Boehringer Ingelheim

RESOMER®

Your Source for Resorbable Polymers

Proven High Quality Products for Medical Devices, Pharmaceutical Formulations and Tissue Engineering

Boehringer Ingelheim

Boehringer Ingelheim Corporation - which is privately held - ranks among the top 20 pharmaceutical companies in the world, and with almost 32,000 employees, maintains its own research, development, production, and distribution facilities around the globe.

The Human Pharmaceutical business is complemented by an innovative Industrial Customer business of Fine Chemicals and Biopharmaceuticals.

Fine Chemicals

As part of the Corporate Division Chemicals, Boehringer Ingelheim Fine Chemicals looks back at more than 100 years of experience in organic chemistry in a Pharmaceutical environment. As a result, Boehringer Ingelheim Fine Chemicals is able to offer a broad range of high quality products and a full line of services, such as process development, laboratory and industrial scale production according cGMP and regulatory support.

Monomers and Resorbable Polymers

Boehringer Ingelheim Fine Chemicals has pioneered the commercial production of monomers and biodegradable polymers for more than 20 years.

The mission of the RESOMER® Group within Boehringer Ingelheim Fine Chemicals Division is to develop, produce, and sell monomers and biodegradable polymers for the use in the medical field.

The trade mark RESOMER® represents a range of proven, high-tech polymers, a result of extensive research and continuous development.

Modern production facilities in France and Germany secure the ongoing supply of a large number of high quality monomers and polymers from lab scale to commercial quantities.

Proven high-tech Products

RESOMER® is Boehringer Ingelheim's brand name for a variety of biodegradable polymers mainly made on the basis of lactide and glycolide. Modification of molecular weight, the monomer ratio or using other monomers provide copolymers with different mechanical and degradation properties.

Homopolymers of lactide (polylactides) are mainly used to produce biodegradable implants such as orthopedic fixation devices.

Copolymers of lactide and glycolide form the basis for sustained release Drug Delivery Systems.

The process

The polymers are produced in technically complex processes which have been optimized continually over the years to assure consistent batch-to-batch quality. Our strength is the purification step included in the polymer production, yielding materials with very low residual monomer content.

Monomers are produced in a fully dedicated plant at our Labso site in France. For polymers the production site is Ingelheim, Germany.

Boehringer Ingelheim offers a wide range of standard products. We are also able to produce polymers according to special customer requirements.

Quality you can trust

Boehringer Ingelheim places particular emphasis on the quality of the products. All materials are carefully tested prior to further processing. All products are subjected to continuous quality control measures during the production process which complies with GMP guidelines. A Certificate of Analysis is issued for every batch produced.

All plant operations meet relevant Environment, Health, and Safety (EHS) requirements.

All our business activities are DIN ISO 9001 certified.

Our products are covered by a DMF or MAF, filed with the FDA and are updated annually. Technical documentation can be provided for European registrations on request.

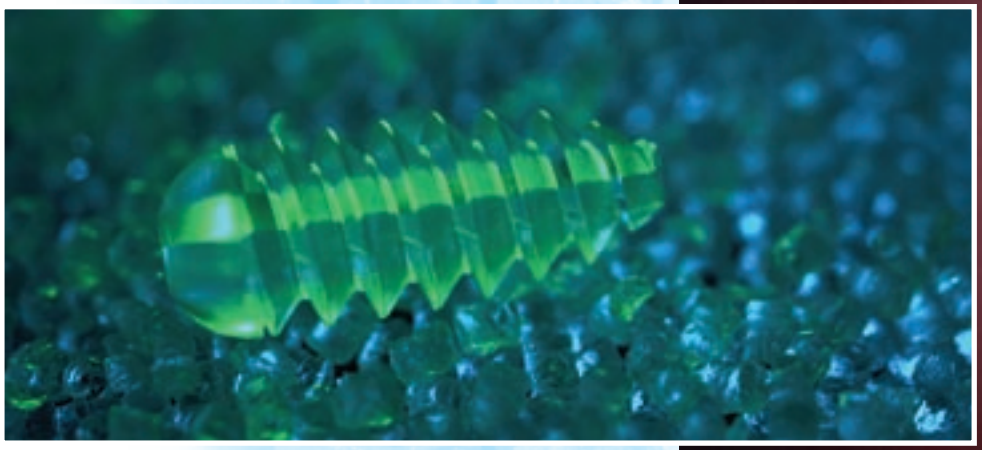
Combined with our competence and the experience we have gained in manufacturing monomers and polymers for over 20 years guarantees top quality and best service.

Biodegradation

Properties

The main benefit of our RESOMER® product line in medical applications is the biodegradation in human tissue after implantation or injection. Body fluids degrade the polymers by hydrolysis into oligomers and eventually monomeric hydroxy acids, which are subsequently metabolised by the body. RESOMER® products have shown good biocompatibility in a wide range of applications.

