

INSTRUCTIONS FOR USE: INTELLISENSE DRILL TECHNOLOGY® SOFTWARE VERSION 0.4.1



MCGINLEY ORTHOPEDICS
ENGINEERING MEDICAL PROGRESS

Device Overview

This document outlines the operation and sterilization requirements for IntelliSense Drill Technology® which is intended to be used by surgeons, nurses, technicians, and other related personnel. The IntelliSense® Drill is the only surgical drill that provides instant feedback of the depth and location of the drill point during a surgery. IntelliSense Drill Technology® includes the IntelliSense® Drill with the tethered power/data cable, the IntelliSense® Controller, the removable drill chuck, and proprietary IntelliSense® Drill Bits. During use, the IntelliSense® Drill shall be in the sterile field of the operating room, with the far end of the cable extending out of the sterile field to be attached to the IntelliSense® Controller. The IntelliSense® Drill will undergo steam sterilization (via autoclave) between each surgery. The IntelliSense® Drill Bits are purchased separately. They are provided sterile and are for single-use.

The IntelliSense Drill uses a combination of sensors to determine the location of the drill bit within the bone. **THE DIMENSION OUTPUT THAT IS GIVEN ON THE USER INTERFACE SCREEN IS THE DISTANCE FROM OUTER SURFACE OF THE NEAR CORTEX TO THE OUTER SURFACE OF THE FAR CORTEX AT THE LOCATION WHERE THE DRILLING OPERATION OCCURRED. THIS IS A MEASUREMENT OF THE DISTANCE BETWEEN THE TWO COMPLETE HOLES CREATED IN THE BONE.** The actual screw length should be confirmed by the doctor, taking into consideration plate thickness, screw head thickness, or any other item that will add length to the overall dimension of the bone thickness at the point of drilling.

Indication for Use Statement: The IntelliSense Drill Technology® is intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc. In Bicortical mode, the IntelliSense Drill Technology® is indicated to be used in bicortical long bone, such as the femur, tibia, fibula, humerus, ulna, and radius.

Training

Documents available on request. Please contact support@mcginleyinnovations.com.

Instructions for use of previous software revisions available on request. Please contact support@mcginleyinnovations.com.

Symbols Descriptions

 Medical Device	 Caution - Read IFU before use	 By Prescription Only
 Consult Instructions for Use	 Please Dispose of Properly	 Manufactured By
 Device is connected to earth ground, Type B applied part.	 Serial Number	 Non-sterile
 Lot Number	 Sterilized through irradiation	 Do Not Reuse
 Do Not Use if Packaging is Compromised	 Batch Code	

****WARNING****

To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

This product is not rated for continuous use. If excessive heat is found in the controller or any attached devices, cease operation immediately and return to manufacturer for evaluation.

- Do not operate this product if it has a damaged cord or plug.
- Do not operate if it has been dropped or damaged.
- If any of the above have occurred, return the product to the manufacturer for evaluation.
- Do not stack. Maintain required distance from other equipment.
- Proximity to other cables and accessories may negatively affect EMC performance.

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The IntelliSense Drill and Controller is intended for use in the electromagnetic environment specified below.

The customer or the user of the IntelliSense Drill and Controller should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Test Description	Compliance Level	Electromagnetic Environment - Guidance
EN 55011 (CISPR 11):2009+A1:2010	Frequency Range (MHz) 0.15 to 30 MHz	Conducted Emissions – Voltage Radiated Emissions Harmonic emissions IEC 61000-3-2 Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A Class A Class A Compliant	The IntelliSense Drill and controller is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded. WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the IntelliSense Drill and controller or shielding the location.
IEC 61000-4-2:2009	±6 kV contact ±8 kV air	Electrostatic Discharge Immunity	±6 kV contact ±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%.
IEC 61000-4-4:2012	±2 kV for power supply lines ±1 kV for input/output lines	Electrical Fast Transient/Burst Immunity	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5:2006	±1 kV for line(s) to line(s) ±2 kV line(s) to earth	Surge Immunity	±1 kV for line(s) to line(s) ±2 kV line(s) to PE,N	Main power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-11:2004	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Voltage Dips, Short Interruptions and Voltage Variations	IEC 60601 Level	Main power quality should be that of a typical commercial or hospital environment. If the user of the IntelliSense Drill and controller requires continued operation during power mains interruptions, it is recommended that the IntelliSense Drill and controller be powered from an uninterrupted power supply or a battery.
IEC 61000-4-8:2010	3 A/m	Power frequency (50/60 Hz) magnetic field	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_i is the a.c. mains voltage prior to application of the test level.

