

5641 SmartDriver DUOe™

Instructions for Use



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For Surgery. For Life.™

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Intended Use

The MicroAire REF 5641 Smartdriver DOUe™ is a dual trigger electric-powered drill for use in orthopedic procedures. The instrument accepts a variety of couplers which are compatible with an assortment of reamers, burs, bits and other disposable accessories.

Intended Users

Orthopedic surgeons, physician's assistants; orthopedic operating room nurses, circulating nurses, and central sterile cleaning personnel.

Indications

Trauma procedures, ACL, IM Nailing, Screwdriving, Tap, shoulder arthroplasty, wrist arthroplasty, pin driving, wire driving both threaded and smooth wires for general orthopedic hand and foot surgery.

Equipment Description

The SmartDriver DUOe™ is a variable speed, multi-purpose hand piece 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.

- Pistol-grip form factor
- Free Run Speed (with instrument connected to console) High Speed/Low Torque output=1 600 RPM Min.
- Minimum torque with high speed/low torque coupler (with instrument connected to a console)= 140 in-oz at or above 750 RPM
- Forward direction of rotation is counterclockwise when viewing from the output of the instrument to the rear of the instrument - actuated with the bottom trigger
- Reverse direction of rotation is clockwise when viewing from the output of the instrument to the rear of the instrument - actuated with the top trigger
- Oscillation mode to rotate through 30°-60° - actuated with top and bottom simultaneously.
- External surface temperature rise less than 30°F from ambient temperature, after 1 minute

DEFINITIONS:

Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE carry special meanings and should be carefully reviewed.

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

GENERAL WARNINGS














- WARNING:** Upon receipt and before each use, you should inspect the system and its components for visible damage. DO NOT use if there is apparent damage to any component. Perform recommended maintenance as indicated in the Instructions for Use. Failure to comply may result in healthcare professional and/or patient injury.
- WARNING:** See IM-5025 for operation of the instrument Control Console.
- WARNING:** Use care to ensure that there is no electromagnetic interference between these devices and other devices in use. See IM-5025 for EMC information.
- WARNING:** When inserting wire or blades, the coupler should be attached to the SmartDriver handpiece, and the SmartDriver should be connected to its corresponding power source. Please see System Setup for instructions on connecting the SmartDriver to the coupler and its corresponding power source to the electric console.
- WARNING:** The healthcare provider performing any procedure is responsible for determining whether this is the appropriate equipment/instrument for the specific procedure that is being performed for each patient. As the manufacturer, MicroAire DOES NOT recommend surgical procedures or offer any guidance in such procedures.
- WARNING:** Only trained and experienced healthcare providers/professionals should use this medical equipment. Before using any component that is compatible with this medical device, read and understand this Instructions for Use document. Pay special attention to the WARNING information and familiarize yourself with the hand piece, compatible components and system console controls and support system components. Failure to comply may result in patient and/or healthcare professional injury.

- WARNING:** Explosion Hazard. Not suitable for use in the presence of flammable anesthetics or oxygen.
- WARNING:** Use care to ensure that there is no electromagnetic interference between this device and other devices in use.
- WARNING:** Prior to use, all system components (handpiece and couplers) should be inspected to detect any damage or malfunction.
- WARNING:** 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.
- CAUTION:** Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- NOTE:** All personnel should become familiar with the power equipment before it is set-up 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.











DUTY CYCLE

Short-Time operation only (20 seconds ON then 1 minute OFF for 3 consecutive cycles). Irrigation must be used when cutting bone to ensure that the temperature at the cutting accessory does not exceed 41°C.

