CONFIDENTIAL TREATMENT REQUESTED

Certain portions of this document have been omitted pursuant to a request for Confidential Treatment and, where applicable, have been marked with "[***]" to indicate where omissions have been made. The confidential material has been filed separately with the Securities and Exchange Commission.

MANUFACTURING AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement (this "Agreement") is entered into as of the Effective Date (as defined below) by and between (1) Apollo Endosurgery, Delaware corporation having offices at 1120 S Capital of Texas Highway #300, Austin, TX 78746 ("APOLLO"), and (2) Establishment Labs, S.A a corporation organized under the laws of Costa Rica and having a principal place of business at Coyol Free Zone, B15, Alajuela, 20113, Costa Rica ("ESTABLISHMENT"). APOLLO and ESTABLISHMENT shall hereinafter be individually referred to as a "Party" and collectively as the "Parties."

RECITALS

- A. APOLLO is engaged in the research and development, manufacture, distribution and marketing of certain medical devices.
- B. ESTABLISHMENT is engaged in the contract manufacturing and packaging of certain medical device products.
- C. APOLLO desires that ESTABLISHMENT be the manufacturer and supplier of the product(s) outlined on Exhibit A of this Agreement ("Product") for APOLLO.
- D. APOLLO and ESTABLISHMENT desire to enter into this Agreement governing the supply of the Product upon the terms and conditions contained herein.

AGREEMENT

NOW THEREFORE, in consideration of the covenants contained herein, the above recitals, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. **DEFINITIONS**

- 1.1 "Affiliates" of a Party shall mean any corporation or other business entity controlling, controlled by, or under common control with such Party.
- 1.2 "Certificate of Conformance" or "COC" shall mean a document prepared by ESTABLISHMENT containing at a minimum: product name, Lot (defined below) number, lot quantity and a statement indicating compliance to all product specifications. Each COC shall be signature approved by ESTABLISHMENT's Quality Assurance department.
- 1.3 "Control" (including "controlling", "controlled by" and "under common control with" of any party, corporation, or other business entity) shall mean the direct or indirect ownership of at least fifty percent (50%) of the voting or income interest in such party, corporation, or other business entity, respectively.

- 1.4 "Current Good Manufacturing Practices" (abbreviated "GMPs" or "cGMPs") shall mean, a) for any period during the Term during which ESTABLISHMENT has received FDA certification, the standards established by the United States Food and Drug Administration (the "FDA") for current Good Manufacturing Practices, as specified in FDA 21 C.F.R. §820 Quality Systems Regulations (or its successor provisions); and b) ISO 13485 Medical Devices Quality Management Systems and other sections so designated by the title "Good Manufacturing Practices"; and c) as applicable to each respective Product to be manufactured and/or supplied by ESTABLISHMENT.
 - 1.5 "Effective Date" shall mean December 5, 2014.
- 1.6 "Facilities" shall mean ESTABLISHMENT's manufacturing facilities at Coyol Free Zone, B15, Alajuela, 20113, Costa Rica.
- 1.7 **'Lead Time**" shall mean the time period that begins on the day ESTABLISHMENT receives a Purchase Order (defined below) for Product from APOLLO and ends on the day ESTABLISHMENT is required to deliver the Product to APOLLO.
- 1.8 "Lot" shall mean a defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.
- 1.9 "**Product**" shall mean the product(s) to be manufactured and supplied by ESTABLISHMENT to APOLLO under Purchase Order(s) issued under this Agreement and as more specifically detailed in Exhibit A attached hereto.
- 1.10 "Purchase Order" shall mean a written purchase order issued to ESTABLISHMENT by APOLLO for the purchase of Product under this Agreement.
- 1.11 "**Span of Control**" shall mean all operational activities that are necessary to occur at ESTABLISHMENT and component suppliers, if any, that are related to the procurement and manufacture of the Product.
- 1.12 "**Specifications**" shall mean the Product specifications provided to ESTABLISHMENT by APOLLO. The Specifications shall include all necessary test protocols, packaging and labeling specifications, bills of materials and other documentation required to describe, control, and assure the quality of the manufacture of the Product.
 - 1.13 "WIP" shall mean Work In Progress.

2. TERM AND TERMINATION

2.1 <u>Term</u>. This Agreement shall commence on the Effective Date and shall be valid for a period of five (5) years with automatic renewal of one year thereafter until terminated

by either party with one (1) year written notice prior to the expiration of the initial period or any extension period thereof.

2.2 Termination.

(a) Either Party may terminate this Agreement (i) for material breach upon one hundred and twenty (120) days written notice specifying the nature of the breach, if such breach has not been substantially cured within the one hundred twenty (120) day period, or (ii) if the other Party shall formally declare bankruptcy, insolvency, reorganization, liquidation, or receivership; or is named in an action for bankruptcy, insolvency, reorganization, liquidation, or receivership proceedings, and fails to remove itself from such proceedings within ten (90) days from the date of institution of such proceedings.

(b) In the event this Agreement is terminated for reasons other than material breach by ESTABLISHMENT, APOLLO shall pay ESTABLISHMENT for all work, material purchases, WIP and finished goods performed pursuant to any unfinished Purchase Order(s) prior to such termination in addition to reparation charges outlined on Exhibit A of this Agreement.

