

MAYFIELD® and BUDDE® surgical devices

DECONTAMINATION PROTOCOL



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MAYFIELD® INFINITY
SKULL CLAMP SYSTEM (A1114)

QUICK REFERENCE CHART

			Medical Device		
Process			Group 1	Group 2	Group 3
			Skull Clamps, Base Units, Adaptors, & Headrests	Gel Pads	Reusable Pins BUDDÉ Halo
Decontamination	Cleaning	Manual	+	+	+
		Machine*	+	-	+
		Ultrasonic	-	-	+
		Alkaline detergent	-	-	-
		Acidic detergent	-	-	-
		Neutral detergent	+	+	+
	Rinsing				
	Disinfection	70% Isopropyl Alcohol	+	-	+
		Bleach	-	-	-
		Hydrogen Peroxide	-	-	-
		Iodine	-	-	-
		Quaternary Ammonium Chloride	-	+	-
		Cidex®	-	-	-
Thermal*		+	-	+	
Sterilization	Steam Autoclave Moist Heat	-	-	+	
	Ethylene Oxide	-	-	-	
	Dry heat	-	-	-	
	Liquid Sterilant	-	-	-	
	H ₂ O ₂ Gas Plasma	-	-	-	

Key:

+ May be suitable

- Not suitable

* Suitable to use under parameters and conditions listed in this document

DECONTAMINATION GUIDELINES AND INSTRUCTIONS

The instructions listed below are general guidelines for proper decontamination methods that are safe for the MAYFIELD and BUDDE products. It is imperative to read this entire manual and follow instructions to avoid damage to the equipment. The MAYFIELD products are classified into three groups for proper handling instructions for reprocessing.¹

Group 1

Non-Critical¹, Heat Sensitive, pH Sensitive

- Skull Clamps
- Base Units
- Headrests
- Adaptors

Group 2

Non-Critical¹, Heat Sensitive
pH Sensitive, Alcohol Sensitive

- Gel Pads

Group 3

Critical¹

- BUDDE HALO
- Reusable Skull Pins

Decontamination Instruction Guide Chart

Group 1

Follow instructions:
Manual wash

Group 2

Follow instructions:
Manual Wash

Group 3

Follow instructions:
Sterilize

References:

¹ AAMI TIR 12:2004 Designing, testing, and labeling reusable medical devices for reprocessing in Health Care facilities.

DECONTAMINATION GUIDELINES AND INSTRUCTIONS

CONSIDERATIONS

- It is up to the user of this manual to follow the instructions exactly as listed. Any deviation from this manual could result in damage to the equipment as well as improper cleaning results.
- Equipment should always be manually cleaned first. An automated washer/disinfector may be used secondary to the manual cleaning procedure, but is not required or recommended for routine reprocessing. See Appendix B for a validated wash/disinfect cycle.
- This protocol has been validated for cleaning effectiveness only. All products in Group 3 were validated for sterilization at a previous time. Cleaning method validations were not performed and are not included for Group 3.
- See Appendix A to read more information on disassembling the product and inspecting it for cleanliness.
- Refer to the product insert for further details on product use and set-up.
- The user should comply with hospital procedures and local laws and ordinances regarding reprocessing requirements.
- Hospitals are responsible for decontaminating and packaging all loaner and demo equipment before returning to Integra.

WARNINGS

- Take all necessary precautions in wearing the appropriate protective garments as specified in the instructions provided by the cleaning agent.²
- Clean device immediately after each use. Failure to do so could cause rust and pitting from harmful dried debris such as blood, saline, or iodine.
- Follow all instructions of the detergent, equipment washer, and sterilizer manufacturer.
- Follow the dosage, temperature, exposure time, material compatibility specifications, and disposal directions of the cleaning agent as recommended by the manufacturer.
- Use only the cleaning tools mentioned in this manual. Never use metal brushes to clean MAYFIELD or BUDDE products.
- Failure to follow the instructions of this document could result in damage to the equipment.
- There is no validated automated cleaning/washing method for Group 2 or Group 3.

