

REF 6643 SmartDriver Duo™

Instructions for Use



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Instruction Manual**

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TECHNICAL DESCRIPTION

REF 6643

INTENDED USE

Multi-purpose, modular, powered instrument system intended for use in general, orthopedic, plastic and trauma surgery.

INTRODUCTION

This manual has been written to help describe the procedures required to keep the MicroAire REF 6643 SmartDriver Duo system operating properly.

Throughout the manual, the following terms are used to identify tips and precautions that will help avoid accidental injury to patients or personnel, or prevent damage to the system.

- NOTE:** Used to point out the easiest means of carrying out techniques.
- WARNING:** Used to indicate that the safety of the patient and hospital personnel could be involved.
- CAUTION:** Used to point out special procedures or precautions that must be followed to avoid damaging the system/instrument.

GENERAL WARNINGS

- WARNING:** Risk of fire. Replace battery pack only with a MicroAire Battery (REF 6640-710, REF 7505-710 or REF 7500-620).
- WARNING:** Explosion Hazard. Not suitable for use in the presence of flammable anesthetics or oxygen.
- WARNING:** Electric Shock. Do not remove cover. Refer servicing to qualified personnel only.
- WARNING:** Medical electrical equipment may be affected by electromagnetic interference. It should be installed and used in accordance with the electromagnetic compatibility information provided herein
- WARNING:** Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING:** Operating Duty cycle is 1 minute on, 1 minute off for a maximum of 6 cycles.
- WARNING:** Irrigation must be applied to the cutting accessory when cutting bone in order to keep bone temperature within safe limits. Cutting without irrigation may cause unsafe temperatures leading to bone necrosis.
- WARNING:** Prior to use, all system components (handpiece, couplers, batteries) should be inspected to detect any damage or malfunction. **DO NOT** use any component if damage is apparent.
- WARNING:** Prior to use, all system component manuals should be reviewed for important warnings and instructions for use.
- WARNING:** 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:** To prevent inadvertent running of handpiece while loading a coupler or surgical accessory, do not attach the battery pack until the coupler and surgical accessory have been loaded for use.
- WARNING:** Excessive heat is the most likely cause of patient injury. Any power instrument is subject to become hot.
- WARNING:** If any corrosion or debris is detected in/on the instrument, it must be considered contaminated. Either replace the instrument immediately or remove it from the sterile field and reprocess. If the instrument looks damaged or shows signs of excessive wear, it should not be used.

- WARNING:** Universal precautions for handling contaminated materials should be observed at all times.
- WARNING:** Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product's warranty, and the customer will be responsible for any costs related to returning the product to working condition.
- WARNING:** When operating this saw, be careful to retract or protect the patient's tissue near the locking collar. Pinching the tissue between the collar and the body of the instrument may cause a severe bruise or friction burn.
- WARNING:** Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING:** Use of the 6643 SmartDriver Duo adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the 6643 SmartDriver Duo and the adjacent equipment should be observed to verify that they are operating normally.
- WARNING:** Portable RF communications equipment should be used no closer than 30 cm (12 inches) away from any part of the 6643 SmartDriver Duo. Otherwise degradation of the performance of the 6643 could result.
- WARNING:** Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING:** 6643 SmartDriver Duo has been tested for use in the vicinity of High Frequency Electrosurgical / Electrocoagulation equipment. Use of such equipment in close proximity to the 6643 SmartDriver Duo may cause unintended interruptions or unintended motion of durations up to 1 second. Place the Instrument on a safe surface when not in use. Do not place powered Instruments on the patient when not in use. Avoid entwining HF surgical cables with powered instruments.
- WARNING:** The following items should be periodically inspected for signs of damage and repaired or replaced as needed to ensure continued safety with regard to electromagnetic disturbances over the life of the system:
- Check that the Battery Connection base, the rear end cap and the front of the instrument remain securely connected to the main instrument body.
 - Check for damage to the battery pack housings.
- CAUTION:** If using the REF 6643-045 or REF 6643-050 Wire/Pin Couplers, make sure you have the REF 6640-002 Wire Guard attached to the rear of the handpiece. Align the threaded portions of the handpiece and guard, and screw the guard into the handpiece.
- CAUTION:** Battery pack should not be left in the instrument when not in use. Leaving a battery pack attached to a handpiece when not in use will accelerate battery drain.
- CAUTION:** Exceeding recommended steam sterilization exposure times or temperatures for the battery may reduce battery life and/or performance.
- CAUTION:** **DO NOT** lubricate or oil the handpieces. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubrication.
- CAUTION:** **DO NOT** immerse the handpiece in any fluid.
- CAUTION:** **DO NOT** utilize cleaning solutions that are not mild pH unless they are approved for use with Anodized Aluminum and Surgical Instruments.
- CAUTION:** **DO NOT** utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.
- CAUTION:** **DO NOT** use an ultrasonic cleaner. Ultrasonic cleaning can damage the bearings in the handpiece, potentially resulting in overheating or failure of the handpiece.
- CAUTION:** Dried blood, saline, and other deposits inside the handpiece are a major cause of equipment malfunction. Proper cleaning and inspection prior to sterilization will avoid delays during the surgical procedure.

- CAUTION:** If using the REF 6643-045 or REF 6643-050 Wire/Pin Couplers, make sure you have the REF 6640-002 Wire Guard attached to the rear of the handpiece. Align the threaded portions of the handpiece and guard, and screw the guard into the handpiece.
- CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- CAUTION:** If using the REF 6643-045 or REF 6643-050 Wire/Pin Couplers, make sure you have the REF 6640-002 Wire Guard attached to the rear of the handpiece. Align the threaded portions of the handpiece and guard, and screw the guard into the handpiece.
- CAUTION:** Battery pack should not be left in the instrument when not in use. Leaving a battery pack attached to a handpiece when not in use will accelerate battery drain.
- CAUTION:** Exceeding recommended steam sterilization exposure times or temperatures for the battery may reduce battery life and/or performance.
- NOTE:** The 6643 SmartDriver Duo is suitable for use in hospitals and surgery centers. These systems should not be used near Magnetic Resonance Imaging equipment.
- NOTE:** All personnel should become familiar with the power equipment before it is setup for use in any procedure. Personnel inserviced should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.
- NOTE:** The oscillate \cup function is intended to make percutaneous drilling and fixation easier. It should not be used with any saw, reaming, driving, or pulse lavage couplers.
- NOTE:** Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
- NOTE:** The emissions characteristics of this product 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 be required to take mitigation measures, such as relocating or re-orienting the equipment.
- NOTE:** Do not use instruments when they are still warm. They need to cool down to room temperature.
- NOTE:** Do not soak instruments to cool them down or wrap cold towels around them.
- NOTE:** Mailing address is located on back cover.
- NOTE:** Does not accept MicroAire 8053-020, 8053-024, 8053-032, 8053-036, 8053-036, 8053-115 and 8053-119.
- NOTE:** Zimmer®-style reamers and accessories are sometimes referred to as “Hudson Modified Trinkle” reamers.
- NOTE:** Do not operate any of the SmartDriver Saw Couplers when the handpiece is set to “oscillate mode”.
- NOTE:** Handpiece “ON/OFF” Safety Switch located on the front base of handpiece.
- NOTE:** Do not use the oscillate function with SmartDriver Saw or Pulse Lavage Couplers.
- NOTE:** Washer/Disinfectors should comply with the requirements of ISO 15883 (in preparation). They should be properly installed and be regularly tested in accordance with ISO 15883.
- NOTE:** If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.
- NOTE:** Does not accept MicroAire ZS-36X and ZS-37X series blades.
- NOTE:** Does not accept MicroAire ZS-36X and ZS-37X series blades.
- NOTE:** Does not accept MicroAire ZR series large reciprocating saw blades.
- NOTE:** 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/2000.3, “WHO Infection Control Guidelines for TSE,” March 1999).

