Report Date: April 22, 2020
Company: Inspire Medical Systems, Inc.
Ticker: INSP US
Industry: Medical Devices
Stock Price (USD): $69.68
Market Cap (USD, Millions): $1,840.1

WOLFPACK RESEARCH

Inspire Medical Systems: *A Nightmare Investment*

Introduction

Wolfpack is short Inspire Medical Systems (INSP). The annual market opportunity promoted by its management is so preposterous that it must be disingenuous, leaving investors holding the bag of this terminally unprofitable business. It turns out that Inspire can barely even give their device away: It has been available to ~9 million enrolled U.S. Veterans *for free* since 2014, but data from the VA hospital system show only 387 *total* patients have opted for Inspire's surgery. Our research shows Inspire can't even sell 20,000 units in a year, much less the 500,000 units claimed by management. Inspire's surgically implanted device comes with a long list of onerous lifestyle restrictions and insufferable side-effects that permanently haunt past patients and drive off potential patients. Insiders have pocketed more than $340 million from stock sales, nearly 3x the company's total revenue since the 2018 IPO. Inspire is only good at selling two things: this ridiculous growth story and their stock.

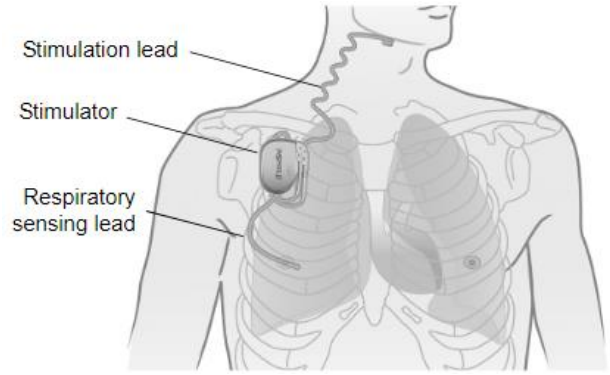
Summary

Inspire's device is far too invasive and restrictive to ever gain traction in a market with numerous non-invasive alternatives.

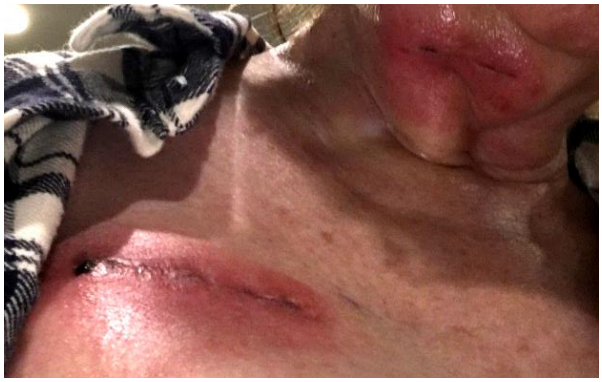
Inspire promotes itself as a minimally-invasive and more convenient solution for Obstructive Sleep Apnea ("OSA"). We found that Inspire's surgery is anything but minimally-invasive. It carries serious risks such as laceration of the jugular, paralysis and leaves large visible scars on the patient's neck and chest. Further, Inspire's device requires additional surgeries to replace the battery every 7-10 years for the rest of your life, which is a shit sandwich in-and-of itself.

In the years between these surgeries, Inspire's device can cause serious injury if the patient has a pacemaker, undergoes an MRI, or requires defibrillation during a cardiac event.[1] All Inspire patients have to live with a nightmarish list of restrictions that make Inspire's *"therapy"* as inconvenient as we could possibly imagine. They must worry about every day activities like answering their cell phone, using a computer or power tools, going to the store and going through airport security because Inspire's device can be damaged by any one of these activities, requiring yet another surgery.

Would you be willing to take on all of these risks and restrictions to *"ease the symptoms"* of a condition that has numerous non-surgical treatment options?



Inspire's promotions



Reality

[1] https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008C.pdf

We reached out to several Inspire patients who had written about their experience online and spoke to four who were willing to share their story with us in detail. After hearing these stories, it appears that the adverse-effects and lifestyle restrictions of Inspire's device can be worse than the symptoms of OSA itself. Inspire's own studies show that the unhappy patients we spoke to were not outliers. During Inspire's self-funded *Stimulation Therapy for Apnea Reduction* ("STAR") study, the key to its FDA approval, 85% (107 out of 126) of patients suffered at least one adverse event. During the 12-month study, these 107 patients experienced 494 total adverse events.[2] We consider this to be very concerning, considering that Inspire hand-picked the patients for this study, rejecting 86% of the original applicants.

Inspire's real-world FDA submitted adverse event reports include horror stories of surgeons lacerating the patient's jugular during surgery and patients nearly dying on the operating table, ending up in ICU without ever receiving the implant.

We have provided a full list of these 192 adverse event reports in Appendix D to this report. In the last month and a half, ten new adverse events were reported to the FDA, five of which resulted in removal of the device for medical necessity.

Two of the Inspire patients we spoke to allowed us to share their stories. We will refer to them as "Patient A" and "Patient B." Patient A felt she was misled about the procedure and the device itself, and that if she had been warned of the potential side-effects, she never would have had the device implanted at all. She told us she experienced three serious adverse events, one of which involved temporary paralysis caused by part of the device slipping down into her abdomen. She claims that when she attempted to contact Inspire about this adverse event, they rejected her claim and "vehemently denied it could have happened." Inspire now ignores her calls, leaving her only with visible scars and regret.

Patient B was nearly 80 years old when she had Inspire's device implanted. She complains that the constant electrical shocks feel like someone is "tugging and twisting" her tongue. This is not an isolated incident – one-third of the patients in Inspire's STAR study complained of similar discomfort from the electrical stimulation.[3] Even worse, Patient B now carries a bucket around her house because of the significant excess mucus production she has experienced since the device was implanted. Inspire does not list this as a potential side-effect of its *"therapy."* Patient B says that the Inspire device has *"ruined her life."* Neither of these patients still use the device, but they are afraid to have it removed due to the serious risks associated with the removal surgery.[4]

We also found a growing list of customer complaints, with terrifying descriptions of the potential downsides to Inspire's invasive procedure, such as *"drooling, facial paralysis or drooping, slurred speech"* and *"nerve damage resulting in numbness and discoloration of one side of the tongue, or battery leaking into body."* These are just a few of the dozens of customer complaints that we found. You can see the full list in Appendix E of this report.

Our research shows that Inspire's management exaggerates its TAM by at least 50x in order to sell investors a growth story they must know is fictional. Despite incessantly touting a $10 billion (500,000 unit) annual market opportunity, insiders have sold more than $340 million worth of stock since the IPO – *nearly 3x the company's total revenues during that period*. Most recently, Chau H. Khuong, an Inspire Director and Partner at OrbiMed Advisors, sold 1.5 million shares for ~$130 million between March 3-6. Just weeks later Inspire pulled its 2020 guidance and announced a secondary offering of 2 million shares at $58.00, a ~35% discount to Khuong's *well-timed* sales.

[2] https://clinicaltrials.gov/ct2/show/results/NCT01161420
[3] https://clinicaltrials.gov/ct2/show/results/NCT01161420?view=results
[4] https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008C.pdf

Sleep Apnea experts we spoke to told us that OSA symptoms are often so subtle that patients don't even realize they have a condition. Inspire's solution for OSA is proving to be about as popular as lobotomies were for treating migraines in the 1950s.[5] Inspire's device has been on the market for 5 years in the U.S. and 9 years in Europe and has only sold ~7,200 units worldwide.

Inspire's massively overstated TAM also underpins investors' dreams of achieving profitability through economies of scale. However, Inspire is actually exhibiting diseconomies of scale. Despite growing its unit sales from ~2,300 in 2018 to ~3,700 in 2019, Inspire's SG&A expense per unit actually *increased* from $23,800 to $24,800. Inspire has already reached the most desperate OSA patients, making each unit more expensive to sell. At an operating margin of -42.5% and free cash flow burn of -$10,000 per unit in 2019, it may seem impossible for INSP's financial performance to get much worse, but it can, and we believe it inevitably will.

This company will likely never make a profit. Its device is only a feasible therapy for Strict Amish Communities who don't use cell phones, power tools, computer disk drives or basically any other technology that we can't live without. Furthermore, we found empirical evidence to prove how unrealistic Inspire's $10 billion per year TAM claim is.

Data from Inspire's most mature markets show that, in reality, the vast majority (99%+) of OSA patients refuse Inspire's surgical solution. Inspire can't even sell patients their device for free. For example, Inspire's device has been available to ~9 million U.S. veterans *at no cost to the patient* through the U.S. Veterans Administration ("VA") for more than five years.[6] However, instead of taking off toward Inspire's massive purported TAM, Inspire's sales to the VA peaked at only 150 units (~1% of VA CPAP) in 2018 and fell to a mere 110 units (~0.7% of VA CPAP) in 2019.[7]

Because patients must first try and reject CPAP treatment to be eligible for Inspire's implant, the number of new CPAP users per year is the starting point for its top-down TAM calculation and the basis for its hyperinflated TAM claims. Inspire uses an internal *"company estimate"* of 2 million new CPAP users per year for this critical assumption. After speaking to numerous industry experts and hearing over and over that Inspire's estimate was far too high, we decided to engage an independent market research firm to get the kind of precise data that Inspire refuses to provide.[8] Their data showed that new CPAP users per year are less than half of the 2 million internal *"company estimate"* Inspire uses in its TAM calculation. After adjusting for patient preference and reviewing Inspire's *actual* sales performance in the five years since its FDA approval, we conclude that Inspire's realistic TAM is less than 2% of what management claims.

Our research proves to us that the internal estimate Inspire uses as the basis for its growth story is a farce. We are providing more truly independent data and estimates for investors than Inspire has. We challenge Inspire's management to provide investors with evidence that supports its opaque internal estimate of 2 million new CPAP prescriptions per year, which it uses as the starting point in its TAM calculation. We spent months speaking to experts, market research firms and other industry participants, none of whom believed Inspire's estimate of 2 million new CPAP prescriptions per year was anywhere near realistic.

Our investment thesis on Inspire: Focus on management's actions, not their words.

Note: *This is not a COVID-19 thesis. While Inspire's 2020 sales will undoubtedly be decimated by the cancellation of elective surgeries, which management unsurprisingly waited as long as possible to mention to investors, our thesis on Inspire has nothing to do with COVID-19 and everything to do with management cashing out while promoting bad faith estimates for future growth, which our research shows to be entirely unrealistic.*

[5] https://link.springer.com/referenceworkentry/10.1007%2F978-0-387-79948-3_44
[6] https://fas.org/sgp/crs/misc/R43579.pdf
[7] https://www.usaspending.gov/#/recipient/68e6bfb0-1569-b78f-12a0-df8a829e29ff-C/latest
[8] We engaged Frost & Sullivan through a third-party, so they were unaware of the short bias in our research.

1. Inspire's Solution is Worse Than the Problem:

In its promotions, Inspire downplays the terrifying side-effects and high adverse event rates of its surgery by referring to its device as a minimally-invasive solution. CEO Tim Herbert made the following statement at the SVB Leerlink Global Healthcare Conference on February 26, 2020:

> *"And so, here's the new brand, keep it really simple, no mask, no hose, just sleep.* ***We don't talk about implant, we don't talk about surgery****, we talk about a therapy that will -- you'll use every night in your -- procedure, and… so, here's two commercials that we ran."*[9]

However, the Inspire surgical manual tells the surgeon to make three cuts of 2.5 inches each. One on the jaw, one on the collarbone, and another on the ribs. The device then goes into a *"pocket"* which is *"scooped out"* of the chest by the surgeon. The lead wires are *"tunneled"* to the throat and rib-cage. Then excess wire is bundled or wrapped around the device. This seems invasive to us, unless you're comparing it to having a lung removed.

Inspire, by its own admission, purposely avoids talking about implants and surgery because they know these are deterrents to potential patients. See Appendix B for the full gauntlet of pre and post-op procedures Inspire's patients must undergo. We spoke to one Inspire patient who felt she was misled about the procedure and the device itself. We will refer to her as "Patient A."

Patient A believes that Inspire's device never would have worked for her and that if she had been warned of the potential side-effects, she never would have had the device installed at all. The picture below, provided by Patient A, shows just how invasive this procedure really is.

10 Days Post-op:

Patient A told us about three serious adverse events she experienced. She claims that one of these events involved part of the device slipping down into her abdomen, resulting in temporary paralysis. She regrets ever getting involved with Inspire and no longer uses the device.

Another Inspire patient we spoke to, who we'll refer to as "Patient B," was nearly 80 when she had the device implanted. She claims the procedure has resulted in the glands in her throat producing significant amounts of excess mucus. She now carries a bucket around her house to avoid making a mess, as she coughs up mucus throughout the day. Although in her 80s now, Patient B had a healthy social life until the Inspire treatment took its toll. Excess mucus production is *not* listed as a potential side effect, but Patient B believes it clearly should be.

[9] Conference Presentation Transcript – SVB Leerlink, 2/26/2020 via Bloomberg LP

She also complains that the constant electrical shocks feel like someone is "tugging and twisting" her tongue. This is a very common complaint from Inspire patients – one-third of the patients in Inspire's STAR study complained of discomfort from the device's electrical shocks, which are supposed to be providing the "therapy."[10] Patient B claims the Inspire treatment has "ruined her life," and we can understand why.

Just like Patient A, Patient B finds the device impossible to live with. She no longer turns it on at night. Both patients want to have the device removed but fear the significant risks associated with the removal surgery. So, they have simply left the device in place – a not-so-subtle reminder of what changed their lives forever.

We include a ***very long*** list of adverse event reports from the FDA database in Appendix D. There are a disturbing number of cases of surgeons "lacerating" the jugular vein during the procedure, as well as other nightmarish, near-death stories like this one:

> *"During a surgical procedure to implant the Inspire System, shortly after putting the stimulation cuff on, the patient coded and his heart rate went down to 28. An emergency team responded in the operating room and provided treatment. Immediately after treatment, the patient's blood pressure dropped and the emergency team again provided treatment. The physician decided to end the case. The patient is currently in the ICU and should make a full recovery."*

Inspire reports having done ~7,200 implants, and there have been 192 adverse events reported to the FDA as of the date of this writing, which equates to a real-world adverse event rate of ~2.7%. However, during Inspire's initial 12-month STAR Study, when all patients were monitored and all adverse events were documented, 107 out of 126 patients (85%) suffered at least one adverse event and there were 494 total adverse events.[11] Several medical experts we spoke to said it's expected that many real-world adverse events would go unreported for a variety of reasons, so a real-world adverse event rate higher than 1% would be considered a major red flag to them.

Inspire's surgery is bad, but the device's restrictions are even worse

Inspire promises patients a mask-free sleep in exchange for long list of more onerous restrictions on their everyday life. The restrictions on cell phones, power tools, computers and other technology makes it impossible for patients to resume their normal lives after surgery.

Every sleep expert we spoke with highlighted that the symptoms of OSA often go unnoticed by the patient themselves. Many patients only go to the doctor for OSA because their bed partner can't tolerate the patient's snoring. The doctor often has to convince the patient that they have an "illness" at all:

> *"A lot of times patients are very reluctant to go for a surgical option. Their perception is that it's not a very high priority or concerning medical issue… So, the number of patients who agree, who even want to discuss surgical options, is fairly low."*[12]

It really is that simple. Patients are unlikely to choose to undergo an invasive, expensive surgery with a cumbersome list of restrictions that must be followed for the rest of their life to fix a condition that generally doesn't bother them very much.

[10] https://clinicaltrials.gov/ct2/show/results/NCT01161420?view=results
[11] https://clinicaltrials.gov/ct2/show/results/NCT01161420
[12] Sleep Apnea expert interview, February 2020

Below is an excerpt of the long list of restrictions – just *a few* things an Inspire patient must think twice about having, doing, or being anywhere near for the rest of their life:[13]

Restriction	Inspire/FDA Guidance
Magnetic Resonance Imaging (MRI)	You should not be exposed to Magnetic Resonance Imaging (MRI). **Exposure to MRI can damage your stimulator or leads, cause serious injury, or result in unintended stimulation. This is the case even if you have had the stimulator removed and only the leads remain implanted.**
Pacemakers	The electrical pulses from the **Inspire system could affect the ability of the cardiac device to sense and respond to heart function as intended. This could result in serious injury.**
Mobile phones and other radio-frequency sources (tablet computers, AM/FM radios, cordless and conventional telephones):	Keep these items at least 15 cm (6 in) away from the stimulator.
Computer disk drives	Keep the stimulator away from disk drives.
Dental drills and ultrasonic probes	**These procedures may cause permanent damage to the stimulator**, particularly if used in close proximity to the device
Theft Detector or Security Screening Devices	Use care when approaching theft detectors and security devices **(such as those found in airports, libraries, department stores, and government buildings)**. ... If you must pass through the theft detector or security screening device, make sure your therapy is off. When walking through the device, **keep as far from it as possible**. Note: Some theft detectors might not be visible. Proceed through the security device. Do not linger near or lean on the security device.
Handheld security wand	Ask them not to hold the security wand near the stimulator longer than needed.
Power tools	Keep the motor away from the stimulator and leads.
Electrolysis	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Laser procedures	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Psychotherapeutic procedures (for example, electroshock therapy)	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Radiation therapy	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Antennas of citizen band (CB) or ham radios	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Electric induction heaters	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Induction range	Keep the stimulator away from the burners while the burners are turned on. Induction ranges, unlike conventional electric stoves, produce magnetic fields to generate heat.
Large stereo speakers	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.

[13] Guidance from Inspire's Patient Manual – See the full list in Appendix G

Any one of those restrictions could be enough to deter a patient from an elective implant – all of these combined are absolutely ridiculous, in our opinion.

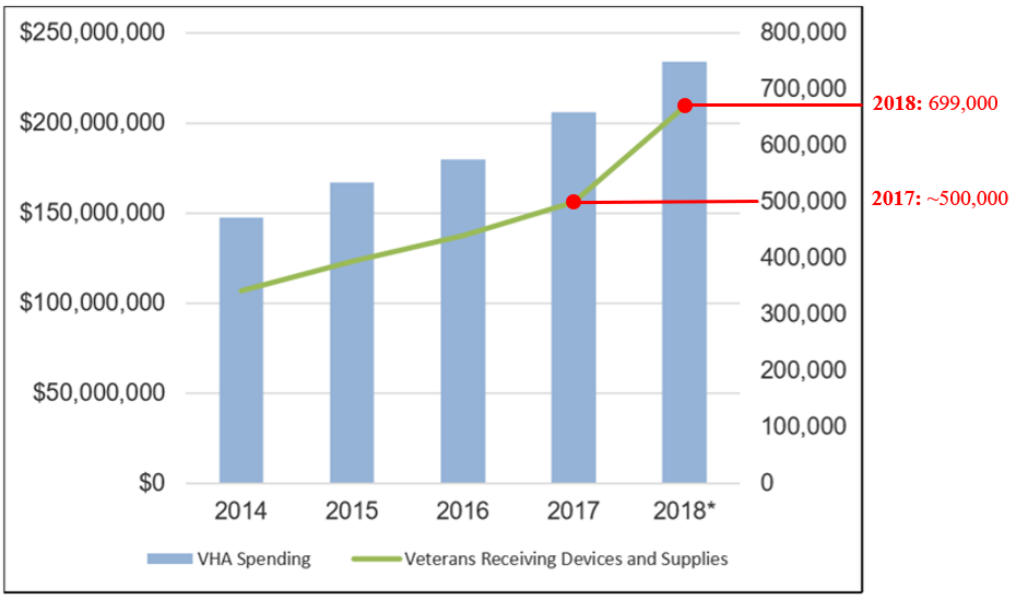
Further, Inspire isn't exactly a new option anymore. It has been commercially available in the U.S. for 5 years and in Europe for 9 years. This is plenty of time to observe real-world adoption rates and use that data to estimate Inspire's true commercial opportunity, rather than continuing to use the hypothetical dream-scenario TAM estimate Inspire's management incessantly pushes on investors. However, if Inspire presented the abysmal real-world numbers, there may not be any investors left.

Inspire can barely give its device away for free:

The VA sleep doctor we spoke with told us that, *even at no cost to the patient*, less than 1% of VA CPAP users go on to try Inspire's implant.[14] We found data from the VA and DoD which supports these claims. It appears that Inspire's sales to the VA peaked at ~1% of VA CPAP prescriptions in 2018 and are now declining.

The VA Hospital System appears to be the optimal market for Inspire's expensive implant: The VA covers all medical costs for ~9 million enrolled veterans. OSA is far more common for military personnel and veterans than the broader population. According to the VA, 20% of veterans have been diagnosed with OSA—compared with only 5% of civilians in the general population.[15] For this reason, VA hospitals were early to try Inspire. The VA first approved the Inspire device for the treatment of OSA ~5 years ago.[16] If Inspire can't be successful in the VA hospital system, we don't believe they will be successful anywhere.

An OIG report on the VA's use of CPAP machines shows that ~500,000 veterans were being treated with CPAP in 2017 and estimated that 699,000 veterans were being treated with CPAP in 2018, implying nearly 200,000 veterans were newly prescribed CPAP in 2018:[17]

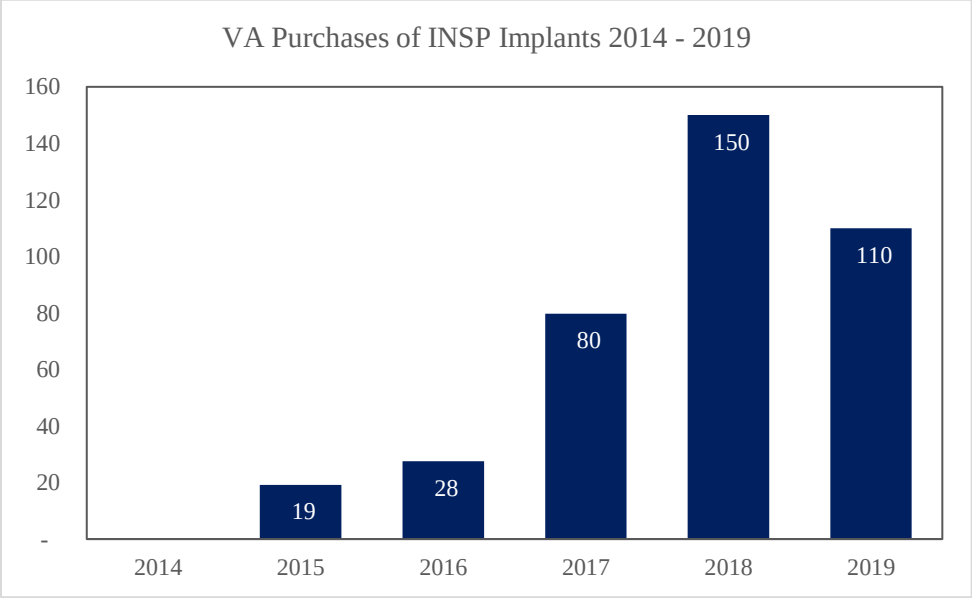


[14] https://www.va.gov/health/aca/NonEnrolledVeterans.asp
[15] PR Newswire: Inspire Therapy Approved for OSA Patients at VA Hospitals
[16] Inspire's therapy has a *"weak for"* recommendation as an OSA treatment. CPAP and educational/behavioral interventions carry *"strong for"* recommendations for treating OSA according to the table on p. 28 of the latest VA guidelines.
[17] The VA/OIG report did not state an exact number for FY2017, although the chart shows its approximately 500,000. The report does state the FY2018 number of 699,000. We used the lowest-end estimate of 150,000 to give Inspire every benefit of the doubt.

However, because the report doesn't disclose the exact number for 2017 and the 2018 figure is *"an estimate based on the average annual number of veterans served from October 2017 through May 2018,"* we used what we believe to be the most favorable number possible for Inspire in the calculations below (150,000 new CPAPs in 2018).[18]

In 2018, VA and Department of Defense (DoD) purchasing data show that a mere 150 patients were treated with Inspire's implant. This means that the ratio of CPAP treatments to Inspire implants was ~1% in 2018. Further, Inspire's sales to the VA peaked in 2018. VA purchasing data shows only 110 purchases from Inspire in 2019, a -26% year-over-year decline. Even if we generously assume that CPAP didn't continue its 8-9% year-over-year growth between 2018 and 2019 and instead remained flat, these 110 implants would only represent ~0.7% of new VA CPAP prescriptions.[19] This data supports the VA clinicians' statements that less than 1% of CPAP users at the VA go on to try Inspire's surgical treatment.

The chart below shows Inspire's unit sales to the VA since its approval in 2014:[20]



According to a senior clinician at the VA, patients ask about Inspire at VA clinics, prompted to do so by Inspire's DTC marketing campaigns. However, when they hear it requires surgery, most simply walk away. One VA clinician made the following statement during our conversation with him:

> *"I am skeptical that Inspire will take a large market share; people just do not want surgery."*[21]

[18] OIG analysis of the NPPD from October 2014 through May 2018. *FY 2018 numbers are based on an estimate of average annual spending and average annual number of veterans served from October 2017 through May 2018. The NPPD database is not publicly accessible due to HIPAA rules, so we were not able to obtain updated data.
[19] https://www.usaspending.gov/#/recipient/68e6bfb0-1569-b78f-12a0-df8a829e29ff-C
[20] https://www.usaspending.gov/#/recipient/68e6bfb0-1569-b78f-12a0-df8a829e29ff-C/latest
[21] Interview with Senior VA Clinician, February 2020

Inspire's most mature market shows its future is bleak

After nearly a decade of commercial availability in Germany, a wealthy country with a population of 83 million that spends ~9% of its GDP on healthcare, Inspire only sold a meager ~300 units there in 2019.[22]

A former Inspire employee told us the company's early business-development strategy focused on Europe, at least in part because the regulatory approval process is less challenging than in the U.S. In Europe, medical devices need a "CE mark" before they can be sold. This designation only proves the device passes certain quality and safety standards, but says nothing about its efficacy. In this sense, it is easier to gain a "CE mark" approval in Europe than an FDA approval in the U.S. Inspire first received a CE mark in Europe in 2011, nearly a decade ago.[23]

According to Inspire's European website, there are 48 Inspire Sleep Clinics in Germany.[24] The costs of the implant and procedure were covered in 113 hospitals under the NUB process of the German federal reimbursement agency in 2019.[25] Given it has been available in Germany for nearly a decade, and the extensive service infrastructure Inspire has established there, Germany serves as an excellent example of what a mature market looks like for Inspire.

