



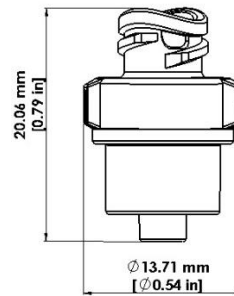
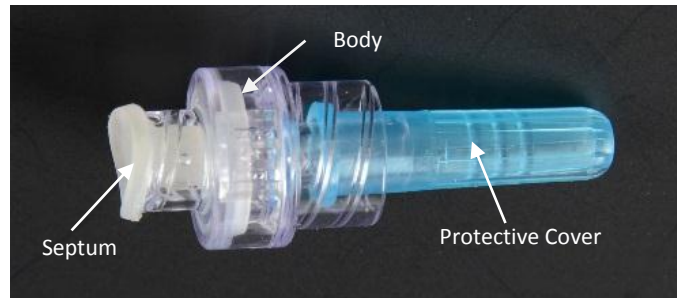
## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

#### BD Q-SYTE (stand alone) GENERAL INFORMATION

#### Indications for Use

An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter. An administration set may include the needle or catheter, tubing, flow regulator, drip chamber, infusion line filter, IV set stopcock, fluid delivery tubing, connectors between parts of the set, side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container. The BD Q-Syte Luer Access Split Septum connector is an accessory to an intravascular administration set that permits injection, gravity flow or withdrawal of fluids.



Weight: 1.0 g

#### Product Description

BD Q-Syte luer access split septum devices consist of a clear housing (body), female Luer connector with pre-slit elastic septum, and ISO male Luer connector with protective cover. The septum opens when a device, such as a syringe tip or IV administration set with an ISO male Luer connection, is inserted. The septum closes when the device is removed.

This device is for single patient use.

**Rx ONLY:** Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.  
MR Safe

Non-sterile: 9000 units/case & 1 case/shipper

Sterile: 50 units/box & 200 units/shipper

REF	Description	Technical Information				Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Storage Conditions
		Power Injectable	Maximum Pressure Limit Setting psi (kPa)	Gravity Flow Rate L/hr	Priming Volume mL					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
380510	BD Q-Syte™ Luer Access Split Septum, stand-alone, non-sterile	No	45 (310)	32	0.16	EO compatible. Customer is responsible to assess further processing.	42631 Split-septum needleless valve-connector	Septum Body Lubricant Protective cover Package	Yes	No	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385100 385103*	BD Q-Syte™ Luer Access Split Septum, stand-alone, sterile					EO (Do not resterilize)		Septum Body Lubricant Protective cover Package										

\* India Catalogue Number Only



## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

#### BD Q-SYTE™ EXTENSION SETS (non power injectable) GENERAL INFORMATION

##### Indications for Use

(REF 385101, 385102, 385104\*, 385105\*)

An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter. An administration set may include the needle or catheter, tubing, flow regulator, drip chamber, infusion line filter, IV set stopcock, fluid delivery tubing, connectors between parts of the set, side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container. The BD Q-Syte Luer Access Split Septum connector is an accessory to an intravascular administration set that permits injection, gravity flow or withdrawal of fluids.

##### Indications for Use

(REF 385150, 385155, 385151, 385156, 385152, 385157, 385153, 385158, 385161, 385162, 385163, 385164, 385165, 385166)

Extension Sets with an attached BD Q-Syte™ Luer Access Split Septum are intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

#### Product Description

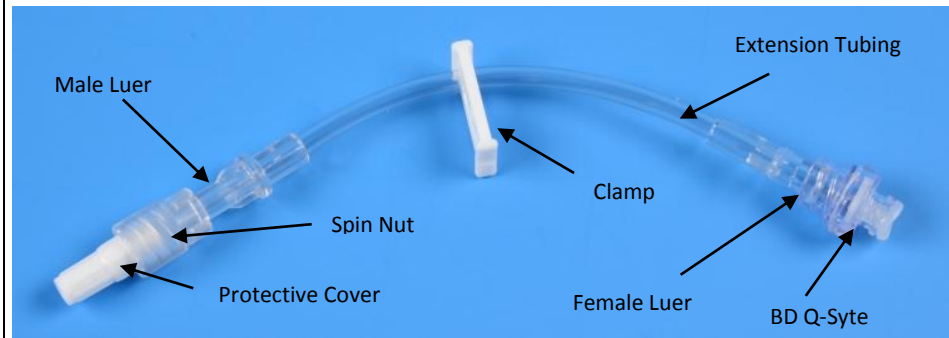
BD Q-Syte extension sets have a BD Q-Syte luer access split septum device attached to length(s) of clear, flexible PVC tubing with non-removable slide clamp. There is an ISO male Luer lock connector with protection cap on the distal end and an ISO female Luer lock connector with BD Q-Syte device or end cap on the proximal end(s). Both Y- and Dual Y-Extension Sets have non-removable BD Q-Syte devices; all other extension sets have removable BD Q-Syte devices. BD Q-Syte extension sets are provided in a variety of tubing lengths and sizes. One Micro/Small bore and one Macro/Standard bore extension Set have a male Luer with a fixed nut; all others have a spin nut. The BD Q-Syte device consists of a clear housing, female Luer connector with pre-slit elastic septum, and ISO male Luer connector. The septum opens when a device, such as a syringe tip or IV administration set with an ISO male Luer connector, is inserted. The septum closes when the device is removed.

