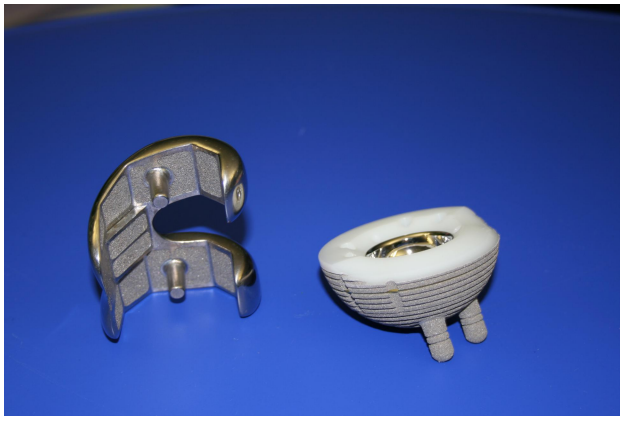
Precision cleaning of chirurgical implants

The biocompatibility criterion is an important part of the cleaning of chirurgical implants.
It is mandatory to fully eliminate mineral oil remaining on the parts after the mechanical processes. This allows an easy and perfectly biocompatible final cleaning. A non chlorinated A3 solvent is used by a leading manufacturer of chirurgical implants and shows how a modern technology improves the cleaning of bio-medical products.

Chirurgical implants : a strong growing market
The growing demand of implants requires an improved capacity of precision cleaning.



Implants.

Implants cleaning
Cleaning is decentralised in our case study. It occurs after each mechanical machining operation. This technique allows to improve the cutting and drilling operations, by removing oil and chips after each step of manufacturing. It avoids also the mixing of various mineral oils, when different oils have to be used for various operations. Such a mixture of various soils may create cleaning problems.

The choice of the cleaning technique has become more complex for various reasons. Various legal requirements require a drastic change of the cleaning methods. The demand for higher cleanliness of parts is growing. Degreasing in open tanks of chlorinated solvents was a simple and efficient way to clean parts. But it was also highly polluting the environment and toxic for the operators. This method has been replaced by fully encapsulated machines using non chlorinated A3 hydrocarbon solvents under vacuum.
Another technology uses water based detergents to remove polar and non-polar soils.
The requirements to cleaning medical implants are twofold. It must first remove all non polar soils (mineral oil for instance) and in a second step remove polar soils like metallic particles and salts for instance.
Using water based detergent poses a major problem. Mineral oil pollute very fast the water based detergent, which loses of its degreasing power. Using oil separators and automatic dosing of components can solve the problem. The detergent loses however of its degreasing capability. Recess holes are another problem where water detergents have a limited efficiency. It is however a prerequisite to remove all mineral oil form the parts.
The technology of A3 non chlorinated solvents ensures a constant solvent capability, thanks to the continuous distillation. The pollution of the solvent is thus limited to a couple of ppm of mineral oil (parts per million).
The currently used cleaning technology of the medical implants uses A3 hydrocarbon solvents. They are used under vacuum, as they have a flash-point over 56°C. They are used to pre-clean the parts during the mechanical processes. The water based cleaning is used for the final cleaning and ensures the bio-compatibility of implants.
The advantage of this cleaning process results in a reduced pollution of the water detergent, as all mineral oil has been removed by the A3 solvent.

The control ob biocompatibility is done periodically on a sample of parts, cleaned according to the validated process.

Vacuum technology and A3 solvents

The legislation and cleaning quality requirements have led to the concept of an efficient and non polluting equipments to replace the chlorinted solvents machine using tri- and perchloroethylene.
The used solvents are non chlorinated hydrocarbons. They have been developped by petrochemical companies and are in general isoparaffines or modified alcohol mixtures. They are fully recyclable by vacuum distillation and undergo no chemical modification in the long range operation. The film remaining on the parts is equivalent to approximately 2-10 nanometers, corresponding to 10 mg per m^2. This is typically precision cleaning.
The operation is secured by using vacuum, in order to avoid any flammability. This concept is validated by all international safety regulations.

The manufacturer of implants has chosen two types of **Amsonic** machines, **ECS 40** and **Egaclean 4100.**
ECS 40 has a basket capacity of 15 litres. One tank of solvent is distilled continuously in order to supply clean solvent at any time during the production.
The tank, cleaning chamber and distiller are all under vacuum (100 mbar). The cleaning cycle includes the following steps :
Immersion in hot solvent with ultrasonics
Filtration
Injection of solvent under pressure and spray rinsing
Vapour phase
Drying under vacuum at 1-3 mbar.
The cycle time is within the range of 6 à 12 minutes, depending on the cleaning requirements and selected programmes.

