Instructions for Use for
KINCISE™ System
Acetabular Cup Extraction

Including glossary of symbols

English (en)

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1. General Instructions

1.1 Application

These Instructions for Use apply to the KINCISE™ System Acetabular Cup Extraction instruments which are manufactured by Spierings Orthopaedics B.V. The instrumentation is supplied non-sterile but is intended to be used in a sterile condition.

The KINCISE™ System Acetabular Cup Extraction is intended to be used for removal of an uncemented acetabular component during revision hip arthroplasty in combination with the power driven *KINCISE™ System Automated Surgical Impactor*, part of the *KINCISE™ 2 Surgical Automated System*. The instrumentation is developed for use by experienced orthopaedic surgeons in operating theatres. The instrumentation is non-sterile and reusable, except for the Blades which are single-use devices.

These Instructions for Use are intended for physicians, trained medical personnel, biomedical equipment technicians and central supply/sterile processing technicians. Keep and consult these Instructions for Use during the service life of the instrumentation.

Note: The KINCISE™ System Automated Surgical Impactor is not manufactured nor supplied by Spierings Orthopaedics B.V., but is available from the distributor.

1.2 Utilization

- The Blades are designed and warranted for single use only.
- Before use, clean and sterilize the instruments that are supplied non-sterile (see section 2 'Device (re)processing').
- Before clinical use, the surgeon shall thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation.
- If applicable, available radiographic templates shall be used to assist in the preoperative prediction of component size and type.
- See Section 3 'Surgical Technique' for additional procedural information.

1.3 Indications / Contraindications

Indications: The KINCISE™ System Acetabular Cup Extraction does not have any specific indications.

These instruments are intended to aid in the explantation of uncemented acetabular components. Any indications for the surgical procedure are based upon the implants to be revised rather than these instruments.

Contraindications: There are no known contraindications for the KINCISE™ System Acetabular Cup Extraction.

These instruments are intended to aid in explantation of uncemented acetabular components. Any contraindications for the surgical procedure are based upon the implants to be revised rather than these instruments.

1.4 Warnings ⚠

- Read and understand these instructions before use. Failure to follow instructions may result in injury.
- The surgeon must evaluate if the KINCISE™ System Acetabular Cup Extraction is appropriate for the intended procedure, based on the designed capabilities of the device with regards to the type of implant to be removed, bone density, bone strength, bone size, surgical approach and anatomical situation.
- Surgeon is responsible for learning proper techniques in use of the device; improper use may cause serious injury to user or to patient.
- Do not (re)use the Blades. Any used or unused Blade that has been exposed to bone, soft tissue, blood or other body fluids must not be reprocessed or resterilized and must be discarded.
- Care shall be taken not to tear surgical gloves when handling any sharp-edged device.
- Do not activate the *KINCISE™ System Automated Surgical Impactor* unless the *Head* is securely positioned inside the cup before removal of the cup. Else, the assembled *Head* may detach from the *Shaft*.

- Maintain firm control of instrument at all times.
- Never use damaged medical devices. Repairs must only be made by the manufacturer. Repairs made by anyone else, void the guarantee and manufacturer is no longer liable.
- Refurbishing of the device is only allowed by the manufacturer.
- Damaged and/or single-use medical devices must be submitted for professional disposal or recycling. Take steps to avoid risk of injury and infection. Be aware of sharp edges. Protect against unauthorized access. Observe national regulations and disposal guidelines.
- Do not use excessive force. Excessive pressure, impaction, twisting or inappropriate use of the medical device can damage it or the bone.
- The user and/or patient shall report any serious incident that has occurred in relation to the device to Spierings Orthopaedics B.V. and the competent authority of the Member State in which the user and/or patient is established.
- The device can contain the following substance(s) which are defined as CMRs 1A/1B in accordance with EU legislation in a concentration above 0.1% weight by weight:
    - Cobalt (CAS no. 7440-48-4, EC no. 231-158-0).
    - Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

1.5 Potential Adverse Events, Undesirable Side Effects and Residual Risks

As with all major surgical procedures, risks, side effects and adverse events can occur. The following potential adverse events can occur:

- Injury to patient and/or user.
- Infection.
- Malfunctions of instruments including, but not limited to, weld fracture, thread gauling and material fatigue, can occur in a small percentage of cases.
- Serious complications may be associated with any surgical procedure. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders including emboli; myocardial infarction or death.
- Metal sensitivity reactions in patients have rarely been reported.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Intraoperative fissure, fracture, or perforation of the bone can occur due to numerous factors including the presence of defects, poor bone stock, the use of the surgical instruments and the impaction of the Blades.

