Risk Factors Comparison 2024-02-29 to 2023-02-27 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

In addition to the other information contained in this Form 10- K, the following risk factors should be considered carefully in evaluating our business. Any of the risks and uncertainties described below could significantly and negatively affect our business, financial condition, or results of operations, as well as our prospects now or in the future. Additional risks and uncertainties that are not presently known to us, or risks that we currently consider immaterial, could also impair our business, financial condition, or results of operations, as well as our prospects. ~~11Risks Relating to Our~~ Business **and Operating Risks**
Our sales could decline materially if we lose business from one or more of our larger customers or a significant number of our smaller customers. Our sales are generally made under open short- term purchase orders or purchase contracts. Customers with purchase orders could reduce their volumes, or cease purchasing our products, with minimal notice. Customers having purchase contracts may elect not to renew those contracts at expiration or the contracts may be renewed on terms less favorable to us. The loss of, or material reduction in orders by, one or more of our larger customers or a significant number of our smaller customers could have a material adverse effect on our business, financial condition, and results of operations. Our business is dependent on the price and availability of resins and our ability to pass on resin price increases to our customers. The principal raw materials that we use in our products are polyethylene, polypropylene, and polyvinyl chloride resins. Our ability to operate profitably is dependent, in part, on the availability and pricing of these resins. The resins we use are derived from petroleum and natural gas; therefore, prices fluctuate substantially as a result of changes in petroleum and natural gas prices, demand, and the capacity of the companies that produce these products to meet market needs. Instability in the world markets for petroleum and natural gas could adversely affect the prices of these raw materials and their availability. Our ability to maintain profitability depends, in part, upon our ability to pass through increases in raw material costs to our customers. If resin prices increase and we are not able to pass on the increases to our customers, our results of operations and our financial condition will be adversely affected.
We depend on third- party suppliers for raw materials and key components used in our manufacturing processes, and the loss of these third- party suppliers or their inability to supply us with adequate raw materials or components could harm our business.
We rely on a limited number of suppliers for raw materials and components for certain of our products. If we experience a shortage in any of these raw materials or components, we will need to identify and qualify new supply sources, which could increase our costs, result in manufacturing delays, and cause delays in the delivery of our products. We may also experience a delay in completing validation and verification testing or sterility audits for controlled- environment rooms at our manufacturing facilities. If any of those suppliers is unable or unwilling to provide these raw materials or produce these components or supply them in the quantities that we need, and at acceptable prices, we would experience manufacturing delays and may not be able to deliver our products on a timely or cost- effective basis to our customers, or at all, which could reduce our product sales, increase our costs, and harm our business. Although we believe that we could obtain replacement raw materials and components from alternative suppliers, we may be unable to do so on a timely basis, or at all. Losing any of these suppliers could cause a disruption in our production. Establishing additional or replacement suppliers for these materials may take significant time, as certain of these suppliers must be approved by regulatory authorities, which could disrupt our production. Some raw materials and components, including those that are available from multiple sources, are at times subject to industry- wide shortages and significant commodity pricing fluctuations that could materially adversely affect our financial condition and operating results. As a result, we could experience significant delays in manufacturing and delivering our products to customers and increased manufacturing costs. We cannot assure you we can continue obtaining required materials and components that are in short supply within the time frames we require at an affordable cost, or at all. If we cannot secure on a timely basis sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then manufacturing our products may be disrupted, which could increase our costs, prevent or impair our development or commercialization efforts, and have a material adverse effect on our business, financial condition, and results of operations. ~~12If~~ **11If** our supply of components for a new or existing product continues to be delayed or constrained for any reason, including if an outsourcing partner delayed shipments of completed products to us or additional time is required to obtain sufficient quantities from the original source, or if we have to identify and obtain sufficient quantities from an alternative source, then our financial condition and operating results could be materially adversely affected. In addition, the continued availability of these components at acceptable prices, or at all, can be affected for any number of reasons, including if suppliers decide to concentrate on the production of common components or components for other customers instead of components customized to meet our requirements. Although we have entered into agreements for the supply of many components, there can be no assurance that we will be able to extend or renew these agreements on similar terms, or at all. Raw material and component suppliers may suffer from poor financial conditions that can lead to business failure for the supplier or consolidation within a particular industry, further limiting our ability to obtain sufficient quantities of raw materials or components on commercially reasonable terms. Additionally, we may be unsuccessful in our efforts to negotiate with existing suppliers to obtain cost reductions and avoid unfavorable changes to terms, source less expensive suppliers for certain raw materials or parts, and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, financial condition, and results of operations.
