DEVICE NAME: MatriDerm® Dermal Matrix

MODELS:	83500-200	83400-200
	83403-200	83401-200
	83404-200	83405-200

PATIENT INFORMATION LEAFLET

This leaflet is to provide patients with a clearer understanding on MatriDerm® Dermal Matrix.

In this leaflet, some common questions about MatriDerm® Dermal Matrix are covered. Some of the information listed may not be applicable to you. For more clarifications, please consult your doctor or specialist.

WHAT IS MATRIDERM USED FOR?

MatriDerm® Dermal Matrix can be used for the following reasons:

- In the reconstruction of deep skin defects and full-thickness skin wounds.
- To acts as a scaffold for tissue regeneration and reduce the formation of scar tissue.
- Under intact skin for the temporary separation of tissues, preventing adherences, especially tendons and their surrounding connective tissue, after injuries or surgical procedures.

The aim of treatment is to construct a layer of new skin after a wound, in order to improve the quality of reformed tissue, reduce scarring, restore functionality and support the natural healing of the wound.

MatriDerm® Dermal Matrix should not be used in patients who have:

- A known sensitivity to cow sourced material.
- Infected wounds.

WHEN WILL I NEED MATRIDERM?

MatriDerm® Dermal Matrix is used in patients who require plastic reconstructive surgery and in the surgical treatment of burns, trauma and skin diseases. It can also be used to support the treatment of grafts and poorly healing and persistent skin wounds.

MatriDerm® Dermal Matrix may also be used under intact skin for the temporary separation of tissues, preventing adherences, especially tendons and their surrounding connective tissue, after injuries or surgical procedures.

HOW DOES MATRIDERM WORK?

MatriDerm® Dermal Matrix is a collagen elastin scaffold, which serves to replace wounded skin. MatriDerm® Dermal Matrix is placed on the wound bed and covered with a skin graft. MatriDerm® Dermal Matrix provides a native three dimensional matrix which facilitates cell migration and guided healing. Connective tissue is guided by the matrix and ensures the structural healing and formation of a new layer of skin at the wound site. The formation of blood vessels ensure supply and the optimal environment for the skin graft to take.

MatriDerm® Dermal Matrix is a permanent implant, which has shown to fully remodel within 6 weeks after implantation.

Once implanted, there are no further operating instruction required for the use of the device.

WHAT SUBSTANCES DOES MATRIDERM CONTAIN?

MatriDerm® Dermal Matrix device is a three-dimensional matrix composed of two biological components: (1) collagen fibrils and (2) elastin.

Both the collagen fibrils and elastin are sourced from cows. The collagen is obtained from the inner layer of the skin and elastin is obtained from a ligament in the neck.

There are no further residuals from the device which can pose a risk to the patient.

WHAT IS THE CARE AFTER USING MATRIDERM?

There are no specific ongoing examinations, monitoring or maintenance activities to be performed post-

operatively. Common post-operative treatment measures and medications are considered to be sufficient. Be sure to follow the instructions provided by your doctor and keep to all appointments for follow-up care.

WHAT ARE THE POSSIBLE ADVERSE EFFECTS?

The use of MatriDerm® Dermal Matrix may give rise to the following complications:

- Potential intolerance reaction to the device.
- A collection of fluid build up under the surface of the skin.
- Blood or bleeding under the skin.
- Development of dark patches of skin.

If you observe any of the above symptoms post-surgery, consult your doctor immediately.

Do not be alarmed by this list of adverse effects. Often people do not experience any of them.

ARE THERE ANY RISKS THAT COULD ARISE FROM THE INTERACTION OF MATRIDERM WITH OTHER DEVICES OR EQUIPMENT?

No, there are no additional risks that could arise from the interaction of MatriDerm® Dermal Matrix and other devices or equipment. MatriDerm® Dermal Matrix does not contain radioactive substances and is safe for use with magnetic resonance imaging (MRI).

WHAT SHOULD I DO IF A SERIOUS INCIDENT OCCURS IN RELATION TO THE DEVICE?

In the case of a serious incident, consult your doctor immediately. Note that any serious incident that occur in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration (http://www.tga.gov.au/).