BSC Design Specification Cover Page

Material Revision Table for DesignSpecification H749FGNTR AO.5, Production

Windchill Material Number	Material Master Revision	Windchill Material State
H749NTR180	J	PRODUCTION
H749NTR18012MSL	01	PREPRODUCTION
H749NTR200	L	PRODUCTION

REV	DESCRIPTION OF CHANGE	CN
AM	Update FGD to current template and update part revision from I to J to match design view in Windchill.	2267004
AN	Brexit implementation and update the document to the latest template revision. Add BSC DFU number and revision to section 1 table.	2314343
AO	Revise LOTUS INTRODUCER SET, LARGE UPN for the removal of BOM structure.	2399237

Boston Scientific

LOTUS INTRODUCER SET

Finished Goods Document

H749FGNTR

1. Finished Good Table

Due to the limitations of BSC ERP system each BSC Material Number/UPN may only be assigned one GTIN. A GTIN change requires the creation of a new BSC Material Number/UPN.

BSC Model/ Reference Number	BSC Material Number/UPN	BSC Material Revision	BSC Description	Supplier Part Number	POUCH BLANK LABEL PN.	POUCH PRINTED LABEL REV.	CARTON BLANK LABEL PN.	CARTON PRINTED LABEL REV.	CE Mark on the Label (Y/N)	DFU Number and Revision and Date of Issue	Primary GS1 Barcode/UPN/ GTIN	BSC DFU Number and Revision
1724-00	H749NTR180 (LIS-S)	J	LOTUS INTRODUCER SET, SMALL	139809-01	139813-01	139818-01 Rev. A	139814-01	139819-01 Rev A	Y	139816-01 Rev A 2020-02	05391526210109	91105646 Rev. AB
	H749NTR200 (LIS-L)	L	LOTUS INTRODUCER SET, LARGE	139809-02	139813-01	139821-01 Rev A	139814-01	139822-01 Rev A	Y	139816-01 Rev A 2020-02	05391526210116	91105646 Rev. AB

Note 1: Creganna Medical (CM) & BSC use identical UPN & Catalog Numbers.

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2. Supplier Information

Supplier Name: **CREGANNA - TACTX MEDICAL (CM)**
Supplier AVL Number: **0000105137**
Manufacturer Name (if different from Supplier Name): N/A
AML Number: 0092078097
Design Controls Owner: Creganna Medical
Regulatory Submissions Owner: Creganna Medical are regulatory owners for US, EU and Canada.
BSC are regulatory submission owners for all other regions

2.1. Category of Supplier

☐ CM (Implantable)
☐ CDM (Implantable)
☐ OEM+ (Implantable)
☐ OEM (Implantable)
☐ CM (Non-Implantable)
☐ CDM (Non-Implantable)
☒ OEM+ (Non-Implantable)
☐ OEM (Non-Implantable)
☐ SFMD Distributor

2.2. CE Documentation Owner

Only required if Finished Good Table(s) indicates CE Mark is present on any UPN.
Creganna Medical owns the CE mark for these products.

2.3. Additional Items

Add any optional additional information related to Vendor/Manufacturer.
N/A

3. General Project and Product Information

3.1. Product Context Number, Description, and Use

Provide the following information:

Product Context Number: S5930

Product Description: Assemblies and Components

Intended Use: The Lotus Introducer Sheath is intended to provide percutaneous femoral access to the vascular system.

3.2. For EU MDR Product Only:

Declaration of Conformity: N/A

Tier 1 Distribution Center(s): N/A

Economic Operator (EO) Importer or EO Distributor for OEM/OEM+ product only: N/A

Authorized representative for OEM/OEM+ product only: N/A

3.3. Device Class

Part Number	Country/Region	Device Class
H749NTR180 H749NTR200	US	Class II
H749NTR180 H749NTR200	EU	Class IIA

3.4. Packaging Description

The Lotus Introducer Set consists of the introducer sheath and dilator. These items are mounted onto a HDPE backing card. After the pouch is labelled, the backing card and its contents are loaded into a pouch that forms the sterile barrier after it is heat sealed. The backing of the pouch is a breathable uncoated 1073B Tyvek that is bonded to a 12/50 PET/PE film that is facing of the pouch. The sealed pouch is loaded along with the DFU into a 24 point SBS shelf carton. Subsequently, fourteen (14) shelf cartons are packaged into a shipping carton. Each pouch and shelf carton is labelled with content identification and traceability information.

The package is intended to create & maintain a sterile barrier that permits Ethylene Oxide (EtO) sterilization, maintains a sterile barrier through sterilization, distribution, handling, & storage, protects the device through sterilization, distribution, handling, & storage, and maintains a sterile barrier for the required shelf-life period.

