Risk Factors Comparison 2023-08-03 to 2022-07-22 Form: 10-K

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In addition to the other information contained in this Annual Report on Form 10- K and in our other filings with the Securities and Exchange Commission, the following risk factors should be considered carefully by investors in evaluating our business. Our financial and operating results are subject to a number of risks and uncertainties, including those set forth below, many of which are not within our control. Our business, financial condition, results of operations and / or liquidity could be materially and adversely affected by any of these risks or by additional risks not presently known to us or that we currently deem immaterial. RISKS RELATED TO OUR BUSINESS AND INDUSTRY We face intense competition in the medical device industry which continues to experience consolidation. We may be unable to compete effectively with respect to technological innovation and price which may have a material adverse effect on our revenues, financial condition, results of operations and / or liquidity. The markets for our products are highly competitive and we expect competition to continue to intensify. The medical device industry is characterized by rapid technological change, frequent product introductions and evolving customer requirements. Our customers consider many factors when choosing products, including technology, features and benefits, quality, reliability, ease of use, clinical or economic outcomes, availability, price and customer service. We face competition globally from a wide range of companies, many of whom have substantially greater financial, marketing and other resources than us. We may not be able to compete effectively, and we may lose market share to our competitors. Our primary device competitors include: Boston Scientific Corporation; Cook Medical; Medical Components, Inc. (MedComp); TeleFlex Medical; Becton Dickinson; Medtronic; Merit Medical; Terumo Medical Corporation; Johnson and Johnson; Philips Healthcare; Inari Medical; Varian Medical Systems and Total Vein Systems. Our competitors may succeed in adapting faster than us to changing customer needs or requirements, in developing and introducing technologies and products earlier, in obtaining patent protection (which could create barriers to market entry for us) or regulatory clearance earlier, or in commercializing new products or technologies more rapidly than us. Our competitors may also develop products and technologies that are superior to ours or that otherwise could render our products obsolete or noncompetitive. The trend of increased consolidation in the medical technology industry has resulted in companies with greater scale and market power, intensifying competition and increasing pricing pressure. We may also face competition from providers of other medical therapies, such as pharmaceutical companies, that may offer non- surgical therapies for conditions that are currently, or in the future may be, treated using our products. If we are not able to compete effectively, our market share and revenue may decline. In addition, the increasing purchasing power of health systems, group purchasing organizations (“ GPOs ”) and integrated health delivery networks (“ IDNs ”), together with increased competition and declining reimbursement rates, has resulted increasingly with the Company competing on the basis of price. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain market prices for our products or obtain or maintain contract positions with major GPOs and IDNs, which could adversely impact our profitability. Also, sales through a GPO or IDN can be significant to our business and our inability to retain contracts with our customers, or acquire additional contracts, could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. Our inability to continue to effectively develop, acquire and / or market new products and technologies could have a material adverse effect on our business, financial condition and / or results of operations. The market for our devices is characterized by rapid technological change, new product introductions, technological improvements, changes in physician requirements and evolving industry standards. Product life cycles are relatively short because medical device manufacturers continually develop more effective and less expensive versions of existing devices in response to physician demand. We engage in product development and improvement programs to maintain and improve our competitive position. Our products are technologically complex and these programs involve significant planning, market studies, investment in research and development, clinical trials and regulatory clearances or approvals and may require more time and expense than anticipated to bring such products to market. We may not, however, be successful in enhancing existing products, or developing new products or technologies that will achieve regulatory approval, be developed or manufactured in a cost- effective manner, obtain appropriate intellectual property protection or receive market acceptance. We also may be unable to recover all or a meaningful part of our investment in these products or technologies. Additionally, there can be no assurance that the size of the markets in which we compete will increase above existing levels or not decline, that we will be able to maintain, gain or regain market share or that we can compete effectively on the basis of price or that the number of procedures in which our products are used will increase above existing levels or not decline. In particular, the future prospects of many of our high growth products, such as the NanoKnife system, the AngioVac system **, the AlphaVac system** and the Auryon system, rely on continued market development and continued generation of clinical data pursuant to clinical trials conducted by us, our competitors or other third parties. If the results of these trials are not what we expect or fail to generate meaningful clinical data, it may adversely impact our ability to obtain product approvals. If any of these products fail to achieve clinical acceptance or are perceived unfavorably by the market, it could severely limit our ability to drive revenue growth, which could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. See Risk Factor titled “ Our business and prospects rely heavily upon our ability to successfully complete clinical trials, including, but not limited to, our NanoKnife DIRECT clinical study, our NanoKnife PRESERVE clinical study, AlphaVac APEX- AV clinical study and clinical studies for AngioVac. We may choose to, or may be required to, suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed. ” As part of our business strategy, we expect to continue to engage in business development activities which includes selectively evaluating and

pursuing the acquisition of complementary businesses, technologies and products. These activities may result in substantial investment of our time and financial resources and competition for targets may be significant. We may not be able to identify appropriate acquisition candidates, consummate transactions, obtain agreements with favorable terms or obtain any necessary financing or regulatory approvals. Further, once a business is acquired, any inability to successfully integrate the business or achieve anticipated cost savings or operating synergies, decreases in customer loyalty or product orders, failure to retain and develop its workforce, failure to establish and maintain appropriate controls, higher or unanticipated expenses, or unknown or contingent liabilities could adversely affect our ability to realize the anticipated benefits of any acquisition. The evaluation and integration of an acquired business, whether or not successful, requires significant efforts which may result in additional expenses and divert the attention of our management and technical personnel from other projects. If we proceed with one or more significant acquisitions in which the consideration consists of cash, a substantial portion of our available cash could be used to consummate the acquisitions. If we consummate one or more acquisitions in which the consideration consists of capital stock, our stockholders could suffer significant dilution of their interest in us. In addition, we could incur or assume significant amounts of indebtedness in connection with acquisitions. These transactions are inherently risky and may not enhance our financial position or results of operations or create value for our shareholders as they are based on projections and assumptions which are uncertain and subject to change and there can be no assurance that any past or future transaction will be successful. If we fail to develop and successfully manufacture and launch new products, generate satisfactory clinical results, provide sufficient economic value, enhance existing products, or identify, acquire and integrate complementary businesses, technologies and products or if we experience a decrease in market size or market share or declines in average selling price or procedural volumes, or otherwise fail to compete effectively, we may not achieve our growth goals, which could have a material adverse effect on our business, financial condition and / or results of operations. If we do not maintain our reputation with interventional physicians, interventional and surgical oncologists, and critical care nurses, our growth will be limited and our business could be harmed. Physicians typically influence the medical device purchasing decisions of the hospitals and other healthcare institutions in which they practice. Consequently, our reputation with interventional physicians, interventional and surgical oncologists, and critical care nurses is crucial to our continued growth. We believe that we have built a positive reputation based on