Instructions for Use
Integrity™ Implant

This Instructions for Use is intended exclusively for distribution within the United States.
In an effort to best meet the needs of our customers and minimize waste, these Instructions for Use are being provided in electronic format. This document is subject to change; the most current version of this IFU is available online. If unsure if using the latest revision, please reprint the IFU at www.anikaifu.com. If a paper copy is preferred it may be requested, free of charge, by contacting Anika Therapeutics, Inc. at www.anikaifu.com. The onus resides with the user to ensure that the most up to date IFU is used.

Products may not be available in all markets. Product availability is subject to the regulatory clearance in individual markets. Please contact your local representative if you have questions *about product availability in your area.*

℞ ONLY
Caution: Federal Law restricts this device to sale by or on the order of a physician.

Read these instructions completely prior to use.

DEVICE DESCRIPTION
The Integrity Implant is designed to provide an augmentation layer over an injured tendon. The implant is a knitted porous mesh comprised of a single composite layer of resorbable Hyaff-11 multifilament fibers and non-absorbable polyethylene terephthalate (PET) fibers. The implant is easy-to-handle, pliable, nonfriable, and porous in both the dry and hydrated state.

HOW SUPPLIED
The Integrity Implant is provided sterile, for single use only, in multiple sizes in a thermoformed tray with peelable lid and outer polymer packaging. DO NOT use if package is damaged or if labeling is incomplete or illegible.

INTENDED USE
The Integrity Implant is a medical device intended for the management and protection of tendon injuries.

INDICATIONS FOR USE
The Integrity Implant is intended for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

CONTRAINDICATIONS
The Integrity Implant is not designed, sold, or intended for use except as described in the indications for use and is contraindicated in the following situations:

- To replace damaged tendon or to reinforce the strength of any tendon repair.
- Use in the presence of infection.
- Conditions which would limit the patient's ability or willingness to restrict activities or follow direction during the healing period.
- For patients with hypersensitivity to the product components.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.

WARNINGS

- Discard any open, unused product.
- Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to the use of this device.
- Do not attempt to trim or otherwise modify the Integrity Implant prior to implantation.

PRECAUTIONS

- Should be used immediately after opening of the pouch. Do not store the product in the tray once the pouch is opened
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- The Integrity Implant should not be applied until bleeding and infection are controlled.
- Application of the Integrity Implant does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

POTENTIAL ADVERSE EVENTS
The following are potential adverse events that may occur from the surgical procedure or complications with the device:

- Allergic Reaction
- Infection
- Pain
- Device may not function as intended.

MRI SAFETY INFORMATION
The Integrity Implant is MRI Safe.

INSTRUCTIONS FOR USE

1. Follow standard procedures for treatment of the injured tendon.
2. Determine the tendon width in millimeters (mm) using a suitable measuring instrument.
3. Select an Integrity Implant size that is slightly smaller than the width of the tendon.
4. Place the implant over the tendon in the desired location to augment the tendon repair.
5. Secure the Integrity Implant to the tendon or tendon/bone by applying fixation at least 2 mm from the outer edge. If using Integrity Bone Staple, apply approximately 4mm from the edge of the Implant. Ensure that the implant is in good contact with the tendon.
6. Close the incision in standard fashion.

STORAGE

- Keep dry.
- Store in a cool and dry place ≤ 40C.
- Avoid temperatures more than 113°F (45°C).
- Outer package includes a temperature indicator. Do not use if central circle of the indicator on the product appears red. In the event of a temperature breach, the indicator window will turn from white to red.

Rx ONLY	CAUTION: Federal Law restricts this device to sale by or on the order of a physician	www.anikaifu.com	Consult electronic instructions for use
STERILE R	Sterilized using irradiation	LOT	Lot number
	Single Sterile barrier system with protective packaging inside		Use by date
MR	MR safe		Manufacturer
	Do not re-use		Date of manufacture
STERILIZE	Do not resterilize	REF	Catalog number
	Do not use if package is damaged and consult instructions for use	UDI	Unique Device Identifier
40°C	Upper limit of temperature		Keep Dry

FOR FURTHER INFORMATION

If further information on this product is needed, please contact Anika Customer Service at 1-888-721-1600 in the U.S., or an authorized representative.

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Made in USA

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