ZIMMER BIOMET

HAMMR

Operation and Maintenance Guide

TABLE OF CONTENTS

INTRODUCTION

HOW TO USE THIS MANUAL

- These instructions for use and maintenance manual specifies characteristics and features of the HAMMR equipment, including the Impaction Hand Piece, its attachments (adapters and impacting accessories) and the sterilization tray.
- It briefly addresses the batteries and battery charger needed to use the product. For further information refer to the Zimmer Biomet X-Series manual.
- It includes setup, maintenance and troubleshooting procedures and guides.
- It includes additional data that is essential for safe operation, storage and transport, and preparing it for use.

SYMBOLS AND CONVENTIONS IN THIS MANUAL AND ON THE PRODUCT

 WARNING	Signifies a general **WARNING** – alerts the user to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of the device.
 CAUTION	Signifies a general **CAUTION** – alerts the operator to the possibility of a problem with the device associated with its use or misuse.
NOTICE	A general notice not associated with operator, patient or device issues.
	To warn of a magnetic field
IPX6	Impaction Hand Piece can resist high-pressure, heavy sprays of water.
SECURITY NOTICE	Signifies a **SECURITY NOTICE** associated with security risk for any person involved in the use of the product.
	Signifies to follow instructions for use (IFU)
REF	Manufacturer's catalog number for hand piece and adapters. The catalog number is placed adjacent to this symbol.
SN	Manufacturer's hand piece serial number. The serial number is adjacent to this symbol.
LOT	Manufacturer's adapters batch or lot code.
MD	Medical Device
℞ ONLY	Prescription only. **CAUTION**: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.
	The device has not been sterilized.
	Temperature limitation
	Humidity limitation
	Do not immerse
	Type BF applied part

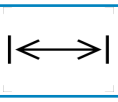
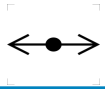
CB	Scheme of the IECEE for Mutual Recognition of Test Certificates for Electrical Equipment.
	Indicates manufacturer and is accompanied by the name and address of the manufacturer.
	Manufacturing date
	This product contains a Li-ion battery that must be recycled.
	The product must not be disposed of in normal household waste and must be disposed of separately. To find out how to properly dispose of this product, please contact your local Zimmer Biomet Representative.
10/10s x 14 I/O	DUTY CYCLE: 10 seconds on max. time followed by 10 seconds off min. time X 14 cycles
GMDN	Global Medical Device Nomenclature
UDI-DI	Unique Device Identifier - Device Identifier
QTY	Quantity
UOM	Unit of Measure. Express the quantity of the package of each (EA or ea.)
	Movement limited in both directions. To indicate that a control, or an object by means of a control, can be moved in both the indicated directions within certain limits.
	Indicates the impacting direction (forward or reverse) which is realized by means of the compression or pulling of the Impaction Hand Piece chuck.
	Direction in general, except for energy and signal flow, for example force or rectilinear motion;
	Interference with other devices can occur in the vicinity of any equipment marked with this symbol

Table 1 - Symbols and conventions used in this manual and in the product

HAMMR INTENDED USE

The HAMMR is indicated for Total Hip Arthroplasty (THA) procedures in the preparation of bone, implantation of acetabular cup and femoral stem implants.

The HAMMR consists of a battery operated Impaction Hand Piece and attachments. The Impaction Hand Piece delivers impacts to instruments and implants similar to a surgical mallet.

User profile is a certified clinician and patient population and contraindications as prescribed by the clinician. HAMMR is intended for clinical environments only.

This equipment is considered to be in NORMAL USE while in:

- operation (impacting or not impacting)
- under cleaning or sterilization processes
- under inspection or in storage

Under NORMAL USE, this equipment has been proved to be free from unacceptable risks directly caused by physical hazards and single fault conditions nor by the degradation or loss of the impacting function.

Device parts that are invasive and come into direct contact with the human body do not contain any harmful biological or chemical agents.

CONTRAINDICATIONS

WARNING The HAMMR automated impaction system is contraindicated for use with the size 7 Echo® Bi-Metric® Full Length High Offset stem (REF: 192107)

CAUTION In every case, the final decision whether to use the HAMMR rests with the attending physician.
He/she should assess prior to use of the system if its performance specifications, precision and handling are suitable for a given application, taking into account bone strength and size and anatomical situation. Moreover, the technique guides and any contraindications of the implant system must be respected.

GENERAL CAUTIONS

- Do not use accessories, adapters or batteries other than those specified or identified as compatible with by Zimmer Biomet.
- The power equipment should never be cleaned in an ultrasonic cleaning system.
- The Impaction Hand Pieces, batteries and battery chargers contain electrical materials. The presence of these materials may, if not disposed of properly, have potential adverse effects on the environment. Do not dispose of normal household waste.
- Refer to the CLEANING & STERILIZATION section of this manual to clean the Impaction Hand Piece and the attachments.
- For cleaning, use only detergents compatible with Impaction Hand Piece materials (see the list in the mechanical characteristics section at the end of this manual)
- The use of the HAMMR Instrument tray for cleaning and sterilization is highly recommended.
- Refer to X-Series Owner's Manual for the battery use and cleaning instructions.

GENERAL WARNINGS AND NOTICES

- Only medical professionals who are thoroughly familiar with this power equipment's function, application and instruction for use should operate it.
- HAMMR adapters and broaches necessarily come into physical contact with the PATIENT in NORMAL USE. HAMMR Impaction Hand Piece does not necessarily come into physical contact with the PATIENT in NORMAL USE.
- Prior to usage, the HAMMR Impaction Hand Piece and attachments must be cleaned and sterilized per the instructions (See Cleaning and Sterilization section)
- Allow the Impaction Hand Piece and adapters to properly cool to room temperature after any autoclave process before using or storing.
- When the Impaction Hand Piece is not in use, place the energy selector in the **0 position** (no impacting mode) to prevent unintended activation.
- Always manipulate or change the adapters and accessories on the back table with the Impaction Hand Piece energy selector set to the **0 position**
- Hand-transmitted vibrations and noise are required in order to carry out the HAMMER impact function.
- Keep HAMMR impacter away from devices and objects that could be damaged by strong magnetic fields. It could damage TVs, laptops, computer hard drives, credit and ATM cards, data storage media, mechanical watches, hearing aids, and speakers.
- For the above mentioned objects, keep a minimum distance as described in the "Pacemaker / implanted defibrillator" security notice. For non-anti-magnetic watches, keep the double minimum distance.
- Do not use the Impaction Hand Piece after a drop. A broken case can result in cutting edges and live parts exposed.In case of a free fall, the hand piece must be returned to maintenance/repair for inspection.

SECURITY NOTICE Pacemaker / Implanted heart defibrillator. HAMMR motor could affect the functioning of pacemakers and implanted heart defibrillators. If you wear one of those devices keep 200 mm (7.8") minimum distance between the pacemaker / defibrillator and internal motor. Inform others who wear these devices to comply with these minimum distances!

INITIAL VISUAL INSPECTION

Unpack the HAMMR upon receipt and inspect the unit for any obvious damage that may have occurred during shipment including damage to any part of the system. If the unit is damaged, notify the carrier and your Zimmer Biomet representative immediately.

WARNING Do not use it if the device appears damaged or does not work as intended.

SYSTEM OVERVIEW

HAMMR DESCRIPTION

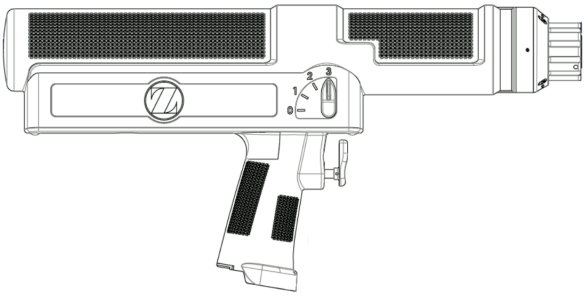
The Impaction Hand Piece, batteries, chargers, attachments and the sterilization tray described in this section are part of the HAMMR system.

WARNING Connect only items specified as part of the HAMMR system.

WARNING All parts described in this section are suitable to use within the PATIENT ENVIRONMENT.

HAMMR Impaction Hand Piece

The HAMMR Impaction Hand Piece is a reusable, handheld device, powered by an external rechargeable battery, used to impact in forward and reverse directions by attaching impacter shafts and broaches to the chuck mechanism.



REF: 110046298

BATTERIES

STERILIZABLE BATTERY

Refer to X-Series Sterilizable Battery

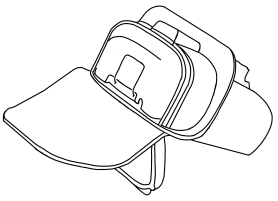
WEIGHT 404.1 g

REF: 89-8521-470-20

ASEPTIC BATTERY

Refer to X-Series Aseptic Battery

WEIGHT 501.6 g

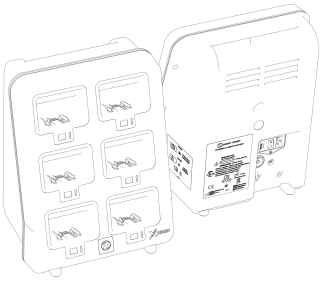


REF: 89-8521-470-30

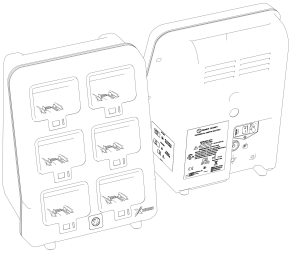
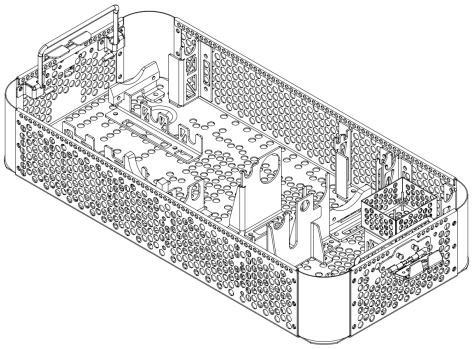
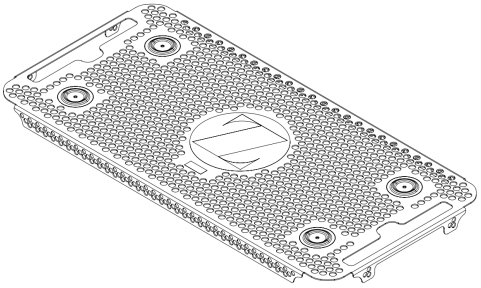
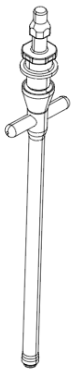
BATTERY CHARGERS

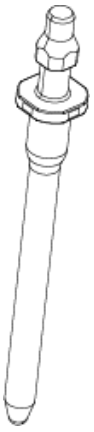
CHARGER FOR STERILIZABLE BATTERY

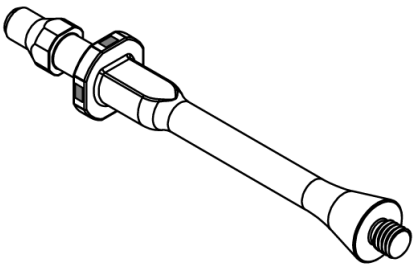
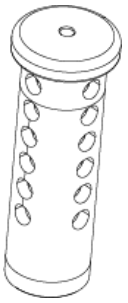
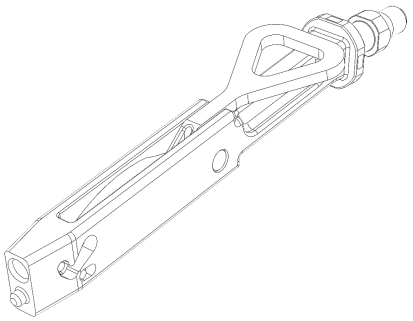
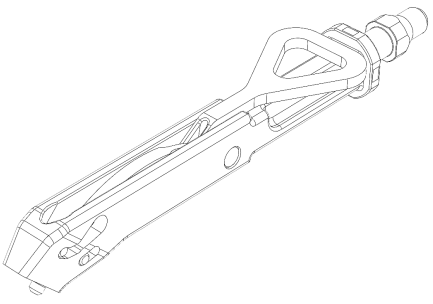
Refer to X-Series manual



