

Tandem and Insulet Will Gain Patients as a Result of the Medtronic Recall

Companies: ABT, DXCM, MDT, MNKD, PODD, TNDM

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Report Type: Initial Coverage Previously Covered Full Report Update Ratings: MDT: 3/5, PODD: 3.5/5, TNDM: 4/5

Research Question:

Will the MiniMed 600 recall result in patient declines for Medtronic and gains for Tandem or Insulet?

Summary of Findings

- The Class I [recall](#) of Medtronic plc's (MDT) [MiniMed](#) insulin pumps is expected to negatively impact future sales. In a market that is constantly changing and looking for the next big breakthrough, Medtronic is currently the dominant insulin pump provider, but sources expect market share to shift. Changes will not be swift, though, as patients must wait until their pump warranty (4 years) expires to select a new pump—unless they are willing to pay out of pocket.
- Beyond this recent recall, Medtronic pump users and medical professionals are frustrated with the MiniMed's long history of performance problems and broken company promises for fixes and innovative updates. Patients are also dissatisfied that they are required to buy only Medtronic proprietary supplies. One source said no new patients at their clinic are selecting Medtronic's pump.
- Tandem Diabetes Care Inc.'s (TNDM) [t:slim X2 with Control-IQ Technology](#) is expected to be the primary beneficiary of Medtronic's anticipated patient loss. The Control-IQ Technology received [FDA approval](#) in December 2019 and has generated great interest and excitement in the diabetic community.
- Sources praised Tandem and its pumps as excellent, with the best trial results. A Tandem pump combined with Dexcom Inc.'s (DXCM) continuous glucose monitor (CGM) is the insulin pump of choice, especially for younger diabetics. Increased sales of the t:slim X2 are expected until the next technology breakthrough comes. These findings mirror Blueshift Research's [Oct. 23, 2019](#), and [June 19, 2019](#), Tandem reports.
- Insulet Corp.'s (PODD) Omnipod insulin pump is considered an excellent device and is expected to gain share. Omnipod's tubeless design is unique and not appropriate for all diabetics. Omnipod is frequently favored by parents of juvenile diabetics and their healthcare providers.
- Insulet's recent announcements of agreements with both [Dexcom](#) and [Abbott Laboratories](#) (ABT) to integrate their CGM systems into Omnipod's upcoming system, [Horizon](#), have been well-received.
- Dexcom is seen as the leader in the CGM market and, as insurance coverage increases and pump manufacturers continue to integrate its CGMs with their devices, Dexcom sales will continue to increase.
- Beta Bionics was noted as a potential game changer—but it is not expected to reach the market for at least 12 months.

Silo Summaries

1) Endocrinologists

Two endocrinologists and a nurse practitioner specializing in endocrinology all expect the Medtronic MiniMed recall to negatively impact sales. Patients and medical professionals are losing confidence in the MiniMed and are frustrated by its requirement to only use Medtronic proprietary supplies. One source said patients are leaving the MiniMed in droves and Medtronic is putting educators in clinics to try to stem this exodus. Another source said new pump patients are not selecting the MiniMed and their clinic views the pump as second tier. The third source said the use of Medtronic pumps will continue to decline until they launch their new product. **Tandem is viewed as a superior product and its Control-IQ technology will drive increased adoption.**

2) Nurse Educators

These two Certified Diabetes Educators (CDE) said they have not experienced any patients switching from Medtronic's MiniMed pumps to other pumps because of the recall. They noted that some Medtronic patients using the company's CGM are switching to Dexcom's CGM, which can be replaced and reimbursed every six months. **Both acknowledge that Medtronic's MiniMed has had problems; one said there is a high frequency of calibration and accuracy issues.** Medtronic is aggressively addressing the recall issues at one source's facility by inspecting all its patient's pumps. **Tandem's t:slim X2 with Control-IQ is generating lots of excitement and one source said its sales are booming and the other said it will gain share.**

3) Diabetes Treatment Sales Channel

Three sales professionals working in the diabetes space expect Tandem to gain share, primarily because of the quality of its insulin pump as compared to Medtronic's. The issues associated with the Medtronic recall are not new and the company is expected to work diligently to correct the problem, but patient anxiety is high. **Tandem's t:slim X2 is generating a great deal of interest—adoption is projected to be slow and steady.**

4) Industry Specialists

Medtronic is currently the insulin pump market leader, but the latest recall will negatively impact sales because of the trust and confidence that patients must have in their equipment. There are other, better alternatives on the market that will likely be used more frequently as patients become nervous about the reliability of their Medtronic pumps. **This diabetic uses the Tandem pump integrated with the Dexcom CGM and thinks it is the best pump on the market today.**

Insulin Pumps

	Medtronic Recall Impact	Tandem	Insulet
Endocrinologists	Patient Losses	Patient Gains	Patient Gains
Nurse Educators	Patient Losses	Patient Gains	Patient Gains
Diabetes Treatment Sales Channel	Patient Losses	Patient Gains	Patient Gains
Industry Specialists	Patient Losses	Patient Gains	Patient Gains

Background

Blueshift Research's ongoing research found Medtronic experiencing another insulin pump recall. The U.S. Food and Drug Administration (FDA) has identified the issue as a Class I recall, the most serious type. This comes on the heels of a June 2019 recall. In the meantime, Tandem and Insulet have published more positive data on their insulin pumps, experienced FDA approvals for enhanced technology, and partnered with other diabetes care providers, all of which may result in share gains for these two companies, especially when combined with the news of Medtronic's recall.

