INSTRUCTIONS FOR USE

ROE ArchBridge OD

ROE TECHNICAL REVIEW

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U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed dental practitioner.

1. Scope

These Instructions for Use apply to the ROE ArchBridge OD devices manufactured by Bhi Implants Ltd. and identified in Section 3 of this document.

The devices covered by this IFU include reusable titanium ArchBridge Scan Bodies intended for digital scanning workflows associated with Zest LOCATOR and LOCATOR FIXED abutments, and the ROE ArchBridge OD ScanAnalog intended for applicable extraoral digital scanning and stone-model workflows.

These Instructions for Use provide information necessary for the safe and proper use, handling, preparation, reprocessing, storage, and disposal of the devices.

Broader laboratory case-management activities, including case submission, prescription processing, file-upload procedures, photographs, and other ROE Dental Laboratory administrative processes, are outside the scope of this IFU.

2. Device Description

2.1 ArchBridge Scan Bodies

ROE ArchBridge OD Scan Bodies are reusable titanium scanning components available in different geometries to facilitate scanner recognition and accommodate variations in available intraoral space and anatomy.

Each ArchBridge Scan Body incorporates an internal interface designed to receive the applicable Zest Processing Spacer. The Processing Spacer provides the interface between the ArchBridge Scan Body and the Zest LOCATOR or LOCATOR FIXED abutment during intraoral use.

The external scanning surface of each ArchBridge Scan Body includes a defined geometry represented in the applicable ArchBridge digital library. A defined scanning surface is sandblasted to reduce reflections from the titanium surface and facilitate optical capture by the scanning system.

Different ArchBridge Scan Body geometries may be selected and used within the same arch according to available space and the clinical situation.

2.2 ScanAnalog

The ROE ArchBridge OD ScanAnalog is a titanium component intended for extraoral workflows. It may be used to represent the position of Zest LOCATOR or LOCATOR FIXED attachment locations during digital scanning of an existing prosthesis and may also be used in a stone model.

The ScanAnalog includes a defined sandblasted scanning area designed to reduce reflections from the titanium surface and facilitate optical capture during extraoral scanning.

2.3 Processing Spacer

The ArchBridge Scan Bodies are designed for use with the Zest Processing Spacer, P/N N2001657108, as specified in this IFU.

The Processing Spacer is a single-use component and is not manufactured by Bhi Implants Ltd. It shall be discarded after use and shall not be cleaned, sterilized, reprocessed, or reused.

3. Product Identification and Devices Covered by this IFU

This IFU applies only to the ROE ArchBridge OD devices listed below. Product identification corresponds to the product name and catalog number shown on the product labeling.

3.1 ArchBridge Scan Bodies

Catalog No.	Product Name
ABO-Apollo	ROE ArchBridge OD Apollo
ABO-Bixby	ROE ArchBridge OD Bixby
ABO-Chaumont	ROE ArchBridge OD Chaumont
ABO-Dragon	ROE ArchBridge OD Dragon
ABO-Hellgate	ROE ArchBridge OD Hellgate
ABO-Rialto	ROE ArchBridge OD Rialto

The different ArchBridge Scan Body models provide alternative external geometries to facilitate scanner recognition and accommodate variations in available intraoral space and anatomy. Different models may be used within the same arch, as appropriate for the clinical situation.

3.2 ScanAnalog

Catalog No.	Product Name
ABO-ScanAnalog	ROE ArchBridge OD ScanAnalog

Only the devices specifically identified in this section are covered by this IFU.

4. Intended Use

The ROE ArchBridge OD Scan Bodies are intended to provide a reference geometry for digital scanning of the position and orientation of Zest LOCATOR and LOCATOR FIXED abutments in the oral cavity. The captured scan data are used with the applicable ArchBridge digital library to support the digital design and fabrication of dental prostheses.