REF: 89-8521-470-10

CHARGER FOR ASEPTIC BATTERY Refer to X-Series manual	 REF: 89-8521-470-00
STERILIZATION TRAY & LID	
HAMMR Instrument Tray MATERIALS Stainless Steel Silicone	 REF: 110046309
HAMMR Instrument Tray Lid MATERIALS Stainless Steel Silicone	 REF: 110046310
IMPACTION TOOLS AND ACCESSORIES	
HAMMR G7 Straight Shell Impacter MATERIAL Stainless Steel MAX LENGTH 12.68 in (322.20 mm) WEIGHT 395.30 g	 REF: 110046303

HAMMR Straight Modular Shell Inserter MATERIAL Stainless Steel MAX LENGTH 12.57 in (319.20 mm) WEIGHT 355.64 g	 REF: 110046314
HAMMR G7 Curved Shell Impacter MATERIAL Stainless Steel MAX LENGTH 12.53 in (318.16 mm) WEIGHT 509.88 g	 REF: 110046312
HAMMR Straight Bullet Tip Stem Driver MATERIAL Stainless Steel MAX LENGTH 7.23 in (183.70 mm) WEIGHT 169.23 g	 REF: 110046305

HAMMR Femoral Head Impacter MATERIAL Stainless Steel MAX LENGTH 6.18 in (156.95 mm) WEIGHT 152.91 g	 REF: 110046304
HAMMR Strikeplate Adapter MATERIAL Stainless Steel LENGTH 4.25 in (108.46 mm) WEIGHT 350.52 g *SHELL impacters	 REF: 110046313
BROACH ADAPTERS	
HAMMR Zimmer Anterior Broach Adapter MATERIAL Stainless Steel WEIGHT 317.3 g	 REF: 110046300
HAMMR Zimmer Posterior Broach Adapter MATERIAL Stainless Steel WEIGHT 286.9 g	 REF: 110046299

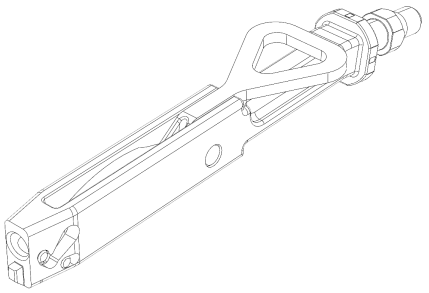
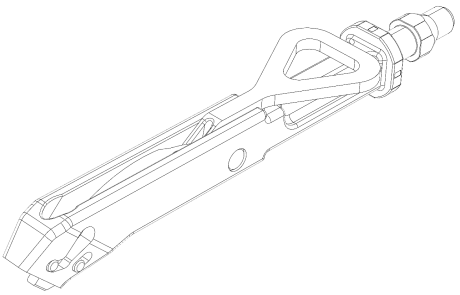
HAMMR Biomet Anterior Broach Adapter MATERIAL Stainless Steel WEIGHT 314.4 g	 REF: 110046302
HAMMR Biomet Posterior Broach Adapter MATERIAL Stainless Steel WEIGHT 292.1 g	 REF: 110046301

Table 2 - HAMMR components

WARNING Prior to initial usage and after each use, HAMMR must be cleaned and sterilized as per the Cleaning and Sterilization Instructions included in this manual.

IMPACTION HAND PIECE

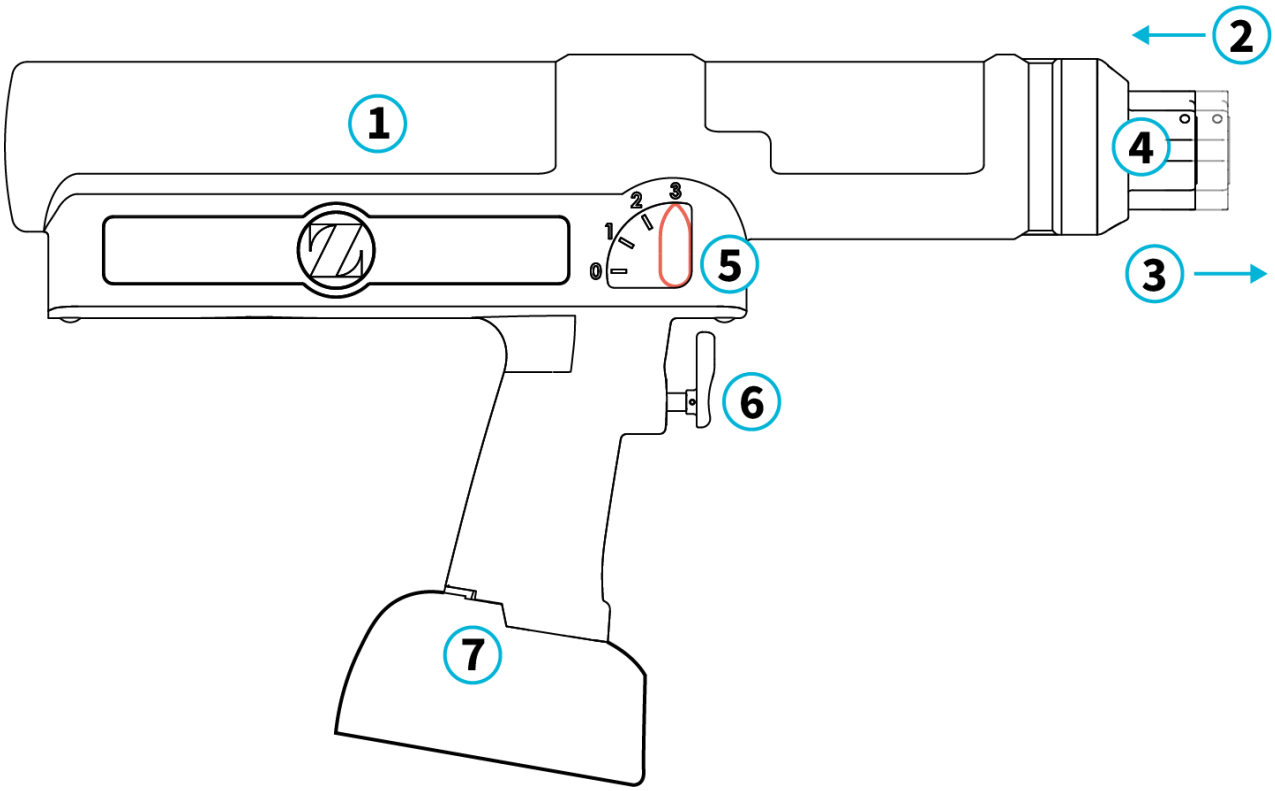


Figure 1 - HAMMR Impaction Hand Piece description

	Part	Features
①	**Main body**	Main body of the Impaction Hand Piece that holds the electronics and precision drive motor.
②	**INSERTION intent mechanism**	Insertion impact is performed when the Impaction Hand Piece control detects the chuck (④) is compressed against the Impaction Hand Piece while the trigger is pulled.
③	**REMOVAL intent mechanism**	Removal impact is performed when the Impaction Hand Piece control detects the chuck (④) is pulled out from the Impaction Hand Piece while the trigger is pulled.
④	**CHUCK**	Fix/Release mechanism that allows the adapters to be fixed/removed to/from the Impaction Hand Piece.
⑤	**ENERGY SELECTOR**	Allows selection of the insertion impact energy delivered: 1 (Low), 2 (Medium), 3 (High) Position 0 inhibits the Trigger.
⑥	**TRIGGER**	TRIGGER BUTTON for activation of the Impaction Hand Piece.
⑦	**BATTERY**	Rechargeable battery that powers the Impaction Hand Piece. Placing the battery automatically turns on the Impaction Hand Piece. Sterilizable and aseptic battery options are available.

Table 3 - HAMMR Impaction Hand Piece parts description

Li-ion	**Battery Disposal**: The battery is of a Lithium-Ion type. When the battery reaches the end of its useful life, the battery should be disposed of by a qualified recycler or hazardous materials handler. Do not mix this battery with the solid waste stream. Contact your local recycler or hazardous material handler for recycling or disposal information.

STERILIZABLE TRAY

Refer to image below to correctly place the Impaction Hand Piece and attachments in the sterilizable tray prior to clean processes.

Generally, instruments shall be placed into the tray in such a way that cannulations point slightly downwards, the instruments do not contact each other and the tray is not overloaded. This helps ensure the instruments are cleaned and dried properly.

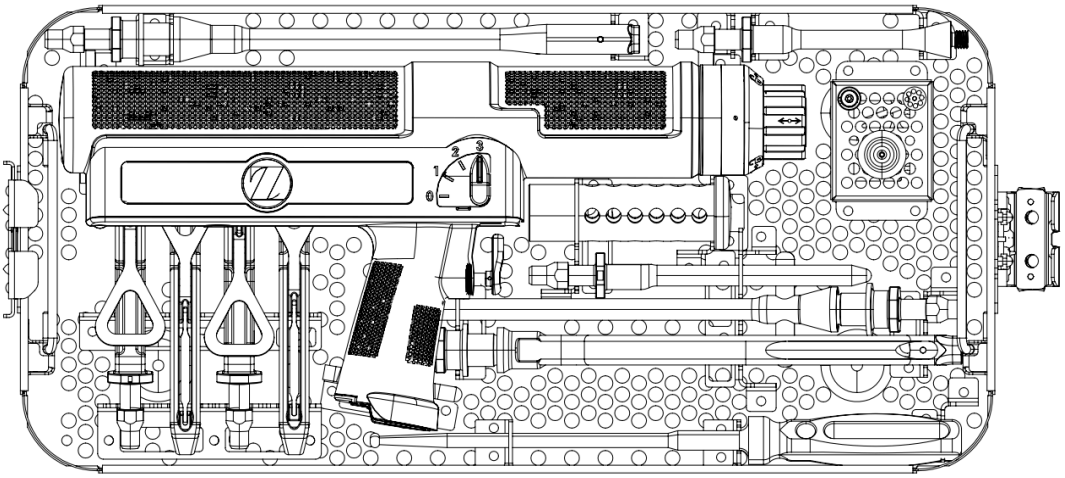


Figure 2 - HAMMR components fitting in the sterilization tray

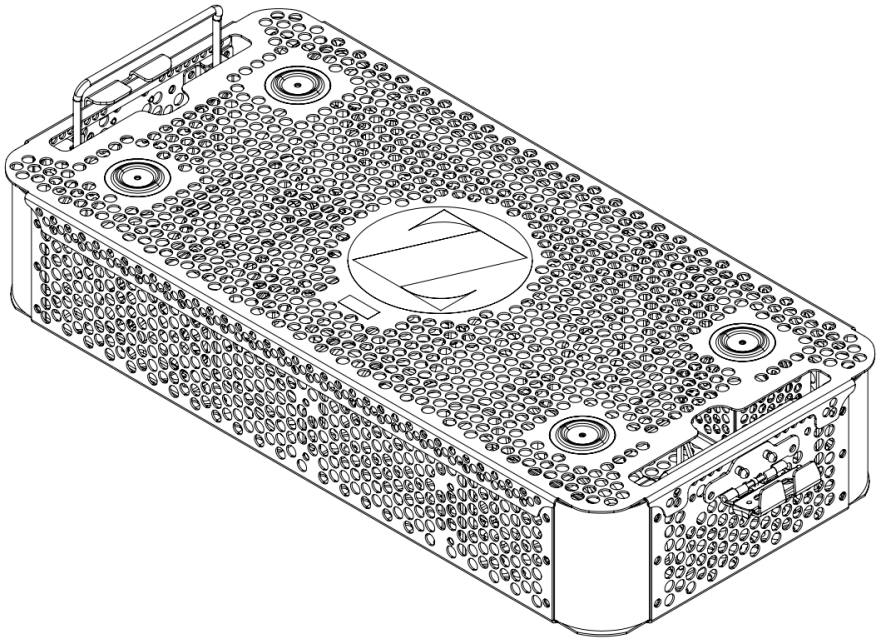


Figure 3 - HAMMR sterilization tray and lid

WARNING When placing components into a basket for cleaning/sterilization, avoid all contact between the devices. Touching devices may cause damage during washing and may jeopardize the efficacy of the reprocessing.