2. Device (Re)processing

2.1 Warnings and Cautions ⚠

These instructions are provided for the processing of heat-resistant, immersible, critical medical devices, unless otherwise noted on specific product inserts. Information given in product specific IFU are given priority over these instructions. This can include heat-sensitive devices and certain power (air- or electric-driven) tool designs that are provided with specific cleaning and sterilization instructions. Consult the product specific instructions for processing in these cases.

The instructions provided are given as guidance for medical device processing and have been validated by the manufacturer. It is the responsibility of the healthcare facility to ensure that processing is performed using the required equipment, materials and personnel at a defined processing area. This will include the handling of devices during transportation, processing and storage prior to use.

Those using these instructions should be qualified personnel with documented training and competency in accordance with local procedures, guidelines, and standards.

Surgically used instruments can be considered a biohazard and facilities should ensure that transport and handling procedures comply with local regulations and guidelines.

Reusable, non-sterile instruments are required to be cleaned, inspected and sterilized prior to use.

Care should be taken in the handling and cleaning of sharp devices.

All devices must be thoroughly cleaned and inspected prior to sterilization. Long, narrow lumens, blind holes, moving and intricate parts require particular attention during cleaning and inspection. During cleaning, only use detergents that are labelled for use on medical devices and in accordance with the manufacturer's instructions (eg temperature, contact time, and rinse time). Cleaning agents with a used dilution pH of within 7 – 9.5 are recommended. Highly alkaline conditions (pH>10) can limit the lifetime of components / devices, such as aluminum materials. Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products). Do not use a cleaning aid that can damage the surface of instruments such as steel wool, abrasive cleaners or wire brushes.

Instruments should be carefully inspected before each use to ensure that they are functional. Scratches, dents or other damage can result in instrument breakage or tissue injury.

Instruments must be cleaned separately from instrument trays and cases. Instrument trays and cases are designed as an organizational tool in preparation for sterilization, storage and surgical use.

Automated equipment, including washer-disinfectors and steam sterilizers must be installed, maintained and operated in accordance with manufacturer's instructions.

Do not exceed 140°C (284°F) during processing steps.

For patients with, or suspected with, Creutzfeldt-Jakob disease (CJD), variant CJD or other transmissible spongiform encephalopathy (TSE) and related infections, it is recommended to treat the patient using single-use instruments. Safely dispose of all devices used in accordance with local procedures and guidelines.

2.2 Limitations on Processing

Repeated processing cycles in compliance with these Instructions for Use have minimum effects on device life and function. Instruments do not have an indefinite functional life. End of life of devices is determined by wear and damage due to surgical use and handling. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.

Step 1: Point of Use Care

All single use devices and materials should be removed and discarded in accordance with local procedures and guidelines.

The drying of gross soil (blood, tissue and/or debris) on devices following surgical use should be avoided. It is preferred that gross soil is removed from devices following use and in preparation for transportation to a processing area. Gross soil can be removed using sponges, cloths, or soft brushes. Water and/or cleaning detergents (labelled for use on medical devices) may be used.

Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products. Flush all lumens, blind holes, small clearances, and moving and intricate parts with water (or detergent solution) to prevent the drying of soil and/or debris.

If gross-soil cannot be removed at the point of use, the devices should be transported to prevent drying (e.g., covered with a towel dampened with purified water) and cleaned as soon as possible at a designated processing area.

Surgical cement should be removed from devices during surgical use and prior to setting. When cement hardens, it will typically require physical methods to remove. Chemical solvents should not be used. Hardened cement may be removed with an approved stylus or removing tool, but these may damage devices.

Step 2: Containment and Transportation

Surgically used devices may be considered bio-hazardous and should be safely transported to a designated processing area in accordance with local policies.