This device is for single patient use.

**Rx ONLY:** Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

MR Safe

50 units/box & 200 units/shipper



**Representative BD Q-Syte Extension Set**



## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

REF	Description	Technical Information					Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Extension Set Inner Diameter	Maximum Pressure Limit Setting	Gravity Flow Rates	Priming Volume					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385101 385104*	BD Q-Syte™ Extension Set 15 cm (6 IN) Macro/Standard bore	No	2.8	45 (310)	27	1.14	EO (Do not resterilize)	17501 Intravenous Line, recessed-needle connector	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC With DOA Slide Clamp HDPE Male Luer PVC with DINP Female Luer PVC with DINP Package Paper/PETG	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385102 385105*	BD Q-Syte™ Extension Set 15 cm (6 IN) Micro/Small bore	No	0.80	45 (310)	3	0.34	EO (Do not resterilize)	17501 Intravenous Line, recessed-needle connector	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with DEHP Slide Clamp HDPE Male Luer PVC with DINP Female Luer PVC Package Paper/EVA	Yes	Yes	Yes	No	Yes	No	No	No	5	No special storage or handling conditions required.
385150	BD Q-Syte™ Extension Set 15 cm (6 IN) BD Rightbore™ 18	No	2.10	45 (310)	19	0.6	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Male Luer ABS Spin Nut ABS Female Luer PVC with DINP Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.



## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

REF	Description	Technical Information					Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Extension Set Inner Diameter mm	Maximum Pressure Limit Setting psi (kPa)	Gravity Flow Rates L/hr	Priming Volume mL					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385151	BD Q-Syte™ Extension Set 15 cm (6 IN) Micro/Small bore	No	0.89	45 (310)	2	0.25	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum: Silicone rubber/parylene Body: Polycarbonate Lubricant: Silicone Protective Cover: HDPE Extension Tubing: PVC with TOTM Male Luer: ABS Spin Nut: ABS Female Luer: PVC with DINP Slide Clamp: HDPE Package: Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385152	BD Q-Syte™ Extension Set 15 cm (6 IN) Macro/Standard bore	No	2.80	45 (310)	22	1.00	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum: Silicone rubber/parylene Body: Polycarbonate Lubricant: Silicone Protective Cover: HDPE Extension Tubing: PVC with TOTM Male Luer: ABS Spin Nut: ABS Female Luer: PVC Slide Clamp: HDPE Package: Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385153	BD Q-Syte™ Extension Set 36 cm (14 IN) Micro/Small bore	No	1.27	45 (310)	3	0.55	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum: Silicone rubber/parylene Body: Polycarbonate Lubricant: Silicone Protective Cover: HDPE Extension Tubing: PVC with TOTM Male Luer: ABS Spin Nut: ABS Female Luer: PVC with DINP Slide Clamp: HDPE Package: Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.



## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

REF	Description	Technical Information					Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Extension Set Inner Diameter mm	Maximum Pressure Limit Setting psi (kPa)	Gravity Flow Rates L/hr	Priming Volume mL					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385161 385155*	BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) Macro/Standard bore	No	2.80	45 (310)	20	1.60	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Bi-Connector PVC Male Luer ABS Spin Nut ABS Female Luer PVC Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385162 385156*	BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) Macro/Standard bore	No	2.80	45 (310)	20	2.25	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Tri-Connector PVC with DINP Male Luer ABS Spin Nut ABS Female Luer PVC Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385163 385157*	BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) Micro/Small bore	No	0.89	45 (310)	2	0.45	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Bi-Connector ABS Male Luer ABS Spin Nut Polycarbonate Female Luer PVC with DINP Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.



## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

REF	Description	Technical Information					Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Extension Set Inner Diameter mm	Maximum Pressure Limit Setting psi (kPa)	Gravity Flow Rates L/hr	Priming Volume mL					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385164 385158*	BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) Micro/Small bore	No	0.89	45 (310)	2	0.80	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Tri Connector PVC Male Luer Polycarbonate Spin Nut Polycarbonate Female Luer PVC with DINP Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.
385165	BD Q-Syte™ "Y" Extension Set 20 cm (8 IN) Macro/Standard bore	No	2.80	45 (310)	22	1.40	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Y Connector PVC with DINP Male Luer ABS Spin Nut ABS Female Luer PVC End Cap LDPE Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.



## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

REF	Description	Technical Information					Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Extension Set Inner Diameter	Maximum Pressure Limit Setting	Gravity Flow Rates	Priming Volume					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385166	BD Q-Syte™ Dual "Y" Extension Set 50 cm (20 IN) Macro/Standard bore	No	2.80	45 (310)	18	3.20	EO (Do not resterilize)	12170 Intravenous administration tubing extension set	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC with TOTM Y Connector PVC with DINP Male Luer ABS Spin Nut ABS Female Luer PVC End Cap LDPE Slide Clamp HDPE Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.

\*India Catalogue Number Only



## Technical Data Sheet

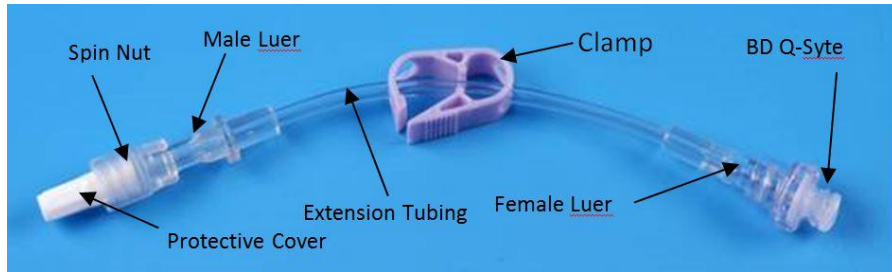
### BD Q-Syte™ Luer Access Split Septum

#### BD Q-SYTE™ EXTENSION SETS (power injectable) GENERAL INFORMATION

#### Indications for Use

The Power Injectable Extension Set with an attached BD Q-Syte™ Luer Access Split Septum is intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused. The Power Injectable Extension Set is also indicated for use with intravascular catheters indicated for power injection of contrast media. The Power Injectable Extension Set is suitable for use with power injectors set to a maximum pressure of 325 psi (2,240 kPa) when the BD Q-Syte device is removed and a direct connection is made.

#### Product Description



BD Q-Syte power injectable extension sets have a removable BD Q-Syte luer access split septum device attached to a length of clear, flexible PVC tubing with a non removable pinch clamp. There is an ISO male Luer lock spin nut connector with protection cap on the distal end and an ISO female Luer lock connector with BD Q-Syte device or end cap on the proximal end(s). The BD Q-Syte device consists of a clear housing, female Luer connector with pre-slit elastic septum, and ISO male Luer connector. The septum opens when a device, such as a syringe tip or IV administration set with an ISO male Luer connector, is inserted. The septum closes when the device is removed. BD Q-Syte power injectable extension sets are suitable for use with power injectors set to a maximum of 325 psi (2240 kPa). BD Q-Syte devices are not suitable for use with power injectors and must be removed prior to power injection. This device is for single patient use.

**Rx ONLY:** Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

MR Safe

50 units/box & 200 units/shipper

REF	Description	Technical Information					Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Extension Set Inner Diameter mm	Maximum Pressure Limit Setting psi (kPa)	Maximum Power Injector Flow Rate mL/sec	Priming Volume mL					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385154	BD Q-Syte™ Extension Set (power injectable) 15 cm (6 IN) BD Rightbore™ 18	Yes	1.67	325 (2240)	5.0	0.5	EO (Do not resterilize)	----	Septum Silicone rubber/parylene Body Polycarbonate Lubricant Silicone Protective Cover HDPE Extension Tubing PVC Male Luer ABS Female Luer PVC Pinch Clamp Polypropylene Package Paper/EVA	Yes	Yes	No	No	Yes	No	No	No	5	No special storage or handling conditions required.





## Technical Data Sheet

### BD Q-Syte™ Luer Access Split Septum

#### BD Q-SYTE™ VIAL ACCESS ADAPTER GENERAL INFORMATION

#### Indications for Use

An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter. An administration set may include the needle or catheter, tubing, flow regulator, drip chamber, infusion line filter, IV set stopcock, fluid delivery tubing, connectors between parts of the set, side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container. The BD Q-Syte Luer Access Split Septum connector is an accessory to an intravascular administration set that permits injection, gravity flow or withdrawal of fluids.