3.5. Additional Items

N/A

4. Product Labeling

4.1. Description

The labelling and Directions for Use/Instructions for Use (DFU/IFU) provide a clear and concise means of communicating product information and use instructions to the customer. The product labelling provides information such as product identification, traceability, sterilization, instructions for use, warranty information and other required information. The product labelling includes printed information in the DFU, printed labels attached to the pouch and shelf carton, printed information and images on the shelf carton, and a shelf carton closure strip. The pouch printed label includes peelable section specifying product information. The DFU, pouch label, and shelf carton labels bear CM's CE mark as appropriate. Barcodes are required on both the pouch and carton labels. The bar code on the packaged product when received will reflect the correct product and lot numbering information.

The labels within this document are representative of the labels that will be placed on the packaging.

4.2. Label and Advertising Review (LAR) Reference (as applicable)

LAR review completed manually per peer review 92570131.

4.3. Label Printing Controls

The product information is stored within the Creganna Medical ERP system. During label printing, the production order is selected in the ERP system and the batch specific information is automatically retrieved from ERP system and sent to the printing application (Bartender) for populating on the label format and sent automatically to the printer. Creganna Medical maintains revision control and releases product to distribution by lots.

4.4. Label Printing Verification Controls

Labels are printed for each work order per label printing procedure MP13977. Manual inspections are performed on 'first off' and 'last off' labels and label reconciliation is performed for each batch per label inspection procedure QP13416 and line clearance is maintained. The first and last off labels for each print run for each batch are retained with the DHR for traceability.
A label verification system (ALPVS) is integrated with the label printer which ensures that each label is inspected with a camera-based system for print defects or blemishes. The inspection verifies legibility of text and verifies barcodes meet the required ISO print quality standards. Batch specific data is confirmed against the ERP system data.

4.5. Labeling Rework Requirements

Manual inspections are performed on 'first off' and 'last off' labels for each print run and label reconciliation is performed for each batch per label inspection procedure QP13416 and line clearance is maintained. The first and last off labels for each print run for each batch are retained with the DHR for traceability. Routine label rework is permitted, with label defects being recorded and segregated for subsequent label reconciliation per inspection procedure QP13416. Standard 'in-process' rework is acceptable for addressing routine in-process yield loss, i.e. label application errors, creasing or tearing of a label during application to packaging or where a non-optimal pouch seal is observed.
Any non-standard rework requires the initiation of an NC (Non-Conformance) report to control the rework activity, including rework documentation approval and authorization. Examples of non-standard rework includes relabeling or re-packaging activity.

4.6. Label Images

See Appendices for Reference label images.

4.7. Sample DFU and/or Labels

Creganna Medical supply a sample DFU, a sample pouch FG label and a sample carton FG label to BSC along with the COC and other shipping documentation for each batch shipped from Creganna Medical.

4.8. Additional Items

N/A

5. Shipper Box Labeling

5.1. Label Content

Each shipper box should contain a shipper box label with the following label content. Bold elements are required for all shipments using Kerkrade as the Tier 1 Distribution Center. (Note: Add/Remove as applicable)

- BSC Purchase Order Number
- Boston Scientific Material Number/UPN
- Batch/Lot/Serial #
- Expiration Date if applicable
- Date of Manufacturer if product is non-sterile
- Box Quantity: How many units are in the shipper box
- Shipper Box X of Y
  - Where X is sequential number of shipper box, and Y is the total number of shipper boxes shipped to BSC, as applicable and agreed upon.
- Scannable Barcodes, as applicable, including the following.
  - UPN
  - Batch/Lot/Serial#

5.2. Label Location (Palletized Product Only)

For best practice Shipper labels or load documentation to face the outside of the pallet when possible to facilitate BSC receipt.

6. Palletized Shipment Requirements

Is product palletized for shipping?

☒ Yes
☐ No (Section 6.1 is not applicable)

6.1. Palletized Shipment Description (as Applicable)

Prior to shipping the order to BSC, boxed and palletized product must meet the following labelling requirements:
Each box must be labelled indicating Creganna product codes, lot numbers, quantities and product title. Each labelled shipper box must be positioned so that the label faces the outside of the pallet to facilitate BSC receipt of product.

Palletization Requirements:

- Each Shipping Carton accommodates 14 pieces.
- Shipping Carton Label is applied to end of Shipping Carton.
- Pallet is a standard pallet (1.20 m X 1.00 m).
- 4 Shipping Cartons per layer.
- 7 layers maximum (4 X 7 = 28 Shipping Cartons maximum).
- Maximum Lotus Introducer Sets to a pallet are 392.
- Corner protectors are positioned along all edges.
- Stack is secured with two bands
- Pallet and stack are wrapped with stretch film to protect and secure the product.

7. Sterilization Requirements

7.1. BSC Material Numbers/UPNs Provided Sterile?

Are any of the BSC Material Numbers/UPNs provided Sterile?

☒ Yes
☐ No (Sections 7.2 and 7.3 are not applicable)

7.2. Sterilization Description

Product is palletized and is processed through Ethylene Oxide (EtO) sterilization process. Pallets are wrapped in stretch wrap in Creganna Medical Galway prior to shipping to sterilizer.

