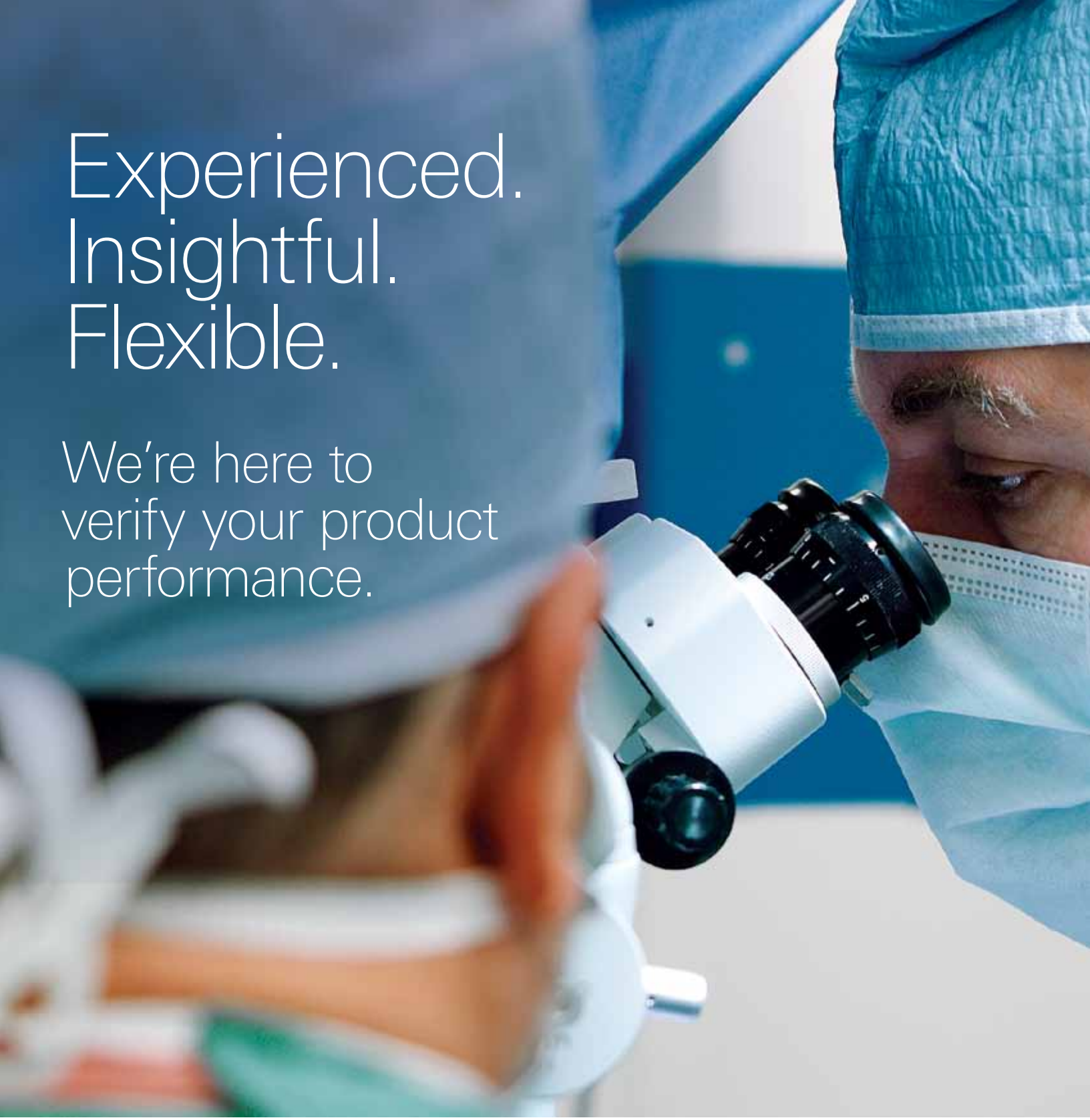

Experienced. Insightful. Flexible.

We're here to verify your product performance.

Efficacy and Functional Studies

NAMSA®

PEOPLE › SCIENCE › SOLUTIONS

Performance. It's the key to a successful product development process.

If your device doesn't perform according to its intended function, your agenda can be turned upside down. So when you're looking for an accelerated path to market, you want a partner who offers a broad range of *in vivo* models and analysis tools that will provide the data you need to support the specific application of your device.

We customize specific methods and models to evaluate the *in vivo* efficacy of your unique device, using preclinical studies to select prototypes and provide understanding of device performance. Our study models are selected by veterinary surgeons to assess function and performance. Our *in vivo* studies mirror the clinical end-use of the device, to verify that it will perform with an appropriate host response in a specific application. We create the most effective program by using the same analysis tools for preclinical and clinical studies. And we follow methods described in the European Committee for Standardization (CEN), U.S. Food and Drug Administration (FDA) standards, and other applicable guidelines.

