ZSI 375 TROUBLESHOOTING MANUAL FOR DISTRIBUTORS

Guidelines and Questions for Approaching Patient Difficulties

Version 1 - March 2015

DOCUMENT FOR DISTRIBUTOR

The goal of this manual is to provide general trouble shooting guidelines for when a patient experiences difficulties with the ZSI 375. Be aware that the following information is not a substitute for the medical knowledge that a Urologist has with respect to his field nor for the implantation process of and an Artificial Urinary Sphincter such as the ZSI 375.

GENERAL TROUBLESHOOTING PROTOCOL

Given the very low probability of mechanical failure of the ZSI 375, when dealing with a difficult situation, it must be assumed that the device is functioning properly, as in almost all cases it will be. If the expected results are not achieved with the ZSI 375, only the following hypothesis should be considered:

What changes has the patient's body and mind undergone for the device to be perceived as not functioning properly?

Having archived your patient's information, you should contact the Urologist to obtain more specific information about the given patient, which could impact the perception of a mal-functioning device.

ANALYZE THE CASE YOURSELF

- Obtain all information that could help you reach a conclusion about the difficulties of the case you are presented with. Only after having studied the case yourself should you contact the Urologist. It is not his responsibility to deal with perceived technical difficulties, such as a mal-function, only medical ones, such as an infection. The doctor should not be stressed with minor situations that can be resolved through simple reasoning.

- Do not contact Zephyr the moment you receive a patient complaint. We assure you that the combination of our documentation about the ZSI 375 provided to you and the Urologists medical knowledge are sufficient in solving almost all patient complaints. We are here only as a last resort unless you are under training.

- If, having gone through all our documentation about the device and consulted with the Urologist, a solution cannot be found and/or the difficulties cannot be clearly pinpointed to a specific cause, you can contact us. When contacting us you must provide all relevant information so that we can be of most help to you.

PSYCHOLOGICAL CONSIDERATIONS

Keep in mind that, for a person to have arrived at the need for an Artificial Urinary Sphincter, they have experienced physical, psychological and/or neurological traumas for a short or long period of their life. Such a state can create an emotionally frail patient who might be expecting too much either from the device and/or you. This is especially the case when the patient themselves has paid the total cost of the device and implantation.

Even though none of us are responsible for the patients past or present trauma, Empathy is a tool that will help you solve almost all cases of which patients come to you with. Sometimes the difficulties perceived by the patients with respect to the device are not because the device is actually mal-functioning, but because it is perceived as so. Our emotions play an important role on how we perceive things around us, and an emotionally frail patient may be perceiving difficulties in the functioning of the device which are not real. In all cases we advise emotional sensitivity with respect to the patient. Most of the times this is enough to resolve any difficulty. If such cases occur or persist, it is best that you help the patient seek psychological help, such as with a psychologist. Their difficulty does not lie with you or the device.

REMEMBER

- It is neither yours nor the Urologists fault for the trauma of the patient that has led them to seek an Artificial Urinary Sphincter, such traumas as cancer, radical prostatectomy, prostatic adenomectomy, trans-urethral resection of prostate or years of difficulty in managing their situation.
- All of us are here to help the patient make best use of the device, but it must also be kept in mind that every human body reacts differently to foreign object that get implanted.
- All cases of infections are due to complications that occurred during the operation and are never a caused by the device. The ZSI 375 is delivered 100% sterile, 100% of times.
- DO NOT PANIC. We assure you that most issues are simple to resolve and have more to do with patient's lack of training on how to use device or high expectation of what the device can do.
- Question the patient concisely about their problematic experience with device and their pathological history.
- Perform an Xray of the device before any other action, especially with complaints of device mal-function. An Xray image of the spring can give a clear reading of the device and whether it is functioning as it should or not.
- If the patient is facing an infection that could lead to urethral necrosis, you should advise their doctor to refer them to a psychologist so that they may best deal with the circumstances of the situation.

BEFORE AND AFTER ACTIVATION

SKIN EROSION AND HEALING

During the activation day you should check the patient's skin and incisions. If unsure of the state of the incisions ask the doctor to check. Very rarely skin erosion can occur after activation.

Due to a patient's genetic predisposition, their incisions may take longer to heal or not heal fully. The healing should be checked frequently for infection, such as kist, which could then contaminate the device.

- Ask the house nurse or someone who is with the patient daily to check the incisions and clean them if necessary until incisions are fully healed.

If the patient's scrotum turns white at the location of the device, it could mean that:

- The device has been contaminated which can lead to urethral and/or scrotal necrosis.
- The device has been implanted without sufficient layers of the scrotal skin covering it.
- Due to patient's genes, there is bad blood circulation at the site.

This could lead to an extrusion of the device out of the scrotal skin. In such situations, ask the medical staff/or a private nurse/ or the patient/or is family to check the site regularly. If it looks like the skin is thinning and there is a risk of extrusion, the patient must be re-operated so that the device can be placed under a sufficient amount of skin to avoid any future issues.

BEFORE ACTIVATION

DURING THE HEALING PERIOD THE PATIENT CLAIMS THAT HE IS NOT INCONTINENT AS HE SHOULD BE.

