

Operating Instructions Rotating Disk System Intrinsic Dissolution Apparatus Set

P/N IDASET ALL
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Revision History

Rev.	Description	Revised By	Revised On	Approved By	Approved On
1.0	Initial Release	MB	10/1/2019	CL	10/1/2019



1.0 General Information

Quality Lab Accessories Intrinsic Dissolution Apparatus is based on the conventional “Wood Apparatus Design” also known as the “Rotating Disk System”. This basic configuration was developed in 1963 and is currently used in numerous validated methods worldwide. QLA has selected this configuration because of its current wide spread usage, ease of use and USP <1087> compliance.

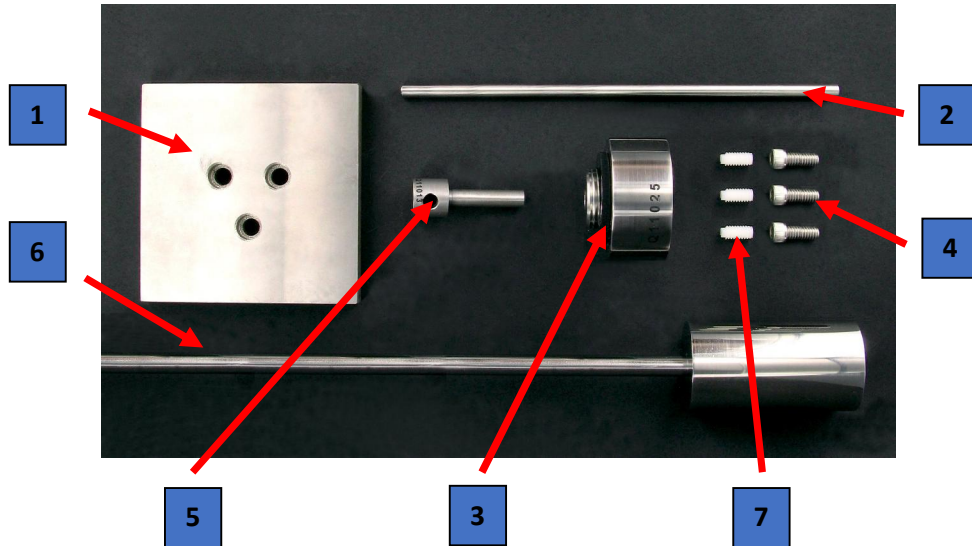
An alternative configuration known as the “Stationary Disk System” requires a custom, flat bottom dissolution vessel (non USP). Since these vessels are handmade, they incorporate significant allowable tolerance for important features such as concentricity of the flat region with respect to the vessel mounting diameter. This tolerance contributes to misalignment with respect to the stirring centerline (centering) and is known to introduce variations in dissolution rates. Verification of centering is not feasible with the “Stationary Disk System”, but is easily verified with the “Rotating Disk System”.

2.0 Unpacking

The set is shipped in a foam padded case to minimize damage during transport. The case can also be used as a convenient and safe storage system when not in use.

Unpack the kit carefully. After unpacking, check the components for possible damage. Report any damage to the forwarding shipper immediately and inform QLA or your local representative.

3.0 Product Description



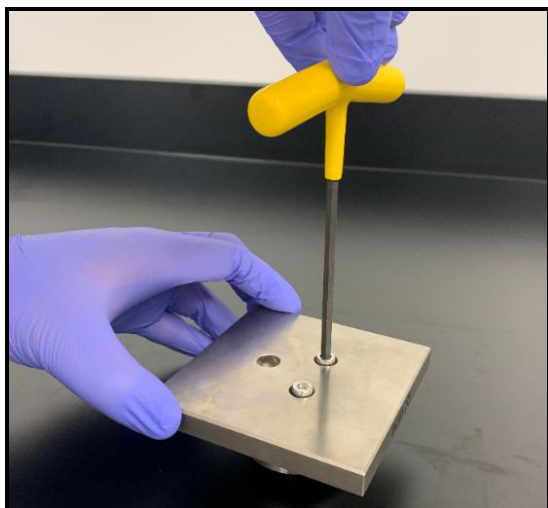
Item #	Description
1	Surface Plate
2	Punch Handle
3	8mm Intrinsic Die
4	Socket Cap Screw
5	8mm Punch
6	Shaft and Holder
7	Nylon Set Screw

4.0 Assembly

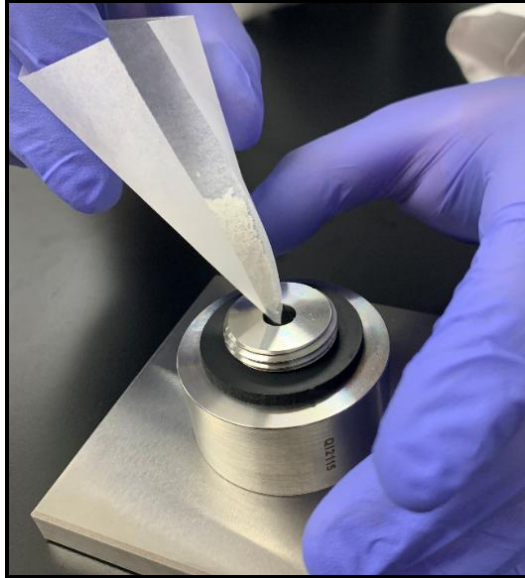
- 4.1 Clean the mating surface of both the 8 mm Intrinsic Die (side without the countersunk holes) and Punch with methanol and a lint free cloth.



