

**Hitna sigurnosna obavijest****Kanila korijena aorte - višak materijala**

Povlačenje proizvoda

Opis proizvoda	Broj modela
Kanila korijena aorte DLP™	11012
	11014
Kanila MiAR™	11012L
	11014L
Kanila korijena aorte DLP™ s ventilacijskim vodom	21012
	21014

5. veljače 2025.

Referencija tvrtke Medtronic: FA1470

jedinствени registracijski broj (SRN) proizvođača iz EU-a: US-MF-000019977

Poštovani,

Tvrtka Medtronic Vas želi obavijestiti o potencijalnom višku materijala u određenim proizvodnim serijama kanile. Prema evidenciji, primili ste najmanje jednu dotičnu seriju s oznakom navedenom u Prilogu A. Ova se obavijest ne odnosi ni na jedan drugi model ili oznaku serije.

**Opis problema:**

Tijekom procesa proizvodnje identificiran je neočekivani labavi materijal u muškom lueru koji se koristi u kanili korijena aorte.

Do 10. siječnja 2025. tvrtka Medtronic primila je nula (0) pritužbi u vezi s ovim problemom. Iako nije bilo opaženih događaja na terenu, postoji potencijalni rizik s obzirom na oblik identificiranog kvara i njegovu 5 %-tnu stopu incidencije. U slučaju da se prije upotrebe greška prepozna, potencijalni rizik je u odgodi postupka dok se ne pronađe druga kanila. Ako se prije uporabe greška ne prepozna te kliničar upotrijebi kanilu, potencijalni rizik je moždani udar (reverzibilan i nepovratan).

**Preporuke u pogledu liječenja pacijenta:**

Pacijenti koji su prethodno zbrinuti upotrebom oštećenog proizvoda nemaju dodatni rizik od komplikacija opisanih u ovom pismu te ih treba nastaviti nadzirati u skladu s uobičajenim postupcima nadzora u vašoj ordinaciji.

**Radnje korisnika:**

Stoga tvrtka Medtronic nalaže da poduzmete sljedeće mjere:

- Potražite pomoću priloga A navedene proizvode u svom inventaru.
- Odmah identificirajte i stavite u karantenu sve navedene neiskorištene proizvode iz vašeg inventara.
- Navedene neiskorištene proizvode iz vašeg inventara vratite tvrtki Medtronic. Predstavnik tvrtke Medtronic može vam pomoći u povratu oštećenog proizvoda, ako je potrebno.
- Prosljedite ovu obavijest drugima u svojoj ustanovi, ako je potrebno. Ako ste navedeni proizvod prosljedili u drugu ustanovu, obavijestite tu ustanovu o ovoj hitnoj sigurnosnoj obavijesti tvrtke Medtronic.
- Molimo vas da sačuvate primjerak ovog pisma u svojoj evidenciji.

**Dodatne informacije:**

Hrvatska Agencija za lijekove i medicinske proizvode (HALMED) je obaviještena o ovoj sigurnosnoj obavijesti.

Žao nam je zbog neugodnosti koje bi Vam ovo moglo prouzročiti. Posvećeni smo sigurnosti bolesnika i cijenimo Vašu hitnu pozornost na ovo pitanje. Ako imate bilo kakvih pitanja u vezi ove obavijesti, obratite se predstavniku tvrtke Medtronic Borisu Filaru na [boris.filar@medtronic.com](mailto:boris.filar@medtronic.com) odnosno na Medtronic Adriatic doo, Folnegovićeva 1c, 10000 Zagreb.