Our people work together—forming teams that include veterinary surgeons, toxicologists, and pathologists—giving you a performance testing program that is driven by a combination of the very best people and processes available anywhere in the world.

CARDIOVASCULAR

- Cardiovascular studies to assess the blood material interface of a device
- Functional models for coronary and peripheral vascular stents, inferior vena cava filters, vascular prostheses, heart valves and other cardiovascular devices
- Angiography
- Quantitative assessment of thrombus deposition
- Computerized angiography, radiography, CT scan, MRI
- Resin technology histopathology
- Image analysis
- Atherosclerotic models
- Aneurysm models
- Patency, duration of permeability
- Flow measurements
- Sequential surface sampling
- SEM examination
- Material/blood interface
- Embolism in distal organs
- Histopathology of device in situ

DENTAL

- Test methods that reproduce clinical exposure
- Procedures that satisfy ISO, FDA, or ADA requirements
- Specific models for dental implants as well as dental material evaluation
- Histopathology of device in situ

DRUG DELIVERY

- Drug delivery studies
- Evaluations under clinical-like conditions
- Blood level evaluations
- Evaluation of local tolerance
- Other studies related to drug use and intended purpose
- Intraduodenal drug administration

GASTROENTEROLOGY

- Clinic-like treatments or implants
- Shunts
- Liver resection
- Pancreas pathologies
- Intragastric methods
- Histopathology of device in situ

SPECIALIZED PATHOLOGY SERVICES

- Exakt® Histological System for specialized tissue-hard implant processing
- Quantitative Pathology
- Biomarkers and immunohistochemistry
- Ultrastructural Pathology (SEM, TEM)

NEUROSURGERY AND SPINE SURGERY

- Spinal fusion
- Reconstruction of intervertebral disc
- Disc replacement
- Dura/vertebrae anti-adhesion
- Hydrocephalic shunt devices
- Bone repair
- Histopathology of device in situ

OPHTHALMOLOGY

- Corneal healing studies
- Intraocular lens studies (ISO standard)
- Vitreal procedures and replacement materials
- Conjunctival implants
- Aqueous shunts
- Ocular pathology consultation
- Histopathology of device in situ

ORTHOPEDIC AND BONE HEALING

- Assessment of joint replacement, and ligament and tendon reconstruction
- Spine surgery and bone reconstruction implantations
- Anterior crutiate ligament repair
- Ligament and tendon fixation
- Fracture repairs
- Long-bone defect repair
- Cortical, trabecular, cranial, and maxillofacial defects
- Osteoporosis
- Osteomyelitis treatment
- Orthopedic prosthetic infection
- Articular cartilage repair
- Ligamentoplasty
- Arthroplasty
- Spinal fusion
- Reconstruction of intervertebral disc
- Disc replacement
- Histopathology of device in situ
- Evaluation of bone formation rate and osteointegration
- Evaluation of bone mineralization, thrombosis and degradation
- Osteoformation, bone ingrowth, cortical bone anchorage and bone substitute evaluation
- Osteoinduction models

TISSUE ENGINEERING

- Treatment or implant with a matrix or scaffold seeded with animal cells
- Final product implant or treatment
- Routine implant of matrix or scaffold

UROGENITAL SYSTEM

- Clinical-like implants or treatments
- Evaluation of catheter encrustation, coatings, or antiadhesion
- Physical or leakage testing
- Local tolerance tests (implants)
- Bladder positioning and repair models
- Anti-adhesion product evaluations in various models
- Vaginal or penile material testing

WOUND HEALING

- Full and partial skin thickness wounds
- Multiple non-clinical models
- Special models using diabetic rats, atonic wounds, and superficial burns
- Wound treatments with growth factors incorporated
- Sutured and unsutured surgical wounds
- Histopathology of wound healing

SAFETY STUDIES

Safety studies to assess biological safety can be included in the design of a performance study. In certain situations, one study can be conducted to address both safety and performance, accelerating time to market.

- Evaluation of localized tissue response and systemic toxicity of implantable test articles

RECONSTRUCTIVE AND GENERAL SURGERY

- Dermal void fillers
- General void fillers
- Hernia repair
- Hemostatic devices or material models
- Abdominal repair meshes
- Adhesion prevention products
- Suture procedures
- Evaluation of new surgical instruments and techniques

We've been the world's leading medical device research organization for over 40 years.

You want sound advice and action from a partner who can quickly move your product into a global market. So we've made a science out of service, identifying challenges and solving them with the right advice at exactly the right time. We can guide and support you through the most complex submissions and the most rigorous testing programs. We do the work that moves things forward quickly without ever compromising quality. And our passion for scientific integrity gives you the security that you're on the optimal path to market, anywhere in the world.

We've worked with thousands of companies to date—bringing safe, effective, and compliant medical products to market. We are passionate about our people, our scientific integrity, and the breadth of solutions we offer our clients globally. And we're ready. Ready to take you to market.

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