:

Penumbra and its “killer catheter”

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

QUINTESSENTIAL
CAPITAL MANAGEMENT

Intelligent Investing

A short activist report by

Quintessential Capital Management (QCM)

11/9/20

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This report was created prior to Penumbra presenting its latest quarterly report so figures are not reflective of Q3 2020.

Quintessential is SHORT shares of Penumbra, Inc. (PEN)

QCM: Identifying, investigating and exposing corporate misconduct

- We uncover concealed information pertaining to **catastrophic** corporate malfeasance
- We collect overwhelming evidence owing to **deep investigative due diligence**
- **Pure activist** approach with element of **surprise**

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QCM's Effectiveness as Short Activist

Reduction in Market Capitalization Following Release of Thesis
(not necessarily indicative of fund's performance)

Bio-on (Italian AIM)

Market Capitalization at Release: $1.2b

Current Value: $0

Folli Follie SA (ATHEX)

Market Capitalization at Release: $1.4b

January 2019 Value: $0

Globo Plc (LSE)

Market Capitalization at Release: £100m

January 2019 Value: £0

Akazoo (NASDAQ)

Market Capitalization at Release: $1.2b

Current Value: $0

Ability Inc (NASDAQ)

Market Capitalization at Release: $135m

October 2018 Value: $11m

AAC Holdings Inc (NYSE)

Market Capitalization at Release: $730m

October 2018 Value: $169m

89%

Average Impact

Undisclosed

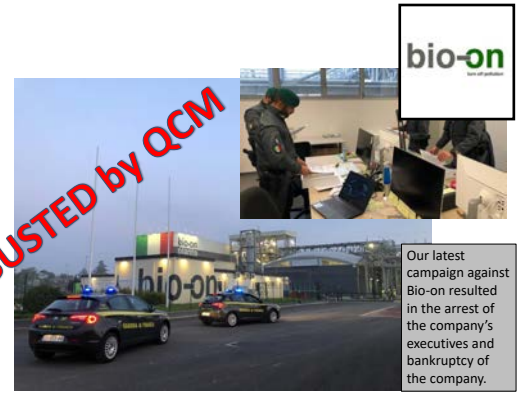
Market Capitalization at Release: ~$500m

Low Value One Year Post Release ~$150m

Aphria Inc (NYSE)

Market Capitalization at Release: $2b

Low Value Post Release: $1.1b



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QCM opinion on Penumbra:
Doomed by its own corporate greed

In our opinion and based on convincing evidence:

- Penumbra's flagship "Jet 7" device is linked to **18 recorded deaths**, **39 injuries**: this might be only the "tip of the iceberg"
- Jet 7 has **critical structural flaws** originating from **insufficient testing**
- The device is **unsafe** and **unmarketable**: we believe an **FDA** class 1 **recall highly likely**
- Penumbra **may have been highly misleading** in critical parts of its communication with doctors and investors
- Sources claim that **Mount Sinai Hospital** has put a **moratorium** on the device. Other **elite US institutions** are discouraging its use
- We flag **multiple malfunctions** with other other PEN devices questioning the Company's **quality assurance** practices
- Despite appearances, financial **metrics are rapidly deteriorating,** anticipating a possible **sharp drop in sales**
- There have been **key staff resignations** and executives have been aggressively **liquidating their Penumbra shares**
- Leading product liability **law firms** are investigating and may eventually file a **class action lawsuit**

Penumbra is threatened by product recall, brand devastation & exposure to legal liability

METHODOLOGY

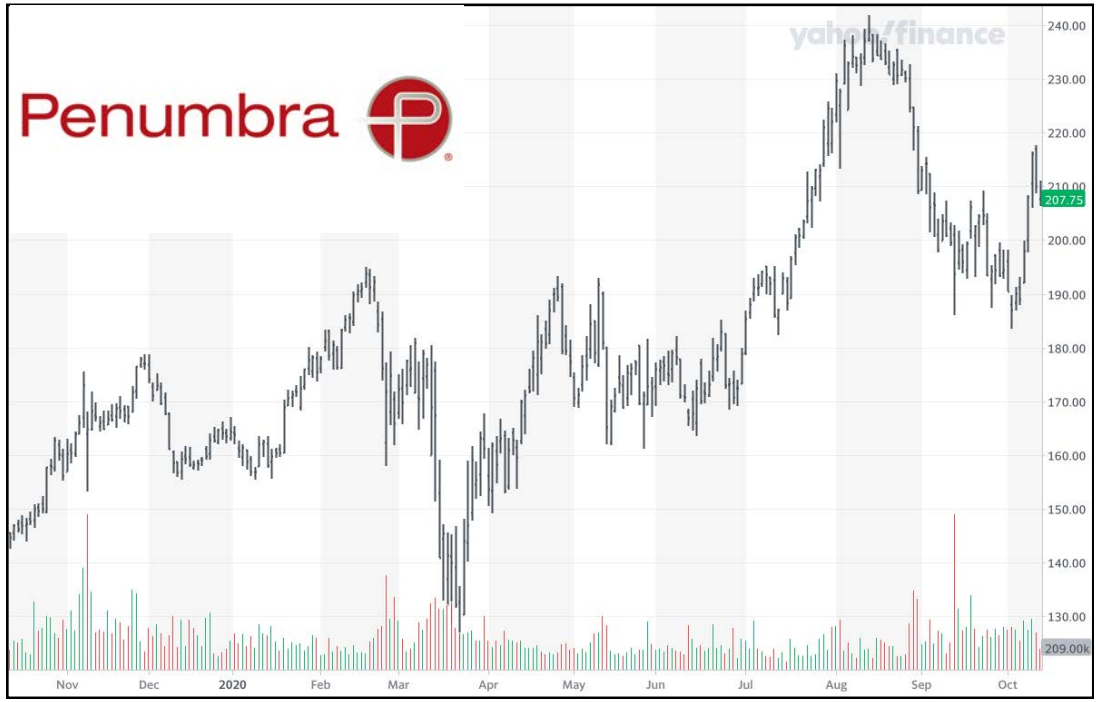
- Dozens of interviews with Neuroradiologists, former FDA senior staff, competitors, engineers.
- Examination of the device and its associated documents
- Due diligence on public FDA filings and databases
- Financial and strategic analysis

The Good

Penumbra has successfully pioneered the aspiration thrombectomy field

A primer on Penumbra Inc. (PEN)

- $9.4b market cap
- Industry: healthcare (medical devices)
- Focus: treatment of ischemic stroke
- Sales (LTM): 530m
- Company <u>not</u> a member of Advamed



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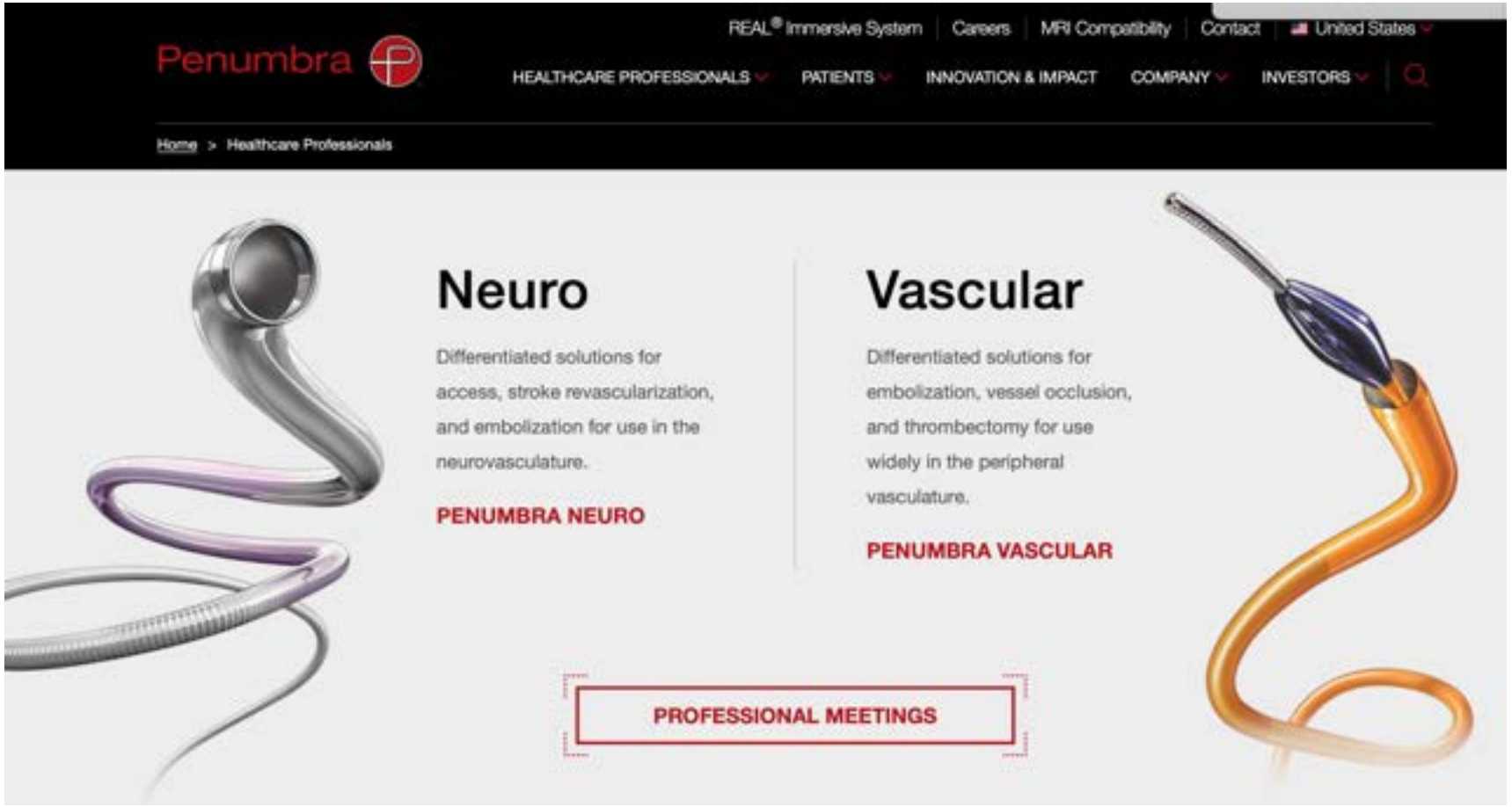
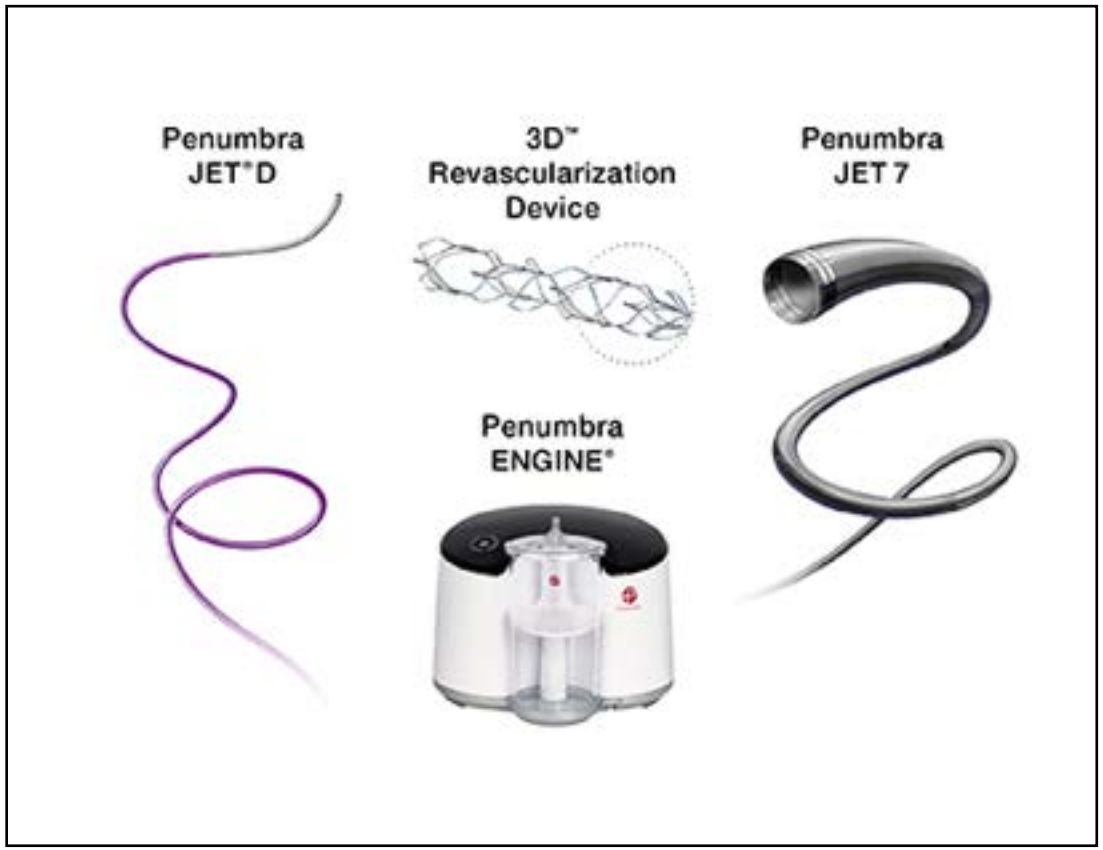
Penumbra's main product lines



55% of sales

45% of sales

Penumbra's Jet 7 System



- Penumbra's **flagship product** for the treatment of ischemic **stroke**.
- Equity research reports claim that ischemic stroke accounts for some **41% of total company revenue**

Thrombectomy through an aspiration catheter

Our own understanding of the procedure based on the literature we examined:

- Allows removal of blood clots causing strokes.
- Consists in introducing set of catheters (basically small tubes) in a patient's artery.
- The ***aspiration catheter*** reaches the blood clot deep inside the brain and removes it from the artery through suction.

