

2025

# RAM LICENSE TOOLKIT

# RAM LICENSE TOOLKIT

## Streamlining Your RAM License Amendment for Cs-131 Gammatile

Facilities must be approved for possession and use of **GammaTiles containing Cs-131 Sealed Sources**, as indicated on a valid **radioactive materials (RAM) license** before GT Medical Technologies can fulfill GammaTile orders. It is the responsibility of GammaTile customers to ensure that Authorized User(s) who will supervise GammaTile implants be included on the RAM license. Adding the GammaTile device and/or Authorized Users to the RAM license may be done by submitting an amendment request letter to the appropriate regulatory body.

To expedite preparation of a RAM license amendment request letter, a **RAM License Toolkit** has been prepared that consists of essential documents, including a **pre-drafted RAM License Amendment Request Letter** in Microsoft Word format. By using this toolkit, facilities can efficiently update their license, maintain compliance, and safely integrate **GammaTile** therapy into patient care.

### INSTRUCTIONS

Download the individual sections of the **RAM License Amendment Request Letter** using the link below. The templates provided for conditions for use, policies and procedures, written directive form, postoperative patient survey and release record form, and written patient safety instructions form should be carefully reviewed and edited, as appropriate. Any highlighted portions should be replaced with site specific information.

## Kit Contents

Access full kit contents by clicking [here](#) (Zip file)

### QUESTIONS AND SUPPORT

For additional questions or support about how to use the contents of the GammaTile RAM License Toolkit, please contact: [support@gammatile.com](mailto:support@gammatile.com).



# Toolkit Contents

Access the downloadable files through the **link provided** to easily tailor content for your needs.

## LETTER TEMPLATE

→ **RAM License Amendment Request Letter** ([Template](#))

## LETTER ATTACHMENTS

- **Attachment A** ([Template](#)): Conditions for Use of GammaTile Sealed Brachytherapy Source
- **Attachment B**: Registry Of Radioactive Sealed Sources and Devices Safety Evaluation Of Device (Amended In Its Entirety)
- **Attachment C**: GammaTile Brachytherapy Source Device, Model GT-001, Instructions for Use
- **Attachment D** ([Template](#)): GammaTile Brachytherapy Policies and Procedures
- **Attachment E** ([Template](#)): Written Directive Form for GammaTile Manual Brachytherapy
- **Attachment F** ([Template](#)): Postoperative Patient Survey and Release Record from GammaTile Manual Brachytherapy
- **Attachment G** ([Template](#)): Written Patient Safety Instructions Form for GammaTile Manual Brachytherapy

## NOT INCLUDED

- **Attachment H**: Additional Areas of Use for Implantation of GammaTile
- **Attachment I**: Authorized User Documentation

## FOR INFORMATIONAL PURPOSES ONLY

→ **GammaTile RAM License Amendment Quick Reference**



For product information or assistance, or to be connected with your GammaTile representative, contact:

**GammaTile Customer Service Department**

(833) 662-0044 | [customerservice@gtmedtech.com](mailto:customerservice@gtmedtech.com)

For adverse event reports and product complaint reports, contact:

**GammaTile Medical Information Department**

(833) 662-0044 | [feedback@gtmedtech.com](mailto:feedback@gtmedtech.com)

GammaTile® is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms. The potential for, and symptoms of, adverse events related to radiation exposure vary depending on the radiosensitivity of the exposed tissue, the amount of radiation delivered, and the placement of GammaTile(s). GammaTile should not be used for patients with known history of hypersensitivity to bovine-derived materials. More information on indications, contraindications, warnings, and instructions for use can be found in the GammaTile Instructions for Use.

**CAUTION:** The law restricts these devices to sale by or on the order of a physician.

©2025 GT Medical Technologies, Inc. GammaTile® is a registered trademark of GT Medical Technologies, Inc. All rights reserved. MKT-419-01