

Author notes

The authors confirm that the Principal Investigator for this study is Philip E Wolfson MD, and that he had direct clinical responsibility for patients. All authors confirm the Originality of this text and this Research Each of the authors state that there are no conflicts of interest and no relationships with commercial interests. The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions. Written informed consent was obtained from all participants and the Informed Consent as approved by both the FDA and the IRB is appended.

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Disclosure statement

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