

2019 General Terms and Conditions of Sale Latin America

1. TERMS: These terms and conditions, together with any Distributor Agreement that may exist between Teleflex and Distributor, constitute the complete conditions of sale (“Conditions”) for the Products and may not be added to, modified, superseded or altered except by written agreement or modification signed by Teleflex 's authorized representative, notwithstanding any other additional or modifying terms or conditions which may now or in the future appear on Distributor's purchase order, acknowledgment or other forms (all of which are objected to by Teleflex without future notification), and notwithstanding any shipments, tenders of delivery, acceptance of payments, or other similar acts of Teleflex. Notification of objection to additional (or different) terms is given hereby. Distributor's acceptance of any performance by Teleflex shall be taken as Distributor's acceptance of these terms and conditions.

NO PERSON (EXCEPT AN OFFICER OF TELEFLEX) IS AUTHORIZED TO BIND TELEFLEX TO ANY ORDER EXCEPT ACCORDING TO THE TERMS AND CONDITIONS ON BOTH SIDES HEREOF.

2. SHIPMENT. All shipments hereunder will be made in the Teleflex's standard shipping practices to Distributor's Freight Forwarder's address as set forth on Distributor's purchase order. **Title and risk of loss to the Products purchased under this Agreement shall pass to Distributor upon and delivery thereof to the first carrier – origin (plant and/or distribution center).**
3. TAXES DUTIES. Distributor shall bear all applicable federal, state, municipal and other government taxes (such as sales, value added, use, or similar taxes); all customs duties, and similar charges (any agent appointed for the purpose of importation of the Products shall be the agent of Distributor not Teleflex); and all personal property taxes assessable on or with respect to the Products.
4. CUSTOMS CLEARANCE. Distributor shall perform the functions necessary to clear the Products through all non-United States customs and similar controls, and it shall arrange for the transportation of the Products from the Port of Entry to the Distributor or the purchaser within the Territory.
5. US EXPORT CLEARANCE

5.a. If Distributor is located outside of the United States, all sales to the Distributor are to be recognized as *Routed Export Transactions*. Distributor hereby recognizes its obligations as Foreign Principal Party in Interest (FPPI) and agrees to act as, and fulfill the obligations of the FPPI as outlined in US Federal Trade statistics regulations FTSR 30.3(e). Distributor therefore agrees to assign a US Agent, whose obligations are outlined in FTSR 30.3(b) (3) (*Teleflex Medical Incorporated or any of its related affiliates will not accept the role of US Agent*) and hereby certifies that:

- The Distributor / FPPI (or its Authorized US Agent) will file Electronic Export Information (EEI) for and on behalf of the Distributor / FPPI and will comply with all applicable US Export regulations
- The Distributor / FPPI (or its Authorized US Agent) accepts responsibility for export license determination and, if applicable, obtaining the necessary license authority prior to export from the United States (*thereby making the Authorized US Agent the Exporter for the purposes of compliance to regulations stated in “the Export Administration Regulations” (the EAR) and Federal Trade regulations*)
- The Distributor / FPPI (or its Authorized US Agent) accepts responsibility for post export reporting requirements associated with the use of any License Exceptions listed in section 740 of the EAR
- The freight forwarder, or Authorized US Agent who acts as export filer acting on behalf of the Distributor / FPPI is authorized by a duly executed Power of Attorney (POA) issued by the Distributor / FPPI and Teleflex Medical Incorporated hereby reserves the right to receive a copy of said Power of Attorney upon request to the Authorized US Agent or the Distributor / FPPI (as outlined in FTSR 30.3 (e)(2))
- The Distributor / FPPI will immediately notify Teleflex Medical Incorporated if said POA is terminated regardless of cause
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- The Distributor / FPPI hereby agree to immediately notify Teleflex Medical Incorporated in the event that the Distributor / FPPI (or its Authorized US Agent) becomes aware of any violations of applicable regulations in connection with transactions covered under these general terms and conditions.

5.b. If Distributor is located inside the United States, sales are to be considered and treated as domestic transactions. Should Distributor choose to export any product(s) out of the United States, Distributor becomes liable for all export licensing, screening, and other formalities associated to regulations governing such transactions. Teleflex Medical Incorporated or any of its affiliates will not accept responsibility as the exporter or U.S. Principal Party in Interest on any documentation or government reporting relating to the export of product(s) covered by these terms and Distributor understands it is acting on its own behalf and not as an agent for export or any other purposes for Teleflex Medical Incorporated.

