SAYAN TIBBI ALETLER PAZARLAMA SANAYI VE TICARET LTD. STI.
Kemalpasa Mahallesi 7110/2 Sokak No:4
35060 Bornova / Izmir / TURKIYE
Tel : +90 232 472 27 78 ***(2 Lines)***
Fax : +90 232 472 27 76
sayan@sayan.com.tr / www.sayan.com.tr

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INSTRUCTIONS FOR USE

BONE CUTTING SYSTEM

IMPORTANT NOTE

This manual is intended for the maintenance, cleaning, use and preservation of reusable SAYAN surgical bone cutting tools.

The components of SAYAN surgical bone cutting system show a variety of products according to different types of surgical motor couplings.

SAYAN surgical bone cutting tools are used for bone reshaping, tapping, perforation, grating, and reaming during surgical interventions.

These products are manufactured in accordance with the requirements of 93/42/EEC Medical Device Directive.

SAYAN surgical bone cutting tools are produced from the raw materials stated in ISO 7153-1 and ISO 16061 standards.

Most of the bone cutting tools are made of stainless steel and are magnetic. Magnetic tools are hardened under vacuum. Polymer materials such as propylux, radel and sterilization-resistant silicone are among other materials used. The raw materials used are indicated on the label.

Stainless steel is used to manufacture flexible/rigid reamer, flexible drill holder, drill bit, saw blade, acetabular reamer and reamer handle body, MIS (minimally invasive surgery) reamer and reamer handle body and set container.

Polymer material is used to manufacture acetabular reamer handle handgrip, MIS reamer handle handgrip, and instrument holder/feet in the sets.

Sayan bone cutting tool sets are punctured to allow steam to enter inside the case during the sterilization process.

The instrument sets do not have a sterile barrier and must be used in conjunction with sterile packaging to preserve sterilization.

SAYAN surgical bone cutting tools and sets are produced non-sterile and should be cleaned and sterilized in accordance with the instructions specified in this document unless otherwise specified on the product package.

WARNINGS AND RISKS

Hospitals should undertake full responsibility of post-surgical cleaning, disinfection, packaging and pre-operation sterilization of all new and used bone cutting tools and sets before next operation. The instruments must be used by trained personal in accordance with their intended purpose of use.

1. Corroded tools should not be used but should be sent to SAYAN for servicing. Instruments must not be co-located with corrosive vapor-producing chemicals nor any other corrosive media.
2. Instruments must be sterilized before use. New instruments should be cleaned before sterilization and should be stored in a clean room environment if removed from the sealed packaging.
3. Cleaning agents should not contain chlorine ions.
4. Enzymatic and cleaning agents at neutral pH value should be preferred for cleaning the tools.
5. Selection of the enzyme solution is important for the removal of blood, body fluid and tissues because some enzymatic solutions are used to disrupt feces or other organic compounds so they may not be suitable for orthopedic instruments.
6. Cleaning and rinsing water before sterilization should be demineralized (pure) water.
7. All instruments should be counted several times defined as below, during the operation because of the possibility of forgetting instrument inside the patient body.
   i. Before starting the operation,
   ii. Before and after a special procedure,
   iii. Before closure of the surgical wound and after closure of the skin,
   iv. Before the change of surgical staff at the end of the operation and during the operation

Bone cutting system instruments can only be used with surgical motor. The connection of the motor must be the same as the intended connection on the instrument. Surgical motors not complying with the connection on the instrument should not be used.

To prevent distal migration and possible injury, verify that the bone cutting instrument system components are correctly inserted and tightened before device activation.

Be sure to perform a functional check before surgery for all components (flexible drill shaft with drill bit, reamer bit with flexible reamer handle and guide rod, reamer with reamer handle, reamer handle and shaft adapter with surgical motor).

To prevent injury to patients and operating room personnel, devices should be controlled thoroughly.

Saw blades, which may appear acceptable but are actually dirty or damaged, may cause the following dangers: necrosis caused by excessive heat accumulation, infection from residues, elongation of the cutting time resulting from poor performance.

SIDE EFFECTS

The side effects of SAYAN surgical bone cutting tools are as follows but not limited to:

1. Since the bone cutting system components are made of stainless steel, the patient can react allergic to this substance.
2. Infection, blood poisoning, bone marrow inflammation, bone resorption and bone softening may occur in the patient.
3. Metabolic disorders that damage the structure of the bone can be seen.
4. Sudden joint damage, significant bone loss or bone resorption in the X-ray film may occur.
5. Circulatory failure, muscle blindness or neuromuscular diseases may occur.

POTENTIAL ADVERSE EFFECTS

All possible adverse effects are associated with hip arthroplasty, knee and bone cutting surgeries. Possible negative effects of the instruments are listed below, but are not limited to.