We are subject to risks associated with public health crises such as pandemics and epidemics, including the COVID-19 pandemic, which may continue to have a material adverse effect on our business, the nature and extent of future impacts of which are highly uncertain and unpredictable. Although **the United States and** many **other** countries have removed or reduced

the restrictions taken in response to the COVID- 19 pandemic, certain COVID- 19 risks remain and the emergence of new variants of the virus may result in new governmental lockdowns, quarantine requirements, or other restrictions to slow the spread of the SARS- CoV- 2 virus. This could result in significant reductions in the demand for certain of our products due to reductions in elective and non- essential procedures, reduced capital spending by customers, decreases in research activity, ~~and~~ reduced hospital and clinical occupancy, and healthcare system staffing shortages. These measures could also include determinations that our or our suppliers' facilities are not essential businesses, which could result in closures or other restrictions that significantly disrupt our operations or those of distributors or suppliers in our supply chain. In addition, any such measures could also impact the global economy more broadly, for example by leading to further economic slowdowns. Although COVID- 19 case volumes have decreased **substantially** in the United States and certain other countries, the global outlook remains uncertain as case counts fluctuate and vaccination and booster rates remain relatively low in many parts of the world. Going forward, medical procedure rates may vary by country based on regional infection and vaccination and booster rates, hospital occupancy and staffing levels, transportation limitations, quarantines and other restrictions, and the emergence of new variants of the virus. In addition, the COVID- 19 pandemic ~~has~~ impacted our global supply chain network, and we may continue to experience significant challenges in our network, including shortages in supply or disruptions or delays in shipments, as well as price increases, of certain materials or components used in our products. The COVID- 19 pandemic ~~has~~ escalated challenges that existed for global healthcare systems prior to the pandemic, including budget constraints and staffing shortages, particularly shortages of nursing staff, that could impact the future demand for our products and services. As COVID- 19 conditions have improved, there have been increases in demand for certain of our products, which may pose challenges to our supply chain and could adversely affect our business. ~~The~~ **12The** scope and duration of any future public health crisis, including the potential emergence of new variants of the SARS- CoV- 2 virus, the pace at which government restrictions are imposed and lifted, the scope of additional actions taken to mitigate the spread of disease, global vaccination and booster rates, the speed and extent to which global markets and utilization rates for our products fully recover from the disruptions caused by such a public health crisis, and the impact of these factors on our business, financial condition and results of operations, will depend on future developments that are highly uncertain and unpredictable. ~~13To~~ **To** the extent the COVID- 19 pandemic or other public health crisis adversely affects our business, prospects, operating results, or financial condition, many of the other risks described in this " Risk Factors " section may also be heightened. Our business is dependent on third- party sterilization for many of our products, and the loss or limitation of access to those facilities could adversely affect our business. In 2019, the FDA issued a caution concerning a nationwide shortage of medical devices due to issues with contract sterilizers, and reductions in sterilization capacity caused significant delays in medical device sterilization in this country' s sterilization facilities. Many of our products require sterilization prior to sale, and we utilize third parties for this process. In some instances, only a few facilities are qualified under applicable regulations to conduct this sterilization. If our third- party providers are unable to sterilize our products, whether due to lack of capacity, availability of materials for sterilization, regulatory requirements, or otherwise, we may be unable to transition sterilization to other sites or modalities in a timely or cost- effective manner, or at all, which could ~~have an adverse~~ **adversely affect** ~~impact on~~ our operating results and financial condition. The United States Environmental Protection Agency and state environmental regulatory agencies have increased their focus on the use and emission of ethylene oxide in sterilization operations. Additional regulatory requirements associated with the use and emission of ethylene oxide for sterilization may be imposed in the future, both domestically and outside the United States. This increased regulation could require our sterilization service providers to temporarily suspend operations to install additional emissions control technology, limit the use of ethylene oxide, or take other actions which would further reduce the available capacity to sterilize medical devices and healthcare products, and could also result in additional costs. Governmental agencies may also regulate the use and emission of ethylene oxide. If any existing regulatory requirements or any such regulatory actions or rulemaking results in the suspension or interruption of sterilization at medical device sterilizers used by us, or otherwise limit the availability of third- party sterilization capacity, this could interrupt or otherwise adversely impact production of certain of our products. Political and economic conditions could materially and adversely affect our revenue and results of operations. Our business may be affected by a number of factors that are beyond our control such as general geopolitical economic and business conditions, conditions in the financial markets, and changes in the overall demand for our products. A severe or prolonged economic downturn could adversely affect our customers' financial condition and the levels of business activity of our customers. Uncertainty about current global political or economic conditions could cause businesses to postpone spending in response to tighter credit, negative financial news, or declines in income or asset values, which could have a material negative effect on the demand for our products. There could be additional effects on our business from these economic developments including the insolvency of key suppliers or their inability to obtain credit, the inability of our customers to pay for or obtain credit to finance purchases of our products, and increased pressure to reduce the prices of our products. Turbulence in the United States and international markets and economies could have a material adverse impact on our business, operating results, and financial condition. In addition, if we are unable to **anticipate** successfully ~~anticipate~~ changing economic and political conditions, we may be unable to **plan** effectively ~~plan~~ for and respond to those changes, which could materially adversely affect our business, financial condition, and results of operations. ~~14International~~ **13International** economic ~~and~~ **,** industry **, and regulatory** conditions constantly change and could materially and adversely affect our business, financial condition, and results of operations. Sales outside the United States accounted for approximately ~~40~~ **37** percent of our net sales during the year ended December 31, ~~2022~~ **2023** . We anticipate that sales from international operations will continue to represent a significant portion of our total sales, and we intend to continue our expansion into emerging or faster- growing markets outside the United States. Our sales and profitability from our international operations are subject to risks and uncertainties that could have a material adverse effect on our business, financial condition, and results of operations, many of which we cannot predict, including: · multiple non- United States regulatory requirements that are subject to change and could restrict our ability to manufacture and

