



**PRENTISS  
SMITH & CO**

Socially Responsible Investment Report for:

## INSPIRE MEDICAL

Maple Grove, MN

Ticker: INSP US Equity

Website: [www.inspiresleep.com](http://www.inspiresleep.com)

Last Updated: 10-09-2022

## I. Exclusionary Screening

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Does INSPIRE MEDICAL appear on any of the following lists? In our exclusionary screening, a single appearance disqualifies an investment.

### Fossil Fuels & Precious Metals Mining

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- ☒ BICS - Oil, Gas & Coal Industries<sup>1</sup>
- ☒ BICS - Precious Metals Mining<sup>1</sup>
- ☒ CDP/CAI Carbon Majors Database<sup>2</sup>

### Pornography, Gambling & Tobacco

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- ☒ BICS - Casinos<sup>1</sup>
- ☒ BICS - Tobacco<sup>1</sup>
- ☒ BICS - Pornography<sup>1</sup>

### Agrochemicals & Animal Cruelty

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- ☒ BICS - Crop Chemicals & Fertilizers<sup>1</sup>
- ☒ Cruelty Free Investing Worst Companies for Animals<sup>3</sup>

### Defense & Retail Gun Sales

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- ☒ BICS - Defense Primes<sup>1</sup>
- ☒ SIPRI Arms Industry Database<sup>4</sup>
- ☒ Gun Retailers<sup>5</sup>
- ☒ NRA Top Allies<sup>6</sup>

### Private Prisons

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- ☒ BICS - Security Services<sup>1</sup>

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<sup>1</sup> BICS = [Bloomberg Industry Classification Systems](#)

<sup>2</sup> [CDP/CAI Carbon Majors](#)

<sup>3</sup> [Cruelty Free Investing 10 Worst Companies for Animals](#)

<sup>4</sup> NRA = [National Rifle Association Top 10 Industry Allies](#)

<sup>5</sup> Prentiss Smith & Company Internal Research

<sup>6</sup> SIPRI = [Stockholm International Peace Research Institute](#)

## II. Research Narrative

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What else has our research process told us about how INSPIRE MEDICAL conducts business, in terms of its products and services, its environmental impact, and its approach to governance?

### Summary

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Inspire Medical Systems became a public company in 2018, having spun off from Medtronic in 2007 to focus on an implantable neurostimulation therapy solution for obstructive sleep apnea (OSA). The company's solution received FDA approval in 2014, when a study demonstrated a 68% decrease in the median number of breathing interruptions for patients using the device. Inspire now reports that over 24,000 patients overall have used its treatment. Estimates are that as many as 30 million Americans may suffer from OSA (with some estimates reaching 1 billion globally), while about 6 million Americans have been clinically diagnosed. Many of those struggle to tolerate the current predominant treatment, a machine delivering CPAP (continuous positive airway pressure), which requires wearing a facemask at night that can be cumbersome and restrictive. The potential health benefits for Inspire's technology, therefore, are quite large, and constitute a clear and singular social good the company can deliver.

Inspire does not publish an annual sustainability report, and does not set targets for carbon emissions, workforce diversity, supply chain transparency, or in other key environmental and social areas. If Inspire continues to grow, we would expect the company to increase its disclosure in these and other areas. Inspire's 11-person executive team has just one woman, although the company does have three Black executives, and there is gender parity on its board.

### Products & Services

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Inspire Medical Systems was spun off by healthcare technology company Medtronic in 2007, although it wasn't until 2018 that Inspire made its initial public offering. Operating as a private medical device company, in 2009 Inspire completed the first human implant of the Inspire II system designed to treat Obstructive Sleep Apnea (OSA), having licensed the intellectual

property and technology from Medtronic.<sup>1</sup> Headquartered in Golden Valley, Minnesota, Inspire's employee base totalled 485 in 2021, a 53% increase from the previous year.<sup>2</sup> Inspire says it is "dedicated to elevating and redefining the standard of care for obstructive sleep apnea"<sup>3</sup> and reports that as of 2022, "physicians have treated more than 24,000 patients with Inspire therapy at over 820 medical centers across the United States and Europe."<sup>4</sup>

OSA is a disorder characterized by recurrent blockages of the upper airway during sleep, resulting in negatively impacted sleep quality and blood oxygen levels. Inspire's neurostimulation technology is intended to provide a minimally invasive alternative to the predominant method of sleep apnea treatment known as CPAP (Continuous Positive Airway Pressure), a system designed to prevent airway blockages by delivering air pressure through a facemask connected by a plastic hose to a machine.<sup>5</sup> Many patients have struggled to tolerate CPAP treatment due to the cumbersome and restrictive aspect of the equipment.

