SUBAN Instruments Hungary Co.
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1. GENERAL INFORMATION

Information included in these instructions are relevant to all instruments and accessories manufactured and distributed by SUBAN Instruments Hungary Co., which can be reused safely and effectively by observing the instructions in this document.

If the handling and maintenance instructions are observed and along with the effects of the strains accompanying the intended purpose, the performance and the structural features of the medical hand instruments would not deteriorate to the extent that would threaten the health and safety of the patient, the user and in certain cases, other persons.

The instruments can be used to treat any patient population without restriction, as long as their dimensions are considered.

The instruments are not containing any medicinal substances (including derivatives of human blood or plasma) tissues or calls of human on animal origin or derivatives of these.

In the case of instruments with scales, the markings are only informational and serve no measuring function.

In order to indicate the expressed usability, the instruments with cutting functions contain information in the form of marks regarding their performance.

The reusable medical devices manufactured and distributed by SUBAN Instruments Hungary Co. are classified as class I as per Council Directive 93/42/EEC.

2. DESIGNED FUNCTION OF THE INSTRUMENT

For the intended purpose of the instruments, using them without proper expertise and qualification is not recommended. Selecting the adequate instrument for the procedure and applying the proper surgical techniques during the use of the instruments are the responsibilities of the user. Using the instruments in any manner other than the intended purpose can lead to irreparable damage to them.

Atraumatic forceps: instruments used in heart, vascular, intestinal and gastric surgeries, where causing the least possible damage to the tissues held with the instrument is important, etc.

Forceps: instruments used for grabbing and holding materials, wound parts and fitting wound edges. *Types: anatomical, surgical, micro-, atraumatic forceps, etc.*

Bone punches, bone forceps: instruments used to grabbing and extracting bones, fitting broken bone edges, removing bone parts and cartilage tissues. *Types: covered bone punches, geared bone punches, simple bone forceps, bone forceps with arresting arm, etc.*

Elevators: instruments used for elevating and moving body parts and organs during surgery. *Types: Durham dissector, Willinger elevator, Freer elevator, etc.*

Hemostatic forceps: instruments used for grabbing blood vessels and controlling bleeding during surgery. *Types: Pean, Kocher, preparing, dissectors, atraumatic hemostatic forceps, etc.*

Dental elevators: instruments used for removing roots and tooth pieces from the oral cavity and the gum. *Types: tooth elevators with hollow handle, tooth elevators with solid handle, etc.*

Tooth forceps: instruments used for the extraction of damaged teeth. *Types: English type tooth forceps, American type tooth forceps, tooth forceps with adhesive clips, etc.*

Dental technology forceps: devices used for bending and cutting plates and wires during the preparation of tooth replacements. *Types: dental technology forceps suitable for bending, dental technology punches, etc.*

Saws: instruments with special cutting edge used for cutting through bones. *Types: blade saw, bow saw, Gigli saw etc.*

Hooks: instruments with radially bent top part, which are used for exploring, distending and fixing wounds. *Types: surgical hooks, ophthalmologic hooks, other hooks, etc.*

Mallets: surgical and diagnostic instruments, in bone surgeries used to gain the strike force necessary for carving and separation of the damaged bone pieces, while in diagnostics applied to examine the reflexes. *Types: Williger's mallet, reflex hammer, etc.*

Clamps: auxiliary surgical instruments used for exposing and retracting the surgical area, pulling and holding soft tissues and organs. *Types: surgical clamps, dental clamps, nasal surgery clamps, ophthalmologic and other clamps, etc.*

Curettes: used for scraping bones, removing purulent or other tissue pieces. *Types: surgical curettes, ophthalmologic curettes, otolaryingologic curettes, dental curettes, gynecologic curettes, gall stone scoops, curettes, etc.*

Towel forceps: used to affix the sterile towels surrounding the surgical area. *Types: Backhaus towel forceps, etc.*

