

Dectroit

Instruction Manual and Operative Technique



Automated Osteotome System

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# **POWERED PRECISION**

## **INTRODUCTION**

This technique manual will introduce the surgeon to the AcuDriver<sup>®</sup> Automated Osteotome System. This system is designed to aid the surgeon in increasing surgical efficiency while improving control. The system consists of an air-driven impact handpiece that is coupled with precision osteotomes of various shapes and sizes. The AcuDriver provides the surgeon with a precise method for positioning the osteotome at a specific location. In addition, AcuDriver's impact characteristics provide effective cleavage of prosthesis/bone or cement/bone interfaces.

Recognizing that surgical needs and patient anatomies vary, this manual depicts a representative sequence of surgical events. The illustrations and techniques presented within the hip and knee sections are not intended to mandate the use of a specific technique or instrument, but rather to suggest a potential means of addressing a given set of conditions.

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### **CLEANING**

For full cleaning instructions, please read the Reprocessing Instructions for AcuDriver Reusable Surgical Instruments (700-096-035).

#### NEVER IMMERSE THE ACUDRIVER COMPLETELY.

The operation of the AcuDriver requires a strict adherence to the cleaning and sterilization techniques. Failure modes can occur prematurely if the device is not appropriately handled during the sterile processing. Immersion in any solution will permanently damage the instrument from liquid entering the mechanical parts. Some solutions will corrode metal and delicate moving parts or break down internal lubricants. Immersion damage will void warranty.

#### **POINT OF USE CLEANING INSTRUCTIONS**

- Remove gross debris immediately after use.
- Modular instruments (osteotomes) that were assembled as part of the surgery should be disassembled for cleaning. It is recommended that the Surgical Air Hose remain attached to the handpiece during cleaning. This will prevent water from entering the air intake port of the AcuDriver handpiece.
- Remove excess soil with surgical wipes/sponges moistened with sterile water. Do not immerse the AcuDriver handpiece or accessories.
- In order to ensure effective cleaning, do not allow soil to dry on instruments. Clean instruments as soon as possible after use.

#### **CLEANING INSTRUCTIONS**

The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.

Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.

In order to prevent damage to instruments, use only mild detergents.

Modular instruments (osteotomes) that were assembled as part of the surgery should be disassembled for cleaning. It is recommended that the Surgical Air Hose remain attached to the handpiece during cleaning. This will prevent water from entering the air intake port of the AcuDriver handpiece.

Instrument cases and trays must be inspected for soil and cleaned according to the cleaning instructions below, if needed.

#### Do not immerse the AcuDriver instruments.

**Do not lubricate the AcuDriver instruments.** The handpiece is pre-lubricated. Lubrication of the AcuDriver handpiece may result in damage to the internal parts.

Never clean the AcuDriver handpiece or accessories with liquid or chemical disinfectants, synthetic detergents, or oil-based soaps.

# Do not ultrasonic clean the AcuDriver handpiece or accessories.

Instruments must be thoroughly cleaned. Thorough cleaning is an essential prerequisite for effective steam sterilization.

Never sterilize the nitrogen regulator or immerse it in any solution.

- It is recommended that the Surgical Air Hose remain attached to the handpiece during cleaning. This will prevent water from entering the air intake port of the AcuDriver handpiece.
- Thoroughly scrub the instrument and accessories with a soft bristled, non-metallic brush with a warm mild soap solution. Pay close attention to threads, crevices, seams and any hard-to-reach areas. Actuate any moveable mechanisms, such as the trigger, to free trapped soil. All traces of blood and debris should be removed.
- Rinse thoroughly under warm, running potable tap water for a minimum of two (2) minutes followed by rinsing under at least one (1) gallon of distilled water. When rinsing, pay particular attention to threads, crevices, seams, and any hard-to-reach areas. Actuate moveable parts such as the trigger while rinsing. Removal of cleaning residues is an essential prerequisite for effective steam sterilization. Keep the nose of the ACUDRIVER handpiece and Osteotome Handle/ Extractor pointed downward when rinsing.

- Carefully dry using an absorbent, non-shedding cloth.
- After cleaning, visually inspect all instruments to ensure the complete removal of soil from surfaces, lumens and holes. No visible contamination should remain. Removal of all visible organic material and other residue is required prior to steam sterilization.
- If contamination is still present, reclean the instrument.
- Automated cleaning is not recommended for the AcuDriver instrumentation.

## **STERILIZATION RECOMMENDATIONS**

For full sterilization instructions, please read the Reprocessing Instructions for AcuDriver Reusable Surgical Instruments (700-096-035).

