



Attachment III to Aspen Surgical Master Materials Purchase Agreement General Terms and Conditions

1 INVOICES; TAXES

- 1.1 **Invoicing.** Seller's invoices (each, an "Invoice") must: (1) reference the applicable Purchase Order number, (2) be based on the quantity, price and other terms set forth in such Purchase Order, (3) include a detailed identification or description of the Product (including item numbers, part numbers, sizes, quantities, purchase price and extended totals), and (4) reflect a separate line item for each additional approved charge, if any, including any approved charges for shipping, handling, expediting, etc. Payment terms will commence upon receipt by Aspen Surgical of a correct invoice issued on or after delivery of the invoiced Product but payment will not be due in any case prior to receipt of the invoiced Product by Aspen Surgical or its customer at its respective facility. Seller warrants that each Invoice will be accurate in every respect. For all costs related to payments made to third parties, Seller will maintain, and will provide to Aspen Surgical upon reasonable request, receipts or other supporting documentation that adequately indicate the amount and purpose of the expense. Any expense paid to or on behalf of a government official, health care professional, or other person affiliated in any way with a government institution must be specifically noted as such on the Invoice. Except as otherwise expressly stated in this Agreement, Seller will perform its obligations included in this Agreement without additional charge.
- 1.2 **Disputed Invoices.** Aspen Surgical may return to Seller any incomplete or incorrect Invoices. Payment of Invoices does not constitute acceptance of, or waiver of dispute related to, the invoiced Product. If Aspen Surgical disputes the accuracy of any Invoice, Aspen Surgical will pay that part of the Invoice that is undisputed, and, after such dispute has been resolved, will promptly pay any remaining balance then due.
- 1.3 **Set Off.** Aspen Surgical may set-off or otherwise withhold from invoiced amounts owed to Seller any amounts due to Aspen Surgical by Seller and any such set-off amount will be treated as a "payment" under this Agreement.
- 1.4 **Taxes.** Seller is solely responsible for filing the appropriate national, federal, state, provincial and local tax forms and paying all such taxes or fees, including income, sales, use, excise, personal property and employment taxes, tariffs, import duties and other governmental charges, due with respect to Seller's sale and delivery of Product and receipt of payment under this Agreement. Seller will reasonably assist Aspen Surgical with any related government audit of Aspen Surgical. Aspen Surgical will have no responsibility to Seller to pay or withhold from any payment to Seller under this Agreement, any national, federal, state, provincial, or local taxes or fees.
- 1.5 **Foreign Entities.** If: (1) Seller is not an entity formed in the United States, (2) Seller is providing anything other than tangible personal property (e.g. services) in the United States, and (3) the Aspen Surgical entity on the Purchase Order is incorporated in the United States, Seller will promptly, but in any event prior to submitting an invoice to Aspen Surgical, provide Aspen Surgical a IRS Form W-8BEN, Form W-8ECI, Form W-8CE, Form W-8EXP, Form W-8IMY or Form W-9, whichever is applicable. Failure to provide the appropriate IRS Form may result in withholding on payments pursuant to this Agreement in accordance with Internal Revenue Code of 1986, as amended, and the regulations thereunder.

2 DELIVERY; SHIPMENT; TITLE AND RISK OF LOSS

- 2.1 **Delivery.** Timely delivery of all Products is essential to Seller's performance obligations. Seller will deliver Product strictly in accordance with a Purchase Order's designated: (1) quantities and/or lot sizes, (2) delivery schedules, (3) Aspen Surgical specified carrier, if any, and (4) specified destination. Seller will use its best efforts to comply with any requests for urgent deliveries in a shorter time frame. Seller will pay return shipping charges for unauthorized or untimely (either early or late) deliveries and pay for the proper disposal of excess quantities of Product and for any damaged Product as determined by Aspen Surgical in its sole discretion. Seller will promptly, but in any event within three (3) business days, notify Aspen Surgical verbally, with written confirmation, of any anticipated or actual delay in making any delivery. Seller will, at Seller's expense, avoid or minimize the delay to the maximum extent possible by appropriate methods, including by incurring expenditures at Seller's expense for overtime and expedited shipment.
- 2.2 **Shipping.** Seller hereby agrees that there will be no additional charge for packaging or storage before shipment of the Products. Seller will package all Products in suitable containers to permit safe transportation and handling and in accordance with all instructions provided by Aspen Surgical. Each delivered container must be labeled and marked legibly to identify its contents, Purchase Order number and Product line number without opening the container, and all boxes and packages must contain packing slips listing their contents. Upon shipment of Product, Seller will provide to Aspen Surgical all shipping documents, including compliance documentation, packing sheets,

delivery tickets and bills of lading, indicating Aspen Surgical's Purchase Order number, description of Products, Aspen Surgical part number and Aspen Surgical revision level, and quantity shipped on all packages and documents. Seller represents and warrants that it will classify, describe, package, mark, label, provide safety data sheets for, and otherwise pack and ship the Products in compliance with all laws, regulations, ordinances and orders. Safety data sheets and labeling, if required by law, will precede each shipment, and Seller will update them as required by law. Seller will promptly, but in any event within three (3) business days, reimburse Aspen Surgical for all expenses incurred by Aspen Surgical because of improper packing, marking, documentation or shipment.

3 ACCEPTANCE AND REJECTION

- 3.1 **Acceptance.** Notwithstanding any prior inspections, tests or payments made by Aspen Surgical, (a) all Product provided by Seller are subject to final inspection at Aspen Surgical's facilities, and (b) Aspen Surgical will not be deemed to have accepted any Product if Aspen Surgical notifies Seller that Aspen Surgical has rejected them within a reasonable time after delivery. If Aspen Surgical receives Product the defects or nonconformity of which are not apparent on examination, Aspen Surgical reserves the right to require replacement or refund as well as payment of damages.
- 3.2 **Rejection.** Any Product or deliveries of Product that are non-conforming as to quality or quantity ordered, that are damaged in any manner, that are not delivered in accordance with the specified delivery schedule, or that are manufactured, packaged, shipped, delivered or are in any way not in conformity with this Agreement will constitute a breach of this Agreement. In such event, Aspen Surgical will have the right to, in its discretion, each of which will be at Seller's risk and expense: (1) reject such Product or revoke acceptance, in whole or in part and return such non-conforming Product to Seller, at Seller's expense, (2) replace or correct such Product, (3) require Seller to replace, re-work or correct such Product or supply replacement parts at Seller's, Aspen Surgical's or Aspen Surgical's customer's location, as specified by Aspen Surgical in its sole discretion, (4) accept such nonconforming Product subject to an equitable price reduction, (5) recover by offset or otherwise any and all expenses, costs, losses resulting from affected operations, price reductions, and damages paid, incurred or suffered by Aspen Surgical or any of its affiliates as a result of such non-conformity, or (6) terminate this Agreement and/or any outstanding delivery of Product, without prejudice to Aspen Surgical's rights to claim damages. Seller's expense will include the cost of transportation, handling and restocking and all expenses of unpacking, examining, and repacking such Product. Seller will ship replacement Product via freight prepaid at Seller's expense and Seller will use expedited delivery if requested by Aspen Surgical. Aspen Surgical may inspect Product by sampling. If sampling reveals defects, Aspen Surgical may elect, in its discretion, either to reject the entire shipment based on such sampling or to inspect the entire shipment.