CAUTIONS

- Never process any products in Groups 1 or 2 through the steam sterilizer. Failure to follow this instruction could result in damage to the equipment.
- Never use any products with corrosive ingredients such as chlorine, phenol, or iodophors or use highly acidic pH or strong alkaline agents on any MAYFIELD or BUDDE products.
- Do not use alcohol based disinfectants on any products in Group 2 (gel pads).
- Never use metal brushes or metal sponges for cleaning MAYFIELD or BUDDE products.
- Never allow MAYFIELD or BUDDE products to soak in water/detergent solution for more than 30 minutes.
- Hard water can damage the surface of the equipment. Avoid using hard water, instead use purified water.
- The equipment contains small crevices and lumens. Pay special attention to these areas when manually cleaning, applying disinfectant and/or drying.

References:

- ² AAMI ST79: 2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in the Health Care Facilities.

Manual Wash - Group 1 and Group 2 - Skull Clamps, Base Units, Headrests and Adaptors

CAUTIONS

- Alkaline and highly acidic detergents and solutions cause damage to the devices.
- Channels and crevices found on this device require particular attention during cleaning.
- Alcohol solutions cause damage to the gel pads and should be avoided. Alcohol will cause gel pads to harden.

Limitations on reprocessing

- Repeated processing has minimal effects on these devices. Product life is normally determined by wear and damage due to use.
- It is important to have Integra NeuroSpecialists perform routine inspections (twice yearly is recommended). See contact information below.

INSTRUCTIONS

Containment/Transportation

- Follow health care facility protocol for safe containment and transport to the decontamination environment.
- It is recommended that devices are cleaned immediately after use.

Preparation for Cleaning

- Disassembly is required. Please see Appendix A for detailed instructions.

Cleaning – Manual Equipment: Water, Neutral pH Detergent, Soft Bristle Brush, Towels

Method

1. Prepare neutral pH cleaning water solution according to detergent manufacturer's instructions.
2. Prepare equipment for soaking by disassembling removable parts and loosening connections.
3. Rinse equipment in warm water before placing into bath.
4. Completely soak equipment in water/detergent solution for 30 minutes maximum.
5. Clean thoroughly with a soft nylon bristle brush. **NOTE** – If possible, use a disposable brush.
6. Rinse in warm purified water until all visible substances and residual detergent are removed. **NOTE** – Make sure to give special attention to hard-to-reach areas.
7. Thoroughly dry equipment with soft clean towels and use medically compressed air if needed, to dry channels, crevices and lumens.
8. Inspect the equipment to make sure there is no visible organic debris or residue from cleaning agent. Repeat process if any soil is detected.

Manual Wash - Group 1 and Group 2 - Skull Clamps, Base Units, Headrests and Adaptors

Drying

- Products should be dry at this point. If wetness or excess liquid is detected, dry with a soft clean towel. Medically compressed air can be used if needed.

Maintenance

- A2000 Skull Clamp can be lubricated (instrument lubricant or simple mineral oil) for 20-30 seconds.
- Refer to the product insert for further product information.

Inspection and Function Testing

- Visually inspect equipment for damage and wear. Make sure all locking mechanisms and joints are functioning normally. See Appendix A to get more information.

Packaging/Storage

- **Store base units, with the transitional, in the locked position at all times.**
- Decontaminated equipment should be placed in a clean environment and can be hung on a wall unit, equipment cart, or in a storage room.
- **Keep all skull clamps in the unlocked position when not in use.** Models A2000 and Radiolucent Skull Clamp A2002 should set at the red engagement line when stored (prior to patient use).

Additional Information

- Never lock the Base Unit handle without the Transitional Member in place – this can cause damage to the equipment.
- Gently lift the end and slide off the gel pads, do not peel off the horseshoe headrest.
- Set pressure knob on Skull Clamps with the first thread showing. For models A2000 and A2002, make sure engagement mark on piston shaft is visible just beyond the Skull Clamp base.
- Set pin carriers on Triad rocker arm with the first thread showing.

Contact Information

- Please call 1.877.444.1114 or 513.533.7979 for Customer Service. The Repair Department can be reached through these numbers.

Sterilization - Group 3 - BUDDÉ Halo and Reusable Skull Pins

CAUTIONS

- Prolonged exposure time may affect product life. Carefully inspect for visible damage and malfunction after sterilization.
- Channels and crevices found on this device require particular attention during cleaning.

WARNING

- Reusable Skull Pins are sharp. Take necessary precautions when handling.

