

THE MENTOR® CPX™4 AND CPX™4 WITH SUTURE TABS BREAST TISSUE EXPANDERS

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

102980-001 Rev. C Effective January 2013
LAB100087137v3

DESCRIPTION

The MENTOR® CPX™4 and CPX™4 with Suture Tabs Breast Tissue Expanders are used for breast reconstruction following mastectomy and are intended for **temporary** subcutaneous or submuscular implantation and are not intended for use beyond six months. In order to provide these tissue expanders with elasticity and integrity, the shells are made with successive cross-linked layers of silicone elastomer. Superior and anterior reinforcement allows for directional expansion in the lower pole of the devices. The devices have integral, silicone elastomer, magnetically detected, injection domes and incorporate a BUFFERZONE® area with self-sealing technology (containing silicone gel) to the front patch of the device to minimize and/or prevent leakage in the event of an accidental needle puncture. The textured shell provides a disruptive surface for collagen interface.

Identification of the injection dome site can be accomplished by use of the CENTERSCOPE® Magnetic Injection Port Locator provided with the Tissue Expander. To use the CENTERSCOPE® Magnetic Injection Port Locator, follow the instructions provided with the specific dome detection device. Injections must be made using sterile, pyrogen-free Sodium Chloride U.S.P. Solution and into the injection dome area. If injections are made on or outside the injection dome, leakage can occur.

The MENTOR® CPX™4 with Suture Tabs Tissue Expander gives surgeons the option to attach the device to surrounding tissue to enhance device stability. Surgeons can suture on any part of the tab surface or the suturing hole can be used for added convenience.

INDICATIONS

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the indications associated with the use of these products.

These tissue expanders can be used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The devices are intended for temporary subcutaneous or submuscular implantation and are not intended for use beyond six months.

CONTRAINDICATIONS

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of these products.

Patient groups in which the product is contraindicated:

The use of these tissue expanders are contraindicated in patients who have any of the following conditions:

- Implanted devices such as pacemakers, drug infusion devices, artificial sensing devices, etc. that would be affected by a magnetic field.
- Active infection anywhere in the body.
- Existing malignant or premalignant breast cancer without adequate treatment.

Surgical practices in which product use is contraindicated due to compromise of product integrity:

- Do not alter the tissue expanders' shell or dome.
- Do not place drugs or substances inside the tissue expanders other than sterile saline for injection.
- Do not allow the devices to come into contact with Betadine®.

NOTE: The satisfactory use of either tissue expander for tissue replacement following mastectomy or trauma may require special reconstructive procedures.

WARNINGS

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible warnings associated with the use of these products.

1. *Magnetic Fields*

- DO NOT use these tissue expanders in patients that have a previously implanted device that could be affected by a magnetic field. MRI is not to be used on a patient implanted with these devices because movement could occur causing patient pain or expander displacement that could require revision surgery.

2. *Radiation Therapy*

- Mentor has not tested the *in vivo* effects of radiation therapy with these devices and cannot warrant the safety of such use. The decision regarding the use of these devices in patients about to undergo radiation therapy should be made by the surgeon and the radiation oncologist.

3. *Extrusion of the Device*

- The incidence of extrusion of either tissue expander has been shown to increase when placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has previously been performed.

4. These devices are for temporary use only.

- These tissue expanders are not intended for use beyond six months.

5. *Reuse*

- Tissue expanders are for single use only. Do not resterilize.

6. *Avoid Damage During Surgery*

- Care should be taken to prevent damaging the devices with surgical instruments.
- Do not insert or repair a damaged tissue expander.
- Use care in subsequent procedures such as tissue expansion, open capsulotomy, breast pocket revision, hematoma or seroma aspiration, and biopsy/lumpectomy to avoid damage to the tissue expanders' shells, domes, or bladders.
- Do not contact the tissue expanders with disposable, capacitor-type cautery devices.

7. *Proper Filling*

- Surgeons should verify the position of the injection dome prior to adding or withdrawing fluid. Needle punctures on or outside of the injection dome may penetrate the shell causing deflation or compromise the fill dome and necessitate device replacement. Although the tissue expanders have a self-sealing BUFFERZONE[®] area around the injection dome, DO NOT ATTEMPT TO INJECT INTO THE AREA AROUND THE DOME, as device damage may still occur.
- Mentor relies on the surgeon to select the optimum incision and pocket size for the chosen tissue expander configuration, style and projected volume.