It is estimated that some 30 million Americans suffer from OSA, but that only about six million have been clinically diagnosed. According to a Johns Hopkins study, approximately 45% of adults experience snoring, and other studies have estimated that 75% of people who snore experience at least some form of sleep apnea.<sup>6</sup> Men are twice as likely as women to develop the disorder, and while this disparity in prevalence has been consistently borne out by research, the actual causes of it are only vaguely understood. Inherent biological differences such as "fat distribution, length and collapsibility of the upper airway, neurochemical control mechanisms, arousal response, and sex hormones" are all thought to be contributing factors to the higher prevalence among males.<sup>7</sup> Regardless of gender, the leading cause of sleep apnea is widely reported to be excess weight and obesity.<sup>8</sup> Other risk factors for OSA include smoking, alcohol abuse, hypothyroidism, and certain anatomical features such as an overbite, wide neck circumference, or narrow throat. Side effects of sleep apnea include daytime fatigue, forgetfulness, and irritability, in addition to the wide-ranging spectrum of adverse health effects attributable to poor sleep quality.

In 2014, the Inspire system became the first implantable neurostimulation therapy for the treatment of OSA to garner FDA approval. That same year, a clinical trial known as the STAR (Stimulation Therapy for Apnea Reduction) trial was conducted to measure the long-term safety

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<sup>1</sup>

<https://www.inspiresleep.com/wp-content/uploads/2015/10/Inspire-Medical-Systems-Completes-First-Implant-of-the-Inspire-II-System.pdf>

<sup>2</sup> <https://www.macrotrends.net/stocks/charts/INSP/inspire-medical-systems/number-of-employees>

<sup>3</sup> <https://www.inspiresleep.com/about-inspire/>

<sup>4</sup> <https://investors.inspiresleep.com/investors/our-company/our-history/default.aspx>

<sup>5</sup> <https://www.yalemedicine.org/news/sleep-apnea-cpap>

<sup>6</sup> <https://www.fool.com/investing/2022/04/20/this-tiny-medical-device-will-make-billions-of-dollars/>

<sup>7</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2642982/#R12>

<sup>8</sup> <https://www.webmd.com/sleep-disorders/sleep-apnea/obstructive-sleep-apnea-causes>

and efficacy of the Inspire system. The findings, published in an article in the New England Journal of Medicine, revealed that in a sample group of 126 participants (83% male, with the mean age and body mass index being 54.5 years and 28.4), the median number of breathing interruptions at 12 months “decreased 68% from 29.3 events per hour to 9 events per hour.”<sup>9</sup> The article furthermore reported that: “secondary outcomes measured showed a reduction in the effects of sleep apnea and improved quality of life.”<sup>10</sup>

Inspire’s implantable device functions as a hypoglossal nerve stimulator. The hypoglossal nerves stem from the brain along both sides of the jaw bone and terminate in the tongue (the literal definition of “hypoglossal” being “under the tongue”). In stimulating the hypoglossal nerve, the device effectively triggers slight motion in the base of the tongue, causing it to shift forward. In many instances of OSA, airway obstructions can be caused by the tongue receding to such an extent that the throat becomes blocked, which is partly why this approach to sleep apnea treatment can be so effective.<sup>11</sup> Stimulation of the hypoglossal nerve corrects the position of the tongue so that the patient’s airway will remain unobstructed over the course of the night. The device consists of three components: the neurostimulator battery, which is implanted in the pectoral muscle just below the collar bone; the breathing sensor lead, implanted in the fourth intercostal region of the ribcage; and the stimulation lead, implanted in the upper neck, in direct contact with the hypoglossal nerve. When the breathing sensor lead detects that breathing has stopped, the stimulation lead is triggered. The device can be powered on or off with a remote control, and patients can also customize the degree of stimulation they wish to receive. The battery has to be replaced approximately every ten years, requiring a relatively straightforward surgical procedure.