6. **PAYMENT.** Any payment not made to Teleflex when due shall be subject to a carrying charge of one and one half percent (1 1/2%) per month on the unpaid balance until paid. Distributor shall have no right to offset any amount whatsoever against any payment or other obligation which Distributor may owe to Teleflex under the terms hereof.
7. **CASUALTY AND AVAILABILITY OF SUPPLIES:** Delivery of all or any part of the Products is contingent upon Teleflex's ability to obtain the Products, other goods, supplies, raw materials and services through its regular and usual sources of supply. If by reason of any contingency beyond Teleflex's control, including (but not limited to) war, governmental requests, restrictions or regulations, fire, flood, casualty, accident, or other acts of God, strikes or other difficulties with employees, delay or inability to obtain goods (including the Products), labor, equipment, material and service through Teleflex's usual sources, failure or refusal of any carrier to transport materials, delay in transport thereof, or any other similar occurrence, Teleflex is not able to meet anticipated deliveries, Teleflex shall not be liable therefore and may, in its discretion without prior notice to Distributor, postpone the delivery date(s) under this document for a time which is reasonable under all the circumstances. Teleflex shall make commercially reasonable effort to notify Distributor of the delay in meeting anticipated deliveries.
8. **ACCEPTANCE.** Distributor shall inspect all Products promptly upon receipt thereof at the shipping destination and may reject any Products which fail in any significant respect to meet the specifications for such Product prevailing on the date of delivery in accordance with the Return Goods Policy and the Damaged Goods process established by Teleflex (See Appendix A).
9. **LIMITED WARRANTY, WARRANTY DISCLAIMERS AND LIMITATIONS OF REMEDIES AND LIABILITIES:** Teleflex warrants that the Products which are manufactured by Teleflex will be free from defects in materials and workmanship for the shelf life of the Products indicated by the lot number and the expiry date on the Products if they have an expiration date. Any Products determined by Teleflex to be defective at time of delivery will be replaced, at Teleflex's option at Teleflex's point of shipment, shipment prepaid by Distributor, provided Distributor has acted in accordance with Paragraph 7 hereof. Teleflex does not warrant against failures or damages caused in transit or by erosion, corrosion, misuse or improper use or application of the Products, use of the Products not in compliance with instructions or use of Products by untrained or unqualified persons.

Except as set forth above, Teleflex makes NO OTHER WARRANTIES concerning the Products whatsoever. TELEFLEX DISCLAIMS AND EXCLUDES ALL OTHER EXPRESS WARRANTIES AND ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, NON-INFRINGEMENT, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE concerning the Products. Distributor acknowledges and agrees that Teleflex's obligation described in this Paragraph 8 is the sole remedy bargained for by Distributor IN LIEU OF ALL OTHER EXPRESS AND IMPLIED WARRANTIES. In no event will Teleflex's liability exceed the payment Teleflex received from Distributor for the Products in question. Teleflex's obligations described in this Paragraph shall be DISTRIBUTOR'S SOLE AND EXCLUSIVE REMEDY AGAINST TELEFLEX OR ANY LIABILITY WITH RESPECT TO THE PRODUCTS WHETHER ANY CLAIM FOR RECOVERY IS BASED UPON OR ARISES OUT OF THEORIES OF CONTRACT, NEGLIGENCE, TORT (INCLUDING STRICT LIABILITY) OR OTHERWISE. Distributor agrees that NO OTHER REMEDY SHALL BE AVAILABLE to Distributor and that IN NO EVENT SHALL TELEFLEX BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES, (including without limitation loss of income, loss of time, loss of sales, cost or replacement items, claims asserted by Distributor's customers, injury to personal property, or injury to any person, whether or not occasioned by Teleflex's negligence) regardless of the form of action, whether in contract, tort, strict product liability, or otherwise, even if Teleflex has been advised of the possibility of such damages.

No accommodation by Teleflex to Distributor, whether by attempt, effort or promise to repair or replace, and whether for sales policy or otherwise shall establish any additional liability of Teleflex or any contract term inconsistent with the term herein. A suit based on any cause of action must be commenced within one year from the date of delivery of the Product in question.