Sterilization tray handling

Close tray

1. Install the lid.
2. Attach the latches on both sides.

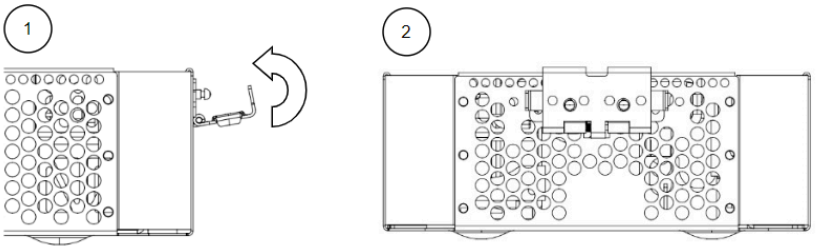


Figure 4 - Close process of the tray.

Accessing tray handles

Pull both tray handles out through the lid openings. Be sure both latches are closed before handling the tray.

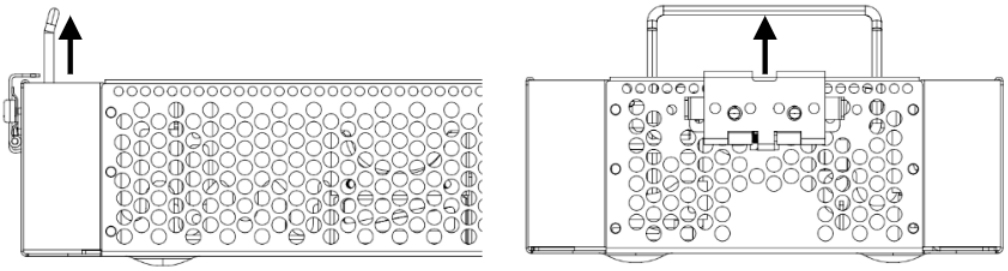


Figure 5 - Handles tray mechanism.

Open tray

1. Set it above a firm surface and press the lateral buttons of each latch.
2. While maintaining the buttons in step 1 pressed, pull the latches down.
3. Release the latch and remove the lid.

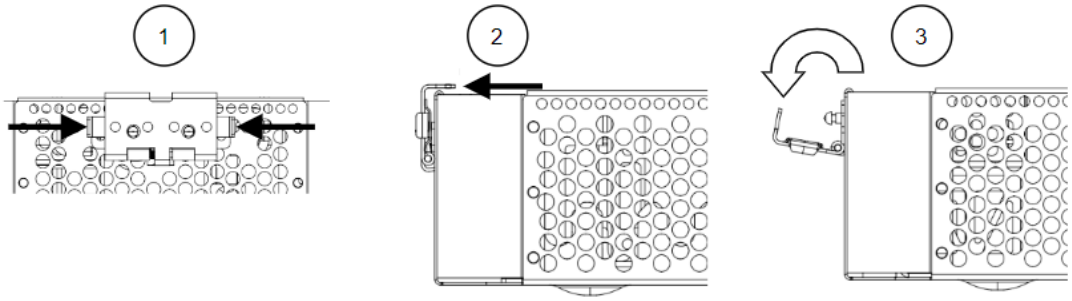


Figure 6 - Open process of the tray.

WARNING A populated tray can weigh up to 24.7lbs (11.2 Kg)

CAUTION Handling and use of this equipment and its contents shall be addressed through the hospital safe work practices, involving management and duty holders.

HAND PIECE USER OPERATION GUIDE

USER RESPONSIBILITY AND DECISIONS

CAUTION Prior to surgery always inspect the HAMMR Impaction Hand Piece and attachments looking for signs of wear and damage. Some visual indications are provided in section **TESTS & CHECKS** included in the **MAINTENANCE** chapter later in this manual.

In every case, the final decision whether to use the HAMMR rests with the attending physician.

He/She should assess prior to use of the system if its performance specifications, precision and handling are suitable for a given application, considering the bone strength, anatomical situation and bone size. Moreover, the technique guides and any contraindications of the implant system must be respected.

The surgeon's discretion will be used to determine:

- When to use the HAMMR.
- The adapters to be used.
- The impact energy setting of the HAMMR.

WARNING Device has to be operated with two hands. One hand holds the handle and presses the trigger, and the other hand supports the device in the normal use position. Use position is expected to be any orientation depending on OPERATOR experience. See figure below

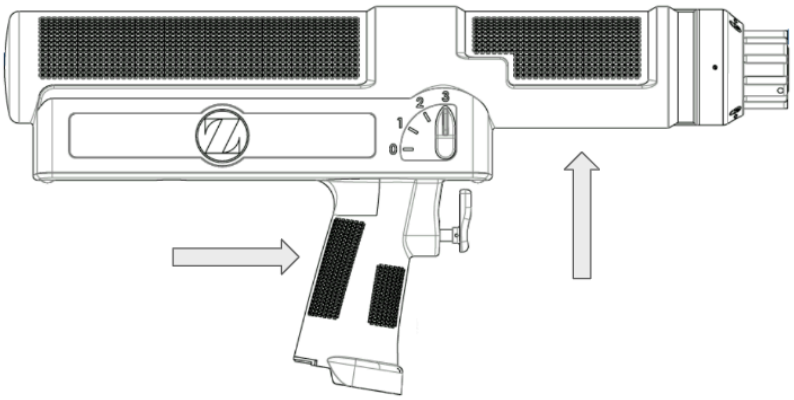


Figure 7 - Handle and top housing grip areas.

WARNING For safety reasons, always use two hands to hold the hand piece. In case of a free fall, do not use the Impaction Hand Piece and return it to service for inspection. A broken case can result in cutting edges and live parts exposed.

NOTICE No calibration is needed during the useful life of the device.

WARNING After the sterilization process and before use, allow the HAMMR equipment to cool to room temperature.

WARNING In case the hand piece doesn't work you can use the Strikeplate Adapter and the mallet to perform the procedure. Strikeplate Adapter use is described in the Surgical Technique document.

SWITCH ON

To switch the HAMMR Impaction Hand Piece on, the battery must be plugged in the hand piece handle connector.

NOTICE HAMMR Impaction Hand Piece is compatible with X Series system sterilizable and aseptic batteries and chargers. See 001811600 X Series Owners Manual for instructions on how to set-up and use the batterles and chargers.

CAUTION Never use any charger other than an X Series battery charger to charge the X-Series batteries.

CAUTION Never charge or discharge a battery that is hot. The battery charger will test the battery temperature and will not allow a hot battery to be charged or discharged.

Plugging The Battery

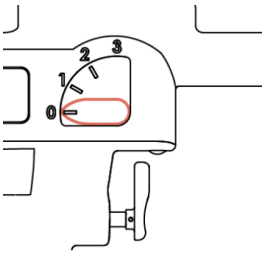
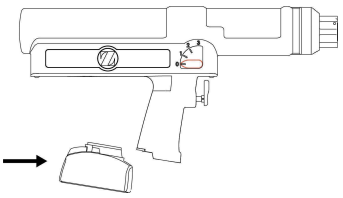
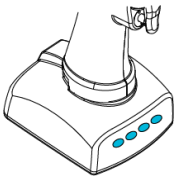
1	Set the Impaction Hand Piece energy selector to **0 position** (inhibit) and select a fresh charged battery.	
2	Push and hold the battery release button with one hand while holding the Impaction Hand Piece with the other. Maintaining the hand piece in horizontal position, slide the battery into the handle plug connector.	
3	TheImpaction Hand Piece turns on and automatically checks the system by moving the motor during 2s. The battery status LEDs are ON	

Table 4 - Battery plugging procedure

CAUTION To achieve optimal performance, hold the Impaction Hand Piece in horizontal position free of attachments during the switch ON procedure. Don't block (push or pull) the chuck during the initial test (step 3) If blocked, the control will produce an error and the system must be reset by removing the battery.

CAUTION The Impaction Hand Piece control will not allow operation if the battery state of health (SOH) is below 60% at startup.

WARNING Before using in a surgical procedure, double check the battery has been properly cleaned and sterilized

WARNING Prior to initial usage, HAMMR Impaction Hand Piece, accessories, impacters and adapters must be cleaned and sterilized as per Cleaning and Sterilization instructions (see related chapter in this manual)

WARNING Before attaching a battery to the Impaction Hand Piece, always slide the hand piece ENERGY SWITCH to the 0 position.

WARNING Remove the battery if the HAMMR is not likely to be used for some time.

SWITCH OFF

To switch the HAMMR Impaction Hand Piece off, the battery must be unplugged from the hand piece battery connector.

Removing The Battery

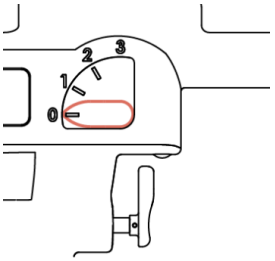
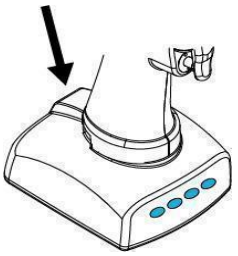
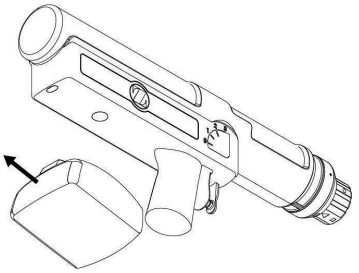
1	Check that the energy selector is in **position 0**	
2	Push and hold the battery release button with one hand while holding the Impaction Hand Piece with the other.	
3	Remove the battery by pulling the battery from the Impaction Hand Piece (the hand piece switches off)	

Table 5 - Battery removal procedure

WARNING After removing a battery, follow the appropriate procedures as per X-Series IFU to process a battery that has been used in a surgical environment.

