm	2-parts	221S130200		10
18 G	200 mm	3 parts	224S130200	259S130200	10
18 G	280 mm	3-parts		259S130280	10

Nukreipiančiosios stygos skersmuo yra suderinamas darbui su punkcinės adatos vidiniu skersmeniu.

47-48 p.d.

Žaizdų tvarščiai



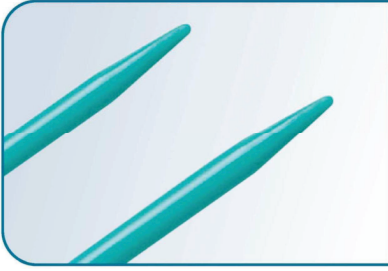
I.V. Plaster

Pleistras sudarytas iš mikroaktytos neaustinės ar permatomos plėvelės, kuri padengta hipoalergine kliju mase. Absorbuojamasis minkštas tamponas su tinklo dangą neprimpa prie injekcijos vietos ir nesukelia skausmo nuimant tvarstį.
Dydis - 6 x 8 cm

Prie odos limpanti kateterio fiksacijos sistema.

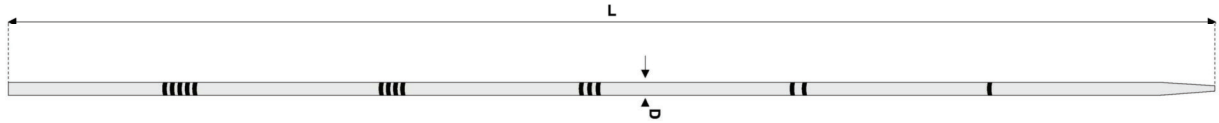
URETERAL DILATOR (ECONOMY) SET

ÜRETERAL DİLATÖR (EKONOMİ) SETİ



Used for dilation of the ureteral strictures and to establish and maintain an access in to the bladder via urethral for flexible cystoscopy.

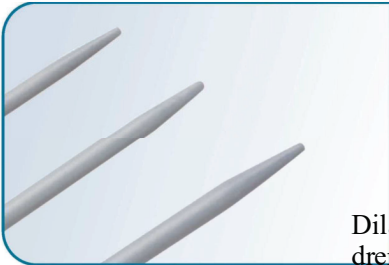
Flexible sistoskopi uygulamaları esnasında olası üretral darlıkları genişletmek için kullanılır.



Code Kod	Tip Uç Ø Fr	Guide Wire Kılavuz Tel Ø inch	Length Uzunluk cm	Catheter Kateter Ø Fr
533001	6	0,038	70	8 - 22

FASCIAL DILATORS & SETS

FASCIAL DİLATÖR ve SETLERİ

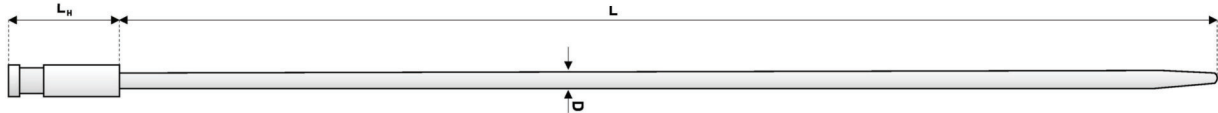


Used for fascial dilatation prior to nephrostomy and/or stone manipulation.

Böbrekte taş tedavisi ve/veya nefrostomi öncesi fasyal dilatasyon amacı ile kullanılır.

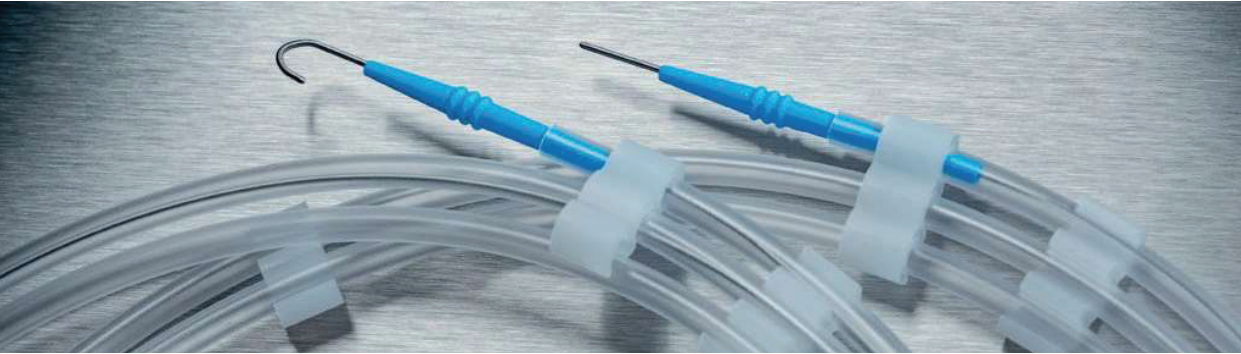
Dilatatorius padengtas hidrofiline danga arba lygiaverte medžiaga, išorinis skersmuo atitinka dreno išorinį skersmenį, tinkamas naudoti su siūloma nukreipiančiaja viela.

