**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** |
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|---|---|---|---|---|---|---|---|---|---|
| 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 |

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|---|---|---|---|---|---|---|---|---|---|
| 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 |
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| 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 |
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| 000673 | 001621 | 003179 | 004901 | 101044 | 101995 | 103554 | 105037 | 105973 | 106336 |

| **Serial Number** |
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|---|---|---|---|---|---|---|---|---|---|
| 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 |

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|---|---|---|---|---|---|---|---|---|---|
| 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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