

## Lubricant solutions for the medical technology



# LUBRICANTS. TECHNOLOGY. PEOPLE.

We focus consistently on high-quality lubricants and related specialties.

We develop innovative and holistic solutions for a wide variety of applications.

We value the high level of commitment of our employees and their trusting interaction with one another.



## Facts and figures

**Holding company:** FUCHS PETROLUB SE

Headquarters in Mannheim, Germany

Established 3 generations ago as a family-owned business

**References:** The world's largest independent lubricant manufacturer with more than 100,000 customers

**Companies worldwide:** 58

**Employees:** Approx. 5,000 employees, over 400 of these in the department research and development

**Product program:** A full range of over 10,000 lubricants and related specialties

### FUCHS SCHMIERSTOFFE GMBH

A company of the FUCHS Group

**Headquarters:** Mannheim

Other plants in Wedel, Kiel

**Employees:** more than 800 employees

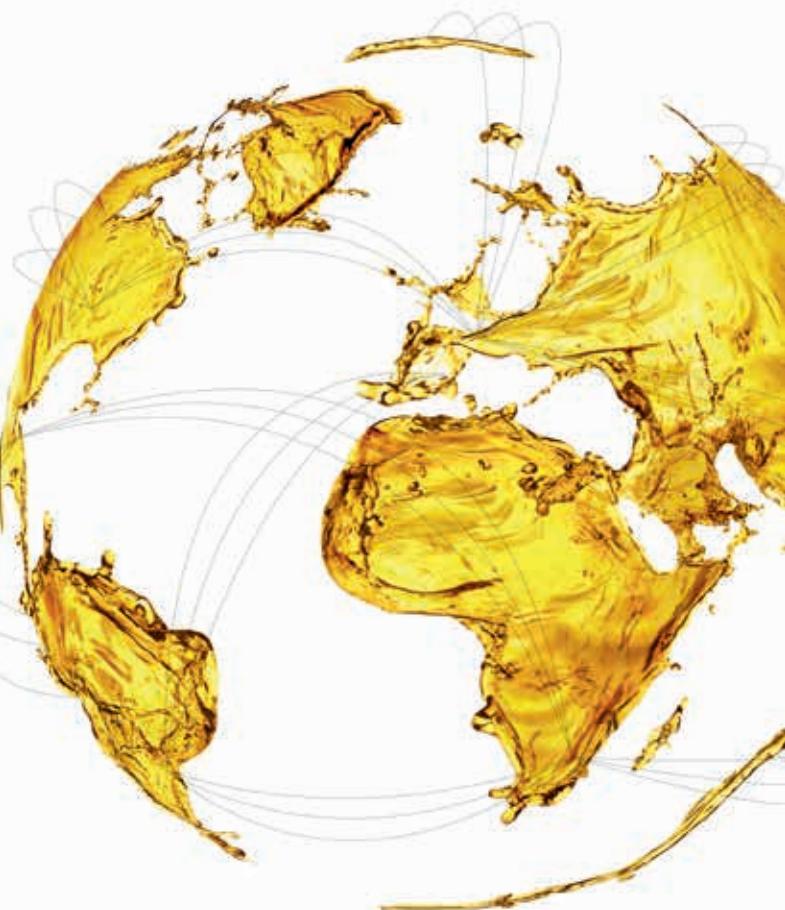
**Certifications:** IATF 16949, ISO 14001, BS OHSAS 18001, ISO 50001

**References:** One of the leading lubricants OEM for the German automotive industry

FUCHS is a global Group with German roots that develops, produces and distributes lubricants and related specialties.

We have more than 100,000 customers, including companies from the following fields: automotive suppliers, OEM, mining and exploration, metalworking, agriculture and forestry, aerospace, power generation, mechanical engineering, construction and transport, as well as steel, metal and cement industries, yet also companies in the food industry, glass production sector and the casting and forging industry – and many others.

Founded in 1931 as a family business in Mannheim today there are more than 58 operating companies with almost 5,000 employees in more than 45 countries under the umbrella of FUCHS PETROLUB SE. FUCHS is the world's largest provider among the independent lubricant manufacturers.



