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Awl DEVICE IFU

1. Medical Device Description

The 360MedCare Awl is a device used to prepare cortical bone to a predeterminted size allowing placement of Tetrous Tack Implants during shoulder orthopaedic surgical procedures.

2. Intended Use

A hand held spike-like,reusable, manual orthopaedic surgical instrument
Cleaning and sterilisation procedures are to be followed prior to use as per supplied cleaning information contained in KIC-REC-RA-56 *Reprocessing of Surgical Instruments*

2.1 Contact

Externally communicating medical devices	*'Tissue/bone/dentil' Medical device that contacts tissue, bone or pulp/dentin systems.*

2.2 Contact Duration

Regulation Number **888.454 Orthopedic manual surgical instrument**	Duration Transient Normally intended for continuous use for less than 60 minutes. Surgically Invasive device - intended to be used with the aid, or in the context, of a surgical operation; Re-usable, NON-Active, NON-Sterile device that does NOT measure quantitatively *a physiological or anatomical parameter; or* *a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the human body.*

3. Indications for Use

KICO AWL is indicated for use in Rotator Cuff repair where Tetrous Rotator Cuff Tacts are required in the treatment of shoulder injuries as a result of

Osteoarthritis, rheumatoid arthritis/inflammatory arthritis, trauma injury, post-traumatic degenerative joint disease, osteonecrosis/joint collapse, cartilage destruction, which has resulted in a clinical decision to undergoe a surgical procedure to alleviate patient pain and increase anatomical function.

4. Contra-Indications

KICO Awls are counter indicated for procedures that do not require prescribed Tetrous Tacts at the anatomical site. This device is counter indicated for use as a measuring device

Please contact KICO, if there is reasonable doubt on device use, misuse or in relation to any performance issues.
Please email compliance@360med.care immediately if the performance of the device changes or it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse conditions

5. Use Environment

Device can be reprocessed multiple times, given adequate cleaning, sterilisation and inspection between processing. If device is bent, exhibits surface deviations or has any sign of soil internally, please DO NOT USE and action its return by contacting compliance@360med.care.	Cyclic Autoclave Sterilisation Conditions

6. Material

Manufactured from 630 Stainless Steel

7. Specific Functional requirements

Not to be connected to any external power sources or modified in any way.
To be connected to a hand powered luer slip syringe.
Users must follow appplicable Tetrous surgical technique.

8. User Training Requirements

User must have completed training as per the requirements of a Licensed Medical Practitioners familiar with rotator cuff repair. Clinicians must be proficient in Class I device use. The trained clinician must be familiar with the use of the surgical technique that this instrument is to be used in conjunction with.

Symbols Used:

REF	Catalogue Number
LOT	Batch Code
	Manufacturer
	Date of Manufacture
	Non-Sterile

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Probe DEVICE IFU

1. Medical Device Description

The 360MedCare Probe is a device used to inspect cortical bone implant sites enabling the placement of Tetrous Tack Implants during shoulder orthopaedic surgical procedures.

2. Intended Use

An instrument with a tip used to probe and explore orifices and soft tissue.

Cleaning and sterilisation procedures are to be followed prior to use as per supplied cleaning information contained in KIC-REC-RA-56 *Reprocessing of Surgical Instruments*

2.1 Contact

Externally communicating medical devices	*'Tissue/bone/dentil' Medical device that contacts tissue, bone or pulp/dentin systems.*

2.2 Contact Duration

Regulation Number **888.4540 Orthopedic manual surgical instrument**	Duration Transient Normally intended for continuous use for less than 60 minutes. Surgically Invasive device - intended to be used with the aid, or in the context, of a surgical operation; Re-usable, NON-Active, NON-Sterile device that does NOT measure quantitatively *a physiological or anatomical parameter; or* *a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the human body.*

3. Indications for Use

The KICo Probe is indicated for use in Rotator Cuff repair where Tetrous Rotator Cuff Tacts are required in the treatment of shoulder injuries as a result of

Osteoarthritis, rheumatoid arthritis/inflammatory arthritis, trauma injury, post-traumatic degenerative joint disease, osteonecrosis/joint collapse, cartilage destruction, which has resulted in a clinical decision to undergoe a surgical procedure to alleviate patient pain and increase anatomical function.

4. Contra-Indications

Probes are counter indicated for procedures that do not require prescribed Tetrous Tacts at the anatomical site. This device is counter indicated for use as a measuring instrument.

Please contact KICO, if there is reasonable doubt on device use, misuse or in relation to any performance issues.
Please email compliance@360med.care immediately if the performance of the device changes or it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse conditions

5. Use Environment

Device can be reprocessed multiple times, given adequate cleaning, sterilisation and inspection between processing. If device is bent, exhibits surface deviations or has any sign of soil internally, please DO NOT USE and action its return by contacting compliance@360med.care.	Cyclic Autoclave Sterilisation Conditions

6. Material

Manufactured from 630 Stainless Steel

7. Specific Functional requirements

Not to be connected to any external power sources or modified in any way.
To be connected to a hand powered luer slip syringe.
Users must follow appplicable Tetrous surgical technique.

