INSTRUCTIONS FOR USE

TissueLock™ Paraffin 56

TL56-01, TL56-08

INSTRUCTIONS FOR USE

PART NUMBER, PRODUCT NAME, SIZE:
TL56-01 TissueLock™ Paraffin 56, 1 kg
TL56-08 TissueLock™ Paraffin 56, 8 kg

UDI-DI:
506002325PHCHWXK

INTENDED USE
Product Function
Paraffin wax is used for infiltrating and embedding biological specimens that have been collected, preserved by fixation, and dehydrated. The prepared samples are infiltrated with molten paraffin wax and then embedded into a mold for sectioning via microtomy. Thin paraffin sections with embedded specimens are mounted on glass slides for further processing to highlight molecular, cellular, or structural features with various techniques including but not limited to, immunohistology or use of biological dyes and stains.

Specific Information
- Infiltrates tissue specimens for preservation of cellular structure.
- Fills tissue block molds for embedding tissue specimens for microtomy.

Detection/Measurement
- Does not measure or detect any analytes or markers.
- Is not quantitative, semi-quantitative, or qualitative.

Specimen Type
- Is suitable for use with any biological specimen type. No limitations known.

Automation
- Is not automated but may be used in automated instrumentation.

Testing Population
- Not intended for self-testing, near patient testing, and has no direct interaction with patients.
- Using auxiliary materials creates patient specimens that enable qualified and authorized personnel to obtain evidence for a diagnosis of a pathological condition.

DEVICE CLASSIFICATION

IVD

Ethos Biosciences' TissueLock™ Paraffin 56 is for *in vitro* diagnostic use only.

INTENDED USER
Trained histopathology/laboratory professionals.

DESCRIPTION AND COMPOSITION
TissueLock™ Paraffin 56 consists of ~5-10 mm solid, white pellets made of paraffin wax and polymer. The melting point is 55-58˚C.

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READINESS FOR USE
Ready-to-use formulation that does require any preparatory treatment(s) prior to melting.

STORAGE AND HANDLING CONDITIONS
Store pellets at room temperature. Do not store above 35˚C. Store in a dry environment, out of direct sunlight.
Avoid heat and ignition sources.
Single use only. Keep sealed between uses.

In-Use Storage Conditions
Melted paraffin should not be stored above 60˚C.

EQUIPMENT REQUIRED
Intended with use with histopathology processing units. Functions in pressure/vacuum fluid flow tissue processors as well as pulsating processors. No known restriction with other equipment.

STERILITY
Non-sterile material

INFECTIOUS MATERIALS
No infectious materials have been identified in the wax pellets. As with any reagent near or around biological specimens, wear appropriate personal protective equipment and follow any institutional guidelines for laboratory safety.

SPECIAL FACILITES OR USER QUALIFICATIONS
For use in laboratory environments. Tissue embedding equipment required. All equipment and instruments should be serviced according to internal SOPs or manufacturers recommendations. For professional use only by qualified personnel that have been trained in preparation of tissue specimens for histological examination.

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PROCEDURE

Infiltration

TissueLock™ Paraffin 56 is made molten and transparent by heating wax pellets approximately 2˚C above melting point of 55-58˚C. Properly prepared and cleared specimens are immersed in the molten wax for 2-4 hours, depending on quantity and type of tissue in a closed tissue processor. For vacuum embedding, a minimum of 2 changes of paraffin is recommended for proper infiltration. This process infiltrates the specimen with wax for hardening and stabilizing the sample.

Embedding

For microtomy, infiltrated specimens are placed in a block mold in the correct orientation, and the mold is filled with molten TissueLock™ Paraffin 56. A tissue cassette is placed on top of the mold and more molten paraffin is added. The optimum cooling temperature during embedding is –5˚C to 0˚C.

Sectioning

During microtomy, the block with the embedded specimen can be sectioned from 5˚C to room temperature. The water bath temperature for floating sections should be 5-10˚C below the melting point of 55-58˚C.

TECHINAL ISSUES

If flocculation is observed (white fibrous masses suspended in solution), increase water bath temperature temporarily to redissolve. Contact us at info@ethosbiosciences.com for any further issues.

RECOMMENDED QUALITY CONTROL PROCEDURES

Not applicable for end user. Quality control is conducted by manufacturer.

TRACEABILITY OF CALIBRATORS AND CONTROL MATERIALS

Not applicable. Device does not provide a measurement or analytical function.

CALCULATIONS AND INTERPRETATION OF RESULTS

Not applicable. Device is not an instrument, does not provide a measurement, or analytical function.

ANALYTICAL PERFORMANCE CHARACTERISTICS

Paraffin in not used to detect a specific markers or analytes. Instead, paraffin infiltrates and embeds biological samples, and therefore, is not subject to analytical performance characteristics such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantification, measuring range, linearity, cut-off, criteria for specimen collection and handling, control of known relevant endogenous and exogenous interferences, or cross reactions.

CLINICAL PERFORMANCE

The performance of TissueLock™ Paraffin 56 has been assessed for use in histological applications, and the performance evaluation is maintained by Ethos Biosciences. Please contact **info@ethosbiosciences.com** for further information.

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DISPOSAL INTRUCTIONS
Disposal should follow all local or national regulation and facility guidelines.

HAZARD CLASSIFICATION
Please follow the hazard classification printed on the label and the information provided in the safety data sheet. The SDS are available via **https://ethosbiosciences.com**.

CE MARKING
CE The produc(s) described in this document meet the Council provisions that apply to them, and the CE Mark is affixed.

Any serious incident related to the device shall be reported to the manufacturer and competent authority of the member state in which the user is established.

DOCUMENT HISTORY

VERSION	DATE	CHANGES
1	2024-10-18	Document created