

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING, AS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY, ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKewise ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.

Literature Citations and References

1. Henschke UK, Lawrence DC, "Cesium-131 Seeds for Permanent Implants," *Radiology*, 85, 1117-1119 (1965).



IMPROVING THE LIVES OF PATIENTS WITH BRAIN TUMORS



GammaTile Radiation Shielding Tray Instructions For Use

REF GT-002

Description

The GammaTile Radiation Shielding Trays are used to contain, protect and provide radiological shielding during handling of GammaTile.

Physical Characteristics

1.5 mm thick type 304 Stainless-Steel

GammaTile utilizes Cesium-131 as its radiation source. The Cesium-131 half-value thickness of lead is 0.025 mm. Thus, a 0.25 mm lead sheet will provide ~99.9% reduction of exposure¹.

Lead Equivalency Statement: 1.5mm of stainless-steel is equivalent to 0.24mm of lead.

Indications

GammaTile Radiation Shielding Trays are intended for use as shields against ionizing radiation during GammaTile procedures.

Contraindications

The improper use of radiation shielding trays during handling, surgical use or reprocessing, for which they are indicated, may result in radiation exposure.

Warnings

If this instrument is/was used during a procedure with a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the instrument cannot be reused and must be destroyed due to inability to reprocess or resterilize to eliminate the risk of cross-contamination. Consult WHO and local regulations for further information.

Sterilization: GammaTile Radiation Shielding Trays must be inspected, cleaned and sterilized before each surgical procedure.

GammaTile Radiation Shielding Tray

Instructions For Use



Precautions

- When reprocessing surgical instruments, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.
- Instruments manufactured from different metals should be processed separately to avoid electrolytic actions between the metals resulting in pitting and rusting of stainless-steel instruments.
- Keep ebonized instruments separate from other stainless-steel instruments to avoid scratches to and removal of the ebonized coating.

Limitations on Reprocessing

- End of useful life for metal surgical instruments is normally determined by wear and damage due to the intended surgical use.
- Always inspect instruments between uses to confirm proper functioning.

Reprocessing Instructions

From Point of Use

Wherever possible, do not allow blood, debris or body fluids to dry on trays. For best results and to prolong the life of the GammaTile radiation shielding tray reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

Cleaning Procedure

The following cleaning method was validated in accordance with the recommended evaluations as listed in AAMI TIR30, AAIR TIR12, and Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling:

- Disassemble the stainless-steel tray and lid and then immerse them in a detergent bath using 1oz. of Enzymatic Detergent per gallon of lukewarm tap water.

- While immersed, the entire tray and lid shall be brushed using a soft bristle brush paying attention to hinged areas, crevices and other difficult to clean locations. Ensure that the stainless-steel tray and lid are not scratched by sharp objects during this procedure.
- Remove the stainless-steel tray and lid from the detergent bath and visually inspect that surfaces are clean and free from damage, stains and soil.
- Rinse the stainless-steel tray using running RO/DI water paying attention to hinged areas, crevices and hard to reach areas.
- Dry the test article with a lint free cloth.

Sterilization Procedure

- Use a validated, properly maintained steam sterilizer.
- Always follow instructions of the machine manufacturer.
- Do not exceed 140° C (284° F) during sterilization cycle.
- Effective sterilization can be achieved following the steam cycle listed below:
- Using a pre-vacuum sterilizer, individually wrap the stainless-steel trays and steam sterilize for 4 minutes at 132°C (270°F)/ dry 30 minutes.

Inspection and Function Testing

- Remove tray lid; ensure that the lid has smooth movement without excess play when removed.
- Visually inspect and check trays for damage and wear.
- Replace tray lid; ensure lid and tray align correctly; ensure lid has smooth movement when replaced

Consider removing for replacement any tray that does not meet the above inspection or is worn out, flaking, fractured, corroded, stained, discolored or damaged.

Storage

Non-sterile instruments or sterile wrapped instruments should be stored in dry, clean conditions at an ambient room temperature.