



INSTRUCTIONS FOR USE

VANGUARD Ultrasonic Shear ET7



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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 ET7 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 Vanguard AG, who markets the device without collaboration by Biosense Webster, 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 VANGUARD Ultrasonic Shear ET7

+ accessories one (1) sterile torque wrench.

+ packaging material one (1) blister, two (2) silicon binders and ETM7 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



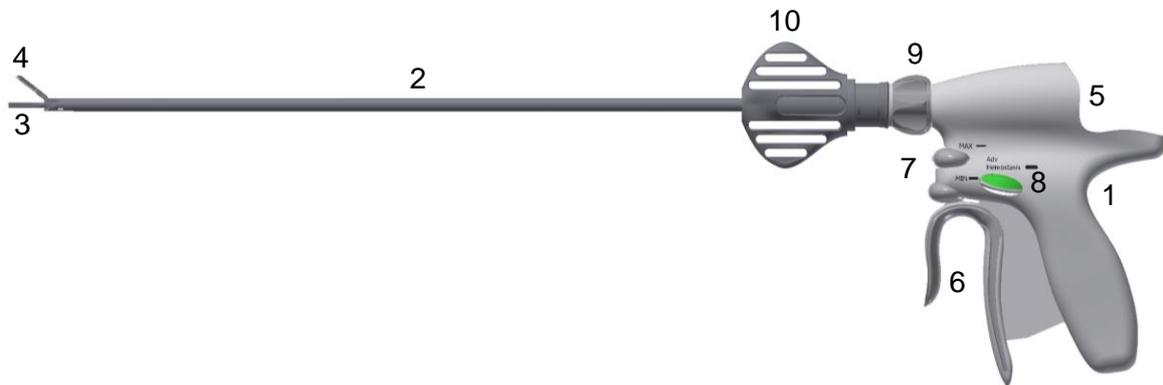
Manufacturer



Item number

PRODUCT DESCRIPTION

The Vanguard VANGUARD Ultrasonic Shear ET7 is intended for soft tissue separation and coagulation. The instrument can also be used for preparation and grasping without necessitating ultrasound activation.



The Vanguard VANGUARD Ultrasonic Shear ET7 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 located on the housing. You can select and power level "MAX" for cutting small vessels and "MIN" (7) for vessels up to and including 5 mm or with the control button "Advanced Hemostasis" (8, on both sides) for vessels up to and including 7 mm. By way of example, vessel thicknesses are illustrated with different line thicknesses next to the control buttons.

Activating the trigger closes the clamp arm (6), 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 (9) integrated in the housing. 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 "Adaptive Tissue Technology" is integrated in the VANGUARD Ultrasonic Shear ET7. 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 power output. The user will hear an audible feedback in the form of a changed generator signal.

The delivery scope of every VANGUARD Ultrasonic Shear ET7 includes one sterile disposable torque wrench (10). The torque wrench is used to attach and detach the instrument at the hand piece.

The VANGUARD Ultrasonic Shear ET7 may only be used in combination with the following accessories and additional devices from Ethicon Endo Surgery, Inc.: Hand piece (HP054), generator G11 (GEN11) with Software version 2013_1 / 2016_1 and adapter (HGA11). Observe the instructions for use of the accessories and additional device.

Intended use

The VANGUARD Ultrasonic Shear ET7 is intended for use to aid the separation and coagulation of soft tissue in combination with the accessories and additional devices listed in the Technical Data section. Safe separation and coagulation of vessels is ensured for vascular diameters of up to 5 mm. When using the "Advanced Hemostasis" function, vessels up to and including 7 mm can be coagulated. The instrument may not be used for the coagulation of larger vessels.