Insulin pumps and their components are complicated devices. They have the highest overall number of malfunctions, injuries, and death reports in the FDA database. In the last decade, Medtronic has faced 20 manufacturer recalls and about 100 lawsuits alleging pump malfunctions. So it is not a surprise that Medtronic is facing yet another recall for some of its pumps. The Class I categorization is due to 26,421 complaints in which the device malfunctioned, 2,175 known injuries, and 1 known death. This latest recall was announced in November 2019 for insulin dosing errors and followed a recall notice issued in June 2019 for cybersecurity issues. These back-to-back serious recalls raise the possibility that patients and physicians may be wary of Medtronic and willing to consider migrating to competing insulin pumps.

Tandem has experienced some recalls of its own. In January 2014, a Class I [recall](#) was issued because of leaking insulin cartridges and in April 2018 a Class II [recall](#) was issued for 55 t:slim G4 insulin pumps with faulty fuel gauges. Recently, however, Tandem has been riding a wave of success. In January 2020 Tandem [began](#) the U.S. commercial launch of its t:slim X2 insulin pump with Control-IQ advanced hybrid closed-loop technology. And in 2019, the FDA approved the t:slim X2 insulin pump with Control-IQ and Health Canada [approved](#) Tandem's t:slim X2 insulin pump with Basal-IQ. Also in 2019, Abbott and Tandem [partnered](#) to develop and commercialize integrated diabetes solutions and Tandem reported positive results from two [studies](#), including the Protocol 3 (DCLP3) of the National Institutes of Health (NIH)-funded International Diabetes Closed Loop (iDCL) trial and interim data from the Freelifx Kid AP study.

Insulet experienced its own Class I [recall](#) in July 2015 for defective insulin pods. But lately the company has experienced a number of positive developments. In early 2020 Dexcom and Insulet announced a commercialization agreement to combine current and future Dexcom CGM systems with Insulet's Omnipod Horizon system and Abbott and Insulet have also partnered to integrate Abbott's CGM technology with the Omnipod Horizon. In 2019, Insulet [secured](#) FDA approval for use of Novo Nordisk A/S's (NVO) Fiasp insulin with the Omnipod insulin management platform, as well as use of Insulet's Omnipod Dash as an alternate controller enabled infusion pump, or ACE pump, allowing it to be a part of an interoperable automated insulin delivery system.

Current Research

Blueshift Research assessed whether the MiniMed recall would lead to patient declines for Medtronic and gains for Tandem and Insulet. We employed our pattern mining approach to establish five independent silos, comprising nine primary sources (including three repeat sources) and three secondary sources focused on the insulin pump market. Interviews were conducted March 2-17.

- 1) Endocrinologists and their medical teams (3)
- 2) Nurse educators (2)
- 3) Diabetes treatment sales channel (3)
- 4) Industry specialists (1)
- 5) Secondary sources (3)

Next Steps

Blueshift Research will continue to monitor the Medtronic Class I recall of its MiniMed to determine if medical professionals and patients are losing confidence in the product and switching to Tandem or Insulet pumps.

Silos

1) Endocrinologists

Two endocrinologists and a nurse practitioner specializing in endocrinology all expect the Medtronic MiniMed recall to negatively impact sales. Patients and medical professionals are losing confidence in the MiniMed and are frustrated by its requirement to only use Medtronic proprietary supplies. One source said patients are leaving the MiniMed in droves and Medtronic is putting educators in clinics to try to stem this exodus. Another source said new pump patients are not selecting the MiniMed and their clinic views the pump as second tier. The third source said the use of Medtronic pumps will continue to decline until they launch their new product. The insulin pump market as a whole was described as constantly changing because of technological advancements. Tandem is viewed as a superior product and its Control-IQ technology will drive increased adoption. Insulet's Omnipod is considered superior to Medtronic by two sources, while one said the company does not have anything new on the short-term horizon. Beta Bionics has potential to be a game changer; however, it is not expected to reach the market for at least 12 months. One source said Dexcom has the leading CGM and will continue to see sales increases as insurance coverage grows and pump manufacturers integrate it with their devices.

Key Silo Findings

Insulin Pump Market Conditions

- 1 said the insulin pump market is constantly changing due to technical innovation.

Medtronic

- 3 said Medtronic will lose share as a result of the latest recall.

Tandem

- 3 said Tandem's pumps are gaining share.
 - o 1 said Tandem is an excellent pump, with the best clinical trials, and expects it to gain share.
 - o 1 said Tandem is the pump of choice, especially with younger patients, and she expects their share gains to continue until the next technology breakthrough.
 - o 1 said the Tandem pump is superior and, with its Control-IQ technology, will continue to gain share.

Insulet

- 2 said the Omnipod is a superior product to Medtronic.
- 1 said Insulet has nothing new coming soon.

Other Technologies

- 1 said Beta Bionics' pump could be a game changer when launched.
- 2 said Beta Bionics will not have a product available for at least 12 months.
- 1 said Dexcom dominates the CGM market and will continue to grow as insurance coverage expands and more pump companies integrate with it.

1) Academic endocrinologist and nationally recognized diabetes management and research expert

Sales of Medtronic's pumps will be negatively impacted by the Class I recall, due to the trust and confidence that patients must have in their equipment. Much better alternatives exist on the market now and will likely be used more frequently as patients become nervous about the reliability of their Medtronic pumps.

