## Q What is your opinion about subcutaneous drains?

Since October 2012 I have placed 96 indwelling subcutaneous drains because they remove subcutaneous exudation rapidly when the wounded area is compressed and subjected to negative pressure and also because they reduce SSI due to increased blood flow . The size used was generally 10Fr and the closure method was changed from subcutaneous and dermal continuous suture to dermal interrupted suture only . The average suction rate was 10ml per day or less, with an indwelling period of between 2 and 8 days. W e had only one case of mediastinitis, which is a clear reduction of SSI when compared to how it was before we started using the Spiral Drains. This finding is similar to those of other facilities, and there is no doubt that the accumulation of exudate, regardless of how small the quantity , triggers infection and I believe that an indwelling subcutaneous drain is an extremely ef fective way to prevent SSI.

## Q Is there a limit to the application of the Spiral Drain after cardiac surgery?

From our experience, the Spiral Drain provided ef fective drainage in all cases. To start with I had doubts about these fluted type drains and had the impression that they might not suction well under real-time conditions of profuse hemorrhage and I also thought they might clog easily . But after actually using them in a substantial number of dif ferent cases it became clear to me that such concerns were unfounded. The Spiral Drain has the same draining capacity as conventional thick drains with side holes and I believe there is no limitation to their application.

Thank you very much for your valuable opinion.

■ Mera Milking Roller

■ Mera Drain Connector and Connecting Tube


Distributor

MERA 泉工医科工業株式会社

■ Inquiries: Head Office Product Planning Department Phone: +81-(0)3-3812-3254 Fax: +81-(0)3-3815-7011

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Manufacturer REDAX®

Manufacturer and Distributor 泉工医科貿易株式会社 3-20-12 Yushima, Bunkyo-ku, Tokyo 113-0034 JAPAN


Caution Please read the instruction manual and all other attached documents thoroughly before handling and using the product.




October 2013 / 3,000 copies





S-1 B-49 BO-0215-01 Certification number: 221ADBZX00077000

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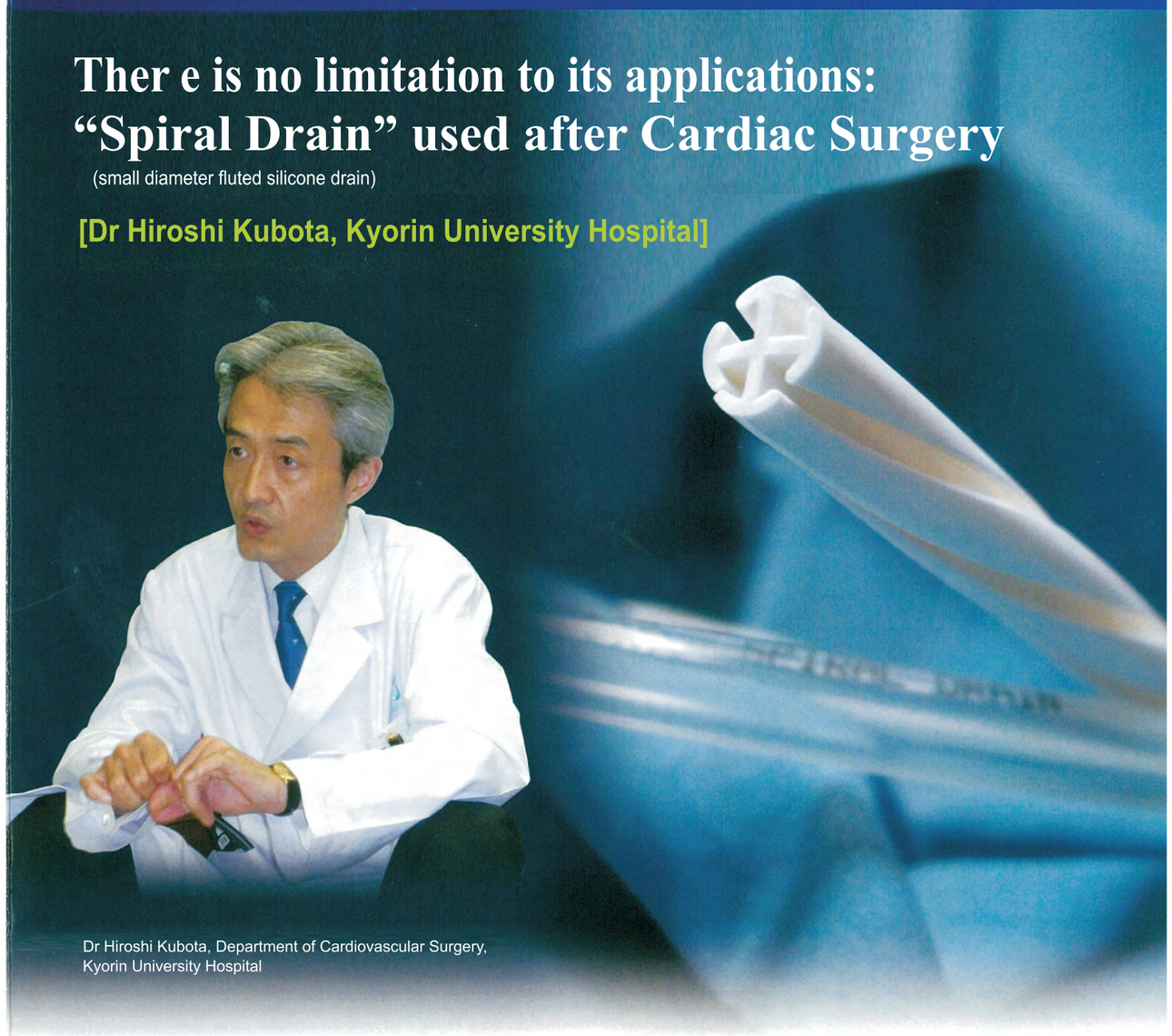
# Ther e is no limitation to its applications: “Spiral Drain” used after Cardiac Surgery

