



MCW Section of EMS Medicine New Product Evaluation: Life Vac

THERAPEUTIC USE

Manual, portable suction apparatus for removal of foreign body obstruction.

<https://lifevac.net/>

SIMILAR PRODUCTS/DRUGS

DeChoker: <https://www.dechoker.com/>

ISSUES FOR CONSIDERATION

1. The product is [FDA](#) registered as a Class I Medical Device for use in the choking patient.
2. Level of evidence using the GRADE method for therapeutic effect: low to moderate
3. Is this product included in the Wisconsin State EMS [Scope of Practice](#)?
Indirectly; the suction device can be interpreted as a skill under b, c, or d.
 - a. Airway Obstruction-Direct Visualization
 - b. Airway Obstruction-Manual
 - c. Suctioning-Tracheobronchial
 - d. Suctioning-Upper Airway, Soft and Rigid
4. Is there a specific therapeutic niche and/or subpopulation of patients to which its use should be restricted? Per manufacturer's website, any adult or child over 22 lbs. (10 kg) with foreign body obstruction after failed attempts at AHA/American Red Cross protocols.
5. It is unclear if the product causes pressure that could potentially lead to worsening of foreign body obstruction-see safety section below.
6. Does a safer or less expensive alternative exist? No
7. Do other operational benefits exceed risks? This product may be operationally beneficial in an EMS agency not authorized or competent to perform forceps removal or if a foreign body is not visualized.

INDICATIONS:

Choking adult or child over 22 lbs. (10 kg) that cannot cough or speak (i.e. concern for airway obstruction) that have failed attempts at American Heart Association/American Red Cross choking guidelines.

CONTRAINDICATIONS:

Responsive patients with partial foreign body obstructions.

Patients weighing less than 22 lbs. (10 kg).

CLINICAL PHARMACOLOGY

Not applicable to this product

THERAPEUTIC EFFICACY

The clinical evidence for this product is of low to moderate quality based mostly on a Correspondence to a peer-reviewed journal, and abstracts submitted to professional organization conferences (which are subsequently published in their accompanying journals) and case reports. The data in these correspondence and abstracts appear to be the same data elements used among a few of the abstracts; conflicts of interest between the investigator and product owner were identified in 2 abstracts.

1. LifeVac tested in an adolescent choking simulator, successfully removing the object (hot dog bolus) 472 out of 500 attempts in one attempt, in 497 out of 500 in two attempts, and all obstructions were removed in three attempts. (Abstract)

[https://www.annemergmed.com/article/S0196-0644\(17\)31252-0/pdf](https://www.annemergmed.com/article/S0196-0644(17)31252-0/pdf)

2. LifeVac tested in 1 human cadaver model, with successful removal of the foreign body in 49/50 attempts, and 50/50 within 2 attempts. (Correspondence)

[https://ac.els-cdn.com/S0735675716002515/1-s2.0-S0735675716002515-main.pdf?_tid=725db023-a21b-4124-](https://ac.els-cdn.com/S0735675716002515/1-s2.0-S0735675716002515-main.pdf?_tid=725db023-a21b-4124-961e671a16fe6168&acdnat=1532605997_053ae6f21ab58d313dc7b8f4a91f2f50)

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3. No studies have compared LifeVac to standard protocols. No studies have compared LifeVac to other anti-choking devices head-to-head. A randomized control trial evaluating this product is unlikely to ever receive IRB approval on live human subjects.

ECONOMIC EVALUATION

- There is no published literature on the economic impacts.
- Cost of product from vendor: \$65 per kit (device, 1 pediatric mask, 1 adult mask, instruction booklet)
- Cost of replacement masks: \$5.95 (adult and pediatric)
- Manufacturer recommends replacing unused masks every 2-3 years
- Reimbursement to EMS providers-consult billing service.

Based on available clinical outcomes and other market alternatives to the product, is the cost justified? Yes.

SAFETY EVALUATION

There is no published literature on safety. The manufacturer discusses a one-way valve that claims to prevent air from being forcibly entered into the mouth of a patient when the plunger is depressed; however there is no data to support this claim. It would be prudent to seek evidentiary data from the manufacturer.

PRODUCT IMAGE



- Look alike / sound alike products: None
- Product size/availability options: The LifeVac EMS kit comes with 1 adult mask, 1 pediatric mask as well as instructions for use; see their website for additional options.

TRAINING REQUIREMENTS

Per manufacturer's website (<https://lifevac.net/training/>), 4'26" online video to watch with a printed certificate.

Didactic and practical training with adult and pediatric masks on a choking mannequin are recommended.

Competency verification and attestation from the service EMS Medical Director are recommended.

PROTOCOL APPLICATION

LifeVac use could be incorporated into an airway obstruction protocol for unresponsive, fully obstructed choking patients when basic dislodging maneuvers are not successful and manual removal is not available or practical based on EMS provider competency or the ability for visualization of the foreign body.

SUMMARY AND RECOMMENDATION

- LifeVac is a manual, portable suction apparatus for removal of foreign body obstruction refractory to other attempts at dislodgement.
- Limited, low to moderate quality data exists to support its use; the device does appear successful in both simulation and cadaver models.
- I recommend that LifeVac supplies performance data regarding their claim that the valve prevents air from being forcibly entered into a patient's mouth.

Based upon this summary and with the caveat of additional data, I recommend approving a portable, manual, suction apparatus as an adjunct in the management of complete foreign body obstruction as outlined; I am not making a product endorsement with this evaluation.

OTHER MATERIALS

<https://fox6now.com/2018/07/05/a-heimlich-alternative-wisconsin-medical-experts-say-anti-choking-device-needs-more-testing/>

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