AuryzoN™ and DimensioN

Cartilage Processing Devices

INSTRUCTIONS FOR USE (IFUs)

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ReconstratA LLC, Baltimore, MD

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AURYZON

AuryzoN™ and DimensioN Cartilage Processing Devices

This document contains general instructions for use for the AuryzoN™ and DimensioN devices, and their associated blades, cutting surfaces, and other replaceable components.

DESCRIPTION

AuryzoN™ and DimensioN are devices specialized for the cutting and processing of cartilage or synthetic cartilage-like material to be utilized in Plastic and Reconstructive surgeries, particularly those of nasal, auricular, and eyelid reconstructions. These devices, used in the operating room by the plastic surgeon, and increase the speed by which cartilage frameworks of the ear/nose/eyelid can be developed, and at a high level of precision.

CAUTION – AURYZON™ AND DIMENSION ARE CURRENTLY PREMARKET DEVICES AND ARE DESIGNATED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) AS NONSIGNIFICANT RISK (NSR) DEVICES. USE OF THESE DEVICES SHOULD BE PERFORMED IN ACCORDANCE WITH THE APPROVED CLINICAL TRIAL AND UNDER THE PROTOCOLS ESTABLISHED BY RECONSTRATA, LLC AND STUDY INVESTIGATORS.

MATERIALS

Aluminum (body of AuryzoN™ and DimensioN)
Polycarbonate
Stainless Steel (blades, cutting surfaces)

CONTRAINDICATIONS

AuryzoN™ and DimensioN should not be used if:

- Inadequate substrate is available for processing of necessary components
- Site of reconstruction is actively infected
- Extracted cartilage is overly fibrotic, coarsely calcified, or grossly deformed

STORAGE

Appropriately sterilized devices and cutting components should be sealed within sterile removable packaging, and stored in a cleaned and dry location. Sterile packaging should only be opened on a back table in the operating room at the time of use in such a way that opening such packaging creates a sterile field around the sterilized device.

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WARNING

- Alteration of cutting components, blades, and cassettes is not recommended. Manipulation of blades may irreversibly damage and alter the specific geometry, and may preclude its safe and/or effective use within the device.
- Blades and cutting surfaces may be very sharp. Care is advised during use of all cutting components to reduce the risk of injury for the operator. Cutting components should be carefully removed from the device upon completion of use.
- AuryzoN™, DimensioN, and cutting components are to be used by a trained physician in the performance of surgery.
- Cutting guides and components should be selected based on a preliminary anatomical survey of the patient, either using direct measurements or extracted measurements from cross-sectional imaging, such as CT or MRI. Cutting cassette sizes should be chosen with the assistance of the device reference guide.
- The devices and cutting components should be properly cleaned before sterilization. These should not be used if they are broken, cracked, or visibly contaminated.
- The devices and cutting components may be provided in a non-sterile package. If so, the devices and cutting components must be properly sterilized prior to use in surgery.

PRECAUTIONS

- Choice of cutting cassette size and type should be established within 6 months of surgery. If a longer period is expected prior to surgery, the patient's anatomy should be re-examined for change and determination of the most appropriate cassette size.
- During installation of cutting surfaces, setting of cartilage, or performance of cutting actions, care must be taken to avoid excessive or abnormal force. Components are designed for intuitive interlocking and ergonomic application of human force. Excessive or abnormal force may irreversibly damage the devices, their components, or the cartilage.
- Prior to use, the devices and cutting surfaces should be inspected for necessary markings. On the DimensioN device, markings indicate stage height. On the AuryzoN™ cutting cassettes, markings indicate the cassette size and orientation. Markings should be clearly visible. If there is damage or illegibility of these necessary markings, the device/components should not be used, and ReconstratA should be contacted.

POSSIBLE ADVERSE EFFECTS

- Infection is the primary theoretical risk, as implantable material is manipulated on a manufactured surface external to the patient.
- Loss of cartilage/synthetic substrate due to inadequate or improper processing.
- Resorption, warping, and shrinkage of cartilaginous constructs.

