Penumbra and its “Killer Catheter”

A tale of corporate greed and seemingly blatant disregard for patients’ lives

Report by Quintessential Capital Management

Tuesday, November 10, 2020

QCM is SHORT Penumbra, Inc. (PEN)

QUINTESSENTIAL
CAPITAL MANAGEMENT

PENUMBRA AND ITS “KILLER CATHETER”

DISCLAIMER

This report reflects the opinions and projections of Quintessential Capital Management ("QCM") as of the date of publication, which is subject to change without notice at any time following the date of issue. QCM does not represent that any opinion or projection will be realized. While the information presented in this report is believed to be reliable, no representation or warranty is made concerning the accuracy of any data presented in this report or its attachments. All information provided in this report is for informational purposes only and should not be deemed as investment advice or a recommendation to purchase or sell any specific security.

QCM is SHORT the stock of Penumbra

QCM's economic interest is subject to change without notice.

The information presented in this report is supplemented by footnotes, which identify QCM's sources, assumptions, estimates, and calculations. The information contained herein should be reviewed in conjunction with the footnotes.

This report shall not constitute an offer to sell or the solicitation of an offer to buy any interests in any fund managed by QCM or any of its affiliates. Such an offer to sell or solicitation of an offer to buy interests may only be made pursuant to definitive subscription documents between QCM and an investor.

Executive Summary

Quintessential Capital Management (QCM) has performed an in-depth investigation into Penumbra, Inc. (PEN), a U.S. manufacturer of medical devices for the treatment of stroke and other vascular pathologies. Our firm conclusion is that Penumbra’s flagship device, the **Jet 7 Xtra Flex**, has a

structural design flaw that makes it prone to **critical malfunctioning**. Unlike competing devices that have a good safety record, in 14 months on the market, Penumbra's "killer catheter" has already malfunctioned at OVER 200 times, **killing 17 patients and leaving 35 others with brain injuries**.

We have compiled compelling evidence that Penumbra knew or should have known about this issue early on but **chose not to pull the device off the market**, even though it continues to malfunction at an alarming rate. In a late and misleading notice to healthcare providers, Penumbra effectively tried to shift the blame to doctors for its device's malfunctions, while at the same time not responding to some requests for information.

After receiving expert opinions from multiple surgeons and former senior FDA personnel, we strongly believe that Penumbra's flagship device may be on the verge of a **class 1 recall by the FDA**. Moreover, the deaths and injuries that already occurred as a result of the device's malfunctions make Penumbra vulnerable to a crippling product liability class action lawsuit (it has already attracted the attention of leading product liability and medical malpractice law firms).

The first signs of the looming catastrophe are already apparent in Penumbra's accounting (collapse in cash generation and sharp drop in gross margins), staff (numerous high-level resignations) and trading patterns (insiders are dumping their Penumbra shares). Our sources in the field claim that elite U.S. institutions (e.g. Mount Sinai, the Mayo Clinic, Ascension and Stanford), may be discouraging the use of the device or of Penumbra's products altogether.

Considering the current rich valuation (16.6x trailing revenue and 270x projected EBITDA), the large proportion of sales directly or indirectly affected by a Jet 7 recall, the likely extent of the reputational damage, the likelihood of numerous lawsuits, and the strength of emerging competitors, we believe that Penumbra's shares are worth a fraction of their current price and are due for a catastophic price collapse**. Our price target is $55, implying a 79% downside.**

IMPORTANT: the following text contains important hyperlinks and footnotes

Quintessential and its goals

We are an American hedge fund based in New York City. Our main activity consists in identifying, investigating and exposing publicly traded companies characterized by fraud, criminal conduct and/or failed business models.

We use state-of-the-art investigative techniques and only act after acquiring strong evidence to substantiate our claims. Since 2015, we have completed nine short activist campaigns exposing various dishonest companies with a 100% success rate.[1]

In July 2019, our in-depth report named “*A Parmalat in Bologna*” led to the collapse of the Italian €1.1b-unicorn **Bio-on S.p.A.** and the arrest of the executives involved, charged with fraud and market manipulation.

In May 2018 our campaign against the Greek retailer **Folli Follie** led to the collapse and de-listing of the company in just three weeks. The perpetrators are currently behind bars.

In December 2018, our action against **Aphria**, a Canadian cannabis company with a market capitalization of more than $4 billion, led to the immediate collapse of the stock and to the dismissal of the entire board of directors.

In 2015 our report entitled "**A Greek Parmalat**" on Globo Plc led to the immediate collapse of the stock, bankruptcy of the company and the resignation of the executives involved, who promptly admitted their guilt.

[1]In virtually all cases our theses have been confirmed by official inquiries. In several cases, the management of the target companies and/or the board of directors has been dismissed. In two cases, the companies ceased to exist weeks after our intervention.

We also recently exposed fraud at Akazoo, a Nasdaq-listed music streaming provider. The stock collapsed and was delisted, and management was sued by the Securities and Exchange Commission.

We are a commercial enterprise and we work for profit. However, we firmly believe in the moral character of our work, which has the effect of removing dishonest companies from the markets. These "bad apples" take financial and human resources away from legitimate companies and it is important to inform the public as quickly as possible to minimize the number of investors and creditors involved. Specifically, in this campaign we hope our intervention will put an end to Penumbra’s irresponsible behavior and save lives.

Description and historical context

Penumbra is a U.S. medical device manufacturer trading on the New York Stock Exchange with a market capitalization of approximately $9.0bn and sales of $530m. The company was founded in 2004 in California and IPO’d in 2015.

Penumbra’s early success was rooted in its commercialization of a set of innovative devices for the treatment of acute ischemic stroke and other vascular pathologies through *aspiration thrombectomy*. Until Penumbra popularized its products, large blood clots (which cause strokes and other serious conditions) were frequently removed through a mechanical thrombectomy, effectively inserting a tool to “grab” and extract the clot from the clogged artery. Penumbra’s device, in contrast, works by inserting an aspiration catheter in the affected artery, reaching the blood clot and literally sucking it out. Extensive clinical studies show that aspiration thrombectomy is a superior technique, allowing for faster procedures with fewer complications. Benefitting from a clear first-mover advantage, Penumbra dominated the aspiration thrombectomy market for several years, which led to rapid growth, expanding profit margins and the development of various related products. Penumbra’s stock price has reflected this success, increasing almost sixfold since its IPO.

Trouble starts with Sofia

Penumbra’s commercial success attracted the attention of large, well-capitalized competitors with significant R&D budgets: Medtronic, Stryker, Boston Scientific and Microvention, which all entered the market with competing aspiration thrombectomy systems. Most damaging to Penumbra, in 2018 Microvention introduced an aspiration catheter named *Sofia*. According to all

of the doctors we interviewed, Sofia was far superior to Penumbra's flagship device at the time, the Jet 7. It was more flexible, trackable and allowed easier and much faster navigation through the arteries (up to three times faster according to our sources). This is a crucial advantage, as faster thrombectomies translate into better clinical outcomes and less time in the operating room, with considerable saving for the hospitals. In summary, many doctors described Sofia as "a game changer."

Predictably, Microvention and other competitors started grabbing market share from Penumbra at an alarming rate. We estimate that PEN's market share in this industry segment decreased from nearly 100% to less than 60% today.

In response to these mounting competitive pressures, in July 2019 Penumbra released an upgraded version of its flagship Jet 7 system, the Jet 7 *with Xtra Flex* technology (the "Xtra Flex"). The Xtra Flex was an initial commercial success, as it seemingly achieved parity with the Sofia in terms of flexibility and allowed Penumbra to temporarily regain part of the lost market share. However, trouble was brewing under the surface…

Bad news from the Land of the Rising Sun

Hirata, Penumbra's distributor in Japan, sent a notice to its clients on June 22nd, 2020 warning about a set of malfunctions with the Xtra Flex that had already resulted in 11 deaths (8 in the U.S. and 3 in Japan). The notice [click here for a Google translation] stated that the malfunctions seemed to originate from "an unexplained damage of the inner layer of the catheter" which causes it "to expand like a balloon and damage the patient's vessel." The note warned doctors not to inject contrast media through that catheter. Shortly after this communication, Hirata voluntary

discontinued sales[2] of the Xtra Flex, which to the best of our knowledge remains off the Japanese market due to the issues we highlight in this report.

