Ministry of Environment
and Food of Denmark
Environmental
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Safe and efficient recycling of soft PVC from medical devices by sustainable supercritical carbon dioxide (scCO2) technology

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Contents

1. Dansk Resumé

Medicinsk engangsudstyr i plast er meget udbredt i hele sundhedssektoren. Vi anslår, at der genereres 1 million tons plastaffald i sundhedssektoren om året i hele Europa. Skaleret til den danske sundhedssektor udgør plastaffaldet cirka 20.000 tons. Størstedelen bortskaffes som restaffald, og mindre end 15% bortskaffes som klinisk affald.
Medicinsk udstyr er designet og produceret til optimal funktionalitet og sikker brug. Polymerråvarer, der bruges til medicinsk udstyr, er generelt af bedre kvalitet end plast generelt. Medicinsk udstyr giver også en unik mulighed for værdibevarelse gennem genanvendelse på grund af lovgivningsmæssige rammer for ingredienser, sporbarhed og kvalitetskontrol.

Det nuværende projekt blev igangsat i 2016 med et partnerskab mellem producenten af medicinsk engangsudstyr AMBU A/S, Region Hovedstaden, PVC Informationsrådet, PVCMed Alliance, producenten af PVC-produkter Gibo Plast A/S og Teknologisk Institut.

Når det gælder fremstillingen af medicinsk udstyr i plast, så udgør PVC den største enkeltfraktion af polymerer. Det anslås, at knap 30 % af det plastbaserede medicinske udstyr fremstilles i PVC. Det gælder globalt, og det gælder også for Europa isoleret set. Der forventes ingen udsving i mængderne de næste ti år. De resterende 70% af det plastbaserede udstyr er fordelt mellem en lang række andre polymerer. (PVCMed Alliance, 2021).

Siden 2016 er der sket flere vigtige udviklinger: Nogle af de ofte anvendte ftalatblødgørere i medicinsk PVC-udstyr er nu opført på ECHA-kandidatlisten som hormonforstyrrende stoffer. Dette medfører, at producenter skal begrunde brugen af DEHP i henhold til Medical Device Regulation (MDR) (PVCMed Alliance, 2020) - og i praksis betyder det, at ftalatblødgørere i medicinsk udstyr er udfaset fra det europæiske marked i løbet af få år. Producenter af medicinsk udstyr skifter mod ftalatfrie produkter og endda PVC-frie produkter. Projektpartneren AMBU A/S har f.eks. substitueret ftalater i alle produkter med andre blødgørere. Ecolabel Danmark opdaterede for nylig deres kriterier for “Engangsposer, slanger og tilbehør til sundhedspleje”, der nu kræver, at de er PVC-frie (Nordic Ecolabelling, 2021).

Brug af genanvendt PVC fra medicinsk udstyr er reguleret af REACH. Koncentrationen af ftalater, der er opført på kandidtatliasten som særligt problematiske stoffer (SVHC) må nu ikke overstige 0,1 %, hvis f.eks. recyklat skal markedsføres som råvare. Udfasningen af ftalatblødgører i medicinsk udstyr betyder, at der kan etableres en levedygtig genanvendelsesordning, hvis:

- Blødgørerindholdet i genanvendt PVC sænkes under genanvendelsesprocessen.
- Der etableres en ordning, der dokumenterer affaldets oprindelse som ftalatfri PVC samt garanterer, at forurening med udstyr af ukendt oprindelse holdes under et givent niveau.

Derudover er der siden 2016 etableret indsamlingsordninger for brugt medicinsk udstyr i blødgjort PVC i både Storbritannien og i Australien. Disse ordninger opfylder ikke ovenstående krav, og PVC'en markedsføres igen på andre måder. En ny ordning igangsættes inden for VinylPlus® Med-samarbejdsprojektet. Her vil der også blive etableret en genanvendelsesordning i Belgien (VinylPlus, 2021).

Projektets formål var at demonstrere, at det er teknisk muligt at genanvende medicinsk engangsudstyr i blødgjort PVC til en PVC-råvare af høj kvalitet med ingen eller lave mængder restblødgører. Desuden at demonstrere, at en effektiv sortering og indsamling af sådanne udstyr er mulig.

I løbet af projektet blev følgende overordnede mål nået:

- Kendskab til værdikæden og sikker håndtering af brugt medicinsk udstyr blev udviklet og kommunikeret til interessenter på en workshop.
- Et første udkast til en designguide for medicinsk udstyr, der er egnet til genanvendelse, blev udviklet af partner AMBU A/S. Under projektet fokuserede partneren AMBU A/S også deres bæredygtighedsindsats (AMBU, 2021) og følger i dag detaljerede retningslinjer for bæredygtighed – denne trend ses i øvrigt i hele medicoindustrien.
- Hospitalspersonalet er entusiastiske omkring perspektiverne for at indsamle og genanvende de store mængder engangsudstyr i plast, de bruger. Pilotindsamlingen beskrevet nedenfor blev organiseret og administreret af en specialeansvarlig sygeplejerske, der engagerede sig dybt i at gøre en forskel for hende og hendes kollegers bæredygtighedsaftryk.
- Der blev etableret en pilotindsamling på fire afdelinger på Rigshospitalet, Glostrup. Et enkelt mærke af engangsanæstesimasker blev leveret af AMBU A/S til de involverede afdelinger over en periode på 6 uger. Masken var udelukkende fremstillet af ftalatfri blødgjort PVC. Sygeplejersker og andet personale sorterede maske fra ikke-infektiøse patienter og sække med masker blev hentet af DTI. Indsamlingen demonstrerede, at kildeseparation af medicinsk udstyr kan implementeres lokalt på hospitaler med en meget lav fejlrate: Under 1 % fejlsorterede masker.
- Den superkritiske ekstraktion af blødgørere blev etableret og demonstreret på DTI's pilotudstyr. Skalering af resultaterne til en indsamling på national størrelse viser, at omkostningerne ved genanvendelsesprocessen kan reduceres til et godt stykke under niveauet for jomfrueligt medical grade PVC-materiale.
- Maskerne opsamlet på Rigshospitalet, Glostrup blev anbragt i karantæne i 14 dage på DTI for at sikre, at hospitalets smitteopsporing kunne nå at advisere om mulig smitterisiko fra patienter, der først efter brug af maskerne var erkendt smitsomme. Efter neddeling og superkritisk CO2 -ekstraktion (ScCO2) betragtes recyklatet som sterilt.
- Der blev påvist mere end 5 x reduktion af blødgørerindholdet.
- Indsamlingsordningen og genanvendelsesprocessen opfylder kravene til en levedygtig genanvendelse som beskrevet ovenfor.

Projektet demonstrerede succesfuldt den tekniske gennemførlighed af at indsamle medicinsk engangsudstyr i PVC og genanvende det ved en superkritisk CO2-ekstraktionsproces. Det viste ikke, hvordan en ordning kunne implementeres på nationalt plan, eller hvordan et fuldt cirkulært kredsløb kunne etableres. Der er stadig mange miljømæssige, sociale og økonomiske udfordringer før dette er muligt - blandt dem:

- Kildesortering af affald er særdeles effektivt for at opnå lave fejlrater, hvis bevidstheden blandt personalet bevares. De Danske Regioner foretrækker imidlertid en central sortering af affald for at holde antallet af affaldsfraktioner nede på både hospitalsafdelinger og på hospitalernes lokale affaldshåndteringsfaciliteter. For at opfylde kravene til en levedygtig ordning skal en central sorteringsfacilitet derfor kunne sortere medicinsk udstyr ved hjælp af produktgenkendelse eller anden digital sporing.
- MDR-forordningen for medicinsk udstyr udelukker ikke brug af genbrugsmateriale, men stiller så strenge krav til kvalitetskontrol af råvarerne, at der først kan etableres en fuld cirkulær model, når der etableres en sikkerhed for levering af genbrugsmateriale af høj kvalitet.
- De økonomiske muligheder for anden brug af recyklat af høj kvalitet er ikke afklaret. En forretningsmodel vil også her være udsat for markedssvingninger og krav til forsyningssikkerhed for affald fra medicinsk udstyr.
- Skalering af ScCO2-ekstraktionen er teknisk og økonomisk etableret for fx ekstrahering af kaffe til koffeinfrit, men der er endnu ikke etableret international affaldshåndtering ved hjælp af ScCO2.

2. Executive summary

Single use medical equipment in plastics is widely used across the entire healthcare sector. We estimate that 1 million tons of plastic waste are generated in the healthcare sector per year across Europe. Scaled to the Danish healthcare sector, the plastic waste approximates 20.000 tons. The majority is disposed as residual waste and less than 15 % is disposed as clinical waste
Medical equipment is designed and produced for optimal functionality and safe use. Polymer raw materials used for medical equipment are often of better quality than plastics in general. Also, medical devices provide a unique opportunity for value preservation through recycling, because of the regulatory framework for ingredients, traceability, and Quality Control.

The current project was initiated in 2016 with a partnership between the medical device manufacturer AMBU A/S, The Capital Region of Denmark, PVC Informationsrådet, The PVCMed Alliance, the manufacturer of PVC products Gibo Plast A/S, and the Danish Technological Institute.

With respect to the manufacturing of medical equipment in plastic, PVC constitutes the largest single fraction of polymers. It is estimated that almost 30% of plastic-based medical devices are made of PVC on a global and European scale. Little fluctuations in volumes are expected over the next ten years. The remaining 70% of the plastic-based equipment is distributed among several other polymer (PVCMed Alliance, 2021).

Since 2016, several important developments have occurred: some of the frequently used phthalate plasticizers in medical PVC devices are placed on ECHA authorization list as endocrine-disrupting substances. This in terms requires manufacturers to justify the use of DEHP according to the Medical Device Regulation (MDR) (PVCMed Alliance, 2020) and in practice it means, that phthalate plasticizers are to be phased out. Medical device manufacturers shift toward phthalate-free products and even PVC-free products. The project partner AMBU A/S e.g., have substituted phthalates in all products with other plasticizers. Nordic Ecolabeling recently updated their criteria for “Disposable bags, tubes and accessories for health care” requiring them to be PVC free (Nordic Ecolabeling, 2021)

Use of recycled PVC from medical devices is regulated by REACH. Concentration of phthalates listed on the authorization list as substances of very high concern is now required not to exceed 0.1 % if e.g., recyclate are to be marketed as a raw material. The out phasing of such phthalates in medical devices means that a viable recycling scheme can be established if:

- Plasticizer content in the recycled PVC is lowered during the recycling process.
- A scheme is established that documents the origin of the waste as phthalate-free PVC and that guarantees that contamination with devices of unknown origin is kept under a certain level.

In addition, since 2016 collection schemes for used medical devices in plasticized PVC was established in both the UK and in Australia. These schemes do not meet the above requirements and the PVC is downcycled by other routes. A new scheme is initiated within the VinylPlus® Med collaborative project. A recycling scheme will be established in Belgium as well (VinylPlus, 2021).

The project aimed to demonstrate that it is technically feasible to recycle medical devices in plasticized PVC to a high-quality PVC with zero or low amounts of additives and that an efficient sorting and collection of such devices are possible.

During the project, the following major goals were reached:

- Knowledge on value chain and safe handling of used medical equipment was gained and communicated to stakesholders at a workshop.
- A first draft for a guide for designing medical devices apt for recycling was developed by partner AMBU A/S. During the project, the partner AMBU A/S also focused their sustainability efforts (AMBU, 2021) and today follows detailed sustainability guidelines – and throughout the medical device industry, the same trend is seen.
- Hospital staff is extremely enthusiastic about the perspective of recycling the lot of disposable equipment they use. The pilot collection described below was organized and managed by a nurse specialist truly committed to making a difference to her and her colleagues' sustainability footprint.
- A pilot collection was established at four departments at Rigshospitalet, Glostrup. A single brand of disposable anesthesia mask was supplied by AMBU A/S to the involved departments over a period of 6 weeks. The mask was made from phthalate-free plasticized PVC solely. Nurses and other staff sorted mask from non-infectious patients and bags with masks were picked up by DTI.
  The collection demonstrated that source separation of medical equipment can be implemented locally at hospitals with a very low failure rate – below 1 % missorted masks.
- The super critical extraction of plasticizers was established and demonstrated at DTI pilot equipment. Scaling of the results to a collection on a national size shows that costs can be reduced to well under the level for virgin material.
- The masks collected at Rigshospitalet, Glostrup was placed in quarantine for 14 days at DTI before shredding and super critical CO2 extraction (ScCO2). After CO2 extraction, the recyclate is considered sterile.
- More than 5 x reduction of plasticizer content was demonstrated.
- The collection scheme and recycling process meets the requirements for a viable recycling as described above.

The project successfully demonstrated the technical feasibility of collecting disposable medical equipment in PVC and recycle it by a super critical CO2 extraction process. It did not show how a scheme could be implemented on a national level or how a full circular loop could be established. Many environmental, social, and economical challenges remain, among those:

- Source separation of waste is most efficient in obtaining low failure rates if awareness among staff is maintained. However, the Danish Regions would much prefer a central sorting of waste to keep the number of waste fractions at both hospital department and in the hospitals local waste handling facilities low. To meet the requirements above, a central sorting facility must hence be able to sort medical devices using product recognition or other digital tracking.
- The MDR regulation for medical devices does not exclude use of recycled material but impose demands so strict on the raw materials that a full circular model can first be established when a security for supply of high-quality recycled material is established.
- The economical options for other uses of a high-quality recyclate was not clarified in the project and all uses will of course also be exposed to market fluctuations and supply security of medical device waste.
- The scaling of the ScCO2 extraction is technically and economically implemented for e.g., decaffeination of coffee but no waste handling using ScCO2 is yet established internationally.

3. Introduction

PVC is the most widely used medical plastic material today and amounts to approx. 30 % of single-use plastic equipment in hospitals. The possibilities for mechanical recycling of soft PVC are limited today and in Denmark soft PVC fractions are primarily disposed by landfill. In addition, a relatively large amount of soft PVC via leakage to residual waste is expected to end up in incinerators. The aim of the project is to develop and demonstrate new opportunities for the recovery of soft PVC from high quality medical equipment in recycling through the safe removal of plasticizers and additives using environmentally friendly supercritical carbon dioxide (scCO2) technology. The objective is to demonstrate sustainable production of high-quality PVC recyclate with Denmark as a pilot case

3.1 Background

The general PVC waste management in Denmark involves division into recyclable and non-recyclable PVC, where the latter is sent to landfill [Affaldsbekendtgørelsen 2020]

Rigid PVC (PVC-U) is recycled through WUPPI - the Danish PVC industry's joint collection scheme for rigid PVC. WUPPI A/S was founded in 1997 as a nationwide collection scheme for construction waste of hard PVC. Behind the company is the entire industry of manufacturers and importers of rigids PVC construction products. The WUPPI system is based on the PVC industry's joint initiative and many years of experience in the collection and recycling of PVC construction waste. The WUPPI scheme also includes municipalities, private craftsmen, and contractors.
WUPPI collaborates with the Danish Environmental Protection Agency, VinylPlus, Plastindustrien and PVC The Information Council to ensure correct handling of hard PVC.

The term “plasticized PVC” substitute the term “soft PVC” forward in the report. Methods for plasticized PVC recycling involves mechanical processes based on melting and solvent-based dissolution giving a recycled PVC compound, and chemical (feedstock) processes where the material is completely degraded into low-molecular weight species. The possibilities for recycling plasticized (used throughout PVC are described in a report from VinylPlus [VinylPlus 2017]. Products recycled include cables, vinyl flooring and tarpaulins.

In Denmark, plasticized PVC must in general be disposed to landfills (Affaldsbekendtgørelsen, 2020), (Miljøstyrelsen, 2001).

Practically, the plasticized PVC from hospitals often ends up in the residual waste and goes to incineration, resulting in hazardous chlorinated compounds which is a concern for health and environment. Therefore, Normal solid-waste incinerators with energy recovery can only tolerate up to 1 % chlorine. There is an urgent need to find new sustainable processes for the recovery of plasticized PVC, to increase the possibilities of PVC recycling and reduce the streams of plasticized PVC to landfill and incineration.

