Internal radiation

For high precision radiation therapy

shielding

EdgeX Co., Ltd

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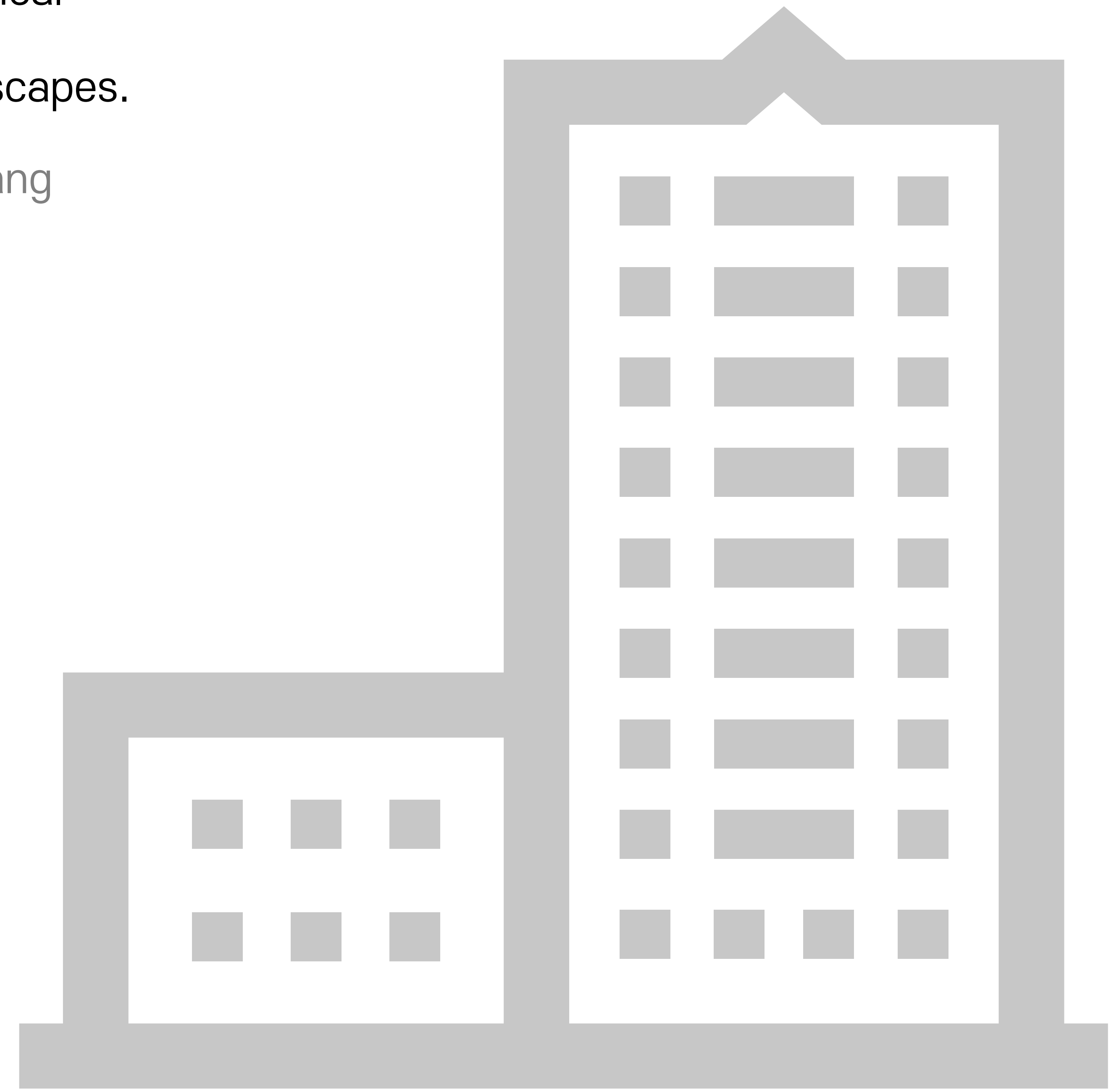
EDGEX CO., Ltd COMPANY PROFILE

EdgeX was established at the heart of Seoul, South Korea with an aim to design and build advanced, sophisticated, outstanding products, technology, and medical solution. Our innovations advance the existing array of products and services towards a new future and seek to improve the quality of life across many landscapes.

We are currently working together with Seoul National University and its Bundang Hospital's Oncology department's team of doctors and researchers conducting preclinical trials for one of our medical innovations.

HEAD COMPANY

Korea Nuclear Engineering Management Corporation (KONEC) focuses on the management of nuclear and radioactive waste, and provides engineering services.



01

Background

01 Background

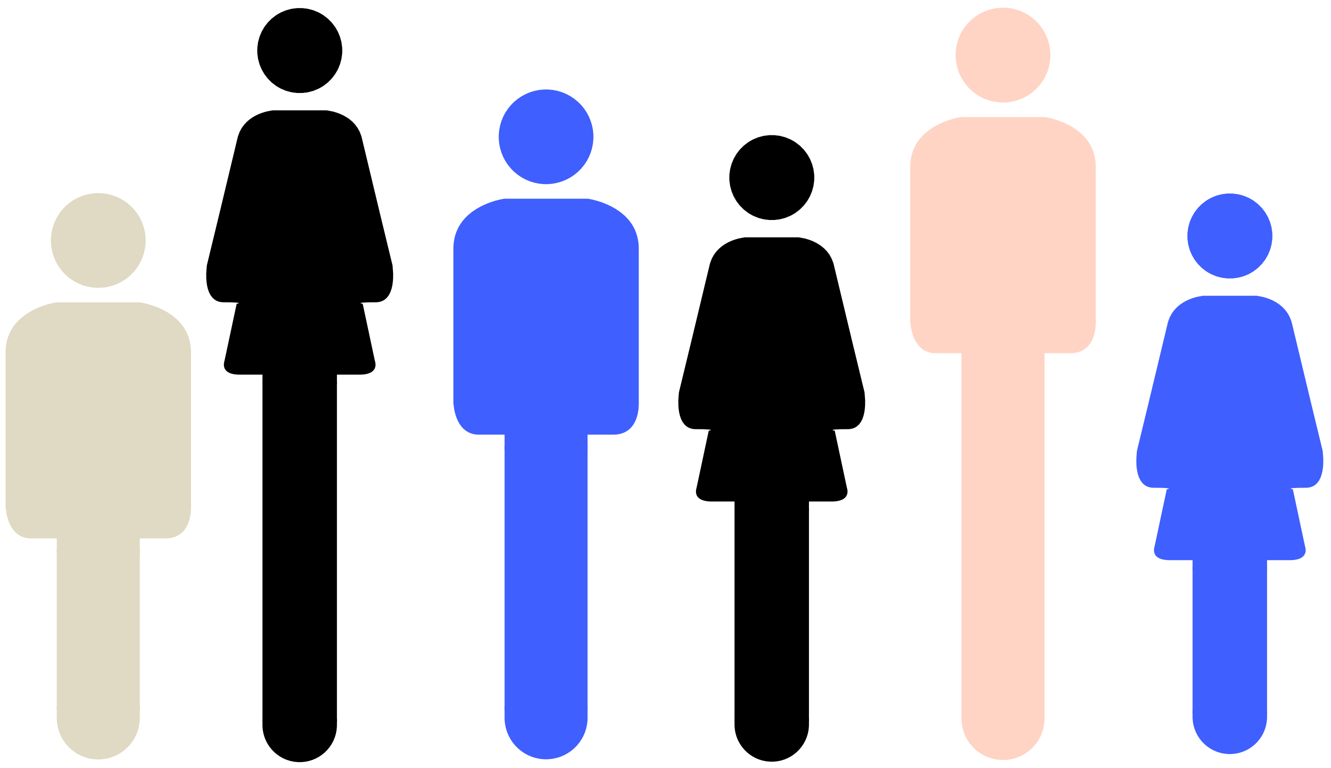
Radiation toxicity

Most cancer patients undergoing radiation therapy will develop injury to normal tissue as a result of treatment.