4 QUALITY SYSTEM

Seller will maintain a formal quality system that meets Aspen Surgical's quality system requirements, including appropriate controls on the design, production, sourcing, inspection and testing, lot traceability, shipping, service and repair, documentation and record keeping, and corrective and preventive action to address defects in the Product and underlying processes, and ensures that each Product provided to Aspen Surgical meets the Specifications for that Product. In addition, Seller will comply with any additional quality or other requirements in Attachment IV.

5 CERTIFICATES OF ORIGIN

Upon request, Seller will immediately provide to Aspen Surgical all certificates of origin or domestic value-added and all other information relating to the costs and places of origin of the Products or the services and the materials contained therein or used in the performance thereof, as may be requested by Aspen Surgical to comply fully with all customs, tariffs and other applicable governmental regulations. Any change which may change the country of origin of a Product will be deemed a change requiring official notice. Seller will comply strictly with any country of origin specifications for the Products.

6 RECORDS

Seller will maintain records as may be necessary to adequately reflect the accuracy of Aspen Surgical's charges and invoices for reimbursement, if applicable, and maintain such other additional records as Aspen Surgical may reasonably request. Seller will preserve such records for a minimum of ten (10) years after the date the last payment is made by Aspen Surgical to Seller. Aspen Surgical and its Representatives will have the right from time to time,

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after notice, to audit, inspect and/or verify the records kept by Seller relating to this Agreement.

7 PRODUCT WARRANTY

- 7.1 In addition to Seller's customary warranties, express warranties associated with the Products, and any other warranties contained herein or required by law, Seller warrants to Aspen Surgical that such Product and all of its components will: (1) comply fully with the requirements of this Agreement, including, if applicable, all drawings, specifications, samples and descriptions referenced in the Agreement, a Purchase Order or provided by Aspen Surgical or at Aspen Surgical's instruction (the "**Specifications**"), (2) be fit, sufficient and suitable for the particular purpose for which Aspen Surgical intends to use the Products or the services, including the specified performance in the component, system, subsystem and product location and the environment in which they are or may reasonably be expected to perform, (3) not infringe or contribute in any way to the infringement of any Intellectual Property Right of Seller or its Representatives or third parties, regardless of whether such are used, sold, or combined with other components or products, or included in a Aspen Surgical product, and Aspen Surgical and its Representatives may use and disclose any such items provided to them under this Agreement, without restriction for any purpose, including to make, develop, use, market, offer for sale, sell, and commercialize any product or service without restriction of any Intellectual Property Right of Seller or its Representatives, or any third party, that may cover such items, (4) be free from all liens, claims and encumbrances, (5) be free from defects in design, structure, materials (to the extent of Seller's responsibility for design, structure or materials, even if such design, structure or materials have been approved by Aspen Surgical) and workmanship and (6) comply fully with all laws, regulations, and governmental rules in the place where the Products are, and will be, used, sold, and offered for sale.
- 7.2 If Aspen Surgical receives a complaint or otherwise becomes aware that any of the Products supplied by Seller fail to conform to the warranties set forth herein or any other warranty approved by Seller in writing, Aspen Surgical will notify Seller of such defect or failure. Seller will, at Aspen Surgical's option, refund the full purchase price or repair or replace the defective Product free of charge to Aspen Surgical. Seller acknowledges that Aspen Surgical has an obligation to service its customers, and therefore, Aspen Surgical may choose to replace a defective Product with another Product, or with a substitute product at Aspen Surgical's discretion and without input from Seller. If Aspen Surgical replaces a Product that is covered by the warranty specified in [Section 7.1](#), Seller will be responsible for any out of pocket costs incurred by Aspen Surgical, including the cost of procuring such product from another source. Such replacement will not relieve Seller of any of its obligations under this [Section 7](#). Each Party will assist and cooperate with the other Party regarding all such defects and failures.
- 7.3 Seller hereby assigns to Aspen Surgical all rights under all warranties and guarantees of any of its suppliers as related to the Products.
- 7.4 Seller will not contact a Aspen Surgical customer directly and Seller further agrees that if a Aspen Surgical customer contacts Seller directly in order to report a warranty claim, request a repair or replacement part or make another inquiry, Seller will immediately direct such customer to contact Aspen Surgical directly.

8 ADDITIONAL REPRESENTATIONS, WARRANTIES AND COVENANTS

Seller represents and warrants to Aspen Surgical, its affiliates and their respective customers and any subsequent owners, operators or recipients of the Product, that:

- 8.1 It has the right to enter into this Agreement, and has not made, and will not make, any contract or commitment contrary to the terms of this Agreement or in derogation of the Intellectual Property Rights acquired or to be acquired hereunder by Aspen Surgical.
- 8.2 Unless otherwise expressly stated in a Purchase Order, the Products are manufactured entirely with new materials and none of the Products are, in whole or any part, governmental or commercial surplus or used, remanufactured, reconditioned or of such age or condition to impair its fitness, usefulness or safety.
- 8.3 It acknowledges that certain products manufactured and/or distributed by Aspen Surgical are intended for worldwide distribution and must comply with applicable international environmental requirements, such as the European Union's Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation and Authorization of Chemicals ("**EU REACH**") and the European Union's Directives on the Restriction of Hazardous Substances ("**EU RoHS**"). To the extent applicable, Seller represents and warrants that the Products provided by Seller to Aspen Surgical comply with the latest

revisions/updates of all applicable international environmental laws, rules, regulations and standards including the requirements of EU REACH and EU RoHS, and do not contain any chemicals over the allowed limit dictated by these laws, enabling Aspen Surgical to distribute on world-wide basis without restrictions. Seller will notify Aspen Surgical if Seller determines any Product provided to Aspen Surgical is out of compliance. Seller will take all actions and deliver all information requested by Aspen Surgical regarding such regulations and standards.

- 8.4 It will conduct all employment and other activities related to this Agreement in compliance with the standards of integrity and human rights set out in Aspen Surgical's Global Third Party Code of Conduct and the Ethical Trading Initiative Base Code available to Seller at [REDACTED], in particular, prohibitions on forced and child labor, excessive working hours, discrimination, harassment and other harsh or inhumane treatment, and their standards related to freedom of association and collective bargaining, safe and hygienic working conditions, and living wages. Seller agrees to hold its suppliers and other third parties to the same standards when performing its obligations under this Agreement, and to ensure that it has human rights policies and a means of raising complaints to address any breaches of such policies. Aspen Surgical and its Representatives will have the right, directly or through an independent agent, to conduct due diligence surveys and audits, staffed as Aspen Surgical deems appropriate, to verify Seller's past and current compliance with this Section, and Seller will cooperate fully and respond in a timely manner and in good faith, including making relevant documents and personnel available, to facilitate any such due diligence surveys or audits.
- 8.5 Aspen Surgical is a federal contractor. As a result, but only if applicable, this contractor and [any] [covered] subcontractor[s] shall abide by the requirements of 41 CFR 60-1.4(a), 60-300.5(a) and 60-741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, sexual orientation, gender identity, national origin, and for inquiring about, discussing or disclosing compensation. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability or veteran status.
- 8.6 The Product does not contain any Conflict Minerals and a good faith inquiry has been made to confirm the same. Upon request of Aspen Surgical, evidence will be provided of the diligence supporting this representation. The term "**Conflict Minerals**" means columbite-tantalite (coltan), cassiterite, gold, wolframite or their derivatives, tantalum, tin and tungsten and any other minerals or derivatives that the United States Secretary of State determines to be financing conflict in a covered country under Section 1502 of the Dodd-Frank Wall Street Reform, Consumer Protection Act or other any similar laws.
- 8.7 All of Seller's representations and warranties set forth in this Agreement will survive any delivery, inspection, acceptance or payment by Aspen Surgical of or for any Product and will be enforceable by Aspen Surgical on its own behalf and on behalf of Aspen Surgical's customers and any subsequent owners, operators or recipients of the Product and will not be deemed to be exclusive of any other remedy at law or in equity available to Aspen Surgical, its customers or any other owners, operators or recipients of the Product.

