

Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Irska

April-2026

NUJNO – OBVESTILO O VARNOSTNEM POPRAVLJANEM UKREPU

| Vrsta ukrepa | Odpoklic – odstranitev |
|--|---|
| Referenca za Teleflex | EIF-000605 |
| Ime izdelka | Izdelek za hemodializno katetrizacijo Arrow Edge® |
| | Antegradni kateter za kronično hemodializo Arrow-Clark™ VectorFlow™ |
| | Retrogradni kateter za kronično hemodializo Arrow-Clark™ VectorFlow™ |
| | Kateter za kronično hemodializo Cannon® II Plus |
| | Antegradni kateter za kronično hemodializo NextStep® |
| Retrogradni kateter za kronično hemodializo NextStep® | |
| Koda izdelka, številka serije/lota in edinstveni identifikator pripomočka (UDI) | Glejte Dodatek 2 |
| Kopijo tega obvestila FSN in možnost pošiljanja potrditvenega obrazca elektronsko lahko najdete na spodnji povezavi. | |
| Povezava do portala FSN | angleščina: https://fca.myteleflex.com/en_EN/recall/000605 |

Spoštovana stranka,

Podrobnosti o prizadetih izdelkih

Arrow International LLC, podružnica podjetja Teleflex Incorporated, je prejela priloženo Obvestilo o varnostnem popravljalnem ukrepu (FSN) od podjetja Merit Medical Systems, Inc. (Merit), ki napoveduje odpoklic izdelka Merit 16F Dual-Valved Splittable Sheath Introducer. (glejte **Dodatek 3**). Zato podjetje Arrow International LLC za določene proizvodne lote zgoraj navedenih izdelkov, ki vsebujejo prizadete uvajalne tulce, izvaja prostovoljni varnostni ukrep (FSCA).

Glejte **Dodatek 2** za kodo izdelka, številko serije/lota in edinstveni identifikator pripomočka (UDI).

Opis težave in ukrepov, ki zahtevajo takojšnjo pozornost

Podjetje Arrow International LLC prostovoljno odpoklicuje zgoraj navedeni izdelek zaradi odpoklica, ki ga je sprožil dobavitelj komponente Merit 16F Dual-Valved Splittable Sheath Introducer, ki je vključena v prizadete komplete in sete za hemodializo Arrow. Po obvestilu FSN podjetja Merit se v nekaterih primerih uvajalni tulec ne razpre, kot je predvideno, zaradi napake povezane z njegovo zasnovo.

Uporaba uvajalnega tulca, ki se med odstranitvijo ne razpre, kot je predvideno, lahko povzroči takojšnje zaplete med posegom, kot so odpor pri odstranjevanju, podaljšan čas posega, lokalizirana bolečina, manjša krvavitev, hematom ali površinska poškodba tkiva. Če se med odstranjevanjem uporabi prevelika sila, to lahko povzroči poškodbe sten žil ali znatno krvavitev, ki zahteva zdravniško ali kirurško oskrbo. Dolgoročne -zdravstvene posledice niso pričakovane, saj do napake pride med odstranjevanjem uvajalnega tulca, ter bi jih takoj opazili in zdravili izurjeni zdravstveni delavci.

Do 24. februarja 2026 je podjetje Teleflex prejelo 33 pritožb glede izdelkov zajetih v tem obvestilu, kjer so uporabniki poročali o težavah pri puljenju tulca, ter da se tulec ni natrgal po pričakovanjih. Nobena od teh 33 pritožb ni poročala o poškodbah pri bolnikih.

Iz naših dokumentov je razvidno, da ste prejeli izdelke, ki so predmet tega obvestila o varnostnem popravljalnem ukrepu.

Glede na vašo lokacijo upoštevajte naslednji seznam ukrepov:

| Lokacija pripomočka | Številka seznama ukrepov |
|--|--------------------------|
| Zdravstvene ustanove (bolnišnice, zdravstveno osebje ipd.) | 1 |
| Distributerji | 2 |

Številka seznama ukrepov **1** – Zdravstvene ustanove

- Zahtevamo, da takoj preverite svoj inventar za izdelke, ki jih zadeva ta popravljalni varnostni ukrep. **Uporabniki morajo prenehati uporabljati in distribuirati zadevne izdelke in jih takoj dati v karanteno.**
- Če imate prizadeti izdelek, označite pravilno polje na potrditvenem obrazcu (Dodatek 1) in stopite v stik s službo za pomoč strankam podjetja Teleflex z uporabo **ene** od sledečih možnosti:
 - Pokličite službo za podporo strankam ali jim pošljite elektronsko pošto s kopijo Dodatka 1 z uporabo podatkov za stik na strani 3
ALI
 - Uporabite spletni portal FSN in izpolnite potrditveni obrazec virtualno na sledeči povezavi: https://fca.myteleflex.com/en_EN/recall/000605
Opomba: Možnost B je na voljo samo strankam, ki so prejele izdelek neposredno od podjetja Teleflex.
- Če tega izdelka nimate, označite ustrezno potrditveno polje na potrditvenem obrazcu (Dodatek 1) in obrazec vrnite podjetju Teleflex z uporabo podatkov za stik.
- Družba Teleflex (ali lokalni zastopnik) bo po prejemu vrnjenega prizadetega izdelka izdala dobropis.

Številka seznama ukrepov **2** Distributerji

- Kopijo tega varnostnega obvestila pošljite vsem strankam, ki so prejele zadevni izdelek. Vsaka od strank mora izpolniti obrazec za potrditev in ga vrniti vam kot njihovemu distributerju.
- Prosimo, da takoj preverite svoj inventar za prizadete izdelke. **Prenehajte z uporabo in distribucijo prizadetih izdelkov in jih takoj dajte v karanteno.** Potem lahko vrnete vse zadevne izdelke.
- Kot distributer morate podjetju Teleflex potrditi, da ste opravili dejavnost, ki je opisana v dejanjih 1 in 2 na tem seznamu dejanj št. 2. Po zaključku postopka prosimo, da izpolnjen obrazec za potrditev **posredujete** na spodnji e-poštni naslov.
Pomembno – Pri izpolnjevanju tega obrazca navedite samo številke serij, ki so vključene v to varnostno obvestilo.
- Če ste izdelek distribuirali izven svoje države, prosimo, da obvestite službo za pomoč strankam podjetja Teleflex po e-pošti na spodnji elektronski naslov.
- Če ste distributer in/ali ste odgovorni za poročanje znotraj ali zunaj območja EGP/CH/UK/TR, o tem ukrepu obvestite svoj lokalni pristojni organ. Obvestilo in vso korespondenco z lokalnim pristojnim organom posredujte podjetju Teleflex.

Opomba: Če želi distributer podjetja Teleflex oddati obrazec o potrditvi v elektronski obliki, lahko to stori preko naslednje povezave: https://fca.myteleflex.com/en_EN/recall/000605

O neželenih učinkih ali težavah s kakovostjo, do katerih pride pri uporabi tega izdelka, je treba službo za pomoč strankam družbe Teleflex obvestiti prek spodnjih podatkov za stik.

Posredovanje obvestila o varnostnem korektivnem ukrepu

To obvestilo je treba posredovati vsem osebam, ki morajo biti seznanjene v vaši organizaciji ali kateri koli organizaciji, v katero so bili poslani potencialno prizadeti pripomočki.

S tem obvestilom seznanite končne uporabnike, klinične zdravnike, odgovorne za obvladovanje tveganja, oskrbovalno verigo/distribucijske centre itd. Poskrbite, da bodo s tem obvestilom seznanjeni vsi, dokler v vaši ustanovi ne bodo izvedeni vsi potrebni ukrepi.

Oseba za stik

Za dodatne informacije ali pomoč glede težave se obrnite na:

Oseba za stik podjetja Teleflex:

Stik: Shane Kenny

Telefon: +353 (0)86 3479154

E-pošta: Recalls.Intl@teleflex.com

Povezava do portala FSN: Angleščina: https://fca.myteleflex.com/en_EN/recall/000605

Družba Teleflex se zavezuje, da zagotavlja visokokakovostne, varne in učinkovite izdelke. Iskreno obžalujemo vse morebitne nevednosti, ki smo vam jih povzročili s tem ukrepom. Z vsemi dodatnimi vprašanji se lahko obrnete na lokalnega prodajnega zastopnika ali službo za pomoč strankam.

Podpisani potrjuje, da je bilo to obvestilo obveščeno ustreznemu regulativnemu organu.

Za in v imenu družbe Teleflex,

Padraig Hegarty

Padraig Hegarty, Podpredsednik svetovne službe za zagotavljanje kakovosti in strateških projektov

Dodatek 1

VARNOSTNO KOREKTIVNI UKREP
POTRREDITVENI OBRAZEC

Št. stranke

UKREP DRUŽBE TELEFLEX ZA IZDELEK – PROSIMO ZA TAKOJŠNJO POZORNOST

Ref. EIF-000605

IZPOLNJEN OBRAZEC TAKOJ VRNITE NA:

E-pošta: Recalls.Intl@teleflex.com

| | |
|--|--|
| <input type="checkbox"/> Potrjujemo prejem tega svetovalnega obvestila in izvedbo zahtevanih ukrepov, ki jih vsebuje. Potrjujemo, da v našem inventarju NIMAMO izdelkov, za katere velja ta varnostni korektivni ukrep. | <input type="checkbox"/> Potrjujemo prejem tega svetovalnega obvestila in izvedbo zahtevanih ukrepov, ki jih vsebuje. Potrjujemo, da v našem inventarju IMAMO izdelke, za katere velja ta varnostni korektivni ukrep. Uporaba in nadaljnja distribucija prizadetih izdelkov je zaustavljena. Vsi izdelki so zadržani. Vrne se spodaj navedena količina. |
|--|--|

Izpolnite ta obrazec za potrditev in ga takoj vrnite, pri čemer uporabite zgornje podatke za stik.

| Koda izdelka | Številka serije | Količina, ki se vrača |
|---|-----------------|-----------------------|
| Pomembno – Pri izpolnjevanju tega obrazca navedite samo številke serij, ki so vključene v to varnostno obvestilo. | | |
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| <ul style="list-style-type: none"> • V paket z vrnjenimi enotami priložite kopijo izpolnjenega potrditvenega obrazca. • Prepričajte se, da je številka RGA jasno vidna na vrnjeni embalaži • Na paket napišite sporočilo “Field Safety Returns” (Vračila zaradi varnostnega opozorila). | | |

IME USTANOVE (NPR. IME BOLNIŠNICE, ZDRAVSTVENE ORGANIZACIJE)

