Instructions for Use: Universal Chuck Set for the IntelliSense® Drill

McGinley Orthopedics
ENGINEERING MEDICAL PROGRESS

Device Overview

This document outlines the operation and sterilization requirements for the Universal Chuck Set for the IntelliSense® Drill. This universal chuck system is a set of drill chucks or attachments, capable of facilitating the use of generic attachments. The Universal Chuck set is comprised of one each of a Keyless, Keyed, AO Adapter and Pin Driver chuck. The system also comes with a Universal Bypass Adapter which is inserted into the drill's depth-sensing arm receptacle, allowing the drill to be used with its depth sensing capability disabled. It is important to note that depth sensing and recording is effectively disabled for all the universal chucks. During use, the Universal Chuck System shall be on the sterile field of the operating room. The system will undergo steam sterilization (via autoclave) between each surgery. The Universal Chuck Set is designed to work exclusively with the IntelliSense® Drill.

Indication for Use Statement: The Universal Chuck Set for the IntelliSense® Drill is intended to provide a surgeon with the ability to use surgical accessories which are not able to be used with the standard IntelliSense® drill chuck.

Training

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

Symbols Descriptions

MD — Medical Device	Rx only — By Prescription Only
Consult Instructions for Use	Manufactured By
SN — Serial Number	NON STERILE — Non-sterile
REF — Batch Code	

Glossary and Abbreviations

AO	American Orthopedics standard interface for drill bits, drivers, burrs, and other like attachments
Keyed Chuck	An adjustable drill chuck requiring the use of the chuck key to apply clamping force
Keyless Chuck	An adjustable drill chuck with the ability to apply clamping force without use of a chuck key
AO Adapter	A chuck providing an interface for commonly used AO interface components
Pin Driver	A drill chuck that allows Kirschner wires (K-wires) to be adequately gripped to facilitate implantation into a patient
Universal Bypass Adapter	A part that is a replacement for the Depth-Sensing Arm and enables the IntelliSense® Drill to be used with the full range of attachments in the Universal Chuck System
Depth-Sensing Arm	An extended piece of the IntelliSense® Drill that serves to measure the depth of holes drilled
Drill Bit Bushing	Plastic IntelliSense® Drill Bit accessory that connects the drill bit to the Depth-Sensing Arm

Technical Data

Keyed Chuck
- Acceptance Diameter: 0.5mm -7.4mm
- Dimensions: 85mm x 30mm x 30mm
- Weight: 105g

Keyless Chuck
- Acceptance Diameter: 0.3mm -7.4mm
- Dimensions: 110mm x 32mm x 32mm
- Weight: 240g

Universal Bypass Adapter
- Acceptance: Depth-Sensing Arm Hole, approximately 6mm in diameter
- Dimensions: 120mm x 10mm x 10mm
- Weight: 20g

AO Adapter
- Acceptance: Standard AO
- Dimensions: 80mm x 30mm x 30mm
- Weight: 160g

Pin Driver
- Acceptance: 0.9mm -3.2mm
- Dimensions: 135mm x 82mm x 28mm
- Weight: 255g

Component Overview

The four aforementioned chucks as well as the Universal Bypass Adapter are all included in the Universal Chuck Set. Each chuck uses the proprietary interface common to all IntelliSense® chucks which is fully compatible with the IntelliSense® Drill.

******CAUTION******

Depth-Sensing and Recording are Disabled for all Universal Chucks.

Operation

Software Version 0.3.17: Controller and Depth-Sensing Arm Operation for All Chucks

Ensure that the drill has been calibrated. This can be verified by looking at the controller and confirming that the "Calibrate" button is NOT illuminated in orange.
If the drill does need to be calibrated, follow these steps:

1. Insert the Depth-Sensing Arm into the drill.
2. Press "Calibrate" on the controller.
3. Follow the on-screen instructions.
4. After completing the steps above, remove the Depth-Sensing Arm and replace with the Universal Bypass Adapter, See Figure 1.

Figure 1

All other Software Versions: Controller and Depth-Sensing Arm Operation for All Chucks

Follow the on-screen instructions to calibrate the drill.
Remove the Depth-Sensing Arm and the screen will display, "Non-sensing mode Triggers active."

Attachment to the IntelliSense® Drill for All Chucks

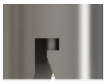

Figure 2

- Locate the lock features on the chuck, see Figure 2.
- Orient the lock features with the sides of the drill featuring the IntelliSense® logo.
- Firmly press the chuck into the drill.
- Some slight rotational movement placed on the chuck may be necessary to take up minor misalignment.
- The chuck release button will slide downward as the chuck is inserted into the drill, coming to a stop in the upward orientation once the chuck is properly seated. Ensure that the chuck release button is seated completely upward, with the top side of the button flush with the body of the drill, see Figure 3.
- The chuck is now ready to operate.

Figure 3

Standard Operating Procedure for Keyed Chuck

Expand the chuck to an opening large enough to accommodate the attachment you wish to use.
Using hand force, clamp onto the attachment. The chuck will need to be gripped and held stationary at the end while tightening.
After the chuck is hand tight, use the chuck key to exert additional force on the attachment. Tightening to just past an 1/8 of a turn will be sufficient for most applications.

Standard Operating Procedure for Keyless Chuck

Expand the chuck to an opening large enough to accommodate the attachment you wish to use.
Using hand force, clamp onto the attachment. The chuck will need to be gripped and held stationary at the end while tightening.
Place as much tightening force as is possible by hand. The Keyless Chuck is most suitable for smaller attachments. Larger attachments requiring large clamping forces may be better suited for the Keyed Chuck.

