



BAIDE Medical

20 YEARS

Instruction Manual

Baide Orthopedic Power Tools System



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BT.power

CONTENTS

1.0 INTRODUCTION

1.1 Operating Principle	P03
1.2 Indications for Use	P03
1.3 Intended Use	P03
1.4 Contraindication	P03
1.5 Warnings and Precautions	
1.5.1 Warnings	P04
1.5.2 Precautions	P05
1.6 Product Photographs and Drawings	P06
1.7 Symbol Definitions	P06
1.7.1 Product Symbols	P06
1.7.2 Warnings and Information Symbols	P07

2.0 SYSTEM INSTALLATION AND OPERATION

2.1 Product Description	P09
2.1.1 BTPower Battery Modular Handpiece	P09
2.1.2 BTPower Battery Oscillator Handpiece	P10
2.1.3 BTPower Battery Reciprocator Handpiece	P11
2.1.4 BTPower Battery Sternum Saw	P12
2.2 Assembly/Installation Instructions	P13
2.2.1 Battery Installation	P13
2.2.2 Connecting and Removing Attachments to the Modular Handpiece	P13
2.2.3 Connecting and Removing Blades to the Oscillator Handpiece	P14
2.2.4 Connecting and Removing Blade to Reciprocator Handpiece	P15
2.2.5 Connecting and Removing Blade and Blade Guard to the Sternum Saw	P16
2.3 Operating Instructions	P18
2.3.1 BTPower Modular Handpiece Operation	P18
2.3.2 BTPower Battery Oscillator Handpiece Operation	P19
2.3.3 BTPower Battery Reciprocator Handpiece Operation	P19
2.3.4 BTPower Battery Sternum Saw Operation	P20
2.4 Preoperative Functional Test	P20

CONTENTS

3.0 MAINTENANCE

3.1 Cleaning Information	P21
3.1.1 Warnings, Precautions and Notes	P21
3.1.2 Manual Cleaning Instructions	P21
3.1.3 Inspection Recommendations	P22
3.2 Sterilization Information	P22
3.2.1 Warnings, Precautions and Notes	P22
3.2.2 Sterilization Instructions	P23
3.3 Troubleshooting	P24
3.4 Maintenance Schedule	P24

4.0 TECHNICAL SPECIFICATIONS

4.1 Product Technical Specifications	P25
4.1.1 BTPower Battery Modular Handpiece	P25
4.1.2 BTPower Battery Oscillator Handpiece	P26
4.1.3 BTPower Battery Reciprocator Handpiece	P26
4.1.4 BTPower Battery Sternum Saw	P27
4.2 Product Environmental Requirements	P27
4.2.1 Environmental Technical Specifications	P27
4.2.2 Electromagnetic Requirements	P28
4.3 Accessories	P32

5.0 CUSTOMER SERVICE

5.1 Assistance and Repair	P36
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1.0 INTRODUCTION

It is recommended that personnel study this manual before attempting to operate, clean, or sterilize this or associated equipment. The safe and effective use of this equipment requires the understanding of and compliance with all warnings, precautionary notices, and instructions marked on the product, and included in this manual.

This equipment is designed for use by medical professionals completely familiar with the required techniques and instructions for use of the equipment.

Service intervals, as listed in Section "**3.4 Maintenance Schedule**", are required to keep the equipment at its optimum operating performance.

1.1 Operating Principle

The BTPower Battery Handpieces are powered by a detachable, rechargeable battery to provide rotary, reciprocating, or oscillating force to the accessory (drill bits, saw blades, reamers, drivers or other attachments) for bone cutting, drilling, driving and soft tissue resection. The handpieces are controlled by an activation trigger and safety/direction lever on the handpiece. The handpieces and accessories, including the batteries may come into physical contact with the patient (applied part).

1.2 Indications for Use

The BTPower Battery Single-Trigger Handpiece and their accessories, perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, hand and foot surgical procedures.

The BTPower Battery Oscillator Handpiece and their accessories, perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, hand and foot surgical procedures.

The BTPower Battery Reciprocator Handpiece and its accessories, perform cutting of soft tissue and bone. The fields of application include: orthopedic, and arthroscopic surgical procedures.

The BTPower Battery Sternum Saw, and its accessories, perform cutting of soft tissue and bone. The fields of application include: orthopedic, and arthroscopic surgical procedures.

1.3 Intended Use

Same as Indications for Use above.

1.4 Contraindication

The BTPower Battery Sternum Saw is not intended for use in repeat sternotomy applications.

1.5 Warnings and Precautions



Do not bypass this section. It contains warnings and precautions that must be thoroughly understood before operating any of the equipment. Lack of understanding or adherence to these warnings and precautions may result in injury or even death to the patient.

The words **WARNING**, **PRECAUTION**, and **NOTE** carry special meanings and they must be read carefully.

WARNING: A warning contains critical information regarding serious adverse reactions and potential safety hazards that can occur in proper use or misuse of the equipment. Failure to observe the information or procedures presented in a Warning may result in injury or other serious adverse reactions to the patient and/or surgical staff.



PRECAUTION: A precaution contains instructions for any special care to be exercised by the practitioner for the safe and effective use of the equipment. Failure to observe the information or procedures presented in a Precaution may result in damage to the equipment.



NOTE: A note is added to provide additional focused information. This information has no critical effect on the patient or equipment.