(small diameter fluted silicone drain)

[Dr Hiroshi Kubota, Kyorin University Hospital]



Dr Hiroshi Kubota, Department of Cardiovascular Surgery, Kyorin University Hospital

Cardiac surgery with minimized invasiveness by such means as MICS, OPCAB and robot assisted surgery has recently made dramatic advances. However, with respect to drainage after surgery, the methods used in many cases have been unchanged for a long time due to the particularity of application and its critical nature. Nevertheless, the number of severe cases that require flexible indwelling drains after complicated surgery, that cannot be catered for by conventional drains, has been increasing. We asked Dr Hiroshi Kubota about the adaptability and benefits of the Spiral Drain, as well as for tips on indwelling positions, based on their extensive clinical experience. Dr Hiroshi Kubota is a professor of cardiovascular surgery at Kyorin University Hospital, where the small diameter fluted silicone drains (Spiral Drain) are in use after a switch was made from standard procedures using conventional side hole drains. This change was made in response to the changing operative and indwelling methods, as well as to further improve the QOL for patients.

## Q Please tell us about the latest status of use and clinical performance.

A retrospective survey was made of 124 cases of open-heart surgery conducted between August 2012 and July 2013 which involved median sternotomy and used an artificial heart-lung unit. Of these, 75 cases were scheduled and 49 cases were emergency surgeries. The cases comprised 58 of ischemia, 39 of valvular disorders, 20 of aortic disorders, two cases of congenital disorders and five cases of other description. Three types of drains (described in the table below) were used in these cases (124) and they were investigated with regards to the volume of drainage after surgery , daily variations and decannulation POD and categorized as pericardial drains and anterior drains. The selection of drains was based on timing and there were no particular reasons for their choice. It was a natural transition to those we found to provide better usability and there was no intentional selection at work, such as “using a particular drain to cope with large volume of hemorrhage”. Looking back we were initially using the conventional side hole drains and gradually transitioned to the Spiral Drain and we are now using the Spiral Drain for all cases.

### Types and characteristics of drains used

| | External (long span) diameter | Material | Suction method | Characteristics |
|---|---|---|---|---|
| Spiral Drain 24Fr | 8.2mm | Silicon | Fluted type | Four fluted channels |
| Conventional type drain 8mm flat type | 10.8mm | Polyurethane | Side hole type | Urokinase solidification |
| Silicon 24Fr | 8.0mm | Silicon | Fluted type | Four parallel channels |

