

Endorsed Procedures and Devices



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MBSAQIP-Accredited centers must receive approval from an Institutional Review Board (IRB) in order to perform primary procedures that are not endorsed by the ASMBS. The IRB approval must be for performing the procedures, and not solely for data collection of outcomes from these procedures. In the event that an IRB determines a study protocol unnecessary for a primary procedure that is not endorsed by the ASMBS, a letter of exemption from the IRB is required to demonstrate compliance with MBSAQIP standards. Procedures and devices used for re-operative purposes do not require IRB approval or IRB exemption. However, the ASMBS recommends conforming to the endorsed procedure list when selecting procedures and devices for re-operative purposes whenever possible:

ASMBS Endorsed Procedures and Devices for Metabolic and Bariatric Treatment

ASMBS Endorsed Procedures and FDA approved Devices which do not require IRB	Primary Case
Adjustable Gastric Banding – is FDA approved	No IRB
Sleeve Gastrectomy	No IRB
Roux-en-Y Gastric Bypass	No IRB
BPD/Duodenal Switch	No IRB
AspireAssist® is FDA approved	No IRB
Intragastric balloons – are FDA approved and endorsed by ASMBS	No IRB
Vagal nerve blocking therapy (vBloc®) is FDA approved	No IRB
Vertical Banded Gastroplasty	No IRB
Bariatric Re-operative Procedures	N/A
Open procedures as deemed appropriate	No IRB

Non-Endorsed Procedures and Devices	Primary Case
Single Anastomosis Duodenal Switch Procedures (SADI, SADI-S, SIPS, Loop DS)	IRB or IRB Exemption Required
Single Anastomosis Gastric Bypass (Mini-Loop Gastric Bypass)	IRB or IRB Exemption Required
Endoluminal/Endoscopic Sleeve Gastroplasty	IRB or IRB Exemption Required
Gastric plication	IRB or IRB Exemption Required

Pathway for Endorsement for New Devices and Procedures

With the advent of new obesity devices and procedures entering our field, ASMBS developed an official pathway for the approval and sanction of new procedures and devices. Any ASMBS member can submit an application for a new procedure or removal of an approved procedure by following the below link.

<https://asmbs.org/pathway-for-approval-for-new-devices-and-procedures>

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