

REUSABLE INJECTING DEVICE

INSTRUCTIONS FOR USE



Subiton Gun

Cleaning Instructions



Important

This device is to be used in a surgical environment with all the aseptic conditions described in these instructions for use, in compliance with the current European Normative.

The Subiton Gun has been exclusively designed to be used together with the components of the Subiton Gun disposable cement application system. It must not be used with products from other manufacturers under any circumstances. Ignoring this warning might entail the malfunctioning, breakage or premature deterioration of this device / affect the outcome of the procedure / put the patient at risk.

The surgeon and the staff at the O.R. are accountable for not respecting the warnings mentioned in these instructions.

Instruments must be kept away from magnetic fields.

Decontaminate the products before removing them from the O.R.

Precaution:

The Subiton Gun has been designed so that it is used in a smooth way. If it becomes stuck or seized, it must never be forced. Apply gentle movements in opposite directions until it works smoothly.

The life span of this device will depend on its correct use, cleaning and maintenance conditions, and storage in a controlled humidity environment.

Do not use if appropriate sterility conditions are not assured.

Decontamination and Cleaning

Important:

These processes must be performed by adequately trained personnel in accordance to validated institutional standards.

The personnel in charge of these processes must wear protective clothing.

No part of the Subiton Gun has to be disassembled for cleaning purposes.

The Subiton Gun has been submitted to a decontaminating and cleaning process in order to eliminate the residues produced during its manufacturing, repair or modification.

Before sterilization: submit to a new cleaning process in order to remove any dirt acquired during transportation, storage or handling. This process must be performed in accordance the health care organization standards, in accordance to the corresponding CE guidelines.

The health care organization will be responsible for this process.

Decontamination:

This process is aimed at reducing the micro-organism burden in order to limit their contaminating power.

Should this not have been done at the operating theatre: Remove the plastic components (syringe / plunger) attached to the Subiton Gun and dispose accordingly.

Use a soft, moistened cloth to wipe off any visible stains from the Subiton Gun surface.

Should it be necessary to set the propulsion rod completely free, turn it 90° right or left in order to disengage the propulsion mechanism.

Immerse into a decontaminating liquid consisting of a Ph 7 multi-enzymatic detergent.

Avoid using alkaline products and corrosive solutions as they may damage the stainless steel and aluminum parts.

In order to achieve an effective decontamination, immerse during 10 minutes. It is not advisable to exceed this time by much, as it may damage the device on the long term.

Once the instrument has been decontaminated, carefully rinse with demineralized, de-ionized cold water. In order to increase the mechanical effectiveness of the process, it is advisable to use a non-metal brush. All these operations must be carried out before the cleaning procedure itself.

Cleaning

This process is performed through a combination of a mechanical action (rubbing, brushing), a chemical action (cleaning agent), and a thermal action (the high temperature reduces the cleaning time), which permits to eliminate dirt.

The most commonly used cleaning methods are: manual, by means of an aspersion machine, through immersion and by ultrasounds.

The choice of the cleaning method corresponds to the authorized staff in the Healthcare care facility.

Do not use alkaline or corrosive products to clean devices in stainless steel or aluminum.

Once the cleaning procedure is finished, the Subiton Gun must be rinsed and dried (either manually, compressed medical grade air or by means of a stove).

For manual drying you must use a clean, soft, absorbing, lint free cloth.

Sterilization

In order to prevent a re-contamination or damage to the Subiton Gun put it immediately back in its metal case. This case must be submitted to the same decontaminating and cleaning processes as the device contained there-in. All the above mentioned elements must undergo a sterilization process according to the standards established by the Healthcare organization, the European Pharmacopoeia and the national regulations in force.

Synimed SARL recommends an autoclave sterilization at a temperature of 134 °C and a 2 bar pressure for 18 minutes. Synimed does not assure the preservation of the sterility of the elements which contain the instruments. According to the regulations in force, this sterility and its preservation

are under the responsibility of the Healthcare organization.

Any decontamination, cleaning and sterilization method implemented by the healthcare institution should be validated.

Storage, transportation and preservation

Between two surgical procedures, the devices must be stored in a clean, dry and temperate environment/place. They must be protected against falls, strikes and any other situation which might damage their integrity, cleanliness and/or sterility.

Their handling and transportation must be performed in such a way as to protect them from strokes or falls which might damage them. It is recommended not to store or transport boxes which are not correctly closed, and also not to pile them up as it might damage their lids and/or seals.

If there is any doubt as to the partial or total integrity of a box, it must immediately be sent to Synimed SARL, in its original packaging.

Maintenance, modification and repairing: Before returning them to the Healthcare organization, Synimed SARL shall verify the operation of the instruments after having performed their corresponding maintenance, modification or repairing.

A follow up card, concerning the composition of the ancillary and the detailed technical verifications performed, shall be attached to the instruments returned to the Healthcare facility.

Once the instruments are received and before they are used in a surgical procedure, their adequate functioning must be controlled by qualified personnel authorized by the Healthcare organization. Defective instruments should immediately be returned to Synimed SARL or to a firm authorized to this end. The instruments, nor their auxiliary elements are not to be repaired or modified by any person or firm not authorized by Synimed SARL. Only Synimed SARL or a firm authorized by Synimed SARL can perform these operations so as to guarantee the functioning and performance of the instruments in question.

Synimed SARL may decide not to repair an instrument, and to replace it by a new one or by one in similar conditions and working order. All verbal communication between Synimed SARL staff and the Healthcare organization must be subsequently confirmed in writing.

Instruments or accessories sent to Synimed SARL:
Before being returned to Synimed, they must be submitted to the necessary decontaminating and cleaning processes. These operations must be recorded in the follow up card designed to this end, which must also be sent to Synimed SARL.

Any exchange or transfer of these instruments between two Healthcare organizations, without the authorization of Synimed SARL, is strictly forbidden.

Attention :

If the Healthcare organization, the surgeon, or the personnel in the O.R. become aware that the instruments have been used in patients who are carriers of severe diseases, with high spread risks, ruled by regulations such as in the case of NCTA (non conventional transmissible agents), the said instruments will be submitted to the treatment required by law/regulations, and Synimed must be informed of the procedure performed.

Synimed shall not be held responsible for the actions of the Healthcare facility regarding the application of the above mentioned procedures.

Assistance and associated services:

Contact Synimed SARL to obtain all complementary information, technical explanations, advice or assistance regarding the performance or use of whichever instrument or accessory.