FUCHS SCHMIERSTOFFE GMBH works with a team of more than 800 specialists on 3 subsidiaries across Germany to guarantee the satisfaction of our customers.

In close contact with its customers FUCHS develops custom-made, innovative and reliable solutions for the most diverse applications. Whatever their requirements we have the ideal lubricant for their specific applications and processes. In our technology center we link interdisciplinary expertise in a quick and efficient way – and work on innovative lubricant solutions to meet the demands of today and tomorrow every single day.

FUCHS lubricants stand for performance and sustainability, for safety and reliability, for efficiency and cost savings. They represent a promise: technology that pays off.

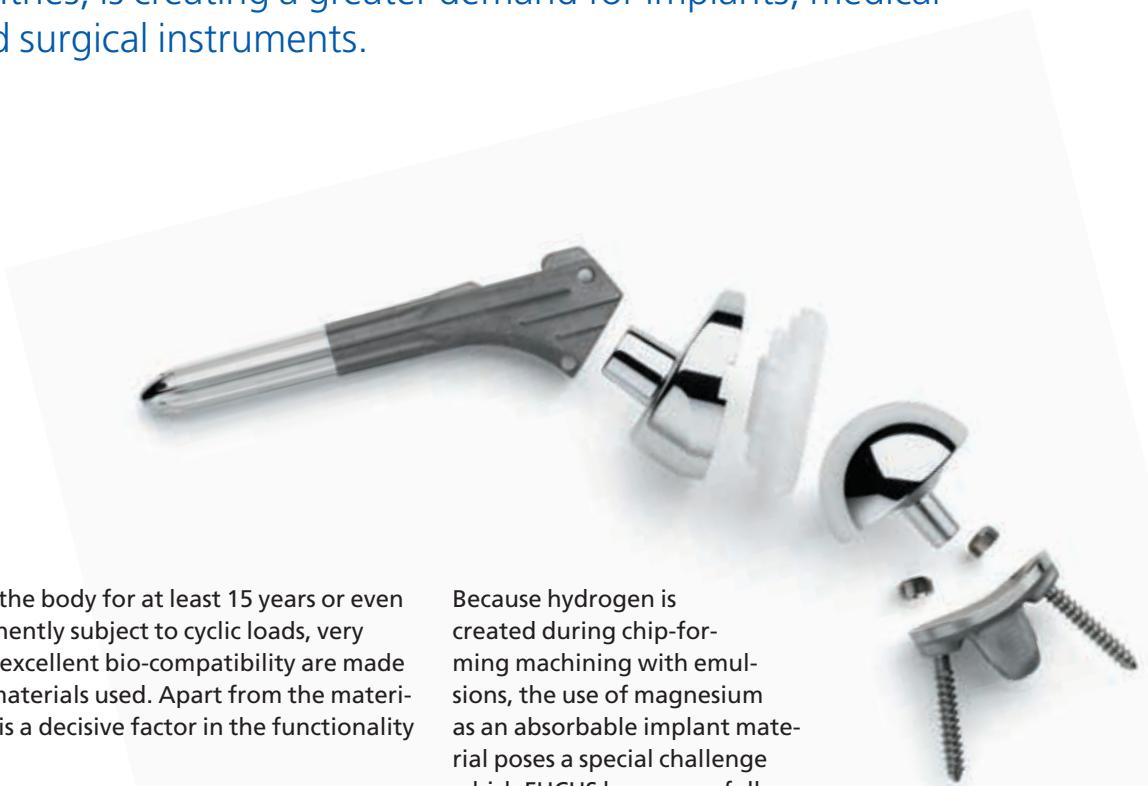
# LUBRICANT SPECIALISTS FOR THE MEDICAL INDUSTRY

The world is changing. Increases in life expectancy spurred by growing awareness of "healthy lifestyles" in the West and increasing populations in emerging countries, is creating a greater demand for implants, medical equipment and surgical instruments.

As implants remain in the body for at least 15 years or even longer and are permanently subject to cyclic loads, very high demands such as excellent bio-compatibility are made on the quality of the materials used. Apart from the material itself, surface finish is a decisive factor in the functionality of an implant.

