

**EN INSTRUCTIONS FOR USE****Pot / kit suitable for transport / storage of human tissue****Storage before pack is opened:**

- Store in clean, dry conditions away from direct sunlight.
- Temperature: 10° C to 35° C. RH : 20% to 80%.

**Operational Information:**

- Do not use if package damaged.
- Pots and caps can be stored as low as -80° C for up to five years.
- Frozen plastic is very brittle. Handle with care and avoid shocks or pressure when frozen.
- If to be excessively handled allow to return to room temperature first.
- Do not re-use due to the risk of cross-infection.
- Do not re-sterilise.

**CS POKYNY K POUŽÍVÁNÍ****Zásobník / sada vhodná pro přepravu / ukládání lidských tkání****Skladování před otevřením balení:**

- Skladujte v čistých a suchých podmínkách mimo dosah přímých slunečních paprsků.
- Teplota: 10 až 35 °C. Relativní vlhkost: 20 až 80 %.

**Informace k používání:**

- Nepoužívejte, pokud je balení poškozené.
- Zásobníky a uzávěry lze skladovat za teploty až -80 °C po dobu až pěti let.
- Zmrazený plast je velmi křehký. Při manipulaci po zmrazení postupujte opatrně a vyvarujte se nárazů nebo působení tlaku.
- V případě nadměrné manipulace umožněte nejprve návrat na pokojovou teplotu.
- Nepoužívejte opakovaně kvůli riziku infekce.
- Nesterilizujte opakovaně.

**DA BRUGERVEJLEDNING****Krukke/sæt velegnet til transport/opbevaring af humant væv****Opbevaring før pakken åbnes:**

- Opbevares tørt, rent og væk fra direkte sollys.
- Temperatur: 10 °C til 35 °C. Fugtighed: 20% til 80%.

**Brugsoplysninger:**

- Må ikke anvendes, hvis emballagen er beskadiget.
- Krukker og hætter kan opbevares ved temperaturer helt ned til -80 °C i op til fem år.
- Frossen plast er meget sprød. Forsigtig. Undgå stød og tryk, når materialet er frosset.
- Ved omfattende håndtering skal materialet nå stuetemperatur først.
- Må ikke genbruges på grund af risikoen for krydsinfektion.
- Må ikke resteriliseres.

**DE GEBRAUCHSANWEISUNG****Behälter/Kit für Transport/Lagerung von menschlichem Gewebe****Lagerung vor Öffnen der Verpackung:**

- In sauberer und trockener Umgebung ohne direkte Sonneneinstrahlung lagern.
- Temperatur: 10 °C bis 35 °C. Relative Luftfeuchte: 20 % bis 80 %

**Betriebsdaten:**

- Nicht verwenden, wenn Packung beschädigt ist.
- Gefäße und Verschlüsse können bei -80 °C bis zu fünf Jahre gelagert werden.
- Gefrorenes Plastik ist sehr brüchig. In gefrorenem Zustand vorsichtig behandeln und Erschütterungen sowie Druck vermeiden.
- Bei weiterer Verwendung zuerst wieder auf Raumtemperatur bringen.
- Aufgrund des Risikos von Kreuzinfektionen nicht wiederverwenden.
- Nicht erneut sterilisieren

**ES INSTRUCCIONES DE USO****Recipiente/Kit apto para transporte/almacenaje de tejido humano****Almacenamiento previo a la apertura del paquete:**

- Conservar en lugar limpio y seco en el que no reciba la luz directa del sol.
- Temperatura: de 10° C a 35° C. HR: del 20% al 80%.

**Información operativa:**

- No utilizar si el paquete está dañado.
- Los recipientes y tapas pueden conservarse a temperaturas de hasta -80 °C durante un máximo de cinco años.
- El plástico congelado es muy frágil. Manipular con cuidado y evitar golpes o presión cuando esté congelado.
- Si es preciso someterlo a una manipulación más brusca, será preciso dejar que adquiera la temperatura ambiente en primer lugar.
- No reutilizar debido al riesgo de infección cruzada.
- No volver a esterilizar.

