

MANUAL CLEANING INSTRUCTIONS CONTINUED:

Option 2:

Step	Minimum Duration	Cleaning Instructions
1	1 Minute	Rinse the Guide/Splint under running cold tap water.
2	2 Minutes	Manually clean the Guide/Splint in a newly-made enzymatic cleaner or detergent solution.
3	1 Minute	Rinse the Guide/Splint using cool to lukewarm running tap water. Use a syringe, pipette or water pistol to flush cylinders, slots, and other hard-to-reach areas.
4	15 Minutes	Clean the Guide/Splint ultrasonically per manufacturer's recommended temperature (usually 32°-60°C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners and medical equipment.
5	2 Minutes	Rinse the Guide/Splint using deionized or purified water using a syringe, pipette, or water pistol to flush cylinders, slots, and other hard-to-reach areas.

AUTOMATED CLEANING INSTRUCTIONS: WASHER/ DISINFECTOR:

Step	Minimum Duration	Cleaning Instructions
Pre-Wash	2 Minutes	Cold tap water
Wash	10 Minutes	Warm tap water (>40°C); use detergent
Neutralize	2 Minutes	Warm tap water with neutralizer, if necessary
Rinse	2 Minutes	Rinse with warm water (>40°C)
Thermal Disinfectant	7 Minutes	At minimum 94°C
Dry	40 Minutes	At minimum 90°C

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

STERILIZATION:

The Guides/Splints can be sterilized once prior to use. The Guides/Splints are intended for single use only and should only be used once. Medical Staff should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved. Sterilize the Guides/Splints using pre-vacuum steam sterilization 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.

Use one of the following standard steam sterilization settings:

1 -Pre-vacuum Cycle UK, NL1,2:
Minimum temperature: 134°C
Minimum exposure time: 3 minutes'
Minimum vacuum drying time: 30 minutes

2 -World Health Organization Pre-Vacuum Cycle 2,3:
Minimum temperature: 134°C (273.2°F)
Minimum exposure time: 18 minutes
Minimum vacuum drying time: 30 minutes

DISPOSAL:

Treat used Guides and Splints as biohazard materials and dispose of in accordance with hospital regulations.

CONTACT INFORMATION

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

Phone: +61 3 9069 6621

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LYKA SMITH
Australian Innovation

Instructions For Use Patient Specific Guides/Splints [PSG/S]

This document contains general instructions for use for the Lyka Smith Patient Specific Guides/Splints [PSG/S] "Guides/Splints"

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

DESCRIPTION:

Lyka Smith Guides & Splints are custom-made devices designed to fit the patient's anatomy. They are intended for improving and simplifying the performance of surgical interventions, the placement of implants or other patient specific implants.

INDICATIONS FOR USE:

Lyka Smith Guides and Splints are intended to be used as surgical tools to transfer a pre-operative plan to surgery. These Guides and Splints are intended to guide the marking of bone and/or guide surgical instruments in mandibular, maxillofacial and orthopaedic surgical procedures. The Guides and Splints are intended for single use only.

MATERIAL:

Nylon, Med610, Ti64

CONTRAINDICATIONS:

Do not use in the case of active infection of the surgical area where the surgery will be performed.

WARNING:

Medical staff should be aware of possible allergic reactions to materials used in the Guide or Splints. The patient should be informed on this matter by the staff. These are custom, single use, disposable Guides and Splints, DO NOT attempt to reuse or recondition the guides. Do not alter the Guides or Splints in anyway. The Guides and Splints are to be used by a trained physician in the performance of surgery. Be aware that these custom Guides or Splints have been manufactured based on CT/MRI scans of the patient. If the patient's anatomy has changed significantly since the time of the CT/MRI scan, the guides should not be used. The Guides and Splints should be properly cleaned before sterilization. Do not use if the broken, cracked, or are visibly contaminated. The Guides or Splints in this package are provided non-sterile. The Guides and Splints in this package must be sterilized prior to use.

PRECAUTIONS:

It is advised to use the Guide/Splint within 6 months after performing the CT/MRI scans on which they are based. If the patient's anatomy has changed significantly since the time of the CT/MRI-scan, the guide should not be used, even if the time period of 6 months is not expired. Do not apply excessive force on the Guide/Splint or place heavy objects on top. Markings on Guides/Splint used for indicating anatomical references and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as implant size and the unique case identifier. Notify your Lyka Smith representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.

