

Nettoyage par CO₂ supercritique :

Une alternative pour les dispositifs médicaux complexes ou sensibles

Supercritical CO₂ cleaning: *An alternative for complex or sensitive medical devices*

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Innovative contract manufacturing services in :



**Consulting &
Laboratory testing**



Clean Room Injection



Surface Treatment



Sterile Packaging

A high level of cleanliness on your devices prior to the final packaging



Our washing / disinfecting cycles have demonstrated a high level of efficiency according to the AAMI TIR 30 and have been validated according to the ISO19227.

OUR CLEANING VALIDATIONS

-  Proprietary OQ/PQ cleaning validations on worst cases
-  Validated for THC, TOC, CFU, LAL, inorganic residues
-  Helps reduce customers' validation budgets

SUITABLE MEDICAL DEVICES

- » Stainless steel
- » Titanium
- » Polyethylene
- » Peek
- » Aluminium
- » Nitinol

| Spray washing limits for complex medical devices



Spray washing process in disinfecting washer may present limits :



- *Inaccessible washing area*
- *Water retention*
- *High temperature incompatibility*
- *Water incompatibility*
- *Chemicals incompatibility*

Materials and products at risk:



- *Parts with blind holes, internal tubing, cannulas*
- *3D-printed lattice geometries*
- *Implantable textiles*
- *Rough/porous surface*
- *Electronics parts*
- *Assemblies*