#### DO NOT STERILIZE BY ETHYLENE OXIDE GAS.

Perform a pre-vacuum steam cycle using one of the following cycles:

Temperature	Minimum Exposure Time	<b>Drying Time</b>
132°C (270°F)	Four (4) minutes	30 minutes

- Do not stack instrument cases in the autoclave.
- Ensure autoclave equipment achieves and maintains the proper time, temperature and pressure.
- Operate equipment in accordance with the equipment manufacturer's instructions.
- When sterilizing multiple instrument sets in one autoclave cycle, ensure the maximum load stated by the equipment manufacturer is not exceeded.



## **ACUDRIVER SPECIFICATIONS**

Maximum Operating Pressure	120 p.s.i. (14' hose)
Power Source Compressed Dry Nitrogen	99.9 percent pure medical grade
Operating Speed (multi-shot)	Greater than 3,000 cycles per minute
Osteotome Excursion	3mm maximum
Nitrogen Consumption	2 SCFM at 100 p.s.i.
Weight of Handpiece	2.25 lbs.
Handpiece Hose Connection	Zimmer-Hall Surgical™ style

# **EQUIPMENT IDENTIFICATION**



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#### **EQUIPMENT OPERATION**

#### 1. PUT INSTRUMENT IN "SAFE" MODE

To prevent accidental activation of the instrument, position the selector knob at the rear of the AcuDriver<sup>®</sup> handpiece to the "SAFE" position.

#### 2. ATTACH HANDPIECE TO HOSE

Attach the AcuDriver handpiece to the pneumatic powered surgical air hose by pushing the two connectors together and twisting until the pins are seated into the indentations.

#### 3. ATTACH HOSE TO NITROGEN SOURCE

Verify nitrogen regulator is reading a pressure level of zero. Firmly push the hose connector end into the receptacle until an audible clicking sound is heard.

#### 4. SET AIR PRESSURE

The AcuDriver handpiece can operate using air pressure between 40 p.s.i. and 120 p.s.i. Exactech recommends using a nominal pressure of 100 p.s.i. and increasing or decreasing the pressure to achieve the preferred impact force, however DO NOT exceed 120 p.s.i.

NOTE: The higher the pressure, the higher the impact force of the osteotome will be when the handpiece is activated.

#### 5. INSERT OSTEOTOME

- A. Remove osteotome from sterile packaging, utilizing appropriate aseptic technique.
- B. With the handpiece set to the "SAFE" position, rotate the locking mechanism on the nose of the handpiece to the "UNLOCK" position.
- C. Insert the proximal end of the osteotome into the nose of the handpiece.
- D. Rotate the locking mechanism to the "LOCK" position and pull on the osteotome shank to ensure proper retention.

#### 6 TEST ACTIVATE HANDPIECE

NOTE: The osteotome is spring loaded inside the nose of the handpiece. When force is applied to the tip of the osteotome, it is pushed further into the nose of the instrument. This positions the osteotome within the travel area of the instrument hammer. When no force is applied, the spring is not depressed and the osteotome is out of reach of the hammer and will not be impacted. When the spring is fully compressed, the instrument delivers full impact energy. The user can adjust the impact force via this mechanism.

- A. Turn the selector knob at the rear of the handpiece to the "SINGLE" shot position and point the instrument away from personnel. Pull the trigger to ensure proper operation of the instrument.
- B. Turn the selector knob to the "MULTI" shot position, point the instrument away

from personnel and again pull the trigger to ensure proper operation. The handpiece and the osteotome will vibrate rapidly and energetically when run in this mode.

- C. Once proper operation has been confirmed, select the position (mode) on the selector knob ("SAFE", "SINGLE" or "MULTI") that is desired.
- D. Listen for air leakage in the air hose or handpiece. Air leaks may also be detected by activating the handpiece and holding your other hand near the nose of the instrument while pointing the osteotome away from self and other personnel. Return instrument for service if leaks are detected.

#### 7. SURGICAL USE OF INSTRUMENT

- A. To improve control and visibility, the "MULTI" shot mode should be activated in short bursts of approximately half (1/2) seconds.
- B. Always return the selector knob to the "SAFE" mode when either changing osteotomes or when the instrument is not in use.
- C. In the event the trigger mechanism fails and the handpiece continues to run when the trigger is deactivated, the handpiece can be deactivated by rotating the selector knob at the rear of the instrument to the "SAFE" mode. The user may also disconnect the surgical air hose from the handpiece to deactivate if run-on occurs. Return the instrument to the manufacturer immediately if any defect is suspected.
- D. If the instrument is dropped, leaks air or operates improperly, return the instrument to the manufacturer immediately.