8. *Suturing Safety*

- Take care when suturing the device into place. Avoid puncturing the tissue expander's shell during implantation and placement. If the tissue expander's shell should become compromised, remove the tissue expander and replace with a new one.
- The injection dome should not be penetrated with a needle larger than 21 gauge standard, as it may not reseal. Injections should be made only into the top of the injection dome, perpendicular to $\pm 30^\circ$ to the base and within the injection dome ring.

- Excessive inflation of the device may result in tissue necrosis/thrombosis.
 - Failure of the device to inflate may be due to leakage or injections which do not penetrate the injection dome.
 - Leakage from the injection dome can result from the use of an improper size of injection needle, injections outside of the injection dome ring or excessive pressure on the overlying tissue at the tissue expander site, resulting in backpressure directed to the injection site.
9. *Patient Instructions*
- The patient should be advised that vigorous body movement (e.g. physical exercise) or excessive manipulation or trauma in the region of the expander may cause stress to the device and result in subsequent deflation.

PRECAUTIONS

- It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of these products.
- Preexisting infection should be treated and resolved before implantation of either tissue expander.
- Any surgeon performing reconstructive mammoplasty with tissue expanders should be familiar with the currently available techniques for measuring the patient, determining the tissue expander size and performing the surgery.
- Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on a tissue expander by improper handling may cause foreign body reactions. Strict adherence to clean, aseptic techniques should be maintained to prevent tissue expander contamination and possible complications. Surgical instruments and gloves should be rinsed clean of any impurities before handling a tissue expander.
- The silicone elastomer shell may easily be cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. Subsequent deflation and/or rupture will result. All prostheses should be carefully inspected for structural integrity prior to and during implantation.
- Any subsequent surgical procedures in the tissue expander area should be undertaken with extreme caution as damage could occur. In the event that a tissue expander is damaged, it must be removed.
- Each device should be checked for patency prior to surgery and continuously monitored throughout the surgical procedure to ensure the structural integrity of the device is not compromised in any way. A standby tissue expander should be available at the time of surgery.
- Potential for contamination exists when fluid is added or removed from the device. Use the aseptic technique in the introduction of saline into a tissue expander, a single-use, sterile saline container is recommended.

ADVERSE REACTIONS

Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications associated with the use of a tissue expander should be discussed with and understood by the patient prior to surgery. It is the responsibility of the surgeon, and Mentor relies on the surgeon, to provide the patient with this information and to weigh the risk/benefit potential for each patient.

Complications which may result from the use of a tissue expander include the risks associated with the medication and methods used in the surgical procedures as well as the patient's degree of intolerance to any foreign object placed in the body. The complications may include, but are not limited to, the following:

Additional Surgeries

- Additional surgery will be required to either replace a deflated tissue expander and/or to complete the breast reconstruction procedure.

Cancer

- Published studies indicate that breast cancer is no more common in women with implants than those without implants.

Capsule Formation and Contracture

- Postoperative formation of a fibrous tissue capsule around an implanted device is a normal physiologic response to the implantation of a foreign object. Capsule formation occurs in all patients in varying degrees. Capsules range from thin to thick.
- Contracture of the fibrous capsule may occur, independent of its thickness. Discomfort, pain, excessive tissue firmness and misshapen expanded tissue, deflation, increased palpability and wrinkling and/or displacement of the tissue expander may occur and may require surgical intervention. In some patients, tissue firmness may recur subsequent to corrective surgical procedures.

Complications of Tissue Expansion

- Tissue thinning or necrosis.
- Sloughing of poorly vascularized tissue.
- Gross postoperative hematoma, manifested by enlargement, tenderness and discoloration leading, if untreated, to device extrusion.
- Undue pressure on the tissue located over the device or trauma to surrounding tissues which may lead to venous thrombosis, the breakdown of skin over the device and subsequent extrusion. Deflation or removal of the device may be necessary for tissue repair.

Connective Tissue Disease

- Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants.

Deflation/Rupture/Leakage

- Saline-filled tissue expanders deflate when saline solution leaks through an unsealed or damaged dome or through a break in the tissue expander shell. Deflation can occur immediately or progressively over a period of days and is noticed by loss of size or shape of the device. Additional surgery is needed to remove deflated devices.

Dissatisfaction With Cosmetic Results

- Incorrect tissue expander size, inappropriate scar location or appearance and misplacement or migration of expanders may interfere with a satisfactory cosmetic result. These complications are generally associated with the surgical procedure and technique.

Extrusion of Tissue Expander/Interruption of Wound Healing

- Skin necrosis and/or sloughing may result from undue tension on the skin overlying the tissue expander, trauma to the skin during surgical procedures or inadequate tissue thickness inhibiting circulation. Subsequent exposure and/or extrusion of the tissue expander may occur.
- Displacement, twisting, fracture or extrusion may occur from improper tissue expander sizing and/or placement, e.g. when the tissue expander is too large or the pocket is too small or when there has been inadequate preoperative assessment of stresses causing movement of the tissue expander.

