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power tools

Modular Cable Surgical Power Tool System for
Orthopedics and Traumatology Operations

User Manual



Please read this manual before operating your device and keep it for future reference



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GENERAL INFORMATION

Introduction

This manual has been written to help describing the procedures required to keep the Modular Battery Surgical Power Tool System of ACF Medical operating properly.

This manual is published by ACF Medical. ACF Medical reserves the right that developing and changing to content of instruction manual without prior notice. But changes will publish in the next versions.

Intended Use

Modular Battery Surgical Power Tool System is used by surgeon specialists and technicians in the field of orthopedics and traumatology for shortening time of cutting, drilling, reaming and revision of operational process of large bones (Femur and Tibia) in orthopedics surgery. Power tools can be used for the functional control by bioengineers before the operation.

This product is a high speed battery-powered surgical power tool to help forming large bones for prosthesis that is used for Arthroplasty operations.

**** WARNINGS, CAUTIONS and NOTES sorted in this guide, are arranged conjugately with the sortings in the *Risk Analysis and Risk Management Report* prepared for the product. Therefore, the numbers go mixed.**

General Warnings and Cautions

Before using the instruments, all system component manuals should be reviewed for important warnings and instructions for use.

Definitions

- Warning is to indicate that the safety of the patient and hospital staff could be involved.
- Caution is to point out special procedures or precautions that must be followed to avoid damaging the system / instruments.
- Note is to point out the easiest means of implementation techniques.

WARNING 1: The end user must follow the rules of asepsis before and during use of the device.

WARNING 3: It should be used in the operating room environment where suitable conditions are provided for orthopedic operations and a spare surgical power tool should be kept during the operation.

WARNING 5: The power line must be at the proper power and capacity required by the product, and if an extension cable is used, it must be ensured that it is grounded and undamaged.

WARNING 6: Make sure that there is no electromagnetic interference between the device and other devices during use.

WARNING 12: Eye protection must be worn when operating any power equipment. Dislodged burs, blades, or bone fragments can result in eye injury, blindness or contamination of the eye from patient tissue or body fluids.

WARNING 13: Do not touch your hand with the blade / attachment attached to the end of the power tool while the device is running. If you do not pay attention to this, you may experience serious injury.

WARNING 14: When you pull the trigger, if you see that the power tools do not have energy / work brokenly; you shouldn't continue the operation with this power tool, continue with other extra power tools and send the power tool to the our technical service.

WARNING 16: The product should not be used if any damage is detected to the product and please contact us.

CAUTION 2: If you drop the product from high, if it has a noticeable damage on and doesn't work properly, please do not use it. Do not open and try to fix it. Send it to our repair service.

CAUTION 5: During operation, do not force the power tool to reduce the speed. Please be sure that to use the power tool as its high performance.

Symbol Explanations

	Caution		Catalogue Number
	Consult instructions for use before operating the device		Batch Code
	Caution, risk of electric shock		Serial Number
	Do not expose to stray magnetic fields		Manufacturer
	Do not lubricate		Manufacturing Date
	Non Sterile		Do not immerse the tool in liquids
	Recycling		Do not step on
	Dispose of this product according to local regulations.		Left
	Right		

SYSTEM OVERVIEW

A01 220 - Saw / Cable / Type / 2



Center
The tool is off for safety



R
Saw is on



L
Saw is on

- 1.Saw Blade Coupling:** Insert or remove a saw blade.
- 2.Locking Knob:** Assembly and removal of a saw blade.
- 3.Trigger:** Variable speed control by contactless trigger.
- 4.Rotational Direction Switch:** Three level rotation key.
- 5.Connector Point:** Section where A03 300 Data Cable is connected.

- Variable speed control by contactless trigger.
- Maximum approach to the cutting area by design of sawing chuck.
- Safety by locking feature of saw holder design.
- Maximum speed, maximum power for knee and hip operations.

