Pricing Agreement

This Pricing Agreement (this "Agreement") is effective as of June 23, 2026 ("Effective Date"), between **EDWARDS LIFESCIENCES LLC**, a Delaware limited liability company, located at One Edwards Way, Irvine, California 92614 ("Edwards") and **SAN BERNARDINO COUNTY on behalf of ARROWHEAD REGIONAL MEDICAL CENTER**, located at 400 N Pepper Ave, Colton, CA 92324 ("Hospital"). Hospital desires to buy the products listed in the attached Schedule A ("Products") from Edwards at the prices set forth therein ("Prices"). Edwards is willing to supply the Products to Hospital upon the terms and conditions set forth herein.

1. **Products**. Edwards agrees to supply Hospital with the Products, and Hospital agrees to buy the Products solely for its own use from Edwards. Edwards does not accept bulk buy purchasing of Products. Any purchases that may be considered a bulk buy or outside of expected procedure use must be reviewed and approved by Edwards prior to acceptance of the order. Edwards reserves the right to reject orders in such cases and such orders will not be invoiced. Edwards does not provide credit or replacement for expired transcatheter heart valve Products or accessories, with the exception of consigned products pursuant to the terms of the Consignment Agreement. Edwards shall not provide Products to Customer under this Agreement with a shelf life of less than twelve (12) months from the date of delivery.

2. **Term**. This Agreement will be in effect for five years from the Effective Date through June 22, 2031 ("Term"). This Agreement may be terminated by either party upon the giving of at least thirty (30) days advance written notice to the other party of its intention to terminate. Upon termination of this Agreement, Edwards will not issue credits or re-bills for Products ordered or received after the date of termination.

3. **Pricing; Payment**. Payment terms are net 30 days from the date Hospital receives the invoice. Purchases shall be shipped FOB destination, freight prepaid, via carriers selected by Edwards, with the exception of special delivery and/or air shipments requested by Hospital, and made in accordance with the terms of this Agreement (including the Transcatheter Heart Valve ('THV') return goods policy in the attached Schedule G) and product price list under Schedule A. Such special delivery and/or air shipment charges shall be prepaid by Edwards and invoiced to Hospital for payment. Purchase order placement, confirmation, and invoices for Products shall be sent by use of electronic data interchange (EDI), except where Hospital does not have such capability. Edwards may suspend sales of the Products to Hospital or terminate this Agreement with respect to Hospital in the event that Hospital fails to timely pay any sum owed by Hospital to Edwards hereunder.

4. **Limited Warranty**. EDWARDS WARRANTS THAT EACH OF THE PRODUCTS IT MANUFACTURES, WHEN USED IN ACCORDANCE WITH THE DIRECTIONS ON THE LABELING, IS FIT FOR THE PURPOSES AND INDICATIONS DESCRIBED IN THE LABELING. A PRODUCT DISTRIBUTED BY BUT NOT MANUFACTURED BY EDWARDS IS WARRANTED BY ITS MANUFACTURER. UNLESS A PRODUCT IS USED IN ACCORDANCE WITH ITS INSTRUCTIONS, THESE WARRANTIES ARE VOID AND OF NO EFFECT. THERE ARE NO OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EDWARDS' SOLE OBLIGATION AND HOSPITAL'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT EDWARDS' OPTION, TO REPAIR OR REPLACE THE PRODUCT. EDWARDS SHALL NOT BE LIABLE FOR PROXIMATE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES.

5. **Force Majeure**. Edwards will use commercially reasonable efforts to fill orders, but Edwards shall not be liable for nonperformance or delays caused by shortage of raw materials, manufacturing problems, labor problems, acts of regulatory agencies, discontinuation of a product line, acts of God, or other causes beyond Edwards' control. Hospital agrees that in such events Edwards may allocate products among all hospitals without liability. In the event that Edwards ceases to manufacture or distribute any of the Products for any reason, Edwards shall have no obligation to supply such Product.

6. **Direct Order Purchases**. Edwards will provide the Products to Hospital through direct order only at the Prices set forth herein.

7. **Intent**. The parties do not intend that any payments made under this Agreement be in return for the purchasing or ordering of any goods or services other than the specific Products described in this Agreement.

8. **Product Education and Support**. Edwards makes available standard education and other product support to hospitals of the Products and to those clinician users of the Products purchased. The cost of such education and other product support is included in the purchase price of the Products and so provided at no additional charge to hospitals, including Hospital. Such education and other product support may include, without limitation: (1) education and training on the safe and effective use of the Product as well as the condition treated with the Products; (2) the provision of general information and analytics on issues relevant to the use of the Products by hospitals, such as coverage and reimbursement of the Products or of services provided using the Products, clinical outcomes resulting from use of the Products, and approaches to improving the efficient use of the Products or clinical outcomes; (3) access to general materials that provide education about, and promote, the Products (such as patient brochures); and (4) access to general templates, tools and other resources that support the provision of services using the Products. Edwards is under no obligation to provide any specific level of education and product support. Edwards may limit any such education and support to Hospital to what Edwards determines in its sole discretion is reasonably necessary and may, in its sole discretion, modify or discontinue any portion of the standard education and product support offered to hospitals, including to Hospital.

9. **Schedules Attached to This Agreement**. The following Schedules are hereby incorporated into and made a part of this Agreement: Schedule A – Products and Pricing – Transcatheter Heart Valves, Schedule B – Accessory Components: Transcatheter Heart Valves, Schedule C – Rebate, Schedule D – Consignment Terms and Conditions, Schedule E – Insurance Requirements, and Schedule F – Levine Act - Campaign Contribution Disclosure (formerly referred to as Senate Bill 1439), Schedule G - THV Return Goods Policy.

10. **Debarment and Suspension**. Edwards hereby represents and warrants to the best of its knowledge that it is not and at no time has been convicted of any criminal offense related to health care nor has been debarred, excluded, or otherwise ineligible for participation in any federal or state government health care program, including Medicare and Medicaid. Edwards will promptly notify Hospital if, during the term of this Agreement, Edwards becomes debarred, excluded, or otherwise ineligible for participation in any federal or state government health care program.

11. **Insurance.** Edwards shall comply with the insurance requirements set forth on the attached Schedule E.

