

Soft Tissue Bioscaffold - US Regulatory Information

Item ID / GTIN	SKU	Layers	Size	US FDA 510(k)	Package Type	Shelf Life (days)	Sterilization Method	Storage Instructions	MRI Compatibility
09421906017663	SR02LG0505US	2 Layer	5 x 5 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017694	SR02LG0710US	2 Layer	7 x 10 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017670	SR02LG1010US	2 Layer	10 x 10 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017687	SR02LG1020US	2 Layer	10 x 20 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017724	SR02LG2020US	2 Layer	20 x 20 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017656	SR03LG0505US	3 Layer	5 x 5 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017700	SR03LG0710US	3 Layer	7 x 10 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017649	SR03LG1010US	3 Layer	10 x 10 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017632	SR03LG1020US	3 Layer	10 x 20 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017731	SR03LG2020US	3 Layer	20 x 20 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017625	SR05LG0505US	5 Layer	5 x 5 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017717	SR05LG0710US	5 Layer	7 x 10 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017618	SR05LG1010US	5 Layer	10 x 10 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017601	SR05LG1020US	5 Layer	10 x 20 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe
09421906017748	SR05LG2020US	5 Layer	20 x 20 cm	K162461, K171231	Envelope	730	Ethylene oxide	Store at room temperature in a dry environment.	MRI Safe