SYMBOL DEFINITIONS

	Follow Instructions for Use. This icon is blue.		Consult Instructions for Use (IFU).
F	Clockwise Rotation Indicator (Forward)	R	Counterclockwise Rotation Indicator (Reverse)
	"ON" Position		"OFF" Position (Safety)
	Oscillating Rotation Indicator		Non-Ionizing Electromagnetic Radiation
	DO NOT Lubricate		DO NOT Immerse
	Atmospheric Pressure Limitations		Humidity Limitations
	Temperature Limitations		DO NOT expose to stray magnetic fields
CE 0086	European Conformity Mark		RoHS Compliance

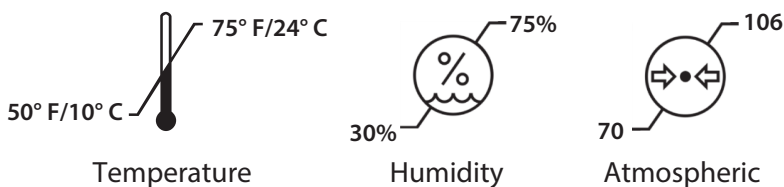
SYMBOL DEFINITIONS (CONTINUED)

	Waste Electrical and Electronic Equipment (WEEE) European Community Symbol. Regarding Electrical Equipment European Union end of life of product, indicating separate collection for electrical and electronic equipment. ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its usual life.		
	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		
	Authorized European Representative		Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner)
	Product Catalog Number		Product Serial Number
	Date of Manufacture YYYY-MM		Manufacturer
	IEC60601-1 TYPE BF Applied Part		Caution; specific warnings or precautions associated with medical device, consult IFU.

ENVIRONMENTAL PARAMETERS

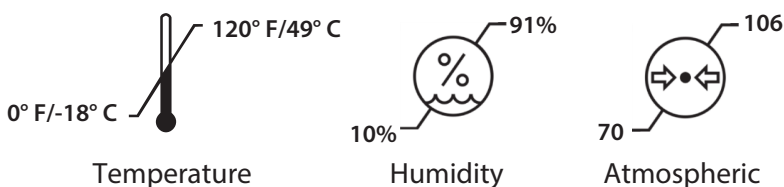
OPERATING CONDITIONS

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.

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 SmartDriver DUOe™ 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

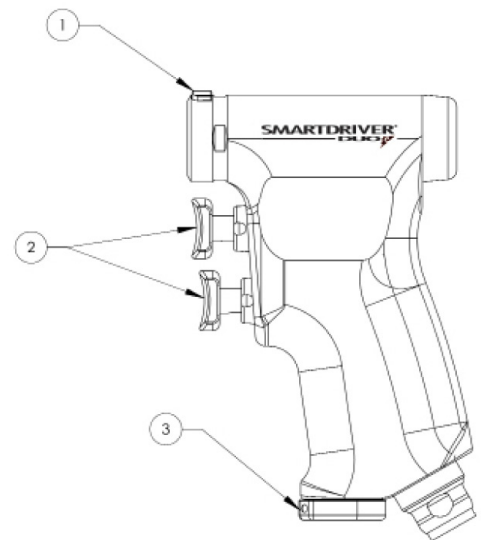
This button releases a coupler from the SmartDriver DUOe™. It does not need to be depressed to load a coupler.

2. Forward / Reverse / Oscillate Control

The SmartDriver DUOe 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 DUOe™ also has an oscillate  feature that turns less than one full turn in alternating forward **F** /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.

3. Trigger/Safety Lock

The MicroAire SmartDriver DUOe™ 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 set to this position .



SMARTDRIVER DUOe

The SmartDriver DUOe™ 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 set-up for use in any procedure. Personnel to be trained should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.

SYSTEM SETUP

WARNING: To prevent inadvertent running of handpiece while loading a coupler or surgical accessory, make sure the instrument Safety Switch is set to the "OFF" position.

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

WARNING: If any corrosion or debris is detected in or 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, do not use. Contact MicroAire Customer Service for repair.

2. Check all surgical accessories. Ensure that blades, drills and wires 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 DUOe™ 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 out on the coupler. The coupler should release easily when the button is depressed.

CAUTION: If using the REF 5641-045 or REF 5641-050 Wire/Pin Couplers, ensure 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 the 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 handpiece).