(c) In the event this Agreement is terminated for any reason, ESTABLISHMENT shall promptly cease performing any work not necessary for the orderly close out of the affected Purchase Order(s) or for the fulfillment of regulatory requirements.

(d) Within thirty (30) days following the termination of this Agreement, and upon receiving payment for any outstanding invoices for previously fulfilled Purchase Orders, ESTABLISHMENT shall deliver to APOLLO all data and materials provided by APOLLO to ESTABLISHMENT for the manufacturing and supply activities under the impacted Purchase Order(s). Within this same timeframe APOLLO shall provide ESTABLISHMENT any reasonable compensation relative to work, materials, and WIP purchased specifically to support APOLLO's Product. Termination of this Agreement, for any reason, shall not release either Party from liability which at said time has already incurred, nor affect in any way the survival of any rights, duties or obligations of either Party which are expressly stated elsewhere in this Agreement to survive termination. Without limiting the generality of the foregoing, the Parties agree that Sections 2.2 and Articles 6, 7, 8, 9, and 10 shall survive termination of this Agreement for any reason.

3. MANUFACTURE AND SUPPLY OF PRODUCT

3.1 <u>Performance Standards</u>. ESTABLISHMENT shall manufacture the Product in accordance with the Specifications of this Agreement, and shall comply with all quality system requirement communicated by Apollo from time to time, ISO 13485:2012 and any applicable cGMPs and all other applicable local, United States or European regulations or laws in connection with the manufacture, testing, packaging, labeling, shipping, and handling of the Product.

(a) ESTABLISHMENT shall be responsible for normal and daily maintenance of all consigned equipment provided by APOLLO, as described in Exhibit C. APOLLO will be responsible for all other repair and/or replacement costs relating to loaned or consigned equipment due to normal wear and use. Unless otherwise agreed upon in writing, at APOLLO's sole discretion, this equipment will be insured by APOLLO while located in ESTABLISHMENT's manufacturing plants.

3.2 ESTABLISHMENT Representations. ESTABLISHMENT makes the following representations to APOLLO:

(a) ESTABLISHMENT is duly organized, validly existing and in good standing under the laws of Costa Rica. ESTABLISHMENT has all requisite power and authority to own, operate and lease its properties and to carry on its business as now conducted. ESTABLISHMENT has full corporate power and authority to execute, deliver and perform this Agreement; all corporate actions of ESTABLISHMENT necessary for such execution, delivery and performance have been duly taken; and this Agreement is a valid and binding obligation of ESTABLISHMENT.

ESTABLISHMENT shall perform all manufacturing, storage, handling, and testing of the Product(s) at the Facilities. ESTABLISHMENT warrants that the Facilities have been periodically inspected by its Notified Body's representatives and auditors and/or any other required government agency and are in good standing with said governmental agencies, are fully compliant with ISO 13485:2012 and that all employees working on the Product whose responsibilities involve work which must be performed under ISO 13485:2012 standards have been properly trained in the requirements of those standards. ESTABLISHMENT additionally warrants that the Facilities hold all necessary licenses and permits from applicable local, national, and European regulatory bodies, required for the manufacture and testing of the Product and that all such licenses and permits are in full force and effect.

(b) ESTABLISHMENT shall comply with all applicable export and import control laws and

3.3 <u>Suppliers</u>. Except as otherwise agreed upon in writing ESTABLISHMENT assumes the responsibility for interacting with all chemical, component and packaging suppliers as required to deliver the Product in accordance with the applicable Purchase Order, including the Specifications, and this Agreement. Payment to the suppliers shall be handled directly by ESTABLISHMENT unless otherwise agreed upon in writing by APOLLO. ESTABLISHMENT shall not change its raw material, component or packaging materials without the prior written consent of APOLLO, which consent shall not be unreasonably withheld. With respect to the supply of the silicone raw materials for the shell and sheath product components, APOLLO shall acquire materials from a third party supplier and arrange for delivery to ESTABLISHMENT and ESTABLISHMENT shall be responsible for inspecting said components to ensure that they meet chemical, component and packaging specifications.

regulations.

