

FAQs about the Teleflex Medical Voluntary Recall of Certain Atomizers included in Some Naloxone (also known as Narcan) Kits



Q: What is a “voluntary” recall?

A: A “voluntary” recall is when a company initiates a recall of a product rather than the government requiring the company to issue the recall. It does not change the level of concern about the effectiveness of the device. You should still check to see whether the atomizer(s) you have is on the list of recalled products as described below.

Q: Are naloxone and Narcan the same thing?

A: Naloxone is the name of the medication used to reverse opioid overdoses. Naloxone is often referred to by the brand name, Narcan. Narcan is the brand name of the one-piece nasal spray that delivers naloxone intranasally in the event of an opioid overdose. Narcan Nasal Spray is manufactured by Adapt Pharmaceutical and is not part of this recall.

Q: Could I hurt the person I’m trying to revive by using the atomizer if it’s defective?

A: No. Using a recalled atomizer to administer naloxone cannot hurt the person, it can only help and its application should be attempted. It’s not the naloxone medication itself that is being recalled, it is only certain Teleflex Medical atomizers designed to deliver the liquid medication as a mist. The problem occurs when the defective atomizer doesn’t deliver the medication as a mist; instead it remains more of a liquid. If you see the naloxone rolling out of the person’s nostril as a liquid as you are administering it, it is possible you have a defective atomizer and you should attempt to administer a second dose with a different atomizer if you have one available. You could also administer another formulation of naloxone if you have that available. It’s very important to remember to always call 911 as soon as possible in an overdose situation and to perform rescue breathing until medical assistance arrives or the naloxone takes effect and the individual is revived.

Q: What part of the naloxone kit is the atomizer?

A: The atomizer is a white cone-shaped piece that screws onto the top of the plastic tubing and converts the liquid naloxone into a mist for spraying up the nose. See the picture above.

Q: Which naloxone formulation is this recall for?

A: The current recall is not for the medication itself, only for certain atomizers used to deliver one formulation of naloxone that is commonly used in the community. The naloxone medication itself is not being recalled. This recall only affects the intranasal formulation manufactured by Teleflex Medical comprised of three pieces (plastic housing around syringe, medication, and atomizer) requiring assembly. The recall does not affect either intramuscular formulation (syringe injection or Evzio auto-injector) or the Adapt Pharmaceutical one-piece Narcan Nasal Spray.

Q: Are all mucosal atomizing devices (MAD devices) being recalled?

A: No, not every atomizer is being recalled. The recall is specific to certain atomizers manufactured by Teleflex Medical. It is possible that the atomizer you have has not been recalled. To see which product codes and batch/lot numbers have been recalled, go to http://www.ct.gov/dmhas/lib/dmhas/newsworthy/mad_recall.pdf.

Q: How do I know if the atomizer I have is on the recall list?

A: The plastic packaging containing the atomizer has printed information on one side. Above the first bar code will be printed the product code, e.g. "MAD 300". The 6-digit number between the bar codes is the batch/lot number. If the numbers match those listed on the Teleflex Medical recall list - then your atomizer has been recalled. To see which product codes and batch/lot numbers have been recalled, go to http://www.ct.gov/dmhas/lib/dmhas/newsworthy/mad_recall.pdf.

Q: If I'm an individual who obtained a kit for free as part of a naloxone distribution effort, do I have to return my atomizer(s)?

A: The Teleflex Medical recall is not directed at you as you did not receive your kit from a Teleflex distributor. You can check with the provider who gave you the kit to see if your atomizer is on the recall list and if a replacement is available. If you choose to use the atomizer anyway, be aware that there is the potential that it may not be fully effective at delivering the naloxone. If you see the naloxone rolling out of the person's nostril as a liquid as you are administering it, it is possible you have a defective atomizer and you should attempt to administer a second dose with a different atomizer if you have one available. You could also administer another formulation of naloxone if you have that available. It's very important to remember to always call 911 as soon as possible in an overdose situation and to perform rescue breathing until medical assistance arrives or the naloxone takes effect and the individual is revived.

Q: What are the steps for rescue breathing?

A:

- Make sure the victim is on their back on the floor.
- Open the airway by lifting their chin and tilting their head back.
- Pinch their nose shut so no air can escape.
- Give two quick breaths followed by one breath every 5 seconds.
- Watch their chest to see if it rises and falls as the air is going in and out.
- Continue to provide rescue breaths until the victim either revives or EMS arrives.

Q: If I choose to use the intranasal assembly I have to administer naloxone to someone who has overdosed, how would I know if the atomizer was defective?

A: The problem with the defective atomizers is that the naloxone comes out more as a stream of liquid than a mist. If you see the naloxone rolling out of the person's nostril as a liquid as you are administering it, it is possible you have a defective atomizer and you should attempt to administer a second dose with a different atomizer if you have one available. You could also administer another formulation of naloxone if you have that available. It's very important to remember to always call 911 as soon as possible in an overdose situation and to perform rescue breathing until medical assistance arrives or the naloxone takes effect and the individual is revived.

Q: I'm administering the naloxone to someone who has overdosed and the atomizer isn't working – the medication is just rolling out of their nose as a liquid. What should I do?

A: Attempt to administer a second dose with a different atomizer if you have one available. You could also administer another formulation of naloxone if you have that available. If you don't have more naloxone available, make sure you have called 911 as soon as possible and perform rescue breathing until medical assistance arrives or the naloxone takes effect and the individual is revived.

Q: If I obtained my naloxone and atomizer from a certified pharmacist and the atomizer is on the recall list, what should I do?

A: You can contact the pharmacy that dispensed the atomizer to you to see if they have other atomizers in stock. Alternatively, the certified pharmacist may suggest that you use the Narcan Nasal Spray product instead. To see the list of Connecticut pharmacists certified to prescribe and dispense naloxone, go to <http://www.ct.gov/dcp/cwp/view.asp?a=1620&q=581898>.