Technical Details

- Speed: 15.000 cpm
- Oscillating Arc: 4°
- Operation Voltage: 14.4 V

A01 130 - Reamer / Cable / Type / 2



Center
The tool is off for safety



R
Clockwise rotation



L
Counterclockwise rotation

- 1. Attachment Coupling and Safety Lock:** To fix the attachments to the handpiece safely.
- 2. Trigger:** Variable speed control by contactless trigger.
- 3. Rotational Direction Switch:** Grey safety key with three gradual. The handpiece work when the grade is in the L(Left) or R(Right). The handpiece doesn't work when the grade is in the middle (safe) and attachment changing can be made safely.
- 4. Connector Point:** Section where A03 300 Data Cable is connected.

- Variable speed control by contactless trigger.
- Maximum approach to the operation area by design of modular coupling.
- Safety by locking feature of attachment holder design.
- Maximum speed, maximum power for knee and hip operations.

Technical Details

- Drilling Speed: 0-750 rpm
 - Drilling Torque: 3.9 Nm
 - Reaming Speed: 0-250 rpm
 - Reaming Torque: 17.8 Nm
 - Operation Voltage: 14.4 V
- *4,2 mm cannulated

A02 200 - Power Supply / Type / 2

- Power supply has "Plug and Play" feature.



Technical Details

- Giriş: 200-240 V ~ 1.7 A
- Çıkış: 24V DC 6.5 A
- Frekans: 50-60 Hz
- Sigorta Değeri: 5 A 250 V

A03 300 - Data Cable/ Type 3 / 2 Pins



- The cable length is 3 meters and it is suitable for sterilization.

A05 100 - Sterilization Container / Type / 01



- For all handpieces and attachments
- Produced by stainless steel material
- Product placement is determined by laser marking on the trays

A05 160 - Sterilization Container / Type / 03



- For all handpieces and attachments
- Produced by stainless steel material
- Product placement is determined by laser marking on the trays

A05 180 - Sterilization Container / Type / 04



- For all handpieces and attachments
- Produced by stainless steel material
- Product placement is determined by laser marking on the trays

Attachments for Modular Handpiece

<p>A01 700 Adapter for Drill (Keyed)</p>		<ul style="list-style-type: none"> • Operating Speed 750 rpm • 0- 8 mm
<p>A01 720 Adapter for Reamer (Zimmer)</p>		<ul style="list-style-type: none"> • Operating Speed 250 rpm
<p>A01 721 Adapter for Reamer (A.O. Synthes)</p>		<ul style="list-style-type: none"> • Operating Speed 250 rpm
<p>A01 723 Adapter for Reamer (Hudson & Stryker)</p>		<ul style="list-style-type: none"> • Operating Speed 250 rpm
<p>A01 740 Adapter for Wire Driver</p>		<ul style="list-style-type: none"> • Operating Speed 750 rpm • 1.6 mm to 2.5 mm
<p>A01 750 Adapter for Pin Driver</p>		<ul style="list-style-type: none"> • Operating Speed 750 rpm • 2.6 mm to 3.2 mm
<p>A04 101 Key for Chuck Type / 01</p>		<ul style="list-style-type: none"> • Available spin gap is 0- 8 mm.

POWER CONSOLE SETUP



WARNING 2: A02 200 Power Supply is not sterile and can not be sterilized.

WARNING 4: In countries where the mains voltage is not 220-240 V, use a voltage converter.

WARNING 9: All staff who is going to use the product (doctors and assistants who will perform the surgical operation, bioengineer, etc.) should have the knowledge about surgical power tools.

1. Place A02 200 Power Supply on the appropriate / flat / dry ground sufficient distance according to the operation type, insert the power cable as appropriate 220 Volts into the slot on the back of the unit.



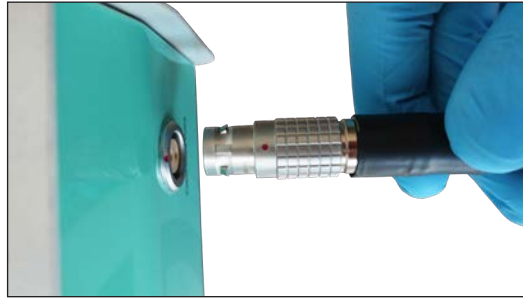
WARNING 16: Do not use the product if it has any noticeable damage and please contact us.