The patient should be completely incontinent during their healing period. If they become continent and/or are experiencing leakage during the healing period, it could be because:

- Patient themselves has activated the ZSI 375. Perform an X-ray to check if device is deactivated/activated.
- The patient has become infected, such as his bladder or urine. Ask to have a blood and urine test performed to check for infection.
- Patient experiencing pain and inflammation longer than 4 days after the operation. There may be an infection which could lead to urethral necrosis.
- Patient experiencing pain and inflammation a few weeks after the operation. There may be an infection which could lead to urethral necrosis.

QUESTIONS TO ASK

1. How was patients physical state before the symptoms appeared and after? Ask for a detailed description of the patient's current physical state?
2. How many pads a day patient was using before device was implanted?
3. How many pads a day patient was using after device was implanted?
4. How many pads a day patient is using since the symptoms started?

RIGHT AFTER ACTIVATION

RIGHT AFTER ACTIVATION THE PATIENT CLAIMS THAT DEVICE IS NOT FUNCTIONING AND/OR IT IS CLOSING TO QUICKLY.

Consider the following:

- Device has not been activated properly. Perform an X-ray to check the state of the device.
- The device is leaking saline solution. Perform an X-ray to check the state of the device.
- Due to the patient's genetics, they might require a little more pressure on their urethra to be fully continent. Perform an X-ray to check.
- The patient has to high an expectation of the device. A normal way of life cannot be given back to them.
- The patient has suffered urethral necrosis.
- Has the patient been trained properly on how to use the device? Did you train them yourself?

QUESTIONS TO ASK

1. Why the patient needed the Artificial Urinary Sphincter?
2. How did they manage their incontinence situation before?
3. How many pads a day patient was using before device was implanted?
4. How many pads a day patient was using after device was implanted?
5. How many pads a day patient is using since the symptoms started?
6. Is the difficulty ongoing or at special times of the day?
7. How was patients physical state before the symptoms appeared and after? Ask for a detailed description of the patient's current physical state?
8. What does the patient mean by a mal-functioning device?

LONG PERIOD AFTER ACTIVATION

PATIENT CLAIMS DEVICE IS NOT FUNCTIONING ANYMORE AND/OR DEVICE IS NOT FUNCTIONING NOW AND/OR DEVICE IS BROKEN AND/OR DEVICE IS CLOSING TO FAST.

Consider the following:

- The device might be leaking. Perform an X-ray to check the state of the device.
- The patient might have suffered urethral atrophia and/or necrosis. Perform an X-ray to check.
- Has the patient been trained properly on how to use the device? Did you train them yourself? Did you check up on them in the days following the operation?

QUESTIONS TO ASK

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5. How many pads a day patient is using since the symptoms started?
6. Is the difficulty ongoing or at special times of the day?
7. How was patients physical state before the symptoms appeared and after? Ask for a detailed description of the patient's current physical state?
8. What does the patient mean by a mal-functioning device?

LONG PERIOD AFTER ACTIVATION

PATIENT CLAIMS THEY HAVE INFLAMMATION WHICH THEY DID NOT HAVE BEFORE AND/OR ARE EXPERIENCING PAIN.

- The patient has an infection
- Patient has suffered urethral atrophia and/or necrosis

QUESTIONS TO ASK

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2. How did they manage their incontinence situation before?
3. How many pads a day patient was using before device was implanted?
4. How many pads a day patient was using after device was implanted?
5. How many pads a day patient is using since the symptoms started?
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DEVICE MAL-FUNCTIONING

In 2014 we implanted 300 devices of the ZSI 375 'Large Button' version. Out of the 300, 6 came back to us classified as mal-functioning.

Among those 6, only one was actually mal-functioning as tested by our engineering team. This means that the other 5 cases the device was working perfectly or it had been damaged by the Urologist during either preparation or implantation. Such cases could have been avoided if the Urologist had received proper information and/or support of the distributor in the Operating Room.

The main errors identified were:

- The device had been improperly prepared and filled, leaving to much air in the hydraulic circuit, and/or
- The septum of the cuff had been pierced improperly, damaging the silicone tube.

All proper technical information for each step involved in preparing the device for implantation is provided in the 'Operating Room Manual' and all other support documents.

5 failed cases could have been avoided if the Urologist had received proper support.

(ZSI reminds all of its distributors that, to properly train a Surgeon on the protocol of implanting a device, a minimum of 3 separate days of 1 to 3 implantations each day, should be accompanied by the distributor in the Operating Room)

Note: During 2014 we had another 10 cases of devices labelled as mal-functioning, but which, when asked to be sent to us along with the complaint form, were never sent. The devices, having never been received, could not be tested and checked by our engineering or quality control team. We have had to conclude that these devices were not in fact mal-functioning.

IMPORTANT

As of the beginning of 2015, all devices that are returned to the ZSI team as mal-functioning due to a lack of support and/or training for the Urologist on the part of the distributor, will not be replaced, for free, by ZSI. It is the distributor's responsibility to train and support the Urologist until he has understood and can confidently perform the preparation and implantation of the device without any help.