Structural flaws and killer balloons?

Based on the data we reviewed on the Xtra Flex catheter and have reached the firm conclusion that it is **structurally flawed and prone to critical malfunctioning**. As Penumbra rushed to introduce the device to contain its market share losses, it altered the design of the existing Jet 7 catheter in a way that increased flexibility, but resulted in **less structural integrity**. It suffers from serious weaknesses that make it hazardous to patients in a number of situations, leading to the appalling number of malfunctions, injuries and deaths that we've seen.

1. *The "breaking of the distal tip"*

Of the 200+ malfunctions and 39 injuries recorded in the FDA Maude database for the Xtra Flex device, the overwhelming majority involve the "breaking of its distal tip." The Xtra Flex is a catheter, basically a small tube. Many doctors complained that during the procedure, the distal extremity of the catheter breaks off (or otherwise malfunctions) and starts floating, uncontrolled, through the blood vessel. This will almost certainly prolong the duration of the procedure and may create serious complications, injuries and even death.

[2] Timing and details of the situation in Japan remain sketchy.

A damaged distal tip of a Jet 7 device

2. *The "killer balloon"*

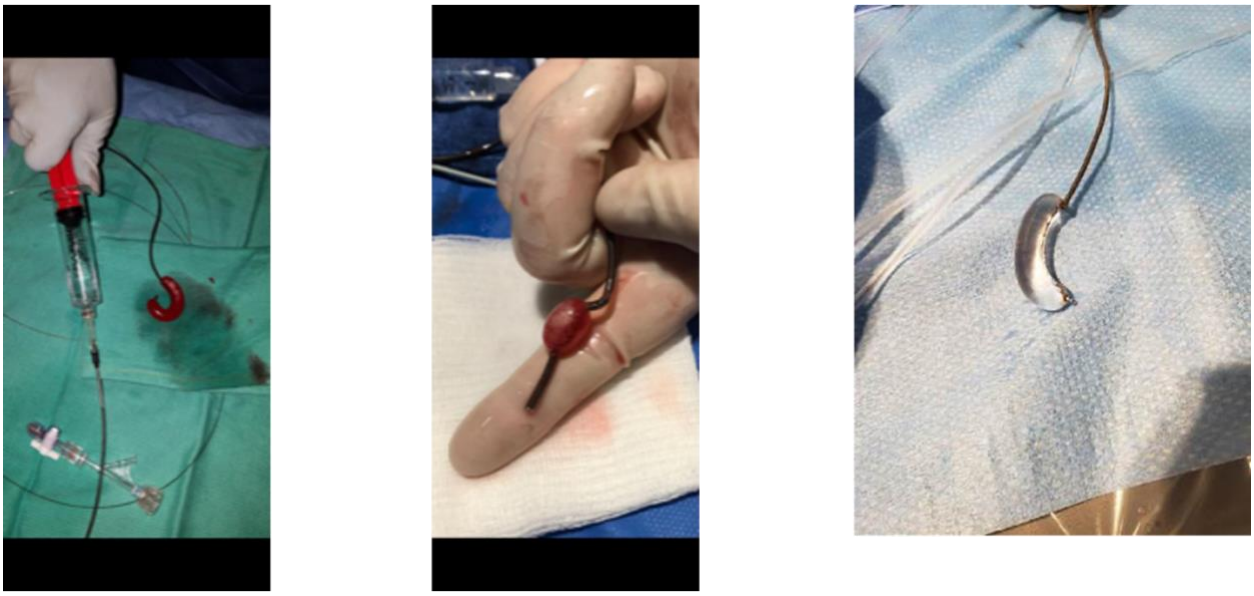
Far more catastrophically, at least **17 patients died**[3] by the Xtra Flex when the distal tip malfunctioned and "expanded like a balloon" inside a brain artery, causing the blood vessel to rupture and the patients to die[4] on the operating table due to massive brain hemorrhage. Most of these cases occurred upon hand injecting contrast media or saline solution through the catheter, a standard procedure that many doctors perform on a routine basis and that doctors affiliated with and working for Penumbra as consultants have been advocating until very recently.

[3] The Maude FDA database reports 17 deaths related to the Jet 7. We found three duplicates, but an additional three patients expired in Japan. The Maude database is notoriously imprecise and often subject to underreporting issues.

[4] Typically, patients experience brain death first in these situations.

A malfunctioning Jet 7 device ballooning after injecting saline solution

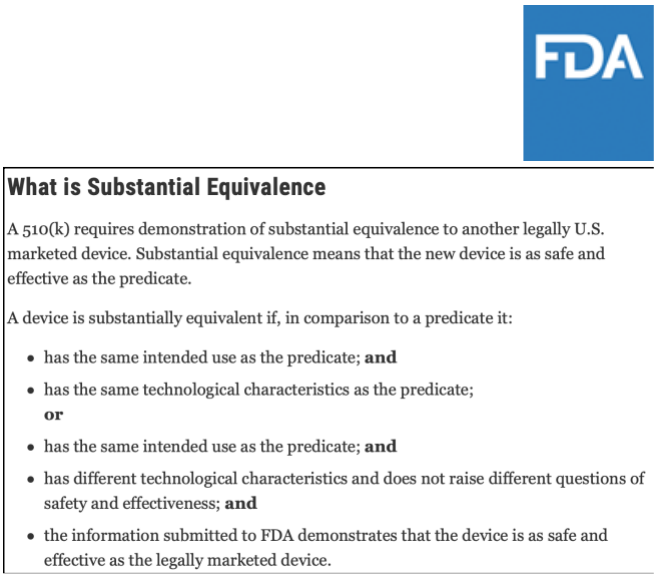
Artist’s rendition of a deadly malfunctioning Jet 7 device ballooning and rupturing an artery



Real-life pictures of a deadly “ballooning” malfunctioning of a Jet 7 Xtra Flex device

Lives vs Money: the making Xtra Flex catastrophe

Penumbra has been presenting the Xtra Flex not as a new device, but rather a simple modification of the existing Jet 7 system. We have been told that the Food and Drugs Administration (FDA) allows a fast-track clearance called 510(k) for new versions of an existing product that can demonstrate being *substantially equivalent* to an older iteration. The definition of *substantially equivalent* includes products with the same technological characteristics or with different characteristics that do not raise questions of safety and effectiveness. Via a 510(k), a manufacturer can commercialize an upgrade of an existing device in a matter of weeks or months, with minimal testing requirements relative to those required for a new device.



What is Substantial Equivalence

A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is as safe and effective as the predicate.

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;
  or
- has the same intended use as the predicate; **and**
- has different technological characteristics and does not raise different questions of safety and effectiveness; **and**
- the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.