4. PRICING AND PAYMENT; Fixtures and Tooling

- 4.1 <u>Product Prices</u>. Pricing for the Product ordered per the terms of this Agreement is set forth in Exhibit A attached hereto. Any penalty for failure to purchase a designated quantity of product for a defined period, if any, shall be clearly described in Exhibit A or in a written amendment. Any future modification to pricing shall be mutually agreed upon and may be captured in a revised Exhibit A or a written amendment signed by both Parties.
- 4.2 <u>Payment Terms</u>. Unless otherwise agreed to by ESTABLISHMENT in writing, ESTABLISHMENT shall invoice APOLLO for Product ordered at the time of shipment and APOLLO shall pay each invoice within thirty (30) days from date of invoice. Each invoice shall set forth, in U.S. Dollars, the applicable price for the shipment properly determined in accordance with the provisions of this Agreement. If APOLLO disputes any portion of an invoice received from ESTABLISHMENT the Parties shall use good faith efforts to reconcile the disputed amounts as soon as practicable. Invoices should be sent to the physical and email addresses as specified in writing by APOLLO in the applicable Purchase Order.
- 4.3 Fixtures and Tooling. In addition, Apollo will pay as set forth in Exhibit A for certain fixtures and tooling to be set forth in Exhibit C, and Apollo will maintain all right, title and interest in and to such fixtures and tooling. During the Term, fixtures and tooling will be identified to Apollo and will be subject to the requirements for ESTABLISHMENT to maintain set forth as part of the Services in Exhibit A. The parties will amend Exhibit C from time to time in writing to set forth an accurate list of such fixtures and tooling. With respect to all tooling and fixtures purchased by Apollo in connection with the manufacture and supply of Product and provision of Services hereunder and listed on Exhibit C (which, in accordance with this Agreement, Apollo shall retain all right, title and interest in and to), for so long as ESTABLISHMENT maintains possession of such tooling and fixtures, Establishment will retain, maintain and use such fixtures and tooling in the ordinary course of business (normal wear and tear excepted) consistent with its handling of other tooling and fixtures and will use such tooling and fixtures only for manufacturing and supply of Product and provision of Services to APOLLO as provided in this Agreement.

5. FORECASTS, PURCHASE ORDERS AND DELIVERY

5.1 Forecasts. APOLLO shall provide ESTABLISHMENT on a monthly basis a twelve (12) month rolling forecast to allow for visibility into expected future demands. APOLLO shall deliver to ESTABLISHMENT a forecast for anticipated monthly deliveries of Product to APOLLO over the subsequent four (4) calendar quarters (the "Forecast"). The Forecast is to be used by the Parties for planning purposes and is not a commitment by APOLLO to purchase the quantities of Products specified in such Forecast, except as described below.

The quantities of Product forecasted for the initial three (3) months of each updated rolling Forecast shall represent a binding obligation of Apollo to purchase from ESTABLISHMENT, and of ESTABLISHMENT to manufacture and supply to APOLLO, such quantities of Product.

ESTABLISHMENT shall, at all times during the Term, maintain an inventory of raw materials and components sufficient to manufacture the binding obligations.

- 5.2 <u>Orders</u>. APOLLO shall routinely provide ESTABLISHMENT Purchase Orders for Product demands. All Product ordered by APOLLO shall be in the form of a firm written Purchase Order. Each Purchase Order shall contain at a minimum, the following information: description of the Product and quantity ordered, price, freight carrier information, payment terms, delivery date, and Purchase Order number for billing purposes. The Parties shall cooperate to establish appropriate lead times for orders; requested delivery dates shall provide sufficient lead times for the products ordered.
- 5.3 <u>Delivery</u>. Unless expressly provided otherwise in the applicable Purchase Order, shipping to APOLLO for the Product shall be Ex Works ESTABLISHMENT (Incoterms 2010). The Product will be packaged and shipped per the Specifications and using a shipper and insurance coverage approved by APOLLO. In the event that any delivery of the Product is anticipated to be late, ESTABLISHMENT will promptly notify APOLLO of the circumstances for the delay and, upon request, ESTABLISHMENT will take reasonable steps to minimize the delay. At the request of APOLLO, ESTABLISHMENT will provide a written corrective action for the result of delays caused by events under the Span of Control of ESTABLISHMENT.
- 5.4 <u>Acceptance, Rejection, and Claims</u>. APOLLO may inspect any or all shipments of Product to insure all specifications are met including proper labeling, packaging and count within thirty (30) business days of APOLLO's receipt of each shipment; however, any such inspection shall not relieve ESTABLISHMENT of any obligations or warranties under this Agreement. APOLLO has the right to reject, via written notification to ESTABLISHMENT within this thirty (30) day period, any or all of a shipment of Product that fails to satisfy any warranty in this Agreement and may reject all of a given Lot of Product if a statistical sample does not meet the Specifications. Upon confirmation of defective condition by ESTABLISHMENT and issuance of a return material authorization ("RMA") number, APOLLO shall be entitled to the immediate return and replacement, free of charge, of any Product supplied by ESTABLISHMENT in breach of any warranty under this Agreement.
- 5.5 <u>Spoilage Due to Change or Obsolescence</u>. APOLLO shall be responsible for any printed packaging components, purchased raw materials, work in progress or finished Product which becomes obsolete as a result of a specification or drawing change so long as the purchased raw materials did not exceed three months of APOLLO's forecast requirements and, upon Apollo's request, such raw materials, work in progress and finished Product are transferred to APOLLO

6. WARRANTIES

6.1 <u>Product Warranty</u>. ESTABLISHMENT warrants that all Product supplied under this Agreement shall, when it leaves ESTABLISHMENT's possession and control, conform with the Specifications and shall be free from defects in materials and workmanship.

ESTABLISHMENT further warrants that the Product shall be manufactured in accordance with applicable ISO 13485:2012 standards and with all applicable laws and regulations.