Knives: instruments used for cutting, exploration and pricking during surgery. *Types: surgical scalpels, cartilage and autopsy knives, amputating knives, ophthalmologic surgery knives and spears, otolaryngologic scalpels, surgery knives with replaceable blades, etc.*

Spatulas: instruments used for retracting and elevating soft tissues and body parts and distending wound edges during surgery. *Types: tongue depressors, dental spatulas, ophthalmologic spatulas, gynecologic spatulas, surgical spatulas, technical spatulas, etc.*

Gynecologic forceps: used for grabbing and pulling forward deep seated tissues and body parts as well as introducing dressings. *Types: dressing forceps, abortion forceps, uterine tenaculum forceps, obstetrical forceps, etc.*

Scissors: used for cutting sutures, dermal tissues, wound dressings, clothing and other materials. Each scissor type can have different intended use. *Types: surgical scissors, gynecologic scissors, dental scissors, ophthalmologic scissors,, microsurgery scissors, pliers with tungsten carbide inserts and other special scissors, etc.*

Raspatories: instruments with handle, used for removing softer tissue parts or foreign materials from some harder tissue parts. Primarily used for removing the periosteum covering the bone tissue and scraping and cleaning the bone surface. *Types: surgical and dental raspatories, etc.*

Suction tubes: instruments used for removing fluids and discharges from the body cavities during surgery. *Types: Frazier suction tube, De Baley suction tube, Fergusson suction tube, etc.*

Probes: used for dilating the wound opening or body cavity and delivering dressing material during surgeries and examinations. Their scope of application is wide, they are used in every field of surgery. *Types: surgical probes, ophthalmologic probes, bayonet-shaped probes, nasal and otologic probes, gynecologic probes, dental probes, myrtle leaf probes, Troeltsch probes, Lucae probes, etc.*

Cotton applicators: used for introducing dressing materials into the wounds and body cavities. These are light and flexible instruments, similar to probes. *Types: nasal dressing applicators, otologic dressing applicators, other dressing applicators, etc.*

Dilators: used for dilating body parts with pathologic deformation of narrowing due to an illness to their functional dimensions. Also used

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in internal cavities, where a volume larger than the normal is necessary for surgical or treatment purposes. *Types: Gynecologic, vascular surgery, urologic dilators, etc.*

Retractors: used for opening the wound during surgery or opening the body cavities during medical examination, as well as increasing and retracting the opening or the cavity. *Types: self-retraining retractors, ophthalmologic retractors, mouth gags and other retractors, etc.*

Needle holders: used for holding the surgical needles during tissue joining and preparing sutures. *Types: ringed needle holders (Hegar), needle holders with handle (Mathieu), geared needle holders, needle holders with tungsten carbide inserts, microsurgery needle holders, etc.*

Chisels: used for rupturing, breaking and destruction of the bone during surgery. *Types: surgical chisels, dental chisels, ophthalmologic chisels, ear and nasal chisels, etc.*

3. MARKINGS AND INFORMATION ON THE PACKAGING

	Manufacturer
	Date of manufacturing
REF	Item code
LOT	Item number of the product
	Non-sterile product in the package
CE	CE mark
	Read the operation manual
MD	Medical device
QTY	Quantity

4. RISKS AND ADVERSE EFFECTS

Risks and adverse effects might occur during the use of the instruments, the same as with any major surgical procedures.

In most cases, the occasionally occurring complications are not related directly to the instrument, but the result of not selecting the right instrument.

The patient must be informed about the postoperative hygienic activities and should be told to seek out their treating physician in the case of nay complaint.