the quality of our products, our physician- driven product development efforts, our marketing and training efforts and our presence at medical society meetings. Any actual or perceived diminution in the quality of our products, or our failure or inability to maintain these other efforts, could damage our reputation with interventional physicians **, interventional and surgical oncologists, and critical care nurses,** and cause our growth to be limited and our business to be harmed, which could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. Our business and prospects ~~depend~~ **rely** heavily ~~on the~~ **upon our ability to successfully complete clinical trials, including, but not limited to, our** NanoKnife ~~system~~ **DIRECT clinical study** , ~~which is currently approved~~ **our NanoKnife PRESERVE clinical study, AlphaVac APEX- AV clinical study and clinical studies** for **AngioVac** ~~the surgical ablation of soft tissue~~ . **We may choose** ~~If we are unable~~ to **,** ~~secure expanded specific regulatory approvals for~~ - **or** ~~the NanoKnife system, our business and prospects~~ may be **required to, suspend, repeat** ~~materially harmed. Our NanoKnife System is indicated for~~ - **or terminate** ~~the surgical ablation of soft tissue. The long- term prospects for~~ our ~~NanoKnife business may rely on securing expanded indications for specific disease states and treatments. Based on our current indication, our ability to promote the NanoKnife system and provide training with respect to the use of the NanoKnife system is limited to the surgical ablation of soft tissue. In the fourth quarter of our 2019, we received approval from the FDA to initiate our DIRECT~~ clinical ~~trial~~ **trials if** ~~to study the~~ **they** ~~use of the NanoKnife system for the treatment of Stage III pancreatic cancer. In the second quarter of our 2022, we received approval from the FDA to initiate our PRESERVE clinical trial to study the use of the NanoKnife system for the treatment of prostate cancer. If we~~ are not ~~able to successfully complete~~ **conducted in accordance with regulatory requirements,** ~~these~~ -- **the results are negative or inconclusive or the** trials ~~and secure clearances or approvals for expanded indications for our NanoKnife system, including for the treatment of Stage III pancreatic cancer or the treatment of prostate cancer, or if expanded indications~~ are **not well designed** ~~significantly delayed or limited, our business and prospects may be materially harmed and we may need to delay our initiatives or even significantly curtail operations, which could have a material adverse effect on our business, financial condition, results of operations and / or liquidity~~ . Clinical trials must be conducted in accordance with the applicable laws and regulations in the jurisdictions in which the clinical trials are conducted, including FDA' s current Good Clinical Practices. The clinical trials are subject to oversight by the FDA, regulatory agencies in other jurisdictions, ethics committees and institutional review boards at the medical institutions where the clinical trials are conducted. Clinical trial protocols may require a large number of patients to be enrolled in the trials. Patient enrollment is a function of many factors, including the size of the patient population for the target indication, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. Clinical trials may be suspended by the FDA or by a regulatory agency in another jurisdiction at any time if the FDA or the regulatory agency finds deficiencies in the conduct of these trials or it is believed that these trials expose patients to unacceptable health risks. We, the FDA or regulatory agencies in other jurisdictions might delay or terminate our clinical trials for various reasons, including insufficient patient enrollment, fatalities, unforeseen adverse side effects by enrolled patients or the development of new therapies that require us to revise or amend our clinical trial protocols. Patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive follow- up to assess safety and effectiveness, if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts or if they participate in contemporaneous clinical trials of competing products. In addition, we rely on contract research organizations, or CROs, with respect to conducting our clinical trials. We may experience significant cost overruns associated with, and we may encounter difficulties managing, these CROs. Termination of our clinical trials or significant delays in completing our clinical trials could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. If we are unable to convince customers that our products

can improve the cost structure of their business, our revenue growth and profitability may be materially and adversely impacted. Worldwide initiatives to contain healthcare costs have led governments and the private sector to enact cost containment efforts as a means of managing the growth of health care utilization. Common techniques include policies on price regulation, competitive pricing, bidding and tender mechanics, coverage and payment, comparative effectiveness of therapies, technology assessments, and managed- care arrangements. These changes are causing the marketplace to put increased emphasis on the delivery of more cost- effective medical devices and therapies. Government programs, including Medicare and Medicaid, private health care insurance, and managed- care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments, tying reimbursement to outcomes, shifting to population health management, and other mechanisms designed to constrain utilization and contain costs. Simultaneously, hospitals are redefining their role in health care delivery as many assume much more risk and control of the total cost of patient care. To successfully make this transformation, health systems are consolidating, purchasing or partnering with physicians and post- acute care providers, while also narrowing networks thus allowing greater control over outcomes. This has created an increasing level of price sensitivity among customers for our products and could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. We are dependent on single and limited source suppliers which subjects our business and results of operations to risks of supplier business interruptions. We currently purchase significant amounts of several key products, raw materials and product components from single and limited source suppliers and anticipate that we will do so for future products as well. Any delays in delivery of or shortages in those or other products and components (like we experienced during our 2022 **and 2023** fiscal year) could interrupt and delay manufacturing of our products, lead to backlogs and result in the cancellation of orders for our products. Any or all of these suppliers could discontinue the manufacture or supply of these products, raw materials and / or components at any time. Due to FDA and other business considerations, we may not be able to identify and integrate alternative sources of supply in a timely fashion or at all. Any transition to alternate suppliers may result in production delays and increased costs and may limit our ability to deliver products to our customers. Furthermore, if we are unable to identify alternative sources of supply, we would have to modify our products to use substitute components, which may cause delays in shipments, backlogs, increased prices for our products or increased design and manufacturing costs. In addition, we purchase certain products as a distributor for the manufacturer of those products. Any constraint or interruption in the supply of raw materials, other product components or finished products that we distribute could materially impact our ability to sell products, and have a material adverse effect on our business, financial condition, results of operations and / or liquidity. We are heavily dependent on third- party distributors to generate a substantial portion of our international revenues and are at the risk of these distributors also selling for our competitors, failing to be financially viable and failing to effectively distribute our products in compliance with applicable laws. Outside of North America we rely heavily on third party distributors, either on a country- by- country basis or on a multi- country, regional basis, to market, sell and distribute our products where we do not have a direct sales and marketing presence (including, among others, China, Japan, Brazil, the Middle East and many European countries). As such, our revenue, if any, depends on the terms of such arrangements and the distributors' efforts. These efforts may turn out not to be sufficient and our third- party distributors may not effectively sell our products. International distributors accounted for approximately ~~61~~ **72** % of international revenues for the fiscal year ended May 31, ~~2022~~ **2023 . International sales grew 12 % in fiscal year 2023 as we continued to develop and foster partnerships with distributors such as Healthcare 21, Cardiva and Mediplast** . If we are unable to maintain our relationships or establish direct sales capabilities on acceptable terms or at all, we may lose significant revenue or be unable to achieve our growth aspirations. In certain circumstances, distributors may also sell competing products, or products for competing diagnostic modalities, and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain our current levels of unit sales or increase or maintain our current unit pricing, which, in turn, could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. In addition, there is a risk that our distributors will not be financially viable due to current economic and / or regulatory events in their respective countries or remit payments to us in a timely manner. If our distributors