

Improving precision cleaning performance in the MedTech industry with safe, sustainable chemistry.

Precision cleaning is a critical practice in the manufacture of high reliability medical devices. This white paper examines the challenges that are unique to this industry, the regulations affecting many previously used solvents, and how 3M is helping Medical Technology (MedTech) manufacturers achieve the twin goals of safety and process optimisation in precision cleaning during product manufacture.

Patient and worker safety Growing public concern about the effects of chemicals on human health, safety and the environment have led to restrictions on many kinds of process solvents previously used by the MedTech industry. There is a duty of care for manufacturers in ensuring workers are not exposed to products with CMR (carcinogenic, mutagenic or toxic to reproduction) potential.

From a patient perspective, any residue, whether particulate or chemical, could ultimately enter a patient's body and therefore stringent assessments regarding the safety of the cleaning process are necessary. A product recall is disastrous for multiple reasons, not least costs to business and damage to reputation.

Process optimisation In addition to patient and worker safety is the drive in the MedTech industry for process optimisation – faster cycle times, reduced power consumption and enablement of cellular manufacturing. Rigorous process analysis and validation, audited by independent and legislative third parties is common. Any change to a production process can be a costly, time consuming and potentially risky business when cleaning to specific regulations. This can lead to a reluctance to change, even when existing processes are awkward, expensive and cumbersome. However, value based outcomes for health care, changes in reimbursement, and restrictions placed on traditional solvents are all driving many companies to take the leap and evaluate alternative, more efficient cleaning processes.

In evaluating different solutions, users of these materials must balance the need for cost-effective performance with that of a sustainable, long-term solution – one that will still be viable for many years to come.

Key considerations in solvent cleaning of medical devices The MedTech industry covers multiple products: implants, instruments and equipment intended for therapeutics, monitoring and diagnostics. These include reconstructive devices such as hip and knee replacements as well as implantable monitors for cardiac and diabetic care.

In manufacture there may be two cleaning steps – an intermediate clean prior to assembly, and a final clean prior to packaging. The second cleaning step is arguably the more important since it is the final step in ensuring medical devices are sufficiently clean prior to packaging.

When designing a cleaning process there are multiple considerations:

- ▶ Adequate removal of soils without transfer of residue or introduction of new contaminants
- ▶ Damage to the components being cleaned (mechanical, thermal, chemical)
- ▶ Cost and process time

There is an important balance between performance in removing residue, versus damage to the medical device being cleaned. Validation of the cleaning process is also an important consideration.

Solvent cleaning vs aqueous cleaning

Since precision cleaning of medical devices requires a high level of cleanliness, solvents are largely preferred over aqueous based cleaning. Solvent cleaning is generally more efficient at penetrating tight spaces on complex parts, and draining off easily to avoid residue, spotting and bioburden. Whilst aqueous cleaning can, on face value seem a more sustainable choice, consideration must be given to energy and water consumption, disposal of waste water, use of drying equipment and overall footprint of equipment. In recent years phase down of traditional solvents used in cleaning has prompted concerns over health and safety and environmental impact of solvents in general. It's important here to distinguish between the traditional solvents which are impacted by legislation (discussed in the next section), and newer, more sustainable alternatives such as 3M™ Novec™ Engineered Fluids, which are unaffected by regulations.

Fig 1:

Solvent cleaning vs. aqueous cleaning
Advantages of solvent cleaning with Novec Fluids vs. aqueous systems
▶ Easier to use with cellular manufacturing
▶ Better solvency for organic soils
▶ No need for waste water treatment
▶ Reduced power consumption
▶ No anti-corrosion additives required
▶ Does not promote growth of bioburden
▶ Smaller equipment 'footprint'
▶ No water spotting
▶ No drying equipment needed

The regulatory environment

Several types of traditional cleaning solvents commonly used during the past 20 years are being phased out, phased down, have toxicity concerns, or have been banned. They include: Methylene Chloride, Perchloroethylene (Perc), Trichloroethylene (Trike), Hydrofluorocarbon (HFC) based Solvents and n-propyl bromide (nPB).

Under the EU Regulatory status Annex XIV listing Commission Regulation (EU) No 348/2013 of 17 April 2013, Trike's sunset date took place on 21st April 2016 and it is now banned with the exemption of pre-authorized

applications linked to specific companies. The sunset date for nPB has also been determined as 4th July 2020.

The F-gas Regulation aims to reduce the emission of fluorinated greenhouse gases, including HFCs used in solvent cleaning applications. The 2014 update prohibits the sale of some HFCs, phasing down all other HFCs (including those used in solvent cleaning) to only 21% of 2009–2012 levels by 2030.

Other cleaning solvents including Isoparaffins and Cyclohexane, though unaffected by regulatory change, are themselves raising safety concerns due to their flammability. Notably, 3M™ Novec™ Engineered Fluids have not been phased out or banned. They have high margins of safety and are non-flammable.