12. **Indemnification**. Edwards shall defend, indemnify, and hold harmless the Hospital, its employees, agents, directors, and officers (collectively "Hospital Indemnitees") from and against any losses, liabilities, damages, expenses, and costs (including reasonable attorneys' fees) arising from any claim, action, suit, or proceeding made or brought by a third party against Hospital Indemnitees for (1) the alleged infringement of intellectual property rights of a third-party by any Products provided by Edwards under this Agreement, or (2) bodily injury (including death) or property damage resulting from any (a) negligent or wrongful act or omission by Edwards, its agents or employees, or (b) defect in any Products provided by Edwards under this Agreement. Edwards' indemnity obligations shall not apply to the extent any claims, liabilities, damages, losses, costs, and expenses are caused by the negligence or fault of Hospital or Hospital Indemnitees or willful or wanton misconduct, modification of any Products or use of any Products in any manner not contemplated hereunder. If any demand or claim is made or suit is commenced against Hospital Indemnitees for which Edwards has an indemnity obligation under this Section ("Indemnity Claim"), written notice of such shall be promptly provided to Edwards. However, Hospital Indemnitees' failure to provide or delay in providing such notice will relieve Edwards of its obligations only if and to the extent that such delay or failure prejudices Edwards' ability to defend such lawsuit or claim. Edwards shall have the right to exercise sole control over the defense and settlement of any such Indemnity Claim for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such Indemnity

Claim or suit; provided that Edwards shall not enter into any settlement or admit fault or liability on the Hospital Indemnitee's behalf without the prior written consent of the Hospital, which consent shall not be unreasonably withheld or delayed. Hospital Indemnitees shall have the right to select and obtain representation by separate legal counsel. If Hospital exercises such right, all costs and expenses incurred by Hospital for such separate legal counsel shall be borne by Hospital. If any injury is caused by the negligence or fault of both Edwards on the one hand, and Hospital on the other hand, the apportionment of said damages shall be shared between Edwards and Hospital based upon the comparative degree of each other's negligence or fault, and each shall be responsible for its own defense and costs, including but not limited to the costs of defense, attorneys' fees, witnesses' fees and expenses incident thereto.

13. **Waiver**. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by an authorized representative of both parties hereto. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

14. **Severability**. In the event any provision of this Agreement shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision hereof.

15. **Compliance with Laws.** The parties' actions under the Agreement shall comply with all applicable laws, rules, regulations, court orders and governmental agency orders. The provisions of this Agreement are specifically made severable. If a provision of the Agreement is terminated or held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall remain in full effect.

16. **Levine Act - Campaign Contribution Disclosure (formerly referred to as Senate Bill 1439)**. Edwards has disclosed to San Bernardino County ("County") using Schedule F – Levine Act - Campaign Contribution Disclosure (formerly referred to as Senate Bill 1439), whether it has made any campaign contributions of more than $500 to any member of the County Board of Supervisors or other County elected officer [Sheriff, Assessor-Recorder-Clerk, Auditor-Controller/Treasurer/Tax Collector and the District Attorney] within the 12 months before the date this Agreement was approved by the Board of Supervisors. Edwards acknowledges that under Government Code section 84308, Edwards is prohibited from making campaign contributions of more than $500 to any member of the Board of Supervisors or other County elected officer for 12 months after the County's consideration of the Agreement.

In the event of a proposed amendment to this Agreement, the Edwards will provide the County a written statement disclosing any campaign contribution(s) of more than $500 to any member of the Board of Supervisors or other County elected officer within the preceding 12 months of the date of the proposed amendment.

Campaign contributions include those made by any agent/person/entity on behalf of the Edwards or by a parent, subsidiary or otherwise related business entity of Edwards.

17. **Assignment**. This Agreement shall be binding upon and shall inure to the benefit of the successors and permitted assigns of the parties. Neither party may assign or otherwise transfer (through merger, consolidation, sale of assets, or otherwise) this Agreement or any interest herein without the prior written consent of the other party. Any purported assignment without such required consent shall be void. No assignment shall relieve any party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

18. **Counterparts; Facsimile Signature Pages**. This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute one and the same Agreement. The parties shall be entitled to sign and transmit an electronic signature of this Agreement (whether by facsimile, PDF or other email transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Agreement upon request.

19. **Governing Law/Venue**. This Agreement shall be governed by and construed in accordance with the laws, without reference to principles of conflicts of laws, of the State of California. The parties agree that the venue of any action or claim brought by any party to this Agreement will be the Superior Court of California, San Bernardino County, San Bernardino District. Each party hereby waives any law or rule of the court, which would allow them to request or demand a change of venue. If any action or claim concerning this Agreement is brought by any third party and filed in another venue, the parties hereto agree to use their best efforts to obtain a change of venue to the Superior Court of California, San Bernardino County, San Bernardino District.

20. **Entire Agreement**. This Agreement, including without limitation Schedules attached hereto, shall supersede all other agreements between Edwards and Hospital, with respect to the Products and constitutes the entire agreement, superseding all prior or contemporaneous agreements, understandings, representations, and negotiations, between the parties on the subject hereof; and there are no conditions to this Agreement that are not set forth herein. No modification to this Agreement or the exhibits attached hereto shall be effected by the acknowledgement or acceptance of any order or shipping instructions forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein. In the event of a conflict between this Agreement and the exhibits hereto, the terms of this Agreement shall control.

21. **General**. No changes to this Agreement, including any conflicting or additional terms contained in any purchase order or other document submitted by Hospital, shall be valid unless approved in writing by Hospital and Edwards at its home office. Any invoice claims or disputes by Hospital must be made in writing within ninety (90) days of invoice date. Edwards will not make payments for or investigate any invoice claims or disputes that are made more than ninety (90) days after invoice date.

22. **Confidentiality**. Hospital and Edwards agree not to disclose the financial terms and conditions of this Agreement without the prior written consent of the other party, except as required by applicable law or regulatory authority, including but not limited to the State of California Ralph Brown Act. Each party agrees that all information provided to it by the other party pursuant to this Agreement, including information concerning pricing, products and customers, is confidential and proprietary information of the disclosing party. Each party agrees not to disclose such confidential information directly or indirectly to any third party or to use such confidential information for any purpose other than for fulfilling its obligations under this Agreement. Upon either party's request, the other party shall return all confidential information to the requesting party or destroy all such information and certify in writing as to its destruction. This provision shall survive the termination or expiration of this Agreement.

