Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-1532
Revision: B
Date: 2014-06

Signature Personalized Patient Care System:
Glenoid Guide System

ATTENTION OPERATING SURGEON

DESCRIPTION

The **Signature Personalized Patient Care System – Glenoid Guide System** are patient-specific instruments used to assist with glenoid positioning during shoulder replacement surgery. The **Signature Glenoid Guide** is based on patient-specific anatomic landmarks necessary for alignment and positioning of the implant identified on preoperative patient imaging scans.

MATERIALS

Polyamide

INDICATIONS FOR USE

The **Signature Personalized Patient Care System – Glenoid Guide System** is intended to be used as a surgical instrument to assist in the positioning of glenoid components intra-operatively using anatomical landmarks of the shoulder that are identifiable on preoperative imaging scans.

The **Signature Personalized Patient Care System – Glenoid Guide System** can be used in conjunction with the Comprehensive Total and Reverse Shoulder Systems (including the Modular Hybrid Glenoid, Bio-Modular Heads and Stems), and their respective components, which require placement of an initial center pin or hole to guide the associated system instruments.

The **Signature Glenoid Guide** is intended for single use only.

CONTRAINDICATIONS

The Signature Glenoid Guides are contraindicated for patients with significant anatomical disruption or distortion of the scapula. This may include patients with scapula and/or glenoid fractures, metabolic disorders which may impair bone formation, neoplasms or other disorders that affect scapular anatomy and bony landmark recognition.

Active infection is a contraindication for use of this device.

WARNINGS

1. The user should be aware of possible allergic reactions to materials used in the guide. The patient should be informed on this matter by the user.
2. The guide's patient specific identifiers are to be checked for readability and confirmed by the surgeon before use.
3. Bio-Modular Glenoid components are not compatible with the Signature Personalized Patient Care System – Glenoid Guide System.
4. Device is single use only. Do not attempt to re-clean or re-sterilize this product for other than its originally-intended patient. After use, this product may be a potential biohazard.
5. Surgeon must ensure that the guide is placed appropriately or malalignment can occur.

PRECAUTIONS

1. The guide is not reusable. Do not use in patients for which the guide is not intended.
2. If the patient's anatomy has changed significantly since the time of the imaging scan, the Signature Guide should not be used.
3. Glenoid guides can only be developed using CT scans.
4. Store it in a properly cleaned and dry place.
5. The guide should be properly cleaned before sterilization.
6. Open, clean and sterilize immediately prior to surgery (non-sterile guides).
7. Do not use if the Signature Guide is broken, cracked, or if loose powder is present.
8. Do not alter the guide.
9. Do not bend or reconfigure pins or alignment devices.
10. The surgeon should be familiar with the package insert and appropriate surgical technique(s) specific to the joint replacement implants utilized in conjunction with the Signature Guides.
11. Care should be taken when drilling the pins to ensure that placement pins do not cause internal soft tissue damage.
12. All trial, packaging, and instrument components must be removed prior to closing the surgical site; do not implant.

POSSIBLE ADVERSE EFFECTS

1. Infection following the procedure.
2. Introduction of foreign materials can result in an inflammatory response or allergic reaction.
3. Wound dehiscence.
4. Nerve damage.
5. Perforation of the glenoid vault causing bone or soft tissue damage.

See also Possible Adverse Effects associated with total shoulder replacement (primary and reverse applications) in general and those associated with the shoulder replacement system utilized in conjunction with the Signature Guides.

STERILITY AND CLEANING

Guides and bone models are provided in sterile and non-sterile condition. Non-sterile guides must be cleaned and sterilized prior to surgery.

Non-Sterile Guides/Bone Models

Guides and bone models must be cleaned until visibly clean prior to sterilization. Visible soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. It is recommended that the instruments be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. The following table outlines a validated automated cleaning method for use.

Phase	Time (Minutes)	Temperature & Water Quality	Detergent & Concentration
Pre-Wash	2:00	95°F (35°C) Tap Water	None
Detergent Wash	6:00	158°F (70°C) Tap Water	Detergent, such as Enzol® 1oz./gallon
Wash	4:00	158°F (70°C) Tap Water	Wash, such as Renu-Klenz™

			¼ oz./gallon
Rinse	2:00	158°F (70°C) Tap Water	None
Drying	7:00	239°F (115°C)	None

The following tables outline sterilization parameters for use.

Dynamic-Air-Removal Sterilization

US Parameters
Temperature: 270°F (132°C)
4 Minute exposure time
30 Minute drying time
Wrapped per manufacturer's instructions*

Parameters for non-US countries
Temperatures: 134°C (273°F) to 140°C (284°F)
3 Minute exposure time minimum
30 Minute drying time minimum
Wrapped per manufacturer's instructions

Gravity Displacement Sterilizer

Parameters for non-US countries
Temperatures: 132°C (270°F) to 140°C (284°F)
10 Minute exposure time minimum
30 Minute drying time minimum
Wrapped per manufacturer's instructions

Sterrad 100S – Short Cycle
US Parameters
Cycle temperature: 113°F - 131°F (45° C - 55°C)
Cycle Time: Approximately 55 minutes (short cycle)
Wrapped per manufacturer's instructions*

Parameters for non-US countries
Cycle temperature: 113°F - 131°F (45°C - 55°C)
Cycle Time: Approximately 55 minutes (short cycle)
Wrapped per manufacturer's instructions

*In the U.S. wraps used during the steam sterilization process are to be FDA cleared (such as Cardinal Health/Allegiance Bioshield® sterilization wrap (FDA 510(k) number K770933)).

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the above general guidelines are followed.

Sterile Guides/Bone Models
Guide components are sterilized by exposure to a minimum dose of 25 kGy of gamma irradiation. Single use only. Do not resterilize. Do not use any component from an opened or damaged package. Do not use guides after expiration date.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

All other trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

Bioshield® is a registered trademark of Cardinal Health/Allegiance
Enzol® is a registered trademark of Johnson & Johnson Co.
Renu-Klenz™ is a trademark of Steris Corporation.

CE Mark on the package insert (IFU) is not valid unless there is a CE mark on the product (description) label.

EC REP Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA UK

CE 0086

Symbol Legend

Manufacturer

Date of manufacture

Do not reuse

Do not resterilize

Caution, see instructions for use

STERILE EO Sterilized using ethylene oxide

STERILE R Sterilized using irradiation

STERILE Sterile

STERILE A Sterilized using aseptic processing techniques

STERILE Sterilized using steam or dry heat

℞ Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Do not use if package is damaged (Pack Damaged)

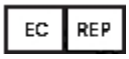
Use by date

WEEE device

REF Catalogue number

LOT Batch code

Flammable



Authorized representative in the European Community

Non-Sterile