

## Hitna sigurnosna obavijest

### Ažuriranje uputa za upotrebu: Novi koraci postupka i upozorenja

#### Perkutane antene Covidien Emprint™ s tehnologijom Thermosphere™

Travanj 2019.

Medtronicova referencija: FA781 – ažuriranje Uputa za upotrebu (IFU)

Poštovani,

ovim vas dopisom želimo obavijestiti o ažuriranju naše obavijesti iz kolovoza 2017. u vezi s **perkutanim antenama Covidien Emprint™ s tehnologijom Thermosphere™** tvrtke Medtronic.

#### Razlog za ovu obavijest

Tvrtka Medtronic će ažurirati Upute za upotrebu (IFU) za perkutane antene Emprint™ s tehnologijom Thermosphere™ kako bi uključile važne informacije utvrđene tijekom naše istrage o odvojenim vrhovima antena. Odvajanje tijekom postupka može dovesti do zadržavanja stranog tijela, što dovodi do rizika od infekcije. Prijavljeni postotak odvojenih vrhova manji je od 0,05 %. Ažuriranja Uputa za upotrebu uključuju važne proceduralne korake i revidirana upozorenja radi smanjenja mogućnosti odvajanja vrha antene.

#### Radnje koje je poduzela tvrtka Medtronic

U tijeku je ažuriranje Uputa za upotrebu za proizvode navedene u nastavku.

Šifra proizvoda			Naziv proizvoda
CA15L1	CA20L1	CA30L1	Perkutane antene Emprint™ s tehnologijom Thermosphere™
CA15L2	CA20L2	CA30L2	Perkutana antena Emprint™ SX Navigation s tehnologijom Thermosphere™
CA15L2N	CA20L2N	CA30L2N	Perkutana antena Emprint™ SX Navigation s tehnologijom Thermosphere™

#### Ažuriranja Uputa za upotrebu su sljedeća:

Nakon koraka 3 ažuriranje je:

#### Upozorenje

*Ako upotrebljavate pomoći proizvod kao pomoć pri umetanju antene (primjerice, kanili ili uvodnicu igle), provjerite sljedeće:*

- osovina i vrh umetnuti su kroz pomoći proizvod bez otpora ili lateralne sile
- osovina antene ne savija se niti struže o pomoći proizvod
- pomoći proizvod ne primjenjuje lateralnu silu na antenu
- zeleni dio koji zrači ne dodiruje neizolirani metal pri isporučivanju energije.

*U suprotnom se može dogoditi sljedeće:*

- može doći do oštećenja antene, uključujući pucanje ili odvajanje osovine i/ili vrha
- može doći do slučajne toplinske ozljede ili promjene obrasca ablacije.

# Medtronic

## Ažuriranje uputa u koraku 5

5. Nakon prestanka isporučivanja energije u antenu ostavite crpku da nastavi raditi 5 sekundi kako bi se antena ohladila. Potom zakrenite osovinu antene da biste oslobođili bilo koje primljeno tkivo. Potom promijenite položaj antene ili je izvadite.

## Novo upozorenje dodano nakon koraka 5

Ostavite antenu da se ohladi prema uputama u koraku 5 prije nego što joj promijenite položaj ili je izvadite. Time se smanjuje rizik od odvajanja vrha antene.

Očekuje se da će se revidirane Upute za upotrebu isporučivati s proizvodima Emprint™ počevši od kraja ljeta 2019.

### Radnje koje vi morate poduzeti:

- Odmah obavijestite sve odgovarajuće odjele u kojima se upotrebljavaju antene Emprint™ o ažuriranjima Uputa za upotrebu. Možete nastaviti upotrebljavati antene Emprint™ u skladu s prethodnom smjernicom.
- Ako ste distribuirali bilo koje prethodno navedene proizvode Emprint™, što hitnije naručiteljima proslijedite informacije iz ovog dopisa.
- Ispunite priloženi obrazac potvrde i vratite ga prema uputama da biste potvrdili da ste primili i razumjeli ove informacije.

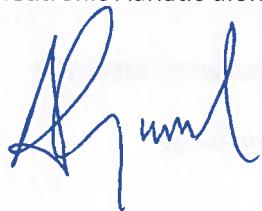
Nadležno tijelo u vašoj zemlji Agencija za lijekove i medicinske proizvode (HALMED) obaviješteno je o ovoj radnji. Spremite kopiju ove obavijesti u svoju evidenciju. Obratite se tvrtki Medtronic ako imate poteškoća s kvalitetom ili ako dođe do štetnih događaja.

Ispričavamo se zbog mogućih neugodnosti. Ako imate kakvih pitanja u vezi s ovim priopćenjem, obratite se lokalnom predstavniku tvrtke Medtronic Alenu Galiću na [alen.galic@medtronic.com](mailto:alen.galic@medtronic.com) odnosno na Medtronic Adriatic d.o.o., Folnegovićeva 1c, 10000 Zagreb.

