Vivano®Med Abdominal Kit, sterile

General Product Description/Intended Purpose
Vivano®Med Abdominal Kit is a foam dressing kit for negative-pressure wound therapy (NPWT) intended to transfer negative pressure to the wound bed and to transport exudates from the wound. The integrated Organ-Protection Layer is intended to protect the foam dressing against adhesion to organs and the organs against adhesion to the abdominal wall, additionally facilitating flow of wound exudate.

Vivano®Med Abdominal Kits are intended for use only in conjunction with the Vivano® system by PAUL HARTMANN AG or the ATMOS S042 NPWT negative-pressure wound-therapy system.

Vivano®Med Abdominal Kit is meant for use only in humans. No general restrictions for the usage of the Vivano® system in different patient populations (e.g., adults and/or children) are given. However, the Vivano® system has not been evaluated for use in pediatrics.

The Vivano® system may be used only by a physician or a qualified person in accordance with a physician's instructions.

Vivano®Med Abdominal Kit may be used only in acute-care surgical environments enabling aseptic working conditions. The abdominal dressing will most often be applied in the operating theatre.

In order to implement NPWT, the Vivano®Med Abdominal Kit must be combined with the following additional components of the Vivano® system:

- Vivano®Tec Exudate Canister
- NPWT control unit (e.g., Vivano®Tec Pro)

Application/Indication
Vivano®Med Abdominal Kit is indicated for the temporary treatment of the open abdomen, where closure of the abdominal wall is not possible or repeated access is required. This involves abdominal wounds with exposed visceral tissue, including abdominal wounds that can occur in the treatment of an abdominal compartment syndrome (ACS).

Reference Numbers

Product	Ref-No.	Total Dimension Organ Protection Layer [cm]	Dimension Foam Dressing [cm] & Quantity [pcs]	Dimension Hydrofilm [cm]	Kits per SBS*	Kits per Shipment Unit
Vivano®Med Abdominal Kit	409 720	Ø 65	38 x 25 x 1.6 cm (2x), perforated	20 x 30 (6x)	1	3
	409 721	Ø 65	38 x 25 x 1.6 cm (2x), perforated	20 x 30 (6x)	1	5

*SBS: Sterile barrier system

CP-C2.2-01, Annex 17, Version 2, valid from: 01.03.2020

Vivano®Med Abdominal Kit, sterile

Contraindications

Contraindications for the use of the Vivano® system:

- Malignant tumor wounds
- Non-enteric/unexplored fistulas
- Untreated osteomyelitis
- Necrotic tissue

Always protect vital structures with the Vivano®Med Abdominal Protection Layer. The Vivano®Med Foam must not be in direct contact with exposed nerves, anastomosis points, blood vessels or organs.

The VivanoMed® Abdominal Kit is not indicated in patients diagnosed with metastatic disease and bleeding diathesis.

Warnings and special precautions
Special precautions should be taken in the context or associated with the risk of:

- bleeding
- intra-abdominal hypertension or abdominal compartment syndrome
- application of the VivanoMed Foam on nerves, anastomosis points, blood vessels or organs
- infected wounds
- blood vessels and organs
- bone fragments or sharp edges
- surgical incisions
- enteric fistulas
- spinal cord injuries with the development of autonomic hyperreflexia
- magnetic resonance imaging (MRI)
- defibrillation
- hyperbaric oxygen therapy (HBO)

For more information on important safety instructions, special and general precautions, please refer to the Warnings and Precautions sections in the Vivano®Med Abdominal Kit instructions for use document.

Preparatory Treatment
Adequate personal protection and institutional infection control measures must be implemented, when applying the dressing. Before applying the dressing for the first time, and after each dressing change, the wound must be thoroughly cleaned and conditioned in accordance with the physician's instructions.
Components of the Vivano®Med Abdominal Kit must always be applied in the order stated in the "Dressing Application" section of the VivanoMed Abdominal Kit instructions for use document.

Application of the wound dressing on necrotic tissue is contraindicated, as it may lead to local spreading of the infection.

The Abdominal Organ Protection Layer must cover all exposed viscera and completely separate the viscera from contact with the abdominal wall. Improper Abdominal Organ Protection Layer size and prolonged contact of visceral tissue with the foam may damage abdominal tissue/organs, lead to fistula development and organ adhesion.

For more information on safety measures and precautions associated with dressing application, please refer to the "General Precautions" and "Dressing Application" section in the Vivano®Med Abdominal Kit instructions for use document.

Vivano®Med Abdominal Kit, sterile

Sterile Device
Do not use any of the components of the Vivano®Med Abdominal Kit, in case of damage, expiration or any suspicion of contamination. It may cause overall decline in the therapeutic efficiency, wound contamination and/ or infection.

Single Use Device
All disposable components of the Vivano®Med Abdominal Kit are meant for single use only.
Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Vivano®Med Abdominal Kit should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

Material Characteristics

Component	Material:
Vivano®Med Organ Protection Layer	Micro-perforated polyethylene film with application pockets
Vivano®Med Foam	Hydrophobic, open-porous, reticulated, anthracite to black-colored polyurethane foam
Vivano®Tec Port	Polyvinylchloride tubing with ABS-connector system and self-adhesive polyurethane film dressing with acrylate adhesive
Hydrofilm®	Self-adhesive polyurethane film dressing with acrylate adhesive
Tray	Polypropylene tray

Product Characteristics
Vivano®Med Abdominal Kit is sterilized by ethylene oxide (EO) in a validated process according to EN ISO 11135.

Vivano®Med Abdominal Kit, sterile

Labelling

Lot-No. with 8-Digit Code
e.g.:

LOT	*0*	*12*	*XXXXX*
	year	week of production	for internal purposes only

Date of Manufacture

e.g.:	*2020*	*08*	*07*
	year	month	day

Use-by-Date

e.g.:	*2020*	*08*	*07*
	year	month	day

Shelf Life:
Date of Manufacture 2019-01-31 and earlier: 5 years
Date of Manufacture 2019-02-01 and later: 3 years

Medical Device

MD

Unique Device Identifier (UDI)

UDI

Single Sterile Barrier System / Double Sterile Barrier System

Vivano®Med Abdominal Kit: Single sterile barrier system

Latest Date of Revision: 2020-07-27