General Instructions for Use

- Use on a single occasion for a single patient only. Once the package is opened, the implant must be used for the current procedure or discarded.
- The outermost packaging is non-sterile and is used to protect the implant during shipping and storage.
- Additional product should be available in case of unexpected need during the procedure.
- Remove the double-barrier packaged product, the package insert, implant identification labels and Tissue Utilization Record (TUR) from the outermost package.
- Inspect the implant, packaging and labeling materials carefully:
  - Do not use past expiration date specified on the labeling.
  - Do not re-use if the packaging is damaged.
  - Do not use if there are discrepancies in label information.
- To prevent contamination of the implant, use sterile technique for preparation and implantation.
- The implant and all packaging materials used by RTI Biologics are latex-free.
- Do not re-sterilize the implant.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all product defects, complaints and patient adverse reactions to RTI Biologics (See Customer Returns and Complaints section).

Directions for Implant Preparation

1. Open the package and pass the implant into the sterile field.
2. Rehydrate the implant before use by soaking in sterile, physiological saline as defined in the table below or until the implant becomes soft and flexible. Use promptly after rehydration.

### Implanted Type

- **Matrix HD®**
- **Matrix HD Fenestrated**

### Rehydration Time

- **At least 30 seconds**
- **At least 5 minutes**

### Antibiotic Precautions

1. The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. The implant should be used with caution in surgical procedures where it is under moderate to high tension.
2. Proper placement and fixation of the implant are critical for success of the surgical procedure.
3. The size of the graft according to the tissue defect and place securely to prevent displacement and to aid incorporation. Implant the graft so that free edges do not protrude.
4. Use absorbable or non-absorbable suture material with a round ortraumatic needle. Select the appropriate suture size for the surgical procedure. Place the stitches 2-3 mm from the edge of the implant, where possible. Use the implant where it is under minor to moderate tension. At suture sites under moderate to high tension, double the implant section if appropriate for surgical technique.

### Tissue Utilization Record (TUR)

- Complete and return the enclosed Tissue Utilization Record (TUR) to RTI Biologics. This information is considered confidential and used only for implant traceability. The TUR should be filled out and returned for all implants, even if the implant was discarded. Refer to the TUR package with the implant for additional information.

### Warranty Statement

This biologic graft, processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, ALL WARRANTIES ARE DISCLAIMED, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN ADDITION, ALL CONSEQUENTIAL DAMAGES, DIRECT, INDIRECT, SPECIAL, OR INCIDENTAL ARISING FROM USE OF THESE GRAFTS ARE HEREBY DISCLAIMED.