

Eastman Tritan™ copolyester

# Medical secondary operations guide

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Complex medical devices can be manufactured from Eastman Tritan™ copolyester by various common commercial methods: injection molding, blow molding, or simple fabrication. Molded parts often require secondary operations to complete the assembly or fabrication process. Although the basic part may be successfully molded or formed, oftentimes the secondary operations prove to be more challenging to accomplish.

For example, multiple subparts may have to be assembled using screws, rivets, snap fits, or other mechanical means to form a more complex device. Assembly and joining can also be accomplished by using adhesives, solvent bonding, ultrasonic/spin/vibration welding, radio frequency (RF) sealing, laser welding, heat/impulse sealing, and other methods.

Assembled parts may then require further alterations, such as decoration and printing, to obtain a finished product. This brochure provides general recommendations to ensure successful assembly of medical devices manufactured with Eastman Tritan™ copolyester.

### Methods for joining/bonding

#### Chemical

- Solvent bonding
- Adhesive bonding
- UV curable adhesive
- Cyanoacrylate adhesive

#### Thermal

- Ultrasonic welding
- Heat/ultrasonic staking
- Spin welding
- Vibration welding
- RF sealing
- Heated bar/impulse sealing
- Laser welding
- Hot-plate welding

#### Mechanical

- Screws
- Threaded inserts
- Snap fit methods

## Chemical bonding methods

### Solvent bonding

Eastman Tritan™ copolyester can be solvent bonded to PVC tubing and films. Solvent bonding utilizes the solubility of the mating plastic surfaces to accomplish a bond. The solvent softens the materials, allowing the surfaces to fuse as the solvent evaporates out of the joint.

Unfortunately, solvents can cause crazing and/or hazing if inappropriate solvents are used or excessive amounts of solvents are applied. The polyester will absorb the solvents and cause a plasticization effect that lowers the glass transition temperature ( $T_g$ ) of the polyester. Once the  $T_g$  is lowered below ambient temperature, crystallization may occur, causing the polyester to haze/whiten and become brittle. This is commonly referred to as solvent-induced crystallization.

Excessive amounts of solvent may become trapped between the mating parts and may prevent the solvent from evaporating quickly from the bond joint. Therefore, always remove excess solvent prior to joining Eastman Tritan™ copolyester to PVC parts.

The following solvents and blends are suggested when solvent bonding Eastman Tritan™ copolyester to PVC tubing:

- Methyl ethyl ketone (MEK)
- Cyclohexanone
- Tetrahydrofuran
- 50/50 cyclohexanone/methylene chloride
- 50/50 to 80/20 MEK/cyclohexanone

An Eastman technical service representative can provide you information regarding solvent bonding methods and techniques. We also highly recommend consulting with Eastman when considering and designing any medical devices requiring solvent bonding.

### Adhesive bonding

Eastman Tritan™ copolyester has been successfully adhesive bonded to itself and other materials, such as other plastics, metals, glass, etc. Several FDA-approved medical grade adhesives are available commercially and find use in applications where mechanical, solvent bonding, or thermal methods of joining parts are not practical or advised.

Some adhesive systems are single-part systems that react with moisture in the atmosphere or require heat to cure. Two-part adhesives require mixing of two or more reactive chemical components to form the final adhesive mixture. These may be acrylic, epoxy, or polyurethane-based clear adhesives.

### Single-part adhesive bonding

#### *Ultraviolet (UV)-light curable adhesives*

UV-light cured adhesives have been used for many years in the medical device industry. These types of single-part adhesive systems use photoinitiator additives that rely on high-intensity UV or visible light to initiate curing in a matter of seconds.

These types of adhesives are well suited for use within a clean room environment. No solvents are involved; however, the uncured adhesive may exhibit some aggressiveness toward the plastic if left on too long in the uncured state.

Several commercial suppliers offer medically approved UV-light curable adhesives. They can also supply application equipment for dispensing and can provide technical assistance regarding the UV-curing lamps and related safety equipment.

**CAUTION:** The UV lights used to cure the adhesives are very dangerous. Eye damage, blindness, and skin burning can quickly result from exposure to the intense and dangerous UV rays. Proper shielding, employee protective clothing, and UV light filtering eyewear are mandatory for safe use.

Contact your Eastman technical service representative for suggested UV-light curable adhesives for use with Eastman Tritan™ copolyester.

## Cyanoacrylate instant-bond adhesives

Cyanoacrylate adhesives were developed by Eastman many years ago. Several non-Eastman commercial suppliers now market these adhesives. They are unique in that they can develop a bond in seconds on contact. They are single-part adhesives that react with moisture in the atmosphere or substrates to form an instant bond by polymerization.

Several commercial suppliers offer medically approved cyanoacrylate adhesives. No solvents are used in these adhesives; however, the uncured adhesive may chemically attack the plastic surface in its uncured state.

These adhesives may also bloom. This occurs when a thin white layer of material forms around the areas where the adhesive is applied. Low bloom adhesives are available.

Contact your Eastman technical service representative for information regarding the use of cyanoacrylate adhesives for bonding Eastman Tritan™ copolyester.

## Design criteria

The medical device designer must determine whether the adhesive meets the fitness-for-use criteria for the specific application.

Selection of the proper adhesive must involve careful consideration of the following points:

- Structural requirements of the bonded joint
- Effects of chemical exposure in the end-use environment
- Effects of thermal exposure
- Effects of sterilization treatments (EtO, gamma, or E-beam)
- Compatibility of adhesive contact with medical substances (blood, lipid solutions, etc.)
- FDA medical compliance requirements

## General precautions

Appropriate safety precautions should be observed when handling and storing solvents and adhesives. Utilize proper ventilation methods and employee protective gear to prevent contact with solvents or adhesives during the handling/assembly process.

