I N S T R U C T I O N S F O R U S E

VANGUARD Ultrasonic Shear ET+

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CE 0086

GENERAL

Read these instructions carefully before using the product described. If you have questions concerning the instructions for use or handling of the product, please contact our Customer Service Centre at service@vanguard.de or contact our field staff before using the product on patients.

General information

These instructions contain certain notations which are intended to help you understand the functions and meaning of the text more quickly:

→ Instructions

- Lists

Device information

This product may only be operated if its safe use is guaranteed. Observe the notes, warnings and precautions!

VANGUARD AG assumes no liability for damages that arise from improper operation of the VANGUARD Ultrasonic Shear ET+ and/or disregard of these instructions for use.

VANGUARD AG and the manufacturer of the original product, Ethicon Endo-Surgery, Inc. (Cincinnati, OH 45242-2839 USA, a subsidiary of the Johnson & Johnson Company), are not affiliated companies; the device is fully refurbished solely by VanguardAG, who markets the device without collaboration by Ethicon Endo-Surgery, Inc. "Harmonic" is a protected brand of the original product’s manufacturer, Ethicon Endo-Surgery, Inc. (Cincinnati, OH 45242-2839 USA, a subsidiary of the Johnson & Johnson Company) or an affiliated company.

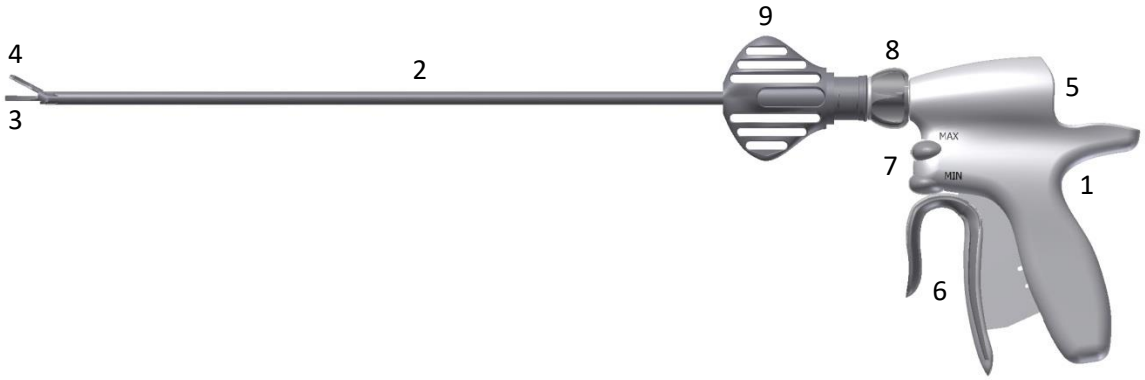
Packaging labelling and symbols

Content:
One (1) sterile VANGUARD Ultrasonic Shear ET+
+ accessories one (1) sterile torque wrench.
+ packaging material one (1) blister, two (2) silicon binders and ETM+ one (1) safety cap
The medical device may only be used until the specified "Expiry date" ( ).

	For single use
	Do not resterilise
	Do NOT use if the sterile packaging is damaged or has been opened
	Sterile, sterilisation using ethylene oxide
	Expiry date
	Serial number
	Store away from light
	Store in a dry place
	Information about acceptable ambient temperature during storage and transportation
	Read the instructions
	CE Mark with the identification number of the notified body
	Manufacturer
	Item number

PRODUCT DESCRIPTION

The VANGUARD Ultrasonic Shear ET+ is intended for soft tissue separation and coagulation. The instrument can also be used for preparation and grasping without necessitating ultrasound activation.