- NOTE:** The reaming couplers for the MicroAire SmartDriver, while high torque, do not produce enough torque to complete the heavy IM and Acetabular Reaming required for total hip arthroplasty. The MicroAire SmartDriver Duo is ideal for reaming in ACL surgeries and for lighter tibial and humeral reaming. Heavy femoral reaming should be completed using the MicroAire Series 7000 Large-Bone Instruments.
- NOTE:** If a rasp becomes loose when the handpiece is running, the rasp was not seated properly in the locking mechanism. Move the rasp from side to side several times, then retighten the locking collar.
- NOTE:** Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
- NOTE:** Do not use instruments when they are still warm. They need to cool down to room temperature.
- NOTE:** Do not soak instruments to cool them down or wrap cold towels around them.

MARKINGS

Name	Ref# (ISO 7000) ²	Symbol	Description	Use Standard
Refer to Instruction Manual / Booklet	ISO-7010 M002		<ul style="list-style-type: none"> Indicates a MANDATORY action for the user to consult the Instructions For Use (IFU). Symbol must be blue, as shown. 	IEC 60601-1:2005 ¹
Consult Instructions For Use (IFU)	1641		Indicates the need for the user to consult the Instructions For Use (IFU). Not required in conjunction with the Caution symbol, if applicable.	ISO 15223-1:2012 ¹
Caution	0434A / 0434B		Indicates the need for the user to consult the Instructions For Use (IFU) for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.	ISO 15223-1:2012 ¹
UL symbol	N/A		MEDICAL-GENERAL MEDICAL EQUIPMENT AS TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY. IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 (2005) + A1 (2012) + CAN/CSA C22.2 No. 60601-1 (2014) Control Number: E494242	UL
Type B Applied Part	5840		Indicates a medical device complying with the specified requirements of IEC 60601-1 to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.	IEC 60601-1:2005 ¹
Forward Direction	N/A	F	Indicates rotation will be counterclockwise when viewed from the front of the instrument.	N/A
Reverse Direction	N/A	R	Indicates rotation will be clockwise when viewed from the front of the instrument.	N/A
Oscillating Rotation Indicator	2493		Indicates the direction of oscillating rotation.	ISO 15223-1:2012 ¹
Locked	5569		To identify on a control that a function is locked or to show the locked status.	IEC 60878:2015 ¹
Unlocked	5570		To identify on a control that a function is not locked or to show the unlocked status.	IEC 60878:2015 ¹
"ON" Position	N/A		Indicates "ON" position (both triggers functional).	N/A
"OFF" Position (Safety)	N/A		Indicates "OFF" position (both triggers will not function when depressed).	N/A

Authorized Representative in the European Community	N/A		Indicates the authorized representative in the European Community. This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol.	ISO 15223-1:2012 ¹
Serial #	2498		<ul style="list-style-type: none"> Indicates the manufacturer's serial number so that a specific medical device can be identified. Per EN980:2008, the SN symbol may be used without surrounding box. 	ISO 15223-1:2012 ¹
Lot / Batch Code	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2012 ¹
REF (Catalog #)	2493		<ul style="list-style-type: none"> Indicates the manufacturer's catalog number so that the medical device can be identified. Per EN980:2008, the REF symbol may be used without surrounding box. 	ISO 15223-1:2012 ¹
Sterile	2499		Indicates a medical device that has been subjected to a sterilization process. Use of the Sterile symbol requires a use-by date (see Use-By Date symbol).	ISO 15223-1:2012 ¹
Do Not Reuse	1501		Indicates a medical device that is not to be resterilized.	ISO 15223-1:2012 ¹
Do Not Use if Package is Damaged	2606		Indicates a medical device that should not be used if the package has been damaged or opened. This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".	ISO 15223-1:2012 ¹
Temperature Limitation	0632		Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits to temperature shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012 ¹
Do Not Expose to Stray Magnetic Fields	N/A		Indicates a medical device that is not to be exposed to stray magnetic fields.	N/A
Humidity Limitation	2620		Indicates the range of humidity to which the medical device can be safely exposed. The humidity limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012 ¹
Atmospheric Pressure Limitation	2621		Indicates the range of atmospheric pressure to which the medical device can be safely exposed. The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012 ¹
Do Not Immerse in any Liquid	5995		Indicates a medical device that is not to be immersed in any liquid.	IEC 60335-2-15
Do Not Lubricate	N/A		Indicates a medical device that is not to be lubricated.	N/A
Date of Manufacture	2497		<ul style="list-style-type: none"> Indicates the date when the medical device was manufactured. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29). If the symbol is filled (see Manufacturer symbol), both the date of manufacture and the name/address of the manufacturer may be combined in one symbol. 	ISO 15223-1:2012 ¹
Manufacturer	3082		<ul style="list-style-type: none"> Indicates the medical device manufacturer. This symbol shall be accompanied by the name and address of the manufacturer. The date of manufacture may be combined with this symbol. When using MicroAire as the manufacturer, use the MicroAire LLC symbol. 	ISO 15223-1:2012 ¹
CE Mark for EU Class IIa and Higher Products	N/A		European Conformity Mark 0086 = Notified Body Number 2007 - Year approved to apply CE Mark	Council Directive 93/42/EEC

Prescription	N/A		Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).	FDA Title 21, Chapter 1, Subchapter H, Part 801.15(F)
Dispose of per WEEE Directive 2012/19/EU	N/A		Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU.	Council Directive 2012/19/EU
Dispose of per WEEE Directive 2012/19/EU	N/A		Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU. This symbol is used in place of the above symbol if the product entered the market after 13 August, 2005.	Council Directive 2012/19/EU (Symbol: European Standard EN 50419)
Packaging is Recyclable	1135		Indicates that the marked item or its material is part of a recovery or recycling process.	IEC 60878:2015

¹ ISO 15223-1:2012 – “Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements”
² ISO 7000/IEC 60417 – “Graphical symbols for use on equipment – Registered symbols”

