Arthrex US Import Logistics Instructions

Section 1 - Shipment Preparation

Preshipment Authorization

All shipments to Arthrex, including commercial purchases, samples, prototypes, and repairs, must be **approved** by Arthrex Imports prior to shipping; sending preshipment approval requests will minimize the risk of late deliveries to Arthrex that may affect your delivery performance metrics.

Send an *Approval Request* to the Arthrex <u>Imports</u> and <u>Transportation</u> Departments. Include commercial invoice(s) or the list of items in the shipment and shipment sizes, dimensions, and weights.

The Imports Department will review your export documents and, within 24 hours, either approve the shipment or request additional information to prepare your shipment for US Customs and FDA review. Your prompt response will help facilitate clearance and timely delivery.

The Arthrex **Transportation Department** will provide transportation instructions based on a shipment's dimensions and weight and answer questions regarding packaging and logistics.

NOTE: You must consolidate all shipments to the same address on the same day onto one Master Air Waybill or Bill of Lading.

Under 45 kg

Ship via courier unless the Transportation Department advises otherwise.

- Specify FedEx International Priority Service
- Declare customs value. Do not declare carriage value.
- Include delivery name, address, contact name, and phone number
- Include Arthrex purchase order number

Over 45 kg

The Transportation Department will arrange for a Freight Forwarder to pick up the shipment.

Email Transportation Department:

 Shipment pickup location name, address, contact name, and phone number

- Description of goods
- Special handling instructions
- Temperature sensitive (Y/N)
- Date and time shipment will be ready for pickup
- Dock hours
- Any additional documents related to the shipment

NOTE: You MUST only use wood packaging treated and marked for international shipping (ISPM-15 compliant).

Advanced Shipping Notice

After receiving approval and shipping instructions, send an Advanced Shipping Notice (ASN) to the Arthrex Imports and <a

Advanced Shipping Notices allow Arthrex to send necessary regulatory information to US Customs. Your assistance in providing required information is crucial for import of the shipment.

Approval Request and Advanced Shipping Notice emails must have the following subject line structure (with as much information as available):

- Specify FedEx International Priority Service
- Declare customs value. Do not declare carriage value.

Over 45 kg

- The Transportation Department will arrange for a freight forwarder to pick up the shipment
- Include:
 - · Request for approval or ASN
 - Shipper name
 - Ship date
 - Courier tracking (no spaces in tracking number)
 - Commercial invoice number(s)

EXAMPLE: Approval Request (or ASN) WOM 10 Jul FedEx 733838393697 9024140



Include all documents that apply:

- Commercial invoice(s) or the list of items in the shipment (refer to the Commercial Invoice Requirements, below)
- Shipment sizes, dimensions, and weights
- Arthrex purchase order number
- Packing list
- Courier name (FedEx)

- Tracking number
- Certificate of Conformity/Sterilization
- Hazardous materials certifications
- FDA Form 2877 (Declaration for Imported Electronic Products Subject to Radiation Control Standards)
- Any additional documents related to the shipment

Section 2 - Commercial Invoice Requirements

All documents, especially commercial invoices, must be in English and include the following information:

Header Details

- FDA product code (2 numerals and 3 alpha characters)
- Invoice number, terms of sale, and terms of delivery (INCOTERMS)
- Shipper/exporter's full name, address, and tax identification number
- Sold-to party, full name, and address
- Ship-to name and address as instructed by the Supply Chain Buyer Planner (also specified on the purchase order)

Note: Failure to identify the correct address will cause delivery delays.

Item Level Details

- Arthrex part number as shown on the purchase order
- Product description
- Country of origin
- Harmonized Tariff Schedule (HTS) classification number
- Quantities and units of measure
- Value (purchase price of each item; if an item is sent at no charge, then include its cost or fair market value of a similar product)

If the imported product is a medical device, provide the:

- FDA product code (2 numerals and 3 alpha characters)
- Medical device listing number: alphanumeric code (1 alpha character, usually "A" through "E", followed by 6 numerals)
- Manufacturer's FDA 510k number if applicable: alphanumeric code ("K" or "BK" followed by 6 numerals)

NOTE: If the manufacturer is different from the exporter, include actual manufacturer's name and address or FDA registration number and the device listing from the actual manufacturer.

Additional Costs or Charges

Declare on the commercial invoice any costs or charges that are not included in the product value, and include their description and cost. For example:

- Arthrex part number as shown on the purchase order
- Product description
- Country of origin
- Dies, molds, or tools Arthrex provided to you free of charge
- Engineering or design work Arthrex asked you to perform
- Components or materials provided by Arthrex at a discount or free of charge (eg, packaging materials, suture components, implant components)
- Customized or special packaging requested by Arthrex that exceeds normal packing and/or packaging costs for the items
- Arthrex purchase order number



Special Invoice Requirements

Repairs, Reworks, and Upgrades

- If you repair, rework, or upgrade a product, you must declare the value of the product, repair, rework, or upgrade on separate lines of the commercial invoice
- If you do not charge Arthrex for the work, you must still declare on the invoice an estimated value for the work performed, including parts and labor

For example:

Part #	Product Description	Qty.		Value Ea.
AR- 1234	Orthopedic manual instrument	2	Product's original value	\$550
	Repair (or upgrade, etc)	2	Value of work	\$18.95

Samples and Prototypes

The commercial invoice for shipments of samples or prototypes must include:

- A value that represents the true manufacturing costs of the samples or prototypes, including charges paid for tooling, setup, limited run fees, and mold creation/modification
- Include a remark with the description of the item, for example: "SAMPLE", "PROTOTYPE", "NOT FOR HUMAN USE"
- Instructions if you expect Arthrex to return an item to you after testing

