**PROTOCOL FOR BLINDING**

\* Levels of Blinding :

- The **Secondary Ultrasound Readers** will be completely blinded.

- The **Patient** will not be told what type of Trial Balloon they receive.

- The **Trial Sonographers** will be largely blinded

- The **Trial Clinicians** will be largely / partly blinded

\* The **Secondary Ultrasound Readers** will not know and cannot know whether the patient they are reporting on received a Sham or a DEB balloon. Furthermore, they will not know whether the ultrasound scan they are reading is the first, 6 week, 3 month, 6 month or 12 month follow-up scan. Hence, it is a truly blinded study in terms of the Primary Trial Endpoint, Late Lumen Loss, as reported by the Secondary Ultrasound Readers.

\* The **Trial Sonographers** will not be informed as to whether the patient received a Sham or DEB, but they may be able to work this out in some cases from the length of the Trial Balloon in the Trial Balloon Xray Image.

The Sonographer will NOT be told on the request form which is the sequence of the current Scheduled Trial Ultrasound they are performing. Importantly, the Sonographer must perform each examination without reference to previous Scheduled Trial Ultrasound findings on that patient.

\* The **Patient** will be kept unaware of the type of Trial Balloon they receive by:

- Not using the phrase “SHAM” or “DEB” during the Trial Procedure.

- Not recording “SHAM” or “DEB” anywhere in the notes, particularly, not on the Operative Report And Diagram. Always use the term “Trial Balloon”.

\* Blinding of the **Trial Clinicians** will be incomplete. Blinding will not be possible with respect to the Trial Balloon Operator and some other members of the team as they will know at the time of Randomisation which Trial Balloon is being applied: Sham or DEB.

However, as the patient does not know the type of Trial Balloon used, and as it is nowhere explicitly recorded what type of balloon was used, the Trial Clinicians would have to go out of their way to find out what type of balloon was used (they may be able to work this out in some cases from the length of the Trial Balloon in the Trial Balloon Xray Image), or they may remember what type of balloon was used, although this will be difficult in over 200 patients in a 2 year trial.

Vs 4 16/03/15