[22] Interview with former Inspire employee in Europe, February 2020
[23] INSP 2019 10-K, p. 12
[24] Inspiresleep.de
[25] INSP 2019 10-K, p. 22: *"In Germany, the Institut für das Entgeltsystem im Krankenhaus, the German federal reimbursement agency, has granted the Neue Untersuchungs-und Behandlungsmethoden ("NUB") Status 1 coverage for our Inspire system. The NUB process allows for the introduction of new and innovative medical devices prior to reaching reimbursement eligibility and provides for a supplemental payment for new technologies in the German reimbursement system. NUB Status 1 is the highest of four levels and allows for full reimbursement for our Inspire system for the 113 hospitals that applied for therapy in 2019."*

2. Inspire's Promotional Management Team Doesn't Buy Their Own Bullshit:

Although Inspire's executives incessantly tout a market opportunity that implies they will grow the Company's sales by 100x, their actions tell an entirely different story. With 99.2% of their purported TAM still in front of them, insiders have decreased their stake in the company from 45.54% to only 4.94% today by selling 5,537,240 shares, cashing out more than $340 million, nearly 3x the company's total revenue since the IPO, without ever buying a single share on the open market.

It appears that management realized that the company would never be profitable, and the only way *they* could personally make money was to take Inspire public. While executives travel from conference to conference selling investors on Inspire's *unbelievable* growth prospects, they cash out stock options as soon as they can. Management's actions contradict their words.

The chart below shows all open market *purchases and sales* by Inspire's insiders since the expiration of its IPO lock-up period on October 31, 2018.[26] In addition to the absence of a single insider purchase, it's hard to miss the massive insider sales in early March 2020, when the stock was at its all-time-high, near $90. The vast majority of these sales were made by Chau Q. Khuong, an Inspire Director and Partner at Orbimed Advisors. He cashed out 1.5 million shares for ~$130 million just weeks before Inspire withdrew its 2020 guidance and executed a two million share secondary offering at $58.00, a discount of ~35% to where Mr. Khuong cashed out.[27]

The table below provides the details of Mr. Khuong's *well timed* sales. These transactions decreased Khuong/OrbiMed's remaining stake in Inspire to only 347,000 shares, a -86% decrease from the 2,444,221 shares they owned when Inspire went public in May 2018.

Trade Date	Participant	Shares	Close Price	Proceeds
3/3/2020	Chau Q. Khuong (Orbimed)	-575,000	82.91	$47,673,250
3/4/2020	Chau Q. Khuong (Orbimed)	-425,000	88.98	$37,816,500
3/6/2020	Chau Q. Khuong (Orbimed)	-500,000	84.21	$42,105,000
Totals		**-1,500,000**	**$85.06**	**$127,594,750**

Also among the sellers in March and April 2020 was Inspire's Chief Commercial Officer, Randy Ban, who sold 20,000 shares. However, this is just his normal practice. Mr. Ban's sales were pursuant to his

[26] INSP Insider Transactions, All Open Market Buys/Sells via Bloomberg LP, accessed April 21, 2020

[27] http://www.globenewswire.com/news-release/2020/04/13/2015201/0/en/Inspire-Medical-Systems-Inc-Provides-First-Quarter-and-Full-Year-2020-Update.html

10b5-1 plan which appears to ensure he doesn't own any shares of Inspire stock by exercising options as they vest and selling them in the open market in the same transaction. Below is an example of a common transaction for Mr. Ban:[28]

FORM 4 — **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP

OMB APPROVAL
OMB Number: 3235-0287
Estimated average burden hours per response: 0.5

☐ Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. See Instruction 1(b).

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934 or Section 30(h) of the Investment Company Act of 1940

1. Name and Address of Reporting Person*	2. Issuer Name and Ticker or Trading Symbol	5. Relationship of Reporting Person(s) to Issuer (Check all applicable)
Ban Randy	Inspire Medical Systems, Inc. [INSP]	Director / 10% Owner / X Officer (give title below) / Other (specify below)
(Last) (First) (Middle): C/O INSPIRE MEDICAL SYSTEMS, INC. 5500 WAYZATA BLVD., SUITE 1600	3. Date of Earliest Transaction (Month/Day/Year): 07/31/2019	Chief Commercial Officer
(Street): GOLDEN VALLEY MN 55416	4. If Amendment, Date of Original Filed (Month/Day/Year)	6. Individual or Joint/Group Filing (Check Applicable Line): X Form filed by One Reporting Person / Form filed by More than One Reporting Person
(City) (State) (Zip)		

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed Of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			
Common Stock	03/04/2020		M		10,000	A	$1.14	10,000	D	
Common Stock	03/04/2020		S[1]		1,801	D	$84.33[2]	8,199	D	
Common Stock	03/04/2020		S[1]		1,673	D	$85.19[3]	6,526	D	
Common Stock	03/04/2020		S[1]		1,613	D	$86.38[4]	4,913	D	
Common Stock	03/04/2020		S[1]		1,730	D	$87.4[5]	3,183	D	
Common Stock	03/04/2020		S[1]		3,044	D	$88.09[6]	139	D	
Common Stock	03/04/2020		S[1]		139	D	$89.1[7]	0	D	
Common Stock								167	I	By son
Common Stock								166	I	By daughter

Notice in the Form 4 above, he exercised options for 10,000 shares at $1.14 each and immediately turned around and dumped them on the market between $85 and $88. Mr. Ban started selling just after the IPO lockup expired on October 31, 2018. Randy's first sales were on November 19 and 20, 2018, when he sold a total of 10,000 shares at prices as low as $39.61.

Of course, Ban and Khuong aren't the only insiders that have been rapidly dumping their stock. CEO Tim Herbert is a habitual seller as well. He is the face and voice of Inspire – he seems to make a living promoting INSP stock at conferences then turning around and dumping 15-25k shares at a time.

On May 22, 2019, CEO Tim Herbert made the following incredibly bold statement at the RBC Capital Markets Healthcare Conference:

> *"Our ASP is $23,500 but for easy math that's a $10 billion annual opportunity just in the United States. Okay, that's just a huge number, we don't look at it that way. We switch up, we look at it as from a bottoms up. How can we establish a number of centers and physicians to be able to treat this population.* ***We know we have an <u>unlimited number of patients</u> that need the therapy****."*[29]

[28] https://www.sec.gov/Archives/edgar/data/1609550/000110465920030294/xslF345X03/a4.xml
[29] INSP 5/22/19 RBC Conference Presentation Transcript via Bloomberg LP

Just six days after making this outrageous claim, Mr. Herbert sold 25,000 shares for a quick ~$1.3 million payday. He's not putting his money where his mouth is – he's just putting it in his pocket. Herbert has pocketed nearly $16 million from stock sales since the IPO.

Unfortunately, we couldn't fit a table of all of Inspire's insider sales on one page, so we had to put it in Appendix A of this report. However, we have listed all of CEO Tim Herbert's sales in the table below:

Trade Date	President/CEO/Founder	Shares	Close Price	Proceeds
11/20/2018	Tim Herbert	-15,000	$40.79	$611,850
12/18/2018	Tim Herbert	-15,000	$42.15	$632,250
1/15/2019	Tim Herbert	-15,000	$49.35	$740,250
2/19/2019	Tim Herbert	-15,000	$57.37	$860,550
3/19/2019	Tim Herbert	-15,000	$56.57	$848,550
4/16/2019	Tim Herbert	-15,000	$54.76	$821,400
5/28/2019	Tim Herbert	-25,000	$53.07	$1,326,750
6/25/2019	Tim Herbert	-25,000	$58.98	$1,474,500
7/3/2019	Tim Herbert	-10,000	$64.11	$641,100
7/23/2019	Tim Herbert	-15,000	$67.81	$1,017,150
8/1/2019	Tim Herbert	-10,000	$67.48	$674,800
8/27/2019	Tim Herbert	-15,000	$65.29	$979,350
9/3/2019	Tim Herbert	-10,000	$66.93	$669,300
9/6/2019	Tim Herbert	-10,000	$68.06	$680,600
9/24/2019	Tim Herbert	-5,000	$65.55	$327,750
10/22/2019	Tim Herbert	-25,000	$54.72	$1,368,000
1/13/2020	Tim Herbert	-9,832	$79.73	$783,905
1/14/2020	Tim Herbert	-15,168	$80.10	$1,214,957
Totals		**-265,000**	**$59.14**	**$15,673,012**

We also put together a table of all insider purchases since the IPO – notice there are no trade dates, participants or share counts because there have been no insider purchases. Not a single one:

Trade Date	Participants	Shares	Close Price	Total Cost
N/A	None	0	$0.00	$0.00

Our investment thesis for Inspire: *follow what management does, not what they say.*

3. Inspire Exaggerates its TAM by ~50x:

Our research shows that Inspire's actual TAM is less than 2% of the $10 billion per year (500,000 units per year) TAM Inspire promotes. Inspire's management mentions this figure repeatedly on earnings calls, at investor conferences and in company presentations as its key selling point for investors. We view this as a baseless claim derived from Inspire's self-serving *"company estimates"* and misleading methodology that ignores important factors such as patient preference, competition and the abysmal real-world adoption rate in Inspire's most mature markets.

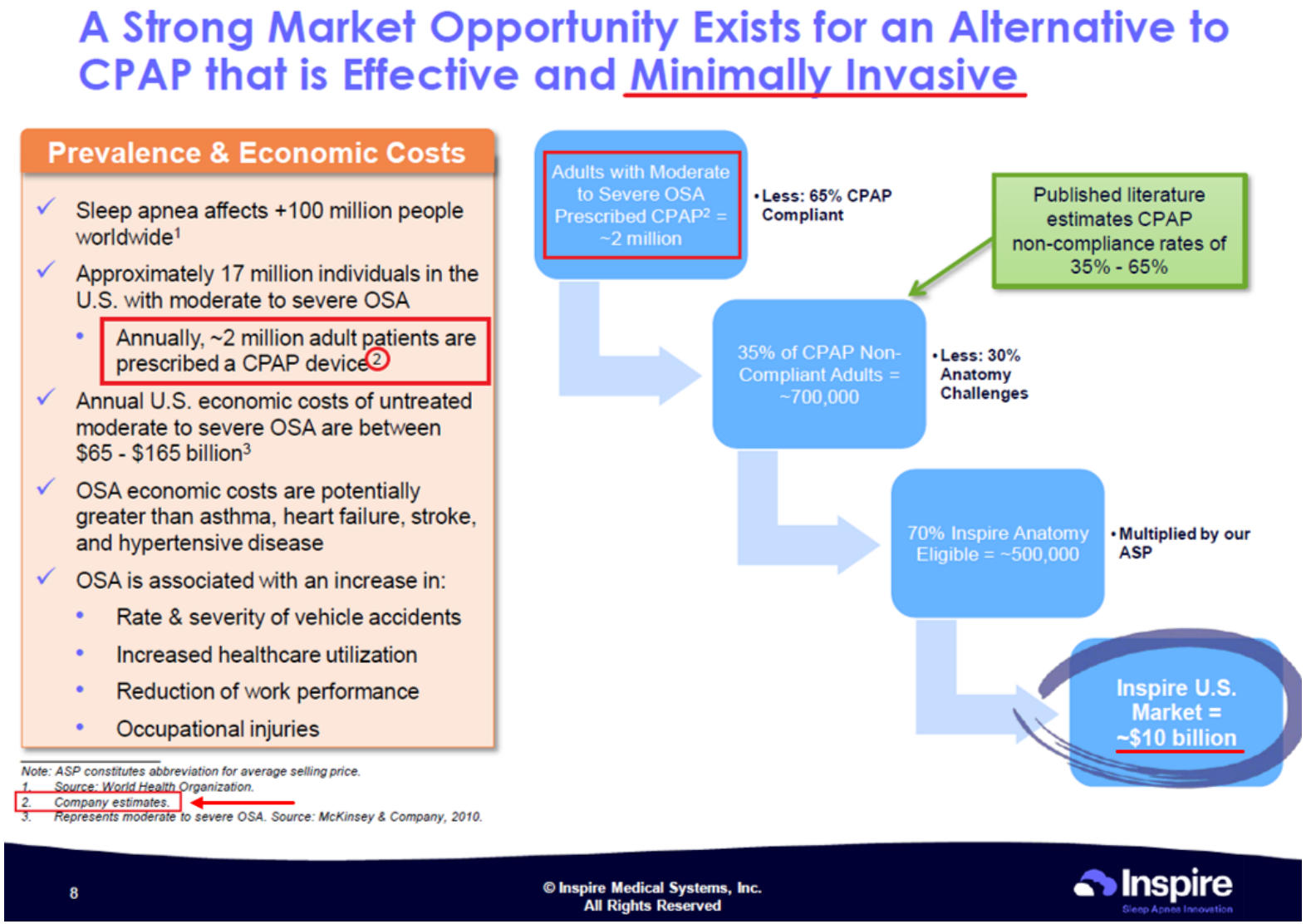
Inspire's TAM Calculation Relies on *"Company Estimates"* and Ignores Key Constraints

Inspire uses an unverifiable *"company estimate"* for the most critical assumption in its TAM calculation: the number of new CPAP prescriptions per year in the U.S. Inspire claims there are 2 million new CPAP prescriptions per year in the U.S. alone. However, data from an independent market research firm shows Inspire's claim to be overstated by ~2.5x. Because patients must first try and reject CPAP treatment to be eligible for Inspire's implant, the number of new CPAP users per year is the key assumption in calculating Inspire's TAM.

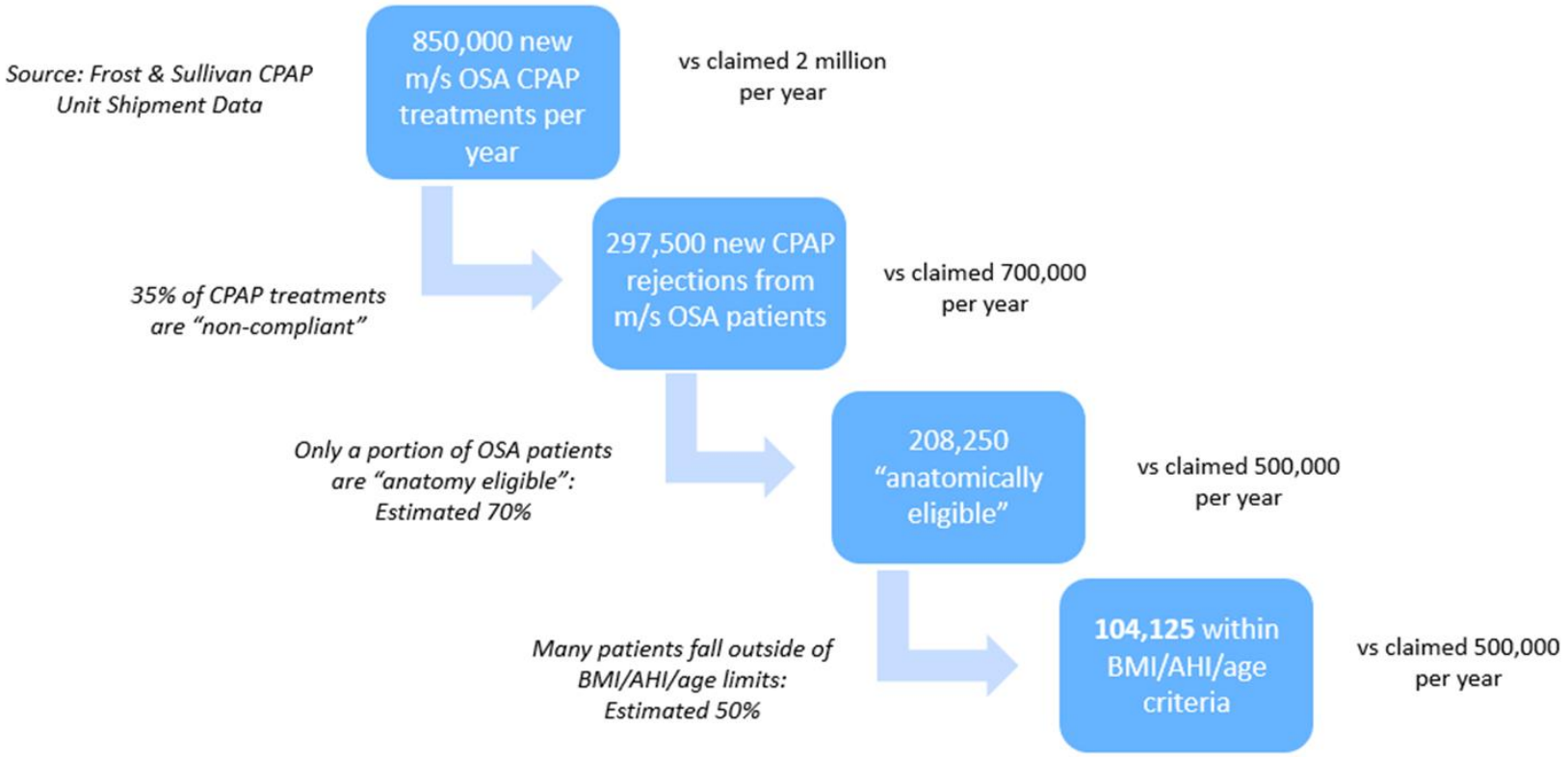
Most importantly, Inspire's in-house TAM estimate completely ignores the effect of patient preference. Contrary to management's delusions, this is an invasive surgical solution aimed at treating a condition that often has mild symptoms which patients generally aren't willing to undergo surgery to treat. We adjust for this factor by looking at parts of the OSA market that have had access to Inspire's device for as long as 9 years and therefore act as a guide for Inspire's adoption rate in a mature market. This adjustment – which we'll refer to as the "reality adjustment" – severely restricts Inspire's actual commercial opportunity.

Below we review the self-serving methodology and assumptions that Inspire uses to calculate its purported market opportunity and show that, even using its self-serving methodology, its TAM falls by ~80% when we input verifiable, empirical data.

Below is the TAM slide from a February 2020 Inspire investor presentation. The ***most important*** assumption for this top-down TAM calculation is the number of adults with moderate to severe OSA prescribed CPAP prescription each year. Inspire claims this number is 2 million – their source? See footnote 2: ***"Company estimates"*** (i.e., "we made it up")



Below is our calculation, employing the same approach, but using realistic and verifiable numbers:



We still consider the above estimate to be highly optimistic because it entirely ignores patient choice, among other factors. However, we felt it was worth showing that simply using realistic estimates, Inspire's best-case TAM falls by ~80%, to 104,125 units versus their claim of 500,000. We elaborate on the numerous other flaws in Inspire's methodology below.

Inspire's *"company estimate"* of 2 million annual CPAP prescriptions is overstated by ~2.5x

CPAP treatment numbers are the most important data point in Inspire's TAM calculation because patients must reject CPAP before they can be a potential Inspire customer.[30] Therefore, annual CPAP treatment numbers provide a starting point for Inspire's top-down TAM calculation.

We commissioned market research firm Frost & Sullivan to compile data and forward estimates for annual CPAP unit sales.[31] They estimated 850,000 CPAP unit sales per year for the U.S. We used the high-end of the data for our estimate to give Inspire the benefit of the doubt. Even so, this crucial assumption is less than half of the 2 million new CPAP users per year in the U.S. that Inspire uses in its self-serving *"company estimate."* Further, a 2018 *Forbes* article suggests a total CPAP population of 8 million, growing at 8-9% a year. This would imply between 600k and 700k new CPAP prescriptions a year.

Not all CPAP prescriptions are for the type of Sleep Apnea that Inspire "treats"

CPAP is used to treat a broad spectrum of sleep-related breathing disorders, such as Central Sleep Apnea ("CSA"), which Inspire's device can't treat.[32] By ignoring the fact that not all patients treated with CPAP are potential Inspire patients, Inspire further exaggerates its realistic TAM.

For the sake of transparency, we have been unable to find an empirical estimate for the exact proportion of CPAP sales that are related to moderate/severe OSA, aside from our experts' opinions. So, we gave Inspire the benefit of the doubt again on this point by not adjusting the market research firm's annual CPAP sales figure down to account for new CPAP users with other conditions.

Inspire appears to conflate *total* and *annual* data points to support its self-serving claims

It appears that Inspire has conflated *total* data points with *annual* data points misleading investors and making their unrealistic *annual* market opportunity appear attainable.

While six sleep experts we spoke to thought Inspire's unsourced claim of 17 million total moderate to severe OSA cases in the U.S. was realistic, they all agreed that ~80% of those cases are undiagnosed. The symptoms of even "moderate to severe" OSA are often mild, so most people don't even bother seeing a doctor about it. If 80% of the 17 million cases are undiagnosed, that implies a diagnosed population of ~3.5 million Americans. Given a diagnosed population of ~3.5 million Americans, it is simply impossible for there to be 2 million new CPAP users each year. The entire population of CPAP users would need to turn over every 21 months for this to be true.

Inspire's estimate for *"Anatomy Eligibility"* ignores crucial constraints, such as BMI and age

We conclude that anatomical eligibility reduces Inspire's realistic TAM by *at least* 50%. The term "anatomically eligible" refers to the multitude of constraints on Inspire's potential patient population, such as the type of sleep apnea the patient has, their BMI, their age and the severity of their OSA. In some cases, the way the patient's airway collapses, such as "concentric collapse," means Inspire's implant will not work.[33]

Inspire's claim that only 30% of OSA patients who reject CPAP treatment will be "anatomy ineligible" is supported only by the hand-picked sample used in Inspire's Stimulation Therapy for Apnea Reduction ("STAR")[34] study, in which only 23% of the patients were rejected on the basis of anatomy ineligibility.

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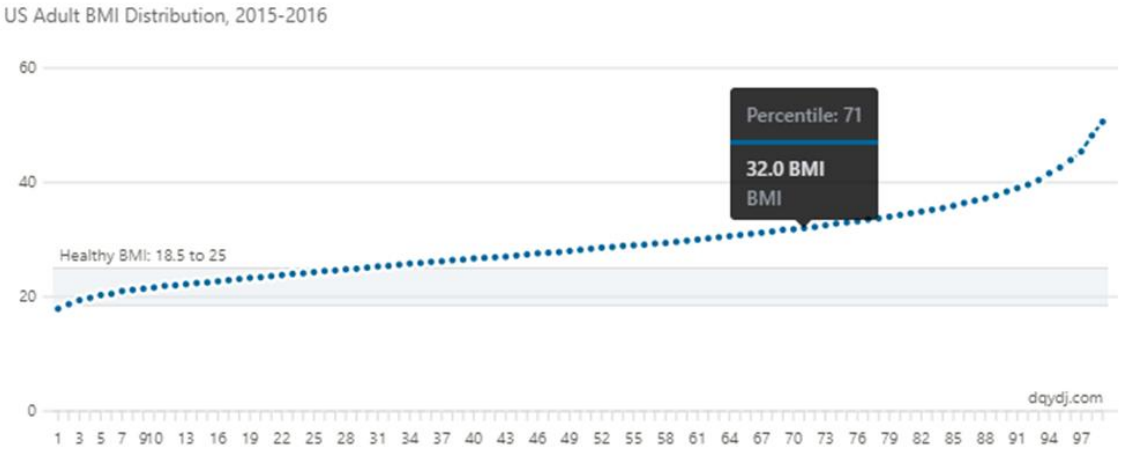
[30] INSP 2019 10-K, p. 6
[31] We engaged Frost & Sullivan under pseudonym, so they were not aware of the short bias in our research.
[32] https://www.mayoclinic.org/diseases-conditions/central-sleep-apnea/diagnosis-treatment/drc-20352114
[33] https://breathepa.org/obstructive-sleep-apnea/3683-2 - *"Individuals with complete concentric collapse are not candidates for Inspire therapy."*
[34] Stimulation Therapy for Apnea Reduction. This was the study undertaken by Inspire to secure FDA approval.

However, this was after heavy pre-screening for age, BMI and OSA severity that ensured most of the STAR study patients met the criteria for these constraints. Nonetheless, we gave Inspire the benefit of the doubt once again and used their assumption that 70% of patients will be anatomically eligible in our estimate presented above.

According to Inspire-sponsored studies, their initial FDA approval, and an FDA patient manual for Inspire's device, the efficacy of Inspire's device declines above a BMI of 32. Among other reasons, the weight of a patient's own flesh can mean that too great an electrical stimulation is required to move the tongue forward and open the airway without causing pain or disturbing sleep. This represents a massive constraint for Inspire's commercial opportunity.[35]



BMI *alone* reduces Inspire's addressable market by *more than* 30%. Nearly 30% of the US population has a BMI of over 32. Furthermore, OSA prevalence correlates with BMI. A study published in 1993 in the *New England Journal of Medicine* concluded that one standard deviation increase in BMI resulted in a *three-fold* increase in the risk of sleep-disordered breathing.

Age is also a major problem for Inspire. The likelihood that a person will suffer from OSA increases with age. A study by the *American Thoracic Society* provides the following figures for the prevalence of sleep apnea in adult men of various ages:

- 3.2% prevalence in men 20-44 years old
- 11.3% prevalence in men 45-64 years old
- 18.1% prevalence in men 61-100 years old

OSA prevalence increases with age, but so do the problems and risks of surgery. A sleep doctor we spoke with indicated that age is an important factor in whether he would recommend a surgical implant like Inspire:

> *"And in general, the older we get the more medical problems we have so, nothing is really absolute as far as upper limit [with respect to patient age]. But in general, I would say the best candidates are probably in their forties and fifties."*

The severity of the OSA and other factors such as neck girth, further reduce the addressable population, but all of these are ignored in the TAM calculation inspire presents to investors.

