The Hall® Mini-Driver™ Pneumatic Handpiece Instruction Manual

Linvatec
Hall® Surgical

Proprietary Information

Record the Model and Serial Numbers of the handpiece(s), and date received. Retain for future reference.

Handpiece Model No.	_____	**Serial No**	_____	**Date**	_____
Handpiece Model No.	_____	**Serial No**	_____	**Date**	_____
Handpiece Model No.	_____	**Serial No**	_____	**Date**	_____
Handpiece Model No.	_____	**Serial No**	_____	**Date**	_____

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1.0 INTRODUCTION

It is recommended that personnel study this manual before attempting to operate, clean or sterilize the Hall® Mini-Driver™ Pneumatic Instrument System. The safe and effective use of this equipment requires the understanding of and compliance with all warnings, caution notices and instructions marked on the product and included in this manual.

1.1 Intended Use

The Mini-Driver Pneumatic Instrument System, combined with the many available attachments, is intended for sawing, reaming, drilling, wiring and pinning small bones or joints and connective tissue during orthopedic surgery.

1.2 General Warnings

1. This equipment is designed for use by medical professionals completely familiar with the required techniques and instructions for use of the equipment. **Read and follow all warning and caution notices and instructions marked on the product and included in this manual**.
2. Eye protection is recommended when operating equipment. 
3. Use only associated Hall® Surgical and Linvatec® attachments and accessories (i.e., saw blades, bits, etc.).
4. Handle all equipment carefully. If any equipment is dropped or damaged in any way, return it immediately for service.
5. Prior to each use, perform the following:
   - Inspect all equipment for proper operation.
   - Ensure all attachments, accessories and hoses are correctly and completely attached to the handpiece.
   - Check all pneumatic equipment for any air or nitrogen leakage. If leakage is noticed, return for service.
   - Always inspect pneumatic hoses for signs of wear or damage. **Do not use worn or damaged hoses. Replace immediately**.
   - Always inspect for bent, dull or damaged blades or drill bits.  Do not attempt to straighten or sharpen. Do not use if damaged. After use, dispose of properly.

6. Sagittal saw blades and drill bits are single use only. Do not resterilize. After use, dispose of properly.

7. Handpieces are factory sealed. Do not disassemble.

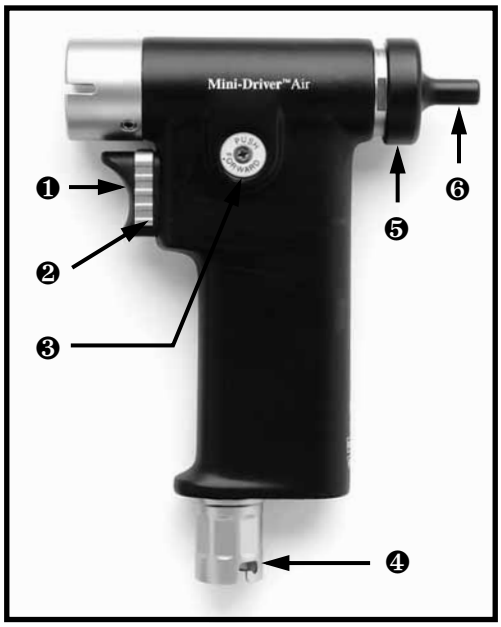
8. Do not pressurize hoses until all fittings have been connected and checked.
9. Never operate pneumatic handpiece above 110 psi (7 kg/cm^2) dynamic pressure unless an extension hose is added to the standard 10 foot hose. Excessive pressure may cause damage to the instrument and exert unusual stress on the hose.
10. The nitrogen regulator is only for use with pneumatically powered surgical devices.
11. Continually check all handpieces and attachments for overheating. Discontinue use and return equipment for service as necessary. Overheating of the bit or blade may cause damage to the bit or blade and may cause thermal necrosis.
12. Do not attach, insert or remove accessories or attachments while the handpiece is operating. **Place the handpiece safety to the appropriate safe position prior to installation or removal of items**.
13. After each use, thoroughly clean the handpiece and attachments (See **"3.1 Cleaning and Sterilizing" on page 22**).

1.3 Symbol Definitions

	**Attention, consult accompanying documents.**
	**No user service recommended. Refer servicing to qualified Linvatec service personnel.**
	**Indicates product component should not be sterilized.**
	**Indicates product component should not be immersed in any type of fluid.**
	**Indicates handpiece should not be immersed in any type of fluid.**
	**Indicates product should not be oiled or lubricated.**
	**Single Use Only.**
	**Eye Protection Required.**

Rx ONLY	**Caution: Federal Law restricts this device to sale by or on the order of a physician**

1.4 Pneumatic Handpiece (K200)



The Mini-Driver handpiece will accept all the attachments listed on pages 8 through 19.

❶ **Activation Trigger —** Used to activate the handpiece when the direction button is in either the forward or reverse position.

❷ **Safety Slide —** Slide the safety slide upward to place the handpiece in the safe, or non-operating position. Slide downward to place the handpiece in an operating mode.

❸ **Direction Button —** Press this button inward to place the handpiece in the forward (clockwise) direction. Press in the opposite direction for reverse (counter-clockwise).

❹ **Hose Connector —** The air hose attaches here from the air supply tank. The connector swivels 360° to help eliminate hose binding.

❺ **Attachment Lock/Release Collet —** Push inward to connect an attachment. Release to lock attachment in place.

❻ **Cannulation —** Used to stabilize long wires or pins.

2.0 SYSTEM INSTALLATION and OPERATION

2.1 Power Source and Regulator Installation and Operation

WARNING: Not for inhalation. Does not support life. For use with powered surgical devices only.

Research and experience have shown that water-pumped dry nitrogen is the ideal source for pneumatically-powered surgical instruments. Water-pumped dry nitrogen is 99.97% pure, and will not support combustion or corrosion. Compressed dry nitrogen is recommended as the pneumatic power source. It is available in standard cylinders.

Compressed dry nitrogen must meet the following specifications to ensure optimum safety for both patient and instrument.

Nitrogen Content: 99.97% pure, dry nitrogen.

Quality Assurance: To obtain the quality of gas needed, "water-pumped dry nitrogen, or liquid nitrogen, pumped dry" should be specified.

Nitrogen is readily available from gas supply houses in **H** cylinders holding slightly more than 300 cubic feet (8.50 cubic meters). Initial set-up costs are relatively inexpensive as compared to compressed air. Nitrogen can be placed in the operating room or in a storage area and piped into the operating room. Manifold systems are available to eliminate frequent tank changes.

CAUTION: Do not exceed 110 psi (7 kg/cm^2) operating pressure unless a hose longer than the standard 10 ft. Air Hose (REF A201) or extension hose is used. Add an additional 1 psi for every extra foot of hose.

The Mini-Driver pneumatic handpiece should be operated at 110 psi (7 kg/cm^2) for maximum operating efficiency, and should be monitored by the operating pressure gauge of the regulator. Lower pressure setting can be set for lower speed and torque requirements. Pressure must be set with the instrument running to ensure proper operating pressure.

