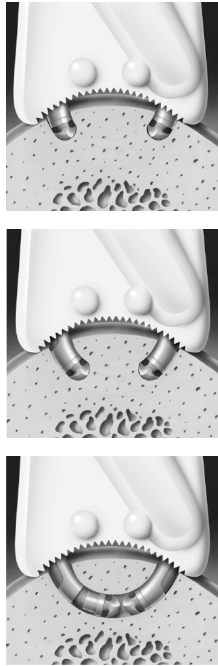


user's manual



®
CurvTek
BONE TUNNELING SYSTEM

ARTHROTEK®
A BIOMET COMPANY

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All other trademarks are not associated with Biomet.

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introduction

The CurvTek® System combines the benefits of preferred soft tissue reattachment with innovative pneumatic technology for creating curved transosseous tunnels. The unique CurvTek® handpiece and cartridge assembly machines curved bone tunnels, creating a strong bony bridge for each suture tie-down.



The “Tunnel/Tie-Down” Technique

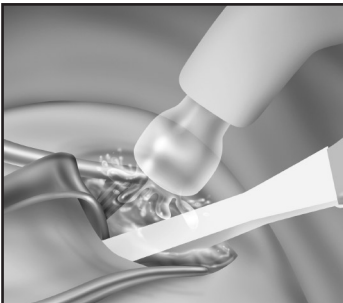
The “Tunnel/Tie-Down” Technique maximizes tissue-to-bone compression for optimum healing by creating a curved tunnel. With the matching curved needle, a suture can be easily passed through the curved tunnel and tied right to the bone.

The CurvTek® System requires attention to bone chip removal to ensure successful results. Unlike conventional straight drills that allow bone debris removal through flutes, the Tunnel/Tie-Down Technique requires two simultaneous activities for bone debris removal: “Chip Cycles” and continuous wound irrigation.



Chip Cycles

The trigger advance and release action is called a “chip cycle.” Chip cycles are required to allow bone debris removal throughout the process of creating a tunnel. As the trigger is pulled, the cutters engage the cortex and bone chips develop. As the trigger is released, the bone chips clear the tunnel. Each pull and release of the trigger is a chip cycle. To adequately create and clear the tunnel, 12 – 15 chip cycles may be necessary for each tunnel.



Wound Irrigation

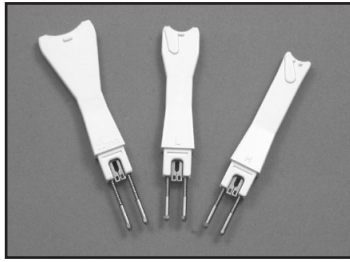
In addition to chip cycles, continuous wound irrigation is necessary to clear bone debris from the tunnel holes. The irrigation method should be either continuous pulsed lavage or submerged.



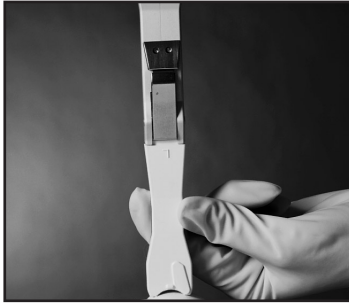
Features of the CurvTek® System



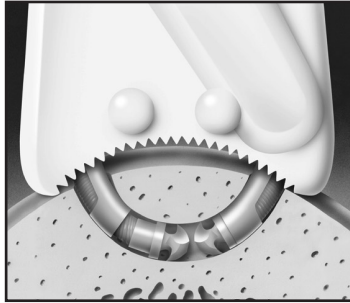
- Handpiece constructed of sturdy anodized aluminum.



- Convenient drill cartridges available in various sizes for added flexibility in tunnel size.



- Simple technique reduces surgery time.



- Pneumatic motor provides high torque for smooth tunneling.