ENERGY LEVEL CONTROL

The HAMMR Impaction Hand Piece energy control has 4 positions:

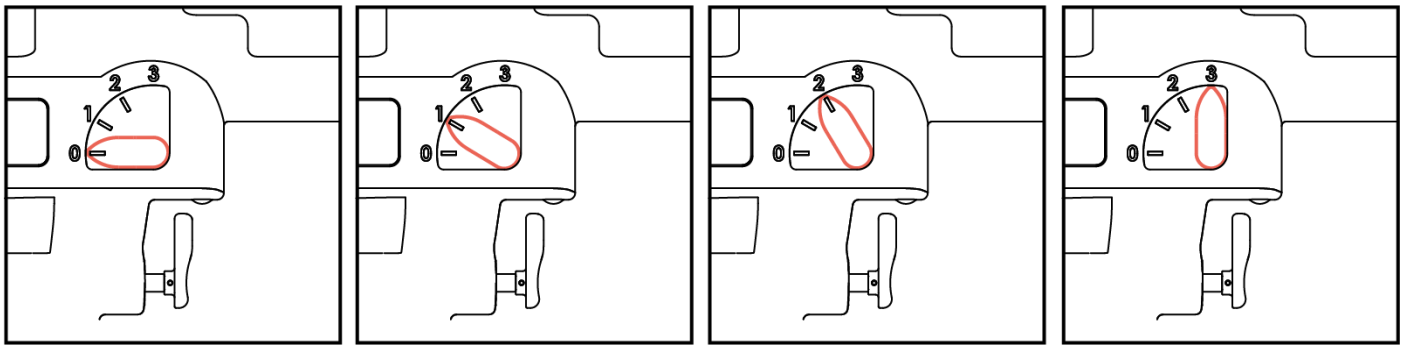


Figure 8 - Energy level selector

0 POSITION -The energy selector prevents the Impaction Hand Piece from delivering impacts.
LEVEL 1 - The energy selector sets the lowest level of inserting (forward) impacts.
LEVEL 2 - The energy selector sets the medium level of inserting (forward) impacts.
LEVEL 3 - The energy selector sets the highest level of inserting (forward) impacts.

WARNING It is the operator's responsibility to use the appropriate level of impact energy according to the surgical step. Understanding how to use and getting familiar with impact energy levels is mandatory for first time use operators.

WARNING Energy selector **0 position** does not turn off the device.

WARNING Changing energy selector position while the trigger is pulled will not affect the impact energy output.

WARNING Changing energy selector to 0 position while the device is impacting does not stop the impact sequence.

CAUTION During impaction, it is recommended to start with impacts at the lowest energy level (level 1) and increase the level until the desired effect is achieved.

FUNCTIONALITY CHECK

CAUTION Before proceeding with functionality check, inspect the hand piece looking for signs of wear and damage. Some visual indications are provided in section **TESTS & CHECKS** included in the **MAINTENANCE** chapter later in this manual.

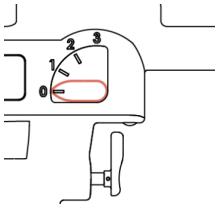
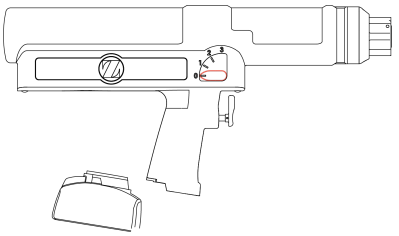
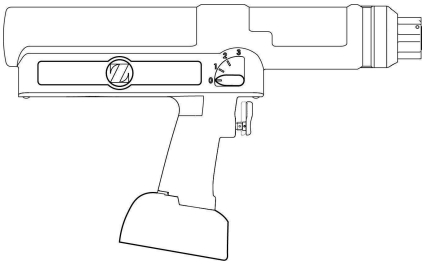
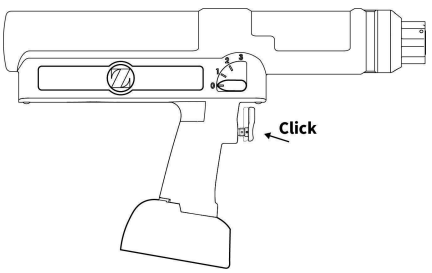
When the battery is plugged, the automatic diagnostics will check the software and hardware functions upon power-up.

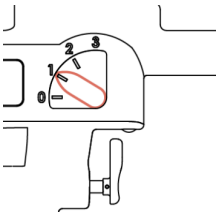
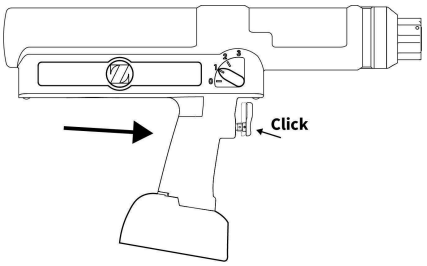
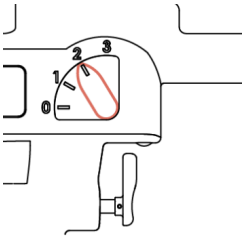
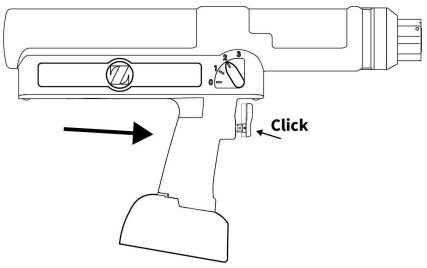
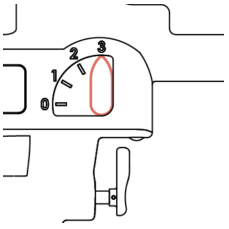
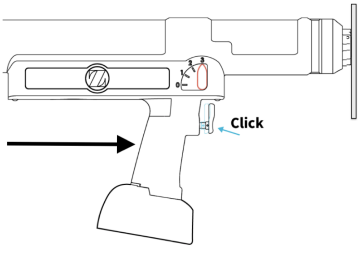
A passing result for the automatic checks allows the Impaction Hand Piece to drive the motor in forward and reverse modes; a failing result stops the Impaction Hand Piece from working. If the automatic checks pass, the following manual checks can be performed.

CAUTION It is recommended to verify the functionality of the Impaction Hand Piece prior to each use. If any of the checks fail, the hand piece must be returned by following the **RETURN AUTHORIZATION AND REPLACEMENT INFORMATION** instructions described in **MAINTENANCE** chapter.

CAUTION Never press the trigger if the chuck is not being pushed against a surface capable of receiving the impact. Dry fire can damage the Impaction Hand Piece impact mechanism.

Trigger, Intent Mechanism And Energy Selector Test

IMPACT DISABLED TEST: **0 POSITION**		
1	Verify the Impaction Hand Piece energy selector is in **0 POSITION** (disabled)	
2	Connect an sterilizable or aseptic battery housing assembled with a fully charged aseptic battery or a fully charged sterilizable battery to the Impaction Hand Piece.	
3	The power will be engaged. This is evident by the battery charge leds illuminating on the battery and the Impaction Hand Piece performing automatic checking of the system by moving the motor for about 2 seconds. Once the motor stops, the Impaction Hand Piece is ready.	
4	Press the trigger and verify the Impaction Hand Piece does not perform any impact.	

FORWARD IMPACTS TEST: ENERGY **LEVEL 1** (MIN)		
5	Change energy selector to **LEVEL 1** (low)	
6	Push the Impaction Hand Piece chuck against a stable surface in order to activate the INSERTION mechanism. Press and release the trigger. Verify impacts are delivered out with the press of the trigger and the impacts stop with the release of the trigger. **NOTICE**: do not dry fire.	
FORWARD IMPACTS TEST: ENERGY **LEVEL 2** (MID)		
7	Change energy selector to **LEVEL 2** (medium)	
8	Push the Impaction Hand Piece chuck against a stable surface in order to activate the INSERTION mechanism. Press and release the trigger. Verify impacts are delivered out with the press of the trigger and the impacts stop with the release of the trigger. **NOTICE:** do not dry fire. Impact energy is higher than in level 1.	
FORWARD IMPACTS TEST: ENERGY **LEVEL 3** (MAX)		
9	Change the energy selector to **LEVEL 3** (high)	
10	Push the Impaction Hand Piece chuck against a stable surface in order to activate the INSERTION mechanism. Press and release the trigger. Verify impacts are delivered out with the press of the trigger and the impacts stop with the release of the trigger. **Notice**: do not dry fire. Impact energy is higher than in LEVEL 2.	

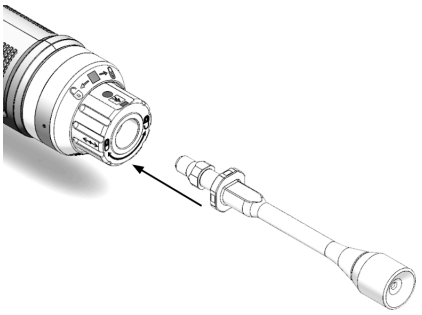
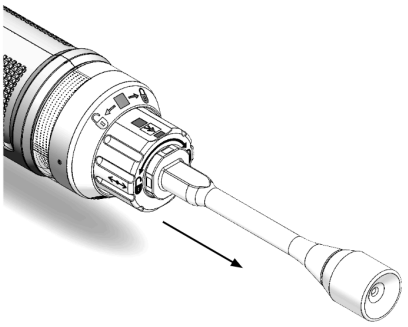
REVERSE IMPACTS TEST: ENERGY **LEVEL 1** (MIN)		
11	Insert an adapter in the chuck so it can be connected to a stable object in order to pull it from the Impaction Hand Piece.	
12	While pulling from the adapter to depress the chuck, press the trigger to produce impacts. Verify delivery impacts perform removal function (reverse) Impacts stop with the release of the trigger.	

Table 6 - Controls Functional Test

CAUTION If the chuck shows loosening, remove the hand piece from service and return it to your distributor for maintenance/repair.

Additional tests and checks, prior to the use, are described in the **MAINTENANCE** section.

CAUTION When the trigger is released, the Impaction Hand Piece will stop. If the Impaction Hand Piece continues impacting, check the trigger to verify it returns all the way to the full out position and is not stuck partially or fully depressed. Remove from service if the Impaction Hand Piece does not stop or the trigger is not returning to the full out position and return for maintenance/repair.

CAUTION If the HAMMR Impaction Hand Piece fails to produce the expected results as described, the affected device must be removed from service and returned for maintenance/repair.

ATTACHMENTS CONNECTION AND DISCONNECTION

Follow the procedure below to connect and disconnect any attachment to the Impaction Hand Piece chuck.

WARNING Always manipulate or change the adapters and accessories on the back table with the hand piece energy selector set to the position 0.

Attachment Connection

1. Unlock the chuck so the UNLOCK mark points to the reference indicator of the impacter top shroud.

STATUS		LOCKED	UNLOCKED
VIEW FROM	TOP	■ — ■	■ — ●
	BOTTOM	● — ●	● — ■
DESCRIPTION			
When the symbols match the chuck will be "lock" when they do not match it will be "unlock"			

Figure 9 - Chuck marking for locking-unlocking function

CAUTION If the chuck shows loosening, remove the hand piece from service and return it to distributor.

2. Insert the attachment by aligning the teeth and pressing the adapter area into the chuck. Connect by twisting the adapter release collar to align the reference indicator with the LOCK indicator.

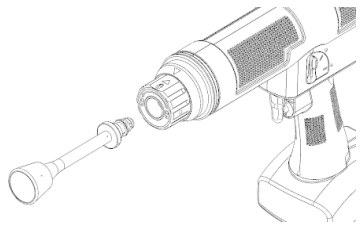
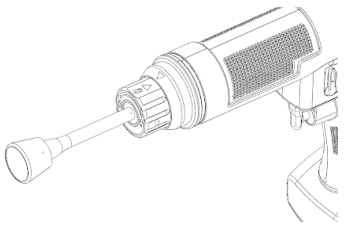
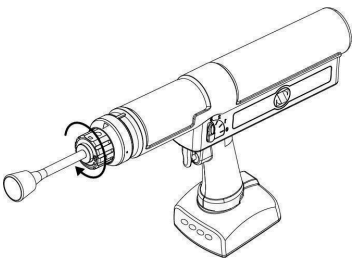
Make sure the padlock is open before inserting the attachment	Insert the attachment keeping the alignment with the Impaction Hand Piece	Lock the attachment by turning the collar chuck until the symbols match.
		

