ARCHBRIDGE KIT
INSTRUCTIONS FOR USE

Indications for use

IPD Instruments and Lab Accessories are devices to be used with abutments and dental implants. They are used as accessories and are indicated in the placement, adjustment or assistance in the fabrication of dental prostheses, among other general tasks in general dentistry by the intended users, dental technicians, doctors and dentists.

Reference Codes–Scope

All IPD references follow the same basic structure:

ROE/AB-CD-XX/(FS)

ROE/ → Element common to all commercial references distributed by Roe Dental.

AB → Compatible with Nobel Multi-unit 4.8.

C → This represents the device category or product family.

D → This represents the platform of the compatible implant system.

XX → These two numbers represent the additional characteristics of the device. They depend on the device's category.

(/FS) → A reference may contain additional alphanumeric codes at the end to provide further information on the device's characteristics.

Product Model	Product Code AB-CD-XX	Description AB-CD-XX
SC3D	ROE/AB-KD-00/FS ROE/AB-SD-XX/FS	**Scan Flag System:** **K** → Relative to the ArchBridge Kit: Combination of a set of Scan Flags. XX identify the type of kit. Range 00-99. **S** → Relative to the single Scan Flag. XX is a number to identify the type of the Scan Flag. Range 00-99.

Arch Bridge Kit – General Description and Components

The Arch Bridge Kit is a medical device designated to be used as part of a restorative prosthetic plan. The kit contains 10x Scan Flags (also known as ArchBridge scan bodies) which are different in shape, geometry and dimensions. The components have been listed as follows:

Scan Flag - Coding	Scan Flag - Description	Quantity
ROE/AB-SR-01/FS	Wingless Scan body	2
ROE/AB-SR-02/FS	Jut Wing	1
ROE/AB-SR-03/FS	Long Bone Wing	1
ROE/AB-SR-04/FS	Wavy Divot Wing	1
ROE/AB-SR-05/FS	Long Wavy Wing	1
ROE/AB-SR-06/FS	Violin Wing	1
ROE/AB-SR-07/FS	Triple Divot Wing	1
ROE/AB-SR-08/FS	Peapod Wing	1
ROE/AB-SR-09/FS	Tapered Wing	1

Materials

List of materials and device categories:

Product Model	Product Category	Material
SC3D	Scan Abutment	Titanium ISO 5832-3 (sandblasted)

Contraindications, Warnings and Precautions

Prosthetic and laboratory products must be used only by sufficiently experienced professionals. The prosthetic restoration techniques required for the correct use of these products are specialised and complex. The use of an inadequate technique might result in the failure of the prosthesis. Please, read all the information contained in these instructions for use carefully.

Disclaimer of liability: The components manufactured by IPD must be used by qualified professionals who are familiar with implant and prosthetic restoration protocols and capable of identifying any device defects. IPD disclaims any liability for direct and/or indirect damages resulting from user negligence, unauthorized modifications to the original shape of the devices beyond the indicated limits, improper use, or incorrect storage and handling.

Contraindications

The products supplied by Implant Protesis Dental 2004 S.L. are of professional use (dental technicians, doctors and dentists).

All of the materials used in the manufacturing of IPD's prosthetic and lab components are suitable, both in type and duration of contact, according to their intended use. Nonetheless, some patients might present allergic reactions or hypersensitivity to some of their materials and/or components. Therefore, IPD recommends not using them in patients who may present a known allergy or hypersensitivity. The materials used in the manufacturing are described in the "Materials" section.

The use of laboratory devices in a clinic environment is contraindicated.

Do not use the devices without verifying the compatibility with any other prosthetic material already present in the oral cavity.

Warnings

Pay attention to the information on the label. Do not use the product if the packaging is damaged.

Implant Protesis Dental 2004 S.L. products are marketed not sterile. Please refer to the "Cleaning, Washing and Sterilisation" section of the instructions for use for more information. The use of non-sterile devices can lead to tissue infections or diseases.

