Medtronic

Dringende veiligheidskennisgeving

Hugo™ RAS monopolaire gebogen kniptang MRASI0001

Recall

Maart 2023

Medtronic-referentie: FA1310
Single Registration Number (SRN) van de fabrikant in de EU: US-MF-000028763, UDI: 10884521836433

Beste risicobeheerder, zorgprofessional en OR-materiaalbeheerder,

Het doel van deze brief is u ervan op de hoogte te stellen dat Medtronic een terugroepactie heeft uitgevaardigd voor het Hugo™ RAS-systeem die betrekking heeft op de monopolaire gebogen kniptang die worden gebruikt bij het Hugo™ RAS-systeem.

Beschrijving van het probleem:
Deze terugroepactie is uitgevaardigd na 17 ingediende klachten met betrekking tot een kabelbreuk in de Hugo RAS monopolaire gebogen kniptang tijdens klinisch gebruik. Een kabelbreuk kan leiden tot onbedoelde beweging van het gewricht en/of de bek van de Hugo RAS monopolaire kniptang in klinische omstandigheden en ertoe leiden dat de bek van het instrument niet meer beweegt of niet meer knipt in het weefsel. Een kabelbreuk voorkomt niet dat het instrument energie levert.

Deze terugroepactie is alleen van toepassing op het bovengenoemde onderdeelnummer en de serienummers die worden vermeld in Bijlage 1: Lijst met betrokken serienummers.

Risico voor gezondheid:
Er zijn geen meldingen geweest van letsel bij patiënten als gevolg van dit probleem, maar de mogelijkheid bestaat dat onder andere de volgende schade zou kunnen worden veroorzaakt: darmbrandwonden, thermische verbranding, darmperforatie, perforatie van grote bloedvaten, bloedvatperforatie, vertraging van de behandeling (langere procedure), weefselbeschadiging/weefseltrauma, of bloeding.

Maatregelen die door de klant moeten worden genomen:

- Breng al het personeel in zorgomgevingen waarin de Hugo RAS monopolaire gebogen kniptang wordt gebruikt op de hoogte van deze terugroepactie van medische hulpmiddelen.
- Plaats hulpmiddelen met de genoemde artikelcode en serienummers uit de lijst met betrokken serienummers in Bijlage 1 in quarantaine en gebruik deze niet meer.
- Stuur de betrokken producten terug zoals hieronder aangegeven. Alle producten met de betreffende productcode en het betrokken serienummers moeten worden teruggestuurd naar Medtronic.

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Door Medtronic getroffen maatregelen:

- Medtronic zal u bijstaan bij het retourneren van het getroffen product.
- Medtronic Start-up Specialists zal de coördinatie met u verzorgen voor het verkrijgen van nieuwe voorraad van de monopolaire geboren kniptang en instructies voor het gebruik van bovengenoemd instrument.

Aanvullende informatie:

Medtronic heeft de bevoegde autoriteit in uw land van deze actie op de hoogte gesteld.

Onze excuses voor het ongemak dat hierdoor kan zijn veroorzaakt. De veiligheid van de patiënt staat bij ons voorop en we waarderen uw snelle afhandeling van deze zaak. Neem bij vragen over deze brief contact op met uw Medtronic-vertegenwoordiger.

Met vriendelijke groet,

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Quality, Regulatory Manager Benelux

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Engineering the extraordinary

Bijlage: Lijst met betrokken serienummers

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Bijlage 1: Lijst met betrokken serienummers

Betrokken serienummers						
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Betrokken serienummers						
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Betrokken serienummers						
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