IEC 61000-4-3:2006 + A1:2008+A2:2010	Frequency Range 80MHz – 2.5 GHz at a level of 10 V/m	Radiated Electromagnetic Field Immunity	E1=10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the IntelliSense Drill and Controller, including cables, than the recommended separation distance calculated from the following equation. Recommended separation distance $d = [3.5/V1] \sqrt{P}$ $d \approx [1.17] \sqrt{P}$ $d = [3.5/E1] \sqrt{P}$ 80 MHz to 800 MHz $d = [0.35] \sqrt{P}$ $d = [7/E1] \sqrt{P}$ 800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$ 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
IEC 61000-4-6:2009	3 Vrms over the frequency range 0.15 MHz to 80 MHz	Conducted Radio-Frequency Immunity	V1=3Vrms	

Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, 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 IntelliSense Drill and controller are used exceeds the applicable RF compliance level above, the IntelliSense Drill and controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IntelliSense Drill and controller.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the IntelliSense Drill and Controller.

The IntelliSense Drill and Controller is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the IntelliSense Drill and Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IntelliSense Drill and Controller as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=[3.5/\sqrt{P}] \sqrt{P}$	80 MHz to 800 MHz $d=[3.5/\sqrt{P}] \sqrt{P}$	800 MHz to 2.5 GHz $d=[7/\sqrt{E1}] \sqrt{P}$
0.01	.12	.04	.07
0.1	.37	.11	.22
1	1.17	.35	.70
10	3.69	1.11	2.21
100	11.67	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Glossary and Abbreviations

Bicortical - Penetrates the bone cortex twice.

MultiCortex - Penetrates multiple bone cortices.

Depth-Sensing Arm (DSA) - Arm that protrudes from the drill to measure drill bit depth.

Freehand - Measures the maximum drill bit displacement.

Technical Data

Maximum drill depth measurement: 60mm

Drill bit diameter range: Ø1.0 mm to Ø4.8 mm

Weight (including cable): less than 1.5Kg

Input power requirements: 120 VAC, 50-60 Hz, 2.2 A

Cable Pull-out force: greater than 45 N

Cable minimum bend radius: 40mm

Transport and storage temperature range: -20°C to 50°C

Duty Cycle: 50%, 1 minute on, 1 minute off for a maximum of 30 minutes; *This product is not rated for continuous use.*

Depth measurement accuracy: ± 0.6mm

Dimensions: 295 mm x 195mm x 40mm envelope

Cannulation: Ø3.4mm

Input power requirements: 220 VAC, 50-60 Hz, 2.2 A

2 White LED lights to illuminate the drill site

Operating temperature range: 10°C to 35°C

Audible indicator (70Db-75Db output at 1 meter)

Component Overview

The **IntelliSense Drill** includes the removable drill chuck, the removable depth-sensing arm, spring, end cap (spring stop), forward and reverse operation triggers, and the tethered power/data cable. During use, the IntelliSense Drill shall be in the sterile field of the operating room, with the far end of the cable extending out of the sterile field to be attached to the IntelliSense Controller. The IntelliSense Drill shall undergo steam sterilization (via autoclave) between each surgery in the provided sterilization tray.

The **IntelliSense Controller** contains the Graphic User Interface and processors used to operate the IntelliSense Drill. The IntelliSense Controller receives power from a standard wall outlet and contains a connector to allow for connection to the IntelliSense Drill cable. The IntelliSense Controller will be placed nearby but outside of the sterile field. If the IntelliSense Controller will be in the sterile field, it will need to be covered using a Microtek Medical microscope drape #48655CL or equivalent.

The **Sterilization Tray** holds the IntelliSense Drill and cord, chuck, DSA, spring, and end cap (spring stop) for processing in the autoclave (steam sterilization).

The **Drill Bits** are of a proprietary shape and come in a range of sizes. The drill bits and companion bushings, chuck end bushing, and depth arm bushing are sold as a unit and are designed to be disposable (single-procedure). The chuck end bushing will deform if autoclaved and will not connect to the IntelliSense Drill.

DRILL BITS CAN BE USED FOR A MAXIMUM OF 10 HOLES THEN THEY SHALL BE PROPERLY DISCARDED

******WARNING******

Keep depth arm bushing free of foreign material when used for drilling multiple holes. This may require removing material from the depth arm bushing prior to drilling the next hole.