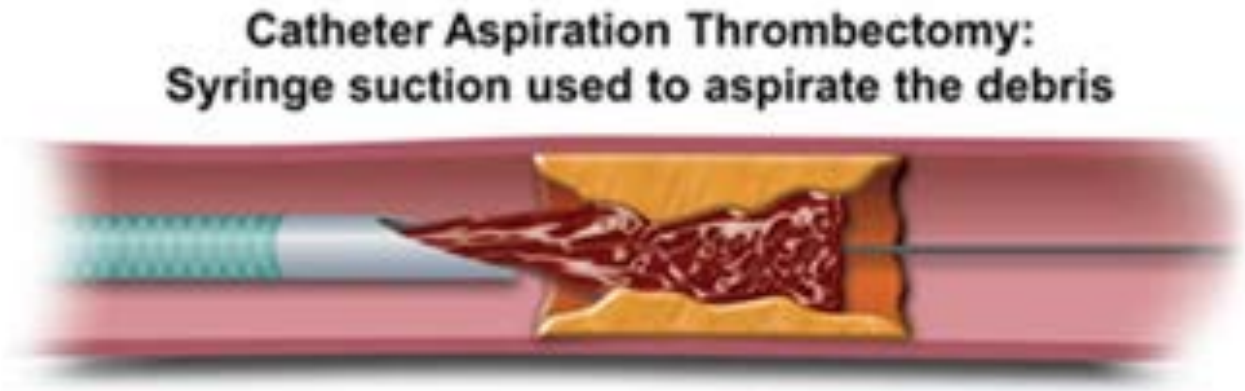


Illustration is for information purposes only does not represent the procedure in detail

Penumbra's history: early successes…

- Pioneered the market for aspiration catheters for the treatment of **acute ischemic stroke**
- **Rapid growth** until 2019 as Penumbra's catheters were the **only option available**
- Recently larger **competitors gradually introduced new devices**

…but being on a roll rarely lasts…

- 2018: Microvention introduces its competing "**Sofia"** device, described as a "**game changer**".
- **Sofia is considered vastly superior** to Penumbra's original Jet 7 due to better **flexibility** and **trackability**, allowing faster surgeries.
- Sofia, and products from Medtronic, Stryker, Boston Scientific started **eroding Penumbra's market share**.

MicroVention TERUMO

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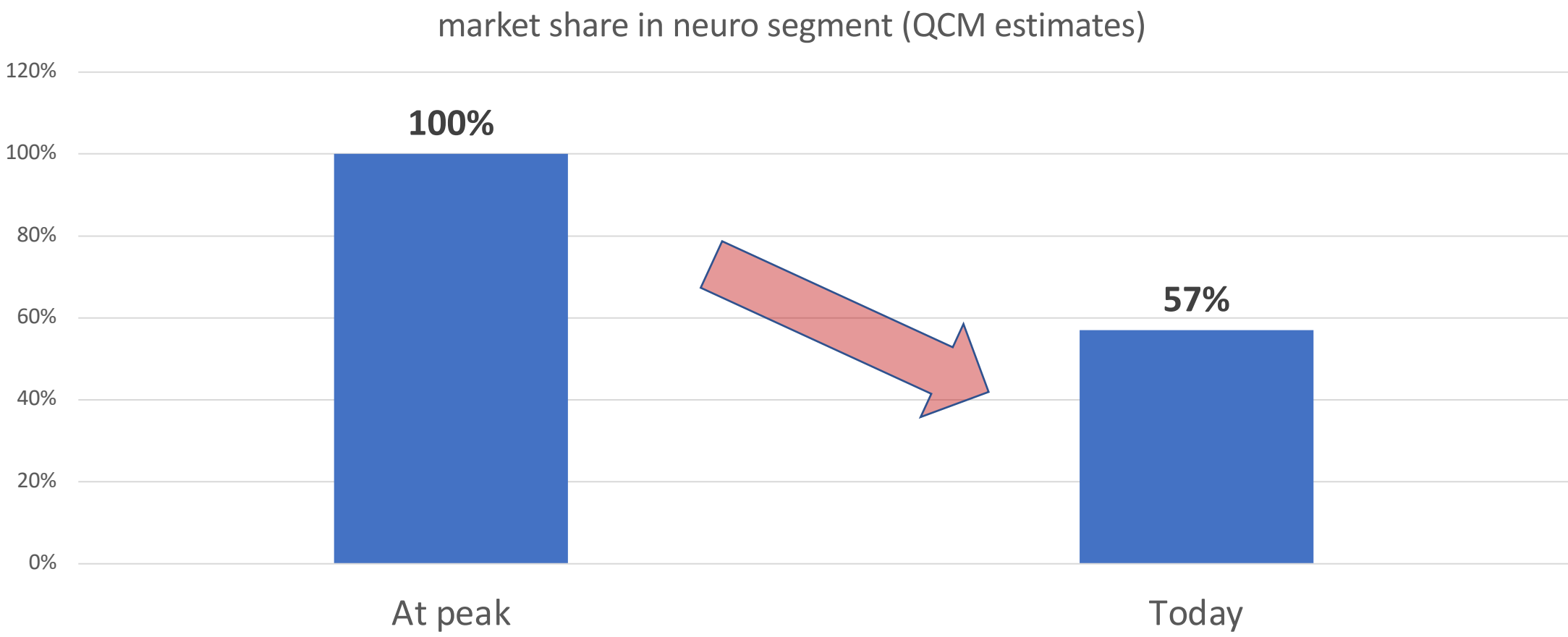
…Penumbra has been losing market shares from larger peers in neuro



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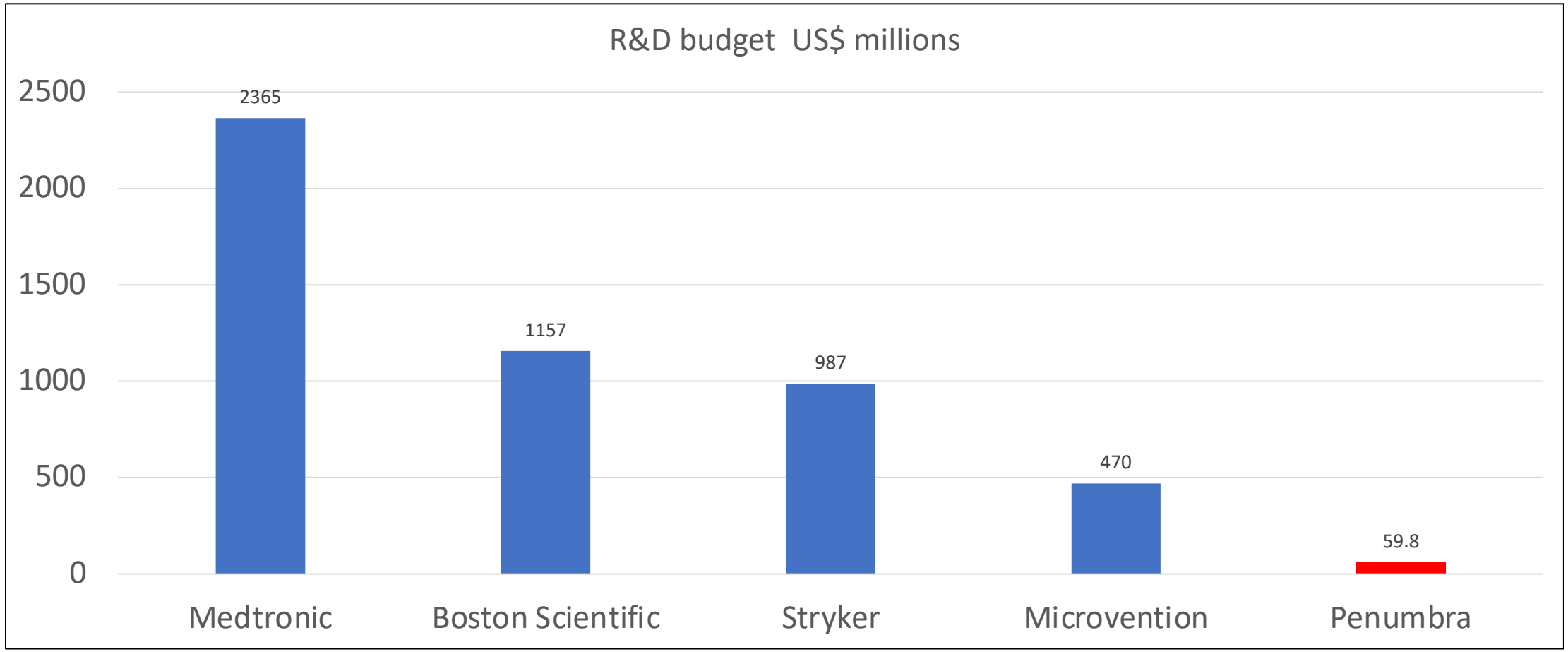
Penumbra's small R&D budget is dwarfed by competitors



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…competitive threats led the Company to launch the **Jet 7 Xtra Flex**

- Launched in July 2019
- New technology makes the device **far more flexible**
- Performance matches Sofia's
- Product approved through FDA 510(k) fast track clearance

TECHNOLOGY | THROMBECTOMY DEVICES | JULY 25, 2019

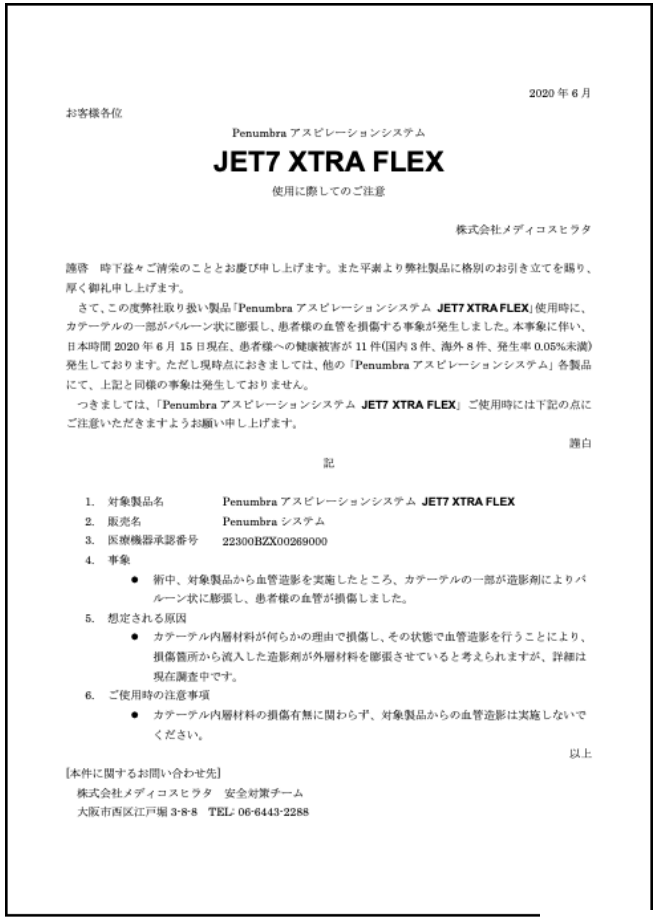
Penumbra Launches Jet 7 Reperfusion Catheter With Xtra Flex Technology in U.S.

Catheter is used with Penumbra Engine in fully integrated Penumbra System for aspiration-based mechanical thrombectomy

The Bad

The Japan letter: trouble from the East…

- June 2020 Hirata, Penombra's distributor in Japan, **warned** hospitals about the new Jet 7 Xtra Flex
- **11 deaths** caused by the Jet 7 malfunctioning in just 11 months
- letter mentions "**catheter expanding like a balloon, damaging the patient's blood vessel**"
- Product subsequently **removed from Japanese market**



2020 年 6 月

お客様各位

Penumbra アスピレーションシステム

JET7 XTRA FLEX

使用に際してのご注意

株式会社メディコスヒラタ

謹啓　時下益々ご清栄のこととお慶び申し上げます。また平素より弊社製品に格別のお引き立てを賜り、厚く御礼申し上げます。

さて、この度弊社取り扱い製品「Penumbra アスピレーションシステム **JET7 XTRA FLEX**」使用時に、カテーテルの一部がバルーン状に膨張し、患者様の血管を損傷する事象が発生しました。本事象に伴い、日本時間 2020 年 6 月 15 日現在、患者様への健康被害が 11 件(国内 3 件、海外 8 件、発生率 0.05%未満)発生しております。ただし現時点におきましては、他の「Penumbra アスピレーションシステム」各製品にて、上記と同様の事象は発生しておりません。

つきましては、「Penumbra アスピレーションシステム **JET7 XTRA FLEX**」ご使用時には下記の点にご注意いただきますようお願い申し上げます。

謹白

記

1. 対象製品名　Penumbra アスピレーションシステム **JET7 XTRA FLEX**
2. 販売名　Penumbra システム
3. 医療機器承認番号　22300BZX00269000
4. 事象
   - 術中、対象製品から血管造影を実施したところ、カテーテルの一部が造影剤によりバルーン状に膨張し、患者様の血管が損傷しました。
5. 想定される原因
   - カテーテル内層材料が何らかの理由で損傷し、その状態で血管造影を行うことにより、損傷箇所から流入した造影剤が外層材料を膨張させていると考えられますが、詳細は現在調査中です。
6. ご使用時の注意事項
   - カテーテル内層材料の損傷有無に関わらず、対象製品からの血管造影は実施しないでください。

以上

[本件に関するお問い合わせ先]
株式会社メディコスヒラタ　安全対策チーム
大阪市西区江戸堀 3-8-8　TEL: 06-6443-2288

[link to the English Google translation of the letter]

What’s going on?