9 ASPEN SURGICAL PROPERTY

If Seller is to produce Product in accordance with designs, Specifications or drawings provided by Aspen Surgical, or if Aspen Surgical pays for or provides to Seller any equipment, supplies, tools, tooling or other property in connection with or used in the performance of this Agreement ("**Aspen Surgical Property**"), Aspen Surgical will own all right, title, and interest in and to such Aspen Surgical Property, and Seller will (1) hold such Aspen Surgical Property in confidence, (2) mark such Aspen Surgical Property in a manner that reflects that it belongs to Aspen Surgical, (3) store such Aspen Surgical Property apart from Seller's other property, (4) not move the Aspen Surgical Property to any location other than the site approved by Aspen Surgical without the prior written consent of Aspen Surgical; (5) not sell, lease, mortgage or otherwise encumber or dispose of any Aspen Surgical

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Property; (6) be responsible for the risk of loss, repair or replacement, and for keeping the Aspen Surgical Property in good working condition; and (7) return such Aspen Surgical Property, at Seller's expense, to Aspen Surgical in good condition, subject to normal wear and tear, at Aspen Surgical's request or when the Aspen Surgical Property is no longer used by Seller or upon the termination or completion of the Agreement. Seller will use the Aspen Surgical Property exclusively for the benefit of Aspen Surgical. Aspen Surgical may, upon not less than one (1) days' notice, enter Seller's premises during regular business hours and take possession of any or all of the Aspen Surgical Property.

10 INTELLECTUAL PROPERTY

10.1 **Product Rights.** Notwithstanding anything to the contrary herein, or in any other confidentiality or non-disclosure agreement between the Parties, and notwithstanding any Intellectual Property Right of Seller, Aspen Surgical and its Representatives will have the unfettered right to use, lease, rent, loan, license, sublicense, dispose of, disclose, offer for sale, sell, maintain, import, have imported, modify, disassemble, repair, deconstruct, test, analyze, reconstruct, transfer, assign, and make Derivative Works and new products and systems from, all materials, documents, information, software, Works, Derivative Works, Products, articles, prototypes, deliverables, Inventions and components thereof provided by Seller or its Representatives to Aspen Surgical or its Representatives in connection with this Agreement. Seller covenants and warrants that it imposes no post-sale restrictions on Aspen Surgical relative to any Product, deliverable, prototype or component thereof provided to Aspen Surgical or its Representatives by Seller or its Representatives under this Agreement. Seller agrees that, notwithstanding any agreement to the contrary, all drawings, documents, deliverables, prototypes, information, and files Seller or its Representatives provides to Aspen Surgical or its Representatives in conjunction with this Agreement, have no confidentiality restrictions on them relative to Aspen Surgical and its Representatives, and that Aspen Surgical and its Representatives have the unrestricted right to copy, display, distribute, and disclose the same, and to use and create Derivative Works therefrom, for any purpose.

10.2 **Inventions, Intellectual Property Rights, and Works.** By detailed written reports, Seller will inform Aspen Surgical promptly and fully of all Inventions and Intellectual Property Rights, whether patentable or not, made or conceived by Seller or its Representatives, either solely or jointly with others, in connection with this Agreement, in the course of providing any services to Aspen Surgical or its Representatives, or in the course of any collaboration with Aspen Surgical or its Representatives, as a result of receiving information or requests from Aspen Surgical or its Representatives, or as a result of access to the facilities, resources or funding of Aspen Surgical or its Representatives. Aspen Surgical will own all rights, title, and interest in and to all such Intellectual Property Rights and Inventions, whether patentable or not, and to each U.S. and foreign patent issuing from any patent application based thereon. Seller agrees that it and its Representatives will assign, sell, transfer and convey to Aspen Surgical, and hereby do assign, sell, transfer and convey to Aspen Surgical, all the rights, title, and interests in and to such Intellectual Property Rights and Inventions, all applications for United States and foreign letters patent covering such Intellectual Property Rights and Inventions, all United States and foreign letters patent issuing therefrom, and all renewals thereof. Seller agrees that it and its Representatives will not practice, utilize, exploit, copy, disclose, or commercialize any such Intellectual Property Right or Invention, and that Aspen Surgical will have sole and exclusive ownership of the same. Aspen Surgical will have sole discretion to decide whether to prepare and file any U.S. or foreign patent applications covering any such Intellectual Property Right or Invention ("**Patent Applications**"). If Aspen Surgical decides to prepare and file Patent Applications, then Aspen Surgical will pay all costs incurred in the preparation, filing, prosecution, and maintenance of such Patent Applications. At Aspen Surgical's request, Seller will disclose to Aspen Surgical or its counsel sufficient technical information concerning such Intellectual Property Rights and Inventions to enable Aspen Surgical and its counsel to prepare, file, and prosecute Patent Applications covering the same. Seller will assist Aspen Surgical and its counsel in the preparation, filing, and prosecuting such Patent Applications. Seller will execute, acknowledge, and deliver to Aspen Surgical all documents required to prepare, file, prosecute, and maintain such Patent Applications and patents covering Inventions or Intellectual Property Rights, and will execute, acknowledge, and deliver to Aspen Surgical all documents necessary to confirm that Aspen Surgical is the owner of all rights in and to each U.S. and foreign patent application and resulting patent. All Works, created by Seller or its Representatives, alone or with others, in connection with this

Agreement, in the course of providing any services to Aspen Surgical or its Representatives, in the course of any collaboration with Aspen Surgical or its Representatives, as a result of receiving information or requests from Aspen Surgical or its Representatives, or as a result of access to the facilities, resources or funding of Aspen Surgical or its Representatives, will be, and will remain, the sole and exclusive property of Aspen Surgical. Each such Work is a "work made for hire" under the copyright law and Aspen Surgical may file applications to register copyright in such Works as author and copyright owner thereof. If, for any reason, such a Work is excluded from the definition of a "work made for hire" under the copyright law, then each of Seller and its Representatives, will assign, sell, transfer and convey to Aspen Surgical, and hereby do assign, sell, transfer and convey to Aspen Surgical, the entire rights, title, and interests in and to such excluded Work, including the copyright therein. Seller will ensure any documents that Aspen Surgical deems necessary or appropriate regarding the assignment of such excluded Work and copyright therein are executed. Seller will take whatever steps and do whatever acts Aspen Surgical reasonably requests to secure or aid in securing and maintaining copyright protection in such Works, including, but not limited to, placement of Aspen Surgical copyright notice on such Works, and will assist Aspen Surgical and its Representatives in filing applications to register claims of copyright in such Works. Seller agrees that it and its Representatives will not reproduce, distribute, display publicly, or perform publicly, alone or in combination with any other work, any such Works and will not create any Derivative Work based upon such Works without the written permission from Aspen Surgical to do so. At any time upon the request of Aspen Surgical, Seller will deliver to Aspen Surgical copies of all such Works then in possession or under control of Seller and its Representatives. Upon termination of this Agreement, Seller will deliver to Aspen Surgical all copies of such Works then in possession or control of Seller or its Representatives, provided, however, that Seller may retain a copy of any Work that does not include Aspen Surgical Confidential Information and that is required for Seller's standard business and accounting purposes. Aspen Surgical and its Representatives will have free and unlimited access at all times to such Intellectual Property Rights, Inventions, and Works, including the right to use and disclose the same, and to make, use, sell, offer for sale, exploit and commercialize products covered by the same.

