Medical Technologies to Watch in 2024: Five transformative areas of innovation

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Contents

Methodology

Selection of technologies

Clarivate™ analysts look for high anticipated growth and industry impact when selecting technologies for this report. The five technologies chosen are forecast to add significant value (>1bn) and/or grow rapidly (double digits-plus) in the next five years.

These technologies are generating buzz and investment, have a range of competitors and cover a range of therapeutic areas.

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Introduction

Medtech is having a moment

It's been a trying several years for many medtech companies, with the impact of the COVID-19 pandemic and economic uncertainty, among other factors. The sector has nonetheless proven resilient, as shown by a spate of game-changing emerging medical technologies like pulsed field ablation.

To give them their due, we convened our Clarivate medtech analysts to look at the technologies driving the greatest clinical and commercial value in devices and diagnostics today — areas that hold the promise of delivering enormous benefit to patients in the coming years. In some cases, such as continuous glucose monitors, these technologies have the potential to complement and/or amplify the impact of traditional medications. In others, like renal denervation, they could replace biochemical solutions altogether.

Each of the five technologies chosen by our analysts shows potential for double-digits-plus market growth over the next five years and/or potential to generate substantial value ($1bn-plus) over the same period. They are generating a lot of buzz and attracting investors, spanning multiple therapy areas and competitors.

These technologies to watch include pulsed field ablation, neurostimulation, surgical robotics, renal denervation and diabetes care devices like continuous glucose monitors (CGMs). Our analysis examines the potential benefits to patients, clinical and market impacts, hurdles to adoption and key competitors in each segment. Our analysts drew on Clarivate's proprietary data and intelligence solutions, including Medtech 360 industry reports, real world data (Procedure Finder), market share and price tracking tools (Marketrack / Pricetrack), and Cortellis Competitive Intelligence™ and Cortellis Deals Intelligence™.

The sector faces its share of challenges in delivering on this promise. Unlike biopharma, whose financing picture has brightened appreciably in the past year, medtech remains in the doldrums. Deals and M&A activity declined in 2023 amid earnings challenges, rising interest rates, macroeconomic uncertainty and antitrust pressures, as noted in our companion report, Medtech Trends to Watch in 2024. However, our analysts are optimistic that 2024 will bring a more favorable economic climate for medtech competitors, noting that the macro trends remain positive.

Unlocking that potential to its fullest requires rock-solid, actionable intelligence that empowers medtech players with an understanding of their patients and clinicians as well as competitive dynamics and a fast-changing regulatory environment.

"The sector faces its share of challenges in delivering on this promise."

"The medical device industry has long supported healthcare deployment and delivery by pushing the boundaries of what technology can achieve. Having access to the right information empowers stakeholders to support the use cases that will make the greatest difference to the future of care."

Andrew Lee,
Vice President, Product Development for Medtech at Clarivate.

Medical Technologies to Watch: **Pulsed field ablation devices**

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Pulsed field ablation (PFA) has emerged as a promising treatment for atrial fibrillation (AF), garnering significant attention from the cardiac ablation community. Pulsed field ablation employs electric pulses, not heat, that help in electroporation of the myocardium without collateral damage to normal heart tissue.

Compared to established treatment options, PFA has remarkably low recurrence rates, shorter treatment durations and higher success rates[1].

PFA at a glance

Key competitors[2]

- Medtronic,
- Boston Scientific,
- Biosense Webster (J&J),
- CardioFocus

Indication treated

- Atrial fibrillation (AF)

Why is it a medical technology to watch?

Impact

- AF affects more than **60m** people worldwide[6]
- In the US, PFA is expected to account for over **400,000** ablation procedures in 2028[6]
- PFA is expected to penetrate **>60%** of all AF procedures performed by 2028[6]

PFA demonstrates a significantly enhanced safety and efficacy profile compared to existing AF ablation treatments. Anticipated to show rapid, widespread adoption, PFA is poised to drive a shift away from traditional ablation methods. Notably, several competitors have been actively developing PFA devices. Boston Scientific, as a first mover, secured global entry in 2021 with CE mark approval for its FARAPULSE device. This was followed by the 2022 CE marking of the CENTAURI PFA system (at the time under Galaxy Medical but now owned by CardioFocus).

In 2023, FARAPULSE gained approval in Australia, while Medtronic achieved the distinction of being the first company to receive CE mark approval for two PFA systems—its PulseSelect and Affera systems—in Europe. In the U.S. market, Medtronic's PulseSelect system obtained approval in December 2023,[3] followed by Boston Scientific's FARAPULSE in January 2024.[2] Biosense Webster and Jinjiang Electronic also made history by securing first-ever approvals for their PFA systems in Japan and China, respectively.[4,5]

The PFA market, projected to reach $3bn by 2028, is highly lucrative, especially considering the potential global population of 60m individuals with AF.[6] As the field of electrophysiology mapping and ablation rapidly evolves, upcoming approvals hold the potential to reshape this dynamic and profitable market.

Key dates

November 2023: Medtronic becomes first company to have CE mark for two PFA systems in Europe[3]

December 2023: Medtronic receives first-ever U.S. FDA approval for its PulseSelect PFA system[3]

January 2024: Biosense Webster receives first-ever approval in Japan for its VARIPULSE PFA system[4]

January 2024: Jinjiang Electronic Science and Technology receives first-ever approval in China for its LEAD-PFA system[5]

January 2024: Boston Scientific receives U.S. FDA approval for its FARAPULSE PFA system[2]

How will PFA impact the electrophysiology mapping and ablation device market?

PFA is expected to cannibalize the electrophysiology mapping and ablation market. While PFA is anticipated to replace existing ablation techniques due to its superior success rates and reduced adverse effects, it is also expected to boost overall ablation volumes owing to its shorter procedure duration.

In 2023, the global PFA market value was estimated at $232m, with the only active players in Europe and Asia Pacific.[6] Driven by rapid developments and heightened interest in PFA, the global PFA market is expected to grow to $3bn by 2028.

The U.S. ablation catheter market is currently estimated at $1.4bn and poised to grow in the double digits over the next five years. PFA, which launched in the U.S. market in 2024, is expected to make up about 50% of the U.S. ablation catheter market by 2028.

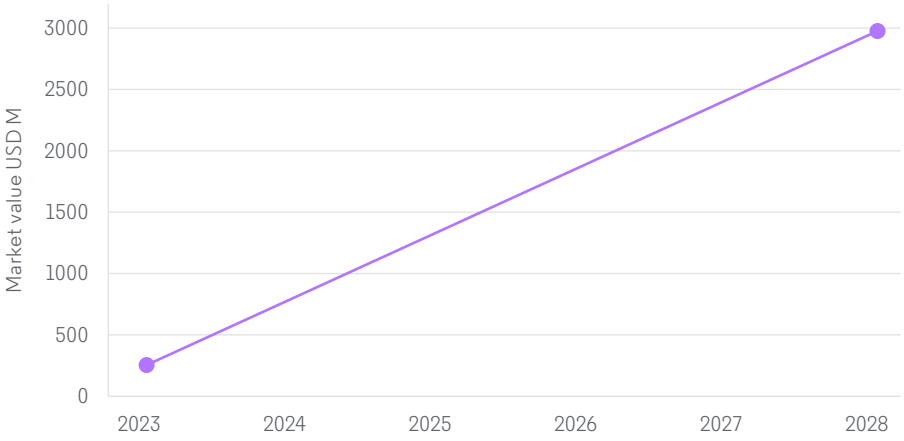
The ongoing approvals and launches of PFA technologies have also intensified competition among players in this space. Given its first-mover advantage, Boston Scientific has dominated the global PFA market. However, Medtronic has two distinct PFA devices approved in multiple markets now and is expected to take over the lead. Biosense Webster will also rapidly capture share once it enters the global market, as its VARIPULSE PFA system is the only system integrated with a 3D mapping system. Several other PFA systems are currently in development alongside these, and upcoming approvals could significantly impact the dynamics of the lucrative electrophysiology mapping and ablation market.

$3bn

expected global PFA market value by 2028

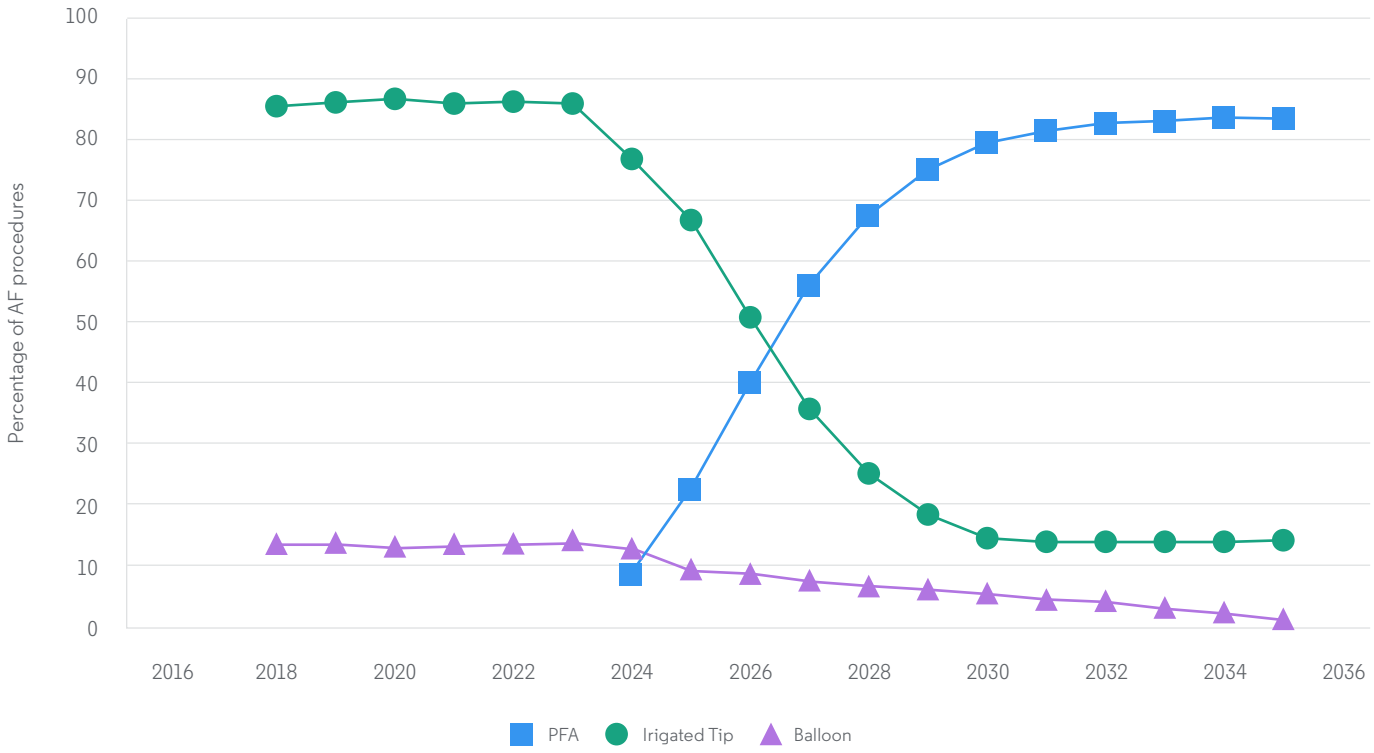
The value of the global PFA market is forecast to rise steadily

Figure 1: Global PFA Market Value



Source: Clarivate

Figure 2: Ablation catheters in AF



Source: Clarivate

What gaps in treatment does PFA fill?