Over 50% of all cancer patients receive radiation therapy in some form, but although the treatment effectively damages tumor cells, it also harms the surrounding tissue, causing toxicity to otherwise healthy tissues.

The toxicities resulting from radiation-induced normal tissue injury are dependent upon the location of treatment, with the most common toxicities involving the oral cavity and gastrointestinal (GI) tract in the forms of oral mucositis, esophagitis, and proctitis.

According to statistics, over 200,000 patients yearly suffer from radiation-induced oral mucositis, esophagitis, and proctitis in the U.S., which may lead to severe morbidity and, ultimately, treatment breaks or discontinuation that adversely impact tumor cure rates.

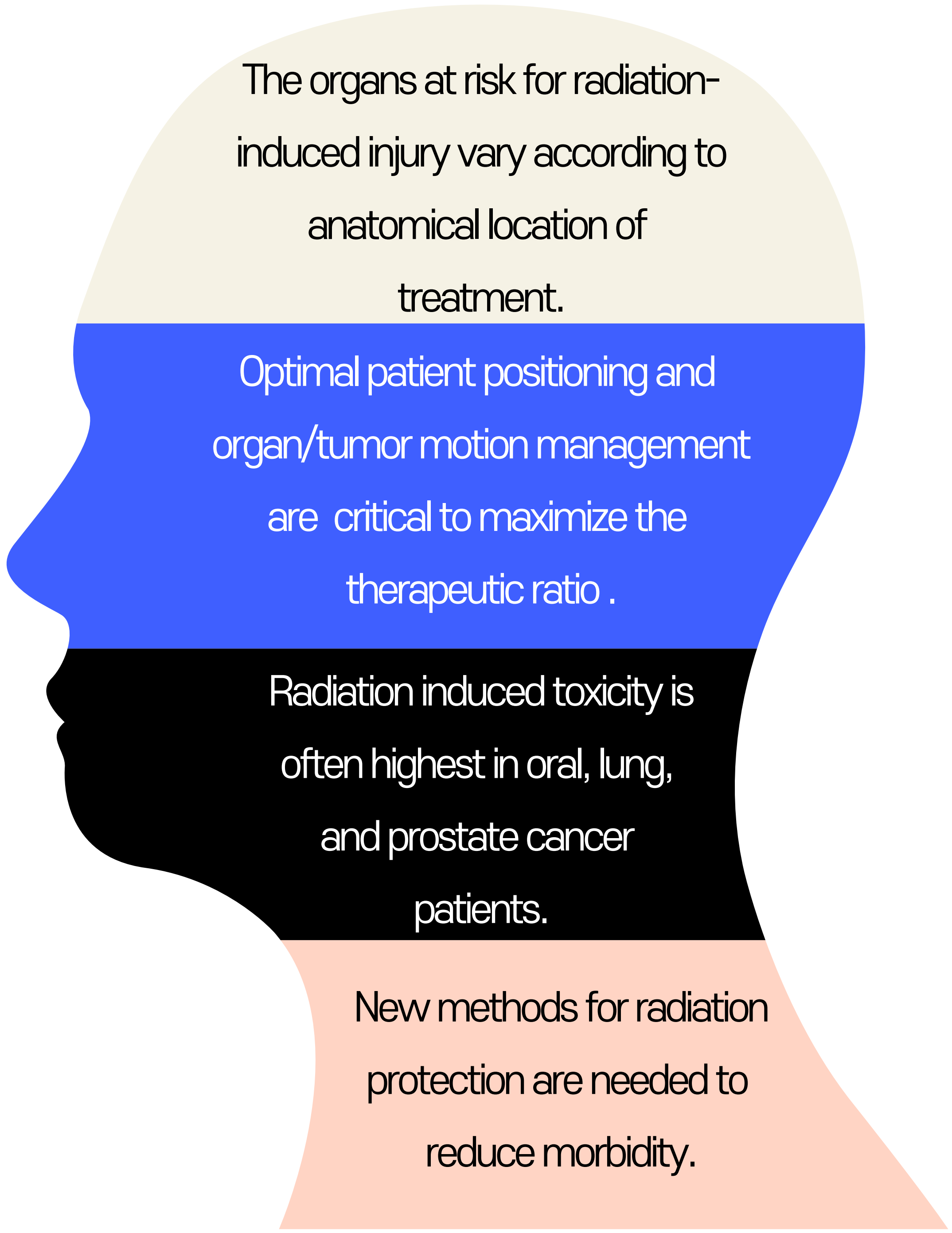


Radiation therapy shielding

Modern advances in high-precision RT delivery, such as intensity-modulated RT (IMRT), stereotactic radiosurgery, and internal radiation therapy such as brachytherapy and intraoperative radiation, allow clinicians to spare organs better while targeting tumors with a higher accuracy.

Toxicity, nonetheless, is common and results from higher RT doses, along with combined effects of other cancer treatments and baseline organ dysfunction.

Attempts to reduce radiation-induced side effects such as physical spacers, shielding, and treatments for radiation-induced mucositis have many limitations in protecting normal tissue, including concerns regarding diminishing intended tumor treatment, dependency on user experience, and additional side effects.



01 Background

Internal shielding for radiation therapy

PROBLEM

High-precision radiation therapies minimize the damage to healthy tissue, nonetheless, toxicity is common and partially results from higher RT doses used with targeted radiation therapies.

→ Patients continue to experience severe oral cavity and GI toxicities that result in morbidity and, at times, mortality.

OPPORTUNITY

Internal radiation therapies (having radiation treatment from inside the body as opposed to external beam therapy (EBRT)) are targeted radiation treatments, that do not affect the tissue or organs between the radiation beam and the specific tumor location.

SOLUTION

High-precision radiation treatment also calls for targeted radiation shields that can protect the healthy tissue and organs surrounding the highly targeted, high-dose radiation treatment.

SOLUTION

If radiation treatment is closely targeted internally to the tumor, radiation shielding is also required *in situ* to protect the surrounding tissue from high dose radiation.