LIST OF COMPATIBLE ACCESSORIES

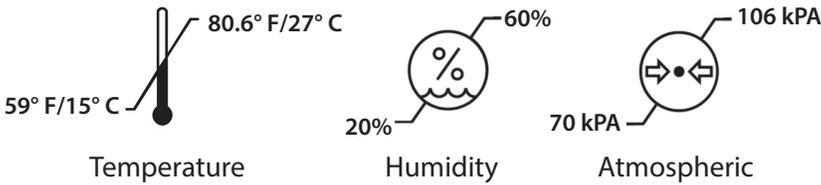
Part Number	Description	Type B Applied Parts
REF 6400	Reciprocating Saw Coupler	Accepts MicroAire® 1400 Series and ZR Series Reciprocating Blades and Rasps
REF 6640-710	NiMH SmartDriver™ Battery Pack	N/A
REF 6643-040	Sterilization Case and Washer Tray	N/A
REF 6643-045	Automatic Wire Driver Coupler	Accepts MicroAire® K-Wires REF 1600-XXX
REF 6643-050	Automatic Pin Driver Coupler	Accepts MicroAire® Steinmann Pins REF 162X-XXX
REF 6660	Trinkle Coupler	N/A
REF 6665	Hudson®-Style High-Torque Reamer Coupler	N/A
REF 6665-M1	Hudson® Coupler	N/A
REF 6670	Sagittal Saw Coupler with Key	Accepts MicroAire® REF ZS-0XX and REF ZS-3XX Sagittal Blades
REF 6672	Keyless sagittal Saw Coupler	Accepts MicroAire® REF ZS-3XX Sagittal Blades
REF 6673	Heavy-Duty Sagittal Saw Coupler (REF 2250-001 Hex Wrench included)	Accepts MicroAire® REF ZO-7XXX (not longer than 71mm), REF ZS-0XX and REF ZS-3XX Sagittal Blades)
REF 6680	Jacobs®-Style Coupler 5/32"	Accepts MicroAire® REF 8054-XXX
REF 6685	Jacobs®-Style High-Torque Reamer Coupler 1/4"	N/A
REF 6686	Jacobs®-Style Coupler 1/4"	Accepts MicroAire® REF 8054-XXX
REF 6687	Zimmer®-Style (Hudson® Modified Trinkle) Reamer Coupler	N/A
REF 6688	Keyless Drill Coupler 1/4"	Accepts MicroAire® REF 8054-XXX
REF 6689	Synthes®-Style Reamer Coupler	N/A
REF 6690	Synthes®-Style Quick Connect Coupler	N/A
REF 7500-615	Aseptic Battery Housing	N/A
REF 7500-620	Aseptic NiMH Battery Pack	N/A
REF 7500-625	Charging Adapter	N/A
REF 7500-630	Aseptic Transfer Shield	N/A
REF 7500-700	Universal Battery Charger	N/A
REF 7505-710	Large NiMH Battery Pack	N/A

WARNING: Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electro-magnetic immunity of this equipment and result in improper operation.

ENVIRONMENTAL PARAMETERS

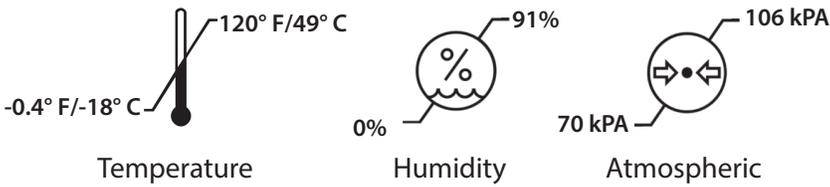
OPERATING CONDITIONS

This device has been tested and proven to operate within the following conditions:



SHIPPING & STORAGE CONDITIONS

This device has been tested and proven to operate after repeated exposure to the following conditions:



Shipping: The materials and components used in the construction of this device were selected to ensure that the device could be shipped by any standard commercial method without special handling conditions.

TECHNICAL DATA - SPECIFICATIONS

High Torque Output:	0 – 500 rpm (nominal)
Low Torque Output:	0 – 1600 rpm (nominal)
Cannulation:	0.125" (3.2 mm)
6643 Handpiece Weight (without battery pack or coupler):	1.55 lb. (703 g)
6640-710 Battery Weight:	0.95 lb. (431 g)
Battery Voltage:	14.4 volts
Duty Cycle:	1 Minute on 1 Minute off 6 cycles maximum
Rating:	14.4 VDC 225W

HANDPIECE SAFETY MECHANISMS



"ON" Position (Both Triggers Fully Functional)



"OFF" Position (Both Triggers will not function when depressed)

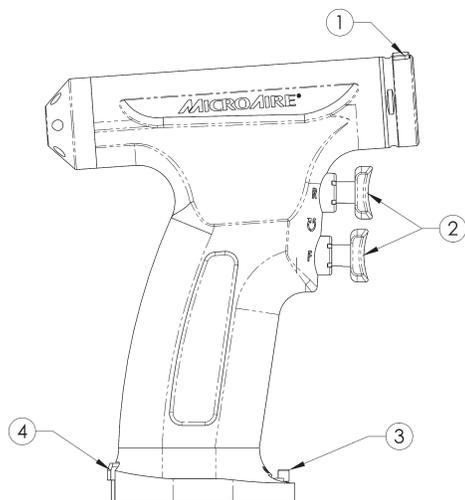
NOTE: Handpiece "ON/OFF" Safety Switch located on the front base of handpiece.

The (REF 6643) also comes with a rear-projection wire guard (REF 6640-002) that screws into the back end of the handpiece. This is recommended for use whenever operating the SmartDriver Wire or Pin Couplers.

REF (6640-002) Wire Guard



HANDPIECE FEATURES



Features & Descriptions

1. Coupler Release Button

This button releases a coupler from the SmartDriver Duo. It does not need to be depressed to load a coupler.

2. Forward / Reverse / Oscillate Control

The SmartDriver Duo will operate in both forward "F" (clockwise), and reverse "R" (counterclockwise).

The bottom trigger operates in forward "F", the top trigger operates in reverse "R". The SmartDriver Duo also has an oscillate  feature that turns less than one full turn in alternating forward "F" and reverse "R" directions.

This feature will minimize soft tissue from wrapping around a twist drill, wire, or pin. Depressing both triggers at the same time will engage the oscillate mode.

NOTE: Do not use the oscillate function with SmartDriver Saw or Pulse Lavage Couplers.

3. Trigger/Safety Lock

The MicroAire SmartDriver Duo operates at variable speeds and is controlled by depressing the trigger.

The instrument is in the off position when the trigger is not depressed. As the trigger is depressed fully the speed increases from 0% - 100%. The handpiece safety switch is located on the front base of the handpiece.

The handpiece is in safe mode when the trigger is in the off position and the safety switch is facing off.

 The handpiece safety is off when the safety switch is to the right. 

4. Battery Release Button

Depress this button to remove a battery/power pack from the SmartDriver Duo. This button does not need to be depressed to load a battery/power pack.

6643 SMARTDRIVER DUO

The 6643 SmartDriver Duo is a variable speed, multi-purpose handpiece with a selection of quick-connect Drive Couplers. The drive couplers are designed to complete a variety of applications from K-wire driving to cutting with a sagittal saw and light reaming.

NOTE: All personnel should become familiar with the power equipment before it is setup for use in any procedure. Personnel to be in-serviced should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.

SYSTEM SETUP

CAUTION: Battery pack should not be left in the instrument when not in use. Leaving a battery pack attached to a handpiece when not in use will accelerate battery drain.

WARNING: To prevent inadvertent running of handpiece while loading a coupler or surgical accessory, do not attach the battery pack until the coupler and surgical accessory have been loaded for use.

1. Inspect the handpiece and couplers for damage, or corrosion, or excessive wear.

WARNING: If any corrosion or debris is detected in/on the instrument, it must be considered contaminated. Either replace the instrument immediately or remove it from the sterile field and reprocess. If the instrument looks damaged or shows signs of excessive wear, it should not be used.

2. Check all surgical accessories. Make sure that blades, drills, and burs are not dull or bent, and that they lock correctly into the handpiece.

3. Make sure handpiece is set to the "OFF" position.

4. Attach a SmartDriver coupler - (66XX Series) to the front of the SmartDriver Duo handpiece. To connect a SmartDriver coupler to the handpiece, insert the coupler with a twist motion until you see and feel the coupler lock into position. The drive coupler is not locked into place until the base of the drive coupler is flush with the locking collar. To remove a coupler, press the coupler release button on the top front end of the handpiece and pull the coupler out. The coupler should release easily when the button is depressed.