10. CANCELLATION: Teleflex may cancel or terminate all or part of any purchase order arising from or evidenced by this document immediately upon the happening of any of the following: Distributor's material delinquency of any of its obligations hereunder or with respect to any other order or transaction with Teleflex; institution of any proceedings by or against Distributor, any of Distributor's property or majority shareholder of Distributor under any law dealing with bankruptcy, insolvency, receivership or other relief of debtors; Distributor's suspension or termination of business or assignment for the benefit of creditors; Distributor assigning rights or delegation of duties without prior written consent of Teleflex or any event, whether or not similar to the foregoing, which in Teleflex's good faith belief materially impairs the prospect of payment or performance by Distributor hereunder. Teleflex's rights to cancel, suspend or terminate set forth herein may be exercised by Teleflex without liability.
11. STATUTORY COMPLIANCE: Teleflex is not responsible for compliance with any laws, standards or specifications applicable to the Products, their delivery, use, handling, labeling, transportation or disposal, whether of general or particular application, unless Distributor has furnished specific written notice thereof prior to Teleflex's entry of Distributor's order and the an officer of Teleflex acknowledges in writing receipt and acceptance as a part of the order such law, standard or specification.
12. PRODUCT LABELS AND MSDS INFORMATION: Distributor acknowledges that it has received and is familiar with Teleflex's and any manufacturer's labeling, Material Safety Data Sheet ("MSDS"), if applicable, and literature concerning the Products and Distributor shall be responsible for forwarding such information to its employees, agents, end-users and customers. Distributor shall not alter, modify, or repackage Products without obtaining Teleflex's prior written approval. Distributor shall not remove or tamper with the original labels on any Products.
13. PERMISSIBLE VARIATIONS: Teleflex has the right, without giving notice to Distributor, prior to the delivery of Products to Distributor to make any changes in the composition of the Products which, in the opinion of Teleflex, does not affect the general characteristics or properties of the Products. In addition, Teleflex may make any change or variation in the Products which is within governmental or industry standards or specifications applicable at the time of manufacture without giving notice to Distributor. Distributor will accept any Products which may incorporate any changes in the composition or specifications, and any increase in price resulting from such change will be paid by Distributor.

14. REPRESENTATIONS BY AGENT OR REPRESENTATIVE: These Conditions shall govern the liability and obligations of Teleflex in regard to the sale of Products, whether the sale was procured directly by Teleflex or indirectly through an authorized sales representative. No agent, employee or representative of Teleflex has any authority to bind Teleflex to any additional or contrary affirmation or representation concerning the Products sold under this document. Unless an affirmation or representation is specifically included within these Conditions or is in writing signed by an officer of Teleflex it shall not be enforceable by Distributor or by any person claiming by or through Distributor.
15. PRODUCT RECALLS: If any products shipped to and held by the Distributor are or become subject to a recall voluntary or mandate by the United States Food and Drug Administration (FDA) and/or EU (European Union) Competent Authority, Distributor shall notify Teleflex immediately of possession of affected product, request a return authorization and promptly return the affected products to the address designated. Distributor shall concurrently execute a local recall to the sub-dealers and/or Hospitals.
16. MISCELLANEOUS: All sales are subject to approval by Teleflex's credit department. Orders entered on Teleflex's books cannot be countermanded nor deliveries deferred except with Teleflex's written consent and upon terms that will indemnify Teleflex against all loss. These Conditions will be governed by the local laws of Pennsylvania unless an existing Distributor Agreement between the parties provides otherwise. If any of the provisions hereof shall be held invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby. No right or interest hereunder shall be assigned or otherwise transferred by Distributor.

The individual rights and remedies of Teleflex reserved in these Conditions shall be cumulative and additional to any other or further remedies provided in law or equity. Waiver by Teleflex of performance or inaction with respect to Distributor's breach of any provision hereof, or failure of Teleflex to enforce any provision hereof which may establish a defense or limitation of liability, shall not be deemed a waiver of future compliance therewith or a course of performance modifying such provision, and such provision shall remain in full force and effect as written.

As used herein, "Distributor" and "Teleflex" include the respective heirs, executors, personal representatives, successor's and permitted assigns of each.