PFA represents an innovative approach for selectively ablating cardiac tissue using a precisely controlled electric field. In contrast to conventional methods, which rely on extreme temperatures, PFA operates non-thermally.

By leveraging high-frequency electrical pulses, PFA minimizes collateral damage to adjacent structures, including the esophagus, pulmonary veins, and phrenic nerve. This irreversible electroporation technique efficiently mitigates risks, surpassing existing technologies and significantly reducing overall procedure durations.

For instance, in the ADVENT clinical trial, Boston Scientific's FARAPULSE demonstrated a remarkably low adverse event rate of 0.9% compared to the head-to-head comparison group using thermal ablation (12%).[7] Furthermore, the PFA group achieved shorter procedure times, with an average duration of 50 minutes, in contrast to the control thermal ablation group's 292 minutes. Notably, the PFA group exhibited comparable or superior efficacy and recurrence rates compared to the control group. These compelling data underscore the disruptive potential of PFA within the electrophysiology mapping and ablation market.

What hurdles will PFA face in terms of adoption?

PFA technology boasts clear advantages and its adoption faces few hurdles. While few inherent limitations exist for PFA, the accumulation of robust clinical evidence will be necessary to facilitate its expansion into other medical indications. Notably, alternative treatment modalities may be more suitable for cases requiring deep tissue ablation, such as ventricular tachycardia, where PFA's penetration depth is limited.

"As the first PFA device to get CE mark approval and also the first PFA device to have received regulatory approval anywhere and to have launched commercially, Farapulse has the advantage of having been available on the global market for a longer period than Medtronic's Pulseselect."

Pankhil Paresh Gandhi,
Senior Team Lead, Healthcare Research & Data Analytics, Medtech Insights.

References

1. Nour Shaheen, et al., 2023. Efficacy and safety of novel pulsed field ablation (PFA) technique for atrial fibrillation: A systematic review and meta-analysis. *Health Science Reports*.

2. BioWorld, 2024. *Boston Sci's Farapulse approval intensifies PFA competition*. [Online] Available at: www.bioworld.com/articles/704936-boston-scis-farapulse-approval-intensifies-pfa-competition

3. BioWorld, 2023. *Medtronic gains FDA approval for Pulseselect PFA system*. [Online] Available at: www.bioworld.com/articles/703546-medtronic-gains-fda-approval-for-pulseselect-pfa-system

4. BioWorld, 2024. *Biosense scores Japan approval for Varipulse PFA system*. [Online] Available at: www.bioworld.com/articles/704287-biosense-scores-japan-approval-for-varipulse-pfa-system

5. BioWorld, 2024. *First PFA device granted NMPA approval in China*. [Online] Available at: www.bioworld.com/articles/704299-first-pfa-device-granted-nmpa-approval-in-china

6. Clarivate | *DRG, 2023. Market Insights: Electrophysiology Mapping and Ablation Devices*, s.l.: Clarivate.

7. Vivek Y. Reddy, et al, 2023. Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. *New England Journal of Medicine*, pp. 1660-1671.

Medical Technologies to Watch: **Diabetes care devices**

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Diabetes care technology is poised for significant growth in the near future, driven by ongoing advancements in medical technology aimed at treating patients with diabetes.

As the population of individuals affected by diabetes globally continues to grow, so does the opportunity for competitors within this sector to continue to innovate and introduce cutting-edge technology for diabetes management.

Key factors affecting the market growth are increasing availability of non-invasive alternatives and diversification of the market, with the entry of newer competitors and increasing patient awareness.

Beyond these developments, significant activity is also underway in the development of alternative treatment options for diabetes management, including new drug therapies and several medical procedures which could potentially impact the growth trend of the diabetes care technology market in the coming years.

Diabetes care at a glance

Key competitors

- Medtronic (MiniMed 640G MiniMed 780G, Guardian Sensor 3)
- Abbott Laboratories (Freestyle libre 3)
- Dexcom (Dexcom G7)
- Insulet (Omnipod 5)
- Tandem Diabetes care

Indication treated

- Type 1 Diabetes
- Type 2 Diabetes

Technologies to watch out for

- CGM market segment
- Insulin pump market

Why is it a medical technology to watch?

Impact

- Diabetes affects approximately **537m** adults worldwide[12]
- **90%** of the diabetes population are diagnosed with type 2 diabetes
- The continuous glucose monitoring segment and insulin pump device segment are projected to reach **$12bn** by 2028[12]
- The patch pump market within the insulin pump device market is projected to grow at a CAGR of **13%** by 2032[12]

The continuous glucose monitoring segment has been growing rapidly in the recent years, and this growth shows no sign of slowing. Dexcom and Abbott Laboratories dominate this market segment, having made considerable strides in their existing products, with a focus on compact, all-in-one sensor transmitter designs and device optimization. Furthermore, the recent expansion of Medicare coverage for CGM devices[1] to encompass individuals with type 2 diabetes using any form of insulin, along with certain non-insulin users who may qualify for CGM device coverage due to a history of problematic hypoglycemia, has made CGM devices more accessible to a broader patient base.

Nonetheless, Medtronic's Simplera CGM, currently seeking FDA approval after receiving CE marking,[2] marks a significant improvement over its previous Guardian sensor 4 CGM in terms of size, ease of use, and accuracy. This could potentially help Medtronic regain ground in the CGM market, in which they haven't actively innovated for some time.

A new wave of non-invasive CGMs is emerging, potentially disrupting the traditional CGM market.

While existing CGM companies focus on minimizing the sensor size for making it aesthetically appealing, Senseonics takes a different approach with their Eversense E3. This FDA-approved CGM[3] features a sensor that is implanted under the skin and lasts six months, compared to current patch-based devices like the Dexcom G7 or Abbott's Freestyle Libre 3, which last for weeks at most. This innovation caters to patients seeking a discreet and long-lasting solution, requiring relatively few sensor changes. It positions Senseonics as a strong competitor with the potential to capture market share from the current leaders moving forward. Additionally, Glysens' fully implantable Eclipse ICGM system, expected to last a full year, is another development to watch in this space.

A new wave of non-invasive CGMs is emerging, potentially disrupting the traditional CGM market. One example is Know Labs' KnowU system, currently in development and expected to enter the pre-FDA approval process later in 2024.[4] This technology utilizes Bio-RFID to measure glucose levels, potentially offering a more affordable option due to its simpler design and lower manufacturing costs as well as eliminating the need for sensor implantation or insertion into the body. However, accuracy of data for detecting hypoglycemia levels through these non-invasive devices remains a major hurdle for these new entrants. Extensive clinical trials and real-world use are needed to verify their long-term performance and effectiveness.

In addition, brand reputation and established clinical data supporting existing Dexcom and Abbott Laboratories CGMs may limit widespread adoption of newer entrants, despite the potential cost benefits of alternatives.

Nemaura Medical's sugarBEAT CGM offers another example of this new segment. The company has already received CE marking and Saudi Arabia's SFDA approval, granting it a first-mover advantage. Nemaura Medical, like Know Labs, is also seeking FDA approval for its non-invasive CGM. While these advancements have great potential, accessibility remains a concern. Establishing both clinical efficacy and affordability will be crucial for widespread adoption of these novel CGM technologies.

Major tech companies like Apple and Samsung are developing smartwatches with non-invasive glucose monitoring capabilities.[5] However, the FDA recently warned against using them for this purpose.[6] Tech giants have made significant progress with smartwatch health features.

For example, Apple's ECG app, approved by the FDA in 2018 to monitor heart rhythm, has seen widespread adoption. While its accuracy may not match medical-grade equipment, it offers a decent alternative. However, the same level of accuracy isn't guaranteed for blood sugar monitoring.

Extensive clinical trials and real-world data are needed to establish the effectiveness of smartwatches for glucose measurement. Inaccurate readings can lead to incorrect insulin or medication dosages, potentially causing dangerously high blood sugar and limiting adoption.

The continued introduction of innovative solutions like hybrid closed-loop systems is fueling the overall growth of diabetes care technology. Medtronic, the first to enter this market, initially faced challenges due to FDA safety concerns and recalls involving its MiniMed devices. However, the company overcame these obstacles and received FDA approval for its advanced MiniMed 780G in April 2023.

Minimizing device size and reducing device complexity remains a key focus for manufacturers. This is evident in the recent growth in the patch pump market. These are a type of insulin pump designed to be worn directly on the skin like an adhesive patch, and are exemplified by the strong performance of Insulet's Omnipod 5, the only tubeless patch pump on the market. The FDA-approved Omnipod 5 offers several advantages over tethered pumps. Similarly, Roche's Accu-Chek Solo patch pump recently received FDA clearance,[7] adding to the company's existing CE mark and potentially boosting market presence.

Recognizing the growing patch pump market within hybrid closed-loop systems, competitors like Medtronic and Tandem Diabetes Care are developing their own patch pumps. They are joined by new entrants like PharmaSens, which is seeking FDA approval for its niia patch pump, promising extended wear time and potentially improving user convenience. If approved, these newcomers will take on Insulet, the current leader in the patch pump market, whose established brand presence and widespread physician adoption could prove formidable.

The use of hybrid closed-loop systems is more common among individuals with type 1 diabetes. Several companies are conducting clinical trials to test the effectiveness of these hybrid closed loop systems for type 2 patients. For instance, insulin pumps from Medtronic (MiniMed 780G)[8] and Insulet (Omnipod 5)[9] are undergoing clinical trials to study their effectiveness. Positive outcomes from these trials could pave the way for expanded indications, making these systems accessible to a much wider range of type 2 diabetes patients.

Another significant area worth monitoring is the fully closed-loop insulin delivery system. On May 22, 2023, the U.S. Food and Drug Administration (FDA) granted 510(k) clearance to Beta Bionics' iLet Bionic Pancreas, marking a pivotal milestone in diabetes management technology.

The iLet stands as the first and sole fully automated insulin delivery system approved for individuals with type 1 diabetes aged six and above. Unlike conventional pumps that necessitate users to calculate and administer insulin doses, the iLet autonomously determines and dispenses both basal and bolus insulin based on CGM data and an algorithm.

The iLet eliminates the necessity for manual carb counting, streamlining management for users. Clinical trials evidenced that the iLet facilitated users in achieving superior time-in-range and HbA1c levels compared to traditional insulin pumps. Beta Bionic's iLet Bionic Pancreas distinguishes itself through its algorithms designed to automate insulin delivery using data from a paired Dexcom G6 CGM device with minimal user input relative to other available devices, including simplified estimations of carbohydrate consumption. Alongside Beta Bionic's iLet Bionic Pancreas, the EOFlow EOpatch pump is another device within the closed-loop insulin delivery market seeking FDA approval.