Step 3: Cleaning

Preparation before Cleaning

It is recommended that devices should be reprocessed as soon as is reasonably practical following surgical use.

Instruments must be cleaned separately from instrument trays and cases.

Care should be taken in the handling and cleaning of sharp devices. These are recommended to be cleaned separately to reduce risks of injury.

Multi-part or complex instruments may require disassembly for cleaning. Refer to any technique guides, disassembly instructions, assembly instructions or other supplemental information for specific device disassembly and/or reassembly instructions.

Any devices with moving parts (e.g. ratchets, box locks, hinges or actuated parts) need to be actuated during manual cleaning and rinsing to ensure access of the cleaning process.

All devices with lumens need to be manually flushed to remove debris and brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brush size should be approximately the same diameter of the lumen to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the lumen. Refer to any technique guides or other supplemental information for specific device lumen diameters. After brushing, rinse with water by flushing and blowing clean compressed air through all lumens.

NOTE: Two cleaning methods are provided, a Manual and an Automated Method, and at least one shall be performed.

Cleaning: Manual

1. Prepare a neutral or mild alkaline cleaning solution (pH 7 to 9.5) in accordance to the detergent manufacturer's instructions. The temperature of the solution should be ≤40°C (104°F) for manual cleaning.

   NOTE: The cleaning solution may contain enzymes. Aluminum-safe alkaline cleaners can be used but can vary in material compatibility overtime based on their formulation. Material compatibility should be confirmed with the detergent manufacturer.

2. Immerse devices and parts in the detergent solution, and soak for a minimum of 5 minutes.

3. While immersed, use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly clean all traces of blood and debris from all device surfaces for a minimum of one minute.

4. Ensure all lumens are thoroughly brushed. Push the brush through the entire length of the lumen using a twisting motion to remove debris from both ends for a minimum of one minute.

5. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Ensure all lumens, blind holes, small clearances, and moving and intricate parts are flushed for a minimum of one minute.

6. Rinse all devices by immersion in ambient, < 40°C (104°F), tap water for a minimum of one minute and until evidence of debris, soil, and cleaning solution are visually removed. Use a large syringe (e.g., 50ml or greater) filled to capacity with tap water to thoroughly flush lumens, blind holes, small clearances, and moving and intricate parts. Actuate joints, handles and other moveable device features to rinse thoroughly.

7. Completely submerge the devices in an ultrasonic bath prepared with a neutral or mild alkaline pH detergent (pH 7-9.5), prepared in accordance with the manufacturer's instructions. Use a large syringe (50ml or greater) flush all lumens, blind holes, small clearances, and moving and intricate parts with the detergent solution to minimize the formation of air pockets or bubbles.

   NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning.

8. Ultrasonically clean the device components for a minimum of 10 minutes in accordance with manufacturer's instructions. An example of a validated cycle used for cleaning validation included 40kHz at 25°C for 10 mins).
9. Rinse all devices by immersion in ambient, < 40°C (104°F), tap water for a minimum of one minute and until evidence of debris, soil, and cleaning solution are visually removed. Use a large syringe (e.g., 50ml or greater) filled to capacity with tap water to thoroughly flush lumens, blind holes, small clearances, and moving and intricate parts. Actuate joints, handles and other moveable device features to rinse thoroughly.
10. Remove the devices and repeat the rinsing using in ambient, < 40°C (104°F) critical water (high purity water generated by processes such as reverse osmosis, deionization or distillation) for at least 15 seconds.
11. Remove and dry device using a clean, soft, lint-free cloth or clean compressed air. Ensure that all lumens and articulated areas are dried using compressed air.

Cleaning: Automated

1. Prepare a neutral or mild alkaline cleaning solution (pH 7 to 9.5) in accordance to the detergent manufacturer's instructions. The temperature of the solution should be ≤40°C (104°F) for manual cleaning.

   NOTE: The cleaning solution may contain enzymes. Aluminum-safe alkaline cleaners can be used but can vary in material compatibility overtime based on their formulation. Material compatibility should be confirmed with the detergent manufacturer.