This Agreement is not binding until approved by Edwards at its corporate headquarters located at One Edwards Way, Irvine, California 92614.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date:

By:	_____	By:	_____
Name:	_____	Name:	Kristen Shelton
Title:	_____	Title:	SVP Sales, THV US
Date:	_____	Date:	_____

SCHEDULE A
PRODUCTS AND PRICING: TRANSCATHETER HEART VALVES

Model Number	Description	Qty	Price Each*
S3URCM20A	**20mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System**	**N/A**	**$34,000**
9755RSL20A	- 20 mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	Included	
9750CM20A	- Commander Delivery System	Included	
914ESPA	- Edwards eSheath+ Introducer Set (14F)	Included	
9600CRA	- Edwards Crimper	Included	
96402	- Atrion Inflation Device/Locking Syringe Device	Included	
S3URCM23A	**23mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System**	**N/A**	**$34,000**
9755RSL23A	- 23 mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	Included	
9750CM23A	- Commander Delivery System	Included	
914ESPA	- Edwards eSheath+ Introducer Set (14F)	Included	
9600CRA	- Edwards Crimper	Included	
96402	- Atrion Inflation Device/Locking Syringe Device	Included	
S3URCM26A	**26mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System**	**N/A**	**$34,000**
9755RSL26A	- 26 mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	Included	
9750CM26A	- Commander Delivery System	Included	
914ESPA	- Edwards eSheath+ Introducer Set (14F)	Included	
9600CRA	- Edwards Crimper	Included	
96402	- Atrion Inflation Device/Locking Syringe Device	Included	
S3URCM29A	**29mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System**	**N/A**	**$34,000**
9755RSL29A	- 29 mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	Included	
9750CM29A	- Commander Delivery System	Included	
916ESPA	- Edwards eSheath+ Introducer Set (16F)	Included	
9600CRA	- Edwards Crimper	Included	
96406	- Atrion Inflation Device/Locking Syringe Device	Included	
9999RFA	**Re-Processing Fee**	**N/A**	**$10,000**

*The System unit price listed in Schedule A includes the above accessory components as outlined. Subject to the provisions of the Agreement, and if medically necessary to complete a single Edwards Transcatheter Heart Valve procedure, Edwards may provide to the Hospital additional individual accessory component(s) and/or transcatheter heart valve(s) at no additional charge. Hospital agrees to use the Products and individual accessory components for Product solely for its own use and for Edwards Transcatheter Heart Valve procedures only. If Hospital damages or uses individual accessory components of Products for procedures other than with Edwards' Products, Hospital may be charged a Re-Processing Fee for such replacement accessory components.

Notwithstanding anything contained in the Agreement to the contrary, the parties agree that Edwards may add commercially available Transcatheter

Heart Valve System products to Schedule A of this Agreement upon written notice to Hospital. The notice will state (i) the model and price of the additional products and (ii) the date upon which such products become "Products" as defined in the Agreement.

Disclosure Requirements. .Hospital shall disclose the discounts or reductions in price under any state or federal program which provides cost or charge-based reimbursement to Hospital for the Edwards Products covered by the purchase in accordance with applicable regulations, and shall provide, upon request by the Secretary of the U.S. Department of Health and Human Services or any State Medicaid agency, information requested about the value of these discounts. Edwards shall provide all documents and information requested by Hospital to assist Hospital in complying with its reporting obligations.

SCHEDULE B
ACCESSORY COMPONENTS: TRANSCATHETER HEART VALVES

THV Accessory Components: Subject to the provisions of the Agreement, and if medically necessary to complete a single Edwards Transcatheter Heart Valve procedure, Edwards may provide to the Hospital additional individual accessory component(s) and/or transcatheter heart valve(s) at no additional charge. These accessory components for use as described above will be included in the System unit price listed in Schedule A. Please consult with your THV Territory Manager in the event that additional accessory components are required. **This policy is subject to change without notice.**

Accessory Components for: 20 mm Edwards SAPIEN 3 Ultra RESILIA THV with Commander System

Model Number	Description
914ESPA	Edwards eSheath+ Introducer Set (14F)
9600CRA	Edwards Crimper
96402	Atrion Inflation Device/Locking Syringe

Accessory Components for: 23 mm Edwards SAPIEN 3 Ultra RESILIA THV with Commander System

Model Number	Description
914ESPA	Edwards eSheath+ Introducer Set (14F)
9600CRA	Edwards Crimper
96402	Atrion Inflation Device/Locking Syringe

Accessory Components for: 26 mm Edwards SAPIEN 3 Ultra RESILIA THV with Commander System

Model Number	Description
914ESPA	Edwards eSheath+ Introducer Set (14F)
9600CRA	Edwards Crimper
96402	Atrion Inflation Device/Locking Syringe

Accessory Components for: 29 mm Edwards SAPIEN 3 Ultra RESILIA THV with Commander System

Model Number	Description
916ESPA	Edwards eSheath+ Introducer Set (16F)
9600CRA	Edwards Crimper
96406	Atrion Inflation Device/Locking Syringe

Notwithstanding anything contained in the Agreement to the contrary, the parties agree that Edwards may add commercially available Transcatheter Heart Valve System accessory components to Schedule B of this Agreement upon written notice to Hospital. The notice will state the model of the additional accessory components.

SCHEDULE C
REBATE
Arrowhead Regional Medical Center
400 N Pepper Ave, Colton, CA 92324

Rebate Eligibility

If Hospital is in full compliance with all terms of this Agreement, including payment terms, Hospital may earn rebates on each unit of commercial Transcatheter Heart Valve ("THV") Product purchased at the prices set forth in the Agreement.

Eligibility for rebates will be calculated for each calendar quarter during the Agreement and for each four calendar quarters of the Agreement (as described below). The effective date of the rebate (and its impact on participation in other rebate programs) will be determined as follows:

- If the Agreement Effective Date is other than the first day of a new calendar month, the rebate will become effective on the first day of the month following the Agreement Effective Date ("Rebate Effective Date") and the volume requirements for earning rebates in any initial calendar quarter and the initial four calendar quarters (set forth below) will be prorated. For example, if the Agreement Effective Date is April 25, 2026, the rebate will take effect on May 1, 2026. Only purchases made on or after May 1, 2026 will count towards the volume requirements and may be eligible for rebates under the Agreement. Quarterly volume rebate requirements for the initial calendar quarter will be 2/3 the volume requirements set forth below and four quarter volume supplemental rebate requirements for the initial four calendar quarters will be 11/12 the volume requirements set forth below.

