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WHITE PAPER

Comparison of Implantable Vascular Access Ports

CT Marker Visualization, CT Induced Artifacts, and Megavoltage X-ray Dosimetry Interference

- All of Smiths Medical power injectable ports can be identified as 'CT' power injectable at angles up to 60 degrees when rotated
- Smiths Medical ProPort® (non-titanium) and P.A.S. PORT® Elite (titanium reservoir, plastic body) non-power injectable ports have low CT artifact and clinically insignificant dosimetry alteration, making them excellent choices for patients requiring radiation for diagnostic and therapy purposes
- Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile power-injectable port with titanium reservoir and polysulfone housing had less artifact when compared to similar competitor non-titanium housing power-injectable ports
- This report offers detailed information addressing artifact relief and radiation dosimetry estimates of attenuation and scattering for radiation oncology purposes using a particle accelerator at 6 MV and 18 MV x-ray energies
- 18 vascular access ports from 5 manufacturers were investigated in this research

ABSTRACT

Vascular access ports are long-term, implanted ports that are commonly used to deliver chemotherapeutic treatments that are best tolerated via the parenteral route. It is important to have a good understanding of how vascular access ports impact the CT image quality for diagnosis by a radiologist, for port placement by surgeons, and for the treatment of patients by oncology specialists. Additionally, if the vascular access port is in the path of a radiation treatment designed concomitantly from a radiation oncologist, it is important to know how the ports affect dosimetry (i.e. the dose distribution of radiation) within the patient. This research report addresses concerns for most of these physician groups. CT image quality of vascular access ports was inspected by visualization of the non-radio opaque 'CT' marker at a high incident viewing angle and artifact presence in water at varying distances. Significance of having the vascular access port in the field of radiation treatment was also examined. The results of the study concluded that the CT markers were visible at angles up to 60 degrees when rotated in all of the Smiths Medical power injectable vascular access port models tested. Artifact and dosimetry via attenuation and scatter were calculated in 18 vascular access ports (Smiths Medical and competitive models). The ports composed of titanium exhibited the highest CT artifact levels. The artifact value is a function of the distance from the port. The titanium ports also had the greatest amount of x-ray beam blocking and scattering. It was concluded that plastic port models were superior to titanium port models as plastic ports affect CT image quality and radiation dosimetry the least. If a titanium port is desired for added port durability, then the Smiths Medical P.A.S. PORT® Elite System demonstrated the lowest artifact level, while exhibiting clinically insignificant effects on radiation dosimetry. The Smiths Medical PORT-A-CATH® II POWER P.A.C® power injectable port with titanium reservoirs and polysulfone body proved to reveal lower artifact levels than similar non-titanium ports.

INTRODUCTION

The study is presented as three parts. Part I addresses 'CT' marker visualization at oblique angles. Part II describes the artifacts exhibited in CT scan image data sets and their relation to proximity to the port. Finally, Part III illustrates the level of interference when a therapeutic x-ray beam is directed through each port. The purpose and rationale for each part is as follows:

Part I – Vascular Access Port 'CT' Marker Visualization

Power injectable infusion ports are implantable access ports designed to allow for repeated access to the vascular system. These devices consist of an injection port with a self-sealing silicone septum and a catheter. If information on 'CT' scan acquisition usability is not readily available and if the patient's port is a power injectable, it is important that the 'CT' label on the lumen of the port be identified under radiographic imaging. This section describes the results of the 'CT' marker radiographic imaging visualization of all of Smiths Medical power injectable ports.

Part II – Vascular Access Port CT Inducted Artifacts

CT scans are performed on all types of patients, but especially for cancer patients that undergo radiation therapy. Metallic and high density plastic medical devices tend to cause CT artifacts which can interfere with the radiologist's ability to diagnose or monitor physiological areas of interest near the device as well as with the radiation oncologist's ability to delineate target structures along with organs at risk when radiation treatment is desired. Physicians attempt to avoid port placement in locations they want to monitor, but in certain situations it is unavoidable. In situations where the vascular access port will be near an area the physician needs to focus attention, it is important for the physician to understand the amount of artifact potentially introduced into the CT scan when selecting which type of vascular access port to implant. This section compares the amount of CT artifact produced by 18 different non-titanium and titanium ports (Smiths Medical and similar competitive models).

