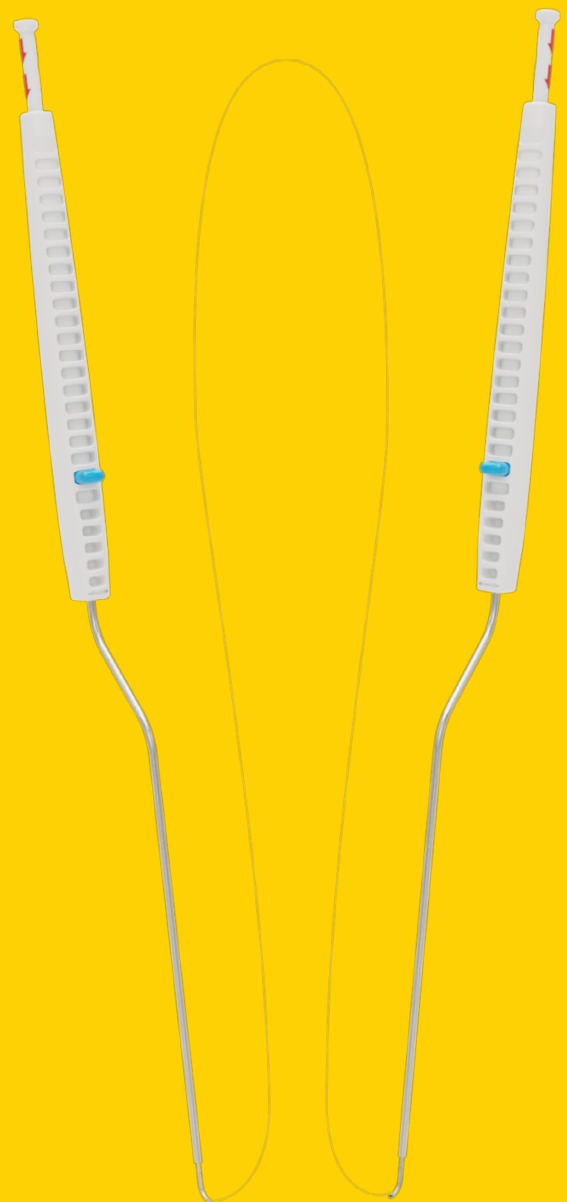


DuraStat®

RELOADABLE

# Dural Repair Device

Product  
Summary  
& Technique  
Guide



## FASTER<sup>1</sup>

DuraStat consolidates steps and automates suture passage with a button-press, helping save time and eliminating supination.

## HIGHER-QUALITY<sup>1</sup>

Sutured repairs are the best-known way to prevent persistent CSF leaks. DuraStat helps gain control of the tear with optimal suture placement and minimized tissue disruption.

### PRODUCT ATTRIBUTES

Innovative design streamlines an otherwise challenging, variable and time consuming procedure.

#### 1 Eliminates Supination

Simple, consistent needle passage with the press of a button.<sup>1</sup>

#### 2 Minimized Tissue Disruption

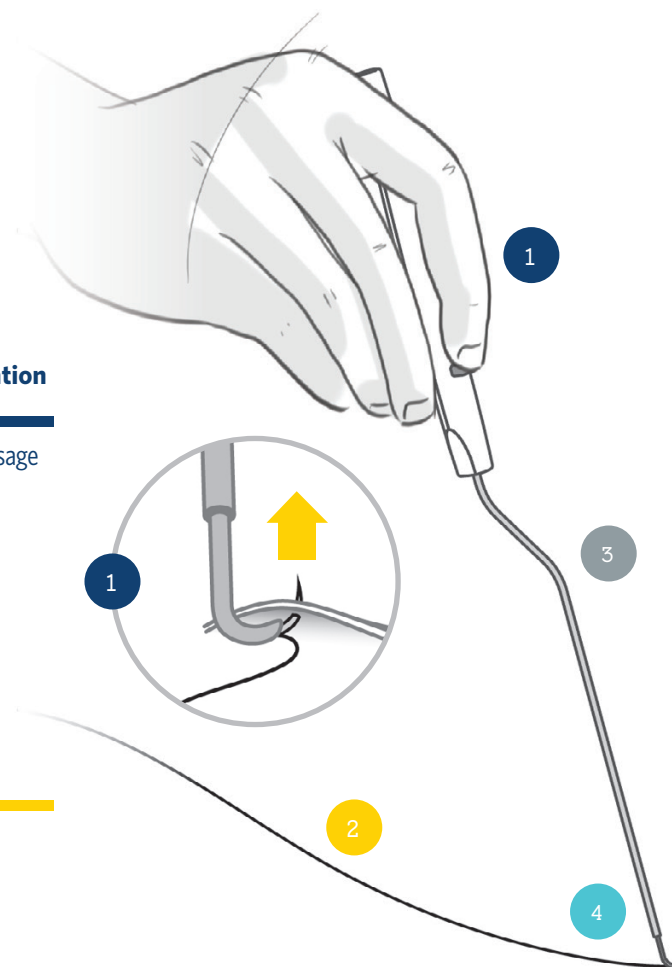
Minimize additional exposure needed to access tear. Needle diameter matches suture diameter to facilitate watertight closure.<sup>1</sup>