Chuck End Bushing

Depth Arm Bushing



Drill Bit Installation

1. Identify desired drill bit diameter.
2. Select the proper drill bit assembly (includes drill bit, chuck end bushing, and depth arm bushing).
3. Remove from packaging in a sterile environment being careful not to drop the depth arm bushing.
4. Attach depth arm bushing with drill bit in the bushing and perpendicular to Depth Sensing Arm (DSA).
5. Retract the outer ring of the drill chuck.
6. Swing chuck end bushing end parallel with DSA and insert into drill chuck.
7. The drill chuck will snap back into its original position when the drill bit is seated properly. Failure to properly install the drill bit will result in an inaccurate depth measurement.
8. Extend DSA and depth arm bushing to end of drill bit.



IntelliSense Controller Graphic User Interface Screens



Calibration Screen



Drill Bit Diameter Selection Screen

Calibration is required and occurs when the IntelliSense Controller is turned on. When the calibration screen appears, push the DSA all the way in towards the drill body until the next screen is shown. Allow the DSA to return to the extended position and repeat to verify calibration.

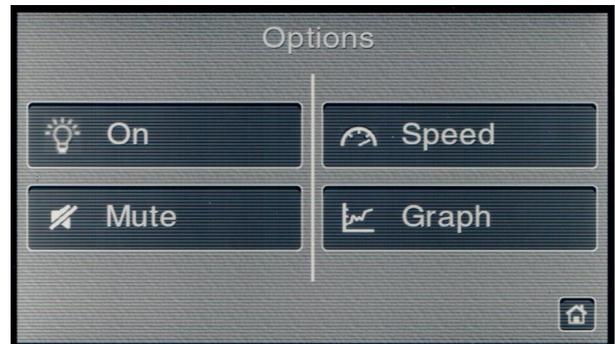
The option to Bypass, will disable depth sensing and measurement. **CAUTION: Triggers will be active at all times when sensing is disabled.**

The IntelliSense Drill is now calibrated. The IntelliSense Controller will show the Drill Bit Selection Screen.

Select the range for the drill bit diameter being used. **THIS VALUE MUST BE UPDATED EACH TIME THE DRILL BIT DIAMETER IS CHANGED DURING A PROCEDURE.**



Home Screen



Options Screen

The Home screen:

- **Mode Selection** options include Bicortical (default setting), Set Depth, MultiCortex, or Freehand
- **IntelliSense Drill Bit Depth** in millimeters (mm)
- **The Hole Counter** is used to determine the number of holes drilled during a procedure and their depth.
 - The highlighted number is the hole that is currently being drilled. Each time a hole is drilled, the hole counter advances.
 - Check the previous hole's depth by selecting a hole number on the hole counter display. This function will work for 17 holes. When hole number 18 is drilled, data from hole 1 will be replaced with the new depth.
- **Bit Size** selection shows the range of drill bit diameter being used. *Drill bit range must be entered every time it is changed during a procedure.*
- **Hardware Offset** can be entered to compensate for the width of hardware and screws from various vendors. It is automatically added to the hole depth detected by the drill. It is recommended to use the McGinley Orthopedics' Equalizer® Offset Reference Guide (sold separately, more information can be found here) which simplifies determining the correct Hardware Offset.
 - To enter a Hardware Offset, press the Hardware Offset button. Enter the desired offset and press the [Enter] button.
 - To remove a Hardware Offset, press the Hardware Offset button,  press [Clear], press [Enter].
- **The Settings Button** opens the **Options Screen**:
 - The IntelliSense Drill is equipped with 2 LED lights to help illuminate the drill site. There are three options:
 - On – The lights will remain on at all times.
 - Off – The lights will not turn on.
 - Auto – The lights will turn on when the trigger (forward or reverse) is depressed.