The VANGUARD Ultrasonic Shear ET+ consists of a housing (1) with control elements, a connection for the hand-piece (5), as well as the shaft (2) with a distal work field consisting of blade (3) and clamp arm (4). The instrument is hand-activated with the control button (7) located on the housing. “MIN” and “MAX” performance levels can be selected. Activating the trigger (6) closes the clamp arm, which then grasps the tissue. Confirmation that the clamp arm is completely closed will be provided by audio-tactile feedback. For simplified use, the instrument shaft is pivoted. The shaft is rotated by using the rotation knob (8) integrated in the handle. Inserting the instrument into the body can occur with suitable trocars for instruments with an external diameter of 5 mm or directly through the incision.

The VANGUARD Ultrasonic Shear ET+ has integrated adaptive tissue technology. This is used by the generator to monitor the tissue’s separation and coagulation progress. Depending on the tissue state, the generator will automatically adjust the output performance. The user will hear an audible feedback in the form of a changed generator signal.

The delivery scope of every VANGUARD Ultrasonic Shear ET+ includes one sterile disposable torque wrench. The torque wrench is used to attach and detach the instrument at the hand piece.

The VANGUARD Ultrasonic Shear ET+ can only be used in combination with the following accessories and supplementary equipment from Ethicon Endo Surgery, Inc.: Hand piece (HP054), generator G11 (GEN11) with Software version 2013_1 or 2016_1 and adapter (HGA11). Observe the instructions for use of the accessories and supplementary equipment.

Intended use

The VANGUARD Ultrasonic Shear ET+ is intended for use to aid the separation and coagulation of soft tissue in combination with the accessories and supplementary equipment listed in the Technical Data section. Safe separation and coagulation of vessels is ensured for vascular diameters of up to 5 mm. The instrument may not be used for the coagulation of larger vessels.

The VANGUARD Ultrasonic Shear ET+ can be used in general surgery, plastic surgery, paediatrics, gynaecology, urology, exposition of orthopaedic structures (such as the spine and joint cavities) during other open and laparoscopic procedures. It can also be combined with other electro-surgical and conventional instruments, as well as with laser instruments.

The medical device may only be used by a trained and experienced specialist physician. All applied surgical procedures and techniques are the responsibility of the attending physician. The information contained in these instructions of use must be observed.

Contraindications

The use of the VANGUARD Ultrasonic Shear ET+ is contraindicated for bone incisions and for gynaecological tube occlusion.

Technical data

REF No.	Working length	Shaft diameter	corresponding REF no. Instrument Ethicon Endo-Surgery	REF no. Accessories / Additional devices Ethicon Endo-Surgery		
				Generator	Adapter	Hand piece
35058	23 cm	5 mm	HAR23	GEN11 with Software version 2013_1 / 2016_1	HGA11	HP054
34958	36 cm	5 mm	HAR36	GEN11 with Software version 2013_1 / 2016_1	HGA11	HP054

CE 0086

This product bears a CE mark in accordance with the requirements in the EC directive 93/42/EEC.

