

# SILICONE FOR THE MEDICAL, PHARMACEUTICAL AND FOOD INDUSTRIES

Choose Primasil as your trusted partner



# YOUR TRUSTED PARTNER



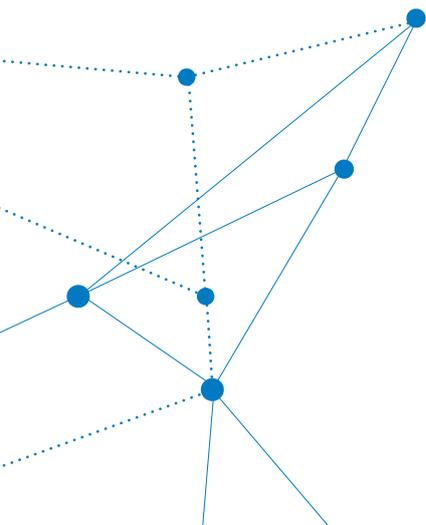
As a privately owned and independent company, we can provide all of the services you need from a leading silicone manufacturer. From sourcing appropriate Liquid Silicone Rubber (LSR), compounding High Consistency Rubber (HCR), right through to processing the material using our extensive moulding, extrusion and calendaring manufacturing facilities, all on one site in the UK.

We work closely with our customers through the product development stages from product realisation to full production. Our manufacturing facilities offer flexibility to cater for low volume prototyping and clinical trials through to large volume production.

**“Primasil has been brilliant. They got involved right at the start of the project and worked hand in hand with us to make it happen”**

**HEALTH PRODUCT OEM PROJECT MANAGER**

- Liquid Silicone Rubber (LSR) and High Consistency Rubber (HCR) mouldings
- Platinum and peroxide catalyst
- Extruded silicone profiles and tubes
- Silicone calendered strip
- Silicone sheets
- Assembly and packaging
- Product development



# FLEXIBILITY WITHOUT LIMITS

## KEY ADVANTAGES OF SILICONE RUBBER

- Biocompatible and non-toxic
- Withstands common sterilisation methods
- Operating temperature range of -50°C to +250°C
- Hardness ranging from 10 to 90 Shore °A
- Can be pigmented to virtually any colour
- Inherently flame-retardant
- Weather and ozone resistant
- Electrically conductive or insulating

Silicone rubber is flexible in every sense of the word. Through subtle alterations of its chemistry, we bend and shape its properties to meet the demands of widely differing products. Tubing, tourniquets, chemotherapy cooling caps, liver slings, mats and inserts for surgical trays, duckbills and conical seals are just a few examples. No matter how large, small or intricate the component, we have the experience and manufacturing capabilities to produce it.

Primasil can offer Liquid Silicone Rubber (LSR) or High Consistency Rubber (HCR), with a platinum or peroxide catalyst.

As the European leader in this field you can trust us to match the exact needs of your application.

Our facilities support both cleanroom and normal shop floor operations, depending on the nature of the product, which gives us the flexibility to tailor production to your project schedule and budget.

Our company is quality-led, as reflected in our certifications below. To produce materials, components and finished items for the medical industry we also have the following specific accreditations:

- ISO 13485:2016 certified
- ISO 9001:2015 certified
- FDA registered
- ISO 14644-1:2015 ISO Class 7 cleanroom
- ISO 14001:2015 certified



# COLLABORATION AND INNOVATION

In many cases, by combining our expertise with that of leading academic institutions and industry partners we have succeeded in accelerating innovation and developing exciting medical solutions.

Our on-site R&D facilities play a crucial role in developing ground-breaking solutions and our passion for advancing science is demonstrated by the success of many of our projects. The knowledge we gain from research benefits all of our customers across many industries and it allows us to apply this state-of-the-art technology throughout our offering.



## CASE STUDY

### BIOFORS

#### UV-induced Biofilm prevention

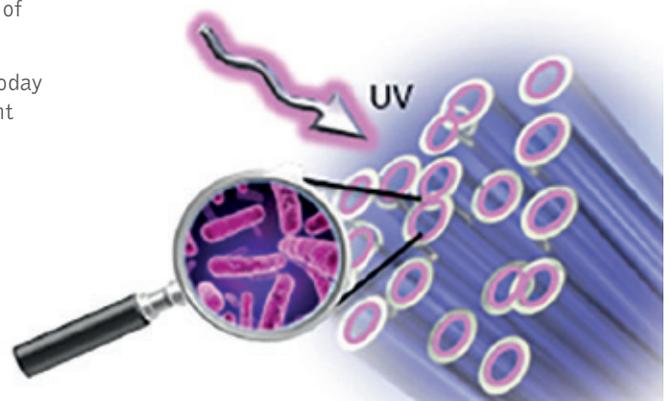
Bacteria-related infections, growing in biofilms on medical equipment during use, is a major problem for hospitalised patients and is associated with high costs for the healthcare system.

