



NOVA PROCESS™ MATERIAL COMPATIBILITY GUIDE

*Supercritical carbon dioxide (scCO₂) sterilization processes are broadly compatible
with natural and synthetic compounds*

NovaSterilis, Inc.
3109 N Triphammer Rd
Lansing, NY 14882

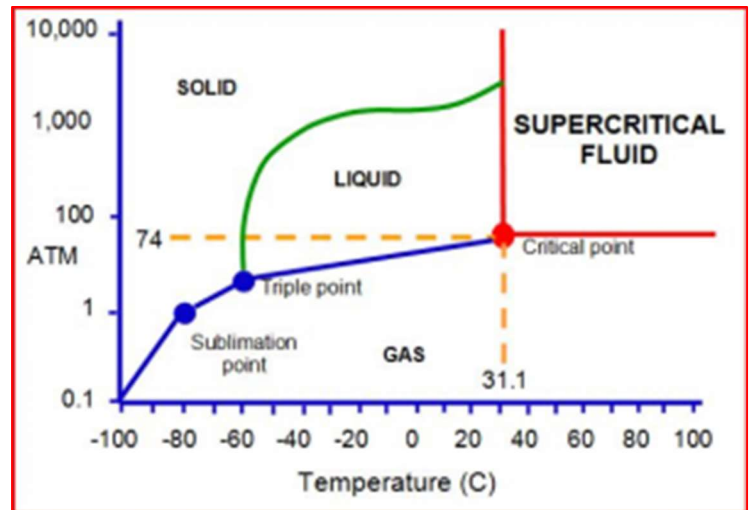
Abstract

NovaSterilis has provided scCO₂ equipment and sterilization process solutions to the medical device and regenerative medicine markets for 15 years. scCO₂ sterilization is a deep penetrating, low-temperature, minimally reactive modality, which has shown broad material compatibility. This process is known as the Nova Process™. This tech bulletin provides an overview of scCO₂, and a material compatibility summary list based on NovaSterilis' experience.

What is Supercritical Carbon Dioxide?

scCO₂ is a phase of carbon dioxide (CO₂) that is achieved when the temperature and pressure are increased above the critical point (31.1°C, 74 atm). In this phase, carbon dioxide has the density of a liquid and the diffusivity of a gas, giving it unique properties that are effective as a solvent and a sterilizer. scCO₂ itself is non-toxic; has a low environmental impact; and is a powerful solvent.

The critical region of CO₂ is characterized by an ability to control solvent power with only minor changes in pressure and temperature. The properties of scCO₂, such as its solvency, gas-like viscosity, diffusivity, compressibility, and very low surface tension, facilitate penetration of CO₂ to the interior of dense products such as bone tissue. As a result, the Nova Process is effective on devices and materials with complex geometries and densities resulting in the efficient inactivation of embedded pathogens unlike any other sterilization modality.



An Overview of scCO₂ Compatibility

The awareness of scCO₂ sterilization continues to grow because of increased adoption in the regenerative medicine market and because low temperature, minimally reactive, and deep penetrating solutions are needed for the emerging combination medical devices that are using a more diverse array of materials. NovaSterilis' proof-of-concept test program and contract research projects have grown dramatically over the past 3 years.

Over the past 20 years of research, development, and commercialization, NovaSterilis has processed hundreds of materials as single elements and as combinations. No sterilization modality is a silver bullet solution for all materials and scCO₂ is no exception to this reality. That said, the breadth of scCO₂ compatible materials, configurations and geometries is significant and are summarized on the following pages. NovaSterilis has shown compatibility with synthetic and natural polymers, therapeutics (both large and small molecules), metal instruments and complex electro-mechanical devices such as flexible endoscopes. The following list is not exhaustive, but it should provide guidance in your evaluation of the appropriateness of scCO₂ for your sterilization needs.



Synthetic Polymers

This summary is to help guide your evaluation of the appropriateness of scCO₂ sterilization in applications that utilize polymeric materials. Polymer compatibility may vary based on specific formulations and to a lesser extent device geometry. This information should be used to further discussions between your team and NovaSterilis

CATEGORY	MATERIAL	RESULT
Synthetic Polymers	Acrylonitrile butadiene styrene, ABS	Compatible
	Nylon 66	Compatible
	PELGA, PLGA-PEG co-polymer	Process dependent
	Poly(lactic-co-glycolic acid) + Polycaprolactone; PLGA (85:15) / PCL 75:25 wt./wt. ratio	Formulation Dependent
	Poly(lactic-co-glycolic acid), PLGA (85:15)	Formulation Dependent
	Poly(L-Lactide-co-ε-Caprolactone), PLCL	Minimally compatible
	Poly(methyl methacrylate), PMMA	Compatible, color change
	Polycaprolactone, PCL	Compatible
	Polycarbonate, PC	Compatible
	Polydioxanone, PDO	Compatible
	Polyether ether ketone, PEEK	Compatible
	Polyethylene terephthalate, PET or PETE	Compatible, form dependent
	Polyethylene, PE	Compatible
	Polyhedral oligomeric silsesquioxane, POSS	Process dependent
	Polyhydroxyethyl-methacrylate, pHEMA	Compatible
	Poly(lactic acid), PLA	Compatible
	Poly-L-lactic acid, PLLA	Compatible
	Polyoxymethylene, POM	Compatible
	Polypropylene, PP	Compatible
	Polystyrene	Incompatible
Polysulfone	Compatible	
Polyurethane	Compatible	
Thermoplastic elastomer, TPE	Process dependent	



Allograft/Xenograft

This summary is to help guide your evaluation and decision making relative to allograft/xenograft compatibility with supercritical carbon dioxide sterilization (scCO₂). This information should be used to further discussions between your team and NovaSterilis

CATEGORY	MATERIAL	RESULT
Tissue	Amniotic membrane	Compatible
	Aorta	Compatible
	Cornea	Compatible
	Dermis	Compatible
	Extracellular Membranes, ECM	Compatible
	Heart Valve	Compatible
	Lung	Process dependent
	Nerve, peripheral	Process dependent
	Pericardium	Compatible
	Porcine fascia	Compatible
	Tendons	Compatible
Collagen & Soft Tissues	Amnion/Chorion	Compatible
	Cartilage	Compatible
	Collagen	Formulation dependent
	eColl dental membrane (collagen)	Compatible
	SIS	Compatible
Bone	Bone crunch	Compatible
	Cortical bone	Compatible
	Decellularized bone matrix, DBM	Compatible
	Teeth	Compatible



Therapeutics & Biomaterials

This summary is to help guide your evaluation and decision making relative to therapeutic compatibility with supercritical carbon dioxide sterilization (scCO₂). This information should be used to further discussions between your team and NovaSterilis

CATEGORY	MATERIAL	RESULT
Natural Polymers	Alginate	Compatible
	Chitosan	Compatible
	Collagen	Compatible
	Gelatin	Compatible
	Hydrogels	Formulation dependent
Proteins	Amino Acids	Functional Compatibility
	Antibodies	Mixed compatibility, molecule specific
	Growth Factors, i.e. EGF = Compatible	Mixed compatibility, molecule specific
Biologics	Liposomal fluid	Compatible
Chemicals	Calcium lactate	Compatible
	Hyaluronic Acid	Compatible (application dependent)
	Lactic acid	Compatible
	Riboflavin	Compatible
	Sodium silicate	Compatible
Therapeutics	Antibiotics, i.e. Vancomycin = Compatible	Mixed compatibility, molecule specific
	Cannabis	Compatible, loss of terpenes
	Corticosteroids	Compatible
	Progestins	Compatible