Medtronic

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Urgent Field Safety Notice

SenSight™ Extension Tunneler Kit, Product Number: B31030

Recall

March 2023

Medtronic Reference: FA1319
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional,

The purpose of this letter is to inform you that Medtronic is initiating a recall that impacts SenSight™ Extension Tunneler kits (Product Number: B31030). The issue is that the dual carrier within each of these kits may be unfinished. You are receiving this letter because Medtronic records indicate that affected kits were shipped to your facility.

Issue Description:
Medtronic has received reports of SenSight™ Extension Tunneler kits that contain dual carriers which have been machined on only one side. As a result of this issue, the dual carrier cannot be used to pass two extensions simultaneously. The surgical procedure may be delayed to obtain another dual carrier or an additional tunneling pass may be necessary to complete the implant of two extensions. This issue only affects the dual carrier; the remaining components in the kit are unaffected.

Medtronic has received three (3) complaints worldwide. We have reports of two (2) serious injuries due to this issue, that required making a second tunneling pass during the procedure. Complications inherent to the tunneling procedure (e.g., tissue trauma, damage to surrounding critical structures, discomfort, etc.) are potential risks; however, no such adverse effects or extension damage were incurred in the cases requiring an additional tunneling pass. The third complaint was completed using a second kit and no additional adverse events were reported.

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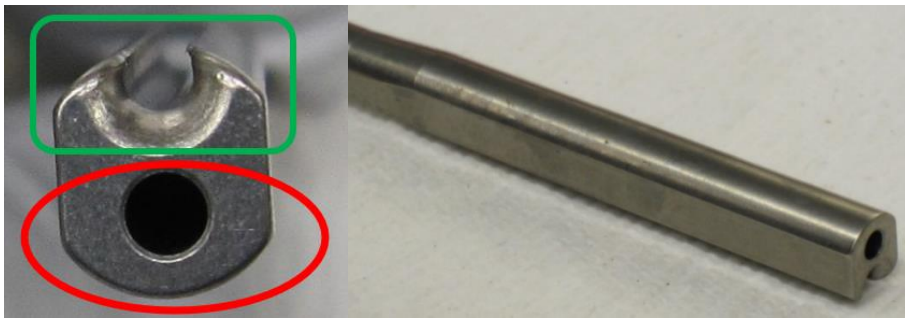

Example of the unfinished dual carrier (two separate angles). The highlighted oval area in red (or bottom) is not machined/milled out. It should be similar to the opposing top side highlighted in green rectangle area.

Product Scope:

Product Name	Product Number	Lot Number
SenSight™ Extension Tunneler Kit	B31030	See Attachment A

Actions:

- Quarantine all unused product from the affected lots of SenSight™ Extension Tunneler kits (Product Number: B31030). See Attachment A for guidance on identifying potentially affected devices.
- Return all unused product from the affected lots in your inventory to Medtronic.
- Complete the enclosed Customer Acknowledgement Form even if you **don't** have unused inventory, please return the form to rs.regulatoryuk-ire@medtronic.com
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product from the specified lots has been transferred or distributed.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative directly or via Tel No: 01 511 1400

