

Staza™ Autorack (IVD)

These instructions apply to the following Staza™ Device configurations:

- Staza Autorack



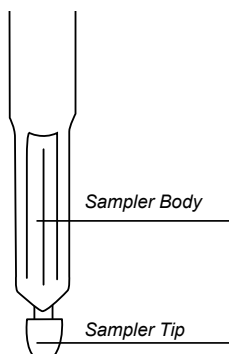
IMPORTANT – Read the entire instructions before use!

Intended Use:

A single-use, non-sterile device intended to contain biological specimens from ex-vivo sources for transport and storage in order that the matter contained therein can be archived and/or used effectively for diagnostic examination.

Device Description:

The Staza Autorack is only available for laboratory professional use. The biological specimen is typically taken from a container (e.g. tube, cup). The sampler tip (contained within the Staza Device) is gently applied to the ex-vivo sample for 12 seconds in total. This process is repeated for each sampler tip in the device.



Product Specifications:

- Sample Type: Biological fluids
- Sample Volume: 20, or 30 μ L
- Substrate: Hydrophilic porous polymer
- Volumetric Precision (%RSD): $\leq 5\%$
- Typical sampling time (per sampling tip): 12 sec
- Number of Samples Collected: Up to 96
- Shelf Life: Refer to expiry date on product label
- Device Storage: Up to 30°C
- Sample Storage: The guidelines for sample storage are analyte dependent and will need to be determined by device end-user

Materials Provided:

- Staza Autorack
- Collection plate
- Sample ID Barcode (if requested)

Warnings and Precautions:

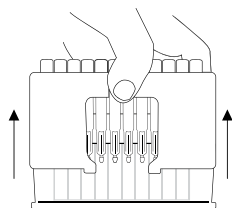
- Single use only for a single individual.
- Do not use after expiration date.
- For external use only.
- Devices should be transported/mailed to the analytical laboratory, and appropriate documentation maintained according to local regulations and the analytical laboratory procedures and policies.
- Do not use if device packaging has been opened or damaged.
- Laboratories must validate use of product for their specific assay.
- Observe universal biological risk precautions.
- All used materials with biological residues must be handled with care and disposed of safely in accordance with local regulations.
- Any serious incident in relationship with the Staza device should be reported as soon as possible to Trajan Scientific and Medical (neo.support@trajanscimed.com) and the competent authority of the Member State in which the user and/or subject is established.
- Please reach out to neo.support@trajanscimed.com in case of multiple under-sampling events.



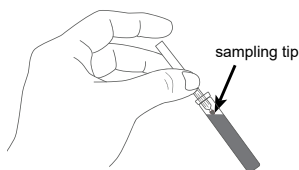
Electronic IFU can be accessed at www.neoteryx.com/collect or scan the QR code to access.

Instructions:

1. Remove Autorack from the collection plate it is resting in by lifting the Autorack up. Set the Autorack down next to the collection plate.



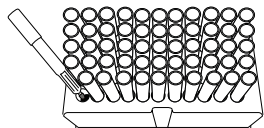
2. Remove a sampler from the Autorack, touch sampler tip to surface of specimen for 12 seconds in total and remove from specimen



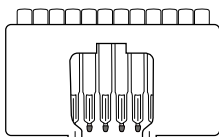
IMPORTANT!

- **Do NOT fully submerge the sampler tip in the specimen.**
- **Sampler tip should always point downward towards floor as illustrated.**
- **Do NOT drip specimen onto the sampler tip.**
- **Ensure sampler tips are filled correctly (Figure 1).**

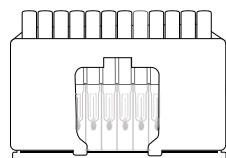
3. Return sampler to Autorack. Repeat step 2 for remaining samplers. Do not touch side walls of Autorack with sampling tip upon entry.



4. Dry sampling tips in Autorack under ambient conditions (~ 3 hours).

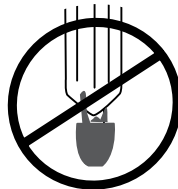


NOTE: The collection plate should ALWAYS be removed from the Autorack during the drying process to allow air to freely circulate around microsamplers. Wait a minimum of 3 hours to ship to ensure dryness of sampling tips.



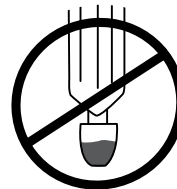
5. Dried samplers can be returned to the collection plate.

Ensure sampler tips are filled correctly.



Over-sampling occurs when:

1. Specimen is dripped onto the sampler tip from above.
2. The entire sampler tip is submerged in the specimen.



Under-sampling occurs when:

1. The sampler tip is removed from the specimen too soon. Touch tip to specimen for 12 seconds in total.
2. Refer to Warnings and Precautions section in case of multiple under-sampling events.



Correctly sampled

Figure 1

For further assistance, please do not hesitate to contact us: neo.support@trajanscimed.com

Specifications are subject to change.

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Trajan Scientific Australia Pty Ltd (Sponsor)
7 Argent Place, Ringwood, VIC 3134, AU
Tel: +61 (0) 3 9874 8577



Trajan Scientific Americas Inc
1241 W Wells Branch Parkway, Suite 108
Austin TX, 78660, USA



www.neoteryx.com/collect

