

# Engineering Services

## Product Development - Competence

Eurotope is the specialist in creating flexible, customized and fully automated solutions for nuclear medicine, radiopharmacies and medical device industry. We provide the solutions which are designed to handle or process radioactive material for use in diagnostic, therapeutic or industrial applications. In particular, Eurotope has designed several radiation therapy products, e.g. prostate seeds, application devices etc. Products are now manufactured by Eurotope's sister company BEBIG and many other clients worldwide.

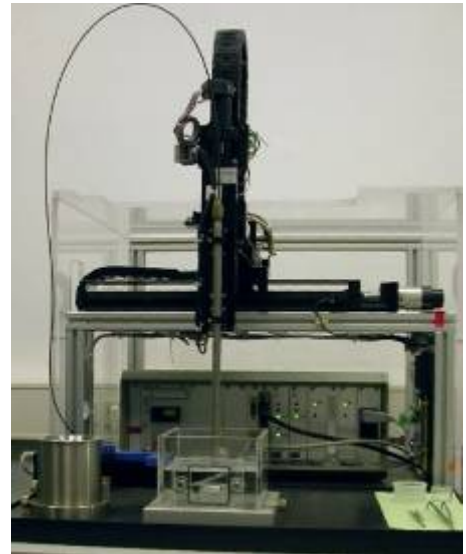
### ■ Development & Testing of Medical and Industrial Sources

Test Parameter:

- Determination of source strength
- Spectrum of photon radiation
- Dose distribution around beta and/or gamma sources
- Automated determination of dose rate distributions in air and tissue substitutes

Implemented Standards:

- ISO 2919 (classification of sealed radioactive sources)
- ISO 9978 (leakage test methods)
- Calibrations, traceable to primary standards of national metrological institutions such as PTB and NIST
- § 719 - § 725 of the IAEA Regulations regarding design conformity of packages for transportation of radioactive material



### ■ Product Registration & Certification

- CE-certification for medical devices
- FDA 510(k) pre-market notifications
- US Sealed Source and Device Registration
- French import authorization for radioactive sources

Eurotope offers regulatory services to our customers as part of design development services, turn key installations and also as a separate consulting service.



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# Engineering Services

Contract Manufacturing - Expertise

Streamlined automation is essential for increased production and profitability of your medical devices. Eurotope designs, develops and produces automated production lines for miniaturized products and components. Our services range from supporting a single stage of your production to the design and manufacture of the complete system. All Eurotope industry solutions are custom-designed and built to your specific requirements.

## ■ Product Examples:

Radiation therapy products

- Radioactive implants
- Afterloader sources
- Radioactive catheter
- Plaques



## ■ Expertise in Medical Device Manufacture

Services:

- Production Process Design
- Facility planning
- Installation

Examples:

- Development of specialized cells for the production of medical devices
- Development of automated systems for mass production of high capacity miniaturized products and components.



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# Engineering Services

## Medical Device Production Equipment – Know How

Competence and Know-How in the development and installation of turnkey production lines for radioactive medical devices stands out for the Eurotope GmbH. Starting from the design and development process to the manufacturing, Eurotope delivers customized turnkey production lines for radioactive medical devices. According to your requirements we build single production devices, which can be easily integrated into your existing environment.

### ■ Project example:

Production lines for biodegradable implant chains and radioactive implants (seeds).

Some Facts:

- Seeds for treatment of prostate cancer
- Seeds dimensions are: 4.5 mm long and 0.8 mm in diameter
- Patients are permanently implanted with 80 to 100 seeds
- Capacity requirements: from 100.000 to 300.000 seeds per year



### ■ Project example:

Device for automated cleaning and leak testing of small radioactive sources.

Some Facts:

- Capacity: up to 2.000 sources in one process step
- Automated counting to divide source batches into smaller sub-batches
- Leak- and immersion testing in a ISO 9978 compliant process



### ■ Sample project:

Radiochemistry device for dilution and measurement of radioactive solutions.

Some Facts:

- Automated process for opening, rinsing, transfer and dilution of stock solution
- Measuring and adjustment of desired concentration
- Different configurations are available



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