CAUTION 4: Make sure the handpiece is connected to the power supply before operating the device.

2. Turn on the device by pressing the On / Off button on the front of the console.



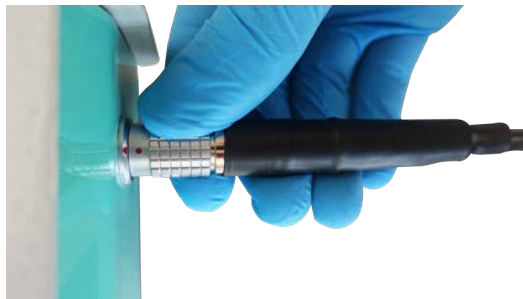
3. Hold the A03 300 Data Cable with the red dot on the connector facing up.



CAUTION 14: Hold the A03 300 Data Cable from connector part when you are fixing; otherwise Data Cable will be damaged.

4. Due to the risk of injury, firstly put the device in a safe (center) position.

5. First of all provide connection between A03 300 Data Cable and A02 200 Power Supply. Fix it as all red points are aligned. Be sure to hear the "Click " sound.



6. Fix the free end of A03 200 Data Cable to the bottom of the handpiece as same as data cable. Be sure to hear the "Click " sound.



CAUTION 1: Do not unplug your product by pulling the power cord.

CAUTION 14: Hold the A03 300 Data Cable while connecting it. Otherwise, the cable will be damaged.

OPERATING INSTRUCTIONS

Saw (A01 220)

Set the rotational direction switch to the centre position in order to avoid unintentional starting.

WARNING 10: If the product is not in the “safe” position, do not fix the blade to the power tools. You may get seriously injured unless you pay attention.

Inserting Saw Blade

- Press the safety lock and provide space at the top where means around saw blade slots.
- Insert an oscillating saw blade to the power tool with a smooth movement left to right.

WARNING 9: All personnel should become familiar with the power equipment before it is set-up for use in any surgical procedure. Personnel to be in-serviced should include specialist physician, members of the surgical team, and the bio-engineering departments etc.

WARNING 16: Do not use the product when the product has any noticeable damage. Please contact us.



CAUTION 3: Pull the trigger to run the power tools; after properly placing the blade in the cutting guide. If you pull the trigger before placing the blade; the blade will be damaged because of rubbing. Therefore it won't cut smoothly.

Operating the Tool

After ensuring that the saw blade is placed properly, move the rotational direction switch on left or right side and then oscillating saw will be ready for use.

Pull the trigger to operate the power tool. If the blade is unplaced; it will be damaged because of friction.

ACF Medical recommends you to use a new saw blade for each operation to ensure that the saw blade is optimally sharpened and clean.

WARNING 15: While using A01 220 Saw, do not use excessive force or pry on the saw blade. Doing so may cause the blade to bend or break, causing potential injury.

CAUTION 13: To ensure optimal performance, only use ACF saw blades. Otherwise, other saw blades may harm your tool.

CAUTION 16: While operating, be sure that the saw blade is at the parallel position with the cutting guide.

Removing Saw Blade

Press again the safety lock until it is fully opened and remove the saw blade.

Reamer / Drill (A01 130)

Set the rotational direction switch to the centre position in order to avoid unintentional starting. Pull the attachment coupling.



Inserting Attachments



Reamer Attachment



Drill Attachment



Pin/Wire Driver Attachment

Push the attachment until it engages in place. If the attachment does not engage properly then rotate the attachment gently until the drive shaft engages.

Check that the attachment coupling is closed properly by lightly pulling the attachment.

WARNING 11: If the rotational switch is not in the “center (safe)” position, do not try to insert the attachments to the power tool. You may get seriously injured.

Operating the Tool

After ensuring that the attachment is placed properly, move the rotational direction switch on left or right side and then the tool will be ready for use.

Pull the trigger to operate the power tool.

To ensure optimal performance, only use ACF attachments. Otherwise, other attachments may harm your tool.

Removing Attachments

Pull the attachment coupling and pull the attachment until it gets out.