Vientisas dilatorius

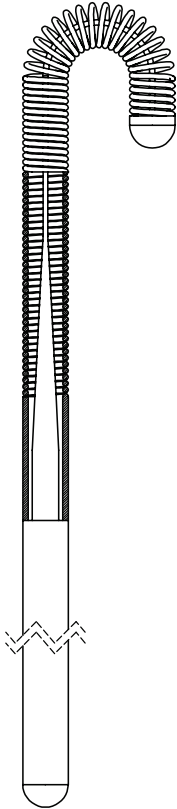


Kodas	Išorinis skersmuo	Ilgis, cm	Description
Code Kod	O.D. Dış Çap Ø Fr	Length Uzunluk cm	Açıklama
542008	6	22	Fascial Dilator
542009	8	22	Fascial Dilator
542010	10	22	Fascial Dilator
542011	12	22	Fascial Dilator
542012	14	22	Fascial Dilator
542013	16	22	Fascial Dilator
542014	6 - 16	22	Fascial Dilator Set

Accoat Standard Guide Wire – Lunderquist PTC



gale lenkta 3 mm spinduliu



Dimensions
Ø 0.025" / 0,64 mm
Ø 0.035" / 0,89 mm

Length
50 cm
60 cm
70 cm
80 cm
90 cm
100 cm
120 cm
150 cm
260 cm

Surface
Stainless steel
PTFE coated

Distal tip form
Straight tip
J-tip radius: 1,5 – 3 – 6 mm


Distal flexible length
5 cm
7 cm
10 cm
12 cm
15 cm
17 cm

Customised products on request

Description of item code
PTC-S/Jx-C-Fx-0xx-L
(example: PTC-S-C-F5-035-150)

S	Straight tip	tiesi
Jx	J-tip radius J1,5 mm tip J3 mm tip J6 mm tip	3mm lenktu galiuku
C	PTFE coated	dengta teflonu
Without C	stainless steel	plieninis troakaro stiletas;
Fx	Distal Flexible length F5 - 5 cm flexible tip F7 - 7 cm flexible tip F10 - 10 cm flexible tip F12 - 12 cm flexible tip F15 - 15 cm flexible tip F17 - 17 cm flexible tip	
0xx:	Diameter of the guide wire 025: 0.025" (0,64 mm) 038: 0.035" (0,89 mm)	skersmuo
L:	Length of the guide wire 50, 60, 70, 80, 90, 100, 120, 150 and 260 cm	

pravedimo stygos skersmuo tolygus punkcinės adatos vidiniam skersmeniui

	TECHNICAL FILE PRODUCT REF. NO: 500XXX, 500XXXH, 510XXX, 510XXXH, 520XXX, 5200XXH, 5311XX, 532XXX, 533XXX, 534XXX, 536XXX, 537XXX, 5370XXH, 538XXX, 539XXX, 540XXX, 5400XXH, 5410XX, 542XXX, 543XXX, 544XXX, 545XXX REF. MDD 93/42/EEC (2007/47/EC)		Document No	KYS.TD.05/4
			Revision No	03
			Revision Date	20.09.2012
			Issue Date	15.04.2011
			Page Number	27 / 32

Nottingham Dilator Catheter: Used to dilate the intramural tunnel and ureter in one step. May also be used to inject contrast medium to determine sub mucosal tunneling or anesthetic jelly to aid in dislodging ureteral stents.

Ureteral Dilators and Sets: It is used for dilatation of the urethral strictures and to establish and maintain an access in to the bladder viaa urethra for flexible cystoscopy.