02 Insertable internal radiation shield

Insertable internal radiation shield

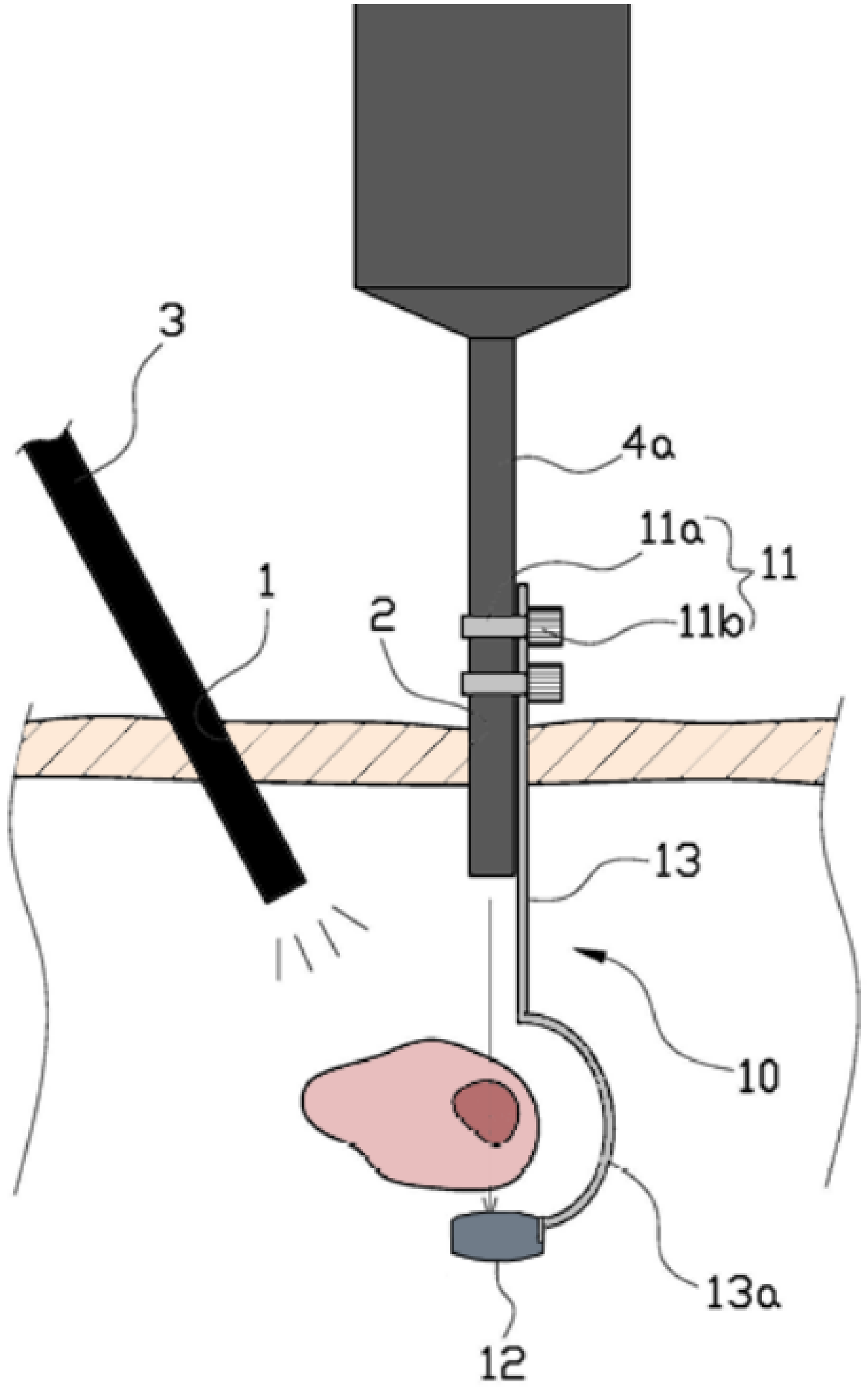
Technology overview

This insertable internal radiation shield is a high-precision radiation treatment shield capable of effectively shielding organs and tissue surrounding cancer tissue during targeted radiation treatment to minimize damage to healthy tissues and to prevent radiation toxicity.

01 The internal radiation protection shield can be moved with ease between cancer tissue and the beneath and surrounding healthy tissue and organs.

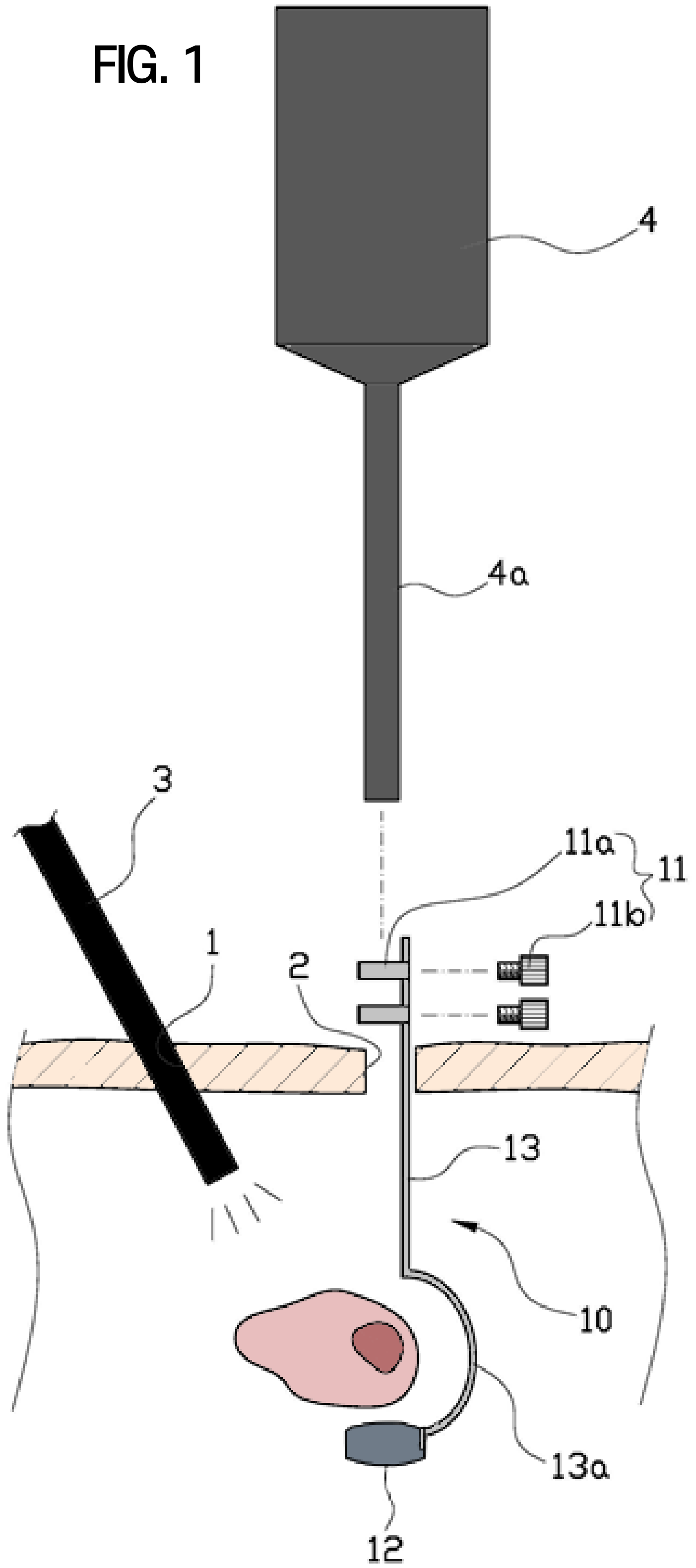
02 Made from radiation attenuating material the shield effectively absorbs the high radiation dosages from high-precision radiation treatment and protects healthy tissue from radiation scatter.