- The incidence of extrusion of the tissue expander has been shown to increase when the tissue expander has been placed in injured areas: scarred, heavily irradiated or burned tissue or crushed bone areas; where severe surgical reduction of the area has been performed; and where steroids are used in the surgical pocket.

Fluid Accumulation

- Excessive post-operative fluid accumulation and transient reaccumulation of fluid around the tissue expander as a result of trauma and after vigorous exercise have been reported.

Hematoma

- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be used until bleeding is controlled.
- Gross postoperative hematoma, manifested by enlargement, tenderness and discoloration of tissue may, if untreated, lead to device extrusion.

Infection

- Infection, manifested by swelling, tenderness, pain and fever, may appear in the immediate postoperative period or at any time after insertion of the device. In the absence of classic symptoms, subacute or chronic infections may be difficult to diagnose. If infection does not subside promptly with the appropriate treatment, removal of the tissue expander is indicated.
- Toxic Shock Syndrome has been reported as a complication of both augmentation and reconstructive mammoplasty.

Pain

- Pain may be felt of varying severity (degrees) and duration (length of time) during the tissue expansion process.

Wrinkling of the Tissue Expander

- Surgeons have reported that in some patients, visible or palpable wrinkling of the envelope, usually associated with textured prostheses, has occurred. Folds in the envelope can be visible beneath the overlying skin. This is reported to occur more frequently with: thin-skinned patients with little or no subcutaneous fat; subglandular rather than submuscular placement; a tissue expander that is too large relative to the pocket size or frame of the patient; overlying tissue that is minimal or of poor quality; or where there is contracture and/or insufficient fill volume.

RECORDING PROCEDURE FOR TISSUE EXPANDERS

Each device is supplied with a patient record label showing the catalog number and lot number for that unit. One of these pressure sensitive labels should be attached directly to the patient's chart. The date of placement, expansion data (date and volume), and date of explant should be indicated on the label.

Sterilization

Tissue expanders are provided sterile. The products are dry heat sterilized and are for single use only. Do not resterilize.

Implant Selection

Some of the important surgical and implant sizing variables that have been identified include the following:

- The tissue expander should not be too small or too large in comparison to the patient's chest wall dimensions.
- Available tissue must provide adequate coverage of the device.

- Submuscular placement of the expander may be preferable in patients with thin or poor quality tissue.
- A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- Avoid too small of an incision.

TESTING PROCEDURES FOR TISSUE EXPANDERS

The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by the following steps:

1. Using a 21 gauge standard needle, partially inflate the device with air through the injection dome.
2. Submerge the air-filled prosthesis in sterile, pyrogen-free testing fluid (water or saline).
3. Apply mild pressure and check for possible punctures or leaks.

MAINTAINING HEMOSTASIS/AVOIDING FLUID ACCUMULATION

Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, the implantation of the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid expander contamination, or damage from sharp instruments.

MENTOR INJECTION PORT LOCATOR

Instructions For Use

Using sterile technique, remove the CENTERSCOPE® Magnetic Injection Port Locator from the sterile pouch. Grip locator with either hand, ensuring that the free-swinging magnetic arm is pointing away from the hand holding it. Place the base of the unit (the flat side) on the patient. Move the unit in a circular motion until the magnetic arm detects (points towards) the location of the injection dome. Follow the direction that the arm points towards until the arm is pointing straight towards the hole in the base of locator (the target). When the arm is centered perfectly in the target, the injection site has been located.

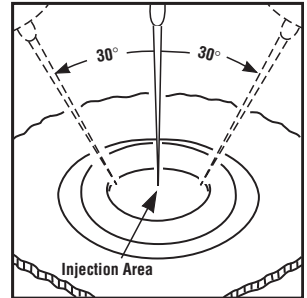
To mark the injection, follow one of these options:

- Option 1:** With the magnetic arm centered in the target, make a mark with a surgical sterile marker in each of the three notches around the anterior perimeter of the base. Next, make a fourth mark in the hole located behind the magnetic arm that runs through the center base of the locator. After all four marks have been made, lift the device from the patient. Using the same marker, carefully connect the opposing dots with a line creating an injection 'crosshair'. Then, make a clear mark at the point where the two perpendicular lines intersect. This point is the injection site.
- Option 2:** With the magnetic arm centered in the target, gently but firmly press the device against the patient. Hold for several seconds. Lift the device from the patient. The raised 'X' on the bottom of the locator will leave a clearly imprinted 'crosshair' mark on the patient's skin. Mark the center of the crosshair with a surgical sterile marker. This point is the injection site.
- Option 3:** Utilize a combination of options 1 and 2 for further confirmation of the best point for injection.

