HemWell MD™

A Comprehensive Hemorrhoid Solution

Presented To:

Medfiniti

www.hemwellmd.com/info

The *Hemwellectomy*® Procedure

- ✓ This *non-thermal* solution is the first FDA approved electrosurgical treatment designed for the entire spectrum of hemorrhoid disease including *ALL grades (I-IV)*.
- ✓ Our device produces an extremely low-energy galvanic current causing profound vasospasm, platelet activation and thrombosis within the terminal branches of the superior rectal artery. In turn, there is dearterialization of the hemorrhoid by electrosurgical ligation with minimal vein and cushion tissue destruction.
- ✓ The ***Hemwellectomy's*** low-current is <0.08 watts of power, or on the order of a temporary transvenous pacemaker. Because of this extreme low current utilized, *there is very little tissue disruption avoiding common complications* seen with rubber band ligation.
- ✓ These complications **HemWellMD** physicians *avoid are the most cited by patients with a negative experience or outcome* from banding such as severe pain, infection, urinary retention, etc.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

CE

NICE National Institute for Health and Care Excellence

FDA U.S. FOOD & DRUG ADMINISTRATION

Hemwellectomy® Versus Other Solutions

	SURGERY	BANDING	HET BIPOLAR	INJECTION	STAPLING (PPH)	INFRARED	*HEMWELLECTOMY*
Avoid Surgery	✗	✓	✓	✓	✗	✓	✓
Reduce Size of Hemorrhoid	✓	✓	✓	✓	✓	✓	✓
No need to take time off for recuperation	✗	✗	✓	✗	✗	✗	✓
Rarely Painful	✗	✗	✗	✗	✗	✗	✓
No Bowel Preparation	✗	✗	✗	✗	✗	✗	✓
No need for General Anesthetic	✗	✗	✗	✗	✓	✓	✓
No Risk of Infection	✗	✗	✗	✗	✓	✓	✓
FDA approved & recommended for all Grades (1-4)	*ONLY* Grades: III & IV	*ONLY* Grades: III & IV	*ONLY* Grades: I & II	*ONLY* Grades: I & II	*ONLY* Grades: III & IV	*ONLY* Grades: I & II	✓
	Preferred by specialists & not needed or approved/ VBC rules.	Patients freq. w/avoidable pain, high% relapse & bad experience	Req specialty trained GE at an expensive cost / lower ROI meant for unique cases	No APP/ GE only w/multiple treatments req, harsh chemical harden veins.	High proportion w/ persistent pain & fecal urgency w/rectal prolapse = multiple pat. visits.	Avg. 4 - 8+ visits over 3 mo. per global payer rules, burning typical.	***No*** risks / pain typical ***No*** recovery period ***No*** burning sensation ***No*** additional visits ***Yes*** to avg 5 min/case

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'The HemWell Procedure: Ligation of Arterial Flow'

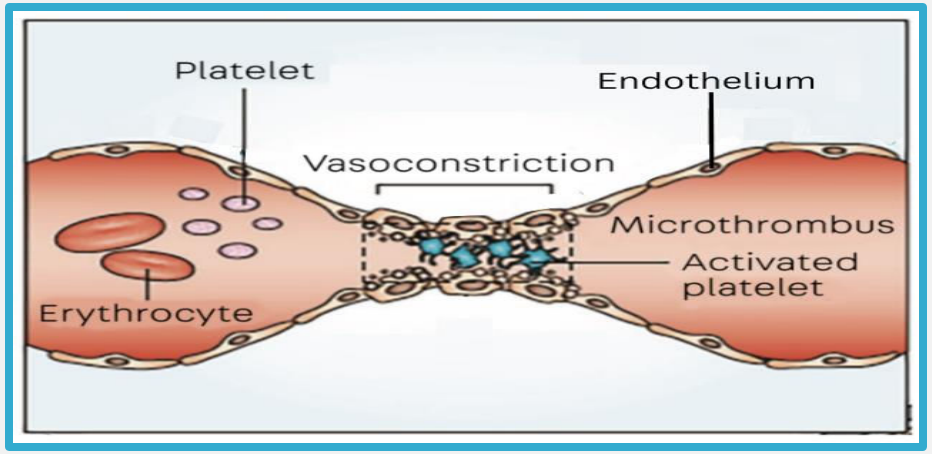
The Oxford Dictionary defines "ligate" as "tie up or otherwise close off (an artery or vessel)."

The HemWell procedure causes profound vasospasm which "closes off" the distal branches of the superior hemorrhoidal artery. In addition, thrombosis and ultimately fibrosis permanently occlude and close off arterial blood flow. This process, by definition, is a type of ligation.

There are multiple ways to ligate: banding, clipping, sealing, cauterizing and vasospasm with thrombosis:
For this reason, "codes 46945/46 have been relocated from the suture section since it does not involve sutures"[1]

Medical publications conclude our technology "closes off the blood supply"[2] resulting in "cessation of blood flow"[3], "disturbance in the blood supply"[4] and "clots"[5].

Direct current causes marked vasospasm as well as an electro-biochemical reaction producing H2 gas, NaOH, and OH-. The blood's pH increases causing protein to denature, damaging vascular endothelial cell membranes and fibrin deposition. Permanent ligation occurs only when both muscle spasm and thrombosis are present. The picture to the right illustrates vasospasm with thrombosis.