Provide protection from inhalation, ingestion, and eye and skin contact with solvent/adhesive vapors, fumes, liquids, particles, and dusts. Some solvents and adhesives can be carcinogenic, highly toxic, and/or corrosive in their uncured forms. They may readily dissolve and transport other toxic substances into the body. Some adhesives can instantly bond skin to skin or other materials.

Solvents and some adhesives can be extremely flammable and/or reactive when mixed with other reactants or substances. They can cause an explosion or violent reaction when in contact with other substances such as catalysts, oxidizers, peroxides, etc. Some reactive adhesives generate excessive heat when mixed with other substances.

You must make your own determination as to the suitability and safety of any solvent or adhesive selected for use in your application and product. You must also determine whether this method satisfies your fitness-for-use criteria and is suitable for your production environment.

Observe appropriate industrial hygiene methods and governmental laws to protect the health and safety of your employees, the purchasers of your product, and the environment.

# Thermal bonding methods

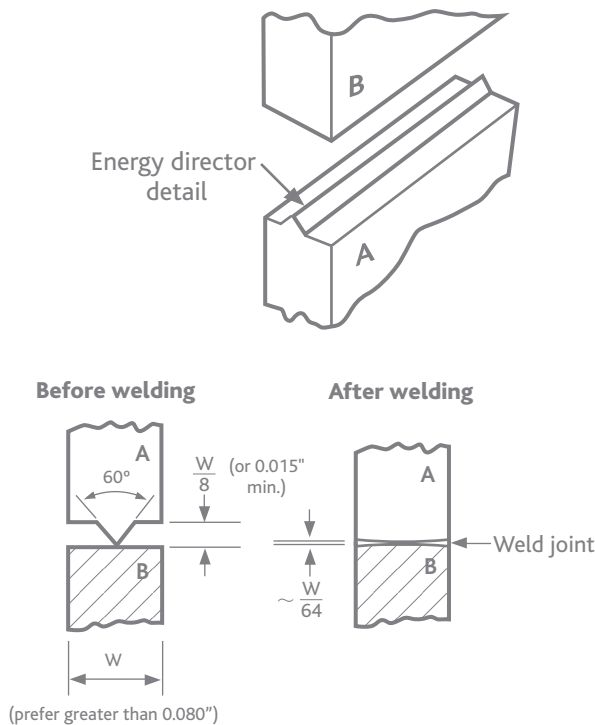
## Ultrasonic welding

Eastman Tritan™ copolyester can be ultrasonically welded using energy director type bond joint designs. We highly recommend that Eastman be involved in the early phases of the medical part design to assure that proper joint design considerations have been implemented. Joint design guidelines can be provided that will help in achieving desired finished part performance.

The following are several critical factors to consider when designing a medical part that will utilize an ultrasonic bond joint:

- Joint strength requirements (external forces applied onto the joint)
- Joint/part impact-resistance requirements
- Effects of chemicals on stressed joint areas
- Proper part design for welding
- Adverse effects of ultrasonic welding on internal part features (i.e., delicate filter media, small appendage parts, etc.)
- Weld joint flash issues
- Weld joint appearance issues

**Figure 1** Design of a typical energy director and mating surfaces



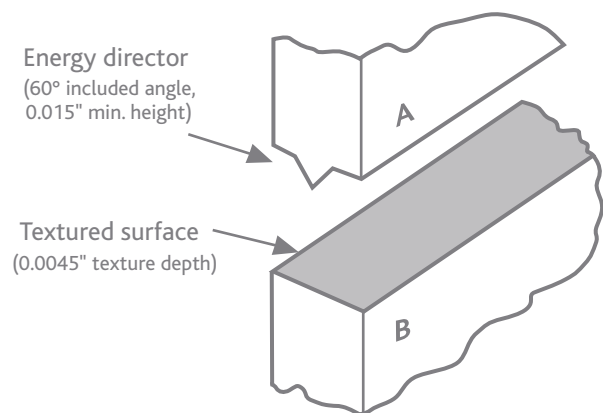
Contact your Eastman technical service representative for information regarding the use of ultrasonic welding for bonding Eastman Tritan™ copolyester.

## Energy director joint design

A standard energy director consists of a simple knife-edge-type feature that is molded into one of the mating surfaces of the weld joint. The included angle of the energy director should be 60°. The height of the energy director should be calculated based on the nominal wall thickness of the part (minimum height of 0.015").

The mating surface to which the energy director welds should have a textured surface for optimum welding strength. A smooth surface can be used, but it requires greater energy and does not yield as strong a bond.

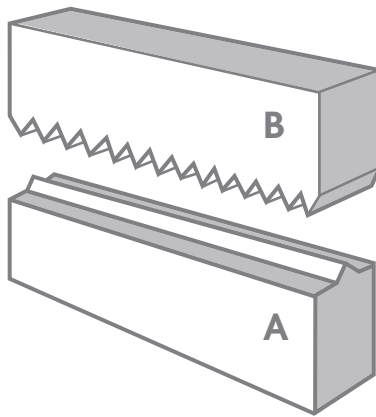
**Figure 2** Energy director used with a textured mating surface for improved bond strength