**ET KASUTUSJUHEND****Tops/komplekt sobib inimekudede transportidiks/säilitamiseks****Säilitamine enne pakendi avamist:**

- säilitada puhtas ja kuivas keskkonnas otsese päikesevalguse eest kaitstult.
- Temperatuur: 10 °C...35 °C. Suhteline niiskus: 20 %...80 %

**Kautusteave:**

- mitte kasutada, kui pakend on kahjustatud.
- Topse ja korke võib säilitada kuni viis aastat temperatuuril kuni -80 °C.
- Külmutatud plast on väga rabe. Käsitleda ettevaatlikult ja vältida lööke või survet külmutatud olekus.
- Lasta toatemperatuurile jahtuda, kui liigne kätlemine on vajalik.
- Ristsaastumise ohu tõttu mitte uuesti kasutada.
- Mitte uuesti steriliseerida.

**FI KÄYTTÖOHJEET****Astia/pakkaus, joka soveltuu ihmiskudoksen kuljetukseen ja säilytykseen****Säilytys ennen pakkauksen avaamista:**

- Säilytettävä puhtaissa, kuivissa olosuhteissa suoralta auringonvalolta suojattuna.
- Lämpötila: 10–35 °C. Suhteellinen kosteus: 20–80 %.

**Käyttötiedot:**

- Ei saa käyttää, jos pakkaus on vahingoittunut.
- Astioita ja kansia voi säilyttää jopa -80 °C:n pakkasessa enintään viiden vuoden ajan.
- Jäädetty muovi on erittäin haurasta. Kun muoviasia on jäädetty, käsittele sitä varoen ja vältä iskuja ja painamista.
- Jos sitä pitää käsitellä huomattavan paljon, sen pitää antaa ensin lämmetä huoneenlämpöön.
- Ei saa käyttää uudelleen sairaalainfektiön riskin vuoksi.
- Ei saa steriloida uudelleen.

**FR INSTRUCTIONS D'UTILISATION****Pot / kit approprié au transport / stockage de tissus humains****Stockage avant l'ouverture du pack :**

- Stocker dans des conditions propres et sèches, loin de la lumière directe.
- Température : entre 10 °C et 35 °C. HR : 20 % à 80 %.

**Informations sur le fonctionnement :**

- Ne pas utiliser si l'emballage est endommagé.
- Les pots et les couvercles peuvent être stockés à des températures pouvant descendre jusqu'à -80 °C pendant près de cinq ans.
- Le plastique congelé est très cassant. Manipuler avec soin et éviter tout choc ou pression après congélation.
- Si une manipulation excessive est prévue, laisser revenir à température ambiante au préalable.
- Ne pas réutiliser en raison du risque d'infection croisée.
- Ne pas restériliser.

**HE הוראות שימוש****מיכל / ערכה מתאימה (ה) להובלה / אחסון של רקמות אנושיות****אחסון לפני פתיחת האריזה:**

- לאחסן בתנאים נקיים ויבשים ולהרחיק מאור-שמש ישיר.
- טמפרטורה: 10 עד 35 צלסיוס. לחות יחסית: 20% עד 80%.

**מידע לזמן השימוש:**

- אין להשתמש אם האריזה ניזוקה.
- ניתן לאחסן מיכלים ומכסים בטמפרטורה נמוכה עד -80 צלסיוס למשך עד חמש שנים.
- פלסטיק קפוא הוא שביר מאוד. יש לטפל במוצר בזהירות ולהימנע מזעזועים או לחץ כאשר הוא קפוא.
- אם מתכוונים לבצע במוצר מספר רב של פעולות, יש לאפשר לו קודם לחזור לטמפרטורת החדר.
- לא לשימוש חוזר עקב הסיכון לזיהום צולב.
- אין לבצע עיקור חוזר.

**HR UPUTE ZA UPORABU**

**Posuda/komplet pogodan za prijenos/  
pohranu ljudskog tkiva**

**Skladištenje prije otvaranja pakiranja:**

- skladištiti u čistim, suhim uvjetima, podalje od sunčeve svjetlosti.
- Temperatura: od 10 °C do 35 °C. Relativna vlažnost: od 20 % do 80 %.

