

Degania[™] G BUTTON BALLOON: DESIGNED FOR SUPPORT AND PERFORMANCE

The G Button Balloon survived in simulated gastric solution for 83 days*, equivalent to an actual lifetime of 332 days.

^{*} Test performed according to ISO 20695-2020

DESCRIPTION

- The Low-Profile G Tube/ G Button (LPGT/B) is a low profile balloon catheter intended for the administration of nutrition fluids and/or medication via well-established stoma.
- For this analysis, three Fr sizes were chosen: 12, 16 and 24 (S, M & L), as representatives to cover the range of the product family sizes.
- The tests were performed according to ISO 20695-2020.

PROCEDURE

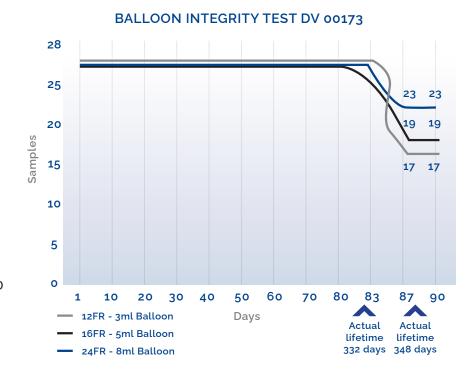
• Based on the ISO 20695-2020 requirements, 28 inflated LPGT/B's of each size (84 samples total) were placed in a bath of simulated stomach gastric fluid (pH 1.2 +/- 0.1) for a period of 90 days. Samples were inspected daily for balloon failures, and weekly for balloon volume.

RESULTS

LPGT/B 12 Fr
First balloon bursts after 87 days
LPGT/B 16 Fr
First balloon bursts after 83 days
LPGT/B 24 Fr

First balloon bursts after 87 days

Surviving in simulated gastric solution for 83 days is equivalent to an actual lifetime of 332 days, and 87 days is equivalent to an actual lifetime of 348 days.



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