TISSUE EXPANDER FILLING PROCEDURE

To inflate either tissue expander:

1. Identify the injection dome site using the CENTERSCOPE® Magnetic Injection Port Locator included with the tissue expander.
2. Once the center of the dome has been identified, a skin marker can be used to identify the area of injection.
3. Inflation is accomplished by premarking the skin, inserting a 21 gauge standard needle into the top of the injection site, perpendicular $\pm 30^\circ$ to the base and filling the device using sterile, pyrogen-free Sodium Chloride U.S.P. Solution for injection.
4. Injections must be made into the injection dome. If injections are made on or outside the injection dome leakage can occur. Although the device has a self-sealing BUFFERZONE® around the area of the injection dome, DO NOT ATTEMPT TO INJECT OUTSIDE THE DOME AS LEAKAGE MAY OCCUR.



SUTURE (applicable only to the MENTOR® CPX™4 with Suture Tabs Breast Tissue Expander)

Mentor does not recommend any specific type of suturing material for device placement. This is left to the surgeon to decide what is appropriate with his/her technique and for the patient.

POSTOPERATIVE CARE

Mentor recommends that the patient be wrapped superiorly with an elastic bandage, taped laterally, and wear a surgical bra 24 hours a day to help prevent shifting of the device.

DEVICE RETRIEVAL EFFORTS

Mentor requests that any explanted devices be sent to Mentor, Product Evaluation Department, 3041 Skyway Circle North, Irving, TX 75038 USA for examination and analysis.

PRODUCT EVALUATION

Mentor requires that any complications or explantation resulting from the use of this device be brought to the immediate attention of the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, TX 75038 USA.

RETURNED GOODS AUTHORIZATION

- US Customers

Merchandise returned must have all manufacturer's seals intact and be returned within 60 days from the date of invoice to be eligible for credit or replacement. Please contact the Mentor Customer Service Department for details. Returned products may be subject to restocking charges.

- International Customers

Authorization for return of merchandise should be obtained from your local Mentor representative. Other conditions noted above also apply.

PRODUCT INFORMATION DISCLAIMER

Mentor expressly disclaims all warranties, whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties or merchantability, fitness or design, to the extent allowed by applicable law. Mentor shall not be liable for any direct, incidental or consequential loss, damages or

expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to the statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by Mentor for any purpose. Mentor neither assumes nor authorizes any other or additional liability or responsibility in connection with this device.

PRODUCT ORDER INFORMATION

To order directly in the USA, please contact the:

Mentor Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111;

Toll free telephone (800) 235-5731, FAX (805) 967-7108.

Orders can also be placed online at www.MentorDirect.com.

International Customers

For product information or to order directly, please contact your local Mentor representative.



























REFERENCES

Literature references are available upon request from:

Mentor Marketing Services, Literature Department

201 Mentor Drive

Santa Barbara, CA 93111 USA

 Nominal Dimensions	 The enclosed device is sterile and nonpyrogenic (unless the package has been opened or damaged).	 For customer service or to return product, please call (800) 235-5731 in USA; or outside of USA, call (805) 879-6000, or contact your local representative.
 Quantity	 Not returnable if opened	 Sterilized using Ethylene Oxide
 Style: nnnn	 MR Unsafe	 Sterilized using irradiation
 Breast; Right (or) Left	 Do Not Reuse	 Sterilized using steam or dry heat
 Do not resterilize	 Attention, see instructions for use	 Date of Manufacture
 Latex free	 Consult instructions for use	 CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
 Fluid added	 Catalogue number	 Mark and Identification Number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC.
 Date	 Batch code	
 Serial number	 Use by	 Warning: Use only a 21 gauge or smaller needle when adding or withdrawing fluid through the reservoir.



MENTOR®

For customer service, please call (800) 235-5731 in USA; or outside of USA, call (805) 879-6000, or contact your local representative.

