JOINT STOCK COMPANY
STATE SCIENTIFIC CENTRE OF THE RUSSIAN FEDERATION –
INSTITUTE FOR PHYSICS AND POWER ENGINEERING
named after A.I. Leypunsky

JSC «SSC RF – IPPE»

OPERATING MANUAL
Э.033.250РЭ

Ophthalmic applicators based on strontium-90 radionuclide

Obninsk

Contents

This Operating Manual (OM) is applicable to ophthalmic applicators (OA) based on strontium-90 (Sr-90) radionuclide.

Operating Manual includes information on OA application and composition as well as guidance on OA safe operation.

Ophthalmic applicators are the source of ionizing radiation, and persons younger than 18 years and having medical contraindications are not allowed to operate with them. Prior to clearance to work with OA the personnel should pass through training, instruction and check of knowledge of safe operation rules and the guidance of medical institution.

1. Manufacturer

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2. Description of medical article

2.1 "Ophthalmic applicators based on strontium-90 radionuclide" according to Technical Specification (TS) 26.60.11-045-08624390-2016 present closed radionuclide beta radiation sources intended for radiation application therapy ("brachytherapy") of eye tumors.

OA design elements are:

- basis (0.8 mm thickness);
- substrate with radionuclide deposited on its surface;
- cover (0.1 mm thickness), through which working surface the tumor is irradiated;
- eyelets, with the help of which OA is fixed referring to tumor.

OA has a spherical cap shape with or without cut depending on OA type. Basis and cover are made of stainless steel of 12X18H10T grade according to State Standard (SS) 5632-2014 and sealed by girth weld.

Substrate is located between the basis and cover. It presents metal foil or glass-cloth with radionuclide deposited on its surface. Shape and size of substrate determine the dose field of OA.

OA thickness is enough for Sr-90 radionuclide beta radiation absorption. Beta radiation is emitted from surface of cover being an OA working surface.

3. Specification

Overall dimensions of OA:

- radius of working surface sphere - from 12 to 14 mm,
- diameter of working surface - from 7 to 22 mm.

OA activity

OA type	Maximal activity	
	MBq	mCi
C1-A	Up to 300	Up to 8.1
C1-B	Up to 300	Up to 8.1
C1-C	Up to 300	Up to 8.1
C2-A	Up to 300	Up to 8.1
C2-B	Up to 300	Up to 8.1
C3 C4 C5 C7	30-60	0.81-1.62
C6	30-60	0.81-1.62
C8	30-60	0.81-1.62
C9	30-60	0.81-1.62

ISO classification

OA strength class designation in accordance with SS R 52241-2004 is ISO "/12/C 43312".

Tightness

OA is subjected to leak test by bubble method in accordance with SS R 50629-93.

Biocompatibility

Basis, cover and eyelets of ophthalmic applicators are made of steel of 12Х18Н10Т grade (SS 5632-2014), substrate is made of steel of 12Х18Н10Т grade (SS 5632-2014), copper М1 (SS 1173-2006) or glass-cloth Э3-100-ПТ (SS 19907-2015), providing good biocompatibility, which is confirmed by Toxicological report # 865МТ/38396 of 07.11.2018 issued by Laboratory center "Quality Control Center of Oncology Scientific Center", Ltd.

Main radiological feature of OA is an absorbed dose rate (ADR) of beta radiation on its working surface being in contact with tissue-equivalent material.

Average absorbed dose rate of beta radiation of strontium OA for posterior eye segment is not less, than 6000 cGy/h, for frontal eye segment - is not less, than 25000 cGy/h.

Radioactive contamination of OA surface is not allowed.

OA is proof against moisture, organic solvents, washing and disinfecting agents, sterilization, biological liquids and effuses of body tissues, with which OA is in contact in the process of operation.

4. Warranty life

Warranty life of OA based on strontium-90 radionuclide is 60 months.

5. Manufacturing date

Precise data on OA manufacturing date and activity are indicated in certificate enclosed in the delivery package.

6. Radiation safety provision

6.1 Persons not younger than 18 years and without medical contraindications to operate with ionizing radiating sources, which belong to A class personnel according to health care center-wide directive, are permitted to work. To check the radiation exposure the personnel should use the personal radiation dosimeters.

6.2 In all premises where OA is operated a radiation situation control should be arranged and implemented, and control results should be recorded.