7.3. ETO Sterilization Cycle

Is the product ETO sterilized by a Boston Scientific sterilization cycle?

☐ Yes
☒ No (Section 7.4 not applicable)

7.4. BSC Sterilization Cycle

N/A

7.5. Non-BSC Sterilization Cycle

Is the product sterilized by a non-BSC sterilization cycle?

☒ Yes
☐ No (Section 7.6 is not applicable)

7.6. Non-BSC Sterilization Cycle

Supplier's Sterilization Cycle: I-CSP-121
Sterilization Site (Name and Address): Steris Tullamore, Co Offaly, Ireland
Load density: Min Density: 52.2kg/m^3 Max Density: 127.7kg/m^3
Load volume: 1 – 5 Pallets

7.7. Additional Items

The product is to be initially delivered sterile to the Boston Scientific Distribution Center Kerkrade, The Netherlands. Ethylene Oxide (EtO) sterilization compliant with ISO 11135-1:2007 is to be performed at Synergy Health Plc. per approved and validated procedures. Verification of sterilization results is to be performed by CM prior to shipment of product to Boston Scientific Corporation. EtO Residual Testing is performed per CM SOP10297 and rechecked annually.

8. Bioburden/Pyrogen/Environmental Monitoring

8.1. Bioburden/Pyrogen/Environmental Monitoring Requirements

Are there Bioburden/Pyrogen/Environmental monitoring requirements for this product?

☒ Yes

☐ No (Section 8.2 not applicable)

8.2. Bioburden/Pyrogen/Environmental Monitoring Responsibility

Identify responsibility for Bioburden/Pyrogen/Environmental Monitoring.

Bioburden	Pyrogen	Environmental
☐ N/A	☐ N/A	☐ N/A
☐ BSC	☐ BSC	☐ BSC
☒ Supplier	☒ Supplier	☒ Supplier

8.3. Additional Items

CM is responsible for ensuring bioburden and environmental monitoring procedures comply with accepted industry standards. CM is responsible to ensure testing and monitoring results are acceptable. Bioburden monitoring is performed on a monthly basis per CM QP7609 requirements.

CM is responsible for ensuring endotoxin testing is performed per appropriate industry standards. CM is responsible to ensure testing results are acceptable. Endotoxin testing is performed on samples from the produced batches per CM QP7609 requirements.

9. Shelf Life

Does product have a shelf life?

☒ Yes: 23 months

☐ No

9.1. Additional Items

The product's shelf life is 23 months from the date of manufacture. A minimum of 6 months shelf life remaining is required for shipment to BSC unless prior approval is obtained from BSC. The expiry date (Use By Date) format for the Certificate of Conformance shall be DD-MMM-YY. The expiry date format for the pouch/shelf carton labels shall be YYYY-MM-DD.

10. Special Storage/Handling Requirements

Do Special Storage/Handling Requirements apply?

☐ Yes (Include a representative from applicable Distribution Site(s) and Supply Chain as Readiness Reviewers on Change Notices releasing or revising the FGD)

☒ No (Section 10.1 not applicable)

10.1. Special Storage/Handling Conditions

This product has no special storage/handling requirements.

10.2. Additional Items

N/A

11. Packaging/Shipping Requirements/Packing Slip

Each device must be packaged to ensure product is received by Boston Scientific undamaged.

The supplier must configure shipments so that:

- If more than one Boston Scientific material number shares a shipping container, a method of separation and organization must be used.
- If more than one manufacturer's lot number shares a shipping container, a method of separation organization must be used.
- Each shipping container contains the Boston Scientific Material Number and quantity.

The supplier must provide a Packing Slip with each shipment. The Packing List must include the following information:

- Suppliers Name and address
- Ship date
- Boston Scientific PO number and line item reference
- Item description, Boston Scientific Material Number/UPN, and quantity
- Manufacturer's lot number
- Transport Company name

Standard Receiving Inspection procedures may require the seal of good product to be broken in order to get access to the product for inspection. Product whose seal has been broken for inspection is scrapped

12. Capital Equipment Shipments

Is product shipped as single packaged capital units?

☐ Yes

☒ No (Section 12.1 not applicable)