**fits 20 mm vials**



#### Product Description

BD Q-Syte vial access adapters have a non-removable BD Q-Syte luer access split septum attached to a plastic vial adapter and spike. When the spike penetrates the rubber stopper the plastic vial adapter snaps onto the standard medication vial. The BD Q-Syte device consists of a clear housing and a female Luer connector with pre-slit elastic septum. The septum opens when a device, such as a syringe tip with an ISO male Luer connector, is inserted. The septum closes when the device is removed. The device allows for repeated needleless access to a single medication vial.

**Rx ONLY:** Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

25 units/box & 100 units/shipper

	Description	Technical Information				Sterilization Method	GMDN Code	Materials	Lipid Resistant	Made with the following materials?							Shelf Life Years	Product Storage Conditions
		Power Injectable	Maximum Pressure Limit Setting	Gravity Flow Rates	Priming Volume					PVC	DEHP	Latex	Bisphenol A (BPA)	Animal Derivatives	Blood Derivatives	Medicinal Substances		
385108 385106*	BD Q-Syte Vial Access Adapter	NA	NA	NA	0.16	EO (Do not resterilize)	58510 Vial transfer spike	Septum: Silicone rubber/parylene Body: Polycarbonate Lubricant: Silicone Vial access adapter: Polycarbonate Package: Paper/EVA	Yes	No	No	No	Yes	No	No	No	5	No special storage or handling conditions required.

\*India Catalogue Number Only



**Technical Data Sheet**  
BD Q-Syte™ Luer Access Split Septum

APPLIED STANDARDS				
• ISO 14971:2007	• ISO 594-1:1986	• ISO 10993-7:2008	• EN 556-1:2001	• EN 1041:2008
• ISO 13485:2003	• ISO 594-2:1998	• ISO 11607-1:2006	• ISO 11135:2014	• ISO 15223-1:2012
• ISO 9001:2008	• ISO 10993-1:2009	• ISO 11607-2:2006	• EN 980:2008	• EN 15986:2011
LEGAL MANUFACTURER INFORMATION				
Legal Manufacturer Address	ISO Certification		FDA Facility Registration Number	
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070 USA	BSI ISO 13485:2003 Certificate Number FM 71665		1710034	
	BSI ISO 9001:2008 Certificate Number FM 504587			
MANUFACTURING SITE INFORMATION				
Manufacturing Site Address	ISO Certification		FDA Establishment Registration Number	
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070 USA	BSI ISO 13485:2003 Certificate Number FM 71665		1710034	
	BSI ISO 9001:2008 Certificate Number FM 504587			
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo, Colosio No. 579 Nogales , Sonora , 84048 , MEXICO	BSI ISO 13485:2003 Certificate Number FM 71665		9610847	
	BSI ISO 9001:2008 Certificate Number FM 504587			
US REGULATORY INFORMATION				
Classification	FDA Product Code	Premarket Status/Medical Device Listing Number	REF	
Class II	FPA	510(k) - K013621/ D041634	385100, 380510, 385101, 385102, 385103, 385104, 385105, 385106, 385108,	
		510(k) - K142547/ D226046	385150, 385151, 385152, 385153, 385154, 385155, 385156, 385157, 385158, 385161, 385162, 385163, 385164, 385165, 385166	



**Technical Data Sheet**  
BD Q-Syte™ Luer Access Split Septum

<b>EU REGULATORY INFORMATION</b>			
Classification		CE Certificate	REF
Class IIa	Rule 2 per Annex IX of Directive 93/42/EEC	BSI Full Quality Assurance Certificate Number CE 01738	385100, 385101, 385102, 385103, 385104, 385105, 385106, 385108, 385150, 385151, 385152, 385153, 385155, 385156, 385157, 385158, 385161, 385162, 385163, 385164, 385165, 385166
<b>CANADA REGULATORY INFORMATION</b>			
Classification	CMDCAS Certificate	License Number	REF
Class II	BSI ISO 13485:2003/CMDCAS Certificate Number FM 71665	68590	385100, 380510
		94200	385161, 385163, 385166, 385150, 385151, 385152, 385153, 385162, 384164, 385165
		68614	385101, 385102
<b>INSTRUCTIONS &amp; LABELING LANGUAGES</b>			
Refer to product insert (IFU) or box			