| NASLOV USTANOVE | TELEFON/FAKS |
|--|--------------|
| | |
| OBRAZEC JE IZPOLNIL | ŽIG |
| IME S TISKANIMI ČRKAMI: _____ _____ PODPIS: _____ DATUM: _____ | |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| AC-15192-SFX | 33F24G0631 | (01)30801902197758(10)33F24G0631(11)240918(17)270831 |
| AC-15192-X | 33F23F0744 | (01)00801902095879(10)33F23F0744(11)230707(17)260630 |
| AC-15192-X | 33F24E0784 | (01)00801902095879(10)33F24E0784(11)240725(17)270630 |
| AC-15192-X | 33F25D0685 | (01)00801902095879(10)33F25D0685(11)250507(17)280430 |
| AC-15232-SFX | 33F23H1018 | (01)00801902095909(10)33F23H1018(11)230928(17)260831 |
| AC-15232-X | 33F23H1013 | (01)00801902095916(10)33F23H1013(11)231018(17)260930 |
| AC-15232-X | 33F24J0068 | (01)00801902095916(10)33F24J0068(11)241206(17)271130 |
| AC-15232-X | 33F25C0675 | (01)00801902095916(10)33F25C0675(11)250417(17)280225 |
| AC-15232-X | 33F25J0589 | (01)00801902095916(10)33F25J0589(11)251107(17)280608 |
| AC-15272-X | 33F23H1023 | (01)00801902095954(10)33F23H1023(11)231119(17)261031 |
| ACS-15192-VF | 33F24G0637 | (01)10801902126693(10)33F24G0637(11)241204(17)271130 |
| ACS-15192-VFI | 33F23G0040 | (01)10801902126709(10)33F23G0040(11)230721(17)260630 |
| ACS-15192-VFI | 33F25C0689 | (01)10801902126709(10)33F25C0689(11)250408(17)280331 |
| ACS-15232-VF | 33F23H1016 | (01)10801902126716(10)33F23H1016(11)231012(17)260930 |
| ACS-15232-VFI | 33F23G0045 | (01)10801902126723(10)33F23G0045(11)230719(17)260630 |
| ACS-15232-VFI | 33F25C0678 | (01)10801902126723(10)33F25C0678(11)250414(17)280315 |
| ACS-15272-VF | 33F23H1024 | (01)10801902126730(10)33F23H1024(11)231003(17)260930 |
| ACS-15272-VFI | 33F24G0638 | (01)10801902126747(10)33F24G0638(11)240917(17)270831 |
| ACS-15552-VF | 33F23H1021 | (01)10801902126792(10)33F23H1021(11)231003(17)260930 |
| CS-15192-SFX | 33F23E0575 | (01)30801902195297(10)33F23E0575(11)230721(17)260630 |
| CS-15192-SFX | 33F23G0530 | (01)30801902195297(10)33F23G0530(11)230830(17)260731 |
| CS-15192-SFX | 33F23K0187 | (01)30801902195297(10)33F23K0187(11)231102(17)261031 |
| CS-15192-SFX | 33F23K1104 | (01)30801902195297(10)33F23K1104(11)231115(17)261031 |
| CS-15192-SFX | 33F23L0929 | (01)30801902195297(10)33F23L0929(11)240110(17)261231 |
| CS-15192-SFX | 33F24A0275 | (01)30801902195297(10)33F24A0275(11)240217(17)270131 |
| CS-15192-SFX | 33F24C0068 | (01)30801902195297(10)33F24C0068(11)240424(17)270331 |
| CS-15192-SFX | 33F24D1012 | (01)30801902195297(10)33F24D1012(11)240503(17)270430 |
| CS-15192-SFX | 33F25C0020 | (01)30801902195297(10)33F25C0020(11)250311(17)280229 |
| CS-15192-SFX | 33F25E1083 | (01)30801902195297(10)33F25E1083(11)250717(17)280630 |
| CS-15192-SFX | 33F25G0636 | (01)30801902195297(10)33F25G0636(11)250818(17)280731 |
| CS-15192-SFX | 33F25H0292 | (01)30801902195297(10)33F25H0292(11)250901(17)280831 |
| CS-15192-SFX | 33F25H0790 | (01)30801902195297(10)33F25H0790(11)251016(17)280524 |
| CS-15192-SFX | 33F25L0038 | (01)30801902195297(10)33F25L0038(11)251127(17)280608 |
| CS-15192-SFXM | 33F25C0015 | (01)10801902127157(10)33F25C0015(11)250310(17)271218 |
| CS-15192-SFXM | 33F25E1084 | (01)10801902127157(10)33F25E1084(11)250620(17)280121 |
| CS-15192-VF | 33F23K0186 | (01)20801902193593(10)33F23K0186(11)231107(17)261031 |
| CS-15192-VF | 33F23L0931 | (01)20801902193593(10)33F23L0931(11)240129(17)261231 |
| CS-15192-VF | 33F24C0082 | (01)20801902193593(10)33F24C0082(11)240425(17)270331 |
| CS-15192-VF | 33F24E0788 | (01)20801902193593(10)33F24E0788(11)240610(17)270531 |
| CS-15192-VF | 33F24J0054 | (01)20801902193593(10)33F24J0054(11)241107(17)271031 |
| CS-15192-VF | 33F24M0162 | (01)20801902193593(10)33F24M0162(11)241213(17)271130 |
| CS-15192-VF | 33F24M0230 | (01)20801902193593(10)33F24M0230(11)250222(17)280131 |
| CS-15192-VF | 33F25D0271 | (01)20801902193593(10)33F25D0271(11)250807(17)280731 |
| CS-15192-VFE | 33F23E0776 | (01)10801902195460(10)33F23E0776(11)230628(17)260531 |
| CS-15192-VFE | 33F23F0728 | (01)10801902195460(10)33F23F0728(11)230706(17)260630 |
| CS-15192-VFE | 33F23G0531 | (01)10801902195460(10)33F23G0531(11)230919(17)260831 |
| CS-15192-VFE | 33F24A0917 | (01)10801902195460(10)33F24A0917(11)240506(17)270430 |
| CS-15192-VFE | 33F24C0063 | (01)10801902195460(10)33F24C0063(11)240429(17)270331 |
| CS-15192-VFE | 33F24D1003 | (01)10801902195460(10)33F24D1003(11)240528(17)270430 |
| CS-15192-VFE | 33F24E0789 | (01)10801902195460(10)33F24E0789(11)240611(17)270531 |
| CS-15192-VFE | 33F24J0039 | (01)10801902195460(10)33F24J0039(11)241106(17)271031 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15192-VFE | 33F24L0069 | (01)10801902195460(10)33F24L0069(11)241119(17)271031 |
| CS-15192-VFE | 33F24M0156 | (01)10801902195460(10)33F24M0156(11)250122(17)271231 |
| CS-15192-VFE | 33F24M0159 | (01)10801902195460(10)33F24M0159(11)241213(17)271130 |
| CS-15192-VFE | 33F25C0683 | (01)10801902195460(10)33F25C0683(11)250408(17)280331 |
| CS-15192-VFE | 33F25D0107 | (01)10801902195460(10)33F25D0107(11)250609(17)280531 |
| CS-15192-VFE | 33F25D0220 | (01)10801902195460(10)33F25D0220(11)250424(17)280331 |
| CS-15192-VFE | 33F25E0343 | (01)10801902195460(10)33F25E0343(11)250620(17)280531 |
| CS-15192-VFE | 33F25F0273 | (01)10801902195460(10)33F25F0273(11)250828(17)280731 |
| CS-15192-VFE | 33F25F0462 | (01)10801902195460(10)33F25F0462(11)250708(17)280510 |
| CS-15192-VFE | 33F25G0444 | (01)10801902195460(10)33F25G0444(11)250929(17)280517 |
| CS-15192-VFE | 33F25H0820 | (01)10801902195460(10)33F25H0820(11)251030(17)280524 |
| CS-15192-VFE | 33F25K0384 | (01)10801902195460(10)33F25K0384(11)251127(17)280608 |
| CS-15192-VFI | 33F23E0579 | (01)10801902127188(10)33F23E0579(11)230608(17)260531 |
| CS-15192-VFI | 33F23G0042 | (01)10801902193572(10)33F23G0042(11)230721(17)260630 |
| CS-15192-VFI | 33F23K0170 | (01)10801902193572(10)33F23K0170(11)231013(17)260930 |
| CS-15192-VFI | 33F23L0933 | (01)10801902193572(10)33F23L0933(11)240417(17)270331 |
| CS-15192-VFI | 33F24E0271 | (01)10801902193572(10)33F24E0271(11)240610(17)270531 |
| CS-15192-VFI | 33F24G0166 | (01)10801902193572(10)33F24G0166(11)240904(17)270831 |
| CS-15192-VFI | 33F24J0086 | (01)10801902193572(10)33F24J0086(11)240918(17)270831 |
| CS-15192-VFI | 33F24L0064 | (01)10801902193572(10)33F24L0064(11)241209(17)271130 |
| CS-15192-VFI | 33F24M0224 | (01)10801902193572(10)33F24M0224(11)250214(17)271125 |
| CS-15192-VFI | 33F25C0652 | (01)10801902193572(10)33F25C0652(11)250409(17)280315 |
| CS-15192-VFI | 33F25D0052 | (01)10801902193572(10)33F25D0052(11)250508(17)280430 |
| CS-15192-VFI | 33F25D0700 | (01)10801902193572(10)33F25D0700(11)250521(17)271125 |
| CS-15192-VFI | 33F25E1081 | (01)10801902193572(10)33F25E1081(11)250602(17)280430 |
| CS-15192-VFI | 33F25F0015 | (01)10801902193572(10)33F25F0015(11)250606(17)280531 |
| CS-15192-VFI | 33F25F0388 | (01)10801902193572(10)33F25F0388(11)250716(17)280630 |
| CS-15192-VFI | 33F25G0702 | (01)10801902193572(10)33F25G0702(11)250901(17)280831 |
| CS-15192-VFI | 33F25H0785 | (01)10801902193572(10)33F25H0785(11)251105(17)280608 |
| CS-15192-VFIE | 33F23D0853 | (01)10801902199659(10)33F23D0853(11)230529(17)260430 |
| CS-15192-VFIE | 33F23E0773 | (01)10801902199659(10)33F23E0773(11)230703(17)260630 |
| CS-15192-VFIE | 33F23G0044 | (01)10801902199659(10)33F23G0044(11)230720(17)260630 |
| CS-15192-VFIE | 33F23G0532 | (01)10801902199659(10)33F23G0532(11)230823(17)260731 |
| CS-15192-VFIE | 33F23H0611 | (01)10801902199659(10)33F23H0611(11)230919(17)260831 |
| CS-15192-VFIE | 33F23K0169 | (01)10801902199659(10)33F23K0169(11)231012(17)260930 |
| CS-15192-VFIE | 33F23K1105 | (01)10801902199659(10)33F23K1105(11)231213(17)261130 |
| CS-15192-VFIE | 33F23L0934 | (01)10801902199659(10)33F23L0934(11)240126(17)261231 |
| CS-15192-VFIE | 33F24A0912 | (01)10801902199659(10)33F24A0912(11)240312(17)270228 |
| CS-15192-VFIE | 33F24A0913 | (01)10801902199659(10)33F24A0913(11)240226(17)270131 |
| CS-15192-VFIE | 33F24C0058 | (01)10801902199659(10)33F24C0058(11)240419(17)270331 |
| CS-15192-VFIE | 33F24D1001 | (01)10801902199659(10)33F24D1001(11)240507(17)270430 |
| CS-15192-VFIE | 33F24G0167 | (01)10801902199659(10)33F24G0167(11)240902(17)270831 |
| CS-15192-VFIE | 33F24G0187 | (01)10801902199659(10)33F24G0187(11)241002(17)270930 |
| CS-15192-VFIE | 33F24J0030 | (01)10801902199659(10)33F24J0030(11)240929(17)270831 |
| CS-15192-VFIE | 33F24J0032 | (01)10801902199659(10)33F24J0032(11)241013(17)270930 |
| CS-15192-VFIE | 33F24J0339 | (01)10801902199659(10)33F24J0339(11)240917(17)270831 |
| CS-15192-VFIE | 33F24J0381 | (01)10801902199659(10)33F24J0381(11)240920(17)270831 |
| CS-15192-VFIE | 33F24K0659 | (01)10801902199659(10)33F24K0659(11)241128(17)271031 |
| CS-15192-VFIE | 33F24L0058 | (01)10801902199659(10)33F24L0058(11)241111(17)271031 |
| CS-15192-VFIE | 33F24L0511 | (01)10801902199659(10)33F24L0511(11)241209(17)271130 |
| CS-15192-VFIE | 33F24M0155 | (01)10801902199659(10)33F24M0155(11)241216(17)271130 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15192-VFIE | 33F24M0215 | (01)10801902199659(10)33F24M0215(11)250131(17)271125 |
| CS-15192-VFIE | 33F24M0265 | (01)10801902199659(10)33F24M0265(11)250122(17)271231 |
| CS-15192-VFIE | 33F25A0143 | (01)10801902199659(10)33F25A0143(11)250214(17)280131 |
| CS-15192-VFIE | 33F25A0407 | (01)10801902199659(10)33F25A0407(11)250205(17)271125 |
| CS-15192-VFIE | 33F25B0259 | (01)10801902199659(10)33F25B0259(11)250228(17)280131 |
| CS-15192-VFIE | 33F25C0037 | (01)10801902199659(10)33F25C0037(11)250319(17)271215 |
| CS-15192-VFIE | 33F25D0285 | (01)10801902199659(10)33F25D0285(11)250701(17)280420 |
| CS-15192-VFIE | 33F25D0738 | (01)10801902199659(10)33F25D0738(11)250716(17)280630 |
| CS-15192-VFIE | 33F25F0060 | (01)10801902199659(10)33F25F0060(11)250620(17)280531 |
| CS-15192-VFIE | 33F25G0635 | (01)10801902199659(10)33F25G0635(11)250926(17)280831 |
| CS-15192-VFIM | 33F24E0792 | (01)10801902193589(10)33F24E0792(11)240904(17)270831 |
| CS-15192-VFIM | 33F25C0676 | (01)10801902193589(10)33F25C0676(11)250429(17)280118 |
| CS-15192-VFIM | 33F25L0035 | (01)10801902193589(10)33F25L0035(11)251127(17)280227 |
| CS-15192-VFM | 33F23K0189 | (01)10801902193602(10)33F23K0189(11)231107(17)260930 |
| CS-15192-VFM | 33F24C0078 | (01)10801902193602(10)33F24C0078(11)240425(17)270331 |
| CS-15192-VFM | 33F24J0049 | (01)10801902193602(10)33F24J0049(11)241113(17)270630 |
| CS-15192-VFM | 33F24M0243 | (01)10801902193602(10)33F24M0243(11)250221(17)280108 |
| CS-15192-VFM | 33F25C0672 | (01)10801902193602(10)33F25C0672(11)250430(17)280118 |
| CS-15192-VFM | 33F25E1077 | (01)10801902193602(10)33F25E1077(11)250718(17)280121 |
| CS-15192-VFM | 33F25F0418 | (01)10801902193602(10)33F25F0418(11)251022(17)280108 |
| CS-15192-X | 33F23C0886 | (01)30801902195303(10)33F23C0886(11)230411(17)260331 |
| CS-15192-X | 33F23E0564 | (01)30801902195303(10)33F23E0564(11)230601(17)260430 |
| CS-15192-X | 33F23G0263 | (01)30801902195303(10)33F23G0263(11)230727(17)260630 |
| CS-15192-X | 33F23G0533 | (01)30801902195303(10)33F23G0533(11)231025(17)260930 |
| CS-15192-X | 33F23K0712 | (01)30801902195303(10)33F23K0712(11)231109(17)261031 |
| CS-15192-X | 33F23L0935 | (01)30801902195303(10)33F23L0935(11)240227(17)270131 |
| CS-15192-X | 33F24E0187 | (01)30801902195303(10)33F24E0187(11)240726(17)270630 |
| CS-15192-X | 33F24E0793 | (01)30801902195303(10)33F24E0793(11)240714(17)270630 |
| CS-15192-X | 33F24G0171 | (01)30801902195303(10)33F24G0171(11)240823(17)260831 |
| CS-15192-X | 33F24J0017 | (01)30801902195303(10)33F24J0017(11)241107(17)271031 |
| CS-15192-X | 33F24J0041 | (01)30801902195303(10)33F24J0041(11)241122(17)271031 |
| CS-15192-X | 33F25D0701 | (01)30801902195303(10)33F25D0701(11)250516(17)280430 |
| CS-15192-X | 33F25E0476 | (01)30801902195303(10)33F25E0476(11)250717(17)280630 |
| CS-15192-X | 33F25F0486 | (01)30801902195303(10)33F25F0486(11)250826(17)280731 |
| CS-15192-X | 33F25H0783 | (01)30801902195303(10)33F25H0783(11)251030(17)280524 |
| CS-15192-X | 33F25H0857 | (01)30801902195303(10)33F25H0857(11)251111(17)280608 |
| CS-15192-XM | 33F25D0711 | (01)10801902127225(10)33F25D0711(11)250507(17)280108 |