12.2. SPECIFICATIONS

Ureteral Access Sheath & Dilator Set	OD: 4,6 mm +/- 0,254 mm ID: 4 mm +/- 0,254 mm Length: 38- 54- 25 cm +/- 0,5 cm
Nottingham Dilator Catheter	OD: 4mm +/- 0,254 mm Tip OD: 2 mm +/- 0,254 mm Length: 70 cm +/- 0,5 cm
Ureteral Dilator Set	OD: 2,66- 3,33- 4 - 4,66- 5,33- 6- 6,66- 7,33 mm +/- 0,254 mm Tip OD: 2 mm +/- 0,254 mm Length: 40 cm +/- 0,5 cm Guide Wire: 0,038 inch

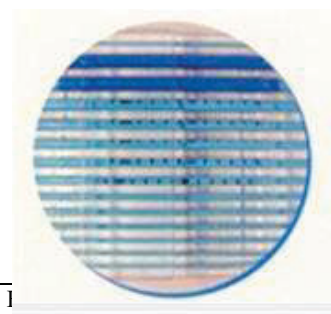
12.3. CLASSIFICATION

As per Annexure IX of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Ureteral Dilators and Access Sheat Sets are classified as Class IIa product ,according to Rule 6, which shall comply with essential requirements of Medical Devices Directive 93/42/EEC and ISO 13485 Standard.

12.4. PRODUCT LIST

CODE	GMDN	UNSPSC	PRODUCT NAME	CLASS	BARCODE	EXPL.
533001	38821	42294909	URETERAL DILATOR (ECONOMY) 8-22 FR. X 70 CM SET	CLASS IIa	8699412312010	Sterile CE 1984
542002	38821	42294909	NOTTINGHAM CATHETER 12/6 FR 70 CM	CLASS IIa	8699412402025	Sterile CE 1984
542015	11265	42295433	URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 38CM	CLASS IIa	8699412402155	Sterile CE 1984
542016	11265	42295433	URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 54CM	CLASS IIa	8699412402162	Sterile CE 1984
542021	11265	42295433	URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 25CM	CLASS IIa	8699412402216	Sterile CE 1984


13. RENAL DILATORS and SETS



13.1. INTENDED USE

Amplatz sheath renal dilator is used to pass in to the body to allow scope to pass through the sheath and dilator is used for dilation for the amplatz sheath to be passed.

Amplatz Renal Sheath: Sheath protects regions which dilator passed through body.

	TECHNICAL FILE PRODUCT REF. NO: 500XXX, 500XXXH, 510XXX, 510XXXH, 520XXX, 5200XXH, 5311XX, 532XXX, 533XXX, 534XXX, 536XXX, 537XXX, 5370XXH, 538XXX, 539XXX, 540XXX, 5400XXH, 5410XX, 542XXX, 543XXX, 544XXX, 545XXX REF. MDD 93/42/EEC (2007/47/EC)		Document No	KYS.TD.05/4
			Revision No	03
			Revision Date	20.09.2012
			Issue Date	15.04.2011
			Page Number	28 / 32

Amplatz Renal Dilator and Sheath Set: Amplatz renal dilator sheath set is used for dilatation, to pass in to the body allow scope to pass through the sheath and sheaths provides a safe environment for holes.

Facial Dilators and Sets: Shorter. It is used for fascial dilatation prior to nephrostomy and/or Stone manipulation.

Screw Dilator: Shape of dilator like screw. Used for one step dilatation. This can be used instead of sequential dilatation.

13.2. SALIENT FEATURES

- Special atraumatic design
- Smooth surfaces for ease of introduction
- Uniform taper to reduce trauma

