

SEP 28, 2023

Medtronic Notification of Stolen Defective Products – Potentially Defective McGRATH™ MAC Video Laryngoscopes

NOTE: McGRATH™ MAC video laryngoscopes purchased directly from Medtronic or via its authorized distributors are not affected by this safety notice.

September 27, 2023 – Medtronic is issuing this notification to inform the public of stolen defective McGRATH™ MAC video laryngoscopes that have been offered for sale illegally by unauthorized third parties through various social media platforms. These affected products did not pass Medtronic's rigorous quality tests established for the product, were not released for sale, distribution, or importation and were designated for destruction. These affected products are defective and should not be used. Medtronic is working closely with regulatory authorities and law enforcement organizations to help ensure that unauthorized advertisements are being removed as identified, and actions to recover the stolen defective products are underway.

The McGRATH™ MAC video laryngoscope is a device used to facilitate intubation of the trachea. The use of a defective McGRATH™ MAC video laryngoscope may result in patient harm, including failed laryngoscopy and/or intubation, potentially resulting in respiratory failure (including hypercarbia), hypoxia (leading to bradycardia, dysrhythmias), hypercapnia, tissue damage/tissue trauma and/or a delay to treatment (prolonged procedure/extended hospitalization).

A population of products affected by this notice (Item Code 301-000-000) are marked with the serial numbers listed below. Additionally, any McGRATH™ MAC video laryngoscopes without a serial number marked on the device are affected by this notice. The stolen defective products are not packaged in the labeled packaging containers shown below:

CONFORMING devices can be identified by the presence of serial number and packaged in either version of container shown.



Patient safety remains at the core of the Medtronic Mission to alleviate pain, restore health, and extend life. Medtronic urges healthcare professionals to purchase products only from trusted and reliable sources, such as directly from Medtronic or its authorized distributors. To find an authorized distributor or to purchase directly from Medtronic, contact Customer Service at 800-962-9888, Option 2.

Medtronic will continue to work closely with regulatory authorities and law enforcement agencies toward resolution of this issue. Anyone with information regarding the promotion or sale of potentially stolen products are encouraged to contact Medtronic Customer Service at 800-962-9888, Monday through Friday from 8AM to 7PM ET.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Serial Number

000063	000677	001629	003191	004912	101048	101996	103596	105062	106061
000076	000745	001631	003201	004915	101049	101997	103623	105064	106080
000085	000752	001669	003288	004942	101050	101998	103672	105071	106087
000092	000753	001760	003464	004960	101053	101999	103684	105075	106108
000093	000760	001826	003678	004965	101058	102000	103711	105106	106109
000112	000764	001829	003693	004975	101065	102001	103835	105225	106117
000120	000769	001859	003720	004976	101120	102002	103900	105303	106139
000121	000781	001952	003733	100010	101158	102003	103921	105325	106213
000146	000809	001985	003889	100012	101182	102011	104155	105341	106225
000153	000810	002008	003957	100015	101229	102140	104164	105363	106226
000154	000821	002016	004035	100080	101317	102223	104198	105367	106239
000155	000823	002017	004075	100083	101391	102358	104207	105382	106303
000166	000847	002037	004076	100130	101394	102435	104224	105387	106305
000179	000850	002042	004178	100145	101405	102492	104419	105391	106306
000190	000871	002056	004409	100168	101445	102591	104420	105409	106307
000197	000879	002151	004444	100235	101452	102594	104428	105412	106308
000202	000887	002160	004491	100243	101463	102598	104436	105427	106309
000224	000891	002174	004525	100256	101513	102676	104444	105432	106310
000233	000913	002197	004532	100264	101529	102693	104460	105434	106311
000238	000914	002234	004545	100289	101530	102694	104477	105460	106312
000255	000918	002242	004580	100318	101555	102741	104479	105474	106313
000308	000939	002279	004608	100329	101624	102752	104598	105479	106314
000329	000958	002282	004610	100349	101683	102780	104663	105498	106316