Part III –Dosimetry Changes of Megavolt X-Ray from Vascular Access Port Interference

An additional issue physicians face with vascular access ports is that a CT scan is used to simulate radiation delivery for radiation treatment modeling using a computer treatment planning system. Medical physicists try to avoid delivering radiation through implanted devices such as vascular access ports, but some situations are clinically unavoidable. If significant amounts of artifact exist, it is difficult to calculate how much radiation will be delivered to a specific location. This section details the amount of radiation attenuation and scatter that is produced, which alters the distribution of dose for the intended target of the x-ray beam. 18 vascular access ports were investigated (Smiths Medical and similar competitive models).

P.A.S. PORT® T2 POWER P.A.C.® Titanium

BOTH THE SMITHS MEDICAL PROPORT® AND P.A.S. PORT® ELITE SYSTEMS PRODUCED LESS THAN 3% CHANGE IN DOSIMETRY DISTRIBUTION, WHICH DOES NOT SIGNIFICANTLY ALTER THE PRESCRIBED THERAPEUTIC DOSE FOR ONCOLOGY RADIATION THERAPY AT 6-18 MV X-RAY BEAM ENERGIES.

PART I - VASCULAR ACCESS PORT 'CT' MARKER VISUALIZATION

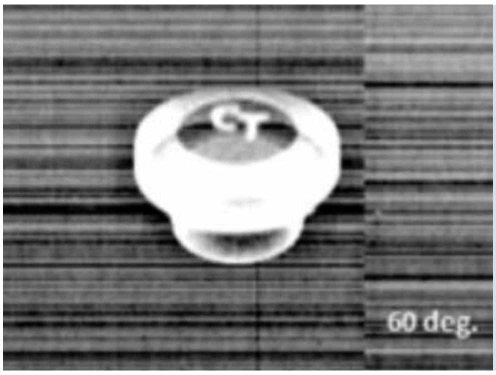
The goal of this testing was to determine if the marking (barium sulfate 'CT' label) on the septum of the Smiths Medical power injectable ports would be visible on a digital radiograph at angles up to 60 degrees when rotated. All ports were imaged with a kilovoltage imaging system having a digital detector panel. The imager was a Varian Medical Systems, Inc. (Palo Alto, CA) diagnostic x-ray On-Board Imager attached laterally to their Triology particle accelerator.

The ports were positioned at 60 degrees with the septum facing the x-ray tube. In all of the dual and single chamber ports tested (**Table 1**), the CT marking was visible. This demonstrated that all Smiths Medical power injectable ports can be identified as 'CT' power injectable at angles up to 60 degrees when rotated.

SMITHS MEDICAL PORTS OFFER EQUIVALENT CT RADIOGRAPHIC IMAGING AS COMPETITORS AT 60 DEGREES

TABLE 1: SMITHS MEDICAL POWER INJECTABLE PORTS TESTED

Product Name	Model No.
PORT-A-CATH® II POWER P.A.C.® Low Profile	21-4482-24
P.A.S. PORT® T2 POWER P.A.C.®	21-4872-24
PORT-A-CATH® POWER P.A.C.®	21-4424-24
PORT-A-CATH® POWER P.A.C.® Low Profile	21-4436-24
PORT-A-CATH® II POWER P.A.C.® Dual	21-8468-24
PORT-A-CATH® II POWER P.A.C.®	21-4452-24
PORT-A-CATH® Dual	21-8010-24



Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile (21-4482-24)

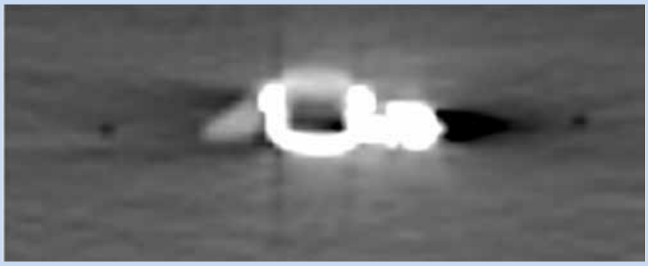
Figure 1.