#### 8. DISCONNECTION FROM NITROGEN SOURCE

- A. Turn the selector knob at the rear of the handpiece to "SAFE" mode.
- B. Adjust regulator pressure to 0 p.s.i. Bleed out all pressure by turning release valve.
- C. The surgical air hose may now be safely disconnected from the nitrogen air source.

#### **RECOMMENDED REGULATOR SETTING**

The performance of the AcuDriver is extremely dependent upon both dynamic airflow and pressure. Pressure can fluctuate significantly from the regulated source due to hose length. The instrument is designed to operate at a pressure no greater than 120 p.s.i., based on tests utilizing an Exactech 14' hose. However, if the length of the hose should change, it will be necessary to adjust the pressure approximately two (2) p.s.i. per foot of hose to obtain the optimal performance range.

## **HIP REVISION TECHNIQUES**

**CEMENTED FEMORAL STEM REMOVAL** 

#### **Removing Proximal Cement and Stem**

Once adequate exposure is achieved, a standard length Notched Osteotome or Vee Osteotome is inserted into the AcuDriver handpiece (Figure 1). One hand is used to grasp the AcuDriver handpiece and the other to precisely guide the osteotome into the chosen site. Forward pressure should be exerted on the osteotome into the interface while the osteotome is directed toward the prosthesis and the trigger is pulled. This action should not be repeated more than three times in any given position. The position is changed to crossfracture the cement. Again, the force is directed inward toward the prosthesis and all cement or bone proximally and laterally is removed so that the prosthesis can be removed without fracturing the metaphyseal region of the bone (Figure 2). Once the cement/implant interface is adequately disrupted, the femoral component can be extracted using an extraction instrument.

The **Straight Gouge** may also be helpful in removing proximal cement. Large pieces of broken cement are removed with a rongeur or with pituitary forceps. Osteotomes are directed toward the center of the canal while working around the periphery to loosen the cement.

#### **Removing Cement at the Distal Stem Level**

The surgeon may use longer osteotomes that allow access to cement distally where the canal is often narrow and curved. For this purpose, a **Long Straight Gouge** and a **Long Notched Osteotome** are included in the AcuDriver system (*Figure 3*).





Figure 3 Longer Osteotomes can be used to Remove Cement at the Distal Stem Level





Figure 5 A Finishing Reamer is Used to Prepare the Canal for Optimal Cement on Prosthesis/Bonding

# Removing a Solid Cement "Plug" Distal to the Prosthesis Tip

A hole should be drilled in the center of the plug using a bit 4-6mm in diameter. The Long Notched Osteotome or **Long Vee Osteotome** can be used to break up the cement. The plug can be removed with a retrograde hook. The hook is used to pull proximally on all of the loose fragments until the canal is clean.

#### Loosening a Tightly Fixed or Broken Prosthesis

The proximal cement is removed using the technique described previously in this manual. A small window (5 x 15mm) can be made in the femoral cortex just distal to the level at which the stem fractured. A small, high-speed burr is then used to cut through the cement until the metal stem is exposed.

The **Long Carbide Punch** is then pressed firmly against the metal component while the trigger is squeezed. This action will drive the prosthesis proximally, and a series of divots will be created as the stem moves past the window (*Figure 4*).

Occasionally, the macro-texturing on the surface of a broken stem will trap cement. In this case, cement may remain attached to the stem. In such situations, metal-cutting, high-speed burrs may be needed to make deeper divots in the metal to gain leverage on the prosthesis.

#### **FINAL CANAL PREPARATION**

To optimize the canal surface for cement bonding or press-fit fixation, a **Finishing Reamer** may be used. A Finishing Reamer may be used in situations where there is little or no remaining cancellous bone in the femoral canal. Finishing Reamers clean and prepare the canal by removing loose cancellous bone and residual cement. In addition, Finishing Reamers lightly score the canal, creating an improved surface for better fixation of cement or prosthesis. The reamer is rotated with a power drill and inserted into the bone canal. The "forward" or "clockwise" rotation setting on the drill should be used and the surgeon should continually push and pull the reamer proximally and distally in the canal *(Figure 5)*.

#### **CEMENTED ACETABULAR CUP REMOVAL**

#### Component Removal

The **Small Cup Osteotome** is used to loosen the prosthesis cement or prosthesis/bone interface around the rim of the acetabular component. As the interface is gradually loosened, the surgeon may move to the **Medium Cup Osteotome** as deeper penetration is required (*Figure 6*).

After the interface is cut, the blunt **Impactor** can be used to dislodge the prosthesis (*Figure 7*).

