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Penumbra: Doctors Express Frustration Over Company Response to Jet 7 Catheter Issue, with Some Abandoning the Jet 7 or Penumbra Products Altogether

Since its introduction in July of 2019, Penumbra's (PEN) Jet 7 XTRA FLEX catheter, designed to vacuum out blood clots in stroke victims, has been involved in over a dozen deaths due to the unintentional expansion of the catheter while in the arteries of a patient's brain.

Penumbra has claimed that all of the deaths associated with the Jet 7 XTRA FLEX have been the result of misuse by neurointerventional surgeons and maintains that it has appropriately informed doctors of the risk of using the device.

However, six practicing nuerointerventionalists from different large hospitals and clinics around the country tell *The Capitol Forum* that Penumbra's efforts to inform surgeons of deficiencies with the Jet 7 XTRA FLEX have been insufficient, with many only having learned of the problems informally from other clinics or when *The Capitol Forum* reached out for interviews.

Furthermore, the doctors tell *The Capitol Forum* that the misuse the company is claiming as responsible for the deaths is an entirely routine use of the catheter, a fact backed up by former sales representatives of the company who stated that Penumbra knew how doctors were using its devices.

The doctors all spoke on the condition of anonymity because they were not authorized to speak with the press, and most of the doctors stated that their clinics and practices would either not use Penumbra products from now on or would revert to Penumbra's older ACE line of catheters until the Jet 7 had been pulled from the market and redesigned.

"We are not carrying any more of their product, period. We are getting rid of everything of theirs," said one practicing neurointerventional surgeon at a large hospital.

In a statement to *The Capitol Forum*, a spokesperson for Penumbra defended the company's handling of the issue, saying that "the vast majority of our customers have responded favorably to our transparency in evaluating these issues and providing the voluntary Notification, and they are continuing to use the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology."

Doctors and former sales reps reiterate that injection of contrast media through aspiration catheter is routine. According to Penumbra, many of the issues with the Jet 7 catheter are related to its use to inject contrast agent, which helps to map the arteries of the brain, through the aspiration catheter. Aspiration catheters like the Jet 7 are designed to vacuum blood clots out of arteries, Penumbra maintains, and not to inject contrast.

Doctors injecting contrast agent through the Jet 7 have found that in some cases the process has caused the tip of the catheter to expand like a balloon, rupturing the arteries of the patient and leading to death, according to an FDA database that tracks device malfunctions.

While the injection of contrast has led to the majority of deaths, the majority of device malfunctions and injuries associated with the catheter have resulted from other mechanical deficiencies. These deficiencies include breaking in two during procedures, bending and kinking during use, or expanding in a similar fashion when flushed with saline.

According to a former sales representative for the company, their clients were experiencing mechanical problems with the catheter totally unrelated to the contrast issue.

"Some clients in my market were testing out the FLEX, and they were using a stent retriever with it," the former salesperson said, "The catheter would always collapse when they pulled the stent retriever through the FLEX, the catheter would collapse and completely unravel. I would tell Penumbra about it but they kept blaming user error."

Asked about these other issues, a spokesperson for Penumbra stated that "we do not comment on specific development projects," but "we are not finished innovating our reperfusion catheters because physicians are continuing to expand their understanding of all the factors needed to optimize treatment of the full range of stroke patients."

The company has labelled the injection of contrast agent as a misuse of the catheter not in line with its FDA clearance, and has advised doctors to inject contrast through a different catheter called the guide catheter. Penumbra has also downplayed the extent to which doctors use it for this purpose.

"The vast majority of customers do not inject contrast," Penumbra CEO Adam Elsesser recently said during the Wells Fargo Virtual Healthcare Conference.

At the Morgan Stanley Global Healthcare Conference yesterday, Elsesser commented again on the Jet 7's inability to safely inject contrast, saying "I think a lot of folks who may have done that, this whole scenario gave them an opportunity to rethink it and go, why was I doing that? Maybe I should limit that."

Doctors, however, tell *The Capitol Forum* that injection of contrast agent through the aspiration catheter is a common practice that both saves time and allows more accurate mapping of the arteries because the aspiration catheter can get closer to clots than the wider guide catheter.

"If they are saying the contrast is breaking the tip of the catheter, it is a problem with the catheter," one doctor told *The Capitol Forum*, "Don't blame the contrast, it does not make any sense. Contrast is everywhere in our job."

According to another surgeon, "you should be able to inject contrast through any catheter used in a thrombectomy, a guide catheter, a microcatheter, an aspiration catheter, all of them. They are all meant to inject contrast through. No one will go through the thought process of, 'Oh, I should do one catheter for contrast and not the other.' It's ridiculous."

Former employees of Penumbra also tell *The Capitol Forum* that, far from being an uncommon practice as described by the CEO, the company knew that doctors were using its reperfusion catheters to inject contrast agent.