Example of Angular CT Marker Test

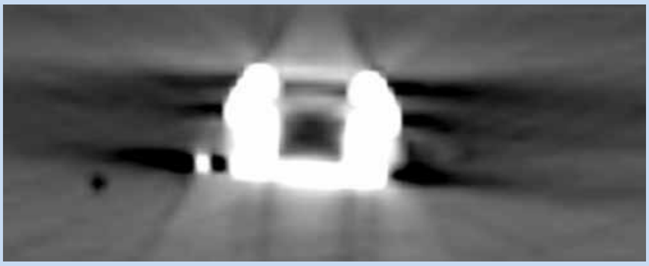
Example of the Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile power injectable vascular access port imaged at 60 degrees to visualize the barium sulfate 'CT' on the port lumen.

PART II – VASCULAR ACCESS PORT CT INDUCTED ARTIFACTS

Metallic and high density plastic medical devices tend to cause CT artifacts, which can interfere with the radiologist's ability to diagnose lesions near the devices. These artifacts can also interfere with the identification of normal tissues and disease by a radiation oncologist. Various Smiths Medical vascular access ports and competitive port models were imaged with a General Electric LightSpeed RT (Fairfield, CT) helical CT scanner to determine which ports caused the least amount of artifact and allowed the greatest visibility near the port. Air was removed from the ports by priming each with water. Each port was imaged consecutively at a depth of approximately 5 cm in a 30x40 cm^2 water phantom tank. A stereotactic radiosurgery scanning protocol was utilized. The technique included 120 keV peak x-ray energy, 50 cm diameter circular field of view and couch increment of 1.25 mm/slice. This small slice thickness was used to enable identification of smaller components within the scan.[2] Ports were imaged and analyzed for their level of artifact, normalized relative to the background water density actually present, in 1 cm increments from the edge of each port (1 cm to a 7 cm distance away laterally) in the direction of the incident x-ray beam.



Smiths Medical PORT-A-CATH® P.A.S. PORT® Elite (21-4591-24) port



Bard Titanium Single Lumen Port (0605320)

Figure 2.

Examples of vascular access port artifact on CT scans.

The black lines adjacent to the bright white vascular access ports are artifacts.
Smiths Medical PORT-A-CATH® P.A.S. PORT® Elite System (21-4591-24) has lower artifact when compared to the Bard Titanium (0605320) port.

THE SMITHS MEDICAL P.A.S. PORT® ELITE AND PORT-A-CATH® II POWER P.A.C.® SYSTEMS WITH TITANIUM RESERVOIRS HAD SIGNIFICANTLY LESS ARTIFACT THAN SIMILAR COMPETITOR MODELS, PERFORMING ALMOST AS WELL AS SOME COMPETITOR NON-TITANIUM PORTS

The amount of artifact produced by a material is expressed in Hounsfield Units (HUs), which are normalized to water (0 HU). HU values that fall within ± 1,000 are in the normal range with – 1000 HU representing air and + 1000 representing dense bone. Values larger than +1,000 HU are in the extended range. Metals can be considerably higher than +1,000 HU (e.g. titanium alloy = 6000-8000 HU), which leads to significant CT artifacts.

As anticipated, non-titanium ports exhibited the least amount of CT artifact (**Table 2**). Similarly, ports that have titanium reservoirs (**Table 3**) revealed the greatest amount of artifact, especially when closer in proximity to the port. The Smiths Medical ProPort® (21-4152-24) non-titanium vascular access port showed little artifact in close proximal distances and was the only port that had no artifact when visualized at 4 cm. The Smiths Medical P.A.S. PORT® Elite (21-4591-24) and PORT-A-CATH® II POWER P.A.C.® Low Profile (21-4482-24) Systems with titanium reservoirs and non-metallic bodies had fewer artifacts than similar competitor models. Each demonstrated slightly elevated, although similar artifact levels as the Medcomp non-titanium ports.