Background

- This source is a full professor at a major university, nationally recognized for his expertise in endocrinology, especially in the areas of diabetes management and research, and a frequently published author.

Insulin Pumps

Insulin Pump Market Conditions

- “Medtronic has had a virtual monopoly in the insulin pump area for years. That’s about to change.”
- “Patients and physicians are totally fed up with Medtronic.”
- “There must be a good patient experience with all of this equipment. Medtronic is far behind in this area. Regardless of how technically good their equipment is, it has historically been annoying and not built around the patient experience. It still requires finger sticks and alarms during the middle of the night, thereby waking up the patient and their partner. All of the other competitors are engineering in convenience and ease of use.”

Medtronic

- “The recall is merely the last straw for patients and physicians. Frustration has been building for 20 years. Patients are fed up with Medtronic and leaving in droves as soon as they can get out of their warranties.”
- “The requirement to use Medtronic supplies with their pumps is very annoying and expensive. The other competitors have figured this out and have designed their equipment to use generic supplies.”
- “They will experience a decrease in sales. They have lost the confidence of their users and prescribers.”
- “Medtronic is trying to decrease the exodus of patients by putting educators in clinics.”
- “Medicare covers their pump but not their sensor. I am actively transitioning patients who are turning 65 to other machines. I prefer Tandem.”

The recall is merely the last straw for patients and physicians. Frustration has been building for 20 years. Patients are fed up with Medtronic and leaving in droves as soon as they can get out of their warranties.

Academic endocrinologist and nationally recognized diabetes management and research expert

Tandem

- “Excellent equipment.”
- “They will definitely experience an increase in sales. The equipment is better and it is all covered by Medicare.”
- “Compatible with Dexcom sensor.”
- “Has conducted the best clinical trials to back up its equipment.”

Insulet

- “Excellent equipment.”
- “Their closed-loop system, probably available next summer, will be called [Horizon](#).”
- “They will be a major competitor and will continue to grow.”

Other Technologies

- “Beta Bionics is developing a system that will incorporate glucagon delivery in with insulin delivery. This is going to be a game changer.”
- “Dexcom is currently, by far, the leader in the CGM area.”

Miscellaneous

- “Thirty percent of Type 1 diabetes patients use pumps.”
- “CGMs will experience a sustained increase in sales as the insurance coverage is improving and all pump systems are working to integrate them into their systems.”

2) Physician assistant in endocrinology at major university clinic

This source has both personal and professional experience with all of the major pump manufacturers. At her clinic Medtronic pumps are considered second tier. Confidence in Medtronic’s pumps is declining, as is their market share. Tandem is the pump of choice for the younger population and is expected to gain share until the next technology breakthrough emerges. She does not actively steer her patients to any one manufacturer but relies on the recommendations of her nurse educators and patient preferences related to their lifestyles.

Insulin Pump Market Conditions

- “Medtronic has dominated, but is clearly slipping.”
- “Medtronic’s closed-loop system uses expensive, proprietary supplies; requires four to five finger sticks per day (including at night) and doesn’t use the most up-to-date technology.”
- “The new system that they are developing will only be a slight improvement and will still be way behind its competitors.”

Insulin Pumps

Medtronic

- “Confidence in Medtronic has been shaken.”
- “At this clinic, Medtronic is considered to be a second-tier pump.”
- “Our patients who are on Medtronic pumps only continue to use them because they have been using them for years and are familiar with them.”
- “There are virtually no new patients choosing them.”

Tandem

- “The younger population of patients want Tandem because of the excellent technology.”
- “On the other hand, the aging population, who have never used pumps, can be intimidated by the technology. I don’t pressure patients to even use pump technology if they aren’t comfortable with it. Comfort and confidence are paramount.”
- “Tandem is experiencing a bump in sales already, which will continue for the foreseeable future—until the next major breakthrough occurs.”

Insulet

- “Outstanding product. This is what I use, personally.”
- “It is a tubeless system. This is a very important lifestyle factor. For instance, if a patient has children, they may not want to use a system that employs tubes. Similarly, if the patient has a very active work life or is into sports, tubes are a real problem. You can even wear the Omnipod in the shower or when you are swimming.”
- “[Insulet has] no closed-loop system yet, but, by the end of the year, it will most likely be approved in conjunction with Dexcom.”
- “The way this system works is that the pump sticks to your skin. You fill a reservoir with insulin and inject it simply by pushing a button. There are no injections. This is fundamentally different than the other pumps and is therefore not considered durable medical equipment (DME). It is actually covered by pharmacy benefits, so is opening up the whole Type 2 population for being able to use pumps. Medicare requires Type 1 diabetes to approve a pump, as do other insurers. This will be huge for the Type 2 patients and for the company as well.”
- “From a financial standpoint, the initial cost for the equipment is far less than for a traditional pump. It doesn’t require expensive annual lab testing to continue to certify the need for a pump and the supply costs are fairly equivalent. So, if a patient has good pharmacy benefits, this will continue to be a very competitive product.”

Other Technologies

- “Beta Bionics is developing a potentially outstanding product, but the FDA is very nervous about approving a device that does not incorporate the personal interaction of the patient with their pumps.”
- “Full approval is likely to take quite a bit more time as the studies aren’t fully there yet.”