Any serious incident related to the product must be reported to IPD by email info@ipd2004.com and to the competent authority of the State in which the user and/or patient is established.

All IPD's reusable products must be cleaned and disinfected before and after use, according to the protocol defined in the "Cleaning, Washing and Sterilization" Section. The products used in the clinic which are reused must be sterilised prior to their use.

IPD recommends replacing reusable devices when their mechanical properties have deteriorated due to their use and their correct functionality cannot be assured.

Always apply the recommended torque according to the specific instructions of the chosen device.

Precautions

Do not remove the device from its original packaging until its use.

IPD recommends implementing the necessary preventive measures to avoid the risk of aspiration or swallowing of the devices during their oral use.

For the safe disposal of the product proceed according to the procedure established in your internal regulations. For the rest of materials, dispose them as assimilable to urban waste.

Cleaning, Washing and Sterilisation

All IPD devices are supplied NON-STERILE. Proper cleaning, disinfection, and sterilization prior to clinical use are essential.

At the Dental Lab:

During laboratory processing phases, the medical devices may be disinfected using cold disinfection methods.
The prosthesis manufactured in the laboratory, must be disinfected before delivery to the dental clinic. It is the dental technician's responsibility to identify a disinfection method compatible with all prosthetic materials used.

At the Dental Clinic:

Protocol:

- Functional verification: Prior to performing the procedure described below, assess the condition of the medical devices. If signs of wear and/or damaged parts are observed, the device must be discarded.

- Pre-washing: Before each use, the medical devices must be immersed in a solution of lukewarm water (<40 °C) and a cleaning/disinfecting agent (e.g., Bactizyme) for 10–15 minutes. Remove the devices and thoroughly brush them under running water using a soft-bristled nylon brush to eliminate any organic residues. Follow the detergent manufacturer's instructions to determine the appropriate amount and/or dilution of the product. When brushing, pay special attention to grooves, holes, and threads, using suitable interdental brushes if necessary to reach difficult areas. After the procedure, visually inspect the devices: if residues are still present, repeat the process until they are completely removed.

- Packaging: IPD recommends the use of a system, blister or packaging that allows the sterilisation cycle planned for the device and that keeps the sterility before use.

- Sterilization: IPD recommends sterilisation prior to use with a pre-vacuum autoclave at 121 ° C for 15 minutes or 132 ° C for 4 minutes. Then let it dry for the necessary time prior to use. The sterilized devices packed must be stored in a cool, dry place, away from sources of heat, light, and dust. Open the packaging only immediately prior to use.

- Number of uses: The medical devices are validated for multiple reprocessing cycles, depending on their condition and degree of wear. At the end of their usable life, they must be discarded. Each cycle is defined as one full sequence of use, pre-washing, ultrasonic cleaning/disinfection, and sterilization. If the devices show any damage or signs of wear before reaching this limit, they must still be disposed of.

Note: To guarantee the correct process, do not mix up with other products (other materials, shapes, dimensions...) of other Manufacturers.

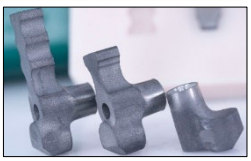
Do not reuse single-use devices. The reuse and re-sterilisation of these products can cause the deterioration of their mechanical characteristics and/or dimensions that can lead to the failure of the prosthetic restoration, in addition to risks of infection or deterioration of the patient's health.

Storage and Handling

IPD devices do not require special storage conditions. IPD recommends to store and to handle in room temperature and humidity.

DIRECTIONS FOR USE

Arch Bridge Kit



The Scan Flags are intended to transfer the spatial position of a dental implant or a multi-unit abutment (MUA) from the patient's oral cavity (digital workflow) or from an analog model to CAD design software, in order to enable the subsequent CAD-CAM fabrication of prosthetic dental restorations.

These restorations may be screw-retained, cement-retained, or bonded, as the devices are linked to their corresponding implant libraries. The device is applied by means of screwing on the implant or multi-unit abutment (MUA) before proceeding with the different scanning procedures.