Standard Operating Procedure for AO Chuck

It may be advantageous to insert the AO accessory into the chuck while the chuck is disconnected from the drill and is placed on a table in its vertical position.
Grip the driver end of the chuck and place downward force (toward the lock features) while the AO attachment is in the chuck receptacle.
Assure that the moving portion of the chuck has returned to its original position after placing the attachment in the chuck.

Standard Operating Procedure for Pin Driver

The Pin Driver uses an automatic holding feature making it possible to hold the drill while placing a pin/K-wire in the driver with one hand. This makes it possible to place the K-wire in the driver without risk of the K-wire falling out.
Grip the handle with the ring and pinky fingers.
Begin placing the wire in desired location.

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

Do not operate if any part has been dropped or damaged. If damaged, return the product to the manufacturer for evaluation.

Manual Cleaning Procedure

1. Clean device prior to first use.
2. Use proper PPE during cleaning process.
3. Immerse all parts into a cold-water bath (the universal chuck set can be cleaned along with other IntelliSense Drill components).
4. Use a soft bristle brush to remove all soil from the parts. Brush over and through the holes or gaps, all around each part.
5. Actuate all movable parts and verify no soil remains in area exposed once actuated.
6. Rinse under cold running tap water, continue to actuate movable parts.
7. Prepare a triple enzyme detergent solution (such as Endozime® AW Triple Plus with APA) per the manufacturer's recommendations at ½ oz./gal using warm tap water.
8. Submerge the soiled article.
9. Using a soft bristled brush with detergent solution, brush all cannulated areas on the chucks paying attention to crevices and hard to reach areas.
10. Actuate all movable parts and verify no soil remains in area exposed once actuated.
11. Pay attention to crevices and hard to reach areas of the articles.
12. Place all articles under warm running water and continue to actuate moving parts.
13. Using an appropriately sized pipe cleaner brush with detergent solution, brush the cannulated areas of the articles from front to back paying attention to all crevices and hard to reach areas.
14. Rinse all articles under warm tap water.
15. Thoroughly dry articles with a lint-free cloth.
16. Visually inspect each article for soil.
17. Use a light to verify the cannulated areas are free from soil.
18. Place the chucks in provided sterilization tray and store in a dry place.

Automatic Cleaning Procedure

1. Clean device prior to first use.
2. Use proper PPE during cleaning process.
3. Use a soft bristle brush to remove all soil from the parts. Actuate movable surfaces and brush out any occluded areas which may contain soil.
4. Load all components into a washer disinfector in a way that allows the article to drain.
5. 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

6. Run the wash cycle.
7. Following the wash cycle, remove the articles from the washer disinfector and allow the cannulated areas to drain. Dry the chuck's cannulated areas with pressurized air (≤ 20 psi). Dry the rest of the articles with a clean, lint-free cloth.
8. 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 UNIVERSAL CHUCK SET PRIOR TO USE.

1. Always use proper PPE during the cleaning process.
2. Wrap the sterilization tray (with all chucks included) in two layers of 1 ply polypropylene wrap (Kimguard KC600 – 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:	30 minutes

Maintenance Requirements

Before each use:

- Ensure that all chucks spin freely relative to their housing.
- Actuate keyed and keyless chucks in order to confirm proper opening and closing of the jaws.
- Engage the handle of the pin driver. Action should be smooth and free of binding.
- Push on the movable end of the AO chuck to ensure smooth operation.
- Visually inspect contents for worn or chipped metal.

Warranty

One-year parts and labor defect warranty is provided for the Universal Chuck set.
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 ATTEMPT TO SERVICE THE UNIVERSAL CHUCK SET. Only McGinley Orthopedics authorized service providers can perform any repair or service work on the Universal Chuck set. There are no user serviceable parts on the Universal Chuck set.

Troubleshooting

Contact Customer Service at support@mcginleyinnovations.com or 307.315.6403

Issue	Possible Cause	Solution
Chuck release button does not seat in upward position.	Chuck is not fully seated in drill.	Place adequate force on the chuck to engage in drill.
Chuck does not spin freely with respect to housing.	Foreign material is preventing free rotation.	Check mating surfaces, possibly send back to sterilization for cleaning.
Chuck does not stay in drill.	Chuck is slightly misaligned, or obstructions exist in chuck or drill	Check mating surfaces for foreign objects, than retry.
Keyed chuck does not properly clamp onto attachment or will not open and close freely.	Obstructions exist in chuck.	Check mating surfaces for foreign objects, than retry.
Keyless chuck does not properly clamp onto attachment or will not open and close freely.	Obstructions exist in chuck.	Check mating surfaces for foreign objects, than retry.
AO chuck does not actuate properly.	Obstructions exist in chuck.	Check mating surfaces, possibly send back to sterilization for cleaning.
AO chuck does not adequately retain attachment.	Obstructions exist in chuck.	Check mating surfaces, possibly send back to sterilization for cleaning.
Pin driver does not actuate properly.	Obstructions exist in chuck.	Check mating surfaces for foreign objects, than retry.
Pin driver does not adequately grip K-wire.	Obstructions exist in chuck.	Check mating surfaces for foreign objects, than retry.

Special Handling Instructions

The chucks and sterilization tray shall be sterilized per the instructions in this manual prior to use.
Store the Universal Chuck Set and attachments common to industry practice, including storing in a dry place.
Store the Universal Chuck Set and attachments in such a way as to maintain sterility after sterilization process.
Dropped chucks should be returned to the manufacturer for inspection and safety testing.
Prior to each use, inspect all attachments for damage from dropping or other mishandling that could affect the installation, use and safety of the product.
The Universal Chuck Set should be cleaned and sterilized before disposal.

Manufactured By:
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