**Upute za rad:**

- Ne upotrebljavajte proizvod ako je pakiranje oštećeno.
- Posude i poklopci mogu se skladištiti najviše pet godina na temperaturi i do -80 °C.
- Zamrznuta plastika vrlo je krhka. Oprezno rukujte njome i nemojte je udarati ili pritiskati dok je zamrznuta.
- U slučaju potrebe za znatnijim rukovanjem ostavite proizvod da se prvo vrati na sobnu temperaturu.
- Nije za višekratnu uporabu zbog opasnosti od unakrsne infekcije.
- Nemojte ponovno sterilizirati proizvod.

**IS NOTKUNARLEIÐBEININGAR**

**Ílát / ílátasett sem hentar fyrir flutninga /  
geymslu á vefsýnum úr mönnum**

**Geymsla í óopnuðum umbúðum:**

- Geymist á hreinum, þurrum stað, fjarri beinu sólarljósi.
- Hitastig: 10 °C til 35 °C. Rakastig: 20% til 80%.

**Upplýsingar um notkun:**

- Notið ekki ef umbúðir eru skemmdar.
- Ílát og lok þola allt að -80 °C, í allt að fimm ár.
- Plast verður mjög stökkt þegar það frýs. Meðhöndlið með varúð og forðist högg eða þrýsting efir að plastið frýs.
- Ef það þarf að meðhöndla vöruna mikið skal láta hana ná stofuhita fyrst.
- Endurnotið ekki, vegna smíðættu.
- Dauðhreinsið ekki aftur.

**IT ISTRUZIONI PER L'USO**

**Contenitore / kit idoneo per il trasporto / la  
conservazione di tessuto umano**

**Conservazione prima dell'apertura della  
confezione:**

- Conservare in un luogo pulito e asciutto, lontano dalla luce solare diretta.
  - Temperatura 10 °C - 35 °C. Umidità relativa 20% - 80%.
- Informazioni operative:**
- Non utilizzare se la confezione è danneggiata.
  - Contenitori e tappi possono essere conservati a temperature fino a -80 °C per un massimo di cinque anni.
  - La plastica congelata è estremamente fragile. Dopo il congelamento, maneggiare con cautela ed evitare colpi o pressioni.
  - Nel caso in cui il contenitore debba essere maneggiato a lungo, attendere che ritorni a temperatura ambiente.
  - Non riutilizzare a causa del rischio di infezione incrociata.
  - Non riutilizzare.

**NL GEBRUIKSAANWIJZING**

**Pot/kit voor het vervoeren/opslaan van  
menselijk weefsel**

**Opslag vóór het openen van de verpakking:**

- Bewaren in schone, droge omgeving zonder direct zonlicht.
- Temperatuur: 10° C tot 35° C. Relatieve luchtvochtigheid: 20% tot 80%.

**Gebruiks-informatie:**

- Niet gebruiken als de verpakking beschadigd is.
- Potten en deksels kunnen maximaal 5 jaar op een temperatuur van -80° C worden opgeslagen.
- Bevroren plastic is erg bros. Ga er na invriezing voorzichtig mee om en voorkom stoten of druk.
- Vóór intensieve hantering eerst op kamertemperatuur laten komen.
- Niet hergebruiken vanwege het risico op kruisbesmetting.
- Niet opnieuw steriliseren.

**NO BRUKSANVISNING**

**Kopp / sett egnet for transport /  
oppbevaring av humant vev**

**Oppbevaring før pakningen åpnes:**

- Oppbevares i rene, tørre forhold og må ikke utsettes for direkte sollys.
- Temperatur: 10 °C til 35 °C. Relativ luftfuktighet: 20 % til 80 %.

**Bruksinformasjon:**

- Skal ikke brukes hvis pakningen er skadet.
- Kopper og lokk kan oppbevares så kaldt som -80 °C i opptil fem år.
- Frossen plast er svært porøs. Den må håndteres med forsiktighet, og støt eller trykk må unngås når plasten er frossen.
- Ved mye håndtering må koppen romtempereres først.
- Ikke gjenbruk på grunn av risiko for kryssinfeksjon.
- Ikke resteriliser.

