

INSTRUCTIONS FOR USE: THE REVOLVER® UNIVERSAL DRILL BIT GUIDE



MCGINLEY ORTHOPEDICS
ENGINEERING MEDICAL PROGRESS

Device Overview

This document outlines the operation and sterilization requirements for the Revolver® Universal Drill Bit Guide. The Revolver® is a variable diameter and variable length drill bit guide for orthopedic bone drilling. It includes the Revolver® handle, a small* and large** attachment for 130mm drill bits, a small and large attachment for 160mm drill bits, a small and large attachment for 190mm drill bits, and a small and large attachment for 220mm drill bits. During use, the drill bit guide system shall be on the sterile field of the operating room. The system will undergo steam sterilization (via autoclave) between each surgery. The Revolver® is designed to work in part with IntelliSense Drill Technology®, but the system is also compatible with other orthopedic surgical drills on the market.

Indication for Use Statement: The Revolver® Drill Bit Guide is intended to provide a surgeon with a guide for the drill bit to follow during a drilling procedure.

*Small is defined as having a diameter of 1.0mm to 2.5mm.

**Large is defined as having a diameter of 2.6mm to 5.0mm.

Training

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

Symbols Descriptions

 Medical Device	 By Prescription Only
 Consult Instructions for Use	 Manufactured By
 Serial Number	 Non-sterile
 Batch Code	

Glossary and Abbreviations

Attachment	Accessory piece that screws onto Revolver® handle. Dependent on drill bit length.
Rotating Chamber	Barrel located on Revolver® handle. Rotation determines the diameter of the drill bit in use.
Locking Pin	Pin that stops the rotating chamber at predetermined hole diameter points and prevents unintended rotation.
IntelliSense® Drill Terms	
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.
Zero	The starting location of the drill bit.

Technical Data

- Drill bit lengths (for IntelliSense Drill): 100mm, 130mm, 160mm, 190mm
- Drill bit diameter range (rotating chamber): ≤Ø1.0 mm, Ø1.1mm to Ø2.0mm, Ø2.1mm to Ø2.5mm, Ø2.6mm to Ø3.0mm, Ø3.1mm to Ø3.5mm, Ø3.6mm to Ø4.5mm, Ø4.6mm to Ø5.0mm
- Drill bit diameter range (attachments): ≤Ø2.5mm, Ø2.6mm to Ø5.0mm
- Dimensions: 254 mm x 210mm x 76mm envelope
- Weight: approx. 2.25Kg
- Maximum cannulation: Ø5.0mm

Component Overview

Revolver® Handle

The Revolver® Handle is the main unit that will be used with the drill bit guide. The Revolver® Handle includes the rotating chamber, the wheel that selects the diameter of the drill bit used. Diameters of 1.5mm, 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.5mm, and 5.0mm can be selected, see Figure 1.



Figure 1

The size selected can be viewed through a small window on the right side of the Revolver® Handle, see Figure 2. Different attachments can be screwed onto the thread at the bottom of the handle to change the length allowed.



Attachments

The Attachments are the threaded accessories that can be screwed onto the bottom of the handle to extend the length of the drill bit guide.

Attachments come in lengths for the following designated/intermittent drill bit lengths: 130mm, 160mm, 190mm, and 220mm. For each of the four lengths, there are two diameter sizes: one for drill bits between 1.0mm-2.5mm in diameter, and one for drill bits between 2.6mm-5.0mm in diameter. Altogether, there are a total of 8 attachments.

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

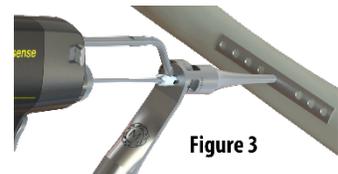
The holes vary in diameter from 1.5mm to 5.0mm. Select the hole that is greater than or equal in diameter to the drill bit in use.



Operation

Operation with the IntelliSense Drill

1. Identify location of drilling procedure.
2. Select and attach the proper attachment based on the length and diameter of your drill bit. Attachments will work on 100mm drill bit however the overall allowable drill depth cannot exceed 30mm.
3. Select the diameter based on the drill bit diameter, round up to the next hole size if your diameter is not specifically mentioned.
 - Push and hold the rotating chamber down so it disengages the locking pin.
 - While holding the chamber down, rotate the barrel until the desired diameter shows in the window at the side of the handle.
 - Lift the chamber back into the upward position, re-engaging the locking pin.
 - Make sure the rotating chamber locks back into position and the rotating chamber can no longer rotate.
4. Place the end of the attachment firmly over the bone region/plate you wish to drill.
5. Insert your drill bit through the hole at the top of the attachment; keep pushing the drill bit through until you can feel the tip of the bit touching the bone.
6. Ensure that the drill bit bushing is engaged with the top of Revolver® Handle so that the drill may be allowed to zero, see Figure 3.
7. Begin and complete the usual drilling process.