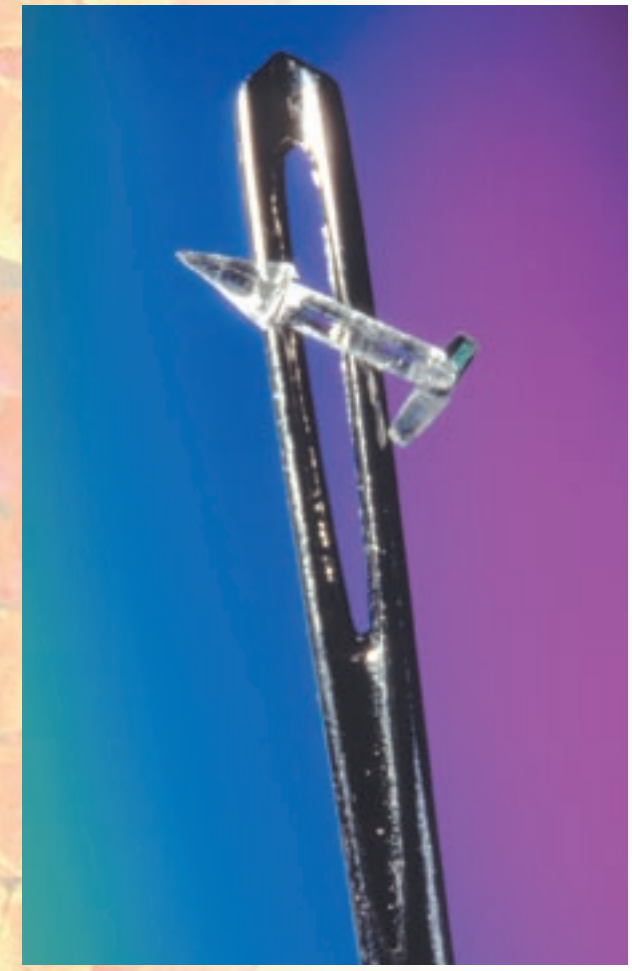
By modification of molecular weight and polymer composition, the degradation rate and mechanical stability can be adopted to the individual requirements of the medical application.



Biodegradable polymers also do not pose any handling problems with regard to processing, storage or safety. They are available in granular form - mainly for medical applications - or in powder form for pharmaceutical formulations.

Stability studies are available, showing the long term shelf life of the polymers under proper storage conditions.

Innovation and Versatility



Applications

Based on its versatile properties, RESOMER® can be used as a raw material for a variety of medical applications.

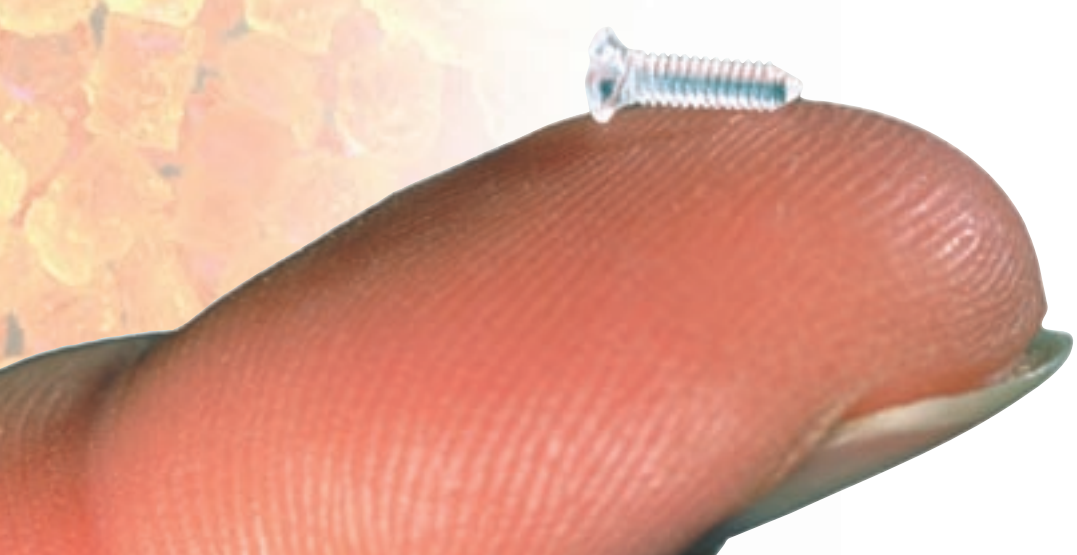
• Osteosynthesis

There are numerous biodegradable implants available in the field of orthopedic surgery, maxillo-facial surgery and operative sports medicine. They have shown distinctive advantages over metal analogs.