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 USA

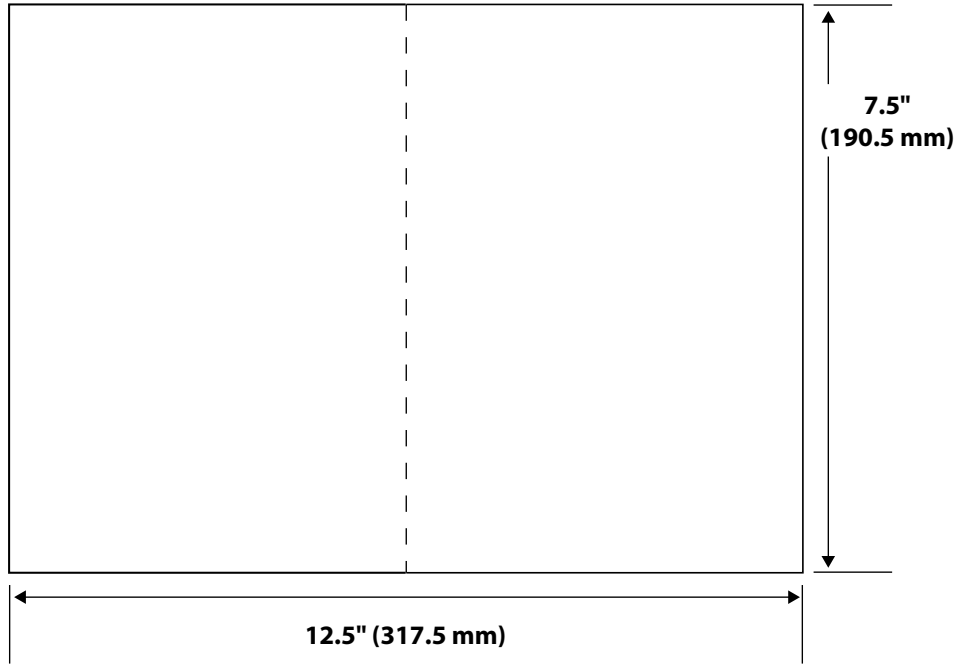
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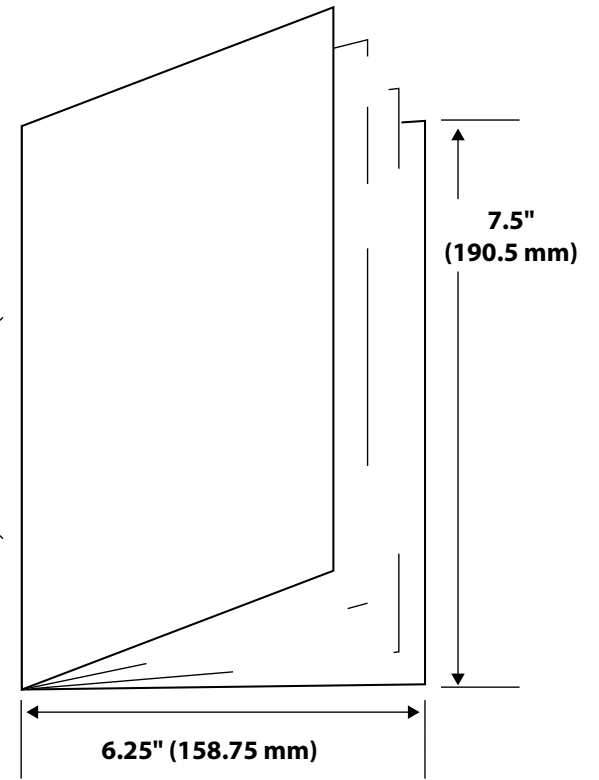
IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



Flat Size

FOLD PATTERN



Folded Size

Binding Method:
Saddle Stitch

TITLE MENTOR® CPX™ 4 TISSUE EXPANDER		DESCRIPTION PIDS (English)		LAB NUMBER LAB100087137v3		SPECIAL INSTRUCTIONS/COMMENTS n/a		BINDING Saddle Stitch		COLORS Black		
FLAT SIZE 12.5" x 7.5" 317.5 mm x 190.5 mm		FOLDED SIZE 6.25" x 7.5" 158.75 mm x 190.5 mm		RMC NUMBER 102980-001 Rev C	PAGE COUNT 8	LANGUAGES EN			SELF COVER <input checked="" type="checkbox"/>	PLUS COVER <input type="checkbox"/>	SEALING METHOD n/a	WAFER SEAL <input type="checkbox"/>
BLEED SIZE <input type="checkbox"/> .5" (12.7 mm) <input checked="" type="checkbox"/> .125" (3.175 mm)		NONE <input type="checkbox"/>	BLEED ALL SIDES <input type="checkbox"/>	BLEED TOP <input checked="" type="checkbox"/>	BLEED RIGHT <input type="checkbox"/>	BLEED LEFT <input type="checkbox"/>	BLEED BOTTOM <input type="checkbox"/>	DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK. This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.				

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