12.1. Single Packaged Capital Unit Shipment Description

N/A

12.2. Additional Items

N/A

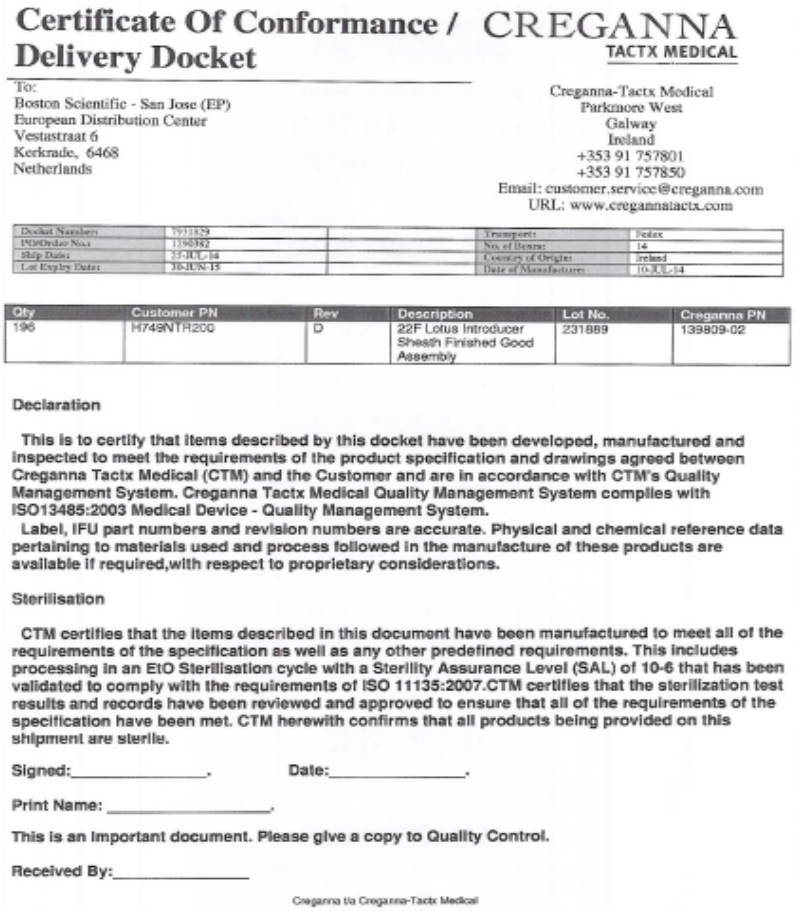
13. Appendices

REPRESENTATIVE CERTIFICATE OF COMPLIANCE OR CERTIFICATE OF ANALYSIS SAMPLE

A Certificate of Conformance or a Certificate of Compliance must be provided by CM to Boston Scientific Corporation Incoming Inspection for each lot. The Certificate of Conformance or a Certificate of Compliance must include the following information:

- Supplier's Name & Address
- BSC UPN & Revision
- Device Description
- Lot Number
- Lot Quantity
- BSC Purchase Order Number.
- Date of Manufacture (DOM) including date format.
- Expiration Date including date format.
- Statement of conformance to quality requirements and specifications for BSC and CM.
- CM representative signature & date.

Additional requirements, as necessary, may be added to the C of C and C of A. The supplier must provide an example of an agreed-upon C of C or C of A document or template to be inserted into Finished Goods Document.



Certificate Of Conformance / Delivery Docket

CREGANNA TACTX MEDICAL

To:
Boston Scientific - San Jose (EP)
European Distribution Center
Vestastraat 6
Kerkrade, 6468
Netherlands

Creganna-Tactx Medical
Parkmore West
Galway
Ireland
+353 91 757801
+353 91 757850
Email: customer.service@creganna.com
URL: www.creegannatactx.com

Docket Number:	7971829		Transport:	Fedex
PO/Order No.:	1190382		No. of Boxes:	14
Ship Date:	25-JUL-14		Country of Origin:	Ireland
Lot Expiry Date:	30-JUN-15		Date of Manufacture:	10-JUL-14

Qty	Customer PN	Rev	Description	Lot No.	Creganna PN
196	H749NTR200	D	22F Lotus Introducer Sheath Finished Good Assembly	231889	139809-02

Declaration

This is to certify that items described by this docket have been developed, manufactured and inspected to meet the requirements of the product specification and drawings agreed between Creganna Tactx Medical (CTM) and the Customer and are in accordance with CTM's Quality Management System. Creganna Tactx Medical Quality Management System complies with ISO13485:2003 Medical Device - Quality Management System.
Label, IFU part numbers and revision numbers are accurate. Physical and chemical reference data pertaining to materials used and process followed in the manufacture of these products are available if required,with respect to proprietary considerations.

Sterilisation

CTM certifies that the items described in this document have been manufactured to meet all of the requirements of the specification as well as any other predefined requirements. This includes processing in an EtO Sterilisation cycle with a Sterility Assurance Level (SAL) of 10-6 that has been validated to comply with the requirements of ISO 11135:2007.CTM certifies that the sterilization test results and records have been reviewed and approved to ensure that all of the requirements of the specification have been met. CTM herewith confirms that all products being provided on this shipment are sterile.

Signed:_____. **Date:**_____.