Warnings:

- The scan flags are used in combination with other devices, such as screws, screwdrivers and dental implants and abutments. Before use, verify the compatibility.

- The supplied medical devices must not be modified.

General Procedure at the clinic:

In the case of restorations on multiple implants, to ensure final scanning accuracy, it is strongly recommended to screw in all individual components and proceed with a single scan, strictly following the instructions provided by the scanner manufacturer.

1. Screw the scan body on the implant using the compatible screw: VORTEX (Torque 15 N·cm).
2. Carefully verify the correct connection between the individual components/implant/MUA through:
    a. Visual inspection;
    b. Radiographic confirmation (strongly recommended).

Note: The scan body must not be in contact with adjacent teeth or other scan bodies, in order to avoid stress, improper seating, tooth displacement, or incomplete scan data capture of the scan body.

In case of contact with teeth: use a scan body with appropriate dimensions.

3. Verify that the components do not cause any interference with the opposing arch during occlusal registration. If interference is present, remove the scan body.
4. Once the scan body has been removed, proceed with cleaning, washing, and sterilization according to the instructions provided in the section "Cleaning, Washing and Sterilization."

Note: It is the clinician's responsibility to select the appropriate digital workflow for case management.

Additional Protocols:

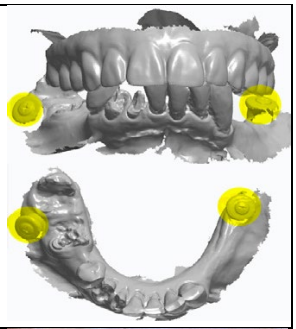
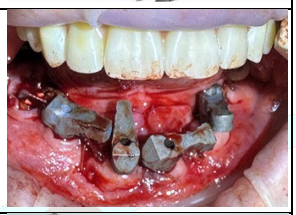
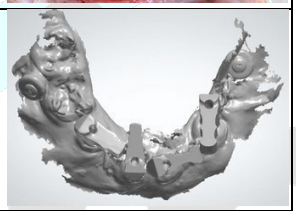
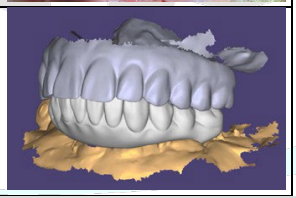
1. TAD as fiducial

2. Teeth as fiducial

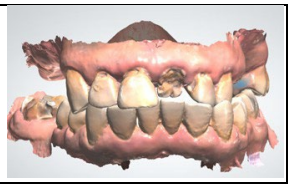
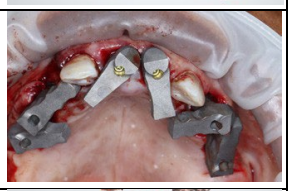
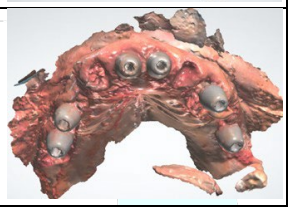
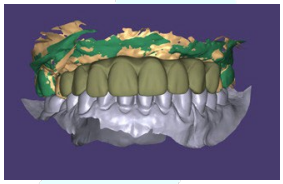
3. Denture method

4. Restorative records

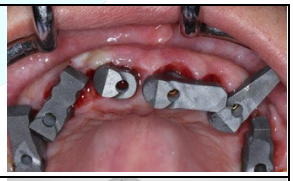
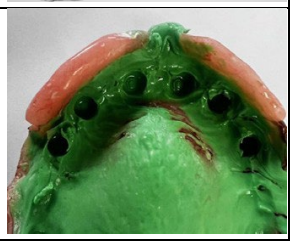
1.TAD as fiducial

