

# CliniMACS Prodigy® TS 320

**REF** 200-073-615

## CAUTION:




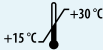


The product as part of the MACS GMP family is for *ex vivo* cell processing only and it is Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval. The product is not intended for human *in vivo* applications.



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<b>Contents</b>	
<b>QTY</b>	One CliniMACS Prodigy TS 320
<b>Intended purpose</b>	The tubing set is intended for <i>in vitro</i> pre-separation or other processing of human cells from heterogeneous cell populations in combination with the CliniMACS Prodigy System only, enabling further cultivation and/or genetic modification of the cells.
<b>Side-effects</b>	Side-effects have not been reported.
<b>Limitation</b>	Miltenyi Biotec as the manufacturer of the CliniMACS® System does not give any recommendations regarding the use of the separated cells.
<b>Disclaimer</b>	The CliniMACS Prodigy Tubing Sets are for research use and <i>ex vivo</i> cell culture processing only, and are not intended for human <i>in vivo</i> applications. For regulatory status in the U.S., contact your local representative. In the U.S. for use in patients the product can only be used under IND/IDE or FDA approval.
<b>Quality Statement</b>	The CliniMACS Prodigy Tubing Sets are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.
<b>Precautions</b>	<p>The corresponding instructions by Miltenyi Biotec must be followed.</p> <p>Aseptic working procedures must be applied for the unpacking, assembly, and use of the tubing set.</p> <p>After installation of the product check all luer connections for tightness. If necessary retighten the luer connections.</p> <p>Before human applications, the suitability of target cells must be demonstrated regarding indication, quality, and quantity.</p> <p>Further processing and use for clinical applications must be in accordance with national legislations or with FDA investigational use regulations.</p> <p>Any clinical application of the separated or otherwise processed cells is exclusively within the responsibility of the user of a CliniMACS Prodigy System.</p> <p>The separation or other processing of cells using the tubing set must be performed by trained operators only.</p> <p>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.</p>

<b>Warnings</b>	<p>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.</p>
	Do not use after the use-by date printed on the product label.
	<p>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.</p> <p>Do not use if the tubing set is damaged. Do not use, if any leakage of the product is observed during priming and separation.</p> <p>Do not connect the tubing set directly to the patient.</p> <p>Do not store blood, blood fractions, or cell fractions in the tubing set.</p>
	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 performance.
<b>Storage</b>	
	The tubing set must be stored at room temperature (+15 °C to +30 °C [+59 °F to +86 °F]).
<b>Further information</b>	
	The tubing set has been sterilized using irradiation.
	The tubing set contains a non-pyrogenic, sterile fluid path.
<b>Performance</b>	The performance of the tubing set depends on the chosen application. For information on the capacity of the different applications, refer to the corresponding instructions by Miltenyi Biotec.
<b>Instructions for use</b>	<p>The use and installation of the tubing set to be used for a specific separation process are described in the corresponding instructions by Miltenyi Biotec for the respective application as applicable.</p> <p>Refer to the corresponding instructions by Miltenyi Biotec of the corresponding application for the validated combinations of instrument, separation programs, reagents, tubing sets, and buffer.</p> <p>The tubing set is equipped with a mounting sheet and an additional information ("Installation aid") is enclosed showing the fluid path of the tubing set.</p>