- a. Ensure that the safe switch is in the OFF position to prevent activation of the motor.
- b. Ensure that, when the handpiece is in the ON position, it allows activation of the motor by depressing the trigger.
- c. Ensure that the triggers do not stick in the fully depressed position. If a trigger has any tendency to stick, re-clean and re-sterilize the handpiece. If the handpiece still does not meet the above requirements, contact MicroAire Customer Service for repair.

6. Insert handpiece cable into receptacle on rear of handpiece, aligning the dots on both the cable end and the handpiece receptacle end to ensure a proper fit.

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 \cup (oscillate function).



NOTE: The oscillate function is intended to make percutaneous drilling and fixation easier and can prevent soft tissue from wrapping around the drill. It should not be used with any saw 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 over heating 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 overheating, especially in the nose section. Even normal operation of the system in a cycle other than 1 minute "ON" and allowing the handpiece to cool to room temperature may cause the handpiece to become hot.

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

Surgical usage, cleaning, and sterilization can be destructive to instruments for several reasons:

- Blood deposits, saline, and bone fragments often 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.

Devices: SmartDriver DUOe™ Instrument and Couplers

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

WARNING: DO NOT lubricate or oil the handpieces. Lubrication may damage the internal motor mechanism. Take special precautions to avoid the use of cleaners that contain lubrication.

WARNING: DO NOT immerse the handpiece in any fluid.

WARNING: DO NOT utilize cleaning solutions that are not a neutral pH unless they are approved for use with Anodized Aluminum and Surgical Instruments.

WARNING: DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.

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.

INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS

per ISO 17664:2003 & AAMI ST 81:2004

Instructions

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.

NOTE: It is recommended that instruments and all non-disposable accessories be cleaned within 30 minutes or end of use to minimize the potential for organic material to dry on the instrument.

Preparation for decontamination

- 1) Remove all inserted surgical cutting accessories (blades, rasps, drill bits, etc.) from the handpiece. Disposable surgical accessories should be discarded after use, handling them as any contaminated sharp accessory is handled. Reuse of surgical cutting accessories is not recommended.
- 2) Disassemble instruments and accessories
- 3) For Automated Cleaning install the electric cable for the instrument.
- 4) For Manual Cleaning install the electric cable for the instrument.

Preparation of cleaning agent

Prepare a neutral pH enzymatic and cleaning agent 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 any openings are oriented downwards (to assist drainage).
- 2) The minimum recommended Washer/Disinfector cycle is below:

#	Title	Detergent	Minutes	Temp
1	Pre-Wash	Neutral pH Enzymatic*	4	< = 50°C (122° F)
2	Rinse	None	1**	< = 50°C (122° F)
3	Wash	Neutral 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 neutral 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 regularly tested in accordance with ISO 15883.

**Cleaning -
Manual:**

- 1) Clean the handpiece and couplers thoroughly with warm ($\geq 60^{\circ}\text{C}$ / 140°F) water, neutral pH enzymatic detergent, and soft brush. Scrub the handpiece with the brush, paying close attention to instrument crevices.
- 2) Rinse handpieces, couplers and electric cables thoroughly under running ($\leq 50^{\circ}\text{C}$ / 122°F) water for a minimum of 2 minutes.
- 3) Clean the handpieces and couplers thoroughly with warm ($\geq 60^{\circ}\text{C}$ / 140°F) water, neutral pH enzymatic detergent, and soft brush. Scrub the handpiece with the brush, paying close attention to instrument crevices.
- 4) 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.
- 5) Rinse handpieces, couplers and electric cables thoroughly under running ($\leq 50^{\circ}\text{C}$ / 122°F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.
- 6) After rinsing all electric cables, it is required that the cables be drained of all residual cleaning fluids.

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 airgun can also be used to dry the handpiece.

**Maintenance,
Inspection and
Function Testing:**

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

NOTE:

If concerns are noted that may compromise the function of any MicroAire device, please contact your MicroAire Sales Representative.

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)

Sterilization:

Steam sterilize using one of the following cycles.