Miscellaneous

- “Many small endocrinology practices don’t even manage pump patients. It’s too complicated. Diabetology is very much a sub-specialty. Those that do, however, frequently have industry-employed nurse educators who don’t even offer different options than those provided by their employer. Frequently, when I get a patient from one of these practices, they don’t even know that there is other technology that is available.”

Confidence in Medtronic has been shaken. ... At this clinic, Medtronic is considered to be a second-tier pump.

Physician assistant in endocrinology at major university clinic

3) Academic endocrinologist; repeat source

This source believes the recall will cause Medtronic sales to continue to decline until they have a new product on the market. Tandem is the leader and sales of its Control-IQ pump will continue to grow. Both Beta Bionics and Tidepool Loop will be important, but will not be on the market for more than a year.

October 23, 2019, interview summary: This source sees Dexcom and Tandem as both well positioned to remain dominant for the foreseeable future. The Control-IQ and t:sport pump are significant innovations for Tandem’s future, as is the recently announced partnership with Abbott. Interoperability is the way of the future. The new partnerships for Abbott with Tandem and Omada Health may be a future threat to Dexcom.

Insulin Pump Market Conditions

- “[This] market changes constantly, improving technology continuously.”

Medtronic

- “Medtronic will continue to fall off until they come out with a new product.”

Insulin Pumps

- “[The] recall continues to hurt Medtronic, especially at a time where Tandem clearly has a superior product.”

Tandem

- “Tandem has the best insulin pump on the market, regardless of Medtronic’s recall.”
- “Their Control-IQ pump is continuing to take off and Medtronic will continue to fall.”

Insulet

- “Omnipod has nothing new on the immediate horizon.”

Other Technologies

- “Beta Bionics will be a big deal but [is] still over a year out.”
- “Tidepool Loop Project is important but probably even further out than Beta Bionics.”

Tandem has the best insulin pump on the market, regardless of Medtronic’s recall. ... Their Control-IQ pump is continuing to take off and Medtronic will continue to fall.

Academic endocrinologist

2) Nurse Educators

These two Certified Diabetes Educators (CDE) said they have not experienced any patients switching from Medtronic’s MiniMed pumps to other pumps because of the recall. One source noted that patients could not switch to a new pump even if they wanted to before the end of their warranty—unless they were willing to pay for it themselves. They noted that some Medtronic patients using the company’s CGM are switching to Dexcom’s CGM, which can be replaced and reimbursed every six months. Both acknowledge that Medtronic’s MiniMed has had problems; one said there is a high frequency of calibration and accuracy issues. Medtronic is aggressively addressing the recall issues at one source’s facility by inspecting all its patient’s pumps. Tandem’s t:slim X2 with Control-IQ is generating lots of excitement and one source said its sales are booming and the other said it will gain share. The Insulet Omnipod is not used at one clinic and the other views it as a unique insulin pump that is not right for all patients, unless they want to go tubeless.

Key Silo Findings

Insulin Pump Market Conditions

- 1 said the CGM and insulin pump market is constantly changing and patients are always looking for the next breakthrough.

Medtronic

- 2 acknowledged Medtronic’s MiniMed performance issues, but neither sees patients at their clinic switching pumps.
 - o 1 said the MiniMed problems are not new. They added that patients are restricted from switching to another pump until the end of their warranty period (usually four years). This source did note that Medtronic patients using Medtronic’s CGM are switching to Dexcom’s CGM at the end of their warranty (usually 6 months).
 - o 1 said there are lots of complaints about the MiniMed because of calibration and accuracy issues. Medtronic is responding by inspecting all its pumps in use by patients at this clinic.

Tandem

- 1 said Tandem sales are booming since the launch of its Control-IQ technology.
- 1 said there is excitement about Control-IQ and Tandem will see gains.

Insulet

- 1 said Insulet’s Omnipod is a unique product that is appropriate for patients that want a tubeless solution.
- 1 said their clinic does not offer the Omnipod.

Other Technologies

- 1 said the last information they heard about Beta Bionics’ iLet was about problems with the glucagon dosage.

1) RN, MSN, and diabetes educator for an East coast medical center with 21 years of experience

This source is not aware of any patients switching pumps because of the Medtronic recall. She has noticed patients dropping the Medtronic CGM in favor of Dexcom’s because of its accuracy and ease of use. Tandem sales are booming because of the recent launch of its Control-IQ technology.

Insulin Pumps

Insulin Pump Market Conditions

- “The pump and sensor [CGM] technology is changing all of the time and patients are always looking for the next improvement.”

Medtronic

- “The problem that led to the Medtronic recall is not a new problem—it has been going on for a while.”
- “However, if a patient’s pump is not experiencing the problem, they are continuing to use it. In fact, it’s not like patients could change if they wanted to until their warranty period runs out or they would have to pay for the pump themselves.”
- “I am really not aware of any kind of migration away from Medtronic because of the recall, but patients are switching their CGM to Dexcom even though it is not integrated with the pump. It is much more accurate and easier to use than the Medtronic sensor and you can switch a CGM every six months and it is covered.”

Tandem

- “Since the launch of Control-IQ Tandem is booming; it’s very popular.”
- “Tandem integrates with the Dexcom sensor so patients seem very happy with both these products.”

Insulet

- “Omnipod is a unique solution that is not right for everyone, but for patients that want to go tubeless it is great.”

Other Technologies

- “I have not kept up with the Beta Bionics iLet. The last I did hear about it was that they could not work out the glucagon dosage.”

“Since the launch of Control-IQ Tandem is booming; it’s very popular.”