1.5.1 Warnings

1. Eye protection is recommended when operating equipment. Eye injury may result. 
2. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of the equipment and its associated accessories.
3. Do not use equipment if, upon receipt, package is opened, damaged, or shows any signs of tampering. 
4. Do not use equipment in the presence of flammable anesthetics, gases, disinfecting agents, cleaning solutions, or any material susceptible to ignition due to electrical sparking.
5. Do not use sterile equipment beyond the expiration date listed on the label. Sterility of the product cannot be assured beyond the expiration date.
6. Handpieces are supplied non-sterile. Clean and sterilize prior to each use. 
7. Do not contact the moving parts on the handpieces. Injury to the operator may occur.
8. Continually check handpiece for overheating. If overheating is sensed, immediately discontinue use and return equipment for service. Overheating of the blade or bur may cause damage to the blade or bur and may cause burns or thermal necrosis.
9. While handpiece is not in use do not place on patient/surgical drapes. Place handpiece on mayo stand.
10. Do not immerse the equipment in fluids. Immersion may render the device inoperable.
11. Failure to follow the specified service interval could result in reduced instrument performance or overheating of the handpiece. Overheating can lead to possible burn injury to the patient or medical personnel. Rotation of handpiece usage per day will assist with proper performance. 

(Refer to section "**3.4 Maintenance Schedule**").

12. Do not attach, insert or remove accessories or attachments while the handpiece is operating. Injury to the operator and/or damage to the equipment may occur. Place the handpiece safety mechanism in the "safe" position prior to installation or removal of items.
13. Avoid contact with cutting tip of blade or bur when locking into handpiece. Tips are sharp and may cause injury.
14. After use blades, burs and tubing sets may be a potential biohazard and should be handled and disposed in accordance with acceptable medical practice and applicable local and national requirements. 
15. Disposable blades and burs are supplied sterile and are for single-use only. Do not re-sterilize or reuse. The ability to effectively clean and re-sterilize these single use devices has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the devices. 
16. Do not operate the oscillating saw or reciprocator handpiece without a blade locked securely in place.
17. Always place the handpiece in the "safe" position when not in use and prior to repositioning the rotating head on the Oscillator Saw, rotating the collet on the Reciprocating Saw, or connecting or removing attachments and accessories.
18. Do not short circuit battery terminals or allow them to contact metal objects. This could cause a shock or burn injury and also damage the battery.
19. Do not expose batteries to fire or incineration. Exposure may cause injuries.
20. Inspect battery pack for damage (e.g., cracks in battery case) prior to use. Do not use damaged battery packs. If battery pack is damaged and leakage or residue is noticed, do not allow it to come in contact with skin, eyes or clothing. Burns may result. If contact occurs, flush area with copious amounts of water and seek medical attention immediately. Dispose of or recycle properly.

1.5.2 Precautions

1. This device should only be used in compliance with its intended use.
2. Handle all equipment carefully. If any equipment is dropped or damaged in any way, return it immediately for service.
3. Use only associated BaiDe Medical approved equipment and accessories. Using unapproved accessories may result in improper operation, and may result in non-compliance to medical standards.
4. The warranty becomes void and the manufacturer is not liable for direct or resulting damage if:
 - The device or the accessories are improperly used, prepared or maintained;
 - The instructions in the manual are not adhered to;
 - Non-authorized persons perform repairs, adjustments or alterations to the device or accessories.
5. There are no user-serviceable parts inside. No modification of this equipment is allowed. 
6. Prior to each use, perform the following:
 - Ensure all accessories are correctly and completely attached. (Refer to section "**2.1.4 BTPower Sternum Saw**").
 - Perform the required Preoperative Functional Tests for the equipment and accessories. (Refer to section "**2.4 Preoperative Functional Test**").

7. Clean and sterilize all equipment and associated accessories according to instructions for use. (Refer to section "**3.1 Cleaning Information**" and section "**3.2 Sterilization Information**").
8. Handpieces are factory sealed. Do not disassemble or lubricate, as this may void the warranty. 
9. Always inspect for bent, dull or damaged blades or burs before each use. Do not attempt to straighten or sharpen. Do not use if damaged.
10. After each use, thoroughly clean the handpiece, attachments and accessories (Refer to section "**3.0 MAINTENANCE**").
11. Do not stall handpieces, damage can occur.
12. Do not operate the Reciprocating Saw attachment with the Battery Handpieces. Damage will occur to the attachment.
13. Depletion of the battery charge will result if the battery pack is attached to a handpiece while the handpiece is stored or is not being used.
14. Battery packs contain materials which must be recycled or disposed of properly. The disposal of nickel cadmium or nickel metal hydride batteries as municipal waste is prohibited. Dispose or recycle in accordance with your local, state and government regulations.
15. Do not operate the Reciprocating Saw with the collet in the "open" position or without a blade locked in the collet. Damage to the handpiece may occur.
16. Avoid contact of blades and burs with cutting blocks, retractors or other instrumentation. Damage to blade, bur or instrumentation may occur.

1.6 Product Photographs and Drawings

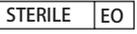
The pictures in this manual are for reference only. Items shown may not represent the actual product. However, procedural steps are identical, unless otherwise specified. When necessary, the actual pictures will be represented.

1.7 Symbol Definitions

1.7.1 Product Symbols

	Indicates the "safe" or "off" position.		
	Indicates the "forward" position of the handpiece.		Indicates the "reverse" position of the handpiece.
	Indicates the "run" positions of the handpiece.		Indicates the "run" position of the handpiece.