Operation with a Standard Surgical Drill

1. Identify location of drilling procedure.
2. Select and attach the proper attachment based on the length and diameter of your drill bit.
3. Select the diameter based on the drill bit diameter, round up to the next hole size if your diameter is not specifically mentioned.
 - Push and hold the rotating chamber down so it disengages the locking pin.
 - While holding the chamber down, rotate the barrel until the desired diameter is showing in the window at the side of the handle.
 - Lift the chamber back into the upward position, re-engaging the locking pin.
 - Make sure the rotating chamber locks back into position and the rotating chamber can no longer rotate.
4. Place the end of the attachment firmly over the bone region/plate you wish to put your hole
5. Insert your drill bit through the hole at the top of the attachment; keep pushing the drill bit through until you can feel the tip of the bit touching the bone.
6. Begin and complete the usual drilling process.

******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. Remove any attachments connected to the Revolver® handle.
4. Immerse all parts into a cold-water bath (the Revolver® can be cleaned along with other IntelliSense Drill components).
5. Use a soft bristle brush to remove all soil from articles. Brush over and through all holes in the rotating chamber.
6. Actuate all movable parts and verify no soil remains in area exposed once actuated.
7. Rinse under cold running tap water, continue to actuate movable parts.
8. 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.
9. Submerge all soiled articles.
10. Using a soft bristled brush with detergent solution, brush all cannulated areas on the handle and rotating chamber. Hold down the rotating chamber to brush out any soil above the rotating chamber.
11. Actuate all movable parts and verify no soil remains in area exposed once actuated.
12. Pay attention to crevices and hard to reach areas of the articles such as areas around springs.

13. Place all articles under warm running water and continue to actuate moving parts.
14. 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.
15. Rinse all articles under warm tap water.
16. Thoroughly dry articles with a lint-free cloth.
17. Visually inspect each article for soil.
18. Use a light to verify the cannulated areas are free from soil.
19. Place Revolver® handle and attachments 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 articles. Brush over and through all holes in the rotating chamber. Hold down the rotating chamber to brush out any soil above the rotating chamber.
4. Load all components disassembled (Revolver® handle and attachments) into a washer disinfector in a way that allows the articles 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 space immediately around the rotating chamber, attachments, and 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. Shine a light into the cannulated areas if needed. If soil is present, repeat the cleaning procedure until no visible soil remains.

Sterilization Requirements

ON-SITE STERILIZATION IS REQUIRED FOR THE REVOLVER® DRILL BIT GUIDE PRIOR TO USE.

1. Always use proper PPE during the cleaning process
2. Wrap the sterilization tray (with the Revolver® and attachments 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: Inspect the rotating chamber. Ensure that it can disengage the locking pin, rotate, and re-engage the locking pin without any difficulty. Visually inspect contents for worn or chipped metal.

Warranty

A one-year parts and labor manufacturing defect warranty is provided for the Revolver® Universal Drill Bit Guide 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) from the manufacture. Please contact customer service at support@mcginleyinnovations.com or 307-315-6403 for details.

Service

DO NOT ATTEMPT TO SERVICE THE DRILL BIT GUIDE SYSTEM.

Only McGinley Orthopedics authorized service providers can perform any repair or service work on the Revolver®.

There are no user serviceable parts on the Revolver®.

Troubleshooting

Contact Customer Service at support@mcginleyinnovations.com or 307.315.6403

Issue	Possible Cause	Solution
Drill bit does not fit through rotating chamber	Wrong diameter selected	Ensure that the drill bit diameter is less than or equal to the diameter selected on the rotating chamber.
Rotating chamber does not rotate	Obstructed axis	Inspect the axis the chamber rotates on to ensure that there is no debris preventing rotation.
Attachment does not seat against handle	Debris on thread of Revolver® handle or attachment	Check the threads on the attachment and the Revolver® handle to ensure that there is no debris between the threads.
Drill bit stops short of reaching desired hole length (IntelliSense Drill)	Wrong attachment used	Check that the length of the drill bit matches the specification of the attachment.
Drill bit stops short of reaching desired hole length (standard surgical drill)	Wrong attachment used	Check that the length of the drill bit is longer than or equal to the specification of the attachment.
Drill bit does not fit through attachment	Wrong attachment used	Check that the diameter of the drill bit is less than or equal to the specification of the attachment.
Drill bit does not fit through attachment	Attachment is bent	Cease use of that attachment. Return or replace attachment from manufacturer.
Rotating chamber rotates freely after selecting diameter	Rotating chamber not engaged with locking pin	Ensure that the rotating chamber returns to its up most position and lines up with the locking pin. Do not use the Revolver® until the rotating chamber is secured in place.

Special Handling Instructions

The Revolver® handle, attachments, and sterilization tray shall be sterilized per the instructions in this manual prior to use.

Store the Revolver® and attachments in a manner common to industry practice, including storing in a dry place.

Store the Revolver® and attachments in such a way as to maintain sterility after sterilization process.

Dropped Revolver®s should be returned to the manufacturer for inspection and safety testing.

Prior to each use, inspect all attachments to ensure that they are straight and none of them have been bent.

Manufactured By:
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