RN, MSN, and diabetes educator for an East coast medical center with 21 years of experience

2) Diabetes educator and registered dietician at a VA hospital in the Midwest; repeat source

Medtronic has been very active in following up after the recall and is inspecting all MiniMed pumps. This source has not seen any patients switching from the MiniMed due to the recall but believes that, if there have been switches, they would be to the Tandem t:slim X2. The MiniMed 600 series has historically had many patient complaints due to the frequency of calibration and problems with accuracy. The t:slim X2 Control-IQ system is exciting and they believe it will gain healthcare professional support over its competitors.

June 19, 2019, interview summary: Most of the people with diabetes at this facility are older and have Type 2 diabetes, so they would not qualify for a pump. Patients who use a pump are losing interest in Medtronic’s 670G because they have experienced or heard complaints about the system’s frequent and lengthy alerts. This VA decided to add Tandem’s t:slim to its formulary because they heard it was easy; however, they are having difficulty getting Tandem’s sales reps and educators to come to their facility. Patients are also anxious to try the Dexcom, which they have heard positive things about. Their patients are not particularly interested in wireless, although some ask for an Omnipod, and some express interest in a closed-loop system.

Insulin Pump Market Conditions

- Did not discuss.

Medtronic

- “A rep has been in our clinics and visually inspects all the MiniMed pumps.”
- “I have not seen anyone switching pumps. If they were going to switch, I believe they would be switching to Tandem.”
- “Frequency of calibration and problems with accuracy with the MiniMed are common complaints with the Medtronic system.”

Tandem

- “Everyone is very excited about Tandem’s new t:slim; this will absolutely gain patient and healthcare professional support.”
- “We added the t:slim X2 to the formulary last year.”

Insulet

- “We are not using Omnipod at this VA.”

Other Technologies

- Did not discuss.

“Everyone is very excited about Tandem’s new t:slim; this will absolutely gain patient and healthcare professional support.”

Diabetes educator and registered dietician at a VA hospital in the Midwest

3) Diabetes Treatment Sales Channel

Three sales professionals working in the diabetes space expect Tandem to gain share, primarily because of the quality of its insulin pump as compared to Medtronic's. The issues associated with the Medtronic recall are not new and the company is expected to work diligently to correct the problem, but patient anxiety is high. Tandem's t:slim X2 is generating a great deal of interest—adoption is projected to be slow and steady. Insulet's Omnipod is strong in the pediatric diabetes segment. Little is known about Beta Bionics technology and it is not expected to enter the market until 2021 or 2022. One source described the insulin pump market as dominated by Medtronic, Tandem, and Insulet. Technology in the space is moving rapidly and medical professionals are open to discussing it. Third-party payments are strong and grassroots advocacy and support for improvement is strong.

Key Silo Findings

Insulin Pump Market Conditions

- 1 said the insulin pump market is dominated by Medtronic, Tandem, and Insulet. Innovative technology in the space is fast-moving and medical professionals and patients are open to it. Third-party reimbursement for pumps is strong and diabetes treatment advocacy groups are active.

Medtronic

- 1 said Medtronic is losing patients and physicians are switching to other insulin pumps.
- 1 said patient anxiety regarding the Medtronic pump problems are real, but they expect the company will deal with the problem.
- 1 said Medtronic has had a history of problems and has not kept pace with the latest technology. No significant patient switching to new pumps is occurring because of the warranty period on pumps.

Tandem

- 1 said the Tandem pump is a salesperson's dream.
- 1 said interest and excitement is high regarding the t:slim x2 and they expect sales to increase.
- 1 said Tandem pumps are favored by diabetic educators and patients and adoption will be slow and steady.

Insulet

- 2 said the Omnipod is strong in the pediatric diabetes treatment segment.
- 1 said Omnipod is different than Medtronic's and Tandem's pumps and the company markets differently.

Other Technologies

- 2 had little knowledge about Beta Bionics and its pump is not expected to launch until 2021 or 2022.

1) Sales manager for major insulin pump manufacturer; repeat source

This source said promoting Tandem's new t:slim X2 is "a salesperson's dream." Tandem sales focus on the new Control-IQ product and the reception has been incredibly positive. Patients on the older Basal-IQ product can upgrade to the new Control-IQ pump for free. Endocrinologists and their staff are initiating discussions on switching from MiniMed on every call and Medtronic is losing patients.

October 23, 2019, interview summary: There are few disruptors to change either Dexcom's or Tandem's growth rates. Tandem should have few negative factors for at least the next year. Dexcom should continue to grow, as new competitive products are not ready to release and are subject to FDA processes. Both companies have positive developments that continue to improve their products.

June 19, 2019, report summary: Tandem's continued growth and future are very positive, due to its easier to use t:slim X2 with Basal-IQ technology and the strong product pipeline. Market leader Medtronic is losing its grip, as the 670G pump is complicated to teach and learn, leading to higher discontinuation rates. Tandem is putting the burden on the machine—not the patient. The Animus exit is favoring Tandem, as its CGM and infusion sets are the most compatible. Tandem is expanding its field presence and has added a team focused on renewals to improve its 50% renewal rate.

Insulin Pump Market Conditions

- Did not discuss.

Medtronic

- "Doctors are switching from the MiniMed and discuss it with our sales force on every call."

Insulin Pumps

- “Medtronic is losing patients and the competition is gaining.”

