

DISINFECTANT INSTRUCTIONS:

Step	Phase	Duration	°C	Action
1	Cleaning	10 Minutes	55°C (+/- 2)	Add in Chosen Detergent
2	Neutralizing	2 Minutes	Cold	Neutralize with cold water
3	Rinsing	1 Minute	Cold	Rinse with Cold Water
4	Thermal disinfection (A0 value > 3000)	5 Minutes	>89°C	Use demineralized and purified water. DO NOT ADD ADDITIONAL DETERGENT
5	Rinsing	1 Minute	Cold	Rinse with demineralized and purified water
6	Dry	As required	Room temperature	

Before the cleaned products are sterilized, carefully examine them to see if they are clean and undamaged.

STERILISATION INSTRUCTIONS:

Procedure	Sterilisation Procedure for Fractional and Dynamic pre-vacuumed	Flow and Gravitational Process
Exposure Time	>4 Minutes	>15 Minutes
Temperature	132°C / 134°C	132°C / 134°C
Drying Time	>20 Minutes	>20 Minutes

RECOMMENDED STERILIZATION SPECIFICATIONS:

The Custom Plate will be delivered unsterilized, but can be sterilized once prior to use. The plate is intended for single use only and should only be used once. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved. Sterilize the Custom Plate using an autoclave sterilization system before use.

During sterilization of single devices pouches may be used. Only standard medical grade steam sterilization polyethylene or Tyvek pouches should be used. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch.

Contact Information

For any questions or concerns, please contact your local Lyka Smith Health Services representative or Customer Service directly at:

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LYKA SMITH
Australian Innovation

Instructions For Use

Patient Specific Plates [PSP]

This document contains general instructions for use for the Lyka Smith Patient Specific Plates [PSP] "Custom Plates"

For case-specific instructions, refer to the corresponding case specific Virtual Surgical Planning Report.

DESCRIPTION:

Lyka Smith Custom Plates are used to either support or replace bone. They are designed based upon the patient's individual CT scan and match the patient's bone curvature, regardless of location of placement. A Custom Plate can function to support the bone, such as in fractures or damage, allowing the bone to heal whilst supported. A custom plate can also function to replace or augment deformed bone growth, such as seen for an orbital plate.

INDICATIONS FOR USE:

The patients eligible for the custom plate are:

1. Patients with deficient bone resulting from treated pathology or trauma
2. Patients who cannot tolerate complex bone grafts
3. Patients with bone fractures

MATERIAL:

Titanium-64 (Ti-64)

CONTRAINDICATIONS:

A Custom Plate is not suitable in the following cases:

1. Those currently dealing with drug and alcohol abuse
2. Unstable diabetes
3. Uncontrolled Psychiatric disorders
4. Currently undergoing radiotherapy to the jaws and face and neck
5. Untreated pathology, such as the formation of cysts, tumours etc.
6. Terminal Illness - such as those requiring chemotherapy
7. Severe Dementia/Alzheimer's

POTENTIAL ADVERSE EFFECTS:

Listed below are the potential adverse effects that may occur following placement of a Custom Plate.

1. Persistent facial swelling
2. Chronic pain
3. Loosening of one or more screws
4. Infection
5. Ear problems including deafness
6. Facial nerve weakness
7. Facial tingling, numbness, hypersensitivity
8. Sensitive teeth
9. Numbness of lower lip, chin or tongue.
10. Altered bite (ie. malocclusion) – malpositioning of prosthesis
11. Foreign body or allergic reaction to implant components
12. Heterotopic bone formation
13. Failure and removal of Custom Plate

PATIENT SPECIFIC PLATE IDENTIFIERS:

Before using the Custom Plate, confirm that it corresponds with the patient's identity.

PRECAUTIONS:

A Custom Plate is only intended to be used by medical practitioners who are adequately trained in the use of plates through hands-on and educational course work. The following patient conditions are recommended restrictions to potential patients; however, they are recommendations the presiding doctor may choose to forgo if they deem the patients suitable despite these concerns, as long as the practitioner is aware they are becoming the responsible party for any potential complications that may arise due to forgoing these suggestions.

1. Patients with osteoporosis and taking bisphosphonates should be cautioned about risk of failure which is presently unqualified.
2. Patients must be fit enough for general anaesthetic.
3. Patient need to maintain an acceptable level of oral hygiene.
4. Patient must not be diagnosed with blood-based disorders which impact patients healing ability.

WARNING:

1. Medical staff should be aware of possible allergic reactions to materials used in the Custom Plate. The patient should be informed on this matter by the staff.
2. Custom Plates are patient-specific, single use and disposable. Do not reuse the plates.
3. It is advised to use the custom plates within 6 months after performing the CT/MRI scans on which the plates are based upon. If the patient anatomy has changed significantly since the time of the CT/MRI scan, the plates should not be used.
4. The LeForte System & Custom Plates has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety of the LeForte System and Custom Plates in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
5. DO NOT attempt to reuse or recondition the plates.
6. Do not alter the Custom Plates in any way.

INSTRUCTIONS FOR USE:

Fixation procedure: The plate is placed upon the bone where titanium screws are positioned into ideal holes and screwed into bone, securing the plate to the bone. The location of the screws and the number of screws to be used will be determined prior to surgery, with the trained surgical staff informed of the correct placement.

CLEANING AND STERILIZATION INSTRUCTIONS:

Lyka Smith Custom Plates are NON-STERILE and must be thoroughly cleaned and sterilized prior to use.

CLEANING INSTRUCTIONS:

Whenever possible, a washer/disinfector (according to ISO 15883) and ultrasonic cleaning equipment should be used to clean the Custom Plate. The detergents and/or enzymatic cleaner should be of neutral or near neutral pH (pH7-9,5). The guides can be cleaned using manual cleaning and/or automated cleaning in a washer/disinfector with manual pre-cleaning and ultrasonic cleaning.

Step	Minimum Duration	Cleaning Instructions
1	15 Minutes	Place Custom Plate components into an Acetone filled ultrasonic bath for a 15-minute cycle.
2	5 Minutes	Empty contents of bath and rinse with tap water using Use a syringe, pipette or water pistol to flush closed holes.
3	1 Minute	Perform visual inspection.
4	15 Minutes	Fill bath with Iso-propanol, place all components into the bath and activate a 15 minute cycle
5	5 Minutes	Empty contents of bath and rinse with tap water using. Use a syringe, pipette or water pistol to flush closed holes.
6	1 Minute	Perform visual inspection
7	15 Minutes	Fill bath with Ethanol, place all components into the bath and activate a 15 minute cycle
8	5 Minutes	Empty contents of bath and rinse with Distilled Water using Use a syringe, pipette or water pistol to flush closed holes.
9	As Required	Perform visual inspection and place components onto a lint free absorbent surface, position to ensure closed holes will dry.

Before the cleaned product are packaged and sterilized, carefully examine them to see if they are clean and undamaged.

Sterilisation and Disinfectant Instructions Continues on Reverse Page

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