sell our products; · restrictive trade policies, including tariffs, trade protection measures, and import or export licensing requirements imposed by the United States and other countries; · local product preferences and product requirements; · less intellectual property protection in some countries outside the United States than exists in the United States; · different labor regulations and workforce instability; · the expiration and non- renewal of foreign tax rulings; · economic instability and inflation, recession or interest rate fluctuations; and · risks and uncertainties described elsewhere in this Risk Factors section. In addition, the United Kingdom' s departure from the European Union, commonly known as " Brexit, " has created uncertainties affecting business operations in the United Kingdom and the European Union and a number of other countries, including with respect to compliance with the regulatory regimes regarding the labeling and registration of the products we sell in those markets. As a result, we could face increased costs, volatility in exchange rates, market instability, and other risks depending on the effects of existing and future agreements between the United Kingdom and the European Union regarding Brexit and ~~the~~ future trading relationships. The military conflict between Russia and Ukraine has resulted in the implementation of sanctions by the United States and other governments against Russia and has caused significant volatility in and disruptions to the global markets. The short- and long- term implications of this conflict, which could include but are not limited to further sanctions, uncertainty about economic and political stability, increases in inflation rates and energy prices, supply chain challenges, and adverse effects on currency exchange rates and financial markets, are unpredictable. In addition, the United States government reported that United States sanctions against Russia in response to the conflict could lead to an increased threat of cyberattacks against United States companies. These increased threats could pose risks to the security of our information technology systems, networks, and product offerings, as well as the confidentiality, availability, and integrity of our data. Further, if the conflict develops beyond Ukraine or further intensifies, it could have an adverse ~~impact~~ **effect** on our operations in the European Union or other affected areas. **The recent crisis related to the Israel- Hamas war is also a source of uncertainty. The conflict could grow and bring about disruption, instability, and volatility in global markets, supply chains, and logistics operations, such as recent shipping disruptions in the Red Sea and surrounding waterways, which could in turn adversely affect our business operations and financial performance. The current domestic and international environment, including volatile trade relations, the conflict between Russia and Ukraine, the Israel- Hamas war, and civil unrest taking place in certain parts of the world have resulted in uncertainty surrounding the future state of the global economy. There is greater uncertainty with respect to potential changes in trade regulations, sanctions, and export controls which also increase volatility in the global economy.** We are continuing to monitor the situation in Ukraine and **in Israel and Gaza and the state of the** ~~globally~~ -- **global economy** as well as assess ~~its~~ **the** potential impact on our business. A significant escalation or further expansion of the ~~conflict~~ **conflicts ' '** ~~s~~ current scope or related disruptions to the global markets could have a material adverse effect on our business, financial condition, and results of operations. ~~Product~~ **14Product** liability claims could adversely affect our financial condition and results of operations. We may be subject to product liability actions asserting claims of personal injury or property damage. Our product liability insurance coverage may not be adequate to cover the cost of defense and the potential award in the event of a claim. A product liability claim, regardless of its merit or outcome, could result in significant legal defense costs. Also, a well- publicized actual or perceived problem with one or more of our products could adversely affect our reputation and reduce the demand for our products. ~~15Issues~~ -- **Issues** with product quality could have an adverse effect upon our business, subject us to regulatory actions, and cause a loss of customer confidence in us or our products. Our success depends ~~upon~~ **on** the quality and reliability of our products. Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving our products, and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. Although we have ~~one~~ **a** quality system that covers the lifecycle of our products, quality and safety issues may occur with respect to any of our products. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations, or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity or a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. Additionally, we have made and continue to make significant investments in assets, including inventory and property, plant, and equipment, which relate to potential new products or modifications to existing products. Product quality or safety issues and costs associated therewith may restrict us from being able to realize the expected returns from these investments and may adversely affect ~~our business, financial condition, and results of operations. Any losses we incur as a result of our exposure to the credit risk of our customers could harm our results of operations. We monitor individual customer payment capability in granting credit arrangements, seek to limit credit to amounts we believe the customers can pay, and maintain reserves we believe are adequate to cover exposure for doubtful accounts. As we have grown our revenue and customer base, our exposure to credit risk has increased. Any material losses as a result of customer defaults could harm, and have an adverse effect on,~~ our business, financial condition, and results of operations. The success of certain of our products depends upon relationships with healthcare professionals. The research, development, marketing, and sales of many of our new and improved products are dependent upon our maintaining working relationships with healthcare professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding our products. If we are unable to maintain our relationships with these professionals and do not continue to receive their advice and input, the development and commercialization of our products could suffer, which could have a material ~~,~~ adverse impact on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under continued scrutiny by the OIG and the DOJ for improper relationships with physicians and other healthcare providers. Our success is measured in part by our ability to develop patentable products, to preserve our trade secrets, and to operate without infringing or violating the proprietary rights of third parties. Our ability to remain competitive is dependent, in part, upon our ability to protect

our intellectual property rights and prevent other companies from using our intellectual property. We seek to protect our intellectual property rights through a combination of patent, trademark, copyright and trade secret laws, and confidentiality agreements. However, these measures afford only limited protection and may be challenged, invalidated, or circumvented by third parties. Additionally, these measures may not prevent competitors from duplicating our products or gaining access to our proprietary information and technology. Third parties may copy all or portions of our products or otherwise use our intellectual property without authorization, and we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees, or current employees despite the existence of nondisclosure and confidentiality agreements and other contractual restrictions, all of which could have an adverse effect on our business, financial condition, and results of operations. Others may challenge the validity of any patents issued to us, and we could encounter legal and financial difficulties in enforcing our patent rights against infringers. In addition, there can be no assurance that other technologies cannot or will not be developed or that patents will not be obtained by others which would render our patents less valuable or obsolete. Our patents expire at various times over the next 18 years. Once patents expire, some customers may not continue to purchase from us, opting for competitive copies instead. In such