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NSTRUCTIONS FOR USE

DimensioN:

- Blade Fitting
    - The DimensioN blades come in a single size and are uniquely designed to fit specifically into the DimensioN device. Use of other blades from other manufacturers is prohibited, as blade security and safety cannot be ensured.
    - Blade fitting should be performed under sterile conditions.
    - The sterilized blade may come either as a pack with other blades, or as an individually packaged blade. If the blade is packaged with multiple units, the packaging should be opened in the operating room and all blades subsequently cleaned and sterilized, whether or not they were used within the device.
    - The blade should be carefully handled at all times to ensure the safety of the operator.
    - The blade is affixed to the device with the use of two (2) screwed wingnuts on either side of the sliding handle. The wingnuts should be released, the blade positioned to align the holes on the blade with the wingnut holes, and the wingnuts replaced.
    - Prior to use, the blade should be examined for security by touching the rear of the blade surface, which is not sharpened.
    - If the blade is cracked or warped, it should not be used.
    - If there are nicks or focal defects in the sharpness of the cutting plane of the blade, it may still be safely used if: 1) the defects are away from the blade center beyond the margins of the stage width, 2) the cartilage can be positioned on the stage in such a way that the defect will not contact the cartilage during cutting.
- Cartilage Processing
    - Cartilage or other commonly used synthetic biomaterials for reconstruction should be first cut roughly by a scalpel if their dimensions grossly exceed those of the stage to ensure stable positioning of the substrate at rest.
    - Once the cartilage is placed on the stage, the roof plate should be carefully lowered. A spring mechanism assures secure positioning of the roof plate against the stage, compressing the substrate in between. During the action of roof lowering, care must be taken to avoid rapid roof drop, which can damage the substrate.
    - Substrate thickness is set by raising or lowering the stage platform using a plastic knob in the rear of the device. An indicator is present along the stage indicating the thickness (in millimeters) of the cut at the set stage height. The indicator should always be referenced prior to any cutting action, as the stage may shift during regular operation.
    - Once the operator is ready to cut the cartilage, steady force should be applied against the handle to slide the blade along the rails and over the stage. A smooth and steady action is recommended, and the blade should be advanced until it makes contact with the rear of the platform. A rapid action may damage the blade and/or the platform at the strike point, as well as potentially harming the

operator. If there are irregularities with movement, there may be debris in the rail, and this should be inspected.
    - Once the cut is complete, the blade should be retracted to its original position before the substrate inspected and collected to reduce risk of injury to the operator.
    - If additional substrate is to be cut, the stage should be wiped with a gauze or sponge between each substrate to clear any liquid or solid material. The blade should be inspected for any defects with each new substrate.

AuryzoN™:

- Cassette Fitting
    - AuryzoN™ is a hinged cutting device for the cutting of cartilage or other substrate material into specific shapes.
    - AuryzoN™ utilizes two separate cassettes with each operation: 1) a cutting cassette which inserts into the device roof, and 2) a guide cassette which inserts into the device base.
    - The cassettes should be chosen based on a review of the patient's contralateral anatomy (if available) or based on patient or operator preference. The cutting and guide cassettes are marked with information regarding size and type. Both cassettes should complement each other. Guide and cutting cassettes of different sizes and types should not be combined.
    - The AuryzoN™ device and chosen cassettes should be placed sterilely on a back table in the operating room.
    - The guide and cutting cassettes insert into grooves in the base and roof of the device, respectively. Cassettes should insert smoothly and with light force. Excessive force may break the plastic cassette or groove. Once the cassette is in position, a locking device should be turned to secure the cassette during use.
    - In order to cut the substrate, the substrate should be positioned over the visual layout as indicated in the guide cassette. The substrate should be gently pushed to secure it against the pins without warping or bending of the substrate.
    - The roof of the device should then be lowered in a steady manner with firm force. Rapid actions may damage the device and cause ineffective cutting.
- Cartilage Processing
    - The cartilage should be positioned on the guide (base) cassette using the visual indicators for guidance.
    - The cartilage should be slightly pushed by hand into the securing pins on the base cassette, with care being taken not to apply rapid or significant force that could damage the cartilage or injure the user.
    - Once the cartilage is secured in the guide cassette and positioning visually confirmed, the roof plate should be firmly held and pressed against the base in a single, smooth motion.

- Avoid rapid movements, which can damage or fracture the cassettes or the cutting components.
- If a repeat cut is required, a second smooth, forceful action should be performed. Rapid, high-velocity actions are not recommended as they would result in damage to the substrate.
- If the cartilage is unable to be cut sufficiently with the device but an imprint of the cut has already been performed, the cartilage should be carefully removed from the guide cassette and the imprint carved using a scalpel.
- Once the cartilage is cut properly, the residual cartilage should be first removed and inspected to make sure that the cut has been made properly. The cut component should then be removed, using the small holes on the back of the cassette to facilitate delivery of the substrate.
- Further trimming of the shaped cartilage may be performed at the discretion of the operator and surgeon, either by hand or utilizing AuryzoN™ or Dimension.