Key dates

February 2022: Senseonics received FDA approval for its Eversense E3 CGM

May 2022: FDA approved Abbott Laboratories' freestyle libre 3 CGM device

December 2022: Dexcom received FDA approval for its G7 CGM product

January 2023: EOFlow submitted application for its EOPatch pump for FDA approval

March 2023: CMS expanded the coverage of CGM devices for the people with type 2 diabetes

April 2023: Medtronic received FDA approval for its MiniMed 780G hybrid closed-loop system

May 2023: Beta Bionic's iLet Bionic Pancreas received FDA approval

July 2023: Tandem Diabetes Care received FDA approval for its Tandem Mobi insulin pump

March 2024: Dexcom received FDA approval for its Stelo glucose biosensor, the first over-the-counter CGM

How will CGM and insulin pump devices impact the market for diabetes care?

The CGM market is expected to boost the overall diabetes care device market and is projected to reach $7.5bn by 2032 in the U.S. Extended CMS coverage makes the device affordable to a larger type 2 diabetic patient pool, thereby increasing demand and the patient base for these products.[12] Nonetheless, the entry of noninvasive competitors will expand the CGM market. Non-invasive alternatives do not pose an immediate threat to established CGM products due to limited accuracy, cost concerns and a lack of clinical backing.

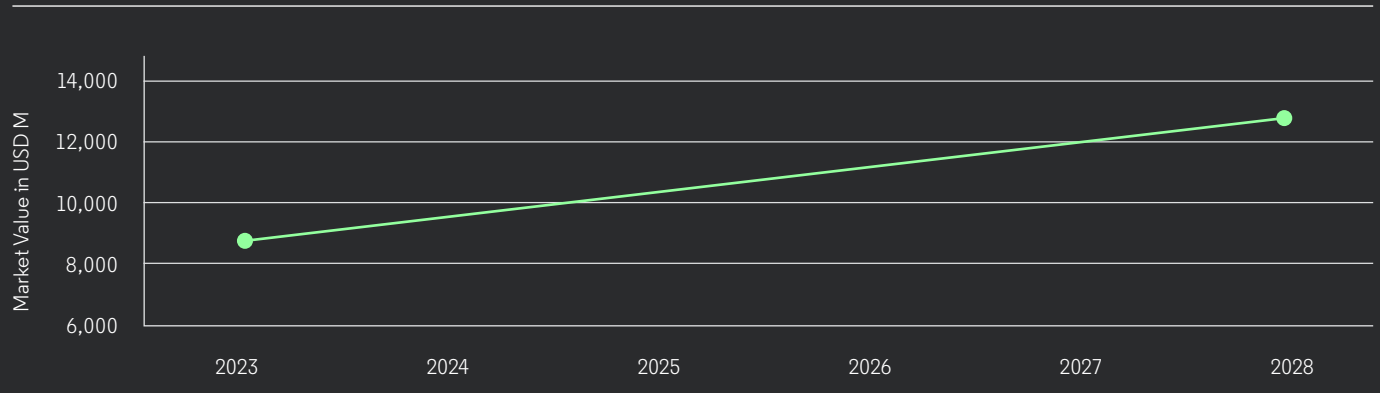
The future of hybrid closed-loop systems in the diabetes care market looks promising, especially with more manufacturers entering this space. Within the hybrid closed-loop system, the patch pump segment is going to experience significant growth relative to tethered pumps and is forecast to grow at a CAGR of 13% by 2032 globally.[12]

If clinical trials show positive results for hybrid closed loop pumps in type 2 diabetes, it could expand treatment options for this population, providing an alternative to traditional insulin therapy and oral medications. This would unlock a significant market opportunity for companies in this segment.

Nonetheless, the fully closed loop systems offer numerous advantages over existing hybrid closed systems, and significant growth is anticipated in this product segment as more companies enter this space. This segment is poised to be the most lucrative area for growth in the future.

CGM and insulin pump uptake is forecast to rise substantially

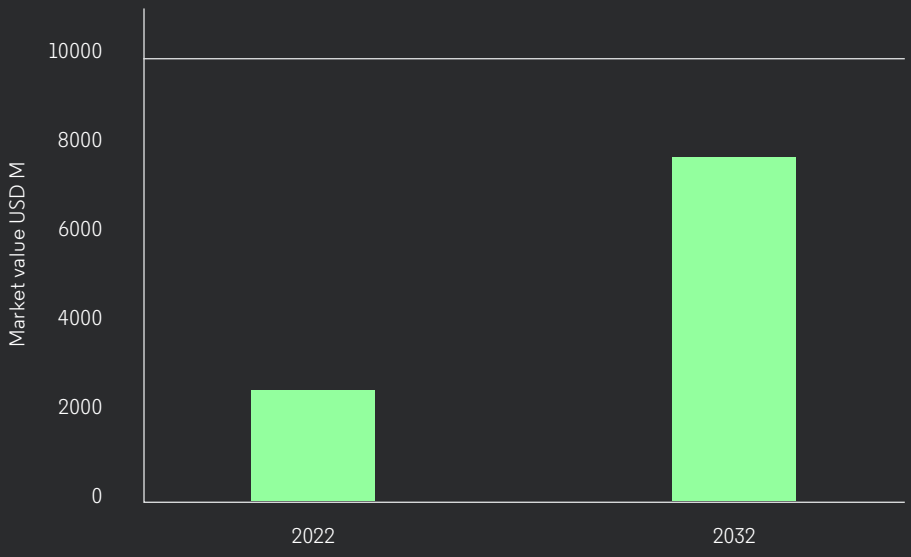
Figure 3: CGM device market



Source: Clarivate

U.S. CGM device sales are expected to double by 2028

Figure 4: CGM Device Market



Source: Clarivate

What gaps in treatment does diabetes care technology fill?

The major challenge in treating Type 1 and Type 2 diabetes lies in the continuous management of blood sugar levels, typically mediated by various methods of insulin injection. Traditionally, patients and caregivers relied on painful fingerprick-style sensing. CGMs offer a valued alternative, helping reduce patient burden and keep blood sugar within an appropriate range. These advances in CGM technology seek to make blood sugar readings more accessible to patients by increasing the lifespan of the device, reducing its invasiveness, or making the implant more aesthetically appealing. With greater usability for patients, CGMs aim to help patients adhere to treatment plans, leading to better long-term outcomes.

Closed-loop systems aim to aid patients in maintaining appropriate blood sugar levels through the direct pairing of an insulin pump to a CGM, which is intended to reduce patient burden and automatically adjust insulin levels in response to patient blood sugar. The development of closed-loop insulin systems benefits patients in offloading the work that patients would otherwise perform with multiple daily insulin injections. Coordination between CGMs and insulin pumps represent another step in diabetes management, which aims to maintain appropriate blood sugar levels while reducing the burden on patients.

What hurdles will diabetes care technology face in terms of adoption?

A potential hurdle for long-term adoption of diabetes care technology is the recent rise of GLP-1 receptor agonists (GLP-1 RAs), due to their demonstrated efficacy in blood sugar control in individuals with type 2 diabetes. However, due to the high relative penetration for insulin pumps in the type 1 diabetic population, GLP-1s are not expected to have a paradigmatically strong effect on the insulin pump market in the short term. Instead, GLP-1 use on those in the early stages of Type 2 diabetes is more likely to limit market uptake by reducing the addressable population of those requiring insulin. Given the low penetration of insulin pump use in Type 2 diabetes, the effect of GLP-1 adoption on the insulin pump market as a whole will be limited, pending approvals for insulin pump systems in type 2 patients.

By contrast, GLP-1 RAs may have a paradoxically positive impact on the CGM market in the long run. Industry leaders like Abbott and Dexcom reported increased stronger correlated use of CGMs with GLP-1 RAs, suggesting stronger adherence to treatment plans with their combined use and reflecting healthcare professionals' advocation for complementary use of both CGMs and GLP-1 drugs.

Additionally, disease-modifying procedures, like those being developed by Endogenex, Fractyl Health, and Morphic Medical, could potentially limit the diabetes care technology market. These procedures aim to address the root cause of the disease, potentially offering a more long-term solution compared to traditional medications.

Endogenex's RECET procedure, for example, uses electroporation therapy to stimulate the regeneration of insulin-producing cells[10]. Unlike medications that only manage symptoms while being taken, RECET aims to modify the underlying condition of type 2 diabetes. Similarly, Morphic Medical's (formerly GI Dynamics) RESET device is undergoing clinical trials to assess its ability to reduce A1c and weight[11].

Clinical trials have shown significant positive results, and while the procedure does not yet have much market penetration, it could ultimately limit sales of insulin and consequently, the insulin pump market segment. However, the associated cost of these procedures and reimbursement availability will be a key factor in determining their growth.

References

1. Centers for Medicare & Medicaid Services, 2024. *Glucose Monitor - Policy Article*. [Online] Available at: www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464

2. BioWorld, 2023. *Medtronic gets CE mark for Simplera continuous glucose monitor.* [Online] Available at: www.bioworld.com/articles/701189-medtronic-gets-ce-mark-for-simplera-continuous-glucose-monitor

3. U.S. Food & Drug Administration, 2022. *Eversense E3 Continuous Glucose Monitoring System - P160048/S016*. [Online] Available at: www.fda.gov/medical-devices/eversense-e3-continuous-glucose-monitoring-system-p160048s016

4. Know Labs, 2024. *Know Labs Announces the KnowU™, its Wearable Non-Invasive Continuous Glucose Monitor.* [Online] Available at: https://www.knowlabs.co/post/know-labs-announces-the-knowu-its-wearable-non-invasive-continuous-glucose-monitor

5. Bloomberg, 2024. *Samsung Races Apple to Develop Blood Sugar Monitor That Doesn't Break Skin*. [Online] Available at: www.bloomberg.com/news/articles/2024-01-22/samsung-races-apple-on-noninvasive-glucose-checks-blood-pressure-monitoring

6. U.S. Food and Drug Administration, 2024. *Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication.* [Online] Available at: www.fda.gov/medical-devices/safety-communications/do-not-use-smartwatches-or-smart-rings-measure-blood-glucose-levels-fda-safety-communication

7. Roche, 2023. *The Accu-Chek Solo micropump system received 510(k) clearance*. [Online] Available at: www.rochediabetes.com/media/blogs/accu-chek-solo-micropump-system-received-510k-clearance

8. Medtronic Diabetes, 2024. *In-Home Study With MiniMed™ 780G Pump Automated Control in Type 2-Evaluation of the AHCL System in Adults With Insulin-requiring Type 2 Diabetes*. [Online] Available at: classic.clinicaltrials.gov/ct2/show/NCT05238142

9. Insulet Corporation, 2024. *OP5-005 Using Omnipod 5 in Adults With Type 2 (SECURE-T2D).* [Online] Available at: classic.clinicaltrials.gov/ct2/show/NCT05815342

10. BioWorld, 2023. *Treatment with Endogenex device eliminates the need for insulin in type 2 diabetes*. [Online] Available at: www.bioworld.com/articles/697485-treatment-with-endogenex-device-eliminates-the-need-for-insulin-in-type-2-diabetes

11. GI Dynamics, 2023. *GI Dynamics announces company rebrand as Morphic Medical, reintroducing flagship product as RESET.* [Online] Available at: morphicmedical.com/gi-dynamics-announces-company-rebrand-as-morphic-medical-reintroducing-flagship-product-as-reset/

12. Clarivate. 2023.Medtech Insight Report: *Diabetes Care Devices*. December 15. Accessed May 15, 2024. insights.decisionresourcesgroup.com/device/diabetes-care-devices/market-insights/united-states/section/abstract

Medical Technologies to Watch: **Neurostimulation devices**

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The multibillion-dollar implantable neurostimulation device market will see continued growth as new and incumbent competitors expand treatable indications and launch new devices with design and lifespan improvements.

