New TheraSorb® - Spare Part Package
Luer Lock caps packed in the TheraSorb® – TSIA 100 tubing set

Affected parts:                              Material No.
Particle filter (5µm)                        150-000-041
Hydrophobic filter (0.2 µm)                  150-000-081
Luer Lock caps                               150-000-271

Deaeration/particle filter as part of the TheraSorb® – TS IA 100 N/A

Affected products:
TheraSorb – TS IA                            330-000-624
TheraSorb – TS TPE                           330-000-623
Ig omni 1 Complete Treatment Set LIFE21      330-000-825
LIFE21 – Disposables Set Large               330-000-778
LIFE21 – Disposables Set Small               330-000-776
LIFE21 – Disposables Set LDL pro             330-000-857
LIFE21 – LDL Complete Disposables Set        330-000-813
LIFE21 Ig omni 5 Disposables Set – Large     330-000-821
LIFE21 Ig omni 5 Disposables Set – Small     330-000-822
LIFE21 Ig omni 1 Disposables Set – Large     330-000-841
LIFE21 Ig omni 1 Disposables Set – Small     330-000-842

Category of change:   Change of spare parts packaging.
          Change of delivery of Luer Lock caps.

Current State:       - Sterile, individually packed particle filter (minimum 1x) and
                      hydrophobic filters (minimum 2 x) are included in each delivery of the
                      above-mentioned disposables sets.

                      - Spare deaeration/particle filters (2x) are part of the TheraSorb –
                        TS IA 100 tubing set.

                      - Sterile, individually packed Luer Lock caps (minimum 4 x) are
                        included in each delivery to allow for storage of multiple use
                        adsorbers after each treatment.

                      - Particle filter, hydrophobic filter, and Luer Lock caps are third-party
                        products.
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Planned change:
- The distribution of third-party spare parts will be discontinued.
- A newly created TheraSorb – Spare Part Package will contain a sterile, individually packed particle filter, 5 µm (1 x), hydrophobic filters, 0.2 µm (2x), and a deaeration particle filter (1x). These filters match the ones within the tubing set manufacturing process. The new spare part package will be free of charge. Ordering information will follow.
- Deaeration/particle filter will no longer be part of the TheraSorb – TS IA 100 tubing set. The filter will be included in the TheraSorb – Spare Part Package as mentioned above.
- Sterile, individually packed Luer Lock caps (4x) will be included in the TheraSorb – TS IA 100 tubing set. These caps match the ones used within the adsorber manufacturing process.

Justification/ Evaluation:
The distribution of the above mentioned third-party spare parts will be discontinued. By changing the packaging configuration (TheraSorb - Spare Part Package), no additional risks to patient/operator safety or product quality and performance were introduced. Identification of each spare part is ensured by its individual product label.

Changing the packaging configuration of the TheraSorb – TS IA 100 has no adverse effects on patient/operator safety or product quality and performance. The change ensures that the operator has sterile Luer Lock caps for the storage of multiple use adsorbers at hand.

Estimated Implementation Q1/2022

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.

Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG

30-Jun-2021