Figure 10 - Attachment connection procedure

3. Verify that the ADAPTER is securely connected prior to each use by pulling the attachment away from the Impaction Hand Piece to ensure that it is fully engaged.

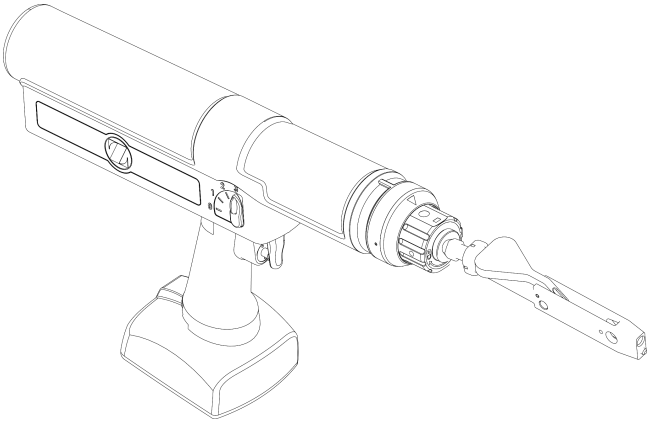


Figure 11 - Adapter inserted into Impaction Hand Piece chuck

Attachment Disconnection

To disconnect an attachment, follow below procedure:

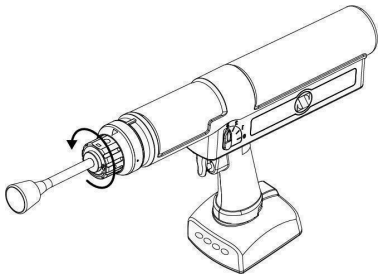
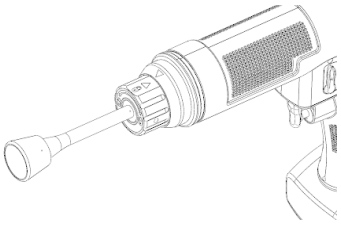
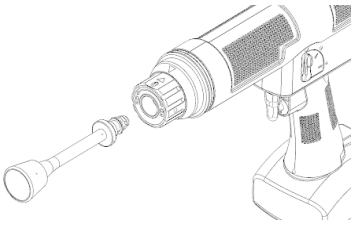
1 Unlock the chuck by turning the collar chuck until the symbols match as per Figure 4.	**2** Make sure the padlock is open before pull away the attachment	**3** Pull away the attachment keeping the alignment with the Impaction Hand Piece
		

Figure 12 - Attachment connection procedure

WARNING Before using, always verify the attachments are locked into place.

WARNING Prior to initial usage, all parts of the system must be cleaned and sterilized as per the instructions described in the Cleaning and Sterilization section of this document.

Broaches Connection And Disconnection

Follow below procedure to attach a broach to the HAMMR Impaction Hand Piece:

1. Insert the BROACH tang into the desired adapter by pressing the BROACH into the ADAPTER interface. Connect by fully closing the ADAPTER release lever.

2. Verify that the BROACH is securely connected prior to each use by pulling the BROACH away from the Impaction Hand Piece to ensure that it is fully engaged.

3. Disconnect by opening the ADAPTER release lever. Then, pull the BROACH away from the Impaction Hand Piece.

WARNING Before using, always verify that the broaches are locked into place.

WARNING Broaches necessarily come into physical contact with the PATIENT in NORMAL USE.

INSERTION/REMOVAL IMPACT CONTROL

The HAMMR has two primary control modes: insertion movement (forward impaction) and removal movement (reverse impaction)

Depending on the trigger press duration, the impaction can be single or multiple.

WARNING Energy Level must be selected before pressing the trigger. While pressing the trigger button, any change in the level selector will have no effect on the energy level.

If changing intention while pulling the trigger, the control changes INSERTION/REMOVAL movements dynamically (broaching function)

Single/Multiple Insertion Impaction (Forward Impact)

This function is intended for the insertion of broaches and implants.

Engaging the target tissue while applying forward pressure on the Impaction Hand Piece results in delivery of inserting (forward) impacts when the trigger is pressed.

WARNING Applied forward force must be adequate to compress the adapter release spring to deliver a forward impact.

Releasing the trigger stops the insertion impacts sequence.

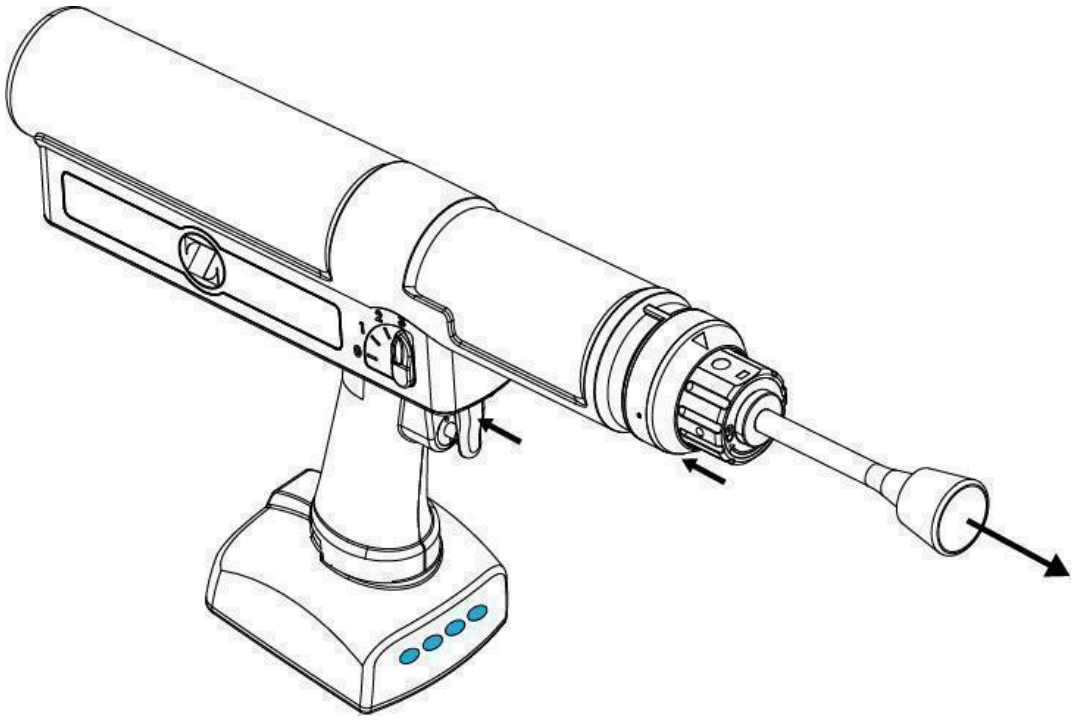


Figure 13 - Single/multiple forward impacts (insertion procedure)

Single/Multiple Removal Impaction (Reverse Impact)

This function is intended for the removal of broaches and implants.

Engaging the target tissue while pulling back on the Impaction Hand Piece results in delivery of removing (reverse) impacts when the trigger is pressed.

WARNING Applied reverse force must be adequate to compress the adapter release spring to deliver a reverse impact.

Releasing the trigger stops the removal impacts sequence.

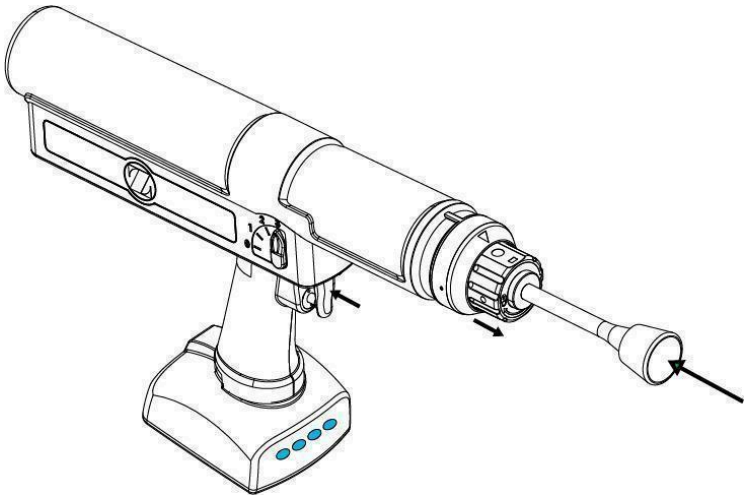


Figure 14 - Single/multiple reverse impacts (removal procedure)

Insertion-Removal Dynamic Operation (Broaching)

This function is intended for the broaching phase in a THA procedure.

While holding the trigger ①, dynamically compressing and releasing the chuck against the Impaction Hand Piece ②, allows to perform continuous inserting and removing the broach ③ "*broaching*" or "*sawing motion"* procedure.

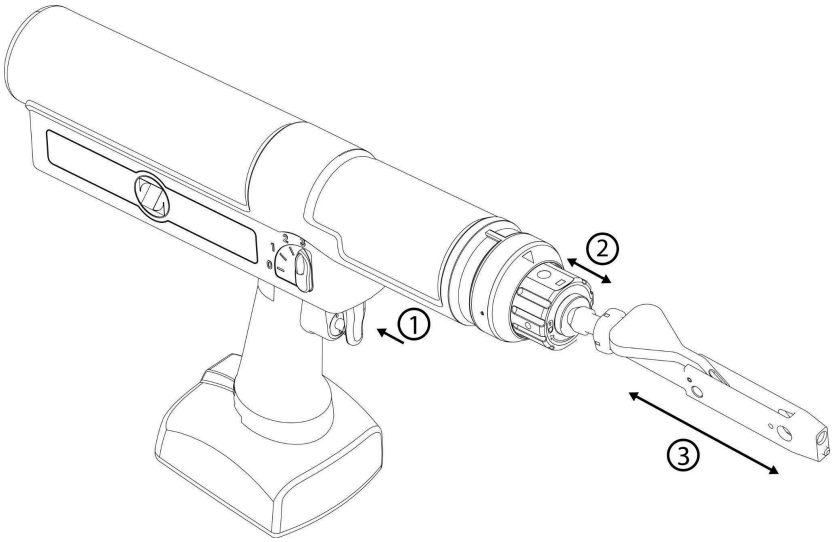


Figure 15 - Broaching or sawing motion procedure (broach not showed)

WARNING Performance depends on operator applied force and frequency while pushing or pulling from the Impaction Hand Piece during the broaching movement.

CLEANING AND STERILIZATION

These instructions cover the HAMMR Impaction Hand Piece and its accessories.

GENERAL CAUTIONS

- Do not immerse the Impaction Hand Piece or batteries in any liquids. Sensitive electronics may be damaged.
- Remove the adapter from the Impaction Hand Piece prior to cleaning.
- Repeat washing at high pH can lead to restricted movement of the tool release mechanism. If the mechanism is observed to not move freely then a sterilizable instrument lubricant can be used to restore free movement.
- Lubricants, such as Hinge-Free or Barrier Milk, intended for steel medical instruments that will not impede the sterilization method used at your facility can be used. Always follow your hospital protocol for lubrication to restore free movement. Hinge-Free is a registered trademark of STERIS. Barrier Milk is a product of L&R Ultrasonics.
- The instrument tray may be placed in an approved and FDA cleared sterilization container with a gasketed lid for sterilization. Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers. The following list contains the approved rigid sterilization containers for use using the steam sterilization instructions.
    - Aesculap® SterilContainer™
    - Case Medical SteriTite®
    - OneTray®

  Note: The drying time using the OneTray® sterilization container was not validated, because the OneTray® Instructions For Use specify to not utilize a drying time.
- Do not use compressed air to dry the device.
- Do not expose the unit to high-pressure water on the battery connector area.