Never start a procedure if the operating pressure gauge indicates less than 500 psi (35.1 kg/cm^2) in the tank. Never run the tank pressure below 200 psi (14.0 kg/cm^2).

The tank should be thoroughly wiped off with disinfectant and draped prior to placement in the operating room. Always have the tank securely fastened to a stable object.

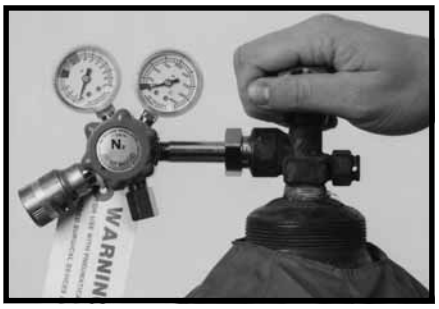
1. Prior to set-up in the operating room, open the tank valve (counterclockwise) slowly and allow enough gas to escape to blow out any debris that may have accumulated in the valve. Stay clear of the opening and the back of the tank during this procedure. Return the valve to the closed position.

2. Install the regulator with a 1 1/8 inch wrench.

NOTE: The threaded adaptor of the nitrogen regulator is designed to fit nitrogen fittings only. Incompatibility of the regulator and tank indicates a gas source other than nitrogen or an improper regulator for use with a nitrogen tank.

3. Once the regulator is securely installed, ensure the regulator knob is in the full off position by turning the regulator control knob counterclockwise. **SUDDEN PRESSURE EXERTED TO THE REGULATOR MAY CAUSE INTERNAL DAMAGE.**

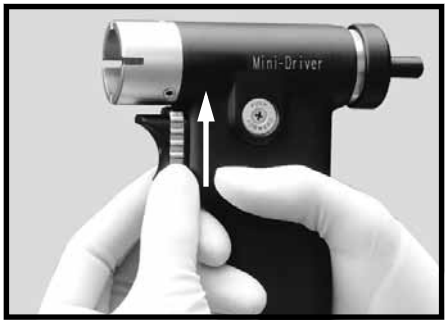
4. Slowly turn the tank valve fully open (counterclockwise). This will allow nitrogen to pressurize the regulator.



5. Insert the male Schrader end of the hose into the female Schrader on the regulator with an upward thrust.

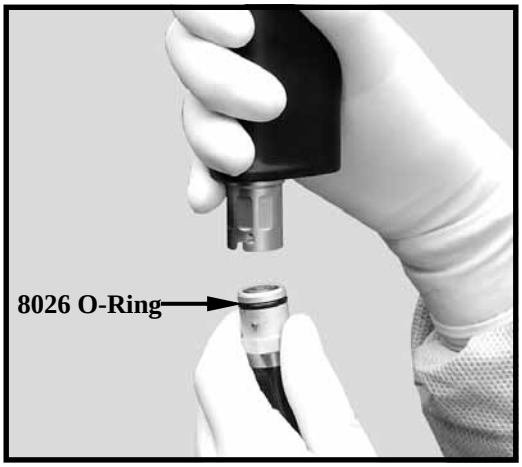
6. To connect the handpiece to the hose.

   (a) Place the handpiece safety slide in the safe (up) position.



(b) Before connecting the hose to the handpiece, ensure that the O-Ring on the end of the hose coupling is in place. If damage is present, replace the O-Ring (REF 8026).

(c) Grasp the hose coupling and insert it into the handpiece hose connector on the bottom of the handpiece.



(d) Grasp the handpiece hose connector to prevent it from turning and twist the hose coupling to the right (clockwise). Slightly pull on the hose so the internal pins securely engage in the indentations.

(e) To remove the hose from the handpiece, reverse steps 6a and 6b.

7. With the safety slide still in the safe position, install the desired attachment and accessory at this time by referencing **"2.2.1 Connecting/Removing Attachments" on page 8**.

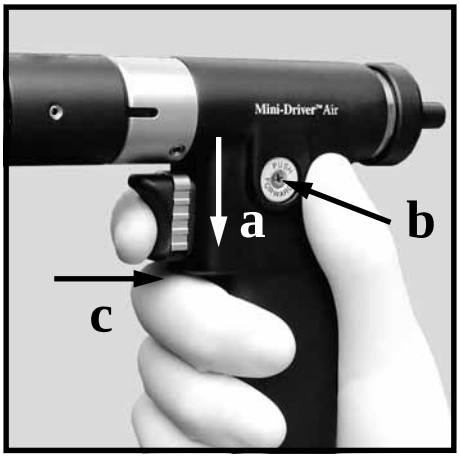
8. Operating pressure is established by gradually turning the regulator control knob clockwise. **ALWAYS establish the designated pressure on the operating pressure gauge with the instrument running.**

9. To operate the handpiece:

(a) Release the safety by sliding the safety slide downward.

(b) Place the directional control button to the desired operating position, either forward (F) or reverse (R).

(c) Depress the trigger.



10. While depressing the trigger adjust the nitrogen regulator until the gauge indicates 110 psi.

11. Before removing the instrument from the regulator:

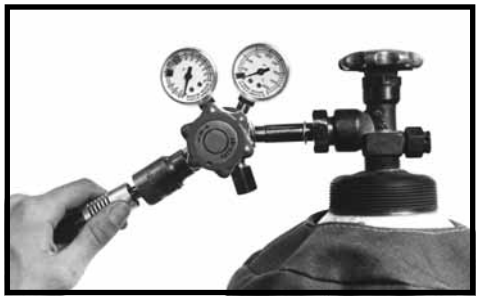
    (a) Close the tank valve by turning it clockwise.

    (b) Activate the instrument to bleed off line pressure.

    (c) Turn the pressure regulator knob counterclockwise until it stops.

    (d) Turn the female Schrader to the right to disengage the male Schrader fitting.

    (e) The hose can then be removed from the connector. Hold the end of the hose securely when disengaging the male Schrader fitting to prevent possible damage to the diffuser.



12. If the Hall Pneumatic Connector* is being used:

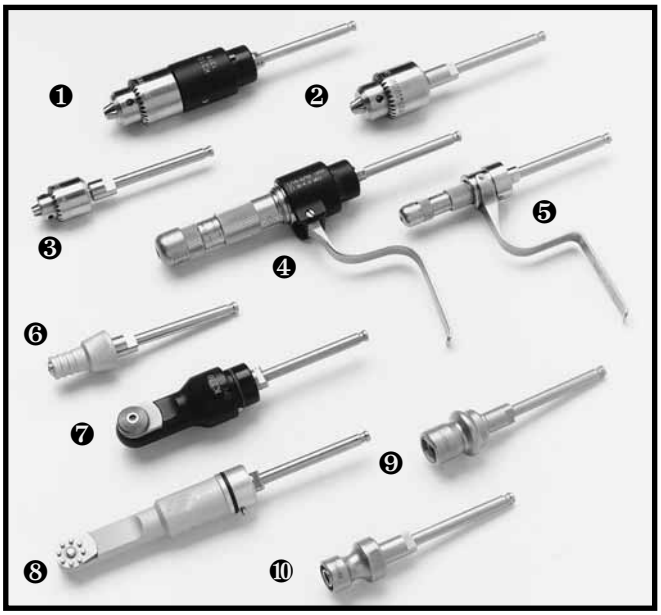
    (a) Locate the button marked “PRESS”.