"Oh God, they were well aware," one former salesperson for Penumbra said, "in terms of injecting contrast, it was never mentioned in marketing materials that you could or could not inject contrast. Penumbra never told us physicians couldn't inject contrast through the Flex, but they knew it was happening. A contrast injection is a common part of the procedure. Not every physician does a run through the aspiration catheter, but it's fairly common."

Another former salesperson for Penumbra confirmed that company never advertised that doctors could inject contrast through the Jet 7, but that it was not actively discouraged in order to broaden appeal to doctors.

"We didn't really make any mention of not doing that," the salesperson said.

Doctors express frustration about method of communication from company. In a statement to *The Capitol Forum*, a representative for Penumbra defended the company's efforts to inform doctors and changes to the device's labelling and its Indications for Use clearance with the FDA.

According to the representative, the company's notice to healthcare providers was "sent via FedEx to the attention of the risk management department at hospitals that had purchased the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology" and "courtesy notices were shared with numerous professional societies… to ensure the communication was widely received."

According to one doctor, however, Penumbra's method of informing clinics was insufficient for the scale of the problem.

"The letter that they sent was a reminder that we can't inject contrast. We do it routinely. If it's buried in the IFU [Indications for Use] somewhere that we can't use it for that, that's bullshit," the

doctor said, adding that Penumbra needs to "get [their] reps out there to tell every single person, not send some bullshit letter. We deal with the reps day in and day out. People should be knocking on our door to say, hey, this is what happened, this is how we'll fix it."

One professional society that received the notice was the Society of Neurointerventional Surgery. Asked about Penumbra's letter, Dr. William Mack, president of the society, said that "SNIS' role is to make sure its members have the information necessary to make good treatment decisions. To this end, we sent the Penumbra letter as part of a safety alert to our members several weeks ago when it was released. The issues you mention are now under review with the FDA, and we will share any guidance or decisions that emerge from that review with our members."

The FDA has also told *The Capitol Forum* that it was looking into the problems with the Jet 7.

Doctors who spoke with *The Capitol Forum*, however, found Penumbra's efforts to inform doctors to be insufficient, with many only having learned of the problems informally from other clinics or when *The Capitol Forum* reached out for interviews.

"If your catheter is posing problems," one doctor told *The Capitol Forum*, "don't send a letter and hope for the best. I didn't learn about these problems with it until just last week, so I had been using the Jet 7 for weeks after they sent out the letter and I could have hurt a patient."

According to that doctor, other neurointerventional surgeons he knew had only just become aware of the problems as well. "At least 10 neurointerventionalists I know had no idea of this, and all of us use [the Jet 7] heavily. They kept us in the dark and didn't really tell us."

In the opinion of that doctor, "this has to be taken off the market. I know it's a big financial loss, but you cannot jeopardize patient safety and doctors' practices. I don't intend to use the Jet 7 until this whole thing is resolved."

One doctor told *The Capitol Forum* that they only discovered Penumbra's July letter in their inbox sometime in August.

"I don't know how many times I used it between when they sent it and I finally saw it. I think my secretary found the email and thought it was just one more thing to sign. They asked for a signature to acknowledge that you had received it. Obviously, they were attempting at minimizing their exposure."

Asked about whether they had received the notice from the company, another doctor replied that "I don't recall that, but I receive many of these from different companies for different devices. I mainly heard about it through the grapevine from physicians that have had a catheter break."

"If there really are arteries rupturing, that is extremely atypical for a catheter," that doctor continued, "with other catheters, these kind of things tend to have been pulled from market. If that is resulting in arteries rupturing, I would expect the device to be pulled… We haven't used it in the last month. I can't say I would never use it again, we would just use it very carefully."

All of the doctors that spoke with *The Capitol Forum* stated that they felt that Penumbra should take the additional step of recalling the Jet 7. However, according to Anne Walsh, an attorney with Hyman, Phelps, and McNamara and a former Associate Chief Counsel with the FDA, Penumbra may have fulfilled its legal obligations when notifying doctors, even if some users did not get the message.

"A recall may not be what is mandated here," Walsh said, noting that most recalls are voluntary on the part of the company, and "a lot of companies deal with use that evolves over time that can be handled with labelling changes that would not necessarily trigger a recall notification."

"However," Walsh continued, "there is a question of good corporate citizenship. If pulling the product is the only way to stop doctors from using it in this way, they obviously should. There is a question of whether the company should've known or had knowledge because of rampant use. Here, I would suggest that if the company knew of this widespread use, they could have decided the product would need a strong contraindication on the box that says 'DO NOT USE WITH CONTRAST AGENT.'"

According to one doctor, however, even large labelling changes would be insufficient given how common it is for doctors to inject contrast.