3.2 Aims

The aim of the present project is to perform a safe and efficient collection and recycling of plasticized PVC from used medical components from a hospital, by separating the additives from the PVC with a sustainable supercritical CO_2 processing technique. The aim is further to produce a high-quality PVC recyclate with zero or low amounts of additives, that can be processed into a master batch for the production of recycled medical or non-medical products or merged with existing well-functioning waste streams for hard PVC from other industries. Relevant goals and the measurable success criteria are visualized in Table 1.

Table 1. Project goals

Project goals	Success criteria
Mapping of PVC value chains (amounts, prices etc) on the local level.	Identification of interests and amounts relevant for a local Danish context, and the potential scaling to European level.
Sorting plasticized PVC from waste streams.	A waste management system at a hospital with practical solutions for manually sorting plasticized PVC items from the medical waste.
Separation of the additive from PVC by sustainable method.	Extraction of additive by supercritical CO2 and chemical characterization of extract.
Move medical waste amounts from landfill and incineration to recycling.	Increased profit for hospitals for handling of plastic waste.
Compounding and extrusion methods for PVC recyclate	Suitable compounding and extrusion methods for processing the additive-free PVC recyclate into a master batch to be used for new products or enter existing waste streams.
High quality PVC recyclate	Establishment of required properties for PVC recyclates.
Establishment of potential use of the PVC recyclate	Identification of suitable recyclable products within the following group: non-critical medical plasticized PVC components, non-medical plasticized PVC products and conventional hard PVC applications.

3.3 Technical developments

Supercritical CO2 is a well-known technique that was developed several decades ago. It has received increased attention the latest years due to its sustainable properties. The use of CO2 at high pressure and moderate temperature implies a supercritical state which gives a solvent-like feature and thereby replaces the need for conventional, hazardous solvents as processing media. The issue of residual solvents in the product/extract is eliminated since the CO2 gas evaporates after use. In addition, the CO2 can be recycled into processing by a re-compression step implying added green value. Supercritical CO2 is in use internationally today in various applications ranging from small-volume analytical techniques to large-scale food processing units. Hence, the know-how and instrumentation for up-scaling supercritical processes are available.

The use of supercritical CO2 in analytical methods for characterization of additives, such as phthalates, in PVC has been reported in several scientific publications (Marin, 1996, 1998), (Ude, 2002). However, supercritical CO2 processing for separation of additives in PVC waste management has, to our knowledge, not been fully addressed. The scCO2 processing would involve separation of the additives from PVC, leaving a PVC recyclate with zero or low additive content, without destruction of the polymer. The PVC recyclate can then enter existing PVC waste streams or be re-processed into new products of hard or plasticized PVC, after careful characterization and evaluation, and possible addition of approved plasticizers. A bonus is that by separation of the additives from the medical PVC waste, the additives can be, possibly, fractionated, and recuperated, or destroyed. This implies the possibility to exclude hormone-

disruptive phthalates from the PVC value chain and avoid them from entering any recycling, incineration, or landfill stream. The present project has a focus on medical PVC waste, but the potential development of a successful project outcome is expected to be large, since the experiences can be transferred to a variety of PVC applications.
Projects for waste management of medical PVC component at hospitals have been performed with promising results in the Recomed project in UK (Recomed, 2021) and the PVCrecovery project in Australia (Vinyl Council Australia, 2021). By collection of used medical devices made of PVC, such as intravenous (IV) fluid bags, oxygen masks and tubing, PVC recyclates were obtained by conventional mechanical processing techniques and directed towards selected non-medical products such as garden tree shelters, industrial tubing and matting. Contacts with the projects in UK and Australia have been taken and will be developed for a dialogue and exchange of experiences regarding hospital collection schemes. The present project will in addition focus on requirements to avoid biological contamination in medical PVC waste and investigate medical device design for achieving efficient sorting and device disassembly.

3.4 Expected environmental impact

Methods for PVC recycling presently involves *i)* mechanical processes based on e.g., melting and solvent-based dissolution/precipitation resulting in a recycled PVC compound including the additives, and *ii)* chemical (feedstock) processes where the material is completely degraded into low-molecular weight species. While there are well-functioning waste streams for recycling hard PVC, the waste management of plasticized PVC remains a challenge. The present project will explore scCO2 processing for recycling plasticized PVC waste, which implies separation of additives from the PVC without destroying the PVC polymer chains. There is no use of chemical solvents that requires additional process steps for removal. The expected outcome is a PVC compound with zero or low amounts of additives. The method will thus allow for exclusion of phthalates from the PVC value chain, as they can be passed on to destruction. The environmental gain is expected to be large since the processing is suitable for plasticized PVC waste where the recycling options are limited.
Danish hospitals have invested time and effort in establishing an internal sorting system for recyclable waste, involving hard and soft plastic, such as medical devices and packaging. However, they have had limited success of securing reutilization of the collected plastic waste due to: 1) waste recyclers are hesitant to deal with the risk of biological contamination of the plastic waste from a hospital, 2) waste recyclers do not want to handle mixed plastic with PVC present and 3) the price for recycling is high due to mixed plastic and low amounts. The present situation is that the hospitals might need to send the sorted plastic waste to incineration instead of recycling. The hospitals welcome an opportunity to create a separate stream for recycling their PVC waste and improve conditions and understanding towards a profitable recycling. The hospitals are also interested in acquiring knowledge and setting up procedures for the handling of biological contamination in plastic waste, based on the requirements for recycling plastic. There is obviously a range from high biological contamination such as blood bags to products with no patient contact such as packaging and tube connectors, where many products are in a grey zone in the middle of high and low contamination. Hence, clarification is needed regarding contamination limits to open for more recycling of hospital plastic waste.

Efficient management of the waste streams from the healthcare sector would provide opportunities to reduce costs of waste disposal, reduce the environmental footprint of hospitals as well as the risks of health and safety to staff and patients. From the PVC industry's perspective, efficient recovery of PVC medical product waste would provide a valuable stream of quality recyclate to support a growing demand from manufacturers for PVC recyclate as well as underpinning a struggling PVC recycling sector.

3.5 Expected business impact

The successful establishment of a local, efficient, and sustainable PVC value chain for medical PVC waste involves several potential business opportunities for the project partners. An

available recycling stream for plasticized PVC from medical waste implies an immediate opportunity for Danish hospitals for increased utilization of their waste fractions, avoiding incineration of the collected plastic waste. In the long term, efficient collection and sorting of used medical components have the potential to contribute to a more profitable waste management from revenue creating trading of high-quality transparent plastic fractions.
The waste recyclers dealing with the plasticized PVC medical waste can expect the following amounts for the waste streams. The estimated amount of medical PVC waste at a Danish hospital is around 15 tons per year, calculated from the supply of a limited proportion of medical devices made of plasticized PVC used daily, such as inhalation devices, oxygen masks, tubings for sample collection and blood bags. A rough estimate of the total amount of medical plasticized PVC waste produced in Denmark is at least 500 tons per year, recalculated by population numbers from the yearly consumption of IV (intravenous) solution sets made of PVC at hospitals in Australia, where 50 million used IV solution sets go to landfill every year (ref. Sophie MacMillian, PVC Recovery in Healthcare, 2014). Plasticized PVC used for medical components are of very high, well-defined, and transparent (medical) quality, which makes it – when modified and cleaned – a valuable resource fraction that offers a significant business opportunity for waste management businesses. The price of PVC regrind approximates that of virgin PVC today – see. e.g., Alibaba. The general price of plastic is somewhat lower - DKK 1.500-3.000 per tons for reprocessed secondary granulates according to a Eurostat statistic, (Eurostat 2020). It sums to an annual 50 million marked potential for processing and trading of PVC recyclate from end-of-life medical components in Denmark alone.
The major advantage of the sustainable supercritical CO2 extraction process described in the present project is that it involves separation of the additives from the PVC, without degrading the PVC polymer chains. Hence, the PVC recyclate has the potential to be re-processed into new products either as hard PVC or as a master batch for plasticized PVC by addition of new approved plasticizers. This is a business potential with added green value not only for the waste collectors, offering collection of plasticized PVC waste, but also for recyclate compounders by offering master batches from recycled high quality medical PVC waste with trackable source. A positive outcome of the present project can be spread to a broad range of other application areas of plasticized PVC products such as cables and electronic industry. Since supercritical CO2 processing is a well-known technique which is scalable to large quantities, the implementation and road to market for this waste management is expected to be short.
The experience of sorting and distributing plasticized PVC waste at one Danish hospital has a high relevance, not only to other Danish hospitals interested in waste management systems for recycling, but also to medical device companies interested in added green value for their products. Today, there are no directives or procedures for the design of medical device products to adapt to recycling, such as facilitation of disassembly and avoiding blending of different plastics. AMBU A/S has a non-phthalate policy since several years and has phased out phthalates from their product portfolio by either exchanging the PVC into other plastics such as polyolefin, or, in the case of products where the choice of PVC is critical, replaced the phthalates with allowed PVC plasticizers. In the present project, AMBU A/S is interested in establishing a disassembly design guide by means of the experiences gained from this project. We initially established small collection schemes at several hospitals in the capitol region and ended up with a major collection scheme for oxygen masks at Rigshospitalet Glostrup. The experiences from the project will be disseminated to other hospitals in Denmark.

3.6 Project activities

The work plan of the present project is divided into five separate work packages (WPs) which are described in Table 3. The deliverables (D), tasks (T) and milestones (MS) associated with each WP are described with due month (M) indicated. The work packages are closely intertwined, where WP2-Wp4 form a recycle loop which is supported by WP1

and WP5 during the project, see Figure 1. Workflow of the projectFigure 1. Milestones and deliveries are summarized in

Table 2.

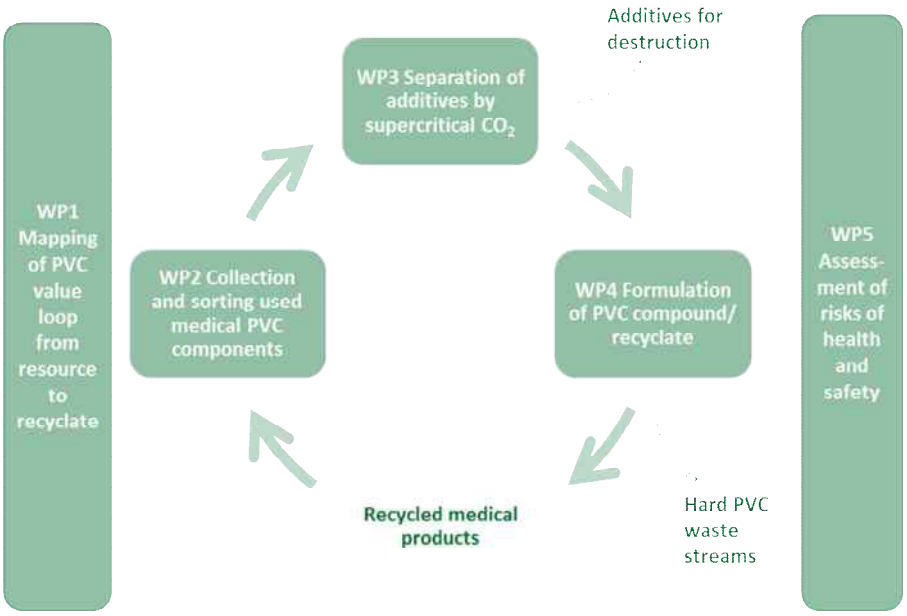


Figure 1. Workflow of the project

Table 2. Milestones and deliverables

WP	Deliverable / Mile-stone	Description
WP1	Deliverable D1.1	A report describing the value chain for recycling PVC from medi-cal waste.
	Deliverable D1.2	A workshop for stakeholders in the PVC value loop for discussion of critical issues and regulatory aspects when recycling PVC from medical devices.
WP2	Milestone MS2	A collection system for PVC components has been tested and evaluated.
	Deliverable D2.1	An amount of collected PVC components for processing in WP3.
	Deliverable D2.2	A report describing a model for collection and sorting used medi-cal PVC components at a hospital.
	Deliverable D2.3	A written guide for disassembly design for medical device pro-ducer Ambu.
WP3	Milestone MS3	Supercritical CO2 extraction of PVC for separation of additives has been demonstrated.
	Deliverable D3.1	An amount of PVC recyclate for compounding in WP4.
	Deliverable D3.2	A report describing the results from supercritical CO2 processing of PVC.
WP4	Milestone MS4	Compounding of a master batch of recycled PVC has been per-formed.
	Deliverable D4.1	A master batch of recycled PVC for use for a selected product type.
	Deliverable D4.2	A report describing the results from compounding and extruding PVC recyclate.

WP5	**Deliverable D5.1**	**A report describing the risks relating to health and safety when recycling PVC from medical waste.**

Table 3. Work package and task breakdown.

Title	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
WP1 Mapping of PVC value loop from resource to recyclate				D1.1		D1.2		
T1.1: Mapping the resource and value loop for recycling PVC from medical devices								
T1.2: Future design of recyclable medical devices.								
T1.3: Investigation of the policy and regulatory aspects in a European scope of recycling PVC from medical devices.								
WP2 Model for collection and sorting used medical PVC components		D2.1		MS2, D2.2		D2.3		
T2.1: Development of model for collection of used medical PVC components at Gentofte hospital (M1-M18)								
T2.2: Evaluation of collection and optimization of design for efficient waste management of medical devices.								
WP3 Separation of additives by supercritical CO_2 technology		D3.1		MS3		D3.2		
T3.1: Establishment of process design and parameters								
T3.2: Supercritical CO2 extraction of PVC								
T3.3: Mechanical and chemical characterization of materials xx								
WP4 Formulation of compound/recyclate				MS4	D4.1	D4.2		
T4.1: Establishment of requirements for master batches of PVC recyclates, process design and parameters								
T4.2: Compounding and extrusion of PVC recyclate into master batches and, optionally, selected recycled products.								
WP5 Assessment of risks of health and safety						D5.1		
T5.1: Mapping of risks for health and safety during collection, sorting and transportation of PVC components								

4. Project outcome

The project explored the various tasks described above, whereas the focus changed during the project into performing a larger scale and more realistic collection and recycling experiment than originally foreseen. Also, the hospital responsible for the collection was Rigshospitalet / Glostrup and not Gentofte / Herlev hospital where initial collections were performed.

4.1 Mapping of PVC value loop from resource to recyclate

A report on “Mapping the PVC based medical device from resource to recyclate” by the PVC Information Council was authored by Ole Grøndahl Hansen & Tobias Johnsen. The report is found in Appendix 1.
The report is parted in five sections describing the value chain and the challenges when it comes to recycling medical devices:

1. Introduction: medical devices in plastics pvc – a revolution in healthcare
2. Value chain – from raw material to pvc device
3. Waste management
4. Plasticizers
5. Case studies of recycling schemes
    5.1. Example Australia
    5.2. Example UK

The report is focused on recycling of PVC devices and hence deals with in particular single use items. The report summarizes some of the findings that was available in 2017 from the recycling schemes in UK and Australia.

4.2 Future design of recyclable medical devices

Medical equipment is designed and produced for optimal functionality and safe use. Polymer raw materials used for medical equipment are often of better quality than plastics in general. Medical devices provide a unique opportunity for value preservation through recycling, because of the regulatory framework for ingredients, traceability, and Quality Control.

Under the project duration, all medical device companies and not the least producers of single-use equipment have increased their sustainability focus. Today, several companies developed design guides helping in choosing more sustainable materials combinations. During the project, the partner AMBU A/S also focused their sustainability efforts (AMBU, 2021) and follows today detailed sustainability guidelines.
During the project, a first draft for a guide for designing medical devices apt for recycling was developed by AMBU. The guide is included in a presentation authored by Anette Bitz, AMBU A/S. The full presentation is found in Appendix 2.
The guidelines are presented schematically by a green, yellow and red category as exemplified for materials selection for medical devices at AMBU A/S in Table 4

Table 4 AMBU A/S design guide – materials traffic signal.

