



# STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-PROC-038 JA1

**DOCUMENT TITLE:**

Checklist for Depletion Tubing Set-DTS

**DOCUMENT NOTES:**

## Document Information

**Revision:** 01

**Vault:** STCL-Processing-rel

**Status:** Release

**Document Type:** STCL-Processing

## Date Information

**Creation Date:** 20 Dec 2012

**Release Date:** 14 Jan 2013

**Effective Date:** 14 Jan 2013

**Expiration Date:**

## Control Information

**Author:** WATE02

**Owner:** WATE02

**Previous Number:** None

**Change Number:** STCL-CCR-047

CliniMACS® System Short instructions

---

**Important:** A 24 hours emergency hotline (0049-2204-8306-80) is available in case of any urgent technical problems during CliniMACS separations.

**Abbreviations used:**

CPB: Cell Preparation Bag  
CCB: Cell Collection Bag  
RAB: Reapplication Bag  
NTCB: Non-Target Cell Bag  
BWB: Buffer Waste Bag  
DTS: CliniMACS Depletion Tubing Set

**Checklist DTS installation and depletion sequence 3.1**

(This checklist considers only the most important issues of the procedure. Please always refer to the CliniMACS User Manual for entire instructions required.)

**Unpacking of the DTS:**

- ☐ All bag connections tight?
- ☐ Spike Adapter available and put aside?
- ☐ Empty Cell Collection Bag (CCB) weighed?

*Only for pre-connection:*

- ☐ Lines clamped before buffer and cell product are connected?
- ☐ First connect filter to DTS (reservoir points toward tubing set), afterwards attach the blunt end of the adapter to the blunt end of the filter. Finally connect the Cell Preparation Bag (CPB) to the sharp end of the adapter.

**Installation of the DTS:**

- ☐ Hold tray with spike connectors for buffer and CPB pointing towards the instrument and the bags towards the operator.
- ☐ Hang Reapplication Bag and Non-Target Cell Bag, (RAB in front) and fix connectors for buffer and CPB.
- ☐ Insert column (never let it hang down)

*Upper part:*

- ☐ Tubings in V1-V4 correctly inserted? (W-course tubings V1-V3 and crossing of tubings CPB to column and V4 to RAB)
- ☐ Carefully check correct tubing insertion, particularly of V3 and V4

*Lower part:*

- ☐ Valve 11 remains empty.
- ☐ Bag heights correctly adjusted? (Buffer the highest, CPB port the lowest, RAB in the middle)?
- ☐ Tubings carefully checked for kinks and torsions?

**Priming:**

- ☐ (If buffer has been pre-connected, remove clamp before priming)
- ☐ Carefully check for remaining air after priming. If required, repeat priming sequence. (Tubing above V2 remains dry after priming.)

---

STCL-PROC-038 JA1  
STCL, DUMC  
Durham, NC

Page 1 of 2

(c) 2009 Miltenyi Biotec GmbH.

No part of this document may be reproduced, stored in a retrieval system, transmitted, published, or distributed in any form or by any means, electronic, mechanical, photocopying, microfilming, recording, or otherwise, without prior written permission from Miltenyi Biotec GmbH; however, notwithstanding the foregoing, the users of the CliniMACS(R) plus Instrument may make copies solely for purposes of training personnel in the use and servicing of the unit within their business or organization.

Maximal care has been taken by Miltenyi Biotec GmbH in the preparation of this document. However, Miltenyi Biotec GmbH shall not be liable for any technical or editorial errors or omissions contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this document. The information in this document is provided "as is" without warranty of any kind, and is subject to change without notice.

Always refer to the CliniMACS(R) User Manual!

CliniMACS® System Short instructions

---

**After priming buffer volume has to be in:**

- ☐ RAB
- ☐ NTCB
- ☐ Buffer Waste Bag (BWB)
- ☐ CCB must be empty

**Integrity Test:**

- ☐ Tubing to NTCB clamped before Integrity Test is done?
- ☐ Clamp removed after Integrity Test is finished?
  
- ☐ CPB correctly connected? (if not already pre-connected):
  - ☐ 1. Connect filter to DTS (filter reservoir points towards DTS).
  - ☐ 2. Attach spike adapter to filter (use blunt end). 3. Connect to Cell Preparation Bag (CPB)
  - ☐ 3. If already pre-connected, remove clamp now.

**Start of depletion**

- ☐ Is filter sufficiently filled with buffer? (tap filter to remove remaining air bubbles, if necessary)
- ☐ Carefully observe sufficient filling of the filter during depletion procedure.
- ☐ Process control after approx. 2 min: Are cells transferred via separation column and V7/V4 to RAB?
- ☐ Did CPB run empty at the end of the bulk depletion?
- ☐ Are filling levels of CPB and RAB balanced after bulk depletion?
- ☐ Are cells loaded simultaneously and consistently from both bags (CPB and RAB) during sensitive depletion?
- ☐ Are depleted cells transferred to the CCB during sensitive depletion?
- ☐ Is Liquid level in filter reservoir still ok?
- ☐ Sensitive depletion: Did RAB run empty before CPB?
- ☐ All cells completely loaded?

**End of depletion:**

- ☐ CPB and RAB empty?
- ☐ CCB filled?
- ☐ Process code recorded?

**Signature Manifest****Document Number:** STCL-PROC-038 JA1**Revision:** 01**Title:** Checklist for Depletion Tubing Set-DTS**STCL-PROC-038 JA1 CKL Depletion Tub****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Dec 2012, 04:26:47 PM	Approved

**Manager Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Dec 2012, 04:27:35 PM	Approved

**Medical Director Approval**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		21 Dec 2012, 07:20:16 PM	Approved

**QA Approval**

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		23 Dec 2012, 04:52:57 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		14 Jan 2013, 04:17:59 PM	Approved

**Notification**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		14 Jan 2013, 04:18:00 PM	Email Sent
Sharon Hartis (SH259)		14 Jan 2013, 04:18:00 PM	Email Sent
Linda Sledge (SLEDG006)		14 Jan 2013, 04:18:00 PM	Email Sent
System Administrator (SYSADMIN)		14 Jan 2013, 04:18:00 PM	Email Sent