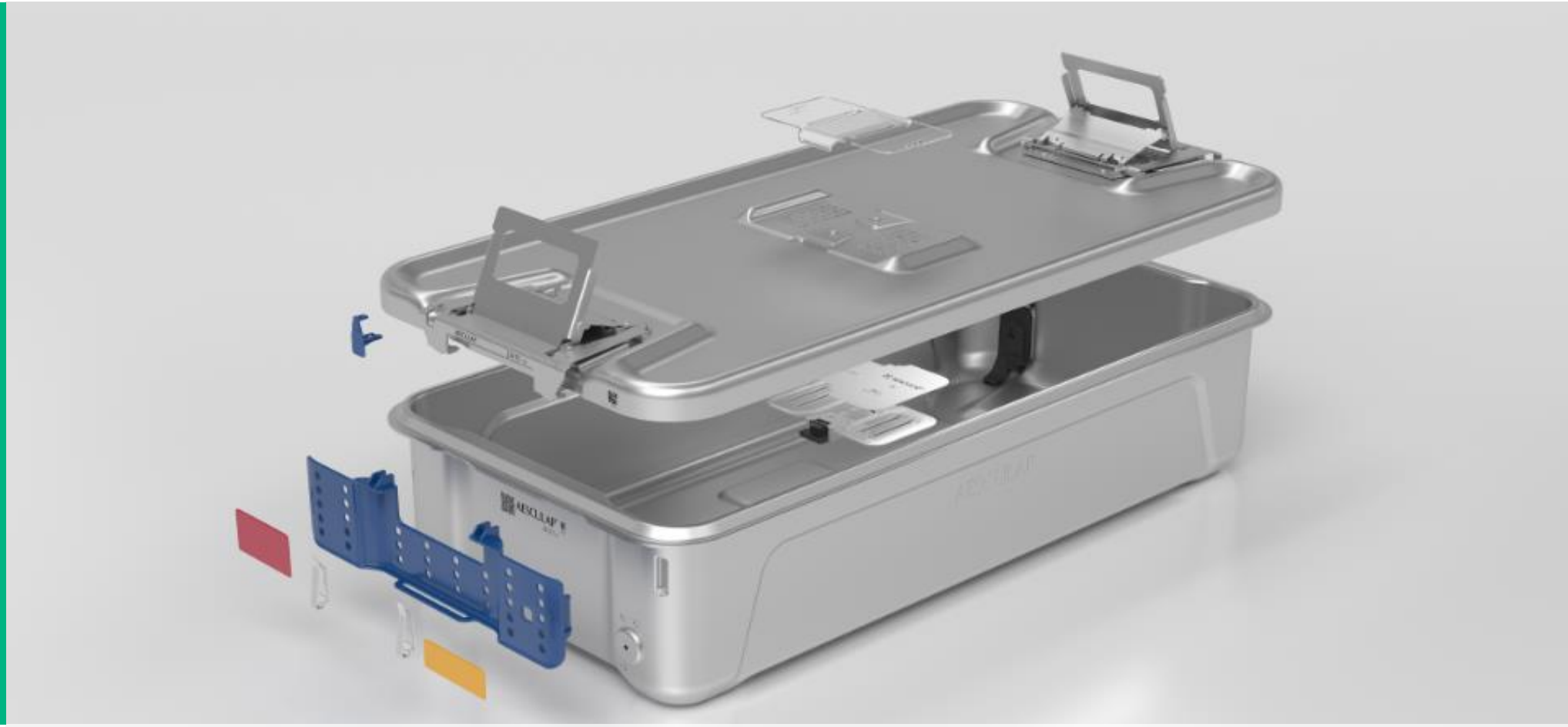
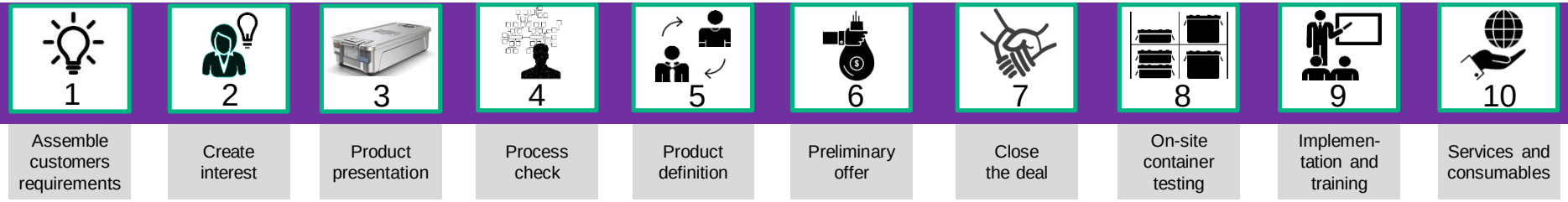