Selection of materials

Material Categories	Preferred	OK but search for alternative	Prohibited (No-Go)
Polymers	Biobased PE,PP,PET Recycled polymers HDPE, LDPE, PP, PET No masterbatch	ABS, POM, PC, PA, PMMA, EVA Composites, filler in polymers	Latex PVC Oxo degradable and biodegradable plastic
Chemicals and additives	Chemical-free Non classified, Ca/Zn stabilisers	SVHC < 0,1% CMR < 0,1% UV-320 CalProp65, PBT	Subject to Authorization Ortho-phthalates Pb, Cd, organotin stabilizers
Flame retardants	Do not contain flame retardants Triophenyl phosphate, resorcinol, magnesium hydroxyde	RDP, BPADP/ BAPP, Phenol, Phosphonate-co-carbonate, aluminum Hydroxide, Melamine Poly-phosphate, Red Phosphorus	PBB, PBDE, Antimony trioxide, BPA,
Packaging	Transparent PE, PP, PET Biobased materials Biodegradable cardboard Recycled materials FCS	Paper labels	Laminated foil Metal clamps Chlor bleached EPS æggebakker
Metals and electronics	Stainless steel, Al, Zn, Pt, Ti	Ni, As, Be, Se, Sb	Pb, Hg, Cd, Cr (>0,1%)

Stakeholder's workshop

A stakeholder's workshop was held in November 2019 concerning the outcome of the project and critical issues and regulatory aspects when recycling PVC from medical devices. The content of the workshop (in Danish) is shown in the insert and the full description is found in Appendix 3. The presentations were distributed among the thirty participants.

The workshop invitation is found on https://www.teknologisk.dk/kurser/genanvendelse-af-plastbaseret-medicinsk-udstyr/k90545 and the PVC Information Council issued a press statement found on https://pvc.dk/2019/11/27/hvordan-kan-plasten-i-sundhedsvaesenet-genanvendes/ about the outcomes of the workshop – also included in Appendix 3.

The workshop consisted of short presentations from environmental authorities, industry, regions and the Danish Technological Institute, incl. plenary discussion

Program

- **Introduction** (Peter Sommer-Larsen, Danish Technological Institute)
- **PVC and plastics in the healthcare sector - a brief historical outline** (Ole Grøndahl Hansen, PVCMed Alliance)
  Why are plastics used for medical equipment and what was used before? What types of plastics are most used today, and which the trends are seen?
- **The environmental challenges of PVC-based medical equipment** (Jesper Skovby Jørgensen, Danish Environmental Protection Agency)
- **The new rules for medical devices** (Morten Sichlau Bruun, Danish Medicines Agency)
  On EU's new medical device regulation and the new European pharmacopoeia as well as assessment of risks of infection
- **Vision technologies and Artificial Intelligence used for inspection and sorting** (Jacob Kortbek, Danish Technological Institute)

Theme 1: Design of medical equipment in plastic for recycling

- **Design for recycling of medical equipment** (Annette Bitz, AMBU A/S)
- **Plastic products and packaging designed for recycling** (Peter Sommer-Larsen, Danish Technological Institute)
- **Plenary discussion**

Theme 2: Recycling of medical equipment

- **Experiences from a Nurse's perspective** (Mette Skriver Revsbech, Rigshospitalet, Glostrup)
- **Supercritical CO2 extraction of plasticizers in medical devices** (Peter Sommer- Larsen, Danish Technological Institute)
- **Recycling of disposable medical equipment - four cases** (Tobias Johnsen, PVCMed Alliance)
  a) Australia; b) UK; c) South Africa; d) Guatemala
- **Practical challenges when sorting plastics for recycling in hospitals** (Bjørn Brix Pedersen, Capital Region Denmark)
- **Plenary discussion**

4.3 Investigation of the policy and regulatory aspects in a European scope of recycling PVC from medical devices

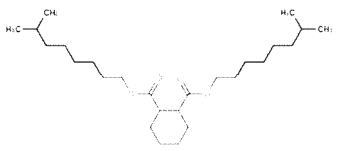
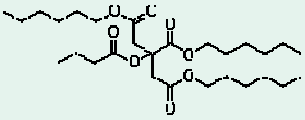
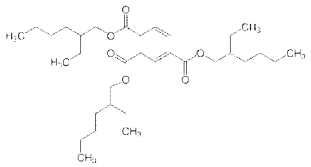
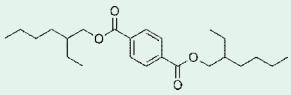
The regulatory aspects are treated in Appendix 1. They address two issues in particular: waste treatment and potential hazards dealt with in the REACH regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals.

An additional aspect is the requirements for medical devices as covered by the “Medical Device Regulation” Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The regulation does not specifically prevent the use of recycled material but imposes strong demands to the documentation of recycled raw materials pureness and tracking of origin. The conclusion in general is that a closed loop recycling system is the only viable option if medical devices are to be recycled for new medical devices. We do not expect such schemes to be demonstrated on a timescale of five years. However, it is foreseen that medical companies demonstrate take-back loops for medical devices and using the recycled materials for devices covered by their own quality assurance systems but not classified as medical devices.

One important conclusion and outcome is that future medical devices in PVC is expected to be phthalate free. The project partner AMBU A/S already reached this goal in 2020 (AMBU, 2020).

Another important conclusion is that one will expect one of the four alternatives to DEHP listed in the European Pharmacopoeia to be used, see Table 5

Table 5. Plasticizers listed in the European Pharmacopoeia

CAS no.	EC / List no.	Chemical name	Structure	Ex. trade name, abbreviation
166412-78-8	431-890-2	1,2-Cyclohexane dicarboxylic acid diisononyl ester		Hexamoll, DINCH
82469-79-2	413-890-4	Butyryl tri-n-hexylcitrate		BTHC
3319-31-1	222-020-0	tris(2-ethylhexyl) trimellitate		TEHM, TOTM
6422-86-2	229-176-9	bis(2-ethylhexyl) terephthalate		Eastman, DOTP, DEHT, DEHTP

4.4 MODEL FOR COLLECTION AND SORTING USED MEDICAL PVC COMPONENTS

During the project, two collection schemes were established. The first scheme was established and tested at Rigshospitalet and Gentofte and Bispebjerg hospitals. An amount of collected PVC devices was delivered to DTI, D2.1. Also partner AMBU has collected unused PVC devices for DTI's recycling. This scheme was partly implemented in a few smaller collections at the hospitals mentioned. These collections gave a multitude of PVC based devices that had to be individually separated at DTI for use in recycling. A simple labeling on bins with a picture of the product was suggested as illustrated here:

Bin marked with pictures of devices apt for recycling. From RECOMed project.

At the same time, DTI recycling experiments revealed that the super critical extraction process will not differentiate different type of plastics and noticeably not PVC from PC or PP. The problem was exemplified by recycling PVC oxygen masks with a small valve made from PC and PP. After granulation and ScCO2 extraction, the recycled fraction was extruded and the extrudate clearly displayed small lumps of PC.
Two designs with and without check valve is illustrated below. Both designs also come with a hook ring in clear polycarbonate that was manually removed before recycling.

AMBU UltraSeal mask with check valve in PC/PP and hook ring

AMBU UltraSeal mask without check valve and with hook ring

The mixed PVC waste collected in this first scheme contained hoses, nasal cannulas, laryngeal masks and face masks from various suppliers. Valves and connectors and even part of the mask contained other polymers than PVC and had manually to be disassembled.
Taking these challenges into account, a second scheme was established. In the scheme, only face mask was collected and the masks were collected at a few departments all at Rigshospitalet, Glostrup: Department of Gynecology; Center for Rheumatology and Spine Diseases;

Department of Ophthalmology; Department of Anesthesiology, Pain and Respiratory Support. The scheme was organized by nurse specialist Mette Skriver Revsbech at Rigshospitalet Glostrup.
The collection and recycling scheme is presented graphically in Figure 2, Figure 3, and by a Mette Skriver Revsbech's presentation at the Stakeholder's workshop found in Appendix 4.

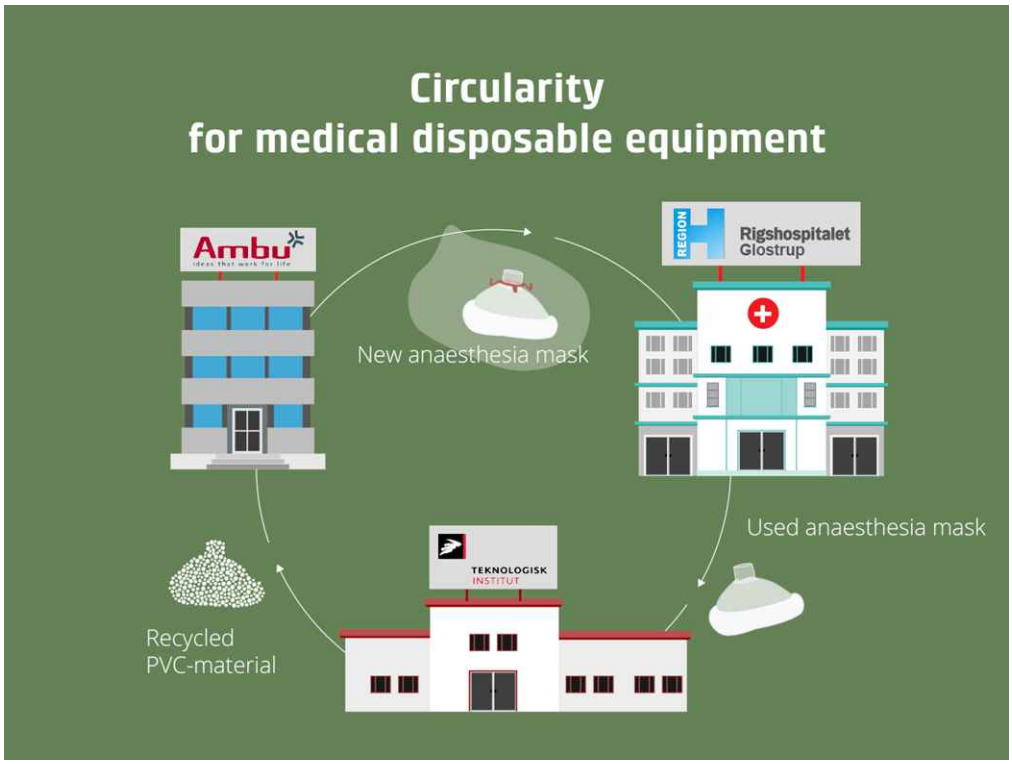


Figure 2. Demonstration of circularity of single use medical equipment. A single type of anesthesia mask was delivered by partner AMBU A/S to the four departments at Rigshospitalet Glostrup for a period of six weeks. After use by non-infectious patients, the masks were recycled at DTI. The loop was not closed however as the material was not used for new production of masks.

At the hospital, masks were collected in plastic bags marked with the department and week where masks were used. The hospital staff removed the hooking ring and disposed it otherwise. The bags were tightly strapped and transported to DTI. No special precautions were taken during transport. The masked collected would typically be discarded as residual waste from hospitals. Masks judged to be clinical hazardous waste did not commonly appear on the chosen sections of the hospital. Normal procedures (Danish Environmental Agency, 1998) for disposing clinical waste are anyway followed at the hospitals and no visually contaminated masks were found among the collected masks during the six weeks period.

After arrival at DTI, each bag was quarantined for 14 days in a locked and duly marked container. This secured that the contagion detection contingency in place at all hospitals could alert DTI if it later was discovered that a patient was infected with a contagious disease during the use of the anesthesia mask. It is the hospital sector's experience that such cases are always discovered within 14 days. At the departments partitioning in the collection scheme, such cases only occur once or twice a year. No cases occurred during the collection period.

DTI personnel was wearing proper protection equipment during handling of the masks until after super critical CO2 treatment. The operations during recycling are graphically illustrated in Figure 3. Details of the super critical CO2 extraction is found in section 5. Super critical treatment has been shown to be an excellent sterilization technique. Over the last decades

hundreds of microorganisms have been treated with super critical CO2 to assess the sterilization efficacy, with good results (log reduction between 4 and 8) for most species, only some bacterial spores have proven difficult to combat (Soares et al, Perrut et al). Most of the research has focused on very mild sterilization conditions targeting implants and other heat susceptible medical applications, thus the conditions here used for extraction of plasticizer from plasticized PVC is much harsher, with higher temperatures and pressure and longer exposure times. This leads us to conclude that the process developed here is very likely to be a great sterilization technique for this application. Particularly because the material comes from a very controlled environment, therefore only a limited number of species of microorganism can be expected. We seek to investigate this further in the future.

Figure 3. Steps taken during the recycling of collected of anesthesia masks. Closely strapped plastic bags were quarantined in a locked container for 14 days before shredding. After shredding, granules were stored in a closed and marked drum before super critical extraction of the plasticizer. The ScCO2 treated PVC is unplasticized (PVC-U) and sterilized.

4.5 How risk of infection is managed in the Australian and UK collection systems

Based on a note by Ole Grøndahl Hansen, PVC informationsrådet, 26.08.19

In neither the Australian nor the British sorting and collection system, detailed descriptions have been prepared of how a possible risk of infection is handled. This is since there are already some general guidelines for how to handle any risk from infectious medical devices. Basically, it is the perception of professional actors working with sorting and recycling in the hospitals that there is nothing particularly risky about starting to sort and recycle medical equipment. The PVC Information Council has gained the same understanding in connection with information meetings at the Royal Infirmary Hospital of Edinburgh in Scotland and Bergen University Hospital in Norway. At both hospitals, we were informed that the hospitals have procedures for clinical hazardous waste, which means that sorting out infected medical equipment will not take place. At Bergen University Hospital, it was also stated that only about 3 % of the waste generated by the hospitals consists of risky and infectious waste. This type of waste is controlled and is safely handled as clinical hazardous waste. Due to the significant difference in the costs involved in disposing of hazardous waste and non-hazardous waste, hospitals have in recent years thoroughly examined whether all waste treated as hazardous waste constitutes a risk. This has reduced the amount of hazardous waste.

4.5.1 The Australian system: PVC Recycling in Hospitals

In the Australian system, some simple guidelines have been developed for what type of medical equipment is suitable to be sorted for recycling and what type of equipment should not be sorted for recycling. In Australia, hospital waste fractions are divided using three popular terms: the good, the bad and the ugly fraction.

THE GOOD FRACTION. The good fraction consists of medical equipment, which is designated to be collected, and which is clearly depicted on posters and on the recycling waste bins in which the waste is to be disposed. Only specific products made of PVC are recycled: IV bags used in intravenous treatment, where either medicine or nourishing fluid is given intravenously; disposable oxygen masks made of transparent odorless PVC with a soft and pliable edge which provides a comfortable fit around the nose, cheeks, and chin. These masks have an aluminum clip over the nose piece which prevents oxygen leakage, and the mask is held in place with an adjustable elastic band. The elastic band and the nose clip must be removed before the product is thrown into the recycling bin. The hoses that attach to the oxygen mask and the IV bags, respectively, may also be disposed in the recycling container. Only these three waste fractions (bags, masks, and hoses) - all made of transparent PVC - are sent for recycling. If for any reason the nurse does not have time to remove the nose clip or elastic band, the nurse is encouraged to dispose of the entire product in the residual waste bin.

THE BAD. Do not dispose hard or colored plastics, metals, rubber, bottles, or cups in the recycling bin. If these fractions are mixed into the transparent PVC fraction, the recycling process cannot be carried out.

THE UGLY. Hose with blood, blood bags, syringes, sharp objects, and patient ID labels must under no circumstances be thrown in the recycling bin. Here, the strict guidelines for clinical hazardous waste must be followed. If an object from the ugly waste fraction ends up in the recycling container, the entire container must be disposed of as clinical hazardous waste. The motto of the Australian system is: If in doubt, throw it out.

4.5.2 The British system: RecoMed

As the UK system for collecting PVC-based medical devices is directly inspired by the Australian system, it is not surprising that there are many similarities between the two systems. This also applies to the way in which they view a possible risk. According to RecoMed, there is no risk associated with the introduction of the system. The equipment collected at UK hospitals comes from a clean environment and from patients who have undergone a thorough assessment that has already been able to identify any potential risk of infection. The products

collected are classified as low-risk waste. In addition, staff undergo thorough training to ensure that the system works as intended. In the UK, the Environmental Agency has approved the system as a low-risk waste activity, and the recycling companies and carriers associated with the project have all relevant licenses and approvals.