#### Acetabular Cement Removal

Typically, the cement is easily removed after the acetabular component is extracted. Occasionally, residual cement can be present upon prosthesis removal, especially in cement fixation holes. The remaining cement should be fragmented for removal.

The standard length Straight Gouge, Notched or Vee Osteotomes can be used to loosen the cement. The surgeon should begin in the center and work toward the outside of the acetabulum to create fractures in the cement or around the periphery of fixation holes (*Figure 8*). The cement can be pried loose and removed using rongeurs and curettes.

#### Figure 6

Cup Osteotomes are Used to Separate the Acetabular Cup from the Prosthesis-Cement or Prosthesis/Bone Interface





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Figure 8 A Standard Length Notched Osteotome can be Used to Break up Acetabular Cement





#### Figure 10 The Long Vee Osteotome can be Used to Remove Pedestal Build-up



#### **CEMENTLESS FEMORAL STEM REMOVAL**

#### **Disrupting Biological Fixation**

Biological fixation is disrupted using a series of thin, flexible osteotomes. These osteotomes are driven anteriorly, posteriorly and laterally down the canal adjacent and parallel to the prosthesis. Begin with a **Flat Narrow Flexible Osteotome** (*Figure 9*). Longer and/or wider flexible osteotomes may be used as the surgeon proceeds deeper into the canal.

The force used must be based upon the cortex strength and the available room between the cortex and prosthesis. Osteotomes have a wedging effect and cannot be inserted with excessive force without risk of fracture. If an osteotome becomes tightly wedged and cannot be easily extracted, the AcuDriver handpiece should be removed and the **Osteotome Handle/Extractor (400-93-14)** attached. Once attached, a light tap on the underside of the "T" handle of the extractor will allow removal of the osteotome.

#### **Extracting Femoral Component**

Once the biological fixation is disrupted, the stem can be removed using a slap hammer/extractor instrument.

#### **Canal Preparation**

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Before a new femoral component can be implanted, any new bone or fibrous tissue that has accumulated, due to an unstable femoral prosthesis, must be removed. The Long Vee Osteotome can be used for pedestal build up distal to the tip of the stem and a curette or retrograde hook to scrape any remaining bony prominence found within the canal (*Figure 10*).

When the canal preparation is complete, a Finishing Reamer can be attached to a standard power drill and passed down the canal. The Finishing Reamer will clean and prepare the canal by removing any loose cancellous bone or fibrous tissue.



#### **CEMENTLESS ACETABULAR CUP REMOVAL**

### Extract the Polyethylene Insert

Many polyethylene inserts are easily removed. For more difficult situations, the Impactor can be used by wedging the sharp edge under the lip of the insert and engaging the handpiece (*Figure 11*).

#### **Removing the Metal Acetabular Component**

Any screws used to secure the implant should be removed prior to using the AcuDriver. The Cup Osteotomes are used to loosen the biological bond. The surgeon may start by using the Small Cup Osteotome around the periphery of the prosthetic socket, beginning in the area of the illium. In this area, bone strength is usually the greatest and biological fixation the strongest. If needed, the Medium Cup Osteotome may be used to further disrupt the biological fixation (*Figure 12*). The cup should be ready to remove, but if the prosthesis is still partially fixed, the Impactor may be used.

Figure 12

Cup Osteotomes may be used to Separate Biologic Fixation in the Acetabulum









# **KNEE REVISION TECHNIQUES**

TIBIAL PLATEAU COMPONENT REMOVAL (CEMENTED AND CEMENTLESS)

The plateau portion should be removed first if it has an all polyethylene tibial component. It can be cut free using a powered saw with a wide, flat Stablecut Blade (available through Exactech) in combination with the AcuDriver, fitted with Flexible Osteotomes (*Figure 13*). After the stem has been transected, the plateau portion of the prosthesis is removed.

In a modular tibial prostheses, the polyethylene component can be removed with standard osteotomes or the AcuDriver and the Impactor *(Figure 14).* The sharp wedge portion of the osteotome can be used to pry underneath the plastic component and drive it upward until the insert is free.

# FEMORAL COMPONENT LOOSENING AND REMOVAL (CEMENTED AND CEMENTLESS)

A stemless femoral component is easily removed after initial loosening. To loosen with the AcuDriver, the appropriate **Flexible Osteotome** is selected and used to cut the interface at the anterior flange, the distal condyles and the posterior condyles of the femoral component (*Figure 15*).

#### **EXTRACTING FEMORAL COMPONENT**

Once the femoral component is loose, the Impactor can be used to drive it from the femur. The Impactor can be placed medially, laterally and anteriorly (*Figure 16*).