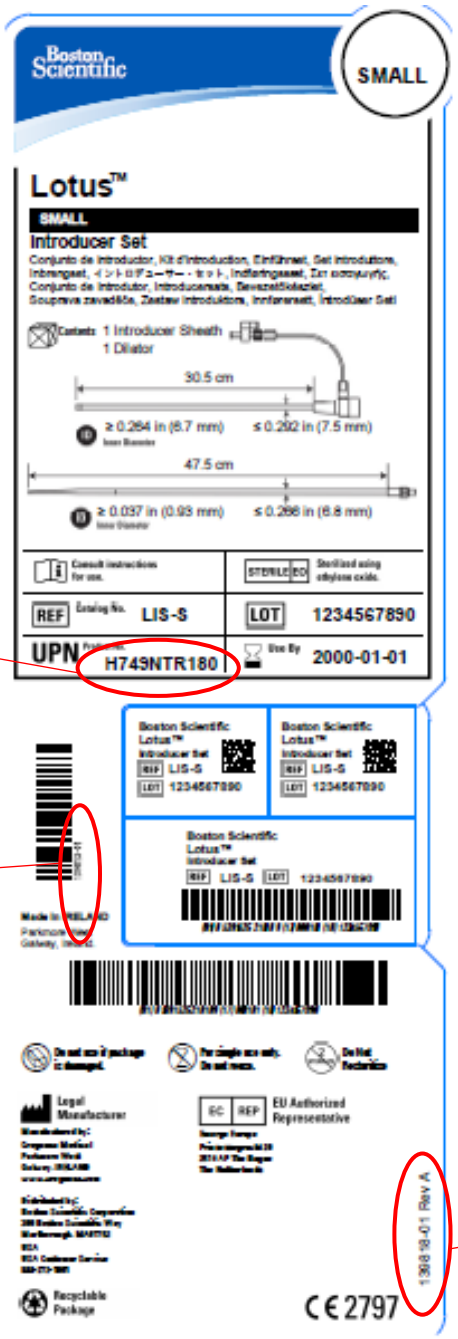
Print Name: _____.

This is an important document. Please give a copy to Quality Control.