CAUTION: If using the REF 6643-045 or REF 6643-050 Wire/Pin Couplers, make sure you have the REF 6640-002 Wire Guard attached to the rear of the handpiece. Align the threaded portions of the handpiece and guard, and screw the guard into the handpiece.

5. Insert a surgical accessory into the coupler, making sure it is secure. (Different handpieces have different mechanisms for attaching these components. Please refer to the instructions specific to the coupler).

a. Make sure that the safe switch is in the "OFF"  position to prevent activation of the motor.

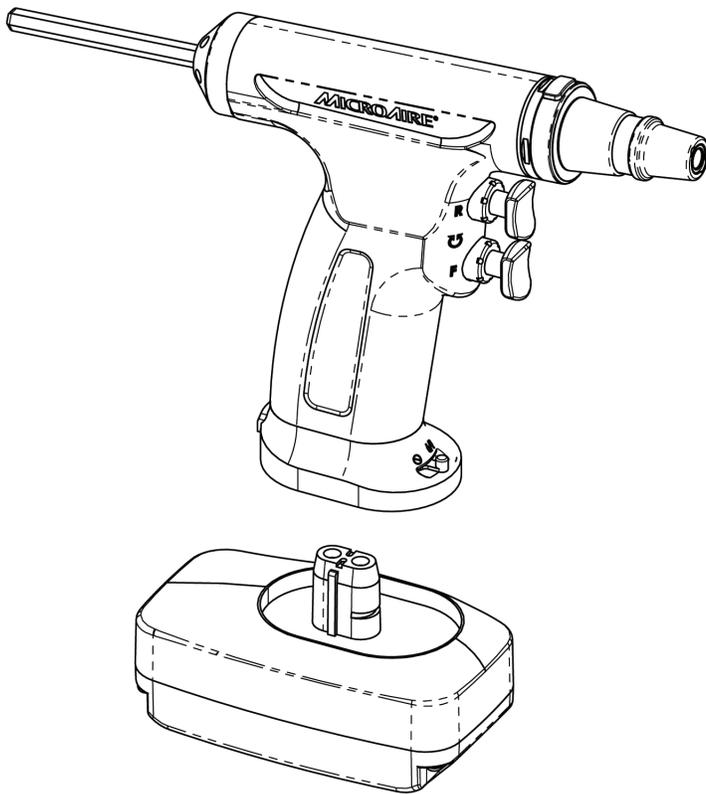
b. When the handpiece is in the "ON" position, make sure that the motor can be activated by depressing the trigger.

c. Make sure that the triggers do not stick in the fully depressed position. If it has any tendency to stick, reclean and re-sterilize the handpiece. If the handpiece still does not meet the above requirements, return the handpiece for service.

6. Attach a fully charged MicroAire Battery Pack (REF 6640-710, REF 7505-710, or REF 7500-615) to the handpiece. To attach the battery/power pack to the handpiece, place the battery under the base of the instrument with the longer side facing the rear of the instrument. Firmly push the battery/power pack into the base of the handpiece until the battery latch clicks into place.

7. Choose designated drive direction with the top or bottom trigger. The bottom trigger will drive the coupler in a clockwise/forward "F" direction. The top trigger will drive the coupler in a counter-clockwise/reverse "R" direction. Depressing both the top and bottom triggers together will drive the coupler in an alternating forward/reverse direction (oscillate function) .

NOTE: The oscillate  function is intended to make percutaneous drilling and fixation easier. It should not be used with any saw, reaming, driving, or pulse lavage couplers.



8. With the surgical accessory inserted, test run the instrument in the sterile field for three 10-second intervals, checking for any indication of irregular noise, or vibration. Irregular grinding noises may indicate impending failure or overheating of the handpiece. If any irregular grinding noises are present, return the instrument for service.

9. Check for excessive heat. To check for overheating, test run the handpiece for approximately 30 seconds. Periodically monitor the temperature of the nose section. The temperature should not become uncomfortable to touch with gloved fingers.

WARNING: Excessive heat is the most likely cause of patient injury. Any power instrument is subject to become hot.

The following conditions may cause overheating or total failure of the instrument:

- Blood deposits, saline, and bone fragments may enter the forward section of the handpiece during operation. Saline causes corrosion, and blood produces restrictive deposits.
- Repeated sterilization removes grease from the bearings, and leaves mineral deposits on moving parts. Regular maintenance is recommended to replace bearings, seals, and O-rings.
- The force of cutting produces wear on bearings and oscillating mechanisms.

10. System is ready for use.

TROUBLESHOOTING

Problem:	Cause:	Troubleshooting Steps:
Trigger will not depress	Debris in trigger assembly	Thoroughly clean and sterilize handpiece
Handpiece does not run when trigger is depressed	Battery pack is discharged	Recharge the battery pack in MicroAire charger
	Battery pack has exceeded life	Replace the battery pack
	Instrument is too cold	Allow to return to room temperature
	Instrument is too hot	Allow to cool to room temperature
	Mechanical malfunction	Return to MicroAire for service
	Electrical/magnetic interference present	Turn off all electrical equipment not in use
		Release trigger for one second, resume use
		Increase spatial distance between equipment and handpiece
Instrument stalls while in use	Excessive load	Reduce load, release trigger for one second, resume use
	Battery pack has exceeded life	Replace the battery pack
	Instrument is too hot	Allow to cool to room temperature
Handpiece runs but blade does not move	Mechanical malfunction	Return saw coupler or handpiece to MicroAire for service
Coupler hard to load/unload in handpiece	Coupler not loaded properly	Insert coupler with twisting motion until fully seated in handpiece
	Debris in handpiece collet	Clean and sterilize handpiece
Blade will not fit in coupler	Incompatible saw blade	Use MicroAire approved saw blade
	Debris in blade collet	Clean and sterilize coupler
Battery does not properly seat in handpiece	Improper battery pack	Use MicroAire approved battery pack
	Battery not oriented properly	Install the battery pack on the handpiece with the long end towards the back of the handpiece

INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS

Per ISO17664:2003 and AAMIST81:2004

Devices: REF 6643, and Drive Couplers

WARNING: Universal precautions for handling contaminated materials should be observed at all times.

CAUTION:

- **DO NOT** lubricate or oil the handpieces. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubrication.
- **DO NOT** immerse the handpiece in any fluid.
- **DO NOT** utilize cleaning solutions that are not mild pH unless they are approved for use with Anodized Aluminum and Surgical Instruments.
- **DO NOT** utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.
- **DO NOT** use an ultrasonic cleaner. Ultrasonic cleaning can damage the bearings in the handpiece, potentially resulting in overheating or failure of the handpiece.
- Dried blood, saline, and other deposits inside the handpiece are a major cause of equipment malfunction. Proper cleaning and inspection prior to sterilization will avoid delays during the surgical procedure.

Limitations On Reprocessing:

Repeated processing, according to the instructions below, has minimal effect on MicroAire reusable surgical instruments. End of life is normally determined by wear and damage due to use.

Point Of Use:

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a cloth dampened with purified water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning (MAXIMUM 30 minutes).