10.3 **Trademarks.** If Aspen Surgical specifies in writing that Seller is authorized to use specific Aspen Surgical trademarks (the "**Trademarks**"), Seller is hereby granted a limited, non-exclusive, non-transferable, non-assignable license solely in connection with the manufacture of the Products for purchase from Seller solely by Aspen Surgical, which license Aspen Surgical may revoke at any time with or without notice. The Trademarks and all associated goodwill and rights arising from use of the Trademarks will remain the sole and exclusive property of Aspen Surgical at all times. Seller specifically agrees that it will not at any time, use the Trademarks or any trademarks or names confusingly similar thereto, on production or manufacture of any other products for any third parties. As a condition of the grant of the license rights in this Section, Seller will, at all times, adhere to its obligations hereunder. In addition, Seller will observe the same quality and control standards as are specified by Aspen Surgical, and Aspen Surgical will have the right to monitor Seller's compliance with such obligations and quality control standards at all times. Seller agrees that it has no right of any kind to sell, resell or to otherwise dispose of any Products bearing the Trademarks to any third parties at any time. Upon the expiration or termination of this Agreement for any reason, Seller will be absolutely prohibited from using any of the Trademarks, or from using any names or trademarks confusingly similar thereto, in any manner whatsoever.

10.4 **Seller's Breach.** If Seller breaches this Agreement for any reason whatsoever, Seller hereby grants to Aspen Surgical a worldwide, transferable, sublicenseable right and license, under any and all Intellectual Property Rights related to the Product remaining with Seller that are necessary (if any) to manufacture, have manufactured, use, import, market, reconstruct, offer for sale, and sell the Products and modifications thereof, in quantities and for a time reasonably required to mitigate the effects of such breach. For the licenses granted by Seller under this Agreement, Aspen Surgical will pay a fee which is part of and reflected in the purchase price of each of the Products provided to Aspen Surgical by Seller.

11 PUBLICITY; CONFIDENTIALITY

11.1 **Publicity.** Except as provided in Section 10.3, Seller will not use Aspen Surgical's name or logo in any public or marketing manner or disclose to other parties the fact that Aspen Surgical has purchased or plans to purchase Product

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from Seller, without Aspen Surgical's prior written consent, or unless required by law or as part of a legal proceeding related to this Agreement.

11.2 **Confidentiality Obligations.** During the Term and thereafter, Seller agrees not to disclose any Confidential Information owned or possessed by Aspen Surgical or its Representatives, or accessed via Aspen Surgical or its Representatives, to any third party, and not to use such Confidential Information except solely to the extent necessary for performance under this Agreement. However, Seller may disclose such Confidential Information to its Representatives, who: (1) have a need to know the Confidential Information for purposes of the relationship between the parties, and (2) have agreed to, or have a duty to, hold such Confidential Information in confidence in a manner consistent with this Agreement. Seller is responsible for its Representatives and their representatives complying with the obligations of this Agreement. Seller will have in place agreements, with all permitted Representatives, that bind and engage them to comply with all of Seller's obligations hereunder, as if they were in the place of the Seller in this Agreement, and all such agreements will inure to the benefit of Aspen Surgical.

11.3 **Exceptions.** Non-disclosure obligations of Section 11.2 will not apply to information that: (1) is now in, or later comes into, the public domain without breach of any obligation; or (2) is rightfully in Seller's possession free of any obligation of confidence or non-use at the time of communication thereof as documented by contemporaneous written records. However, information will not be deemed to be within the foregoing exceptions if (a) such information is specific and merely embraced by more general information in the public domain or in Seller's possession, or (b) such information constitutes a combination which can be reconstructed from multiple sources in the public domain or in the Seller's possession, none of which shows the whole combination of the information included in the Confidential Information.

11.4 **Legally Required Disclosure.** In the event Seller becomes legally compelled to disclose any such Confidential Information, Seller agrees to provide Aspen Surgical with prompt written notice of such requirement so that Aspen Surgical may seek a protective order or other appropriate remedy. Seller agrees to cooperate with Aspen Surgical in obtaining any such protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained prior to the time such Confidential Information is required to be disclosed, Seller may furnish only that portion of the Confidential Information which it is advised by opinion of counsel is legally required and will exercise its best efforts to obtain reliable assurance that confidential treatment will be accorded the Confidential Information.

11.5 **Non-Disclosure Agreements.** If Seller and Aspen Surgical are a party to any form of confidentiality agreement and a conflict arises between such form of confidentiality agreement and this Agreement, the agreements will be interpreted cumulatively to provide maximum protection to Confidential Information

12 INSURANCE

Seller will provide to Aspen Surgical a certificate(s) of insurance before any Products are delivered or services are performed. Seller will maintain Commercial General Liability insurance which includes products/completed operations liability, contractual liability, personal injury liability and broad form property damage coverage with limits of at least \$5,000,000 per occurrence combined single limit. Such limits may be satisfied by a combination of primary and umbrella/excess liability policies. Coverage must include worldwide coverage territory, including the U.S. and Canada and must name Aspen Surgical as an additional insured. Seller will maintain Workers Compensation insurance in the state in which the work is being performed and must evidence a limit of liability for Employers Liability of not less than \$1,000,000 per accident. Coverage will include a waiver of subrogation in favor of Aspen Surgical. If Seller brings vehicles onto Aspen Surgical's or Aspen Surgical's customers' premises, Seller will maintain insurance covering any owned, non-owned or hired vehicles with limits of at least \$1,000,000 per occurrence combined single limit bodily injury and property damage. If Seller is providing professional services (e.g., engineering, design, software/programming, etc.), Seller will maintain Professional Liability (Errors & Omissions) insurance for a limit of liability of not less than \$2,000,000 per loss. Such insurance must include worldwide coverage territory. Insurance evidenced above will be primary and not entitled to contribution from any insurance maintained by Aspen Surgical Holdings, Inc. or any of its subsidiaries. If Seller employs any subcontractors, Seller will require that the subcontractors carry the same coverages in the same limits as set out in this Agreement.

13 INDEMNIFICATION

13.1 **Indemnification by Seller.** Seller will indemnify and hold harmless, and upon Aspen Surgical's request defend, Aspen Surgical and its respective shareholders, employees, officers, directors, agents, suppliers and representatives, from and against any and all claims, actions, damages, costs and losses, expenses (including legal costs and expenses) penalties, fines, obligations and liabilities of any kind (including damage to the environment), (collectively, "Losses"), relating to or arising out of (1) any negligence, bad faith or willful misconduct of Seller or Seller's Representatives; (2) breach of any representation, warranty or covenant of Seller or Seller's Representatives; (3) violations of law by Seller or Seller's Representatives in the performance of the Agreement or while entering, being present at, or leaving Aspen Surgical's or Aspen Surgical customers' property; (4) any claim or litigation which asserts or is based upon any alleged design (except to the extent of Aspen Surgical's responsibility for the design) or manufacturing defect, negligence, professional liability, error or omission, willful misconduct, failure to warn, or breach of warranty relating to Seller Product(s) (including parts and components thereof purchased by Seller from its suppliers) purchased by Aspen Surgical; or (5) any infringement of Intellectual Property Rights relating to a Product or component thereof (whether by the Product or component thereof alone or in combination or use with other products or components).