2. Immerse devices and parts in the detergent solution, and soak for a minimum of 5 minutes.
3. While immersed, use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly scrub all traces of blood and debris from all device surfaces for at least one minute.
4. Ensure all lumens are thoroughly brushed. Push the brush through the entire length of the lumen using a twisting motion to remove debris from both ends for at least one minute
5. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Ensure all lumens are flushed for at least one minute.
6. Rinse all devices by immersion in ambient, < 40°C (104°F), tap water for a minimum of one minute and until evidence of debris, soil, and cleaning solution are visually removed. Use a large syringe (e.g., 50ml or greater) filled to capacity with tap water to thoroughly flush lumens, blind holes, small clearances, and moving and intricate parts. Actuate joints, handles and other moveable device features to rinse thoroughly.
7. Completely submerge the devices in an ultrasonic bath prepared with a neutral or mild alkaline pH detergent (pH 7 to 9.5), prepared in accordance with the manufacturer's instructions. Use a large syringe (50ml or greater) flush all lumens, blind holes, small clearances, and moving and intricate parts with the detergent solution to minimize the formation of air pockets or bubbles.

   NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning.

8. Ultrasonically clean the device components for a minimum of 10 minutes in accordance with manufacturer's instructions. An example of a validated cycle used for cleaning validation included 40kHz at 25°C for 10 mins).
9. Rinse all devices by immersion in ambient, < 40°C (104°F), tap water for a minimum of one minute and until evidence of debris, soil, and cleaning solution are visually removed. Use a large syringe (e.g., 50ml or greater) filled to capacity with tap water to thoroughly flush lumens, blind holes, small clearances, and moving and intricate parts. Actuate joints, handles and other moveable device features to rinse thoroughly.
10. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens have maximum exposure to detergents and rinse water and can drain freely.
11. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and -2, or to an equivalent standard. Automated washing can be included as part of a validated washing,

disinfection, and/or drying cycle in accordance to manufacturer's instructions. An example of a validated cycle used for cleaning validation included:

Phase	Recirculation Time (mins)	Water Temp	Detergent/Water Type
Pre-Wash	2	Cold Tap Water	N/A
Enzyme wash	1	< 40°C (104°F)	Neutral, Enzymatic Cleaner
Wash	5	66°C (151°F)	Neutral pH Detergent
Rinse	2	> 40°C (104°F)	Tap water
Rinse	0.25	Ambient	Critical water (RO, deionized or distilled water)

Step 4: Thermal Disinfection

Thermal disinfection is recommended to render devices safe for handling prior to steam sterilization. Thermal disinfection should be conducted in a washer-disinfector compliant to ISO 15883-1 and-2, or to an equivalent standard. Thermal disinfection in the washer-disinfector shall be validated to provide an A_0 of at least 600 (e.g., 90°C (194°F) for 1 min). Higher levels of A_0 can be achieved by increasing the exposure time and temperature (e.g., A_0 of 3000 at >90°C (194°F) for 5 min, in accordance with local requirements). Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Lumened devices should be placed in a vertical position. If this is not possible due to space limitations within the washer-disinfector, use an irrigating rack /load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if provided.

The following automated cycles are examples of validated cycles:

Phase	Recirculation Time (mins)	Water Temp	Water Type
Thermal Disinfection	1	> 90°C (194°F)	Critical water (RO, deionized or distilled water)
Thermal Disinfection	5	> 90°C (194°F)	Critical water (RO, deionized or distilled water)

Step 5: Drying

It is recommended that drying is conducted in a washer-disinfector compliant to ISO 15883-1 and-2, or to an equivalent standard. Drying efficiency in washer-disinfectors can range considerably based on the automated system design and load configuration.

The following automated cycle is an example of a validated cycle:

Phase	Recirculation Time (minutes)	Air Temp	Air Type
Dry	7	115°C (239°F)	Medical grade

Following automated drying, inspect the device for residual moisture. Any residual moisture identified should be dried manually (as described below).

For manual drying:

- Ensure each device is dried and inspected thoroughly.
- For external surfaces, use a clean, soft, lint-free cloth to avoid damage to the surface.
- Open and close, or actuate any applicable devices with moving parts during drying. Pay special attention to any device threads, ratchets and hinges or areas where fluid can accumulate. Clean, compressed air (e.g., medical grade) may be used to facilitate surface drying.
- Dry all lumen/cannulated parts using clean compressed air (e.g., medical grade).