Preparation For Decontamination/Disassembly

1. Disposable surgical accessories should be discarded after use, handling them as any contaminated sharp accessory is handled. Reuse of surgical cutting accessories (burs, blades, drills) is not recommended.
2. Turn the handpiece to the "OFF" position.
3. Remove the battery pack from the handpiece by depressing the button located on the back of the handpiece base, and firmly pulling the battery out of the handpiece. Use two hands, with one hand holding the handpiece and pressing the release button and the other pulling straight down on the battery.
4. Remove the surgical accessory from the coupler.
5. Remove the coupler from the handpiece.

Preparation of Cleaning Agent

Prepare mild pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Determination of cleaning agents shall be by local or country regulations.

Cleaning: Automated

1. Load the medical devices into the Washer Disinfector.
 - a) Avoid contact between devices (movement during washing could cause damage, and washing action could be obstructed). DO NOT overload the trays.
 - b) Arrange medical devices so that cannulations are not horizontal and battery openings are oriented

downwards (to assist drainage).

2. The minimum recommended Washer/Disinfector cycle is below:

#	Title	Detergent	Minutes	Temp
1	Pre-Wash	Mild pH Enzymatic *	4	< = 50 °C (122 °F)
2	Rinse	None	1**	< = 50 °C (122 °F)
3	Wash	Mild pH	4	> = 60 °C (140 °F)
4	Drain for 1 minute minimum			
5	Rinse	None	2**	> = 60 °C (140 °F)
6	Drain for 1 minute minimum			
7	Thermal Disinfect	None	10	> = 93 °C (200 °F)
8	Drain for 1 minute minimum			

* Detergent can be omitted at the pre-wash stage if the equipment does not have this ability.

** If not using mild pH detergent, extend rinse time if possible to reduce possible degradation.

NOTE: Washer/Disinfectors should comply with the requirements of ISO 15883 (in preparation). They should be properly installed and be regularly tested in accordance with ISO 15883.

Cleaning: Manual

1. Clean the device immediately with warm water (> 60 °C / 140 °F), mild pH enzymatic detergent, and a soft brush. Scrub the handpiece with the brush, paying close attention to instrument crevices. Make sure the handpiece is held upright as often as possible during cleaning and rinsing to keep moisture away from the battery receptacle.
2. Use a cannulation brush on cannulation of the REF 6643 SmartDriver Duo and cannulated drive couplers.
 - a. Clean the cannulated shaft of the wire/pin drivers with the small cylindrical wire driver cannulation brush (REF 9600-063), or equivalent brush or pipe-cleaner.
 - b. Continue to brush clean the cannulation in the handpiece and drive couplers until the brush comes out clean and no longer contains signs of blood or tissue.
3. Rinse thoroughly under running water (< 50 °C / 122 °F) for a minimum of 2 minutes.
4. Clean the handpiece thoroughly with warm water (> 60 °C / 140 °F), mild pH detergent, and a soft brush. Scrub the handpiece with the brush, paying close attention to the instrument crevices.
5. Flush the lumens of instruments and the nose of drills and wire drivers with a Water-Pik or similar device. Flushing removes blood, debris, and saline deposits.
6. Rinse all items thoroughly under running water (< 50 °C / 122 °F) for a minimum of 2 minutes. If possible, use distilled water for the final rinse.

Disinfection:

Disinfection is only acceptable as an adjunct to full terminal sterilization for reusable surgical instruments. See sterilization section below.

Drying:

Wipe off any water from the handpiece with a soft lint-free towel. An air gun can also be used to dry the handpiece.

Maintenance, Inspection and Function Testing:

1. Carefully inspect each device to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
3. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
4. Where instruments form part of a larger assembly, check that the devices assemble with mating components.

NOTE: If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.

Accidental Immersion:

If a handpiece is accidentally immersed in saline, disinfectant, cleaning fluid or any other corrosive substance, take the following steps to save the handpiece.

- a. Totally immerse the handpiece in distilled water for 1 minute to dilute the corrosive fluid. DO NOT allow water to dry in the handpiece.
- b. Immediately after soaking, steam sterilize in a prevacuum sterilizer at 270°F (132°C) for 4 minutes followed by a minimum drying time of 8 minutes. Sterilizing will dry out the handpiece, avoid rusting, and prevent contamination from collecting in the motor.
- c. Return the handpiece to MicroAire or MicroAire authorized service center for service.

Packaging:

1. Single Instruments – A standard medical grade steam sterilization wrap may be used. Ensure that the wrap is large enough to contain the instrument without stressing the packaging. (ANSI/AAMI ST46-1993)
2. Sets of Instruments – sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method (ANSI/AAMI ST46-1993)

Instrument Sterilization Instructions (See separate section for Battery Sterilization Instructions):

MicroAire powered surgical instruments (including handpieces and drive couplers) are normally sterilized by steam, using either a gravity displacement or Dynamic Air Removal (Pre-vacuum) sterilizer.

1. Steam Sterilization

Steam sterilize using one of the following cycles:

Sterilization Cycle	Instrument	Minimum Time & Temp	Min Heated Dry time
Dynamic Air Removal (Pre-Vacuum)	Single Instrument	3 minute full cycle @ 134 – 137°C (273 – 279°F)	8 minutes
		4 minute full cycle @ 132 – 135°C (270 – 275°F)	8 minutes
	Sterilization Tray	3 minute full cycle @ 134 – 137°C (273 – 279°F)	45 minutes
		4 minute full cycle @ 132 – 135°C (270 – 275°F)	45 minutes
Gravity Displacement	Single Instrument	30 minute full cycle @ 132 – 135°C (270 – 275°F)	8 minutes
	Sterilization Tray	35 minute full cycle @ 132 – 135°C (270 – 275°F)	60 minutes

NOTE: 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/2000.3, "WHO Infection Control Guidelines for TSE," March 1999).

NOTE:

- Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
- Do not use instruments when they are still warm. They need to cool down to room temperature.
- Do not soak instruments to cool them down or wrap cold towels around them.

2. Flash Sterilization

Flash sterilization is not recommended for powered surgical instruments. The SmartDriver Duo has not been validated for flash sterilization.

3. Ethylene Oxide Sterilization

Ethylene is NOT recommended for powered surgical instruments because lengthy aeration time is needed to assure that no ethylene oxide is left in the internal mechanisms or on the surface of the instrument.

4. Peracetic Acid

DO NOT process powered surgical instruments in equipment that uses peracetic acid as a liquid sterilant.

5. Sterrad® Sterilizers

Sterrad® is not recommended for powered surgical instruments. Sterrad® systems use concentrated hydrogen peroxide that will strip some of the metal surfaces throughout the handpiece.

Storage:

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

Disposal

Follow federal, state and local ordinances governing the proper disposal of medical equipment.

WARRANTY, SERVICE AND REPAIR

Periodic inspection and service is essential to keep precision MicroAire instruments running properly.

IN HOSPITAL SERVICE

All MicroAire equipment should be inspected and tested periodically in accordance with the facility's bio-engineering policy.

WARNING: Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product's warranty, and the customer will be responsible for any costs related to returning the product to working condition.

MICROAIRE REPAIR SERVICE

If a problem occurs with your equipment, contact MicroAire Customer Service at:

	Telephone:	Fax:	Email:
USA:	800-722-0822	800-438-6309	inquiry@microaire.com
Outside USA:	434-975-8000	434-975-4134	intlsvc@microaire.com

NOTE: Mailing address is located on back cover.

PERIODIC INSPECTION

Because of the stressful nature of surgical use, decontamination, and sterilization, we recommend that all instruments be returned for routine inspection and service at least once a year. There is no charge for service during the warranty period.