TABLE 2: NON-TITANIUM PORTS: HU VALUES

	Artifact Distance from the Port (cm)						
	1	2	3	4	5	6	7
Bard MRI Port (0602830)	22	21	14	4	0	0	0
Smiths Medical ProPort® (21-4152-24)	43	9	5	0	0	0	0
Medcomp Dignity®	84	51	48	27	10	0	0
Medcomp Pro-fuse®	197	98	28	2	0	0	0
Medcomp Dignity Mini®	269	103	58	26	8	0	0

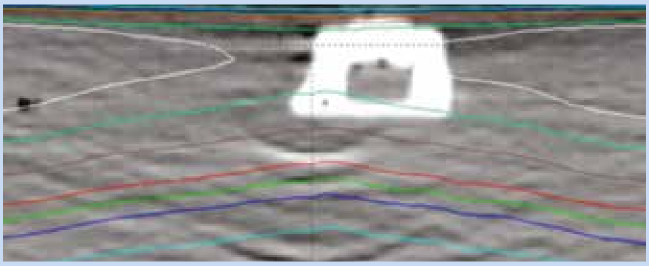
TABLE 3: TITANIUM PORTS: HU VALUES

	Artifact Distance from the Port (cm)						
	1	2	3	4	5	6	7
Smiths Medical PORT-A-CATH® P.A.S. PORT® Elite (21-4591-24)	84	58	57	27	16	2	0
Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile (21-4482-24)	186	110	73	60	52	23	16
Smiths Medical PORT-A-CATH® II POWER P.A.C.® (21-4452-24)	382	239	150	119	99	78	61
Bard Titanium (0605320)	384	336	238	140	135	133	108
Bard PowerPort ISP (1708060)	409	236	119	118	97	58	48
AngioDynamics Vortex® VX (P5455K)	450	322	231	188	135	81	51
Navilyst Vaxcel® U/PASV (M1001452130)	453	242	144	116	89	84	42
AngioDynamics Smart Port™ CT (CT805TPD)	487	329	186	109	53	50	22
Smiths Medical P.A.S. PORT® T2 POWER P.A.C.® (21-4872-24)	606	344	172	155	71	75	61
Smiths Medical PORT-A-CATH® POWER P.A.C.® Low Profile (21-4436-24)	637	296	202	180	136	81	40
Smiths Medical PORT-A-CATH® POWER P.A.C.® (21-4424-24)	643	270	205	173	143	119	89
Smiths Medical PORT-A-CATH® II Dual (21-8050-24)	850	507	271	185	111	60	50
Smiths Medical PORT-A-CATH® Dual (21-8010-24)	987	539	413	289	240	192	120

PART III – DOSIMETRY CHANGES OF MEGAVOLT X-RAY FROM VASCULAR

Access Port Interference Radiation oncologists face difficulty when vascular access ports remain implanted in the patient near anatomy important to view in a CT scan. It is the CT scan that is often used to simulate radiation delivery for radiation treatments, when combined with computer software that include radiation beam data. Although the associated medical physicist should try to avoid delivering radiation through implanted devices such as vascular access ports, some situations are clinically unavoidable. If a significant amount of artifact exists, it is difficult to calculate how much radiation will be delivered to a specific location. A Varian Medical Systems, Inc. Model Eclipse external beam treatment planning software was used to calculate the amount of radiation scattering and attenuation caused by vascular access ports, after correcting CT scan data for the artifacts observed.[1] For modeling, a dose[1] rate of 400 cGy/min was set to each beam with 100 cGy per beam, generating a treatment time of 15 seconds to achieve the desired dose with a 1.25 mm calculation grid. Calculation points of interest were placed in a series of five points anterior and posterior to the port surface based on knowledge of each port's HU results. The points were positioned in areas where the highest dose gradients were expected and repositioned, as appropriate, to those high HU locations. Eighteen vascular access ports were analyzed for 6 MV and 18 MV x-ray beam affects. An example of how the radiation distribution was affected by a vascular access port is shown in **Figure 3**.

SMITHS MEDICAL PROPORT® AND P.A.S. PORT® ELITE SYSTEMS ARE BOTH SHOWN TO HAVE CLINICALLY INSIGNIFICANT DOSIMETRY ALTERATIONS FOR APPLICATIONS NOT REQUIRING POWER INJECTION CAPABILITIES



Smiths Medical ProPort® (21-4152-24) port

Smiths Medical P.A.S. PORT® Elite (21-4591-24) port

Figure 3.