8. User Training Requirements

User must have completed training as per the requirements of a Licensed Medical Practitioners familiar with rotator cuff repair. Clinicians must be proficient in Class I device use. The trained clinician must be familiar with the use of the surgical technique that this instrument is to be used in conjunction with.

Symbols Used:

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REPROCESSING OF SURGICAL INSTRUMENTS

GENERAL

- The instructions outlined in this document apply to all 360KS surgical instruments and should be studied carefully.
- New and used instruments must be thoroughly processed according to these instructions prior to use.
- The central sterile supply department (CSSD) should comply with local laws and regulations in countries where reprocessing requirements are more stringent than those detailed in this guide
- This document has been developed in accordance with ISO 17664:2017.

⚠ Warnings and Precautions

- Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Do not place heavy instruments on top of delicate devices.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilisation steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices. Refer to 'Point of Use' section.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
- Mineral oil or silicone lubricants should not be used because they coat microorganisms, prevent direct contact of the surface with steam and are difficult to remove.

Limitations and Restrictions

- Automated cleaning using a washer/disinfector alone may not be effective for orthopaedic instruments.
- Use the enzymatic and cleaning agents recommended in these instructions. Kico recommend 8mL/L Neodisher Mediclean Forte Detergent, or equivalent.
- Instruments must be removed from metal or polymer trays for cleaning. Instrument trays, cases and lids must be cleaned separately.
- Repeated processing, according to the instructions in this manual has minimal effect on 360KS surgical instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse osmosis (RO), deionised (DI), distilled water, or equivalent.
- Ethylene oxide (EO), gas plasma and dry heat sterilisation methods are not recommended for sterilisation of 360KS surgical instruments. Steam (moist heat) is the recommended sterilisation method for 360KS surgical instruments.

REPROCESSING INSTRUCTIONS

Point of Use

- Used instruments must be transported to the CSSD in closed or covered containers to prevent unnecessary contamination risk.
- Instruments should be cleaned within 30 minutes of use to minimise the potential for drying prior to cleaning.
- Flush the instrument in running water, within the temperature range 15-30°C/59-86°F, to remove gross visible blood and body substances.

Preparation for Decontamination

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Disassembly, where necessary is generally self-evident. Care should be exercised to avoid losing small screws and components.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Manual Cleaning and Disinfection

Cleaning and disinfection are achieved through enzymatic soak and scrub followed by sonication.

Step 1	Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Kico recommend 8mL/L Neodisher Mediclean Forte Detergent, or equivalent. Scrub using a soft-bristled, nylon brush (crevices, lumens, mated surfaces and other hard to clean areas should be attended) until all visible soil has been removed. Clean cannulations and holes using an appropriate brush ensuring that the full depth of the feature is reached. Hold the items low in the sink to limit the generation of aerosols during scrubbing.
Step 2	Remove the device from solution and rinse in purified water (from one or any combination of the following: ultra-filter (UF), reverse osmosis (RO), deionised (DI) or distilled) for a minimum of 3 minutes. Thoroughly flush holes and other difficult to reach areas. Ensure that running water passes through the cannulations, and that blind holes are repeatedly filled and emptied.
Step 3	Pour the prepared neutral pH cleaning solution into a sonication unit and completely submerge the device in the solution and sonicate for 10 minutes at 40-50 kHz.
Step 4	Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 5	Repeat the sonication and rinse steps above.
Step 6	Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Automated Cleaning

Automated cleaning using a washer/disinfector without manual pre-cleaning is not recommended.

Step 1	Prepare the Instrument Tray (empty, without Surgical Instruments)
Step 2	Transfer each instrument and empty instrument tray to the automatic washer.
Step 3	Select the cycle parameters as listed in the table below

Manual Pre-cleaning:

- IS NOT REQUIRED if the instruments do not have dried-on visible debris. Proceed to step 2.
- IS REQUIRED if the instruments have dried-on visible debris. Follow the manual pre-cleaning steps below prior to proceeding to step 2.
    a) Rinse instruments under running cold tap water for a minimum of one (1) minute. Remove gross debris using a soft-bristled brush.
    b) Immerse and soak instruments for a minimum of five (5) minutes in enzymatic detergent. Kico recommend 8mL/L Neodisher Mediclean Forte Detergent, or equivalent. Use a soft-bristled nylon brush to remove visible debris from challenging design features. Actuate joints, handles and other movable device features to expose all areas to detergent solution, if applicable.
    c) Rinse instruments under running cold tap water for a minimum of one (1) minute, ensuring that running water passes through cannulations and that blind holes are repeatedly filled and emptied.
    d) Pour a prepared neutral pH cleaning solution into a sonication unit and completely submerge each instrument in the solution and sonicate for 10 minutes at 40-50 kHz.
    e) Rinse instruments in purified water for at least three (3) minutes.
    f) Visually inspect instruments. Repeat steps a)-f) until no visible soil remains on instruments.