    (b) Depress and hold the button until the audible release of residual gas is completed.

    (c) Release the button and remove the hose.

    (d) If the hose cannot be easily removed, depress the “PRESS” button again, release it and remove the hose.

* U.S. Patent 4,863,201



2.2 Attachments and Accessories

❶ High Torque Jacobs Chuck (K210)

❷ 1/4” Jacobs Chuck (K109)

❸ 5/32” Jacobs Chuck (K110)

❹ Automatic Pin Driver (K211)

❺ Automatic Wire Driver (K111A)

❻ ASIF/AO Twist Drill Chuck (K114A)

❼ Sagittal Saw (K220)

❽ Sagittal Saw (K120)

❾ Hudson Chuck (K113)

❿ Trinkle Chuck (K112)

2.2.1 Connecting/Removing Attachments

All Mini-Driver Handpiece attachments connect/disconnect in the same manner. See pages 9 through 16 for attachment information.

1. To connect an attachment:

   (a) Ensure the handpiece is in the safe, or off position.

   (b) Press the lock/release collet and insert the arbor end of the attachment into the handpiece. Release the lock/release collet to secure the attachment to the handpiece.

   (c) Ensure the attachment is secure by pulling it outward.

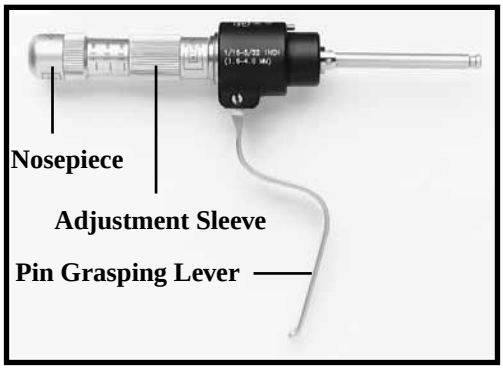
NOTE: On attachments that contain alignment pins, guide the alignment pin into one of the four available slots on the nosepiece.

(d) To remove the attachment, repeat steps 1(a) and 1(b) and pull out the attachment.

2.2.2 Pin and Wiredriver Attachments

Insertion of pins and wires, and the functionality of the handpiece with either pins or wires, is the same with either attachment.

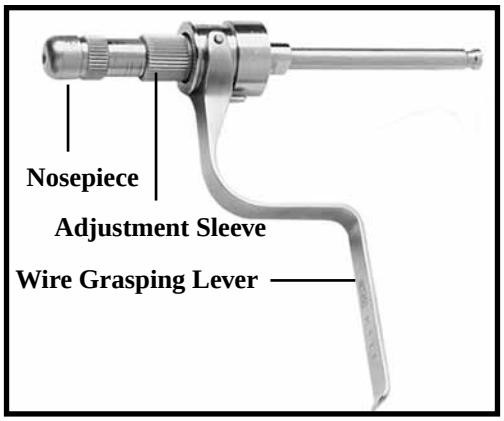
2.2.2.1 Pin Driver Attachment (K211)



The Automatic Pin Driver is designed to drive pins (wires) and drill bits compatible with the specifications below:

Through Cannulation: 1.6 - 4.0 mm
(0.062 in to 0.156 in.)
(1/16 - 5/32 in.)

2.2.2.2 Wiredriver Attachment (K111A)



The Automatic Wire Driver has a quick release for easy wire insertion, removal and advancement.

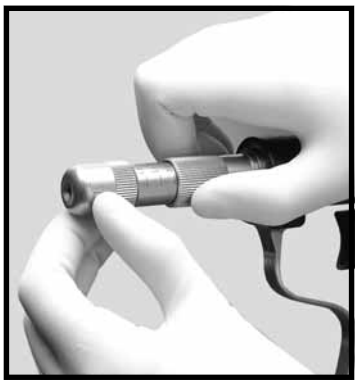
Through Cannulation: 0.7 - 1.8 mm
(0.028 in to 0.071 in.)
(1/32 - 5/64 in.)

2.2.2.3 Pin and Wire Insertion

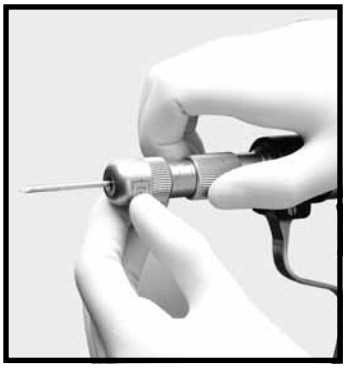
1. To insert a pin or wire:

   (a) Ensure the handpiece is in the safe position before inserting or removing a pin or wire.

   (b) Rotate the adjustment sleeve until the desired pin/wire size graduation appears on the shaft of the nosepiece. Do not turn the adjustment sleeve more than one turn past the marked graduation limits.



   (c) Insert the pin or wire. While holding the nosepiece, tighten the adjustment sleeve until the pin or wire is held firmly in place.



(d) Loosen the adjustment sleeve one half turn. The pin or wire should slide freely within the Pin/Wire Driver until the grasping lever is depressed.

(e) For pin/wire sizes that fall between the pin/wire size graduation, loosen the adjustment sleeve one full turn. The pin or wire should slide freely within the Pin/Wire Driver until the grasping lever is depressed.

2. To operate the handpiece:

   (a) Release the safety and place the handpiece in the forward position.

   (b) To grip and drive the wire or pin, depress the grasping lever until flush with the handpiece and depress the trigger.

3. To reposition the handpiece on the wire or pin:

   (a) Release the trigger and grasping lever.

   (b) Slide the handpiece along the wire or pin.

   (c) Follow step 2 to further drive the wire or pin.

4. To remove threaded wires from the patient:

   (a) Insert the wire into the front of the attachment (see step 1(a) through 1(e)).

   (b) Place the handpiece in the reverse position.

   (c) Simultaneously squeeze the grasping lever and depress the trigger.

2.2.3 Sagittal Saw Attachment (K120)

NOTES:

1. **The K120 Sagittal Saw attachment only accepts K120 and K130 series blades.**
2. **For more precise osteotomies, lower cutting temperatures, and reduced instrument wear, use a new blade for each procedure.**
3. **Sagittal Saw blades are single-use only. Dispose of properly after use.**

1. To attach the Sagittal Saw attachment, reference **“2.2.1 Connecting/Removing Attachments” on page 8**.

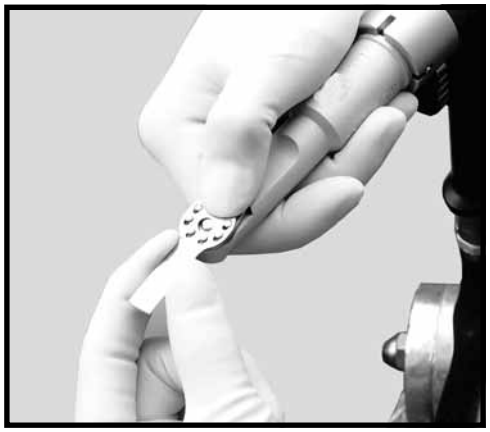
2. The Sagittal Saw attachment may be placed in any of four positions at 90 degree angles.