13.2 **Indemnification by Aspen Surgical.** Aspen Surgical will indemnify, defend, and hold harmless Seller and its Representatives from and against any and all third-party Losses, relating to or arising out of (a) any gross negligence, bad faith or willful misconduct of Aspen Surgical or Aspen Surgical's Representatives; or (b) violations of law by Aspen Surgical or Aspen Surgical's Representatives in the performance of this Agreement.

13.3 This Section 13 will survive the expiration or termination of the Agreement and will survive any delivery, inspection, acceptance or payment by Aspen Surgical for any Product.

14 CONFLICTS OF INTEREST

Neither Seller nor any subcontractor or agent of Seller will: (1) pay any amounts in any form to any employee of Aspen Surgical or any of his or her designees, or (2) favor any employee of Aspen Surgical, or any of his or her designees, with gifts or entertainment of significant cost or value, or with services or goods sold at less than full market value. Seller will notify Aspen Surgical immediately upon becoming aware of any conflicts of interest that may exist from time to time between Seller, its subcontractors or any of their respective employees, and Aspen Surgical. If Aspen Surgical becomes aware of any such conflict of interest, Aspen Surgical may request that such employee not be involved, directly or indirectly, in the work contemplated by this Agreement, and Seller will honor such request.

15 COMPLIANCE REQUIREMENTS

15.1 **Debarment.** Seller represents and warrants that Seller and its directors, officers and employees have not been, and are not currently, excluded, debarred, or otherwise made ineligible to participate in any "Federal health care program" (as defined at 42 U.S.C. § 1320a-7b(f)) or any Federal procurement or non-procurement program (the "Federal Programs"). Seller further represents and warrants that Seller and its directors, officers and employees (1) have not been convicted of a criminal offense related to the provision of health care items or services, and (2) are not under investigation or otherwise aware of any circumstances which may result in Seller being excluded from participation in any Federal Programs. Seller will immediately notify Aspen Surgical, in writing, of any change in the status of the representations and warranty set forth in this Section.

15.2 **Anti-Corruption.** Seller represents and warrants that it has complied and will comply with all applicable anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, and that it has not made, offered, or authorized and will not make, offer, or authorize any payment, gift, promise or other benefit, whether directly or through any other person or entity, to any "government official" (i.e., any official or employee of any government, or any department, agency, or instrumentality thereof, including any person employed by or acting on behalf of a public agency, government-controlled enterprise, or public international organization, or any political party, political official, or candidate for political office), health care professional, any immediate family member of a "government official" or health care professional (i.e. spouse, parent, child, sibling, sibling's spouse, or financial dependent), or any other person or organization for purposes of influencing official actions or decisions or securing any improper advantage in order to obtain or retain business. Except as otherwise disclosed in writing to Aspen Surgical, as of the date of this Agreement's execution and during the Term, no "government official" or

Attachment III to Aspen Surgical Master Materials Purchase Agreement

General Terms and Conditions

- immediate family member of a "government official" is or will become associated with, or presently owns or will own any interest in Seller.
- 15.3 **Inquiries by Government Authority.** Seller represents and warrants that it has not received any notice, subpoena, demand or other communication (whether oral or written) from any governmental authority at any time in the last five (5) years regarding Seller's actual, alleged, possible, or potential violation of, or failure to comply with, any laws, regulations, or industry codes governing bribery, money laundering, or other corrupt practices or behavior.
- 15.4 **Aspen Surgical Due Diligence.** Aspen Surgical will be entitled to conduct regular due diligence surveys and audits, staffed as Aspen Surgical deems appropriate, and at Aspen Surgical's own cost and expense, to verify Seller's past and current compliance with the anti-corruption laws of any relevant jurisdiction, Aspen Surgical's Code of Conduct, and Seller's obligations under this Section. Seller will cooperate fully and respond in a timely manner and in good faith, including making relevant documents and personnel available, to facilitate any such due diligence surveys or audits.
- 15.5 Seller understands that work under this agreement is subject to compliance with United States and any other applicable export laws, including but not limited to any local laws, the Export Administration Regulations ("EAR"), the anti-boycott and embargo regulations and guidelines issued under the EAR, the anti-boycott provisions of the Internal Revenue Code, the International Traffic in Arms Regulations ("ITAR"), and the various sanctions regulations and authorizations implemented by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Seller agrees to abide by any restrictions or conditions respecting the export, re-export, or other transfer of the deliverables that are in effect now or are hereafter imposed by the U.S. Government, and will not export, re-export, transfer or otherwise release, export, disclose, furnish or otherwise provide any article, technical data, technology, defense service, or technical assistance to any foreign person or entity, whether within the U.S. or abroad, without obtaining in advance any necessary export authorizations, licenses, or other approvals from applicable governmental authorities. Seller further agrees to determine whether it is, and represents that it is not, owned directly, indirectly, or in the aggregate 50% or more by Specially Designated Nationals ("SDNs") or parties designated on Sectoral Sanctions Identifications Lists ("SSIs") or Foreign Sanctions Evaders List ("FSEs") under Executive Orders of the President of the United States or the regulations of OFAC. Seller agrees to inform Buyer of any changes in its ownership structure that will cause it to be 50% or more owned by SDNs, SSIs or FSEs. Aspen Surgical will be entitled to conduct regular due diligence surveys and audits, staffed as Aspen Surgical deems appropriate, and at Aspen Surgical's own cost and expense, to verify Seller's past and current compliance with all applicable export controls and economic sanctions laws and Aspen Surgical's Code of Conduct. Seller will cooperate fully and respond in a timely manner and in good faith, including making relevant documents and personnel available, to facilitate any such due diligence surveys or audits. Nothing in the Agreement is intended to amend, waive or supersede any of the requirements applicable to Seller under applicable export controls and economic sanctions laws.
- 15.6 Seller will require any subcontractors or other persons or entities that provide services to Seller under this Agreement to agree to and abide by the representations and warranties in this Section 15.
- 15.7 Periodically, as requested by Aspen Surgical, Seller will cause one of its authorized officers to execute and deliver to Aspen Surgical a Certificate of Ethical Practices that confirms Seller's continued compliance with the provisions of this Section 15.
- 15.8 Seller will promptly notify Aspen Surgical of (a) the occurrence of any fact or event that would render any representation, warranty, covenant, or undertaking in this Section 15 incorrect or misleading, (b) any notice, subpoena, demand or other communication (whether oral or written) from any governmental authority regarding Seller's actual, alleged, possible or potential violation of, or failure to comply with, any laws or regulations governing bribery, money laundering, or other corrupt payments, or any export laws, and (c) any governmental investigation, audit, suit, or proceeding (whether civil, criminal, or administrative) regarding Seller's violation of, or failure to comply with, any such laws or regulations.
- 15.9 Seller will cooperate fully with Aspen Surgical regarding the investigation of any allegation, event, fact or occurrence which calls into question Seller's compliance with any representation, warranty, or covenant in this Section 15. If requested by Aspen Surgical, Seller will (a) appoint an executive with sufficient seniority and authority to respond to requests from Aspen Surgical, and (b) promptly provide such records and information, and provide access to such of its employees, contractors and consultants, as may be reasonably requested by Aspen Surgical regarding any such investigation.
- 15.10 Periodically, as requested by Aspen Surgical, Seller will provide Aspen Surgical the names of its employees and representatives who will interact with health care professionals and government officials on behalf of Aspen Surgical, as well as certain other employees specified by Aspen Surgical, and will cause such employees to undertake compliance training in a form approved by Aspen Surgical.
- 15.11 Seller will designate a compliance officer to oversee and ensure Seller's compliance with its obligations under this Section 15. The compliance officer will be of sufficient seniority, and will be provided with sufficient resources, to fulfill his or her obligations under this Section 15.
- 15.12 Seller will indemnify and hold Aspen Surgical harmless from and against any liability claims, demands or expenses (including attorney's or other professional fees) arising from or relating to Seller's noncompliance with the terms of the anti-corruption and export controls and sanctions clauses of this Agreement.
- 15.13 Notwithstanding anything to the contrary in this Agreement, Aspen Surgical may, in addition to its other remedies, immediately terminate this Agreement and/or any outstanding purchase orders, without prejudice to Aspen Surgical's rights to claim damages if Aspen Surgical should receive information which it determines in its sole discretion to be evidence of a breach by Seller of any representation or warranty set forth in this Section 15. In the event of such termination, Aspen Surgical will have no liability to Seller for any fees, reimbursements or other compensation under this Agreement, including for services previously performed.
- 16 CHANGE ORDERS**
- Aspen Surgical may, from time to time, in an executed written document (a "Change Order") make changes to this Agreement, Specifications, technical requirements, packaging or shipment methods. Upon acceptance of the Change Order, Seller will proceed immediately to make such changes. If Seller objects to such Change Order, the Parties will negotiate in good faith to mutually agree upon a modification of this Agreement to address the changes set forth in such Change Order and will document any such changes in a Change Order to be executed by both Parties. If the Parties cannot reach agreement on such dispute, this Agreement will continue in full force and effect as if the Change Order had not been submitted. Nothing herein will excuse Seller from proceeding promptly with a Change Order pending resolution of any dispute arising from a Change Order to which Seller objected.
- 17 SELLER CHANGE NOTIFICATION**
- To allow Aspen Surgical time to review, test, and qualify proposed changes, as soon as possible (but at least 90 days) prior to the planned implementation of any of the following changes, Seller will provide Aspen Surgical written notice of its, or any of its affiliates', or permitted subcontractors' intent to (1) substitute any product for the Product or any component of the Product, (2) make (a) any modifications to the Specifications for any Product, or (b) any substantial modifications to the manufacturing or quality processes used in making any Product, (3) change the location at which any of the Products or any components of the Product are manufactured, or (4) use a new subcontractor in making Product provided by Seller. Seller will not implement any such modification unless and until it receives an approved Change Order. To the extent Seller implements any such modifications in derogation of this Section 17, Seller will be subject to financial penalties. Aspen Surgical will have the ability, in its sole discretion, to reject the planned modification or to require a delay in the implementation of such change to mitigate any associated consequences and risks. In addition, Seller will notify Aspen Surgical immediately of (a) any change to or loss of any certifications required by Seller or any permitted subcontractor hereunder, to manufacture, package, deliver or sell the Product or for Aspen Surgical to purchase the Product, or (b) the sale of all or substantially all the equity or assets of Seller or any permitted subcontractor hereunder. Seller will indemnify and hold harmless, and upon Aspen Surgical's request defend, Aspen Surgical and its respective shareholders, employees, officers, directors, agents, suppliers and representatives, from and against all Losses relating to or arising out of breach of this Section. For the avoidance of doubt, Seller acknowledges that modifications to Products that are parts, components, or subassemblies may affect the performance or regulatory status of other products into which such Products are incorporated, and that modifications to any Product covered by this Agreement (whether a finished product or a part, component, or sub-assembly) are strictly subject to this and other modification provisions.