**PL INSTRUKCJE UŻYCIA**

**Pojemnik/zestaw przeznaczony do transportu /  
przechowywania tkanek ludzkich  
Przechowywanie przed otwarciem pakietu:**

- Przechowywać w suchym, czystym miejscu, z dala od bezpośredniego oddziaływania promieni słonecznych.
- Temperatura: od 10°C do 35°C. Wilgotność względna: od 20% do 80%.

**Informacje eksploatacyjne:**

- Nie używać, jeśli opakowanie jest uszkodzone.
- Pojemniki i pokrywy można przechowywać w temperaturze nie niższej niż -80°C przez okres do pięciu lat.
- Zamrożone tworzywo sztuczne jest bardzo kruche. Należy obchodzić się z nim ostrożnie i nie uderzać ani nie wywierać nacisku na zamrożone tworzywo.
- W przypadku planowanego intensywnego używania pojemnika należy najpierw doprowadzić go do temperatury pokojowej.
- Nie używać ponownie ze względu na ryzyko zakażeń krzyżowych.
- Nie sterylizować ponownie.

**PT INSTRUÇÕES DE**

**Frasco/kit adequado para transporte/  
armazenamento de tecido humano**

**Armazenamento antes de o pacote ser aberto:**

- Guardar em ambiente limpo e seco, longe da luz solar direta.
- Temperatura: 10° C a 35° C. HR : 20% a 80%.

**Informação Operacional:**

- Não utilizar se o pacote estiver danificado.
- Os frascos e tampas podem ser armazenados a temperaturas tão baixas como -80° C durante o máximo de cinco anos.
- O plástico congelado é muito quebradiço. Manuseie com cuidado e evite choques ou pressão quando estiver congelado.
- Se planeia manusear excessivamente, primeiro deixe voltar à temperatura ambiente.
- Não reutilizar devido ao risco de infeções cruzadas.
- Não reesterilizar.

**RO INSTRUCȚIUNI DE UTILIZARE**

**Recipient/Kit adecvat pentru transportarea/  
păstrarea țesuturilor umane  
Depozitarea produsului înainte de deschiderea  
ambalajului:**

- Depozitați într-un loc curat, uscat și ferit de lumina directă a soarelui.
- Temperatură: între 10°C și 35°C. UR: între 20% și 80%.

**Informații operaționale:**

- A nu se utiliza dacă ambalajul este deteriorat.
- Recipientele și capacele pot fi depozitate la temperaturi scăzute de până la -80°C, timp de maximum cinci ani.
- Plasticul congelat este foarte fragil. Când produsul este în stare congelată, evitați lovirea sau strângerea acestuia.
- Dacă se preconizează o manipulare excesivă, așteptați întâi să revină la temperatura camerei.
- Nu reutilizați produsul, deoarece prezintă risc de infecție încrucișată.
- A nu se resteriliza.

**SV BRUKSANVISNING**

**Behållare/lämplig sats för transport/  
förvaring av human vävnad**

**Förvaring innan förpackningen öppnas:**

- Förvaras rent och torrt och skyddas mot direkt solljus.
- Temperatur: 10 °C till 35 °C. Relativ luftfuktighet: 20 % till 80 %.

**Användningsinformation:**

- Använd inte om förpackningen är skadad
- Behållare och lock kan förvaras så kallt som -80 °C i upp till fem år.
- Frusen plast är mycket spröd. Hantera med försiktighet och undvik stötar eller tryck i fruset tillstånd.
- Om behållaren ska tåla kraftig hantering bör den först få rumstemperatur.
- Återanvänd inte på grund av risk för korsinfektion.
- Får inte återsteriliseras.



The management system of

# Medfor Products Ltd

Unit 2, Gresham Industrial Estate, Eastern Road,  
Aldershot, Hampshire, GU12 4YD, UK

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex V

For the following products

**Sterile and non sterile containers for the transit and storage of human organs and tissues prior to transplantation.**

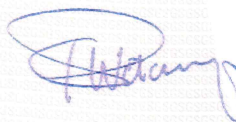
For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 31 October 2019 until 19 December 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 17 September 2001.  
and first certified by SGS Belgium on 31 October 2019.

