

**Description/Intended Use**

The catheter stabilizer system can be used to secure any compatible catheter system to a surgical drape or skin.

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**Package Contents**

Dispose of all single-use accessories according to local environmental requirements. The accessories are supplied sterile. Each package contains the following items:

- One catheter stabilizer
- One small stabilizer strip
- One large stabilizer strip
- Product documentation

**Instructions For Use**

Peel the release liner off from the back of the selected STABILIZER STRIP.

Place the STABILIZER STRIP on the desired location on the sterile drape or skin (Figure 1).

Slip the CATHETER STABILIZER over the tip of the catheter (Figure 2).

When the CATHETER STABILIZER is in the desired position on the catheter, tighten the wing piece to clamp the CATHETER STABILIZER in place (Figure 3).

When the catheter is clamped in the desired location, then place the CATHETER STABILIZER on the STABILIZER STRIP (Figure 4).

The CATHETER STABILIZER may be adjusted by repositioning on the STABILIZER STRIP or by loosening the cap and retightening it (Figure 4).

The CATHETER STABILIZER may be removed by loosening the wing piece and sliding the CATHETER STABILIZER off of the catheter.

The CATHETER STABILIZER may be secured with a suture at the suture groove on the CATHETER STABILIZER (Figure 5).

**Precautions**

- Read instructions for use before use.
- Inspect the sterile package with care before opening it.
- Single Use – Do not re-sterilize or reuse.
- Sterile in unopened, undamaged package.
- Do not use the CATHETER STABILIZER if the package is broken or soiled. The CATHETER STABILIZER should be used immediately after opening the package and be disposed of properly after use.
- AVOID EXPOSURE TO WATER, DIRECT SUNLIGHT, HIGH TEMPERATURES, OR HIGH HUMIDITY DURING STORAGE.
- Do not reuse the CATHETER STABILIZER on another catheter.
- Do not remove the wing piece from the CATHETER STABILIZER.
- Do not use for neurovascular procedures.
- Do not use the product after its expiration date.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

**Disclaimer of Warranty**

ALTHOUGH THE KUSMO™ CATHETER STABILIZER AND CATHETER STABILIZER STRIPS, HEREAFTER REFERRED TO AS 'PRODUCTS' HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, KUSMO HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THE PRODUCTS ARE USED. KUSMO THEREFORE DISCLAIMS ALL WARRANTIES BOTH EXPRESS AND IMPLIED WITH RESPECT TO THE PRODUCT. INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. KUSMO SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCTS, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND KUSMO TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCTS.

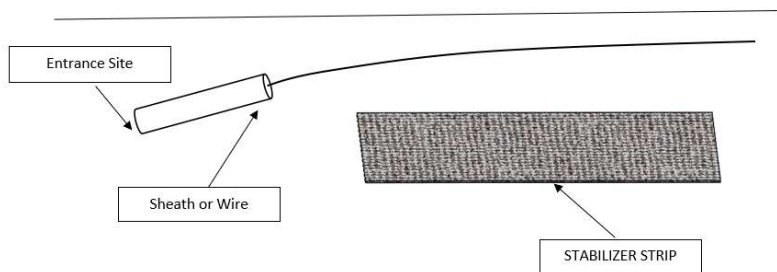
The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of the Disclaimer of warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this disclaimer of warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this disclaimer of warranty did not contain the particular part of term held to be invalid.

**General Warning**

The PRODUCTS in this package are designed for use with catheter products. Despite the exercise of all due care in design, component selection, manufacture, and testing prior to sale, products may be easily damaged by improper handling or use because of their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of catheter products will not occur.

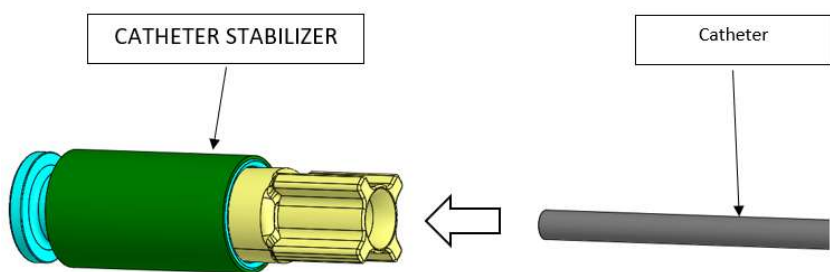
**Figures**

Figure 1:



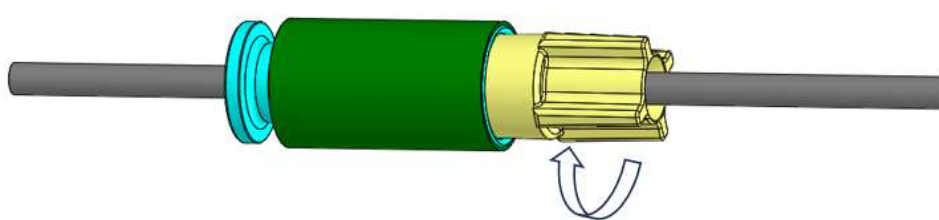
Place the STABILIZER STRIP at desired anchor point for catheter on skin or surgical drape. The large and small STABILIZER STRIPS can be placed adjacent to each other to create a larger landing zone for the CATHETER STABILIZER.