The hypoglossal nerve stimulation device (HGNS) market in particular has witnessed rapid growth, and it is expected to surpass most other neurostimulation device markets in size in upcoming years.

Neurostimulation devices at a glance

Key competitors

- Medtronic
- Boston Scientific
- Abbott Laboratories
- Inspire Medical
- LivaNova

Indication treated

- Chronic pain
- Incontinence
- Parkinson's disease
- Obstructive sleep apnea
- Epilepsy
- Others

Why is it a medical technology to watch?

Impact

- The implantable neurostimulation device market is large and growing; the U.S. and European markets were valued at over **$4.7bn** (combined) in 2023 and are expected to reach **$7.1bn** by 2028[15]
- The rapidly growing U.S. HGNS device market is expected to reach a value approaching **$2bn** by 2028[15]
- SCS devices—primarily used for the treatment of chronic pain—represent the highest revenues in U.S. and Europe, and this will remain the **largest market** through 2028[15]

Competitive dynamics are evolving at a rapid pace in both large, established device segments — such as the spinal cord stimulation (SCS) device and deep brain stimulation device (DBS) markets — and in newer, rapidly growing segments, such as the HGNS device market. While the individual neurostimulation device markets have reached varying levels of maturity, companies are seeking to expand revenue potential through the pursuit of expanded indications, as well as by introducing products with novel or improved mechanisms of action. The push for more effective and widespread treatment will drive revenues in this already sizeable market.

Companies are beginning to bring 'closed-loop' devices to market. These devices are intended to adjust stimulation in real time based on the patient's physiological response, and this model has the potential to provide effective, patient-specific treatment and extend implantable pulse generator lifespans through lower battery use.

- Saluda Medical's Evoke System closed-loop SCS system adjusts stimulation for chronic pain based on evoked compound action potential (ECAP) readings. This product is available in both the U.S. and Europe, and recent results from the Evoke and Avalon studies have been promising.[1,2]
- Medtronic is investigating closed loop technology in both the SCS and DBS device spaces. The company has incorporated 'adaptive' technologies (capabilities that enable better tailoring to patients) into its Percept PC DBS and Percept RC DBS devices, and it has received approval in Europe, and more recently, the U.S., for its Inceptiv closed-loop SCS device for the treatment of chronic pain[16].
- NeuroPace's RNS System, which treats epilepsy, responds to neurological readings that indicate that a seizure will occur.

Entrenched and emerging companies have been competing fiercely in the large SCS, DBS, and sacral nerve stimulation (SNS) device markets. For example, competitors have been increasing their focus on rechargeable device segments.

- Axonics brought the first rechargeable SNS device to the U.S. market in 2019. This launch broke Medtronic's monopoly in the SNS market and kicked off intense competition between the two players, each of which now offers both rechargeable and non-rechargeable devices.
- Abbott Laboratories has expanded its portfolio to include rechargeable SCS and DBS devices, bringing it to portfolio parity with Medtronic and Boston Scientific within these device segments.
- Medtronic recently launched the Percept RC, a new rechargeable DBS model that features significant battery improvements compared to its previous model, Activa RC. Medtronic has been facing competition from Boston Scientific's rechargeable Vercise Genus model, which boasts a long battery life, and the launch of Percept RC will improve Medtronic's competitiveness in this regard.

The SCS device market has been characterized by the pursuit of new indication approvals in the past few years as companies seek to bring their technologies to new patient groups.

- Nevro has been leading the charge, becoming the first competitor to gain FDA approvals for both the painful diabetic neuropathy and nonsurgical back pain indications.

- Major players are now assessing treatment of upper limb and neck pain.

- Use of HGNS for obstructive sleep apnea (OSA) has seen a made an impact on the U.S. in recent years. Inspire Medical, which currently monopolizes the U.S. market, has benefited from the rising number of insurance plans providing coverage there, enabling patient access.[3] The company has also been actively pursuing reimbursement for its Inspire system across various European countries.[4,5] HGNS is indicated for patients in whom continuous positive airway pressure (CPAP) devices have not been effective or tolerated, parameters within which some level of physician discretion is possible. For this reason, use has likely been bolstered in the wake of concerns about the safety of CPAP machines resulting from a series of safety-related recalls of systems manufactured by Philips Healthcare that began in June 2021 and ultimately culminated in Philips ceasing its sales of these systems in the U.S.early in 2024.[6]

LivaNova—a long-standing player in the neurostimulation device market through its vagus nerve stimulation (VNS) devices—is conducting the OSPREY trial to assess its aura6000 HGNS device. The approval of this device would propel further growth in this space. The aura6000 would be the first rechargeable HGNS device available in the U.S. This could give it a competitive advantage versus Inspire Medical's nonrechargeable device alone, and it would likely be sold at a higher price.

Key dates

August 2023: Medtronic receives approval in Europe for its Inceptiv closed-loop SCS device

December 2023: Medtronic receives approval in Europe for its Percept RC rechargeable DBS device

January 2024: Boston Scientific announces that it will acquire Axonics

January 2024: FDA approves Medtronic's Percept RC DBS device

January 2024: FDA approves Abbott Laboratories' Liberta RC DBS device

February 2024: FDA approves Boston Scientific's WaveWriter SCS device for nonsurgical back pain

April 2024: FDA approves Medtronic's Inceptiv closed-loop rechargeable SCS device

How will new approvals impact the market for neurostimulation devices?

The indications treated by neurostimulation devices are highly varied, but have in common severity and significant impact on patient lifestyles. These devices are generally used to treat patients that have not found success with other treatments. Because there remains high unmet need within these ailments, the potential efficacy of neurostimulation devices across a broad range of additional indications is being evaluated.

In the SCS device space, companies offering devices for the treatment of chronic pain have seen success in recent years in expanding the types of pain that their devices are able to treat.

Traditionally, SCS devices have been used for patients with chronic lower back pain that have previously undergone back surgery. A number of competitors have recently gained approval for treatment of painful diabetic neuropathy and non-surgical back pain. Notably, according to U.S. procedure claims analysis, SCS volumes associated with painful diabetic neuropathy, while remaining low overall, saw rapid growth in 2022. Competitors such as Nevro and Medtronic are exploring use of SCS for the treatment of upper limb and neck pain, but no company has received approval to date.

NeuroPace has initiated the NAUTILUS IDE study to assess the efficacy of its RNS technology in the treatment of idiopathic generalized epilepsy. Idiopathic generalized epilepsy represents a large portion of the epilepsy patient population, and receiving approval in this indication would greatly expand the number of patients who are eligible for treatment with neurostimulation. Neither VNS nor conventional DBS is currently approved in the U.S. for treatment of generalized epilepsy.

In addition to indications that have not previously been treated by implantable neurostimulation devices, there has been competitive interest in treating existing indications with different neurostimulation device types. Notably, the first implantable tibial nerve stimulation (TNS) device — Valencia Technologies' eCoin — was approved in the U.S. for the treatment of urge urinary incontinence in 2022, and BlueWind Medical's Revi followed closely behind in 2023. Despite the recency of their entries compared to SNS devices, which also treat urge incontinence, these products are attractive in that they are less invasive than SNS devices; both eCoin and Revi feature leadless designs and can be implanted in outpatient settings with local anesthesia.[7,8] Despite these advantages, some patients may continue to prefer SNS devices. Valencia Technologies' current device has a shorter device lifespan relative to recent SNS device models, and while BlueWind Medical's Revi device does not require replacement, it must be activated by an external device that is worn on the ankle.[9]

Medtronic is investigating a leadless implantable TNS device in the urge urinary incontinence indication in the TITAN 2 trial,[10] and should it successfully bring the device to market, the company would be well positioned to drive greater awareness of implantable TNS overall given its established relationships with practitioners in the urology space and presence in the SNS device market.

LivaNova's VNS devices have been available for the treatment of treatment-resistant depression for many years, but multiple DBS competitors are evaluating device use for this indication. The FDA granted Abbott Laboratories Breakthrough Device Designation for DBS stimulation therapy of treatment-resistant depression in 2022,[11] while Boston Scientific has initiated the FORESEE III trial in Europe, assessing the efficacy of its Vercise Gevia rechargeable DBS for this indication.[12] Medtronic's Activa devices have also been used in trials for treatment-resistant depression.[13,14] Although investigation is ongoing and it is unclear whether DBS will ultimately be approved for this indication, if DBS competitors are able to demonstrate greater treatment efficacy compared to VNS, they could see significant uptake among this patient population, although the greater invasiveness versus VNS is likely to remain a barrier.

What gaps in treatment does neurostimulation fill?

Implantable neurostimulation devices are typically used when a patient has been shown to be refractory to standard treatments. While this restricts the number of patients who are eligible for treatment with neurostimulation (see below), those that have been shown to be refractory to other treatments typically have limited options.

The indications treated by neurostimulation devices — for example, chronic pain, epilepsy, and incontinence — can have a significant impact on a patient's lifestyle and quality of life, and neurostimulation devices represent an important option for those who have not found sufficient efficacy in other treatments.

Neurostimulation devices represent an important option for those who have not found sufficient efficacy in other treatments.