"There is too much user error that can occur if you have a catheter that has to be used in such a specific way that is out of character for how a catheter should be used," the doctor said, explaining that "it is kind of like buying a car. One of the integral functions of a car is to drive forward and backward, right? Imagine buying a car and then noticing a label that says don't drive it backwards, or that you can drive your car but make sure you drive only in this specific gear and only in this specific way. That would never work. Where is the FDA on this?"

Differences with other product lines. Penumbra received what is known as a substantially equivalent designation for its Jet 7 XTRA FLEX catheter from the FDA, indicating that the device was close enough to previously approved devices that it did not require independent evaluation and

testing. The FDA based its decision solely off information provided by Penumbra, according to an FDA representative.

A former salesperson for Penumbra stated there appeared to be much more than small changes between the Jet 7 XTRA FLEX and its predicate devices.

"The catheter kept collapsing when tested, it was definitely a different catheter," the former salesperson said, "You could just tell by the flexibility, you could tell by touching the tip."

Doctors who spoke with *The Capitol Forum* noted that the previous product lines that the Jet 7 was based on could inject contrast agent without any problems, indicating that defects in the Jet 7, rather than doctor practice, were likely responsible for the reported injuries and deaths. While those devices were not specifically cleared by the FDA to inject contrast, the practice became common during stroke procedures.

"Contrast never broke a catheter before," one doctor said, adding that "It's a problem with the catheter. They had multiple generations before the Jet 7, the ACE line, and we used contrast with them before with no problems and they know that."

Penumbra recently updated its clearance for the Jet 7 with the FDA, informing the regulator that it was solely making "labeling changes for more clarity to include additional warnings, precautions, and instructions to enhance the safety of device use," without any technological changes.

Asked whether the company planned to make the same changes to labelling for the ACE line of catheters given that they also do not have FDA approval for the injection of contrast media, a spokesperson for Penumbra emailed a statement emphasizing that the updates "*only apply* to the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology" (emphasis in original).

In a follow up question asking whether the company planned to make any technological changes to the Jet 7 XTRA FLEX, a spokesperson declined to comment on specific development projects, but said that "Penumbra remains committed to innovating until we have exhausted the engineering possibilities and provided physicians with the tools to benefit the most patients possible from endovascular stroke treatment."

Company fix impractical due to Jet 7 size. As previously mentioned, Penumbra has advised doctors to inject contrast agent through the guide catheter, rather than the Jet 7 aspiration catheter.

According to doctors *The Capitol Forum* interviewed, the size of the Jet 7 catheter, which Penumbra markets as its widest aspiration catheter, doesn't allow for contrast agent to be injected through the guide catheter.

"Even if you used Penumbra's own Neuron Max guide, it isn't wide enough for the Jet 7 to still allow for contrast injection around it," one surgeon said, "The Neuron sheath is only 6 French [Unit of Measurement]. Even if you use the Neuron Max with their flex catheter, the discrepancy between the two isn't sufficient to inject enough contrast for a useful angiographic run. How could they not know that? This doesn't pass any test of logic."

This fix also requires doctors to remove the Jet 7 from the guide catheter before injecting contrast, adding additional time to a procedure where doctors often say "time is brain."

According to analysts at Wells Fargo, Penumbra is planning on introducing a new guide catheter that would allow for doctors to inject contrast without removing the Jet 7 from the guide catheter.

Doctors shift away from Penumbra over response. The general consensus of the surgeons who spoke with *The Capitol Forum* indicated that the Penumbra's response of blaming doctors rather than the catheter would end up hurting the company more than just the malfunctions themselves.

"I am very angry with this company," one doctor said, "I don't believe the contrast is the problem, that's a BS excuse. I asked around and people had problems without the contrast. Focusing on the contrast is just an excuse. If they actually care, they should pull this catheter from the market and figure out what the problem is…We are not using a catheter that you can't use with contrast."

"They are going to lose a lot because of this," said another doctor, adding that "It's just like a politician that gets caught with their pants down, they should just fess up. To be honest, I am not sure the company will survive this, that's how big a PR gaff it is. That's my 2 cents, but that's the sentiment of a lot of people who do this, and I am on a lot of neuro chat and message boards."

"I think that this catheter should absolutely be taken off the market and improved, and I don't have any trust for it based on reports I have heard," another doctor stated, adding that "I think the number of reports of this catheter suffering this kind of failure is vastly out of proportion to other catheter failures."

All but one of the doctors said they would either stop using the Jet 7 altogether or until the mechanical issues are fixed, with that one doctor saying they would use it only in very limited scenarios. Two of the doctors who spoke with *The Capitol Forum* stated that they had switched from using the Penumbra Jet 7 catheter to the Microvention Sofia catheter for good.

Some competitors to Penumbra are also seeing an opportunity to win business from the problems with the Jet 7. Medtronic, for example, recently began advertising that surgeons can "feel confident manually injecting contrast media" with its React catheters.