3. To attach a blade:

   (a) Ensure the handpiece is in the safe position before attaching or removing blades.

   (b) Press the blade down and onto the holding pins, then push down and back to allow the center retaining button to pop up and lock the blade in place.

   (c) Ensure the blade is secured by pulling outward on the blade.



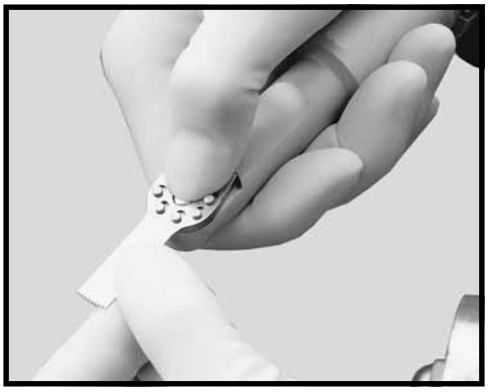
4. The blade may be placed in five positions with a 180 degree radius.

5. To operate the handpiece, release the safety and depress the trigger.

6. To remove a blade:

   (a) Ensure the handpiece is in the safe position.

   (b) Depress the center retaining button, pull the blade forward and lift off the pins.

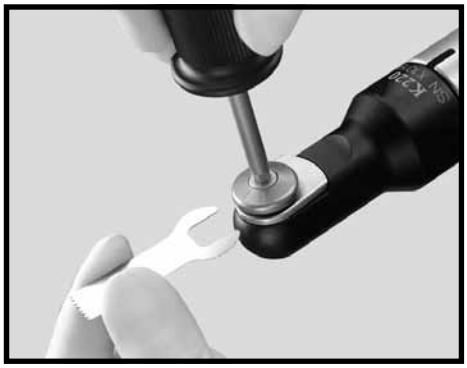


2.2.4 Sagittal Saw Attachment (K220)

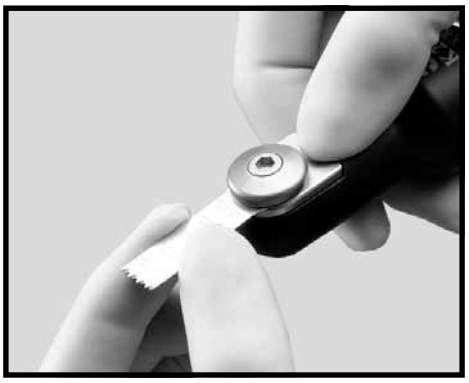
NOTES:

1. **The K220 Sagittal Saw attachment only accepts K140 and K150 series blades.**
2. **For more precise osteotomies, lower cutting temperatures, and reduced instrument wear, use a new blade for each procedure.**
3. **Sagittal Saw blades are single-use only. Dispose of properly after use.**

1. To attach the Sagittal Saw attachment, reference **"2.2.1 Connecting/Removing Attachments" on page 8**.
2. The Sagittal Saw attachment may be placed in any of four positions at 90 degree angles.
3. To attach a blade:
   (a) Ensure the handpiece is in the safe position before attaching or removing blades.
   (b) Insert the blade into the blade holder in the desired blade position. Blades may be placed in any of five positions with a 180 degree radius.
   (c) Tighten the blade by inserting the K201 Wrench and turning clockwise until secure.



   (d) Ensure the blade is secured by pulling outward on the blade.



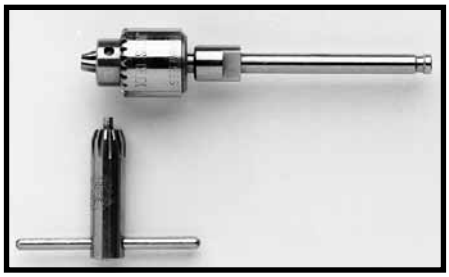
4. To operate the handpiece, release the safety and depress the trigger.
5. To remove a blade:
   (a) Ensure the handpiece is in the safe, or off position.
   (b) Insert the wrench and turn one-half turn counterclockwise while simultaneously pulling out the blade.

2.2.5 All Jacobs Chuck Attachments

CAUTION: Do Not use burs in any Jacobs Chuck attachment.

1. To attach any Jacobs Chuck attachment, reference **“2.2.1 Connecting/Removing Attachments” on page 8**).
2. Insert the desired accessory into the chuck and secure it with the appropriate key.

2.2.5.1 5/32” Jacobs Chuck (K110)

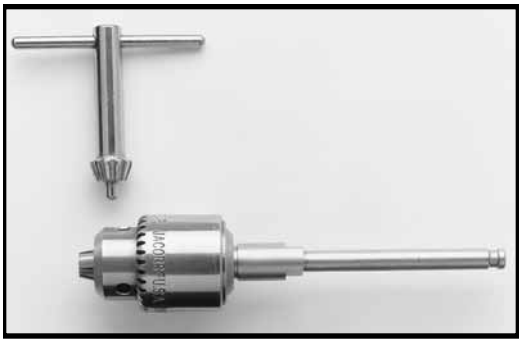


This attachment is designed to drive straight plain shank twist drill bits, pins, and wires compatible with the specifications below:

Specifications:

Jaw Cannulation:	0 - 4.0 mm (0 to 0.156 in.) (0 to 5/32 in.)
Through Cannulation:	4.0 mm (0.156 in.) (5/32 in.)
Associated Chuck Key:	REF D298K and 5044-999-53

2.2.5.2 1/4” Jacobs Chuck (K109)

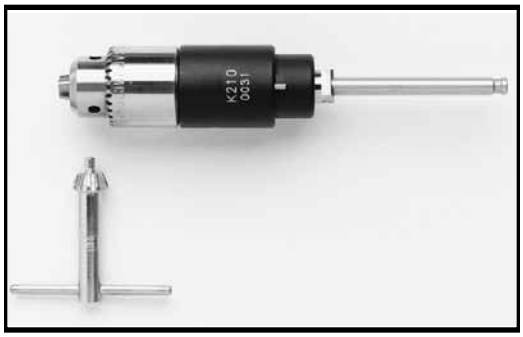


This attachment is designed to drive straight shank twist drill bits, pins, and wires compatible with the specifications below:

Specifications:

Jaw Cannulation:	0 - 6.35 mm (0 to 0.25 in.) (0 to 1/4 in.)
Through Cannulation:	4.0 mm (0.156 in.) (5/32 in.)
Associated Chuck Key:	REF D298L and 5044-999-52

2.2.5.3 High-Torque Jacobs Chuck (K210)

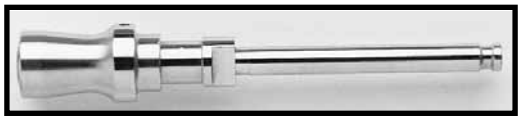


This attachment is designed to drive large (6 mm - 14 mm) cannulated drill bits and pins. Accepts drill bits and other accessories compatible with the specifications below:

Specifications:

Jaw Cannulation:	0 - 6.35 mm (0 to 0.25 in.) (0 to 1/4 in.)
Through Cannulation:	2.4 mm (0.094 in.) (3/32 in.)
Associated Chuck Key:	REF D298L and 5044-999-52

2.2.6 Trinkle Chuck Attachment (K112)

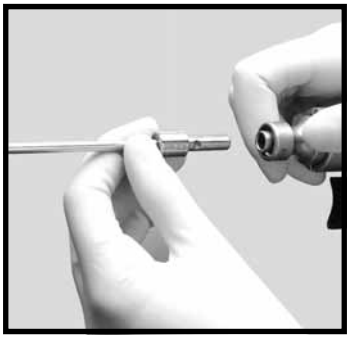


This attachment is designed to drive drill bits, automatic screwdrivers, and other accessories with Trinkle fittings.

