21/06/2017

ATTN: Risk Manager, Materials Manager, Operating Room Director

Dear Customer,

In conjunction with an industry-wide labeling update initiated by the FDA, additional information is being added to the Instructions For Use (IFU) for bone cement products. Cement leakage into the venous system during vertebroplasty or kyphoplasty procedures is recognized as a possible complication and warnings regarding pulmonary embolism are addressed in the current IFU. Intracardiac bone cement embolism will also be referenced in the updated version of the IFU.

The following language will be included in the appropriate sections of our labeling:

> *Warnings*
> *Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.*
>
> *Adverse Events*
> *Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty* include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.*
>
> *Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty* include:*
> *Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.*

*statements for products that contain VertaPlex HV include “and sacroplasty”.

Stryker Instruments and Stryker Spine bone cement products manufactured after June 30, 2017 will include the updated IFU. If you would like to request an updated copy of the IFU, please contact your Stryker Sales Representative. A complete product list is provided on the next page to identify applicable products.

There is no need to respond to this letter, which is intended to apprise you of the update and the reason for the change. If you have any questions, please feel free to contact us.

Sincerely,

Product Number	Product Name
0406-202-000	SpinePlex 20g Twin Pack (½-dose) (2/pkg)
0406-222-000	VertaPlex ½-dose 2 pack
0406-402-000	VertaPlex 20g Twin Pack (½-dose) (2/pkg)
0406-422-000	SpinePlex ½-dose 2 pack
0406-622-000	VertaPlex HV 20g Twin Pack (½-dose) (2/pkg)
0406-622-015	VertaPlex HV single Pack
0505-582-000	PCD Kit - Long 90, 10g Match-Ground w/ Bevel w/ SpinePlex (4/pkg)
0505-583-000	PCD Kit - Long 90, 11g Match-Ground w/ Bevel w/ SpinePlex (4/pkg)
0505-585-000	PCD Kit - Long 90, 13g Match-Ground w/ Bevel w/ SpinePlex (4/pkg)
0505-587-000	PCD Kit - Long 90, w/ SpinePlex (4/pkg)
0507-486-000	PCD PREC. SYS with 90 Degree Extension Tube and VertaPlex Bone Cement
0507-489-000	PCD PREC. SYS with Short Extension Tube and VertaPlex Bone Cement
0507-586-000	PCD PREC. SYS with 90 Degree Extension Tube and VertaPlex HV Bone Cement
0507-589-000	PCD Kit - Short Tube w/ VertaPlex HV (4/pkg)
0605-683-000	AutoPlex System - 11g Match-Ground w/ VertaPlex (2/pkg)
0605-685-000	AutoPlex System - 13g Match-Ground w/ VertaPlex (2/pkg)
0605-687-000	AutoPlex System - w/ VertaPlex (2/pkg)
0607-687-000	AutoPlex System - w/ VertaPlex HV (2/pkg)
1040-100-000	AVAmax Cement
1040-200-000	AVAmax Kit
1040-200-500	AVAmax Plus Additional Tray
1040-300-000	AVAmax Plus Kit
1040-300-500	AVAmax Plus Additional Tray
BCPM003	AVAmax Radiopaque Bone Cement
BCT00CT	AVAmax Procedure Tray
BCTXLCT	AVAmax Extra Level Tray
VMX00CT	AVAmax PLUS Procedure Tray
VMXXLCT	AVAmax PLUS Extra Level Tray
2101-0000	Cortoss 10cc Cartridge, (OUS)
2101-0002	Cortoss 5cc Cartridge, (OUS)
2101-0005	Cortoss 5cc Cartridge, (US)
2101-0010	Cortoss 10cc Cartridge, (US)
2101-0105	Cortoss 5cc Cartridge, (Canada)
2101-0110	Cortoss 10cc Cartridge, (Canada)