

**HITNO: OBAVIJEST O SIGURNOSTI UPORABE PROIZVODA (povlačenje)**

**Specifične šifre proizvoda i serije:**

- **mikrokirurških rukavica od lateksa Protexis tvrtke Cardinal Health™**

**Događaj-2020-03063**

29. srpnja 2020.

**Na pažnju: voditelju upravljanja rizikom i odjelu za upravljanje materijalima u operacijskoj dvorani**

Poštovani kupci,

ovim dopisom vas obavještavamo da tvrtka Cardinal Health dobrovoljno opoziva specifične proizvodne serije **mikrokirurških rukavica od lateksa PROTEXIS™ tvrtke Cardinal Health™** isporučene u razdoblju između lipnja 2019. i srpnja 2020. godine.

**Opis problema**

Ovaj opoziv provodi se zbog nedostatka u obliku degradacije pronađenog na **mikrokirurškim rukavicama od lateksa PROTEXIS™ tvrtke Cardinal Health™**, koji tijekom nanošenja može dovesti do stvaranja rupa i poderotina na području presavijanja oko manšeta (za primjere nedostataka pogledajte prilog B). Tvrtka Cardinal Health nije upoznata ni s jednim izvještajem o štetnim posljedicama za pacijente.

Tvrtka Cardinal Health pokreće ovaj dobrovoljni opoziv za sljedeće šifre proizvoda i brojeve serija:

Šifra proizvoda	Opis proizvoda	Br. serije
2D72NT55X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 5,5	TS19060034, TS19060253, TS19060338, TS19070077, TS19070176, TS19070246, TS19070318, TS19080036, TS19080091, TS19080137, TS19090125, TS19090164, TS19090248, TS19100272, TS19110080, TS19110205, TS19110313, TS19120119, TS19120120, TS20010146, TS20010214, TS20020201, TS20020202, TS20030154, TS20030155, TS20030279, TS20040092, TS20040093, TS20040248
2D72NT60X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 6,0	TS19060010, TS19060043, TS19060123, TS19060199, TS19060234, TS19070005, TS19070027, TS19070067, TS19070130, TS19070179, TS19070245, TS19070273, TS19080030, TS19080092, TS19080119, TS19080124, TS19080208, TS19080211, TS19080300, TS19080329, TS19090067, TS19090158, TS19090226, TS19090289, TS19100051, TS19100085, TS19100172, TS19100240, TS19100300, TS19110022, TS19110079, TS19110184, TS19110207, TS19110333, TS19120019, TS19120083, TS19120213, TS19120322, TS20010037, TS20010094, TS20010191, TS20010202, TS20010258, TS20010329, TS20020121, TS20020209, TS20030015, TS20030092, TS20030093, TS20030172, TS20030264, TS20030265, TS20030324, TS20040033, TS20040137