Stainless steels, cobalt and chrome alloys as well as ceramics but above all titanium alloys are mostly used. These materials are characterized by high tensile strength, resistance to fatigue and thus by difficult and cost-intensive machining. For these reasons, cutting fluid selection plays an essential role in guaranteeing the highest medical standards while maintaining machining efficiency. For each processing step, FUCHS offers an optimum product, from water-miscible metalworking fluids, neat oils and for minimum quantity lubrication applications to special universal oils which display excellent properties for both machining operations and machine tool hydraulics.

Because hydrogen is created during chip-forming machining with emulsions, the use of magnesium as an absorbable implant material poses a special challenge which FUCHS has successfully overcome with special, newly-developed products. The advantage of magnesium, which is also present in the body, is its automatic degradation which eliminates the need for further surgery after the implant has been fitted. We are also fully conversant with the latest cleaning processes through our participation in the NMI research project into innovative cleaning procedures in medical technology as well as the enormously important certification process. Reassure yourself about the effective and efficient application of the latest high-tech cutting fluids and comprehensive service offer from the initial consultation to routine subsequent checks from the number one lubricant specialist.





### Highest lubricant performance

Cutting and grinding fluids in the medical technology industry along with the manufacturing methods as well as the final cleaning of the components are an integral part of the component licensing. This means that every change must be examined for influence on the life or the sterility of the component.

Very high demands are thus made on the lubricants and the qualified cleaners.

### Special demands

When developing innovative solutions, cooperation with the lubricant manufacturer starting at the development phase is crucial.

Firstly, to guarantee the economics of the process and to prolong tool life. Secondly, to perform the process with the maximum reliability.

One possible risk is the drag-in of contaminants which could cause problems during final cleaning.

### Specialists for the machining of medical technology materials

The materials used in the medical sector pose great demands on a cutting fluid. Special demands are made on material compatibility, foaming, high-pressure stability and lubricity.

FUCHS has perfect lubricant solutions for every medical material.



Source: BVMed





## NON-CYTOTOXIC METALWORKING FLUIDS

All FUCHS metalworking fluids fulfill the highest technical standards with an emphasis on long tool life, high cutting performance, excellent surface finish and outstanding removability. At the same time, health and safety at work are fulfilled as well as good skin compatibility.

## 1. Metalworking fluids for all machining processes:

### Titanium and Cobalt alloys, Chrome-Nickel steels

Water-miscible cutting fluid Emulsion	Water-miscible cutting fluid Synthetic	Neat oil	Minimum quantity lubrication (MQL)
ECOCOOL TN 2525 HP-BFH	ECOCOOL S-AERO	ECOCUT 7520 LE-S	ECOCUT MIKRO PLUS 20
ECOCOOL AFC 1515 BF		PLANTOCUT 10 SR	PLANTO MIKRO UNI
		ECOCUT HS	PLANTO MIKRO 830 S-CS
		ECOCUT FE	
		ECOCUT HFN 46 LE	
		UNIFLUID 10 und UNIFLUID 32	