GENERAL WARNINGS

- Do not use metallic brush or sponge, abrasive brush or shedding dry cloth.
- Do not use detergent exceeding pH 10.8, phenol, aldehyde or chlorine bleach.
- Do not immerse, do not use ultrasonic bath.
- Use of the Zimmer Biomet sterilization tray is strongly recommended. The processes described in this manual are the only cleaning and sterilization processes recommended by Zimmer Biomet.
- Final responsibility for verifying cleaning and sterilization, using the equipment and processes of the healthcare facility, and the equipment and parameters supplied by Zimmer Biomet, lies with the healthcare facility. To ensure optimal processing all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load conditions.
- When placing components into a tray for cleaning or sterilization, avoid all contact between the devices. Touching devices may cause damage during washing and may jeopardize the efficacy of the reprocessing.
- All system components must be disconnected from each other prior to reprocessing in order to ensure the efficacy of the cleaning and sterilization processes.
- These instructions must be performed by professional staff appropriately trained in cleaning methods.

MANUAL CLEANING

Initial Treatment At The Point Of Use

WARNING Reprocessing should be performed immediately after use of the devices (maximum 30 minutes).

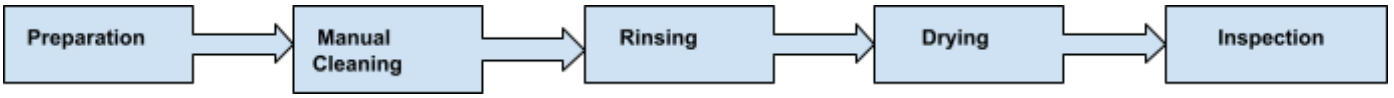
1. Turn the energy switch to 0 POSITION and remove the battery.
2. If present, disconnect the adapter from the Impaction Hand Piece.
3. Rinse the devices in clean, cold tap water (15-25°C) to remove visible soil.
4. Prevent from drying by wrapping the devices in a non-linting cloth saturated with water or with an enzymatic neutral cleaning solution prepared per manufacturer's instructions. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Impaction Hand Piece Manual Cleaning Process

Manual cleaning is required to remove gross debris and traces of blood, debris and stains from usage. This is a critical step in the cleaning and sterilization strategy.

Step	Phase	Directions
1	Preparation	Prepare an enzymatic cleaning detergent solution such as neodisher MediClean Forte (0.5-2.0%) per manufacturer instructions (Max 40°C).
2	Manual Cleaning	• Rinse with clean, cold reverse-osmosis or distilled water (15-25°C) to remove visible soil and for a minimum of 10 seconds. • Soak soft clothes in the enzymatic cleaning detergent solution, then wipe the Impaction Hand Piece with the soaked clothes for a minimum of 2 minutes. • With a soft brush soaked with the enzymatic cleaning detergent solution, brush all devices for a minimum of 2 minutes per device paying particular attention to critical areas such as joints, cavities, holes, small openings, moving parts and mated areas. • Flush and brush cannulas with the enzymatic cleaning detergent solution at least once each.
3	Rinsing	Rinse all of the devices under running water for a minimum of 30 seconds and until no more detergent remains. Use distilled or reverse-osmosis water at 15-25°C .
4	Drying	Dry the devices with a soft, non-linting cloth. **Do not use compressed air.**
5	Inspection	Inspect the Impaction Hand Piece to ensure all visible soil and detergent is fully removed. In case of remaining soil, repeat manual cleaning.

Table 7 - Manual cleaning procedure



WARNING Not following the above process may result in insufficient removal of biological contaminants or cleaning agents.

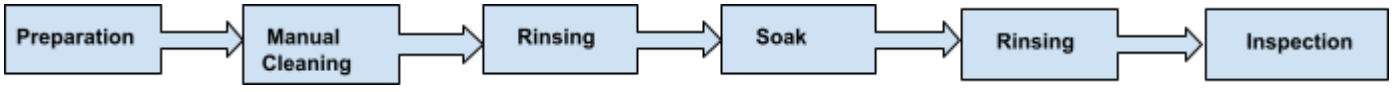
CAUTION Do not use compressed air for the drying process. Allow the device to air dry.

CAUTION Do not expose the unit to high-pressure water on the battery connector area.

Manual Cleaning Process For Adapters

Step	Phase	Directions
1	Preparation before cleaning	• Where applicable, multiple component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components. If a part is lost, notify your Zimmer Biomet representative when the instrument set is returned. • Only agents with proven efficacy (FDA approved) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, Zimmer Biomet does not recommend any specific brand. • Prepare an enzymatic and neutral detergent: Steris, Prolystica 2x Enzymatic Pre Soak and Cleaner and Steris Prolystica 2x Concentrate Neutral detergent. **WARNING** It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of fecal matter or other organic contaminants and may not be suitable for use with orthopedic instruments.
2	Manual Cleaning	**Adapters** • Rinse soiled instruments, trays, cases, and lids under running cold tap water for a minimum of one minute. Remove gross soil and debris using a soft bristled, nylon brush. • Completely submerge the instruments, trays, cases, and lids in an enzyme solution and allow to soak for 10 minutes. Instruments must be removed from the trays or cases during the cleaning. Use a soft nylon-bristled brush to gently scrub the device for a minimum of one minute and until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner) **NOTE** Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.
3	Rinsing	Remove instruments, trays, cases, and lids from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
4	Soak	Completely submerge the instruments, trays, cases, and lids in an enzyme solution and sonicate for 10 minutes at 40±5 kHz. Instruments must be removed from the trays or cases during the cleaning.
5	Rinsing	Remove instruments, trays, cases, and lids from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
6	Inspection	Inspect all of the devices to ensure all visible soil and detergent is fully removed. In case of remaining soil, repeat manual cleaning.

Table 8 - Adapters manual cleaning procedure



Automated Cleaning Process For Adapters

After performing the Manual Cleaning process above, inspect the adapters for any signs of residual soil. Repeat the entire Manual Cleaning process if signs of residual soil are detected.

Place adapters into their assigned positions within the tray, secure lid and process through a standard instrument washer cleaning cycle.

CAUTION The HAMMR Impaction Hand Piece is not intended to be cleaned in an automatic washer.

The following minimum parameters are essential for thorough cleaning and disinfection:

Step	Phase
1	2 minute pre-wash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66°C/146-150°F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93°C/176-200°F)
8	10 second purified water rinse with optional lubricant (64-66°C/146-150°F)
9	7 to 30 minute hot air dry (116°C/240°F)

Table 9 - Typical USA automated washer/disinfector cycle for surgical instruments

CAUTION The washer manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer. A washer with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

STEAM STERILIZATION (STORAGE)

The steam sterilization procedure must be carried out by qualified personnel in a qualified autoclave. All components should be positioned in the tray following the outlines printed on the base of the tray.

The "Dynamic-air-removal (Pre-vac) Steam Sterilization Cycle" is a pressure-cycle defined by AAMI. The Impaction Hand Piece and attachments are to be sterilized using a custom steam sterilization cycle defined in this manual.

The manual cleaning steps must be followed prior to sterilization regardless of the sterilization exposure parameters being used. Use only the Zimmer Biomet specified sterilization tray for processing.

1. Place the devices in the specific sterilization tray.
2. Double wrap the tray with wraps conforming to ISO 11607 and ANSI/AAMI ST7 and appropriate for steam sterilization. For the USA, use FDA approved wraps.
3. Physical-chemical indicators may be used on or in the system.
4. Use a steam sterilizer conforming to EN13060, EN 285, and ISO 17665.
5. Use the sterilization parameters provided in table below:

Procedure	Dynamic-air-removal (Pre-vac) Steam Sterilization Cycle
min. Exposure Time	4 minutes
Temperature	132 °C
min. Drying Time	45 minutes

Table 10 - Steam sterilization parameters.

6. At the end of the cycle, check the chemical indicator and controls to confirm the efficiency (wrapped or tray integrity, no humidity, color change of sterilization indicators, digital records of cycle parameters).

WARNING Use only the Zimmer Biomet specified sterilization tray for autoclave sterilization processing and allow the hand piece to cool to ambient temperature and evacuate any residual inner condensed water before use.

WARNING Failure to allow the package to cool at the end of the sterilization cycle may decrease performance, compromise sterility or result in burnt patient tissue or healthcare staff.

CAUTION Do not perform rapid cooling techniques on the load as this could damage the Impaction Hand Piece.

STORAGE OF STERILIZED PARTS

- Keep the doubled-wrapped sterilized tray in a dry and clean environment protected from direct light.

WARNING Sterility cannot be guaranteed if the wrapping is opened, modified, damaged, or wet.

- Check the tray and the instruments of the HAMMR before using any of them (integrity, no excessive humidity).

CAUTION Ensure that the tray, the hand piece and all accessories have been sterilized before storing. Do not store contaminated objects in a sterilized tray or vice versa.

- If traces are exposed to moisture, the HAMMR components must be cleaned and sterilized again.

IMMEDIATE USE STEAM STERILIZATION (IUSS)

Sterilizable devices can be sterilized using an IUSS cycle in situations intended for immediate use (flash cycle). This method is not intended for devices that need to be stored for future use, nor held from one surgical case to another.

WARNING Use only the Zimmer Biomet specified sterilization tray for autoclave sterilization processing and allow the hand piece to cool to ambient temperature and evacuate any residual inner condensed water before use.
Do not use compressed air for drying the HAMMR hand piece. Allow the device to air dry.

The cleaning steps must be followed prior to sterilization regardless of the sterilization exposure parameters being used.

1. Ensure the device has been cleaned using the cleaning process.
2. The sterilizable battery does not need to be charged for IUSS sterilization.
3. Place the cleaned device in the tray. Do not wrap or pouch the device.
4. Use a steam sterilizer conforming to EN13060, EN 285, and ISO 17665.
5. Use the sterilization parameters provided in table below:

Procedure	Dynamic-air-removal Steam Sterilization Cycle
min. Exposure Time	4 minutes
Temperature	132 °C
Drying Time	No dry time

Table 11 - Immediate steam sterilization parameters.

6. Let the device cool (no rapid cooling techniques allowed as it could damage the device).

WARNING Failure to allow the package to cool at the end of the sterilization cycle may decrease performance, compromise sterility or result in burnt patient tissue or healthcare staff.

CAUTION Do not perform rapid cooling techniques on the load as this could damage the Impaction Hand Piece.

CAUTION Do not use compressed air for the drying process. Allow the device to air dry.

MAINTENANCE

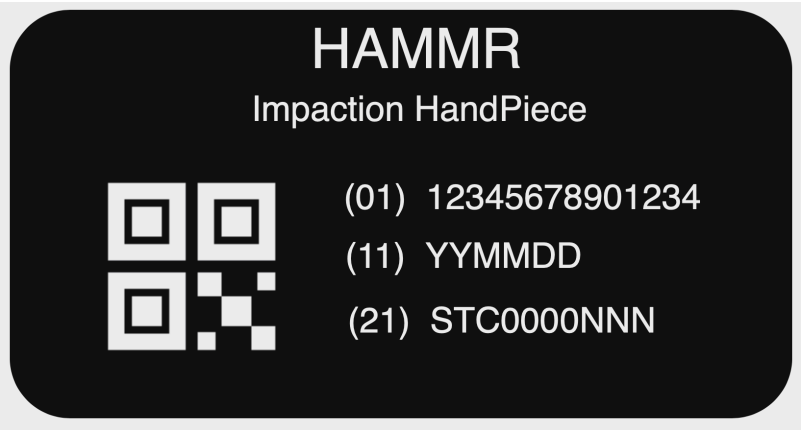
GENERAL MAINTENANCE INFORMATION

While the HAMMR has been designed and manufactured to high industry standards, it is recommended that regular cleaning, sterilization and inspection be performed to ensure continual safe and effective operation. This section contains information to assist in the effort as well as serve as a guide to expediting unscheduled maintenance.