Tandem

- “Conversations led by pump sales reps in the endo office aren’t surrounding the recalls but more on the shortcomings of the MiniMed 600 and the advantages of the new t:slim X2 Control-IQ technology.”
- “Discussions initiated by the healthcare professionals are about the Tandem technology and switching from whatever their patients are currently using.”
- “Switching discussions are occurring on every call—initiated by the medical staff.”
- “This is a great time to be a Tandem rep.”
- “The t:slim X2 Control-IQ is a salesperson’s dream come true. The reception by the customer has been incredibly positive. Every office is interested.”
- “Patients on the 2019 technology—the t:slim Basal-IQ—can upgrade to the new Control-IQ pump without charge. This upgrade policy will be in place definitely for 2020.”

Medtronic is losing patients and the competition is gaining.

Sales manager for major insulin pump manufacturer

Insulet

- “[It is] interesting where the Omnipod is best used. I was in a pediatrician’s office recently and they felt the tubeless Omnipod had an advantage over ‘tube’ Tandem and Medtronic systems—kids might pull the tubes out. But the trade-offs are that the untethered Omnipod has no built-in CGM and you have to carry a receiver or controller and don’t have the integration that the other products do.”
- “In discussing this with a pediatrician recently, they commented that the trade-off—tube for controller/monitor—is too great and they are rethinking their tubeless approach.”
- “Omnipod is designated DME or pharmacy benefit according to the insurance carrier. This policy cuts both ways: if the plan designates the Omnipod as pharmacy, it typically loses its extended warranty—usually three to four years—and may get 200 days coverage. It is a big trade-off—easier to get covered and less in price but a change in warranty. This differs by insurance carrier so I can’t make a blanket statement, but some treat it almost like a disposable.”
- “Omnipod does target Type 2 diabetics with this pharmacy benefit position. It’s an easier sell but they are limited to 200 IU of insulin with their product—a compromise.”

Other Technologies

- “Beta Bionics is rumored to have gained a major grant, but word is they are in the 2021-2022 timeframe for introduction.”

2) Territory sales manager for Tandem

This source reports very high interest, open discussion, and excitement from endocrinologists for Tandem’s new t:slim X2 Control-IQ pump. Patients on the Tandem t:slim X2 Basal-IQ technology can upgrade for free, which has been very positively received. Patients are anxious about the Medtronic recall, but the market believes Medtronic is able to handle the situation. This source has not heard much about patients switching because of the recall.

Insulin Pump Market Conditions

- “[There are] three players in the market today: Medtronic, Tandem, and Insulet.”
- “Today the market is not deep in the U.S. It’s moving faster than ever before. Doctors are very open to listen to what we have to say about new technology and changes with insulin pumps.”
- “There is a lot of excitement and open discussions going on with endocrinology offices. The conversations are very positive, with great feedback.”
- “There have been few changes in insurance coverage of which I’m aware. Grassroots advocacy for diabetics is very strong. [Medicare] coverage is good and coverage is generally comprehensive. I know of no changes with United Healthcare and their relationship with Medtronic.”

Medtronic

- “Patient anxiety over the recall is real.”
- “The market has complete confidence that Medtronic will handle the recall and address each and every patient affected.”
- “I haven’t heard of a lot about switching from endocrinologists. They are looking to explore options, so discussions with them are more about how Omnipod and Tandem’s products compare to Medtronic.”

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Tandem

- “Tandem is a transparent, ethical company that doesn’t operate in the grey. Their message about the recall is simply, ‘Sorry to hear about that and we hope that all the patients affected are ok and safe.’”
- “The excitement in the field is with the discussions about the t:slim X2 Control-IQ technology. This is a free upgrade from the t:slim X2 Basal-IQ technology, which is received extremely positively. Patients on another product with a typical three- to five-year warranty are not eligible for a ‘free state-of-the-art’ upgrade.”

The excitement in the field is with the discussions about the t:slim X2 Control-IQ technology.

Territory sales manager for Tandem

Insulet

- “[Insulet’s] Omnipod is difficult to compare to Tandem and Medtronic. It is the only tubeless product. Their marketing is different. They tend to target the Type 2 patients in my area, but they don’t have a hybrid closed-loop system at this time.”

Other Technologies

- “Beta Bionics is a future product introduction that conceptually has very positive features, but, as it is in the future, we don’t know when it will hit the market and what its functionality actually will be.”

3) Former Tandem sales representative now selling insulin

This source has witnessed years of problems patients have experienced since the introduction of the MiniMed 600 series. Medtronic’s older technology has not kept pace with the needs of patients. Patients have been convinced to stay on the MiniMed series because of promises that the next upgrade would solve the problems and patients could upgrade to the 670 for free. The 670 is not the solution Medtronic promised—it continues to have problems and continues to underperform. Because most endocrinologists were trained on the Medtronic system, they have not wanted to switch, but the new Tandem t:slim line is now favored by diabetes educators and patients and will grow steadily.

Insulin Pump Market Conditions

- Did not discuss.