03 The shield can be inserted through minimally invasive surgery techniques and removed immediately after the procedure.



Detailed technology description

FIG. 1

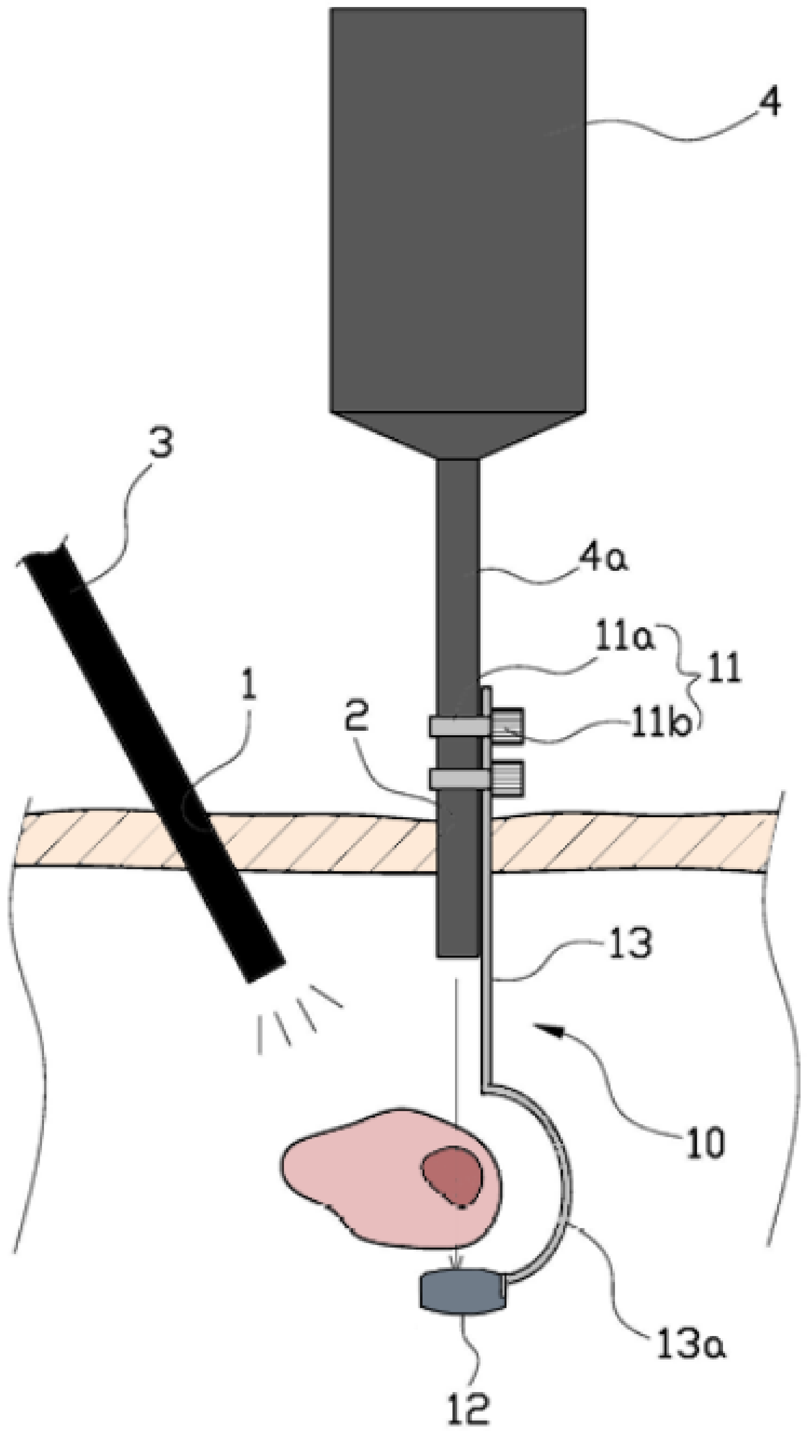


FIGS. 1 & 2

1 and 2 are cross-sectional views illustrating an example usage of the insertable internal radiation for high-precision radiation treatment

1: First incision
2: Second incision
3: Laparoscope
4: Radiation source
4(a): Rod-shaped collimator
10: Shielding device
11: Fixture
11(a): Bolts
11(b): Screws
12: Radiation shield (lead or tungsten coated with surgical silicone)
13: Connecting portion
13 (a). Curved placement portion

FIG. 2



Detailed technology description

01 The fixure (11) can be used to attach the shield to a laparoscope or a radiation therapy device, and can be easily and flexibly attached and detached.

02 The radiation shield (12) is made of radiation attenuating material such as lead or tungsten and is coated with thin acetal-based plastic or surgical silicone.

03 The shield (12) covers the range of the high-precision radiation beam, protecting the tissue beneath the targeted tumor

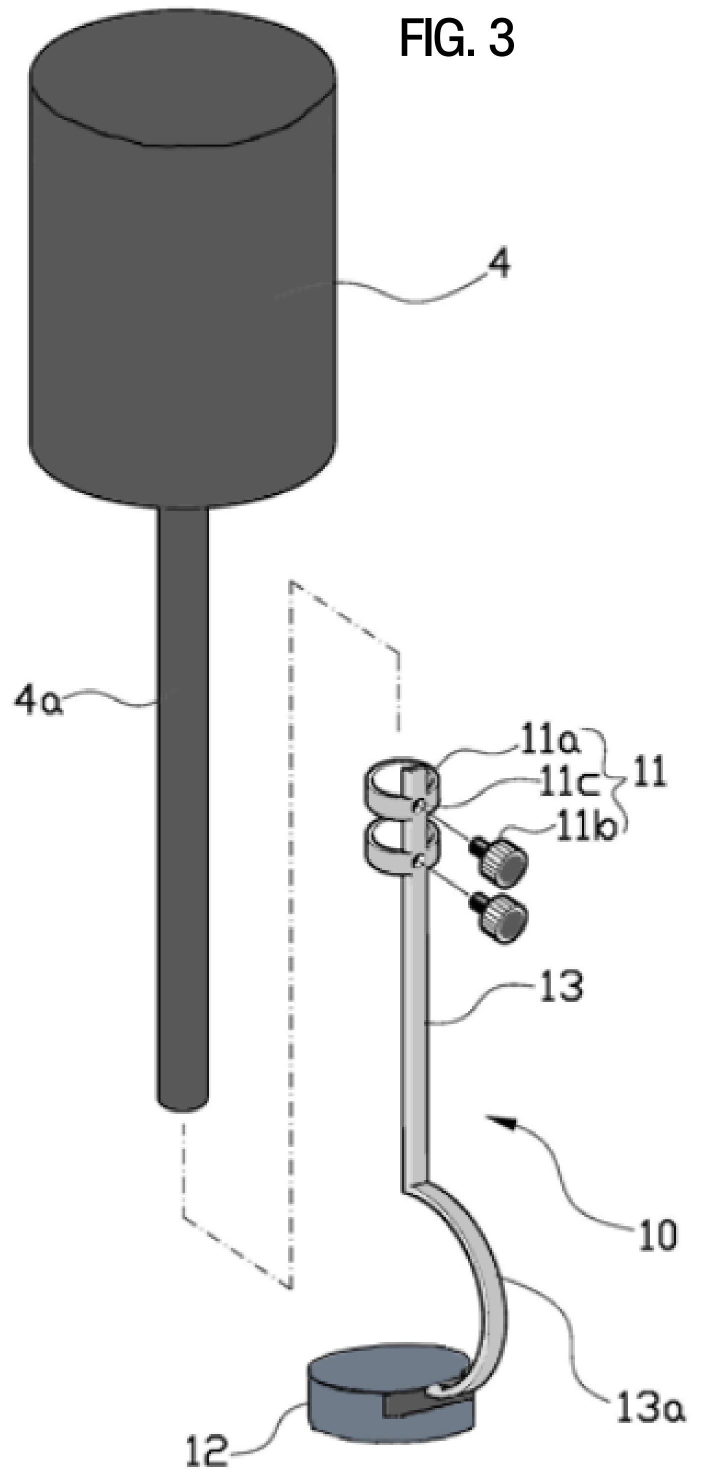
04 The curved placement portion (13a) is connected to the shield (12) and the connecting portion (13) so that the connecting portion does not press the organs when the shielding part is positioned behind the cancer tissue.

FIG. 3

3 is an exploded perspective view illustrating the insertable internal radiation shield and its attachment mechanism, which can be used to attach it to a laparoscopic radiation device as expressed in the illustration.