1. Tool bending, breaking, movement or migration.
2. Tissue / bone damage caused by vestigial tool parts.
3. Regional and / or systemic infection, pain.
4. Tissue or bone damage during surgery

Note: The possible risks identified as above due to the use of the devices may require additional surgery.

Acetabular reamer / saw blade / flexible & rigid reamer and drill can create temperature and pressure causing tissue or bone damage during carving / cutting / drilling processes.

When using sharp tool holders, more care must be taken to avoid injury. Consult an infection control practitioner to develop and verify appropriate safety procedures for all levels of direct device contact.

Electrical safety of the surgical motors must comply with IEC 60601-1.

1. The bone cutting tool system is intended for use only by trained medical professionals who are associated with the use and application.
2. Be careful to avoid improper use, as blunt or damaged cutting teeth may cause improper engraving / cutting / drilling.
3. The blunt incisors lead to the resorption of the soft bone and the resilience of the hard bone. This may result in an irregular or enlarged bone formation.
4. If you notice any blunt cutting teeth on the tools, please send products to Sayan for servicing.

SAYAN bone cutting system components can be used with a device that provides electrical power, and may cause electric shock if any short cut occurs during surgery. In this case or under similar conditions, you should inform the manufacturer of the surgical motor.

5. Instruments made of different metals must be treated separately to prevent the electrolytic reaction between metals.
6. The tools with coating on should be kept away from other instruments in order not to damage or scratch the coating.
7. All hospital personnel who work with contaminated or potentially contaminated medical devices must comply with the general rules of contamination and use of protective equipment.
8. In case of request, information about surgical techniques is given. The surgeon must be well aware of the design features of the products and surgical techniques before surgery.

CLEANING AND CARE

Surgical instruments or kits are susceptible to damage for a number of reasons, such as long-term use, improper and harsh use. Care should be taken not to compromise high performance of the instruments. What to do to minimize the risk of injury are listed as follows;

1. Inspect instruments for damage after collection and after each use and cleaning. Inadequately cleaned tools should be cleaned again. Tools that require repair should be left aside and returned to SAYAN.
2. The tools should only be used for their intended purpose.
3. Extreme care must be taken to avoid injuries while handling sharp instruments.

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4. Appropriate safety procedures must be verified and developed for direct contact levels of all instruments.
5. After the operation, blood and body fluids should not be allowed to dry on surgical bone-cutting tools. Contamination risks should be taken into consideration and appropriate chemical substances should be used.
6. Do not use metal brushes or metal tools during cleaning. Soft bristle nylon brushes and pipe cleaners should be used
7. During the manual cleaning process, low-foaming surfactant cleaning detergents should be used to ensure that the instruments are visible in the cleaning solution.
8. In order to prevent accumulation of detergent residue on the tools, the cleaning agent should be rinsed completely and easily from the instruments.
9. Heavy tools should not be placed on sensitive instruments and tools with mechanism should be disassambled / kept open before cleaning.
10. Aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine-containing salts and cleaning, disinfection solutions are corrosive and should not be used.
11. Mineral oil and silicone lubricants should not be used due to the formation of microorganism layers on the tools, preventing the steam from direct contact with the surface and creating difficulty in cleaning.
12. Descaling agents containing morpholine should not be used in steam sterilizers. These agents leave residues leading to wear over time on the polymer tools.
13. After cleaning, make sure that the instruments are rinsed and dried. Stained and damaged tools should be separated to check corrosion and functionality.
14. Due to the cutting and penetrating properties of bone cutting tools, care must be taken to ensure that cleaning personel and tools are not damaged when they are cleaned and placed in place.
15. Automatic cleaning using a washer / disinfector may not be effective for cannulated, dead holes, mat finishes and complex orthopaedic instruments. Manual or manual / automatic combination cleaning process is recommended.
16. If applicable, the multi-component tools must be disassembled before cleaning. Make sure that small parts are not lost.
17. The tools must be removed from the metal or polymer trays for manual or automatic cleaning processes. The instrument case, tray and covers must be cleaned separately from the tools.
18. The polymers used in making the various components of the tools cannot withstand the conditions of the washer / sterilizer operating at temperatures equal to or greater than 141°C / 285°F and which use fresh vapor jets as cleaners. Under these conditions, polymer surface defects may occur.
19. The polymers used in SAYAN bone cutting system can be sterilized at steam / moisture temperatures. Polymer materials have a limited service life. If the surface color of the polymer shows excessive surface wear (cracking, stratification, etc.), or if the polymer devices are crimped they must be replaced.