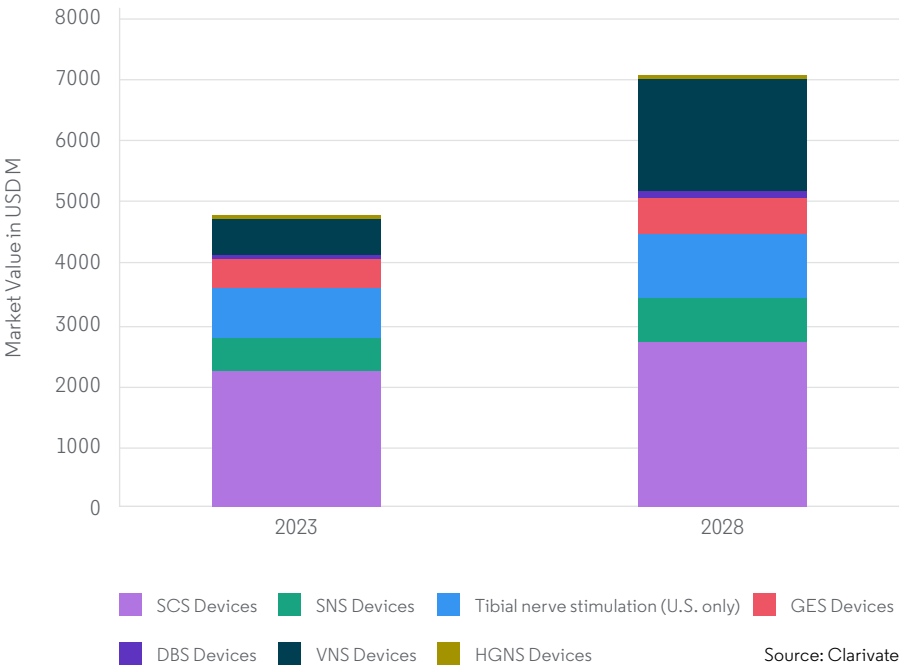
What hurdles will neurostimulation devices face in terms of adoption?

For most indications, implantable neurostimulation devices continue to be a last-line treatment that is considered once other options are exhausted, and reimbursement is typically dependent on evidence that these other avenues have been ineffective for the patient. Unless treatment guidance and reimbursement parameters change, the patient pool eligible for treatment with neurostimulation devices will remain limited compared to alternatives, particularly pharmaceuticals. Because neurostimulation devices are sold at a high price, reimbursement is critical for driving use.

An increasing number of noninvasive and transcutaneous devices are becoming available in the U.S., and they are sold at a much lower cost than the implantable products covered. As non-implantable device manufacturers pursue approval for more indications treated by implantable devices, such as epilepsy, the availability of these alternatives could limit implantable device use to a greater degree in the future, particularly if more robust data for their efficacy can be established.

HGNS devices, in particular, are forecast to drive growth in the U.S. and Europe

Figure 5: Neurostimulation device market, U.S. and Europe 2023 and 2028



Source: Clarivate

"Medtronic has been assessing 'adaptive DBS' in its Percept PC nonrechargeable device; this technology is an important step in the direction of closed loop deep brain stimulation. If successful, adaptive technology could provide benefits such as maintaining effective, individualized stimulation while maximizing battery longevity. Closed-loop stimulation has been a key area of competitive interest in the neurostimulation device space and could provide an important advantage."

Veronica Ross,
Senior Manager, Healthcare Research & Data Analytics, Clarivate,
quoted in BioWorld (FDA greenlights Medtronic sensing-enabled DBS system)

References

1. Mekhail, N., et al, 2020. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. *Lancet Neurology*, 19(2), pp. 123-134.

2. Brooker, C., et al, 2021. ECAP-Controlled Closed-Loop Spinal Cord Stimulation Efficacy and Opioid Reduction Over 24-Months: Final Results of the Prospective, Multicenter, Open-Label Avalon Study. *Pain Practice*, 20(6), pp. 680-691.

3. Inspire Medical Systems, Inc., 2022. *Inspire - 1st Quarter Updates*. [Online] Available at: s22.q4cdn.com/384014896/files/doc_presentations/2022/05/INSP_Co_Pres_2022-05-03.pdf [Accessed 15 May 2024].

4. Inspire Medical Systems, Inc. , 2020. *Inspire Medical Systems, Inc. Announces Full Integration of Inspire Therapy into German DRG Reimbursement System to Begin in 2021*. [Online] Available at: investors.inspiresleep.com/investors/press-releases/press-release-details/2020/Inspire-Medical-Systems-Inc.-Announces-Full-Integration-of-Inspire-Therapy-into-German-DRG-Reimbursement-System-to-Begin-in-2021/default.aspx [Accessed 15 May 2024].

5. Inspire Medical Systems (via Cortellis), 2024. Q4 2023 Inspire Medical Systems Inc Earnings Call. [Online] Available at: www.cortellis.com/intelligence/report/ci/eventTranscripts/15849435 [Accessed 15 May 2024].

6. New York Times, 2024. *Philips Suspends U.S. Sales of Breathing Machines After Recall*. [Online] Available at: www.nytimes.com/2024/01/29/health/philips-cpap-breathing-devices.html [Accessed 15 May 2024].

7. Kaaki, B., et al, 2022. Six-Month Outcomes of Reimplantation of a Coin-Sized Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome With Urgency Urinary Incontinence. *Female Pelvic Medicine & Reconstructive Surgery*, 28(5), pp. 287-292.

8. BioWorld, 2023. *FDA blows good news Bluewind's way with de novo approval for urgency incontinence device*. [Online] Available at: www.bioworld.com/articles/700077-fda-blows-good-news-bluewinds-way-with-de-novo-approval-for-urgency-incontinence-device?v=preview [Accessed 15 May 2024].

9. Blue Wind Medical, n.d. Revi: *Unlock a path forward for urgent bladder leaks*. [Online] Available at: bluewindmedical.com/ [Accessed 15 May 2024].

10. MedtronicNeuro, 2024. *Evaluation of Implantable Tibial Neuromodulation Pivotal Study (TITAN 2)*. [Online] Available at: classic.clinicaltrials.gov/ct2/show/NCT05226286 [Accessed 15 May 2024].

11. Abbott, 2022. *ABBOTT RECEIVES FDA'S BREAKTHROUGH DEVICE DESIGNATION TO EXPLORE USE OF DEEP BRAIN STIMULATION TO MANAGE SEVERE DEPRESSION*. [Online] Available at: abbott.mediaroom.com/2022-07-12-Abbott-Receives-FDAs-Breakthrough-Device-Designation-to-Explore-Use-of-Deep-Brain-Stimulation-to-Manage-Severe-Depression [Accessed 15 May 2024].

12. Schlaepfer, T. E., 2022. *Efficacy Study of Deep Brain Stimulation in Patients With Treatment Resistant Major Depression (FORESEE III)*. [Online] Available at: clinicaltrials.gov/study/NCT03653858 [Accessed 15 May 2024].

13. Bergfeld IO, et al, 2022. Efficacy and quality of life after 6–9 years of deep brain stimulation for depression. *Brain Stimulation*, 15(4), pp. 957-964.

14. Alagapan, S., et al, 2023. Cingulate dynamics track depression recovery with deep brain stimulation. *Nature*, Issue 622, pp. 130-138.

15. Clarivate. 2023.Medtech Insight Report: *Neurostimulation Devices*. December. Accessed May 15, 2024. insights.decisionresourcesgroup.com/device/neurostimulation-devices

16. Medtronic. 2024. Medtronic receives FDA approval for Inceptiv™ closed-loop spinal cord stimulator. April 26. Accessed May 15, 2024. news.medtronic.com/2024-04-26-Medtronic-receives-FDA-approval-for-Inceptiv-TM-closed-loop-spinal-cord-stimulator

Medical Technologies to Watch: **Surgical robotics**

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Surgical robotic systems are revolutionizing the field of medicine, offering better visualization, increased precision, and better ergonomics for surgeons. These systems are beyond simple robotic systems, providing a platform for minimally invasive surgeries with numerous benefits for both surgeons and patients. Despite being considered relatively new technology, robotics has become increasingly common; in the orthopedics space, for example, all major companies now offer a robotic system and have had to do so to remain competitive against their leading peers.

Surgical Robotics at a glance

Key competitors

- Intuitive Surgical
- Stryker
- Zimmer Biomet
- Medtronic
- Smith and Nephew
- Think Surgical
- CMR Surgical
- J&J
- Asensus Surgical

Indications treated/specialties

- General surgery
- Urology
- Gynecology
- Orthopedics
- Cardiothoracic
- Head and neck
- Others

Why is it a medical technology to watch?

Impact

- An estimated **4.8m** laparoscopic procedures will be performed globally using robots by 2032[4]
- The global orthopedic robotic device market is estimated to grow to be over **$5bn** by 2032[5]
- **56%** of all laparoscopic procedures in the U.S. will be robot-assisted by 2032[4]

Robot-assisted surgery has grown exponentially in the past few years. It has seen rapid adoption around the globe due to the following advantages:

- Robotic systems provide surgeons improved precision and control during the surgery.[1]
- Operating from the console can help surgeons reduce fatigue and strain during long duration surgeries.
- Robotic systems enable better visualization of the surgical area through magnified 3-D images.
- Robotic-assisted procedures yield faster recovery times, and reduced pain and complications from minimally invasive surgeries using robotic systems help with patient satisfaction.
- Robotic systems have the potential for better long-term outcomes for patients by more accurate implant placement and improved tissue/bone preservation.
- Robotic systems have the potential to encourage procedures/techniques/approaches that are challenging using traditional techniques.

Why it's important to keep an eye on this space:

Companies are leveraging robotics to evolve into comprehensive solution providers for healthcare facilities. In the future, these companies will establish robust ecosystems that include not only robotic systems but also specialized instruments designed to work exclusively with their robotic platforms.

Healthcare providers may find it increasingly difficult to switch ecosystems due to the significant investment in time, money, and resources required. Consequently, players that do not adapt to the rapid advancements in robotics may eventually find themselves at a disadvantage.

56%

of all laparoscopic procedures in the U.S. will be robot-assisted by 2032[4].

Future focus areas

The focus of development in robot-assisted surgery is shifting towards miniaturization. The current generation of robotic systems is often bulky, but the industry is moving towards creating smaller, more compact systems. These advancements can offer greater flexibility and access, making surgeries even less invasive and potentially expanding the range of procedures that can be performed robotically.

Another area of focus for robot-assisted surgery is to develop applications for new indications. For example, Zimmer Biomet launched the total shoulder application for its ROSA orthopedic surgical robot in February 2024. Several startups are working on other applications for extremities like the foot and ankle segment and for soft tissue repair.

Manufacturers are in the early stages of integrating Artificial Intelligence and Machine Learning to assist with surgical planning. With the aid of sensors, easy to use interface and advanced algorithms, a future where these systems can transform each phase of the continuum of a surgery (pre-, intra- and post-surgical phases) can be envisioned.

Use of Augmented Reality is being explored for robot-assisted surgery to overcome some of the disadvantages of two-dimensional screens in an operating room (OR). This could potentially drive the mass adoption of robotic systems for surgery.

As robot-assisted surgery becomes more widespread, there will be a drive to reduce costs. This could lead to increased penetration of the technology, making it accessible to a larger number of healthcare facilities and, ultimately, more patients.

Performing surgeries remotely could revolutionize the field. This could make top-level surgical expertise accessible even in remote or underserved areas, greatly improving patient outcomes. For instance, Virtual Incision recently sent its spaceMIRA robot to the International Space Station; surgeons were able to control the robot remotely to perform several operations in space. This testing of remote-controlled robotic technology has broader implications on earth as well, demonstrating the increasing potential for robotic systems to aid in performing procedures in remote areas and difficult-to-access locations.