The monitoring uses a PC. The choice of cleaning programmes and operating parameters is user friendly. The documentation of the process and cleaning parameters guarantees a continuous updating and control of the validated operations.

Egaclean 4100

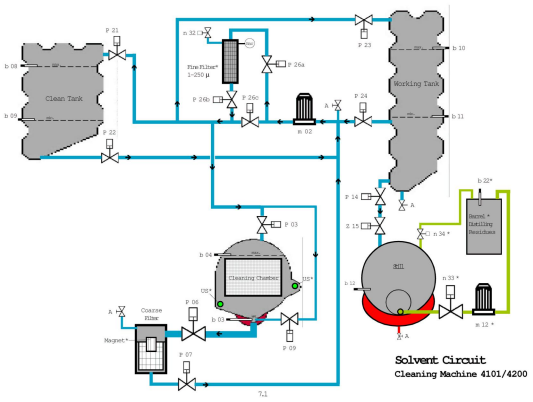


Diagramm of the Egaclean process

Egaclean 4100 has an increased capacity with baskets of 33 liters volume. The machine is equipped with two tanks, one to pre-clean and the second for final cleaning using distilled solvent. The cleaning cycle is identical to the one of the ECS 40 machine.

The operator may select on both machines to rotate or oscillate the basket or to chose the static mode. The ultrasonic power is variable and the frequency is chosen in function of the type of material to clean.

Cleaning quality tests have given the following results regarding the thickness of the hydrocarbon layer. This layer is a pure hydrocarbon layer of approximately 10 nanometers and not a film of oil. Other types of A3 solvents like modified alcohol (a combination of alkoxy-propanol) show a reduced pollution in residual carbon of 3 mg C/m^2. Considering that the final water based cleaning removes residues of hydrocarbon it is recommended to use isoparaffine for this type of application, as it has a high degreasing capability and a lower price. Modified alcohols are however preferred, when quality criteria like low electrical resistance or residual carbon residues are important..

One of the advantages of the vacuum technology lays in the increased throwing power of the solvent in recess holes. In the case of drills of about 200 mm in length and cooling channels of 1 mm in diameter on the whole length, the cleaning inside the channel is easily achieved with A3 and vacuum. Such cleaning problems cannot be solved when using a water detergent.
The good solvability of mineral oils in A3 solvents is improved by the high temperature of the solvent. Typical values are from 65 to 80°C.
One important element of the cleaning quality is in keeping narrow distillation parameters. It is part of Amsonic's know-how.

Operating costs
The investment of a cleaning equipment is made of various elements in supplement to the purchase price itself. Maintenance, consumables like solvent and energy must all be considered when analyzing various types of machines.

Table 1 : Operating costs for EGAclean 4100 (without fixed expenditures)

Base : 8h/day 220 days/year	**Unit cost**	**Consumables**	**Total cost**
Solvent	2.-- €/l	200 l	400
Energy	0.08 €/kWh	10 kWh	1408
Maintenance in hours	33.--€/h	5 min/day	605
Spare Parts	1600		1600
Waste elimination	53 €/barrel	4 barrels	212
Total			**4225**

Emissions

The new legislation, especially the german "31. BImSchV" targets a reduction of the VOC emissions (Volatile Organic Components) in order to reduce the greenhouse effect. A3 **Amsonic** machines have especially reduced emissions. Laboratory measures gave the following results.

Table 2 : VOC emissions

	Emissions in mg C/m^3
Amsonic	21
Average of competitor's equipment	889

Return on investment

The choice of the cleaning technique was based on various supplier's quotations. Cleaning quality, the experience in the A3 technology and the process documentation as well as the references of Amsonic in the medical implants industry are the main elements leading to the choice of Amsonic.

The cleaning quality is oh constant and high quality. The maintenance of the four machines is supervised by the computer software. This allows a preventive maintenance and informs the operator about the needs of changing filters or other spare parts.

Maintenance time is minimized and requires no more than approximately five minutes per day on an average.

The solvent's quality is kept constant by the continuous distillation. The distillation quality allows to keep the same solvent without having o empty periodically the machine. The losses of distillation represent approximately 5% of the volume of oil dragged into the machine are compensated by periodical addition of fresh solvent. Due to the fact that the solvent cannot become acidic it must not be replaced, which was the case with chlorinated solvents.

Cleaning with A3 isoparaffine has further advantages as it is compatible with practically all types of mineral oils. The EGAclean technology cleans even complex shaped parts like implants, in a hot solvent under vacuum.

The investment is paid back by the high degree of automatisation, low operating costs and the guarantee of a constant cleaning quality.