Eligible Products

Eligibility for rebates is based on the number of units of Eligible Product purchased by the Hospital. "Eligible Product" includes:

1. Commercial THV Products purchased at the prices set forth in the Agreement, and
2. Clinical THV products purchased in connection with participation in clinical trials.

Eligible Product shall be deemed purchased by Hospital on the date set forth on the invoice provided by Edwards. Calculation of the number of units of Eligible Product purchased shall be net of returns.

Additional Terms

- Edwards does not accept bulk buy purchasing of Products. Any purchases that may be considered a bulk buy or outside of expected procedure use must be reviewed and approved by Edwards prior to acceptance of the order. Edwards reserves the right to reject such orders, which will not be invoiced.
- Rebates earned shall be applied **only** to units of commercial THV Products purchased at the prices set forth in the Agreement.
- Notwithstanding anything contained herein or in the Agreement, rebates shall not exceed the maximum quarterly rebate amount per unit as indicated in the Quarterly Volume Rebate.
- Rebates will be paid 45 days after the end of each calendar quarter.

Please choose the preferred rebate distribution method for earned rebates:

- ☐ ACH Direct Deposit – please provide:
  - W9 (copy of 2018 or newer)
  - Bank details on bank's letterhead
- X Credit Memo

If no option is selected, earned rebates will be distributed via credit memo.

Quarterly Volume Rebate

The quarterly volume rebate will be calculated based on the share commitment and purchases of Eligible Product during each calendar quarter. The rebate amount per unit will reduce the net price of each unit of commercial THV Product purchased in that quarter.

Quarterly Unit Requirement **< 90% Market Share**	**Quarterly Unit Requirement** **≥ 90% Market Share**	**Quarterly Rebate Amount per Unit of Commercial THV Products**
8 to 19 units	1 to 7 units	$750
20 to 29 units	8 to 19 units	$1,000
30 or more units	20 or more units	$1,500

Hospital agrees to provide Edwards within thirty (30) days following the expiration of each quarter during the Term, written documentation signed by Hospital in the form set forth on Attachment 1 evidencing Hospital's total unit purchases of THV products during such quarter. Units purchased shall be net of returns.

At the end of each quarter, after receipt of documentation of THV product purchases, Edwards will determine whether Hospital is eligible for a rebate and the applicable rebate amount per unit (if any) in accordance with the table set forth herein ("Rebate Amount Per Unit"). If Hospital is eligible for a rebate, Edwards will provide Hospital the Rebate Amount Per Unit for each unit of commercial Edwards THV Product purchased at the prices set forth in this Agreement during such applicable Agreement quarter (and not returned). The Rebate Amount Per Unit paid shall reduce the net price paid for each unit of commercial Edwards THV Product purchased that Agreement quarter.

Four Quarter True-up Rebate

A "true-up rebate" refers to an additional rebate payment made at the end of a four-quarter period if the total rebate earned during the individual quarters is less than the maximum rebate amount eligible for that period, based on an aggregate performance.

The true-up rebate will be calculated based on purchases of Eligible Products during each set of four consecutive calendar quarters of the Rebate Term, beginning with the quarter in which the Rebate Effective Date falls. Hospital may be eligible for a true-up rebate if the maximum true-up rebate amount, as set forth in the chart below, for the applicable volume of Eligible Products purchased exceeds the quarterly volume rebate amount earned in those four quarters. If this condition is met, Hospital will receive a true-up rebate for each unit of commercial THV Product purchased during the applicable period. This rebate will equal the difference between the quarterly volume rebate earned in the quarter and the maximum true-up rebate amount collectively earned. This true-up rebate will reduce the net price paid for each applicable unit of commercial THV Product purchased during that quarter.

Annual Unit Requirement **< 90% Market Share**	**Annual Unit Requirement** **≥ 90% Market Share**	**Maximum True-Up Rebate Amount per Unit of Commercial THV Products**
32 to 79 units	1 to 31 units	$750
80 to 119 units	32 to 79 units	$1,000
120 or more units	80 or more units	$1,500

Notice to Customer: The rebates set forth in this schedule constitute a “discount or other reduction in price” to Hospital under the federal anti-kickback statute (42 U.S.C. 1320a-7b(b)(3)(A)) and its implementing regulations (42 C.F.R. 1001.952(h)). Hospital shall fully and accurately disclose the discounts or reductions in price to any federal health care program and shall provide, upon request by the Secretary of the U.S. Department of Health and Human Services or any state agency, any information requested about the value of these discounts. Hospital acknowledges that the rebates earned (if any) will be paid after the purchase of the commercial THV Product and so will not be disclosed on the invoice. Hospital will receive a statement detailing the rebates earned in connection with each rebate payment.

Attachment 1

Total Unit Purchases Documentation

Arrowhead Regional Medical Center
400 N Pepper Ave, Colton, CA 92324

Hospital shall provide Edwards within thirty (30) days following the expiration of each quarter during the Term, a signed copy of this Attachment 1 setting forth Hospital's total unit purchases of THV products during such quarter. Units purchased shall be net of returns. Hospital shall provide documentation supporting the reported totals as requested by Edwards.

Product	**Total Units Purchased Per Quarter**			
	Q1 Jan-Mar	**Q2 Apr-Jun**	**Q3 Jul-Sep**	**Q4 Oct-Dec**
Edwards Transcatheter Heart Valve Products				
Other Transcatheter Heart Valve products				

Arrowhead Regional Medical Center
Hospital Name

_____
Hospital Signature

By: Dawn Rowe

Title: Chair, Board of Supervisors

Date: _____

SCHEDULE D

CONSIGNMENT TERMS AND CONDITIONS

WHEREAS, Edwards manufactures and distributes, among other medical devices, a proprietary line of transcatheter heart valve therapy systems (hereinafter, the "Products"); and

WHEREAS, Hospital is an existing customer for Products and requires the ready availability of Products for implantation in patients as the need arises, and wishes to maintain an inventory of Products at its premises at 400 N Pepper Ave, Colton, CA 92324 (hereinafter, the "Premises") on a consignment basis; and

WHEREAS, Edwards is willing to supply Products to Hospital on a consignment basis subject to the terms and conditions set forth below ("Consigned Products"); and

WHEREAS, Edwards will ship to Hospital upon full execution of the Agreement, and Hospital will thereafter maintain in storage at the Premises, the Products more particularly described in Exhibit A attached hereto (hereinafter, the "Initial Consigned Products" and, together with Products hereafter shipped by Edwards to Hospital pursuant to Section I below, the "Consignment Inventory").