While this piece focuses on orthopedic and laparoscopic surgical robotic systems, many other robotic systems are being developed to address specific therapy areas. For example, several manufacturers have recently launched robotic systems for use in interventional oncology. These systems are used to either guide/align or drive needles for minimally invasive biopsies and tumor ablations. Epione from Quantum Surgical, MAXIO from Perfint Healthcare, and Micromate from Interventional Systems are robotic systems for CT-guided procedures that support needle path planning and alignment. Other robotic systems like XACT Robotics' XACT ACE are capable of automated needle insertion.

Key dates

April 2023: THINK Surgical receives FDA clearance for its handheld robotic knee surgery robot TMINI

August 2023: Levita Magnetics gained FDA clearance for its MARS platform aimed at abdominal surgery

February 2024: Zimmer Biomet gets FDA clearance for ROSA Shoulder system

February 2024: Virtual Incision gains the de novo clearance from the FDA for its MIRA surgical robot

March 2024: Intuitive gains FDA clearance for 5th generation of da Vinci Robotic System

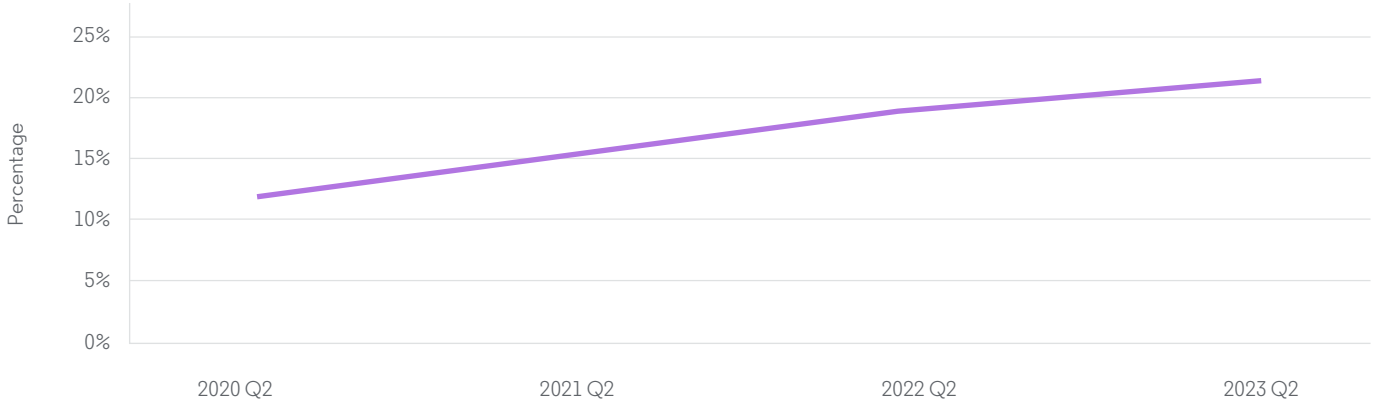
How will robotic systems impact the medtech market?

60%

of knee replacement surgeries being done using MAKO

Robotic systems are seeing rapid adoption, further accelerated by the COVID-19 pandemic, since robot-assisted procedures are associated with better outcomes, and minimally invasive approaches associated with robot-assisted procedures result in shorter hospital stays, reducing the chance of infection. In orthopedics, companies like Stryker are seeing close to 60% of knee replacement surgeries being done using MAKO. There is still significant room for expansion as the use of surgical robotic systems remains underpenetrated. Favorable leasing terms for robotic systems coupled with faster recovery times for minimally invasive procedures performed using these systems have increased their adoption in the ASC setting, opening a new avenue for revenue generation.

Figure 6: U.S. ASCs with a Robotic System for Large-Joint Reconstructive Implant Procedures



Source: Clarivate. clarivate.com/blog/tailoring-medtech-sales-strategies-for-the-asc-market-using-a-data-driven-approach/

Faster recovery times and potentially better long-term outcomes will encourage more people to get surgeries, expanding the total volume of surgical procedures performed. In addition, by improving physician workflow these systems help reduce physician fatigue. Together, these will help drive growth for the market in the long-term.

Major players in this industry have engaged in mergers and acquisitions to incorporate key technologies and patent rights to advance their share in the segment. Major examples in the past include Stryker's acquisition of MAKO in 2013, Smith and Nephew's acquisition of Blue Belt Technologies in 2016, and Medtronic's acquisition of Mazor in 2018.

J&J marked its entry into the laparoscopic surgical robotic market in 2019 with the acquisition of Auris Health and Verb Surgical.

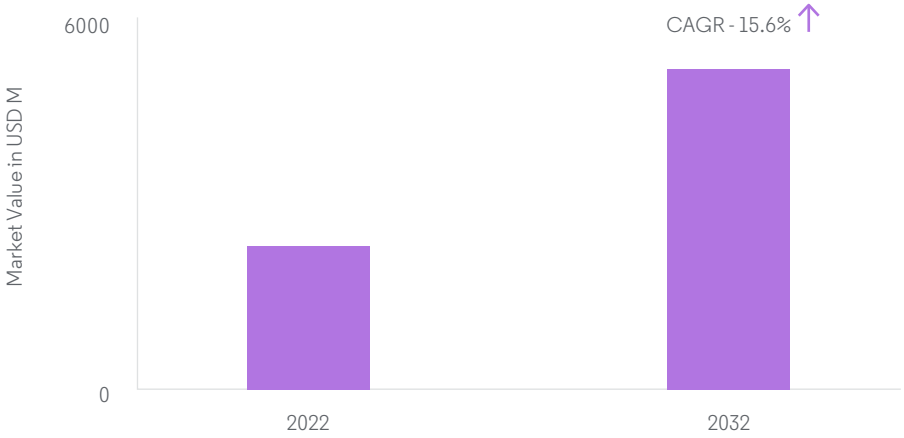
In addition to the well-established multinationals that dominate the market, emerging players from other countries, particularly from China, are gaining significant traction in the market and are now expanding internationally. One such example is TINAVI's TiRobot and TiRobot II Systems. Furthermore, Chinese company MicroPort Scientific's subsidiary MicroPort NaviBot received NMPA clearance, FDA clearance, and the CE Mark for its orthopedic robotic system Skywalker in 2022. Within the laparoscopic robotic market, MicroPort Scientific subsidiary MicroPort MedBot's Toumai received approval from NMPA in January 2022.

Recent launches of surgical systems are focusing on miniaturization of these systems, reducing the OR footprint and making them easier to use. Examples of these are the TMINI system launched by THINK Surgical, Smith & Nephew's CORI handheld and handheld robotic system launched by Chunli, a Chinese MedTech company. For laparoscopic robots, Johnson & Johnson's OTTAVA has a zero-footprint design, with four arms mounted to the operating table, enabling faster and easier set up. Virtual Incision's MIRA miniaturized robotic system, which is designed for single-incision procedures, weighs two pounds, requires minimal setup time, and can be easily moved from one OR to another. By using a smaller form factor, it utilizes less space in the OR and is especially useful for facilities with limited space like ASCs. Manufacturers are also working on new applications to expand approved indications for their robotic systems, such as extremities reconstruction and surgical sports procedures. These procedures are commonly performed at ASCs, and robotic systems designed for the procedures will therefore help these technologies increase their presence in those settings.

Along with compatible implants, manufacturers are creating digital ecosystems that providers subscribe to. For instance, most manufacturers are beginning to integrate digital enablement services like surgery planning, AI-assisted decision making (like implant selection), intraoperative devices that help with tasks like tensioning and balancing, as well as tracking post-surgery outcomes with their robotic systems. These ecosystems encourage customer loyalty because switching ecosystems would require significant investment in time and money for training surgeons and in new capital equipment.

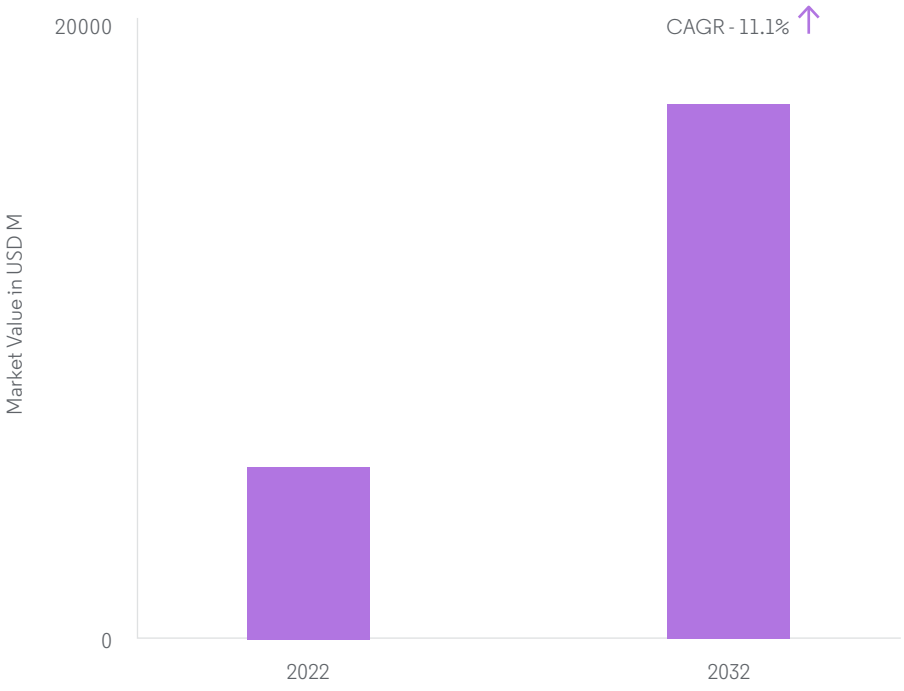
Competition in the surgical robotics space is beginning to heat up, with several new robotic systems and new applications for existing systems being launched or expected soon. New 'open' robotic platforms are creating an opportunity for implant manufacturers who do not have a system of their own to enter this space. This trend is expected to accelerate in the next few years.