# CardinalHealth

Sifra proizvoda	Opis proizvoda	Br. serije
2D72NT65X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 6,5	TS19060012, TS19060037, TS19060064, TS19060118, TS19060140, TS19060158, TS19060235, TS19060257, TS19060303, TS19060340, TS19060393, TS19070019, TS19070068, TS19070084, TS19070138, TS19070185, TS19070231, TS19070247, TS19070297, TS19070317, TS19080022, TS19080040, TS19080051, TS19080093, TS19080110, TS19080128, TS19080134, TS19080209, TS19080239, TS19080258, TS19080269, TS19080326, TS19090044, TS19090058, TS19090104, TS19090200, TS19090212, TS19090262, TS19090295, TS19100043, TS19100099, TS19100138, TS19100173, TS19100221, TS19100280, TS19100310, TS19110023, TS19110058, TS19110076, TS19110083, TS19110150, TS19110211, TS19110349, TS19120020, TS19120073, TS19120084, TS19120233, TS19120323, TS20010017, TS20010048, TS20010072, TS20010109, TS20010166, TS20010193, TS20010265, TS20010306, TS20020024, TS20020098, TS20020108, TS20020149, TS20020247, TS20020248, TS20020262, TS20030066, TS20030078, TS20030179, TS20030191, TS20030219, TS20030220, TS20030318, TS20030325, TS20040039, TS20040116, TS20040175, TS20040259
2D72NT70X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 7,0	TS19060002, TS19060036, TS19060115, TS19060216, TS19060238, TS19060258, TS19060274, TS19060339, TS19070029, TS19070092, TS19070108, TS19070180, TS19070285, TS19070320, TS19080035, TS19080037, TS19080064, TS19080138, TS19080140, TS19080186, TS19080210, TS19080257, TS19080271, TS19080320, TS19090004, TS19090054, TS19090126, TS19090149, TS19090263, TS19090266, TS19100058, TS19100107, TS19100186, TS19100253, TS19100308, TS19110026, TS19110038, TS19110068, TS19110090, TS19110157, TS19110225, TS19110324, TS19120005, TS19120056, TS19120109, TS19120141, TS19120161, TS19120162, TS19120257, TS19120258, TS19120299, TS20010002, TS20010051, TS20010085, TS20010129, TS20010184, TS20010246, TS20010247, TS20010305, TS20020074, TS20020075, TS20020140, TS20020146, TS20020223, TS20020227, TS20020284, TS20030094, TS20030165, TS20030166, TS20030227, TS20030228, TS20030299, TS20040045, TS20040046, TS20040130, TS20040197, TS20040139, TS20040367, TS20050112, TS20050158
2D72NT75X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 7,5	TS19060031, TS19060065, TS19060081, TS19060129, TS19060168, TS19060302, TS19070161, TS19070201, TS19070229, TS19080080, TS19080176, TS19080203, TS19080262, TS19090027, TS19090064, TS19090167, TS19090272, TS19100068, TS19100111, TS19100197, TS19100244, TS19100262, TS19110041, TS19110102, TS19110176, TS19110238, TS19110314, TS19120002, TS19120044, TS19120093, TS19120166, TS19120274, TS19120275, TS19120298, TS20010009, TS20010064, TS20010070, TS20010155, TS20010217, TS20010255, TS20010315, TS20020092, TS20020115, TS20020161, TS20020162, TS20020236, TS20020237, TS20020286, TS20030110, TS20030111, TS20030192, TS20030215, TS20030240, TS20030288, TS20040029, TS20040030, TS20040086, TS20040147, TS20050114, TS20050115
2D72NT80X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 8,0	TS19060053, TS19060095, TS19060169, TS19060273, TS19060328, TS19060357, TS19070100, TS19080183, TS19080200, TS19080225, TS19080308, TS19090043, TS19090188, TS19090292, TS19100150, TS19100214, TS19100269, TS19100282, TS19110056, TS19110050, TS19110115, TS19110249, TS19110295, TS19110334, TS19120049, TS19120122, TS19120215, TS19120308, TS19120309, TS20010031, TS20010103, TS20050122, TS20050165
2D72NT85X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 8,5	TS19060044, TS19060122, TS19060189, TS19060356, TS19080111, TS19080184, TS19080227, TS19080321, TS19090008, TS19090127, TS19100079, TS19100220, TS19100271, TS19100309, TS19110075, TS19110069, TS19110109, TS19110148, TS19110285, TS19110331, TS19120038, TS19120118, TS19120214, TS19120316, TS19120317, TS20010036, TS20010093, TS20050031, TS20050139
2D72NT90X	Mikrokirurške rukavice od lateksa PROTEXIS™ veličine 9,0	TS19080275, TS19090162, TS19090231, TS19110286, TS19120251, TS20010216, TS20030153

Ova korektivna radnja povezana sa sigurnosti uporabe proizvoda odnosi se samo na specifične kombinacije gore navedenih šifri i serija proizvoda. Mjerodavne regulatorne agencije obaviještene su da tvrtka Cardinal Health dobrovoljno poduzima ovu radnju. U slučaju problema s kvalitetom ili pojave štetnih događaja, obratite se svom lokalnom predstavniku tvrtke Cardinal Health.