[35] *Data taken from a 2015-2016 NHANES survey from the Centre for Disease Control (https://wwwn.cdc.gov/nchs/nhanes/)*

4. Cheaper, Less Invasive Competition is Growing Quickly:

When Inspire was launched, it was not a new concept and it did not use game-changing technology. Medtronic had first tried hypoglossal nerve stimulation back in the late '90s. Their first patents were filed in 1998, nearly a decade before Inspire was spun off from Medtronic. Inspire's CEO, Tim Herbert, acts obnoxiously confident about this perceived lack of competition:

> *"So, we don't have competition -- it's not like we're grabbing market share. It's our market to create. So this is the what keeps me up at night. It's the question -- it's about how do we stay in control while we're growing fast."*[36]

There are similar surgically implanted OSA treatments working towards FDA and Medicare approval, such as LivaNova's "Aura 6000" device and Nyxoah's "Genio System" which already received CE Mark approval in Europe. The introduction of direct competition will put pressure on Inspire's ASP,[37] and inherently reduce Inspire's realistic commercial opportunity.[38]

Inspire Medical, Respicardia, LivaNova, and Nyxoah share the latest data on their devices.

[36] RBC Capital Markets Healthcare Conference, May 22, 2019, accessed via Bloomberg, LP
[37] Average selling price
[38] http://www.sleepreviewmag.com/2019/05/neurostimulators-sleep-apnea/

Nyxoah:

Nyxoah, a privately held Belgian company, is currently on the path for commercial launch in the U.S. It received CE approval in Europe during 2019. Nyxoah received an investment from ResMed in January 2020. ResMed is the leading CPAP manufacturer globally. Their investment in Nyxoah provides it the sales infrastructure and FDA trial experience to quickly compete with Inspire and should be concerning for Inspire investors. The Nyxoah device is powered by an external battery pack, so it doesn't require an additional surgery to replace the battery every 7 to 10 years.

LivaNova:

LivaNova is a mid-sized listed, profitable company, which owns a portfolio of products including a number of neurostimulation devices. It has extensive experience rolling out new neurostimulation devices and an existing sales infrastructure from its acquisition of Imthera last year. LivaNova is currently reconfirming trial results ahead of an FDA submission, which is expected to be made later this year.[39]

In its 12 month pilot study, LivaNova's patients saw a mean reduction in AHI of 53% after 12 months and a mean ODI reduction of around 50% - almost exactly the same as Inspire. The LivaNova device requires no DISE procedure ahead of implant, and does not rely on a chest-implanted sensor, so the surgery is less invasive.

The table below compares Inspire's results to its direct competitors:[40,41]

	Inspire	LivaNova	Nyxoah
mean AHI reduction	52%	53%	43%
mean ODI reduction	52%	50%	51%

Numerous *non-invasive* options already exist

Oral appliance therapy is an effective, non-invasive treatment that fits easily into the patient's lifestyle. They are completely non-invasive, easy to wear, comfortable, convenient and don't come with a long list of restrictions or a $40,000+ price tag.

The American Academy of Sleep Medicine ("AASM") has approved oral appliance therapy ("OAT") as a first line treatment for patients diagnosed with mild to moderate OSA. The AASM also recommends oral appliances for patients with severe OSA, who are unable to tolerate or cannot wear CPAP devices. Another option for people with severe OSA is combination therapy (wearing CPAP and an oral appliance together) to help reduce the pressure on a CPAP machine, making it more comfortable to use.[42]

One of the sleep apnea experts we spoke to was shocked to hear Inspire's TAM estimate and their promotional language. Her immediate reaction was:

> *"In their literature, Inspire almost pretends that oral appliances don't exist Oral appliances are a much better first choice. A dentist makes it for you, and ADA is cranking out dentists who make these."*[43]

The American Academy of Dental Sleep Medicine (AADSM) says that there are over 100 oral appliances for sleep apnea that have received FDA approval. Oral appliances are essentially custom-fit mouthpieces

[39] https://www.livanova.com/en-US/Home/Products-Therapies/Neuromodulation/Obstructive-Sleep-Apnea.aspx
[40] https://erj.ersjournals.com/content/41/2/360
[41] https://erj.ersjournals.com/content/55/1/1901320.abstract
[42] https://www.sleepapnea.org/treat/sleep-apnea-treatment-options/
[43] Sleep Doctor expert call, February 2020

that you wear while you sleep. They are completely non-invasive and only require a trip to the dentist to have the device fitted.[44]

Numerous recent studies show patient compliance/adherence with oral devices is as high as 86% over a 3 year period.[45] Unlike Inspire, the bugs are worked out of them. One of the largest makers of oral appliances, SomnoDent/SomnoMed, has already treated over 400,000 patients.

Below are a few of the oral appliances currently on the market:[46]

Company		Airway Management Inc		Apnea Sciences	Dream Systems LLC	
Product		 myTAP	 TAP 3 Elite	 ApneaRx	 OASYS Hinge Appliance	 OASYS with Option for Combination Therapy
Website		www.myTAPappliance.com	www.amisleep.com	www.apnearx.com	www.dreamsystemsdentallab.com	www.oasyssleep.com
Warranty (days)		90 (30-day satisfaction guarantee)	365 (for parts) (60-day satisfaction guarantee)	30 (guarantee with full refund); 90 (replacement)	365	365
INDICATIONS	Mild to Moderate OSA	X	X	X	X	X
	Severe OSA				X	X
	Snoring	X	X	X	X	X
	Bruxism				X	X

Company		Myerson	OravanOSA	Quali-Som LLC	ResMed	SML–Space Maintainers Laboratories
Product		 Myerson EMA	 Oravan	 TheraSom Cast	 Narval CC	 Lamberg–Sleep Well Appliance
Website		www.myersontooth.com	www.oravanosa.com	www.quali-som.com	www.resmed.com/narval	www.smlglobal.com
Warranty (days)		N/A	730	1,825	1,095	1,095
INDICATIONS	Mild to Moderate OSA	X	X	X	X	X
	Severe OSA	X		X		X
	Snoring	X	X	X	X	X
	Bruxism	X		X		X

Most importantly, oral appliances do not require surgery. Many are covered by Medicare and private health insurance – they don't require separate dental plans. The Inspire device and surgery costs upwards of $40,000, while these oral appliances only cost between $5,000 and $10,000.

[44] https://www.sleepapnea.org/treat/sleep-apnea-treatment-options/oral-appliance/
[45] https://aadsm.org/journal/special_article_2_issue_61.php
[46] http://a360-wp-uploads.s3.amazonaws.com/wp-content/uploads/sleeprev/2015/09/OralAppliancesGuide082015.pdf

Appendix A – Insider Sales

Date	Participants	Shares	Price	Proceeds
11/19/2018	Randy Ban	-5,000	$40.50	$202,500
11/20/2018	Tim Herbert, Randy Ban	-20,000	$40.79	$815,800
12/11/2018	Chau Khuong (OrbiMed), Jerry C. Griffin	1,230,844	$39.48	$48,593,721
12/18/2018	Tim Herbert	-15,000	$42.15	$632,250
1/14/2019	Amzak, Randy Ban	-93,000	$48.19	$4,481,670
1/15/2019	Amzak, Tim Herbert, Randy Ban	-134,568	$49.35	$6,640,931
1/16/2019	Amzak	-98,136	$50.90	$4,995,122
1/17/2019	Amzak	-203,680	$53.60	$10,917,248
1/18/2019	Amzak	-64,820	$55.40	$3,591,028
1/22/2019	Amzak, Richard Buchholz	-26,905	$54.21	$1,458,520
1/23/2019	Amzak	-12,773	$52.39	$669,177
1/24/2019	Amzak	-28,718	$53.05	$1,523,490
1/25/2019	Amzak	-21,379	$52.85	$1,129,880
1/28/2019	Amzak	-34,752	$53.87	$1,872,090
1/29/2019	Amzak	-19,120	$52.28	$999,594
1/30/2019	Amzak	-13,149	$51.55	$677,831
1/31/2019	Amzak	-20,035	$53.63	$1,074,477
2/1/2019	Amzak	-15,311	$53.09	$812,861
2/4/2019	Amzak	-16,708	$52.34	$874,497
2/5/2019	Amzak	-37,946	$54.65	$2,073,749
2/19/2019	Tim Herbert	-15,000	$57.37	$860,550
2/20/2019	Richard Buchholz	-2,000	$58.26	$116,520
3/7/2019	Chau Khuong (OrbiMed), Casey Tansey	-93,218	$54.92	$5,119,533
3/8/2019	Chau Khuong (OrbiMed)	-290,231	$56.06	$16,270,350
3/19/2019	Tim Herbert	-15,000	$56.57	$848,550
3/20/2019	Richard Buchholz	-2,000	$55.97	$111,940
4/1/2019	GDN, Randy Ban	-94,554	$51.83	$4,900,734
4/2/2019	GDN, Randy Ban	-68,431	$50.65	$3,466,030
4/5/2019	Randy Ban	-10,000	$52.11	$521,100
4/10/2019	GDN	-47,015	$55.63	$2,615,444
4/16/2019	Tim Herbert, Richard Buchholz	-19,000	$54.76	$1,040,440
5/1/2019	Randy Ban	-5,037	$50.08	$252,253
5/2/2019	Randy Ban	-1,637	$49.96	$81,785
5/3/2019	Randy Ban	-3,400	$51.92	$176,528
5/20/2019	Richard Buchholz	-4,000	$52.77	$211,080
5/21/2019	Amzak	-12,854	$54.67	$702,728
5/22/2019	Amzak	-26,388	$54.52	$1,438,674
5/23/2019	Amzak	-137	$53.29	$7,301
5/24/2019	Amzak	-23,004	$53.99	$1,241,986
5/28/2019	Tim Herbert, Amzak	-25,600	$53.07	$1,358,592
5/29/2019	Amzak	-20,449	$54.29	$1,110,176
5/30/2019	Amzak	-32,073	$55.10	$1,767,222
5/31/2019	Amzak	-34,495	$56.47	$1,947,933
6/3/2019	Randy Ban	-7,000	$56.07	$392,490
6/4/2019	Randy Ban	-3,000	$54.21	$162,630
6/17/2019	Richard Buchholz	-4,000	$56.99	$227,960
6/25/2019	Tim Herbert	-25,000	$58.98	$1,474,500

Date	Participants	Shares	Price	Proceeds
7/3/2019	Tim Herbert, GDN	-16,102	$64.11	$1,032,299
7/8/2019	Amzak, GDN	-117,253	$66.60	$7,809,050
7/9/2019	Amzak	-38,122	$65.91	$2,512,621
7/10/2019	Amzak	-54,715	$67.16	$3,674,659
7/11/2019	Amzak	-31,519	$67.33	$2,122,174
7/12/2019	Amzak	-41,075	$67.15	$2,758,186
7/15/2019	Amzak, Mudit K. Jain	-57,666	$68.88	$3,972,034
7/16/2019	Amzak, Richard Buchholz	-26,738	$67.89	$1,815,243
7/17/2019	Amzak	-53,964	$68.54	$3,698,693
7/18/2019	Amzak	-39,750	$68.03	$2,704,193
7/23/2019	Tim Herbert	-15,000	$67.81	$1,017,150
8/1/2019	Tim Herbert	-10,000	$67.48	$674,800
8/16/2019	Mudit K. Jain	-490	$65.48	$32,085
8/19/2019	Richard Buchholz, Mudit K. Jain	-5,750	$67.53	$388,298
8/20/2019	Mudit K. Jain	-270	$68.39	$18,465
8/21/2019	Mudit K. Jain	-980	$67.53	$66,179
8/27/2019	Tim Herbert	-15,000	$65.29	$979,350
9/3/2019	Tim Herbert	-10,000	$66.93	$669,300
9/6/2019	Tim Herbert	-10,000	$68.06	$680,600
9/9/2019	GDN	-60,000	$66.11	$3,966,600
9/12/2019	Randy Ban	-10,000	$62.68	$626,800
9/20/2019	GDN	-30,000	$66.81	$2,004,300
9/24/2019	Tim Herbert	-5,000	$65.55	$327,750
10/7/2019	Randy Ban	-700	$56.47	$39,529
10/22/2019	Tim Herbert	-25,000	$54.72	$1,368,000
10/25/2019	Randy Ban	-9,300	$58.16	$540,888
10/28/2019	Randy Ban	-5,000	$58.62	$293,100
10/29/2019	Randy Ban	-5,000	$59.82	$299,100
11/18/2019	Randy Ban	-6,390	$63.39	$405,062
11/25/2019	GDN, Mudit K. Jain	-29,500	$68.31	$2,015,145
11/26/2019	Chau Khuong (OrbiMed), GDN, M. Jain	-88,790	$70.75	$6,281,893
11/27/2019	Chau Khuong (OrbiMed), Mudit K. Jain	-53,687	$71.50	$3,838,621
12/4/2019	Mudit K. Jain	-300	$72.27	$21,681
12/6/2019	GDN, Mudit K. Jain	-15,500	$75.00	$1,162,500
12/18/2019	Jerry C. Griffin	-10,000	$71.93	$719,300
1/6/2020	Jerry C. Griffin, Mudit K. Jain	-5,500	$75.48	$415,140
1/7/2020	Jerry C. Griffin	-5,000	$76.14	$380,700
1/8/2020	Mudit K. Jain	-500	$77.22	$38,610
1/13/2020	Tim Herbert	-9,832	$79.73	$783,905
1/14/2020	Tim Herbert	-15,168	$80.10	$1,214,957
1/21/2020	Jerry C. Griffin	-5,000	$81.00	$405,000
1/22/2020	Jerry C. Griffin	-1,312	$80.61	$105,760
2/4/2020	Randy Ban	-10,000	$75.48	$754,800
2/28/2020	Casey Tansey	-70,000	$85.87	$6,010,900
3/3/2020	Chau Khuong (OrbiMed)	-575,000	$82.91	$47,673,250
3/4/2020	Chau Khuong (OrbiMed), Randy Ban	-435,000	$88.98	$38,706,300
3/6/2020	Chau Khuong (OrbiMed)	-500,000	$83.52	$41,760,000
4/9/2020	Randy Ban	-10,000	$64.61	$646,100
Totals		**5,537,240**	**$61.74**	**$341,892,534**

Appendix B – The Inspire Process:

1. The patient first has to be diagnosed with sleep apnea, and then with obstructive sleep apnea.

2. The patient has to undergo a sleep-study.

3. The patient has to try CPAP, and then ultimately fail with CPAP either for insufficient effect or due to habitual noncompliance.

4. The patient must have a drug-induced sleep endoscopy (DISE) at a sleep lab, which involves general anesthetic and a team watching how the patient's throat collapses during apnea events.

5. Then the patient needs to be recommended for Inspire. Then evaluated for Inspire. Then approved for Inspire by their insurer.

6. Then the patient needs to have the surgery, which requires full sedation and three 2.5-inch incisions.

7. Then after three weeks there is a post-operative visit to check the incisions.

8. Then the patient has to spend a month or so with the device implanted, but not yet 'activated'.

9. After that, the patient returns to a doctor for a full sleep study, to have the device turned on and given its initial programming.

10. Then, after four months of using the device, the patient returns to a doctor for a further sleep study, to have the device programming 'adjusted'.

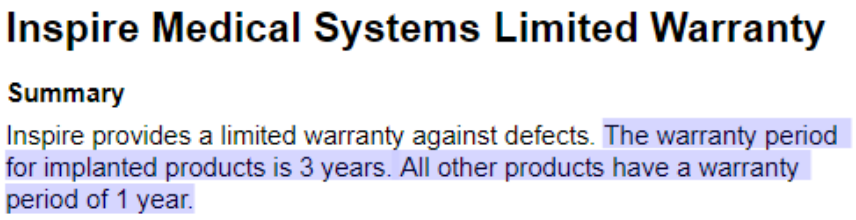
11. Then 60 days after that, the patient returns for even more re-programming.

12. Then if all is well, the patient must undergo another sleep study.

13. Then, though nothing in this life of rue can be certain, the patient may have to return periodically over the years for further program adjustments.

14. Then at some point between 7 and 11 years, the patient will have to undergo another surgery to replace the battery in the device, which will have died by then, or sooner depending on use/adherence.

Each of these steps of course requires an office visit, with the potential for a co-payment and follow-up bill for the portion not covered. Some of the visits will be to a sleep doctor, some to an ENT surgeon. After all of this, the device that is to be **permanently implanted in your body until you die** is covered by a 'limited' warranty for three whole years.[47]



Inspire Medical Systems Limited Warranty

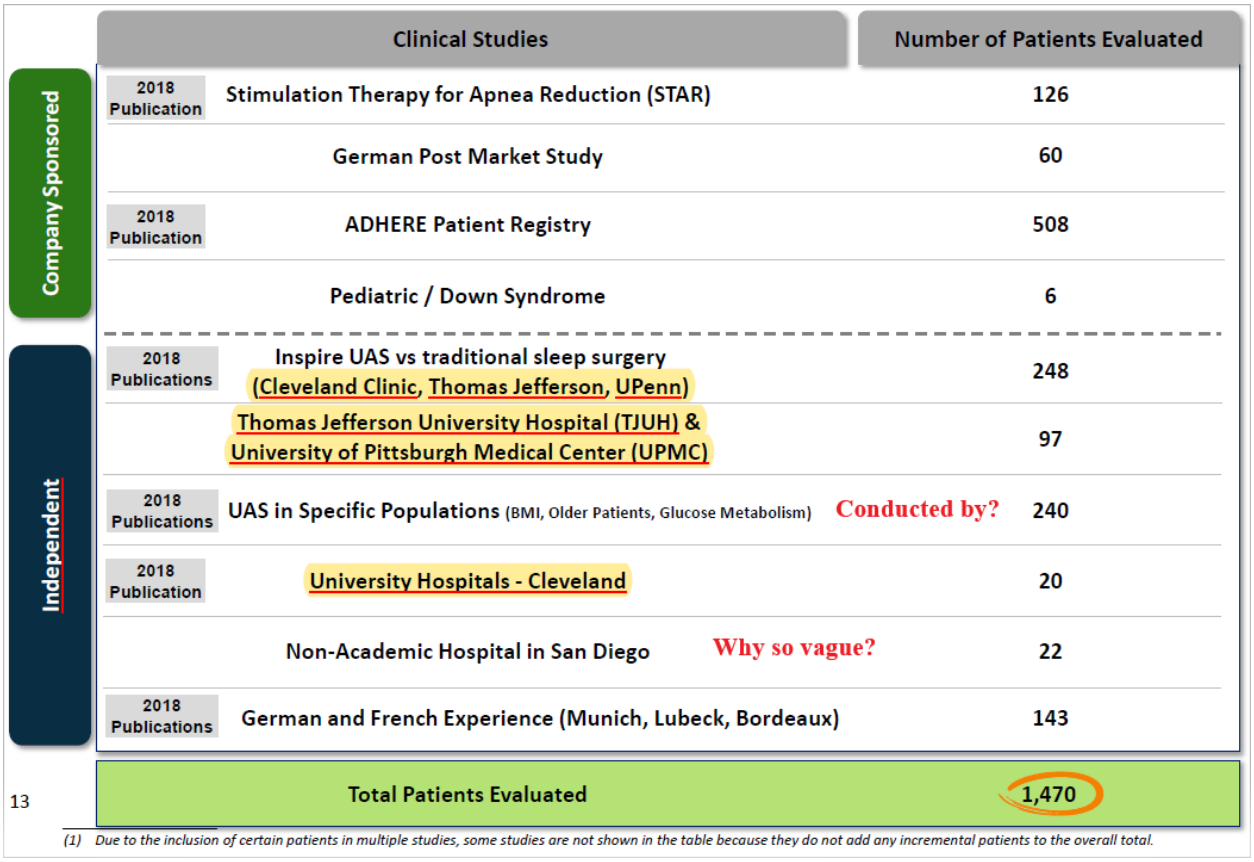
Summary

Inspire provides a limited warranty against defects. The warranty period for implanted products is 3 years. All other products have a warranty period of 1 year.

[47] https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008C.pdf

Appendix C – "Independent" Clinical Studies

Every hospital that Inspire *names* under "independent" clinical studies has received substantial payments from Inspire for vaguely named post-approval studies:[48]



Recipient Entity Name	Name of Study	Principal Researcher	Payments
Thomas Jefferson University (TJUH)	Post approval study	Maurits Boon	$167,962.00
Cleveland Clinic Hospital	Post approval study	Tina Elizabeth Waters	$113,680.00
UPenn Hospital	Post approval study	Richard J Schwab	$73,373.96
University Hospitals Cleveland MC	Post approval study	Kingman P Strohl	$21,440.00
University of Pittsburgh (UPMC)	Post approval study	Ryan Jeremy Soose	$16,912.50

[48] https://openpaymentsdata.cms.gov/company/100000061308

Appendix D – FDA Reported Adverse Events

This table contains summaries and dates drawn from the FDA database of adverse events. These are reported malfunctions and other issues with the Inspire device that resulted in injury, reversal of surgery, or other issues.

Event Date	Event Description
02/27/2020	THE PATIENT PRESENTED TO THE PHYSICIAN WITH SWELLING FROM A HEMATOMA IN THE NECK TWO WEEKS POST IMPLANT SURGERY. THE PHYSICIAN DRAINED 4-5 CC OF FLUID FROM THE HEMATOMA. THE ISSUE WAS RESOLVED AND THE PATIENT WAS ACTIVATED ON (B)(6) 2020.
02/24/2020	THE PHYSICIAN REPORTED THAT THE PATIENT HAS THE SLIGHTEST EVIDENCE OF NEUROPRAXIA AT THEIR POST-OPERATIVE APPOINTMENT ON (B)(6) 2020. THE PHYSICIAN PRESCRIBED STEROIDS AND THE PATIENT RETURNED (B)(6) 2020 WITH ALL SYMPTOMS RESOLVED.
02/18/2020	PATIENT EXPERIENCING NEURAPRAXIA ONE MONTH AFTER SURGERY TO RE-POSITION THE CUFF LEAD ON (B)(6) 2020. PATIENT PRESENTED TO PHYSICIAN WITH SLURRED SPEECH, INABILITY TO SWALLOW ANYTHING BUT SOFT FOODS AND LIQUIDS, SORENESS IN THROAT, SLIGHT DROOLING AND WHEN HE EXTENDS HIS TONGUE OUT, IT CURVES TO PATIENTS RIGHT SIDE. NO INTERVENTION TO ADDRESS INJURY HAS TAKEN PLACE AT THIS TIME. THE PHYSICIAN PLANS TO DELAY ACTIVATION TO GIVE THE PATIENT TIME TO HEAL.
02/12/2020	THE PATIENT WAS IMPLANTED ON (B)(6) 2019 AND DEVELOPED AN INFECTION. THE SURGEON REMOVED THE INSPIRE SYSTEM ON (B)(6) 2020 TO TREAT THE INFECTION.
02/11/2020	PATIENT DEVELOPED A HEMATOMA AT THE IPG SITE AFTER HIS ORIGINAL (B)(6) 2020 IMPLANT. HEMATOMA EVACUATION WAS PERFORMED IN THE OR WITHOUT INCIDENT.
2020/01/31	WOUND DEHISCENCE WAS OBSERVED AT THE IPG INCISION. PATIENT DEVELOPED AN INFECTION AND HAD THE ENTIRE INSPIRE SYSTEM SURGICALLY REMOVED ON (B)(6) 2020.
2020/01/16	SMALL SEGMENT OF THE STIMULATION LEAD HAS ERODED THROUGH THE SKIN IN THE NECK BETWEEN THE CLAVICLE AND MANDIBLE DUE TO SURGICAL WOUND DEHISCENCE. TREATED WITH ANTIBIOTICS, FLUOROQUINOLONE AND TOPICAL BACTROBAN. REMOVAL SURGERY IS SCHEDULED.
2020/01/10	PATIENT PRESENTED TO THE PHYSICIAN WITH A DEVICE INFECTION. THE PHYSICIAN PRESCRIBED THE PATIENT KEFLEX AND DOXYCYCLINE AND SURGICALLY REMOVED THE INSPIRE SYSTEM ON (B)(6) 2020. THE PATIENT HAS RECOVERED AND THE INFECTION IS CLEARING.
2020/01/06	THE PATIENT IS EXPERIENCING DIFFICULTY SWALLOWING AND PAIN SINCE SHE WAS IMPLANTED THREE MONTHS PRIOR. NO INTERVENTION HAS TAKEN PLACE AT THIS TIME.
2020/01/06	THE PATIENT HAS A SECTION OF THEIR STIMULATION LEAD PROTRUDING FROM THEIR NECK. THE PATIENT HAS BEEN ADVISED TO TURN THERAPY OFF AND IS AWAITING FURTHER INTERVENTION FROM THEIR HEALTHCARE PROVIDER.
2020/01/13	PATIENT HAD WOUND DEHISCENCE AT THE IPG INCISION. PHYSICIAN SURGICALLY REMOVED THE IPG ON (B)(6) 2020.
2019/12/30	WHILE PLACING THE 4340 SENSING LEAD, THE SURGEON OBSERVED AIR ESCAPE WHICH COULD AUDIBLY BE HEARD WITH VENTILATION AND VERIFIED WHEN BUBBLES WERE SEEN WHEN THE SURGICAL POCKET WAS FILLED WITH SALINE. A CHEST TUBE WAS PLACED TO ADDRESS THE PNEUMOTHORAX. THE ISSUE WAS RESOLVED AND THE CHEST TUBE WAS REMOVED THE DAY AFTER SURGERY.

