## *s*tryker

February 13, 2019

Dear Valued Customer,

Stryker's Neptune 2 and Neptune 3 Waste Management systems are designed to provide maximum patient and caregiver protection. Our Smoke Evacuation ULPA Filter (part number 0702-040-000) is one critical protection element that provides filtration efficiency exceeding 99.999%, even for sub-micron particle sizes. Stryker verifies ULPA filtration performance to IEST-RP-CC007 through independent aerosol lab testing and has done so on multiple occasions before and after product launch. Rigorous manufacturing process controls and quality checks help to ensure that every filter meets or exceeds your safety expectations.

In 2013, Stryker submitted a new ULPA Filter – manufactured by Buffalo Filter (part number VSNEP01) – for the same independent lab testing to IEST-RP-CC007. However, it failed to reach ULPA or even HEPA-level filtration efficiency performance. Again in 2018, Stryker sent another set of three new Buffalo Filter samples for independent lab testing, but they also failed to meet the ULPA rating or even the HEPA rating.

In light of this objective evidence collected by our quality monitoring diligence, we strongly discourage the use of Neptune 2 ULPA filters manufactured by anyone other than Stryker to ensure the highest levels of patient and caregiver safety.

As always, here at Stryker, we stand ready to answer any questions our customers may have concerning our products. If you have any questions pertaining to the contents of this letter, please contact us immediately.

Yours Sincerely,

**Nick Meginnis** 

E-SEP Brand Manager

N. Meginnis

**Brian MacLachlan** Sr Principal Engineer

Big. hola

Catherine McNally

Sr Regulatory Affairs Specialist

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## Reference Stryker internal test reports:

- S1756.071362
- S1756.071444
- S1756.071469
- S1756.071450
- S1988.150724
- F0702.131658
- F0702.190145