event, our sales and profits could decline substantially. During the terms of our patents, third parties may develop similar or superior technology independently or by designing around our patents. Additionally, if we do not develop and launch new products prior to the expiration of patents or before the demand for our existing products declines, our sales and profits could be adversely affected. ~~16Changes~~ **15Changes** in patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection, Future changes in patent laws or in their interpretation may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. We have developed technical knowledge which, although non- patentable, we consider to be significant in enabling us to compete. However, the proprietary nature of such knowledge may be difficult to protect. We have entered into agreements with key employees prohibiting them from disclosing any of our trade secrets or other confidential information. In addition, generally these agreements also provide that inventions or discoveries relating to our business by these individuals will be assigned to us and become our sole property. We cannot ensure, however, that the enforceability of these agreements will not be challenged or that our trade secrets will not become known to, or be independently developed by, our competitors The medical device industry is characterized by extensive intellectual property litigation, and companies in the medical device industry sometimes use intellectual property litigation to gain a competitive advantage. Intellectual property litigation, regardless of outcome, is often complex and expensive, and the outcome of this litigation is generally difficult to predict. An adverse determination in any such proceeding could subject us to significant liabilities to third parties or require us to seek licenses from third parties ~~,~~or pay royalties that may be substantial. Furthermore, there can be no assurance that necessary licenses would be available to us on satisfactory terms, or at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing or selling certain of our products, which could have a material adverse effect on our business, financial condition, and results of operations. New lines of business or new or enhanced products and services may subject us to additional risks. We may implement new lines of business or offer new or enhanced products and services within existing lines of business. There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. In developing and marketing new lines of business or new or enhanced products and services, we may invest significant time and resources. Initial timetables for the introduction and development of new lines of business and new or enhanced products or services may not be achieved and price and profitability targets may not prove feasible. External factors, such as compliance with regulations, competitive alternatives, and shifting market preferences, may also impact the successful implementation of a new line of business or a new or enhanced product or service. Furthermore, any new line of business or new or enhanced product or service could have a significant impact on the effectiveness of our system of internal control. Failure to successfully manage these risks in the development and implementation of new lines of business or new or enhanced products or services could have a material adverse effect on our business, financial condition, and results of operations. ~~Some~~ **16Some** of our competitors have significantly greater resources than we do, and it may be difficult for us to compete against them. In many of our markets, we compete with numerous other companies that have substantially greater financial resources and engage in substantially more R & D activities than we do. Furthermore, innovations in surgical techniques or medical practices could have the effect of reducing or eliminating market demand for one or more of our products. In addition, the trend of consolidation in the medical device industry and among our customers could result in greater competition and pricing pressure. ~~17Some~~ -- **Some** of the markets in which we compete are dominated by established manufacturers that have broader product lines, greater distribution capabilities, and substantially larger marketing and R & D staffs and facilities than we do. Many of these competitors offer broader product lines within the specific product market and in the general field of medical devices and supplies. Broad product lines give many of our cardiovascular and fluid delivery competitors the ability to negotiate exclusive, long- term medical device supply contracts and, consequently, the ability to offer comprehensive pricing of their competing products. By offering a broader product line in the general field of medical devices and supplies, competitors may also have a significant advantage in marketing competing products to group purchasing organizations. In addition, our competitors may use price reductions to preserve market share in their product markets. Any major disruption or failure of our information technology systems, or our failure to successfully implement new technology effectively, could adversely affect our business and operations. We rely on various information technology systems to manage our operations. Over the last several years, we have been implementing and continue to implement modifications and upgrades to our systems, including making changes to legacy systems, replacing legacy systems with successor systems with new functionality and acquiring new systems with new functionalities. ~~For example, we are in the process of transforming our Enterprise Resource Planning software solutions and other complementary information technology systems, which is expected to be completed over the next year.~~ The implementation of these solutions and systems is highly dependent on the coordination

of numerous software and system providers and internal business teams. We could experience changes in our operational processes and internal controls, which in turn could require significant capital investments and personnel changes, including recruiting and training of qualified personnel. The interdependence of these solutions and systems is key to the successful completion of this project. The failure of any one solution or system could have a material impact on our business processes and information systems, including loss or corruption of data, delayed shipments, decreases in productivity as our personnel and third- party providers implement and become familiar with new systems, increased costs, and lost revenues, which could have an adverse effect on our overall information technology infrastructure. These activities subject us to inherent costs and risks associated with replacing and upgrading these systems, including impairment of our ability to fulfill customer orders, potential disruption of our internal control structure, substantial capital expenditures, additional administration and operating expenses, retention of sufficiently skilled personnel to implement and operate the new systems, demands on management time, and other risks and costs of delays or difficulties in transitioning to new or upgraded systems or of integrating new or upgraded systems into our current systems. Our system implementations may not result in productivity improvements at a level that outweighs the costs of implementation, or at all. In addition, the difficulties with implementing new or upgraded technology systems may cause disruptions in our business operations and have an adverse effect on our business and operations, if not anticipated and appropriately mitigated **. If we fail to maintain proper and effective disclosure controls and procedures and internal control over financial reporting or fail to remediate a material weakness in internal control, our consolidated financial statements could be materially misstated. Our management has identified a material weakness in our internal control over financial reporting and has concluded that, due to such material weakness, our disclosure controls and procedures were not effective as of December 31, 2023. The material weakness in internal control over financial reporting resulted from our controls being inadequate to prevent and detect misstatements of inventory quantities at one of our subsidiaries that could have resulted in us not disclosing a material loss. The material weakness has not been remediated as of February 29, 2024. If not remediated, or