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Voditelj OU Cardiovascular

**U prilogu:**

- Prilog A: Dotični proizvod i oznaka serije

**Prilog A - Dotični proizvod i oznaka serije**

<b>Kanila korijena aorte DLP™ - CFN 11012</b>		
2022020438	2023040433	2024020238
2022030157	2023040806	202402C163
2022030297	2023041172	2024030255
2022030478	2023050066	2024030256
2022030747	202305C067	2024030692
2022040309	202307C101	2024040471
2022040902	2023100087	2024040472
2022050053	2023100234	2024040473
2022050697	2023100235	2024040474
2022050698	2023100489	2024040475
2022060347	2023100490	2024040476
2022061333	2023100876	2024040575
2022070054	2023111145	2024051027
2022070055	2023111146	2024051028
2022081070	2023120073	2024051029
2022081428	2023120484	2024060711
202209C071	2023120485	2024060712
202211C054	202312C018	202406C113
2023020719	2024011341	202406C114
2023020720	2024011342	202407C087
2023030372	2024011344	2024100440
2023031531	202401C303	2024100441
2023040161	202401C304	

**Kanila korijena aorte DLP™ - CFN 11014**

2022010949	2023050068	2024010350
2022020094	2023050394	2024010351
2022020439	2023050395	2024010419
2022020440	2023050396	2024010566
2022031296	2023050790	2024010907
2022050367	2023051166	2024010908
2022050702	2023051167	202402C164
2022060276	202305C077	2024030495
202206C093	2023060413	2024030496
2022070409	2023060414	2024030693
2022070410	2023060416	2024030694
2022070411	2023060417	2024030695
2022070840	2023061123	2024030696
2022070841	2023061124	2024030964
2022071072	2023061125	2024030965
202207C093	2023061126	2024040576
2022080418	2023061327	2024040577
2022080815	202306C142	2024040807
2022081073	202306C143	2024050923
202209C066	202307C098	2024050924
2022110377	202307C099	202405C078
2022110378	2023080113	202405C088
2022110379	2023080115	2024060413
202301C158	2023080116	2024060414
202301C159	2023080118	2024060415
2023020394	2023080720	2024060416
2023040163	2023080721	2024071241
2023040435	2023080722	202407C089
2023040809	2023080724	202407C090
2023041174	202308C215	202409C108
2023041175	2023111148	202308C214

<b>Kanila MiAR™ CFR 11012L</b>		
2022010947	2023021129	2023111645
2022020079	202304C091	2023111646
2022020081	2023070452	2023111647
2022020084	2023070455	2023111648
2022030745	2023070456	2023111649
2022030989	2023070457	2023111650
2022031294	2023070458	202312C209
2022040135	2023070461	202401C030
2022040136	2023070466	202401C031
2022040308	2023070954	2024030801
2022060274	2023070955	2024030803
2022070048	2023070956	2024030978
2022070049	2023070957	2024030979
2022070050	2023070958	2024030980
2022070051	2023070959	2024040008
2022070052	2023070960	2024040009
2022070053	2023070961	2024040029
2022080060	2023070962	2024040040
2022080414	2023070963	2024040041
2022090111	202308C216	2024040042
2022090112	202308C217	2024040043
2022090113	202310C187	2024040044
2022090114	2023110161	2024050060
2022090828	2023111071	202405C075
202209C072	2023111072	202405C076
202209C083	2023111073	202406C128
202211C036	2023111074	2024070439
2023021125	2023111075	2024070499
2023021126	2023111279	2024070501
2023021127	2023111280	2024080674
2023021128	2023111644	2024100439

<b>Kanila MiAR™ - CFN 11014L</b>		
2022010948	2022110054	2023060115
2022020086	2022110055	2023060116
2022020088	2022110057	2023060119
2022020091	2022110714	2023060120
2022030298	2022110715	2023060233
2022030479	2022110716	2023061326
2022030748	202211C037	202306C138
2022030990	202301C133	202306C140
2022031295	202301C164	202307C100
2022040310	2023020721	2023101327
2022050699	2023020722	2023101328
2022050700	2023020723	2023101329
2022050701	2023020724	2023101351
2022060275	2023021130	2023110217
2022061047	2023021131	2023110253
2022061048	2023021132	2023110294
2022070056	2023030373	2023110302
2022070408	2023030374	2023110318
202207C105	2023031532	2023110553
202207C106	202303C270	2023110554
2022080061	202303C272	2023110555
2022080415	2023040162	2023110556
2022080416	2023040434	2023110557
2022080417	2023040807	2023110558
2022081071	2023040808	2023110559
2022081072	2023041173	2023110560
202209C075	2023050067	2023111069
2022100740	2023050391	2023111070
2022100741	2023050392	2023111651
2022100742	2023050393	2023111652
2022100743	2023050788	2023111653
2022100744	2023051165	2023111654
2022100745	202305C076	2023111655
2022110052	2023060113	