CAUTION The HAMMR Impaction Hand Piece must be functionally checked following the **Functional Check** section of the **USER OPERATION GUIDE** chapter prior to any use. If any of the checks fail, the hand piece must be removed from service and returned to the distributor for maintenance/repair.

CAUTION The HAMMR Impaction Hand Piece must be returned properly cleaned and sterilized every 12 months for inspection and preventive maintenance. See **WARNING** below.

WARNING A HAMMR manufactured prior to December 20, 2024 - marking value (11) lower than 241220, must be returned after 8.7 months service for first maintenance check. After the first maintenance check, the unit must be returned every 12 months.



CAUTION The sterilization tray (PN 110046309) and lid (PN 110046310) is a medical device and is not to be shipped, either empty or loaded, without a protective outer shipping container.

SERVICING

Precautions In Service

- Rough shocks/handling should be avoided.
- Do not attempt to disassemble the equipment. It is a factory sealed unit with no user serviceable parts inside.
- Zimmer Biomet is not liable for any device malfunction resulting from repairs or maintenance/repair not performed by a Zimmer Biomet authorized Service Center.
- **Always clean and sterilize the system before returning to Zimmer Biomet.**

WARNING No modification of this equipment is allowed. All internal parts and components must be serviced by the manufacturer. Do not attempt to dismantle, modify or repair internal components. When testing, it is the user's responsibility to ensure that the appropriate and proper measuring equipment is used. Improper or poorly maintained equipment may result in incorrect or misleading results.

Unscheduled Maintenance

The HAMMR is designed with several specific self-test features to assist in fault isolation. In the event the system malfunctions, the device is likely to stop in a SAFE STATE.

This SAFE STATE will keep the device disabled. The system should be removed from service immediately along with all accessories and reported to the designated individual responsible for equipment repair within the healthcare organization.

The system should be returned to Zimmer Biomet for maintenance/repair.

TESTS AND CHECKS

The HAMMR components shall produce the results explained in the **FUNCTIONALITY CHECK** procedure. Failure to do so indicates that a problem may exist and the device is not to be used until necessary repair has been made.

A visual inspection of the Impaction Hand Piece must be performed prior to the use or after any scheduled or unscheduled maintenance. Failure to perform routine visual inspection and functionality checks may result in undesired performance.

Maintenance Indicators

This section is intended to assist the user in determining whether a HAMMR instrument has worn to an extent that it is no longer suitable for use by providing some visual indications.

Several indicator categories that could render the instrument no longer suitable for use are described below. These indicators are signs of wear and damage.

If any of these indicators is observed on an instrument, contact Zimmer Biomet Customer Service or your local representative and return the product for investigation and repair if applicable.

WARNING Not following this instruction can lead to an unusable device during surgery that could potentially lead to harm to the user or patient. All visual assessment of indicators shall be executed after cleaning and sterilization of the devices.

INDICATOR	DESCRIPTION	SPECIFIC CHECKS
Fracture	Cracked or broken into two or more pieces.	Check Impaction Hand Piece housing and all other polymer components
Deformation	Bent, deformed, melted.	Check especially the Impaction Hand Piece housing, trigger assembly, adapter release, and battery interfaces
Surface damage	Wear, excessive scratches/dents, flaking, abrasion of top layer or coating.	Check especially the Impaction Hand Piece housing and other mating surfaces.
Chuck loosening	The chuck shows loosening	Connect any accessory to the chuck show any evidence of loosening
Discoloration	Loss of color	Check especially the surface of the device and the adapters.
Corrosion	Potential corrosion or traces of corrosion on the device.	Check especially in the adapter release, battery connections, openings and grooves.
Marking damage	Marking and/or UDI unreadable, unrecognizable or damaged (including barcodes).	Check markings on the device.
Leakage	Substances leaking from the device due to cracked or damaged seals.	Check especially moving parts and seal surfaces.
Functional damage	Does not work as intended. Non-function of the device.	Refer to the individual component sections in this manual for specific functional checks.

Particle Release	Debris, particle release.	Check especially in openings and grooves. Check especially for particles or loose parts that may fall from the device.
Overheating	Device too hot to handle during operation.	If users experience pain or discomfort due to elevated temperatures of the device, the device shall be returned for maintenance/repair.
Adapter damage	See Zimmer Reusable Instrument Lifespan Manual-1219.2-GLBL-en-REV1018	See Zimmer Reusable Instrument Lifespan Manual specifics
Internal loosen particles	Internal particles or broken parts are audible when shaking the hand piece.	Turn on the device and check again. If the indicator persists, the device shall be returned for maintenance/repair.
Handle gasket protrusion	The handle gasket is out of place after an autoclave sterilization	The device shall be returned for maintenance/repair.

Table 12 - Maintenance indicators and checks

TROUBLESHOOTING GUIDE

To aid in unscheduled maintenance, the TROUBLESHOOTING table delineates a number of possible malfunctions that could occur with the unit.

The most likely causes are shown for each symptom. While it is not practical to enumerate every conceivable malfunction and all possible causes, the table will assist in isolating the most common problems.

CAUTION During some abnormal use conditions, the hand piece may not work for safety reasons.

SYMPTOM	CAUSE	SOLUTION
Impaction Hand Piece does not turn ON (battery lights are ON) or stops running	• The Impaction Hand Piece control has detected an error and has stopped all function.	• Restart the system. Release trigger button and any adapter from chuck during start.
	• Trigger is pressed during startup.	
	• The chuck is pushed/pulled during startup.	
	• Battery is too hot.	• Allow the battery to cool to room temperature. • Replace battery or return for maintenance/repair if the problem persists.
	• Dirty or corroded battery or Impaction Hand Piece terminals.	• Remove the battery from the Impaction Hand Piece and clean battery and/or Impaction Hand Piece side terminals if necessary.
	• Battery SOH less than 60%	• Replace battery or return for maintenance/repair if the problem persists.
	• Battery is not Zimmer's original product.	
	• The motor is too hot.	• Allow the motor to cool to room temperature
Hand Piece does not turn ON (battery lights are OFF)	• The battery is empty or has reached the end of life.	• Replace the battery.
The Hand Piece is running but the adapter will not move any of tools	• The adapter is not fully inserted into the Impaction Hand Piece. • The drivetrain has issues. • The intent sensing magnet is out of place.	• Remove and re-insert the adapter. Make sure the adapter is fully inserted and clicks into place. • Return for maintenance/repair if the problem persists. • Turn off the hand piece and compress the chuck until the magnet engages the impact assembly (a click is produced)
The Hand Piece does not produce reverse impacts when triggered.	• The intent sensing magnet is not following the chuck motion.	• Turn off the hand piece and compress the chuck until the magnet engages the impact assembly (a click is produced) • Return for maintenance/repairif the issue persists.

The Impaction Hand Piece is running without the trigger being pressed.	● The trigger is contaminated with debris causing sticking. ● The trigger is collapsed and not returning. ● The controller has issues.	● Clean the trigger per manual cleaning instructions. ● Add approved lubricant to the trigger shaft. ● Return for maintenance/repair if the problem persists.
The Impaction Hand Piece becomes abnormally hot during use.	● The adapter has issues. ● The motor has issues. ● The controller has issues.	● Replace the suspect adapter. ● Return for maintenance/repair if the problem persists.
The battery becomes abnormally hot during use.	● The battery has issues.	● Install battery on battery charger to determine if there are any faults. Replace battery if the problem persists.
The adapter is stuck and cannot be removed from or installed into the Impaction Hand Piece.	● The chuck barrel is dirty and contains dried debris. ● The Impaction Hand Piece adapter socket is dirty and contains dried debris. ● The adapter has been dropped or damaged. ● The Impaction Hand Piece has been dropped or damaged	● Clean adapter per the cleaning instructions. ● Clean the Impaction Hand Piece per the cleaning instructions. ● Replace the damaged adapters. Return the Impaction Hand Piece for maintenance/repair if the problem persists.
The adapter creates an abnormal noise or vibration when used	● The adapter is misaligned in the Impaction Hand Piece. The adapter has issues.	● Remove the adapter and reinstall. Replace the damaged adapter.
The Impaction Hand Piece has an abnormal noise or vibration when used.	● The Impaction Hand Piece has issues.	● Return the Impaction Hand Piece for maintenance/repair if the problem persists.
The Impaction Hand Piece runs but cuts-out under abnormal heavy loading	● The Impaction Hand Piece is experiencing abnormal loading and is entering protection mode. ● The battery is weak.	● Avoid abnormal loading when possible. Install battery on battery charger to determine if there are any faults. ● Replace battery if the problem persists.
The Impaction Hand Piece slows down or is weak under heavy loading.	● The Impaction Hand Piece is experiencing extreme loading and reducing the power to avoid entering protection mode. ● The battery is weak.	● Avoid extreme loading when possible. Install battery on battery charger to determine if there are any faults. ● Replace battery if the problem persists
The energy output is too low	● The battery charge is low. ● The motor has issues.	● Change or charge the battery. ● Return Impaction Hand Piece to the manufacturer.
The chuck does not return to middle position when pulled or pushed (battery is not connected)	● The equipment is brand new	● Connect a fresh charged battery and use the hand piece until the battery drains. Check again. If the chuck does not get the middle position, the device must be returned for maintenance/repair.

Liquid pours out from the hand piece after sterilization process	● The sterilization cycle is not correct ● The unit is damaged	● Allow the unit to evacuate the inner liquid and change cycle parameters according this manual (see sterilization section) ● If the unit is damaged return for maintenance/repair (see maintenance section)
A rubber plug comes out of the hand piece chuck during cleaning or sterilization	● Trapped air under the plug pushed out the plug.	● Push plug into chuck bore with square end of the plug to the outside. Ensure to minimize trapped air.

Table 13 - Troubleshooting

WARNING In case the hand piece doesn't work you can use the Strikeplate Adapter and the mallet to perform the procedure. Strikeplate Adapter use is described in the Surgical Technique document.

SERVICE INFORMATION

The HAMMR Impaction Hand Piece must be returned for inspection and preventive maintenance. See detailed information in the MAINTENANCE section.

WARNING In order to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE, please perform quarterly functionality check and follow maintenance requirements.

RETURN AUTHORIZATION AND REPLACEMENT INFORMATION

- When it is necessary to return the HAMMR Impaction Hand Piece for inspection, preventive maintenance or repair within the U.S.A. call 1-800-830-0970 to receive a Return Goods Authorization (RGA) number.
- Outside the U.S.A., contact your local *Zimmer Biomet* representative.
- The instrument must be cleaned, sterilized and properly packaged when sent for inspection, preventive maintenance or repair. If the original packaging is no longer available, proper packaging can be requested when the RGA is received.
- A purchase order must accompany all equipment for repair.
- The customer will be responsible for all shipping charges.

WARRANTY

Contact the Manufacturer to check the Warranties covering HAMMR. See CONTACT INFORMATION section at the end of this manual.