Step 6: Maintenance and Inspection

Instruments should be visually inspected under ambient lighting, to verify that the devices do not have visible soil, damage or moisture.

Inspect devices for:

6 (a) Lack of moisture. Carefully inspect device lumens and moving parts. If moisture is detected, manually drying should be performed.

6 (b) Cleanliness. If any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.

6 (c) Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear

6 (d) Proper function, including but not limited to, sharpness of cutting tools, bending or distortion of devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings and missing or removed part numbers

6 (e) Improperly functioning devices, devices with unrecognizable markings, missing or removed part numbers, damaged and worn devices should be discarded.

Disassembled devices should be reassembled prior to sterilization when specified.

Lubricate any moving parts with a water-soluble surgical instrument lubricant. The lubricant should be approved for use on medical devices and provided with data to ensure biocompatibility and compatibility with steam sterilization.

Step 7: Packaging

Place cleaned, dry devices into the specified locations within the cases provided, if applicable.

Only legally marketed, and locally approved sterilization barriers (e.g. wraps, pouches or containers) should be used for packaging terminally sterilized devices, in compliance to the manufacturer's instructions.

Step 8. Sterilization

Steam (moist heat) sterilization shall be performed in a locally approved, pre-vacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8. The steam sterilizer should be installed and maintained in compliance to manufacturer's instructions and local requirements. Ensure that the steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions and does not exceed the criteria for sterilizer load.

The following steam sterilization cycles are examples of validated cycles:

Conditioning Phase	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Dry Time
Prevacuum	4	132°C (270°F)	30 minutes
Prevacuum	3	134°C (274°F)	30 minutes

Extended steam exposure cycle can be used to meet local requirements such as 134°C (274°F) for 18 minutes.

The efficiency of steam sterilizer drying can range considerable depending on the sterilizer design, loading, packaging and steam supply during the sterilization process. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Extended drying within the sterilizer or in an external drying cabinet in accordance with manufacturer's instructions may be necessary. Do not exceed 140°C (284°F) during drying.

The following steam sterilization cycle is an example of a validated cycle for individual instruments only:

- Unwrapped instrument
- A minimum 3 (three) pulse prevacuum cycle
- 132 °C (270 °F) for 4 minutes

Step 9: Storage

Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

2.3 Additional Information

Cleaning agent information: Examples of detergents that have been used during cleaning validations include Prolystica™ 2X Concentrate Enzymatic Cleaner, Prolystica™ 2X Neutral Detergent, Enzol™, Endozime™, Neodisher Medizym™, Terg-A-Zyme™, and NpH-Klenz™.

Further information regarding the use of specific cleaning agents, ultrasonic washers, washer-disinfector, packaging materials or sterilizers during validation studies are available on request.

The chemical quality of the water used during processing can impact device safety. Facilities should use the recommended water quality requirements for device processing in accordance with local guidance (such as AAMI TIR 34, *Water for the reprocessing of medical devices*) and these instructions for use.

These Instructions for Use have been validated in accordance with ISO 17664. It remains the responsibility of the facility to ensure that the processing is performed using equipment, materials and personnel at a designated area, and achieves the desired requirements. This includes validation and routine monitoring of the process. Likewise, any deviation by the processor from these recommendations should be evaluated for effectiveness and any potential adverse consequences.

All personnel using these instructions should be qualified with documented expertise, competency and training. Users should be trained on healthcare facility policies and procedures along with current applicable guidelines and standards.

3. Surgical Technique

⚠ ***Warning***: ***Always*** *remove the Battery Pack from the KINCISE™ System Automated Surgical Impactor before attaching or removing any instruments (Shaft, Blade, Bolt or Head) to or from the Impactor. Removing the battery will prevent unexpected operation that could cause injury.*

Do not use tools other than the instruments referred to during assembly or disassembly.

STEP 1: PREOPERATIVE EXAMINATION

Examine the presence of adjunctive fixation of the cup to be removed, such as screws, pegs or spikes. If applicable, remove the screws and pegs from the cup. If applicable, cut in between the spikes.