6643 BATTERY SmartDriver Duo & SMARTDRIVER COUPLER WARRANTY

MicroAire Surgical Instruments LLC warrants its REF 6643 SmartDriver Duo and all 66XX SmartDriver Couplers to be free from defects in material and workmanship for a period of 1 year from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge.

This warranty is void in the event of abuse, misuse, or use in other than normal surgical environment, or in the event disassembly, alteration, or repair of the product not authorized by the manufacturer, or in the event that the product has not been used in compliance with this manual.

All other expressed or implied warranties of fitness and merchantability are excluded here from, and manufacturer shall have no liability of any kind for incidental or consequential damages.

EXTENDED WARRANTY / SERVICE AGREEMENT

Extended warranties and service agreements are available on MicroAire power equipment. Extended warranties may be purchased while the equipment is covered by the original warranty. If the equipment is out of warranty, it must first be restored, if necessary, to full serviceable condition before being eligible for a service agreement.

SMARTDRIVER COUPLER INSTRUCTIONS

The REF 6643 SmartDriver Duo is a variable speed, multi-purpose handpiece with a selection of quick-connect Drive Couplers. The drive couplers are designed to complete a variety of applications from K-wire driving to cutting with a sagittal saw and light reaming.

HOW TO CONNECT DRIVE COUPLERS

To connect a Drive Coupler to the handpiece, insert the coupler with a twist motion until you see and feel the coupler lock into position. The drive coupler is not locked into place until the base of the drive coupler is flush with the locking collar. To remove a Drive Coupler, press the Coupler Lock/Release button on the top front end of the handpiece and pull the coupler out. The coupler should release easily when the button is depressed.

DRILL / SCREWDRIVER COUPLERS

REF 6680 Jacobs® 5/32" (3.17mm) Drill Coupler - 1600 RPM (nominal)

Requires 1645-004 5/32" Jacobs® Key (included)



The Jacobs® Drill coupler accepts MicroAire 8051 and 8054 Series Jacobs®-style twist drills with diameters between 1.0mm (.039") and 4.0mm (.15").

To insert a twist drill into the REF 6680 Jacobs Style Drill handpiece:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Using a 5/32" Jacobs chuck key (REF 1645-004), open the chuck to the desired size.
3. Insert the twist drill, making sure that it seats properly.
4. Tighten the Jacobs chuck using the same Jacobs chuck key (REF 1645-004).
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

REF 6686 1/4" Jacobs® Drill Coupler (6.35mm) – 1600 RPM (nominal)

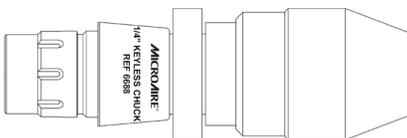


The Jacobs® Drill coupler accepts MicroAire 8051 and 8054 Series Jacobs-style twist Drills with diameters between 1.0mm (.039") and 6.5mm (.25").

To insert twist drill into REF 6686 Jacobs Drill coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Using a 1/4" Jacobs chuck key (REF 4100-030), open the chuck to the desired size.
3. Insert the twist drill, making sure that it seats properly.
4. Tighten the Jacobs chuck using the same Jacobs chuck key (REF 4100-030).
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

REF 6688 1/4" Keyless Drill Coupler (6.35mm) – 1600 RPM (nominal)



Warning – Keyless couplers may loosen if used in reverse in high-torque applications.

The Keyless Drill coupler accepts MicroAire 8051 and 8054 Series Jacobs style twist Drills with diameters between 1.0mm (.039") and 6.5mm (.25").

To insert twist drill into REF 6688 Keyless Drill coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Open the chuck to the desired size.
3. Insert the twist drill, making sure that it seats properly.
4. Tighten the chuck
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

REF 6690 Synthes® Quick-Connect Drill Coupler - 1600 RPM (nominal)



The Synthes-Style drill coupler, accepts MicroAire 8053-type drills and taps with the Synthes style quick connect shank.

NOTE: Does not accept MicroAire REF 8053-020, 8053-024, 8053-032, 8053-036, 8053-036, 8053-115 and 8053-119.

To insert a twist drill into the REF 6690 Synthes® Quick-Connect Drill Coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Pull back on the locking collar located on the front of the coupler.
3. Insert the twist drill, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

REF 6660 Trinkle Drive Coupler - 1600 RPM (nominal)

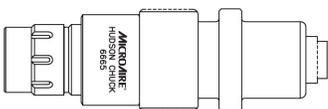


The Trinkle drive coupler accepts standard Trinkle shank drills and Trinkle Automatic Screwdriver bits.

To insert a Trinkle accessory into the REF 6660 Trinkle Drive Coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Pull back on the locking collar located on the front of the coupler
3. Insert the accessory, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill flutes, pull on the accessory to make sure it does not slip loose.

REF 6665-M1 Hudson® Chuck HS (High-Speed) - 1600 RPM (nominal)



The Hudson® Chuck accepts standard Hudson-style attachments.

To insert a Hudson accessory into the REF 6665-M1 Hudson Chuck:

1. Make sure the handpiece is set to the "OFF"  position and the chuck is properly locked into the handpiece.
2. Pull back on the locking collar located on the front of the chuck.
3. Insert the accessory, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill flutes, pull on the accessory to make sure it does not disengage.

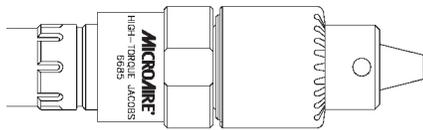
REAMING COUPLERS

NOTE: The reaming couplers for the MicroAire SmartDriver, while high torque, do not produce enough torque to complete the heavy IM and Acetabular Reaming required for total hip arthroplasty. The MicroAire SmartDriver Duo is ideal for reaming in ACL surgeries and for lighter tibial and humeral reaming. Heavy femoral reaming should be completed using the MicroAire Series 7000 Large-Bone Instruments.

REF 6685 High-Torque Jacobs® ¼" (6.35mm) Drill Coupler - 500 RPM (nominal)

Requires REF 4100-030 ¼" Jacobs® Key (included)

This coupler offers higher torque for pins up to 3.2mm.

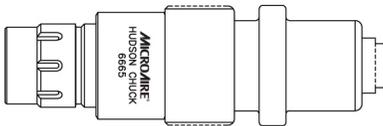


The Jacobs® Drill coupler accepts MicroAire 8051 and 8054 Series Jacobs®-style twist drills with diameters between 1.0mm (.039") and 6.5mm (.25").

To insert a twist drill into the REF 6685 High-Torque Jacobs® Drill coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Using a 1/4" Jacobs chuck key (REF 4100-030), open the chuck to the desired size.
3. Insert the twist drill, making sure that it seats properly.
4. Tighten the Jacobs chuck using the same Jacobs chuck key (REF 4100-030).
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

REF 6665 Hudson® Reaming Coupler (High Torque) - 500 RPM (nominal)

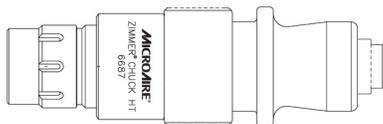


The Hudson® Reaming Coupler accepts standard Hudson®-style reamers.

To insert a reamer or other Hudson accessory into the REF 6665 Hudson®-style Reaming Coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Pull back on the locking collar located on the front of the coupler
3. Insert the accessory, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill flutes, pull on the accessory to make sure it does not disengage.