The ROE ArchBridge OD ScanAnalog is intended to provide a reference for the position and orientation of Zest LOCATOR or LOCATOR FIXED attachment locations during extraoral digital scanning. The ScanAnalog may also be used in a stone model to represent the position of a Zest LOCATOR or LOCATOR FIXED attachment.

The devices are intended for use as part of a digital restorative workflow and are not intended to remain in the patient’s mouth as part of the final prosthetic restoration.

5. Indications for Use

The ROE ArchBridge OD Scan Bodies and ScanAnalog are indicated for use as components of a digital restorative workflow involving Zest LOCATOR and LOCATOR FIXED abutments.

The devices may be used in digital workflows for:

- fabrication of a new dental prosthesis;
- fabrication of a new dental prosthesis based on an existing denture or prosthesis;
- refitting of an existing prosthesis, as applicable; and
- full-arch or partial-arch restorations,as clinically appropriate.

The ArchBridge Scan Bodies are intended for temporary intraoral placement during digital scanning and shall be removed after completion of the scanning procedure.

The ScanAnalog is intended for extraoral use only, including applicable scanning of an existing prosthesis and use in a stone model to represent the position of a Zest LOCATOR or LOCATOR FIXED attachment.

6. Intended Users and Use Environment

The ROE ArchBridge OD devices are intended for use by qualified dental professionals and trained dental laboratory personnel, as applicable to the specific workflow.

ArchBridge Scan Bodies are intended for use by qualified dental professionals in a professional dental care environment during intraoral digital scanning procedures.

The ScanAnalog is intended for extraoral use only. It may be used by qualified dental professionals or trained dental laboratory personnel during extraoral scanning of a prosthesis or when used in a stone model.

Users shall be familiar with:

- the applicable Zest LOCATOR or LOCATOR FIXED restorative system;
- the intraoral or laboratory scanning system being used;
- the applicable ArchBridge digital library; and
- the procedures described in this IFU.

The devices are intended for professional use only and are not intended for use by patients.

7. Required Components and Equipment

7.1 Applicable Restorative Systems

The ROE ArchBridge OD Scan Bodies are designed for use with:

- Zest LOCATOR abutments
- Zest LOCATOR FIXED abutments

The applicable instructions for use, including limitations and angulation requirements, provided by Zest Dental Solutions for the LOCATOR or LOCATOR FIXED system shall be followed.

7.2 Processing Spacer

The ArchBridge Scan Bodies are designed for use with the Zest Processing Spacer, P/N N2001657108. The Processing Spacer provides the interface required to properly seat and stabilize the ArchBridge Scan Body on the Zest LOCATOR or LOCATOR FIXED abutment.

Use only the Zest Processing Spacer, P/N N2001657108. Do not use alternative or third-party processing spacers, as they will not fit properly into the Scan Body and will not provide the seating and stability required for accurate positioning of the ArchBridge Scan Body.

A new Processing Spacer shall be used for each application. The Processing Spacer is single-use and shall not be reprocessed or reused.

The Enhanced LOCATOR & LOCATOR FIXED Systems Core Tool shall be used for insertion and removal of the Processing Spacer in accordance with the tool manufacturer’s instructions.

7.3 Digital Library

The applicable ArchBridge digital library is required for identification and digital processing of the scanned ArchBridge geometry. The user shall ensure that the correct digital library corresponding to the ArchBridge component used in the scan is selected.

7.4 Scanning Equipment

ArchBridge Scan Bodies are intended to be scanned using an intraoral scanner suitable for implant/restorative scanning applications in accordance with the scanner manufacturer's instructions for use.

The ScanAnalog may be scanned using suitable extraoral digital scanning equipment, as applicable to the workflow. Scanning equipment shall be operated in accordance with its manufacturer's instructions for use.

8. Contraindications

The ROE ArchBridge OD devices shall not be used when the applicable Zest LOCATOR or LOCATOR FIXED system is contraindicated for the intended clinical application.

The ScanAnalog is intended for extraoral use only and shall not be used intraorally.