4.6 Collection details

Over six weeks, DTI picked up bags with disposed anesthesia masks three times for a total of 522 masks. All masks were visually examined. In total, 1 % of the masks was discarded due to errors. 5 masks were of a different brand, and other mask had paper labels attached, which were removed. Also, one mask still had the hooking ring attached, which was removed.
We estimate that the missorted masks will constitute a pollution by weight of less than 1 percent. In total 23 kg of granulate was produced and 17.5 kg was treated in the super critical reactor.
If the waste fraction is mixed with medical devices of unknown origin, e.g., the 5 face masks of another brand found during the collection, it will lead to a contamination of the residual plasticizer after extraction that will influence its usefulness in a circular loop.
Assuming that the limit of contamination must be below 0.1 % of unknown plasticizer – e.g., DEHP and that all other properties are unchanged - at most 1.6 % contamination of the input fraction can be allowed. Hence the collection scheme set up at Rigshospitalet, Glostrup was efficient in keeping contamination of residual plasticizer concentration below 0.1 %.
The importance is not only related to the products that the recyclate can be used for but also to the fact that the recyclate can be sold and transported as a raw material keeping contamination levels of substances of very high concern (SVHC) below the general ECHA limit of 0.1 %.

4.7 Final extrusion

10 kg of recycled PVC with the plasticizer extracted were shipped to Gibo Plast in December 2019 for extrusion. It was decided to add the recyclate in the end of a production slot for flexible tubing made from plasticized PVC. Approximately 8 kg were extruded. The extrusion conditions used for plasticized PVC was not changed and it had an impact on the result: The hoses got a yellowish coloration. The extrusion was performed at a single screw extruder as typical for plasticized PVC production. Also, the hoses became “frosty” – see Appendix 5.4. The discoloration may be a result of poor processing conditions, both temperature and residence time in each zone and the die temperature, but equally important are two observations: clear grains with a different index of refraction than the bulk of the tubing is observed throughout the tubing; ICP/MS analysis showed a strong reduction in the process stabilizer upon ScCO2 extraction. As described in Appendix 5.4, we believe that the grains stem from the softer cuff which is more heavily plasticized. After extrusion, the plasticizer content in the grains is twice that of the harder fragments. To produce a homogenous material out of the recyclate with two differently plasticized components higher shear mixing is needed. This can be obtained with a twin-screw extruder with screw and barrel design and temperatures optimized for extrusion of PVC-U. Also, additional process stabilizer most be introduced to avoid discoloration. The final extrusion was designed to gain knowledge on the processing properties of the recyclate and not to demonstrate a circular loop.

Figure 4. Tubings produced by Gibo Plast A/S from the recycled PVC.

5. Super critical carbon dioxide extraction of plasticizer

A range of experiments to establish the optimal process extraction of plasticizers from plasticized PVC with super critical carbon dioxide ($scCO_2$) was performed at the Danish Technological Institute (DTI). The super critical region (see Figure 5) is reached when heating a compound under pressure. Super critical fluids have physical properties that lies between a gas and a liquid. This gives a range of advantages such as superior diffusivity compared to traditional solvents and complete evaporation after extraction leaving no solvent residues behind. Furthermore, the solvent characteristics can be tuned by changing the temperature and the pressure during extraction to optimize the solubility of the product.

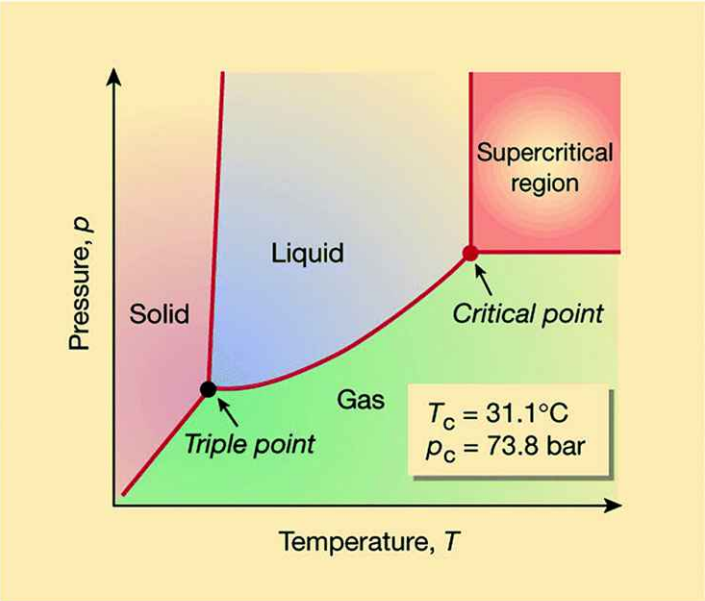


Figure 5. Phase diagram of CO2 – showing all four phases incl. the super critical. For CO2 the critical point is relatively easy to reach at 31,1 C and 73.8 bar.

The project focus was on medical equipment due to the superior value and traceability of the raw materials used. Together with the other project partners, we decided to use a disposable anaesthesia face mask from Ambu A/S as the test product. This mask consists of mainly two kinds of plasticized PVC, a harder part with approx. 20 wt% plasticizer and a softer part (the cuff) containing approx. 50 wt% plasticizer. Throughout the project we treated three different face masks, see Figure 6 and Table 6.

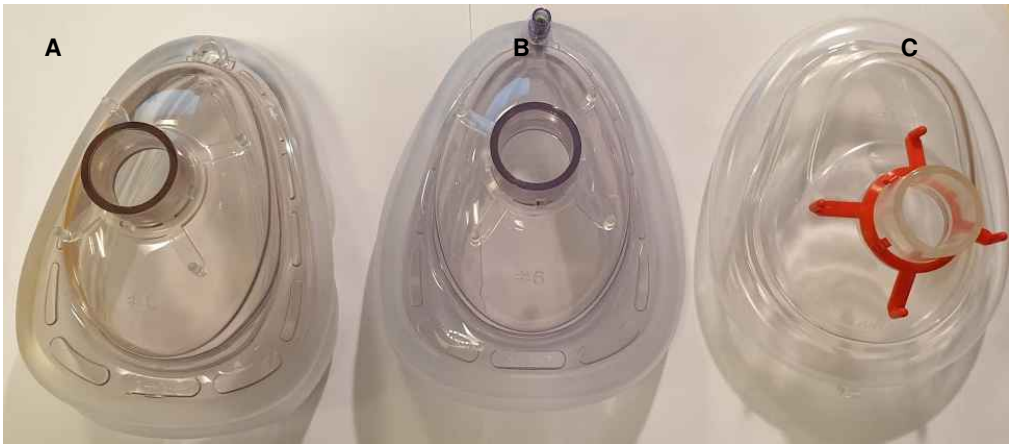


Figure 6. The three masks used in the project. Mask A decommissioned and phthalate containing, B phthalate free but containing a polycarbonate valve and C, a phthalate free mask made solely from PVC and used for collection trial and final recyclate production.

The initial extraction tests were done with mask A. The use of diethylhexyl phthalate (DEHP) as plasticizer in this mask allowed us to test whether we could decrease the phthalate content below the threshold of 0.1 wt% for restricted commerce defined in the REACH regulative. We optimized our process using this mask. Mask B was introduced to allow us to produce a quantity of recyclate to WP4 in our newly upscaled 5 L reactor. Mask B and C use the newly developed formulation with non-phthalate plasticizer instead of DEHP. The polycarbonate valve did however introduce impurities in the recyclate forcing us to change mask model. This coincided with the start-up of our collection trial at Glostrup Hospital where they used mask C already. The mono material design of mask C only contains plasticized PVC and is thus the perfect candidate for our purpose of making usable recyclate directly from used medical equipment, thus we used this to produce the recyclate for WP4. Both mask A and B was clean unused masks supplied by AMBU A/S for laboratory testing, whereas mask C was supplied to the Hospital and used during their daily routines before it was collected and treated at DTI.

Table 6 Mask overview

Mask moniker	AMBU A/S face mask product no.	Plasticizer	Valve	Comments
A	305014000	DEHP	No	Decommissioned model
B	305015000	Non-phthalate	Yes	Valve made of polycarbonate/polypropylene
C	000252056	Non-phthalate	No	Used in collection trial

The super critical extraction process changed the look and feel of the plasticized PVC from hazy blue and soft to white and hard. This change coincided with a slight swelling of the

granules due to the creation of voids from the washed-out plasticizer and swelling with CO2 during depressurization. This can be clearly seen in the figure below.

Figure 7. Plasticized PVC shredded before and after extraction. Before extraction the shredded masks are soft with a hazy bluish tint. After extraction they are opaque white and hard.

5.1 Results summary

For Mask A and B, we concluded that we could remove 76 % of the plasticizer in the masks by reducing the average content from 41 % to 10 %. We measured the plasticizer content by Gas chromatography. The masks were almost identical except A had DEHP and B had a non-phthalate as plasticizer. The plasticizer reduction was not established for Mask B, but since plasticizer and weight reduction is very similar to mask A – see Appendix 5 - we estimate they are similar. We saw similar results for Mask C with approximately 80 % reduction of plasticizer content, calculated by peak fitting of IR spectra, see Appendix 5 and Table 7. For mask C, we also conducted GC/MS analysis indicating that the content of Zink and Calcium stabilizers was reduced by 75 %.

Table 7. Plasticizer content after extraction

Average plasticizer content	Before extraction	Reduction
Mask A	41.2 wt%	76,2 %
Mask B	~ 40 wt%	similar
Mask C	~33 wt%	>80 %

The mechanical properties of the extruded material from Mask C were measured after ISO 527 giving 30 times increase of the elastic modulus and doubling of the tensile strength. We are still somewhat under the mechanical properties of hard PVC (modulus: 2000 MPa), but the material is clearly a much better starting point for recycling and for mixing with virgin PVC creating new high value products – refer to Table 8.

Table 8. Mechanical properties of recyclate

The mechanical properties of Mask C granules	Before	After
Elastic modulus	15 MPa	450 MPa
Tensile strength	10 MPa	20 Mpa

6. Conclusions

Use of recycled PVC from medical devices is regulated by REACH. Concentration of phthalates listed on the authorization list as substances of very high concern is now required not to exceed 0.1 %, if e.g., recyclate are to be marketed as a raw material. The out phasing of such phthalates in medical devices means that a viable recycling scheme can be established if:

- Plasticizer content in the recycled PVC is lowered during the recycling process.
- A scheme is established that documents the origin of the waste as phthalate-free PVC and that guaranties that contamination with devices of unknown origin is kept under a certain level.

The project aimed to demonstrate that it is technically feasible to recycle medical devices in plasticized PVC to a high-quality PVC with zero or low amounts of additives and that an efficient sorting and collection of such devices are possible.
Assuming that the limit of contamination must be below 0.1 % of unknown plasticizer – e.g., DEHP and that all other properties are unchanged - at most 1.6 % contamination of the input fraction can be allowed. Hence, the collection scheme set up at Rigshospitalet, Glostrup in combination with ScCO2-extraction of plasticizer was efficient in keeping contamination with residual – or unknown - plasticizer concentrations below 0.1 %.
The importance is not only related to the products that the recyclate can be used for but also to the fact that the recyclate can be sold and transported as a raw material keeping contamination levels of substances of very high concern (SVHC) below the general ECHA limit of 0.1 %.

6.1 Major results

Knowledge on the value chain and safe handling of used medical equipment was gained and communicated to stakes holders at a workshop.

A first draft for a guide for designing medical devices apt for recycling was developed by AMBU. During the project, the partner AMBU also focused their sustainability efforts (AMBU, 2021) and today follows detailed sustainability guidelines.

Hospital staff is extremely enthusiastic about the perspective of recycling the lot of disposable equipment they use. The pilot collection described below was organized and managed by a nurse specialist truly committed to making a difference to her and her colleagues sustainability footprint.

A pilot collection was established at four departments at Rigshospitalet, Glostrup. A single brand of disposable anesthesia mask was supplied by AMBU A/S to the involved departments over a period of 6 weeks. The mask was made from phthalate-free plasticized PVC solely. Nurses and other staff sorted mask from non-infectious patients and bags with masks was picked up by DTI.

The collection demonstrated that source separation of medical equipment can be implemented locally at hospitals with a very low failure rate – below 1 % missorted masks.
The super critical extraction of plasticizers was established and demonstrated at DTI pilot equipment. Scaling of the costs for a plant handling waste on a national level shows that costs can be reduced well below the price of virgin material.

More than 5 x reduction of plasticizer content was demonstrated.

The tensile mechanical properties of the plasticized PVC were increased by a factor of 30 to 25 % of the strength of hard PVC, thus enabling a wide range of new use cases. These could be by addition of new plasticizers or mixed with virgin PVC to match the new product specifications.

The masks collected at Rigshospitalet, Glostrup were placed in quarantine for 14 days at DTI before shredding and super critical CO2 extraction (ScCO2). After CO2 extraction, the recyclate is considered sterile. Based on experienced gained in the project, literature studies and experiences abroad, the process developed here is very likely to be a great sterilization technique for this application. Particularly because the material comes from a very controlled environment, therefore only a limited number of species of microorganism can be expected.

The collection scheme and recycling process meet the requirements for a viable recycling as described above.

6.2 Challenges

The project successfully demonstrated the technical feasibility of collecting disposable medical equipment in PVC and recycle it by a super critical CO2 extraction process. It did not show how a scheme could be implemented on a national level or how a full circular loop could be established. Many environmental, social, and economical challenges remain, among those:

Source separation of waste is most efficient in obtaining low failure rates if awareness among staff is maintained. However, the Danish Regions would much prefer a central sorting of waste to keep the number of waste fractions at both hospital department and in the hospitals local waste handling facilities low. To meet the requirements above, a central sorting facility must hence be able to sort medical devices using product recognition or other digital tracking.

The MDR regulation for medical devices does not exclude use of recycled material but impose demands so strict on the raw materials that a full circular model cannot be established until a security for supply of high-quality recycled material is established.

The economical options for other uses of a high-quality recyclate was not clarified in the project and all uses will of course also be exposed to market fluctuations and supply security of medical device waste.

The scaling of the ScCO2 extraction is technically and economically well understood but no waste handling using ScCO2 is yet established internationally.

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Appendix 1. Mapping the PVC based medical device from resource to recyclate

Appendix 1.1 Content

Ole Grøndahl Hansen & Tobias Johnsen, PVC Information Council DK, 2017.

2. Introduction: medical devices in plastics pvc – a revolution in healthcare
3. Value chain – from raw material to pvc device
4. Waste management
5. Plasticisers
6. Case studies of recycling schemes

- Example Australia
- Example UK

Appendix 1.2 Introduction

Plastics based medical devices were originally introduced as replacements for natural rubber, glass and metal. Medical devices made of these traditional materials required cleaning and re-sterilization before re-use. The safety, high performance, low cost and versatility of plastics made it possible to manufacture single-use medical devices.

Affordable plastics-based medical devices thus improved medical safety dramatically by reducing the risk of life-threatening healthcare-acquired infections caused by traditional multiple use medical devices. In the early 1960s, this resulted in a revolution within the healthcare sector.

Medical devices made in plastics are manufactured in different polymers. When it comes to disposable medical devices the most used polymer is PVC. Disposable medical devices are devices which are thrown away when they have been used only once. It is estimated that around 30% of disposable medical devices are manufactured in PVC, which makes PVC the single most used plastics in the health care sector.

The main reason for the dominance of PVC is the resin's low cost, ease of processing and the ability to tailor its properties to a wide range of applications. PVC is compatible with different kinds of additives that makes it a versatile polymer and thus suitable to be used in manufacturing of medical devices. PVC is mostly used in manufacturing of Class I medical devices. Class I medical devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III medical devices. However, PVC is also used in the manufacture of Class II and Class III medical devices.