- 6.2 <u>Debarment</u>. ESTABLISHMENT represents, warrants and covenants that no person or entity that will be involved in the performance of ESTABLISHMENT's obligations under this Agreement is under investigation by the FDA or other Regulatory Authority for debarment or is presently debarred by the FDA or other Regulatory Authority. In addition, ESTABLISHMENT represents and warrants that it has not engaged in any conduct or activity that could lead to any such debarment actions. If during the Term, ESTABLISHMENT or any person or entity that will be involved in the performance of ESTABLISHMENT's obligations under this Agreement (i) comes under investigation by the FDA for a debarment action, (ii) is debarred, or (iii) engages in any conduct or activity that could lead to debarment, ESTABLISHMENT shall notify APOLLO immediately after gaining knowledge of the situation.
- 6.3 Intellectual Property. ESTABLISHMENT represents, warrants and covenants to APOLLO that ESTABLISHMENT will not, in the course of performing obligations hereunder, infringe or misappropriate any intellectual property of any other person. APOLLO represents, warrants and covenants to ESTABLISHMENT that by complying with its obligations under this agreement APOLLO will not knowingly direct ESTABLISHMENT to incur any violation, infraction or misappropriation of any intellectual property of any other party.
- 6.4 <u>Training</u>. ESTABLISHMENT represents, warrants and covenants to APOLLO that all of its employees and personnel that will be performing any work in connection with this Agreement will have the appropriate training and skill necessary to perform their job functions.
- 6.5 No Conflicts. ESTABLISHMENT represents, warrants and covenants that it shall not enter into any agreement or arrangement with any other entity that would prevent or in any way negatively interfere with ESTABLISHMENT's ability to perform it obligations hereunder.

7. <u>REGULATORY AND QUALITY</u>

- 7.1 <u>Compliance</u>. ESTABLISHMENT agrees that its work under this Agreement will be conducted in compliance with all applicable laws, rules and regulations, and with the standard of care customary in the industry. If requested by APOLLO, ESTABLISHMENT shall provide APOLLO with a certificate evidencing its accreditation by the appropriate accrediting body. Such accreditation shall remain in force during the term of this Agreement. ESTABLISHMENT agrees that all Product shipments to APOLLO shall be in accordance with APOLLO's instructions governing the shipment, labeling, and packaging of the Product.
- 7.2 <u>Quality Control</u>. Establishment shall maintain and follow a quality control and testing program consistent with the Product Specifications, ISO 13485:2012, Applicable Laws and quality system requirements communicated in writing by APOLLO from time to time

(the "Quality Control Procedures"). All Product supplied to APOLLO hereunder shall be manufactured in compliance with ISO 13485:2012 and all other applicable requirements of Regulatory Authorities, and in compliance with all other Applicable Laws (collectively, "Regulatory Standards"). At all times the Products shall be manufactured in an ISO Class 7 Clean Room, unless otherwise set forth in an amendment to this Agreement or the Exhibits hereto signed by both Parties.

- 7.3 Records. Establishment shall keep complete, accurate and authentic accounts, notes, data and records pertaining to the manufacture, processing, testing, storage, and distribution of the Product, including without limitation master production and control records, in material compliance with applicable Regulatory Standards. Establishment shall use commercially reasonable efforts to maintain and store such records in a manner to prevent loss, theft or deterioration. Establishment shall retain such records for five (5) years following the date of manufacture, or such longer period of time if consistent with Regulatory Standards, and shall make available to Apollo copies of such records; and upon the expiration of such period, Establishment shall contact Apollo and give Apollo the option to have such quality control documentation transferred to Apollo or destroyed. Unless this Agreement is terminated by Apollo due to a Triggering Event, in which case APOLLO shall bear the following costs: (i) ESTABLISHMENT may charge APOLLO for ESTABLISHMENT actual, documented, reasonable labor expenses incurred by ESTABLISHMENT for transfer or destruction of such documents and (ii) in the event of transfer of documents all freight costs shall be borne by APOLLO.
- 7.4 Product Complaints/Reports. The parties expect that APOLLO shall receive any complaint, claim or adverse reaction report regarding the Product. However (and except as otherwise noted below) in the event that ESTABLISHMENT receives any complaint, claim or adverse reaction report regarding any Product, including, but not limited to, notices from a competent Regulatory Authority regarding any regulatory non-compliance of a Product, upon notice, ESTABLISHMENT shall within a reasonable time frame provide APOLLO with all information related to such complaint, report, or notice and such additional information regarding the Product as may be reasonably requested. ESTABLISHMENT shall provide as much information as it has, to allow APOLLO comply with the competent Regulatory Authority requirements for complaint handling. If Product contains a defect which could or did cause death or serious bodily injury, ESTABLISHMENT shall immediately provide APOLLO with a complete description of all relevant details known to ESTABLISHMENT concerning any such incident, including but not limited to, a description of any defect and such other information which may be necessary to report to the competent Regulatory Authority or any Ministry of Health. APOLLO is responsible for filing any/all MDR Reports as required by the competent Regulatory Authority.

7.5 <u>Recalls</u>. APOLLO shall have the right to reasonably declare any recall of, or field corrective action to, any Product supplied to APOLLO under this Agreement. ESTABLISHMENT agrees to cooperate with APOLLO in connection with any such recall inasmuch as related to its concern in the Product.

