

AutoElite Console Label:

AutoElite



Thrombectomy System Console, Consola del Sistema de trombectomía, Console pour système de thrombectomie, Konsole für das Thrombektomie-System, Console del sistema per trombectomia, Console voor thrombectomiesysteem, Consola do Sistema de Trombectomia, Trombektomisystemkonsol, Κονσόλα συστήματος θρομβεκτομής, Konsol till trombektomisystem, Trombektómiás rendszer konzolja, Konzole trombektomického systému, Consola systemu do trombektomii, Systemkonsoll for trombektomi, 혈전절제 시스템 콘솔, Trombektomi Sistemi Konsolu, Trombektomiajärjestelmän konsoli, Consolă pentru sistem de trombectomie, Konzola pre trombektomický systém, Конзола за система за тромбектомия, Konzola sustava za trombektomiju, Trombektoomiasüsteemi juhtpult, Trombektomijas sistēmas vadības pults, Trombektomijos sistemos valdymo pultas, Konsol Sistem Trombektomi, Konzola sistema za trombektomijo, Пульт керування системи для тромбектомії

162 lb (73.48 kg) +/- 5 lb (2.26 kg)



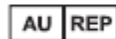
10 °C 40 °C

30% 75%

700 hPa 1060 hPa



Rx ONLY



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

FCC ID: 2BCX3M001AJAEC

IC: 31504-M001AJAEC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

ETL CLASSIFIED



Intertek
5028357

Medical Electrical Equipment
Conforms to ANSI/AAMI STD E560601-1, and IEC STD 60601-1-6
Certified to CSA STDs C22.2# 60601-1, and 60601-1-6

DRAFT

This artwork is not ready for release until this note is removed.



Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

40 min. on
60 min. off

Made in Mexico:
Paseo Del Norte #4640
Guadalajara Technology Park
Zapopan, Jalisco, MX 45010

www.bostonscientific.com

INSTRUCTIONS FOR USE

The Instructions for Use (IFU) for this product are supplied in electronic form over the Internet. IFU-BSCI.com. If you have difficulty accessing the IFU online, or would prefer to receive a paper copy, please contact Boston Scientific Customer Service or your local country contact. A copy will be sent to you at no charge and should arrive within seven days.


This product may be protected by one or more patents. Patent information can be obtained at <http://www.bostonscientific.com/patents>

www.bostonscientific.com/SymbolsGlossary

51678551-01B



Label inside blue window on console:

Window Label Content – US M001AJAEC0100		
Description of element	Symbol to be printed	Data to be printed
Global Trade Item Number (GTIN)	GTIN	00191506047832
Catalog Number (REF) and UPN: REF (catalog) number is embedded within the UPN and is printed in bold and larger font. Embedded catalog number digits appear 4pts larger than the rest of the UPN.	REF	M001AJAEC0100
Printed Content Part Number and Revision Control	N/A	97085778-01A
Serial Number: Print to max of 7 spaces Generated in production	SN	Generated in production
Date of Manufacture: Format: YYYY-MM-DD		Generated in production
GS1 2D barcode	UDI	Generated in production

Example (for reference only)




Packaging Crate Label:




97050153-01 AutoElite Label Specification, US, Crate

This document outlines the variable label stock and content requirements for the AutoElite crate labels.

Description	AutoElite Label Specification, US, Crate
Label Stock No.	51510868-02
Printer Ribbon	97017939-01

