

SUMMARY OF SAFETY AND EFFECTIVENESS

Becton Dickinson and Company Perisafe™ Epidural Anesthesia Tray

1.0 **BD CONTACT PERSON**

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2.0 **DEVICE NAME**

BD Perisafe™ Epidural Anesthesia Tray

3.0 **PREDICATE DEVICE**

Kendall SafeTrak™ Continuous Epidural Anesthesia Tray - Catalog No. 5186

Abbott Continuous Epidural Anesthesia Tray - Catalog No. 11826-08

Burton® PERIFIX® Continuous Epidural Anesthesia Tray - Catalog No CE18TK-1OL

BD Perisafe™ Epidural Anesthesia Kit - Catalog No 405049

Individual components

4.0 **PRODUCT DESCRIPTION/ FUNCTION**

4.1 **Description** - The BD Perisafe™ Epidural Anesthesia Tray

series will consist of several different trays. Each tray will include components that are needed to perform the epidural anesthesia procedure. There is some variation with respect to the anesthetic drugs and some of the procedural components.

4.2 **Function** - The subject device will function the same as predicate devices. The procedure for administering Epidural anesthetic is well documented and follows the steps briefly described below. These steps may vary slightly depending on whether the device is used to perform a continuous epidural or a single shot epidural.

1. Clean the immediate area around the puncture site.

2. Anesthetize the topical tissue of puncture site.

3. Insert the epidural needle and locate the epidural space through accepted technique (Loss of Resistance technique)

4. Insert the catheter through the epidural needle.

5. Verify correct catheter placement with a Test Dose injection or other accepted method.

6. Inject the epidural anesthetic into the epidural space.

7. Remove catheter at termination of procedure.

It is the function of BD Perisafe™ Epidural Anesthesia Tray to contain all the necessary components to complete this procedure.

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5.0 COMPARISON OF MODIFIED AND PREDICATE DEVICES EQUIVALENCE

5.1 Descriptive Comparison To a Legally Marketed Device

The components in subject device are similar to the predicate devices in all respects.

5.2 Performance Data Supporting Substantial Equivalence

Product specifications do not change from individually marketed devices. All components **conform** to the physical mechanical and biological specifications **found** in the product standards referenced below.

ISO 594	Conical Fittings with a Luer Taper
ISO 7886	Sterile Disposable Syringes
ISO 7864	Sterile Disposable Needles
ISO 10993-1	Biological Evaluation of Medical Devices Part I: Guidance on Selection of Tests

5.3 Reference Table A For Comparison Table

This summary of Safety and Effectiveness data is being submitted in compliance with the Safe Medical Device Act.

TABLE A

See next page

TABLE A COMPARISON TO A LEGALLY MARKETED DEVICE

BD PERISAFE™ CONTINUOUS EPIDURAL ANESTHESIA TRAY

		SUBJECT DEVICE	PREDICATE DEVICES				
		BD	BD - KIT 405040	BRAUN CE16TK-10L	ABBOTT 4810-05	KENDALL 5186	
DRUGS AND AGENTS		COMPONENT					
		SKIN WHEEL DRUG	5 ml LIDOCAINE (1%)	N/A	5 ml LIDOCAINE (1.5%) W/ 1:200,000 EPI	5 ml LIDOCAINE (1.5%) W/ 1:200,000 EPI	N/A
		TEST DOSE	5 ml LIDOCAINE (1.5%) W/ 1:200,000 EPI	N/A	5 ml LIDOCAINE (1.5%) W/ 1:200,000 EPI	N/A	N/A
		ADJUNCTIVE	N/A	1ml 0.1% EPINEPHRINE	1ml 0.1% EPINEPHRINE	N/A	N/A
		10 ml .9% NaCl	N/A	10 ml .9% NaCl	10 ml .9% NaCl	N/A	N/A
SKIN PREP COMPONENTS	DRAPE	FENESTRATED	N/A	FENESTRATED ANT2 NON-FENESTRATED	FENESTRATED	FENESTRATED	FENESTRATED
	SPONGE APPLICATORS	3	N/A	3	3	3	3
	GAUZE PADS	4	N/A	4	4	4	3
	PREP TRAY	REMOVABLE	N/A	REMOVABLE	UPPER DECK	REMOVABLE	REMOVABLE
	TOWELS	2	N/A	1	2		
	IODINE	30 ml POVIDONE	N/A	30 ml POVIDONE	N/A	N/A	N/A
SKIN WHEEL COMPONENTS	SYRINGE	3 ml PLASTIC u	N/A	3 ml PLASTIC u	3 ml PLASTIC u	3 ml PLASTIC ULL	3 ml PLASTIC ULL
	SYRINGE #2	N/A	N/A	N/A	1ml PLASTIC LS	N/A	N/A
	ASPIRATION FILTER	19Gx1.5" NEEDLE	N/A	4" FILTER SITLAW	N/A	20G X 1.5" FILTER NEEDLE	20G X 1.5" FILTER NEEDLE
	NEEDLE #1	22 Gx1.5"	N/A	22Gx1.5"	22Gx1.5"	21Gx1.5"	21Gx1.5"
	NEEDLE #2	25G x 1"	N/A	25G X 5/8"	25G X 5/8"	25G X 5/8"	25G X 5/8"
	NEEDLE #3	N/A	N/A	18G x 1.5"	18G x 1.5"	18G X 1.5"	18G X 1.5"
PROCEDURAL	PROCEDURAL NEEDLE #1	18Gx3.5" WEISS EPIDURAL	18Gx3.5" WEISS EPIDURAL	18Gx3.5 TOUHY-SCHLIPP EPIDURAL NEEDLE	18Gx3.5" THINWALL EPIDURAL NEEDLE	17Gx3.5" TOUHY-WEISS EPIDURAL NEEDLE	17Gx3.5" TOUHY-WEISS EPIDURAL NEEDLE
	CATHETER	20G X 36" CLOSED -END CATH WITH GUIDE	20G X 36" CLOSED -END CATH WITH GUIDE	20G CLOSED TIP CATH WITH GUIDE	CATHETER WITH STYLET	19G X 36" OPEN -END CATH WITH STYLET	19G X 36" OPEN -END CATH WITH STYLET
	LOR SYRINGE	5 ml CLASS SYRINGE u	10 ml PLASTIC "LOR" SYRINGE LS	113111 GLASS SYRINGE U	10ml GLASS SYRINGE U	5 ml GLASS SYRINGE LS	5 ml GLASS SYRINGE LS
	EPIDURAL PROCEDURAL SYRINGE	20 ml PLASTIC u	N/A	20 ml PLASTIC U	N/A	20 ml PLASTIC U	20 ml PLASTIC U
	CATHETER ADAPTERS	CATHETER CONNECTOR W/ CAP	CATHETER CONNECTOR	CATHETER CONNECTOR	CATHETER ADAPTER WJTH CAP	CATHETER ADAPTER WJTH C/	CATHETER ADAPTER WJTH C/
	CATHETER SUPPORT PAD	N/A	N/A	1	1		
	MEDICINE CUP	50mL BASIN	N/A	50mL BASIN	50 ml REMOVABLE BASIN	REMOVABLE DRUG CUP	REMOVABLE DRUG CUP
	MISCELLANEOUS	N/A	N/A	N/A	N/A	ADHESIVE BANDAGE	ADHESIVE BANDAGE
	FILTERS	.2 MICRON	.2 MICRON W/ CAP	.2 MICRON	.2 MICRON	.2 MICRON	.2 MICRON

The BD tray is one example of a series of Epidural Anesthesia trays.