Event Date	Event Description
2020/01/07	PATIENT WENT TO THE HOSPITAL COMPLAINING OF PAIN AT SENSE LEAD SITE. HOSPITAL SUSPECTED INFECTION AND SURGEON OPENED THE SITE, DIAGNOSED A (B)(6) INFECTION, AND TREATED BY REMOVING FLUIDS AND PACKING THE SITE. REVISION SURGERY IS SCHEDULED.
2019/12/11	PATIENT HAS INFECTION AT NECK INCISION ATTRIBUTED TO AN INGROWN HAIR. INFECTION WAS TREATED WITH KEFLEX AND BACTROBAN.
2019/11/29	THE PATIENT WAS IMPLANTED ON (B)(6) 2019. PATIENT REPORTS RIGHT NECK PAIN AND STIFFNESS. THE PHYSICIAN SUSPECTS AN INFECTION AND STARTED TREATMENT WITH CLINDAMYCIN ON (B)(6) 2019.
2019/11/21	A VESSEL WAS DAMAGED WHEN THE STIMULATION LEAD WAS IMPLANTED. THE VESSEL WAS REPAIRED INTRA-OPERATIVELY WITHOUT FURTHER ISSUE. AN ADDITIONAL INCISION WAS NEEDED TO REPAIR THE VESSEL.
2019/11/18	PATIENT WAS IMPLANTED WITH THE INSPIRE SYSTEM ON (B)(6) 2019 AND DEVELOPED A SEROMA POST-OPERATIVELY. THE SEROMA WAS ASPIRATED AND THE PATIENT WAS PUT ON ANTIBIOTICS. THE LABS CAME BACK CLEAR OF INFECTION. THE SEROMA WAS RESOLVED AS OF (B)(6) 2019.
2019/11/18	PATIENT EXPERIENCED INTERMITTENT SENSE LEAD PAIN SYMPTOMATIC OF INTERCOSTAL NEURALGIA. THE SURGEON REMOVED THE INSPIRE SYSTEM (B)(6) 2019.
2019/11/22	EROSION OF THE STIMULATION LEAD AT THE MANDIBLE. STIMULATION LEAD AND IPG SURGICALLY REMOVED (B)(6) 2019.
2019/09/14	IN 2018 I HAD A DISE (DRUG-INDUCED SLEEP ENDOSCOPY) TO DETERMINE IF I WAS A GOOD CANDIDATE TO HAVE THE INSPIRE DEVICE IMPLANTED IN MY CHEST TO TREAT MY SLEEP APNEA. AFTER THE TEST, I WAS TOLD THAT I WAS AN EXCELLENT CANDIDATE BECAUSE OF THE FACT THAT MY TONGUE FALLS BACK WHEN I FALL ASLEEP BLOCKING MY AIRWAY. ON (B)(6) 2019, I HAD SURGERY TO HAVE THE INSPIRE DEVICE IMPLANTED. THEY ALSO CONNECTED A WIRE FROM THE NERVE OF MY TONGUE TO THE DEVICE AND A SENSOR WAS PLACED IN BETWEEN MY RIBS TO MONITOR MY BREATHING WHICH WAS ALSO CONNECTED TO THE DEVICE. I WAS THEN TOLD THAT I NEEDED TO HEAL FOR A MONTH BEFORE THEY COULD ACTIVATE THE DEVICE. AFTER A MONTH, IT WAS ACTIVATED. I WAS TOLD TO INCREASE THE INTENSITY EVERY COUPLE OF DAYS UNTIL IT WAS FELT TOO INTENSE, AND THEN TO STEP IT DOWN TO A COMFORTABLE LEVEL. FIRST I DISCOVERED THAT NO MATTER WHAT INTENSITY I USED, IT WAS NOT HELPING WITH MY SLEEP APNEA. I WAS SNORING AND CLEARLY STOP BREATHING SEVERAL TIMES PER HOUR, EACH NIGHT. I ALSO NOTICED THAT IT WAS CAUSING MY TONGUE TO ‘DOUBLE AND TRIPLE TRIGGER’, WHICH MEANS THE DEVICE WAS APPARENTLY BEING TOLD TO STIMULATE THE NERVE SEVERAL TIMES AT ONCE. STILL, MY DOCTOR WANTED ME TO HAVE A SLEEP STUDY TO PROPERLY TITRATE THE DEVICE. I HAD THE SLEEP STUDY (INSPIRE EMPLOYEES WERE PRESENT) AND UNFORTUNATELY, THEY WERE NOT ABLE TO GET IT TO PROPERLY WORK. IN FACT, THEY WERE CONCERNED THAT THE SENSOR THAT MONITORS MY BREATHING WAS NOT WORKING PROPERLY. AFTER THE SLEEP STUDY, I WENT TO SEE MY SLEEP DOCTOR AND THE INSPIRE TEAM WAS THERE TO CAPTURE DATA AND DO ADDITIONAL TESTING. AFTER TESTING, THEY DETERMINED THAT THE BREATHING SENSOR THAT WAS NOT WORKING PROPERLY AND THEY RECOMMEND REVISION SURGERY TO REPLACE IT. THEY ALSO ASKED ME TO GET CHEST X-RAY. ON (B)(6) 2019 I HAD THE REVISION SURGERY. THEY DETERMINED THAT THE REASON THINGS WEREN’T WORKING PROPERLY WAS THAT THE CONNECTION FROM THE SENSOR TO THE ‘CAN’ HAD PARTIALLY DISCONNECTED. THE SURGEON RECONNECTED IT AND TESTED IT WHILE I WAS UNDER ANESTHESIA. WHEN I AWOKE, HE TOLD ME THAT EVERYTHING WAS WORKING WELL AND I COULD IMMEDIATELY START USING THE DEVICE AGAIN. I

Event Date	Event Description
	STARTED USING THE INSPIRE IMMEDIATELY AND BASED ON HOW I WAS FEELING AND THE FACT THAT MY WIFE SAID I WAS STILL SNORING, I KNEW IT WASN'T WORKING FOR ME. MY SLEEP DOCTOR HAD 'ME' GO FOR ANOTHER SLEEP STUDY TO PROPERLY TITRATE THE DEVICE. THEY SENT A TEAM FROM INSPIRE AGAIN, TO RUN THE SLEEP STUDY. WHEN I WOKE IN THE MORNING, THE INSPIRE PEOPLE TOLD ME THAT THEY WEREN'T SUCCESSFUL BUT WERE STILL CONFIDENT THAT WITH ADDITIONAL TUNING, IT WOULD BE SUCCESSFUL. THEY SAID THAT THEY WOULD MAKE A PLAN WITH MY DOCTORS. ON (B)(6) 2019, I WENT TO MY SURGEON'S OFFICE AND WAS MET BY A TEAM FROM INSPIRE, MY SLEEP DOCTOR, AND A RADIOLOGIST WHO BROUGHT AN ULTRASOUND MACHINE. THE SURGEON PERFORMED AN ENDOSCOPY WHILE THE INSPIRE PEOPLE ACTIVATED THE DEVICE AT MULTIPLE INTENSITY LEVELS WHILE THE ULTRASOUND WAS POSITIONED UNDER MY CHIN. WHEN THEY WERE DONE, THE TEAM LEFT THE ROOM TO CONFER AND THEN CAME BACK POUT TO SPEAK WITH ME. THEY DETERMINED THAT MY PALATE WAS NOT MOVING FORWARD WHEN MY TONGUE WAS MOVING FORWARD (THIS SHOULD HAVE BEEN DISCLOSED A POSSIBILITY BEFORE I HAD THE INITIAL INTENSITY). THEY EXPLAINED THAT WITH MOST PEOPLE THE PALATE MOVES FORWARD WITH THE TONGUE AND BECAUSE OF THAT, THEY DIDN'T THINK IT WOULD WORK. HOWEVER, THEY STILL SET IT TO AN 'OPTIMAL' INTENSITY LEVEL AND ASKED FOR ME TO TRY IT ANOTHER 2 WEEKS. I BELIEVE I USED IT FOR A WEEK AND THEN CONTACTED MY DOCTOR TO LET HIM KNOW THAT I WAS EXHAUSTED AND THAT IT CLEARLY WAS NOT WORKING FOR ME. I LET HIM KNOW THAT THE INTENSITY LEVEL WAS SO HIGH THAT IT WAS WAKING ME SEVERAL TIMES PER HOUR THROUGHOUT THE NIGHT. WE AGREED THAT I SHOULD STOP USING IT AND HE WAS GOING TO DO SOME MORE RESEARCH. AT THAT TIME, I SUGGESTED THAT I SHOULD JUST HAVE THE DEVICE REMOVED. I THEN WENT BACK TO CPAP. ABOUT A WEEK LATER, I HEARD FROM MY SLEEP DOCTOR. HE SAID THAT HE SPOKE WITH INSPIRE ASKED FOR ME TO GET A CHEST X-RAY TO SEE IF EVERYTHING LOOKED CORRECT AND CONNECTED. IT WAS. FDA SAFETY REPORT ID # (B)(4).
2019/11/11	TWO WEEKS AFTER IMPLANT, THE PATIENT PRESENTED WITH TWO LARGE HEMATOMAS AT THE CHIN AND IPG WITH CONSIDERABLE BRUISING ACROSS THEIR TORSO. THE PATIENT IS ON ANTICOAGULANTS, WHICH COULD NOT BE STOPPED DUE TO A HEART VALVE. THE PHYSICIAN DRAINED THE HEMATOMAS, AND PUT A DRAIN IN THE CHIN. THE PATIENT HAS BEEN ON ANTIBIOTICS SINCE IMPLANT, AND WILL CONTINUE.
2019/10/28	AT ROUTINE POST-OP APPOINTMENT, THE PHYSICIAN NOTICED THAT THE PATIENT'S IPG SITE WAS RED AND SWOLLEN. THE PHYSICIAN PRESCRIBED ANTIBIOTIC TREATMENT WHICH RESOLVED THE INFECTION.
2020/02/07	STIMULATION LEAD MIGRATED OUT OF THE SKIN AT THE LEVEL OF THE MANDIBLE. A PROCEDURE WAS DONE TO RE-INSERT A 2 CM PORTION OF THE STIM LEAD THAT HAD EMERGED THROUGH INCISION DEHISCENCE. THE PHYSICIAN RE-INCISED THE NECK INCISION, CONFIRMED THERE WAS NO INFECTION, THEN TUCKED AND SUTURED THE EXPOSED LEAD SUB-PLATISMALLY IN PLACE AFTER HEAVY IRRIGATION.
2019/10/28	DURING A SURGICAL PROCEDURE TO IMPLANT THE INSPIRE SYSTEM, SHORTLY AFTER PUTTING THE STIMULATION CUFF ON, **THE PATIENT CODED AND HIS HEART RATE WENT DOWN TO 28. AN EMERGENCY TEAM RESPONDED IN THE OPERATING ROOM AND PROVIDED TREATMENT. IMMEDIATELY AFTER TREATMENT, THE PATIENT'S BLOOD PRESSURE DROPPED AND THE EMERGENCY TEAM AGAIN PROVIDED TREATMENT. THE PHYSICIAN DECIDED TO END THE CASE. THE PATIENT IS CURRENTLY IN THE ICU AND SHOULD MAKE A FULL RECOVERY**.

Event Date	Event Description
2019/05/29	THE PATIENT IS EXPERIENCING MILD MARGINAL MANDIBULAR NERVE WEAKNESS. AT 6 MONTH POSTOP FOLLOW UP APPOINTMENT, HIS NERVE FUNCTION HAD IMPROVED ABOUT 50% BUT HAD NOT ENTIRELY RESOLVED. THE PHYSICIAN BELIEVES IT IS LIKELY HE WILL HAVE SOME RESIDUAL DEFICIT. FOLLOW UP CHECK IS PLANNED AT 12 MONTHS POSTOP.
2019/01/22	THE CHEST WALL WOUND EXHIBITED POOR HEALING AND THE IPG WAS MALPOSITIONED ON THE CHEST WALL, ROTATED APPROXIMATELY 90 DEGREES. A SURGICAL PROCEDURE WAS REQUIRED ON (B)(6) 2019 TO REPOSITION THE IPG.
2019/10/15	THIS PATIENT WAS IMPLANTED WITH INSPIRE ON (B)(6) 2019. TWO WEEKS AFTER SURGERY SHE PRESENTED WITH A WOUND INFECTION, REDNESS, SWELLING AND DRAINAGE WITH ASSOCIATED PAIN. THE CULTURE SHOWED THAT THE WOUND IS GROWING GRAM-POSITIVE COCCI. THE PHYSICIAN PRESCRIBED HER VANCOMYCIN.
2019/09/16	THE PATIENT WENT TO URGENT CARE ON (B)(6) 2019 WITH CONCERNS THAT HIS RIGHT CHIN INCISION SITE WAS INFECTED. THE SITE WAS ERYTHEMATOUS AND OOZING PUS-LIKE DRAINAGE. THE PATIENT WAS TREATED WITH MUPIROCIN OINTMENT AND BACTRIM. THE PATIENT WAS SEEN AGAIN ON (B)(6) 2019 WITH NO FURTHER TENDERNESS OR DRAINAGE.
2019/09/10	THE PATIENT REPORTED THAT HE HAD AN (B)(6) INFECTION IN HIS IPG POCKET AND AT THE INTERCOSTAL SURGICAL SITE. THE IMPLANTING PHYSICIAN PRESCRIBED THE PATIENT WITH ANTIBIOTICS. DURING AN UNRELATED MEDICAL EVENT, HOSPITAL STAFF SWITCHED THE PATIENT TO DIFFERENT ANTIBIOTICS MORE COMPATIBLE WITH A PRE-EXISTING KIDNEY CONDITION. THE DOCTOR REPORTS THAT THE INFECTED AREA IS RESOLVING WELL.
2019/09/11	THE PATIENT PRESENTED AT THE DOCTOR'S OFFICE ON (B)(6) 2019 WITH AN INFECTION AT THE IPG AND SENSE LEAD SITES. THE PHYSICIAN PRESCRIBED LEVAQUIN AND ROCEPHIN. ON (B)(6) 2019, THE PHYSICIAN DRAINED AN AREA OF FLUCTUANCE OVER THE IMPLANT SITE WITH NO MATERIAL PRODUCED. TO TREAT THE INFECTION, THE ENTIRE SYSTEM WAS EXPLANTED ON (B)(6) 2019.
2019/09/19	DEVICE INFECTION DISCOVERED BY THE ON-CALL PHYSICIAN. AFTER REVIEW BY THE IMPLANTING PHYSICIAN, IT WAS DETERMINED TO BE AN INFECTION THAT WILL REQUIRE TOTAL SYSTEM EXTRACTION. ANTIBIOTICS HAVE BEEN PRESCRIBED AND THE SYSTEM IS SCHEDULED FOR EXTRACTION.
2019/09/29	RESPIRATORY SENSORY INCISION SITE INFECTION NOTED UPON ADMISSION TO THE HOSPITAL ON (B)(6) 2019. THE PATIENT WAS TREATED WITH IV ANTIBIOTICS. THE PHYSICIAN REPORTS A DECREASE IN THE PATIENT'S PAIN AND INDURATION IMPROVEMENT. THE CARE PLAN FOR THE PATIENT INCLUDES LONG TERM ORAL ANTIBIOTICS.
2019/09/23	THE PHYSICIAN FOUND VIA X-RAY THAT THE IPG HAS MIGRATED DOWNWARD. THE PHYSICIAN PERFORMED REVISION SURGERY ON (B)(6) 2019 TO RE-SECURE THE IPG WITH SUTURES. ISSUE IS NOW RESOLVED WITHOUT COMPLICATIONS.
2019/09/10	THE PATIENT WAS IMPLANTED ON (B)(6) 2019. THE PATIENT RETURNED TO HEAVY PHYSICAL WORK 10 DAYS POST-IMPLANT AND DEVELOPED DEVICE-RELATED INFECTION AT THE IPG INCISION. THE INFECTION MIGRATED TO THE IPG POCKET AND STIMULATION LEAD. INSPIRE SYSTEM WAS EXPLANTED ON (B)(6) 2019.
2018/10/15	DURING THE POST-TITRATION VISIT, THE PHYSICIAN REPORTED THAT THE PATIENT HAD AN INFECTION. PURULENCE WAS EXPRESSED FROM A 5MM STITCH ABSCESS WHICH WAS JUST INFERIOR TO THE INCISION. THE PATIENT WAS PRESCRIBED KEFLEX FOR 7 DAYS AND THE INFECTION WAS RESOLVED WITH TREATMENT.

Event Date	Event Description
2019/09/19	ON (B)(6) 2019, THE PATIENT PRESENTED AT THE EMERGENCY ROOM WITH A POCKET INFECTION AND WAS RETREATED WITH STEROIDS VIA IV AND PRESCRIBED ANTIBIOTICS (KEFLEX). THE WOUND IS OPEN AND THERE IS A CAVITY IN THE POCKET. THE STIMULATOR COULD BE SEEN AT LAST EXAMINATION. SHE WAS IMPLANTED ON (B)(6) 2019.
2019/09/10	THE PATIENT WAS IMPLANTED ON (B)(4) 2019. HE DEVELOPED A SEROMA ONE WEEK AFTER THE IMPLANT AND WAS ADMITTED TO THE HOSPITAL ON (B)(4) 2019 WITH A LOCAL WOUND INFECTION AT THE IPG SITE. THE WOUND WAS ASPIRATED AND A SMALL AMOUNT OF SANGUINEOUS FLUID WAS EXPRESSED. HE WAS PLACED ON IV VANCOMYCIN. CULTURES SHOWED STAPH AUREUS INFECTION. THE PATIENT WAS EXPLANTED ON (B)(6) 2019 (ALL COMPONENTS).
2019/08/27	THE PATIENT PRESENTED AT THE ER WITH HER CHEST WOUND OPENED UP. SHE WILL FOLLOW UP WITH AN OFFICE VISIT TO THE IMPLANTING MD.
2019/08/07	THE PATIENT EXPERIENCED LOCALIZED SWELLING UNDER HER CHIN NEAR THROAT INCISION AFTER IMPLANT. SHE WAS SEEN BY THE HEALTHCARE PROVIDER AND WAS GIVEN ANTIBIOTICS (AMOX-CLAV GENERIC FOR AUGMENTIN). THE ISSUE IS NOW RESOLVED.
2019/08/07	**WHILE TUNNELING BETWEEN THE IPG AND THE NECK INCISION, THE PHYSICIAN HIT THE JUGULAR.** THE PHYSICIAN REPAIRED THE VESSEL INTRAOPERATIVELY.
2019/08/23	AFTER IMPLANT ON (B)(6) 2019, THE PATIENT DEVELOPED A RASH ON HIS CHEST MEDIAL TO THE DISTAL ASPECT OF THE SENSING LEAD INCISION. ALL THREE INCISIONS LOOKED GREAT AND THE PHYSICIAN DID NOT THINK THERE WAS ANY INFECTION BUT PRESCRIBED THE PATIENT A COURSE OF ANTIBIOTICS OUT OF PRECAUTION.
2019/07/30	THE PATIENT HEARD A ‘POP’ AND THE IMPLANT BECAME MOBILE. IN A REVISION PROCEDURE ON (B)(6) 2019, THE PHYSICIAN OPENED THE POCKET AND THE IPG WAS RE-SUTURED TO THE RIGHT PECTORALS MAJOR.
2019/07/29	DURING A REVISION TO RESTORE THERAPY, EXTENSIVE DAMAGE TO THE INSPIRE SYSTEM WAS DISCOVERED RESULTING FROM TWIDDLER'S SYNDROME. THE IPG HAD BEEN FLIPPED +50 TIMES, CAUSING DAMAGE TO BOTH LEADS. THE PHYSICIAN REMOVED THE PROXIMAL SECTIONS OF THE LEADS AND RESECURED THE IPG IN THE POCKET FOR POTENTIAL FUTURE RE-IMPLANTATION. THE EXPLANT PROCEDURE TOOK PLACE ON (B)(6) 2019. I WALKED HER STEPPING UP WITH HER REMOTE. SHE GOT FROM LEVEL 6 TO 7. BUT SAYS IT WON’T GO HIGHER. THE UPPER LIMIT LIGHT ISN’T ON. I THINK SHE WAS JUST IMPATIENT AND NOT WAITING LONG ENOUGH TO CONNECT TO THE IPG, SINCE IT WENT UP ONE LEVEL AT FIRST. SHE NEEDS TO BE SEEN IN OFFICE. I DON’T THINK IT’S A REMOTE ISSUE. IT’S POSSIBLE IT’S JUST SOME LATER HEALING, BUT THERE MIGHT BE AN ISSUE.

Event Date	Event Description
2018/12/13	THIS INSPIRE PATIENT HAS ALSO HAD A HEART TRANSPLANT AND IS CURRENTLY ON COUMADIN. OVER 5 MONTHS, THE PATIENT WAS SEEN THREE TIMES BY HIS PHYSICIAN FOR PAIN, SWELLING, AND DRAINAGE IN THE AREA OF HIS STIMULATION LEAD NECK INCISION. THE PHYSICIAN CONDUCTED AN ULTRASOUND OF THE AREA AND PRESCRIBED BACTRIM. AT THE SECOND VISIT, THE INCISION APPEARED SLIGHTLY RAISED BUT OTHERWISE OKAY. HOWEVER, THE PHYSICIAN PRESCRIBED ANOTHER ROUND OF BACTRIM OUT OF CAUTION. AT THE NEXT VISIT, THE PHYSICIAN NOTED THAT SWELLING AT THE SITE HAD INCREASED, THERE WAS ALSO DRAINAGE, BUT NO FEVER. THE PHYSICIAN PRESCRIBED ANOTHER ROUND OF BACTRIM AND REFERRED THE PATIENT TO AN INFECTIOUS DISEASE PHYSICIAN. **THAT PHYSICIAN CONFIRMED THAT THERE WAS AN INFECTION AT THE STIMULATION LEAD SITE BUT RECOMMENDED A DAILY ANTIBIOTIC FOR LIFE, AND AN ULTRASOUND EVERY 3-4 MONTHS TO ENSURE THAT THE INFECTION IS NOT SPREADING, AS OPPOSED TO EXPLANTING THE SYSTEM.**
2017/09/20	REDNESS/SORENESS AT THE RIGHT LATERAL MIDCHEST INCISION. TREATED WITH KEFLEX AND RESOLVED WITHOUT FURTHER TREATMENT.
2018/02/01	SUTURE ABSCESS WHICH WAS TREATED WITH 7 DAYS OF ANTIBIOTICS. NO ADDITION INTERVENTION NEEDED. Manufacturer Narrative: CAPA REMEDIATION.
2019/07/02	THE PATIENT EXPERIENCED EXCESSIVE BLEEDING AT IPG POCKET INCISION. THE PHYSICIAN DETERMINED IT WAS A HEMATOMA AND MOVED THE PATIENT BACK TO THE OPERATING ROOM. UNDER STERILE CONDITIONS, THEY REMOVED THE DEVICE FROM THE POCKET AND RESOLVED THE ISSUE.
2019/09/06	THE PATIENT IS EXPERIENCING A FACIAL DROOP ON THE RIGHT SIDE SEVERAL MONTHS AFTER SURGERY.
	ANTIBIOTICS (DICLOXACILLIN) PRESCRIBED TO TREAT SWELLING AT THE SITE OF THE INCISION.
	RIGHT SUBMANDIBULAR SIALOADENITIS TREATED WITH ANTIBIOTICS.
	THE PATIENT DEVELOPED VERY MILD ERYTHEMA OVER THE IPG SITE NOTED ON THE POST-OP VISIT AND WAS STARTED ON AN ANTIBIOTIC. IT COMPLETELY RESOLVED, UNEVENTFULLY ON FOLLOW UP VISIT. DATE OF EVENT UNKNOWN. Manufacturer Narrative: CAPA REMEDIATION.
2019/06/27	DURING A REVISION SURGERY TO RESTORE THERAPY, THE SURGEON FOUND EXTENSIVE DAMAGE TO BOTH LEADS DUE TO TWIDDLER'S SYNDROME. THE STIMULATION LEAD WAS FOUND FRACTURED IN THE RIGHT SUBLINGUAL REGION NEAR THE SUBMANDIBULAR GLAND. THE REMAINDER OF THE STIMULATION LEAD RETRACTED INTO THE CHEST WALL AND COILED IN THE AREA OF THE BATTERY PACK. THE SENSING LEAD WAS ALSO DAMAGED.
2019/06/20	DURING AN IMPLANT PROCEDURE, THE PHYSICIAN HIT AN UNEXPECTED BLOOD VESSEL DURING THE TUNNELING PORTION OF THE CASE. THE PHYSICIAN MADE AN EXTRA INCISION TO ENSURE ALL BLEEDING WAS CONTAINED. THEY SEARCHED UNTIL NO BLEEDING WAS OBSERVED WITH VALSALVA, THEN CLOSED THE INCISION. THE PATIENT WAS KEPT OVERNIGHT FOR OBSERVATION AND THE ISSUE RESOLVED WITH NO HEMATOMA.
2017/02/15	DATE OF EVENT START IS UNKNOWN; ASSOCIATED STUDY VISIT (B)(6) 2017. PATIENT WAS ADMITTED TO THE HOSPITAL WITHIN ONE MONTH OF IMPLANT FOR THE TREATMENT OF NECK SWELLING, EPISODES OF DIZZINESS, SWEATING, AND SEEING SPOTS. ADVERSE EVENT RESOLVED BY (B)(6) 2017. Manufacturer Narrative: CAPA REMEDIATION.
2017/07/14	THE PATIENT COMPLAINED OF A LISP WITH NO NERVE WEAKNESS 3 MONTHS AFTER IMPLANT. THE PHYSICIAN REPORTED THAT THIS RESOLVED WITHOUT INTERVENTION. Manufacturer Narrative: CAPA REMEDIATION.