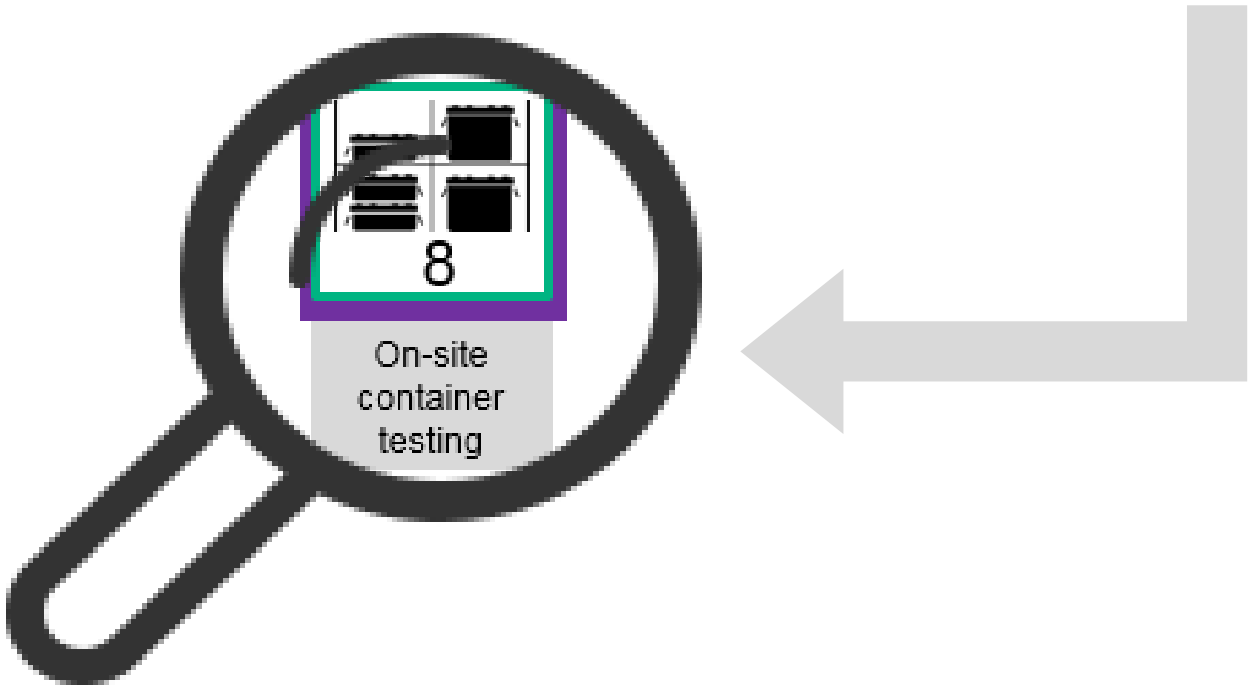