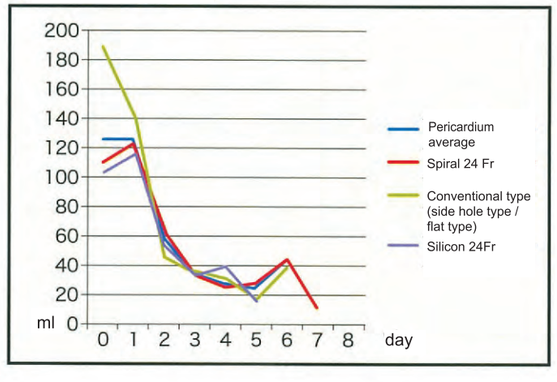
During this period complications that occurred included one case of hemostasis drift with a reopened chest, one case of sternal osteomyelitis and no cardiac tamponade. The amount of fluid discharged on the day of surgery using the conventional drain stands out with pericardial drainage, but this was due to the fact that there were particular cases with large amounts of hemorrhaging and because the sampling number was small. In the end any of the drains would have been adequate for such an amount of hemorrhaging. CT scans after surgery showed no cases of pericardial fluid accumulation and the conclusion was that the drainage was favorable in all cases.

## Pericardium drainage

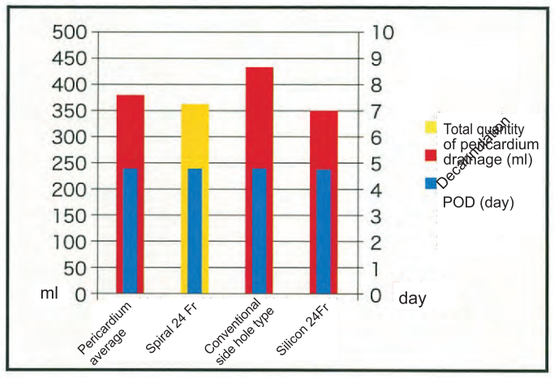
### ❶ Quantity used and maximum daily liquid discharge

| Pericardium drainage | Quantity used | Max. daily liquid discharge |
|---|---|---|
| Spiral Drain 24Fr | 92 sets | 510ml |
| Conventional drain 8mm flat type | 27 sets | 640ml |
| Silicon 24 Fr | 6 sets | 310ml |

### ❷ Daily variation in quantity of liquid discharge




### ❸ Total quantity of pericardium drainage and decannulation POD

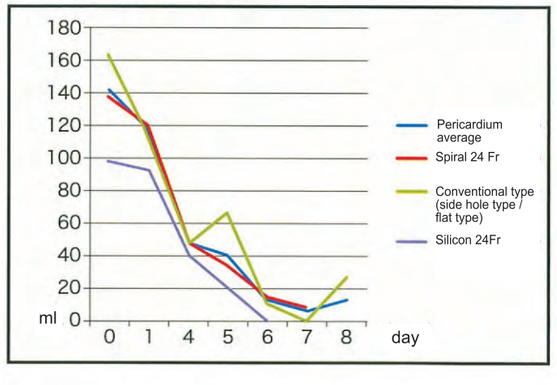



## Anterior drainage

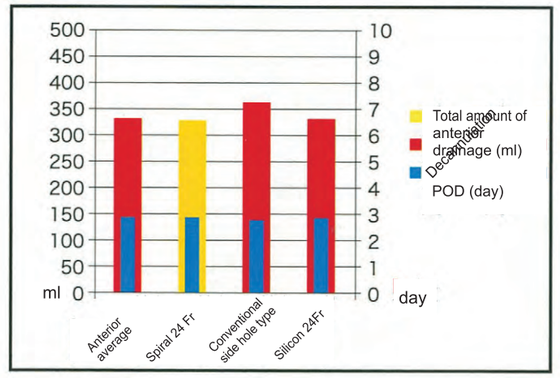
### ❶ Quantity used and maximum daily drainage

| Anterior drainage | Quantity used | Max. daily liquid drainage |
|---|---|---|
| Spiral Drain 24Fr | 86 sets | 650ml |
| Conventional drain 8mm flat type | 25 sets | 630ml |
| Silicon 24Fr | 7 sets | 162ml |

### ❷ Daily variation in quantity of liquid discharge




### ❸ Total amount of anterior drainage and decannulation POD




## Q What you are telling us is that there was absolutely no difference between the fluted type such as the Spiral Drain and the conventional side hole type drains, is that correct?