| CS-15232-SFX | 33F23E0576 | (01)30801902195549(10)33F23E0576(11)230707(17)260630 |
| CS-15232-SFX | 33F23G0534 | (01)30801902195549(10)33F23G0534(11)231026(17)260930 |
| CS-15232-SFX | 33F23L0936 | (01)30801902195549(10)33F23L0936(11)240110(17)261231 |
| CS-15232-SFX | 33F24A0279 | (01)30801902195549(10)33F24A0279(11)240215(17)270131 |
| CS-15232-SFX | 33F24C0067 | (01)30801902195549(10)33F24C0067(11)240418(17)270331 |
| CS-15232-SFX | 33F24D1006 | (01)30801902195549(10)33F24D1006(11)240502(17)270430 |
| CS-15232-SFX | 33F24E0684 | (01)30801902195549(10)33F24E0684(11)240531(17)270430 |
| CS-15232-SFX | 33F24H0258 | (01)30801902195549(10)33F24H0258(11)240824(17)270731 |
| CS-15232-SFX | 33F24J0033 | (01)30801902195549(10)33F24J0033(11)241122(17)271031 |
| CS-15232-SFX | 33F24J0085 | (01)30801902195549(10)33F24J0085(11)241031(17)270930 |
| CS-15232-SFX | 33F24J0342 | (01)30801902195549(10)33F24J0342(11)240920(17)270831 |
| CS-15232-SFX | 33F24L0056 | (01)30801902195549(10)33F24L0056(11)241107(17)271031 |
| CS-15232-SFX | 33F24M0231 | (01)30801902195549(10)33F24M0231(11)250124(17)271031 |
| CS-15232-SFX | 33F25A0405 | (01)30801902195549(10)33F25A0405(11)250226(17)280131 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15232-SFX | 33F25C0036 | (01)30801902195549(10)33F25C0036(11)250311(17)271215 |
| CS-15232-SFX | 33F25C0664 | (01)30801902195549(10)33F25C0664(11)250417(17)280225 |
| CS-15232-SFX | 33F25D0739 | (01)30801902195549(10)33F25D0739(11)250729(17)280630 |
| CS-15232-SFX | 33F25E0433 | (01)30801902195549(10)33F25E0433(11)250519(17)280430 |
| CS-15232-SFX | 33F25G0716 | (01)30801902195549(10)33F25G0716(11)250901(17)280831 |
| CS-15232-SFX | 33F25H0248 | (01)30801902195549(10)33F25H0248(11)251031(17)280928 |
| CS-15232-SFXM | 33F25C0671 | (01)10801902127232(10)33F25C0671(11)250404(17)280118 |
| CS-15232-VF | 33F23C0873 | (01)10801902193626(10)33F23C0873(11)230428(17)260331 |
| CS-15232-VF | 33F23J0546 | (01)10801902193626(10)33F23J0546(11)231011(17)260930 |
| CS-15232-VF | 33F24A0294 | (01)10801902193626(10)33F24A0294(11)240114(17)261231 |
| CS-15232-VF | 33F24C0071 | (01)10801902193626(10)33F24C0071(11)240605(17)270531 |
| CS-15232-VF | 33R24G0168 | (01)10801902193626(10)33R24G0168(11)241023(17)270831 |
| CS-15232-VF | 33F24J0044 | (01)10801902193626(10)33F24J0044(11)241031(17)270930 |
| CS-15232-VF | 33F25D0089 | (01)10801902193626(10)33F25D0089(11)250422(17)280225 |
| CS-15232-VF | 33F25E0333 | (01)10801902193626(10)33F25E0333(11)250718(17)280420 |
| CS-15232-VF | 33F25E0427 | (01)10801902193626(10)33F25E0427(11)250520(17)280430 |
| CS-15232-VF | 33F25E1095 | (01)10801902193626(10)33F25E1095(11)250910(17)280831 |
| CS-15232-VF | 33F25F0404 | (01)10801902193626(10)33F25F0404(11)250805(17)280510 |
| CS-15232-VF | 33F25H0294 | (01)10801902193626(10)33F25H0294(11)250930(17)280831 |
| CS-15232-VF | 33F25J1009 | (01)10801902193626(10)33F25J1009(11)251205(17)270427 |
| CS-15232-VFE | 33F23E0775 | (01)10801902195132(10)33F23E0775(11)230628(17)260531 |
| CS-15232-VFE | 33F23F0720 | (01)10801902195132(10)33F23F0720(11)230629(17)260531 |
| CS-15232-VFE | 33F23K0176 | (01)10801902195132(10)33F23K0176(11)231101(17)261031 |
| CS-15232-VFE | 33F23K0194 | (01)10801902195132(10)33F23K0194(11)231130(17)261130 |
| CS-15232-VFE | 33F23L0937 | (01)10801902195132(10)33F23L0937(11)231206(17)261130 |
| CS-15232-VFE | 33F24A0927 | (01)10801902195132(10)33F24A0927(11)240213(17)270131 |
| CS-15232-VFE | 33F24C0059 | (01)10801902195132(10)33F24C0059(11)240528(17)270430 |
| CS-15232-VFE | 33F24D1010 | (01)10801902195132(10)33F24D1010(11)240506(17)270430 |
| CS-15232-VFE | 33F24E0270 | (01)10801902195132(10)33F24E0270(11)240605(17)270531 |
| CS-15232-VFE | 33F24E0796 | (01)10801902195132(10)33F24E0796(11)240904(17)270831 |
| CS-15232-VFE | 33F24G0045 | (01)10801902195132(10)33F24G0045(11)240714(17)270630 |
| CS-15232-VFE | 33F24J0035 | (01)10801902195132(10)33F24J0035(11)241203(17)271130 |
| CS-15232-VFE | 33F24J0083 | (01)10801902195132(10)33F24J0083(11)240909(17)270831 |
| CS-15232-VFE | 33F24L0171 | (01)10801902195132(10)33F24L0171(11)241122(17)271031 |
| CS-15232-VFE | 33F24M0216 | (01)10801902195132(10)33F24M0216(11)250109(17)271231 |
| CS-15232-VFE | 33F25A0004 | (01)10801902195132(10)33F25A0004(11)250214(17)280131 |
| CS-15232-VFE | 33F25A0083 | (01)10801902195132(10)33F25A0083(11)250122(17)271231 |
| CS-15232-VFE | 33F25C0023 | (01)10801902195132(10)33F25C0023(11)250325(17)280229 |
| CS-15232-VFE | 33F25C0659 | (01)10801902195132(10)33F25C0659(11)250409(17)280331 |
| CS-15232-VFE | 33F25D0106 | (01)10801902195132(10)33F25D0106(11)250502(17)280131 |
| CS-15232-VFE | 33F25D0219 | (01)10801902195132(10)33F25D0219(11)250422(17)280131 |
| CS-15232-VFE | 33F25D0726 | (01)10801902195132(10)33F25D0726(11)250626(17)271125 |
| CS-15232-VFE | 33F25E0478 | (01)10801902195132(10)33F25E0478(11)250523(17)280430 |
| CS-15232-VFE | 33F25E1105 | (01)10801902195132(10)33F25E1105(11)250725(17)280420 |
| CS-15232-VFE | 33F25F0298 | (01)10801902195132(10)33F25F0298(11)250829(17)280731 |
| CS-15232-VFE | 33F25J1056 | (01)10801902195132(10)33F25J1056(11)251023(17)280524 |
| CS-15232-VFE | 33F25K0335 | (01)10801902195132(10)33F25K0335(11)251106(17)280608 |
| CS-15232-VFE | 33F25L0011 | (01)10801902195132(10)33F25L0011(11)251205(17)280608 |
| CS-15232-VFI | 33F23C0864 | (01)10801902194463(10)33F23C0864(11)230404(17)260331 |
| CS-15232-VFI | 33F23E0578 | (01)10801902127263(10)33F23E0578(11)230608(17)260531 |
| CS-15232-VFI | 33F23E0832 | (01)10801902194463(10)33F23E0832(11)230708(17)260630 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15232-VFI | 33F23G0535 | (01)10801902194463(10)33F23G0535(11)230802(17)260630 |
| CS-15232-VFI | 33F23G0840 | (01)10801902194463(10)33F23G0840(11)230816(17)260731 |
| CS-15232-VFI | 33F23H0612 | (01)10801902194463(10)33F23H0612(11)230919(17)260831 |
| CS-15232-VFI | 33F23K0144 | (01)10801902194463(10)33F23K0144(11)231012(17)260930 |
| CS-15232-VFI | 33F24A0914 | (01)10801902194463(10)33F24A0914(11)240306(17)270228 |
| CS-15232-VFI | 33F24C0079 | (01)10801902194463(10)33F24C0079(11)240509(17)270430 |
| CS-15232-VFI | 33F24E0269 | (01)10801902194463(10)33F24E0269(11)240903(17)270831 |
| CS-15232-VFI | 33F24J0042 | (01)10801902194463(10)33F24J0042(11)241011(17)270930 |
| CS-15232-VFI | 33F25B0256 | (01)10801902194463(10)33F25B0256(11)250219(17)280131 |
| CS-15232-VFI | 33F25C0014 | (01)10801902194463(10)33F25C0014(11)250325(17)280229 |
| CS-15232-VFI | 33F25C0709 | (01)10801902194463(10)33F25C0709(11)250401(17)280331 |
| CS-15232-VFI | 33F25C0650 | (01)10801902194463(10)33F25C0650(11)250409(17)280225 |
| CS-15232-VFI | 33F25E1085 | (01)10801902194463(10)33F25E1085(11)250603(17)280427 |
| CS-15232-VFI | 33F25E1130 | (01)10801902194463(10)33F25E1130(11)250716(17)280630 |
| CS-15232-VFI | 33F25F0009 | (01)10801902194463(10)33F25F0009(11)250610(17)280531 |
| CS-15232-VFI | 33F25G0023 | (01)10801902194463(10)33F25G0023(11)250818(17)280731 |
| CS-15232-VFI | 33F25G0450 | (01)10801902194463(10)33F25G0450(11)250910(17)280831 |
| CS-15232-VFI | 33F25H0341 | (01)10801902194463(10)33F25H0341(11)251016(17)280930 |
| CS-15232-VFI | 33F25J1014 | (01)10801902194463(10)33F25J1014(11)251212(17)280629 |
| CS-15232-VFIE | 33F23D0855 | (01)10801902195149(10)33F23D0855(11)230529(17)260430 |
| CS-15232-VFIE | 33F23E0774 | (01)10801902195149(10)33F23E0774(11)230706(17)260630 |
| CS-15232-VFIE | 33F23G0047 | (01)10801902195149(10)33F23G0047(11)230721(17)260630 |
| CS-15232-VFIE | 33F23G0048 | (01)10801902195149(10)33F23G0048(11)230727(17)260630 |
| CS-15232-VFIE | 33F23G0049 | (01)10801902195149(10)33F23G0049(11)230810(17)260731 |
| CS-15232-VFIE | 33F23K0145 | (01)10801902195149(10)33F23K0145(11)231019(17)260930 |
| CS-15232-VFIE | 33F23K0175 | (01)10801902195149(10)33F23K0175(11)231025(17)260930 |
| CS-15232-VFIE | 33F23L0938 | (01)10801902195149(10)33F23L0938(11)231208(17)261130 |
| CS-15232-VFIE | 33F24A0915 | (01)10801902195149(10)33F24A0915(11)240306(17)270228 |
| CS-15232-VFIE | 33F24C0069 | (01)10801902195149(10)33F24C0069(11)240417(17)270331 |
| CS-15232-VFIE | 33F24G0169 | (01)10801902195149(10)33F24G0169(11)240905(17)270831 |
| CS-15232-VFIE | 33F24J0026 | (01)10801902195149(10)33F24J0026(11)241011(17)270930 |
| CS-15232-VFIE | 33F24J0027 | (01)10801902195149(10)33F24J0027(11)241011(17)270930 |
| CS-15232-VFIE | 33F24J0028 | (01)10801902195149(10)33F24J0028(11)241029(17)270930 |
| CS-15232-VFIE | 33F24J0084 | (01)10801902195149(10)33F24J0084(11)241111(17)271031 |
| CS-15232-VFIE | 33F24K0700 | (01)10801902195149(10)33F24K0700(11)241205(17)271130 |
| CS-15232-VFIE | 33F24L0178 | (01)10801902195149(10)33F24L0178(11)241125(17)270811 |
| CS-15232-VFIE | 33F24M0005 | (01)10801902195149(10)33F24M0005(11)250122(17)271231 |
| CS-15232-VFIE | 33F24M0214 | (01)10801902195149(10)33F24M0214(11)250108(17)271231 |
| CS-15232-VFIE | 33F24M0219 | (01)10801902195149(10)33F24M0219(11)250214(17)280131 |
| CS-15232-VFIE | 33F25C0646 | (01)10801902195149(10)33F25C0646(11)250402(17)280331 |
| CS-15232-VFIE | 33F25C0665 | (01)10801902195149(10)33F25C0665(11)250424(17)280331 |
| CS-15232-VFIE | 33F25D0097 | (01)10801902195149(10)33F25D0097(11)250508(17)280430 |
| CS-15232-VFIE | 33F25E0358 | (01)10801902195149(10)33F25E0358(11)250530(17)280430 |
| CS-15232-VFIE | 33F25E0434 | (01)10801902195149(10)33F25E0434(11)250520(17)280430 |
| CS-15232-VFIE | 33F25F0012 | (01)10801902195149(10)33F25F0012(11)250618(17)280531 |
| CS-15232-VFIE | 33F25F0275 | (01)10801902195149(10)33F25F0275(11)250805(17)280731 |
| CS-15232-VFIE | 33F25F0328 | (01)10801902195149(10)33F25F0328(11)250618(17)280531 |
| CS-15232-VFIE | 33F25G0069 | (01)10801902195149(10)33F25G0069(11)250821(17)280731 |
| CS-15232-VFIE | 33F25H0293 | (01)10801902195149(10)33F25H0293(11)250929(17)280517 |
| CS-15232-VFIE | 33F25H0822 | (01)10801902195149(10)33F25H0822(11)251022(17)280524 |
| CS-15232-VFIE | 33F25K0235 | (01)10801902195149(10)33F25K0235(11)251207(17)280629 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15232-VFIM | 33F23C0879 | (01)10801902193619(10)33F23C0879(11)230429(17)260331 |
| CS-15232-VFIM | 33F23L0939 | (01)10801902193619(10)33F23L0939(11)231207(17)260930 |
| CS-15232-VFIM | 33F24A0304 | (01)10801902193619(10)33F24A0304(11)240115(17)261231 |
| CS-15232-VFIM | 33F24E0798 | (01)10801902193619(10)33F24E0798(11)240903(17)270831 |
| CS-15232-VFIM | 33F24J0047 | (01)10801902193619(10)33F24J0047(11)241212(17)271130 |
| CS-15232-VFM | 33F23J0547 | (01)10801902193633(10)33F23J0547(11)230927(17)260930 |
| CS-15232-VFM | 33F24A0289 | (01)10801902193633(10)33F24A0289(11)240115(17)261231 |
| CS-15232-VFM | 33F24C0077 | (01)10801902193633(10)33F24C0077(11)240508(17)270430 |
| CS-15232-VFM | 33F24E0799 | (01)10801902193633(10)33F24E0799(11)240712(17)270531 |
| CS-15232-VFM | 33F24J0045 | (01)10801902193633(10)33F24J0045(11)241014(17)270930 |
| CS-15232-VFM | 33F24J0093 | (01)10801902193633(10)33F24J0093(11)240915(17)270831 |
| CS-15232-VFM | 33F25A0026 | (01)10801902193633(10)33F25A0026(11)250217(17)280108 |
| CS-15232-VFM | 33F25C0050 | (01)10801902193633(10)33F25C0050(11)250325(17)280108 |
| CS-15232-VFM | 33F25E0348 | (01)10801902193633(10)33F25E0348(11)250618(17)280121 |
| CS-15232-VFM | 33F25K0348 | (01)10801902193633(10)33F25K0348(11)251104(17)280227 |
| CS-15232-X | 33F23C0862 | (01)30801902195556(10)33F23C0862(11)230405(17)260331 |
| CS-15232-X | 33F23E0566 | (01)30801902195556(10)33F23E0566(11)230605(17)260531 |
| CS-15232-X | 33F23F0722 | (01)30801902195556(10)33F23F0722(11)230706(17)260630 |
| CS-15232-X | 33F23K0171 | (01)30801902195556(10)33F23K0171(11)231018(17)260930 |
| CS-15232-X | 33F23L0940 | (01)30801902195556(10)33F23L0940(11)240220(17)270131 |
| CS-15232-X | 33F24A0916 | (01)30801902195556(10)33F24A0916(11)240305(17)270228 |
| CS-15232-X | 33F24C0061 | (01)30801902195556(10)33F24C0061(11)240509(17)270430 |
| CS-15232-X | 33F24D1037 | (01)30801902195556(10)33F24D1037(11)240531(17)270531 |
| CS-15232-X | 33F24E0800 | (01)30801902195556(10)33F24E0800(11)240610(17)270531 |
| CS-15232-X | 33F24J0043 | (01)30801902195556(10)33F24J0043(11)241107(17)271031 |