#### 3 All-in-One Functionality

Combines the functionality of a nerve hook and needle driver into one while maximizing visualization.<sup>1</sup>

#### 4 Recessed Needle

Blunt tip helps protect nerves and tissues during positioning.<sup>1</sup>



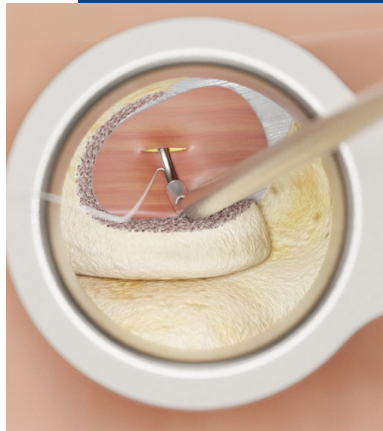
<sup>1</sup>Shenoy K, et al. (2021). Front. Surg. 8:642972. doi:10.3389/fsurg.2021.642972

Disclaimer: Bench top testing showed DuraStat reduced procedure time and improved repair quality compared to conventional techniques under laboratory conditions. Bench testing may not be representative of actual clinical performance. General claims are inherent to design.

# How to Use DuraStat

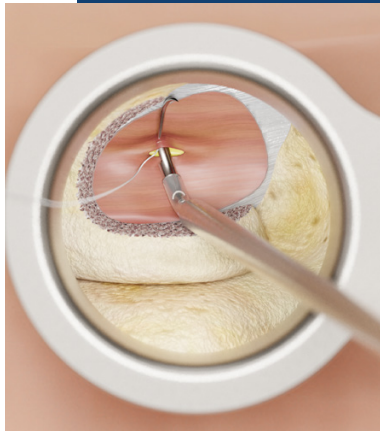
1

POSITION



2

TENT &amp; DEPLOY



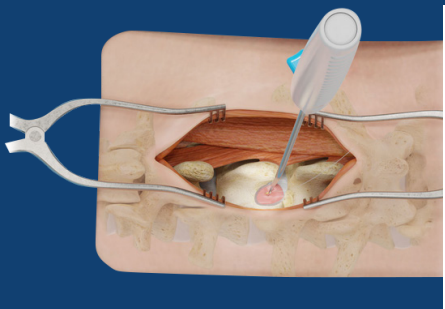
3

REPEAT &amp; KNOT

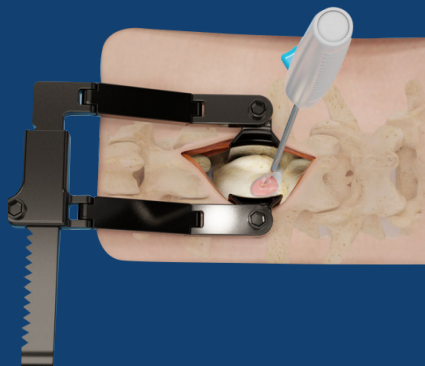


## Designed for Difficult to Reach Tears

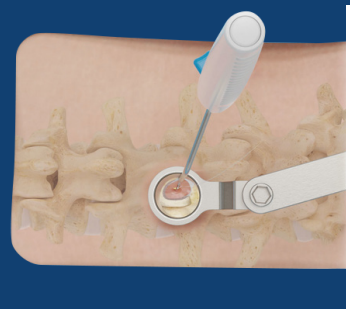
OPEN



MINI OPEN



MINIMALLY INVASIVE



DuraStat is applicable in any situation where access to repair a dural tear is limited and hand-suturing is difficult. DuraStat closures are also higher-quality<sup>1</sup> due to precisely aligned edges and minimized suture hole leakage; because of this, DuraStat is applicable for all tears.