1.7.2 Warnings and Information Symbols

	Catalog Number		Serial Number
	Manufacturer		Date of Manufacture
	Consult Instructions for Use		Refer to Instruction Manual/Booklet (for critical safety instruction)
	Caution		DEHP Symbol
	Authorized Representative in the European Community		CE Mark of Conformity
	Prescription Only: Federal Law restricts this device to sale by or on the order of a physician		No User Service Recommended. Refer servicing to qualified BaiDe Linvatec service personnel
	Non Sterile		Sterile
	Sterile - Sterilized Using EO		Sterile - Sterilized Using Irradiation
	Do Not Steam Sterilize		Do Not Sterilize
	Do Not Resterilize		Do Not Reuse (for Single Use Only)
	Do Not Use Oil		Do Not Use for Plunge Cutting
	Eye Protection Required		Biohazard Risk
	Do Not Immerse		Quantity
	Type B Applied Part		Type BF Applied Part

	UL Classification Mark		UL Recognized Components
	Rating Fuse		Fuse Location
	Alternating Current		Protective Earth Ground
	Equipotentiality (Equipment Potential)		Non-Ionizing Electromagnetic Radiation (RF Symbol)
	Temperature Limitation		Humidity Limitation
	Atmospheric Pressure Limitation		Use by Date
	Fragile		This Side Up
	Do Not Use if Package is Damaged		Keep Dry
	Warning: Corrosive Substance		Warning: Electrical Hazard/High Voltage
	Waste Electrical and Electronic Equipment (WEEE) Symbol. Regarding European Union end-of-life of product, indicating separate collection for electrical and electronic equipment		
	Recycle. Batteries contain materials which must be recycled or disposed of properly. The disposal of batteries as municipal waste is prohibited. Dispose or recycle in accordance with your local, state and governmental regulations.		

2.0 SYSTEM INSTALLATION AND OPERATION

2.1 Product Description

2.1.1 BTPower Battery Modular Handpiece

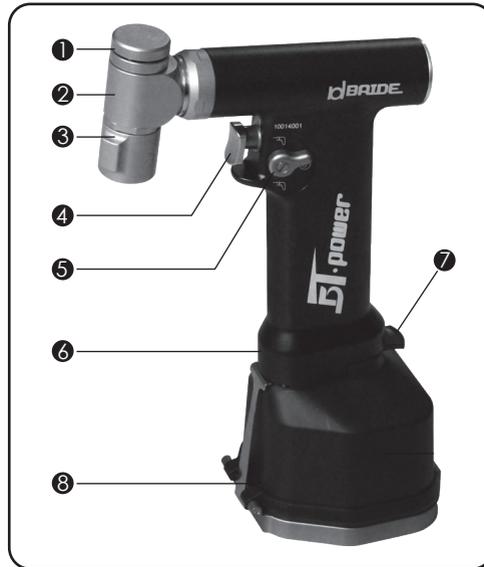


The BTPower Handpiece is designed to be used as an all-purpose driver for reaming, drilling, wire and pin driving, and with the proper attachments (reciprocator and sagittal only) will perform sawing applications. This handpiece is designed to accept most PowerPro attachments.

1. **Attachment Collet-Lock** — Twist to unlock and remove attachments from the handpiece. It is not necessary to twist for insertion of attachment. Simply insert and push attachment to lock in place.
2. **Activation Trigger** — Used to activate the handpiece. Depress when the mode lever is in the "forward" or "reverse" position to operate.
3. **Mode Lever** — To operate the handpiece, place in either the "forward" or "reverse" position. Place in the "safe" position prior to connecting or removing any attachment or accessory and during non-use of the handpiece.
4. **Battery Receptacle** — The battery attaches here.
5. **Battery Release Lever** — Depress this lever to remove the battery from the handpiece.
6. **Battery Pack** — Refer to section "4.3 Accessories" for compatible batteries.



2.1.2 BTPower Battery Oscillator Handpiece



The BTPower Handpieces are designed for sawing in large and transverse or longitudinal bone osteotomies, removal of the femoral head and neck, removal of the greater trochanter, repeat sternotomies, resurfacing the tibial plateau, and the distal end of the femur as required in total knee or total hip arthroplasties.

1. **Blade Locking Collet** — Holds and locks the blade in place.
2. **Rotating Head** — The rotating head gives the surgeon the ability to position the cutting blade for appropriate surgical access. The oscillator handpiece contains an 8 position, 45° indexing head. To position the rotating head, grasp the rotating head, pull it out from the handpiece body, and turn it to the desired position.

NOTE: Mode lever is to be in the "safe" position when positioning head.

3. **Blade Locking Knob** — Rotate to the "open" position to insert a blade. Rotate in the opposite direction to lock the blade securely in place.
4. **Activation Trigger** — Used to activate the handpiece. Depress when the mode lever is in the "run" position to operate the handpiece. 
5. **Mode Lever** — To operate the handpiece, place in the "run" position. Place in the "safe" position prior to connecting or removing an accessory and during non-use of the handpiece. 
6. **Battery Receptacle** — The battery attaches here.
7. **Battery Release Lever** — Depress this lever to remove the battery from the handpiece.
8. **Battery Pack** — Refer to section "4.3 Accessories" for compatible batteries.

