

Eric Jameson - Beta-Cath System

From: "Reed, Craig" <CReed@novoste.com>
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Date: 01/25/2002 13:50
Subject: Beta-Cath System

Eric,

Any word on the SS&D update?

Also, two notes

- I mentioned that the Beta-Cath 3.5Fr System has a wire in the catheter that replaces the Dummy Run but forgot to mention that we don't recommend use of the Arrow Pediatric Introducer Sheath with the Beta-Cath 3.5Fr System: the 3.5Fr delivery catheter diameter and material are more resistant to crushing in the Touhy Borst hemostasis valve than the 5Fr. 3.5Fr System User's Manual will not mention the introducer sheath. To avoid recommending use of a medical device not described in our approved labeling you might want to say that "user's who have concerns regarding crimp may consider .

- Also, I noticed that one of the figures in the proposed revision to the SS&D that I sent you sometime ago was mislabeled. I think the 3.5 Fr catheter with two concentric circles was mislabeled with "Corona" instead of "3.5Fr".

Craig