H-GRAFT™ Interspinous Cortical Allograft System
Instrument Instructions for Use: Cleaning and Sterilization Instructions

GENERAL INFORMATION

The H-GRAFT™ Interspinous Cortical Allograft System of Xtant Medical consists of various sizes of structural cortical allograft blocks and associated instrumentation.

INDICATIONS FOR USE

The H-GRAFT instrumentation is intended for to be used for the placement of the H-Graft Cortical Allograft.

⚠ **Warnings and Precautions**

Instruments are provided non-sterile and must be cleaned and sterilized before use.

Do not use oil-based instrument lubricants, as these may interfere with the sterilization process.

CLEANING OF INSTRUMENTS

⚠ CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments and trays prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
2. Loosen and disassemble instruments with removable parts in accordance with **Table 1** below.

Table 1 – Instruments Requiring Disassembly for Cleaning

Part Number	Instrument Name	Disassembly Instructions	Reassembly Instructions
X078-0030	Dorsal Inserter	Unthread the inserter shaft from the inserter handle	Thread the inserter shaft into the inserter handle assembly by rotating the knob clockwise until fully seated. Verify that the inserter shaft smoothly travels in both directions within the assembly.
X078-0050	Lateral Inserter	assembly by rotating the knob counter-clockwise. Inspect both components for visible evidence of wear and tear.	

3. **Table 2** below describes the required steps for thoroughly cleaning the system instruments.

Table 2 – Cleaning Parameters

Step	Agent / Instructions	Time (mm:ss)
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	3:00
	Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for three (3) minutes. While submerged, use a soft bristle brush that is intended for use with surgical instruments, to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.	
2. Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for one (1) minute.	

Table 2 continued on page 2.

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Step	Agent / Instructions	Time (mm:ss)
3. Ultrasonic Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for ten (10) minutes.	
4. Ultrasonic Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for one (1) minute.	
5. Inspection	Unaided eye	
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. If the instruments are not dry, use filtered pressurized air or lint-free wipes to dry.

INSPECTION OF INSTRUMENTS

1. Carefully inspect each instrument and tray to ensure all visible blood and soil has been removed. Repeat cleaning if necessary.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Xtant Medical representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Xtant Medical representative for a replacement.

STERILIZATION OF INSTRUMENTS

All instruments are provided clean and non-sterile and must be sterilized before use. All instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile instruments should be autoclave sterilized using the following validated cycle parameters:

Saturated steam method (pressure 41.9 psia, 205.5 kPa), pre-vacuum air removal (3 pulses), 270° F (132° C), 4-minute exposure time, 30-minute dry time, in a double–wrapped case configuration.
Note: Most sterilizers automatically control pressure to ensure saturated steam and may not be adjusted by the user.

Use FDA cleared sterilizers and sterilization packaging materials/accessories (wraps, biological indicators, chemical indicators, etc.) for sterilization of instruments.

Do NOT stack instrument trays during sterilization.

For additional instructions regarding the proper use of the H-GRAFT instruments, please refer to the H-GRAFT™ Surgical Technique Manual (available at no charge upon request).

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

REF

Part Number
X078-1000-EN Rev F
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