Received By:_____

Creganna t/a Creganna-Tactx Medical

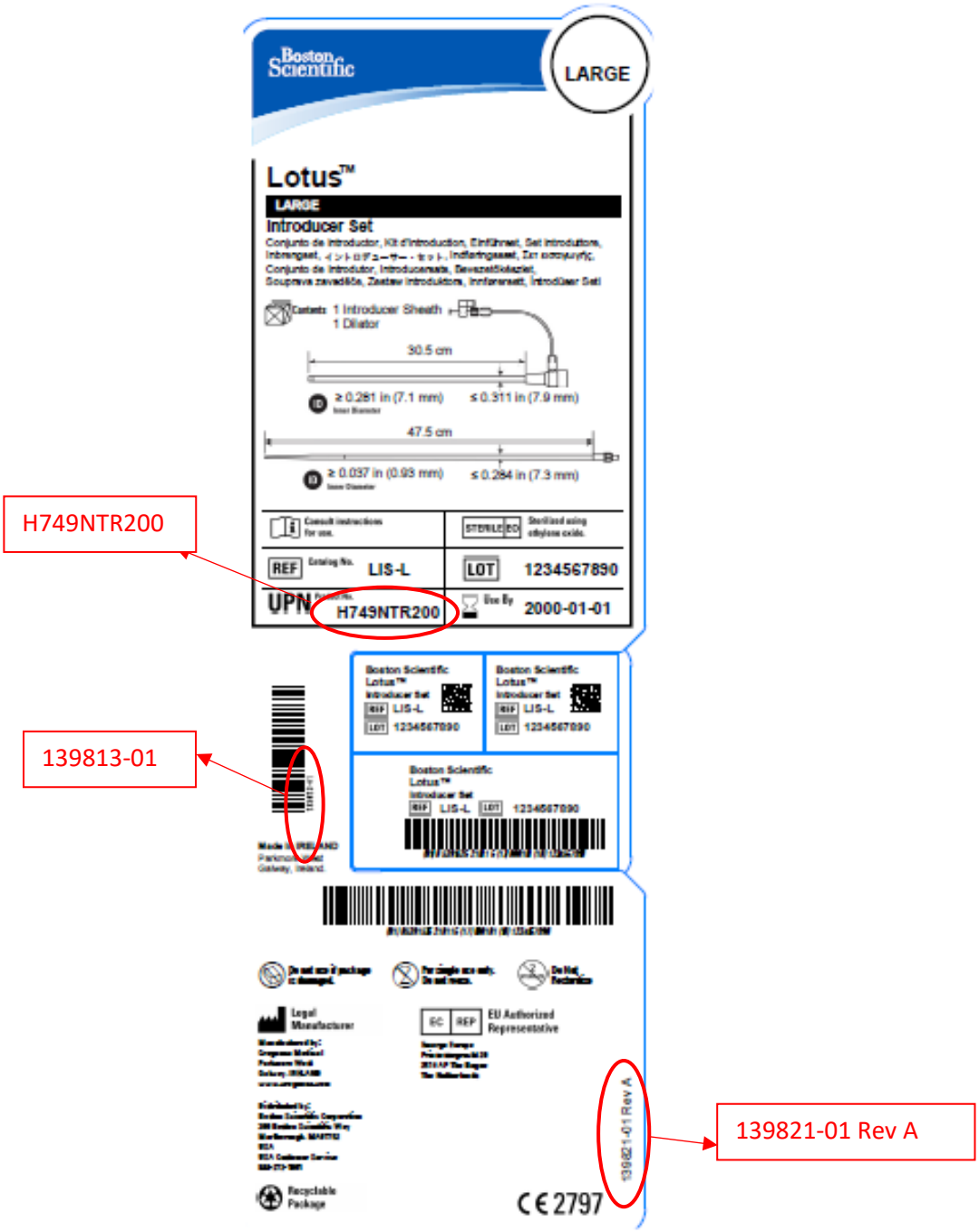
REPRESENTATIVE POUCH/TRAY LABEL SAMPLES



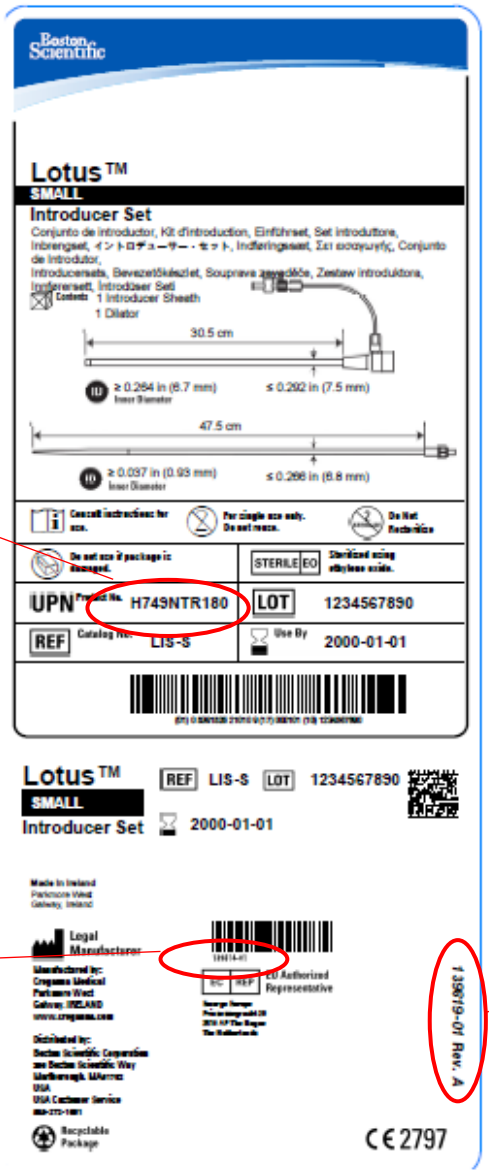
H749NTR180

139813-01

139818-01 Rev A


Boston Scientific
LARGE
Lotus™
LARGE
Introducer Set
Contents 1 Introducer Sheath
1 Dilator
30.5 cm
≥ 0.281 in (7.1 mm)
≤ 0.311 in (7.9 mm)
47.5 cm
≥ 0.037 in (0.93 mm)
≤ 0.284 in (7.3 mm)
REF LIS-L
LOT 1234567890
UPN H749NTR200
Use By 2000-01-01
H749NTR200
139813-01
139821-01 Rev A
Legal Manufacturer
EU Authorized Representative
Recyclable Package
CE 2797

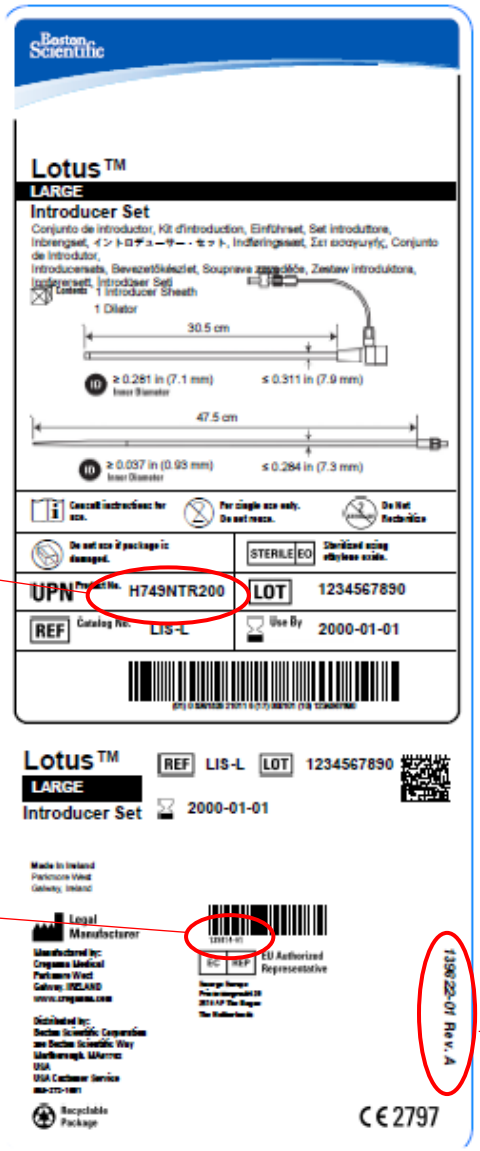
REPRESENTATIVE CARTON/BOX LABEL SAMPLES



H749NTR180

139814-01

139819-01 Rev A



H749NTR200

139814-01

139822-01 Rev A

REPRESENTATIVE DFU SAMPLE (First and Last Page)