13.3. SPECIFICATIONS

Amplatz Renal Sheath	Amplatz Renal Sheath OD: 6,66- 8- 8,66- 9,33- 10- 10,66- 11,33 mm +/- 0,254mm Amplatz Renal Sheath ID: 5,33- 6,66- 7,33- 8- 8,66- 9,33- 10mm +/- 0,254 mm Length: 17- 20- 30 cm +/- 0,5 cm	
Amplatz Renal Dilator Sheath Set	Amplatz Renal Sheath OD: 2- 2,66- 3,33- 4- 4,66- 5,33- 6- 6,66- 7,33- 8,66- 9,33- 10 mm +/- 0,254 mm Catheter OD: 2,33 mm +/- 0,254 mm Length: 25- 30- 80 cm +/- 1 cm	
Facial Dilators and Set	OD: 2- 2,66- 3,33- 4- 4,66- 5,33 mm +/- 0,254 mm Length: 22 cm +/- 0,5 cm, Hydrophilic coating	dilatatorius padengtas hidrofilinė danga, išorinis skersmuo atitinka dreño išorinį skersmenį, o vidinis – pravedamosios stygos skersmenį
Screw Dilator	OD: 5,33 mm +/- 0,254 mm Tip OD: 2 mm +/- 0,254 mm Length: 22 cm +/- 0,5 cm	
Percutaneous Tract Dilatation Kit with Amplatz Renal Dilator Set	18 Gauge * 20cm Introducer Needle; 0.038 inch * 150cm Hydrophilic Nitinol Guidewire; 0,035 inch* 150cm Hydrophilic Nitinol Amplatz Type Renal Dilator and Sheath Set ; 14 Fr Re-Entry Malecot Drainage Catheter; Dual Lumen Ureteral Catheter 10 Fr, 50cm; Standart Percutaneous Drape Set	
Percutaneous Tract Dilatation Kit with Nephrostomy Balloon Dilator	18 Gauge * 20cm Introducer Needle; 0.038 inch * 150cm Hydrophilic Nitinol Guidewire; 0,035 inch* 150cm Hydrophilic Nitinol Nephrostomy Tract Balloon Dilatation Catheter; 30 Fr*17 cm Length PTFE Radiopaque Sheath; 20 cc Inflator with Pressure Gauge; 14 Fr Re-Entry Malecot Drainage Catheter; Dual Lumen Ureteral Catheter 10 Fr, 50cm; Standart Percutaneous Drape Set	

13.3. CLASSIFICATION


As per Annexure IX of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Renal Dilators and Sets are classified as Class IIa product, according to Rule 6, which shall comply with essential requirements of Medical Devices Directive 93/42/EEC and ISO 13485 Standard.

13.4. PRODUCT LIST

CODE	GMDN	UNSPSC	PRODUCT NAME	CLASS	BARCODE	EXPL.
542001	38821	42294909	SCREW DILATOR 6-16 FR 22 CM	CLASS IIa	8699412402018	Sterile CE 1984
542003	38821	42295433	AMPLATZ RENAL DILATOR SET 8-30 FR.	CLASS IIa	8699412402032	Sterile CE 1984

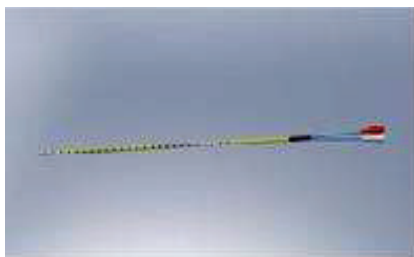
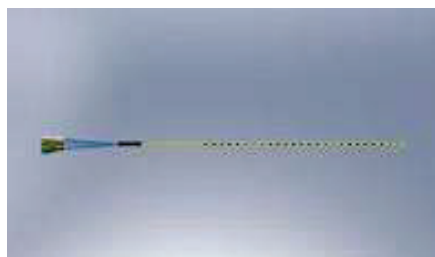
HAZIRLAYAN: QM

ONAYLAYAN:GM

	TECHNICAL FILE PRODUCT REF. NO: 500XXX, 500XXXH, 510XXX, 510XXXH, 520XXX, 5200XXH, 5311XX, 532XXX, 533XXX, 534XXX, 536XXX, 537XXX, 5370XXH, 538XXX, 539XXX, 540XXX, 5400XXH, 5410XX, 542XXX, 543XXX, 544XXX, 545XXX REF. MDD 93/42/EEC (2007/47/EC)		Document No	KYS.TD.05/4
			Revision No	03
			Revision Date	20.09.2012
			Issue Date	15.04.2011
			Page Number	29 / 32