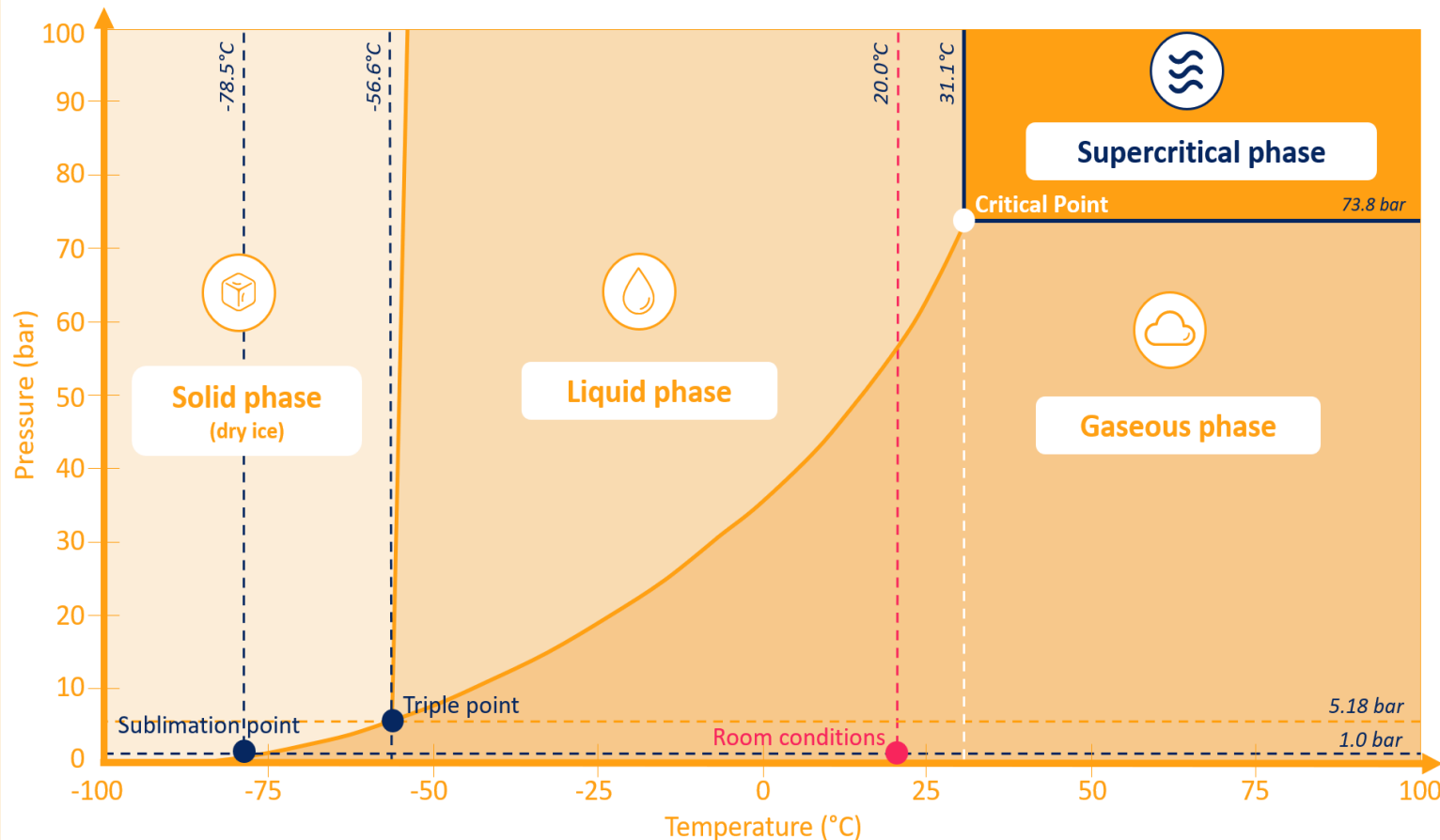


Supercritical CO₂ final cleaning
as alternative technology to overcome limits of spray washing process

CO₂ in supercritical phase (= scCO₂)



CO₂ usually behaves as a gas under standard temperature and pressure conditions, or as a solid when frozen under -80°C.