AESCULAP Aicon® – GUIDANCE FOR…

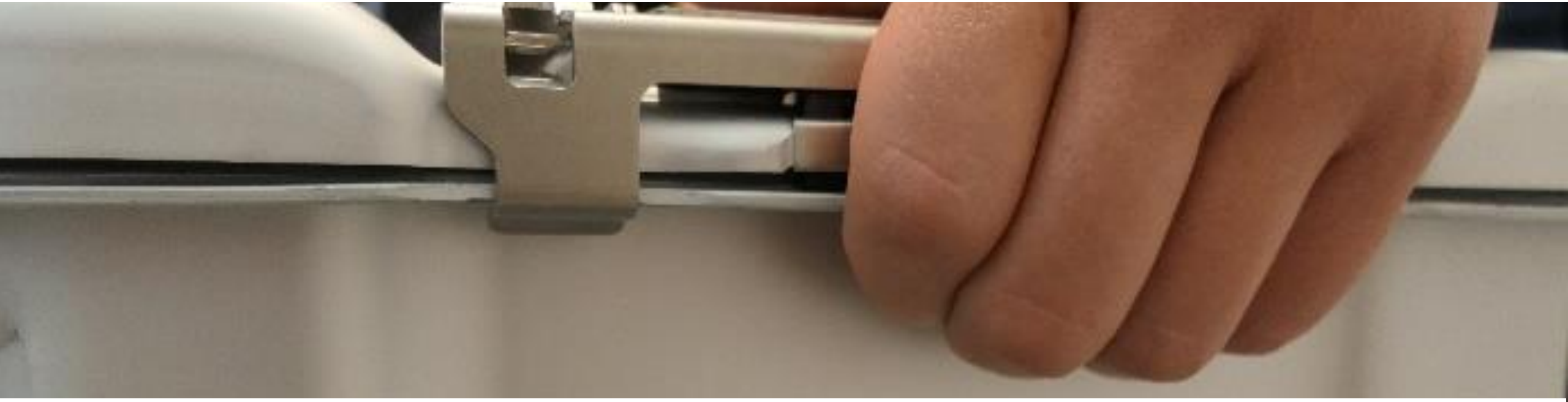
FAQ‘S

Selling process





7. FAQs: **Handle**



Difficulty

1. The integrated handle is only suitable to a limited extent for transporting the container. Heavy load on the fingertips especially at high weight.
2. With protective gloves, it is very difficult to reach into the recessed handle.
3. Pulling the container out of the shelf is problematic due to the integrated handle.

Solution

1. Practical comparison test - have a heavy instrument set carried in an old and a new container.
2. With normal silicone gloves you can easily reach into the hollows. The use of gloves with heat protection function should not be necessary as the container should be allowed to cool before handling.
3. Test together with the customer. Compare loud and not very ergonomic handles with the new comfortable handles.

7. FAQs: **Face plate**

Difficulty

1. Plastic is not a particularly stable and durable material.

2. The retaining clips cover the view of the inserted labels.

Solution

1. Consists of PPSU plastic. The front flap was subjected to almost 1,000 reprocessing cycles in the test and was then loaded 2,000 times without breaking.

2. New label solution: **AESCULAP Aicon® Label All In One.** These labels can be affixed.

   Alternatively, move the retaining clamps.