Example of vascular access port dosimetry alteration.

The colored lines below the Smiths Medical ports show the amount of radiation that was absorbed by the vascular access port and local water. The same energy was employed for each plan.

The flat and smooth lines not in the path of the vascular access port show no alteration in dosimetry and were expected to be the shape of the beam. The lines that are skewed and trend upward and rippled under the device demonstrates the unwanted amount of radiation that is absorbed by the device (i.e. attenuation). The calculated attenuation and scatter for all devices is shown in **Table 4** and **Table 5** for 6 MV and 18 MV, respectively.

PORT-A-CATH® II POWER P.A.C.® Polysulfone

1. The gray (Gy) is the International System of Units standard unit for absorbed dose, defined as the absorption of 1 Joule of ionizing radiation by 1 kilogram of matter (i.e. human tissue or water). It is equivalent to 100 cGy or 100 rads

TABLE 4: 6 MV X-RAY ATTENUATION AND SCATTER DATA

	16 MV X-rays		
	Attenuation (%)	Backscatter (%)	Lateral Scatter (%)
Angio Dynamics Vortex® VX (P5455K)	0.0	0.0	0.0
Smiths Medical ProPort® (21-4152-24)	-0.7	0.2	0.1
Bard MRI Port (0602830)	-1.0	0.4	0.2
Medcomp Dignity®	-1.0	0.4	0.3
Smiths Medical P.A.S. PORT® Elite (21-4591-24)	-2.7	0.8	0.6
Medcomp Pro-fuse®	-3.0	1.0	0.7
Medcomp Dignity® Mini	-5.1	1.3	0.9
Smiths Medical PORT-A-CATH® II POWER P.A.C.® (21-4452-24)	-7.5	2.2	1.5
Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile (21-4482-24)	-8.3	2.4	1.7
Smiths Medical P.A.S. PORT T2 POWER P.A.C.® (21-4872-24)	-11.8	3.4	2.3
Navilyst Vaxcelv U/PASV (M1001452130)	-11.9	3.4	2.3
Bard PowerPort ISP (1708060)	-14.3	3.8	2.6
AngioDynamics Smart Port® CT (CT805TPD)	-14.8	4.1	2.8
Bard Titanium (0605320)	-15.6	4.2	2.9
Smiths Medical PORT-A-CATH® POWER P.A.C.® (21-4424-24)	-16.0	4.3	3.1
Smiths Medical PORT-A-CATH® II Dual (21-8050-24)	-18.8	5.9	4.4
Smiths Medical PORT-A-CATH® POWER P.A.C.® Low Profile (21-4436-24)	-19.1	6.0	4.6
Smiths Medical PORT-A-CATH® POWER P.A.C.® Dual (21-8010-24)	-22.6	6.4	5.0

TABLE 4: 6 MV X-RAY ATTENUATION AND SCATTER DATA

	18 MV X-rays		
	Attenuation (%)	Backscatter (%)	Lateral Scatter (%)
Angio Dynamics Vortex® VX (P5455K)	0.0	0.0	0.0
Bard MRI Port (0602830)	-0.3	0.1	0.0
Smiths Medical ProPort® (21-4152-24)	-0.5	0.2	0.1
Medcomp Dignity®	-0.5	0.2	0.1
Smiths Medical P.A.S. PORT® Elite (21-4591-24)	-1.2	1.1	1.2
Medcomp Pro-fuse®	-1.4	1.3	1.4
Medcomp Dignity® Mini	-2.0	1.8	1.9
Smiths Medical PORT-A-CATH® II POWER P.A.C.® (21-4452-24)	-3.0	3.0	3.4
Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile (21-4482-24)	-3.2	3.1	3.5
Smiths Medical PORT-A-CATH® II Dual (21-8050-24)	3.7	-3.3	3.2
Smiths Medical PORT-A-CATH® POWER P.A.C.® Low Profile (21-4436-24)	-3.6	3.4	3.8
Navilyst Vaxcelv® U/PASV (M1001452130)	-4.6	4.5	4.9
Smiths Medical P.A.S. PORT® T2 POWER P.A.C.® (21-4872-24)	-5.2	4.9	5.3
AngioDynamics Smart Port® CT (CT805TPD)	-5.7	5.5	5.8
Bard PowerPort ISP (1708060)	-6.1	6.0	6.6
Smiths Medical PORT-A-CATH® POWER P.A.C.® (21-4424-24)	-6.2	6.1	6.7
Bard Titanium (0605320)	-6.6	6.7	7.1
Smiths Medical PORT-A-CATH® POWER P.A.C.® Dual (21-8010-24)	-8.7	7.6	8.3