REF 6687 Zimmer® Reaming Coupler (High Torque) - 500 RPM (nominal)



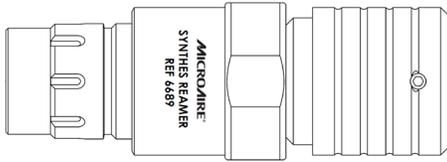
The Zimmer® Reaming Coupler accepts standard Zimmer®-style reamers.

NOTE: Zimmer®-style reamers and accessories are sometimes referred to as "Hudson Modified Trinkle" reamers.

To insert a reamer or other accessory into the REF 6687 Zimmer® Reaming Coupler :

1. Make sure handpiece is set to the "OFF" Ⓞ position and the coupler is properly locked into the handpiece.
2. Pull back on the locking collar located on the front of the coupler
3. Insert the accessory, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill flutes, pull on the accessory to make sure it does not disengage.

REF 6689 Synthes® Reamer Coupler (High Torque) – 500 RPM (nominal)



The Synthes® Reamer coupler accepts standard A.O. Synthes®-style reamers.

To insert a reamer or other Synthes®-style accessory into REF 6689 Synthes®-style Reamer coupler:

1. Make sure handpiece is set to the "OFF" Ⓞ position and the coupler is properly locked into the handpiece.
2. Pull back the locking collar located on the front of the coupler.
3. Insert the accessory, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

SAW COUPLERS

The three sagittal saws for the MicroAire SmartDriver are excellent for transverse and wedge osteotomies.

NOTE: Do not operate any of the SmartDriver Saw Couplers when the handpiece is set to "oscillate mode".

REF 6670 Sagittal Saw Coupler - 18,000 cpm (nominal) - 7° blade arc.

Requires REF 2250-001 Key (included)

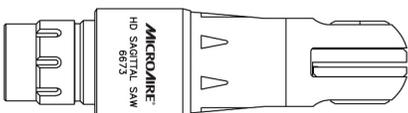


This saw coupler accepts MicroAire ZS-0XX and ZS-3XX Hall®-style sagittal saw blades.

NOTE: Does not accept MicroAire ZS-36X and ZS-37X series blades.

REF 6673 Heavy Duty Sagittal Saw Coupler - 18,000 cpm (nominal) - 7° blade arc.

Requires REF 2250-001 Hex Driver (included)

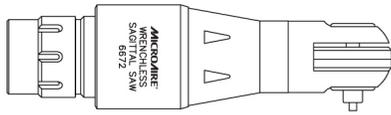


This saw coupler accepts the full series of blades that the REF 6670 accepts, but the REF 6673 Heavy Duty Sagittal Saw is designed to accept a larger, more aggressive saw blade for difficult osteotomies. This saw will also accept MicroAire ZO-7XXX series oscillating blades not greater than 71mm in length.

To insert a blade into either the REF 6670 or REF 6673 Sagittal Saw Couplers:

1. Make sure handpiece is set to the "OFF" Ⓞ position and the coupler is properly locked into the handpiece.
2. Insert the REF 2250-001 hex driver in the locking hole on the sagittal saw.
3. Turn the REF 2250-001 hex driver counterclockwise until there is room to insert the blade.
4. Insert the saw blade in the space between the two jaws, making sure that the blade is fully seated.
5. Turn the REF 2250-001 hex driver clockwise to lock the blade.
6. Run the instrument for 10 seconds then retighten blade if necessary.

REF 6672 Keyless Sagittal Saw Coupler - 18,000 cpm (nominal) - 7° blade arc.



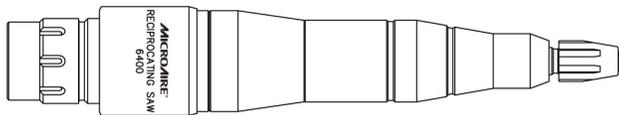
This saw coupler accepts MicroAire ZS-3XX Hall®-style sagittal saw blades.

NOTE: Does not accept MicroAire ZS-36X and ZS-37X series blades.

To insert a blade into either the REF 6672 Keyless Sagittal Saw Coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Depress the small push button on the head of the saw and insert the blade between the two jaws making sure that the blade is fully seated over the indexing pins.
3. Release push button.

REF 6400 Reciprocating Saw Coupler 16,000 cpm (nominal)

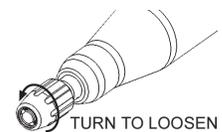


This saw coupler accepts MicroAire 1400 Series blades and rasps, and certain MicroAire ZR series small blades and rasps.

NOTE: Does not accept MicroAire ZR series large reciprocating saw blades.

To insert a blade into either the REF 6400 Reciprocating Saw Coupler:

1. Loosen the locking collar by turning it approximately four (4) times in a counter-clockwise direction as shown.
2. Insert the surgical accessory, making sure it is fully seated in the locking collar.
3. Tighten the locking collar by turning it in a clockwise direction as shown. Turn the locking collar until tight.
4. Run the instrument for 3-5 seconds, then confirm the blade is locked in properly. Retighten if necessary.
5. Attempt to pull the surgical accessory out of the module to confirm it is secure. If accessory can be removed by hand, re-insert and properly tighten locking collar.



NOTE: If a rasp becomes loose when the handpiece is running, the rasp was not seated properly in the locking mechanism. Move the rasp from side to side several times, then retighten the locking collar.

WARNING: When operating this saw, be careful to retract or protect the patient's tissue near the locking collar. Pinching the tissue between the collar and the body of the instrument may cause a severe bruise or friction burn.

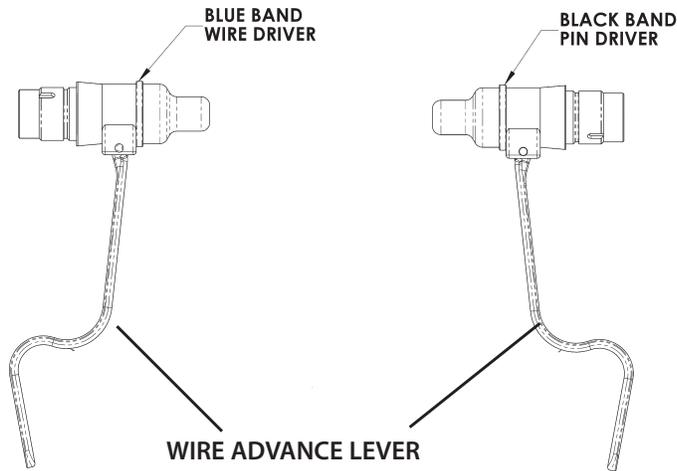
K-WIRE AND PIN DRIVING COUPLERS

REF 6643-045 K-Wire Driver Coupler

Accepts Wires from .028" (0.7mm) - .062" (1.6mm) The **BLUE** Band identifies the wire driver coupler.

REF 6643-050 Pin Driver Coupler

Accepts Pins from .078" (1.7mm) - .125" (3.2mm) The **BLACK** Band identifies the pin driver coupler.



CAUTION: If using the REF 6643-045 or REF 6643-050 Wire/Pin Couplers, make sure you have the REF 6640-002 Wire Guard attached to the rear of the handpiece. Align the threaded portions of the handpiece and guard, and screw the guard into the handpiece.