| CS-15232-X | 33F24L0176 | (01)30801902195556(10)33F24L0176(11)241119(17)271031 |
| CS-15232-X | 33F25A0028 | (01)30801902195556(10)33F25A0028(11)250221(17)280131 |
| CS-15232-X | 33F25C0029 | (01)30801902195556(10)33F25C0029(11)250311(17)271215 |
| CS-15232-X | 33F25C0644 | (01)30801902195556(10)33F25C0644(11)250402(17)280331 |
| CS-15232-X | 33F25D0096 | (01)30801902195556(10)33F25D0096(11)250516(17)280430 |
| CS-15232-X | 33F25E0352 | (01)30801902195556(10)33F25E0352(11)250610(17)280531 |
| CS-15232-X | 33F25F0300 | (01)30801902195556(10)33F25F0300(11)250804(17)280420 |
| CS-15232-X | 33F25F0513 | (01)30801902195556(10)33F25F0513(11)250909(17)280831 |
| CS-15232-X | 33F25E0477 | (01)30801902195556(10)33F25E0477(11)250723(17)280630 |
| CS-15232-X | 33F25J0745 | (01)30801902195556(10)33F25J0745(11)251016(17)280517 |
| CS-15232-XM | 33F25E0435 | (01)10801902127300(10)33F25E0435(11)250519(17)280118 |
| CS-15242-I | 33F23G0536 | (01)30801902195280(10)33F23G0536(11)230905(17)260831 |
| CS-15242-SPM | 33F23D0867 | (01)10801902193527(10)33F23D0867(11)230529(17)260430 |
| CS-15242-SPM | 33F23K0192 | (01)10801902193527(10)33F23K0192(11)240305(17)260930 |
| CS-15242-SPM | 33F24A0288 | (01)10801902193527(10)33F24A0288(11)240419(17)260930 |
| CS-15242-SPM | 33F24E0802 | (01)10801902193527(10)33F24E0802(11)240725(17)270630 |
| CS-15242-SPM | 33F24M0244 | (01)10801902193527(10)33F24M0244(11)250227(17)280108 |
| CS-15242-SPM | 33F25C0669 | (01)10801902193527(10)33F25C0669(11)250502(17)280118 |
| CS-15242-SPM | 33F25E0338 | (01)10801902193527(10)33F25E0338(11)250627(17)280108 |
| CS-15242-SPM | 33F25G0586 | (01)10801902193527(10)33F25G0586(11)250822(17)280121 |
| CS-15242-VSP | 33F23C0870 | (01)30801902195273(10)33F23C0870(11)230411(17)260331 |
| CS-15242-VSP | 33F23D0857 | (01)30801902195273(10)33F23D0857(11)230525(17)260430 |
| CS-15242-VSP | 33F23F0719 | (01)30801902195273(10)33F23F0719(11)230629(17)260531 |
| CS-15242-VSP | 33F23K0182 | (01)30801902195273(10)33F23K0182(11)231206(17)261130 |
| CS-15242-VSP | 33F24A0265 | (01)30801902195273(10)33F24A0265(11)240211(17)270131 |
| CS-15242-VSP | 33F24C0062 | (01)30801902195273(10)33F24C0062(11)240424(17)270331 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|--------------|------------|--|
| CS-15242-VSP | 33F24D1000 | (01)30801902195273(10)33F24D1000(11)240506(17)270430 |
| CS-15242-VSP | 33F24D1039 | (01)30801902195273(10)33F24D1039(11)240530(17)270430 |
| CS-15242-VSP | 33F24E0803 | (01)30801902195273(10)33F24E0803(11)241115(17)271031 |
| CS-15242-VSP | 33F24H0038 | (01)30801902195273(10)33F24H0038(11)240808(17)270731 |
| CS-15242-VSP | 33F24H0261 | (01)30801902195273(10)33F24H0261(11)240827(17)270731 |
| CS-15242-VSP | 33F24K0505 | (01)30801902195273(10)33F24K0505(11)241128(17)271031 |
| CS-15242-VSP | 33F24M0039 | (01)30801902195273(10)33F24M0039(11)241220(17)271130 |
| CS-15242-VSP | 33F24M0218 | (01)30801902195273(10)33F24M0218(11)250122(17)271231 |
| CS-15242-VSP | 33F25A0141 | (01)30801902195273(10)33F25A0141(11)250222(17)280131 |
| CS-15242-VSP | 33F25C0657 | (01)30801902195273(10)33F25C0657(11)250401(17)280331 |
| CS-15242-VSP | 33F25D0125 | (01)30801902195273(10)33F25D0125(11)250414(17)280225 |
| CS-15242-VSP | 33F25E0305 | (01)30801902195273(10)33F25E0305(11)250520(17)280430 |
| CS-15242-VSP | 33F25E0429 | (01)30801902195273(10)33F25E0429(11)250602(17)280531 |
| CS-15242-VSP | 33F25E0430 | (01)30801902195273(10)33F25E0430(11)250619(17)280531 |
| CS-15242-VSP | 33F25E1131 | (01)30801902195273(10)33F25E1131(11)250715(17)280510 |
| CS-15242-VSP | 33F25F0042 | (01)30801902195273(10)33F25F0042(11)250808(17)280731 |
| CS-15242-VSP | 33F25G0070 | (01)30801902195273(10)33F25G0070(11)250818(17)280731 |
| CS-15242-VSP | 33F25H0295 | (01)30801902195273(10)33F25H0295(11)250910(17)280831 |
| CS-15242-VSP | 33F25H0366 | (01)30801902195273(10)33F25H0366(11)251006(17)280524 |
| CS-15242-VSP | 33F25H0674 | (01)30801902195273(10)33F25H0674(11)250901(17)280731 |
| CS-15242-VSP | 33F25J1015 | (01)30801902195273(10)33F25J1015(11)251105(17)280524 |
| CS-15272-SFX | 33F23B0321 | (01)10801902195217(10)33F23B0321(11)230217(17)260630 |
| CS-15272-SFX | 33F23D0859 | (01)10801902195217(10)33F23D0859(11)230706(17)260630 |
| CS-15272-SFX | 33F23H0500 | (01)10801902195217(10)33F23H0500(11)230829(17)260731 |
| CS-15272-SFX | 33F23K0177 | (01)10801902195217(10)33F23K0177(11)231107(17)261031 |
| CS-15272-SFX | 33F23L0943 | (01)10801902195217(10)33F23L0943(11)240110(17)261231 |
| CS-15272-SFX | 33F24A0280 | (01)10801902195217(10)33F24A0280(11)240213(17)270131 |
| CS-15272-SFX | 33F24C0083 | (01)10801902195217(10)33F24C0083(11)240425(17)270331 |
| CS-15272-SFX | 33F24H0042 | (01)10801902195217(10)33F24H0042(11)240809(17)270731 |
| CS-15272-SFX | 33F24H0260 | (01)10801902195217(10)33F24H0260(11)240823(17)270731 |
| CS-15272-SFX | 33F24J0022 | (01)10801902195217(10)33F24J0022(11)240909(17)270831 |
| CS-15272-SFX | 33F24J0038 | (01)10801902195217(10)33F24J0038(11)241209(17)271130 |
| CS-15272-SFX | 33F24J0088 | (01)10801902195217(10)33F24J0088(11)241025(17)270930 |
| CS-15272-SFX | 33F24L0177 | (01)10801902195217(10)33F24L0177(11)241121(17)271031 |
| CS-15272-SFX | 33F25C0028 | (01)10801902195217(10)33F25C0028(11)250311(17)271215 |
| CS-15272-SFX | 33F25E1090 | (01)10801902195217(10)33F25E1090(11)250723(17)280630 |
| CS-15272-SFX | 33F25F0301 | (01)10801902195217(10)33F25F0301(11)250805(17)280420 |
| CS-15272-SFX | 33F25F0514 | (01)10801902195217(10)33F25F0514(11)250905(17)280831 |
| CS-15272-VF | 33F23C0880 | (01)10801902193657(10)33F23C0880(11)230430(17)260331 |
| CS-15272-VF | 33F23F0740 | (01)10801902193657(10)33F23F0740(11)230706(17)260630 |
| CS-15272-VF | 33F23L0944 | (01)10801902193657(10)33F23L0944(11)231210(17)261130 |
| CS-15272-VF | 33F24C0081 | (01)10801902193657(10)33F24C0081(11)240422(17)270331 |
| CS-15272-VF | 33F24E0804 | (01)10801902193657(10)33F24E0804(11)240611(17)270531 |
| CS-15272-VF | 33F24J0051 | (01)10801902193657(10)33F24J0051(11)240917(17)270831 |
| CS-15272-VF | 33F24J0686 | (01)10801902193657(10)33F24J0686(11)241203(17)271031 |
| CS-15272-VF | 33F24M0228 | (01)10801902193657(10)33F24M0228(11)250214(17)280131 |
| CS-15272-VF | 33F25C0668 | (01)10801902193657(10)33F25C0668(11)250408(17)280331 |
| CS-15272-VF | 33F25E0337 | (01)10801902193657(10)33F25E0337(11)250627(17)280420 |
| CS-15272-VF | 33F25F0403 | (01)10801902193657(10)33F25F0403(11)250719(17)280630 |
| CS-15272-VF | 33F25J0590 | (01)10801902193657(10)33F25J0590(11)251030(17)280524 |
| CS-15272-VFE | 33F23E0777 | (01)10801902195248(10)33F23E0777(11)230629(17)260531 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15272-VFE | 33F23F0732 | (01)10801902195248(10)33F23F0732(11)230706(17)260531 |
| CS-15272-VFE | 33F23H0980 | (01)10801902195248(10)33F23H0980(11)230914(17)260831 |
| CS-15272-VFE | 33F23K0172 | (01)10801902195248(10)33F23K0172(11)231017(17)260930 |
| CS-15272-VFE | 33F23L0945 | (01)10801902195248(10)33F23L0945(11)231206(17)261130 |
| CS-15272-VFE | 33F24A0918 | (01)10801902195248(10)33F24A0918(11)240212(17)270131 |
| CS-15272-VFE | 33F24C0064 | (01)10801902195248(10)33F24C0064(11)240603(17)270531 |
| CS-15272-VFE | 33F24H0044 | (01)10801902195248(10)33F24H0044(11)240812(17)270731 |
| CS-15272-VFE | 33F24H0255 | (01)10801902195248(10)33F24H0255(11)240826(17)270731 |
| CS-15272-VFE | 33F24M0237 | (01)10801902195248(10)33F24M0237(11)250222(17)280131 |
| CS-15272-VFE | 33F25C0049 | (01)10801902195248(10)33F25C0049(11)250325(17)280229 |
| CS-15272-VFE | 33F25E0349 | (01)10801902195248(10)33F25E0349(11)250627(17)280420 |
| CS-15272-VFE | 33F25E1132 | (01)10801902195248(10)33F25E1132(11)250721(17)280420 |
| CS-15272-VFE | 33F25G0637 | (01)10801902195248(10)33F25G0637(11)251031(17)280928 |
| CS-15272-VFI | 33F23E0871 | (01)10801902193640(10)33F23E0871(11)230606(17)260531 |
| CS-15272-VFI | 33F23F0742 | (01)10801902127362(10)33F23F0742(11)230710(17)260630 |
| CS-15272-VFI | 33F23H0981 | (01)10801902193640(10)33F23H0981(11)230912(17)260831 |
| CS-15272-VFI | 33F23K0181 | (01)10801902193640(10)33F23K0181(11)231025(17)260930 |
| CS-15272-VFI | 33F24A0306 | (01)10801902193640(10)33F24A0306(11)240115(17)261231 |
| CS-15272-VFI | 33F24C0084 | (01)10801902193640(10)33F24C0084(11)240501(17)270331 |
| CS-15272-VFI | 33F24J0062 | (01)10801902193640(10)33F24J0062(11)241003(17)270930 |
| CS-15272-VFI | 33F25D0098 | (01)10801902193640(10)33F25D0098(11)250508(17)280430 |
| CS-15272-VFI | 33F25E0307 | (01)10801902193640(10)33F25E0307(11)250512(17)280225 |
| CS-15272-VFI | 33F25E0332 | (01)10801902193640(10)33F25E0332(11)250530(17)280430 |
| CS-15272-VFI | 33F25E0354 | (01)10801902193640(10)33F25E0354(11)250519(17)280430 |
| CS-15272-VFI | 33F25F0058 | (01)10801902193640(10)33F25F0058(11)250610(17)280531 |
| CS-15272-VFI | 33F25F0245 | (01)10801902193640(10)33F25F0245(11)250710(17)280420 |
| CS-15272-VFI | 33F25J0659 | (01)10801902193640(10)33F25J0659(11)251106(17)280608 |
| CS-15272-VFIE | 33F23E0886 | (01)10801902195255(10)33F23E0886(11)230606(17)260531 |
| CS-15272-VFIE | 33F23G0537 | (01)10801902195255(10)33F23G0537(11)230802(17)260630 |
| CS-15272-VFIE | 33F23H0982 | (01)10801902195255(10)33F23H0982(11)230913(17)260831 |
| CS-15272-VFIE | 33F23K0180 | (01)10801902195255(10)33F23K0180(11)231026(17)260930 |
| CS-15272-VFIE | 33F23L0946 | (01)10801902195255(10)33F23L0946(11)231206(17)261130 |
| CS-15272-VFIE | 33F24A0922 | (01)10801902195255(10)33F24A0922(11)240212(17)270131 |
| CS-15272-VFIE | 33F24C0065 | (01)10801902195255(10)33F24C0065(11)240415(17)270331 |
| CS-15272-VFIE | 33F24D1011 | (01)10801902195255(10)33F24D1011(11)240509(17)270430 |
| CS-15272-VFIE | 33F24E0686 | (01)10801902195255(10)33F24E0686(11)240531(17)270430 |
| CS-15272-VFIE | 33F24E0805 | (01)10801902195255(10)33F24E0805(11)240610(17)270531 |
| CS-15272-VFIE | 33F24K0508 | (01)10801902195255(10)33F24K0508(11)241205(17)271130 |
| CS-15272-VFIE | 33F24M0223 | (01)10801902195255(10)33F24M0223(11)250219(17)300731 |
| CS-15272-VFIE | 33F25A0410 | (01)10801902195255(10)33F25A0410(11)250224(17)280131 |
| CS-15272-VFIE | 33F25C0009 | (01)10801902195255(10)33F25C0009(11)250325(17)280229 |
| CS-15272-VFIE | 33F25G0717 | (01)10801902195255(10)33F25G0717(11)250905(17)300731 |
| CS-15272-VFIM | 33F23H1027 | (01)10801902197761(10)33F23H1027(11)230930(17)260831 |
| CS-15272-VFM | 33F25C0687 | (01)10801902127393(10)33F25C0687(11)250414(17)280118 |
| CS-15272-X | 33F23C0887 | (01)10801902195224(10)33F23C0887(11)230411(17)260331 |
| CS-15272-X | 33F23F0731 | (01)10801902195224(10)33F23F0731(11)230706(17)260630 |
| CS-15272-X | 33F23H0983 | (01)10801902195224(10)33F23H0983(11)230927(17)260831 |
| CS-15272-X | 33F23K0190 | (01)10801902195224(10)33F23K0190(11)231107(17)261031 |
| CS-15272-X | 33F23L0947 | (01)10801902195224(10)33F23L0947(11)240226(17)270131 |
| CS-15272-X | 33F24E0807 | (01)10801902195224(10)33F24E0807(11)240730(17)270630 |
| CS-15272-X | 33F24F0124 | (01)10801902195224(10)33F24F0124(11)240612(17)270531 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|--------------|------------|--|
| CS-15272-X | 33F24J0018 | (01)10801902195224(10)33F24J0018(11)240909(17)270831 |
| CS-15272-X | 33F24J0050 | (01)10801902195224(10)33F24J0050(11)221125(17)270930 |
| CS-15272-X | 33F24L0054 | (01)10801902195224(10)33F24L0054(11)241108(17)271031 |
| CS-15272-X | 33F24L0063 | (01)10801902195224(10)33F24L0063(11)241209(17)271130 |
| CS-15272-X | 33F24M0006 | (01)10801902195224(10)33F24M0006(11)250124(17)271125 |
| CS-15272-X | 33F25C0684 | (01)10801902195224(10)33F25C0684(11)250522(17)280430 |
| CS-15272-X | 33F25E0342 | (01)10801902195224(10)33F25E0342(11)250722(17)280630 |
| CS-15272-X | 33F25F0276 | (01)10801902195224(10)33F25F0276(11)250801(17)280420 |
| CS-15272-X | 33F25J0641 | (01)10801902195224(10)33F25J0641(11)251105(17)280608 |
| CS-15272-XM | 33F25C0680 | (01)10801902127409(10)33F25C0680(11)250430(17)280118 |
| CS-15272-XM | 33F25K0272 | (01)10801902127409(10)33F25K0272(11)251205(17)270427 |
| CS-15282-I | 33F23C0877 | (01)30801902195532(10)33F23C0877(11)230503(17)260430 |