9. Warnings and Precautions

9.1 Warnings

- ArchBridge Scan Bodies are intended for temporary intraoral use during the scanning procedure only. Remove all ArchBridge Scan Bodies from the oral cavity immediately after completion of the scan.
- The ScanAnalog is intended for extraoral use only and shall not be placed in the patient's mouth.
- ArchBridge Scan Bodies are small components. Appropriate precautions shall be taken during intraoral placement and removal to minimize the risk of accidental swallowing or aspiration.
- Do not use an ArchBridge Scan Body intraorally without the Zest Processing Spacer, P/N N2001657108, properly installed. Do not use alternative or third-party processing spacers.
- Insert and remove the Processing Spacer using the Enhanced LOCATOR & LOCATOR FIXED Systems Core Tool in accordance with the tool manufacturer's instructions.
- Before placing the assembled ArchBridge Scan Body on the abutment, verify that the Processing Spacer is fully inserted and flush with the ArchBridge Scan Body.
- Before scanning, verify that each ArchBridge Scan Body is fully seated and stable, with no movement or internal looseness. Improper seating or movement may result in inaccurate digital position information and an improperly fitting restoration.
- Do not modify, grind, polish, reshape, or otherwise alter the ArchBridge Scan Body or ScanAnalog. Modification of device geometry or the defined sandblasted scanning area may prevent correct digital recognition and may result in inaccurate scan data.
- Do not use a device that is damaged, deformed, corroded, visibly worn, contaminated, or has a damaged or deteriorated scanning surface.

9.2 Precautions

- Select an ArchBridge Scan Body geometry that can be positioned without contact or interference with adjacent Scan Bodies, teeth, prosthetic structures, or surrounding anatomy.
- Different ArchBridge Scan Body models may be used within the same arch when necessary to accommodate available intraoral space.
- Orient the ArchBridge Scan Body toward the center of the arch where possible. When anatomy, available space, or abutment angulation prevents this orientation, position the component along the ridge or in another orientation that permits complete seating and avoids interference.
- Keep scanning surfaces clean and as dry as reasonably achievable before and during scanning.
- ArchBridge scanning surfaces are intended to be scanned directly as supplied. Scanning powder may be used when necessary to address challenging scanning conditions and when permitted by the scanner manufacturer's instructions.
- During scanning, ensure adequate capture of the defined circular scanning feature of the ArchBridge Scan Body.
- Visually inspect the digital scan on screen during and after scanning. Do not proceed with the digital workflow if an ArchBridge component is incompletely captured or cannot be reliably identified.

- Follow the applicable manufacturer's instructions for the Zest LOCATOR or LOCATOR FIXED system, including applicable clinical limitations and angulation requirements.
- Follow the instructions for use of the intraoral or extraoral scanning equipment being used.
- Use the applicable ArchBridge digital library corresponding to the ArchBridge components used for the scan.

10. Preparation and Inspection Before Use

10.1 Inspection

- Verify that the correct ArchBridge Scan Body model has been selected for the available intraoral space and intended scanning position.
- Visually inspect the device for damage, deformation, excessive wear, contamination, or other conditions that may affect proper seating or scanning.
- Inspect the defined scanning surface/area for visible damage or deterioration that may interfere with optical capture.
- Ensure that the device is clean and, before scanning, as dry as reasonably achievable.
- Do not use a device that cannot be fully and securely seated or that shows visible damage or deterioration that may affect its function.
- Ensure that the Processing Spacer is fully inserted and flush with the ArchBridge Scan Body.

Reusable ArchBridge Scan Bodies shall be cleaned and sterilized before intraoral use in accordance with Section 15 of this IFU.