Definition of “substantial equivalence” according to the FDA website

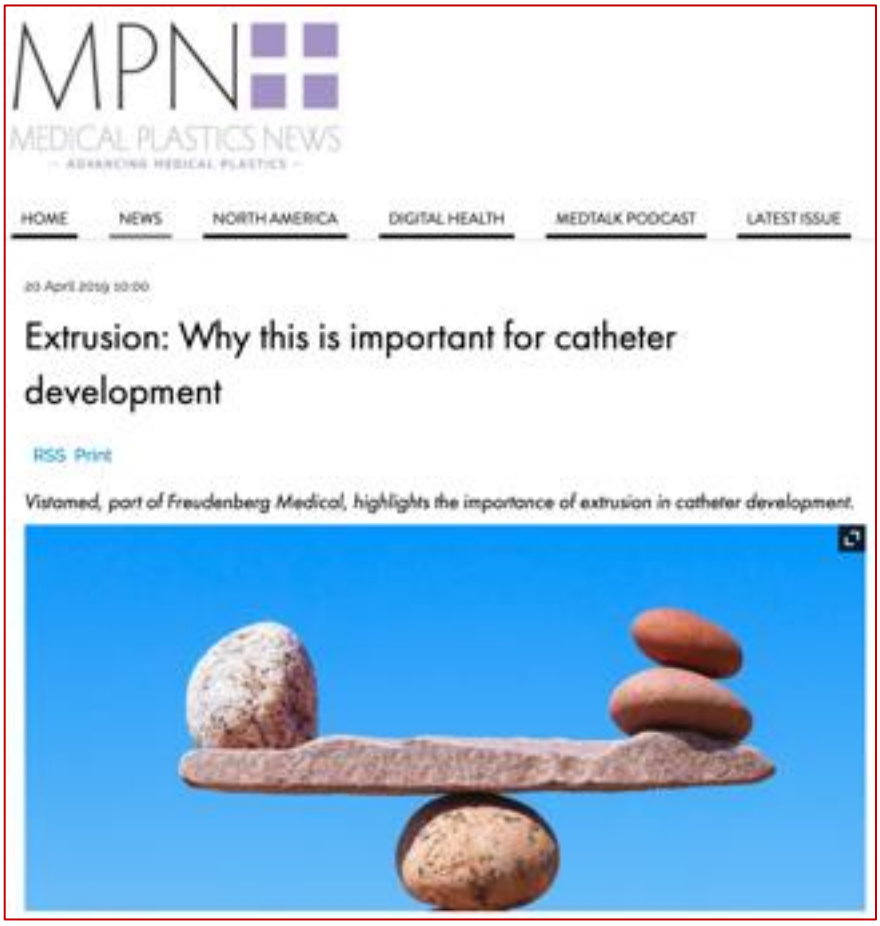
We reviewed a part of Penumbra’s original clearance application for the Xtra Flex upgrade and learned that, while most components of the device were indeed identical (“SAME”) to its “predicate” (the original Jet 7), Penumbra listed its coating and, more importantly, the extrusions[5] as “equivalent”. It is reasonable to infer that in tampering with the extrusion process and materials seeking a more flexible device, Penumbra may have inadvertently designed a more unstable product prone to failure. The testing required for the 510(k) clearance obviously failed to detect these issues before going to market.

[5] process used to create objects of a fixed cross-sectional profile. Based on the documents we reviewed, we understand that Penumbra changed the material used for the extrusions of the shaft from polyurethane to some other unspecified material

System Name	Penumbra System®	
Device Name	**JET 7 (Predicate)**	**Modified JET 7 (Subject)**
Materials		
Proximal hub	Grilamid (TR55-LX)	SAME
Strain Relief [Hub Sleeve]	Grilamid (TR55)	SAME
Strain Relief	304 Stainless Steel (SS)	SAME
ID Band	Polyolefin, PET black [white foil]	SAME
Liner	PTFE	SAME
Catheter Shaft		
Extrusions	Polyurethane	Equivalent
	Polyether Block Amide	SAME
	Nylon 12	SAME
Distal Coil Reinforcement	NiTi wire	SAME
Proximal Coil Reinforcement	SS wire and NiTi wire	SAME
Extrusion Colorants	Clear/ Natural or Purple	SAME
Tip Shape	Straight	SAME
Markerband	Platinum/Iridium (90% Pt, 10% Ir)	SAME
Coating	Hydrophilic (proprietary)	Equivalent
Dimensions		
Proximal OD	0.085 in Max	SAME
Proximal ID	0.072 in Min	SAME
Distal OD	0.085 in Max	SAME
Distal ID	0.072 in Min	SAME
Effective Length	115, 120, 125, 127, 132 cm	SAME
Distal Flex Length	30 cm	SAME
Coating Length	30 cm	SAME
Accessories		
Peelable Sheath	PTFE	SAME
Rotating Hemostasis Valve	Polycarbonate, silicone o-ring	SAME
Shaping Mandrel	0.038in OD stainless steel	SAME

Substantial equivalence form presented by Penumbra to the FDA for its Xtra Flex model. Note how the material for the extrusions has changed from polyurethane to some other unspecified material

Confirming our educated guess, we found a scientific article Iin the *Medical Plastics News* journal and another one in *Medical Design* that both emphasize the critical role of extrusion in the development of medical catheters.


MPN
MEDICAL PLASTICS NEWS
HOME NEWS NORTH AMERICA DIGITAL HEALTH MEDTALK PODCAST LATEST ISSUE
Extrusion: Why this is important for catheter development
RSS Print
Vistamed, part of Freudenberg Medical, highlights the importance of extrusion in catheter development.

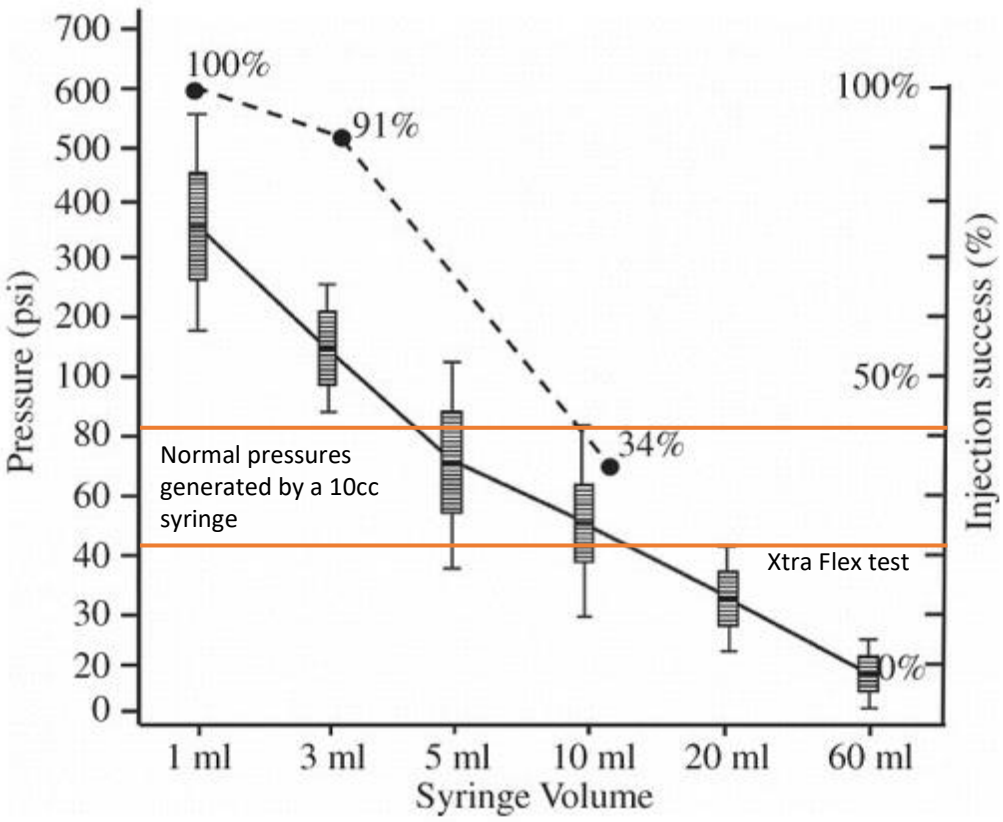
Journal article emphasizing the critical role of extrusion in the development

Upon reviewing Penumbra’s 501(k) application, we discovered that Xtra Flex was indeed tested for resistance to pressure. The test however, consisted in subjecting the catheter to a pressure of only 45 psi for 30 seconds (as the current FDA standards indeed require). Now, as deadly accidents involving the Xtra Flex were caused by the injection of contrast media through the catheter, we investigated this specific procedure. We discovered that doctors typically use a 10cc syringe to inject contrast media through a catheter: research shows that such syringe

generates an *average* pressure of 53 psi that can easily reach 82 psi or more if vigorous force is applied. These figures clearly exceed the 45 psi testing threshold by a wide margin. Therefore, despite being consisted with FDA standards, we believe that **testing used by Penumbra was insufficient** as it failed to take into real world use of the device. For comparison, the competing catheter Sofia has been tested for pressures up to 300 psi!