RESOMER® products with their adjustable degradation rate and variable mechanical strength offer the right choice for biodegradable implants.

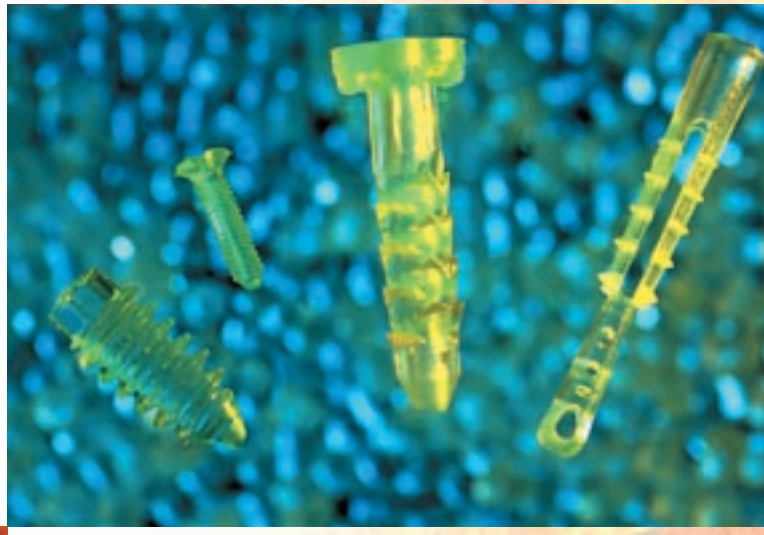
• Wound closure

A traditional field of application of biodegradable materials are surgical sutures. RESOMER® is an ideal raw material for wound closure products as it is easy to handle, well tolerated, and fully absorbed by the body.



• Drug delivery systems

RESOMER® polymers are biodegradable carriers for active pharmaceutical ingredients. Several long-acting formulations, providing therapeutic drug levels to patients over a period of up to four months, are registered and are in clinical use.



Other uses...

for RESOMER® are primarily found in dental medicine as well as in general and plastic surgery. Further exciting new applications are presently under evaluation, for example in Tissue Engineering/Regenerative Medicine.

RESOMER® a brand you can trust

The advantages provided by RESOMER® are obvious:

- low residual monomer content
- high level of purity and good product tolerance
- excellent mechanical properties
- a wide range of standard formulations, covered by DMF or MAF in the USA
- an effective custom synthesis service tailored to individual product requirements
- comprehensive and competent technical assistance
- a high standard of quality in line with GMP requirements
- DIN EN ISO 9001 certification
- the experience and resources of a global company

Technology of the future

The wide range of possible uses for biodegradable polymers will continue to be explored and expanded in the future.

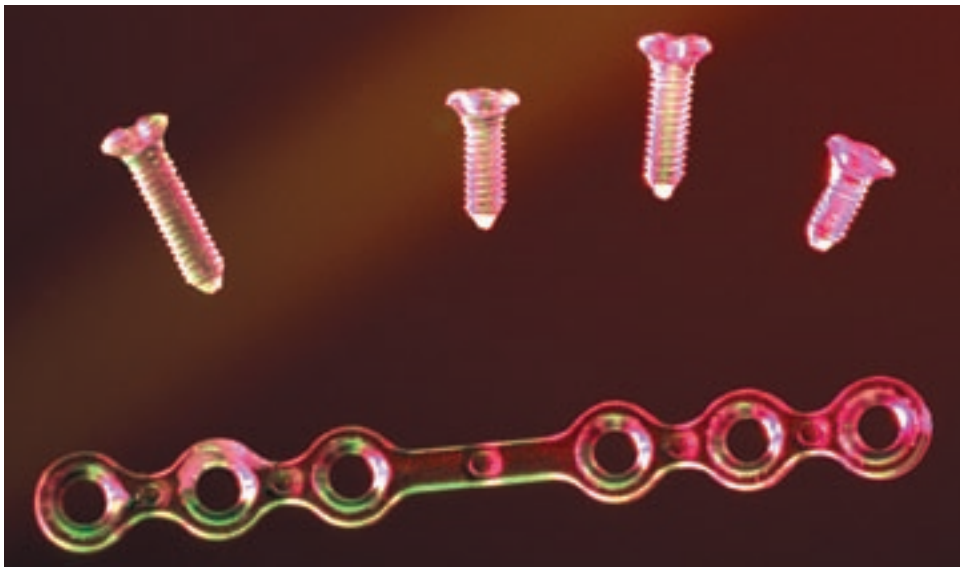
More and more products benefit from the innovative and, above all, patient-friendly properties of polymer based applications.

As in the past, Boehringer Ingelheim will continue to be a reliable and professional partner in the field of biodegradable polymers.