if we identify further material weaknesses in our internal control, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and results of operations and investor confidence in our consolidated financial statements** . We face cybersecurity risks and may incur increasing costs in an effort to minimize those risks. We utilize systems and websites that allow for the secure storage and transmission of proprietary or confidential information regarding our customers, employees, and others, including personal information. As evidenced by the numerous companies that have suffered serious data security breaches, we may be vulnerable to, and unable to anticipate or detect, data security breaches and data loss, including rapidly evolving and increasingly sophisticated cybersecurity attacks. In addition, data security breaches can also occur as a result of a breach by us or our employees or by persons with whom we have commercial relationships that result in the unauthorized release of personal or confidential information. In addition to our own databases, we use third- party service providers to store, process, and transmit confidential or sensitive information on our behalf. Although we contractually require these service providers to implement and use reasonable security measures, we cannot control third parties and cannot guarantee that a data security breach will not occur in the future either at their location or within their systems. A data security breach may expose us to a risk of loss or misuse of this information, and could result in significant costs to us, which may include, among others, fines and penalties, potential liabilities from governmental or third- party investigations, proceedings **,** or litigation, and diversion of management attention. We could also experience delays or interruptions in our ability to function in the normal course of business, including delays in the fulfillment of customer orders or disruptions in the manufacture and shipment of products. In addition, actual or anticipated attacks may cause us to incur costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants. Any compromise or breach of our security could result in a violation of applicable privacy and other laws, significant legal and financial exposure, and a loss of confidence in our security measures, which could have an adverse effect on our results of operations and our reputation. ~~18We~~ **17We** are increasingly dependent on the consistent functioning of our information technology and cybersecurity systems along with our information technology dependent product portfolios. If we are exposed to any intrusions, disruptions, corruption, or destruction, or if we fail to maintain the integrity of our systems or products, or the privacy of our data, our business and our reputation could be materially adversely affected. We are increasingly dependent on consistent functioning of our information technology and cybersecurity systems for our infrastructure and software- based products. Our information technology and cybersecurity systems have been and may continue to be subjected to viruses or other malicious codes, unauthorized access attempts, cyber- or phishing- attacks, tampering, or other security breaches. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, regulatory standards, integration of acquisitions, and the increasing need to protect patient, customer, and supplier information. In addition, the EU- wide General Data Protection Regulation imposes stringent data protection requirements and provides for significant penalties for noncompliance. Our products include technologies that support connectivity and decision support infrastructure, which could be subject to intrusion, disruption, or corruption and could impact the quality of care that patients receive or the confidentiality of patient information. In addition, third parties might attempt to hack into our products or systems in an effort to obtain proprietary information. As a result of the COVID- 19 pandemic, we have faced and may continue to face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. If we fail to maintain or protect our information technology and cybersecurity systems and information technology- dependent products effectively, we could lose existing customers or suppliers, have difficulty attracting new customers or suppliers, have problems that adversely impact internal controls, have difficulty preventing, detecting, and

controlling fraud, have disputes with customers and suppliers, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or cyber- based attack, or suffer other adverse consequences. Any significant breakdown, intrusion, interruption, corruption, or destruction of these systems, as well as any data breaches or cyber- based attacks, could have a material adverse effect on our business. We have experienced targeted and non- targeted cybersecurity attacks and incidents in the past, and we could in the future experience similar attacks. We are continuously investing in our cybersecurity program to ~~[~~mature~~]~~current capabilities, in addition to accelerating the implementation of new capabilities to keep pace with the changing threat landscape. To date, no cybersecurity incident or attack has had a material impact on our business, financial condition, or results of operations. Our current credit agreement contains restrictions that may limit our flexibility in operating our business. We have pledged certain of our assets as collateral under our current credit agreement. If we borrow funds under that credit agreement and default on the terms of such credit agreement and the holder of our indebtedness accelerates the repayment of such indebtedness, there can be no assurance that we will have sufficient assets to repay our indebtedness. ~~Our~~ **18Our** current credit agreement contains, and any future agreements may contain, covenants that could impose significant operating and financial restrictions on us **and** ~~. Although we currently do not have any borrowings under our credit agreement, the covenants in those agreements may~~ limit the manner in which we conduct our business, and we may be unable to engage in favorable business activities or finance future operations or capital needs. ~~19Under~~ -- **Under** our current credit agreement, we are required to satisfy and maintain specified financial ratios. Our ability to meet those financial ratios can be affected by events beyond our control, and there can be no assurance that we will meet those ratios. A failure to comply with the covenants contained in the agreement could result in an event of default under such agreement, which, if not cured or waived, could have a material adverse effect on our business, financial condition, and results of operations. In the event of any default under our credit agreement, the holder of our indebtedness thereunder: · will not be required to lend any additional amounts to us; · could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable; or · could require us to apply all of our available cash to repay such indebtedness. If we are unable to repay our indebtedness, the holder could proceed against the collateral securing that indebtedness. If the indebtedness under our current credit agreement were to be accelerated, there can be no assurance that our assets at that time would be sufficient to repay such indebtedness in full. We may not be able to attract and retain skilled people. Our success depends, in large part, on our ability to attract and retain key people. Competition for the best people in most activities we engage in can be intense, and we may not be able to hire qualified people or to retain them. The unexpected loss of services of one or more of our key personnel could have a material adverse impact on our business if we are unable to promptly find qualified replacement personnel. A portion of our business relies on distribution agreements and relationships with various distributors, and any adverse change in those relationships could result in a loss of revenue and harm that business. We have strategic relationships with, and sell many of our products through, a number of distributors. To the extent that we rely on distributors, our success ~~will depend~~ **depends** on the efforts of others over whom we may have little or no control. Some of our distributors also sell our competitors' products, and, if they favor our competitors' products for any reason, they may fail to market our products as effectively or to devote resources necessary