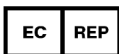




ENDOVASCULAR AORTIC STAPLER (EVAS): INSTRUCTIONS FOR USE



WARNING:
THIS DEVICE IS FOR INVESTIGATIONAL USE



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ABOUT THE ENDOVASCULAR AORTIC STAPLER (EVAS)

The Endovascular Aortic Stapler (EVAS) is a device intended to facilitate proximal fixation of an aortic-stent graft during endovascular aneurysm repair (EVAR) of an abdominal aortic aneurysm (AAA). Following an EVAR procedure, the EVAS is used to secure a stent graft to the internal aortic wall within the aneurysmal neck.

The EVAS is suitable for use with any manufactured stent-graft.

DEVICE DESCRIPTION

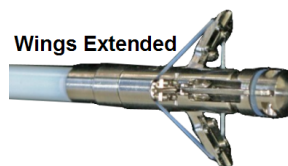
The EVAS is comprised of an elongated flexible hollow rod with a control handle (Figure 1). The head of the stapler is comprised of a round cassette with extendable “wings” that are pre-loaded with three stainless steel staples (Figure 2). The cassette is controlled via a switch on the control handle. As the handle is squeezed, the switch is released; this extends the wings to the appropriate diameter and pushes the staples out of the cassette, securing the stent graft to the aortic wall. Each staple opens to both sides, securing the stent graft to the aortic wall at two points.

The EVAS is available in three different wing span diameters (28, 32, 34 mm), according to the stent graft and aortic neck diameter. The staples are provided in one size, pre-installed and pre-positioned in the stapler. When the staples are fixed to the vessel wall, a constant distance between each staple is maintained.



Figure 1. Endovascular Aortic Stapler (EVAS).

Figure 2. EVAS Head (Close-Up)



DEVICE TECHNICAL SPECIFICATIONS

Available Diameters: 28, 32, or 34 mm
Subject-contacting materials: Biocompatible Stainless Steel 316 LVM
Non-contact materials: Biocompatible Ultem
Packaging: Sterile; single-use only; cannot be re-sterilized

SAFETY INFORMATION

INDICATIONS FOR USE

The Endovascular Aortic Stapler (EVAS) is a device used as an adjunct to the EVAR procedure. The EVAS is intended to aid in the proximal fixation of approved endovascular stent grafts to the aortic wall.



WARNING:
USE OF THIS DEVICE FOR APPLICATIONS OTHER THAN THOSE INDICATED HAS THE POTENTIAL FOR SERIOUS COMPLICATIONS, AND THEREFORE IS NOT ALLOWED.

CONTRAINDICATIONS

The EVAS should not be used under the following circumstances:

- The patient is allergic to one of the materials that comprise the device.
- The patient has ruptured or leaking aneurysms, or suffers from dialysis-dependent renal failure.

POSSIBLE ADVERSE DEVICE EFFECTS

Possible adverse reactions which may occur in conjunction with the use of any anastomosis technique include: damage to vessels, aortic laceration, hemorrhage, infection at the treated site and foreign body reaction to the clips/sutures, excessive operative bleeding, thrombosis, inflammation, hematoma, false aneurysm, continued anastomosis enlargement, decreased blood flow to the iliac or femoral arteries, allergic reaction to the clips/sutures, clips/suture detachment, rejection of the clips, extrusion (a pushing out) or erosion (a wearing away) of the artery where the clips meet the inside of the artery wall, device/clips deterioration or breakage, re-operation, renal effects, peripheral vascular events, fistula formation, adhesions, fluid accumulation, seroma, and DVT.

Non-device related major adverse events may include: anesthetic complications such as cardiac and respiratory complications, and abnormal reaction or allergies to anesthetic drugs, as well as device unrelated stroke, organ failure or death.