000375	000960	002291	004624	100354	101692	102827	104721	105526	106317
000389	001015	002294	004650	100368	101711	102865	104724	105545	106318
000436	001027	002321	004664	100383	101716	102917	104735	105552	106319
000446	001135	002322	004686	100393	101782	102968	104776	105579	106320
000455	001140	002363	004706	100397	101791	102969	104807	105610	106321
000464	001191	002386	004722	100406	101799	103052	104829	105620	106322
000465	001211	002480	004731	100431	101810	103056	104839	105623	106323
000497	001348	002676	004745	100432	101816	103058	104841	105665	106324
000512	001355	002777	004749	100439	101881	103070	104843	105730	106325
000526	001385	002780	004756	100455	101896	103187	104848	105757	106326
000528	001418	002786	004762	100459	101945	103200	104903	105818	106327
000546	001446	002793	004765	100556	101958	103203	104920	105819	106328
000553	001491	002853	004776	100577	101968	103209	104925	105828	106329
000597	001504	002858	004809	100597	101989	103318	104934	105837	106330
000607	001534	002888	004827	100785	101990	103380	104953	105841	106331
000628	001555	002908	004833	100787	101991	103410	104960	105867	106332
000641	001561	002991	004836	100803	101992	103458	104984	105935	106333
000648	001596	003001	004851	100822	101993	103461	104986	105941	106334
000650	001605	003090	004890	100914	101994	103474	105016	105947	106335
000673	001621	003179	004901	101044	101995	103554	105037	105973	106336

Serial Number

106337	106500	108080	109367	110749	111940	112534	113240	114161	114659
106338	106538	108090	109457	110828	111943	112610	113258	114176	114662
106340	106589	108142	109483	110837	111954	112619	113263	114185	114663
106341	106626	108175	109506	110911	111957	112639	113265	114201	114677
106342	106752	108191	109558	110921	111962	112694	113267	114204	114691
106343	106760	108209	109563	110925	111988	112700	113271	114210	114732
106344	106762	108283	109571	110926	111998	112718	113274	114228	114786
106345	106773	108301	109655	110930	112000	112737	113302	114245	114787
106346	106883	108304	109662	110950	112013	112757	113330	114275	114789
106347	106889	108323	109707	110951	112027	112760	113344	114277	114841
106348	106976	108348	109718	110966	112054	112786	113388	114281	114842
106349	106986	108377	109730	110967	112059	112822	113403	114284	114844
106350	106992	108390	109773	111003	112084	112826	113454	114289	114857
106351	107037	108422	109791	111023	112088	112834	113474	114293	114861
106352	107216	108481	109913	111064	112093	112846	113487	114296	114867
106353	107277	108550	109984	111097	112096	112847	113517	114298	114870
106354	107281	108562	110066	111219	112114	112850	113520	114302	114872
106355	107384	108585	110102	111243	112117	112894	113528	114306	114873
106356	107414	108588	110135	111292	112124	112909	113543	114309	114880
106357	107461	108598	110167	111298	112141	112916	113563	114311	114904
106358	107468	108617	110170	111318	112145	112920	113588	114319	114910
106359	107488	108663	110173	111364	112146	112922	113604	114327	114949
106360	107507	108672	110176	111366	112180	112934	113620	114334	114951
106361	107534	108746	110178	111384	112182	112941	113660	114338	114960

106362	107548	108827	110181	111417	112188	112974	113704	114343	115000
106363	107549	108871	110203	111453	112190	112984	113705	114346	115002
106364	107550	108898	110206	111498	112195	112989	113810	114354	115072
106365	107553	108901	110293	111503	112199	113007	113814	114357	115077
106366	107612	108966	110301	111508	112210	113009	113822	114389	115087
106367	107613	108971	110303	111516	112221	113032	113837	114397	115158
106368	107623	108980	110332	111576	112245	113065	113886	114400	115227

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