

Nujno varnostno obvestilo

Katetri za akutno hemodializo MAHURKAR™* in Argyle™*

Maj 2019

Referenca družbe Medtronic: FA866

Spoštovani,

S tem pismom vas obveščamo, da družba Medtronic izdaja prostovoljno nujno obvestilo o varnostnem popravilnem ukrepu za svoje katetre za akutno hemodializo MAHURKAR™* and Argyle™*.

Opis težave:

V tem obvestilu je pojasnjeno, da so vrednosti prostornine polnjenja, natisnjene na akutnih katetih MAHURKAR™* in Argyle™* ter v navodilih za uporabo, višje od prostornin, potrebnih za polnjenje posamezne svetline.

OPOMBA: To nujno obvestilo o varnostnem popravilnem ukrepu se nanaša samo na akutne katetre MAHURKAR™* in Argyle™*. To nujno obvestilo o varnostnem popravilnem ukrepu se NE nanaša na katetre MAHURKAR™* Elite, kronične katetre MAHURKAR™*, katetre za peritonealno dializo Argyle™* ali druge dializne katetre družbe Medtronic.

V nekaterih primerih so bile prostornine polnjenja za akutne katetre MAHURKAR™* in Argyle™* določene na podlagi največje izračunane prostornine, kateri je bila prišteta dodatna prostornina, s katero se je zagotovilo, da je bil kateter v celoti zaprt. Ta pristop je bil izbran zaradi zagotavljanja, da je svetlina vedno popolnoma napolnjena, s čimer se zmanjša tveganje za katetrsko trombozo. Zato prostornine polnjenja, natisnjene na trenutnih akutnih katetih MAHURKAR™* in Argyle™* ter v navodilih za uporabo presegajo dejansko zaporno prostornino, potrebno za napolnitev posamezne svetline. Glede na velikost in konfiguracijo katetra je mogoče opaziti odstopanje od natisnjene vrednosti polnjenja za 0,1–0,5 ml na svetlino (dejanska zaporna prostornina je nižja).

Tveganje za zdravje

Pomanjkljiva jasnost glede natisnjene prostornine polnjenja bi lahko povzročila, da bi zdravnik dovedel več heparina, kot je nameraval. Ob pregledu pritožb od leta 2003 so bile odkrite tri pritožbe (od približno pet milijonov vstavitvev akutnih katetrov MAHURKAR™* in Argyle™*) glede prostornin polnjenja katetra. V enem primeru je bolnik utrpel hematoma po navalu heparina. Pri drugih dveh pritožbah pa ni bilo poročano o nobeni škodi, ki bi bila povzročena bolniku.

Ukrepi, ki jih je izvedla družba Medtronic

Družba Medtronic trenutno posodablja navodila za uporabo akutnih katetrov MAHURKAR™* in Argyle™* tako, da bo povečala jasnost glede trenutno natisnjenih prostornin polnjenja.

Dodatno bo družba Medtronic, da bi še dodatno izboljšala trenutno označevanje, ponovno ocenila prostornino polnjenja za vse konfiguracije in velikosti akutnih katetrov MAHURKAR™* in Argyle™* ter bo nato v sodelovanju z regulativnimi organi po vsem svetu posodobila izdelek in označevanje izdelka s temi vrednostmi.

Priporočila

Med tem ko družba Medtronic posodablja navodila za uporabo, priporočamo uporabo neheparinirane blokirne raztopine, kot je 4 % natrijev citrat ali heparin v vrednosti 1000 enot/ml, s čimer boste zmanjšali tveganje, povezano z nenamernim dovajanje dodatnega koncentriranega heparina.

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™* Blagovne znamke tretjih oseb so blagovne znamke njihovih lastnikov. MAHURKAR™*, Double-D™* in Double-D design so ameriške registrirane blagovne znamke podjetja Sakharam D. Mahurkar, ki se uporabljajo z licenco. Argyle™* je blagovna znamka podjetja Cardinal Health, inc., ki se uporablja z licenco. Vse druge blagovne znamke so blagovne znamke družbe Medtronic.