fail to comply with applicable laws or fail to effectively market and sell our products, our financial condition and results of operations could be materially and adversely impacted. Failure to secure adequate reimbursement for our products could materially impair our ability to grow revenue and drive profitability. Our products are used in medical procedures and purchased principally by hospitals or physicians which typically bill various third- party payors, such as governmental programs (e. g., Medicare, Medicaid and comparable foreign programs), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain appropriate reimbursement for products and services from third- party payors is critical to the success of medical device companies because it affects which products customers purchase and the prices they are willing to pay. In general, a third- party payor only covers a medical product or procedure when the plan administrator is satisfied that the product or procedure improves health outcomes, including quality of life or functional ability, in a safe and cost- effective manner. Even if a device has received clearance or approval for marketing by the FDA, there is no assurance that third- party payors, including Medicare and managed care companies, will cover the cost of the device and related procedures. Even if coverage is available, third- party payors may place restrictions on the circumstances where they provide coverage or may offer reimbursement that is not sufficient to cover the cost of our products. Third- party payors who cover the cost of medical products or equipment, in addition to allowing a general charge for the procedure, often maintain lists of exclusive suppliers or approved lists of products deemed to be cost- effective. If our products are not on approved lists of third- party payors, healthcare providers must determine if the additional cost and effort required in obtaining prior authorization, and the uncertainty of actually obtaining coverage, is justified by any perceived clinical benefits from using our products. Finally, the advent of contracted fixed rates per procedure has made it difficult to receive reimbursement for disposable products, even if the use of these products improves clinical outcomes. In addition, many third- party payors are moving to managed care systems in which providers contract to provide comprehensive healthcare for a

fixed cost per person. Managed care providers often attempt to control the cost of healthcare by authorizing fewer elective surgical procedures. Under current prospective payment systems, such as the diagnosis related group system and the hospital out- patient prospective payment system, both of which are used by Medicare and in many managed care systems used by private third- party payors, the cost of our products will be incorporated into the overall cost of a procedure and not be separately reimbursed. If hospitals and physicians cannot obtain adequate reimbursement for our products or the procedures in which they are used, this could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. Reimbursement varies by country and can significantly impact the acceptance of new technology. Implementation of healthcare reforms in the United States and in other countries may limit, reduce or eliminate reimbursement for our products and adversely affect both our pricing flexibility and the demand for our products. Even when we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third- party payors. Changes in healthcare systems in the United States or elsewhere in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for these procedures, or adverse decisions relating to our products by administrators of these systems in coverage or reimbursement issues, would have an adverse impact on the acceptance of our products and the prices which our customers are willing to pay for them. If a product liability claim is brought against us or our product liability insurance coverage is inadequate, our business could be harmed. The design, manufacture and marketing of the types of medical devices we sell entail an inherent risk of product liability. Our products are used by physicians to treat seriously ill patients. We are periodically subject to product liability claims, and patients or customers may in the future bring claims against us in a number of circumstances and for a number of reasons, including if our products were misused, if a component of our product fails, if our manufacture or design was flawed, if the product produced unsatisfactory results or if the instructions for use and operating manuals and disclosure of product related risks for our products were found to be inadequate. In addition, individuals or groups seeking to represent a class may file suit against us. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. We carry a product liability policy with a limit of $ 10. 0 million per product liability claim and an aggregate policy limit of $ 10. 0 million, subject to a self-insured retention of $ 0. 5 million per occurrence and $ 2. 0 million in the aggregate. We believe, based on claims made against us in the past, our existing product liability insurance coverage is reasonably adequate to protect us from any liabilities we might incur. However, there is no assurance that this coverage will be sufficient to satisfy any claim made against us. In addition, we may not be able to continue to maintain adequate coverage at a reasonable cost and on reasonable terms, if at all. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing any coverage in the future. Additionally, if one or more product liability claims is brought against us for uninsured liabilities or is in excess of our insurance coverage, our financial condition, results of operations and / or liquidity could be negatively impacted. Further, such claims may require us to recall some of our products, which could result in significant costs to us. **We may be exposed to risks associated with product line divestitures as we may never realize the expected benefits and could cause operational disruptions with personnel, systems and infrastructure changes. On June 8, 2023, the Company entered into an asset purchase agreement (the" Asset Purchase Agreement") with Merit Medical Systems, Inc. pursuant to which Merit acquired the dialysis product portfolio and BioSentry tract sealant system biopsy businesses for $ 100. 0 million in cash. The Company and Merit entered into various agreements to facilitate the transition to Merit, including a Transactions Services Agreement and Contract Manufacturing Agreement. This divestiture along with potential future divestitures of certain product lines will allow us to transform ourselves into a high growth, highly profitable, medical technology company. If we are unable to achieve our growth and profitability objectives due to competition, lack of acceptance of our products, failure to generate favorable clinical data or gain regulatory approvals, or other risks as described in this section, or due to other events, we will not be successful in transforming our business and may not see the appropriate market valuation. The divestiture of product lines will impact revenue, earnings and cash flows, which over time we expect to replace by investing in higher margin revenue streams. There is a risk that we will be unable to replace the revenue, earnings and cash flow that these product lines generated, or that the cost of such will be higher than expected. If we are unable to achieve our profit and growth objectives, such failure will be exacerbated by the loss of revenue, earnings and cash flow generated by our divested product lines and could materially impact our financial position and results of operations, resulting in a decline in our stock price. The sale of product lines could require us to restructure significant personnel, systems and infrastructure. In some instances, we may enter into short term transition service arrangements, under which the parties perform certain services for each other pending establishment of new processes and systems. Although these transitions are thoroughly planned, it is not unlikely in a transaction of this complexity that disruptions could occur. If disruptions to our financial controls, IT, administrative support, manufacturing or regulatory processes occur, and if such disruptions prove to be more severe than our planning anticipated, this could have a material adverse effect on our business.** International and national economic and industry conditions constantly change, and could materially and adversely affect our business, financial condition and results of operations. Our business, financial condition and results of operation are affected by many changing economic, industry and other conditions beyond our control. Actual or potential changes in international, national, regional and local economic, business and financial conditions, including recession, high inflation and trade protection measures, creditworthiness of our customers, may negatively affect consumer preferences, perceptions, spending patterns or demographic trends, any of which could adversely affect our business, financial condition, results of operations and / or liquidity. We are subject to macro- economic fluctuations in the U. S. and worldwide economy. Concerns about consumer and investor confidence, volatile corporate profits and reduced capital spending, international conflicts, terrorist and military activity, civil unrest and pandemic illness could