Figure 2:



Insert catheter into the CATHETER STABILIZER, in either direction, based on operator preference. Slide the CATHETER STABILIZER onto the desired location on the catheter.

Figure 3:

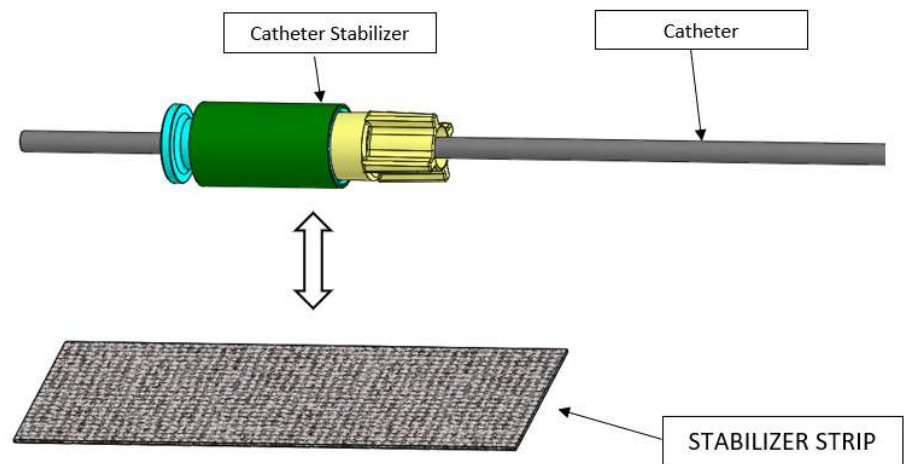


Once catheter stabilizer is at desired location, tighten the wing piece clockwise, which clamps the catheter stabilizer onto the catheter. If the catheter stabilizer needs to be moved along the catheter after initial positioning, the wing piece can be turned counter-clockwise to loosen the clamp and the catheter stabilizer can be moved to the new desired location.

CAUTION: Too much counter-clockwise rotation may disengage the wing piece from the rest of the catheter stabilizer.

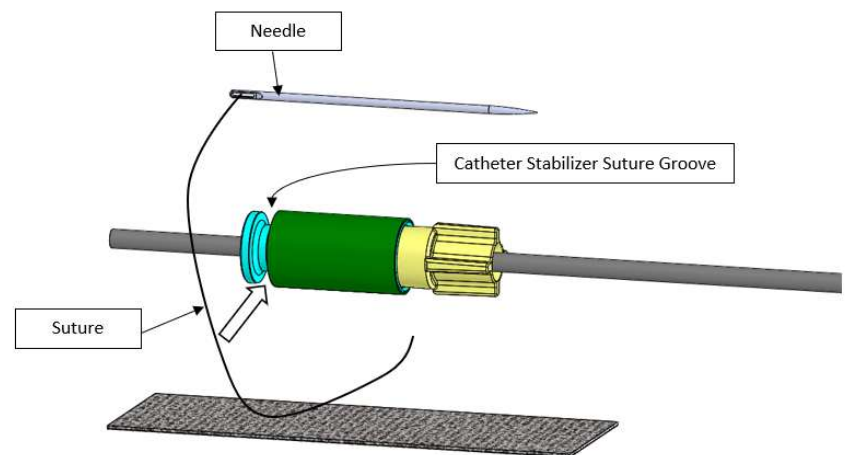
CAUTION: Once catheter stabilizer is clamped onto the catheter do not pull or push the catheter out of the catheter stabilizer as to damage the catheter stabilizer and/or catheter.

Figure 4:



The catheter stabilizer can then be attached to and detached from the STABILIZER STRIP as desired by the operator.

Figure 5:



As an additional option, a suture using normally available surgical needles can be tied around the suture groove and then tied down on tissue at the desired location in addition to the STABILIZER STRIP.


















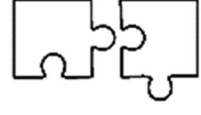




CAUTION: If using a needle, do not puncture adhesive pad or CaTHSTIX assembly as to break sterility.

CAUTION: Do not cinch the CATHETER STABILIZER onto skin too tight with suture as to cause erosion of the skin.

**Explanation of Symbols**

Table 1: Explanation of symbols on package labeling

Refer to the package labels to see which symbols apply to this product.

 For U.S. audiences only	 Date of manufacture
 Manufacturer	 Use By
 Lot number	 Model number
 Serial number	 Do not reuse
 Do not use if package is damaged	 +XX°C +XX°F Upper limit of temperature
 Open here	 Consult Instructions for Use at this website
 Package contents	 Product documentation
 Catheter stabilizer	 Small stabilizer strip
 Large stabilizer strip	 Use with
 Catheter	 Radiation Sterilized
 Unique Device Identifier	 Prescription Only