Primasil and a number of partners in research, development and production have come together in one interdisciplinary, international collaboration known as BIOFORS. The prime goal is to find an appropriate solution for medical tubing, using controlled release of UV light, but also through surface modifications.

UV light has a well-known cell-killing effect and is today used in many different areas such as water treatment and disinfection of air. The European consortium is developing a UV-conductive structure on the inside of medical tubing using silicone.

The UV light will then be transported along the length of the tube and continuously released from its inside in order to prevent biofilm growth.

Minimising biofilm formation on the inner surface of medical tubing will lead to reduced risk of patient infection and related health problems, and result in huge savings for the healthcare system.



**CASE STUDY**

**PAXMAN COOLING CAPS**

**If the cap fits...**

For many cancer patients, the worry and discomfort from their diagnosis and chemotherapy treatment is compounded by the confidence-sapping side effect of hair loss.

In collaboration with a university partner, Primasil helped Paxman to develop its initial, innovative cooling cap in the 1990s. Essentially it consists of a compact refrigeration system connected to a lightweight silicone rubber cap made from HCR. By lowering the head and scalp temperature immediately before, after and during treatment, it reduces blood flow to the follicles and so prevents or minimises damage.

To make the device even more effective and satisfy growing demand, the collaboration improved the cap's fit and introduced greater levels of automation to its production process.

Our first challenge was to create a new formulation which would give the cap sufficient flexibility to adapt to varying head shapes and sizes across the world. Our second task was to review the manufacturing process and automate it wherever possible, allowing more efficient and higher volume supply in response to market needs and opportunities.



**CASE STUDY**

**EmerEEG**

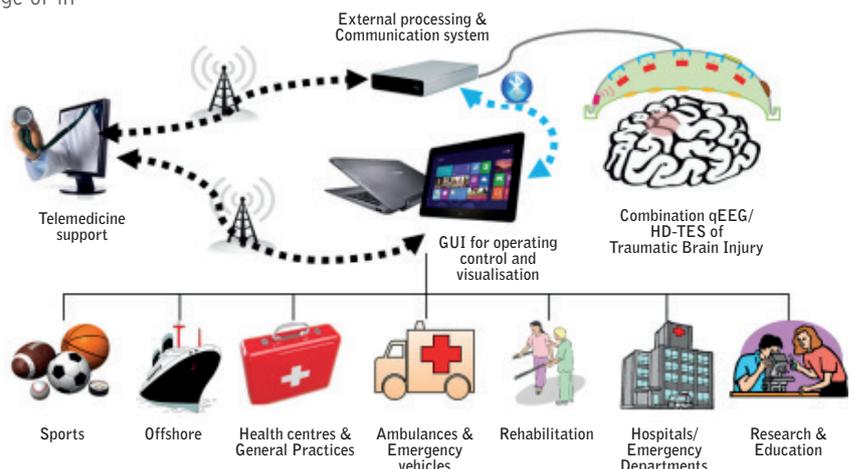
**Traumatic Brain Injury diagnosis**

Traumatic Brain Injury (TBI) is recognised as a major public health concern, especially for teenagers and young adults, since it can lead to significant disruptions in education, working ability and quality of life in general. It is one of the leading causes of death and disability worldwide. Currently, there is no objective method for diagnosing TBI in an early stage or in emergency, which is a premise to prevent serious health impact.

Primasil have joined forces with a European consortium to develop a portable medical device for the reliable emergency diagnosis of TBI. Primasil's expertise has been fundamental to the development of a vacuum-based helmet device that

allows accurate positioning of up to 32 electrodes as part of the diagnosis method.

The innovation will increase quality of life, improve first-aid care, and healthcare in remote and rural areas. Moreover, society will benefit from sustainable savings in costs for healthcare and for work disability.



# SILICONE COMPOUNDS

## LIQUID SILICONE RUBBER

The popularity of Liquid Silicone Rubber (LSR) in medical device manufacturing owes much to its biocompatibility and the excellent quality of production components.

It is typically supplied in two parts, one of which contains a curing catalyst. These are automatically mixed, along with colours and any other ingredients, as the material is pumped to a press.