Srdačan pozdrav

Alen Galić, voditelj MITG odjela

Medtronic Adriatic d.o.o.



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



**Obvezno je potrebno ispuniti Obrazac odgovora kupca.**

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**POPUNITE OVAJ OBRAZAC FA781 faza 3.**

**Popunite cijeli ovaj obrazac.**

Datum: \_\_\_\_\_

Ime i prezime osobe koja ispunjava ovaj obrazac: \_\_\_\_\_

Titula: \_\_\_\_\_

Izravan telefonski broj: \_\_\_\_\_

E-pošta: \_\_\_\_\_

Naziv računa: \_\_\_\_\_

Broj računa tvrtke Covidien \_\_\_\_\_

Adresa računa: \_\_\_\_\_

Grad: \_\_\_\_\_ Država: \_\_\_\_\_ Poštanski broj: \_\_\_\_\_

Potpisom u nastavku potvrđujem da sam s razumijevanjem pročitao/la navedene upute te potvrđujem primitak sigurnosne obavijesti za medicinski proizvod u vezi s perkutanim antenama Covidien Emprint™ s tehnologijom Thermosphere™.

Prihvaćam i da će važne informacije iz ovog dopisa proslijediti svim naručiteljima kojima sam dalje distribuirao/la bilo koji od prethodno navedenih proizvoda Emprint™.

\_\_\_\_\_ Ime i prezime (tiskanim slovima)

\_\_\_\_\_ Potpis

\_\_\_\_\_ Datum

Ako imate kakvih pitanja o ovoj HITNOJ SIGURNOSNOJ OBAVIESTI, obratite se prodajnom predstavniku tvrtke Medtronic.

**MOLIMO DA OVU ISPUNJENU POTVRDU POŠALJETE E-POŠTOM NA ADRESU:**  
**[vedran.biondic@medtronic.com](mailto:vedran.biondic@medtronic.com)**

and "single" inflationary or deflationary effects.<sup>1</sup> These results are consistent with the general literature on the short-run Phillips curve.

### 3.2. Long-run Phillips curves

Table 3 presents the results for the long-run Phillips curves. The first panel shows the results for the model with no nominal rigidities. The second panel shows the results for the model with nominal rigidities. The third panel shows the results for the model with nominal rigidities and a time-varying money supply. The fourth panel shows the results for the model with nominal rigidities and a time-varying money supply and a time-varying money demand. The fifth panel shows the results for the model with nominal rigidities and a time-varying money supply and a time-varying money demand and a time-varying output gap. The sixth panel shows the results for the model with nominal rigidities and a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate. The seventh panel shows the results for the model with nominal rigidities and a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate and a time-varying money demand elasticity. The eighth panel shows the results for the model with nominal rigidities and a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate and a time-varying money demand elasticity and a time-varying money supply elasticity. The ninth panel shows the results for the model with nominal rigidities and a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate and a time-varying money demand elasticity and a time-varying money supply elasticity and a time-varying money demand elasticity.

In the first column of each panel, the first row shows the results for the model with no nominal rigidities. The second row shows the results for the model with nominal rigidities. The third row shows the results for the model with a time-varying money supply. The fourth row shows the results for the model with a time-varying money supply and a time-varying money demand. The fifth row shows the results for the model with a time-varying money supply and a time-varying money demand and a time-varying output gap. The sixth row shows the results for the model with a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate. The seventh row shows the results for the model with a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate and a time-varying money demand elasticity. The eighth row shows the results for the model with a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate and a time-varying money demand elasticity and a time-varying money supply elasticity. The ninth row shows the results for the model with a time-varying money supply and a time-varying money demand and a time-varying output gap and a time-varying real interest rate and a time-varying money demand elasticity and a time-varying money supply elasticity and a time-varying money demand elasticity.

<sup>1</sup> The term "single" inflationary effect refers to the effect of a one-time increase in the money supply on the long-run inflation rate. The term "deflationary effect" refers to the effect of a one-time decrease in the money supply on the long-run inflation rate. The term "double" inflationary effect refers to the effect of a one-time increase in the money supply on the long-run inflation rate, given that the money supply has already increased in the past. The term "double" deflationary effect refers to the effect of a one-time decrease in the money supply on the long-run inflation rate, given that the money supply has already decreased in the past.

<sup>2</sup> The term "single" inflationary effect refers to the effect of a one-time increase in the money supply on the long-run inflation rate. The term "deflationary effect" refers to the effect of a one-time decrease in the money supply on the long-run inflation rate. The term "double" inflationary effect refers to the effect of a one-time increase in the money supply on the long-run inflation rate, given that the money supply has already increased in the past. The term "double" deflationary effect refers to the effect of a one-time decrease in the money supply on the long-run inflation rate, given that the money supply has already decreased in the past.