



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-PROC-047 JA1

DOCUMENT TITLE:

Installation of CliniMACS DTS Tubing Set JA1

DOCUMENT NOTES:

Document Information

Revision: 01

Vault: STCL-Processing-rel

Status: Release

Document Type: STCL

Date Information

Creation Date: 23 Aug 2021

Release Date: 01 Sep 2021

Effective Date: 01 Sep 2021

Expiration Date:

Control Information

Author: WATER002

Owner: WATER002

Previous Number: None

Change Number: STCL-CCR-524

STEP 3

Installation of CliniMACS DTS

Follow the installation instructions given on the CliniMACS^{plus} Instrument Screens.

- Install upper part (1)
- Install lower part (2)

Proceed to the priming procedure.

Perform integrity test (3):

WARNING:

- To perform the integrity test, clamp the tubing below the Non-Target Cell Bag, before starting the integrity test.
- Remove the clamp after completion of the integrity test.

Connect Cell Preparation Bag (4)

- Firmly insert the spike of the Pre-System Filter into the Tubing Set
- Connect Pre-System Filter and Spike Connector
- Spike Cell Preparation Bag
- Ensure that the connections are secure and that free liquid flow is possible

Leveling of Bags (5):

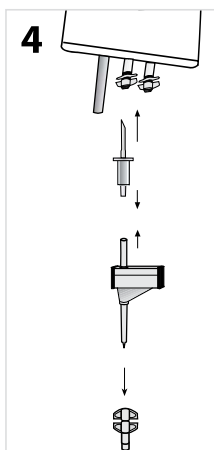
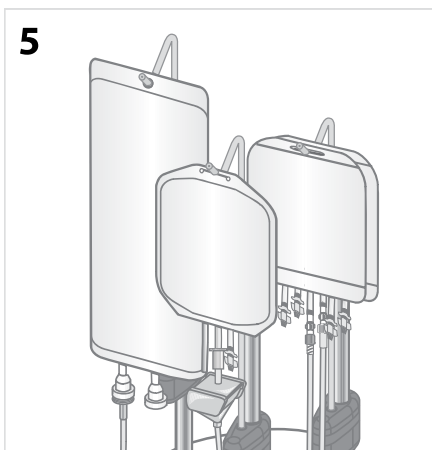
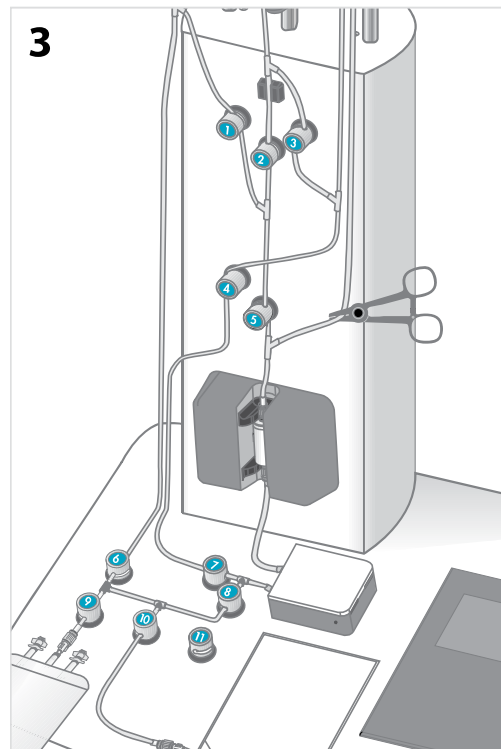
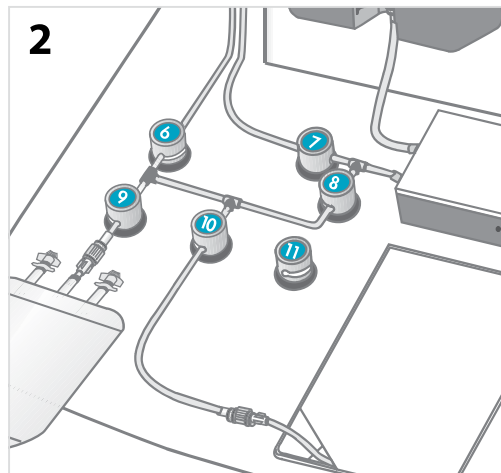
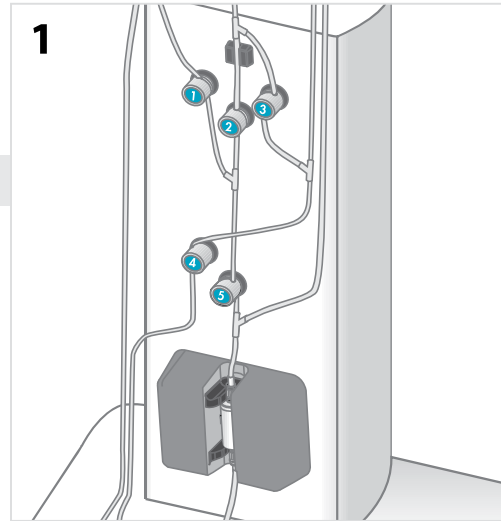
VERY IMPORTANT:

- Ensure that the Buffer Bag, the Cell Preparation Bag, the Non-Target Cell Bag and the Reapplication Bag are leveled correctly as displayed and that the bags and tubings are neither stretched nor bent.