Most of these complications are not restricted to the EVAS and are similar to those associated with the conventional and EVAR repair. Biocompatibility related complications may be specifically related to the EVAS; however, the stapler clips are made of medical grade 316 LVM and the biocompatibility of the final sterile clips has been fully validated according to applicable international standards.

WARNINGS AND PRECAUTIONS

- The EVAS device is provided sterile. The EVAS packaging should be examined for integrity before use. If the package is open or damaged, or sterility or performance of components is subject to compromise, the EVAS should not be used.
- The EVAS is intended for single use only: Do Not Re-Sterilize.
- Do not use the device if expiration date has passed.
- Squeeze the EVAS handle as far as it will go when applying the staples. Failure to do so may result in improperly formed staples, and compromised integrity of the fixation.
- To avoid damage or contamination, always wear sterile gloves and use a-traumatic instruments when handling the EVAS device.
- The EVAS should not be used in the following circumstances:
 - If the EVAS wings do not open.
 - If the EVAS trigger does not work.
 - If the pre-installed staples are not released.
 - If you have difficulty navigating or positioning the device.
 In all such situations, discard the device and replace with a new one. Return all faulty devices to the manufacturer.

STORAGE

Store the EVAS in a dry, cool, dark place.

SAFE DISPOSAL OF THE DEVICE

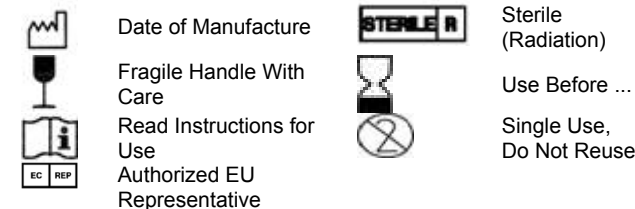
The used EVAS should be disposed in biohazard waste.

QUALIFIED USERS AND TRAINING

Only a specialized surgeon or radiologist with adequate training should perform an endovascular aortic repair using the EVAS.

ACCOMPANYING LABELS

The EVAS packaging may include labels, as indicated below:



USING THE EVAS FOR AN EVAR PROCEDURE

The EVAS is used for a treatment procedure, as detailed below:

1. Following standard procedure,
 - a. Prepare the patient for the EVAR.
 - b. Introduce and place the stent in the aorta.
 - c. Confirm placement of the stent.
2. After the proximal endovascular stent graft (EVG) is deployed, introduce the appropriately sized head of the EVAS via the same incision used for EVAR, until it is positioned opposite the EVG markers.
3. Press the EVAS control handle trigger until the wings are visibly extended to the inner diameter of the EVG.



WARNING:

SQUEEZE THE EVAS HANDLE AS FAR AS IT WILL GO WHEN APPLYING THE STAPLES. FAILURE TO DO SO MAY RESULT IN IMPROPERLY FORMED STAPLES, AND COMPROMISED INTEGRITY OF THE FIXATION.

4. Continue to the second trigger phase on the control handle to deploy the staples in to the EVG and aneurysmal neck. When the levers are fully displaced, the staples are released from the wings and pass through the walls of the EVG and the walls of the aorta, fastening them together.
5. Release the EVAS handle gently retract the head of the stapler.
6. Follow standard closing procedure as per a standard EVAR.
7. Verify placement of the secured stent and the absence of endoleak via arteriogram.

SERVICE INFORMATION

For all problems related to the EVAS, or to return the device due to a malfunction, contact one of the following:

ES Vascular Ltd.
20 Yohanan Hasandlar St.
Haifa Bay
Israel
Tel: +972 (0)4.840.8737
Fax: +972 (0)4.840.8697
Email: contact@esvascular.com

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COMPLIANCE STANDARDS

Standard No.	Standard Name	FDA	EU
Labeling Certifications			
ISO 15223:2000	Medical devices symbols to be used with medical device labels, labeling and information to be supplied	√	
EN 980:1996+A1:1999+A2:2001; EN 980:2003	Graphical symbols for use in the labeling of medical devices	√ 1996	√ 2003