to provide effective sales, which would cause our results to suffer. The success of the arrangements with these distributors depends, in part, on the continued adherence to the terms of our agreements with them. Any disruption in these arrangements may adversely affect our business, financial condition, and results of operations. The actions of distributors in foreign countries may adversely affect our ability to market effectively our products in those countries, particularly if a distributor holds the regulatory authorization in such countries and such actions result in the suspension or revocation of such authorization. In such cases, re- establishing market access or regulatory authorization may be difficult, expensive, ~~or~~ **and** time consuming. Also, we may be named as a defendant in litigation against our distributors related to sales of our products by them. Severe weather, natural disasters, acts of war or terrorism **,** or other external events could significantly impact our business. We currently conduct all our development, manufacturing, and management at three locations. Severe weather, natural disasters, public health crises, including the occurrence of a contagious disease or illness such as a novel coronavirus, acts of war or terrorism, and other adverse external events at any one or more of these locations could have a significant impact on our ability to conduct business. We have the ability to transfer the production of certain products from a facility affected by such events but doing so would be expensive. Our disaster recovery policies and procedures may not be effective and the occurrence of any such event could have a material adverse effect on our business, financial condition, and results of operations. The insurance we maintain may not be adequate to cover our losses. ~~20We~~ **19We** may lose revenues, market share, and profits due to exchange rate fluctuations related to our international business. Fluctuations in exchange rates may affect the prices that our international customers are willing to pay for our products and may put us at a price disadvantage compared to our competitors. Potentially volatile shifts in exchange rates may negatively affect our financial condition and operations. Because payments from our international customers are received primarily in United States dollars, increases in the value of the United States dollar relative to foreign currencies could make our products less competitive or less affordable, and therefore adversely affect our sales in international markets. We continue to evaluate expansion through acquisitions of, and investments in, other companies or technologies, which may carry significant risks. If we pursue acquisitions of, or investments in, other companies or technologies, we may: · use cash that we may need in the future to operate our business; · incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay; · structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step- up in the tax basis for the assets acquired; · be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales; · be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target; · be unable to secure or retain the services of key employees related to the acquisition; · be unable to succeed in the marketplace with the acquisition; or · assume material unknown liabilities associated with the acquired business. Any of the above risks,

should they occur, could materially adversely affect our business, financial condition, and results of operations, including the inability to recover our investment or cause a write down or write off of such investment, associated goodwill, or assets. If we make divestitures, we could encounter difficulties that harm our business. We may sell a business or product line. Any divestiture may result in significant write- offs, which could have a material adverse effect on our business, financial condition, and results of operations. Divestitures could also involve additional risks, including difficulties in separation of operations, services, and personnel, the diversion of management' s attention from other operations, and the potential loss of key personnel. If we fail to manage our exposure to market risk and credit risk successfully, our financial condition could be adversely impacted. We have exposure to market risk and credit risk in our investment activities. The fair values of our investments vary from time to time depending on economic and market conditions. Fixed income securities expose us to interest rate risk as well as credit risk. Equity securities expose us to equity price risk. Interest rates are highly sensitive to many factors, including governmental monetary policies and domestic and international economic and political conditions. These and other factors also affect the equity securities owned by us. The outlook of our investment portfolio depends on the future direction of interest rates, fluctuations in the equity securities market, and the amount of cash flows available for investment. Our investments may decline in value in future periods, which could have a material adverse effect on our financial condition. ~~21Risks Related~~ **Any losses we incur as a result of our exposure** to ~~Our~~ **the credit risk of our customers could harm our results of operations. We monitor individual customer payment capability in granting credit arrangements, seek to limit credit to amounts we believe the customers can pay, and maintain reserves we believe are adequate to cover exposure for credit losses. As we have grown our revenue and customer base, our exposure to credit risk has increased. Any material losses as a result of customer defaults could harm, and have an adverse effect on, our business, financial condition, and results of operations. 20Legal,** Regulatory ~~Environment~~ **, and Compliance Risks** We are subject to healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices, and restrict our operations in the future. We are subject to various federal, state, and local laws targeting fraud and abuse in the healthcare industry, including anti- kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment, and exclusion from participation in healthcare programs such as Medicare and Medicaid as well as healthcare programs outside the United States. These laws and regulations are wide ranging and subject to changing interpretations and applications, which could restrict our sales or marketing practices. A violation of these laws could have a material adverse effect on our business, financial condition, and results of operations. We and our suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have a material adverse effect on our business, financial condition, and results of operations. As a medical device manufacturer, we must register with the FDA and non- U. S. regulatory agencies, and we are subject to periodic inspection by the FDA and similar foreign regulatory agencies for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control, and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Some of our suppliers are also required to meet certain standards applicable to their manufacturing processes. We cannot assure you that we or our suppliers comply or can continue to comply with all regulatory requirements. A failure by us or one of our suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a supplier, until a new supplier has been identified and evaluated. Our or any of our suppliers' failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension, or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions, and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements we will be able to locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition, and results of operations. We will be unable to sell our products if we fail to comply with governmental regulations. To manufacture our products commercially, we must comply with governmental regulations that govern design controls, quality systems, and documentation policies and procedures, including continued compliance with the Quality System Regulation. The FDA and similar foreign governmental authorities periodically inspect our manufacturing facilities and the manufacturing facilities of our Original Equipment Manufacturer, or OEM, medical device customers. If we or our OEM medical device customers fail to comply with these manufacturing regulations, including meeting reporting obligations to the FDA or foreign governmental authorities, or fail any FDA or foreign governmental authority