Limitations on Reprocessing

- Repeated processing has minimal effects on these devices. Product life is normally determined by wear and damage due to use.
- It is important to have Integra NeuroSpecialists perform routine inspections (twice yearly is recommended). See contact information on page 9.

INSTRUCTIONS

Containment/Transportation

- Follow healthcare facility protocol for safe containment and transport to the decontamination environment.
- It is recommended that devices are cleaned immediately after use.

Preparation for Cleaning

- Disassembly is required. Please see Appendix A for detailed instructions.

Cleaning

- Follow hospital procedure.

Drying

- Products should be dry at this point. If moisture or excess liquid is detected, dry with a soft clean towel.
- Medically compressed air can be used if needed.

Maintenance

- Refer to the product insert for further product information.

Inspection and Function Testing

- Visually inspect equipment for damage and wear. Make sure all locking mechanisms and joints are functioning normally. See Appendix A to get more information.

Packaging

- Wrapped – using wrappers designed for steam sterilization.

Sterilization Equipment: Steam Sterilizer

Method

1. Follow sterilizer manufacturer's instructions for loading and operating the sterilizer.
2. Make sure direct steam exposure to all surfaces is possible.
NOTE – Avoid heavy loads and overcrowding on sterilizer shelf/racks.
3. Steam sterilize at 132.2°C – 135°C high vacuum (2psia) for 3 minutes.
4. Remove tray from sterilizer following hospital procedure and allow cooling.
NOTE – Allow components to reach room temperature before use.

Sterilization - Group 3 - BUDDÉ Halo and Reusable Skull Pins

Storage

- Store equipment according to hospital procedures.

Additional Information

- Use caution when handling reusable Skull Pins.

Contact Information

- Please call 1.877.444.1114 or 513.533.7979 for Customer Service. Repair Department can be reached through these numbers.



Appendix A - Disassembly and Cleanliness Inspection

Group	Product Name(s)	Disassembling Equipment	Inspecting for Cleanliness
1	<ul style="list-style-type: none"> • 2000 Skull Clamp (A2000) • Radiolucent Skull Clamp (A2002) 	Take the ratchet arm out of the skull clamp base by releasing the plunger knob. Keep lock knob in unlocked position.	Pay close attention for organic debris in the channel on the skull clamp base, hole passing through the starburst, pin carriers, and lock knob.
1	<ul style="list-style-type: none"> • Modified Skull Clamp (A1059) 	Take the ratchet arm out of the skull clamp base by releasing the plunger knob. Keep lock knob in unlocked position. Remove 80 lb Pressure Knob.	Pay close attention for organic debris in the channel on the skull clamp base, hole passing through the starburst, pin carriers, and lock knob.
1	<ul style="list-style-type: none"> • Triad Skull Clamp (A1108) 	Take the ratchet arm out of the skull clamp base by releasing the plunger knob. It is also possible to unscrew all three pin carriers. Keep lock knob in unlocked position.	Pay close attention for organic debris in the channel on the skull clamp base, hole passing through the starburst, pin carriers, and lock knob.
1	<ul style="list-style-type: none"> • Infinity Skull Clamp (A1114) 	Remove rocker arm attachment from skull clamp and remove ratchet arm out of the skull clamp base. Keep lock knob in unlocked position. Remove 80 lb or 18 lb pressure knob.	Pay close attention for organic debris in the channel on the skull clamp base, hole passing through the starburst, pin carriers, lock knob, and area where rocker arms attach.
1	<ul style="list-style-type: none"> • Ball Socket Swivel Adaptor (A1064) • Swivel Adaptor (A1018) • Modified Swivel (A1115) 	Completely remove the swivel adaptor from any components. The swivel adaptor itself cannot be disassembled any further.	Inspect the teeth of the starbursts, the area around the locking screw, and the base of the swivel adaptor for organic debris.
1	<ul style="list-style-type: none"> • Radiolucent Swivel Adaptor • Radiolucent Dual transitional member 	Completely remove the swivel adaptor from any components. The swivel adaptor itself cannot be disassembled any further.	Inspect the teeth of the starbursts, the area around the locking screw, and the base of the swivel adaptor for organic debris.