Novec engineered fluids

Novec engineered fluids have the following important benefits:

- ▶ Zero ozone depletion potential
- ▶ Low global warming potential
- ▶ Non-flammable
- ▶ High worker safety margin

Novec fluids offer a number of advantages for manufacturers of medical devices and equipment. They have demonstrated excellent compatibility with a wide range of plastics, elastomers and metals, including Titanium (common in implants). They are suitable for cleaning a wide range of parts, substrates and soils, as seen at Figure 2. The very low surface tension, low vapour diffusion rates and high liquid densities of Novec engineered fluids make them ideal for use in vapour degreasing equipment. They are fast-drying, and typically offer lower drag-out losses than conventional degreasing solvents.

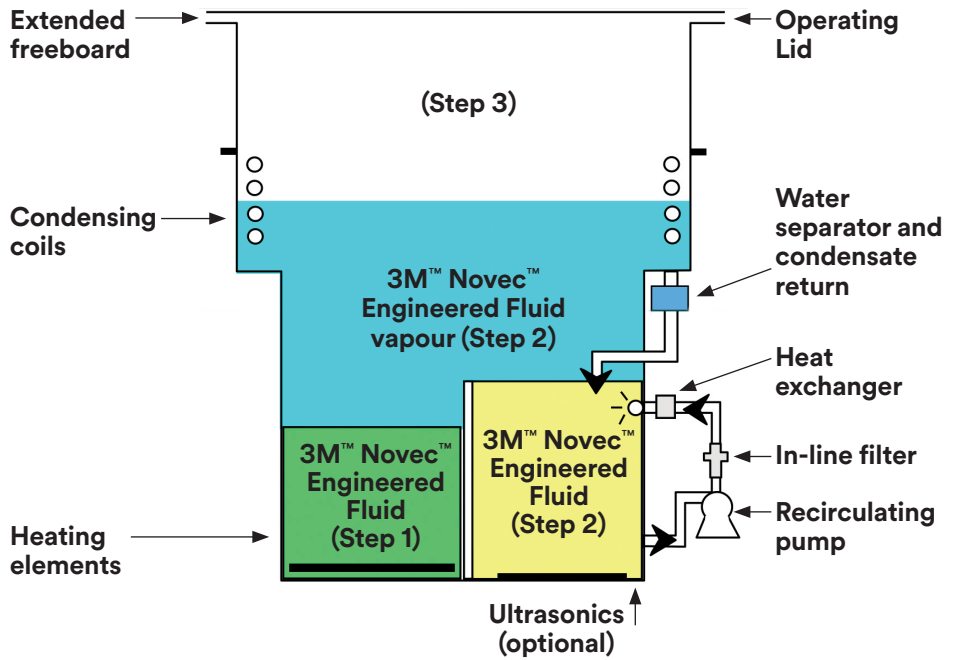
Fig 2: Cleaning with 3M™ Novec™ Engineered Fluids

Parts	Substrates	Soils
Artificial hearts	Polycarbonate	Oils
Heart valves	Silicone rubber	Particulate
O-rings	Plastics	Mould releases
Guidewires	Stainless steel	Mounting wax
Eyeglass lenses	Titanium	Skin oils
Catheters	Nickel/cobalt	Buffing compound
Needle caps	Aluminium	
Endoscope parts	Skin	
Gel Capsules		
Needles		
Stents		
Wires		
Cables		
Capillary tubes		
Orthopaedic implants		
Dental implants		
Spinal implants		

3M™ Novec™ Engineered Fluids are non-flammable and more efficient for cleaning complex geometries, thanks to their low surface tension and low viscosity. These properties, combined with low vapour diffusion rates, high liquid density and boiling points range (from 41 to 76°C), mean Novec engineered fluids are easily incorporated into typical vapour degreasing equipment. They are easily contained and recirculated in these machines, avoiding loss of product.

