thermoscientific

Instructions for Use

These instructions are valid for:

IVD	**Samco™ Bio-Tite™ Specimen Containers for Sterile Environment**
REF	**07 0006**
GTIN	**10850016060560**
GMDN	**63838**

Intended Use

Intended purpose/use	The Samco™ Bio-Tite™ Specimen Containers for Sterile Environment are covered specimen receptacles and are intended to be used for the collection, preservation and/or transport, of any type of tissue specimen (e.g., biopsy tissue) collected from any body part for *in vitro* diagnostic investigation. They do not contain patient-contact specimen sampling/extraction devices such as swabs/brushes. The container can be used to store samples at temperatures down to -80°C. The containers are for single use only. Intended for use by healthcare and laboratory professionals.
Indications for use	To be used when a healthcare professional determines an area of tissue in the body is not presenting as normal and biopsy is recommended.
Intended user group	Healthcare and laboratory professionals.
Use environment	Operating rooms of hospitals and associated laboratories.
Intended patient population	Patients with a medical or clinical condition that require a biopsy for *in vitro* diagnostic investigation, diagnosis, and possible medical treatment.
Contraindications	No known contraindications have been identified.

Instructions for Use

The specific use of these containers must be defined and implemented by the standard operating procedures and policies of the healthcare facility to whom they are sold.

Conditions of Use

Samco™ Bio-Tite™ Specimen Containers for Sterile Environment	
Transportation conditions	Ambient temperature (-40°C to 50°C or -40°F to 122°F)
Storage conditions	Room temperature (20°C to 26°C or 68°F to 77°F)

Limitation of use

The Samco™ Bio-Tite™ Specimen Containers for Sterile Environment are only intended for the collection, preservation and/or transport, of any type of tissue specimen (e.g., biopsy tissue) collected from any body part for *in vitro* diagnostic investigation.

Technical information

Disposal of the device must be handled according to local regulations.

⚠ Warnings and precautions

To ensure correct usage, familiarise yourself with the following warnings before using the device.

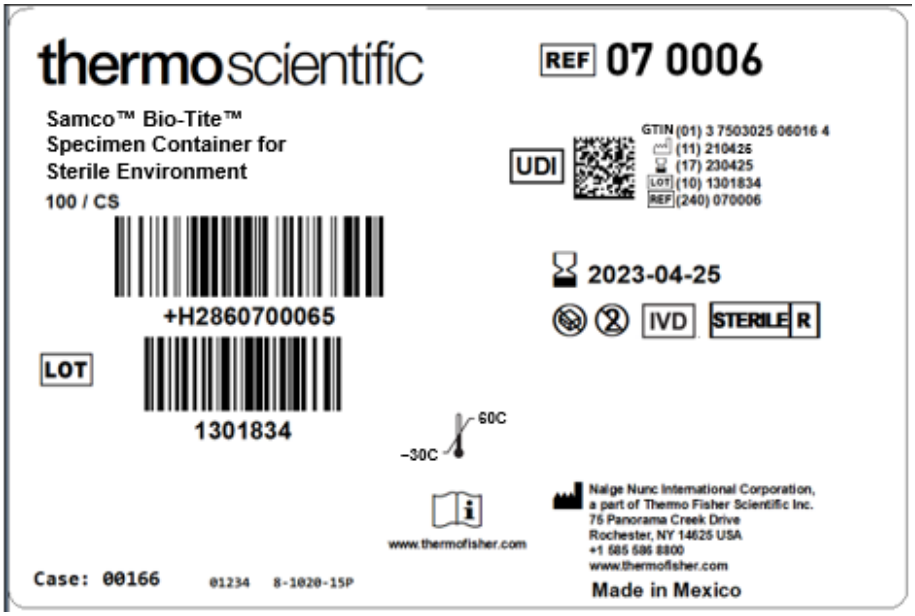
1. Device is not intended for repeated use; this is a single use container.
2. The shelf life of this device is two (2) years from the date of manufacture, as stated on the labeling. Do not use after expiration date.
3. This device is supplied sterile via irradiation sterilization method. Do not use if product packing is unsealed or damaged.
4. The product is not a sealed container; in use, ensure the lid is properly seated and tightened to prevent possible leakage.
5. Dispose of the used product after use in an appropriate biohazard collection container.
6. Report any serious incident that occur in relation to these devices to the manufacture.

Report to the manufacturer and local competent authority if you experience unexpected operation or serious incident with the device during or because of its use. The manufacturer will support and if relevant report it to the competent authorities.

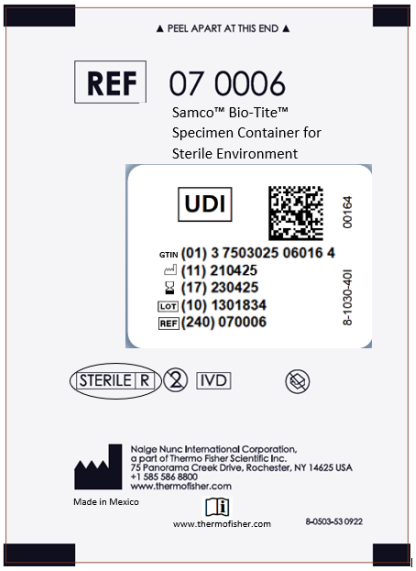
Quality Assurance Release Specifications

TEST	RELEASE LIMIT(S)
Irradiation Cert. Review	25 – 40 kGy

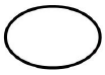
Case Label



Pack Label



Symbols Glossary in accordance with ISO 15223-1:2021 and other references

Symbol	Title of Symbol	Description of Symbol	Reference Number
	Manufacturer	Indicates the medical device manufacturer as defined in EU Regulation 2017/745 and 2071/746	5.1.1
	Date of Manufacture	Indicates the date the medical device was manufactured.	5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Single *sterile* barrier system	Indicates a single barrier system.	5.2.11
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution	Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions	5.4.4
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device	5.5.1
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	5.7.10

Contact Information

Legal Manufacturer 

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a part of Thermo Fisher Scientific Inc.
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www.thermofisher.com

This is Revision 2.00 of this IFU. This revision updated the following information:

- Updated name of product to better reflect intended purpose.
- Noted that the device is intended for use by healthcare and laboratory professionals.
- Organized the symbols glossary by numeric order of reference number.
- Added the temperature limit symbol.
- Added warning symbol.
- Included device shelf life in warnings and precautions.
- Included device is supplied sterile via irradiation sterilization method in the warnings and precautions.
- Removed CE Mark and associated references.