- 7.6 Government Inquiries. Without limiting the generality of Section 7.2, ESTABLISHMENT shall use its best efforts to:
- (a) Respond fully and accurately to all inquiries directed to it by the competent Regulatory Authority or any government agency or regulatory body with respect to the manufacture and testing of the Product.
- (b) Assist APOLLO in responding to inquiries directed to APOLLO by any competent Regulatory Authority or any government agency or regulatory body with respect to the manufacture and testing of the Product.
 - 7.7 Inspection of Manufacturing Facilities.
- (a) ESTABLISHMENT shall permit APOLLO and its agents, during business hours and upon notice to ESTABLISHMENT, to inspect the Facilities where the Product is manufactured, handled, stored or tested, as well as all processes relating to the manufacture, handling, storage, or testing of the Product, as well as all test records regarding the Product.
- 7.8 ESTABLISHMENT warrants and agrees that it will correct within a reasonable amount of time from the date of notification, all deficiencies and/or non-conformances found during an APOLLO or any competent Regulatory Authority (regulatory body or agency) audit; and that it will take reasonable steps to correct such deficiencies and/or non-conformances or issue an approved plan, including a timetable, to correct all deficiencies and/or non-conformances within a reasonable time period.
- 7.9 <u>Control Testing</u>. ESTABLISHMENT shall perform quality control testing in accordance with the Specifications for release of each Lot of Product to APOLLO. Quality control testing shall include testing associated with the production of the Product, including, but not limited to, incoming component and raw material testing, in process testing, and final release testing as agreed upon from time to time between APOLLO and ESTABLISHMENT.
 - 7.10 Specifications and Change Control.
 - (a) The Specifications may not be changed without prior written approval by APOLLO.
- (b) ESTABLISHMENT shall not make any changes to the manufacturing process, Facilities, or equipment used in the manufacture that affects the form, fit or function of the Product without APOLLO's prior written approval.
- (c) APOLLO shall use commercially reasonable efforts to provide ESTABLISHMENT with sufficient written notice of any instructions or requirements of a government regulatory agency that may require a change of the Specifications. ESTABLISHMENT shall immediately notify APOLLO if any such changes in the Specifications

shall render ESTABLISHMENT unable to supply the Product in accordance with the terms and conditions of this Agreement or if they would cause a delay in supply of the Product.

- 7.11 <u>Technical Assistance</u>. ESTABLISHMENT shall provide APOLLO with certain technical support regarding the Product as reasonably requested by APOLLO, including, but not limited to, analytical test methods, manufacturing process development, and validation support. If there are charges associated with these services, a separate quote will be provided to APOLLO.
- 7.12 <u>Quality Agreement</u>. ESTABLISHMENT and APOLLO shall execute a written Quality Agreement between the Parties (the "**Regulatory Agreement**"). Upon execution, the Quality Agreement shall be attached hereto as Exhibit B and shall be incorporated herein. The Quality Agreement may be updated from time to time upon the mutual written agreement of the Parties. ESTABLISHMENTs agrees to comply with any reasonable requirements of APOLLO's quality system.

8. <u>INDEMNIFICATION, LIMITATION OF LIABILITY AND INSURANCE</u>

- 8.1 <u>Indemnification by APOLLO</u>. APOLLO agrees to indemnify, defend and hold harmless ESTABLISHMENT, its officers, agents, and employees from any and all liability, loss (including reasonable attorneys' fees) or damage they may suffer as the result of claims, demands, costs or judgments against them arising out of the negligence, recklessness or willful misconduct on the part of APOLLO, its officers, agents, employees, contractors or consultants in connection with this Agreement.
- 8.2 <u>Indemnification by ESTABLISHMENT</u>. ESTABLISHMENT agrees to indemnify, defend and hold harmless APOLLO, its officers, agents, and employees from any and all liability, loss (including reasonable attorneys' fees), or damage they may suffer as the result of claims, demands, costs or judgments against them arising out of:
- (a) a failure by ESTABLISHMENT, its officers, agents, employees, contractors or consultants to adhere to the terms of a Purchase Order or written instructions received from APOLLO in accordance with this agreement;
- (b) negligence, recklessness or willful misconduct on the part of ESTABLISHMENT, its officers, agents, employees, contractors or consultants; or
- (c) a breach of any applicable local law or regulation or of this Agreement by ESTABLISHMENT, its officers, agents, employees, contractors or consultants in relation to the execution of this agreement.
- 8.3 <u>General Conditions of Indemnification</u>. Each Party's agreement to indemnify, defend and hold the other harmless is conditioned on the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within thirty (30) days after the indemnified Party has knowledge of

such claim, demand or action; (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand; (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand; and (iv) not compromising or settling such claim or demand without the indemnifying Party's written consent; provided, however, that the failure of the indemnified Party to undertake any of the foregoing actions shall not relieve the indemnifying Party of any obligation it may have under this Article 8, except to the extent that the indemnifying Party's ability to fulfill such obligation has been materially prejudiced thereby.