Certification is based on reports numbered GB/PC 200659

Authorised by



Pieter Weterings  
Certification Manager

**SGS Belgium NV, Notified Body 1639**

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LPMD5008 - Certificate CE1639 AnnexV\_EN rev. 01

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# Freezable Tissue Storage Kits

Medfor's range of *Freezable Tissue Storage Kits* are intended for the storage of tissue grafts, such as amniotic membrane, bone, cardiovascular, sclera, skin and tendon.

- All caps are tamper-evident
- Each kit consists of a transparent pot inside a transparent pot plus caps
- Each pack consists of a kit double-bagged in peel-back pouches
- Kits can be frozen to -80 ° C for up to five years
- Sterilised by ethylene oxide (EO)
- CE-marked as medical devices for in vivo use
- Medfor is certified to ISO 13485:2016



| Reference  | Volume (ml) |           | Internal Diameter (mm) |           | Height incl. cap (mm) |           | Packaging                           |
|------------|-------------|-----------|------------------------|-----------|-----------------------|-----------|-------------------------------------|
|            | Inner Pot   | Outer Pot | Inner Pot              | Outer Pot | Inner Pot             | Outer Pot |                                     |
| SKA0050Z-K | 50          | 100       | 35                     | 49        | 57                    | 63        | 1 kit per pack<br>10 packs per case |
| SKA0100Z-K | 100         | 300       | 49                     | 72        | 63                    | 83        |                                     |
| SKA0300Z-K | 300         | 500       | 72                     | 87        | 83                    | 110       |                                     |
| SKA0500Z-K | 500         | 1000      | 87                     | 109       | 110                   | 127       | 1 kit per pack<br>8 packs per case  |

Contact us for free evaluation samples and prices



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## DECLARATION OF CONFORMITY

|                             |                                                                                                                                    |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer                | Medfor Products Limited<br>Unit 2, Gresham Industrial Estate<br>Eastern Road<br>Aldershot, Hampshire<br>GU12 4YD<br>United Kingdom |
| Representative              | Mr Rob Stephens, Commercial Director                                                                                               |
| Devices                     | Storage Containers and lids - as per attached Device Schedule                                                                      |
| Notified Body               | SGS Belgium NV<br>SGS House Noorderlaan 87<br>2030 Antwerp<br>Belgium                                                              |
| Notified Body Number        | 1639                                                                                                                               |
| EC Certificate number       | GB19/964231                                                                                                                        |
| Classification              | Class IIa                                                                                                                          |
| Classification Rule         | MDD 93/42/EEC Annex IX, Section III, Rule 2                                                                                        |
| Conformity Assessment Route | MDD 93/42/EEC Annex V                                                                                                              |

Medfor Products Ltd. declares, under our sole responsibility, that the devices listed on the attached Device Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC, dated 14th June 1993 and the relevant amendments of 2007/47/EEC, Annex V.

Medfor Products Ltd agrees to develop, implement and maintain a formally recognised Quality Management System to ensure continued adequacy and efficacy.

Medfor Products Ltd manufactures according to the following harmonised standards:

| Standard                         | Description                                                                                                                                                              |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2016/EN ISO 13485:2016 | Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes                                                                                      |
| EN ISO 14971:2012                | Medical Devices – Application of Risk Management to Medical Devices                                                                                                      |
| ISO 15223-1:2016                 | Medical Devices - Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements                                 |
| EN 1041:2008+A1:2013             | Information supplied by the manufacturer of medical devices                                                                                                              |
| ISO 11135:2014                   | Sterilisation of health care products – Ethylene Oxide. Requirements for the development, validation and routine control of a sterilisation process for medical devices. |

|                             |                                                                                                                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 11137-1:2015            | Sterilisation of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices |
| ISO 11137-2:2015            | Sterilisation of health care products-Radiation-Part 1: Establishing the sterilisation dose                                                                         |
| ISO 11138:2006              | Sterilisation of health care products-Biological Indicators-Part1: General Requirements                                                                             |
| ISO 14644-1:2015            | Cleanrooms and associated controlled environments. Classification of air cleanliness                                                                                |
| ISO 10993-1:2009            | Biological Evaluation of medical devices – Part 1: Evaluation and testing within a Risk Management process                                                          |
| EN ISO 11607-1:2009+A1:2014 | Packaging for terminally sterilised medical devices. Requirements for materials, sterile barrier systems and packaging systems                                      |
| EN ISO 11607-2:2006+A1:2014 | Packaging for terminally sterilised medical devices. Validation requirements for forming, sealing and assembly processes                                            |