V skladu z navodili za uporabo želi družba Medtronic ponovno poudariti svoja priporočila glede heparinizacije in ustrezno prilagajanje edinstvenim potrebam posameznega bolnika glede koagulacije. Natančneje:

- Pri izbiranju heparinskega režima je treba v vseh primerih upoštevati stanje bolnika. Pri otrocih in odraslih z motnjami strjevanja krvi uporabite manj heparina.
- Vedno upoštevajte izkušnje in presojo zdravnika ali protokol ustanove.

O ukrepu je bil obveščen JAZMP v vaši državi. Kopijo tega obvestila shranite za svojo evidenco.

Zahvaljujemo se vam za pozorno branje tega obvestila. Če imate kakršna koli vprašanja ali pomisleke, se obrnite na predstavnika družbe Medtronic Anita Djedović na anita.djedovic@medtronic.com ali na Medtronic Adriatic doo, Folnegovićeva 1c, 10000 Zagreb, Hrvaška.


Lep pozdrav,

Alen Galić,
BU Manager MITG
Medtronic Adriatic doo

MEDTRONIC ADRIATIC d.o.o.
Folnegovićeva 1c
10000 ZAGREB 2

Priloga: Kode izdelkov, na katere to vpliva

Dodatek A: Kode izdelkov, na katere to vpliva

Koda izdelka	Opis	Koda izdelka	Opis
8813793009	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 19.5 cm	8830416021	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 16 cm
8813793013	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 11.5 Fr x 19.5 cm	8830416023	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 16 cm
8813794005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 19.5 cm	8831173010	Argyle™ Acute Single Lumen Catheter Kit Straight Extension - 8 Fr x 15 cm
8813794009	MAHURKAR™ Acute Dual Lumen Catheter Curved Extensions with 2 Sealing Caps - 11.5 Fr x 19.5 cm	8831173011	Argyle™ Acute Single Lumen Catheter Kit Straight Extension - 8 Fr x 19.5 cm
8813816005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 13.5 cm	8831173012	Argyle™ Acute Single Lumen Catheter Kit Curved Extension - 8 Fr x 15 cm
8813816009	MAHURKAR™ Acute Dual Lumen Catheter Curved Extensions with 2 Sealing Caps - 11.5 Fr x 13.5 cm	8831661001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 24 cm
8813817005	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 13.5 cm	8831662001	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 24 cm
8813817009	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 11.5 Fr x 13.5 cm	8831663001	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Components - 11.5 Fr x 24 cm
8815668007	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Components - 11.5 Fr x 19.5 cm	8831663002	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 24 cm
8815668011	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 19.5 cm	8831663021	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 24 cm
8815668021	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 19.5 cm	8831663022	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 24 cm
8815668027	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 19.5 cm	8832539001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 8 Fr x 9 cm
8817142005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 10 Fr x 12 cm	8832539002	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 8 Fr x 12 cm
8817143005	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 10 Fr x 12 cm	8832539003	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 8 Fr x 15 cm
8817145005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 10 Fr x 15 cm	8832539006	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 8 Fr x 12 cm
8817146001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 10 Fr x 15 cm	8832539007	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 8 Fr x 15 cm
8817146007	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 10 Fr x 15 cm	8888115132	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 13.5 cm
8817149007	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 10 Fr x 19.5 cm	8888115133	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 13.5 cm
8817232018	Argyle™ Acute Single Lumen Catheter Straight Extensions - 8 Fr x 15 cm	8888115162	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 16 cm
8817232019	Argyle™ Acute Single Lumen Catheter Straight Extension - 8 Fr x 19.5 cm	8888115163	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 16 cm
8817277007	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Components - 11.5 Fr x 13.5 cm	8888115192	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 19.5 cm
8817277011	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 13.5 cm	8888115193	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 19.5 cm
8817277021	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 13.5 cm	8888115242	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 24 cm
8817277027	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 13.5 cm	8888115243	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 24 cm
8830414001	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 16 cm	8888135131	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions - 13.5 Fr x 13.5 cm
8830414002	MAHURKAR™ Acute Dual Lumen Catheter Curved Extensions with 2 Sealing Caps - 11.5 Fr x 16 cm	8888135132	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions - 13.5 Fr x 13.5 cm
8830415001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 16 cm	8888135133	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved Shafts - 13.5 Fr x 13.5 cm
8830415003	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 11.5 Fr x 16 cm	8888135134	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions - 13.5 Fr x 13.5 cm (IC tray)
8830416001	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions w/ IC* Components - 11.5 Fr x 16 cm	8888135135	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components - 13.5 Fr x 13.5 cm
8830416003	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 16 cm	8888135136	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-curved with IC* Components - 13.5 Fr x 13.5 cm

