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**Company:** Pneumatic, Inc.

**Market:** Emergency Medical Services (EMS) Products

**Product:** Capnospot®

### Company Highlights

- In July 2021, Pneumatic, Inc., signed an exclusive patent license with Mayo Clinic for the Capnospot® medical device
- Device used in both preclinical animal studies and in human studies at Mayo Clinic
- In September 2021, Pneumatic, Inc. established a manufacturing partnership with Nagreiter, a medical device development organization
- Raised \$783,500 to date from investors including angel groups and medical professionals, such as trauma and thoracic surgeons

### WHY IT'S INTERESTING

A third of preventable trauma deaths result from tension pneumothorax, or a collapsed lung. These happen as a result of a traumatic injury to the lung, like a gunshot wound, broken rib, certain medical procedures, or damage from underlying heart disease.<sup>i ii</sup> In these cases, air becomes trapped outside the lung, which can become fatal if not treated immediately. The current standard of care to prevent these deaths is to use a needle to therapeutically decompress the excess air and listen for an audible “gush”. This manual process can be prone to human error, as the emergency maneuver is usually performed in stressful and noisy environments. Successful completion of the decompression is critical to the care of a collapsed lung.<sup>iii</sup>

Pneumatic's Capnospot® is a simple medical device designed to assure the user that therapeutic decompression has been successful, helping to remove the concern of human misjudgment. Instead of listening for the standard “gush of air” to confirm successful decompression, the Capnospot® uses a visual color change. Pneumothorax air contains CO<sub>2</sub>, which alters the Ph on colorimetric paper, changing the color. A piece of this reactive paper is contained in the device and changes from blue to yellow to confirm procedure success.

The Capnospot® is designed to be intuitive to the end user, inexpensive to manufacture, and the technology is protected through a licensed-patent agreement with Mayo Clinic, a renowned 158-year-old medical institution. Capnospot® is a Class I type device with an abbreviated 510k requirement and once cleared, the company will be able to market and sell the device in the U.S. Pneumatic has raised \$784,000 to date from angel groups and medical professionals.



Pneumeric, Inc. is a medical device company aimed at improving care in military and civilian trauma for those affected by pneumothorax, or a collapsed lung. Their mission is to “save soldiers and civilian lives from traumatic injuries that kill.” The company has developed the Capnospot<sup>®</sup>, a device for needle thoracostomy that changes color upon successful completion, providing a visual confirmation. The team believes the Capnospot<sup>®</sup> has the potential to become the new standard of care for collapsed lungs. In the same month of incorporation, the company entered a licensing agreement with Mayo Clinic to use its patented technology of the Capnospot<sup>®</sup>. Only a few months later, the company established a contract manufacturer partnership and initiated its design and manufacturing phases. In March 2022, the Capnospot<sup>®</sup> was classified as a Class I device by the FDA and requires an abbreviated 510(k). The company is currently preparing to file this 501(k) to receive the Food and Drug Administration’s (FDA’s) clearance prior to marketing the device in the United States.

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## **COMPANY SUMMARY**

### **Opportunity**

Tension pneumothorax occurs as a result of traumatic lung injury, like a gunshot wound or broken rib. Air becomes stuck outside the lung,<sup>iv</sup> which increases in pressure and represses blood circulation. This condition is a common cause of death in trauma and must be decompressed successfully and expeditiously to save the patient’s life. The current standard of care relies on a manual needle thoracostomy for decompression; however, it leads to subjective assessments as operators must listen for a “gush of air” and/or feel for a “pop” or “sudden decrease in resistance”. With many of these emergency operations taking place in noisy, tense, and stressful environments, this current standard of care can become ineffective with human error.<sup>v</sup>

Pneumeric, Inc. has developed a novel visual detection device for these procedures. The Capnospot<sup>®</sup> is engineered to provide visual detection of a successful decompression using reactive paper that changes color when it comes in contact with the trapped air. With this device, operator uncertainty during tension pneumothorax operations can be reduced, as the Capnospot<sup>®</sup> gives operators a visual “yes” or “no” result to confirm success.