Variable Data Definition																	
Serial Number:	7 digits alphanumeric code (AE00000)																
Date of Manufacture:	Format: YYYY-MM-DD																
GS1 Linear Barcode encodes the following production identifiers:	<table border="1"> <thead> <tr> <th>Application Identifier</th> <th>Field Length</th> <th>Fixed or Variable data</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>01</td> <td>14</td> <td>Fixed</td> <td>GTIN, numeric</td> </tr> <tr> <td>11</td> <td>6</td> <td>Fixed</td> <td>Production date of manufacture (DOM) in numeric form YYMMDD*</td> </tr> <tr> <td>21</td> <td>1-18</td> <td>Variable</td> <td>Serial number; alphanumeric (GS1 allows up to 20 characters in this field; however, SAP serial numbers are currently limited to 18)</td> </tr> </tbody> </table>	Application Identifier	Field Length	Fixed or Variable data	Description	01	14	Fixed	GTIN, numeric	11	6	Fixed	Production date of manufacture (DOM) in numeric form YYMMDD*	21	1-18	Variable	Serial number; alphanumeric (GS1 allows up to 20 characters in this field; however, SAP serial numbers are currently limited to 18)
	Application Identifier	Field Length	Fixed or Variable data	Description													
	01	14	Fixed	GTIN, numeric													
	11	6	Fixed	Production date of manufacture (DOM) in numeric form YYMMDD*													
21	1-18	Variable	Serial number; alphanumeric (GS1 allows up to 20 characters in this field; however, SAP serial numbers are currently limited to 18)														
NOTE: Barcodes shall meet 90009554, Corp SOP Bar Code Requirements																	
* When indicating year and month only, DD digits are "00".																	
Font Information	Minimum size: XXX Font: SST Medium recommended																

Label Content		
Description of element	Symbol to be printed	Data to be printed
Global Trade Item Number (GTIN)	GTIN	00191506047832
Catalog Number (REF) and UPN: REF (catalog) number is embedded within the UPN and is printed in bold and larger font. Embedded catalog		M001AJAEC0100

number digits appear 4pts larger than the rest of the UPN.		
Printed Content Part Number and Revision Control	N/A	97050153-01A
Serial Number: Print to max of 7 spaces Generated in production		Generated in production
Date of Manufacture: Format: YYYY-MM-DD		Generated in production
GS1 2D barcode		Generated in production

Example

(AutoElite label showing preprinted information)

(Examples of information populated)

AutoElite™

Boston Scientific

Thrombectomy System Console

Sistema de trombectomia Console, Système de thrombectomie Console, Thrombektomie-System Console, Sistema per trombectomia Console, Thrombektomie-system Console, Trombektomiesystem Konsole, Σύστημα Θρομβεκτομής Κονσόλα, Sistema de Trombectomia Console, Trombektomi Sistemi Konsole, Trombektómia rendszer Konsole, Trombektomické systémy Konzola, System de trombectomie Console, Trombektomiesystem Konsole, Sistem Trombektomi Konsole, Sistema para trombectomia Console, Trombektomia-ijerstelimi Konsole, Sistem de trombectomia Console, Sistem za trombektomiju Konzola, Система за тромбектомия Конзола, Trombektomični systém Konzola, Trombektomia sistēma Atpūlīt, Karfi Ayril bölüsgenäm Sijärberü, Trombektomijas sistēma Vadības pults, Trombektomijas sistēma Valdymo pultas, Trombektomski sistem Konzola, Trombektomiesystem Konsole, コンソール 血栓除去システム, 血栓 제거 제어 시스템, Консоль Система для тромбектомия Система для тромбектомия, Пульт управления Система для тромбектомия, 控制台 血栓切除系统

Contents: (1)



GTIN

SN

REF



BS.com



97050753-01A

Make in Mexico:
Paseo Del Norte #4640
Guadalajara Technology Park
Zapopan, Jalisco, MX 45010



CE 2797

Rx ONLY

FCC ID: 2BCX3M001AJAEC
KCLXXXX-XXXX



(0)1234567890123(1)17121215(10)12345678(2)07654321

UK REP Boston Scientific Limited
100 New Bridge Street
London EC4W 6JA
England United Kingdom

Store between 15°C - 25°C (59°F - 77°F);
excursions permitted to
-30°C - 60°C (-22°F - 140°F)

EC REP Boston Scientific Limited
Ballybri Business Park
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USA Customer Service +1-800-272-1001

Intertek
XXXXXXXX
Medical Electrical Equipment
ANSL/KAME ES 00001-1
CAN/CSA C22.2 No. 90601-1

EU Importer: Boston Scientific International BV, Vestdijk 5, 6450 DK Kerkrade, The Netherlands
This product may be protected by one or more patents. Patent information can be obtained at
<http://www.bostonscientific.com/patents>

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MD



85%

GTIN 08714729891307

SN

XXXXXXXXXXXXXX

REF

105650-02s

GTIN 08714729996262

LOT

12345678

REF

H7493946200s



2000-09-30



Label location on back of the AutoElite Console



Crate Label Location (label contents for reference only)