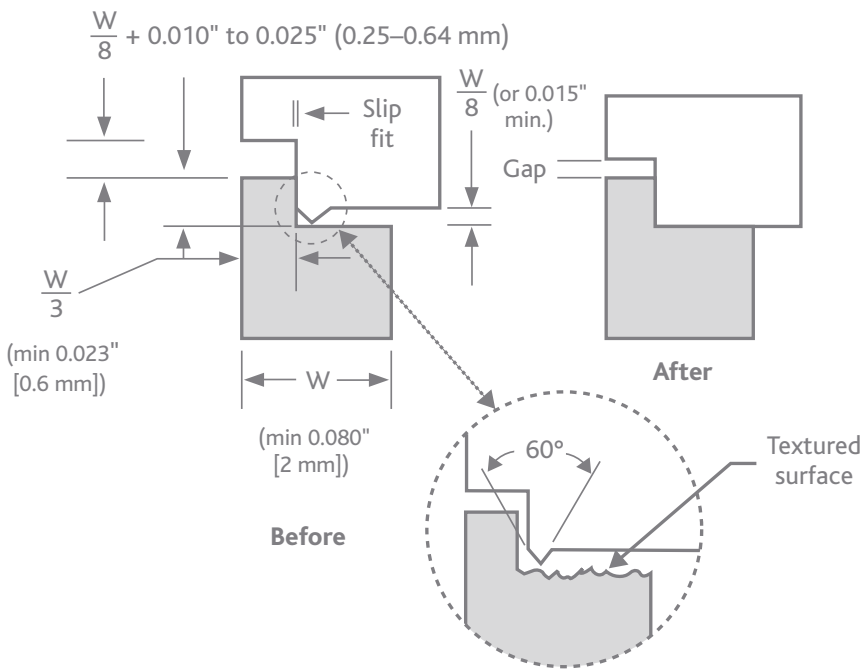
A second method is to use a series of segmented energy directors aligned at right angles to each other in a crisscrossed pattern relative to the main opposing energy director. This design has been successfully used in the industry to obtain an air- or liquid-tight seal. Figure 3 shows a typical continuous crisscross energy director design.

Another method is to use a step joint energy director. This type of joint should be used to weld Eastman Tritan parts in the most demanding applications. Figure 4 shows a typical step joint design.

**Figure 3** Crisscross design for air- or liquid-tight seals



**Figure 4** Typical step joint design



## Typical ultrasonic welding conditions\*

Welding time (seconds)	~ 0.5 s–0.75 s
Hold time (seconds)	~ 1.0 s (minimum)
Welding pressures	~ 0.207–0.483 MPa (30–70 psig)
Trigger pressure	Minimize
Downspeed	Minimize

## Typical ultrasonic welding setup requirements\*

Horn type	Aluminum or titanium
Typical horn output amplitude	75–100 microns (suggest using a 1:3 gain booster)
Welder power range	3000–4000 watts
Frequency range	15–20 kHz
Fixture/nest	Rigid or semirigid
Welder options	Collapse control, constant weld-energy control, computer control with data logging

\*Actual welding conditions and setup depend greatly on the part size, design, and bond joint design. These are suggested starting conditions only.

## Ultrasonic and heat staking methods

Ultrasonic and heat staking is a commonly used method to assemble parts. This process involves the controlled melting and reforming of a plastic stud that is used to capture and lock two or more components together.

This method employs the use of a plastic stud on part A, which protrudes through a hole or slot on the second part B. Ultrasonic vibration energy or heat is applied to the top of the stud using a special staking horn device which heats and melts the plastic stud. The molten plastic is deformed by pressure into a new shape, forming a cap or head. After the head/cap is formed, it is allowed to cool into its new shape, locking the parts together. Figure 5 illustrates some typical staking designs.

Ultrasonic and heat staking should be limited to applications where dissimilar materials are being joined. For example, we do not suggest staking Eastman Tritan™

copolyester to itself. Ideally, the mated parts should consist of different materials, i.e., a stud made of Tritan with a steel plate. For best results, select mating materials that have at least a 22°C (40°F) difference in their melting temperatures. This should prevent melting and bonding of the two materials.

Staking Eastman Tritan™ copolyester to itself can result in a brittle failure of the joint due to the formation of micronotches at the interface between the formed head/cap and the second part. These micronotches can be starting points for cracks when the joint is subjected to impact forces or flexural loads.

We suggest using an alternative joining method if this is a critical bonding application where the joint may see high impacts or dynamic loads (e.g., use structural adhesives, screws, etc.).

## Heat staking method

Heat staking is similar to ultrasonic staking, offering some of the same advantages. The process is much simpler and lower in cost. The same principles and guidelines apply to both methods.

A recommended starting temperature for heat staking Eastman Tritan™ copolyester is ~260°C (~500°F). Raise the staking horn temperature gradually until the polymer begins to soften and deform. Increase the temperature until the material starts to stick to the horn, then reduce the temperature by 6°–8°C (10°–15°F). This should be the optimum staking temperature. The main objective is to evenly melt and deform the stud while not sticking and burning the material.

Some manufacturers offer Teflon™<sup>1</sup> or other nonstick coatings on the heat staking horn to reduce sticking/stringing.