5. GENERAL WARNINGS

- The instruments are distributed in NON-STERILE condition, therefore, they need to be cleaned and sterilized before use.
- Upon reception, check that the package contains the instrument named on the label as well as the integrity, intactness and functionality of the instrument.
- Upon reception, check that the devices are undamaged, not broken, deformed and there are no other function failures. Areas like blades, tips, locks and any moving parts should be examined especially.
- Using worn, corroded, porous or otherwise damaged devices is forbidden.
- Selecting the adequate instrument for their activity, knowing the intended use thereof and applying the current technical knowledge during their use are the responsibility of the surgeon and any other user.
- Remove all packaging material and the safety covers from the instrument before cleaning and sterilization.
- Use of personal protective equipment is recommended during the cleaning and use of contaminated or potentially contaminated instruments.
- Do not let the occurring biological contamination dry on the instruments. It makes every listed cleaning and sterilization step easier, if you do not let these contaminations dry on the used instruments.
- Use only neutral (pH 7) deionized water for the cleaning and rinsing. Do not use a wire brush or abrasive materials for cleaning.
- Fine instruments e.g. microsurgery instruments reasonably should be cleaned manually, using a soft cleaning brush and a neutral (pH 7) aqueous solvent.
- Dry the instruments in the shortest time possible after cleaning.
- Never clean and sterilize instruments made from carbon steel, or coated with nickel or chromium together with other stainless steel instruments.
- Avoid temperatures above 200 °C when handling the instrument (primarily during sterilization), because it could result in loss of their hardness and the life of the cutting edges.
- In the case of hemostatic forceps, avoid constricting the plastic tubes, because in might lead to the sliding and quick breaking of the clips.
- Avoid cutting thick tissues, textiles and suture materials with the dissecting scissors.
- Only stress the instruments with forces corresponding their structure and cross section.
- Avoid throwing the fine, sharp and pointed instruments and protect those from falling.
- The instruments must not be used during examinations applying magnetic resonance (MR) or x-ray radiation.
- During the use of instruments containing moving parts there is a risk of injury caused by nipping, cutting or pricking at the joining parts.
- During the use and cleaning of instruments with sharp edges or pointed parts there is a risk of injuries caused by cutting or pricking.
- Avoid storing the instruments in closed and humid places.

6. GENERAL ACTIVITIES TO PERFORM BEFORE USE

All instruments are thoroughly checked before delivery, however, the products may become damaged in the course of shipping, and therefore it is important to check those upon reception and before use. During the checking examining the following is especially important:

- The cutting edges should be continuous without any chipping.
- The clips and dents should fit adequately.
- The moving parts should move smoothly across the whole movement range.
- The locking mechanisms should lock easily and fixed safely.
- The long and thin instruments should not be contorted or twisted.
- In the case of instruments composed of several parts, check that each part is present and assemble the instrument.

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If any damage or wear is visible on the instrument that might affect the functioning, using the instrument is strictly forbidden.

Each instrument should be cleaned, dried and sterilized observing the local requirements and the recommendations in this guide. Even with careful cleaning by the manufacturer, there may remain materials originating from processing on the surfaces of the instrument, and they need to be removed in the course of cleaning.

Instruments with frictional and fitting parts should be dried following the before-use cleaning and before sterilization (the covered part blown out with compressed air) then the joining parts and the frictional surfaces of the springs should be greased with a few drops of acid-free oil. Prior to the first cleaning and sterilization safety caps and other safety packaging materials, if any, should be removed from the instruments. The instrument should be left resting for a few minutes before sterilization, so that the oil could disperse adequately on the surface. Greasing the instrument should be performed after each cleaning.

7. TASKS AFTER USE

7.1. Tasks to be performed at the place of use.

After use, check the integrity and completeness of the instruments. Check if bolts, springs, other parts had not become loosened or dropped out. Instruments planned to be dismantled must be dismantled prior to cleaning.

If the instruments cannot be soaked or kept wet they are to be cleaned prior to use as soon as possible (ideally within 60 minutes) so that possibility of drying out before cleaning is minimized.

7.2. Rinsing

Medical hand instruments come in contact with various substances and fluids (e.g. tissues, blood, etc.) during their intended use. These substances and fluids can enter the gaps on the instrument that are hard to access and dry on their surface or gaps. For these reasons, the instruments should be rinsed with running tap water quality water immediately after use.