- The minimum and maximum percentage of speed of the motor can be changed anytime during the procedure.
- The IntelliSense Drill can be muted at anytime during the procedure.
- The graph can be accessed anytime during the procedure. Scroll the graph to find the depth of various locations that occurred during the drilling procedure by touching and moving the bars on the right hand side of the graph. This is only possible for the last completed hole. Scroll the line graph to a depth to help identify changes in the material (bone, marrow) in particular regions. Depth is the horizontal axis.
- **Unicortical/Dense Bone** detects if an unicortical hole is drilled, stops the drill, and warns the surgeon with an audible tone and a warning screen. To continue drilling pull the forward trigger. If you do not want to continue, pull the reverse trigger to remove the drill bit from the bone. It is on by default and can be turned off by pressing the button. 🏠
- **Safety Stop** gives the surgeon the option to set a maximum depth for the drill to auto stop. When this is activated, the drill stops at the corresponding location depending on the mode set. For example, in Bicortical Mode if the second cortex is breached before the safety stop is reached the drill will stop at the second cortex. This feature is not available in Set Depth Mode. If desired an Additional Increment can be set which will allow the drill to continue that amount after stopping. To continue drilling, release the trigger, press it and allow the drill bit to rotate, and drill forward with steady forward pressure. This feature can be repeated multiple times. The Safety Stop and the Additional Increment are limited to a maximum value of 50.0mm.



Mode Selection Screen



Sensing Disabled Screen

On the Mode Selection Screen, the mode can be changed from Bicortical (default) to Set Depth, Freehand, or MultiCortex.

Bicortical – (Default) This mode is used when the operation requires the drill to penetrate both bone cortices. The controller makes an audible signal as the drill exits the first cortex. As the drill moves through and exits the second cortex, the controller will stop the rotation of the drill motor, make an audible signal, and the drill hole depth is displayed. Depth displayed is the displacement at the moment of the second audible signal (the final exit). Once the drill has auto stopped, the operator has the option to press the reverse trigger and remove the drill bit from the bone or release and press the forward trigger to continue drilling.

****WARNING****

Please note this is not a physical stop in the drilling direction. The stop is only activated for the rotation of the drill motor. If excessive force in the drilling direction is used, plunging may occur.

If the operator would like to drill multiple holes in the far cortex: after bicortical breach has been detected, pull the reverse trigger and partially back the drill bit out of the far cortex without removing from the bone (still in the medullary canal), redirect the drill in a new direction then pull the forward trigger. The next cortex will be sensed, and the drill will stop. Repeat if desired. Once the drill bit is completely removed from the bone and the depth sensing arm is fully extended, the bicortical sensing will occur as normal for the next hole drilled.

****WARNING****

**When redirecting the drill bit be aware that sensing will only occur with full cortical breaches.
If an existing hole is re-drilled, plunging may occur.**

Set Depth - This mode allows the operator to set a particular depth at which the surgeon requires the drill to auto stop. Once the predetermined depth is set, the drill will operate until that depth is reached and auto stop. If desired an Additional Increment can be set which will allow the drill to continue that amount after stopping. To continue drilling, release the trigger, press it and allow the drill bit to rotate, and drill forward with steady forward pressure. This feature can be repeated multiple times. The Set Depth and the Additional Increment are limited to a maximum value of 65.0mm.

Freehand - The system will record depth, indicate every cortical exit, and display the depth of the final point of the drill bit. The drill will make an audible signal every time the drill has passed through a cortex. The controller will continuously display the maximum displacement of the DSA, as well as the depth of each cortex through which the drill bit passed.

****WARNING****

The drill rotation will not stop when the second cortex is breached in Freehand Mode. If excessive force in the drilling direction is used, plunging may occur. Triggers will be active at all times when sensing is disabled.

MultiCortex – This mode allows the operator to set a number of cortices. The drill will move through and exit the set number of cortices, making an audible signal as it exits each cortex. When it reaches the last numbered cortex, the controller will stop the rotation of the drill motor, make an audible signal, and the drill hole depth is displayed, as well as the depth of each cortex through which the drill bit passed.



Bicortical



Set Depth



MultiCortex

Operation

1. Identify location of drilling procedure.
2. Move drill into position with depth arm bushing in contact with bone cortex or hardware.
3. The IntelliSense Drill will not operate until the depth arm bushing is placed on the bone at the location of the desired hole.
4. The zero point will be determined once the drill is in position and the forward trigger is pulled to begin the drilling operation.
5. In Bicortical Mode, the length displayed is the total length of the cylinder produced by the drill bit from the zero point to the point where a complete hole is produced on the exit of the second cortex.
6. In Freehand Mode, the length displayed is the maximum displacement of the DSA, as well as the depth of each cortex through which the drill bit passed.
7. In Set Depth Mode, the operator sets a particular depth at which the surgeon requires the drill to auto stop. Once the predetermined depth is set, the drill will operate until that depth is reached and auto stop.
8. In MultiCortex Mode, the length displayed is the distance from the zero point to the point at which the set cortex is breached as well as the depth of each cortex through which the drill bit passed.
9. After drilling the desired hole, you can access the graph through the Options Screen and move the sliders on the drilling graph screen to a given location and the measurement given will be at that location.
10. If other drill bits are needed, the Universal Chuck Set for the IntelliSense Drill (sold separately) can be used. The depth sensing arm can be removed. This will activate Sensing Disabled Mode. Upon re-installation of the depth sensing arm the IntelliSense Controller will return to the previous settings. For safety purposes, Unicortical Detection will turn on.