## Additional thermal methods of bonding

### Radio frequency (RF) welding

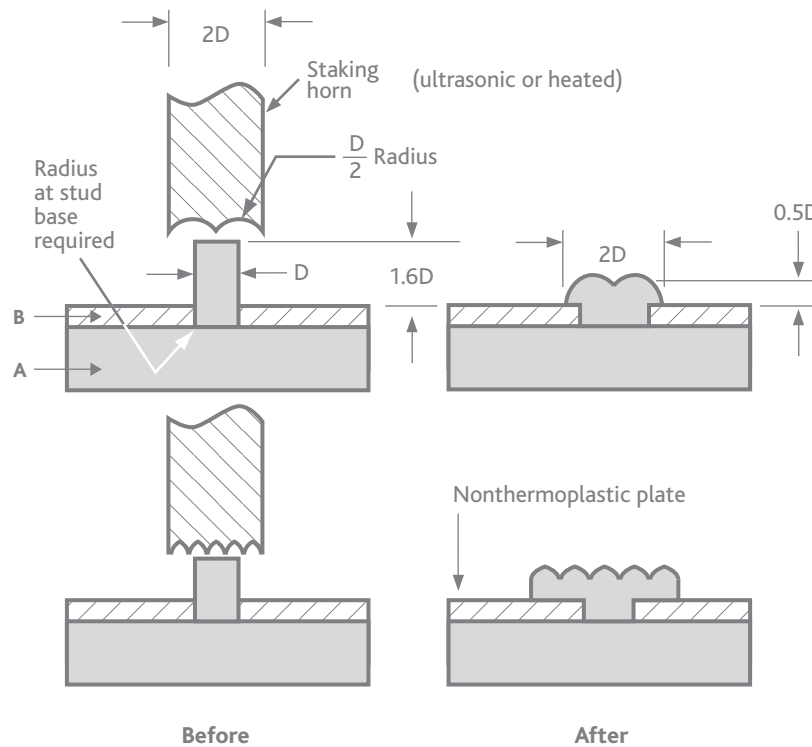
RF welding is a specialized method of joining two or more plastics. This process works best with bonding thin films versus thick structures.

RF welding machines utilize the dielectric properties of the plastics to generate heat due to the excitation of the molecules in the mated plastics. RF energy, usually operating at ~27.12 MHz, is generated and directed into the bond area of the mated parts.

The mated plastics are pressed together while the plastic surfaces are RF heated. The resulting molten surfaces then fuse, forming a strong seal.

RF sealing PVC films to Eastman Tritan™ copolyester is possible. However, RF sealing Tritan to Tritan is not recommended due to the potential of forming a bond with stress concentrators that can lead to brittle behavior.

Figure 5 Ultrasonic/heat staking methods



<sup>1</sup>Teflon is a trademark of E. I. du Pont de Nemours and Company.



RF sealing can also be used to bond heat-activated adhesives that are preapplied to the mating surfaces. This method is commonly used in blister packaging applications.

Contact your Eastman technical service representative for more information.

### ***Laser welding***

Laser welding is another unique bonding process where a laser beam is used to heat the mating surfaces of two or more thermoplastic parts that are to be joined. There are currently two approaches to laser welding parts together: clear-to-opaque and clear-to-clear methods.

#### **Clear-to-opaque laser welding method**

The more conventional clear-to-opaque welding method consists of molding or forming a part A that is clear. The laser light is transmitted through this part.

The mating part B has an opaque additive melt-blended into it that preferentially absorbs that laser light. The laser light energy heats the additive which in turn heats the polymer beyond its softening point.

The intense laser light beam is directed through the clear part A as it is focused on the mating surface of the two joined parts, thus, heating the interface while the parts are pressed together. The resulting molten surfaces are then fused and cooled, forming the bond joint.

#### **Clear-to-clear laser welding method**

A second new technology has been developed which allows one to laser weld clear thermoplastic parts. In this process, a special clear additive, which is designed to absorb at the wavelength of the laser light, is melt-blended into the clear B part. The laser light energy is transmitted through the clear A part. The light energy is then absorbed by the special additive in the clear B part. The light energy then heats the additive which in turn heats the polymer during this bonding process. The parts are joined and fused in a similar manner as described above.

Eastman can provide masterbatch additive packages that will allow one to utilize either of the above laser welding methods. These masterbatch formulations are specifically designed for use with Tritan copolyesters.

### ***Topical coating method***

A third method that has successfully been used in commercial applications consists of applying a thin coating of the clear laser welding material onto one of the mating parts. This coating is a blend of a special laser welding additive and a solvent carrier.

The coating can be applied precisely onto the bond area using a brush, a roll coater, a pad printer, or even an ink jet printer. The coating is allowed to dry prior to bonding. The parts are joined at a prescribed clamping force as the laser light is directed onto the coated interface, the coating heats and melts the polymer surfaces, and then the bond is allowed to cool.

We suggest consulting with Eastman technical service representatives before considering the use of laser welding methods in any new product development programs.

# Mechanical joining methods

Eastman Tritan™ copolyester can be joined by using screws, rivets, threaded inserts, snap fits, and other mechanical means.

Molded-in bosses are commonly used to accept screws and/or threaded inserts. Molded-in inserts or postmold inserts are commonly used where a plastic cover or part must be removed repeatedly. Proper design of the boss or receiver hole is important to avoid excessive stresses in the plastic part due to external static/dynamic loads or impacts. Postmold inserts can be installed via heat or ultrasonic methods.

## Screw fastening methods

Special screws have been developed over the years that incorporate uniquely designed threads that help to reduce radial/hoop stresses in the plastic material while providing increased pull-out resistance. Standard screws, like those used in sheet metal fabrication are not suggested because they tend to cause excessive radial/hoop stresses in plastics. These excessive stresses can cause cracking of the boss or hole with or without exposure to chemicals in the end-use environment. Standard sheet metal screws typically have shorter and wider threads than the special screws designed for use with plastics. The specialized plastic screws also tend to exhibit improved pull-out resistance versus standard screws.

Figure 6 shows the differences between standard sheet metal screws versus screws specifically designed for use in plastics.

