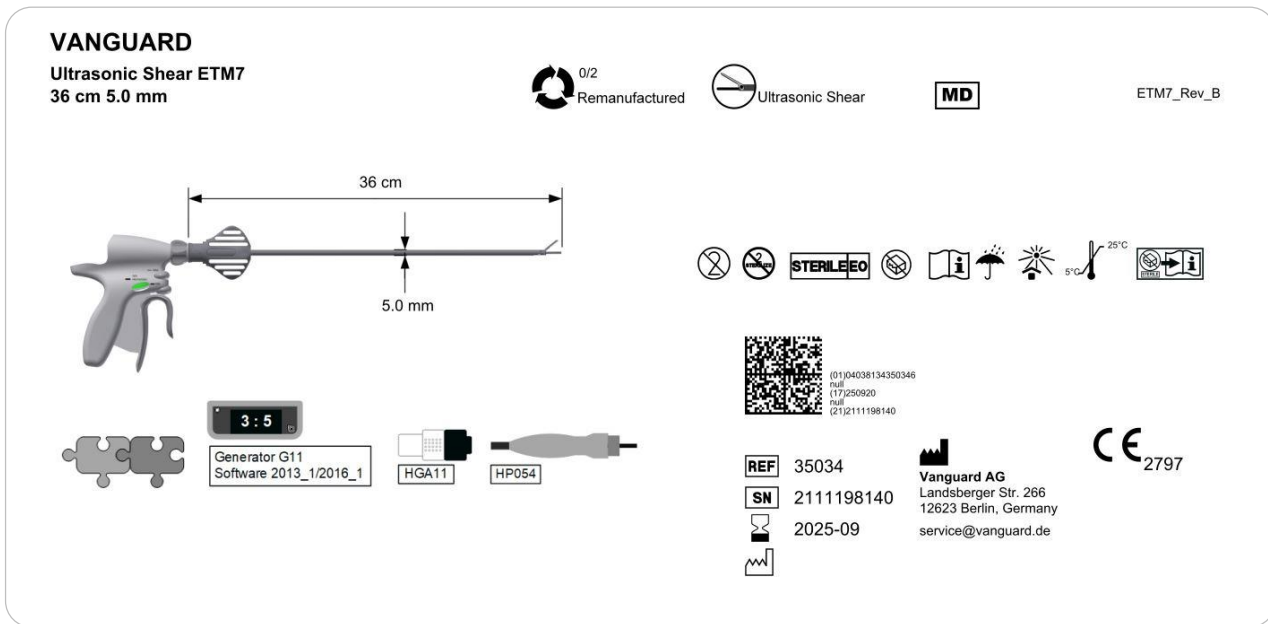


Product Information Label, IFU and packaging

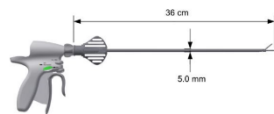
Multi language product label CE

Information on the label:

1. Name
2. Technical properties and details
3. Informations of the manufacturer
4. Storage conditions
5. Identification number
6. Use-by-date
7. Number of Remanufactured cycles
8. CE marking with identification number of notified body



Product Label - Symbols



Usable length and shaft diameter



Compatible with Software Versions



Adapter



Hand Piece



Product



This is a remanufactured product with number of cycles already performed X / maximum number of possible reprocessing cycles Y



Do not reuse



Do not resterilize



Sterile, sterilization with ethylene oxide



Do NOT use if the [sterile] packaging is damaged or opened



Consult the instruction for use



Keep in a dry place



Keep away from sunlight



Storage temperature limits



Check the instructions for use if the sterile packaging is damaged or unintentionally opened before use

IFU

Important and helpful information are available in the IFU

- Intended Use
- Reference to the OEM product
- Explanation of symbols
- Technical Data
- Compatible devices, accessories and settings
- Safety instructions
- Declaration of being substantial equivalent to the OEM product

➤ <https://www.vanguard.de/en/vanguard-oem-service/downloads/>

VANGUARD ULTRASONIC SHEAR ETM+ VANGUARD ULTRASONIC SHEAR ETS+

GEBRAUCHSANWEISUNG
 INSTRUCTIONS FOR USE
 MODE D'EMPLOI
 GEBRUIKSAANWIJZING
 ISTRUZIONI PER L'USO
 MANUAL DE INSTRUCCIONES
 INSTRUÇÕES DE UTILIZAÇÃO
 BRUKSANVISNING
 BRUKSANVISNING
 INSTRUKCJA OBSŁUGI

Deutsch
 English
 Français
 Nederlands
 Italiano
 Español
 Português
 Norsk
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 Polski

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Verpackungsbeschriftung und –symbole/Packaging and labelling symbols/
 Etiquetage et symboles sur l'emballage/Verpakkingstekst en –symbolen/
 Stampigliature e simboli sull'imballo/Étiquetas y símbolos del envase/Rot-
 ulagene e símbolos de embalagens/Påskrift og symboler på forpakningen/
 Förpackningsmärkning och symboler/Napisy i symbole na opakowaniu

Inhalt/Content/Contenu/Inhoud/Contenido/Conteúdo/Contento/Innehåll/Innhold/
 Zawartość/Vsebina:

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.