Attribute	Specification	Results
Particulate testing	≥ 10 µm will be ≤ 6000 particles	Pass
	≥ 25 µm will be ≤ 600 particles	Pass
	≥ 75 µm will be measured for informational purposes only (FIPO)	FIPO
	≥ 125 µm will be measured for informational purposes only (FIPO)	FIPO
Coating Integrity	Coating has not delaminated, peeled, or flaked prior to or after simulated use particulate testing	Pass
Markerband Visibility	The markerband is fluoroscopically visible	Pass
Hub Air Aspiration	No leaks detected when vacuum is pulled on the injection lumen	Pass
Pressure Test	45 psi for 30 sec minimum	Pass
JET 7 / Sheath or 8F Guide Catheter Friction Force	Maximum value per specification	Pass
JET 7 / 0.014 in. Guidewire Friction Force	Maximum value per specification	Pass
Joint sections bond strength	Minimum value per specification	Pass
Markerband Section Bond Strength	Minimum value per specification	Pass
Hub to Shaft Bond Strength	Minimum value per specification	Pass
Hub to Hypotube Bond Strength	Minimum value per specification	Pass
Elongation to failure	Elongation ≥ 5%	Pass
Torsion	Number of turns will be recorded for informational purposes only.	FIPO
Corrosion	No visible corrosion on Reperfusion Catheter immediately after corrosion testing procedure	Pass

Extract from the Xtra Flex FDA application showing that pressure testing was performed at 45 psi



Extract from a research report showing that pressures normally generated by a 10cc syringe easily exceed those for which the Xtra Flex has been tested

Penumbra's misleading crisis communication

Misleading Communication?

On July 27th 2020, more than a month after the warning that its Japanese distributor had sent to its clients, Penumbra finally sent out a notice to healthcare providers warning them to exercise caution with its Xtra Flex device. The note acknowledged reports of issues with the distal tip of the catheter that in some cases broke or expanded, carrying a risk of injury or death. Unlike its Japanese counterpart, however, the U.S. note did not mention that *actual deaths and injuries had indeed already occurred* when using the device.

Specifically, the note warned against injecting contrast media through the catheter by hand or through automated high-pressure contrast injection equipment. Interestingly, the note included the following statement:

> *"Performing contrast injections through JET 7 Xtra* ***Flex is not consistent with the intended use of the product or the Instructions for Use****, which instructs the user to perform contrast injections through the guide catheter."*

In other words, Penumbra is blaming doctors for failing to follow the warnings in the user instructions [IFU] of the device. Confirming Penumbra's position on this issue, CEO Adam Elsesser said the following at the 2020 Wells Fargo Virtual Healthcare Conference when asked about the July 27th notice):

> *"As soon as we did our evaluation [on the Jet 7 device issues], we made the determination that rather than rely on the IFU that existed that said, do not do a contrast injection through the catheter, we wanted to make that even more strong, more aware so that physicians would be notified."*

So, Mr. Elsesser appears to claim that the original IFU contained a warning for doctors not to inject contrast through the catheter. Yet when one of our affiliates contacted Penumbra and requested a copy of the original IFU, the company refused to provide it, making unconvincing excuses (none of Penumbra's competitors had any issues with sending us their own IFUs).

Smoking guns

Despite Penumbra's reticence, QCM easily obtained copies of the paper IFU from three different doctors. We also downloaded both the current IFU as well as the original version (prior to the July notice) using the Wayback Machine[6]. Our findings were damning for Penumbra:

- The current online IFU, drafted after upon the July notice, contains the appropriate warning, as we expected: *"Do not inject contrast media through the Penumbra [...] using a syringe or automated high-pressure contrast injection equipment"*.
- The original IFU, however, **does not contain any warning against injecting contrast media *by hand***. It only warns against injection through high pressure *automated equipment*.

It is important to note that, unlike injecting through a high-pressure machine, hand injection of contrast media through any catheter **is a common practice in a thrombectomy** that a **large number of doctors perform on a routine basis**[7]. Every doctor we spoke with said this is completely normal.

[6] The Wayback Machine is a digital archive of the World Wide Web. It allows the user to go "back in time" and see what websites looked like in the past.

[7] Interviews with neuroradiologists suggest that between 20% and 50% of them perform contrast media injection through the aspiration catheter on a regular basis.

Regarding Penumbra's claim that "Performing contrast injections through JET 7 Xtra Flex is not consistent with the intended use of the product," we reviewed this article posted on the prestigious Neurosurgery journal (and reposted in April 2020 as a commentary). As the title suggest, the study reviews lessons learned after performing multiple aspiration thrombectomies – the procedure Jet 7 is used for – with the ADAPT technique that Penumbra has promoted repeatedly. When detailing the steps of the procedure, the articles contain the following statement:

> *"After confirming patency of the lumen of the aspiration catheter,* ***follow-up angiography can then be performed with injection of contrast directly into the aspiration catheter*** *[…]*

In other words, this study recommends that doctors inject the contrast media by hand, further confirming what we've heard from doctors.

Damningly for Penumbra, the co-author of both papers is Dr. Alejandro Spiotta[8], who has received over $400,000 of compensation from Penumbra as a consultant for multiple years and who is an enthusiastic evangelist and promoter of the Company's products (he frequently appears on Penumbra-sponsored events that the Company regularly promotes on its Twitter account).

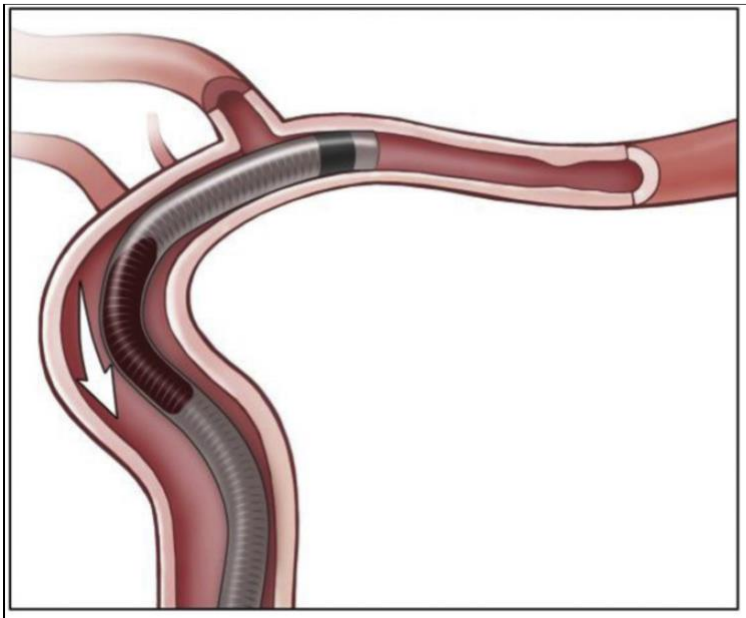
In conclusion, we have a doctor who has been defined a "quasi-spokesperson" of Penumbra's[9], publishing a journal article that prescribed injecting contrast media into the aspiration catheter

[8] We do not mean to imply that Dr. Spiotta is doing anything wrong. On the contrary, he has been using Penumbra's products clearly in good faith.