As of 2022, the cost of an Inspire implant device (including outpatient surgery) amounted to about \$30,000, as compared to \$45,000 in 2015.<sup>12</sup> Given that CPAP machines tend to only cost between \$250 and \$1,000, patients will often have to make the case that CPAP wasn’t a suitable treatment method before Medicare or other insurers will subsidize the cost of Inspire’s neurostimulation treatment. Currently, most major U.S. insurance companies cover Inspire, and Medicare and Veterans Affairs (VA) will generally fund a significant portion of the cost. In order to be eligible for an Inspire implant, the patient must have a BMI below 32.<sup>13</sup>

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<sup>9</sup> <https://pubmed.ncbi.nlm.nih.gov/24401051/>

<sup>10</sup> <https://pubmed.ncbi.nlm.nih.gov/24401051/>

<sup>11</sup> <https://www.youtube.com/watch?v=NJV8JPGuEIM>

<sup>12</sup> <https://www.healthline.com/health/sleep-apnea/sleep-apnea-implant>

<https://www.cnet.com/health/medical/what-is-inspire-for-sleep-apnea-what-to-know-about-the-new-treatment/>

<sup>13</sup> <https://www.entlubbock.com/blog/inspire-for-sleep-apnea/>

In 2020, Inspire Medical established an advisor care program (ACP), which serves as a call center to “provide potential patients with information about Inspire therapy, available commercial and Medicare insurance coverage, and make a tailored referral to an ENT surgeon or sleep physician in the patient’s local area.”<sup>14</sup> In addition to improving and expanding accessibility to American consumers, Inspire is working to strengthen its base in European countries that provide sufficient reimbursement levels, such as Germany and the Netherlands, while also laying the groundwork for future expansion in the British, French, and Belgian healthcare systems. In Asia, Inspire Medical has established an exclusive distribution agreement with Japan Lifeline, a leading medical technology distributor in Japan.<sup>15</sup> Inspire reports that in 2021 the number of independent and company-supported peer-reviewed publications by researchers on Inspire therapy grew by 40, “increasing the total number of such publications to over 190.”<sup>16</sup>

In furthering the mission to improve patient outcomes and the standard of Obstructive Sleep Apnea care, Inspire is developing the Inspire V next generation neurostimulation system, as well as the next phase of the Inspire digital patient data management system, the Inspire Cloud. The new system will utilize an FDA-approved Bluetooth® enabled patient remote, which will facilitate and enhance the transmission of patient and device information to the Inspire Cloud via the Inspire Sleep smartphone application.<sup>17</sup>

## Environment

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As a relatively early-stage company, Inspire Medical does not provide significant environmental reporting or disclosure. Given the very low profile of Inspire’s main product, there is likely relatively little environmental impact to consider from a product standpoint, although the company does acknowledge that its third-party manufacturers may deal with hazardous materials, and are bound by all laws governing safe handling and disposal.<sup>18</sup> Aside from products, the environmental concerns facing the company are likely related to energy consumption associated with its offices and its manufacturers.

## Management Integrity and Ethics

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<sup>14</sup> [https://s22.q4cdn.com/384014896/files/doc\\_financials/2021/ar/2021-AnnualReport.pdf](https://s22.q4cdn.com/384014896/files/doc_financials/2021/ar/2021-AnnualReport.pdf)

<sup>15</sup> [https://s22.q4cdn.com/384014896/files/doc\\_financials/2021/ar/2021-AnnualReport.pdf](https://s22.q4cdn.com/384014896/files/doc_financials/2021/ar/2021-AnnualReport.pdf)

<sup>16</sup> [https://s22.q4cdn.com/384014896/files/doc\\_financials/2021/ar/2021-AnnualReport.pdf](https://s22.q4cdn.com/384014896/files/doc_financials/2021/ar/2021-AnnualReport.pdf)

<sup>17</sup> [https://s22.q4cdn.com/384014896/files/doc\\_financials/2021/ar/2021-AnnualReport.pdf](https://s22.q4cdn.com/384014896/files/doc_financials/2021/ar/2021-AnnualReport.pdf)

<sup>18</sup> <https://www.sec.gov/ix?doc=/Archives/edgar/data/1609550/000160955022000014/insp-20211231.htm>

Inspire's founder, Tim Herbert, has served as the President and CEO of the company since 2007, prior to which he spent 11 years at Medtronic, where he held management positions in a variety of departments across the company, including R&D, sales, marketing, and healthcare reimbursement.

<sup>19</sup> Inspire's 11-person executive team includes one woman and three persons of color, while there are five women on its 10-member Board of Directors. Inspire Medical receives a 4.5-star rating (out of 5 stars) from employee review site Glassdoor.<sup>20</sup>

Our research did not find that Inspire Medical is involved in any significant, material legal proceedings.

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<sup>19</sup> <https://www.inspiresleep.com/leadership/>

<sup>20</sup> [https://www.glassdoor.com/Overview/Working-at-Inspire-Medical-Systems-EI\\_IE837302.11.34.htm](https://www.glassdoor.com/Overview/Working-at-Inspire-Medical-Systems-EI_IE837302.11.34.htm)

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