STEP 2: INSTRUMENT SELECTION

⚠ *Warning: do not use visually damaged instruments or blades.*

Determine the *Head* size and the *Blade* size which is needed for acetabular cup removal. The *Head* size corresponds to the inner diameter of the cup. If the *Head* does not fit inside the cup, select one *Head* size smaller. The *Blade* size corresponds to the outer diameter of the cup. If the *Blade* does not fit around the cup, select one *Blade* size larger.

STEP 3: HEAD ASSEMBLY

⚠ *Warning: first assemble the Head before assembling the Blade. Blade edges are sharp.*

Place the *Head* onto the *Shaft* end. Ensure a complete fixation by sliding the *Head* over the *Shaft* until it clicks, to prevent loosening of the *Head* during cup removal. When using two *Shafts*, place a *Head* of same size onto each of both *Shafts*.

STEP 4: BLADE ASSEMBLY

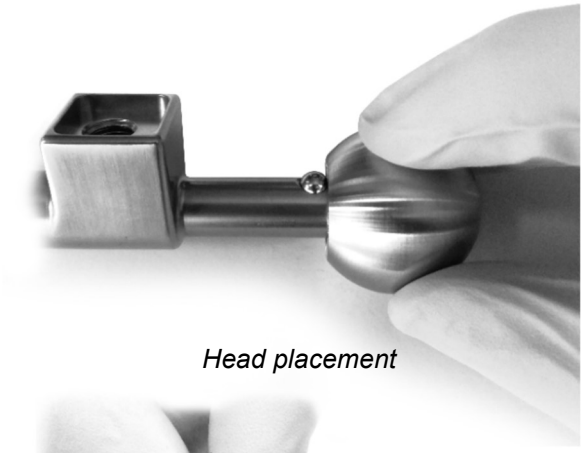
⚠ *Warning: Do always use a new (single-use) Blade. Do not use any used or damaged Blades. First assemble the Head before assembling the Blade. Blade edges are sharp.*

- Screw the *Bolt* halfway into the *Shaft's* thread.
- Place the *Blade* beneath the *Bolt's* head and ensure the *Blade* is entirely enclosed by the *Shaft*. When the *Blade* does not fit beneath the *Bolt*, screw the *Bolt* a few rotations counterclockwise and place the *Blade* again.
- Screw the *Bolt* tightly using the *Hex Key*. Ensure a firm fixation to prevent loosening of the *Bolt* during cup removal.
- Check concentricity of the *Blade* with the *Head* after assembly.
- When using two *Shafts*, place the *Starter Blade* in one *Shaft* and the corresponding *Finisher Blade* in the second *Shaft*.

STEP 5: SURGICAL IMPACTOR ASSEMBLY

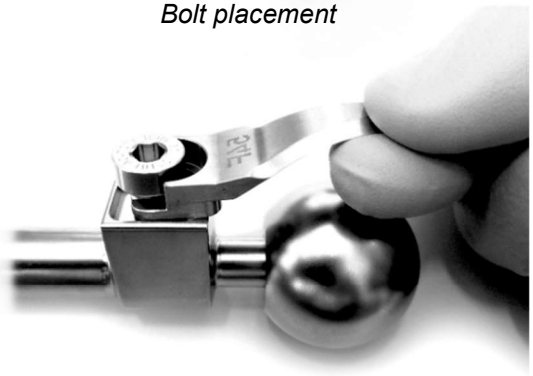
Choose to assemble with or without the *Wrench* positioned on the hexagon.

Attach the *Shaft* to the *KINCISE™ System Automated Surgical Impactor* according to the assembly instructions as described in the Instructions for Use of the KINCISE™ System Handpiece.



