

ASMBS NEW DEVICES & PROCEDURE APPLICATION

Review the Pathway for Approval for New Devices and Procedures prior to completing this application.

Name of ASMBS Sponsor:

Name of ASMBS Co-Sponsor:

Email of ASMBS Sponsor:

New or extinct procedure: New Extinct

There may be procedures there are no longer viable and these may be removed from approval list.

Device or Surgery: Device Surgery

Device: FDA Approval Required? Yes No

Surgery: Novel Similar to Established Procedure

If similar to established procedure, describe how the new procedure differs from current established procedure.

Do you or your co-sponsors have a financial relationship with the new device or procedure including but not limited to consulting, ownership, proctoring, etc. : Yes No

If yes, what is the relationship?

Publications with Evidence Grades

Please attach the publications with an evidence grade utilizing established evidence scales such as, Oxford Centre for Evidence-based Medicine - Levels of Evidence (March 2009).

If a new procedure, please respond to below:

Is this a new procedure or a modification of an existing procedure? Yes No

Based on current knowledge does the new procedure or modification of an existing procedure potentially have a different risk/benefit profile than an existing procedure?

Does it add a new mechanism to an existing procedure?

Does it have a new name or names that should be standardized as part of the approval process?