## DuraStat

The repair kit contains everything required to create primary sutured closures, including a knot pusher.

PART NUMBER

### DURASTAT KIT CONTENTS

(2) DuraStat Devices  
(1) 24" 5-0 PTFE Double-Armed Suture  
(1) Knot Pusher

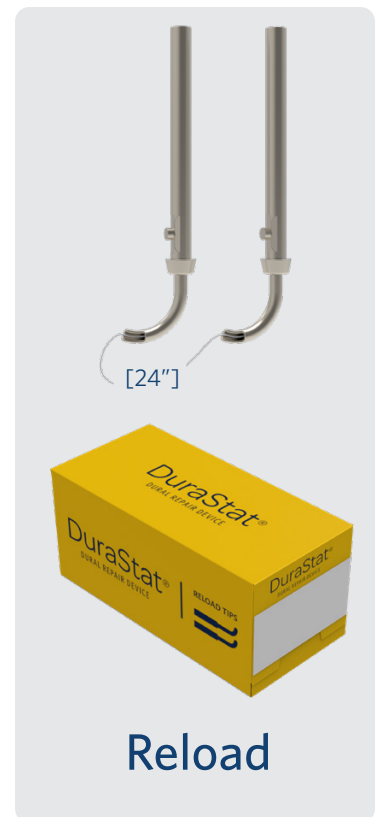
GZL-002

### RELOAD KIT CONTENTS

(2) DuraStat Reload Tips  
(1) 24" 5-0 PTFE Double Armed Suture

DUR-011

## Product Packaging & Kit Contents



# Handling DuraStat

## STERILE TRAY

The devices are delivered in a sterile tray for ease of use and to avoid suture tangling. Remove the first DuraStat device while keeping the tray and second device in close proximity.

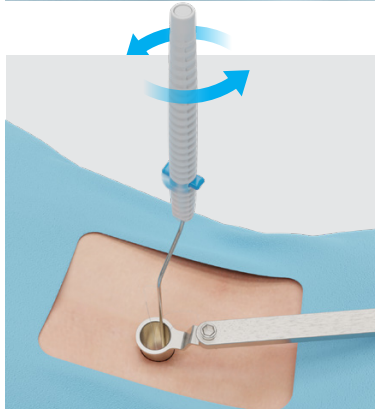


### TIP

The DuraStat devices are connected by a 24" suture. It is helpful if an assistant to the surgeon holds the tray while the first device is being used.

## ROTATION & GRIP

The handle may be rotated as it relates to the shaft to optimize the angle of approach while maintaining visualization.

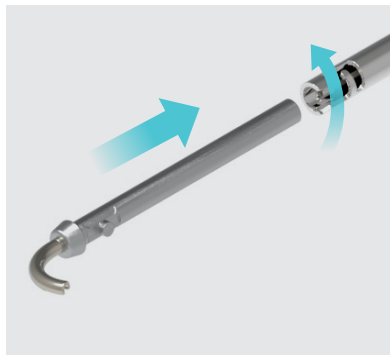


### TIP

Rotations should be made with the device outside of the exposure.

## MULTIPLE NEEDLE DEPLOYMENTS

The tip can be removed and replaced with additional sutures as needed to achieve the ideal closure.



### TIP

Make sure that the inner shaft is not visible when connecting.

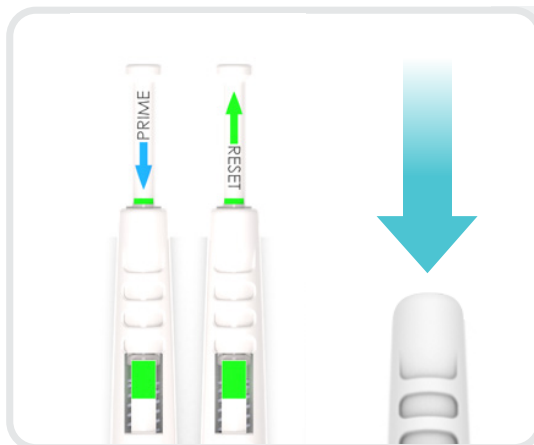
## SUTURE POSITIONING GUIDE<sup>1</sup>

| TEAR LENGTH | SUTURE QTY | APPROXIMATE POSITION(S)                                                                                                                        |
|-------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| 1-2mm       | 1          | Place in the center of the tear<br>                        |
| 2-5mm       | 2          | 1/3 spacing<br>                                            |
| 5-8mm+      | 3+         | Place the center suture first to help control the tear<br> |

<sup>1</sup> General guide for illustration purposes, developed in conjunction with surgeon advisors.

