

October 21, 2013

Medical Device Correction Notice TRUFILL® n-BCA Liquid Embolic System

Dear Manager of Neuroendovascular Surgery, Interventional Neuroradiology,

This notification is being issued to highlight important safety information regarding the mix ratios used for TRUFILL n-BCA. *Codman Neuro* has identified an incorrect statement in the Instructions For Use (IFU) that describes suggested mixing ratios for use in certain treatment conditions. All customers are asked to review the following information and contact your *Codman Neuro* sales representative for additional support.

TRUFILL n-BCA Liquid Embolic System product codes associated with this notice include the following (all lots):

Product Code	Description
631400	Two 1 gram tubes nBCA
631500	One 1 gram tube nBCA

Please be aware that the Instructions for Use describing the mix ratios noted in Table 4 of the IFUs incorrectly note:

“A 2:1 (67%Ethiodized Oil / 33% nBCA) for feeding pedicle injections close to the nidus at high flow rates where venous opacification occurs on contrast injections within 1/2 second.”

The correct information should state:

“A 2:1 (67% Ethiodized Oil / 33% nBCA) for Intranidal injections without AV fistulae or high flow rates in order to more deeply penetrate the nidus.”

Codman Neuro is in the process of updating these Instructions for Use as indicated in the enclosed tables which show the incorrect and corrected Table 4 contents.

Potential Clinical Impact

Recommended ratios of n-BCA to ethiodized oil vary depending on the characteristics of the injection site. Higher concentrations of ethiodized oil increase polymerization time, ideal for more distal penetration. In contrast, higher concentrations of n-BCA reduce polymerization time, ideal for more proximal penetration.

If higher concentrations of ethiodized oil are used in areas of high blood flow rates, it may lead to polymerization distal to the targeted site. This prolonged polymerization could result in embolization of draining vessels with subsequent venous occlusion, reflux into other arterial branches, or pulmonary emboli. This could result in significant impact to the patient, including neurological deficits, pulmonary tissue damage and possibly death.

Thorough product training is required before purchasing the TRUFILL n-BCA Liquid Embolic System. *Codman Neuro* has verified that all related physician training materials and collateral documents (e.g., brochures) contain correct information.

Additional Resources

We are committed to addressing your questions. For additional information, please contact your *Codman Neuro*

representative. Please report any malfunction or adverse event related to this device to *Codman Neuro* at 1-866-491-0974, Option 2.

Patient safety is the highest priority for *Codman Neuro*. We appreciate your assistance with this matter and regret any inconvenience this may cause.

Sincerely,

A handwritten signature in black ink, appearing to read "Matthew King", with a long horizontal flourish extending to the right.

Matthew King

Director, Regulatory Compliance

Codman Neuro

Table 4 Content

Incorrect Table 4

Table 4 Recommended Mixtures (Listed volumes based on a total volume of 1.0 mL—actual total volumes may vary)			
Conditions	TRUFILL Ethiodized Oil: n-BCA Ratio (EO: n-BCA)	TRUFILL Ethiodized Oil Volume (mL)	TRUFILL n-BCA Volume (mL)
Intranidal injections without AV fistulae or high flow rates, in order to more deeply penetrate the nidus	3:1 (75% EO/ 25% n-BCA)	0.75	0.25
	2:1 (67% EO/ 33% n-BCA)	0.67	0.33
Feeding pedicle injections close to the nidus, at high flow rates where venous opacification occurs on contrast injections within 0.5 second	1:1 (50% EO/ 50% n-BCA)	0.50	0.50*
	1:2 (33% EO/ 67% n-BCA)	0.33	0.67*
*TRUFILL Tantalum Powder may also be added to ethiodized oil to augment radiopacity. Tantalum powder should not be used alone with n-BCA. At higher n-BCA concentrations (>50%), addition of up to 0.5 g tantalum powder is advised.			

Corrected Table 4

Table 4 Recommended Mixtures (Listed volumes based on a total volume of 1.0 mL—actual total volumes may vary)			
Conditions	TRUFILL Ethiodized Oil: n-BCA Ratio (EO: n-BCA)	TRUFILL Ethiodized Oil Volume (mL)	TRUFILL n-BCA Volume (mL)
Intranidal injections without AV fistulae or high flow rates, in order to more deeply penetrate the nidus	3:1 (75% EO/25% n-BCA)	0.75	0.25
	2:1 (67% EO/33% n-BCA)	0.67	0.33
Feeding pedicle injections close to the nidus, at high flow rates where venous opacification occurs on contrast injections within 0.5 second	1:1 (50% EO/50% n-BCA)	0.50	0.50*
	1:2 (33% EO/67% n-BCA)	0.33	0.67*
*TRUFILL Tantalum Powder may also be added to ethiodized oil to augment radiopacity. Tantalum powder should not be used alone with n-BCA. At higher n-BCA concentrations (>50%), addition of up to 0.5 g tantalum powder is advised.			

CODMAN NEURO



Correction Notice Acknowledgement Form

The undersigned acknowledges receipt of the correction notice in reference to the TRUFILL® n-BCA Liquid Embolic System IFU discrepancy.

Date: _____

Name (please print): _____

Signature: _____

Hospital Name: _____

Address: _____

Please fax this completed form to *Codman Neuro* at 508-977-6665.