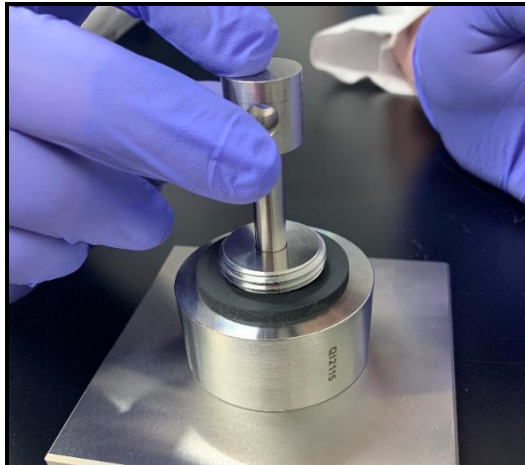
- 4.2 Bolt the 8mm Intrinsic Die to the Surface Plate.



- 4.3 Add the appropriate amount of material to be tested into the hole in the top of the 8mm Intrinsic Die.

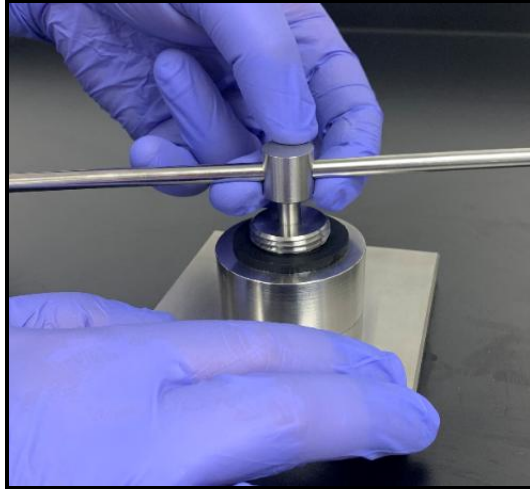


- 4.4 Install the 8mm Punch.

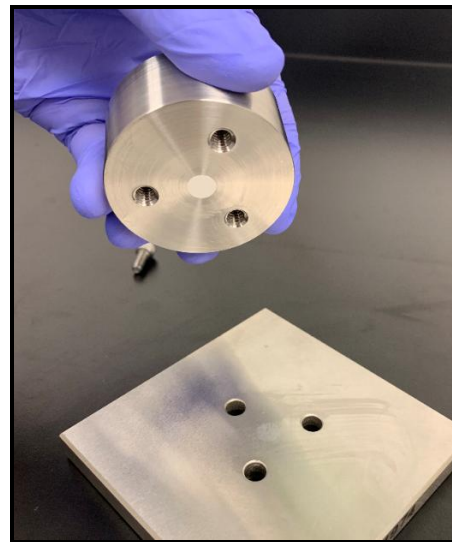
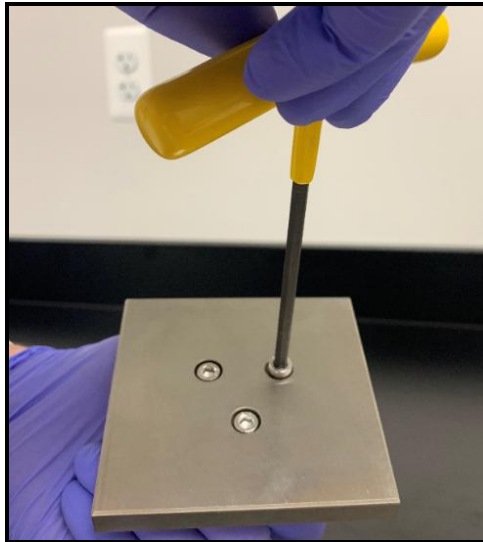


- 4.5 Perform compaction using a suitable press. It is recommended that a pressure of 15 MPa be applied for at least one minute.

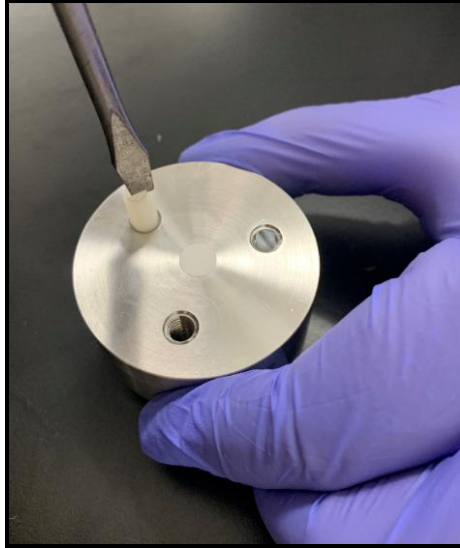
- 4.6 Insert the Punch Handle into the hole in the 8mm Punch and pull up to separate the punch from the die.



