BRIJ™ MEDICAL **Force Modulating Tissue Bridges**

Instructions for Use

PRODUCT DESCRIPTION

The BRIJJIT® force modulating tissue bridge (BRIJJIT device) is a single-use, non-invasive wound closure and wound support device. BRIJJIT devices can be applied to support and evert the wound immediately following cleaning and debridement using standard method of care.

BRIJJIT devices consist of a polymeric backbone with medical-grade adhesive pads on each end. An applicator is used to flex the device to an open position, apply and then release allowing the BRIJJIT device to pull the wound closed.

Each sterile packet contains an applicator and six BRIJJIT devices mounted on a loading tray.

INDICATIONS FOR USE

BRIJJIT devices are indicated for non-invasive wound closure and support of lacerations, wounds and surgical incisions. BRIJJIT devices are indicated for tissue support in healing wounds and scars.

CONTRAINDICATIONS

BRIJJIT device use is contraindicated in the following circumstances:

- Chronic, contaminated or infected wounds, or when necrotic tissue is present.
- Anatomical sites where BRIJJIT devices could obstruct an orifice (e.g., mouth, eyes, ear canal, vagina, urethra or anus) or irritate sensitive tissue (e.g., cornea).
- Anatomical sites where BRIJJIT devices could interfere with normal movement, such as the flexor surface of the fingers, elbow, axilla or knees or on the sole of the foot.
- Anatomical sites where BRIJJIT devices cannot be adequately secured, such as in areas of heavy hair or excessive moisture.

WARNINGS AND PRECAUTIONS

- BRIJJIT devices are intended for use by or under the instruction of licensed medical professionals trained in their use.
- Users should be familiar with the indications and contraindications for use.
- Each package of BRIJJIT devices and each BRIJJIT applicator is indicated for use in a single patient only. Do not apply unused BRIJJIT devices on a loading tray to more than one patient. Do not use an applicator on more than one patient.
- BRIJJIT devices and the BRIJJIT applicator are stored in a sterile package. Only newly opened, sterile devices should be used for application to acute wounds. Do not use if packaging is damaged or was previously opened.
- Do not re-sterilize BRIJJIT devices or BRIJJIT applicators, as this may lead to device failure, and sterilization cannot be assured.
- BRIJJIT devices are intended for use on external skin surfaces only. Refer to CONTRAINDICATIONS section for additional details.
- BRIJJIT devices can be a choking hazard for young children. Appropriate caution should be observed at all times.
- Use BRIJJIT devices with caution in any patient with a known history of sensitivity to skin adhesives. BRIJJIT devices should be avoided in patients with a known allergy to acrylic adhesives.
- BRIJJIT devices are not intended for use on broken skin for longer than 30 days.

INSTRUCTIONS FOR USE

Use of analgesia: The placement of BRIJJIT devices on intact skin should not result in pain. To assess the need for analgesia in minor wounds, the user can gently approximate the wound edges manually and, if there is no discomfort, then BRIJJIT device placement can proceed without the injection of local anesthetic agents or other analgesic methods.

Preparation of the skin for application: The skin surrounding the wound or scar should be clean and dry prior to device application. Because prior use of lotions, moisturizers, oils or some surgical skin preparation solutions may inhibit adhesion, routine pre-application degreasing of the skin with alcohol or another appropriate degreasing solution is recommended. If the skin surface is cold, initial adherence strength of the BRIJJIT device may be reduced. Adhesive enhancers are not typically required or recommended, but can be considered in situations where enhanced initial tack may be beneficial. In circumstances when significant hair could interfere with adhesion of the BRIJJIT devices to the skin, hair removal should be performed as directed by the physician. If removal of hair is not possible or desired, an alternative wound closure mechanism is indicated.

Preparation of the wound for closure: BRIJJIT devices should be applied only to wounds or incisions that are clean and free of debris, foreign body, tissue necrosis or active bleeding, in keeping with standard principles of wound care and wound closure. If debris or foreign bodies are present, these should be removed. Non-viable tissue should be debrided. Hemostasis should be achieved by standard means. In wounds that penetrate significantly into the subcutaneous or deeper tissues, that gape or are located in high-tension areas, supportive, deep wound closure should be completed prior to placement of BRIJJIT devices in keeping with standard, accepted wound care principles. The skin of the wound margins should be clean and as dry as possible prior to application of BRIJJIT devices.

Preparation for re-application: If reapplying BRIJJIT devices to a healing wound or scar, existing BRIJJIT devices should be removed according to the section titled Removing and replacing BRIJJIT devices. Any residual skin adhesive from previous dressings in the application area should be removed.