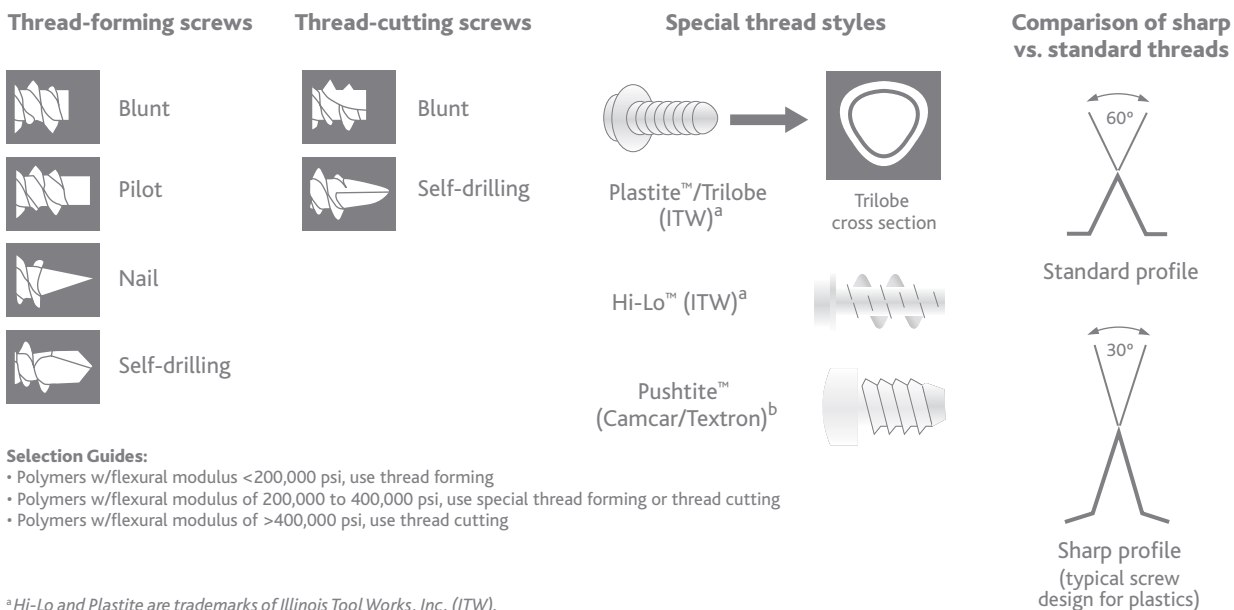
We suggest following the screw vendors design guidelines regarding the use of their products. They can suggest proper starter-hole dimensions, engagement lengths, and the proper screw thread design that matches the physical properties of the plastic material.

Avoid using screws that have a chamfered head that can induce excessive radial/hoop stresses on the plastic lead-in hole. Use a screw with a flat seating area under the head (see Figures 6 and 7). Avoid overtightening the screws. Utilize a shoulder bolt or metal spacer to prevent overtightening the screw. Utilize washers to help distribute the compressive stresses over a larger area under the screw head. Provide a slotted hole to allow for thermal expansion and contraction.

Avoid using PVC-type washers or seals. Plasticizers used in PVC can chemically attack the copolyester material, particularly around high-stress areas. Use neoprene, Teflon™, or other nonplasticized materials.

Carefully consider the adverse effects of the end-use environment (e.g., chemical exposure, temperature extremes, vibration, static/dynamic loads, and tensile/compressive stresses) on the assembled plastic parts.

**Figure 6** Standard sheet metal screws vs. screws for plastics



## Boss design for screws or inserts

Eastman Tritan™ copolyester can be molded into various shapes that can accept screws or inserts. For example, a boss consists of a slender protruding feature that extends from the base surface. A boss is usually hollow and provides a specifically designed hole for insertion of a screw or insert.

Bosses or cored-out holes require special care in their design to allow for proper flow of the plastic. An improperly designed boss can result in flow lines, waviness, weld lines, splay, sinks, trapped air/gas burning, warping, part breakage, and other undesirable problems. Proper sizing of the boss and related gussets must be considered to avoid sink marks while providing adequate structural strength. We suggest adding a radius to all sharp corners to further reduce stress concentrations around the boss.

A finite element analysis (FEA) may need to be conducted on the part design to help determine how the assembled structure will handle external loads and forces. This analysis will help to properly size the boss and determine how many attachment points will be needed to distribute the load or forces properly. Eastman can provide this design service and assistance.

Carefully consider the adverse effects of vibration or cyclic loading on the material. Fatigue effects are often overlooked and underestimated in their adverse effect on a part's structural performance and durability.

