

Urgent Field Safety Notice

Passive Biopsy Needle Kit - Model Number 9733068

Passive Biopsy FPU Kit - Model Number 9731754

Recall

October 2019

Medtronic reference: FA893

Dear Healthcare Professional,

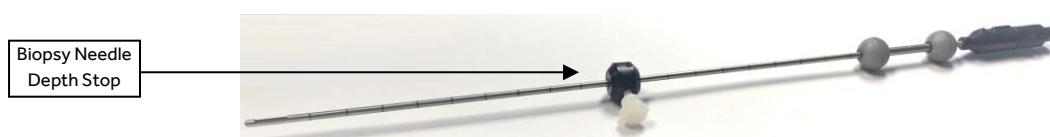
Medtronic is conducting a voluntary recall for specific lot numbers of the Passive Biopsy Needle Kits. This recall only affects the lot numbers listed below:

Model	Description	Affected Lot Numbers			
9733068	Biopsy Needle Kit, 9733068, Passive	066503918A	066513519A	066529218A	066535518A
		066503919	066513519C	066531018	
		066512319A	066513519E	066531018A	
		066512319C	066529218	066535518	
9731754	FPU Kit Passive Biopsy	0009665221	0009709452	0009960538	

Issue Background and Summary:

The biopsy needle depth stop is a mechanical stop on the biopsy needle that is set during the surgical procedure to prevent the biopsy needle from being inserted past the target location.

Medtronic has become aware that due to a manufacturing issue impacting the biopsy needle depth stop, there exists the potential that some biopsy needle depth stops, when tightened, may not securely tighten to the biopsy needle. The manufacturing issue has been resolved, and this notification is limited to the lot numbers identified above.



As of October 1, 2019, Medtronic has identified 14 complaints worldwide associated with this issue. Seven of these events reported that the issue resulted in a procedural delay of less than an hour. Additionally, in one case, the issue resulted in the biopsy needle being removed after insertion into the brain, and a needle from a different kit was placed along the same stereotactic trajectory. All other complaints did not report hazardous situations to the patient.

The inability to securely connect the biopsy needle depth stop to the biopsy needle has no effect on the StealthStation™ system's navigation accuracy or ability of the software to visually display the location of the tip of the biopsy needle and the cut window.

Required Actions:

1. Identify, segregate, and quarantine affected products within your inventory.
2. Return all unused affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return of this product as necessary.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

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, please contact your Medtronic Representative directly or via Tel No: 01 511 1400.

Sincerely,

Keith Taverner: Regulatory Affairs Manager UK & Ireland