## 2. Industrial lubricants for the medical technology:

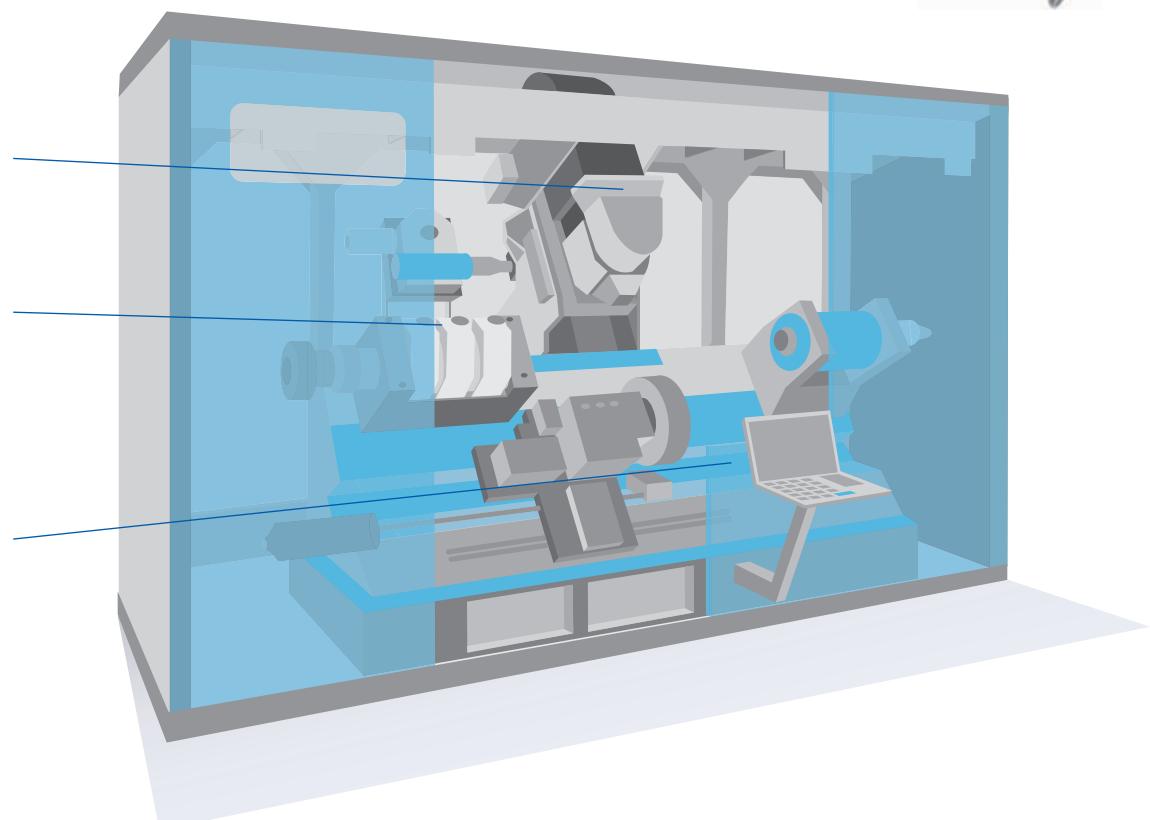
### Complete machine program with cytotoxic test