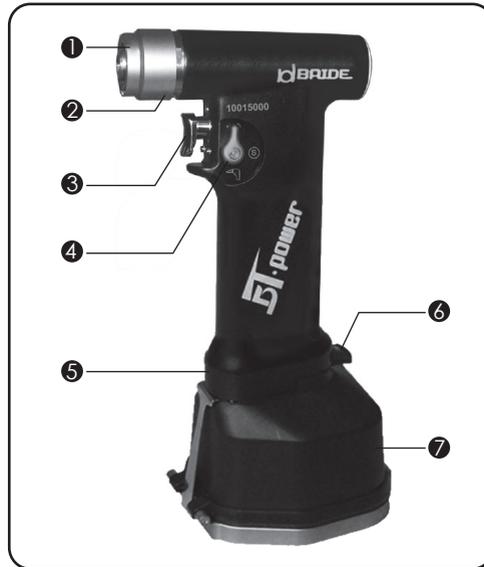
2.1.3 BTPower Battery Reciprocator Handpiece



The BTPower Handpiece is designed for sawing in large bone total arthroplasties.

1. **Blade Collet** — Insert a blade here. Also used to rotate the blade to any of four (4) positions at 90° intervals for appropriate surgical access. Blade positioning must be done prior to locking the blade in the collet. To rotate, grasp the blade at the base of the collet and rotate to the desired position.
2. **Blade Locking Knob** — Rotate counterclockwise to open the collet to insert a blade. Rotate clockwise to lock the blade securely in place.
3. **Activation Trigger** — Used to activate the handpiece. Depress when the mode lever is in the "run" position to operate the handpiece. 
4. **Mode Lever** — To operate the handpiece, place in the "run" position. Place in the "safe" position prior to connecting or removing an accessory and during non-use of the handpiece. 
5. **Battery Receptacle** — The battery attaches here.
6. **Battery Release Lever** — Depress this lever to remove the battery from the handpiece.
7. **Battery Pack** — Refer to section "4.3 Accessories" for compatible batteries.

2.1.4 BTPower Battery Sternum Saw



The BTPower Battery Sternum Saw is designed to be used for primary sternotomies and provides smooth, reliable power with variable speed from 0 to 14,500 cpm.

The BTPower Battery Sternum Saw is designed to accept blades, and to be used with blade guards.

1. **Collet Nut** — Accepts and locks a blade into the handpiece.
2. **Blade Guard Locking Sleeve** — Used to lock the sternum saw blade guard to the handpiece.
3. **Activation Trigger** — Used to activate the handpiece. Depress when the mode lever is in the "run" position to operate the handpiece.
4. **Mode Lever** — To operate the handpiece, place in the "run" position. Place in the "safe" position prior to connecting or removing an accessory and during non-use of the handpiece.
5. **Battery Receptacle** — The battery attaches here.
6. **Battery Release Lever** — Depress this lever to remove the battery from the handpiece.
7. **Battery Pack** — Refer to section "4.3 Accessories" for compatible batteries.



2.2 Assembly/Installation Instructions

2.2.1 Battery Installation

To attach the desired battery pack to the handpiece:

1. Align the contacts on the top of the battery pack with the connector on the handpiece.
2. Slide the battery pack until it snaps into place.



To remove the battery pack from the handpiece:

1. Depress the release lever and pull the battery pack from the handpiece.



2.2.2 Connecting and Removing Attachments to the Modular Handpiece

All attachments for the BTPower Handpiece connect/disconnect in the same manner. For more information, refer to the PowerPro Attachment Instruction Manual or the Information Insert supplied with each attachment.

To connect an attachment:

1. Place the mode lever in the "safe" position.
2. Orient the attachment shaft to the handpiece opening. Insert the shaft and press them until they snap together.





To disconnect an attachment:

1. Place the mode lever in the "safe" position.
2. Twist the attachment collet-lock in the direction of the arrow. Remove the attachment.



2.2.3 Connecting and Removing Blades to the Oscillator Handpiece

To attach a blade:

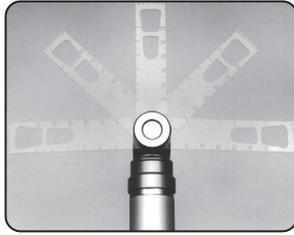
1. Place the mode lever in the "safe" position.
2. Rotate the blade locking knob in the direction of the arrow to the "open" position. The blade locking collet will disengage.



3. Align the blade shank to the desired angle with the blade locking collet. Insert the blade.



4. Blades can be positioned 45° off the center line in either direction.



5. Rotate the blade locking knob in the opposite direction of the arrow to lock the blade into place.
6. Carefully pull on the blade to ensure it is securely in place.

WARNING: The blade locking knob must be completely closed to hold the blade firmly in place.



To remove the blade:

1. Ensure the mode lever is in the "safe" position.
2. Rotate the blade locking knob to the "open" position. The blade locking collet will disengage.
3. Remove the blade.



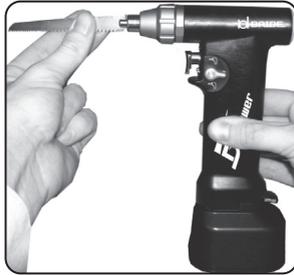
2.2.4 Connecting and Removing Blade to Reciprocator Handpiece

To attach a blade:

1. Place the mode lever in the "safe" position.
2. Rotate the blade locking knob counterclockwise to open the blade collet.



3. Completely insert the blade shank.



4. The rotating head may be set in any of 4 positions at 90° intervals for the appropriate surgical access. Position the blade to the desired position by grasping the blade at the base of the collet and rotating it to the desired position.