Figure 7: Orthopedic robotic device market



Source: Clarivate Medtech 360 report

Figure 8: Laparoscopic surgical robot device market

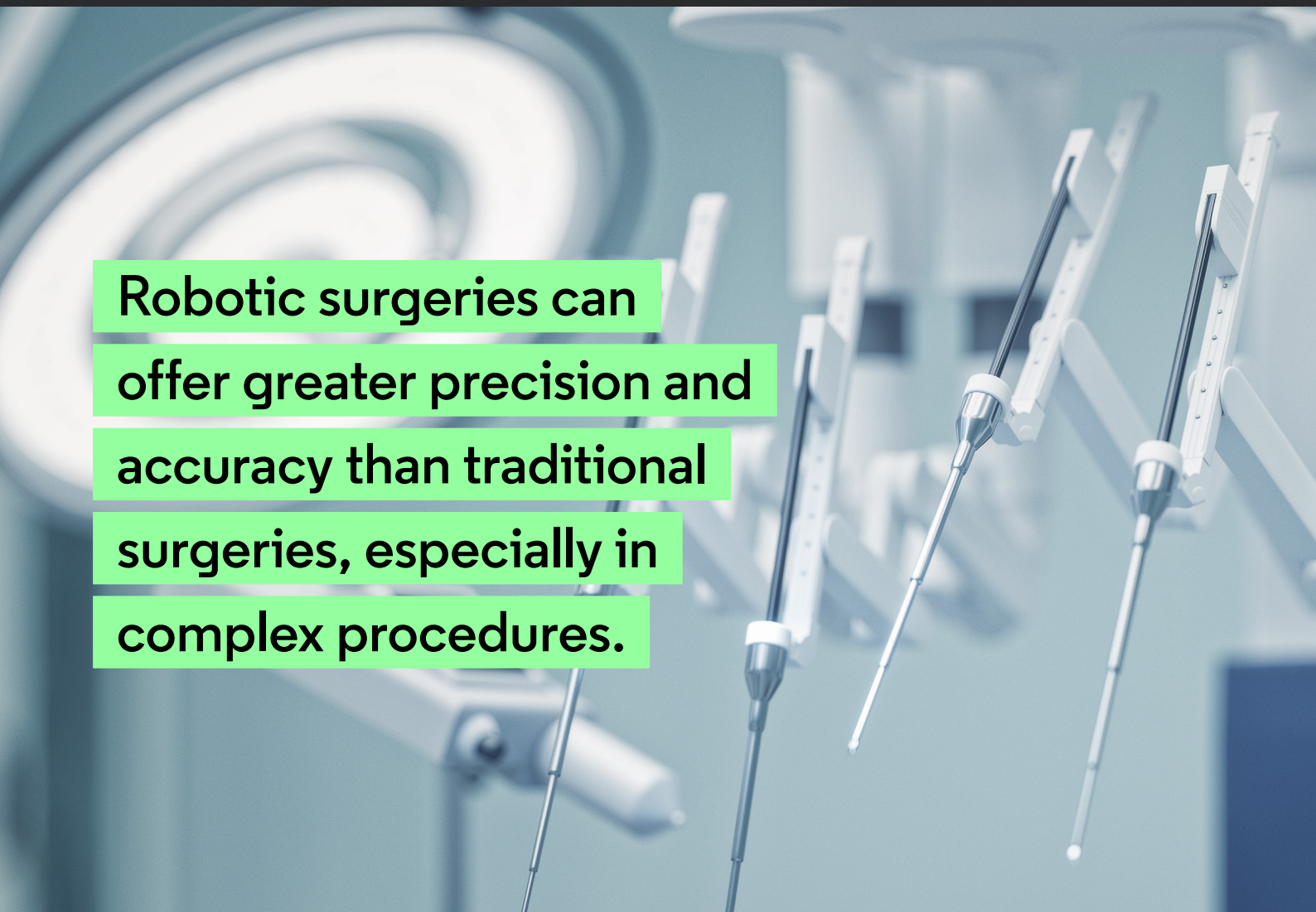


Source: Clarivate Medtech 360 report

What gaps in treatment do robotic systems fill?

Robotic systems offer advantages to both patients and providers/surgeons:

- For surgeons, robotic systems help improve workflow by allowing for preplanning, assistance with decision making and helping to reduce fatigue.
- These systems can encourage surgeons to try new approaches which are considered challenging using traditional surgical methods. Robotic surgeries can offer greater precision and accuracy than traditional surgeries, especially in complex procedures.
- For patients, these systems usually rely on less-invasive techniques reducing pain and recovery time for patients. This can help improve quality of life. In addition, more accurate placement of implants could potentially lead to better outcomes in the long run.
- Telerobotic assisted surgeries can be beneficial to patients in rural areas who may not have easy access to healthcare facilities. This also helps mitigate physician shortages by helping doctors. perform surgeries remotely.



Robotic surgeries can offer greater precision and accuracy than traditional surgeries, especially in complex procedures.

What hurdles will robotic systems face in terms of adoption?

Some of the hurdles to adoption of robotic systems include:

- **Cost:** These systems are expensive and require significant investment, and maintenance costs are high. For example, a Stryker MAKO system can cost around $1m,[6] while Intuitive Surgical's da Vinci systems can cost up to $2.5m.[7] These costs can be prohibitive for smaller facilities with fewer resources. However, manufacturers are increasingly offering different payment models like leasing agreements, reducing the initial investment costs to providers.

- **Learning Curve:** Surgeons must be extensively trained to use these systems. In addition, current systems require a surgeon to look away from the patient towards 2-D screens while operating, which requires extensive training. Some companies are starting to investigate augmented reality systems to mitigate this issue. This adds a cost to acquiring new systems.

- **Limited surgeries:** Not all surgeries can be done using robotic systems. Additionally, each indication usually requires the development of a new application, and a separate regulatory approval process. This can present significant challenges to the expansion of these systems.

- **Reimbursement:** Robotic procedures are reimbursed using the same codes as their laparoscopic counterparts. There are no additional payments for robotic procedures (i.e. the time to set-up, dock, undock the robot).

- **Accessibility:** The limited accessibility of robotic systems in rural regions poses a barrier to their widespread adoption. High costs have resulted in the distribution of these systems being predominantly concentrated affluent urban centers of Europe, North America, and Asia.

- **Lack of implant compatibility:** A limited number of implants compatible with dominant robotic systems also reduces adoption of these systems. Current manufacturers limit their robotic systems to running proprietary applications and are usually compatible with their own implants, limiting adoption. However, some manufacturers, like THINK Surgical, are creating 'open' platforms (like the TMINI), that allow other implant manufacturers to create applications for their system to make their implants compatible with the system. This may encourage adoption in the future.

References

1. Deckey, D. G., et al, 2021. Robotic-assisted total knee arthroplasty improves accuracy and precision compared to conventional techniques. *The Bone & Joint Journal*, Issue 103-B, pp. 74-80.

2. Clarivate, 2023. *Tailoring medtech sales strategies for the ASC market using a data-driven approach*. [Online] Available at: clarivate.com/blog/tailoring-medtech-sales-strategies-for-the-asc-market-using-a-data-driven-approach/ [Accessed 15 May 2024].

3. BioWorld, 2024. *Zimmer Biomet wins new FDA clearance of Rosa robotic shoulder system*. [Online] Available at: www.bioworld.com/articles/705458-zimmer-biomet-wins-new-fda-clearance-of-rosa-robotic-shoulder-system [Accessed 15 May 2024].

4. Clarivate, 2023. *Medtech Insight Report: Laparoscopic Surgical Robotic Devices*. Available at: Abstract | Insight Platform (decisionresourcesgroup.com) [Accessed 15 May 2024].

5. Clarivate, 2023. Medtech Insight Report: *Orthopedic Surgical Robotic Devices*. [Online] Available at: insights.decisionresourcesgroup.com/device/orthopedic-surgical-robotic-devices/market-insights/global/section/abstract [Accessed 15 May 2024].

6. Walgrave, S., et al, 2023. Comparative assessment of current robotic-assisted systems in primary total knee arthroplasty. *Bone & Joint Open*, 4(1), pp. 13-18.

7. Eckhoff, J. A., et al, 2023. Do the costs of robotic surgery present aninsurmountable obstacle? A narrative review. *International Journal of Abdominal Wall and Hernia Surgery*, 6(2), pp. 71-76.

Medical Technologies to Watch: **Renal denervation**

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The hypertension management market will regain its momentum with the dawn of the long-awaited age of renal denervation (RDN) as a treatment for hypertension finally arriving in the U.S. 2023 was eventful, with the U.S. approvals of devices from Recor Medical and Medtronic in this space.

Renal denervation at a glancee

Key competitors

- Medtronic (FDA approval)
- Recor Medical (FDA approval)
- Abbott Laboratories (CE mark)
- Boston Scientific (CE mark)
- Ablative Solutions (CE mark)

Indications treated

- Lowering blood pressure in patients who have uncontrolled hypertension despite the use of anti-hypertensive medications or for those who have difficulty tolerating other blood pressure reduction therapy.

Why is it a medical technology to watch?

Impact

- Hypertension affects one in three adults worldwide, in the U.S. alone **24m** patients are estimated to be diagnosed with uncontrolled hypertension in 2024 according to Clarivate's Epidemiology product
- Over **70%** of hypertension patients are willing to consider RDN as a hypertension management approach given high likelihood of meaningful blood pressure drop[3]
- The global RDN market value is projected to exceed **$2bn** by 2031.

The established 5-10 mmHg of systolic blood pressure (BP) reduction with RDN treatment renders this an effective hypertension management treatment tool with the accompanied benefits of reduced cardiovascular risk[1].

RDN is an adjunctive treatment suitable for chronic hypertensive patients who are resistant to anti-hypertensive drugs[2].

After a 10-year long wait, RDN approval comes in at a time where patients globally have an increased preference for a one-time solution for chronic conditions, paving the way for this minimally invasive solution to transform the hypertension management market.

70%

of hypertension patients are willing to consider RDN

Key dates

December 2013: Medtronic becomes the first company to have CE mark in Europe and TGA listing in Australia for its Symplicity Spyral RDN system[4].

August 2023: Medtronic received a mixed vote from an FDA advisory committee meeting on the efficacy of its Symplicity Spyral RDN system[5].

October 2023: Recor Medical announced six months positive results from its RADIANCE trials, following up on positive vote from an FDA advisory committee meeting[6].

November 2023: Recor Medical receives the first-ever U.S. FDA approval for its Paradise Ultrasound RDN system[7].

November 2023: Medtronic receives FDA approval for its Symplicity Spyral RDN system[8].

April 2024: Ablative Solutions' TARGET BP I trial results presented at ACC.24, meeting its primary endpoint of 24-hour ambulatory BP reduction, though office BP reduction was not statistically significant[14].

How will renal denervation impact the market for hypertension treatment?