Attachment III to Aspen Surgical Master Materials Purchase Agreement

General Terms and Conditions

Aspen Surgical may at any time, without cause, cancel one or more Purchase Orders, or any portion thereof, or change the quantities or types covered by a Purchase Order at any time, provided that (1) if Aspen Surgical cancels or changes a Purchase Order after Seller has started manufacturing the items covered by such Purchase Order, and (2) if Seller cannot, using commercially reasonable efforts, repurpose such Product or raw material for which manufacturing has begun within a reasonable amount of time (including using such Product or material for a future Aspen Surgical order), then Aspen Surgical will compensate Seller for such reasonable expenses incurred prior to such cancellation. Notwithstanding the above, it is confirmed that any non-compliance with the obligations set forth in [Section 15](#) and [Section 17](#) will be considered a material breach and, therefore, will entitle Aspen Surgical to immediately terminate this Agreement and/or any outstanding purchase orders, and all obligations to pay consideration thereunder.

19 MISCELLANEOUS

19.1 **Assignment.** Seller may not assign, delegate or otherwise transfer this Agreement or any of its obligations, without Aspen Surgical's prior written consent. Any attempted assignment or transfer will be null and void. The rights and obligations of the Parties under this Agreement will inure to the benefit of and will be binding upon the successors and permitted assigns of each Party.

19.2 **Governing Law.** Any matters relating to this Agreement are governed and construed in accordance with the laws of New York, USA, without regard to any applicable conflicts of law. The application of the United Nations Convention on Contracts for the International Sale of Goods is expressly excluded.

19.3 **Venue.** If Seller is in the United States, each Party: (1) will bring such actions in a state court sitting in New York, or a Federal court in the Southern District of New York; and (2) submits to the jurisdiction any and all of the courts identified in (1), together with their respective appellate courts. If Seller is outside of the United States, (a) any dispute relating to this Agreement, including the breach, termination or validity thereof, will be finally resolved by arbitration in the English language, in accordance with the International Institute for Conflict Prevention & Resolution Rules for Non-Administered Arbitration currently in effect at the time of the dispute, (b) each Party will designate one arbitrator and the sole responsibility of the Party-designated arbitrators will be to appoint a third, neutral arbitrator, (c) such third arbitrator will be the sole arbitrator of the dispute, (d) the arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., (e) the arbitrator will follow [Section 19.2](#), (f) judgment upon the award rendered by the arbitrator may be entered by any court having jurisdiction thereof, and (g) for purposes of confirming an award into judgment, the petition for confirmation may be served by mail to the party's registered office. The place of arbitration will be New York, NY. The foregoing is without prejudice to the right of Aspen Surgical to (x) bring suit against Seller with the competent court where Seller has its registered office or place of business and (y) bring suit and seek relief at any court in connection with seeking injunctive relief. Each Party waives any right to a jury trial and for a retrial in the local court when a local enforcement order is sought.

19.4 **Third Party Beneficiaries.** Aspen Surgical's parent, subsidiaries and affiliates (each a "**Beneficiary**") will be third party beneficiaries under this Agreement to the extent the Products provided under this Agreement impact a Beneficiary and any such Beneficiary will have the right to enforce this Agreement as if it were a party hereto. Except as set forth in the preceding sentence, no person, other than the parties and such Beneficiaries, has any rights or remedies under this Agreement. The Parties reserve the right to amend or terminate this Agreement without the consent of the any Beneficiaries.

19.5 **Amendments.** Any changes to this Agreement must be executed in a writing signed by both Parties.

19.6 **Inconsistencies.** If there is ambiguity or conflict in the specifications, drawings or other requirements of this Agreement, Seller must, before proceeding, consult Aspen Surgical, whose written interpretation will be final.