5. Rotate the blade locking knob clockwise to lock the blade into place.
6. Carefully pull on the blade to ensure it is securely in place.

WARNING: The blade locking knob must be completely closed to hold the blade firmly in place.



To operate the handpiece, move the mode lever to the "run" position and depress the trigger. To remove the blade:



1. Ensure the mode lever is in the "safe" position.
2. Rotate the blade locking knob counterclockwise. The blade locking collet will disengage. Remove the blade.



2.2.5 Connecting and Removing Blade and Blade Guard to the Sternum Saw

WARNING: Never operate the Sternum Saw without the saw blade, collet nut, and blade guard locked securely in place. !



Place the handpiece in the "safe" position.

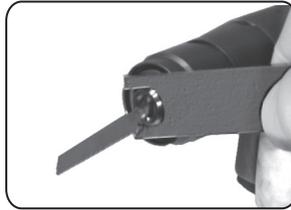


To install a blade:

1. Using the Locking Wrench, loosen the collet nut by placing the locking wrench over the flats of the collet and turning counterclockwise one or two revolutions.
2. Completely insert the flat blade shank into the collet.



3. The blade may be inserted in either of two positions to allow cutting in a push (blade teeth pointing upwards - photo above) or pull direction (blade teeth pointing downwards - photo below).



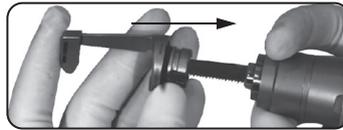
4. Place the opening of the locking wrench over the flats on the collet nut. Turn in a clockwise direction and tighten the collet nut securely.
5. After the blade has been completely seated and locked, move the mode lever to the "run" position.
6. Briefly activate the handpiece by depressing the trigger. Return the mode lever to the "safe" position.
7. Pull on the blade to ensure there is no movement in the blade. If there is movement, tighten the collet nut more securely.



To attach the sternum saw blade guard:

NOTE: Ensure the O-Ring is present on the blade guard prior to installing.

1. Slide the sternum saw blade guard over the blade. Always align the support strut on the blade guard with the non-cutting side of the blade.



2. Align the slots on the connecting portion of the blade guard with the pins inside the blade guard locking sleeve. Pull the locking sleeve back (see above picture) and insert the blade guard completely into the blade guard locking sleeve.
3. With the blade guard in the proper position, release the locking sleeve. It will snap into place, locking the blade guard to the handpiece.

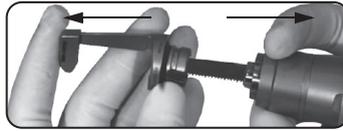


WARNING: Make sure the blade is inserted inside the slot of the blade guard, not outside. Otherwise damage or injury may occur.



To remove the sternum saw blade guard and blade:

1. Ensure the handpiece is in the "safe" position.
2. Slide the locking sleeve towards the back of the handpiece.



3. Pull the blade guard out and away from the handpiece. Release the locking sleeve.
4. Place the opening of the locking wrench over the flats on the collet nut. Turn the wrench in a counterclockwise direction and loosen the collet nut. Do not turn the collet nut more than two or three revolutions.



5. Remove the blade and dispose of blade properly.

2.3 Operating Instructions

NOTE: The connected attachment (drill or reamer) determines the speed and torque of the handpiece.

2.3.1 BTPower Modular Handpiece Operation

To operate the handpiece, place the handpiece mode lever in either the "forward" or "reverse" position and depress the trigger.

1. With the mode lever in the "forward" position, depressing the trigger operates the handpiece in the clockwise direction as viewed from the rear of the handpiece. The speed is variably controlled with the trigger.
2. With the mode lever in the "reverse" position, depressing the trigger operates the handpiece in the counter-clockwise direction as viewed from the rear of the handpiece. The speed is variably controlled with the trigger.



2.3.2 BTPower Battery Oscillator Handpiece Operation

Position the rotating head to the desired position for the appropriate surgical access.

1. Ensure the mode lever is in the "safe" position.
2. Pull the rotating head out and away from the handpiece body.



3. Twist the rotating head to the desired position and release the rotating head. Ensure it is locked into place and does not rotate.



4. Move the mode lever to the "run" position.
5. To activate the handpiece, depress the trigger.



2.3.3 BTPower Battery Reciprocator Handpiece Operation

1. Move the mode lever to the "run" position.
2. To activate the handpiece, depress the trigger.



2.3.4 BTPower Battery Sternum Saw Operation

1. Move the mode lever to the "run" position.
2. To activate the handpiece, depress the trigger.



PRECAUTION: Do not operate the Handpiece with the collet in the "open" position or without a blade locked in the collet. Damage to the handpiece may occur.



2.4 Preoperative Functional Test

Prior to each use, perform the following preoperative functional test:

1. Attach battery to handpiece.
2. Insert an attachment or blade into the handpiece. Gently pull on the attachment or cutting accessory to ensure it is properly seated.
3. Run the handpiece for less than 5 seconds to observe any abnormal noises, vibrations or heat rise.
4. If any operating difficulties occur, return the handpiece for service.