542004	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 28FR I.D 24 FR	CLASS IIa	8699412402049	Sterile CE 1984
542005	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 30 FR I.D 26 FR	CLASS IIa	8699412402056	Sterile CE 1984
542006	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 32 FR I.D 28 FR	CLASS IIa	8699412402063	Sterile CE 1984
542007	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 34 FR I.D 30 FR	CLASS IIa	8699412402070	Sterile CE 1984
542008	38821	42295433	FASCIAL DILATOR 6 FR. 22 CM	CLASS IIa	8699412402087	Sterile CE 1984
542009	38821	42295433	FASCIAL DILATOR 8 FR. 22 CM	CLASS IIa	8699412402094	Sterile CE 1984
542010	38821	42295433	FASCIAL DILATOR 10 FR. 22 CM	CLASS IIa	8699412402100	Sterile CE 1984
542011	38821	42295433	FASCIAL DILATOR 12 FR. 22 CM	CLASS IIa	8699412402117	Sterile CE 1984
542012	38821	42295433	FASCIAL DILATOR 14 FR. 22 CM	CLASS IIa	8699412402124	Sterile CE 1984
542013	38821	42295433	FASCIAL DILATOR 16 FR. 22 CM	CLASS IIa	8699412402131	Sterile CE 1984
542014	38821	42295433	FASCIAL DILATOR SET 6-16 FR	CLASS IIa	8699412402148	Sterile CE 1984
542017	11265	42295433	PERCUTANEOUS TRACT DILATATION KIT WITH NEPHROSTOMY BALLOON DILATOR	CLASS IIa	8699412402179	Sterile CE 1984
542018	38821	42295433	PERCUTANEOUS TRACT DILATATION KIT WITH AMPLATZ RENAL DILATOR SET	CLASS IIa	8699412402186	Sterile CE 1984
542019	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 20 FR I.D 16 FR	CLASS IIa	8699412402193	Sterile CE 1984
542020	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 34 FR I.D 30 FR (20cm)	CLASS IIa	8699412402209	Sterile CE 1984
542022	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 24 FR I.D 20 FR	CLASS IIa	8699412402223	Sterile CE 1984
542023	38821	42295433	AMPLATZ TYPE RENAL SHEATS O.D 26 FR I.D 22 FR	CLASS IIa	8699412402230	Sterile CE 1984
542024	38821	42295433	FASCIAL DILATOR 6-10-12FR - KOAKSIYEL	CLASS IIa	8699412402261	Sterile CE 1984
542025	38821	42295433	FASCIAL DILATOR 8-10FR - BÖBREK	CLASS IIa	8699412402278	Sterile CE 1984

14. URIDYNAMIC CATHETERS and SETS



14.1. INTENDED USE

Installation of fluids in the urinary bladder during urodynamic examination

Urodynamic Cystometry Catheter: Cystometry catheters enable ease of patient catheterisation and simultaneous bladder filling and pressure measurement

Hydrophilic Urodynamic Cystometry Catheter: Hydrophilic coating provides an easy transition.

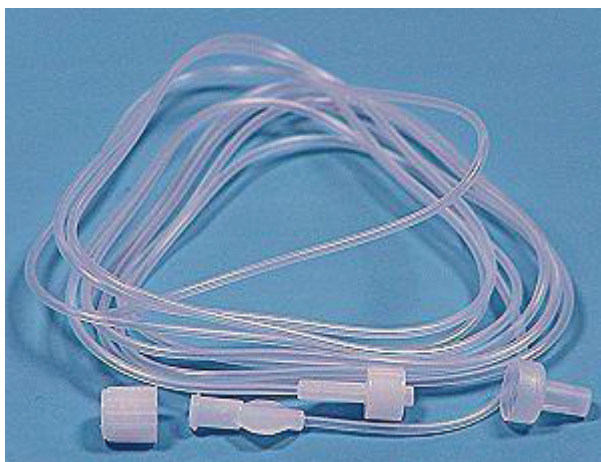
Urodynamic Cystometry Catheter& UPP Catheter: To estimate urinary pressure profile of patient, UPP catheter is used.

Hydrophilic Urodynamic Cystometry Catheter& UPP Catheter: Hydrophilic coating provides an easy transition.

Jiangsu Shenli Medical Production Co., Ltd.

Extension line

15cm, 30cm, 60cm, 90cm, 120cm, 150cm, 200cm ir 250cm



PVC tube with protection, impermeable to active substances.

- PROTECTIVE CAP= PE
- Flexible tube made of PVC
- Luer lock thread M/F. LUER LOCK & LUER SLIP CONNECTOR= ABS
- With ventilated plugs.
- Diameter 1,3x2,7 mm;
- Suitable for 4 bar pressures;
- Individually packaged and sterilized.

JIANGSU SHENLI MEDICAL PRODUCTION CO., LTD.

Address.: No. 20, Changzheng Rd, Zhenglu Tianning District 213111 Changzhou, Jiangsu People's Republic of China

STATEMENT

We, **Jiangsu Shenli Medical Production Co., Ltd.** Address: **No. 20, Changzheng Rd, Zhenglu Tianning District 213111 Changzhou, Jiangsu People's Republic of China**, hereby declare that the product **EXTENSION TUBE** (Size: 30CM, 60ML, 90CM, 120CM, 150CM, 200CM) we are manufacturing, having the following characteristics:

- Disposable
- Hermetic (tight)
- Flexible and transparent
- Can be attached to intravenous cannulas, syringes, catheters

