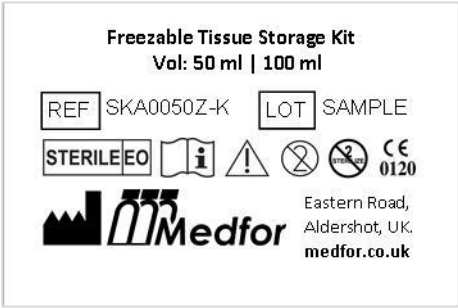
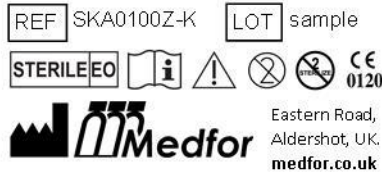
		TECHNICAL DATA SHEET						TDS No 012	
		Freezable Tissue Storage Kit, double bagged, Sterile EO						Issue 04	
Product Ref(s)		Pot sizes	Blank label on outer pot			Pre-printed label on both pots			
		50 ml / 100 ml				SKA0050Z-K			
		100 ml / 300 ml				SKA0100Z-K			
		250 ml/500 ml	S600-K						
		300 ml / 500 ml				SKA0300Z-K			
		500 ml/1000 ml	S610-K			SKA0500Z-K			
1	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.						
2	CE marking		CE 0120 (Class IIa medical device suitable for storage of human tissue for in vivo use)						
3	Manufacture		Product assembled in class 7 cleanroom in accordance with BS/EN/ISO 14644-1:2015.						
4	Dimensions and Volume			Height including cap (mm)	Diameter including 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	
		S600-K	Inner pot	87	72.2	64.0	250	257	
			Outer pot	110	95.2	86.5	500	587	
		SKA0300Z-K	Inner pot	83	80.2	72.1	300	312	
Outer Pot	110		95.2	86.5	500	587			
S610-K SKA0500Z-K	Inner pot	110	95.2	86.5	500	587			
	Outer pot	127	117.8	108.7	1000	1096			
5	Material composition		Jar	Natural polypropylene					
			Cap	White HDPE					
6	Type of closure		Tamper-evident screw cap						
7	Sterilisation		Sterilisation has been carried out using ethylene oxide in accordance with ISO 11135-1:2014.						
8	Labelling		Case, pack and product labelling in accordance with ISO 15223-1:2016						
9	Temperature range		-80° C to 75° C						
10	Autoclavability		Not suitable.						
11	Physical resistance		Flexible to rigid, good mechanical resistance, high chemical resistance						
12	Shelf life		Packs contents remain sterile for up to 3 years from date of manufacture or until pack is opened or breached, whichever occurs first.						
13	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.
		S600-K	10 packs per case	Pack description: 250ml pot inside 500ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Outer pot 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.
		S610-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. Outer pot 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.
14	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.		
15	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 		
16	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>		

Freezable Tissue Storage Kit
Vol: 100 ml | 300 ml



S600-K – label size on outer pot is 185 mm wide x 55 mm high (no image)

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



S610-K – label size on outer pot is 185 mm wide x 55 mm high (no image).

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