Jet 7 Xtra Flex is **malfunctioning**

- Penumbra **altered** the design of the original Jet 7 device to better compete with its peers
- Modifications presumably **increased flexibility at the expense of structural integrity** of the device
- Device seems prone to malfunction, at times with **catastrophic consequences**

The “deadly balloon”

- During the thrombectomy, doctors occasionally ***inject contrast medium*** *inside the Jet 7* catheter to monitor blood flow
- At times, the injection causes the catheter to fail**, expanding like a balloon inside a brain artery**
- The expansion to several times the diameter of the artery, **ruptures the blood vessel** and causes massive hemorrhage and **death**

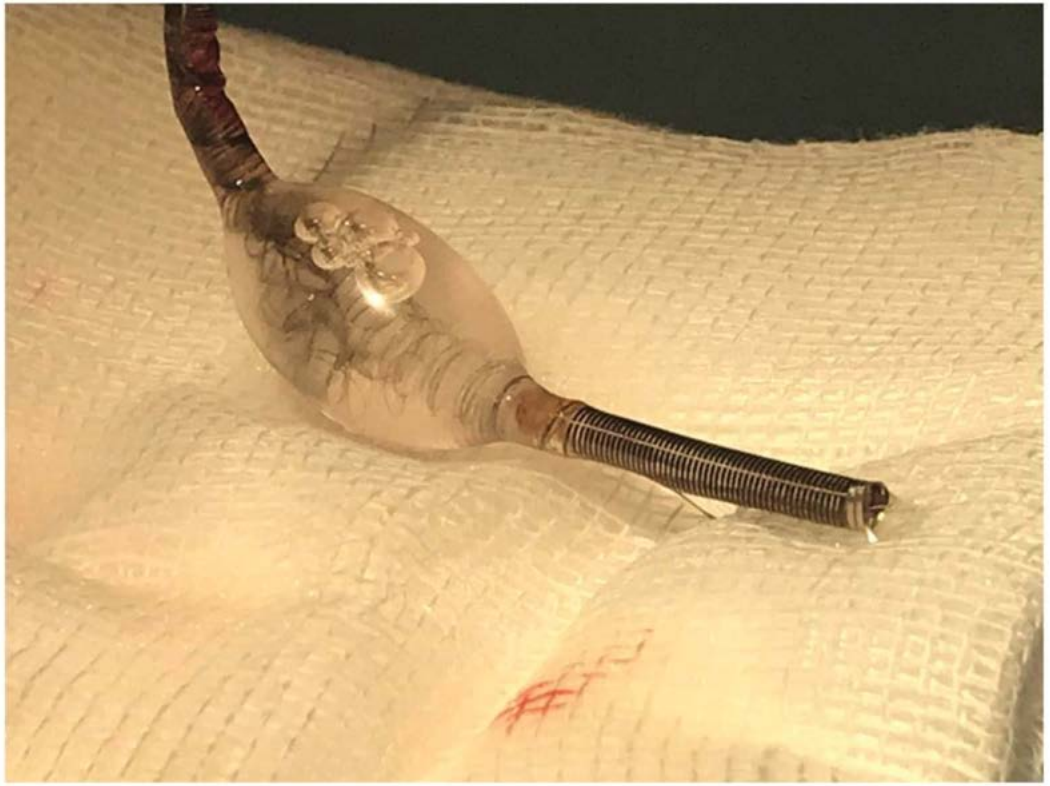
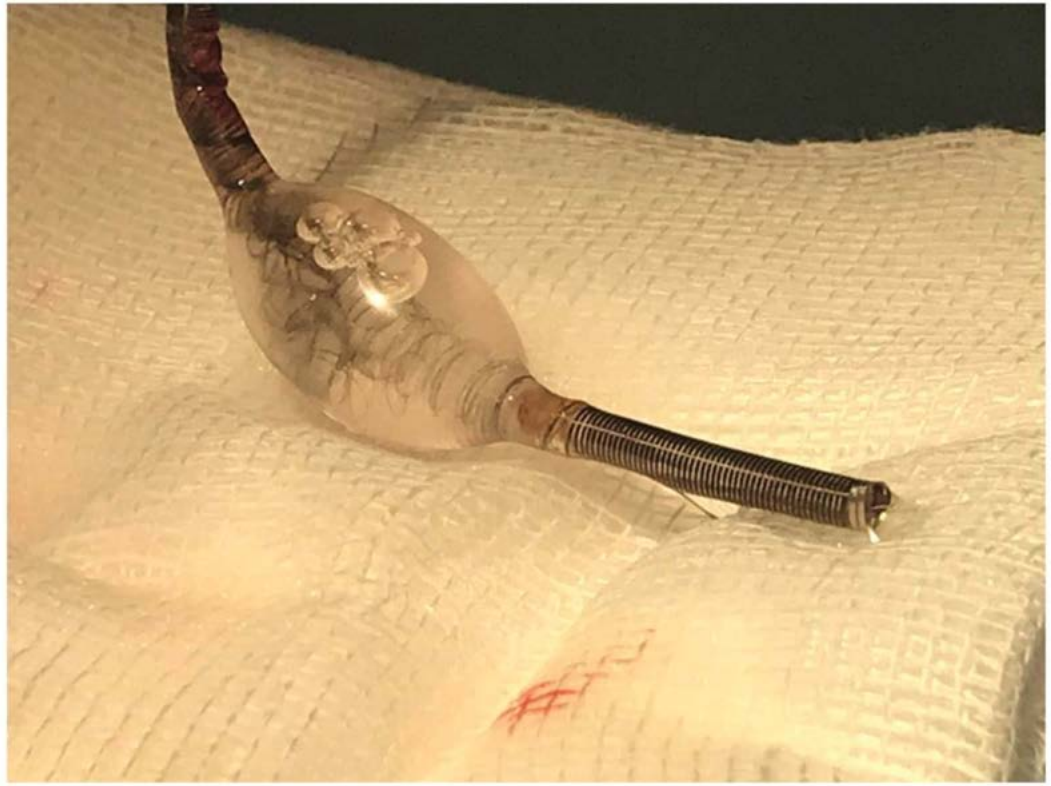
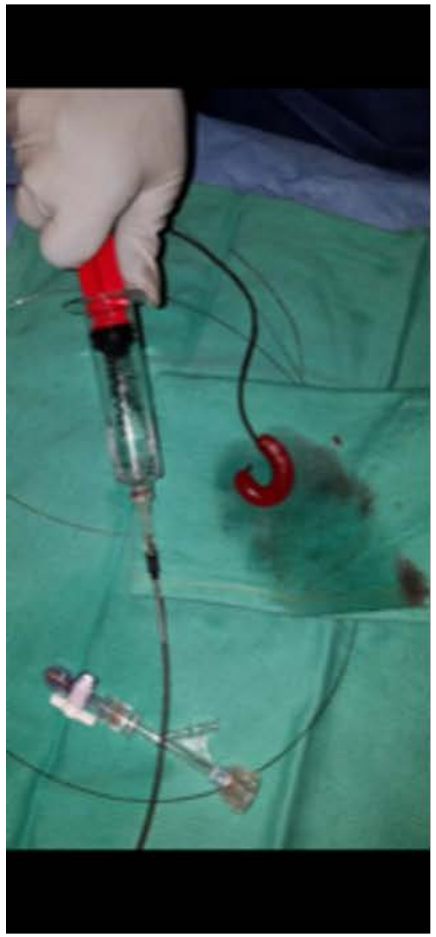


Photo and artist’s rendition of a ballooning Jet 7 rupturing an artery



Jet 7 catheter “inflating like a balloon” [real photographs from clinical settings]



When balloons kill…

- FDA Maude database lists **18 records of death*** associated with a Jet 7 device malfunction since launch in July 2019
- Most accidents involve the “ballooning” of the catheter causing the rupture of brain arteries.

LINK to the Maude database

*Based on the entries we reviewed, three entries might be duplicates. 3 additional deaths occurred in Japan and do not show up on the Maude

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A typical Jet 7 death report (they sadly almost all look alike)

PENUMBRA, INC. PENUMBRA SYSTEM JET7 REPERFUSION CATHETER NRY Back to Search Results

Model Number 5MAXJET7KIT-B
Device Problem Adverse Event Without Identified Device or Use Problem (2993)
Patient Problems Death (1802); Rupture (2208)
Event Date 07/03/2020
Event Type Death
Manufacturer Narrative

The product was not returned for evaluation. Without the return of the device, the root cause of the problem cannot be determined. Potential adverse events in the labeling with the penumbra system include, but are not limited to, hematoma or hemorrhage at the site, inability to completely remove thrombus, intracranial hemorrhage, distal embolization, neurological deficits including stroke, including death. Therefore, it was determined that the reported adverse events were anticipated complicatio

During the procedure, the physician injected contrast through the jet7 and the artery ruptured. Subsequently, the patient expired.

Event Description

The patient was undergoing a thrombectomy procedure in the m1 segment of the middle cerebral artery (mca) using a penumbra system jet 7 reperfusion catheter (jet7), a non-penumbra stent retriever, a microcatheter, and a guidewire. During the procedure, the physician injected contrast through the jet7 and the artery ruptured. No action was taken to treat the artery rupture and the procedure was ended. Subsequently, the patient expired. It was reported that the patient expired due to the vessel rupture. It was also reported that after inspecting the jet7 after removal, there was no noticeable damage to the jet7.

Search Alerts/Recalls

The breaking distal tip of the Jet 7…

- Notwithstanding contrast injections, the device may have **malfunctioned over 200 times** in 16 months*.
- Distal tip of the catheter tends to break and occasionally **detach inside a patient's brain artery**, often causing injuries and requiring complex interventions to retrieve it.
- The breakage occurs almost always in the very same spot, suggesting a **design flaw**

*Source: Maude FDA database. True figures may be higher due to underreporting

…frequently injuring patients..

- **39 injuries*** due to Jet 7 malfunction since launch
- Most injuries involved the breaking of the device's distal tip.

LINK to the Maude database

*a number of entries could be duplicates, however actual number may be higher due to underreporting

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…or malfunctioning

- The Jet 7 device failed in at least 224* instances since July 2019 (launch date of Xtra Flex).
- Again, most cases involved the breaking of the distal tip.

LINK to the Maude database

*a number of entries could be duplicates

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Why is this important?

- Presence of fractures, exposed coils, ballooning suggest a **systematic structural integrity issue** with the Jet 7
- All **surgeons we questioned assume catheters are safe** for hand injection of contrast media. Many (20-50%) do so on a regular basis during a thrombectomy.
- With one possible exception, to our knowledge competing devices have not resulted in any confirmed deaths, far fewer injuries and malfunctions*

The Jet 7 device is **defective** and **unsafe**.

*this statement is based on our analysis of the Maude database, which an imperfect tool. We did find one patient's death associated with a competitors device. However, Upon reading the accident report we are of the opinion that the issue was likely human error rather than a malfunction

Dr. Kurt Yaeger

Neuroendovascular Fellow at Mount Sinai, New York

"We were withdrawing the [Jet 7] catheter from the body and the ***catheter literally just broke*** *with a clot inside of it.*

Same thing happened to another colleague, then happened to me again. To have a catheter break on you like that during a procedure is really devastating.

I don't see how you can morally or medical-legally use this product [Xtra Flex] anymore"

SMOKING GUNS!

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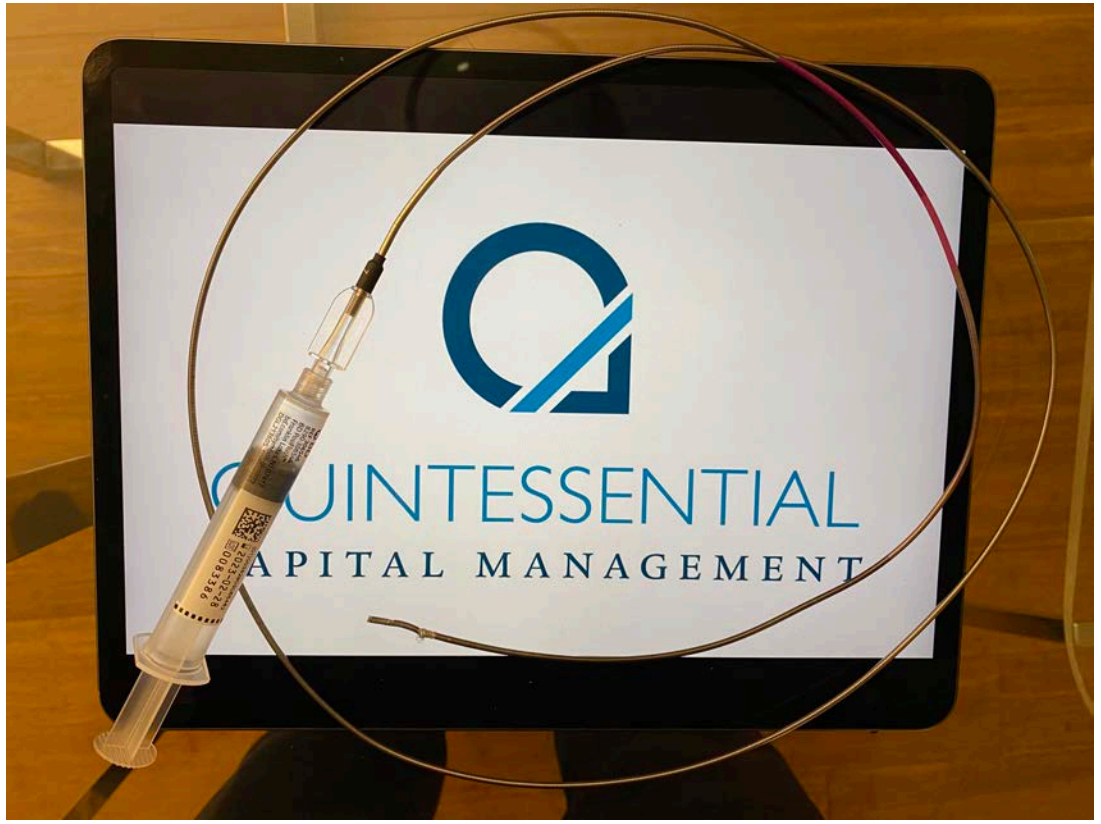
We observed a Jet 7 failure with our own eyes

- Quintessential has obtained a functioning Jet 7 device
- Through an affiliate, we informally tested the device injecting saline solution
- As expected, the device broke and inflated like a balloon with minimal pressure
- The event that we captured in a video, would have injured or killed the patient had it happened inside the body.



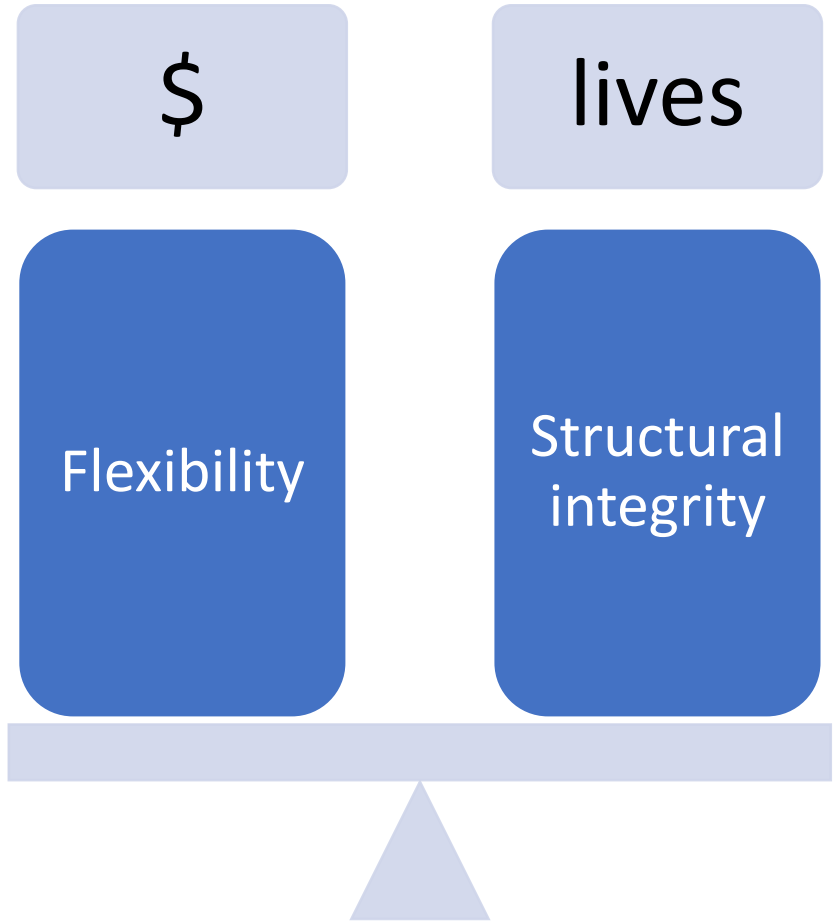
A Jet 7 Flex device in the hands of Quintessential Capital Management

How could this happen?