NOTE: Devices / Instruments must be removed from Instrument Trays or any other packaging for manual and/or automated cleaning procedures.

NOTE: the automatic washer should fulfil requirements specified in ISO 15883.

NOTE: Instrument trays, cases, lids should be cleaned separately.

Parts Washer Cleaning Parameters			
Phase	**Recirculation Time**	**Temperature**	**Detergent type and concentration**
Pre-wash 1	4 minutes	Cold tap water	N/A
Wash 1	2 minutes	65° C tap water	Neodisher Mediclean Forte 8mL/L
Rinse 1	2 minutes	Hot tap water	N/A
Thermal Disinfection	1 minute	82.2°C RO/DI water	N/A
Drying	7 minutes	115°C	N/A

Post-cleaning Inspection, Maintenance and Testing

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning and disinfection process.
- Visually inspect each instrument for corrosion, damaged surfaces, recessed features and cracks. The end of component service life is normally determined by wear and damage due to use. If any once of the visual or functional inspections are deemed to fail, the failed part must be immediately removed from service and 360 Knee Systems must be contacted to replace the defective part.
- Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Where instruments form part of a larger assembly, check that devices assemble readily with mating components.
- Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Surgical Milk or equivalent lubricant) intended for surgical instruments that must be sterilised. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. Manufacturer's expiration dates and instructions should be adhered to for both stock and use-dilution concentrations.

Packaging

- Trays shall be wrapped in standard medical grade, steam sterilisation wrap using the AAMI double wrap method or equivalent.
- The user must ensure that the instrument tray is not tipped or the contents shifted once the devices are arranged in the tray. Refer to the 360KS Surgical Instruments IFU for instrument tray configuration.
- Where specialised and standalone instruments are provided by 360KS to meet surgeon preferences they may not be provided in a tray. The hospital shall ensure that these instruments are properly prepared and packaged in trays that will allow steam to penetrate and make direct contact with all surfaces.
- Instruments must not be stacked or placed in close contact and must be disassembled where possible prior to packaging.
- Customised trays with areas designated for specific instruments may be supplied by 360KS. CSSD staff must ensure that these areas only contain specified instruments.

Sterilisation

- Disinfection is only acceptable as a precursor to full sterilisation for surgical instruments. Refer to the following table for recommended minimum sterilisation parameters that have been validated by 360KS to provide a 10^{-6} sterility assurance level (SAL).
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned. Instruments must be disassembled and packaged in a manner that will ensure steam sterilant penetration and adequate drying. Refer to the appropriate 360KS Surgical Instruments Surgical Technique for instrument assembly and disassembly instructions. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- Moist heat/steam sterilisation is the recommended and validated method for 360KS surgical instrument sets.
- The sterilising unit manufacturer's recommendations should always be followed. When sterilising multiple instrument sets in one sterilisation cycle, ensure that the manufacturer's maximum load is not exceeded.
- Instrument sets must be properly prepared and packaged in trays that will allow steam to penetrate and make direct contract with all surfaces. Refer to the 360KS Surgical Instruments IFU for instrument tray configuration.
- Ethylene oxide (EO) or gas plasma sterilisation methods should not be used.
- Gravity displacement sterilisation cycles are not recommended because cycle times are too long to be practical.
- Local or national specifications may be followed where steam sterilisation requirements are stricter or more conservative than those listed in the table. It is then the responsibility of the user to validate the specification.
- Drying times vary according to load size and should be increased for larger loads.

Recommended Steam Sterilisation Parameters

Pre-vacuum Autoclave Cycle		
Temperature	**Exposure Time**	**Dry Time**
132°C / 270°F	4 minutes	30 minutes

Storage

- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

ADDITIONAL INFORMATION

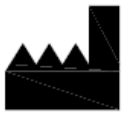
Responsibilities

- Orthopaedic surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to 360KS to be discarded. Notify your 360KS representative of any instrument problems.
- Loan sets must undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilisation before being returned to 360KS. Decontamination certificates or indicators must be provided with instruments being returned to 360KS.
- The instructions provided have been validated by 360KS as being capable of preparing orthopaedic devices for use. It is the responsibility of the hospital to ensure that reprocessing is performed using the appropriate equipment and materials and that CSSD personnel have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Important Notice

- 360KS validated reprocessing instructions are not applicable to 360KS instrument trays that include devices that are not manufactured by 360KS, not packed in accordance with 360KS specifications or provided with their own instructions.
- 360KS strictly prohibits the modification or rework on any instruments or instrument trays.
- In a sterilisation process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. This probability can only be assured for validated processes.
- If these instructions are not followed, 360KS disclaims any liability for any subsequent consequences.

Please contact your product representative, or 360KS at info@kneesystems.com, for the Surgical Technique, Instructions for Use, or further information.



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US Sale

Caution: Federal law restricts this device to sale by or on order of a physician.

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