reduce customer orders or cause customer order cancellations. In addition, political and social turmoil may put further pressure on economic conditions in the United States and abroad. The global economy has been periodically impacted by the effects of global economic downturns (such as **those** recently related to COVID- 19). There can be no assurance that there will not be further such events or deterioration in the global economy. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities. Volatility in the cost of raw materials, components, freight and energy increases the costs of producing and distributing our products. New laws or regulations adopted in response to climate change could also increase energy and transportation costs, as well as the costs of certain raw materials and components. Increases in oil prices may increase our packaging and transportation costs. Recently, the costs of labor, raw materials, transportation, construction, services, and energy necessary for the production and distribution of our products have increased significantly. While we have implemented cost containment measures, selective price increases and taken other actions to offset these inflationary pressures in our supply chain, we may not be able to completely offset all the increases in our operational costs, any of which could adversely affect our business, financial condition, results of operations and / or liquidity. Sales outside the U. S. accounted for approximately ~~16~~ **17** % of our net sales during our fiscal year ended May 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 and / or faster- growing markets outside the U. S. 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 / or results of operations, many of which we cannot predict, including: • fluctuations in currency exchange rates which may, in some instances affect spending behavior and reduce cash flows and revenue outside the U. S.; • healthcare reform legislation; • multiple non- U. S. regulatory requirements that are subject to change and could restrict our ability to manufacture and sell our products; • local product preferences and product requirements; • longer- term receivables than are typical in the U. S. and / or the ability to obtain payment; • trade protection measures and import or export licensing requirements; • less intellectual property protection in some countries outside the U. S. than exists in the U. S.; • different labor regulations and workforce instability; • the potential payment of U. S. income taxes on earnings of certain foreign subsidiaries subject to U. S. taxation upon repatriation; • the expiration and non- renewal of foreign tax rulings; • potential negative consequences from changes in or interpretation of tax laws, including changes in our effective tax rate or the applicable tax rate in one or more jurisdictions; and • economic instability and inflation, recession or interest rate fluctuations. ~~In addition, the United Kingdom' s (" UK ") departure from the European Union (" EU ") (commonly known as " Brexit ") has created uncertainties affecting business operations in the UK, the EU 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 these markets. While we have taken proactive steps to mitigate possible disruption to our operations, 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 UK and EU regarding Brexit and the future EU / UK trading relationship.~~ Russia' s invasion and military attacks on Ukraine have triggered significant sanctions from U. S. and European leaders. These events may escalate and have created increasingly volatile global economic conditions. Resulting changes in U. S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a " trade war. " A trade war could result in increased costs for raw materials we use in our manufacturing and could result in Russia and other foreign governments imposing tariffs on products that we export outside the U. S. or otherwise limiting our ability to sell our products abroad. These increased costs could have a material adverse effect on our business, financial condition and results of operations. Furthermore, if the conflict between Russia and Ukraine continues for a long period of time, or if other countries, including the U. S., become further involved in the conflict, we could face material adverse effects on our business, financial condition, results of operations and / or liquidity. Our business could be harmed if we cannot hire or retain qualified personnel. Our business depends upon our ability to attract and retain highly qualified personnel, including managerial, sales **,** and technical personnel. We compete for key personnel with other companies, healthcare institutions, academic institutions, government entities and other organizations. We do not have written employment agreements with our executive officers, other than the CEO. Our ability to maintain and expand our business may be impaired if we are unable to retain our current key personnel or hire or retain other qualified personnel in the future, including personnel for our manufacturing facilities **and field based sales employees** . If we are not able to hire and retain personnel in our manufacturing facilities, we may not meet our production demand. We **have** experienced labor shortages in fiscal ~~year~~ **years** 2022 **and 2023** that significantly contributed to the backlog. In addition, our sales force is highly talented and we face intense competition in our industry for sales personnel which could have an adverse effect on our business **and revenue** if there is significant turnover. If we are unable to manage our growth profitably, our business, financial results and stock price could suffer. Our future financial results will depend in part on our ability to profitably manage our growth. Management will need to maintain existing customers and attract new customers, recruit, retain and effectively manage employees, as well as expand operations and integrate customer support and financial control systems. If integration- related expenses and capital expenditure requirements are greater than anticipated or if we are unable to manage our growth profitably, our financial results and the market price of our common stock may decline. In recent years we have begun to implement operational excellence initiatives which include a number of restructuring, realignment and cost reduction initiatives. We may not realize the benefits of these initiatives to the extent or on the timing we anticipated and the ongoing difficulties in implementing these measures may be greater than anticipated and / or offset by inflationary pressures, which could cause us to incur additional costs or result in business disruptions like the backlogs we **have** experienced in fiscal ~~year~~ **years** 2022 **and 2023** . In addition, if these measures are not successful or sustainable, we may undertake additional realignment and cost reduction efforts, which could result in significant additional expenses and adversely impact our ability to achieve our other strategic goals and business plans. We may fail to attract additional capital necessary to expand our business or may incur additional indebtedness which, together with our current indebtedness levels, could impose operating and financial restrictions

on us as a result of debt service obligations which could significantly limit our ability to execute our business strategy or curtail our growth. We may require additional capital to expand our business. If cash generated internally is insufficient to fund capital requirements, we may require additional debt or equity financing. In addition, we may require financing to fund any significant acquisitions we may seek to make. Disruptions in the capital markets and increases in the cost of capital have previously resulted, and could again result, in volatility, decreased liquidity, and widening of credit spreads, which could make needed financing either unavailable or available on terms unsatisfactory to us which could result in significant stockholder dilution. We may incur additional indebtedness or draw additional amounts on our existing credit facilities in the future subject to limitations contained in the agreements governing our debt. The interest rate on potential borrowings could be a floating rate which could expose us to the risk of increased interest expense in the future. The terms of indebtedness could require us to comply with certain financial maintenance covenants. In addition, the terms of our existing indebtedness include, and any future indebtedness could include, covenants restricting or limiting our ability to take certain actions. These covenants could adversely affect our ability to obtain additional financing, to finance future operations, to pursue certain business opportunities or take certain corporate actions. The covenants could also restrict our flexibility in planning for changes in our business and the industry and could make us more vulnerable to economic downturns and adverse developments, could limit our flexibility in planning for, or reacting to, changes and opportunities in the markets in which we compete, could place us at a competitive disadvantage compared to our competitors that have less debt or could require us to dedicate a substantial portion of our cash flow to service our debt. Our ability to meet our cash requirements, including our debt service obligations, could be dependent upon our operating performance, which would be subject to general economic and competitive conditions and to financial, business and other factors affecting our operations, many of which could be beyond our control. We cannot provide assurance that our business operations would generate sufficient cash flows from operations to fund potential cash requirements and debt service obligations. If our operating results, cash flow or capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt and other obligations. If we incurred indebtedness and were unable to service our debt, we could be forced to reduce or delay planned expansions and capital expenditures, sell assets, restructure or refinance our debt or seek additional equity capital, and we could be unable to take any of these actions on satisfactory terms or in a timely manner. Further, any