To insert a wire or pin into the REF 6643-045/ REF 6643-050 Wire/Pin Coupler:

1. Make sure handpiece is set to the "OFF"  position and the coupler is properly locked into the handpiece.
2. Insert wire or pin into the front of the coupler or back of the handpiece.
3. Insert battery/power pack into handpiece, and turn the handpiece in the "ON"  position.
4. Squeeze the wire/pin advance lever to hold wire/pin in place.
5. Depress the trigger while holding advance lever to drive wire/pin.
6. Release advance lever and pull back on handpiece to advance more wire/pin.
7. Use reverse "R" when removing threaded wire/pin. Hold advance lever and depress the trigger and while pulling back on the handpiece.

SMARTDRIVER BATTERY INSTRUCTIONS

Battery Charging

See the separate operating instructions provided with the MicroAire Battery Charger (REF 7500-700).

Battery Installation

The 6643 SmartDriver Duo Handpiece must have a fully charged MicroAire battery REF 6640-710, REF 7505-710 or Aseptic Battery installed before each use. To attach the battery to the handpiece, place the battery under the base of the instrument with the longer side facing the rear of the instrument. Firmly push the battery into the base of the handpiece until the battery latch clicks into place.

Aseptic Battery

The MicroAire Series 6643 battery instruments have been designed to operate using the MicroAire Aseptic Battery. The aseptic battery uses a non-sterile battery pack REF 7500-620 that is placed in a sterilized housing REF 7500-615 with locking door and removes the need to steam sterilize battery packs. The aseptic battery system has been designed for use with all MicroAire battery operated instruments and uses smaller battery cells than the conventional REF 7505-710 Large Power Battery Pack. The aseptic battery provides comparable power, but will have reduced run times. See separate instructions provided with the REF 7500-6XX Aseptic Battery System.

CAUTION: Battery pack should not be left in the instrument when not in use. Leaving a battery pack attached to a handpiece when not in use will accelerate battery drain.

CAUTION: Exceeding recommended steam sterilization exposure times or temperatures for the battery may reduce battery life and/or performance.

MICROAIRE BATTERY WARRANTY

MicroAire Surgical Instruments warrants the REF 7505-710 Large Battery Pack and REF 6640-710 Small Battery Pack to be free from defects in material and workmanship for a period of one (1) year from the original purchase date by the end customer. MicroAire warrants the REF 7500-620 Aseptic Battery to be free from defects and workmanship for a period of ninety (90) days from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge.

This warranty is void in the event of abuse, misuse, or use in other than normal surgical environment, or in the event disassembly, alteration, or repair of the product not authorized by the manufacturer, or in the event that the product has not been used in compliance with the written instructions furnished by the Manufacturer.

All other expressed or implied warranties of fitness and merchantability are excluded here from, and manufacturer shall have no liability of any kind for incidental or consequential damages.

Extended warranties and/or service agreements are not available on MicroAire batteries.

Part Number		6643 - Smart Drive Duo
Power Output	kW	0.065
	KiloWatts	
Vibration Exposure	$a_{HV} (m/s^2)$	1.68
	Uncertainty $K (m/s^2)$	1.5
Noise Emission Value	$L_{PA} (db(A))$	74
	$L_{C,peak} (db(C))$	-
	$L_{WA} (dbA)$	-
Mass	Weight (kg)	0.86

ELECTROMAGNETIC COMPATIBILITY

NOTE: The 6643 SmartDriver Duo is suitable for use in hospitals and surgery centers. These systems should not be used near Magnetic Resonance Imaging equipment.

EMC Test & Standard	Test Levels / Limits	Compliance
Mains terminal disturbance voltage (conducted emissions): CISPR 11	Not Applicable for Battery Powered Equipment	Not Applicable
Electromagnetic radiation disturbance (radiated emissions): CISPR 11	CISPR 11 Class A	Complies with Class A Limits
Harmonic distortion: IEC 61000-3-2	Not Applicable for Battery Powered Equipment	Not Applicable
Voltage fluctuations and flicker: IEC 61000-3-3	Not Applicable for Battery Powered Equipment	Not Applicable
Electrostatic discharge immunity: IEC 61000-4-2	Discharge Level (kV) Contact – Direct: +/- 8 Contact – Indirect: +/- 8 Air +/- 2, 4, 8, 15	Complies Per Note* Complies Per Note* Complies Per Note*
Radiated RF electromagnetic field immunity: IEC 61000-4-3	3V/m 80MHz to 2700 MHz 80% AM at 1 KHz	Complies Per Note*
Immunity to proximity fields from RF wireless communications equipment: IEC 61000-4-3	IEC 60601-1-2 Table 9	Complies Per Note*
Immunity to High Frequency Surgical Equipment: IEC 60601-2-2	Tested for immunity to modern (non-spark gap) HF Surgical Equipment per the guidelines of IEC60601-2-2:2017 Annex BB. Cut Mode at 150 Watts: Coagulate Mode at 70 Watts: The HF Surgical generator was in operation as part of the EM environment for all other immunity tests.	Complies Per Note* Complies Per Note* See Other Immunity Tests
Electrical fast transient/burst immunity – IEC 61000-4-4 AC mains: I/O SIP/SOP Ports:	Not Applicable for Battery Powered Equipment Series 7000 Instruments have no I/O SIP/SOP Ports	Not Applicable Not Applicable
Surge Immunity: IEC 61000-4-5 Input Power Ports (Line to Line) (Line to Earth)	Not Applicable for Battery Powered Equipment	Not Applicable

ELECTROMAGNETIC COMPATIBILITY

EMC Test & Standard	Test Levels / Limits	Compliance
Immunity to conducted disturbances induced by RF fields (conducted RF disturbance immunity) – AC mains: IEC 61000-4-6 Patient Connected Ports: IEC 61000-4-6	Not Applicable for Battery Powered Equipment	Not Applicable
Power Frequency Magnetic Field Immunity: IEC 61000-4-8	Frequency: 50 Hz or 60 Hz Test Level: 30 A/m	Complies Per Note*
Voltage Dips: IEC 61000-4-11	Not Applicable for Battery Powered Equipment	Not Applicable
Voltage Interruptions Immunity: IEC 61000-4-11	Not Applicable for Battery Powered Equipment	Not Applicable

NOTE *: The 6643 SmartDriver Duo has no Essential Performance. Compliance with Immunity Testing is defined as a) the instrument will remain functional after the test, and b) the instrument in a standby mode will not run for more than 1 second as a result of the test.

WARNING: Use of the 6643 SmartDriver Duo adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the 6643 SmartDriver Duo and the adjacent equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment should be used no closer than 30 cm (12 inches) away from any part of the 6643 SmartDriver Duo. Otherwise degradation of the performance of the 6643 could result.

WARNING: Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 6643 SmartDriver Duo has been tested for use in the vicinity of High Frequency Electrosurgical / Electrocoagulation equipment. Use of such equipment in close proximity to the 6643 SmartDriver Duo may cause unintended interruptions or unintended motion of durations up to 1 second. Place the Instrument on a safe surface when not in use. Do not place powered Instruments on the patient when not in use. Avoid entwining HF surgical cables with powered instruments.

WARNING: The following items should be periodically inspected for signs of damage and repaired or replaced as needed to ensure continued safety with regard to electromagnetic disturbances over the life of the system:

- Check that the Battery Connection base, the rear end cap and the front of the instrument remain securely connected to the main instrument body.
- Check for damage to the battery pack housings.

NOTE: The emissions characteristics of this product 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 be required to take mitigation measures, such as relocating or re-orienting the equipment.

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