CLEANING INSTRUCTIONS

Manual Cleaning

1. Before cleaning, remove all instruments and attachments from the power tool.
2. Do not use pointed objects for cleaning.
3. Rinse the device under running cold tap water.
4. Scrub debris from the handpiece using a sponge.
5. Use an enzymatic detergent to remove organic and inorganic debris according to manufacturer's directions.



6. Manipulate all moving parts of the handpiece such as to ensure all debris is removed.
7. For cannulations of the handpiece and attachments, use a syringe and an air blow gun.
8. Hold the handpiece upright to prevent water from running.
9. Visually inspect the handpiece for any remaining debris. If any debris is present, repeat the cleaning and rinsing procedure.
10. Gently shake the handpiece free of water.
11. Dry the handpiece with a clean lint-free soft cloth.





CAUTION 15:

- DO NOT lubricate the handpieces. Lubrication may damage the internal motor mechanism.
- DO NOT immerse the handpieces and the batteries in any fluid.
- DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.
- Cleaning with an ultrasonic cleaner may harm your handpieces.
- Body fluids and tissue should not be allowed to dry on instruments prior to cleaning (Maximum 30 minutes)

Attachments are suitable for use in an ultrasonic cleaner and immerse in a fluid. Only use approved cleaning agents according to manufacturer's recommendations.



Automated Cleaning

Even if you have an automated cleaning system, pre-cleaning is recommended.

Modular Battery Surgical Power Tool System is suitable for use in washer. They are designed with advanced materials and sealing technologies are tested to ensure the prevention of ingress of fluids during using and cleaning.



Modular Cable Surgical Power Tool System has a water protection rating of **IPX 6**, protected against high pressure water stream from any angle.

1. Remove all instruments and attachments from the power tool. Remove the battery from the handpiece.
2. Under running tap water, remove all traces of blood and debris.



3. Load handpieces and attachments in a washer basket. Take care not to fill the basket too much and make sure that instruments have enough space to be freely cleaned. The handpieces must be in an upright position.



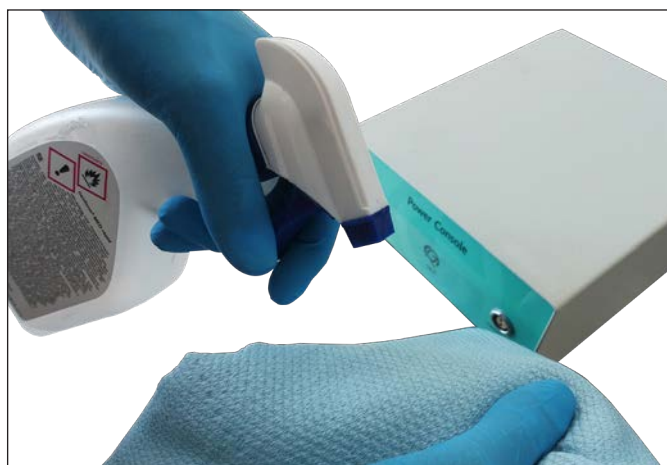
4. Operate according to washer manufacturer's instructions. Only use approved solutions for cleaning powered instruments according to manufacturer's recommendations.



WARNING 17: Never immerse the handpieces and the batteries in aqueous solutions or in an ultrasonic bath. Do not use pressurized water during washing process.