19.7 **Severability.** If a court of competent jurisdiction finds any clause of this Agreement void or unenforceable, such findings will not be construed to render any other clause of this Agreement either void or unenforceable, and all other clauses will remain in full force and effect.

19.8 **Survival of Covenants.** Any provision of this Agreement which contemplates performance or observance following any termination or expiration of this Agreement will survive the termination or expiration of this Agreement.

19.9 **Independent Contractor.** Seller is an independent contractor and nothing in this Agreement will create, or be construed to create, any agency, partnership,

joint venture or other form of joint enterprise between Seller and Aspen Surgical.

19.10 **Notices.** Communications regarding orders may be sent by local mail, electronically transmitted or faxed. All amendments and official notices will be in writing to the addresses listed on the Cover Page and will be considered given (a) when delivered personally, (b) when sent by commercial express carrier, or (c) three (3) calendar days after having been sent, postage prepaid, by registered mail.

19.11 **Waiver.** Either Party's failure to enforce any of the provisions of this Agreement will not be construed as a waiver of such provisions. Either Party's waiver of any of its remedies for a breach of this Agreement is without prejudice and will not operate to waive any other remedies that the non-breaching Party will have available to it at law or in equity, nor will it waive the non-breaching Party's rights to any remedies for a future breach.

19.12 **Cumulative Remedies.** All rights and remedies set forth in this Agreement are cumulative and in addition to the Parties' rights and remedies at law or in equity. A Party's exercise of any such right or remedy shall not prevent the concurrent or subsequent exercise of any other right or remedy.

20 DEFINITIONS

The following terms will have the following meanings:

"**Confidential Information**" means ideas, concepts, data, technology, techniques, equipment, software, prototypes, drawings, files, notes, documents, and/or other information which is considered to be proprietary, non-public, and/or confidential. Confidential Information may be in any form, including written, recorded, electronic, displayed, presented, or oral information, as well as products, samples or prototypes.

"**Derivative Works**" means Works that are based upon one or more pre-existing works, information, or material, such as: (a) for copyrightable or copyrighted material, any translation, portation, modification, correction, addition, extension, upgrade, improvement, compilation, abridgment, revision or other form in which such material may be recast, transformed, or adapted; (b) for patentable or patented material, any improvement thereon; and (c) for material that is protected by trade secret, any new material derived from such existing trade secret material, including new material that may be protected by any copyright, patent, and trade secret.

"**Intellectual Property Right**" means any right relating to patents, trademarks, trade names, service marks, service names, brand names, inventions, processes, formulae, copyrights, circuit layouts, Derivative Works, business and product names, logos, slogans, trade secrets, industrial models, designs, computer programs and software (including all source codes) and related documentation, drawings, know-how, methods, processes, technology, specifications, procedures, bills of material and any other intangible property right.

"**Inventions**" means discoveries, concepts, inventions, creations, prototypes, improvements, and ideas, whether patentable or not, whether or not reduced to practice, and whether or not in the form of apparatuses, systems, devices, processes, methods, compositions of matter, techniques, formulae, know-how, or other form.

"**Representatives**" means all directors, officers, employees, agents, legal representatives, and subcontractors of a party, and a party's parents, subsidiaries, and corporate affiliates, and their directors, officers, employees, agents, legal representatives, and subcontractors.

"**Works**" means works of authorship fixed in any tangible medium of expression, including, but not limited to, notes, specifications, drawings, blueprints, circuits, memoranda, correspondence, records, notebooks, databases, charts, schematics, artwork, tooling design drawings, documents, files, and similar repositories of information, regardless of the medium in which it is fixed.

Attachment IV to Aspen Surgical Master Materials Purchase Agreement Quality Agreement