1: First incision
2: Second incision
3: Laparoscope
4: Radiation source
4(a): Rod-shaped collimator
10: Shielding device
11: Fixture
11(a): Bolts
11(b): Screws
11(c): Placement for the screws
12: Radiation shield (lead or tungsten)
13: Connecting portion
13 (a). Curved placement portion

FIG. 3

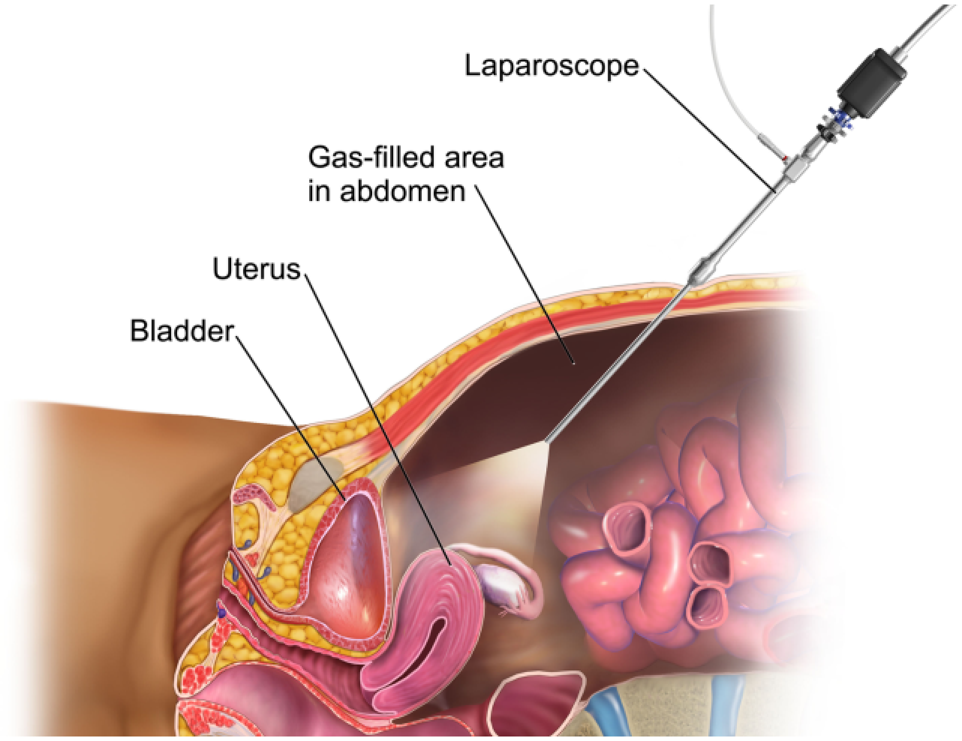


Clinical applications

Laparoscopic application

Can be incorporated to a laparoscope, with which it can be used to shield organs and healthy tissue from external radiation treatment.

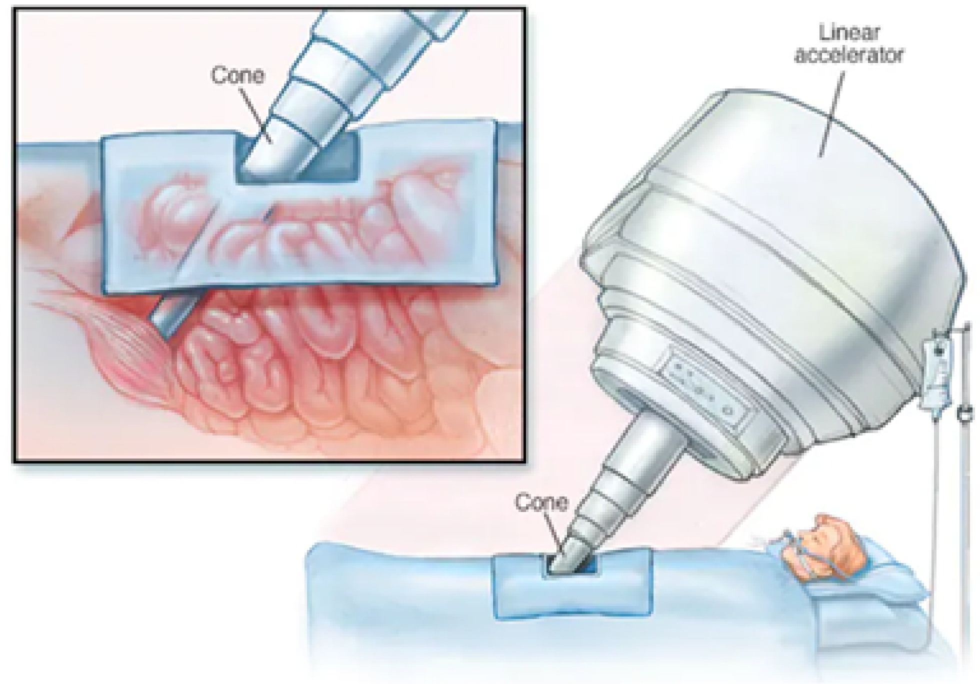
The shield can be applied to a laparoscopic radiation treatment as illustrated in Fig. 1~3, to be used to shield during internal radiation treatment.



Intraoperative radiation therapy

Intraoperative radiotherapy (IORT) involves the precise delivery of large doses of ionizing radiation to a tumor or tumor bed during surgery with the the advantage that surrounding organs can be better shielded or moved. However, in certain situations, normal tissues cannot be physically moved out of the radiation field.

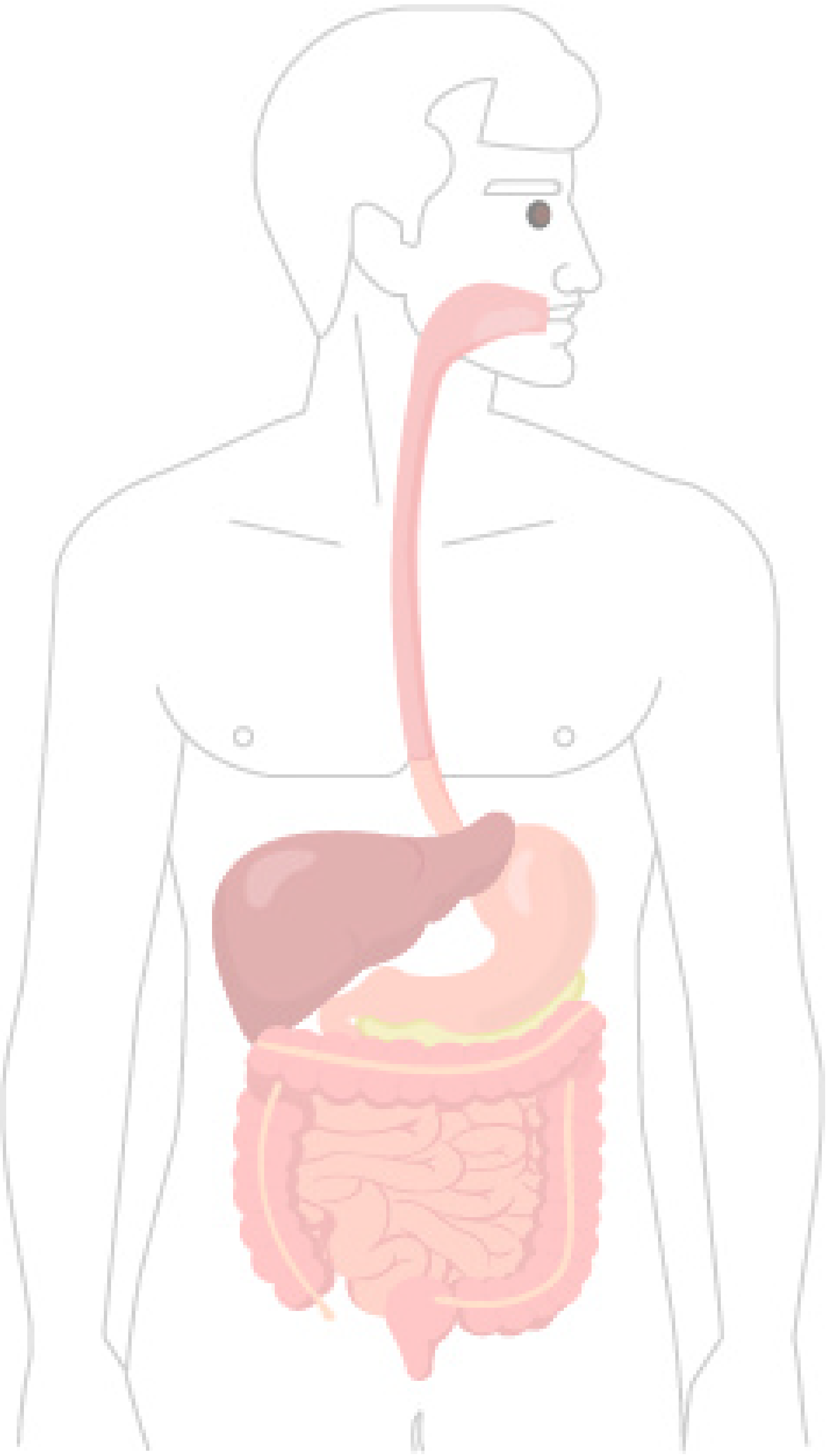
Our internal radiation shield can be used to protect the healthy tissue beneath and around the tumor when giving intraoperative radiation therapy.