Event Date	Event Description
2018/06/07	THE PATIENT PRESENTED WITH SEVERE POST-SURGICAL EAR PAIN WHICH AFFECTED THE PATIENT'S HEARING. THE PHYSICIAN ORDERED ANTIBIOTICS AND EXTENDED THE PATIENT'S POST-SURGICAL STAY IN THE HOSPITAL. THE ISSUE RESOLVED AFTER TREATMENT. Manufacturer Narrative: CAPA REMEDIATION.
2015/08/15	POSTOPERATIVE CELLULITIS AROUND THE SUBMANDIBULAR INCISION, WHICH DEVELOPED AFTER THE SUBJECT PICKED OFF THE SURGICAL DRESSING. FULLY RESOLVED AFTER ADMINISTERING ORAL MEDICATIONS. Manufacturer Narrative: CAPA REMEDIATION.
2019/06/07	**THE PATIENT HAS AN INFECTION THAT THE PHYSICIAN IS TRYING TO TREAT, BUT HE THINKS WE MAY HAVE TO EXPLANT.**
2019/06/08	PAIN, SWELLING, FEELING OF HEAT AT IPG SITE REPORTED TO BY THE PATIENT. THE PHYSICIAN PRESCRIBED ANTIBIOTICS ON (B)(6) 2019. SITE DRAINAGE (B)(6) 2019. PAIN, SWELLING AND DRAINAGE UNDETECTABLE AND RESOLVED ON (B)(6) 2019.
2014/09/05	RIGHT CHEST SEROMA AT 5 WEEKS POST-OP. ISSUE REPORTED AS RESOLVED BY THE PHYSICIAN. Manufacturer Narrative: CAPA REMEDIATION.
2014/12/11	CHEST SEROMA. THE PATIENT HAD BEEN DOING SOME HEAVY LIFTING AFTER IMPLANT AND THE SEROMA RESULTED. THE SURGEON, DR. (B)(6), EVACUATED THE SEROMA IN OFFICE AND SENT THE PATIENT HOME. THE PHYSICIAN CONFIRMED THAT THE SEROMA WAS RESOLVED. Manufacturer Narrative: CAPA REMEDIATION.
2017/06/01	THE PATIENT COMPLAINED OF LISPING, RIGHT LOWER LIP NUMBNESS, AND A CROOKED SMILE AT HIS POST-OP, 1-MONTH, AND 2-MONTH APPOINTMENTS. THE PHYSICIAN CONFIRMED THAT THE ISSUE IS NOW RESOLVED. Manufacturer Narrative: CAPA REMEDIATION.
2019/05/31	**DURING A REVISION WHICH WAS INITIALLY INTENDED TO RESTORE THERAPY, THE SURGEON DISCOVERED DEVICE MIGRATION**. THE IPG WAS UPSIDE DOWN (I.E., ETCHING DEEP TOWARD THE PECTORALIS MAJOR) UPON FIRST OPENING THE SCAR CAPSULE. THE PHYSICIAN DETERMINED TWIDDLING OF IPG OCCURRED (TWIDDLER'S SYNDROME). NO PRIOR INDICATION FROM THE PATIENT OR PHYSICIAN OF DEVICE MIGRATION. IN THE REVISION, THE SURGEON REPLACED THE IPG AND SENSE LEAD, RESOLVING THE ISSUE. THE IPG WAS ATTACHED WITH WIDE SET ANCHOR POINTS TO PREVENT FUTURE MIGRATION.
2018/02/18	THE PATIENT CALLED THE CLINIC ON (B)(6) 2018 WITH COMPLAINTS OF NECK SWELLING AND DIFFICULTY SWALLOWING. THE PHYSICIAN PRESCRIBED A STEROID (MEDROL DOSE PACK) OVER THE PHONE. THE PATIENT CALLED THEIR PHYSICIAN ON (B)(6) 2018 WITH NO RESOLUTION AND CAME TO THE CLINIC. THERE THEY WERE EVALUATED BY A NURSE PRACTITIONER AND FOUND TO HAVE A NECK HEMATOMA. THE PATIENT WAS STARTED ON ANTIBIOTICS TO PREVENT INFECTION. AT POST OP VISIT ON (B)(6) 2018 ISSUE WAS RESOLVED. Manufacturer Narrative: CAPA REMEDIATION.
2017/05/10	THE ANCHOR OF THE STIMULATION LEAD WAS NOTED TO HAVE MIGRATED. THE SURGEON REPOSITIONED THE ANCHOR IN A REVISION SURGERY WHICH RESOLVED THE ISSUE. Manufacturer Narrative: CAPA REMEDIATION.
2017/01/01	SLURRED SPEECH WAS REPORTED AT THE POST-TITRATION VISIT AND FINAL VISIT (1 YEAR APART). THE PHYSICIAN CONFIRMS THAT SLURRED SPEECH ISSUES HAVE RESOLVED. Manufacturer Narrative: CAPA REMEDIATION.

Event Date	Event Description
2019/05/20	PATIENT REPORTS SEVERE NERVE PAIN RADIATING FROM HER NECK TO THE TOP OF HER HEAD AND MIGRAINE HEADACHES. THE PHYSICIAN REPORTS THAT THE PATIENT'S ISSUE IS NOT RELATED TO THE IMPLANT, BUT THAT SOME ASPECT OF THE PROCEDURE TRIGGERED THE PROBLEM AS THERE WAS NO HISTORY PRIOR AND SYMPTOMS STARTED IMMEDIATELY POST-OP IN THE RECOVERY ROOM WHEN SHE WAS COMING OUT OF ANESTHESIA. HER PHYSICIAN HAS NOT ACTIVATED HER DEVICE. THE PHYSICIAN REFERRED THE PATIENT TO A NEUROLOGIST WHO PRESCRIBED MULTIPLE MEDICATIONS FOR SYMPTOM RELIEF AND AN MRI. MRI RESULTS WERE WITHIN NORMAL LIMITS. NEITHER THE NEUROLOGIST NOR THE ENT FEELS THIS IS RELATED TO THE IMPLANT ITSELF, BUT POSSIBLY POSITIONING ON THE TABLE INJURED THE CERVICAL NERVE DURING THE PROCEDURE.
2019/05/31	THE PATIENT PRESENTED WITH THE STIMULATION LEAD WIRE PARTIALLY EXTRUDED OUT OF THEIR SURGICAL INCISION. THE SURGEON EXAMINED THE LEAD UNDER A SCOPE TO ACCESS FOR ANY DAMAGE AND RAN PROGRAMMING TESTS TO ENSURE THE LEAD WAS INTACT. THE PHYSICIAN THEN PROCEEDED WITH DEBRIDEMENT AND CLEANING OF THE WOUND. THE PHYSICIAN RE-MANEUVERED THE LEAD TO LIE FLAT AND CLOSED THE WOUND WITHOUT FURTHER INCIDENT.
2019/04/18	THE SURGERY WAS COMPLETED BY DR. (B)(6) ON (B)(6) 2019. THE PATIENT EXPERIENCED A HEMATOMA IN HIS NECK POST-SURGERY. HE CONTINUES TO HAVE SOME SWELLING AND THERE IS A PROMINENT MASS/HEMATOMA AROUND THE INCISION SITE.
2019/04/05	THE PHYSICIAN INFORMED INSPIRE OF A SENSE LEAD REVISION THAT TOOK PLACE ON (B)(6) 2019. PATIENT COMPLAINED OF PAIN. THE RESPIRATORY LEAD WAS READJUSTED WITHIN THE INTERCOSTAL SPACE AND THE SYSTEM TESTED INTRAOPERATIVELY.
2019/04/23	**DURING THE IMPLANTATION OF THE INSPIRE STIMULATION LEAD, THE PATIENT'S EXTERNAL JUGULAR VEIN WAS LACERATED DURING TUNNELING. THE BLEEDING WAS NOT EASILY CONTROLLED AND MORE ADVANCED INTERVENTION WAS NEEDED. THE SURGEON MADE A SECONDARY INCISION APPROXIMATELY 5CM LONG AND 5CM BELOW THE PRIMARY STIMULATION LEAD INCISION. THIS ALLOWED ACCESS TO THE SOURCE OF THE BLEEDING AND HE WAS ABLE TO DELIVER THE PROPER INTERVENTION TO CONTROL THE BLEED.**
2019/04/22	THE PHYSICIAN REPLACED A PATIENT'S STIMULATION LEAD WHICH HAD BEEN IMPLANTED TOO SUPERFICIALLY. THE REVISION WAS SUCCESSFUL.
2018/02/16	THE PHYSICIAN'S OFFICE INFORMED INSPIRE ON (B)(6) 2019 OF A PATIENT WHO HAD EXPERIENCED AN ADVERSE EVENT IN (B)(6) 2018 WHEN THE PATIENT'S SIMULATION WIRE TEMPORARILY EXTRUDED FROM THE SKIN AFTER LIFTING A 200-POUND PIECE OF SHEETROCK. INSPIRE PERSONNEL WAS NOT AWARE OF THE ISSUE AND THE PHYSICIAN'S OFFICE WAS CONTACTED (B)(6) 2019 FOR ADDITIONAL INFORMATION. THE PHYSICIAN DID NOT SEE THE PATIENT IN THE OFFICE AND PRESCRIBED BACTRIM REMOTELY. THE PHYSICIAN INDICATED THAT THE EVENT WAS NON-SERIOUS AND RESOLVED (B)(6) 2018.
2019/04/08	PHYSICIAN TREATED AN INFECTION AT THE STIMULATION LEAD WITH BACTRIM OVER THE COURSE OF 5 MONTHS. PHYSICIAN REPORTS THAT THERE IS NOW NO EVIDENCE OF ONGOING INFECTION.
2019/04/09	THE PATIENT WAS SEEN BY A PHYSICIAN ON (B)(6) 2019. THE PHYSICIAN NOTED THAT THERE WAS PUS COMING OUT OF CHEST (IPG) INCISION. THE PHYSICAN STARTED THE PATIENT ON AUGMENTIN, PEROXIDE, AND BACITRACIN OINTMENT. THE PHYSICIAN REPORTED THE EVENT AS RESOLVED WITHOUT SEQUELAE ON (B)(6) 2019.

Event Date	Event Description
2019/03/23	THE PATIENT EXPERIENCED WOUND DEHISCENCE AT THE SENSING LEAD INCISION SITE, AS WELL AS SENSE LEAD MIGRATION TO THE SURFACE OF THE SKIN.
2019/03/22	PATIENT EXPERIENCED DEEP VEIN THROMBOSIS BLOOD CLOT POST SURGERY.
2019/03/25	THE PATIENT COMPLAINED OF BEING ABLE TO EASILY MOVE THE IPG OFF OF THE CHEST WALL. THE IPG MOVES AND FLIPS WHEN THE PATIENT LIES ON HER LEFT SIDE. THIS WAS DEMONSTRATED TO A HEALTH PROFESSIONAL. DOCTOR WILL BE SCHEDULING THE PATIENT FOR A POCKET REVISION.
2019/03/09	AFTER THE IMPLANT SURGERY, THE PATIENT COMPLAINED OF RIGHT BACK PAIN WHICH WAS WORSE LYING FLAT OR TO THE RIGHT SIDE AND WORSE WITH INSPIRATION. PAIN GOES AWAY WHEN HE HOLDS HIS BREATHE. HE IS FINE WHEN HE IS UPRIGHT. HE DENIES ANY COUGH, FEVER, SHORTNESS OF BREATH OR ISSUE WITH EATING. THREE WEEKS POST SURGERY THE PATIENT RECEIVED A CT OF THE CHEST WHICH SHOWED SMALL TO MODERATE RIGHT PLEURAL EFFUSION WITH ADJACENT LIMITED INFILTRATE AND ATELECTASIS POSTERIOR RIGHT LOWER LOBE. PATIENT'S SYMPTOMS ARE STABLE BUT THE EFFUSION APPEARED TO BE SIMILAR ONE WEEK LATER IN CT SCAN.
2019/03/20	THE PATIENT WAS BROUGHT BACK INTO THE OR SEVERAL MONTHS AFTER IMPLANT DUE TO AN ABSCESS AT THE NECK INCISION.
2019/04/26	THE PATIENT PRESENTED AT THE DOCTOR'S OFFICE ON (B)(6) WITH STIMULATION LEAD EROSION AT THE INCISION SITE. THE DOCTOR REPORTED THAT THE PATIENT IS ON BIOLOGIC FOR PSORIASIS THAT MAKES THE PATIENT IMMUNOSUPPRESSED. REMOVAL OF THE IMPLANT IS SCHEDULED FOR (B)(6) 2019.
2019/04/01	THE PATIENT COMPLAINS OF INTERNAL PAIN AND SKIN SENSITIVITY AT THE IPG SITE ONGOING SINCE HER (B)(6) 2018 IMPLANT. THIS WAS FIRST REPORTED ON (B)(6) 2019. THE IPG SITE IS SENSITIVE TO MOVEMENT AND CLOTHING. IT ALSO OCCASIONALLY HAS BRUISING. PATIENT HAS ALSO EXPERIENCED UNRELATED SURGERIES AND ILLNESS SINCE THE IMPLANT. SHE HAS SCHEDULED A FOLLOW-UP VISIT WITH HER MD.
2019/03/01	DURING IMPLANT, THE SENSING LEAD PENETRATED THE SPACE BETWEEN THE INTERNAL INTERCOSTALS AND LUNG. THE ISSUE WAS RECOGNIZED, THE AREA WAS OVERSEWN WITH TWO LAYERS OF SUTURE. THE AREA WAS FLOODED WITH SALINE, ANESTHESIA PERFORMED VALSALVA WITHOUT ANY BUBBLES BEING SEEN. THE LEAD WAS THEN MOVED TO A DIFFERENT RIB SPACE SUCCESSFULLY. POST-OP CHEST X-RAY DID NOT SHOW PNEUMOTHORAX. THE PATIENT WAS CLINICALLY ASYMPTOMATIC AND DISCHARGED PER USUAL.
2019/02/11	ON (B)(6) 2019, I HAD AN INSPIRE SLEEP DEVICE IMPLANTED TO HELP ME WITH MY SLEEP APNEA. AFTER SURGERY, I HAD TO WAIT A MONTH TO HEAL. I WENT TO THE DR ON (B)(6) 2019, FOR THEM TO TURN THE DEVICE ON AND START USING IT. VERY SHORTLY THEREAFTER, I STARTED NOTICING PAIN IN MY RIB WHERE THEY PLACED THE SENSOR WHICH MONITORS MY BREATHING AND TELLS THE DEVICE WHEN TO STIMULATE MY TONGUE NERVE. SOMETHING (THEY THINK THE SENSOR) WAS TELLING THE DEVICE TO DELIVER STIMULATION INCORRECTLY. I WENT IN FOR FURTHER TESTS AND AM AWAITING THEIR CALL. HOWEVER, THEY SUSPECT THAT I WILL NEED A "REVISION" WHICH WILL REQUIRE THEM TO REPLACE THE DEVICE AND THE SENSOR BELOW.
2019/02/22	THE PATIENT DESCRIBED RECENT PAIN AT THE INTERCOSTAL INCISION SITE. CT ORDERED BY IMPLANTING SURGEON AND POSSIBLE BREATHING SENSOR MIGRATION INTO PLEURAL SPACE. HARDWARE/EQUIPMENT IS FUNCTIONING AS IT SHOULD, PATIENT AHI HAS BEEN REDUCED FROM 47 TO 1.4.
2019/02/20	STIMULATION LEAD WAS IMPLANTED TOO SUPERFICIAL AND NEEDED A REVISION PROCEDURE TO BE RE-TUNNELED DEEPER.

Event Date	Event Description
2019/02/18	**PATIENT INFECTION CONFIRMED - TOTAL INSPIRE SYSTEM EXTRACTION BEING SCHEDULED.**
2019/02/02	WHILE SYMPTOMS APPEAR TO BE IMPROVING DURING POST-IMPLANT HEALING, THE PATIENT WAS SEEN AT HER POST-OP CHECK AND PRESENTED WITH SIGNS OF TONGUE WEAKNESS, DIFFICULTY WITH SPEECH, AND PAIN IN THE JAW. ACTIVATION HAS BEEN DELAYED.
2019/02/13	PATIENT REPORTS THAT THE DEVICE TURNS ON UNEXPECTEDLY. THE PATIENT ALSO REPORTS A PAINFUL AND BURNING SENSATION IN THE MOUTH HE ASSOCIATES WITH USING INSPIRE THERAPY.
2019/02/13	PATIENT HAS CONTINUED PAIN POST-IMPLANT. PAIN STARTED IN HIS SIDE BUT IS NOW IN HIS CHEST. DEVICE IS NOT CURRENTLY BEING USED.
2019/02/12	PATIENT UNDERWENT A SENSING LEAD REVISION. THE LEAD WAS NOT REPLACED OR EXPLANTED. THE LEAD'S STRAIN-RELIEF WAS INCREASED TO ADDRESS DEVICE TRACTION. THE LEAD WAS TESTED AFTER BEING REPOSITIONED AND PERFORMED ADEQUATELY.
2019/02/12	PATIENT IS EXPERIENCING ENLARGED SALIVARY GLANDS LEADING TO EXCESSIVE SALIVA AND CHOKING THAT CORRELATES WITH INSPIRE THERAPY USE. PATIENT UNDERWENT ENDOSCOPY AND HAS A BIOPSY SCHEDULED WITH AN ENT.
2019/02/12	PNEUMOTHORAX FOUND ON CHEST X-RAY FOLLOWING IMPLANT PROCEDURE. DOCTOR BELIEVES IT WAS CAUSED DURING TUNNELING. THE PATIENT HAD A CHEST TUBE PLACED AND WAS KEPT IN THE HOSPITAL OVERNIGHT.
2019/02/01	PATIENT HAS A BULGE NEXT TO THE SENSE LEAD INCISION. IT APPEARED AFTER SURGERY AND THOUGH STILL PALPABLE, THE PATIENT REPORTS THAT IT IS SMALLER THAN WHEN SHE FIRST DISCOVERED IT. THE AREA AROUND THE INCISION AND BULGE IS TENDER AND FEELS LIKE A BRUISE.
2019/02/05	PLANNED REVISION SURGERY FOR STIMULATION LEAD WHICH IS TOO SUPERFICIAL TO THE SURFACE OF THE SKIN. THE PHYSICIAN WOULD LIKE TO REMOVE THE LEAD AND RE-TUNNEL IT DEEPER.
2019/02/05	THE PATIENT PRESENTED TO THE PHYSICIAN'S OFFICE FOR SURGICAL FOLLOW UP WITH A RASH AT SENSE LEAD INCISION SITE. PATIENT REPORTS RASH BEGAN ON (B)(6) 2019. CONSULTATION WITH DERMATOLOGIST SUGGESTS CLASSIC CONTACT DERMATITIS FROM EITHER BETADINE OR IOBAN.
2019/01/29	PATIENT IS EXPERIENCING MIGRATION OF THE IPG. DEVICE IS MOVING INTO A POSITION DURING SLEEP THAT COULD LEAD TO TWISTING AND COMPROMISE THE SENSE OR STIMULATION LEAD. REVISION SURGERY TO ADDRESS IS LIKELY.
2019/01/22	THE PATIENT REPORTED THEY EXPERIENCED DIFFICULTY SWALLOWING FOOD AND LIQUID AFTER THE DEVICE WAS IMPLANTED.
2019/01/18	PATIENT SAW IMPLANTING PHYSICIAN ON (B)(6) AND WAS PRESCRIBED 800 MG OF IBUPROFEN AND PREDNISONE DUE TO FACIAL SWELLING. PATIENT LATER EXPERIENCED SIGNIFICANT RASH ON TORSO AND THE RIGHT SIDE OF FACE. PATIENT SAW PHYSICIAN AGAIN ON (B)(6) 2019. PHYSICIAN PRESCRIBED BENADRYL, AMOXICILLIN-CLAV 875-125 MG TAB TWICE A DAY AND METHYLPREDNISOLONE 4 MG DOSE PACK (21). THERAPY ACTIVATION DELAYED AS A RESULT.
2019/01/11	PHYSICIAN INFORMED INSPIRE THAT PATIENT WAS EXPERIENCING RIGHT MOUTH DISCOMFORT AND TONGUE WEAKNESS, NEUROPRAXIA, AND SOME DROOLING FROM RIGHT SIDE OF MOUTH AT POST-OP WOUND CHECK 10 DAYS POST OP. THE PHYSICIAN INDICATED THAT THE PATIENT IS NOW DOING MUCH BETTER BUT IS STILL DROOLING WITH SOME TONGUE WEAKNESS RESULTING IN A DELAY IN DEVICE ACTIVATION.

Event Date	Event Description
2019/09/09	PATIENT COMPLAINS OF PAIN ASSOCIATED WITH DEVICE PLACEMENT (IPG, STIM AND SENSING LEAD). **"SHARP NEEDLE-LIKE" PAIN AND SHORTNESS OF BREATH. PATIENT HAS DISCONTINUED THERAPY.**
2019/01/04	ONE MONTH POST IMPLANT PATIENT COMPLAINED ABOUT HAVING SWALLOWING AND SPEECH PROBLEMS AND WAS DIRECTED TO SEE HIS PHYSICIAN. THE PHYSICIAN, A NEUROLOGIST/SLEEP PHYSICIAN, NOTED THAT THE PATIENT HAS TONGUE WEAKNESS WHICH INCLUDES SYMPTOMS OF TONGUE DEVIATION. HE ALSO HAS TROUBLE MOVING THE TONGUE TO THE LEFT SIDE. THE PATIENTS SWALLOWING ISSUES HAD RESOLVED SIGNIFICANTLY BY THE TIME OF THE PHYSICIAN VISIT, BUT THE SLURRED SPEECH CONTINUES. PATIENT REPORTED THAT THE SPEECH SLURRING HAS IMPROVED A LITTLE BIT. ACTIVATION OF THE SYSTEM HAS BEEN POSTPONED TO ALLOW MORE TIME FOR THE PATIENT TO HEAL FROM THE IMPLANT SURGERY. PATIENT WAS SCHEDULED FOR ANOTHER OFFICE VISIT WITH THE DOCTOR IN 8 WEEKS AND WAS INSTRUCTED TO REACH OUT TO THE DOCTOR IF SYMPTOMS CHANGE.
2019/01/09	PHYSICIAN SUSPECTS PATIENT MAY BE ALLERGIC TO A MATERIAL OF THE IMPLANTED SYSTEM.
2019/01/09	PHYSICIAN CONTACTED INSPIRE BY TEXT MESSAGE STATING THAT A PATIENT HAD A MINOR PNEUMOTHORAX ON X-RAY POST OP. NO SIGNS OF PROBLEMS INTRAOPERATIVELY AND THE PATIENT WAS TOTALLY ASYMPTOMATIC, BUT VERY CLEAR SMALL PNEUMO ON POST-OP X-RAY. NO ADDITIONAL FOLLOW-UP OR INTERVENTION IS EXPECTED FROM THIS.
2019/01/09	PATIENT EXPERIENCED UNINTENDED STIMULATION ON THE RIGYT SIDE OF THEIR NECK AND THORAX.
2019/07/23	**PATIENT PRESENTED WITH A PARTIALLY EXPOSED SENSOR LEAD AND A SWOLLEN IPG POCKET. THERE WAS INFECTION IN BOTH OF THESE SITES. PATIENT UNDERWENT SURGERY TO EXPLANT THE SENSOR LEAD AND IPG. THOROUGH IRRIGATION WAS USED TO CLEAN BOTH SITES AND THE INCISIONS WERE THEN CLOSED. THE EXPLANTED PRODUCT WAS SENT TO THE HOSPITALS PATHOLOGY LAB PER THEIR STANDARD OPERATING PROCEDURE.**
2018/04/18	DURING A FOLLOW UP APPOINTMENT THE PATIENT SHARED THAT HE HAS EXPERIENCED NAUSEA AND "VOMITTING" FOLLOWING HIS IMPLANT PROCEDURE. HE ALSO COMPLAINED OF PAIN AT THE IPG SITE WHICH WAS TENDER AND AT TIMES THE IPG CAN ANGLE UP IF PUSHED ON ACCIDENTALLY. THE PATIENT WAS INSTRUCTED TO SEE HIS PCP AND A GI DOCTOR.
2018/12/13	PATIENT IS EXPERIENCING TRACTION ON THE STIMULATION LEAD.
2018/12/17	PATIENT REPORTED THAT THE STIMULATION WAS PAINFUL AND THAT THERE WAS SWELLING IN THEIR TONGUE AN ON THEIR NECK.
2018/12/05	THE PATIENT STATED THAT HE HAD NOTICED A LISP AFTER HIS IMPLANT SURGERY WHICH HAS IMPROVED WITH TIME.
2018/12/05	PATIENT HAD 3MM'S OF FLUID ACCUMULATION UNDER NECK INCISION SITE OF THE STIMULATION LEAD AND A SWOLLEN LYMPH NODE. THE PHYSICIAN IT DRAINED THE FLUID AND CHECKED FOR INFECTION. THERAPY ACTIVATION DELAYED FOR ONE WEEK. THE ISSUE HAS RESOLVED. THERE WAS NO INFECTION AND NO ANTIBIOTICS WERE NEEDED.
2018/11/27	PATIENT EXPERIENCED A PNEUMOTHORAX DURING THE IMPLANT WHICH WAS ADDRESSED DURING THAT PROCEDURE. PATIENT WAS MONITORED FOLLOWING IMPLANT AND IS DOING WELL.
2018/11/15	PATIENT REPORTS FEELING PAIN ON THE RIGHT SIDE OF HIS TONGUE. HIS SYSTEMS SENSING WAVEFORM ALSO APPEARS TO BE ABNORMAL.