SAFETY MEASURES AND WARNINGS

1. A basic understanding of the principles and techniques of surgical ultrasound procedures is a prerequisite to avoid dangers for patients and medical personnel and to protect medical devices and instruments from being damaged.
2. Surgical interventions may only be conducted by trained and experienced specialists familiar with the appropriate procedure.
3. The device may only be used and stored as intended to prevent damaging the device.
4. The VANGUARD Ultrasonic Shear ET+ is a component of the Ultrasound Surgical System. A suitable reserve system must be available in the event of system failure during use.
5. The VANGUARD Ultrasonic Shear ET+ may only be used in combination with compatible accessories and supplementary equipment (refer to Technical Data). The compatibility of the software version of the GEN11 generator must be checked. The respective operating instructions must have been read and understood.
6. The VANGUARD Ultrasonic Shear ET+ is a disposable product and only intended for single use on one patient.
7. The use of non-sterile instruments may cause infection of the patient. Instruments with damaged or opened sterile packaging may therefore not be used.
8. Before using the VANGUARD Ultrasonic Shear ET+, conduct a careful visual and functional inspection. Damaged or defective instruments may injure the patient or user and may therefore not be used.
9. Incorrect blade attachment or an exceeded life cycle of the hand piece may lead to high temperatures during use and therefore to injury of the patient or user. This error state can be recognised by high-pitched sounds issued by the blade or hand piece.
10. Any static electricity must be kept away from the Ultrasound Surgical System when activating the VANGUARD Ultrasonic Shear ET+. Electrical insulation and earthing must be ensured.
11. Do not immerse the VANGUARD Ultrasonic Shear ET+ in liquids. However, you may immerse the tip of the instrument in saline solution to remove any residues. This process is described in the appropriate section of these instructions for use.
12. To prevent damage to the instrument, the trocar or injuries to patients, the clamp arm of the VANGUARD Ultrasonic Shear ET+ must be closed during insertion or retraction through the trocar or the incision.
13. Changing the blade in any form is prohibited. This could lead to malfunction and injuries to the patient or user.
14. Prevent the blade from touching metal or plastic objects or instruments when activating the VANGUARD Ultrasonic Shear ET+. If the blade comes into contact with clamps, clips or other instruments during simultaneous activation, the blade may be damaged and could lead to its breakage. The generator will issue an error message when the blade is damaged. These error messages must be noted.

15. The exposed parts of the blade and shaft can separate or coagulate tissue when the instrument is activated. You should therefore prevent unintended contact between these surfaces when activating the instrument.
16. For use on solid organs, you may have to take additional measures to achieve successful haemostasis. Large amounts of tissue should be separated slowly in several stages, as internal structures cannot be taken into sufficient consideration. In the event of limited knowledge of the internal structures, the separation of large vascular and biliary bundles must be avoided.
17. Tissue must always be checked for reliable haemostasis, which must be ensured with the use of suitable techniques.
18. The use of energy sources with temperature effect on tissue creates smoke and spray. There are indications that smoke and spray may be carcinogenic or infectious. The use of goggles or masks and sufficient smoke-evacuation measures are recommended when using the VANGUARD Ultrasonic Shear ET+ for open and laparoscopic surgeries:
19. Any spray created during activation in fatty tissue is potentially flammable. To protect patients and users from injury, electro-surgical instruments may not be activated during the activation of the VANGUARD Ultrasonic Shear ET+ .
20. When activating the instrument, direct contact between the blade and clamp arm (no tissue between the blade and clamp arm) may damage the tissue pad in the clamp arm. Temperature increases at the blade, clamp arm and distal shaft may also occur and could damage the instrument. If the instrument is damaged, the generator issues an error message.
    The instrument with a closed clamp arm may only be activated when there is tissue between the blade and the clamp arm. If cutting is conducted with the active side of the blade, the clamp arm must be open.
21. The activation of the instrument causes the blade, the clamp arm and the distal 7 cm of the shaft to heat up. Avoid unintentional contact with sterile wipes, surgical clothing or other flammable materials as well as with tissue.
22. Accumulated blood or tissue could lead to higher temperatures in the distal shaft area. To prevent risk of burning, the removal of visible residue in the distal shaft area is recommended.
23. Longer activation and unintentional activation on solid surfaces (e.g. bone) lead to blade heating. This may cause the instrument’s malfunction.
24. To protect the user or third parties from infection, the instruments and torque wrench must be disposed of after application.

HANDLING INSTRUCTIONS

Transport

Temperature: -29 °C to +50 °C

Storage

Temperature: not exceeding room temperature

Removal from packaging

→ Check that the packaging is not damaged. If the packaging is damaged, discard the instrument and use another one.

→ Remove the instrument from its packaging under aseptic conditions and transfer it to a sterile working environment. Do not throw the instrument.

→ Check the VANGUARD Ultrasonic Shear ET+ for obvious defects indicating external influence. The VANGUARD Ultrasonic Shear ET+ may not be used if there are any obvious damages.

