Patient Information Leaflet:

Name and Model:

Kyocera Medical – Tesera SA Anterior Lumbar Interbody Fusion (ALIF) System.

Intended Purpose & Performance:

Spinal fusion is a surgical procedure used to correct problems with the small bones (vertebrae) in the backbone (spine). It is essentially a "welding" process. The basic idea is to fuse together two or more vertebrae so that they heal into a single, solid bone. This is done to eliminate painful motion or to restore stability to the spine. Spinal fusion stops movement between vertebrae. It also prevents the stretching of nerves, surrounding ligaments and muscles.

The Tesera SA Spinal System is an implant which is intended to be used to stabilise and immobilise the portion the vertebrae in the middle or lower sections of the spine after you have had a spinal fusion. The Tesera SA implant provides support to prevent the vertebrae moving while the bone healing process takes place, and the vertebrae fuse together.

Your surgeon will have performed this operation because you have a problem with your back such as degeneration of the disc that lies between the vertebrae or a slippage of one of the vertebrae among other possible conditions.

Your surgeon will use the Tesera SA implant as part of the spinal support required to allow healing and fusion of the vertebrae. Your surgeon will explain the operation and provide instructions for your recovery after the operation to optimise the bone healing process.

Post-operative Care:

It is extremely important that you comply with your surgeon's instructions for your recovery after you have had your spinal fusion operation to ensure the Tesera SA implant provides the support to the healing vertebrae and does not become damaged.

1. Your surgeon will follow up after the surgery to check on the progress of the fusion of the vertebrae and that the Tesera SA implant is intact.
2. Your surgeon will provide detailed instructions on the limitations to the amount and type of physical activity you can do in the period after your fusion surgery. Following these instructions is extremely important to allow the maximum chances of a successful surgical result. These instructions are intended to protect both the bone healing process and the Tesera SA implant.
3. Implants can break when subjected to the increased loading associated with delayed union or non-union. Internal fixation cages are load-sharing devices that are used to obtain alignment until normal healing occurs. If Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue.
4. Bending at the point of the spinal fusion should be avoided.
5. Many patients will notice improvement of some or all their symptoms and pain may diminish a few weeks after surgery. However, recovery time varies between patients.
6. Typically, it is the surgeon's goal for the patient to eventually return to his/ her preoperative activities. A positive attitude, reasonable expectations and compliance with your doctor's post-surgery instructions may all contribute to a satisfactory outcome.

7. Once your surgeon is satisfied with the quality of your bony fusion, no additional care or maintenance of the Tesera SA Implant is required. The expected life of the device is 30 years, but this lifetime is heavily dependent on the quality of the bone fusion between the adjacent vertebrae.

Possible Adverse Events:

A listing of possible adverse events includes, but is not limited to:

1. Problems with anesthesia.
2. Blood vessel damage.
3. Nerve and spinal cord damage.
4. Early or late loosening of any or all components.
5. Disassembly, bending, and/or breakage of any or all of the components.
6. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumour formation, and/or auto-immune disease.
7. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
8. Graft donor site complications including pain, fracture, or wound healing problems.
9. Failure to achieve bony fusion.
10. Ongoing pain.

Note: Additional surgery may be necessary to correct some of these adverse events if they occur.

Materials:

All components of the Tesera SA implant are made of Titanium Alloy (Ti-6AL-4V ASTM F136 and F-2924).

Warnings and Precautions:

The Tesera SA Spinal System has not been evaluated for safety and compatibility in the MR environment. The Tesera SA Spinal System has not been tested for heating or migration in the MR environment.

Product Complaints:

If you have any complaint or have experienced any problem with the quality, identity, durability, reliability, safety, effectiveness and/or performance of the Tesera SA implant, you should notify the Tesera SA implant distributor/sponsor and manufacturer (see contact details below). Distributor/sponsor information can be provided by the manufacturer.

If any serious incident occurs in relation to the implant, this should be reported to the Therapeutic Goods Administration (TGA; www.tga.gov.au) and the manufacturer.

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