I had previously thought that fluted type drains could not keep up with large quantities of hemorrhaging, but the results of our survey indicated that there was no significant dif ference between any of the drains. The Spiral Drain handled anterior drainage discharges that involved hemorrhaging of 650gm daily , as can be seen in our data. In terms of drainage, I now know from my own experience, using 178 sets over the past year , that the Spiral Drain is capable of keeping up and providing drainage for hemorrhages in real time, even in cases of large hemorrhage volume. No clogging occurred even though blood with high hematocrit levels was suctioned.

## Q Please tell us the specific reason for your decision to change from conventional side hole type drains to the Spiral Drain.

It is because I learned from experience that the Spiral Drain, in spite of its slimness, was capable of handling the volumes of hemorrhaging we encountered. Initially I was concerned that if the spiral drain could not keep up with the large volumes of hemorrhaging, things could become bad and it might be too late for us to deal with the situation. But, by gradually increasing the number of instances where we used the Spiral Drain in place of the conventional ones I came to realize that they were quite able to keep up, even in cases that involved profuse hemorrhaging. Furthermore, the impression I got from our post-operative CT scans was that the amount of accumulated pericardial fluid was less than was usual with conventional drains and I reached the conclusion that the Spiral Drains provided better drainage. This led to a gradual transition from the conventional side hole type drains to the Spiral Drain. Needless to say , if the drain of fers the same ef fect, then the one that is slimmer , more flexible and that causes less pain to the patient is the better choice. Also, the fact that indwelling to the target can be set more easily with a flexible drain was also one of the reasons for the choice.

## Q What is your impression about pain caused by the drainage device?

This is purely my impression, but it appears that the indwelling Spiral Drain causes less pain than the thick and less flexible drains. V ery few patients ever complain about indwelling pain from these thin flexible drains.

Patients do experience pain when they are extracted but the pain is brief and never prolonged.
Conventional flat drains are bigger , 10mm across or more, and the incision needs to be larger . The round Spiral Drain is 8mm in diameter and the SSI is much reduced.

## Q What is the most important aspect of drainage after cardiac surgery?

Without any doubt, real-time drainage of hemorrhaging is the most critical issue. The drainage must keep up with even large amounts of hemorrhaging. Blood must not be allowed to accumulate for suctioning later . If drainage does not keep pace with hemorrhaging, cardiac tamponade may be triggered and the decision to reopen the chest can potentially come too late. The Spiral Drain provides real-time suctioning and is capable of suctioning from the entire 30cm channel section and can drain from wherever hemorrhaging occurs, unlike the conventional drains that can only suction from the side holes. The Spiral Drain is capable of keeping up with hemorrhaging up to 605ml (per day) and post-op CT scans also clearly show that there is very little accumulation of pericardial fluid. In my opinion the Spiral Drain satisfies all the necessary conditions. These drains also need much smaller incisions and are far less intrusive and painful for the patent. So I would say this is an ef icient drain that of fers advantages for both the patient and the surgeon.

## Q Please tell us about the indwelling method.

A drain is basically anchored on the skin at the section with a black dot, located at five centimeters from the channel. So if we are dealing with the pericardium, then we bring the tip of the drain to the reverse side of the auricle of the left atrium, cut of f the excessive portion and set up indwelling. If we are dealing with the anterior , then we bring the tip of the drain up to the recessed portion at the upper edge of the sternum and in a similar manner cut of f the excessive portion and set up the indwelling. In such cases it is not possible to insert a conventional flat drain very deeply . This is an important aspect since accumulation of liquid in the recessed space on the upper edge of the sternum can cause mediastinitis. The Spiral Drain proved to be extremely convenient for this purpose as it is capable of draining even in such sections. I believe that having ef fective drainage in this area is one of the contributing factors behind the reduction in the incidence of mediastinitis. Drainage of the recessed space on the upper edge of the sternum was considered extremely important when I worked at the Blaise Pascal University some time ago, the practice there was to indwell another drain on the upper side, as well as from the anterior . The Spiral Drain is very slim and flexible, and so it is possible to deal with situations where it is dif ficult to position the drainage. For example where the chest cavity and the pericardium run into each other and the cardiac membrane is extensively extracted due to constrictive pericarditis it is possible to quite freely place two or three sets of indwelled drainages to the anterior . Furthermore, since fluted type drains in general provide suction from the starting point of the channels, they provide a thorough suctioning throughout their lengths, and also become buried in tissues in areas where there is little liquid discharge. For this reason, when setting indwelling, I do not place the starting point of the channel at the most critical location.