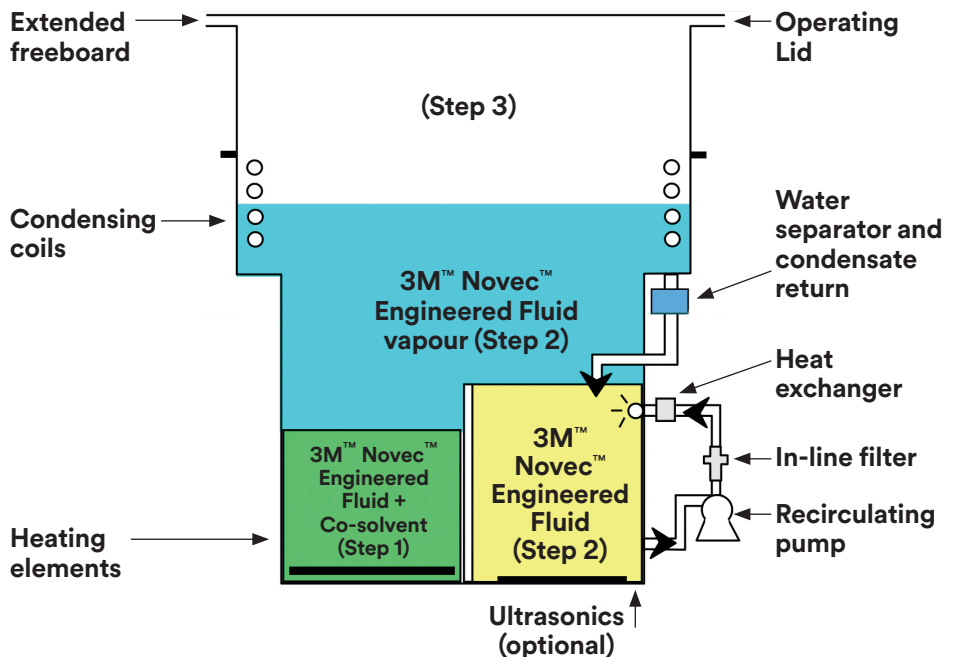
A vapour phase cleaning process has multiple benefits – short cycle time, and ease of use with consistent results in each process step: cleaning (1), rinsing (2) and drying (3), as can be seen in the diagram below.

Cleaning process equipment: monosolvent



Novec engineered fluids are also suitable for use in a co-solvent process, or as rinsing agents in conjunction with low volatility co-solvents. This co-solvent cleaning process is effective for the removal of the most challenging soils, such as heavy oils, greases and waxes.

Cleaning process equipment: co-solvent



Summary

There are three key dimensions to consider in solvent cleaning within the MedTech industry: performance, safety and environmental factors. In the past, performance was arguably the single most important parameter. Yet today, drivers for changing/updating a cleaning process may include process optimisation to deliver more value, improving worker safety, or sustainability, in reducing an organisation's environmental footprint. It is important to choose a solution that has the highest margin of safety, is not subject to current regulations, and performs effectively. 3M™ Novec™ Engineered Fluids strike a balance between all these demands. 3M continues to innovate and commercialise additional fluids in the 3M™ Novec™ range that meet our customers' demanding and evolving needs in the MedTech market.

3M™ Novec™ Engineered Fluids – the right balance on performance, safety and environment

Safety

- ▶ stability
- ▶ high margin of safety
- ▶ non flammability

Performance

- ▶ solvency
- ▶ compatibility
- ▶ low viscosity
- ▶ evaporates without residue
- ▶ low surface tension

Environment

- ▶ zero ozone depletion
- ▶ short atmospheric lifetime
- ▶ low global warming impact
- ▶ low water solubility

Technical support from 3M

Novec engineered fluids have replaced a wide variety of solvents that have been restricted due to regulations, including HFCs, nPB and TCE. Our global technical service team has significant experience assisting customers with conversions to Novec fluids. There are many factors to consider in these conversions and our team can work with you side-by-side to assist with process optimisation factors.

Safety, handling and storage

To make sure your cleaning solutions perform as designed, it is important that they are handled and stored appropriately. Please follow the 'Safety, Handling and Storage' information on the 3M Technical Data Sheets and Safety Data Sheets for these products.

Before using 3M products, please read the current product Safety Data Sheet (SDS), which is available through your 3M sales or technical service representative or at 3M.com/Novec, and the precautionary statement on the product package. Follow all applicable precautions and directions. Always practice smart and safe industrial hygiene practices.

3M EMSD Medical Device Policy

3M™ Novec™ products are intended for use as process solvents in applications, such as cleaning and coating. They are not intended, nor approved, for incorporation into medical devices or for use in pharmaceuticals. 3M will not support applications that involve temporary or permanent implantation of the Novec product.

The 3M™ Novec™ brand family

The Novec brand is the hallmark for a variety of proprietary 3M products. Although each has its own unique formula and performance properties, all Novec products are designed in common to address the need for smart, safe and sustainable solutions in industry-specific applications. These include precision and electronics cleaning, heat transfer, fire protection, protective coatings, immersion cooling, advanced insulation media replacement solutions and several specialty chemical applications.

3M™ Novec™ Engineered Fluids ■ 3M™ Novec™ Aerosol Cleaners ■ 3M™ Novec™ 1230 Fire Protection Fluid ■ 3M™ Novec™ Electronic Grade Coatings ■ 3M™ Novec™ Electronic Surfactants ■ 3M™ Novec™ Insulating Gases

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Regulatory: For regulatory information about this product, contact your 3M representative.

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