Head placement

Bolt placement



Blade placement

Blade fixation

Starter Blade *Finisher Blade* *Impaction by Impactor* *Rotation by Wrench*

STEP 6: CUP RESECTING

⚠ *Warning: Ensure proper centering of the Blade to prevent Blade-cup impingement and to minimize acetabular bone loss. If the cup liner is damaged or has an offset, remove the liner and use a provisional insert.*

⚠ *Warning: If the Wrench is assembled, hold the Wrench as shown in the picture above during impacting to prevent damage to the instrumentation.*

Starter Blade

The cup resecting procedure is started using the *Starter Blade*. Place the *Head* into the liner of the cup. The *Head* works as a guide during cutting around the cup's periphery. Use the *KINCISE™ System Automated Surgical Impactor* to guide the *Blade* into the surrounding bone of the cup. Use the bottom trigger for forward operation. Create slots around the periphery of the cup. Use the *Wrench* for axial rotation. The *Wrench* can be used in six different positions. Alternate between impacting and rotating. Remove the *Shaft* with *Starter Blade* when the periphery part of the cup is resected from the bone.

Finisher Blade

The *Finisher Blade* is used to complete the resection of the acetabular cup. Use the same technique described for the *Starter Blade*. Alternate between impacting and rotating until the cup is resected completely.

STEP 7: SURGICAL IMPACTOR DISASSEMBLY

Remove the Battery Pack from the *KINCISE™ System Automated Surgical Impactor*. Then, remove the *Shaft* from the *KINCISE™ System Automated Surgical Impactor* according to the disassembly instructions as described in the Instructions for Use of the *KINCISE™ System Automated Surgical Impactor*.

STEP 8: BLADE DISASSEMBLY

⚠ *Warning: first disassemble the Blade before disassembling the Head. Blade edges are sharp.*

Disassemble the *Blade* from the *Shaft* by unscrewing the *Bolt* using the *Hex Key*. To switch *Blades*, unscrew the *Bolt* only for a few rotations. To clean and sterilize the instruments, completely unscrew the *Bolt* from the *Shaft*.

⚠ *Warning: Discard the single-use Blades after cup resection.*

STEP 9: HEAD DISASSEMBLY

⚠ *Warning: first disassemble the Blade before disassembling the Head. Blade edges are sharp.*

Disassemble the *Head* from the *Shaft* end. Pull away the *Head* from the *Shaft*.

4. Glossary of standard Symbols

Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer.
	Country / Date of manufacture	Indicates the country 'CC' of manufacture of medical device. The date of manufacture may be added adjacent to this symbol.
	Lot number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. *Note: the distributor can be using an own catalogue number, also shown on the product label where applicable.*
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information. Depicted as datamatrix only or datamatrix with human readable information (HRI) adjacent to the datamatrix. HRI is depicted using the following UDI codes: (01) GTIN (Global Trade Item Number) (10) Lot number (11) Manufacturing date
	Quantity	Indicates the number of medical devices included in the packaging.
	Do not re-use	Indicates a medical device that is intended for one single use only.
	Consult (electronic) Instructions for Use	Indicates the need for the user to consult the Instructions for Use.
	Do not use if package is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process
Rx ONLY	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Where applicable, the symbols and descriptions are according to ISO 15223-1.