Controller Disinfection Procedure

1. Use clean gloves to disconnect the drill from the controller and disconnect the controller power cable from the wall outlet.
2. Disconnect the power cord from the controller.
3. Use a fresh CaviWipe or equivalent to wipe the handle in the back of the controller to remove soil.
4. Wipe the front touch display screen gently with a fresh CaviWipe or equivalent to remove soil. Do not apply excessive force to the display surface or the adjoining areas, this may cause the color tone to vary. The polarizer covering the display surface of the LCD module is soft and easily scratched. Handle this polarizer carefully. DO NOT USE WATER, KETONE, or AROMATIC SOLVENTS on the touch display. Discard CaviWipe or equivalent after use in this area.
5. Use a fresh CaviWipe or equivalent to wipe the release knob to remove soil. Discard CaviWipe or equivalent after use in this area.
6. Use a fresh CaviWipe or equivalent to wipe the soiled area of the power cord to remove soil. Discard CaviWipe or equivalent after use in this area.
7. Repeat the previous steps until no visible soil remains.

Manual Drill Cleaning Procedure

1. Clean device prior to first use.
2. Use proper PPE during cleaning process.
3. Remove drill bit and dispose of properly.
4. Remove chuck, depth sensing arm (DSA), spring, and end cap.
5. Prepare a triple enzyme detergent solution (such as Endozime AW Triple Plus with APA or equivalent) per the manufacturer's recommendations at ½ oz./gal using warm tap water.
6. Do not submerge the articles in the prepared detergent solution. Saturate and wring out a lint-free cloth moistened with the prepared detergent solution. Use this to remove all gross soil from the drill body, depth sensing arm, spring, and end cap.
7. Make sure all soiled surfaces including the drill body are wetted with warm tap water. Do not to let the control cable end come in contact with running water, use a wetted lint-free cloth instead. Other parts of the article can be placed under running water. Actuate moving parts while wetting.
8. Saturate a clean, lint-free cloth with the prepared detergent solution. Wring out the cloth so that it is not dripping wet. Wipe the surfaces of the article with the cloth to remove soil. Pay particular attention to crevices and hard to reach areas of the article such as behind the drill triggers, around the drill chuck release, the depth sensing arm release, the controller connection area, and the soiled end of the cable. Actuate moving parts while wiping. Ensure the article remains wet with the detergent solution for a minimum of 2 minutes.
9. Use an appropriately sized pipe cleaner brush wetted with prepared detergent solution and brush the cannulated areas of the article from the front to the back.
10. Use a soft-bristled brush wetted with prepared detergent solution and brush the article. Pay particular attention to crevices and hard to reach areas while brushing the article.
11. Rinse all cleaned surfaces of the article with tap water to remove detergent residue and/or remaining soil. This may be done using running tap water or a wetted, clean, lint-free cloth.
12. Visually inspect each article for visible soil. If needed shine a light into the cannulated areas. If soil is present, repeat the cleaning procedure until no visible soil remains.
13. Disassemble the IntelliSense Drill and place drill and cord, chuck, DSA, spring, and end cap in provided sterilization tray.

Automatic Cleaning Procedure

1. Load all components disassembled (drill and cable, depth sensing arm, chuck, spring, and end cap) into a washer-disinfector in a way that allows the articles to drain.
2. Verify the protective cap is on the control cable connector.
3. Select a cycle and ensure the following set of cycle parameters are properly programmed: **Motor Speed: HIGH**

Phase	Minimum Recirculation Time (minutes)	Temperature	Detergent Type and Concentration
Pre-wash	02:00	Cold tap water	Prolystica 2X Alkaline or equivalent 1/8 oz./gal
Enzyme wash	02:00	Hot tap water (approx. >43°C)	Endozime AW Triple Plus with APA or equivalent ½ oz./gal
Wash 1	02:00	Heated tap water 60°C	Prolystica 2X Alkaline or equivalent 1/8 oz./gal
Wash 2	02:00	Heated tap water 60°C	N/A
Drying	15:00	115.5°C (Setpoint)	N/A

4. Run the wash cycle.
5. Following the wash cycle, remove the articles from the washer disinfector and allow the cannulated areas to drain. Dry the drill chuck, depth sensing arm, spring, end cap, and cannulated areas with pressurized air (≤ 20 psi). Dry the rest of the article with a clean, lint-free cloth.
6. Visually inspect each article for visible soil. If needed shine a light into the cannulated areas. If soil is present, repeat the cleaning procedure until no visible soil remains.