<b>Kanila korijena aorte DLP™ s ventilacijskim vodom - CFN 21012</b>		
2022011031	2023031039	2024011375
2022020476	2023031040	2024011377
2022020860	2023031041	2024011378
2022030187	2023031555	202401C104
2022030188	2023031556	202401C136
2022030342	2023031557	2024020259
2022030509	2023040199	2024020260
2022030796	2023040200	2024030275
2022040355	2023040201	2024030276
2022040942	2023040470	2024030277
2022050019	2023040471	2024030278
2022050095	2023040851	2024030279
2022050399	2023041219	2024030502
2022051040	2023041220	2024030503
2022051041	202304C103	2024030504
2022060388	2023050113	202403C129
2022060389	2023050114	202403C130
2022060761	202305C119	2024040485
2022060762	202305C120	2024040486
2022060763	202305C121	2024040596
2022060764	202306C184	2024040597
2022061357	2023070519	2024051034
2022061358	2023100245	2024051035
202206C139	2023100246	2024051036
202207C140	2023100511	2024051284
2022080099	2023100512	2024051285
2022080100	2023100896	2024051286
2022081112	2023100897	2024051287
2022081113	2023110464	202405C115
2022081450	2023110465	202405C116
2022081451	2023110467	2024060539

2022081452	2023110944	2024070226
202209C146	2023111164	2024070519
202209C149	2023111165	2024080125
202301C214	2023120093	2024080390
2023020764	2023120094	2024080929
2023020765	2023120095	2024080930
2023021173	2023120096	202408C046
2023021174	2023120097	202408C047
2023030170	2023120505	202410C025
2023030171	202312C034	202410C026
2023030407	202312C035	
2023030971	2024011374	

<b>Kanila korijena aorte DLP™ s ventilacijskim vodom - CFN 21014</b>		
2022011033	2023020424	2023111167
2022011174	2023020425	2024010335
2022020477	2023031042	2024010336
2022020861	202303C309	2024010435
2022020862	2023040202	2024010436
2022030343	2023040472	2024010578
2022030973	2023040852	2024010579
2022031019	2023040853	2024010931
2022031322	2023041221	2024010932
2022040356	2023041222	2024010933
2022040943	2023041223	2024010998
2022050026	2023050115	202403C131
2022050096	2023050116	202403C132
2022050400	2023050435	2024040598
2022051042	2023050436	2024040823
202205C067	2023050861	2024040824
2022060390	2023050862	2024040825
2022061076	2023050864	2024050940



<b>Kanila korijena aorte DLP™ s ventilacijskim vodom - CFN 21014 (nastavak)</b>		
2022061078	2023050865	2024050941
2022061079	202305C122	2024050942
202206C140	2023060162	2024050943
2022070457	2023060163	2024051288
2022070458	2023060465	2024060291
2022070912	2023060466	2024060292
2022070913	2023061168	2024060293
2022071098	2023061169	2024060541
202207C141	2023061390	202406C117
2022080101	2023061391	202406C118
2022080102	2023061392	2024070994
2022080456	2023061393	202408C048
2022080952	202306C185	202408C049
202209C168	202306C186	2024090331
202209C171	202306C187	2024090658
2022110406	202307C133	2024090936
2022110425	202307C135	2024100069
2022110426	2023080188	2024100070
202301C208	2023080190	2024100071
202301C209	2023080723	2024100072
2023020364	202309C018	2024101042
2023020423	2023111166	202410C027