

HITNA SIGURNOSNA OBAVIJEST

Kateteri za akutnu hemodijalizu MAHURKAR™* i Argyle™*

Svibanj 2019.

Medtronicova referencija: FA866

Poštovani,

ovim vas putem želimo obavijestiti da Medtronic samoinicijativno izdaje hitnu sigurnosnu obavijest za svoje katetere za akutnu hemodijalizu MAHURKAR™* i Argyle™*

Opis problema:

Svrha ove obavijesti je pojasniti da su vrijednosti volumena punjenja otisnute na kateterima za akutnu dijalizu MAHURKAR™* i Argyle™* i u Uputama za upotrebu veći od volumena potrebnih za punjenje svakog lumena.

NAPOMENA: Hitna sigurnosna obavijest odnosi se samo na katetere za akutnu dijalizu MAHURKAR™* i Argyle™*. Ova hitna terenska sigurnosna obavijest NE odnosi se na katetere MAHURKAR™* Elite, katetere za kroničnu dijalizu MAHURKAR™*, katetere za peritonealnu dijalizu Argyle™* ili druge katetere za dijalizu tvrtke Medtronic.

U nekim su slučajevima volumeni punjenja za katetere za akutnu dijalizu MAHURKAR™* i Argyle™* određeni na temelju maksimalnog izračunatog volumena plus dodatni volumen kako bi se osiguralo da je kateter potpuno napunjen. Taj je pristup odabran kako bi se osiguralo da je lumen uvijek do kraja napunjen, čime se smanjuje rizik od nastanka kateterske tromboze. Stoga volumeni punjenja otisnuti na postojećim kateterima za akutnu dijalizu MAHURKAR™* i Argyle™* i u uputama za upotrebu premašuju stvarni volumen potreban za punjenje svakog lumena. Ovisno o veličini katetera i konfiguracija, primijećena je varijacija od 0,1 ml do 0,5 ml po lumenu u odnosu na otisnutu vrijednost punjenja (stvarna vrijednost potrebna za punjenje bila bi niža).

Opasnost po zdravlje

Zbog nedostatka pojašnjenja u vezi s otisnutim volumenom punjenja moglo bi se dogoditi da zdravstveni djelatnik primijeni više heparina nego što je namjeravao. Pregledom pritužbi od 2003. pronađene su tri pritužbe (od približno pet milijuna uvedenih katetera za akutnu dijalizu MAHURKAR™* i Argyle™*) u vezi s volumenima punjenja katetera. U jednom je slučaju kod bolesnika došlo do nastanka hematoma nakon heparinskog ispiranja. U druge dvije pritužbe nije prijavljeno da je došlo do ozljede bolesnika.

Radnje koje je poduzela tvrtka Medtronic

Tvrtka Medtronic trenutačno ažurira upute za upotrebu za katetere za akutnu dijalizu MAHURKAR™* i Argyle™* na koje se to odnosi kako bi se pojasnili trenutačno otisnuti volumeni punjenja.

Osim toga, kako bi dodatno poboljšala postojeće označavanje, tvrtka Medtronic provodi ponovno ocjenjivanje volumena punjenja za sve konfiguracije i veličine katetera za akutnu dijalizu MAHURKAR™* i Argyle™* i u suradnji s regulatornim agencijama na cijelom svijetu naknadno će ažurirati proizvod i označavanje proizvoda tim vrijednostima.

Preporuke

Dok tvrtka Medtronic ažurira upute za upotrebu, preporučujemo da upotrebljavate nehepariniranu otopinu za punjenje, kao što je 4% natrijev citrat ili 1000 U/ml heparina radi ublažavanja mogućeg rizika povezanog s nehotičnom primjenom dodatnog koncentriranog heparina.

Stranica 1 od 4

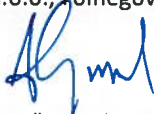
™™™ Robne marke trećih strana zaštitni su znakovi svojih odgovarajućih vlasnika. MAHURKAR™, Double-D™™ i Double-D design registrirani su zaštitni znakovi tvrtke Sakharam D. Mahurkar u SAD-u koji se koriste u sklopu licence. Argyle™™ je zaštitni znak tvrtke Cardinal Health, Inc. koji se koristi u sklopu licence. Sve druge robne marke zaštitni su znakovi tvrtke Medtronic.

U skladu s uputama za upotrebu tvrtka Medtronic želi ponovno naglasiti preporuke u vezi s heparinizacijom i odgovarajuće upravljanje jedinstvenim potrebama svakog bolesnika u vezi s koagulacijom. Konkretno rečeno:

- U svim se slučajevima mora uzeti u obzir stanje bolesnika pri odabiru heparinskog režima. Upotrijebite manje heparina kod djece i kod odraslih s poremećajima krvarenja.
- Uvijek poštujujte iskustvo i prosudbu liječnika ili protokol ustanove.

Agencija za lijekove i medicinske proizvode (HALMED) obaviještena je o ovoj radnji. Spremite kopiju ove obavijesti u svoju evidenciju.

Hvala vam na pažnji koju ste posvetili ovoj obavijesti. Ako imate pitanja ili ste u nedoumici, slobodno se obratite predstavniku tvrtke Medtronic Aniti Djedović na anita.djedovic@medtronic.com odnosno na Medtronic Adriatic d.o.o., Folnegovićeva 1c, 10000 Zagreb.



S poštovanjem,

Alen Galić, voditelj MITG odjela

Medtronic Adriatic d.o.o.

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

Prilog: Kataloški brojevi proizvoda na koje se obavijest odnosi:

Dodatak A: Kataloški brojevi proizvoda na koje se obavijest odnosi

| Šifra proizvoda | Opis | Šifra proizvoda | 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 |

Dodatak A: Kataloški brojevi proizvoda na koje se obavijest odnosi (nastavak)

| Šifra proizvoda | Opis | Šifra proizvoda | Opis |
|-----------------|--|-----------------|--|
| 8888135137 | MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5FrX13.5cm(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-13.5FrX16cm (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-13.5FrX19.5cm(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-13.5FrX24cm(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 |

Stranica 4 od 4

™** Robne marke trećih strana zaštitni su znakovi svojih odgovarajućih vlasnika. MAHURKAR™, Double-D™** i Double-D design registrirani su zaštitni znakovi tvrtke Sakharam D. Mahurkar u SAD-u koji se koriste u sklopu licence. Argyle™** je zaštitni znak tvrtke Cardinal Health, Inc. koji se koristi u sklopu licence. Sve druge robne marke zaštitni su znakovi tvrtke Medtronic.