APPENDIX A

Latin America Customer Service Information:

Teleflex Medical
3015 Carrington Mill Blvd.
Morrisville, NC 27560 - USA
Phone: + 919-361-3921
Fax: + 919-361-4111

Hours: 8:00am – 5:00PM EST; Monday-Friday

Ordering Information:

The terms on our Acknowledgment and Invoices state Teleflex's entire contract. Teleflex shall not be bound by any different, additional or conflicting terms and conditions contained in Buyer's Purchase Order unless expressly agreed to in writing by Teleflex. Teleflex's Acknowledgment will not hereafter be subject to any change, modification or conflicting language without Teleflex's prior written consent. The customer will **have 48 hours to revise the Acknowledgement** and make any adjustment; otherwise they will need to place a new purchase order for the additional needs. Any changes on a Purchase Order whether price, volume, codes, etc. after the order is entered in the system, the customer must send a revised Purchase Order for our records.

Minimum amount per purchase order shall be US\$2,500.00.

Purchase Orders must specify the following when ordering:

- Teleflex customer account number
- Purchase Order number
- Billing and shipping address
- Shipping mode including carrier account numbers as applicable
- Payment Terms
- INCO terms – must indicate a three-letter INCO term plus the port/terminal
- Product Catalog number, description, pricing and quantity
- Special shipping instructions including 3rd party inspection requirements, documentation, etc.
- Freight Forwarder if other than the one on record

Payment Terms:

Payment terms are established by the Teleflex Accounts Receivable Department.

INCOTerms: Freight

Unless otherwise stipulated, delivery of all products to third party dealers out of a North America distribution center is **FCA in-land freight within the Continental US**.

Delivery of products out of Belgium, Malaysia, and Uruguay will be **EXW-Factory/DC**.

The title of the goods, all risk of loss, and all transportation and insurance cost passes to the buyer upon delivery to the first carrier. The dealer is responsible to nominate a fix Freight Forwarder/Agent within the country where the DC/Plant is located.

Shipment Discrepancies:

Upon receipt of shipment, all products should be unpacked and inspected. Notification of short shipments and other shipping discrepancies must be reported to Teleflex's Customer Service within 60 days of invoice date for Dealers and 14 days for US Exporters using the discrepancy form, a copy of which is attached hereto ("Discrepancy Form") (a log number will be assigned to the customer for reference). Any damage to final destinations should be noted on the freight bill and reported to the dealer's carrier.

Forwarder scheduling policy: once the order is ready to ship and communicated to the Distributor, it is the Distributor's responsibility to have its appointed freight forwarder receive the goods within 48 hours. If the freight forwarder does not accept the shipment, Teleflex reserves the right to use its in-house freight forwarder to carry out the shipment at the Distributor's expense forfeiting the FCA terms with no reimbursement.

Coated Catheters: purchase orders for this family of products must be submitted separately from other Arrow branded products. The transport mode must be air; effective January 1, 2012 coated catheter will be shipped air at the Distributor's expense.

Delinquent Payments

In the event of nonpayment of an invoice, all interest, collection fees and/or legal fees incurred by Teleflex will be added to the balance owed on the account, as permitted by law.

Pricing:

Current year pricing (pursuant to a Special Price Agreement (“SPA”) or Price List (“PL”)) is valid only for shipments scheduled to ship in the same calendar year and placed within the lead-time policy. Any order placed in one calendar year to be delivered in a subsequent calendar year will be priced at the subsequent calendar year’s SPA or PL.

Purchase orders may not be processed if price discrepancies are found at order entry. If there is a price discrepancy, customer must send a revised Purchase Order reflecting the price approved in the Teleflex system, an email will not suffice.

Lead Times* (third party dealers only):

The calculated lead-time is based on day of order entry plus A/R release at the time of shipment. Lead time will not be adjusted due to receipt of non-conforming purchase orders. Calculations are based on calendar days; in the event that the lead time date falls on a weekend or holiday, the lead time should be extended to the 1st business day after the calculated lead time date. Lead times are detailed below based on Order Management.

1) Morrisville, USA – 21 days, except for:

a. Drop Shipment:

Malaysia – 60 days
Belgium – 30 days

b. Made-To-Order (MTO):

Arrow Pumps – 45 days
Arrow CVC/PICC/Dialysis/Coated Catheters – 60 days
Instruments – 60 to 90 days depending on the instrument (check with Customer Service).