Specifications:

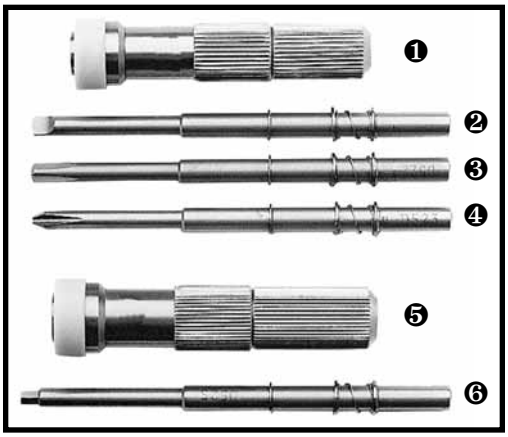
Through Cannulation: 4.0 mm
(0.156 in.)
(5/32 in.)

1. To attach a Trinkle Chuck attachment, reference **"2.2.1 Connecting/Removing Attachments" on page 8**).
2. To insert a Trinkle Shank accessory into the Trinkle Chuck attachment:
   (a) Pull the locking sleeve chuck back. Insert the accessory and release the locking sleeve.
   (b) Turn the accessory in the chuck until it locks.



   (c) Ensure the attachment is secure by pulling it outward.
   (d) Ensure the accessory is securely seated in the attachment before use by pulling outward on it.
3. To remove the accessory, pull back the locking sleeve chuck and remove the accessory.

2.2.6.1 Automatic Screwdrivers for the Trinkle Chuck Attachment (D520/D524)



❶ Screwdriver (D520)

❷ Slotted Bit (D521)

❸ Cruciate Bit (D522)

❹ Phillips Bit (D523)

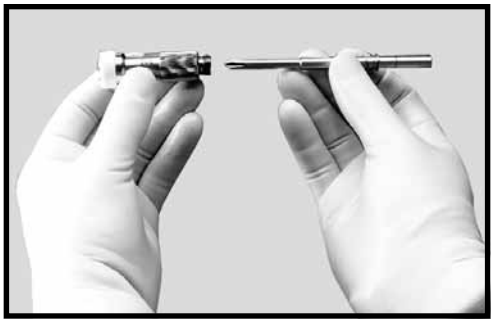
❺ Screwdriver (D524)

❻ Hex Bit for AO type screws (D525)

1. To insert a bit into the screwdriver.

   (a) Unscrew the bit retainer section (counterclockwise) from the screwdriver.

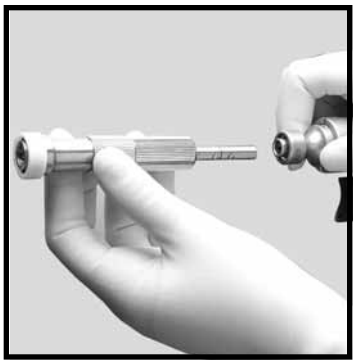
   (b) Insert the bit into the back of the screwdriver, tip first.



   (c) Slide the bit retainer over the bit and thread the retainer back on the screwdriver by turning it clockwise until tight.

   (d) While retracting the locking sleeve on the Trinkle Chuck attachment, insert the screwdriver into the chuck and release the locking sleeve.

   (e) Turn the accessory in the chuck until it locks.



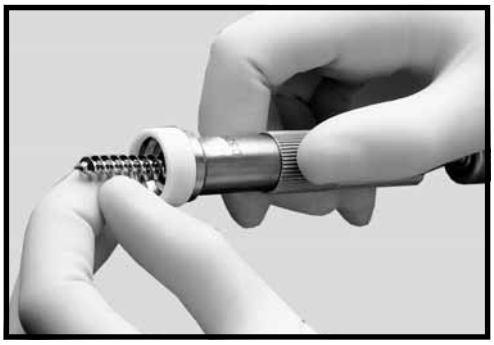
(f) Ensure the attachment is secure by pulling outward on it.

CAUTION: Ensure that the screwdriver is securely seated in the Trinkle Chuck before use.

2. To engage the screwdriver bit into the screw head.

   (a) Insert the head of the screw into the screwdriver.

   (b) Hold the screw firmly and press the knurled portion of the screwdriver body forward so the teflon collar snaps over the head of the screw.



3. To remove the screw, retract the teflon collar and remove the screw.

2.2.7 Hudson Chuck Attachment (K113)

This attachment is designed to drive accessories with Hudson type fittings.

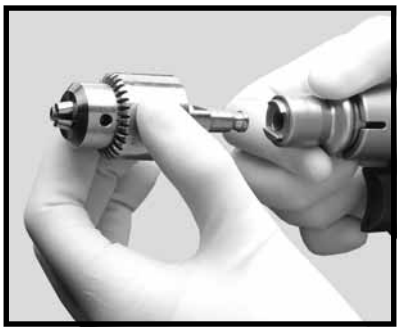
Specifications:

Through Cannulation: 4.0 mm
(0.156 in.)
(5/32 in.)

1. To attach a Hudson Chuck attachment, reference **“2.2.1 Connecting/Removing Attachments” on page 8**).

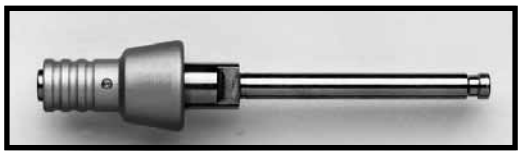
2. To insert a Hudson Shank accessory into the Hudson Chuck attachment:

   (a) Pull the locking sleeve chuck back. Insert the accessory and release the locking sleeve.



   (b) Ensure the accessory is fully seated by pulling outward on it.

2.2.8 ASIF/AO Twist Drill Chuck Attachment (K114A)

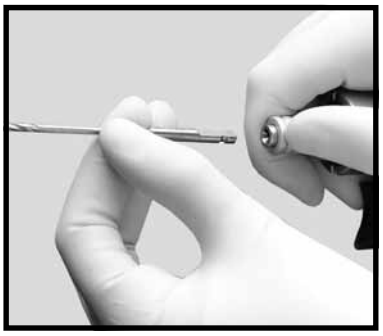


This attachment is designed to drive drill bits with ASIF/AO (Synthes) type fittings.