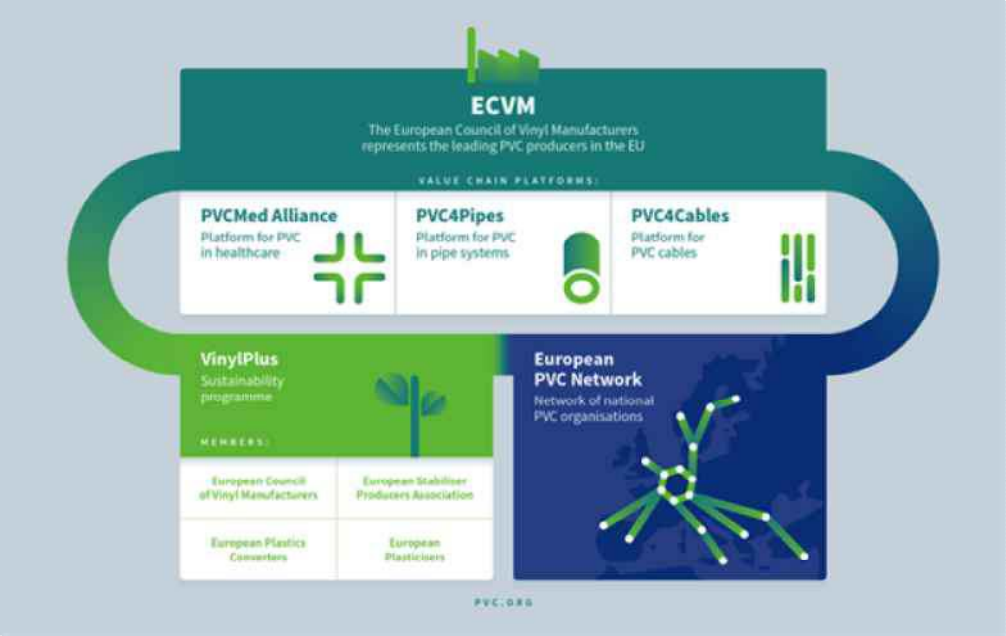
The two main medical application areas for PVC are flexible containers and flexible tubing. Flexible containers include blood bags, which are crucial in today's healthcare. Plasticized PVC is considered the material of choice for these kinds of devices. It is light and almost impossible to tear, making it ideal for quick and effective emergency treatment of accident victims.

Typical requirements for PVC medical tubing include clarity, flexibility, kink and scratch resistance, toughness, ease of bonding with common solvents or adhesives, and suitability for different types of sterilisation.
Other important healthcare applications manufactured in PVC are surgical and examination gloves, as well as oxygen masks. Also, within medical packaging area PVC is widely used, for example in blister packaging.

Appendix 1.3 Value chain – from raw material to PVC device

The value chain of a PVC medical device is best explained by using medical tubing as an example. Medical tubing might at first hand be considered as a mundane object, but in fact the quality of the device and the value chain from the making of the raw material to the use of the device in the hospital is quite sophisticated.
PVC medical tubing is a result of extensive research and development within the chemical and plastics industry. It has been challenging to develop tubing which is flexible, resistant to kinking and scratches, tough, easy to bond, biocompatible and capable of being sterilised – and not least cost effective.

The PVC resin producer
The first step in the value chain of a PVC medical device is the raw material production of the PVC resin. We have no PVC raw material production in Denmark. In Scandinavia PVC production takes place in Norway and in Sweden. In Europe around 5 million tons of PVC are produced every year. Only a small fraction of the PVC is used for the manufacture of medical devices. Around one percent goes to medical applications. Compared to other types of polymers PVC is unique because 57 percent of the resin is produced from salt. The remaining part is oil. Other polymers require much more fossil feedstock.



Figur 1. The European resin producers are organised in ECVM, the European Council of Vinyl Manufacturers

The plasticiser and the stabiliser producer
It is not possible to produce any applications on the basis of the PVC resin alone. Additives are needed. A wide range of additive producers within the chemical industry manufacture additives for PVC compounds. The most important additives in PVC based medical devices are plasticisers and stabilisers.

Figur 2. The plasticiser producers in Europe are organised in European Plasticisers.

Figur 3. The stabiliser producers in Europe are organised in European Stabiliser Producers Association (ESPA).

The compounder

The compounder buys additives from the different additive producers and is specialised in compounding PVC resin with the needed additives. Within the medical device sector some additive producers have specialised in producing medical approved PVC compound.

The converters

There are around 30.000 plastics c
onverters in Europe. Only a fraction of these companies are so called subcontractors for the medical device industry. A medical plastics converter buys PVC compounds from the PVC compounder and transforms the compound into semi-finished products like medical tubing, medical film, medical containers etc. This is done by using different processing technologies like extrusion and injection molding. The products are sold to the medical device companies.

Figur 4. The European plastics compounders and converters are organised in European Plastics Converters (EuPC)

The medical device company

The medical device company buys semi-finished products from converters and carry out the assembly, the packaging and the sterilisation of the final medical device.

Figur 5. The European medical device companies are organised in MedTechEurope

The distributor

Most medical devices are sold directly from the medical device company to the hospitals. The reason for this is that there is often an educational/training component to the sales which is taking care of by the medical device company. However some medical device companies sell their devices to distributors, in particular manufactures of commodity types of devices. The distributor takes care of the distribution of the final product. The distributor is most often supplied with medical devices from several medical device companies.

The hospital

End-users of medical devices are mainly hospitals (public/private) and other healthcare facilities but can also be individual patients in home treatment.

Appendix 1.4 Waste management

Today the most common waste management option for medical devices is incineration. The environmental consequences related to the incineration of PVC based medical devices have been undergoing scientific scrutiny for many years.
As mentioned earlier, PVC is made partly of salt and partly of oil. In the chemical production of PVC, the salt is converted into chlorine. When the PVC products become waste and the waste management option is incineration, the chlorine content presents some challenges. Typically two environmental issues are related to the discussion of the incineration of PVC waste, namely dioxin formation and the formation of residues, which must be disposed of as hazardous waste.

Whereas the dioxin issue related to incineration of PVC has been largely eliminated due to better waste incineration technologies, the neutralisation residue issue still remains for some incineration plants. In a recent report published by the Danish EPA, *Recycling of rigid PVC in Denmark* (Miljøprojekt nr. 1717, 2015, Danish EPA), the current state of PVC waste incineration is summarised. In regard to dioxin emissions associated with incineration of waste there has been a very positive development. In the report it is stated that "dioxin emissions from waste incineration are greatly reduced … It is estimated that the emissions in 2006 were less than 2% of what it was in 1999 without any significant changes in the amount of waste being incinerated" (page 54).

When it comes to the relationship between PVC waste and the formation of neutralisation residues, the reports quotes a report which states that PVC waste should be kept away from incineration plants as much as possible. "PVC waste generates HCl when incinerated. In incineration plants with dry and semi-dry flue gas cleaning systems, HCl is neutralised with lime. Diverting PVC waste from incineration reduces the amount of neutralisation residues, which must be disposed of as hazardous waste" (page 54). In incineration plants with wet flue gas cleaning systems, neutralisation residues are less of an issue.

It should be mentioned that it is only the chlorine content of the PVC based medical devices which can have negative consequences in the incineration process. The plasticiser used does not cause any issues when incinerated.

Appendix 1.5 Plasticisers

Many types of plasticisers are used to produce flexible PVC medical devices. These plasticisers are added to the PVC compound in amounts ranging from 40 to 65%. Increasing the amount of plasticiser will improve the flexibility and reduce the hardness of the material. Phthalates are the most common plasticiser in all flexible PVC products, with di(2-ethylhexyl) (DEHP) being the most common phthalate when it comes to PVC medical devices. This is due to its properties, cost-effectiveness and ease of manufacture.

For several decades DEHP has raised concerns among scientists because the chemical might have adverse effects on human health. It is well established in academia that the plasticiser leaches into the body from tubing, blood bags and other medical devices, and a number of animal studies show that DEHP can potentially cause cancers and harm reproduction, liver and kidneys. At the heart of the matter is whether DEHP puts the most vulnerable patients at risk: new-born babies, also known as neonates. Because of their low body weight, scientists worry that the same adverse effects seen in animals might be present for neonates, and those born premature in particular. In other words, there are worries that the same medical devices that save lives might be harmful in the long run.

Classification and regulations
The concerns related to the use of DEHP as a plasticiser in medical devices have lately resulted in EU classifications followed up by regulation initiatives within the medical device area.

1. In the EU, DEHP is classified as toxic to reproduction under Category 1B. A classification 1B means that the substance is a *presumed* human reproductive toxicant based largely on animal evidence. In contrast to substances classified in Category 1A which means that the substance is a *known* human reproductive toxicant based largely on human evidence.

2. Substances that may have serious and often irreversible effects on human health and the environment can be identified as Substances of Very High Concern (SVHCs). The ECHA Member State Committee has agreed that DEHP is a Substance of Very High Concern (SVHC) because it is an endocrine disruptor (EDC) for the environment. If a substance is identified as an SVHC it will be added to the Candidate List for eventual inclusion in the Authorisation List under the REACH regulation.

3. The International Agency for Research on Cancer (IARC) has indicated that there is sufficient evidence for the carcinogenicity of DEHP. Thus, DEHP has been classified by IARC as *possibly* carcinogenic to humans in Group 2B. In contrast to substances in Group 1 which *are* carcinogenic to humans and Group 2A which are substances that *probably* are carcinogenic to humans.

Regulatory issues related to the presence of DEHP in medical devices

According to the new Medical Device Regulation adopted by the EU, medical devices shall not contain CMR-substances, or endocrine disruptive chemicals (EDCs) in a concentration above 0.1%. If they do, presence of the substances must be justified by manufacturers. This justification for their presence will be essential. The justification for the presence of such substances shall be based upon:

1. An analysis and estimation of potential patient or user exposure to the substance.

2. An analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer reviewed studies, scientific opinions from relevant Scientific Committees and an analysis of the availability of such alternatives.

3. Argumentation why possible substance and/or material substitutes or design changes, if available, are inappropriate to maintain the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials.

Alternatives to DEHP in medical devices now in the European Pharmacopoeia

During the last decade the plasticiser industry has succeeded in developing several alternatives to DEHP. One of the main reasons why medical device companies have been restraining in using them is that that none of them have been listed in the European Pharmacopoeia. The Pharmacopoeia has the duty to list substances that can be used for manufacturing containers and tubing sets for the transfusion of blood and blood containers.

Based on the development in the classification of DEHP as a substance of very high concern, European Directorate for the Quality of Medicines (EDQM) now believes that there is a strong need to promote alternative materials that could replace DEHP in medical devices. Consequently EDQM has in 2017 announced that four alternatives to DEHP will now be listed with all their properties as suitable alternatives to DEHP in the revised European Pharmacopeia. It is therefore expected that after the consultation process has ended – properly in 2018 – four new plasticisers will officially be taken up into the pharmacopoeia in order to help the medical device companies to choose alternatives to DEHP. As the European Pharmacopoeia does not accept brand names the substances are listed with its chemical name:

- cyclohexane1,2-dicarboxylic acid, diisononylester – plastic additive 24
- butyryltri-n-hexylcitrate - plastic additive 25

- tris(2-ethylhexyl) trimellitate – plastic additive 26
- bis(2-ethylhexyl) terephthalate - plastic additive 27

The four alternatives to DEHP now expected to be included in the European Pharmacopoeia are also substances mentioned as alternatives to DEHP in a 2014 report published by the Danish Environmental Protection Agency and the Danish Health Authorities that evaluates alternatives to classified phthalates in medical devices (*Alternatives to classified phthalates in medical devices,* Environmental Project No. 1557, 2014, Danish EPA).

Appendix 1.6 Case studies of recycling schemes

Example Australia

In 2009, a working group of hospital staff, Vinyl Council Australia and a recycler started a pilot trial at Western Health's Footscray Hospital. The aim was to see which PVC medical devices were feasible to be separated and whether the products could be safely and practically recycled. The trials took nearly two years. The programme was officially launched in 2011, followed by an education & training toolkit in 2013. Medical device company Baxter joined the programme in 2013. Currently about 120 hospitals in Australia and New Zealand are part of the programme.

Devices & quantities

Recycled devices are IV/saline fluid bags, dialysis bags, oxygen masks and oxygen tubing. A standard 240 litre recycling bin will hold around 40 kilograms of PVC – equivalent to about 1000 IV bags. A typical Australian hospital of 300 beds can recycle 2.5 tons of PVC each year. Currently 16 tons/month are collected from about 80 hospitals and healthcare facilities in the state of Victoria alone.

Outlets for recyclate

The recyclate is considered good quality, flexible PVC partly because it has no colour pigments. This means it can be used for a wider range of applications. Vinyl Council of Australia's member companies would like more of the recyclate. The main Australian reprocessor seeks to avoid all contamination by foreign materials, and has implemented separation systems to remove them. They sell the recyclate to industrial and garden hose manufacturers. The New Zealand reprocessor uses the recyclate themselves in combination with other material to make playground safety-fall matting.

Though DEHP is not subject to the same regulatory restrictions as in Europe, the presence of DEHP is an issue. Ideally the recyclate could be used for new vinyl flooring designed to go back into the healthcare sector but the local flooring manufacturer has a global policy which restricts them from using DEHP in products, also in recyclate.

Training

Initially Vinyl Council of Australia, and now Baxter, provide on-site "in service" training through their sales team to nursing teams. The Nursing and Midwifery Federation now includes PVC recycling in their professional training and some universities have started doing the same. Hospital staff are responsible for ongoing training, inductions and maintaining the system. Initiation of the programme in a hospital is almost always by staff. The program is voluntary however, so training includes messaging that if a staff member is not interested/does not have time, they should throw the waste in the general bin not the PVC bin. Training videos, stickers, posters etc. show staff how to sort and treat the PVC products so that there is minimal contamination – it does take extra time but as one nurse says, it becomes second nature to do it. It is important to recognise it is a behavioural change program.

Contamination risks

Australian healthcare has stringent and effective training to divert clinical (infected) waste from general landfill waste. While occasionally sharps such as scissors have been found, clinical waste contamination is infrequent.

The reprocessers try to avoid any manual handling of the waste and use wash and granulation to separate any non-PVC. The reprocessing temperature of the material will effectively

'sterilise' it so the risk of infection is considered extremely low, no higher than for kerbside collected recyclables such as milk bottles.
As waste is unloaded onto the conveyor, visual inspections occur to identify any clinical waste or contamination. Any occurrence is reported back to the hospitals. Waste is returned to hospitals, particularly any clinical waste as it must be sent for separate treatment at the hospital's expense.
Appropriate OHS standards and handling are followed by hospital staff, collectors and reprocessors. Baxter have followed up contaminated collections to urge change and deliver training in hospitals to improve their separation, systems, checks etc. Vinyl Council of Australia has provided a newsletter on how to recycle safely, and reiterate the point all the time.
There are no regulations restricting the collection of PVC medical waste (other than clinical waste regulations applying to infectious waste). The products collected are considered "general waste". The contracted waste collectors are already trained and registered to collect other hospital collections. The reprocessor handles other PVC materials.

Practical barriers
Contamination is an issue that requires constant vigilance. Hospitals benefit from having a "champion" who regularly checks bins visually for contaminants and addresses any issues with staff. Ideally, hospital Environmental Service Staff/Waste depot should check and remove contaminated waste, rather than hand the problem on to the collectors and reprocessor. Contracted waste collectors check bins visually and take photos of contaminated bins, reporting it back to the hospital for action. Contracted waste collectors can trace collections through bin/pallet box labelling identifying the hospital and date of collection etc.
Space is also an issue as hospitals were not designed to do at-source separated recycling. Each hospital department has to determine bin sizes and placements that works for them. Some have small caddies in the theatre/work areas and empty these into larger PVC bins in sluice rooms. Some larger hospitals have pallet boxes in the waste depot and the PVC contents of 240 litre wheelie bins are unloaded into these bigger boxes for collection by the contracted waste collector.
It is important that bins should not be located in public corridors as it leads to high contamination rates.