3.0 MAINTENANCE

3.1 Cleaning Information

3.1.1 Warnings, Precautions and Notes



1. Follow universal precautions for protective apparel when handling and cleaning contaminated instruments.
2. Clean instruments within 30 minutes after use to minimize the potential of blood and debris drying.
3. Never clean equipment in an ultrasonic cleaner.
4. Always disconnect the handpiece cord prior to cleaning.
5. Always detach accessories from equipment prior to cleaning.
6. Never clean handpieces with bleach, chlorine-based detergents, liquid or chemical disinfectants, or any products containing sodium hydroxide (such as, INSTRU-KLENZ or Buell Cleaner). These products degrade the anodized aluminum coating and may result in reduced handpiece reliability.
7. For aluminum surfaces, a neutral-pH agent should be used. To prevent corrosion, avoid contact with strong alkaline solutions (pH over 10.5) or agents containing iodine or chlorine.
8. Prior to using a washer/sanitizer, consult product labeling on all washer/sanitizer cleaning solutions for compatibility with aluminum. Use of a washer/sanitizer may decrease the life expectancy of the handpiece.

Refer also to Section "1.5 Warnings and Precautions".

NOTE: For battery cleaning information refer to the corresponding battery charger instruction manual or the associated information insert supplied with the battery.

3.1.2 Manual Cleaning Instructions

1. Thoroughly scrub the handpiece and attachments with a clean, soft brush dampened with a mild, pH-balanced detergent. Remove all traces of blood, debris and stains.
2. Using a low-velocity spray of water, spray into the collet. Ensure the collet operates smoothly and that no debris is binding the internal mechanism of the collet. Clean until all debris is removed.
3. To clean the cannulated section of the handpiece and attachment, feed the wire end of a cleaning brush through the cannulation of the handpiece or attachment. Pull the brush completely through and repeat until all debris is removed.
4. Manipulate all moving parts of the handpiece to ensure all debris is removed. If not, clean again until all debris is removed.

5. Keeping the nose of the handpiece pointed downward, rinse under running water to remove all traces of soap. Rinse all attachments in the same manner.
 6. Flush the surfaces free of tap water with distilled water to prevent metal discoloration.
 7. Gently shake the equipment free of water and wipe the surfaces with a clean, lint-free towel.
 8. Visually inspect handpiece and accessories under good light conditions to check for visible soil and/or corrosion.
 9. Perform functional checks according to Section "**2.4 Preoperative Functional Test**". Check mating accessories closely for proper assembly.
 10. Repeat Manual Cleaning Instructions as necessary.
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3.1.3 Inspection Recommendations

1. Inspect Device Prior to Sterilization.
 2. Generally, unmagnified visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion.
 3. Functional checks should be performed where possible.
 4. Mating devices should be checked for proper assembly.
 5. Remove and replace damaged instruments/containers.
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3.2 Sterilization Information

3.2.1 Warnings, Precautions and Notes



1. The use of disinfecting solutions for an exterior instrument wipe will not sterilize the equipment and is not recommended.
2. Do not sterilize equipment or accessories using Ethylene Oxide (EtO).
3. Do not sterilize equipment or accessories using a STERIS system or by comparable sterilization methods.
4. Do not sterilize equipment or accessories in cold sterilants like CIDEX.
5. Always detach accessories from equipment prior to sterilization.
6. Do not "Peel Pack" handpieces for sterilization. Sterilization in a sealed pouch traps moisture which can cause damage.
7. The suction control valve, if one exists, must be in the fully open position during sterilization.
8. Attachments with collet mechanisms must be sterilized with the collet fully open.
9. Do not use equipment while warm. Allow adequate time for cooling prior to use. Cool by exposure to room temperature. Operation of equipment that is not completely cool or dry may decrease performance and/or reliability.

10. When sterilizing equipment and attachments in a system sterilization tray, use the recommended sterilization parameters in its instruction manual.
11. An eight (8) minute minimum dry cycle must be run on all equipment and attachments every time the product is sterilized. Failure to use a dry cycle on the products may lead to reduced product performance or premature product failure.

Refer also to Section “**1.5 Warnings and Precautions**”.

3.2.2 Sterilization Instructions

Steam sterilization is safe and effective and has no contraindications for sterilizing this equipment.

NOTES:

- **For battery sterilizationV information refer to the associated information insert supplied with the Battery Charger Instruction Manual or the associated information insert supplied with the battery.**
1. Individually wrap handpiece and accessories.
 2. Follow the recommended minimum sterilization exposure times listed below.
 3. Use the recommended tray parameters in its instruction manual when sterilizing handpieces and attachments in a system sterilization tray.
Handpieces and attachments may be processed in a pre-vacuum steam sterilizer (Steam Pre-vacuum) or in a gravity (downward) displacement sterilizer (Steam Gravity).

Minimum recommended sterilization exposure times are as follows:

Table 1: Sterilization Parameters, BTPower

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam	Pre-vacuum	270°F(132 C)	4 minutes	8 minutes
Steam	Gravity	250°F(121 C)	30 minutes	8 minutes

3.3 Troubleshooting

Table 2: Troubleshooting Guide

Symptoms	Possible Cause	Corrective Action
Handpiece does not operate.	<ul style="list-style-type: none">• Handpiece mode lever in "safe" position.• Battery pack not charged.• Battery pack faulty. • Handpiece faulty.	<ul style="list-style-type: none">• Move handpiece mode lever to an operating position.• Replace with a charged battery pack.• Connect another, fully charged battery pack to the handpiece. If handpiece works, battery pack was either not charged or faulty. Try recharging battery pack and reconnecting to handpiece. If handpiece still does not operate, the battery pack is faulty. Discard battery pack.• Return handpiece for service.
Blade does not insert easily.	<ul style="list-style-type: none">• Collet contains debris.• Blade is bent.	<ul style="list-style-type: none">• Thoroughly clean collet to remove all debris.• Do not use. Replace blade.