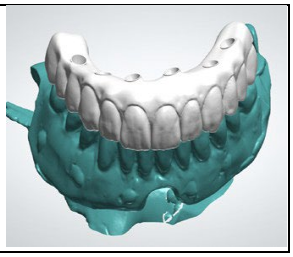
1. Pre-Surgical IOS Scan (1st scan) On the day of surgery, prior to beginning the surgical protocol: a. Place at least two TADs on the palate or retromolar pads. b. Capture pre-surgical IOS scan of teeth, tissue and TADs, opposing and bite. **Important:** Ensure that the TADs are fully visible in the scan capture.	
2. Place ArchBridge on MUAs After implant and MUA placement, but prior to suturing, place one ArchBridge scan body on each MUA. Rotate until they are almost touching, for ease of scanability. Tighten each ArchBridge to the recommended torque of 15 Ncm.	
3. ArchBridge Scan (2nd scan) Capture IOS scan, following the protocol of focusing on the scan bodies, not surrounding surfaces. Start scanning the occlusal and move across the arch rotating from buccal to lingual while capturing all of the Archbridges. Only scan once across the arch for best accuracy.	
4. Post-Surgical Scans (3rd scan) Two options: a. **IOS**: Capture an IOS scan of the tissue with healing collars seated, and TADs (no ArchBridge). This can be pre- or post-suturing. b. **PVS**: If having trouble scanning intraorally, capture a PVS impression of the tissue with healing collars seated (no ArchBridge) and scan the PVS impression with IOS.	
5. Upload Files and Complete Rx Go to the ROE portal, https://www.roedentallab.com/collaboration/grammetry-case-submission, and upload patient photographs, completed Rx, and the following .STL files. - Presurgical scans - ArchBridge intraoral scan - Post-surgical intraoral scans	

2.Teeth as fiducial

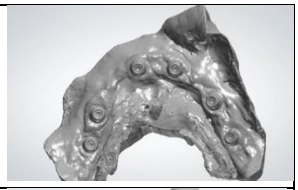
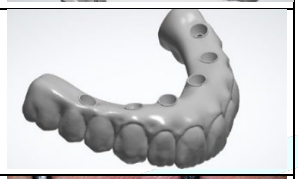
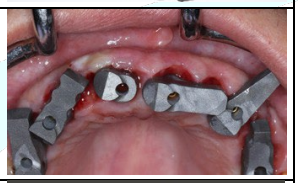
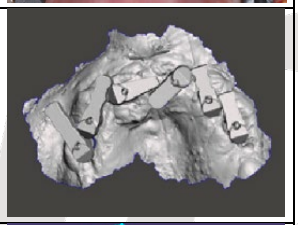
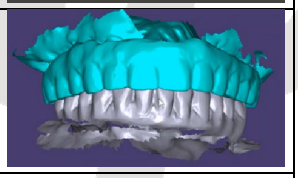
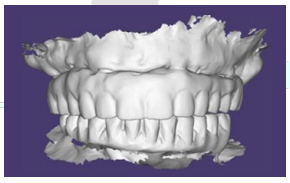
1. Pre-Surgical Scan (1st scan) On the day of surgery, capture a pre-surgical IOS scan of the teeth, including the reference teeth.	
2. Place ArchBridge on MUAs After implant and MUA placement, but prior to suturing, place one ArchBridge scan body on each MUA. Rotate until they are almost touching, for ease of scanability. Tighten each ArchBridge to the recommended torque of 15 Ncm.	
3. ArchBridge Scan (2nd scan) Capture an IOS scan of the ArchBridge scan bodies, including the teeth references, but excluding surrounding surfaces. Start scanning the occlusal and move across the arch rotating from buccal to lingual while capturing all of the Archbridges. Only scan once across the arch for best accuracy.	
4. Tissue Scan (3rd scan) Capture an IOS scan of the tissue with reference teeth visible and healing collars seated (no ArchBridge).	
5. Upload Files and Complete Rx Go to the ROE portal, https://www.roedentallab.com/collaboration/grammetry-case-submission, and upload patient photographs, completed Rx, and the following .STL files. - Pre-surgical scans - ArchBridge intraoral scan - Post-surgical intraoral scans	