Finances
Vinyl Council of Australia pays for staff time for administration, management and shares promotion costs with Baxter. Baxter underwrites the cost of collections; its sales teams provide training and promote the program; and the company contributes to promotion costs. Baxter essentially "takes back" the material (incl. tubing and masks) after hospital use, and sells it to the reprocessor under a commercial arrangement. The reprocessor sells the reprocessed material to the market.
Hospitals pay a collection fee of up to $10/bin which is no more than they would be paying for general waste bin collection, however there is no landfill levy to be paid on the PVC recycled.

The programme is priced to be cost neutral or slightly positive for hospitals.

Design for recycling
There are several ways to make recycling of PVC medical devices easier. Facemasks could be re-designed to be single polymer (PVC) with easily removable non-PVC nose clip. Recyclable items could be marked with PVC identification symbol (no. 3), which Baxter Australia already has done with their IV bags. The same applies to the packaging of PVC products: the PVC symbol indicative could be put on the product inside as well as a plastics/material identification code related to the packaging material (Baxter has done this with its boxes). DEHP-containing products are (or should be) already labelled as "PHT" containing. A lot of PVC medical tubing cannot be collected (e.g. giving sets, suction tubing) because of connectors made from other polymers too hard to remove and/or infection risk.

Example UK

In 2014 the RecoMed medical PVC recycling scheme was set up in the UK. The programme is financed by the European PVC industry's sustainable development programme VinylPlus and run by Axion Consunlting and the British Plastics Federation. Initially, contact was established with hospitals that already had recycled schemes for other products. Today around 10 hospitals are part of the RecoMed scheme.

Devices and quantities

Currently PVC oxygen masks, tubing, anesthetic mask, IV & irrigation bags are collected. So far 3570 kg have been collected, which is equivalent to 119,100 oxygen masks.

Outlets for recyclate

The oxygen masks are turned into tree ties in one process from waste to product. Without the presence of DEHP the recyclate could be used for a wide range of products, for instance garden hoses.

Training

RecoMed works with each hospital to confirm that they are a suitable site to run the scheme. RecoMed provide the hospitals with training and support to ensure the trials run smoothly. Training either takes the form of small group discussions or a teaching presentation. RecoMed also revisits hospitals to provide refresher training. Clearly labeled bins and posters are used to highlight the project.

During hospital training sessions, RecoMed has received positive feedback from hospital staff when they are asked to segregate waste. Staff understand that RecoMed has environmental and economic benefits, and that they make a positive difference. Also, the extra time spent segregating the waste is minimal and causes minimal/no disruption.

Contamination risks

RecoMed has EA (Environment Agency - England's equivalent to EPA) approval for the project as a low risk waste activity, and the recycler and transporters all hold the relevant licenses & exemptions.

RecoMed provides thorough staff training to hospitals to reduce the risk of the bins being used incorrectly.

Clinical staff members recognise that the material collected is clean. The PVC equipment is used in a clean environment and comes from patients who have been through a thorough pre-assessment process, which would identify any potential infection risk.

Practical barriers

RecoMed has visisted a number of hospitals which would like to run the scheme, but are unable to. Reasons include;

1. Hospital is too small and cannot accommodate another waste stream. For example, there is no space on the corridor waste rooms to store RecoMed waste sacks.
2. Some hospitals have infection control concerns which prevents them joining.
3. Some others will not 'double handle' waste sacks. This means RecoMed could only be implemented if we provided a fleet of 770L wheelie bins, which is not feasible.

Some hospital are concerned that if they take part in RecoMed they will be in breach with their waste contract. Several hospitals have contracts with their waste management companies that guarantee them all the waste and does not allow them to work with third parties.

Finances

For the scheme to operate in the short term there needs to be external funding/sponsoring. At the moment the material is not collected in high enough volumes to be self-sufficient. This could change once volumes increase.

The amount saved by hospitals depends on the quantity of PVC collecting via RecoMed, as well as the amount the hospital is currently paying for the treatment of their clinical/offensive waste. Average figures show that hospitals are saving around £600 per ton of waste diverted away from the clinical waste stream.

Design for recycling

Ideally, medical devices would be single polymer and DEHP-free. Single polymer devices are much simpler to recycle, and result in a higher grade recyclate.

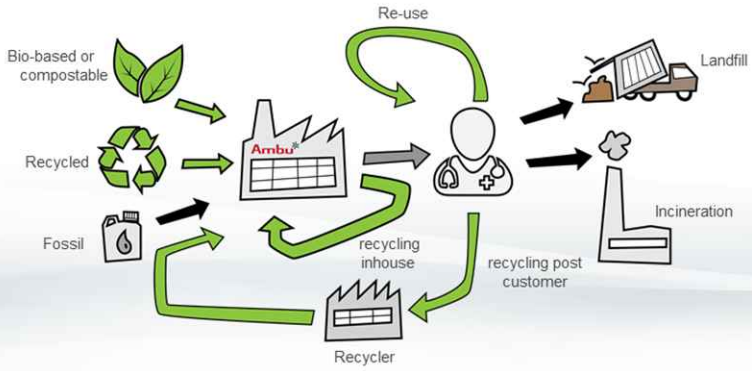
Appendix 2. FUTURE DESIGN OF RECYCLABLE MEDICAL DEVICES

The following are based on a presentation by AMBU A/S at the stakeholder's conference

Scope for guideline

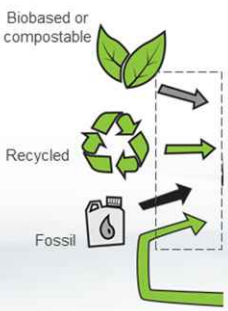
- Shall be used by R&D product design engineers.
- Shall be performed in the concept phase or early design phase
- Shall cover all main components (electronic parts, main plastic components and packaging) and decisions.
- Compare with reference product/solution

Circular economy Ambu - from material perspective



Selection of materials

Questions



- Could recycled plastic be a possibility?
- Are the packaging 100% recyclable, reusable or compostable
- Are the electrical component RoHS compliant and free from conflict minerals?
- Does the product contain harmful chemicals, heavy metals and manufacturing by-products
- Several bio-based plastics currently exist: PP, PE and POM. Could these be relevant for your project?
- Could you limit the number of materials?

=> Consult AMBU Design for recycling tool

Selection of materials

Material Categories	Preferred	OK but search for alternative	Prohibited (No-Go')
Polymers	Biobased PE,PP,PET Recycled polymers HDPE, LDPE, PP, PET No masterbatch	ABS, POM, PC, PA, PMMA, EVA Composites, filler in polymers	Latex PVC Oxo degradable and biodegradable plastic
Chemicals and additives	Chemical-free Non classified, Ca/Zn stabilisers	SVHC < 0,1% CMR < 0,1% UV-320 CalProp65, PBT	Subject to Authorization Ortho-phthalates Pb, Cd, organotin stabilizers
Flame retardants	Do not contain flame retardants Triophenyl phosphate, resorcinol, magnesium hydroxyde	RDP, BPADP/ BAPP, Phenol, Phosphonate-co-carbonate, aluminum Hydroxide, Melamine Polyphosphate, Red Phosphorus	PBB, PBDE, Antimony trioxide, BPA,
Packaging	Transparent PE, PP, PET Biobased materials Biodegradable cardboard Recycled materials FCS	Paper labels	Laminated foil Metal clamps Chlor bleached EPS aggebakker
Metals and electronics	Stainless steel, Al, Zn, Pt, Ti	Ni, As, Be, Se, Sb	Pb, Hg, Cd, Cr (>0.1%)

Design for recycling inhouse

Questions

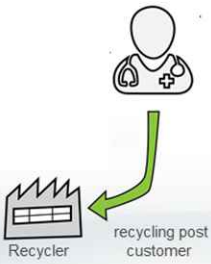
- Can we design out scrap in moulding and assembly?
- Is there new manufacturing processes that allow for more efficient & less material consuming manufacturing?
- Consider how the expected scrap of assembled products can be disassembled or crushed locally, and sorted into valuable material fractions?
- Are the raw materials suitable for inhouse recycling?
- Use as few material types as possible?
- => Consult AMBU Design for recycling tool

Design for inhouse recycling

Recyclability criteria	Preferred	OK but search for alternative	Avoid (No-Go')
Number of materials	As low as possible and less than reference product	Equivalent to reference product	
Disassembling of products	No Glue Mechanical joints Welding without adhesives Products can be disassembled or crushed locally, and sorted into valuable material fractions	Glue Welding with additives Products can be disassembled or crushed locally, and sorted into valuable material fractions Two component molding of different materials Coextruded films/tubes	
Colorants	No pigments or light pigments	Pigments	
Recyclable materials	Material is suitable for recycling without post processing	Material is not suitable for inhouse recycling	
Less material consumption	Hot-runners Reduced sprue and runners Reduced gitterspild	Non recyclable "gitterspild"	

Design for recycling post consumer

Questions



- Can you label the packaging and product with recycling label?
- Can you standardize to reduce pages in leaflets and print on cartons?
- Can the raw material be used in new products without losing material quality?
- Consider where the product will be disposed and the availability of recycling options in that country?
- Is the product after use contaminated with bodyfluids, medicine?
- Use as few material types as possible?

=> Consult AMBU Design for recycling tool

Design for recycling post consumer

Recyclability criteria	Preferred	OK but search for alternative	Prohibited [No-Go]
Number of material types in final product	As low as possible and less than reference product	Equivalent to reference product	Higher than reference product
Colorants	No pigments	Light pigments	
Recyclable materials	Transparent PE, PP, PET Biobased or biodegradable materials Recycled materials FCS	Paper labels	Laminated foil Metal clamps Chlor bleached EPS oxobakker
Metals and electronics	Stainless steel, Al, Zn, Pt, Ti	Ni, As, Be, Se, Sb	Pb, Hg, Cd, Cr (>0.1%)

Implementation plan

Wk 45: Review of draft guideline (Teknologisk Institut and Essensus)

Wk 48: Presentation at the MUDP workshop

Wk 50: Ambu workshop using cases

Wk 51: Adjust recycling guideline

Q1 2020: Implementation of the guideline in R&D – training sessions etc.

Appendix 3. STAKEHOLDER'S WORKSHOP

Appendix presents the program and the summary of the workshop as presented in the press release.

Appendix 3.1 Program

Mandag d. 25. november 2019 afholder PVCMedAlliance, AMBU A/S og Teknologisk Institut workshop om Genanvendelse af plastbaseret medicinsk udstyr.

Hvilke muligheder og begrænsninger ligger der i at genanvende plastbaseret medicinsk udstyr på hospitalerne?

En overset affaldsfraktion, mht. genanvendelse, er det plastbaserede medicinske udstyr. Til trods for at affaldsmængden er relativ stor og synlig, og at plast er velegnet til genanvendelse, har man af risikohensyn afholdt sig fra at genanvende denne type affald. Men nu begynder også denne fraktion at blive genstand for bæredygtig opmærksomhed rundt omkring i verden.

Der benyttes mange forskellige plasttyper til fremstilling af medicinsk udstyr. Det anslås at mange af engangsartiklerne er fremstillet i PVC. Resten er fordelt over mange forskellige andre plasttyper. På workshoppen tager vi udgangspunkt i det PVC-baserede udstyr.

Der er mange forskellige hensyn, der skal tages, hvis et hospital beslutter sig for at indsamle medicinsk udstyr til genanvendelse. PVC-baserede udstyr er stadig i dag blødgjort med klassificerede ftalater, og det er en væsentlig barriere for at genanvendelse. Den nye EU Medical Device Regulation (MDR) implementeres per Maj 2020, vil at betyde, at ftalaterne vil være ude af PVC'en i nær fremtid.

På workshoppen vil vi gennemgå internationale cases for genanvendelsen af det PVC-baserede medicinske udstyr og en dansk case til inspiration for danske hospitaler.

På workshoppen vil både Miljøstyrelsen og Lægemiddelstyrelsen gennemgå de miljø- og sundhedsmæssige aspekter ved PVC-genanvendelse.

Teknologisk Institut vil fortælle om at udrense blødgørerne fra PVC-affaldet inden det sendes til genanvendelse. Processen er en superkritisk CO2 ekstraktion, der fx også anvendes til at trække koffein ud af kaffe.

Workshoppen henvender sig til ansatte i sundhedssektoren, der beskæftiger sig med indkøb, patientbehandling, miljø og affaldshåndtering, samt til plastvirksomheder, der fremstiller medicinsk udstyr, og virksomheder, der genanvender plast.

PVC Med Alliance

Ambu

TEKNOLOGISK INSTITUT

Workshoppen vil bestå af korte indlæg fra miljømyndigheder, industri, regioner og Teknologisk Institut inkl. plenum diskussion

Program
Kl. 10:00 til 12:00

1. **Indledning**
   (Peter Sommer-Larsen, Teknologisk Institut)
2. **PVC og plast i sundhedssektoren – et kort historisk rids**
   (Ole Grøndahl Hansen, PVCMed Alliance)
   Hvorfor bruges plast til medicinsk udstyr og hvad brugte man før? Hvilke plasttyper er de mest anvendte i dag, og hvad er tendensen?
2. **De miljømæssige udfordringer ved PVC-baseret medicinsk udstyr**
   (Jesper Skovby Jørgensen, Miljøstyrelsen)
3. **De nye regler for medicinsk udstyr**
   (Morten Sichlau Bruun, Lægemiddelstyrelsen)
   Om EUs nye forordning for medicinsk udstyr og den nye europæiske farmakopé samt vurdering af evt. smitterisici
4. **Visionteknologier og Kunstig Intelligens anvendt til inspektion og sortering**
   (Jacob Kortbek, Teknologisk Institut)

Frokost
kl. 12.00-13:00

Tema 1: Design af medicinsk udstyr i plast til genanvendelse
kl. 13:00 – 14:00

- **Design for genanvendelse af medicinsk udstyr** (Annette Bitz, AMBU)
- **Plastprodukter og emballage designet til genanvendelse** (Peter Sommer-Larsen, Teknologisk Institut)
- **Plenum diskussion**

14:00 Kaffe

Tema 2: Genanvendelse af medicinsk udstyr
Kl. 14:00 – 16:00

- **En sygeplejerskes erfaringer** (Mette Skriver Revsbech, Glostrup Hospital)
- **Superkritisk CO2-ekstraktion af blødgørere i medicinsk udstyr** (Peter Sommer- Larsen, Teknologisk Institut)
- **Genanvendelse af medicinsk engangsudstyr - fire cases** (Tobias Johnsen, PVCMed Alliance)
  a) Australien; b) England; c) Sydafrika; d) Guatemala
- **Praktiske udfordringer ved udsortering til genanvendelse på hospitaler** (Bjørn Brix Pedersen, Region Hovedstaden)
- **Plenum diskussion**

Workshoppen gennemføres i regi af projektet "Sikker og effektiv genanvendelse af blød PVC fra medicinsk udstyr ved miljøvenlig superkritisk kuldioxid (scCO2) teknologi", der er støttet af Miljøstyrelsen under MUDP.
https://www.teknologisk.dk/ydelser/hospitalspersonale-indsamler-medicinsk-udstyr-i-plast-til-genanvendelse/41188

Aktiviteten er også støttet af Styrelsen for Institutioner og Uddannelsesstøtte under Uddannelses- og Forskningsministeriet.

Appendix 3.2 Press release and summary of the workshop (in Danish)

Stor interesse for at genanvende hospitalsplast på workshop hos Teknologisk Institut den 25. november. De største danske producenter af medicinsk udstyr, regioner, privathospitaler, sygeplejersker, Miljøstyrelsen, Lægemiddelstyrelsen og PVC-industrien drøftede muligheder og udfordringer ved genanvendelse af denne specielle affaldsfraktion.

Medicinsk engangsudstyr i plast er selve fundamentet for det moderne sundhedsvæsen. Det kom frem i introduktionen til workshoppen, som var arrangeret af Teknologisk Institut, Ambu og PVC Informationsrådet. Direktør for PVC Informationsrådet Ole Grøndahl Hansen redegjorde i et kort historisk rids for hvordan plasten revolutionerede sygdomsbehandling, da den kom frem i 1960'erne. En markedsrapport viste, at det suverænt mest anvendte plastmateriale på hospitalerne er PVC, hvilket resulterede i at workshoppen havde denne plasttype som omdrejningspunkt.