- Disposable cartridges reduce risk of contamination and ensure that the cutters are always sharp.

system components



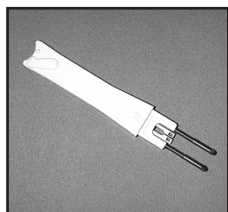
CurvTek® Handpiece
906740



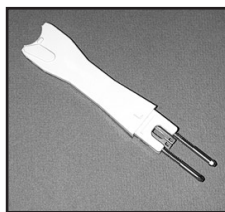
CurvTek® Lubricant, 1 oz.
906744



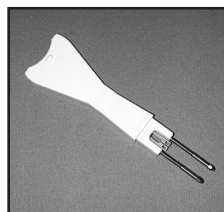
Nitrogen Hose 3 Meters Long (Hall® and Schrader® connectors)
906743



CurvTek® Cartridge, Medium (7mm)
906750 Single Pack



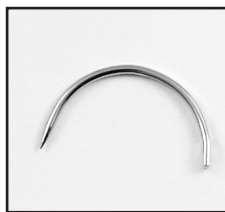
CurvTek® Cartridge, Large (12mm)
906754 Single Pack



CurvTek® Cartridge, X-Large (22mm)
906000 Single Pack



CurvTek® Eye Needle (3 per pack), Medium (7mm)
906760 Single Pack



CurvTek® Eye Needle (3 per pack), Large (12mm)
906764 Single Pack



CurvTek® Eye Needle (3 per pack), X-Large (22mm)
906768 Single Pack



CurvTek® Eye Needle (3 per pack), Extra Long (7mm)
906771 Single Pack



CurvTek® Eye Needle (3 per pack), Extended Flat (7mm)
906775 Single Pack



CurvTek® Sterilization Case
906796

operating instructions

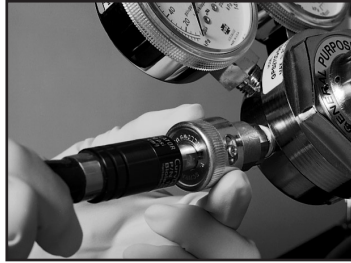
To ensure the successful operation of the CurvTek® TSR System, carefully read the following instructions prior to use in surgery.

CurvTek® Hose Instructions

Hose to Regulator Connection



To connect the CurvTek® hose, push the male Schrader® fitting of the hose into the female Schrader fitting of the nitrogen regulator.



To disconnect the hose, twist the collar on the regulator fitting clockwise.

Hose to CurvTek® Handpiece Connection

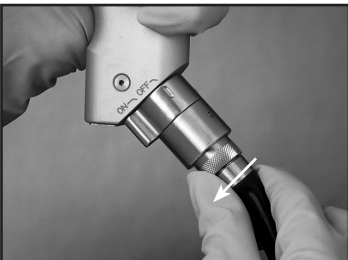


Rotate the handpiece's On-Off switch to the "Off" position (clockwise).



Insert the Hall® hose connector and twist it clockwise to the locked position. (Pull on the hose connector to verify that the hose has locked into position.)

Disconnecting the Hose



To disconnect the hose from the handpiece, depress the Hall® hose connector and twist it counter-clockwise.

nitrogen pressure instructions



Set the nitrogen regulator to indicate 90 – 100 PSI

Compensate for extension hoses by adding 2 PSI per foot of extension hose to the above pressure setting.

Hose Length	PSI
10 ft.	100
12 ft.	104
15 ft.	110

Caution: Over-pressure may increase wear of the hose and may reduce the life of the handpiece. Pressure less than 90 PSI may result in lower torque (power) being supplied to the cutter heads which could adversely affect the drilling performance.