Event Date	Event Description
2018/11/01	SURGEON INADVERTENTLY CUT THE DIGASTRIC TENDON DURING THE STIMULATION LEAD IMPLANTATION. THE TENDON WAS SURGICALLY REPAIRED DURING THE IMPLANT PROCEDURE. IMPLANT PROCEEDED WITHOUT FURTHER INCIDENT OR COMPLICATION.
2018/10/15	PATIENT WAS IMPLANTED (B)(6) 2018 AND SUBSEQUENTLY DEVELOPED AN INFECTION AT THE SENSING LEAD IMPLANT SITE. PATIENT HAS BEEN PUT ON ANTIBIOTIC TREATMENT AND **HAD THE ENTIRE INSPIRE SYSTEM EXPLANTED** ON (B)(6) 2018.
2018/09/27	AFTER THE IMPLANT SURGERY THE PATIENT EXPERIENCED SOME SWELLING AT THE INCISION SITE OF HIS STIMULATION LEAD. HE CALLED THE DOCTORS OFFICE AND THEY PRESCRIBED HIM AN ANTIBIOTIC WHICH RESOLVED ALL SWELLING AND IRRITATION. THE PATIENT ALSO HAD SOME WEAKNESS IN HIS LOWER RIGHT LIP BUT SAID IT WAS IMPROVING OVER TIME. AT THE PATIENT'S THERAPY ACTIVATION VISIT, THE DOCTOR DID A FUNCTIONAL TONGUE EXAM WHICH SHOWED NORMAL FUNCTION. THE PATIENT WAS ACTIVATED AND SENT HOME.
2018/10/02	DURING A SURGICAL PROCEDURE UNRELATED TO INSPIRE THERAPY THE SURGEON OBSERVED THAT THE SENSING LEAD, IMPLANTED 2.5 YEARS EARLIER, WAS PLACED IN THE PLEURAL SPACE. THERE IS NO PATIENT INJURY AND THE THERAPY IS WORKING WELL, BUT IT APPEARS THAT THE PATIENT EXPERIENCED A SELF HEALING PNEUMOTHORAX DURING THE IMPLANT PROCEDURE.
2017/09/21	DURING TUNNELLING, PRIOR TO PLACEMENT OF THE SENSOR LEAD, PHYSICIAN WAS USING A MALLEABLE RIBBON RETRACTOR WHICH IS NOT AN INSPIRE PRODUCT. THE RETRACTOR WAS PLACED INTO THE INTERCOSTAL SPACE BUT PLANED SLIGHTLY BELOW THE INTERNAL INTERCOSTAL FIBERS. A SLIGHT NOISE WAS NOTED AND SOME SMALL BUBBLES WERE OBSERVED. CORRECTIVE MEASURES WERE TAKEN TO MANAGE WHAT APPEARED TO BE A SMALL PNEUMOTHORAX. NO LUNG COLLAPSE OR VOLUME CHANGE WAS NOTED AND ONCE IT WAS DETERMINED THE SITUATION WAS STABLE THE SENSOR WAS PLACED AND THE CASE COMPLETED AS NORMAL. THE PATIENT WAS OBSERVED AND NO FURTHER COMPLICATIONS WERE NOTED. Manufacturer Narrative: THE PNEUMOTHORAX WAS CAUSED BY A SURGICAL TOOL CALLED A RIBBON RETRACTOR. THIS TOOL IS NOT MANUFACTURED BY INSPIRE MEDICAL SYSTEMS BUT SINCE IT CAUSED THE PNEUMOTHORAX WHILE BEING USED DURING AN INSPIRE IMPLANT PROCEDURE, SPECIFICALLY IN PREPARATION FOR PLACEMENT OF THE INSPIRE MODEL 4323 SENSING LEAD WE ARE FILING THIS MDR.
2018/09/28	PATIENT SHOWED UP AT THE OFFICE WITH A SMALL BUMP ON HIS NECK. HE THOUGHT IT WAS A PIMPLE AND PICKED AT IT, BUT IT WAS A PART THE STIMULATION LEAD BELOW THE STIM INCISION. NO INFECTION, BUT PATIENT PUT ON ANTIBIOTICS AS A PRECAUTION. PATIENT WAS BROUGHT INTO THE OR AND THE SMALL AREA WAS OPENED UP, LEAD WAS REPOSITIONED UNDER THE PLATISMA AND SUTURED LOOSELY DOWN. AND THE INCISION CLOSED.
2018/06/19	INITIAL REPORT WAS THAT PATIENT REQUIRED DEVICE SETTING ADJSUTMENTS BUT SUBSEQUENTLY IT WAS MADE KNOWN TO INSPIRE THAT ISSUES WITH SENSING AND WAVEFORMS LED TO TWO REVISION SURGERIERS, ONE TO REPLACE THE SENSING LEAD (B)(6) 2018), AND THEN LATER (B)(6) 2018) THE IPG WAS REPLACED. THIS RESOLVED THE ISSUES AND THERE WAS NO PATIENT INJURY. Manufacturer Narrative: RETURNED PRODUCT ANALYSIS OF THE SENSING LEAD REVEALED THAT THE DIP CPAT INSULATION ON THE SENSE LEAD HAD BEEN CUT, POSSIBLY DURING IMPLANT PROCEDURE. THIS DAMAGE WOULD BE CONSISTENT WITH THE DEVICE ISSUES REPORTED.

Event Date	Event Description
2018/10/02	PATIENT FELT THAT HIS IPG MAY HAVE SHIFTED POSITION AND THE SENSE LEAD WAS PROVIDING ABNORMAL WAVEFORMS AND IMPEDANCE READINGS. REVISION SURGERY WAS CONDUCTED TO REPLACE THE SENSE LEAD AND ADDRESS DEVICE MIGRATION.
2018/09/20	PHYSICIAN REPORTS PATIENT IS EXPERIENCING TRACTION ON THE STIMULATION LEAD AND HAS SCHEDULED A REVISION SURGERY FOR (B)(6) 2018 TO ADDRESS THIS ISSUE.
2018/09/20	PHYSICIAN REPORTED PATIENT IS EXPERIENCING AN INFECTION AT THE SITE OF THE SENSING LEAD IMPLANT. MEDICAL INTERVENTION TO TREAT THE INFECTION IS LIKELY.
2018/09/20	DR REPORTED THAT THE PATIENT HAS AN INFECTION AT THE IPG IMPLANT SITE AND HAS SCHEDULED AN EXPLANT PROCEDURE AS A RESULT.
2018/10/01	DURING THE PATIENTS DEVICE CHECK VISIT, THE SLEEP TECH NOTICED THAT THE IPG INCISION WAS CRUSTED OVER AND WHEN THE PATIENT LAID DOWN, IT BROKE OPEN AND PUS CAME OUT. ALSO, THE SENSE LEAD INCISION WAS RED AND CRUSTED OVER AND LIKELY INFECTED AS WELL. THE ON-CALL PHYSICIAN SENT THE PATIENT HOME AND DIRECTED THE PATIENT TO GET IN TOUCH WITH THEIR PRIMARY PHYSICIAN THE NEXT DAY.
2018/04/16	DURING THE IPG RE POSITIONING FOR COSMETIC PURPOSES, A BREACH IN THE SENSING LEAD INSULATION WAS NOTICED. IT WAS NOT ADDRESSED DURING THIS INITIAL REVISION PROCEDURE. THERAPY WAS DISCONTINUED AND ANOTHER PROCEDURE WAS DONE TO REPLACE THE SENSING LEAD AND RESTORE THERAPY. THIS RESOLVED THE ISSUE.
2018/08/27	PATIENT EXPERIENCED PAIN/HEAT AND A SEROMA AT THE IPG INCISION SITE. PHYSICIAN ASPIRATED 5-7 CC OF FLUID FROM THE IPG SITE, AND STARTED ANTIBIOTICS.
2018/08/28	AT PATIENT'S MONTH 2 TITRATION VISIT HE PRESENTED WITH A SUPERFICIAL INFECTION AT THE IPG INCISION SITE WHICH THE DR. CLEANED OUT.
2018/08/21	PATIENT IS EXPERIENCING TRACTION ON THE STIMULATION LEAD. MAY REQUIRE MEDICAL INTERVENTION TO ADDRESS.
2017/09/06	NO PATIENT INJURY, BUT PATIENT UNDERWENT A REVISION SURGERY TO REPLACE A SENSING LEAD. THE EXPLANTED LEAD WAS NOT RETURNED. HOWEVER ON (B)(6) 2018 AFTER REVIEWING THE RELATED INFORMATION PROVIDED THE LIKELY ROOT CAUSE LEADING TO THE NEED FOR A REVISION SURGERY WAS ELECTRICAL LEAKAGE DUE TO A N INSULATION BREACH.
2017/12/13	NO PATIENT INJURY BUT THE SENSOR LEAD PRODUCED ABNORMAL WAVEFORMS. PATIENT CONTINUED TO USE THERAPY ANYWAY FOR A WHILE BUT EVENTUALLY HAD A REVISION PROCEDURE TO REPLACE THE SENSOR LEAD TO ADDRESS ELECTRICAL LEAKAGE FROM THE ORIGINAL LEAD.
2018/08/22	PATIENT WAS EXPERIENCING PAIN DUE TO IPG POSITION. ON (B)(6) 2018 WE WERE INFORMED THAT PATIENT HAD THE IPG REPOSITIONED WHICH RESOLVED THE ISSUE.
2018/08/21	PATIENT EXPERIENCED DISCOMFORT AND RADIATING PAIN IN THE INTERCOSTAL AREA NEAR THE SENSING LEAD AS WELL AS HEADACHES AND RESTLESS SLEEP. SHE ALSO STATED THAT WHEN SHE AWAKENS THAT SHE GETS 3-4 QUICK PULSES FROM THE THERAPY. PATIENT WILL BE RETURNING TO THE CLINIC FOR A FOLLOW UP REGARDING THESE ISSUES.
2018/08/09	PATIENT WAS ACTIVATED AND TONGUE MOTION WAS POSITIVE. SENSE AND FUNCTIONAL THRESHOLDS WERE CAPTURED. HOWEVER ABNORMAL IMPEDANCE VALUES WERE NOTED AND THERAPY ACTIVATION WAS POSTPONED. THERE WAS NO PATIENT INJURY HOWEVER, UNUSUAL IMPEDANCE READINGS PROMPTED THE PHYSICIAN TO DO A REVISION SURGERY TO REPLACE THE SENSE LEAD ON (B)(6) 2018.

Event Date	Event Description
2018/11/01	THE DOCTOR CALLED REGARDING A PATIENT WHO MAY HAVE AN INFECTED INCISION FOR THE STIMULATION LEAD IMPLANT. HE CULTURED THE SITE ON (B)(6) 2018 AND IS AWAITING PATHOLOGY REPORT. IN THE MEANTIME HE HAS BEGUN A COURSE OF ANTIBIOTICS AND UPON CONFIRMATION OF PATHOLOGY WILL DETERMINE IF EXPLANT IS NECESSARY.
2018/07/19	PATIENT IS EXPERIENCING TRACTION ON THE STIMULATION LEAD. PHYSIICAN WILL BE SCHEDULING A REVISION SURGERY TO ADDRESS THE ISSUE.
2018/07/31	NO INJURY BUT PATIENT EXPERIENCED VARIATION IN STIMULATION STRENGTH FOR OVER A MONTH AND THEN CONTACTED HIS PHYSICIAN TO HAVE HIS DEVICE ASSESSED. A DEVICE CHECK REVEALED ABNORMAL IMPEDANCES AND ABNORMAL SENSOR WAVEFORMS. THE ISSUE RESULTED IN DISCONTINUED THERAPY AS A PRECAUTION AND IT MAY REQUIRE CLINICIAN INTERVENTION TO RESOLVE. POSSIBLE DEVICE MALFUNCTION.
2018/07/31	ON (B)(6) 2018 PATIENT REPORTED THAT HE ATTENDED A PARTY ON (B)(6) WEEKEND AND WAS APPROACHED BY A HEALTHCARE PROFESSIONAL THERE WHO STATED HE WAS EXHIBITING SIGNS OF A STROKE. HE HAD A DROOPY SMILE AND APPEARED TO HAVE PARALYSIS ON THE RIGHT SIDE OF HIS FACE. **HE THEN WENT TO THE EMERGENCY ROOM WHERE THE HOSPITAL WANTED TO PERFORM AN MRI BUT DECIDED TO WAIT UNTIL FURTHER INFORMATION WAS RECEIVED ABOUT THE DEVICE.** AT THE TIME PATIENT REPORTED THIS EVENT HE STILL APPEARED TO HAVE SOME PARALYSIS ON THE RIGHT SIDE OF HIS FACE. INSPIRE ASKED HIM TO FOLLOW UP WITH HIS ENT AS WELL REGARDING THIS EVENT.
2018/08/15	EXPLANT OF RESPIRATORY SENSING LEAD SCHEDULED DUE TO EVIDENCE OF INFECTION.
2018/08/01	PATIENT HAD PREVIOUSLY UNDERGONE A REVISION SURGERY TO CREATE MORE SLACK IN A LEAD TO ADDRESS TRACTION ISSUE. FOLLOWING THIS REVISION PATIENT REPORTED THAT HIS TONGUE STARTED TO GO IN AND OUT OF THE MOUTH IN RAPID SUCCESSION WHILE USING THE THERAPY CAUSING PATIENT TO DISCONTINUE THERAPY.
2018/11/01	MANUFACTURER RECEIVED A FACEBOOK MESSAGE FROM AN INSPIRE PATIENT STATING THAT HE CANNOT SPEAK NORMALLY DUE TO HIS TONGUE NOT WORKING PROPERLY AFTER THE IMPLANT OF THE SYSTEM. THERAPY HAD NOT BEEN ACTIVATED YET. PATIENT ADVISED TO INFORM HIS PHYSICIAN ABOUT THIS ISSUE.
2018/08/09	PHYSICIAN REPORTED THAT HE HAS SCHEDULED A REVISION SURGERY TO REPOSITION THE SENSE LEAD FOR A PATIENT THAT WAS IMPLANTED LAST FALL. THE PATIENT IS COMPLAINING OF SHARP PLEURAL PAIN WHEN HE COUGHS. ADDITIONALLY, PATIENT NOTED THAT WHEN THE HE ROLLS ONTO HIS SIDE HE EXPERIENCES DISCOMFORT AS WELL.
2018/07/03	PATIENT NOTICED THE IPG IMPLANT SITE WAS WARM AND SWOLLEN. AFTER THERAPY WAS TURNED OFF, THE SWELLING WENT DOWN AND THE HEAT WENT AWAY. HE HAS BEEN ADVISED TO RETURN TO THE CLINIC TO HAVE THIS EVALUATED.
2018/07/06	PATIENT WENT TO ER WITH DRAINAGE FROM THEIR STIMULATION LEAD'S NECK INCISION. HE HAS BEEN ASKED TO COME BACK IN TO THE CLINIC FOR FURTHER EVALUATION.

Event Date	Event Description
2018/06/22	WHILE INSERTING THE BREATHING SENSOR THE PHYSICIAN ACCIDENTALLY ENTERED INTO THE PLEURAL SPACE. A THORACIC SURGEON WAS CALLED INTO THE ROOM TO CONFIRM THERE WAS NO PNEUMOTHORAX. HE INSTRUCTED THE SURGEON TO SUTURE THE MUSCLE OVER BACK TOGETHER OVER THE PLEURAL SPACE AND USE THE RIB SPACE ABOVE THE ONE HE WAS WORKING WITH TO INSERT THE BREATHING SENSOR. THE REMAINDER OF THE PROCEDURE WAS COMPLETED WITH NO ISSUES. THE ENT ELECTED TO KEEP THE PATIENT OVERNIGHT FOR OBSERVATION.
2018/05/07	THE PATIENT WAS IMPLANTED ON AND WAS SENT HOME THE SAME DAY. THE PATIENT HAD GONE OFF HIS BLOOD THINNING MEDICATIONS EARLIER THAT WEEK, PRIOR TO SURGERY. HIS CARDIOLOGIST INSTRUCTED HIM TO RESUME HIS BLOOD THINNING MEDICATION 2 DAYS AFTER THE IMPLANT PROCEDURE. THE NEXT DAY HE WOKE UP AND HAD DEVELOPED A HEMATOMA AT THE SITE OF THE STIMULATION LEAD. THE PATIENT WAS ADMITTED TO THE HOSPITAL FOR THE HEMATOMA AND THE BLOOD THINNERS WERE DISCONTINUED FOR 72 HRS AND HE WAS PRESCRIBED ANTIBIOTICS. THE HEMATOMA LOOKED MUCH BETTER THE FOLLOWING MORNING AND THE PATIENT WAS DISCHARGED. THE PATIENT WAS BROUGHT BACK IN ABOUT 2 WEEKS LATER AND WAS DOING WELL.
2018/04/27	NO DEVICE MALFUNCTION BUT PATIENT DEVELOPED A HEMOTOMA NEAR SITE OF SENSOR LEAD POST IMPLANT WHICH REQUIRED ANTIBIOTICS TO TREAT. EVENT FULLY RESOLVED.
2018/03/08	THE **PHYSICIAN HIT A BRANCH OF THE ANTERIOR JUGULAR VEIN WHILE USING THE CODMAN CATHETER PASSER TO TUNNEL THE STIMULATION LEAD DOWN INTO THE IPG POCKET. HE WAS UNABLE TO CONTROL THE BLEEDING THROUGH THE EXISTING INCISIONS AND HAD TO MAKE AN EXTRA 1 CM INCISION TO ACCESS THE VEIN AND STOP THE BLEEDING**. POSTOPERATIVELY THE PATIENT HAD A NOSEBLEED IN THE PACU FROM INTUBATION, WAS HYPERTENSIVE AND THE MARGINAL MANDIBULAR BRANCH OF THE FACIAL NERVE WAS WEAK, LIKELY FROM RETRACTION. NO HEMATOMA. SHE WAS FINE WITH EXTRA 1 CM INCISION. LATER THE NEXT MORNING: NO NOSEBLEED OVERNIGHT, BLOOD PRESSURE BETTER, NO HEMATOMA, IN GOOD SPIRITS, RIGHT LOWER LIP WEAKNESS WILL BE FOLLOWED.
2018/03/13	PATIENT HAS AN INFECTION AT THE IPG IMPLANT SITE. HE HAS BEEN GIVEN ONE ROUND OF ANTIBIOTICS, BUT THE SITE IS STILL INFLAMED. THE PATIENT MAY NEED TO BE EX-PLANTED IN THE NEAR FUTURE.
2018/03/07	PATIENT COMPLAINED OF PAIN AT INTERCOSTAL SITE. DURING PHYSICAL EXAM THE DOCTOR DETERMINED THE IPG HAD FLIPPED 180 DEGREES. PATIENT WILL LIKELY REQUIRE A REVISION SURGERY TO ADDRESS THIS IN THE NEAR FUTURE.
2018/02/07	PATIENT WAS IMPLANTED ON (B)(6) 2018. ON (B)(6) 2018 PATIENT REPORTED WEEKNESS OF TOUNGE, NUMBNESS OF TONGUE AND SLIRRING OF SPEECH, DIFFICULTY SPEAKING LOUD OR PRONUNCIATING. SYMPTOMS HAVE BEEN IMPROVING, BUT ARE STILL PRESENT. APPOINTMENT FOR ACTIVATION WAS CANCELED TO ALLOW TIME FOR THIS TO RESOLVE, BUT NO INTERVENTION WAS DEEMED NECESSARY. HOWEVER, ON (B)(6) 2018 WE WERE INFORMED THAT, DESPITE FURTHER IMPROVEMENT IN SYMPTOMS, PATIENT WAS GOING TO BE SEEN BY THE PHYSICIAN IN EARLY (B)(6) 2018 TO FURTHER ASSESS SYMPTOMS.
2017/06/26	PATIENT COMPLAINED OF REDNESS AND SORENESS AT INCISION SITES BACK ON (B)(6) 2017 BUT NO INTERVENTION HAD BEEN TAKEN AT THAT TIME. DEVICE WAS LATER EXPLANTED DUE TO INFECTION ON (B)(6) 2017. INSPIRE WAS INFORMED OF THE EXPLANT ON (B)(6) 2018.
2018/04/11	PATIENT PRESENTED TO CLINIC WITH STIMULATION LEAD ERODING THROUGH SKIN. SYSTEM EXPLANT WAS SCHEDULED AND PERFORMED ON (B)(6) 2018.

Event Date	Event Description
2018/09/13	NO DEVICE MALFUNCTION BUT PATIENT HAD A SURGERY TO REPLACE STIMULATION LEAD DUE TO A POST OPERATIVE INFECTION. THIS WAS A CLINICAL STUDY PATIENT BEING FOLLOWED WITH IN A POST APPROVAL STUDY WHERE THE ADVERSE EVENT WAS FIRST MADE KNOW TO THE MANUFACTURER ON (B)(6) 2017. PARALLEL REPORTING REQUIREMENT AS A COMMERCIAL PATIENT WAS INITIALLY MISSED UNTIL RECENTLY.
2018/01/10	INSPIRE 3028 IPG AND LEADS WERE EXPLANTED AT PATIENTS REQUEST FOR PATIENT'S POSSIBLE ALLERGIC REACTION TO MATERIALS.
2017/12/05	PATIENT WAS SUCCESSFULLY IMPLANTED WITH INSPIRE SYSTEM ON (B)(6) 2017 WITH NO COMPLICATIONS. PATIENT WAS DISCHARGED FORM HOSPITAL SAME DAY. PATIENT PRESENTED TO THE ER OF A DIFFERENT FACILITY COMPLAINING OF PAIN. CLINICIANS AT THIS FACILITY NOTICED FACIAL WEAKNESS/DROOP. POSSIBLY BELIEVED THE PATIENT WAS HAVING A STROKE AND PLACED A CENTRAL LINE ON PATIENTS RIGHT SIDE, VIOLATING THE INSPIRE IPG POCKET (SUBCLAVICULAR). PATIENT WAS ADMITTED INTO THIS HOSPITAL AND IS NOW (B)(6). PATIENT WAS TRANSFERRED BACK TO IMPLANTING FACILITY AND IS UNDER THE CARE OF INFECTIOUS DISEASE. IMPLANTING PHYSICIAN WAS NOTIFIED, ALL HARDWARE WAS SUCCESSFULLY EXPLANTED ON (B)(6) 2017 AND PATIENT IS CONTINUING ANTIBIOTIC TREATMENT.
2017/09/27	PATIENT PRESENTED WITH A DROOPY RIGHT LOWER LIP. PHYSICIAN REPORTED THAT PATIENT'S MARGINAL MANDIBULAR NERVE WAS DAMAGED DURING IMPLANT, AND THE NERVE MAY OR MAY NOT IMPROVE DURING THE HEALING PROCESS. IMPLANT WAS STILL ACTIVATED AS PLANNED. THE PHYSICIAN DID NOT THINK THAT IT HAD ANY BEARING ON THE FUNCTIONALITY OF THE INSPIRE DEVICE AND WANTED TO MOVE FORWARD, AS DID THE PATIENT. NO NEURAPRAXIA OF THE TONGUE WAS NOTED.THIS IS A FOLLOW UP REPORT TO MDR REPORT # 3007666314-2017-00019, FILED TO UPDATE THE REPORT WITH THE INFORMATION THAT THE INJURY COMPLETELY RESOLVED WITHOUT INTERVENTION.
2017/09/26	REVISION OF SENSOR LEAD FOR ONGOING PAIN. PATIENT HAD PERSISTENT PAIN IN THE INTERCOSTAL SPACE WHERE SENSOR LEAD WAS PLACED ABOUT 3 MONTHS AFTER THE SURGERY. DR. WAS MONITORING THIS PATIENT AS HE WAS NOT SURE IF IT WAS THE LEAD OR SOMETHING CERVICAL THAT WAS CAUSING THIS PAIN. WE HAD DONE A SYSTEM/COMPLIANCE CHECK AND PATIENT WAS DOING WELL IN THAT REGARD. LATER IT WAS DETERMINED THAT THE LEAD WAS PRESSING INTO A NERVE BRANCH. DR. DECIDED TO MOVE IT DOWN A LEVEL TO RELIEVE THE PAIN.
2017/10/10	PATIENT CAME IN FOR HIS ACTIVATION APPOINTMENT YESTERDAY AFTERNOON AND INFORMED US THAT HE HAD A SLIGHT INFECTION IN HIS BREATHING SENSOR INCISION. PATIENT SAID HE SAW THE NURSE PRACTITIONER FOR HIS POST-OP VISIT WHO PUT HIM ON ANTIBIOTICS FOR SEVERAL WEEKS WHICH RESOLVED THE INFECTION.
2017/10/17	AT THE TIME OF IMPLANT WHILE ANCHORING THE SENSING LEAD, THE SURGEON NOTICED SOME AIR BUBBLES FROM THE LEAD TRACT. SHE WAS CONCERNED WITH POSSIBLE PNEUMOTHORAX SO SHE INJECTED SOME SALINE AND ASKED ANESTHESIA FOR SOME MANUAL BREATHS. DID NOT NOTICE ANYTHING MORE SO SHE CONTINUED WITH PROCEDURE. SHORTLY AFTER, WHEN ANCHORING THE SECOND ANCHOR MORE AIR BUBBLES WERE NOTICED. SHE CALLED FOR XRAY POST IMPLANT BEFORE WAKING THE PATIENT. XRAY READ BY RADIOLOGIST AND A PNEUMOTHORAX WAS DETECTED. THE PATIENT RETURNED TO HOSPITAL AND WAS ADMITTED AND A CHEST TUBE WAS INSERTED TO TREAT THE PNEUMOTHORAX.