Application

→ With consideration to aseptic standards, create an access to the surgical site, via which you can feed or insert the VANGUARD Ultrasonic Shear ET+.

→ Connect the VANGUARD Ultrasonic Shear ET+ to a compatible, sterile hand piece (refer to Technical Data). Place the instrument onto the hand piece and attach it manually be rotating the shaft in clockwise direction. To ensure complete attachment of the instrument, only use the provided torque wrench to prevent damage to the instrument and hand piece. Hold the hand piece and rotate the torque wrench in clockwise direction from the hand piece until the torque wrench clicks twice to confirm correct attachment.
To facilitate the application or removal of the torque wrench onto or from the shaft, the clamp arm must be closed. This requires a completely closed trigger.

→ Connect the VANGUARD Ultrasonic Shear ET+ and attached hand piece to the compatible generator (refer to Technical Data). Activate the generator only once it is connected.

→ To initialise the VANGUARD Ultrasonic Shear ET+, follow the menu prompts of the generator. Instruments with the error message “Advanced features not available for this instrument” were not initialised correctly. In this case, do not use the instrument for application.

→ The maximum output level (MAX) is set to Stage 5 on the generator and cannot be adjusted. The minimum output level (MIN) can be adjusted on the generator. To start, the recommended minimum output level is preset to Stage 3.

→ Ultrasound energy is activated via the appropriately marked buttons on the instrument.

→ Select a high output level for high cutting speed and a low output level for deep coagulation effect.

→ When inserting and retracting the VANGUARD Ultrasonic Shear ET+ through the trocar or incision, the clamp arm must be closed. This requires a completely closed trigger.

→ Once the application is completed, deactivate the generator at the mains switch.

→ Disconnect the VANGUARD Ultrasonic Shear ET+ from the hand piece with the provided torque wrench. Detaching the instrument from the hand piece follows in the same way as the attachment, whereby rotation is in the opposite direction.

→ Dispose of the torque wrench and the VANGUARD Ultrasonic Shear ET+. Attention: Do not dispose of the hand piece!

NOTE: For easier access to the tissue and a better view of the surgical site, you can change the alignment by rotating the shaft. Operate the rotation knob on the handle with your forefinger until the required position is reached. Rotation is continuous in both directions.

NOTE: The instrument's best possible performance can be achieved if the blade is free of residue and the clamp arm pressed the tissue against the blade. This requires a completely closed trigger. The complete closure and release of the operating lever from this position is confirmed by audio-tactile feedback.

NOTE: The VANGUARD Ultrasonic Shear ET+ can be used to separate tissue with two methods. The tissue can either be grasped between blade and clamp arm and separated under pressure or separated by traction with the active side of the blade opposite the clamp arm. To cut with the activate side of the blade, the clamp arm must be open.

NOTE: The energy, which the VANGUARD Ultrasonic Shear ET+ emits to the tissue, and the resulting effect on the tissue depend on, for example, the following factors: selected output level, blade properties, the pressure or traction on the tissue, the tissue type, tissue tension and tissue pathology, as well as the applied surgical technique.

NOTE: The activation of the VANGUARD Ultrasonic Shear ET+ is confirmed by the generator with an audible signal. The signal tone changes as soon as there is no or only a little tissue between the blade and the clamp arm. A changed signal tone indicates a thermal change in the blade. Due to the indirect correlation between the changed blade temperature and the tissue status, the achievement of the intended effect on the tissue should be verified by conventional controls, e.g. visual or tactile, with appropriate subsequent reactions.

NOTE: To remove residues, the distal end (blade, clamp arm and shaft) should be activated in saline solution. You can use moist gauze swabs to wipe the blade. Do not use abrasive cleaning agents.
Residual tissue in the clamp arm is removed with a clamp, whereby the instrument may not be activated.

NOTE: Only dispose of the torque wrench after completing the application, as it may still be required for repeat tightening and detachment.

Disposal

The product must be disposed of in accordance with the applicable national laws and directives.