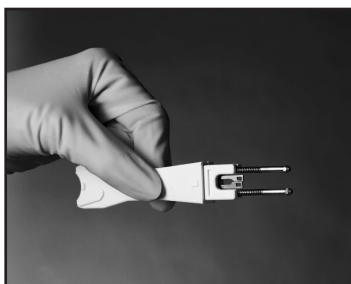
Caution: If a hose is cut or internally damaged, the loose end of the hose may flail and whip. If this occurs, immediately shut off the valve on the nitrogen supply and disconnect the hose from the Schrader® connection of the nitrogen regulator.

cartridge insertion

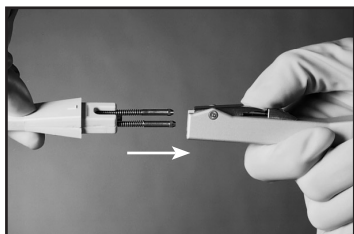
Cartridge Insertion into Handpiece



Be certain that the handpiece's On-Off switch is in the "Off" position (clockwise) whenever inserting or removing a cartridge.

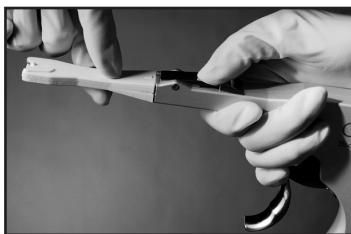


Hold the cartridge between thumb and forefinger of one hand.



With the free hand, grasp the "barrel" of the handpiece and depress the toggle latch on the handpiece with the thumb.

Caution: Keep hands away from, and do not push on, the serrated front end of the cartridge during insertion since this could result in injury from the sharp cutter tips.



Carefully insert the back end of the cartridge, with the two male hex drives, into the barrel of the handpiece until the cartridge slips into place.

Incorrect Cartridge Insertion



Note: If one or both cutter heads advance from the cartridge while it is being inserted into the handpiece, this indicates that the associated male and female hex drive(s) did not mate properly. If this occurs, remove the cartridge and rotate the non-mating male hex drive(s) slightly. Reinsert the cartridge into the handpiece. Repeat until properly seated.

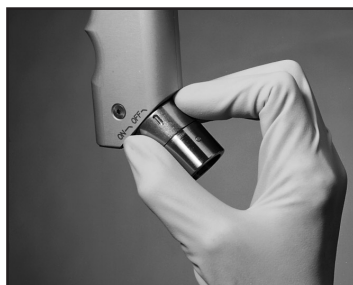


Cartridge Use



CurvTek® cartridges are Gamma radiated, sterile packaged, and designed for single patient use only. When a cartridge is fully seated into the handpiece, the cartridge/handpiece assembly is ready for use. The cartridge may be used to drill a maximum of 4 transosseous tunnels to provide maximum cutter head sharpness. If more than 4 transosseous tunnels are required, another sterile cartridge should be used.

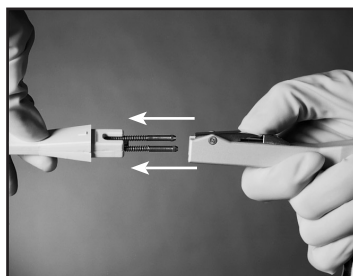
Cartridge Removal from Handpiece



Rotate the handpiece's On-Off switch to the "Off" position (clockwise) whenever removing a cartridge.



Hold the cartridge with the thumb and forefinger of one hand, and hold the handpiece with your free hand.



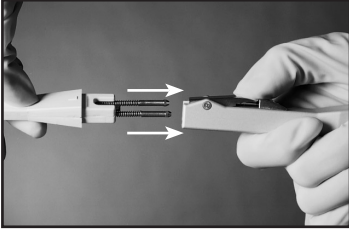
Completely depress the toggle latch on the handpiece, and pull firmly on the cartridge to remove it from the handpiece.

Properly dispose of the cartridge after single patient use.

handpiece instructions

Read the cartridge instructions before operating the cartridge/handpiece assembly. Ensure that the bone quality at the repair site is adequate for the integrity of the repair. Also be certain that the repair site is free from soft tissue to prevent interference with the cutting performance of the cutter heads.

Tunneling Operation



Before inserting the cartridge into the handpiece, ensure the “barrel” of the handpiece is unobstructed and that the female hex components inside the handpiece are unobstructed.