HAND PIECE SPECIFICATIONS AND PERFORMANCE

MECHANICAL CHARACTERISTICS

Weight And Dimensions

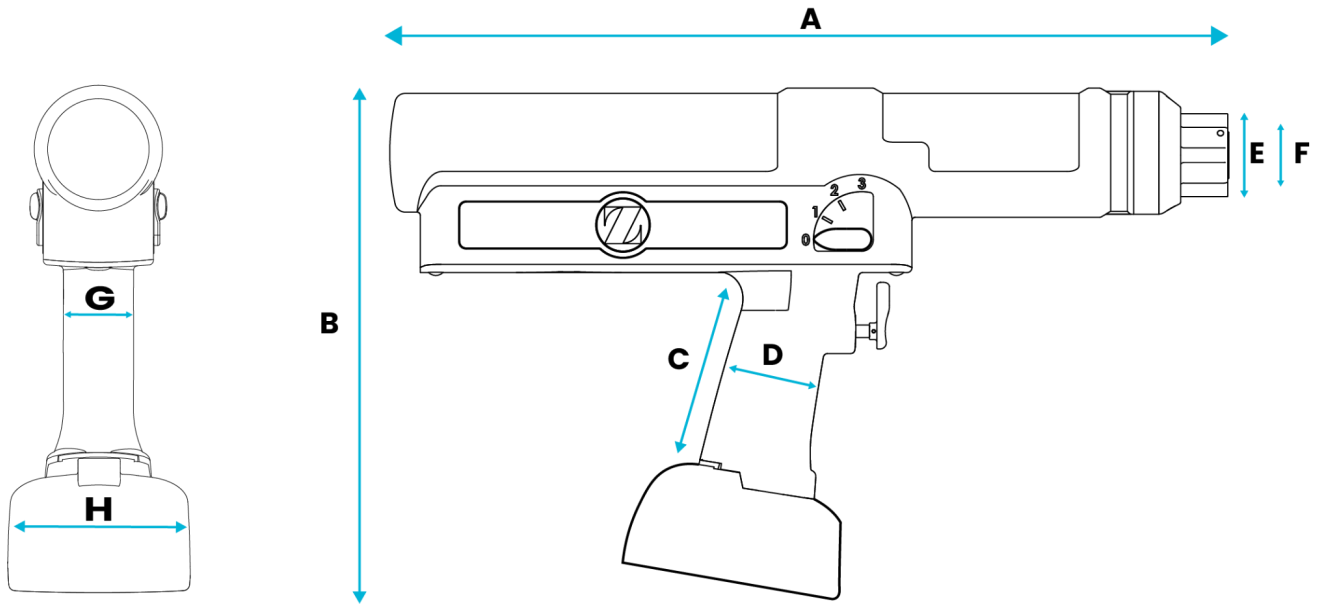


Figure 16 - HAMMR device dimensions

Dimensions in inches (mm)							
A	B	C	D	E	F	G	H
15.5 (395)	8.2 (210)	3.93 (100)	1.7 (45)	1.6 (42.3)	0.7 (17)	1.3 (35)	3.34 (85)

Weight in lb (g)		
Impaction Hand Piece	Impaction Hand Piece with battery	Impaction Hand Piece with battery and curved shell impacter (+509.88g)
6.99 (3171)	7.3 (3572.3)	8.45 (4082.3)

Case materials

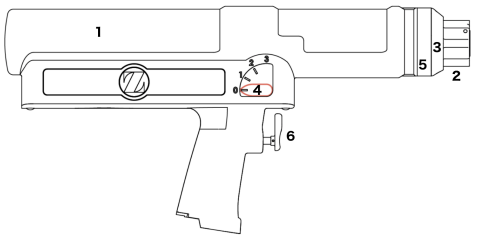
1. Hand Piece enclosure	PEEK plastic	
2. Chuck	Stainless steel AISI 316L	
3. Finger cover	Al 6061-T6 Hard anodized	
4. Energy Selector	Stainless steel AISI 316L	
5. Front cap	Al 6061-T6 Hard anodized	
6. Trigger button	PEEK plastic	

Table 14 - Mechanical characteristics of the hand piece

ELECTRICAL CHARACTERISTICS

Supply Mains

Rated Supply Voltage	14.4VDC ⎓
Battery Peak Current	25.5 Amps

IEC 60601-1 Classification

Protection against electric shock	INTERNALLY POWERED ME EQUIPMENT Contains no replaceable fuses
	TYPE BF APPLIED PARTS 
Protection against harmful ingress of water or particulate matter	IPX6 – Protection against powerful water jets
Methods of sterilization	By moist heat (autoclave)
Mode of operation	non-CONTINUOUS OPERATION DUTY CYCLE: 10/10s x 14 I/O

Table 15 - Electrical characteristics of the hand piece

CAUTION These devices are not suitable for use in the presence of flammable anesthetic or gasses.

ELECTROMAGNETIC COMPATIBILITY GUIDANCE TABLES

The HAMMR Impaction Hand Piece complies with electromagnetic compatibility (EMC) criteria set forth in the latest Medical Electrical Equipment regulation. The user of this device should be aware that precautions should be taken in regards to EMC. The device should be used according to the EMC information provided in these instructions for use. See EMC Guidance Tables included in this manual.

WARNING The reciprocal interference produced by other medical equipment may adversely influence the function of the HAMMR Impaction Hand Piece. When other medical devices are in use, maximize the separation distance and verify that the HAMMR is working correctly. Do not use in environments with uncontrolled or strong radiofrequency energy, a static magnetic field, or a magnetic field that changes with time. If placed in these environments, the HAMMR Impaction Hand Piece should be observed to verify it is functioning normally.

The following tables provide guidance on needs and installation of the HAMMR Impaction Hand Piece regarding EMC.

EMC GUIDANCE AND DECLARATION – EM EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions.
The HAMMR is intended for use in the electromagnetic environments specified below. The OPERATOR should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The HAMMR Impaction Hand Piece uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	**NOTE** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A) If it is used in a residential **ENVIRONMENT** (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 16 - EM emissions

EMC GUIDANCE AND DECLARATION – EM IMMUNITY/DISTURBANCES

Guidance and manufacturer's declaration – electromagnetic emissions.
The HAMMR is intended for use in the electromagnetic environments specified below. The customer or the user of the HAMMR should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact	± 8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%
	± 15 kV air	± 15 kV air	

Table 17 - EM immunity/disturbances

EMC DECLARATION – EM EMISSIONS/RF/MAGNETIC FIELDS

Manufacturer's declaration – electromagnetic emissions.
The HAMMR is intended for use in the electromagnetic environments specified below. The customer or the user of the HAMMR should assure that it is used in such an environment.

Immunity Test	Test level	Compliance level
Radiated RF IEC 61000-4-3	80 to 2700 MHz 1KHz (80% AM)	3V/m
Enclosure port immunity to RF wireless communications equipment EN 61000-4-3	380-390MHz 430-470MHz 704-787MHz 800-960MHz 1700-1990MHz 2400-2570MHz 5100-5800MHz	Table 9, EN60601-1-2:2015+A1:2021.
Power frequency magnetic field EN 61000-4-8	50Hz	30A/m
Proximity magnetic fields EN 61000-4-39	30kHz (CW) 134,2 kHz (PM 2.1kHz) 13,56MHz (PM 50 kHz)	8 A/m 65 A/m 7.5 A/m

NOTES

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HAMMR is used exceeds the application RF compliance levels above, the HAMMR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HAMMR.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 18 - EM emissions/RF and magnetic fields

EMC GUIDANCE AND DECLARATION – IMMUNITY/SEPARATION DISTANCES

Recommended separation distances between portable and mobile RF communication equipment and the HAMMR
The HAMMR is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HAMMR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HAMMR as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in Watts (W)	Separation distance according to frequency transmitter in Meters (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 19 - EM immunity separation table

ENVIRONMENTAL CONDITIONS

	OPERATION	STORAGE
Temperature	68 °F (20 °C) 75.2 °F (24 °C)	5 °F (-15 °C) 140 °F (60 °C)
Relative Humidity	20% 60%	30% 85%
Altitude (Pressure)	≤2,000 m (80KPa)	≤2,000 m (80KPa)
Pollution Degree	2	2

Table 20 - HAMMR System operation and storage environmental conditions

The following are the sounds pressure emission levels and sound power levels according to IEC 60601-1:2005 + Corr.1:2006 + Corr.2:2008 + A1:2012 + A2:2020

DEVICE	SOUND PRESSURE LEVEL (LpA) in dBA
HAMMR Impaction Hand Piece	< 140

Table 21 - Sound pressure level

INSTRUMENTS TRAY CHARACTERISTICS

Weight And Dimensions

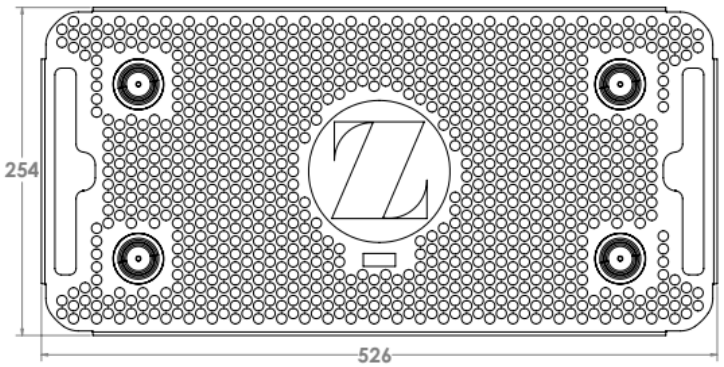


Figure 17 - HAMMR Instrument Tray Lid dimensions

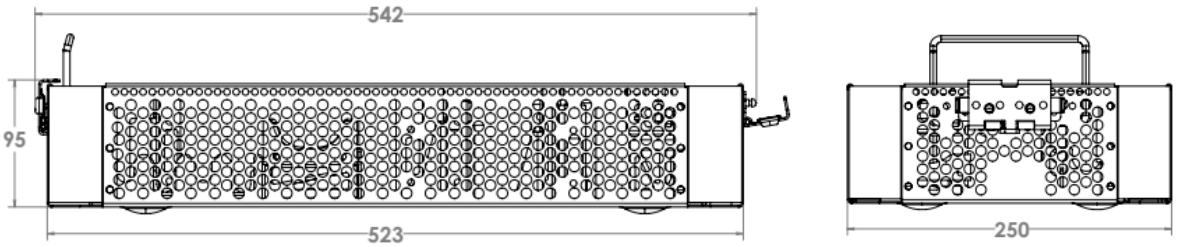


Figure 18 - HAMMR Instrument Tray dimensions

Weight in lb (Kg)		
Tray	**Tray Lid**	**Tray loaded**
7.5 (3.4)	2.0 (0.9)	24.7 (11.2)

Table 22 - HAMMR instrument Tray weight

CONTACT INFORMATION

MANUFACTURER INFORMATION

Celestica Valencia S.A.U.
Ctra. Valencia Ademuz, km 17, 6
46185 La Pobla de Vallbona, Spain
Manufactured for Zimmer Biomet

TECHNICAL SERVICE

To obtain part or additional information regarding your unit or technical assistance, please inform of the model marked in the device or its package label underneath the **SN** or **LOT.**

- Inside the U.S.A., call the Zimmer Biomet Customer Service Department at 1-800-348-2759.
- Outside the U.S.A., contact your local Zimmer Biomet sales representative.

REPORTING PROBLEMS

The user should report any suspected serious incident related to the HAMMR by informing Zimmer Biomet official distributor and the competent authority of the state or the country in which the serious incident has occurred.