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TANDEM™

EMBOZENE TANDEM MICROSPHERES

Microspheres for Embolization

51100850-01

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TANDEM™

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Microspheres for Embolization

℞ ONLY

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

WARNING

Contents supplied STERILE using a steam process. Do not use if sterile barrier is damaged. If damage is found, call your Customer Service representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

TANDEM Microspheres are spherical, tightly calibrated, biocompatible, non-resorbable, hydrogel microspheres coated with an inorganic perfluorinated polymer (Polyzene™-F). TANDEM Microspheres are capable of being loaded with drugs and can elute a local, controlled, sustained dose of a drug to targeted tumor sites after embolization. TANDEM Microspheres are opaque in color, supplied in prefilled syringes and available in three sizes suitable for embolic therapy. TANDEM Microspheres may be loaded with doxorubicin hydrochloride (HCl) and irinotecan hydrochloride (HCl).

Syringe

TANDEM Microspheres are supplied in a 20 ml syringe prefilled with 2 ml or 3 ml of product suspended in a non-pyrogenic, sterile transport solution of physiological saline. The total volume of TANDEM Microspheres including transport solution is approximately 7 ml. Prefilled syringes of TANDEM Microspheres are packaged in a sterile, sealed tray with a peel-away lid. The label indicates the specific size of the microspheres contained in the syringe (see Table A).

User Information

Contents

Quantity	Material
1	TANDEM Microspheres Prefilled Syringe

INTENDED USE/INDICATIONS FOR USE

TANDEM Microspheres are indicated for embolization of the following conditions:

- Hypervascular tumors
- Arteriovenous malformations
- Unresectable hepatocellular carcinoma

This device is not intended for neurovascular use.

CONTRAINDICATIONS

Embolization procedures shall not be performed if:

- Patient is unable to tolerate vascular occlusion procedures.
- Vascular anatomy precludes correct catheter placement or embolic injection.
- Presence or likely onset of vasospasm.
- Presence of a blood coagulation disorder that would prohibit arterial punctures.
- Presence of severe atheromatous disease that would preclude correct catheter placement.
- Presence of patent extra-to-intra-cranial anastomoses or shunts from the arterial to the venous circulation.
- Presence of collateral vessel pathways which could potentially endanger non-targeted tissue during an embolization procedure.
- Presence of any vasculature where TANDEM™ Microspheres could pass directly into the central nervous system, central circulatory system or other non-target territories.
- Patient has high-flow arteriovenous shunt with diameter greater than the selected TANDEM Microspheres.
- Patient is pregnant.
- Patient has known allergies to barium sulfate, 3-aminopropyltrialkoxysilane, polyphosphazene, IV radiopaque contrast agent, or the drugs and their additives (see corresponding instructions for use).
- Due to the small size of Tandem Microspheres (< 500 µm), do not use for uterine fibroid embolization.

WARNINGS

Vascular embolization is a high risk procedure. The procedure should be performed by specialized physicians trained in vascular embolization procedures:

- Care must be taken to choose larger sized TANDEM Microspheres when embolizing arteriovenous malformations with large shunts to avoid passage of the microspheres into the venous and subsequently to the pulmonary circulation.
- Extreme caution should be used for any procedures above the neck, and risk benefit assessment should be performed to avoid non-target embolization complications.
- Risks of radiation from angiography and fluoroscopy used to visualize the blood vessels during embolization, which may include a radiation burn and risks to future fertility.
- Do not use TANDEM Microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol or dimethyl sulfoxide (DMSO) at the same embolization site.
- Do not use ionic contrast agent with this product. Ionic contrast agents could alter the microsphere characteristics resulting in microsphere deformation and procedure failure.
- Do not use heparinized saline as this could lead to microsphere agglomeration. Agglomeration may impede microsphere delivery through the catheter or result in non-target embolization.
- Should catheter obstruction occur, remove the catheter from the patient. Do not use forceful injection, guidewires or other instruments to dislodge the blockage.