Can greed trump common sense and ethics?

In our opinion:

- Penumbra **rushed** to modify its Jet 7 device to face its rivals.
- Flexibility achieved **at the expense of structural integrity**.
- **Insufficient testing** of new device
- **Dangerous** device put on the market



Inadequate testing?

- Jet 7 device **pressure tested at 45 psi** for 30 seconds (this meets FDA requirements)
- **10cc syringe** used to inject contrast media into a catheter routinely **exceeds 80 psi**
- Jet 7 not tested for real world use

➢Contrast media injection may cause Jet 7 catheter to fail

- Competing Sofia catheter has been pressure tested at 300 psi!

Pressure generated by a syringe for contrast injection exceed the Jet 7 test limit!

Attribute	Specificat
Particulate testing	≥ 10 µm will be ≤ 6000 particles
	≥ 25 µm will be ≤ 600 particles
	≥ 75 µm will be measured for informat
	≥ 125 µm will be measured for inform
Coating Integrity	Coating has not delaminated, peeled, o simulated use particulate testing
Markerband Visibility	The markerband is fluoroscopically vis
Hub Air Aspiration	No leaks detected when vacuum is pul
Pressure Test	45 psi for 30 sec minimum
JET 7 / Sheath or 8F Guide Catheter Friction Force	Maximum value per specification
JET 7 / 0.014 in. Guidewire Friction Force	Maximum value per specification
Joint sections bond strength	Minimum value per specification
Markerband Section Bond Strength	Minimum value per specification
Hub to Shaft Bond Strength	Minimum value per specification

Excerpt for the Jet 7 FDA clearance application

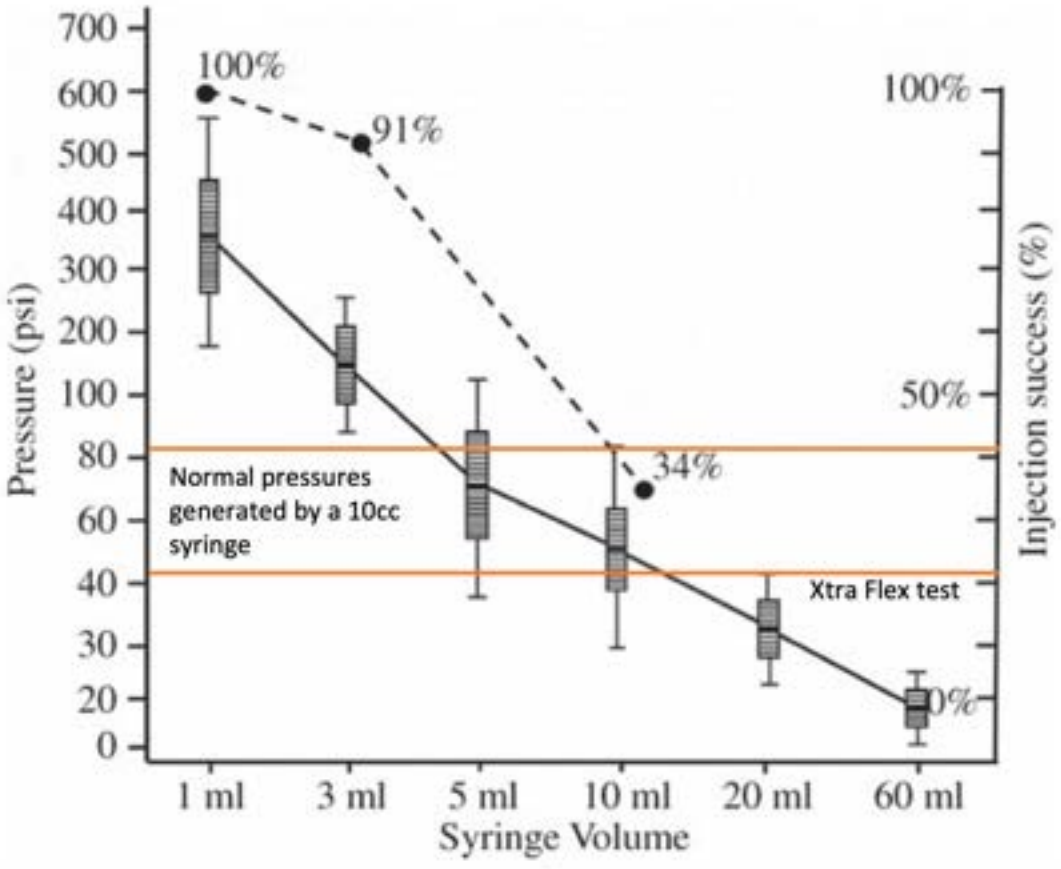


Chart shows pressure generated by syringes of different volumes. The 10cc syringe used for contrast injection exceed the test threshold for the Jet 7

The Ugly

July 27th notice to healthcare providers

- Over one month after the “Japan letter”, Penumbra warned doctors to exercise caution with the new device.
- The letter warned doctors not to inject contrast media into the Jet 7 aspiration catheter, mentioned only risk of death/injury

Penumbra

Notification to Healthcare Providers

July 27, 2020

Dear Healthcare Provider:

Penumbra has received reports of Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology (JET 7 Xtra Flex) distal tip expansion or rupture when used during injection of contrast media. JET 7 Xtra Flex may become susceptible to expansion or rupture during contrast injection due to distal tip weakening from manipulation against resistance or use with other manufacturers' revascularization devices. Distal tip expansion or rupture may cause vessel damage and subsequent patient injury or death.

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. The use of JET 7 Xtra Flex with other manufacturers' revascularization devices is not an authorized use per the Instructions for Use. JET 7 Xtra Flex has not been tested for compatibility with other manufacturers' revascularization devices.

In response to these reports, Penumbra is notifying healthcare providers of a labeling update to include the following WARNING, PRECAUTIONS and REVISIONS in the Instructions for Use:

Warning: Do not inject contrast media through the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology using a syringe or automated high-pressure contrast injection equipment. Injecting contrast media through the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology may cause the distal tip of the catheter to expand or rupture, resulting in potential vessel damage and subsequent patient injury or death. When injecting contrast media for angiography, always inject through the guide catheter.

Precaution: The Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology has not been tested for compatibility with other manufacturers' revascularization devices. The safety and effectiveness of combined use is unknown and could result in damage to the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology.

Precaution: Use caution and slowly flush heparinized saline. If you see expansion of the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology, immediately discontinue use of the catheter.

Revision: Obtain a post-treatment angiogram by injecting contrast media through the guide catheter. Remove the Reperfusion Catheter from the guide catheter if necessary for adequate visualization.

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…late communication

- Penumbra issued a notice on July 27th:
  - 12 months after launch of Jet 7
  - 9 months after the first patient was killed.
  - 5 weeks after the warning by the Japanese distributor

- By then:
  - Some 15 people had already died in the US and 3 in Japan*
  - Many more injured

Penumbra's delay to issue a warning may have resulted in avoidable deaths and injuries

* Figures based on our understanding of the Maude database.

…incomplete and ineffective

Japan letter (by 3rd party)

- **Explicitly** mentions number of deaths occurred
- Describes **in detail** how the device likely failed
- Resulted in taking the **device off the market**

US letter (by Penumbra)

- Mentions only a risk of death (not actual deaths occurred)
- May have **failed to reach all surgeons** and failed to emphasize the gravity of the issue
- Was **dismissed by many surgeons** as unimportant communication

Expert opinion: Dr. Tareq Kass-Hout

Medical Director of Neurosciences Inpatient Operations and Director of the Neuroendovascular Service at UChicago Medicine

"We did not see the notification letter, that's the problem! I heard about it from a journalist"

"None of my colleagues anywhere that I know […]in the Chicago area knew about it"

"Spoke with at least 5 physicians in 5 different hospitals and none of them had any idea about this"

Dr. Kurt Yaeger on Penumbra's ineffective communication

*"**It doesn't seem to be effectively communicated by Penumbra**. People sort of heard of the deaths in the field and so some of that information has been kind of percolating through as a result […]*

*I don't know exactly what they're doing, but it seems to me that what they're doing is **trying to sort of keep this […] quiet** "*

Misleading?

- Penumbra's notice seemed to **blame doctors** implying that accidents occurred because surgeons did not follow the correct instructions and warnings.
- In fact, **Penumbra seems to have changed the instructions** upon issuing the notice.
- In the original Jet 7 instructions seen by QCM, **there was NO warning against hand injecting contrast media**.
- A warning did exist against using high-pressured, automated, machine injections (implying that hand injections are okay]

Penumbra claims it warned doctors not to inject contrast into the aspiration catheter…

Notification to Healthcare Providers

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CEO doubles down on this statement in a call with investors…

“As soon as we did our evaluation […] 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.”

Adam Elsesser, CEO Pemumbra

In fact: we found NO WARNING!

- **Company refused to hand out a copy of the Jet 7 IFU (competitors did so without problem with their own IFU)**
- **The original IFU we examined did not warn doctors against hand-injecting contrast**
- **Original IFU warned only against high-pressure machine injection (implying that hand injection is allowed)**

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Proof 1: we obtained copies of original paper IFUs from various neuroradiologists

A photograph of the original paper IFU next to the Jet 7 packaging

IFU contains **no warning against contrast injection by hand!**

Penumbra Aspiration Pump

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

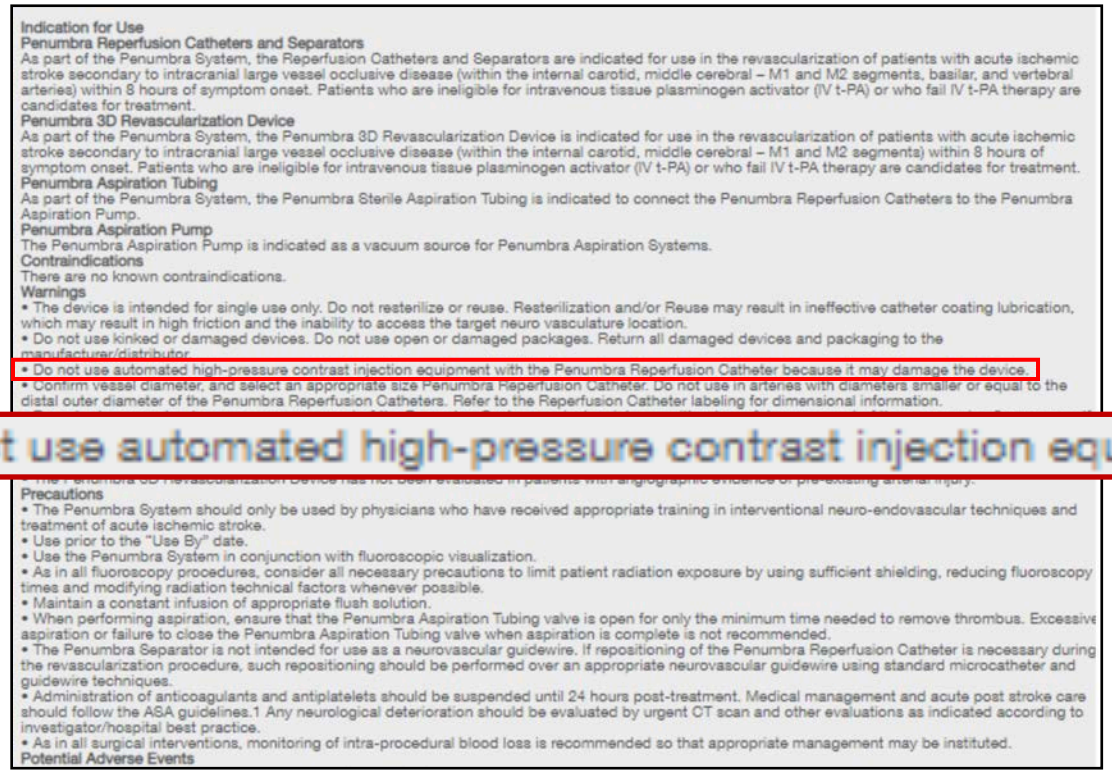
CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.

Proof 2: copy of original online IFU



Indication for Use
Penumbra Reperfusion Catheters and Separators
As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Penumbra 3D Revascularization Device
As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Penumbra Aspiration Tubing
As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.
Penumbra Aspiration Pump
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.
Contraindications
There are no known contraindications.
Warnings
• The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
• Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
• Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
• Confirm vessel diameter, and select an appropriate size Penumbra Reperfusion Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Penumbra Reperfusion Catheters. Refer to the Reperfusion Catheter labeling for dimensional information.

• Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter

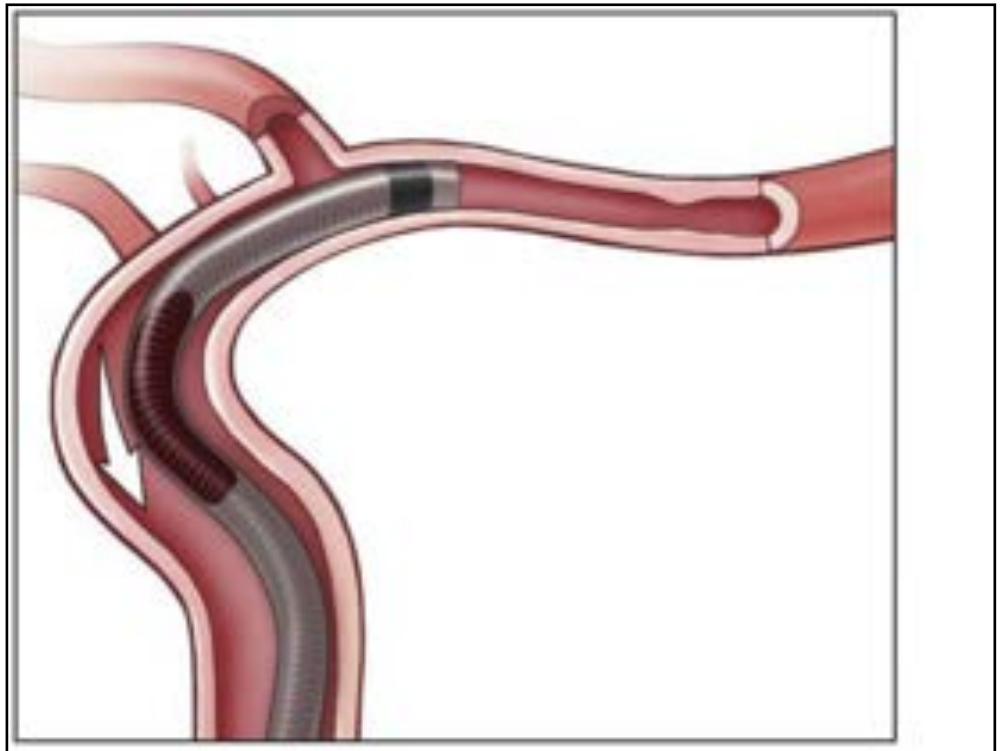
Precautions
• The Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
• Use prior to the "Use By" date.
• Use the Penumbra System in conjunction with fluoroscopic visualization.
• As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible.
• Maintain a constant infusion of appropriate flush solution.
• When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended.
• The Penumbra Separator is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques.
• Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.1 Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
• As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
Potential Adverse Events

- We obtained prior online version of IFU using the “wayback machine”*
- Wording on old IFU does not include hand injection of contrast media and only mentions high-pressure.
- Penumbra seems to have changed the Jet 7 online instructions and warned for hand-injection **after** the accidents took place

* The Wayback Machine is an internet tool that allows the user to retrieve old, deleted pages from the web

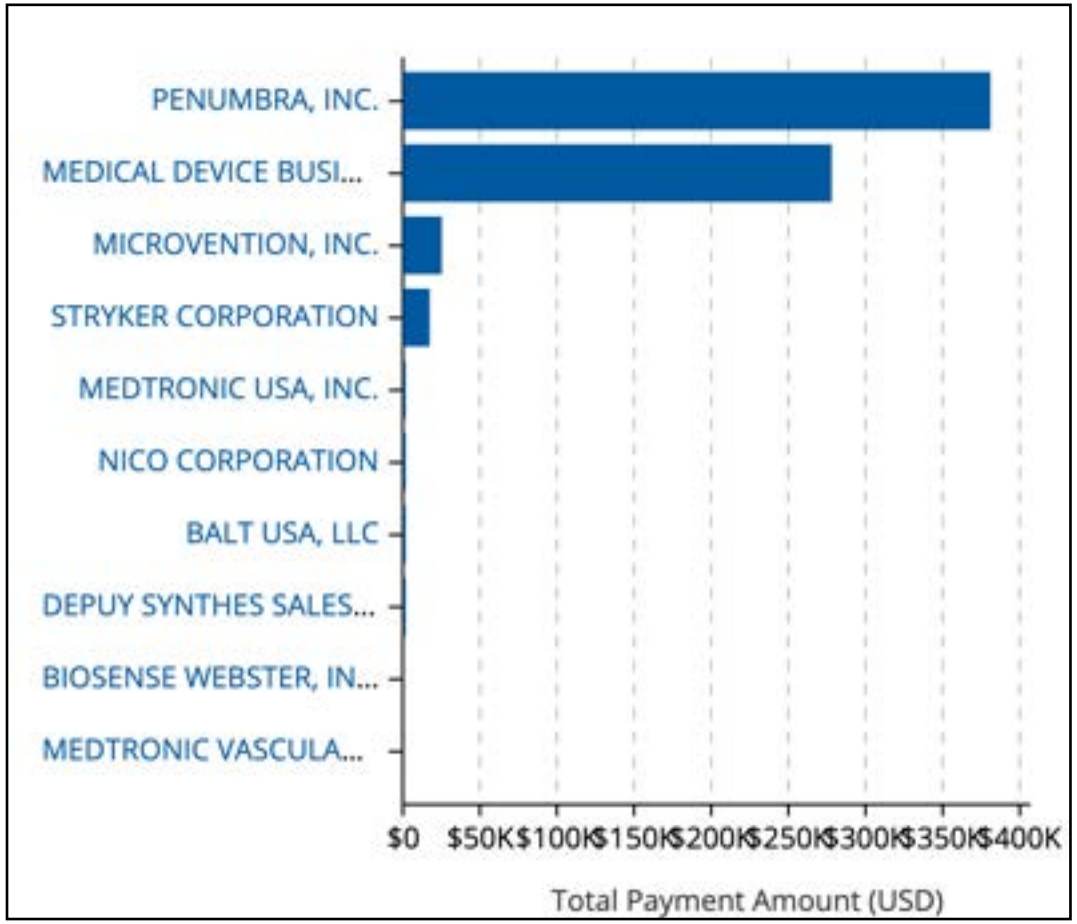
Proof 3: journal articles

- In April 2020 a study was released by **Dr. Spiotta**: *"Reflections on Direct Aspiration Thrombectomy"*
- study mentions the "**ADAPT**" procedure for aspiration thrombectomy
- Study **explicitly mentions possibility of injecting *directly into the aspiration catheter***
- Doctor Spiotta works on a regular basis as a consultant for Penumbra and is a known evangelist for its products.



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.

Penumbra-affiliated doctor Spiotta promotes injecting contrast into aspiration catheter!



Link to Dr. Spiotta payments summary

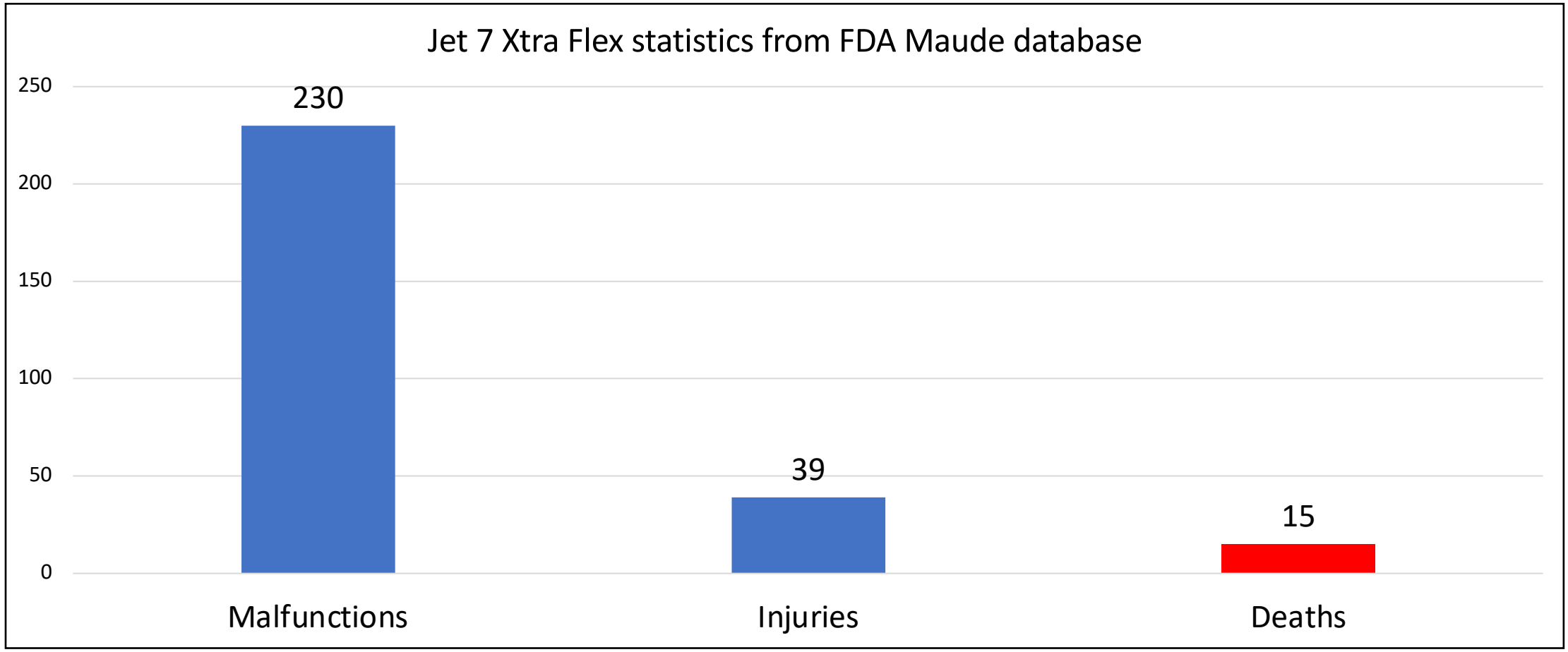
QUINTESSENTIAL CAPITAL MANAGEMENT

Dr. Tareq Kass-Hout

"they [Penumbra] are trying to blame it on the contrast which does not make any sense, because ***we use contrast ALWAYS through any catheter, it's very common to use it through the aspiration catheter*** *[…] You can't give me a catheter and tell me you can't use contrast with it,* ***they're designed for that****."*

Why we believe this device should be taken off the market

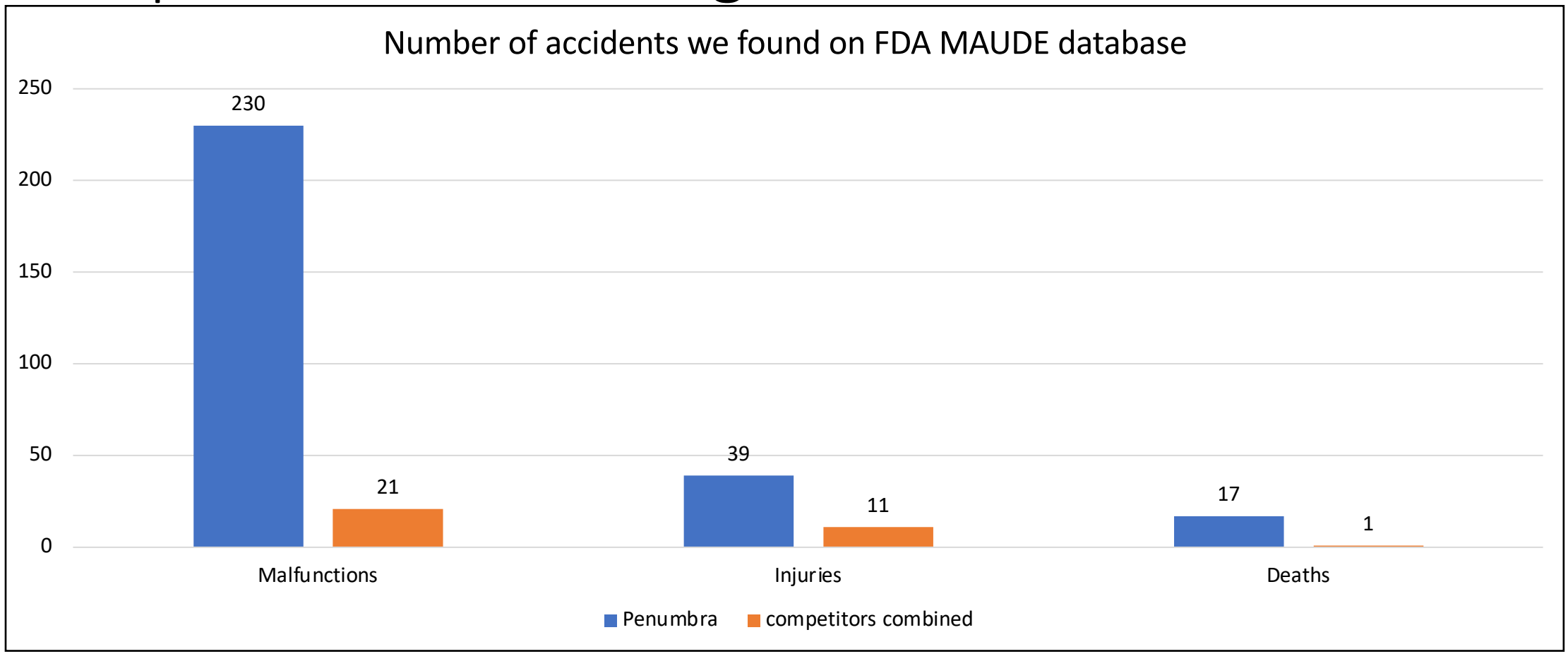
Very high absolute number number of avoidable deaths, injuries and malfunctions



*figures for death are corrected for likely duplicates, but excludes deaths occurred in Japan

QUINTESSENTIAL CAPITAL MANAGEMENT

A first look at the Maude database may suggest that Jet 7 accidents may be over-represented vs comps even considering market shares



QCM **very rough estimates** using notoriously imprecise MAUDE FDA database and our market shares estimates.
*we found a single death associated with a competitor, but based on the accident narrative, the event looked to us more like a procedural issue than a malfunction

QUINTESSENTIAL CAPITAL MANAGEMENT

Malfunctions, injuries persist despite July 27th notice

- 48 new Jet 7 malfunctions, 1 or injury appeared in the FDA database since Penumbra's notice to doctors in late July
- Luckily no new recorded deaths
- Most malfunctions still involve breaking of distal tip or ballooning

QUINTESSENTIAL CAPITAL MANAGEMENT

Recorded deaths are only tip of the iceberg? We think so

- Misattribution to other causes
- Misattribution to other devices
- Reporting bias
- Delays in data entry
- Guidant precedent (10x underreporting)

➢**Actual number of victims may be higher**

Doctor at Radiology and Neurosurgery at Stanford

"Rupturing of the vessel is a known complication that many doctors might not recognize as being caused by the device. Due to misattribution and reporting bias, ***actual numbers might be much larger****"*

QUINTESSENTIAL CAPITAL MANAGEMENT

Doctor at Radiology and Neurosurgery at Stanford

“I am surprised that the product is not recalled. This is clearly a design problem. ”

“Weak structural integrity means device likely to fail in other circumstances (e.g. with other devices, heavy use, etc.)”

Prior catheter recalls happened despite far fewer injuries, no deaths vs Jet 7!

RECALLED CATHETERS ALL APPROVED THROUGH FDA 510(K) CLEARANCE PROTOCOL

June 20, 2017, 10:30AM. By **Gordon Gibb**

Washington, DC – Various reports of **defective catheters causing injury** have also been associated with product recalls initiated by respective manufacturers and supported by the US Food and Drug Administration (FDA).

Three recalls that have been the focus of frequent reports involve the Fetch 2 Aspiration Catheter, manufactured by Boston Scientific, and catheters featuring the Beacon tip made by Cook Inc., a manufacturer also known as Cook Medical. The three recalls combined, involve in excess of a half-million catheters.