Handling of the applicator and BRIJJIT devices

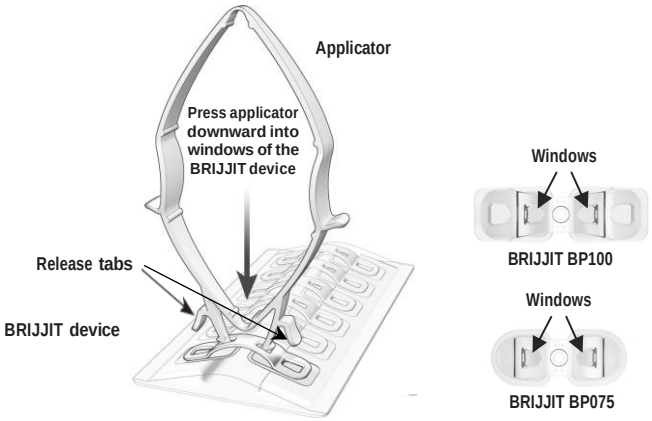
Standard wound handling practices should be employed, including the use of aseptic technique and gloves. No special handling precautions are required when applying to closed, intact skin.

Open the BRIJJIT device applicator and loading tray packages by peeling back the package tabs. Maintain sterility as required during unpackaging.

Application of BRIJJIT devices

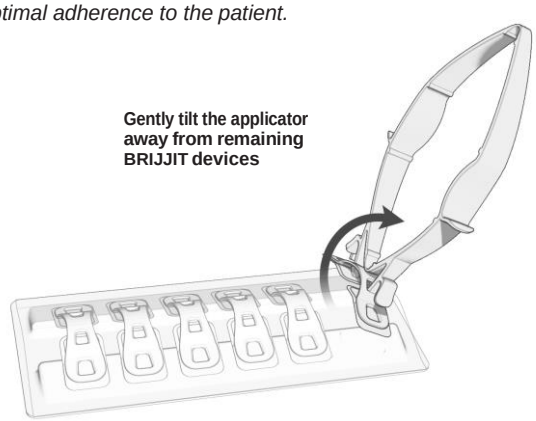
For best results, apply the BRIJJIT device immediately following cleaning and debridement using standard method of care.

Load a BRIJJIT device into the applicator by applying downward pressure on the applicator into the corresponding windows of a single BRIJJIT device. The applicator should not be squeezed (compressed) during the loading process. The BRIJJIT device will connect to the applicator with an audible click.



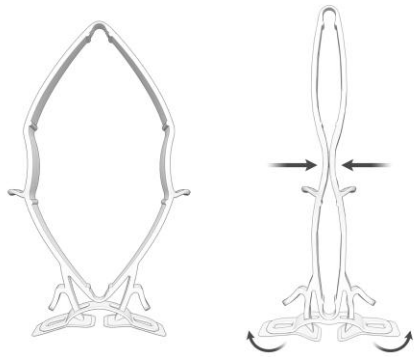
Remove the BRIJJIT device with applicator from the loading tray by gently tilting the applicator away from the remaining BRIJJIT devices on the tray.

NOTE: *Once a BRIJJIT device is lifted off of the loading tray, do not touch the exposed adhesive on the underside of the BRIJJIT device as this may prevent optimal adherence to the patient.*



The BRIJJIT device is then applied to the skin as follows:

a. Squeeze the applicator to spread the adhesive pads and flatten the BRIJJIT device before applying to skin.



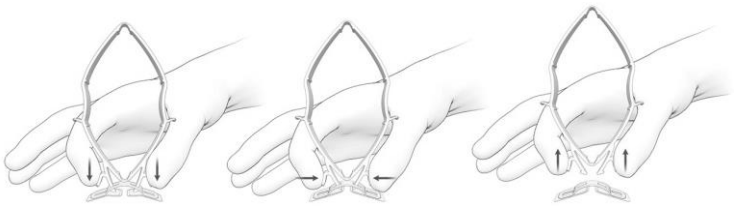
b. Next, center the BRIJJIT device and applicator over the approximated wound or scar, with the BRIJJIT device at a 90-degree angle to the wound/scar.

c. The wound margins should be pushed together with gloved fingers or forceps until the wound edges are aligned with slight eversion. The wound edges must remain aligned and everted during application of the BRIJJIT device. Forceps may be required in higher wound tension settings. If applying a BRIJJIT device to a healed, closed wound or scar, no manipulation of the wound/scar is required; however, if increased eversion or tension reduction is desired, the tissues can be manually pushed together prior to BRIJJIT device application.