3. Denture Method

1. Place ArchBridge on MUAs After implant and MUA placement, but prior to suturing, place one ArchBridge scan body on each MUA. Rotate until they are almost touching, for ease of scanability. Tighten each ArchBridge to the recommended torque of 15 Ncm.	
2. ArchBridge Scan (1st scan) Capture an IOS scan of the ArchBridge scan bodies, excluding surrounding surfaces. Start scanning the occlusal and move across the arch rotating from buccal to lingual while capturing all of the Archbridges. Only scan once across the arch for best accuracy.	
3. Denture Scan Protocol (2nd and 3rd scan) a. Seat healing caps on each MUA and suture. Relieve denture intaglio of to ensure passivity. b. Reline denture(s) with light body PVS. Place in the mouth and let set, in occlusion. c. Remove denture and take scan of the opposing. d. Take 360 IOS scan of the denture, capturing a clear image of the intaglio and healing cap impression. e. Re-seat denture and scan the bite.	

4. Upload Files and Complete Rx Go to the ROE portal, https://www.roedentallab.com/collaboration/grammetry-case-submission, and upload patient photographs, completed Rx, and the following .STL files. - ArchBridge intraoral scans - Extraoral 360 relined denture scan - Bite and opposing scan	

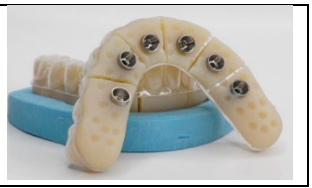
4. Restorative Records

1. Tissue Scan (1st scan) Remove the prosthesis. Capture a scan of the tissue and multi-unit abutments, preferably with MUA healing caps on.	
2. Extraoral Scan (2nd scan) Capture a 360° scan of the prosthesis. We recommend holding the prosthesis in hand while scanning until the full surface is captured. *Capturing this extraoral scan prior to the intraoral scan typically enables better scan stacking and bite capture.*	
3. Place ArchBridge on MUAs Place one ArchBridge scan body on each MUA. Rotate until they are almost touching, for ease of scanability. Tighten each ArchBridge to the recommended torque of 15 Ncm.	
4. ArchBridge Scan (3rd scan) Capture an IOS scan of the ArchBridge scan bodies, excluding surrounding surfaces. Start scanning the occlusal and move across the arch rotating from buccal to lingual while capturing all of the Archbridges. Only scan once across the arch for best accuracy.	
5. Bite and Opposing Scan (4th scan) Reseat the appliance(s). Perform a complete scan of the appliance(s), capturing as much tissue landmarks as possible. Scan the opposing. Then scan the bite.	
6. Upload Files and Complete Rx Go to the ROE portal, https://www.roedentallab.com/collaboration/grammetry-case-submission, and upload patient photographs, completed Rx, and the following .STL files. - Tissue scan - 360° prosthesis scan - ArchBridge intraoral scan - Seated prosthesis scan, opposing and bite scans	

Optional iJIG, verification jig workflow:

Optional and applicable to all above-described workflows (1-4).

Doctors have an option to verify implant positions before going to final by using the iJIG workflow. This method allows the lab to create a verified model to design a final zirconia to. Visit www.roedentallab.com/ijig for complete workflow.

1.Verification Appointment From your post-healing updated IOS records (upper, lower, bite and 360 scan of the prosthesis), the lab will fabricate and ship an iJIG for the verification appointment prior to going to final zirconia.	

Glossary of Symbols

	Manufacturing Date	LOT	*Batch Number*	Rx only	*Professional use only*
	Manufacturer	CE	*CE mark*	*US Federal law restricts this device to sale by or on the order of a dental professional.*	
UDI	*Unique Device Identifier*	MD	*This product is a medical device*		
REF	*Catalogue number*		*Consult the instructions for use*		
#	*Model Number*		*Do not use if package is damaged*		

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