**Hydraulic oils**  
RENOLIN ZAF B 46 HT  
UNIFLUID REIHE

**Greases**  
RENOLIT SF7/041  
RENOLIT GFW 00  
RENOLIT HI-SPEED 2  
RENOLIT CHUCK PASTE

**Slideway oils**  
RENEP CGLP 220  
RENEP CGLP 68



## Non-cytotoxic cutting and grinding fluids



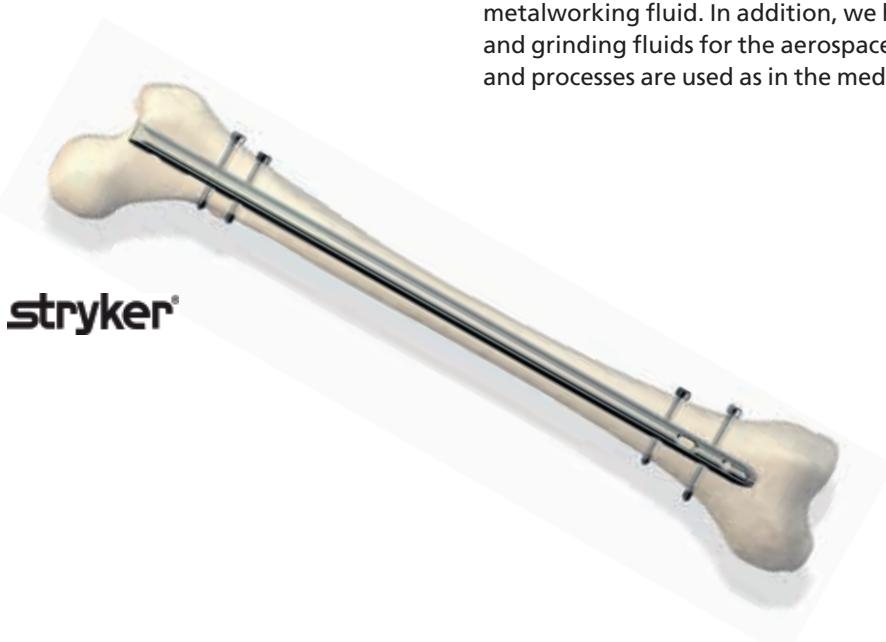
Bildquelle: BVMed



The ability of a substance to damage tissue cells is described as cytotoxicity. This characteristic plays an important role in the manufacturing of implants because these have to grow together with body tissues to function as planned. If however, traces of cutting and grinding fluid residues remain on the implant which cannot be completely removed during final cleaning, there may be a risk of complications developing such as the implant working loose or that its integration by cell fusion may be impaired. To avoid such risks, FUCHS has a number of non-cytotoxic cutting and grinding fluids in its product line-up for all machining processes on the common implant materials so that all conceivable medical technology applications can be performed without risk. These products fulfill the highest demands on the machining of medical technology materials. PLANTOCUT 10 SR is rapidly biodegradable along with offering very high machining performance; ECOCUT 7520 LE-S is not water-miscible and is recommended for applications which demand very good surface finishes. Both products have passed cytotoxicity tests.

For the machining of ceramics, only tools with non-geometrically defined cutting edges are used. In particular for grinding operations on aluminium or zirconium oxides, which are often used for hip joint balls, knee implants or medical instruments, the lubricant plays an important role because even the smallest of flaws can lead to cracks and breakages because of the brittleness of ceramics. Research by the University of Iowa has shown that the use of certain neat oils causes  $\text{Al(OH)}_3$  and  $\text{Me}_2\text{SiO}_5$  to be formed on surfaces which allows easier material removal and significantly less below-surface damage. Here again, we recommend the two non-cytotoxic neat oils ECOCUT HS and ECOCUT FE.

The two multifunctional oils UNIFLUID 10 and UNIFLUID 32 are also non-cytotoxic and are perfect as cutting fluids and hydraulic oils. The experience which FUCHS has gathered in numerous research and development projects and practical trials with leading medical technology companies means that the company has the first-class technical knowhow necessary to select the optimum metalworking fluid. In addition, we have a wealth of experience with cutting and grinding fluids for the aerospace industry where almost identical materials and processes are used as in the medical technology sector.



**stryker®**



Brand name	Properties	Application
<b>ECOCUT 7520 LE-S</b>	Low misting and evaporation (improved workplace hygiene), non-water soluble, non-cytotoxic, generates excellent surface finishes, long tool life.	Especially suitable for difficult-to-machine materials such as titanium, cobalt-chrome alloys, chrome-nickel alloys and other high-alloy steels. For deep-hole drilling, broaching and thread cutting.
<b>PLANTOCUT 10 SR</b>	Synthetic esters based on harvestable raw materials, low water pollution potential, non-water soluble, non-cytotoxic, almost fully biodegradable. Optimized wetting, cooling and flushing, minimal workplace pollution, very low evaporation losses and very high flashpoint.	Universally-applicable, especially for the machining and grinding of difficult-to-machine materials (titanium, cobalt, stainless steels).
<b>ECOCUT HS</b>	Based on semi-synthetic, aromatic-free hydrocarbons, non-water soluble, non-cytotoxic, good flushing, low foaming, good corrosion protection, low odour.	Especially suitable for the high-speed grinding of CoCr steels and ceramics. Also for other grinding operations and honing.
<b>ECOCUT FE</b>	Based on aromatic-free hydrocarbons, non-water soluble, non-cytotoxic, low viscosity, outstanding surface finishes, very long product life, good flushing, extremely low evaporation, minimal workplace pollution.	Optimized for tool grinding, superfinishing and the fine grinding of ceramics.



## Manufacturing process of medical products

Raw material



Metalworking

### **ECOCOOL / ECOCUT**

- turning
- milling
- drilling
- thread cutting
- grinding
- polishing

Corundum  
blasting

Cleaning  
**RENOCLEAN**

Fuchs offers special cleaners for optimum intermediate and final cleaning of medical implants and instruments.

These have been designed specifically for use following processing with FUCHS machining cleaners.



## Coating

## Laser printing

Every product gets its own serial number. This ensures full traceability if necessary.