| CS-15282-I | 33F24A0281 | (01)30801902195532(10)33F24A0281(11)240116(17)261231 |
| CS-15282-I | 33F24H0041 | (01)30801902195532(10)33F24H0041(11)240809(17)270731 |
| CS-15282-SPM | 33F23C0872 | (01)10801902193688(10)33F23C0872(11)230408(17)260331 |
| CS-15282-SPM | 33F23D0864 | (01)10801902193688(10)33F23D0864(11)230506(17)260430 |
| CS-15282-SPM | 33F23G0539 | (01)10801902193688(10)33F23G0539(11)231005(17)260930 |
| CS-15282-SPM | 33F23L0949 | (01)10801902193688(10)33F23L0949(11)231206(17)260930 |
| CS-15282-SPM | 33F24A0278 | (01)10801902193688(10)33F24A0278(11)240123(17)261231 |
| CS-15282-SPM | 33F24C0075 | (01)10801902193688(10)33F24C0075(11)240419(17)270331 |
| CS-15282-SPM | 33F24E0808 | (01)10801902193688(10)33F24E0808(11)240712(17)270630 |
| CS-15282-SPM | 33F24H0254 | (01)10801902193688(10)33F24H0254(11)240823(17)270731 |
| CS-15282-SPM | 33F24J0036 | (01)10801902193688(10)33F24J0036(11)241108(17)271031 |
| CS-15282-SPM | 33F24L1166 | (01)10801902193688(10)33F24L1166(11)241128(17)271031 |
| CS-15282-SPM | 33F24M0233 | (01)10801902193688(10)33F24M0233(11)250124(17)271125 |
| CS-15282-SPM | 33F25A0413 | (01)10801902193688(10)33F25A0413(11)250204(17)271125 |
| CS-15282-SPM | 33F25C0666 | (01)10801902193688(10)33F25C0666(11)250331(17)271218 |
| CS-15282-SPM | 33F25H0824 | (01)10801902193688(10)33F25H0824(11)251001(17)280108 |
| CS-15282-VSP | 33F23C0866 | (01)30801902195518(10)33F23C0866(11)230406(17)260331 |
| CS-15282-VSP | 33F23D0854 | (01)30801902195518(10)33F23D0854(11)230503(17)260430 |
| CS-15282-VSP | 33F23E0572 | (01)30801902195518(10)33F23E0572(11)230525(17)260430 |
| CS-15282-VSP | 33F23F0594 | (01)30801902195518(10)33F23F0594(11)230630(17)260531 |
| CS-15282-VSP | 33F23G0540 | (01)30801902195518(10)33F23G0540(11)231006(17)260930 |
| CS-15282-VSP | 33F23J0544 | (01)30801902195518(10)33F23J0544(11)231020(17)260930 |
| CS-15282-VSP | 33F23K0174 | (01)30801902195518(10)33F23K0174(11)231130(17)261130 |
| CS-15282-VSP | 33F23L0950 | (01)30801902195518(10)33F23L0950(11)240108(17)261231 |
| CS-15282-VSP | 33F24B0010 | (01)30801902195518(10)33F24B0010(11)240301(17)270228 |
| CS-15282-VSP | 33F24C0060 | (01)30801902195518(10)33F24C0060(11)240416(17)270331 |
| CS-15282-VSP | 33F24D0993 | (01)30801902195518(10)33F24D0993(11)240508(17)270430 |
| CS-15282-VSP | 33F24D1040 | (01)30801902195518(10)33F24D1040(11)240527(17)270430 |
| CS-15282-VSP | 33F24E0268 | (01)30801902195518(10)33F24E0268(11)240603(17)270531 |
| CS-15282-VSP | 33F24E0809 | (01)30801902195518(10)33F24E0809(11)240619(17)270531 |
| CS-15282-VSP | 33F24F0155 | (01)30801902195518(10)33F24F0155(11)220825(17)270630 |
| CS-15282-VSP | 33F24J0037 | (01)30801902195518(10)33F24J0037(11)230125(17)271130 |
| CS-15282-VSP | 33F24M0007 | (01)30801902195518(10)33F24M0007(11)230225(17)271231 |
| CS-15282-VSP | 33F24M0040 | (01)30801902195518(10)33F24M0040(11)230125(17)271130 |
| CS-15282-VSP | 33F24M0165 | (01)30801902195518(10)33F24M0165(11)241220(17)271130 |
| CS-15282-VSP | 33F24M0217 | (01)30801902195518(10)33F24M0217(11)250121(17)271222 |
| CS-15282-VSP | 33F25A0406 | (01)30801902195518(10)33F25A0406(11)250218(17)280131 |
| CS-15282-VSP | 33F25B0269 | (01)30801902195518(10)33F25B0269(11)250226(17)280131 |
| CS-15282-VSP | 33F25C0021 | (01)30801902195518(10)33F25C0021(11)250311(17)280105 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15282-VSP | 33F25C0045 | (01)30801902195518(10)33F25C0045(11)250325(17)280229 |
| CS-15282-VSP | 33F25C0642 | (01)30801902195518(10)33F25C0642(11)250402(17)280331 |
| CS-15282-VSP | 33F25D0013 | (01)30801902195518(10)33F25D0013(11)250506(17)280406 |
| CS-15282-VSP | 33F25D0713 | (01)30801902195518(10)33F25D0713(11)250628(17)280510 |
| CS-15282-VSP | 33F25F0249 | (01)30801902195518(10)33F25F0249(11)251006(17)280524 |
| CS-15282-VSP | 33F25H0296 | (01)30801902195518(10)33F25H0296(11)251105(17)280608 |
| CS-15282-VSP | 33F25J0051 | (01)30801902195518(10)33F25J0051(11)251208(17)280524 |
| CS-15312-SFX | 33F23G0541 | (01)30801902197529(10)33F23G0541(11)230822(17)260731 |
| CS-15312-SFX | 33F23H0984 | (01)30801902197529(10)33F23H0984(11)230906(17)260831 |
| CS-15312-SFX | 33F23L0951 | (01)30801902197529(10)33F23L0951(11)240112(17)261231 |
| CS-15312-SFX | 33F24A0283 | (01)30801902197529(10)33F24A0283(11)240213(17)270131 |
| CS-15312-VF | 33F24G0060 | (01)10801902127447(10)33F24G0060(11)241106(17)271031 |
| CS-15312-VF | 33F25D0216 | (01)10801902127447(10)33F25D0216(11)250422(17)280131 |
| CS-15312-VFE | 33F23F0734 | (01)10801902195484(10)33F23F0734(11)230706(17)260630 |
| CS-15312-VFE | 33F23G0542 | (01)10801902195484(10)33F23G0542(11)231107(17)261031 |
| CS-15312-VFE | 33F23L0952 | (01)10801902195484(10)33F23L0952(11)231211(17)261130 |
| CS-15312-VFE | 33F24A0925 | (01)10801902195484(10)33F24A0925(11)240212(17)270131 |
| CS-15312-VFE | 33F24C0076 | (01)10801902195484(10)33F24C0076(11)240419(17)270331 |
| CS-15312-VFE | 33F24J0053 | (01)10801902195484(10)33F24J0053(11)241126(17)271031 |
| CS-15312-VFE | 33F24M0225 | (01)10801902195484(10)33F24M0225(11)250121(17)271222 |
| CS-15312-VFE | 33F25A0033 | (01)10801902195484(10)33F25A0033(11)250220(17)280131 |
| CS-15312-VFE | 33F25C0667 | (01)10801902195484(10)33F25C0667(11)250402(17)280331 |
| CS-15312-VFE | 33F25E0320 | (01)10801902195484(10)33F25E0320(11)250516(17)280430 |
| CS-15312-VFE | 33F25E0469 | (01)10801902195484(10)33F25E0469(11)250704(17)280630 |
| CS-15312-VFE | 33F25G0603 | (01)10801902195484(10)33F25G0603(11)251113(17)280524 |
| CS-15312-VFI | 33F23G0543 | (01)10801902197778(10)33F23G0543(11)230802(17)260731 |
| CS-15312-VFI | 33F23L0953 | (01)10801902197778(10)33F23L0953(11)231206(17)261130 |
| CS-15312-VFI | 33F24D1007 | (01)10801902197778(10)33F24D1007(11)240509(17)270430 |
| CS-15312-VFI | 33F24E0810 | (01)10801902197778(10)33F24E0810(11)240804(17)270731 |
| CS-15312-VFI | 33F24J0048 | (01)10801902197778(10)33F24J0048(11)241014(17)270930 |
| CS-15312-VFI | 33F25C0039 | (01)10801902197778(10)33F25C0039(11)250318(17)280225 |
| CS-15312-VFI | 33F25D0218 | (01)10801902197778(10)33F25D0218(11)250417(17)280225 |
| CS-15312-VFI | 33F25E0470 | (01)10801902197778(10)33F25E0470(11)250716(17)280630 |
| CS-15312-VFI | 33F25J0021 | (01)10801902197778(10)33F25J0021(11)251016(17)280930 |
| CS-15312-VFIE | 33F23K0183 | (01)10801902195491(10)33F23K0183(11)231102(17)261031 |
| CS-15312-VFIE | 33F23L0954 | (01)10801902195491(10)33F23L0954(11)231206(17)261130 |
| CS-15312-VFIE | 33F24A0923 | (01)10801902195491(10)33F24A0923(11)240212(17)270131 |
| CS-15312-VFIE | 33F24D1013 | (01)10801902195491(10)33F24D1013(11)240508(17)270430 |
| CS-15312-VFIE | 33F25A0403 | (01)10801902195491(10)33F25A0403(11)250222(17)280131 |
| CS-15312-VFIE | 33F25F0534 | (01)10801902195491(10)33F25F0534(11)250707(17)280112 |
| CS-15312-VFIE | 33F25G0722 | (01)10801902195491(10)33F25G0722(11)250825(17)280731 |
| CS-15312-X | 33F23C0863 | (01)30801902195310(10)33F23C0863(11)230405(17)260331 |
| CS-15312-X | 33F23D0858 | (01)30801902195310(10)33F23D0858(11)230530(17)260430 |
| CS-15312-X | 33F23G0544 | (01)30801902195310(10)33F23G0544(11)231014(17)260930 |
| CS-15312-XM | 33F25E0442 | (01)10801902127508(10)33F25E0442(11)250523(17)280108 |
| CS-15322-I | 33F23G0545 | (01)30801902197451(10)33F23G0545(11)230904(17)260831 |
| CS-15322-SPM | 33F23D0865 | (01)30801902193538(10)33F23D0865(11)230507(17)260430 |
| CS-15322-SPM | 33F23H1010 | (01)30801902193538(10)33F23H1010(11)231005(17)260930 |
| CS-15322-SPM | 33F23L0955 | (01)30801902193538(10)33F23L0955(11)231214(17)260930 |
| CS-15322-SPM | 33F24E0812 | (01)30801902193538(10)33F24E0812(11)240715(17)270630 |
| CS-15322-SPM | 33F25C0682 | (01)30801902193538(10)33F25C0682(11)250430(17)280118 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|--------------|------------|--|
| CS-15322-SPM | 33F25E0335 | (01)30801902193538(10)33F25E0335(11)250716(17)280121 |
| CS-15322-VSP | 33F23C0869 | (01)20801902195184(10)33F23C0869(11)210526(17)260331 |
| CS-15322-VSP | 33F23D0862 | (01)20801902195184(10)33F23D0862(11)210625(17)260430 |
| CS-15322-VSP | 33F23F0723 | (01)20801902195184(10)33F23F0723(11)210825(17)260630 |
| CS-15322-VSP | 33F23H0985 | (01)20801902195184(10)33F23H0985(11)240104(17)261231 |
| CS-15322-VSP | 33F24A0272 | (01)20801902195184(10)33F24A0272(11)240212(17)270131 |
| CS-15322-VSP | 33F24C0066 | (01)20801902195184(10)33F24C0066(11)240618(17)270531 |
| CS-15322-VSP | 33F24E0813 | (01)20801902195184(10)33F24E0813(11)240722(17)270630 |
| CS-15322-VSP | 33F24G0170 | (01)20801902195184(10)33F24G0170(11)240802(17)270731 |
| CS-15322-VSP | 33F24G0185 | (01)20801902195184(10)33F24G0185(11)240802(17)270731 |
| CS-15322-VSP | 33F24H0256 | (01)20801902195184(10)33F24H0256(11)240829(17)270731 |
| CS-15322-VSP | 33F24J0040 | (01)20801902195184(10)33F24J0040(11)250122(17)271231 |
| CS-15322-VSP | 33F24L0183 | (01)20801902195184(10)33F24L0183(11)241126(17)271031 |
| CS-15322-VSP | 33F24M0222 | (01)20801902195184(10)33F24M0222(11)250204(17)280131 |
| CS-15322-VSP | 33F25A0426 | (01)20801902195184(10)33F25A0426(11)250224(17)280131 |
| CS-15322-VSP | 33F25C0022 | (01)20801902195184(10)33F25C0022(11)250311(17)271215 |
| CS-15322-VSP | 33F25C0593 | (01)20801902195184(10)33F25C0593(11)250325(17)280229 |
| CS-15322-VSP | 33F25E1082 | (01)20801902195184(10)33F25E1082(11)250721(17)280630 |
| CS-15322-VSP | 33F25G0024 | (01)20801902195184(10)33F25G0024(11)250930(17)280524 |
| CS-15322-VSP | 33F25H0297 | (01)20801902195184(10)33F25H0297(11)251105(17)280608 |
| CS-15362-SPM | 33F24G0062 | (01)20801902193548(10)33F24G0062(11)241128(17)271031 |
| CS-15362-VSP | 33F23C0875 | (01)30801902195525(10)33F23C0875(11)230504(17)260430 |
| CS-15362-VSP | 33F23G0546 | (01)30801902195525(10)33F23G0546(11)230915(17)260831 |
| CS-15362-VSP | 33F23K0195 | (01)30801902195525(10)33F23K0195(11)240213(17)270131 |
| CS-15362-VSP | 33F24E0186 | (01)30801902195525(10)33F24E0186(11)240620(17)270531 |
| CS-15362-VSP | 33F24H0039 | (01)30801902195525(10)33F24H0039(11)240823(17)270731 |
| CS-15362-VSP | 33F24L0201 | (01)30801902195525(10)33F24L0201(11)241122(17)271031 |
| CS-15362-VSP | 33F24M0235 | (01)30801902195525(10)33F24M0235(11)250129(17)271125 |
| CS-15362-VSP | 33F25C0647 | (01)30801902195525(10)33F25C0647(11)250408(17)280331 |
| CS-15362-VSP | 33F25E0326 | (01)30801902195525(10)33F25E0326(11)250526(17)280430 |
| CS-15362-VSP | 33F25G0058 | (01)30801902195525(10)33F25G0058(11)250919(17)280831 |
| CS-15362-VSP | 33F25J0043 | (01)30801902195525(10)33F25J0043(11)251107(17)280608 |
| CS-15422-SFX | 33F23K0179 | (01)30801902195327(10)33F23K0179(11)231027(17)260930 |
| CS-15422-SFX | 33F23L0956 | (01)30801902195327(10)33F23L0956(11)240111(17)261231 |
| CS-15422-SFX | 33F24A0290 | (01)30801902195327(10)33F24A0290(11)240501(17)270331 |
| CS-15422-SFX | 33F24E0814 | (01)30801902195327(10)33F24E0814(11)240612(17)270531 |
| CS-15422-VF | 33F23H1020 | (01)10801902128666(10)33F23H1020(11)230929(17)260831 |
| CS-15422-VF | 33F25G0734 | (01)10801902128666(10)33F25G0734(11)250825(17)280731 |
| CS-15422-VFE | 33F23G0548 | (01)10801902197341(10)33F23G0548(11)230802(17)260531 |
| CS-15422-VFE | 33F23H0986 | (01)10801902197341(10)33F23H0986(11)230905(17)260831 |
| CS-15422-VFE | 33F23L0957 | (01)10801902197341(10)33F23L0957(11)231206(17)261130 |
| CS-15422-VFE | 33F24A0929 | (01)10801902197341(10)33F24A0929(11)240201(17)270131 |
| CS-15422-VFE | 33F24J0483 | (01)10801902197341(10)33F24J0483(11)241205(17)271130 |
| CS-15422-VFE | 33F24M0229 | (01)10801902197341(10)33F24M0229(11)250120(17)271231 |
| CS-15422-VFE | 33F25C0681 | (01)10801902197341(10)33F25C0681(11)250417(17)280225 |
| CS-15422-VFE | 33F25E0440 | (01)10801902197341(10)33F25E0440(11)250523(17)280430 |
| CS-15422-VFE | 33F25F0250 | (01)10801902197341(10)33F25F0250(11)250709(17)270731 |
| CS-15422-VFE | 33F25G0484 | (01)10801902197341(10)33F25G0484(11)250825(17)280731 |
| CS-15422-VFI | 33F23G0549 | (01)10801902193664(10)33F23G0549(11)230802(17)260731 |
| CS-15422-VFI | 33F24E0815 | (01)10801902193664(10)33F24E0815(11)240621(17)270531 |
| CS-15422-VFI | 33F25E1074 | (01)10801902193664(10)33F25E1074(11)250825(17)280420 |

