


CliniMACS Prodigy® TS 320









REF 200-073-616

CAUTION:
Investigational Device
 Limited by Federal (or United States) Law to
 Investigational Use or under an FDA Approval.



Miltenyi Biotec B.V. & Co. KG
 Friedrich-Ebert-Straße 68
 51429 Bergisch Gladbach
 Germany
 ☎ +49 2204 8306-80

Distributed by:
Miltenyi Biotec Inc.
 2303 Lindbergh Street
 Auburn, CA 95602
 USA
 ☎ 1 800 367 6227

Contents	One CliniMACS Prodigy® TS 320
Intended purpose	The tubing set is intended for <i>in vitro</i> separation or other processing of human cells from heterogeneous cell populations in combination with the CliniMACS Prodigy System only under an approved IDE/IND or FDA approval.
Side-effects	Side-effects have not been reported.
Precautions 	The corresponding CliniMACS Prodigy User Manuals (U.S. Edition) must be followed. Aseptic working procedures must be applied for the unpacking, assembly, and use of the tubing set. After installation of the product check all luer connections for tightness. If necessary retighten the luer connections. Before human applications, the suitability of target cells must be demonstrated regarding indication, quality, and quantity. Further processing and use for clinical applications must be in accordance with FDA investigational use regulations. Any clinical application of the separated or otherwise processed cells is exclusively within the responsibility of the user of a CliniMACS Prodigy System. The separation or other processing of cells using the tubing set must be performed by trained operators only. All materials which have come into contact with blood and blood products must be treated as infectious material. Regulations for the treatment of infectious materials must be observed.
Warnings	The CliniMACS Prodigy TS 320 contains a large CentriCult Chamber requiring a specific drive shaft. Ensure the drive shaft is installed by Miltenyi Biotec Instrument Service before using the tubing set. Any CliniMACS Prodigy with the SN 490 or lower needs the installation of the new drive shaft.
	Do not use after the use-by date printed on the product label.
	Do not use the tubing set if package is damaged. Before opening, inspect the packaging for damage, punctures, or tears. Use the product only if package is undamaged and sealed. Do not use if the tubing set is damaged. Do not use, if any leakage of the product is observed during priming and separation. Do not connect the tubing set directly to the patient. Do not store blood, blood fractions, or cell fractions in the tubing set.
	Do not re-use. The re-use of the tubing set or its parts leads to the endangerment of the patient due to biological contamination and to inefficient cell separation.
Storage	
	The tubing set must be stored at room temperature of +15 °C to +30 °C (+59 °F to +86 °F).
Further information	
	The tubing set has been sterilized using irradiation.
	The tubing set contains a non-pyrogenic, sterile fluid path.
Processing capabilities	The performance of the tubing set depends on the application procedure as applicable. For information on the capacity of the different processes, refer to the corresponding CliniMACS Prodigy User Manual (U.S. Edition).
Instructions for use 	The use and installation of the tubing set is described in the corresponding CliniMACS Prodigy User Manual (U.S. Edition) of the application procedure as applicable. Refer to the corresponding CliniMACS Prodigy User Manual (U.S. Edition) of the corresponding application for the validated combinations of instrument, separation programs, reagents, tubing sets, and buffer. The CliniMACS Prodigy TS 320 is equipped with a generic mounting sheet and additional information ("Installation aid") is enclosed showing the fluid path of the tubing set.