2) Montevideo, Uruguay

Anesthesia – 45 days
Urology – 60 days

3) Athlone, Ireland

LMA – 5 days

* As products become available, Teleflex reserves the right to ship in advance of the stated lead time set forth above.

- **Exception:**

1. **As products become available, Teleflex reserves the right to ship in advance of the stated lead time set forth above.**
2. **Order volumes outside normal forecast values and/or stock availability may be subject to an extended lead-time.**

Arrow Shelf Life

The following Arrow brand product families will have a minimum fourteen (14) month shelf life (using a 30 day month, a 14 month policy would equate to 420 days) upon shipment out of North America Distribution Center:

1. Wedge Pressure
2. Intra-Aortic Balloons (IAB)
3. ARROWg⁺ard Blue coated products
 - a. Multi Lumen
 - b. Single Lumen
 - c. Acute Catheters
 - d. Large Bore Catheters
 - e. MAC
4. Thermo dilution Catheters
5. Berman
6. Epidural Kits
7. Peripheral Nerve Block (PNB)

Note: We reserve the right to ship anything between 390 – 420 days of remaining shelf life.

The shelf life for all other Arrow brand products will ship with a minimum 18 months or 540 days.

Return Goods Policy

Return Goods:

A Return Goods Authorization (RGA) number must be received from Teleflex Customer Service prior to returning any Products. International customers may send their information by facsimile to 919-361-4111 within sixty (60) calendar days of invoice date for dealers outside the US and (14) days for US Exporters and must include:

- Invoice Number
- Purchase Order number
- Date of purchase
- Product catalog number
- Quantity of terms returned
- Lot or serial number
- Reason for Return

With the exception of defective Product and Teleflex error, all authorized return shipments must be shipped freight prepaid. Upon issuance of the RGA number, the customer will be advised as to which Distribution Center to ship the products. Goods returned without an RGA number will not be accepted or credited. Teleflex will not accept return shipments after 30 days of the RGA issue date.

Acceptable Returns and Credit Schedule

Reason for Return	Credit
Defective product	Invoiced price
Teleflex's shipping error	Invoiced price
Teleflex's order error	Invoiced price
Pattern variation (instruments)	Invoiced price*
Customer order error	Invoiced price less 30%*

* Customer must bear the freight expenses and all taxes and duties to clear products from US Customs.

Unacceptable Returns:

- Merchandise damaged in transit. The Freight forwarder's customer will be responsible and Distributors should file claim with their freight forwarder and not Teleflex
- Custom, special order, MTO (made to order)
- Sterile products (regardless of shelf life)
- Disposable products
- Products engraved, etched or labeled by Distributor or anyone other than Teleflex
- Products not in the original packing and original outside master packing with the original seal tape.
- Products in less than sales unit quantity
- Products used or not in saleable condition
- Obsolete or discontinued product
- Private labeled products
- Non-sterile products with a designated shelf life having less than 12 month's duration

At the sole discretion of Teleflex, any return shipments that do not comply with the above policy may be refused and returned to Distributor at its expense.

Shipment Discrepancies:

In the event that Distributor receives merchandise that does not match the Product described on the packing slip and/or purchase order acknowledgement issued by Teleflex and the incorrect Products are discovered prior to acceptance of the delivery as set forth in Paragraph 7 of these Conditions:

- A. Distributor shall notify Teleflex's Customer Service Department within 60 calendar days of invoice for such incorrect Products.
- B. Distributor shall communicate the discrepancy by filling in the Discrepancy Form and processing the Form through Customer Service (form attached on page 11).
- C. At its discretion, and taking into consideration cost effectiveness, Teleflex shall issue a Return Authorization Number to be used by Distributor on all correspondence relating to the shipment containing incorrect Products.
- D. Distributor shall return any incorrect Product to Teleflex, freight collect, within 10 working days of receipt of a Return Authorization Number.

Returns of Unsaleable Products:

Damaged Goods

Orders: If shipments arrive at final country destination in broken or damaged condition, Distributor shall report this to its transportation/freight company and file its claim. **Teleflex shall not be responsible for issuing credits for the Products or for any transportation charges for the Products damaged in transit.**

Defective Products

If any defective Product is discovered, Distributor shall notify Teleflex's Product Complaint Department with details. At its discretion, Teleflex shall authorize return of such Product for evaluation/review. If defective Product is to be returned, Distributor shall return such to Teleflex, freight collect, within 10 working days of authorization from the Product Complaint Department. Teleflex shall inspect the Products returned by Distributor and, if Teleflex determines in its sole discretion that the Products are defective, Teleflex shall at its option and expense, either repair or replace rejected Products.