10.2 Preparation of the ArchBridge Scan Body

1. Select the ArchBridge Scan Body geometry appropriate for the available intraoral space and anatomy.
2. Insert a new Zest Processing Spacer, P/N N2001657108, into the internal interface of the ArchBridge Scan Body using the Enhanced LOCATOR & LOCATOR FIXED Systems Core Tool in accordance with the tool manufacturer's instructions.
3. Verify visually that the Processing Spacer is fully inserted and flush with the ArchBridge Scan Body.
4. Place the assembled ArchBridge Scan Body onto the applicable Zest LOCATOR or LOCATOR FIXED abutment.
5. Verify that the Scan Body is fully seated and stable, without movement or internal looseness.
6. If the selected Scan Body cannot be fully seated or causes interference with adjacent components, teeth, prosthetic structures, or surrounding anatomy, remove it and select another ArchBridge Scan Body geometry as appropriate.

Do not proceed with scanning until all ArchBridge Scan Bodies are fully seated and stable.

11. ArchBridge Intraoral Scanning Procedure

The following procedure applies to intraoral scanning using the ROE ArchBridge OD Scan Bodies.

1. **Prepare the scanning site.** Ensure that the Zest LOCATOR or LOCATOR FIXED abutments and surrounding area are sufficiently clean and accessible for scanning.
2. **Capture the required baseline scan.** Scan the Zest LOCATOR or LOCATOR FIXED abutments and relevant surrounding oral anatomy before placement of the ArchBridge Scan Bodies, as required for the digital restorative workflow.
3. **Prepare the ArchBridge Scan Bodies.** Select the appropriate ArchBridge Scan Body geometry for each position and install a new Zest Processing Spacer, P/N N2001657108, as described in Section 10.
4. **Seat the Scan Bodies.** Place each assembled ArchBridge Scan Body onto the corresponding Zest LOCATOR or LOCATOR FIXED abutment. Verify that the Processing Spacer is fully inserted and flush with the Scan Body, each Scan Body is fully seated and stable, and no contact or interference prevents proper seating or scanning.

5. **Orient the Scan Bodies.** Where possible, orient the ArchBridge Scan Bodies toward the center of the arch. If anatomy, available space, or abutment angulation prevents this orientation, the Scan Body may be oriented along the ridge or in another position that permits complete seating, stability, adequate separation, and capture of the scanning geometry.
6. **Perform the intraoral scan.** Scan the ArchBridge Scan Bodies using the applicable intraoral scanner in accordance with the scanner manufacturer's instructions for use. Beginning from a posterior ArchBridge Scan Body and proceeding in a continuous scan is recommended to facilitate consistent scan capture but is not mandatory.
7. **Verify scan quality.** During and after scanning, visually inspect the digital scan on screen. Confirm that each ArchBridge Scan Body and the defined circular scanning feature have been adequately captured and that no obvious missing or distorted areas prevent reliable identification. Do not proceed if any ArchBridge Scan Body has not been adequately captured.
8. **Remove the devices.** After completion and verification of the scan, remove all ArchBridge Scan Bodies from the patient's mouth.
9. **Discard the Processing Spacers.** Remove each used Processing Spacer from the ArchBridge Scan Body and discard it. Do not reuse or reprocess the Processing Spacer.
10. **Prepare reusable devices for reprocessing.** Handle used ArchBridge Scan Bodies in accordance with Section 15 of this IFU.

12. Scan Quality and Troubleshooting

Before proceeding with the digital restorative workflow, visually verify that each ArchBridge Scan Body has been adequately captured and can be reliably identified in the scan. If scan capture is incomplete or inadequate, correct the applicable condition before proceeding.