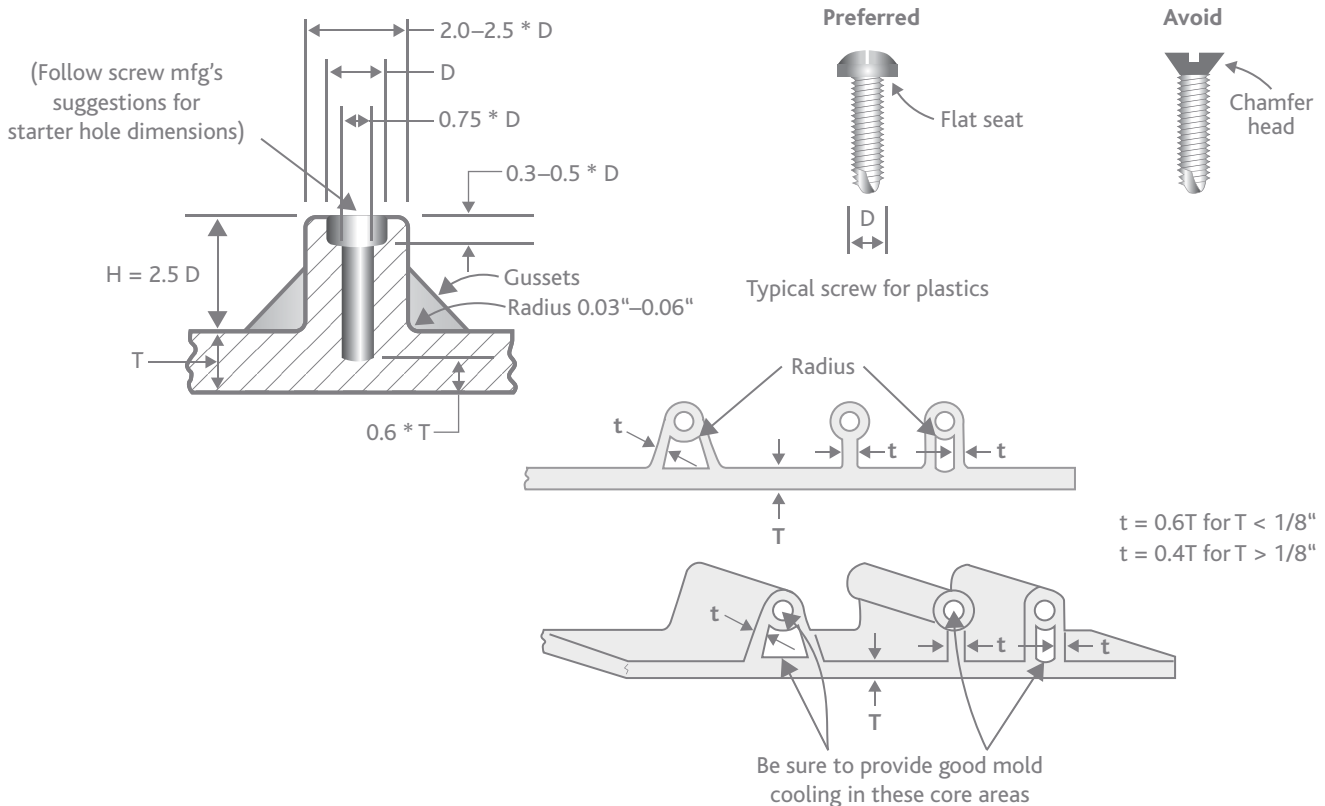
Core pins that form the hollowed-out screw guide hole require adequate cooling to prevent sticking of the polymer as the core pin heats up during molding. We suggest using water-cooled bubblers or baffles in the core pins and ample cooling circuits around the bosses to provide adequate cooling to prevent sticking and sinks. Alloy metals also enhance heat conduction away from the core pins as long as adequate water cooling is close by the base of the core pin.

Special nonstick coatings are available for core pins and mold cavities. However, good cooling is always critical.

The cavity which forms the boss should also have adequate venting to prevent gas trapping which can burn the plastic and cause poor filling of the boss feature.

Figure 7 shows how a typical boss should be designed to accept a screw designed for use in plastics. We suggest consulting with the screw or insert manufacturer for details on how to design the boss or receiver hole for their product.