of these actions may not be sufficient to allow us to service our potential debt obligations or could have an adverse impact on our business. Our potential debt agreements could limit our ability to take certain of these actions. Our failure to generate sufficient operating cash flow to pay our potential debts or to successfully undertake any of these actions could have a material adverse effect on us. **Inflationary pressure and unfavorable economic conditions could negatively affect our operations and business. A significant deterioration in economic conditions, including economic slowdowns or recessions, increased unemployment levels, inflationary pressures or disruptions to credit and capital markets, could lead to decreased consumer confidence and spending and availability of credit. For example, in 2022 and continuing into 2023, the United States and other** ~~Uncertainty ---- certain relating to the LIBOR calculation method and potential phasing out of LIBOR after 2021~~ **foreign countries have experienced a rapid increase in inflation levels. Such heightened inflationary levels** may ~~adversely affect the~~ **negatively impact demand for our products and increase our costs. Additionally, we finance a portion of our portfolio with unhedged floating- rate debt from our Credit Agreement. The rapid increase in inflation during fiscal year 2023 led to a rapid increase in market** interest rates **, which materially increased** ~~under our Credit Agreement. Certain of~~ the interest **rate on our floating rate debt. In addition, if** rates ~~applicable~~ **continue** to **increase** ~~our Credit Agreement~~ , **we may incur significant additional expense and adversely impact** ~~are LIBOR- based. On July 27, 2017, the U. K. Financial Conduct Authority (the " FCA ") announced that it will no longer persuade or~~ **our ability** ~~compel banks~~ to **achieve our** ~~submit rates for the calculation of LIBOR rates after 2021. Actions by the FCA,~~ other **strategic goals** ~~regulators or law enforcement agencies may result in changes to the method by which LIBOR is calculated. At this time, it is not possible to predict the effect of any such changes or any other reforms to LIBOR that may be enacted in the UK or elsewhere. Uncertainty as to the nature of such potential changes may adversely affect the trading market for LIBOR- based securities, including the floating rates applicable to our Credit Agreement. It is possible that the changes in how LIBOR is calculated, changes in the trading market for LIBOR- based securities or actions of the FCA~~ and ~~other government entities may cause unexpected increases in LIBOR rates or a breakdown in the LIBOR systems. If these issues arise, we could experience increased interest rates or uncertainty with respect to the calculation of interest on our Credit Agreement, which could adversely affect our~~ business **plans** ~~, financial condition, results of operations and / or liquidity~~ . Our goodwill, intangible assets and fixed assets are subject to potential impairment; we have recorded significant goodwill impairment charges and may be required to record additional charges to future earnings if our goodwill or intangible assets become impaired. A significant portion of our assets consists of goodwill, intangible assets and fixed assets, the carrying value of which may be reduced if we determine that those assets are impaired, including intangible assets from recent acquisitions. During the fourth quarter of fiscal year 2021, the Company made the decision to abandon the OARtrac product technology and trademark. This resulted in an impairment charge of $ 14. 0 million. The impairment charge is recorded in" Acquisition, restructuring and other items, net", on the Consolidated Statements of Operations (see Note ~~18~~ **19," Acquisition, restructuring and other items, net" set forth in the Notes in the consolidated financial statements included in this Annual Report on Form 10- K**). Most of our intangible and fixed assets have finite useful lives and are amortized or depreciated over their useful lives on either a straight- line basis or over the expected period of benefit or as revenues are earned from the sales of the related products. The underlying assumptions regarding the estimated useful lives of these intangible assets are reviewed quarterly and more often if an event or circumstance occurs making it likely that the carrying value of the assets may not be recoverable and are adjusted through accelerated amortization if necessary. Whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable, we test intangible assets for impairment based on estimates of future cash flows. Factors that may be considered a change in circumstances indicating that the carrying value of our intangible assets and /

or goodwill may not be recoverable include a decline in stock price and market capitalization, slower growth rates in our industry or our own operations and / or other materially adverse events that have implications on the profitability of our business. When testing for impairment of definite- lived intangible assets held for use, the Company groups assets at the lowest level for which cash flows are separately identifiable. The Company operates as a single asset group. If an intangible asset is considered to be impaired, the amount of the impairment will equal the excess of the carrying value over the fair value of the asset. Goodwill ~~is required to be~~ **and other intangible assets that have indefinite useful lives are not amortized, but rather, are** tested for impairment ~~at least~~ annually ~~. We historically reviewed our~~ **or** ~~single~~ **more frequently if impairment indicators arise. Prior to the first quarter of fiscal year 2023, the Company managed its operations as one** reporting unit ~~for potential goodwill impairment in the third fiscal quarter of each year as part of our annual goodwill impairment testing, and more often if an event or circumstance occurred making it likely that impairment exists~~ . ~~In~~ **At** the ~~fourth~~ **beginning of the first** quarter of fiscal year ~~2022~~ **2023** , the Company ~~changed~~ **began to manage** its **operations as two operating segments and two reporting units, namely Med Tech and Med Device (see Note 18" Segment and Geographic Information" set forth in the Notes to our consolidated financial statements included in this** ~~annual~~ **Annual Report on Form 10- K)** ~~impairment assessment date from December 31 to April 30 to more closely align the impairment assessment date with the Company' s long term planning and forecasting process~~ . The annual goodwill impairment review performed in ~~December 2021 and~~ April **2023 and** 2022 indicated no goodwill impairments. **As of May 31, 2023, the Company concluded that the sale of the dialysis product portfolio and BioSentry tract sealant system biopsy businesses to Merit Medical Systems,** ~~In~~ **Inc** ~~fiscal year 2020~~ **. was a triggering event for the Med Device report unit. The Company utilized the income approach to determine the fair value of the remaining Med Device reporting unit. Based on the results of this evaluation** , ~~we~~ **the Company** recorded a goodwill impairment ~~loss~~ **charge** of $ ~~158~~ **14** . ~~6~~ **5** million **for the year ended May 31, 2023 to write down the carrying value of the Med Device reporting unit to fair value** . If actual results differ from the assumptions and estimates used in the goodwill and intangible asset calculations, we could incur future impairment or amortization charges, which could negatively impact our financial condition and results of operations. We may be limited in our ability to utilize, or may not be able to utilize, net operating loss carryforwards to reduce our future tax liability. IRC Section 382 and related provisions contain rules that limit for U. S. federal income tax purposes the ability of a Company that undergoes an " ownership change " to utilize its net operating loss carryforwards and certain other tax attributes existing as of the date of such ownership change. Our Federal net operating loss carryforwards as of May 31, ~~2022~~ **2023** after considering IRC Section 382 limitations are $ ~~174~~ **169** . ~~2~~ **7** million. The expiration of the Federal net operating loss carryforwards is as follows: $ ~~8~~ **5** . ~~6~~ **2** million between ~~2022 and~~ 2023 **and 2024** , $ 79. 4 million between 2028 and 2037 and $ ~~86~~ **85** . 1 million indefinitely. Our state net operating loss carryforwards as of May 31, ~~2022~~ **2023** after considering remaining IRC Section 382 limitations are $ ~~30~~ **24** . 