1. Legal Requirements. Seller agrees to comply with all applicable legal and regulatory requirements that apply to the Products that are medical devices or Products that are components that go into an medical device, including regulations promulgated by the U.S. Food and Drug Administration (the "FDA") under the Federal Food, Drug, & Cosmetic Act as amended from time to time at Title 21, Chapter 9 of the U.S. Code, 21 U.S.C. §§ 301–399a and Title 21 of the U.S. Code of Federal Regulations Part 820 (the "Legal Requirements").
2. Authorizations. As applicable, Seller has obtained or made and will maintain all licenses, permits, registrations, authorizations, and submissions as are necessary to perform Seller's services and to manufacture and sell the Product. Seller will provide copies of such licenses, permits, registrations, authorizations, and submissions to Aspen Surgical, upon request.
3. Product Changes. Seller will manufacture the Product in accordance with the Agreement, the applicable Legal Requirements, the Specifications, and any applicable regulatory approval, marketing clearance, or other marketing authorization. Seller acknowledges that modifications to Products may affect the performance or regulatory status of other products into which such Products are incorporated, and that modifications to any Product covered by this Agreement (whether a finished product or a part, component, or sub-assembly) are strictly subject to this and other modification provisions. Seller will not implement any such modification unless and until it receives written acceptance of such modification by Aspen Surgical in the form of an approved Change Order. Seller implementing any such modifications without proper approval will be subject to financial penalties. Seller will maintain a formal process to document changes to Seller's policies, procedures, operations, and the Specifications and will evaluate all proposed changes to the Products with regard to potential impact on the Products' safety, efficacy, performance, and intended use(s).
4. Supplier Evaluation. Seller will establish and maintain quality requirements that must be met by suppliers, contractors, to ensure that all purchased products and services conform to specified requirements. Seller will monitor the performance of suppliers supplying materials for use in the Products. To the extent Seller subcontracts any Product manufacturing or Services provided to Aspen Surgical, Seller will ensure that such subcontractor(s) are bound by the Agreement.
5. Manufacturing Standards: Quality Assurance
- 5.1. Manufacturing and Quality Records. Seller will maintain complete and accurate manufacturing and quality records for the Products in accordance with Legal Requirements, including as applicable Product master records, Product history records, master production and control records, batch production and control records, and laboratory records. Seller will retain such records in accordance with Legal Requirements. Such records will be made available to Aspen Surgical upon request.
- 5.2. Incoming Inspections. Seller is responsible for the identification, sampling, testing, and approval of any incoming materials, components, and packaging materials used in the manufacture of the Products in accordance with Legal Requirements. All sampling and testing will become part of the batch records and will be reviewed by Seller's quality assurance department before release of the Product. Seller will make inspection documentation available to Aspen Surgical upon request. Documentation must be provided at the time of receipt of the related Product by Aspen Surgical. Documentation will be included with shipment and emailed to SQACerts@aspensurgical.com.
- 5.3. Material Control and Traceability. All materials and components used in the manufacturing, assembling, and packaging of the Products will be stored and handled in accordance with Legal Requirements. Materials used to manufacture the Products must be controlled, identified by lot number, and traceable.
- 5.4. Verification and Validation. Seller will ensure that its manufacturing processes and equipment are appropriately verified and validated as required by Legal Requirements. Verification, validation, equipment calibration, and equipment validation data will be documented and made available to Aspen Surgical upon request.
- 5.5. Quality Control. Seller will verify that the Products are manufactured, tested, and stored in accordance with the specific processes and methods specified in applicable Legal Requirements and the Specifications and otherwise comply with the representations and warranties given by Seller in this Agreement.
- 5.6. Certificate of Analysis/Batch Records. When requested by Aspen Surgical, Seller will complete and send with each shipment of Product a Certificate of Compliance and full batch records certifying that each Product was: (1) manufactured according to Seller's procedures and in compliance with applicable Legal Requirements; and (2) tested and confirmed to meet all Specifications. Each Certificate of Compliance will be signed and dated by a duly authorized official of Seller's Quality Control or Quality Assurance department.
- 5.7. Nonconforming Products. Seller will control and physically segregate all nonconforming Products, or any material considered unacceptable for use in the manufacture of Products, from conforming Products and approved material in accordance with Legal Requirements. Seller will immediately notify Aspen Surgical of any nonconforming Product that was released for shipment to Aspen Surgical or Aspen Surgical's designee(s) or customers and will provide Aspen Surgical with all investigation reports, quality reports, or other means of reporting Seller's investigation process. For nonconforming Products that were released, Seller, in consultation with Aspen Surgical, will decide whether nonconforming Products should be destroyed or returned to Seller. Seller will pay all expenses related to destroying or returning the Products. At Aspen Surgical's sole discretion, without prejudice to Aspen Surgical's rights, Aspen Surgical may cancel any order or payment covering nonconforming Products or may elect to have Seller replace the nonconforming Product(s), and Seller will pay all expenses related to such replacement.
- 5.8. Product Quality Issues. Aspen Surgical will notify Seller of any problems isolated as Seller defects that are found during the use or distribution of the Product. When requested by Aspen Surgical, Seller will promptly investigate the identified issue(s) within timeframes established by Aspen Surgical. Seller will provide timely updates and completed investigation reports to Aspen Surgical as reasonably requested. When the need for a corrective action has been identified, Seller will investigate appropriately, determine root cause, develop an action plan to address the problem, implement proposed corrections, evaluate and determine effectiveness in accordance with applicable Legal Requirements and Seller's quality system.
6. Postmarket Reports. Aspen Surgical may be responsible for preparing a periodic postmarket report (e.g., annual report required by regulatory standards). Promptly, upon Aspen Surgical's request, Seller will provide to Aspen Surgical in writing any data required for submission of any postmarket or annual report.
7. Labeling and Packaging. Seller will label and package Products in accordance with applicable Legal Requirements and Specifications and will include a unique identifying lot number.
8. Compliance Deficiencies. Should Seller become aware of any issue that could affect the quality, safety, identity, efficacy, or regulatory compliance of Product (whether or not already shipped and/or distributed), Seller will immediately notify Aspen Surgical in writing (but in any event, no later than twenty-four (24) hours after the discovery of such issue). If Seller becomes aware of any safety, quality or efficacy issues relating to the Products, Seller will (1) immediately inform Aspen Surgical of the same, (2) contain and segregate any affected Product on Seller's premises, (3) initiate corrective actions and (4) periodically update Aspen Surgical regarding the status of the same, including upon Aspen Surgical's request.
9. Regulatory Authority Communications and Investigations. Seller will promptly notify Aspen Surgical in writing of any Regulatory Authority communications, actions or inquiries that relate to the Products, whether oral or written, of which Seller receives or becomes aware. Seller will promptly provide Aspen Surgical with copies of any documentation relating to same. If necessary, Seller may redact names of other customers or products to protect confidentiality. In the event of an investigation or inspection of Seller by Regulatory Authorities, Seller will notify Aspen Surgical within two (2) business days prior to any such inspection, or if prior notice is not possible, Seller will notify Aspen Surgical immediately after learning of such inspection. Seller will promptly provide Aspen Surgical with copies of all documentation relating to such inspection and Seller's response(s). Seller will immediately notify Aspen Surgical in writing if Seller becomes aware of any Regulatory Authority investigations related to a recall, field alert, stock recovery, Product withdrawal, field correction, or other similar corrective action (each a "Recall") or other corrective actions relating to the Products.
10. Product Complaints. Seller will collect, investigate, and timely respond to complaints or inquiries from Aspen Surgical relating to Product safety, quality, or efficacy and will initiate corrective actions as necessary. To the extent Seller investigates any complaints relating to the safety, efficacy, or quality of a Product, Seller will notify Aspen Surgical within fifteen (15)



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- days of Seller's findings. Seller will maintain a complaint file and records relating to each complaint as required by Legal Requirements.
11. **Adverse Event Reports.** If Seller is the Legal Manufacturer for a finished Product, Seller is responsible for making all filings and reports relating to an Adverse Event relating to a Product with Regulatory Authorities. Aspen Surgical will report to Seller any information of which Aspen Surgical becomes aware that may constitute a Product-related adverse event, including any event involving death, serious injury or potential malfunction of a Product, whether or not such event has been definitively determined to be associated with a Product (each an "Adverse Event"). Unless otherwise agreed in writing, any other reporting obligations relating to the Product will be the responsibility of Seller.
 12. **Recalls.** Seller will notify Aspen Surgical no later than twenty-four (24) hours of discovery if any Product is alleged or proven to be the subject of a Recall, or if Seller believes a Recall may be necessary with respect to a Product. The Parties will cooperate in the handling and disposition of such Recall; provided, however, Aspen Surgical's quality assurance department may institute a Recall due to any defect it considers sufficiently serious. Seller will provide at no charge (a) technical assistance and information as Aspen Surgical may request in order to enable Aspen Surgical to investigate quality issues that may be related to or caused by the Products; and (b) reasonable cooperation and assistance to Aspen Surgical in executing a Recall. Seller will be responsible for all expenses incurred by Aspen Surgical and its customers in undertaking a Recall to the extent such Recall results from Seller's failure to manufacture the Products in accordance with the Products' specifications, this Agreement, or Seller's negligence, bad faith or willful misconduct. For purposes of this Agreement, the expenses of the Recall include the reasonable direct expenses of notification and return or destruction of recalled Products, the cost to replace or refund the price of the recalled Product, and any costs directly associated with distribution of replacement Product. In all cases, the Parties will conduct any Recall in a manner that is appropriate and reasonable under the circumstances and in conformity with accepted trade practices and Legal Requirements.
 13. **Audits.** "Audit" will mean an audit of Seller's facility for purposes of reviewing Seller's procedures, processes, facilities, personnel, and records used in or created during the design, manufacture, or distribution of the Product to assure conformance to the Agreement and applicable Legal Requirements. Aspen Surgical will have the right to conduct Audits as needed to evaluate the Seller. Aspen Surgical will comply with all of Seller's facility rules regarding safety and security notified by Seller to Aspen Surgical. Each Audit will be conducted during Seller's business hours and, unless a shorter period is required by Aspen Surgical because of an urgent issue, upon at least fourteen (14) days' prior written notice to Seller. During an Audit, upon Aspen Surgical's request, Seller will make available for Aspen Surgical's review, interview, and inspection all equipment, personnel, and facilities used in or in relation to the manufacture of the Product, records, complaints and supporting documents (e.g., manufacturing, analytical, and testing documentation) with respect to the Product and materials used in the manufacture of the Product. Aspen Surgical will have the right to obtain copies of records concerning the Product. After the Audit, Aspen Surgical will provide a written audit report. Within thirty (30) days of audit report receipt, Seller will provide a written response to all findings that details corrective action to be implemented. Seller will ensure that all corrective actions are implemented. Aspen Surgical may confirm corrective action by performing a follow-up Audit.
 14. **Third-Party Audits.** Seller agrees to cooperate with third-party audits by Aspen Surgical's certifying body as required to maintain Aspen Surgical's ISO 13485 and/or MDSAP certifications.