8.4 Limitation of Liability. EXCEPT FOR BREACHES OR VIOLATIONS OF ARTICLE 9, OR INDEMNITY LIABILITIES ARISING UNDER THIS ARTICLE 8, OR CASES OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INDIRECT, SPECIAL, INCIDENTAL OR PUNITIVE DAMAGES INCLUDING LOSS OF USE, REVENUES OR PROFITS, INTERRUPTION OF BUSINESS OR CLAIMS AGAINST EITHER PARTY OR ITS CUSTOMERS BY ANY THIRD PARTY, WHETHER SUCH CLAIM IS BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, EVEN IF THE PARTY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

8.5 <u>Insurance</u>. ESTABLISHMENT, at its sole cost and expense, will maintain appropriate insurance including, but not limited to, Commercial General Liability Insurance with premises, operations coverage including Person Injury/Property Damage coverage, with limits of not less than \$1,000,000 per occurrence. As of January 1, 2015, such insurance shall also have annual aggregate limits not less than \$2,000,000. Evidence of insurance indicating such coverage will be delivered to APOLLO upon request. The evidence will (a) indicate that the policy will not change or terminate without at least fifteen (15) days prior written notice to APOLLO, (b) APOLLO shall be listed as an additional insured on the commercial general liability policy.

9. <u>CONFIDENTIALITY</u>

9.1 Confidential Information. For purposes of this Agreement, "Confidential Information" shall mean all information relating to the subject matter of this Agreement (i) identified in written or oral format by the disclosing Party as confidential, trade secret or proprietary information and, if disclosed orally, summarized in written format within thirty (30) days of disclosure, or (ii) the receiving Party knows or has reason to know is confidential, trade secret or proprietary information of the disclosing Party. Notwithstanding the foregoing, "Confidential Information" shall not include any information which the receiving Party can show: (i) is now or subsequently becomes legally and publicly available without breach of this Agreement by the receiving Party, (ii) was rightfully in the possession of the receiving Party without any obligation of confidentiality prior to receiving it from the disclosing Party, (iii) was rightfully obtained by the receiving Party from a source other than the disclosing Party without

any obligation of confidentiality, or (iv) was developed by or for the receiving Party independently and without reference to such information as shown by documentary evidence.

9.2 Nondisclosure. Each Party agrees not to use the Confidential Information of the other Party for any purpose, including trading in the financial instruments of the other Party, except in its performance under this Agreement. In addition, the receiving Party shall treat and protect such Confidential Information in the same manner as it treats its own information of like character, but with not less than reasonable care. The receiving Party agrees to take appropriate measures by instruction and/or written agreement prior to disclosure of Confidential Information to its employees and contractors to prevent unauthorized use or disclosure. Confidential Information may be disclosed to the extent necessary to comply with an order of an administrative agency or court of competent jurisdiction provided, however, that the Party so required to disclose Confidential Information shall provide prior written notice thereof to the other Party in sufficient time to enable that Party to seek a protective order or otherwise prevent such disclosure. The receiving Party's confidentiality obligations under this Article 9 shall survive the termination of this Agreement, and shall remain binding on the Parties hereto until the earlier of a) the Confidential Information falls within one of the exceptions stated in Section 9.1 and b) five (5) years from the expiration or termination of the Agreement. Previously executed non-disclosure agreements between the Parties will remain in effect in conjunction with The Agreement until the termination dates specified in those agreements and any Confidential Information shall also be considered to be Confidential Information hereunder. Disclosure of Confidential Information under this Agreement will create no license, right, interest, or ownership in any such information in a receiving Party.

10. GENERAL PROVISIONS

- 10.1 <u>Relationship Between the Parties</u>. In fulfilling its obligations pursuant to this Agreement, each Party shall be acting as an independent contractor. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party.
- $10.2 \, \underline{\text{Nonexclusivity}}$. Nothing in this Agreement shall limit or restrict Apollo from establishing a second source for the manufacture of the Products.
- 10.3 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.
- 10.4 <u>Severability</u>. If, for any reason, any part of this Agreement or any Purchase Order is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such provision will be changed and interpreted to accomplish the objectives of such provision to the greatest extent possible under applicable law and the remaining provisions of this Agreement or Purchase Order (as the case may be) will continue in full force and effect.
- 10.5 <u>Notices</u>. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt,

or by overnight courier, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be presumptively deemed to be sufficiently given for all purposes upon the earlier of: (a) the date of actual receipt; (b) if mailed, three (3) calendar days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to ESTABLISHMENT: Establishment Labs S.A. Coyol Free Zone, B15, Alajuela 20113, Costa Rica Attention: Luis Gutierrez. General Counsel

If to APOLLO: Apollo Endosurgery, Inc. 1120 S. Capital of Texas Hwy, Suite 300 Austin, TX 78746 Attn: Brian Szymczak, Legal Dept.

10.6 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control, including, but not limited to, Acts of God, other natural forces or war. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party seeking relief has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within three (3) calendar days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure.

10.7 <u>Legal Fees</u>. The prevailing Party in any litigation between the Parties relating to this Agreement may be awarded some or all of its reasonable attorneys' fees and court costs if the Court (in its reasonable discretion) finds that a non-prevailing party has not acted in good faith in the pursuit or defense of a claim hereunder, in addition to any other relief that it may be awarded.