Medtronic

- “The MiniMed recall did not surprise me. This is older technology in a new wrapper.”
- “Endocrinologists have been very loyal to Medtronic. Most trained on Medtronic systems and the MiniMed and don’t really want to acknowledge its shortcomings.”
- “The Medtronic MiniMed sensors have had a poor reputation and a history of problems since its launch. The sensors would fail and had to be replaced. Medtronic told their customers the 670G would be replacing the 630 and this would solve the problem, but it never did.”
- “Medtronic told their customer base when they were having these problems with the MiniMed 630 to stay with them, as the 670G was coming to market soon and all patients could be upgraded to the 670 without a charge. Now, as we’ve seen, the 670 did not solve the problem and they are still fixing the system, one patient at a time.”
- “The four-year warranty is a program that keeps the patient on the MiniMed. I don’t see where there will be significant changes with the MiniMed in the short term.”
- “I remember at a meeting where we were shown that it takes approximately 15 years for an endocrinologist trained on one system—they referenced the MiniMed system—to completely change to a new manufacturer with a new technology.”

Omnipod is strong with pediatrics. If the doctor asks parents if they would prefer a tubeless system, many will say yes and not focus on the shortcoming of the non-integrated system. Once they start, at an early age, they are more likely to stay on the system for a longer time.

Former Tandem sales representative now selling insulin

Tandem

- “Tandem never had problems like Medtronic has.”
- “Younger endos and patients new to therapy will continue to drive the growth of Tandem. The t:slim X2 product line is superior to the MiniMed system and does not have the problems that the MiniMed can’t shake.”
- “Tandem’s growth will be slow but steady. Patients and diabetic educators

Insulin Pumps

will drive this growth more than the endos will.”

Insulet

- “Omnipod is strong with pediatrics. If the doctor asks parents if they would prefer a tubeless system, many will say yes and not focus on the shortcoming of the non-integrated system. Once they start, at an early age, they are more likely to stay on the system for a longer time.”

Other Technologies

- “Another important innovation in insulin delivery is how to get past the bolus and get insulin acting faster. The technology of the MiniMed pump was credited to [Dr. Mann](#) who left Medtronic to start up the [MannKind Corporation](#) (MNKD) focused on more rapid insulin delivery and the inhaled insulin product they have recently introduced.”

4) Industry Specialist

Medtronic is currently the insulin pump market leader, but the latest recall will negatively impact sales because of the trust and confidence that patients must have in their equipment. There are other, better alternatives on the market that will likely be used more frequently as patients become nervous about the reliability of their Medtronic pumps. This diabetic uses the Tandem pump integrated with the Dexcom CGM and thinks it is the best pump on the market today. They expect both Tandem and Insulet will experience increased sales because of the Medtronic recall.

Key Silo Findings

Insulin Pump Market Conditions

- The insulin pump market is competitive, with Medtronic the dominant provider for now. Pump technology is constantly changing and patient loyalty to any brand is limited.

Medtronic

- Patient and medical professional trust in Medtronic is being eroded because of the MiniMed recall. Also, the company’s proprietary supplies and add-on equipment requirement aggravates patients and is expensive.

Tandem

- Tandem integrated with a Dexcom CGM is this source’s pump of choice—they believe it is the best pump on the market. They do expect the Medtronic recall to lead to more sales of the Tandem pump.

Insulet

- The Omnipod is considered technologically advanced and it should see increased sales due to the MiniMed recall.

Other Technologies

- This source is watching Beta Bionics and if it is truly a breakthrough they will consider switching.

1) Diabetes patient for more than 30 years who has done extensive research on insulin pumps

Insulin Pump Market Conditions

- “The market is fairly competitive, with only one leader—Medtronic—for now.”
- “The technology is changing literally on an almost daily basis.”
- “Patient trust is huge. If a patient gets nervous about their equipment, their loyalty to that product is very thin. They’ll switch in a minute.”
- “My doctor and I are a team when it comes to my diabetes care. I don’t know if this is typical or not. I decide which pump and supplies I am going to use, present the data to my doctor, and we go forward together. I would hope that this is more of the typical way that patients and endocrinologists relate to each other. Either way, I can’t imagine that an endocrinologist would continue to prescribe a piece of equipment that her/his patient is not comfortable with.”

Medtronic

- “The reaction to the recall is likely to impact Medtronic’s sales of pumps, due to eroding patient trust.”

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- “There are other considerations for the patient than just the make of their pump. Medtronic equipment and supplies are totally proprietary, meaning that only Medtronic supplies can be used with their pumps. This is quite aggravating for many patients, as it is expensive. Other pumps use a generic Luer lock to connect the tubing, etc. These can be purchased locally and generically and are much less expensive.”

Tandem

- “I use Tandem now and am totally comfortable with it.”
- “It is smaller than most pumps [at 2 x 3½ inches]. It has a touchscreen and is very easy to use. I continue to monitor the technology and will switch if anything better is developed, but it is my opinion that this pump is the best on the market.”
- “Recently the FDA approved the Dexcom continuous glucose monitoring device. I am using it together with my Tandem pump. The two work together and, with minor programming that I did myself, monitor my blood sugar 24/7.”
- “The satisfaction that I am having with the combination of these two devices is not going unnoticed. I suspect that more patients will begin to do what I am doing.”

Insulet

- “These pumps are also technologically advanced, but I don’t think that they are quite as good as Tandem, yet.”
- “I think they will also experience a jump in sales due to the recall, but just how much, I am not sure.”

Other Technologies

- “The development of the interactive glucose monitoring devices is going to be a game changer. The one that I use, after I input my base amount, adjusts to what I eat, how much exercise I am doing, etc. It’s extraordinary.”
- “I am watching the Beta Bionics developments, but am totally satisfied with what I have now. If this turns out to be a true breakthrough, then I’ll consider it after it is proven.”