inspections, marketing or distribution of our products may be prevented or delayed, which would negatively impact our business. Our products are subject to product recalls even after receiving regulatory clearance or approval, and any such recalls would negatively affect our financial performance and could harm our reputation. Any of our products may be found to have significant deficiencies or defects in design or manufacture. The FDA and similar governmental authorities in other countries have the authority to require the recall of any such defective products. A government- mandated or voluntary recall could occur as a result of component failures, manufacturing errors, or design defects. We do not maintain insurance to cover losses incurred as a result of product recalls. Any product recall would divert managerial and financial resources and negatively affect our financial performance and could harm our reputation with customers and end- users. ~~22We~~ **21We** may not receive regulatory approvals for new product candidates or for modifications of existing products or approvals may be delayed. Regulation by governmental authorities in the United States and foreign countries is a significant factor in the development, manufacture, and marketing of our proposed products and in our ongoing research and product development activities. Any failure to receive the regulatory approvals necessary to commercialize our product candidates, or the subsequent withdrawal of any such approvals, would harm our business. Additionally, modification of our existing products may require regulatory approval. The process of obtaining these approvals

and the subsequent compliance with governmental regulations require spending substantial time and financial resources. If we fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, the marketing of any products we develop or modify, our ability to receive product revenues, and our liquidity and capital resources could be adversely affected. We sell many of our products to healthcare providers that rely on Medicare, Medicaid, and private health insurance plans to reimburse the costs associated with the procedures performed using our products and these third- party payors may deny reimbursement for use of our products. We are dependent, in part, upon the ability of healthcare providers to obtain satisfactory reimbursement from third- party payors for medical procedures in which our products are used. Third- party payors may deny reimbursement if they determine that a product has not received appropriate regulatory clearances or approvals, is not used in accordance with cost- effective treatment methods as determined by the payor, or is experimental, unnecessary, or inappropriate. Failure by hospitals and other users of our products to obtain reimbursement from third- party payors, or adverse changes in government or private third- party payors' policies toward reimbursement for procedures utilizing our products, could have a material adverse effect on our business, financial condition, and results of operations. Major third- party payors for medical services in the United States and other countries continue to try to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to charges for services performed. Further implementation of legislative or administrative reforms to the United States or international reimbursement systems in a manner that significantly reduces reimbursement for procedures using our products or denies coverage for such procedures may result in hospitals or physicians substituting lower cost products or other therapies for our products which could have a material adverse effect on our business, financial condition, and results of operations. Additionally, uncertainty about whether and how changes may be implemented could also have a negative impact on the demand for our products. Changes in healthcare legislation and policy may have a material adverse effect on our business, financial condition, and results of operations. A number of legislative initiatives to contain healthcare costs have been and continue to be introduced in the United States. In March 2010, the Affordable Care Act was enacted, which made changes that impacted and ~~are expected~~ **may continue** to **impact** significantly ~~impact~~ the pharmaceutical and medical device industries. Among other things, the Affordable Care Act contains a number of provisions designed to generate the revenues necessary to fund health insurance coverage expansions. The Affordable Care Act also implemented a number of Medicare payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models, and appropriated funding for comparative effectiveness research. The expansion in the government' s role in the United States healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and reduced medical procedure volumes, all of which may have a material adverse ~~impact~~ **effect** on our business, financial condition, and results of operations. ~~23In~~ **22In** addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions to Medicare payments to providers. It is unclear what ~~impact~~ **effect** new quality and payment programs may have on our business, financial condition, and results of operations. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints and discounts, and require marketing cost disclosure and transparency measures. We believe that additional state and federal healthcare reform measures will be adopted in the future that could have a material adverse effect on our industry generally and on our customers. Any changes in, or uncertainty with respect to, future reimbursement rates could impact our customers' demand for our products, which could have a material adverse effect on our business, financial condition, and results of operations. Future significant changes in the healthcare systems in the United States or other countries, including changes intended to reduce expenditures along with uncertainty about whether and how changes may be implemented, may have a material adverse ~~impact~~ **effect** on our business, financial condition, and results of operations. The enactment of tax reform legislation could materially ~~impact~~ **affect** our financial position and results of operations. Legislation or other changes in tax laws could materially affect our financial position and results of operations. In the ordinary course of our business, there are many transactions and calculations in which tax determinations may be uncertain. There can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge, which could result in additional taxation, penalties, and interest payments. ~~Unfavorable outcomes related to uncertain tax positions could result in significant tax liabilities. We have recorded tax benefits related to various uncertain tax positions taken or expected to be taken in a tax return. Although we believe our positions are appropriate, the United States Internal Revenue Service [IRS], or state tax authorities could disagree with our positions, which could result in significant tax liabilities.~~ The regulatory environment surrounding information security and privacy is increasingly demanding. The regulatory environment surrounding information security and privacy is increasingly demanding, with frequent imposition of new and changing requirements. In the United States, various laws and regulations apply to the collection, processing, disclosure, and security of certain types of data, including the Electronic Communications Privacy Act, the Computer Fraud and Abuse Act, the Health Insurance Portability and Accountability Act of 1996, the Gramm Leach Bliley Act, and state laws relating to privacy and data security. Several foreign countries and governmental bodies, including the European Union, also have laws and regulations dealing with the handling and processing of personal information obtained from their residents, which in certain cases are more restrictive than those in the United States. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, and security of various types of data, including data that identifies or may be used to identify an individual, such as names, email addresses, and, in some jurisdictions, internet protocol addresses. Such laws and regulations may be modified or subject to new or different interpretations, and new laws and regulations may be enacted in the future. Within the European Union, the General Data Protection Regulation, or GDPR, which became effective in May 2018 and is one of the strictest and most comprehensive privacy laws in the world, is being continuously enforced, and increasingly heavy fines are now being levied on businesses. The