The VANGUARD Ultrasonic Shear ET7 can be used in general surgery, plastic surgery, paediatrics, gynaecology, urology, thoracic surgery, in the exposition of orthopaedic structures (such as the spine and joint cavities), in the sealing *and transection* of lymphatic vessels and 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 VANGUARD Ultrasonic Shear ET7 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
35033	23 cm	5 mm	HARH23	GEN11 with Software version 2013_1 / 2016_1	HGA11	HP054
35034	36 cm	5 mm	HARH36	GEN11 with Software version 2013_1 / 2016_1	HGA11	HP054



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

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 ET7 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 ET7 may only be used in combination with compatible accessories and additional devices (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 ET7 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 ET7, 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 or a defective blade 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. If an error message about the advanced functions is displayed during application on the generator, the automatic adjustment of the output power by the "Adaptive Tissue Technology" and the sealing of vessels larger than 5 mm with the "Advanced Hemostasis" are not available.
11. Any static electricity must be kept away from the Ultrasound Surgical System when activating the VANGUARD Ultrasonic Shear ET7. Electrical insulation and earthing must be ensured.
12. Do not immerse the VANGUARD Ultrasonic Shear ET7 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.
13. To prevent damage to the instrument, the trocar or injuries to patients, the clamp arm of the VANGUARD Ultrasonic Shear ET7 must be closed during insertion or retraction through the trocar or the incision.
14. Changing the blade in any form is prohibited. This could lead to malfunction and injuries to the patient or user.

15. Prevent the blade from touching metal or plastic objects or instruments when activating the VANGUARD Ultrasonic Shear ET7. 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.
16. 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.
17. For use on solid organs, you may have to take additional measures to achieve successful Hemostasis. 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.
18. Tissue must always be checked for reliable Hemostasis. This may have to be ensured through appropriate techniques.
19. 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 ET7 for open and laparoscopic surgeries.
20. 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 ET7 .
21. 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.
22. If the "Advanced Hemostasis" function is used for longer periods, the fabric pad mounted in the clamp arm may be damaged.
23. The activation of the instrument causes the blade, the clamp arm and the distal 7 cm of the shaft to heat up.
24. Avoid unintentional contact with sterile wipes, surgical clothing or other flammable materials as well as with tissue.
25. 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.
26. Longer activation and unintentional activation on solid surfaces (e.g. bone) lead to blade heating. This may cause the instrument's malfunction.
27. 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: 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 ET7 for obvious defects indicating external influence. The VANGUARD Ultrasonic Shear ET7 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 ET7.
- Connect the VANGUARD Ultrasonic Shear ET7 to a compatible, sterile hand piece (refer to Technical Data). Place the instrument onto the hand piece and attach it manually by 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 ET7 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 ET7, follow the menu prompts of the generator. Instruments with an error message for the extended functions could not be initialised successfully. In this case, do not use the instrument for application.
- Ultrasound energy is activated via the appropriately marked buttons on the instrument: MAX, MIN and Adv Hemostasis for the function "Advanced Hemostasis".
- 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.

- The "Advanced Hemostasis" function can only be used when there is full contact between the blade and the clamp arm. For applications without complete contact between blade and clamp arm, "Advanced Hemostasis" should not be used.
- When using the "Advanced Hemostasis" function, it is recommended to use it to fully separate the vessel.
- If the "Advanced Hemostasis" function is inadvertently interrupted, it must be reactivated in the case of fixed tissue between blade and clamp arm.
- Activation of the "Advanced Hemostasis" function can be switched to the MIN control button on the generator. After the switch, the "Advanced Hemostasis" control button is deactivated.
- 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 ET7 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 ET7 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.
- The torque wrench and the VANGUARD Ultrasonic Shear ET7 must be discarded.
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 housing with your forefinger until the required position is reached. Rotation is continuous in both directions.

NOTE: The instrument is able to best achieve sealing results for tissues which are fully located between the clamp arm and 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. The blade should also be free of residue.

NOTE: The VANGUARD Ultrasonic Shear ET7 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 ET7 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 ET7 is confirmed by the generator with an audible signal. The signal tone changes as soon as power output is regulated by the “Adaptive Tissue Technology”. A changed signal tone indicates a thermal change in the blade. The thermal changes can be caused by little or no tissue between the blade and the clamp arm or liquids. 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.