[9] Source: interviews with a reputable neuroradiologist

when only a few months later Penumbra claimed that "*Performing contrast injections through JET 7 Xtra Flex is not consistent with the intended use of the product.*"

Our conclusion is that Penumbra has made misleading statements about both the IFU and the intended use of the Jet 7 Xtra Flex in order to distance itself from the deaths and injuries that occurred, in what seems like a desperate attempt to avoid exposure to legal liability.



thrombus to "ingest" it. (**C**) Direct aspiration is then applied, and typically the thrombus is entirely ingested into the tubing of the aspiration system. After confirming patency of the lumen of the aspiration catheter, follow-up angiography can then be performed with injection of contrast directly into the aspiration catheter and further attempts at aspiration can be made without the need to deliver the catheter over the carotid siphon again.

Extract from Dr. Spiotta article suggesting to perform a contrast injection "directly into the aspiration catheter" (the action that led to a number of patients'deaths and injuries using Penumbra's catheter)

Late communication?

Penumbra didn't issue its notice to healthcare providers until July 27th,2020, more than a month after its Japanese distributor sent out its warning. This was also more than **nine months after the first patient died**[10]. By July 27th, according to the Maude database and the Japanese distributor, 17 people had died, and 39 others suffered injuries.

Ineffective communication?

In our multiple calls with doctors, we were surprised to discover that, at least until very recently, most surgeons seemed completely unaware of the gravity of the problem with the Jet 7 device. In fact, three quarters of the doctors in an informal survey conducted by one of our affiliates were unaware that *any* deaths had occurred using the device[11]. This is likely due to the fact that Penumbra, unlike its Japanese distributor, failed to mention any deaths in its July 27 notice. Doctors, understandably, take notices involving deaths much more seriously than generic ones such as the one sent by Penumbra (which doctors receive frequently and are typically less important). Virtually every doctor we spoke to was of the opinion that Penumbra had been grossly ineffective in transmitting the importance of the Jet 7 issues, especially when compared to similar situations that have occurred with its peers.

[10] According to what we read in the Maude database taking into account its lack of rigor and limitations
[11] This is unsurprising since Penumbra did not mention the deaths in the July notice. Doctors, understandably, take notices involving deaths much more seriously.

A loose cannon on the market

Every neuroradiologist and regulatory consultant we spoke to agrees with our recommendation that Penumbra's Jet 7 Xtra Flex device should be immediately taken off the market in a mandatory recall, for the following reasons:

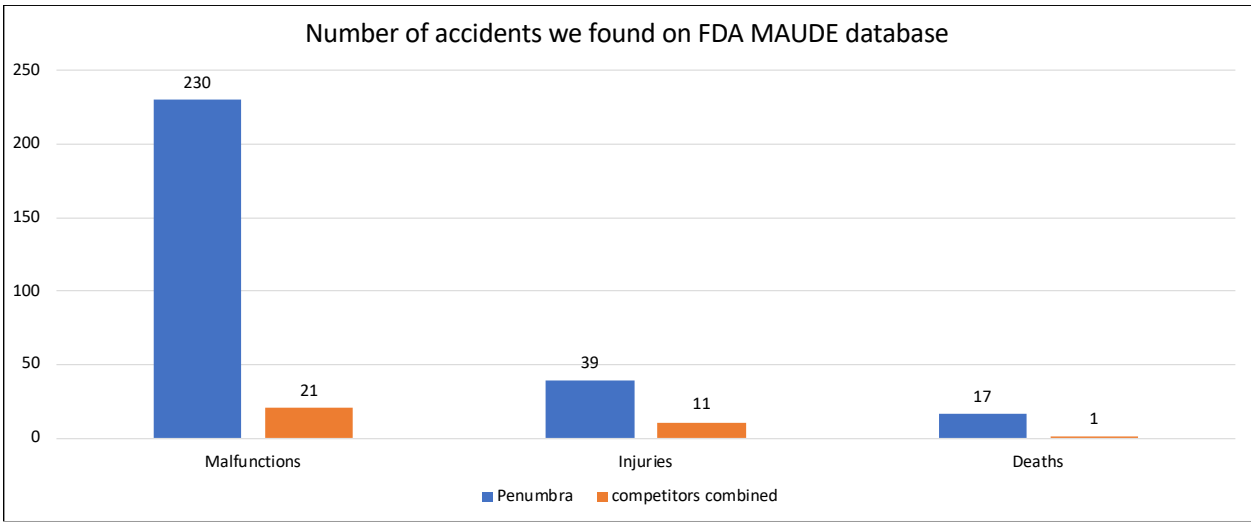
Very high absolute and relative number of accidents

According to the Maude database, there are 17 deaths, 39 injuries and 200+ malfunctions[12] caused by the catheter. These numbers are staggering even taking into account that thrombectomies are a high-volume procedure[13] (a neuroradiologist we interviewed referred to the number of Jet 7 deaths as "*monstrous*"). More importantly, the numbers appear extremely high also relative to the alternative products available on the market. According to our interpretation of the Maude database records, among the 15 deaths we identified in the US as caused by a thrombectomy aspiration catheter in the past 16 months, 14 were caused by the Jet 7[14]. Similarly, 39 out of 50 injuries and 230 out of 245 malfunctions were caused by Penumbra's catheter. The relative differences in accident rates are notable even when taking into account Penumbra's higher market share (currently we estimate around 57%).

[12] The deaths figure takes into account three likely duplicates and three deaths which occurred outside of the US.

[13] Number of thrombectomies in the US per annum is in the order of magnitude of a few tens of thousands.

[14] One death was apparently caused by Medtronic's React catheter. However, we read the associated narrative and it was unclear whether this was a malfunction or a procedural issue.



QCM **very rough estimates** using notoriously imprecise MAUDE FDA database and our market shares estimates.

Accidents (injuries and malfunctions) persist at comparable rates despite the July 27 notice

There have thankfully not been any additional recorded deaths since Penumbra warned doctors not to inject contrast media into its catheter. Worryingly, however there have been some 48 new malfunctions and 1 new injury since the July notice. The malfunction rate seems constant at a rate of about 14 malfunctions/month and has not decreased materially after Penumbra warned in July. This is a strong indication that despite the label changes, the device is inherently dangerous and should be taken off the market.

Tip of the iceberg

According to nearly every expert we consulted with, the number of accidents recorded in the Maude database is likely to be a gross underestimation of the real figure. There are multiple reasons. First, accidents can easily be misattributed to other causes or to other medical devices used in the same procedure. For example, the massive blood hemorrhage caused by the

ballooning of the Jet 7 could be blamed on natural causes (especially when saline solution is involved as it does not show up on an angiography). Second, reporting bias may keep doctors from blaming a device if they think this will jeopardize their relationship with the manufacturer (consider that surgeons frequently receive generous perks and occasionally consulting fees from manufacturers). Third, there are often long lags between when an accident occurs versus when it shows up in the database. Fourth, manufacturers may refrain from reporting accidents as they have some leeway in assessing how serious an accident is. As an interesting precedent, one of the largest medical device makers, Guidant, reported only 172 out of 2,600 accidents (15 times less) to the FDA (this came out during litigation following a recall). We understand this pattern of behavior is quite common when devices malfunction.

Prior recall

Many surgeons and former regulators we spoke with observed that in prior cases involving a malfunctioning catheter, the FDA has been justifiably aggressive in removing the faulty devices from the market. For example, the *Fetch 2* aspiration catheter by Boston Scientific was recalled after it caused only 14 injuries and the *Shuttle Select* by Cook Medical was recalled after only 4 injuries. Unlike the Jet 7, neither catheter seemingly caused any deaths and, interestingly, both devices were also approved through the 510(k) clearance process (both events are described in detail in this article). Experts we spoke with speculate that the current Covid-19 pandemic may slowed down the FDA's response time, but are convinced that an investigation and a Class 1 recall is highly likely given the high safety risk of the device.