### **Product**

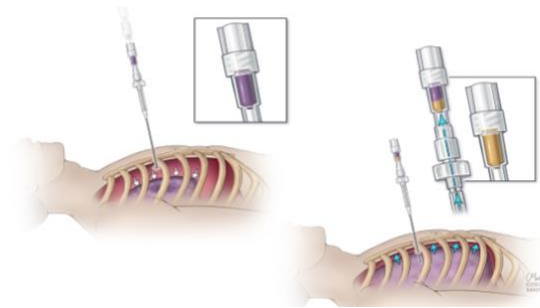
The Capnospot<sup>®</sup> is a visual detection device for needle thoracostomy designed to replace the current standard of care. The Capnospot<sup>®</sup> is a lightweight and portable device that provides near real-time confirmation of successful treatment with a color change, representing a binary “yes” or “no” and helps remove operator subjectivity during collapsed lung treatment. The Capnospot<sup>®</sup> uses a colorimetric indicator (Ph paper) to detect CO<sub>2</sub> present in the expired air of a collapsed lung. When the colorimetric indicator detects the presence of CO<sub>2</sub>, it changes from blue to yellow, indicating whether or not the collapsed lung has successfully been decompressed.



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Capnospot® affixed to needle **A.** Before decompression and. **B.** after successful needle

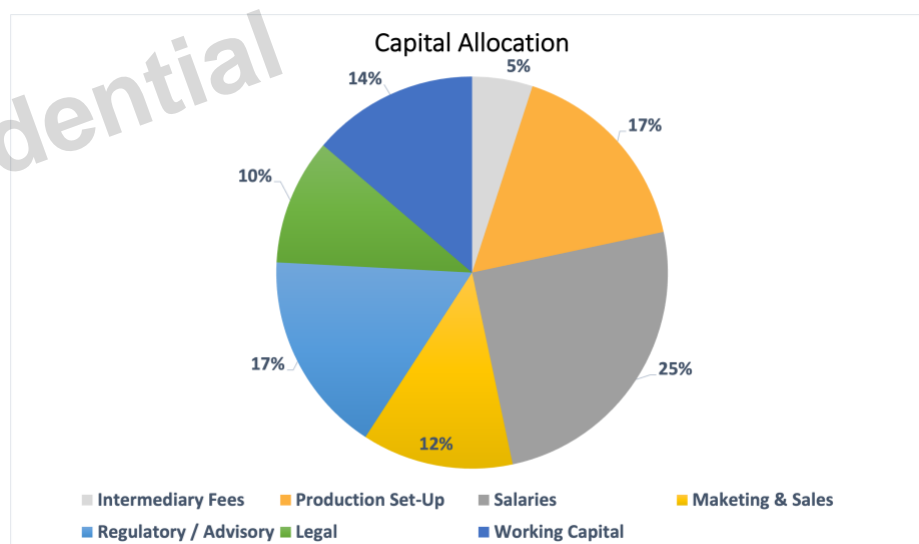


Left: Placement of Capnospot® before encountering pressurized pneumothorax gas with elevated CO<sub>2</sub>.  
Right: Color change after detection of waste gas passing detector with elevated CO<sub>2</sub>.

The Capnospot® was designed and developed at the Mayo Clinic, where it exhibited compelling pre-clinical and clinical data supported through government funding. Pneumatic currently has an exclusive licensing agreement with Mayo Clinic to use two U.S. issued utility patents and one PCT for the Capnospot® device covering all aspects of the system for the qualitative and quantitative measurement of CO<sub>2</sub> and pressure of gas coming out of the chest. Additionally, during subsequent commercial development with Naglreiter, an additional provisional patent was filed.

### Use of Proceeds and Product Roadmap

Pneumatic, Inc. plans to use the funds for additional working capital required for sales and marketing, administration and operations, manufacturing, and distribution to bring the device to market. If the company raises the minimum amount of \$25,000, the funds will go towards "Production Set-Up," minus the intermediary fee. If the company raises the full amount of \$1.2 million, it will allocate the capital in the following ways.