TECHNICAL DATA

REF No.	Work- ing length	Shaft diameter	corresponding REF no. Instrument Ethicon Endo-Sur- gery	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

Packaging

- One Blister packaging for both length
- Blister with tyvek sterile bag



Remanufacturing Process

Ultrasonic shears

Clean & Collect, Preparation in the hospital

1. Check device if defect
2. Wipe the ultrasonic shears from proximal to distal immediately after use
 - With a moist and lint-free cloth
 - Moisten with normal or distilled water
3. Also, wipe the handle thoroughly
4. Pay particular attention to the lever and buttons
5. Place ultrasonic shear in a Vanguard collection bag and put the original label inside!
6. Attention! Only for Harmonic ultrasonic shears:
 - Place the blade key in the collection bag
 - The device cannot be used without it

Clean & Collect



VORREINIGUNG

Hinweis: Zur Vorreinigung benötigen Sie keine Desinfektionsmittel und müssen nicht bürsten. Sie brauchen auch keine maschinelle Reinigung vornehmen. Sie erledigen die Vorreinigung quasi im Handumdrehen.



1. Unmittelbar nach Gebrauch das Produkt mit sauberem Wasser abspülen.



2. Vorsichtig mit einem fusselfreiem Tuch abtrocknen.



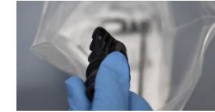
3. Mechanische Beschädigungen, speziell im Klingengebiet vermeiden.



4. Anschließend bitte vollständig trocknen lassen.

VERPACKUNG

Legen Sie die Ultraschallschere mit dem Klingenschlüssel (ohne den Schlüssel kann das Produkt nicht wiederhergestellt werden) in einen Sammelbeutel. Reusprodukte unbedingt mit dem Original-Label (Herstellernummer) in den Sammelbeutel legen. Den Sammelbeutel dann einfach in die Vanguard Box legen.



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1000003052/2108

Incomming inspection

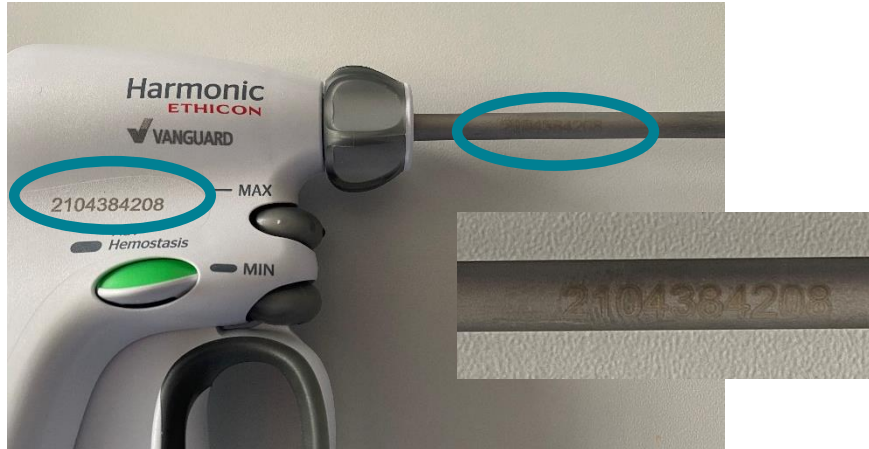
1. Products without OEM labels will be rejected
 - We always keep up with OEM recalls
-> patient safety
 2. Other reasons for rejection:
 - Instrument is too dirty/contaminated
Clean carefully (no visible blood stains)
 3. Defect device or parts
 - Inspect products before preparation
and treat them carefully
 - Maximum Remanufacturing cycle reached
- Additional Training with staff is sometimes needed



Laser marking and traceability

When arriving at Vanguard's:

1. Devices is getting decontaminated
2. Laser marked
 - 2x PID – Product ID number (10 digits)
 - 2x Vanguard



Remanufactured by Vanguard

1. Disassembly in individual components
2. Cleaning and disinfection of individual components



Remanufactured by Vanguard

1. Assembly of the individual parts
(replacement of worn parts)
2. Testing of all electronic and mechanic functions on each instrument
 - Defect products are being discarded
 - 100% Testing → No batch testing



Remanufactured by Vanguard

1. Packaging
2. Sterilization with ethylene oxide (low temperature)

