Clinical Evidence

Toouli 2012

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vBloc neurometabolic therapy

Vagal Blocking: Treatment of Obesity Related Type 2 Diabetes and Blood Pressure – 18 Month Results

DESCRIPTION

Prospective, multi-center, obese subjects with DM2	28 subjects *n=21 subjects at 18 months with ≥12 hours therapy per day* 5 centers
4 and 12 weeks follow-up 6, 12, 18 months follow-up	

RESULTS & SUMMARY

- **vBloc was safe, and associated with sustained clinically significant weight loss and improvements in glycemic control and blood pressure.**

Parameters	Wk 4	Wk 12	Mo 6	Mo 12	Mo 18
EWL (%)	14	23	28	30	26
HbA1c (%)	-0.7	-0.9	-0.9	-1.1	-1.2
FPG (mg/dL)	-25	-32	-31	-36	-37
MAP (mmHg)	-10	-10	-12	-10	-13
DBP (mmHg)	-12	-9	-13	-12	-16

- **1 SAE related to implant procedure**
- **No SAEs related to the device or therapy**

To learn more, visit www.vBloc.com

vBloc neurometabolic therapy

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The Maestro® Rechargeable System is indicated for use in weight reduction in patients aged 18 years through adulthood who have a Body Mass Index (BMI) of 40 to 45 kg/m², or a BMI of 35 to 39.9 kg/m² with one or more obesity related co-morbid conditions, and have failed at least one supervised weight management program within the past five years. The device should not be implanted in patients with cirrhosis, portal hypertension, esophageal varices or a significant hiatal hernia; patients for whom magnetic resonance imaging (MRI) or diathermy is planned; patients with an implanted electrical medical device or gastrointestinal device or prosthesis.

The most common related adverse events include pain, heartburn, nausea, dysphagia, eructation, and abdominal cramping.

Carefully read the product instruction manuals for complete safety information.