Boston Scientific

Lotus™
Introducer Set

Directions for Use	3
Instrucciones de Uso	5
Mode d'Emploi	8
Gebrauchsanweisung	11
Istruzioni per l'Uso	15
Gebruiksaanwijzing	19
Instruções de Utilização	22

2020-02

13801G-01 Rev. A

EC REP **EU Authorized Representative**

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd.
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Manufactured by:
Creganna Medical
Parkmore West
Galway, IRELAND
www.creganna.com

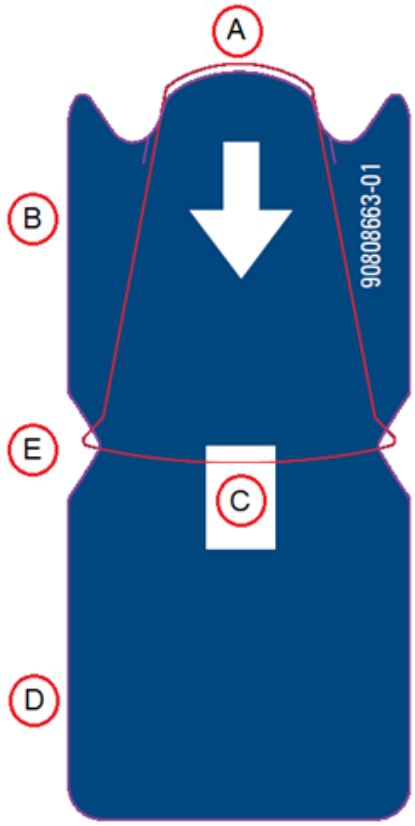
Distributed by:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service
888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 2797

CLOSURE STRIP SAMPLE
(Reference Only)



A= Tear Tab

B= Wings

C= Visual Registration Mark

D= Foot Print, Materials, and Perforations

E= Side Placement Notches

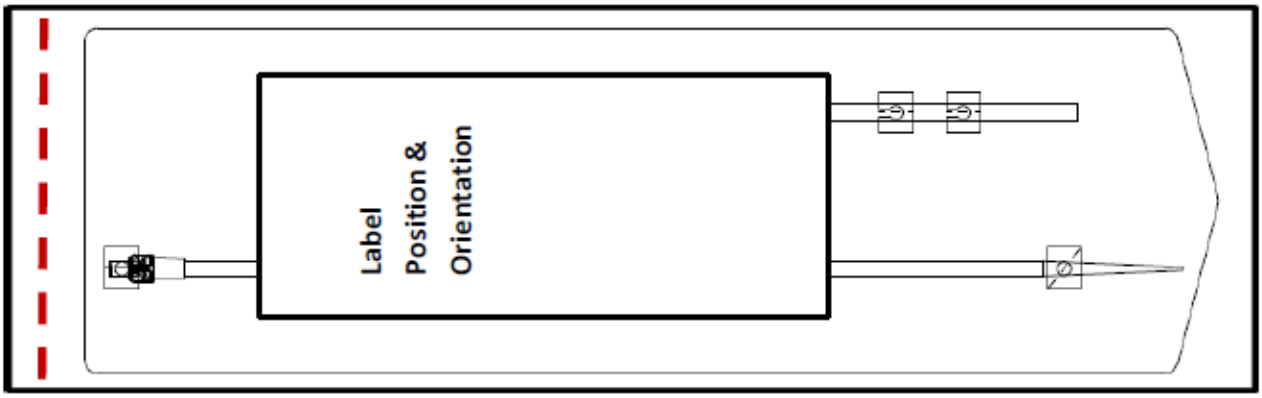
REPRESENTATIVE IMPLANT CARD SAMPLES

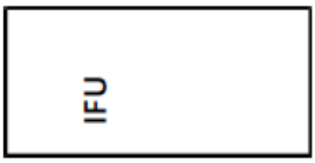
N/A

CARTON SAMPLE
(Reference Only)