» Above the **critical point** (31.1°C, 73.8 bar), CO₂ becomes a **supercritical fluid** with properties of both a gas and a liquid.

» scCO₂ has both:

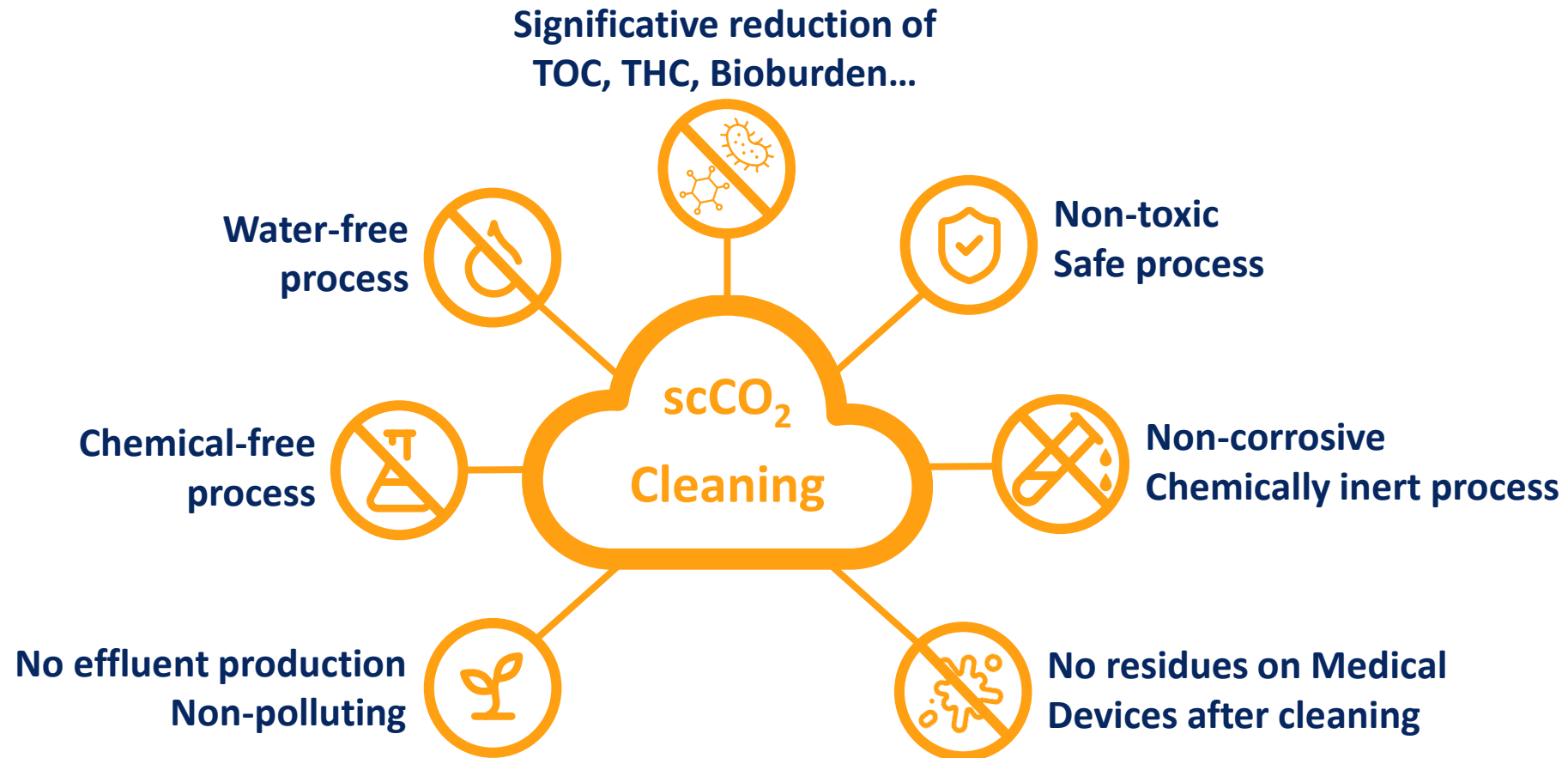
- High diffusivity, compressibility and very low surface tension of a gas.