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## Business Model

Pneumeric, Inc. plans to use established distribution partnerships and channels for both military and civilian sales. Pneumeric, Inc. plans to distribute the Capnospot® through three channels:

1. Direct Retail/Wholesale Civilian to Hospital & Emergency Medical Services (EMS)
2. Indirect Wholesale Military/Civilian
3. Strategic Partnerships with Distributors and Governments

## USER TRACTION

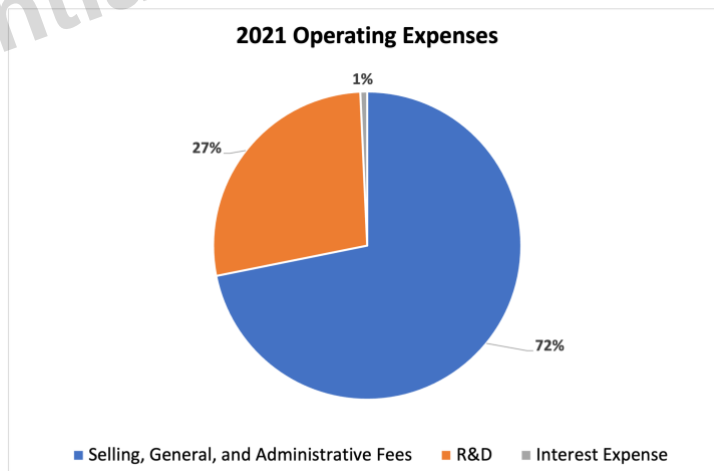
In September 2021, Pneumeric, Inc. established a manufacturing partnership with Naglreiter, a medical device development organization. The manufacturing process has two main phases: design and verification/validation. The design phase has been completed and the verification and validation phase is nearing completion. The activities in each phase will be performed in compliance with ISO standards and FDA standards and regulations.



As of March 2022, the Capnospot® is a Class I type device with an abbreviated 510k requirement based on an official FDA 513g response from the FDA. Pneumeric, Inc. is in the process of filing a 510(k) with the Food and Drug Administration, and once cleared, the Company will be able to market and sell the device in the U.S.

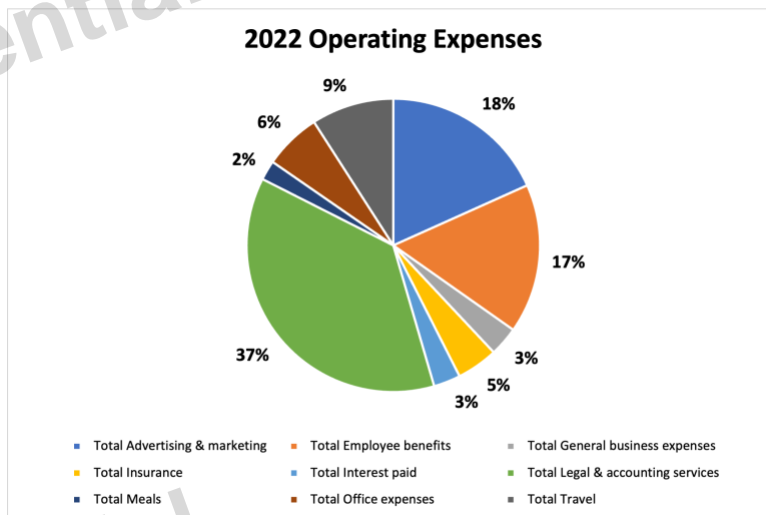
## HISTORICAL FINANCIALS

The Company is in the early stages of developing a commercially viable product and has not generated revenues. The Company has obtained an exclusive license for the patented product that is being developed and engaged with a manufacturing company to design, prototype, and develop the product for large scale production.





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From October 2021 through July 2022, the company averaged a monthly cash burn of \$73,143, and had \$220,728 cash on hand as of August 2022.