## Passivation

## Finished part



The only way to guarantee consistently high quality of medical products is to understand the entire process and the matched auxiliary materials used during machining and to employ reliable quality control.

Irrespective of this, each new process or process change must pass the necessary tests (for example cytotoxicity test, etc.) and be both checked and validated in its entirety.

Source: BVMed

## Special lubricants



To improve the machining of high-tensile and ductile materials such as titanium, FUCHS has developed ECOCOOL TN 2525 HP-BFH, a new high-pressure and high-performance water-miscible cooling lubricant. It is suitable for use at pressures of over 100 bar. The coolant is free of boron and formaldehyde and requires very little maintenance. High pressure machining generates early chip breakage and thus

significantly better surface finishes and longer tool life because the heat normally generated when titanium is machined is significantly lowered. An increase in cutting speed may also be realized. In addition, synthetic ester-based cooling lubricants are well-suited to high-pressure machining because of their outstanding air separating capabilities.

Brand name	Properties	Application
ECOCOOL TN 2525 HP-BFH	Water-miscible, high lubricity, boron-free, free of formaldehyde	For high pressure applications > 100 bar.

## Multifunctional oils



By using the two special, non-cytotoxic multipurpose oils UNIFLUID 10 and UNIFLUID 32, which can be used as cutting oils as well as hydraulic oils, cross-contamination can be prevented so that no problems arise when components are finally cleaned. Cleaners are easily saturated with contaminants and cleaning performance then suffers. In addition, mixtures can impair the functionality and service life of cutting fluids. Disadvantages caused by leakage losses via com-

ponents or chips are eliminated by the use of universal oils. Large potential savings and lower maintenance and monitoring costs can be achieved by internal recycling while maintaining optimum performance. With its universal fluids, FUCHS products can offer significant cost reductions. Both products are suitable for about 80 % of all machining processes on materials which are used in medical engineering applications.

Brand name	Properties	Application
UNIFLUID 32	Multipurpose oils based on synthetic esters, non-cytotoxic, rapidly biodegradable, non-water polluting, high flash-point, can be recycled.	High cutting and machining performance, for machining and hydraulics.
UNIFLUID 10	Multipurpose oils based on synthetic esters, non-cytotoxic, rapidly biodegradable, non-water polluting, high flash-point, high-pressure stable, homogenous recycling possible.	For machining and machine lubrication.

## Magnesium machining



The use of magnesium alloys for the application as body-absorbable components is in its infancy. However, FUCHS already has suitable cutting fluids in its product portfolio for these implant materials. The absorption characteristics of this implant material, which is primarily used for broken bones, can be influenced by geometry and the machining process. Porous implants as well as solid implants are used. FUCHS has already gathered comprehensive experience with this material from the automotive sector. As magnesium reacts with water to form magnesium hydroxide while

releasing hydrogen, all machining operations with water-miscible cutting fluids pose considerable challenges which FUCHS has succeeded in controlling with specially matched products. As the hydrogen formation increases when porous magnesium implants are machined due to the larger surface area, FUCHS uses special water-miscible cutting fluids which largely inhibit hydrogen formation. But straight cutting fluids based on highly-refined mineral oils and synthetic esters can also be used.

Brand name	Properties	Application
ECOCOOL 2516 MG-REIHE	Water-miscible, good emulsion stability.	For magnesium machining.
ECOCUT HFN 16 LE	Non-water-miscible, based on mineral oil.	For magnesium machining.
UNIFLUID 10	Multipurpose oils based on synthetic esters, high pressure suitability.	For machining and machine lubrication, magnesium machining.

## Minimal quantity lubrication (MQL)



Source: Bielomatik Leuze GmbH + Co. KG

Minimum Quantity Lubrication is gaining increasing acceptance in the area of machining operations on very difficult-to-machine metals. The reduction in the amount of the MQL-fluid used results in significant cost savings.

Minimum Quantity Lubrication is ideally suited to the drilling of implant plates or the micro-milling of the "shape-memory" alloy Nitinol which displays an extraordinary tendency to form cutting edge build-up.