7. FAQs: **Labels**

Difficulty

1. Labels can fall out of the retaining clamps of the face plate during the sterilization process.

2. Do the **AESCULAP Aicon® Label All In One** fit into the insert plates according to their size?

3. How long does the adhesive of the new **AESCULAP Aicon® Label All In One** last?

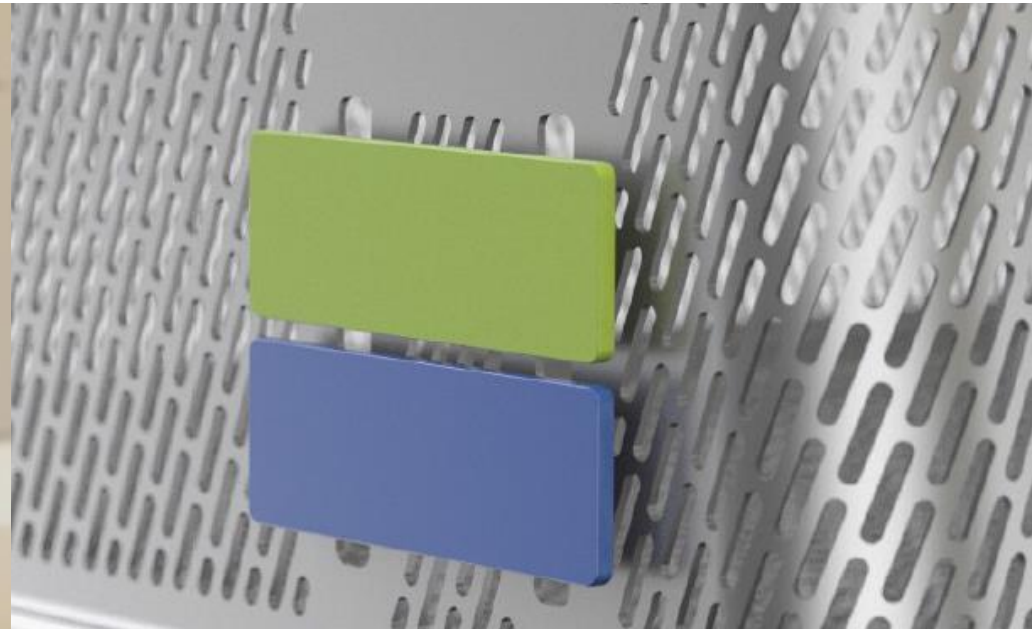
Solution

1. There is a label holder for standard labels. Recommendation: place it centrally on the face plate. The spring holder is primarily intended for labels outside the instacount standard size.

2. Yes.

3. 30 years according to documentation regulations

7. FAQs: **Signs for face plate**



Difficulty

1. The signs detach too easily from the face plate.

Solution

1. Show how tight they are.

7. FAQs: **Lid lock**

Difficulty

1. Accidental opening due to resemblance to handles.
2. A lot of mechanics that can lead to abrasion and errors during continuous use.
3. High resistance to closing. If the lid does not fit properly, it may happen that the user pushes the lock further, as at first glance it appears to be in order. This leads to damage to the closures and lids.

Solution

1. Carry out employee training courses for hospital staff.
2. Perform an endurance test in which the closing was opened and closed 20,000 times without oil. There was no particular abrasion -> *only a faulty application will lead to damage*
3. Carry out employee training courses for hospital staff.

7. FAQs: **Lid lock**

Difficulty

4. High cleaning effort for manual cleaning.

5. Cleaning the closures? Very complex construction, thus doubting the cleanability of the closures.

6. A lot of care is required (e.g. oiling).

Solution

4. Normally, the closing is not very dirty in the first place, so that manual cleaning can still be carried out without any problems. Machine cleaning should also be standard.

5. The process is machine and manual validated, and the machine cleaning takes place in closed condition.

6. An endurance test was carried out. The cap was opened and closed 20,000 times without oil. There was no indication of the need to oil the cap.

7. FAQs: **Single use filter**

Difficulty

1. Permanent filter desired.
2. The perforation field cover does not protect enough against dust.
3. The filter is now much smaller. Performance of the filter?

Solution

1. Currently in the planning phase.
2. Dust is deposited on the top of the lid. Thus the perforation field is sufficiently protected.
3. The filter holder is pressed down by the pressure of the steam with the help of two springs. This allows the steam to approach the contents with the same effectiveness as with the previous filter solution.

7. FAQs: **Single use filter**

Difficulty

4. Open perforation field. When wiping the lid, cleanser may get onto the filter and into the container.
5. Plastic cover can become porous due to rinse aid.

Solution

4. The lid should only be wiped with a damp cloth. Do not wipe with a wet cloth.
5. The cover is made of PPSU plastic, which is already contained in other medical products. 500 reprocessing cycles with the cover were carried out as a test and the cover was then subjected to 2,000 bending cycles. There was no breakage.