PRECAUTIONS

To maintain safety, the following precautions shall be considered:

- Each package of TANDEM Microspheres is intended for single patient use only. Discard any unused material.
- Physicians using TANDEM Microspheres should have appropriate training and experience in a related interventional procedure.
- Do not use TANDEM Microspheres if the sterile barrier, the syringe or the package appears to be opened or damaged prior to use.

- Do not use TANDEM™ Microspheres that have been improperly stored or mishandled.
- The physician should carefully select the size and quantity of TANDEM Microspheres according to the lesion to be treated based on the physician's education and training and currently available scientific evidence.
- Physicians must decide the most appropriate time to stop the infusion of TANDEM Microspheres. Typically the artery will accept fewer TANDEM Microspheres as the treatment progresses. Proximal slowing or termination of flow may indicate that the vessel or the target area is occluded by TANDEM Microspheres. Careful fluoroscopic monitoring is required.
- Microsphere embolization must be performed slowly. The injection speed and manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to embolization of other non-target healthy tissue or organs.
- Do not use saline as it may interfere with drug loading capability.
- If arteriovenous anastomoses, branch vessels which lead away from the targeted embolization area, or emergent vessels not evident prior to embolization are present, it can lead to non-target embolization and cause severe complications for the patient.
- TANDEM Microspheres smaller than 100 µm can migrate to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller particles have a greater likelihood of causing unwanted ischemic injury. This should be considered prior to starting the embolization procedure.
- Ischemia of tissue adjacent to the targeted area may result from post-embolization swelling. Therefore, special care should be taken to avoid such ischemia of non-tolerant, non-targeted tissue such as the nervous system.
- Consider upsizing TANDEM Microspheres if angiographic appearance of embolization does not quickly appear during injection of the microspheres.
- If there are any symptoms of non-target embolization during injection, consider stopping the procedure to evaluate the possibility of shunting. Such symptoms may include changes in patient vital signs, such as hypoxia or central nervous system changes.

Interaction with Pharmaceuticals

There are no known chemical interactions between TANDEM Microspheres and pharmaceuticals.

ADVERSE EVENTS

Potential adverse events associated with the use of TANDEM Microspheres include, but may not be limited to:

- Allergic reaction
- Capillary bed saturation and tissue damage
- Cerebrovascular accident (CVA)
- Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the microcatheter and subsequent dislodgement, vasospasm, nerve injury, vessel trauma [e.g., dissection, perforation, rupture])
- Death
- Foreign body reactions (e.g., pain, rash, fever, inflammation)
- Hemorrhage
- Incomplete occlusion of vascular beds or territories may give rise to the possibility of post-procedural hemorrhage, development of alternative vascular pathways, recanalization, or recurrence of symptoms
- Infection
- Ischemia at an undesirable location
- Ischemic infarction
- Neurological deficits including cranial nerve palsies
- Post-embolization syndrome
- Pulmonary embolization

- Thrombosis
- Undesirable reflux, passage/migration or placement of TANDEM™ Microspheres, resulting in non-target embolization
- Vessel or lesion rupture

Refer to the drug manufacturer's package insert for drug specific adverse events.

HOW SUPPLIED

Prefilled syringes of TANDEM Microspheres are packaged in a sealed tray with a peel-away lid.

Sterile

Non-pyrogenic

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

Product must be used prior to expiration date on label.

OPERATIONAL INSTRUCTIONS

Additional Materials and Equipment

(1) Microsphere delivery syringe

(1) 3-way stopcock

Delivery catheter

Non-ionic contrast media

Water for injection (WFI)

Catheter Compatibility

TANDEM Microspheres are designed to be used with a variety of catheters and microcatheters. Select a delivery catheter of appropriate size, suitable for the dimensions of the target vessels. TANDEM Microspheres can tolerate temporary compression to facilitate passage through the delivery catheter. Utilize the catheter's minimum inner diameter measurement to determine catheter-to-microsphere compatibility. You may use Table A as a reference.

Device Preparation

1. Position the catheter at the desired site and perform baseline angiography to evaluate the blood supply to the lesion.
2. Carefully select the size of TANDEM Microspheres according to the size of the vessel identified and catheter used.
3. Verify that the sterile packaging was not previously compromised and the catheter is not damaged.