Observed Condition	Recommended Action
Incomplete capture of an ArchBridge Scan Body	Continue or repeat scanning of the affected area. Ensure adequate capture of the defined circular scanning feature.
Scan Body is unstable or appears incorrectly positioned	Stop scanning. Remove the Scan Body, verify that the Processing Spacer is correctly installed, re-seat the Scan Body, and confirm full seating and stability before rescanning.
Contact or interference between Scan Bodies or adjacent structures	Select a different ArchBridge Scan Body geometry or adjust its orientation while maintaining complete and stable seating.
Scanning surface is contaminated or wet	Remove contamination and keep the scanning surface as clean and dry as reasonably achievable before rescanning.
Reflection or optical capture difficulty	Adjust scanning conditions in accordance with the scanner manufacturer's instructions. Scanning powder may be used when necessary and when permitted by the scanner manufacturer's instructions.
Scan Body cannot be reliably captured or identified after corrective actions	Do not proceed until an adequate scan has been obtained. Verify device condition, seating, scanning conditions, and use of the applicable ArchBridge digital library before repeating the scan.
Device is damaged, deformed, or the scanning surface is visibly deteriorated	Do not use the device. Replace it with a suitable ArchBridge component.

Do not proceed using scan data known or suspected to contain incomplete or inaccurate ArchBridge position information.

13. ScanAnalog – Extraoral Use

The ROE ArchBridge OD ScanAnalog is intended for extraoral use only. Do not place the ScanAnalog in the patient's mouth.

The ScanAnalog may be used in applicable extraoral digital scanning workflows involving an existing prosthesis or a stone model.

13.1 Existing Prosthesis – Alternative ScanAnalog Workflow

The ScanAnalog may be used as an alternative scanning workflow when a direct 360° scan of an existing prosthesis does not provide adequate capture to reliably establish the position of the attachment housings.

Before use, visually inspect each ScanAnalog and its defined sandblasted scanning area. Do not use a ScanAnalog that is damaged, deformed, contaminated, or has visible deterioration that may affect scanning.

1. Remove the applicable retention inserts from the attachment housings located within the intaglio surface of the prosthesis. Insert new LOCATOR black processing inserts to permit placement of the ScanAnalog.
2. Place a ScanAnalog into each applicable attachment housing within the intaglio surface of the prosthesis.
3. Verify that each ScanAnalog is fully seated and stable within the attachment housing.
4. Perform a 360° extraoral scan of the prosthesis using suitable scanning equipment.
5. Visually inspect the completed digital scan and confirm that each ScanAnalog and its relevant scanning geometry have been adequately captured.
6. If the scan is incomplete or inadequate, correct the applicable scanning condition and repeat the scan before proceeding with the digital workflow.
7. After completion and verification of the scan, remove all ScanAnalogs from the prosthesis.
8. Restore the prosthesis to the appropriate clinical configuration before returning it for patient use.

13.2 Use of the ScanAnalog in a Stone Model

The ScanAnalog may be incorporated into a stone model to represent the position of a Zest LOCATOR or LOCATOR FIXED attachment for applicable laboratory and digital scanning workflows.

Before scanning:

- verify that each ScanAnalog is correctly positioned and stable within the model;
- ensure that the defined scanning areas are clean and suitable for optical capture; and
- visually inspect the ScanAnalogs for damage, deformation, or deterioration that may affect scanning.

Perform the extraoral scan using suitable scanning equipment and visually verify adequate capture of the ScanAnalogs before proceeding with the digital workflow.

When incorporated into a stone model, the ScanAnalog is intended for single use in that model. Do not recover a ScanAnalog from a stone model for subsequent reuse.

14. Post-Use Handling

14.1 ArchBridge Scan Bodies

1. Remove all ArchBridge Scan Bodies from the patient's mouth immediately after completion and verification of the scan.
2. Remove the used Zest Processing Spacer, P/N N2001657108, from each ArchBridge Scan Body.
3. Discard the used Processing Spacer. Do not clean, sterilize, reprocess, or reuse the Processing Spacer.
4. Handle used ArchBridge Scan Bodies as contaminated devices and transfer them for cleaning and sterilization in accordance with Section 15.
5. Do not allow contaminants to dry on the device before cleaning. Begin reprocessing as soon as reasonably practical after use.

