

			TECHNICAL DATA SHEET				TDS No 012		
							Issue 07		
1	Description		Freezable Tissue Storage Kit, double wrapped, Sterile EO						
2	Ref(s)		Pot sizes:		Ref:				
			50 ml / 100 ml		SKA0050Z-K				
			100 ml / 300 ml		SKA0100Z-K				
			300 ml / 500 ml		SKA0300Z-K				
			500 ml/1000 ml		SKA0500Z-K				
3	Regulatory		Conform to the relevant provisions of the EC Council Directive 93/42/EEC, dated 14th June 1993 and all the relevant amendments. Annex V sterility aspects only. Medfor is registered to ISO 13485:2016.						
4	CE marking		CE 1639 (Class IIa medical device suitable for storage of human tissue for in vivo use)						
5	Manufacture		Product assembled in class 7 cleanroom in accordance with BS/EN/ISO 14644-1:2015.						
6	Dimensions and Volume			Height incl. cap (mm)	Diameter incl.cap(mm)	Internal neck bore (mm)	Nominal capacity (ml)	Brimful capacity (ml)	
		SKA0050Z-K	Inner pot	57	41.4	34.8	50	50	
			Outer pot	63	55.4	48.6	100	105	
		SKA0100Z-K	Inner pot	63	55.4	48.6	100	105	
			Outer pot	83	80.2	72.1	300	312	
		SKA0300Z-K	Inner pot	83	80.2	72.1	300	312	
			Outer Pot	110	95.2	86.5	500	587	
		SKA0500Z-K	Inner pot	110	95.2	86.5	500	587	
			Outer pot	127	117.8	108.7	1000	1096	
7	Material composition		Jar	Natural polypropylene					
			Cap	White HDPE					
8	Biocompatibility		Literary review of comparative products and historic usage of this type of product sold by Medfor has established that the kits do not affect the quality or integrity of tissue stored within them.						
9	Type of closure		Tamper-evident screw cap						
10	Sterilisation		Sterilisation has been carried out using ethylene oxide in accordance with ISO 11135-1:2014.						
11	Labelling		Case, pack and product labelling in accordance with ISO 15223-1:2016						
12	Temperature range		-80° C to 75° C. Can be stored to -80° C for up to five years.						
13	Autoclavability		Not suitable.						
14	Physical resistance		Flexible to rigid, good mechanical resistance, high chemical resistance						
15	Shelf life (before use)		Packs contents remain sterile for up to 3 years from date of manufacture or until pack is opened or breached, whichever occurs first.						
16	Pack quantities	SKA0050Z-K	10 packs per case	Pack description: 50 ml pot inside 100 ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots					

				labelled.
		SKA0100Z-K	10 packs per case	Pack description: 100 ml pot inside 300 ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.
		SKA0300Z-K	10 packs per case	Pack description: 300 ml pot inside 500 ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.
		SKA0500Z-K	8 packs per case	Pack description: 500ml pot inside 1000ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.
17	Storage conditions before packs opened	Temperature: 10°C to 35°C Relative Humidity: 20% to 80% Store in clean, dry conditions away from direct sunlight.		
18	Other information	<ul style="list-style-type: none"> Do not use if package damaged. Single Use only. Do not reuse due to risk of cross-infection. Do not irradiate The range of Tissue transport freezing storage pots and Tissue transport storage pots are both DEHP and Latex Free The range does not contain tissues of animal origin nor human blood derivative products. The devices do not require to be connected to other devices in order to be used. 		
19	Product labels	<p>SKA0050Z-K – image of label applied to both pots (actual size 60 mm wide x 40 mm high):</p>  <p>SKA0100Z-K – image of label applied to both pots (actual size 60 mm wide x 40 mm high):</p> 		

SKA0300-K – image of label applied to both pots (actual size 90 mm wide x 35 mm high):

Freezable Tissue Storage Kit Vol: 300 ml | 500 ml

REF SKA0300Z-K **STERILE EO**     **CE 1639**
LOT SAMPLE
FTK_90x35_v2  Eastern Road,
Aldershot, UK.
medfor.co.uk

SKA0500Z-K – image of label applied to both pots (actual size 90 mm wide x 35 mm high):

Freezable Tissue Storage Kit Vol: 500 ml | 1000 ml

REF SKA0500Z-K **STERILE EO**     **CE 1639**
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