Rubber band hemorrhoid ligation “closes off” afferent and efferent blood flow causing thrombosis within the prolapsed hemorrhoid. The hemorrhoid takes days to be reabsorbed. The HemWell procedure acts at the submucosal level, not within the prolapsed hemorrhoid producing a more efficacious and immediate hemorrhoidal shrinkage.

We understand a surgeon might feel coagulation is not ligation because ligation occurs at a specific location while coagulation is a non-localized process. The HemWell procedure, however, acts at a specific location, the hemorrhoid’s afferent circulation (branches of the superior hemorrhoidal artery). It “closes off” the hemorrhoid’s arterial blood supply while preserving veinous return.

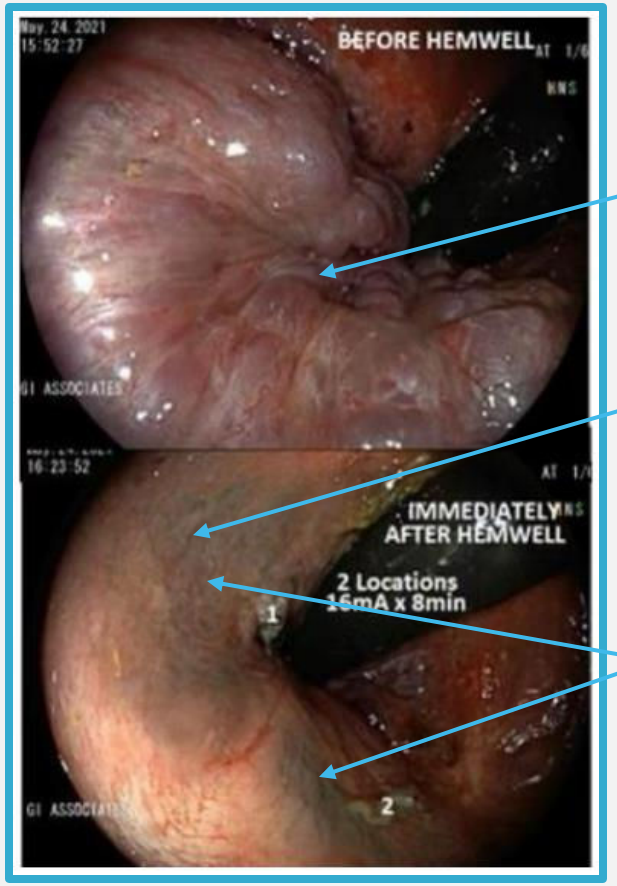
Ligation by electrocoagulation is common in surgical practice, including tubal ligation. “Ligation” and “coagulation” are terms used interchangeably in this medical reference: “Laparoscopic tubal ligation or coagulation is an operation done for permanent birth control.”[6] Describing the different types of tubal ligation, this resource indicates the electric current may be “Bipolar tubal coagulation” or “Monopolar tubal coagulation.”[7] Tubal ligation by coagulation occurs at a specific location and “closes off” one side of the fallopian tube from the other. It, therefore, becomes a type of ligation.

HemWell’s very low energy current creates profound smooth muscle contraction without destroying the muscle cells, mucosal endothelial cells, or nerve cells (much like a pacemaker does not damage myocardial cells). The current has direct electrical effects and causes an electro-biochemical reaction within the blood. This results in fibrin deposition, protein denaturing and vascular endothelial cell membrane damage which enhances thrombogenesis.[8] Vessels with smooth muscle, the hemorrhoid’s arteries and arterioles are most affected. There is little to no effect on the hemorrhoidal cushion

or veins because they have no smooth muscle. The current does not enter the prolapsed hemorrhoid since it lies in the opposite direction of the current flow which is toward the patient's left hip. Coagulation does not occur within the prolapsed hemorrhoid and, therefore, if punctured will bleed.

Because the HemWell procedure "closes off" or ligates only the afferent circulation and has little to no effect on the efferent circulation, it causes immediate shrinkage of the hemorrhoid to the submucosa. There is no way to produce this rapid degree of hemorrhoidal shrinkage except by ligation of arterial blood flow with preservation of veinous return.

The photos to the right confirm the HemWell procedure's mode of action. The top photo is a Grade 3 hemorrhoid before treatment. The bottom photo was taken 10 minutes following treatment with 16 mA administered at two sites for 8 minutes each, 16 minutes in total. These pictures confirm the dramatic effect ligation of the afferent circulation with preservation of the efferent circulation has.



Grade 3 hemorrhoid prior to treatment

Complete shrinkage of the hemorrhoid to the submucosa immediately following 16 minutes of treatment

Dark spots represent deoxygenated blood present within the submucosal hemorrhoid

HemWell MD™

Just as tubal ligation can be performed by suture or electrical energy, so can hemorrhoid's afferent circulation be ligated by suture or electrical energy.

Please see our website for a more detailed explanation of our mode of action at www.HemWellMD.com.

Significant scientific and medical evidence confirms the HemWell procedure "closes off" the hemorrhoid's afferent circulation and meets the definition of ligation: as used in common medical practice, stated in medical dictionaries, and used in medical literature.

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