1 million which expire in various years from 2029 to 2042. Future ownership changes within the meaning of IRC Section 382 may also subject our tax loss carryforwards to annual limitations which would restrict our ability to use them to offset our taxable income in periods following the ownership changes. See Note ~~9 to~~ **10," Income Taxes" set forth in** our consolidated financial statements included in our Annual Report on Form 10- K for the fiscal year ended May 31, ~~2022~~ **2023** for a further discussion of our tax loss carryovers. A cyber- attack or other breach of our **, our distributors,** or our supply chain partners' information technology systems could have a material adverse effect on our business, financial condition and / or results of operations. We rely on information technology systems to process, transmit, and store electronic information in our day- to- day operations. Similar to other large multi-national companies, the size and complexity of our information technology systems makes them vulnerable to cyber- attacks, malicious intrusions, breakdowns, destruction, losses of data privacy, or other significant disruptions. Our **distributors and** supply chain partners face similar risks. Our information systems require an ongoing commitment of resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information, and changing customer patterns. In addition, third parties may attempt to gain access into our systems or products or those of our supply chain partners to obtain data relating to patients or our proprietary information. Any failure by us **, our distributors,** or our supply chain partners to maintain or protect information technology systems and data integrity, including from cyber-attacks, ransomware, intrusions or other breaches, could result in the unauthorized access to supply chain partners or vendors and personally identifiable information, theft of intellectual property, misappropriation of assets, or otherwise compromise confidential or proprietary information and disrupt operations of our Company **, our distributors,** or our supply chain partners. Any of these events, in turn, may cause us to lose existing customers, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, our supply chain partners, physicians, and other health care professionals, be subject to legal claims and liability, 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 theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition and / or results of operations. Any disaster at our manufacturing facilities or those of our suppliers could disrupt our ability to manufacture our products for a substantial amount of time. We conduct manufacturing and assembly at facilities in Queensbury, New York, Glens Falls, New York, and other third parties in Costa Rica, **Israel,** Latvia, **China** and other locations. It would be difficult, expensive and time- consuming to transfer resources from one facility to the other and / or replace or repair these facilities or manufacturing equipment if they were significantly affected by a disaster. Additionally, we might be forced to rely on third- party manufacturers or delay production of our products. Insurance for damage to our properties and the disruption of our business from disasters may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If one of our principal suppliers were to experience a similar disaster, uninsured loss or under- insured loss, we might not be able to obtain adequate alternative sources of supplies or products. Any significant uninsured loss, prolonged or repeated disruption, or inability to operate experienced by us or any of our principal suppliers could cause significant harm to our business, financial condition,

results of operations and / or liquidity. Anti- takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could cause our stock price to decline and prevent attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that may enable our management to resist a change in control. For example, our Board of Directors is classified so that not all members of our Board of Directors are elected at one time and our Board of Directors is authorized, without prior stockholder approval, to create and issue " blank check " preferred stock with rights senior to those of our common stock and stockholder action by written consent is prohibited. 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 % or more of our outstanding voting stock. These provisions may discourage, delay or prevent a change in the ownership of our Company or a change in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline. The COVID- 19 pandemic has negatively impacted our business and operations around the world and may continue to materially and adversely impact our business, operations and financial results. The COVID- 19 pandemic has created significant disruption and uncertainty in the global economy and has negatively impacted our business and results of operations and financial condition **during fiscal years 2021** ~~most recently with~~ **2022 and 2023. Although the impact of COVID- 19 and the resulting measures decreased during 2023,** ~~the~~ **they have** ~~escalation of~~ the **potential to** ~~Omicron and subsequent variants, and we anticipate that it may~~ continue to negatively impact our business, results of operations and financial condition ~~for~~ **in** the ~~foreseeable~~ future. Numerous national, international, state and local jurisdictions have imposed, and others in the future may impose, a variety of government orders and restrictions for their residents to control the spread of COVID- 19. Such orders or restrictions may cause significant alteration of our operations, work stoppages, slowdowns and delays, travel restrictions and event cancellations, among other effects, thereby significantly and negatively impacting our operations. Other disruptions or potential disruptions include: (i) restrictions on our personnel and personnel of business partners to travel and access customers for training and case support ; (ii) reductions in spending by our customers; (iii) delays in clearance, approvals or certifications by regulatory bodies ; (iv) diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people ; (v) reductions in our sales team, including through layoffs, furloughs or other losses of sales representatives ; (vi) additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our products; (vii) disruption of our research and development activities; and (viii) delays in ongoing studies and pre- clinical trials. In addition, elective procedures that use our products significantly decreased in number during fiscal year 2021, as health care organizations around the world prioritized the treatment of patients with COVID- 19 and reduced spending in other areas. We experienced a similar impact to procedure volumes with the resurgence of COVID- 19 in fiscal year 2022 **which continued through fiscal year 2023** . For example in fiscal year 2021, U. S. governmental authorities had recommended, and in certain cases required, that elective, deferrable, specialty and other procedures and appointments, be suspended or canceled to avoid non- essential patient exposure to medical environments and potential infection with COVID- 19 so that limited resources and personnel could be focused on the treatment of infected patients. Many of these procedures that use our products were suspended or postponed at times during fiscal years 2021 ~~and~~ **,** 2022 **and 2023** . Similarly, our clinical trials were impacted by COVID- 19 as hospitals prioritized treating these patients. It is unclear when or if other resurgences of COVID- 19, or increased spread of its variants, may again cause a rise in infections and result in authorities and / or customers imposing restrictions that could adversely affect our business, financial condition, results of operations and / or liquidity. In addition, most of the hospitals and clinics that purchase our products have instituted strict procedures at their facilities in an effort to prevent the spread of COVID- 19, including restrictions on sales representatives entering these facilities. This has been, and currently remains, a major impediment to our sales efforts, as supporting existing customers and acquiring new customers is much more difficult in this environment. These restrictions have had an effect on our sales and, until they are lifted, our business, operations and financial results will continue to be adversely impacted. These challenges and restrictions will likely continue for the duration of the pandemic, which is uncertain, and may even continue beyond the pandemic. Many areas have relaxed restrictions from time- to- time and have resumed business operations, but a resurgence in infections or mutations of the coronavirus that causes COVID- 19 could cause authorities and / or our customers to reinstate such restrictions or impose additional restrictions. All of these factors also may cause or contribute to disruptions and delays in our logistics and supply chain. The extent to which the COVID- 19 pandemic impacts our business, operations and financial results will depend on future developments that are uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of the virus and the actions by government entities, our customers and other parties to contain the virus or treat its impact, among others. To the extent the COVID- 19 pandemic adversely affects our business, operations and financial results, it may also have the effect of heightening other risks described herein, such as those relating to general economic conditions, demand for our products, relationships with suppliers and sales efforts. We could be negatively impacted by Environmental, Social and Governance (ESG), climate change and other sustainability- related matters. Governments, investors, customers, employees and other stakeholders are increasingly focusing on corporate ESG practices and disclosures, including risks associated with climate change and expectations in this area are rapidly evolving. Shifts in weather patterns caused by climate change are expected to increase the frequency and severity of adverse weather conditions such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause or contribute to reduced workforce availability, increased production and distribution costs and disruptions and delays in our logistics and supply chain / operations as well as the operations of our customers. The increasing attention to corporate ESG initiatives and ESG risks could result in reduced demand for products, reduced profits and increased investigations and litigation. If we are unable to satisfy any new

