



# CUT

February 5, 2014

## Field Safety Notice - Change of Instructions for Use ACRA-CUT Inc.™ Reusable Cranial Perforators:

### Models:

- 200-141 14/11mm DGR-I**
- 200-151 14/11mm DGR-II**
- 200-152 11/7mm DGR-II**
- 200-171 14/11mm DGR-O**

Dear Sir/Madame:

ACRA-CUT has made the following revision to our Reusable Cranial Perforator Instruction for Use to include a more detailed method of Manual Disinfection, Cleaning and Sterilization guideline for all Models as per DIN EN ISO 17664. **Specifically Sections 4.0 and 5.0:**

### Revision IFU is as follows:

#### **4.0 Manual Cleaning/Disinfection Instructions: Machine Cleaning is not recommended.**

- 4.1 Disassemble perforator per ACRA-CUT's Instructions for use (See Paragraph 2.0)
- 4.2 Prepare disinfectant and hospital grade enzymatic detergent as per manufacturer's instructions for use. In case of doubt, contact the manufacturer or ACRA-CUT directly.
- 4.3 Perform disinfection and cleaning per the steps listed in the following table:

Step	Solution	Time Minutes	Temperature	Instruction
1	Hospital Grade Disinfectant	As required	N/A	All surfaces should be wiped immediately after use with lint free cloth soaked in disinfectant or should be sprayed with a disinfectant spray in order to avoid adhering material and encrustation.
2	Hospital Grade Enzymatic Detergent	14-15	Room Temperature	Immerse and soak for required time.

3	Hospital Grade Enzymatic Detergent	As required	Room Temperature	Clean thoroughly - Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that the flutes are effectively cleaned. Use a small diameter brush or pipe cleaner to clean cannulation holes. Inspect for visible soil on exposed surfaces.
4	Water	2-3	Warm as delivered from hot water tap	Rinse thoroughly for required time immediately after step 2.
5	Hospital Grade Disinfectant	As required	N/A	All surfaces should be wiped with lint free cloth soaked in disinfectant or should be sprayed with a disinfectant spray.
6	Air	As required	Ambient	Allow to air dry in clean area. Blow lumens with clean air using filtered air source or syringe.

**5.0 Sterilization:**

5.1 Perforator must be manually cleaned prior to sterilization. See Paragraph 4.0 for recommended procedure.

5.2 Full Cycle Steam Guidelines are as follows:

Cycle #	Cycle Type	Temp (C°)	Expos	Dry Time (Minutes)
1	Pre-Vac, wrapped	134	4	20
2	Gravity, wrapped	121	30	30

5.3 The use of other sterilization methods is outside of ACRA-CUT's responsibility. If the described equipment, materials and chemicals are not available, it is the responsibility of the user to validate their method accordingly.

5.4 Frequent reprocessing has few effects on these instruments. The end of the instrument's working life is normally determined by wear and damage through use.

**Reusable Cranial Perforator Instructions for Use Version 101036 Rev B**

Note: ACRA-CUT is not initiating a product recall; this is a notification of a change in IFU only.

Please ensure that the information in this notice is made available to all relevant personnel within your organization and/or customer base and that awareness is maintained for an appropriate period.

If you have any questions relating to this bulletin or should you require any additional information please contact ACRA-CUT directly via email at [info@acracut.com](mailto:info@acracut.com) or telephone at 978-263-9186.

Sincerely,



Vice President & General Manager  
Quality Assurance Department  
ACRA-CUT Inc.  
989 Main Street  
Acton, MA 01720 USA  
Tel 978-263-9186  
FAX 978-263-4102  
Email [info@acracut.com](mailto:info@acracut.com)  
[www.acracut.com](http://www.acracut.com)