MANUAL

English

CE

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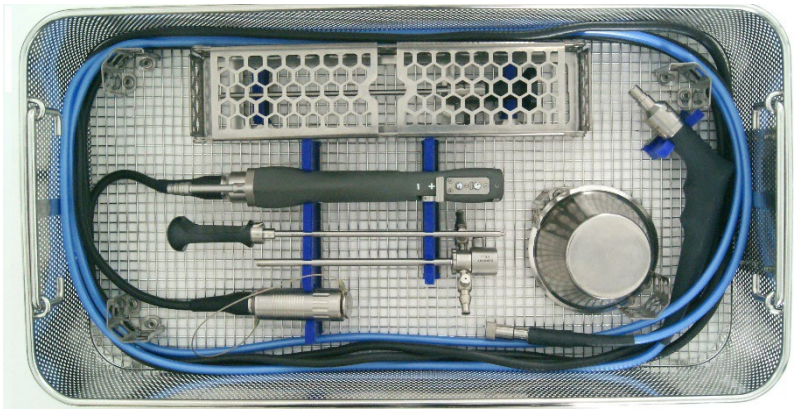
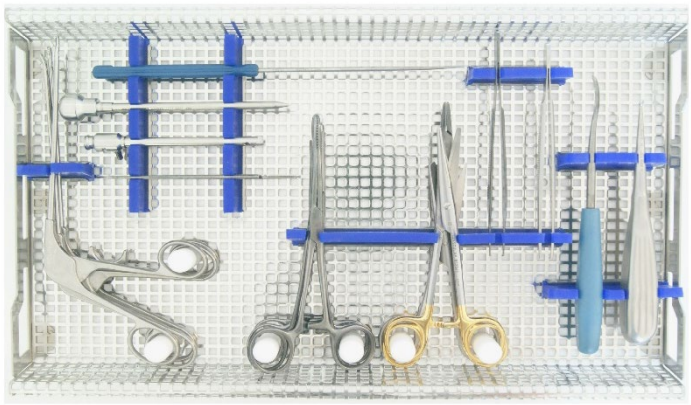
MEDEX FIXATION SOLUTIONS





Important information regarding reusable instruments from Medex Instrumenten Service

Medex
Instrumenten Service

SYMBOLS

The symbols below are used in the instructions for use, cleaning, disinfection and sterilization instructions and/or on the label.

	Consult instructions for use
	Warning symbol. Failure to observe this may result in fatal or serious injury and/or material damage (loss of time, loss of data, defect in aids/equipment, etc.).
	Article number
	Batch code
	Serial number
	GS1 code/GTIN for globally uniform product labelling according to world standard for industry and healthcare
	Unique Device Identification
	Medical Device
	Non-sterile
	Manufacturer
	Production date
	CE marking of conformity for medical devices
	Not for general waste

English

GENERALl

Failure to observe this document poses a risk of serious injury to the patient or user!

Improper handling and maintenance as well as improper use can lead to premature wear of the medical device and/or to risks for patient and user!

It is the responsibility of the operator that all persons handling the product have understood and follow the instructions and directions in this document..

Each user must read and observe this document in its entirety.

- In particular, observe all caution, warning and hazard instructions.
- The user must have access to this document at all times.
- This text applies equally to male and female persons. Only for the sake of better legibility, double spelling has been dispensed with.
- In this document, instrument(s), instrumentation and device(s) have the same meaning as medical device(s).
- The user is responsible for informing the patient as to the application, caution, warning and hazard instructions contained in this document and should verify that the patient has understood this information.

COMPLAINTS AND WARRANTY

We are very pleased that you have chosen a product from Medex Instrumenten Service, hereinafter also referred to as MEDEX. This product bears the CE mark, i.e. it thereby complies with the fundamental requirements laid down in the European Regulation EU 2017/745 for medical devices.

Medex Instrument Service is the manufacturer of this medical device.