5. Product List

Product Name	Manufacturer Part Number	Distributor Part Number
KINCISE™ System Acetabular Cup Extraction Shaft	KIN-2110-01	200005000
KINCISE™ System Acetabular Cup Extraction Bolt	KIN-2110-04	200005015
KINCISE™ System Acetabular Cup Extraction Hex Key	KIN-2110-05	200005016
KINCISE™ System Acetabular Cup Extraction Wrench	KIN-2110-02	200005017
KINCISE™ System Acetabular Cup Extraction SST Head 26mm	KIN-2110-26-SS	200005026
KINCISE™ System Acetabular Cup Extraction SST Head 28mm	KIN-2110-28-SS	200005028
KINCISE™ System Acetabular Cup Extraction SST Head 32mm	KIN-2110-32-SS	200005032
KINCISE™ System Acetabular Cup Extraction SST Head 36mm	KIN-2110-36-SS	200005036
KINCISE™ System Acetabular Cup Extraction SST Head 40mm	KIN-2110-40-SS	200005040
KINCISE™ System Acetabular Cup Extraction Polymer Head 42mm	KIN-2110-42-PP	200005042
KINCISE™ System Acetabular Cup Extraction Polymer Head 44mm	KIN-2110-44-PP	200005044
KINCISE™ System Acetabular Cup Extraction Polymer Head 46mm	KIN-2110-46-PP	200005046
KINCISE™ System Acetabular Cup Extraction Polymer Head 48mm	KIN-2110-48-PP	200005048
KINCISE™ System Acetabular Cup Extraction Polymer Head 50mm	KIN-2110-50-PP	200005050
KINCISE™ System Acetabular Cup Extraction Polymer Head 52mm	KIN-2110-52-PP	200005052
KINCISE™ System Acetabular Cup Extraction Polymer Head 54mm	KIN-2110-54-PP	200005054
KINCISE™ System Acetabular Cup Extraction Polymer Head 56mm	KIN-2110-56-PP	200005056
KINCISE™ System Acetabular Cup Extraction Starter Blade 44mm	KIN-2110-44S-SU	200005144
KINCISE™ System Acetabular Cup Extraction Starter Blade 46mm	KIN-2110-46S-SU	200005146
KINCISE™ System Acetabular Cup Extraction Starter Blade 48mm	KIN-2110-48S-SU	200005148
KINCISE™ System Acetabular Cup Extraction Starter Blade 50mm	KIN-2110-50S-SU	200005150
KINCISE™ System Acetabular Cup Extraction Starter Blade 52mm	KIN-2110-52S-SU	200005152
KINCISE™ System Acetabular Cup Extraction Starter Blade 54mm	KIN-2110-54S-SU	200005154
KINCISE™ System Acetabular Cup Extraction Starter Blade 56mm	KIN-2110-56S-SU	200005156
KINCISE™ System Acetabular Cup Extraction Starter Blade 58mm	KIN-2110-58S-SU	200005158
KINCISE™ System Acetabular Cup Extraction Starter Blade 60mm	KIN-2110-60S-SU	200005160
KINCISE™ System Acetabular Cup Extraction Starter Blade 62mm	KIN-2110-62S-SU	200005162
KINCISE™ System Acetabular Cup Extraction Starter Blade 64mm	KIN-2110-64S-SU	200005164
KINCISE™ System Acetabular Cup Extraction Starter Blade 66mm	KIN-2110-66S-SU	200005166
KINCISE™ System Acetabular Cup Extraction Starter Blade 68mm	KIN-2110-68S-SU	200005168
KINCISE™ System Acetabular Cup Extraction Finisher Blade 44mm	KIN-2110-44F-SU	200005244
KINCISE™ System Acetabular Cup Extraction Finisher Blade 46mm	KIN-2110-46F-SU	200005246
KINCISE™ System Acetabular Cup Extraction Finisher Blade 48mm	KIN-2110-48F-SU	200005248
KINCISE™ System Acetabular Cup Extraction Finisher Blade 50mm	KIN-2110-50F-SU	200005250
KINCISE™ System Acetabular Cup Extraction Finisher Blade 52mm	KIN-2110-52F-SU	200005252
KINCISE™ System Acetabular Cup Extraction Finisher Blade 54mm	KIN-2110-54F-SU	200005254
KINCISE™ System Acetabular Cup Extraction Finisher Blade 56mm	KIN-2110-56F-SU	200005256
KINCISE™ System Acetabular Cup Extraction Finisher Blade 58mm	KIN-2110-58F-SU	200005258
KINCISE™ System Acetabular Cup Extraction Finisher Blade 60mm	KIN-2110-60F-SU	200005260
KINCISE™ System Acetabular Cup Extraction Finisher Blade 62mm	KIN-2110-62F-SU	200005262
KINCISE™ System Acetabular Cup Extraction Finisher Blade 64mm	KIN-2110-64F-SU	200005264
KINCISE™ System Acetabular Cup Extraction Finisher Blade 66mm	KIN-2110-66F-SU	200005266
KINCISE™ System Acetabular Cup Extraction Finisher Blade 68mm	KIN-2110-68F-SU	200005268
KINCISE™ System Acetabular Cup Extraction Case Standard Set	KIN-2110-06	200005100
KINCISE™ System Acetabular Cup Extraction Case Outlier Set	KIN-2110-07	200005200

Manufactured by:
Spierings Orthopaedics B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands

www.spierings.biz
info@spierings.biz

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The Anspach Effort, Inc.
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