Instructions for use

Recommended maintenance, cleaning and sterilization of medical hand instruments

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.

Instruments with cutting functions contain information in the form of markings on performance characteristics when necessary for clear usability.
Based on Regulation (EU) 2017/745 of the European Parliament and of the Council, SUBAN Kéziműszer Hungary Zrt., as the manufacturer and distributor, recommends its Class I medical devices for transient use (continuous use lasting less than 60 minutes).
These instructions for use have been prepared in accordance with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council.

2. INDICATIONS

The device can be used in various surgical procedures to manipulate, grasp, cut, separate, hold, spread and perform other surgical procedures on soft and hard tissues. The device can be used in general surgery, dentistry, orthopaedics, otorhinolaryngology, gynaecology and other specialised surgical procedures. The devices can be used without restriction for all patient populations, taking into account their dimensions.

3. CONTRAINDICATIONS

- The device may not be used for any purpose other than that for which it is intended.
- The device must not be used if it is not properly sterilised or disinfected.
- For the intended purpose of the instruments, using them without proper expertise and qualification is not recommended.
- Using worn, corroded, porous or otherwise damaged devices is forbidden.
- The device should not be used in a patient with a known allergy or hypersensitivity to the device material.
- The device must not be used for surgical procedures requiring an instrument of special design or characteristics.
- 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.
- For instruments with locking mechanisms, improper locking may result in the cessation of bending, clamping, twisting, pulling, and compressing operations with the working part of the instrument, which may result in the release of kinetic energy that could cause injury.
- The instruments must not be used during examinations applying magnetic resonance (MR) or x-ray radiation.

4. DESIGNED FUNCTION OF THE INSTRUMENT

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.

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.

Tweezers (forceps), dental tweezers (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, or nails. *Types: covered bone punches, geared bone punches, simple bone forceps, nail nippers, 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.*

Forceps: A manually operated surgical/medical device consisting of two opposing arms that are connected at a point and have a clamping or grasping function to grasp, hold, manipulate or remove tissue, materials or objects during medical procedures. Types: vascular forceps, bandage forceps, gynaecological forceps, needle forceps.

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.*

Drills: Hand-powered drilling units and accessories used during orthopedic or cranial surgical procedures for cutting, shaping, trephining, drilling bone, and driving Kirschner wires.

Skin punches: Manual surgical instruments used for excising skin defects or taking skin tissue samples.

ENT forceps: Manual surgical instruments inserted into the ear through the ear canal or surgical incision to remove tissues, typically tumorous or damaged tissues, from the ear during ENT surgical procedures.

Ear specula: Cone-shaped rigid metal tubes (with a standardized base size that narrows to a small opening) that are manually inserted or fitted onto a compatible otoscope and then inserted into the ear canal, thus forming a channel for examination, suction, irrigation, or insertion of other surgical instruments during ENT procedures.

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Laryngeal mirrors: Surgical hand instruments with a mirror or sufficiently polished surface capable of reflecting enough non-scattered light to form a virtual image of an object placed in front of its distal end for laryngeal examination.

Tuning forks: Manual mechanical test instruments, acoustic resonators used to examine a patient's hearing ability, diagnose hearing-related disorders, and test vibratory sensation.

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.*

Sharp 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.*

Curettes: Thin surgical hand instruments used for scraping out and/or excising bones and tissues.

Laboratory tools: General-purpose trays or cups with various applications, such as storing fluids, transporting or storing instruments before or during procedures, collecting bodily waste or other materials.

Tracheal cannulas: Hollow, cylindrical, curved devices designed as an independent, internal component of a metal tracheostomy tube, which, when removed, facilitate the evacuation of secretions, mucus, and accumulated contaminants, thus preventing blockage and infection of the stoma and eliminating the need for traumatic removal of the tracheostomy tube.

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.*

Obstetric forceps: Scissors-like obstetric instruments used to assist in difficult vaginal deliveries of the fetus.

Vaginal specula: Manual hand instruments used for expanding the vagina after insertion, typically used for visual examination of the vagina and cervix and/or during gynecological procedures.

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.*

Nasal specula: Manual surgical instruments inserted into the nostrils which, when fully opened manually, make the area accessible for examination or ENT surgical procedures by stretching the tissues around the nasal opening.

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.*

Sterilizing units: Generally flat, shallow containers with raised edges, suitable for storing multiple surgical instruments during and after sterilization.

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

Technical pliers: Strong manual surgical instruments with specially designed, powerful handles and jaws, used during surgical procedures for grasping, tightening, and/or twisting wires.

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.*

Needles: Cylindrical solid instruments with various diameters, used for introducing and pulling suture material through surface tissues, such as skin. The distal tip can have various geometric shapes. The suture is used to join the surfaces of two tissue parts.

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.*

5. MARKINGS AND INFORMATION ON THE PACKAGING

Manufacturer

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HU	Date of manufacturing, country of manufacture
REF	Item code
LOT	Item number of the product
NON STERILE	Non-sterile product in the package
CE	CE mark
	Read the operation manual
MD	Medical device
QTY	Quantity
UDI	UDI code

6. 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.

7. 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.
- 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.
- 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.
- Appropriate collection and transport containers are required for the disposal of instruments as clinical waste. Sharp instruments should only be disposed of in containers approved for this purpose and subjected to type testing, thus protecting waste handlers from contamination during disposal.

8. 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.

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.

9. TASKS AFTER USE

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

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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.

9.2. 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.

9.3. 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.

9.3.1. Manual cleaning and automatic cleaning in a washer

Prepare the PROLYSTICA ® 0.2-0.8 ml/l 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.

According to the washing equipment manufacturer's instructions, apply a standard instrument cleaning cycle using their recommended PROLYSTICA ® 0.2-0.8 ml/l enzymatic instrument disinfectant solution and PROLYSTICA ® 0.2-0.8 ml/l instrument cleaning solution. Below is a list of recommended minimal washing cycle parameters:

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	

9.4. 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.

10. STERILIZATION

The manufacturer recommends a thermal sterilization procedure using saturated steam at 132°C with an overpressure of 2.1 kp/cm² for 10 minutes, or a hot air sterilization procedure at 160°C for 60 minutes. The cycle time for the technology used by the end-user must not be shorter than the value recommended by the manufacturer.

Based on validation documents issued by an accredited laboratory, the results of biocompatibility tests (cytotoxicity and TOC) performed on products sterilized at half the recommended sterilization cycle meet the requirements even after 200 sterilization cycles.

Additional sterilization procedures may be provided by the sterilization equipment manufacturer.

11. 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.

12. 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.
Avoid alkaline detergents (pH >7) for aluminium-based devices, and clean them by hand instead of using an ultrasonic washing machine. Do not sterilize such instruments together with stainless steel instruments, as this may cause a chemical reaction.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

SUBAN Instruments Hungary Co.
HUNGARY, Hajdú-Bihar country
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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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