The Cook Medical recall is the larger of the three, with no fewer than 451,550 catheters affected, according to the official FDA online listing for the recall that was originally initiated by the manufacturer on July 2, 2015. A little more than a month later, the FDA issued a Class 1 recall of the Beacon Tip Torcon NB Advantage Catheter on August 5, 2015.

The recall, on a webpage that was most recently updated three days ago on June 16, 2017 retains a classification as 'open' as not all recalled catheters have been accounted for. "Not all products have been corrected or removed," the FDA says.

The Shuttle Select Slip Catheter, also manufactured by Cook Medical, was recalled April 15 of last year. It's also an open recall, with not all of the 60,302 catheters accounted for.

Both recalls involve reports of catheter tips splitting, or separating from the catheter. The concern remains the potential for defective catheters causing injury.

The Boston Scientific recall involves 21,155 units of its Fetch 2 Aspiration Catheter. Boston Scientific issued the recall March 22 of last year with the FDA following up with a Class 1 Device Recall a little less than a month later, on April 18, 2016.

- Catheters approved through 510k clearance are frequently recalled
- Fetch 2 (Boston Scientific)
- Shuttle Select (Cook Medical)
- Both devices recalled after only 13 and 4 injuries respectively

FDA rules are clear: dangerous medical devices are subject to recall

"If […] FDA finds that there is a ***reasonable probability that a device intended for human use would cause serious, adverse health consequences or death****, the FDA may issue a cease distribution"*

Mandatory Device Recalls - 21 CFR 810

Medical device recalls are usually conducted voluntarily by the manufacturer under 21 CFR 7. In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer under 21 CFR 810, Medical Device Recall Authority. 21 CFR 810 describes the procedures the FDA will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act (Act).

If, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the FDA may issue a cease distribution and notification order requiring the person named in the order to immediately:

- cease distribution of the device;

FDA

QUINTESSENTIAL CAPITAL MANAGEMENT

SMOKING GUNS!

Formal expert opinion

QCM has received a formal assessment on the Jet 7 regulatory situation and its likely developments

Steven S. Brooks, MD MBA FACC

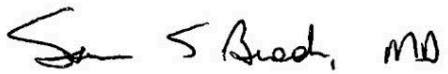
- Interventional Cardiologist University of Maryland 2003-2005, Private Practice 2005-2007
- FDA Medical Officer, Office of Device Evaluation (ODE), Division of Cardiovascular Devices (DCD), Peripheral Interventional Devices Branch (PIDB) 2007-2014
- VP Regulatory Affairs & Health Economics Ablative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

Steven Brooks MD: formal opinion

- 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

Steven Brooks MD: conclusion

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

Quotes by industry experts

Former FDA (consultant): **“I think they’re screwed!”**

“I wouldn’t be surprised if there wasn’t an FDA auditor reviewing all the records at Penumbra”

“it wouldn’t surprise me if they were doing more work AFTER the notification… just because the company put a band aid on it doesn’t mean the agency will accept that…”

Senior Neuroradiologist at major US hospital: "Probability of recall? If everyone was behaving as they should, 100% …"

"unfathomable that they'd leave this on the market…"

"what they're doing is trying to fix this, and will sneak this through for the next 2-3 months and then release a new catheter and pull all of these…"

Meanwhile at Penumbra…

Executive behavior seems to suggest that management if aware of serious problems brewing at the Company

CEO Adam Elsesser increased **selling** Penumbra's shares since the Jet 7 trouble begun…

QUINTESSENTIAL CAPITAL MANAGEMENT

CIO and co-founder Arani Bose **liquidated 50% of his shares** since the trouble begun…

Sofia launch

Xtra Flex launch

Deaths and injuries mount

QUINTESSENTIAL CAPITAL MANAGEMENT

Former CFO and President Sri Kosaraju liquidating his shares

Sofia launch

Xtra Flex launch

Deaths and injuries mount

QUINTESSENTIAL CAPITAL MANAGEMENT

Fleeing a sinking ship? Plenty of resignations at Penumbra

- Sri Kosaraju – former CFO & President at PEN
- 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

Fleeing a sinking ship? Sri Kosaraju

- Promoted to **CFO** and **President** in August 2019
- **Replaced** as CFO (but stayed on as president) in November of 2019
- **Resigned** as president in May 2020
- Joined a non-profit (?!)

Was Sri **spooked** by anything going on at Penumbra as he **left his new CFO position only three months into the role**?

A 5-fold increase in legal job openings. Is Penumbra “lawyering up”?

PREMIUM

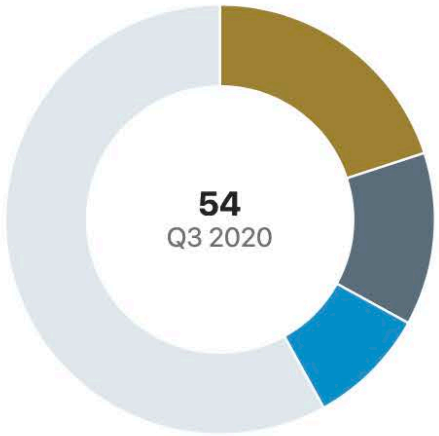
LinkedIn

Total job openings

Based on LinkedIn data. Excludes subsidiaries.

Functions

Functional distribution



Job openings growth	3m	6m	1y
Engineering	▲ 450%	▲ 267%	▲ 450%
Quality Assurance	▲ 250%	▼ 30%	▲ 17%
Legal	▲ 150%	▲ 500%	▲ 500%
Other	▲ 417%	▼ 16%	▼ 16%
Total	▲ 350%	▲ 8%	▲ 20%

QUINTESSENTIAL CAPITAL MANAGEMENT

First cracks in financials?

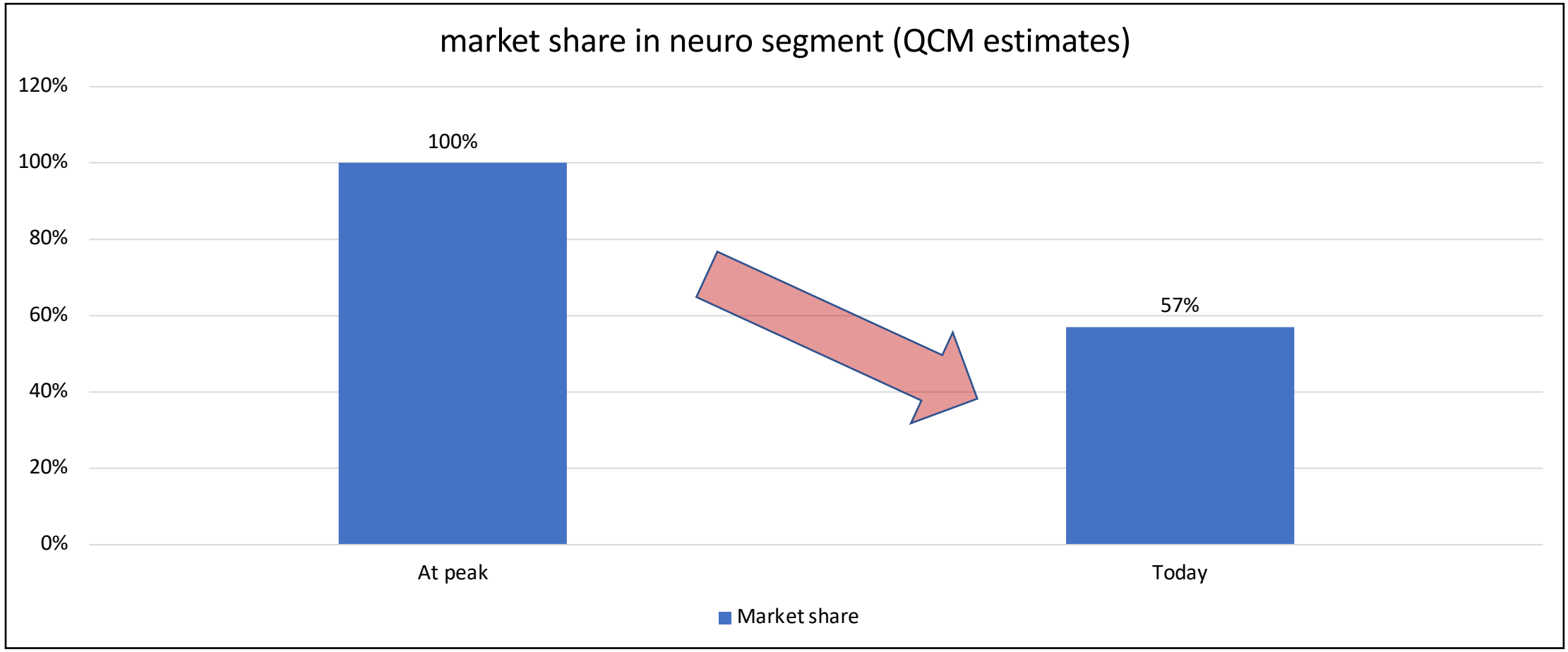
Data obtained from S&P Capital IQ

First major cracks showing in the numbers*

- **Competition**, **quality issues** prominent in PEN's financials.
- **Sharp drop** in **cash-generation**
- Ballooning **working capital**
- Rapid and substantial **gross margin compression**
- **Double-digit** contraction in revenue
- Recent quarter (Q3) was stronger, but led from peripheral division

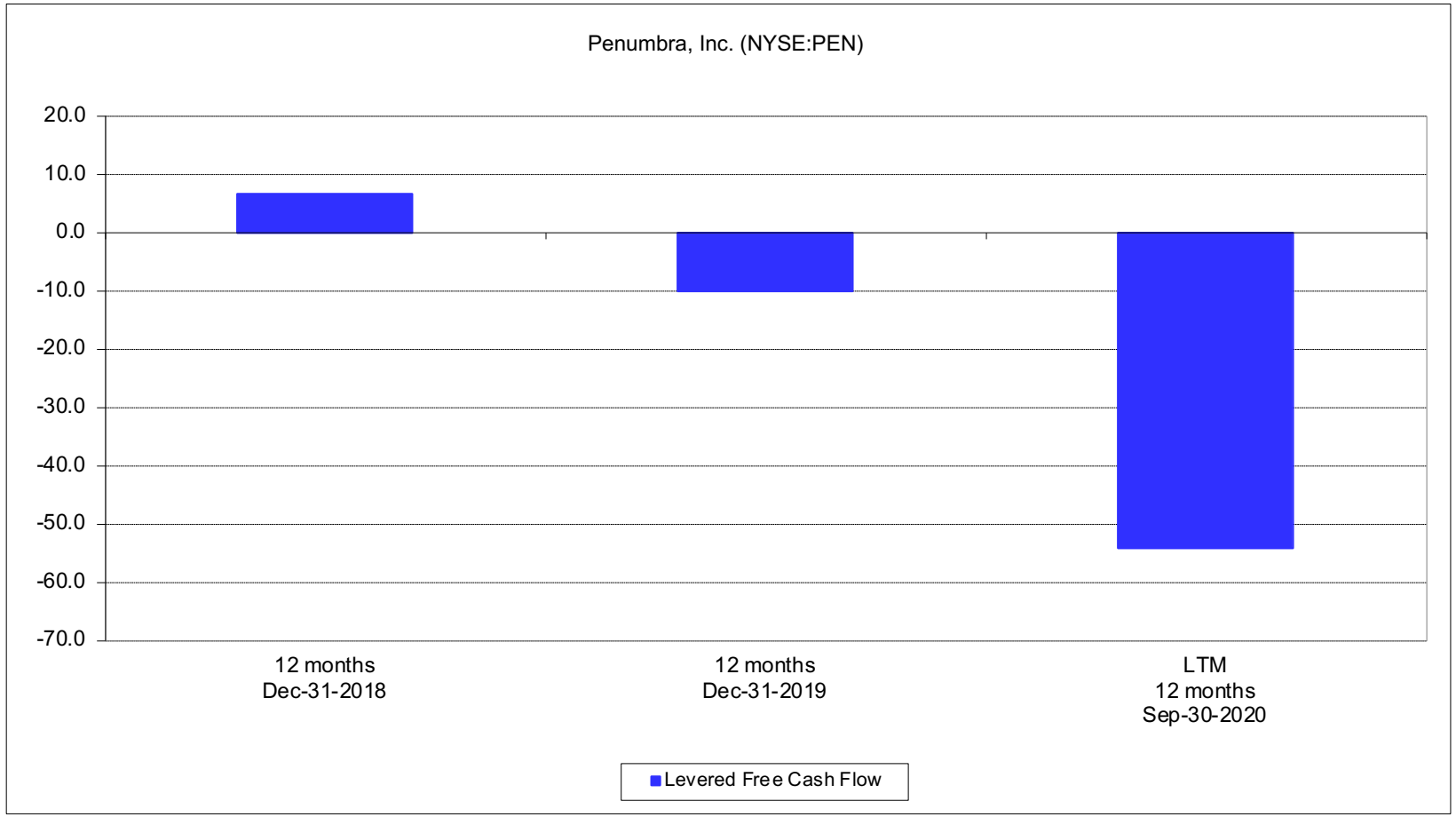
* this report was created prior to Penumbra presenting its latest quarterly report so figures are not reflective of Q3 2020.

