

A little help goes a long way. Endoscopic Sleeve Gastroplasty (ESG) reduces stomach size using sutures placed through the mouth during an outpatient procedure – helping patients eat less, feel fuller faster, and achieve significant, lasting weight loss when combined with lifestyle modifications.



No incisions. No scars. Quick recovery.

Endoscopic Sleeve Gastroplasty (ESG) may be an effective option for adults with a BMI of 30–50 who want a minimally invasive, lasting weight loss solution.



In a randomized clinical study,¹ ESG patients:

Lost an average of

13.6% total body weight at year one.

68% maintained

25%

excess body weight loss or more, 24 months after the procedure.

ESG is performed using the OverStitch™ Endoscopic Suturing System and OverStitch NXT™ System.

There are risks associated with all medical procedures. Please talk with your doctor about the risks and benefits associated with the ESG procedure. For questions about these devices contact Boston Scientific, US Customer Service +1-888-272-1001 or visit Endura.com.

Endoscopic Suturing System & OverStitch NXT Endoscopic Suturing System ("OverStitch") for bariatric surgery: IMPORTANT SAFETY INFORMATION

Talk with your doctor to fully understand all the risks and benefits associated with using this device. Ask your doctor whether this device is right for you.

INDICATIONS FOR USE:

OverStitch is for adult patients with obesity with BMI between 30-50 kg/m². OverStitch can reduce the size of the stomach by stitching the inside. It can also fix the stomach outlet from previous bypass surgery.

When OverStitch is used to help with weight loss, you need to follow a healthy diet and exercise program. You may not lose weight if you do not adopt healthy habits.

CONTRAINDICATIONS:

Your doctor will ask you about your medical history and perform a physical exam to decide if OverStitch is right for you. At the time of your procedure, the doctor may detect internal issues that prevent you from receiving OverStitch. For example, stomach ulcers or inflammation in the stomach may impact device placement.

You should not receive OverStitch if you: have a large hiatal hernia; have a history of bleeding in your stomach or food pipe; have a history of eating disorders; are pregnant; have bleeding disorders or are on blood thinners.

WARNINGS:

Talk to your doctor if you develop major, continued upper abdominal or back pain with difficulty breathing at any time after getting OverStitch. OverStitch contains nickel. Nickel may cause an allergic reaction in people with nickel sensitivity.

POTENTIAL RISKS:

Breathing any foreign object or substance such as food, saliva, or stomach contents into your lungs; Intestine blockage; Switching to a different type of surgery; Nausea, vomiting, dehydration; Bleeding; Infection; Swelling, redness, and pain in tissues caused by injury or damage; Damage to or a hole through the tissue around the stomach, food pipe or surrounding organs; Unintended transfer of fluid or gas from one area of the body to another; Pain; Feeling pins and needles; Buildup of fluid around the stomach; Air leaking from the lungs; Difficulty breathing; Narrowing or tightening in the stomach; Wound opening; Death.

MRI SAFETY INFORMATION:

OverStitch can be MRI scanned under certain conditions. Scanning under other conditions may result in injury or device malfunction. Inform your doctor or MRI technician of the device before undergoing an MRI scan. This allows them to take any needed precautions.

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1. Abu Dayyeh BK, Bazerbachi F, Vargas EJ, et al. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. *Lancet*. 2022;400:441–451.

CAUTION: U.S. Federal law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found at www.IFU-BSCI.com.
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