criteria by which our ESG practices may be assessed, investors may conclude that our policies and / or actions with respect to ESG matters and risks are inadequate. If we fail or are perceived to have failed to accurately disclose our progress on such initiatives or goals, our reputation, business, financial condition and results of operations could be adversely impacted. RISKS RELATED TO THE REGULATORY ENVIRONMENT We are subject to a comprehensive system of federal, state and international laws and regulations, and we could be the subject of investigations, enforcement actions or face lawsuits and monetary or equitable judgments. We operate in many parts of the world, and our operations are affected by complex state, federal and international laws relating to healthcare, environmental protection, antitrust, anti- corruption, anti- bribery, fraud and abuse, export control, tax, employment and laws regarding privacy, personally identifiable information and protected health information, including, for example, the Food, Drug and Cosmetic Act (" FDCA "), various FDA and international regulations relating to, among other things, the development, quality assurance, manufacturing, importation, distribution, marketing and sale of, and billing for, our products, the federal Anti- Kickback Statute and Federal False Claims Act (Note ~~16~~ **17**), the U. S. Foreign Corrupt Practices Act (" FCPA ") and similar anti- bribery laws in international jurisdictions, including the UK Anti-Bribery Act, the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), General Data Protection Regulation (" GDPR "), domestic and foreign data protection, data security and privacy laws, laws related to the collection, storage, use and disclosure of personal data and laws and regulations relating to sanctions and money laundering. The failure to comply with these laws and regulatory standards, allegations of such non- compliance or the discovery of previously unknown problems with a product or manufacturer: (i) could result in FDA Form- 483 notices and / or warning letters or the foreign equivalent, fines, delays or suspensions of regulatory clearances, investigations, detainment, seizures or recalls of products (with the attendant expenses), the banning of a particular device, an order to replace or refund the cost of any device previously manufactured or distributed, operating restrictions and / or civil or criminal prosecution, and / or penalties, as well as decreased sales as a result of negative publicity and product liability claims; (ii) could expose us to breach of contract claims, fines and penalties, costs for remediation and harm to our reputation; (iii) could result in criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States; and (iv) could otherwise disrupt our business and could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. The healthcare industry is under continued scrutiny from state, federal and international governments, including with respect to industry practices in the area of sales and marketing. Certain states, including Massachusetts, have recently passed or are considering legislation restricting our interactions with health care providers and requiring disclosure of many payments to them. The federal government has recently introduced similar legislation, which may or may not preempt state laws. If our marketing, sales or other activities fail to comply with the FDA' s or other comparable foreign regulatory agencies' regulations or guidelines, or other applicable laws, we may be subject to warnings from the FDA or investigations or enforcement actions from the FDA, Medicare, the Office of Inspector General of the U. S. Department of Health and Human Services or other government agencies or enforcement bodies. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by governmental authorities may increase compliance costs, increase exposure to litigation and may have other adverse effects to our operations. The Company' s failure to comply with any marketing or sales regulations or any other applicable regulatory requirements could adversely affect our business, results of operations, financial condition and / or liquidity. In addition, lawsuits by or otherwise involving employees, customers, licensors, licensees, suppliers, vendors, business partners, distributors, shareholders or competitors with respect to how we conduct our business could be very costly and could substantially disrupt our business. The occurrence of an adverse monetary or equitable judgment or a large expenditure in connection with a settlement of any of these matters could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. If we or some of our suppliers fail to comply with the FDA' s Quality System Regulation, or QSR, and other applicable post- market requirements, our manufacturing operations could be disrupted, our product sales and profitability could suffer, and we may be subject to a wide variety of FDA enforcement actions. Our manufacturing processes and those of some of our suppliers must comply with the FDA' s Quality System Regulation, or QSR, which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage and shipping of medical devices, and with current medical device adverse event reporting regulations, and similar foreign rules and regulations. The FDA enforces the QSR through unannounced inspections. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from negligent, reckless or criminal acts committed by our employees or agents. If we, or one of our suppliers, fail a QSR inspection, or if a corrective action plan adopted by us or one of our suppliers is not sufficient, the FDA may bring an enforcement action, and our operations could be disrupted and our manufacturing delayed. We are also subject to the FDA' s general prohibition against promoting our products for unapproved or " off- label " uses, the FDA' s adverse event reporting requirements and the FDA' s reporting requirements for field correction or product removals. The FDA has recently placed increased emphasis on its scrutiny of compliance with the QSR and these other post- market requirements. In addition, most other countries require us and our suppliers to comply with manufacturing and quality assurance standards for medical devices that are similar to those in force in the United States before marketing and selling our products in those countries. If we, or our suppliers, should fail to do so, we would lose our ability to market and sell our products in those countries. If we cannot obtain and maintain marketing clearance or approval from governmental agencies, we will not be able to sell our products. Our products are medical devices that are subject to extensive regulation in the United States and in the foreign countries in which they are sold. Unless an exemption applies, each medical device that we wish to market in the United States must receive either 510 (k) clearance or Pre- Market Approval (" PMA ") from the FDA before the product can be sold. Either process can be lengthy and expensive. The FDA' s 510 (k) clearance procedure, also known as " premarket notification, " is the process we have used for our current products. This process usually takes from four to twelve months from the date the premarket notification is submitted to the FDA, but may take significantly longer. Even after a device

receives regulatory approval it remains subject to significant regulatory and quality requirements, such as manufacturing, recordkeeping, renewal, recertification or reporting and other post market approval requirements, which may include clinical, laboratory or other studies. Product approvals by the FDA and other foreign regulators can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval or may be re- classified to a higher regulatory classification, such as requiring a PMA for a previously cleared 510 (k) device. The PMA process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is submitted to, and filed with the FDA, and may take even longer. In addition, any modification to an FDA- cleared medical device that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new FDA 510 (k) clearance or, possibly, a PMA. Regulatory regimes in other countries similarly require approval or clearance prior to our marketing or selling products in those countries. We rely on our distributors to obtain regulatory clearances or approvals of our products outside of the United States. If we are unable to obtain additional clearances or approvals needed to market existing or new products in the United States or elsewhere or obtain these clearances or approvals in a timely fashion or at all, or if our existing clearances are revoked, our revenues and profitability may decline. In general, we intend to obtain Medical Device Regulation (" MDR") approvals for our principal products sold in the European Union (" EU") ahead of expiration dates; however for multiple reasons, including but not limited to changing business strategies, labor shortages and contract resources, administrative delays, increased costs of obtaining MDR certification, availability of necessary data and notified body capacity, certain products may not be fully compliant at the time of CE mark expiration. The additional time and resources required to obtain MDR certification has been a significant factor in, and will likely continue to influence, our decisions whether to discontinue sales and distribution of certain products in the EU. Complying with and obtaining regulatory approval in foreign countries, including our efforts to comply with the requirements of the MDR, have and will likely continue to lead to additional uncertainty, risk, expense and delay in commercializing products in certain foreign jurisdictions, which could have a material adverse effect on our business, financial condition and / or results of operations. Our products may be subject to product recalls, which may harm our reputation and divert managerial and financial resources. The FDA and similar governmental authorities in other countries have the authority to order mandatory recall of our products or order their removal from the market if there are material deficiencies or defects in design, manufacture, installation, servicing or labeling of the product, or if the governmental entity finds that our products would cause serious adverse health consequences. A government mandated