## 1 PRIME

Press down on the primer until it clicks into place. This will prime the blue button on the handle for needle deployment. Ensure devices primed prior to inserting into the exposure.

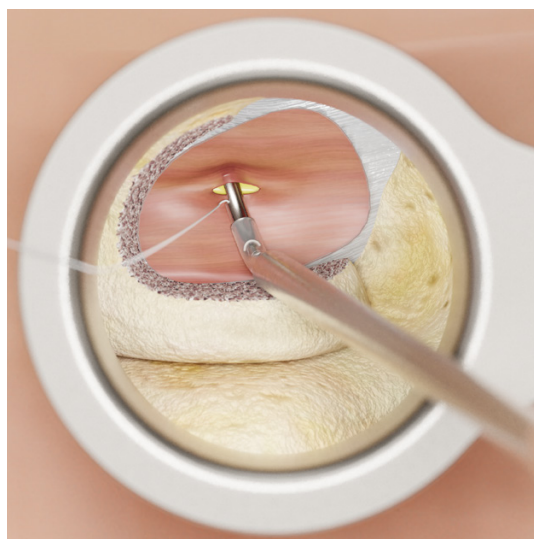


### TIP

Prime prior to inserting into the exposure. **The needle will not deploy unless the device is primed.**

## 2 POSITION

Use the smooth tip of the nerve-like hook to target the precise location for needle deployment utilizing the inside-to-out technique.

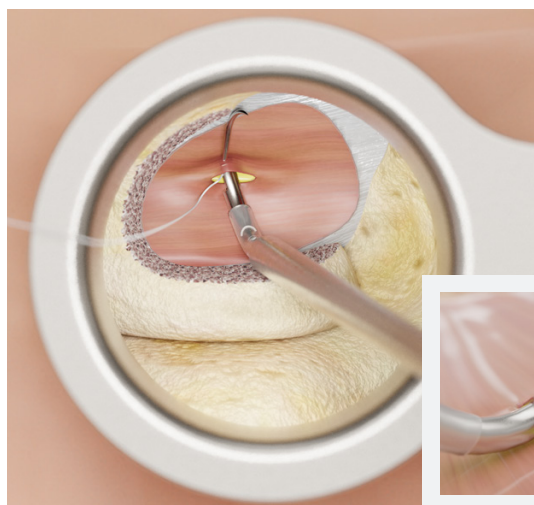


### TIP

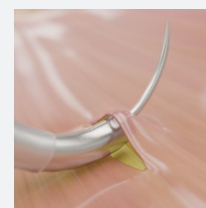
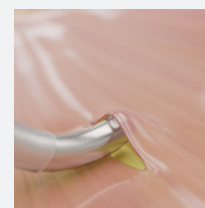
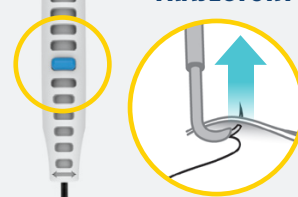
Avoid being too close to the edge of the tear. Leave approximately 1.5mm and engage the instrument tip firmly up into the tissue.

## 3 TENT TISSUE & DEPLOY

While in the desired needle passage position maintain sufficient tenting pressure on the tissue and press the blue button to deploy the needle. Carefully remove the device after the needle has been deployed. Using forceps or a pituitary, collect the needle from within the exposure.



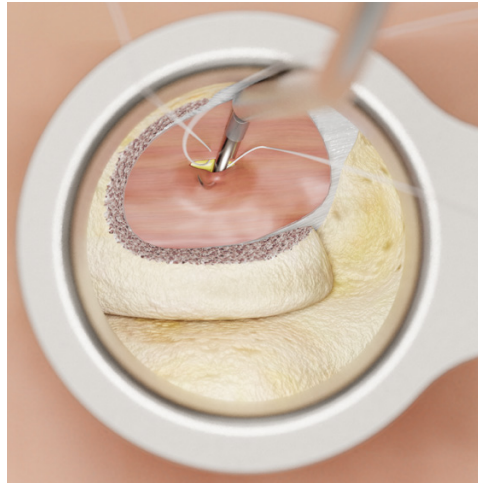
### TRAJECTORY



4

**RETRIEVE NEEDLE**

Using forceps or a pituitary, collect the first needle from within the exposure.



5

**REPEAT**

Use the second device and repeat steps 1-4 on the opposite side of the tear.