6.3 Individual radiation doses obtained by patients during the procedures are to be registered, information on their values should be written in the personal record form of medical radiation, which is a mandatory annex of medical chart.

7. OA intended use and maintenance

7.1 OA is applied in strict compliance with the medical procedural guidelines and Operating Manual.

7.2 Patient medical irradiation with the purpose to obtain therapeutic effect is carried out by medical prescription only and with the agreement of patient.

7.3 OA is a non-repairable article, so it should be preserved from damage. OA must not be in contact with cutting and sharp things. They need to avoid scratches or any other surface damage as well as OA deformation. In case of deformation it should

be immediately checked for OA leak and excluded from further use. Anyway, OA mechanical changes result in dose rate curve changes.

7.4 In all premises where OA is operated a radiation situation should be controlled in accordance with Radiation Safety Regulations (RSR)-99/2009.

8. OA leak test

8.1 If OA leak test is needed in medical institution it is recommended to carry out swab test with the help of alcohol or distilled water according to SS R 51919-2002 (ISO 9978-92).

8.2 All the outside surfaces of OA should be cleaned carefully with whatman swab or any other similar material with high absorbing capacity.

ATTENTION: AVOID SCRATCHES OR ANY OTHER OA SURFACE DAMAGES!

8.3 Swab activity should be measured by calibrated measuring device.

8.4 If measured activity does not exceed 200 Bq (5 nCi), OA is tight.

9. OA sterilization

9.1 Prior to every application OA should be disinfected and sterilized.

9.2 Disinfection is carried out by Alaminol according to “Guidelines on Alaminol application for disinfection” or by soaking in 2% solution of chloramine within two hours.

After disinfection OA should be washed with (0.3-0.5) % water solution of any neutral synthetic washing agent by dipping in this solution and following washing with distilled water.

9.3 Sterilization is carried out by one of the following methods:

- boiling in water within not less than 60 minutes;
- holding in 70 % alcohol within not less than 45 minutes;
- autoclaving at 120 °C temperature not less than 30 minutes.

9.4 When OA operating one should follow the Guidelines on disinfection and sterilization and meet the requirements of the Main Sanitary Rules on Radiation Safety (MSRRS-99/2010) and Radiation Safety Regulations (RSR-99/2009).

10. OA storage

10.1 Prior to operation OA is stored in transport package set at environmental temperature from 5 °C to 40 °C and 65 % air relative humidity.

10.2 OA storage place should be equipped in accordance with MSRRS-99/2010 requirements without any special requirements to storage room.

10.3 OA being not in operation should be stored in a shielding container in special places or equipped rooms where its safe storage is provided without access of unauthorized persons.

10.3.1 After every application OA should be immediately washed with water, ethyl alcohol or neutral washing agent.

ATTENTION: DO NOT USE ALKALI OR ACIDS!

10.3.2 If immediate cleaning is impossible OA should be placed in distilled water or ethyl alcohol but not longer than for 5 hours. Then OA should be dried in the air.

HUMID OA IS PROHIBITED FOR STORAGE IN SHIELDING CONTAINER!

10.4 Accounting and control of OA integrity during its storage and operation should be arranged in accordance with the requirements of MSRRS-99/2010 and according to Standards and Regulations (SR)-067-16 as well as to clauses and instructions valid at medical institution.

11. OA transportation

11.1 OA should be transported in the transport package container. Transport climatic conditions are in accordance with storage conditions 5 (ОЖ4) SS 15150-69, but the temperature range is from minus 40 to plus 70 °C.

11.2 OA transportation in transport package set as in radiation package of III transport category is allowed on specially equipped vehicles only or in special places on ships according to SR-053-16 and Sanitary Regulations on Radiation Safety of Personnel and Population during Radioactive Material Transportation (SanPin) 2.6.1.1281-03.

12. OA utilization

12.1 OA is not subjected to utilization.

12.2 After service life termination OA should be disposed in accordance with the established procedure at dedicated plant in accordance with Sanitary Rules for Radioactive Waste Management (SRRWM)-2002 and SR -067-16.

13. Indications and contraindications

13.1 *Brachytherapy in epibulbar tumors neoplasms of eyelid.*

Indications: Melanoma of conjunctiva and cornea, conjunctiva cancer, malignant lymphoma, Bowen disease, capillary haemangioma, lymphangioma. Brachytherapy is carried out only after the tumor morphological structure determination (biopsy data), except for pigment tumors (melanomas).