Cleaning and Disinfection of Power Console

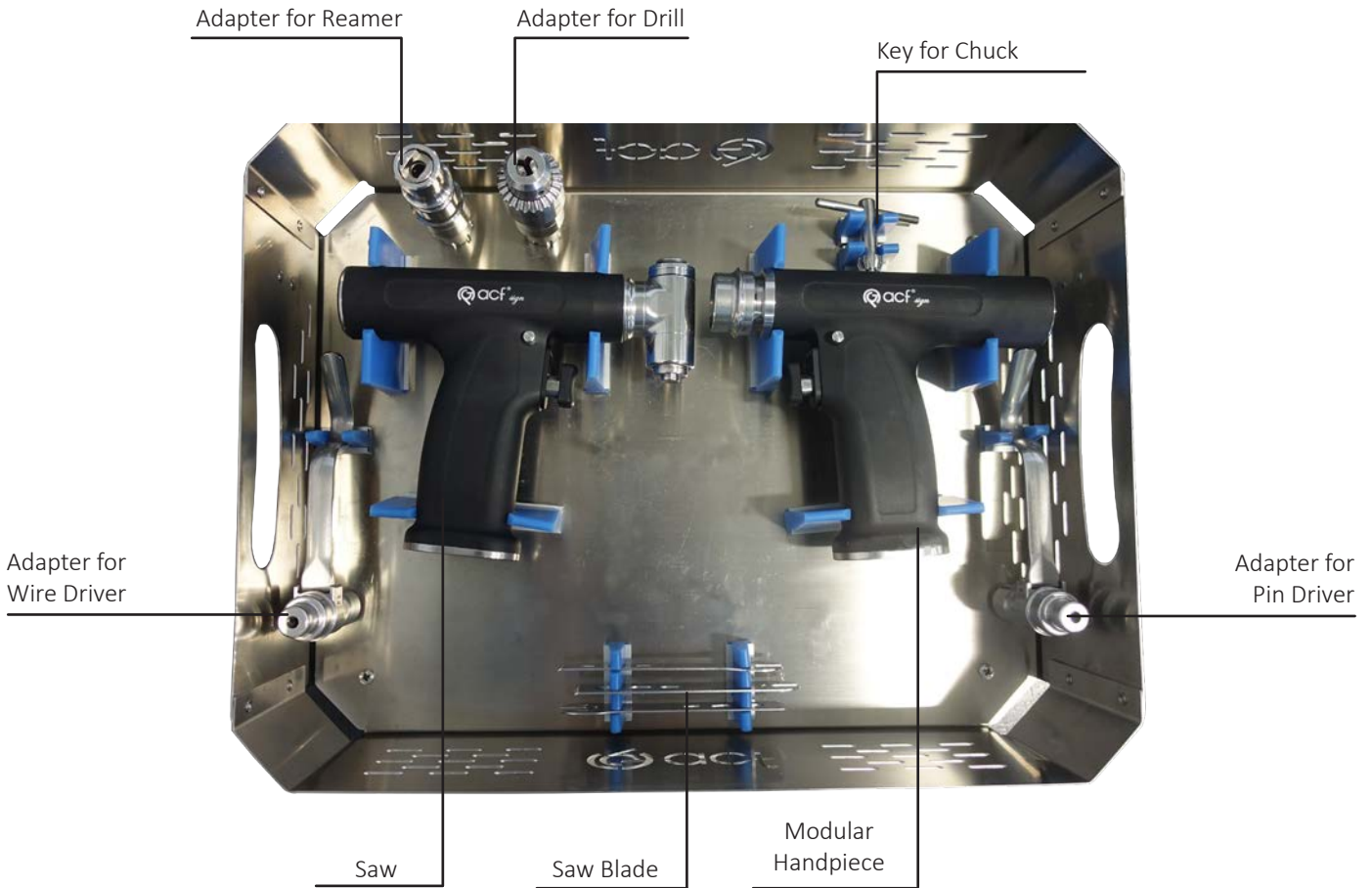
1. **To clean** the power supply wipe them off with a clean, soft and lint-free cloth dampened with deionized water and dry prior to processing.
2. **To disinfect** the power supply, apply a disinfectant on a new, clean, soft and lint-free cloth and wipe it off. Please pay attention **not to spray directly to the device**. Follow the instructions provided by the manufacturer of the disinfectant.



STERILIZATION INSTRUCTIONS

Preparing for Sterilization Process

Place clean and dry products (handpieces, attachments, sterilization guides) into designated locations in the sterilization container. Fasten sterilization case lid.



Sterilization Container Dimensions: Length x Width x Height
425 x 305 x 120 mm

WARNING 7: Instruments are manufactured as non-sterile. They need to be sterilized before using.

CAUTION 10: ACF Medical recommends you to autoclave your tools and accessories in ACF sterilization container. Every instrument should be sterilized independent of each other.