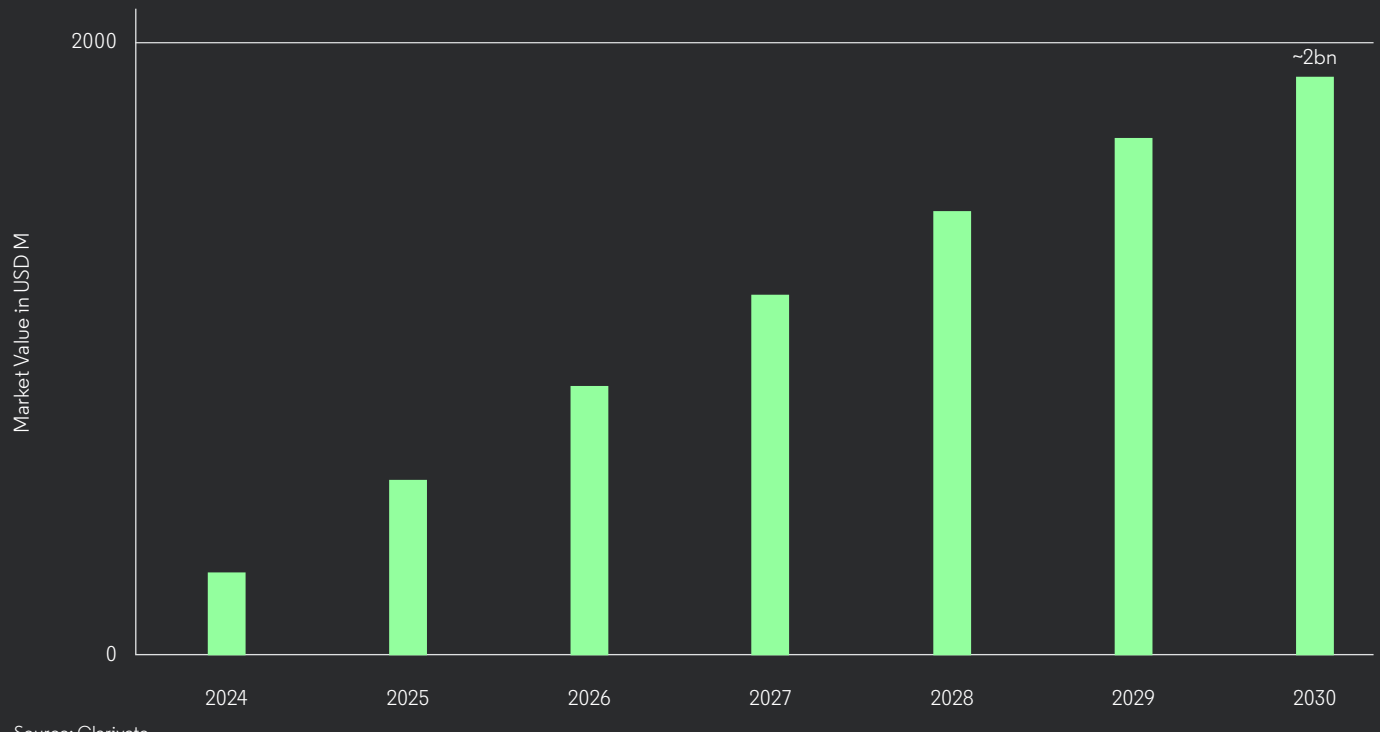
RDN is poised to become an effective and safe hypertension management tool for growing hypertension patient population. The introduction of RDN brings a completely new therapeutic approach for addressing uncontrolled hypertension where existing drug treatment options are inadequate.

Compared to the drug treatment of hypertension, RDN offers a one-and-done treatment of hypertension, with the demonstrated blood pressure reduction on top of the antihypertensive drug-induced blood pressure drop. The durable nature of the treatment outcome — demonstrated up to three years post-treatment[9] — makes this an attractive treatment option not just for patients with uncontrolled hypertension, but also for patients with a preference for a non-medication route.

According to Clarivate's Hypertension Unmet Need analysis, RDN, based on the additional 5-10 mmHg of blood pressure drop on top of medication-induced blood pressure decreases, is a strong candidate for treating over 50% hypertension patients in the U.S. and close to 60% in Europe. While there are hurdles to rapid and widespread adoption of RDN globally (see below), use of RDN will gain traction through the latest device launches in the U.S. market and the recent European guideline update on RDN, which endorsed the technique for use in patients with uncontrolled hypertension.[10]

The global RDN market is expected to exceed $500m by 2025 while growing at a CAGR of 39% from 2024 to 2030, driven by a growing hypertension patient population, rising penetration of RDN use in hypertension patients, anticipated favorable reimbursement decisions, and increasing availability. By 2030, the global RDN market is projected to be at nearly $2bn.

Figure 9: Global renal denervation market forecast



Source: Clarivate

What gaps in treatment does RDN fill?

An increase in sensory nerve signalling, as seen in chronic lifestyle disorders such as obesity, chronic kidney disease, and obstructive sleep apnea, is an important factor in the pathophysiology of hypertension. The mechanism of action for renal denervation is to modulate this overstimulation of sensory nerve signalling between the kidney and the central nervous system in resistant hypertension.

The current treatment approach for hypertension has drawbacks driving the need for an invasive approach such as RDN to effectively treat these patient populations. These include:

- Poor treatment adherence and persistence
- Resistance to hypertension drugs secondary to inadequate adherence or core resistance to treatment regime
- Inadequate treatment regimen
- Lifestyle factors such as diet and exercise.

Currently, renal denervation is indicated as an adjunctive treatment for uncontrolled hypertension patients who are resistant to antihypertensive medications. A reduction of at least 5mmHg was seen in patients evaluated in the clinical trial utilising radiofrequency renal denervation.[11]

According to one U.K. study, renal denervation was also estimated to add an additional 0.4 quality-adjusted life years at the expense of nearly £5,000, resulting in a cost-effectiveness ratio gain of about £14,000.[12]

What hurdles will RDN face in terms of adoption?

An FDA advisory panel evaluated the two breakthrough renal denervation devices extensively in 2023, landing on mixed votes, placing renal denervation only as an adjunctive treatment for hypertensive patients.[13] As a result, the technology faces the following hurdles to adoption in the U.S.:

Based on the panel recommendations, we assume that there will be close to 30%-50% physicians who will have reservations about recommending this therapy until long-term clinical efficacy is proven.

Potential reimbursement hurdles can be expected for this therapy due to approved indication and lack of long-term clinical data to back the claim for efficacy.

The therapy is likely to see a gradual uptake after the entry of competitors. The current lack of treatment alternatives will limit the uptake to some extent.

"Clarivate's analysis initially projected first-year revenues of approximately $150m for RDN in the U.S., unchanged over the past few years, suggesting achieving this might be ambitious. On the other hand, a faster response from payers could potentially confirm the $150m mark. Notably, while Recor beat Medtronic to FDA approval, advisory hearings did not suggest that either device enjoys broader clinical acceptance, however, Medtronic benefits from stronger brand awareness among administrators responsible for hospital and outpatient surgical center purchases."

Sean Messenger,
Director of Operations, Clarivate, in BioWorld, Medtronic rolls out Spyral in U.S. after circuitous journey.

References

1. Mahfoud, F., et al, 2022. Cardiovascular Risk Reduction After Renal Denervation According to Time in Therapeutic Systolic Blood Pressure Range. *Journal of the American College of Cardiology*, 80(20), pp. 1871-1880.

2. European Society of Hypertension, 2023. *ESH Guidelines for the management of arterial hypertension.* [Online] Available at: www.eshonline.org/guidelines/arterial-hypertension/ [Accessed 15 May 2024].

3. Medtronic, 2021. *Medtronic study shows patients with high blood pressure are interested in an interventional procedure treatment option.* [Online] Available at: news.medtronic.com/2021-11-04-Medtronic-study-shows-patients-with-high-blood-pressure-are-interested-in-an-interventional-procedure-treatment-option [Accessed 15 May 2024].

4. BioWorld, 2013. *Report from europe: Medtronic gets approval for flexible 4 Fr Symplicity catheter.* [Online] Available at: www.bioworld.com/articles/403108-report-from-europe-medtronic-gets-approval-for-flexible-4-fr-symplicity-catheter [Accessed 15 May 2024].

5. Medtronic, 2023. *Medtronic issues statement on the FDA Circulatory Systems Devices Advisory Panel vote for the Symplicity Spyral Renal Denervation System.* [Online] Available at: news.medtronic.com/2023-08-23-Medtronic-issues-statement-on-the-FDA-Circulatory-Systems-Devices-Advisory-Panel-vote-for-the-Symplicity-Spyral-Renal-Denervation-System [Accessed 15 May 2024].

6. Recor Medical, 2023. *Recor Medical Announces Positive Results from Six-Month Pooled Analysis of Data from the RADIANCE Global Clinical Trial Program at TCT 2023.* [Online] Available at: www.recormedical.com/recor-medical-announces-positive-results-from-six-month-pooled-analysis-of-data-from-the-radiance-global-clinical-trial-program-at-tct-2023/ [Accessed 15 May 2024].

7. BioWorld, 2023. *FDA greenlights Recor's Paradise system for renal denervation.* [Online] Available at: www.bioworld.com/articles/702476-fda-greenlights-recors-paradise-system-for-renal-denervation

8. BioWorld, 2023. *Medtronic rolls out Spyral in US after circuitous journey.* [Online] Available at: www.bioworld.com/articles/702887-medtronic-rolls-out-spyral-in-us-after-circuitous-journey [Accessed 15 May 2024].

9. Deepak L Bhatt, MD, et al., 2022. Long-term outcomes after catheter-based renal artery denervation for resistant hypertension: final follow-up of the randomised SYMPLICITY HTN-3 Trial. *The Lancet*, 400(10361), pp. 1405-1416.

10. Barbato, E., 2023. Renal denervation in the management of hypertension in adults. A clinical consensus statement of the ESC Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *EuroIntervention*, 18(15), pp. 1227-1243.

11. Shah, R. T., et al, 2022. Effectiveness of renal denervation in the treatment of hypertension: a literature review. *Clinical Hypertension*, 28(11).

12. Sharp, A. S., et al, 2024. Cost-effectiveness of catheter-based radiofrequency renal denervation for the treatment of uncontrolled hypertension: an analysis for the UK based on recent clinical evidence. *European Heart Journal*.

13. Society for Cardiovascular Angiography & Interventions, 2023. *SCAI Statement on FDA Circulatory Systems Devices Panel on RDN Systems.* [Online] Available at: scai.org/scai-statement-fda-circulatory-systems-devices-panel-rdn-systems [Accessed 15 May 2024].

14. Clarivate proprietary data.

Conclusion

Tremendous potential, but challenges and opportunities to be addressed

We see the medtech sector continuing to evolve rapidly, generating exciting new technologies like pulsed field ablation while iterating on more mature platforms such as CGMs and surgical robotics.

However, the industry will have to work through some challenges along the way. In addition to near-term questions around financing, which should ease as the pandemic-induced economic crunch subsides, these include:

- Shifting sites of service in the critical U.S. market, where ambulatory surgical centers, remote and at-home care are displacing the centrality of hospitals
- The lingering threat of global supply chain disruptions, which emerged as a vulnerability for life science companies across the board in the teeth of the COVID-19 outbreak
- The emergence of AI and machine learning, which is already revolutionizing fields like endoscopy and diagnostic imaging, but where regulators are playing catch-up and the policy landscape is fast changing
- The rise of GLP-1 receptor agonists, which will have direct and indirect impacts on multiple medtech markets, most notably obesity interventions and aesthetics.

Learn more

We have addressed these challenges and opportunities in our forthcoming companion paper, Medtech Trends to Watch. To learn more about how Clarivate helps medtech companies deliver innovative technologies to patients or to speak with a representative, please visit us here.

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