Signed .....  
Rob Stephens, Commercial Director

Date: 1 November 2019

## DEVICE SCHEDULE

|              |                                                                             |             |                                                                             |
|--------------|-----------------------------------------------------------------------------|-------------|-----------------------------------------------------------------------------|
| OWE0125D-K   | Pot suitable for freezing to -80° C for transport / storage of human tissue | S248-J      | Pot for transport / storage of human tissue                                 |
| OWE0250D-K   | Pot suitable for freezing to -80° C for transport / storage of human tissue | S253-J      | Pot for transport / storage of human tissue                                 |
| OWE0500D-K   | Pot suitable for freezing to -80° C for transport / storage of human tissue | S296-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| OWE0750D-K   | Pot suitable for freezing to -80° C for transport / storage of human tissue | S348-K      | Pot for transport / storage of human tissue                                 |
| OWE1000D-K   | Pot suitable for freezing to -80° C for transport / storage of human tissue | S400-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| OWE2000D-K   | Pot suitable for freezing to -80° C for transport / storage of human tissue | S401-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNA0500E-L   | Pot for transport / storage of human tissue                                 | S402-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNC0025D-K   | Pot for transport / storage of human tissue                                 | S403-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNC0250D-K   | Pot for transport / storage of human tissue                                 | S406-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNC1000D-K   | Pot for transport / storage of human tissue                                 | S411-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNF0050D-K   | Pot for transport / storage of human tissue                                 | S412-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNF0050D-K2  | Kit for transport / storage of human tissue                                 | S450-K      | Pot suitable for freezing to -80° C for transport / storage of human tissue |
| PNF0050D-K20 | Kit for transport / storage of human tissue                                 | S600-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| PNF0050D-K4  | Kit for transport / storage of human tissue                                 | S610-K      | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| S072         | Kit suitable for freezing to -80° C for transport / storage of human tissue | S631-K      | Accessory for pot for transport / storage of human tissue                   |
| S146-K       | Kit suitable for freezing to -80° C for transport / storage of human tissue | SKA0050Z-K  | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| S147-K       | Kit suitable for freezing to -80° C for transport / storage of human tissue | SKA0100Z-K  | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| S148-K       | Kit suitable for freezing to -80° C for transport / storage of human tissue | SKA0300Z-K  | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| S152-K       | Pot for transport / storage of human tissue                                 | SKA0500Z-K  | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| S212-J       | Kit for transport / storage of human tissue                                 | SKB0050Z-K  | Kit suitable for freezing to -80° C for transport / storage of human tissue |
| S215-K       | Kit for transport / storage of human tissue                                 | SPA0050Z-K5 | Pot suitable for freezing to -80° C for transport / storage of human tissue |
| S216-K       | Kit for transport / storage of human tissue                                 | SPA0100Z-K5 | Pot suitable for freezing to -80° C for transport / storage of human tissue |
| S224-J       | Pot for transport / storage of human tissue                                 |             |                                                                             |
| S227-K       | Kit suitable for freezing to -80° C for transport / storage of human tissue |             |                                                                             |
| S234-J       | Kit for transport / storage of human tissue                                 |             |                                                                             |
| S238-K       | Kit for transport / storage of human tissue                                 |             |                                                                             |
| S241-K       | Kit for transport / storage of human tissue                                 |             |                                                                             |
| S242-K       | Kit for transport / storage of human tissue                                 |             |                                                                             |
| S245-J       | Pot suitable for freezing to -80° C for transport / storage of human tissue |             |                                                                             |

## Freezable Tissue Storage Kits



### Pack Description

Each pack consists of a kit double wrapped in peel-back pouches. Each kit consists of a transparent pot inside a transparent pot plus white caps.

### Application

The transport and storage of tissue grafts, such as amniotic membrane, bone, cardiovascular, sclera, skin and tendon.