10.8 <u>Governing Law and Venue</u>. Notwithstanding its place of execution or performance, this Agreement shall be governed by and construed in accordance with the laws of the State of Texas, irrespective of its laws regarding choice or conflict of laws. Any dispute arising under or relating to this Agreement shall be submitted for resolution to a state or federal court of competent jurisdiction in Austin, Texas, and the Parties hereby agree to submit to the jurisdiction and venue of such court.

10.9 <u>Assignment</u>. This Agreement is binding upon and inures to the benefit of the Parties to it, and to their successors and assigns. Neither Party shall have the right to assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party; provided, however, APOLLO may assign the Agreement to and may, without the

prior consent of ESTABLISHMENT, assign all of its rights under this Agreement to (i) a parent or subsidiary of Apollo, (ii) a purchaser of all or substantially all the Apollo assets related to this Agreement, or (iii) a third party acquiring control of Apollo through a merger, acquisition, sale of assets or other corporate reorganization.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

ESTABLISHMENT LABS, SA		Apollo Endosurgery, Inc.		
By:	/s/ Juan Jose Chacon	By:	/s/ Todd Newton	
Name:	Juan Jose Chacon	Name:	Todd Newton	
Title:	CEO	Title:	CEO	
		-15-		

EXHIBIT A

Product & Price Listing

Apollo BIB Sheath and Balloon Assembly Transition to E-LABS Rev.4

Transition Plan Milestones & Description	Approximate Timeline	Fee	Notes	
Project Launch Apollo to define component requirements (draft drawings) Onsite review of Allergan process in Costa Rica (1 trip). Agreement on specification/requirements Production to be performed in an ISO Class 7 Clean Room.	[***]	[***]	Agreement to be signed before project launch	
2. Proof of Process a. Obtain raw materials b. Prototype 1 st mandrels/fixtures c. Deliver samples (10 pcs each) to Apollo (or Allergan) to agreed draft specification	[***]	[***]	Requirements: -Drawings from Allergan for molds and toolingSTL files from AllerganMaterials standard specifications from AllerganContact information of suppliersNo cost for raw materials is includedTooling and Materials to be provided from Allergan.	
 3. Process Set Up & Scale Up (for initial annual volumes of up to 50,000 pcs/each) a. Define production mandrels/fixtures b. Measurement system process set up c. Manufacturing Documentation d. Process characterization & definition of process limits Tooling (for annual volumes of 50,000 pcs/each) BIB Balloon Mandrels BIB Sheath Mandrels 	[***]	[***]	Completion is achieved when ready for first wet run.	
4. E-Labs Process Validation a. Equipment qualification b. Measurement systems c. Apollo review of protocol	[***]	[***]	No raw materials or equipment cost are considered.	
5. First Articles / Validation (Apollo) a. Quantities to be determined by Apollo b. Deliver first articles to Apollo c. Transition project complete	[***]	[***]	Patched BIB ballon with Sheath, including raw material.	
Manufacture / Deliver BIB Components for Commercial Use Apollo receives approval from applicable government/regulatory agencies. Order quantities to be determined Anticipate first delivery by [***].	[***]	[***]	Patched BIB ballon with Sheath, including raw material.	

Tooling & Other Program Requirements	Unit	Price	Notes
Shell, BIB Sheath, DWG BSS Rev. 08 [***] • Material: NuSil [***] Silicone • Assumes NuSil MED 4-2014 [***], Xylene [***]/liter • Bulk packaged in double poly bags and labeled • Lead time: [***] weeks	For annual volumes between [***]	See below	
Shell, BIB Sheath, [***] and E-Labs Draws from Apollo Stock] • Material: NuSil [***] Silicone • Assumes NuSil MED [***]/kg, Xylene [***]/liter • Bulk packaged in double poly bags and labeled • Lead time: [***] weeks	For annual volumes between [***]	See below	
Budgetary pricing for higher volumes of Shell Bib Sheath, [***] Note: This row should accommodate the two scenarios: Purchasing NuSil	Annual Volumes [***]		
Material & Apollo Purchases NuSil Material and E-Labs Draws from Apollo Stock	Annual [***]	See below	
Balloon Assembly, BIB (E/S), per [***] Includes Shell, BIB BB, [***] Material: NuSil [***] Assumes NuSil [***]kg, Xylene [***]/liter Includes Valve Ring, BIB produced [***] Includes Valve Cylinder Slit, [***] for [***] Bulk packaged in double poly bags and labeled Lead time: [***] weeks	For annual volumes between [***]	See below	
Balloon Assembly, BIB (E/S), per drawing 6870 Rev 10 [Apollo Purchases Nusil Material and E-Labs Draws from Apollo Stock] • Includes Shell, BIB BB, [***] • Material: NuSil [***] Silicone • Assumes NuSil [***]/kg, Xylene [***]/liter • Includes Valve Ring, BIB [***] • Includes Valve Cylinder Slit, [***] for [***] each • Bulk packaged in double poly bags and labeled • Lead time: [***] weeks	For annual volumes between [***]	See below	
Budgetary pricing for higher volumes of BIB [***]	Annual Volumes [***] pieces Annual [***]+ pieces	See below	

PRICES

		TRANCHE	TRANCHES		
BIB SYSTEM PRICING MATRIX	[***]	[***]	[***]	[***]	
BIB SYSTEM	[***]	[***]	[***]	[***]	
BIB SHELL	[***]	[***]	[***]	[***]	
BIB SHEATH	[***]	[***]	[***]	[***]	

Conditions:

- Prices have been calculated considering the information available to Establishment Labs on this date, subject to the requirements noted on each item. Prices may vary with further information.

