

INVENTORY: EMERGING TECHNOLOGY AND PROCEDURES COMMITTEE OCTOBER 2012

To submit new or updated information and comments on emerging bariatric procedures and devices, please email emergingtech@asmbs.org

CATEGORY	COMPANY	DEVICE OR DRUG	INDICATION	MECHANISM	STATUS	TRAILS TRAILS PI	WEBSITE CONTACT INFO	SUMMARY OF PUBLICATIONS	PUBLICATIONS
Electrical Manipulation	Enteromedics	V-Bloc/Maestro	Primary/Revision	Vagal nerve blockade	Investigational, not FDA approved	http://www.rechargestudy.com/ - FDA clinical trial Empower trial	www.enteromedics.com		V-Block/Maestro Publication
Electrical Manipulation	Intrapace	Abiliti	Primary	Gastric Stimulation		CE mark approval	www.abiliti.com/en/about_abiliti		
Electrical Manipulation	MetaCure	Tantalus	Diabetes Treatment	Gastric Electrical Stimulation		In trials			Metacure Tantalus Publications
Electrical Manipulation	Transneuronix	Transcend IGS	Primary	Gastric Pacing	Investigational, not FDA approved	Didn't meet the end points on clinical trial			Transneuronix - Transcend IGS Publications
Endoscopic	GI Dynamics, Inc.	Endobarrier	Primary/Metabolic	Duodenal Jejunal Bypass Sleeve	On market in Europe (3 centers in Germany), Australia, and South America; Clinical Trials in US. Currently not approved for sale in the U.S. Considered investigational.	1. Study of EndoBarrier Liner for Treatment of Type 2 Diabetes Study (Brazil) (Ricardo Cohen) 2. Safety and Efficacy Study of EndoBarrier in Subjects With Type II Diabetes and Obesity (Netherlands)(Jan Willem Greve) 3. Study of Obese Subjects Previously Implanted With the EndoBarrier Gastrointestinal Liner (Chile) (Alex P. Escalona) 4. Post Marketing Study in Subjects Who Have Type 2 Diabetes Using the EndoBarrier™ Gastrointestinal Liner (UK)	www.gidynamics.com ; info@gidynamics.com		Endobarrier publications
Endoscopic	Allergan	Botox injection	Primary	Dysmotility	Investigational, not FDA approved		www.allerganclinicaltrials.com/inquiries/trialsubject.aspx www.allergan.com		Botox Publications
Endoscopic	ValenTx	Gastric Bypass Sleeve	Primary	Endolumenal bypass	Clinical trials Investigational, not FDA approved	Clinical trials in Latin America			
Endoscopic	BaroNova	Transpyloric Shuttle	Primary/Revision	Gastric Outlet Obstruction	In development Investigational, not FDA approved		www.baronova.com/products.html		
Endoscopic	Allergan	BioEnterics BIB, Orbera	Primary	Intragastric Restriction	CE mark. Investigational, not FDA approved		www.allergan.com	Summary and Publications	

Endoscopic	Apollo Group	Eagle Claw/Overstitch	Primary/Revision	Intragastric Restriction	Clinical Trials	yes	www.apolloendo.com/Our-Technology/Overstitch.aspx		Eagle Claw – Overstitch Publications
					Investigational, not FDA approved	Chris Thompson	info@ApolloEndo.com		
Endoscopic	Barosense, Inc.	Teris	Primary	Intragastric Restriction	In trials Investigational, not FDA approved	trials ongoing in Latin America	www.barosense.com info@barosense.com (no responses)		None
Endoscopic	Cook	Balloon	Primary	Intragastric Restriction	No longer available				
Endoscopic	Cook	Endolumenal magnets	Anastomosis Creation	Malabsorption	Human and animal Investigational, not FDA approved		www.cookmedical.com	Summary and Publications	
Endoscopic	CR Bard	EndoCinch	Primary/Revision	Intragastric Restriction	On market		www.crbard.com/prlanding.aspx?releaseID=353187 medical.services@crbard.com		EndoCinch Publications
Endoscopic	Dow Corning	silicone rubber acid resistant balloon			No longer available				
Endoscopic	Endogastric Solutions	Stomaphyx	Primary/Revision	Intragastric Restriction	On market		www.endogastricsolutions.com www.clinicaltrials.gov/ct2/show/NCT00939055?term=stomaphyx&rank=2 (not listed on their website anymore)		Stomaphyx Publications
Endoscopic	Satiety	TOGA	Primary	Intragastric Restriction	no FDA approval; Investigational, not FDA approved	Successful trial (Devière) www.satietyinc.com/toga-clinical-trial/overview/	Currently this procedure is not available for use.	Summary and Publications	
Endoscopic	Tremco	Balloon	Primary	Intragastric Restriction	No longer available Investigational, not FDA approved			Summary and Publications	
Endoscopic	USGI Medical	Incisionless Operating Platform	Primary (POSE)/Revision (ROSE)	Intragastric Restriction	Investigational, not FDA approved	Not approved by the FDA, only available clinically outside the US	www.usgimedical.com/		
Intragastric	Allergan	BioEnterics BIB, Orbera	Primary	Intragastric Restriction	CE mark. Investigational, not FDA approved		www.allergan.com	Summary and Publications	
Intragastric space occupying	Helioscope	Heliosphere Bag system	Primary	Intragastric Restriction			www.helioscopie.fr/en	Summary and Publications	
Intragastric space occupying	Hourglass	Balloon	Primary	Intragastric Restriction				Summary and Publications	
Intragastric space occupying	Reshape	Reshape Duo Intragastric Balloon	Primary	Intragastric Restriction		FDA trial	www.reshapemedical.com www.reshapemedical.com/contact/	Summary and Publications	
Intragastric space occupying	Silimed	BIS, Balloon	Primary	Intragastric Restriction	Investigational, not FDA approved		www.silimed.com	Summary and Publications	

space occupying				Restriction	approved				
Intragastric space occupying	Spatz	Spatz balloon	Primary	Intragastric Restriction	Investigational, not FDA approved		www.spatzmedical.com www.spatzmedical.com/con	Summary and Publications	
Laparoscopic	Vibrynt	Prevail	Primary/Revision	Paragastric adjustable Implant	Clinical trials – 3 in Investigational, not FDA approved		www.vibrynt.com		
Pharmaceutical	(Generic Pharmaceutical)	Sodium Morrhuate	Revision	Anastomotic sclerosis	On market		Sodium Morrhuate Link		Catalano MF, Rudic G, Anderson AJ et al. Weight gain after bariatric surgery as a result of a large gastric stoma: endotherapy with sodium
Surgical Procedure		Banded gastric plication		Gastric restriction	One case series; Investigational, not FDA approved				
Surgical Procedure		Laparoscopic Gastric Plication	Primary/Revision	Gastric restriction	One multicenter clinical Investigational, not FDA approved				
Surgical Procedure	Ethicon	Cervical Banding	Primary/Revision	Cervical esophageal restriction	Animal studies (porcine)	Investigational, not FDA approved	www.ees.com customersupport@eesus.inj	Summary and Publications	