**Figure 7** Typical boss design for screws



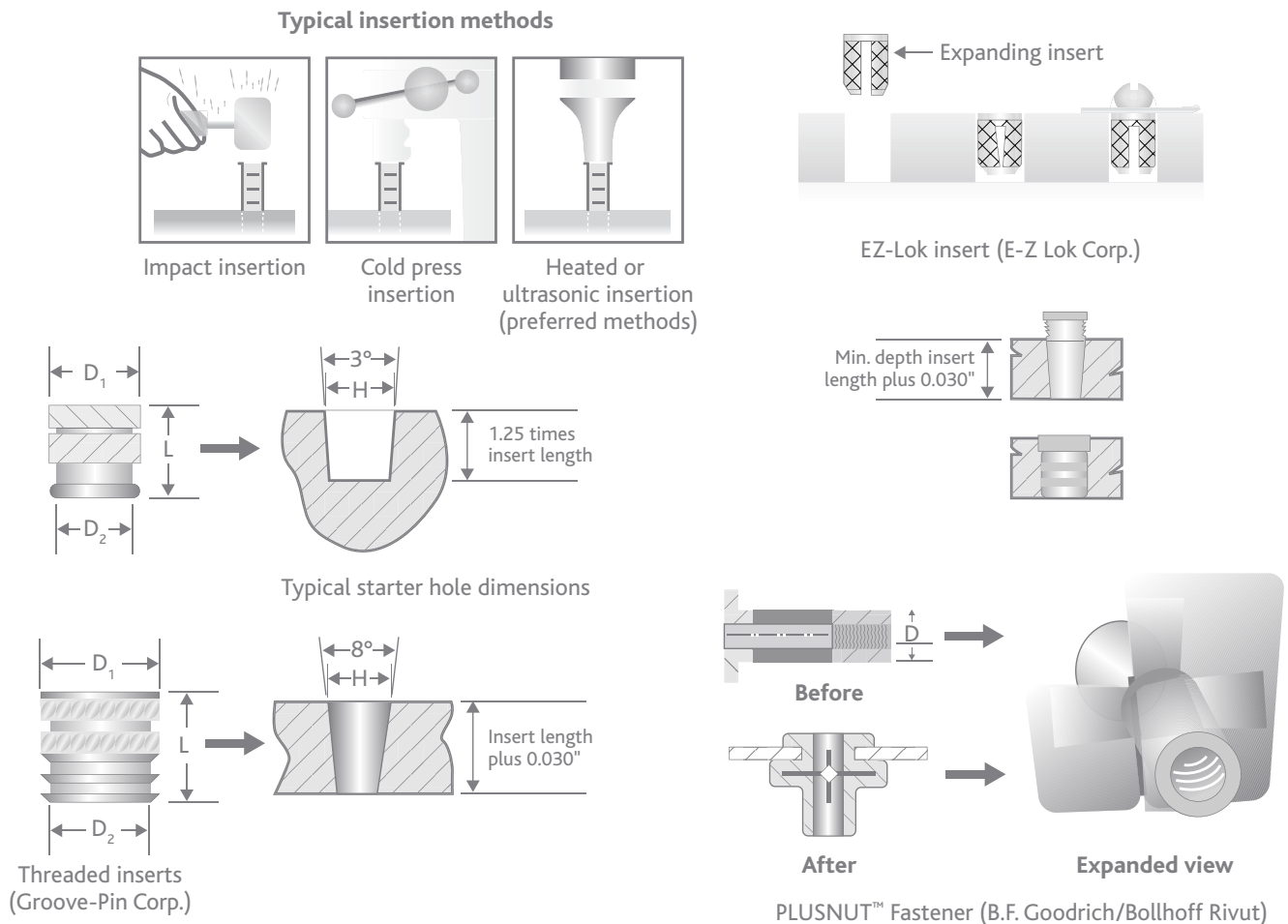
## Threaded inserts

Threaded inserts typically have either a male- or female-threaded feature that allows one to use standard thread nuts or bolts to assemble two or more parts. The inserts can be installed in the plastic part during molding or postmolding. Inserts are typically used when the part will be repeatedly disassembled in the field.

Threaded inserts typically consist of metals (brass or steel). They have specially designed grooves/ferrules that grip the plastic and hold firmly once inserted into the plastic material. Inserts typically exhibit acceptable pull-out resistance; however, one should conduct rigorous testing to assure that fitness-for-use criteria are achieved.

Inserts are often installed in a boss. Refer to the section regarding proper boss design and guidelines. Figure 8 shows various insert details.

Figure 8 Typical insert designs for plastics



Note: Follow manufacturer's recommendations regarding exact starter hole dimensions for good performance.

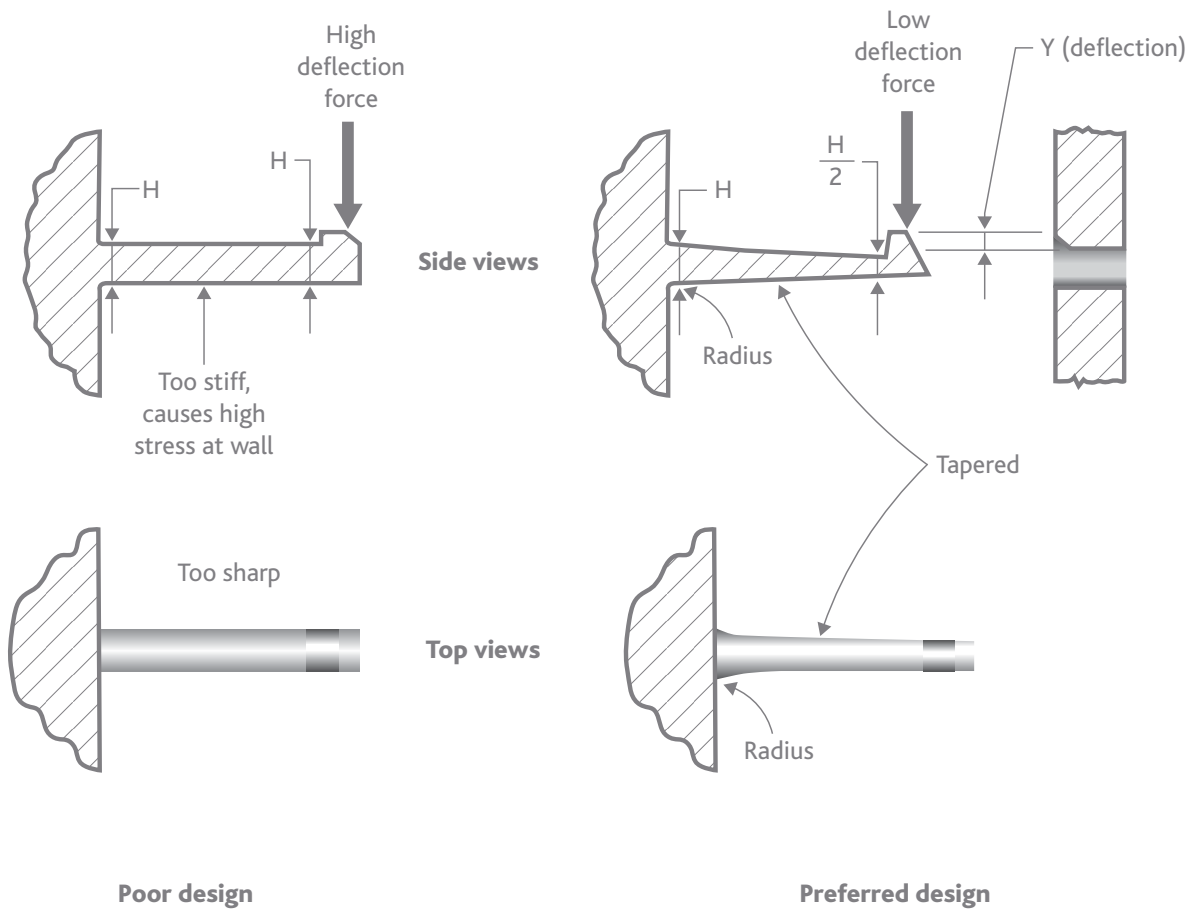
## Snap fit design

Snap fits allow the medical device designer to utilize the natural flexibility of Eastman Tritan™ copolyester. A snap fit is often used to avoid the use of a permanent joining method to assemble multiple parts. Snap fits can allow parts to be disassembled. However, some snap fits may be designed for a permanent one-way engagement of the mating parts.