CLEANING / DISINFECTION OPTIONS

MANUEL CLEANING

1. Separate any mated instruments before cleaning. For any instruments with moving pieces, move the pieces throughout their range of motion during cleaning to clean moving pieces in all positions.

2. Rinse with cold tap water (< 45°C) to remove visible contamination.

3. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes. Water temperature 30°C ±5°C (Cleaning bath with %2 (20ml/l) Neodisher Mediclean Forte)

4. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.

5. Rinse with cold tap water (< 45°C) for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.

6. Sonicate the device in Enzymatic detergents for a 10 minutes in an Ultrasonic Cleaner (tap water - 65°C ±5°C) (ultrasonic cleaning bath with 2% (20ml/l) Neodisher Mediclean Forte), 37 kHz Ultrasonic frequency, 200W effective ultrasonic power.

7. Rinse thoroughly/flush with cold tap water for 1 minute.

8. Dry with a clean, soft, absorbent, disposable cloth.

9. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

AUTOMATIC CLEANING

1. Separate any mated instruments before cleaning. For any instruments with moving pieces, move the pieces throughout their range of motion during cleaning to clean moving pieces in all positions.

2. Rinse with cold tap water (< 45°C) to remove visible contamination. While rinsing, scrub thoroughly with a soft brush and/or pipe cleaner and repeatedly flush lumens and blind holes with a syringe.

3. Transfer to washer for processing. See table below for cycle parameters.

Phase	Recirculation Time (Minute)	Temperature	Detergent/ Water Type
Rinse	2	< 30°C	Potable Water
Cleaning	7	55°C	Enzymatic Detergent For Example -Neodisher® MediClean Forte ; Dr. Weigert GmbH & Co. KG. -Potable Water
Intermediate Wash with Water	3	10°C	Deionized Water
Disinfection	7	90°C	Deionized Water
Drying	15	90°C	N/A

4. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

Note: Using a water jet or syringe will provide better cleaning of hard-to-reach areas and mat areas.

PREPARATION FOR CLEANING AND INSTALLATION

To remove the handgrip, press the pin on the shaft of the handle and slide the handgrip onto the pin.

Clean the instruments before sterilization and as soon as possible after use. Do not allow blood or debris to dry on tools. All tools that are used or in contact with blood or saline solution should be washed. After cleaning / disinfecting, disassembled tools must be reassembled and individual instruments can be placed in the case for sterilization. Slide the drill bit and flexible retainer shaft over the guide rod before connecting with the surgical motor. Attach the twist drill to the flexible shaft securely before connecting with the surgical motor.

USER'S RESPONSIBILITIES

The healthcare personnel have the ultimate responsibility to ensure that packaging method as well as packaging material is suitable for sterilization and maintain sterility.

Cleaning / Decontamination: SAYAN recommends decontaminating the devices as disassembled or open in an automatic washer disinfection unit using thermal disinfection. This process must be ultrasonic or continuous tunnel operation cabin type manual operation is an acceptable alternative.

Suitable detergent and rinsing solutions as recommended by the manufacturer of the washer-disinfection unit can be used. However, these detergents and / or rinsing solutions should have neutral pH value.

Extremely acidic or alkaline solutions may cause corrosion on tools.

During cleaning care should be taken not to splash water by keeping instruments under the water surface in the sink.

Operators should wear protective equipment. Care should be taken to avoid injuries and to provide the necessary conditions for health care, safe transportation and decontamination. ANSI / AAMI ST35 standards regulate the handling and transportation of contaminated goods, decontamination processes, service, repair, and monitoring process performance.

BEFORE OPERATION

1. Review patient history, physical examination, and imaging studies to identify possible contraindications for the operation and determine the appropriate symptomatic level.
2. Only patients meeting the criteria defined in the indications should be selected.
3. Patients under conditions that could be effected by the contraindications of the device should be operated very carefully or not operated if possible.
4. Care must be taken when handling and storing tool components.
5. Components and instruments should be checked if they are damaged during storage or prior to operation procedures.

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6. Functional and visual control should be done with the surgical motor and other components of the bone cutting tools used before the operation.
7. Accurate selection of device size and type is extremely important on the properties and size of bone
8. All components and tools must be cleaned and sterilized before use. In the event of unexpected need, additional sterile spare components must be available.