Dodatek 2: EIF-000605 - Koda izdelka, številka serije, informacije o edinstvenem identifikatorju pripomočka (UDI)

| Koda izdelka | Serija | UDI# |
|---------------|------------|--|
| CS-15422-VFIE | 33F23G0550 | (01)10801902197440(10)33F23G0550(11)230905(17)260831 |
| CS-15422-VFIE | 33F23K0178 | (01)10801902197440(10)33F23K0178(11)231108(17)261031 |
| CS-15422-VFIE | 33F23L0958 | (01)10801902197440(10)33F23L0958(11)231209(17)261130 |
| CS-15422-VFIE | 33F24A0919 | (01)10801902197440(10)33F24A0919(11)240207(17)270131 |
| CS-15422-VFIE | 33F24C0073 | (01)10801902197440(10)33F24C0073(11)240501(17)270430 |
| CS-15422-VFIE | 33F24E0816 | (01)10801902197440(10)33F24E0816(11)241003(17)270930 |
| CS-15422-VFIE | 33F25F0303 | (01)10801902197440(10)33F25F0303(11)250825(17)280731 |
| CS-15502-SFX | 33F23L0959 | (01)30801902195563(10)33F23L0959(11)240110(17)261231 |
| CS-15502-SFX | 33F24A0286 | (01)30801902195563(10)33F24A0286(11)240502(17)270430 |
| CS-15502-SFX | 33F24J0060 | (01)30801902195563(10)33F24J0060(11)241011(17)270930 |
| CS-15552-VF | 33F23H1012 | (01)10801902128703(10)33F23H1012(11)230928(17)260831 |
| CS-15552-VF | 33F25C0674 | (01)10801902128703(10)33F25C0674(11)250404(17)280331 |
| CS-15552-VF | 33F25J0588 | (01)10801902128703(10)33F25J0588(11)251029(17)280930 |
| CS-15552-VFE | 33F23D0868 | (01)10801902195156(10)33F23D0868(11)230529(17)260430 |
| CS-15552-VFE | 33F23G0261 | (01)10801902195156(10)33F23G0261(11)230719(17)260630 |
| CS-15552-VFE | 33F23G0551 | (01)10801902195156(10)33F23G0551(11)230905(17)260831 |
| CS-15552-VFE | 33F23K0173 | (01)10801902195156(10)33F23K0173(11)231018(17)260930 |
| CS-15552-VFE | 33F24A0928 | (01)10801902195156(10)33F24A0928(11)240129(17)261231 |
| CS-15552-VFE | 33F24D1014 | (01)10801902195156(10)33F24D1014(11)240607(17)270531 |
| CS-15552-VFE | 33F24E0818 | (01)10801902195156(10)33F24E0818(11)240611(17)270531 |
| CS-15552-VFE | 33F24J0059 | (01)10801902195156(10)33F24J0059(11)241004(17)270930 |
| CS-15552-VFE | 33F24K0511 | (01)10801902195156(10)33F24K0511(11)241129(17)271031 |
| CS-15552-VFE | 33F25C0670 | (01)10801902195156(10)33F25C0670(11)250401(17)280331 |
| CS-15552-VFE | 33F25E0471 | (01)10801902195156(10)33F25E0471(11)250620(17)280531 |
| CS-15552-VFE | 33F25F0455 | (01)10801902195156(10)33F25F0455(11)250707(17)280510 |
| CS-15552-VFE | 33F25G0447 | (01)10801902195156(10)33F25G0447(11)250825(17)280731 |
| CS-15552-VFI | 33F23K0184 | (01)10801902193671(10)33F23K0184(11)231109(17)261031 |
| CS-15552-VFI | 33F24J0076 | (01)10801902193671(10)33F24J0076(11)241205(17)271130 |
| CS-15552-VFI | 33F25E1075 | (01)10801902193671(10)33F25E1075(11)250704(17)280630 |
| CS-15552-VFIE | 33F23E0865 | (01)10801902195163(10)33F23E0865(11)230606(17)260531 |
| CS-15552-VFIE | 33F23F0743 | (01)10801902195163(10)33F23F0743(11)230710(17)260630 |
| CS-15552-VFIE | 33F24D0972 | (01)10801902195163(10)33F24D0972(11)240501(17)270430 |
| CS-15552-VFIE | 33F24E0819 | (01)10801902195163(10)33F24E0819(11)240718(17)270630 |
| CS-15552-VFIE | 33F24G0098 | (01)10801902195163(10)33F24G0098(11)241025(17)270902 |
| CS-15552-VFIE | 33F24K0656 | (01)10801902195163(10)33F24K0656(11)241206(17)271130 |
| CS-15552-VFIE | 33F25A0032 | (01)10801902195163(10)33F25A0032(11)250228(17)280131 |
| CS-15552-VSP | 33F23G0552 | (01)30801902195198(10)33F23G0552(11)230802(17)260731 |
| CS-15552-VSP | 33F23H0987 | (01)30801902195198(10)33F23H0987(11)230906(17)260831 |
| CS-15552-VSP | 33F23L0961 | (01)30801902195198(10)33F23L0961(11)240103(17)261130 |
| CS-15552-VSP | 33F24C0070 | (01)30801902195198(10)33F24C0070(11)220625(17)270430 |
| CS-15552-VSP | 33F24E0820 | (01)30801902195198(10)33F24E0820(11)240801(17)270731 |
| CS-15552-VSP | 33F24H0257 | (01)30801902195198(10)33F24H0257(11)240824(17)270731 |
| CS-15552-VSP | 33F24L0068 | (01)30801902195198(10)33F24L0068(11)250220(17)280131 |
| CS-15552-VSP | 33F24M0227 | (01)30801902195198(10)33F24M0227(11)250124(17)271125 |
| CS-15552-VSP | 33F25C0654 | (01)30801902195198(10)33F25C0654(11)250422(17)280225 |
| CS-15552-VSP | 33F25E0432 | (01)30801902195198(10)33F25E0432(11)250519(17)280430 |
| CSD-15242-SP | 33F24A0303 | (01)20801902096610(10)33F24A0303(11)240411(17)270331 |
| CSD-15242-SP | 33F25C0688 | (01)20801902096610(10)33F25C0688(11)250423(17)280225 |
| CSD-15282-SP | 33F23K1087 | (01)20801902096634(10)33F23K1087(11)240114(17)261231 |
| CSD-15282-SP | 33F24A0297 | (01)20801902096634(10)33F24A0297(11)240116(17)261231 |