Expert opinion

Our investigation included dozens of in-depth interviews with neuroradiologists familiar with thrombectomies and Penumbra devices as well as former senior FDA staff now working as consultants. We have published their opinions on our website and in the slides that complement this report. We also hired a prestigious life sciences consultancy firm, NDA Partners, and asked them to investigate the subject of this report and provide an unbiased opinion. The brilliant consultant who assisted with this task was Mr. Steven Brooks, a cardiologist and former FDA Medical Officer at the Office of Device Evaluation (ODE). His full assessment is enlightening and damning and can be read here.

Steven S. Brooks, MD MBA FACC

- Interventional Cardiologist University of Maryland 2003-2005, Private Practice 2005-2007
- FDA Medical Officer, Office of Device Evaluation (ODE), Division of Cardiovascular Devices (DCD), Peripheral Interventional Devices Branch (PIDB) 2007-2014
- VP Regulatory Affairs & Health Economics Ablative Solutions 2015-2017
- Expert Consultant NDA Partners 2016-Present

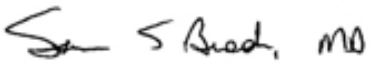
66

Here are the main findings:

- Jet7 Flex malfunction carries a **very high risk of patient injury and death**
- Mechanism of malfunction is **poorly mitigated by labeling modifications**
- Highly likely **FDA will investigate and issue Class 1 recall** (or already is)
- Possibility of **legal action** for denials and **misleading characterizations** of injuries and their **inadequate responses**
- **Revenues are likely to be damaged** as doctors shift to competing devices

We report the conclusion of the assessment in full as it appears definitive:

In conclusion, the Jet7 Flex catheter appears to have an important design flaw. While it passed premarket testing to achieve 510(k) clearance, the boundary conditions and test criteria did not reflect real world use, or the device was not developed to high enough tolerances for real world use. Regardless, the product has an extremely high safety risk that can result in stroke or death. Nothing short of not using the devices will fully protect patients for this risk. Pre-procedural inspection and in-factory visual inspection of the catheters are clearly not curtailing this risk. Labeling mitigations will not adequately penetrate to all operators and may be inadequate anyway. It seems highly likely that FDA will investigate this product, and if/when they do, it is likely that they will mandate a Class 1 recall. Penumbra's revenues are likely to be damaged by decreased sales and the possibility of legal action for their denials and misleading characterizations of the injuries and their inadequate responses in the face of the malfunctions.



Steven S. Brooks, MD MBA FACC
Expert Consultant NDA Partners

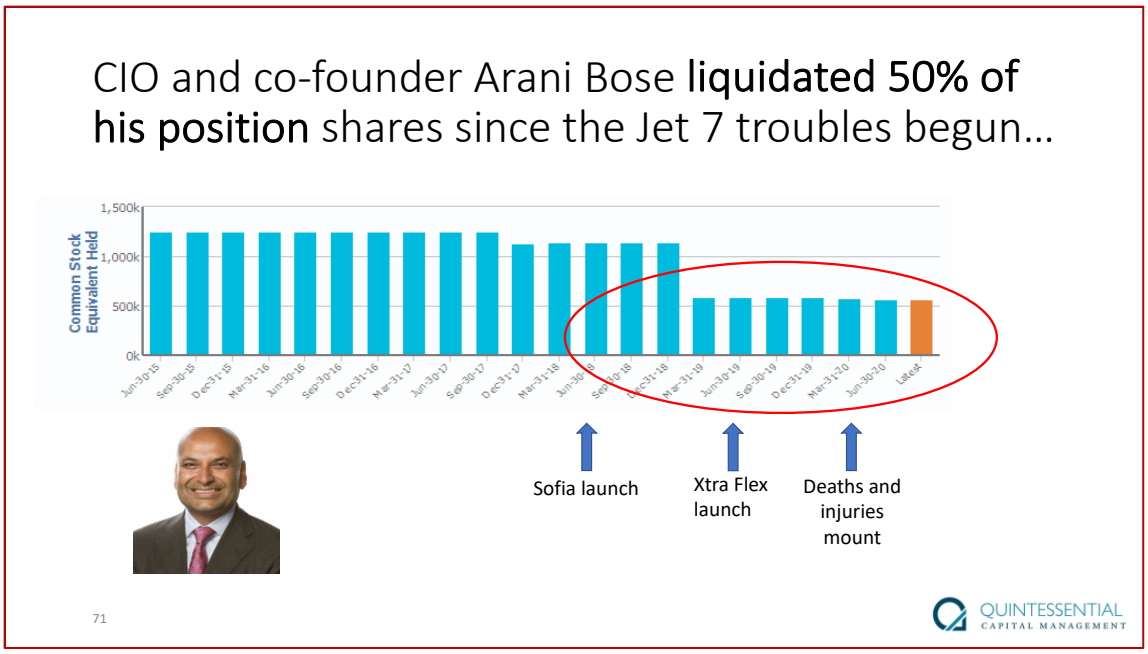
40 Commerce Lane, Suite D • Rochelle, VA 22738 • 540-738-2550

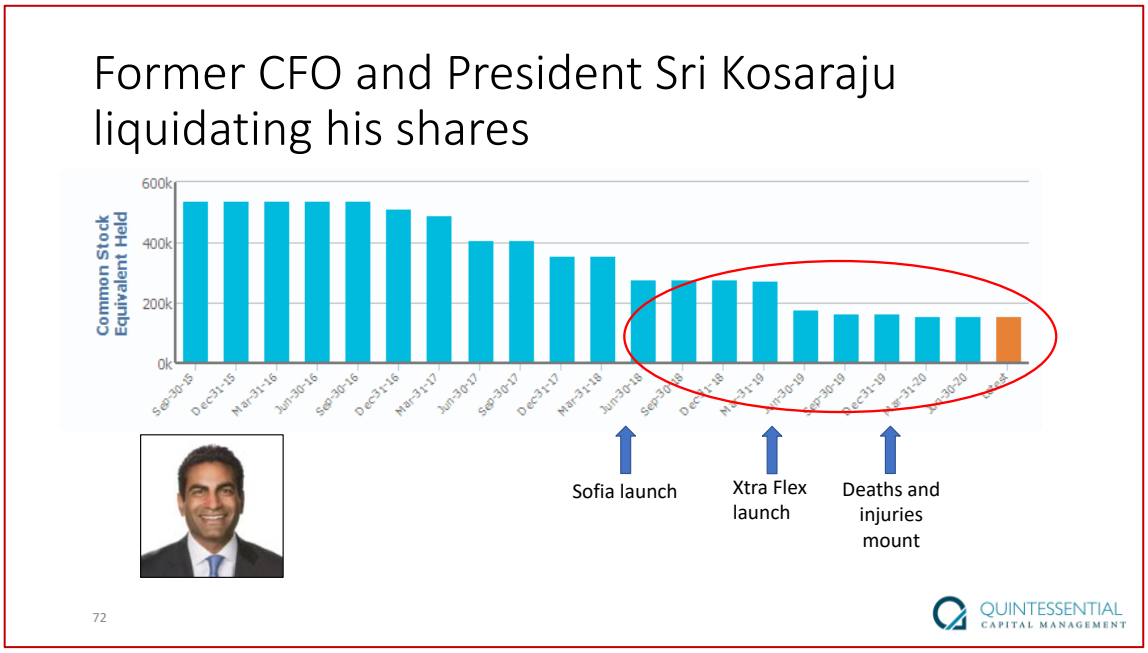
Fleeing a sinking ship: Meanwhile at Penumbra

The peculiar behavior of a large number of Penumbra’s insiders may be circumstantial evidence suggesting that management is well aware of the issues we have highlighted in this report and is feeling increasingly uncomfortable as a result.