## INDUSTRY AND MARKET ANALYSIS

In 2020, the global emergency medical services (EMS) products market size was estimated at \$21.5 billion and is expected to grow to \$34.3 billion by 2027, representing a CAGR of 6.9%. Catalysts driving growth to the market include the increasing demand for emergency care, the rising frequency of trauma, and the growing spending on health care worldwide.<sup>vi</sup> According to data from the Centers for Medicare and Medicaid Services (CMS), health spending in the U.S. is expected to grow at a CAGR of 5.4% through 2028, accumulating to \$6.2 trillion and 19.7% of GDP.<sup>vii</sup> Additionally, data from the National Fire Protection Association (NFPA) reveals that EMS calls have continued to increase almost every year, further driving demand to the market.<sup>viii</sup>

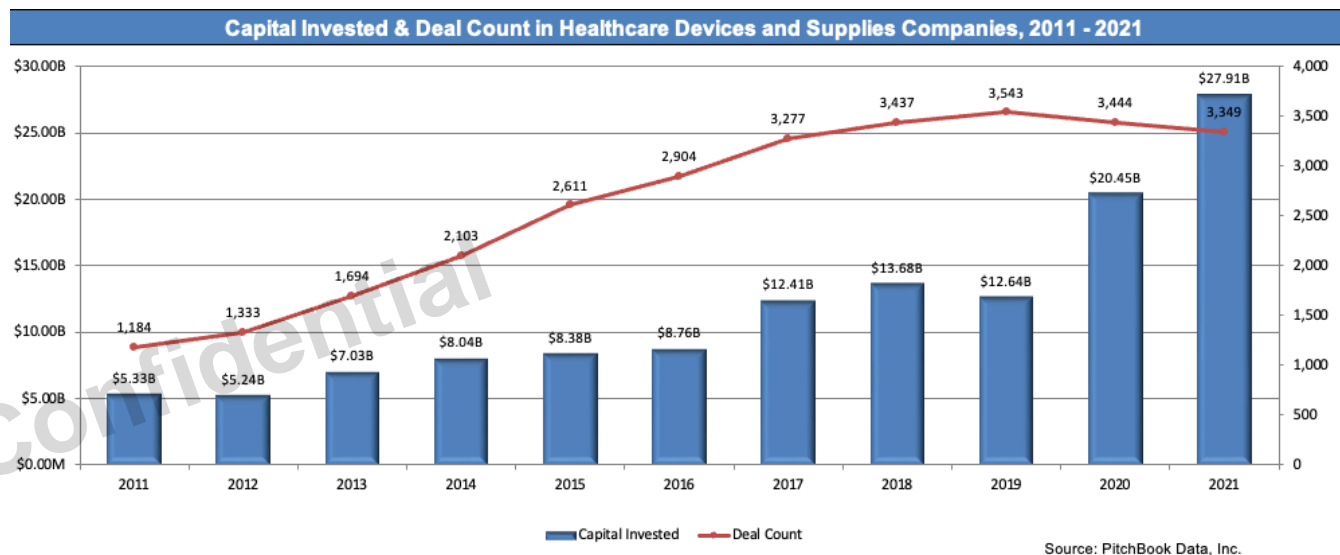
Based on end-users, the U.S. EMS products market is segmented into: fire department services, government or third-party services, private transport services, hospital-owned services, public utility models, and volunteer services. Fire department services typically make up the largest portion of the market as they are usually the first responders to a call.<sup>ix</sup> In 2020, there were approximately 1.1 million firefighters in the U.S. alone, and experts predict that number will continue to increase over the next 8 years, driving growth to the total addressable market (TAM) of Pneumeric. <sup>x</sup> Other end-users of Pneumeric's Capnospot® include Active-Duty Combat Military, Ground and Air Ambulance Vehicle, Hospital Emergency Rooms, and Commercial Aircraft. All the end-user categories are expected to increase over the next several years as populations and healthcare infrastructure investments continue to grow.