### Features

- All caps are tamper-evident
- Kits can be frozen to -80° C for up to five years
- Sterilised by ethylene oxide (EO)
- CE-marked as medical devices for in vivo use

### Orders



This range of products is not available via our website. For pricing, evaluation samples, more information or to place an order, please call us or email [sales@medfor.co.uk](mailto:sales@medfor.co.uk)

## Product Information Leaflet

To download the PDF product information leaflet for this range, go to the [Downloads section](https://www.medfor.co.uk/article/20/brochures-and-other-downloadable-documents/52ab1235014c8c6727e392c3ce8d6e12) (<https://www.medfor.co.uk/article/20/brochures-and-other-downloadable-documents/52ab1235014c8c6727e392c3ce8d6e12>), of our website.

## Regulatory / Quality Assurance

- CE-marked and conforms to Medical Device Directive 93/42/EEC including 2007/47/EC.
- Medfor is approved to ISO 13485:2016.

## Sizes

Available in: 50ml , 100ml , 300ml and 500ml

## Sterility

Available in: Sterile EO

## Labels

Available with: Tissue Bank

## Volume Discounts

This product is eligible for [volume discounts](https://www.medfor.co.uk/article/15/discounts/52ab1235014c8c6727e392c3ce8d6e12) (<https://www.medfor.co.uk/article/15/discounts/52ab1235014c8c6727e392c3ce8d6e12>).

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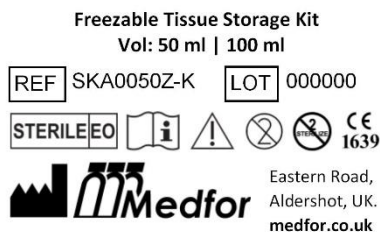
([https://www.medfor.co.uk/customer?](https://www.medfor.co.uk/customer?xCmd=acshow&jssCart=52ab1235014c8c6727e392c3ce8d6e12)

[xCmd=acshow&jssCart=52ab1235014c8c6727e392c3ce8d6e12](https://www.medfor.co.uk/customer?xCmd=acshow&jssCart=52ab1235014c8c6727e392c3ce8d6e12)).

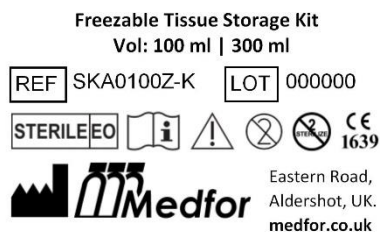
|                                                                                   |                         |                      |                                                                                                                                                                                                         |                           |                            |                         |                                |                       |  |
|-----------------------------------------------------------------------------------|-------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------------|-------------------------|--------------------------------|-----------------------|--|
|  |                         | TECHNICAL DATA SHEET |                                                                                                                                                                                                         |                           |                            | TDS No 012              |                                |                       |  |
| Issue 06                                                                          |                         |                      |                                                                                                                                                                                                         |                           |                            |                         |                                |                       |  |
| 1                                                                                 | Description             |                      | Freezable Tissue Storage Kit, double bagged, Sterile EO                                                                                                                                                 |                           |                            |                         |                                |                       |  |
| 2                                                                                 | 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                     |                       |  |
| 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 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<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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<br>Relative Humidity: 20% to 80%<br>Store in clean, dry conditions away from direct sunlight.                                                                                                                                                                                                                                                                                                                                                                                   |                   |                                                                                                                                                                           |
| 18 | Other information                      | <ul style="list-style-type: none"> <li>Do not use if package damaged.</li> <li>Single Use only. Do not reuse due to risk of cross-infection.</li> <li>Do not irradiate</li> <li>The range of Tissue transport freezing storage pots and Tissue transport storage pots are both DEHP and Latex Free</li> <li>The range does not contain tissues of animal origin nor human blood derivative products.</li> <li>The devices do not require to be connected to other devices in order to be used.</li> </ul> |                   |                                                                                                                                                                           |
| 19 | Product labels                         | SKA0050Z-K – image of label applied to both pots (actual size 60 mm wide x 40 mm high):                                                                                                                                                                                                                                                                                                                                                                                                                   |                   |                                                                                                                                                                           |





SKA0100Z-K – image of label applied to both pots (actual size 60 mm wide x 40 mm high):



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):



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):