## HIGH CONSISTENCY RUBBER

High Consistency Rubber (HCR), or Heat Cured Rubber, also plays a big part in our silicone rubber manufacturing operations. Again a choice is available between platinum and peroxide curing.

## PLATINUM-CURED

For medical applications, we often recommend platinum as the catalyst. Ideally suited for applications where strength, durability, long-life and non-reactivity with bodily fluids and skin are important. Platinum-cured products meet or exceed these global standards:

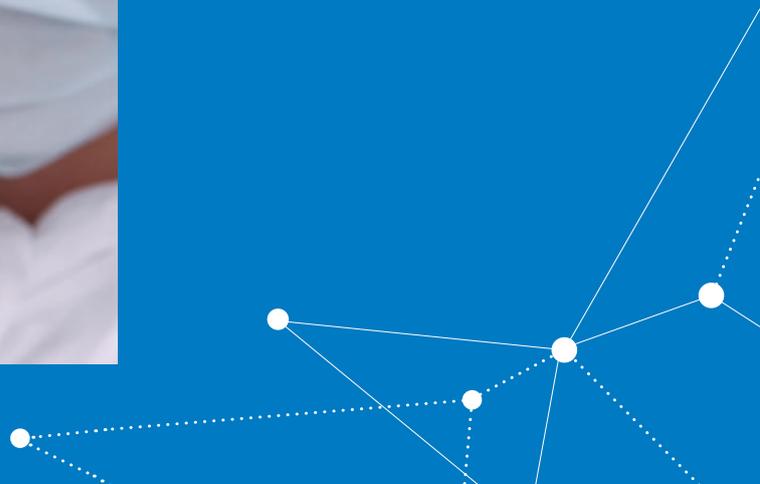
- ISO 10993
- US Pharmacopoeia Class VI
- European Pharmacopoeia 3.1.9
- FDA CFR177.2600
- BfR and FDA Food Contact Regulations

Compared to peroxide-cured materials they have the following advantages:

- Superior clarity
- Smoother inner wall which results in less protein binding
- No contamination from peroxide residues
- Fewer extractables

## PEROXIDE-CURED

Primasil can also provide medical peroxide-cured materials where required.



# EXTRUSION AND INJECTION MOULDING

## EXTRUSION

Extrusion is used to produce tubes, cords or other elongated shapes. Compared to other materials, silicone rubber extrusions typically last longer and withstand a wider variety of environmental and thermal conditions.

## MEDICAL TUBING

Silicone medical tube has two main advantages over other materials: it is highly flexible and tear-resistant, and hence ideal for transporting fluids. Plus it contains no plasticisers or other additives that could leach into a drug product and cause toxicological issues.

We can manufacture medical tubing to your preferred bore size and tube length. We also extrude thin-walled medical tubing.

Primasil medical tube is manufactured in line with our ISO 13485 certification and the platinum-cured products are made in our ISO Class 7 cleanroom.

## MOULDING

Injection moulding is particularly useful for large components, high-precision work and high volumes. This production process is extremely efficient and economical, and items can be automatically placed directly into a box avoiding wasteful trimming operations. The savings are

at their greatest with high volume items, so we work closely with specialist tool makers, using the latest CAD technology, to create bespoke steel tooling for optimum precision.

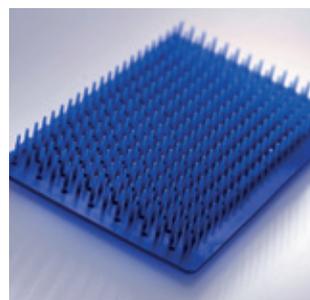
Compression and transfer moulding silicone can be used to support low volume production, as well as providing an alternative approach where the component design demands it. Liquid Silicone Rubber (LSR) moulding is offered in our ISO class 7 cleanroom and our High Consistency Rubber (HCR) production is available on the shop floor.

## THE SAINT TOURNIQUET

The SAINT – the ultimate Single-use Anti-Infection Tourniquet – has been developed to help prevent the spread of hospital-acquired infections.

While other tourniquets tend to be uncomfortable and difficult to use, the SAINT offers a special high-comfort silicone rubber formulation and an easy-secure, easy-release functionality. Its other key benefits are:

- 100% latex free
- FDA compliant
- Conforms to USP Class VI
- Complies with EU MDR 2017/745 and UK MDR 2002, Class 1 Medical Device Single-use only
- ISO 10993



Trust Primasil to meet your medical silicone rubber needs.

Who else would you choose?



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PRIM 09/15 V1