Sterilization Cycle	Instrument	Minimum Time & Temp	Minimum Heated Dry Time
Dynamic Air Removal (Pre-Vacuum)	Single Instrument	4 minute Full Cycle @ 132–135°C (270–275°F)	8 Minutes
		3 minute Full Cycle @ 134–137°C (273–279°F)	8 Minutes
	In Sterilization Tray	4 minute Full Cycle @ 132–135°C (270–275°F)	45 Minutes
		3 minute Full Cycle @ 134–137°C (273–279°F)	45 Minutes
Gravity Displacement	Single Instrument	30 minute Full Cycle @ 132–135°C (270–275°F)	8 Minutes
	In 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).

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, temperature and humidity extremes.

Additional Information:

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

Manufacturer Contact: MicroAire Surgical Instruments
3590 Grand Forks Boulevard
Charlottesville, VA 22911 U.S.A.
Inside the USA Dial: 1-800-722-0822
Outside the USA, dial the local international access code followed by +1-434-975-8000

TECHNICAL DATA - SPECIFICATIONS

High Torque Output:	0 – 500 rpm (nominal)
Low Torque Output:	0 – 1600 rpm (nominal)
Cannulation:	0.125" (3.2 mm)
5641 Handpiece Weight (without cable or coupler):	1.40 lb. (635 g)
Duty Cycle:	Continuous operation with intermittent loading. (20 seconds ON then 1 minute OFF for 3 consecutive cycles.)

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	Instrument is too hot or cold	Allow to return 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 is in the "OFF" position	Move safety switch to "ON" position	
Instrument stalls while in use	Excessive load	Reduce load, release trigger for one second, resume use
	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

WARRANTY, SERVICE AND REPAIR

Warranty

MicroAire Surgical Instruments warrants the REF 5641 Smart Driver DUOe™ to be free from defects in material and workmanship in their manufacture for a period of 1 (one) year from the original purchase date by the end customer. This warranty is limited to the repair or replacement of the product without charge.

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

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

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

Extended Warranty

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 the full serviceable condition before being eligible for a service agreement.

Periodic inspection and service is essential to keep precision MicroAire products running properly. If repairs are required, they can be accomplished quickly with a minimal disruption to the hospital's schedule.

Service and Repair

Responsive service comes with every MicroAire product. If a problem with your equipment should arise, contact our Customer Service Department at:

	Telephone:	Fax:	E-Mail:
USA	800-722-0822	800-648-4309	inquiry@microaire.com
Outside USA	434-975-8000	434-975-4134	intlsvc@microaire.com

Mailing address information is located on the back cover.

MicroAire may be able to solve the problem quickly without requiring return of the item for service. **DO NOT** disassemble or attempt to service the equipment. It can only be serviced by MicroAire or an Authorized MicroAire Repair Facility. Unauthorized service will void the warranty.

To return an item for service, follow these guidelines listed below.

1. Contact Customer Service for a Return Material Authorization (RMA) number.

NOTE: DO NOT return equipment without an RMA number. This could cause delays in service, and/or problems tracking returns.

2. Clean and disinfect equipment before sending for repair.

3. Along with the items sent for repair, enclose a detailed description of the problem encountered, the type of use, the place of use, a contact name, and a telephone number. This information is helpful to our repair technicians.

4. If the instrument is out of warranty, enclose a purchase order number with the instrument. If the instrument is under warranty, include the purchase date.

5. In the United States, ship the merchandise by Express Mail, Federal Express, or UPS Blue Label to prevent shipping delays. From outside the United States, return goods by Federal Express, UPS, or Air Freight.

6. Return the merchandise prepaid.

7. If an estimate of repair costs is needed before the repair technicians begin work, include the name and telephone number of the person to contact.

8. MicroAire will repair and re-ship the item by 2nd Day Air within the United States and by Federal Express or Air Freight outside the U.S. unless specified otherwise.

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.

MICROAIRE WILL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY USE OF THIS PRODUCT.

By using this handpiece and its accessories, you acknowledge and agree that you have read, understood and agree to be bound by these terms and conditions.