Drug Selection and Loading

TANDEM Microspheres can load and elute drugs that may be useful in the treatment of diseases in which embolization is also effective. Refer to TANDEM Microspheres Loading Guidance for step-by-step instructions on loading TANDEM Microspheres with doxorubicin HCl or irinotecan HCl. The loading of TANDEM Microspheres with other drugs has not been evaluated.

Contrast Mixing and Microsphere Delivery

1. Gently swirl the contents before opening the syringe.
2. Use only non-ionic contrast agent in accordance with the contrast agent labeling with respect to dosage.

Warning: Do not use ionic contrast agent with this product. Ionic contrast agents could alter the microsphere characteristics resulting in microsphere deformation and procedure failure.

3. Add an appropriate amount of contrast agent to the product syringe to obtain homogeneous suspension and fluoroscopic visibility. Pure contrast agent or a mixture of contrast agent and water for injection (WFI) may be used.

Caution: Do not use saline.

A mixture is especially recommended when less than 50 mg of drug per mL of microspheres has been loaded or when using contrast agent with iodine concentrations higher than 300 mg iodine/mL. The suspension is usually obtained with a mixture of 50% contrast agent and 50% water for injection. Contrast agent and water for injection can be added in the same proportions to obtain a more dilute suspension.

To obtain a homogeneous suspension, rotate or gently swirl the syringe every 30 seconds to agitate the microspheres and contrast agent until a homogeneous suspension is achieved. For the smaller sizes, a homogenous suspension may be achieved in less than a minute. For the larger sizes, a few additional minutes may be required to achieve a homogeneous suspension.

4. Confirm suspension prior to delivery. If microspheres have begun to settle, gently swirl or agitate to re-suspend before delivery.
5. Purge all air from the syringe.
6. Attach the 20 ml syringe to one port of the luer-lock 3-way stopcock and a 1 ml injection syringe to another port of the stopcock. Attach a delivery catheter to the remaining port on the stopcock. Ensure the stopcock is securely attached.
7. Draw the TANDEM™ Microsphere mixture slowly and gently into the injection syringe to minimize the potential of introducing air into the system.
8. Under continuous fluoroscopic control, slowly infuse TANDEM Microspheres into the blood stream. Always inject under free flow conditions by fully opening the stopcock. To optimize injection through the catheter, it is recommended that the syringe remains in a horizontal position during injection.

Caution: Microsphere embolization must be performed slowly. The injection speed and manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to embolization of non-target healthy tissue or organs.

9. Continue infusion until the desired devascularization is achieved.
10. Once the procedural endpoint is reached, wait for 5 minutes to observe whether the microspheres redistribute themselves and re-establish flow to the target. If flow is re-established, inject an additional volume of microspheres until the final procedural endpoint is achieved.
11. At the end of the infusion, remove the catheter while maintaining gentle aspiration to avoid dislodging any residual TANDEM Microspheres still inside the catheter.
12. Discard any opened TANDEM Microspheres prefilled syringe units.

Table A. Design Specifications for TANDEM Microspheres

Nominal Microsphere Size	Design Specifications	Compatible Catheter size Minimum Inner Diameter in (mm)
40 µm	40 µm ± 10 µm	0.008 (0.2)
75 µm	75 µm ± 15 µm	0.008 (0.2)
100 µm	100 µm ± 25 µm	0.008 (0.2)

WARRANTY

The Manufacturer warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond the Manufacturer's control directly affect the instrument and the results obtained from its use. The Manufacturer's obligation under this warranty is limited to the repair or replacement of this instrument and the Manufacturer shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. The Manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **The Manufacturer assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Catalog Number
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Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização

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Wettelijke fabrikant
Fabricante Legal

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Lot
Charge
Lotto
Partij
Lote

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Sterilized using steam (or dry) heat.
Esterilizado por vapor (o) calor (seco).
Stérilisé à la vapeur ou par chaleur (sèche)
Mit Dampf- oder (Trocken-) Hitze sterilisiert.
Sterilizzato mediante calore umido (o secco).
Gesteriliseerd met stoom- (of droge) hitte.
Esterilizado por aquecimento com vapor (ou a seco).

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Do not use if package is damaged.

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