There are other considerations for the patient than just the make of their pump. Medtronic equipment and supplies are totally proprietary, meaning that only Medtronic supplies can be used with their pumps. This is quite aggravating for many patients, as it is expensive.

Diabetes patient for more than 30 years who has done extensive research on insulin pumps

Secondary Sources

These three secondary sources focused on a recent security breach at Tandem, the FDA’s approval of Tandem’s Basal-IQ as an interoperable automated glycemic controller (iAGC), and the impact of diabetic device recalls.

March 23 The Daily Swig [article](#)

Tandem suffers a data security breach.

- “A US-based manufacturer of medical devices for diabetes patients has revealed that customer data was exposed during a phishing attack that breached five employee email accounts in January.”
- “In a [press release](#) issued on March 16, San Diego-based Tandem Diabetes Care said the compromised email accounts contained “customer contact information, information related to the use of Tandem’s products or services, and/or clinical data regarding customer diabetes therapy.”
- “In some ‘very limited instances,’ customer Social Security numbers may also have been compromised.”
- “After discovering the attack, the company said it immediately secured the affected email accounts and launched an investigation, which found that an unauthorized user had gained access to the affected accounts between January 17-20, 2020.”
- “Tandem Diabetes Care said there was ‘no indication that any customer information was accessed by the unauthorized user and there has been no indication that any customer information has been misused.’”
- “The company said it notified potentially affected customers of the incident via letters sent out on March 17.”
- “Customers whose Social Security numbers were potentially exposed have been offered complimentary membership of credit monitoring and identity protection services.”

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- “We take the protection of our customer data very seriously, and regrettably, we did not meet the high standard we set to prevent this type of phishing attack from occurring,” said John Sheridan, president and chief executive officer of Tandem Diabetes Care.”

March 2 AP News [article](#)

Tandem’s Basal-IQ technology receives FDA interoperable automated glycemic controller (iAGC) designation.

- “Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced U.S. Food and Drug Administration (FDA) clearance of its Basal-IQ™ technology as an interoperable automated glycemic controller (iAGC). This is the second system to receive iAGC designation by the FDA, following the Company’s clearance of the t:slim X2™ insulin pump with Control-IQ™ technology in December 2019.”
- “The FDA has classified three categories for the interoperability of devices as a complete automated insulin dosing (AID) system, which include an alternate controller-enabled insulin pump (ACE pump), an integrated continuous glucose monitor (iCGM) and an iAGC. The t:slim X2 insulin pump was also the first to receive an ACE infusion pump classification in February 2019, and the first insulin pump designated as compatible with iCGM devices in June 2018.”
- “Aligning Basal-IQ technology with Control-IQ technology under the FDA’s new regulatory path helps streamline our internal processes and provides us with a consistent approach to making future product enhancements,” said John Sheridan, president and chief executive officer. “Customer choice is a core tenet of our Company and this clearance supports our commitment to the interoperability of our AID technologies with our current and future insulin pump offerings.”

Feb. 25 Healthline [article](#)

This article addresses the impact of diabetes product recalls and covers both the recent Medtronic and Insulet recalls.

- “In light of recent product safety news about [Medtronic insulin pumps](#) and [Insulet’s Omnipod DASH system](#), (see details below), we started thinking about the chain of events that follows the headlines:
 - What if customers are concerned about continuing to use the product?
 - Is the company communicating clearly and providing adequate customer service?
 - Do health insurance companies care if a product they cover or recommend is presenting possible dangers?
 - How do doctors and diabetes care specialists respond to patients with concerns?”
- “All of this hit home recently for Paul Dobbertin, a longtime type 1 in the Chicago suburbs who became concerned about his Medtronic insulin pump after seeing a swarm of media coverage following the recent FDA warning about a product recall. He phoned the company and fought to get a replacement device, despite customer service downplaying the situation and insisting his unit didn’t need replacing.”
- “‘We are right to be concerned,’ he says. ‘Managing all the details of a system along with type 1 diabetes is a lot of work and expensive already, without the added worry of faulty equipment and a known problem.’”
- “The Minimed 600 series of devices are impacted by a tiny part on the top of the pump called the retainer ring, which is supposed to keep the insulin reservoir secure inside the pump. A malfunction can cause it to crack or come loose, interfering with insulin delivery and possibly leading to a user receiving more or less insulin than they’re supposed to. It wouldn’t lead to an emptying of the reservoir, Medtronic tells us, but could cause an insulin delivery delay or a faster, unscheduled bolus different than what was expected.”
- “Within a day of the Medtronic 600 series recall announcement, Insulet issued a medical device correction alert about the tubeless Omnipod DASH patch pump and its personal diabetes manager (PDM) used to control the system. Described as a precautionary measure, the notification says there’s a remote possibility that the PDM “may suggest an insulin bolus amount based on incorrect information” and that could result in too much or too little insulin being delivered.”
- “In Texas, endocrinologist and diabetes author [Dr. Stephen Ponder](#) says he also discusses any recalls with patients and lets them decide how to proceed. Sometimes, they’ll want to contact a company about a specific concern, whereas at other times patients are confident they don’t have a malfunctioning device and are happy to keep using it.”
- “‘In my experience, recalls are simply a part of life,’ he said. ‘I don’t know if we are rushing products to market too soon or not. We do have a more sophisticated user base in diabetes now than any time in history and that user base

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is interconnected through social media. That allows product problems to reverberate with greater and more rapid intensity than in the 70s, 80s, or 90s.”

Additional research by James Boland and Bruce Wicks.

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