Appendix A - Disassembling and Cleanliness Inspection

Group	Product Name(s)	Disassembling Equipment	Inspecting for Cleanliness
1	<ul style="list-style-type: none"> • Tri-Star Swivel Adaptor (A2008) • Modified Tri-Star (A1116) 	Completely remove the swivel adaptor from any components. Unlock the Tri-Star bar and remove torque screw and Tri-Star bar.	Inspect the teeth of the starbursts, the area around the locking screw, and the base of the swivel adaptor for organic debris.
1	<ul style="list-style-type: none"> • General Purpose Headrest (A1008) • Horseshoe Headrest (A1012) • Pediatric Headrest (A1051) 	Remove the gel pads from the unit by sliding off. Keep all joints in the unlocked position. Slide the adjustable headrest base until it comes apart.	Inspect the teeth of the starbursts and make sure to inspect all joints. Pay close attention to the area around the locking screw.
1	<ul style="list-style-type: none"> • Ultra Base Unit (A2101) 	Keep the unit in the unlocked position and remove the transitional member. DO NOT lock the handle without the transitional member in place.	Pay close attention to the area around the locking mechanism and the teeth of the starburst.
1	<ul style="list-style-type: none"> • Ultra 360 Patent Positioning System (A2009) 	Keep the unit in the unlocked position and remove the transitional and adaptor attachment. DO NOT LOCK handle without the transitional member or adaptor attachment in place.	Pay close attention to the area around the locking mechanism and the teeth of the starburst.
1	<ul style="list-style-type: none"> • Radiolucent Base Unit (A1079) 	Unlock both handles on the sides of the base unit and make sure the lock knob underneath is unscrewed. Completely remove the swivel adaptor and dual transitional member.	Inspect both of the joints surrounding the table locking mechanisms and the lock knob. Pay close attention to the teeth on the starbursts.
2	<ul style="list-style-type: none"> • Gel pads 	Slide the gel pads off the headrest base. No further disassembly can be performed.	Inspect the bottom plastic canal for organic debris.
3	<ul style="list-style-type: none"> • Radiolucent Budde Halo (A1096) 	Disassemble components as normal and place back into tray.	Before sterilizing look into tray for any sign of organic debris.
3	<ul style="list-style-type: none"> • Budde Halo (A1040) 	Disassemble components as normal and place back into tray.	Before sterilizing look into tray for any sign of organic debris.
3	<ul style="list-style-type: none"> • Reusable Skull Pins (A1047, A1048) 	No disassembly. Make sure O-Ring is in place and intact. Look for bent or hooked pin points.	Inspect reusable pin closely for any sign of visible organic debris.

Appendix B - Optional Automatic Wash / Disinfect Instructions

CAUTIONS

- Alkaline and highly acidic detergents and solutions cause damage to the devices.
- Channels and crevices found on these devices require particular attention during cleaning.

Limitations on Reprocessing

- **Repeated processing has negative effects on these devices and is not recommended for routine use.**
- It is important to have Integra NeuroSpecialists perform routine inspections (twice yearly is recommended). See contact information.

INSTRUCTIONS

Cleaning - Automated Equipment: Neutral pH Detergent

Method

1. Prepare equipment for cleaning by disassembling removable parts and loosening connections.
2. Rinse equipment in warm water before placing into washer.
3. Load device into the washer and place small parts in container or tray inside the washer unit in order to avoid losing small components.

NOTE – Load devices carefully into washer in order to avoid collision. Place open hinges and cannulation in a position for proper drainage (Ultra Base Unit A-2101).