7. FAQs: **Bottom**

Difficulty

1. In the inside of the flanged edge, water residues occur in the RDG. This causes reworking.

2. Other dimensions than previous containers. Storage in existing systems is therefore not possible. Also not compatible with W&D.

Solution

1. Basically, the bottoms should be positioned at an angle on the loading trolleys. This is already in consultation with the relevant manufacturers.

2. The measurements of the containers are according to the STU dimension (STU = standard sterilizer chamber size). Please check the STU conformity of the storage systems at the customer's site in reference to the document “ AESCULAP Aicon®, Guidance, Step 4, english, System Compatibility”.

7. FAQs: **Lid**

Difficulty

1. There is a small gap between the lid and the gasket. Residual humidity can develop there. Dirt can also accumulate, which is difficult to remove. The sterility of the contents is endangered.

Solution

1. The cleaning process was validated by an external laboratory. Sterility has been confirmed in tests.

   Please see document „Cleaning validation“.

7. FAQs: **Lid**

Difficulty

1. Since the container lid is square, it can be misplaced by 90 degrees and thus placed the wrong way round. This can damage the lid locks and cause the front face to fall off.
2. Sterility is not guaranteed.

Solution

1. Orientation on the front face. The lid lock must also be attached to this side. Carry out practical tests.
2. Sterility is guaranteed even if the lid is placed incorrectly.

7. FAQs: **Condensate discharges**

Difficulty

1. Can the plastic withstand the use of rinse aid?

Solution

1. The EDS housing is made of PEEK plastic, which is already used as a proven material in other medical products and can withstand rinse aid treatment.

7. FAQs: **Cleaning**

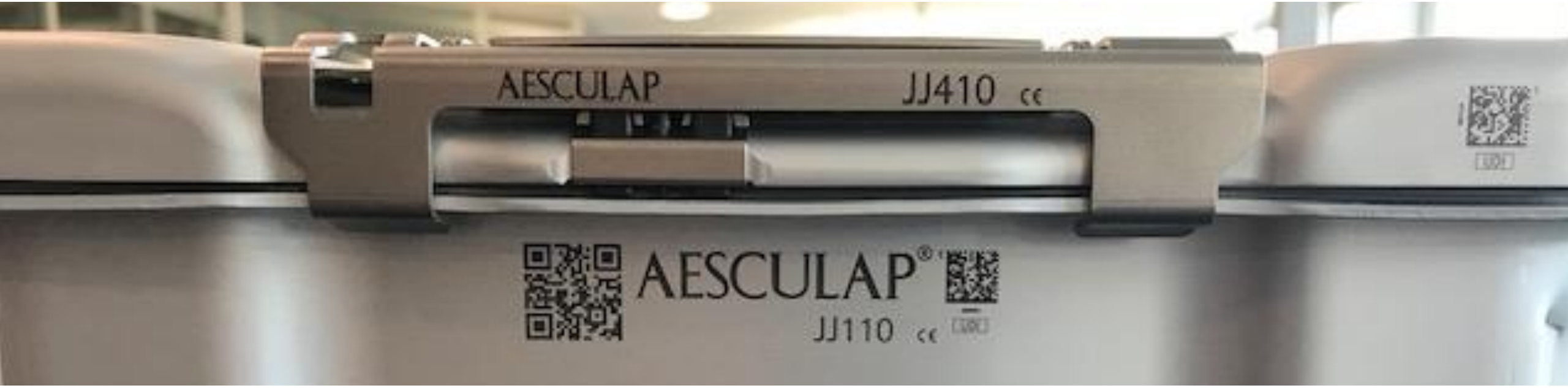
Difficulty

1. How to clean the container?

Solution

1. Cleaning validation was done with latches in closed position, EDS system, face plate and perforation cover in place.

7. FAQs: **Tracking**



Difficulty

1. How can the life cycle of the container be tracked?

Solution

1. A Data Matrix code with a worldwide standardized serialization is applied to the side of the lid and the bottom.

   This enables separate tracking of the lid and the bottom.