Expired Products

Teleflex shall not issue credit or replace expired Products after the acceptance of the Products.

If Teleflex issues a Return Authorization Number to have unexpired Product returned, Distributor shall return any unexpired Products to Teleflex, freight prepaid. Teleflex will not accept any authorized return shipments shipped after 30 calendar days of the Return Authorization Number issuance. Credit (net of discounts) shall be issued after receipt and inspection of the Products by Teleflex and only if the Products are determined in Teleflex's sole discretion to be in good, unused condition, and with an excess of 12 months of shelf life for non-sterile Products. A 30% restocking fee will be charged on such returns.

Proper disposal of Teleflex Products

Distributor shall be responsible for the proper disposal of any of the Products that are returned to Distributor's specific location in accordance with the laws and regulations of the Territory relating to disposal of Products and any procedures established by Teleflex from time to time regarding disposal of the Products.

Deviation from these Conditions is at the discretion of Teleflex Senior Management. Disputes concerning this policy and its administration should be addressed to the Vice President of Latin America. **This document supersedes any previous version issued.**

Teleflex's Complaint Procedure

PURPOSE

The purpose of this document is to establish a procedure for receiving, recording and resolving customer complaints received by Distributor (third party dealer). This procedure also establishes Distributor's responsibility in assisting Teleflex in implementing a recall/correction of any Product in the Territory.

II. SCOPE

This procedure applies to Distributors and Teleflex's personnel involved in complaint handling and recalls of Products (Sales and Marketing, Customer Service, Manufacturing, Quality Control, Quality Assurance and Regulatory Affairs).

III. REFERENCES

U.S. FDA's Quality System Regulation (21 CFR Part 820) Medical Device Directive (93/42/EEC)
 Guidelines on a Medical Device Vigilance System, MEDDEV2.12-1
 Canada's Medical Device Regulations & Food and Drug Regulations

IV. FORMS

- A. Distributor Complaint Submittal Form: Teleflex MPR-08-03 and Arrow RAQA-F226.

V. DEFINITIONS

A **Complaint** is any indication of the failure of a device or Product, its labeling, or packaging to meet customer or user expectations for quality or to meet performance specifications. Thus, any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability safety, reliability, efficacy, or performance of any Product after it has been released for distribution would be considered a complaint.

A **Complainant** is a person from the facility/customer account who is reporting a complaint.

An **Incident/Adverse Event** is a death or serious deterioration in health associated with the use of any Product.

A **Near Incident/Malfunction** is any complaint, which could result in serious injury or death if it were to re-occur.

A **Reportable Incident** is an incident or near incident that needs to be reported to a regulatory agency (i.e. U.S. FDA, Canada's HPFB, Australia's TGA, New Zealand's Medsafe, or a European Competent Authority) in a particular country to ensure continued regulatory compliance.

A **Recall** is the systematic removal or correction of a marketed device or Product (or a specific lot) that poses a risk of death or serious deterioration to the state of health that requires: the return of a medical device or Product to Teleflex, for its modification, its exchange or its destruction.

VI. PROCEDURE FOR COMPLAINT HANDLING

NOTE: If the Complaint relates to an injury or unsafe situation, Distributor shall ensure that treatment and/or elimination of the unsafe condition is carried out prior to gathering information.

A. Receiving a Complaint

1. Upon receiving a Complaint concerning a Product, Distributor's complaint coordinator shall be responsible for ensuring that information concerning the Complaint is documented.

2. Distributor shall gather and record as much information as possible on the Distributor Complaint Submittal Form, including, but not limited to the following:
 - a. Name and title of person reporting the Complaint
 - b. Name and title of Complainant (if different from person reporting)
 - c. Phone Number, Fax Number and address of Complainant
 - d. Date Complaint information was received by the Distributor
 - e. Date Complaint occurred
 - f. Name of Product involved in Complaint
 - g. Product Lot Number(s) and Expiration date(s)
 - h. Description of the Complaint
 - i. Outcome (i.e. death, serious injury)
 - j. Description of any immediate corrective action taken by Distributor

B. Reporting Complaints to Teleflex

1. Distributor shall immediately report all Complaints, including any available information regarding the Complaint to Teleflex Product Complaints Department via telephone, fax or email.
2. Complaints regarding a death or serious injury shall be reported by Distributor to Teleflex within 24 hours of becoming aware of the complaint.
3. Distributor shall immediately notify Teleflex of any Complaint concerning a Product that has been reported to Distributor from a regulatory agency. Any communication from a regulatory agency concerning a Product must be forwarded to Teleflex immediately by Distributor.