Disposal - (2002/96/EC Directive on Waste Electrical and Electronic Equipment)

In accordance with the 2002/96/EC Directive on Waste Electrical and Electronic Equipment (the WEEE Directive) and the current national provisions, the organization of the transfer of these wastes for devices sold by MANUFACTURER shall be undertaken by DISTRIBUTOR. For this reason, DISTRIBUTOR shall organize a system for the collection, storage and arrange transfer of any and all WEEE components to Manufacturer's approved WEEE collection facility in Europe. Distributor shall provide on request to the manufacturer, the proof of compliance with the European and national provisions regarding the WEEE Directive. Please refer to www.microaire.com/weee-directive for WEEE Compliance Instructions.

SMARTDRIVER DUOe COUPLER INSTRUCTIONS

The SmartDriver DUOe 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 out on the coupler. 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)

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

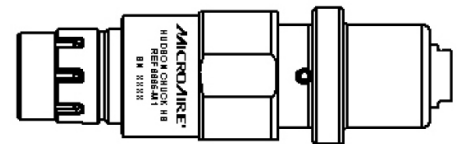


To insert a twist drill into the Jacobs Style Drill coupler:

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 (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 (1645-004).
5. Being careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

REF 6665M1 Hudson® Coupler - 1600 RPM (nominal)

This Hudson® Coupler accepts standard Hudson-style accessories.



To insert a Hudson accessory into the Hudson® 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 6690 Synthes® Quick-Connect Drill Coupler - 1600 RPM (nominal)

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

NOTE: The Synthes-style drill coupler does not accept MicroAire 8053-020, 8053-024, 8053-032, 8053-036, 8053-115 and 8053-119 twist drills.



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)

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

To insert a Trinkle accessory into the 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.



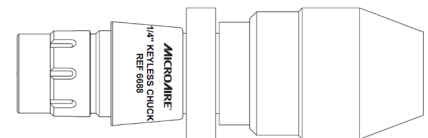
REF 6688 1/4" Keyless Drill Coupler (6.35mm) – 1600 RPM (nominal)

WARNING: Keyless couplers may loosen if used in reverse in high torque applications.

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

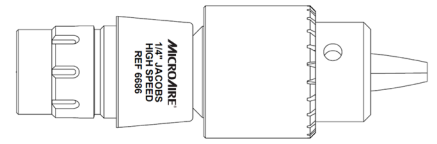
To insert twist drill into Keyless Drill coupler:

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

This 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 the Jacobs Style 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 style chuck using the same Jacobs chuck key (REF 4100-030).
5. Be careful of sharp drill flutes, pull on the drill bit to make sure it does not disengage.

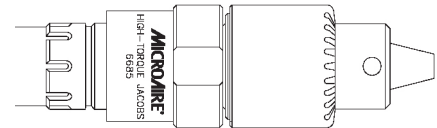
REAMING COUPLERS

NOTE: The Reaming Couplers for the MicroAire SmartDriver DUOe, while high torque, do not produce enough torque to complete the heavy IM and Acetabular Reaming required for total hip arthroplasty. The MicroAire SmartDriver DUOe 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 Power Instruments.

REF 6685 High-Torque Jacobs® 1/4" (6.35mm) Drill Coupler - 500 RPM (nominal)

Requires 4100-030 1/4" Jacobs® Key (included)

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



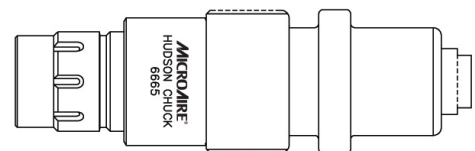
To insert a twist drill into the High-Torque Jacobs® Drill coupler:

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 (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)

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

To insert a reamer or other Hudson accessory into the Hudson® Reaming Coupler:

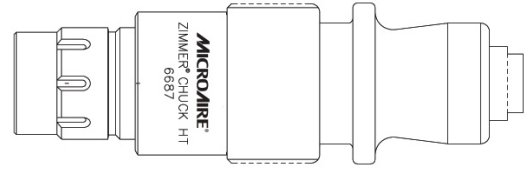


1. Make sure handpiece is set to the "OFF" position and the coupler is properly locked into the handpiece.
2. Pull back on the locking collar located on the front of the coupler
3. Insert the accessory, making sure that it seats properly.
4. Release the locking collar.
5. Being careful of sharp drill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

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

This Zimmer® Reaming Coupler accepts standard Zimmer® style reamers.