Sterilization Requirements

ON-SITE STERILIZATION IS REQUIRED FOR THE DRILL UNIT PRIOR TO USE.

1. Always use proper PPE during the cleaning process
2. Wrap the sterilization tray (with drill and cable, depth sensing arm, chuck, spring, and end cap included) in two layers of 1 ply polypropylene wrap (Kinguard KC300 – 510(k) K082554 or equivalent) using sequential envelope folding techniques.
3. Follow this chart for sterilization settings

Sterilizer Type:	Pre-vacuum
Precondition Pulses:	4
Temperature:	132°C
Full Cycle Exposure Time:	4 minutes
Dry Time:	50 minutes

Maintenance Requirements

- After each use: Inspect cord assembly for defects
Inspect drill body for damaged or loose components
- Weekly: Inspect Controller casing for defects
Inspect Controller pole mount for defects

Warranty

One-year parts and labor on IntelliSense Drill and Controller.

Please contact McGinley Orthopedics for any questions regarding warranty items. A completed Service and Warranty Report is required prior to receiving a return merchandise authorization (RMA) form. Please contact customer service at support@mcginleyinnovations.com or 307-315-6403 for details.

Service

DO NOT OPEN OR ATTEMPT TO SERVICE THE INTELLISENSE DRILL TECHNOLOGY®; Only McGinley Orthopedics authorized service providers can perform any repair or service work on the IntelliSense Drill Technology®. There are no user serviceable parts on the IntelliSense Drill Technology®.

Troubleshooting

Contact Customer Service at support@mcginleyinnovations.com or 307.315.6403

Issue	Possible Cause	Solution
Error Notification	Sensor Malfunction	Contact Customer Service, with the number displayed
Drill does not operate	Loose cord(s)	Make sure the power cord is fully attached to the controller and plugged into a functioning outlet. Make sure the drill cord is fully inserted into the controller.
Controller does not power up	Power loss	Check the on/off switch on the controller. Make sure the power cord is fully attached to the controller and plugged into a functioning outlet. The drill must be recalibrated after a loss of power.
Controller audible indicator does not sound	Defective buzzer	Hit [Reset] button or turn on controller. If no sound is heard, discontinue use and contact customer service.
Drill does not auto stop	Drill is in Freehand Mode	The auto-stop feature is only available in Bicortical, Set Depth, and MultiCortex mode. Select one of these modes on the controller.
Depth sensing arm does not move properly	Foreign material restricting movement	Clear the foreign material from the depth sensing arm, depth arm bushing and drill bit with a sterile gauze sponge.
Extended drilling time or excessive heat is produced while drilling	Dull drill bit	Drill bits are certified to drill up to 10 holes, replace drill bits at this point. Drill bits are not to be reused.
Drill bit wobbles during drilling process	Incorrect bushing size	Make sure to use the depth arm bushing provided with the drill bit.
Missing/Lost part		Contact customer service to order replacement parts.

Special Handling Instructions

IntelliSense Drill and cord, chuck, depth sensing arm, spring, end cap, and sterilization tray shall be sterilized per the instructions in this manual prior to use.

Store IntelliSense Drill and Controller in a dry place.

Store IntelliSense Drill in such a way as to maintain sterility after sterilization process.

Do not drop the IntelliSense Drill or Controller.

The device shall be evaluated by an authorized service provider after 15 years or 500 uses and autoclave cycles.

The device contains components that require special disposal. Make sure that the unit is properly disposed of at the end of its service life and in accordance with local regulations.

DO NOT SUBMERGE THE INTELLISENSE CONTROLLER IN WATER.

Manufactured By:
McGinley Orthopaedic Innovations, LLC
234 E. 1st Street, Suite 242
Casper, WY USA 82601
<http://www.intellisensedrill.com/>

LA-042 Rev 12
Issued: 03/23/2021