recall, voluntary recall or field action by us could occur as a result of component failures, manufacturing errors or design defects, including labeling defects. Any recall of our products may harm our reputation with customers and divert managerial, engineering and financial resources. There is no assurance that we will not incur warranty or repair costs, be subject to liability claims for damages related to product defects, or experience manufacturing, shipping or other delays or interruptions as a result of these defects in the future. Our insurance policies may not provide sufficient protection should a claim be asserted. A recall of any of our products could harm our reputation, divert managerial and financial resources and have a material adverse effect on our business, financial condition, results of operations and / or liquidity. We may be subject to fines, penalties, injunctions or costly investigations if we are determined to be promoting the use of our products for unapproved or " off- label " uses. If we are incorrect in our belief that our promotional materials and training methods regarding ~~physicians~~ **the use of our products** are conducted in compliance with regulations of the FDA and other applicable regulations, and the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, the FDA could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Any of these results could have a material adverse effect on our business, financial condition, results of operations and / or liquidity. Laws and regulations governing the export of our products could adversely impact our business. If the U. S. government imposes strict sanctions on Iran, our revenue could be impacted. The U. S. Department of the Treasury' s Office of Foreign Assets Control (OFAC), and the Bureau of Industry and Security at the U. S. Department of Commerce (BIS), administer certain laws and regulations that restrict U. S. persons and, in some instances, non- U. S. persons, in conducting activities, transacting business with or making investments in certain countries, governments, entities and individuals subject to U. S. economic sanctions. Due to our international operations, we are subject to such laws and regulations, which are complex, restrict our business dealings with certain countries and individuals, and are constantly changing. Further restrictions may be enacted, amended, enforced or interpreted in a manner that materially impacts our operations. In fiscal year ~~2022~~ **2023** we generated $ 1. 2 million of revenue for sales to distributors doing business in Iran. We continuously review our ability to sell products to distributors that conduct business in Iran in accordance with all applicable U. S. laws. If laws, rules or regulations of the United States, with respect to doing business in or with parties that do business in Iran, change to restrict our ability to generate revenue in Iran, our revenue could decline, impacting our results of operations. From time to time, we have limited business dealings in countries subject to comprehensive sanctions. These business dealings may expose us to a heightened risk of violating applicable sanctions regulations. Violations of these regulations are punishable by civil penalties, including fines, denial of export privileges, injunctions, asset seizures, debarment from government contracts, revocations or restrictions of licenses, and / or criminal fines and imprisonment. We have established policies and procedures designed to assist with our compliance with such laws and regulations. However, there can be no assurance that our policies and procedures will effectively prevent us from violating these regulations in every transaction in which we may engage, and such a violation could adversely affect our reputation, business, financial condition, results of operations and cash flows. RISKS RELATED TO INTELLECTUAL PROPERTY If we fail to adequately protect our intellectual property rights, we may not be able to generate revenues from new or existing products and our business may suffer. Our success depends in part on obtaining, maintaining and

enforcing our patents, trademarks and other proprietary rights, and our ability to avoid infringing the proprietary rights of others. We rely upon patent, trade secret, copyright, know- how and trademark laws, as well as license agreements and contractual provisions, to establish our intellectual property rights and protect our products. However, no assurances can be made that any pending or future patent applications will result in the issuance of patents, that any current or future patents issued to, or licensed by us, will not be challenged or circumvented by our competitors, or that our patents will not be found invalid. Patent positions of medical device companies, including our Company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or whether any existing or future patent will be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. Additionally, we rely on trade secret protection for certain unpatented aspects of our proprietary technology. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques, that others will not gain access to our proprietary technology or disclose such technology, or that we can meaningfully protect our trade secrets. We have a policy of requiring key employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment with us. We also generally require our consultants to assign to us any inventions made during the course of their engagement by us. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of confidential information or inventions. If we are not able to adequately protect our intellectual property, our market share, financial condition and results of operations may suffer. If third parties claim that our products infringe their intellectual property rights, we may be forced to expend significant financial resources and management time defending against such actions and our financial condition and our results of operations could suffer. Third parties may claim that our products infringe their patents and other intellectual property rights. Identifying third- party patent rights can be particularly difficult because, in general, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date, and publication of discoveries in the scientific or patent literature often lag behind actual discoveries. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product design, pay royalties or other fees to license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third- party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management' s time and effort. Such claims could also cause our customers or potential customers to purchase competitors' products or defer or limit their purchase or use of our affected products until resolution of the claim. See Part I, Item 3" Legal Proceedings" of this report for additional details on litigation regarding proprietary technology. RISKS RELATED TO OUR STOCK PRICE Our future operating results are difficult to predict and may vary significantly from quarter to quarter, which may adversely affect the price of our common stock. The ongoing introduction of new products and services that affect our overall product mix make the prediction of future operating results difficult. You should not rely on our past results as any indication of future operating results. The price of our common stock will likely fall in the event that our operating results do not meet the expectations of analysts and investors. Comparisons of our quarterly operating results are an unreliable indication of our future performance because they are likely to vary significantly based on many factors, including: • the level of sales of our products and services in our markets; • our ability to introduce new products or services and enhancements in a timely manner; • the demand for and acceptance of our products and services; • the success of our competition and the introduction of alternative products or services; • our ability to command favorable pricing for our products and services; • the growth of the market for our devices and services; • the expansion and rate of success of our direct sales force in the United States and internationally and our independent distributors internationally; • actions relating to ongoing FDA compliance; • our ability to integrate acquired assets or companies; • the effect of intellectual property disputes; • the size and timing of orders from independent distributors or customers; • the attraction and retention of key personnel, particularly in sales and marketing, regulatory, manufacturing and research and development; • unanticipated delays or an inability to control costs; • general economic conditions, including inflationary pressure, as well as those specific to our customers and markets; and • seasonal fluctuations in revenue due to the elective nature of some procedures. Our stock price may be volatile, which may cause the value of our stock to decline or subject us to a securities class action litigation. The trading price of our common stock price may be volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, attributable to outside factors and / or unrelated to operating performance. Such factors may include comments by securities analysts or other third parties, including blogs, articles, message boards and social and other media coverage which may not be attributable to us and may not be reliable or accurate. The NASDAQ Stock Market and medical devices companies in particular have experienced substantial price and volume volatility that is often seemingly unrelated to the operating performance of the companies. These broad market fluctuations may cause the trading price of our common stock to decline. In the past, securities class action litigation has often been brought against a company after a period of volatility in the market price of its common stock.