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



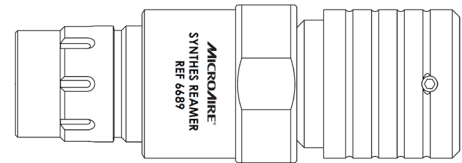
To insert a reamer or other accessory into the Zimmer® Reaming Coupler :

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)

This SYNTHES® Reamer coupler accepts standard A.O. SYNTHES reamers.

To insert a reamer or other SYNTHES accessory into the SYNTHES® 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 2250-001 Key (included)

NOTE: The MicroAire Sagittal Saw Coupler does not accept MicroAire ZS-36X and ZS-37X series blades.

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



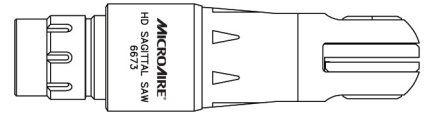
REF 6673 Heavy Duty Sagittal Saw Coupler - 18,000 cpm (nominal) - 7° blade arc.

Requires 2250-001 Hex Driver (included)

This saw coupler accepts the full series of blades that the 6670 accepts, but the 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.

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

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

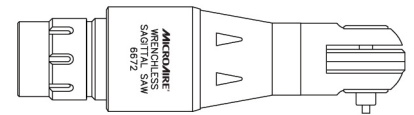


1. Make sure handpiece is set to the "OFF" position and the coupler is properly locked into the handpiece.
2. Insert the 2250-001 hex driver in the locking hole on the sagittal saw.
3. Turn the 2250-001 hex driver counterclockwise until there is room to insert the blade.
4. Insert the saw blade in the space between the two jaws, making sure that the blade is fully seated.
5. Turn the 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.

NOTE: The Keyless Sagittal Saw Coupler does not accept MicroAire ZS-36X and ZS-37X series blades.

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



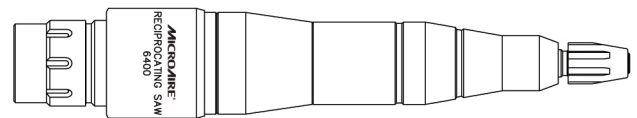
1. Make sure handpiece is set to the "OFF" position and the coupler is properly locked into the handpiece.
2. Depress the small push button on the head of the saw and insert the blade between the two jaws making sure that the blade is fully seated over the indexing pins.
3. Release push button.

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

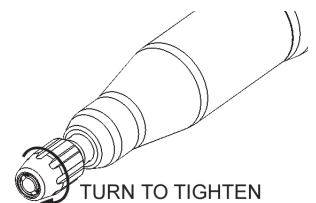
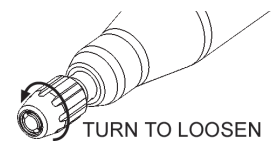
NOTE: The MicroAire Reciprocating Saw Coupler does not accept MicroAire ZR series large reciprocating blades.

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

To insert a blade into the Reciprocating Saw Coupler:



1. Loosen the locking collar by turning it approximately four (4) times in a counterclockwise 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 properly locked. 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.



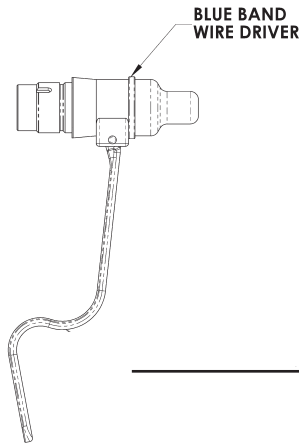
NOTE: If a rasp becomes loose when the handpiece is running, the rasp was not seated properly in the locking mechanism. Move the rasp from side to side several times, then retighten the locking collar.