14.2 ScanAnalog

After extraoral use, remove the ScanAnalog from the prosthesis or model configuration and inspect it for damage, deformation, contamination, or deterioration of the defined scanning area. ScanAnalogs intended for subsequent extraoral use shall be cleaned in accordance with Section 15. A ScanAnalog incorporated into a stone model is single-use in that model and shall not be recovered for reuse.

15. Cleaning and Sterilization

The ROE ArchBridge OD Scan Bodies are supplied non-sterile and shall be cleaned and sterilized before first intraoral use and before each subsequent intraoral use.

The ROE ArchBridge OD ScanAnalog is intended for extraoral use only. Clean the ScanAnalog before reuse following contact with a used prosthesis or other patient-derived contamination. When a ScanAnalog is incorporated into a stone model, it is single-use in that model.

15.1 Preparation for Cleaning

- Remove and discard the used Zest Processing Spacer before cleaning an ArchBridge Scan Body.
- Reprocess devices as soon as reasonably practical after use. If cleaning is delayed, prevent contaminants from drying on the device.
- Visually inspect the device for damage or deformation before cleaning.
- Do not use metal brushes or abrasive cleaning tools that may damage the device geometry or sandblasted scanning surface.

15.2 Manual Pre-Cleaning

1. Carefully remove visible residues using a soft nylon brush and a freshly prepared solution of Prolystica® 2X Concentrate Neutral Detergent at 1 mL/L, at room temperature. Brush for a minimum of 30 seconds.
2. Rinse thoroughly with cool-to-lukewarm purified water for at least 2 minutes and 30 seconds.
3. Place the device in an ultrasonic cleaner containing Prolystica® 2X Concentrate Neutral Detergent at 1 mL/L, diluted with purified or sterile water in accordance with the detergent manufacturer's instructions.
4. Sonicate for 10 minutes.
5. Rinse with purified or sterile water for 3 minutes.
6. Immediately after washing, dry all device surfaces using clean, lint-free, single-use absorbent wipes.

Avoid cleaning agents containing phenol, alcohol, chlorine, acids, or quaternary ammonium compounds.

15.3 Automated Cleaning

Following manual pre-cleaning, process the device in a qualified washer-disinfector using the following cycle:

Cycle Step	Minimum Time	Temperature	Detergent / Water
Pre-Cleaning	2 min	Cold, <45°C	Tap water
Cleaning	5 min	Heated, 55°C	Prolystica® 2X Concentrate Neutral Detergent, 0.4%
Rinse 1	2 min	Cold, <45°C	Tap water
Rinse 2	2 min	Cold, <45°C	Tap water
Thermal Rinse	5 min	Heated, 93°C	Reverse osmosis water
Drying	22 min	Heated, >50°C	Not applicable

15.4 Inspection and Steam Sterilization of ArchBridge Scan Bodies

After cleaning:

1. Visually inspect the device under adequate lighting and confirm that no visible contamination remains.
2. Inspect for damage, deformation, corrosion, deterioration, or other conditions that may affect seating or scanning performance.
3. Ensure that the device is completely dry before packaging.
4. Place each ArchBridge Scan Body in an appropriate sterilization pouch suitable for steam sterilization.

Sterilize the ArchBridge Scan Body using a Dynamic Air Removal (Pre-Vacuum) steam sterilization cycle with the following parameters:

Parameter	Requirement
Temperature	134°C (273.2°F)
Exposure Time	6 minutes
Drying Time	20 minutes

Allow the sterilized device to cool and dry before handling or use. Do not use the device if the sterilization pouch is wet, opened, damaged, or otherwise compromised following sterilization.

15.5 ScanAnalog Cleaning

The ScanAnalog is intended for extraoral use only. When reuse is intended following contact with a used prosthesis or other patient-derived contamination, clean the ScanAnalog using Sections 15.1 through 15.3 and inspect it before reuse.

