

Urgent Field Safety Notice

Medtronic Clip Gun™ Scalp Clip System

Model CG8900, CG8901, CG8901A

Recall

December 2017

Medtronic reference: FA798

Dear Chief of Neurosurgery / Risk Manager,

The purpose of this letter is to inform you that Medtronic is initiating a recall for specific lot numbers of the Clip Gun™ Scalp Clip (see Appendix A).

The Medtronic Neurosurgery's Clip Gun Kit and accessory products (magazines and clip packs) are intended to be used by physicians during cranial surgery to provide hemostasis by preventing arterial bleeding from small vessels of the skin and deeper vessels under the scalp. By providing hemostasis, the clips allow the surgical field to remain clear for the physician to proceed with the desired surgical procedure.

Medtronic is initiating this recall because the affected products did not adequately demonstrate acceptable packaging performance to current standards.

Testing performed by Medtronic showed that the outer sterile pouch of the product did not meet standards for package integrity. Specifically, the testing demonstrated that the outer pouch could be compromised and possibly go undetected by the user which could potentially lead to patient infections. In an abundance of caution, these affected products are being removed from the field.

Required actions:

1. Please locate and remove the impacted product from normal storage locations. Do not use this product.
2. Your Sales Representative will contact you to facilitate the return of any impacted products you may have in your possession
3. Pass this notice to all those who need to be aware within your organization or to any organization where the affected products have been transferred.
4. Maintain a copy of this notice in your records

The Competent Authority of your country has been notified of this action.

We sincerely apologise for any inconvenience this action may cause but it is necessary to assure that our high standard of quality is maintained. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Medtronic

Appendix A: List of affected lots

List of affected lot numbers of Medtronic Clip Gun™ Scalp Clip System Model CG8900, CG8901, CG8901A:

E20599	E09145
D80412	E09146
D80413	E09149
D84100	E14782
D84101	E14784
E00008	E14896
E00009	E15195
E00983	E19181
E00984	E19182
E03049	E19183
E03050	E19185
E03716	E19187
E03717	E19868
E05233	E19869
E05235	E19871
E05806	E20599
E05807	E20600
E07257	E23631