



CONTRACT MANUFACTURING SERVICES

Reliable coating services for medical devices

ON THE SURFACE
We touch life first

MANUFACTURING



In today's rapidly changing world,
it makes sense to outsource to a specialist.

Your partner for
**RELIABLE
COATING SERVICES**

World class Medical Device
manufacturers are leveraging
their resources by collaborating
with domain experts.

- Proven manufacturing process
- FDA/CE regulatory support
- ISO 13485 quality system



From small and intermittent runs to high
volume and continuous production, we are
set up to handle your lot quantities and
production needs.

Each lot of products we coat is backed up with rigorous inspection and testing and is
shipped with complete documentation.

Predictable results are critical to successful outsourcing.

In manufacturing, the last things you need are surprises or unpredictability. A reliable and dependable manufacturing partner can be one of your greatest assets, freeing up in-house resources and increasing your ability to deliver consistent results to your customers.

As a highly specialized contract manufacturer, we employ processes that are efficient, reliable, and economical. We perform regular testing and reporting to ensure that you have a clear view of the manufacturing process and the quality of your product.

Incoming Inspection

Following a previously agreed upon inspection plan, we will receive, document and warehouse each incoming lot of materials.

Raw Material Sourcing

Harland offers efficient sourcing of raw materials that conform to your specifications helping optimize the efficiency of your supply chain.

Coating Services

Harland offers fully integrated coating services. From surface preparation to device fixturing, coating and curing, our skilled technicians deliver results. Harland Coating Services can handle any commercial or in-house coating technology, and all services are provided in compliance with our ISO13485 certification.

Inspection and Quality

Based on the quality plan for your product, we inspect and test for a variety of parameters including surface coverage, coating thickness, lubricity, and durability.

Sterilization Services

We coordinate all aspects of sterilization including sterilization validations quarterly dose audits, annual ETO re-qualifications and routine processing.

Warehousing and Delivery

We provide warehousing solutions for coated sub-assemblies or finished products, allowing you to manage your inventory off-site so you can devote your own space to what you do best. We can even work with you to coordinate shipments to your end users.

Documentation

We establish and implement written procedures to ensure that device history records are maintained in accordance with the Device Master Record (DMR) including information on incoming material acceptance, the manufacturing process, dates of manufacture, quantities manufactured, quantities released for distribution and acceptance records.

*Harland Manufacturing
Service save you time and
resources, freeing you to focus
on other opportunities*

*Be confident that
production of your device
is under control.*

MANUFACTURING



THE 4M FRAMEWORK™

Harland manages all of these elements as an integrated program to provide you with a complete surface enhancement solution tailored to precisely meet your particular technical, functional and economic requirements.



MATERIALS — proprietary chemistries that enable advanced surface enhancement on your medical devices, healthcare disposables or life science products. Harland provides unique, world class chemistry platforms for solving customer surface enhancement challenges.

METHODS — processes and protocols to effectively and efficiently apply and cure surface enhancing materials. Harland creates and validates robust methods that optimize the integration of Materials and Machines to meet your product's requirements.

MACHINES — automated systems designed specifically to apply and test advanced Materials on your device. Engineered to meet your technical, commercial and operating requirements including throughput and total cost of ownership.

MANUFACTURING — with either Harland Contract Coating Services or customer- owned coating operations. Harland is uniquely positioned to offer a full spectrum of surface enhancement manufacturing options based on your manufacturing strategy and volume requirements.

Total Solution

As a total solution provider, Harland Medical Systems will work with your team through the entire project, providing feasibility and prototype coated devices, process development (OQ and PQ), regulatory and automation support.

Whether you ultimately choose to take advantage of Harland Medical Systems' ISO13485 certified contract coating capabilities or coat your devices in house, you can be assured of total support through the entire process.

Radically reduce and control the surface friction of you medical device.

Lubricent® UV

Lubricent UV coatings reduce friction forces as much as 98%. This performance enhances the device's ability to navigate through tortuous anatomical pathways while reducing tissue damage and adding to patient comfort.

The photochemical covalent bond to the substrate produces superior adhesion and wear-resistance while minimizing particulate formation.

Lubricent UV is compatible with the substrate materials typically used in the construction of medical devices.

Transform your medical device into a powerful weapon in the fight against healthcare associated infections.

Bacticent® CHX

Broad-spectrum antimicrobial coatings are a powerful weapon in the fight against health care associated infections.

Bacticent CHX features the highly effective chlorohexidine precisely dosed and delivered right from the surface of your medical device.

Engineered to provide the elution profile required by the clinical needs of your device and applications.

Bacticent CHX is effective against the most common gram negative and gram positive bacteria associated with health care associated infections.



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