

RECOMBUMIN®

Medical Device Coating

Due to its natural propensities, albumin is widely utilized in the medical device industry for coating of stents and tubing, for instance in dialysis, to improve their biocompatibility. By coating with albumin, a biological interface is created, thereby limiting the exposure of the otherwise incompatible surface to the patient thus increasing product safety. The improved purity and defined nature of our rHA product Recombumin® consistently produces the same surface coverage.

ADDRESSING THE CHALLENGES OF MEDICAL DEVICE COATING

Finding the right coating, which enhances the performance and maneuverability of the medical device and protects it from pathogenic attacks, is an integral part of the development and regulatory pathway.

The ideal product should be biocompatible and biostable, offer excellent lubricity and thermal stability, and moisture-, chemical- and dielectric-barrier protection. Stability and batch-to-batch consistency are also paramount considerations, owing to their impact on performance, efficacy, and safety.

NATURE'S OWN COATING

The biocompatibility of coatings is crucial for developers building the next generation of advanced medical devices while avoiding the risk of toxicity or an immunological response.

The natural properties of recombinant human albumins (rAlb) make them the natural choice for medical device coatings. As a naturally occurring protein, albumin is widely recognized as safe and, with it being ubiquitous throughout the body, is fully biocompatible. In addition, human- and animal-free recombinant versions reduce the risk of unexpected pathogens to zero.

BENEFITS OF RECOMBUMIN®

Only a highly pure albumin, like Recombumin®, facilitates the full exploitation of albumin's potential while eliminating variability and reducing risk. The animal- and human-free product offers excellent batch-to-batch consistency and security of supply, providing safety, efficacy, reliability, and regulatory peace of mind.

As a medical coating, Recombumin is:

- Biocompatible
- Biologically stable
- Chemically inert
- Non-toxic
- Solvent free
- USP-NF compliant
- Manufactured to GMP-grade
- Supported by comprehensive regulatory documentation

CUSTOMER CASE STORY

One of Albumedix valued medical device partners is UK based Chalice Medical. Chalice utilizes Albumedix' product in the surface coating of their ECMO devices (oxygenators/life support machines).

In 2020 Chalice experienced a surge in demand due to the Covid-19 pandemic. In response, Albumedix did all we could to prioritize their shipments and any others related to the outbreak of the virus.



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Albumedix recombinant human albumin (rHA) products are manufactured at cGMP ICH Q7 standards at our own manufacturing site in Nottingham, UK. The products are produced using a proprietary yeast strain (*Saccharomyces cerevisiae*) with very high batch-to-batch consistency. We have more than 25 years of manufacturing experience