CLEANING

- Upon completion of use, AuryzoN™ and DimensioN must be thoroughly manually cleaned.
- All visible blood products, fluids, and tissue fragments must be removed prior to sterilization.
- Sterile water may be used to help wipe down used components.
- Saline should not be used, as the salt may affect the mechanical and mobile components of the device. Please follow the instructions below for cleaning before sterilization:

1. Prepare ENZOL® Enzymatic Detergent (manufactured by Advanced Sterilization Products) according to the product label IFU.
2. Wipe all exposed surfaces of the DimensioN with ENZOL Enzymatic Detergent, ensuring a minimum contact time of 1 minute.
    a. Do not use ENZOL detergent with anodized aluminum materials for longer than 8 hours to prevent slight discoloration.
3. Fully submerge the AuryzoN, AuryzoN Cassettes, Dimension Blade, and DimensioN Winged Screws in the ENZOL solution for a minimum of 1 minute.
4. While submerged, gently scrub and wipe any soil from the devices.
5. Thoroughly rinse all parts in running water to until no detergent remains.
6. Inspect the devices and repeat the cleaning procedure if soil is still present.
7. Proceed to disinfection and/or sterilization.

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STERILIZATION

Sterilization should be performed on STERRAD Systems.

AuryzoN™ and DimensioN have been validated for sterilization in the STERRAD 100S, NX, and 100NX System.

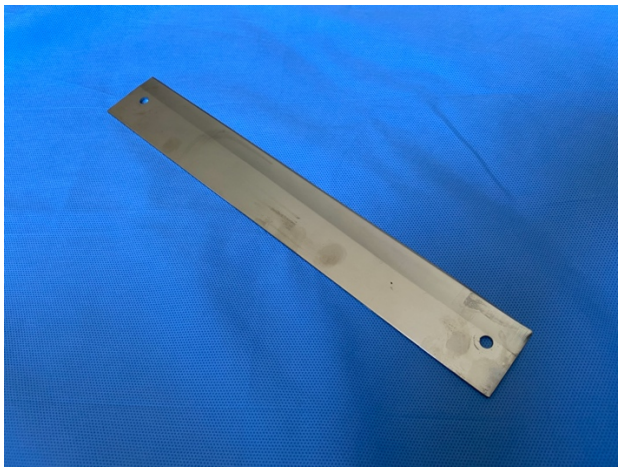
STERRAD System	Cycle
STERRAD 100S	Short
STERRAD NX	Standard
STERRAD 100NX	Standard

Packaging:

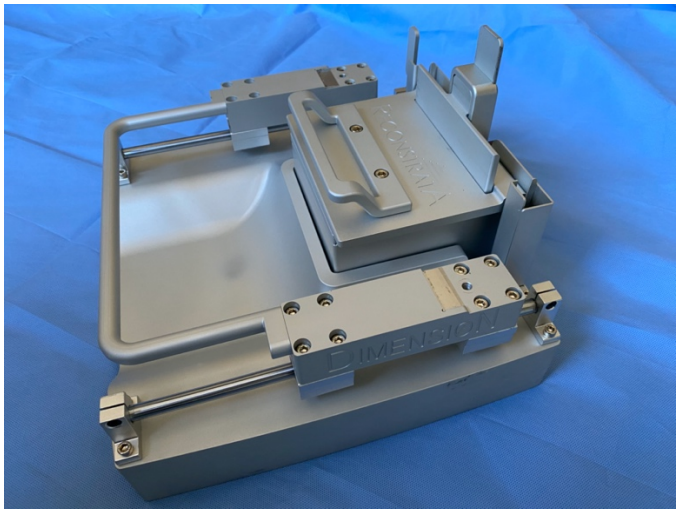
Use only STERRAD Sterilizer-compatible polypropylene sterilization wrap and/or Tyvek® pouches, following all recommended directions included in the instructions for use.

DimensioN can be wrapped in a 48” x 48” sterilization wrap.
AuryzoN™ with cassettes can be wrapped in a 36” x 36” sterilization wrap.

Process the DimensioN blade(s) separately from the DimensioN cutting device.