Sincerely,

Keith Taverner: Regulatory Affairs Manager UK & Ireland

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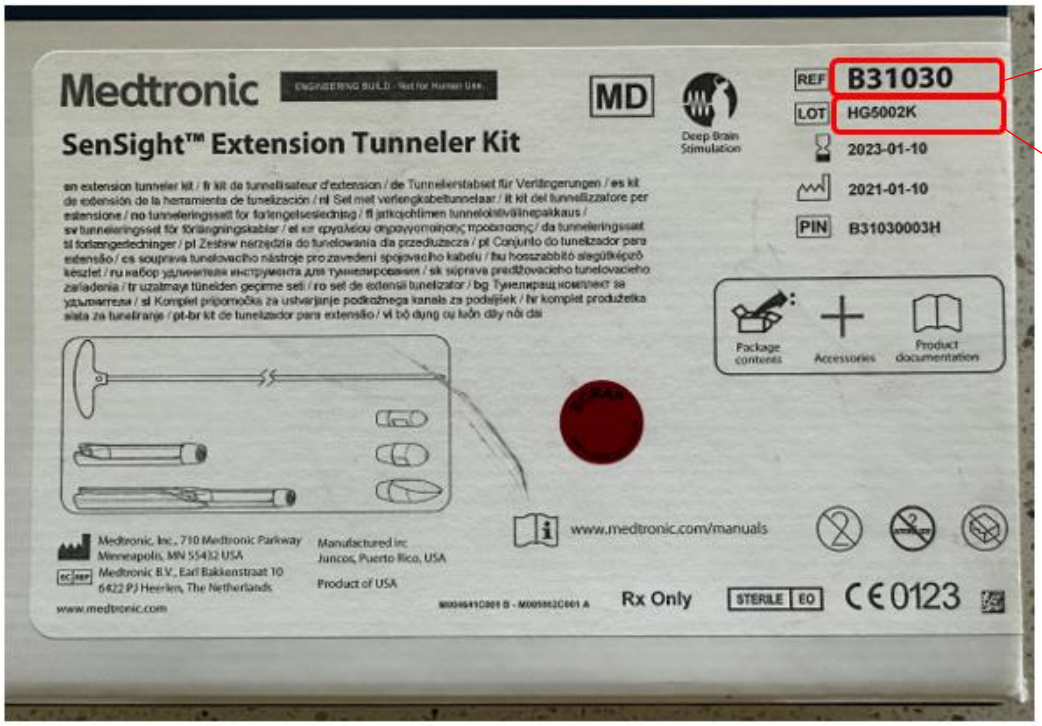
Enclosure: Attachment A: Identifying Affected Products.

Attachment A: Identifying Affected Products

Affected Lot Numbers							
HG56BR6	HG56C4R	HG56CJAH01	HG56CLE	HG586N7	HG586UM	HG58704	HG58VM0
HG58VQH	HG58VQHH01	HG58VY5	HG58W7H	HG58WWC	HG58WYB	HG58WYBH01	HG58X0E
HG597BH	HG597DH	HG597M8	HG59ABH	HG59AFC	HG59AV6	HG59RY0	HG59SJ4
HG59SNC	HG5A9GT	HG5A9H3	HG5A9NB	HG5A9VY	HG5A9VZ	HG5AQH0	HG5AQQE
HG5BQ5Y	HG5BQAW	HG5BQAWH01	HG5BQLR	HG5BQPJ	HG5BTW7	HG5BTZX	HG5BU5W
HG5BU77	HG5EPSB	HG5EQ0C	HG5EQ2A	HG5EQ69	HG5F31N	HG5F338	HG5F3AZ
HG5F3EH	HG5F3G6	HG5F3K5	HG5F3NF	HG5FP0Y	HG5FP3B	HG5FP70	HG5FP70H01
HG5FPBE	HG5HQBM	HG5HQF8	HG5LJTL	HG5LJZQ	HG5LK2J	HG5LK4H	HG5LK5Y
HG5LK7C	HG5LK8P	HG5LK92	HG5LKAL	HG5LKC9	HG5LKEL	HG5LKGT	HG5LR02
HG5LR33	HG5LTWA	HG5LTWP	HG5LTXU	HG5LTYY	HG5LU12		

SenSight™ Extension Tunneler Kit (Product Number: B31030)



Product Number

Lot Number

Medtronic

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CUSTOMER ACKNOWLEDGEMENT FORM

- **Please email this form back to Medtronic (even if you do not have affected inventory):**
- rs.regulatoryuk-ire@medtronic.com before 19th April 2023

Urgent Field Safety Notice - Recall

FA1319: SenSight Extension Tunneler Kit

Customer Contact Details			
Hospital name:		Account number (optional):	
Address:	City:		Country:
• I confirm that I have read and understood the Urgent Field Safety Notice • I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred. • I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following: ☐ No affected products are located at our facility. ☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.			
Name (print):	**Job title**:	**Date**:	**Signature**:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note *(if available)*	**Item Code**	**Lot #**	**Quantity Each**
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			**Total**:
Contact Person at Point of Collection:			
Pick-up address / Department *(please provide location details. Eg: collection/accessible area):*			
City:			Post code:
Pick-up phone number:		Pick-up email:	
When the product will be ready for pick-up? *(Please allow 2 days for handling your request):*			
Opening hours of the pick-up location:			Dimension LxWxH (in cm): … x … x …
# Pallets:	# Parcels:	Number of parcels weighing over 45 KG:	

- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.