Insider sales

Three key company insiders, Mr. Adam Elsesser, Mr. Bose Arani and Mr. Sri Kosaraju, sharply decreased their (previously relatively stable) equity positions in Penumbra around the time that the trouble with the Jet 7 began (including the loss of market share related to the launch of the competing Sofia catheter).





Executive turnover

A large number of company executives and senior sales managers have left the company during the last 18 months, coinciding with the emergence of the issues highlighted in this report. Many

of the managers who resigned had been at the Company for several years and, in many cases, joined competitors (notably Imperative Care). Interestingly, Mr. **Sri Kosaraju** resigned soon after he was promoted to CFO and President of Penumbra, initially to join a non-profit.

Some notable resignations include:

- Sri Kosaraju –CFO & President
- Daniel Davis – Chief commercial officer
- Theo Jourdan – Director of vascular strategy
- Grant Weenig – VP of product strategy
- Kavi Vyas – Global head of embolization
- David Hasselbach – VP of vascular strategy
- Plus at least 11 senior sales managers and many others

First cracks in financials?

In our opinion, the issues we have highlighted in this report are already showing up prominently in Penumbra's financials, though they are to some extent masked and mitigated by the Covid-19 crisis and by the still healthy growth of the Company's vascular segment, which is unaffected for the moment by the developing situation in the neuro division.

Specifically, we observe what looks to us like a collapse in cash generation, as free cash flow[15] dropped sharply from $6.6m in 2018 to negative $56m during the last 12 months (period coinciding with the issues in the neuro division). It appears to us that this copious cash burn is driven by a sharp increase in working capital, especially inventories and receivables. Based on

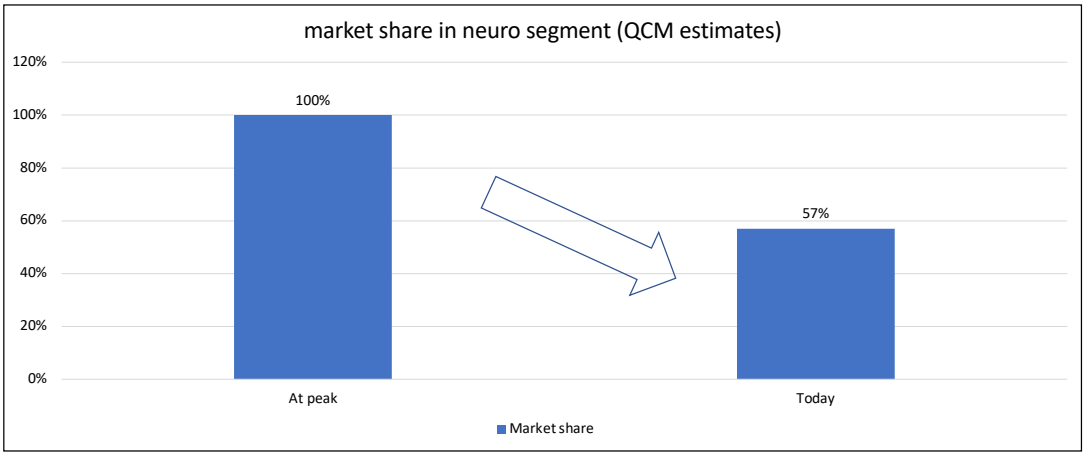
[15] Source: S&P CapitalIQ

interviews with doctors and hospitals, we understand that Penumbra is offering them generous quantity discounts for bulk purchases (this is also clear from a sharp contraction in gross margin). Under Penumbra's revenue recognition policy, sales are registered immediately after selling to distributors and hospitals, but cash arrives only when distributors sell out or when hospitals actually use the end products. We speculate[16] that, as doctors refrain from using the Jet 7 following the horror stories around the device, the unsafe tools are piling up in hospitals' warehouses.

Penumbra's cash situation deteriorated to such an extent that the Company recently raised $130m by issuing new shares.

Finally, revenue growth rate has turned negative (from recent peaks of 50%/year).

…Penumbra has been losing market shares from larger peers in neuro

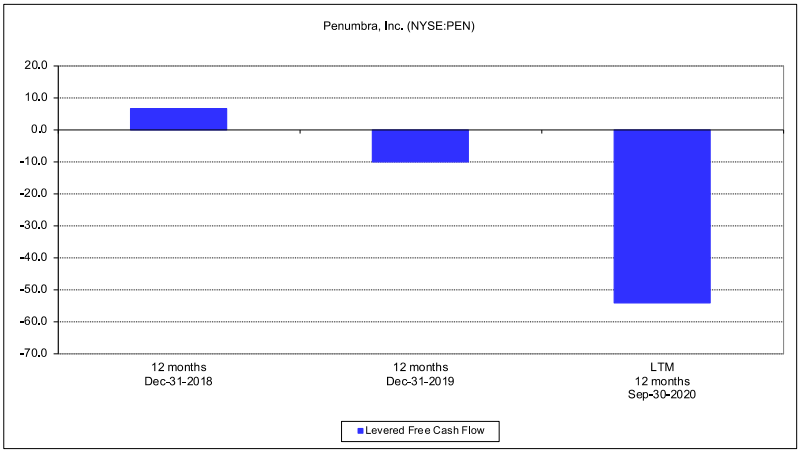


78

QUINTESSENTIAL CAPITAL MANAGEMENT

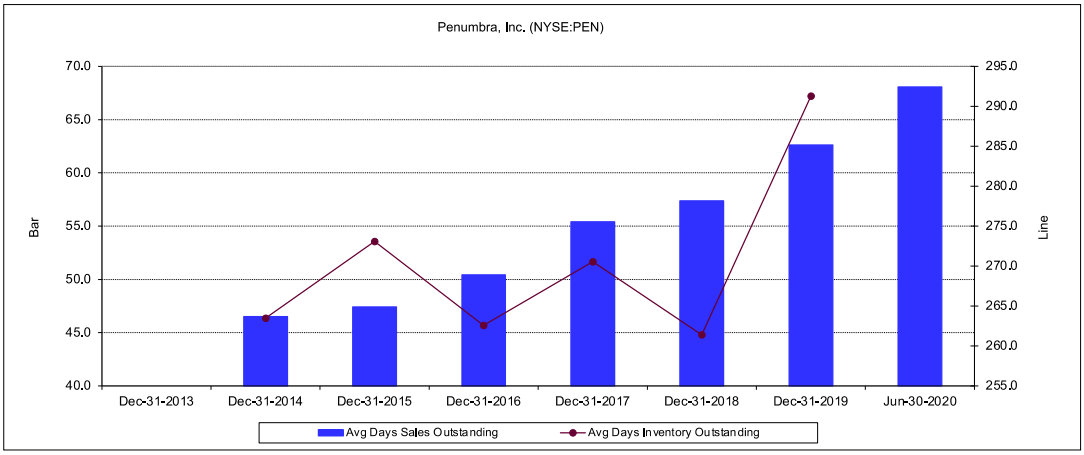
[16] This is also corroborated by multiple interviews with hospital staff

Free cash flow generation took a turn for the worse since the Jet 7 was introduced…