3.4 Maintenance Schedule

Regular and proper maintenance of your equipment is the best way to protect your investment. It is essential that you have your equipment serviced as scheduled in order to retain its optimum performance and reliability, which will reward you with safer, less problematic product performance over time.

The equipment is not field repairable. Your BaiDe Medical authorized service department is the most knowledgeable about this equipment and its accessories and will provide competent and efficient services. Service at BaiDe Medical at the recommended service interval is mandatory to keep your product warranties in effect. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the equipment or equipment failure. (Refer to section "5.0 CUSTOMER SERVICE").

4.0 TECHNICAL SPECIFICATIONS

Medical electrical equipment complies with and was tested with respect to electric shock, fire, electromagnetic compatibility, mechanical and other specified hazards only, in accordance with UL60601-1, CAN/CSA C22.2 No. 601.1-M90, IEC60601-1:1988 +A1:1991 +A2:1995, ES60601-1:2005 +A1:2009 +A2:2010, CAN/CSA C22.2 No.60601-1-1-08 and IEC60601-1:2005 +C1:2006 +C2:2009.

Tested to IEC60601-1-2:2007 and Part 15 of the FCC Rules as follows: 1) The system may not cause harmful interference: 2) The system will accept interference, including interference that might cause undesired operation. If interference occurs, separate the instruments. For more information, contact customer service.

4.1 Product Technical Specifications

4.1.1 BTPower Battery Modular Handpiece

Classification:	Class I, Applied Part Type BF.
Protection Ingress of Fluids:	IPX6 and IPX8
Mode of Operation:	Intermittent Loading
Height:	16cm
Length:	10cm
Weight:	680g
Duty Cycle (once daily):	12 seconds ON, 12 seconds OFF (4 x) 1 minute OFF 12 seconds ON, 12 seconds OFF (4 x) 8 minute OFF 30 seconds ON 1 minute OFF 1 minute ON

Attachment Specifications:	9.6V, 1.25Ah Battery	9.6V, 2.4Ah Battery	12V, 1.6Ah Battery	12V, 0.5Ah Battery
Drill Attachments:				
Nominal Speed Range:	0-1250rpm	0-1250rpm	0-1500rpm	0-1500rpm
Max. Torque:	3.7Nm	3.7Nm	3.7Nm	2.5Nm
3:1 Reaming/High Torque Attachments:				
Nominal Speed Range:	0-417rpm	0-417rpm	0-500rpm	0-500rpm
Max. Torque:	10.2Nm	10.2Nm	10.2Nm	6.8Nm
5:1 Reaming Attachments:				
Nominal Speed Range:	0-250rpm	0-250rpm	0-300rpm	0-300rpm
Max. Torque:	15.3Nm	15.3Nm	15.8Nm	11.3Nm

4.1.2 BTPower Battery Oscillator Handpiece

Classification:	Class I, Applied Part Type BF.
Protection Ingress of Fluids:	IPX6 and IPX8
Mode of Operation:	Intermittent Loading
Speed Range:	0-11,000cpm
Oscillation Range:	4.5°
Height:	
10014001	16.5cm
10014030	16.3cm
Length:	
10014001	14.0cm
10014030	16.3cm
Weight:	964g
Duty Cycle (once daily):	40 seconds ON, 10 minutes OFF (3x)

4.1.3 BTPower Battery Reciprocator Handpiece

Classification:	Class I, Applied Part Type BF.
Protection Ingress of Fluids:	IPX6 and IPX8
Mode of Operation:	Intermittent Loading
Speed Range:	0-14,500cpm
Stroke:	3.2mm
Height:	15.6cm
Length:	12.3cm
Weight:	720g
Duty Cycle (once daily):	15 seconds ON

4.1.4 BTPower Battery Sternum Saw

Classification:	Class I, Applied Part Type BF.
Protection Ingress of Fluids:	IPX6 and IPX8
Mode of Operation:	Intermittent Loading
Speed Range (9.6V):	0-13,500cpm
Speed Range (12V):	0-14,500cpm
Stroke:	3.2mm
Height:	15.9cm
Length:	10.2cm
Weight:	680g
Duty Cycle (once daily):	20 seconds ON

4.2 Product Environmental Requirements

4.2.1 Environmental Technical Specifications

Environmental Conditions	Operating	Storage and Transport
Temperature:		
Relative Humidity:		
Atmospheric Pressure:		

4.2.2 Electromagnetic Requirements

Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. this device must accept any interference received, including interference that may cause undesired operation.

Use of accessories other than those recommended may result in non-compliance with electromagnetic compatibility and immunity standards.

