

poz. 2 Radioaktyviuoju Holmiu-166 žymėtos mikrosferos radioembolizacijai, diagnostinė dozė

poz. 3 Radioaktyviuoju Holmiu-166 žymėtos mikrosferos radioembolizacijai, gydomoji dozė



TECHNICAL SHEET

QuiremScout™ consists of low dose holmium-166 (poly-L-lactic acid) (PLLA) microspheres, and is intended for evaluation of lung-shunt, extrahepatic deposition and intrahepatic distribution of intra-arterially injected microspheres to assess whether a patient is eligible for SIRT.

QuiremSpheres® consists of therapeutic holmium-166 PLLA microspheres and is indicated for the SIRT treatment of unresectable liver tumours.

Q-Suite™ is a dosimetry software and is intended to support the evaluation of the medical treatment with radioactive holmium-166 microspheres. The medical device software calculates the tissue absorbed radiation dose after injection of radioactive holmium-166 microspheres based on medical images.

PRODUCT CHARACTERISTICS AND SPECIFICATIONS*

		
Particle		
Isotope	Holmium-166	Holmium-166
Material	poly-L-lactic acid (PLLA)	poly-L-lactic acid (PLLA)
Particle size (µm)	30 (15-60)	30 (15-60)
Gamma energy	81 keV	81 keV
Beta radiation (E_{max})	1.77 MeV (48.7%) 1.85 MeV (50.0%)	1.77 MeV (48.7%) 1.85 MeV (50.0%)
Half-life (hours)	26.8	26.8
Amount of microspheres (million)	2.6 3	3.4 8-12.5 (3 GBq)
Activity administrated	250 MBq	1 GBq - 15 GBq
Contra-indications*	<ul style="list-style-type: none"> • Are not eligible for SIRT • Have uncorrectable abnormal vascular anatomy that would result in significant reflux of hepatic arterial blood to the lungs, stomach, pancreas or bowel 	<ul style="list-style-type: none"> • >30 Gy lung dose during SIRT work-up • Uncorrectable extrahepatic deposition* • Activity in the falciform ligament, portal lymph nodes and gallbladder is accepted*

*Only contra-indications related to SIRT work-up are provided. For the full list of contraindications, refer to the QuiremSpheres® Instructions for Use.

Q-SUITE™ SOFTWARE INFORMATION*

Q-suite™ version 1.2	
Software requirements	<ul style="list-style-type: none"> x64 based computer running Microsoft Windows 7, 8.1 or 10 Microsoft .NET version 4.5.2 framework
Hardware recommendations	<ul style="list-style-type: none"> Dual-core CPU, 2.0GHz or higher 16 GB RAM SSD with 20 GB free disk space

REGULATORY INFORMATION*

- QuiremSpheres® and QuiremScout™ are designed, manufactured and distributed according to ISO 13485
- All products and packages do not contain components of natural rubber (latex)
- QuiremSpheres®, QuiremScout™ & Q-suite™ have received CE mark.

CE 0344

ORDERING INFORMATION*

Item reference	Product	Description
QS-V001	QuiremSpheres®	V-vial containing of Holmium-166 PLLA microspheres
QS-S001	QuiremScout™	V-Vial containing a small quantity of Holmium-166 PLLA microspheres with low activity
QS-Q001	Q-Suite™	Dosimetry software for Holmium-166-SIRT
QS-C001	Customer Kit	Set of re-usable administration box and accessories for administration of QuiremSpheres® and QuiremScout™
QS-C003	Vial Holder	Vial holder for patient administration kit for QuiremSpheres® and QuiremScout™
QS-D001	Delivery Set	Set of disposable products for patient administration QuiremSpheres® and QuiremScout™
QS-T001	TestSpheres	V-Vial with Holmium-166 microspheres for calibration purposes 2.9; 3.4
QS-T002	HolmiumSolution	V-Vial with HoCl solution for calibration purposes 2.9; 3.4

*For the complete information, please look at the IFU of Quiremspheres®, QuiremScout™, Q-suite™ or contact your local Terumo representative.



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