Event Date	Event Description
2017/09/25	THE PATIENT EXPERIENCED VOCAL CORD WEAKNESS AND NUMBNESS WHILE DEVICE WAS ACTIVATED, AND THESE ISSUES WOULD RESOLVE WHEN THE SYSTEM WAS DEACTIVATED. PATIENT DECIDED TO HAVE THE SYSTEM EXPLANTED, WHICH WAS ON (B)(6). THERE WERE NO COMPLICATIONS.
2017/06/09	NO EVIDENCE OF MALFUNCTION BUT THE PATIENT DID EXPERIENCE AN INFECTION I THE IPG POCKET. UPDATE WAS RECEIVED 9/14/2017 - PATIENT HAD THEIR SYSTEM EXPLANTED, AND PATIENT'S INFECTION RESOLVED WITHOUT ISSUE.
2017/07/14	TWO (2) MONTHS POST IMPLANT (1 MONTH POST THERAPY ACTIVATION) PATIENT REPORTS PERIODIC INSTANCES OF SLURRED SPEECH. IN PARTICULAR FOLLOWING PERIODS OF TIME WHEN HE HAS NOT SPOKEN FOR A WHILE. NO MEDICAL INTERVENTION HAS BEEN SOUGHT AT THIS POINT.MDR FILED PREVIOUSLY UNDER # 3007666314-2017-00015. THIS IS A FOLLOW UP REPORT TO ADD THAT A LEAD REVISION WAS DONE TO ADDRESS THE TUGGING SENSATION, AND THAT THE OTHER ISSUES RESOLVED WITH OUT INTERVENTION, AND THAT THERE ROOT CAUSE WAS DETERMINED TO BE THERAPY ACCLIMATION. THIS MDR REPORT NUMBER IS 3007666314-2017-00015-1.
2017/07/18	PATIENT HAS EXPERIENCED SLURRED SPEED IN CERTAIN INSTANCES 6 MONTHS POST IMPLANT.
2017/05/24	THE PATIENT IS EXPERIENCING VARIATION IN STIMULATION STRENGTH. THE PATIENT ALSO FELT IPG HAS MIGRATED. IS NOT USING THERAPY MUCH AT HOME DUE STIMULATION FEELING VERY STRONG AT TIMES. DEVICE TESTING REVEALED ABNORMAL IMPEDANCES AND ABNORMAL WAVEFORMS AND ABNORMAL MOTION OF THE TONGUE DURING TEST TELEMETRY MODE. INSTRUCTED PATIENT TO DISCONTINUE THERAPY UNTIL FURTHER NOTICE FROM HER PHYSICIAN AND NURSE PRACTITIONER. ON (B)(6), IT WAS DETERMINED THAT THERE MAY BE ELECTRICAL LEAKAGE ASSOCIATED WITH THE SENSOR LEAD AND THAT A REVISION SURGERY WOULD BE CONDUCTED, UT HAS NOT BEEN CONDUCTED AS OF YET.
2017/07/13	PATIENT HAS HAD DIFFICULTY WITH SWALLOWING AND SPEAKING. DEVICE WAS NOT USED FOR A PERIOD OF TIME TO ALLOW THE PATIENT TO HEAL FROM IMPLANT. ISSUES RESOLVED FOR A TIME BUT THEN RETURNED A WHILE AFTER THE DEVICE WAS REACTIVATED. PHYSICIAN IS HAVING THE PATIENT LEAVE THE DEVICE OFF FOR NOW TO ALLOW THE PATIENT MORE TIME TO HEAL FROM IMPLANT.
2017/02/17	PATIENT HAS RIGHT HYPOGLOSSAL NERVE PARALYSIS.
2017/06/05	PATIENT REPORTED TO THE CLINIC WITH ONE CENTIMETER OF LEAD LENGTH EXTRUDED FROM THE NECK INCISION; THE PHYSICIAN DECIDED TO OPEN THE STIMULATION LEAD INCISION AND CLEAN IT UP. THE TISSUE LOOKED HEALTHY WITH NO SIGN OF INFECTION. DR IRRIGATED AND THEN CLOSED OVER GOOD HEALTHY MUSCLE AND TESTED THE DEVICE WITH GOOD RESULTS. FOLLOWED WITH TWO DAYS OF INTRAVENOUS ANTIBIOTICS FOLLOWED BY TWO WEEKS OF ORAL ANTIBIOTICS.

Event Date	Event Description
2017/05/12	PATIENT WAS IMPLANTED ON THE AFTERNOON OF (B)(6). PRIOR TO BEING DISCHARGED, LATER THAT EVENING, HE DEVELOPED A HEMATOMA AT THE NECK INCISION SITE. HE WAS RETURNED TO THE OR TO DRAIN AND CLEAN OUT THE OPERATIVE SITE. PATIENT WAS DISCHARGED LATER THAT MORNING AND RETURNED HOME. LATER THE PATIENT RETURNED TO THE ER BECAUSE HE WAS HAVING TROUBLE BREATHING. WIFE OF PATIENT TOLD DR. MOELLER THE PATIENT HAD IGNORED POST-OP INSTRUCTIONS AND BEGAN MOVING BOXES AROUND HIS HOME. DR. (B)(6) BROUGHT HIM BACK INTO THE OR TO DRAIN THE HEMATOMA, HE ADMINISTERED KEFLEX INTRAVENOUSLY AND CONFIRMED THAT THE STIMULATION CUFF WAS STILL IN THE CORRECT ANATOMICAL POSITION. HE ALSO SAID THE HEMATOMA WAS NOT NEAR THE CUFF. HE SENT PATIENT HOME WITH A 10 DAY PRESCRIPTION OF KEFLEX ANTIBIOTICS AND INSTRUCTED HIM NOT TO MOVE HIS ARM AND CONTINUE TO REST. Manufacturer Narrative: DEVICE STILL IMPLANTED AND IN USE.
2017/04/18	PATIENT IS EXPERIENCING TETHERING ON HIS STIMULATION LEAD DUE TO IMPROPER ROUTING OF THE LEAD AROUND THE DIGASTRIC TENDON. A REVISION SURGERY WILL BE REQUIRED TO ADDRESS THIS ISSUE. Manufacturer Narrative: DEVICE STILL IMPLANTED.
2017/04/18	DR. NOTICED THE PATIENT'S IPG HAD MIGRATED AND FLIPPED IN HER POCKET, CAUSING MILD DIS-COMFORT. SHE ALSO NOTICED THE STRAIN RELIEF ON THE STIM LEAD IS NO LONGER THERE AND HAS BEEN PULLED TIGHT. SHE ALSO BELIEVES THE LEAD HAS MIGRATED SUPERFICIALLY AND IS NOW NOTICEABLE UNDER THE SKIN. A REVISION SURGERY TO REPOSITION THE DEVICE WILL BE REQUIRED. Manufacturer Narrative: STILL IMPLANTED AND IN USE.
2017/04/20	PATIENT HAD BEEN PREVIOUSLY IMPLANTED WITH THE INSPIRE SYSTEM. LATER PATIENT UNDERWENT SPINAL FUSION SURGERY, UNRELATED TO HIS INSPIRE THERAPY, IN HIS NECK AREA DURING WHICH HIS STIMULATION LEAD WAS ACCIDENTALLY CUT. PATIENT CAN NO LONGER USE HIS INSPIRE THERAPY. LEAD WILL BE REPLACED AFTER THE PATIENT HAS HEALED SUFFICIENTLY FROM HIS SPINAL FUSION SURGERY. Manufacturer Narrative: STILL IMPLANTED.
2017/03/10	THE THERAPY ACTIVATED ON ITS OWN AND THE PATIENT WAS UNABLE TO TURN IT OFF. PATIENT HAD TO GO TO THE CLINIC WHERE THEY WERE ABLE TO TURN THE THERAPY OFF. Manufacturer Narrative: DEVICE NOT RETURNED.
2017/03/21	THE PATIENT HAD USED HIS INSPIRE THERAPY AS NORMAL DURING THE NIGHT AND SHUT THE DEVICE OFF AFTER WAKING UP. SHORTLY AFTER THIS THE PATIENT STATES THE DEVICE AGAIN CAME ON BY ITSELF AND HE WAS UNABLE TO TURN THE DEVICE BACK OFF WITH HIS REMOTE. AFTER CALLING FOR ASSISTANCE WITH THIS HE WAS DIRECTED TO GO TO THE CLINIC FOR HELP TURNING THE DEVICE OFF. AT THE CLINIC WHILE USING THE 2740 PROGRAMMER FOR ANALYSES THE DEVICE WAS READING THERAPY OFF BUT THE PATIENT STATED HE WAS STILL RECEIVING STIMULATION AND THAT IT FELT LIKE IT WAS GETTING STRONGER. AFTER WORKING WITH THE STAFF OVER THE PHONE TO HELP DISCONTINUE THERAPY THE PHYSICIAN STATED THE PATIENT WAS HAVING SOME MUSCLE CONTRACTIONS IN THE FACE THAT HE DESCRIBED AS "FISH FACE LIKE" THAT HE THOUGHT WAS A SIDE EFFECT OF THE PROLONGED STIMULATION. THIS SUBSIDED WITHIN 10 MINUTE AFTER STIMULATION HAD BEEN STOPPED. Manufacturer Narrative: DEVICE NOT RETURNED. STILL IMPLANTED.

Event Date	Event Description
2017/03/03	PATIENT CALLED THE THERAPY SUPPORT LINE. HIS SYSTEM WAS ACTIVATED RECENTLY . HE COMPLAINED THAT THE RIGHT SIDE OF HIS MOUTH DROOPS WHEN HE SMILES. THE DR. SAID HE ADDRESSED IT WITH HIM ALREADY AT THE PATIENT'S VISIT, HOWEVER THE PATIENT WANTED ADDITIONAL FEEDBACK/REASSURANCE. INSPIRE CONTACTED THE PHYSICIAN'S OFFICE AND THEY SAID THEY WOULD FOLLOW UP WITH THE PATIENT AGAIN REGARDING HIS CONCERN.THIS IS A FOLLOW UP REPORT REGARDING MDR FILE # 3007666314-2017-00003 FILED ON MARCH 31, 2017. PATIENT HAD CALLED THE THERAPY SUPPORT LINE. HIS SYSTEM WAS ACTIVATED RECENTLY . HE COMPLAINED THAT THE RIGHT SIDE OF HIS MOUTH DROOPED WHEN HE SMILED. INSPIRE CONTACTED THE PHYSICIAN WHO SAID HE ADDRESSED IT WITH HIM ALREADY AT THE PATIENT'S VISIT, HOWEVER THE PATIENT WANTED ADDITIONAL FEEDBACK/REASSURANCE. PHYSICIAN'S OFFICE SAID THEY WOULD FOLLOW UP WITH THE PATIENT AGAIN REGARDING HIS CONCERN. UPDATED FOLLOW UP INFORMATION: PHYSICIAN'S OFFICE TRIED TO REACH THE PATIENT AND LEFT MESSAGES. PATIENT DID NOT RESPOND TO THE MESSAGES. PHYSICIAN BELIEVES THAT THE CONCERN RESOLVED ON ITS OWN BUT WILL CONTACT US IF THEY OBTAIN INFORMATION TO INDICATE THAT THIS WAS NOT THE CASE. Manufacturer Narrative: DEVICE NOT RETURNED TO MANUFACTURER.
2017/02/27	SURGEON COMPLETED AN INSPIRE SYSTEM IMPLANT FOR A PATIENT AT (B)(6) MEDICAL CENTER ON (B)(6) 2017. DURING PREPARATION OF THE SENSOR LEAD LOCATION HE FELT THE RIBBON RETRACTOR PENETRATED NEAR THE PLEURA POTENTIALLY THROUGH THE EXTERNAL AND INTERNAL INTERCOSTAL MUSCLES. HE HALTED PREPARATION OF THE SENSOR SPACE AND TOOK ACTION TO ASSES FOR POTENTIAL PNEUMOTHORAX. WITH ASSISTANCE FROM ANESTHESIA HE IRRIGATED THE INCISION SITE WHILE THE LUNGS WERE EXPANDED. A SMALL AMOUNT OF AIR BUBBLES WAS NOTED INITIALLY BUT RESOLVED UPON FURTHER TESTING. LUNG VOLUME REMAINED STABLE DURING TESTING AND AFTERWARD DURING SUCCESSFUL PLACEMENT OF THE SENSOR AND COMPLETION OF THE IMPLANT PROCEDURE. THE PATIENT REMAINED STABLE FOR THE REMAINDER OF THE CASE AND DURING TIME IN POST OP. THE PATIENT WAS KEPT OVERNIGHT FOR OBSERVATION WHICH WAS PRE-PLANNED PRIOR TO THE CASE AND REMAINED ASYMPTOMATIC UPON DISCHARGE. OBSERVATION OF SURGEON AND INSPIRE PERSONNEL WAS THAT THE RIBBON RETRACTOR USED FOR THE CASE WAS MORE RIGID THAN THE RECOMMENDED RUGGLES AND MAY HAVE CONTRIBUTED TO THE DEEPER PLANE. A RUGGLES RETRACTOR WAS USED DURING AN EARLIER CASE WITHOUT INCIDENT. Manufacturer Narrative: NO EVIDENCE OF DEVICE MALFUNCTION BUT USER ERROR MAY HAVE CAUSED A PNEUMOTHORAX. WHILE IT APPEARED TO RESOLVE DURING THE INITIAL IMPLANT PROCEDURE, THE PROCEDURE WAS PROLONGED AS A RESULT OF THIS ISSUE. DEVICE REMAINS IMPLANTED AND IN USE.
2017/01/09	I DISCUSSED THE FEASIBILITY PATIENT WHO REPORTED A POTENTIAL IMPLANT-RELATED INFECTION WITH THE DR. THE INVOLVED PATIENT HAD THE IPG REMOVED ABOUT 2 YEARS AGO DUE TO A COMPLAINT OF DISCOMFORT WITHOUT ANY INFECTION SIGNS. THE CURRENT INFECTION WAS REPORTED IN THE IPG POCKET AND SENSE LEAD AREA RECENTLY. THE SENSE LEAD REGION BECAME SENSITIVE AND SHOWED CLEAR SIGNS OF INFECTION AFTER THE ANTIBACTERIAL TREATMENT. THE SOURCE OF THE INFECTION IS UNKNOWN. THE DR. REMOVED THE SENSE LEAD TO ADDRESS THE INFECTION AND HAS SHIPPED THE EXPLANTED LEAD TO INSPIRE.

Event Date	Event Description
2016/12/08	THE PATIENT WAS IMPLANTED ON (B)(6) 2016. THE PATIENT WAS POST BILATERAL MASTECTOMY AND SUBSEQUENT RADIATION TREATMENT. THE RIGHT SIDE OF THE CHEST WALL DEMONSTRATED MORE THINNING OF THE SKIN AND SUBCUTANEOUS TISSUES THAN THE LEFT. THE IPG WAS PLACED IN A SUBCUTANEOUS POCKET ON THE LEFT SIDE, AND THE SKIN/SUBCUTANEOUS LAYER NOTED TO BE THIN. ON POSTOPERATIVE DAY SEVEN THE PATIENT PRESENTED FOR WOUND INSPECTION AND SUTURE REMOVAL. A PATCH OF CRUSTED SKIN 1 CM IN DIAMETER WAS NOTED AT THE INFERIOR MARGIN OF THE IMPLANT. OVER THE NEXT THREE WEEKS THIS AREA DECLARED ITSELF AS A FULL THICKNESS NECROSIS OF SKIN AND THE IMPLANT BECAME VISIBLE. THE DAY FOLLOWING THIS OBSERVATION THE PATIENT WAS BROUGHT TO SURGERY WHERE THE IPG POCKET WAS REOPENED, PURULENCE NOTED, AND THE IMPLANT REMOVED FROM THE WOUND WITH SENSING AND STIMULATION WIRES UNDISTURBED. THE POCKET WAS DEBRIDED OF GRANULATION AND CAPSULE TISSUE AND IRRIGATED WITH ANTIBIOTIC SOLUTION. THE UNIT WAS REPLACED INTO A SUB PECTORALIS MUSCLE POCKET AND SECURED AND THE WOUND SUTURED. POSTOPERATIVE COURSE WAS UNEVENTFUL. PATIENT WAS REFERRED TO INFECTIOUS DISEASE AND APPROPRIATE ANTIBIOTIC THERAPY INSTITUTED. IMPLANT ACTIVATION AND TITRATION WAS PERFORMED OVER THE ENSUING WEEKS AND PATIENT DID EXTREMELY WELL WITH UAS. ORAL ANTIBIOTIC THERAPY DISCONTINUED AFTER FOUR MONTHS AND TWO WEEKS LATER SKIN OVERLYING IMPLANT BECAME SWOLLEN AND RED AND SCANT DRAINAGE OCCURRED FROM SENSING LEAD INCISION SITE. PATIENT WAS PLACED BACK ON ANTIBIOTICS AND ARRANGEMENTS MADE FOR EXPLANTATION ON (B)(6). ON DAY OF EXPLANT SURGERY NO EVIDENCE OF INFLAMMATION, PAIN, OR DRAINAGE. IPG POCKET WAS OPENED FIRST AND THERE WAS NO EVIDENCE OF INFECTION. SENSING LEAD INCISION WAS OPENED NEXT AND GRANULATION TISSUE AND PUS ENCOUNTERED OVERLYING THE WIRE LEADING TO THE SENSOR, BUT THIS AREA NOT CONTIGUOUS WITH THE IMPLANT POCKET. NECK WOUND OPENED LAST AND ACTIVATION LEAD/WIRE REMOVED WITHOUT EVIDENCE OF INFECTION. ALL WOUNDS WERE IRRIGATED WITH ANTIBIOTIC SOLUTION. INFECTED WOUND PACKED WITH MEDICATED GAUZE TO BE ADVANCED AND REMOVED.
2016/11/18	MUCOSAL TEAR IN FLOOR OF THE MOUTH EITHER HAPPENING FROM THE BLUE NIM PROBE (ANOTHER MANUFACTURERS DEVICE) USED TO MONITOR GENIOHYOID OR FROM NERVE DISSECTION DUE TO CHALLENGING ANATOMY WHILE IMPLANTING THE MODEL 4063 STIMULATION LEAD. THE DOCTOR PLACED 3 DISPOSABLE STITCHES IN THE FLOOR OF THE PATIENTS MOUTH AND SENT HIM HOME ON ANTIBIOTICS. Manufacturer Narrative: DEVICE IMPLANTED AND IN USE.
2016/11/18	ON (B)(6) 2016 AN INSPIRE PATIENT, WHO HAD BEEN IMPLANTED 1 MONTH EARLIER, COMPLAINED OF PAIN AND INFLAMMATION AT THE IPG AND STIMULATION LEAD SITES. THIS PATIENT HAD BEEN PRESCRIBED KEFLEX POSTOP BUT DID NOT FOLLOW THE REGIMEN. THE DOCTOR DIRECTED THE PATIENT TO TAKE KELFLEX FOLLOWING PATIENT'S COMPLAINT OF INFLAMMATION, AND THE PATIENT BEGAN TO FEEL BETTER HOWEVER, ON (B)(6) THE PATIENT BEGAN LEAKING SEROMA FROM HER IPG SITE SO THE PHYSICIAN EXPLANTED THE SYSTEM. UPON EXPLANTING THE SYSTEM THE PHYSICIAN CONFIRMED THAT THERE WAS INFECTION PRESENT AT BOTH THE IPG AND STIMULATION LEAD SITES. THE LIKELY CAUSE WAS DUE TO THE NEED FOR A MORE COMPLEX TUNNELLING ROUTE IN ORDER TO AVOID THE PATIENTS BREAST PROSTHESIS. Manufacturer Narrative: DEVICE NOT YET RETURNED FOR EVALUATION. DEVICE NOT YET RECEIVED AT MANUFACTURER.

Event Date	Event Description
2016/10/19	PATIENT PRESENTED AT DR.'S OFFICE WITH A GOLF BALL SIZE MASS NEAR THE SENSING LEAD INCISION. LOOKED A LITTLE SWOLLEN BUT THE SKIN WAS NORMAL. DR. SAID IT WAS FIRM AND MOBILE BUT NOT TENDER. PATIENT IS BEING BROUGHT BACK FOR AN ADDITIONAL DR VISIT AND FOR A CHECK TO ENSURE THE INSPIRE SYSTEM IS FUNCTIONING NORMALLY.PHYSICIAN AND PATIENT DECIDED TO HAVE THE MASS AND THE SENSING LEAD REMOVED. THE REMOVAL WENT WELL. UPON INSPECTION OF THE EXPLANTED LEAD WE COULD SEE A "NICK" NEAR THE FIXED ANCHOR THAT ENGINEERS HYPOTHESIZED WAS THE CAUSE OF THE MASS. ALL PATHOLOGY REPORTS WERE CLEAR NO SIGN OF INFECTION. PATIENT HAS SINCE BEEN SEEN BY ENT MULTIPLE TIMES AND HOPING TO GET SCHEDULED FOR REIMPLANTATION OF SENSING LEAD.
2016/08/03	**SURGEON NICKED THE PATIENT'S JUGULAR VEIN DURING THE IMPLANT SURGERY, SPECIFICALLY WHILE TUNNELLING IN PREPARATION FOR IMPLANT OF THE STIMULATION LEAD**. THE SURGEON WAS ABEL TO STOP THE BLEEDING AND CONTINUED WITH THE IMPLANT OF THE SYSTEM. THE PATIENT IS DOING WELL AND IS RESPONDING NICELY TO THE THERAPY BUT THE PATIENTS SURGICAL PROCEDURE WAS PROLONGED BY 2.5 HOURS AS A RESULT THIS EVENT. Manufacturer Narrative: DEVICE NOT RETURNED TO MANUFACTURER.
2016/08/19	NO PATIENT INJURY BUT PATIENT FELT THAT HIGHER STIMULATION SETTINGS WERE NEEDED TO ACHIEVE EFFICACY. AFTER TRYING DIFFERENT DEVICE SETTINGS, THE PATIENT UNDERWENT A SURGERY TO REPLACE HIS IPG AND LEADS. SUBSEQUENT ANALYSIS OF THE RETURNED PRODUCT NOTED THAT THERE HAD BEEN FLUID INGRESS IN TO THE SENSOR LEAD PORT ON THE IPG WHICH WAS THE LIKELY CAUSE OF THE LOSS OF EFFICACY.
2016/06/07	PATIENT EXPERIENCED SWELLING OF THEIR TONGUE AFTER USING THE THERAPY WHICH WOULD RESOLVED ON ITS OWN DURING THE DAY. PATIENT DID GO TO THE ER AT ONE POINT WHEN THEIR TONGUE SWELLED OVER CONCERNS THAT IT MIGHT HAVE BEEN DUE TO A STROKE, WHICH IT WAS DETERMINED THAT IT WASN'T. PATIENT HAD DEVICE SETTINGS ADJUSTED TO PERMIT A LOWER STIMULATION AMPLITUDE AT THE BOTTOM END OF HIS STIMULATION RANGE. Manufacturer Narrative: DEVICE STILL IMPLANTED AND IN USE.
2016/06/05	THE PHYSICIAN CONFIRMED THAT THE PATIENT HAS AN INFECTION IN THE IPG DEVICE POCKET AND HAS DECIDED TO SCHEDULE A SURGICAL PROCEDURE TO REMOVE THE DEVICE AS A RESULT. Manufacturer Narrative: DEVICE STILL IMPLANTED, EXPLANT PROCEDURE.
2016/04/19	PATIENT WAS NOT FEELING ANY STIMULATION FROM THE SYSTEM. THIS WAS ULTIMATELY RESOLVED BY ADJUSTING THE DEVICE SETTINGS, BUT PRIOR TO THIS THE PATIENT UNDERWENT AN EXTRA SURGICAL PROCEDURE TO DETERMINE WHETHER OR NOT THE STIMULATION LEAD IMPLANT NEEDED TO BE REVISED. Manufacturer Narrative: DEVICE REMAINS IMPLANTED AND IN USE.
2015/12/30	PNEUMOTHORAX OCCURRED ASSOCIATED WITH PLACEMENT OF SENSOR LEAD. CHEST TUBE PLACED TO TREAT PNEUMOTHORAX. REVISION PROCEDURE CONDUCTED (B)(6) 2015 TO REPOSITION SENSOR LEAD DISTAL PORTION. PATIENT TREATED WITH ANTIBIOTIC PROPHYLAXIS TO MINIMIZE RISK OF DEVICE-RELATED INFECTION WITH OR WITHOUT CONCOMITANT INVOLVEMENT OF CHEST TUBE. Manufacturer Narrative: DEVICE NOT RETURNED. REMAINS IMPLANTED.