→ High penetration to the dense products

- High solvent power of a liquid.

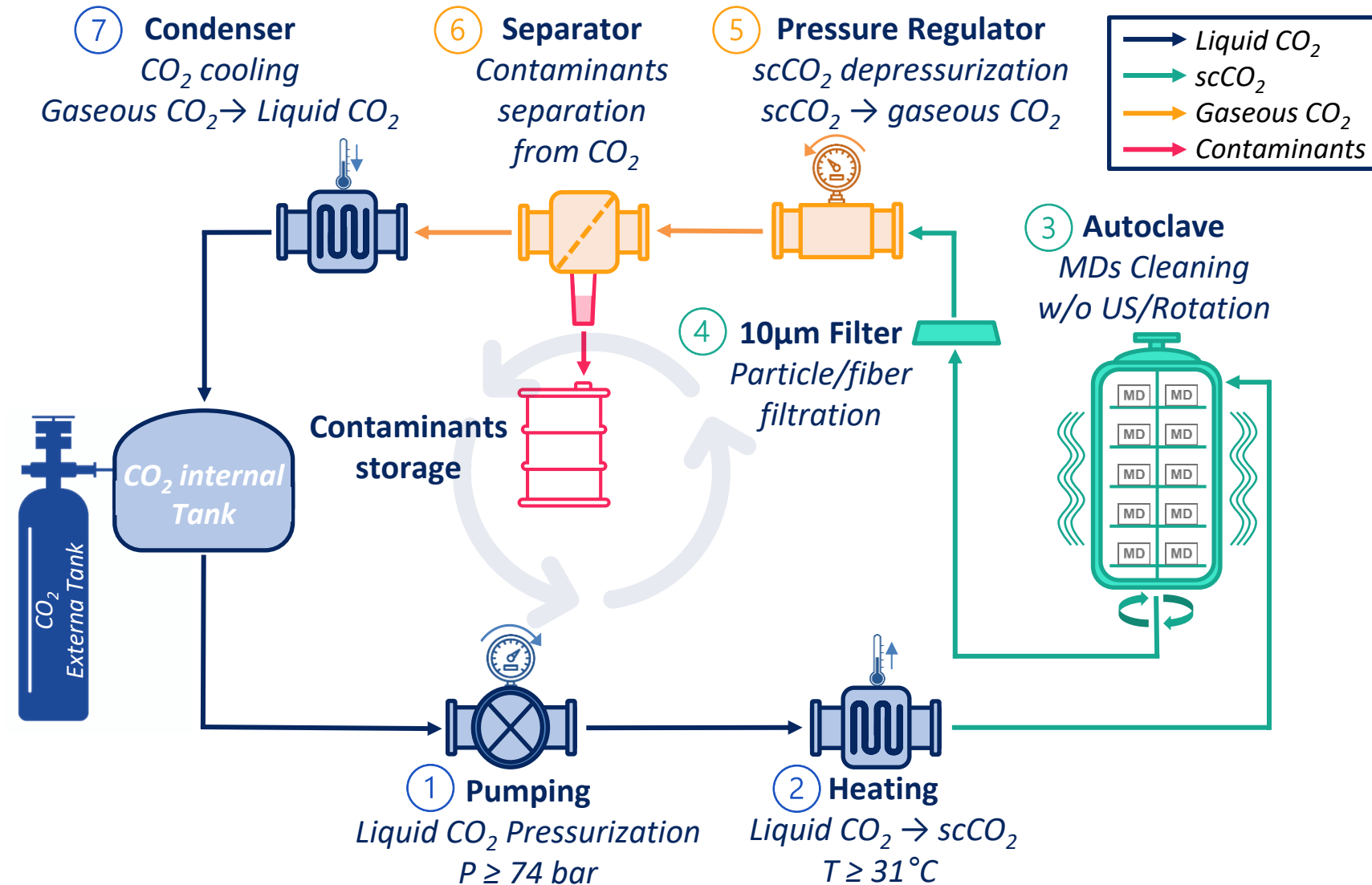
→ High performance of contamination extraction