The density of the material was used to calculate the absorbed dose of radiation incident through it. As anticipated, the results were consistent with CT artifact findings. The vascular access ports with titanium reservoirs had the greatest amount of attenuation and scatter when compared to the non-titanium ports. Smiths Medical ProPort® (21-4152-24) and P.A.S. PORT® Elite (21-4591-24) Systems were both shown to induce clinically insignificant, albeit measurable changes in dose at 6 and 18 MV x-ray energies. This was observed by the limited to no dosimetric line disturbances in the computer modelled plan.[1]

CONCLUSIONS

All of the Smiths Medical power injectable port models can be identified as 'CT' power-injectable up to 60 degrees when rotated on a digital radiograph. This is important for physicians if they need to identify the port as power injectable.

When considering artifact production, the Smiths Medical ProPort® (21-4152-24) Systems was superior to all other Smiths Medical vascular access ports examined at 2 cm proximal to the port and beyond. It was the only port tested that had no artifact at a distance of 4 cm or more away from the port. Trabecular bone has a Hounsfield Unit value of nearly +200 HU. At approximately +200 HU, the computer simulation shows that the radiation beam interacts significantly with these higher density materials. This study showed that nearly all artifacts observed were caused by higher density composite materials and were either below or near to +200 HU at a distance of 4 cm away. Therefore, the clinical significance of artifacts was within the first 4 cm away from the port for this study

In cases where a titanium port reservoir is desired for long-term durability, the Smiths Medical PORT-A-CATH® P.A.S. PORT® Elite (21-4591-24) system also generated a small amount of artifact and clinically insignificant dosimetry via attenuation and scattering processes. The advantage of ports with titanium reservoir is that they offer the durability of a titanium reservoir (resists gouging of the port floor) and still allow physicians to visualize the tissues surrounding the device. These also have the added benefit of being made with plastic, which make them lightweight for added patient comfort. Both the Smiths Medical ProPort® and P.A.S. PORT® Elite Systems produced less than 3% change in dosimetry distribution. This small amount does not significantly alter the prescribed therapeutic dose in oncology radiation therapy at 6-18 MV x-ray beam energies.

For patients requiring a power injectable port, the Smiths Medical PORT-A-CATH® II POWER P.A.C.® Low Profile (21-4482-24) System with titanium reservoirs and non-metallic bodies exhibited fewer artifacts than competitive Medcomp non-titanium ports.

This comprehensive look at titanium and non-titanium vascular access ports will assist physicians in defining which products are ideal for patients needing diagnostic radiology and radiation therapy to manage their disease. This information can also be used by vascular surgeons to help them make decision about port placement. Fewer artifacts were present for all models at distances further away from the port. Plastic port models performed the best in this research study, causing the least amount of CT artifact and markedly reduced therapeutic dose disturbance.

The high magnitude of CT artifacts observed for ports with titanium reservoirs were proven to be a consequential factor in dosimetry, where a greater amount of beam blocking and scattering were determined for these ports. For therapeutic purposes in radiation oncology, dealing with plastic ports will be less of a challenge than titanium ports or very dense port models, since these alter the dose distribution the least. However, it is highly difficult for surgeons to prospectively know if a patient has a reasonable potential to be diagnosed with cancer, to which the location of port placement could be an obstacle for pending radiologist imaging needs and radiation oncology treatment needs.

Smiths Medical P.A.S. PORT® Elite (21-4591-24)

ACKNOWLEDGEMENTS

The opportunity to study all vascular access ports examined here was supported by the issuance of donated devices and materials from Smiths Medical.

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Michael Gossman, M.S., DABR, FAAPM, was paid by Smiths Medical to perform the testing presented here. He has no known affiliation or conflict of interest with Smiths Medical.

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