03

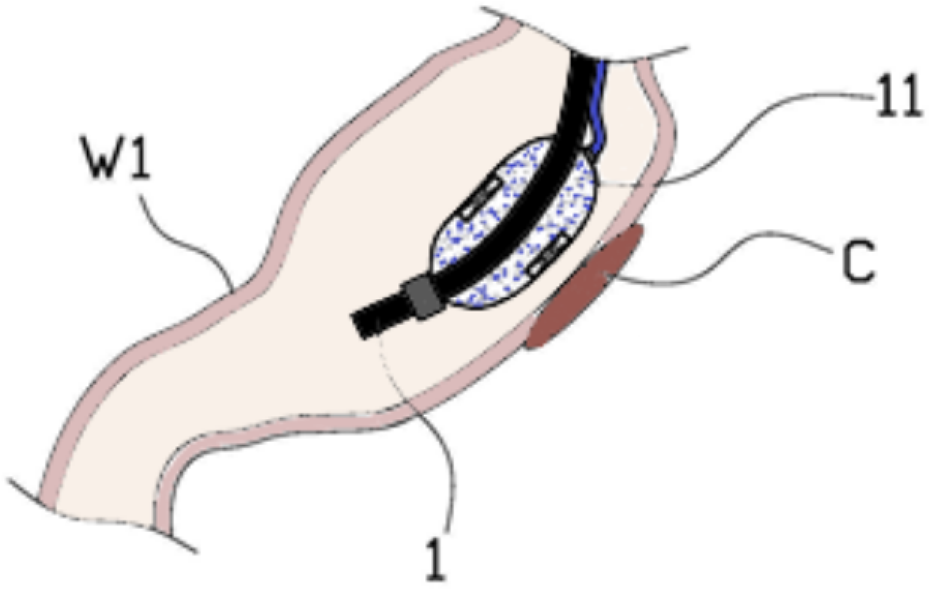
Intracavitary radiation shield

Intracavitary radiation shield



Technology overview

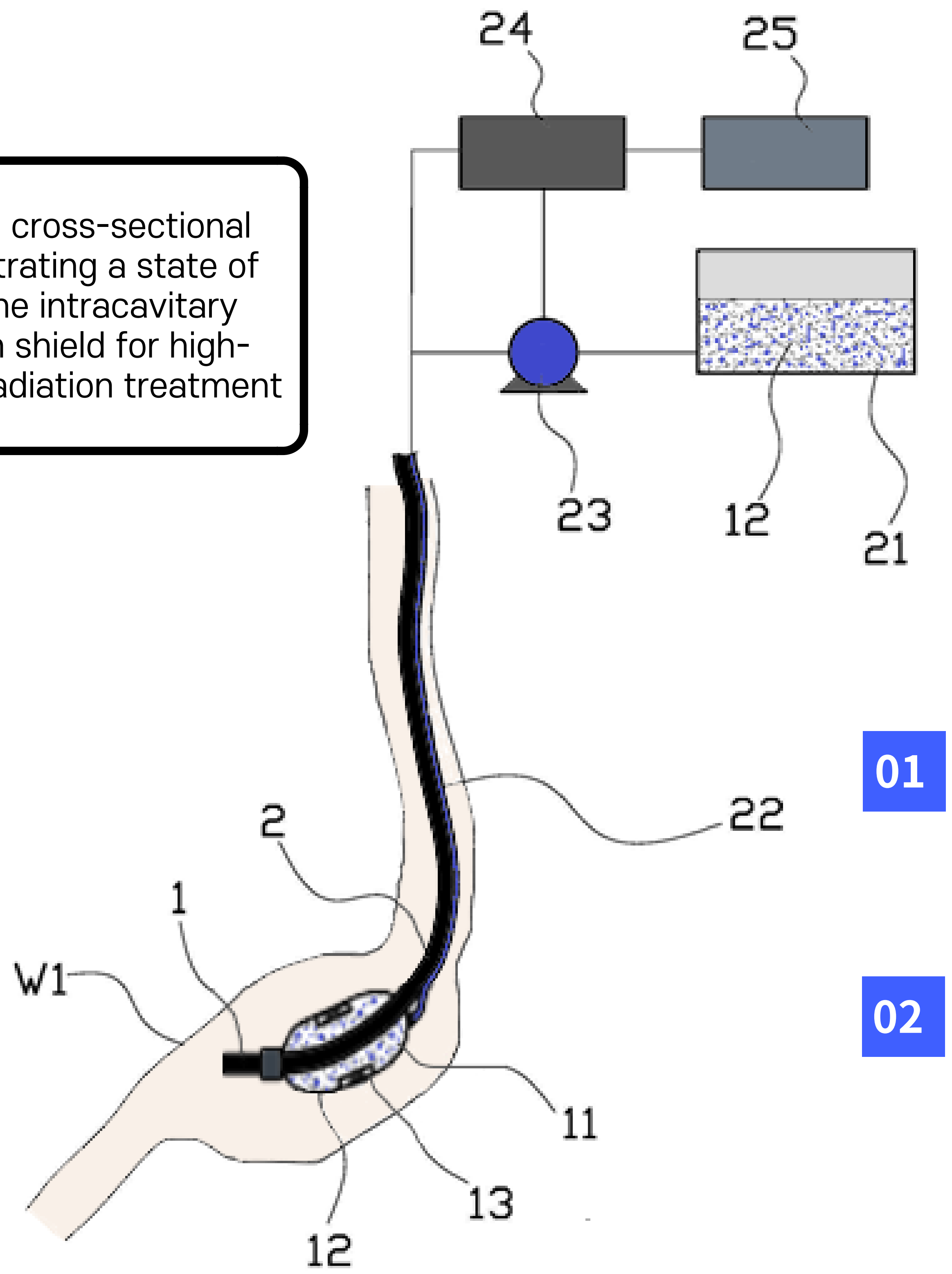
The intracavitary radiation shield for local radiation therapy effectively protects the healthy tissue and organs surrounding the targeted tumor and cancer tissue during targeted radiation treatment for cancers placed in or close to the GI tract, for instance the stomach or colon.