Specifications:

Through Cannulation: 3.2 mm
(0.125 in.)
(1/8 in.)

1. To attach an ASIF/AO Drill Chuck attachment, reference **“2.2.1 Connecting/ Removing Attachments” on page 8**).
2. To insert an ASIF/AO drill bit into the an ASIF/AO Drill Chuck attachment:
   (a) Pull the locking sleeve chuck back. Insert the drill bit and release the locking sleeve.



   (b) Ensure the drill bit is fully seated by pulling outward on it.

3.0 MAINTENANCE

This section explains the importance of keeping your Mini-Driver Pneumatic System well maintained. It contains a maintenance schedule to assist you in determining the maintenance interval requirements of your instruments.

Regular and proper maintenance of your powered surgical instruments are the best way to protect your investment. It is essential that you have your powered surgical instruments serviced as scheduled so as to retain their optimum performance and reliability, which will reward you with safer, less problematic product performance over time. The following maintenance schedule specifies which instruments need attention and how often you should have them serviced.

The service and time intervals shown in the maintenance schedule assume you will use the instruments as indicated in this manual, including proper day-to-day operation, cleaning, and sterilization. Proper care and handling of the instruments on a day-to-day basis are extremely important to ensure safe and efficient operation. Refer to section 2.0 of this instruction manual for information on proper system installation and operation and section 3.0 for proper day-to-day maintenance.

Your authorized Linvatec Service Department is the most knowledgeable about the instruments and will provide competent and efficient service. Service at Linvatec at the indicated service intervals 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 instruments or instrument failure and is not recommended. See **“5.3 Linvatec and Hall® Surgical Instrument Warranty” on page 34** for more information on product warranties.

Table 1: Maintenance Schedule

Catalog Number	Product Description	6 Months	12 Months
K200	Mini-Driver Pneumatic Handpiece		•
K109	1/4” Jacobs Chuck Attachment		•
K110	5/32” Jacobs Chuck Attachment		•
K111	Automatic Wire Driver Attachment		•
K112	Trinkle Chuck Attachment		•
K113	Hudson Chuck Attachment		•
K114A	ASIF/AO Twist Drill Chuck Attachment		•
K120	Sagittal Saw Attachment		•
K210	High Torque Jacobs Chuck Attachment		•
K211	Automatic Pin Driver Attachment		•
K220	Sagittal Saw Attachment		•

3.1 Cleaning and Sterilizing

3.1.1 Cleaning Precautions

1. Follow universal precautions for protective apparel when handling and cleaning contaminated instruments.
2. Saw blades are single-use only. Dispose of properly after use.

3. **Never immerse the handpiece, hoses, pressure regulator, or attachments**.

4. Never sterilize the regulator.

5. Never clean handpieces with bleach, chlorine-based detergents, liquid or chemical disinfectants, or any products containing sodium hydroxide (i.e., INSTRU-KLENZ, Buell Cleaner). They will degrade the anodized aluminum coating.
6. Do not allow any fluids such as water or Blitz™ II Surgical Instruments Cleaner and Lubricant (M105A) to enter handpiece. Fluid contacting internal parts will cause corrosion. Surface cleaning with Blitz II Cleaner is recommended.
7. Never clean equipment in an ultrasonic cleaner or combination washer/sterilizer.

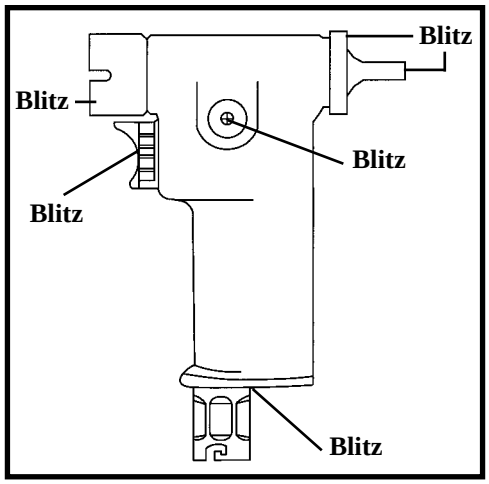
3.1.2 Handpiece and Attachment Cleaning Instructions

Clean the handpiece and attachments as soon as possible after use.

1. Leave the hose attached to the handpiece, but remove all attachments (i.e., chucks, saws) and accessories (i.e., saw blades, bits) prior to cleaning.
2. Thoroughly scrub the handpiece with a clean, soft brush dampened with a mild, pH-balanced detergent. Likewise, clean the handpiece hose and attachments. Remove all traces of blood, coagulated material, stains, etc. **Do not immerse** equipment in soap solution or rinse water.
3. Thoroughly clean the cannulation with a cleaning brush. Feed the wire end of the brush through the back of the handpiece. Repeat until all debris is removed.
4. Manipulate all moving parts of the handpiece and attachments to ensure all debris is removed. If not, clean again until all debris is removed.
5. Keep the nose of the handpiece pointed downward and rinse under a fine spray of water to remove all traces of soap. Likewise, rinse all attachments. Flush the surfaces free of tap water with distilled water to prevent metal discoloration.
6. Shake the equipment free of water and wipe the surfaces with a clean, lint-free towel.

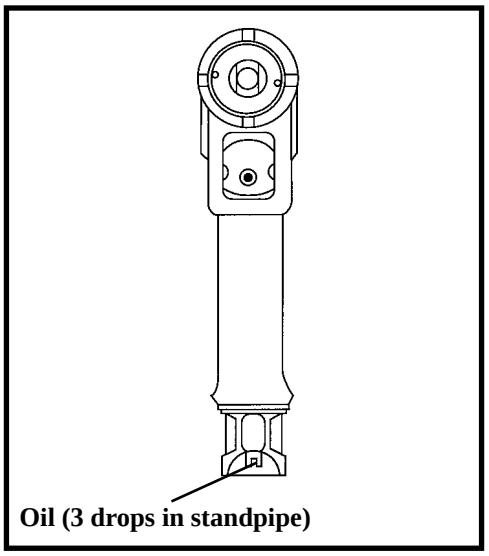
3.1.3 Handpiece and Attachment Lubricating Instructions

1. Spray Blitz II Surgical Instruments Cleaner and Lubricant liberally over exposed surfaces of handpiece and attachments, especially all moving parts.



2. Wipe the surfaces with a clean, lint-free towel.

3. Disconnect the hose from the handpiece. While depressing the trigger, apply three (3) drops of Lubricant (M317) into the handpiece standpipe.



4. Reconnect the hose to the handpiece and operate at full speed for five seconds to disperse lubricant.

3.1.4 General Sterilization Information

Steam sterilization is safe and effective and has no contraindications for its use in sterilizing powered surgical handpieces, accessories and attachments.

3.1.4.1 Sterilizing Warnings, Precautions and Notes

WARNING: The use of disinfecting solutions for an exterior instrument wipe will not sterilize equipment and is not recommended.