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™ Blagovne znamke tretjih oseb so blagovne znamke njihovih lastnikov. MAHURKAR™, Double-D™ in Double-D design so ameriške registrirane blagovne znamke podjetja Sakharam D. Mahurkar, ki se uporabljajo z licenco. Argyle™ je blagovna znamka podjetja Cardinal Health, Inc., ki se uporablja z licenco. Vse druge blagovne znamke so blagovne znamke družbe Medtronic.

Dodatek A: Kode izdelkov, na katere to vpliva (nadaljevanje)

Koda izdelka	Opis	Koda izdelka	Opis
8888135137	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components- 13.5Fr x 13.5cm(PASS	8888340637	MAHURKAR™ Acute Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 24 cm
8888135138	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components - 13.5 Fr x 13.5 cm	8888345504	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions-12FR x 13cm
8888135139	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components-13.5 X 13.5CM (PASS Tray)	8888345512	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions-12 Fr x 16 cm
8888135140	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components -13.5X16CM (PASS Tray)	8888345520	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions- 12 FR x 20 cm
8888135141	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components -13.5 X 19CM (PASS Tray)	8888345538	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions- 12 Fr x 24 cm
8888135142	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components 13.5 X 24CM (PASS Tray)	8888345603	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 13 cm
8888135161	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions -13.5 Fr x 16 cm	8888345611	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 16 cm
8888135162	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Curved Extensions -13.5 Fr x 16 cm	8888345629	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 20 cm
8888135163	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved - 13.5 Fr x 16 cm	8888345637	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 24 cm
8888135164	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components- 13.5 Fr x 16 cm(IC Tray)	8888101001HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components -12 Fr x 13 cm (IC
8888135165	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components- 13.5 Fr x 16 cm (IC Tray)	8888101002HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Components - 12 Fr x 16 cm
8888135166	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved with IC* Components-13.5 Fr x 16 cm	8888101003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Components - 12 Fr x 20 cm
8888135167	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components- 13.5 Fr x 16 cm(PASS	8888101004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Components - 12 Fr x 24 cm
8888135168	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components-13.5Fr x 16cm (PASS Tray)	8888102003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Components - 12 Fr x 20 cm
8888135191	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions - 13.5 Fr x 19.5 cm	8888102004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Components - 12 Fr x 24 cm
8888135192	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Curved Extensions -13.5 Fr x 19.5 cm	8888103001HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components -12 Fr x 13 cm
8888135193	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved- 13.5 Fr x 19.5 cm	8888103002HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components - 12 Fr x 16 cm
8888135194	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5Fr x 19.5cm(IC Tray)	8888103003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components - 12 Fr x 20 cm
8888135195	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components- 13.5 Fr x 19.5 cm	8888103004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components - 12 Fr x 24 cm
8888135196	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved with IC* Components - 13.5 Fr x 19.5 cm	8888104003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Safety Components - 12 Fr x 20 cm
8888135197	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components - 13.5 Fr x 19.5 cm	8888104004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Safety Components 12 Fr x 24 cm
8888135198	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions -13.5 Fr x 19.5 cm	8888340629HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 20 cm
8888135241	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions- 13.5 Fr x 24 cm	8888340637HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 24 cm
8888135242	MAHURKAR™ Acute Dual Lumen Catheter Kit Tray High Flow Curved Extensions -13.5 Fr x 24 cm	8888345504HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 13 cm
8888135243	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved -13.5 Fr x 24	8888345512HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 16 cm
8888135244	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5 Fr x 24 cm (IC Tray)	8888345520HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 20 cm
8888135245	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components -13.5 Fr x 24 cm (IC Tray)	8888345538HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 24 cm
8888135246	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved with IC* Components-13.5 Fr x 24 cm	8888345603HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 13 cm
8888135247	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5 Fr x 24 cm (PASS	8888345611HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 16 cm
8888135248	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components-13.5Fr x 24cm(PASS Tray)	8888345629HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 20 cm
8888340629	MAHURKAR™ Acute Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 20 cm	8888345637HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 24 cm

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