Please check the delivery immediately upon receipt for completeness and damage.
Report any transport damage as well as deviations from the packing slip immediately.

For questions regarding the application of the product and for technical questions, please contact one of our employees:
Tel.: 0031 (0)36 534 12 98
E-mail: postbus@medex-instrumenten.com

Medex Instrumenten Service
Markerkant 10-136[E]
1316 AL Almere
The Netherlands
Tel.nr. 0031 (0)36 534 12 98
postbus@medex-instrumenten.com

The employees of Medex Instrument Service do their utmost to ensure delivery of medical devices of high quality. Should you nevertheless have any comments and/or remarks or a complaint about our products, please contact one of our employees using the contact options above, stating the item number (REF) and the lot number (LOT) and/or serial number (SN).

Any serious device-related incident must be reported to Medex Instrument Service and the competent authority of the Member State where the user and/or patient is located. Clearly state the classification of the incident and where possible the part number (REF) and lot (LOT) and/or serial number (SN) of the device.

Our general terms and conditions of sale in the currently valid version filed with the Chamber of Commerce shall apply. Agreements deviating from them do not limit the legal rights of the buyer.
A further warranty requires the contractual form and excludes consumables as well as vandalism to components.

Medex Instrumenten Service as manufacturer or sales organization accepts no liability for direct, indirect, unforeseen or consequential damage caused by improper and/or unprofessional use and careless handling. MEDEX as manufacturer or sales organization does not accept liability for direct, indirect, unforeseen or consequential damages due to improper handling for the first use, reprocessing, preparation, sterilization and maintenance of the medical device.

If MEDEX Instruments are repaired by firms or persons not authorized by MEDEX for the repair, the warranty will be voided. Change/modification of MEDEX devices will void the CE and warranty and Medex Instrument Service cannot be held liable for consequences/incidents that occur after change/modification of the MEDEX device.

Failure to comply with instructions, incorrect handling or incorrect and non-purposeful use of medical devices supplied and/or manufactured by MEDEX will result in exclusion of all warranty and/or liability claims.

INTENDED USE

Intended purpose

Instrument nets, also referred to as nets, (instrument) baskets, or cassettes, with or without fixation solution are reusable medical devices produced by MEDEX for the purpose of transportation and reprocessing processes to:
- Minimize the risk of damage to medical devices in instrument nets during logistics and reprocessing processes;
- Achieve device grip through minimal contact; and
- Organize the contents of the nets and promote overview.

Fixation solution refers to the components in the basket that achieves fixation of the contents. The contents of the nets vary from net to net, but primarily involve surgical instruments, implants and other medical devices.
Use in accordance with local hospital guidelines or follow local protocol.

Users

Use: These devices are to be used exclusively by professional users. The devices may only be used effectively in the medical fields by appropriately trained and qualified personnel. The attending physician or user is responsible for the selection of the device for particular applications and (surgical) use, adequate training and information, as well as adequate experience for handling the device.
(Re-)Processing: Processing for initial use and reprocessing is carried out by trained competent personnel in the Central Sterilization Department.

Environmental Conditions

Use: Use can take place under surgical conditions in an OR conditioned according to national laws and regulations, in a Central Sterilization Department conditioned according to national laws and regulations or under outpatient conditions.
(Re-)Processing: Processing for initial use and reprocessing takes place in a Central Sterilization Department conditioned according to national laws and regulations.
Storage: These devices should be stored outside of purpose in a dry and clean environment and protected from vermin, extreme temperatures and humidity. Do not store products with other rubbers for long periods of time, as the plasticizers of other products may affect the silicone. Never store products near oil, gasoline or solvents.

USE

Product description

These medical devices are made from a range of materials that meet specifications in national or international standards. Although the intended use is obvious, each configuration is accompanied by a classification overview. For more information and options, contact MEDEX.

Combination products

Each configuration is designed for a specific content. These contents can but need not be MEDEX specific system accessories..