6

**KNOT**

The knot pusher included in the DuraStat Kit may be used to help place knots. Four knots are recommended.

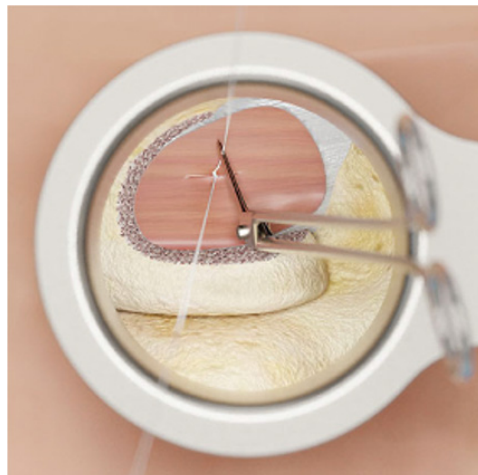
**TIP**

Apply adequate tension to each end of the suture while using the knot pusher to advance the knot.

7

**TRIM**

Use scissors to cut excess suture, allowing approximately ¼ inch to remain.

**CAUTION**

Count and properly dispose of needles.

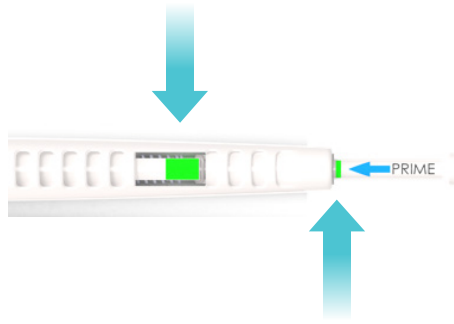


Sharps Disposal

8

**RESET**

Press both green buttons on the proximal end of the handle. Pull the primer away from the handle until the green line is visible.

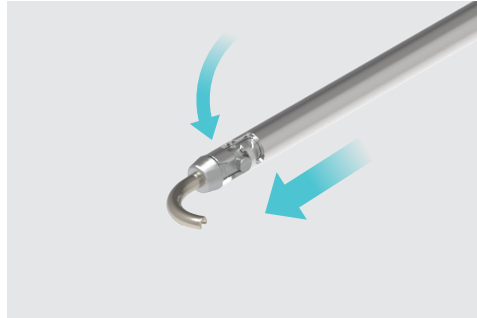
**NOTE**

Ensure the primer is fully reset with green ring exposed before reloading.

9

**REMOVE TIP**

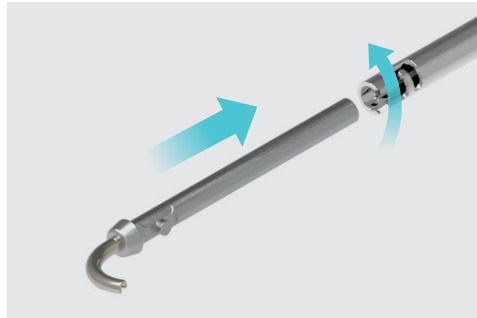
Remove the tip by rotating it 90° to the right of the handle. Detach the tip from the shaft.



10

**RELOAD**

Locate the reload tip and insert it into the shaft at a 90° angle to the right. Push the tip toward the handle until it reaches a stop, then rotate it 90° to the left until it aligns with the handle.

**TIP**

Ensure that the Nitinol wire is fully seated within the shaft to assure the device is properly reset.

11

**REPEAT**

Repeat Steps 1-10 as additional sutures are needed.

## Ordering Information

**PART NUMBER**

GZL 002 | DUR-011

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BY MEDTRONIC**

Please refer to package insert for instructions, warnings, precautions, and contraindications.

Durastat® is Indicated for use in general soft tissue approximation and/or ligation, Including cardiovascular, dental, general surgical procedures and repair of the dura mater. Durastat® PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. Durastat is provided sterile as a single-use device.

**OUR COMMITMENT TO ENVIRONMENTAL SUSTAINABILITY**

All packaging is recyclable | CA Prop 65 and ROHS testing showed device is free of SVHC, BPA and other chemicals of concern



Durastat® - Device for Dural Repair: Covered by one or more of the following U.S. Patents: D828,555; D828,921; 10,610,215; 10,736,623; 10,779,812; 10,835,236; 10,888,314; 10,918,379; 10,952,722; 11,090,042 or International equivalents. Other patents may be pending.

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1101 E 6th St, Unit B  
Austin, TX 78702  
www.durastat.com

DST-078 Rev. C