Detailed technology description

FIG. 1

FIG.1 is a cross-sectional view illustrating a state of use of the intracavitary radiation shield for high-precision radiation treatment

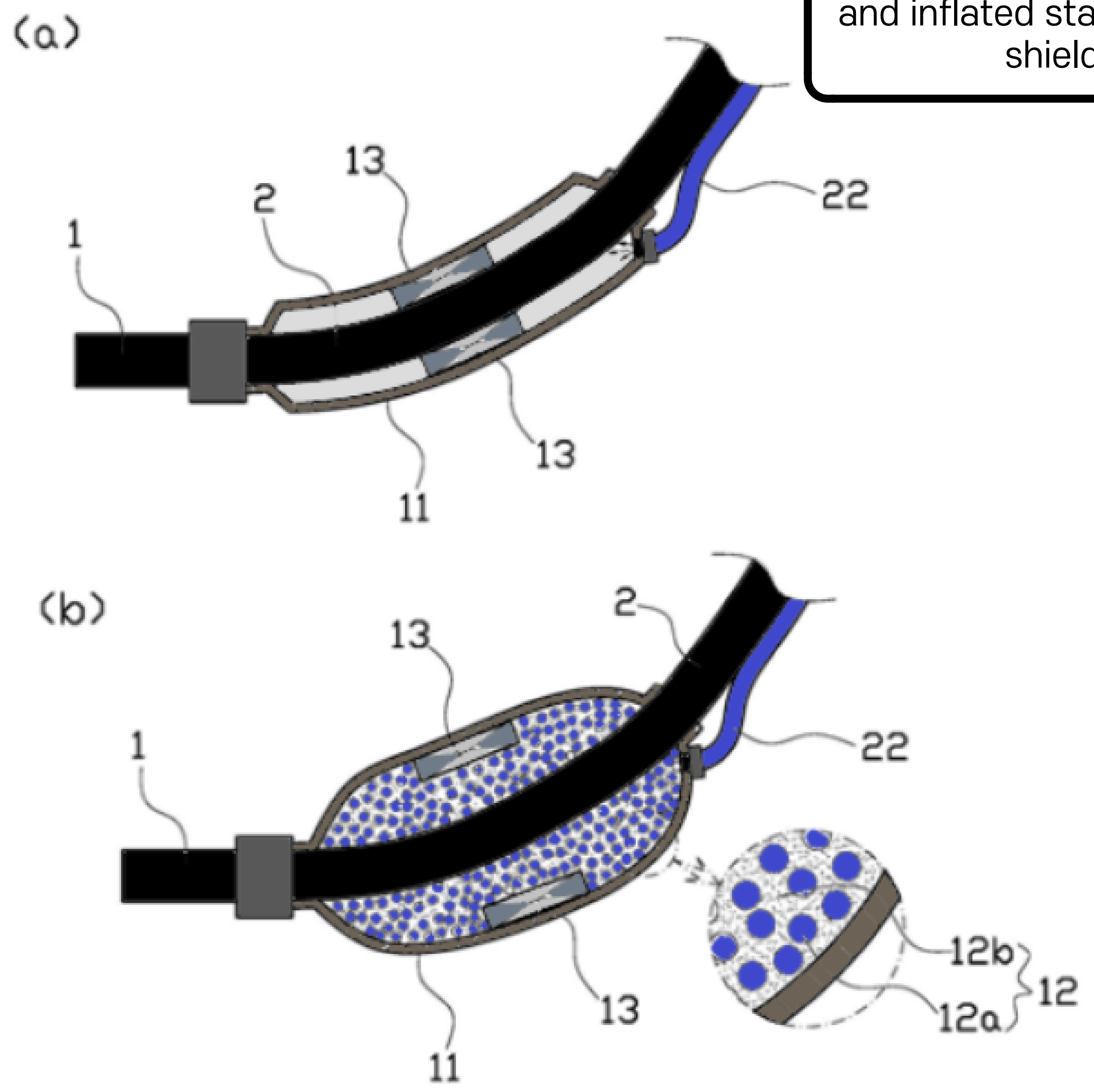


1. Endoscope
2. Insertion tube
11. Shielding balloon (made of contractible and expandable surgical material.)
12: Radiation attenuating material
13. Dosimetric sensor
21. Storing container
22. Inflation tube
23. Pump
24. Controller
25. Display
W1. Stomach

01 The shield comprises of an inflatable shielding balloon (11) that can be attached to conventional endoscope equipment or an inserting tube (2).

02 When inflated the shielding balloon is pumped with radiation attenuating spheres (12) made of lead or tungsten that offer high radiation protection.

Detailed technology description



FIGS. 2 (a & b)

2(a) and FIG. 2(b) are cross-sectional views illustrating the insertion and inflated states of the shield

03 The shield is inserted and placed in a noninflated state as shown in Fig. 2 (a). After placement, it is pumped with a mixture of lead or tungsten spheres (12a) and a lubricant (12b) (Fig 2. (b)).

04 Dosimetry sensors (13) are also incorporated into the shield to measure the radiation dose given to the tumor and passing the shield.

1. Endoscope
2. Insertion tube
11. Shielding balloon (made of contractible and expandable surgical material.)
12 (a): Lead or tungsten spheres (1~2 mm diameter)
12 (b): Sterile saline
13. Dosimetric sensor
22. Inflation tube

