



FRONTAL SINUS 2MM MINI TREPHINE DRILL

Warnings / Precautions	Do not cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilize, as damage to the instrument finish may occur.				
Limitations	The Mini Trephine 2mm Drill has been tested for reuse up to five (5) times without noticeable performance degradation.				
INSTRUCTIONS					
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. Rinse instrument immediately after use in distilled or demineralized water				
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use. An available tray for the Frontal Sinus set (Ref: 37-17005) is recommended for sterilization and handling.				
Preparation for decontamination	No particular requirements				
Cleaning: Automated (Do NOT use ultrasonic washer)	Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.				
Cleaning: Manual	Soak in lukewarm (less than 43°C), mild (pH 7.0 - 8.5), enzymatic detergent and deionized water for a minimum of 2 minutes, then clean ultrasonically in a lukewarm (less than 43°C), mild (pH 7.0 - 8.5), detergent and deionized water for at least 30 seconds. Rinse thoroughly with deionized water immediately, for at least 30 seconds, and wipe dry. Examine instrument for any staining or deterioration; remove from use as appropriate. Note: When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations, particularly with regard to articulated instruments and positioning of instruments.				
Disinfection	No particular requirements				
Packaging	No particular requirements				
Sterilization (Temperatures are minimum required, times are minimum required)	Cycle:	Gravity	Gravity	Pre-Vac	
	Temperature:	121°C	132°C	134°C	
	Time:	30 min	10 min	3 min	
	Drying:	8 minutes, or until visibly dry			
	EtO: Not validated		STERRAD Sterilization: Not validated		
Maintenance, Inspection and Testing	Inspect the instrument for any damage before and after each use. If damage is observed do not use the instrument. See limitations (above).				
Storage	Maintain care in storage and handling of the system to not drop the press or piston parts as misalignment of these components may create incomplete tissue cutting.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.