IndiTreat®
Shipping Container

Instructions For Use- EN English

2CX-SC-01

IFU is available in other languages at:
www.inditreat.com/eIFU

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INTENDED USE

The intended use for the IndiTreat® Shipping Container is to a provide a controlled cooling temperature shipping system for transport of a specimen to laboratories performing in vitro diagnostic IndiTreat® testing.

PRODUCT USE

The IndiTreat® Shipping Container is a single-use accessory device and is not intended to detect or measure.

INTENDED USER

Intended users of the IndiTreat® Shipping Container are healthcare professionals and laboratory professionals.

INTENDED USE ENVIRONMENT

The IndiTreat® Shipping Container is intended to be used at hospital departments such as surgery, radiology, pathology, or other hospital departments where tumor biopsies are taken.

BASIC PRINCIPLES OF THE PROCEDURE

The IndiTreat® Shipping Container is a specialized single-use shipping container capable of supporting specimen with optimal shipping conditions by providing stable temperatures within 2-8°C in the sealed payload compartment for at least 48 hours. The advanced technology of the cooling insert is designed to transfer the heat from inside of the sealed payload compartment to the silver-foil side. The exterior cardboard may feel warm from this controlled cooling process.

COMPONENTS INCLUDED

Components included	**Description**
IndiTreat® Shipping Container	Specialized shipping container designed to maintain specimen temperature at 2-8°C for at least 48 hours during shipment. The container consists of a white outer cardboard box with a removable cooling insert fitted into an insulated payload inside. The shipping container is labelled with a UN 3373 sticker and is intended for shipment of Biological Substance Category B specimens. The shipping container also has an

	attached packing-list envelope for insertion of printed shipping instructions.

COMPONENTS REQUIRED, BUT NOT INCLUDED

Component	Description
Printed shipping instructions • Visit Ordering.inditreat.com or contact 2cureX Support (see section for SUPPORT) for help and guidance for organizing specimen shipment with currier.	Printed shipping instructions for shipment to laboratories performing IndiTreat® testing. The shipping instructions must be aligned with UN3373 requirements for transport of Biological Substance Category B.

WARNINGS AND PRECAUTIONS

- Do not reuse the IndiTreat® Shipping Container. It is only intended for single use.
- Do not use the IndiTreat® Shipping Container after its expiry date.
- Do not store the IndiTreat® Shipping Container under freezing conditions as this could result in product failure.
- Do not use IndiTreat® Shipping Container if there is sign of leakage from the cooling insert.

CMR OR ENDOCRINE DISRUPTING SUBSTANCES

No data is available regarding carcinogenic, mutagenic or reprotoxic chemicals, or other endocrine disrupting substances for this product.

DISPOSAL

Dispose the IndiTreat® Shipping Container as general waste or recycle according to local disposal regulations.

STORAGE AND STABILITY

- The IndiTreat® Shipping Container should be stored under dry and clean conditions at ambient temperatures between 17°C to 25°C.
- Storage above 25°C is not recommended as this could negatively affect the product's shelf life.
- Do not freeze the IndiTreat® Shipping Container as this could result in product failure.
- Check the label on the IndiTreat® Shipping Container for expiration date.

- The IndiTreat® Shipping Container is a single-use product. Once the cooling insert has been activated it will maintain temperature of the payload section within 2 -8°C for at least 48 hours during storage/transportation.

STERILITY

Not sterile.

PROCEDURE

IT IS RECOMMENDED THAT THE USER READ THESE INSTRUCTIONS BEFORE USE

PROCEDURE STEP	TASK
STEP 1: Remove the cooling-insert from the IndiTreat® Shipping Container	• Open the IndiTreat® Shipping Container and take out cooling insert compartment. The cooling insert does not require to be cold prior to use.  

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	• Place the cooling insert on a hard, flat and clean surface with the foil-side facing down and the activation button facing upwards. 
STEP 2: Activate the cooling insert	• Activate the cooling insert by pressing down the button with your thumb. DO NOT use a sharp object to press the Button. 
STEP 3: Check cooling insert is cold	• Check that the colling insert has been activated. When activated, the NanoCool logo on the insert should turn blue within 30 seconds to 3 minutes. Touch the surface around the button to confirm that the cooling process has begun. 

STEP 4: Pack the payload compartment	• Place the collected specimen to be shipped inside the payload compartment of the IndiTreat® Shipping Container. For ordering of IndiTreat® Specimen Collection kit see section for Ordering Information.  ⚠ **WARNING- RISK OF INFECTION** Specimen could potentially be infectious and should be handled according to local and national guidelines [1].
STEP 5: Place cooling insert back into shipping container	• Place the activated cooling insert back into the shipping container with the foil side of the cooling insert facing upwards. • Firmly press the cooling insert down to ensure a tight fit into the shipping container.