| scCO₂ as cleaning solution



Deformable Materials with non-through holes/internal porosities may be subject to degradation.
The materials must be able to withstand pressure of several hundred bars.

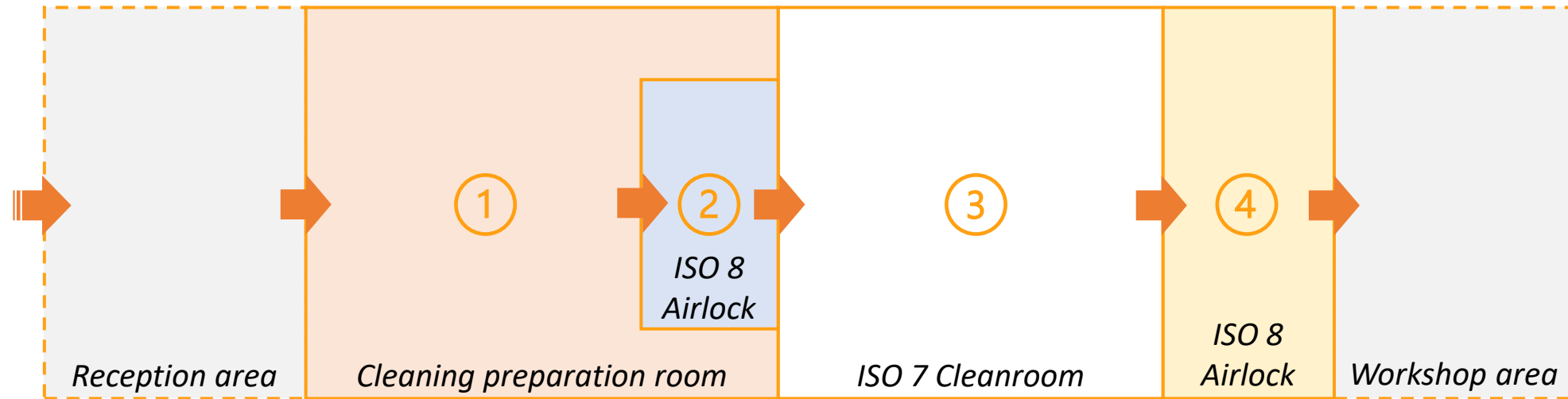
scCO₂ cleaning process principle



scCO₂ cleaning process environment

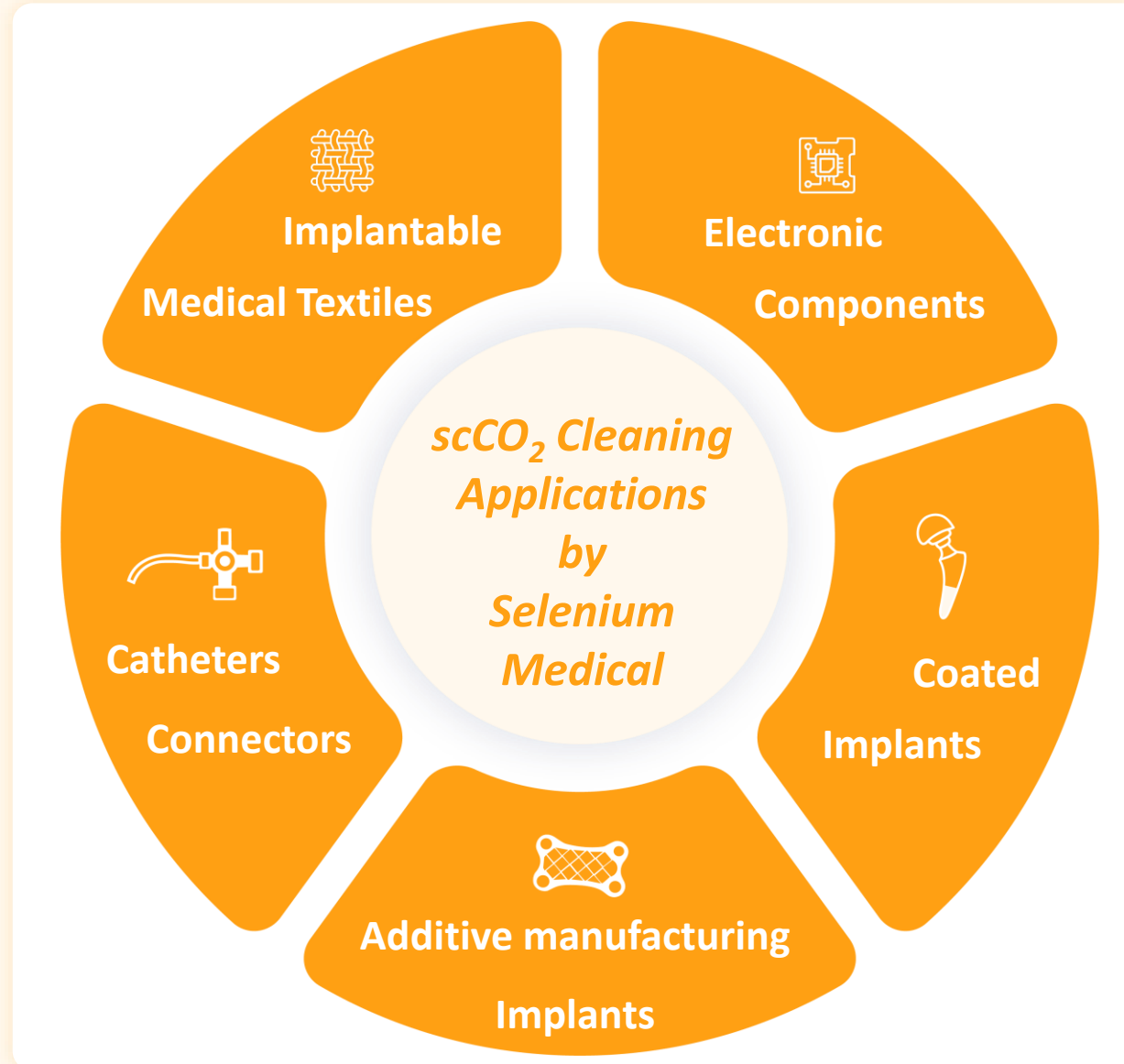


One-way cleaning process in controlled environment



- ① Product preparation in dedicated room :
 - Preparation **specification** in accordance with customer
 - **Adapted** cleaning support optimizing cleaning process
- ② scCO₂ autoclave final cleaning process :
 - **Controlled automatic** autoclave lid
 - **ISO 8 airlock** with interlocked double door
 - **Clear separation** between uncontrolled and controlled environment
 - **Validated cleaning recipes** adapted to customer product
- ③ Cleaned products reception in ISO 7 cleanroom:
 - Validation of **cleaning compliance** before door unlocking
 - **Controlled reception** of cleaned products
 - Assembly and packaging process in **controlled environment**
- ④ Final products exit :
 - **ISO 8 airlock** with interlocked double door

| scCO₂ cleaning by Selenium Medical



Thank you!

CONTACT INFORMATION

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