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Highlights from venture capital financings into the healthcare devices and supplies industry include:<sup>xi</sup>

- Total investments of \$129.85 billion across 28,879 deals from 2011 to 2021
- Capital invested peaked in 2021, with more than \$27 billion invested
- Deal count peaked in 2019
- Median pre-money valuation was \$13.94 million in 2021, a high during the observed period



## COMPETITORS

The Capnospot<sup>®</sup> device could potentially be one of the first portable devices to specifically assess whether therapeutic decompression has been successful for pneumothorax with a visual confirmation. To our knowledge, there is no known device that has been developed as an adjunct for decompression that is simple, reproducible, portable, and generalizable to the broad treatment of trauma patients in the prehospital setting. In this case, the following companies have various adaptations of spring loaded or modified angiocatheters and could serve as potential licensing opportunities owing to the Capnospot's<sup>®</sup> complementary ability to detect CO<sub>2</sub>.



**H&H Medical:** H&H Medical is the manufacturer and wholesaler of critical trauma care products intended to meet immediate and urgent needs. Among its many products, the Company offers a Tension Pneumothorax Access Kit (TPAK) at \$17.76 per unit. The device is a 14 gauge by 3.25-inch needle and catheter for use in the management of combat casualties who present with the signs and symptoms of a tension pneumothorax.<sup>xii</sup> H&H Medical was acquired by Safeguard Medical in April 2021 for an undisclosed amount.<sup>xiii</sup>



**Chinook Medical Gear, Inc.:** Chinook Medical Gear is an online retailer that provides custom medical solutions for the harshest environments. Among its many products, the Company offers a SPEAR-Simplified Pneumothorax Emergency Air Release 10g at



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\$45.99 per unit. The convenient device allows either lateral decompression or traditional anterior needle thoracostomy.<sup>xiv</sup>



**North American Rescue:** North American Rescue is the developer and distributor of tactical emergency medical equipment. The company offers ways to decrease preventable deaths by providing survivability and casualty-care medical equipment to military, law enforcement, and EMS first responder markets. Among its many products, the Company offers a North American Rescue ARS for Needle Decompression at \$9.60 per unit.<sup>xv</sup>



**Integrated MedCraft:** Integrated MedCraft is a network of patriotic solution providers that are driven to introduce quality medical devices and therapies to market.<sup>xvi</sup> The Company offers a 2<sup>nd</sup> Rib Needle Chest Decompression, 14g x 3.25g at \$8.45-unit.<sup>xvii</sup>

## EXECUTIVE TEAM



**John Aho MD, PhD – CEO & Chief Medical Officer:** Prior to founding Pneumatic, John Aho spent 12 years working for Mayo Clinic in various roles including General Surgery Resident, Chief Resident General Surgery, and Assistant Professor of Biomedical Engineering. Aho is also a licensed board-certified general surgeon. Before his time at the Mayo Clinic, he spent 2 years as a Researcher at the University of Minnesota.



**Jonathan Sackner-Bernstein, MD – Chief Regulatory Officer:** Prior to joining Pneumatic, Jonathan Sackner-Bernstein served as Chief Medical Officer and Board Member for various medical companies. Before those roles, he was a senior official at the United States Food and Drug Administration (FDA). While serving at the FDA, Sackner-Bernstein led a team that created the first two prototypes of what became the Breakthrough Therapy Designation Program and several similar outwardly looking programs. Additionally, he helped The Defense Advanced Research Projects Agency (DARPA) launch its Biological Technologies Office with its research program focused on medicine and biology, with an emphasis on neurosciences.





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**Todd Wiltshire – CFO & Chief Investment Officer:** Todd Wiltshire has over 30 years of experience in finance, including products and development, government affairs/public policy, and trading functions. He's worked at Morgan Stanley, UBS, and most recently spent 14 years in Fidelity Investments Capital Markets unit. Wiltshire earned an AD in Government and Law from Lafayette College and an MBA in Finance from Fordham University.