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



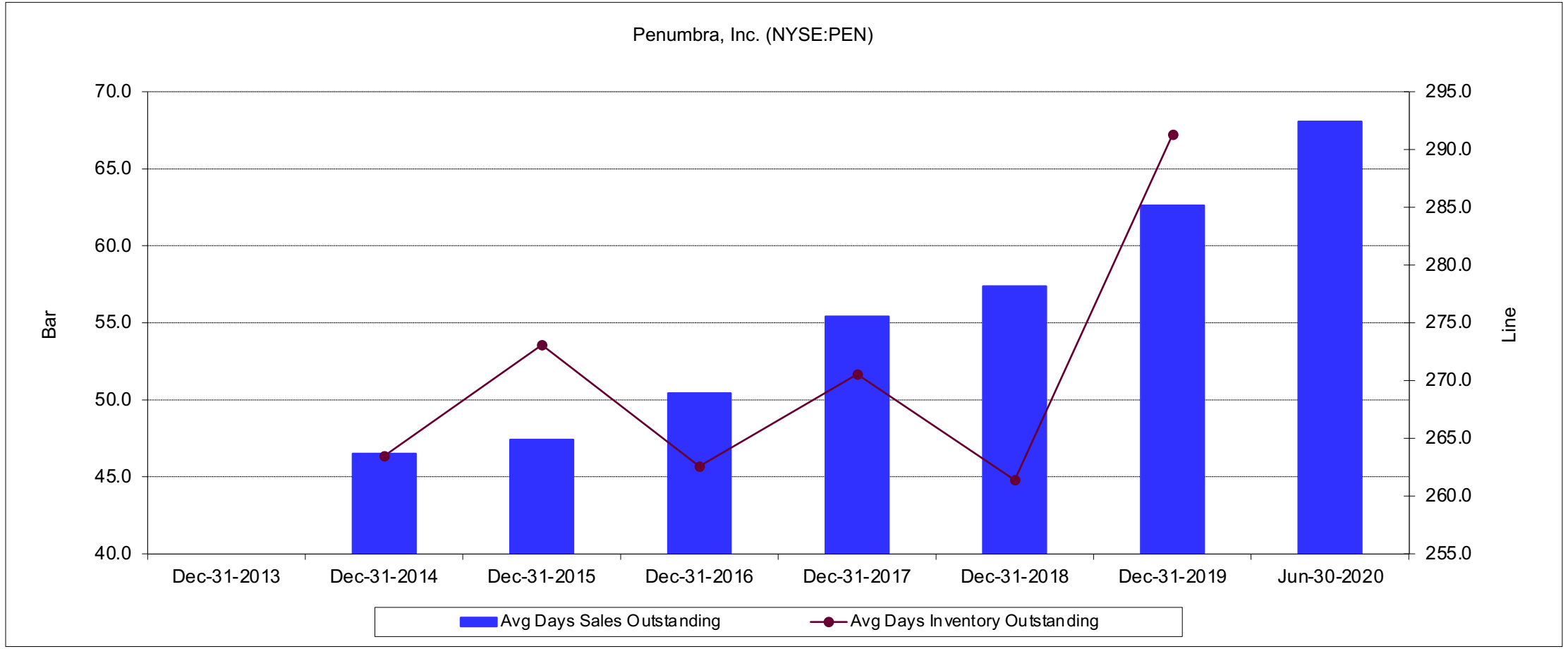
QUINTESSENTIAL CAPITAL MANAGEMENT

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



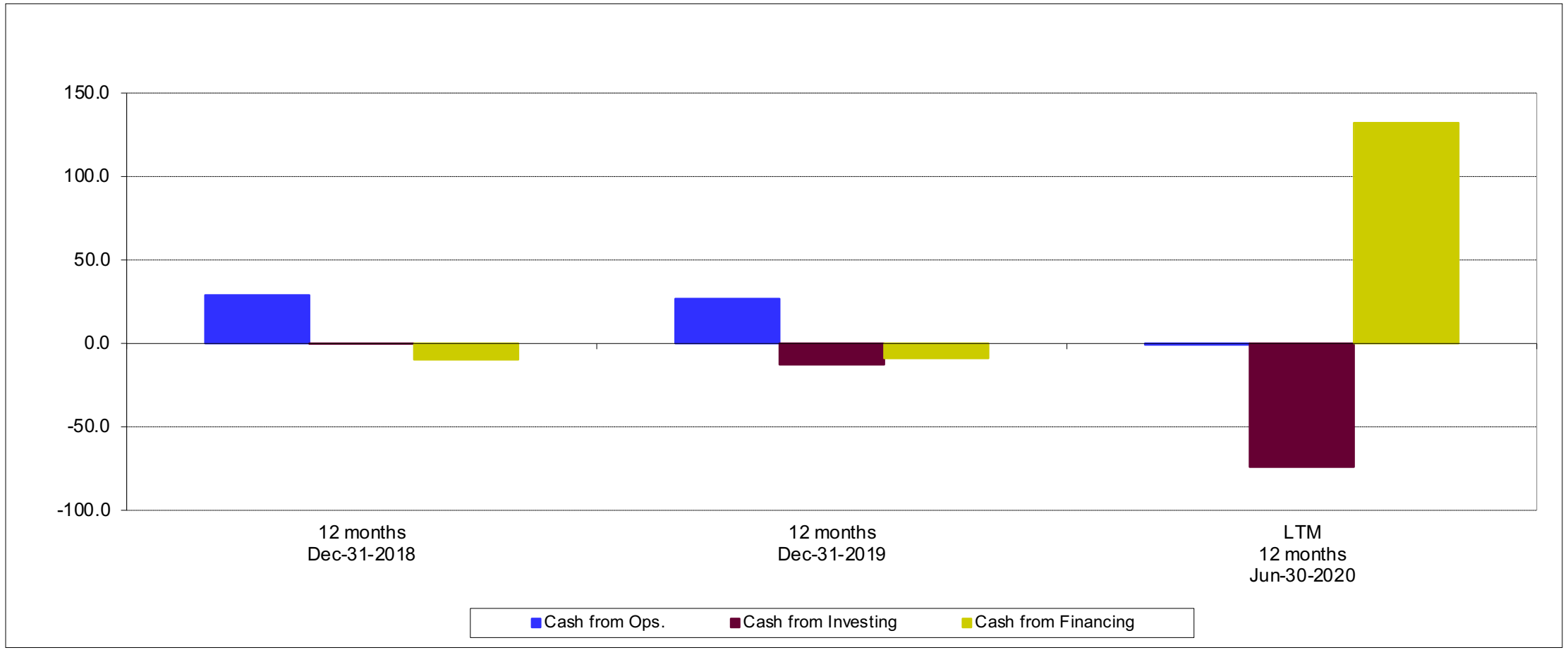
QUINTESSENTIAL CAPITAL MANAGEMENT

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



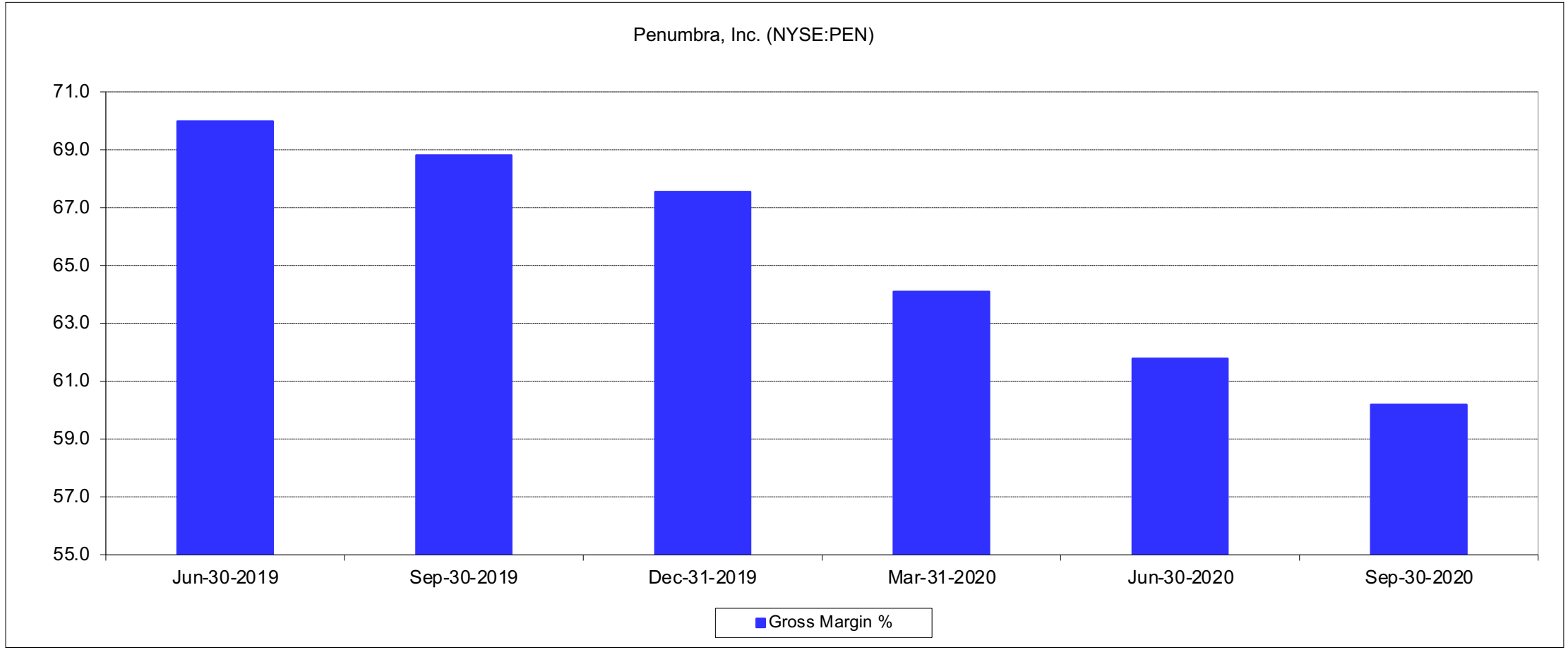
QUINTESSENTIAL CAPITAL MANAGEMENT

Cash shortfall financed by share issues



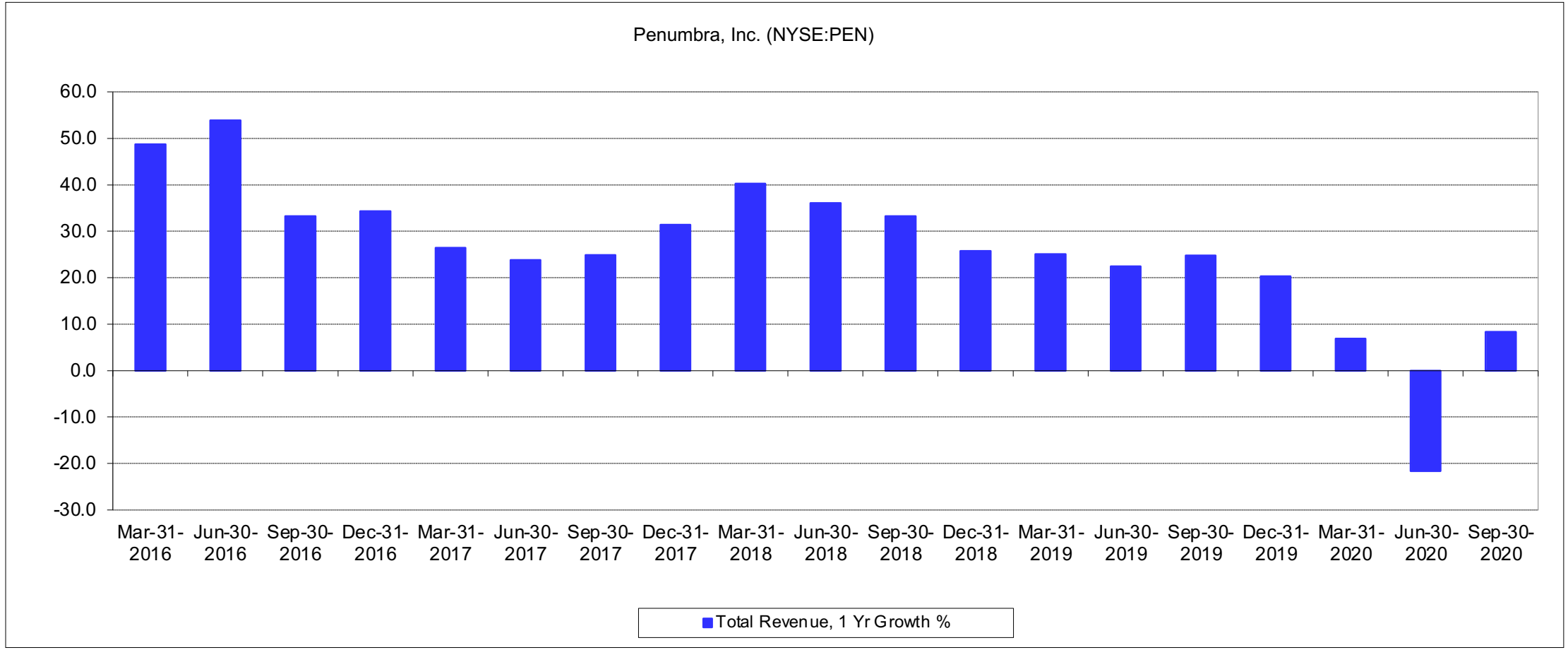
QUINTESSENTIAL CAPITAL MANAGEMENT

Sharp gross margin compression since Jet 7 issues began



QUINTESSENTIAL CAPITAL MANAGEMENT

Revenue growth rate has sharply contracted



QUINTESSENTIAL CAPITAL MANAGEMENT

What happens when the full situation becomes public knowledge?

Jet 7 recall a may be a **near-existential threat** for Penumbra

- Stroke business accounts for some 40% of Penumbra's revenue
- Neuro about 55% and **likely to be severely impacted** by a Jet 7 recall
- Peripheral business is the remaining 45% and will likely suffer from a **damaged brand**
- **Warning signs** may point to **issues with the peripheral division**
- Potentially **most company's business may be under threat**

Indigo system with Lightning: early signs of **trouble in peripheral division?**

- Latest <u>peripheral</u> product added in July.
- Maude: **65 malfunction** records in 3 months.
- Malfunctions seem alike, suggesting another **engineering flaw**.
- Is this issue a further sign of poor design and quality control at Penumbra?

65 records meeting your search criteria returned- **Brand Name:** *lightning*
10/31/2020

New Search

Manufacturer	Brand Name
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12
PENUMBRA, INC.	INDIGO SYSTEM LIGHTNING 12

Researchers are coming out with studies documenting the Jet 7's malfunctions!

American Society of Neuroradiology

Published October 15, 2020 as 10.3174/ajnr.A6804

BRIEF/TECHNICAL REPORT
INTERVENTIONAL

FIG 1. The JET 7 catheter used in the thrombectomy for patient 1 shows ballooning of its distal end with separation of the reinforcing braids from the surrounding polymer.

FIG 2. The damaged distal segment of the JET 7 thrombectomy catheter used in patient 2 has ballooned on flushing.

procedure time was 50 minutes, and the time from ictus to recanalization was 7 hours. A postprocedural CT scan on day 4 did not show any hemorrhagic changes or new infarcts. However, there was no significant clinical improvement in the neurologic deficits at the 3-month follow-up with a modified Rankin Score (mRS) of 4, starting from a baseline of 3.