Standard No.	Standard Name	FDA	EU
EN 1041:1998	Information supplied by the manufacturer with medical devices		√
Packaging Certifications			
EN 8681:1997	Packaging materials and systems for medical devices which are to be sterilized. Part 1: General requirements and test methods		√
AAMI/ANSI /ISO 11607:2000	Packaging for terminally sterilized medical devices	√	
ASTM F1980:2002	Standard guide for accelerated aging of sterile medical device packages	√	
ASTM F1886:1998 (2004)	Standard test method for determining integrity of seals for medical packaging by visual inspection	√	
Gamma Sterilization Certifications			
AAMI/ TIR 27: 2001	Sterilization of health care products-- Radiation sterilization substantiation of 25kGy as a sterilization dose method VDmax		
AAMI / ANSI / ISO 117371:1995	Sterilization of medical devices--microbiological methods. Part 1: Estimation of the population of microorganisms on product	√	
AAMI / ANSI / ISO 117372:1998	Sterilization of medical devices--microbiological methods. Part 2: Tests of sterility performed in the validation of a sterilization process	√	
AAMI / ANSI / ISO 11137:1994 (Amendment 1:2002)	Sterilization of health care products. - Requirements for validation and routine control radiation sterilization	√	
BS EN 552:1994; A1:1999; A2:2000	Sterilization of medical devices. - Validation and routine control of sterilization by irradiation		√
EN 556:1994	Sterilization of medical devices - requirements for medical devices to be labeled sterile		√
EN 5561: 2001	Sterilization of medical devices. - Requirements for medical devices to be designated 'Sterile'. Part 1: Requirements for terminally sterilized medical devices		√
Implants and Materials Certifications			
AAMI / ANSI / ISO 109931:1997	Biological evaluation of medical devices. Part 1: Evaluation and testing	√	√
AAMI VP20:1994 (Revision of ANSI/AAMI VP 201986)	Cardiovascular implants vascular prostheses.	√	
ASTM F1801-97:1997	Standard practice for corrosion fatigue testing of metallic implant materials	√	
ASTM F2119-01:2001	Standard test method for evaluation of MR image artifacts from passive implants	√	

Standard No.	Standard Name	FDA	EU
ASTM F62102:2002	Standard specification for stainless steel forgings for surgical implants. (Materials)	√	
ISO 58321:1997	Implants for surgery, metallic materials. Part 1: Wrought stainless steel	√	
ISO 14630:1997	Nonactive surgical implants General requirements.	√	√
EN 120061:1999	Non-active surgical implants: Particular requirements for cardiac and vascular implants. Part 1: Heart valve substitutes		√
EN 120062:1998	Non-active surgical implants. Particular requirements for cardiac and vascular implants. Part 2: Vascular prostheses including cardiac valve conduits		√
EN 120062:1998	Non-active surgical implants. Particular requirements for cardiac and vascular implants. Part 3: Endovascular devices		√
EN 12011:1998	Instrumentation to be used in association with non-active surgical implants. General requirements		√
Clinical Certifications			
United States (US) 21 Code of Federal Regulations (CFR) Part 812	Investigational device exemptions	√	
ICH GCP	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline; 1997	√	
EN ISO 14155-1:2003	Clinical investigation of medical devices for human subjects. Part 1: General requirements		√
EN ISO 14155-2:2003	Clinical investigation of medical devices for human subjects .Part 2: Clinical investigation plans		√
Risk Analysis Certifications			
ISO 14971:2000	Medical devices Application of risk management to medical devices	√	√
IEC 60812(1985)	Analysis technique for system reliability Procedure for failure modes and effects analysis (FMEA)	√	
QA Certifications			
United States (US) 21 Code of Federal Regulations (CFR) Part 820	Quality system regulation	√	
EN ISO 13485:2003	Medical devices. Quality management systems: Requirements regulatory purposes		√