**Sasha Gentling, CFA – EVP, Business Development:** Prior to joining Pneumeric, Sasha Gentling served as Director of Investor Relations at a public medical device company. Before that role, she was an Investment Officer at Mayo Clinic where she oversaw external manager relationships and conducted comprehensive due diligence on new investments in public and private markets. Gentling holds a BA from Middlebury College and an MBA from Columbia Business School. Additionally, she is a current CFA charterholder.

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### PAST FINANCING

Since inception, the company has raised \$783,500 in convertible notes and \$150,000 via a promissory note. The capital from most of these notes was received in early 2022 for use as operating capital. The specific terms for each convertible note, and promissory note, can be found in the "Capitalization & Ownership" section of the Form C.

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### INVESTMENT TERMS

**Security Type:** Crowd Notes

**Round Size:** Min: \$25,000 Max: \$1,200,000

**Discount Rate:** 20%

**Valuation Cap:** \$9 million

**Conversion Provisions:** In connection with equity financing of at least \$1 million, the Company has the option to convert the Crowd Note into non-voting preferred stock at a price based on the lower of (A) a 20% discount to the price per share for preferred stock by investors in the qualified equity financing or (B) the price per share paid on a \$9 million valuation cap. Please refer to the Crowd Note for a complete description of its terms, including the conversion provisions.





### Investment Risk

An investment in the company is speculative, and as such is not suitable for anyone without a high tolerance for risk and a low need for liquidity. You should invest only if you are able to bear the risk of losing your entire investment. There can be no assurance that investors will receive any return of capital or profit. Investors should have the financial ability and willingness to accept the risks (including, among other things, the risk of loss of their entire investment and the risks of lack of liquidity) that are characteristic of private placement investments. There will be no public market for the securities being offered, applicable securities laws will restrict any transfer of the securities, and the securities will not be transferable without the company's consent.

The information provided herein is not intended to be, nor should it be construed or used as, investment, tax or legal advice, a recommendation to purchase, or an offer to sell securities of the company. You should rely on the offering statement and documents attached as exhibits to the offering statement when making any investment decision. An investment in the company is not suitable for all investors.

### Company Risk

The company's industry is highly competitive, and the company may not be able to compete effectively against the other businesses in its industry. The company is subject to a number of significant risks that could result in a reduction in its value and the value of the company securities, potentially including, but not limited to:

- Rapidly changing consumer preferences and market trends,
- Inability to expand and maintain market acceptance for the company's services and products,
- Inability to gain access to international markets and comply with all applicable local laws and regulations,
- Inability to achieve management's projections for growth, to maintain or increase historical rates of growth, to achieve growth based on past or current trends, or to effectively manage rapid growth,
- Inability to develop, maintain and expand successful marketing relationships, affiliations, joint ventures and partnerships that may be needed to continue and accelerate the company's growth and market penetration,
- Inability to keep pace with rapid industry, technological and market changes that could affect the company's services, products and business,
- Technological problems, including potentially widespread outages and disruptions in Internet and mobile commerce,
- Potential costs and business disruption that may result if the company's customers complain or assert claims regarding the company's technology,
- Failure to adequately address data security and privacy concerns in compliance with U.S. and international laws, rules and policies,
- Performance issues arising from infrastructure changes, human or software errors, website or third-party hosting disruptions, network disruptions or capacity constraints due to a number of potential causes including technical failures, cyber-attacks, security vulnerabilities, natural disasters or fraud,
- Inability to adequately secure and protect intellectual property rights,
- Potential claims and litigation against the company for infringement of intellectual property rights and other alleged violations of law,



- Difficulties in complying with applicable laws and regulations, and potential costs and business disruption if the company becomes subject to claims and litigation for legal non-compliance,
- Changes in laws and regulations materially affecting the company's business,
- Liability risks and labor costs and requirements that may jeopardize the company's business,
- Dependence on and inability to hire or retain key members of management and a qualified workforce,
- Ongoing need for substantial additional capital to support operations, to finance expansion and/or to maintain competitive position,
- Issuance of additional company equity securities at prices dilutive to existing equity holders,
- Potential significant and unexpected declines in the value of company equity securities, including prior to, during, and after an initial public offering, and
- Inability of the company to complete an initial public offering of its securities, merger, buyout or other liquidity event.