QUINTESSENTIAL CAPITAL MANAGEMENT

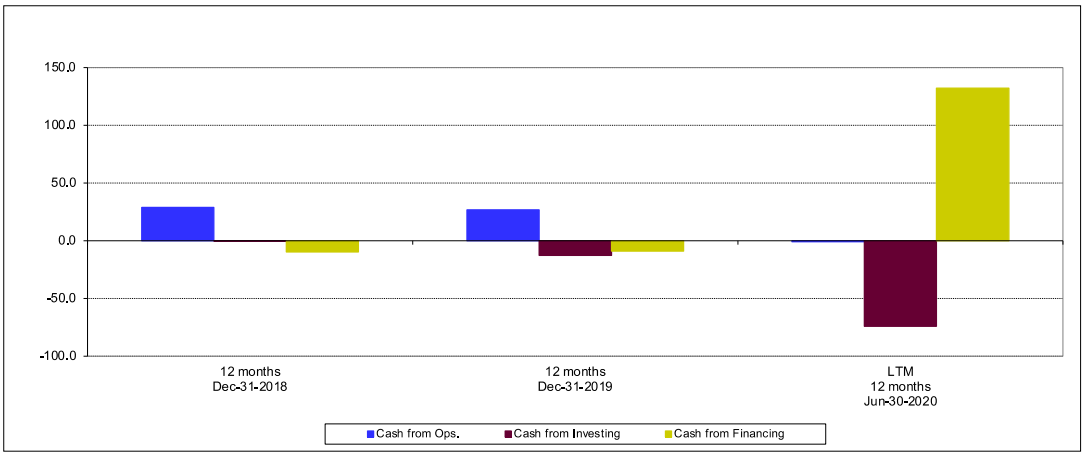
…driven by receivables and inventories, **ballooning like a Jet 7** catheter…



QUINTESSENTIAL CAPITAL MANAGEMENT

QUINTESSENTIAL CAPITAL MANAGEMENT

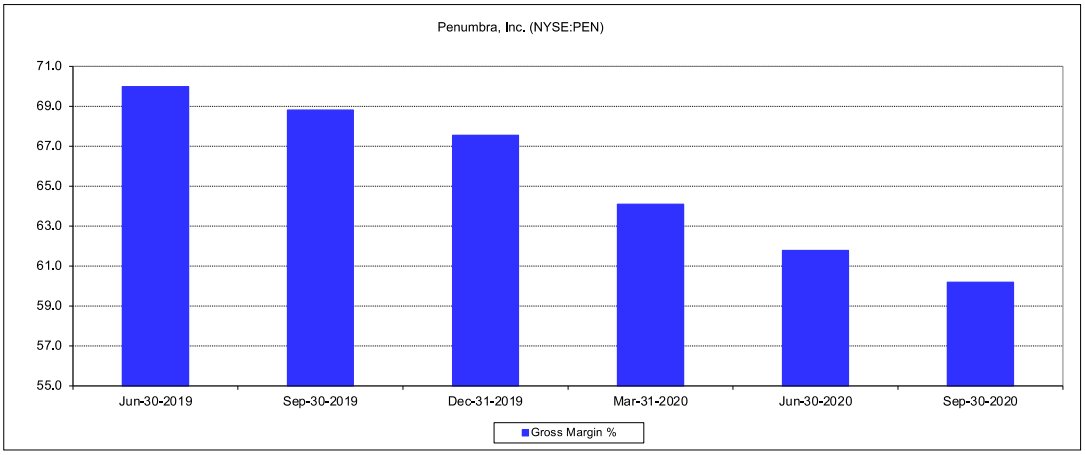
Cash shortfall financed by share issues



80

QUINTESSENTIAL CAPITAL MANAGEMENT

Sharp, accelerating gross margin compression since Jet 7 issues began



82

QUINTESSENTIAL CAPITAL MANAGEMENT

What happens when the true state of affairs becomes public knowledge?

Despite the recent share performance, we are of the opinion that Penumbra's current situation is perilous and that the Company might well be facing near-existential threats.

Sales at risk

First, the issues we highlighted in this report and the nearly unanimous opinions of multiple experts we spoke with point to a likely recall of the Jet 7. Penumbra's flagship product. A recall would put a large percentage of revenue in immediate jeopardy, with likely spillover effects across the entire product line due to reputational damage (especially if, following an investigation, it turns out that Penumbra's management acted with negligence or malice). Even before a recall materializes, according to former FDA expert Steven Brookes:

> *"Given the risk of complications which appear to be of much greater frequency with the Jet7 Flex catheter and the availability of competing technology, physicians are likely to change their adoption practices.* ***Penumbra is at risk for a significant drop in sales of this catheter and possibly the entire line of catheters****. Penumbra has also pointed to use of other manufactures equipment concurrently with the Jet7 Flex as a possible cause of complications, and therefore to use the catheter only with other Penumbra equipment. Due to the complexities of hospital purchasing and contracting, individual labs may not have access to the full Penumbra lineup, even if operators wanted to use the Jet7 Flex.* ***This reality could further limit sales.****"*

Our interviews with neuroradiologists confirm that the issues we have highlighted have generated an enormous amount of distrust of Penumbra and its products within the medical community.

Reputational damage

Despite what looks to us like an attempt by Penumbra to keep quiet the deaths likely caused by its Jet 7 device[17], news of the deaths have spread far and wide through the medical community. Virtually all surgeons we spoke to are extremely upset with the company's behavior, consider the device unsafe and don't plan to use it anymore. A recent study by the American Society of Neuroradiology closely examined two instances of Jet 7 malfunctions, noting how the race to achieve greater catheter flexibility may have compromised its strength. A similar study is being prepared by the Mount Sinai hospital in New York[18], which has put a moratorium on the Penumbra device. Likewise, Ascension, Stanford and the Mayo Clinic appear to be either discontinuing the use of the device or discouraging it[19].

While it's difficult to say for sure, we believe that the loss of trust together with a justified fear of legal liability might well deter a large proportion of hospitals from using *all* Penumbra devices in the future. Consider that most Penumbra products are not unique solutions —there are almost always multiple competitors with matching or superior performance characteristics. Why would a neurosurgeon or hospital choose a Penumbra device today when there's an equivalent Sofia

[17] As noted elsewhere, the Company did not acknowledge the number of deaths occurred in its July notice nor elsewhere as far as we could find.

[18] Source: interviews with neurosurgeons at Mount Sinai.

[19] Sources: interviews with multiple neuroradiologists.

catheter that hasn't caused deaths or injuries? Switching away from Penumbra products also reduces the chance of getting sued if something goes wrong.

Exposure to legal liability

After multiple consultations with leading law firms in the field who have examined our research, we believe that Penumbra is likely to soon face numerous, enormous product liability lawsuits due to the issues we've highlighted. In particular, one of America's most prestigious medical malpractice and product liability law firms is actively investigating the events described in this report and has clearly expressed its intention to file a class action lawsuit against the Company in the near future.

The evidence makes it clear that the deaths and injuries associated with the Jet 7 Xtra Flex are likely the result of a design flaw of the device, which Penumbra didn't catch due to its inadequate testing, and therefore Penumbra will likely be liable for damages. The fact that Penumbra, despite its arguably misleading communication, has not warned against hand-injecting contrast media, the main culprit for the deaths that occurred, makes the case against the company even stronger.

Estimating liability exposure is notoriously hard, but again, based on our conversation with specialized law firms, each death and brain injury may correspond to millions in damages. Considering some 60 recorded victims, and possibly many more unrecorded ones, liability exposure might be of the order of hundreds of millions of dollars – possibly exceeding $1 billion, if punitive damages apply.

Issues elsewhere?

It's too early to know for sure, but one of Penumbra's latest product additions in its vascular division, the *Indigo System with Lightning*, is already flashing warning signs about its safety and reliability. Launched in July, the system has already malfunctioned 65 times in only three months. The type of malfunctions we reviewed on the FDA Maude database tend to closely resemble each other, again suggesting a possible design/engineering flaw. We wonder whether this issue might point to widespread quality-control issues at Penumbra and a corporate culture that places profits and share price above patient safety.

QCM informs the authorities

As we have always done in the past, we are sharing our findings with a wide range of relevant institutions and stakeholders, including:

- Food and Drug Administration (Mr. Carlos Pena, Director of the Office of Neurological and Physical Medicine Devices, at the Center for Devices and Radiological Health)
- U.S. Securities & Exchange Commission
- American Stroke Association
- American Heart Association
- Leading law firms specialized in product liability
- Sell-side research firms and investment banks covering Penumbra's stock
- Large shareholders
- Major news media and financial press