NOW, THEREFORE: in consideration of the mutual promises and accommodations contained herein, the parties agree as follows:

I. SHIPMENT, STORAGE, AND PURCHASE/SALE OF PRODUCTS

1. Inventory of Consigned Products. From time to time during the term of this Agreement the level and product mix of the Consignment Inventory maintained at the Premises pursuant to this Agreement may be changed by mutual written agreement of the parties to meet the changing needs of Hospital's operations by executing an amendment to Exhibit A; however, Edwards may provide additional Inventory as needed by a Hospital for a specific case beyond Consignment Inventory levels set forth in its respective Exhibit A ("Short Term Consignment") upon receipt of a no charge purchase order. Due to the temporary nature of such Short Term Consignment, a written amendment increasing par levels shall not be required for the short term basis, but such Short Term Consignment Inventory shall nevertheless be subject to the terms and conditions of this Consignment Agreement. The Hospital's purchasing agent is authorized to execute amendments to Exhibit A.

Notwithstanding the foregoing, if in the course of its inspections performed pursuant to Section 7 below Edwards determines that models in Consignment Inventory have not been used by Hospital in the preceding three (3) month period, Edwards shall have the right, but not the obligation, to remove such models from Consignment Inventory and adjust Hospital's product mix and par levels as deemed necessary in Edwards's reasonable discretion. Hospital shall use the Consignment Inventory only for its own internal use. All Products ordered by Hospital to maintain as the Consignment Inventory, as well as all of the Initial Consigned Products, shall be considered to have been consigned pursuant to the terms of this Agreement.

2. Delivery and Sales Terms. The parties acknowledge that Consigned Products shall be deemed to be consigned to Hospital FOB destination, freight prepaid, via carriers selected by Edwards with the exception of special delivery and/or air shipments requested by Hospital. Such special delivery and/or air shipment charges shall be prepaid by Edwards and invoiced to Hospital for payment. Hospital shall at that place and time promptly take possession of the Consigned Products and pay all costs incident to the eventual arrival and storage of the Consigned Products at the Premises. All anticipated purchases of Consigned Products by Hospital shall be governed by the terms and conditions of this Agreement. This Agreement will take precedence in the event of any conflict with the provisions set forth in any other agreement with respect to the consignment of Consigned Products.

3. Ownership. Anything in this Agreement to the contrary notwithstanding, the Consigned Products will remain the sole and exclusive property of Edwards until purchased as provided below, at which point title to each of the Consigned Products

shall pass from Edwards to Hospital. Hospital shall not represent itself to any third party as being the owner of any such Consigned Products, claim any rights of ownership therein, nor encumber, lease, transfer or otherwise dispose of (other than in accordance with the terms of Section 6 below) any such Consigned Products.

4. Storage of Consigned Products. Hospital shall hold the Consigned Products at the Premises as agent and bailee of Edwards, and will store the Consigned Products at the Premises at no cost to Edwards. Hospital shall have full responsibility for the care and condition and the safe and satisfactory storage and maintenance of the Consigned Products and exercise due care when shipping or returning any Consigned Products to Edwards. Hospital assumes full liability for any Consigned Products that are missing, damaged, destroyed, or otherwise no longer in saleable condition (i.e., properly stored and maintained and in unopened and undamaged packages) resulting from any cause whatsoever, including but not limited to breakage, theft, damage by water, fire, or other occurrences, except to the extent of a patent or latent defect in the Consigned Products. Edwards shall remove and may replace expired and defective Consigned Products at no cost to Hospital and upon expiration of Consigned Product, Edwards shall review product usage and determine if Consigned Product(s) will be replaced to the Hospital or an adjustment to Hospital's consigned inventory levels is necessary. Hospital shall be solely responsible for all applicable taxes imposed with respect to the Consigned Products while they are stored at the Premises. Hospital further agrees to segregate the Consigned Products physically from any Products owned by Hospital and to post one or more signs conspicuously identifying the Consigned Valves as the property of Edwards.

5. Insurance. Hospital shall procure and maintain in force at all times during the term of this Agreement, at Hospital's expense, a program of self-insurance or all-risk property insurance reasonably acceptable to Edwards covering the Consigned Products, in an amount at least equal to the aggregate prices as set forth in Edwards's published price list for Consigned Products in effect for the period of the insurance by Hospital for all Consigned Products stored in the Premises, Upon request from Edwards, Hospital shall furnish a certificate of the existence of such insurance executed by Hospital's insurance carrier.

6. Purchase of Consigned Products. Hospital shall have the right to withdraw Consigned Products from storage, from time to time, but only for immediate use in providing care to Hospital's patients. Hospital agrees to withdraw for use those Consigned Products, from the Consignment Inventory, which have the shortest remaining shelf life, based on the expiration date on the package. Upon such withdrawal, or upon report by Edwards to Hospital of any "Discrepancy" as described in Section 7 below, Hospital shall be considered to have purchased the pertinent Consigned Products. Following such purchase of each Consigned Product, Hospital shall promptly issue to Edwards an order, but in no event later than seven (7) days after such purchase, for a replacement Consigned Product, thereby fully replenishing the Consignment Inventory (unless the parties have implemented an automated process, such as RFID, that detects withdrawal of Product and automatically places an order for replenishment). Hospital shall be responsible for maintaining traceability of the Products used. All orders for Consigned Products shall include: (i) the Product name and catalog/item number; (ii) serial number of Consigned Product purchased; (iii) the number of units to be delivered; (iv) the delivery address; (v) any special shipping instructions; and (vi) reference to this Agreement. Upon receipt of any such order, Edwards will issue an invoice for the Consigned Product or Products that was or were purchased. Consigned Products purchased by Hospital will be billed to Hospital at the price set forth in this Agreement.

7. Inspection. Upon reasonable request, Edwards shall have the right to conduct a physical inspection of the Consigned Products at the Premises to verify the quantity and condition of the Consigned Products, to ensure that the Consignment Inventory is being maintained. Edwards will identify and report to Hospital any discrepancy between

(a) the Consigned Products located at Premises that are undamaged and in saleable condition, and
(b) the Consignment Inventory

(hereinafter, a "Discrepancy"). If, within seven (7) days of Edwards's report of a Discrepancy, Hospital fails to issue to Edwards an order for Consigned Products sufficient to replenish the Consignment Inventory or if the Discrepancy is not resolved to the reasonable satisfaction of Edwards, Edwards is entitled to deliver Consigned Products sufficient to replenish the Consignment Inventory and/or issue an invoice for Consigned Products subject to the Discrepancy. Hospital shall provide Edwards's representatives reasonable access to the Premises to conduct such inspections.