If the femoral component has a stem, the difficulty of removal increases because there is no way to loosen the stem without causing significant femoral cortex damage. In these instances, a specialized device, designed specifically for prosthesis removal will be helpful. The appropriate manufacturer should be consulted prior to surgery.

**TIBIAL STEM REMOVAL** 

The remaining stem portion of an all polyethylene tibial prosthesis is removed by freeing the interface with the AcuDriver using the Straight Gouge, Notched Osteotome, Vee Osteotome, or the flexible osteotomes.

To remove the metal component of a modular prosthesis, a powered oscillating saw with a flat Stablecut blade (available through Exactech) is used in combination with the AcuDriver. The thin, flexible osteotomes can be used to loosen the accessible interface between the bone and tibial plateau (*Figure 17*).

Once the interface between the tibial plateau and metal plate is sufficiently loosened, proximal extraction force should be exerted with the AcuDriver and the Impactor. Be alert to signs of impending tibial fracture. Extraction instruments provided by the manufacturer of the implant being revised may be helpful in final removal.







#### **CEMENT REMOVAL**

After the prosthesis is extracted, the AcuDriver is used with the Straight Gouge, Notched Osteotome or Vee Osteotome to fragment the remaining cement (*Figure 18*).

#### **CANAL PREPARATION**

After the femoral and tibial canals are clear of obvious cement fragments, a Finishing Reamer can be used to clean the canal surfaces. This reamer will help create a uniform surface for optimal fixation. The handpiece should be engaged and the reamer inserted into the canal. The "forward" or "clockwise" rotation setting on the drill or reamer should always be used, and the Finishing Reamer should be used in a continuous pushing and pulling motion (*Figure 19*).

#### PATELLAR COMPONENT REMOVAL

To remove the patellar component, the exposed plastic portion should be transected using a powered oscillating saw and Stablecut blade (available through Exactech) in combination with the AcuDriver and flat thin osteotomes (*Figure 20*).

Figure 20 Flexible Osteotomes can be used to Remove a Patellar Component

## **INSTRUMENT LISTING**





## INDICATIONS AND CONTRAINDICATIONS FOR USE

**INDICATIONS** 

- 1. Cement removal for revision reconstructive prosthesis surgery.
- 2. Prosthesis removal/cutting in joint replacement or revision procedures.
- 3. Bone sculpting in reconstructive prosthesis surgery.

#### **CONTRAINDICATIONS**

- 1. The device is not for use in removing soft tissue pathology.
- 2. Any application not suitable for using any common mallet with osteotomes.

## **CAUTIONS AND WARNINGS**

- 1. Read this manual thoroughly prior to using the AcuDriver<sup>®</sup> Automated Osteotome System.
- 2. Prior to each use, the handpiece and all accessories should be inspected for proper operation.
- 3. AcuDriver osteotomes are provided sterile and intended for single use only. Inspect packaging and product for shipping damage. Do not use dull or damaged osteotomes. Properly dispose of used osteotomes immediately following surgery.
- 4. The debris shield near the proximal end of the osteotome must be intact and firmly in place.
- 5. AcuDriver osteotomes are very sharp and should be handled with extreme caution.
- 6. The instrument should be in the "SAFE" position when changing accessories and inserting or removing osteotomes.
- 7. Always wear face protection when using or observing AcuDriver procedures.
- Before each use, be sure the osteotome is correctly attached to the handpiece by gently pulling on the shank. The plastic debris shield at the instrument end of the osteotome must be intact and firmly in place.
- 9. Be sure the pneumatic powered surgical air hose is securely fastened to the AcuDriver handpiece before each use.

- 10. Follow all instructions for "care and cleaning", "sterilization" and "precautions" in the cleaning instruction section of this manual. Do not submerge or rinse instruments in cold water or other fluids.
- Avoid contact of fiber optic cable and air hose with sharp edges or pointed objects to prevent cuts and/ or punctures. Do not pull, kink or stretch the cable.
- 12. Before each use, check the equipment for air or nitrogen leakage and return the instrument for service if leakage is noticed. Leakage may cause emboli, which could result in serious injury to the patient or patient death.
- 13. The instrument must not be operated above 120 p.s.i. Excessive pressure may cause damage to the instrument and exert unusual stress on the hose.
- 14. HANDLE ALL POWERED SURGICAL EQUIPMENT CAREFULLY. Should the instrument be dropped or damaged, return it to the manufacturer immediately.
- 15. Exactech surgical equipment is intended for use by trained medical professionals who are familiar with revision surgical techniques and instructions.
- 16. Only Exactech supplied accessories and osteotomes should be used.

For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, Inc., as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience.

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