7.3. Cleaning

Cleaning can be performed in ultrasonic cleaning equipment, automated washing devices or manually. As irrespective of the form of washing, always wash and flush the instruments when they are open. Apply only disinfecting and washing solutions that have been designed for the intended purposes. In the case of cleaning in a washing equipment, the requirements of the manufacturer of the equipment regarding the cleaning process (e.g. cycle time, applied chemicals and their concentration, instructions regarding the placement of the instruments to be cleaned in the equipment, etc.) should be observed. If there are contamination residues on the instrument following the cleaning, repeat the cleaning process.

7.3.1. Manual cleaning and cleaning with ultrasonic cleaning equipment

Prepare the enzymatic solution with a cleaning effect that is recommended by the manufacturer of the instrument disinfectant.

Place the instruments into the solution so that they are wholly submerged. Keep the instrument in the solution for a period of time as per the recommendation of the manufacturer of the instrument disinfectant, subject to the concentration of the solution, for a minimum of 15 minutes. During soaking, watch out for contaminants of the instruments. In case macroscopically visible contaminants are found on the instrument, the surface of the instrument must be cleaned mechanically with a plastic bristle brush. Operate the moving mechanisms. Special attention should be paid to the surfaces of slits, joints, locks, dents, rough surfaces and moving parts or springs.

Remove the instrument from the solution after the exposure and rinse it with running tap water for at least one (1) minute. During rinsing operate all moving parts and joints. A thorough rinsing is needed at the surfaces that are difficult to access.

Prepare an ultrasonic cleaning bath as per the recommendation of the manufacturer of the cleaning solution.

Place the instruments into the solution so that they are wholly submerged. Shake the instruments carefully to remove any trapped bubbles. Clean the instruments in the ultrasonic cleaner applying the temperature, frequency and exposure time recommended by the manufacturer of the device. The ultrasonic cleaning process should not be shorter than ten (10) minutes.

Remove the instruments from the ultrasonic bath and rinse them in ion exchanged water for a minimum of one (1) minute or until the remaining cleaning liquid is completely removed from the instrument. During rinsing operate all moving parts and joints. A thorough rinsing is needed at the surfaces that are difficult to access.

Use a clean, water absorbent, lint-free cloth to dry the instruments. To remove the water from the auger holes, or the areas that are difficult to access clean, filtered, compressed air can be used.

After drying, all moving parts must be oilded using oil manufactured for oiling surgical instruments and the functionality of the instrument must be checked.

7.3.2. Manual cleaning and automatic cleaning in a washer

Prepare the enzymatic solution with a cleaning effect that is recommended by the manufacturer of the instrument disinfectant.

Place the instruments into the solution so that they are wholly submerged. Keep the instrument in the solution for a period of exposure time as per the recommendation of the manufacturer of the instrument disinfectant subject to the concentration of the solution for a minimum of 15 minutes. During soaking, watch out for impurities of the instruments. In case macroscopically visible contaminants are found on the instrument, the surface of the instrument must be cleaned mechanically with a plastic bristle brush. Operate the moving mechanisms. Special attention should be paid to the surfaces of slits, joints, locks, dents, rough surfaces and moving parts or springs.

Remove the instrument from the solution after the exposure period and rinse it with tap water for at least one (1) minute. During rinsing operate all moving parts and joints. A thorough rinsing is needed at the surfaces that are difficult to access.

Place the instruments into an appropriate, validated automatic washer. Follow the manufacturer's instructions when loading the washer in order to achieve maximum cleaning effect. The instruments must be open when placed into the washer with their cavities facing downwards. Instruments should be placed onto trays or into baskets, with the heavier ones being at the bottom of the trays or baskets.

The washer should use a standard instrument cleaning cycle according to the manufacturer's instructions. Below is a list of recommended minimal washing cycle parameters:

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Cycle No.	Definition	Exposure time (min)	Water type, and temperature	Detergent type
1	Pre-wash	1	Cold tap water	
2	Washing	5	50°C tap water	enzymatic
3	Rinsing	1	Cold tap water	
4	Washing	5	65°C tap water	alkaline
5	Rinsing	1	Cold tap water	
6	Warm water rinsing	1	90°C ion exchanged water	
7	Drying	10	Max 90°C	

7.4. Disinfecting

A lower level disinfection can be applied as part of the cycle performed with the washing-sterilizing equipment, however, the instruments must be sterilized before each use.

