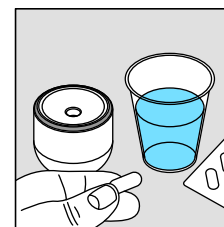


4.1.6 Immediately swallow the Capsule with one glass (-8 ounce of water. After removing the Capsule from the Pod, the light ring indicator turns blue.

4.1.7 Replace the Pod cover.

4.1.8 Keep the Pod powered on for approximately 10 minutes before disconnecting it.

4.1.9 The Capsules are intended to be orally ingested up to 5 times per week, as directed by a physician. The Capsule should be taken shortly before going to sleep on 5 out of 7 days of the week according to the following schedule:
3 days on, 1 day off, 2 days on, 1 day off.



Caution: Do not connect the USB cable to any other device (such as a computer) as this may potentially harm the Pod.

5. Storage and Maintenance Instructions

Pod

- Keep the Pod in a dry place away from direct sunlight (not in the kitchen or in the bathroom.)
- Thoroughly clean the Pod prior to first use and after each use. The Pod should be cleaned using a clean cloth and 70% isopropyl alcohol and the lid should be closed after cleaning and between uses.
- In the case of electromagnetic disturbance (refer to Section 7, Table 10: Impact of Electromagnetic (EM) Disturbances on Device Function/Performance), reset the Pod by unplugging the AC/DC adaptor from the wall power outlet and plugging it back in after a few seconds.

Capsules

- The Vibrant Capsules should be stored in a dry, cool place (below 25°C/77°F), away from magnetic sources and away from direct sunlight (not in the kitchen or in the bathroom).
- Keep the Vibrant Capsules in the sealed blister pack until use.
- Even if stored in their original containers and according to recommendations, the Vibrant Capsules can be kept for a limited period only. Please note the expiration date of the Capsules.

6. Summary of Clinical Information

A pivotal study (V270) was conducted to evaluate the safety and effectiveness of the Vibrant Capsules. The study was conducted in compliance with 21 CFR parts 50, 56, and 812. V270 was a prospective, randomized, multi-center, double-blinded, placebo-controlled pivotal study. The study included 2 active treatment arms that used different vibration patterns (i.e., Active Mode 1 and Active Mode 2) and a placebo control arm. For the first part of the study, subjects were randomized equally to each arm in a 1:1:1 ratio, for a treatment period of 8 weeks. A "drop the loser" design was pre-specified, whereby the lower performing active treatment was dropped from the study following an interim analysis. After the lower performing active arm was dropped, future subjects were randomized to each of the remaining arms on a 1:1 ratio. The alpha value was adjusted to two-sided 0.025 to account for this design.

Vibrant Capsules were administered 5 times per week, and the treatment arm was compared to a placebo which consisted of a biodegradable soft-gel Capsule filled with soybean oil, beeswax and calcium carbonate. The study population was comprised of subjects with chronic idiopathic constipation (CIC) who were refractory to existing OTC or Rx treatments or could not tolerate the side effects. Patient eligibility was assessed during the initial screening visit and was re-assessed and confirmed during the Baseline visit following a 2 to 3-week run-in period. Randomization occurred following the 2 to 3-week run-in period and verification that the patient satisfied all inclusion criteria and did not meet any exclusion criteria.