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	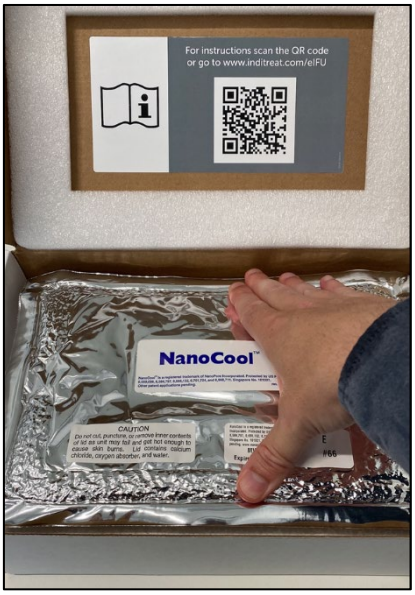
STEP 6: Seal IndiTreat® Shipping Container and prepare shipping box	• Close the shipping container and insert the flaps. Apply tape on the locations as indicated on the container to ensure correct sealing. • **DO NOT** cover the UN3373 sticker with tape.  

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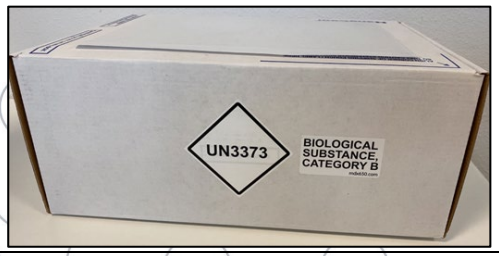
- Insert the shipping instruction into the packing-list envelope attached onto the IndiTreat® Shipping Container.

- Peel off the plastic on the tape and seal the envelope.

CAUTION-RISK OF DAMAGE TO SPECIMEN

- Incorrect shipping temperature can compromise specimen viability. Ensure that the IndiTreat® Shipping Container has been activated to cool the specimen during shipment.

- Delay in shipment can compromise the specimen viability. To avoid delay in shipment, ensure that the IndiTreat® Shipping Container is labelled with a clear visible UN 3373 label. Do not cover this label with tape. Contact 2cureX directly for further help and guidance regarding shipment instructions (see section for SUPPORT).



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LIMITATIONS OF PROCEDURE

No data is available for this product.

CONTROL PROCEDURE

The activation of the advanced colling mechanism of the cooling insert of the IndiTreat® Shipping Container is controlled by observing that the NanoCool logo on the insert turns blue. Touching the surface around the activation button on the cooling insert can also confirm that the cooling mechanism has been activated.

PERFORMANCE CHARACTERISTICS

Once activated, the cooling insert of the IndiTreat® Shipping Container can provide stable temperature within 2-8°C inside the sealed payload compartment for at least 48 hours. The shipping container has been tested against ASTM D4169:2022 DC 13- Assurance level II and P650 guidelines in compliance with UN3373 shipment requirements.

SUPPORT

For technical support and other product-related inquiries, please contact your local distributor or contact 2cureX Support directly (email: support@2cureX.com).

Any serious incidents by user occured in relation to product use shall be reported to 2cureX and the competent authority of the Member State where the user is established.

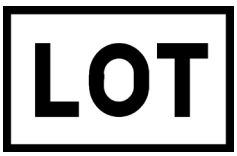
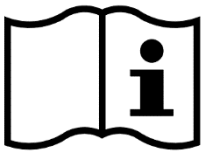
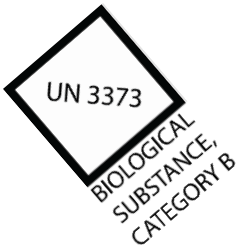
ORDERING INFORMATION

Item product reference code	Description
2CX-SCK-01	IndiTreat® Specimen Collection Kit
2CX-SC-01	IndiTreat® Shipping Container

Contact your local distributor for ordering or contact 2cureX (email: customerservice@2curex.com).

2cureX complies with the IVD regulation and is ISO 13485 certified [2 and 3].

LABELING SYMBOLS

	Manufacturer		In vitro diagnostic product
	Caution or warning		Product reference code
	Temperature limitations		LOT number
	Expiry date		Do not re-use
	Consult online Instructions For Use		EU conformity mark
	UN3373 conformity mark for transport of biological substance, category B		

REFERENCES

1. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline –Fourth Edition. CLSI document M29-A4E. 2014

2. 2017/746/EU IVD European Regulation
3. ISO13485:2016 Medical Device Standard

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