PLANTO MIKRO UNI and ECOCUT MIKRO PLUS 20 are

recommended for Minimum Quantity Lubrication applications. These products are characterized by the following properties:

- **neutral odour**
- **no residue formation**
- **extend tool life**
- **non-toxic**
- **low water pollution potential**

Brand name	Properties	Application
PLANTO MIKRO UNI	Synthetic esters based on harvestable raw materials, low water pollution potential.	Minimum Quantity Lubrication.
ECOCUT MIKRO PLUS 20	Based on fatty alcohols, good cooling, no residues.	Minimum Quantity Lubrication.

PLANTO MIKRO UNI is ester-based; ECOCUT MIKRO PLUS 20 contains fatty alcohol. Both products are suitable for internal and external fluid feeds in 1 and 2 channel systems.

## Cleaners for optimum process safety



The manufacture of instruments and implants is subject to very strict requirements. The cleaners used for intermediate cleaning must reliably and thoroughly remove machining materials such as oil, wax, cooling lubricants, lapping and polishing pastes, etc. The final cleaning process always requires the highest cleanliness levels here.

Cleaning of implants and surgical instruments not only has a key part to play at the end of the manufacturing process. Even impurities or soiling in the ppm range can lead to serious complications with implants, for example. A stable process is therefore a top priority for compliance with the high quality standards that medical devices must meet. However, there is no patent solution for optimum coordi-

nation of the cleaning process or system & process engineering. Instead, this results from assessment of the entire production environment. Key criteria in this regard are the materials to be cleaned, the size and geometry of the components, the type and quantity of soiling, the throughput, the necessary flexibility and obviously the specifications in terms of film-based and particulate cleanliness. When using aqueous cleaners, it is a good idea to clarify material compatibility and the results that can be achieved in advance by performing cleaning tests.

Shipping/freight containers, tools and tool holding fixtures, as well as the production rooms must also be properly sanitized using suitable cleaning products.

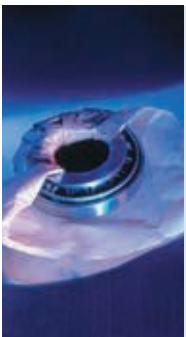
Brand name	pH/FP	Intermediate cleaning	Final cleaning	Description
RENOCLEAN FDC 4001	12.1	++	+	High-alkaline, phosphate-based cleaner for cleaning medical components in dipping and ultrasonic systems
RENOCLEAN MTA 3003	9.7	++	-	Phosphate-based cleaner for dipping and spray cleaning systems used to clean steel, stainless steel, cast iron, non-ferrous metal and aluminum surfaces
RENOCLEAN MTA 2001	7.7	++	++	Neutral, phosphate-based builder, free of surfactants, silicates and borates; suitable for dipping, ultrasonic and spray cleaning systems when used in connection with corresponding surfactant
RENOCLEAN MTA 4001	10.2	++	++	Medium-alkaline, phosphate-based builder, free of surfactants, silicates and borates; suitable for dipping, ultrasonic and spray cleaning systems when used in connection with corresponding surfactant
RENOCLEAN FTA 4001	12.9	++	++	High-alkaline, phosphate-free builder, suitable for steel, cast materials, titanium; suitable for dipping, ultrasonic and spray cleaning systems when used in connection with corresponding surfactant
RENOCLEAN FTA 4002	12.5	++	+	High-alkaline, phosphate-based builder, suitable for steel, cast materials, titanium; suitable for dipping, ultrasonic and spray cleaning systems when used in connection with corresponding surfactant
RENOCLEAN TENSID 161	8.6	++	++	Surfactant combination with demulsifying properties for pressure-flooding, dipping, ultrasonic and, in some cases, also spraying applications
RENOCLEAN MST 2001	6.0	++	++	Surfactant combination with demulsifying properties for spray, dipping, ultrasonic and spraying applications
RENOCLEAN VR 1500	8.5	++	++	Surfactant combination with demulsifying properties primarily for spraying applications
RENOCLEAN MTS 7001	≥ 61 °C	+	++	Modified alcohol, predominantly for final/fine cleaning
RENOCLEAN MVS 8015	≥ 56 °C	+	++	Isoparaffin-based Hydrocarbon cleaner primarily for the final and fine cleaning
RENOCLEAN MVS 8016	≥ 62 °C	+	++	Isoparaffin-based Hydrocarbon cleaner primarily for the final and fine cleaning
RENOCLEAN GSO 3001	8.5	--	--	Cleaning of shipping/freight containers and all kinds of tool holding fixtures, including those made from plastics
RENOCLEAN GXA 4014	11.7	--	--	Cleaners for maintenance, for example used for general cleaning, as well as cleaning transport devices, tiles, workshop equipment and workshop floors (both manually and with machines)
RENOCLEAN SPEZIAL 2000	10.9	--	--	Cleaners for cleaning metal and plastic surfaces, as well as hall and workshop floors

