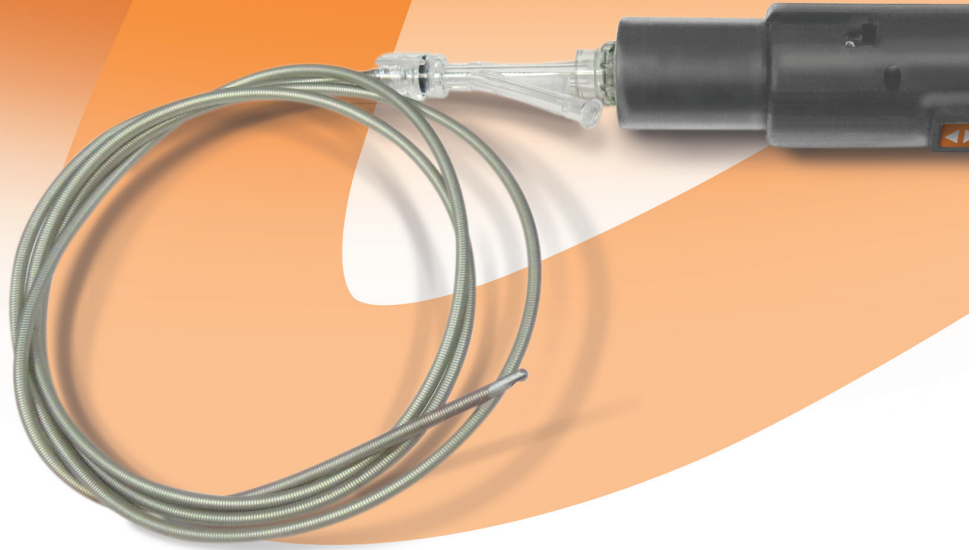


BleedClear™

Endoscopic Clot Clearing System

Allows for quicker and more effective removal of coagulated blood masses during upper GI bleed treatments.

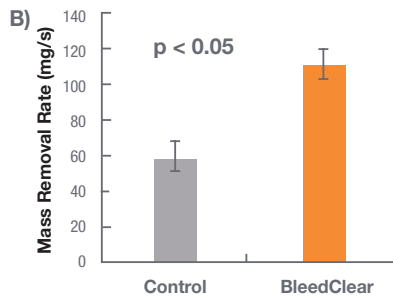
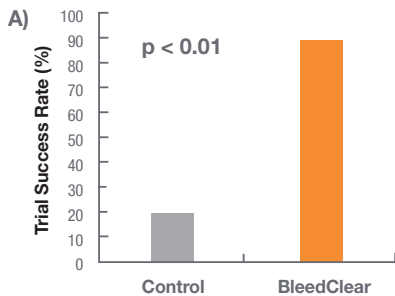


Upper GI Bleeds (UGIBs) are normally treated with minimally invasive surgery endoscopically. However, the presence of blood and clots reduces endoscopic visibility and limits diagnosis/treatment of the bleeding site. Actuated Medical developed the BleedClear System to allow clinicians treating UGIBs improved visualization. An actuated Suction Stem powered by a Handheld Driver inserted through the working channel of a standard endoscope rotates a Shearing Paddle at the Suction Inlet – breaking up the clotted material into fine pieces and aspirating, allowing for faster UGIB visualization and treatment.

“If the device is simple to use and effective there should not be any roadblocks to its adoption because it is currently needed for many GI procedures.”

+ GI Specialist*

* Fraser JW. Technology Niche Analysis. In: Foresight Science & Technology; 2016:24.



	BleedClear System	Standard Suction
Trial Success (%) of 10 Trials <i>In-vitro</i> 60g clot in 15 min	90%	20%
Average Clot removal time (seconds)	577(± 172)	1477(± 715)
Average Clot material adherence and suction interrupted (over 10 Trials)	1x	185x
Average Mass Removal Rate (g/min)	6.7	3.7
Average Remaining Clot material (%) of successful clearing attempts	9.5%	44 ± 19%

In-vitro Efficacy testing using 200 mmHg applied suction pressure. Control: 3.63 mm open channel. N=10 trials/treatment. A) Success rate comparison. A successful trial is defined as the complete clearance of *in-vitro* porcine blood clot (starting size: ~60g) in 15 minutes or less, $p < 0.01$, 2 proportion test. B) Comparison of the calculated mean mass removal rate (mass removed/procedure time). Error bars indicate standard error of the mean, $p < 0.05$, Kruskal-Wallis test. C) Summary Table comparing the BleedClear System to the Control Standard suction with an open channel.

Key Advantages

The BleedClear System improves UGIB treatments by:

- + Increasing clot removal success.
- + Greater clot removal rate allows for faster visualization of bleed source
- + Reduced need to withdraw and reinsert endoscope into patient

Call us for more info
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Pending 510(k), not available for sale within the United States.