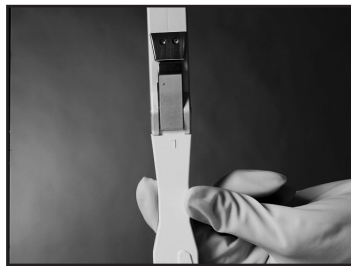
Insert the cartridge into the handpiece.



Hold the handpiece in one hand with index and middle fingers on the trigger.

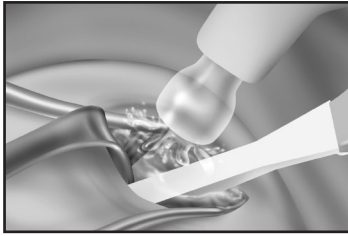


Rotate the On-Off switch to the “On” position.

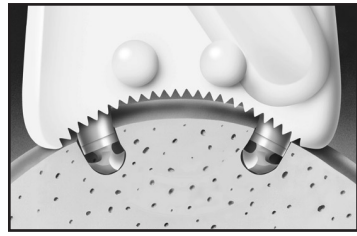


Stabilize the instrument perpendicular to the bone by holding the cartridge between the thumb and forefinger of the free hand.

Caution: Do not aggressively advance the cutter heads into the bone or attempt to create a complete tunnel with one continuous trigger motion. This will damage the cutter heads, flexible shafts, and drill guides. This action may also cause the cutter heads to overheat and thus prevent them from retracting from the prepared tunnel properly.



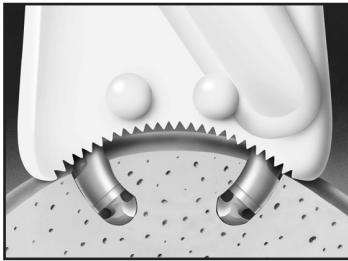
Continuous irrigation or immersion during the tunneling procedure is necessary to ensure bone chip clearance from the tunnel holes and to ensure adequate cooling of the cutter heads.



Depress the trigger to advance the cutter heads approximately one (1) millimeter into the bone. Then release the trigger, allowing the cutter heads to retract and clear the bone chips. This trigger action is known as “chip cycle.”

Note: If the CurvTek® trigger sticks during the tunneling procedure, slowly push the trigger forward until it is in the fully released position. A smooth release of the trigger allows the cutter heads to clear the bone chips from the curved transosseous tunnels.

Caution: If the cutter heads fail to retract from the tunnel holes, DO NOT pull the handpiece away from the bone. Reference Troubleshooting section.

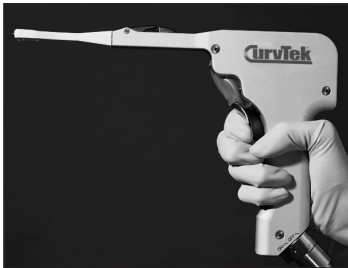


When the cutter heads clear the tunnel holes, smoothly depress the trigger again to advance the cutter heads approximately another millimeter into the bone.



Continue to depress and release the trigger (“chip cycle”) as many times as necessary until the transosseous tunnel is complete.

Note: The number of chip cycles needed to create a transosseous tunnel is dependent on the density and quality of the bone. At least 12 – 15 chip cycles is recommended. Denser bone may require more chip cycles.



The transosseous tunnel is complete when the trigger is fully depressed.

Caution: Before creating another transosseous tunnel, turn the handpiece off and be certain that the cutter heads are intact and clean of debris. Creating subsequent transosseous tunnels with clean cutter heads will contribute to better tunneling performance. In the event that a cutter head and/or flexible shaft breaks while operating, retrieve it and properly dispose of it and the damaged cartridge from which it came. Open and insert a new cartridge to continue with the operation.

cleaning and maintenance

To maintain the CurvTek® TSR System components in proper operating condition, please observe the following general cleaning and maintenance instructions.

Warning

DO NOT disassemble the handpiece or attempt to repair it. The handpiece can only be serviced at the Arthrotek, Inc. factory. There are no user-serviceable parts inside the handpiece.