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: 16F Dual-Valved Splittable Sheath Introducer

Action Required: Destroy at the point of use

Merit Medical Systems, Inc. (Merit) is conducting a voluntary recall of the Merit 16F Dual-Valved Splittable Sheath Introducer due to a design defect. Specifically, the sheath introducer may not split as intended. This sheath introducer is used in several Merit finished devices, a complete list of affected products and lots can be found in the table attached or can be accessed at "<https://www.merit.com/products/documents/product-notices/16FDualValvedSheath-recall/>".

Merit has received customer complaints regarding this issue, some of which involve patient injury. Failure of the sheath introducer to split as intended may result in hemorrhage, foreign bodies, and procedure delay.

Merit is requesting you to immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at point of use. The other products included with the sheath introducer may continue to be used.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
2. A picture of the 16F Dual-Valved Splittable Sheath Introducer is attached to help you identify the product. Please place this notice and the picture on or near the affected Merit product in your inventory (if applicable).



3. Please immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at the point of use.
4. Ensure that applicable personnel within your organization are made aware of this field action.
5. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities.
6. Please fill out, scan and email the completed Customer Response Form to Customer Service at [REDACTED] within 10 business days. All affected product shipped to you must be accounted for on the CRF.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.



Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Enclosure(s)

Affected Lots Table
(16F Dual-Valved Splittable Sheath Introducer)

| Catalog Code | Lot Number |
|--------------|------------|
| CENFP15K/A | H3357122 |
| CENFP15K/B | H2797565 |
| CENFP17K/A | H2643728 |
| | H2644554 |
| | H2755843 |
| | H2777866 |
| | H3357123 |
| CENFP19K/A | H2415318 |
| | H2466455 |
| | H2466456 |
| | H2608337 |
| | H2632772 |
| | H2632921 |
| | H2643525 |
| | H2643729 |
| | H2658246 |
| | H2658395 |
| | H2663614 |
| | H2708827 |
| | H2777850 |
| | H2817064 |
| | H2817066 |
| | H2834183 |
| | H2834184 |
| | H2835774 |
| | H2875195 |
| | H2892153 |
| | H2900496 |
| | H2900649 |
| | H2918430 |
| | H2938756 |
| | H2982068 |
| | H2998532 |
| | H3019164 |
| | H3028009 |
| | H3089474 |
| | H3096774 |
| | H3101839 |
| | H3110067 |
| | H3123035 |
| H3131873 | |
| H3139507 | |
| H3143969 | |
| H3152236 | |
| H3328470 | |
| H3332131 | |
| H3332133 | |
| H3357124 | |
| H3383280 | |
| H3398546 | |
| CENFP23K/A | H2368055 |
| | H2460265 |
| | H2543292 |
| | H2612929 |

| Catalog Code | Lot Number |
|--------------|------------|
| DC21453227/C | H2630602 |
| DC21454035/C | H2628887 |
| DC21455550/C | H2630553 |
| | H2659229 |
| FCL-174-00/B | I2362705 |
| | I2370091 |
| | I2370711 |
| | I2370712 |
| | I2377840 |
| | I2377841 |
| | I2391548 |
| | I2397290 |
| | I2415120 |
| | I2417400 |
| | I2417401 |
| | I2417402 |
| | I2428656 |
| | I2428657 |
| | I2428658 |
| | I2428659 |
| | I2469204 |
| | I2469205 |
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| | I2469207 |
| | I2473119 |
| | I2485668 |
| | I2485669 |
| | I2485670 |
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| | I2485675 |
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| | I2496790 |
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| I2516613 | |
| I2516614 | |
| I2516615 | |
| I2539710 | |
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| I2539715 | |
| I2539717 | |
| I2561078 | |
| I2561079 | |
| I2561081 | |
| I2561082 | |
| I2573969 | |
| I2606642 | |

| Catalog Code | Lot Number |
|------------------|------------|
| H965103028031/A | I3120008 |
| | I3156395 |
| | I3161825 |
| | I3178917 |
| | I3202927 |
| | I3236144 |
| | I3236147 |
| | I3236157 |
| | I3236162 |
| | I3236164 |
| I3368281 | |
| H965103028031/EU | I3219447 |
| | I3270828 |
| H965103028041/A | I3288591 |
| | I2838431 |
| | I2910263 |
| | I2910264 |
| | I2910265 |
| | I2973186 |
| | I2975804 |
| | I2975805 |
| | I2979959 |
| | I2979960 |
| | I3015758 |
| | I3064923 |
| | I3064925 |
| | I3072563 |
| | I3108163 |
| | I3120003 |
| | I3120006 |
| I3156399 | |
| I3165147 | |
| I3175748 | |
| I3178899 | |
| I3208677 | |
| I3236145 | |
| I3236148 | |
| I3236158 | |
| I3236163 | |
| I3236165 | |
| I3312321 | |
| I3315961 | |
| I3323271 | |
| I3347039 | |
| H965103028041/EU | I3217180 |
| | I3270829 |
| H965103028051/A | I3302439 |
| | I2929337 |
| H965103028051/EU | I2997999 |
| | I3311219 |
| H965103028061/A | I3219448 |
| | I3270832 |
| | I3302440 |
| | I2920321 |