8. Payment for Consigned Products. Payment will be in accordance with the terms under the Agreement.

9. Obligations Upon Termination. Notwithstanding any past, present, or future commitment by Edwards to ship Products to Hospital, Hospital shall, at Edwards' expense and no later than ten (10) days following the expiration or termination of this Agreement: (i) return to Edwards, through an authorized Edwards sales representative, any or all Consigned Products then in Hospital's possession, FOB the Premises, that are unexpired, undamaged, and in saleable condition; (ii) issue a final order for all Consigned Products that are not returned or that are not in saleable condition, including any Consigned Products that are lost, opened, or damaged; and (iii) pay any outstanding invoices by the payment due date, including for the final order. At that time, Hospital shall prepare, pack, and crate the applicable Consigned Products for shipment, and arrange for shipment to such new location and via such carrier as Edwards directs.

10. Evidence of Ownership of Consigned Products. Hospital agrees to execute and deliver to Edwards, at any time and from time to time upon Edwards's request, such documentation as Edwards may deem necessary or advisable to evidence Edwards's ownership of the Consigned Products. Hospital will pay all costs and expenses of recording same, in order to establish, preserve, protect, and maintain Edwards's right and title to and ownership of the Consigned Products.

EXHIBIT A

Consignment Inventory

Arrowhead Regional Medical Center

400 N Pepper Ave, Colton, CA 92324

Model Number	Description	U/M	Current Par Level*
	Edwards SAPIEN Transcatheter Heart Valve Systems:		
S3URCM20A	20mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System	1EA	2
S3URCM23A	23mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System	1EA	4
S3URCM26A	26mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System	1EA	4
S3URCM29A	29mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System	1EA	3
	Edwards Transcatheter Heart Valve Accessory Components:		
	20mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System:		
9750CM20A	Edwards Commander Delivery System	1EA	
914ESPA	Edwards eSheath+ Introducer Set (14F)	1EA	
9600CRA	Edwards Crimper	1EA	
96402	Atrion Inflation Device/Locking Syringe Device	1EA	
	23mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System:		
9750CM23A	Edwards Commander Delivery System	1EA	
914ESPA	Edwards eSheath+ Introducer Set (14F)	1EA	
9600CRA	Edwards Crimper	1EA	
96402	Atrion Inflation Device/Locking Syringe Device	1EA	
	26mm Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) with Commander System:		
9750CM26A	Edwards Commander Delivery System	1EA	
914ESPA	Edwards eSheath+ Introducer Set (14F)	1EA	
9600CRA	Edwards Crimper	1EA	
96402	Atrion Inflation Device/Locking Syringe Device	1EA	

*Subject to the provisions of the Agreement and if medically necessary to complete a single Edwards' Transcatheter

Heart Valve Procedure, Edwards may provide Hospital with additional accessory component(s) and / or transcatheter heart valve(s) at no additional charge. Hospital agrees to use the Products and individual accessory components solely for its own use and exclusively for Edwards' transcatheter heart valve procedures.

Edwards may also provide additional Inventory as needed by Hospital for a specific case beyond the Consignment Inventory levels set forth in Exhibit A ("Short Term Consignment") upon receipt of a no charge purchase order. Due to the temporary nature of such Short Term Consignment, a written amendment increasing par levels is not required for the short term; however all Short Term Consignment Inventory remains subject to the terms and conditions of this Consignment Agreement.

SCHEDULE E

INSURANCE REQUIREMENTS

Edwards agrees to provide insurance set forth in accordance with the requirements herein.

1. Without in anyway affecting any indemnity obligations provided and in addition thereto, Edwards shall secure and maintain throughout the contract term the following types of insurance through an insurance program or a program of self-insurance or any combination thereof with limits as shown:

    a. Workers' Compensation/Employer's Liability – A program of Workers' Compensation insurance or a state-approved, self-insurance program in an amount and form to meet all applicable requirements of the Labor Code of the State of California, including Employer's Liability with $250,000 limits covering all persons including volunteers providing services on behalf of Edwards and all risks to such persons under this contract. If Edwards has no employees, it may certify or warrant to Hospital that it does not currently have any employees or individuals who are defined as "employees" under the Labor Code and the requirement for Workers' Compensation coverage will be waived by Hospital's Director of Risk Management. With respect to contractors that are non-profit corporations organized under California or Federal law, volunteers for such entities are required to be covered by Workers' Compensation insurance.

    b. Commercial/General Liability Insurance – Edwards shall carry General Liability Insurance covering all operations performed by or on behalf of Edwards providing coverage for bodily injury and property damage with a combined single limit of not less than one million dollars ($1,000,000), per occurrence. The policy coverage shall include:
        i. Premises operations and mobile equipment.
        ii. Broad form property damage (including completed operations).
        iii. Explosion, collapse and underground hazards.
        iv. Personal injury.
        v. Contractual liability.
        vi. $2,000,000 general aggregate limit.

    c. Product Liability Insurance/Completed Operations - Edwards shall carry Product Liability insurance of not less than one million dollars ($1,000,000) per occurrence (claims-made basis) and $2,000,000 aggregate limit,

    d. Automobile Liability Insurance – Primary insurance coverage shall be written on ISO Business Auto coverage form for all owned, hired and non-owned automobiles or symbol 1 (any auto). The policy shall have a combined single limit of not less than one million dollars ($1,000,000) for bodily injury and property damage, per occurrence. If Edwards is transporting one or more non-employee passengers in performance of contract services, the automobile liability policy shall have a combined single limit of two million dollars ($2,000,000) for bodily injury and property damage per occurrence. If Edwards owns no autos, a non-owned auto endorsement to the General Liability policy described above is acceptable.

    e. Umbrella Liability Insurance – An umbrella (over primary) or excess policy may be used to comply with limits or other primary coverage requirements. When used, the umbrella policy shall apply to bodily injury/property damage, personal injury/advertising injury and shall include a "dropdown" provision providing primary coverage for any liability not covered by the primary policy. The coverage shall also apply to automobile liability.