PATIENT SPECIFIC GUIDE/SPLINT IDENTIFIERS:

A unique identifier is indicated on each Guide and Splint. This alphanumeric code links the guide unambiguously to the patient case. The last two characters of the unique identifier are a part identifier that uniquely identifies the part within the patient case. A list of all unique identifiers is present in the case report shipped with each patient case. Before using the guide, check the unique identifier for read ability and confirm that it corresponds with the patient's identity. If the Guide/Splint contains an external tag with the unique identifier, this tag can be removed before coming in contact with the patient.

POSSIBLE ADVERSE EFFECTS:

Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

INSTRUCTIONS FOR USE:

Fitting of the Guide or Splint: The Guide/Splint is designed to fit the patient anatomy. The supporting surface (bone, cartilage, teeth, soft tissue) should be completely free and accessible to assure good fit of the guide/splint. Take enough time to correctly fit the Guide/Splint on the patient. The case report shipped with every Guide/Splint indicates the position of the Guide/Splint relative to the surrounding anatomy.

Try different positions and check whether or not the Guide/Splint stays in place. Choose the most stable position, i.e., the position in which the least pressure must be exerted in order to keep the Guide/Splint in place. Don't push the Guide/Splint down onto the patient too hard. Make sure critical anatomical structures are not damaged during fitting. Lyka Smith always offers the possibility to order anatomical models together with the Guide/Splints. As such, fitting the Guide/Splint can be tried on the anatomical models before surgery. When a stable position for the Guide/Splint is obtained, fixate the Guide/Splint by means of fixation pins or screws (if present). Make sure fixation holes are correctly identified, and not mixed with holes for drilling (if present). If it is not possible to place the Guide/Splint on the patient in a unique and stable position, the Guide/Splint does not guarantee an accurate transfer of the pre-operative planning.

Even in a stable position it is possible that the Guide/Splint doesn't make contact with the bone over its full length, since it isn't always possible to solve all of the undercuts. The undercuts depend on the shape of the patient's anatomy. Do not alter the Guide/Splint before use. Small particles might come off, which could contaminate the operating region. In addition, altering the size of the Guide/Splint may lead to its no longer fitting to the patient's anatomy. Therefore, it is the total responsibility of the user when altering the Guide/Splint before surgery.

DURING CUTTING AND DRILLING:

- Make sure the Guide/Splint maintains its position on the contact surface during cutting and/or drilling.
- All necessary measures should be taken to avoid excessive heat generation during cutting and/or drilling. Please consult the procedures outlined by the manufacturer of the cutting and/or drilling equipment on this matter.
- Do not try to use a sawing blade that is thicker than the indicated thickness of the cutting slot (if present).
- Do not try to use a drill that is larger than the indicated diameter of the drill hole. The case report shipped together with the guide lists the drill diameters to be used.
- Make sure the sawing blade follows the cutting surface or slot to obtain a correct osteotomy and to avoid cutting into the Guide's cutting surface or slot.
- Since the inner diameters of the drill holes are larger than the diameter of the drill (0.1 to 0.2 mm), try to drill along the center line of the drill holes to obtain a correct hole and to avoid drilling into the inner wall of the drill hole.

CLEANING AND STERILIZATION INSTRUCTIONS:

Lyka Smith Guides and Splints are NON-STERILE and must be thoroughly cleaned and sterilized prior to use. Cleaning: Whenever possible, a washer/disinfector (according to ISO 15883) and ultrasonic cleaning equipment should be used to clean the Guides/Splints. The detergents and/or enzymatic cleaner should be of neutral or near neutral pH (pH7-9,5). The Guides/Splints can be cleaned using manual cleaning and/or automated cleaning in a washer/disinfector with manual pre-cleaning and ultrasonic cleaning.

MANUAL CLEANING INSTRUCTIONS:**Option 1:**

Step	Cleaning Instructions
1	Prepare a fresh, newly-made solution using warm de-ionized (DI) or purified water (PURW) and enzymatic cleaner or detergent.
2	Carefully wash the Guide/Splint manually
3	Rinse the Guide/Splint thoroughly with DI or PURW.
4	Dry the Guide/Splint using a clean, soft, lint-free cloth or clean compressed air.

Manual Cleaning Instructions Continues on Reverse Page

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