8. STERILIZATION

In the case of instruments manufactured by SUBAN Instruments Hungary Co. all sterilization procedures can be applied. The cycle time might be longer for certain cases, due to the features of the instrument, but it should not be shorter that the manufacturer's recommendation.

The sterilization procedures recommended by the manufacturer include thermal sterilization procedures performed with saturated steam at 121 °C with 1.1 kp/cm^2 overpressure for 20 minutes or at 134 °C with 2.1 kp/cm^2 overpressure for 10 minutes.

Further sterilization procedures can be provided by the manufacturer of the sterilizing equipment.

9. STORAGE

Following sterilization the products should be stored in a dedicated place with limited access, good ventilation, protected from dust, moisture, insects, extreme temperatures and humidity.
Every package should be checked before use, for tearing or perforation of the sterile sealing (e.g. packaging material, bag, filter, etc.) and for signs of wetness or unauthorized opening. If any of these occurs the instrument in the package cannot be considered sterile and the cleaning, packaging and sterilization processes should be repeated.

10. RESISTANCE AGAINST OTHER MATERIALS

When selecting the washing solution and the sterilizing solution, make sure that the solutions are not containing the following components:

- Organic, mineral or oxidizing acids;
- Strong alkali solutions (pH>11);
- Organic solvents (alcohol, acetone, etc.), petrol derivates;
- Halogenated hydrocarbons, chlorine, iodine;
- Ammonia.

Avoid cleaning the instruments and the sterilizing trays with metal brushes.

11. MAINTENANCE

Any repair due to wearing in the course of the use of the instruments may be performed solely by qualified professionals. Non-adequate maintenance can affect the product functionality and have unfavorable effect on the safe use of the product.

12. GUARANTEE

SUBAN Instruments Hungary Co. assumes 10-year guarantee for all the products distributed under its name. In the event of any defect of base materials or workmanship, hand instruments are repaired or replaced free of charge. In order to claim the guarantee, contact the manufacturer at any of the contacts listed in this guide.

13. RETURNING INSTRUMENTS TO THE MANUFACTURER

All instruments returned to the manufacturer (e.g. for repair) should be cleaned and sterilized before packaging in accordance with the hygienic and company requirements. The manufacturer provides repair and service only for instruments returned in sterile condition.

14. APPLIED STANDARDS

ASTM A380 / A380M-17 – Standard Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems

ASTM A967 / A967M-17 – Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts

ASTM F1089-18 – Standard Test Method for Corrosion of Surgical Instruments

DIN 96298-1:2016-10 – Medical instruments – Terms, measuring methods and tests – Part 1: Terms and definitions

DIN 96298-2:2016-10 – Medical instruments – Terms, measuring methods and tests – Part 2: Measuring methods for the determination of basic measurements of surgical standard instruments

DIN 96298-3:2017-10 – Medical instruments – Terms, measuring methods and tests – Part 3: Tests

ISO 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

MSZ EN 10088-1:2015 – Stainless steels. Part 1: List of stainless steels

MSZ EN ISO 7153-1:2017 – Surgical instruments. Materials. Part 1: Metals (ISO 7153-1:2016)

MSZ EN ISO /IEC 17050-1:2010 – Conformity assessment. Supplier's declaration of conformity. Part 1: General requirements (ISO/IEC 17050-1:2004, corrected version 2007-06-15)

MSZ ISO 2768-1:1991 – General tolerances. Tolerances for linear and angular dimensions without individual tolerance indications.

16. CONTACT INFORMATION

Please notify us at one of the following contacts in the case of serious unexpected events occurring in connection with medical hand instruments manufactured and distributed by SUBAN Instruments Hungary Co.

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Please report the serious unexpected events occurring in connection with the instruments also to the competent authorities of the Member State in which the user and/or patient is resident.

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