WARNING: When operating the MicroAire Reciprocating 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

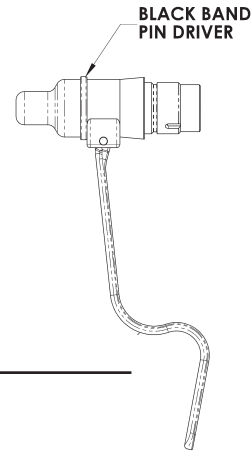
REF 5641-045 K-Wire Driver Coupler

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



REF 5641-050 Pin Driver Coupler

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



CAUTION: If using the REF 5641-045 or REF 5641-050 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 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. Squeeze the wire/pin advance lever to hold wire/pin in place.
4. Depress the trigger while holding advance lever to drive wire/pin.
5. Release advance lever and pull back on handpiece to advance more wire/pin.
6. Use reverse **R** when removing threaded wire/pin. Hold advance lever and depress the trigger and while pulling back on the handpiece.

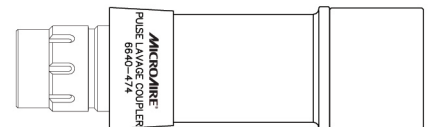
PULSE LAVAGE COUPLER

REF 6640-474 Pulse Lavage Coupler

This coupler is designed to adapt the SmartDriver DUOe handpiece to MicroAire Pulse Lavage tubing sets.

To attach Pulse Lavage tubing to the Pulse Lavage Coupler:

1. Make sure handpiece is set to the "OFF" position and the coupler is properly locked into the handpiece.
2. Insert the Pulse Lavage pump assembly into the Pulse Lavage Coupler, lining up the tabs on the pump with the notches on the coupler.
3. Once inserted, twist in a clockwise direction to lock into place
4. Attach any nozzles or accessories to pump assembly.



NOTE: Do not operate the pulse lavage coupler when the handpiece is set to "oscillate mode" .

LIST OF COMPATIBLE ACCESSORIES

Part Number	Description	Type BF Applied Parts
5025	MicroAire Electric Instrument Control Console	N/A
5006-5000	Series 5000 Instrument Cable	N/A
5641-SC	Sterilization Case	N/A
5641-045	Automatic Wire Driver Coupler	Accepts MicroAire® K-Wires 1600-XXX
5641-050	Automatic Pin Driver Coupler	Accepts MicroAire® Steinmann Pins 162X-XXX
6665-M1	Hudson® Coupler	N/A
6680	Jacobs®-Style Coupler 5/32"	Accepts MicroAire® 8054-XXX
6690	Synthes® Quick Connect Coupler	N/A
6660	Trinkle Coupler	N/A
6686	Jacobs®-Style Coupler 1/4"	Accepts MicroAire® 8054-XXX
6688	Keyless Drill Coupler 1/4"	Accepts MicroAire® 8054-XXX
6685	Jacobs®-Style High-Torque Reamer Coupler 1/4"	N/A
6665	Hudson® High-Torque Reamer Coupler	N/A
6687	Zimmer® (Hudson® Modified Trinkle) Reamer Coupler	N/A
6689	Synthes® Reamer Coupler	N/A
6670	Sagittal Saw Coupler with Key	Accepts MicroAire® ZS-0XX and ZS-3XX Sagittal Blades
6672	Keyless sagittal Saw Coupler	Accepts MicroAire® ZS-3XX Sagittal Blades
6673	Heavy-Duty Sagittal Saw Coupler (2250-001 Hex Wrench included)	Accepts MicroAire® ZO-7XXX (not longer than 71mm), ZS-0XX and ZS-3XX Sagittal Blades)
6400	Reciprocating Saw Coupler	Accepts MicroAire® 1400 Series and ZR Series Reciprocating Blades and Rasps
6400	Reciprocating Saw Module	Accepts 1400 series and ZR Series Reciprocating Blades

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