 Minimum yearly purchases of [***] units on each contract year. Five-year contract term is considered.

- As discussed with client, the quote given is for the manufacture of both components; prices for individual components is for reference only.
- No cost of equipment or molds is included in the pricing. Item 3, *Tooling*, does include the cost of specific tooling as requested, for reference.
- Process set-up and validation is considered on as-is condition. No process modification is quoted at this stage.
- Quality control and certificates included as detailed in Exhibit B
- Product sold [***]
- Item 3, Tooling includes ONLY:
 - For BIB Balloon, each run consists of [***]
 - For BIB Sheath each run consists of [***]
- Unit Prices of tools:
 - BIB Balloon Mandrel [***]
 - BIB Balloon Handle [***]
- BIB Sheath Mandrel [***]
- Note: The Tooling price is incomplete, prices for the following were not requested and are not included: cutters, inserts, racks, carts and machines (sheath dipping, mixing, cutting, vulcanizing).
- Invoicing during the first six months after deliver of First Article should be a minimum of [***]. Any difference will be paid by Apollo.
- Payment Terms:
 - Fee for project launch payable upon signing.
- Transition Plan payments: on milestone completion.
- Net 30 on product sales.
- Projected timeline for First Articles / Validation is [***]. For every month Establishment comes in earlier than said date, [***] incentive payment will be paid to Establishment.
- For clarity, for the period from the delivery date of the first Purchase Order (as described in Item 6(c) above) until the end of the Calendar Year in which such delivery date occurs, Company shall be required to order only [***] to be given the pricing on such Purchase Orders for [***] annual units for such Calendar Year. Thereafter, in subsequent Calendar Years, the annual volume minimums to be given volume pricing shall be as set forth above and shall be per Calendar Year. [NOTE: This is to bring the contract pricing into a calendar year basis after the first purchases.]
- In the event of termination under section 2.2(b) no additional reparation charges have been agreed upon by the parties; any future agreed upon reparation charge or amount shall be binding only if adopted as an amendment to this Agreement.

Exhibit B Regulatory Agreement

Establishment Labs Apollo BIB Balloon and Sheath Testing & Inspection Proposal

- 1. Manufacturing facility capabilities:
- ISO Class 7 (ISO 14644-1:1999) Certified clean room.
- ISO 13485:2003 and ISO 9001:2008 Certified facility.
- RDC#16:2013 Brazilian GMPs Approved facility.
- SAP inventory levels remote consultation interface. Optional.
- 2. Certificate of raw material conformance as per specification for all supplier lots of silicone dispersions, valve ring, slit valve and silicone adhesive:
- Incoming inspection testing, as applicable:
 - Appearance, viscosity, Shore A durometer value, tear strength, refractive index, supplier certificate review, tack free time, tensile strength, and elongation.
- Verification of Slit Valve functionality at incoming receiving.
 - Pre-process testing and statistical analysis report to comply with mechanical properties of the shell:
- Shell thickness lot analysis.
- Shell elongation and break force.
- Tensile set.
- Lot viscosity and devol time process parameters definition.
- 3. Certificate of product conformance per lot, including:
- Reference to Apollo/EL specifications drawing or Material Standard Specification.
- EL Product Lot Number.
- QTY description per lot.
- Product Part Number and Description.
- Raw Materials description with related documents including:
- Part number and supplier lot number.
- Supplier product certificates.
- In process product testing controls, including:
- 100% shell and Sheath thickness report.
- 100% shell and Sheath visual inspection.
- 100% assembly visual inspection.
- Sampling testing for shell elongation and break force.
- Sampling testing for patch-joint.
- Sampling testing tensile strength.
 - 100% leak test inspection of the balloon assembly.
- DHR Review and QA approvals.
- Other as required.
- 4. Process engineering:
 - Manufacturing procedures engineering change orders managing and execution.
- Process parameters improvement and DMR's updating, if applicable.
- Process data analysis.

- Process Control Plans that identify Procedures, tooling, critical process controls, inspection requirements, inspection frequency, and inspection equipment.
- 5. Digital back-up at Establishment Labs in accordance with Quality Standards of:
- Raw material incoming inspection reports.
- Pre-process testing reports.
- DHRs for every lot number.
- Lot processing parameters.
- Clean room monitoring.
- Equipment maintenance and calibration records.
- Tensile tester testing raw data.
- 6. Validations:
- All processes that cannot be verified need to be validated.
- Quality System:
- Must be updated to allow business as a contract manufacturer.
- For Apollo product, updates should include but not limited to: customer related processes, customer audits, feedback, monitoring and measurement of product, management review, and analysis of non-conforming product.

Exhibit C

Fixtures and Tooling

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