++ suitable    + suitable after test    - not recommended    -- other application

# Perfect solutions for your manufacturing process

FUCHS, the world's largest independent lubricant manufacturer, offers not only a broad product-range of lubricants for metal working processes, but much more the specific know-how, the experience in applications and customized solutions.

**Example:** The manufacturing of gears.

 <p><b>ECOCOOL</b></p> <p><b>MACHINING: WM*</b></p> <ul style="list-style-type: none"> <li>▪ High performance</li> <li>▪ High efficiency</li> <li>▪ Excellent lubricating characteristics</li> </ul>	 <p><b>ECOCUT</b></p> <p><b>MACHINING: NWM**</b></p> <ul style="list-style-type: none"> <li>▪ Increased safety</li> <li>▪ High efficiency</li> <li>▪ Reduced oil mist and low evaporation</li> </ul>	 <p><b>THERMISOL</b></p> <p><b>QUENCHING</b></p> <ul style="list-style-type: none"> <li>▪ Reduced distortion</li> <li>▪ Low consumption</li> <li>▪ low evaporation losses</li> </ul>
 <p><b>RENOCLEAN</b></p> <p><b>CLEANING</b></p> <ul style="list-style-type: none"> <li>▪ High washing performance</li> <li>▪ High process stability</li> <li>▪ Excellent emulsifying and demulsifying properties</li> </ul>	 <p><b>RENOLIT</b></p> <p><b>LUBRICATING: GREASES</b></p> <ul style="list-style-type: none"> <li>▪ Compatible</li> <li>▪ Permanent and long-term lubrication</li> <li>▪ Optimal compatibility with sealing materials</li> </ul>	 <p><b>RENOLIN</b></p> <p><b>LUBRICATING: OILS</b></p> <ul style="list-style-type: none"> <li>▪ Compatible</li> <li>▪ High corrosion prevention</li> <li>▪ Optimal wear protection</li> </ul>
 <p><b>ANTICORIT</b></p> <p><b>PROTECTING</b></p> <ul style="list-style-type: none"> <li>▪ Perfect corrosion protection</li> <li>▪ Clean application</li> </ul>		

## Notes

The information contained in this product information is based on the experience and know-how of FUCHS SCHMIERSTOFFE GMBH in the development and manufacturing of lubricants and represents the current state-of-the-art. The performance of our products can be influenced by a series of factors, especially the specific use, the method of application, the operational environment, component pre-treatment, possible external contamination, etc. For this reason, universally-valid statements about the function of our products are not possible. Our products must not be used in aircrafts/spacercrafts or their components, unless such products are removed before the components are assembled into the aircraft/spacercraft. The information given in this product information represents general, non-binding guidelines. No warranty expressed or implied is given concerning the properties of the product or its suitability for any given application.

We therefore recommend that you consult a FUCHS SCHMIERSTOFFE GMBH application engineer to discuss application conditions and the performance criteria of the products before the product is used. It is the responsibility of the user to test the functional suitability of the product and to use it with the corresponding care.

Our products undergo continuous improvement. We therefore retain the right to change our product program, the products, and their manufacturing processes as well as all details of our product information sheets at any time and without warning, unless otherwise provided in customer-specific agreements. With the publication of this product information, all previous editions cease to be valid.

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## Experienced consultation

Every lubricant change should be preceded by expert consultation on the application in question. Only then the best lubricant system can be selected. Experienced FUCHS engineers will be glad to advise on products for the application in question and also on our full range of lubricants.

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