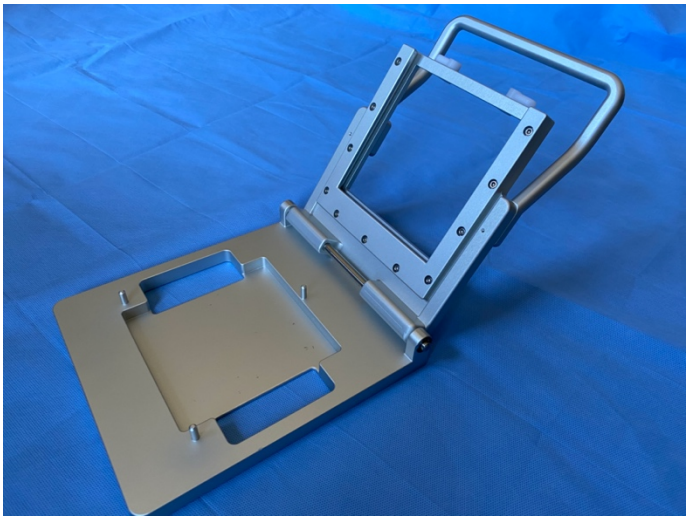
DimensioN Blade



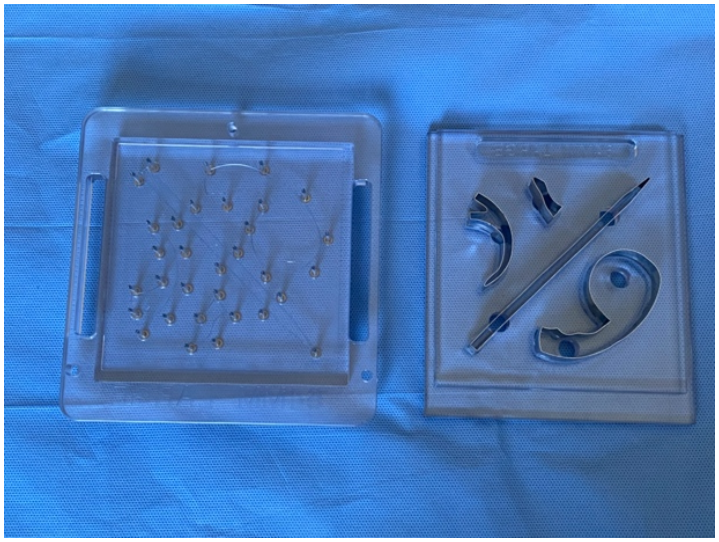
Dimension Device

The top shelf of the 100NX must be removed to accommodate the height of the DimensioN cutting device.

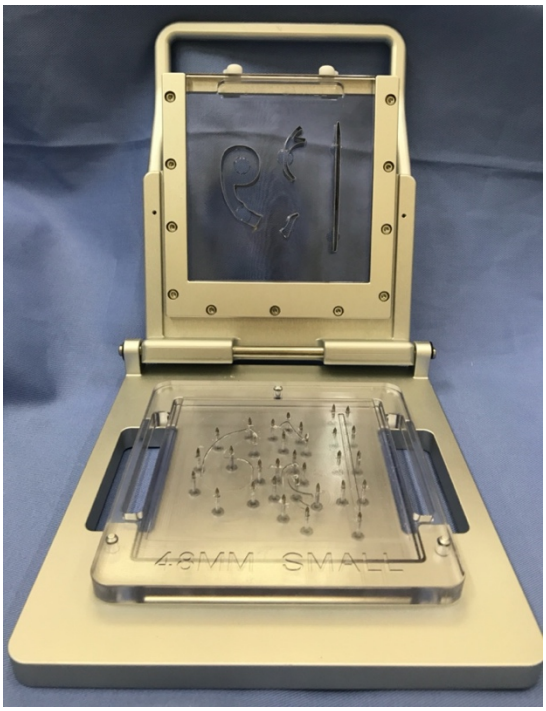
The AuryzoN™ and AuryzoN™ Cassettes can be sterilized in an assembled configuration, however it is recommended to package and sterilize the AuryzoN™ Cassettes separately to ensure adequate sterilant diffusion throughout the load.



AuryzoN™ disassembled configuration (preferred during sterilization)



AuryzoN™ cassettes in *disassembled configuration (preferred during sterilization)*



AuryzoN™ *assembled configuration (once assembled on the sterile field))*

Loading:

Arrange the packaged devices in the sterilization chamber properly to ensure adequate diffusion of hydrogen peroxide throughout the load. Place peel pouches on edge, if possible.

Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch. Do not stack pouches on top of each other or other trays, and allow at least 1" of clearance between wrapped devices and trays.

Ensure the packaged devices are not in contact with the sterilization chamber, door, or electrode.

**Testing was performed in accordance with AAMI TIR No. 12-2010 guidelines, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."

**Please refer to the STERRAD System User's Guides for general reprocessing instructions, including proper cleaning, drying, and packaging information prior to reprocessing any medical device in a STERRAD System.

CONTACT INFORMATION

The AuryzoN™ device, DimensioN device, and associated cutting components are distributed by:
ReconstratA, LLC
2007 Clipper Park Rd Unit 326
Baltimore, MD 21211

The AuryzoN™ device, DimensioN device, and associated cutting components were manufactured by:
Leardon Solutions
9877 Waples Street
San Diego, CA 92121

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USPTO patent number: 10,485,665, November 26, 2019.