Affected Lots Table
(16F Dual-Valved Splittable Sheath Introducer)

| Catalog Code | Lot Number |
|-------------------|------------|
| CENFP23K/A | H2622368 |
| | H2623456 |
| | H2631340 |
| | H2640771 |
| | H2663612 |
| | H2663613 |
| | H2719753 |
| | H2812164 |
| | H2817069 |
| | H2834179 |
| | H2834181 |
| | H2847016 |
| | H2868174 |
| | H2880283 |
| | H2897527 |
| | H2900497 |
| | H2900550 |
| | H2907334 |
| | H2911460 |
| | H2938761 |
| | H2978595 |
| | H2990699 |
| | H3004608 |
| | H3019163 |
| | H3049760 |
| | H3049761 |
| | H3052479 |
| | H3071291 |
| | H3075039 |
| | H3089475 |
| | H3092914 |
| | H3096777 |
| | H3104588 |
| | H3107507 |
| | H3120779 |
| | H3131874 |
| | H3143970 |
| | H3145117 |
| | H3191613 |
| | H3211721 |
| H3316467 | |
| H3328494 | |
| H3332218 | |
| H3332219 | |
| H3332220 | |
| H3351695 | |
| CENFP27K/A | H2286892 |
| | H2480924 |
| | H2623453 |
| | H2643731 |
| | H2643732 |
| | H2653626 |
| | H2663616 |
| | H2777861 |

| Catalog Code | Lot Number |
|---------------------|------------|
| FCL-174-00/B | I2606643 |
| | I2606644 |
| | I2606645 |
| | I2619459 |
| | I2621646 |
| | I2621647 |
| | I2621648 |
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| I2759261 | |
| I2759268 | |

| Catalog Code | Lot Number |
|-------------------------|------------|
| H965103028061/A | I2980492 |
| | I3154945 |
| H965103028061/EU | I3254911 |
| | I3196140 |
| H965103028070/A | I3270833 |
| | I3312332 |
| | I3015819 |
| H965103028070/EU | I3113237 |
| | I3170179 |
| | I3247943 |
| H965103028080/A | I3288616 |
| | I3255305 |
| H965103028080/EU | I3307483 |
| | I3002021 |
| | I3064921 |
| H965103028090/A | I3178919 |
| | I3302450 |
| | I3343031 |
| H965103028090/EU | I3196137 |
| | I3302445 |
| H965103028090/A | I3334625 |
| | I2920165 |
| | I3103138 |
| H965103028090/EU | I3178922 |
| | I3290565 |
| H965103028161/A | I3196135 |
| | I3302441 |
| H965103028181/A | I3352493 |
| | I2914680 |
| | I2980457 |
| | I3098578 |
| | I2890978 |
| | I2902665 |
| | I2909617 |
| | I2909618 |
| | I2929338 |
| | I3076856 |
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| | I3098579 |
| | I3178915 |
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| I3255301 | |
| I3283028 | |
| H965103028191/A | H2936911 |
| | I2870746 |
| | I2908636 |
| | I2909637 |
| | I2910257 |
| | I2920337 |
| | I2927199 |
| | I3144031 |
| I3164176 | |
| I3219662 | |
| I3236146 | |

Affected Lots Table
(16F Dual-Valved Splittable Sheath Introducer)

| Catalog Code | Lot Number |
|-------------------|-----------------|
| | H2798003 |
| CENFP27K/A | H2833668 |
| | H2834185 |
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| | H2900619 |
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| | H2911565 |
| | H2978601 |
| | H2986646 |
| | H2998508 |
| | H3004606 |
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| | H3019148 |
| | H3096779 |
| | H3110068 |
| | H3131879 |
| | H3143988 |
| | H3145119 |
| | H3156431 |
| | H3357125 |
| H3383281 | |
| CENFP31K/A | H2623455 |
| | H2643737 |
| | H2663617 |
| | H3052480 |
| | H3071293 |
| | H3071294 |
| | H3110069 |
| | H3113265 |
| | H3143998 |
| | H3196708 |
| | H3328496 |
| | H3332421 |
| | CENFT15K |
| H2907340 | |
| H2911505 | |
| H2978606 | |
| H3004602 | |
| CENFT15K/D | H3071303 |
| | H3075046 |
| | H3116838 |
| CENFT17K | H2750962 |
| | H2755782 |
| | H2777600 |
| | H3034899 |
| | H3059017 |
| | H3059018 |
| H3062346 | |
| CENFT17K/A | H2911456 |
| CENFT17K/D | H3139508 |
| CENFT19K | H2632775 |
| | H2658397 |
| | H2709212 |

| Catalog Code | Lot Number |
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| FCL-174-00/B | I2781492 |
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| I2942571 | |

| Catalog Code | Lot Number |
|-------------------------|------------|
| | I3288655 |
| H965103028191/A | I3368110 |
| H965103028191/EU | I3309111 |
| H965103028201/A | I2973187 |
| | I3173621 |
| | I3178898 |
| | I3236149 |
| | I3288573 |
| H965103028211/A | I2909764 |
| | I3144033 |
| | I3302435 |
| | I3343037 |
| H965103028220/A | I2909788 |
| | I3394016 |
| H965103028230/A | I2982337 |
| | I3044847 |
| | I3191920 |
| | I3288574 |
| | I3334623 |
| H965103028240/A | I2929339 |
| | I3002035 |
| | I3049565 |
| | I3108165 |
| | I3254923 |
| | I3302451 |
| H965103038181/A | I2890952 |
| | I2902661 |
| | I2902662 |
| K12-03886DP | H3138928 |
| H787103028235/A | I3178905 |
| H965103028011/A | I3105589 |
| | I3115469 |
| | I3314948 |
| | I3343030 |
| H965103028021/A | I2985084 |
| | I3235297 |
| | I3302100 |
| | I3343023 |
| H965103028021/EU | I3254932 |
| H965103028031/A | I2890967 |
| | I2909607 |
| | I2909610 |
| | I2909613 |
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| | I2928443 |
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| | I2973185 |
| | I2975817 |
| | I2979931 |
| | I2979932 |
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| | I3015730 |
| I3015731 | |
| I3072562 | |

Affected Lots Table
(16F Dual-Valved Splittable Sheath Introducer)

| Catalog Code | Lot Number |
|--------------|------------|
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| | H2864393S1 |
| | H2884659 |
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| | H2907322 |
| | H2907349 |
| | H2918517 |
| | H2933863 |
| | H2937909 |
| | H2937910 |
| | H2978622 |
| | H2999167 |
| | H3019145 |
| | H3034898 |
| | H3049764 |
| CENFT19K/A | H2907422 |
| CENFT19K/B | H2801414 |
| CENFT19K/D | H3049766 |
| | H3049767 |
| | H3071304 |
| | H3075050 |
| | H3089478 |
| | H3126999 |
| | H3144001 |
| | H3152238 |
| | H3156433 |
| | H3162590 |
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| | H3233980 |
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| | H3253651 |
| | H3261220 |
| | H3283451 |
| | H3306069 |
| | H3350849 |
| | H3357127 |
| | H3357128 |
| | H3365884 |
| | H3372112 |
| H3398547 | |
| CENFT23K | H2368107 |
| | H2657097 |
| | H2709213 |
| | H2719652 |
| | H2783586 |
| | H2812165 |
| | H2834187 |
| | H2834188 |
| H2864382S1 | |

| Catalog Code | Lot Number |
|-----------------|------------|
| | I2942667 |
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| FCL-174-00/B | I2988895 |
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| | I2988897 |
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| | I3159777 |
| I3186218 | |
| I3257331 | |
| H787103028015/A | I3049562 |
| H787103028025/A | I3309371 |
| H787103028031/A | I2929299 |
| | I3072553 |
| | I3154760 |
| | I3175731 |
| | I3178921 |
| | I3315957 |
| H787103028035/A | I2910259 |
| | I2910261 |
| | I2910262 |
| | I2980545 |
| | I2995795 |
| | I3021388 |
| | I3076851 |
| | I3085062 |
| | I3219446 |
| | I3219454 |
| I3255314 | |
| | I3288649 |
| | I3334618 |

| Catalog Code | Lot Number |
|--------------|------------|
| | I3108161 |
| | I3115487 |

Affected Lots Table
(16F Dual-Valved Splittable Sheath Introducer)

| Catalog Code | Lot Number |
|-------------------|-------------------|
| | H2870049 |
| | H2892155 |
| | H2898665 |
| CENFT23K | H2900501 |
| | H2907365 |
| | H2911451 |
| | H2911452 |
| | H2934395 |
| | H2971862 |
| | H2986161 |
| | H2986162 |
| | H2998549 |
| | H3007025 |
| | H3019139 |
| | H3028000 |
| | CENFT23K/A |
| H2817068 | |
| H2911454 | |
| H2990794 | |
| H3013830 | |
| H3019136 | |
| H3034895 | |
| CENFT23K/B | H2801413 |
| CENFT23K/D | H3049771 |
| | H3049772 |
| | H3071305 |
| | H3071306 |
| | H3145122 |
| | H3152240 |
| | H3170518 |
| | H3196713 |
| | H3201956 |
| | H3211729 |
| | H3221345 |
| | H3233987 |
| | H3239915 |
| | H3249275 |
| | H3275167 |
| | H3301761 |
| | H3306072 |
| | H3323733 |
| | H3332225 |
| | H3342600 |
| CENFT27K | H2618709 |
| | H2642807 |
| | H2783590 |
| | H2817065 |
| | H2835374 |
| | H2884649 |
| | H2892156 |
| | H2900227 |
| | H2910433 |
| | H2937927 |
| | H2949972 |

| Catalog Code | Lot Number |
|------------------------|------------------------|
| H787103028041/A | I2909647 |
| | I3115465 |
| | I3178909 |
| | I3236154 |
| H787103028045/A | I3004072 |
| | I3015761 |
| | I3044845 |
| | I3072554 |
| | I3108153 |
| | I3176646 |
| | I3178918 |
| | I3213147 |
| | I3219456 |
| | I3281054 |
| | I3334627 |
| | H787103028051/A |
| I3072556 | |
| I3213145 | |
| I3219455 | |
| I3288560 | |
| I3302443 | |
| H787103028055/A | I3178903 |
| H787103028061/A | I2929300 |
| | I2995814 |
| | I3072557 |
| | I3165105 |
| | I3207168 |
| | I3236155 |
| | I3334619 |
| H787103028075/A | I2995817 |
| | I3209313 |
| | I3270826 |
| H787103028085/A | I2890956 |
| | I3072561 |
| | I3108155 |
| | I3288562 |
| | I3302444 |
| H787103028095/A | I2909667 |
| | I2929315 |
| | I3021151 |
| | I3098576 |
| | I3219463 |
| | I3288581 |
| H787103028165/A | I3049563 |
| H787103028181/A | I2929317 |
| | I3178900 |
| | I3208675 |
| H787103028185/A | I2927170 |
| | I2929318 |
| | I2929319 |
| | I3002050 |
| | I3015762 |
| | I3021450 |
| | I3049572 |

| Catalog Code | Lot Number |
|--------------|------------|
|--------------|------------|

Affected Lots Table
(16F Dual-Valved Splittable Sheath Introducer)

| Catalog Code | Lot Number |
|--------------------|------------|
| | H2971939 |
| | H3019133 |
| | H3027993 |
| | H3059051 |
| CENFT27K | H3062349 |
| | H3071308 |
| CENFT27K/A | H2831335 |
| | H2847031 |
| | H2911463 |
| | H3019129 |
| CENFT27K/B | H2801412 |
| CENFT27K/D | H3049776 |
| | H3049777 |
| | H3080509 |
| | H3152241 |
| | H3179811 |
| | H3186110 |
| | H3191615 |
| | H3201954 |
| | H3206164 |
| | H3301764 |
| | H3323734 |
| | H3342755 |
| | H3372113 |
| | H3385315 |
| CENFT31K | H2821396 |
| | H2884650 |
| | H2900615 |
| | H2911536 |
| | H2933865 |
| | H2971861 |
| | H3003224 |
| | H3059059 |
| | H3059060 |
| | H3089477 |
| | H3101838 |
| CENFT31K/A | H2938653 |
| | H3013843 |
| CENFT31K/B | H2811536 |
| CENFT31K/D | H3071085 |
| | H3071309 |
| | H3082414 |
| | H3144317 |
| | H3163092 |
| | H3179823 |
| | H3191620 |
| | H3206153 |
| | H3239916 |
| | H3249277 |
| | H3275168 |
| | H3283445 |
| | H3306075 |
| | H3323741 |
| DC0145550/C | H2600169 |

| Catalog Code | Lot Number |
|-------------------------|------------|
| | I3085060 |
| | I3173615 |
| | I3178896 |
| | I3195157 |
| H787103028185/A | I3288651 |
| | I3334629 |
| H787103028191/A | I2909758 |
| H787103028195/A | I2890957 |
| | I2929321 |
| | I3021395 |
| | I3049573 |
| | I3076853 |
| | I3124837 |
| | I3169030 |
| | I3213148 |
| | I3236141 |
| | I3236161 |
| | I3302447 |
| | I3343042 |
| H787103028205/A | I2927146 |
| | I2995766 |
| | I3015801 |
| | I3044846 |
| | I3144026 |
| | I3219464 |
| | I3288564 |
| | I3302448 |
| H787103028215/A | I3178904 |
| H787103028225/A | I3044836 |
| | I3108157 |
| | I3236142 |
| | I3315958 |
| DC21452419/C | H2659228 |
| DC21452419-NE5/C | H3249278 |
| DC21452823/C | H2600164 |
| | H2628890 |
| DC21452823-NE5/C | H2990807 |

| Catalog Code | Lot Number |
|--------------|------------|
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