Contacts

If you are interested in learning more about RESOMER® and / or if you have any questions, our competent RESOMER® product team will be pleased to assist you.

You will find the address, telephone or fax number of a representative in your area on the back of this brochure.

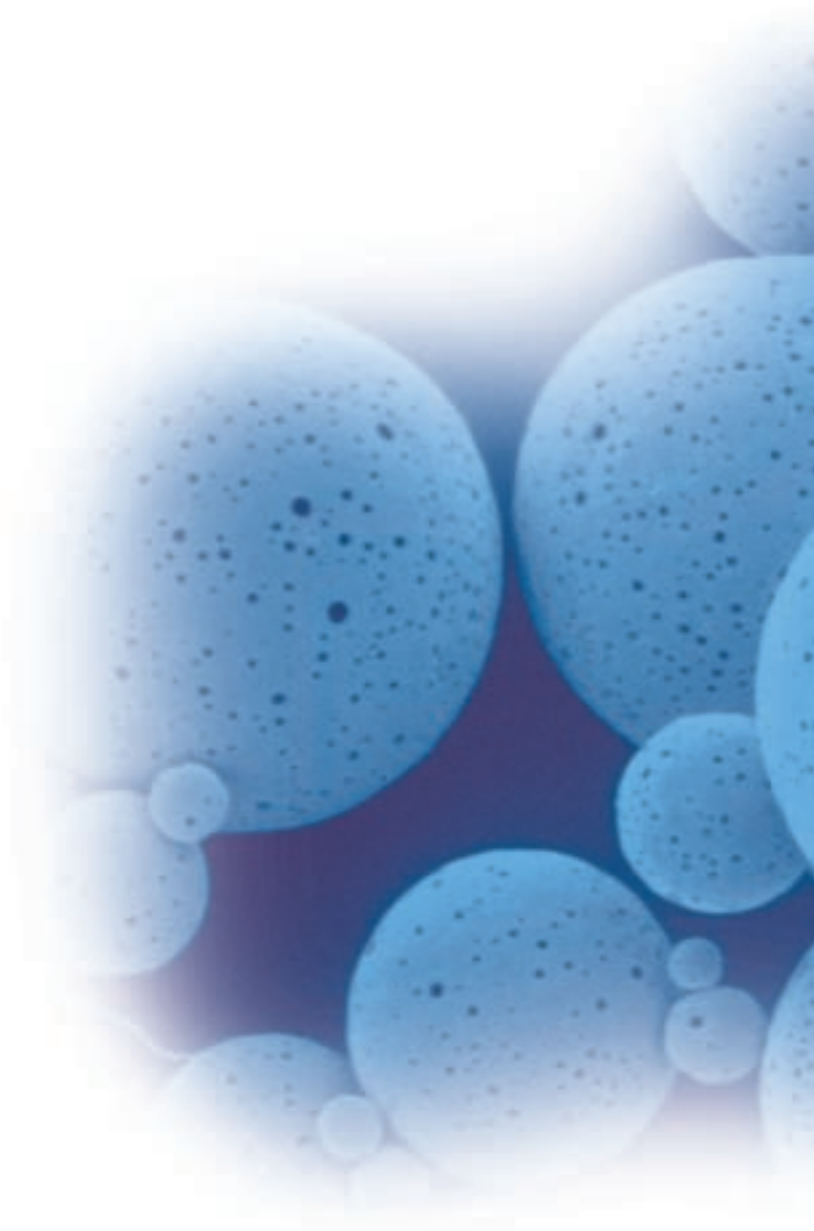


BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG
Fine Chemicals
Binger Straße 173
55216 Ingelheim
Germany
Telephone: ++49 6132 77 2633
Telefax: ++49 6132 77 4330

BOEHRINGER INGELHEIM CHEMICALS, INC.
2820 North Normandy Drive
Petersburg, VA 23805
USA
Telephone: ++1 804 5048600
Telefax: ++1 804 5048637

NIPPON BOEHRINGER INGELHEIM CO., LTD
Fine Chemicals Dept.
Sumitomo-Fudosan Sarugaku-cho Building 10F.
2-8-8, Sarugaku-cho
Chiyoda-ku
Tokyo-101-0064
Japan
Telephone: ++813 5280 7123
Telefax: ++813 5280 0851

BIDACHEM S.P.A.
Strada Statale 11 (Padana Superiore) 8
24040 Fornovo San Giovanni
Italy
Telephone: ++390 363 3552258
Telefax: ++390 363 351330



The products of the Boehringer Ingelheim companies are produced or distributed in accordance with the applicable local laws in the country of origin. However, it is the sole responsibility of the user of our products to make sure that the application of the products is done in accordance with the applicable laws.

e-mail: resomer@ing.boehringer-ingelheim.com
Internet: www.boehringer-ingelheim.com/finechem

18803/06/03