Reviewer’s report

Title: Comparison of the Novel Medtentia Double Helix Mitral Annuloplasty System with the Carpentier-Edwards Physio Annuloplasty Ring: Morphological and Functional Long-Term Outcome in a Mitral Valve Insufficiency Sheep Model

Version: 1 Date: 1 January 2013

Reviewer: Wolfgang Bothe

Reviewer’s report:

In this work the authors compared a novel mitral annuloplasty ring system to a CE Physio ring in a chronic large animal study. Primary outcome measures included macro- and microscopic findings surrounding the rings at the time of sacrifice (morphological outcomes) as well as functional outcomes such as implantation time, freedom from mitral regurgitation and LV dimensions.

First of all, the authors should be congratulated for having performed such a complex large animal study using a chronic model of functional mitral regurgitation.

I have, however, several concerns which mainly refer to the clarity of the manuscript.

1. Starting with the abstract: The terms ‘morphological and functional outcome’ are broad and it is not directly intuitive what the authors were aiming to investigate. The following methods section does not describe when and how the endpoints (which are not clear) were assessed (Echo? Histology? Timeline of the protocol?). Since the device used is almost unknown, both, a description of the device as well as of the method of implantation are needed. Finally, authors draw conclusions that are not supported by their results. Was a ‘projected mitral valve area’ assessed (not described in any of the previous sections of the abstract)? If yes, how was it assessed and what were the results? And would it be valid to conclude that this novel device prevents mitral regurgitation by decreasing the orifice area?

With respect to the manuscript:

2. In the Methods section the implantation of the device should be described in more detail. It is not clear why the implantation of the novel device is faster than implanting a CE Physio if a similar number of sutures is placed.

Were the animals randomized? Why does one group consist of seven and the other of 13 animals?

3. In the Results section, MR grade, which is one of the fundamental parameters of this study, should be added to Figure 2. This Figure should also be revised carefully with respect to formal errors (hidden legends, inappropriate boxes etc.).
Fundamental surgical parameters should be emphasized (clamp time) and less relevant parameters be deleted.

Furthermore, major parts of the Results section are not understandable. What does ‘Flno1’ or ‘Fl250237458’ mean and why is this relevant? No conclusions should be drawn in this part of the manuscript and this section needs to be more clear, concise and should focus on the most relevant findings.

4. In the Discussion section, attention must be paid that all conclusions are supported by the data presented.

Currently some parts of the manuscript sound more like wishful thinking rather than a scientific article.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.