Table 3: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

BaiDe Medical BTPower Handpieces are intended for use in the electromagnetic environment specified below. The customer or the user of the BTPower Handpieces should assure that they are used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	BaiDe Medical BTPower Handpieces use RF energy only for internal functions; therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	BTPower is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	Not Applicable
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	Not Applicable

Table 4: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

<p align="center">BaiDe Medical BTPower Handpieces are intended for use in the electromagnetic environment specified below. The customer or the user of the BTPower Handpieces should assure that they are used in such an environment</p>			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact Unit was not compliant at ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV lines to earth	± 1 kV line to line ± 2 kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5%Ut(>95% dip in Ut) for 0.5 cycle 40%Ut(60% dip in Ut) for 5 cycles 70%Ut(30% dip in Ut) for 25 cycles < 5%Ut(>95% dip in Ut) for 5 seconds	< 5%Ut(>95% dip in Ut) for 0.5 cycle 40%Ut(60% dip in Ut) for 5 cycles 70%Ut(30% dip in Ut) for 25 cycles < 5%Ut(>95% dip in Ut) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BTPower Handpieces requires continued operation during power mains interruptions, it is recommended that the BTPower Handpieces be powered from an uninterruptable power supply or battery.
<p>NOTE: Ut is the a.c. mains voltage prior to application of the test level.</p>			
<p>Portable and mobile RF communications equipment should be no closer to any part of the BTPower Handpieces, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>			

Table 4: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

<p>BaiDe Medical BTPower Handpieces are intended for use in the electromagnetic environment specified below. The customer or the user of the BTPower Handpieces should assure that they are used in such an environment</p>			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>150kHz-80MHz</p>	<p>3Vrms</p>	<p>Recommended Separation Distance $d=1.2\sqrt{P}$</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>80MHz-2.5GHz</p>	<p>3V/m</p>	<p>$d=1.2\sqrt{P}$80MHz-800MHz $d=2.3\sqrt{P}$800MHz-2.5GHz</p>
<p>Where P is the maximum output where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol: </p>			
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and/or people.</p>			
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BTPower Handpieces is used exceeds the applicable RF compliance level above, BTPower Handpieces should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BTPower Handpieces.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 5: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BTPower Handpieces @ 3Vrms

<p>BaiDe Medical BTPower Handpieces are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BaiDe Medical BTPower Handpieces can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTPower Handpieces as recommended below, according to the maximum output power of the communications equipment.</p>			
	<p>Separation Distance According to Frequency of Transmitter (meters)</p>		
<p>Rated Maximum Output Power of Transmitter (Watts)</p>	<p>m</p>		
	<p>150kHz-80MHz $d = \left[\frac{3.5}{v_1} \right] \sqrt{P}$</p>	<p>80MHz-800MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$</p>	<p>800MHz-2.5GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$</p>
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distances d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p>			
<p>Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

4.3 Accessories

Product No.	Product Description
Attachments	
10011005	Pin Driver,2.0-4.0mm
10011006	Pin Driver,0.7-1.6mm
10014011	Oscillating Blade,19.5×90mm
10014013	Oscillating Blade,25×90mm
10014015	Oscillating Blade,12.5×70mm
10016001	Reciprocating Blade,12.5×38mm
10016006	Reciprocating Blade,12.5×76mm
10016007	Reciprocating Blade,12.5×89mm
10016008	Reciprocating Blade,9.4×54.5mm
10015010	Sternum Guard,57.2mm
10015011	Sternum Guard,79.2mm
10015021	Sternum Blade,10×35mm
10015022	Sternum Blade,10×54mm

Product No.	Product Description
1:1 Multipurpose Attachments	
10011003	Chuck,4.0mm
10011014	Key,4.0mm
10011002	Chuck,8.0mm
10011015	Key,8.0mm
10011004	Keyless Chuck,4.0mm
10011012	Keyless Chuck,8.0mm
10011040	Cranial Drill Chuck,Φ7.0mm
10011041	Cranial Drill Chuck,Φ9.0mm
10011042	Cranial Drill Chuck,Φ11mm

Product No.	Product Description
1:1 Quick Connect Drill Attachments	
10011013	AO/Trinkle Attachments
10011007	Small AO Attachments
10011008	Zimmer/Hudson Attachments
10011009	Large AO Attachments
10011010	Hudson/DePuy Attachments
10011011	Mini AO Attachments

Product No.	Product Description
3:1 Reamer Attachment	
10011021	High Torque Chuck,Max Dia. 4.0mm
10011022	Zimmer/Hudson Reamer Attachment
10011023	Hudson/DePuy Reamer Attachment
10011024	Large AO Reamer Attachment
10011025	Aesculap Reamer Attachment
10011026	DHS Reamer Attachment
10011027	Trinkle Reamer Attachment

Product No.	Product Description
5:1 Reamer Attachment	
10011031	High Torque Chuck,Max Dia. 4.0mm
10011032	Zimmer/Hudson Reamer Attachment
10011033	Hudson/DePuy Reamer Attachment
10011034	Large AO Reamer Attachment
10011035	Aesculap Reamer Attachment

Product No.	Product Description
Batteries	
10014003	Battery Pack,68.1×65.3×43.3mm
10014033	Battery Pack,68.1×65.3×51.9mm
10014004	Battery Case with latch,9.6V-1.25Ah
10014007	Battery Case without latch,9.6V-1.25Ah
10014008	Battery Case without latch,12V-0.5Ah
10014009	Battery Case without latch,12V-1.6Ah
10014032	Battery Case with knob,9.6V-1.25Ah
10014031	Battery Case with knob,9.6V-2.4Ah
10014005	Charger
10014006	Charging Platform
10014002	Transfer Shroud
10014010	Transfer Shroud,PPSU
10011030	Container

5.0 CUSTOMER SERVICE

5.1 Assistance and Repair

If you need technical assistance regarding the use or application of this product, or you encounter a problem that requires servicing or repair, contact BaiDe Medical Customer Service at +86-512-58198689 or your BaiDe Medical Sales Representative.

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