DO NOT immerse the handpiece in fluid or place the handpiece under running water. Water (or any fluid) may affect internal assemblies.

DO NOT use a bleach or chlorine based detergent to clean the handpiece. The use of chlorine or bleach will cause corrosion to components.

DO NOT clean the handpiece in an ultrasonic cleaner. Use of an ultrasonic cleaner may damage the special lubricant of the bearings and cause a freeze-up of the handpiece during use.

DO NOT lubricate any part of the handpiece with anything other than the CurvTek® Lubricant mentioned in the cleaning and maintenance section. Lubricating with other oils or silicone may cause the handpiece to run hot and slow. If you suspect that the handpiece was lubricated improperly, return it immediately to Arthrotek, Inc. for inspection and cleaning.

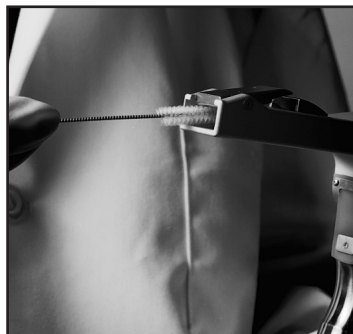
DO NOT re-sterilize cartridges.

Note: In the event of accidental immersion in fluid, remove the handpiece from the fluid, wipe it dry, and blow out with an air supply. Connect the handpiece to a hose, then to a nitrogen source, and run it with the trigger fully advanced for 20 to 30 seconds. Autoclave immediately and return to Arthrotek, Inc. for inspection.

handpiece and hose cleaning maintenance

Arthrotek, Inc. recommends that each handpiece be returned every six (6) months to the Arthrotek, Inc. facility for preventive maintenance.

Gloves should be worn when cleaning and handling contaminated instruments. Also, disconnect and properly dispose of the cartridge before cleaning the handpiece and hose.



Clean the handpiece and hose as soon as possible after use, especially in and around the “barrel” of the handpiece.

Use the CurvTek® Cleaning Brush to clean the two hex-shaped tubes inside the barrel of the handpiece.

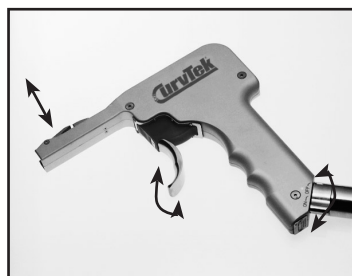
Remove all blood and debris from the surface of the handpiece with a soft bristle brush.

Note: A damp cloth or brush soaked in mild non-chlorine based detergent and water may be used to clean the handpiece and hose.



Connect the nitrogen hose to the handpiece to help protect the internal parts of the handpiece from water. (The hose should not be connected to a nitrogen source at this time).

Place the “barrel” of the handpiece downward while cleaning to help protect the internal parts from water.



Remove all debris by manipulating each moving part of the handpiece (On-Off switch, trigger and toggle latch).



Dry the surface with a soft cloth.

sterilization guide

1. Disconnect and properly dispose of used cartridges.
2. Clean all instruments. Do not sterilize dirty instruments.
3. Disconnect the nitrogen hose from the handpiece.
4. Properly place the handpiece and hose in the CurvTek® Sterilization Container System.

Recommended Sterilization Times for Handpiece and Hose Enclosed in the CurvTek® Sterilization Container System:

Type of Sterilizer and Temperature Setting	Condition of Case	Actual Steam Exposure Time
Gravity Discharge 250°	Wrapped	60 minutes
High Speed Pre-Vacuum 270° F	Wrapped	10 minutes
Pre-Vacuum (Flash) 275°	Wrapped	4 minutes

Note: The term “wrapped” means the handpiece and hose are enclosed in the CurvTek® Sterilization Container System without external hospital wrapping.

troubleshooting

I. If the handpiece will not start:

1. Check that the regulator valve is turned on and that the regulator is set at 90 – 100 PSI.
2. Ensure that the handpiece is receiving nitrogen pressure, and that the nitrogen supply tank has at least 500 PSI.
3. Ensure that the nitrogen hose is properly attached to the handpiece and regulator and ensure that the handpiece's On-Off switch is rotated to the “On” position.
4. Attach another hose to the regulator and handpiece if necessary.

