

# INSTRUCTIONS FOR USE: THE EQUALIZER® OFFSET REFERENCE GUIDE



**MCGINLEY ORTHOPEDICS**  
ENGINEERING MEDICAL PROGRESS

## Device Overview

This document outlines the operation and sterilization requirements for the Equalizer® Offset Reference Guide. The Equalizer® is a tool exclusively made for the IntelliSense Drill. It allows for the built-in offset of orthopedic plates to be implemented into the IntelliSense Drill Technology®, which provides accurate cortex-to-cortex depth measurement but excludes manufactured plate offsets. During use, the Equalizer® shall be on the sterile field of the operating room. The Equalizer® will undergo steam sterilization (via autoclave) between each surgery.

**Indication for Use Statement:** The Equalizer® Offset Reference Guide is intended to provide a surgeon using the IntelliSense Drill with the offset manufactured into an orthopedic plate.

## Training

Documents available on request. Please contact [support@mcginleyinnovations.com](mailto: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

- Head** The rounded portion at the top of the Equalizer® in which the plate rests on.
- Gauge** The series of tick marks on the forward face along the hole that determines the offset of the plate.

## Technical Data

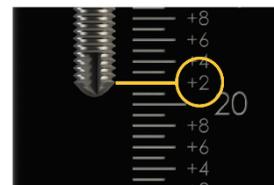
- Compatible screw sizes – 10, 20, 30, 40, 50, 60  
Compatible screw diameters -  $\leq \varnothing 5.1$  mm  
Dimensions: 72 mm x 54 mm x 26 mm envelope  
Weight: approx. 0.16 Kg  
Maximum cannulation:  $\varnothing 5.16$  mm

## Component Overview

The Equalizer® is compatible with most surgical plates. As long as the bottom diameter of at least one hole on the plate can sit flush against the hole at the head of the Equalizer®, the offset of that plate can be determined. Screw lengths compatible with the Equalizer® include screws marked for lengths 10, 20, 30, 40, 50, and 60. Maximum thread diameter allowed through the hole is 5.1mm. The Equalizer® is meant for tabletop use on the sterile field.

## Operation

1. Identify desired plate to be used in the procedure.
2. Within the kit that the plate was taken from, select a screw with a length marked 10, 20, 30, 40, 50, or 60.
3. While leaving the Equalizer® on a sterile table or tray, place the plate flush on the Equalizer®'s head as one would place a plate on a bone.
4. Align at least one of the holes on the plate with that of the Equalizer®'s.
5. Insert the selected screw through the hole in the plate and the Equalizer®, pushing the screw down to its lowest position.
6. Use a thumb to hold the screw in place against the back of the hole, keeping the screw parallel to the gauge.
7. Locate the tick mark at the point of the screw where the shank meets the widest part of the conical tip. See image.
8. The tick mark will be a particular value between and including +0 to +9. The value at the tick mark in the previous step will be the offset for the plate.
9. Press the Hardware Offset Button,  on the controller console of the IntelliSense® Drill and enter the hardware offset.
10. Drill a regular hole with the IntelliSense® Drill intended for use with the offset measured with the Equalizer®.



- After drilling the hole, the controller console will display a depth which includes the offset. The number displayed will be the screw size from the kit that will fixate the plate to the bone.
- So long as the thickness of the plate remains constant, the offset found for that plate will be applicable to all holes in the plate.

**\*\*\*WARNING\*\*\***

**Do not operate if it has been dropped or damaged. If damaged, return product to the manufacturer.**

**Manual Cleaning Procedure**

- Clean device prior to first use.
- Use proper PPE during cleaning process.
- Immerse Equalizer® into a cold-water bath (the Equalizer® can be cleaned along with other IntelliSense Drill components).
- Use a soft bristle brush to remove all soil from the part. Brush over and through the holes running through the head and body of the part.
- Rinse under cold running tap water.
- 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.
- Submerge the soiled article.
- Using a soft bristled brush with detergent solution, brush over and through the holes running through the head and body of the article.
- Pay attention to crevices and hard to reach areas of the article.
- Place the article under warm running water.
- Using an appropriately sized pipe cleaner brush with detergent solution, brush the cannulated areas of the article from front to back paying attention to all crevices and hard to reach areas.
- Rinse the article under warm tap water.
- Thoroughly dry article with a lint-free cloth.
- Visually inspect the article for soil.
- Use a light to verify the cannulated areas are free from soil.
- Place the Equalizer® in provided sterilization tray and store in a dry place.

**Automatic Cleaning Procedure**

- Clean device prior to first use.
- Use proper PPE during cleaning process.
- Use a soft bristle brush to remove all soil from the part. Brush over and through the holes running through the head and body of the part.
- Load the Equalizer® into a washer disinfectant in a way that allows the article to drain.
- 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

- Run the wash cycle.
- Following the wash cycle, remove the article from the washer disinfectant and allow the cannulated areas to drain. Dry the Equalizer®'s cannulated areas with pressurized air (≤ 20 psi). Dry the rest of the article with a clean, lint-free cloth.
- 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 EQUALIZER® UNIT PRIOR TO USE.**

- Always use proper PPE during the cleaning process.
- Wrap the sterilization tray (with the Equalizer® included) in two layers of 1 ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or equivalent) using sequential envelope folding techniques.
- 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

After each use visually inspect the article for worn or chipped metal.

## Warranty

One-year parts and labor defect warranty is provided for the Equalizer®.

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](mailto:support@mcginleyinnovations.com) or 307-315-6403 for details.

## Service

**DO NOT ATTEMPT TO SERVICE THE EQUALIZER®.** Only McGinley Orthopedics authorized service providers can perform any repair or service work on the Equalizer®. There are no user serviceable parts on the Equalizer®.

## Troubleshooting

Contact Customer Service at [support@mcginleyinnovations.com](mailto:support@mcginleyinnovations.com) or 307.315.6403

Issue	Possible Cause	Solution
Offset is unusually high or falls below bench line	Wrong screw selected	Ensure that the screw selected is one of the six lengths compatible with the Equalizer® by measuring it. Some screws could be misplaced in their respective kits.
Offset is unusually high	Plate not flush against head	Ensure that the plate is flush with the Equalizer® head, and that the bottom diameter of the plate's hole meets the upper diameter of the Equalizer®'s hole. Rotate plate if necessary, to find a flush fit.
Offset is unusually high	Obstruction on Equalizer® head	Clear the Equalizer® and the plate of any foreign material before use.

## Special Handling Instructions

The Equalizer® and sterilization tray shall be sterilized per the instructions in this manual prior to use.

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

Store the Equalizer® in such a way as to maintain sterility after sterilization process.

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

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