Incident 2

An 88-year-old woman presented with right M1 MCA occlusion and an NIHSS score of 12. Because she was outside the time window for intravenous thrombolysis, she was directly transferred to the angiosuite for mechanical thrombectomy. With the intention of using the direct aspiration first-pass technique, a JET 7 catheter was advanced over a 3MAX (Penumbra) and Transend 0.014-inch microcatheter-wire assembly, through a 6F Neuron MAX. However, it could not be navigated past the ledge of the ophthalmic artery origin. Hence, the procedure was converted to stent retriever thrombectomy. A 6 × 30 mm Solitaire-2 stent retriever (Medtronic) was deployed across the occlusion and allowed to integrate with the clot for 4 minutes. The Solitaire and the microcatheter were retrieved through the JET 7 with continuous suction using the ENGINE aspiration system. While we withdrew the stent retriever, the JET 7 spontaneously advanced beyond the ophthalmic segment of the ICA and wedged at the right M1–clot interface. Therefore, the operator decided to completely retrieve the Solitaire-microcatheter combination and left the JET 7 catheter in situ. The aspiration was continued for a further 3 minutes during which the aspiration tubing demonstrated slow continuous movement of blood toward the canister before removal of the JET 7. A subsequent angiogram showed TICI 3 reperfusion. When the JET 7 was flushed to check for clots ex vivo, we noted a similar ballooning (Fig 2) of the distal aspect of the catheter as described in case 1.

DISCUSSION

In this report, we have described 2 instances of unforeseen damage to the JET 7 reperfusion catheter encountered during thrombectomy. These procedures were performed by 2 different operators at different institutions. Between the two, the operators have >15 years of experience in neurointervention and have performed >250 thrombectomies using various generations of Penumbra aspiration catheters with stent retrievers. The thrombectomy techniques used in these 2 cases are comparable with the steps described in published literature; the first one was like the stent retriever–assisted vacuum-locked extraction technique, and the conventional Solumbra technique was used in the second case. In the Solumbra technique, a stent retriever is placed across the clot, while a DAC is advanced to the clot face. Subsequently, the stent retriever is pulled back into the DAC, while negative pressure within the aspiration catheter is preserved with pump aspiration or a negative-pressure syringe. Meanwhile, in the stent retriever–assisted vacuum-locked extraction technique, the stent retriever is deployed with its proximal segment within the clot and the distal segment beyond it. Next, the DAC under suction is advanced to the clot face with gentle traction on the stent wire until a wedged position with the proximal end of the stent is achieved. This wedged stent retriever–DAC assembly is pulled out as a single unit with suction applied on the guide catheter.[3] At the time of these incidents, the JET 7 catheter with XTRA FLEX technology had been newly introduced into our practice. The 2 events happened 3 weeks apart. One of authors (G.A.) had used the JET 7 uneventfully with first-pass TICI 3 reperfusion on 3 previous occasions. Similarly, the second operator (J.P.T.) had also used the JET 7 twice for aspiration thrombectomy with good angiographic outcomes and no adverse events.

The exact mechanism of the damage to the catheter in these cases is not clearly understood. Pulling an unsheathed stent through the aspiration catheter could potentially harm its integrity due to the friction between the two. However, in the first case, even this mechanism is not plausible because the stent retriever was pushed out of the distal end of the catheter after removing both the catheter and stent together as a single assembly, ie, without pulling it through the JET 7. We did not encounter similar incidents with use

2 Pearly Ti • 2020 www.ajnr.org

Doctors from Mount Sinai claim are working at additional studies

- Paper analyzing patients deaths in New York and in Maryland using the Jet 7 Flex
- Analysis of cases through the Maude database

Our sources suggest that elite US institutions may already be ceasing to use the device or discouraging it

MAYO CLINIC

Ascension

Mount Sinai Hospital

Stanford HEALTH CARE

Dr. Tareq Kass-Hout: “I stopped using the Jet7”

Medical Director of Neurosciences Inpatient Operations and Director of the Neuroendovascular Service at UChicago Medicine

“I stopped using [the Jet 7] since I read the letter… how about others? At least 3 people he knows said they’d stop using it until we figure out what’s going on… everyone agreed let’s not use it…”

Dr. Kurt Yaeger: “Mt. Sinai moratorium on the Jet 7”

“Mt. Sinai faculty put a moratorium on Xtra Flex and is ***not using it at all****. We shifted to other catheters. So yeah, has a* ***big impact on them as a company*** *and we’re starting to drift away from their devices. This is* ***not just me, whole institution has gone this way****”*

A menacing product-liability class action coming? Yes, in our opinion

- Penumbra may have **substantial liability exposure** for deaths and injuries occurring before their July 27th notice.
- The Xtra Flex catheter has a **demonstrated structural flaw** that resulted in deaths and injuries.
- The original instructions did **not** warn surgeons against using hand injection of contrast media.

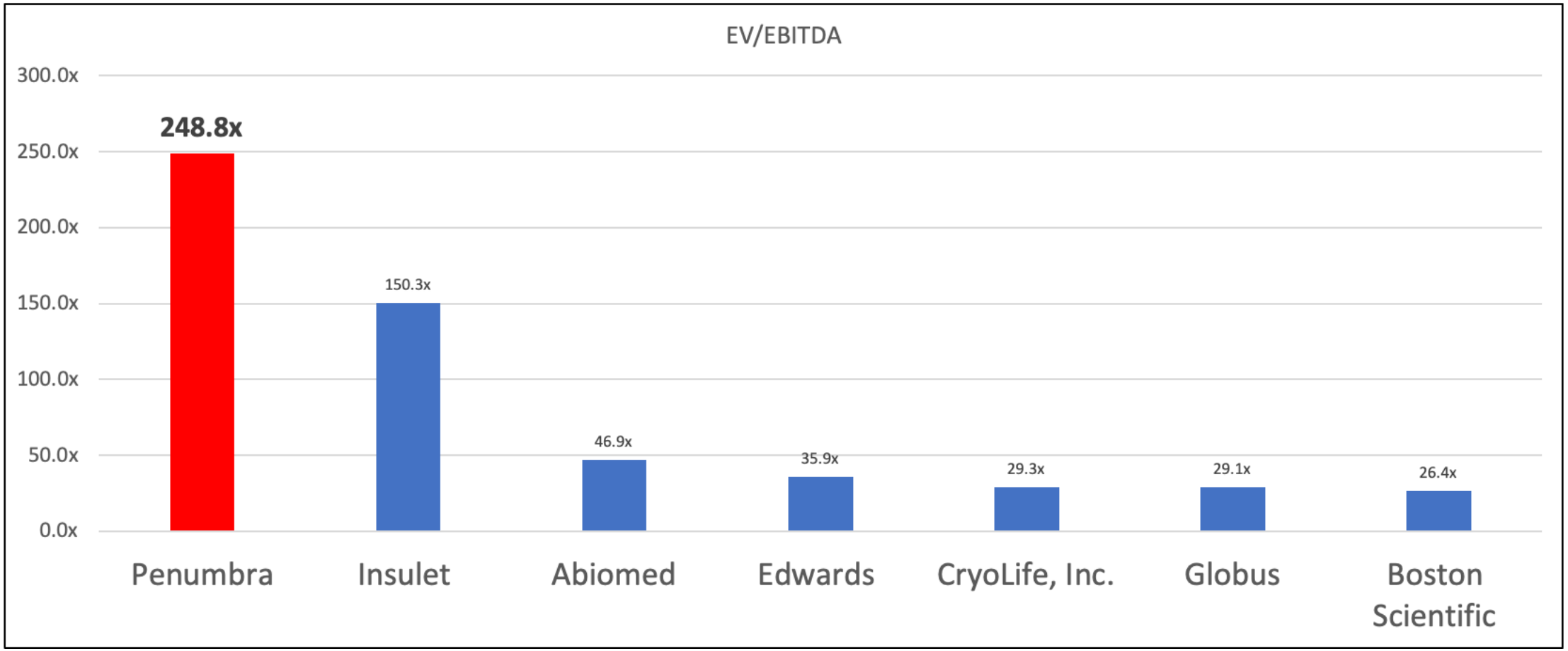
It’s hard to estimate liability exposure, but we think it could be significant…

- # of US Maude documented deaths: 14*
- # of Maude documented injuries: 39
- Damages per death/injury: $2-10m (qcm educated guess)
- Real number of victims could be higher (due to bias, underreporting, misattribution, etc.)

Liability exposure might be of the order of **hundreds of millions US$** or possibly exceeding one billion **if punitive damages apply**

*removed likely duplicates from the count and excluded victims in Japan

Penumbra is **already overvalued** at 16.6x sales and 250x EBITDA!



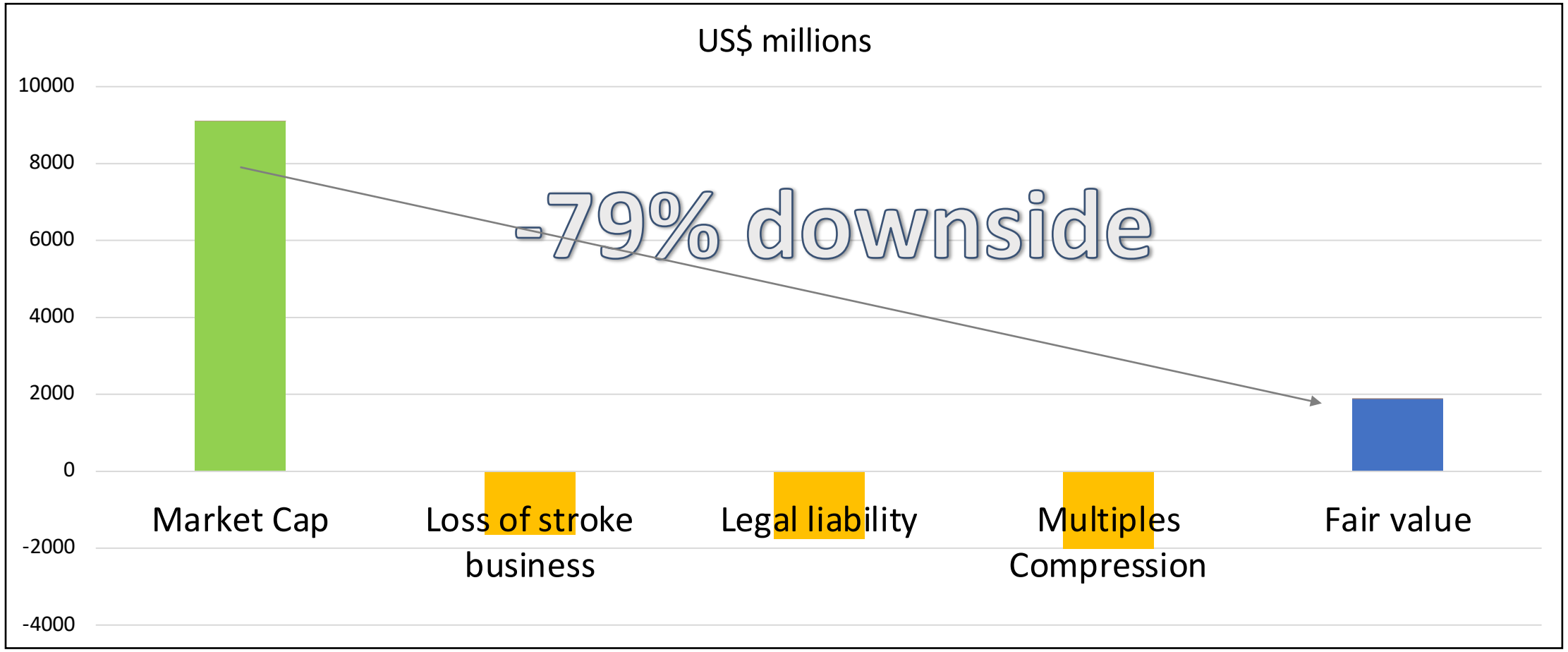
QUINTESSENTIAL CAPITAL MANAGEMENT

Valuation assumptions

- Jet 7 **recall** hits at least 50% of stroke business
- Full **legal liability*** materializes
- Sales multiples revert to peers' median
- Brand and sales in non-stroke are unaffected

* Estimating legal liability is notoriously hard. Here we assumed what we believe is close to a worst-case-scenario with large settlements per victim and 4x punitive damages. On the other hand, this estimate may prove conservative if, as we believe is the case, additional victims are identified beyond those documented in the Maude database.

So, who much is Penumbra worth? Less than $2bn in our opinion



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Conclusion, in our opinion:

- Key product with documented **record of death** facing likely **recall**
- Potentially fatal **brand devastation**
- Looming **product liability lawsuit**
- At least **40% of revenue** under direct **threat**
- **Intense competition** from stronger competitors
- We question **management's ethics** in behavior and communication

Penumbra is a doomed company, and our price target is $55

QCM is sharing this report with relevant authorities and law firms

- Regulators
- Elite hospitals and stroke centers
- Large shareholders
- Sell side analysts
- Patient Advocacy Groups
- **Top medical malpractice & product liability law firms**

American Stroke Association
A division of the American Heart Association.

FDA

U.S. SECURITIES AND EXCHANGE COMMISSION MCMXXXIV

American Heart Association
American Stroke Association
CERTIFIED
Meets standards for
Primary Stroke Center

This is just the beginning

We will make public additional documents in the next few days.

STAY TUNED follow us on Twitter
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*Percentages reflect maximum price drop achieved since QCM's intervention

Past short activist campaigns by QCM

Company Name	Location, Exchange	Outcome	Price Impact (%)
Akazoo	NASDAQ (USA)	Company exposed by QCM as total fraud is currently in liquidation. Management sued by the SEC for securities fraud.	**100%**
Bio-on	AIM (Italy)	Company exposed by QCM as total fraud is currently in liquidation. Management arrested and facing criminal charges.	**100%**
Aphria	Canada (NYSE)	Company exposed by QCM as a scheme to enrich insiders with conflicted acquisitions: executives and board members fired when internal review confirmed findings.	**43%**
Folli Follie	Greece, (Athens)	Company exposed by QCM as total fraud is currently in liquidation. Management arrested and facing criminal charges.	**100%**
Globo	Greece (London AIM)	Company exposed by QCM as total fraud ceased to exist as a commercial entity.	**100%**
Ability Inc	Israel (NASDAQ)	Company exposed by QCM as total fraud. Price collapsed, entire board resigned.	**100%**
American Addiction Centers	United States (NYSE)	QCM (together with Bleecker) exposed serious fraudulent practices.	**100%**
Eros International	India (NYSE)	Exposed as total fraud by Hindenburg (collaboration with QCM).	**90%**

Selection of QCM campaign outcomes

Bio-on

Our latest campaign against Bio-on resulted in the arrest of the company's executives and bankruptcy of the company.

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Folli Follie

Our campaign against Folli Follie resulted in the arrest of the company's executives and bankruptcy of the company

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Akazoo

Institutional Investor

Portfolio Corner Office Culture Premium Resear

Richard Teitelbaum

For Quintessential, a Campaign Both Short and Sweet

Just two weeks after short seller Gabriel Grego blasted music streamer Akazoo, the company's board ousts its CEO.

May 04, 2020

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