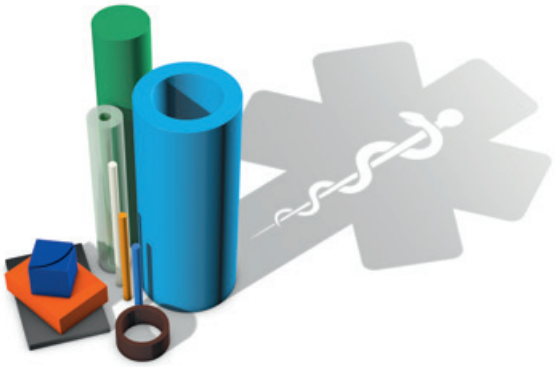
Quadrant® LSG PPSU Natural
In Brachytherapy Device

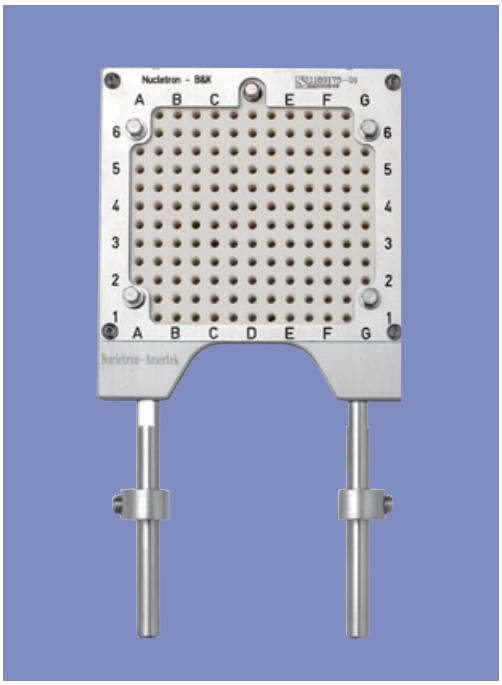


Challenge

Biocompatible polymer material supporting the special requirements of oncological treatments

Brachytherapy, a form of radiotherapy, is an advanced minimally invasive oncology procedure commonly used in the treatment of prostate, vaginal, cervical and head and neck cancer. A small radioactive source is placed in or near the tumour itself, giving a high radiation dose while minimising the radiation exposure of the surrounding healthy tissues.

Brachytherapy applicators are used in the surgical procedure to insert the radioactive source and to position it in or near the area to be treated. Positioning often takes place with the aid of CT (Computerised Tomography) and MRI (Magnetic Resonance Imaging) scans. Crucially, these scans need to provide extremely clear images for accurate positioning of the probe.
Following treatment procedures, the applicators and applicator accessories are sterilised through high-temperature autoclaving and hence the materials used need to be able to withstand both frequent autoclaving cycles and harsh chemical cleaning for repeat use.



Prostate stepper template set (using Quadrant® LSG PPSU natural) applied in prostate brachytherapy, from Nucletron B.V. / photo courtesy of Nucletron B.V

Key Requirements

Conventional metal-based applicators can produce distorted imaging. Other engineering polymer materials such as POM (polyacetal) and PSU (polysulfone) are vulnerable to repeat sterilisation cycles.
Materials used in the manufacture of Brachytherapy applicators therefore need to contain a combination of key properties that includes biocompatibility (USP XXIII Class VI and ISO ISO 10993) for in-vivo insertion; excellent resistance to steam autoclaving for repeat sterilisation; excellent chemical cleaner resistance, ability to produce clear, non-distorted CT and MR images to aid in-body positioning of the probe, and have good impact resistance. In this case, Quadrant performed additional testing on ISO 10993-10 (Intracutaneous Reactivity) and ISO 10993-11 (Accute Systemic Toxicity) on Quadrant® LSG PPSU natural.

Quadrant's Recommendation: Quadrant® LSG PPSU

Customer Benefits

- Economically advantageous solution due to the optimal combination of material properties
- Option to offer & support a more comfortable experience for the patient during treatment, as PPSU acts as a thermal insulator, i.e. does not conduct any heat or cold

Why Quadrant® LSG PPSU

- Biocompatibility on stock shape (USP XXIII Class VI and ISO 10993-10 [Intracutaneous Reactivity] and -11 compliant)
- Excellent resistance against steam autoclaving
- Very good impact resistance

Quadrant Added Values

- Extensive experience in biocompatibility validation and assistance in validation of the chosen material
- Expertise in testing of autoclaveability, and chemical resistance behavior of materials, e.g. in cleaning processes
- Able to deliver a solution, both material, finished part and technical trainings to engineers & co-engineering

Biocompatibility status of Quadrant® LSG PPSU grades:

TESTS (1) (2) / MATERIALS	1. Cytotoxicity – Ref.: ISO 10993-5 and USP <87> Biological Reactivity, In Vitro Elution Test	2. Sensitization – Ref.: ISO 10993-10, Magnusson & Kligman Maximization Method	3. Intracutaneous Reactivity – Ref.: ISO 10993-10 and USP <88>, Biological Reactivity Tests, In Vivo - Intracutaneous Test	4. Acute Systemic Toxicity – Ref.: ISO 10993-11 and USP <88>, Biological Reactivity Tests, In Vivo - Systemic Injection Test	5. Implantation Test – Ref.: USP <88>, Biological Reactivity Tests, In Vivo - Implantation Test (7 days)	6. Human blood compability – Ref.: ISO 10993-4, Indirect Hemolysis (in vitro)	7. USP-Physicochemical Tests for Plastics – Ref.: USP <661> Containers, Ultra Pure Water extract 70°C/24h	USP Class VI (conclusion from tests 3,4 and 5)
Quadrant® LSG PPSU black	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PPSU natural (ivory)	✓	V(3)	✓	✓	V(3)	V(3)	✓	V(3)
Quadrant® LSG PPSU blue, green, grey, orange, red, rust, yellow	✓	V(3)	V(3)	V(3)	V(3)	V(3)	✓	V(3)

✓ This test was carried out and the material passed the test.
V(3) An abbreviated biocompatibility type testing programme was run on these Quadrant® LSG PPSU products, which are colour variations of Quadrant® LSG PPSU black. A comprehensive biocompatibility type testing programme was run on Quadrant® LSG PPSU black.
(1) All tests were run on test specimens machined from rod diameter 50 mm shortly after manufacture.

(2) Quadrant EPP performs testing on its Life Science Grades in order to facilitate evaluatio by its customers of their biocompatibility with regard to the requirements applicable to the specific use of the finished product. Quadrant EPP does not possess expertise in evaluating the suitability of its tested materials for use in specific medical, pharmaceutical, or biotechnological applications. It remains the customer's sole responsibility to test and assess the suitability of Quadrant's Life Science Grades for its intended applications, processes and uses.

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