If the handpiece still fails to operate, return it to Arthrotek, Inc. for inspection.

II. If the handpiece's trigger sticks while tunneling:

1. Slowly push the trigger forward until it is in the fully released position.

III. If the cutter heads fail to retract from the tunnel holes:

1. DO NOT pull the handpiece away from the bone, and DO NOT depress the handpiece's trigger.
2. Attempt to dislodge the cutter heads with a slight side-to-side handpiece motion.

service and ordering

To return the handpiece:

1. Contact Arthrotek Customer Service for a Return Goods Authorization (RGA) number at 1.800.535.8692.
2. Ship the handpiece via FedEx or UPS Air to Arthrotek, Inc. and be certain the RGA number is clearly marked on the outside of the box. International customers may return goods by standard AirMail or Air Parcel Post with a Customs Declaration.
3. Enclose a description of the problem you encountered such as, "Handpiece will not run," "Handpiece runs without depressing trigger," "Cartridge will not insert into the handpiece." This information is very helpful in diagnosing the problem.
4. If the instrument is out of warranty, enclose a purchase order number for the repair. If the handpiece is under warranty, enclose a purchase order number for the shipping charges.

A CurvTek® handpiece not under warranty that is sent to Arthrotek, Inc. for repair is subject to a minimum charge of \$50.00 to cover cleaning, inspection, testing, and processing.

Repairs estimated to cost less than 25 percent of the handpiece's current list price will be initiated immediately. Repairs estimated to exceed 25 percent of the handpiece's current list price will not be performed without customer authorization.

Arthrotek, Inc. will repair the handpiece within fifteen days from the time it is received. The handpiece will be returned to you via FedEx Standard Overnight unless you specify otherwise in writing with the return. All shipping charges are pre-paid and added to the invoice amount, if any.

limited warranty

Arthrotek, Inc. warrants to the first purchaser-user that each new handpiece shall be free from defects in material and workmanship for a period of one (1) year from the date of shipment from Arthrotek, Inc.

Arthrotek, Inc. warrants to the first purchaser-user that any handpiece service or repair work performed by Arthrotek, Inc. shall be free from defects in material and workmanship for a period of six (6) months from the date of shipment from Arthrotek, Inc. This warranty only applies to the actual work performed by Arthrotek, Inc.

Arthrotek, Inc.'s sole obligation in the event of a defect in material or workmanship during the warranty period shall be, at its option, to repair or replace the handpiece or to refund the amount paid for the handpiece.

The foregoing warranties apply only under normal use and do not cover (1) any damage or defect caused by accident, misuse, or abuse, (2) any damage or defect caused by alteration, tampering, repair or attempted repair by anyone other than Arthrotek, Inc., and (3) any damage or defect caused by unauthorized attachments or accessories.

EXCEPT AS SPECIFICALLY REQUIRED BY APPLICABLE LAW, THE FOREGOING WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND ARTHROTEK, INC. SPECIFICALLY DISCLAIMS ANY AND ALL WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. UNDER NO CIRCUMSTANCE SHALL ARTHROTEK, INC., ITS AUTHORIZED REPRESENTATIVES OR ITS AFFILIATED OR SUBSIDIARY COMPANIES BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES.