1. Do not sterilize handpieces in cold sterilants like CIDEX.
2. Never sterilize any handpiece in a Washer/Sterilizer, STERIS System, STERRAD System, Abtox Plazlyte™ or comparable sterilization methods.
3. Do Not "Peel Pack" handpieces or attachments for sterilization. Sterilization in a sealed pouch traps moisture which can cause damage.
4. Remove the hose from the handpiece before sterilizing.
5. Use of an autoclave case is recommended.
6. Do not run handpieces while warm. Allow adequate time for cooling prior to surgery. Do not immerse in liquid or cover with a damp cloth to cool. Cool by exposure to room temperature.

NOTES:

1. **The following guidelines do not guarantee the device is sterile after the procedure. Your institution is still responsible for the normal sterility assurance validation.**
2. **Additional drying time may be required for complete heat and moisture dissipation. Operation of a handpiece that is not completely cool or dry may decrease performance and/or reliability**
3. **Sterilization validation is based on AAMI guidelines (Association for the Advancement of Medical Instrumentation).**

All handpieces and attachments may be processed in a pre-vacuum steam sterilizer (Steam Pre-vacuum) or in a gravity (downward) displacement sterilizer (Steam Gravity).

Before Sterilization:

- Remove all accessories (e.g., drill bits, blades) from attachments.
- Remove all attachments (e.g., chucks, saws, and/or hoses) from the handpiece.
- Ensure all attachments were cleaned.
- Lubricate, as necessary, equipment requiring lubrication, per guidelines in **"3.1.2 Handpiece and Attachment Cleaning Instructions" on page 22**, prior to sterilization.

Recommended sterilization exposure times of individual handpieces and attachments are as follows:

Table 2: Sterilization Parameters

Sterilization Type	Temperature	Exposure Time	Dry Time
Mini-Driver Handpiece and Attachments			
Steam Pre-vacuum	270 - 272°F (132 - 133°C)	4 minutes	8 minutes minimum *
Steam Gravity	270 - 272°F (132 - 133°C)	25 minutes	8 minutes minimum *
Steam Gravity	250 - 254°F (121 - 123°C)	50 minutes	8 minutes minimum *
*** CAUTION: An eight (8) minute minimum dry cycle must be run on handpieces and attachments every time the product is sterilized. Failure to use a dry cycle may lead to reduced product performance or premature product failure. Operation of a handpiece that is not completely cool or dry may decrease performance and/or reliability.**			

3.2 Troubleshooting

Table 3: Troubleshooting

Symptom	Possible Cause	Corrective Action
Mini-Driver Pneumatic (K200) Handpiece		
Lack of handpiece power.	♦ Forward/Reverse button not in full operating position.	♦ Push button fully into position.
	♦ Regulator malfunction.	♦ Run handpiece on another regulator to see if the problem is the handpiece or regulator. Replace/ repair appropriate piece of equipment.
	♦ Operating pressure incorrect.	♦ Set pressure to recommended operating pressure.
		♦ If using a hose longer than 10 ft. or an extension hose is being used, add an additional one psi of pressure per each additional foot of hose.
	♦ Hose not fully or properly seated in regulator and/or handpiece.	♦ Check hose connections, ensure they are completely seated.
	♦ Restrictions in hose.	♦ Remove any hose restrictions.
	♦ Tank pressure below 500 psi.	♦ Do not start procedure if tank pressure is below 500 psi. Replace tank.
	♦ Tank valve not completely open.	♦ Completely open tank valve.
	♦ Ensure nitrogen is being used.	♦ Compressed air (especially if contaminated) may reduce performance.
	♦ Trigger safety activated.	♦ Slide trigger safety to the off position.

Table 3: Troubleshooting

Symptom	Possible Cause	Corrective Action
Mini-Driver Pneumatic (K200) Handpiece		
Lack of handpiece power (continued).	♦ Lack of lubrication in motor.	♦ Follow lubrication instructions (reference **"3.1.2 Handpiece and Attachment Cleaning Instructions" on page 22**). ♦ If malfunction persists, return for service.
Hose leaking at hose/handpiece connection.	♦ Missing or worn O-Ring on hose connector.	♦ Replace O-Ring (REF 8026).
Air leakage between air control dial and hose swivel connector of handpiece.	♦ Debris around ball seal of hose connector at handpiece end.	♦ Remove hose. Depress and spray ball seal with Blitz II Cleaner and Lubricant. Reconnect hose. ♦ If problem persists, replace hose.
Hose has tears and/or cuts.	♦ Improper storage.	♦ To prevent recurrence, disconnect hose from handpiece before placing in autoclave case. ♦ When placing in case, take care not to pinch hose. ♦ Return hose for repair or replace hose.

Table 3: Troubleshooting

Symptom	Possible Cause	Corrective Action
Attachments do not lock into handpiece.	♦ Attachment not oriented correctly. ♦ Debris in locking collar or attachment.	♦ Will only attach in correct position (reference **“2.2.1 Connecting/Removing Attachments” on page 8**). ♦ Clean thoroughly with Blitz II Cleaner and Lubricant (reference **“3.1.2 Handpiece and Attachment Cleaning Instructions” on page 22**). ♦ If problem persists, return for service.

4.0 TECHNICAL SPECIFICATIONS

Linvatec Corporation is certified by TÜV Product Service to EN ISO 9001 and EN 46001, and to the Medical Device Directive 93/42/EEC with certificates for Annex II, Clause 3; Annex II, section 4; and Annex V.

4.1 Handpiece

Typical Operating Requirements:

Motor:	Vane (Variable Speed)
Operating Speed (forward/reverse):	0 - 1000 rpm (nominal)
Torque (nominal):	6 in.-lbs. forward 6 in.-lbs. reverse
Through Cannulation:	0 - 4.0 mm (0 - 0.156 in.)
Operating Pressure:	620 - 760 kPa (90 - 110 psi)
Nitrogen Consumption:	140 L/min (5.0 scfm)
Duty Cycle:	1 minute ON, 3 minutes OFF
Width:	4.375 in. (11.1 cm)
Height:	6.25 in. (15.9 cm)
Weight:	19.7 oz. (560 g)
Hose Length:	10 ft. (3m)

NOTE: There are no toxic components used in the manufacture of the Mini-Driver System. After the useful life of the product, dispose of components and service parts properly.

4.2 System Environmental Requirements

Operating:

Ambient Operating Temperature:	+ 50°F to 77°F (+ 10°C to + 25°C)
Relative Humidity:	30% to 75%
Atmospheric Pressure:	700 hPa to 1060 hPa

Transport and Storage:

Ambient Temperature:	- 40°F to 158°F (- 40°C to + 70°C)
Relative Humidity:	10% to 100% including condensation
Atmospheric Pressure:	500 hPa to 1060 hPa

5.0 CUSTOMER SERVICE and WARRANTY

5.1 Customer Service

If you need technical assistance regarding the use or application of this product, or you encounter a problem that requires servicing or repair, contact Linvatec Customer Service at 800-925-4255 or your Hall Surgical Sales Representative. Outside the U.S. contact your Linvatec/Hall Representative.

Report any events involving injuries or malfunctions to the Linvatec Regulatory Affairs Department.