Sygeplejeske Mette Skriver Revsbech fortalte forsamlingen om, hvordan sygeplejerskerne på hendes afdelingen er tændt på ideen om at få indsamlet plastaffald, så det kan blive genanvendt.

Grøn omstilling kommer nedefra

På workshoppen blev det klart at det er sygeplejerskernes engagement, som er afgørende for om den grønne omstilling af sundhedsvæsenet vil finde sted. Sygeplejerske Mette Skriver Revsbech fra Rigshospitalet Glostrup viste fotos af hvor utroligt meget plastaffald, der genereres efter blot fem operationer. Denne mængde synliggør over for sygeplejerskerne, at handling over for plastaffald er påkrævet. Det var derfor let at overbevise kollegerne om at deltage i et projekt, hvor målet var at indsamle 2000 brugte iltmasker, hvilket blev nået på rekordtid.

Betydningen af sygeplejerskernes engagement blev cementeret af Tobias Johnsen fra PVCMed Alliance, der viste eksempler på genanvendelse fra andre steder i verden. Både i Australien, New Zealand, Sydafrika, Guatemala og England var det påfaldende, at det var sygeplejersker der havde igangsat indsamlingsordninger for plast. Ligeledes er det essentielt for engagementet, at sygeplejerskernes ekstra indsats i en travl hverdag resulterer i at det indsamlede affald forvandles til samfundsnyttige produkter. Et overbevisende eksempel herpå var de skolesko, der blev sendt rundt på open. Kun 20 IV-poser bliver til et par 100% genanvendelige sko, som udleveres til nogle af de 5 millione nske børn, der lever i dyb fattigdom og derfor ikke har råd til skoleuniform.

Tobias Johnsen fra PVCMed Alliance redegjorde for, hvordan man i andre dele af verden allerede er i gang med at indsamle brugt medicinsk udstyr til genanvendelse.

Design til genanvendelse

Hovedudfordringen ved plastgenanvendelse er de mange typer plast der findes. Det besværliggør både sortering og genanvendelse. Afgørende er derfor, at produkterne designes med genanvendelse for øje. Annette Bitz fra Ambu præsenterede en ny designmanual, hvor hovedbudskabet er, at man så vidt muligt skal designe det medicinske udstyr i én plasttype. Det blev bakket op af plastekspert Peter Sommer-Larsen fra Teknologisk Institut, der ved hjælp af iltmasker eksemplificerede godt og dårligt design. En iltmaske består af en blød og en hård del. Den kan enten fremstilles i PVC af varierende blødhed, eller af to forskellige plasttyper. Vælger man den sidste mulighed, umuliggøres genanvendelse, blandet andet fordi forskellige plasttyper har forskellige smeltepunkter.

En anden forudsætning for den cirkulære økonomi er, at skadelige stoffer ikke recirkuleres. Nye EU-forordninger vil sikre, at medicoplast i fremtiden ikke vil indeholde uønskede stoffer. Det blev slået fast af Lægemiddelstyrelsens Morten Sichlau Bruun, som redegjorde for de nye EU-forordninger om medicinsk udstyr, der træder i kraft i maj 2020.

Ole Grøndahl Hansen fra PVC Informationsrådet fortalte om, hvor vigtigt det er for patienterne, at plastprodukter er tilgængelige på hospitalerne.

Skal plasten sorteres af sygeplejersker eller robotter?

Et diskussionspunkt var sortering af plastaffaldet. Bjørn Brix Pedersen fra Region Hovedstaden fortalte, at deres region har valgt en løsning, hvor plasten indsamles på hospitalerne uden nærmere sortering. Sorteringen skal ske efterfølgende udenfor hospitalerne. Denne løsning er blandt andet valgt på grund af pladshensyn. Robotekspert Jacob Kortbek fra Teknologisk Institut viste hvordan kunstig intelligens og robotteknologi muligvis kan gøre sorteringen mere effektiv i fremtiden, da man får mulighed for at sortere i de forskellige plasttyper.

PVC Informationsrådet plæderede – lært af erfaring fra de igangværende indsamlingsordninger verden rundt – for en mere lavpraktisk løsning, hvor sorteringen kommer til at foregå på de respektive hospitalsafdelinger. Man kunne forestille sig, sagde PVC Informationsrådet, at hvert enkelt hospital indkøber en granulator og simpelthen knuser plasten. Når mængderne er tilstrækkeligt store kan man sælge regeneratet til genanvendelse. En sådan praksis udgør rlig smitterisiko. Hospitalsaffaldet håndteres udelukkende af professionelle sygeplejersker, der ved hvil som udgør en risiko. Ligeledes viser erfaringen fra Rigshospitalet Glostrup og rundt om i verden, at fejl e sjældent.

Workshoppen blev afholdt i regi af projektet "Sikker og effektiv genanvendelse af blød PVC fra medicinsk udstyr ved miljøvenlig superkritisk kuldioxid (scCO2) teknologi", der er støttet af Miljøstyrelsen under MUDP. Projektet, der blev styret at Teknologisk Institut, har demonstreret, at den såkaldte superkritiske CO2-teknologi kan fjerne blødgørere fra det PVC-baserede medicinske udstyr inden det genanvendes.

De største danske producenter af medicinsk udstyr var tilstede på Teknologisk Institut for blandt andet at høre om, hvorfor det er vigtigt, at de i fremtiden skal designe deres medicinske udstyr med henblik på genanvendelse.

Del

Relaterede nyheder

Appendix 4. Collection scheme at Rigshospitalet, Glostrup.

The following presentation in Danish was given by nurse specialist Mette Skriver Revsbech at the Stakeholder's workshop in 2019. It describes (in Danish) the actions taken at the hospital.

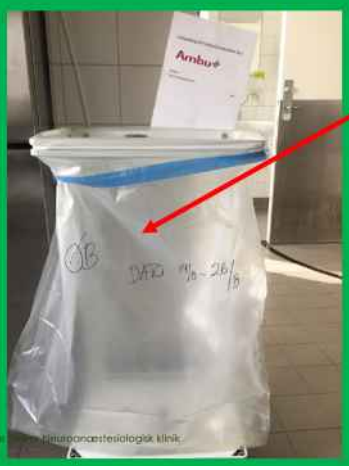
Ventilationsmasker

- Er ftalatfri og består af få forskellige plastik dele, dvs. de er lettere at anvende til genbrug.

Cirkulær ressource økonomi

- Formål: At indsamle Medicinsk udstyr indeholdende ftalatfri PVC af god kvalitet med henblik på genanvendelse af dette. Således en etablering af "cirkulær ressource økonomi" dvs medicinsk udstyr flyttede vi fra at være affald og forbrænding til genanvendelse.
- Ambu leverede ventilationsmasker til elektive anæstesiologiske procedure, herunder til ECT behandling (elektrochok)
- Dansk Teknologisk Institut stod for afhentning ca hver 14.dag og videre forarbejdning af ventilationsmaskerne.

Cirkulær ressource økonomi



- Sækkene blev datomærket af hensyn til karantæne, hvis vi opdagede smitsomme sygdomme
- De masker der ikke indgik i i projektet, var masker der var kontamineret med sekret, blod, opkast, og patienter der er i isolation

Plastikhandlingsplan og den cirkulære ressource økonomi

Den vil vi rigtig gerne være en den af, og er parat til at yde en ekstra indsats

Hvordan er det gået

- Afdelingen og kollegaer har bakket op om, at de ventilationsmasker der skulle anvendes i projektet, også er blevet brugt.
- Vi har haft en fejlsortering på 1 %.

Hvordan er det gået

- Viden og forskning er baseret på entusiasme
- Gå på mod fra investigator og velvillighed fra kollegaer
- Dataindsamling til projekter er i ens fritid, og det er vi bekendt med, når vi siger ja til et projekt

Hvordan er det gået

- Logistik har der været en del af, når der skulle etableres nyt midlertidigt lagersystem
- Ventilationsmaskerne skulle fyldes i div. skabe/skuffer og "af os selv"
- Ikke fra centrallageret for bl.a at sikre, at det var de rigtige masker der blev anvendt til vores elektive anæstesier
- Opbevaring af fyldte sække frem til afhentning

Vi har rigtig meget plastik

Vi er i høj grad blevet meget opmærksomme på, at vi i langt højere grad skal have genanvendelse med i vores overvejelser mht indkøb

Refuce – Reuse – Reduce – Recycle

ANÆSTESI OG CIRKULÆR RESSOURCE ØKONOMI

Summa summarum :
At udvikle et "MASKE-FLASKE" retur system

Det har været en fornøjelse at have jer som eksterne samarbejds-partnere

TAK!!!
FOR JERES OPMÆRKSOMHED

Appendix 5. Super critical extraction of plasticizers – technical details

Appendix 5.1 Process optimization and initial experiments

The physical and chemical basic understanding of the super critical extraction process is well known. Extraction of plasticizers have also been investigated and work done by Hunt et al. in 1991 found optimal temperature ranges between 90 C and 100 C and the need of pressures up to 450 bar. Later Marin et al in 1996 and in 1998 further studied a variety of phthalate plasticizers and the effects of temperature and pressure on extraction efficiency. They concluded that a pressure of 300 bar and a temperature of 95 C was the optimal extraction conditions. Later the parameters found by Marin et al. was used by Granados et al. in 2003 to study the reusability of catheters. By extracting DEHP with super critical carbon dioxide they concluded that the extractable plasticizer content was reduced upon continues reuse, thus a significant amount was leached out during operation potentially causing unwanted exposure to patients. Based on data from the literature review we decided to fix our temperature at 95 C and a pressure of 300 bar. Before we started with the masks our initial experiments were performed on tubing collected at Gentofte hospital by PVC informationsrådet. We sorted the tubing's into clear and hazy, assuming the hazy ones were rubber and the clear plasticized PVC. We then treated the plasticized PVC tubings as stated in Table 9. We conducted four experiments on the tubings in our 1 L reactor. All experiments had a duration of 60 min and were performed with the reactor almost full, se figure 2. Prior to extraction we cut the tubings up into smaller pieces measuring 1-3 cm in length with a branch shredder to increase surface to volume ratio and ease filling of the reactor.

Table 9 Initial experiments on used collected tubings.

Exp.	Material	Time /min	Temp.	Pressure	Mass /g	Flow g/min	Residence time /min	g CO2/g mat	Weight loss %
1	Clear tubings	60	95	300	172	20	34,1	7,0	12,2
1	2. treatment	60	95	300	151	20	34,1	7,9	5
2	Clear tubings	60	95	300	174	50	13,64	17,2	12,8
2	2. treatment	60	95	300	131	50	13,64	22,9	5,5
3	Clear tubings	60	95	300	155	50	13,64	19,4	11,5
4	Clear tubings	60	95	300	155	Batch		4,4	7,7

Experiment 1 and 2 showed similar extraction efficiencies with both 20 g/min flow and 50 g/min flow. This tells us that extraction speeds were limited by diffusion and not solubility of the plasticizer in $scCO_2$. A total weight loss of 18 % was observed after 2 treatments of 60 minutes duration. The significant reduction in yield of the second treatment indicated a diffusion limited process state was reached close to the total potential of the process. We also tested ethyl acetate as a cosolvent in experiment 3 but did not see any gains in efficacy. Finally, we did a

batch experiment where we just filled the reactor with CO_2 and left it for 60 min before evacuating the system. The batch processed tubes showed a weight loss of 7,7 % about half the other experiments, thus confirming a very high solubility of plasticizer in the CO_2. From this data we can estimate the solubility if we assume a steady state equilibrium have established after the 60 min. The mass of plasticizer dissolved is 7.7 % of 155 g = 11.9 g. The free volume in the reactor is 1 L – 155 g/1300 g/l = 781 ml. With the density of $scCO_2$ at these conditions being 683 g/l the solubility is then the mass of the solute divided by the mass of the solvent: 11,9 g / (0.781*683 g/l) = 22 g/kg CO_2.

Figure 8 Clear tubings before and after extraction

The tubings were all white and swollen after the treatment, they also exhibited more stiff and brittle properties. The white color disappeared after melting the PVC confirming our suspicions that it originated from porosities created during the extracting process. The tensile properties also changed as the elongation at break changed from >100 % @ 80 N to 43 % @ 165 N in our initial tests, see Figure 9.

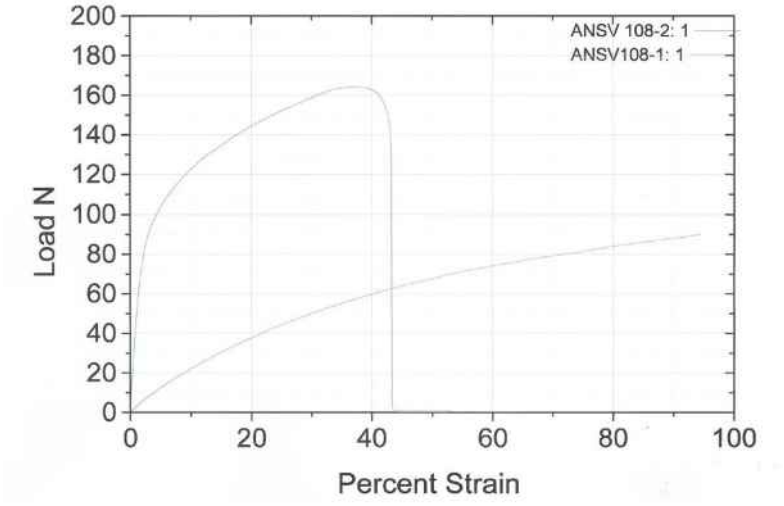


Figure 9 Tensile properties of plasticized PVC tubes before (red) and after (blue) extraction with $scCO_2$

All in all, the initial experiments confirmed a successful extraction of plasticizers with $scCO_2$. The collected tubes lost weight, swelled, and turned white. They became stiffer and more brittle, and we even confirmed a glass transition temperature with DSC and the plasticizer to be DEHP with FTIR.

Appendix 5.2 Shredded masks and Upscaling to 5 L reactor

Due to the diffusion limitations observed with the tubings we decided to invest in a shredder to chop the masks into finer pieces. The shredder yields quite monodisperse pieces only a few mm in size, see figure 4. With the shredded masks we furthermore increased extraction time to 120 minutes as it was observed with the tubings that an extra hour of extraction gave a significantly higher yield. We observed a weight loss of up to 30 wt% for mask A, with the extract being a light-yellow clear oil. We confirmed it to be mostly DEHP with Gas chromatography.

Figure 10 Plasticized PVC shredded before and after extraction. Before extraction the shredded masks are soft with a hazy bluish tint, after extraction they are opaque white and hard.

We tested two different kinds of granulators: the Rapid 150 Deltatech (R150) granulator and the Rapid RG3 (RG3) a slow-speed shredder for hard and more brittle plastics. As observed from the results in Table 10 and Table 11, there was not much difference in extraction efficiency but a slight advantage to the higher capacity R150 model, made it our pick. After analyzing the initial test, we decided on a flow speed of 40 g/min, this flow speed gives a theoretical max extraction speed of 40 g/min * 60 min * 0.022 g = 52,8 g/h or almost 25 wt%/h. We observed a high yield of nearly 30 wt% after 2 h with this flow speed. With the observed yields of around 30 wt%, we concluded the extraction after 2-hour process was severely diffusion limited or at least very close to completion. We confirmed our thesis with an extra 2 h extraction

of the R150 shredded masks, this only yielded a low weight loss of < 1 %. We also tested the shredder on clear tubings, this time collected at another hospital though making a 1:1 comparison difficult and got a weight loss of 19,9 % after 2 hours extraction. This confirms a slight advantage to the shredded materials caused by the decreased diffusion distance and increase in surface to volume ratio. The successful extraction yielded hard white recyclate ready for further processing, see Figure 10.