d. Lower the device straight down onto the skin. The medial edge of the adhesive pads will make contact first. Maintain the squeeze on the applicator while pressing downward to adhere the central area of adhesive pads to the skin. Ensure that the adhesive portions of the device contact only intact skin.

e. After firm contact with the site of application, relax the downward pressure and stop squeezing the applicator. The backbone will spring back to its original shape. Disengage the applicator from the BRIJJIT device as follows:

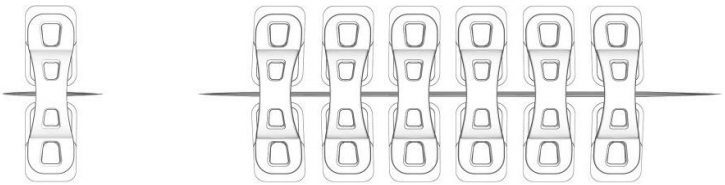
- Lightly squeeze both BRIJJIT device adhesive pads and lift the applicator away from the BRIJJIT device (as shown below).



f. With the applicator removed, apply downward pressure to the BRIJJIT device adhesive pads to firmly adhere the device to the patient's skin.

Spacing of BRIJJIT devices

Small wounds or healing scars can be treated by a single BRIJJIT device. The maximum length of a wound that should be closed by a single BRIJJIT device is 1.5 times the width of the BRIJJIT device. For longer wounds, BRIJJIT devices can be placed in series.



Typical spacing for most acute wounds would be a distance of 1/2 of the width of the BRIJJIT device between each BRIJJIT device. In wounds of higher tension or when the tissues are thicker and less pliable, the BRIJJIT devices can be placed closer to provide additional wound support and strength. In healing wounds/scars after the acute phase, especially in anatomical locations where tissue tension is lower, a slightly wider spacing can be used. However, the space between adjacent BRIJJIT devices should not be wider than the width of the BRIJJIT device size being used.

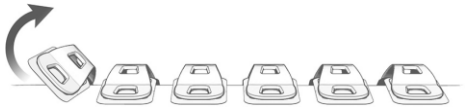
Aftercare of BRIJJIT devices

After BRIJJIT device placement for acute wound closure, wound care should follow principals of standard suture care, including the use of dressings or avoidance of moisture when indicated. When BRIJJIT devices are applied to a closed, stable wound for support or tension reduction, dressings are not required over the devices unless desired to hide the wound or to keep the devices from rubbing against body areas or from catching on clothing. If dressings or compressive garments are placed over wound closed with BRIJJIT device(s), tape or the adhesive of the dressing should not make contact with the BRIJJIT device itself, as the BRIJJIT device may inadvertently become dislodged during dressing removal.

BRIJJIT devices may be exposed to water, as with normal showering, bathing or exercise if deemed appropriate by the treating physician or health care provider. However, significant exposure of BRIJJIT devices to increased heat, moisture or sweating may cause premature loosening of the devices, leading to loss of therapeutic effect and necessitating earlier replacement.

The wearer should be instructed to contact the physician immediately if a significant skin irritation, blistering or a rash develops at the site of BRIJJIT device placement. Such a reaction may necessitate BRIJJIT device removal and use of an alternate wound closure or wound support treatment. (see Removing and replacing BRIJJIT devices)

Removing and replacing BRIJJIT devices



BRIJJIT devices can be allowed to loosen and fall off passively, or they can be removed manually. BRIJJIT devices placed for wound closure should not be removed until sufficient wound strength is achieved such that removal will not create a risk of wound separation. To remove BRIJJIT device(s), gently lift from one side, not from end to end. If desired, medical adhesive remover can be used to assist in removal.

To reapply BRIJJIT devices, the user should follow the instructions (above) for application to healing wounds or scars. BRIJJIT devices should not be reapplied if there is skin irritation, rash or blistering at the site of placement, or if they have developed an allergic reaction to BRIJJIT devices at any site.

STERILITY

BRIJJIT devices are sterilized. Do not resterilize. Do not use if package is opened or damaged. Discard opened packages and unused devices.

STORAGE

Store unopened at room temperature, away from moisture and direct heat. Do not use after expiry date.

DISPOSAL

Discard used BRIJJIT devices, trays and applicators after use.

SYMBOLS USED FOR LABELING

REF	Product Code		Do Not Resterilize
	Consult, see instructions for use	LOT	Lot Code
	Do Not Reuse		Manufacturer
	Use by		Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide	Rx Only	CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

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