Highest position: Buffer Bag

Middle Position: Reapplication Bag and Non-Target Cell Bag

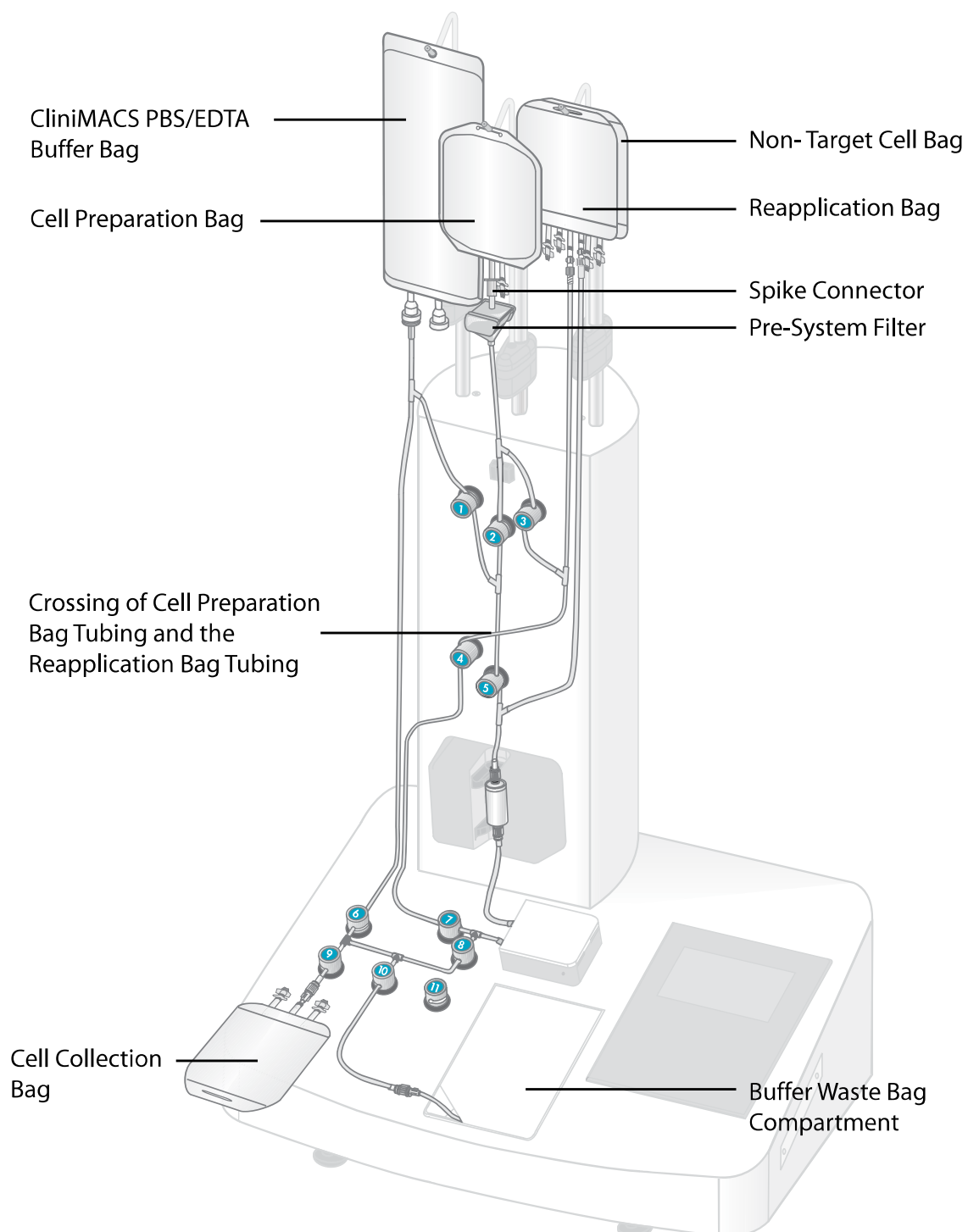
Lowest position: Cell Preparation Bag



Installation of CliniMACS[®] Depletion Tubing Set

Installation of CliniMACS® Depletion Tubing Set

CliniMACS® Depletion Tubing Set



Signature Manifest**Document Number:** STCL-PROC-047 JA1**Revision:** 01**Title:** Installation of CliniMACS DTS Tubing Set JA1**Effective Date:** 01 Sep 2021

All dates and times are in Eastern Time.

STCL-PROC-047 JA1 Installation of CliniMACS DTS Tubing Set JA1**Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		30 Aug 2021, 05:16:01 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		30 Aug 2021, 05:16:19 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		30 Aug 2021, 05:41:47 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch De Gracia (IMS19)		30 Aug 2021, 06:54:20 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		30 Aug 2021, 08:37:05 PM	Approved