2. **Certificate Holder.** All policies, except for Worker's Compensation, Errors and Omissions and Professional Liability policies shall contain additional endorsements naming Hospital with respect to liabilities arising out of the performance of obligations hereunder the Agreement. The certificate holder status shall not limit the scope of coverage for Hospital to vicarious liability but shall allow coverage for Hospital to the full extent provided by the policy.

3. **Severability of Interests**. Edwards agrees to ensure that coverage provided to meet these requirements is applicable separately to each insured and there will be no cross liability exclusions that preclude coverage for suits between Edwards and Hospital or between Hospital and any other insured or additional insured under the policy.

4. **Proof of Coverage**. Edwards shall furnish Certificates of Insurance to Arrowhead Regional Medical Center evidencing the insurance coverage at the time the Contract is executed, additional endorsements, as required shall be provided prior to the commencement of performance of services hereunder, which certificates shall provide that such insurance shall not be terminated or expire without thirty (30) days written notice to Arrowhead Regional Medical Center, and Edwards shall maintain such insurance from the time Edwards commences performance of services hereunder until the completion of such services. Within fifteen (15) days of the commencement of this contract, Edwards shall furnish Certificates of Insurance to Arrowhead Regional Medical Center upon request.

5. **Acceptability of Insurance Carrier**. Unless otherwise approved by Risk Management, insurance shall be written by insurers authorized to do business in the State of California and with a minimum "Best" Insurance Guide rating of "A-VII".

6. **Failure to Procure Coverage**. In the event that any policy of insurance required under this contract does not comply with the requirements, is not procured, or is canceled and not replaced, Hospital has the right but not the obligation or duty to cancel the contract.

7. **Insurance Review.** Insurance requirements under this Agreement are subject to periodic review by Hospital. The Hospital's Director of Risk Management or designee is authorized, but not required, to reduce, waive or suspend any insurance requirements whenever Risk Management determines that any of the required insurance is not available, is unreasonably priced, or is not needed to protect the interests of Hospital. In addition, if the Department of Risk Management determines that heretofore unreasonably priced or unavailable types of insurance coverage or coverage limits become reasonably priced or available, the Director of Risk Management or designee is authorized, but not required, to change the above insurance requirements to require additional types of insurance coverage or higher coverage limits, provided that any such change is reasonable in light of past claims against Hospital, inflation, or any other item reasonably related to Hospital's risk. Any change requiring additional types of insurance coverage or higher coverage limits must be made by amendment to this contract. Edwards agrees to execute any such amendment within a reasonable time frame of receipt. Any failure, actual or alleged, on the part of Hospital to monitor or enforce compliance with any of the insurance and indemnification requirements will not be deemed as a waiver of any rights on the part of Hospital.

SCHEDULE F

Levine Act – Campaign Contribution Disclosure

(formerly referred to as Senate Bill 1439)

The following is a list of items that are not covered by the Levine Act. A Campaign Contribution Disclosure Form will not be required for the following:

- Contracts that are competitively bid and awarded as required by law or County policy
- Contracts with labor unions regarding employee salaries and benefits
- Personal employment contracts
- Contracts under $50,000
- Contracts where no party receives financial compensation
- Contracts between two or more public agencies
- The review or renewal of development agreements unless there is a material modification or amendment to the agreement
- The review or renewal of competitively bid contracts unless there is a material modification or amendment to the agreement that is worth more than 10% of the value of the contract or $50,000, whichever is less
- Any modification or amendment to a matter listed above, except for competitively bid contracts.

DEFINITIONS

Actively supporting or opposing the matter: (a) Communicate directly with a member of the Board of Supervisors or other County elected officer [Sheriff, Assessor-Recorder-Clerk, District Attorney, Auditor-Controller/Treasurer/Tax Collector] for the purpose of influencing the decision on the matter; or (b) testifies or makes an oral statement before the County in a proceeding on the matter for the purpose of influencing the County's decision on the matter; or (c) communicates with County employees, for the purpose of influencing the County's decision on the matter; or (d) when the person/company's agent lobbies in person, testifies in person or otherwise communicates with the Board or County employees for purposes of influencing the County's decision in a matter.

Agent: A third-party individual or firm who, for compensation, is representing a party or a participant in the matter submitted to the Board of Supervisors. If an agent is an employee or member of a third-party law, architectural, engineering or consulting firm, or a similar entity, both the entity and the individual are considered agents.

Otherwise related entity: An otherwise related entity is any for-profit organization/company which does not have a parent-subsidiary relationship but meets one of the following criteria:

(1) One business entity has a controlling ownership interest in the other business entity;
(2) there is shared management and control between the entities; or
(3) a controlling owner (50% or greater interest as a shareholder or as a general partner) in one entity also is a controlling owner in the other entity.

For purposes of (2), "shared management and control" can be found when the same person or substantially the same persons own and manage the two entities; there are common or commingled funds or assets; the business entities share the use of the same offices or employees, or otherwise share activities, resources or personnel on a regular basis; or there is otherwise a regular and close working relationship between the entities.

Parent-Subsidiary Relationship: A parent-subsidiary relationship exists when one corporation has more than 50 percent of the voting power of another corporation.

Contractors must respond to the questions on the following page. All references to "Contractor" on this Schedule refer to Edwards. If a question does not apply respond N/A or Not Applicable.

1. Name of Contractor: _____

2. Is the entity listed in Question No.1 a nonprofit organization under Internal Revenue Code section 501(c)(3)?

   Yes ☐ If yes, skip Question Nos. 3-4 and go to Question No. 5 No ☐

3. Name of Principal (i.e., CEO/President) of entity listed in Question No. 1, if the individual actively supports the matter and has a financial interest in the decision: _____

4. If the entity identified in Question No.1 is a corporation held by 35 or less shareholders, and not publicly traded ("closed corporation"), identify the major shareholder(s):

   _____

5. Name of any parent, subsidiary, or otherwise related entity for the entity listed in Question No. 1 (see definitions above):

Company Name	Relationship

6. Name of agent(s) of Contractor:

Company Name	Agent(s)	Date Agent Retained (if less than 12 months prior)

7. Name of Subcontractor(s) (including Principal and Agent(s)) that will be providing services/work under the awarded

contract if the subcontractor (1) actively supports the matter and (2) has a financial interest in the decision and (3) will be possibly identified in the contract with the County or board governed special district.