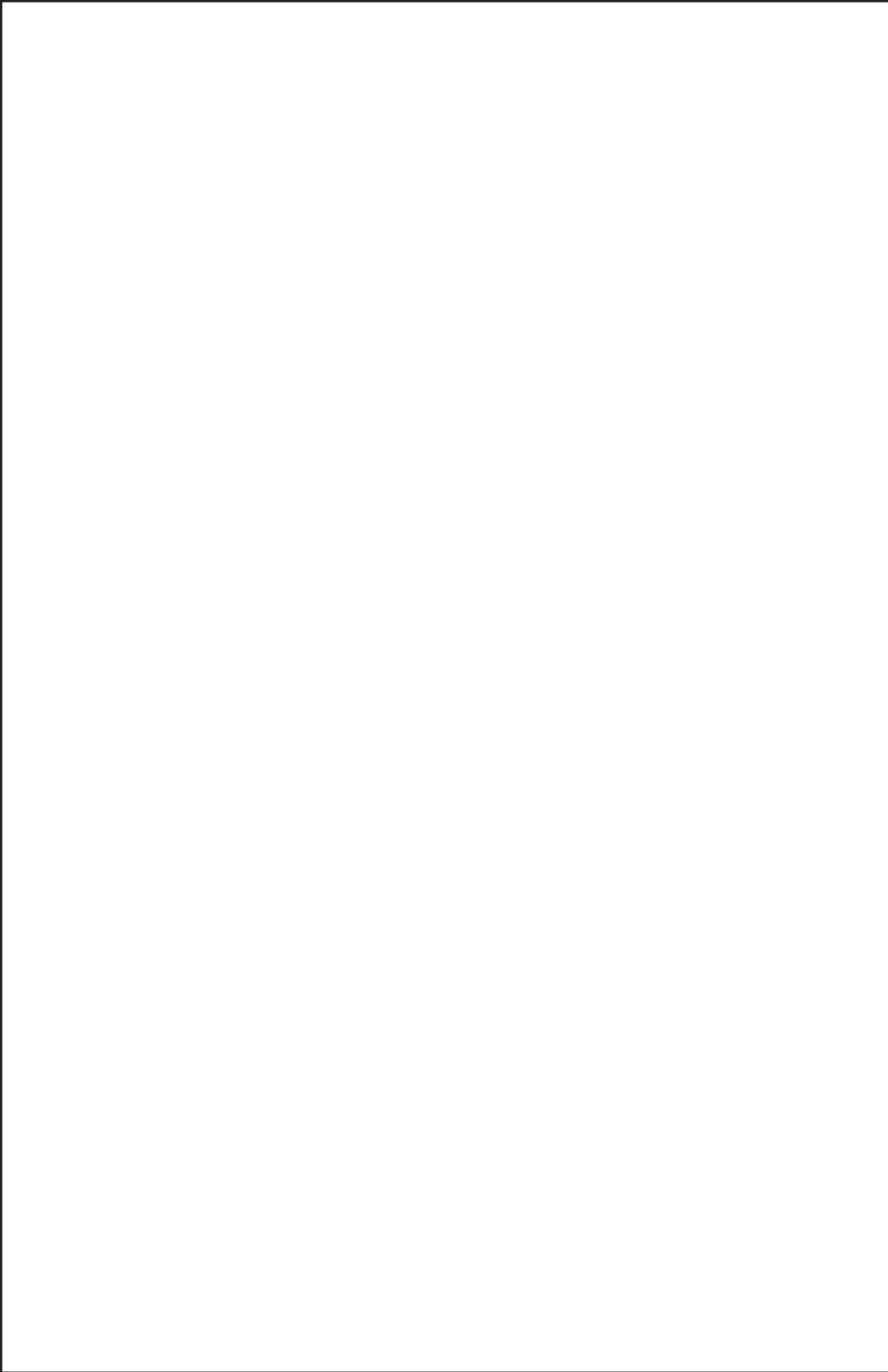
The foregoing warranties are not assignable or transferable and may not be extended or modified except in writing by an officer of Arthrotek, Inc.

Consigned or loaned handpieces will be maintained at no charge unless damaged during use.

Inquiries and Ordering Information:

In the United States,

Phone: 800.348.9500
Fax: 219.372.1718
Write: Arthrotek, Inc.
P.O. Box 587
Warsaw, IN 46581-0587





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