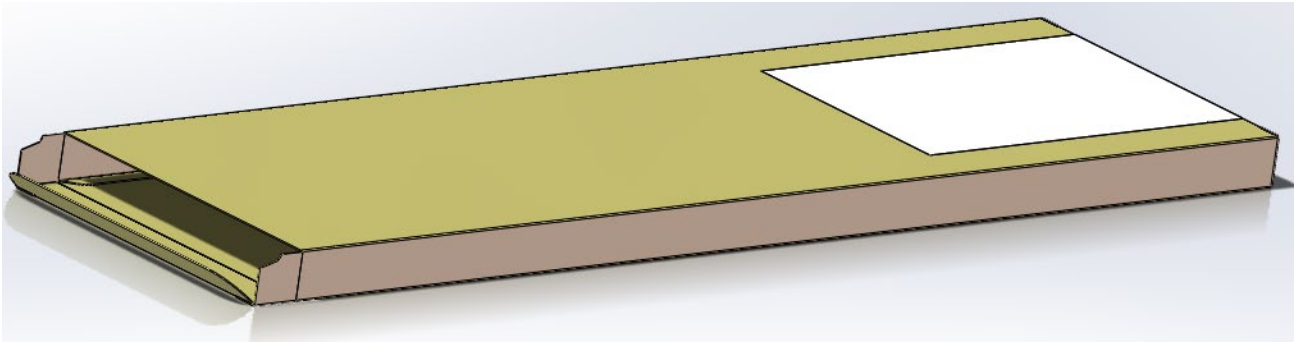


Packaging Configuration Drawings

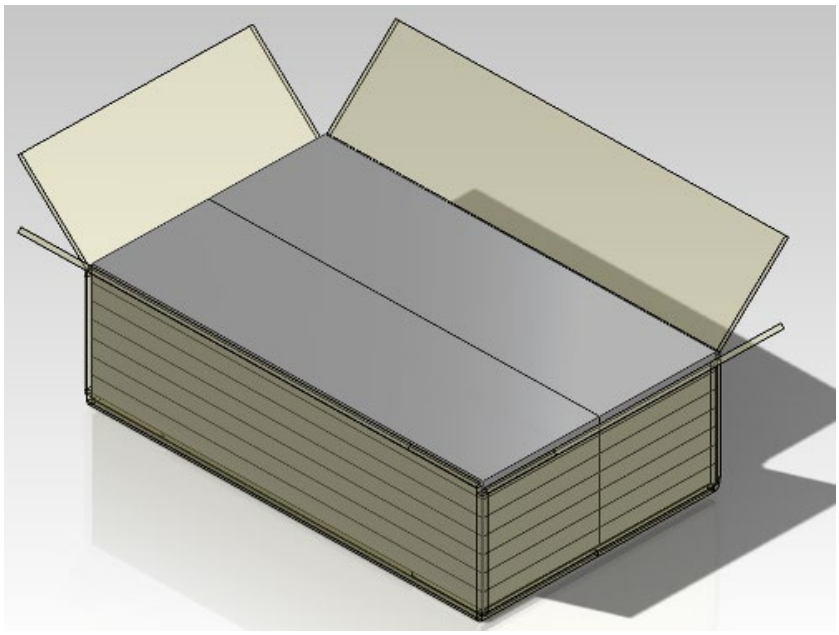




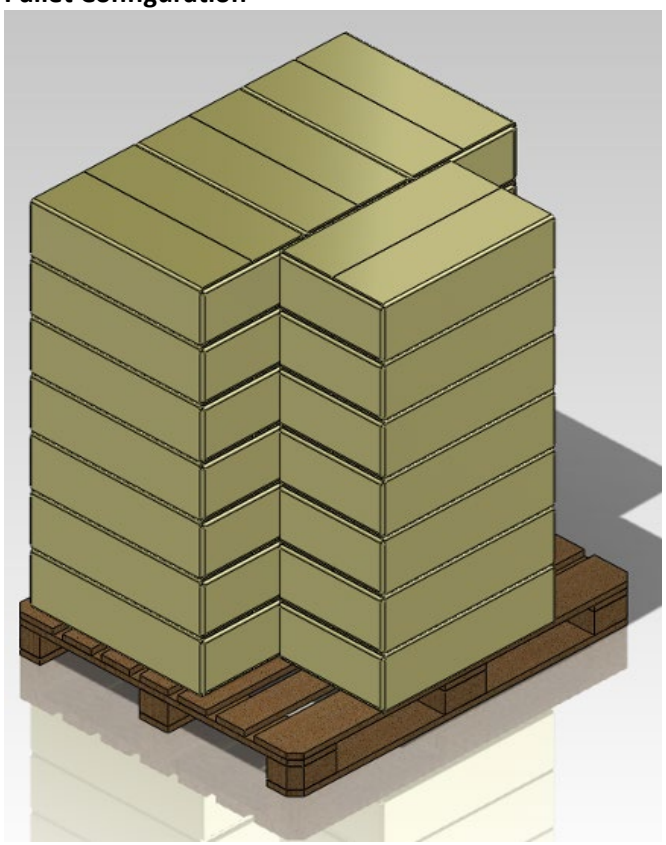




Shipper Box Configuration



Pallet Configuration



14 cartons per shipper box
4 shipper boxes per layer
7 layers of shipper boxes

Total Units = 392