Indications for brachytherapy are set individually in every case, they significantly depend on neoplasm thickness. When use of strontium OA the neoplasms must not

exceed 4 mm. Tumor maximum diameter is not significant in practice because irradiation can be carried out in several fields, if needed. However, OA should overlap the visible tumor margins by 3-4 mm from every side. Installed OA should contact with the whole tumor surface. After surgery a brachytherapy is indicated for diseased tissue after oncotomy.

Contraindications: Brachytherapy is not indicated if tumor attaches to palpebral conjunctiva or grows in fornix of orbital cavity or in paranasal sinuses with the presence of lymphogenic or hematogenic metastases, when the tumor is located near the ciliary margin or has hummocky surface. If brachytherapy possible or not under the evident comorbidities is solved individually.

Radioreaction of irradiated site and surrounding tissues depends on the dose, radiation area and the individual sensitivity of patient. It typically appears in 2 weeks after the treatment termination and more seldom after 4-5 radiation sessions.

Late complications — teleangiectases, stromal keratitis, radiation cataract, secondary glaucoma can appear in 1-3 years. They appear more often after irradiation of bulbar conjunctiva close to sulcus by superficial dose 200Gy and higher.

13.2 *Brachytherapy in uveal melanomas and retinoblastomas*

Indications: single tumor nidus; tumor thickness is not more than 5 mm, maximum diameter – not more than 14 mm; tumor posterior margin should be spaced away from optic disc at 3 mm; in juxtapapillary localization the tumor must not surround optic disc more than 120° of its circle.

Contraindications: tumor multicentric growth; tumor thickness is more than 5 mm and diameter – more than 14 mm; tumor spread to ciliary body; presence of metastases; acute inflammatory diseases of eye and its adnexa; heavy comorbidities including acute febricities.

Radioreaction. On 3-5 days after irradiation beginning an albedo retinae appears, tumor tissue edema on eyeground grows gradually, and this gives the appearance that tumor becomes larger. Hemodynamic disorders are possible.

Early and late complications

- paresis of rectus muscle;
- increase of ocular pressure;
- iridociclitis;
- reactive exudative retinal detachment;
- radiation vasculitis, part hemophtalmia;
- optical neuropathy;
- neovascular glaucoma;
- radiation sclera necrosis.

14. OA radiological features and dose calculation

OA main dosimetric feature is its dose field generated in nidus and eye surroundings.

Dose, exposure duration and OA location are determined depending on the tumor place and size. Attending doctor is responsible for radiotherapy planning and its progress control.

OA dose fields have been obtained from the experimental and calculation results. Values of deep dose rates in soft biological tissues are presented in percent relative to dose rate value on OA surface presented in its certificate. OA dose rate in biological tissue is presented in the Table.

Depth, mm	% of superficial dose
	^{90}Sr
0	100
1.0	68
1.5	52
2.0	42
2.5	33
3.0	25
3.5	20
4.0	15
4.5	11
5.0	3

Thus, with the information of dose rate of specific OA and percent of superficial dose at needed depth one can calculate the total and single doses (superficial and on set depth) and radiation period.

Example of dose calculation during irradiation of basal cell carcinoma of eyelid: brachytherapy with strontium OA is needed for eyelid skin of 2 mm thickness. Total dose on the tumor floor should be equal to 100 Gy. At 2 mm depth the dose rate of strontium OA is 42 % of superficial one.

So, total dose on the surface = 100 Gy·100:42= 238,1 Gy. Let the dose in a single session equals to 19 Gy, then to obtain the needed dose it is needed to perform 238:19=12,5 sessions of brachytherapy. OA rate according to certificate is 2 Gy/min. Radiation session duration (exposure) is 19 Gy:2 Gy/min = 9,5 min. Thus, 12 sessions of 9,5 min duration are needed and the last session is 4,75 min.

Revision history				
Version	**Date**	**Reason**	**Distribution**	**Signature**
1.0	01.12.2018	Acceptance	Dossier “Ophthalmic applicators” of the Research and Production Complex of Isotopes and Radiopharmaceuticals of the Department of Physical and Chemical Technologies