GDPR' s extraterritorial scope makes it applicable to our United States- based legal entities whenever our business activities, systems, and products process the personal data of European Union residents. Any failure or perceived failure by us to comply with laws, regulations, policies, or regulatory guidance relating to privacy or data security may result in governmental investigations and enforcement actions, litigation, fines and penalties, or adverse publicity, and could cause our customers to lose trust in us, which could have an adverse effect on our reputation and business. ~~24Our~~ **23Our** sales and operations are subject to the risks of doing business internationally. A substantial portion of our sales occur outside the United States ~~, and we are increasing our presence in international markets~~ . Sales outside the United States subject us to many risks, including regulatory risks such as: · the imposition of governmental controls; · less favorable intellectual property or other applicable laws; · protectionist laws and business practices that favor local competitors; · the inability to obtain any necessary foreign regulatory or pricing approvals of products in a timely manner; and · changes in trade policies, tariffs, and tax laws. Our operations and marketing practices are also subject to regulation and scrutiny by the governments of the other countries in which we operate. In addition, we and those acting on our behalf operate in a number of jurisdictions where companies in the medical device industry are exposed to a high risk of potential FCPA violations associated with sales to healthcare professionals and institutions. We participate in transactions with third parties whose corrupt or illegal activities could potentially subject us to liability under the FCPA or local anti- corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope **,** or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are subject to other United States laws in our international operations. Failure to comply with domestic or foreign laws could result in various adverse consequences. If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence or due to the acts or inadvertence of others), we could suffer from civil and criminal penalties or other sanctions, including contract cancellations, recalls, seizures, withdrawal of an approved product from the market, debarment, or loss of reputation, any of which could have a material adverse ~~impact~~ **effect** on our business, financial condition, and results of operations. Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our products may be subject to United States export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined, or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation **,** or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to **,** existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations. ~~25Climate~~ **24Climate** Change Risks Climate change, or legal, regulatory, or market measures to address climate change, could adversely affect our business, financial condition, and results of operations. The long-term effects of climate change are difficult to predict and may be widespread. The impacts of climate change may include physical risks (such as rising sea levels or frequency and severity of extreme weather conditions), social and human effects (such as population dislocations or harm to health and well- being), compliance costs and transition risks (such as regulatory or technology changes), shifts in market trends (such as customers putting an increased priority on purchasing products that are sustainably made), and other material effects. Such impacts may disrupt our supply chain and operations by adversely affecting our ability to procure goods or services required for the operation of our business due to impairment of the availability and cost of certain products, materials, commodities, and energy. In addition, the increasing concern over climate change has resulted, and may continue to result, in more regional, national, and global legal and regulatory requirements relating to climate change, including regulating greenhouse gas emissions, alternative energy policies, and sustainability initiatives. If legislation or regulations are enacted or promulgated in the United States or in any other jurisdictions in which we do business that impose more stringent restrictions and requirements than our current legal or regulatory obligations, we may experience disruptions in, or increases in the costs associated with, sourcing, manufacturing, and distributing our products, which may adversely affect our business, financial condition, and results of operations. Any such regulatory changes could ~~have a significant~~ **significantly** ~~effect~~ **affect** ~~on~~ our operating and financial decisions, including those involving capital expenditures to reduce emissions and comply with other regulatory requirements. Risks Related to Our Stock We may experience fluctuations in our quarterly operating results. We have historically experienced, and may continue to experience, fluctuations in our quarterly operating results. These fluctuations are due to a number of factors, many of which are outside our control and may result in volatility of our stock price. Future operating results will depend on many factors, including: · demand for our products; · pricing decisions, and those of our competitors, including decisions to increase or decrease prices; · regulatory approvals for our products; · timing and levels of spending for R & D, sales, and marketing; · timing and market acceptance of new product introductions by us or our competitors; · development or expansion of business infrastructure in new clinical and geographic markets; · tax rates in the jurisdictions in which we operate; · supply chain delays or interruptions; · customer credit holds; · timing and recognition of certain R & D milestones and license fees; and · ability to control our costs; Our stock price has been and may continue to be volatile. Stock price volatility may make it more difficult for our stockholders to sell their common stock when they want to and at prices they find attractive. Our stock price can fluctuate significantly in response to a variety of factors including, among other things: · actual or anticipated variations in quarterly results of operations; · recommendations by securities analysts; **25** ·

operating and stock price performance of other companies that investors deem comparable to the Company; · perceptions in the marketplace regarding the Company and our competitors; · new technology used, or services offered, by competitors; · trading by funds with high- turnover practices or strategies; · significant acquisitions or business combinations, strategic partnerships, joint ventures, or capital commitments by or involving the Company or our competitors; · failure to integrate acquisitions or realize anticipated benefits from acquisitions; · our stock repurchase program; · changes in government regulations; and · economic or political instability, natural disasters, public health crises, acts or threats of terrorism **,** or military conflicts. ~~26Additionally --~~ **Additionally** , our public float is small which can result in large fluctuations in stock price during periods with increased selling or buying activity. General market fluctuations, industry factors, and general economic and political conditions and events, such as economic slowdowns or recessions, interest rate changes, or credit loss trends, could also cause our stock price to decrease regardless of operating results. Provisions in our governing documents and Delaware law may discourage or prevent a change of control, which could cause our stock price to decline and prevent attempts by our stockholders to replace or remove our current management. Our certificate of incorporation and bylaws contain provisions that may discourage, delay **,** or prevent a change in the ownership of the Company or a change in our management. We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15 percent or more of our outstanding common stock. Although a delay or prevention of a change of control transaction or of changes in our Board of Directors could be effective in improving stockholder value, they also carry a risk of causing the market price of our common stock to decline.