Sterilization Recommendations

1. The most effective and safe sterilization method is steam sterilization for Modular Battery Surgical Power Tool System. The instruments are capable of withstanding the recommended exposure times and temperatures of steam sterilization. Other sterilization methods are not recommended.
2. Sterilization must be carried out through a validated steam sterilization process (according to ISO 17665-1:2006).

In case of any urgent need;

- a. Instruments can be sterilized with parameters of **134° C program for a minimum holding time of 4 minutes** as can be seen below. For normal operation procedures, validated steam sterilization process should be followed.
- b. Sterilized instruments should be used not long after sterilization. Steam autoclave should be in the most closest location to the operating room and/or sterilized instruments should be transported to the point of use under aseptic conditions.
- c. Quality controls should be recorded such as all indicator results, emergency reasons and patient information.

Parameters for Sterilizing

Sterilization Type	Minimum Temperature	Minimum Exposure	Dry Time
Pre-Vacuum	273° F (134° C)	4 Minutes	5-30 Minutes

WARNING 7: Instruments are manufactured as non-sterile. They need to be sterilized before using.

CAUTION 11: The following value must not be exceeded for sterilizing: 134° C. Higher values can damage the sterilized products.

CAUTION 12: Do not use the handpiece just after autoclave process till temperature of trigger mechanism to cool down and reach to room temperature. If you use it before cooling; handpiece will be damaged.

CAUTION 8: Products such as coolant should not be used to speed up the cooling of the instruments.

CAUTION 6: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes at 134 °C (273 °F). (WHO/CDS/CSR/ APH 2000.3, “WHO Infection Control Guidelines for TSE,” March 1999).

WARNING 18: Return the device to the manufacturer if there is visible dirtiness on it.

Storage

Packaged and sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Use products in the order in which they are received (first-in, first-out principle), taking note of any expiration date on the label.

WARNING 8: Although there is no special condition; storage or shipment should not be performed and the device should not be used outside of the specified conditions.

CAUTION 7: In order to prevent any missing product in the set to be sterilized; be ensure that the set content is checked before sterilization process.

AFTER SALE SERVICES

Troubleshooting

Problem	Cause	Steps
<i>Handpiece is not working when pulling the trigger.</i>	Rotation switch is on the "center" position	Switch the Left/Right safety key on the middle of handpiece body L or R position.
	Handpiece is taken out from autoclave and it is till warm	Wait for till handpiece is cooled down sufficiently (room temperature)
	Data Cable is not inserted to the handpiece or power supply sufficiently	Remove the data cable and insert it again. Make sure you hear "Click " sound.

Repairs and Technical Service

The power tool should be sent to ACF Medical for repair if it is faulty or malfunctions.

Contaminated products have to be cleaned before being sent to ACF Medical for repair or technical service.

Faulty devices must not be used. If it is no longer possible or feasible to repair the power tool it should be disposed of the following section “Disposal of Waste”.

Please refer to the regulations for transporting Li-Ion batteries when returning them to the ACF Medical.

ACF Medical excludes liability for damage resulting from unauthorized servicing of the tool.

Returning Procedure

Firstly contact with ACF Technical Service when you see a fault on the product.

Make clear with the technical team that which piece of the product is out of order.

Return the fault detected product to the factory in accordance with the directions as determined by the ACF Team.

The products, which are not shipped according to ACF instructions, will be returned to the customer.

Any repair costs may arise out of warranty, you will be informed by ACF Medical to get your approval.

Please return the products in accordance with the following procedures;

- Sterile products in accordance with instruction for use of products.
- Make the product is packaged to not be damage during the shipment.
- Please call the ACF customer support team before shipping if Lithium-Ion battery is damaged.
- Please add related product’s LOT and S/N (serial) number and brief description of product’s breakdowns on the delivery note to send the product.

Disposal of Waste

In most cases, faulty power tools can be repaired.

Please send devices that are no longer used to ACF Medical. This ensures that they are disposed of in accordance with the national application of the respective directive. The device must not be disposed of with household waste.

The European Directive 2012/19/EC on waste electrical and electronic equipment (WEEE) applies to this device. This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe national regulations.