The snap fit feature should be designed properly to avoid creating stress concentrators or high stresses in the snap fit structure. Also, the snap fit should be properly designed to provide sufficient holding/engagement force. Figure 9 shows snap fit design.

Contact your Eastman technical service representative for assistance regarding snap fit features and acceptable designs.

Figure 9 Snap fit designs



## Coloration, decoration, and printing

Molded or fabricated parts made from Eastman Tritan™ copolyester may require coloration, decoration, or printing to complete the finished product. Molded products often require decorative treatments or printing as part of the function of the medical device.

The decoration or printing must often withstand the same rigorous environmental conditions that the plastic part must withstand (e.g., chemicals, heat, abrasions, sterilization conditions, moisture, and other exposure).

Note that some solvents and colorants used in inks and paints may chemically attack the plastic substrate or may form a brittle coating on the copolyester material. Both of these problems can adversely affect the toughness and durability of the finished parts.

### Coloration

Eastman Tritan™ copolyester can be tinted with several FDA-approved transparent and opaque colorants. However, the selection of FDA-approved colorants is very limited when compared to industrial-grade colorants. Eastman is an industry leader in the formulation of standard and specialized color and additive concentrates and can assist in both selecting and supplying a suitable colorant.

Eastman suggests using a color masterbatch versus using a fully compounded color product. The color masterbatch is typically mixed at a precise loading into the clear base material of Eastman Tritan™ copolyester. The Tritan color masterbatch will distribute and homogenize into the Tritan base material during the plastication/extrusion process.

If needed, an external mixing nozzle may be used to further mix the colorant into the melt. Mixing sections on the screw are typically not recommended. They can impart excessive shear heating of the melt and can have hang-up points where the polymer may stick on the screw and degrade.

Contact your Eastman technical service representative for assistance, if needed.

### Decoration and printing

A molded or fabricated part made of Eastman Tritan™ copolyester may require decoration or printing to complete the finished product. Numerous types of paints and inks are available. However, not all inks, paints, or decals behave the same.

For example, some solvents used in inks and paints can chemically attack the plastic. Some types of colorants and pigments used in paints and inks can form a brittle coating on the copolyester material which can adversely affect toughness and durability of the finished parts.

Polyurethane-based inks and paints that exhibit flexibility after curing perform best in conjunction with Eastman Tritan™ copolyester. Flexible polyurethane-based primers typically exhibit good impact-resistance performance in painted applications utilizing Tritan copolyesters.

### Laser marking

Eastman Tritan™ copolyesters can be marked using a CO<sub>2</sub> or Nd:YAG-type laser device. Both methods have been successfully used to print lettering/images or impart a roughened surface on clear and opaque parts. However, there are subtle differences in the performance and operation of each of these methods when marking plastics.

Laser marking methods are fast and typically require no inks or paints to impart a permanent letter/image onto the plastic part. Some operations use the laser to ablate a thin layer of ink/paint to reveal underlying surfaces.

Most modern laser marking systems utilize computer-controlled director devices that sweep the beam over the target parts. Multiple parts can be printed very quickly within the effective working area of the printing device. Printing speeds of one second or less are achievable.

CO<sub>2</sub>-type lasers use gas to generate the intense light energy beam. This type of marking device will typically only etch/engrave a narrow groove into the plastic surface with each beam pass. When marking clear parts, the resulting etched grooves may appear to be clear with little charring or darkening of the marked area. Good letter/image contrast is more difficult with a CO<sub>2</sub>-type laser. Opaque additives may have to be added to the plastic to improve marking performance.

Nd:YAG-pulsed fiber lasers utilize a solid-state crystal to generate the high-energy light beam and have been shown to produce acceptable letter/images with good contrast and sharpness. The top surface of the clear or opaque plastic is darkened or charred as the laser light beam traces over the surface. They typically operate in the 10 to 30 watt power range for marking operations.

Lasers can also be used to cut through the plastic completely if sufficient energy levels are used.

### General precautions

Lasers generate extremely dangerous high energy light beams that must be properly controlled and shielded to prevent injury to employees. Serious skin and eye injury can result if contact with the laser beam occurs.

Polymers are combustible and vapors may be generated during laser marking or cutting operations. Provide adequate fire protection equipment and training. Proper smoke/vapor confinement and ventilation hoods should be used to protect the employees and the environment.

Contact your Eastman technical representative for more information regarding laser marking Eastman Tritan™ copolyesters and equipment supplier information.

### Typical coloration, decorating, and printing methods

Eastman can help with a wide variety of decoration processes such as:

- Transparent colors (FDA-approved)
- Opaque colors (FDA-approved)
- Pad printing
- Silk-screen printing
- Offset roll printing
- Gravure roll printing
- Inkjet printing
- Air/airless spraying
- Dip coating
- Spin coating
- In-mold decorative labels/decals
- Thermal/heat transfer decals
- Pressure-sensitive adhesive decals
- Shrink-wrap labels
- Decorative film lamination (thermally activated adhesive)
- Laser marking (opaque and clear parts)
- Hot stamping (thermal adhesive-coated colored/metallic foils)
- Vacuum metallizing
- Vapor deposition/sputtered metallization

Contact your Eastman technical service representative if you need guidance regarding the preceding information and require sources for suitable inks or paints for use on Eastman Tritan™ copolyesters.

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Material Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

*It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.*

*Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.*

*For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.*

*The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.*

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