DURING OPERATION

1. The tools function with other instruments and power tools during the operation.
2. The handle might need to be connected to an adapter first to connect to a power supply.
3. Breaking, sliding or misuse of the tool components can cause injury to the patient or operative personnel.
4. Care must be taken when selecting the size of the reamer. Improper reamer size may cause the prosthesis to dislocate or the bone to crack.
5. The reamer should be chosen 1-2 mm smaller than the acetabular prosthesis for pretreatment otherwise the bone may crack or break because of bigger sized reamer.
6. Do not apply excessive torque to the flexible drill handle when drilling the acetabulum. The hard bone can cause breakage.
7. Care should be taken when selecting the size of the saw blade.
8. The wrong saw blade size not suitable for the cutting guide may not work properly. The temperature may increase due to friction between the guide and the blade, causing tissue / bone damage.
9. When using corrugated fixtures or alignment / cutting guides, first insert the blade into the slot and ensure the blade is passing through the guide freely before any application.
10. Do not change the angle of the surgical motor while working on the tissue / bone. It can cause the blade to break.
11. Wash the blades with saline to minimize friction during use.
12. When using blades with alignment guides or slotted cutting features, pre-washing is always necessary.
13. Do not apply excessive lateral force to bone cutting tools.
14. Drill breakage may occur when working around metallic implants (prosthetic components, internal fixation implants, etc.). To minimize these incidents, make sure that the tip of the drill does not come into contact with an implant.
15. Avoid excessive surgical motor speeds.
16. When using a flexible reamer, never insert it into the medullary canal without the ball tip guide as ball tip guide helps to pull the reamer out of the intramedullary canal after reaming.
17. To protect patient tissue, do not use bone cutting tools without necessary attachments, guides, and protective equipments.
18. Proper eye protection equipment should be used during the surgical procedure, which requires the use of bone cutting devices (drills, knives, reamers).

POSTOPERATIVE

After cutting / engraving / drilling the bone, proper operation steps should be carried out according to the user manual. After the operation, the patient must follow the procedures until no indication of surgery is observed.

STERILIZATION / RESTERILIZATION

SAYAN bone cutting tools and sets are served as non-sterile. They must be sterilized before use.
When sterilizing multiple instruments in a single autoclave cycle ensure that the maximum loading capacity of the sterilizer, specified by the manufacturer, isn't exceeded and the products are dry before sterilization. Pack the instruments by placing them in the trays that allow the vapor to contact their entire surface. Ensure that the surfaces which come in contact don't damage /scratch each other. If applicable use standard medical grade steam sterilization wrap according to ANSI/AAMI ST79.

The autoclave sterilization method validated by SAYAN, is as follows.

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 134°C	Exposure Temperature	134°C
	Exposure Time	4 minutes
	Dry Time	15 minutes

SAYAN does not recommend neither the use of low temperature in non-pressurized cycle nor rapid sterilization.

Check that there is no damage on the tools before and after sterilization. Do not use the tools until damage is repaired. After cleaning and sterilization, review functionality before reuse.

REPAIRING AND MAINTENANCE

Disassemble damaged tools and return to SAYAN. All tools must be free of any defects before use.

If any of the bone cutting system components is defective (that is, it does not meet any of its performance characteristics or does not function as intended) or is suspected to be defective, SAYAN must be notified immediately.

After cleaning and sterilization, review functionality before reuse.
Check that there is no damage on the tools before and after use. Do not use the tool until damage is repaired.

The assembled (contacting) parts of stainless steel surgical instruments may be lubricated with instrument care oil before steam sterilization. Sayan recommends the use of the proven biocompatibility Dr. Schumacher 'Spezial Olsprey Medical Instrument Care Spray'.

CONTACT INFORMATION

In case of any incident or for more information on SAYAN bone cutting tools and sets, please contact customer service as below.

Tel : +90 232 472 27 78 (2 Lines)
Fax : +90 232 472 27 76
sayan@sayan.com.tr / www.sayan.com.tr

SAYAN TIBBI ALETLER PAZARLAMA SANAYI VE TICARET LTD. STI.
Kemalpasa Mahallesi
7110/2 Sokak No:4
35060 Bornova / Izmir / TURKIYE

For Use in AUSTRALIA
ARTG Identifier No: 393360
Sponsor: Compliance Management Solutions Pty Ltd
Phone: +61 4 33 124 266
e-mail: info@compliancems.com.au
1B 85 Curzon Street
North Melbourne / Victoria 3051 / AUSTRALIA

For Use in USA
Registration Number / FEI Number: 3012710941
Sponsor: Unique Surgical / Richard Lane
Phone: +1 (260) 242-0025
e-mail:unique.surgical@comcast.net
6435 W. Jefferson Blvd. No:242
Fort Wayne / IN 46804 / USA

SYMBOLS (according to ISO EN 15223-1)


Symbol for "Caution"


Symbol for "The Name and the Address of the Manufacturer"

Symbol for "Contents Packed without Sterilization"

Symbol for "Lot Number"

Symbol for "Catalogue Number"


Symbol for "Electronic IFU"

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Symbol for "Date of Manufacture"

Symbol for "Medical Device"

Symbol for "Unique Device Identificator"

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