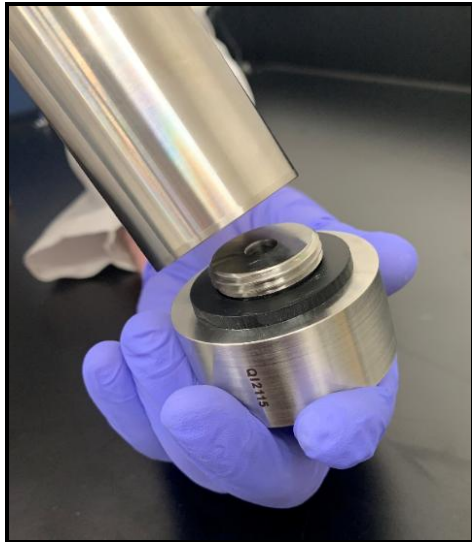
- 4.7 Remove the bolts from the bottom of the surface plate and carefully lift off the die and punch assembly. Remove any loose powder from the surface of the compact and die by using compressed air or nitrogen.



4.8 Install the Nylon Set Screws, ensuring they are flush with the Die.



4.9 Screw the 8mm Intrinsic Die onto the Shaft and Holder assembly.



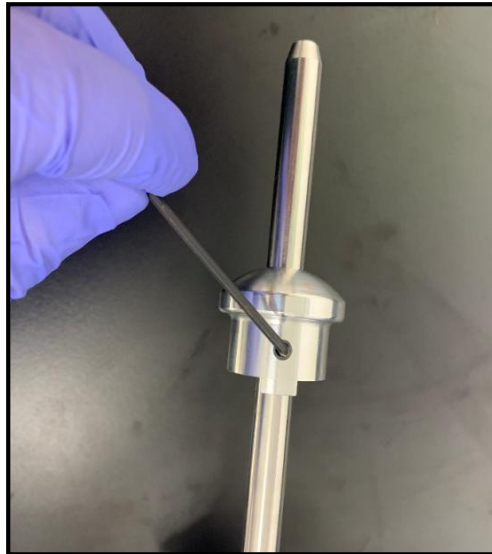
5.0 Installation

5.1 Solid Shaft Assemblies (Non-Hanson Vision Classic 6™)

- 5.1.1 Raise the drive head of the dissolution tester to its highest position.
- 5.1.2 Insert the assembled shaft into the spindle position to be tested.
- 5.1.3 Lower the drive head and adjust the height of the assembly so the exposed surface of the compact is not less than 1 cm from the bottom of the vessel.

5.2 Hanson Vision Classic 6™ Two Piece Shaft Assemblies

- 5.2.1 Assemble the 8 mm Intrinsic Die as per section 4.0 of this manual.
- 5.2.2 Slide the shaft clamp onto the upper shaft of the Shaft and Holder Assembly and tighten the set screw. Note: the shaft clamp should be approximately 4 cm from the top of the Shaft and Holder Assembly.

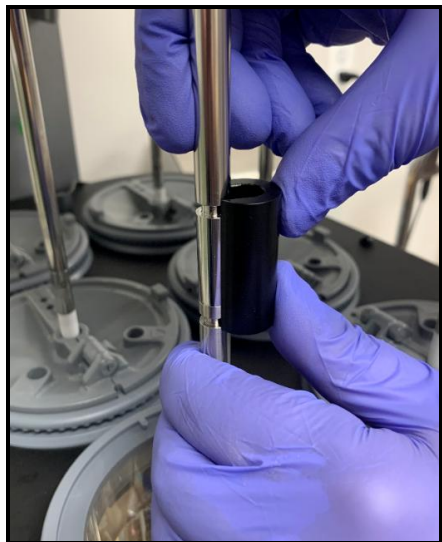


- 5.2.3 Install the upper shaft only of the Shaft and Holder assembly in the position to be tested.

5.2.4 Screw on the lower shaft of the Shaft and Holder Assembly.



5.2.5 Install the Safety Clip to secure the upper and lower shafts.



- 5.2.6 While holding the assembly secure in one hand, loosen the shaft clamp and adjust the height to no less than 1 cm from the bottom of the vessel.

CAUTION: Be sure to hold the shaft securely when loosening the Shaft Clamp. Failure to do so may cause sever damage to the vessel or apparatus.



6.0 Qualification and Validation

Prior to shipment, the assembly is evaluated for quality assurance and includes a Certificate of Conformance.

7.0 Maintenance

The assembly is maintenance free and does not require any daily service. The entire assembly should be cleaned and dried after each use and stored in an appropriate location.

8.0 Warranty

This product is warranted to be free from defects in materials and workmanship under normal installation, use and service for a period of (1) year from the date of purchase as shown on the purchase order receipt. The obligation of QLA under this warranty shall be limited to repair or replacement (at our option) during the warranty period, provided the product is returned to QLA with transportation charges prepaid. This warranty shall be invalid if the product is damaged as a result of defacement, misuse, accident, destruction or alteration of the serial numbers, repair alteration or maintenance by any person or party other than our own service facility or authorized QLA service technician.