



iJig® Cleaning Instructions IFU Addendum

CAUTION: USA FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

If there are any questions, contact restor3d, Inc. at +1.781.345.9001 or your local sales representative/



Important Information: Please read before use.



Refer to <https://www.restor3d.com/resources/instructions-for-use> for an electronic version of this IFU.

For a printed copy or to have an electronic copy e-mailed to you call +1.781.345.9001



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ATTENTION: This addendum is to be used in conjunction with the device's corresponding IFU.

iJig® cleaning instructions are applicable to the following devices:

- iTotal® Identity™ Total Knee Replacement System (LS-04133, LS-04015)
- Identity™ Imprint™ Total Knee Replacement System (LS-04192)
- CORDERA™ Hip System (LS-04316, LS-04317)
- ACTERA™ Hip System (LS-04245)

Cleaning Instructions





In the event of an iJig® being dropped and contaminated, perform the following cleaning steps before steam re-sterilization:

1. Prepare a cleaning bath with an enzymatic detergent such as Steris Prolystica 2X Concentrate Enzymatic Pre-soak and Cleaner or equivalent at the concentration and temperature specified by the detergent manufacturer
2. Completely submerge instruments in an enzyme solution for 5 minutes.
3. Scrub with soft bristle brush to remove all visible soil. Pay close attention to threads, crevices, seams and any other hard to access areas. Actuate any moving mechanisms to free trapped blood and debris.
4. Remove instruments from the cleaning solution. Rinse in running (tap) water for 3 minutes or until all traces of cleaning solution are removed, whichever is longer. Thoroughly and aggressively flush lumens, holes or other hard to access areas.
5. Repeat Steps 2, 3 and 4.
6. Rinse instruments in purified water for 3 minutes or until rinse stream is clean of blood or soil, whichever is longer. Thoroughly and aggressively flush lumens, holes or other hard to access areas.
7. Visually inspect each device for remaining soil to ensure device is visibly clean. If soil remains repeat steps 2 thru 6.
 - a. Blood from patient may stain instruments. However, these cleaning instructions pertain to patient specific devices which are not intended to be used on other patients. The device in question is intended to be used on the same patient in which it has potentially come in contact with prior to cleaning.
8. Dry instruments immediately after final rinse.
9. Proceed to steam sterilization steps outlined in the Instructions for Use

Additional Information

If further information is desired, please contact restor3d®, Inc. at +1.781.345.9001.

Labeling Symbol Definitions

	Caution. Consult Accompanying Documents
	Consult electronic Instructions For Use (eIFU)
	Single Use Only. Do Not Reuse
	Manufacturer

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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