C. Complaint Investigation

1. Once a Complaint is reported to Teleflex, an investigation will be conducted according to established internal procedures.
2. Distributor shall be responsible for (i) providing information regarding a Complaint requested by Teleflex from time to time; (ii) conducting investigation as requested by Teleflex; and (iii) providing full cooperation to Teleflex in completing any required investigational activities.
3. Distributor shall document and provide to Teleflex all information gathered throughout the investigation of the Complaint, including, but not limited to, providing record of all communications with the Complainant including telephone conversations, faxes and emails.

D. Closing a Complaint

1. Once the investigation is completed, the Complaint will be closed in accordance with Teleflex's internal procedures.
2. Teleflex in its sole determination shall determine if a replacement of the Product is warranted. If Teleflex determines that a replacement of the Product is warranted, Teleflex's Quality Assurance Coordinator shall notify Teleflex's International Marketing and Sales Manager or designate to authorize Distributor to replace the Product. Distributor's inventory will be adjusted for the replacement free of charge.

E. Reporting of Complaints to Regulatory Authorities

1. A number of countries have specific requirements for reporting certain types of complaints (Reportable Incidents) to the appropriate regulatory agency. Distributor shall advise Teleflex regarding any specific requirements for reporting Complaints to regulatory agencies in the Territory for Canada.
2. Teleflex shall be responsible for determining if a Complaint needs to be reported to the regulatory agency.
3. If Teleflex determines that a report to a regulatory agency for a reportable incident is required, Teleflex shall work with Distributor to submit all required documentation and information to the regulatory agency.
4. Distributor shall be responsible for assisting in this process if requested by Teleflex. This assistance may include but is not limited to contact with the regulatory agency, translation of documents etc.
5. Any communication Distributor receives from a regulatory agency concerning a Reportable Incident must be forwarded to Teleflex immediately.

Signature

Date

END OF DOCUMENT



The following form is intended to document customer order/shipment reporting to Teleflex Customer Service. Complete the form by providing the required information below and submit the document to your Customer Service Representative within **60 days (14 days if US Exporter)** of invoicing. This form is **NOT** to be used in place of a Product/Technical Complaint Form.

CUSTOMER SERVICE ORDER/SHIPMENT DISCREPANCY FORM						
1. TO: (Name of Dealer)						
DISTRIBUTOR NAME/ADDRESS				PERSON TO CONTACT (<i>Printed Name</i>)		
				TITLE		
				DATE		
			PURCHASE ORDER #		SALES ORDER #	
2. NATURE OF DISCREPANCY						
SHORTAGE			DAMAGE IN TRANSIT/ US INLAND TO FREIGHT FORWARDER			
OVERAGE			INCORRECT ITEM RECEIVED			
3. DISCREPANCY DATA						
ITEM	MATERIAL	LOT #	INVOICE NUMBER	QUANTITY RECEIVED	QUANTITY INVOICED	DISCREPANT QUANTITY
1.						
2.						
3.						
4.						
INTERNAL USE ONLY (DO NOT WRITE BELOW THIS LINE)						
ISSUE CREDIT			BILL OVERAGE			
SHIP SHORTAGE QUANTITY			ITEM TO BE RETAINED/PLEASE BILL			
ISSUE RETURN AUTHORIZATION			OTHER (See remarks)			
RETURNS		CARTON WEIGHT				
REMARKS					ORIGINAL SHIPMENT DATE:	
TO BE COMPLETED BY						
International Customer Service						
REQUESTED ACTION APPROVED			REMARKS			
REQUESTED ACTION NOT APPROVED						
APPROVING OFFICIAL (Signature)						
MANAGER, CSI			DATE			

Please refer to page 6 of our T&Cs: "Distributor shall have no right to offset any amount whatsoever against any payment or other obligation which Distributor may owe to Teleflex Medical under the terms hereof"