

**From:** Ciavarella, David [/O=BARD/OU=MHL AG/CN=RECIPIENTS/CN=DCIAVA  
RELLA]

**Date:** 12/27/2005 2:33:22 PM

**To:** Barry, Brian

Ganser, Christopher

**Subject:** FW: G2 Caudal Migrations

My comments to Cindi and Gin.

**From:** Ciavarella, David

**Sent:** Friday, December 23, 2005 2:32 PM

**To:** Walcott, Cindi

**Cc:** Allen, Shari; Schulz, Gin

**Subject:** RE: G2 Caudal Migrations

Thank you Cindi.

I think we should discuss these further so I can get a better understanding of each one. But first, it would help if I had a little more information.

From what you've sent me, it seems to me that the biggest (worst case) consequence of these migrations is that they are accompanied in a majority of cases by tilting. This raises the concern of lack of efficacy, that is, are the filters now in place to perform clot interruption? I would guess not in several of these cases at least.

I would like to look more generally at the G2 complaints. I have seen problems with caudal migration, tilting, perforation, mis-deployment and maybe one or two additional things. Can you tell me the total number of complaints (not damaged packages and the like) and total number of units distributed?

How many MDRs have we had for G2?

The G2 is a permanent filter; we also have one (the SNF) that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2? Can you also send me the total complaints rate and MDR complaint rate for SNF?

I'll be in the office next Tues and Wed; maybe we can talk one of those days.