Detailed technology description

22. Inflation tube
30. Syringe

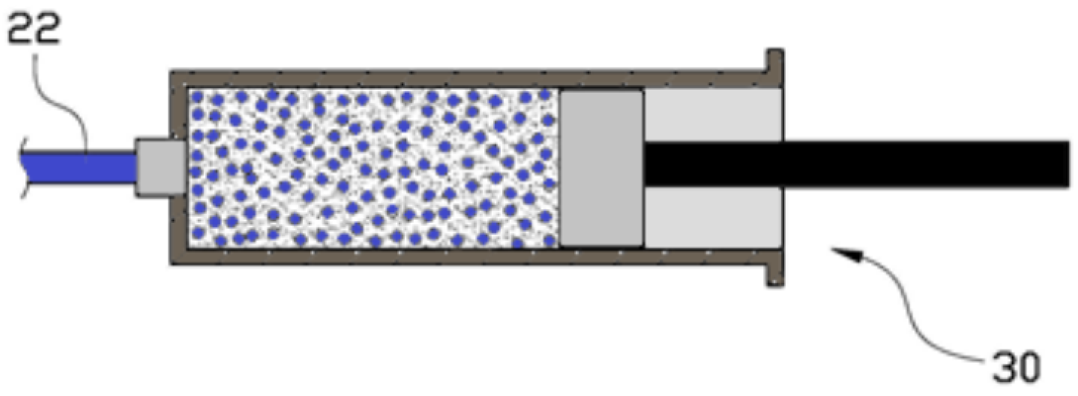


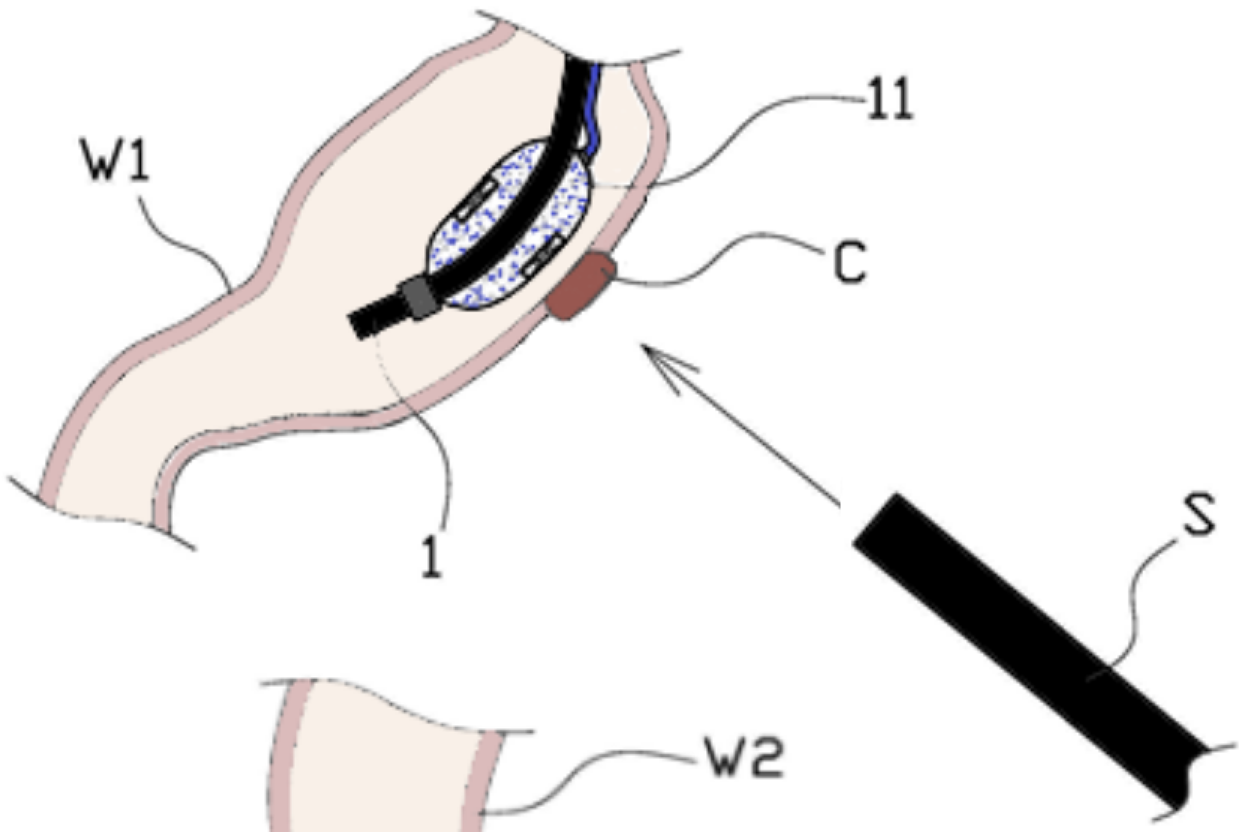
FIG.3

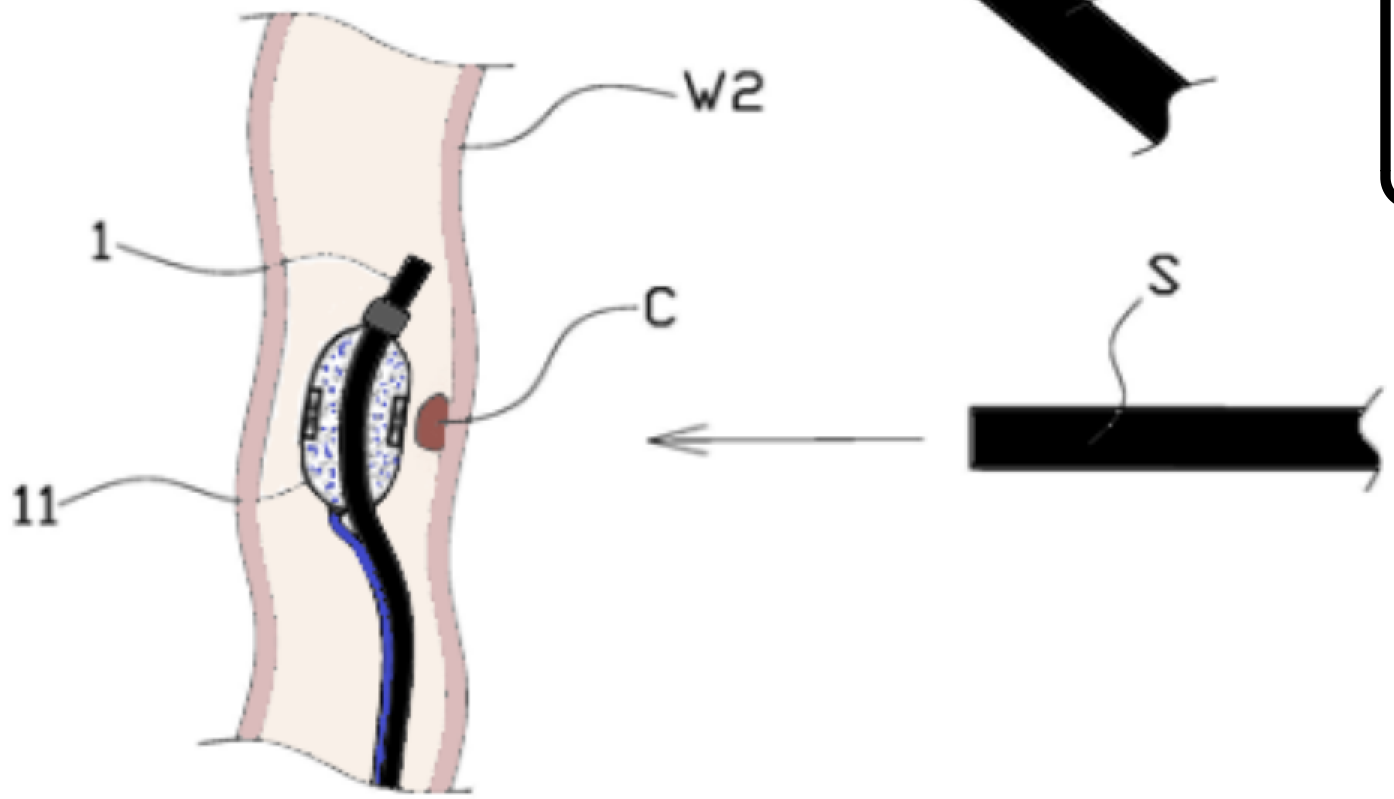
FIG. 3 is a cross-sectional view illustrating an embodiment of the mechanism through which the shield balloon can be inflated with the radiation attenuating material mechanism of our technology.

05 The radiation attenuating materials can be pumped or alternatively injected into the inflation tube with a syringe (30).

03 Intracavitary radiation shield

Detailed technology description





1. Endoscope
11. Shielding balloon (made of elastic materials e.g, silicone or soft synthetic resin)
W1. Stomach
W2. Colon
C. Tumor
S. Radiation source

FIG.4

FIG.4 is a cross-sectional view illustrating an example of use of the shield according to the present invention in radiation treatment.

FIG.5

FIG. 5 is a cross-sectional view illustrating an example of use of the shield port according to the present invention in radiation treatment of the large intestine.

03 Intracavitary radiation shield

Clinical applications

Offers internal protection to the GI tract from the mouth to the stomach and intestine to prevent toxicity and mucositis, without requiring insertions or surgery.

Can be utilized similarly to a rectal balloon, offering more sufficient protection due to the lead spheres used to inflate the shield that absorb the radiation better to conventional methods.

Radiation therapy dosimetrc sensors are incorporated into the shield enabling the determination of the exact radiation dose given to the tumor internally and absorbed by the shield.

Applicable to brachytherapy

Brachytherapy is radiation treatment that is given inside the patient, as close to the cancer as possible but usually does not require surgical procedures.

The radiation dose deliverable with conventional brachytherapy is limited by the presence of organs at risk adjacent to the tumor.

Our intracavitary radiation shield can be utilized to protect healthy tissue and vital organs when delivering brachytherapy.

- Inflatable with high radiation attenuating material
- Incorporated docimetric sensors
- Endoscopic application
- Rectal and gynecological application

04 Conclusions

Conclusions

We offer the following distinctive advantages:

Our internal radiation shield technologies have the potential to shift the paradigm of clinical management of patients receiving radiation therapy for cancer by reducing radiation-associated morbidity and therefore improving treatment adherence, having the potential to improve survival.

- Minimizes radiation caused damage and toxicity preventing the exposure of organs or tissues other than cancer tissue to the radiation treatment.
- Increased protection, reduced severe morbidity, treatment breaks or discontinuation that adversely impacts tumor cure rates.
- Decreases radiation toxicity and the occurrence of related complications such as mucositis, esophagitis, and proctitis.
- Flexible and easy to apply around cancer tissue to effectively protect organs and healthy tissue compared to lead plates currently in use.
- Dosimetric advantage and compliance compared to generic systems.
- Enables the usage pf higher radiation dosage for treatment.

Thank you

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