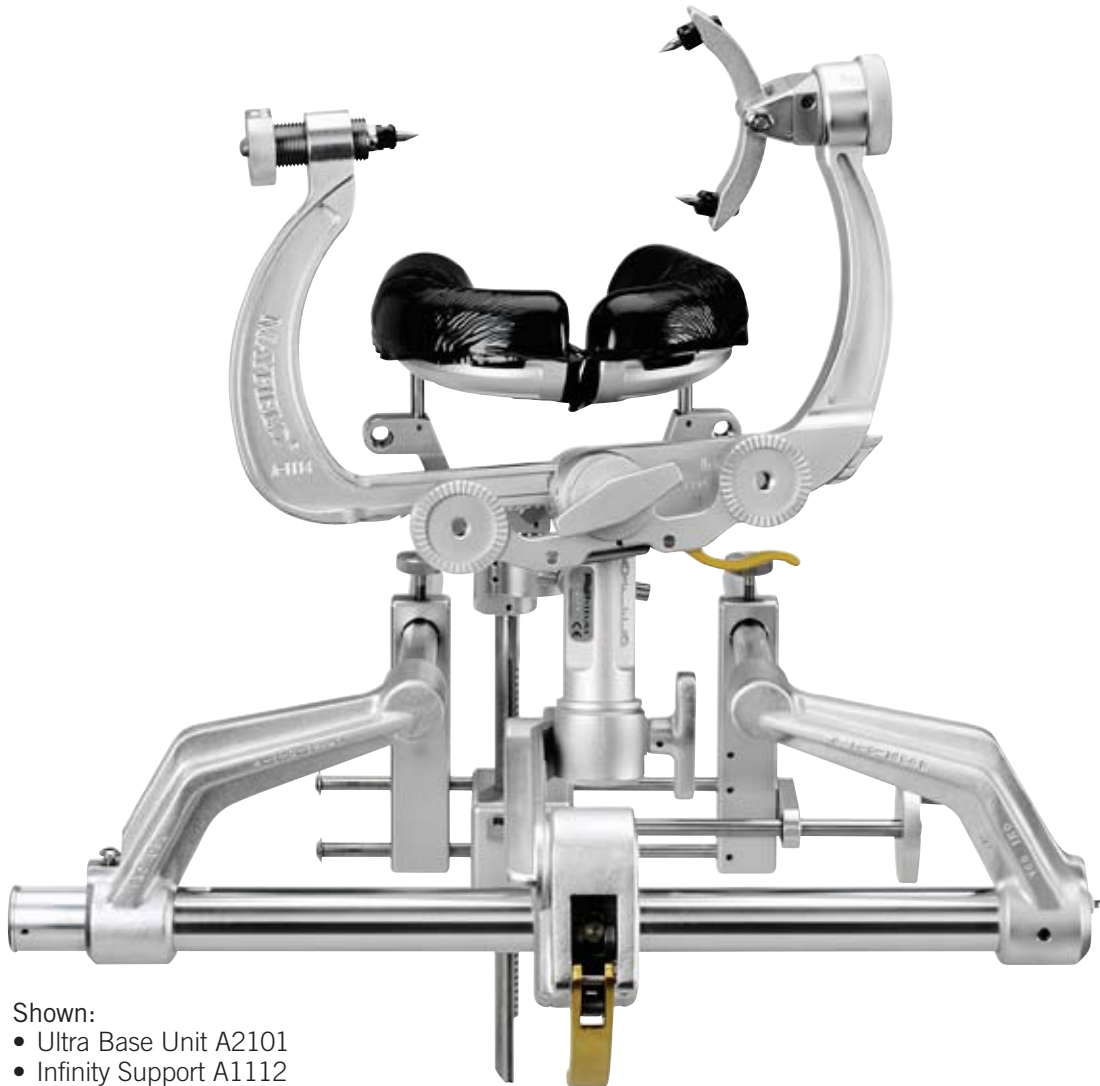
4. Follow the instructions listed below and set washer machine to these exact parameters:

Phase	Time (Min.)	Water Temperature	Detergent and Concentration
Pre-wash 1	4:00	Cold water	N/A
Enzyme Wash	4:00	Hot water	Neutral pH enzymatic
Wash 1	10:00	60.0°C (140° F)	Neutral pH detergent
Rinse 1	0:30	Hot water	N/A
Thermal Rinse	2:00	82.2°C (180° F)	N/A

NOTE – Any deviation from this guideline could result in damage to the equipment as well as improper cleaning results. Rinse with purified water. Do not perform if parameters cannot be achieved.

6. Remove from washer and dry completely if needed.
7. Inspect equipment to make sure there is no visible organic debris or residue from cleaning agent. Repeat process if any visible soil is detected.

DECONTAMINATION PROTOCOL



Shown:

- Ultra Base Unit A2101
- Infinity Support A1112
- Tri-Star Swivel Adapter A2008
- Infinity Skull Clamp A1114
- Disposable Skull Pins A1072



Customer Service/Ordering Information

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