Returning products for any reason requires a Return Goods (R.G.) number that can be obtained by contacting Linvatec Customer Service. Please provide the following information:

- Product Number
- Serial/Lot Number
- Reason for Return
- Original Invoice Number
- Date of Purchase

Repairs

Products returned for repair must have an authorized Return Goods (R.G.) number prominently displayed on the box and included on all paperwork. Refer to this number if making inquiries about the repair status. Please call Linvatec Customer Service and provide the following information to obtain an R.G. number prior to returning any product for repair:

- Product Number
- Serial/Lot Number - if applicable
- Original Invoice Number
- Date of Purchase
- Detailed description of the problem
- Purchase Order Number

If you require a quote - Notify Customer Service when requesting your R.G. number, or on the paperwork returned with the product indicate that a quote is required. If a quote is not requested the repair will be processed and your account billed accordingly - provided the repair is not covered under warranty.

Minimum repair charge - There is a minimum repair charge (except for products covered under warranty). This charge also applies to products returned for repair in which a problem cannot be verified.

Whenever it is required to return your product for repairs, be sure to package it in a protective carton. We recommend that you save the original shipping container for this purpose. In-transit damage is not covered by the warranty, therefore, it is best to always insure shipments.

Returned Goods

Products must be returned within 45 days of ship date. Returned products are subject to a restocking fee of fifteen percent (15%) of the purchase price (minimum charge $25). Products returned as a result of errors attributable to Linvatec are exempt from this fee.

Returns must have an authorized Return Goods (R.G.) number prominently displayed on the box and included on all paperwork.

Returns must be shipped prepaid freight, otherwise they will not be accepted. **Products must be decontaminated and sterilized before returning. Products that are contaminated with biohazardous materials will be immediately returned to you for proper decontamination and sterilization**.

Linvatec
Attn.: Customer Service Dept.
11311 Concept Boulevard
Largo, Florida 33773-4908 USA

Customer Service

(within U.S.)	**Phone:**	**800-925-4255**
	FAX:	**727-399-5256**
(outside U.S.)	**Phone:**	**727-392-6464**
	FAX:	**727-397-4540**

Linvatec Regulatory Affairs

(within U.S.)	**Phone:**	**800-237-0169**
(outside U.S.)	**Phone:**	**727-399-6620**

5.2 Handpieces, Attachments and Accessories

REF	Description
K200	Pneumatic Handpiece
K210	High Torque Jacobs Chuck
K109	1/4” Jacobs Chuck
K110	Small Jacobs Chuck
K111A	Automatic Wire Driver
K112	Trinkle Chuck
K113	Hudson Chuck
K114A	ASIF/AO Twist Drill Chuck
K120	Sagittal Saw
K211	Automatic Pin Driver
K220	Sagittal Saw
D520	Screwdriver
D521	Slotted Bit
D522	Cruciate Bit
D523	Phillips Bit
D524	Screwdriver
D525	Hex Bit for AO type screws
M105A	Blitz II Surgical Instrument Cleaner and Lubricant
M317	Lubricant
E306	Autoclave Case
A201	Pneumatic Hose, 10 ft.
M207	Single Regulator
M208	Dual Regulator

5.3 Linvatec and Hall® Surgical Instrument Warranty

Linvatec Corporation, ("the Company"), warrants to the first purchaser or lessee ("Customer") that the Linvatec and Hall Surgical instruments, attachments and parts manufactured by or for the Company (hereinafter collectively "Instruments") have been tested, inspected, and shipped in proper working order.

The Company warrants all new Instruments to be free from defects in materials and workmanship for the following periods, measured from Customer's receipt:

1. Powered Surgical Equipment (battery, electric, pneumatic) - Twelve (12) Months
2. Battery Chargers - Twelve (12) Months
3. Battery Packs - Three (3) Months
4. Burs and Blades - Upon receipt
5. Bur Guards, Blade Guards, and Attachments - Six (6) Months
6. Skull Perforators - Six (6) Months
7. Pneumatic Hoses - Six (6) Months
8. Handpiece Cords and Power Cords - Six (6) Months
9. Camera Consoles - Twenty-four (24) Months
10. Video Components - Twelve (12) Months
11. Video Cables and Light Guides - Three (3) Months
12. Non-autoclavable Camera Heads - Twelve (12) Months
13. APEX® Autoclavable Camera Heads - 500 use service program (prorated credit after 250 uses)
14. Envision 1/4" Autoclavable Camera Heads - 500 use or Twelve (12) months, whichever comes first
15. Envision Autoclavable 3CCD Camera Heads - Twelve (12) months
16. Shutt SLG Instruments - Lifetime
17. Shutt Non-SLG Instruments - Twelve (12) Months
18. Footswitches - Twelve (12) Months
19. Irrigation Systems - Twelve (12) Months
20. Reusable Procedure Specific Instruments - Twelve (12) Months

The Mini-Driver handpiece and attachments described in this manual are to be returned to the factory or a Linvatec authorized service facility for routine maintenance according to the Maintenance Schedule Table starting on page 21.

Failure to follow this routine maintenance schedule may result in damage to the handpiece and/or console, and may invalidate the product warranty.

If within the specified warranty period the Customer discovers that an Instrument has a defect in material and/or workmanship, it must promptly notify the Company. If it becomes necessary to return the Instrument to the Company, the Customer must (a) acquire a "Returned Goods" authorization from the Company Customer Service, (b) pack the unit carefully, and (c) return it to the Company via air freight, prepaid.

Within a reasonable time after receipt of Instrument, the Company will investigate and shall correct any defect covered by warranty by providing, at its option, one of the following: service or repair of the Instrument, a replacement of the Instrument, or a refund of the purchase price of the Instrument. These remedies are the Customer's exclusive remedies under this warranty.

The Company warrants that all parts and assemblies used in the repair or service of Instruments meet new part functional specifications, although some parts or assemblies may have been remanufactured.

All parts and assemblies replaced by the Company shall become the property of the Company.

The foregoing limited warranties do not apply to:

1. Instruments which have been tampered with, altered, abused or misused.
2. Instruments damaged through use with other than Company authorized accessories, attachments, burs or blades.
3. Instruments not manufactured by or for the Company.
4. Instruments used for purposes other than those for which they were designed and manufactured, including use in any way inconsistent with the instructions and warnings contained in the Company instruction manuals and package inserts.
5. Instruments which were last serviced, refurbished, reprocessed or reconditioned by a nonauthorized service entity.
6. Instruments which did not have their aforementioned routine maintenance schedule followed.

The foregoing limited warranties are in lieu of all other warranties, expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Except claims for personal injury, in no case shall the Company be liable for any special, incidental or consequential damages based upon breach of warranty or any other legal theory. Some jurisdictions do not allow limits on warranties, or on remedies, and, in such jurisdictions, the limits in this and the preceding paragraphs may not apply.

The Company reserves the right (a) to make design changes to Instruments at anytime without notice to Customer and without incurring any obligation to incorporate those changes into Instruments previously purchased or leased, and (b) to make changes from time to time in the contents of any publication, instruction manual or package insert without any obligation to notify Customers of such revisions or changes.

Hall® Surgical

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