16. Storage, Handling and Reuse

16.1 Storage

Store unused ROE ArchBridge OD devices in their original packaging in a clean, dry area at room temperature, protected from direct sunlight, contamination, and physical damage. After reprocessing, store reusable devices in a manner that protects them from contamination, moisture, and physical damage until the next use.

Sterilized ArchBridge Scan Bodies shall remain in their sterilization packaging until required for use. Do not use a sterilized device if the sterilization packaging is wet, opened, damaged, or otherwise compromised.

16.2 Handling

- Handle ArchBridge Scan Bodies and ScanAnalogs carefully to prevent damage, deformation, or alteration of device geometry or scanning surfaces.
- Do not modify, grind, bend, polish, or otherwise alter the device.
- Do not use metal brushes, abrasive instruments, or other methods that may damage the scanning surface.
- Do not use a device that does not seat properly or cannot be maintained in a stable position during use.

16.3 Inspection Before Reuse

Before each reuse, visually inspect the device under adequate lighting. Do not reuse the device if any of the following are observed:

- deformation or physical damage;
- corrosion;
- residual contamination that cannot be adequately removed;
- damage or deterioration of the scanning surface that may affect optical capture;

- damage to the connection/interface that may affect proper seating or stability; or
- any other condition that may compromise the intended function of the device.

If suitability for continued use is uncertain, discontinue use and replace the device.

16.4 Reuse

ArchBridge Scan Bodies are reusable provided that they remain functional, can be adequately cleaned and sterilized, and meet the inspection criteria specified in this IFU.

The ScanAnalog may be reused for applicable extraoral workflows provided that it remains functional and meets the applicable inspection and cleaning requirements. A ScanAnalog incorporated into a stone model is single-use in that model.

17. Potential Complications

Potential complications associated with improper use of the ROE ArchBridge OD devices may include:

- inaccurate or incomplete digital scan data;
- inaccurate transfer of the position of the applicable attachment;
- improper fit of the resulting prosthetic restoration;
- need for repeat scanning or additional clinical procedures;
- damage to or malfunction of the ArchBridge component; and
- accidental ingestion or aspiration of a component during intraoral use.

If a component becomes loose or unstable during intraoral use, discontinue the procedure and retrieve the component before proceeding. Do not proceed with the restorative workflow when the accuracy or completeness of the scan data is uncertain.

18. Adverse Event / Serious Incident Reporting

Any serious incident or adverse event associated with the device should be reported to Bhi Implants Ltd. and to the applicable regulatory authority, as required by local regulations.

19. Disposal

Dispose of used single-use components and any ArchBridge component that is damaged, worn, contaminated beyond effective cleaning, or otherwise unsuitable for continued use in accordance with applicable local regulations and the healthcare facility's procedures.

Components that have been exposed to patient biological material shall be handled and disposed of in accordance with the healthcare facility's procedures for contaminated medical devices.

The Zest Processing Spacer is single-use only and shall be discarded after use.

20. Symbols and Labeling Information

The symbols used on the product labeling and packaging should be interpreted as described below.

Symbol	Meaning	Description
	Manufacturer	Identifies the medical device manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	Catalog Number / REF	Identifies the manufacturer's catalog number.
	Lot / Batch Code	Identifies the manufacturer's lot or batch code for traceability.

Symbol	Meaning	Description
	Consult Instructions for Use	Indicates that the user should consult the Instructions for Use.
	Caution	Indicates that caution is necessary when operating or handling the device.
	Non-Sterile	Indicates that the device is supplied non-sterile.
	Keep Dry	Indicates that the product should be protected from moisture.
	Keep Away from Sunlight	Indicates that the product should be protected from direct sunlight.

21. Manufacturer and Contact Information

Manufacturer:

Bhi Implants Ltd.

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For product-related questions or to report a complaint or adverse event, contact Bhi Implants Ltd. using the contact information above.

22. Document Identification and Revision Information

Field	Information
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Document No.	LAB 283
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Revision History

Revision	Effective Date	Description of Change
0	2026-08-12	Initial release