Application

The attending physician or user, respectively, is responsible for proper application of the device.
Apply the device as intended, usage speaks for itself:
- Place the device on a stable surface
- Remove or place contents in accordance with the classification chart

Closure

After completion of the treatment/surgical procedure:
- Discard the device properly and, if applicable, return it for reprocessing.

WARNING

- The baskets are not supplied sterile. Before use, the medical device should be sterilized.
- Do not use this device for activities for which it is not intended.
- The baskets are not designed to be reprocessed, transported and/or stored upside down or sideways. In addition, they are not suitable for stacking.
- Never use sterilized components whose sterile packaging has deteriorated or deviates from standard condition.
- Improper maintenance, improper handling, improper use and/or poor cleaning procedures may result in premature wear and/or failure and may cause the device to become unsuitable for its intended use and even dangerous to the patient.
- Decontaminate medical devices resting on (not in) the fixation, as contaminated medical devices will not be cleaned at contact points. If medical devices do decontaminate in the fixation, the user should ensure that the contact points are visually clean prior to the sterilization process.
- After the decontamination process, the medical devices should be fixed in the correct location according to the provided chart after which the sterilization process can follow.
- The user must ensure that specific instructions from the manufacturer of the fixed medical devices take precedence over the information in these operating instructions. This relates to cleaning, disinfection and sterilization methods of the devices as well as technical and practical requirements, such as e.g. maximum temperature. The user is responsible to assess whether the specifications of the fixed medical devices and the instrument nets do not affect each other negatively. Medex has not validated the instructions of the manufacturer of the medical instruments in the baskets.

PRECAUTIONS

- Do not use this device for activities for which it is not intended.
- The device should be carefully examined for functionality or damage prior to use. The attending physician, resp. user, must ensure that the device functions as intended and is safe to use. A damaged device must not be used.
- Care should be taken when securing and removing medical instruments, as especially sharp medical instruments can damage the fixation material, which could leave fixation material on the device. User should visually inspect medical instruments for possible fixation material residue prior to use.
- Check instrument net contents and layout prior to use. Numerical markings in instrument nets serve only as an aid to the correct positioning of medical devices to be fixed. The user is responsible for using the correct length of implant at all times.
- Regularly review the condition of the devices and use repair and replacement services if necessary.

POSSIBLE SIDE EFFECTS

- Infection, if instruments have not been properly cleaned and sterilized.
  - In patients with Creutzfeldt-Jakob disease (CJK), suspicion of CJK or possible variants, observe the applicable national regulations regarding reprocessing of the instruments.
  - Please note that the successful processing for the first use and reprocessing of this medical device can only be guaranteed after prior validation of the (re)processing process. The operator/(re)processor is responsible for this.

This device should only be used by personnel familiar with the device, its intended use and any additional information related to the combination material.

EXTERNAL INFLUENCES AND ENIRONMENTAL CONDITIONS

These instruments have not been evaluated for safety, heating, migration or compatibility in environments with magnetic resonance, electrostatic discharges or radiation during diagnostic or therapeutic procedures.
These instruments or parts thereof are made of stainless steel with high corrosion resistance, nevertheless, the instrument may corrode under specific conditions. Because of this, MEDEX recommends not exposing the instrument to acids and keeping it free of contamination and prolonged contact with moisture to keep the passivation layer intact. Therefore, store the instrument in a dry environment.

PACKAGING

The device packaging must be intact upon receipt. Remove transport packaging from devices at all times, as exposure to temperature fluctuations could lead to condensation in dense plastic packaging, increasing the risk of corrosion. If a kit is delivered, it must be carefully checked for completeness and all components must be carefully inspected for damage before use. Damaged packaging or products should not be used and should be returned to MEDEX.

INSPECTION

Devices should always be inspected by the user prior to treatment.
Inspection should be thorough and include both visual and functional inspection of the working surfaces, cleanliness of the cavities and/or cannulae (see Cleaning, disinfection and sterilization instructions) and the presence of cracks, bends, distortion and/or disruption.

