HARTMANN fixation products
non-sterile

EN Instruction for processing of medical devices

Product
HARTMANN fixation products non-sterile

Product description
HARTMANN self-adhesive fixation products (e.g. OR Tapes and Hook & Loop fasteners) are single-use products for short-term use in combination with surgical drapes and equipment covers. HARTMANN fixation products can be grouped according to the following fields of application: general surgery; gynaecology and obstetrics surgery; orthopaedics and accident surgery; ENT, oral, and maxillofacial surgery; urology surgery; ophthalmology surgery; and cardiothoracic, cardiovascular, and neurosurgery. HARTMANN fixation products non-sterile are considered a medical device in Class I. They are delivered in a non sterile condition and must be sterilized before use.

Intended use
HARTMANN self-adhesive fixation products (e.g. OR Tapes and Hook & Loop fasteners) are single-use products for short-term use in combination with Foliodrape® surgical drapes and equipment covers enabling the fixation of cables and tubes on surgical drapes or equipment covers. OR Tapes are also used for the fixation of a stockinet on patient´s extremity. The HARTMANN fixation products are intended to be used in combination with surgical drapes and equipment covers in operating theatres and all other surgical environments (e.g., ambulance, doctor's surgery).

Processing limitations
Supplied product is non-sterile and single-use. Sterilize prior to usage according to the instructions. Reusing or reprocessing a single-use medical device is dangerous as it may seriously damage the medical device's integrity and performance.

Special precautions

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 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.

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

Instructions

Storage and transportation	Packed in PE-bags combined with protective packaging unit (e.g. plastic box). Store in a dry place, protect against sunlight
Preparation at place of packaging	Optical inspection for potential contamination or damages.
Packaging	A suitable sterile barrier system in accordance with EN ISO 11607 (current version) and EN 868 (current version) as well as protective packaging must be validated and used.
Sterilization	Product is compatible with ethylene oxide sterilization only. To ensure required SAL of 10-6 the sterilization process must be validated according to ISO 11135 (current version). The sterilization process key parameters should not exceed the following values: - Ethylene oxide concentration: 338 – 866 mg/l - Ethylene oxide exposure time: 3 – 6 h - Temperature: 20 - 66 °C - Relative humidity: 42 - 85% - Pressure range: 80 mbar – 2.2 bar (absolute) - Pressure change rate: 15 - 90 mbar/min A second sterilization (e.g. after an interruption of the sterilization process) is in principle possible, considering the process key parameters mentioned above After ethylene oxide treatment, levels of the residuals in the product as well as analysis methods must comply with ISO 10993-7 (current version).
Additional information	The repackaging must be done by qualified staff meeting appropriate requirements concerning personal hygiene in appropriately controlled environment to maintain the required level of microbial cleanliness of ≤ 300 CFU/100 cm2 on the non sterile product according to EN 13795-1.

It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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