Event Date	Event Description
2015/12/21	THE PATIENT EXPERIENCED EPISODES WHERE THE SYSTEM'S STIMULATION DID NOT WORK PROPERLY, SPECIFICALLY IT WOULD FEEL WEAKER THAN NORMAL. A CHECK OF THE SYSTEM SHOWED THAT THE PATIENT'S STIMULATION SENSATION THRESHOLD HAD NEARLY DOUBLED. THE SYSTEM WAS EXPLANTED AND A NEW SENSING LEAD AND IMPLANTABLE PULSE GENERATOR WERE IMPLANTED. THE EXPLANTED DEVICES WERE DECONTAMINATED, AND RETURNED TO THE MANUFACTURER WHERE ANALYSIS INDICATED THAT THE SENSING LEAD HAD SHIFTED POSITION THRU THE MOVEABLE LEAD ANCHOR. THIS REDUCED THE SIZE OF THE LOOP BETWEEN THE TWO ANCHORS WHICH IS REQUIRED FOR STRAIN RELIEF. THE PATIENT WAS NOT INJURED AS A RESULT OF THIS INCIDENT, BUT IF THE EVENT WERE TO RECUR IT IS POSSIBLE THAT IT COULD LEAD TO INAPPROPRIATE STIMULATION THEREFORE THE MANUFACTURER IS FILING THIS REPORT.
2015/06/12	TWO MONTHS AFTER IMPLANT THE PATIENT DEVELOPED A SMALL AREA OF GRANULATION/SUPERFICIAL INFECTION IN THE SENSOR WOUND. THE PHYSICIAN INITIALLY TREATED THE PATIENT WITH TOPICAL AND ORAL ANTIBIOTICS AND THEN ON (B)(6) 2015 EXPLANTED THE ENTIRE SYSTEM. THE EXPLANT PROCEDURE WAS SUCCESSFULLY COMPLETED WITHOUT ISSUE. NO SIGN OF INFECTION WAS NOTED AT THE STIMULATION LEAD IMPLANT SITE HOWEVER SIGNS OF INFECTION WERE NOTED AT THE IPG AND SENSOR LEAD IMPLANT SITES. ALL INCISION SITES WERE THOROUGHLY IRRIGATED WITH ANTIBIOTIC LACED SALINE SOLUTION. THE ORIGIN OF THE INFECTION IS UNKNOWN. Manufacturer Narrative: MODEL 3024 NEUROSTIMULATOR SERIAL # (B)(4) MANUFACTURER DATE 06/28/2014, EXPIRATION DATE 06/28/2016, (B)(4). MODEL 4063 STIMULATION LEAD SERIAL # (B)(4) - MANUFACTURER DATE 09/01/2014, EXPIRATION DATE- 09/01/2016, (B)(4). MODEL 4323 SENSING LEAD SERIAL # (B)(4) - MANUFACTURE DATE 07/13/2014, EXPIRATION DATE 07/13/2016, (B)(4).: EXACT IMPLANT DATE UNKNOWN BUT APPROXIMATE IMPLANT DATE IS (B)(6) 2015. THREE REQUESTS FOR RETURN OF THE DEVICES FROM THE USER FACILITY HAVE BEEN MADE BUT USER FACILITY IS UNWILLING TO RETURN THEM.
2015/04/09	ON (B)(6) 2015 INSPIRE BECAME AWARE OF THE FOLLOWING EVENT. A PT WHO WAS IMPLANTED WITH THE INSPIRE SYS ON (B)(6) 2015. ON (B)(6) PT CONTACTED HIS PHYSICIAN TO REPORT A HEMATOMA ON THEIR NECK AND AT THE IPG (IMPLANTABLE PULSE GENERATOR) INCISION SITE. THE EVENT WAS SURGICAL IN NATURE. NO ALLEGED PROD DEFICIENCIES, AND THE DEVICE WAS NOT EXPLANTED. GIVEN THAT THE PT WAS ON BLOOD THINNERS THE PHYSICIANS FELT IT WOULD BE A SAFETY ISSUES TO LEAVE THE HEMATOMA UNTREATED. CONSEQUENTLY THE PT WAS BROUGHT BACK IN SO THAT THE PHYSICIAN COULD CONDUCT AN EVACUATION OF THE HEMATOMA ON (B)(6) 2015 WHICH RESOLVED THE EVENT.
2015/02/11	PT WAS IN THE IDE PIVOTAL STUDY FOR THE INSPIRE UPPER AIRWAY STIMULATION SYSTEM. RECENTLY HE CALLED HIS PHYSICIAN AND STATED THAT HE WAS HAVING TROUBLE WITH HIS PT REMOTE, SPECIFICALLY THE PT WAS UNABLE TO TURN OFF HIS THERAPY SO THE STIMULATION CONTINUED TO ENGAGE THE TONGUE PROTRUSION MUSCLES. THE PT WAS EXPERIENCING DISCOMFORT SO RATHER THAN WAITING FOR THE THERAPY TO TIME OUT AUTOMATICALLY HE WENT TO THE CLINIC WHERE HIS PHYSICIAN TURNED OFF THE THERAPY USING HIS PROGRAMMER. THE PT STATED HE HAD MILD DISCOMFORT AFTER HAVING THE THERAPY OFF BUT NO OTHER INTERVENTION WAS NEEDED AND THE PT RETURNED HOME.

Event Date	Event Description
2014/02/08	PATIENT WAS IN THE IDE FEASIBILITY STUDY FOR THE INSPIRE UPPER AIRWAY STIMULATION SYSTEM AND HAS BEEN IMPLANTED WITH THE SYSTEM FOR 4 YEARS. RECENTLY HE CALLED HIS PHYSICIAN AND STATED THAT HE WAS HAVING TROUBLE MOVING THE RIGHT SIDE OF HIS TONGUE FOLLOWING A NIGHT IN WHICH HE AWOKE FROM A SHARP PAIN ON THE SIDE OF HIS NECK. TWO TO THREE DAYS PRIOR TO THIS HE NOTED THAT THE STIMULATION SEEMED DIFFERENT THAN IT HAD PREVIOUSLY. PATIENT EXPERIENCED SOME SWELLING IN THE NECK AND CHEST AREA WHICH RESOLVED WITHIN 2 TO 3 WEEKS. PATIENT HAS EXPERIENCED SOME SLURRING OF SPEECH WHICH HAS IMPROVED OVER TIME. Manufacturer Narrative: SYSTEM REMAINS TURNED OFF WHILE PHYSICIAN AND PATIENT CONSIDER THE POSSIBILITY OF USING AN ALTERNATIVE THERAPY FOR PATIENT'S OBSTRUCTIVE SLEEP APNEA. INVESTIGATION INTO ROOT CAUSE OF THIS EVENT IS ONGOING. IF A SPECIFIC DEVICE IN THE SYSTEM IS FOUND TO BE RELATED TO THIS EVENT, THAT SPECIFIC DEVICE'S INFORMATION WILL BE INCLUDED IN A FOLLOW UP REPORT. IN THE MEANTIME ALL THAT INFORMATION FOR ALL IMPLANTED SYSTEM COMPONENTS IS INCLUDED HERE: MODEL 3024 IPG SERIAL #(B)(4), MANUFACTURE DATE 12/09/2009; MODEL 4063 STIMULATION LEAD SERIAL # (B)(4), MANUFACTURE DATE 08/2009; AND MODEL 4323 SENSING LEAD SERIAL # (B)(4), MANUFACTURE DATE 06/2009.

Appendix E – Customer Complaints

Below is a table negative comments about Inspire's device, primarily pulled from 2018 or 2019. The comments were posted on various sleep apnea boards and other internet fora, and are linked in the table.

Verbatim Customer Complaint	Source
Here are the issues I've had with the procedure: *Lead wire/electrode between the stimulator under my chin and the generator in my chest is very prominent in appearance and looks very odd in my opinion. Very difficult to shave that area now which would not be your problem :) Overall it causes my entire neck area to look odd, when I raise my chin, it feels very taut it is quite unsettling. Also on several occasions the area under my chin feels like it is knotting up for some reason which is painful. Generator planted in my chest wall is also very prominent and does not look good (Took away some muscle mass which I have not been able to regenerate with all types of exercise) not being able to have an MRI is also huge for me. I did not know I would have that limitation until after surgery :(The actual sleep outcome results of using this technology has also been unsatisfactory for me. I was waking up more tired using Inspire that I was using a CPAP. Also it would cause my jaw to pop and my ears to ring after a night of using inspire. There were other issues as well but I won't burden you with too many details.	https://myapnea.org/forum/inspire-implant
I had the Inspire device implanted almost 3 years ago and I've basically given up trying to use it. I wake up in the night and have to pause the unit (as designed) to go back to sleep. But when it comes back on, it comes on at therapeutic strength and is like an alarm clock going off in my mouth; it just keeps waking me back up and I always resort back to CPAP. I have repeatedly asked Inspire to modify their code to slowly ramp the stimulation up over several minutes so I will sleep right through the un-pausing but they have so far been unwilling to do so. In fact they have stopped following up with me all together. In my experience it does not work and is not yet ready for prime time.	http://www.apneaboard.com/forums/Thread-Inspire--13275
It is surgery. They say its outpatient but I spent the night. I would not have wanted to go home that first day. Three incisions. One by your ribs, one below your collarbone and one on your neck. They are each about 2-3 inches long. The one by the ribs was the worst. Like a bruised rib.	https://talk.sleepapnea.org/t/experience-with-with-inspire-therapy-for-sleeep-apnea/2793/5
I have been a snorer and a gasper for years. You are not alone! In fact, I'm still doing both, according to my husband, with the INSPIRE implant activated. I'm about to go back to square one, wearing CPAP while my hypoglossal nerve stimulator is taking my tongue out to the left corner of my mouth when I'm sleeping, and it is on. ... Keeping my oxygen sats above 75 is tricky for me without the CPAP and Inspire together.	https://talk.sleepapnea.org/t/question-on-gasping-for-air/3352/7
I too have extreme daytime sleepiness with the INSPIRE device implanted, so I take Modafinil if I know I need to stay awake during a class or will need to drive more than 5 miles from home.	https://talk.sleepapnea.org/t/daytime-sleepiness-even-with-successful-cpap-treatment-of-apnea/3103/9
It was tolerable and actually he maxed out on the highest setting two weeks ago. He is still exhausted and has no energy. I can tell you that since I sleep right next to him his apnea has gotten worse ... the duration is longer with much more gasping. We have double checked the battery life and ensured that the device is on due to the issues explained...everything is AOK in that arena.	https://myapnea.org/forum/inspire-implant

Verbatim Customer Complaint	Source
I have had the Inspire implant put in and recently had it removed. Long and short of it, I was NEVER a candidate for this IMPLANT my INSPIRE TRAINED SURGEON SHOULD HAVE KNOW THAT and INSPIRE SHOULD HAVE MADE SURE OF IT!!! I have professionals to back that up. Medicare has denied payment finding the provider liable for the cost of the $88,240.30 surgery. I've spent 2yrs of my life, dozens of appointments, I have very visible scars and for what???.....THEM to make MONEY REGARDLESS of if this was RIGHT for ME!	https://myapnea.org/forum/inspire-implant-for-osa/1#comment-12238
Lets try more like 50%. Cost [insurance reimbursement], I was told 40k got billed 115k. Darn thing doesn't work. How do you get it removed. Who pays for that?	https://myapnea.org/forum/inspire-implant-for-osa/1#comment-12238
But a few months ago it started to malfunction, turning off after about two hours each night, instead of the eight hours it should last. The Inspire representatives were very helpful, even sending a representative to meet with me and a doctor in Dallas (I live in Texas now, several hours from the nearest doctor who uses the device). They were unable to fix the problem with their device readers, so I was told that the implant would need to be replaced.	https://myapnea.org/forum/about-the-inspire-implant/1#comment-28017
Victoria McCullough, 69, of Escondido, California, was one of the first to receive a pacemaker-like device that stimulates a nerve to push the tongue forward during sleep. Now, more than 3,000 people worldwide have received the Inspire implant. Infections and punctured lungs have been reported; the company says serious complications are rare. McCullough said she asked her doctor to remove the device soon after it was activated in 2015. "It was Frankenstein-ish. I didn't like it at all," McCullough said. "My tongue was just thrashing over my teeth."	https://www.ctvnews.ca/health/new-ways-to-conquer-sleep-apnea-compete-for-place-in-bedroom-1.4010249
So, my device was installed on 9/11/19 and turned on for the first time a month later. Everything went well during the activation, but I quickly realized that something wasn't right when I started to sleep. The device would give the initial stimulation with I turned it on with the remote, but then it would intermittently work throughout the night. I kept telling my rep what was happening, but he kept telling me that it was just my body getting adjusted to it. After a month of the device literally not working at night, my device was reprogrammed and on the first night, it was difficult to breath and I got severe pain to the side of my head every time the device would fire. So, it took a while to get seen again and last week I was reprogrammed, AGAIN. Now, it seems as though the device is "on" all night, but I feel as though the stimulation significantly decreases throughout the night, almost like a battery dying. It's always much stronger at the beginning of the night.	https://myapnea.org/forum/inspire-device
I was a good candidate so I went ahead with the surgery. It was about three hours long and the scarring was a bit more than I expected. My speech was slightly slurred for a few months but it returned to normal. There are three incisions. One just below the jaw line, one for the device itself just below my right clavicle, and a third one near the bottom of the rib cage on the right side as well. The incision near the rib cage was not fun for about a week (like a cracked rib).	http://www.apneaboard.com/forums/Thread-Inspire--13275?page=2
As much of a pia an inelegant CPAP is as a treatment, using a glorified tazer on your tongue is every worse!	http://www.apneaboard.com/forums/Thread-Equipment-Doctor-stated-BCBS-insurance-will-start-covering-Inspire-Implant-next-month-Defi

Verbatim Customer Complaint	Source
Sep 26, 2019: Does anyone have the VA criteria for getting authorized to have the Inspire Sleep Apnea device implanted? ... I did a search on the site and only had one hit from 2016 - no one answered the questions then. ... - got a call back from the VA asking why I wanted to do this and questions about what the problems were with my CPAP - just wondering if there is any printed criteria as to who is allowed the procedure. Sep 26, 2019: Inspire is new and VA lags on new things. Nov 5, 2019: Called the VA to check on my referral request - apparently they denied my request - back on the 26th of September.	https://www.pebforum.com/threads/inspire-sleep-apnea-device.65203/
My husband had the Inspire device implanted two years ago, and it no longer works for him as a viable means to control his sleep apnea. He went in for a wet endoscopy a couple of weeks ago, so they could take a look at his throat while he was sleeping and the Dt's are now telling him to go back on the CPAP again. He will likely go back into surgery to have the Inspire device removed in a few months. So not worth the surgery or expense for him to have this device implanted.	https://www.sleepdr.com/the-sleep-blog/answers-to-your-questions-about-inspire-upper-airway-stimulation-therapy/
I dislike the feeling when it is turned on, I was told it is milder than what happens when you are asleep. Unfortunately, I feel the zaps in the middle of the night, I pause the remote, finally turning it off.	https://www.sleepdr.com/the-sleep-blog/answers-to-your-questions-about-inspire-upper-airway-stimulation-therapy/
My experience was terrible. After the surgery and the consequential all the outcomes publicized on the Inspire website, plus all the information my doctor provided me, were not fulfilled at all. First, before the surgery, my doctor described the surgery. According to him, he was going to insert the device by making two incisions; one on the right side of my chest, the other in my throat under my chin. After I came out of the surgery, I realized that the "incision" in my throat wasn't a simple "incision", it was a radical deep cut of about 4.5 inches, which until today (four months after the surgery) has not healed completely and it still painful. You should notice that on the Inspire website they never show a picture or a video of the patient's right side where the cut has been performed. Second, the doctor told me that I was going to be able to recuperate from the surgery in about 4 to 6 days after the surgery. This is not the case. It took more than two weeks for me to be able to go to work due to the intense pain and discomfort I experienced. My neck was extremely swollen (I can provide you with pictures) for about 4 weeks, the inflammation hasn't yet disappeared completely after 4 months since the surgery. Third, one month after the surgery, the doctor activated the device. He told me that it was going to take about one month to get used to the electric impulse that moves my tongue forward to open the airway during the time I am sleeping. That day, I found out for the first time that this device does not work by sending an electric impulse when you are having an apnea, but rather it constantly fires the electric impulse during all the time you are sleeping or trying to sleep. By doing this, you have to subject yourself to a constant electric shock sent to the hypoglossal nerve which moves your tongue forward. This electric shock is painful and excruciating, it is literally a torture, you cannot sleep at all while Inspire is doing "its job". Fourth, I went back to my doctor to see what I could do in order to find out how we could solve these issues. After going through this very painful and expensive surgery, I didn't want to give up, I wanted this to work for me, I was desperate. The doctor decided to adjust the setting by lowering the intensity of the electric	http://www.cpaptalk.com/viewtopic.php?f=1&t=178202&p=1338053&hilit=inspire#p1338053

Verbatim Customer Complaint	Source
shock. He told me that I should get used to this electric shock little by little and eventually I was going to be able to sleep with Inspire on. He also informed me that I had to increase the level of the intensity gradually (the device has 10 levels) all the way up to level 10, where level 10 is the only effective setting that makes the apneas less severe. I started with level one. After three weeks, I was able to reach level 3. At that point, I experience a severe symptom of vertigo that took me to the ER. Every doctor I saw at the ER thought that the reason for the vertigo was the use of this device. When I consulted with the doctor who implanted, he denied that there is a correlation between the use of Inspire and vertigo. At that point, I decided to stop using Inspire and wait until vertigo disappears. Three weeks after that, I used Inspire again; after three hours the vertigos came back. It was sad and disappointing that after going through all these suffering I had to give up using Inspire to solve my sleep apneas.	
I went through a lot of hurdles with my insurance company to have this device implanted. Cost me roughly $8,000.00 (with my annual max insurance deductible). I have severe sleep apnea. The device does not work for me at all. I'm very disappointed. I've reverted to a CPAP device. The Inspire device will be implanted in me for life but it doesn't bother me…I just don't activate it any longer.	https://www.consumerhealthdigest.com/sleep-aid-reviews/inspire-sleep-apnea-therapy.html
I can't get a decent night's sleep. The tongue stimulation wakes me. I suffer with dry mouth, throat irritation, swallowing difficulty, and speaking problems. I'm trying to make it work but am getting discouraged.	https://www.entandaudiologynews.com/development/how-i-do-it/post/selective-upper-airway-stimulation
I had Inspire implanted early 2017. First AHI decreased, than it went up. Couldnt sleep without medicatie due to voltage stimulation. Algorithm seems weird but they don't like to admit. Didn't loose weight as well which was the idea. Didn't sleep better and couldn't tolerate it well. I asked my doc to again allow me a CPAP which was strangely refused. Bought myself another CPAP and now ahi and sleep are back in control. I don't recommend Inspire.	https://www.entandaudiologynews.com/development/how-i-do-it/post/selective-upper-airway-stimulation
Inspire is a terrible company to deal with. I had my surgery done over a year ago and had have had problems ever since every time I've gone back for them to do an adjustment to make it work right not only did they not fix the problem they charge me an extraordinary amount each time even though they said it was stuff they had to adjust to make it work right I still don't sleep I still can't sleep and I can't get anybody from the company to return my phone calls	https://www.entandaudiologynews.com/development/how-i-do-it/post/selective-upper-airway-stimulation
I have had my inspire for 1.5 years. I am very unhappy with my Inspire. It is impossible to get a good nights sleep with the devise on. It causes severe dry mouth. During the day my tongue does not work correctly. I have difficulty talking. How do I get this devise removed?	https://www.entandaudiologynews.com/development/how-i-do-it/post/selective-upper-airway-stimulation

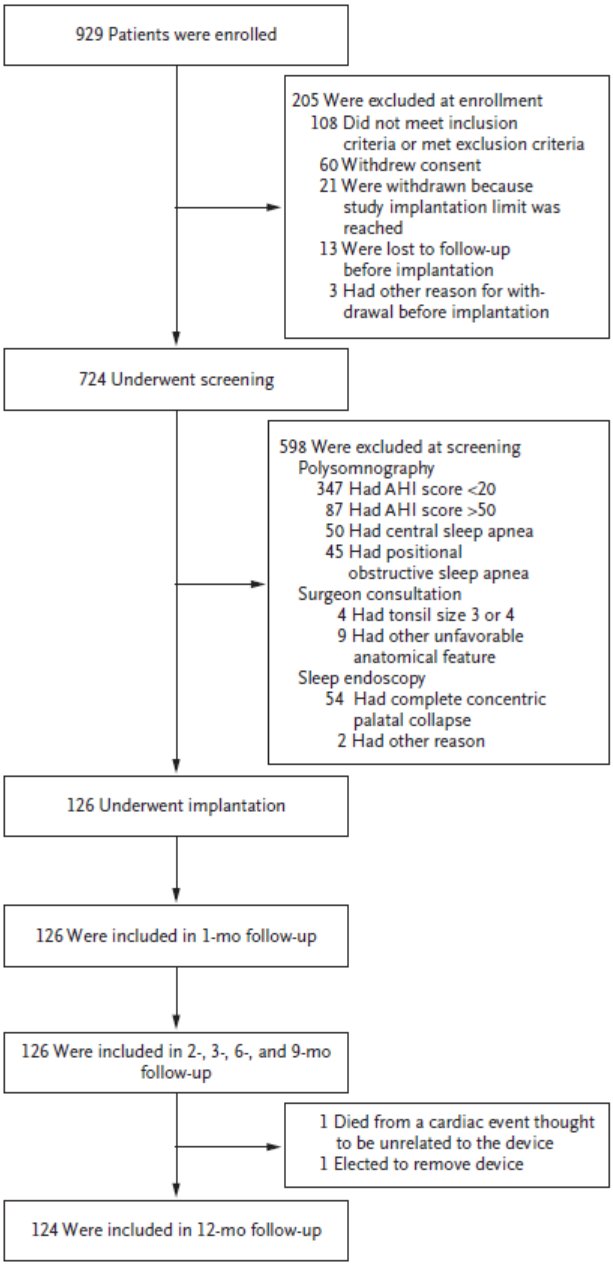
Verbatim Customer Complaint	Source
Here are the issues I've had with the procedure: (please note that I am a fit, 158 lb man) *Lead wire/electrode between the stimulator under my chin and the generator in my chest is very prominent in appearance and looks very odd in my opinion. Very difficult to shave that area now which would not be your problem :) Overall it causes my entire neck area to look odd, when I raise my chin, it feels very taut it is quite unsettling. Also on several occasions the area under my chin feels like it is knotting up for some reason which is painful. generator planted in my chest wall is also very prominent and does not look good (Took away some muscle mass which I have not been able to regenerate with all types of exercise) not being able to have an MRI is also huge for me. I did not know I would have that limitation until after surgery :(The rib cage sensor has not been a problem The actual sleep outcome results of using this technology has also been unsatisfactory for me. I was waking up more tired using Inspire that I was using a CPAP. Also it would cause my jaw to pop and my ears to ring after a night of using inspire. There were other issues as well but I won't burden you with too many details. If you do wish to discuss further if you may feel free to call me at 205-254-0460.	https://myapnea.org/forum/inspire-implant
I had mine done not long ago, I am at week six I believe. They tried to turn it on last week but as I discussed with my docs I am having problems with my tongue. The right half of my tongue is a different color and the muscle is relaxed and not working properly. When I stick my tongue out it now shoots over to the right. I believe I took some damage to a nerve and that is what is causing the issue. Hopefully it heals. They decided to keep the device turned off for another month or so to try and let me heal. Have your had any problems with your tongue? I also have a numb spot near my stomach on my ribs I fear I took some nerve damage causing that as well. All of my incisions are healing well though. Thank you for sharing your experience. I think I will eventually make a post detailing mine. If you don't mind answering, how painful was your throat incision? I think that was the worst part of my surgery. It wasn't terrible pain wise but it was more than advertised. Also where do you feel the tongue simulator? I feel the wire pulling well to the right of center, I figured it would be right in the middle. I guess that's another thing my throat wire is quite tight, I can't look up all the way and even have limited range of motion side to side. Have you experienced any of this? Again thanks for sharing!	https://www.reddit.com/r/SleepApnea/comments/avt66l/inspire_surgery_onemonth_update/
Hi. I'm a sleep tech who has done a few Inspire titrations and maybe I can offer some insight into this decision you're about to make. ... In my professional opinion, Inspire therapy should be the last option, failing everything else. It is a semi-permanent device that you put in your body and you will feel a bump on your chest where the body of the stimulator is placed, much like a pacemaker or a defibrillator. I've heard that Inspire is in the process of making MRI-safe devices, but I don't know if they've already been rolled out or are still being figured out. As previously mentioned by other redditors, they have a ten-year battery lifespan, and will have to be replaced. You will have to have a remote with you and if you lose it or break it, you can get another one sent to you under warranty or pay like some hundreds of dollars to get a new one. Your tongue may stick out slightly out of your open mouth with every breath or it may very well be completely extended out of your mouth. You may also have dry mouth in the morning which may require something like Biotene to solve.	https://www.reddit.com/r/SleepApnea/comments/743wnp/my_doctor_recommends_inspire_therapy/

Appendix F – STAR Study Patient Selection Process

Source: Upper-Airway Stimulation for Obstructive Sleep Apnea, p. 145

Figure 2. Study Enrollment.

Of 929 participants enrolled, 205 were excluded before undergoing a screening test. An additional 598 participants were excluded after the screening assessment, which included polysomnography, consultation with the surgeon, and endoscopy during sleep; 56 of these participants were excluded after the endoscopy was performed during drug-induced sleep (25% of the 222 participants who underwent the procedure). A total of 126 participants underwent implantation. The apnea–hypopnea index (AHI) measures the number of apnea or hypopnea events per hour. A tonsil size of 3 indicates that the tonsils are visible beyond the pillars, and a tonsil size of 4 that they extend to the midline.



Appendix G – Table of Restrictions

Restriction	Inspire Explanation
Magnetic Resonance Imaging (MRI)	You should not be exposed to Magnetic Resonance Imaging (MRI). Exposure to MRI can damage your stimulator or leads, cause serious injury, or result in unintended stimulation. This is the case even if you have had the stimulator removed and only the leads remain implanted.
Pacemakers	The electrical pulses from the Inspire system could affect the ability of the cardiac device to sense and respond to heart function as intended. This could result in serious injury.
Dental drills and ultrasonic probes	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Electrolysis	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Bone growth stimulators	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Laser procedures	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Psychotherapeutic procedures (for example, electroshock therapy)	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Radiation therapy	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
High-output ultrasonics / lithotripsy	These procedures may cause permanent damage to the stimulator, particularly if used in close proximity to the device
Antennas of citizen band (CB) or ham radios	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Electric arc welding equipment	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Electric induction heaters	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.

Induction range	Keep the stimulator away from the burners while the burners are turned on. Induction ranges, unlike conventional electric stoves, produce magnetic fields to generate heat.
Electric steel furnaces	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
High-power amateur transmitters	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Large stereo speakers	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Perfusion systems	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Power lines or power generators	could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your stimulator. Avoid them if possible.
Theft Detector or Security Screening Devices	Use care when approaching theft detectors and security devices (such as those found in airports, libraries, department stores, and government buildings). ... If you must pass through the theft detector or security screening device, make sure your therapy is off. When walking through the device, keep as far from it as possible. Note: Some theft detectors might not be visible. Proceed through the security device. Do not linger near or lean on the security device.
Handheld security wand	Ask them not to hold the security wand near the stimulator longer than needed.
Mobile phones and other radio-frequency sources (tablet computers, AM/FM radios, cordless and conventional telephones):	Keep these items at least 15 cm (6 in) away from the stimulator.
Computer disk drives	Keep the stimulator away from disk drives.
Power tools	Keep the motor away from the stimulator and leads.

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