# CardinalHealth

## Potrebne radnje:

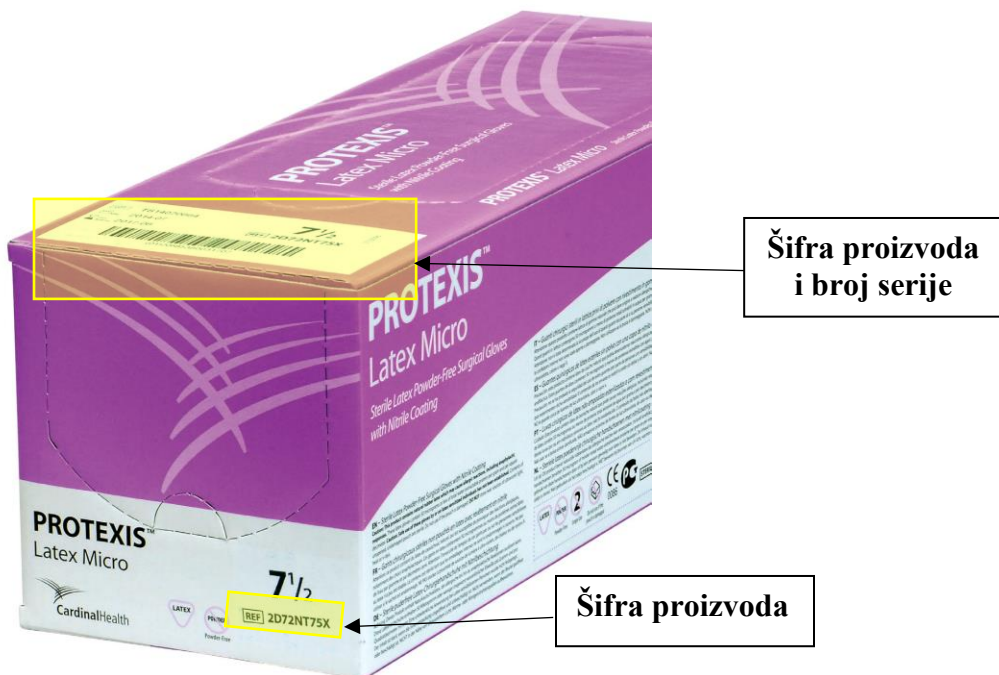
1. **PROVJERITE** sve lokacije skladištenja i uporabe kako biste potvrdili imate li jedinice sa zahvaćenim šiframa proizvoda i brojevima serija. U prilogu A prikazani su primjeri oznaka proizvoda i način identifikacije zahvaćenog proizvoda. U prilogu B označena je lokacija nedostatka.
2. Pregledajte, ispunite, potpišite i vratite priloženu Potvrdu primitka u skladu s uputama u obrascu.
3. Vratite sve zahvaćene proizvode ili se obratite svom lokalnom prodajnom predstavniku koji će vam olakšati povrat zahvaćenog proizvoda. Vaš prodajni predstavnik obavijestit će vas o mogućnostima zamjene proizvoda ili povrata.
4. Ovaj dopis podijelite s drugim osobama u svojoj ustanovi koje trebaju biti upoznate s ovim opozivom. Kontaktirajte sve druge ustanove kojima ste isporučili jedinice zahvaćene serije.
5. Ovu obavijest imajte na umu dok se svi zahvaćeni proizvodi ne vrate tvrtki Cardinal Health.
6. Kopiju ove obavijesti čuvajte sa svakim zahvaćenim proizvodom dok se on ne vrati.

Ispričavamo se zbog ove neugodnosti. U slučaju pitanja ili nedoumica obratite se svom lokalnom prodajnom predstavniku ili lokalnom prodajnom uredu.

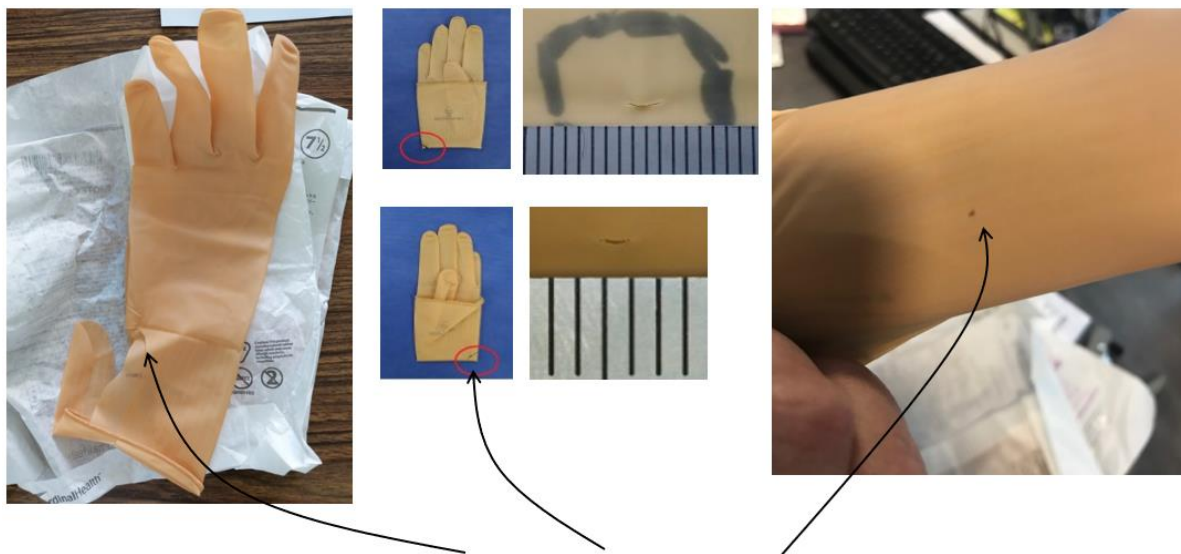
Srdačan pozdrav,

Karl Vahey  
Zamjenik predsjednika, odjel za osiguranje kvalitete proizvodnje

**Prilog A – Pakiranje zahvaćenog proizvoda**



**Prilog B – Primjeri nedostataka**



Nedostatak u obliku degradacije pronađen na manšeti (području presavijanja).