i J. J. McPherson, D. S. Feigin, R. F. Bellamy, Prevalence of Tension Pneumothorax in Fatally Wounded Combat Casualties, *J. Trauma Inj. Infect. Crit. Care* 60, 573–578 (2006).

ii J. B. Holcomb, N. R. McMullin, L. Pearse, J. Caruso, C. E. Wade, L. Oetjen-Gerdes, H. R. Champion, M. Lawnick, W. Farr, S. Rodriguez, F. K. Butler, Causes of Death in U.S. Special Operations Forces in the Global War on Terrorism, *Ann. Surg.* 245, 986–991 (2007).

iii <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7870512/>

iv <https://www.verywellhealth.com/pleural-cavity-function-conditions-2249031#:~:text=The%20pleural%20cavity%20is%20the,expand%20and%20contract%20during%20resp>iration.

v <https://europepmc.org/article/pmc/pmc7870512>

vi <https://www.expertmarketresearch.com/reports/emergency-medical-services-products-market>

vii <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet#:~:text=NHE%20grew%209.7%25%20to%20%244.1,16%20percent%20of%20total%20NHE>.

viii <https://www.nfpa.org/News-and-Research/Data-research-and-tools/Emergency-Responders/Fire-department-calls>

ix <https://www.grandviewresearch.com/industry-analysis/us-emergency-medical-services-ems-products-market>

x <https://www.firerescue1.com/fire-products/firefighter-accountability/articles/top-12-firefighter-facts-ZNtSIYDCA0tbwJ2P/>

xi PitchBook Data; Downloaded January 11<sup>th</sup>, 2022

xii <https://buyhandh.com/collections/advanced-trauma/products/h-h-tension-pneumothorax-needle>

xiii <https://www.bioworld.com/articles/506163-safeguard-medical-acquires-hh-medical-corp?v=preview>

xiv [https://www.chinookmed.com/02228/spear-simplified-pneumothorax-emergency-air-release-10g?source=froogle&gclid=CjwKCAjw9qiTBhBbEiwAp-GE0ZsxqIqGmlqBcwtvw2Yez9oiMbekms8bw-7ooWsqi4HzcKGf06Fo9xoCDk4QAvD\\_BwE](https://www.chinookmed.com/02228/spear-simplified-pneumothorax-emergency-air-release-10g?source=froogle&gclid=CjwKCAjw9qiTBhBbEiwAp-GE0ZsxqIqGmlqBcwtvw2Yez9oiMbekms8bw-7ooWsqi4HzcKGf06Fo9xoCDk4QAvD_BwE)

xv <https://liveactionsafety.com/north-american-rescue-ars-for-needle-decompression-14g-x-3-25/?sku=STZZ->



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mD7KcaApcrEALw\_wcB

<sup>xvi</sup> <https://integratedmc.com/pages/about-us>

<sup>xvii</sup> [https://integratedmc.com/products/2nd-rib-needle-chest-decompression-14g-x-3-25?currency=USD&utm\\_medium=cpc&utm\\_source=google&utm\\_campaign=Google%20Shopping&gclid=Cj0KCQjw4uaUBhC8ARIsANUuDjVy9zYwRVpY4iPSl5nSetECDoMi2yhjurp2A0BAGEfnWl5S6cgaxy8aAsKU](https://integratedmc.com/products/2nd-rib-needle-chest-decompression-14g-x-3-25?currency=USD&utm_medium=cpc&utm_source=google&utm_campaign=Google%20Shopping&gclid=Cj0KCQjw4uaUBhC8ARIsANUuDjVy9zYwRVpY4iPSl5nSetECDoMi2yhjurp2A0BAGEfnWl5S6cgaxy8aAsKU)  
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