Table 10 First tests with shredded masks

Exp.	Material (Mask A)	Time /min	Temp. / °C	Pressure / bar	Mass /g	Flow g/min	Residence time /min	g CO2/ g mat	Weight loss %
1	Ambu DEHP (RG3)	120	95	300	222	40	17,05	21,6	28,8
2	Ambu DEHP (R150)	120	95	300	232	40	17,05	20,7	29,9
2	2. treatment Ambu DEHP (R150)	120	95	300	161	40	17,05	29,8	<1
3	Slanger RH m klister (RG3)	120	95	300	209	40	17,05	23,0	19,9

GC analysis performed inhouse of the processed recyclate showed a surprisingly high remnant of DEHP of 9.8 wt% in the double extracted R150 shredded masks (exp. 2). The method was established specifically for this purpose. A linear standard curve from clean DEHP dissolved in ethyl acetate (both Sigma Aldridge) was used to calculate the plasticizer content in mask A before and after extraction. Mask A contained a total of 41.2 wt% plasticizer before extraction. This gives a reduction of 76.2 % of the initial amount. To validate our GC method we asked our accredited lab to make an analysis on some of our samples and they got similar results confirming our method.

Table 11 Plasticizer reduction Mask A shredded

Plasticizer content		Reduction
Before extraction	41.2 %	
After extraction	9.8 %	76.2 %

Upon receiving the new shredder, we also installed a new larger 5 L reactor for the production of a sizable amount of recyclate to WP4, we knew Gibo Plast A/s needed at least 10 kg to start the pilot tests with their industrial scale equipment. The 5 L reactor was installed in our facilities and our large 200 g/min CO_2 pump should be sufficient to run the large reactor efficiently with similar residence times as the smaller reactors. Simultaneously it was decided that we would change to Mask B with the non-phthalate plasticizer more suited to represent Ambu's current line-up of products. The next range of experiments was performed on new masks supplied by Ambu. The valve on this mask consists of polycarbonate and was cut off manually before shredding. A total of 10 times 5 L extractions was performed yielding 12.5 kg recyclate. The weight loss of the non-phthalate containing mask B was similar to mask A with an average weight loss of 29 %, see Table 12. This result confirms that the solubility and extraction efficacy of non-phthalate is similar to DEHP – it is expected given the two compounds are merely isomers of the same molecule the phthalate and the terephthalate, respectively. The extraction times are noted as being between 120 and 300 minutes, see Table 12, due to limitations in our extraction setup preventing it from maintaining the high flow speed needed for the large 5 L reactor for an extended amount of time. We believe it is caused by decreasing temperature and resulting lower backpressure in the CO_2 gasflask. To overcome this, we invested in a heating jacket to the flask, but only minor improvements followed.

Table 12 Mask B non-phtalate extraction. Pilot scale production of recyclate

Material (Mask B)	Time /min	Temp. / °C	Pressure / bar	Mass /g	Flow g/min	Residence time /min	g CO2/ g mat	Weight loss %
Ambu non-phthalate	120-300	95	300	2000	150	22.7	11-22	29

The 12.5 kg recyclate produced from Mask B was further processed to assess applicability. We pressed plates and extruded a small test amount with our single screw extruder. Both tests revealed a number of white grains in the materials that seemed not to be melting as the remainder of the PVC. We identified the grains with FTIR as polycarbonate from the valve system. A thorough investigation of the mask design revealed that a fraction of the valve remained in the mask when removed by hand. This meant the recyclate could not be easily sorted as polycarbonate and PVC both are heavier than water and thus separation is more cumbersome.

Appendix 5.3 Extraction of masks from collection pilot at Glostrup Hospital

As described above, a pilot collection scheme was established at Glostrup Hospital where the staff collected used masks in a dedicated established bin. Ambu A/S supplied mask C to the Hospital over a period of six weeks, DTI picked up bags with disposed anesthesia masks three times for a total of 522 masks.
We granulated a total of 23 kgs of masks and treated 17,5 kg with the super critical extraction equipment giving a total of 14,5 kg of treated granules, of which 10 kg was sent to Gibo plast for extrusion experiments.
We averaged only a 18 % weight loss for Mask C, but a lower starting concentration of plasticizer meant a total reduction of up 80 % was accomplished. A similar extraction scheme was used for Mask C as for Mask B above. Due to the problems with maintaining high flowrates – as mentioned above - we varied the extraction time from run to run to ensure a complete extraction. The parameters used are listed in Table 13.

Table 13. Mask C plasticizer extraction. Pilot scale production of recyclate

Material (Mask C)	Time /min	Temp. / °C	Pressure / bar	Mass /g	Flow g/min	Residence time /min	g CO2/ g mat	Weight loss %
Ambu non-phthalate	180-300	95	300	2000	150	22.7	11-22	18

Appendix 5.4 Analysis of hard and soft parts in extruded PVC

Grains of a clear material makes the tube uneven and frosty. Grains were spread throughout the extruded tubing – see Figure 11.

Figure 11. Extruded tubing with grains of a different composition that makes the tube “frosty”.

The hose was analyzed by FTIR spectroscopy of a cross section of the tubing. Both the major tubing material and the grains are PVC – there is no signs of contamination with other type of polymers.
The grains are assumed to stem from the part of the anesthesia mask which is a soft cuff made from plasticized PVC with a higher content of plasticizer than the bulk mask. After ScCO2 extraction, two types of granulates are identified: hard lumps of white material and thinner plates of clear material. The white material is shown below to have less plasticizer left after ScCO2 extraction than the clear material. The white opaque occurrence is assumed to occur on depressurizing the super critical reactor: under ScCO2 conditions, the PVC is swollen in CO2. When most plasticizer has been extracted, a partly swollen structure is frozen out during depressurizing and cooling. The granules are however not foamed on a scale observable by light microscopy and do not have a markedly different density. When heated, the granules become transparent again. The clear plates are also sometimes white along the edges.
We used FTIR peak fitting to evaluate the content of plasticizer. The plasticizer content is calculated from the ratio between areas of the 4-5 central PVC C-Cl stretching vibrations from 660-590 cm^{-1} and a characteristic plasticizer peak at 732 cm^{-1}. The peak fit resolves the spectra into non-overlapping peaks
In Table 14, the ratios between peak areas for the granulate before extraction, for the hard white granules and the clear plates after extraction. When normalized to the known content of plasticizer in the mask, these ratios correspond to a 5.5 times reduction in plasticizer content upon extraction for both types. Only one sample was examined, hence no statistics is given.

Table 14. Peak area analysis

	Area plasticizer 732 cm^{-1}	Area PVC-stretch 660 cm^{-1} – 590 cm^{-1}					Area Σ PVC peaks	Area ratio Plasticizer/ΣPVC	Plasticizer content reduction
Hard granulate before extrusion	4.58	1.77	10.55	10.79	4.80	4.47	32.37	0.14	1 x
Hard granulate after extrusion	0.69	4.84	11.62	0.51	11.95	3.63	32.55	0.02	5.4 x
Clear plates after extrusion	1.31	4.37	11.23	2.18	9.68	3.85	31.31	0.04	5.7 x

The plasticizer content is calculated as:

$$w_{plasticizer} = \frac{m_{plasticizer}}{m_{plasticizer} + m_{PVC}} = \frac{1}{1 + \frac{\alpha}{A_{plasticizer} / A_{\Sigma PVC}}}$$

$$\frac{A_{plasticizer}}{A_{\Sigma PVC}} = \alpha \cdot \frac{m_{plasticizer}}{m_{\Sigma PVC}}$$

Here, w is the plasticizer content in w/w %; m is the mass; A are the integrated peak areas, ΣPVC refers to the sum of all resolved C-Cl stretching peaks. α is a proportionality constant, which can be determined if the plasticizer content of one sample is known. Figure 12 demonstrates the peak fitting for one of the experimental spectra and the peak fitting program output is found in Table 15.

Based on relative weights of the mask parts, the overall plasticizer content is found to be reduced by a factor 5.6 x meaning that the recycled PVC contains 6 % residual plasticizer.

If the waste fraction is mixed with medical devices of unknown origin, e.g., the 5 face masks of another brand found during the collection, it will lead to a contamination of the residual plasticizer that will influence its usefulness in a circular loop.

Assuming that the limit of contamination must be below 0.1% of unknown plasticizer – e.g., DEHP and that all other properties are unchanged - at most 1.6 % contamination of the input fraction can be allowed.

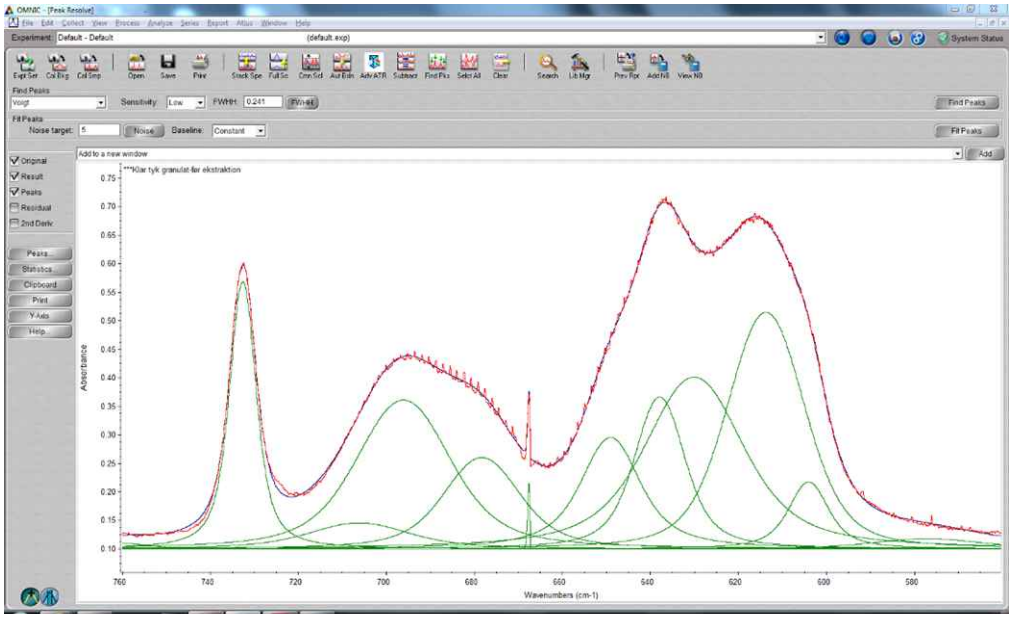


Figure 12. FTIR peak fitting example for hard granulate before extraction. The peak at 732 cm^{-1} is solely from the plasticizer and the peaks between 660-590 cm^{-1} are solely from PVC. Baseline is also fitted automatically. Red line is the experimental spectrum (baseline corrected) and the blue is the fitted spectrum. Green lines are the resolved peaks.

Table 15. Fit to the experimental FTIR spectrum. The resolved peaks used in the analysis is found in lines with white filling.

PEAKS RESOLVED:
Spectrum: hard granulate before extraction, Region: 760.291 560.144, Baseline: Constant
Peak list:

	Peak Type	Center X	Height	FWHH	Other	Area
	Voigt	577.033	0.0179	18.224	17.796	0.7141
ΣPVC	Voigt	604.046	0.1174	5.990	7.321	1.7681

	Voigt	613.746	0.4154	16.670	7.116	10.5466
	Voigt	630.065	0.3016	16.660	15.706	10.7888
	Voigt	637.913	0.2666	9.055	7.367	4.7986
	Voigt	649.082	0.1954	8.377	11.602	4.4704
	Log Normal	667.600	0.1152	0.540	1.562	0.0688
	Voigt	678.343	0.1604	14.371	10.207	4.2862
	Voigt	696.145	0.2614	18.030	12.137	8.5442
	Voigt	706.234	0.0456	17.069	16.325	1.6858
Plasticizer	Voigt	732.665	0.4695	4.335	4.424	4.5811
	Voigt	759.856	0.0095	4.721	13.398	0.2159

Appendix 5.5 Mechanical test of recyclate

Plates were hot pressed from granulates both before and after plasticizer was extracted. Both plates showed yellow discoloration in the bulk and spots of more brown flakes. Again, the flakes are assumed to stem from the cuff material. Only a fraction of the cuff material was brownish discolored in any of the samples. The plate made from non-extracted granulate was pliable and rough with a clear visual indication that the granulates were not fully coalesced and had elastically expanded after pressure was released. The plate pressed from extracted granulates however was hard and smooth. The plates are shown in Figure 13. Rectangular test specimens were cut from the plates and tested with a Shimadzu tensile testing machine. The mechanical properties measured in tension is found in Table 16. The measured stress-strain curves are displayed in Figure 14.

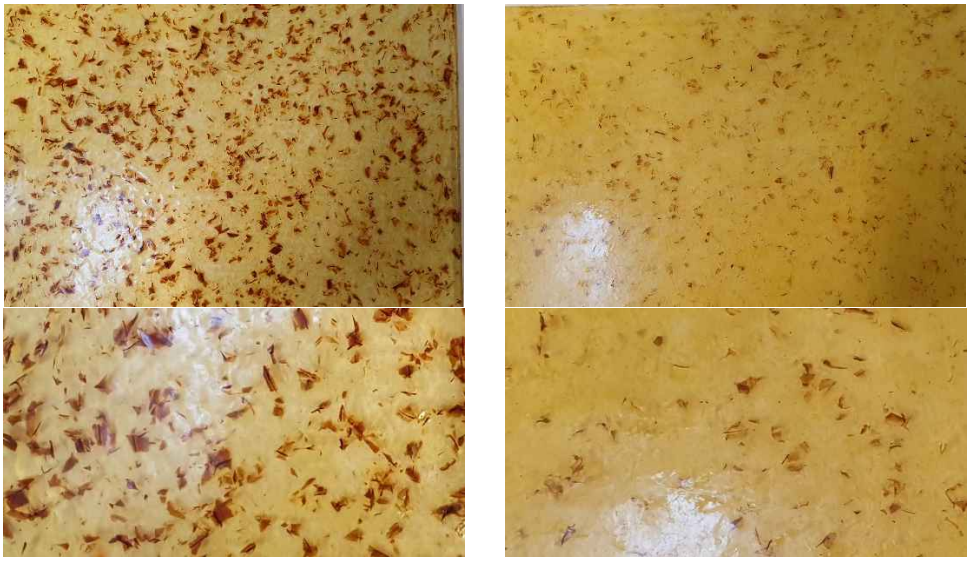


Figure 13. Hot pressed plates from non-extracted granulate (left) and ScCO2-extracted granulate (right). Closeup in second row. **Pressed at 180 °C with 55 tons for 6 min followed by cooling under pressure in 20 min.**

Table 16. Mechanical tensile properties of specimens cut from hot pressed plates. The specimens made from non-extracted granulate behaves rubbery and the materials made from extracted granulate behaves thermoplastic.

Specimen	Modulus / MPa (SD in parenthesis)	Yield stress / MPa (SD in parenthesis)	Yield strain / % (SD in parenthesis)	Stress at break (SD in parenthesis)	Strain at break / % (SD in parenthesis)
Before extraction	15.2 (2.2)			10.3 (0.7)	191 (19)
After extraction	453 (41)	19.5 (0.5)	9.0 (2.0)		

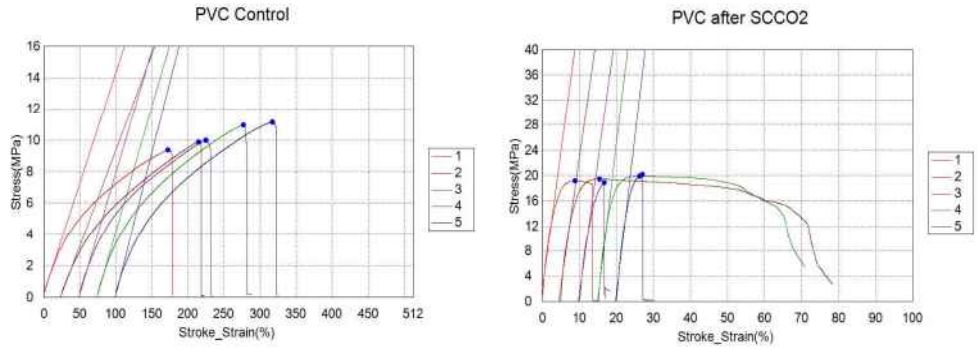


Figure 14. Tensile test results for specimens made from non-extracted granulate (left) and ScCO2-extracted granulate (right).