Company Name	Subcontractor(s):	Principal and//or Agent(s):

8. Name of any known individuals/companies who are not listed in Questions 1-7, but who may (1) actively support or oppose the matter submitted to the Board and (2) have a financial interest in the outcome of the decision:

Company Name	Individual(s) Name

9. Was a campaign contribution, of more than $500, made to any member of the San Bernardino County Board of Supervisors or other County elected officer within the prior 12 months, by any of the individuals or entities listed in Question Nos. 1-8?

   No ☐ If **no**, please skip Question No. 10.

   Yes ☐ If **yes**, please continue to complete this form.

10. Name of Board of Supervisor Member or other County elected officer: _____

    Name of Contributor: _____

    Date(s) of Contribution(s): _____

    Amount(s): _____

    Please add an additional sheet(s) to identify additional Board Members or other County elected officers to whom anyone listed made campaign contributions.

By signing the Agreement, Contractor certifies that the statements made herein are true and correct. Contractor understands that the individuals and entities listed in Question Nos. 1-8 are prohibited from making campaign contributions of more than $500 to any member of the Board of Supervisors or other County elected officer while award of this Agreement is being considered and for 12 months after a final decision by the County.

SCHEDULE G

THV RETURN GOODS POLICY

EDWARDS TRANSCATHETER HEART VALVE POLICIES

Customer Service:

- Phone: 1-800-4-A-Heart (1-800-424-3278)
- Fax: 1-800-422-9329 or 1-949-250-3489
- Hours: 5:00 am – 4:30 pm PT
  — Available 24 hours a day

Technical Support 24-Hour Hotline:

The technical support 24-hour hotline is available for discussion of all issues relative to the use, care, and operation of Edwards products. For assistance on these issues, please contact Technical Support via:

- Phone: 1-800-822-9837
- Fax: 1-949-250-2625
- Email: Tech_Support@edwards.com
- Hours: 6:00 am – 4:30 pm PT
  — Available 24 hours a day

A Technical Support Specialist will review the problem and issue authorization for the return if the problem cannot be resolved. Please be prepared to provide the technical support representative with the purchase order and serial numbers.

RETURN ADDRESS:
Edwards Lifesciences Return Department
12050 Lone Peak Pkwy · Draper, UT 84020

Attn: RGA#_____

FedEx Accouont #307840197

Edwards Lifesciences is committed to providing our customers with quality products and service. For this reason, Edwards has implemented the following policies:

Stocking Order:

- A minimum stocking order of **Edwards transcatheter heart valves systems** is not required for transcatheter heart valve programs.
- Units will be shipped following successful completion of the Edwards Fundamentals Training.

Reorder:

- Please contact your Edwards THV Territory Manager or call **Customer Service**
- At the time of reorder, please **provide the serial number** of all Edwards transcatheter heart valves implanted and the lot number of all delivery systems used since the last order
- If medically necessary to complete a single Edwards transcatheter heart valve procedure, Edwards may provide to the Purchaser additional individual accessory component(s) and/or transcatheter heart valve(s) at no additional charge

Terms:

- Standard terms are **net 30** from invoice date

Shipping:

- All orders will be shipped via **Priority Next Day** service for arrival by 10:30 am
- Alternate expedited shipping options can be requested if paid for by customer

Expired Goods:

- Edwards Lifesciences does not provide a credit or replacement for expired transcatheter heart valve goods unless they are Consigned Product.
- Your dedicated THV Territory Manager will assist you in effectively managing your inventory

Returned Goods:

Edwards Lifesciences will accept any product for return that:

- Is a result of error by Edwards
- Does not perform to specification

Full credit or replacement will be issued for these products, and no restocking fee will be assessed.

Questions regarding shipment errors should be addressed within two business days of receipt of goods.

EDWARDS TRANSCATHETER HEART VALVE POLICIES

Returned Goods Authorization:

Authorization is required for all returns. Authorization may be obtained through the Customer Service department. A RGA number will be issued, and this number must be referenced on all returned packages.

The following merchandise is **not** acceptable for return:

- Sterile items that are returned without the factory seals intact
- Incomplete systems
- Product that has expired
- Special order products
- Product that has been marked or labeled with anything other than the standard Edwards label

Transcatheter heart valve products manufactured by Edwards are NOT returnable for credit. Edwards does not offer any reculturing, resterilization, or refurbishing services for any transcatheter heart valve products. Contact your THV Territory Manager for specific information on the shelf life of all Edwards products.

Products that have been used must be packaged as described in "Instructions for Returning Used Products."

Should questions arise regarding the performance of any product manufactured by Edwards Lifesciences, please contact Technical Support for assistance.

Instructions for Returning Used Product:

Edwards Lifesciences requests that all used products be double-bagged prior to returning them and, if possible, please follow these instructions prior to bagging:

- Prior to handling used product, wear appropriate personal protective equipment
- Visually inspect the product and remove all needles
- Remove all external organic material by carefully wiping the exterior surface with gauze pad or paper towel saturated with tap water
- Flush blood products from lumens and tubing
- Wipe dry with gauze or paper towel
- Wiping may also be done using one of the following:
  - Rubbing alcohol
  - Normal saline
  - Cidex
  - Omnicide

CAUTION: Do not use any other cleansing agents other than those listed above; other agents may interfere with evaluation testing.

- **Do not** wrap product in tissue paper or apply adhesive tape directly to product; attachments to the product or writing on the product may interfere with evaluation testing
- Double-bag using two self-sealing plastic bags. First, place product in one bag and seal. Then place bagged product in second bag and seal
- Place all individual plastic bags in one large plastic bag when possible. Then place large bag in shipping container
- Complete Returned Goods Authorization form describing the reason for return, and attach the form to top of plastic bag

NOTE: Documentation must remain on the outside of the plastic bag to avoid contamination. Attach customer identification label to outside of plastic bag. Place bagged product into shipping container, place mailing label with Edwards Lifesciences address on the shipping container, and mark the container with the wording "*used product.*"

Reminder: The purpose of this procedure is only to clean the outer surface area of used products, not to decontaminate it. Should you have any questions regarding these procedures, please call the Edwards Lifesciences Customer Service department at: 1-800-424-3278.

Disclosure Requirements. You shall disclose the discounts or reductions in price under any state or federal program which provides cost or charge-based reimbursement to you for the Edwards products covered by your purchase in accordance with applicable regulations, and shall provide, upon request by the Secretary of the U.S. Department of Health and Human Services or any State Medicaid agency, information requested about the value of these discounts.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards, Edwards Lifesciences, the stylized E logo and 1-800-4-A-Heart are trademarks of Edwards Lifesciences Corporation.
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