The service life of fixation baskets is affected by several factors, such as the reprocessing method and how they are handled between applications. Therefore, no maximum number of applications is established. The end of life is generally determined by wear and damage due to use.

Never use tools when in doubt of, or obvious signs of excessive wear or damage, or a tool that is incomplete or otherwise not functioning.

Visual inspection
Please convince yourself of the following:
- Laser, engraved and other markings are legible.
- No cracks, tears, burrs and/or deformities are present in the device.
- The device shows no signs of wear, is not corroded, porous or otherwise damaged.
- Discoloration, corrosion, stains or rust are not present. If present, wiping should be attempted in accordance with the instructions in the “Manual Cleaning” section of the Cleaning, Disinfection and Sterilization Instructions.
- There is no damage to the working end(s). The working end should be free of cracks, burrs, sharp edges and other damage.
- All parts are present, and free of damage and wear.
- Matching ends of connectors are free of damage (kinks, grooves, bends, burrs, etc.) that could interfere with combination function. The instrument and machine connection point should also be checked for breakage and/or damage before insertion.

Functional inspection
Confirm the following:
- The device functions as intended (with associated parts/combination hardware).

If applicable:
- The parts that require movement do so without obstruction, binding, or chafing.
- The locking/retention device functions as intended without releasing under pressure.
- Clamping parts clamp without loosening.
- Blunt edges are blunt to the touch and not sharp, kinked, or otherwise damaged.
- The holes/cannulas/lumens in the device are clear and free of damage.
- The device size matches the combination device.
- Inspect the combination function.

INSPECTION AND REASSEMBLY

1. Carefully inspect the devices for damage by performing a thorough examination as indicated in the “Inspection” section of this document.
2. If the instrument shows obvious signs of excessive wear or damage, is incomplete or otherwise not functioning, contact MEDEX immediately for maintenance, repair or replacement. Do not continue to decontaminate a damaged instrument if applicable and remove it from service.
3. If the instrument was disassembled prior to cleaning and sterilization, it must be reassembled.

Although instrument handling, materials used and sterilization information have an important effect, in practice there is no limit to the number of times the device can be sterilized.

CLEANING, DISINFECTION AND STERILISATION

Processing before first use

Remove all packaging material before use. The baskets are not supplied sterile. Before use, the medical device should be sterilized.

Reprocessing

Only sterile instrumentation should be used in surgery. Instruments used in surgery should be cleaned and resterilized immediately. Instrumentation must be thoroughly cleaned prior to sterilization. For reprocessing of medical instruments specific instructions from the manufacturer of the fixed medical devices take precedence over the Cleaning, disinfections and sterilization instructions of Medex Instrumenten Service. Cleaning and disinfection procedures must be carried out before returning it to MEDEX. They must be marked as such, otherwise no further handling can take place. A decontamination statement must be enclosed.

Please be advised that Medex Fixation Solution is validated by using a steam sterilization process of 3 minutes at 134°C.

MAINTENANCE

This instrumentation does not require specific periodic or preventive maintenance.

WASTE DISPOSAL

Packaging

The packaging can be disposed of with paper and household waste and/or plastic, depending on hospital guidelines..

Disposal of the product

End of life: Maintenance and circularity have been taken into account in design of this instrument for a sustainable life cycle. This allows the instrument to be largely recyclable. Upon end of life, return the instrument to MEDEX or to a point for expert disposal.
CAUTION: Instrumentation must be decontaminated before disposal. Sharp instrumentation must be handled appropriately to avoid injury.
Excess instrumentation: If instrumentation has become surplus for any reason, a match can be found through MEDEX's “Second Chance Circularity” to use instrumentation in countries and areas where proper care is not evident.

National regulations

All waste disposal measures must comply with national regulations and waste disposal guidelines.